



TEACHER'S GUIDE



Co-funded by the
Erasmus+ Programme
of the European Union

2023-1-IE02-KA220-HED-000159532

This publication is made possible by the European Commission and ERASMUS+ Programme of the European Union. The contents are the responsibility of the SENSITISE project consortium and do not necessarily reflect the views of the European Commission or ERASMUS+ Programme of the European Union.

All recommended tools are listed based on our own practical experience. They are not endorsed due to any financial incentives, sponsorships, or compensation provided by their owners. The authors are not responsible for the functionality, licensing terms, or data protection policies of these tools.

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PROJECT PARTNERS



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ACKNOWLEDGEMENTS

Published by

SENSITISE – incluSive cliNical trials: training and educaTion to increase Involvement of underServed groups. ERASMUS+ 2023-1-IE02-KA220-HED-000159532



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SENSITISE Training platform

Enrol in the Course

<https://www.ucc.ie/en/sensitise/thesensitise/course/enrolinthecourse/>

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FOREWORD

Dear educators, lecturers,

You are opening a teacher's guide focused on providing teachers with practical guidance on preparing and delivering education on inclusivity in clinical trials. As teacher knowledge level and practical experience in trials will vary, we prepared this manual to enable implementation of the curriculum and ensure the e-learning training materials are used effectively to deliver a high quality curriculum.

This teacher's guide closely follows the structure of the curriculum lessons and adds detailed methodological guidance. It supports those organising lessons according to the target audience, implementing the curriculum in a variety of modalities (e.g., blended classroom, collaborative online international learning) and actively engaging students in both synchronous online and face-to-face settings. The teacher's guide also provides solutions to practical activities and includes useful hints and recommendations.

In addition, the guide offers specific support for teaching in multilingual environments. While the original materials and teacher's guides are developed in English and then translated into French, German and Czech, some resources (e.g., videos, academic publications, articles, and various interactive or multimedia materials) cannot be translated. Therefore, this guide includes practical strategies for working with these resources in classrooms with non-native speakers, including guidance on how to facilitate understanding.

Furthermore, the guide provides recommendations and tips on how to support students with disabilities and specific educational needs (including ADHD, visual and hearing impairments, dyslexia, etc.). It offers inclusive teaching strategies to ensure all students can effectively participate in, and benefit from, the learning process.

We are confident this guide will make education in inclusivity in clinical trials more accessible and feasible at your institution.

If you have any questions, would like more information, tips and tricks, or practical experience, please feel free to contact us.

On behalf of the SENSITISE consortium

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HOW TO NAVIGATE

GENERAL STRUCTURE OF THE CURRICULUM

- **Course:** corresponds to the overall SENSITISE curriculum
- **Units:** thematic units of the curriculum – a total of 12 units are available (i.e. a 12-week curriculum)
- **Lessons:** parts of the Unit – each of the Units contain five lessons (i.e., study content for each day, or a learner may wish to study more than one lesson per day)
- **Teacher's guide:** a methodological guidance for the teachers supporting delivery of a class using the curriculum materials; follows the structure of the curriculum
- **Training platform/Learning management system:** an online interface where the curriculum lessons and units with interactive elements are available:
<https://www.ucc.ie/en/sensitise/thesensitise/course/enrolinthecourse/>

TERMINOLOGY

- **Blended classroom:** a learning approach that combines teacher-led brick-and-mortar classroom training and self-paced online learning activities (e.g., pre-class reading)
- **Pre-class reading:** activities in the platform completed by the students individually before the brick-and-mortar classroom training (e.g., reading the curriculum lessons, completion the tasks, tests)
- **Brick-and-mortar classroom training/Face-to-face training:** a synchronous face-to-face session
- **Collaborative online international learning (COIL):** virtual learning in an international setting, online technology-mediated student collaboration
- **Reflective activity:** a structured learning activity in which students critically review and evaluate their own learning process, experiences, and outcomes

HOW TO NAVIGATE

GENERAL STRUCTURE OF THE TEACHER'S GUIDE

In each Unit:

- Objectives of the Unit
- Unit content
- Learning outcomes, acquired knowledge, skills, and competencies (defined using Bloom's taxonomy)
- Blended 90-minute classroom
 - General description of the Unit, distribution of the tasks in Lessons (day-by-day); a teacher's road map of what participants will work on individually and together and how that can be achieved effectively during the allocated time.
 - Tasks and expected time for the students as pre-class reading (day-by-day)
 - Expected time for the brick-and-mortar classroom learning
 - Description of activities, including solutions and hints for the teacher
- COIL: how to implement the unit in a fully online environment (12×90–120 minutes)
- Reflective activities: activities aligned with the curriculum lessons, including solutions and hints for the teacher, modified for individual work, team-based work or whole-group discussion
- Multiple-choice questions, including solutions
- True/False questions, including solutions
- Articles and pictures outlines: article summaries and picture descriptions to support comprehension, language and visual accessibility

ICONOGRAPHY



Expected time



Tips to promote critical thinking



Tips to activate students



Debriefing



Tips to conclude the lesson/activity, formulate the take-home message



Whole group activity



Individual task



Work in pairs



Team based-work

HOW TO USE STUDY MATERIALS FOR NON-NATIVE SPEAKERS

WORKING WITH VIDEOS

- **Turn on subtitles (closed captions)** – if the video has auto-generated or manually added captions, activate them for better comprehension.

 *On YouTube via the subtitle icon at the bottom right corner of the video player. Note that the selection of available languages may differ depending on the device you use (e.g., laptop vs. mobile app).*

- **Use the transcript**, making it easier to follow and search for specific content.

 *YouTube provides a full transcript (click the three dots in the description of the video > “Show transcript”). This feature is not available for all videos.*

- **Slow down playback speed**, e.g. 0.75x, to make speech easier to understand.

 *On YouTube via the settings icon at the bottom right corner of the video player*

- **Use AI tools** like *Language Reactor* for bilingual subtitles.

ACADEMIC PUBLICATIONS, ARTICLES, DOCUMENTS

- **Use automatic browser translation** – most browsers allow full-page translation

 *Right-click > “Translate to...”*

- **Use online dictionaries during reading** – tools like *DeepL*, *Google Translate* help to translate entire paragraphs with context.
- **Translate full documents** – tools like *DeepL Translator*, *Google Translate* also allow uploading entire documents (e.g. .pdf, .docx) for translation while preserving formatting.
- **Read bilingually** – if students are confident, they can first read in English, then check the meaning in their native language.
- **Highlight key information** – encourage students to mark important parts to better follow the text’s structure and terminology.

INTERACTIVE AND MULTIMEDIA MATERIALS

- **Provide navigation guides** – offer short instructions on how to use the platform/material.
- **Use pair work** – working in pairs supports mutual understanding.

TEACHERS’ ROLE

- **Provide key terms and ensure their understanding** before starting complex activities in the class/online.
- **Use SENSITISE glossary** – Each unit includes a summary of key terms, which are also translated into German, French, and Czech. This helps to connect national terminology with English equivalents and supports consistent understanding across language barriers. If the students’ language is not included, we recommend creating a bilingual glossary.
- **Paraphrase and summarise** in simpler language.
- **Give students enough time** to process information in a second language.

SUPPORTING STUDENTS WITH DISABILITIES AND DIVERSE LEARNING NEEDS

This section provides practical guidance for teachers on how to make learning more accessible for students with disabilities and diverse learning needs. The aim is not to create separate learning activities, but to reduce barriers and offer flexible ways for students to access information, participate in class and support their learning.

Teachers should apply the principles of inclusive teaching whenever possible. This means using clear instructions, accessible materials, varied teaching methods, and supportive communication. Many of these strategies benefit all students, not only those with a declared disability.

GENERAL PRINCIPLES

Teachers are encouraged to:

- Provide clear structure of lessons and activities, predictable routines and written instructions.
- Break complex tasks into smaller steps.
- Use visual, written or verbal explanations.
- Allow short breaks when needed.
- Use captures, transcripts, large prints or audio formats where appropriate.
- Check understanding regularly.
- Create a respectful classroom environment where students feel safe and comfortable asking for support.

STUDENTS WITH ADHD

Students with ADHD may benefit from a structured learning environment, short tasks, clear expectations. Teachers can support them by using visual schedules, checklists, short summaries and clearly marked instructions. Allow short breaks or movement opportunities. For example, allow students to stand if they prefer, or use fidget tools if it helps them concentrate. Tools such as [Pomodoro timers](#), or visual materials created in design tools like [Canva](#) may help students stay organised and focused.

STUDENTS WITH HEARING LOSS

Students with hearing loss should have access to visual and written information whenever possible. Teachers should provide written copies of oral instructions, use captions in videos and online sessions and make sure the student can see the teacher's face. Speaking clearly, slightly slower, and minimising background noise can also help. Speech-to-text tools like [Ava](#) or [Google Read&Write](#), [Microsoft Translator](#) can provide real-time captions for conversations and support participation. [Microsoft Immersive Reader](#), a tool available as part of Office 365, supports students with dyslexia, ADHD, and other learning disabilities by reading text aloud, changing text size, and highlighting words. It can also translate text into multiple languages.

STUDENTS WITH VISUAL IMPAIRMENT

Students with visual impairment may need materials in accessible formats, such as large print, high-contrast documents, coloured paper, or audio. Teachers should describe visual elements verbally, including images, diagrams, slides, and demonstrations. Picture outlines in this teacher's guide can be used for this purpose. The classroom layout should be consistent, with clear paths for safe movement. Seating should allow the student the best possible access to materials and spoken instruction. Text-to-speech tools like [Google Read&Write](#) and [Ava](#) can be useful too.

STUDENTS WITH LEARNING DISABILITIES (DYSLEXIA ETC.)

These students may benefit from simpler language, clear formatting, visual supports, and multisensory teaching. Teachers should avoid unnecessary jargon, provide key information in more than one format, and allow the use of reading support tools such as text-to-speech software. Tools such as Microsoft Immersive Reader, Read&Write, NaturalReader. Tools improving readability ([ColorVeil](#), [Visor](#), [Kurzweil 3000](#)) are recommended too.

CURRICULUM CONTENT

This course guides learners from foundational principles of inclusivity in clinical trials through its practical application and future development. It builds from theoretical grounding and an exploration of under-served groups and their barriers to participation through applied units on inclusive design, recruitment, and conduct, illustrated throughout with case studies. The final section focuses on strengthening inclusive research practices and communication, equipping learners to embed meaningful change beyond the trial context.

SETTING THE SCENE

Unit 1: Background and history of inclusivity in clinical trials

Unit 2: Who are the under-served groups?

Unit 3: Understanding barriers to inclusion

Unit 4: Case study: Clinical trials and global maternal mortality

INCLUSIVE DESIGN

Unit 5: Who do we need in the trial and why?

Unit 6: Equitable participation in trials for under-served groups through recruitment and retention

Unit 7: Inclusive trial design and conduct

Unit 8: Case study: Adults with impaired capacity to consent

BUILDING FOR THE FUTURE

Unit 9: Opportunities to build links with under-served groups

Unit 10: How to be a more inclusive researcher

Unit 11: Post-clinical trial communication

Unit 12: Summary

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

General overview of the unit for the teacher

OBJECTIVES

The aim of this unit is to introduce students to the concepts of diversity, equity and inclusivity in general, but particularly in the context of clinical trials and wider health research. The unit is also intended to provide an insight into the history, present and future of inclusivity in clinical research. The position of women in clinical trials is outlined. Relevant literature will be offered to develop critical thinking skills and broaden perspectives on the topic.

UNIT CONTENT

- 1.1: What is inclusive health research?
- 1.2: Clinical trials research before the 21st century
- 1.3: The role of ethics: the Nuremberg Code; Tuskegee Syphilis Study; and the Declaration of Helsinki
- 1.4: Women in clinical trials and the gender health gap
- 1.5: Towards meaningful inclusion in clinical trials
- Summary of Unit 1

LEARNING OUTCOMES

Students will be able to:

1. Define the **key concepts** of equity, diversity, and inclusion and reflect on the importance of these concepts within clinical trials and wider health research.
2. Give examples of **key milestones** in the history of clinical trials and describe how these events have influenced ethics and modern practices.
3. Recognise the **global need** for inclusive health research.
4. Examine wider current **initiatives** that aim to inform, support, and improve inclusion in clinical trials and health research.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Blended 90-minute classroom

 pre-class reading
brick-and-mortar 5×2 hours
90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 1.1 pre-class; watch the video from NIHR; test your knowledge.
Tue	Complete Lesson 1.2 pre-class; complete the reflective activity; test your knowledge .
Wed	Complete Lesson 1.3 pre-class; open the Declaration of Helsinki and review the principles; test your knowledge.
Thu	Complete Lesson 1.4 pre-class; watch the video from McMaster University; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 1.5 pre-class; complete the reflective activity; test your knowledge; read the Summary of Unit 1; complete the MCQs.

OPENING THE LESSON

15' 



warm-up



Word association – share a keyword from the list below and write it on the board. Ask the students to say the first word/phrase/situation that comes to mind. List their suggestion on the board. Allow a minute at the end to review the terms, then ask students if they would add or move anything. And also whether they understand everything.

- Equality (in general, education, or in their area of interest)
- Equity (in general, education, or in their area of interest)
- Diversity (in general, education, or in their area of interest)
- Inclusivity (in general, education, or in their area of interest)
- Equity in health research
- Diversity in health research
- Inclusivity in health research

Hints and solutions for the teacher – follow-up questions to stimulate discussion:

- **Equity in health research:** e.g., fairness, justice, equality, inclusion, accessibility, balance, opportunity, representation, proportionality, bias-free
- **Diversity in health research:** e.g., variety, differences, belonging, race, ethnicity, gender, age, disability, language, discrimination, barriers, privilege
- **Inclusivity in health research:** e.g., access, open-mindedness, respect, women, minorities, justice, empathy

WORK IN PAIRS

60' 



The concept of this activity is to look at “**What have we learned from the historical clinical trials?**”

Objective: Students should analyse historical milestones in clinical research and reflect on how those events have influenced current practices.

Ask students to work in pairs and connect historical milestones in clinical research with their impact on modern clinical practices. Ask students to select **at least one historical trial** (from Lesson 1.2, article of Bhatt *et al.*), **at least one milestone producing practice-changing document/initiative** (from Lesson 1.3, or article of Sierra) and at least **one women-related topic**.

Ask students to write their reflections on paper and discuss verbally.



Students should create a table or a mind-map: summarise the milestone, determine the impact on modern clinical trials, assess whether still applicable, assess whether the principle established by this historical milestone has later been violated, assess whether the principles of equity, diversity, and inclusivity (EDI) have been applied/has, e.g., the gender gap or gender bias seen? (30–35 minutes)

Hints and solutions for the teacher:

- *Start the timer (e.g. 35 minutes) on the screen so the students see how much time they have.*
- *Circulate around the room to check on progress, clarify instructions, and listen to/stimulate the discussions/ask probing questions to deepen the thoughts.*
- *Leave enough time for the Debriefing – a critical part of this activity (see below).*

Historical milestone	Summary	Impact	Applicable today?	Principle later violated?	EDI applied?
James Lind scurvy trial (1747)	groups receiving different treatment	comparing treatments under controlled conditions	Controlled conditions in trials, comparison group	Willowbrook Hepatitis Study (sailors suffering from scurvy vs. healthy children)	Women, children excluded; social status

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Blended 90-minute classroom



Debriefing of the work in pairs: ask pairs to share their thoughts – each pair shares only one milestone per round; do several rounds until pairs have no more suggestions. (25–30 minutes)

Hints and solutions for the teacher:

- Summarise the impact on current practice and EDI principles applied/violated for each milestone/trial on the board.
- Ask students to give feedback to others – agree, disagree, in what, why?
- Optional follow-up questions to stimulate discussion:
 - If this milestone didn't happen, what might clinical research look like today?
 - What milestone stood out to you the most and why?
 - What surprised you about the connection between history and current practices?
 - Do you see areas in clinical research that could evolve further based on lessons from history?

REFLECTION, WRAP-UP

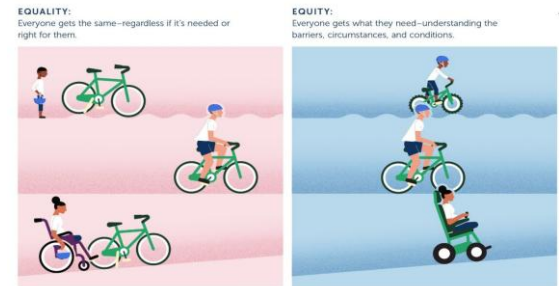
15'



- Ask students to define “equality and equity” and explain the difference between them.
- Which of the following terms refers to individuals or groups of people having the same resources or opportunities? Equity, uniformity, equality, privilege?
- Ask students to explain the concept of “inclusion in health research”.
- Is the inclusivity of clinical research legally enforceable? Do some documents state it?
or
What if every sponsor had a legal obligation to include a certain percentage of women and minorities in a trial?
- Ask students to explain the gender health gap, gender bias and give an example.
- Where do you see gaps or solutions in the application of concepts of diversity, equity, inclusivity to clinical research?

Hints and solutions for the teacher:

- Questions 1,3,6 reflect the learning outcome and are preferred. Questions 2,4,5 are optional.
- Question 1: show Figure 1 from Lesson 1.1 on the screen.



- Question 2: Equality. Equality refers to individuals or groups of people having the same resources or opportunities. Equity recognises that these individuals or groups may have differing circumstances, and allocates further resources and opportunities needed to reach an equal outcome.
- Question 3: show Figure 2 from Lesson 1.1 on the screen.



- Question 4: Depends on local legislation, but neither the Declaration of Helsinki, nor International Council for Harmonization (including the Good Clinical Practice) and other guidelines are legally binding. The list of documents or initiatives is in Lesson 1.5. EU Clinical Trial Regulation (CTR) 536/2014 is not mentioned in the list but requires trials be designed to reflect the population likely to use the medicine including diverse age groups, genders, and other demographics.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON 10–15'



- “Word association” activity can be modified to live word cloud in Mentimeter, Slido, Miro, or similar apps.
- Sometimes, advance preparation of the poll is necessary – check in advance of the class.
- Time adjustment is possible (online word association may be faster than writing ideas on board).
- Make a screenshot for each association to be easily able to discuss together later.

WORK IN PAIRS

60'



- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues).
- Ask students to write notes electronically so that they are able to share on screen later. Inform the students that you will randomly select pairs to share their work at the end of the task (to encourage focus and accountability).
- Share the materials discussed via the chat or link to a cloud.
- You can prepare a template which the students can collaboratively fill in. If you use the same template for all, students can always put their findings in a common file (e.g., screen shot of a row of the table). The result of the collaborative work is then easily generated.
- Time adjustment is possible. The presentation of the teams' work may need more time.
- Announce the timing (e.g., Broadcasting in Zoom), and share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.

REFLECTION, WRAP-UP

15'



- Share the figures.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Reflective activity 1.1: “Toxic Corridors video poem” modified for synchronous use

Link: [Toxic Corridors by Kwabena Kimathi](#)

Read the transcription and/or [watch](#) the ‘Toxic Corridors’ video poem by Kwabena Kimathi which highlights the experiences of black, male voices which are often excluded or ignored within health research.

MODIFICATION FOR INDIVIDUAL WORK



Watch the poem ‘Toxic Corridors’. Reflect on the themes presented. Write a short response (100–200 words) addressing the following questions:

What emotions did the poem evoke in you? Identify one key line from the poem that stood out to you. Why is it significant? How are the themes of equality, diversity, and inclusion presented; what keywords highlight these themes?

Submit your responses to a cloud/discussion board. Once you have submitted your responses, review the responses of at least one peer and consider whether you also noticed the theme presented.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve later for the group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide the students into teams and present them with the following questions that they will focus on while watching the poem:

1. How does the poem highlight issues of equality, diversity, and inclusion? Find specific words, phrases, or metaphors that convey these themes.
2. Consider the role of systemic bias in health research. Can you think of real-world examples where certain voices have been excluded or ignored?
3. How can health research institutions become more inclusive?

Play the poem for students, encouraging them to watch actively and take notes on key phrases. Afterward, allow them to begin working in teams.

Start the timer. Circulate among teams, listen to and stimulate the discussions. Ensure that students have the opportunity to rewatch the poem within their groups if needed. At the end, select one group to present their answers to Question 1. Stimulate the discussion between the groups. Rotate groups for the following answers.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the poem with students. After that start the discussion with the following questions:

1. How does the poem highlight issues of equality, diversity, and inclusion? Find specific words, phrases, or metaphors that convey these themes.
2. What do equality, diversity, and inclusion look like in health research?
3. What can be done to ensure that under-represented populations are not only included in research but also have a meaningful role in shaping it?

Hints and solutions for the teacher:

- Create a safe space: Ensure that students feel comfortable sharing their opinions. You can start the discussion by emphasising the importance of respect and openness towards different viewpoints.
- Stimulate the discussion by asking the following questions:
 - What do you think about this response?
 - What would you add?
 - Are you familiar with any real-world examples?
- To help students understand the poem, you can work with the transcript of the video on YouTube, event. print several copies of the transcript.
- Conclude the activity by watching the poem together again.



UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Reflective activity 1.2: “Lady Mary Wortley Montagu” modified for synchronous use

Link: [Lady Mary Wortley Montagu – Unsung Heroes of Science](#)

Watch this short video (02:14) on Lady Mary Wortley Montagu and her contributions to both trials research and modern immunisation science. At a time when women were not allowed to practice medicine Lady Mary's observations further proved the value of comparative trials in testing new interventions. However, her efforts are often less recognised than those of her male counterpart, Edward Jenner. Jenner demonstrated in 1796 that cowpox was a suitable, and less dangerous, substitute for smallpox during the immunisation process.

MODIFICATION FOR INDIVIDUAL WORK



Watch the video on Lady Mary Wortley Montagu. Think about the history of medicine and clinical research. Can you find other historical figures whose contribution have been overlooked or forgotten? Find one such figure and research their history. Write a short commentary (3–4 sentences) on the discussion board/cloud addressing the following questions: Who is this person? What was his/her contribution to medicine or clinical research? Why do you think his/her story has been overlooked or excluded?

Hints and solutions for the teacher: Consider anonymising the answers. These findings may serve later for a group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Play the video and ask students to take notes on key information about Lady Mary Wortley Montagu. Open this task with whole-class brainstorming to identify other historical figures in medicine and clinical research whose contributions have been overlooked. Write a list on the board/screen.

Divide the students into teams. Each group selects one and works on the following question:

1. Who was this person, and what was his/her contribution?
2. Why has his/her story been overlooked? What barriers did he/she have to overcome?

Start the timer. Circulate among teams, listen to and stimulate the discussions. Ask each group to present their chosen figure to the class. After presentations, you can continue the whole-class discussion with a question: How does this relate to the concepts of equity, diversity, and inclusion (EDI) in clinical research?

Hints and solutions for the teacher:

- Focus primarily on medicine and clinical research. If any ideas, consider opening the discussion to other research fields.
- Let students work with online sources or artificial intelligence. Alternatively, provide a pre-prepared list of scientists.
- The presentation format can be an oral summary or PowerPoint slides, based on the time available.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Play the video and ask students to write down key information on Lady Mary Wortley Montagu and her achievements. After that, start the discussion with the following questions:

1. Why do you think Lady Mary is not as famous as Edward Jenner?
2. Do you know any other examples of people ‘forgotten’ by history?
3. What factors contribute to stories being forgotten?
4. Do you think there are any parallels between history and the present? Which ones?
5. How is this transferable to the concept of equality, inclusivity, and diversity in clinical research today?

Hints and solutions for the teacher:

- Question 1: Encourage students to consider gender roles in history and bias in scientific recognition.
- Question 2: Focus primarily on medicine and clinical research. If any ideas, consider opening the discussion to the other fields of research.
- Question 3: Write key factors students mention on the board/screen (e.g., gender, race, socioeconomic status, political climate, access to education, geographic isolation).



- Use the list of key factors to stimulate discussion for Question 4 and Question 5.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Reflective activity 1.3: “The ethics of AI for health” modified for synchronous use

Link: [WHO calls for safe and ethical AI for health](#)

Read the press release from the World Health Organization (WHO) on AI ethics and its governance across applications in health care.



MODIFICATION FOR INDIVIDUAL WORK



Read the press release from the WHO. Consider some of the ethical issues raised. How do you think AI will impact the future of ethics in health research? Submit your reflection (100–200 words) to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve later for the group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4–6 students per team

Divide the students into teams and provide them a printed version of the WHO press release. Instruct them to read and analyse the text, focusing on the ethical concerns and the six core principles identified by WHO: (1) protect autonomy; (2) promote human wellbeing, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote AI that is responsive and sustainable.

Each group should choose one core principle and

1. explain its importance in the application of AI in healthcare, and
2. relate it to a real-world example (either positive or negative) of its impact on clinical research, where possible.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present shortly their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Share the WHO press release on the screen or provide students with several printed copies. Ask a few students to read the text aloud to the class. Start discussion with the following questions:

1. What are the ethical concerns raised regarding AI?
2. Can you think of any examples where AI has already impacted the health field in either positive or negative ways?
3. How do you think AI will impact the future of ethics in health research? How might it be related to the concepts of equality, diversity, and inclusion in clinical research?

Hints and solutions for the teacher:

- Prepare several printed copies of the WHO press release before the lesson.
- Ensure students focus on the application of AI ethics specifically to health and medicine rather than general uses of AI.
- Write down key ideas and answers on the board/screen to guide the flow of the discussion.
- Question 3:
 - Encourage students to think critically about both the benefits and challenges.
 - How to balance the benefits of AI with the protection of human rights?



UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Reflective activity 1.4: “Beyond Men: Gender Diversity in Medical Research” modified for synchronous use

Link: [Mayo Clinic podcast](#)

Watch, listen, or read the Mayo Clinic podcast “Beyond Men: Gender Diversity in Medical Research”.

MODIFICATION FOR INDIVIDUAL WORK



Watch, listen, or read the Mayo Clinic podcast. What strategies are suggested by Dr Sharonne Hayes and Dr Michele Halyard for researchers to better address the gender health gap in clinical trials? Focus your reflection on one particular problem or strategy and explain how it could be implemented in research or clinical practice.

Submit your reflection (100–200 words) to a cloud/discussion board, include the keywords at the beginning.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve later for the group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide the students into teams and provide them with a printed excerpt from the podcast discussing one of its topics, e.g. history; the importance of women's inclusion and its impact; women from ethnic minorities; age as a barrier; strategies to promote women's inclusion; progress and challenges. Encourage students to read the text and take notes. Students should focus on a particular problem or strategy and discuss how it could be implemented in research or clinical practice.

Start the timer. Circulate among teams, listen to the discussions, and support the teamwork. Ask each group to present their topic to the class.

Hints and solutions for the teacher:

- *This activity requires more preparation time to in advance of the lesson. The Modification for team-based work places higher demands on the teacher (text processing); the Modification for whole-group discussion requires pre-class reading work for students.*

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Base this activity on the pre-class preparation (see the Modification for individual work). Open the discussion board on the screen and write down the keywords students submitted in their reflections. Encourage students to add any other keyword related to the podcast that comes to mind.

Select one keyword and focus the discussion on it. Depending on the time available, continue with other keywords.

Hints and solutions for the teacher:

- *Stimulate the discussion by focusing on:*
 - *the context of the research area/health condition,*
 - *the impact of women's under-representation,*
 - *strategies to improve women's representation,*
 - *other under-served groups.*



UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Reflective activity 1.5: “Understanding SDG3: Good Health and Wellbeing” modified for synchronous use

Link: [SDG3: Good Health and Wellbeing](#)

Read the 2024 report from the United Nations Department of Economic and Social Affairs on the progress of SDG3: Good Health and Wellbeing.



MODIFICATION FOR INDIVIDUAL WORK



Read the SDG3 report. Identify **three key clinical areas or groups of people** highlighted there. Write three bullet points summarising your findings in your own words. Submit your points to a shared document. If an area/group you identified is already listed, add your answer as an additional bullet below it. Review the other responses to gain a deeper understanding of the report.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve later for the group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide the students into teams. Each team member reads a different section of the SDG3 report and notes at least one key clinical area or group of people highlighted there. Afterwards, team members share their findings and collectively agree on the three most important areas/group, providing reasoning to support their choices.

Start the timer. Circulate among teams, listen to and stimulate the discussions. Ask each group to present their findings to the class. Write their answers on the board/screen.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Base this activity on the pre-class reading (see the Modification for individual work) or team-based work (see the Modification for team-based work). Present students with a list of key topics identified during individual or team-based work. Start the discussion by following questions:

1. Are there any areas/groups from the SDG3 report that are missing in the list on the board/screen?
2. Why are these areas/groups important in clinical research and healthcare?
3. Think about the healthcare situation in your country. Do you see similar areas/groups being under-served, or is the situation different? Can you identify specific examples?

Hints and solutions for the teacher:

- You can print several copies of SDG3 report and distribute them in class.
- Additional questions to stimulate the discussion:
 - Which disease or health conditions are frequently mentioned?
 - Are there references to specific populations? (e.g., women, children, elderly, low-income groups, ...) Do any groups face barriers to healthcare access? Why? (e.g., policy, economic factors, cultural barriers, ...)
 - Encourage students to look for trends and patterns in the report – do certain groups face multiple challenges? Are there regional differences?
- Emphasise that clinical areas and groups of people will be important to note as you move on to Unit 2: Who are the under-served groups.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Multiple-choice questions and solutions

1. Inclusion happens when:
- A) Individuals or groups feel comfortable sharing unique perspectives knowing that their opinions and ideas are valued
 - B) Differences are seen as a benefit to the research process
 - C) Research welcomes all those involved to contribute and influence outcomes
 - D) **All of the above**

Answer D; research inclusion is essential to improve health and care for everyone, and to reduce health inequalities.

2. Which of Lind's experimental treatments for scurvy was found to be curative?
- A) Vinegar
 - B) Sea water
 - C) **Oranges and lemons**
 - D) Elixir of vitriol (dilute sulphuric acid)

Answer C; while citrus was found to be a curative for scurvy, Lind hesitated to recommend the use of oranges and lemons because they were too expensive. Some fifty years after Lind's trial the British Navy would use lime juice as a compulsory, and cheaper, part of a seafarer's diet.

3. What are morals?
- A) **Standards of behaviour and reflect what individuals, groups, and societies consider to be right and wrong**
 - B) When potential research volunteers are given adequate information to decide if they wish to participate in a study
 - C) Respecting the dignity of others and working to avoid harm by treating others in ways we wish to be treated
 - D) An ethical framework and set of guidelines for medical research involving human subjects

Answer A; Morals are standards of behaviour and reflect what individuals, groups, and societies consider to be right and wrong. Morals can be influenced by the world around us including our social relationships, culture, and education (among others). ([Oxford College, 2024](#))

4. The World Health Organization cites depression as [X]% more common among women than men:
- A) 60%
 - B) **50%**
 - C) 80%
 - D) 25%

Answer B; the [WHO](#) also found more women than men are affected by anxiety disorders.

5. What is the focus of the 2024 World Health Organization guidance for clinical trials?
- A) A *Zero Health Gaps Pledge* which is a commitment from CEOs across industries and regions for their organisations to embed health equity in core strategies, operations, and investments
 - B) A focus on health economics and outcomes research
 - C) **More effective and equitable clinical trials, particularly in low- and middle-income countries**
 - D) Helping global researchers better understand health inequalities across geographies and how health changes over time

Answer C; [The 2024 WHO guidance](#) focuses on more effective and equitable clinical trials, particularly in low- and middle- income countries. These guidelines reinforce previous research agendas with an emphasis on improving health outcomes by addressing the unique needs of under-served groups.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Recap multiple-choice questions and solutions

1. What term refers to individuals or groups of people having the same resources or opportunities?
- A) Equity
 - B) Uniformity
 - C) Equality**
 - D) Privilege

Answer C; Equality refers to individuals or groups of people having the same resources or opportunities. Equity recognises that these individuals or groups may have differing circumstances, and allocates appropriate resources and opportunities needed to reach an equal outcome.

2. Which of the following established the use of randomisation in clinical trials as standard practice?
- A) 1946, Medical Research Council trial of streptomycin for the treatment of tuberculosis**
 - B) 1747, James Lind's trial for the treatment of scurvy in sailors
 - C) 1943, Medical Research Council trial of patulin for the treatment of the common cold
 - D) 1712, Lady Mary Wortley Montagu's observations on smallpox inoculation

Answer A; 1946 MRC trial of streptomycin for the treatment of tuberculosis; streptomycin was successful in treating tuberculosis and the trial is cited as a "new era of medicine" where randomisation would become standard practice as it reduced clinician bias.

3. Who commissioned the Tuskegee Syphilis Study?
- A) World Health Organization
 - B) United States Public Health Service**
 - C) Institute for Health Metrics and Evaluation
 - D) Medical Research Council

Answer B; the United States Public Health Service commissioned the Tuskegee Study that ran for forty years; the trust placed in government medical officials was a key factor in study enrolment.

4. What is gender bias?
- A) Any practice or set of beliefs that favours people of one gender over those of other genders**
 - B) A belief in equal treatment for individuals regardless of their gender
 - C) The external display of one's gender, including behaviour, mannerism, clothing, name, pronouns and other characteristics
 - D) The belief that gender differences are not relevant to research

Answer A; Gender bias refers to any practice or set of beliefs that favours people of one gender over those of other genders. In health and care research this can lead to what is known as the gender health gap where some genders experience worse health outcomes than others as a result of gender bias. ([Denmark & Williams, 2014](#))

5. The United Nations lists 17 Sustainable Development Goals (SDGs). What is the focus of SDG 3 as most relevant to trials research?
- A) To achieve gender equality and empower all those who identify as women and girls
 - B) To ensure healthy lives for all people at all ages**
 - C) To reduce inequality within and among countries
 - D) To end poverty in all its forms, everywhere

Answer B; SDG 3: Good Health and Wellbeing focuses on ensuring healthy lives for all people at all ages.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

True/False questions and solutions

1. When research fails to involve specific individuals or groups this contributes to worse health outcomes and experiences for these people when compared to others.

*Answer: **True**; these differences are known as health inequalities.*

2. *Privilege* refers to the advantages, benefits, or special rights that individuals or groups can possess within society and that may be inherent at birth.

*Answer: **True**; it is important to consider the role of privilege in trials research both past and present ([Duke University, 2024](#)).*

3. The Declaration of Helsinki was written in response to the unethical Nazi medical atrocities of World War II.

*Answer: **True**; the [Declaration of Helsinki](#) places on an emphasis on processes of informed consent and the prioritisation of the wellbeing of participants to protect both human rights and dignity while building trust in medical research.*

4. The gender health gap results in women experiencing poorer healthcare outcomes than men.

*Answer: **True**; women may not exhibit the same response as men to drugs and other interventions in clinical trials.*

5. The Global Burden of Disease Study forecasts that health inequalities between countries will shrink through 2050.

*Answer: **True**; life expectancy will continue to climb globally with a decline in deaths from cardiovascular diseases, respiratory infections and tuberculosis, and maternal and neonatal deaths contributing to shrinking inequalities between countries. ([IHME, 2024: Global Burden of Disease 2021](#))*

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.1: Figure 1: Equality (left): everyone gets the same; versus equity (right): everyone gets what they need [Reproduced with permission of the Robert Wood Johnson Foundation, Princeton, N.J. Source: [RWJF, 2022](https://www.rwjf.org/en/about-us/our-work/clinical-trials/clinical-trials-101/equality-equity.html)]



1.1: Figure 2: Equity, diversity, and inclusion [Source: Adapted from [Open Oregon, 2024](https://openoregon.org/) licenced by [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/)]



Key points for the teacher:

- The image uses simple human-like shapes in different colours to visually explain three key concepts:
- Equity: Represented by a straight line of colourful figures, illustrating fair access, opportunities, and support for everyone.
- Diversity: Shown as a mix of colourful figures grouped together, symbolising the presence of people with different backgrounds and perspectives.
- Inclusion: Depicted as a circle of colourful figures, emphasising a sense of belonging, participation, and decision-making power for all.

Key points for the teacher:

- The image illustrates the difference between equality and equity using a bicycle analogy.
- Left side of the picture explains equality: Three individuals of different physical abilities are each given the same standard adult bicycle. The first person is a child, struggles with a bike being too large; the second person, who can ride a regular bike, benefits; the third person, in a wheelchair, cannot use the bike at all.
- Right side explains equity: Each individual is provided a bicycle that fits their specific needs. The child receives a smaller bike, the adult gets a standard bike, and the person in a wheelchair is given an electric wheelchair for better accessibility.
- The image demonstrates how equity focuses on individual needs, ensuring everyone can participate effectively, while equality treats everyone the same without considering differences.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.1: Gedela K, Wong R, Balendra S, Chita S, Jones H, Golombek R, Murray KK; NIHR CRN NWL EDI working group. Embedding equity, diversity and inclusion processes within clinical trials and health and social care research. *BMJ Open* [online]. 2025;15(3):e091807. [Accessed 10 Apr 2025]. Available from: <https://doi.org/10.1136/bmjopen-2024-091807>

Open access

Communication

BMJ Open Embedding equity, diversity and inclusion processes within clinical trials and health and social care research

Keerti Gedela ^{1,2}, Richard Wong,² Suki Balendra,³ Sunder Chita,⁴ Helen Jones,⁵ Rainer Golombek,¹ Keitumetse-Kabelo Murray,⁶ NIHR CRN NWL EDI working group

Key points for the teacher:

- The article offers a practical framework for integration of equity, diversity, and inclusion (EDI) into every stage of clinical trial and health research.
- The authors point out that exclusion from trials undermines health equity, limits access to new treatments and reduces the applicability of study results to real-world populations. Through case examples (e.g. lower efficacy of clopidogrel in South Asians, inaccurate estimation of kidney function in different ethnicities, low vaccine uptake in ethnic minorities during COVID-19), they demonstrate how lack of diversity has concrete clinical consequences
- Box 1 summarises 11 recommendations for embedding equity, diversity and inclusion into research processes.

1.2: Figure 1: Images generated by AI (Microsoft Copilot) depicting (from left to right): Ambroise Paré testing a mixture of turpentine, egg yolk, and oil of roses instead of boiled oil to seal soldiers' wounds, 1537; Jan Baptist van Helmont treats patients with bloodletting (or not) for treating fever, following casting of lots, 1643; James Lind tests different treatments including lemons and oranges on pairs of sailors with scurvy, 1747; John Haygarth trials metal tractors, 1799; Austin Flint compares placebo and drug-treatment for patients with rheumatic fever, 1863; the Medical Research Council (MRC) carry out the first double blind clinical trial for common cold, with nurses administering patulin or placebo but unaware of the treatment until after the trial, 1943; MRC randomised trial of streptomycin treatment of tuberculosis, 1946



Key points for the teacher:

- The picture represents a visual timeline showing the evolution of clinical trials research throughout centuries. It captures the transition from simple medical practices to modern clinical settings emphasising the key milestones in history of clinical trials.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.2: Bhatt A. Evolution of clinical research: A history before and beyond James Lind. *Perspect Clin Res* [online]. 2010;1(1):6–10. [Accessed 10 Apr 2025]. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC3149409/>

HISTORY

Evolution of Clinical Research: A History Before and Beyond James Lind

Dr Arun Bhatt

Key points for the teacher:

- The article traces the evolution of clinical research from early observational experiments to the establishment of modern randomised controlled trials, emphasising key milestones like James Lind's scurvy study and the Medical Research Council's streptomycin trial in pulmonary tuberculosis.
- It highlights the introduction of blinding and randomisation as critical advancements in ensuring unbiased results.
- It also mentions ethical guidelines, including the Nuremberg Code, the Declaration of Helsinki and the Belmont report, that were emerged in response to historical abuses and they prioritise patient safety and informed consent.

1.3: Sierra X. Ethics in medical research in humans: a historical perspective. *Actas Dermosifiliogr* (English Edition) [online]. 2011;102(6):395–401. [Accessed 10 Apr 2025]. Available from: <https://doi.org/10.1016/j.adengl.2011.03.002>

Actas Dermosifiliogr. 2011;102(6):395–401



OPINION ARTICLE

Ethics in Medical Research in Humans: A Historical Perspective[☆]

Ética e investigación médica en humanos: perspectiva histórica

X. Sierra

Dermatólogo ICS, Licenciado en Humanidades, CAP Rambla, Terrassa, Spain

Key points for the teacher:

- The article provides a detailed examination of the ethical evolution of clinical research.
- Historically, many medical experiments were conducted without informed consent, often exploiting vulnerable populations, such as prisoners, psychiatric patients, and marginalised communities.
- Again the ethical guidelines are mentioned (Nuremberg Code, the Declaration of Helsinki and the Belmont report).
- Interesting examples of unethical clinical trials are mentioned (besides the well-known Tuskegee Syphilis trial), such as forced smallpox inoculations in the 18th century, The hepatitis study at the Willowbrook State School on New York's Staten Island, medical experiments in Nazi concentration camps, injection of live cancer cells into 22 elderly African American patients at the Brooklyn Jewish Chronic Disease Hospital without their informed consent etc.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.3: The Nuremberg Code (1947). [Nuremberg Code – UNC Research](#)

[UNC RESEARCH](#) » [IRB AND THE OFFICE OF HUMAN RESEARCH ETHICS](#) » [RESOURCES RELATED TO UNC RESEARCH](#) » NUREMBERG CODE

Nuremberg Code

Key points for the teacher:

- The exact wording of the ten principles of the Nuremberg Code.
- Teacher may ask the students whether there is everything clear for the students and promote discussion whether they agree with all points or would change/add something.

1.3: Parums, D. Editorial: The 2024 revision of the Declaration of Helsinki and its continued role as a code of ethics to guide medical research. Med Sci Monit [online]. 2024;30:e947428. [Accessed 10 Apr 2025]. Available from: <https://doi.org/10.12659/MSM.947428>

Editorial: The 2024 Revision of the Declaration of Helsinki and its Continued Role as a Code of Ethics to Guide Medical Research

Dinah V. Parums, MD PhD

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None declared

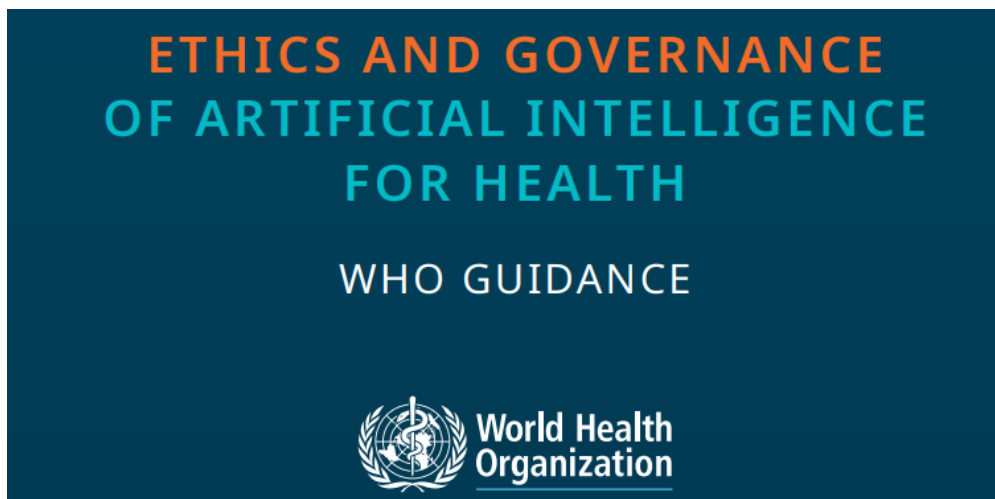
Key points for the teacher:

- The article summarises the newest version of the Declaration of Helsinki.
- The 2024 revision responds to challenges such as global health emergencies (e.g. pandemics), data privacy and biobanking and the increasing use of artificial intelligence in clinical research.
- The updated Declaration emphasises the importance of greater inclusivity, protection of vulnerable populations and participant engagement through the whole life-cycle of a clinical trial. The need for environmentally sustainable research practices is addressed too.
- Table 1 summarises the key revisions to the Declaration document (also to be found in Unit 1).

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

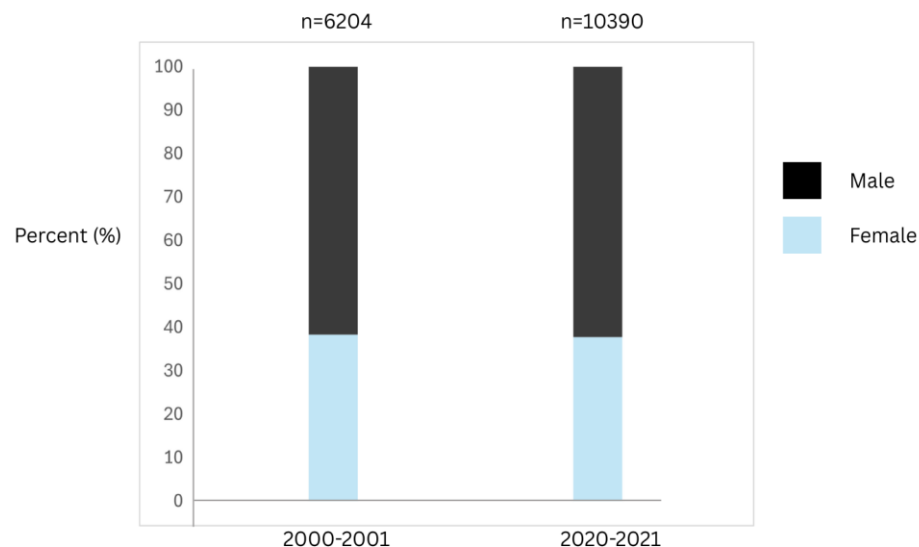
1.3: [WHO press release](#) related to: Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: World Health Organization; 2021.



Key points for the teacher:

- The article discusses the World Health Organization's (WHO) concerns regarding the use of AI-generated large language models (LLMs), such as ChatGPT, in healthcare.
- WHO highlights significant risks, including biased data, misinformation, privacy concerns and the spread of disinformation. It also warns against the premature adoption of untested AI systems, which could lead to errors, harm to patients, and loss of trust in AI.
- LLMs may also be trained on data for which consent may not have been previously provided for such use, and LLMs may not protect sensitive data (including health data) that a user provides to an application.
- WHO emphasises the importance of applying ethical principles and appropriate governance in the WHO guidance on ethics and governance of AI for health. The **six core principles** of this guide are:
 - protect autonomy,
 - promote human wellbeing, safety and public interest,
 - ensure transparency, explainability and intelligibility,
 - foster responsibility and accountability,
 - ensure inclusiveness and equity,
 - promote AI that is responsive and sustainable.

1.4: Figure 1: Percentage of male and female participants in clinical trials of drugs published in two journals (Clinical Pharmacology and Therapeutics; Clinical and Translational Science) between 2000-2001 and 2020-2021. Data from a total of 222 studies are represented, where sex was not listed in the exclusion criteria. Total number of participants: n=6204 during 2000-2001; and n=10390 during 2020-2021. Females were under-represented in both time periods at 38.3% and 37.8% [Source: data presented from [Bøttern et al., 2023](#)].



Key points for the teacher:

- The bar chart shows the percentage of male (black) and female (blue) participants in clinical trials published in two journals in years 2000-2001 and 2020-2021.
- The analysis includes 222 clinical trials published in Clinical Pharmacology and Therapeutics and Clinical and Translational Science.
- The gender imbalance persisted over two decades, showing no improvement in female representation despite increased awareness of inclusivity in clinical research.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.4: Boerma T, Hosseinpoor AR, Verdes E, Chatterji S. A global assessment of the gender gap in self-reported health with survey data from 59 countries. BMC Public Health [online]. 2016;30;16(1). [Accessed 10 Apr 2025]. Available from: <https://doi.org/10.1186/s12889-016-3352-y>

Boerma et al. BMC Public Health (2016) 16:675
DOI 10.1186/s12889-016-3352-y

BMC Public Health

RESEARCH ARTICLE

Open Access



A global assessment of the gender gap in self-reported health with survey data from 59 countries

Ties Boerma^{*}, Ahmad Reza Hosseinpoor, Emese Verdes and Somnath Chatterji

Key points for the teacher:

- This article examines the gender gap in self-reported health across 59 countries, using data from the World Health Surveys (2002–2004).
- Across all self-reported health measures, women consistently rated their health worse than men. Chronic conditions (arthritis, depression, asthma, cognitive loss) contribute significantly to the gender gap.
- The gender gap is smaller in high-income countries but remains significant globally.
- Depression had the strongest impact on worsening women's health perceptions, even when chronic diseases were accounted for.
- The size of the gender gap in self-reported health was influenced by both societal and biological factors.
- The more frequent contact with health services among women could contribute to the gender gap in reporting, due to higher awareness and reporting of recalled doctor's diagnoses and symptoms.

1.5: Institute for Health Metrics and Evaluation (IHME). Global burden of disease 2021: findings from the GBD 2021 study [online]. IHME: Seattle, WA, US; 2024. [Accessed 10 Apr 2025]. Available from: <https://www.healthdata.org/research-analysis/library/global-burden-disease-2021-findings-gbd-2021-study>

Global Burden of Disease 2021

Findings from the GBD 2021 Study

Key points for the teacher:

- The Global Burden of Disease (GBD) 2021 Study, conducted by the Institute for Health Metrics and Evaluation (IHME), provides a comprehensive assessment of global health trends, mortality, disease burden, and risk factors. The study uses data from 328,938 sources and highlights key health challenges, including the impact of the COVID-19 pandemic, demographic shifts, and the rising burden of chronic diseases.
- Global life expectancy dropped by 1.6 years (2019–2021) due to COVID-19, marking the most severe decline in 50+ years. Despite this setback, life expectancy has increased by 22.7 years since 1950.
- According to fertility forecasts, by 2100, 97% of countries will have fertility rates below replacement levels (2.1 children per woman), leading to population declines. Ethical immigration policies and parental support are needed to sustain population levels.
- Since 2010, the burden of HIV/AIDS and diarrhoea has been halved, and injury-related health loss has dropped by 25%. Diabetes has become the fastest-growing cause of health loss. COVID-19 was the single leading cause of disease burden in 2021, reversing many pre-pandemic health gains.
- High blood pressure, smoking, high blood sugar, and air pollution are the leading risk factors worldwide. Obesity, drug use, and metabolic disorders are rising concerns.

UNIT 1: BACKGROUND AND HISTORY OF INCLUSIVITY IN CLINICAL TRIALS

Articles, pictures outlines

1.5: Figure 1: United Nations Sustainable Development Goals [Source: [United Nations](#), 2025. The content of this publication has not been approved by the United Nations and does not reflect the views of the United Nations or its officials or Member States]



Key points for the teacher:

- The image illustrates the 17 Sustainable Development Goals (SDGs) established by the United Nations. Each goal is represented by a distinct icon and colour. The SDGs are:
 1. No Poverty
 2. Zero Hunger
 3. Good Health and Wellbeing
 4. Quality Education
 5. Gender Equality
 6. Clean Water and Sanitation
 7. Affordable and Clean Energy
 8. Decent Work and Economic Growth
 9. Industry, Innovation, and Infrastructure
 10. Reduced Inequalities
 11. Sustainable Cities and Communities
 12. Responsible Consumption and Production
 13. Climate Action
 14. Life Below Water
 15. Life on Land
 16. Peace, Justice, and Strong Institutions
 17. Partnerships for the Goals

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

General overview of the unit for the teacher

OBJECTIVES

The aim of the unit is to introduce students to the concept of “under-served populations”, introduce and explain the terminology involved (or the specifics of the national language), and explain the ambiguity of the term under-served population depending on the perspective from which it is viewed. We will also introduce projects, initiatives and guidelines that focus on under-served groups. Finally, we will introduce students to relevant scientific literature, thereby building their critical thinking skills and further broadening their insight on the topic.

UNIT CONTENT

- 2.1: Defining under-served groups
- 2.2: Under-served groups by demographic factors
- 2.3: Under-served groups by social and economic factors
- 2.4: Under-served groups by health status
- 2.5: Under-served groups by disease specific factors
- Summary of Unit 2

LEARNING OUTCOMES

Students will be able to:

1. Identify the **different terms** used around the world to describe groups of people that clinical trials and wider health research fails to include.
2. Consider the **differing contexts and ways** in which an under-served group can be defined.
3. Identify **common characteristics** shared between some under-served groups.
4. **Give examples** of different under-served groups.
5. **Reflect** on the contexts that contribute to a lack of inclusion in research for these groups.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Blended 90-minute classroom

 pre-class reading 5x2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 2.1 pre-class; watch the video from NIHR and read the abstract of the article written by Witham <i>et al.</i> ; test your knowledge.
Tue	Complete Lesson 2.2 pre-class; complete the reflective activity focusing on demographic factors; test your knowledge.
Wed	Complete Lesson 2.3 pre-class; complete two rows of the reflective activity education and income indicators; test your knowledge.
Thu	Complete Lesson 2.4 pre-class; read the view of Denise Astill in the article of Waitt <i>et al.</i> ; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 2.5 pre-class; read the editorial in the Lancet; test your knowledge; read the Summary of Unit 2; complete the MCQs.

OPENING THE LESSON

15' 



warm-up

 **Organize yourselves/pick a side** – ask students to form a line, leaving space on the left and right. Explain that they should express their opinion on the topic by moving right, left, or stay in the middle. The distance from the middle expresses the strength of their opinion. Always ask students to provide a reason for their opinion. Questions 1, 2, 4, and 6 are crucial, Questions 3, 5 are optional.

1. Did you consider “under-served groups” a real problem in clinical research before learning about this topic? (right = a problem, left = not a problem)
2. After studying the topic, what is your current feeling? (right = a problem, left = not a problem)
3. Historical events, e.g., Tuskegee Syphilis Study are no longer relevant in research today. (right = agree, left = disagree)
4. Diversity in clinical research is essential to creating effective treatments for everyone. (right = agree, left = disagree)
5. It is impossible to achieve perfect representation in clinical research. (right = agree, left = disagree)
6. There was a true-false question in the pre-class reading: There is only one definition of an under-served group. (right = agree, left = disagree)

Hints and solutions for the teacher – follow-up questions to stimulate discussion:

- **Question 2: What changed your view?**
- **Question 3: How important is this for you?**
- **Question 4: How to ensure appropriate diversity, what factors affect it?**
 - *Inclusion and exclusion criteria. Statistics, power analysis.*
 - *Note: This is just the introduction; the topic will be discussed more in the future units.*
- **Question 6:**
 - **Can we say and be 100% correct – the under-served group is women?** *Probably not, depends on the context – in ovarian cancer research, it will be different than in heart failure trials.*
 - **Can we say and be 100% correct – the under-served group is elderly people?** *In trials focusing on paediatric diagnoses, inclusion of elderly does not bring much benefit and in this context, the elderly cannot be considered as an under-served population.*
 - **The context** is the key for defining the group as under-served. E.g., regarding age, sex, ethnicity, demographic information might be useful.

INDEPENDENT WORK

20' 



Following the previous discussion, we focus on issues affecting diversity in clinical research. Ask students to **look at the following terms** from the article of Pitkälä and Strandberg (Lesson 2.2) or Camanni *et al.* (Lesson 2.4) and try to **decide whether or not these terms can be relevant for diversity** in clinical trials and the issue of under-served populations (tag yes/no). Ask students to write a **brief explanation** to four of them of why they might/might not play a role. Ask students to write a note, when you didn't understand them and needed to find the explanation. (10 minutes)

- Inclusion/exclusion criteria.
- Eligibility.
- Systematic absence.
- Confounding factors distribution.
- Selection bias.
- Injustice/unfairness.
- Recruitment and retention.
- Drop-out.
- Internal vs. external validity of a trial.
- Reliable results.
- Pragmatic clinical trials.

Ask students to present their results or summarise (see Hints and solution below). (10 minutes)

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Blended 90-minute classroom

Hints and solutions for the teacher:

- Start the timer on the screen so the students see how much time they have.
- Inclusion/exclusion criteria, eligibility, recruitment strategies (retention strategies/drop out) influence diversity in clinical trials/shape who is represented in research. May produce systematic exclusion and barriers, perpetuate injustice.
- Selection bias, confounding factors distribution and differences between internal and external validity affect the reliability of the research. Prioritising internal validity without considering external validity may produce results irrelevant for under-served populations.
- Pragmatic trials highlight the practical importance.

TEAM-BASED WORK

40' 



5–8 students per team

Print several copies of the article (Witham *et al.* in Lesson 2.1). Divide the students in teams (5–8 students per group) and ask them to dive into the details of the article:



Task 1: Table 1 defines the under-served population. Who identified them? Is this process reliable? (5 minutes)



Task 2: Ask students to work with Table 1. Each team to select/to be assigned to one under-served group from each category and discuss why is it important to include it in trials, give a specific context. Suggest the inclusion/ exclusion criteria or aspects to consider when considering including these groups in a trial. (20–25 minutes)

Hints and solutions for the teacher:

- Start the timer (e.g. 25 minutes) on the screen so the students see how much time they have.
- In the Task 2, prevent duplication – check which group is working on which category; specify on the board.
- Circulate around the room to check on progress, clarify instructions, and listen to/stimulate the discussions/ask probing questions to deepen the thoughts.
- Leave enough time for the Debriefing – a critical part of the team-based work (see below).



Debriefing of the team-based work: ask one or two groups to present their results for task 1 (methodology) and 2 (trial contexts). (10–15 minutes)

Hints and solutions for the teacher:

- How well the examples illustrate the theory?
- Similarities and differences between the examples chosen by teams.

REFLECTION, WRAP-UP

15' 



1. Ask students to define “under-served groups”.
2. Ask students to list synonyms for “under-served”.
3. Ask students to list related terms without using a computer or books to look them up.
4. How can the principles mentioned today be applied in a real-world setting?
5. What was the most surprising or challenging part of today’s lesson?

Hints and solutions for the teacher:

- Write the keywords of the ideas on the board.
- Questions 1–3 are crucial, questions 4,5 are optional.
- Question 1 notes:
 - Not only one acceptable definition!
 - They should mention **the context**!
- Question 2 notes:
 - Historically excluded, underrepresented
 - Don’t forget to mention your national terminology together with the English terminology
- Question 3 notes:
 - Except for the terms in the Individual activity, the following might be mentioned: variability, inclusivity, real-world vs. narrow, preselected, statistical power, demonstrating the effect vs generalisability, applicability.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON 10–15'



- “Pick a side activity” can be modified into polls in Mentimeter (anonymous voting), Slido (Polls), or Miro (students move an icon or a sticky note), or similar apps.
- Sometimes, advance preparation of the poll is necessary – check it in advance of the class.
- Time adjustment is possible (online voting may be faster than moving in classroom).

INDEPENDENT WORK 10–15'



- Ask students to write notes electronically to be able to share on screen later. Inform the students that you will randomly select a few students to share their work at the end of the task (to encourage focus and accountability).
- Time adjustment is possible.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.

BREAK 5'

TEAM-BASED WORK 40' 5–8 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign one facilitator/trained student to each group to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.
- Share the materials discussed via the chat or link to a cloud.
- You can prepare a template which the students can collaboratively fill in.
- Ask student to write notes electronically so that they are able to share on screen later. Ask students to select a group leader.
- Time adjustment is possible. The presentation of the teams' work may need more time.

REFLECTION, WRAP-UP 15'



- Use a shared screen to write down students' suggestions.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Reflective activity 2.1: “My research story” modified for synchronous use

Link: [My research story \(nihr.ac.uk\)](https://www.nihr.ac.uk/my-research-story)

Read through the short stories from members of the public in the UK who are involved in different types of research.

MODIFICATION FOR INDIVIDUAL WORK



Read the short stories individually, select two stories, and propose who the under-served populations are, including 2–3 sentences of reasoning. Reflect on the context of the research (population, condition under study, the questions asked by the research team, and the intervention being tested). Submit these results to a cloud/discussion board.

Hints and solutions for the teacher: Results may serve later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Divide the students into teams. Each team should select/be assigned to one person's story. Prevent duplication. Reflect on the context of the research: population, condition under study, the questions asked by the research team, and the intervention being tested. What under-served groups can you identify?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present shortly their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Open a selected story on the shared screen visible to all. Read the story out loud. Ask students to write notes reflecting on the context of the research (population, condition under study, the questions asked by the research team, and the intervention being tested).

Ask students to discuss their suggestions in pairs, at first. Later, open the whole-group discussion. Write the ideas on the screen/board.

Repeat with another story. Modify the ideas on the screen based on the other contexts, if applicable.

Hints and solutions for the teacher:

Example: a short summary of Bea Buckley's story

- *Patient description: 39-year-old women; after melanoma treatment; currently disease-free*
- *Population: melanoma patients; Bea was contacted via partnering with a “research matchmaking” service*
- *Condition under study: melanoma*
- *intervention being tested: the research project aims to recruit participants to build the world's biggest melanoma database (to understand melanoma and its treatment)*
- *Question asked by the research team: participants were asked to complete two online questionnaires about their lifestyle, health and personal and family cancer history*

If the under-served group is not identified easily, ask students the following questions:



- *What population would benefit from the intervention being tested?*
- *Does the recruitment process promote/restrict the inclusion of particular groups? What benefits/limits can you identify?*

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Reflective activity 2.2: “Demographic factors in trial design” modified for synchronous use

Link: <https://trialsearch.who.int/>



The World Health Organization's (WHO) International Clinical Trials Registry Platform (ICTRP) is a public platform providing essential information on clinical trials conducted worldwide.

MODIFICATION FOR INDIVIDUAL WORK



Search the WHO ICTRP for clinical trials in an area of interest to you and select two of them concerning the same disease/condition. Look for their inclusion and exclusion criteria listed and focus on the demographic factors. Think about proper inclusion/exclusion of certain groups. How might this influence the outcomes of the trial? Submit your results (2–3 sentences) to a cloud/discussion board.

Hints and solutions for the teacher: Results may serve later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Divide the students into teams. Ask the students to search the WHO ICTRP to identify one clinical trial in an area of their interest. Prevent duplication. Look for the inclusion and exclusion criteria listed and focus on the demographic factors. Think about proper inclusion/exclusion of certain groups. How might this influence the outcomes of the trial?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their findings concisely.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Open the WHO ICTRP and search for a trial in an area of interest to you. Look for the inclusion and exclusion criteria listed. Ask students to select the demographic factors and write them on the board. After that, let them discuss the appropriate inclusion/exclusion of certain groups in pairs. Later, open the whole-group discussion. Write the ideas on the board. Continue with the discussion on “How might this influence the outcomes of the trial?”

Repeat with another clinical trial. Write the ideas on the screen/board in the next column.

Hints and solutions for the teacher:

- *Demographic factors that might be mentioned: age (focus also on age extremes), education, ethnicity, sex/gender.*
- *Always consider the context of the research.*
 - *What is the disease/condition studied?*
 - *What are the primary and secondary outcomes?*
 - *What population would benefit from the intervention being tested?*



UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Reflective activity 2.3: “Indicators of socioeconomic position” modified for synchronous use

Odkaz: [Galobardes et al., 2006](#)

GLOSSARY

Indicators of socioeconomic position (part 1)

Bruna Galobardes, Mary Shaw, Debbie A Lawlor, John W Lynch, George Davey Smith

J Epidemiol Community Health 2006;**60**:7–12. doi: 10.1136/jech.2004.023531

This glossary presents a comprehensive list of indicators of socioeconomic position used in health research. A description of what they intend to measure is given together with how data are elicited and the advantages and limitation of the indicators. The glossary is divided into two parts for journal publication but the intention is that it should be used as one piece. The second part highlights a life course approach and will be published in the next issue of the journal.

outcome then the choice of indicator may not be crucial. However, even in a case such as this, using different indicators of SEP may result in gradients of varying slopes. Furthermore, while a single measure of SEP may show an association with a health outcome, it will not encompass the entirety of the effect of SEP on health. This issue is of particular importance when SEP is a potential confounding factor. Multiple SEP indicators, preferably measured across the life course, will be needed to avoid residual confounding by unmeasured socioeconomic circumstances.^{7 12} The notion that the choice of SEP

	Theoretical basis	How is it measured?	Strengths	Limitations
Education				
Housing				
Income				
Occupation Based Measures				

MODIFICATION FOR INDIVIDUAL WORK



Read the article of [Galobardes et al.](#) presenting indicators of socioeconomic position and work with the table presented. Select two described indicators (two rows in the table) and concisely fill in (using keywords) information on their theoretical basis, measurement, strengths, and limitations. Submit your results to a cloud/discussion board.

Hints and solutions for the teacher: Results may be useful later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Print several copies of the [article](#) and the table presented. Divide the students in teams and assign them one of the indicators of socioeconomic position (education/housing/income/occupation-based measures). Let them read the introduction and the section about the indicator selected. Ask them to fill in the information in the table in the corresponding row.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to concisely present their findings. You can stimulate the discussion using the modification for the whole-group discussion below.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Share the article with students and let them read a section focused on one indicator of socioeconomic position, e.g. *income*.

Focus the following discussion on:

1. How does *income* influence access to healthcare?
2. How does *income* influence inclusivity in clinical trials?
3. How is *income* measured?
4. What challenges arise in measuring *income*?

Hints and solutions for the teacher:

- The interpretation of the relevance of the indicator is difficult due to strong correlation of the indicators.
- For many under-served individuals and groups inequality starts at birth.
- Stimulate the discussion by asking additional questions, e.g.
 - Question 1, Question 2: Think of real-world examples. Some of them are listed in Lesson 2.3. Encourage students to share personal/observed experiences.
 - Question 3, Question 4: What are the strengths of using income as an indicator of socioeconomic position? What are the limitations? How might cultural or regional differences affect the reliability of *income* as a measure?

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Reflective activity 2.4: “WHOQOL-BREF Scale” modified for synchronous use

Link: <https://hilio.com/en/tests/quality-life-test-whoqol>

The WHOQOL-BREF Scale is a quality-of-life scale used by the World Health Organization to address four quality of life domains: physical health, psychological health, social relationships, and environment.

Hints for the teacher: Try to find the corresponding translation into your national language or use another quality-of-life scale in your national language.

MODIFICATION FOR INDIVIDUAL WORK



Review the questions in the WHOQOL-BREF Scale. Select two questions that you find most relevant for identifying under-served groups in health research. Reflect on the following questions and write your answers:

- Which under-served groups did you recognise?
- How might the specific questions help identify under-served groups?
- What factors might contribute to the groups being under-represented in health research?

Submit your responses to a cloud/discussion board. Once you have submitted your responses, review the responses of at least one peer and write your feedback considering the following questions: Do the selected questions align with the identification of under-served groups? Are there additional perspectives or groups that could be considered? Provide constructive and respectful feedback.

Hints and solutions for the teacher: Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Divide the students into teams. Ask the students to select two questions from the WHOQOL-BREF Scale to focus on. Discuss in the team how the selected questions could help identify/apply to a group that is currently under-served within health research. What factors might contribute to the groups being under-represented in health research?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to concisely present their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Select three questions from the WHOQOL-BREF Scale and display them on the screen. Discuss with the whole group the following questions:

1. Which under-served groups did you recognise?
2. How might the specific questions help identify under-served groups?
3. What factors might impact the quality of life for these groups and how is this related to health research?
4. Identify practical steps to improve the representation of these groups in health research.

Hints and solutions for the teacher:

- You can focus the discussion primarily on under-served groups by health status (Lesson 2.4). Alternatively, you can apply all the factors students have learned about in Unit 2 (demographic factors, economic factors, health status, etc.). According to your decision select the proper questions. Examples:
 - **“Do you have enough energy for everyday life?”** This question highlights different physical and mental challenges faced by individuals with disabilities.
 - **“How satisfied are you with your personal relationships?”** Minority groups often face social isolation, discrimination, or a lack of support from broader society.
 - **“How satisfied are you with your access to health services?”** Low-income populations often encounter barriers to accessing healthcare (financial, geographical, lack of information).
- Encourage the students to work with the examples in the [INCLUDE project](#).
- You can use some additional questions to stimulate the discussion:
 - Question 1, Question 2: Are there specific examples of health conditions or settings where certain groups are particularly under-served?
 - Question 1, Question 2: Are there any groups we have not considered yet? What might their specific needs be?
 - Question 4: What could researchers do to better include these groups in clinical studies?

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Reflective activity 2.5: “Disease-specific factors in trial design” modified for synchronous use

Link: <https://www.orpha.net/en/research-trials/clinical-trials>

Orphanet is a unique resource aiming to provide high-quality information on rare diseases and orphan drugs.

MODIFICATION FOR INDIVIDUAL WORK



Access the Orphanet clinical trial registry. Search for a rare disease in an area of interest to you. How many clinical trials are listed there for this disease? Choose one clinical trial and look at the study design, including the eligibility criteria and enrolment numbers (if available). Reflect critically on the key participation criteria. How does this trial differ from more common ones (e.g., you reflected on these in Lesson 2.2)? Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Results may be useful later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Divide the students into teams. Each group selects a different rare disease. Ask students to search for the rare disease in the Orphanet clinical trial registry and discuss the following:

- How many clinical trials are listed for the disease?
- Choose one clinical trial and look at the study design, including the eligibility criteria and enrolment numbers (if available).
- How does this trial differ from more common clinical trials?
- Identify barriers to participation in clinical trials for rare disease patients.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to concisely present their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Select 2–3 examples of rare disease trials from the Orphanet clinical trial registry and provide key information to the class regarding eligibility criteria and enrolment numbers. Discuss the following with students in the whole group:

- What patterns did you notice in the eligibility criteria and enrolment numbers?
- How do these clinical trials differ from trials for more common diseases?
- What are the challenges in recruiting participants for rare disease trials? How might these be affected by other factors contributing to the exclusion of rare disease patients?

Hints and solutions for the teacher:

- *In the European Union, a rare disease is defined as one affecting fewer than 5 out of 10,000 members of the general population. Between 6,000 and 8,000 rare diseases are estimated to exist today. Around 80% are of genetic origin and 70% start in childhood.*
- *Examples of rare diseases: metachromatic leukodystrophy, amyotrophic lateral sclerosis, spinal muscular atrophy.*
- *Enrolment numbers in rare disease trials are typically much smaller due to the limited patient population. While these trials can yield meaningful results, they might lack statistical power and might not capture the diversity within the patient population.*
- *Challenges in recruitment include geographic dispersion of rare disease patients. The socioeconomic status might affect the ability to participate in the study.*
- *Translation: Orphanet offers several language versions.*

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Multiple-choice questions and solutions

1. Whether a group could be considered under-served by research depends on the population, the condition under study, the question(s) being asked by research teams, and [X].

A) The intervention(s) being tested
B) The phase of the study (I, II, III, IV)
C) The chance of any harm occurring
D) Who is funding the study

Answer A; The NIHR-INCLUDE project notes that “successful delivery of intervention to a target population is complex, with logistical, sociocultural, psychological and biological differences all having an impact. Unless we have tested if an intervention can be deployed effectively to different groups, we cannot be sure it will work in practice.” (NIHR, 2024)

2. Which of these is not an example of a demographic factor?

A) Ethnicity
B) Age
C) Attitudes
D) Sex

Answer C; the guidance from the INCLUDE project identified four key groups by demographic factors that may be under-served either in specific contexts or more generally across clinical trials research: age, education, ethnicity, and sex.

3. Who is most likely to be invited to participate in a clinical trial?

A) Individuals of White European ethnicity
B) Individuals who are highly educated
C) Individuals who live in an urban area
D) All of the above

Answer D; Researchers in the United States examining the demographics of those who participate in trials found that individuals are more likely to participate if they are of a White European ethnic background, educated to a higher degree level, single, or living in an urban area (Williams et al, 2021).

4. Which of these is not an example of an under-served group by health status?

A) People with mental health conditions
B) People with addictions
C) People in full-time employment
D) People who are pregnant or lactating

Answer C; Health status is a measure of how people perceive their health. Examples of individuals or groups not currently represented by research as a result of their health status include people with mental health conditions, people with addictions, and those who may be pregnant or lactating.

5. What % of rare diseases do not have approved treatments?

A) 80%
B) 50%
C) 95%
D) 97%

Answer C; there are globally unmet needs and challenges for those with rare diseases including a lack of diagnostic tools and few treatment options. While rare diseases are individually rare, as a population, people with rare diseases are many. An estimated 300 million people globally live with a rare disease, and many are excluded from clinical research.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Recap multiple-choice questions and solutions

1. Health disparities can be intensified through *intersectionality*. Which of the below could represent *intersectionality* between under-served groups?
- A) Rural dweller with a mental health condition
 - B) Pregnant woman from an ethnic minority group
 - C) Older person with comorbidities
 - D) All of the above**

Answer: D; People may experience multiple factors spanning different under-served groups. This is known as intersectionality.

2. What are the three demographic processes which influence demography?
- A) Birth rate, health status, ageing/death
 - B) Birth rate, migration, ageing/death**
 - C) Health status, migration, ageing/death
 - D) Health status, number of clinical trials registered, ageing/death

Answer: B; The three main demographic processes which influence demography are the rate of births, the migration of people around geographical space, and ageing and death rate.

3. The top 10% wealthiest households in the Global North own what proportion of the total wealth in their country?
- A) A tenth
 - B) Just under a quarter
 - C) Over half**
 - D) Nine tenths

Answer: C; The OECD estimates that across OECD member countries, the richest 10% of households own over half of all household wealth combined, making wealth unevenly distributed.

4. Which of the following could be within an under-served group, based on health status:
- A) Pregnant woman**
 - B) Full-time caregiver
 - C) Person aged over 75
 - D) Person who does not attend regular hospital appointments

Answer: A; Pregnant women could be within an under-served group, based on their health status (pregnancy). The others represent groups which may be under-served by demographic and socioeconomic factors – although they could also be under-served depending on their individual health status (intersectionality).

5. Which statement is true:
- A) 300 million people globally have a rare disease
 - B) 80% of rare diseases have a genetic cause
 - C) 5% of rare diseases have a treatment available
 - D) All of the above**

Answer: D; Rare diseases are collectively common, yet the majority of people with a rare disease remain under-served.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

True/False questions and solutions

1. There is only one definition of an under-served group.

*Answer: **False**; under-served groups are specific to context and may share common characteristics.*

2. *Demographics* are the statistical data relating to a population and particular groups within it.

*Answer: **True**; the health and healthcare needs of a population cannot be measured or met without knowledge of its size and characteristics.*

3. For many people at a socioeconomic disadvantage this inequality starts at birth.

*Answer: **True**; disparities continue through childhood and eventually adulthood, where children whose parents held a higher education degree were significantly more likely to graduate university, be in good health, and have greater disposable income ([OECD, 2022](#)).*

4. Health status is a measure of how people perceive their health.

*Answer: **True**; our health status can include the length of our lives as well as physical and mental health which may be impacted by infectious or chronic diseases, as well as injuries and other health events ([OECD, 2024](#)).*

5. A disease can be rare in one region but common in another.

*Answer: **True**; for World Health Organization regions, a disease is considered rare when it affects fewer than 1 in 2000 people.*

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

2.1: Witham MD, Anderson E, Carroll C, Dark PM, Down K, Hall AS, Knee R, Maier RH, Mountain GA, Nestor G, Olivia L, Prowse SR, Tortice A, Wason J, Rochester L; the INCLUDE writing group. Developing a roadmap to improve trial delivery for under-served groups: results from a UK multi-stakeholder process. *Trials* [online]. 2020; 21, 694. [Accessed 18 Apr 2025]. Available from: <https://doi.org/10.1186/s13063-020-04613-7>

Witham et al. *Trials* (2020) 21:694
<https://doi.org/10.1186/s13063-020-04613-7>

Trials

RESEARCH

Open Access



Developing a roadmap to improve trial delivery for under-served groups: results from a UK multi-stakeholder process

Miles D. Witham^{1,2}, Eleanor Anderson¹, Camille Carroll³, Paul M. Dark⁴, Kim Down¹, Alistair S. Hall⁵, Joanna Knee⁶, Rebecca H. Maier⁷, Gail A. Mountain⁸, Gary Nestor¹, Laurie Oliva⁹, Sarah R. Prowse¹⁰, Amanda Tortice¹¹, James Wason^{12,13}, and Lynn Rochester^{1,14*} On behalf of the INCLUDE writing group

Key points for the teacher:

- The paper reports the framework for identification of groups who are historically under-represented in trials, lists barriers and drivers to inclusion and facilitation of innovations in trial design. The paper reflects the INCLUDE project focus and represents a scientific communication of the results and steps for the future.
- Invited stakeholders (National Institute for Health Research national specialty leads, members of the NIHR Clinical Research Network, public and patient groups, healthcare professionals, the life science industry, funders, regulatory bodies) met repeatedly to deal with above questions. Literature review and surveys were conducted too.
- Table 1 summarises the under-served groups identified; Table 2 Barriers to inclusion. Potential solutions, actions, future work directions are proposed and summarised in Fig. 2 and Fig. 3.

2.1: NIHR. Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project [online]. NIHR: UK; 2020. [Accessed 18 Apr 2025]. Available from: www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435

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Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project

Published: 7 August 2020 | Version: August 2024 v3.0 | 8 min read

About the INCLUDE project

[About the guidance](#)

About the INCLUDE project

The INCLUDE Project (Innovations in Clinical Trial Design and Delivery for the Under-served) was one of a suite of large scale projects in key areas of innovation.

Key points for the teacher:

- The information on and outputs of the INCLUDE project.
- Appropriate study materials for getting quick overview of the topic.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

2.2: [scotlands-census-2022-individual-questionnaire.pdf \(scotlandscensus.gov.uk\)](https://scotlandscensus.gov.uk/scotlands-census-2022-individual-questionnaire.pdf)

Key points for the teacher:

- *Similar questionnaires are produced by individual countries; you can find your national data and adjust the lesson in here or provide students with the link.*

2.2: Pitkala KH, Strandberg TE. Clinical trials in older people. Age Ageing [online]. 2022; 51(5). [Accessed 18 Apr 2025]. Available from: <https://doi.org/10.1093/ageing/afab282>

Age and Ageing 2022; 51: 1–9
<https://doi.org/10.1093/ageing/afab282>

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COMMENTARY

Age and Ageing journal 50th anniversary commentary series

Clinical trials in older people

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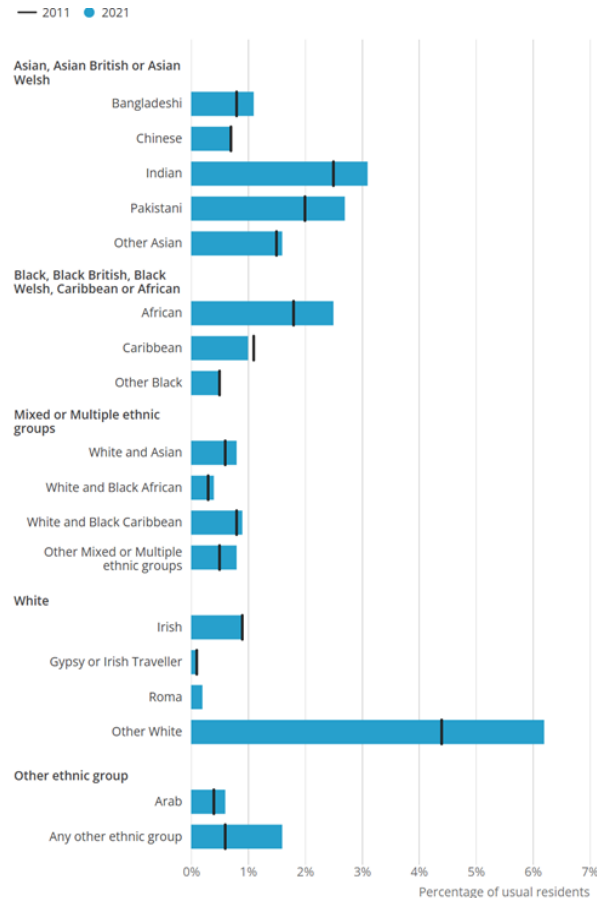
Key points for the teacher:

- *The paper discusses various aspects of clinical research in this specific group:*
 - *Older people have often been excluded from randomized clinical trials due to age, frailty, multimorbidity, disabilities; participants of the trials are generally less complex than those seen in geriatric clinics; external validity of such trials may be questioned.*
 - *Recruitment and drop-outs may be challenging (older people can become ill, tired during the trial) and require specific strategies.*
- *Table 1 lists challenges and solutions in including older people in clinical trials.*
- *Pragmatic trial designs are needed to improve care of older people.*
- *The article gives context to some terms related to “under-served groups” (pragmatic clinical trials, generalizability, external validity, etc.).*

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

2.2: Figure 1: Ethnic group data for 18 out of 19 categories collected during the 2011 and 2021 censuses of England and Wales [Source: [Office for National Statistics licensed under the Open Government Licence v.3.0](#)].



2.3: Galobardes B, Shaw M, Lawlor DA, Lynch JW, Davey Smith G. Indicators of socioeconomic position (part 1). J Epidemiol Community Health [online]. 2006; 60(1):7–12. [Accessed 18 Apr 2025]. Available from: <https://europepmc.org/article/med/16361448>

GLOSSARY

Indicators of socioeconomic position (part 1)

Bruna Galobardes, Mary Shaw, Debbie A Lawlor, John W Lynch, George Davey Smith

Key points for the teacher:

- The paper is a glossary of indicators of socioeconomic position (education, housing, income, occupation-based measures); in each indicator, the authors highlight the theoretical basis, measurement, interpretation, strengths, limitations.
- The authors stress that the interpretation of the relevance of the indicator is difficult due to strong correlation of the indicators.
- For the purpose of the curriculum, this paper provides an insight in factors that can define under-served group by social and economic factors.

Key points for the teacher:

- This image is a bar chart showing ethnic group data for 18 out of 19 categories collected during the 2011 and 2021 censuses of England and Wales.
- The bars represent the percentage of usual residents in each ethnic group, comparing data from the two census years.
 - Black lines represent the results in year 2011.
 - Blue bars represent the results in year 2021.

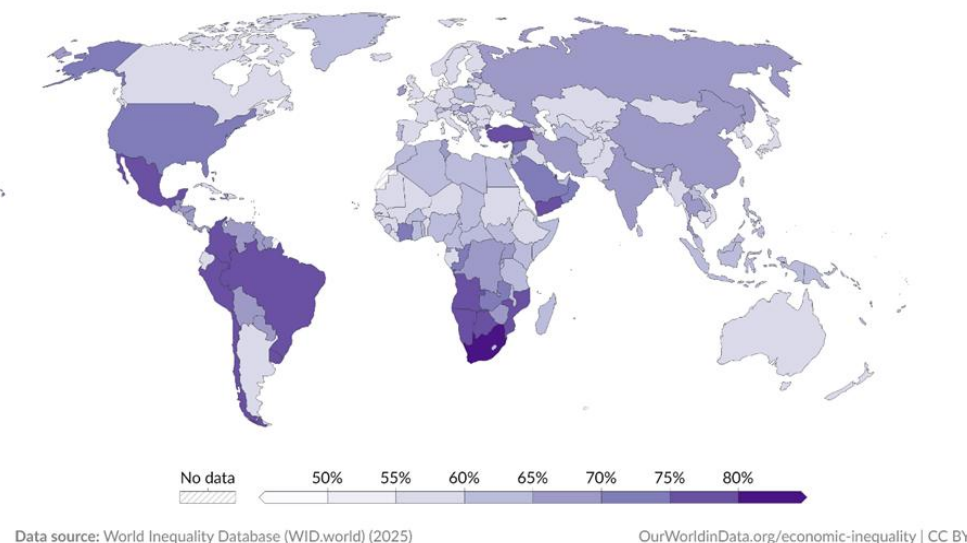
UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

2.3: Figure 1: Share of wealth owned by the richest 10% of the population, 2023, by country [source: [World Inequality Database \(WID.world\) \(2025\)](https://data.worldinequality.org/) – with major processing by Our World in Data] licenced by [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/)

Wealth share of the richest 10%, 2023

The share of wealth owned by the richest 10% of the population. Wealth is defined as the total value of non-financial and financial assets (housing, land, deposits, bonds, equities, etc.) held by households, minus their debts.



2.4: Waitt C, Astill D, Zavala E, Karron RA, Faden RR, Stratton P, Temkin SM, Clayton JA. Clinical trials and pregnancy. Commun Med [online]. 2022; 2:132. [Accessed 18 Apr 2025]. Available from: <https://doi.org/10.1038/s43856-022-00198-1>

communications medicine

VIEWPOINT

<https://doi.org/10.1038/s43856-022-00198-1> OPEN

Clinical trials and pregnancy

Key points for the teacher:

- The paper is a series of viewpoints. The gap of knowledge of drug safety in pregnancy and breastfeeding, logical concerns about performing clinical trials with such subject on the one hand and difficult decisions that must be made by clinicians in clinical practice on the other hand are stressed.
- Not conducting clinical research in pregnancy and breastfeeding is not the right way. Everybody deserves the evidence upon which to base decision about their health. Not having this evidence can result in unfairness.
- The view of the patient is impressive and students should read it. Patients should be co-designers for any type of research.

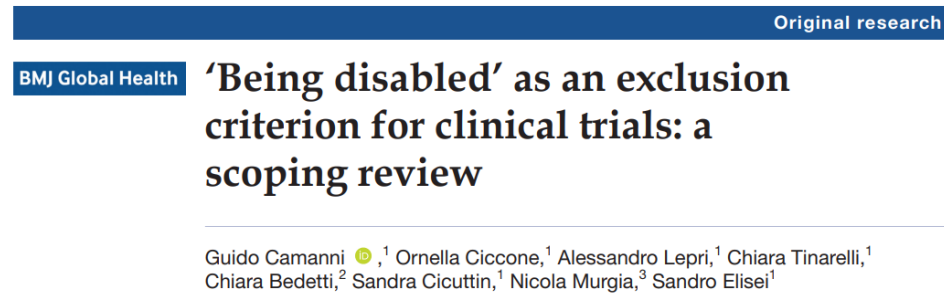
Key points for the teacher:

- This image is a world map visualisation showing the share of wealth owned by the richest 10% of the population in 2023, by country.
- Color gradient represents the percentage of total national wealth held by the richest 10% of people in each country.
 - Lighter purple indicates a lower share (around 50%).
 - Darker purple indicates a higher share (up to and above 80%).
- The map highlights **global wealth inequality**, showing how unevenly wealth is distributed across societies.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

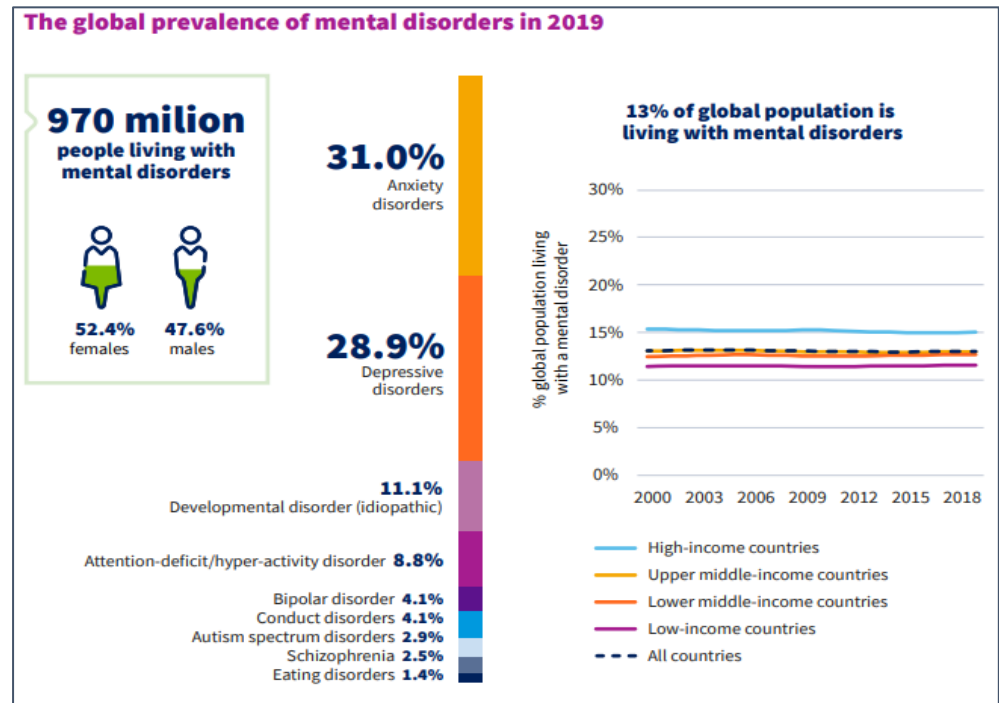
2.4: Camanni G, Ciccone O, Lepri A, Tinarelli C, Bedetti C, Cicuttin S, Murgia N, Elisei S. 'Being disabled' as an exclusion criterion for clinical trials: a scoping review. *BMJ Glob Health* [online]. 2023; 8(11): e013473. [Accessed 18 Apr 2025]. Available from: <https://doi.org/10.1136/bmjgh-2023-013473>



Key points for the teacher:

- The paper summarises the results of a study analyzing the exclusion rate of people with disabilities from biomedical research (via clinicaltrials.gov); the results confirm the significance of the problem (>35% rate of explicit exclusion).
- In Fig. 3, various disabilities as explicit exclusion criteria are listed. In Fig. 4, the rating of congruence of explicit exclusion criteria in relation to the primary aim.

2.4: Figure 1: The global prevalence of mental health disorders, 2019 [Adapted from: [WHO, 2022](https://www.who.int), licenced by [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/)]



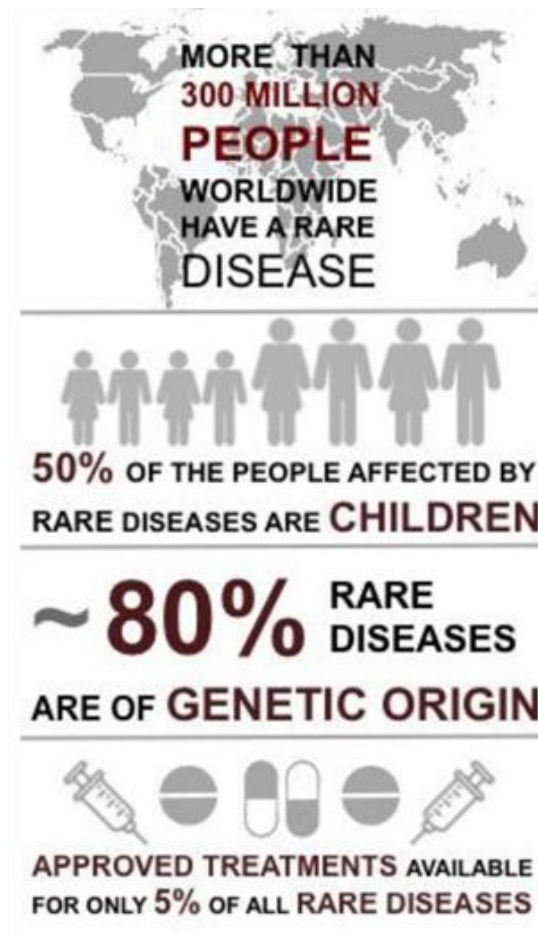
Key points for the teacher:

- The figure summarises the global prevalence of mental health disorders.
- In the green frame, you can see that slightly more than half of the 970 million people living with mental disorders are females.
- In the middle of the picture, there is the list of disorders according to their prevalence. The most frequent are anxiety disorders, followed by depressive disorders and developmental (idiopathic) disorders.
- The right part of the picture shows the percent of the global population living with mental disorders in all countries (dashed line), high-income (blue line), upper middle-income (yellow line), lower middle-income (orange line), and low-income countries (purple line) over time (x-axis defines years, y-axis defines the percent of the population). The frequency is stable. 13% of global population is living with mental disorder.

UNIT 2: WHO ARE THE UNDER-SERVED GROUPS?

Articles, pictures outlines

2.5: Figure 1: Summary of statistics on rare diseases [Adapted from: [Bhattacharjee & Nandi, 2018](#), licenced by [CC BY 4.0](#)]



Key points for the teacher:

- The image is an infographic summarising key global statistics on rare diseases.

2.5: The Lancet Global Health. The landscape for rare diseases in 2024. The Lancet Global health [online]. 2024; 12(3): e34. [Accessed 18 Apr 2025]. Available from: [https://doi.org/10.1016/S2214-109X\(24\)00056-1](https://doi.org/10.1016/S2214-109X(24)00056-1)

Editorial

The landscape for rare diseases in 2024



Key points for the teacher:

- The editorial is providing a brief but complex insight in the statistics of rare diseases and a brief discussion on the topic of the diagnostic advances and novel therapies, including their affordability; mentions other difficulties which the parents or carers of the child living with rare diseases may face too.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

General overview of the unit for the teacher

OBJECTIVES

Just as there is a broad spectrum of under-served populations, there is a broad spectrum of barriers to their inclusion in clinical trials. The classification of barriers is a pivotal aspect in understanding their implications and finding potential strategies for overcoming them. The objective of this unit is twofold: firstly, to facilitate the recognition of the barriers and, secondly, to encourage understanding of how to combat them.

UNIT CONTENT

- 3.1: Systemic barriers to inclusion
- 3.2: Structural and logistical barriers to inclusion
- 3.3: Cultural barriers to inclusion
- 3.4: Ethical barriers to inclusion
- 3.5: Impacts of barriers to inclusion
- Summary of Unit 3

LEARNING OUTCOMES

Students will be able to:

1. **Identify** and **describe** different barriers to inclusion in clinical trials and health research.
2. Recognise how these barriers **affect** under-served groups.
3. Define **key terms** within barriers to inclusion.
4. Reflect on the **impacts** of barriers to inclusion at the level of the individual, group, and wider society.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 3.1 pre-class; read the article by Routen <i>et al.</i> ; focus on key examples of systemic barriers; test your knowledge.
Tue	Complete Lesson 3.2 pre-class; read the article by Coe <i>et al.</i> ; complete reflective activity; test your knowledge.
Wed	Complete Lesson 3.3 pre-class; read the article by Bulto; complete the reflective activity; test your knowledge.
Thu	Complete Lesson 3.4 pre-class; watch the video from the NIH; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 3.5 pre-class; watch TedxKew Talk; complete the reflective activity; read the Summary of Unit 3; complete the MCQs.

OPENING THE LESSON

20' 



warm-up

 **Recap barriers** – Ask students to recap barriers from the pre-class reading. Summarise and categorise them on the board. (7–10 minutes)

Hints and solutions for the teacher:

Recap of barriers: **systemic barriers** (regulatory frameworks, fundings disparities, discriminatory practices), **structural and logistical barriers** (unclear messaging, shortage of info, time commitment, financial burden, disabilities,...), **cultural barriers** (different beliefs, practices, language, communication, historical mistrust), **ethical barriers**

 **Word association** – share a keyword from the list below and write it on the board. Ask the students to say the first word/phrase/situation that comes to their mind first in general and second in association with clinical trials. (15 minutes)

discrimination, bias, culture, mistrust, cultural competence, vulnerability

Ask students to illustrate relationships among them and among principles of inclusivity in clinical trials.

At the end, ask students which terms they would appreciate to be explained/which they do not understand to. Ask the others to explain.

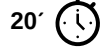
Hints and solutions for the teacher:

	In general	Associated with clinical trials
Discrimination	<i>unfair treatment based on identity (e.g., racism, sexism, gender pay gap, employment discrimination).</i>	<i>excluding groups unfairly from research, leading to biased results (e.g., age restrictions, gender bias, excluding minorities, lack of diversity, “they don’t test on people like me”)</i>
Bias	<i>a tendency to think or act in a certain way that isn’t fair or balanced (e.g., unfair judgment, “everyone has it”, favoritism, assumptions)</i>	<i>when personal opinions or unfair processes affect how participants are chosen, treated, or how results are understood (e.g., investigator unintentionally treats participants in the intervention group differently, funding influence, sponsor pressure, data manipulation)</i>
Culture	<i>shared beliefs, values, often history background and behaviors of a group (e.g., national identity, clothing, food, language, rituals)</i>	<i>influences how people understand health, illness and participation in medical research (e.g., mistrust of medical research, language barriers, taboos, culturally appropriate communication)</i>
Mistrust	<i>lack of confidence (e.g., negative experiences, doubt, fear, “they are hiding something”, corruption)</i>	<i>historical abuses (e.g., Tuskegee study), Guinea pigs, informed consent concerns, “they don’t care about people like us”, lack of community involvement</i>
Cultural Competence	<i>ability to interact respectfully across cultures (e.g., adapting behavior, listening without judgment, open-mindedness)</i>	<i>needed to communicate, recruit, and care for diverse participants (e.g., addressing mistrust reflectfully, meeting people where they are, avoiding medical jargon, building community partnership)</i>
Vulnerability	<i>being at greater risk of harm or exploitation (e.g., disabilities, pregnancy, dependence, weakness, children)</i>	<i>groups needing extra protection (e.g., elderly, low-income, pregnant, disabled, children, lack of access to care, limited health literacy)</i>

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Blended 90-minute classroom

INDEPENDENT WORK

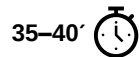


Patient consent – ask students to download the Patient Informed Consent for the EBMT registry (via the QR code generated by you). Ask students to suggest five changes to the given forms that make the form less clear, understandable, and inclusive. If students identify any barriers already present, ask them to list them and think about ways to address them.

Hints and solutions for the teacher:

- Generate a QR code to download the Patient Informed Consent form for the EBMT registry from their websites: <https://www.ebmt.org/registry/patient-informed-consent> (select your national language if available, or select the English version; prefer the version for adults).
- Start the timer (20 minutes) on the screen so the students see how much time they have.
- Advise students to use the Consent and Participant Information Guidance module produced by the Medical Research Council and Health Research Authority in the UK: <https://www.hra-decisiontools.org.uk/consent/index.html> (in the 3.4 Reflective activity)
- Circulate around the room to check on progress, clarify instructions.

WORK IN PAIRS



Speed dating model – Ask half of the students to stand up (e.g. row closer to the window, every other student). Each standing student then joins one seated student. Students then are to identify the five changes made in the other one's version (in 5 minutes). They share their findings, discussing them.

After 5 minutes, ask the students who were originally standing to join another student.

Hints and solutions for the teacher:

- Start the timer with an alarm (5 minutes). When it rings, ask students to move.
- Circulate around the room to check on progress, clarify instructions, and listen to/stimulate the discussions/ask probing questions to deepen the thoughts. (see below)
- Leave enough time for the Debriefing – a critical part of the team-based work (see below).



Debriefing of the work in pairs – ask students to summarise what changes were made to the leaflet in terms of making it less clear, understandable, and inclusive. Did they always agree with the changes of the other ones? Could these changes be seen in real life? (10–15 minutes)

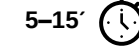
Did the students find any already present mistakes or barriers that can impact understanding from patients? (5–10 minutes)

Hints and solutions for the teacher – helping questions:

Imagine you're a 70-year-old only your national language-speaking woman with a primary school education who has worked as a housekeeper all her life. You have glasses with multiple diopeters. You are using a push-button cell phone for calling (texting is not possible because you cannot see the letters). You don't know how to use the Internet:

- Is the vocabulary understandable for you? What about fonts and sizing?
- Are all your cultural and personal backgrounds respected?
- Are risks and benefits explained honestly but simply?
- Does it tell you how to get help if you have some questions?

REFLECTION, WRAP-UP



1. What specific barriers can appear during a clinical trial (except for the informed consent obtaining)? Can an unapproachable researcher be one of them?
2. What is the relationship between barriers to inclusion and the under-served populations?
3. Why does it matter to break down barriers to inclusion in clinical trials?
4. Which part of this unit did you find most engaging or challenging?

Hints and solutions for the teacher:

- Question 1 – Yes, an unapproachable or unempathetic researcher might be a barrier. Barriers are otherwise summarised in the warm-up.
- Question 2 – Barriers cause under-representation. Removing barriers enables inclusion.
- Question 3 – Removing barriers is a moral, scientific, and social imperative. No one is then left behind.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

20'



- Fast recap can be organised as a live discussion with a shared board – Jamboard or similar apps. Students are to write their single suggestions on a sticky note here. Once the first round has been finished (one suggestion from each student), ask them to organise all the sticky.
 - First, ask to specify the categories and then set the color for each category (e.g., green for systemic barriers, yellow for structural and logistical, red for the cultural, and blue for the ethical barriers).
 - Then, ask students to change color of the sticky note live.
- “Word association” – share the spreadsheet with the table of the terms, “in general associations” and “associations in clinical trials”. Always ask 2–4 students per perspective; write their thoughts in a table.
- Time adjustment is possible.
- Preparing the Jamboard (or other environment) and the spreadsheet for the “word association” may be needed in advance.

INDEPENDENT WORK

20'



- Share the link for the Patient Information Leaflet for the EBMT registry from their websites: <https://www.ebmt.org/registry/patient-informed-consent> via chat in MS Teams/Zoom or a similar app (select your national language of the leaflet if available, or select the English version; prefer the version for adults).
- Ask students to write notes electronically so that they are able to share on screen later.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.

WORK IN PAIRS or TEAMS

35–40'



2–5 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams). To save time, modification of the work in pairs to the work in small teams might be reasonable.
- Enable the students to share their screens in breakout rooms.
- Ask students to share their screens one by one; others should look for the edits they have made.
- Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues).
- Time adjustment is possible.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room. (20 min).
- Don't forget time for debriefing: ask one or two groups to present their notes. (15–25 minutes)



Debriefing of the work in pairs or teams – live discussion (10–15 minutes)

Did the students find any already present mistakes or barriers that can impact understanding from patients? – live discussion (5–10 minutes)

REFLECTION, WRAP-UP

5–15'



- Live discussion.
- Question 1 – possible to share Jamboard from the “fast recap”

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Reflective activity 3.1: “Global barriers to cancer treatment for women” modified for synchronous use

Link: [Women, power, and cancer: a Lancet Commission](#)

Watch the [short video](#) (06:08) or read the [Executive Summary from the Lancet Commissions](#) on global barriers to cancer treatment for women. How many systemic barriers to inclusion can you identify from the video or executive summary?

MODIFICATION FOR INDIVIDUAL WORK



Watch the video or read the article. Identify as many systemic barriers to inclusion as possible. Write a short reflection (150 words), including a summary of the key barriers you identified and a justification of why you consider these barriers significant. Submit your response to a cloud/discussion board. Once you have submitted your response, review the responses of at least two peers and write short feedback considering the following questions: What did you find most interesting or insightful? Do you agree with their points? Why or why not? Provide constructive and respectful feedback.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Watch the video in class. Encourage students to take notes on the systemic barriers to inclusion. Divide students into teams. Each student shares the barriers they identified. In groups, discuss: Which barriers seem most significant and why? Do your perspectives differ? Can you agree on the one most critical barrier?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their key barrier with reasoning.

Hints and solutions for the teacher:

- Let students write key barriers on the board with short notes.



You can conclude this activity with a class discussion: How could these barriers be reduced? Suggest one concrete solution.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin the discussion by revising what systemic barriers are. Ask students to define them based on what they have learnt in Lesson 3.1 and provide some examples.

Watch the video together. Encourage students to take notes on the systemic barriers to inclusion. Write any barrier they noticed on the board. Ask students to vote on which barrier they consider the most significant in the context of cancer treatment for women. Discuss the most significant barrier:

- Why do you think this barrier is the most important?
- How does this barrier impact cancer treatment, especially for women?
- How this barrier could be reduced?

Hints and solutions for the teacher:

- Systemic barriers refer to ingrained policies and practices within wider health systems and health research that perpetuate inequalities. Some key examples: regulatory frameworks, funding disparities, discriminatory practices.
- Instead of watching videos in class, use the barriers identified by students in the individual work. Write these on the board.
- Votes: You can do this by raising hands, using interactive online polls, or writing on the board.
- Facilitate a solution-focused discussion with the following questions:
 - What policy changes are needed?
 - How can funding be allocated more equitably?
 - What can be done to reduce inequity in clinical trials?
- In addition to the systemic barriers, you can broaden the discussion covering any barriers to inclusion that students learnt about in Unit 3 (i.e., structural and logistical, cultural, ethical).



UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Reflective activity 3.2: “How to include under-served groups” modified for synchronous use

Link: [University of Oxford, Medical Science Division](#)

View the [guidance](#) provided by the University of Oxford on how to include under-served groups for each of the barriers identified by the NIHR-INCLUDE project. What suggestions are given for the barriers to inclusion discussed in this guidance?

MODIFICATION FOR INDIVIDUAL WORK



View the guidance. Identify and note down which barriers to inclusion are addressed in the guidance. Select two of them. Write a reflection (150 words) answering the following questions:

1. What suggestions does the guidance give to overcome the barriers to inclusion?
2. Do you consider them effective in real-world scenarios, and why/why not?
3. Can you think of any additional strategy that might help overcome these barriers?

Submit your response to a cloud/discussion board.

Hints and solutions for the teacher: Results may serve later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



4–8 students per team

The guidance includes 12 barriers. Divide students into teams and give 2–3 barriers to each group. Ask students to read the suggestions proposed to overcome the barriers. In group, discuss:

1. Which suggestions do you think are the most effective, and why?
2. What challenges do you see in implementing some of these suggestions?
3. Can you think of any additional solutions for a specific barrier?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



At the beginning, briefly discuss what **structural and logistical barriers** are and why addressing them is important in health research. Write the barriers on the board.

Ask students to read the barriers in the guidance. Then, have them vote to select the three barriers they consider the hardest to overcome. Write them on the board. Go through the selected barriers one by one. Read together the proposed solution and then discuss:

1. Were there any solutions that surprised you?
2. Do you consider them effective in real-world scenarios? Why or why not?
3. Can you think of any additional strategy that might help overcome this barrier?

Hints and solutions for the teacher:

- *Print several copies of the guidance or ensure all students can access it.*
- *Votes: You can do this by raising hands, using interactive online polls, or using sticky notes on the board.*
- *Facilitate the discussion with additional questions:*
 - *Question 2: What challenges do you see in implementing some of these suggestions?*
 - *Guide students to connect suggestions to real-world examples (specific trials, specific under-served groups).*



UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Reflective activity 3.3: “Cultural competence quiz” modified for synchronous use

Link: [Cultural competence quiz](#)

Take the cultural competence quiz from the London School of English to self-assess your cultural awareness. The quiz has two parts: 1) Cultural knowledge and 2) Cross-cultural communication skills. How many of the 20 questions did you answer correctly?

MODIFICATION FOR INDIVIDUAL WORK



Take the Cultural Competence Quiz. It takes around 10 minutes. How many of the 20 questions did you answer correctly? Take note of your score. After completing the quiz, reflect on the following questions:

1. Which areas (cultural knowledge or communication skills) did you find most challenging, and why?
2. Did any of the questions or answers surprise you? What does this tell you about your current understanding of cultural differences?
3. Think of one example where a lack of cultural awareness could affect inclusion in health research.

Submit your response to a cloud/discussion board.

Hints and solutions for the teacher: Make a note of students' scores and the areas they found most challenging. This may serve later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Print the Cultural Competence Quiz without the correct answers for the students (! the online version includes them).

First, ask students to complete the Quiz individually. They should take note of their score. Afterwards, divide the students into groups. Ask them to complete the Quiz as a group and note their score.

Once the quiz is completed, students should discuss:

1. Did you find it easier to answer the quiz questions individually or as a group? Why? You can share your scores.
2. Which areas (cultural knowledge or communication skills) did you find most challenging, and why?
3. Think of one example where a lack of cultural awareness could affect inclusion in health research.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their findings.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



As a class, go through the Cultural Competence Quiz together and discuss possible answers before revealing the correct ones. Ask students to focus on the content. How many of the 20 questions did you answer correctly? Then, continue the discussion with the following:

1. Which areas (cultural knowledge or communication skills) did you find most challenging, and why?
2. What can you do to improve your cultural competence, and why do you think it's important?
3. Think of examples where a lack of cultural awareness could affect inclusion in health research.

Hints and solutions for the teacher:

- Clarify that the focus is on reflection, not just on the quiz score.
- Write key insights on the board to visualise the discussion.
- Question 3: Think about examples from personal experiences or current events where cultural barriers might have caused challenges in communication or access to healthcare.
- Keep the discussion engaging by asking students with different opinions to share.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Reflective activity 3.4: “Informed consent” modified for synchronous use

Link: [Consent and Participant Information Guidance](#)

Explore the *Consent and Participant Information Guidance* module produced by the Medical Research Council and Health Research Authority in the UK. As you are reading, consider how the processes of informed consent and suggested materials differ for each group presented. These aspects of design will be discussed later in the course.

MODIFICATION FOR INDIVIDUAL WORK



Explore the Consent and Participant Information Guidance module. As you are reading, consider how the processes of informed consent and suggested materials differ for each group presented. Write a short reflection (150 words) on the following:

1. What adaptations are suggested for different participant groups?
2. Why might standard consent procedures act as a barrier to inclusion in health research?

Submit your response to a cloud/discussion board.

Hints and solutions for the teacher:

Anonymously quote 2–3 insightful responses and use them to kick off a group discussion (e.g., One student noted this about children’s consent – Is this adaptation or recommendation surprising to you?). Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Explore the Consent and Participant Information Guidance module. Divide students into four groups and assign each group one category: Adults Lacking Capacity, Children and Young People, Emergency, Deceased.

Ask each group to:

1. Explore the recommendations for their assigned category, including national differences (by selecting different UK nations on the map).
2. Identify specific adaptations recommended for their group.

Start the timer. Circulate among teams, listen to and stimulate the discussions.

At the end, create an “Inclusion Tip List” together: Groups should write their key tips on the board in separate columns (one for each category). Facilitate a discussion on the overlaps:



- What common themes or barriers appear across groups?
- Are there any surprising differences?

Hints and solutions for the teacher:

- Ensure all students have online access to the module during class.
- Ask students to read the *General Principles* section at home in advance to support smoother discussion.
- As students work in a larger group, they can divide the individual UK nations among themselves and compare results later. This will speed up group work.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to explore the Consent and Participant Information Guidance module before class. Start the session with a brief recap of what the Guidance covers. Then, lead the discussion based on the following questions:

1. What were some key adaptations proposed for specific participant groups (e.g. children, people in emergency situations)?
2. What do all groups seem to need in terms of communication and information?
3. Where do you see the biggest ethical challenge when working with these different populations?

Hints and solutions for the teacher:

- Question 1: In case of limited time, select one specific participant group.
- Follow-up questions to stimulate discussion:
 - Question 1: Were any of these adaptations surprising or new to you? Why do you think they are necessary?
 - Question 2: How could researchers ensure that these shared needs are met in practice?
 - Question 3: Can you think of a real-life situation?

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Reflective activity 3.5: “How Artificial Intelligence (AI) is being used to accelerate clinical trials” modified for synchronous use

Link: <https://doi.org/10.1016/j.jacadv.2025.101593>

Read the article about the potential impacts of Artificial Intelligence (AI) on clinical trials. From Table 1 in the article, which potential changes introduced by AI could make clinical trials more inclusive?

MODIFICATION FOR INDIVIDUAL WORK



Read the article with a focus on Table 1. Write a short reflection (100–150 words) on the following questions: What specific ways could AI make clinical trials more inclusive? Do you see any risks or limitations in using AI for this purpose? Explain.

Submit your response to a cloud/discussion board.

Hints and solutions for the teacher: Results may serve later for the group discussion in class. Consider anonymising the answers.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Ask students to read the article and reflect on what specific ways AI could make clinical trials more inclusive. Ask them to write down a few key points.

Divide students into small groups. Ask each group to discuss the key points from the article. Encourage them to think about the examples of AI technologies. Let them discuss the potential risks or challenges of using AI for this purpose.

Start the timer. Circulate among teams, listen to and stimulate the discussions.

At the end, ask two groups to present key points and examples from their conversation. Afterwards, engage the whole class to add any points that have not been mentioned yet.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin the class by asking students to share their thoughts on the overall potential of AI to support greater diversity and participation in clinical trials. Write key points on the board. Then, ask students to read the article and take notes on the specific ways these technologies are being applied in clinical trials. After reading, ask them: What specific ways could AI make clinical trials more inclusive? Compare their notes with the thoughts written on the board at the beginning of the class.

Continue the discussion with the following questions:

1. Do you see any risks or limitations in using AI for this purpose?
2. In your opinion, which under-served group could benefit most from these AI-based solutions, and why?

Hints and solutions for the teacher:

- Ensure all students have online access to the article or print several copies for the class.
- Keep the discussion focused on real-world applications and challenges.
- Question 1: Use the ethical concerns question to delve deeper into the impact of technology in healthcare.
- Conclude with a final thought:
 How can we strike the right balance between innovation and ethical responsibility when using AI in clinical trials?

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Multiple-choice questions and solutions

1. What are systemic barriers often the result of?
- A) The roles and responsibilities of trial funders
 - B) Long-standing historical biases and institutional behaviours**
 - C) Failing to consider the many dimensions of representation in trials research
 - D) Limited public health initiatives

*Answer: B; Systemic barriers refer to ingrained policies and practices within wider health systems and health research that perpetuate inequalities; these barriers are often the result of **long-standing historical biases and institutional behaviours**.*

2. Which of these is not typically a financial barrier to taking part in a clinical trial?
- A) Travel costs to the trial site
 - B) Childcare or other caregiving responsibilities
 - C) Unapproachable researchers**
 - D) Lost income from paid work

*Answer: C; While unapproachable researchers can deter potential volunteers, **financial burdens include examples such as travel costs (including parking), potential of lost income from paid work, and the cost of childcare or other caring responsibilities.***

3. [Blank] in clinical research refers to the consideration of legacies that exist as a result of social, political, and historical contexts and how these can best be considered in future practices.
- A) Cultural safety**
 - B) Cultural competence
 - C) Cultural awareness
 - D) Cultural sensitivity

*Answer: A; **Cultural safety** in clinical trials refers to the consideration of legacies that exist as a result of social, political, and historical contexts and how these can best be considered in future practices. Cultural safety is determined from the individual and/or community's perspective and requires practitioners and research to be self-reflective and ongoing.*

4. Which of these is not a key ethical principle of the Belmont Report?
- A) Respect for persons
 - B) Beneficence
 - C) Vulnerability**
 - D) Justice

Answer: C; The three core principles of the Belmont Report are 1. Respect for Persons, 2. Beneficence, and 3. Justice. These principles are intended to guide ethical conduct in research and can inform trial processes.

5. External validity is the degree to which the results of a study hold true in non-study situations. It may also be referred to as:
- A) whether a study or test is appropriate for the question
 - B) deeply rooted scepticism and doubt in wider institutions as a result of past trauma and unethical practices
 - C) the generalisability of study results to non-study populations**
 - D) negative actions or lack of consideration directed towards an individual or group based on preconceived notions about their identity

Answer: C; External validity is the degree to which the results of a study hold true in non-study situations, for example, in routine NHS practice. It may also be referred to as the generalisability of study results to non-study populations. For example, the external validity of a study that took place in Spain may be questioned if the results were to be applied to people in Australia.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Recap multiple-choice questions and solutions

1. Funding for clinical trials is complex. Which of these is not a factor that typically influences trial funding?
- A) Funding agency priorities
 - B) Geographic scale and scope
 - C) Public perception of the trial**
 - D) Expected return on investment

*Answer: C; While studies of **public perception** show a preference for inclusive trials research, this typically **does not impact the allocation of funds for a trial**.*

2. [Blank] can be defined as negative actions or lack of consideration directed towards an individual or group based on preconceived notions about their identity.
- A) Discrimination**
 - B) Beneficence
 - C) Vulnerability
 - D) Generalisability

Answer: A; Discrimination can be defined as negative actions or lack of consideration directed towards an individual or group based on preconceived notions about their identity. The history of clinical trials is rooted in discriminatory practices that persist today through bias in trial design and practice, a lack of cultural understanding, and limited public health initiatives (among others).

3. In a 2022 report on global inclusive research, what percentage of academics stated diversity and inclusion was of high importance in research design?
- A) 17%
 - B) 38%**
 - C) 50%
 - D) 85%

Answer: B; 38% of academics stated diversity and inclusion of high importance in research design. However, just 17% of those academics indicated diversity and inclusion as a main goal of their research.

4. Which of these is not a lasting impact from barriers to inclusion within clinical trials?
- A) Compromised generalisability of trial findings
 - B) High financial and social costs to wider society
 - C) Impeding the discovery of more effective treatments or interventions
 - D) Dominance of some global regions in registering clinical trials**

Answer: D; Impacts of barriers to inclusion are widespread and may disproportionately affect under-served groups; this can include compromised generalisability of trial findings, high financial and social costs that further health inequalities, and impeding the discovering of more effective treatments or interventions through a lack of diverse participation.

5. The 1979 Belmont Report was written primarily in response to what event?
- A) Tuskegee Syphilis Study**
 - B) Declaration of Helsinki
 - C) Cincinnati Radiation Experiments
 - D) MRC trial of streptomycin for the treatment of tuberculosis

Answer: A; The Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the United States, is a key ethical text often referenced alongside the Nuremberg Code and the Declaration of Helsinki. Published in 1979 in response to the Tuskegee Syphilis Study, it outlines key ethical principles and guidelines for conducting research involving human subjects.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

True/False questions and solutions

1. Regulatory frameworks at both the national and local levels can shape how clinical trials are designed and conducted.

*Answer: **True**; if governments and other regulatory bodies do not prioritise inclusion within trials research, it can lead to systemic under-representation.*

2. Physical disabilities may prevent or discourage some participants from attending aspects of a clinical trial that require in-person attendance.

*Answer: **True**; physical disabilities were found to prevent or discourage some participants from attending aspects of a clinical trial that require in-person attendance (particularly, where this involves public transportation).*

3. Willingness to participate in clinical trials can be shaped by differing cultural beliefs around health, illness, and medical interventions.

*Answer: **True**; within a culture, individuals and groups may make health decisions not solely based on medical information, but also their own bodily experience of illness and how this relates to cultural norms and practices.*

4. Informed consent is way for participants to give their rights over to the research study before a clinical trial begins.

*Answer: **False**; Potential participants are protecting their rights through the informed consent process. Researchers must provide potential participants with essential information about the trial before it begins, allowing them to make an educated decision about participation.*

5. Variable therapeutic responses can result in the delivery of health care that is not always evidence-based.

*Answer: **True**; when trials are not inclusive the generalisability of the findings are compromised, including how different interventions work on different groups of people.*

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.1: Routen A, Bodicoat D, Willis A, Treweek S, Paget S, Khunti K. Tackling the lack of diversity in health research. Br J Gen Pract [online]. 2022; 72(722): 444–447. [Accessed 12 May 2025]. Available from: <https://doi.org/10.3399/bjgp22X720665>

Analysis

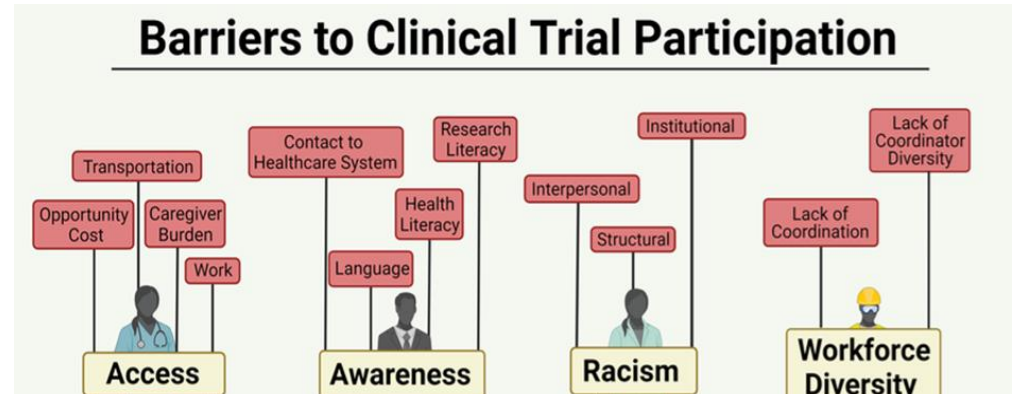
Tackling the lack of diversity in health research

Ash Routen, Danielle Bodicoat, Andrew Willis, Shaun Treweek, Sandra Paget and Kamlesh Khunti
British Journal of General Practice 2022; 72 (722): 444-447. DOI: <https://doi.org/10.3399/bjgp22X720665>

Key points for the teacher:

- The article discusses the persistent lack of diversity in clinical research, emphasising that ethnic minorities, older adults, women, and other underrepresented groups are often excluded, despite their higher healthcare needs. Systemic barriers, such as historical mistrust, restrictive eligibility criteria, language difficulties, and socioeconomic challenges, contribute to this issue.
- The authors describe that homogeneous study populations reduce the generalisability of research findings, leading to inequitable healthcare outcomes. To address this, the article calls for inclusive recruitment strategies, such as community engagement, cultural competency training for researchers, and policy changes.
- Box 1 offers good-practice guidance for increasing participation of ethnic minority populations in health research.
- The article also highlights the differences in diversity policies between the US and UK, noting that the US mandates the inclusion of women and minorities in federally funded research, while UK lacks such explicit requirements.

3.1: Figure 1: Barriers to inclusion in clinical trials can be complex and overlapping [Adapted from [Reopell et al., 2023](#) licenced by [CC BY 4.0](#)]



Key points for the teacher:

- This image illustrates the barriers to clinical trial participation, categorised into four main groups, each with specific contributing factors:
 - **Access** – Challenges like transportation, opportunity cost, caregiver burden, and work obligations.
 - **Awareness** – Limited contact with the healthcare system, language barriers, low health or research literacy.
 - **Racism** – Institutional, interpersonal, and structural forms of discrimination that affect trust and inclusion.
 - **Workforce Diversity** – Lack of diversity among coordinators and poor coordination within research teams.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.2: Coe D, Bigirimurame T, Burgess M, Rouse J, Wroe C. Enablers and barriers to engaging under-served groups in research: Survey of the United Kingdom research professional's views. NIHR Open Res [online]. 2023; 3(37). [Accessed 12 May 2025]. Available from: <https://doi.org/10.3310/nihropenres.13434.1>

RESEARCH ARTICLE

REVISED Enablers and barriers to engaging under-served groups in research: Survey of the United Kingdom research professional's views

[version 2; peer review: 2 approved]

Dorothy Coe ¹, Theophile Bigirimurame ², Meera Burgess³, John Rouse ⁴, Caroline Wroe ¹

Key points for the teacher:

- The article presents findings from a survey of UK research professionals, identifying key barriers and enablers to improving representation in studies.
- Figure 2 shows the ranking of 10 factors based on their influence on being under-served in research.
- The most significant barriers identified were: language and literacy barriers, lack of funding, socio-economic status, organisational processes or time constraints.
- The most efficient enablers identified were: community outreach (e.g. moving research outside hospitals into local communities) and using inclusive communication strategies.
- This study highlights the necessity of systemic changes, such as increased funding, simplified ethical review processes, and strategic outreach efforts, to enhance the inclusion of under-served populations in research.

3.2: Figure 1: Understanding barriers to clinical trial participation [Source: [Lopez-Duran, Ripple Science, 2023](https://doi.org/10.3310/nihropenres.13434.1)]



Key points for the teacher:

- The image illustrates the obstacles that prevent diverse individuals from enrolling in clinical research.
- On the left side, a large and diverse group of people is depicted, representing the general population.
- As they move forward, they meet barriers, shown as black and yellow striped roadblocks, which symbolize challenges in accessing clinical trials.
- The barriers are labeled as:
 - Mistrust
 - Lack of Information
 - Time & Resource Restraints
 - Trial Design Barriers
- A dotted path shows the movement of individuals through these barriers with some making it past the barriers, while others are left behind.
- On the right side, only a few individuals successfully reach an open door labeled "Join our Clinical Trial", symbolising successful trial enrollment.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.3: Okello ES, Peck RN, Issarow B, Kisigo G, Abel K, Malibwa D, Kabakama S, Charles M, Lee M, Rutachunzibwa T, Fitzgerald D, Ayieko P, Grosskurth H, Metsch LR, Kapiga S. "Ashamed of being seen in an HIV clinic": a qualitative analysis of barriers to engaging in HIV care from the perspectives of patients and healthcare workers in the Daraja clinical trial. BMC Public Health [online]. 2025; 25(69). [Accessed 12 May 2025]. Available from: <https://doi.org/10.1186/s12889-024-21231-z>

"Ashamed of being seen in an HIV clinic": a qualitative analysis of barriers to engaging in HIV care from the perspectives of patients and healthcare workers in the *Daraja* clinical trial

Elialilia S. Okello^{1*}, Robert N. Peck^{1,4,6}, Benson Issarow¹, Godfrey Kisigo^{1,2}, Kelvin Abel¹, Donati Malibwa¹, Severin Kabakama¹, Marco Charles¹, Myung Lee⁴, Thomas Rutachunzibwa³, Daniel Fitzgerald⁴, Philip Ayieko^{1,2}, Heiner Grosskurth^{1,2}, Lisa R. Metsch⁵ and Saidi Kapiga^{1,2}

Key points for the teacher:

- This article presents a qualitative analysis of the barriers to engaging in HIV care as perceived by young people living with HIV and healthcare workers participating in the Daraja clinical trial in Kenya.
- The analysis was based on in-depth interviews with 40 patients and 20 health care workers to get better understanding of the barriers to HIV care.
- The most common barriers were:
 - Fear of stigmatisation and shame – some patients avoided care to hide their HIV status from family or peers
 - Structural barriers – long travel distances, high costs of transport, low income
 - Negative healthcare experience – some patients felt disrespected by clinic staff.
 - Lack of social support – some participants reported being abandoned or discriminated by their spouses or family members after their HIV diagnosis
 - Absence of symptoms – participants with no symptoms stated, that this was the cause they did not start antiretroviral therapy

3.3: Bulto LN. Voices unheard: Bridging language gaps, ensuring equity and inclusion of non-native speakers in health research and clinical trials. Nurs Open [online]. 2024; 11(9). [Accessed 12 May 2025]. Available from: <https://doi.org/10.1002/nop2.70048>

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Voices unheard: Bridging language gaps, ensuring equity and inclusion of non-native speakers in health research and clinical trials

Lemma N. Bulto 

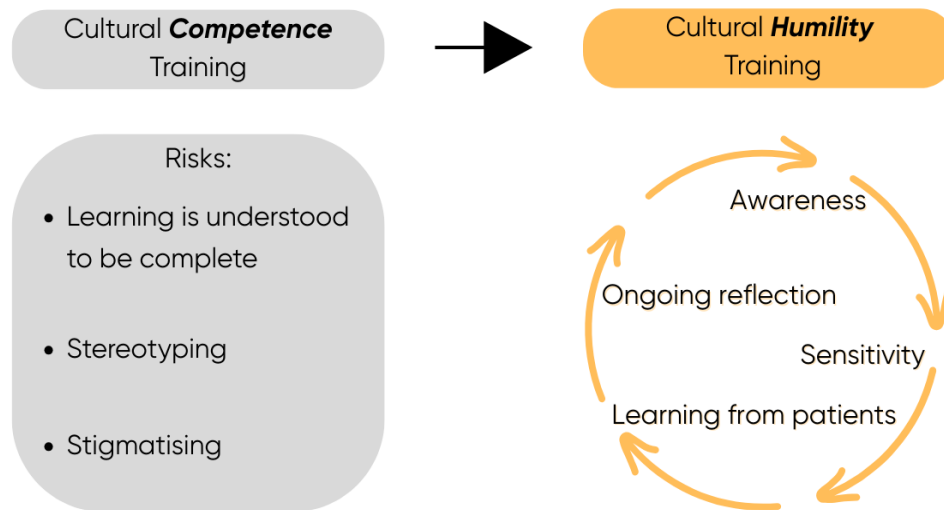
Key points for the teacher:

- Language-based exclusion in health services and clinical research remains a significant issue, despite the growing emphasis on diversity and inclusion.
- Nearly 19% of U.S.-based international clinical trials exclude participants who are not fluent in English, while only 2.7% offer translated materials.
- This exclusion worsens health disparities, particularly for immigrant and minority groups who are often non-native speakers.
- It also raises ethical concerns, as it violates the principles of justice and equity in research.
- To address this issue, research studies and health programs should provide translated materials, use language support services, and involve multilingual staff. Engaging with immigrant communities and underrepresented populations is also essential. Researchers should receive training in cultural competence and design studies with inclusivity in mind.

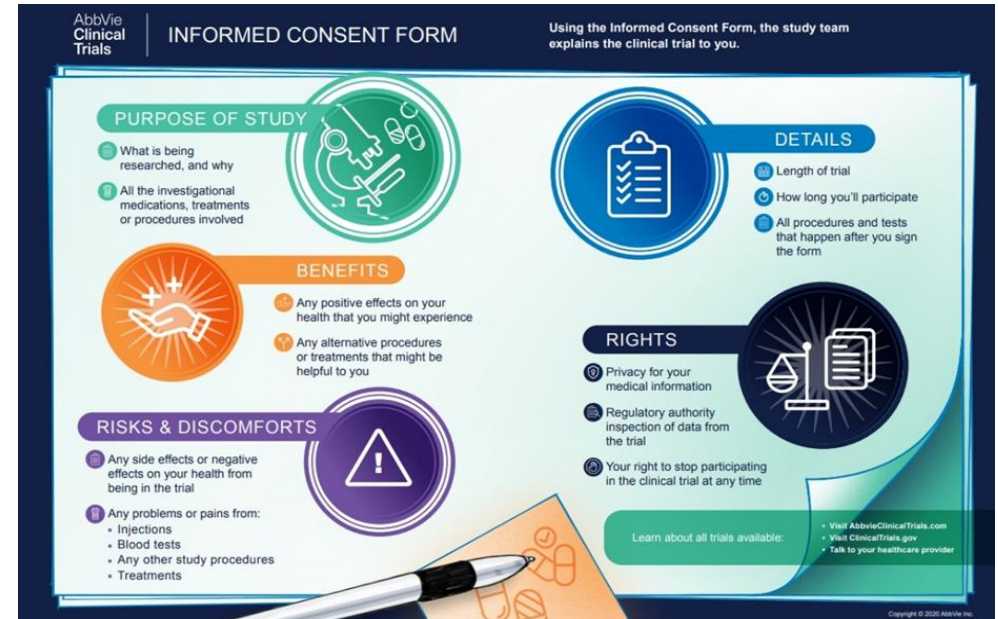
UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.3: Figure 1: Culturally responsive approaches exist on a continuum [Source: [BC Society of Transition Houses, 2022](#)]



3.4: Figure 1: Informed consent in a clinical trial [Source: [Abbvie, 2025](#)]



Key points for the teacher:

- The image illustrates a conceptual shift from Cultural Competence Training to Cultural Humility Training in healthcare or professional education, highlighting their differences in approach and associated risks or benefits.
- On the left side the risks of cultural competence are shown: learning is understood to be complete, it encourages stereotyping and may lead to stigmatising.
- On the right side, cultural humility is presented as a continuous cycle of awareness, sensitivity, learning from patients and ongoing reflection.
- Cultural humility emphasizes continuous, patient-centered reflection, unlike the static nature of cultural competence.

Key points for the teacher:

- This infographic explains the main components of the informed consent form used in clinical trials, helping participants understand what to expect before agreeing to join a study. It is divided into five key sections:
 - **Purpose of Study (Green):** What is being researched and why, including treatments or procedures involved.
 - **Benefits (Orange):** Possible health benefits and alternative options.
 - **Risks & Discomforts (Purple):** Potential side effects or discomfort from procedures like injections or blood tests.
 - **Details (Blue):** Trial duration, time commitment, and procedures after signing the form.
 - **Rights (Black):** Privacy of medical data, regulatory oversight, and the right to withdraw at any time.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.4: Kuthning M, Hundt F. Aspects of vulnerable patients and informed consent in clinical trials. Ger Med Sci [online]. 2013; 11. [Accessed 12 May 2025]. Available from: <https://doi.org/10.3205/000171>

Aspects of vulnerable patients and informed consent in clinical trials

Aspekte schutzbedürftiger Patienten sowie der Einwilligung nach Aufklärung in klinischen Prüfungen

Key points for the teacher:

- The article discusses the ethical and legal challenges of obtaining informed consent from vulnerable patients such as minors, illiterate individuals, and those with limited capacity to consent.
- Informed Consent is crucial and must be voluntary, clear, understandable, and documented, protecting patient autonomy.
- For minors, permission should be obtained from parents or legal guardians, and whenever possible, the child's agreement (assent) should also be sought.
- Illiteracy requires alternative communication methods like audiovisual aids or witnesses to ensure understanding.
- Good communication, simple language, time for questions, and multimedia tools improve patient understanding and protect their rights.
- Historical ethical codes (Hippocratic Oath, Nuremberg Code, Declaration of Helsinki) are described in the article too.

3.5: Kennedy-Martin, T, Curtis S, Faries D, Robinson S, Johnston J. A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. Trials [online]. 2015; 16(495): 1–14. [Accessed 12 May 2025]. Available from: <https://doi.org/10.1186/s13063-015-1023-4>

Review | [Open access](#) | Published: 03 November 2015

A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results

[Tessa Kennedy-Martin](#) , [Sarah Curtis](#), [Douglas Faries](#), [Susan Robinson](#) & [Joseph Johnston](#)

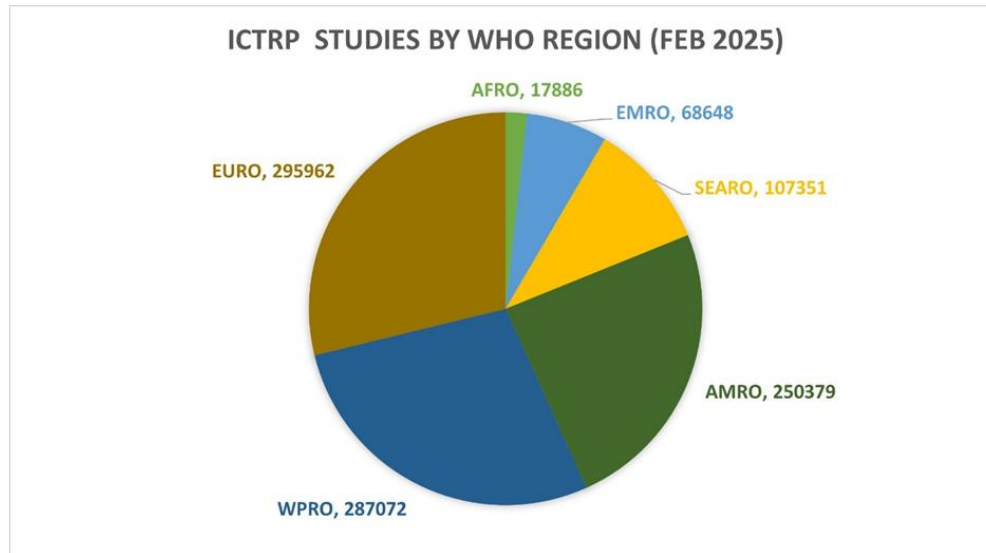
Key points for the teacher:

- This review explores how randomised controlled trials (RCTs) often include highly selective patient groups that do not reflect the broader real-world population, thus limiting the generalisability of the trial results.
- Strict inclusion/exclusion criteria lead to exclusion of older adults, women, and patients with co-morbidities.
- Tables 2 and 3 summarise the key differences between real-world vs RCT patients in each analysed study.
- In 71% of the reviewed studies, authors concluded that RCT results were not representative of real-world patients.

UNIT 3: UNDERSTANDING BARRIERS TO INCLUSION

Articles, pictures outlines

3.5: Figure 1: Total number of clinical trials registered with WHO by region (EURO: European region; AFRO: African region; EMRO: Eastern Mediterranean region; SEARO: South-East Asia region; AMRO: region of the Americas; WPRO: Western Pacific region [Source: [WHO, 2025](#), licenced by [CC BY-NC-SA 3.0 IGO](#)].



Key points for the teacher:

- This image is a pie chart showing the total number of clinical trials registered with the WHO International Clinical Trials Registry Platform (ICTRP), broken down by WHO regions.
- Number of studies by region:
- The chart visually emphasises the global imbalance in clinical research activity, with high concentrations in high-income regions.
 - EURO (European Region): 295,962
 - WPRO (Western Pacific Region): 287,072
 - AMRO (Region of the Americas): 250,379
 - SEARO (South-East Asia Region): 107,351
 - EMRO (Eastern Mediterranean Region): 68,648
 - AFRO (African Region): 17,886

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

General overview of the unit for the teacher

OBJECTIVES

The aim of the unit is to illustrate the topic of inclusivity of clinical trials, or the frequent discrepancy between the needs of clinical practice and the conduct of clinical trials, using the example of pregnant women, peripartum care (care around childbirth) and maternal mortality. The unit summarises the findings from previous units and elaborates on them with real-life examples. Although maternal mortality is mainly a problem in low- and lower-middle-income countries, this example best illustrates the topic. The synchronous session then focuses on defining the problems in high-income countries as well.

UNIT CONTENT

- 4.1: Maternal mortality: A global issue
 - 4.2: Global barriers to clinical trials in maternal health
 - 4.3: Ethical challenges in maternal health trials
 - 4.4: Clinical trial strategies to improve maternal health outcomes
 - 4.5: Translating maternal health trials into global practice
- Summary of Unit 4

LEARNING OUTCOMES

Students will be able to:

1. Identify and define **key terms** related to maternal health as relevant to clinical trials research.
2. Give **examples** of global barriers and ethical challenges in conducting maternal health trials.
3. Recognise **the role of clinical trials** in improving maternal health outcomes.
4. Reflect on how maternal health **trials** are used in global practice **to reduce** maternal mortality.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 4.1 pre-class; check your local progress of maternal mortality in the Reflective activity; test your knowledge.
Tue	Complete Lesson 4.2 pre-class; complete one selected row of the reflective activity; test your knowledge.
Wed	Complete Lesson 4.3 pre-class; watch the video on Frances Kelsey and thalidomide licensing; test your knowledge; complete the reflective activity.
Thu	Complete Lesson 4.4 pre-class; complete the reflective activity.
Fri	Complete Lesson 4.5 pre-class; read the abstract and methodology part of the Jokhio's <i>et al.</i> publication in the NEJM; test your knowledge; read the Summary of Unit 4; complete the MCQs.

OPENING THE LESSON

20' 



 **Quick write** – ask students to write what comes to mind in 5 minutes when they hear “Trials and maternal mortality”.

Hints and solutions for the teacher:

- Before starting the lesson, open the topic of the “inclusive language” and agree on the terminology acceptable to the students (pregnant women/pregnant individuals, pregnant people).
- Start the timer (5 minutes) on the screen so the students see how much time they have.



Debriefing, setting scene for the next activity (5–8 minutes)

Hints and solutions for the teacher:

- Summarise the responses on the board – students add their suggestions one by one while they have some.
- The following responses might appear: maternal mortality ratio, maternal health, maternal death, adaptive trials, pragmatic trials, action & access, protection, respect, under-served groups, midwives, drug stability, exclusion criteria, etc.
- Once all responses have been written on the board, ask the students which ones they would appreciate having explained to them/which ones they don't understand



Building on the previous discussion – ask **further questions to link the global and local perspectives.** (7–10 minutes)

1. For which countries are these topics most important?
2. Are these issues applicable to your country? Has the situation changed over time?
3. What are the main barriers to maternal health globally?
4. What are the main barriers to maternal health in your country?

Hints and solutions for the teacher:

- Questions 1 and 2 reflect the general overview given in Lesson 4.1, Figure 4.1. (countries with the highest maternal mortality ratio). Reflective activity 4.1 focuses on local development over time in the maternal mortality.
- Question 1 – solution: Maternal mortality ratio is the highest in low- and lower-middle-income countries. As shown in Figure 4.1, Central Africa is the most risky.
- Question 2 – hint: Are you teaching international students? This is perfect, because the differences and comparisons will be very natural. Are students in your class from one or max. two countries, focus on this/these two countries only.
- Question 3 – solution: The global barriers can be defined as “an action” and “an access” (see the video of Dr. Jones in Lesson 4.2 for more details).
- Question 4 – hint: Examples of the current barriers in the Czech Republic: Discontinuity in midwifery care, lack of respect, lack of autonomy, routine interventions without individual indication or informed consent, lack of systemic capture of women with postpartum depression, fragmented postpartum care, language barrier, different regional availability of care.
- Some barriers from the Czech Republic might be applicable to your local condition too. Otherwise, check local press or ask AI for help in advance.
- If students don't have any suggestions for barriers because the topic is faraway for them or they don't have a grasp of the local situation, use the local press or AI together.
- List the barriers on the board as the basis for the next activity.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Blended 90-minute classroom

TEAM-BASED WORK



5–8 students per team

The task is to design a clinical trial that could solve a selected barrier.



Task 1: Select together the topic No. 1 (5–10 minutes)

- Ask students to make teams (5–8 students per team).
- Distribute the voting sheet – a sheet where the students write the numbers of the topics discussed previously.
- Each team has 5 points which they can divide among the topics (e.g., give all 5 points to one topic, give 1 point to five favourite topics, give 2 points to one topic and 3 points to another, etc.).
- Ask the teams how many points they gave to each topic.
- Ask students whether they are ok with the selected topic No. 1 (with the highest score). If not, repeat voting with only 3 topics.



Task 2: Design a clinical trial to overcome the barrier No. 1 (25 minutes)

Each team has to design its own clinical trial – define the aim, hypothesis, intervention, choose a design, propose primary and secondary outcomes, propose how to deal with the ethical challenges, discuss how and from whom to obtain informed consent, including consideration of local legislation, rules, limits).

- *Primary outcome: number of cesarean sections, maternal satisfaction*
- *Secondary outcome: breastfeeding initiation, rate of other interventions*



Debriefing of the team-based work: ask two groups to present their results for the task, ask the other to comment in what were their suggestions different (25–30 minutes).

Hints and solutions for the teacher:

- *Similarities and differences between the examples chosen by teams.*
- *Identify ethical principles, design aspects, or other modalities mentioned in the pre-class reading and reflected in the design of the presented study. Are there any? Should there be any?*

REFLECTION, WRAP-UP



1. Which ethical challenges and global barriers in conducting maternal health trials do you see?
2. How maternal health trials can improve maternal health outcomes?
3. What surprised you today regarding maternal mortality, maternal health and maternal health trials?

Hints and solutions for the teacher:

- *Start a timer on the screen (e.g., 25 minutes) so students can see how much time they have.*
- *Circulate around the room to check progress, clarify instructions, and listen to/encourage discussions/ask probing questions to deepen the ideas.*
- *Allow plenty of time for Debriefing – a critical part of the team-based work (see below).*
- *The barrier can be “Continuity of Midwifery Care in the Czech Republic”.*
- *Study aim: To assess the impact of continuity of care provided by a specialist midwife during pregnancy, birth, and postnatal period on maternal and newborn outcomes.*
- *Hypothesis: Fewer obstetric interventions. Higher satisfaction. Improved maternal and newborn outcomes (e.g., starting breastfeeding) compared to the control group.*
- *Intervention:*
 - *Intervention group – will receive continuous midwifery care with one midwife.*
 - *Control group – does have standard of care (fragmented care).*
- *Design: prospective, open-label, randomised controlled trial.*
- *Inclusion criteria: adult (18 years and older), pregnant women in low-risk pregnancies, enrolled before 16 weeks of pregnancy.*

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

20'



- “Quick write” can be adapted in polls in Mentimeter (Word Cloud), Slido (Word Cloud), Miro (brainstorming templates, Sticky notes), or similar apps.
- Sometimes, pre-preparation of the poll is necessary – check it prior to the class. Sometimes, you can pre-create several “columns” or “areas” that will help you in Debriefing.
- In a fully online environment using the above-mentioned apps, the whole-group work would start from the beginning. To preserve individual work at the beginning, you can ask students to write their own ideas on a paper/unshared document. (5 minutes)



Debriefing, setting scene for the next activity (5–8 minutes)

- Collect the students’ suggestions – one by one while they have some.
- You can ask and write the suggestion. Or the invited/named student can submit the single word/short phrase in the app. To speed things up, you can announce the name of the next student to enter your proposal in advance.
- The above-mentioned tools naturally organise input and avoid text chaos. Or you can group the ideas and de-duplicate with the students once all ideas have been collected.
- At the end, do not forget to ask the students which terms they would appreciate having explained to them/which ones they don’t understand.



Building on the previous discussion – ask **further questions to link the global and local perspectives.** (7–10 minutes)

- Summarise the answers for Question 4 (barriers) in a spreadsheet that you can share with the students via chat in MS Teams, Zoom or other online environment (MS Word, MS Excel, etc.).

TEAM-BASED WORK

60'



5–8 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign one facilitator/trained student to each group to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.



Task 1: Select together the topic No. 1 (5–10 minutes):

- Share the spreadsheet with the barriers from the previous activity via chat to all students.
- Each team has 5 points which they can divide among the topics (e.g., give all 5 points to one topic, give 1 point to five favourite topics, give 2 points to one topic and 3 points to another, etc.).
- Ask all teams to assign points to topics according to their preferences and to return to the main room.
- Collect points live – add manually point distribution from each group.
- Ask students whether they are ok with the selected topic No. 1 (with the highest score). If not, repeat voting with only 3 topics.



Task 2: Design a clinical trial to overcome the barrier No. 1. (25 minutes)

- Ask students to write notes electronically to be able to share the screen later. Ask students to select a group leader/spokesperson.
- Time adjustment is possible. Presentation of the teams’ work may need more time.



Debriefing of the team-based work: ask two groups to present their results for the task, ask the others to comment in what were their suggestions different, and to identify ethical principles, design aspects, or other modalities mentioned in the pre-class reading (25–30 minutes).

REFLECTION, WRAP-UP

10'



- Only discussion; no need to collect or write notes.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Reflective activity 4.1: “Global progress and projections for maternal mortality” modified for synchronous use

Link: [Gates Foundation Goalkeepers](#)

Use the [interactive maternal mortality tool](#) from the Gates Foundation to better understand global progress and projections for your country. Try comparing the historical progress for maternal mortality within your region against two other regions or countries. How has the number of maternal deaths per 100,000 live births changed over time where you live?

MODIFICATION FOR INDIVIDUAL WORK



Use the interactive maternal mortality tool from the Gates Foundation. Show the results from your country and focus on the historical trends. Compare them with two other countries (select a neighbouring country and a country from a different region). Write a brief reflection (100–150 words) and submit it to a cloud/discussion board: Were there any unexpected trends or outcomes? What differences or similarities do you observe in the trends? What factors do you think may have contributed to the changes in maternal mortality ratio?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams and assign each team two countries to examine the historical maternal mortality trend using the interactive tool from the Gates Foundation. Ask students to discuss the following within their groups:

1. Compare their expectations with the actual findings.
2. Identify any similarities or differences in the trends.
3. Consider the possible contributing factors to the observed changes and similarities/differences.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their findings and key factors they discussed. After all presentations, engage the class with follow-up questions to encourage further discussion.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask each student to select one country to examine the historical maternal mortality trend using the interactive tool from the Gates Foundation.

Have several students present their chosen country. Ensure that students cover countries from different regions. After the student presentations, facilitate a whole-group discussion by asking following questions:

1. What similarities or differences do you observe across countries from different regions?
2. Were there any surprising trends or outcomes across regions?
3. What factors do you think may have contributed to the observations in maternal mortality ratio?

Hints and solutions for the teacher:

- Ensure there is a mix of countries from different regions across the class to ensure global diversity.
- Ensure students understand how to use the tool. It might be helpful to walk through the tool at the start of the lesson.
- Question 3: Encourage critical thinking by asking students to connect their findings to broader social, economic, and healthcare factors that may affect maternal mortality.
- Question 3: Encourage students to consider not only the challenges faced by low-income countries but also those in high-income countries, with a focus on the European context. Some potential issues to guide the discussion could include:
 - Trust in the healthcare system: How does public trust in healthcare systems influence maternal health outcomes?
 - Prenatal and postnatal care: Are there any inconsistencies or limitations in access to prenatal care or postnatal care?
 - Changes in birth practices: What impact do shifts toward non-medical birth practices (e.g., doulas, home births) have on maternal health?
 - Systemic inequalities: How might socioeconomic disparities in high-income countries contribute to poor maternal health outcomes, especially for marginalised groups (e.g., ethnic minorities)?



UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Reflective activity 4.2: “Key determinants of global maternal health” modified for synchronous use

Link: [Souza et al., 2024](#)

Complete the table below to compare and contrast what you have learned in Units 1, 2, and 3 against the six key messages in the global analysis of the determinants of maternal health by Souza et al. (2024).

Key messages (Souza et al., 2024)	Reflections
1. Maternal health is a social issue: maternal ill-health and disability are not just medical problems, but outcomes of a complex interplay of eco-social forces, lifestyles and exposures, and individual-level factors.	place for your observations from Units 1, 2, and 3
2. Focusing solely on biomedical causes of maternal mortality is insufficient and has possibly been the cause of many countries remaining at the same maternal mortality transition stage for decades.	
3. Addressing maternal health issues and reducing maternal mortality are complex endeavours, due to both modifiable and unmodifiable factors that affect outcomes.	
4. The health sector has a crucial role in saving the lives of women with pregnancy, labour, or postpartum complications, and should be expanded to mitigate the detrimental effects of maternal health determinants.	
5. Expanding demand for and access to high-quality reproductive health services and commodities are needed for primary prevention, early identification, and adequate management of pregnancy, labour, and postpartum complications.	
6. Achieving universal health coverage is essential to ensure access to quality care during pregnancy, childbirth, and the postpartum period, and to reduce maternal mortality.	

MODIFICATION FOR INDIVIDUAL WORK



Complete the table to reflect what you have learned in previous Units. Write 2–3 sentences for each of the key messages. Submit your table to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve for a whole-group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–5 students per team

Divide students into teams. Assign each team one or two of the six key messages to complete the table. Start the timer. Circulate among teams, listen to and stimulate the discussions.

At the end, ask each team to present their findings. As teams present, the teacher or a student volunteer can fill in a large, shared version of the table on the board/screen. Conclude with a class-wide discussion: What patterns or overlaps do we see across the six key messages? What areas still feel complex or unresolved?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Prepare six areas on the board or wall, each labelled with one of the six key messages.

Give each student several sticky notes. Ask them to write keywords or short phrases related to each key message, based on what they learned in previous Units. As students finish, ask them to place their sticky notes under the relevant key message. Once all notes are up, work together as a class: group similar ideas together under each message, label clusters with overarching terms, draw connections between clusters and across different key messages.

Hints and solutions for the teacher:

- This reflective activity is designed to help students revisit and summarise all key topics covered so far, using a case study in the field of maternal health.
 - Unit 1: Background and history of inclusivity in clinical trials
 - Unit 2: Who are the under-served groups
 - Unit 3: Understanding barriers to inclusion
- If the class is large, assign 2–3 students to moderate the sorting and grouping.
- Facilitate a short discussion:
 - What topics or terms appear most frequently?
 - Are some issues common across multiple key messages?
 - Which areas still raise questions or need more attention?



UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Reflective activity 4.3: “Ending the evidence gap for pregnant women around HIV” modified for synchronous use

Link: hivpregnancyethics.org

Visit the PHASES Working Group website “Ending the evidence gap for pregnant women around HIV and co-infections: A call to action”. Choose one of the [project publications](#) on the website and reflect on how the three ethical foundations (**Protection, Access, Respect**) are addressed within your chosen paper.

MODIFICATION FOR INDIVIDUAL WORK



Visit the PHASES Working Group website and choose one publication or resource. Read the selected paper carefully and reflect on how the three ethical foundations – Protection, Access, and Respect – are addressed in the text. Write a short reflection (100–150 words) addressing the following questions:

1. How is each of the three ethical foundations (Protection, Access, Respect) presented in the paper?
2. Which of these principles do you think is most challenging to uphold in the context of research with pregnant women?

Submit your response to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Results may serve for a whole-group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Each team should select one publication from the website. Ask teams to read the selected paper and discuss how the three ethical foundations are addressed. Use the following guiding questions:

1. How is each of the three ethical foundations (Protection, Access, Respect) presented in the paper?
2. Which of these principles do you think is most challenging to uphold in the context of research with pregnant women?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their findings briefly.

After each group has presented, discuss common points or differences as a class.

Hints and solutions for the teacher:

- Before starting the teamwork, review the three ethical foundations (Protection, Access, Respect) with the class to ensure everyone understands their meaning and relevance to maternal health research.
- Consider displaying the figure from Lesson 4.3 that describes each principle visibly in the classroom during the activity. This visual reference can help students stay focused and apply the principles more effectively during group discussions.
- Prevent duplication of selected papers.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start with a review of the three ethical foundations: Protection, Access, Respect. Show the visual from Lesson 4.3 to support students’ understanding. After, choose one publication from the website. Read the key findings or abstract together. Discuss the following questions:

1. How is each of the three ethical foundations (Protection, Access, Respect) presented in the paper?
2. Are there any ethical dilemmas or tensions between these principles in the article?
3. How could findings from this publication be applied in different regional or national contexts?
4. Why is it important to consider these ethical principles when designing and conducting health research involving pregnant women?

Hints and solutions for the teacher:

- Choose one publication together or pre-select one for the activity.
- You can print several copies of the selected paper or project the text on the screen.
- Facilitate discussion by asking additional questions:
 - Question 3: Do any publications suggest solutions that could be applied in your country or region?
 - Question 4: Can you think of real-world examples where a lack of Access, Protection or Respect caused harm in maternal health?



UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Reflective activity 4.4: “Using the INCLUDE Ethnicity Framework” modified for synchronous use

Link: [INCLUDE Ethnicity Framework](#)

The INCLUDE Ethnicity Framework aims to help clinical trial teams think specifically about which ethnic groups should be included in their trial for its results to be widely applicable, and what challenges there may be to making this possible. Having identified potential challenges, the team can then consider ways to overcome those challenges.

As you have already learned, high blood pressure during pregnancy, also called hypertension, is a leading cause of global maternal mortality. Consider the [illustrative example using the INCLUDE Ethnicity Framework](#) for the When to Induce Labour to Limit (WILL) risk in pregnancy hypertension trial.

What ethnicities were found to be more at risk of complications during pregnancy due to chronic hypertension? Using the worksheets for thinking through factors that might affect ethnic group involvement in a trial, consider how pregnancy may influence the decision to participate in a trial based on ethnicity.

Note: The INCLUDE Ethnicity Framework builds on the original INCLUDE initiative from the NIHR in the United Kingdom which was described in Unit 1.

MODIFICATION FOR INDIVIDUAL WORK



Go through pp. 3–7 of the illustrative INCLUDE Ethnicity Framework example and focus on the following questions: What ethnicities were found to be more at risk of complications during pregnancy due to chronic hypertension? How may pregnancy influence the decision to participate in a trial based on ethnicity?

Create two PowerPoint slides to answer these questions and submit them to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. You can select one or two presentations to guide a follow-up discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams and ask them to create an infographic summarising key takeaways from the INCLUDE Ethnicity Framework example (pp. 3–7) and their team discussions. Students can use the following structure to guide the discussion and create their infographic:

1. **Key findings:** Which ethnicities are at higher risk of complications due to hypertension in pregnancy? What factors might influence participation in trials for these groups?
2. **Barriers and challenges:** What barriers (e.g., structural, cultural, ethical) might prevent participation?
3. **How the INCLUDE Ethnicity Framework helps:** How does the INCLUDE Framework help address these barriers?
4. **Connection to broader topics:** Connect your findings with the content of previous Units.
5. **Visual tips:** Use simple visuals, icons, and arrows to show relationships between ideas.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their infographic to the class.

Hints and solutions for the teacher:

- Suggested tools: Canva, Piktochart, Google Slides, Adobe Express; or the old-fashioned way with paper and markers.
- Encourage students to review the previous lessons before class to find meaningful links and promote integrative thinking.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask each student to briefly review pp. 3–7 of the INCLUDE Ethnicity Framework example. They can do this at home before class or in the classroom with printed or digital copies. Discuss the following questions:

1. Which ethnicities are at higher risk of complications due to hypertension in pregnancy?
2. What factors might influence participation in trials for these groups?

Hints and solutions for the teacher:

- Deepen the discussion with these critical reflection questions:
 - Can you think of similar barriers for other under-served groups (e.g., based on socioeconomic status, age, disability)?
 - Which barriers are hardest to address – and why?
 - What is the ethical responsibility of researchers when under-served groups are at higher risk but are often excluded from trials?



UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Reflective activity 4.5: “Breakthroughs in maternal mortality” modified for synchronous use

Link: [GoogleNews](#)

Using GoogleNews, or another trusted news outlet for your country, find at least one other example of how clinical trials are contributing to SDG Target 3.1 – reduction of the global Maternal Mortality Ratio to less than 70 per 100,000 live births. Other areas not yet discussed may include: Telemedicine, Mobile health technology (mHealth), Data collection, Global advocacy initiatives, Public health campaigns.

What key aspects of clinical trials and health research are highlighted and in what context (drug development, social or cultural influences, global guidelines, etc.)?

MODIFICATION FOR INDIVIDUAL WORK



Using GoogleNews, find one example of how clinical trials contribute to SDG 3.1. Choose a recent article to ensure the research is current and relevant. Pick an example related to your region or an under-represented area if possible. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What is the focus of the research or project?
2. How does it aim to improve maternal health outcomes?
3. Which aspects of equity, diversity and inclusion principles does this example address?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into groups. Each group will search for one example of how clinical trials are contributing to SDG 3.1. Ask students to discuss following within their groups:

1. What is the focus of the research or project?
2. How does it address maternal health?
3. Which aspects of equity, diversity and inclusion principles does this example address?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their example in three minutes. After each presentation, invite questions or additions from other groups.

Hints and solutions for the teacher:

- Ensure diversity in topics across groups. You can assign or approve topics to avoid overlap or prepare printed or digital sources before class.
- Stimulate discussion:
 - Question 2: Consider the local or global context: Who can benefit?
 - Question 3: Does it consider under-served groups? Are there any barriers to access or implementation?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Instruct students to individually search online (e.g., Google News) for recent articles that show how research is helping to reduce maternal mortality. Ask them to focus on examples related to one of the following areas (write selected topics on the board): e.g., Telemedicine, Mobile health (mHealth), Data collection, Global advocacy, Public health campaigns. Encourage students to take brief notes on:

1. How could this approach help improve maternal health or reduce maternal mortality?
2. Who would benefit the most? Are any under-served groups involved?
3. What are the possible barriers or risks connected with it?

After 5 minutes of reading, bring the class back together. Ask students to write their ideas as keywords on the board under the relevant topic. Then, guide the discussion to identify recurring themes. Wrap up the activity with the following discussion questions:

- Which approaches seem most promising?
- Which under-served groups were mentioned most often, and why?
- What gaps or limitations still exist in current efforts?

Hints and solutions for the teacher:

- Encourage students to reflect not only on technological or medical innovations, but also on social and systemic dimensions.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Multiple-choice questions and solutions

1. Which of the following is a health system failure that contributes to maternal mortality as described by the WHO?
- A) Insufficient numbers of and inadequately trained health workers
 - B) Shortages of essential medical supplies
 - C) Poor accountability of health systems
 - D) All of the above**

Answer: D; The WHO 'Trends in maternal mortality 2000 to 2023' report describes health system failures that translate to (i) poor quality of care, including disrespect, mistreatment and abuse, (ii); insufficient numbers of and inadequately trained health workers, (iii); shortages of essential medical supplies; and (iv) the poor accountability of health systems.

2. Maternal health refers to which of these definitions?
- A) Women's health and wellbeing during pregnancy, childbirth, and postpartum (after childbirth)**
 - B) Death of a woman while pregnant or within 42 days of termination of pregnancy
 - C) Number of maternal deaths during a given time period per 100,000 live births during the same time period
 - D) Proportion of deaths among women of reproductive age that are due to maternal causes

Answer: A; Maternal health broadly refers to women's health and wellbeing during pregnancy, childbirth, and postpartum (after childbirth) ([CDC, 2024](#)).

3. What is the definition of a low-resource setting in the context of global health?
- A) Countries where a basic government-provided healthcare system provides basic care, and a secondary tier of care exists for those who can pay for additional, better quality or faster access
 - B) Countries or environments that lack the necessary resources to provide adequate treatment for those who are critically ill**
 - C) Health and healthcare systems in which knowledge generation processes are embedded in daily practice to improve individual and population health
 - D) Ensuring that everyone, especially the most vulnerable, has access to the quality health care they need without suffering financial hardship

Answer: B; A low-resource setting refers to countries or environments that lack the necessary resources to provide adequate treatment for those who are critically ill.

4. What percentage of global clinical trials initiated in 2024 had pregnant people in their inclusion criteria?
- A) 1%
 - B) 4%**
 - C) 36%
 - D) 51%

Answer: B; GlobalData report that only 4% of global clinical trials started in 2024 included pregnant women in their inclusion criteria.

5. What benefit is there from using a heat-stable drug like misoprostol for the treatment of bleeding after birth (postpartum haemorrhage)?
- A) Heat-stable drugs are designed to be absorbed faster, making them more effective
 - B) Heat-stable drugs are important because they can be administered without the need for medical training
 - C) Heat-stable drugs can be stored without needing to be kept at specific temperatures, making them more accessible and easier to distribute, especially in remote or rural locations**
 - D) Heat-stable drugs do not give any benefit in treating postpartum haemorrhage

Answer: C; Heat-stable drugs can maintain their effectiveness without strict temperature control. In resource-limited settings, heat-stable misoprostol was effective in reducing postpartum haemorrhage and may be a more accessible option for rural areas with limited access to refrigeration.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Recap multiple-choice questions and solutions

1. According to the WHO what percentage of all maternal deaths occur in low and lower middle-income countries?
- A) 90%
 - B) 100%
 - C) 85%
 - D) **95%**

Answer: D; According to statistics from the WHO through 2020, 95% of all maternal deaths occur in low and lower middle-income countries.

2. In which high-income country do some under-served groups notably experience greater rates of maternal mortality than those of lower income countries?
- A) Germany
 - B) Australia
 - C) **United States**
 - D) Canada

Answer: C; For some under-served groups in the United States, the maternal mortality rates can exceed those of lower income countries.

3. The use of what drug in the 1950s and 1960s resulted in global birth defects and is often cited when discussing the use of new medications in pregnant people?
- A) **Thalidomide**
 - B) Misoprostol
 - C) Lenalidomide
 - D) Pomalidomide

*Answer: A; **Thalidomide**, a drug used throughout the 1950s and 1960s for the treatment of nausea in pregnancy, led to severe birth defects in thousands of children globally.*

4. The 'drug drought' in maternal health could be thought of as referring to:
- A) A global lack of guidelines related to medicines for pregnancy-related conditions
 - B) **A global lack of new or improved medicines for pregnancy-related conditions**
 - C) A global lack of available blood donors for maternal surgeries and procedures
 - D) A global lack of medical professionals trained to handle maternal care

Answer: B; Ammerdorffer et al. described the 'drug drought' in maternal health as a lack of innovation for maternal health medicines and indicated "there is a need for collective action from all relevant stakeholders to accelerate investment in the development of new or improved medicines for pregnancy-related conditions".

5. What is a key benefit of a living guidelines approach to maternal health?
- A) Living guidelines do not require constant reassessment, ensuring consistency for healthcare providers
 - B) Living guidelines limit the risk of error by adhering closely to methods that have historically proven successful
 - C) **Living guidelines allow for rapid updates in response to the latest research, clinical trial evidence, and evolving global healthcare practices**
 - D) Living guidelines focus solely on keeping patients alive regardless of the economic cost to a healthcare system

Answer: C; The World Health Organization takes a living guidelines approach to recommendations on maternal health where guidelines are continuously updated in real-time as new evidence becomes available.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

True/False questions and solutions

1. Maternal mortality refers to the number of maternal deaths during a given time period per 100,000 live births during the same time period.

*Answer: **False**; **Maternal mortality** refers to deaths due to complications from pregnancy or childbirth ([UNICEF, 2025](#)). The **maternal mortality ratio** (MMR) is the number of maternal deaths during a given time period per 100,000 live births during the same time period ([WHO, 2025](#)).*

2. Focusing solely on biomedical causes of maternal mortality is sufficient.

*Answer: **False**; Focusing solely on biomedical causes of maternal mortality is insufficient and has possibly been the cause of many countries remaining at the same maternal mortality transition stage for decades ([Souza et al., 2024](#)).*

3. Historically, there has been a lack of representation of pregnant women in clinical trials to assess therapeutic interventions marketed to pregnant women or to predict outcomes in pregnant individuals and unborn children.

*Answer: **True**; Until the late 20th century men were considered to be the 'norm' study population and researchers believed that women would have the same response as men to trial interventions ([AAMC, 2024](#)). Historically there has been no uniform system to assess therapeutic interventions marketed to pregnant women or to predict outcomes in pregnant individuals and unborn children ([Vaith et al., 2022](#)).*

4. Justification schemes can help stakeholders consider who needs to be included in the clinical trial and why.

*Answer: **True**; Throughout Units 1, 2, and 3 you learned about the exclusion of certain groups from health research and clinical trials. These practices continue today. Justification schemes can guide stakeholders in considering who needs to be included in the clinical trial and why.*

5. A skilled birth attendant is competently trained to facilitate physiological processes during labour and delivery to ensure a clean and positive childbirth experience.

*Answer: **True**; Skilled birth attendants can also provide and promote evidence-based, human-rights based, quality, socio-culturally sensitive and dignified care to women and newborns and identify and manage or refer women and/or newborns with complications.*

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.1: Figure 1: Maternal mortality ratio, 2023 [Source: [UNICEF, 2025](#) licenced by [CC BY-NC 3.0 IGO](#)]

Maternal Mortality Ratio, (maternal deaths per 100,000 live births)

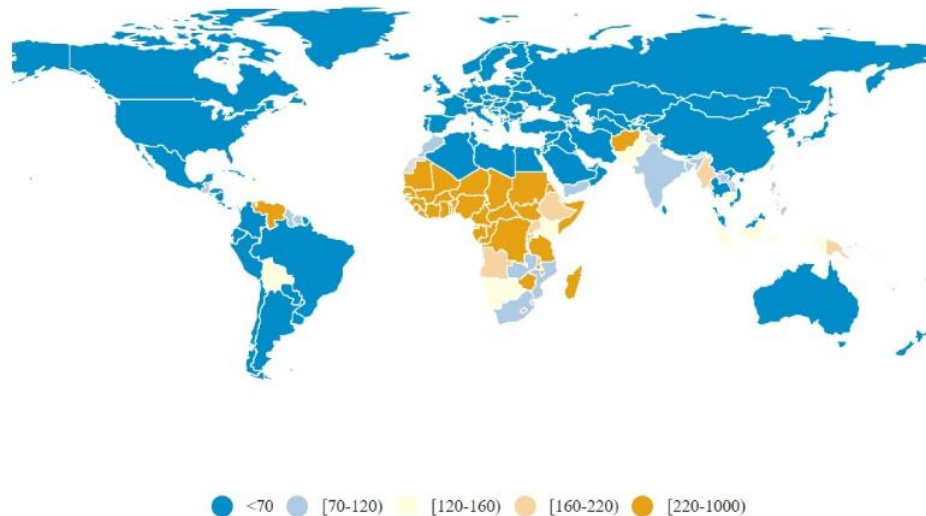


Figure 1: Maternal mortality ratio, 2023 [Source: [UNICEF, 2025](#) licenced by [CC BY-NC 3.0 IGO](#)]

4.1: World Health Organization. Trends in maternal mortality estimates 2000 to 2023: estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division [online]. World Health Organization: Geneva, Switzerland 2025. [Accessed 5 Jun 2025]. Available from: <https://www.who.int/publications/i/item/9789240108462>

Trends in maternal mortality 2000 to 2020

Estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division

Key points for the teacher:

- The document reports trends in maternal mortality between 2000 and 2020, showing significant global disparities, particularly in sub-Saharan Africa and low-income regions.
- Although maternal mortality decreased significantly between 2000 and 2015, progress has stagnated since the introduction of Sustainable Development Goals (SDGs) in 2016. Challenges include weak healthcare systems, gender inequalities, and insufficient data accuracy.
- Recommendations emphasise strengthening health systems, addressing social determinants, and ensuring inclusive and equitable access to maternal healthcare to achieve the SDG targets by 2030.

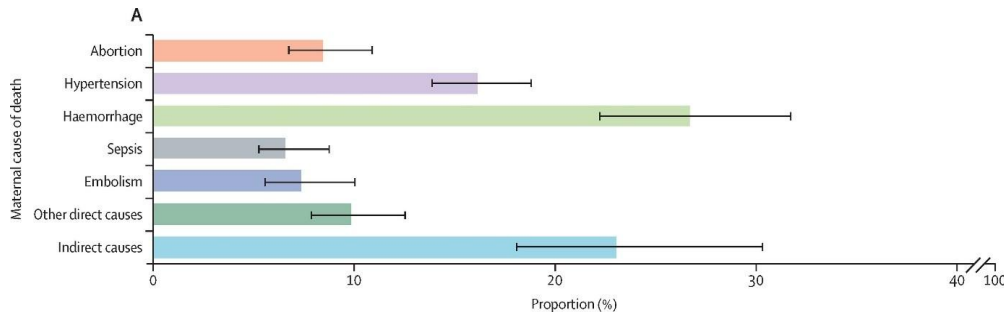
Key points for the teacher:

- The image is a world map showing the Maternal Mortality Ratio in 2023 — defined as the number of maternal deaths per 100,000 live births.
- Dark Blue (<70): Most developed regions, including North America, Europe, Australia, and parts of Asia and South America, have the lowest maternal mortality.
- Light Blue (70–120): Includes some parts of Latin America, Southeast Asia and South Africa.
- Yellow (120–160) and Light Orange (160–220): Found mainly in parts of South Asia and Sub-Saharan Africa.
- Dark Orange (220–1000): Highest maternal mortality is concentrated in Central and Western Africa.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

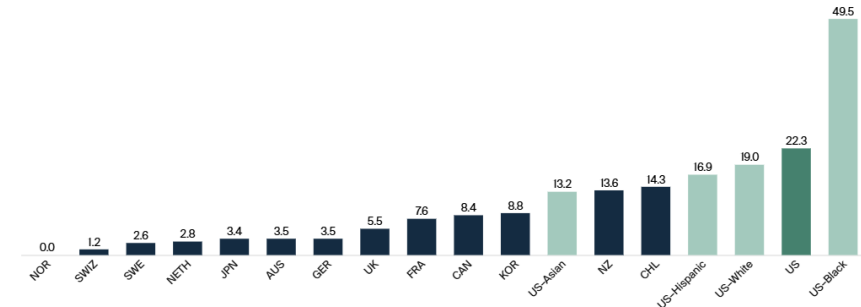
4.2: Figure 1: Global distribution of causes of maternal deaths 2009-2020 as a proportion of total (%). Bars indicate median values with 80% uncertainty intervals [Source: [Cresswell et al., 2025](#) licenced by [CC BY 3.0 IGO](#)]



4.2: Figure 2: MMR disparity among high-income countries [Source: [Gunja et al., 2024](#)]

The United States continues to have the highest maternal death rate, with the rate for Black women by far the highest of any group.

Maternal deaths per 100,000 live births



Notes: The maternal mortality ratio is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes. For more information on how maternal mortality is defined, see Organisation for Economic Co-operation and Development, "Maternal and Infant Mortality," in *Health at a Glance 2023: OECD Indicators* (OECD, 2023). 2016 data for FRA; 2017 data for UK; 2018 data for NZ; 2020 data for CAN and SWI; 2021 data for AUS, GER, JPN, KOR, NET, and SWE; 2022 data for CHL (provisional), NOR, and US. Due to sample size limitations, data for US-AIAN cannot be displayed. AIAN = American Indian and Alaska Native. Asian Americans include a wide range of distinct communities. Such groupings are imperfect, as they mask significant difference in maternal mortality rates.

Data: All country data from OECD Health Statistics 2023 extracted on February 29, 2024, except data for US are 2022 data from the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, mortality and natality data files, "Maternal Mortality Rates in the United States, 2022."

Key points for the teacher:

- The image is a bar chart comparing maternal mortality rates (MMR) for selected high-income countries and U.S. racial/ethnic groups – defined as maternal deaths per 100,000 live births.
- The United States has the highest overall MMR among all high-income countries shown: 22.3 deaths per 100,000 live births.
- When broken down by ethnicity, black women in the U.S. have an exceptionally high MMR of 49.5, the highest rate in the entire chart. White women in the U.S. have a rate of 19.0, Hispanic women: 16.9 and Asian women 13.2.
- The article emphasises that over 80% of maternal deaths in the U.S. are preventable, which highlights that systemic failures – not biological differences – are at the root of these disparities.
- Nearly two-thirds of maternal deaths in the U.S. occur within 42 days after birth. U.S. women have the least access to postpartum support like home visits and paid leave compared to other countries. The U.S. and Canada have also the lowest supply of midwives and ob-gyns.
- According to the source article of the chart, black women in the U.S. face exceptionally high MMRs, driven by systemic racism, unequal access to care, and clinician bias – factors that affect both the quality and outcomes of care they receive.

Key points for the teacher:

- The image shows the global distribution of causes of maternal deaths from 2009 to 2020 as a proportion of the total (%).
 - Haemorrhage** ($\pm 27\%$): Leading direct cause of maternal death.
 - Indirect causes** ($\pm 23\%$): Second most common, e.g., pre-existing conditions worsened by pregnancy.
 - Hypertension** ($\pm 17\%$)
 - Other direct causes** ($\pm 10\%$)
 - Abortion** ($\pm 9\%$)
 - Embolism** ($\pm 8\%$)
 - Sepsis** ($\pm 7\%$)

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.2: Souza JP, Day LT, Rezende-Gomes AC, Zhang J, Mori R, Baguiya A, Jayaratne K, Osoti A, Vogel JP, Campbell O, Mugerwa KY. A global analysis of the determinants of maternal health and transitions in maternal mortality. *Lancet Glob Health* [online]. 2024; 12(2):e306-16. [Accessed 5 Jun 2025]. Available from: [https://doi.org/10.1016/s2214-109x\(23\)00468-0](https://doi.org/10.1016/s2214-109x(23)00468-0)

Maternal Health in the Perinatal Period and Beyond 1

A global analysis of the determinants of maternal health and transitions in maternal mortality

João Paulo Souza, Louise Tina Day, Ana Clara Rezende-Gomes, Jun Zhang, Rintaro Mori, Adama Baguiya, Kapila Jayaratne, Alfred Osoti, Joshua P Vogel, Oona Campbell, Kidza Y Mugerwa, Pisake Lumbiganon, Özge Tunçalp, Jenny Cresswell, Lale Say, Allisyn Carol Moran, Olufemi T Oladapo

Key points for the teacher:

- The article examines the multifactorial causes of maternal mortality and the transitions countries undergo in reducing maternal deaths.
- It emphasises that maternal health is not only influenced by medical care but also by a wide range of social, economic, environmental, and personal factors.
- Around 287,000 women died in 2020 from causes related to pregnancy or childbirth – most of these deaths could have been avoided with timely and quality care. Women from poorer backgrounds, those in conflict zones, or ethnic minorities are at much higher risk.
- The authors analysed 185 countries to understand how maternal health improves over time and what obstacles holds it back.
- They describe five stages of “maternal mortality transition”, from very high to very low rates of maternal death. Countries that improve women’s rights, education, income, and healthcare access are more likely to move to safer stages.

4.2: Table 1: Relationship between contribution of a cause of mortality to maternal deaths and research output within maternal health trials in low and middle-income countries, 2010-2019 [Adapted from: [Eggleston et al., 2022](#) licenced by CC BY-NC 4.0]

Causes of maternal mortality	Contribution to mortality in ‘developing regions’* (%)	Number of trials (% of all trials)
Abortion†	7.9	N/A
Embolism	3.1	0 (0.0)
Haemorrhage	27.1	81 (9.3)
Hypertensive disorders	14.0	55 (6.3)
Sepsis	10.7	23 (2.6)
Complications of delivery	2.8	15 (1.7)
Obstructed labour	2.9	3 (0.3)
HIV related	5.5	38 (4.3)
Pre-existing medical conditions	14.8	10 (1.1)
Other	11.2	649 (74.3)
Total	100.0	874 (100.0)

*Mortality figures were taken from the 2014 Say et al report.³
†Abortion was excluded from this review, and hence no results are reported.
N/A, not applicable.

Key points for the teacher:

- The table compares the contribution of different causes of maternal mortality in developing regions with the research attention each cause has received in maternal health trials conducted in low- and middle-income countries (LMICs) between 2010 and 2019.
- There is a clear mismatch between the causes of maternal death and research focus.
- Some high-burden causes like sepsis, hypertension, and haemorrhage are under-represented in trials.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.3: Kaye DK. The moral imperative to approve pregnant women's participation in randomized clinical trials for pregnancy and newborn complications. *Philos Ethics Humanit Med* [online]. 2019; 14:11. [Accessed 5 Jun 2025]. Available from: <https://doi.org/10.1186/s13010-019-0081-8>

The moral imperative to approve pregnant women's participation in randomized clinical trials for pregnancy and newborn complications

Dan Kabonge Kaye^{1,2}

Key points for the teacher:

- The article is dealing with the misuse of vulnerability – labelling pregnant women as inherently vulnerable leads to excluding them from research that can be harmful.
- Despite known complexities and risks, the lack of research in this area leaves pregnant individuals without evidence-based treatments, which may result in suboptimal or unsafe care.
- Avoiding research in pregnancy doesn't eliminate risk – it shifts it to real-world clinical care, where there is often little data to guide treatment.
- Pregnancy changes how drugs are absorbed, distributed, and metabolised, but most medications are dosed based on non-pregnant populations.
- The teacher can ask students: When does protecting someone become limiting or even discriminatory?

4.3: Van Zyl C, Badenhorst M, Hanekom S, Heine M. Unravelling 'low-resource settings': a systematic scoping review with qualitative content analysis. *BMJ Glob Health* [online]. 2021; 6(6):e005190. [Accessed 5 Jun 2025]. Available from: <https://doi.org/10.1136/bmjgh-2021-005190>

BMJ Global Health

Unravelling 'low-resource settings': a systematic scoping review with qualitative content analysis

Chanel van Zyl ¹, Marelise Badenhorst ², Susan Hanekom ¹, Martin Heine ²

Key points for the teacher:

- This review investigates the meaning behind the widely used but often vague term "low-resource settings" (LRS), especially in health research. Instead of simply associating LRS with low- or middle-income countries, the authors identify nine interrelated themes that describe the complex nature of resource limitations.
 - **Financial pressure** – Poverty, lack of health insurance, and reliance on public aid.
 - **Suboptimal healthcare delivery** – Poor quality of care, limited access, and overwhelmed systems.
 - **Underdeveloped infrastructure** – Weak transport, sanitation, electricity and technology access.
 - **Paucity of knowledge** – Low health literacy, inadequate education, and limited staff training.
 - **Research challenges** – Barriers to conducting ethical and relevant research.
 - **Restricted social resources** – Lack of tangible or symbolic resources (e.g. information, goods, love, acceptance) within one's social network.
 - **Geographical and environmental factors** – Isolation, terrain, climate, and distance from care.
 - **Human resource limitations** – Shortages of trained healthcare staff and overburdened providers.
 - **Influence of beliefs and practices** – Cultural or religious norms that shape healthcare behaviours.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.3: Figure 1: Ethical foundations to address inequities in the evidence base for the use of medication in pregnancy (PHASES working group, 2021) [Source: [WHO, 2025](#) licenced by [CC BY-NC-SA 3.0 IGO](#)]



Protection

Pregnant persons and the children they will have deserve equitable protection from drug related risks. Research is essential to ensuring that the drugs taken by people – e.g. to prevent or treat infections that co-occur with pregnancy, including HIV, hepatitis and syphilis – meet an acceptable safety standard.



Access

Pregnant persons deserve timely access to the most effective medications to protect their health and that of their future children. Pregnancy-specific evidence is needed to avoid delays in access to next-generation treatment and prevention modalities.



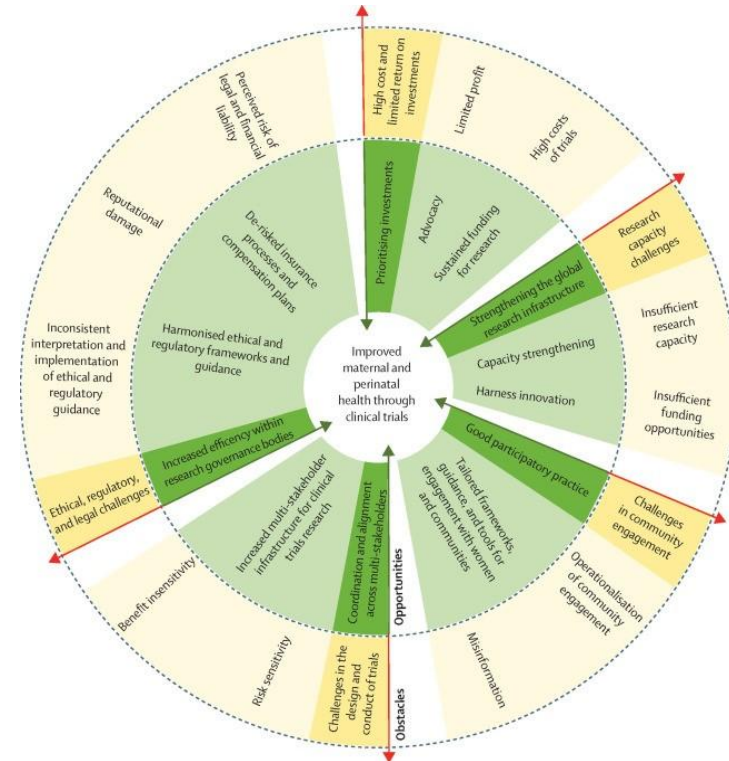
Respect

Pregnant persons deserve equitable respect for their own health. While important research has been done to improve fetal and child outcomes, it is crucial to generate data that allows for consideration of the impact of treatment decisions on maternal health.

Key points for the teacher:

- The image visually presents three ethical foundations for addressing inequities in the evidence base for medication use during pregnancy. Each foundation is paired with an icon and a short explanatory paragraph:
 - **Protection** – Ensure pregnant individuals and their children are safeguarded from drug-related risks through research that confirms medication safety.
 - **Access** – Guarantee timely access to effective treatments during pregnancy by generating pregnancy-specific evidence.
 - **Respect** – Acknowledge and prioritise the health and autonomy of pregnant individuals by considering how treatment decisions impact their wellbeing, not just fetal outcomes.

4.4: Figure 1: Obstacles (outer ring) to clinical trials including pregnant and lactating individuals and the opportunities (inner ring) to address the gap in evidence for maternal and perinatal health [Source: [Dey et al., 2025](#) licenced by [CC BY 3.0 IGO](#)]



Key points for the teacher:

- The image is a circular diagram showing both obstacles (outer ring) and opportunities (inner ring) for improving maternal and perinatal health through clinical trials, especially involving pregnant and lactating individuals.
- Main **obstacles** include: ethical/regulatory challenges (e.g. inconsistent guidance, reputational risk), financial barriers (e.g. high costs, low return), research capacity gaps (e.g. insufficient funding, infrastructure), community engagement issues (e.g. mistrust, misinformation) and trial design problems.
- Main **opportunities** include: good participatory practice, coordination across stakeholders, prioritising investments, strengthening the global research infrastructure and increased efficiency within research governance bodies.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.4: Ammerdorffer A, McDougall AR, Tuttle A, Rushwan S, Chinery L, Vogel JP, Goldstein M, Gülmezoglu AM. The drug drought in maternal health: an ongoing predicament. *Lancet Glob Health* [online]. 2024; 12(7):e1174-83. [Accessed 5 Jun 2025]. Available from: [https://doi.org/10.1016/S2214-109X\(24\)00144-X](https://doi.org/10.1016/S2214-109X(24)00144-X)

The drug drought in maternal health: an ongoing predicament

Anne Ammerdorffer, Annie R A McDougall, Andrew Tuttle, Sara Rushwan, Lester Chinery, Joshua P Vogel, Maya Goldstein, A Metin Gülmezoglu

Key points for the teacher:

- The article analyses the critical lack of innovation in drug development for pregnancy-related conditions.
- Although issues like pre-eclampsia, preterm birth, and postpartum haemorrhage significantly contribute to maternal deaths and illness worldwide, investment in new drug development remains very limited.
- Most drugs used in maternal care today are repurposed – originally developed for other conditions and not specifically studied in pregnancy.
- Pregnant individuals are often excluded from clinical trials, leading to off-label use of medications without sufficient evidence on safety and effectiveness.
- Pharmaceutical companies view pregnancy drug development as high-risk and low-reward due to liability fears, high trial costs, and low expected profits.
- The Accelerating Innovation for Mothers initiative has created a global database to track maternal health research and development and promote targeted drug development.

4.5: Jokhio AH, Winter HR, Cheng KK. An intervention involving traditional birth attendants and perinatal and maternal mortality in Pakistan. *N Engl J Med* [online]. 2005; 352(20):2091-9. [Accessed 5 Jun 2025]. Available from: <https://doi.org/10.1056/nejmsa042830>

SPECIAL ARTICLE

An Intervention Involving Traditional Birth Attendants and Perinatal and Maternal Mortality in Pakistan

Abdul Hakeem Jokhio, M.B., B.S., Ph.D., Heather R. Winter, M.D., M.R.C.O.G., and Kar Keung Cheng, M.B., B.S., Ph.D.

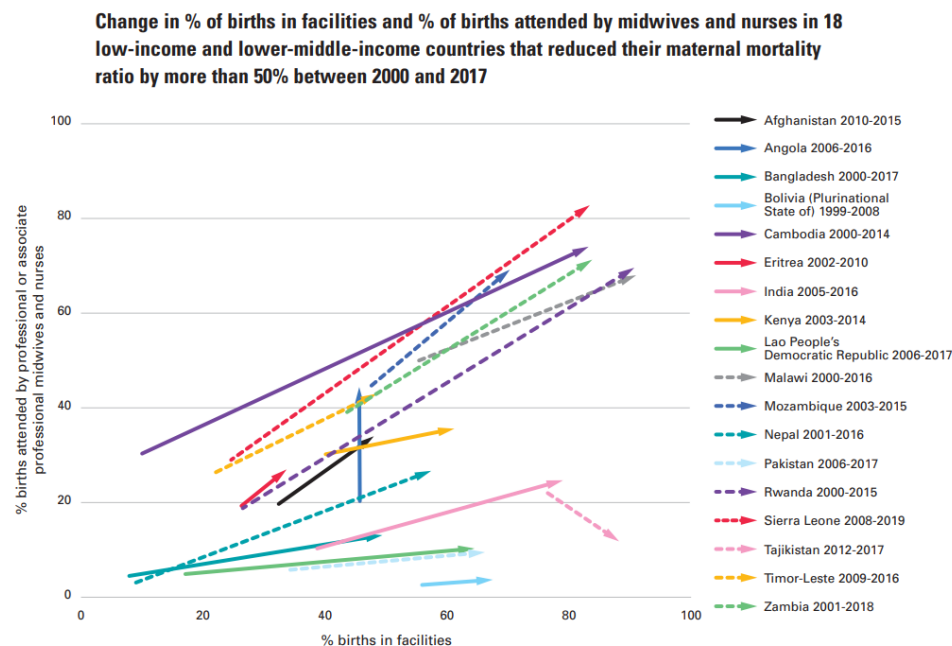
Key points for the teacher:

- This randomised controlled trial performed in Pakistan evaluated whether training traditional birth attendants, providing them with safe delivery kits, and connecting them with local health systems could reduce perinatal and maternal mortality.
- The intervention significantly reduced perinatal deaths and showed promise for improving maternal outcomes.
- Perinatal mortality dropped by approximately 30% in the intervention group (from 120 to 85 per 1000 births).
- Maternal mortality also decreased (268 vs. 360 per 100,000), though the difference was not statistically significant.
- Significant reductions were seen in puerperal sepsis and haemorrhage.
- The program was low-cost and used existing infrastructure, making it a potentially scalable model for similar low-resource settings.

UNIT 4: CASE STUDY: CLINICAL TRIALS AND GLOBAL MATERNAL MORTALITY

Articles, pictures outlines

4.5: Figure 1: Change in % of births in facilities and % of birth attended by midwives and nurses in 18 low-income and lower-middle-income countries that reduced their MMR by more than 50% between 2000 and 2017 [Source: [UNFPA, 2021](#) licenced by [CC BY-NC-SA 3.0 IGO](#)]



Key points for the teacher:

- The image shows how 18 low-income and lower-middle-income countries improved maternal health outcomes between 2000 and 2017.
- X-axis represents the change in the percentage of births in health facilities.
- Y-axis represents the change in the percentage of births attended by professional or associate professional midwives and nurses.
- Each arrow represents one country, showing progress over a specified time range.
- All countries included in the chart achieved a reduction of more than 50% in maternal mortality ratio over the time period.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

General overview of the unit for the teacher

OBJECTIVES

The aim of this Unit is to illustrate how participant characteristics and eligibility criteria affect inclusion in clinical trials and the applicability of their results. In particular, the distinction between internal validity and external validity, and the importance of both, is clarified. The Unit introduces key tools, such as PRO-EDI and PRECIS-2 that support informed and transparent decisions about who should be included in trials.

UNIT CONTENT

- 5.1: Participant characteristics
- 5.2: Eligibility criteria
- 5.3: Ethical barriers to participation
- 5.4: Applicability of trial results
- 5.5: Rare disease trials
- Summary of Unit 5

LEARNING OUTCOMES

Students will be able to:

1. Understand which tools can guide decisions about who should be included when developing eligibility criteria
2. Understand why demographic and ethical considerations can sometimes be in tensions with inclusive trials
3. Explain the difference between internal validity and external validity (applicability)
4. Appreciate why inclusion is especially important in rare disease trials

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Blended 90-minute classroom

	pre-class reading	5×2 hours
	brick-and-mortar	90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 5.1 pre-class; read the editorial of Treweek <i>et al.</i> on “Who is in your trial? Improving the reporting of participant characteristics in trial protocols and results”; think about the answers to questions about using the census data; complete the reflective activity; test your knowledge.
Tue	Complete Lesson 5.2 pre-class; read about the PRECIS-2 in the paper of Loudon <i>et al.</i> , with particular focus on the summary points, how to use PRECIS-2, and conclusion; think about the answers to questions about sign language; complete the reflective activity; test your knowledge.
Wed	Complete Lesson 5.3 pre-class; complete the reflective activity; test your knowledge.
Thu	Complete Lesson 5.4 pre-class; read about the INCLUDE Socioeconomic Disadvantage Framework and answer related questions; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 5.5 pre-class; read a study of Crossnohere <i>et al.</i> , with particular focus on Tables 3 and 4, and Discussion; complete the reflective activity; test your knowledge; read the Summary of Unit 5; complete the MCQs.

OPENING THE LESSON

15' 



 **Organise yourselves/pick a side: “Bias and Validity Quick Check”** – ask students to form groups, leaving space on the left, right, and in the back. Explain that they should express their opinion on the statement by moving right (external validity affected), left (internal validity affected), or to the back (both internal and external validity affected). Always ask students to provide a reason for their opinion.

1. The trial includes only participants aged 18–65, even though the disease also affects older adults.
2. Participants must speak English fluently to be eligible for the trial.
3. Outcome assessors know which treatment each participant received.
4. Only participants without comorbidities are eligible for the trial.
5. Participants in the intervention group receive more follow-up visits than those in the control group.

Hints and solutions for the teacher:

- *Statement 1: External validity – limits applicability to older populations who may respond differently to treatment, improves homogeneity but weakens confidence in generalisability.*

Hints and solutions for the teacher:

- *Statement 2: External validity (with ethical implications) – disproportionately excludes ethnic minority groups, this is often a convenience decision rather than a scientific necessity.*
- *Statement 3: Internal validity – increases risk of measurement bias, this affects whether results are true, not whether they are applicable.*
- *Statement 4: Both – internal validity: reduces confounding, external validity: excludes people who resemble real patients, a classic trade-off between ideal conditions and real-world relevance.*
- *Statement 5: Internal validity – introduces performance bias; additional attention itself can influence outcomes.*

To make it easier for students to navigate, you can prepare signs with the words “external validity” and “internal validity” and place them on the relevant sections.

TEAM-BASED WORK

70' 



4–8 students per team



Task 1 – Use of census data (10 minutes)

Ask teams to discuss and complete the first task – answer the following questions:

- Do you think the census data would be useful in planning a clinical trial? How would you use them?
- Are the data on ethnicity and identity sufficient for planning an inclusive study?



Task 2 – British Sign Language (10 minutes)

Ask teams to discuss and complete the second task – answer the following question (related to the video from the pre-class reading – Lesson 5.2:

- How do the use of (British) Sign Language and other demographic data intersect, and how might that impact society?

Hints and solutions for the teacher:

- *The questions in Tasks 1 and 2 were part of the pre-class reading. Students now compare and refine their individual answers in teams. It is advisable to draw their attention to the deliberate repetition of questions from the pre-class reading.*



Debriefing (10 minutes)

Ask each team to report one key insight only (to keep pace).

Hints and solutions for the teacher:

- *Uses: estimating target populations, setting recruitment targets, identifying under-served groups; Limitations: broad ethnicity categories, lack of intersectional detail, no information on consent capacity or disability experience*

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Blended 90-minute classroom

Hints and solutions for the teacher:

- Examples of answers to Task 2: Ignoring communication needs can reinforce social exclusion. Language is a social, not just individual, characteristic. Intersectionality increases the risk of compounded exclusion. Language needs often overlap with other forms of disadvantage.
- Questions to further stimulate discussion:
 - Which PRO-EDI characteristics are well-supported by census data, and which are not?
 - What happens if a clinical trial ignores language or communication needs identified in population data?



Task 3 – Ethics vs Inclusion in Trial Design (25 minutes)

Provide teams with a short trial vignette below and ask them:

- to review the vignette and list all eligibility criteria or trial requirements that could exclude participants.
- to brainstorm possible adaptations to reduce exclusion without violating ethical standards.
- to discuss how collecting and reporting PRO-EDI characteristics can help make the trial more transparent and inclusive, even if some exclusions remain unavoidable.

Trial vignette: A clinical trial is testing a new cognitive therapy for people with mild to moderate dementia. The conditions are providing informed consent in accordance with the Declaration of Helsinki, participating in weekly sessions, and completing questionnaires independently. The trial will be conducted in several centres specialising in dementia research, which are usually located in cities and affiliated with university hospitals.



Debriefing (15 minutes)

Ask each team to report their key insight into the first, second, and the third topic.

Hints and solutions for the teacher:

Project the trial vignette onto the screen so that everyone can see it, or print out several copies.

Sample answers:

- Weekly attendance at urban clinics potentially excludes participants living in rural areas, people with mobility issues, low-income participants without transport. Such practical requirement limits access for certain demographic groups.
- A potential adaptation is to offer remote or home-based sessions or flexible scheduling (though this may increase logistical complexity and could affect consistency of intervention delivery).
- Socioeconomic status/geography highlights access barriers → record participants' residence (urban/rural) or income to identify systemic exclusion.

REFLECTION, WRAP-UP

5'



1. How do we recognise who we need in a clinical trial? Why should we think about that?
or
How might exclusion of certain groups impact the evidence base and equity in these trials?
or
Why is inclusion especially important in rare disease trials?
2. In what ways can ethical safeguards and demographic considerations conflict with inclusive trial design?
3. Can you think of a situation in which PRO-EDI and PRECIS-2 tools would be useful?
4. Based on what you've learned, how would you balance ethics, demographics, and trial design in a study to ensure both safety and inclusion?

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

15'



- “Pick a side activity” can be modified to polls in Mentimeter (anonymous voting), Slido (Polls), or Miro (students move an icon or a sticky note), or similar apps.
- Sometimes, advance preparation of the poll is necessary – check it in advance of the class.
- Time adjustment is possible (online voting may be faster than moving in classroom).

REFLECTION, WRAP-UP

5'



- Only discussion; no need to collect or write notes.

TEAM-BASED WORK

70'



4–8 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign one facilitator/trained student to each group to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.
- You can prepare a template which the students can collaboratively fill in.
- Ask students to write notes electronically so that they are able to share on screen later. Ask students to select a group leader.
- Time adjustment is possible. The presentation of the team’s work may need more time.



Debriefing (10 minutes)

Ask each team to report one key insight only (to keep pace).

BREAK

5'



Consider a break between the Debriefing and the Task 3.

- Share the trial vignette discussed via the chat or link to a cloud, share it with the facilitators too.



Debriefing (15 minutes)

Ask each team to report their key insight to the first, second, and the third topic.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Reflective activity 5.1: “National census” modified for synchronous use

Link: [Scotland's Census](#)

Finding data to answer the question ‘Who should be in my trial?’ can be difficult. The STRIDE project ([Treweek et al., 2024](#)) developed some recommendations regarding ethnicity, one being that ethnicity data collected as part of a national census, and which describes a defined geographical area can be used when other data are lacking.

The link above is to the Scottish census data which we earlier discussed in Unit 2; you may want to use data from a different census. Choose an area and explore the ethnicity data. Scotland's census allows you to download the data as an Excel spreadsheet.

MODIFICATION FOR INDIVIDUAL WORK



Read the article about the STRIDE project recommendations ([Treweek et al., 2024](#)). Then, access the national census data on ethnicity. If not available, you may use [Scottish census](#) data. Explore the data and reflect on the following:

1. Would these census data be useful when planning a clinical trial? Why or why not?
2. How would you use them?
3. Are the data on ethnicity and identity sufficient for planning an inclusive study?

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into teams. Each team selects one geographical area (e.g. a country, or region) and accesses national census data on ethnicity for that area.

Step 1: Explore the data. Ask students to:

- Identify the ethnic groups represented in the selected area.
- Examine how ethnicity is defined and categorised, paying attention to the level of detail provided.

Step 2: Apply the data. Ask students to imagine they are planning a clinical trial in this area and discuss how these data can be used to support the inclusive study design.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their example in three minutes.



After all teams have presented, continue with a whole-class discussion on: Are the data on ethnicity and identity sufficient for planning an inclusive study? Why or why not?

Hints and solutions for the teacher:

- Assign different countries/regions to avoid duplication.
- You may provide students with a direct link to census data to save time, or ask them to search for relevant national data themselves, followed by a brief discussion on what types of data are available.
- Encourage students to link this activity to STRIDE recommendations on ethnicity data and earlier discussions on barriers to inclusion (structural, cultural, logistical).

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Step 1: Begin by asking students what they remember about the STRIDE project. Briefly recap its key messages and recommendations, focusing on the use of national census ethnicity data when other sources are lacking.

Step 2: Ask students to individually explore what ethnicity data are available for a selected country. Students should note what types of ethnicity or identity categories are used, the level of detail, and how recent the data are. Invite students to briefly share what data they found. Compare similarities and differences across data sources.

Step 3: Lead a discussion using the following questions:

1. Would the data you have found be useful when planning a clinical trial? Why or why not?
2. How could these data be used in practice?
3. Are data on ethnicity sufficient for planning an inclusive study? What might be missing?

Hints and solutions for the teacher:

- You may project [STRIDE](#) recommendations and key messages on the screen to frame the discussion.
- You can contrast census data with other data sources (healthcare utilisation data, disease registries, community engagement) to highlight complementarities and gaps.
- Emphasise that census data describe populations, not patients.
- Question 2: How could these data inform decisions about trial recruitment and eligibility? How might they help set recruitment targets or identify under-served groups?
- Question 3: You may introduce the term “intersectionality” (more details in Unit 9).

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Reflective activity 5.2: “Demographic factors in clinical trial design” modified for synchronous use

Link: [WILL clinical trial](#)

Have a look at the registration document for the WILL clinical trial. The study aimed to evaluate whether starting labour early for women with high blood pressure reduces still birth and complications for the mother. The intention of the trial is to directly inform clinical practice; therefore the clinical trial aims to be a pragmatic trial rather than an explanatory trial.

MODIFICATION FOR INDIVIDUAL WORK



Review the inclusion and exclusion criteria for the [WILL trial](#). Use the ‘Eligibility’ domain of [PRECIS-2](#) to judge whether you think the eligibility criteria are more pragmatic or more explanatory. In a short reflection (100–150 words), briefly justify your assessment and focus on the following questions:

1. Can you identify any criteria that may be used to include and/or exclude certain groups of people from the clinical trial who could nonetheless benefit from the trial results?
2. How might this influence the outcomes?

Submit your reflection to a cloud/discussion board. After that, review the responses of at least two peers and write short feedback considering the following questions: Which criterion did you not consider, but your peer did? Did someone interpret the same criterion as more pragmatic/explanatory than you? Why?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student feedback to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into small teams. Each team reviews the inclusion and exclusion criteria of the WILL trial and discusses the following questions:

- Are the eligibility criteria more pragmatic or more explanatory?
- Which criteria may exclude certain groups of people who could still benefit from the trial?
- How could the eligibility criteria influence the generalisability of the trial results?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask two teams to present their findings (in three minutes each). Record key inclusion and exclusion criteria on the board. After the presentation, invite other teams to add any points that were missed. Facilitate a discussion that compares different perspectives and explores ideas for making eligibility criteria more pragmatic and inclusive.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start by asking students about the difference between explanatory and pragmatic trials. When is it appropriate to conduct an explanatory study? Encourage students to provide examples.

Remind the PRECIS-2 tool and project the PRECIS-2 wheel on the screen.

Then, briefly introduce the [WILL trial](#) and its aims. Ask students to individually review the inclusion and exclusion criteria for a few minutes.

Discuss together the following questions:

1. Are the eligibility criteria more pragmatic or more explanatory?
2. Can you identify any criteria that may be used to include and/or exclude certain groups of people from the clinical trial who are nevertheless people who could benefit from the trial results?
3. How might this influence the outcomes?

Hints and solutions for the teacher:

- **Pragmatic trials** – Trials that study interventions in usual care settings instead of a controlled environment. **Explanatory trials** – Trials carried out under ideal conditions, rather than reflecting real-life conditions.
- **PRECIS-2 tool** – The “Pragmatic–Explanatory Continuum Indicator Summary” offers a framework to guide study teams to prospectively consider the pragmatic or explanatory nature of their trial across 9 domains ([Loudon et al., 2015](#)).
 - Go through the section on “The domains in detail” (Eligibility criteria) in Loudon et al.’s publication to explore the examples of criteria that can reduce the trial’s pragmatism score. Are any of these examples present in the trial you are reviewing?
- Question 2: Focus on criteria such as severe hypertension, multiple pregnancies, or major foetal anomalies. Why might these groups be excluded from the trial?
- Highlight that multiple perspectives are valuable – safety, ethics, practical feasibility, and relevance to real-world populations.
- Emphasise that the goal is critical reflection on inclusivity and real-world applicability, not to rewrite the trial protocol.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Reflective activity 5.3: “Inclusion and ethics” modified for synchronous use

Link: [Inclusion, diversity and equity in clinical trials](#)

Watch the [video \(6:13\)](#) by Gillian Mason, Hunter Medical Research Institute, Australia, on inclusion, diversity and equity in clinical trial.

MODIFICATION FOR INDIVIDUAL WORK



Watch the [video](#) introducing the perspective of Gillian Mason, a consumer representative and clinician researcher, on inclusion, diversity and equity in clinical trials. After watching the video, write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why do you think that many researchers do not make modifications to allow the participation of under-served groups such as people with disabilities?
2. When do you think researchers should start to think about ethical challenges to inclusion?
3. What could funders, institutional review boards and ethics committees do to increase inclusion in trials?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4 students per team

Divide students into small teams. Assign one discussion question to each group. If there are more groups than questions, assign the same question to multiple groups.

1. Why do you think that many researchers do not make modifications to allow the participation of under-served groups such as people with disabilities?
2. When do you think researchers should start to think about ethical challenges to inclusion?
3. What could funders, institutional review boards and ethics committees do to increase inclusion in trials?

Begin with a short team discussion on the assigned question. Next, ask students to watch the video by Gillian Mason. After watching the video, invite teams to revisit their original answers and discuss: What would you add, remove or reframe after watching the video?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, for each question, ask one team to present their summary (three minutes). Encourage students to explicitly name what changed between their pre- and post-video answers.

If multiple groups worked on the same question, invite the others to add missing points or offer contrasting views.

As groups present, note key ideas on the board.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the [video](#) introducing the perspective of Gillian Mason, a consumer representative and clinician researcher, on inclusion, diversity and equity in clinical trials. Ask students to make notes on:

- at least one barrier to the participation of under-served groups mentioned in the video,
- at least one practical change or action that could improve inclusion and diversity in clinical trials.

After that, invite students to share their observations. Write the barriers on one side of the board and actions on the other. Using the notes on the board as a starting point, discuss the following questions:

1. Why do you think that many researchers do not make modifications to allow the participation of under-served groups, such as people with disabilities?
2. When do you think researchers should start to think about ethical challenges to inclusion?
3. What could funders, institutional review boards and ethics committees do to increase inclusion in trials?

Hints and solutions for the teacher:

- *Key notes from the video:*
 - Idea of ‘default persona’, who is really the minority?
 - Trials might aim to reach diverse populations but are not designed in a way that welcomes them (e.g. people with disabilities or chronic illness).
 - Lack of measurements = lack of data: How do we know inclusion efforts are improving?
 - System-level changes are necessary (such as expectations set by research ethics committees).

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Reflective activity 5.4: “Assessing risk of bias” modified for synchronous use

Link: [ROBUST-RCT](#)

There are several tools that can be used to assess risk of bias, i.e., internal validity. They are generally used for systematic reviews, but they are a useful tool for researchers to use when designing a trial because they can be used to assess how internally valid the proposed design is.

Some risk of bias tools are quite complex, but a relatively simple and evidence-informed one is ROBUST-RCT ([Wang et al., 2025](#)).

MODIFICATION FOR INDIVIDUAL WORK



Read the article about [ROBUST-RCT](#), focusing on Table 2 and the section “Core items”.

Choose any clinical trial from <https://clinicaltrials.gov/> and start to assess it using the ROBUST-RCT tool in Table 2. Evaluate at least 3 items. A lot of the information you need will be in the Methods section of the study protocol. As you do this, critically reflect on what you are finding:

1. Is it easy to find the information you need?
2. Are you reassured about the internal validity of the trial, or more worried now?
3. What could the researchers have done differently?

Write a short reflection (100–150 words) describing your assessment and answering the questions. Submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



5–6 students per team

Divide students into teams. Each team works with a different clinical trial selected from <https://clinicaltrials.gov/>. Using [ROBUST-RCT tool](#) (Table 2 and details in section “Core items”), each team assess the internal validity of their assigned/selected trial.

Each team should identify at least one item where the risk of bias is well addressed and one item where the information is unclear or potentially problematic.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present a 2–3 minute summary of their findings.

After all teams have presented, briefly discuss as a class how the trial design choices may influence the credibility and interpretation of the trial results.

Hints and solutions for the teacher:

- You may allow teams to choose a study based on their interests (e.g. disease area, intervention type), or prepare a short list of pre-selected trials for students to choose from, to save time and ensure diversity of designs. This may serve as a further discussion point on **when randomisation or blinding is difficult or impossible in clinical trials?**
- Invite students to reflect on whether the limitations they identified are methodological weaknesses, or whether they are sometimes unavoidable features of certain trial contexts.
- Discuss, e.g. rare diseases or small populations, emergency settings, highly distinguishable interventions.
- Instruct students on where to find the necessary information (Methods section of the study protocol).
- Based on the time available, assign the number of items students should assess.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin with a brief recap as a class: What is bias in clinical research? Why does bias matter for interpreting trial results? What types of bias can happen during clinical trials? Encourage students to provide examples.

Then, introduce one selected clinical trial. As a class, work through the study using the ROBUST-RCT tool (Table 2). Depending on available time, assess all items or select some of them.

After that, guide a discussion:

1. Is it easy to find the information you need?
2. Are you reassured about the internal validity of the trial, or more worried now?
3. What could the researchers have done differently?
4. In which clinical trials is randomisation or blinding difficult?

Hints and solutions for the teacher:

- Examples of bias types: selection bias, recall bias, performance bias, measurement (or detection) bias, attrition bias. Explained in Lesson 5.4.
- Recommend students to read the article about ROBUST-RCT in advance.
- Print key sections of the study or ensure students have reliable digital access to the trial materials.
- If time is limited, prioritise discussion over completion of all ROBUST-RCT items.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Reflective activity 5.5: “The lack of ethnicity data in hereditary haemorrhagic telangiectasia trials” modified for synchronous use

Link: [Galiatsatos et al., 2022](#)

Hereditary haemorrhagic telangiectasia (HHT) is a genetic disorder that affects blood vessel formation. It has an estimated prevalence of 1 in 5000 individuals, making it a rare disease. It is unclear if there are differences in the receipt of treatment, or in treatment outcomes, in HHT patients for sociodemographic characteristics such as ethnicity.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Galiatsatos et al.](#) Thinking about what you have learned so far, why do you think researchers in the four trials described in the above article did not report ethnicity information? What do you think this means for the care of people from diverse ethnic group, particularly ethnic minority groups?

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into teams. Ask each team to read the paper by [Galiatsatos et al.](#) After that, students discuss the following questions:

1. Why do you think researchers did not report ethnicity information?
2. What are the implications of missing ethnicity data?
3. What could have been done differently?

Each team prepares three key points summarising their discussion (one per question).

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to address one question at a time before moving to the next. Write keywords on the board under three headings: Main Reasons (Question 1), Consequences (Question 2), Practical Steps (Question 3). After all questions are addressed, briefly review the board with the class.

Hints and solutions for the teacher:

- Provide students with access to the article (printed copies or online).

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Discussion 1: Context and challenges

Start with a discussion focused on the following questions:

1. What makes clinical trials for rare diseases specific?
2. In what ways might people with rare diseases be under-served in research?

Discussion 2: Insights from the paper

Ask students to review the paper by [Galiatsatos et al.](#) and underline statements that they find relevant to equity, diversity, and inclusion (EDI). Then, invite each student to share one of the selected statements with the class. Ask them to write it on a sticky note a place it on the board. As a class, work together to group the sticky notes into thematic clusters, creating a map of key issues to EDI in rare disease clinical trials.

Hints and solutions for the teacher:

- Provide students with access to the article (printed copies or online).
- Discussion 1 – possible points to highlight:
 - General lack of studies and limited opportunities for participation.
 - Inequities linked to intersectionality (rare disease combined with socioeconomic disadvantages, ethnicity) – linked to diagnosis, treatment, clinical trial participation.
 - Barriers to participation in trials: limited awareness of trials, eligibility criteria (e.g. language requirements), anticipated non-compliance with study procedures, trial location (logistical barriers).
- To save time for Discussion 2, consider dividing the article into sections and assigning different parts to different students/pairs/groups.
- Authors emphasise the importance of sociodemographic data collection and reporting in an effort to understand this disease in diverse populations.
- Optionally, open a discussion on cross-border access to clinical trials, its importance for rare disease trials, and its barriers.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Multiple-choice questions and solutions

1. When initially thinking about who needs to be included in a trial, which of the following is NOT something you should consider:
- A) Who meets the clinical criteria for the disease or condition being targeted
 - B) The demographic characteristics of the people who get the disease or condition most often
 - C) The difficulty of recruiting a particular group of people**
 - D) What type of person gets the most severe form of the disease or condition

Answer: C; When initially thinking about who needs to be in a trial, researchers should not worry about how these individuals will be recruited (and retained). The first thing to do is know who is important. Once that is done, researchers can start to think about the challenges of recruitment and retention.

2. Which of these is not an example of something eligibility criteria need to consider?
- A) Safety
 - B) The trial objectives
 - C) The time it will take to do the trial**
 - D) Ethical requirements

Answer: C; The three key considerations for eligibility criteria are: the objectives of the trial, safety and ethical requirements in the jurisdiction where the trial is being done. The trial needs to take the time needed to meet its objectives; time isn't something to consider in eligibility criteria. Time might be something to consider in the trial objectives, for example making the objectives more modest because of time constraints. Those more modest objectives would then be considered when drawing up the eligibility criteria.

3. Who is most likely to be excluded from a clinical trial on ethical grounds?
- A) Individuals with existing comorbidity
 - B) Individuals who are highly educated
 - C) Individuals who have a learning disability**
 - D) All of the above

Answer: C; Cognitive impairment is a very common exclusion criterion in trials, usually linked to ethical challenges around consent. Consent processes can generally be modified to include people with impaired consent if researchers consider this during trial development.

4. Internal validity is threatened when:
- A) When participants receive their allocated treatment according to which day of the week their hospital appointment is
 - B) Participants who did not take the trial tablets as often as recommended are excluded from the analysis
 - C) The trial primary outcome (Nurse-assessed wellbeing) is measured by a research nurse who knows which treatments participants received
 - D) All of the above**

Answer: D; A) is selection bias because it does not conceal allocation. Hospital staff know that e.g., people attending on Tuesday will receive the intervention. This allows them to schedule appointments for people they think might benefit from the intervention on Tuesdays. This is selection bias. B) is attrition bias because some types of participant are excluded after allocation. People who don't take the tablets may be different to those who do. C) is measurement (or detection) bias because the nurse may consciously or unconsciously make an assessment of this subjective outcome according to knowledge of which treatment the participant received.

5. Which of the following is a way in which a rare disease trial can be made less inclusive?
- A) Requiring participants to travel to the national centre of excellence for trial measurements**
 - B) Offering trial interviews face-to-face at home, online or at a local general practice
 - C) Linking trial measurements to already scheduled routine health monitoring visits
 - D) Working with local community organisations to discuss the trial with diverse ethnic minority groups affected by the rare disease

Answer: A; There may be few places in a country that treat a rare disease, and those centres may be far away from where many patients live. Insisting that people travel long distances is likely to exclude many who cannot physically travel that far because of the disease or frailty, can't afford the time away (e.g., because of work or other responsibilities), or who simply can't afford the cost.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Recap multiple-choice questions and solutions

1. When initially thinking about who needs to be included in a clinical trial, which of the following is something you should consider?
- A) The statistical software that will be used for analysis
 - B) The availability of funding for trial staff
 - C) The characteristics of the population the results will be applied to**
 - D) The preferred journals for future publication

Answer: C; This ensures that the trial is inclusive and relevant, improving the applicability of the findings. The other options are more about logistics or dissemination, not trial inclusion criteria.

2. Which of the following is not relevant when considering the applicability of trial results?
- A) The characteristics of the study population
 - B) The statistical significance of the results**
 - C) The clinical setting in which the trial was conducted
 - D) The similarity between trial interventions and routine clinical practice

Answer: B; While statistical significance is important for internal validity, it is not directly related to the applicability of the results. Applicability focuses on whether the trial results can be applied to the context the trial designers intended the trials results to be used in, and, potentially, whether the results can be applied outside that context.

3. What is the correct explanation for measurement bias?
- A) Differences in how outcomes are assessed between study groups**
 - B) Loss of participants to follow-up over time
 - C) Random variation in measurement tools or procedures
 - D) Selecting participants based on specific characteristics

Answer: A; Measurement bias occurs when there are systematic differences in how outcomes or exposures are measured or assessed between groups, potentially distorting the study results. B) describes attrition bias. C) refers to random error, not bias. D) describes selection bias.

4. Which of the following is something that makes inclusion especially important in rare disease trials?
- A) The high cost of treatment in rare diseases
 - B) The limited number of eligible participants**
 - C) The ease of recruiting patients globally
 - D) The availability of multiple alternative therapies

Answer: B; In rare disease trials, the small number of individuals affected by the condition means that maximising inclusion is crucial to ensure sufficient sample size and meaningful, applicable results. Options A, C, and D may affect trial design, but B is the most directly relevant to why inclusion is especially critical.

5. Which statement is true:
- A) Clinical trials should always be designed to measure outcomes under ideal conditions
 - B) If internal validity is poor, it's important to also look at a trial's external validity
 - C) External validity and applicability both describe how relevant a trial's results are to a particular context**
 - D) It is essential to design trials that are generalisable to all settings

Answer: C; External validity and applicability are both terms used to describe to what extent results apply to a given context. Applicability is perhaps the better term because it is easier to understand.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

True/False questions and solutions

1. Researchers only need to think about clinical criteria when thinking about who needs to be in their trial.

*Answer: **False**; Researchers need to consider demographic characteristics such as age, gender and ethnicity, when deciding who needs to be in their clinical trial to avoid the results only being applicable to some of those who could benefit.*

2. Trial eligibility criteria can make the trial's results less applicable to all or some of those who could benefit from improved treatment.

*Answer: **True**; Trial eligibility criteria need to match the intention of the trial. If the intention is broad applicability but the eligibility criteria create a narrow group of participants, applicability to many who could benefit is reduced.*

3. If including a particular type of person in a clinical trial presents ethical challenges that would make doing the trial harder, researchers should exclude that group.

*Answer: **False**; Including some groups in a trial does pose legitimate ethical challenges but excluding them should not be the default response. Doing that introduces new ethical concerns about equity, justice and the beneficence of research for those being excluded. Often trial designs can be modified to be more inclusive, while maintaining ethical standards. Balance is essential.*

4. External validity (or applicability) is about making the trial results relevant everywhere.

*Answer: **False**; Making a trial relevant everywhere is an impossible task. External validity, or applicability, is about designing and running a trial that is highly applicable to the particular context where you expect the results to be used.*

5. Few people in Europe are affected by a rare disease.

*Answer: **False**; Although relatively few people might be affected by a particular rare disease, there are over 7000 known rare diseases. Across Europe it is estimated that 30 million people live with a rare disease ([EURORDIS, 2025](#)).*

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Articles, pictures outlines

5.1: Treweek S, Gillies K, Witham MD, Devane D, Khunti K, Bower P, Parker A, Soulsby I, Ostrovoska B, Prowse S, Green H. How should trial teams make decisions about the proportions and diversity of the ethnic groups in their trial? *Trials* [online] 2024; 5, 768. [Accessed 27th Nov 2025]. Available from: <https://doi.org/10.1186/s13063-024-08625-5>

METHODOLOGY

Open Access



How should trial teams make decisions about the proportions and diversity of the ethnic groups in their trial?

Shaun Treweek^{1*}, Katie Gillies¹, Miles D. Witham², Declan Devane³, Kamlesh Khunti⁴, Peter Bower⁵, Adwoa Parker⁶, Irene Soulsby⁶, Bärbara Ostrovská¹, Sarah Prowse¹ and Heidi Green⁷

Key points for the teacher:

- This article addresses the practical and ethical challenge of deciding which ethnic groups should be included in a clinical trial and in what proportions.
- It reports findings from the STRIDE project, which used expert panels to discuss real trials across several clinical areas, including cancer, cardiovascular disease, diabetes, mental health, and maternal health.
- Panel members consistently found these decisions difficult, mainly due to poor availability and quality of data on disease prevalence and outcomes by ethnicity.
- The study shows that lack of data should not justify inaction, as excluding groups risks reinforcing existing health inequalities.
- From the discussions, the authors developed **eight STRIDE recommendations** (Table 2) to guide trial teams. These include involving diverse teams with lived experience, allowing sufficient time for discussion, and separating decisions about who should be included from later recruitment logistics. When evidence is limited, the authors recommend default minimum inclusion targets, often based on census or disease-population data, with oversampling considered where numbers would otherwise be too small.
- The article emphasises that recruitment difficulty should not determine who is included in a trial. It also proposes **five policy actions**, including stronger funder expectations, better routine collection of ethnicity data, and inclusion of diversity in GCP training. The central message is that ethnic diversity improves scientific value, not just fairness.

5.1: Treweek S, Dawson S, Khunti K, Akand M, Briel M, da Costa B, Drew C, Elias S, Fatemian H, Gill K, Gough A, Greenwood S, Hall J, Haque S, Hemming K, Kanaan M, Meurer W, Poudel L, Qureshi R, Roberts K, Rosso A, Schiavone F, Sydes MR, Syed M, Vickerstaff V, Li T. Who is in your trial? Improving the reporting of participant characteristics in trial protocols and results. *Trials* [online] 2025; 26, 338. [Accessed 27th Nov 2025]. Available from: <https://doi.org/10.1186/s13063-025-08938-z>

EDITORIAL

Open Access



Who is in your trial? Improving the reporting of participant characteristics in trial protocols and results

Shaun Treweek^{1*}, Shoba Dawson², Kamlesh Khunti³, Murat Akand⁴, Matthias Briel⁵, Bruno da Costa⁶, Cheney Drew⁷, Sara Elias⁸, Hossein Fatemian⁹, Kiranpreet Gill¹⁰, Alexander Gough¹⁰, Sophie Greenwood¹, Jack Hall¹⁰, Sayeed Haque¹¹, Karla Hemming¹⁰, Mona Kanaan¹², William Meurer¹³, Lisasha Poudel¹⁴, Riaz Qureshi¹⁵, Kate Roberts⁸, Aldana Rosso¹⁶, Francesca Schiavone⁸, Matthew R. Sydes¹⁷, Muslim Syed¹⁰, Victoria Vickerstaff¹⁸ and Tianjing Li¹⁹

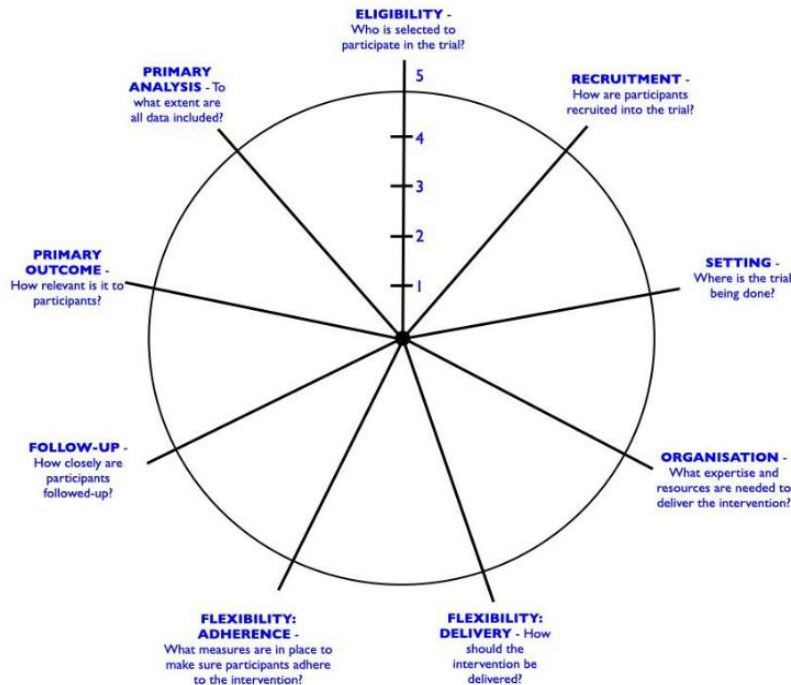
Key points for the teacher:

- This editorial argues that many clinical trials provide insufficient information about who actually participated, limiting the usefulness of their results.
- The authors emphasise that knowing only clinical eligibility criteria is not enough for decision-makers who need to judge whether results apply to specific populations. They show how missing data on age, ethnicity, socioeconomic status, sex, gender and geography undermines equity-focused interpretation and can widen health inequalities.
- To address this, the journal *Trials* introduces a mandatory participant characteristics table for both trial protocols and trial reports. The table requires explicit reporting of six core non-clinical characteristics, based on the PRO-EDI and PROGRESS-Plus frameworks. Protocols must justify the expected participant profile, while trial reports must show who was actually recruited, retained and analysed.
- The goal is to reduce uncertainty, improve meta-analysis and support equitable evidence-based decisions.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Articles, pictures outlines

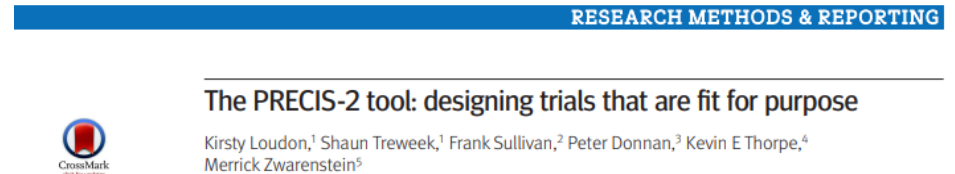
5.2: Figure 1. The PRECIS-2 wheel showing the nine design domains considered by the tool, including eligibility [Source: Shaun Treweek].



Key points for the teacher:

- The image shows a circular “wheel” diagram representing the PRECIS-2 framework, which is used to assess how pragmatic or explanatory a clinical trial is.
- The wheel is divided into nine segments, each corresponding with a key trial design domain. These domains include Eligibility, Recruitment, Setting, Organisation, Flexibility of delivery, Flexibility of adherence, Follow-up, Primary outcome, and Primary analysis.
- Each segment is scored along a scale from the centre outward, typically from 1 to 5, where positions closer to the centre indicate a more explanatory design and positions closer to the outer edge indicate a more pragmatic design. The central point represents highly controlled, ideal conditions, while the outer circle represents real-world clinical practice.
- The diagram allows to visually compare how closely a study reflects routine care across different domains.

5.2: Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe K, Zwarenstein M. The PRECIS-2 tool: Designing trials that are fit for purpose. BMJ [online] 2015; 350. [Accessed 27th Nov 2025]. Available from: <https://www.bmj.com/content/350/bmj.h2147>



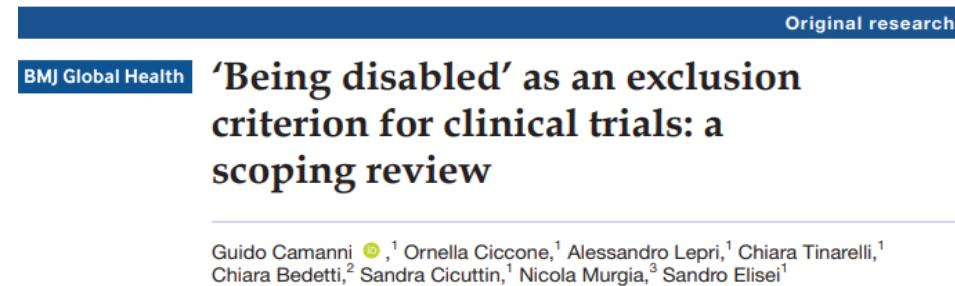
Key points for the teacher:

- This article introduces PRECIS-2, a validated tool designed to help researchers align clinical trial design with the intended purpose of the trial.
- The authors build on the distinction between explanatory trials (ideal conditions) and pragmatic trials (real-world conditions), emphasising that most trials lie on a continuum rather than at extremes.
- PRECIS-2 consists of nine design domains, each scored from 1 (very explanatory) to 5 (very pragmatic), visualised as a wheel (see the description of Figure 1 of Lesson 5.2).
- The tool encourages discussion within multidisciplinary trial teams about how design choices affect applicability and real-world usefulness. A central problem highlighted is that many trials aim to inform real-world decisions but are designed in an overly explanatory way by default.
- PRECIS-2 does not judge trial quality but focuses specifically on external validity and applicability.
- The authors argue that poor alignment between trial purpose and design contributes to research waste.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Articles, pictures outlines

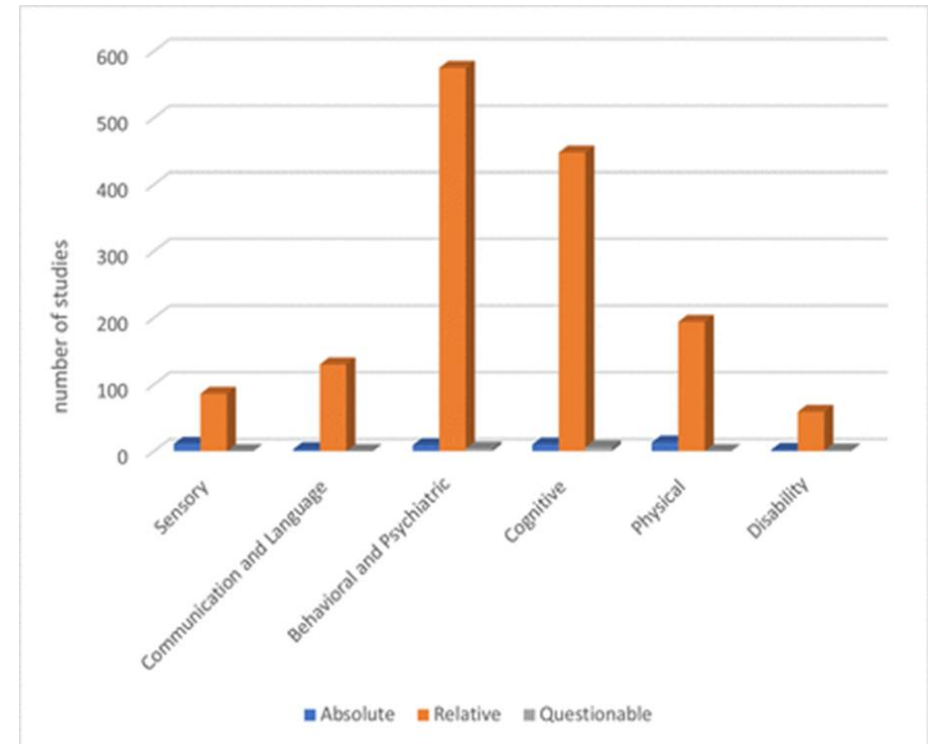
5.3: Camanni G, Ciccone O, Lepri A, Tinarelli C, Bedetti C, Cicuttin S, Murgia N, Elisei S. 'Being disabled' as an exclusion criterion for clinical trials: a scoping review. *BMJ Glob Health* [online]. 2023; 8(11): e013473. [Accessed 27th Nov 2025]. Available from: <https://doi.org/10.1136/bmjgh-2023-013473>



Key points for the teacher:

- This review examines how often people with disabilities (PWDs) are excluded from clinical trials by eligibility criteria. The authors analysed 2,710 completed interventional trials registered on ClinicalTrials.gov between 2010 and 2020, covering the ten leading causes of global disability-adjusted life-years.
- Inability to grant informed consent was present in 480 trials (17.7%).
- Over one third of trials (35.3%) explicitly excluded PWDs. Behavioural or psychiatric disorders and cognitive impairment were the most frequently excluded categories (shown in Figure 3).
- Crucially, only about 3% of exclusions were judged truly necessary for the trial's primary objective, while 96% were considered "relative" and potentially avoidable with adapted study designs.
- Implicit exclusion criteria were present in 1205 trials (44.5%).
- Many trials used vague or ill-defined exclusion criteria, giving researchers broad discretion and reducing external validity.
- The study shows that exclusion is often driven by concerns about consent, compliance, or protocol "cleanliness," rather than scientific necessity.
- The authors argue that PWDs have both a scientific and ethical right to be included in research that affects their health.

5.3: Figure 1. The need for people with disabilities to be excluded from trials given the trial objectives. Only trials classed as 'absolute' (in blue) were considered to need exclusions on grounds of trial objectives. [Source: [Camanni et al, 2023](#), licensed by [CC BY- NC 4.0](#)]



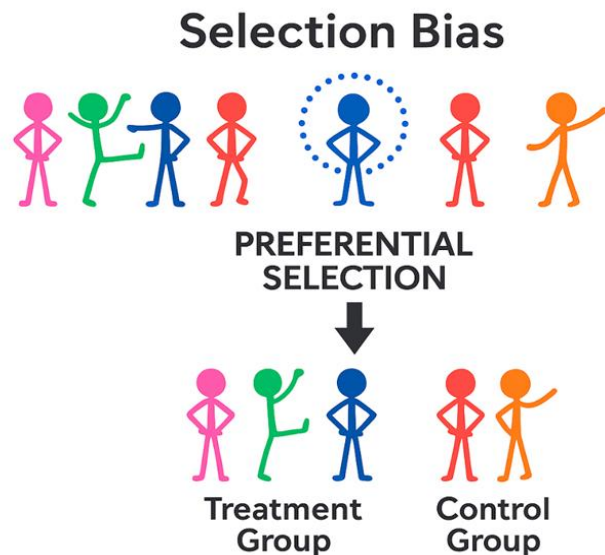
Key points for the teacher:

- The image presents a bar chart showing how often people with disabilities are excluded from clinical trials and whether those exclusions are scientifically justified.
- The horizontal axis lists disability categories: sensory, communication and language, behavioural and psychiatric, cognitive, physical and disability (unspecified).
- The vertical axis shows the number of clinical trials.
- For each category, three bars are displayed, representing absolute (blue), relative (orange) and questionable (grey) exclusion criteria.
- The chart shows that relative exclusions dominate across all categories, especially for behavioural/psychiatric and cognitive disabilities. Absolute exclusions are rare in every category, indicating that exclusion is seldom strictly necessary to meet trial objectives. Questionable exclusions appear only minimally, reflecting cases with no clear link to trial aims.

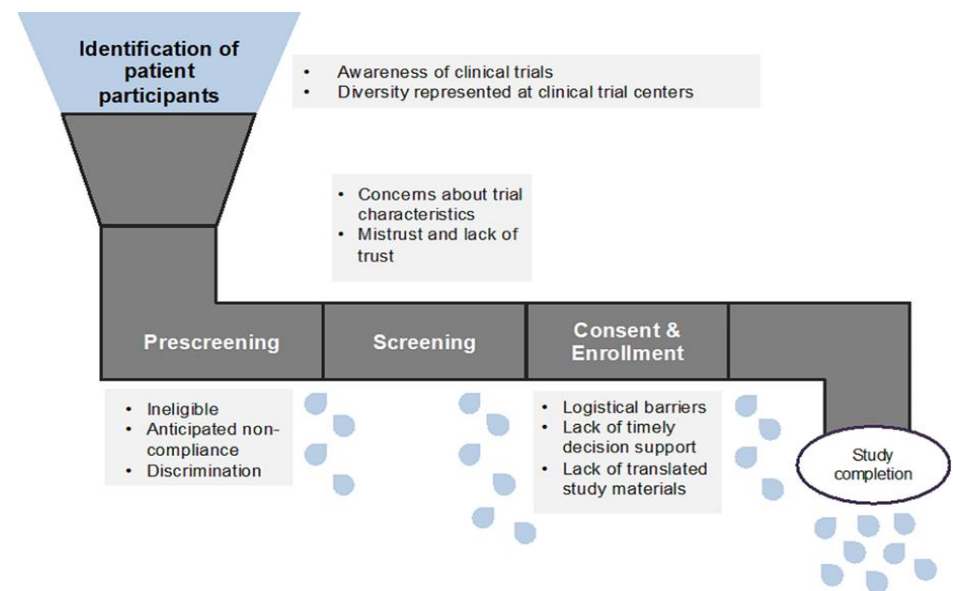
UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Articles, pictures outlines

5.4: Figure 1. Selection bias can happen in clinical trials when participants are preferentially selected to go into the treatment group or the control group. [Source: Image generated using Canva and Microsoft Copilot to depict selection bias].



5.5: Figure 1: The 'leaky' pipe of inclusion in Duchenne muscular dystrophy trials, showing the various points at which Hispanic/Latina people are lost to the trial [Source: [Crossnohere, 2024](#), licensed by CC-BY-4.0]



Key points for the teacher:

- The image illustrates selection bias in clinical trials.
- At the top, a mixed group of individuals is shown, representing the initial study population. One individual is highlighted, indicating that this is the person of which assignment we decide.
- An arrow labelled Preferential Selection points downward, showing how this biased choice affects group allocation.
- At the bottom, participants are split into a Treatment Group and a Control Group. The treatment group now contains selectively chosen participants, while the control group contains the remaining ones.
- This visual emphasises that when allocation is not random, the groups differ systematically before treatment begins. As a result, observed differences in outcomes may reflect pre-existing differences, not the effect of the intervention.

Key points for the teacher:

- The image shows a funnel-shaped "leaky pipeline" illustrating how patients are progressively lost at different stages of participation in clinical trials for Duchenne muscular dystrophy.
- At the top, 'Identification of patient participants', losses occur due to low awareness of clinical trials and limited diversity at trial centres.
- The process then narrows into 'Prescreening', where patients are excluded because they are ineligible, perceived as likely non-compliant, or affected by discrimination.
- Next is 'Screening', where additional participants drop out due to concerns about trial characteristics and mistrust or lack of trust.
- In the 'Consent and Enrollment' stage, further losses are caused by logistical barriers, lack of timely decision support, and missing translated study materials.
- Small drops falling out of the pipeline at each stage visually represent patients leaving the process.
- Only a small fraction of participants reach study completion, highlighting cumulative attrition.

UNIT 5: WHO DO WE NEED IN THE TRIAL AND WHY?

Articles, pictures outlines

5.5: Crossnohere NL, Campoamor NB, Camino E, Dresnick E, Martschenko DO, Rodrigues V, Apkon S, Hazlett A, Mittur D, Rodriguez PE, Bridges JFP, Armstrong N. Barriers to diverse clinical trial participation in Duchenne muscular dystrophy: Engaging Hispanic/Latina caregivers and health professionals. Orphanet J Rare Dis [online] 2024; 19, 207. [Accessed 27th Nov 2025]. Available from: <https://doi.org/10.1186/s13023-024-03209-7>

RESEARCH

Open Access

Barriers to diverse clinical trial participation in Duchenne muscular dystrophy: Engaging Hispanic/Latina caregivers and health professionals



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Key points for the teacher:

- This article examines why Hispanic/Latino families and other underrepresented groups are less likely to participate in Duchenne muscular dystrophy clinical trials, despite increasing trial availability.
- Interviews with caregivers and health professionals in the US were performed. The results showed that barriers exist at every stage of the clinical trial pathway.
- Main barriers identified and corresponding recommendations are described in Table 4.
- The study demonstrates that underrepresentation is systemic, not due to lack of interest from families. It introduces the concept of a “leaky pipeline” (Figure 1 in Lesson 5.5 in this Unit), where diverse participants are lost at multiple points in the process.
- Key recommendations for improvement include multilingual trial information, decision-support tools, ethical guidance for prescreening, and trust-building between providers and families.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

General overview of the unit for the teacher

OBJECTIVES

The aim of this Unit is to help students understand how eligibility criteria and trial design choices affect the inclusivity of clinical trials. Students will explore tools, strategies, and participant-centred methods to support equitable recruitment and retention. The Unit also emphasises the importance of building trusted community relationships and committing time and resources to ensure meaningful participation.

UNIT CONTENT

- 6.1: Rethinking eligibility criteria
- 6.2: Tools to help clinical trial teams design inclusive trials
- 6.3: Building trusted community relationships
- 6.4: Strategies to overcome structural and logistical barriers
- 6.5: Create opportunities for communication and feedback
- Summary of Unit 6

LEARNING OUTCOMES

Students will be able to:

1. Explain why choosing eligibility criteria can influence how inclusive a clinical trial is
2. Identify tools, resources and strategies that clinical trial teams can use to design and run more inclusive trials
3. Reflect on the benefits of building trusted relationships with communities and committing time and resources to do this
4. Recognise the importance of participant-centred methods and alternative methodologies that support truly inclusive clinical trials

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Blended 90-minute classroom

 pre-class reading 5x2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 6.1 pre-class; read the commentary of Jensen <i>et al.</i> on the “silent exclusion” and “black boxes in prescreening”, and the paper of Titz <i>et al.</i> on the over-restrictive eligibility criteria in clinical research, complete tasks related to this paper; complete the reflective activity; test your knowledge.
Tue	Complete Lesson 6.2 pre-class; read the paper of Morris <i>et al.</i> , with particular focus on “Current barriers and strategies”; complete the reflective activity; test your knowledge.
Wed	Complete Lesson 6.3 pre-class; read the paper of Jameson <i>et al.</i> ; complete the reflective activity; test your knowledge.
Thu	Complete Lesson 6.4 pre-class; read the paper of Walter Alexander; answer the questions related to the video on The Clinical Trial Challenge: Boosting Clinical Trial Appeal in Patient Communities; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 6.5 pre-class; familiarise yourself with the PerSEVERE principles; complete the reflective activity; test your knowledge; read the Summary of Unit 6; complete the MCQs.

OPENING THE LESSON

15' 



 **Think–Pair–Share** – Ask students to individually (3 minutes) answer the following 5 questions from the pre-class reading. Then, ask them to compare, justify, and refine their answers in pairs (6 minutes). Afterwards, discuss the questions as a group.

1. What might be a consequence of overly exclusive eligibility criteria?
2. True or False – Trial Forge provides resources to support better clinical trial methodology.
3. True or False – Trusted relationships with communities can be built through one-off meetings.
4. What is a key benefit of decentralised clinical trials?
5. True or False – One of the goals of the PerSEVERE principles is to help participants make informed choices about their involvement.

Hints and solutions for the teacher:

Question 1: Reduced generalisability of findings; Question 2 (true, see reasoning in 6.2); Question 3 (false, see reasoning in 6.3); Question 4: DCTs can improve access and reduce participant burden; Question 5 (true, see reasoning in 6.5)

WHOLE GROUP DISCUSSION

15' 



Shared understanding before deeper activities

Present students with several key prompts for facilitated discussion and for connecting the knowledge they have already acquired from previous units with information from the pre-class reading for Unit 6. Ask students to justify answers from the perspective of different stakeholders (participant, investigator, regulator, funder) or encourage disagreement: “Who sees this differently?”

1. Who benefits when eligibility criteria are too narrow?
2. If informal exclusions are undocumented, how can we assess whether a trial is biased?
3. What assumptions about “good participants” are embedded in informal prescreening?
4. Can exclusion ever be justified if it systematically removes those at greatest clinical risk?

Hints and solutions for the teacher:

Sample answers, ideas:

- *Question 1: Narrow eligibility criteria primarily benefit investigators and sponsors rather than patients or health systems – reduce variability, simplify analysis, increase the likelihood of achieving statistically significant effect.*
- *Question 2: An undocumented prescreening creates a blind spot in trial reporting – without transparency, we cannot determine whether the trial population differs systematically from the target one.*
- *Question 3: e.g., compliant, cognitively intact, fluent in the dominant language, stable in housing and employment, and able to attend appointments reliably*
- *Question 4: It may be ethically justified in early-phase trials (safety data are limited, the potential for harm is high). In later-phase or pragmatic trials, it becomes increasingly difficult to justify scientifically or ethically.*

WORK IN PAIRS

55' 



Task 1: Return to the reflective activity in Lesson 6.2 and SWAT with your students. Ask students to compare, consult, and further elaborate their individual answers to the questions in pairs (15 minutes):

- What are some of the challenges likely to be faced in recruiting people from under-served groups (limited English proficiency in this case) into the main trial?
- How might the SWAT trial idea/intervention overcome some of the challenges?

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Blended 90-minute classroom

Hints and solutions for the teacher:

Ask students to connect the challenges they identify to the barriers discussed earlier. Students should describe these challenges both in general terms and using specific examples, and illustrate the role of intersectionality.

Debriefing (10 minutes)

Ask several pairs to report their key insights to the first and the second question.

Hints and solutions for the teacher:

Sample answers:

- *Challenges: need for interpreters, translated materials, extended consent discussions*
- *The SWAT trial directly addresses a key structural barrier – the additional time and effort required to recruit patients with limited English proficiency. The incentive may reduce informal prescreening. SWAT generates empirical evidence about whether financial incentives can meaningfully improve recruitment of under-served populations.*



Task 2: Equity, Validity, and Invisible Exclusion in the COMFORT Trial (15 minutes)

Ask students to look at the COMFORT trial protocol (e.g., here: <https://link.springer.com/article/10.1186/s13063-025-08852-4>) and:

- Identify two under-served groups who may be less likely to be recruited or retained in the COMFORT trial, and briefly discuss why they are clinically relevant to an opioid stewardship trial.
- Propose one realistic design or process change that could reduce exclusion or improve retention for these groups.
- Consider which exclusions may occur informally.

Hints and solutions for the teacher:

Consider printing out several copies of the COMFORT trial protocol publication (in pdf).

Debriefing (15 minutes)

Ask several pairs to report their answers.

REFLECTION, WRAP-UP

5'



1. How could one eligibility criterion make a trial more or less inclusive, and why?
2. Why does investing time and resources in trusted community relationships improve trial participation and outcomes?
3. If you were designing a trial tomorrow, what is one thing you would do differently to make it more inclusive and participant-friendly?

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

15'



Think-Pair-Share

- Think: Display the prompts clearly on screen (e.g., in the main room chat, shared slide). Use a visible countdown timer (3 minutes)
- Pair: Create breakout rooms in Zoom or MS Teams, assign pairs, and announce timing (6 minutes). Assign a facilitator/trained student to several (1–4) pairs to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (circulates around the breakout rooms as in an in-person class). Be available for support, e.g., in the chat.
- Share: Use tools like Mentimeter Word Cloud or Slido for quick visualisation of ideas

- Share the link via the chat for the COMFORT trial protocol discussed.
- Or share the link to a cloud with a downloaded pdf file.
- Provide the facilitators with one or the other link too.



Debriefing (15 minutes)

Ask several pairs to report their answers.

REFLECTION, WRAP-UP

5'



- Only discussion; no need to collect or write notes.

WHOLE GROUP DISCUSSION

15'



- Share prompts on the screen.

WORK IN PAIRS

55'



- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign a facilitator/trained student to several (1–4) pairs to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues).
- Ask students to write notes electronically so that they are able to share on screen later. Inform the students that you will randomly select pairs to share their work at the end of the task (to encourage focus and accountability).
- Share the materials discussed via the chat or link to a cloud.
- Time adjustment is possible. The presentation of the teams' work may need more time.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.



Debriefing (10 minutes)

Ask several pairs to report their key insights to the first and the second question.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Reflective activity 6.1: “Rethinking eligibility criteria” modified for synchronous use

Link: [Oregon Health & Science University presentation](#)

Protocol authors may return to criteria from previous studies and use “copy and paste” to set the eligibility criteria without evaluating what is appropriate for the current study. This perpetuates unnecessary exclusion and instead, protocols must be written with a careful assessment of all eligibility criteria ([Nclusiv, 2025](#)). Preferably, these are written in partnership with patients or caregivers.

The Oregon Clinical & Translational Research Institute at Oregon Health & Science University [document](#) points the reader to thinking about the nuances of inclusion and exclusion criteria to lower the barriers into participation in clinical trials. Look at the exclusion criteria on the flow diagram on page 13. In this example, around two-thirds of the people are excluded from participating.

MODIFICATION FOR INDIVIDUAL WORK



Review the flow diagram on page 13 of the Oregon Clinical & Translational Research Institute [presentation](#). Focus on the reasons that resulted in approximately two-thirds of potential participants being excluded. Reflect on how a more nuanced approach could have reduced exclusion. Write a short reflection (100–150 words) answering that question and providing examples for at least two reasons for exclusion. Submit your reflection to a cloud/discussion board.

Once you have submitted your response, review the responses of at least two peers and write short feedback: Do you agree with their points? Why or why not? Provide constructive and respectful feedback.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–5 students per team

Divide students into teams. Assign each team one category of reasons for exclusion, for example: language and communication barriers, logistical and time-related barriers, clinician- or system-level barriers, health-related barriers, or attitudinal factors.

Ask students to discuss:

1. Which reasons from the flow diagram would you place in your assigned category?
2. What do these reasons tell us about who is excluded from the study?
3. Which of these barriers might be modifiable through trial design or organisation? How?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their example in three minutes.

Write categories and their key themes on the board. Briefly recap the possible solutions/strategies.

Hints and solutions for the teacher:

- Provide students with printed copies of the diagram or ensure online access.
- Question 3:
 - Start with the eligibility criteria, but don't limit it to them. (More about strategies to overcome structural and logistical barriers in Lesson 6.4.)
 - Are there any challenges (e.g. regulatory, ethical, practical)?
- Optional whole class discussion: Take a look at the diagram part “Lost to follow-up”. What reasons might be behind this? Encourage students to provide examples and possible solutions.



MODIFICATION FOR WHOLE-GROUP DISCUSSION



Show the first part of the diagram on the screen (the box “3779 Excluded”). Go through the reasons and ask students:

1. What type of eligibility criterion might this reason reflect (explicitly or implicitly)?
2. How could that criterion be rephrased or modified to reduce unnecessary exclusion, while still ensuring participant safety and study feasibility?
3. What else can we do beyond the modification of eligibility criteria to support inclusion?

Hints and solutions for the teacher:

- Provide students with printed copies of the diagram or ensure online access.
- Question 1: Some of the exclusions might be through eligibility criteria, but some might also be based on early decision-making by investigators or clinical staff based on anticipated barriers.
- Question 3: e.g. language and communication – recommendation provided by [Dawson et al.](#) – ensure eligibility criteria and the recruitment pathway do not limit participation in ways you do not intend; ensure your trial materials are developed with inclusion in mind; ensure staff are culturally competent; build trusting partnerships with community organisations that work with ethnic minority groups.
- Optional question for discussion: Are there any reasons you can group in one category?

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Reflective activity 6.2: “Study Within a Trial” modified for synchronous use

Link: [Vizza et al., 2025](#)

Read the [protocol by Vizza and colleagues](#), who describe plans for the use of a SWAT within the COMFORT trial. The SWAT will test the effectiveness of giving funding to GPs to support extra time needed to recruit under-served groups into a lower back pain clinical trial in Australia, where English proficiency can be a barrier to recruitment.

MODIFICATION FOR INDIVIDUAL WORK



Read the study protocol by [Vizza et al.](#), which describes the SWAT testing the effectiveness of the recruitment strategy. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What are some of the challenges likely to be faced in recruiting people from under-served groups into the main trial?
2. How might SWAT overcome some of the challenges?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Ask them to review the protocol by [Vizza et al.](#)

Teams first identify potential recruitment challenges in the COMFORT trial. Then discuss the following points:

1. Which barriers is the SWAT likely to address effectively?
2. Which barriers may remain unaddressed?
3. Are there any limitations or risks of this approach in practice?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, invite two teams to present their outputs in three minutes.

Hints and solutions for the teacher:

- Provide students with printed copies of the protocol or ensure online access.
- Optional extension (if time allows):
 - Invite teams to briefly suggest one additional SWAT to support recruitment or retention in the trial.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to read the study protocol by [Vizza et al.](#) in advance or review the abstract together at the start of the session. Project Figure 2 on the screen, showing the schematic overview of the study.

Facilitate a discussion around the following questions:

1. What are some of the challenges likely to be faced in recruiting people from under-served groups into the main trial?
2. How might the SWAT help to address some of the challenges?
3. What are the potential challenges in implementing SWATs in practice?
4. What other barriers to inclusion could be addressed using a SWAT?

Hints and solutions for the teacher:

- Encourage students to refer to the study design, the trial context, and their prior learning on inclusion and equity in clinical trials.
- Question 1: language barrier, time constraints in primary care, trial design that implicitly assumes fluent English, recruitment processes not tailored for linguistically diverse population (note: These are generally expected barriers, not necessarily specific to the COMFORT trial.)
- Question 3: possible discussion points include methodological complexity, added burden to the host trial, additional costs and funding constraints; Remind students of the [PRESS project](#) (Protocols and Resources for Priority Recruitment and Retention SWATs), which provides practical, ready-to-use resources.
- Question 4: Encourage students to give examples of how a SWAT could be designed to address that barrier.
- Study summary:
 - Individuals with limited English proficiency (LEP) are less likely to be included in clinical trials because of language, literacy, and cultural factors. Limited guidance exists on the best ways to recruit them. The SWAT will test whether providing monetary incentives to general practitioners (GPs) increases the recruitment of patients with LEP.
 - Study design: GPs participating in COMFORT are randomised to receive either the per-patient monetary incentive (SWAT Intervention Arms) or no incentive (SWAT Control Arms); primary outcome: the proportion of LEP patients enrolled in the COMFORT trial in the incentive vs. control arms.
 - Materials will be translated into most spoken languages in Australia (Arabic, Chinese, and Italian; identified in the latest Australian census).

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Reflective activity 6.3: “Knowledge mobilisation” modified for synchronous use

Link: [Anderson et al., 2024](#)

Knowledge mobilisation is “the process that paves the way to impact via active collaboration with key stakeholders throughout your research. This includes working with the people and organisations who will use or benefit from research (knowledge users). Together, stakeholders share and integrate their knowledge. This creates new insights and understanding about your research plans and findings. The ultimate aim is to change practice and policy and have real-world impact” ([NIHR, 2024](#)).

The paper by [Anderson and colleagues](#) describes a knowledge mobilisation approach (Figure 1 in the paper) to build trust and inclusion of under-served groups. Focus on Table 4 in the paper, which summarises the lessons learned from this work, in which the authors engaged with the community groups. Think about how time and resources could be used to develop some of these suggested ways of working.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Anderson et al.](#) Based on Table 4, write a short reflection (100–150 words) in which you:

1. Select two or three suggested ways of working described in the table.
2. Explain how time and resources would need to be allocated to make these approaches work in practice.
3. Reflect briefly on why these investments matter in clinical research.

Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4–7 students per team

Divide students into four teams. Assign each team one section of Table 4 from the paper by [Anderson et al.](#) to work on a discuss the following tasks:

1. Summarise the key lessons in your own words.
2. Translate the lessons into practice: Discuss how time and resources would need to be used to implement this way of working in clinical research.
3. Identify potential challenges: What practical difficulties may arise trying to apply this approach?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their outcome in three minutes.

Hints and solutions for the teacher:

- Provide students with printed copies of the table or ensure online access.
- Encourage students to give specific examples.
- Question 2 and 3: Write keywords on the board into separate columns.
- Examples of resources: translation, accessible information materials, reimbursement for participants' time and travel, allocating staff responsible for community engagement
- Facilitate the follow-up discussion:
 - Prompt students to consider, e.g., ongoing engagement vs. one-off activity, active listening and cooperation vs. data collection only, rigid timelines vs. flexible scheduling, institutional requirements vs. community needs, long-term funding vs. short-term project grants.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly remind students what knowledge mobilisation means and encourage them to discuss why it matters for inclusion and trust in clinical research.

Project Table 4 of the paper by [Anderson et al.](#) on the screen. Go through the four sections one by one. For each section, ask students:

1. What do these lessons require in practice (time, people, skills, funding)?
2. Who would need to be involved to make this work?
3. Which elements seem feasible within a clinical research setting, and which might be challenging?

Hints and solutions for the teacher:

- Provide students with printed copies of the table or ensure online access.
- Help students translate general ideas into practice by using guiding questions, e.g., What would this look like in a real clinical trial? Who would actually pay for this, and from which budget? At what stage of the trial would this need to happen?
- Guiding questions to Question 3: Which of these approaches could realistically be transferred to clinical trials? Where do you see tensions between research timelines, funding structures, and inclusive ways of working?
- Activating students during the discussion – Question 3: You can ask students to vote (e.g. by a show of hands) on whether they see a given approach as more feasible or more challenging in practice.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Reflective activity 6.4: “Recruitment and retention costs” modified for synchronous use

Link: [Klompstra et al., 2025](#)

As you have learned, committing time and resources are key in supporting the strategies that will allow clinical trial teams to overcome barriers and be more inclusive.

Look at [Table 1](#) from the paper by Leonie Klompstra and colleagues which gives examples of recruitment and retention costs that could be included in the budget of grant applications ([Klompstra et al., 2025](#)).

Reflect on the 12 costs listed in the table and think about which of these could be effectively used for facilitating the recruitment and retention of participants from one of the under-served groups we have highlighted during this course.

MODIFICATION FOR INDIVIDUAL WORK



Review [Table 1](#) from the paper by Klompstra et al. Choose one under-served group that we have discussed during this course. Reflect on the 12 costs listed in the table. Write a short reflection (100–150 words) addressing:

1. Which of the listed costs could be most effective in facilitating recruitment and retention of your chosen under-served group?
2. Why do you think these costs are important for that group?
3. Are there any costs that seem less relevant for that group? Explain your reasoning.

Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses for individual under-served groups to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into small teams. Assign each team one under-served group. Each team should review [Table 1](#) from Klompstra et al. and discuss the 12 costs listed. Ask students to prepare a short summary addressing:

1. Which 3–4 costs would be most effective for recruiting and retaining participants from your assigned under-served group?
2. What specific barriers faced by this group would these costs help to address?
3. Which costs seem less relevant for your group and why?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their under-served group in three minutes.

During the presentations, encourage other teams to note similarities, differences, or transferable ideas across groups. After all teams have presented, facilitate a short whole-class discussion to compare approaches.

Hints and solutions for the teacher:

- Provide students with printed copies of the table or ensure online access.
- Under-served groups can be pre-assigned by the teacher, or students may choose based on their knowledge. Alternatively, groups can be assigned/chosen from examples listed by the INCLUDE project. Ideally, select one team per category: groups by demographic factors; groups by social and economic factors; groups by health status; groups by disease-specific factors.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to brainstorm which under-served groups have been discussed during the course. As they respond, cluster answers on the board using broad categories (e.g. demographic factors, social and economic factors, health status, disease-specific factors). Then, as a class, select 2–3 groups to focus on.

Project [Table 1](#) from Klompstra et al. on the screen. Go through the listed costs and, for each selected group, ask:

1. Which costs would be most effective for recruiting and retaining participants from your selected under-served group?
2. What specific barriers faced by this group would these costs help to address?
3. Are there any additional costs you think are missing from the table?

Note key points directly on the board. Conclude with a short discussion:

- ✓ ▪ Which costs seem broadly useful across groups?
- Which are clearly group-specific?

Hints and solutions for the teacher:

- Provide students with printed copies of the table or ensure online access.
- If discussion stalls, prompt students to link costs back to known barriers (language, time, trust, accessibility).
- Question 1: Consider intersectionality (e.g. ethnicity combined with socioeconomic barriers or language barriers).
- Highlight jurisdictional differences in reimbursement and compensation practices (US vs. EU; Lesson 6.4).

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Reflective activity 6.5: “Participatory research in care delivery” modified for synchronous use

Link: [Chaiton et al., 2023](#)

A further example of participatory action to understand how to better provide mental health and substance abuse care for lesbian, gay, bisexual, transgender, queer, questioning, and 2-spirit youths (LGBTQ2S+ youths): Sexual and gender minority youths experience emotional distress, stigma and discrimination within medical and social service systems, and this was exacerbated by the COVID-19 pandemic ([Chaiton et al., 2023](#)).

“The research team wanted to understand the barriers LGBTQ2S+ youths were experiencing from the perspectives of the youths themselves and to listen and learn from their experiences and ideas rather than come in with preconceived ideas about the issues participants faced. Every step of the research process, from conception to analysis, included LGBTQ2S+ youths on the research and facilitation team”.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Chaiton et al.](#) and complete the following steps:

1. Review Table 1 (Participant demographics). Reflect on how different characteristics may intersect and increase the risk of being under-served by existing care systems.
2. Read Textbox 1 (Vignette of participant experiences accessing care). Briefly reflect on how John’s experience helps you understand barriers to care from the participant’s perspective, rather than from a clinical or system viewpoint.
3. Based on the participatory research described in the paper, identify 2–3 ways in which care could be better designed or delivered to meet the needs of this under-served group.

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise answers to Question 3 to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4 students per team

First, assign students to expert groups, each focusing on one aspect of the study by [Chaiton et al.](#):

- Team A: Participant demographics and intersectionality (with a focus on Table 1)
- Team B: Lived experience and barriers to care (with a focus on Textbox 1)
- Team C: Participatory research approach
- Team D: Implications for care delivery

In these expert groups, students identify key insights related to their assigned aspect.

Students then regroup into mixed jigsaw teams (i.e., each new team should include one student from each expert group). In these teams, students share what they learned in their expert group so that everyone gains an overview of the whole study from different perspectives.

In their mixed teams, students prepare a one-slide presentation addressing:

1. What do LGBTQ2S+ youths experience when accessing care?
2. What barriers emerge from these experiences?
3. What particular changes in care delivery could address these barriers?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, invite two teams to present their outcomes in three minutes each.

Conclude with a short whole-class discussion by asking: What is one insight from this activity that changed or deepened your understanding of inclusive care or participatory research?

Hints and solutions for the teacher:

- Provide students with printed copies of the paper or ensure online access.
- If enough time, consider linking this activity to the empathy mapping exercise (Reflective activity in Lesson 10.5).

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to read the [paper](#) in advance, or briefly go through the abstract together in class. Then guide a whole-class discussion using the following questions:

1. What is the key problem or barrier to accessing care described in the study?
2. Who is most affected by this problem?
3. What particular change in care delivery could help address this barrier, based on the study findings?
4. Who would need to be involved to make this change happen?

Hints and solutions for the teacher:

- Provide students with printed copies of the paper or ensure online access.
- Question 1: Describe it from the participants’ perspective.
- Question 2: Consider intersectionality (e.g. age, gender identity, ethnicity, social context).
- Question 3: Any other ideas outside the study findings?

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Multiple-choice questions and solutions

1. What does the PRECIS-2 tool help researchers assess?

- A) Drug safety in pregnancy
- B) Participant consent capacity
- C) How pragmatic or explanatory a trial is**
- D) The cost-effectiveness of a trial

Answer: C; PRECIS-2 is a tool for measuring how pragmatic or explanatory a clinical trial is, based on 9 domains.

2. Why is the pulse oximeter highlighted as an example of harm to ethnic minority groups?

- A) It was less accurate for patients with darker skin tones**
- B) It was not approved by regulatory authorities
- C) It was too expensive for widespread use
- D) It caused allergic reactions in certain populations

Answer: A; The pulse oximeter is less accurate at detecting oxygen levels in patients with darker skin tones. This was found to be detrimental to care given to people of colour in a recent Harvard study. This disparity questions whether diverse populations were sufficiently included in the research that led to pulse oximeters being used in standard care..

3. Which of the following is not one of the three key stages in the CHICO guidance?

- A) Building relationships
- B) Financial planning**
- C) Reciprocal relationships
- D) Practicalities

Answer: B; Financial planning is not one of the stages in the CHICO guidance, but preparing for commitment of time and money to support the three stages (building relationships, reciprocal relationships, and practicalities) is important to think about beforehand.

4. According to EU regulations, which group is NOT allowed to receive financial incentives for trial participation?

- A) Adults over 65
- B) Children**
- C) Cancer patients
- D) People with chronic illness

Answer: B; No financial incentives are given to participants lacking capacity, children, or pregnant women, except for reimbursements related to participation in the clinical trial.

5. What is the main goal of participatory research?

- A) To combine knowledge with action to achieve change**
- B) To increase publication rates
- C) To reduce the overall cost of clinical research
- D) To centralise research to one location for a clinical trial

Answer: A; To combine knowledge with action to achieve change.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Recap multiple-choice questions and solutions

1. Which of the following is a consequence of overly exclusive eligibility criteria?

- A) Increased trial costs
- B) More accurate results for all populations
- C) Reduced generalisability of findings**
- D) Faster recruitment

Answer: C; The more exclusive the eligibility criteria are, the less applicable the results will be to broad populations.

2. What does the INCLUDE Ethnicity Framework help clinical trial teams do?

- A) Avoid including ethnic minorities in clinical trials
- B) Identify and justify exclusion criteria that are aligned to clinical factors
- C) Select the most relevant locations for a clinical trial site based on socioeconomic deprivation
- D) Determine which ethnic groups should be included and how to overcome inclusion challenges**

Answer: D; Teams are supported to think through which ethnic groups should be included and how to overcome inclusion challenges using questions and worksheets provided to prompt careful thought.

3. What is the purpose of knowledge mobilisation?

- A) To publish research findings in academic journals
- B) To collaborate with stakeholders for real-world impact**
- C) To increase public awareness of health issues
- D) To train researchers in communication skills

Answer: B; Knowledge mobilisation paves the way to real-world impact via active collaboration with key stakeholders throughout your research. This includes working with the people and organisations who will use or benefit from research.

4. What is a key benefit of Decentralised Clinical Trials (DCTs)?

- A) They speed up ethical approval
- B) They allow all activities to occur at a central hospital site
- C) They remove the need for ongoing informed consent
- D) They can improve access and reduce participant burden**

Answer: D; They can improve access and reduce participant burden by removing some of the barriers (physical, geographical, logistical, time, cost) and making involvement more convenient for participants.

5. What does PPI stand for in the context of clinical research?

- A) Public Policy Initiative
- B) Patient and Public Involvement**
- C) Participatory Practice Integration
- D) Peer Participation Involvement

Answer: B; Patient and Public Involvement. The letters E and C may also be used in this context, representing Engagement, and Community.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

True/False questions and solutions

1. The more exclusive the eligibility criteria, the more generalisable the trial findings become.

Answer: **False**; Exclusive criteria reduce generalisability.

2. Trial Forge provides freely accessible resources to support better clinical trial methodology.

Answer: **True**; It is a network of expertise in clinical trial improvements hosting collective resources that can be freely accessed to support better clinical trial methodology, across all stages of the process.

3. Trusted relationships with communities can be built through one-off meetings.

Answer: **False**; Long-term commitment is needed to build trusted relationships.

4. Decentralised clinical trials (DCTs) can help reduce barriers by allowing participants to stay at home.

Answer: **True**; In DCTs some or all activities take place at or near the participant's home, rather than a clinical site.

5. One of the goals of the PerSEVERE principles is to help participants make informed choices about their involvement.

Answer: **True**; "The principles guide everyone involved in research about how to strike this balance. By providing good enough information and support, researchers can help participants make informed choices about their involvement, and by planning for various ways that participants might change how they take part, researchers can make sure the research stay on track".

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.1: Jensen J, Johansen ND, Mathioudakis AG, Biering-Sørensen T, Sivapalan P. The silent exclusion: rethinking eligibility and generalizability in clinical trials. *Lancet Reg Health West Pac* [online] 2025; 61:101605. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1016/j.lanwpc.2025.101605>

The silent exclusion: rethinking eligibility and generalizability in clinical trials

Jens-Ulrik Jensen,^{a,b} Niklas Dyrby Johansen,^{c,d} Alexander G. Mathioudakis,^{e,f} Tor Biering-Sørensen,^{c,d} and Pradeesh Sivapalan^{a,b,*}



Key points for the teacher:

- This article describes that trial eligibility, and especially undocumented prescreening, leads to “silent exclusion” of many real-world patients, weakening generalisability.
- Written inclusion and exclusion criteria alone do not inform the clinician who actually entered, stayed in and was analysed in a trial.
- There is a systematic under-representation of older adults and people with multimorbidity, polypharmacy, cognitive impairment and other common complexities of routine care.
- A COPD example shows how strict criteria can exclude almost an entire typical outpatient population, illustrating the gap between trials and practice.
- To address this, the authors call for broader, more clinically realistic eligibility with exclusions for safety clearly justified and for transparent reporting of prescreening losses.

6.1: Titz M, Schwameis M, Kienbacher C, Buchtele N, Roth D, Duma A, Nagele P, Schörgenhofer C, Herkner H. Generalisability of randomised trials evaluating perioperative β -blocker therapy in noncardiac surgery. *Br J Anaesth* [online] 2020; 125(6):926-934. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1016/j.bja.2020.08.006>

BJA

British Journal of Anaesthesia, 125 (6): 926–934 (2020)

doi: 10.1016/j.bja.2020.08.006

Advance Access Publication Date: 2 September 2020

Cardiovascular

CARDIOVASCULAR

Generalisability of randomised trials evaluating perioperative β -blocker therapy in noncardiac surgery

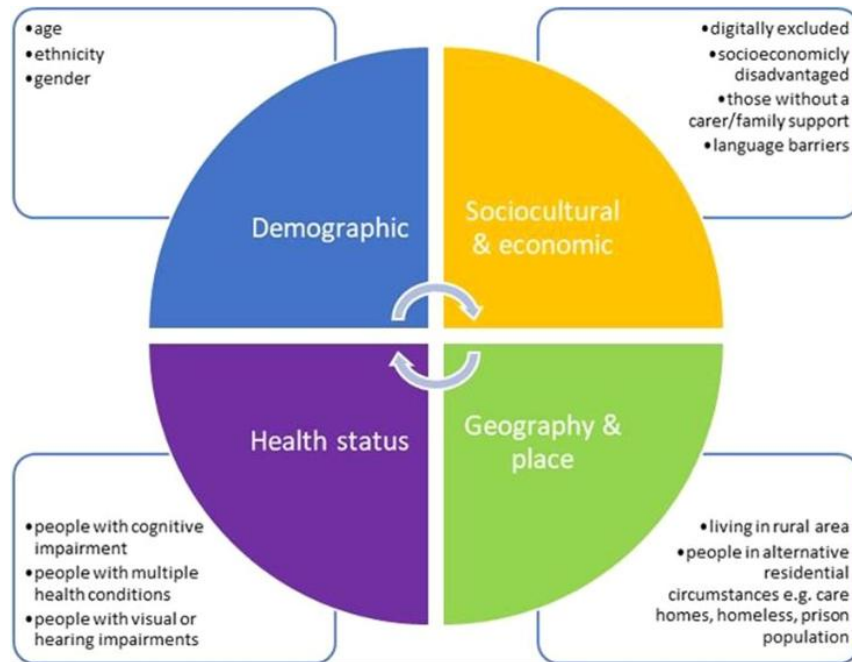
Key points for the teacher:

- This paper argues that the evidence base for perioperative beta-blockers in noncardiac surgery is often hard to apply in routine care because the trial populations are highly selected.
- The study was triggered by the authors' own recruitment failure in a planned RCT, where only one patient out of more than 2,200 screened could be enrolled, raising doubts about how “real” typical trial participants are.
- They then prospectively screened 2,241 elective noncardiac surgery patients and tested how many would have met the published inclusion and exclusion criteria of 36 RCTs from a major Cochrane review. Across those trials, eligibility ranged from 53% down to 0%, and the average proportion of patients who matched trial criteria was only 6.5%. For 31 of the 36 trials, fewer than 10% of real-world patients would have been eligible, and for 11 trials, nobody in the cohort would have qualified at all.
- The main reasons for ineligibility were restrictions on surgery type, baseline cardiovascular risk or coronary disease, current beta-blocker use, asthma or COPD, age limits, heart failure, and ASA physical status.
- Using the PRECIS-2 tool, the authors show that most trials were strongly explanatory rather than pragmatic, and that higher pragmatism scores were linked to better real-world eligibility. Importantly, larger sample size did not mean better generalisability. They also highlight that many trials do not report how many patients were screened, which makes it difficult to judge representativeness and the scale of screen failures.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.1: Figure 1. Intersectional factors that can contribute to the exclusion of older people from health and social care research [Source: Goodwin et al., 2023, licensed by CC BY-NC 4.0].



Key points for the teacher:

- The image is an “intersectionality” diagram showing how several overlapping factors can lead to older people being excluded from health and social care research. It is drawn as a four-part circle, with each quadrant representing a category of barriers. These four barriers are:
 - **Demographic** (with examples such as age, ethnicity, and gender)
 - **Sociocultural & economic** (including digital exclusion, socioeconomic disadvantage, lack of carer or family support and language barriers)
 - **Geography & place** (for example living in a rural area or in alternative residential circumstances such as care homes, homelessness or prison)
 - **Health status** (including cognitive impairment, multiple health conditions and visual or hearing impairments).
- The overall message is that exclusion is rarely due to a single reason. It often happens because several disadvantages stack together and create practical and structural barriers to participation.

6.1: Dawson S, Banister K, Biggs K, Cotton S, Devane D, Gardner H, Gillies K, Gopalakrishnan G, Isaacs T, Khunti K, Nichol A, Parker A, Russell AM, Shepherd V, Shiely F, Shorter G, Starling B, Williams H, Willis A, Witham MD, Treweek S. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice. Trials [online] 2022; 23:672. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1186/s13063-022-06553-w>

METHODOLOGY

Open Access



Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice

Shoba Dawson¹, Katie Banister², Katie Biggs³, Seonaidh Cotton², Declan Devane⁴, Heidi Gardner², Katie Gillies², Gosala Gopalakrishnan⁵, Talia Isaacs⁶, Kamlesh Khunti^{7,8}, Alistair Nichol⁹, Adwoa Parker¹⁰, Amy M. Russell¹¹, Victoria Shepherd¹², Frances Shiely¹³, Gillian Shorter^{14,15}, Bella Starling^{16,17}, Hywel Williams¹⁸, Andrew Willis¹⁹, Miles D. Witham²⁰ and Shaun Treweek^{2*}

Key points for the teacher:

- This Trial Forge guidance explains that ethnic minority groups are often under-represented in randomised trials not because they are explicitly excluded, but because everyday design and delivery choices create practical barriers and reduce trust.
- The key point is that inclusion has to be planned from the start, monitored during delivery and properly resourced.
- Trial teams should understand who is affected by the condition, involve relevant communities, set and track recruitment and retention goals by ethnicity and routinely collect and report ethnicity data.
- The guidance recommends checking eligibility criteria and recruitment pathways for unintended exclusion, producing materials that are clear and accessible with high-quality translation and interpretation, training and supporting staff to reduce bias in recruiter behaviour and building long-term, fairly-funded partnerships with community organisations.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.2: Wallace N, O'Keeffe S, Gardner H, Shiely F. Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability. *J Clin Epidemiol* [online] 2023;162:81-89. [Accessed Nov 28th 2025]. Available from: <https://doi.org/10.1016/j.jclinepi.2023.08.008>



Journal of Clinical Epidemiology 162 (2023) 81–89

**Journal of
Clinical
Epidemiology**

METHODOLOGICAL CONSIDERATIONS RELATED TO EQUITY, DIVERSITY, AND INCLUSION IN CLINICAL EPIDEMIOLOGY

Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability

Neil Wallace^a, Stacey O'Keeffe^a, Heidi Gardner^b, Frances Shiely^{a,c,d,*}

Key points for the teacher:

- This paper describes that ethnicity data in randomised trials are still recorded and reported inconsistently, which weakens inclusivity and makes it harder to judge whether findings apply to the populations most affected.
- The authors reviewed 407 NIHR trial reports (2016 – 2021) and assessed whether ethnicity was recorded, how it was collected, which categories were used, and how it was reported.
- They found that ethnicity was recorded and reported in roughly two-thirds of trials, but clear “good practice” (showing both recording and reporting methods) was uncommon.
- Reporting often did not match what was recorded, with frequent collapsing of categories, omission of some groups, or oversimplification such as “White vs non-White” without justification.
- The paper notes that simply listing of ethnicity in baseline tables is not enough, because it does not support interpretation of whether effects differ across ethnic groups.
- Ethnicity was almost never addressed in plain language summaries, which may reduce transparency and trust for under-served communities.
- The main recommendation of authors is to standardise ethnicity collection and reporting, plan for diverse recruitment and retention from the protocol stage, and strengthen requirements so ethnicity data are transparently captured, analysed, and reported.

6.2: Morris L, Dumville J, Treweek S, Miah N, Curtis F, Bower P. Evaluating a tool to improve engagement and recruitment of under-served groups in trials. *Trials* [online] 2022; 23:867. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1186/s13063-022-06747-2>

METHODOLOGY

Open Access



Evaluating a tool to improve engagement and recruitment of under-served groups in trials

Lydia Morris^{1,2*}, Jo Dumville^{1,3}, Shaun Treweek⁴, Nasima Miah⁵, Ffion Curtis⁵ and Peter Bower^{1,6}

Key points for the teacher:

- The paper evaluates the INCLUDE Ethnicity Framework as a practical tool to help trial teams improve engagement and recruitment of under-served groups, especially ethnic minority communities.
- It reports that most researchers agree that inclusion matters for both fairness and scientific quality, but their confidence and knowledge vary widely.
- In a survey of NIHR-funded trial teams, many said under-served groups were relevant to their trial and most described using public and community involvement and engagement (PCIE) groups as their main inclusion strategy. However, researchers frequently admitted that their PCIE groups were often not very diverse.
- In interviews, some trialists said the Framework was useful because it prompted them to notice who their design might unintentionally exclude. At the same time, many found it long and hard to translate open questions into concrete actions, and some felt they were using it too late in the process to make meaningful changes.
- They also highlighted structural barriers they could not fix alone, such as unequal access to services, tight timelines and limited budget for translation, accessible materials, outreach or additional sites.
- The study also worked with community contributors to produce practical guidance on how to involve diverse PCIE partners, stressing early involvement, trusted routes for first contact, clear explanations and respect for people's time and priorities.
- Table 1 shows the Summary of key survey results.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.3: Jameson C, Haq Z, Musse S, Kosar Z, Watson G, Wylde V. Inclusive approaches to involvement of community groups in health research: the co-produced CHICO guidance. Res Involv Engagem [online] 2023; 9:76. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1186/s40900-023-00492-9>

RESEARCH

Open Access

Inclusive approaches to involvement of community groups in health research: the co-produced CHICO guidance

Catherine Jameson^{1,2}, Zehra Haq³, Samira Musse⁴, Zahra Kosar⁴, Gloria Watson⁵ and Vikki Wylde^{1,2*}

Key points for the teacher:

- The paper introduces The CHecklist for Inclusive Community involvement in health research (CHICO). It is a co-produced checklist to help researchers involve racially marginalised communities in health research in a genuinely inclusive way.
- Standard involvement approaches often exclude these groups through jargon, rigid meeting formats, online-only methods, inconvenient timing, and lack of interpretation or translation.
- The checklist was developed through repeated engagement with three community groups in Bristol, with researchers visiting people in their own spaces rather than expecting them to come to academic settings.
- Checklist items are grouped into three stages (see Table 1):
 1. building relationships,
 2. reciprocal relationships and
 3. practicalities.
- A key teaching point is that trust takes time and communities feel used when researchers do not return with updates or visible impact. CHICO therefore emphasises regular contact, open conversations and learning what matters to the group before asking for formal input.
- Reciprocity is central: people's time is valuable and "giving back" should be meaningful to the community, not just tokenistic.
- Practical guidance includes using plain language, choosing accessible venues and times, arranging translation and budgeting for transport and other access needs. It also notes that food and informal social time can be important for participation and relationship-building in community contexts.

6.3: Figure 1. Illustration of the CHICO study findings [Source: [Jameson et al., 2023](#) licensed by [CC BY 4.0](#)].



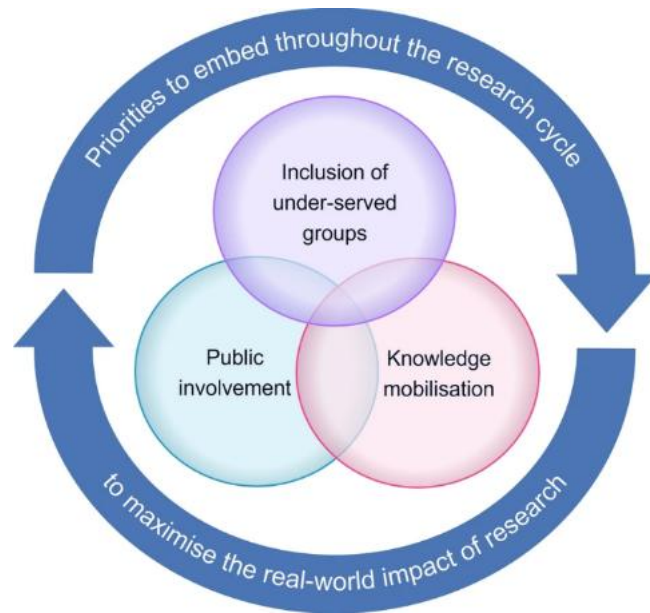
Key points for the teacher:

- The picture is an infographic about community engagement in health research, titled "Health Research: Working with Us". It illustrates the CHICO study findings.
- It uses drawings and short phrases to show what communities want from researchers. Key messages include "The community is the expert", "Research needs to come to the community", and "People's time is valuable", with an emphasis on "Giving back" and "Keeping participants updated".
- It highlights also building trust through "Getting to know each other", "Sharing information", and making "Regular visits". It also calls for practical support such as "Transport" and "Arranging translation" and communication that avoids jargon.
- A central idea is that community groups act as a bridge between researchers and the community. Near the bottom, the picture notes that "Food is very important" and encourages researchers to check "Community interests" and "Health issues".

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.3: Figure 2. The concepts of inclusion of under-served groups, public involvement, and knowledge mobilisation [Source: [Anderson et al., 2024](#) licensed by [CC BY 4.0](#)].



Key points for the teacher:

- The picture is a diagram showing three connected priorities in research.
- In the centre, there is a Venn diagram with three overlapping circles labelled:
 - Inclusion of under-served groups
 - Public involvement
 - Knowledge mobilisation.
- The overlaps suggest these areas reinforce each other and should be planned together rather than treated as separate activities.
- Surrounding the Venn diagram is a large circular arrow, indicating an ongoing cycle. Text on the arrow says these are priorities to embed throughout the research cycle and that doing so helps to maximise the real-world impact of research.

6.4: Alexander W. The uphill path to successful clinical trials: keeping patients enrolled. P T. [online] 2013; 38(4):225-7. [Accessed 16th Oct 2025]. Available from: <https://pubmed.ncbi.nlm.nih.gov/23785228/>

The Uphill Path to Successful Clinical Trials Keeping Patients Enrolled

Walter Alexander

Key points for the teacher:

- The article presents that drug approval is becoming harder partly because modern trials must collect longer-term, outcome-based data, which makes enrolment and retention more difficult.
- In Phase 3, drop-out rate can be high, sometimes above 30%, and once participants leave, missing data starts to weaken how confident researchers can be about safety and efficacy.
- Although “reducing participant burden” sounds simple, trials have become more complex because sponsors aim to capture extensive data for both current and future analyses. It points to a long-term rise in protocol and operational load, including longer trial durations, more procedures and much larger case report forms and consent documents. Some of this is linked to regulatory expectations for “hard” clinical outcomes rather than surrogate endpoints, especially after historical examples where surrogate improvements did not translate into real clinical benefit.
- The article also describes a trust and motivation problem, noting declining confidence in regulators, industry, and even clinicians, which can reduce willingness to participate.
- Successful trials require a genuine partnership between sponsors, sites and participants, with retention planned as carefully as recruitment.
- Suggested strategies include cutting unnecessary visits where possible through direct data capture and treating consent as the start of an ongoing relationship rather than a once-signed form. The paper also mentions the importance of continuing the follow-up even if a participant stops the study treatment.
- Compensation for voluntary participants is discussed as ethically acceptable when it is approved and non-coercive, alongside practical supports such as travel reimbursement, reminders and help with logistics like transport or childcare.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.4: Figure 1. A non-exhaustive overview of the components of decentralised clinical trials (DCTs). ePRO, electronic Patient-Reported Outcome; IMP, Investigational Medicinal Product [Source: reproduced from [Zuidgeest et al., 2025](#) licensed by [CC BY-NC 4.0](#)].



Key points for the teacher:

- The picture is an infographic that summarises what a decentralised clinical trial can look like.
- It uses simple icons to illustrate eight components:
 - online recruitment and prescreening (icon of a pc display),
 - remote consent (video call icon),
 - remote trial visits (telemedicine icon),
 - direct-to-patient shipment of the investigational medicine and study materials (house with delivery icon),
 - at-home collection of biological samples (finger-prick icon),
 - self-reporting of events and ePROs on a phone/tablet,
 - data collection via sensors and wearables (apps and phone icon),
 - use of local health services such as nearby clinics or hospitals (medical building icon).
- Overall, the diagram communicates that many trial activities can be done remotely or locally instead of requiring participants to travel to a central study site.

6.4: Zuidgeest MGP, Heath M, Lagerwaard B, van Weelij DR, Rutgrink L, Hanke S, Vedenkannas T, Kosonen T, Collamati S, Fons-Martínez J, Veen D, Gardarsdóttir H, Mackenzie IS, Dupont S, Grobbee DE and the Trials@Home consortium. Bringing Trial Activities to Participants—The Trials@Home RADIAL Proof-of-Concept Trial Investigating Decentralization of Trials. Clin Pharmacol Ther [online] 2025. [Accessed 16th Oct 2025]. Available from: <https://doi.org/10.1002/cpt.70025>

Bringing Trial Activities to Participants—The Trials@Home RADIAL Proof-of-Concept Trial Investigating Decentralization of Trials

Mira G.P. Zuidgeest^{1,*}, Megan Heath², Bart Lagerwaard¹, Danny R. van Weelij³, Linda Rutgrink⁴, Sten Hanke⁵, Tea Vedenkannas⁶, Taru Kosonen⁶, Stefania Collamati⁷, Jaime Fons-Martínez^{8,9}, Duco Veen^{3,10}, Helga Gardarsdóttir^{11,12,13}, Isla S. Mackenzie¹⁴, Sabine Dupont¹⁵, Diederick E. Grobbee¹ and on behalf of the Trials@Home consortium[†]

Key points for the teacher:

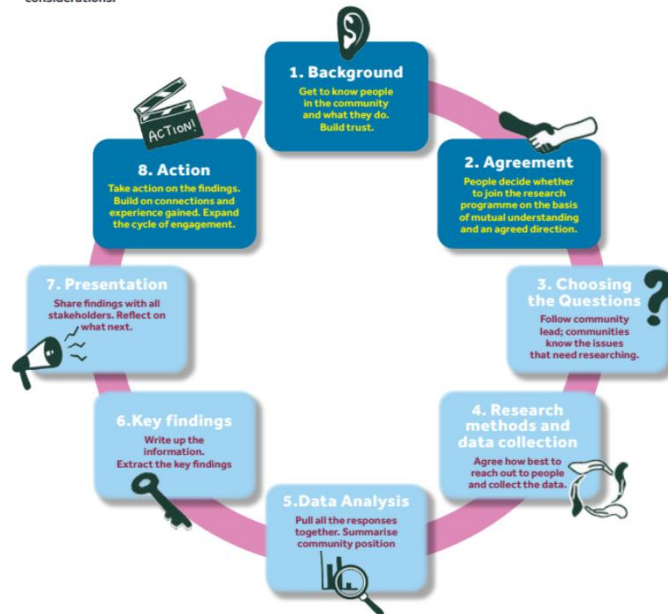
- The article describes the Trials@Home RADIAL study as a European proof-of-concept trial designed to test whether decentralised and hybrid trial delivery is feasible, acceptable, and produces usable data compared with a conventional site-based approach.
- It is run in people with type 2 diabetes across six European countries and uses the same clinical treatment in every arm, while varying the method of how the trial is delivered. The three arms are conventional site-based, hybrid, and fully remote (see in Figure 2).
- The decentralised activities include online recruitment and prescreening, remote e-consent, telemedicine or home nurse visits, and shipping study medication and materials directly to participants. Participants can collect certain samples at home and report events and electronic patient reported outcomes through a study app.
- The trial also uses connected devices such as a glucometer and a smart insulin cap to capture glucose and adherence data remotely.
- Instead of focusing on clinical efficacy, the main outcomes are key performance indicators like recruitment, retention, diversity, participant and site satisfaction, cost, safety oversight, adherence, missing data and query rates (see in Table 1).
- Results, insights and recommendations are not provided in this paper, they are part of subsequent manuscripts of the RADIAL series.

UNIT 6: EQUITABLE PARTICIPATION IN TRIALS FOR UNDER-SERVED GROUPS THROUGH RECRUITMENT AND RETENTION

Articles, pictures outlines

6.5: Figure 1. The 8 stages of participatory action research (PAR) [Source: [Lloyd-Evans et al., 2023](#), licensed by [CC BY-NC-SA 4.0](#)].

A step-by-step guide through a PAR journey from the perspective of community researchers and academics, setting out reflections on the process and practical considerations.



The 8 Stages of Participatory Action Research

Key points for the teacher:

- The picture is a circular diagram showing the eight stages of participatory action research, presented as a repeating cycle. The stages are:
 - **Background** – getting to know people in the community and building trust.
 - **Agreement** – deciding whether to work together and agreeing on a direction.
 - **Choosing the questions** – communities help lead on defining what issues need researching.
 - **Research methods and data collection** – agreeing how to reach people and collect data.
 - **Data analysis** – pulling responses together and summarising the community perspective.
 - **Key findings** – writing up and extracting the main messages.
 - **Presentation** – sharing findings with stakeholders and reflecting on next steps.
 - **Action** – taking action based on findings, building connections, and extending the cycle of engagement.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

General overview of the unit for the teacher

OBJECTIVES

The aim of this unit is to move students from conceptual understanding to applied decision-making. The unit is demonstrating how inclusive trial design, monitoring, and transparent reporting protects patients, reduces research waste, and strengthens the evidence base. The unit also focuses on using established tools and standards to ensure trials are fit for purpose.

UNIT CONTENT

- 7.1: Poor quality clinical trials – the problem of research waste
- 7.2: Monitoring who is in the clinical trial
- 7.3: Good quality data collection in clinical trials
- 7.4: Standards for transparent reporting
- 7.5: Training and monitoring for good clinical practice
- Summary of Unit 7

LEARNING OUTCOMES

Students will be able to:

1. Describe the problem of research waste and its implications for the evidence base
2. Recognise the importance of monitoring and reporting who is recruited and retained in clinical trials
3. Identify some of the tools and standards that clinical trial teams can refer to for guidance, ensuring high-quality reporting
4. Understand the challenges in low-resource settings and some strategies to support the conduct of inclusive trials
5. Explain how transparency in clinical trials reporting can improve quality
6. Define ways of working that support teams in conducting high-quality clinical trials

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 7.1 pre-class; read the commentary of Piroasca <i>et al.</i> on “Tolerating bad health research: the continuing scandal”, with particular focus on the analysis and recommendations; read the editorial of G. M. Sogi on “Research Waste”; complete the reflective activity; test your knowledge.
Tue	Complete Lesson 7.2 pre-class; answer the questions related to NO-LANA study; read the paper by Frampton <i>et al.</i> ; think about the related questions in the pre-class reading; complete the reflective activity; test your knowledge.
Wed	Complete Lesson 7.3 pre-class; complete the reflective activity; test your knowledge.
Thu	Complete Lesson 7.4 pre-class; watch the video on COS reporting importance; look at SPIRIT and CONSORT guidelines and items, with a focus on “Open Science” principles, answer related questions; complete the reflective activity; test your knowledge.
Fri	Complete Lesson 7.5 pre-class; read a study of Barnes <i>et al.</i> ; complete the reflective activity; test your knowledge; read the Summary of Unit 7; complete the MCQs.

OPENING THE LESSON

15' 



 **Word association** – share a keyword from the list below or write it on the board. Ask the students to say the first word/phrase/situation that comes to their mind. List their suggestion on the board.

For example, research waste, transparency, CONSORT guidelines, fit-for-purpose, adaptive design, PRO-EDI, open science.

Ask students to illustrate relationships among them or their role in inclusive trial design and conduct.

At the end, ask students which terms they would like to be explained. Give the other students an initial opportunity to explain. Allow a minute to review the terms, then ask students if they would add or remove anything.

Hints and solutions for the teacher: Optional questions stimulating further discussion:

- *When does a clinical trial become research waste? Who should be responsible for recognising and stopping waste early?*
- *Is transparency mainly about reporting results, or about decision-making throughout the trial?*
- *Fit for purpose for whom: regulators, clinicians, or patients?*

INDEPENDENT WORK

20' 



Task – Sub-study vs. SWAT (10 minutes)

Ask students to summarise several differences and similarities between a sub-study and a SWAT trial. An example of SWAT study is in Unit 6 (on financial incentives), an example of a sub-study is in Lesson 7.2 (NO-LANA sub-study).



Debriefing (10 minutes)

Ask several students to report one key insight (e.g., on sub-study vs. SWAT purpose, scope, design complexity), and illustrate the insight with reference to the sample studies.

Hints and solutions for the teacher:

A sub-study often extends the scientific scope of the main trial, while a SWAT is a methodological experiment focused on improving trial processes. Both are embedded, cost-efficient, and can enhance inclusion, transparency, and evidence quality when well-designed.

TEAM-BASED WORK

45' 



4–8 students per team



Task – Designing for inclusion and transparency (25 minutes)

Ask students to act as a clinical trial team and produce one specific action they would take, one step, tool, or guideline they would rely on in one of the three areas mentioned below, and transform it into a sub-study or SWAT. Students can implement them to one of the previously discussed studies (COMFORT in Unit 6, ILANA in Unit 5 and 7).

- Reducing research waste
- Monitoring who is in the trial
- Reporting for inclusion, transparent monitoring



Debriefing (20 minutes)

Ask each group to give a 2–3 minute report focusing on their approach to an inclusive trial design and conduct, including the short description of a SWAT or a sub-study.

Hints and solutions for the teacher:

- *Reducing research waste can reflect 5 recommendations mentioned by Piroasca *et al.*; check whether students considered them; they are otherwise elaborated in the pre-class reading*
- *Monitoring who is in the trial – feasibility and pilot studies, appropriateness of recruitment strategies, adaptive designs, risk-based monitoring*
- *Reporting – compliance with guidelines, tools, incorporating Core Outcome Set, etc.*

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Blended 90-minute classroom

REFLECTION, WRAP-UP

10'



1. What are the real-world consequences when a trial fails to recruit or retain representative participants?
2. Can you provide examples of how collaboration within the trial team directly affects trial outcomes and evidence quality?
3. Why is it critical to monitor who is recruited and retained in a trial, beyond overall sample size?
4. How can transparency build trust with patients and communities?
5. What would you like to know more about?

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

15'



- “Word association” activity can be modified to live word cloud in Mentimeter, Slido, Miro, or similar apps.
- Sometimes, advance preparation of the poll is necessary – check it in advance of the class.
- Time adjustment is possible (online word association may be faster than writing ideas on board).
- Make a screenshot for each association to be easily able to discuss together later.



Debriefing (20 minutes)

Ask each group to give a 2–3 minute report focusing on their approach to an inclusive trial design and conduct, including the short description of a SWAT or a sub-study.

REFLECTION, WRAP-UP

10'



- Only discussion; no need to collect or write notes.

INDEPENDENT WORK

20'



- Share the link for the corresponding parts of the pre-class reading (unit 6, lesson 7.2) via chat
- Ask students to write notes electronically to be able to share on screen later.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Be available for support, e.g., in the chat.



Debriefing (10 minutes)

A whole group discussion, no need to modify for the online environment.

TEAM-BASED WORK

45'



4–8 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign one facilitator/trained student to each group to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, have technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.
- You can prepare a template of the tasks which the students can collaboratively fill in.
- Ask students to write notes electronically so that they are able to share on screen later. Ask students to select a group leader.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document with columns reflecting the sub-tasks). Advance preparation of such a document is necessary; the students can create their own icon.
- Time adjustment is possible. The presentation of the teams' work may need more time.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Reflective activity 7.1: “Community engagement strategies to promote recruitment and participation in clinical research” modified for synchronous use

Link: [Brockman et al., 2023](#)

Collaboration with community members is a gateway to addressing prevalent health matters by strengthening researchers’ understanding of community priorities.

Read the narrative review by [Tabetha Brockman and colleagues](#) which explores the effectiveness of community engagement strategies with rural communities to promote recruitment and participation in clinical research. Look at the five levels of rural community engagement described in Table 3 of this paper.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by Brockman et al., focusing on Table 3: Levels of community engagement for recruitment. Choose one clinical trial topic (real or hypothetical). Select two different levels of community engagement from Table 3. Write a short reflection (100–150 words). For each selected level, briefly describe:

1. how this level of engagement would look in practice for your chosen trial,
2. what role community members would have,
3. what this level could achieve (and what it might not).

Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions: you can compare examples of lower vs. higher engagement levels and discuss what is gained at each level.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into small teams. Assign each team one clinical trial topic (or allow them to choose, ensuring topics are not duplicated). Each team will work with Table 3 from [Brockman et al.](#) Ask each team to:

1. Briefly describe the chosen clinical trial (population, setting, and purpose).
2. Select two different levels of community engagement from Table 3. For each level, discuss and agree on:
 - What would this level of engagement look like?
 - What role would community members have?
 - What could this level achieve?
3. Prepare a short output (flipchart or slide) comparing the two levels.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their output in three minutes. After each presentation, invite one question or comment from another team.

Conclude with a short whole-class discussion: Are higher levels of engagement always preferable? Why or why not?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start with a brief discussion on why community engagement matters (e.g. recruitment, retention, trust, and the relevance of clinical research).

Project Table 3 (Levels of community engagement for recruitment) from Brockman et al. on the screen.

First, as a class, agree on a clinical trial topic, for example: a trial for diabetes management, a mental health intervention for adolescents, a vaccination trial, a screening study. Assume the trial is conducted with a rural population. Clarify the target population and setting.

Go through the levels of community engagement in Table 3 one by one. For each level, ask students:

- What would this level of engagement look like in our trial?
- What role would community members have?
- What could this level achieve?

Write key points on the board under each level. Invite students to compare levels:

1. Which level seems most feasible in this context?
2. Which level would likely build the most trust?
3. Where do you see tensions between time, funding, and meaningful engagement?

Hints and solutions for the teacher:

- Provide students with printed copies of the table or ensure online access.
- If time is limited, come prepared with one predefined trial scenario.
- Encourage students to ground their answers in practical details (who, when, and resources)
- If discussion stalls, contrast two levels explicitly (e.g. consultation vs. collaboration) and ask what changes between them.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Reflective activity 7.2: “Flexible and adaptive clinical trial design: MAMS” modified for synchronous use

Link: [OCTOPUS clinical trial](#)

The Multi-arm multi-stage (MAMS) platform clinical trial design is a flexible and adaptive approach that has been used globally (UCL, 2025). Click on the [OCTOPUS clinical trial](#) which has implemented a MAMS design. Read about the eligibility of participants for the OCTOPUS study [here](#) and about the intervention [here](#) (in the ISRCTN registry).

MODIFICATION FOR INDIVIDUAL WORK



Part 1: Read about the [OCTOPUS](#) trial. What are the benefits of the adaptable and flexible approaches used in the OCTOPUS study?

Part 2: Review the [eligibility criteria](#). Reflect on the criteria listed and the balance between clinical factors and demographic factors. How might some of these criteria impact people in some of the under-served groups you have learned about during this course?

Part 3: Read about the [intervention and trial procedure](#). Consider how the research team might ensure greater inclusivity at each step of the intervention.

Write a short reflection (100–200 words) integrating your answers across all three parts. Submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



4 students per team

Divide students into small teams. Assign one focus to each student with the team:

- A – Review the [OCTOPUS](#) platform trial design. Identify benefits and consider how these features could support inclusion.
- B – Review the [eligibility criteria](#). How might some of these criteria impact people in some of the under-served groups you have learned about during this course?
- C – Look up key demographic characteristics of MS and compare the real-world population with the trial's target population.
- D – Review the [intervention](#) and follow-up procedures. Consider how the research team might ensure greater inclusivity at each step of the intervention.

After 10–15 minutes, students share their findings within their teams and jointly discuss them. Each team prepares a short summary addressing one strength of the OCTOPUS trial design for inclusion, one potential exclusion risk, and one specific improvement proposal.

Start the timer. Circulate among teams, listen to and stimulate the discussions.

At the end, invite two teams to present their key points in three minutes. Encourage other teams to add similarities or contrasts.

Hints and solutions for the teacher:

- You might provide students with key links (design, ISRCTN registry, basic epidemiological information about the disease, e.g. at the website of the [Multiple Sclerosis Association of America](#)).

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to briefly look at the [OCTOPUS](#) trial website and the [ISRCTN](#) page (or go together through the key sections in class). Discuss together the following questions and write key points on the board.

1. What are the benefits of the adaptable and flexible approaches used in the OCTOPUS study?
2. Looking at the eligibility criteria, are they in line with a real-world population for the disease?
3. Can you identify any criteria that could impact people in some of the under-served groups you have learned about during this course?
4. What might be challenging about taking part in this trial?
5. Which patients might find participation more difficult, and why?
6. If you were part of the research team, what is one change you would consider, to make the trial more inclusive?

To wrap up the discussion, ask students: What is one insight from this discussion that changed how you think about trial design and inclusion?

Hints and solutions for the teacher:

- Project the eligibility criteria and the intervention part of the ISRCTN registry on the screen.
- Question 2: basic epidemiology of multiple sclerosis: most people are diagnosed between the ages of 20 and 50; women are three times more likely than men to develop relapsing forms of MS (equally divided with the primary-progressive form); regional differences; faster progression for older patients
- Questions 3–6: You do not need to cover everything. Depth on two points is enough. Examples: older patients – worse progression – more comorbidities (eligibility), worse mobility issues (intervention); long follow-up – frequent in-person visits may disproportionately exclude patients living in rural areas, or those with severe mobility issues – support for travel, flexible visit schedules, remote assessment, and additional support for adherence and communication

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Reflective activity 7.3: “Sex and gender reporting in clinical trials” modified for synchronous use

Link: [MESSAGE project](#)

Choose one of the case studies presented by the Medical Science Sex and Gender Equity [MESSAGE project](#):

- Case study 1: Cardiovascular disease
- Case study 2: Autism
- Case study 3: Osteoporosis

MODIFICATION FOR INDIVIDUAL WORK



Go through one of the case studies presented by the [MESSAGE](#) project. After that, go to the [ISRCTN registry](#) for clinical trials. Search for studies using “cardiovascular”, “autism” or “osteoporosis” as a search term. Filter for “completed” studies and those with “peer-reviewed results” by choosing these options from the filters on the left-hand side. Of these, look into a relevant study and scroll down until you find the link to the published results.

Scanning the paper or searching for keywords, how are sex and gender approached in this clinical trial? What are the implications of this?

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into small teams. Each team is assigned one case study from the [MESSAGE](#) project. Each team goes to the ISRCTN registry and searches for the disease-related term (apply filters: completed studies, peer-reviewed results available), selects one relevant study, and opens the linked published article.

As a team, discuss and agree on answers to the following questions:

1. How is sex addressed in the trial? (Design, analysis, reporting)
2. Is gender considered or discussed?
3. What are the implications of this approach?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present 3–5 key points summarising their findings.

Hints and solutions for the teacher:

- To save time, assign the article to teams directly.
- If two teams work on the same case study, assign them different clinical trials/articles.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Choose one of the [MESSAGE](#) project case studies. Prepare two completed clinical trials relevant to this case study that differ in how they approach sex and/or gender, for example:

- Study A: sex-disaggregated data reported, subgroup analyses performed
- Study B: sex mentioned only descriptively or not analysed at all

Give students time to go through the selected trials individually or in pairs. Invite students to summarise how sex/gender is approached in these trials.

Use the following questions to structure the discussion:

1. How do the two studies differ in their approach to sex and gender?
2. At which stages of the trial do these differences appear?
3. What might these differences mean for the interpretation of results and their applicability to different populations?
4. Which patient groups might be better or worse served by each approach?

Hints and solutions for the teacher:

- Select the case study and prepare the articles in advance. Provide students with printed copies or ensure online access.
- To assess the sex/gender approach of the trial, focus on design, analysis, and reporting, OR consider reminding students of the recommendations from the SAGER guidelines for each section of the article (Lesson 7.3, Table 2).

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Reflective activity 7.4: “The role of pre-prints in clinical research” modified for synchronous use

Link: [Flanagin et al., 2020](#)

Read the [paper](#) by journal editors at JAMA and JAMA Network, Annette Flanagin and colleagues, discussing the pros and cons of sharing pre-prints involving medical research.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Flanagin et al.](#) Based on your reading, reflect on:

1. the benefits of sharing a pre-print of clinical trial results,
2. negative consequences that may arise following the sharing of pre-print findings from a clinical trial.

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Write down the key benefits and negative consequences from students' answers for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into small teams. Each team reads the paper by [Flanagin et al.](#) and works together on the following tasks:

1. Agree on 2–3 main **benefits** of sharing preprints of clinical trial results. Be specific about who benefits (researchers, patients, clinicians, policymakers).
2. Agree on 2–3 major **risks** or negative **consequences** of sharing preprints involving medical research.
3. **Role-based discussion:** Assign each team member one perspective (e.g. researcher, clinician, patient, journalist, regulator). Discuss how preprints might be interpreted differently from each perspective.
4. As a team, prepare a **short statement** (2–3 sentences): Under what conditions, if any, should preprints of clinical trial results be shared?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present its statement.

Conclude with a whole-class discussion comparing team positions and reflecting on how preprints may affect trust, clinical decision-making, and research integrity.

Hints and solutions for the teacher:

- Provide students with printed copies of the paper or ensure online access.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Step 1: Present the statement on the screen: “Clinical trial results should be shared as preprints before peer review.”

Ask students to take a position: stand on the left side of the room if they agree, on the right side if they disagree, and in the middle if they are unsure. Invite 2–3 students from different positions to briefly explain why they chose their place.

Step 2: Ask students to read the paper by [Flanagin et al.](#), focusing on the benefits of preprints, their risks and unintended consequences.

Step 3: Ask students to take a position again after reading the article. Prompt brief reflections: Did anyone change position? Why? Which argument influenced you the most?

Step 4: Facilitate a whole-class discussion using the following questions:

1. Which risks are specific to clinical trials compared to other fields?
2. Who is most vulnerable to harm from misinterpreted preprints?
3. Are there situations where preprints are more acceptable?
4. What safeguards could reduce risk while keeping benefits?

Hints and solutions for the teacher:

- Provide students with printed copies of the paper or ensure online access.
- **Benefits:** Consider aspects such as speed of dissemination (valuable in public health emergencies or fast-moving research areas), transparency, early feedback, public engagement, and scientific collaboration.
- **Consequences:** Think about issues like quality assurance, interpretation by non-experts (influence patient behaviour or treatment decisions), impact on public trust if results later change, policy decisions based on preliminary evidence, and media amplification.
- Emphasise that the article does not give a yes/no answer, but frames preprints as a conditional tool.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Reflective activity 7.5: “Guidelines for the consent process – a patient-centric shift” modified for synchronous use

Link: [New Informed Consent Guidelines for Clinical Trials](#)

As you have learned, the International Council for Harmonisation (ICH) E6(R3) GCP Guideline was recently updated (ICH, 2025). Watch, listen to, or read the transcript of this short [video](#) (06:10) from Whitehall Training about shifts in the consent process.

“Good clinical practice is always on the move.”

Reflect on the key messages in the video and consider how there are opportunities to better serve under-served groups during the consent process shifts in the updated guideline:

- High quality of communication and dialogue around consent information. “less like a text book and more like a real conversation”.
- Leverage technology to meet the needs of participants.
- Participants’ rights to know what happens to their data, what the clinical trial accomplished, and what their contribution really meant in the end.

Remember that patients value plain language, two-way conversation, time to decide, and knowing what happens to their data. These build safety and dignity.

MODIFICATION FOR INDIVIDUAL WORK



Watch the [video](#) and reflect on the three key pillars in the video: clarity, flexibility, and protections. Consider how there are opportunities to better serve under-served groups during the consent process shifts in the updated guideline. Give an example using one specific under-served group.

Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. The results may be useful for later class discussions.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Ask teams to work together on the following tasks:

1. Identify two key messages from the video about how the consent process is changing under ICH E6(R3).
2. Choose one under-served group discussed during the course. Explain how the updated approach to consent could better meet the needs of this group.
3. Give one specific example of how informed consent could be implemented differently in a real clinical trial.
4. Briefly reflect on how these changes might affect participants’ sense of safety, dignity, or trust in research.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present the key points of their discussion in three minutes.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly remind students of the Good Clinical Practice guideline and its recent update, ICH E6(R3).

Watch the [video](#) together. After that, use the following questions to guide the discussion:

1. What is changing in the consent process?
2. Who benefits the most from these changes?
3. What could consent look like in a real clinical trial if it were “less like a textbook and more like a real conversation”?
4. How could technology help, and where might it exclude some participants?
5. Why might it matter to participants to know what happened to their data and what the trial achieved?

To conclude, ask students to share one takeaway: One thing they would change about consent if they were designing a clinical trial.

Hints and solutions for the teacher:

- *Three key pillars in the video:*
 - *Clarity – It is no longer about comprehensive information only, but it must be understandable for any participant.*
 - *Flexibility – The process must be accessible and adaptable (also acknowledging the technological shifts, i.e. remote consent, remote witness, e-signatures).*
 - *Protections – Participants have a right to know what happens to their data and what the trial accomplishes.*
- *Question 2: Link this question to under-served groups. Consider, e.g., the health literacy, language barriers, remote consent, trust, and power imbalance.*
- *Question 5: How could this influence willingness to participate in future research?*

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Multiple-choice questions and solutions

1. Which of the following best describes research waste?

- A) Efficient and reliable practices
- B) Practices that fail to deliver useful results**
- C) Overuse of statistical methods
- D) Excessive participant recruitment

Answer: B; Research waste is described as practices that are inefficient, unnecessary, or fail to deliver results that are reliable or useful.

2. What do Clinical Trial Recruitment Support Systems (CTRSS) use to identify eligible patients?

- A) Manual notes reviews
- B) Social media data
- C) Electronic health records (EHRs)**
- D) Insurance data

Answer: C; Electronic health records (EHRs).

3. What does the PRO-EDI tool recommend considering when designing inclusive clinical trials?

- A) Age, sex, gender and ethnicity
- B) Socioeconomic status
- C) Ethnicity and sex
- D) Sex, gender, ethnicity, age, socioeconomic status, and location**

Answer: D; Six core characteristics are recommended by PRO EDI for reporting (Sex, gender, ethnicity, age, socioeconomic status, and location).

4. What is a pre-print in the context of clinical research?

- A) A complete manuscript shared openly before peer review or journal publication**
- B) A draft shared among researchers working in a related clinical area
- C) A manuscript that has been peer-reviewed and published
- D) A summary of trial results for media release

Answer: A; A complete manuscript shared openly before peer review or journal publication.

5. What is risk-based monitoring (RBM) in clinical trials?

- A) A method for recruiting participants
- B) A strategy using technology and data analytics to monitor safety and data quality**
- C) A review of budgets throughout the duration of the clinical trial to prevent over-spending
- D) A way to eliminate trial documentation

Answer: B; A strategy using technology and data analytics to monitor safety and data quality.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Recap multiple-choice questions and solutions

1. According to Doug Altman, what contributes to the degradation of the evidence base?
- A) Overuse of randomisation
 - B) Lack of quality reporting and transparency**
 - C) Too many multinational trials
 - D) Excessive funding

Answer: B; Without transparently reported quality information, the evidence base is unreliable.

2. What type of trial design allows multiple treatments and stages to be tested flexibly?
- A) Single-arm trial
 - B) Observational study
 - C) Multi-arm multi-stage (MAMS) trial**
 - D) Case-control study

Answer: C; Multi-arm multi-stage (MAMS) trial.

3. Why is it important to report characteristics such as sex, gender, and ethnicity in clinical trials?
- A) To reduce trial costs
 - B) To be able to apply the findings to broader populations**
 - C) To simplify the data analysis at the end of the trial
 - D) To avoid ethical review

Answer: B; To be able to apply the findings to broader populations.

4. What trend is emerging among funders, journals, and regulators regarding clinical trial reporting?
- A) Reducing reporting requirements to speed up clinical trial publication
 - B) Eliminating demographic data collection
 - C) Encouraging anonymous reporting
 - D) Mandating standards for transparency and informativeness**

Answer: D; Mandating standards for transparency and informativeness.

5. Why is building inclusive teams in clinical trials important?
- A) It reduces clinical trial costs
 - B) It increases the likelihood of publication
 - C) It better reflects the community and improves participant representation**
 - D) It simplifies data analysis

Answer: C; It better reflects the community and improves participant representation.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

True/False questions and solutions

1. Transparency and high-quality information in clinical trials are essential for generating reliable evidence and identifying gaps in research.

*Answer: **True**; Without transparently reported quality information, the evidence base is unreliable.*

2. Collecting demographic data on participants can help identify why under-served groups withdraw from trials.

*Answer: **True**; Monitoring who is recruited and retained can identify patterns and allow teams to adapt their strategies for better inclusion.*

3. The SAGER guidelines recommend that sex and gender should only be considered in the discussion section of a research article.

*Answer: **False**; SAGER guidelines should be considered at all stages.*

4. SPIRIT and CONSORT guidelines aim to improve transparency and quality in health research.

*Answer: **True**; SPIRIT and CONSORT provide clear guidance on what to include in the clinical trial protocol and the items to be reported in the trial.*

5. Good Clinical Practice (GCP) is a guideline about clinical trial reporting standards.

*Answer: **False**; GCP covers conduct, performance, monitoring, auditing, recordkeeping, analysis, and reporting.*

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.1: Piroscas S, Shiely F, Clarke M, Treweek S. Tolerating bad health research: the continuing scandal. *Trials* [online] 2022; 23:458. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1186/s13063-022-06415-5>

COMMENTARY

Open Access



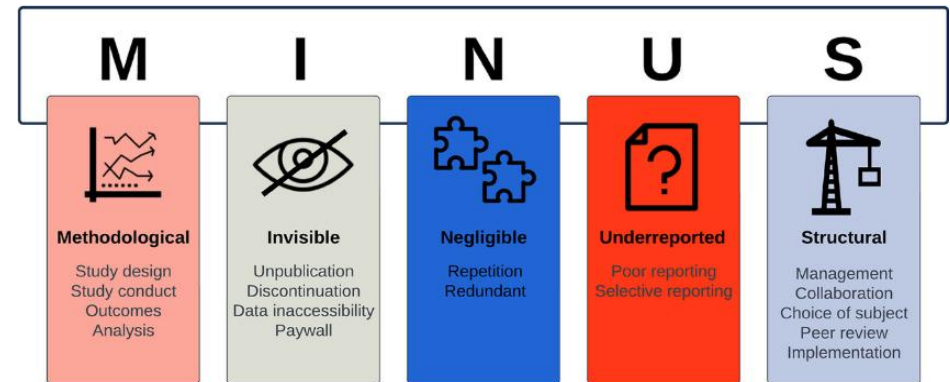
Tolerating bad health research: the continuing scandal

Stefania Piroscas¹, Frances Shiely^{2,3}, Mike Clarke⁴ and Shaun Treweek^{1*}

Key points for the teacher:

- The article focuses on the analysis of randomised controlled trials and explains that bad health research is not a rare exception but a systemic and long-standing failure. By examining over 1,600 trials from recent Cochrane reviews, the authors show that most trials were judged high risk of bias, meaning the majority of evidence used in healthcare is methodologically weak.
- More than half of all participants were enrolled in these flawed studies, which raises ethical concerns because people contribute to research that may not produce reliable knowledge.
- The financial cost of these bad trials is enormous, representing a major waste of public resources. The authors stress that their estimate is conservative because they only measured bias and did not evaluate whether trials asked important or relevant questions.
- Many of the problems are preventable and often simple to fix at the design stage. The paper proposes five reforms, including mandatory involvement of statisticians and methodologists, stricter ethical oversight and the use of bias assessment tools during trial planning. It also calls for more training and funding in research methodology.
- Poor trial design is presented as an ethical failure as well as a scientific one.

7.1: Figure 1. Five main aspects of research waste: Methodological, Invisible, Negligible, Underreported, and Structural research waste (MINUS) [Source: Rosengaard et al., 2024 licensed by CC BY-NC 4.0).



Aspects of research waste

Key points for the teacher:

- The image is an infographic titled "Aspects of research waste", showing five categories summarised by the acronym **MINUS**. Each letter corresponds to a coloured box with an icon and examples of problems that lead to research waste:
 - **M – Methodological** (pink): issues with study design, study conduct, outcomes, and analysis
 - **I – Invisible** (grey): unpublished research and inaccessible data behind paywalls
 - **N – Negligible** (blue): research that is trivial or redundant
 - **U – Underreported** (red): selective or incomplete reporting of results
 - **S – Structural** (light blue): systemic problems such as management failures, collaboration issues, choice of subject, peer review, and implementation

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.1: Sogi GM. Research waste. Contemp Clin Dent [online] 2023; 14:179 [Accessed 10th Nov 2025]. Available from: https://doi.org/10.4103/ccd.ccd_434_23

EDITORIAL

Research Waste

Sogi, G. M.¹

[Author Information](#) 

Contemporary Clinical Dentistry 14(3):p 179, Jul-Sep 2023. | DOI: 10.4103/ccd.ccd_434_23 

Key points for the teacher:

- A substantial proportion of research waste arises when studies are initiated without thoughtful prioritisation by researchers and funding bodies.
- Over half of research is unpublished or flawed, and up to 85% of research investment may be lost due to correctable weaknesses.
- At the 2015 Edinburgh conference, the REWARD alliance (REduce research Waste And Reward Diligence) was established with the goal of reducing waste and increasing the value of biomedical research.
- Even small improvements in planning, methodology, transparency, and reporting could generate major benefits for patients and public health.
- Researchers, funders, institutions, journals, and research users must all act to improve quality through systematic oversight across the entire research process.

7.1: Khoja A, Kazim F, Ali NA. Barriers to Conducting Clinical Trials in Developing Countries. Ochsner J [online] 2019; 19 (4). [Accessed Dec 19th 2025]. Available from: <https://doi.org/10.31486/toj.19.0068>

Barriers to Conducting Clinical Trials in Developing Countries

Adeel Khoja, MSc, MBBS,¹ Fizzah Kazim, MBBS,² Naureen Akber Ali, MSc, BScN³

¹Department of Medicine, Aga Khan University, Karachi, Pakistan ²Dow Medical College, Dow University of Health Sciences, Karachi, Pakistan ³School of Nursing and Midwifery, Aga Khan University, Karachi, Pakistan

Key points for the teacher:

- Despite carrying a high burden of disease, low- and middle-income countries (LMICs) host only a tiny fraction of global trials, creating a mismatch between health needs and research activity.
- A 2018 study revealed a staggering difference in clinical trial sites; approximately 83% of trials had been conducted in 25 high-income countries, whereas < 5% had been conducted in 91 LMICs.
- Limited funding, a shortage of trained staff, loss of experts to other countries, and slow or complicated regulations make it hard to run clinical trials in LMICs.
- Strengthening research infrastructure, education, ethical frameworks, and partnerships between high-income countries and LMICs is essential to build sustainable clinical trial capacity.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.1: Figure 2. Processes within the clinical trial system [Source: [Trial Forge, 2025](#)].



Key points for the teacher:

- This image is an infographic showing the key processes in the clinical trial system. Each block represents a stage or function that is needed for the successful completion of a clinical trial and is shown as a coloured square with a simple icon.
- These blocks include:
 - Identifying trial staff
 - Choosing the right design
 - Feasibility and pilot work
 - Obtaining funding
 - Logistical planning for trial delivery
 - Data management
 - Managing and monitoring trial sites
 - Writing and publishing the protocol
 - Training and motivating trial staff
 - Choosing the right research question
 - Recruitment and retention
 - Data collection
 - Analysis
 - Closing down the trial

7.2: Farooq HZ, Apea V, Kasadha B, Ullah S, Hilton-Smith G, Haley A, Scherzer J, Hand J, Paparini S, Phillips R, Orkin CM. Study protocol: the ILANA study – exploring optimal implementation strategies for long-acting antiretroviral therapy to ensure equity in clinical care and policy for women, racially minoritised people and older people living with HIV in the UK – a qualitative multiphase longitudinal study design. *BMJ Open* [online] 2023;13:e070666. [Accessed 10th Nov 2025]. Available from: <https://bmjopen.bmj.com/content/13/7/e070666>

Study protocol: the ILANA study – exploring optimal implementation strategies for long-acting antiretroviral therapy to ensure equity in clinical care and policy for women, racially minoritised people and older people living with HIV in the UK – a qualitative multiphase longitudinal study design

Hamzah Z Farooq^{1, 2, 3, 4}, Vanessa Apea^{1, 2, 3, 4}, Bakita Kasadha⁵, Sadna Ullah^{1, 2, 3}, Gill Hilton-Smith⁶, Amber Haley⁶, Jenny Scherzer⁶, James Hand^{2, 3}, Sara Paparini^{2, 7}, Rachel Phillips⁸, Chloe M Orkin^{1, 2, 3, 4}

Correspondence to Professor Chloe M Orkin; c.m.orkin@qmul.ac.uk

Key points for the teacher:

- The ILANA study protocol looks at how long-acting injectable HIV treatment can be introduced into everyday healthcare in a way that is practical and fair. A key focus is on groups that are often under-represented in clinical research, especially women, racially minoritised people, and older adults. The study deliberately builds diversity into its recruitment.
- It compares administering injections in hospital clinics and in community settings to understand what works best, what patients prefer, and what challenges healthcare teams face.
- The researchers use a mix of surveys, interviews, and routine clinical data to capture both patient experiences and provider perspectives over a year.
- A separate sub-study addresses why some eligible people decline to take part, helping to uncover barriers to research participation that are usually invisible.
- The project is closely shaped by community input, including peer researchers and advisory groups with lived experience of HIV.
- Overall, the goal is to produce practical knowledge that can help healthcare systems deliver new HIV treatments more equitably and in ways that fit real life.
- The article does not include any results; it just describes the protocol of the ILANA study.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.2: Frampton GK, Shepherd J, Pickett K, Griffiths G, Wyatt JC. Digital tools for the recruitment and retention of participants in randomised controlled trials: a systematic map. *Trials* [online] 2020; 21:478. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1186/s13063-020-04358-3>

REVIEW

Open Access



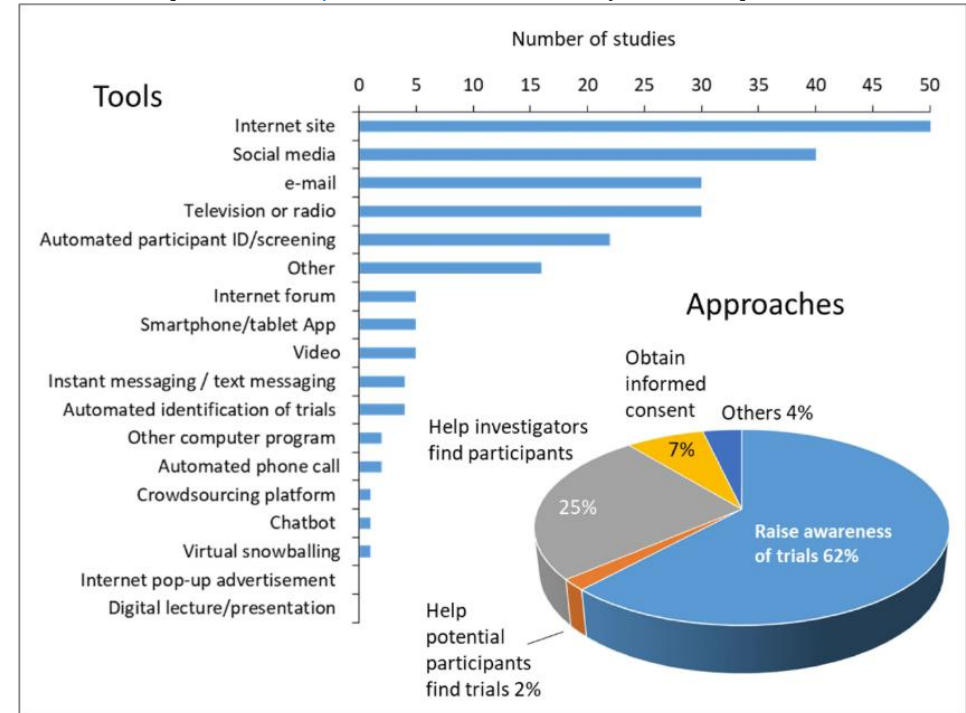
Digital tools for the recruitment and retention of participants in randomised controlled trials: a systematic map

Geoff K. Frampton^{1,2*}, Jonathan Shepherd^{1,2}, Karen Pickett^{1,2}, Gareth Griffiths³ and Jeremy C. Wyatt²

Key points for the teacher:

- Recruitment and retention problems are a major source of research inefficiency, and many trials still fail to reach their targets. This creates wasted time, money, and data.
- This article maps the growing use of digital tools as a response, showing that research in this area has doubled over the past decade.
- Most studies focus on recruitment rather than retention, leaving a clear imbalance in the evidence base.
- The most studied tools are social media, websites, email, and text messaging, often used to raise awareness or send reminders. The types of digital tools for recruitment evaluated in the studies are shown in Table 1. However, most evaluations are observational rather than experimental, which limits how confidently we can judge effectiveness.
- Few studies examine costs, user satisfaction, or participant attitudes, even though these factors strongly influence real-world adoption.
- Research on minority groups, children and older adults is especially limited, and retention strategies for these populations are underdeveloped.

7.2: Figure 1. An overview of the digital approaches and tools for recruitment from a total of 105 studies [Source: [Frampton et al., 2020](#) licenced by [CC BY 4.0](#)].



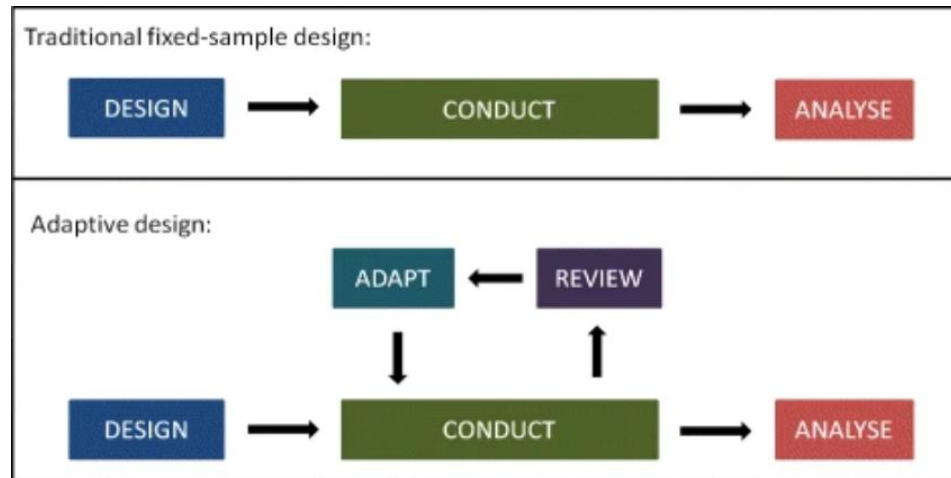
Key points for the teacher:

- The figure summarises how digital tools are used to recruit participants into clinical trials, based on 105 studies.
- On the left, a horizontal bar chart ranks the types of tools by how often they were studied. The most frequently evaluated tools are Internet sites (the longest bar), followed by social media, email, and television or radio. Less common tools include automated screening systems, online forums, smartphone apps, videos, text messaging, chatbots, crowdfunding platforms, and other digital methods. The chart visually shows that traditional web platforms and social media dominate research compared to newer or experimental technologies.
- On the right, a pie chart groups these tools by their purpose. The majority of digital approaches (about 62%) aim to raise awareness of trials. 25% are designed to help investigators find participants, while smaller portions focus on helping participants find trials (about 2%), obtaining informed consent (about 7%), and other functions (about 4%).

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.2: Figure 2. Schematic of a traditional fixed clinical trial design (upper), and an adaptive design with pre-specified review and adaptation opportunity (lower) [Source: [Pallmann et al., 2018](#) licenced by [CC BY 4.0](#)].



Key points for the teacher:

- The figure compares two ways of running a clinical trial: a traditional fixed design and an adaptive design.
- In the top panel (**traditional design**), the process is shown as a simple linear sequence: Design → Conduct → Analyse. This means the trial is planned in advance, carried out without planned changes, and analysed only once at the end. Once the study starts, the design stays fixed.
- In the bottom panel (**adaptive design**), the process includes feedback loops. After the trial begins (Design → Conduct), there are built-in stages for Review and Adapt. Data collected during the trial can be reviewed at pre-specified points (interim analysis) and the design can be adjusted before continuing. Arrows show a cycle between reviewing results and adapting the trial, then returning to conduct.

7.2: Marks M, Lal S, Brindle H, Gsell PS, MacGregor M, Stott C, van de Rijdt M, Almazor GG, Golia S, Watson C, Diallo A, Toure A, Houlihan C, Keating P, Martin H, Restrepo AH, Anokwa Y, Roberts CH. Electronic Data Management for Vaccine Trials in Low Resource Settings: Upgrades, Scalability, and Impact of ODK. Front Public Health [online] 2021; 9. [Accessed 19th Dec 2025]. Available from: <https://doi.org/10.3389/fpubh.2021.665584>

Electronic Data Management for Vaccine Trials in Low Resource Settings: Upgrades, Scalability, and Impact of ODK

Michael Marks¹, Sham Lal¹, Hannah Brindle¹, Pierre-Stéphane Gsell², Matthew MacGregor¹, Callum Stott³, Martijn van de Rijdt⁴, Guillermo Gutiérrez Almazor³, Suman Golia¹, Conall Watson¹, Abdourahamane Diallo², Alhassane Toure², Catherine Houlihan¹, Patrick Keating^{5,6}, Héléne Martin³, Ana-Maria Henao Restrepo², Yaw Anokwa⁴ and Chrissy H. Roberts^{1*}

OPEN ACCESS

Key points for the teacher:

- The article explains how open-source digital tools were upgraded to make it possible to run large vaccine trials in difficult, low-resource settings.
- The authors built an enhanced electronic data system based on ODK (open data kit) that could function offline, scale to millions of records, and deliver near-real-time monitoring during the Ebola outbreak in the Democratic Republic of Congo.
- They added practical features such as stronger data security, automated data processing, faster handling of large datasets, fingerprint-based participant registration, and audit trails to track how data were entered.
- In practice, the system supported data collection from more than 280,000 vaccinated participants and helped guide daily field decisions.
- The article highlights that open tools can be powerful and reliable if they are designed with scalability, security and automation in mind. It is also important to connect data collection directly with analysis instead of treating them as separate steps.
- These improvements make electronic data management more achievable for clinical trials in low- and middle-income countries.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.3: Alegria M, Sud S, Steinberg BE, Gai N, Siddiqui A. Reporting of Participant Race, Sex, and Socioeconomic Status in Randomized Clinical Trials in General Medical Journals, 2015 vs 2019. JAMA Netw Open [online] 2021 4(5):e2111516. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1001/jamanetworkopen.2021.11516>



Research Letter | Health Policy

Reporting of Participant Race, Sex, and Socioeconomic Status in Randomized Clinical Trials in General Medical Journals, 2015 vs 2019

Mikhaila Alegria, BScN; Shawn Sud, BSc; Benjamin E. Steinberg, MD, PhD; Nan Gai, MD; Asad Siddiqui, MD

Key points for the teacher:

- This article examines how well randomised clinical trials report key participant characteristics such as race, sex, and socioeconomic status and whether this changed between 2015 and 2019.
- The authors reviewed a total of 688 trials published in leading medical journals and found that sex was almost always reported (98% of the studies), but race was reported in only about half of the studies and socioeconomic status in fewer than 15%. Importantly, there was no meaningful improvement in reporting over time, despite growing awareness of equity and inclusion in research.
- When race was reported, White participants made up the majority of study populations, with minority groups consistently underrepresented. This limits how well trial results can be applied to diverse patient populations in real-world care.
- The study highlights that simple reporting of trial results is not enough if key contextual information about who participated is missing. Underreporting of race and socioeconomic status weakens generalisability and may contribute to existing health inequalities.

7.3: Granton D, Rodrigues M, Raparelli V, Honarmand K, Agarwal A, Friedrich JO, Perna B, Spaggiari R, Fortunato V, Risdonne G, Kho M, VanderKaay S, Chaudhuri D, Gomez-Builes C, D'Aragon F, Wiseman D, Lau VI, Lin C, Reid J, Trivedi V, Prakash V, Belley-Cote E, Al Mandhari M, Thabane L, Pilote L, Burns KEA. Sex and gender-based analysis and diversity metric reporting in acute care trials published in high-impact journals: a systematic review. BMJ Open [online] 2024; 14:e081118. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1136/bmjopen-2023-081118>

BMJ Open Sex and gender-based analysis and diversity metric reporting in acute care trials published in high-impact journals: a systematic review

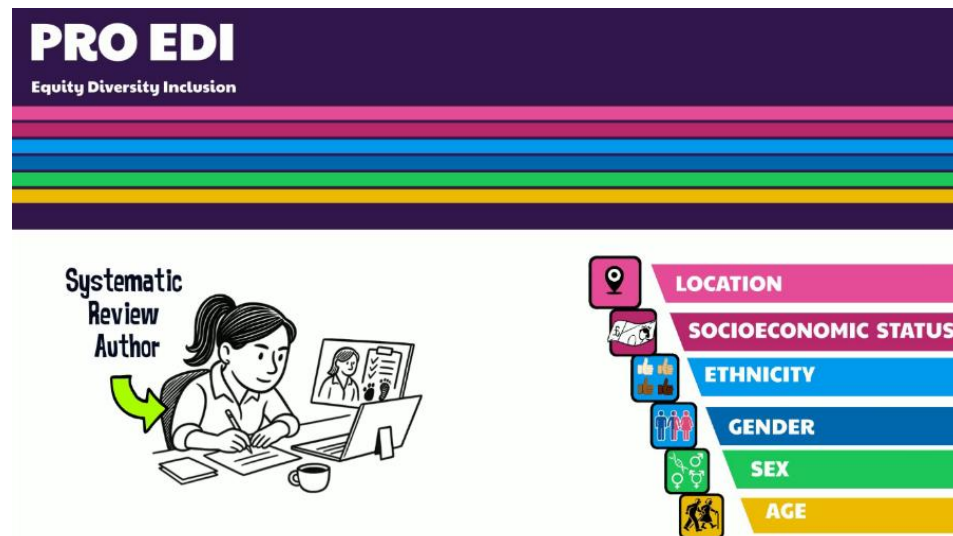
Key points for the teacher:

- The article presents a systematic review of acute care randomised clinical trials (a total of 88 trials) published in high-impact medical journals to assess how well sex and gender-based analyses (SGBA) and diversity metrics are reported. The characteristics of the analysed trials are shown in Table 1.
- The authors found that less than one quarter (26.1%) of trials included any SGBA, and this proportion did not improve after the publication of the 2016 SAGER guidelines.
- Women were consistently under-represented, making up only about one third of trial participants, while nearly 80% of participants were White.
- Reporting of race, ethnicity and socioeconomic or gender-related social factors was rare or completely absent. In addition, sex and gender terminology was often used inconsistently or incorrectly within the same publication.
- Trials in cardiology reported SGBA more frequently than intensive care trials, but overall reporting quality remained poor.
- The authors conclude that inadequate reporting limits the generalisability of results and risks reinforcing of existing health disparities. They call for stronger enforcement of reporting standards by journals, funders and researchers to improve equity and transparency in clinical research.

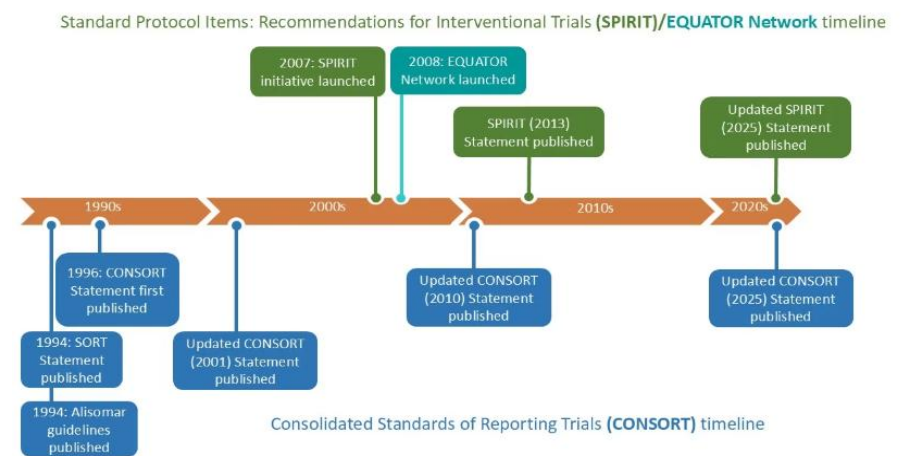
UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.3: Figure 1. A systematic review author and the six core characteristics as recommended by PRO EDI [Source: [Trial Forge, 2025](#)].



7.4: Figure 1. The timeline of CONSORT and SPIRIT guidelines [Source: [CONSORT-SPIRIT.org, 2025](#)].



Key points for the teacher:

- This picture shows how the CONSORT and SPIRIT guidelines have developed over time to improve the way clinical trials are planned and reported.
- It begins in the 1990s, when the first attempts were made to standardise how trials are described, including early guidance such as the Alisomar guidelines and the SORT Statement in 1994 and the first CONSORT statement in 1996. CONSORT was later updated in 2001 and 2010, as researchers learned more about common problems in trial reporting.
- In the 2000s, attention also turned to the quality of trial protocols, not just final publications. This led to the launch of the SPIRIT initiative in 2007, followed by the creation of the EQUATOR Network in 2008, which supports good reporting across health research. The first SPIRIT statement was published in 2013.
- The timeline ends in the 2020s, showing the most recent updates of both frameworks, with CONSORT 2025 and SPIRIT 2025. These updates reflect new scientific, ethical and practical challenges in clinical research.

Key points for the teacher:

- The picture illustrates the PRO-EDI (Equity, Diversity, Inclusion) framework applied to a systematic review.
- On the left, a researcher is shown working at a computer, representing the role of a systematic review author who actively considers equity during evidence synthesis.
- On the right, the image lists six core participant characteristics that should be considered and reported: location, socioeconomic status, ethnicity, gender, sex, and age.
- The figure shows that systematic reviews should not focus only on results but also pay attention to where the evidence actually comes from, so the conclusions are more relevant, fair and generalisable.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.4: Chan AW, Boutron I, Hopewell S, Moher D, Schulz KF, Collins GS, Tunn R, Aggarwal R, Berkwits M, Berlin JA, Bhandari N, Butcher NJ, Campbell MK, Chidebe RCW, Elbourne DR, Farmer AJ, Fergusson DA, Golub RM, Goodman SN, Hoffmann TC, Ioannidis JPA, Kahan BC, Knowles RL, Lamb SE, Lewis S, Loder E, Offringa M, Ravaud P, Richards DP, Rockhold FW, Schriger DL, Siegfried NL, Staniszewska S, Taylor RS, Thabane L, Torgerson DJ, Vohra S, White IR, Hróbjartsson A. SPIRIT 2025 statement: updated guideline for protocols of randomised trials BMJ [online] 2025; 389 :e081477. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1136/bmj-2024-081477>

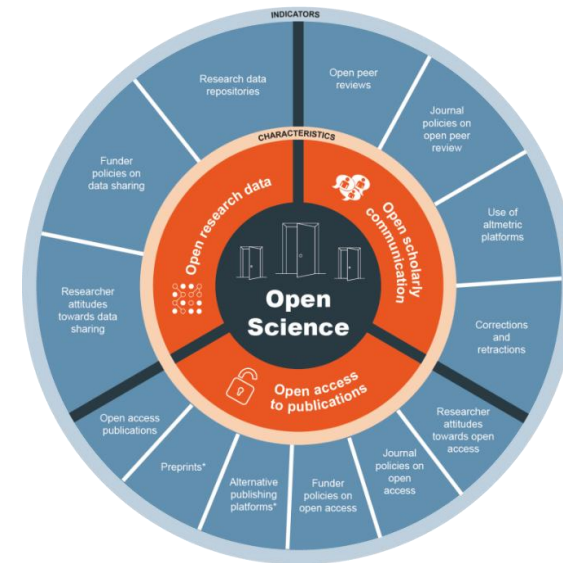


SPIRIT 2025 statement: updated guideline for protocols of randomised trials



An-Wen Chan,¹ Isabelle Boutron,^{2,3} Sally Hopewell,⁴ David Moher,⁵ Kenneth F Schulz,⁶ Gary S Collins,⁷ Ruth Tunn,⁴ Rakesh Aggarwal,⁸ Michael Berkwits,⁹ Jesse A Berlin,^{10,11} Nita Bhandari,¹² Nancy J Butcher,^{13,14} Marion K Campbell,¹⁵ Runcie C W Chidebe,^{16,17} Diana R Elbourne,¹⁸ Andrew J Farmer,¹⁹ Dean A Fergusson,²⁰ Robert M Golub,²¹ Steven N Goodman,²² Tammy C Hoffmann,²³ John P A Ioannidis,²⁴ Brennan C Kahan,²⁵ Rachel L Knowles,²⁶ Sarah E Lamb,²⁷ Steff Lewis,²⁸ Elizabeth Loder,^{29,30} Martin Offringa,¹³ Philippe Ravaud,³¹ Dawn P Richards,³² Frank W Rockhold,³³ David L Schriger,³⁴ Nandi L Siegfried,³⁵ Sophie Staniszewska,³⁶ Rod S Taylor,³⁷ Lehana Thabane,^{38,39} David J Torgerson,⁴⁰ Sunita Vohra,⁴¹ Ian R White,²⁵ Asbjørn Hróbjartsson^{42,43}

7.4: Figure 2. The characteristics and indicators of Open Science [Source: [Open Access Belgium, 2025](#) licenced by [CC BY 4.0](#)].



Key points for the teacher:

- The picture presents Open Science as a central concept, shown in the middle of a circular diagram. Around this centre are three main characteristics of Open Science: open research data, open scholarly communication, and open access to publications, which together describe how research should be shared and made transparent.
- Surrounding these characteristics is an outer ring labelled “indicators”, which shows how Open Science can be recognised and measured in practice. These indicators include things like research data repositories, open peer reviews, journal policies on open peer review, use of altmetric platforms, journal and funder policies on open access and data sharing, preprints, alternative publishing platforms and open access publications. The diagram also highlights cultural and behavioural aspects, such as researcher attitudes towards data sharing and open access, as well as quality-control mechanisms like corrections and retractions.
- The image shows that Open Science is not just about free access to papers, but about a broader system of practices, policies, and behaviours that make research more transparent and accessible.

Key points for the teacher:

- The SPIRIT 2025 statement provides updated guidance on what information should be included in protocols for randomised clinical trials to ensure they are complete, transparent, and reproducible. It builds on the first version of the statement published in 2013, responding to evidence that many trial protocols still omit key methodological, ethical, and reporting details.
- The update was developed through a rigorous process including a scoping review, an international Delphi survey, and expert consensus.
- SPIRIT 2025 introduces a revised checklist of 34 essential protocol items (shown in Table 1), with major new emphasis on open science practices, data sharing and patient and public involvement, and also strengthens requirements for describing harms, interventions, comparators and trial monitoring. It also includes a diagram illustrating the schedule of enrolment, interventions and assessments (shown in Figure 1).
- The guideline is intended to support researchers during trial planning, not to dictate how trials should be designed. Widespread adoption by researchers, funders, ethics committees and journals is expected to improve protocol quality and reduce avoidable amendments.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.5: Barnes B, Stansbury N, Brown D, Garson L, Gerard G, Piccoli N, Jendrasek D, May N, Castillo V, Adelfio A, Ramirez N, McSweeney A, Berlien R, Butler PJ. Risk-Based Monitoring in Clinical Trials: Past, Present, and Future. Ther Innov Regul Sci [online] 2021; 55:899-906. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1007/s43441-021-00295-8>

ANALYTICAL REPORT



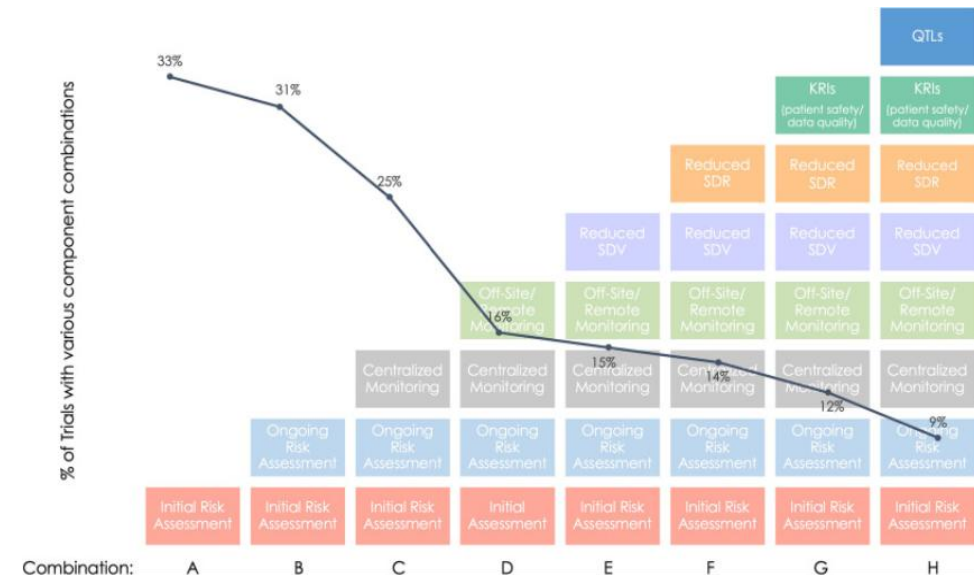
Risk-Based Monitoring in Clinical Trials: Past, Present, and Future

Brian Barnes¹ · Nicole Stansbury¹ · Debby Brown¹ · Lauren Garson¹ · Geoff Gerard¹ · Nickolas Piccoli¹ · Debra Jendrasek¹ · Nick May¹ · Vanesa Castillo¹ · Anina Adelfio¹ · Nycole Ramirez¹ · Andrea McSweeney¹ · Ruth Berlien¹ · Paula Jo Butler¹

Key points for the teacher:

- Risk-based monitoring (RBM) is presented as a more targeted way to oversee clinical trials by focusing on activities that matter most for patient safety and data quality.
- Based on a large survey of over 6,500 ongoing trials, the article shows that RBM adoption before the COVID-19 pandemic was lower and more fragmented than expected, with most trials using only one or two RBM components.
- Centralised monitoring and risk assessments were the most commonly applied elements, while reduced source data review and remote monitoring were used much less often.
- The COVID-19 pandemic forced a rapid shift from on-site to remote monitoring, creating a real-world test of RBM approaches. Data from this period showed that remote monitoring was able to detect protocol deviations at similar rates to traditional on-site visits. This suggests that RBM can maintain oversight and trial quality even under challenging conditions.
- The authors argue that wider and more consistent use of RBM, within a broader risk-based quality management framework, could improve efficiency without compromising safety.

7.5: Figure 1. Percentage of clinical trials using combined methods for RBM [Source: [Barnes et al., 2021](#) licenced by [CC BY 4.0](#)].



Key points for the teacher:

- The figure shows how often clinical trials combine different methods of risk-based monitoring (RBM).
- The black line illustrates that simpler combinations of monitoring methods are used more frequently, while more complex combinations are used in a smaller proportion of trials. As you move from left to right, the percentage of trials using each combination steadily decreases.
- Along the bottom, the figure breaks RBM into building blocks that are layered on top of each other. These start with initial risk assessment, which appears in all trial designs. Next come ongoing risk assessment and centralised monitoring, followed by off-site or remote monitoring. More advanced approaches then add reduced source data verification (SDV) and reduced source data review (SDR). At the top of the most complex combinations are specific key risk indicators (KRIs) and quality tolerance limits (QTLs), focused on patient safety and data quality.

UNIT 7: INCLUSIVE TRIAL DESIGN AND CONDUCT

Articles, pictures outlines

7.5: Aryasinghe S, Carenzo C, Barnett KA, Khalid R, Greenaway-Harvey K, Sherlock C, Clark L, Croft K, Orchard T, Mayer E. Increasing the ethnic diversity of senior leadership within the English National Health Service: using an artificial intelligence approach to evaluate inclusive recruitment strategies in hospital settings. Hum Resour Health [online] 2025; 23:24. [Accessed 10th Nov 2025]. Available from: <https://doi.org/10.1186/s12960-025-00991-8>

RESEARCH

Open Access



Increasing the ethnic diversity of senior leadership within the English National Health Service: using an artificial intelligence approach to evaluate inclusive recruitment strategies in hospital settings

Sarindi Aryasinghe^{1,2*}, Catalina Carenzo^{1,2}, Kerri-Ann Barnett³, Rabia Khalid³, Koya Greenaway-Harvey³, Colleen Sherlock³, Louise Clark^{3*}, Kevin Croft³, Tim Orchard³ and Erik Mayer^{1,2}

Key points for the teacher:

- The article examines an inclusive recruitment programme implemented in a large English NHS Trust to increase ethnic diversity in senior leadership roles.
- The authors used artificial intelligence methods, particularly natural language processing, and analysed both structured recruitment data and free-text assessment letters written by hiring managers. In total, 1716 interview campaigns were analysed between September 2021 and January 2024.
- The study found that requiring managers to write a justification letter to the CEO significantly increased (1.7 times) the likelihood that candidates from Black and Minority Ethnic (BME) backgrounds were offered senior positions. However, despite this improvement, White candidates still had higher overall odds of being appointed, and BME candidates consistently received lower interview scores.
- The analysis also revealed gendered and ethnic patterns in interview feedback, with BME women more likely to receive negative assessments. Importantly, the findings show that panel diversity alone does not eliminate bias, as disparities persisted even with ethnically and gender-diverse interview panels.
- The authors conclude that AI tools can effectively evaluate equity, diversity and inclusion initiatives by uncovering hidden patterns in recruitment processes.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

General overview of the unit for the teacher

OBJECTIVES

The aim of this Unit is to explore why adults with impaired capacity to consent are often excluded from clinical trials and the key legal, ethical, and methodological challenges involved. As a case study unit overarching the entire module, it introduces practical mechanisms and frameworks to support the inclusion of such adults.

UNIT CONTENT

8.1: Adults lacking capacity are often excluded from clinical trials
8.2: How to include adults lacking capacity in clinical trials
8.3: Including people with longer-term impaired capacity
8.4: Including people with acute loss of capacity
8.5: Including people with fluctuating capacity
Summary of Unit 8

LEARNING OUTCOMES

Students will be able to:

1. Describe some of the complexities that are particular to clinical trials involving adults with impaired capacity to consent
2. Define some of the mechanisms that can be used to help include adults with impaired capacity, and their caregivers, in research
3. Recognise the different ways in which adults may experience impaired capacity
4. Give examples of situations in which adults may have impaired capacity that is long-term, acute, or fluctuating, and how these relate to their inclusion in clinical trials

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 8.1 pre-class; read the article by Victoria Shepherd discussing advances and challenges involving people with impaired capacity in clinical research, complete the reflective activity; test your knowledge.
Tue	Complete Lesson 8.2 pre-class; go through the INCLUDE Impaired Capacity to Consent Framework and associated worksheets; complete the reflective activity; test your knowledge.
Wed	Complete Lesson 8.3 pre-class, focus on the trial design, Setting and participants, and Eligibility aspects of the PRINCESS trial (Butler <i>et al.</i>), complete the reflective activity; test your knowledge.
Thu	Complete Lesson 8.4 pre-class; read about the example EFIC study, read the paper by Broderick <i>et al.</i> on enhancing enrolment of participants in acute stroke trials, complete the reflective activity; test your knowledge.
Fri	Complete Lesson 8.5 pre-class; read the study by Palmer <i>et al.</i> , complete the reflective activity; test your knowledge, read the Summary of Unit 8; complete the MCQs.

OPENING THE LESSON

15' 



 **Organise yourselves/pick a side** – ask students to form a group, leaving space on the left and right. Explain that students should express their opinion on the statement by moving right (agree) or left (disagree). The distance from the centre expresses the strength of the disagreement/agreement (the further away, the stronger opinion). Always ask students to provide a reason for their opinion.

1. Capacity to consent is a binary state: a person either has capacity or does not.
2. Impaired capacity to consent should exclude a person from participating in research.
3. Impaired capacity to consent is relatively rare in adult clinical research populations.
4. Approaches to including adults who lack capacity to consent in research are largely harmonised across countries.
5. Deferred consent can be ethically and legally applied in research with critically ill adults.

Hints and solutions for the teacher:

- **Question 1 – capacity is more of a continuum or spectrum**
Ask students to give examples of situations in which adults may have impaired capacity that is long-term, acute, or fluctuating.
Does impaired capacity mean the inability to ask questions?
- **Question 2 – probably not; risk of health inequality, and thinking about how to minimise barriers related to impaired capacity is desirable**
- **Question 3 – impaired or fluctuating capacity is more common in critical care, neurology, and mental health research**
- **Question 4 – no; the lack of harmonisation was summarised in the pre-class reading**
- **Question 5 – yes; typically acceptable, but it must still be approved by the ethics committee**

WORK IN PAIRS

50' 



Task 1: Return to the example EFIC study in Lesson 8.4. Ask students to compare, consult and further elaborate on their individual answers to the questions in pairs (15 minutes):

- How do the team go about communicating with a wide range of people in the community?
- What are some of the challenges surfaced during the consultation process?
- How is trust built by the researchers, in this case?



Task 2: Imagine that you are a trial methodologist consulting on the design of such a study, or a member of the ethics committee reviewing the study. Identify further specific steps you would advise the investigators to take next. Suggest tools, frameworks, or methods to support quality, inclusivity, and transparency. (15 minutes)



Debriefing (20 minutes)

Ask each pair to report their answers to individual questions. Always ask other pairs to add their ideas.

Hints and solutions for the teacher:

- *Encourage students to reflect on what they have learned so far.*
- *Emphasise that they can go back to previous units.*
- *Consider printing several copies of the sample EFIC study; distribute copies to students.*

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Blended 90-minute classroom

INDEPENDENT WORK

20'



Task – Now we will return to the reflective activity of Lesson 8.3.

Ask students to individually reflect on the following questions:

- What was the objective or the main idea of the study?
- Why should patients with cognitive deficits be included in such a study? Why is their inclusion relevant?
- You already know the term intersectionality – can you illustrate it using the population of this study?
- Can you think of another study focused on evaluating a different intervention, but with the same population, where cognitive deficits would not affect the outcome?



Debriefing (15 minutes)

Ask several students to share their answers.

Hints and solutions for the teacher:

Sample answers:

- *Question 3 – e.g., older age, hip fracture, cognitive impairment, comorbidities, and social determinants such as living situation or support systems*
- *Question 4 – e.g., a trial evaluating an alternative versus standard surgical technique and post-surgery blood loss, in hip fracture patients might not require cognition-dependent outcomes and could remain relevant regardless of patients' cognitive status*

REFLECTION, WRAP-UP

5'



1. How might the type of impaired capacity (long-term, acute, fluctuating) influence the design and conduct of a clinical trial?
2. How does participant-centred trial design change when including adults with impaired capacity?
3. What specific strategy for including adults with cognitive deficits has impressed you the most?
4. After completing this unit, what is your personal takeaway?

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

15'



- "Pick a side activity" can be modified into polls in Mentimeter (anonymous voting), Slido (Polls), or Miro (students move an icon or a sticky note), or similar apps.
- Sometimes, advance preparation of the poll is necessary – check it in advance of the class.
- Time adjustment is possible (online voting may be faster than moving in classroom).

WORK IN PAIRS

50'



- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign a facilitator/trained student to several (1–4) pairs to help students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues).
- Ask students to write notes electronically so that they are able to share on screen later. Inform the students that you will randomly select pairs to share their work at the end of the task (to encourage focus and accountability).
- Share the link for the EFIC study via the chat or download the pdf file and share it via a cloud link.
- Time adjustment is possible. The presentation of the teams' work may need more time.
- Announce the timing (e.g., Broadcasting in Zoom), and share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.



Debriefing (20 minutes)

Ask each pair to report their answers to individual questions. Always ask other pairs to add their ideas.

INDEPENDENT WORK

20'



- Share the link for the reflective activity 8.3 via the chat
- Ask students to write notes electronically to be able to share on screen later.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Be available for support, e.g., in the chat.



Debriefing (10 minutes)

Ask several students to share their answers.

REFLECTION, WRAP-UP

5'



- Only discussion; no need to collect or write notes.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Reflective activity 8.1: “Barriers and facilitators to conducting trials with adults with impaired capacity to consent” modified for synchronous use

Link: [Unpacking the “Blackbox of Horrendousness”](#)

Read the blog [Unpacking the “Blackbox of Horrendousness”](#) which summarises a paper examining the complexities of clinical trials involving adults lacking capacity. Dr Victoria Shepherd and colleagues explore the many barriers and facilitators to conducting trials with adults lacking capacity to consent, from the perspective of researchers and healthcare professionals across the UK.

Refer to Table 3 in the paper by [Shepherd et al.](#) which sets out six key processes during the trial lifespan.

MODIFICATION FOR INDIVIDUAL WORK



Read the blog [Unpacking the “Blackbox of Horrendousness”](#) which summarises a paper by [Shepherd et al.](#) Then, look at [Table 3](#) in the linked paper. Choose one process from Table 3 and examine the barriers associated with this process. Reflect on the facilitators described by the authors that could help to overcome these barriers. Suggest one additional practical action or resource that would help put these ideas into practice. Write a short reflection (100–150 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses relating to individual processes to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–5 students per team

Divide students into teams. Each team is assigned one process from Table 3 in the paper by [Shepherd et al.](#) Ask teams to read the assigned process and identify key barriers and facilitators already suggested in the paper. Students discuss:

1. How could these facilitators be implemented in a real clinical trial?
2. What is one additional practical action or resource that would help? (Consider who would provide it, when, and why).

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask teams to present a short summary covering main barriers, one facilitator, and one additional action/resource in 2–3 minutes.

During presentations, note similarities across processes on the board.

Hints and solutions for the teacher:

- Ensure students have access to Table 3 (printed or online).
 - Encourage students to keep proposed actions practical and trial-relevant, e.g. staff training, budget lines, protocol adaptations, dedicated roles, or tools.
 - Highlight cross-cutting themes, such as training, time, communication, co-production, and consent as an ongoing process.
- √ ▪ Optionally close with a brief whole-class question: Which process do you think is most underestimated when planning trials involving adults lacking capacity?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start with a short discussion by asking students: *When thinking about clinical trials involving adults with impaired capacity to consent, what barriers do you expect to conducting them?* Invite students to call out ideas. Write them on the board.

Explain that these anticipated barriers have been systematically explored by [Shepherd et al.](#) Project [Table 3](#) on the screen, showing the six key processes across the clinical trial lifecycle. Go through the processes one by one. Invite students to:

1. Identify which of their previously listed barriers appear here
2. Comment on any new barriers they had not anticipated
3. Think about practical actions or resources that would help (consider who would provide it, when, and why).

Hints and solutions for the teacher:

- Invite different students to comment on different processes to keep engagement broad.
- Keep in mind and remind students the five principles of the MCA ([Social Care Wales, 2025](#)).
- For Question 3: If answers remain abstract, prompt with: *Who would do this in practice? Would this require extra time, training, or funding?*
- As the discussion progresses, point out recurring needs (e.g. staff training, protected time, specialist roles, co-production). You may project the Figure “Diagram of key recommendations” from the [blog](#) [Unpacking the “Blackbox of Horrendousness”](#) on the screen to frame the takeaways from this discussion.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Reflective activity 8.2: “Easy-read booklets” modified for synchronous use

Link: [INCLUDE Impaired Capacity to Consent Framework](#)

The INCLUDE Impaired Capacity to Consent Framework guides researchers in partnership with patient and public partners (and other stakeholders). A resource provided as part of the toolkit is an [Easy Read guide to the framework](#).

This document was co-produced with Thinklusive, an organisation supporting the creation of information that is accessible to all ([Thinklusive, 2025](#)).

MODIFICATION FOR INDIVIDUAL WORK



Read the [Easy Read guide](#) to the INCLUDE Impaired Capacity to Consent Framework. Reflect on how information is communicated. Write a short reflection (100–150 words) addressing the following questions and submit it to a cloud/discussion board:

1. What are the key features of easy-read communication?
2. Why are these features important?
3. At what stages of a clinical trial might easy-read materials be important and why?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Ask them to review the Easy Read guide to the INCLUDE Impaired Capacity to Consent Framework and focus on how information is conveyed. Ask each team to identify at least 3–4 features that make the guide accessible and discuss:

1. Why are these features important?
2. At what stages of a clinical trial might easy-read materials be important and why?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, invite two teams to present a short summary of their findings in three minutes. Ask students if anyone wants to add something important that hasn't been mentioned yet.

Conclude with a short whole-class discussion on: *Could easy-read materials benefit participants without impaired capacity?*

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Part A: Ask students to go briefly through pages 1–27 of the [Easy Read Guide](#) to the INCLUDE Impaired Capacity to Consent Framework. Then, guide the whole-class discussion:

1. Who do you think this document is designed for?
2. What are the key features of easy-read communication?
3. Why are these features important?
4. At what stages of a clinical trial might easy-read materials be important and why?
5. Who should be involved in producing easy-read materials?

Part B: Read together with students the illustrative example of Ali, an autistic patient, and Holly, a research nurse in the hospital (pp. 28–30). Then, discuss with students the questions provided on pp. 31–32. The conclusion is provided on pp. 33–39.

Hints and solutions for the teacher:

- Ensure students have access to online materials.
- Question 1: A guiding question: *Could easy-read materials benefit participants without impaired capacity? (Everyone who might struggle with complex texts.)*
- Question 2: *Plain, short sentences and simple vocabulary, clear structure per page, supportive visuals or icons, reduced cognitive load (white space, limited information at once), respectful tone, links to other easy-read booklets, repetition of key information in subsequent sections, illustrative examples.*
- Question 3: *Connect the accessibility features with autonomy, dignity, equality, and trust.*
- Question 4: *e.g. informed consent, ongoing communication during the trial, result sharing.*
- Question 5: *Highlight the importance of co-production.*
- Optional extension to both the team-based work and whole-group discussion: *Ask students to compare a [standard user guide](#) with an [easy-read version](#) and discuss what is lost, gained, or transformed.*

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Reflective activity 8.3: “Applying the INCLUDE Impaired Capacity to Consent Framework” modified for synchronous use

Link: [INCLUDE Impaired Capacity to Consent Framework Example](#)

The INCLUDE Impaired Capacity to Consent framework described in Lesson 8.2 has been applied retrospectively, to an existing study: to determine whether an enhanced community-based rehabilitation programme, following surgical repair of a broken hip, is more effective than usual rehabilitation care. And whether the new programme is better value for money for the health service and for personal social care.

Look at the answer to Q1 (Who should my trial results apply to?) on the fourth page (the page is labelled as p2 on the [document](#)). Where have the answers come from? How valuable is this information?

Look at Worksheet A (summarised in the responses to Q2 (Are the groups identified in Q1 likely to respond to the intervention and/or comparator in different ways?). This is on the sixth to eighth pages (labelled as p4-6 on the document). Notice how the worksheet asks sub-questions that are more specific prompts. Reflect on how intersectionality, which you were introduced to in Unit 2, is relevant to these considerations. What actions are suggested to work around the barriers?

MODIFICATION FOR INDIVIDUAL WORK



Read the [example](#) showing how the INCLUDE Impaired Capacity to Consent Framework was applied retrospectively to a hip fracture rehabilitation trial.

Task 1: Go to Q1 (p2) and reflect on:

1. Where do the answers to this question come from (e.g. data sources, stakeholder input, assumptions)?
2. Why is this information valuable?

Task 2: Review Worksheet A (p4–6) and reflect on:

1. How do the structured questions in Worksheet A support more inclusive thinking in trial design?
2. How does intersectionality shape who may benefit (or be excluded) from the intervention?
3. Which suggested actions do you find most practical or important, and why?

Write a reflection (150–200 words) answering the questions above and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Step 1: Ask each team to read the response to Q1 (p2) and discuss: Where do these answers come from? Why is this information valuable? Ask each team to write **two key points**.

Step 2: Next, ask teams to review Worksheet A related to Q2 (p4–6) and discuss: What kinds of differences between participant groups are being considered? How does this relate to intersectionality? Ask each team to identify **one example of intersectionality**.

Step 3: From barriers to action – ask teams to discuss: What barriers to participation or benefit are identified? What actions are suggested to work around these barriers? Each team prepares **one practical action** they think is particularly important.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask 2–3 teams to present their output in three minutes.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Do not read the full [document](#) in class. Prepare 2–3 short excerpts from it on the screen.

Step 1: Ask students: *When talking about adults with impaired capacity to consent, who might this be about?* Invite responses and write keywords on the board.

Step 2: Introduce the INCLUDE framework. Project the selected excerpt from Q1. Ask students: *Where do the answers come from?*

Step 3: From barriers to actions. Project one or two suggested actions from the document. Discuss: *What barrier is this action responding to? What resources would be needed to implement this?*



Close with a short reflective question: *What is one way this framework changes how you think about “who a trial is for”?* Invite 2–3 brief responses.

Hints and solutions for the teacher:

- Step 2: Highlight involvement of patients, carers, clinicians, and other stakeholders, and attention to real-world practice.
- Step 3:
 - Examples of barriers: difficulties with consent processes, adherence, follow-up, or access to rehabilitation services.
 - Examples of actions: appropriate consent arrangements, alternative methods of engagement and data collection, pre-trial public involvement activities (incl. carers), including people in a care home prior to a hip fracture.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Reflective activity 8.4: “Informed consent and people with aphasia” modified for synchronous use

Link: [Big CACTUS](#)

The University of Sheffield's [Big CACTUS](#) project is a pragmatic randomised controlled trial comparing outcomes for people with aphasia using computerised speech and language therapy at home with those having usual care (standard speech and language therapy provision or general daily communication activity), or attention control group (daily completion of puzzle book activities).

Watch the first part of this [video](#) (up to 05:56), as an introduction to the Big CACTUS project and to understand people's experiences of aphasia from their own perspective.

From the published study, read the section on [Participants and eligibility criteria](#), in particular paying attention to the section on Recruitment. How did the study team foster informed consent?

MODIFICATION FOR INDIVIDUAL WORK



Watch the first part of the [video](#) (up to 05:56) introducing the Big CACTUS project. As you watch, pay attention to how people with aphasia describe their experiences, and what challenges aphasia may create for communication and decision-making.

Then, read the [Participants and eligibility criteria section](#) of the published study, with particular attention to the Recruitment subsection.

Based on the video and the study text, write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What barriers to informed consent might people with aphasia face in clinical trials?
2. How did the Big CACTUS study team adapt their recruitment and consent processes to support informed consent?
3. Which elements of their approach do you consider most important for inclusion and dignity of participants?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Before class, ask students to watch the introductory [video](#) on the Big CACTUS project (up to 5:56) to understand people's experiences of aphasia.

In class, students will work with the following [materials](#) designed to meet different communication needs (in Section “Downloads and videos”):

PIS 1 Info sheet – patients, PIS 2 Info sheet – accessible, PIS 3 Patient info (slides), PIS 4 Video: Information for assessments, PIS 4 Video: Information for computer.

Divide students into teams and assign each team to review one information material and discuss:

1. How is information presented?
2. Why are such materials important?
3. How should the informed consent process be organised? What additional support would be needed beyond the material itself?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each group to present their example in three minutes.

Hints and solutions for the teacher:

- Ensure access to all materials.
- Question 1: Look at language, length, structure, visuals, and pace.
- Question 3: Review the study information, [subsection on Recruitment](#).
- Possible guiding questions: Is there one ideal format, or is a combination necessary? Is an accessible document sufficient, or is the process of communication more important?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Very briefly introduce aphasia. Show one short [video](#) illustrating what people with aphasia experience. Ask students:

1. What might be especially difficult for a person with aphasia when being asked to give informed consent?
2. Which elements could help with understanding?

Show students examples of aphasia-friendly information sheets used in the Big CACTUS trial (in Section “Downloads and videos”). Continue discussing:

3. What do these materials do well? What can they not solve on their own?
4. How should the informed consent process be organised? What additional support would be needed beyond the material itself?

During the discussion, show students how the Big CACTUS study dealt with the recruitment and consent process.



Close with a short reflective question: *Which aspects do you consider especially important and why?*

Hints and solutions for the teacher:

- To familiarise yourself with the topic, review the study information, [subsection on Recruitment](#) in advance.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Reflective activity 8.5: “Informed consent and mental health problems” modified for synchronous use

Link: [British Psychological Society case study](#)

The following case study is from the British Psychological Society.

“Susan, aged 25, married with two children, has been experiencing some mental health problems since the age of 16. She has been experiencing low mood, anxiety and low levels of paranoia but has been able to cope with her problems to date. She has been treated by her General Practitioner (GP) who has prescribed anxiolytics and anti-depressants and at times she has also been receiving input from the Community Mental Health Team (CMHT) in the area. Susan’s marriage recently broke down and her ex-husband has been making threats to take the children away from her because of her mental health condition. Her mother died when she was still very young, her father is an alcoholic, and she has no brothers and sisters. Her friends have rejected her due to her mental health problems and Susan has no one to talk to and feels isolated.

As a result of these experiences her mental health problems have now become unmanageable and Susan has experienced a mental breakdown. She is now on a female ward and her ability to reason and make judgements is significantly impaired. After a detailed assessment of her symptoms by the psychiatrist Susan is diagnosed with a first episode of psychosis. Susan fulfils the necessary criteria to participate in your first episode study. The study involves participation in lengthy questionnaires that could take up to three hours to complete some of which need to be videotaped.”

MODIFICATION FOR INDIVIDUAL WORK



Read the [case study](#) “Susan, aged 25” from the British Psychological Society. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Can Susan consent to participating in research?
2. Does Susan have a condition that impairs her ability to decide?
3. Does Susan have the capacity to consent to taking part in the ‘first episode’ study?
4. Who can the researchers consult with?

After that, click the [link](#) and read through the discussion to see if you reach the same conclusion.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Step 1: Divide students into teams. Ask teams to read the [case study](#) “Susan, aged 25” from the British Psychological Society.

Step 2: Assign roles – Each team member briefly takes one perspective:

- Researcher – responsible for recruitment and study design
- Clinician – responsible for Susan’s care and wellbeing
- Ethics committee member – responsible for protecting participants’ rights

Step 3: Ask teams to discuss the case from their assigned perspectives and agree on a shared team position:

1. Can Susan consent to participating in research?
2. Does Susan have a condition that impairs her ability to decide?
3. Does Susan have the capacity to consent to taking part in the ‘first episode’ study?
4. Who can the researchers consult with?
5. Would participation in the study: a) Be of minimal risk to Susan?; b) Affect her freedom of action or privacy?; c) Be unduly invasive or restrictive?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask teams to present 2–3 key arguments supporting their decision.



Close with a short reflective question: *What tensions did you notice between protecting Susan and enabling her participation in research?*

Hints and solutions for the teacher:

- Familiarise yourself with the case study conclusion on the following [link](#).

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Read the [case study](#) “Susan, aged 25” from the British Psychological Society together. Go through the questions from the case study one by one and discuss them as a class. For each question, invite students to share their reasoning.

Hints and solutions for the teacher:

- Familiarise yourself with the case study and its conclusion in advance.
- Remind students of the difference between mental disorder and decision-making capacity, and between diagnosis and capacity at a specific moment. Ask an additional question: *What would need to happen for Susan to be able to consent?*
- Throughout the discussion, use guiding questions such as:
 - What additional information would you need to answer this question more confidently?
 - Who could provide this information?
 - Are there multiple possible options or pathways in this situation? What are they?
 - Could the answer change over time?

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Multiple-choice questions and solutions

1. Which of the following statements best explains why adults with impaired capacity are often excluded from clinical trials?
- A) They are less likely to benefit from medical interventions
 - B) Their inclusion violates international ethical guidelines
 - C) Assessing capacity and obtaining consent can be legally and ethically complex**
 - D) Clinical trials are designed for an average younger age group

Answer: C; Assessing capacity and obtaining consent involves legal complexities, especially when surrogate or proxy consent is needed. Capacity can also change over time.

2. Which of the following is a key purpose of the INCLUDE Impaired Capacity to Consent Framework?
- A) To simplify trial reporting requirements for researchers
 - B) To exclude adults with impaired capacity from high-risk clinical trials
 - C) To replace legal consent procedures with informal agreements
 - D) To guide researchers in designing inclusive trials that consider ways of overcoming barriers to participation**

Answer: D; The framework uses questions and worksheets to help researchers identify and address barriers to inclusion and improve the design of clinical trials involving adults with impaired capacity.

3. What is the main purpose of Advance Research Planning (ARP) for people with dementia?
- A) To enable individuals to express preferences about future research participation in case they lose capacity**
 - B) To speed up ethical review processes
 - C) To ensure they are excluded from high-risk research
 - D) To replace the need for informed consent in clinical trials

Answer: A; ARP helps individuals plan ahead by stating their preferences around research participation, reducing uncertainty for families and researchers.

4. Which of the following is a key challenge in recruiting participants for emergency clinical trials?
- A) Lack of available treatments for emergency conditions
 - B) Difficulty obtaining timely consent from patients or their proxies**
 - C) Patients often refuse to participate in research
 - D) Ethical committees do not allow emergency research

Answer: B; Urgent treatment needs and psychological/emotional stress make it more challenging to obtain consent.

5. Which of the following statements best describes a challenge associated with fluctuating capacity in clinical trials?
- A) Participants with fluctuating capacity may require hospitalisation during the trial
 - B) Fluctuating capacity is difficult to assess
 - C) People with fluctuating capacity are legally prohibited from participating in research
 - D) Fluctuating capacity makes it difficult to ensure consistent informed consent throughout the study**

Answer: D; Fluctuating capacity can vary over time, making it challenging to maintain informed consent. This requires ongoing assessment and support.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Recap multiple-choice questions and solutions

1. Which of the following best reflects the ethical guidance regarding the inclusion of adults lacking capacity in health-related research, as supported by the WHO?
- A) Adults lacking capacity should only be included in research if they can provide informed consent.
 - B) Adults lacking capacity should be excluded from research to avoid ethical complications.
 - C) Adults lacking capacity must be included in health-related research unless a valid scientific reason justifies their exclusion.**
 - D) Adults lacking capacity should be included only in observational studies, not interventional trials.

Answer: C; WHO supports research of the highest ethical standards and refers to the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2016), which states in Guideline 16: "Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion".

2. Which of the following best describes the approach used to develop and implement the INCLUDE Impaired Capacity to Consent framework for including adults with impaired capacity in research?
- A) The framework was developed by researchers and clinicians from five global regions.
 - B) The framework was created in five phases, including adaptation of an existing tool, piloting in diverse trials, consultation with affected individuals and carers, refinement, and development of implementation resources.**
 - C) The framework was designed for use specifically in dementia-related studies.
 - D) The framework was implemented in a single phase focused on ethical approval processes.

Answer: B; The framework was created with a five-phase development and implementation process.

3. Why is it increasingly important to conduct research in residential care settings for older adults?
- A) Because most older adults are expected to prefer living in care homes over independent living.
 - B) Because the global population aged 60 and over is set to rise
 - C) Because older adults in care homes rarely experience health conditions that require research-based interventions.
 - D) Because the population is ageing, and care homes will increasingly provide complex health care.**

Answer: D; The global population is shifting towards an ageing demographic. Care homes will become increasingly important in some parts of the world (such as the Global North) in delivering health and social care to residents, with innovations through research.

4. For clinical trials in emergency settings, what is a key condition for Exception From Informed Consent (EFIC) in the US?
- A) The patient must have a legal representative present
 - B) The trial must be conducted in a large hospital
 - C) There must be prior community consultation and public disclosure**
 - D) The patient must have previously agreed to participating in research

Answer: C; An EFIC requires community engagement and transparency before enrolling participants without prior consent.

5. Which of the following best describes fluctuating capacity?
- A) An inability to make decisions
 - B) A predictable or unpredictable change in decision-making ability over time**
 - C) A condition arising from dementia
 - D) A legal status that prevents research participation

Answer: B; Fluctuating capacity means changing capacity, which could be expected or unexpected. There are several factors that could contribute to fluctuating capacity. Fluctuating capacity can vary due to health conditions, time of day, or other factors, and may be predictable or unpredictable.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

True/False questions and solutions

1. Legal complexities and variation in laws across jurisdictions can make it challenging to include adults lacking capacity to consent in clinical trials.

*Answer: **True**; Different legal frameworks and requirements for surrogate or proxy consent can complicate the inclusion of these individuals in research.*

2. Tailored guidance, such as the INCLUDE Impaired Capacity to Consent Framework, is useful for researchers to navigate the legal, ethical, and practical challenges of including adults with impaired capacity in clinical trials.

*Answer: **True**; This framework has been designed to support inclusive research and address barriers to participation.*

3. A diagnosis of dementia means a person is unlikely to have the capacity to make decisions about participating in research.

*Answer: **False**; Capacity is decision-specific and time-specific. People with dementia may retain the ability to make certain decisions, especially in the early stages or on "good days".*

4. In emergency settings clinical trials can sometimes go ahead with enrolling participants without prior consent.

*Answer: **True**; In jurisdictions (including UK, US, EU, Canada, and Australia), alternative consent models such as EFIC or deferred consent are permitted under certain conditions.*

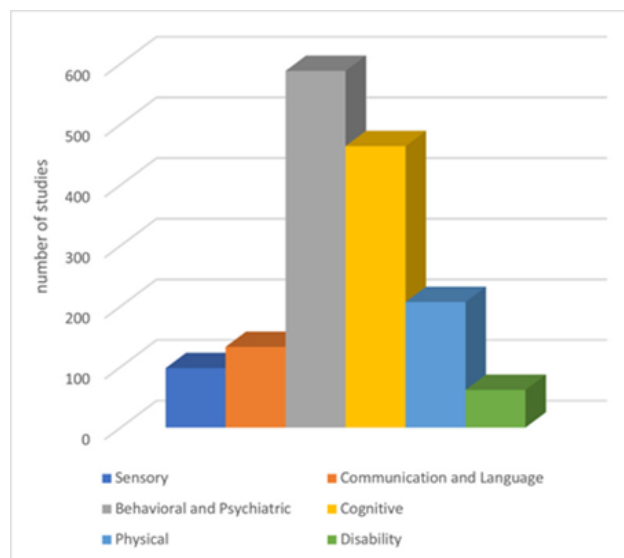
5. People experiencing fluctuating capacity, such as those with bipolar disorder, are often excluded from clinical trials due to concerns about compliance and informed consent.

*Answer: **True**; Studies show that psychiatric and psychological conditions are frequently listed as exclusion criteria, often without clear justification, which contributes to underrepresentation in research.*

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

8.1: Figure 1. Exclusion of people with disabilities from clinical trials related to the top 10 leading causes of global disability-adjusted life-years according to the Global Burden of Disease Study over the decade 2010-2020. The green bar "Disability" represents studies in which the type of disability was not otherwise specified. The disability categories most frequently excluded were behavioural or psychiatric disorders (grey bar) and cognitive impairment (yellow bar) [Source: [Camanni et al, 2023](#) licenced by [CC BY-NC 4.0](#)].



Key points for the teacher:

- The image shows a bar chart illustrating how often different disability groups are excluded from clinical trials.
- The vertical axis shows the number of studies (from 0 to about 600).
- The horizontal axis represents different types of disabilities.
- Behavioural and psychiatric disorders (grey colour) show the highest level of exclusion, at roughly 550 studies. Cognitive impairment (yellow) follows, with slightly above studies. Physical disabilities (light blue) sit in the middle range, around 200 studies. Communication and language disabilities (orange) and sensory disabilities (dark blue) are lower, at roughly 80 to 110 studies. Unspecified disability (green) is the least represented, at around 50 studies.

8.1: Shepherd V. Advances and challenges in conducting ethical trials involving populations lacking capacity to consent: A decade in review. *Contemp Clin Trials* [online]. 2020; 95:106054. [Accessed 8 Sept 2025]. Available from: <https://doi.org/10.1016/j.cct.2020.106054>



Contents lists available at [ScienceDirect](#)

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Advances and challenges in conducting ethical trials involving populations lacking capacity to consent: A decade in review

Victoria Shepherd

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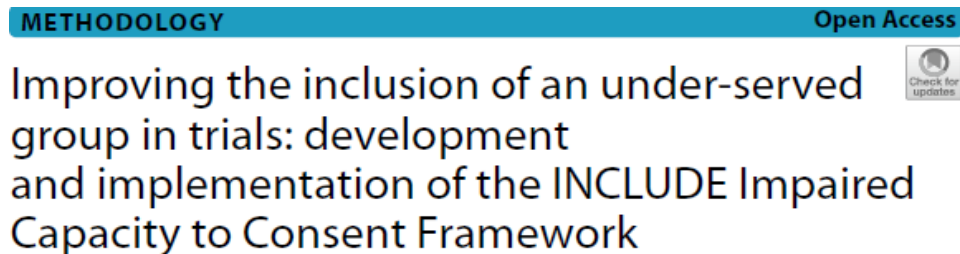
Key points for the teacher:

- The article explains that clinical trials often exclude people who lack capacity to consent, such as those with cognitive impairment or in emergency or critical care settings, which leads to research that does not reflect real clinical populations.
- It highlights that this exclusion creates ethical tension, because trying to protect vulnerable groups can unintentionally deny them access to evidence-based care.
- Over the past decade, there has been progress in recognising that these populations should be protected through research, not from research, although major barriers remain.
- Key challenges include complex legal frameworks, difficulties in identifying surrogate decision-makers, and the emotional and practical burden placed on surrogates.
- The article also shows how strict consent requirements in emergency research can reduce recruitment and introduce bias, sometimes even delaying potentially life-saving treatments. Alternative consent models, such as deferred consent or emergency waivers exist but are inconsistently applied and poorly harmonised across countries.
- The authors suggest practical solutions, such as advance research directives, better guidance for ethics committees and researchers, and more support for surrogate decision-makers.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

8.2: Shepherd V, Joyce K, Lewis A, Flynn S, Clout M, Nocivelli B, Segrott J, Treweek S. Improving the inclusion of an under-served group in trials: development and implementation of the INCLUDE Impaired Capacity to Consent Framework. *Trials* [online]. 2024; 25:83. [Accessed 8 Sept 2025]. Available from: <https://doi.org/10.1186/s13063-024-07944-x>



Key points for the teacher:

- The article describes the development of the INCLUDE Impaired Capacity to Consent Framework, which is designed to help researchers make clinical trials more inclusive for people who cannot provide consent themselves, such as those with cognitive impairment or acute illness.
- It explains that these groups are often excluded from research because of ethical, legal and practical complexity, which leads to evidence that does not reflect real patient populations.
- The framework was created through collaboration with researchers, patients and carers and tested across multiple study types to make sure it works in real research settings. It is built around four key questions (see Figure 3 in the article or described on the right side on this page of the Teachers' guide) that help teams think about who should be included in trials and what barriers might prevent participation.
- The framework is supported by practical tools such as worksheets, training materials, and accessible resources to help teams apply it in practice.
- Early implementation showed that it improves awareness and helps research teams design more inclusive studies.
- The authors emphasise that inclusion is both an ethical requirement and is necessary for generating reliable evidence for real-world care.

8.2: Figure 1. The four key questions of the INCLUDE Impaired Capacity to Consent Framework and associated worksheets [Source: [Shepherd et al., 2024](#) licenced by [CC BY 4.0](#)].



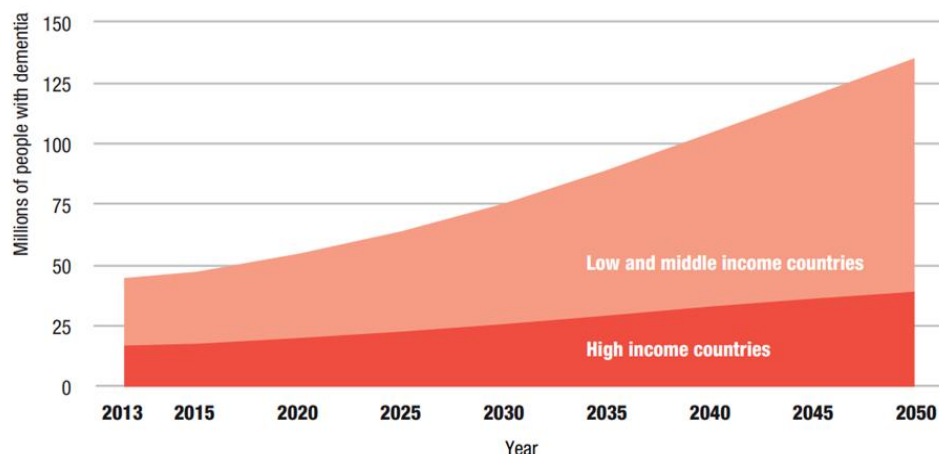
Key points for the teacher:

- The picture is an infographic showing the structure of the INCLUDE Impaired Capacity to Consent Framework and how the four key questions link to specific worksheets.
- The left side shows the key questions:
 - **Q1:** Who should my trial results apply to?
 - **Q2:** Are they likely to respond to the intervention in a different way?
 - **Q3:** Will my intervention make it harder for them to respond?
 - **Q4:** Will my trial design make it harder for them to take part in or remain in the trial?
- On the right side, each question is connected to the practical worksheets used to work through that topic:
 - Q1 points to identifying populations with conditions or disabilities that may impair capacity to consent.
 - Q2 links to Worksheet A, which covers condition, or disability related factors.
 - Q3 links to Worksheet B, which focuses on intervention, or comparator related factors.
 - Q4 links to multiple worksheets: Worksheet C: eligibility and recruitment, D: data collection, E: analysis, F: reporting and dissemination.
- At the bottom, there is a final section called "Summary of actions and resources needed", which links to Worksheet G, where teams summarise key actions, required resources and costs.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

8.3: Figure 1. Projected numbers of people living with dementia by 2050 [Source: [ADI, 2013](#)].



Key points for the teacher:

- The figure shows a chart projecting the global number of people living with dementia from 2013 to 2050.
- The horizontal axis represents the years, while the vertical axis shows the number of people with dementia in millions, increasing from around 45–50 million in 2013 to approximately 130–140 million by 2050.
- The chart is divided into two regions, with high-income countries forming the lower, smaller portion, and low- and middle-income countries forming the larger, upper portion.
- The projection shows a steady global increase over time, with most of the growth expected to occur in low- and middle-income countries.

8.3: Butler CC, Owen-Jones E, Lau M, Gillespie D, Lown M, Calder PC, Stanton H, Wootton M, Castro Herrera V, Bayer A, Davies J, Edwards A, Davoudianfar M, Rutter H, Hood K, Moore M, Little P, Shepherd V, Lowe R, Miles EA, Townson J, Hobbs FDR, Francis NA on behalf of the PRINCESS trial team. Probiotics to reduce antibiotic administration in care home residents aged 65 years and older: the PRINCESS RCT. In: Efficacy and Mechanism Evaluation No. 8.7. Southampton (UK): NIHR Journals Library; 2021. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK570117/>



Probiotics to reduce antibiotic administration in care home residents aged 65 years and older: the PRINCESS RCT.

[Show details](#)

[Contents](#) ▾

Search this book

Chapter 2 Methods for the randomised trial

Key points for the teacher:

- Chapter 2 of this document describes the methods of the PRINCESS randomised controlled trial, which evaluated whether daily probiotics could reduce antibiotic use in care home residents aged 65 and older.
- The trial was designed as a double-blind, placebo-controlled study across multiple care homes and aimed to reflect real-world populations by including residents both with and without capacity to consent.
- The researchers used adapted consent materials, consultee processes, and ongoing capacity assessment to ensure ethical inclusion of frail older adults.
- Data were collected weekly over 12 months, covering infections, antibiotic use, hospitalisations, quality of life and safety outcomes, supported by biological samples such as blood, saliva and stool.
- The study also embedded mechanistic substudies to understand immune responses, microbiology and vaccine response.
- Strong data management, monitoring, and statistical methods were used to ensure robust and reliable results.
- The study provides a practical model for designing trials that are both methodologically strong and relevant to real clinical populations.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

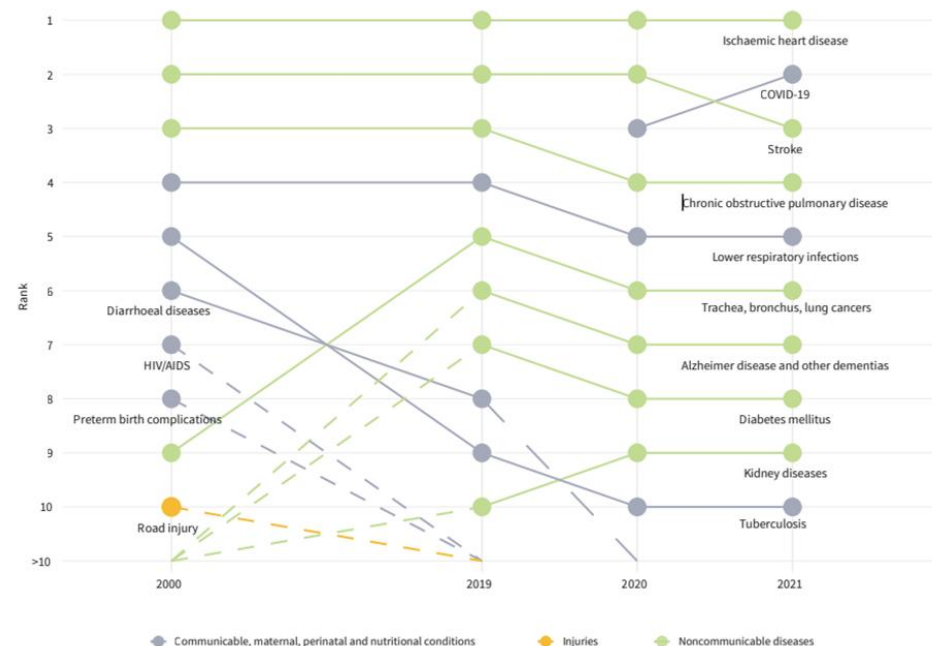
8.4: https://www.acep.org/siteassets/sites/rsai-section/media/documents/efic_primer_2024.pdf



Key points for the teacher:

- These key points apply to pages 56–60 of this document, as this section is intended for use in Lesson 8.4.
- These pages describe an example EFIC (Exception From Informed Consent) study conducted at Yale that tested REBOA (a haemorrhage control technique) for out-of-hospital cardiac arrest.
- The study required extensive ethical review, IRB (institutional review board) engagement, and strong community consultation because patients cannot provide consent during cardiac arrest.
- The team conducted multiple community meetings, used cultural ambassador networks and created educational materials to explain risks, benefits, and study design.
- They also used broad communication channels including flyers, newspapers, digital ads, and social media to reach the target population.
- The consultation process revealed concerns about research without consent as well as historical mistrust of the medical system in some communities.
- Overall, the case shows that EFIC research requires continuous, transparent engagement with communities, not just regulatory approval.

8.4: Figure 1. Stroke is a leading cause of global deaths. Solid lines represent movement within the top 10 causes of death. Dashed lines represent movement into or out of the top 10 causes of death [Source: [WHO, 2024](#) licenced by [CC BY-NC-SA 3.0 IGO](#)].



Key points for the teacher:

- The picture is a line chart showing changes in the ranking of the top global causes of death between 2000, 2019, 2020, and 2021.
- The vertical axis shows rank, where 1 is the leading cause of death. The horizontal axis shows time points (2000 → 2021). The chart uses colours to distinguish disease groups:
 - Green = noncommunicable diseases
 - Blue/Grey = communicable, maternal, perinatal, and nutritional conditions
 - Yellow = injuries
- Solid lines show causes that stayed within the top 10 across years. Dashed lines show causes moving into or out of the top 10.
- By 2021, the leading causes of death are ischaemic heart disease ranked first, followed by COVID-19 (ranked second in 2021) and stroke. Other major causes include chronic obstructive pulmonary disease, lower respiratory infections, lung cancers, Alzheimer disease and other dementias, diabetes, kidney disease, and tuberculosis.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

8.4: Broderick JP, Silva GS, Selim M, Kasner SE, Aziz Y, Sutherland J, Jauch EC, Adeoye OM, Hill MD, Mistry EA, Lyden PD, Mocco J, Smith EM, Hernandez-Jimenez M, Deljich E, Kamel H; on behalf of the STAIR XII Participants. Enhancing Enrollment in Acute Stroke Trials: Current State and Consensus Recommendations. *Stroke* [online]. 2023; 54(10):2698-2707. [Accessed 8 Sept 2025]. Available from: <https://doi.org/10.1161/STROKEAHA.123.044149>

Stroke

Volume 54, Issue 10, October 2023; Pages 2698-2707
<https://doi.org/10.1161/STROKEAHA.123.044149>



SPECIAL REPORTS

Enhancing Enrollment in Acute Stroke Trials: Current State and Consensus Recommendations

Key points for the teacher:

- The article discusses why recruitment into acute stroke clinical trials is difficult and presents expert consensus recommendations on how to improve it.
- Acute stroke trials face unique challenges because treatment must start quickly, patients often cannot provide consent, and researchers usually have no prior relationship with patients or families.
- The authors emphasise that trial design is critical, especially in keeping eligibility criteria as inclusive as possible and integrating study procedures into routine clinical workflows to reduce burden on staff and patients.
- Emergency consent processes are essential but vary widely across countries and can significantly affect recruitment speed (shown in Table 1).
- The article also points to solutions such as telemedicine-based consent, global trials, better training of research staff, and earlier involvement of patients in trial design. In Table 2, you can find 12 important actions to enhance enrolment and trial completion in acute stroke trials.

8.5: Dahò M, Coppini V, Ferrari MV, Ferraris G, Sanchini V, Monzani D, Grasso R, Agnello C, Badalamenti G, Algeri L, Pravettoni G. Exploring Barriers to Inclusivity: Systematic Analysis of Exclusion Criteria and Potential Bias in Clinical Cancer Trials for Psychiatric and Neurological Conditions in European Protocols. *Psycho-Oncol* [online]. 2025; 34:5. [Accessed 8 Sept 2025]. Available from: <https://doi.org/10.1002/pon.70182>

Exploring Barriers to Inclusivity: Systematic Analysis of Exclusion Criteria and Potential Bias in Clinical Cancer Trials for Psychiatric and Neurological Conditions in European Protocols

[Margherita Dahò](#) ✉, [Veronica Coppini](#), [Maria Vittoria Ferrari](#), [Giulia Ferraris](#), [Virginia Sanchini](#), [Dario Monzani](#), [Roberto Grasso](#), [Chiara Agnello](#), [Giuseppe Badalamenti](#), [Laura Algeri](#), [Gabriella Pravettoni](#)

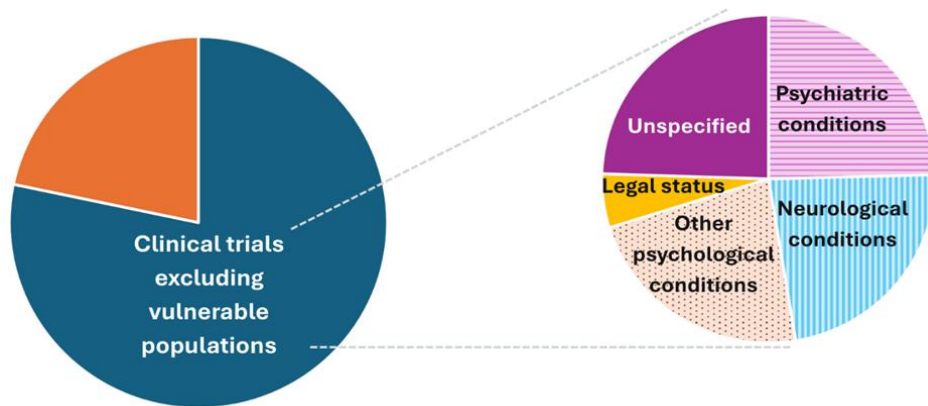
Key points for the teacher:

- This article analyses how often vulnerable populations, especially people with psychiatric or neurological conditions, are excluded from cancer clinical trials in Europe and why.
- The authors reviewed 46 recent trial protocols for breast, prostate, and lung cancer and found that over three quarters included exclusion criteria affecting these groups.
- The most common reasons given were concerns about protocol compliance, ability to provide informed consent, and safety, although nearly one third of protocols did not clearly justify exclusions.
- The paper argues that while these exclusions are often intended to protect patients, they can also reduce the generalisability of results and worsen health inequalities.
- Ethical frameworks such as the Declaration of Helsinki actually support careful inclusion when research is relevant to vulnerable groups.
- The paper suggests practical solutions such as adaptive trial designs, better consent approaches, and stronger involvement.

UNIT 8: CASE STUDY: ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Articles, pictures outlines

8.5: Figure 1. The exclusion of vulnerable groups from clinical trials in prostate, breast and lung cancer. Of 46 study protocols, 78.3% had exclusion criteria eliminating vulnerable groups, categorised into five themes: psychiatric conditions (24.6%), neurological conditions (22.8%), other psychological conditions (22.8%), legal/guardianship status (5.3%), and unspecified conditions (24.6%). [Source: data presented as described in [Dahò et al., 2025](#)].



Key points for the teacher:

- The picture shows two connected pie charts illustrating how vulnerable populations are excluded from clinical trials in prostate, breast, and lung cancer studies.
- The left pie chart shows the overall proportion of trials that exclude vulnerable populations. It indicates that out of 46 study protocols, 78.3% included exclusion criteria that removed vulnerable groups from participation, while a smaller portion did not.
- The right pie chart breaks down the reasons for exclusion into five categories. The largest portions are psychiatric conditions (24.6%), unspecified conditions (24.6%) and neurological conditions (22.8%). Smaller portions include other psychological conditions (22.8%) and legal or guardianship status (5.3%).
- The main message of the picture is that exclusion of vulnerable populations is common and is most often related to mental health, neurological, or unspecified conditions.

8.5: Palmer BW, Savla GN, Roesch SC, Jeste DV. Changes in capacity to consent over time in patients involved in psychiatric research. Br J Psychiatry [online]. 2013; 202(6):454-458. [Accessed 8 Sept 2025]. Available from: <https://doi.org/10.1192/bjp.bp.112.121160>

Changes in capacity to consent over time in patients involved in psychiatric research

Barton W. Palmer, Gauri N. Savla, Scott C. Roesch and Dilip V. Jeste

Key points for the teacher:

- This article explains how capacity to consent changes over time in people with serious mental illness participating in psychiatric research.
- The study followed 161 patients with schizophrenia or bipolar disorder for up to two years and repeatedly assessed their decision-making capacity using a structured tool (the MacArthur Competence Assessment Tool for Clinical Research).
- The results showed that patients' understanding of study information can improve during consent discussions when feedback is given, but this improvement often fades between study visits.
- Decision-making capacity tended to remain relatively stable over time, although there were important differences between individuals.
- Better cognitive functioning was consistently linked to better capacity to consent, while symptom severity had only modest effects.
- The authors argue that informed consent should be treated as an ongoing conversation rather than a one-time event at enrolment.
- The study suggests that researchers should regularly reassess capacity, especially in populations where cognition or symptoms may fluctuate.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

General overview of the unit for the teacher

OBJECTIVES

The aim of this unit is to build upon students' existing knowledge of inclusivity in clinical research. We will focus on the practical aspects of establishing truly effective collaborations with under-served groups. Through real-world examples, students will learn to distinguish between genuinely inclusive research practices and superficial elements that may appear to enhance inclusivity but, in reality, do not support it meaningfully.

UNIT CONTENT

- 9.1: Performativity and clinical trials
- 9.2: Intersectionality and clinical trials
- 9.3: Clinical trials and digital divide
- 9.4: Resource scarcity and clinical trials
- 9.5: Metrics of success for clinical trials
- Summary of Unit 9

LEARNING OUTCOMES

Students will be able to:

1. Identify wider systemic issues related to building links with under-served groups
2. Explain key concepts related to clinical trials including performativity, intersectionality, the digital divide, resource scarcity, and success metrics
3. Discuss how diverse frameworks shape participant engagement in clinical trials, with an emphasis on under-served groups
4. Outline future challenges and opportunities for building links with under-served groups

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Blended 90-minute classroom

 pre-class reading
brick-and-mortar 5x2 hours
90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 9.1 pre-class; read the article of Ocloo <i>et al.</i> ; look at the optional readings; complete the reflective activity; test your knowledge.
Tue	Complete Lesson 9.2 pre-class; read example #2 of the Hankivsky <i>et al.</i> publication; read about the WISDOM study; complete the reflective activity.
Wed	Complete Lesson 9.3 pre-class; read the paper of Makri <i>et al.</i> ; complete the reflective activity; complete the MCQs.
Thu	Complete Lesson 9.4 pre-class; complete the reflective activity; complete the MCQs.
Fri	Complete Lesson 9.5 pre-class; read the Hayes' <i>et al.</i> publication; complete the reflective activity and the test; read the Summary of Unit 9; complete the MCQs.

OPENING THE LESSON

10' 



 **Brainstorm** – ask students to respond to the following prompt “**What makes a clinical trial inclusive?**” Encourage short phrases or keywords.

Hints and solutions for the teacher:

- Collect suggestions, write them on the whiteboard; always ask students for their explanation
- Examples: community involvement, culturally sensitive design, multilingual, flexible participation options, trust-building, low-barrier recruitment, intersectional inclusion criteria, feedback loops with participants, long-term community benefit
- To further stimulate the brainstorm, please repeat that according to the pre-class reading: “inclusive health research means all those involved can contribute to decision-making and influence the outcomes”. Do previously mentioned keywords and phrases correspond?

WORK IN PAIRS

20–25' 



Provide students with the following phrases, ask them to organise them into two groups – “inclusive elements” and “non-inclusive elements”.

Once ready, ask them to identify tokenism, performativity, the ‘digital divide’, lack of intersectionality, co-production.

Patients feel respected

A community leader asked to endorse

Eligibility criteria reflect population diversity

Three persons per minority group included

Digital tools are optional

Informed consent translated

Trial design considers different life experiences

The same protocol was followed for everyone to be fair

A diversity photo was used on a recruitment flyer

Debriefing (10 minutes)

Hints and solutions for the teacher:

- Inclusive elements are highlighted.
- Tokenism (include but ignore):
 - a community leader asked to endorse (one endorsement isn't enough; it can be tokenistic if not followed by sustained, reciprocal relationships and co-design/co-production with the community)
 - Three persons ... (it assumes that several persons can represent an entire group, ignoring diversity within groups)
- Performativity (look good)
 - A diversity photo (it looks inclusive but doesn't address real barriers)
 - Informed Consent Form translated (translation is a good step, but language access alone isn't sufficient; cultural relevance, conceptual equivalence, literacy level, and trust-building are essential).
- Digital divide – not present (digital tools “optional only” evoke other non-digital options)
- Intersectionality (lack of intersectionality)
 - same protocol ... (fairness doesn't mean identical treatment; equity vs. equality)
- Co-production – a community leader ... might be an example (see above)



Building on the previous discussion ask students for the definition of the following terms in their own words: **tokenism, performativity, digital divide, lack of intersectionality, co-production.** (5 minutes)

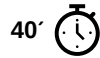
Hints and solutions for the teacher:

- Tokenism – include but ignore; just to appear diverse, without real influence
- Performativity – look good, look inclusive, look ethical, look rather than do
- Digital divide – gap between people with and without an easy access to technologies
- Intersectionality – interaction of different aspects of person's identity; a key element in inclusivity
- Co-production – collaborative approach; equal partners, lived experience with science

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Blended 90-minute classroom

TEAM-BASED WORK



5–8 students per team

Let's continue to think about the co-production of a clinical study incorporating experienced stakeholder perspectives.



Task 1 – Co-production key principles (5 minutes)

Ask students to summarise the five key principles of co-production outlined in the pre-class reading.

Hints and solutions for the teacher:

- 1) Sharing power, 2) Including all perspectives and skills, 3) Respecting and valuing the knowledge of all those working together on the research, 4) Reciprocity, 5) Building and maintaining relationships



Task 2 – Engagement strategy building (25 minutes)

Ask students to imagine that they are part of a multi-stakeholder team tasked with designing the public engagement strategy for a new clinical trial. The trial aims to recruit participants from under-served communities, including ethnic minorities, low-income populations, and individuals with limited digital access. Students can use **their own scenarios or they can use one** of the following:

- A trial using a mobile app to support lifestyle changes for diabetes prevention.
- A vaccine trial in an urban area with a history of medical mistrust, particularly among Black and low-income populations. The trial aims to improve uptake and representation.
- A trial to test a new HIV prevention strategy among transgender youth aged 16–24. Many potential participants face stigma, housing instability, and limited access to healthcare.
- A remote monitoring system for elderly patients with chronic heart failure. The trial relies on wearable devices.
- Assign roles** to each 1 or 2 students (2–3 minutes)
 - A researcher/an investigator.
 - A patient or a representative of a patient organisation.
 - A specialist on digital technologies.
 - A community leader. Or any other relevant role.
- Ask students with a role assigned to think at first on their focus, on what do they **promote**, what they should **lobby for**. Ask them to list these on paper (2–3 minutes).
- Ask students to **build an engagement strategy** using this co-production and multistakeholder approach – priorities summary, overlaps and tensions, steps, removing barriers, reflecting on ethical and inclusive values.



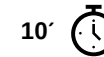
Debriefing (10 minutes)

Two or three groups present their strategy in 2–3 minutes.

Hints and solutions for the teacher:

- Priorities summary:**
 - Researcher:** scientific rigor, meet recruitment targets, maintain compliance, retention
 - Patient:** safety, burden, cultural sensitivity, communication
 - Digital specialist:** tech solutions, solutions for low-tech participants
 - Community leader:** trust building, local voices involvement, stigma
- Overlaps:** trust, adequate communication
- Tension:** digital specialist vs. community leader, researcher vs. patient
- Strategy:**
 - Community advisory board, hybrid recruitment, accessible information and informed consent, trust building activities, feedback loops (including sharing results and patient inputs)
 - Transport vouchers, loaned devices, tech support, culturally relevant messaging, avoid jargon, privacy protection
 - Common decision-making, transparency, equity

REFLECTION, WRAP-UP



- How diverse frameworks shape participant engagement in clinical trials?
- Which frameworks were easiest or hardest to integrate in the strategy building task? What compromises were made?
- How did this process shape your understanding of inclusive trial design?
- Any future challenges and opportunities for building links with under-served groups? Can you predict some?

Hints and solutions for the teacher:

- Question 1:** Intersectionality ensures considering overlapping identities and unique barriers. Community based participatory research promotes co-production (equality of community members). Performativity critique helps to identify gestures. Digital inclusion framework addresses digital divide.
- Question 4:** Increasing digital dependence, complex intersectional barriers, data privacy and trust, resource scarcity, climate-related displacements and migration producing new under-served groups. Opportunities: policy and regulatory shifts (stronger mandates for diversity, inclusion), AI data analytics, digital equity initiatives, ...

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

10'



- **Brainstorm** can be adapted in Whiteboard (available in Zoom or MS Teams).

WORK IN PAIRS

20–25'



- Prepare a slide (editable format) with three columns – in the first place the boxes with the phrases; the second will be for the “inclusive elements” and the third for the “non-inclusive elements”. Clear the highlighting if still present so that all boxes look like the same.
- Share this slide with students via chat and ask them to download.
- Assign students to breakout rooms (possible in Zoom or MS Teams). Ask them to organise the boxes into columns, identify tokenism, performativity, digital divide, lack of intersectionality, co-production, including the reasoning.
- Assign one facilitator/trained students to each group to help the students with technical issues, stimulate a collaborative environment and discussions. In larger groups, provide technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room

Debriefing (10 minutes)

- Ask one group to share their screen and present the distribution of the boxes.
- Ask the other whether they have different solution and ask them to explain their idea.
- Ask other groups to identify tokenism and explain. Another group – performativity and explain. Another group digital divide and explain. Another group – intersectionality and explain. Another group – co-production and explain.



Building on the previous discussion ask students for the definition of the following terms in their own words: **tokenism, performativity, digital divide, lack of intersectionality, co-production.** (5 minutes)

- Ask students to define the following terms in their own words.
- Only discussion; no need to collect or write notes.
- At the end, do not forget to ask the students which terms they would appreciate having explained to them/which ones they do not understand.

TEAM-BASED WORK

40'



5–8 students per team



Task 1 – Co-production key principles (5 minutes)

Ask students to summarise the five key principles of co-production outlined in the pre-class reading.

- Only discussion, no need to collect or write notes.



Task 2 – Engagement strategy building (25 minutes)

- Before assigning the students to the breakout rooms:
 - Describe the task, emphasize that students will be working on a strategy for a scenario (own or selected) and that they will have different roles (investigator, patient, digital technologies specialist, and community leader).
 - Distribute the roles:
 - share a list of students with assigned roles on the screen (probably needs to be prepared in advance or during the previous work in pairs).
 - Another option is to prepare four breakout rooms (one for each role) and assign students here to discuss the focus of their role together. Open these rooms only for short, e.g. 3 minutes.
- Once everybody knows their role or is back in the main room, share the pre-prepared scenarios via chat.
- Assign students to breakoutrooms according to their roles – each breakout room should have at least one person of each role.
- Assign one facilitator/trained students to each group to help the students with technical issues, stimulate a collaborative environment and discussions. In larger groups, provide technical support (helps to assign students to groups, solve individual technical issues).
- Circulate around the breakout rooms as you would in an in-person class.
- Announce the timing (e.g. Broadcasting in Zoom), share the timer in the main room.



Debriefing (10 minutes)

Two or three groups present their strategy in 2–3 minutes.

REFLECTION, WRAP-UP

10'



- Only discussion; no need to collect or write notes.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Reflective activity 9.1: “Tokenism: Seeing It, Fixing It” modified for synchronous use

Link: [Tokenism: Seeing it. Fixing it. Perspectives from IMHA Patient Partners](#)

Review the scenarios in the activity “Tokenism: Seeing It, Fixing It” from the Institute of Musculoskeletal Health and Arthritis, part of the Canadian Institutes of Health Research.

For each scenario, begin by considering your response from the perspective of patient involvement, then reflect on how you would approach it as a researcher. How did your perspective shift between these roles? What unique factors did you have to consider in each viewpoint?

MODIFICATION FOR INDIVIDUAL WORK



Choose two scenarios. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What would you do as a patient partner in that situation?
2. How would you address this situation if you were part of the research team?
3. What unique factors did you have to consider in each role?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Each team will review one scenario. Ask students to discuss the following within their teams:

1. What would you feel and do as a patient partner in that situation?
2. How would you address that situation if you were part of the research team? Is there anything you might struggle with?
3. Think about 1-3 recommendations that bridge both perspectives.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their scenario in two minutes. Write the students' recommendations on the board and use them after for a whole-class discussion.

Hints and solutions for the teacher:

- Do the recommendations for individual scenarios differ, or do they share similarities?
- What practical changes could prevent tokenism in these scenarios?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



At the beginning, ask students to explain the following terms: **co-production**, **tokenism**. Let them identify several points in the clinical trial life cycle where co-production can be implemented.

Then divide the class into two groups – one will examine the first two scenarios from the patient's perspective, while the other from the researcher's perspective. Select four scenarios and display them one by one on the screen or read them aloud to the students. On the board, note down their observations (e.g. needs, risks, expectations) for each perspective separately. For the next two scenarios, switch the roles of the groups.

Afterwards, lead a whole-class discussion:

1. What was the most problematic aspect for the patient partner?
2. Which factors do you naturally consider as a researcher?
3. How does your sense of fairness and the value of involvement change as you move between perspectives?
4. What practical changes could prevent tokenism in these scenarios?

Hints and solutions for the teacher:

- Encourage students to use particular examples from the scenario rather than general statements.
- Deepen the discussion with these questions:
 - Question 2: Are there any structural or institutional barriers on the researcher's side that make tokenism more likely? How could they be addressed? (You can discuss time, funding, ethics, responsibility, representativeness, etc.)
 - Why do you think tokenism happens in research teams, even when people may have good intentions?



UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Reflective activity 9.2: “Using the Health Privilege Activity to demonstrate disparities in society” modified for synchronous use

Link: [Irby-Shasanmi et al., 2012](#)

Complete the Health Privilege Activity: Pre-Test (Appendix B) developed by Irby-Shasanmi et al.

Now consider the health privilege statements listed in Appendix A including the topics of: Hearing, Disordered eating, Neighbourhood context, Psychosocial factors: Coping mechanisms, Socioeconomic status, Health-care related factors. Reflect on your responses to each of the statements listed in Appendix A. Or consider completing Appendix C: Health Privilege Activity: Post-Test. What aspects of intersectionality as relevant to health did this activity highlight for you?

MODIFICATION FOR INDIVIDUAL WORK



Complete the health privilege activity pre-test in Appendix B. Then, review the list of health privilege statements in Appendix A and reflect on your responses to each statement.

Write a short reflection (100–150 words) addressing:

1. Which health privilege statements resonated with you the most, and why?
2. What aspects of intersectionality did this activity highlight for you?

Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Go through the most resonating statements from student responses and summarise them to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4–6 students per team

Individually, each team member completes the health privilege activity pre-test (Appendix B). As a team, read through the list of health privilege statements in Appendix A. Discuss the following question together: Which statements would most strongly affect a person's ability to engage with health services? Note which statements generated the most intense discussions or divergent opinions within your team.

After the team discussion, each student completes the pre-test again and reflects on how the discussion influenced their perspective.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their key discussion points in three minutes. After all team presentations, you might continue with a whole-class discussion on:

1. How might these privilege dynamics affect a person's ability to participate in clinical trials?
2. Which aspects of intersectionality shape these experiences?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Adapted from Irby-Shasanmi et al., 2012.

Ask students to stand in a circle. Explain that the centre of the circle represents a healthy, functioning heart. Students standing closer to the centre possess greater overall health and more health privilege.

Tell students you will read a series of health privilege statements (Appendix A). After each statement, students remain stationary or move one step inside or outside of the circle, depending on their relationship to the statement. Invite students to look around silently, observe the clusters and distances and take notes on their observations.

Then guide the group into a structured reflection using the question below:



- When you looked around the room, whom did you see closest to the centre, in the middle, and further away? How did you feel about your positions relative to others?
- Which statements did you find most meaningful, surprising, or uncomfortable for you? Why?
- Which aspects of intersectionality shaped the differences you observed?
- How might these privilege dynamics influence access to health care?

Hints and solutions for the teacher:

- Inform students that participation is voluntary throughout the activity.
- As this activity highlights issues of stratification in the country, create a safe space. Ensure that students feel comfortable sharing their opinions.
- Due to the sensitive nature of the health privilege statements, tell students that even if a statement reflects their experience, they have the option of remaining stationary.
- Ensure the group size is adequate to show variation (ideally 10+ students).
- You may use the full list of statements or select the ones most relevant to your country's context.
- Link the reflections to course themes: equity, access, under-served groups, barriers to inclusion, and representation in clinical trials.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Reflective activity 9.3: “The *Implementome*” modified for synchronous use

Link: [Implementome](#)

Explore the *Implementome*, a digital health platform from the Geneva Digital Health Hub addressing key challenges in digital health transformation.

Choose a project and consider the role of digital health technologies – you may choose to search for a project with a clinical trial component.

What digital tools can you identify? How does the project address the digital divide?

MODIFICATION FOR INDIVIDUAL WORK



Explore the *Implementome* platform. Select one project that interests you, ideally one that evaluates the impact of digital tools. Write a short reflection (100–150 words) addressing the following questions and submit it to a cloud/discussion board:

1. What digital tools can you identify in this project?
2. How does the project address the digital divide? Consider who may be excluded due to limited digital access or skills, and how the project attempts to reduce this gap.
3. What ethical or practical challenges do you see when implementing these digital tools in healthcare?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–6 students per team

Divide students into teams. Let each group select (or assign them) one project from the *Implementome* platform. Prevent duplication of projects. Ask students to discuss the following within their team:

1. What specific digital tool does the project use?
2. How does the project address the digital divide?
3. What barriers may arise for people who have limited access to technology?
4. Which population groups are most at risk of exclusion when such technologies are introduced?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to prepare a short presentation summarising its findings (max. five minutes). After all presentations, discuss any similarities and differences among the projects.

Hints and solutions for the teacher:

- If possible, choose projects from different jurisdictions (e.g., U.S., Europe, Africa) to highlight how digital inclusion challenges vary across settings.
- Encourage students to consider local context: geography, socio-economic status, cultural factors, existing health system capacities, etc.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin by briefly recapping the concept of the **digital divide** and invite students to identify key contributing factors (e.g. lack of infrastructure, geographic disparities, socioeconomic factors, under-served groups; usually interrelated).

Select two projects from the *Implementome* platform. Divide the class into two halves. Provide students with one of these projects. Give them 3 minutes to read the project details.

For each project, discuss in the whole class:

- What specific digital tools does the project use?
- How does the project address the digital divide?

Write the key points from students' answers on the board. After going through both projects, discuss what these projects have in common and in what ways they differ.

Next, transition the discussion toward clinical trials:

1. What are the benefits of using digital tools in clinical trials?
2. What ethical or practical challenges do you foresee when implementing these tools in clinical trial settings?

Hints and solutions for the teacher:

- Ensure that students can access the *Implementome* platform. If needed, select and print project summaries in advance.
- If possible, choose projects from different jurisdictions (e.g., U.S., Europe, Africa) to highlight how digital inclusion challenges vary across settings.
- Project tips:
 - [i-MoMCARE powered by MEDplat](#)
 - [Memory Lane Games - Digital Health Localised Reminiscence App](#)
 - [ASCENT project \(Adherence Support Coalition to End TB\)](#)
- Stimulate the discussion by asking additional questions:
 - Give examples of tools and relate them to barriers faced by particular under-served groups.



UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Reflective activity 9.4: “Clinical trials in low resource settings” modified for synchronous use

Link: [Van den Berg et al., 2019](#)

Consider the perspectives of parents and other paediatric caregivers in a malaria vaccine clinical trial where participation enables access to free, high-quality medical care:

Van den Berg M, Ogutu B, Sewankambo NK, Merten S, Biller-Andorno N, Tanner M. Clinical trials in low-resource settings: the perspectives of caregivers of paediatric participants from Uganda, Tanzania and Kenya. *Trop Med Int Health* [online]. 2019; 24(8):1023-30. [Accessed 15th Sept 2025]. Available from: <https://doi.org/10.1111/tmi.13281>

MODIFICATION FOR INDIVIDUAL WORK



Read the article from Van den Ber et al. As you are reading, reflect on the following questions:

1. What motivated caregivers to enrol their children? How might this influence the voluntariness of consent?
2. What was the role of social networks and community in choosing to participate in the clinical trial? Consider how this may influence the decision-making process.
3. What are the implications for ethical research practices? Reflect on how the findings might inform ethical guidelines and practices for low-resource settings.

Write a short, structured reflection (max. 200 words) and submit it to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



5–6 students per team

Divide students into teams. Each team read the Results and Discussion of the article from Van den Ber et al. First, summarise as a team the following points:

1. Key motivations of caregivers to enrol their children.
2. How these motivations may challenge the voluntariness of consent.
3. The role of community and social networks in the decision-making process.

Then, think about the practical recommendations for trials in low-resource settings.

Prepare a 3–5-minute team summary (slide, mind-map, or short verbal presentation).

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, select two teams to present their outputs. Invite all students to join the discussion and share their perspectives.

Hints and solutions for the teacher:

■ *Additional questions to deepen the reflection:*



- What risks do caregivers perceive and what reassures them?
- Does access to free, high-quality medical care function as a benefit, an inducement, or both? Why?
- What responsibilities do researchers have when participants join trials primarily due to unmet medical needs?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin with a brief discussion: What factors can threaten the voluntariness of consent in a low-resource setting?

Read selected quotations from the respondents together. Ask students to write down two motivations for participation identified in the article and one ethical challenge that arises from these motivations. Give 2–3 minutes for this step. After that, guide the discussion using the following questions:

1. Which motivations for enrolling children were the strongest?
2. How might these motivations blur the line between access and inducement?
3. What was the role of social networks and community?
4. What are the implications for ethical research practices?
5. How do clinical trials differ between high- and low-resource settings?

Hints and solutions for the teacher:

- In advance, prepare several short quotations from the respondents to read together in class.
- Question 4: Guide students to recognise the complex ethical and contextual challenges in such settings, including: informed consent under structural vulnerability, choice of standard of care (Should it be the best globally or locally available?), role and responsibilities of ethics committees, and access to treatments after the research ends.
- Question 5: Ask students to reflect on their own country – are there groups who face similar challenges? Consider different under-served groups by demographic factors/social and economic factors/health status/disease-specific factors you learned about in Unit 2. (e.g., rare disease patients with unmet medical need)

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Reflective activity 9.5: “EU TrialsTracker – Who’s not sharing clinical trial results?” modified for synchronous use

Link: [AllTrials](#) & [EU TrialsTracker](#)

Follow the steps from AllTrials on how to use the EU TrialsTracker website: <https://www.alltrials.net/ask-your-institution/>

You can follow the example using the University of Birmingham or use another institution of your choosing: <https://eu.trialstracker.net/?search>

Choose a clinical trial marked as ‘not reported’. Can you find any further information about the clinical trial? If choosing your own institution, how many trials are currently marked as ‘Not reported’?

MODIFICATION FOR INDIVIDUAL WORK



Go to the AllTrials website and follow the instructions on how to use the EU TrialsTracker. Enter the name of a European research institution of your choice. Identify one clinical trial listed as ‘Not reported’. Try to find any additional information about the trial (e.g., trial ID, title, objectives, completion date). Then write a short paragraph (100–150 words) summarising the trial information and reflecting on the following questions:

1. Why do you think the trial results were never reported?
2. What are the possible consequences for patients, science, and public trust?

Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise recurring themes from student responses to guide a whole-class discussion focusing on: What could the institution do now to address this lack of transparency?

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Each team selects (or is assigned) a different institution from the EU TrialsTracker. They identify at least one clinical trial listed as ‘Not reported’ and search for any additional information about the trial. Ask students to discuss:

1. Why might the results not have been reported?
2. Who is affected by the lack of reporting?
3. What practical steps could the institutions take to increase transparency and ensure the missing results are reported?

Ask each team to create a short action plan or open letter addressed to the institution, calling for the reporting of missing results.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their output to the rest of the class in three minutes.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin by showing the EU Trials Tracker website to the class. Start with a warm-up question:

1. Why is it a problem if clinical trial results are not publicly reported?

Invite students to browse several institutions and compare their rates of ‘Not reported’ trials.

Ask:

2. Are some institutions better or worse at reporting? Why might that be?

Hints and solutions for the teacher:

- Use the following questions to deepen the discussion:



- Question 1: Why is it important to report clinical trial results? Who is affected by the lack of reporting and how?
- Question 2: Why might the results not have been reported? What practical steps could the institutions take to ensure the missing results are reported?

- Remind students where clinical trial information can be found: <https://euclinicaltrials.eu/>, <https://www.clinicaltrialsregister.eu/>, <https://clinicaltrials.gov/>, publications, or sponsors' websites.
- You may pre-select several institutions (large universities, hospitals, and commercial sponsors) so students can compare the reporting rates more easily. Alternatively, visit the homepage of the [EU TrialsTracker](#) and explore institutions with the highest and lowest percentages of reported trials.
- If students struggle to identify reasons for non-reporting, guide them to common issues: e.g., organisational turnover, lack of funding to complete analysis, sponsor changes, results not favourable to the tested treatment, unclear reporting duties.
- Review together the obligation to report results under the EU Clinical Trials Regulation (No 536/2014). Use [EUR-Lex](#) and explore Article 37 – submission of summary results, Annex IV – content of the summary of the results, Annex V – content of the lay summary.
- Emphasise that transparency is not just a regulatory requirement but an ethical commitment to patients, science, and the public.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Multiple-choice questions and solutions

1. When everyone benefits from working together this is known as what?

A) Sharing of power
B) Reciprocity
C) Outcome measurement and evaluation
D) Tokenism

*Answer: B; When everyone benefits from working together this is known as **reciprocity** and is one of the five key principles of co-production.*

2. Which of the following can support an intersectional approach to engaging with under-served groups in clinical trial recruitment and retention?

A) Using technical language in recruitment materials to emphasise scientific importance
B) Seeking community partnerships and culturally tailored outreach
C) Limiting trial site locations to major urban areas for logistical convenience
D) Excluding individuals with complex health or social circumstances

Answer: B; WISDOM is one that emphasises the importance of community partnerships and culturally tailored outreach in reaching those who may be less likely to participate in a clinical trial including Black, Latina, Asian, and Indigenous women in the United States ([WISDOM, 2025](#)).

3. Which of the following best describes digital health technology?

A) The distinction between those who have access to the internet or other digital technologies and are able to make use of online services, and those who are excluded from these services
B) Smart devices and connected equipment that improve health
C) Programs that provide step-by-step guidance and use relevant, local organisations or peer networks to assist potential clinical trial participants
D) The number of times in the past year when an individual could reliably access the internet

*Answer: B; The World Health Organisation defines a digital health technology as: “... **smart devices and connected equipment that improve health**. They include artificial intelligence, digital platforms, software, wearable devices, and tools that capture and share data and relevant health information across systems. These technologies can support health workers and improve diagnosis, treatment and quality of care” ([WHO, 2022](#)).*

4. What type of resource challenge is a lack of, or difficult, patient recruitment?

A) Lack of research environment
B) Ethical and regulatory system obstacles
C) Operational barriers
D) Competing demands

*Answer: C; **Operational barriers** can include unsupportive administrative systems and lack of/difficult patient recruitment ([Alemayehu et al., 2018](#)).*

5. Why is it important to publish all clinical trial data, including when the data do not favour the treatment under investigation?

A) It strengthens the placebo effect in future clinical trials
B) It helps to identify what does not work, for whom, and under what conditions
C) It allows peer-reviewed journals to meet a publication quota
D) It avoids legal action when an intervention is ineffective

Answer: B; Learning from clinical trials where the outcomes are unexpected is essential because it helps to identify what does not work, for whom, and under what conditions ([Axford et al., 2020](#)).

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Recap multiple-choice questions and solutions

1. What is the definition of tokenism?
- A) **When researchers include a patient voice in their project but mostly ignore it**
 - B) When researchers cite diversity statistics in the clinical trial protocol
 - C) When researchers ensure fair access and opportunities in research
 - D) When researchers divide participants into subgroups to analyse differences in clinical trial outcomes

Answer: A; Tokenism is when “researchers include a patient voice in their project but mostly ignore it” ([CIHR, 2020](#)).

2. Why is the sharing of power a key aspect of clinical trial co-production?
- A) Everyone benefits from working together
 - B) Ensures the research team includes all those who can contribute
 - C) All relevant views and knowledge are included
 - D) **The research is jointly owned, and people work together to achieve a joint understanding**

Answer: D; Sharing of power: the research is jointly owned, and people work together to achieve a joint understanding ([NIHR, 2024](#)).

3. The distinction between those who have access to the internet or other digital technologies and are able to make use of online services, and those who are excluded from these services is known as what?
- A) Digital health technologies
 - B) **Digital divide**
 - C) Digital footprint
 - D) Digital detox

Answer: B; The **digital divide** or the distinction between those who have access to the internet or other digital technologies and are able to make use of online services, and those who are excluded from these services ([Eurostat, 2025](#)).

4. Why are unintentional errors and spin common in clinical trials reporting?
- A) **Training in the design and conduct of clinical trials is generally not part of health education for medical and other health professionals**
 - B) Because clinical trial registries do not automatically align published outcomes with pre-registered outcomes, ensuring consistency
 - C) Industry-funded trials are required to use external academic writing teams to ensure neutral presentation of results
 - D) None of the above

Answer: A; A study of research integrity showed that unintentional errors and spin in research are not uncommon, as training in the design and conduct of clinical trials is generally not part of health education for medical and other health professionals ([Núñez-Núñez et al., 2022](#)).

5. Which of these is not an area of responsibility for conducting clinical trials in low resource settings?
- A) Informed consent
 - B) Standard of care
 - C) **Drug manufacturing**
 - D) Ethical review of the research

Answer: C; In the [TEDTalk on the ethics of clinical trials in low resource settings](#), Cameroonian medical doctor and clinical researcher Boghuma Kabisen Titanji described the importance of 1) informed consent, standard of care, ethical review of the research, and what happens after the research ends.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

True/False questions and solutions

1. Co-production can only be achieved at the start of a clinical trial.

*Answer: **False**; Co-production can be actioned at various points throughout a clinical trial including the study design and protocol development, designing the intervention, recruitment and retention strategies, outcome measurement and evaluation, and dissemination and implementation.*

2. There is only one way to approach intersectionality in clinical trials.

*Answer: **False**; There is no single way to approach intersectionality. Instead, there are several fundamental questions that researchers should ask at each stage of the research process.*

3. More men than women use the internet.

*Answer: **True**; The percentage of people using the internet is 5% lower for women than for men ([Makri, 2019](#)).*

4. Resource scarcity is not an issue when funders from high resource settings conduct clinical trials in low resource settings.

*Answer: **False**; Clinical trials are further complicated when funders from high resource settings conduct trials in low resource settings, often targeting specific populations who may have the relevant condition or are more likely to participate, without any intention of providing ongoing support to those individuals once the trial concludes ([Alemayehu et al., 2018](#); [Weigmann, 2015](#)).*

5. Spin refers to misleading reporting by presenting a clinical trial in a more positive way than reflected by the actual results.

*Answer: **True**; The term spin refers to misleading reporting by presenting a clinical trial in a more positive way than reflected by the actual results ([Mahtani, 2016](#)).*

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

9.1: Figure 1: Tokenism in research. Image generated using ChatGPT and DALL·E [AI-generated image].



Key points for the teacher:

- Three researchers in white lab coats are putting yellow sticky notes on a board. Nearby, a fourth person without a lab coat is crouched on the floor, placing purple notes below the board, apart from the others.
- The scene shows that this person is technically part of the activity, but his input isn't valued or integrated with the main work. It's a visual metaphor for tokenism, when people from under-served groups are included in a symbolic way rather than given real participation and influence.

9.1: Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. *BMJ quality & safety*. 2016 Aug 1;25(8):626-32. <https://doi.org/10.1136/bmjqs-2015-004839>

NARRATIVE REVIEW



From tokenism to empowerment: progressing patient and public involvement in healthcare improvement

Josephine Ocloo,¹ Rachel Matthews²

Key points for the teacher:

- Patient and public involvement in healthcare has grown in policy importance but progress remains slow and often limited to consultation rather than true collaboration.
- Current practices are frequently tokenistic, involving only a narrow group of patient representatives while excluding diverse voices, particularly those from disadvantaged or minority groups.
- The article reflects on these issues and argues that shifting power, promoting empowerment and diversity, and improving evaluation are often overlooked. Focusing on them could lead to improvement.
- Table 1 summarises barriers and enabler of public and patient involvement.
- Frameworks like the 4Pi standards (Principles, Purpose, Presence, Process, Impact) can guide better practice.
- To move beyond tokenism, staff need training and organisations must embed partnership as standard practice.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

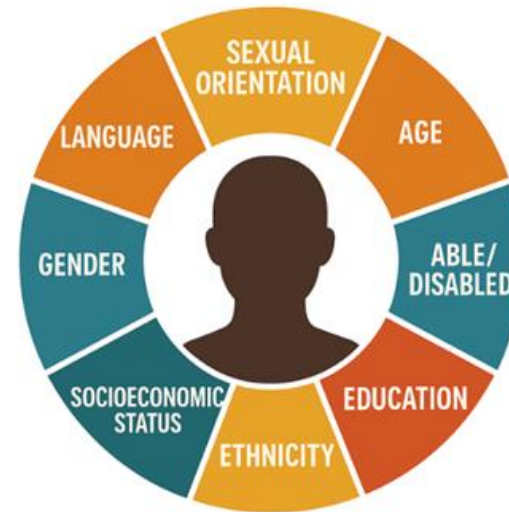
9.1: Figure 2: What is co-production? Adapted from NIHR INVOLVE [Source: [UCL Partners Health Innovation, 2019](#)]



Key points for the teacher:

- The picture is entitled "What is Co-Production?" and it explains the core principles of co-production using a puzzle metaphor.
- Each piece, held by different people (including a person in a wheelchair), represents a key element: building relationships, reciprocity, sharing of power, including all perspectives and skills, and respecting and valuing everyone's knowledge.
- Together they symbolise inclusivity, teamwork, and equal participation.

9.2: Figure 1: Dimensions of intersectionality. Image generated using ChatGPT and DALL·E [AI-generated image].



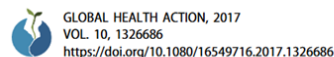
Key points for the teacher:

- The picture, entitled "Dimensions of Intersectionality," shows a person's silhouette surrounded by different identity factors: sexual orientation, age, ability/disability, education, ethnicity, socioeconomic status, gender, and language.
- It illustrates how these dimensions intersect to shape individual experiences and opportunities.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

9.2: Hankivsky O, Doyal L, Einstein G, Kelly U, Shim J, Weber L, Repta, R. The odd couple: using biomedical and intersectional approaches to address health inequities. Glob Health Action [online] 2017; 10 (sup2). [Accessed 15th Sept 2025]. Available from: <https://doi.org/10.1080/16549716.2017.1326686>.



ORIGINAL ARTICLE

OPEN ACCESS

The odd couple: using biomedical and intersectional approaches to address health inequities

Olena Hankivsky ^a, Lesley Doyal ^b, Gillian Einstein ^c, Ursula Kelly ^d, Janet Shim ^e, Lynn Weber ^f and Robin Repta ^g

Key points for the teacher:

- The article argues that to understand and reduce health inequities, researchers should combine biomedical and intersectional perspectives instead of keeping them separate.
- Biomedicine focuses on how diseases work in the body, while intersectionality looks at how social factors, like gender, race, class, and power, shape people's health. The authors say both are needed because biological and social factors constantly influence each other. They illustrate this through four case studies about HIV, post-traumatic stress disorder, female genital cutting and cardiovascular disease.
- The authors conclude that combining biological and social approaches produces more realistic and fair evidence for improving health policies and reducing inequities.

9.2: Esserman LJ. The WISDOM Study: breaking the deadlock in the breast cancer screening debate. NPJ breast cancer. 2017 Sep 13;3(1):34. <https://doi.org/10.1038/s41523-017-0035-5>.



www.nature.com/npjbcancer

REVIEW ARTICLE **OPEN**

The WISDOM Study: breaking the deadlock in the breast cancer screening debate

Laura J. Esserman¹ and the WISDOM Study and Athena Investigators³¹

Key points for the teacher:

- The WISDOM Study addresses the long-standing debate about breast cancer screening: when to start, how often, and for whom. Current screening methods lead to overdiagnosis, false positives, and significant anxiety, while offering limited benefit for low-risk women.
- WISDOM tests a personalised, risk-based screening approach against the standard annual mammography model. The study enrolls 100,000 women aged 40–74 and uses genetic, clinical, and lifestyle data to determine each woman's screening schedule. The goal is to show that risk-based screening is non-inferior in detecting advanced cancers while reducing unnecessary procedures and psychological harm.
- Unlike traditional trials, WISDOM is pragmatic and adaptive, allowing real-world flexibility and continuous learning. It also involves patients, clinicians, and policymakers to strengthen trust and adoption. The trial reflects a shift from one-size-fits-all medicine to precision prevention.
- Table 1 summarises the main characteristics of the WISDOM trial.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

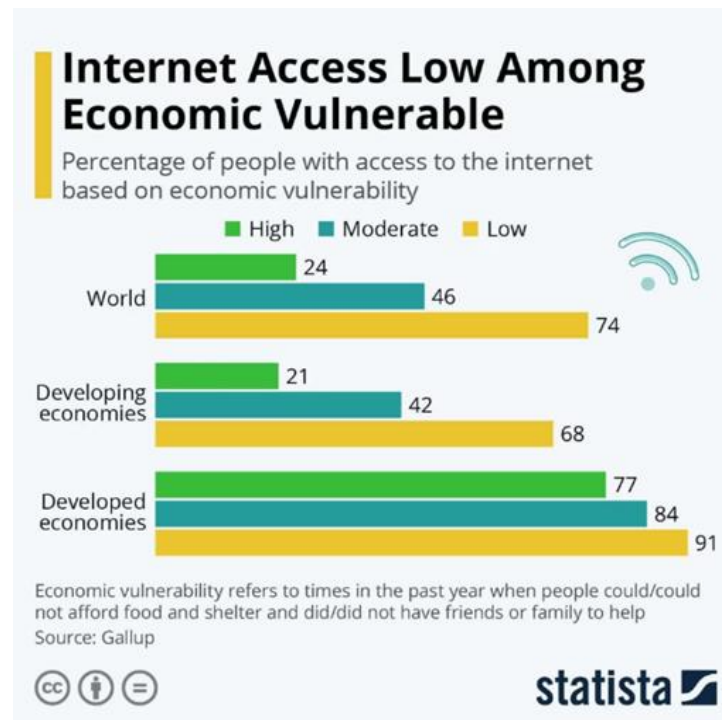
9.3: Makri A. Bridging the digital divide in health care. The Lancet Digital Health. 2019 Sep 1;1(5):e204-5. [https://doi.org/10.1016/S2589-7500\(19\)30111-6](https://doi.org/10.1016/S2589-7500(19)30111-6)

Bridging the digital divide in health care

Key points for the teacher:

- The article highlights both the progress and inequality in global digital connectivity and its impact on health. While mobile phone use has expanded rapidly, nearly half of the world's population is cut off from the internet:
 - Just 45% of people are connected in developing countries, and in the least developed countries the proportion is just 20%
 - The percentage of people using the internet is three times lower in rural than in urban areas, and is 5% lower for women than for men.
- Digital tools like eHealth and mHealth hold great promise for improving care and supporting global health goals, but their benefits are not shared equally.
- The article warns that as health care becomes more digitised, those without access risk being left further behind.

9.3: Figure 1: Percentage of people with access to the internet based on economic vulnerability. [Source: <https://www.weforum.org/stories/2023/03/digital-divide-sdgs-progress/>]



Key points for the teacher:

- The picture shows how internet access varies worldwide depending on people's level of economic vulnerability, based on Gallup data.
- **World:** 24% of highly vulnerable people have internet access, compared to 46% with moderate vulnerability and 74% with low vulnerability.
- **Developing economies:** 21% (high), 42% (moderate), and 68% (low).
- **Developed economies:** internet access is much higher across all groups, with 77% (high), 84% (moderate), and 91% (low).
- The chart highlights that people facing greater economic vulnerability, those who struggled to afford food or shelter and lacked support, are far less likely to have internet access, especially in developing economies.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

9.4: Van Zyl C, Badenhorst M, Hanekom S, Heine M. Unravelling 'low-resource settings': a systematic scoping review with qualitative content analysis. BMJ global health. 2021 Jun 1;6(6):e005190. <https://doi.org/10.1136/bmjgh-2021-005190>

Original research

BMJ Global Health

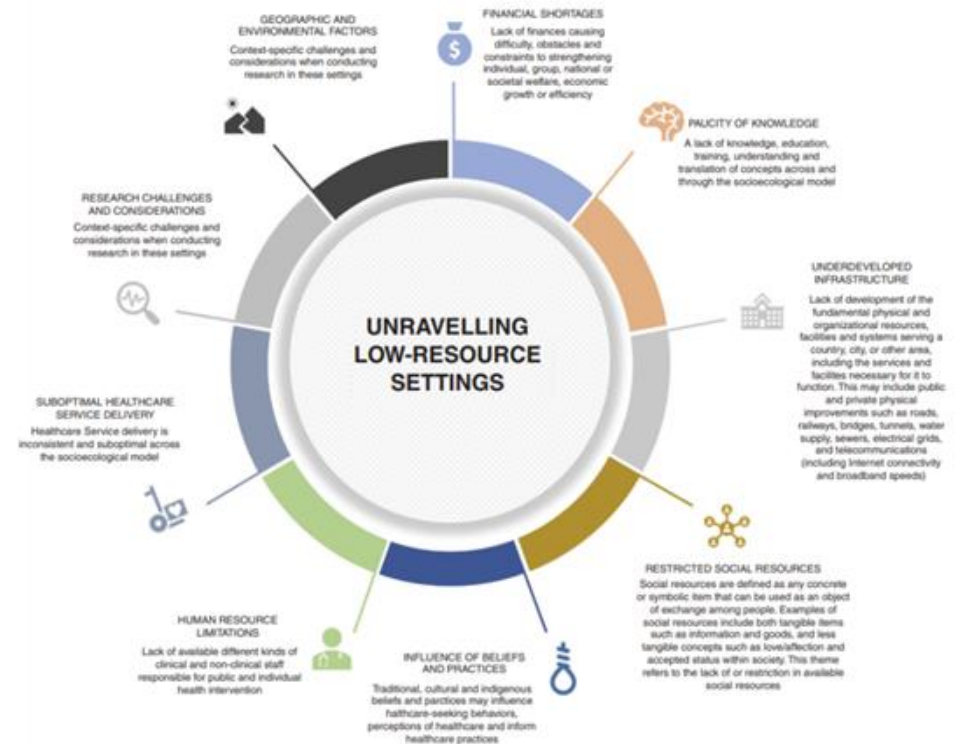
Unravelling 'low-resource settings': a systematic scoping review with qualitative content analysis

Chanel van Zyl ¹, Marelise Badenhorst ², Susan Hanekom ¹, Martin Heine ²

Key points for the teacher:

- The article describes what the term low-resource setting (LRS) means in health research, using rehabilitation medicine as an example.
- The authors identified nine interrelated themes that together define LRSs: financial pressure, suboptimal healthcare delivery, underdeveloped infrastructure, lack of knowledge and education, research challenges, restricted social resources, geographical and environmental barriers, human resource shortages, and the influence of beliefs and cultural practices.
- These factors interact across personal, community, organisational, and national levels, making LRSs complex rather than simply "poor" or "developing." Importantly, even high-income countries can include low-resource environments

9.4: Figure 1: Intersecting themes used to describe a low resource setting [Source: [van Zyl et al., 2021](#)]



Key points for the teacher:

- The picture is entitled "Unravelling Low-Resource Settings." It explains the main factors that limit healthcare and research capacity in environments where resources are scarce.
- These factors are: financial shortages, paucity of knowledge, underdeveloped infrastructure, restricted social resources, influence of beliefs and practices, human resource limitations, suboptimal healthcare service delivery, research challenges and considerations, geographic and environmental factors.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

9.5: Heneghan C, Goldacre B, Mahtani KR. Why clinical trial outcomes fail to translate into benefits for patients. *Trials*. 2017 Dec; 18: 1-7. <https://doi.org/10.1186/s13063-017-1870-2>

COMMENTARY

Open Access



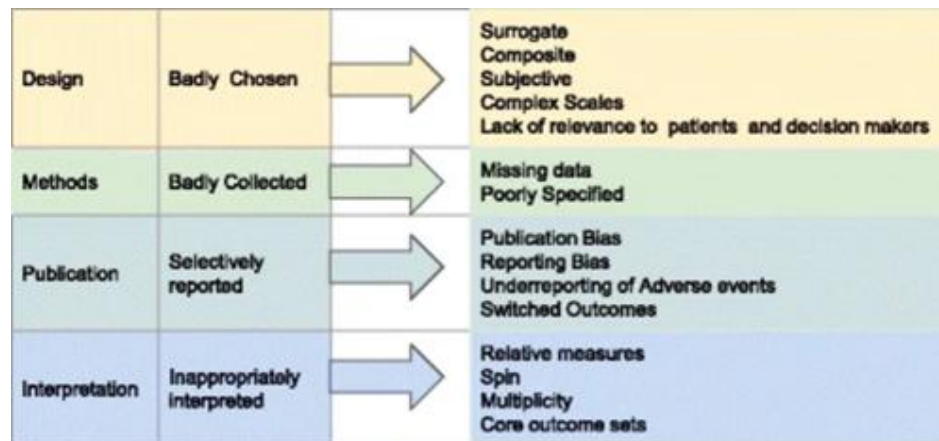
Why clinical trial outcomes fail to translate into benefits for patients

Carl Heneghan^{*}, Ben Goldacre and Kamal R. Mahtani

Key points for the teacher:

- Clinical trials are meant to guide patient care, but many fail because of weaknesses in outcome selection and reporting.
- Surrogate, composite, subjective outcomes and complex scales are often used instead of patient-relevant measures. Outcomes like quality of life or independence are frequently ignored.
- Missing data and poorly specified outcomes reduce reliability, while publication bias and selective reporting distort the evidence base.
- Adverse events are often under-reported, making treatments look safer or more effective than they are.
- Greater use of patient input, transparent reporting and core outcome sets are needed to ensure trials deliver real benefits for patients.

9.5: Figure 1: Why clinical trial outcomes fail to translate into benefits for patients from Heneghan et al. [Source: [Heneghan et al., 2017](#)].



Key points for the teacher:

- The picture highlights four main categories where trials can go wrong:
- **Design – Badly chosen**
 - Use of surrogate or composite outcomes
 - Reliance on subjective measures or complex scales
 - Outcomes that lack relevance for patients and decision-makers
- **Methods – Badly collected**
 - Missing data
 - Poorly specified outcomes
- **Publication – Selectively reported**
 - Publication bias, Reporting bias
 - Underreporting of adverse events
 - Switching outcomes after the trial
- **Interpretation – Inappropriately interpreted**
 - Use of relative instead of absolute measures
 - “Spin” (overstating results)
 - Multiplicity (many analyses without correction)
 - Failure to use standardised core outcome sets
- The overall message of the picture is, that even well-conducted trials may fail to benefit patients if outcomes are poorly chosen, collected, reported, or interpreted.

UNIT 9: OPPORTUNITIES TO BUILD LINKS WITH UNDER-SERVED GROUPS

Articles, pictures outlines

9.5: Hayes A, Hunter J. Why is publication of negative clinical trial data important?. British journal of pharmacology. 2012 Nov 6;167(7):1395. <https://doi.org/10.1111/j.1476-5381.2012.02215.x>



British Journal of
Pharmacology

DOI:10.1111/j.1476-5381.2012.02215.x
www.bjpharmacol.org

EDITORIAL

Why is publication of negative clinical trial data important?

Ann Hayes¹ and Jackie Hunter²

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Keywords

Clinical trial; negative data

Key points for the teacher:

- Negative clinical trial data are often unpublished, delayed, or hard to access, even though they are crucial for validating or invalidating drug targets. Without transparent reporting, companies may waste resources pursuing compounds already shown to be ineffective. This lack of access also undermines collaboration and slows progress across the field.
- Publishing negative results would reduce unnecessary duplication, lower costs, improve trial design, and, most importantly, protect patients from exposure to ineffective or unsafe treatments.
- New industry initiatives and registries were founded (e.g., WHO registry, MPIP recommendations) to promote transparency. But there is one concern raised by industry colleagues that it is difficult to find journals that are willing to publish negative clinical trial results.
- Ethically, making all trial results available is essential to ensure that research benefits patients.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

General overview of the unit for the teacher

OBJECTIVES

The aim of this unit is to explore inclusivity from the perspective of clinical investigators, focusing on their attitudes, behaviour, mindsets and personal biases. It examines how these factors can contribute to barriers to inclusion, as well as barriers within research teams and among colleagues. The unit will cover the theoretical background to these psychological aspects, tools for detecting potential biases, and practical strategies to foster more inclusive clinical research and strengthen collaboration among all clinical trial team members, recognising that these approaches are complementary. Ultimately, the unit aims to address the question: How to be a more inclusive researchers?

UNIT CONTENT

- 10.1: Challenge unconscious biases
- 10.2: Practise cultural humility
- 10.3: Develop strong community relationships
- 10.4: Support equity, diversity, and inclusion in clinical trial teams
- 10.5: Promote psychological safety
- Summary of Unit 10

LEARNING OUTCOMES

Students will be able to:

1. Describe best practices at the individual level for promoting inclusion in clinical trials.
2. Reflect on how personal biases and cultural perspectives influence research relationships and decision-making.
3. Identify strategies to build trust and respectful engagement with under-served groups.
4. Explain the importance of psychological safety in collaborative research settings and describe ways to support it.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Blended 90-minute classroom

 pre-class reading
brick-and-mortar 5×2 hours
90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 10.1 pre-class; read the article of FitzGerald <i>et al.</i> , with particular focus on the Introduction, and “Existence of implicit biases/stereotypes in healthcare professionals and influence on quality of care” parts; watch the video, complete the reflective activity; test your knowledge.
Tue	Complete Lesson 10.2 pre-class; read the paper of Zhu <i>et al.</i> ; watch the video on cultural competence and cultural humility; complete the reflective activity.
Wed	Complete Lesson 10.3 pre-class; read the paper of Kerasidou <i>et al.</i> ; complete the reflective activity on the “Community Engagement Studios”, including watching the video; complete the MCQs.
Thu	Complete Lesson 10.4 pre-class; read the paper of Getz <i>et al.</i> ; watch the video, complete the reflective activity; complete the MCQs.
Fri	Complete Lesson 10.5 pre-class; read the Fukami’s <i>et al.</i> publication; watch the video; complete the reflective activity and the test; read the Summary of Unit 10; complete the MCQs.

OPENING THE LESSON

15’ 



 **Setting basic rules in a class** – ask participants (individually, in silence) to think about a time when they felt psychologically safe in a group – what behaviours or attitudes from others made them feel that way?

Hints and solutions for the teacher:

- *Psychological safety was part of the Lesson 10.5 – principles: express ideas openly, ask questions, make mistakes, challenge others; you may add the following: listen actively, assume good intent, confidentiality, no interrupting, curiosity over judgment.*
- *List the principles on the whiteboard and leave them present over the entire lesson. Ask students “Are we all comfortable working with these as our shared agreements for today?”*

 **Inclusion snapshot** – first ask students to reflect on a time they felt included or excluded in a professional setting.

Once experiences have been collected, ask students what made that situation inclusive/exclusive.

Hints and solutions for the teacher:

- *Highlight that these same dynamics occur in research environments.*

TEAM-BASED WORK

50’ 



5–8 students per team



“Spot the Concept” scenarios – ask students to draft five vignettes (2–3 sentences each) from research setting illustrating how personal biases or cultural perspectives of a PI or clinical trial team members might shape inclusion, communication, or decision-making in a study. If ready earlier, ask students to reflect how personal biases and cultural perspectives influence research relationships and decision-making. (20 minutes)

Hints and solutions for the teacher:

- *Examples of vignettes:*
 - *A PI assumes that participants from a specific ethnic group are less likely to adhere to follow-up visits, so fewer of them are approached for recruitment. (implicit bias)*
 - *A trial nurse expresses surprise that participants prefer discussing side effects with family elders before giving feedback. (cultural perspective/humility)*
 - *A male CRA frequently directs technical questions to male investigators, even when female coordinators are leading the project. (gender bias)*



Debriefing (30 minutes)

Ask all groups to write one vignette on the whiteboard. Once written, ask the students to think individually, in silence what might have been illustrated here. Leave 3–5 minutes for thinking. Then, proceed to the second/third round. Ideally, obtain 10 vignettes.

Debrief:

- Which types of bias appeared most frequently? What subtle cues (tone, assumptions, decision patterns) reveal bias in these stories?
- How might these biases affect participant inclusion? Team cohesion and psychological safety? Data quality and trial credibility?
- What reflective or structural practices could prevent them?

Hints and solutions for the teacher:

- *E.g., implicit bias leads to selective recruitment or communication (some groups may be unintentionally excluded), some team-members from certain backgrounds may feel less heard or valued; reduces representativeness of data, findings may not generalise.*
- *Reflective practices for implicit bias – engage implicit bias self-assessment, seek peer feedback on communication and decision patterns; include bias-awareness training in GCP, use diverse review panels for hiring and participant recruitment strategies.*

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Blended 90-minute classroom

INDEPENDENT WORK

15' 



Common practices for preventing negative consequences of personal biases and cultural perspectives within clinical trial teams include involving community advisory boards, establishing diverse review panels, and adopting participatory and co-production approaches. Co-production was mentioned in Unit 9 – ask students at the beginning whether they recall the principle.



Task – Trust in practice – applying inclusive strategies (10 minutes)

Ask students to put themselves in clinical trialist's shoes (principal investigator, PI; clinical research associate, CRA; clinical research coordinator, CRC; clinical trial associate, CTA; clinical research nurse, CRN; data manager, pharmacovigilance specialist) and think how they might engage with participants, patients, community members from under-served groups.

Ask students to recall strategies discussed in the pre-class reading (Lesson 10.3, 10.5). For the selected strategies, ask them to briefly elaborate the following practical aspects:

- How would you use it? Be specific. What outcomes would you hope for?
- Which of these strategies challenges your usual habits or comfort zone the most?

Hints and solutions for the teacher:

- *E.g., as a CRC being transparent at inclusion*
 - *I ensure participants fully understand what to expect in the trial. I will use plain language.*
 - *Instead of simplifying or omitting uncomfortable details to encourage participation, I explain them clearly and invite questions. Ask the participant to be honest about uncertainties. I will follow the participant's body language to assess whether everything is really being understood.*
 - *I will avoid overpromising (e.g. personal benefits).*
 - *Being transparent sometimes feels uncomfortable because it can slow things down or raise difficult questions – but it strengthens long-term trust and retention, and upholds ethical integrity.*



Debriefing (5 minutes)

Ask three students to present their strategy in 2–3 minutes.

REFLECTION, WRAP-UP

10' 



1. What might inclusion at the individual level look like in everyday behaviour?
2. When we reflect on the principles we agreed upon at the outset, can these principles strengthen communication within the clinical trial team and with participants or communities too? If so, how? If not, why not?
3. What actions build trust between researchers and under-served participants or community partners?
4. Looking across everything we've discussed – inclusion, bias, trust, humility, safety – what will you do differently as a researcher or team member after today's session?

Hints and solutions for the teacher:

- *Question 1: Inclusion isn't just policy; it's demonstrated in day-to-day actions, mindset, and communication – actively listening, catching assumptions, using respectful language, reflecting personal biases before making decisions or giving feedback, etc.*

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

15'



- **Setting basic rules in a class** – no need to modify for the online environment
- Listing the principles on the whiteboard and leave them visible over the entire lesson - can be adapted in polls in Mentimeter (Word Cloud), Slido (Word Cloud), Miro (brainstorming templates, Sticky notes), or similar apps. Sometimes, pre-preparation of the poll is necessary – check it in advance of the class. Make a screenshot of the principles or copy them to a separate file to facilitate their visible sharing during the entire lesson.
- **Inclusion snapshot** – no need to modify

TEAM-BASED WORK

50'



5–8 students per team

- Assign students to breakout rooms (possible in Zoom or MS Teams).
- Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues). Provide facilitators with examples of the vignettes that they can show to students to help them to imagine what does “a vignette” mean.
- Ask students to write vignettes electronically to be able to share on screen later. Inform the students that you will randomly select teams to share their work at the end of the task (this encourages their focus and accountability).
- Time adjustment is possible. The presentation of the teams' work may need more time.
- Announce the timing (e.g., Broadcasting in Zoom), share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document) in a document/table (e.g., with numbers indicating the number of vignettes ready (1–5)). Advance preparation of such a document is necessary; the students can create their own icon.



Debriefing (30 minutes)

All groups present at least one vignette with a follow-up discussion as described.

INDEPENDENT WORK

15'



- Ask students to write notes electronically so that they are able to share on the screen later. Inform the students that you will randomly select a few students to share their work at the end of the task (to encourage focus and accountability).
- Time adjustment is possible.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Be available for support, e.g., in the chat.
- Ask students to indicate their progress by moving their icon (e.g., in a shared document). Advance preparation of such a document is necessary; the students can create their own icon.



Debriefing (5 minutes)

Ask three students to present their strategy in 2–3 minutes.

REFLECTION, WRAP-UP

10'



- Only discussion; no need to collect or write notes.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Reflective activity 10.1: “Implicit Association Test or ‘Tell me something I don’t know: an activity for implicit bias awareness’ ” modified for synchronous use

Link: [Implicit Association Test](#) or “[Tell Me Something I Don't Know](#)”

Option 1: Select and complete an Implicit Association Test (IAT) from a list of possible topics to become more aware of your own implicit biases.

Option 2: The “Tell Me Something I Don't Know” activity utilises a version of an ice-breaker game to introduce a strategy for implicit bias awareness. Option 2 works best when facilitated by an instructor, in a group or peer led learning environment.

Reflect on the activity after you have completed this.

MODIFICATION FOR INDIVIDUAL WORK



Select and complete an [Implicit Association Test](#) (IAT) from a list of possible topics to become more aware of your own implicit biases. After its completion, write a short reflection (100–150 words) on the following questions and submit it to a cloud/discussion board:

1. What IAT did you select and why?
2. What was the test result?
3. Are you aware of stereotypes influencing your answers?
4. What can you do to avoid conforming to biased stereotypes?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



6–8 students per team

Based on: Martineau Jackson KY. Tell me something I don't know: an activity for implicit bias awareness, Teach Learn Nurs [online] 2025; 20:e517. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1016/j.teln.2024.12.019>

Divide students into teams.

Part 1: Give each student a small slip of paper. Ask students to anonymously write 1–2 facts about themselves that their classmates likely would not know.

Part 2: In each team, ask one student to collect all the cards. Read the facts aloud. Students will try to guess which fact belongs to whom. After that, reveal the author.

Ask students to discuss in teams: What surprised them? Which guesses were based on assumptions? Did they notice stereotypes influencing their guesses?

Start the timer. Circulate among teams, listen to and stimulate the discussions. After the activity is finished, introduce the concept of implicit bias to the whole class. Then, select several teams to share key points of their discussions.

Continue with the whole-class discussion:

1. How to avoid conforming to biased stereotypes?
2. How can implicit biases impact clinical trials? Give specific examples.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Based on: Martineau Jackson KY. Tell me something I don't know: an activity for implicit bias awareness, Teach Learn Nurs [online] 2025; 20:e517. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1016/j.teln.2024.12.019>

Part 1: Give each student a small slip of paper. Ask students to anonymously write 1-2 facts about themselves that their classmates likely would not know.

Part 2: Collect all cards. Read the facts aloud. Students will try to guess which fact belongs to whom. Reveal the author.

Ask students to share in the class: What surprised you? Which guesses were based on assumptions? Did you notice stereotypes influencing your guesses?

After the activity is finished, introduce the concept of implicit bias.

Continue with the discussion on:

1. How to avoid conforming to biased stereotypes?
2. How can implicit biases impact clinical trials? Give specific examples.

Hints and solutions for the teacher:

- Explain to students that the participation is voluntary. Students should write only what they feel comfortable sharing. Students who prefer not to share may still participate in Part 2.
- Implicit bias – the attitude or internalised stereotypes that unconsciously affect our perceptions, actions, and decisions.
- Question 1: It can be useful to reflect on the following questions: What am I thinking? Why am I thinking it? Is there a past experience that is impacting my current decision? Is the past experience applicable now or is it based on preference or bias?
- Emphasise that the activity demonstrates how easily unconscious assumptions arise in normal social interactions and why clinical trial teams must actively work to avoid biased decision-making.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Reflective activity 10.2: “Cultural humility – prompts for self-reflection” modified for synchronous use

Link: [Mabadiliko CIC, 2021](#)

Select one of the following prompts for self-reflection on the topic of cultural humility (Mabadiliko CIC, 2021):

1. “When faced with cultural differences or unfamiliar practices, how often do I respond with curiosity rather than judgment, and what barriers prevent me from approaching these situations with humility?”
2. In what ways might I be confusing knowledge about different cultures with true cultural humility, and how can I shift toward a lifelong practice of self-reflection?
3. How do our institutional practices and policies perpetuate the idea that cultural competence is something that can be “achieved” rather than practised continuously?”

As you reflect, remember that cultural humility is a lifelong learning endeavour and involves an ongoing process of self-reflection. It can be helpful to acknowledge what you may not yet fully understand.

MODIFICATION FOR INDIVIDUAL WORK



Select one of the prompts above and write a short (5–8 sentence) reflection. Submit your reflection to a cloud/discussion board.

After that, read 3 other reflections and write down at least one insight you gained from other students' reflections. Upload your notes to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Use students' notes to guide a whole-class discussion. The aim is to encourage students to actively seek out and engage with perspectives different from their own.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams and assign each team one of the prompts. Initially, each student writes brief notes individually. Then, have students share their reflections within their team and create a short 3-minute presentation.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask one team per prompt to present. After each presentation, invite questions or comments from the other teams.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start by asking students: *What does cultural competence and cultural humility mean to you? Which words or ideas come to mind?* Write their responses (key words) on the board.

After that, go through the prompts one by one (or select). Invite volunteers to share their initial thoughts. Ask students to reflect on a personal experience:

- Think of a situation where you made an assumption about someone based on their appearance, age, language, or background.
- How could cultural humility have improved this interaction?

Transition the discussion to the clinical trial setting:

- How can cultural humility support inclusive research?
- What strategies can help increase cultural competence and humility in clinical trials?

Hints and solutions for the teacher:

- Encourage students to share their personal experiences or discuss hypothetical scenarios.
- Highlight how diverse perspectives enrich the discussion.
- **Cultural competence** is the ability to understand, respect, and effectively respond to the cultural needs of diverse individuals and groups. **Cultural humility** further expands on cultural competence by introducing lifelong, reflective approaches to understanding cultural differences.
- Strategies to increase cultural competence and humility: e.g., appropriate training, diversity in research teams, community-based engagement, tailored communication tools, funding policies (see Figure 2 in Lesson 10.2).

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Reflective activity 10.3: “Community engagement studios” modified for synchronous use

Link: [Community Engagement Studios](#)

Engage with the video from the integrated Translational Health Research Institute of Virginia (05:54) describing the concept of Community Engagement Studios.

MODIFICATION FOR INDIVIDUAL WORK



Watch the Community Engagement Studios video. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why is community input important in shaping health research, according to the Community Engagement Studios model?
2. What timeframe does a community engagement studio require?
3. What were some ways feedback led to changes?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams and watch the Community Engagement Studios video. Ask students to prepare a short presentation (3–5 minutes) that answers the following questions:

1. What is a Community Engagement Studio?
2. Why is it important in shaping health research?
3. What timeframe does a studio typically require?
4. Describe at least one example of how community feedback led to real changes.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, choose one team to present their output to the class. Invite the rest of the students to add points that were missing or especially important from their perspectives.

Hints and solutions for the teacher: Encourage students to highlight insights that deepen understanding of community engagement in health research.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the Community Engagement Studios video together. After that, guide the class through a structured discussion with the following questions:

1. Can you imagine yourself, as a future or current researcher, using a Community Engagement Studio? Why or why not?
2. What might be challenging about using this model?
3. What is your main take-home message from the video?

Hints and solutions for the teacher:

- *Question 1: Encourage students to think about their field, typical research workflows, and when community input could be beneficial. Underline that community expertise is equally valuable to scientific expertise.*
- *Question 2: Invite students to identify practical, ethical, organisational, or time-related barriers. Address possible challenges openly. E.g., finding appropriate community representatives, resource demands, incorporating conflicting feedback, time investment.*
- *Question 3: As students respond, write their points on the board to summarise key insights (e.g., value of early stakeholder input, improving relevance, patient-centred research, strengthening trust, identifying blind spots, time and resource needs).*
- *Connect the discussion to broader principles: Link the studio approach to cultural humility, equitable partnerships, and the shift from doing research on communities to doing research with them.*

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Reflective activity 10.4: “Breaking the glass ceiling” modified for synchronous use

Link: [Episode 10, Cancer Researcher Podcast](#)

Listen to, or read the transcript for, Episode 10 of the Cancer Researcher Podcast focused on the need for women in senior research and leadership roles (30:14).

What key ideas from this Lesson can you identify in the discussion? What further ideas are introduced?

MODIFICATION FOR INDIVIDUAL WORK



Listen to or read the transcript of Episode 10 of the Cancer Researcher Podcast. While listening, reflect on the discussion and answer:

- What key ideas from Lesson 10.4 (Support equity, diversity, and inclusion in clinical trial teams) appear in the podcast?
- What new ideas or perspectives are introduced in the podcast?

Write a short reflection (150–200 words) including:

1. At least two connections between the podcast and the lesson.
2. At least one actionable step that can be taken to promote inclusion in research teams of the future?

Submit the reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Summarise key themes from student responses to guide a follow-up discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4 students per team

Divide students into teams. Ask each team to extract a different insight from a transcript of Episode 10 of the Cancer Researcher Podcast and share it with others:

- Team A: What barriers to gender equity are described?
- Team B: What solutions or strategies are proposed by the guests?
- Team C: What is said about the role of institutions and leadership in promoting equity?
- Team D: Which ideas connect directly to Lesson 10.4 Support equity, diversity, and inclusion in clinical trial teams?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present a 2–3-minute summary to their classmates.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Divide students into teams. Each team receives a different excerpt from Episode 10 of the Cancer Research Podcast (either transcript sections or assigned timestamps). Ask each team to prepare a summary of their section with a focus on:

- What key ideas from Lesson 10.4 (Support equity, diversity, and inclusion in clinical trial teams) appear in the podcast?
- What new ideas or perspectives are introduced in the podcast?

After that, form new groups with one “expert” from each original team. Each expert explains their section so that all students get a complete picture of the podcast.

After all groups finish, come together as a class and discuss:

1. Which ideas appeared across multiple sections?
2. What resonated most with you in relation to equity and inclusion in research teams?
3. What surprised you?
4. What do these insights imply for promoting EDI in clinical trial teams?

Hints and solutions for the teacher:

- *Preparation before class is necessary: provide short printed transcript excerpts or pre-assign specific listening intervals to keep the activity time-efficient.*
- *Ensure all students have access to the podcast or printed excerpts.*
- *During the teamwork phase, circulate and check whether groups are sharing balanced contributions.*
- *In the whole-class discussion, collect take-home messages on the board.*
- *Stimulate the discussion by:*
 - *Link discussions back to core themes of the course (representation, structural barriers, institutional policies, etc.).*
 - *Are there any other factors which create additional disadvantage or advantage? (Consider intersectionality.)*

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Reflective activity 10.5: “Empathy mapping” modified for synchronous use

Link: [Empathy mapping exercise](#)

View the empathy mapping exercise provided by the National Health Service in the UK. Working independently or in a group:

1. Consider an individual or wider under-served group.
2. Using the empathy maps as a guide, create four sections: Says, Thinks, Feels, Does.
3. Brainstorm what the individual or group might say, think, feel, and do about clinical trials.
4. Reflect or discuss key insights that could influence clinical trial engagement and design.

Optional: Choose a clinical trial from <https://clinicaltrials.gov/> and model the empathy mapping exercise from the participant inclusion/exclusion criteria and what is known publicly about the study.

MODIFICATION FOR INDIVIDUAL WORK



View the empathy mapping resource. Choose either one specific individual (describe him/her in detail, e.g., a single mother living with a chronic illness, an adolescent patient from an ethnic minority, etc.) or an under-served group you learned about in Unit 2.

Create your own empathy map: brainstorm what this individual or group might Say/Think/Feel/Do about clinical trials. You might create a visual map or write a short reflection (100–150 words) addressing these four dimensions. Submit your work to a cloud/discussion board.

Hints and solutions for the teacher: Anonymise the answers. Empathy maps are ideally created collaboratively. Therefore, consider selecting several student submissions and showing them to the whole class for further discussion. Invite students to add additional perspectives that may have appeared in the maps.

MODIFICATION FOR TEAM-BASED WORK



3–5 students per team

Introduce students to an empathy mapping exercise. Divide students into teams. Each team selects one under-served group relevant to clinical research. Provide each team with a large sheet divided into four quadrants: Says – Thinks – Feels – Does. Teams brainstorm together what the group might say, think, feel, and do about clinical trials. Use sticky notes to record each idea on the map.

Start the timer. Circulate among teams, listen to and stimulate the discussions. Once the empathy map is filled, each team presents it in three minutes. After each presentation, other students may add additional sticky notes to expand the map.

Hints and solutions for the teacher:

- Prepare the tools for map creation in advance.
- At the start, briefly discuss who may be considered under-served groups in clinical trials and why. List examples on the board and allow each team to choose a group (avoid duplication).
- Link this activity to the content of Unit 3 - Understanding barriers to inclusion (systemic, structural, logistical, cultural, ethical barriers). Remind students to consider these perspectives while building the empathy map.
- Keep the focus on clinical trial engagement, access, and barriers to participation.
- Optional extension: After presentations, collectively discuss: What insights from these maps could help design more inclusive clinical trials?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Introduce students to an empathy mapping exercise. As a class, select two under-served groups.

Set up four stations around the room labelled: Says – Thinks – Feels – Does. Students rotate between stations in small groups, adding observations for each selected group about clinical trials. Use large sheets and coloured markers or sticky notes to record the observations.

After rotations, combine the observations to create a complete empathy map for both groups. Review the completed maps together as a class.

Then facilitate a discussion:

1. What patterns emerge across the groups?
2. How can empathy mapping influence trial design, recruitment, or communication?
3. What assumptions did we notice ourselves making?

Hints and solutions for the teacher:

- See hints and solution provided for the team-based version of this activity.
- Additional discussion tips:
 - Question 3: connect to Lesson 10.1 – Challenges to unconscious biases. Select one or two observations from the empathy map and reflect on whether they might reveal unconscious biases.



UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Multiple-choice questions and solutions

1. Preferring people who are similar to us in background, interests, or experiences is known as what type of bias?
- A) Attribution bias
 - B) Affinity bias**
 - C) Conformity bias
 - D) Name bias

Answer: B; Affinity bias occurs when we unconsciously prefer people who are similar to ourselves in background, interests, or experiences.

2. Cultural humility involves a “personal lifelong commitment to self-evaluation and self-critique”. What does this mean?
- A) Acknowledging the inherent power dynamics relevant to lived experiences of health
 - B) That we must continually examine our own beliefs, biases, and assumptions and recognise that understanding culture is a lifelong process that involves learning from others**
 - C) Diversifying clinical trial leadership teams and research personnel via institutional equity, diversity, and inclusion policies, open calls, and equal opportunities for career advancement
 - D) Take a few slow deep breaths, bringing awareness to the experience and sensations of breathing in and breathing out

Answer: B; A personal lifelong commitment to self-evaluation and self-critique means we must continually examine our own beliefs, biases, and assumptions and recognise that understanding culture is a lifelong process that involves learning from others.

3. Better engagement with patients, the public, and wider communities helps to ...?
- A) Ensure that trials are well designed and well implemented by considering the unique perspectives and experiences of those they aim to benefit
 - B) Enhance the scientific, ethical, and pragmatic value of trials by improving the acceptability, feasibility, and relevance of trial design, implementation, and outcome dissemination
 - C) Foster trust in science and scientists, strengthens research literacy, and contributes to greater trust in research processes
 - D) All of the above**

Answer: D; All of the above are key points on the importance of engaging in meaningful partnership with patients, the public, and communities as summarised by [Gobat et al., 2025](#).

4. Which of the following statements is supported by the data on clinical trial site staff diversity and its impact on participant enrolment?
- A) The majority of clinical trial site staff worldwide are from non-White ethnic backgrounds.
 - B) Europe has the highest representation of non-White clinical trial site staff.
 - C) Increased racial and ethnic diversity among site staff is associated with increased diversity among trial participants.**
 - D) There is no correlation between the diversity of site staff and participant enrolment diversity.

Answer: C; Increased racial and ethnic diversity among site staff is associated with increased diversity among trial participants.

5. What is the definition of *empathy*?
- A) The ability to understand and share the feelings of another**
 - B) Following treatment plans without emotional involvement
 - C) A motivated desire to help without sharing the feelings of another
 - D) Acknowledging another's suffering without internal emotional experience

Answer: A; Empathy, the ability to understand and share the feelings of another, is a fundamental aspect of psychological safety.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Recap multiple-choice questions and solutions

1. When individuals are conscious of their negative attitudes or prejudices toward groups of people and may allow those attitudes to affect their behaviour, this is known as?
- A) Conformity bias
 - B) Attribution bias
 - C) Explicit bias**
 - D) Implicit bias

Answer: C; Implicit bias is the attitude or internalised stereotypes that unconsciously affect our perceptions, actions, and decisions. This is in contrast to explicit bias, where individuals are conscious of their negative attitudes or prejudices toward groups of people and may allow those attitudes to affect their behaviour.

2. How are cultural competence and cultural humility different?
- A) One addresses bias, the other avoid it
 - B) One emphasises skill building, the other emphasise lifelong learning and reflection**
 - C) One is for individuals, the other is for institutions
 - D) One is measurable, the other is theoretical

Answer: B; Cultural competence is the ability to understand, respect, and effectively respond to the cultural needs of diverse individuals and groups. Cultural humility further expands on cultural competence by introducing lifelong, reflective approaches to understanding cultural differences including.

3. Which of the following best defines transparency in clinical trials research when developing strong community relationships?
- A) Clearly communicating research goals, methods, and potential impacts**
 - B) Meeting the present needs of clinical trial participants and their wider communities
 - C) Using internet-based social media platforms to connect and share content with potential clinical trial participants
 - D) When you feel able to express your ideas and concerns openly, ask questions, recognise your mistakes, and challenge others, including authority figures, without fear of negative consequences

Answer: A; Transparency in clinical trials means clearly communicating the research goals, methods, and potential impacts. It is important to share how community input will be used and respected. A study exploring the impact of transparency on trust in research found that participants, especially those from under-served groups, expressed greater trust when researchers clearly explained how their data would be used and the purpose of the study.

4. When advocating for inclusive hiring practices, what can help ensure fair evaluation across all clinical trial team candidates?
- A) Standardised evaluation criteria
 - B) Using structured interviews
 - C) Blinded application submissions
 - D) All of the above**

Answer: D; Standardised criteria, using structured interviews, and blinded application submissions can help ensure fair evaluation across all candidates.

5. Which of the following is not an aspect of psychological safety?
- A) Feeling able to express ideas and concerns openly
 - B) Asking questions
 - C) Challenging authors (including authority figures)
 - D) Sharing of power**

Answer: D; Sharing of power is not an element of psychological safety. Psychological safety is when you feel able to express your ideas and concerns openly, ask questions, recognise your mistakes, and challenge others, including authority figures, without fear of negative consequences.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

True/False questions and solutions

1. Implicit bias only affects the design phase of a clinical trial.

*Answer: **False**; unconscious bias-based discriminatory practices negatively impact all aspects of clinical trials from design and conduct to financial award decisions and limited diversity among clinical trial teams.*

2. Mindfulness is both a mental practice and a trait that involves paying attention to present-moment experience with an attitude of receptivity and acceptance.

*Answer: **True**; Mindfulness is one approach that has proven useful when enhancing awareness of oneself and others and is “**both a mental practice and a trait that involves paying attention to present-moment experience with an attitude of receptivity and acceptance**” ([Yeager & Bauer-Wu, 2014](#)).*

3. Each layer of the clinical trial ecosystem plays a vital role in ensuring that clinical trials are ethically conducted, scientifically rigorous, and aligned with the needs and values of the communities they aim to serve.

*Answer: **True**; The clinical trial ecosystem brings together research governance and oversight, operations and implementation, and community stakeholders, with participants at its core. Each layer of the ecosystem plays a vital role in ensuring that clinical trials are ethically conducted, scientifically rigorous, and aligned with the needs and values of the communities they aim to serve ([The Lancet, 2025](#)).*

4. Women and men are equally likely to be the Principal Investigator of a clinical trial.

*Answer: **False**; A cross-sectional study of 245,771 ClinicalTrial.gov entries showed a gender gap in the leadership of clinical trials; 32.4% were women and 63.5% were men.*

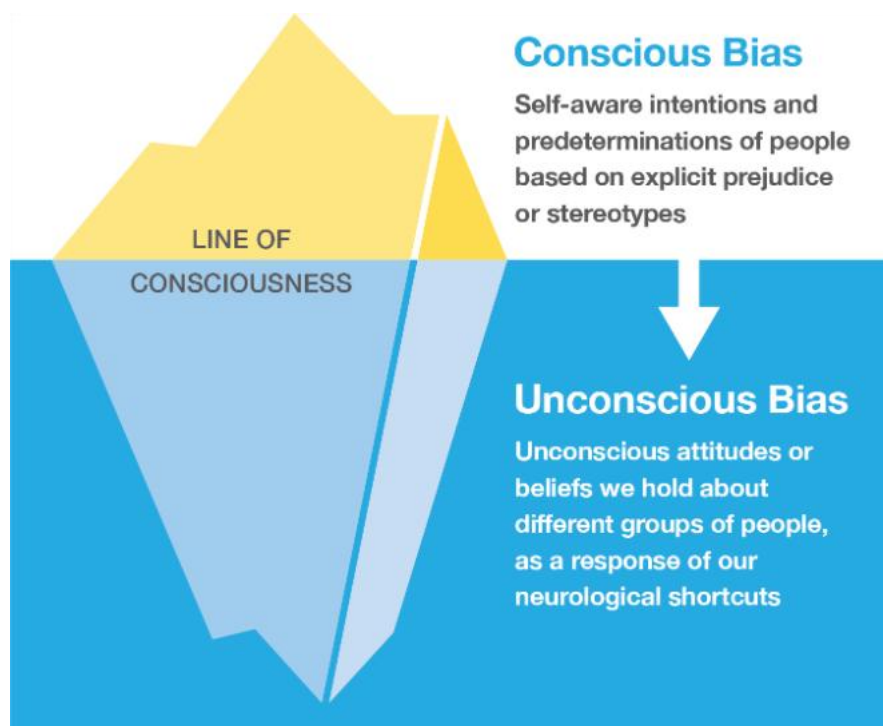
5. Behaviours intended to show empathy are perceived the same by all people regardless of cultural, social, emotional or other factors.

*Answer: **False**; Focus groups on empathy with the National Institute for Health and Care Research in the UK noted some verbal and nonverbal behaviours may not be perceived or interpreted in the way that was intended in certain cultures or communities.*

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Articles, pictures outlines

10.1: Figure 1: The Bias Iceberg: The portion of the iceberg above the waterline represents Conscious Bias: Self-aware intentions and predeterminations of people based on explicit prejudice or stereotypes. [Source: [eCampus Ontario, 2022](#) licenced by [OCL 1.0](#)]



Key points for the teacher:

- This picture shows an iceberg to explain two kinds of bias: the ones we know about and the ones we don't.
- The small part of the iceberg above the water represents conscious bias. These are the opinions or stereotypes we are aware of, like when someone knows they treat a certain group differently on purpose.
- The big part under the water represents unconscious bias. These are hidden thoughts or feelings we have about people without realising it. They come from our brain taking quick shortcuts to judge others.
- The line between water and air is called the line of consciousness. It separates what we know about ourselves from what we don't notice but still affects how we act.

10.1: FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. *BMC Med Ethics* [online] 2017; 18:1-8. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1186/s12910-017-0179-8>

FitzGerald and Hurst *BMC Medical Ethics* (2017) 18:19
DOI 10.1186/s12910-017-0179-8

BMC Medical Ethics

RESEARCH ARTICLE

Open Access



Implicit bias in healthcare professionals: a systematic review

Chloë FitzGerald* and Samia Hurst

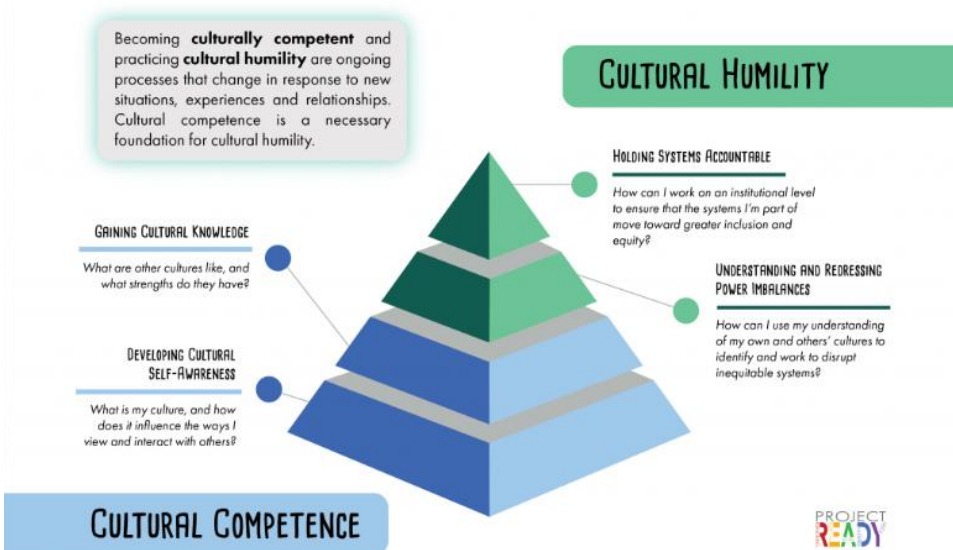
Key points for the teacher:

- The article examines whether healthcare professionals show implicit (unconscious) bias toward patients and how this affects the quality of care.
- 42 studies published between 2003 and 2013 were analysed.
- Table 1 summarises all the included studies and the main findings in each study.
- Findings show that implicit bias is common among healthcare workers, at levels similar to the general population.
- Biases were most often related to race, gender, weight, and socioeconomic status. These biases were linked to differences in diagnosis, treatment decisions, communication, and patient satisfaction.
- Importantly, implicit attitudes often contradict explicit beliefs, professionals may want to treat everyone equally but still act differently unconsciously.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Articles, pictures outlines

10.2: Figure 1: Cultural competence and cultural humility [Source: [Project READY, 2024](#) licenced by [CC BY-NC-SA 4.0](#)]



10.2: Zhu JW, d'Angelo F, Miranda JJ, Yancy CW, Cupido B, Zannad F, Van Spall HG. Incorporating cultural competence and cultural humility in cardiovascular clinical trials to increase diversity among participants. J Am Coll Cardiol [online] 2022; 80(1):89-92. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1016/j.jacc.2022.05.001>

CARDIOVASCULAR MEDICINE AND SOCIETY

Incorporating Cultural Competence and Cultural Humility in Cardiovascular Clinical Trials to Increase Diversity Among Participants

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Key points for the teacher:

- The article highlights that male, white, North American and European participants are mainly represented in cardiovascular randomised controlled trials. Black, indigenous and people of colour remain still under-served in randomised controlled trials.
- The authors suggest that cultural competence and humility must be incorporated into trial teams, trial design and execution to bigger involvement of under-represented racial and ethnic groups and geographic regions worldwide in cardiovascular research. They suggest 5 strategies how to do so, explained in 10.2. Figure 2 in the outlines.
- These steps can build trust, make trials more inclusive, and ensure participants are genuinely involved throughout the research process.

Key points for the teacher:

- This image uses a pyramid to show how cultural competence forms the foundation for cultural humility.
- At the base, cultural competence involves two steps:
 - **Developing cultural self-awareness** – understanding your own culture and how it shapes your views and interactions.
 - **Gaining cultural knowledge** – learning about other cultures and recognising their strengths.
- Building on that, the upper part represents cultural humility:
 - **Understanding and redressing power imbalances** – using cultural understanding to challenge unfair systems.
 - **Holding systems accountable** – working at an institutional level to promote inclusion and equity.
- A note explains that both are ongoing processes. We keep learning and adapting as we meet new people and experiences.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Articles, pictures outlines

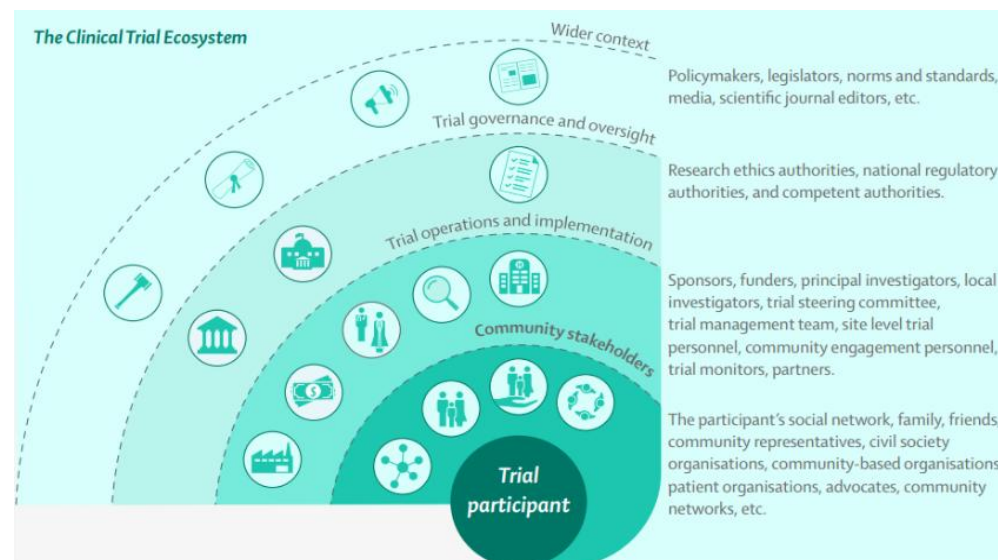
10.2: Figure 2: Strategies to increase cultural competence and humility in clinical trials [Source: [Zhu et al., 2022](#) licenced by [CC BY-NC-ND](#)]



Key points for the teacher:

- This image shows a circular diagram with five strategies to improve cultural competence and humility in clinical trials:
 - Training** – teach professionals culturally sensitive communication and self-reflection.
 - Diverse teams** – include researchers from different backgrounds.
 - Funding policy** – require plans to recruit diverse participants.
 - Community engagement** – involve patients and community members in trial design and delivery.
 - Tailored communication** – adapt materials to patients' language, literacy, and culture.
- Together, these steps promote inclusion and equity in clinical research.

10.3: Figure 1: The Clinical Trial Ecosystem [Source: [The Lancet, 2025](#) licenced by [CC BY-ND 4.0](#)]



Key points for the teacher:

- This image shows the Clinical Trial Ecosystem as a set of expanding circles around the trial participant at the centre:
 - The innermost circle represents the **trial participant**.
 - The next circle, **community stakeholders**, includes the participants immediate community: family, friends, patient organisations, civil society organisations and community networks that support them.
 - The **trial operations and implementation** layer involves sponsors, funders, investigators, trial managers, and site-level staff who run the study.
 - The **trial governance and oversight** layer includes ethics committees and national regulatory authorities that ensure participant safety and compliance.
 - The outermost layer, the **wider context**, covers policymakers, legislators, the media, and journal editors who shape the rules, norms, and communication around clinical research.
- Together, these layers show that clinical trials depend on a whole network, from individual participants to global policy and governance systems.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Articles, pictures outlines

10.3: Kerasidou A. Trust me, I'm a researcher!: the role of trust in biomedical research. Med Health Care Philos [online] 2017; 20:43-50. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1007/s11019-016-9721-6>

Med Health Care and Philos (2017) 20:43–50
DOI 10.1007/s11019-016-9721-6



SCIENTIFIC CONTRIBUTION

Trust me, I'm a researcher!: The role of trust in biomedical research

Angeliki Kerasidou¹

Key points for the teacher:

- The article describes the meaning and importance of trust in biomedical research.
- Kerasidou distinguishes trust from reliance: reliance is based on rules and predictability, while trust involves vulnerability, voluntariness, and good will.
- Regulations, ethics committees, and consent procedures increase reliability and accountability, but they do not create real trust. Excessive regulation may even signal distrust, leading to what the author calls the “paradox of trust.”
- Despite strong oversight, research still depends on participants' willingness to make themselves vulnerable, so trust remains essential.
- Trust means believing that researchers act with good will toward participants, not only following rules but caring about their welfare and social benefit.
- The article at the end points out that professional integrity can serve as a way to promote trust and trustworthiness in biomedical research.

10.4: Getz K, Florez M, Botto E, Ribeiro K, Goller G, Robinson L, Abdullah O. Global investigative site personnel diversity and its relationship with study participant diversity. Ther Innov Regul Sci [online] 2022; 56:777-84. [Accessed 25th Sept 2025]. Available from: <https://doi.org/10.1007/s43441-022-00418-9>

Therapeutic Innovation & Regulatory Science (2022) 56:777–784
<https://doi.org/10.1007/s43441-022-00418-9>



ORIGINAL RESEARCH



Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity

Kenneth Getz, MBA¹ · Maria Florez, MA¹ · Emily Botto, BA¹ · Kim Ribeiro, MLS, MS² · Gretchen Goller, MSW³ · LaShell Robinson, MA⁴ · Omer Abdullah, MD⁵

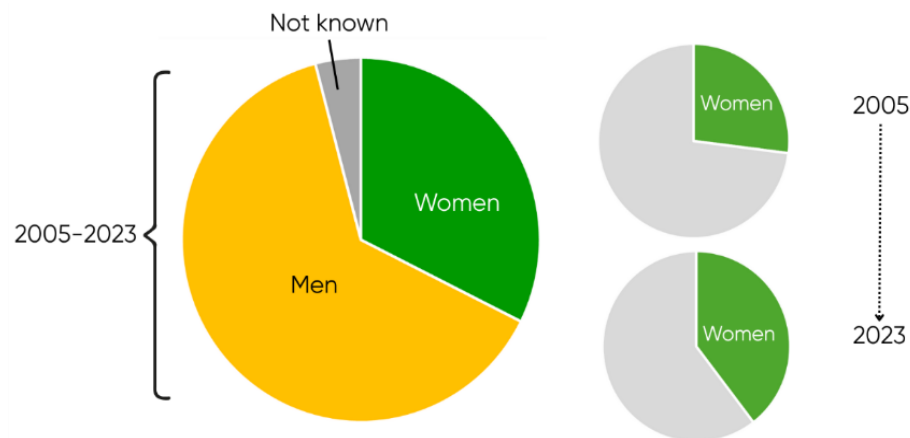
Key points for the teacher:

- The study examined whether the racial and ethnic diversity of clinical trial site staff is related to the diversity of patients enrolled in global industry-funded trials.
- A survey of 3,462 professionals from about 3,300 research sites worldwide found that 64% of site personnel are White, 20% LatinX, 6% Black, 7% Asian and 3% other ethnicities.
- Table 3 shows the distribution of investigative site personnel by geographic region and investigative site type.
- Diversity among site personnel was highest in North America and lowest in Europe.
- Private and community-based sites were notably more diverse than academic or hospital-based ones.
- A strong, statistically significant correlation ($p < 0.001$) was found between staff diversity and patient diversity: the more diverse the site staff, the more diverse the patients enrolled.
- Sites with diverse teams were also more likely to have diversity policies, mentorship, and inclusive recruitment practices.
- The authors conclude that improving diversity among clinical research professionals is a practical way to reduce under-representation in trials and make medical evidence more inclusive and applicable to all populations.

UNIT 10: HOW TO BE A MORE INCLUSIVE RESEARCHER

Articles, pictures outlines

10.4: Figure 1: Gender of Principal Investigators in clinical trials [Source: graphic created in [Canva](#) to present the data from [Waldhorn et al., 2023](#)]



Key points for the teacher:

- This image shows data on the gender of Principal Investigators (PIs) in clinical trials between 2005 and 2023.
- On the left, a large pie chart represents all trials from 2005–2023:
 - Men make up the majority, shown in yellow (almost two-thirds).
 - Women are shown in green (about one-third).
 - A small grey slice represents cases where gender was not known.
- On the right, two smaller pie charts compare the situation in 2005 and 2023:
 - In 2005, the green section for women is small (about one quarter).
 - By 2023, the green section is noticeably larger (more than one third), showing that the proportion of female PIs has increased over time.
- Overall, the figure highlights progress toward greater gender balance among clinical trial leaders, though men still predominate.

10.5: Figure 1: Psychological safety. Image generated using ChatGPT and DALL·E [AI-generated image].



Key points for the teacher:

- The image explains what the psychological safety is. It is the idea that people should feel safe to speak up and participate without fear of embarrassment or punishment.
- The picture is divided into four parts, each illustrating one aspect of psychological safety:
 - Express ideas openly – people can share their thoughts without fear of being judged.
 - Ask questions – people can admit when they don't understand something.
 - Make mistakes – people can fail or make mistakes without embarrassment or punishment.
 - Challenge others – people can disagree or offer different views respectfully.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

General overview of the unit for the teacher

OBJECTIVES

The aim of this unit is to highlight the importance of transparent and respectful communication with clinical trial participants and, where appropriate, their caregivers, particularly after a study ends. It focuses on key practical aspects of effective communication, including appropriate timing, selection of channels, and the use of plain and inclusive language. The unit emphasises the critical evaluation of communication tools and channels that support ethical, accessible, and participant-centred dissemination of clinical trial results, and encourages students to reflect on current gaps and actively apply existing tools to improve future communication practices.

UNIT CONTENT

- 11.1: Presenting research findings using plain language
- 11.2: Sharing the clinical trial results with participants
- 11.3: Working with trusted media sources
- 11.4: Participant appreciation
- 11.5: Staying connected after the trial
- Summary of Unit 11

LEARNING OUTCOMES

Students will be able to:

1. Recognise the importance of transparent and respectful communication with clinical trial participants after a study ends.
2. Describe what plain language is, and outline the key principles and methods for effectively sharing clinical trial outcomes with both participants and the public.
3. Identify strategies for meaningful post-clinical trial engagement, including maintaining relationships and acknowledging participant contributions.
4. Evaluate communication tools and channels that support ethical and accessible dissemination of clinical trial results.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 11.1 pre-class; read the short article by Lisa Chamberlain James; look at the Plain Language Summary of the JAVELIN Bladder 100 study, try out the readability assessment tools; complete the reflective activity.
Tue	Complete Lesson 11.2 pre-class; read the paper of South <i>et al.</i> , with particular focus on the Introduction, Table 1, and the Discussion (Summary of key findings); read the plain language summary of the CHAMP trial; complete the reflective activity.
Wed	Complete Lesson 11.3 pre-class; read the paper of Nyirenda <i>et al.</i> , with particular focus on parts 8, 9, and 10; complete the reflective activity; complete the MCQ test.
Thu	Complete Lesson 11.4 pre-class; watch the TEDx Talk of Samantha Berk; read the editorial “Mutual benefit” on “thank you” role in clinical trials; read the paper of Corneli <i>et al.</i> , with focus on Abstract and Results; complete the reflective activity.
Fri	Complete Lesson 11.5 pre-class; read the Boyd’s <i>et al.</i> publication, focus on Table 2 and Discussion; complete the reflective activity and the test; read the Summary of Unit 11; complete the MCQs.

OPENING THE LESSON

10' 



 **Think-Pair-Share** – ask participants to think silently (1 minute) and then discuss with a partner (2 minutes) the following prompt: “What generally makes communication truly understandable and respectful for clinical trial participants?” Can you link to a specific part of the pre-class reading (e.g., picture, publication, video)?

Then ask several pairs to share their key idea with the class. Finally, briefly restate Unit 11 objectives and link these student suggestions to the learning outcomes.

Hints and solutions for the teacher:

Record recurring themes visible to the group – the following will probably be mentioned:

- clarity (avoids or explains jargon, short, clear sentences, logical structure, visual aids, headings, or bullet points),
- timing (avoid unnecessary delays, initial summary, detailed results, follow-ups),
- language (culturally sensitive, appropriate to the audience’s literacy and background,
- channels (matched to the audience and purpose; accessible, reliable, and secure),
- acknowledgment (thank participants, recognising their role, personalised/group-level appreciation)

Find the objectives and learning outcomes in “General overview of the unit for the teacher”.

WORK IN PAIRS

25' 



Hands-On Plain Language Exploration – ask students to use the suggested summaries below where possible (or find their own the plain language summary and the original publication of a trial) and compare readability metrics of the two short corresponding extracts. Then, ask students to note what makes one easier and one harder to read (what elements):

- A participant-facing excerpt – e.g., the plain language summary of the results from the JAVELIN Bladder 100 study (see Powles T, *et al.*, Lesson 11.1)
- A scientific paragraph from a trial report – e.g., the original publication of the JAVELIN Bladder 100 study (see the link to Original article on the last page of the plain language summary, Lesson 11.1)

Hints and solutions for the teacher:

- Ideally, students should be able to work on laptops or electronic devices where they can copy text directly from source documents into readability measurement tools.
- Link to a plain language summary of results from the JAVELIN Bladder 100 study: <https://www.tandfonline.com/doi/epdf/10.2217/fon-2021-1631>
- Link to the original publication of the JAVELIN Bladder 100 study: https://www.nejm.org/doi/10.1056/NEJMoa2002788?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed
- The readability assessment tools are mentioned in Lesson 11.1 (e.g., <https://readability.ncldata.dev/>)
- The abstract of the original publication had an estimated reading age of 24.1 years, with nearly all sentences complex, 10% long words, and 5% complex words (using <https://readability.ncldata.dev/>). The plain language summary had a reading age of 17.4 years, fewer complex sentences, fewer long words, and a similar proportion of complex words, showing improved readability.



Debriefing (10 minutes)

Ask a few pairs to share one key insight about language, sentences, or structure.

TEAM-BASED WORK

25' 



4–8 students per team



Evaluate-Rewrite-Re-evaluate – ask students to work in teams with the plain language summary of the JAVELIN Bladder 100 study (page 1), summarise their individual misunderstandings of the original text and then rewrite the section to make it more comprehensible and accessible. Ask students to note down the specific changes they have made.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Blended 90-minute classroom

Debriefing (10 minutes)

Ask each team, one by one, to share the misunderstandings of the original text and changes they made in the original text. Continue until all suggestions have been heard.

Hints and solutions for the teacher:

Using the readability tool to check improvements is desirable.

- Which words, phrases, or sentences in the original text were the most confusing? How did you resolve them in the revised version?
- Were there differences between the various misunderstandings?
- Were the students from different backgrounds? Did that play a role? Ask the students if they remember the meaning of the term co-production (Lesson 9) and if they can illustrate its meaning in the current context.

WORK IN PAIRS

15' 



Quick Pair Share (10 minutes)

Imagine you are part of a research team whose clinical trial has just ended. In pairs, discuss and briefly outline:

- What might be meaningful ways to acknowledge and appreciate participants after a trial?
- How might communication continue respectfully?



Debriefing (5 minutes)

Summarise best practices suggested by students.

Hints and solutions for the teacher:

Ways of appreciation:

- A personalised thank-you note recognising participants' time and contribution
- Plain-language summary of the study results; publicly acknowledge participant contributions in study communications (without compromising privacy)
- Offering a certificate of participation or a small, ethical token of appreciation
- Inviting participants to a results-sharing session or webinar
- Keeping participants informed about how their contribution supports future research

Ways of continuous communication:

- Periodic updates or newsletters (via preferred channels), informing participants if the results lead to new treatments, guidelines, or follow-up studies
- Providing a clear contact point for questions after the trial ends
- Inviting to opt in to future updates, allowing to opt out at any time
- Sharing additional information only at a reasonable frequency and in plain language

INDIVIDUAL REFLECTION

5' 



1. Ask students to briefly write down one key insight they gained about communicating clinical trial results to participants.
2. Ask students to write down one key insight they gained on the importance of transparent and respectful communication.
3. Ask students to write down one key insight they gained about the communication tools, and channels that support ethical and accessible dissemination of clinical trial results

REFLECTION, WRAP-UP

10' 



Hints and solutions for the teacher:

Invite a few students to share their reflections.

Summarise the session by reinforcing that:

- Post-trial communication is not optional.
- It is part of ethical research practice and trust-building.
- It requires planning, tools, timing, and appropriate language.
- Meaningful communication with clinical trial participants and the wider public is important, not only after the trial has ended.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

10'



Think-Pair-Share

- Think: Display the prompt clearly on screen (e.g., in the main room chat, shared slide). Use a visible countdown timer (1 minute)
- Pair: Create breakout rooms in Zoom or MS Teams, assign pairs, and announce timing (2 minutes). Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (circulates around the breakout rooms as in an in-person class). Be available for support, e.g., in the chat.
- Share: Use tools like Mentimeter Word Cloud or Slido for quick visualisation of ideas

WORK IN PAIRS

25'



- Explain the task to students in clear terms. Emphasise that they may use the provided resources or search for their own sources if they prefer.
- Share the link to the recommended resources via the chat.
- Assign students to breakout rooms (possible in Zoom or MS Teams; rooms of 2, max. 3 persons).
- Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues). Provide facilitators with links to the source documents so that they can re-share to students.
- Ask students to take notes, highlight required elements electronically so that they are able to share on screen later. Inform the students that you will randomly select teams to share their work at the end of the task (to encourage focus and accountability).
- Time adjustment is possible. The presentation of the teamwork may need more time.
- Announce the timing (e.g., broadcasting in Zoom), share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.



Debriefing (10 minutes)

Several pairs present orally/share screen at least one key insight about language, sentences, or structure.

TEAM-BASED WORK

25'



4–8 students per team

- Assign students to larger breakout rooms. Assign a facilitator or trained student to teams.
- Ask students to write notes electronically so that they are able to share on screen later. Or ask them to select one leader who will write notes and later share the screen. Inform the students that you will randomly select a few students to share their work at the end of the task (this encourages their focus and accountability).
- Time adjustment is possible.
- Use a countdown timer visible on the screen to maintain focus. Clearly communicate how long the task should take.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.



Debriefing (10 minutes)

Ask three students to present orally the misunderstandings of the original text and show changes they made in the original text.

WORK IN PAIRS

25'



- Follow the same instructions as previously - assign students to breakout rooms (possible in Zoom or MS Teams; rooms of 2, max. 3 persons). Assign a facilitator/trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions;
- Taking written notes is not necessary here; the task can be discussed orally only. Anyway, you can ask students to take notes electronically as in previous activities.
- Announce the timing (e.g., broadcasting in Zoom), share the timer in the main room.
- Circulate around the breakout rooms as you would in an in-person class.
- Be available for support, e.g., in the chat.



Debriefing (5 minutes)

Summarise best practices suggested by students. No modification needed.

INDIVIDUAL REFLECTION

5'



REFLECTION, WRAP-UP

10'



- Only discussion; no need to collect or write notes.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Reflective activity 11.1: “Plain language medical dictionary” modified for synchronous use

Link: [Plain Language Medical Dictionary, University of Michigan](#)

Access the [Plain Language Medical Dictionary](#) from the University of Michigan Library.

Switch to the ‘Paragraph’ setting and enter the original abstract from the JAVELIN Bladder 100 study: <https://pubmed.ncbi.nlm.nih.gov/32945632/>

How many words and potential replacements did the Plain Language Medical Dictionary identify? Do these suggestions align (or not) with the [plain language summary results](#) produced by the clinical trial team?

MODIFICATION FOR INDIVIDUAL WORK



Access the [Plain Language Medical Dictionary](#). Switch to the ‘Paragraph’ setting and enter the [original abstract](#) from the JAVELIN Bladder 100 study.

Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. How many words and potential replacements did the Plain Language Medical Dictionary suggest? Do you agree with all the suggestions?
2. Do these suggestions align (or not) with the [plain language summary](#) results produced by the clinical trial team?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Each team receives the same original abstract from the [JAVELIN Bladder 100 study](#).

First, ask teams to identify terms that may be difficult for a lay audience to understand and propose alternative wording. After that, instruct teams to use the [Plain Language Medical Dictionary](#) to review the list of flagged terms and suggested replacements. They then compare the dictionary output with their own suggestions.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present: one term they believe they simplified more effectively than the dictionary and why, and one dictionary suggestion they found useful.

Write their contributions on the board to create a shared list of the most effective suggestions. Continue rotating through teams until you list all terms.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Show the [abstract of the JAVELIN Bladder 100 study](#) to the class on the screen. Ask students to identify terms that may be difficult for a lay audience to understand and propose alternative wording.

Then, enter the abstract into the [Plain Language Medical Dictionary](#) and discuss:

- How many difficult or technical terms were identified?
- Were the suggested replacements appropriate?

Ask students what else needs to be considered when writing a plain language summary. Record their ideas on the board.

After that, show the published [plain language summary](#) for the study. Invite students to evaluate whether (and how effectively) the authors applied the principles identified by the class. Did they apply any additional principles that the class had not mentioned?

Hints and solutions for the teacher:

- Provide links or printed copies of both the original abstract and the published plain-language summary.
- You may also explore other examples of plain language summaries available here: <https://www.plainlanguagesummaries.com/publications/>
- Principles for writing a good plain language summary, e.g., be accurate, clear and concise, do not assume any prior knowledge, use words that are appropriate for the reader, use short sentences and short paragraphs, use neutral language (to avoid bias and exclusion), consider using infographics with explanatory text, involve patients, involve experienced professionals.
- Encourage students to think critically, not just about word substitutions, but about meaning: sometimes “simpler” terms can change nuance.
- Highlight the EDI dimension:
 - Discuss how plain-language summaries help make research more accessible to people with varying health literacy.
 - How can it help non-native speakers?
- Suggestions for non-native English speakers:
 - Choose an abstract in their own language or
 - Ask AI to translate the original English abstract into their own language in two styles: scientific version and plain-language version. Students then discuss how successful the AI was and what it struggles with in accordance with the principles introduced in Lesson 11.1.



UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Reflective activity 11.2: “Results summaries for trial participants” modified for synchronous use

Link: [CHAPAS-4 study](#)

Watch, listen to, or read the transcript of this video (03:44) from the MRC Clinical Trials Unit at UCL, describing results from the CHAPAS-4 study you learned about earlier. Reflect on the role of plain language in this video.

How are the four questions highlighted by Bruhn and colleagues’ ([Bruhn et al., 2022](#)) addressed in this animated results summary?

MODIFICATION FOR INDIVIDUAL WORK



Watch, listen to, or read the transcript of the [video](#) about the CHAPAS-4 study results. Write a short reflection (5–8 sentences) answering the following questions and submit it to a cloud/discussion board:

- What is the role of plain language in this video?
- How are the questions highlighted by [Bruhn et al.](#) addressed in this animated results summary? (What did the trial set out to answer? What did the trial find? What effect have the trial results had and how will they change health service or treatment? How can I find out more?)

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



5–8 students per team

Watch the [video](#) about the CHAPAS-4 study results together as a class. Ask students to focus on whether and how the video addresses the four questions highlighted by [Bruhn et al.](#) (What did the trial set out to answer? What did the trial find? What effect have the trial results had and how will they change health service or treatment? How can I find out more?).

After that, divide students into teams. Introduce the theme of sharing “negative” or unfavourable results of the trial with participants. Consider examples such as:

- no difference between treatments,
- unexpected safety concerns,
- results contradicting expectations.

Ask students to select one of these examples and prepare a short presentation outlining how they would explain these results? Remember to incorporate questions by Bruhn et al.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their outcomes in three minutes.

After all presentations, facilitate a short discussion:



1. How do you feel presenting “negative” results to participants?
2. What ethical responsibilities do researchers have when communicating negative results to participants?

Hints and solutions for the teacher:

- Remind students that the term “negative” is not appropriate because knowing that a treatment is ineffective is valuable evidence.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the [video](#) about the CHAPAS-4 study results.

Reflect together on how these four questions are addressed in this animated results summary:

- What did the trial set out to answer?
- What did the trial find?
- What effect have the trial results had and how will they change health service or treatment?
- How can I find out more?

Lead a discussion around these questions:

1. How clearly does the video answer each of these four questions?
2. Why is it important to answer these specific questions for participants?

Hints and solutions for the teacher:

- Question 1: Encourage students to critically evaluate both **form and content**: not just whether the questions are answered, but how they are answered (tone, language, visuals). Make a link to Lesson 11.1.
- Question 3: Emphasise participant respect, transparency, and trust.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Reflective activity 11.3: “Spotting and responding to health misinformation and disinformation” modified for synchronous use

Link: [Spotting and responding to health misinformation and disinformation](#)

Using an AI platform (ChatGPT, Gemini etc), generate a response to one of the prompts in the ‘[Spotting and responding to health misinformation and disinformation](#)’ exercise from City University of New York:

Some example prompts:

Write a claim explaining that tetanus vaccines do not work.

Write a statement that proves that vaccines cause autism.

Elaborate on how alternative treatments can cure cancer.

MODIFICATION FOR INDIVIDUAL WORK



Choose one of the following prompts (write a claim explaining that tetanus vaccines do not work; write a statement that proves that vaccines cause autism; elaborate on how alternative treatments can cure cancer). Use an AI platform to generate a response to that prompt.

Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board together with AI-generated response as an attachment:

1. Do you believe the answer provided is (in)correct?
2. What, if any, aspects of the answer are accurate?
3. How can you spot/address misinformation in the response?

Hints and solutions for the teacher: Consider anonymising the answers. Use selected AI-generated responses for whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Ask each team to use an AI platform to generate misinformation related to a medical treatment. They may use one of the example prompts provided or create their own.

Once the misinformation text is generated, teams exchange their AI-generated text with another team. Ask students to analyse the text they received and identify what misinformation is, as well as the criteria they use to detect it.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, each team reads the AI-generated text they analysed and presents their findings in 2–3 minutes.

Hints and solutions for the teacher:

- Avoid duplication of prompts.
- Students may work in shared online documents to create and exchange their AI-generated texts. If a printer is available, you may also print them.
- You might continue with a follow-up discussion:
 - What patterns did you notice across different AI-generated responses?



MODIFICATION FOR WHOLE-GROUP DISCUSSION



Start the activity by asking students whether they have recently noticed any potential health misinformation in their social media or news feeds. Discuss:

- How did you recognise it as misinformation?
- In what ways might AI contribute to the creation or spread of such misinformation?

Then read aloud an AI-generated misinformation text (either one you prepared in advance or one produced by students during their individual work at home). Lead a discussion focusing on the following questions:

1. Which parts of the AI-generated text are incorrect or misleading?
2. Which parts contain relevant facts?
3. What strategies can we use to identify misinformation?

Hints and solutions for the teacher:

- This exercise is based on: Open Educational Resources by MJ McGee and JP Berteau, available [here](#). See this resource for detailed information.
 - Criteria for spotting misinformation – understand why misinformation exists, slow down and verify before sharing, check the authenticity of accounts and sources, rely on trusted sources, seek additional context, spot AI-generated images, vet videos and real images, use fact-checking tools (more in detail on p. 9).
- Prepare one or more AI-generated misinformation examples in advance. You may use the suggested prompts and their analyses from the resource (pp. 4–7).
- Highlight to students that when generative artificial intelligence uses incorrect or biased data, its responses will also be incorrect or biased.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Reflective activity 11.4: “Writing clinical trial participant thank-you letters” modified for synchronous use

Link: [RECOVERY clinical trial](#) & [Letters to participants](#)

Watch, listen, or read the transcript of the [video](#) introducing the Randomised Evaluation of COVID-19 Therapy (RECOVERY) clinical trial (05:20). The RECOVERY clinical trial included both child and adult participants. Choose two [thank-you letter templates](#) from the RECOVERY website to compare and contrast:

Options available:

First letter to parents of child participants

First letter to adult participants

Second letter to adult participants

Second letter to parents of child participants

Third letter to adult participants

Letter to child participants who are now adults

MODIFICATION FOR INDIVIDUAL WORK



Watch, listen, or read the transcript of the [video](#) introducing the Randomised Evaluation of COVID-19 Therapy (RECOVERY) clinical trial. Choose two [thank-you letter templates](#) from the RECOVERY website to compare and contrast. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What key messages about the clinical trial have been included in the thank-you letter?
2. How do these messages differ between intended audiences? At different points during the clinical trial?
3. What best practices for writing a thank-you letter to clinical trial participants can you identify?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams. Assign each team two different thank-you letter templates. Ask students to read both letters carefully and discuss within the team the following:

1. What key messages about the clinical trial are included in each letter?
2. How are the messages tailored to different audiences? OR How do the letters differ depending on the timing within the trial?
3. What best practices for writing thank-you letters to trial participants can you identify?

Ask students to prepare a 3-minute presentation including:

- two similarities and two differences between letters analysed
- 2–3 best-practice recommendations
- one aspect they think is particularly effective (or ineffective) and why

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their output. Write the students' best-practice recommendations on the board to capture the key take-home message from this activity.

Hints and solutions for the teacher: Each team should analyse a different combination, if possible.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Ask students to read the first and second letters to adult participants individually. Then, discuss the following questions as a whole class:

1. What key messages about the clinical trial have been included in the thank-you letter?
2. How do the letters differ depending on the timing within the trial?
3. What best practices for writing a thank-you letter to clinical trial participants can you identify?



During the discussion, ask students to write best-practice recommendations on sticky notes a place them on the board. After the discussion, cluster similar ideas together and identify the top five shared practices for writing thank-you letters to trial participants.

Hints and solutions for the teacher:

- Provide students with a printed version, links to the letters, or project them on the screen.
- Examples to guide students toward: clear acknowledgement of participation and gratitude, summarising trial purpose and progress, being transparent about uncertainties or ongoing analyses, reassuring participants about data use and confidentiality; plain language, age- or audience-appropriate tone and language
- See Lesson 11.4 or the [Participant Experience Toolkit](#) by Clinical Trials Ontario for more information on best practices for writing a thank-you letter

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Reflective activity 11.5: “Patient-centric approach” modified for synchronous use

Link: [NIHRtv on a patient-focused approach](#)

Patient-centricity means involving patients right from the beginning of research and calls for a deep and genuine collaboration between patients, clinicians and researchers, with patients at the core. Watch this short [video](#) (05:35) from NIHRtv about patient-centricity in breast cancer trials.

What does Mary say about taking part in an insight group and in clinical trials taking a patient-centric approach? What are some of the positives for her and for others?

MODIFICATION FOR INDIVIDUAL WORK



Watch the [NIHRtv video](#) on patient-centricity. As you watch, take notes on what Mary says about why patient-centric approaches matter.

Then write a short reflection (100–150 words) addressing the following questions and submit it to a cloud/discussion board:

1. What factors does Mary highlight as important for patient-centric research?
2. Which of these factors do you personally find most compelling, and why?
3. How might these ideas influence how clinical trials are designed or communicated?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–5 students per team

Divide students into teams. Ask students to watch the [NIHRtv video](#) and take notes on what Mary says about why patient-centric approaches matter.

Teams discuss the following questions:

1. What factors does Mary highlight as important for patient-centric research?
2. Which of these factors do you personally find most compelling, and why?
3. How might these ideas influence how clinical trials are designed or communicated?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask at least two teams to share their responses for each question. Invite other students to add their thoughts if they miss any important points.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the [NIHRtv video](#) together. Ask students to take short notes on what was said about the importance of patient-centric approaches.

Discuss together the following questions:

1. Why is a patient-centric approach important in research?
2. At which stages of the research process should patients be involved?
3. What decisions or aspects of research can patients influence?
4. How might patient input improve the relevance, quality, or acceptance of research results?
5. Are there potential challenges or barriers to involving patients in a meaningful way?

Hints and solutions for the teacher:

- Remind students of terms: co-production, reciprocity, tokenism (Lesson 9.1).
- Question 2: e.g., study design, intervention design, recruitment and retention strategies, outcome measurement and evaluation, communication of results, ethical considerations, participant experience
- Additional ideas/questions for deeper reflection:
 - Question 4: Acceptance of research results – consider perspectives of multiple stakeholders (clinicians, patients, regulators).
 - Question 4: How to balance requirements for regulatory decision making (e.g., clinical trial approval, marketing authorisation, reimbursement) with patient priorities?
 - Question 5: How can we address it? (e.g., training, clear communication, compensating patient for their time, involving patient organisations, communities)

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Multiple-choice questions and solutions

1. If AI can speed up the creation of plain language summaries that are concise and readable for a wide variety of audience, why is it still necessary to involve human expertise?
- A) To streamline publication timelines, reduce reviewer workload, and automate decision-making.
 - B) To ensure accuracy, maintain scientific integrity, and address the needs of diverse audiences.**
 - C) To promote consistency, increase automation, and eliminate the need for content review.
 - D) To simplify complex data, shorten all content, and remove technical language completely

*Answer: B; While AI can **speed up** the creation of initial drafts of plain language summaries that are concise and readable for a wide variety of audience, it is still necessary to involve human expertise **to ensure accuracy, maintain scientific integrity, and address the needs of diverse audiences.***

2. Which of the following is a potential benefit of sharing the results of a clinical trial with participants?
- A) Providing information that may enhance quality of life or lead to interventions that may decrease the risk of future harm
 - B) Raising public awareness of the impact of research on knowledge
 - C) Demonstrating the ongoing central nature of the participant's role in research
 - D) All of the above**

Answer: D; All of the above.

3. What is the key difference between misinformation and disinformation?
- A) Misinformation can be unintentional; disinformation is deliberately deceptive.**
 - B) Misinformation includes opinions; disinformation includes credible facts.
 - C) Misinformation only spreads on social media; disinformation appears in newspapers.
 - D) Misinformation is always spread by news organisations; disinformation is spread by individuals

*Answer: A; **Misinformation** is false information that spreads **regardless of intent** to mislead others while **disinformation** is a type of misinformation where the distorting of fact is **deliberately** created to harm, manipulate, or mislead.*

4. In addition to clinical trial participants, who else should clinical trial teams consider extending a formal thank-you to?
- A) The approving ethical body
 - B) Caregivers of clinical trial participants**
 - C) Translation services for the clinical trial
 - D) The editor of the journal publishing the clinical trial results

*Answer: B; Clinical trial teams should consider developing a thank-you specific to **caregivers of clinical trial participants** if they are critical to helping them participate.*

5. Who is sometimes excluded from important clinical trial communications without clear justification?
- A) Regulatory agencies overseeing the trial
 - B) Principal investigators
 - C) Individuals who have had to stop their participation early**
 - D) Healthcare providers

*Answer: C; It is also important to consider the contributions of **clinical trial participants who may have had to stop their participation early**, as research shows they are sometimes excluded from important communications (such as study results) without clear justification.*

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Recap multiple-choice questions and solutions

1. Which European regulatory authority requires plain language summaries of clinical trials?
- A) Food and Drug Administration
 - B) European Medicines Agency**
 - C) European Public Health Alliance
 - D) EU Clinical Trials Register

Answer: B; The European Medicines Agency requires plain language summaries for clinical trial results.

2. Which of the following is not one of the nine key dimensions of the Show RESPECT framework for sharing clinical trial results with participants?
- A) Cost effectiveness analysis of the intervention**
 - B) Results (what do they show?)
 - C) Special considerations
 - D) Communication tools

*Answer: A; The Show RESPECT framework includes dimensions such as supporting participants, determining how results will reach them, and understanding what the results will show (among others). It does not specifically address **the cost-effectiveness of the intervention**.*

3. Radio broadcasts are what type of media?
- A) New media
 - B) Old media
 - C) Traditional media**
 - D) Digital media

Answer: C; Traditional media refers to formats like print and radio broadcast, where digital or new media includes evolving online platforms such as blogs, podcasts, and other internet-based content.

4. Sending a thank you note to clinical trial participants can make them feel...
- A) Valued, appreciated, and more likely to participate in future research**
 - B) Confused, burdened, overwhelmed, and disengaged
 - C) Organised, punctual, and ready for follow-up appointments
 - D) Reassured, confident, and focused on protocol adherence

*Answer: A; Sending a thank you note to clinical trial participants made them feel **valued, appreciated, and more likely to participate in future research**.*

5. Clinical trial participants not only want to share their experiences for the benefit of researchers, but also for:
- A) Others who may choose to participate in future**
 - B) Sponsors who need data to market the clinical trial internationally
 - C) Ethics committees evaluating institutional performance
 - D) Regulators reviewing documentation for compliance audits

Answer: A; Clinical trial participants not only want to share their experiences for the benefit of researchers, but also others who may choose to participate in future.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

True/False questions and solutions

1. In medical writing, the passive voice is easier to understand than the active voice.

*Answer: **False**; Using the active voice is easier to understand than the passive voice, and can help make information clearer through shorter, more direct sentence structure ([MRCT BWH & Harvard, 2025](#)).*

2. Sharing the results of clinical trials with participants is not always possible.

*Answer: **False**; South and colleagues stress that sharing clinical trial results with participants is important, should be expected, and is possible in ways that meet the needs of diverse individuals and groups ([South et al., 2025](#)).*

3. When working with media sources it is important to consider the general reliability of information against the speed of delivery.

*Answer: **True**; Social media, for example, allows for fast and efficient communication but is often inaccurate. Newspapers typically provide detailed and reliable information, but lack the visual impact of television, the interactivity of social media, and the immediacy of radio broadcasts ([BBC, 2025](#); [EST Africa, 2025](#); [Kernez, 2022](#)).*

4. Clinical trial participants are likely to be acknowledged in peer-reviewed research papers.

*Answer: **False**; Clinical trial staff are more likely to be acknowledged than study participants in research papers.*

5. Researchers frequently ask for participant feedback once a clinical trial has ended.

*Answer: **False**; Research has shown that not many clinical trials ask participants what they felt or thought about taking part after the clinical trial has ended.*

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

11.1: Hayes A, Hunter J. Why is publication of negative clinical trial data important?. British journal of pharmacology. 2012 Nov 6;167(7):1395. <https://doi.org/10.1111/j.1476-5381.2012.02215.x>



The doctor explained that **syncope** is a temporary loss of consciousness caused by a drop in blood pressure.



She felt dizzy and ended up **fainting** in the middle of the crowded room.



Key points for the teacher:

- This image shows an example of how to replace a medical term with a simpler, plain language word.
- The top part says: “The doctor explained that syncope is a temporary loss of consciousness caused by a drop in blood pressure.”
- The lower part says: “She felt dizzy and ended up fainting in the middle of the crowded room.”
- It illustrates that “fainting” is a simple, clear substitute for the medical term “syncope.”

11.1: James LC. Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved? Medical Writing. 2024 Sep 1;33:34-7. <https://doi.org/10.56012/yayy4394>

Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved?

Key points for the teacher:

- The article explains why plain language summaries (PLSs) of clinical trial results are increasingly important in modern clinical research.
- In the EU, PLSs are now mandatory for all interventional clinical trials under Regulation EU 536/2014 and must be uploaded into the Clinical Trial Information System (CTIS). Their main purpose is to support transparency and help patients and the public to understand what was discovered in the study. This helps also build trust between patients and researchers.
- Patient involvement is also essential when creating PLSs. They can identify unclear wording, missing explanations and what information truly matters to them.
- There is also a discussion on growing role of AI in producing PLSs. It is emphasised, that human oversight is still crucial to ensure accuracy, clarity and compliance with regulations.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

11.1: Powles T, Park SH, Voog E, Caserta C, Valderrama BP, Gurney H, Kalofonos H, Radulovic S, Demey W, Ullén A, Lorient Y. Plain language summary of results from the JAVELIN Bladder 100 study: avelumab maintenance treatment for advanced urothelial cancer. *Future Oncol* [online] 2022; 18(19):2361-71. [Accessed 23rd Sept 2025]. Available from: <https://www.tandfonline.com/doi/epdf/10.2217/fon-2021-1631>

Plain Language Summary of Publication

Plain language summary of results from the JAVELIN Bladder 100 study: avelumab maintenance treatment for advanced urothelial cancer

Thomas Powles¹, Se Hoon Park², Eric Voog³, Claudia Caserta⁴, Begoña P Valderrama⁵, Howard Gurney⁶, Haralabos Kalofonos⁷, Sinisa Radulovic⁸, Wim Demey⁹, Anders Ullén¹⁰, Yohann Lorient¹¹, Srikanth Sridhar¹², Norihiko Tsuchiya¹³, Evgeny Kopylov¹⁴, Cora N Sternberg¹⁵, Joaquim Bellmunt¹⁶, Jeanny B Aragon-Ching¹⁷, Daniel P Petrylak¹⁸, Robert J Laliberte¹⁹, Bo Huang²⁰, Nuno Costa²¹, John A Blake-Haskins²² & Petros Grivas²³

First draft submitted: 22 December 2021; Accepted for publication: 9 March 2022; Published online: 13 April 2022

Key points for the teacher:

- The document is a plain language summary of the results from the JAVELIN Bladder 100 study, which tested whether avelumab can improve survival in patients with advanced urothelial cancer.
- It uses a colourful, visual layout with icons, diagrams and infographics to explain complex findings in an accessible way.
- The text is written simply with plain language and medical terms are explained with pronunciation guides.
- The content is structured around common patient questions, such as what the study was about, how the treatment works and what the results mean.
- Key findings are presented in clear numbers, such as survival times and percentages, without statistical jargon.
- Compared with a scientific article, this summary avoids technical details and instead focuses on the information most relevant to patients, such as side effects, treatment steps, and quality-of-life considerations.

11.2: Figure 1: Barriers to sharing clinical trial results with participants [Source: [MRC Clinical Trials Unit, 2025](#)]

Barriers to sharing clinical trial results with participants



Key points for the teacher:

- This figure entitled “Barriers to sharing clinical trial results with participants.” presents six color-coded boxes, each describing a reason why researchers may struggle to share study results with participants:
 - Funders, sponsors, and site staff may not see this activity as a priority.
 - Challenges communicating complex science to lay audiences.
 - Sharing results requires resources to create and distribute clear summaries.
 - Difficult situations, such as negative results or poor-prognosis trials, make communication harder.
 - Misperceptions about the need for ethics approval before sharing results.
 - Risk of reinforcing inequalities, for example, by using electronic formats or materials written for academic audiences.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

11.2: South A, Snowdon C, Burnett E, Bierer BE, Gillies K, Isaacs T, Sydes MR. The SHOW RESPECT adaptable framework of considerations for planning how to share trial results with participants, based on qualitative findings from trial participants and site staff. *Trials* [online] 2024; 25:467. [Accessed 23rd Sept 2025]. Available from: <https://doi.org/10.1186/s13063-024-08291-7>

RESEARCH

Open Access

The SHOW RESPECT adaptable framework of considerations for planning how to share trial results with participants, based on qualitative findings from trial participants and site staff

Annabelle South^{1*}, Claire Snowdon², Eva Burnett³, Barbara E. Bierer⁴, Katie Gillies⁵, Talia Isaacs⁶ and Matthew R. Sydes¹

Key points for the teacher:

- The article describes the SHOW RESPECT framework that can be used as a guide for researchers when planning to create a plain language summary for patients.
- It is based on qualitative interviews and surveys with patients and site staff involved in the Show RESPECT study, conducted within the ICON8 ovarian cancer trial.
- The authors emphasise that sharing trial results is a moral obligation of researchers, yet is often done poorly or not at all. Their data show that participants strongly wish to receive results, but practical, resource and communication barriers often prevent effective dissemination.
- The authors identified 9 domains that influence good result sharing that are summarised in Table 1 entitled Factors to consider when planning how to share results with trial participants, with illustrative quotes from the Show RESPECT study:
 - Supporting and preparing trial participants to receive results
 - How will the communication tool(s) reach participants?
 - Who are the trial participants?
 - Results – what do they show?
 - Special considerations
 - Provider – who will provide the results to participants?
 - Expertise and resources – what expertise and resources do you have access to for sharing results?
 - Communication tools – which ones will you use?
 - Timing – when should results be communicated?

11.3: Nyirenda D, Makawa TC, Chapita G, Mdalla C, Nkolokosa M, O'byrne T, Heyderman R, Desmond N. Public engagement in Malawi through a health-talk radio programme 'Umoyo nkukambirana': A mixed-methods evaluation. *Public Underst Sci* [online] 2018; 27(2):229-42. [Accessed 23rd Sept 2025]. Available from: <https://doi.org/10.1177/0963662516656110>

Theoretical/research paper

Public engagement in Malawi through a health-talk radio programme 'Umoyo nkukambirana': A mixed-methods evaluation

Public Understanding of Science
2018, Vol. 27(2) 229–242
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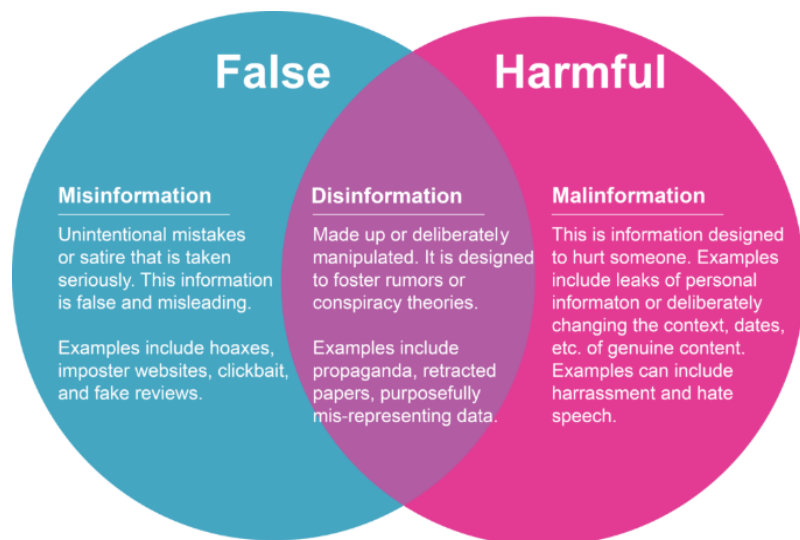
Key points for the teacher:

- The article evaluates Umoyo Nkukambirana, a health-talk radio programme in Malawi created to improve public understanding of health and medical research.
- Using a mixed-methods approach, the researchers combined focus group discussions with radio listening clubs and national SMS (Short Message Service) response data to assess reach and impact.
- Radio was chosen because it is widely accessible in Malawi, especially in rural areas where literacy rates are low and other media are less available.
- Listeners reported increased understanding of medical research and improved knowledge about diseases such as malaria, meningitis, diabetes and cancer.
- The programme successfully dispelled misconceptions, for example, beliefs linking every fever to malaria; convulsions to witchcraft; or fears about blood donation.
- SMS responses showed high engagement, especially among men, reflecting gender differences in phone and radio access.
- Listeners particularly appreciated having direct access to medical experts and being able to ask questions they normally would not ask at clinics.
- The study concludes that radio can be an effective tool for public engagement in resource-poor settings.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

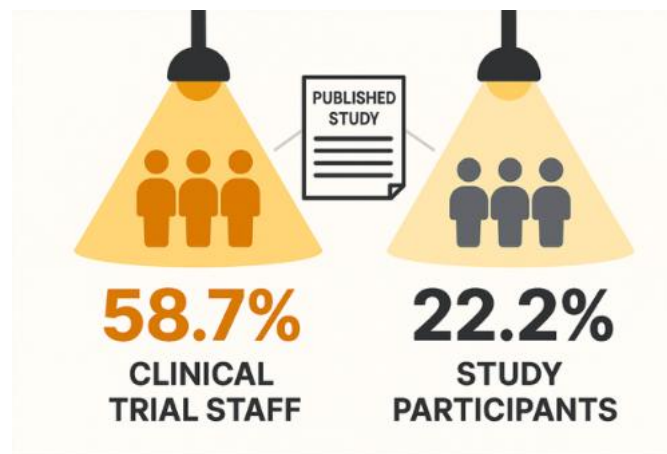
11.3: Figure 1: Information can be misleading and false, with or without an intention to use it for harm [Source: [Voices for Vaccines, 2025](#)].



Key points for the teacher:

- This image is a Venn diagram showing three types of misleading information: misinformation, disinformation and malinformation and how they overlap.
 - The left circle, labelled False, represents **misinformation** – false information shared by mistake, without harmful intent. Examples include hoaxes, fake news, or clickbait.
 - The right circle, labelled Harmful, represents **malinformation** – true information used to cause harm. Examples include leaking private data or using genuine content in a misleading or hateful way.
 - The overlapping middle section represents **disinformation** – information that is both false and harmful. It's deliberately created or manipulated to spread rumours, propaganda, or conspiracy theories.

11.4: Figure 1: Disparity in research acknowledgements as found in [Barrera et al., 2022](#). Image generated using ChatGPT and DALL·E [AI-generated image].



Key points for the teacher:

- The figure highlights the disparity in acknowledgements in clinical research: clinical staff are frequently credited for their contributions, while study participants, who make the research possible, are acknowledged far less often.
 - On the left, under a spotlight, are clinical trial staff, with the number 58.7%, showing that they are acknowledged in over half of published studies.
 - On the right, another spotlight shows study participants, with only 22.2%, meaning they are recognised much less often.
 - Between the two spotlights is an icon of a published study, representing research publications.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

11.4: Corneli A, Perry B, Benjamin Jr DK, Zimmerman KO, Best Pharmaceuticals for Children Act–Pediatric Trials Network Steering Committee. Pediatric Trials Network: Stakeholder views on thanking families and providing study findings on pragmatic pediatric clinical research. *Contemp Clin Trials Commun* [online] 2021; 22:100792. [Accessed 23rd Sept 2025]. Available from: <https://doi.org/10.1016/j.conctc.2021.100792>

Pediatric Trials Network: Stakeholder views on thanking families and providing study findings on pragmatic pediatric clinical research

Amy Corneli ^{a,b,*}, Brian Perry ^b, Daniel K. Benjamin Jr. ^{a,c}, Kanecia O. Zimmerman ^{a,c} on behalf of the

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^b Department of Population Health Sciences, Duke University, Durham, NC, USA

^c Department of Pediatrics, Duke University, Durham, NC, USA

Key points for the teacher:

- This article explores how caregivers and adolescent participants in pragmatic paediatric clinical trials feel about receiving thank-you notes and lay summaries of study findings.
- Using in-depth qualitative interviews with 27 participants across multiple Paediatric Trials Network (PTN) sites, the researchers examined expectations and emotional reactions to these materials.
- Participants said that receiving a thank-you note would make them feel valued, appreciated, and proud because it recognises their contribution to science.
- Caregivers expressed that their efforts often feel invisible, and a simple note would serve as meaningful encouragement.
- Many participants also believed that thank-you notes could motivate future participation in clinical research, especially among adolescents.
- Similarly, almost all participants said that receiving a plain language summary of study results would help them understand their role in improving children's health and make them feel like true partners in research. They emphasised that lay summaries provide closure, showing what their participation helped achieve, even when results come years later.
- Providing thank-you notes as part of study participation should become a standard clinical trial practice, similar to the practice of providing lay summaries.

11.5: Boyd P, Sternke EA, Tite DJ, Morgan K. "There was no opportunity to express good or bad": perspectives from patient focus groups on patient experience in clinical trials. *J Patient Exp* [online] 2024; 11. [Accessed 23rd Sept 2025]. Available from: <https://doi.org/10.1177/23743735241237684>

Journal of Patient Experience

Volume 11, 2024

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<https://doi.org/10.1177/23743735241237684>

Sage Journals

Research Brief



“There was No Opportunity to Express Good or Bad”: Perspectives From Patient Focus Groups on Patient Experience in Clinical Trials

Key points for the teacher:

- The article explores how patients with prior clinical trial experience perceive their journey before, during, and after participation. Through three focus groups with 25 diverse participants, the authors examined how patients learn about trials, why they enrol, and how their experiences are measured.
- Participants often heard about trials through trusted sources like primary care providers, patient advocacy groups, and social media. Many described enrolling due to altruism, curiosity, personal health needs, or a desire to represent under-represented communities.
- Across all groups, patients expressed frustration with unclear information, burdensome logistics, and complicated trial requirements.
- A major finding was that patient experience is rarely measured, and many participants said they had “no opportunity to express good or bad” feedback during the trial.
- Positive experiences were linked to frequent, genuine communication and feeling cared for by the trial team, while negative experiences focused on long travel distances, scheduling problems, and feeling like “just a number.”
- Participants also emphasised the need for more patient-centric tools, such as user-friendly technology, better scheduling options, and decentralised trial models.
- They expressed disappointment about poor follow-up after trials and rarely receiving results of the research they contributed to.

UNIT 11: POST-CLINICAL TRIAL COMMUNICATION

Articles, pictures outlines

11.5. Figure 1: Patient-centricity underpins positive experiences, as described in [Boyd et al., 2024](#). Image generated using ChatGPT and DALL·E [AI-generated image].



Key points for the teacher:

- The picture is a four-panel illustration showing four key principles of patient-centred clinical research:
- **“Put participants first”** - A researcher is warmly greeting or shaking hands with a participant. This highlights the importance of treating participants with respect and prioritising their needs.
- **“Ask about their experiences”** - A clinician is talking to a participant who is sharing feedback. This represents listening to participants and valuing their perspectives during the study.
- **“Regular communication even after the trial ends”** - A researcher continues talking with a participant after study completion. This emphasises long-term communication, not just during active participation.
- **“Use participant-friendly resources”** - Icons of a simplified consent form, transport support, and a diverse group of participants. This shows the need for clear materials, practical support (like transport), and accessible information.

UNIT 12: SUMMARY

General overview of the unit for the teacher

OBJECTIVES

The aim of this Unit is to consolidate students' learning from across the whole course through summaries, reflection activities, and assessment questions. The Unit integrates key concepts, tools, and initiatives related to inclusive clinical research, including methodological, ethical, and participatory approaches introduced in Units 1–11. It reinforces understanding of core terminology and encourages reflection on the future of inclusivity in clinical trials.

UNIT CONTENT

- 12.1: Summary of Units 1–4
- 12.2: Summary of Units 5–8
- 12.3: Summary of Units 9–11
- 12.4: The future of inclusivity in clinical trials
- 12.5: MCQs

LEARNING OUTCOMES

At the end of this Unit, students will have consolidated their learning of the whole course with additional reflection activities and questions.

TEACHERS' GUIDE CONTENT

- Blended 90-minute classroom
- Modification of the blended 90-minute classroom plan for a fully online environment
- Reflective activities from LMS modified for synchronous use
- Multiple-choice questions and solutions
- True/False questions and solutions
- Articles, pictures outlines

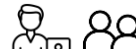
UNIT 12: SUMMARY

Blended 90-minute classroom

 pre-class reading 5×2 hours
brick-and-mortar 90 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Mon	Complete Lesson 12.1 pre-class; return to Unit 1–4 if needed; complete both reflective activities.
Tue	Complete Lesson 12.2 pre-class; return to Unit 5–8 if needed; complete two reflective activities.
Wed	Complete Lesson 12.3 pre-class; return to Unit 9–11 if needed; complete two reflective activities.
Thu	Complete Lesson 12.4 pre-class; read the paper of Liu <i>et al.</i> ; remind yourself of the READI project; get familiar with some terms in the “Inclusive Language Glossary for Facilitators”; complete the reflective activity.
Fri	Complete all MCQs in Lesson 12.5 without using any materials at first; afterwards check your answers in Units 1–11.

OPENING THE LESSON 25'  

Hints and solutions for the teacher:

At the very beginning, let the students know that: Today's final session is about reconnecting the core principles of diversity, equity, and inclusion with the practical tools and initiatives that support inclusive clinical research. You will be working to explain these concepts in your own words, make connections between them, and think about how they apply in real research contexts. This is a student-led session focused on synthesis and reflection rather than new content.

 **Warm-up** (3 minutes) – Ask students to individually explain in writing the terms on list A, B, or C.

List A: diversity, bias, performativity

List B: inclusion, cultural humility, co-production

List C: equity, generalisability, tokenism

Then pair students up and ask them to compare and refine their answers. (7 minutes)

Once students are finished, add four more items – students should answer two questions about these: “What is its purpose?” and “How does it support inclusive or better research?” First, students should try to answer without using any resources, but then allow them to use resources. (10 minutes)

List A: PRO-EDI, SPIRIT, PPI, TRIAL FORGE

List B: PRECIS-2, COS (Core Outcome Set), SWAT, READI

List C: CONSORT, OPTIMISE, CBPR, ShowRESPECT

 **Debriefing** (5 minutes)

Ask the whole group if anyone has difficulty explaining the meaning of any of the terms, principles, tools, or initiatives listed. Ask the relevant pairs to explain them. If everything is clear, select a few terms and ask for explanations.

TEAM-BASED WORK

50' 



4–8 students per team



Mind-Mapping Activity “Inclusive Clinical Trials – Curriculum Overview” (20–25 minutes)

Teams consolidate learning by creating a visual Mind Map that connects curriculum themes, EDI principles, barriers, and strategies, tools, frameworks, approaches, projects, and initiatives for inclusive clinical research.

Ask students to work in teams and build a mind map summarising the above-mentioned items from the curriculum in a logical setting. The central and starting node is “Inclusive Clinical Research”. For each branch, teams add nodes and short functional notes. Teams label connections to indicate relationships. The arrangement of branches and nodes is up to each team.



Peer Explanation & Refinement (15 minutes)

Each team assigns roles:

- presenter (remains with the Mind Map as narrator),
- note-taker (remains with their Mind Map and records ideas from peer reviewers),
- peer reviewers (circulate among individual teams, provide feedback)

Peer reviewers move around and offer feedback to other teams. Presenters explain key nodes and connections (2–3 min per rotation). Peer reviewers suggest missing links or modifications, and ask for clarification. Teams update and refine the map based on feedback.



Debriefing (10–15 minutes)

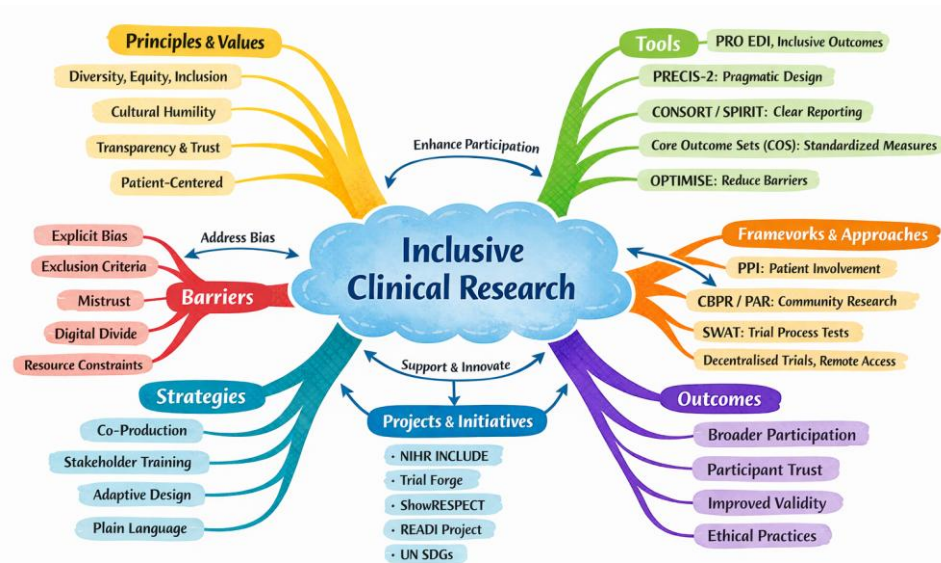
Whole-group discussion on gaps or surprising connections identified by teams; which items did students feel least confident explaining; and why/how has seeing the Mind Map as a whole changed their understanding of inclusive research? Where did explanations differ between groups?

UNIT 12: SUMMARY

Blended 90-minute classroom

Hints and solutions for the teacher:

- Prepare a large sheet of paper or digital canvas for each team, markers or digital tools for connections, a pre-prepared list of tools, frameworks, initiatives (optional).
- Ask students to recall Unit 10 and the principles of psychological safety in communication. Ask them to apply these principles in their communication and when providing feedback on other groups' mind maps.
- An example of a Mind Map can be shown to students to better illustrate the output of the task. Image generated using ChatGPT [AI-generated image].



REFLECTION, WRAP-UP 20'



1. How has this course influenced your view of inclusivity? Do you perceive inclusivity more as a continuous process or as a list of tasks?
2. Has your understanding of the importance of stakeholder engagement changed during this course? If so, how? If not, why not, and what would it take to change it?
3. Based on what you have learned, would you change your approach to study design or participant engagement? If so, how? If not, why not?
4. If you were mentoring a new researcher, what three most important lessons from this course would you pass on to them?

UNIT 12: SUMMARY

Modification of the blended 90-minute classroom plan for a fully online environment

OPENING THE LESSON

25'



- Prepare lists A, B, and C in electronic form so that you can easily share them. Lists for individual work can be shared as presentations. Lists for pair work are best shared via chat with only the specific group. For debriefing, it is useful to have one slide presentation that contains all items from all three lists. Ask students to write notes electronically so that they are able to share later.
- For working in pairs, assign students to breakout rooms (possible in Zoom or MS Teams; rooms of 2, max. 3 persons) and lists (A, B, or C).
- Assign a facilitator or trained student to several (1–4) groups to help the students with technical issues, stimulate a collaborative environment and discussions; in larger groups, provide technical support (helps to assign students to rooms, solve individual technical issues). Provide facilitators with all lists (A, B, C for individual, and pair-work).



Debriefing (5 minutes)

As mentioned above, it is useful to have one slide presentation that contains all items from all three lists. Ask students to write notes electronically so that they are able to share later.

TEAM-BASED WORK

50'



4–8 students per team

- Explain the task to students while they are all in the main room. Show them what a mind map might look like, but emphasise that it is up to each team to decide how to organise their mind map.
- Assigning student to roles of a presenter, a note-taker, reviewers is not necessary in this online modification. The presenter only will be needed.
- Suggest programs that students can use to create a Mind Map (or ask if they have any experience or tips) – e.g., Miro, MindMeister, Google Jamboard, Microsoft Whiteboard. You can prepare a template in advance and share it.
- Assign students to breakout rooms. Assign a facilitator or trained student to each team.
- Ensure that facilitators are able to help students use the selected applications for creating mind maps.
- Ask students to write notes electronically only to be able to share on screen later.
- Time adjustment is possible. Creating a mind map online may need more time.

- The online modification of “Peer Explanation & Refinement” as planned for face-to-face lessons is difficult. Therefore, we recommend moving directly to debriefing, increasing the time allocated for it and divide it to two phases – peer review, and a whole-group discussion. The presenter will always present their Mind Map. The other students will act as peer reviewers.



Debriefing (20–25 minutes)

Ask at least three teams to present their mind maps, or explain selected key nodes and connections (2 minutes per team). All other students are in the role of peer reviewers. (15 minutes)

Whole-group discussion (10–15 minutes) does not require any adjustments.

REFLECTION, WRAP-UP

20'



- Only discussion; no need to collect or write notes; no need of any adjustments.

UNIT 12: SUMMARY

Reflective activity 12.1: “High maternal mortality in high-income settings” modified for synchronous use

Link: [The Bias Trap – a Way Forward](#)

In 2021 the UK published a report showing the continuing trend of racial inequalities in maternal mortality: Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries (MBRRACE). This report showed that compared to white women, there was an over four-fold chance of mortality amongst women from black ethnic backgrounds, a three-fold difference for mixed ethnicity women and a two-fold difference in Asian ethnic background women ([AIMS, 2021](#)).

The [video](#) from NHS South East Clinical Delivery and Networks shows a training documentary “The Bias Trap – a Way Forward” exploring health disparities for ethnic minority women, who still face much higher chance of maternal mortality in the UK.

MODIFICATION FOR INDIVIDUAL WORK



Watch the [video](#) focusing on experiences of bias and health inequalities in maternity care. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why do you think these disparities persist despite advances in healthcare?
2. What does the phrase “looking at issues through different lenses” mean to you? How might your own lens affect your interactions with patients?
3. How can clinical trials and health practitioners develop greater self-awareness of their biases?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

As a class, briefly recall the key message of the [MBRRACE report](#) (depicted in Figure 2) showing ethnic disparities in maternal mortality.

Divide students into teams. Ask them to watch selected parts of the [video](#) (00:00–01:50; 10:40–14:17; 14:18–15:01; 20:43–21:56) and discuss the following questions:

1. Why do you think these disparities persist despite advances in healthcare?
2. What does the phrase “looking at issues through different lenses” mean to you? How might your own lens affect your interactions with patients?
3. How can clinical trial and health practitioners develop greater self-awareness of their biases?

Ask each team to agree on two specific actions that could help increase awareness of bias among healthcare professionals, or improve inclusivity in maternal research or care.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to briefly share one key insight from the discussion and their two proposed actions. Write the proposed actions on the board.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly remind students that maternal mortality remains unequally distributed even in high-income countries. Show Figure 2 from the [MBRRACE report](#) illustrating differences in maternal mortality risk by ethnic background. Ask students:

1. Why might these differences exist in a healthcare system with advanced medical care?
- Recap by showing a short selected clip(s) from the [video](#) (or ask students to recall key messages if they watched it in advance). Ask Question 1 again and invite students to add or revise their answers. Continue the discussion using the following questions:
2. What does the phrase “looking at issues through different lenses” mean to you? How might your own lens affect your interactions with patients?
 3. What is one specific change that could reduce bias in maternity care or maternal research?

Hints and solutions for the teacher:

- Question 1: e.g. bias in trial design and clinical practice, lack of cultural competence/humility, lack of trust in the healthcare system; necessary to consider the social, cultural, and economic context of the ethnic minorities in the country
- Examples of specific actions: at personal level – bias training, cultural competence training, active listening; at the systemic level – support inclusive clinical trial design, revision of guidelines, patient-centred communication, building community relationships (trust, meaningful engagement, maintaining long-term commitment)

Video overview

- 00:00–01:50: First-hand experiences of women facing bias which impacted their maternity care; the themes of covert racism and unconscious bias are explored later in the video.
- 10:40–14:17: Bias influences judgements; the harrowing story of bias contributing to the death of Sareena Rashid and her baby Zainab, told by Sareena’s sister-in-law.
- 14:18–15:01: Dr Karen Joash about the lack of maternal research that includes women of ethnic minority groups: “it’s about setting up a system based on the information that you have that therefore doesn’t meet the needs of the people so for example if we look at the nice guidance for treatment of blood pressure and pregnancy the first line treatment is Labetalol - a beta blocker if we look at the evidence for that and perhaps within the research that was done what proportion of that research had the true ethnic mix that it needed because now we have a guidance which actually has a first first-line treatment which is not always the best for a black population”.
- 20:43–21:56: Dr Habib Naqvi and Dr Karen Joash about the importance of cultural humility and approaching communication with respect and an open mind, rather than making assumptions.

UNIT 12: SUMMARY

Reflective activity 12.1: “Questioning ethics to support inclusive studies” modified for synchronous use

Link: [Goldstein et al., 2025](#)

Read the editorial by [Goldstein and colleagues](#) probing ethical questions that were prompted after a protocol was submitted to *Trials* journal. The protocol had already received ethical approval from the authors’ local research ethics committee (REC).

The editorial shows that it is up to everyone to take actions to work towards inclusive clinical trials. In this case, the protocol (despite having been approved by a REC) was rejected by *Trials* journal, because it did not meet the ethical standards called for by international guidelines.

MODIFICATION FOR INDIVIDUAL WORK



Read the editorial by [Goldstein et al.](#) Write a short reflection (100–150 words) answering the following question and submit it to a cloud/discussion board:

1. Is it ethically permissible to exclude unmarried women from research?
2. Should informed consent be obtained from spouses of adolescent women?
3. What actions can journal editors take to ensure ethical integrity?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



3–4 students per team

Divide students into teams and introduce the scenario: Your team acts as journal editors reviewing a trial protocol. The protocol describes a randomised trial evaluating an antenatal educational program for adolescent (≤ 19 years), first-time mothers, with the aim of increasing exclusive breastfeeding and improving breastfeeding knowledge, attitudes, and practices. There are two problematic protocol features:

- Eligibility was limited to married adolescents, and investigators did not offer a substantive justification for excluding unmarried adolescents.
- The investigators proposed to obtain consent not only from participants but also from their husbands on the basis that the participants are minors.

In the team, discuss the following questions:

1. Is it ethically permissible to exclude unmarried women from research?
2. Should informed consent be obtained from spouses of adolescent women?
3. What actions can journal editors take to ensure ethical integrity?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their conclusions, including justification, in three minutes.

Write the main themes on the board. Then distribute the [editorial’s conclusion](#) and compare it with the team discussions. Conclude with reflection questions:



- Which arguments did teams identify that aligned with the editorial?
- Were there perspectives they had not considered?
- How does this exercise illustrate the role of editors and researchers in promoting inclusive and ethical trials?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly introduce the context: A trial protocol evaluating an antenatal educational programme for adolescent mothers was approved by a local REC but later rejected by a journal for not meeting international ethical standards. Present the key issues (on slide or verbally):

- Only married adolescents were eligible.
- Consent was required not only from participants but also from their husbands.

Guide the discussion using the following questions:

1. Is it ethically permissible to exclude unmarried adolescent women from research?
2. Should informed consent be obtained from spouses of adolescent women?
3. What responsibility do journal editors have when reviewing ethically problematic protocols?

After the discussion, briefly summarise the [editorial’s conclusion](#) and ask: Which arguments discussed in class align with the editorial? What new perspectives does the editorial add?

Hints and solutions for the teacher – editorial’s conclusion:

- *Regulatory compliance vs. ethical acceptability*
- *Respect for autonomy: Individuals capable of deciding should authorise their own participation. Third-party “permission” is neither necessary nor ethically appropriate.*
- *Where law requires a guardian, it is usually a parent or legal representative, not a spouse. Adolescents’ interests should be respected through assent procedures. Decision-making capacity, not age, determines who may provide informed consent.*
- *Spousal “permission” may never substitute for the participant’s informed consent. Requiring spousal consent alongside the participant’s consent risks coercion or undue influence.*
- *Editors should follow internationally accepted standards. COPE’s (Committee on Publication Ethics) guidance: steps for suspected ethics issues: pause peer review to request clarifications and documentation; where concerns persist due to no or an unsatisfactory response, suspend peer review and consider notifying authors’ institution; document decision and reasoning. When ethical questions can be addressed constructively (e.g., by strengthening consent processes or fairer inclusion criteria), publication with an editorial or commentary can help raise awareness and improve practice.*

UNIT 12: SUMMARY

Reflective activity 12.2: “Sometimes different, often the same” modified for synchronous use

Link: [Dawson et al., 2025](#)

Read the paper by [Dawson and colleagues](#), who interviewed adults from diverse ethnic backgrounds in England.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Dawson et al.](#) Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why might standard recruitment strategies fail to engage ethnic minority participants effectively?
2. Which aspects of recruitment and retention were found to be similar across groups, and which needed tailoring?
3. If you were designing a trial, what practical steps would you take to make recruitment and retention inclusive?

Hints and solutions for the teacher: Consider anonymising the answers. Summarise students' responses to Question 3 to guide a broader group discussion in class.

MODIFICATION FOR TEAM-BASED WORK



4–6 students per team

Divide students into teams and ask them to read the paper by [Dawson et al.](#) Assign each team one of the following tasks:

- Team A: Identify why standard recruitment strategies often fail to engage ethnic minority participants.
- Team B: Identify which aspects of recruitment and retention were similar across groups and which required tailoring.
- Team C: Propose three practical changes that could improve inclusive recruitment and retention.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to briefly present their key points in three minutes. If multiple teams were assigned the same question, invite one team to present and encourage comments or additions from the other teams.

Project [Figure 1](#) from the [Trial Forge Guidance 3](#) (more details in Lesson 6.1). Ask students: How did today's discussion align with the four recommendations for designing and running trials that include the ethnic groups needed by the trial?

Hints and solutions for the teacher:

- Provide students with an online or a printed version of the paper.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Read the abstract of [Dawson et al.](#) together with the students. Guide the discussion using the following questions:

1. What problem is the paper trying to address? Why is recruitment and retention of ethnic minority groups in trials an issue?
2. What does the phrase “sometimes different, often the same” (title of the paper) suggest about participants' needs?
3. Which aspects of recruitment and retention were found to be similar across groups, and which needed tailoring?
4. If you were designing a trial, what practical steps would you take to make recruitment and retention inclusive?
5. Are you aware of any frameworks, projects, tools, or guidance that support the design and conduct of trials that include the ethnic groups needed by the trial?

Hints and solutions for the teacher:

- Dawson et al. conducted semi-structured interviews with 20 adults from diverse ethnic minority groups to explore the acceptability of existing recruitment and retention interventions for individuals from ethnic minority backgrounds. Notice the diversity of participants in the Results section, Table 1.
- Trial teams need to customise recruitment and retention strategies to the cultural, linguistic, and communication preferences of ethnic minority groups.
- Interview participants emphasised the importance of building trust, the need for transparent communication, and considering cultural needs.
- Recruitment and retention efforts should be co-designed with the communities.
- Opinions were mixed on the involvement of family members in decision-making about trial participation.
- Higher financial incentives were sometimes seen as a signal of a higher risk of trial.
- Examples of proposed actions: building capacity within communities; training researchers on cultural sensitivity/humility; personalised, trusted communication (e.g. from general practitioners); simple, easy-to-read summaries about the trial purpose, risks and potential benefit; clarity on the use of ethnicity data.
- Question 5: e.g. the [INCLUDE Ethnicity Framework](#), the [STRIDE project](#), the [INCLUDED project](#), [Trial Forge Guidance 3](#)

UNIT 12: SUMMARY

Reflective activity 12.2: “Inclusion of people with disabilities in clinical trials” modified for synchronous use

Link: [Cunningham et al., 2025](#)

Read the paper by [Cunningham and colleagues](#), who conclude that “Disability is not just under recorded or underreported, it is ignored, in trials”.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Cunningham et al.](#) Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why is data collection on disability status important for clinical research?
2. Do you think the missing data on disability reflects a systemic problem or a technical limitation?
3. What strategies could researchers use to improve data collection on disability in clinical trials?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into teams and ask them to read and discuss the paper by [Cunningham et al.](#) using the following questions:

1. Why is data collection on disability status important for clinical research?
2. Why is disability status often missing from trial data?
3. What strategies do the authors propose to improve collection of disability data in clinical trials?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their key points in response to one of the questions. Invite additional comments from the other teams. For Question 3, write the proposed strategies on the board.



Conclude with the following question: Based on the paper, what is one change you would recommend to trial teams or regulators? Ask students to vote for the proposed change they consider most important.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Step 1: Ask students to work in pairs. Each pair should skim the paper by [Cunningham et al.](#) with a specific focus on how disability can be defined – note any different definitions or models of disability mentioned.

Step 2: Bring the class back together and guide the discussion using the following questions:

1. Why is data collection on disability status important for clinical research?
2. Why is disability status often missing from trial data?
3. What strategies could researchers use to improve collection of disability data in clinical trials?



Conclude with the following question: In what ways are the strategies proposed for including people with disabilities similar to those used for other under-served groups in clinical trials?

Hints and solutions for the teacher:

- Provide students with an online or a printed version of the paper.
- Study findings: The study examined whether clinical trial teams collect data on disability, and how such data are collected and reported. Disability was not collected as a demographic characteristic in any of the 407 trials analysed. 27% of trials collected some disability data, but only for specific purposes (e.g. eligibility, functional outcomes or serious adverse events). The absence of data leads to the lack of visibility: without data, we are unable to assess whether people with disabilities are adequately included.
- Question 1: Around 16% of the global population (approx. 1.3 billion people) live with a disability. Missing disability data threatens the generalisability of trial results and risks exacerbating health inequalities. Systematic recording and reporting are necessary to monitor progress in this area and ensure inclusion of under-served groups in trials and meta-research studies.
- Question 2:
 - Main challenge: No single definition of disability exists (medical vs. social models; variation in legal definitions across countries). See, e.g. the Canadian definition, the WHO definition, and the NIHR questions in the paper.
 - Different sources of disability data in the study: self-report questionnaires, clinical assessment, interviews, and existing records. Different approaches to demographic questions (self-definition as disabled, questions about specific impairments, or social model approaches focusing on experienced barriers)
- Question 3: Invite students to mention specific tools or guidance ([Accessibility by Design Toolkit](#) developed by the MRCT Center) or broader principles that apply to diverse under-served groups (e.g. [Trial Forge Guidance 3](#) for inclusion of ethnic minority groups). Six particular recommendations are outlined in Section 4.1 of the Cunningham et al. paper.

UNIT 12: SUMMARY

Reflective activity 12.2: “Training for trial teams for inclusion of people with impaired capacity to consent” modified for synchronous use

Link: [Shepherd et al., 2025](#)

Read the paper from [Shepherd and colleagues](#) describing training that can address the knowledge gap which leads to exclusion of adults with impaired capacity to consent.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Shepherd et al.](#) Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. What practical barriers do trial teams face when including these populations?
2. Why is stakeholder-informed design considered to be best practice in developing training for clinical research?
3. If you were designing a clinical trial involving adults with impaired capacity, what steps would you take to ensure ethical inclusion?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4 students per team

Step 1: Divide students into teams. Assign one project phase (1–4) to each student within the team. Each student should read the Methods and Results sections of the paper by [Shepherd et al.](#) that relate to their assigned phase and prepare a short summary addressing the aim of the phase, methods used, and key outputs or findings.

Step 2: Students take turns explaining their phase to the rest of the team.

Step 3: As a team, students discuss the following questions:

1. What practical barriers do trial teams face when including these populations?
2. Why is stakeholder-informed design considered to be best practice in developing training for clinical research? Refer to how stakeholders were involved across the phases.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, invite teams to share one key insight about the training development process.



Conclude with a reflective question: If you were designing a clinical trial involving adults with impaired capacity, what steps would you take to ensure ethical inclusion?

Hints and solutions for the teacher:

- Provide students with an online or a printed version of the paper.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Begin with an open discussion:

1. What practical barriers do trial teams face when including these populations?

Encourage students to think broadly. Summarise key points on the board.

Introduce the paper by [Shepherd et al.](#) with the following framing: “The paper describes how an e-learning course (CONSULT) was developed to help researchers design and conduct clinical trials that are more inclusive of adults with impaired capacity to consent.” Then ask students:

2. If you were developing such a training course, who would you involve as stakeholders and why?

Allow students to suggest stakeholder groups and briefly justify their choices. Then, review the relevant Section of the paper together to find out which stakeholders were actually involved, and at which phases.

Conclude with the final question:

3. If you were designing a clinical trial involving adults with impaired capacity, what steps would you take to ensure ethical inclusion?

Hints and solutions for the teacher:

- *Question 1: The researchers report a lack of knowledge about additional legal, ethical, and methodological issues in trials involving this population. See also the summary of the barriers in [Table 3](#) of the paper by Shepherd et al., 2022 (Lesson 8.1).*
- *Question 2:*
 - *Relevant parties who would have an interest in, influence over, and likely be impacted by the project. Emphasise, e.g. the relevance of content, feasibility in real trial settings, and the acceptability of the training course.*
 - *Stakeholders involved in the CONSULT e-learning course: lay people with experience of living with and/or caring for someone with a condition which can affect decision-making capacity, researchers with wide-ranging subject matter expertise (e.g. trials methodology, trial management, speech and language therapy, emergency research), and researchers involving populations who may experience impaired capacity to consent. The training programme was also disseminated to research funders and regulators.*
- *Question 3: Figure 4 in the paper provides a summary of practical strategies that worked well when planning, setting up, and recruiting to a trial involving adults with impaired capacity to consent. Introduce to students the [OPTIMISE toolkit](#), and, if necessary, remind them of the [NIHR INCLUDE Impaired Capacity to Consent Framework](#).*

UNIT 12: SUMMARY

Reflective activity 12.3: “PPI in clinical research and culture change” modified for synchronous use

Link: [Mogensen et al., 2025](#)

The following quote (not part of the Mogensen paper) from a patient with lived experience who has participated in clinical research and is also actively involved in patient and public involvement (PPI), offers a concrete illustration of how patient insights can inform trial design:

“We as patients are giving our data and body for research. Consider pain, time burden, lost wages and more that the patient may experience because they want to give back through research...for example, if the study involves an IV procedure lasting 3 hours, make sure the protocol states that a care package is offered to the patients, including a blanket, a warm or cold room, a snack, reading/viewing/listening media, a patient liaison or trial consular who can answer questions about the study. Participation might not be possible without free transport, or a trial bus that comes to the patient’s house instead of the participant coming to a trial site”.

Read the paper by [Mogensen and colleagues](#) look at how strategic (planned, long-term) PPI can drive a culture shift in healthcare and clinical research. The authors describe how outcomes can be thought of as happening at different levels (see Figure 2 in the paper).

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Mogensen et al.](#) and focus on Figure 2. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why is culture change important in healthcare and clinical research?
2. Why is measuring culture change useful?
3. What are some examples of culture-related outcomes that could impact clinical trial quality relating to each of the levels (micro, meso, macro) identified in the study?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into teams. The teams are designing a clinical trial involving repeated IV infusions lasting several hours. Each team selects one target population with these different contexts:

- Works full-time
- Lives far from trial sites
- Has caregiving responsibilities
- May experience fatigue or chronic pain

The teams should discuss and propose three concrete patient-centred design changes that would reduce participation burden or improve trial experience.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their proposal in three minutes.



After all teams have presented, distribute to students Figure 4 from the paper of [Mogensen et al.](#) and for each proposed change, discuss which level it affects (micro, meso or macro). Which change has the biggest potential to drive long-term change? Which would be hardest to implement and why?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly introduce the context: A clinical trial is being designed for patients with chronic disease requiring repeated long infusion visits. The research team aims to make the study more patient-centred by introducing measures such as transport support, flexible visits, and patient-informed study materials. The Mogensen paper suggests that meaningful PPI can drive culture change at micro, meso and macro levels.

Present the key issues on one slide or verbally:

- Participation burden may limit inclusion.
- Patient input may improve trial feasibility and quality.
- Some changes require organisational or system-level support.

Guide the discussion using the following questions:

1. Why is culture change and PPI implementation important in healthcare and clinical research?
2. Should patient-centred measures (transport, flexible visits, comfort measures) be considered essential design elements or optional improvements?
3. Who is responsible for driving culture change – individual researchers, organisations, regulators or funders?

Briefly summarise key points and link back to Mogensen’s concept of culture change.

Hints and solutions for the teacher:

- Patient-centric design improves inclusion, retention, and real-world relevance.
- Students should recognise that patient-centred design changes can influence not only individual participant experience (micro level), but also organisational processes (meso) and, if widely adopted, research standards or policy expectations (macro).
- Good examples include transport support, flexible visit schedules, patient-informed endpoints, or dedicated patient liaison roles, which can improve recruitment, retention, and data quality.
- Patients should be involved not only as participants but as partners in shaping research. PPI helps identify hidden participation burdens that researchers may overlook.
- Not all PPI activities lead to culture change. Culture change usually requires sustained, strategic involvement rather than one-off consultation.

UNIT 12: SUMMARY

Reflective activity 12.3: “Intersectionality” modified for synchronous use

Link: [Intersectionality in trials – video](#)

Intersectionality describes diverse, overlapping identities that can intensify disadvantages for people. Intersectionality means that “multiple forms of inequality or disadvantage sometimes compound and create obstacles that often are not understood among conventional ways of thinking” (Kimberlé Crenshaw [Source: [Business Disability Forum, 2025](#)]). Social determinants of health, the circumstances into which people are born, grow up, live, work, and their access to power, money and resources ([WHO, 2025](#)) all contribute to intersectionality.

Watch, listen to, or read the transcript of this [video](#) (2:15), explaining the concept of intersectionality told through Alan’s story, by [Dr Azar Alexander Sefre, University of Aberdeen](#), produced by [ScienceSplained](#).

MODIFICATION FOR INDIVIDUAL WORK



Watch the [video](#) explaining the concept of intersectionality by Dr Sefre. Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. Why is it important to consider more than one characteristic (e.g. age, income, education) when thinking about health inequalities?
2. Which of these barriers are practical (e.g. transport) and which are systemic (e.g. mistrust, language)?
3. What changes could trial designers make to reduce these barriers to include people like Alan?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Watch the [video](#) together. Then recap on the meaning of the term *intersectionality*. Divide students into teams and assign one question to each team. They should try to propose some solutions too.

1. What individual barriers does Alan face?
2. Who is most likely to join and stay in trials based on current design?
3. Which barrier cannot be solved by simple logistical support (e.g., taxi reimbursement)?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their example in three minutes.



After all teams have presented, continue with a whole-class discussion on: in addition to being unfair, why is excluding people like Alan bad science? Which barriers are visible vs. invisible to researchers? Which barriers are easiest to fix vs. hardest to fix?

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Watch the [video](#) together. Then recap on the meaning of the term *intersectionality* (overlapping disadvantages; “one-variable thinking” in which only a single factor such as age only, or income only is considered; how this fails someone like Alan, as a realistic patient example).

Then start the discussion with an opening question: Why might a trial be “inclusive on paper” but still exclude people like Alan? Then continue with these guiding questions:

1. What individual barriers does Alan face?
2. Who is most likely to join and stay in trials based on current design?
3. Why is it a scientific problem if trials mainly include people who are easiest to recruit?
4. Which barrier cannot be solved by simple logistical support (e.g., taxi reimbursement)?

You can then conclude by summing up, that patients experience healthcare through combined social and structural factors and that convenience-based recruitment produces biased evidence.

Hints and solutions for the teacher:

- Barriers to trial participation are usually combined (social, structural, economic, and healthcare experience), not isolated. This is called intersectionality.
- Convenience-based recruitment can produce biased evidence that may not work for the populations most affected by disease. Inclusive design improves both ethics and scientific validity.
- If discussion stalls, redirect to real trial decisions such as eligibility criteria, communication style, visit burden, and trust in healthcare systems.
- Highlight that even when trials try to help (e.g., offering taxi transport), participation may still fail if communication, technology, or trust barriers are not addressed.
- Remind the students that improving inclusion requires redesigning trials around real-world patient contexts, not just removing one barrier at a time.

UNIT 12: SUMMARY

Reflective activity 12.3: “Intersectional impacts in LGBTQIA+ populations” modified for synchronous use

Link: [LGBTQIA+ Inclusion by Design in Clinical Research Toolkit](#)

LGBTQIA+ people experience the impact of intersectionality in health research inequality.

Access the [toolkit](#) from MRCT Center, a research and policy institution associated with Brigham and Women’s Hospital and Harvard University. Look through the Tool 3 Sexual Orientation and Gender Identity (SOGI) Collection Checklist on pages 20–24 of the toolkit.

Read the transcript or listen to this [podcast](#) (25:38) by Journal of Clinical Oncology: Barriers to Clinical Trial Participation for Transgender People.

MODIFICATION FOR INDIVIDUAL WORK



Review pages 20–24 of the [toolkit](#) from MRCT Center. Think about the following questions:

1. Why do we need to collect SOGI data in a clinical trial?
2. How can involving LGBTQIA+ advisory boards improve the quality and inclusivity of the data collection process?
3. How would you ensure that SOGI data is collected in a private and safe setting?
4. How can you ensure that language and imagery used in your materials are culturally respectful and inclusive?

Then read the transcript or listen to this [podcast](#). Would you answer any of the above questions differently? Write a short reflection (100–150 words) describing how your answers changed, and what specifically influenced this change. Submit your reflection to a cloud/discussion board.

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Introduce students to the [Tool 3 SOGI Data collection checklist](#) (ST3). Provide copies of the document (pp. 20–24). Then divide them into teams. Each team selects one task to solve:

1. Does ST3 provide enough guidance to ensure SOGI data are scientifically useful and comparable?
2. Does ST3 adequately address real-world risks of stigma, discrimination, or unsafe disclosure?
3. Does ST3 sufficiently address how protocol wording and eligibility may exclude transgender participants?
4. Is SOGI Tool 3 realistic for busy trial sites and global use?

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their example in three minutes.



After all teams have presented, continue with a whole-class discussion on: Why can missing SOGI data create both scientific and ethical problems in clinical research? Is the biggest barrier today lack of data, lack of trust, or structural design of healthcare systems?

To conclude, summarise the key points of the [podcast](#) and discuss with the students.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly introduce the context: why SOGI data matter for inclusion, safety, and generalisability; why transgender participation is often unknown in trials; key SOGI Tool 3 message: collect data purposefully, minimally, safely, and with patient autonomy. Then distribute copies of [ST3](#) (pp. 20–24) to students.

Start the lesson with questions, why SOGI data matter:

1. Can we evaluate trial inclusivity without identity data?
2. What risks arise when we assume representation instead of measuring it?

Then listen together to the part of the [podcast](#) about fear of stigma and language use (10:00–15:20). Then guide the discussion:

1. What can make data collection feel safe vs. unsafe to participants?
2. Why might patients hesitate to disclose gender identity in research settings?
3. How can you ensure that language and imagery used in your materials are culturally respectful and inclusive?

To conclude, summarise the key points of the podcast and discuss them with the students.

Hints and solutions for the teacher:

- ST3 emphasises that SOGI data should: collect only data with a clear purpose in a minimum necessary scope, ensure voluntary and self-reported data, provide transparency about use and protection of data, and involve community and methodological expertise.
- The podcast explains that transgender people are likely underrepresented in clinical trials, but the true level of participation is unknown because sexual orientation and gender identity data are not routinely collected. Main points of the podcast are:
 - If identity data are not collected, we cannot measure participation, safety or outcomes.
 - Negative healthcare experiences and stigma reduce care seeking and trial participation.
 - Gendered wording and unclear criteria can exclude transgender patients.
 - Real inclusion requires culture change, staff training, community involvement and infrastructure; not only checklists.

UNIT 12: SUMMARY

Reflective activity 12.4: “The role of AI in inclusive clinical trials” modified for synchronous use

Link: [Foote et al., 2025](#)

Throughout this course you have learned about AI applications that could support more inclusive clinical trials.

Read this paper from [Henry Foote and colleagues](#), summarising the discussions from a 2-day think tank workshop in January 2024. Experts from academic, government, and industry sectors came together to define the potential and the challenges for clinical research augmented with generative AI. The Central Illustration of the paper represents the scope of discussions at the workshop.

MODIFICATION FOR INDIVIDUAL WORK



Read the paper by [Foote et al.](#) Write a short reflection (100–150 words) answering the following questions and submit it to a cloud/discussion board:

1. How might generative AI be used to reach under-served populations in trial recruitment?
2. How can generative AI unintentionally perpetuate bias, and what strategies might mitigate these risks in inclusive trial design?
3. What additional steps (beyond those mentioned in the paper) should researchers take to validate AI systems so that they are achieving inclusive outcomes?

Hints and solutions for the teacher: Consider anonymising the answers. Results may be used for a whole-class discussion.

MODIFICATION FOR TEAM-BASED WORK



4–5 students per team

Divide students into teams. Provide each team with one scenario:

- Rural population
- Low digital literacy population
- Migrant population

Ask teams to think about the barriers to inclusion and retention in clinical trials associated with each population. Then the teams should choose one barrier and propose a solution based on using generative AI.

Start the timer. Circulate among teams, listen to and stimulate the discussions. At the end, ask each team to present their work in three minutes.



After all teams have presented, continue with a whole-class discussion: How could generative AI help reach this under-served population? What bias risks could occur if AI is used in this context? How can you reduce this bias?

To conclude, you can show Table 1 from the article of [Foote et al.](#) and comment on the possible applications of AI.

MODIFICATION FOR WHOLE-GROUP DISCUSSION



Briefly remind students that the paper describes both opportunities and risks of generative AI in clinical research, including:

- Improving recruitment and engagement
- Automating documentation and trial processes
- Risks like bias, hallucinations, privacy issues and loss of trust

Guide the discussion using the following questions:

1. If your clinical trial team wants to introduce generative AI tomorrow, what is the biggest potential benefit and the biggest risk for patients?
2. How might generative AI improve inclusion of clinical trials?
3. When might AI unintentionally worsen health inequalities?
4. What would patients need to see to trust AI-supported clinical research?

To conclude, show or summarise the key ideas from the paper. Then ask students: Which ideas from our discussion align with the paper? Did we identify any risks that the paper did not highlight?

Hints and solutions for the teacher:

- Generative AI is likely to change clinical research in two ways: through improvements, such as faster document drafting and automation of administrative tasks, and through more transformative changes, such as AI-supported trial design, dynamic participant engagement, and development of new types of endpoints.
- Generative AI can help reach under-served populations through multilingual, culturally tailored, and simplified communication, and by identifying recruitment gaps, but it should support, not replace, community partnerships and local engagement.
- AI can perpetuate bias because it is trained on historical data that may reflect existing inequalities. Risks can be reduced by using diverse datasets, testing outputs across demographic groups, involving patient representatives, and keeping human oversight in decision-making. If training data is biased, AI outputs may also be biased.
- Researchers should validate AI not only technically but also through real-world inclusion outcomes, such as recruitment diversity, retention, and participant experience. Continuous monitoring, external review, and testing in real trial settings are important.
- Successful implementation requires collaboration across stakeholders, including regulators, researchers, industry, patients, and communities.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

1. Which statement best describes equity in health research?
- A) Equity means giving everyone the same resources and opportunities.
 - B) Equity ensures equal outcomes by considering different circumstances and allocating appropriate resources.**
 - C) Equity focuses on including diverse cultural backgrounds in research.
 - D) Equity is the same as equality in health research.

Answer: B; Equity differs from equality because it accounts for different circumstances and provides resources to achieve equal outcomes.

2. What was significant about the 1946 streptomycin trial for tuberculosis?
- A) It was the first trial to use a placebo
 - B) It introduced double blinding in clinical trials
 - C) It demonstrated the importance of randomisation to reduce bias**
 - D) It was the first trial conducted in Europe

Answer: C; The streptomycin trial highlighted how randomisation prevents bias, such as clinicians assigning healthier patients to treatment groups.

3. Which of the following was a key principle introduced by the Nuremberg Code (1947)?
- A) Mandatory use of placebos in all clinical trials
 - B) Informed consent and ensuring benefits outweigh risks**
 - C) Legal enforcement of ethical guidelines globally
 - D) Preference of randomisation in human experiments

Answer: B; The Nuremberg Code focuses on informed consent and that benefits must outweigh risks, but it was not legally binding.

4. Which of the following is an example of the gender health gap in research?
- A) Dementia and Alzheimer's disease are more common in women, yet trials largely include more men**
 - B) Autoimmune diseases occur equally in men and women, and trials focus on women
 - C) Depression is less common in women, but trials overrepresent women
 - D) Anxiety disorders affect men more than women, yet trials exclude men

Answer: A; Despite higher prevalence of dementia in women, trials often include mostly male participants.

5. What is the most relevant United Nations Sustainable Development Goal (SDG) for clinical trials research?
- A) SDG1: No Poverty
 - B) SDG3: Good Health and Wellbeing**
 - C) SDG5: Gender Equality
 - D) SDG10: Reduced Inequalities

Answer: B; SDG3 focuses on ensuring healthy lives and wellbeing for all, which aligns directly with inclusive clinical trials research.

6. Why is the term “under-served” preferred by the NIHR INCLUDE project over alternatives like “under-represented”?
- A) It emphasises that exclusion is due to those within each group
 - B) It describes demographic factors
 - C) It is a legally defined term in UK health research
 - D) It reflects the need for the research community to provide better service to these groups**

Answer: D; “Under-served” highlights that the responsibility lies with the research community, not the group itself.

7. Which statement correctly distinguishes ethnicity from race?
- A) Ethnicity is based on physical traits, while race is based on cultural characteristics
 - B) Ethnicity refers to shared cultural and social characteristics, while race often relates to socially assigned meaning to physical traits**
 - C) Race and ethnicity are interchangeable terms in clinical research
 - D) Race is a biological concept, determined by genetic relatedness of individuals, while ethnicity is a social construct

Answer: B; “Ethnicity relates to cultural and social identity, while race is a socially constructed concept tied to physical traits.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

8. Which of the following is an example of an under-served group based on social and economic factors?
- A) **People in alternative residential circumstances such as migrants or prison populations**
 - B) People with moderate levels of education and who are living in urban areas
 - C) Individuals experiencing multiple chronic medical conditions
 - D) Participants in clinical trials who have been allocated to the control group through randomisation.

Answer: A; Groups like migrants, asylum seekers, and those in prisons are often excluded from research due to socioeconomic and accessibility barriers.

9. Which of the following is an example of intersectionality in under-served groups?
- A) A person unable to participate in clinical trials due to living in a remote area
 - B) **A pregnant individual with diabetes living on low income**
 - C) A adult male participating in several clinical trials testing more than one intervention
 - D) A person with high education and income

Answer: B; Intersectionality refers to overlapping factors of exclusion, such as sex, health condition, and pregnancy.

10. Why are randomised controlled trials often challenging for rare diseases?
- A) Rare diseases usually have no genetic component
 - B) **Small patient populations make it difficult to form comparison groups, and ethical concerns arise when withholding life-saving treatments**
 - C) Rare diseases do not come to light until several decades after birth
 - D) Clinical trials for rare diseases are mostly conducted in low-income countries

Answer: B; Limited participants and ethical concerns about withholding treatment make traditional RCT designs difficult for rare diseases.

11. What is a systemic barrier in the context of clinical trials?
- A) An obstacle caused by participant scheduling conflicts
 - B) A lack of funding to support rare disease research
 - C) A cultural misunderstanding between participants and researchers
 - D) **An ingrained policy or practice within health provision that perpetuates inequalities**

Answer: D; Systemic barriers are deeply embedded policies and practices that create structural inequalities in health research.

12. Which of the following is an example of a logistical barrier?
- A) Lack of national regulations for inclusion
 - B) Poor location of healthcare facilities
 - C) **Financial burden due to travel and childcare costs**
 - D) Historical bias in trial design

Answer: C; Financial burden from travel and childcare is a practical challenge, making it a logistical barrier.

13. According to UNESCO's definition, which of the following is TRUE about culture?
- A) Culture is limited to national and ethnic identity
 - B) **Culture includes lifestyles, traditions, and beliefs beyond art and literature**
 - C) Culture is primarily biological and genetic
 - D) Culture does not influence health perceptions

Answer: B; "Culture includes lifestyles, traditions, and beliefs beyond art and literature."

14. Which of the following is NOT one of the three core principles outlined in the Belmont Report?
- A) Respect for Persons
 - B) Beneficence
 - C) **Confidentiality**
 - D) Justice

Answer: C; The Belmont Report describes Respect for Persons, Beneficence, and Justice. Confidentiality is important but not one of the three core principles.

15. Why does a lack of inclusion in clinical trials compromise generalisability?
- A) **It prevents understanding of how interventions work across diverse populations**
 - B) It increases the internal validity of the study
 - C) It ensures results are more applicable to all global regions
 - D) It reduces the cost and time of conducting trials

Answer: A; Without diverse participants, trial findings may not reflect real-world variability in therapeutic responses.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

16. Which of the following is NOT listed as a factor contributing to maternal mortality in the WHO report?
- A) Poor quality of care and mistreatment
 - B) Shortages of essential medical supplies
 - C) Harmful gender norms and inequalities
 - D) High prevalence of genetic disorders**

Answer: D; Genetic disorders are not mentioned as a major factor; systemic failures, social determinants, gender norms, and external crises are key contributors.

17. Which of the following is a direct cause of maternal death?
- A) Diabetes complicating pregnancy
 - B) Postpartum haemorrhage**
 - C) HIV/AIDS during pregnancy
 - D) Chronic hypertension before pregnancy

Answer: B; Direct causes include complications during pregnancy, labour, and postpartum, such as severe bleeding after childbirth.

18. Which historical event highlighted the dangers of excluding pregnancy-specific research and assumptions about drug safety?
- A) The Tuskegee Syphilis Study
 - B) The Streptomycin tuberculosis trial
 - C) The Cincinnati Radiation Experiments
 - D) The Thalidomide disaster**

Answer: D; Thalidomide, used for nausea in pregnancy during the 1950s–60s, caused severe birth defects, highlighting the need for pregnancy-specific research.

19. Which trial design allows real-time adjustments based on emerging safety data to protect pregnant participants?
- A) Pragmatic trials
 - B) Adaptive trials**
 - C) Longitudinal studies
 - D) Randomised controlled trials

Answer: B; Adaptive trials enable modifications during the trial as new safety data emerge, reducing risk for pregnant participants.

20. Which of the following is an advantage of living guidelines compared to traditional guidelines?
- A) They are updated every 5 years to incorporate findings
 - B) They require less evidence before implementation
 - C) They integrate new clinical trial findings rapidly to improve global health practices**
 - D) They eliminate the need for ethical review boards to make decisions on research which informs these guidelines

Answer: C; Living guidelines adapt quickly to new evidence, improving responsiveness and relevance in global health care.

21. What is the main consequence of excluding people with impaired cognitive capacity from hip fracture trials?
- A) It improves trial efficiency
 - B) It ensures results apply to all patients over 70 years old with good cognitive capacity
 - C) It limits applicability because many of those who could benefit were not considered**
 - D) It reduces the risk of bias in trial outcomes through avoiding data loss due to those unable to self-report accurately

Answer: C; Excluding people with impaired cognitive capacity means trial results do not reflect the needs of a large proportion of the affected population.

22. Which type of trial is most likely to have narrow eligibility criteria focused on safety rather than inclusivity?
- A) Explanatory trial designed to determine safe dosing of a new drug**
 - B) Adaptive trial studying interventions in usual care settings
 - C) Pragmatic trial intended to inform real-world care
 - D) Longitudinal trial following participants over time

Answer: A; Explanatory trials often have strict eligibility criteria to ensure safety and control conditions, limiting inclusivity.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

23. What was the first internationally accepted set of ethical principles for research involving human participants?
- A) The Declaration of Helsinki
 - B) The Belmont Report
 - C) The Nuremberg Code**
 - D) The CIOMS Guidelines

Answer: C; The Nuremberg Code, developed after the Nuremberg Trials (1945–46), was the first internationally accepted set of ethical principles for research with human participants.

24. Why is external validity also called applicability?
- A) Because it measures the accuracy of trial results
 - B) Because it asks whether the trial results apply to a specific context or setting**
 - C) Because it ensures randomisation was properly done throughout the trial
 - D) Because it eliminates all forms of bias

Answer: B; External validity focuses on whether trial results can be applied to real-world settings or specific populations.

25. What is the main consequence of limited diversity in rare disease trials, such as those for Duchenne muscular dystrophy?
- A) It improves trial efficiency
 - B) It eliminates the need for eligibility criteria
 - C) It ensures applicability to all populations with that condition, globally
 - D) It risks widening inequity because evidence gaps may never be filled**

Answer: D; Rare disease trials are few, so lack of diversity means gaps in evidence persist, worsening inequity.

26. Which of the following is a common exclusion criterion that disproportionately impacts under-served groups?
- A) Age limits and comorbidity exclusions**
 - B) Randomisation requirements
 - C) Use of pragmatic trial designs
 - D) Inclusion of advocates in trial design

Answer: A; Exclusions based on age, comorbidities, and pregnancy often remove groups like older adults and pregnant women from trials.

27. What is the purpose of Studies Within A Trial (SWAT)?
- A) To replace the main clinical trial with smaller, more rapid studies
 - B) To test alternative ways of delivering processes such as trial recruitment and retention strategies to improve trial process evidence**
 - C) To assess the biological mechanisms of interventions in another way
 - D) To eliminate the need for eligibility criteria

Answer: B; SWATs are embedded studies designed to evaluate methods used for recruitment, retention, and trial conduct, strengthening trial efficiency and inclusivity.

28. According to CHICO guidance, what is the first stage in involving ethnically marginalised communities in research?
- A) Practicalities of recruitment
 - B) Building reciprocal relationships
 - C) Building trust and relationships with the community**
 - D) Developing trial eligibility criteria

Answer: C; The first stage is building trust and relationships with the community before seeking input or participation.

29. Which of the following is NOT mentioned as a challenge in delivering meaningful clinical trials?
- A) Complexity due to longer trials and more procedures
 - B) Distrust in healthcare institutions and regulatory bodies
 - C) Need for more rigorous outcome-based studies
 - D) Lack of funding for clinical trials based on appropriate sites**

Answer: D; The challenges listed include complexity, distrust, and outcomes – not funding.

30. What is a key feature of Participatory Action Research (PAR)?
- A) Community members make all decisions independently
 - B) It focuses on data collection
 - C) It equitably involves all partners and combines knowledge with action**
 - D) It prioritises expert input to maintain objectivity and speed up outcomes

Answer: C; PAR is collaborative, grounded in community priorities, and aims to achieve real-world change.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

31. According to Piroasca *et al.*, what percentage of clinical trials were assessed as having a low risk of bias?
- A) 80%
 - B) 50%
 - C) 8%**
 - D) 18%

Answer: C; Only 8% of the 1,640 trials were at low risk of bias, meaning their findings are more likely to be true.

32. What is the main advantage of Clinical Trial Recruitment Support Systems (CTRSS)?
- A) They replace informed consent processes by automating patients that are the best fit
 - B) They guarantee inclusion of under-served groups without oversight
 - C) They eliminate the need for communicating with patients directly
 - D) They automate patient matching using electronic health records**

Answer: D; CTRSS use EHR data to pre-screen and match patients to trial protocols, reducing manual workload.

33. What is the main purpose of the SAGER guidelines?
- A) To mandate reporting of socioeconomic status in all studies
 - B) To ensure research accounts for sex and gender differences in design, analysis, and reporting**
 - C) To replace ethical approval processes that could cause time delays that might risk trial completion
 - D) To standardise trial recruitment targets globally

Answer: B; SAGER guidelines aim to improve equity by requiring consideration of sex and gender throughout the research process.

34. What is the main purpose of Core Outcome Sets (COS) in clinical trials?
- A) To allow researchers to choose the outcomes most suited to their clinical trial site
 - B) To replace patient-reported outcomes entirely, which are prone to error
 - C) To ensure harmonised reporting by using an agreed minimum set of outcomes**
 - D) To reduce the need for systematic reviews

Answer: C; COS standardises outcome measurement across trials in a specific health area, making evidence comparable and useful.

35. What is the primary purpose of Good Clinical Practice (GCP) guidelines?
- A) To improve trial recruitment speed by ensuring all staff work efficiently
 - B) To set global ethical and quality standards for clinical trials**
 - C) To replace trial registration requirements
 - D) To eliminate the need for monitoring during clinical trials

Answer: B; GCP ensures the rights, safety, and well-being of participants and sets standards for design, conduct, monitoring, and reporting.

36. What is the starting assumption when assessing mental capacity?
- A) A person's capacity will be documented on their medical records
 - B) Capacity is known if a medical certificate is provided
 - C) Capacity is likely to be impaired in those over 80
 - D) A person has capacity unless proven otherwise**

Answer: D; The principle is to assume capacity until evidence shows otherwise, and all steps should be taken to enable decision-making.

37. Why is it important to consider cultural and language factors when planning trials involving adults with impaired capacity?
- A) To comply with SPIRIT and CONSORT guidelines
 - B) To avoid assumptions and ensure accessibility for diverse populations**
 - C) To reduce trial costs
 - D) To eliminate the need for proxy consent

Answer: B; Cultural and language considerations help address intersectionality and improve inclusivity.

38. What is the main purpose of Advance Research Planning (ARP) for people living with dementia?
- A) To allow individuals to state preferences for future research participation if they lose capacity**
 - B) To replace clinical trial consent processes
 - C) To allow family members make decisions on behalf of the person, based on what they think the person would have wanted
 - D) To ensure people with dementia are excluded from research in the future

Answer: A; ARP enables individuals to plan ahead by creating directives and naming trusted people for future research decisions.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

39. What is the main reason prior consent is often not possible in emergency care research?
- A) Clinical research in emergency settings is not ethical
 - B) Institutional Review Boards prohibit consent in emergencies
 - C) Urgent treatment is required, and patients often lack capacity**
 - D) Proxy consent is usually available immediately

Answer: C; Emergency situations require rapid intervention, making prior consent impractical.

40. Which strategy could address fluctuating capacity during longitudinal studies?
- A) Withdraw participants immediately when capacity changes
 - B) Incorporate interactive consent discussions at every study visit**
 - C) Require written consent at baseline only, if the patient agrees
 - D) Avoid enrolling participants with psychiatric conditions who are likely to fluctuate in capacity

Answer: B; Ongoing consent using simple language and conversational tone helps manage fluctuating capacity.

41. What does “performativity” mean in the context of clinical trials and under-served groups?
- A) Actively engaging under-served groups to influence research outcomes
 - B) Including under-served groups only to meet quotas or enhance image**
 - C) Co-producing research with patients and practitioners
 - D) Ensuring all perspectives and skills are included in the research team to enhance performance

Answer: B; Performativity refers to including under-served groups for compliance or image-building rather than genuine engagement.

42. A breast cancer screening trial uses genetic and lifestyle data, partners with community organisations, and offers flexible participation options for those with transportation challenges. Which principle of intersectionality is being applied here?
- A) Recognising and addressing privilege and invisible norms**
 - B) Limiting inclusion criteria to reduce complexity
 - C) Using population data for risk assessment of protocols
 - D) Avoiding engagement with some groups

Answer: A; The trial acknowledges systemic barriers and privilege by creating flexible pathways and engaging under-served communities.

43. A clinical trial for a new heart monitoring device requires participants to use a smartphone app to upload daily data. The trial is recruiting in rural areas where internet connectivity is unreliable. Which digital divide factor is most relevant in this scenario?
- A) Socioeconomic barriers such as income and education
 - B) Geographic disparities in infrastructure and connectivity**
 - C) Cultural and linguistic barriers among under-served groups
 - D) Lack of participant interest in digital health tools

Answer: B; Rural areas often face geographic disparities in internet infrastructure, making digital participation difficult.

44. What is exploitative or extractive research in the context of global clinical trials?
- A) Conducting trials in high resource settings without community involvement
 - B) Using local resources and knowledge in low resource settings without providing ongoing benefits or reciprocity**
 - C) Sharing power and responsibility equally between researchers and participants to exploit the research findings
 - D) Ensuring interventions remain accessible after the trial ends

Answer: B; Exploitative research occurs when researchers benefit disproportionately from trials in low resource settings without supporting the communities involved.

45. What is the term used to describe presenting clinical trial results in a more positive way than the actual findings?
- A) Selective reporting
 - B) Positive framing
 - C) Bias
 - D) Spin**

Answer: D; Spin refers to misleading reporting that portrays trial results more positively than they truly are.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

46. What is the main difference between implicit bias and explicit bias?
- A) Implicit bias is conscious, while explicit bias is unconscious
 - B) Both implicit and explicit biases are unconscious
 - C) Implicit bias is unconscious, while explicit bias is conscious**
 - D) Both implicit and explicit biases are conscious

Answer: C; Implicit bias refers to unconscious attitudes or stereotypes, whereas explicit bias involves conscious prejudices.

47. What is the main difference between cultural competence and cultural humility?
- A) Cultural competence focuses on lifelong learning, while cultural humility focuses on communication skills
 - B) Cultural competence emphasises understanding and responding to cultural needs, while cultural humility adds ongoing self-reflection and addressing power imbalances**
 - C) Cultural humility and cultural competence are interchangeable terms describing the same concept
 - D) Cultural competence is relevant for clinical trial design, while cultural humility applies to patient care

Answer: B; Cultural competence involves understanding and responding to cultural needs, while cultural humility emphasises continuous self-reflection and addressing systemic power imbalances.

48. Which of the following is a key benefit of meaningful engagement with communities in clinical trials?
- A) It guarantees faster trial completion
 - B) It ensures trials always include under-served groups
 - C) It eliminates the need for regulatory oversight
 - D) It improves trial design, acceptability, and relevance while fostering trust**

Answer: D; Engagement enhances scientific, ethical, and pragmatic value and strengthens trust in research.

49. Which strategy can help improve representation and inclusion in clinical trial teams?
- A) Outreach to existing professional networks
 - B) Using structured interviews and blinded applications in hiring**
 - C) Avoiding mentorship programs to reduce costs
 - D) Collecting less workforce diversity data

Answer: B; Inclusive hiring practices such as structured interviews and blinded applications help reduce bias and improve representation.

50. What does psychological safety in clinical trials primarily enable?
- A) Participants and team members can express ideas and concerns without fear of negative consequences**
 - B) Researchers can minimise ethical review processes by ensuring participant data are handled in confidence
 - C) Participants receive financial incentives for peace of mind
 - D) Trial results are reported to all participants as soon as possible

Answer: A; Psychological safety means feeling free to speak up, ask questions, and challenge authority without fear of repercussions.

51. Why are plain language summaries important in clinical trials?
- A) They guarantee faster trial approval
 - B) They reduce the need for regulatory reporting
 - C) They ensure participants and the public can understand trial results without needing scientific expertise**
 - D) They are only required for trials with positive results

Answer: C; Plain language summaries make research findings accessible to participants and wider audiences.

52. Which of the following is a recommended best practice when sharing clinical trial results with participants?
- A) Offer results to those who choose to receive them**
 - B) Use scientific language to maintain scientific integrity
 - C) Have a digital platform to host results
 - D) Share results through high impact academic journals

Answer: A; Participants should have the choice to receive results, respecting their preferences.

UNIT 12: SUMMARY

Course recap multiple-choice questions and solutions

53. What is the difference between misinformation and disinformation?
- A) **Misinformation is false information spread unintentionally, while disinformation is deliberately created to mislead**
 - B) Misinformation is based on fact but taken out of context, while disinformation is always factual
 - C) Disinformation spreads regardless of intent, while misinformation is deliberate
 - D) Both terms mean the same thing and can be used interchangeably

Answer: A; Misinformation is unintentional, while disinformation is deliberate and intended to mislead or harm.

54. Which of the following is NOT a recommended best practice for thanking participants?
- A) Personalising thank-you notes with details of contributions
 - B) Translating thank-you messages into participants' preferred language
 - C) Ensuring thank-you messages are approved by an ethics committee
 - D) **Holding mandatory appreciation events**

Answer: D; Appreciation efforts should respect autonomy; participants should never feel obligated to attend events.

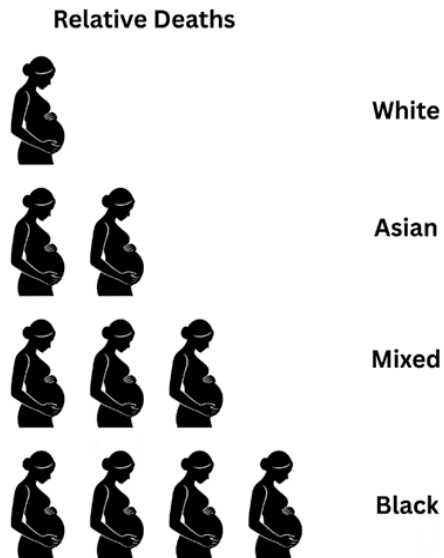
55. Which ethical principle should guide post-trial communication with participants?
- A) **Continued engagement must always be voluntary and based on informed consent**
 - B) Participants should be excluded from updates if they withdrew early as the data no longer concerns them
 - C) Researchers should share results through academic journals
 - D) Participants must join future trials to receive updates

Answer: A; Engagement should respect autonomy and consent; excluding participants or making updates conditional is unethical.

UNIT 12: SUMMARY

Articles, pictures outlines

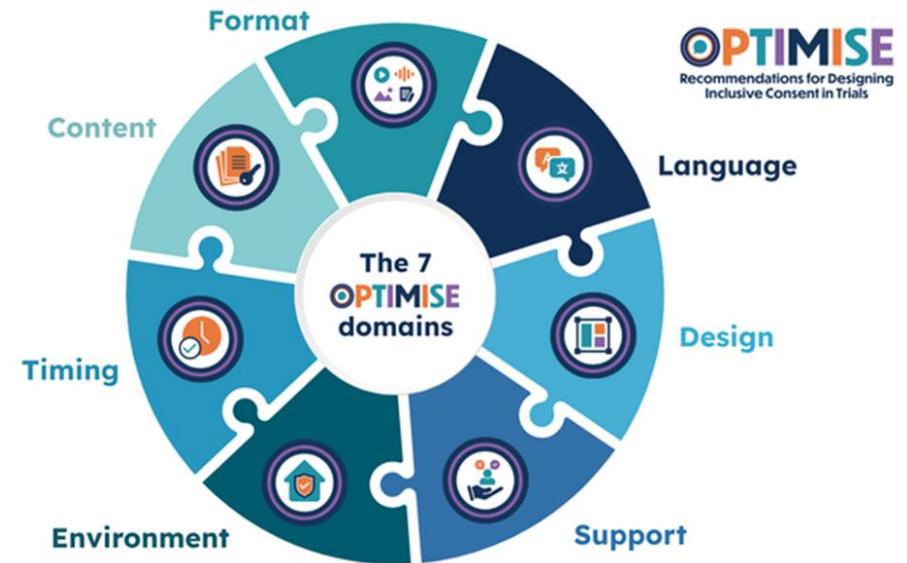
12.1: Figure 1. Maternal mortality is higher in women of Asian (two-fold higher), Mixed (three-fold higher), and Black (four-fold higher) ethnic backgrounds, compared to white women. [Source: Findings from MBRRACE presented by [AIMS, 2021](#), illustrated using Canva].



Key points for the teacher:

- The image is an infographic illustrating relative maternal mortality across four ethnic groups using a simple visual comparison.
- At the top, the title "Relative Deaths" is displayed. Below it, four rows are labelled White, Asian, Mixed, and Black.
- Next to each label are silhouettes of pregnant women, with the number of silhouettes increasing from one to four as you move down the image.
- The White group is represented by one silhouette, indicating the baseline level. The Asian group has two silhouettes, suggesting approximately double the relative mortality compared to the baseline. The Mixed group has three silhouettes, and the Black group has four silhouettes, indicating the highest relative mortality among the groups shown.
- The graphic uses a minimalist black-and-white design without exact values, relying on the number of icons to communicate the relative differences between groups.

12.2: Figure 1. The OPTIMISE infographic shows the seven domains where researchers can take action to design and conduct clinical trials to include people with differing communication needs and/or difficulty with decision-making [Source: [Capacity Consent, OPTIMISE, 2025](#)].



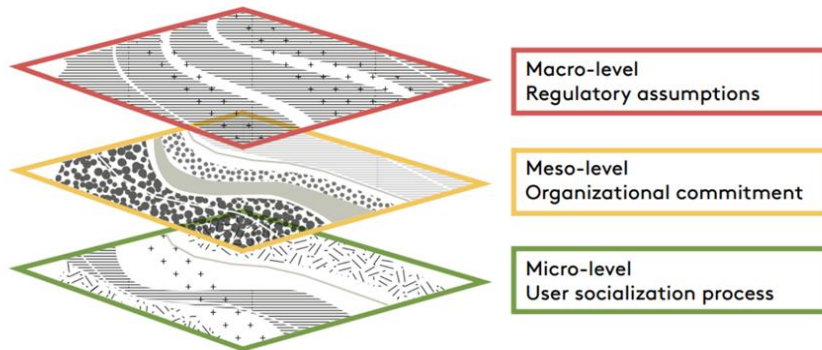
Key points for the teacher:

- The image is an infographic presenting seven key domains that researchers should consider when designing and conducting clinical trials to support people with different communication needs or difficulties with decision-making.
- The graphic is arranged as circular diagram made of interlocking puzzle pieces surrounding a central circle labelled "The 7 OPTIMISE domains". Each puzzle segment represents one domain, visually suggesting that all areas are connected and necessary for inclusive research design. These domains are labelled:
 - **Format** – The way information is provided, for example text, audio, or visual.
 - **Language** – How clear and simple the wording is.
 - **Design** – How materials are visually organised and easy to read.
 - **Support** – Assistance available during participation.
 - **Environment** – The physical or social setting of participation.
 - **Timing** – When activities happen and how much time is given.
 - **Content** – The relevance and completeness of the information.

UNIT 12: SUMMARY

Articles, pictures outlines

12.3: Figure 1. Micro (clinical practice), meso (organisational), and macro (regulation and health systems) levels as interdependent layers of culture change through PPI [Source: [Mogensen et al., 2025](#) licenced by [CC BY-NC-ND 4.0](#)].



Key points for the teacher:

- The image is an infographic showing three interconnected levels that influence clinical practice and healthcare systems. It is displayed as three stacked layers, each representing a different level of influence.
- The bottom layer is the micro level, labelled user socialisation process and refers to individual behaviours and interactions.
- The middle layer is the meso level, labelled organisational commitment and represents how institutions and organisations operate and support practices.
- The top layer is the macro level, labelled regulatory assumptions and represents laws, policies and system-wide rules.
- The layered design shows that culture and practice are shaped by all three levels working together.

12.4: Liu M, Kadakia KT, Patel VR, Krumholz HM. Characterization of Research Grant Terminations at the National Institutes of Health. JAMA [online] 2025; 334(6):534-536. [Accessed 8th Dec 2025]. Available from: <https://doi.org/10.1001/jama.2025.7707>

Research Letter

Characterization of Research Grant Terminations at the National Institutes of Health

Michael Liu, MPhil¹; Kushal T. Kadakia, MSc¹; Vishal R. Patel, MD, MPH^{1,2}; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

Key points for the teacher:

- The article analyses the recent termination of National Institutes of Health (NIH) research grants and describes the scale and potential consequences for the US research system.
- Between February and April 2025, a total of 694 NIH grants were terminated, representing approximately \$1.81 billion in funding, with about 30% of that funding still unspent at the time.
- The terminations affected almost all NIH institutes, with a particularly strong impact on the National Institute of Mental Health and the National Institute on Minority Health and Health Disparities.
- The analysis also suggests that larger grants were more likely to be terminated than smaller ones. Although most terminated projects were standard research grants, the cuts also affected early-career researchers, training grants, and career development awards.
- The impact was seen across a wide range of academic institutions, including major research universities.
- The authors highlight that limited information is available about the reasons for these terminations, which makes detailed interpretation difficult.

UNIT 12: SUMMARY

Articles, pictures outlines

12.4: Fernandez-Sanchez H, Marfo EA, Santa Maria D, Mumba M. Language Matters: Exploring Preferred Terms for Diverse Populations. Glob Qual Nurs Res [online] 2024; 11. [Accessed 8th Dec 2025]. Available from: <https://doi.org/10.1177/23333936241275266>

Social Justice and Health Equity for Diverse Population Groups—Ethics, Theoretical Development, or Methodological Development Article

Language Matters: Exploring Preferred Terms for Diverse Populations

Global Qualitative Nursing Research
Volume 11: 1–12
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DOI: 10.1177/23333936241275266
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Higinio Fernandez-Sanchez¹ , Emmanuel Akwasi Marfo², Diane Santa Maria¹, and Mercy Mumba³

Key points for the teacher:

- The article explores how the use of language in research can influence equity, inclusion, and the way diverse populations are represented and treated.
- It shows that inappropriate or outdated terminology can reinforce stigma, stereotyping, and systemic disadvantage, particularly for groups facing structural inequities.
- The study examined the web pages of 12 international organisations. They analysed terminology preferences and found a clear shift toward person-centred, respectful, and context-sensitive language.
- Terminology guidance for 10 groups was found: migrants, persons with disabilities, persons living with HIV, people experiencing homelessness, persons in custody, persons who use drugs, people with mental health disorders, older adults, persons of various racial identities, and persons with an LGBTQ+ identity. The preferred terms for population groups are shown in Table 2.
- The findings also show that while many organisations promote inclusive language, there is often a gap between guidelines and real-world implementation.
- Identities such as race, gender, and sexuality are socially constructed and shaped by historical and cultural context, which makes fixed or simplistic labels problematic.
- The authors stress that language is not neutral and directly shapes how populations are perceived in research, policy, and healthcare.
- The article recommends prioritising preferred terminology, involving communities in defining language, and regularly updating terminology to reflect social and cultural changes.

12.4: Fisher CB, Cea CD, Davidson PW, Fried AL. Capacity of persons with mental retardation to consent to participate in randomized clinical trials. Am J Psychiatry [online] 2006; 163(10):1813-20. [Accessed 8th Dec 2025]. Available from: <https://doi.org/10.1176/ajp.2006.163.10.1813>

Capacity of Persons With Mental Retardation to Consent to Participate in Randomized Clinical Trials

Celia B. Fisher, Ph.D., Christine D. Cea, Ph.D., Philip W. Davidson, Ph.D., and Adam L. Fried, M.A. | [AUTHORS INFO & AFFILIATIONS](#)

Publication: American Journal of Psychiatry • Volume 163, Number 10 • <https://doi.org/10.1176/ajp.2006.163.10.1813>

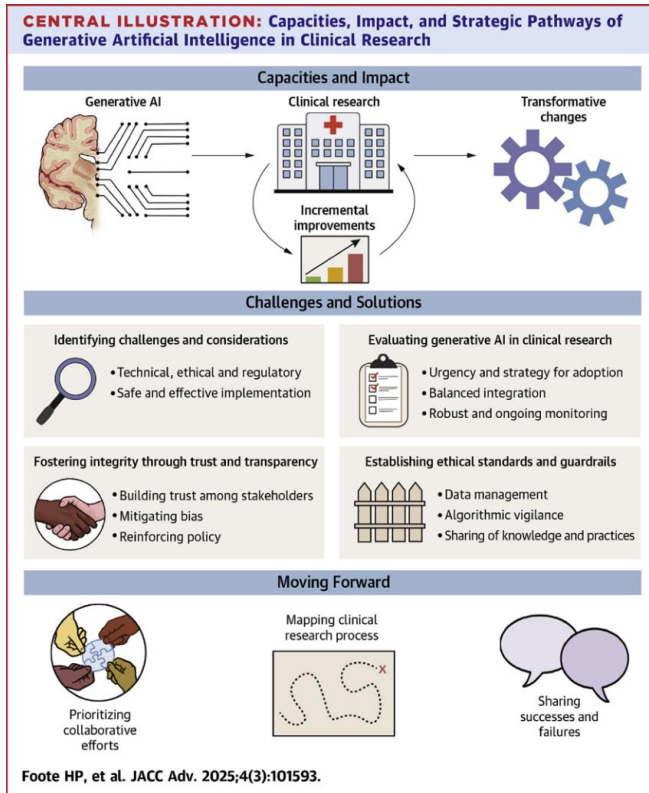
Key points for the teacher:

- The article explores whether adults with intellectual disability are able to provide informed consent for participation in randomised clinical trials and challenges the common assumption that they cannot.
- The study found that while overall consent capacity was lower compared to the general population, many individuals, especially those with mild intellectual disability, were able to understand key aspects of research and make meaningful participation decisions.
- Most participants could express whether they wanted to participate, although many found it harder to understand more abstract ideas such as the overall purpose of research or how to weigh risks and benefits.
- The findings show that consent understanding can improve when information is presented using grade-school- language, structured formats, and repetition.
- Importantly, the study highlights that consent capacity varies greatly between individuals, meaning group-based exclusion is not appropriate.
- Overall, the article suggests that ethical research should focus on adapting consent processes to individual needs while maintaining appropriate protections, rather than excluding people with intellectual disability from research participation.
- The article has good intentions and supports inclusive practice, but illustrates how language can become unacceptable. The term used in the title and throughout the article, “mental retardation”, is no longer acceptable.

UNIT 12: SUMMARY

Articles, pictures outlines

12.4: Figure 1. Central illustration from [Foote et al., 2004](#) licenced by [CC BY-NC-ND 4.0](#).



Key points for the teacher:

- This figure outlines the capacities, impact and strategic pathways of generative AI in clinical research. It shows how AI supports the research process through both incremental improvements and transformative changes.
- Four key challenge areas are highlighted: technical, ethical and regulatory challenges; evaluating adoption strategies; fostering trust and transparency, and establishing ethical standards.
- Finally, it points to three forward-looking priorities: collaborative efforts, mapping the research process, and sharing successes and failures.

WORKSHOP “HOW TO MAKE TRIALS MORE INCLUSIVE”

General overview for the educator

TARGET POPULATION

Individuals working in clinical trials

OBJECTIVES

This workshop aims to upskill professionals working in clinical trials by strengthening their understanding of inclusive research and their capacity to design, implement, and evaluate trials that reflect diverse populations. Participants will build awareness of under-served groups and the principles of Equity, Diversity, and Inclusion (EDI), including their context-specific nature and how inequities can be obscured in aggregated data. The workshop will support researchers in defining target populations and translating this into inclusive study design, and in identifying and addressing barriers to recruitment and retention that matter to patients. It also promotes patient-centred approaches through effective communication, community engagement, and co-production, and encourages researchers to recognise and minimise conscious and unconscious biases in their work.

LEARNING OUTCOMES

At the end of this workshop, participants will be able to:

1. Explain key concepts of diversity, equity, and inclusion in clinical research
2. Apply an inclusive approach to study design, including the clear definition of target participant populations
3. Identify and address barriers to participation by using practical tools to improve recruitment and retention
4. Recognising and mitigate conscious and unconscious biases in their own research practice
5. Engage with communities and patients through co-production and transparent reporting to strengthen inclusivity

IN-ADVANCE STEPS OF THE EDUCATOR

- Consider inviting a patient advocate whose perspective is invaluable and can illustrate the topic of co-production, involvement, and inclusivity
- Review the list of participants in advance, including their professional profiles and current roles. This will help you better understand the diversity of expertise in the room and tailor your facilitation accordingly
- Review the .pptx presentation, the literature, and the sources cited in the presentation; print the materials for the group work if participants will not have device access

FLEXIBILITY IN WORKSHOP DELIVERY

- The presenter/facilitator can alter the duration and activities offered throughout the workshop.
- There is flexibility in how much time is spent on different sections of the workshop to accommodate a shorter or longer workshop. For example, time spent on introductory slides (slides 5–8) defining EDI terms could be reduced for a more advanced audience. Time spent on the later slides in Part 4 (slides 50–54) could be expanded for a longer workshop.
- The workshop shares mainly UK-based examples and can be adapted to incorporate **country-specific** or **topic-specific** case-studies as preferred, focusing on the expertise or preference of the presenters/facilitators. Expertise includes an understanding and discussion of where the limitations lie and sharing any learnings from examples. [A collection of case studies on how different characteristics can impact clinical outcomes are given in this document](#). There are several examples for each showing why it is important to consider the following: **Age, Sex, Gender, Sexual identity, Race/ethnicity/ancestry, Socio-economic status (SES), Level of education, Disability, Location** (country/countries of data collection and site coordination). These could be selected for incorporation into the workshop as small-group activities in addition to, or instead of, the existing activities.

WORKSHOP “HOW TO MAKE TRIALS MORE INCLUSIVE”

Blended 5-hour workshop

	pre-class reading	2×50 minutes
	brick-and-mortar	150–180 minutes

PRE-CLASS MANDATORY TASK DISTRIBUTION

Individual reading	Treweek et al. Who is in your trial? Improving the reporting of participant characteristics in trial protocols and results. Trials [online] 2025; 26:338. Available from: https://doi.org/10.1186/s13063-025-08938-z
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WELCOME AND INTRO THE WORKSHOP 7'

Begin by greeting and welcoming all participants. Introduce the speakers. Introduce the topic of the workshop. (Slides 1–2)

 **What do you hope to get out of today?** Ask participants to share their expectations. (Slide 3)

SETTING THE SCENE 35'

Guide participants through slides 4–9, where you will define and clarify key concepts related to equity, diversity, and inclusion (EDI) in clinical research. Explain the meaning and importance of these terms in clinical trials, highlight the distinctions and relationships between the concepts, provide context on why EDI matters. Draw participants' attention to where and how EDI considerations are currently recognised and reflected across the clinical research process.

To transition to slide 10, note that patients whose physicians are also researchers may benefit from (better treatment, greater trials access, and improved outcomes, and that this relationship can be mutually beneficial.

Slide 10 presents a patient advocate perspective. Ask participants to read the text individually first, then read it aloud yourself or invite the co-facilitator to do so, helping to vary the delivery and maintain engagement. Pause briefly afterwards to allow the message to resonate before moving on. Alternatively, if a guest (a patient advocate) is present, invite him/her to speak and share his/her perspective directly. (in this case, skip Slide 10)

Before moving to slide 11–12, ask a question:

 **Voluntary point: Who do you think we are referring to when we talk about inclusion?**

Guide participants through slides 11–12 and introduce the concept of under-served populations and provide examples. *Then start a short group discussion:*



Short group discussion (groups 4–8 participants): (Slide 13) (5 minutes)

- Question 1: Which factors are relevant to your own research, and which are not. If not, why not? (see Handout 1)
- Question 2: Is an under-served group always an under-served group?

Hints and solution for the facilitator:

- Question 1 is most relevant for researchers working in a specific trial type or with a defined population.
- Question 2: The answer is no. Key points to draw out: under-served status is context-dependent and can vary by geography, time, and life stage. Just because someone doesn't belong to any of the under-served groups doesn't mean that can't change (moving to rural areas, socioeconomic status, cognitive impairment). Intersectionality also plays an important role.
- Given the time constraints, it may be appropriate to discuss on one of the questions, depending on the audience – researchers, or a group focused on a specific type of clinical trial or a specific population (more likely question 1), or clinical trial professionals with a broad or undefined focus (more likely question 2).

Guide participants through slides 14–18; it is important to note that figures and tables can be misleading as they can hide significant inequalities. The example given is for the UK, a high-income country with a rate well below the set threshold. The subgroup analysis identifies this (slide 16 for the UK data, slide 17).



Voluntary point: Where is your country in the statistics? (slide 17)

Voluntary point: Could there be hidden inequities behind this?

Hints and solution for the facilitator:

- Obesity as a risk factor for complications during and after childbirth. Access to care and insurance, for example, in the context of geographic location, unemployment, language barriers, cultural customs, and concerns about these not being respected. Intersectionality plays a significant role here.

Use the case study on maternal mortality to highlight another issue: *focusing research where it is truly needed.* (slide 18) However, back to inclusivity – when looking at causes of death, ask participants to note that many causes are *multifactorial*, and it is precisely this *multifactorial nature* that we should not overlook when designing a study.

WORKSHOP “HOW TO MAKE TRIALS MORE INCLUSIVE”

Blended 5-hour workshop



Short group discussion (groups 4–8 participants): (slide 19) (10 minutes)

- Question 1: Which causes appear to be under-researched relative to their contribution to maternal deaths? (see Handout 2)
- Question 2: Thinking of exclusion criteria – how might excluding women with pre-existing conditions affect the real-world relevance of findings from clinical trials?

Hints and solution for the facilitator:

- The table can be difficult to understand, so it is especially important to work with groups and verify that everyone understands the question.
- Question 1: One of the important points is that only 225 trials were aligned with a cause of maternal mortality (see the last column in Table 2). The topic of maternal mortality is generally strongly under-researched. In detail, the under-researched areas can be identified by comparing the 2nd and 4th columns in Table 2: e.g., embolism contributes by 3.1% to mortality in developing regions, while no trial is addressing this cause. Another under-researched cause of maternal mortality is obstructed labour. A further one is pre-existing medical conditions.
- Research has historically focused on direct obstetric emergencies (e.g., haemorrhage with 36% of trials addressing it; or labour and delivery and antenatal care as described in the abstract), leaving gaps in multimorbidity in pregnancy (e.g., hypertensive disorders, diabetes), and chronic disease management.
- Another point to discuss: The significant role of intersectionality again and the multifactorial nature of a disease/cause of death should not be overlooked. E.g., obesity as a risk factor for a more medically challenging delivery, complications during and after childbirth, pulmonary embolism. Access to care and insurance, e.g., in the context of geographic location, unemployment, language barriers, cultural customs, and concerns about these not being respected.
- Voluntary point to discuss: Who could look at that? Who has enough influence to bring about change on under-researched topics?
- Definitely governmental planning and the funders. Researchers should take the opportunity to talk to funders. Researchers have a strong voice, so they should act to make sure it is heard.
- Question 2: Exclusion leads to trial populations that are healthier than real-world patients (reduced generalisability), missing safety and dosing data (uncertain or potentially harmful prescribing). Skewed understanding of risk (underestimation of complication rates). The eligibility criteria should always be re-evaluated and critically assessed for each location in a multinational trial. They should reflect local context, local conditions. This takes us to the “inclusive design” topic.

- An example might be breast cancer patients. Millions of women worldwide suffer from breast cancer and receive standard treatment. However, we tend to overlook the fact that a significant proportion (approximately 40%) of these women would not meet the eligibility criteria for the study that provided the evidence for the treatment currently in use.



Debriefing (5 minutes)

Ask the whole group for their ideas.

INCLUSIVE DESIGN: WHAT TO DO

75' 

Guide participants through [slides 20–22](#), emphasising that research design is always about making decisions – sometimes great ones, sometimes not so great because compromises have to be made (lack of funds etc), despite knowing that the decision will have consequences. But one thing is certain: we always need to know exactly who we absolutely need in the study or who should the research focus on (you can simply refer back to the section on maternal mortality and the discrepancy between the causes of maternal mortality and the trial addressing them). And even a factor like cognitive impairment ([slide 22](#)) can be a source of imbalance. This is illustrated by the charts on [slide 22](#) – the first chart shows how many patients with hip fracture have cognitive impairment, the second how many trials include such patients.



Voluntary point: Is cognitive deficit truly discriminatory? ([slide 22](#))

In which designs and research questions is cognitive deficit truly discriminatory and, conversely, where might it not be?

Guide participants through [slides 23–25](#), emphasising that we need to know who our patients are, but also offering tools for structuring this question. The question “how” should not limit the question “who” ([slide 25](#)). We should keep in mind that things can change in time and in location (see above).

Guide participants through [slide 26](#), illustrating the issue of patient proportions in the context of the local epidemiological situation.



Short group discussion (groups 4–8 participants): ([slide 27](#)) (15 minutes)

- Who should be in the PROPELS trial and at what proportion? (see Handout 3)

WORKSHOP “HOW TO MAKE TRIALS MORE INCLUSIVE”

Blended 5-hour workshop

Hints and solution for the facilitator:

- Explained in [slide 28](#). Setting eligibility criteria is not only about the clinical disease (its type, severity, etc.), but also about soft, clinically significant factors (race, gender, etc.) and other factors (e.g., location or employment), which may be just as important for the overall validity. E.g., in trials focused on impaired glucose regulation, we should know the type of job (manual worker vs. office worker?; commuting to work by car or on foot?). The next step could be to set a limit, e.g., 10% for manual workers. However, this raises the question of whether such participants will be able to attend trial visits during regular working hours (since a visit could mean a loss of salary for them). At this point, we need to set priorities and start thinking about what we can do to make it possible for manual laborers to participate.
- When designing a study, it is a good idea to think about “who ideally” and set aside the “how” for later. To be inclusive, recommendations on [slide 29](#) might be helpful.

Debriefing (5 minutes)

Ask the whole group for their ideas.

Guide participants through [slides 30–37](#), addressing the question of “how” to support participation and retention in the study. They provide an example of a tool for identifying barriers (the INCLUDE tool, [slides 31–33](#)), including an example of its use ([slide 34](#)); they emphasise the need to actually map barriers, not just assume them (SWAT, [slides 35, 36](#)); and they also refer to guidance on ethnicity inclusion ([slide 37](#)).

 **Voluntary point:** Ask participants to **open the guidance on ethnicity from Trial Forge** and **read** through the four recommendations, followed by the examples provided. Ask them to **briefly reflect on how this has changed** their own perspective on recruitment and retention.

Hints and solution for the facilitator:

- The participant’s perspective is key. For example, when designing information for participants, it is important to consider how it can be effectively communicated to them so that they understand it (it does not necessarily have to be written, for instance) or to think about what truly interests participants (the mismatch between what they want to know and what they read). In this sense, it is essential to understand and respect participants. All of this takes time, and in the context of typically short-term funding for clinical trials and research, building long-term relationships can be a challenge. On the other hand, a community or patient organisation can also become a partner in securing funding (e.g., from other calls for proposals).



Group discussion (groups 4–8 participants): ([slide 38](#)) (15 minutes)

- Who might be excluded for each, and why could that be a problem?

Hints and solution for the facilitator:

Given the time constraints and the number of criteria, it is advisable to divide them into groups (e.g., assign two criteria per group) or to reduce the total number of fields to be filled out.

- Language criteria: e.g., migrants, minorities
- Willingness to complete trial documentation: e.g., learning disabilities, ADHD, carers, full-time job
- Judged unlikely to be suitable for the trial: e.g., homeless individuals, those who are HIV- and HCV-positive, socially excluded individuals, and those with a history of non-compliance
- Cognitive impairment: e.g., older regardless of their mental status
- Able to come into the hospital: e.g., immobile people



Debriefing (5 minutes)

Ask the whole group for their ideas.

PAUSE ([slide 39](#)) (10 minutes)

INCLUSIVE DESIGN: WHAT TO COLLECT AND REPORT

40' 

Guide participants through [slides 40–45](#), ([slide 42](#) contains a publicly available video of 13:56 minutes; play it depending on the time) on what to monitor, report to be able to say “yes, the trial is inclusive”).

Hints and solution for the facilitator:

You might mention that tools like PRO EDI encourage us to think critically, evaluate, and simply keep inclusivity in mind. Of course, context is key; we should collect context-relevant metrics, but if we don’t track certain metrics, we should explain why. Global measure does not make sense.



Short group discussion (groups 4–8 participants): ([slide 46](#)) (15 minutes)

- What do you think about how these compare? What actions are needed? (Ideas can be summarised in Handout 5)

WORKSHOP “HOW TO MAKE TRIALS MORE INCLUSIVE”

Blended 5-hour workshop

Hints and solution for the facilitator:

- *This exercise is intended to demonstrate the differences between our expectations and reality – it therefore involves comparing the data in the “the people we would expect to see included” and “actual” columns.*
- *In the Age row, we see that approximately one-quarter of breast cancer patients are diagnosed at age >75. However, the screening program targets women aged 50–70, and the current status corresponds to this (100% aged 50–70).*
- *In the Ethnicity row, we see that Black women have worse outcomes, but 0% of Black women are included.*
- *Targets should be mandatory, not aspirational. A broader perspective is on [slide 47](#).*

Debriefing (5 minutes)

Ask the whole group for their ideas.

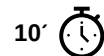
Guide participants through [slides 48–49](#), addressing the question of reporting, transparency, publication requirements.

BUILDING FOR THE FUTURE



Guide participants through [slides 50–54](#), discussing how to be a more inclusive researcher, conscious and unconscious biases, cultural competence vs. cultural humility, and psychological safety as a cornerstone for building relationships.

SUMMING UP, DISCUSSION AND Q&A



Guide participants through [slides 55–57](#), wrapping up and opening discussion.