NATIONAL PERINATAL EPIDEMIOLOGY CENTRE

NPEC online database (Castor):

Severe Maternal Morbidity (SMM)
&
Major Obstetric Haemorrhage (MOH) audits

User Manual

January, 2021

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Data Entry in Castor: SMM & MOH audits

1. <u>**Register an account**</u>

You will receive an invitation by email for the study for which you need to do data entry. Please click the link in the email, it will redirect you to the registration page.

To register your Castor account:

1. *Server. You can leave the default server that is selected when you clicked the link in the invitation email. Leave the server that is used for your study in order to be able to access the study. (The server for SMM & MOH Audits is the EU server: The Netherlands).*
2. Fill in your first and last name(s).
3. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
4. Click on 'Register'. Shortly after registering your details, an email with an activation link will be sent to the email address you have provided. Click on this link to confirm that the supplied email address belongs to you and verify your account.

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[1] The server you choose is not related to your own location; it is where your study data is stored. For example, if you work from the US, but your study admin from the Netherlands has chosen to store the study on the EU server, you should also choose the EU server when you login.

2. **Log in**

1. To access the study, log into Castor EDC via https://data.castoredc.com.

2. Enter your email address and password.

3. Click on 'Login'.

3. **Open an audit form[2]**

Once you have logged into Castor EDC, you will see the Study overview where all of your studies (audits) are shown. If a study is live (indicated by a green button and 'Live' to the left of the study name),

you can click on the study name to enter the study and start data entry.

You will see two studies:

1. Severe Maternity Morbidity (SMM) audit 2020 - For SMM 2020 cases only
2. Severe Maternal Morbidity (SMM) and Major Obstetric Haemorrhage (MOH) from 2021 - for SMM and MOH cases for 2021 onwards.

My Studies

● Live

🧪 **Test Study:** Severe Maternal Morbidity (SMM) and Major Obstetric Haemorrhage (MOH) from 2021

● Live

Severe Maternity Morbidity (SMM) audit 2020

If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') you will only be able to open the study if you have management rights.

4. **Open a case2 for data entry**

Once you enter the study, you will see a list of all records available for your access level . To add a new patient to the database, you will need to create a new record. Creating new records must be done from the Records tab), by clicking on the "+ New record" button (2).

2 In CASTOR EDC "audit forms" are called "studies" and "cases" are called "records".
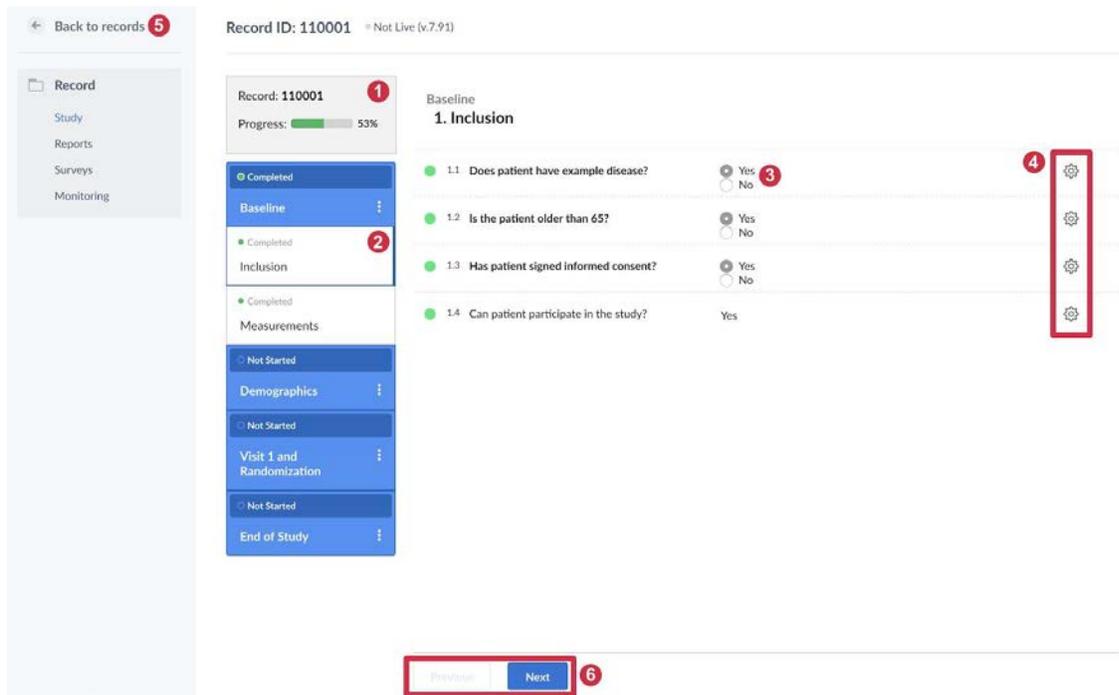
To open a previously created record click the eye icon (👁) in the 'Actions' column or double click the line the record is on.
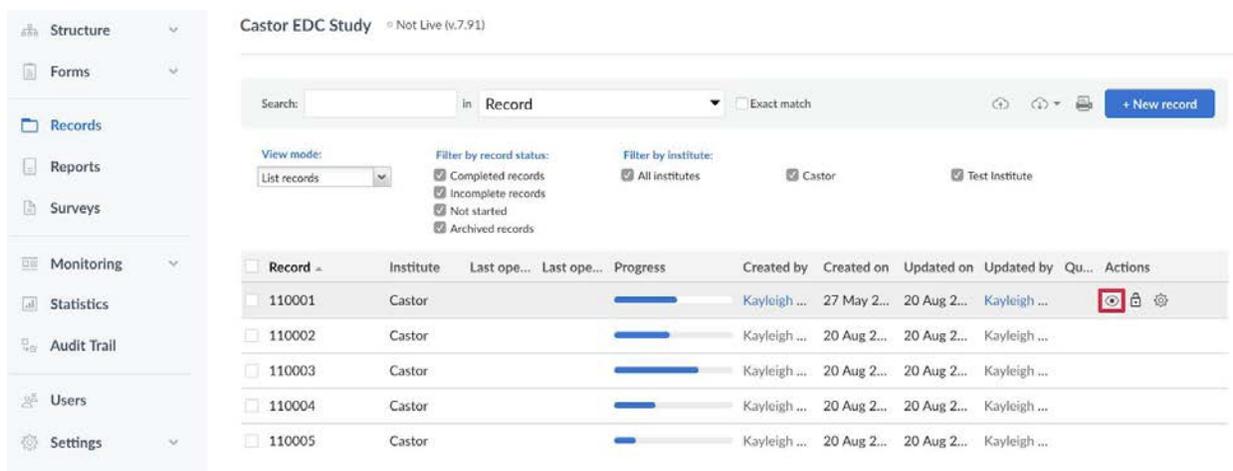
5. **Doing data entry**

When you open a record, you will be taken to the main data entry view:

It consists of the following elements:

1. Record ID and progress of completion.
2. An overview of the study forms (phases and steps of the study). Phases consist of steps

and each step contains a set of questions. You can click on the step of interest in this panel to start entering the required data. Once you answer a question in the form, you will see a small wheel turning to the left of the field and this means the data is being saved.

3. Data is entered into questions, or fields within the study forms (steps).

4. Each field is accompanied by a cogwheel menu, containing options for each record. In this menu, you can clear the data from a field, add a comment or mark the field as 'missing' data.

5. To exit the record and return to the record list, click on the 'Back to records' button.

6. Once you have completed the first form, you can navigate to the next step by clicking on 'Next'.

5.1 - Elements in each question

Depending on the type of question, you will need to select one or more of the provided options, enter a number or date, upload a file etc.

Some fields will appear only under certain conditions. In the example below, question 1.6.1 is shown only because the question 1.6 is answered with 'Yes'.

5.2 - Major Obstetric Haemorrhage (MOH) audit

Commencing 1st January 2021, the NPEC is implementing a national audit of Major Obstetric Haemorrhage (MOH). In the event of a MOH case, the NPEC kindly requests completion of a detailed audit form available online. In the event of an MOH case, a new phase (blue tap on the left side of the screen) will be available. See screenshot below.

SMM
7. Maternal Morbidity Category

Record: 000001

Progress: 30%

In Progress

SMM

In Progress

MOH

Please tick all that apply

● 7.1 SMM reportable events

☑ Major Obstetric Haemorrhage (MOH)
☐ Uterine Rupture
☐ Peripartum hysterectomy (PH)
☐ Eclampsia
☐ Renal or liver dysfunction
☐ Pulmonary Oedema
☐ Acute respiratory dysfunction
☐ Pulmonary Embolism
☐ Cardiac arrest
☐ Coma
☐ Cerebro-vascular event
☐ Status epilepticus
☐ Septicaemic shock
☐ Anaesthetic problem

5.3 - Status icons

Shown to the left of each question is the status icon, which indicates whether the question has been answered (green) or not answered (orange). Where there is a problem with the provided answer, the icon will turn red and a red warning message will appear to provide more information about the problem.

● *Green*   The input is valid and the data is saved.

● *Orange*   Data is required and no input has been entered yet.

● *Red*   The input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message.

No icon   Data entry is not required and no values have been saved.

5.4 - Additional information

If additional information has been provided with a question, the ⓘ icon will be displayed beside the input. Clicking on the icon will allow you to view the information:

2.3 Patient uses folic acid   ☐ Yes ☐ No

It is recommended for pregnant women or women who want to get pregnant to take folic acid (vitamin B11).

6. **Additional options**

To the right of each question there is a cogwheel with additional options:

1. To clear the value already entered for a field, press "Clear".

2. If data is not available for a question, tick the "User missing" box. A window will open to ask the user to provide the reason why the data is missing:

Select the appropriate option and if necessary, add a comment. Click Save to store the option and

return to the question list. The field marked as 'User Missing' will be grayed out in the list and marked as 'Completed'.

Please indicate missing data from the charts to avoid further queries from NPEC

If you initially marked a field as missing but receive information for this field at a later

date, you can click on the cogwheel again (even if the question is grayed out) and should

unselect the option "User

missing".

3. If you want to add a comment to a field, press "Comments". Add your text and press "Add comment":

7. **Record progress**

In the left panel in data entry, you can view the progress of the steps which will update as you fill in the data.
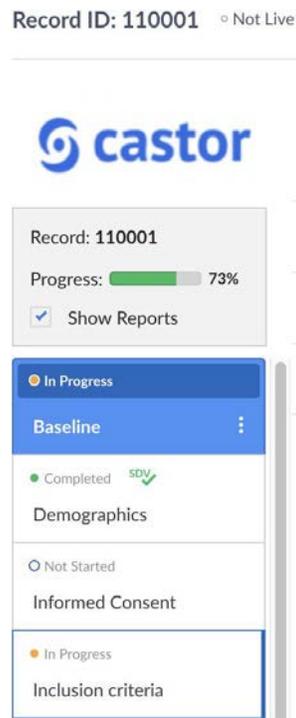
A step can have three different completion stages:

- ○ *Gray*   Not started
- ● *Orange*   In Progress
- ● *Green*   Completed

The overall record progress bar shown in the phase tab (blue) will also update automatically.

Once all required fields have been completed, the icon will turn green.

8. **The Records tab**

In the Records tab, a list is displayed showing all records you have created (see Section 6). You

may also see records that have been created by other users at your institute.

1. In the 'Records' tab, a search box is available, in which you can search for a particular record ID. More information on the search is provided in section 7.1.
2. It is possible to change the view mode to show the progress of the records by phases or steps. By default, all records are shown, however you can use the Filter by record status boxes to show records that are complete, incomplete or not started.
3. This will show you the status of completion of each step for each record. The same color scheme as for the steps applies (see section 6). You can double click on any step to directly access it.

9. <u>Search for data</u>

You can use the search bar to find records that contain certain data, for example if you want to find the patients with a certain age at onset.

1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the left search box (in this example 'Male') and all matching record will be displayed.

10.   **Finish entering data in a case/record**

Once you finish entering once you finish completing a form, once you have entered all the information for a case, you will see the following message, you will see the following step:

Thank you completing the SMM and MOH forms.

NATIONAL PERINATAL
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This means that you have finished the SMM and/or MOH forms. All the information entered in CASTOR is automatically saved. You can close the case by clicking in the "Back to records" button. This will also allow you to start a new record by clicking in the "the record/case" button.
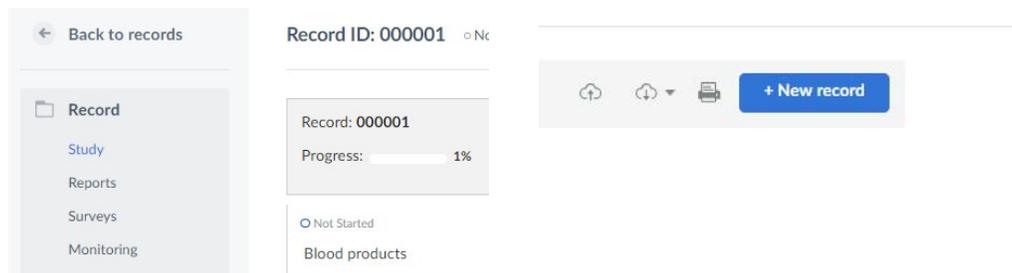
It can happen that the following warning message appears in your screen when changing steps or when clicking the "Back to records" button:
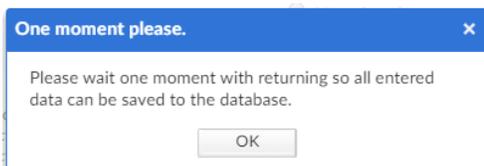
This might be because CASTOR EDC might need more time to save your data into the system or because CASTOR EDC is trying to connect to the Internet server.
Please click "OK" and stay in the same page until you do not see any other warning message. Fail to do that will erase all the data that you entered in the last session.

For data protection and security reasons, we will strongly encourage you to make sure you have logged out every time you are leaving CASTOR EDC. This can be done by clicking in the "profile" symbol on the left side of the page (the one which is highlighted in yellow).
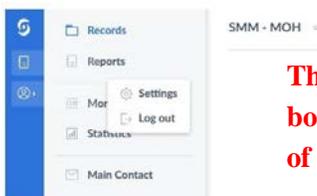
This will allow you to leave CASTOR EDC safely by clicking in the "log out" bottom. Otherwise, your account would remain open and compromise the security of the audit.

11.   **Further information**

If you would like to watch a video tutorial for performing data entry, you can do so by clicking

here. For   more   information   regarding   data   entry,   please   check

Castor EDC's knowledge base: https://helpdesk.castoredc.com

12.   **Validation of data when entering data**

CASTOR EDC allows us to validate the data for a more accurate data entering process.
For example, if a pregnant woman was admitted to the ICU, when you click in "ICU/CCU" in the "Location of care" section, then a warning message appears:

This message "alerts" us that there is more information needed to be completed in relation to the "ICU/CCU" admission in the next section.
In the Maternal Morbidity Category section, we can find another validation step. In this case, a question is automatically answered depending on the information completed in the "Location of care" section.
For example, in this case, the woman was admitted to the ICU; therefore, the question is affirmatively answered, and we should select "yes" for question 4.16.

Failing to do this will create an incongruence as we can see in the imagine below. This means that we did not selected ICU/CCU in the "Location of care", but then it was selected in the Maternal Morbidity Category section. **Both answers should match.**

If we review the charts again and realise that this woman was not admitted to the ICU, then we will have to go back to the "Location of care" section and "deselect" the "ICU/CCU" option. Then, the answer will change to "No", and we will able to answer "No" for the 4.16 question.

	4.15	Was ICU selected as location of care?	No
●	4.16	ICU/CCU admission. Please ensure this information matches the information selected in the location of care	○ Yes ◉ No

13.   "Not Live" Status on SMM/MOH audits

The NPEC might require to make edits, amendments or further work on the forms after this has been live.

This means that once the audit goes "Live" on CASTOR EDC, any change that needs to be done to the SMM/MOH forms will require that the audit form will be put into a "Not Live" status for a limited period of time while the work is being done.

NPEC will notify all the NPEC Coordinators in advance when a change to the SMM/MOH audits is needed, specifying the date and the time during which the SMM/MOH audit forms will be in the "Not Live" status. If your Castor forms remain "not Live" beyond the period established by NPEC please contact us

This is important because you will not have access to enter your data if the audit is "Not Live". If data is entered minutes before the form goes "Not Live", this might not be saved.

○ Not Live   🧪 **Test Study:** SMM - MOH

14. OTHER FEATURES INCLUDED IN CASTOR EDC

14.14 Print record data

Print a single record

It is possible to print out the complete data for a record in Castor. While in the 'Records' tab, click on the cog wheel icon next to a record and select 'Print record':

The print dialog will open and you can select which information types should be added to the printed record:

Print with helptexts: This will include the additional helptext you included in that field during field creation.

Print with additional info: This includes field type, variable name, and whether or not the field is required.

Print calculation field templates: This includes the calculation templates for every calculation field in the study.

Include hidden calculation fields: This includes all calculation fields that are hidden; it will still print for your record.

Print steps on separate pages: If 'Yes' is selected, the data for each step of the study will be printed on separate pages.

When you print the CRF for one record, it will look like this:

1. Helptext
2. Additional info
3. Calculation field template

14.15 Print multiple records

You can print multiple records by following these steps:

1. In the 'Record' tab, select the records you want to print. If you want to print all records, click the top checkbox (indicated by a red arrow below).
2. Click 'Print selected' located at the bottom of the screen (outlined below).
3. The print dialog will open and you can choose which additional information types are included in the printed record. This follows the same rules as for a single record.

14.16 Export data

Data can be exported in SPSS, Excel, and CSV formats, which in turn can be easily imported into SAS, Stata or R. Please note that multiple variable names beginning with the same 64 characters will not be able to be exported due to duplicate records.

Apart from the study data, the export file will contain list of all the variables created in the study and list of all the option groups with the option group names and values.

14.17 How to export data

Navigate to the 'Records' tab and click the 'Export' icon. Choose 'Export all Records' to export all record data. If you are exporting only data from selected records, first select the records you wish to export and then click the 'Export' icon and select 'Export Selected Records' from the list:
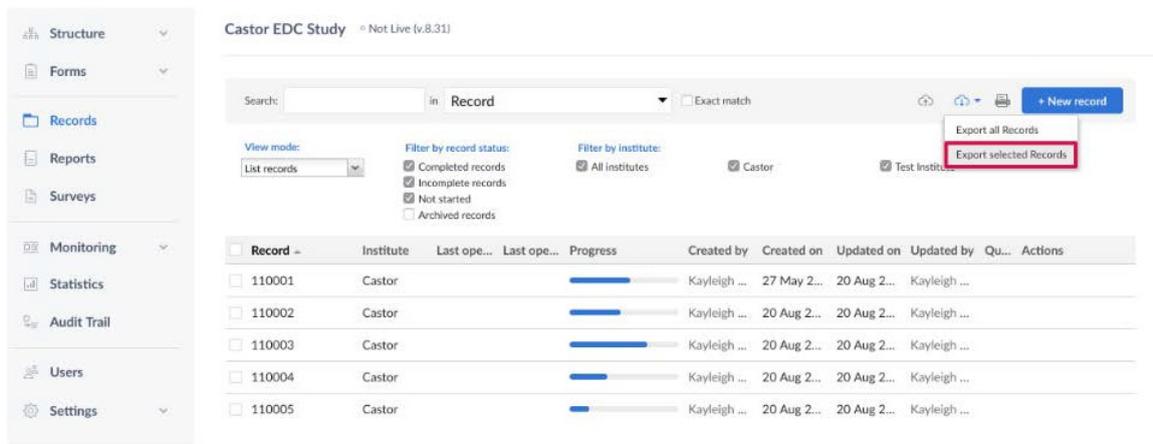
Please note: Selecting 'All records' will only export the records from the institute(s) for which you have Export rights.

In the Export options dialog window you can adjust export settings:
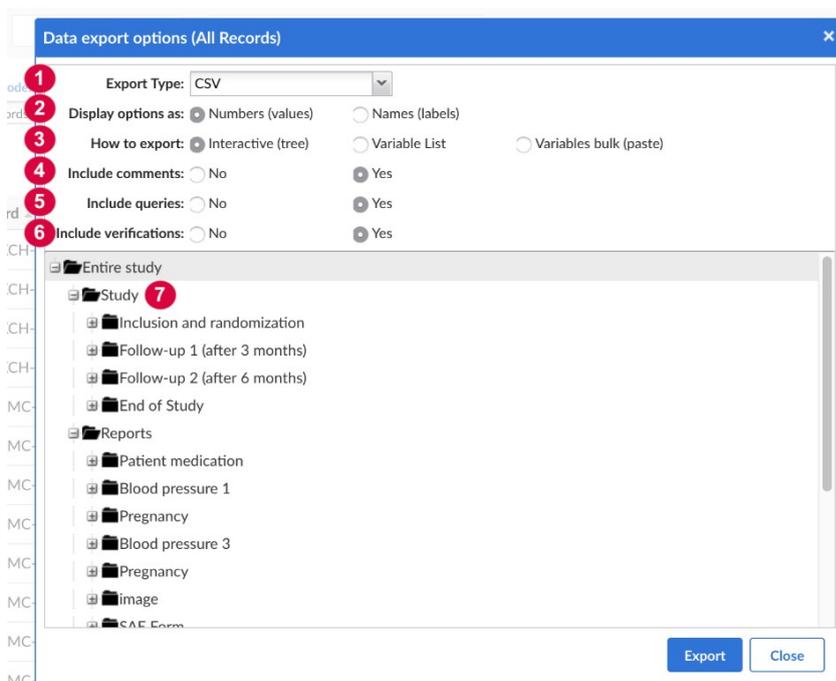
1. Select the file format you want to export your data in. You can choose between CSV, Excel and SPSS formats. You also have the option to download all uploaded files in the 'Upload file field' in your study by selecting 'Uploaded files (to zip-file)'. With the option Upload CSV to sFTP you can send exported CSV files directly to another computer over sFTP, allowing for integration with other data processing platforms.
2. In case you select CSV or Excel as export type, pick the way options are displayed in the export. Numbers will export the option values, while Names will export the options labels.
3. Select between exporting the certain parts of the study, variable list or specific variables.
4. Choose whether you want to export all comments. These will be exported to a separate sheet in Excel, or in a separate CSV file. The export for comments contains the following information: current value of the field, which type of form the field is located on (study/report) and the report name if applicable.
5. Choose whether you want to export all queries. These will be exported to a separate sheet in Excel, or in a separate CSV file.
6. Choose whether you want to export data verifications. These will be exported to a separate sheet in Excel, or in a separate CSV file.
7. It is possible to decide which part of the study you want to export. By default, the export will contain all the data from your study, reports and surveys. This is shown in the Entire study export structure immediately being selected in the tree-view.

In this interactive tree-view you can select smaller subsets (on the step-level). Using this tree-view you can export only a subset of your data, for example only study, reports, surveys or steps of your study, any report or any particular survey.

Next steps: What are the exported files?

The export includes multiple data sets. In an Excel export, these datasets are in different Excel sheets. In CSV and SPSS exports, the data sets are in separate files.

- Study data in one file called 'STUDYNAME_export_DATE.csv' or 'STUDYNAME_date.dat'
- Report data in separate files. Every report has its own Excel sheet or file. For example, SAE reports and blood pressure reports will be in 2 sheets or files, which are called 'STUDYNAME_SAE_date' and 'STUDYNAME_blood_pressure_date', respectively. See here how you can merge study and report data in SPSS.
- Survey data in separate files. Like reports, every survey has its own file.
- Variable lists of study forms, reports, and surveys - a list of all fields.
- Comments, incl. the current field value
- Queries

Your export will be saved as a zip-file, containing either:

1. An Excel file with separate sheets for the study data, each report, each survey, a list of variables and option groups. Examples of a study export and report export are shown below:

	Repeated_Measure	SAE_Form	Serious_Adverse_Event	Report variable list	Short_Form_He...urvey_(SF-36)	Survey variable list	Field options	Comments

	A	B	C	D	E	F	G	H
1	Survey name	Step name	Step number	Field number	Field type	Variable name	Field label	Optiongroup name
2	Short Form Health Survey (SF-36)	General health	1	1	radio	general_health	In general, would you say your health is	Excellent-Poor
3	Short Form Health Survey (SF-36)	General health	1	2	radio	general_yearago	Compared to one year ago, how would you rate your health in general now?	Health a year ago
4	Short Form Health Survey (SF-36)	Limitations of activities	2	1	remark		The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?	

	Repeated_Measure	SAE_Form	Serious_Adverse_Event	Report variable list	Field options	Comme

	A	B	C	D	E	F	G	H	I
1	Record Id	Report Creation Date	Report Name Custom	Report Parent	Date_SAE	Year_of_birth	Age_SAE	Gender_	Consequ
2	000001	29-11-2018 12:09:08	000001 Report	Baseline (example phase)	04-12-2018	2000	18	0	0

2. A set of separate CSV files, one for study data and one for each report and survey, a list of variables and option groups, example below:

Name

- comments.csv
- EDC_Test_Study_export_20181204.csv
- EDC_Test_Study_Repeated_Measure_export_20181204.csv
- EDC_Test_Study_SAE_Form_export_20181204.csv
- EDC_Test_Study_Serious_Adverse_Event_export_20181204.csv
- EDC_Test_Study_Short_Form_Health_Survey_(SF-36)_export_20181204.csv
- field_options.csv
- queries.csv
- report_variablelist.csv
- study_variablelist.csv
- survey_variablelist.csv

3. A set of .dat and .sps files to import into SPSS, including a PDF instructions file, example below:

Name

- EDC_Test_Study_20181204.dat
- EDC_Test_Study_Repeated_Measure_20181204.dat
- EDC_Test_Study_Repeated_Measure_syntax.sps
- EDC_Test_Study_SAE_Form_20181204.dat
- EDC_Test_Study_SAE_Form_syntax.sps
- EDC_Test_Study_Serious_Adverse_Event_20181204.dat
- EDC_Test_Study_Serious_Adverse_Event_syntax.sps
- EDC_Test_Study_Short_Form_Health_Survey_(SF-36)_20181204.dat
- EDC_Test_Study_Short_Form_Health_Survey_(SF-36)_syntax.sps
- EDC_Test_Study_syntax.sps
- SPSS_Instructions.pdf