



**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. Register an account

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:

Already registered? [Log in](#) →

First Name Last Name

Email

Phone Number (Optional)

Password Show

Password should contain at least 8 characters with 1 uppercase, 1 lowercase and 1 numeric character.

I declare that I have read the [Terms of Use](#)

I would like to receive email updates and tips

[Create Account](#)

**castor**

Sign up and join 28,000+ researchers in 50+ countries

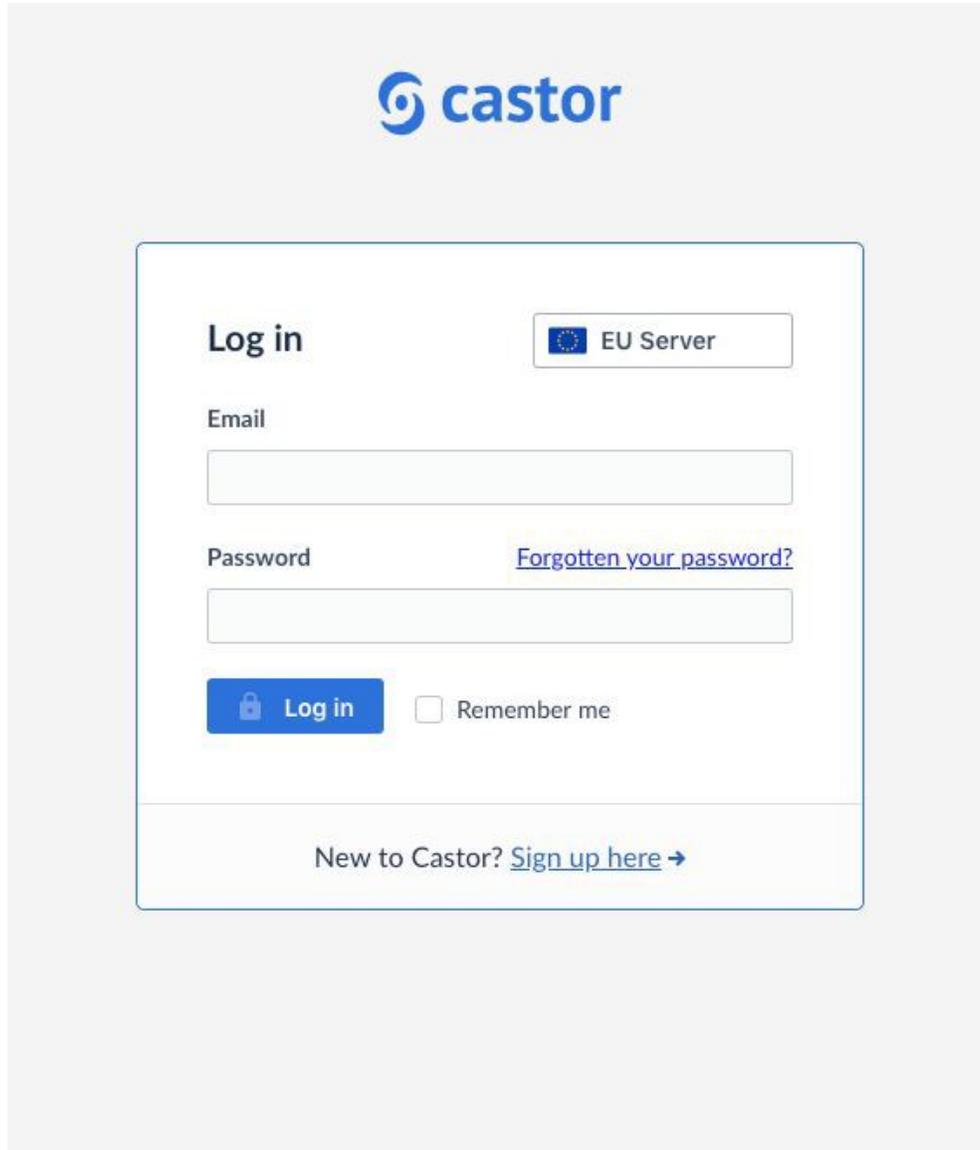
- Build forms in minutes
- Secure and compliant
- No credit card required

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.

---

<sup>1</sup> 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



The image shows the Castor EDC login interface. At the top center is the Castor logo, which consists of a blue circular icon with a white swirl and the word "castor" in a blue sans-serif font. Below the logo is a white rectangular login form with a thin blue border. Inside the form, the text "Log in" is displayed in a bold, dark grey font. To the right of "Log in" is a button with a blue European Union flag icon and the text "EU Server". Below this, there are two input fields: "Email" and "Password", both with light grey text labels and empty white input boxes. To the right of the "Password" field is a blue hyperlink that reads "Forgotten your password?". Below the input fields is a blue "Log in" button with a white padlock icon, followed by a checkbox labeled "Remember me". At the bottom of the form, centered, is the text "New to Castor? [Sign up here](#) →".

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<sup>2</sup>

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**

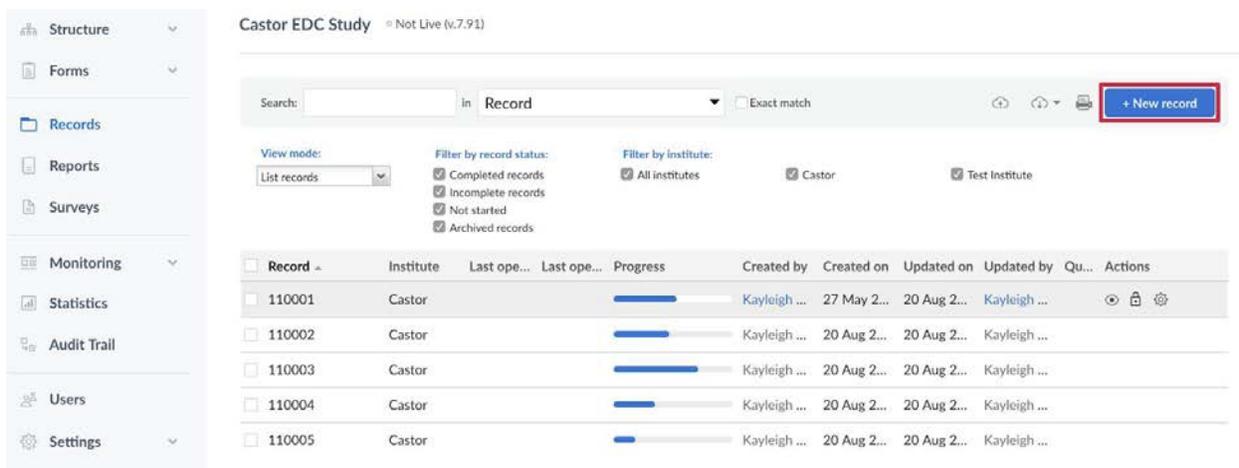
● Live

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.

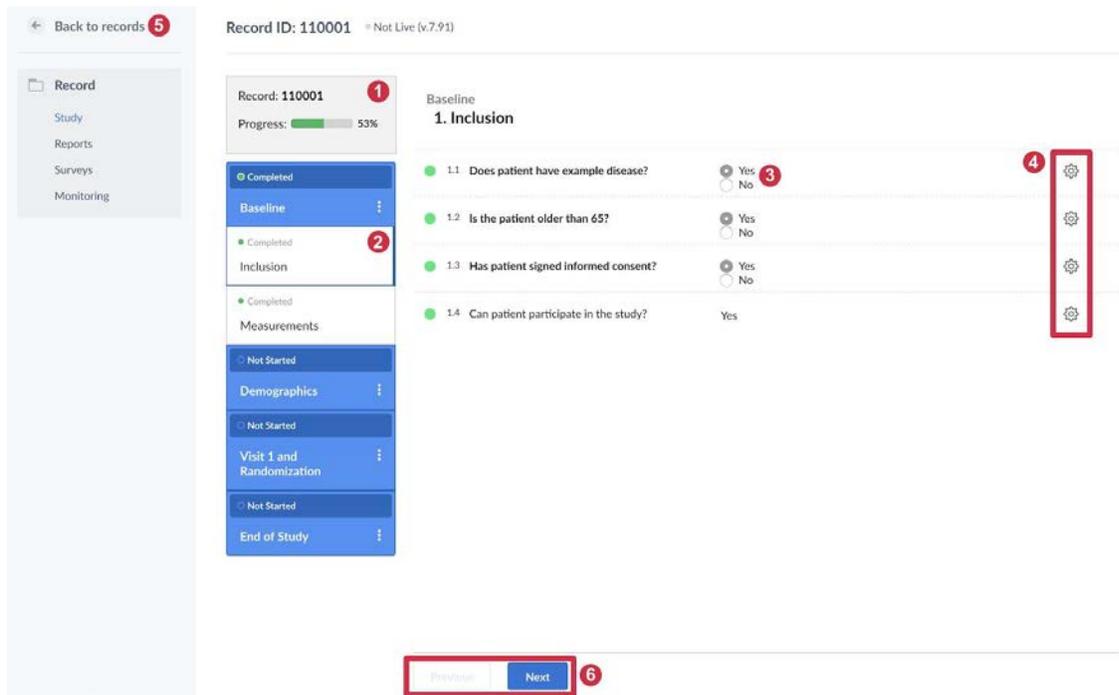
### 4. Open a case<sup>2</sup> for data entry

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).



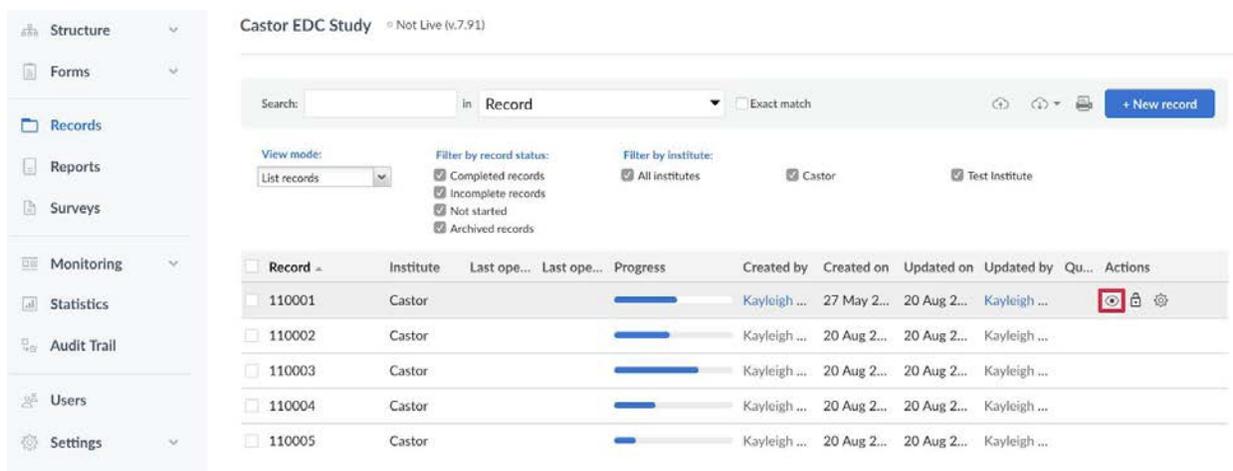
The screenshot shows the 'Castor EDC Study' interface. The top navigation bar includes 'Structure', 'Forms', 'Records', 'Reports', and 'Surveys'. The 'Records' tab is active, displaying a table of records. A '+ New record' button is highlighted in the top right corner. The table has columns for Record ID, Institute, Last opened, Last opened, Progress, Created by, Created on, Updated on, Updated by, and Actions. The records listed are:

Record	Institute	Last opened	Last opened	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
110001	Castor			<div style="width: 100%;"><div style="width: 100%;"></div></div>	Kayleigh ...	27 May 2...	20 Aug 2...	Kayleigh ...		
110002	Castor			<div style="width: 100%;"><div style="width: 100%;"></div></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
110003	Castor			<div style="width: 100%;"><div style="width: 100%;"></div></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
110004	Castor			<div style="width: 100%;"><div style="width: 100%;"></div></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
110005	Castor			<div style="width: 100%;"><div style="width: 100%;"></div></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		



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'.

Record ID: 110005 Not Live (v.17.41)

castor Baseline

1. Demographics

Record: 110005  
Progress: 54%

Record: 110005

1.1 Age at inclusion 43

1.2 Gender  
 Male  
 Female

1.3 Race  
 White or Caucasian  
 Asian  
 Black or African American  
 American Indian or Alaska Native  
 Native Hawaiian or Pacific Islander  
 Other

1.4 Date of diagnosis 07-05-2016 (dd-mm-yyyy)

1.5 Does the patient smoke?  
 Yes  
 No

1.6 Does the patient drink alcohol?  
 Yes  
 No

1.6.1 Number of units per week

## 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**

Please tick all that apply

Record: 000001  
Progress: 30%

**In Progress**  
**SMM**  
**In Progress**  
**MOH**

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:

Record ID: 110005 Not Live (v.17.41)

castor Baseline  
1. Demographics

Record: 110005  
Progress: 54%

1.1 Age at inclusion 43

1.2 Gender  Male  Female

1.3 Race  White or Caucasian  
 Asian  
 Black or African American  
 American Indian or Alaska Native

Clear  
User missing  
Comments  
Audit trail  
Queries

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:

Choose reason for missing value for field Units ("Emergency" O negative blood) .

Choose reason:  Measurement failed (-95)  
 Not applicable (-96)  
 Not asked (-97)  
 Information is missing from the charts  
 Not done (-99)

Comment:

Save Cancel

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”:



Comments for field 'Age at inclusion'

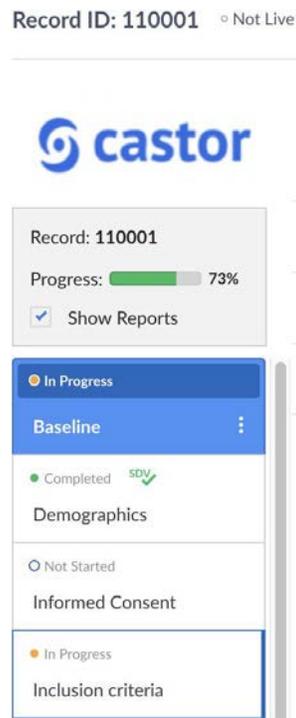
New comment:

Add comment Close

Castor EDC - Version 2019.2

## 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.

Castor EDC Study - Not Live (v.7.41)

Search:  in Record  Exact match

View mode:

Filter by record status:  Completed records  Incomplete records  Not started  Archived records

Filter by institute:  All institutes  Castor  Test Institute

Record	Institute	Last ope...	Last ope...	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/> 110001	Castor			<div style="width: 100%;"></div>	Kayleigh ...	27 May 2...	16 Aug 2...	Kayleigh ...		
<input type="checkbox"/> 110002	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/> 110003	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		

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. Search for data

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.

Castor EDC Study - Not Live (v.7.41)

Search: Male  in Gender   Exact match

View mode:

Filter by:  Comp  Incom  Not s  Archi

Test Institute

Record	1	2	3
110003	<div style="width: 100%;"></div>	<div style="width: 100%;"></div>	<div style="width: 100%;"></div>
Castor	<div style="width: 100%;"></div>	<div style="width: 100%;"></div>	<div style="width: 100%;"></div>

Can patient participate in the study? var: inc\_pat\_participatio  
Study Step: 1. Inclusion

Visit date var: pat\_visit  
Study Step: 2. Measurements

Patient height var: pat\_height  
Study Step: 2. Measurements

Blood pressure (systolic) var: pat\_systolic  
Study Step: 2. Measurements

Blood pressure (diastolic) var: pat\_diastolic  
Study Step: 2. Measurements

Gender var: pat\_gender  
Study Step: 3. Patient Demographics

Is patient pregnant? var: pat\_pregnant

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.

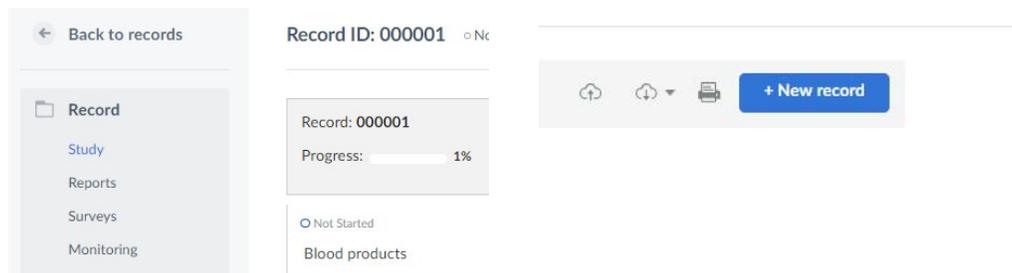
## 10. Finish entering data in a case/record

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:

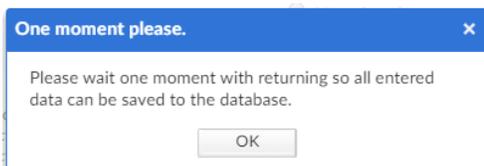
Thank you completing the SMM and MOH forms.



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.



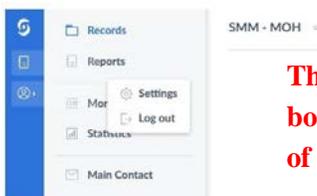
It can happen that the following warning message appears in your screen when changing steps or when clicking the "Back to records" button:



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:

SMM  
3. Location and level of care

3.1 Please tick all that apply

On the ward  
 Delivery Suit  
 Theatre  
 High Dependency Unit  
 ICU/CCU

Please complete indication of ICU and duration of days at ICU in the next Maternal Morbidity Category section

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.

4.15 Was ICU selected as location of care? Yes

ICU/CCU was selected as location of care. Please complete the following information

4.16 ICU/CCU admission. Please ensure this information matches the information selected in the location of care

Yes

No

4.16.1 Please specify indication for admission

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

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

4.16.1 Please specify indication for admission

4.16.2 Please specify the duration of ICU care in days/part days (e.g. 1.5 days)

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 be 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':

Castor EDC Study - Not Live (v.7.91)

Search: [ ] in Record [ ] Exact match [ ] [ + New record ]

View mode: List records [ ]

Filter by record status:  Completed records  Incomplete records  Not started  Archived records

Filter by institute:  All institutes  Castor  Test Institute

Record	Institute	Last operation	Last operation	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/> 110001	Castor			<div style="width: 100%;"></div>	Kayleigh ...	27 May 2...	20 Aug 2...	Kayleigh ...		  
<input type="checkbox"/> 110002	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/> 110003	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/> 110004	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/> 110005	Castor			<div style="width: 100%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		

- Import spreadsheet
- Print record**
- Update institute
- Update email address
- Archive this record
- Delete this record

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

### Print dialog

Print with helptexts:  No  Yes

Print with additional info:  No  Yes

Include calculation field templates:  No  Yes

Include hidden calculation fields:  No  Yes

Print steps on separate pages:  No  Yes

**Print** **Close**

**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:

### 3. Baseline (example phase) - Measurements

Number	Question	Answers	Comments
3.1	<p>Length</p> <p><i>Warning shown if field's value is larger than 2.8: 'This cant be right'</i></p> <p><i>Notice shown if field's value is larger than 2: 'Please remeasure the patient'</i> <i>Warning shown if field's value is larger than 2.5: 'This person is really tall, are you sure?'</i></p> <p>Length should be in meters.</p> <p>Field type: Numeric field Variable name: dem_patlen Field required: Required Field min: 0.00 Field max: 2.00 Measurement Unit: m</p>	<p>1.8 m</p>	<ul style="list-style-type: none"> <li>Tech Support : Reason for changing the field's value to '1.6': j.</li> </ul>
3.2	<p>Weight</p> <p><i>Notice shown if field's value is larger than 150: 'Please verify this patient's weight'</i></p> <p>Enter the patient's weight</p> <p>Field type: Numeric field Variable name: dem_patweight Field required: Required Field min: 40.00 Field max: 250.00 Measurement Unit: kg</p>	<p>70 kg</p>	
3.3	<p>BMI</p> <p>Field type: Calculation Variable name: demo_patbmi</p>	<p>21.6</p> <p>3 Template: {dem_patweight}/({dem_patlen}<sup>2</sup>)</p>	

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.

The screenshot shows the 'Castor EDC Study' interface. On the left is a navigation menu with options like Structure, Forms, Records, Reports, Surveys, Monitoring, Statistics, Audit Trail, Users, and Settings. The main area displays a table of records for 'Castor EDC Study' (Not Live v.7.91). The table has columns for Record ID, Institute, Last opened, Progress, Created by, Created on, Updated on, Updated by, and Actions. Records 110002 and 110003 are selected, indicated by red checkmarks in the first column. At the bottom of the screen, a 'Print selected' button is highlighted with a red box. Other UI elements include a search bar, filter options for record status and institute, and a footer showing 'Page 1 of 1' and 'Records per Page 25'.

Record	Institute	Last ope...	Last ope...	Progress	Created by	Created on	Updated on	Updated by	Qu...	Actions
<input type="checkbox"/>	110001	Castor		<div style="width: 50%;"></div>	Kayleigh ...	27 May 2...	20 Aug 2...	Kayleigh ...		
<input checked="" type="checkbox"/>	110002	Castor		<div style="width: 50%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input checked="" type="checkbox"/>	110003	Castor		<div style="width: 50%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/>	110004	Castor		<div style="width: 50%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		
<input type="checkbox"/>	110005	Castor		<div style="width: 50%;"></div>	Kayleigh ...	20 Aug 2...	20 Aug 2...	Kayleigh ...		

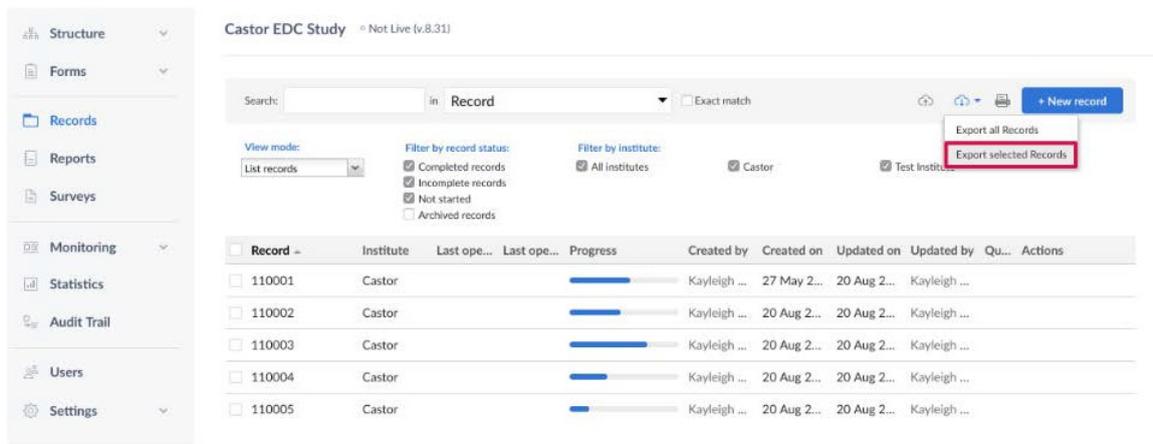
## 14.16 Export data

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.

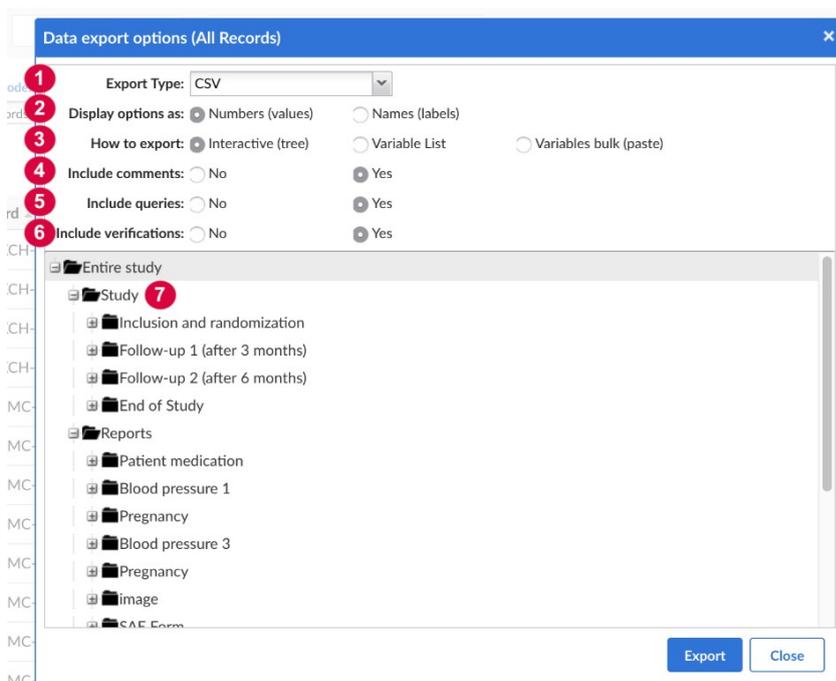
## 14.17 How to export data

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_Health_Survey_(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	Comments			
	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