

Castor

Castor CDMS Data Management User Guide

Version 2023.1

1. Study Set-up	5
1.1. CRF Review	5
1.1.1. Data Dictionary	5
1.1.2. Blank CRFS	7
1.2 Randomization Review	8
1.2.1. Randomization User Rights	8
1.3. Data Validations/Edit Checks	10
1.3.1. Data validation: Single Field	10
1.3.2. Data validation: Multi-Field	11
1.4. eLearning	12
1.5. User Acceptance Testing (UAT)	12
1.5.1 User Acceptance Testing Environment	12
2. Tracking	13
2.1. Enrollment Status	13
2.2 Progress of completion	15
2.2.1 Participants	16
2.2.2 Repeating Data	20
2.2.3 Surveys	21
2.3 Data Review	22
2.3.1 Verification	22
3. Data Processing	24
3.1 Medical Coding	24
3.2. Loading Electronic Data	25
3.2.1 CSV Import	25
3.2.2 Application Programming Interface (API)	25
3.3. Data Queries	26
3.3.1 Exporting Queries	27
3.4. Missing Pages	29
3.4.1 User missing	29
3.4.2 Mark full forms/visits as missing	30
3.5. Notifications	31
3.6. Signing and Locking	33
3.6.1 Sign or unsign a visit or form	33
3.6.1 Signing the Participant	35

3.6.2 Lock or unlock a visit or form	36
4. Study Conduct	37
4.1 Protocol Amendments	37
4.2 Deviations	38
4.3 Closeout Activities	39
5. Further Information	39

The following user guide contains suggestions and ideas for managing your data. The manual uses activities outlined in the [GCDMP](#) as a guide and is divided based on those activities. This manual may reference information provided in our other role specific manuals for Data Entry, Monitoring, and Study Admin.

1. Study Set-up

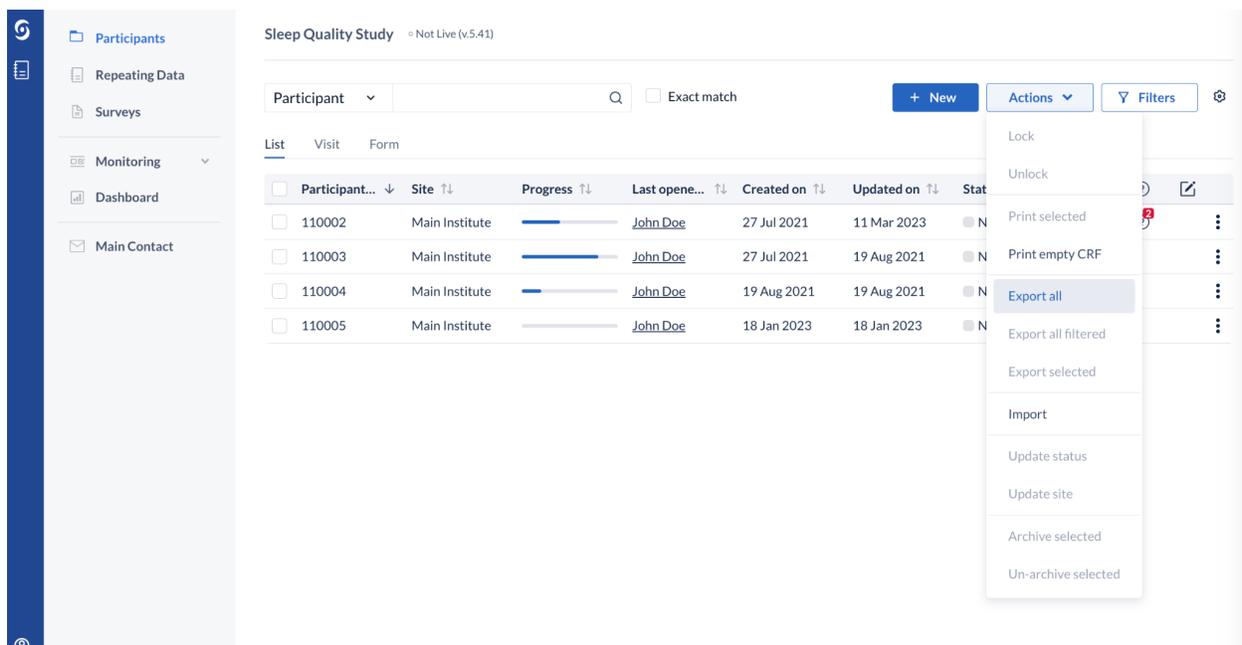
1.1. CRF Review

To review the entire CRF, there are two options: export the data dictionary or print the CRF to PDF.

1.1.1. Data Dictionary

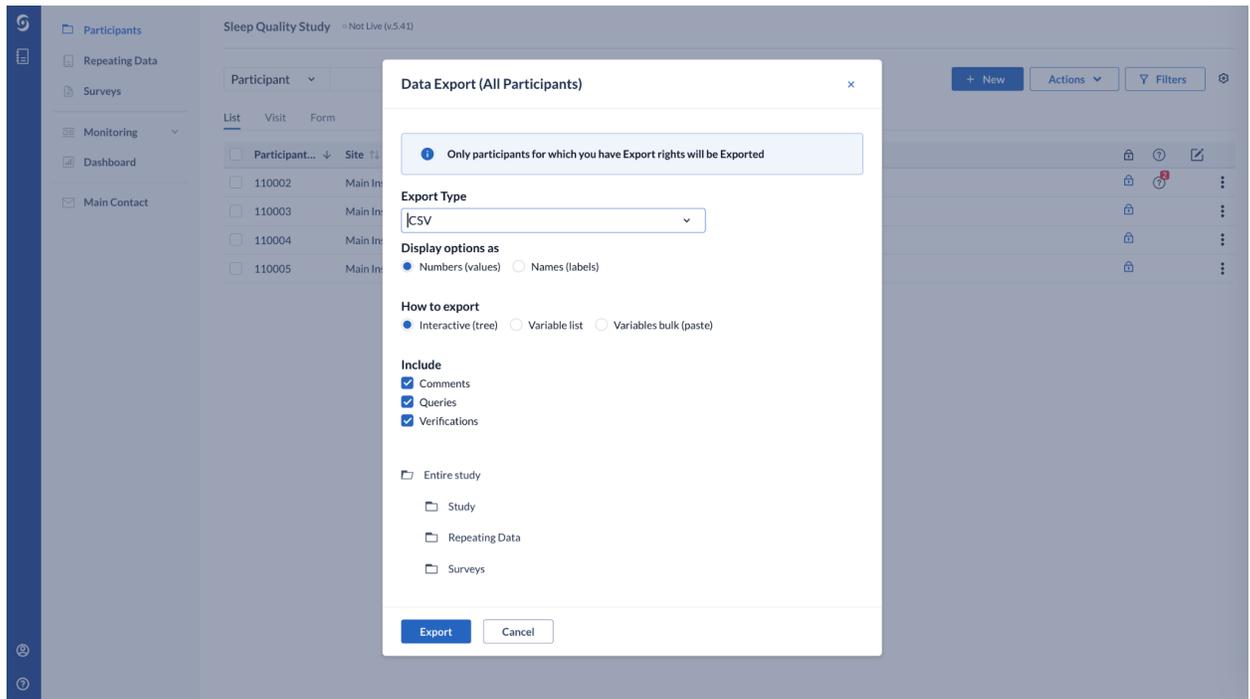
A data dictionary is included with each data export. The data dictionary includes all of the variables within the study, including option groups, and field dependencies.

In the 'Participants' Overview, click on the 'Actions' button and choose the option to 'Export all' to export all participants. If you would like to export only a selection of participants, click on the checkbox next to each participant or use the 'Filters' button to filter the participants based on certain criteria. Afterwards, the options 'Export all filtered' or 'Export selected' will be activated in the 'Actions' menu.



In the 'Data Export' window:

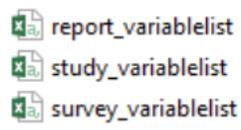
1. Select either Excel or CSV.



- An Excel export will produce one workbook with multiple worksheets.



- A CSV export will produce a ZIP file with individual worksheets.

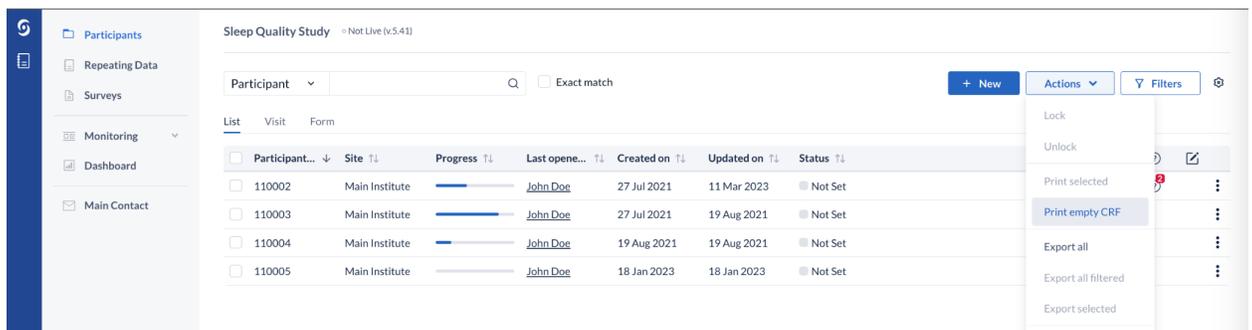


2. Select 'Entire Study'.
3. Click 'Export'.

Study variables, repeating data variables, and survey variables will be exported as separate variable lists.

1.1.2. Blank CRFS

1. Navigate to the 'Participants' tab. In the upper right corner, click on the 'Actions' button, then click on 'Print empty CRF':



2. Here you will select the options for your PDF.

Print empty CRF ✕

Print structure

Study ▼

Include

Helptexts

Additional info

Calculation field templates

Hidden calculation fields

Print steps on separate pages?

Yes No

Print Cancel

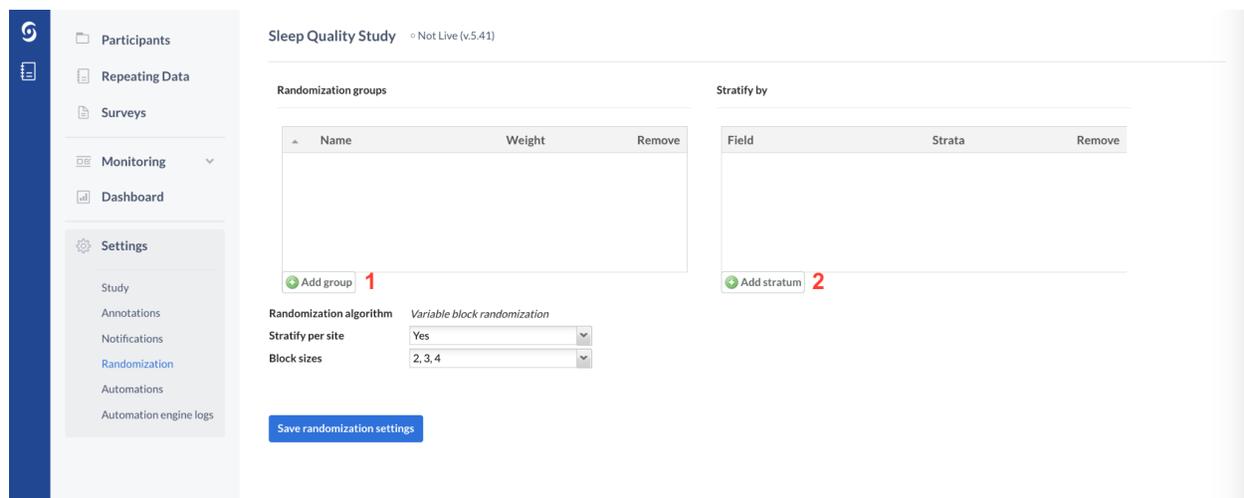
- Select the structure (Study, Repeating Data, Surveys) you would like to print.
- Choose the options you would like to include in the PDF.
- Click 'Print'.

A new page will open, which contains a preview of the printable study form. You can save this page as a PDF by selecting the option 'Save as PDF' from the available options.

1.2 Randomization Review

Castor uses a variable block randomization method. Randomization settings can be viewed in the Settings tab. You are able to define randomization groups and weights (1), block sizes, and fields within the CRF for stratification (2). Customized randomization settings are available for an additional fee. Please contact your account executive for more information.

The option 'Stratify per site' is set to 'Yes' by default.



1.2.1. Randomization User Rights

There are two separate user rights related to randomization in Castor CDMS. A user can have none, one, or both rights. The 'Randomization' right allows a user to randomize a participant. 'View randomization' allows a user to view the randomization allocation for a participant. Both rights together will allow a user to both randomize and view the randomization allocation for a participant.

User rights for [redacted]

Site Rights		Management Rights												
Site ^	User role	Add <i>i</i>	View <i>i</i>	Edit <i>i</i>	Email <i>i</i>	Rand. <i>i</i>	View ran <i>i</i>	Sign <i>i</i>	Lock <i>i</i>	Verify <i>i</i>	Query <i>i</i>	Archive <i>i</i>	Export <i>i</i>	Sen
All sites	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Main Institute	Data-e...	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Test Institute	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please note that users that do not have view randomization rights will be unable to export randomization data when performing data exports.

1.3. Data Validations/Edit Checks

Data validations, or real-time edit checks, are able to be programmed at the field level. A simple or single field validation can be created on the field properties tab. You are able to use these data validations to warn data entry users about a possible error or provide further instructions.

1.3.1. Data validation: Single Field

There are 4 validation types:

- **Message:** A simple indication message, outlined in blue, that the user needs to take a certain action.

3.4 Can patient participate in the study? Yes 

 Patient can participate, please continue.

- **Warning:** An orange coloured message bar appears to warn the user that something is incorrect.

3.4 Can patient participate in the study? Data missing 

 Patient cannot participate, all inclusion fields must be completed

- **Error:** A red outlined message can be used to indicate data has been entered that is not accepted or wrong. When the error message type is displayed, the data for that field is not saved. This means that a subsequent field cannot be dependent on a value that would trigger the 'Error' message.

3.1 Does patient have example disease?  Yes No 

 Patient must have example disease to be eligible for participation.

- **Exclusion:** A message in purple that excludes the subject from the study; when this message is visible the user, it is possible to navigate to different forms in a form:
- If an exclusion occurs on the study form, data entry is blocked on the entire study form and on any repeating data instances. The Exclusion message will be displayed on every form in the study data view with the name of the form where the

exclusion has been triggered. The repeating data data view will be grayed out:

The patient cannot participate in the study
Step: Grid Calculations

- If an exclusion occurs on a repeating data instance form, data entry is blocked on that repeating data instance form, but not blocked on any other repeating data instances or study data.

You can use this for validating inclusion and exclusion criteria. Please be aware, that it's not possible to leave fields with exclusion criteria empty (user missing), nor possible to enter values which are outside the boundaries you have set.

2.1 Is informed consent signed?
 Yes
 No

The subject cannot participate if informed consent is not signed!

1.3.2. Data validation: Multi-Field

If you would like to validate multiple fields, for example, eligibility criteria, it is necessary to first create a calculation field that considers the variables in the study. For an example calculation, please see the [article](#) in our helpdesk. You can then create a data validation in the field properties on the calculation field.

Baseline (example phase)

1. Inclusion

<input checked="" type="radio"/>	1.1 Does the patient have example disease?		<input checked="" type="radio"/> Yes <input type="radio"/> No	
<input checked="" type="radio"/>	1.2 Is patient older than 65		<input type="radio"/> Yes <input checked="" type="radio"/> No	
<input checked="" type="radio"/>	1.3 Has patient signed informed consent?		<input checked="" type="radio"/> Yes <input type="radio"/> No	
<input checked="" type="radio"/>	1.4 Can patient participate in the study?		Yes	

Patient can participate, please continue to demographics.

1.4. eLearning

The [Castor Academy](#) contains a structured series of videos with form-by-form instructions for each selected Castor feature. After each section you will receive a practical assignment to get hands-on experience with what you have learned. Some lessons contain optional reading resources if you would like to deepen your knowledge on a particular feature or topic. Finally, you can take quizzes to see how you are progressing with the course. Quizzes are also essential if you would like to obtain a certificate of completion.

1.5. User Acceptance Testing (UAT)

Castor does not offer UAT for studies not created by our Professional Services team. However, we have provided guidance documentation in our online manual. This documentation can be reviewed [here](#).

For studies that are created by our Professional Services team, Castor offers an extensive Quality Assurance process for study builds.

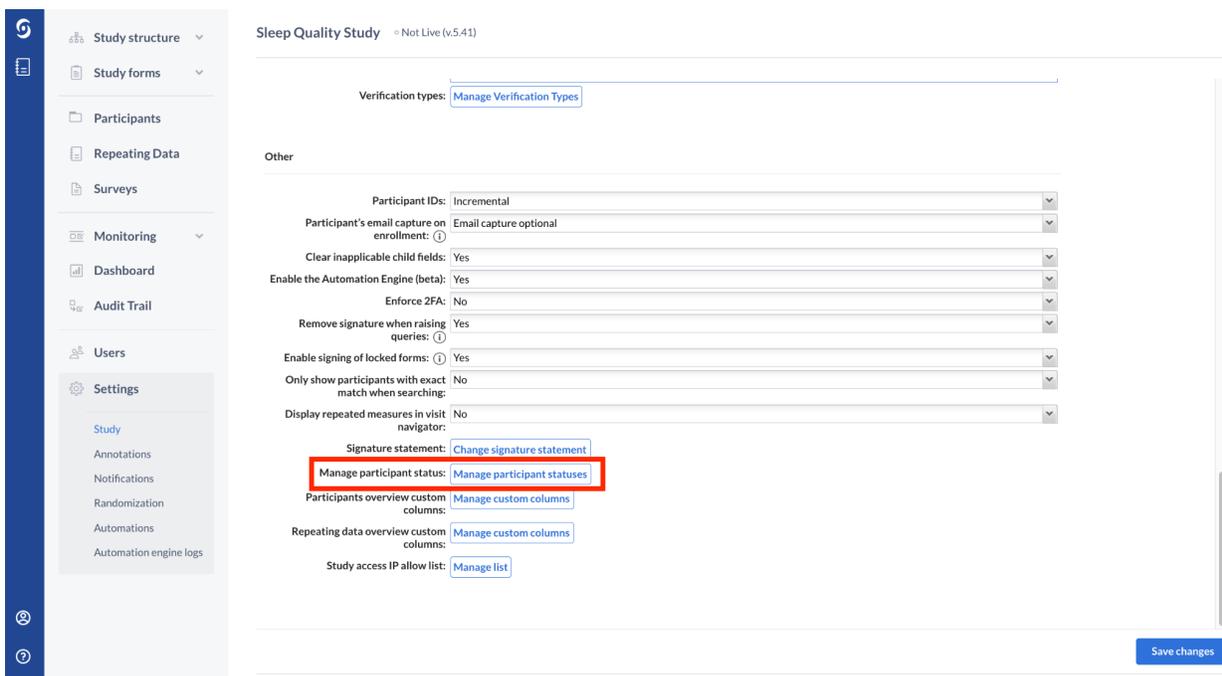
1.5.1 User Acceptance Testing Environment

Castor CDMS offers a separate User Acceptance Testing (UAT) Environment. The purpose of the UAT environment is to test the upcoming release ahead of time in order to accustom with new features, update the Standard Operating Procedures (SOPs) and perform any other necessary testing. You can learn more about the UAT environment [here](#).

2. Tracking

2.1. Enrollment Status

It is possible to track enrollment status using the 'Participant Status' feature in Castor CDMS. Study admins with 'Manage Settings' rights can create, update and delete participant statuses from the 'Study' settings.



Screenshot of the Castor CDMS 'Study Settings' page for 'Sleep Quality Study' (v.5.41). The 'Settings' tab is selected in the left sidebar. The 'Other' section contains various configuration options, with 'Manage participant status' highlighted by a red box. Other settings include 'Verification types', 'Participant IDs', 'Participant's email capture on enrollment', 'Clear inapplicable child fields', 'Enable the Automation Engine (beta)', 'Enforce 2FA', 'Remove signature when raising queries', 'Enable signing of locked forms', 'Only show participants with exact match when searching', 'Display repeated measures in visit navigator', 'Signature statement', 'Participants overview custom columns', 'Repeating data overview custom columns', and 'Study access IP allow list'. A 'Save changes' button is located at the bottom right.

Once a status is defined in the Settings tab, data entry users will be able to select the status in the Participants view.

Participant ID: 000004 Not Live (v0.91) Participant status: Not Set

Participant: 000004
Not Set
 Progress: 22%

Screening
1. Demographics

Please complete the inclusion criteria for this subject.

- 1.1 Year of birth: 1990 (yyyy)
- 1.2 Gender: Female, Male
- 1.3 Height: 170 cm
- 1.4 Weight: 62 kg
- 1.5 BMI: 21.45
- 1.6 Country of origin: Netherlands
- 1.7 Screening Complete?: Yes, No

Previous Next

The participant status is also visible in the Participants overview in the Status column.

Castor EDC Study Not Live (v0.01) Successfully updated Participant status

Participant Exact match + New Actions Filters

Participant ID	Site	Randomiza...	Progress	Created on	Updated on	Status
<input type="checkbox"/> 100001	Test Institute	B	<div style="width: 100%;"></div>	07 Jun 2022	21 Jul 2022	Enrolled
<input type="checkbox"/> 100002	Test Institute	-	<div style="width: 50%;"></div>	07 Jun 2022	19 Jul 2022	Not Set

2.2 Progress of completion

Completion for each area of the CRF is generally coded using colored status icons.

- Green** The input is valid and the data is saved. For example, field 2.1 after the data has been entered and saved:

 2.1 Are you 16 years of age or older? Yes No

- Orange** Data is required and no input has been entered yet. For example, field 2.3:

 2.3 Are you planning to reside in this area for the next 6 months? Yes No

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

 3.5.1 Error Date of consent is not entered 

 Date of consent is mandatory. Please provide the date.

- No icon** Data entry is not required and no input has been entered yet.

2.14.2 Pre-screen successful?

Not all values for this calculation are available (yet).

These field level status icons (1) in data entry view are the lowest status level for progress indication in visits, forms, repeating data, and surveys.

Participant ID: 110003 Not Live Participant status: Not Set

Participant: 110003
Not Set
Progress: 7%

Screening
3. Study inclusion

Previous trial participation is an exclusion criterion. You cannot proceed with data entry. Form: Study inclusion

1 3.1 Informed consent signed? Yes No

3.1.1 Date of informed consent (YYYY-MM-DD)

3.2 Has the patient previously participated in a clinical trial? Yes No

Previous trial participation is an exclusion criterion. You cannot proceed with data entry.

3.3 Is the patient older than 18? Yes No

2 3.4 Inclusion criteria met? Not all values for this calculation are available (yet).

Previous Next

Progress for visits, forms, repeating data, and surveys are calculated based on the fields that are marked required in the fields' settings. Fields that are not required are not included in the completion progress.

2.2.1 Participants

Participant progress can be viewed on the Participant Overview screen (1). List view (2) provides an overall view of required fields in the study form in the column 'Progress' (3).

Study structure
Study forms
Participants **1**
Repeating Data
Surveys
Monitoring
Statistics
Audit Trail
Users
Settings

Castor EDC Study Not Live (v0.01)

Participant Exact match + New Actions Filters

2 List Visit Form

3

Participant...	Site	Randomiza...	Progress	Created by	Created on	Updated by	Updated on	Status		
<input type="checkbox"/> 100001	Test Institute	B	<div style="width: 100%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 100002	Test Institute	-	<div style="width: 50%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 100003	Test Institute	B	<div style="width: 100%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 100004	Test Institute	-	<div style="width: 100%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 110005	Main Institute	B	<div style="width: 100%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 110006	Main Institute	-	<div style="width: 100%;"></div>		07 Jun 2022		19 Jul 2022	Not Set		
<input type="checkbox"/> 110007	Main Institute	-	<div style="width: 100%;"></div>		07 Jun 2022		07 Jun 2022	Not Set		
<input type="checkbox"/> 110008	Main Institute	-	<div style="width: 100%;"></div>		19 Jul 2022		19 Jul 2022	Not Set		

A participant will show as incomplete until required fields in all visits and forms are complete.

- **Green:** All field values are complete and valid.
- **Gray:** No values have been saved or data entry has not begun.
- **Blue:** Data Entry has started but is not complete.
- **Purple with an icon:** Patient is excluded from the study.

Please note that if a participant contains an unclosed query, progress will remain incomplete even if all data has been entered.

'Visit' View provides an overview of the progress for each visit.

Castor EDC Study Not Live (v0.01)

Participant Exact match

List **Visit** Form

<input type="checkbox"/>	Participant...	Site	Screening	First Study Visit	Follow-up	Outcome
<input type="checkbox"/>	100001	Test Institute				
<input type="checkbox"/>	100002	Test Institute				
<input type="checkbox"/>	100003	Test Institute				
<input type="checkbox"/>	100004	Test Institute				
<input type="checkbox"/>	110005	Main Institute				

'Form' View provides an overview of the progress for each form.

Castor EDC Study ◦ Not Live (v.0.01)

Participant ▼ Exact match

List Visit **Form**

<input type="checkbox"/>	Participant... ↓	Site ↑↓	Demographics	Diagnosis and medi...	Study inclusion	Physical exam	E
<input type="checkbox"/>	100001	Test Institute	... SDV	...			
<input type="checkbox"/>	100002	Test Institute			... SDV		
<input type="checkbox"/>	100003	Test Institute					
<input type="checkbox"/>	100004	Test Institute	SDV	SDV			
<input type="checkbox"/>	110005	Main Institute					
<input type="checkbox"/>	110006	Main Institute					
<input type="checkbox"/>	110007	Main Institute					
<input type="checkbox"/>	110008	Main Institute					

2.2.2 Repeating Data

Since each repeating data structure can have none to many instances for each participant, progress for repeating data does not influence the progress of the participant. Like study data, progress is only influenced by those fields that are required. The color coded status icons indicate the completion status of each repeating data instance.

← Back to participants
Participant ID: 110003 ◦ Not Live (v.5.41)
Participant status: Not Set ▼

Participant: 110003

Not Set

Progress: 80%

- Participant
- Visits
- Repeating Data
- Surveys
- Monitoring
- Randomization

All repeating data -

Filter by Repeating Data type: ▼ Filter by Repeating Data: ▼ Filter by status: ▼

Select Repeating Data type to filter Select Repeating Data to filter Unarchived

Filter by name: Filter by visit: ▼

Select visit to filter

Add a repeating data instance

Status	Repeating Data ▲	Name	Type	Created on	Created by	Assigned to	
●	Medication history	Medication histor...	Repeated measure	2023-03-11 21:0...	John Doe	No parent	⚙️
●	Medication history	Medication histor...	Repeated measure	2023-03-11 21:0...	John Doe	No parent	⚙️
○	Medication history	Medication histor...	Repeated measure	2023-03-11 21:0...	John Doe	No parent	⚙️

⏪ Page 1 of 1 ⏩ ⏲ Show 25 Repeating Data 1 - 3 of 3

Repeating Data +

Previous
Next

2.2.3 Surveys

Survey progress is displayed as a percentage of required fields that have been completed in the Progress column in the global Surveys tab (1). You further have the option to automatically lock surveys using the lock icon (3) when a respondent submits a survey and [create notifications](#) each time a survey is completed. If a respondent does not complete a survey in one sitting, responses are saved and the respondent can continue answering where they left off.

The screenshot shows the 'Surveys' tab in the Castor interface. A table lists survey data with columns for Participant ID, Site, Package name, Status, Assigned to, Progress, Created on, Planned on, Sent on, Completed on, and Sent via. A red box labeled '1' highlights the 'Progress' column. A dropdown menu is open for the first row, with a red box labeled '2' around the menu and a red box labeled '3' around the lock icon. The menu options are: Edit invitation properties, View survey (un-editable), Open survey in popup, Open survey in new window, Resend invite, Print survey, and Archive. The table shows three survey entries, all with a status of 'Sent' and a progress bar.

Participant ID	Site	Package name	Status	Assigned to	Progress	Created on	Planned on	Sent on	Completed on	Sent via
110025	Amsterdam Hospita	Health and Anxiety Disorder su	Sent			22 Mar 2023	22 Mar 2023	22 Mar 2023		Email invite
110025	Amsterdam Hospita	Health survey package	Sent			22 Mar 2023	22 Mar 2023	22 Mar 2023		Email invite
110030	Amsterdam Hospita	Health survey package	Sent			20 Mar 2023	20 Mar 2023	20 Mar 2023		Email invite

2.3 Data Review

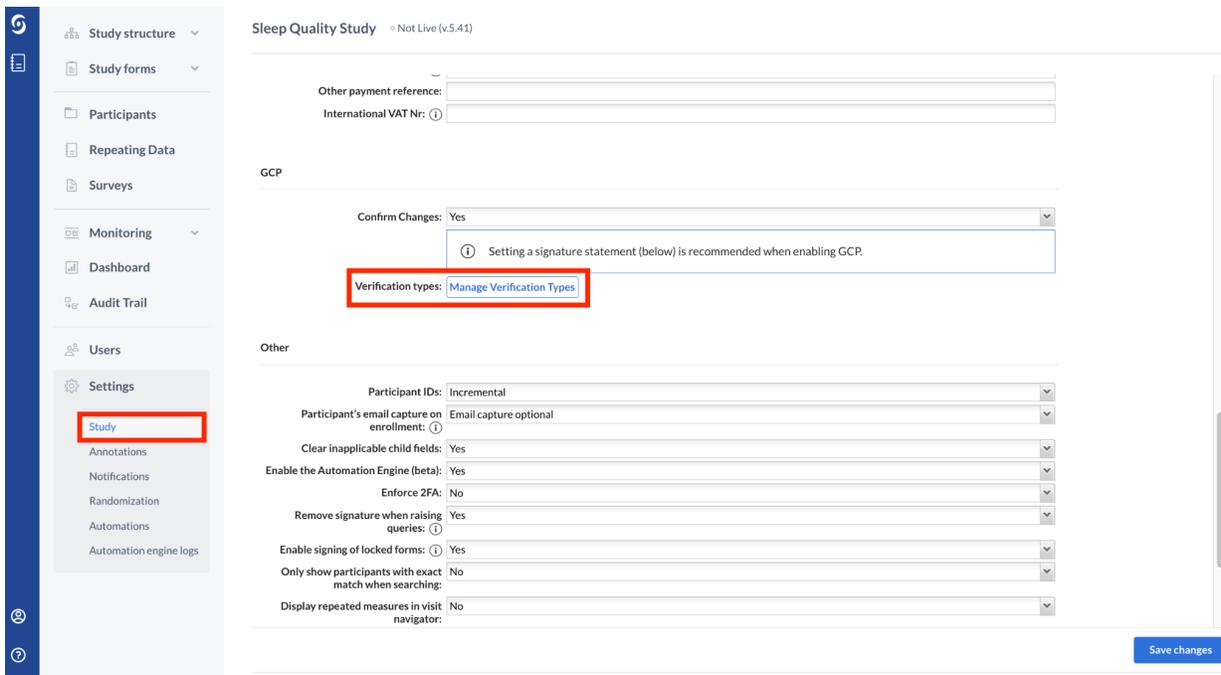
2.3.1 Verification

In Castor you have the option to verify collected data in your study. The most common example is source data verification (SDV), but you can also define your own verification type depending on the quality control that you want to use for your study data.

The SDV option is included by default if 'Monitoring' is enabled. To use this feature you have to first ensure that the correct study settings are applied and that the correct [user rights](#) are assigned to users in the study.

Data verification is linked to Monitoring, so to be able to use it, first enable Monitoring in your study settings. Please note that 'Monitoring' cannot be enabled for retrospective studies.

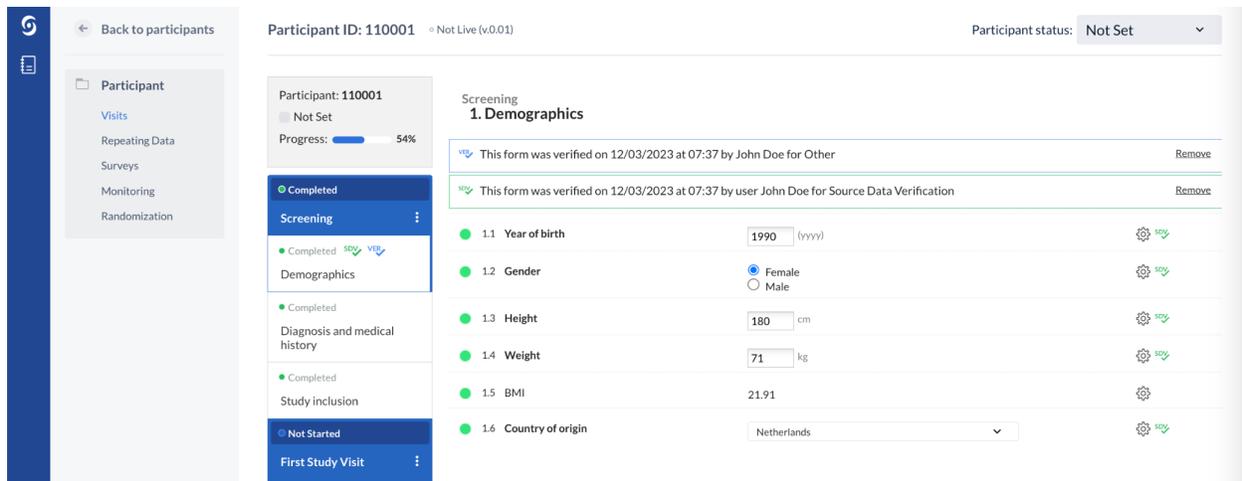
Under 'Manage verification types', located in the 'GCP' section of the study settings, you can add or edit the verification types in your study:



The screenshot displays the 'Sleep Quality Study' settings page. On the left, a navigation sidebar lists various study management options, with 'Settings' expanded and 'Study' selected. The main content area is divided into sections: 'Other payment reference' and 'International VAT Nr.' at the top; 'GCP' (Good Clinical Practice) settings in the middle, including 'Confirm Changes' (set to 'Yes') and 'Verification types' (set to 'Manage Verification Types', highlighted with a red box); and 'Other' settings at the bottom, such as 'Participant IDs' (set to 'Incremental') and 'Participant's email capture on enrollment' (set to 'Email capture optional'). A 'Save changes' button is located at the bottom right of the settings area.

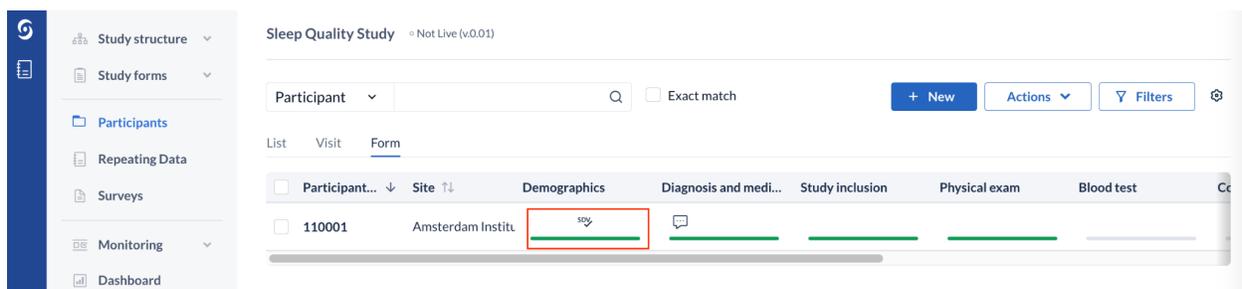
You have the option to SDV all forms in a visit, a form (including all fields or required fields) as well as individual fields. For other custom verification types, you cannot verify individual fields.

At the top of each verified page, a banner is displayed with the verification details. This banner is only visible if SDV has been performed on an entire form.



1. A custom verification banner
2. An SDV banner
3. The form verification icons

Visits and forms that have been SDV'd can be seen on the Participants overview page when in Visit or Form view. Remember that an entire visit or form would need to have SDV performed in order for the SDV icon to appear.



3. Data Processing

3.1 Medical Coding

Castor CDMS allows for medical coding of adverse events and concomitant medications. We have implemented an out-of-the-box integration with a Medical Coding platform: [MedCodr](#).

MedCodr is a web based solution for coding medical terms and products to standard dictionaries including [MedDRA](#) and [WHODrug](#) or custom dictionaries.

It is possible to attach metadata from the MedDRA and WHODrug to Adverse Event (AE) dictionaries. This means that, upon adding terms in a text field in an AE, Medical History, or Concomitant Medication repeating data instance, it is possible to use MedCodr (an external service) to browse and attach the correct translation from the MedDRA and WHODrug to these repeating data instances.

Once one of the above-mentioned repeating data instances are created and a term is added to a text field, codes are pushed back to Castor CDMS in dedicated coding repeating data that can be exported separately.

Castor also provides Coding-as-a-Service for when your team does not have the time or capabilities to perform this task. Medical Coding is a premium feature. If you are interested in adding this service, please contact your account executive or reach out to support@castoredc.com.

3.2. Loading Electronic Data

There are two methods available to add electronic data to the CDMS: CSV import or Application Programming Interface (API).

3.2.1 CSV Import

You are able to import data into the CDMS via CSV. You can import data for one participant at a time or for multiple participants. For importing via CSV, variable names must exist in the database and there is a limit of 25,000 data points per single import. This limit is much lower for importing encrypted data.

When importing via CSV, it is possible to import study data and repeating data only. The Survey data can only be imported via API. Study and repeating data must be imported separately. It is not possible to import the following:

- Queries
- Comments
- Signatures
- Data verifications

Note that in certain circumstances data in the CSV file must be formatted properly for a successful import. Details about these formats can be found in our [online manual](#). Please review [Import Study Data](#) and [Import Repeating Data](#) for more information about importing.

3.2.2 Application Programming Interface (API)

Castor CDMS allows for linking the CDMS database to other applications via API. The API supports authentication and authorization of API calls through the industry standard [OAuth2](#). To start, you will need to create [API credentials](#) in the Account Settings.

It is possible to retrieve (GET) and send (POST) using API endpoints.

These endpoints can be found in our online manual based on the server you are using for your study:

- EU: <https://data.castoredc.com/api>
- US: <https://us.castoredc.com/api>

- UK: <https://uk.castoredc.com/api>
- AUS: <https://au.castoredc.com/api>

If questions arise during your setup, please contact support@castoredc.com.

3.3. Data Queries

Data queries can be viewed on the Participant Overview for each participant. The counter displays only queries that have not been closed.

Participant ID	Site	Randomiza...	Progress	Created on	Updated on	Status	Query Icon
100001	Test Institute	B	<div style="width: 100%;"></div>	07 Jun 2022	21 Jul 2022	Enrolled	
100002	Test Institute	-	<div style="width: 50%;"></div>	07 Jun 2022	19 Jul 2022	Not Set	
100003	Test Institute	B	<div style="width: 100%;"></div>	07 Jun 2022	21 Jul 2022	Not Set	
100004	Test Institute	-	<div style="width: 100%;"></div>	07 Jun 2022	21 Jul 2022	Not Set	
110005	Main Institute	B	<div style="width: 100%;"></div>	07 Jun 2022	19 Jul 2022	Enrolled	
110006	Main Institute	-	<div style="width: 20%;"></div>	07 Jun 2022	21 Jul 2022	Not Set	
110007	Main Institute	-	<div style="width: 100%;"></div>	07 Jun 2022	07 Jun 2022	Not Set	
110008	Main Institute	-	<div style="width: 100%;"></div>	19 Jul 2022	19 Jul 2022	Not Set	

The query icon can also be seen when in visit and form view.

The status and comments for each query can be reviewed on the Monitoring tab, Queries subtab.

Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to res...
100004	Test Institute			test	test	New	2	2
100004	Test Institute			a	done	Resolved	0	2
100001	Test Institute			a	a	New	0	0
110006	Main Institute			test	test	New	0	0

When an existing query is opened, the status is set as New. A normal user can either set the status to:

- **Open:** The user has acknowledged/opened the query, and added a remark. The status changes from New to Open.
- **Unconfirmed:** The user does not agree with the monitor.

- **Confirmed:** The user agrees with the monitor and will try to resolve the issue.
- **Resolved:** The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment. In this case the query is not closed which is why the form status is shown as amber, and not green - the query is still open.
- [Only with 'Query' right (monitor)] **Closed:** The monitor indicates the issue is resolved and marks the query as closed. The query icon will turn into a green check mark and the progress button of the entire form will be green indicating that the form has been completed - all data entered and there are no open queries.

The icon that is displayed next to the field with the query or in the Monitoring tab displays the status of the query:

1. Open/Unconfirmed/Confirmed.



2. Resolved.



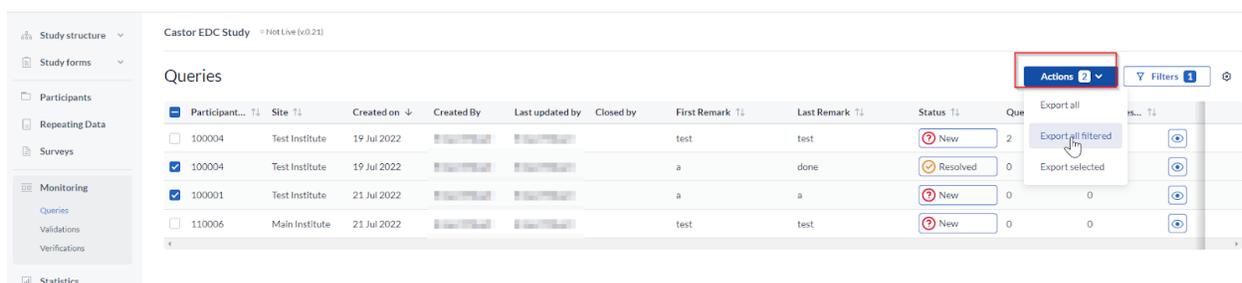
3. Closed.



3.3.1 Exporting Queries

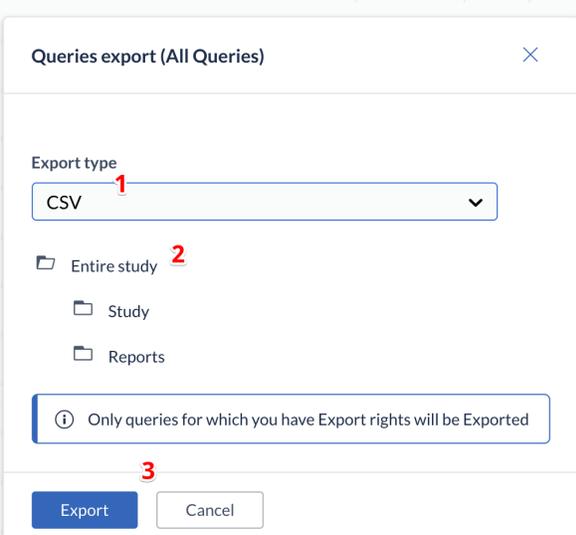
Users with Export rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the forms below:

- Click on the Actions button and choose to Export either all queries, export all filtered or all selected:



- In Queries export dialog window, you can specify:

- Export type: choose to export into CSV or Excel (1)
- Export tree: choose if you would like to export queries for entire study, specific study visits or forms in your study or for repeating data, a specific repeating data or a repeating data form (2)
- Export: click on Export button to generate export of the queries (3)



Queries export (All Queries) ×

Export type

CSV 1

Entire study 2

Study

Reports

i Only queries for which you have Export rights will be Exported

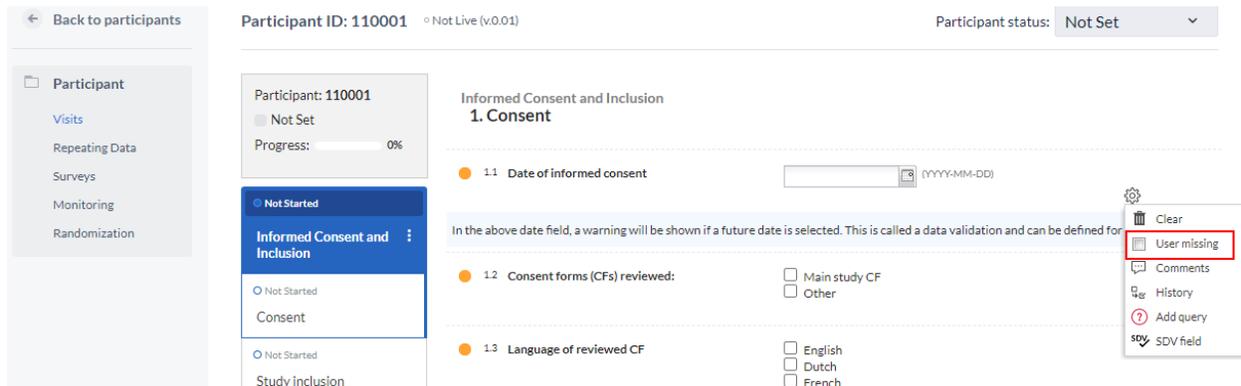
3

Export Cancel

3.4. Missing Pages

3.4.1 User missing

If a data point cannot be answered due to missing data or other known reason, you can address this in the study forms by defining the data as 'user missing'. This option can be accessed by clicking on the cogwheel next to the field and selecting 'User missing':



The screenshot shows the Castor study form interface for Participant ID: 110001. The participant status is 'Not Set'. The form is titled 'Informed Consent and Inclusion' and is currently on the '1. Consent' page. The progress bar shows 0% completion. The 'Date of informed consent' field (1.1) is highlighted, and a cogwheel menu is open next to it, showing options: Clear, User missing (highlighted with a red box), Comments, History, Add query, and SDV field. Below the field, a warning message states: 'In the above date field, a warning will be shown if a future date is selected. This is called a data validation and can be defined for...'. Other fields include 'Consent forms (CFs) reviewed:' (1.2) with checkboxes for 'Main study CF' and 'Other', and 'Language of reviewed CF' (1.3) with checkboxes for 'English', 'Dutch', and 'French'.

A dialog window will open, in which you are prompted to select the most applicable reason for the missing data point and to add a comment. The selected reason will assign the associated value to the field and this value will also be exported as data values. It is not possible to change the predefined values for missing data. The available values are:

- Measurement failed (-95)
- Not Applicable (-96)
- Not asked (-97)
- Asked but unknown (-98)
- Not done (-99)

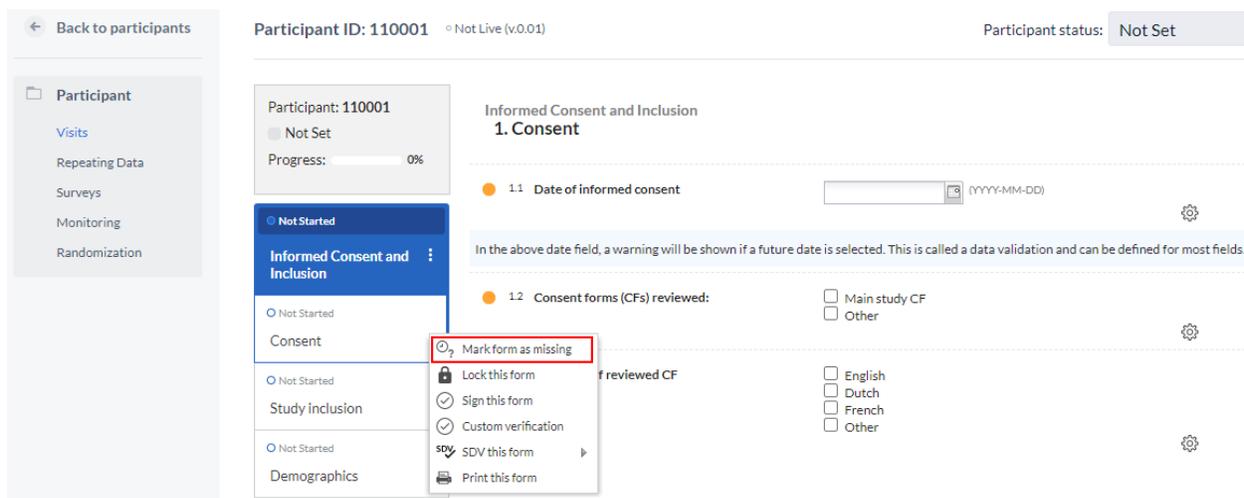
The field marked as missing will be faded/greyed in the form, but the status icon will update to show that the field has been completed. A comment will be added to the field, containing the reason entered.

If needed, it is possible to remove the 'user missing' entry by clicking on the cogwheel menu and selecting the checkbox 'User missing' again. This will remove the 'User missing'

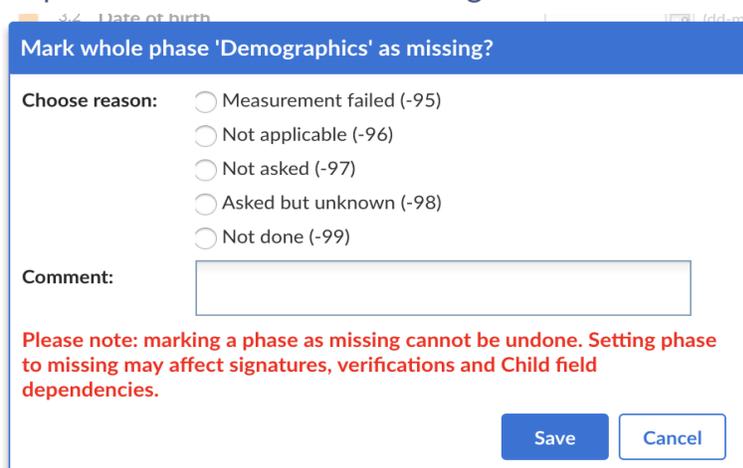
status and allow entry of data into the field. The comment will be kept and each of these actions will be logged in the audit trail.

3.4.2 Mark full forms/visits as missing

Full forms and visits can also be marked as missing by selecting Mark visit / form as missing in the data entry navigator using the cogwheel right next to the visit/form:



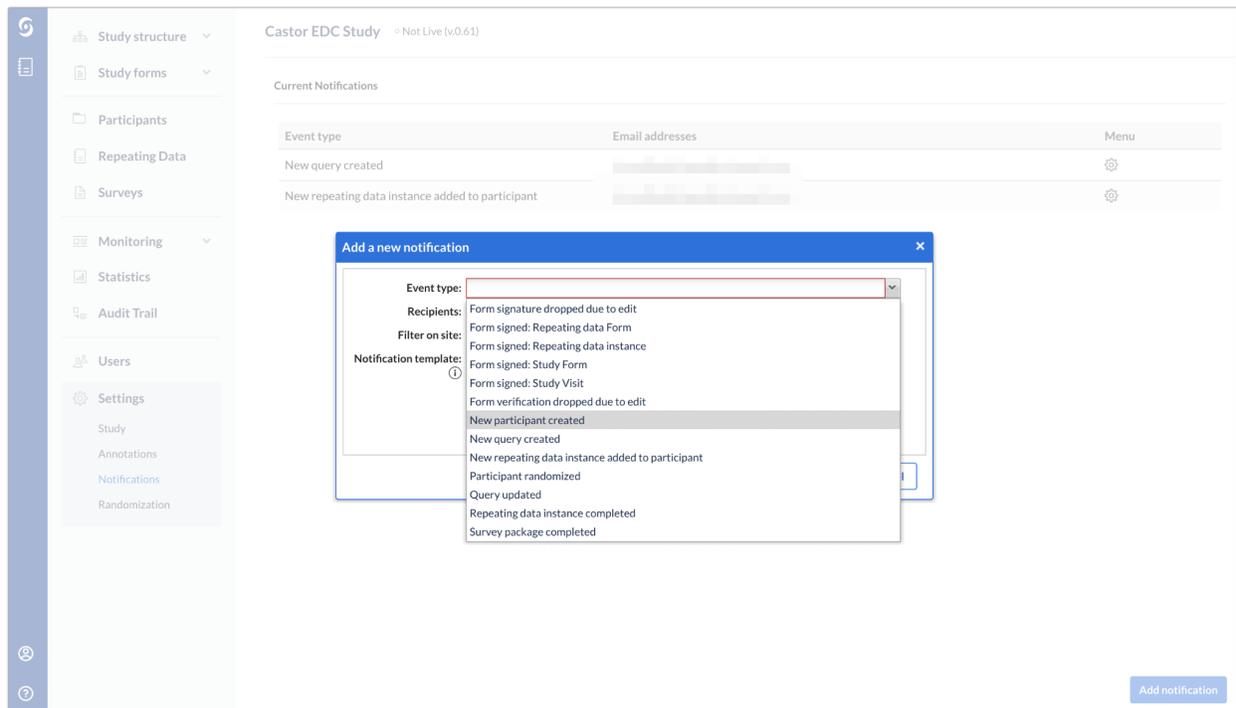
After 'Mark form/visit as missing' is clicked, a new dialog window will open in which you can provide a reason for the missing information and include a comment:



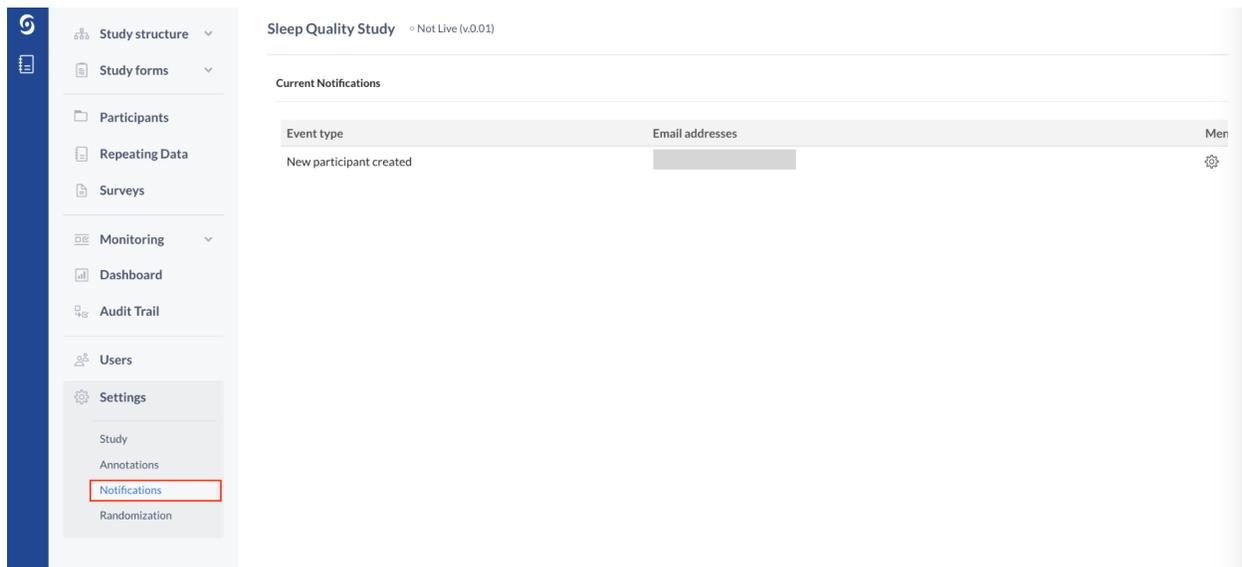
3.5. Notifications

Notifications for specific study events can be created in the study settings. Notifications are not possible for individual fields or completion statuses. Available study events include:

- Field result: Repeating Data
- Field result: Study
- Field result: Survey
- Form signature dropped due to edit
- Form signed: Repeating Data
- Form signed: Repeating Data Form
- Form signed: Study Visit
- Form signed: Study Form
- Form verification dropped due to edit (and field form verification dropped due to edit)
- New query created
- New participant created
- Query updated
- Participant randomized
- Repeating data instance completed
- Survey package completed
- New repeating data instance added to participant: when selecting new repeating data added to a participant, choose from the drop-down menu which is the specific repeating data that you are interested in receiving the notification



1. **Recipient:** Choose a recipient of the notification email in the drop-down (which shows all users added to the study).
2. **Filter on site:** Choose one or multiple sites for which you want to receive the notifications (i.e. only your own hospital). Leave this field empty if you want to receive notifications for all sites.
3. **Notification template:** This is the email text that will be sent when the event occurs. You can modify this as you like. The listed available tags will be replaced by their real values when the notification is sent.
4. Press the 'Save' button to save the notification or the cancel button to return to the notifications overview. This is also where you can find all current the notifications created for your study:



3.6. Signing and Locking

In order to sign or lock a visit, form, or repeating data, it is necessary to have sign and lock user rights. One or both of these rights can be assigned to a user as they are separate rights.

3.6.1 Sign or unsign a visit or form

You can sign individual visits and forms. Open the participant for which you want to sign forms/visits. On the left side you will find the visit and form navigator. In our example, we will sign and lock the form "Inclusion".

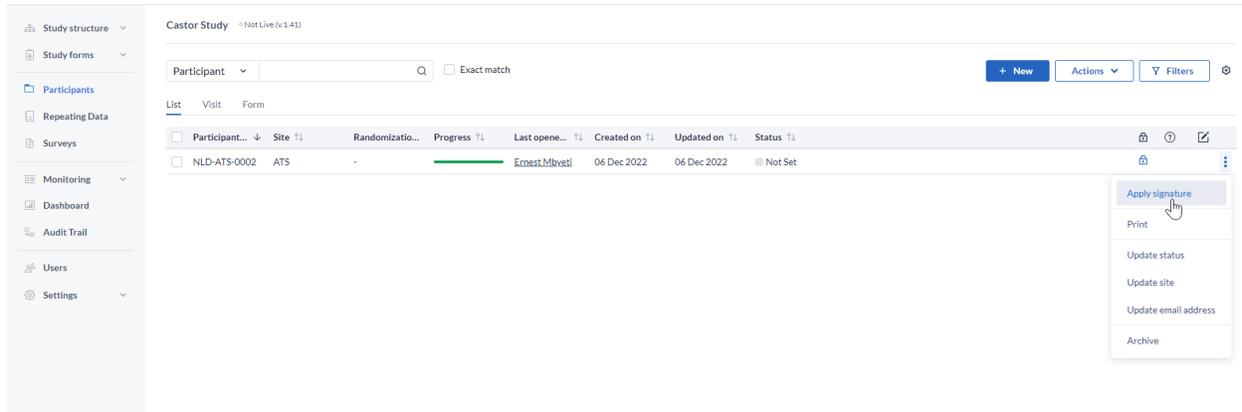
1. When in a participant, click on a form or visit. Click on the three dots that appear to the right.
2. Click on "Sign this visit" for visits or "Sign this form" for forms.

3. Enter your password to confirm your identity. You can choose to also lock the visit/form in the same instance, to prevent further data entry. Click "Sign" to confirm and to sign the visit or form. In order to lock during signing, it is necessary to have the lock user right. For users without the lock user right, an error message will appear if they attempt to lock.

A warning will be displayed at the top of the data entry screen, warning the user that the current form has been signed and/or locked. It is also possible to unsign a form/visit.

3.6.2 Signing the Participant

Castor CDMS offers the ability to seamlessly sign all forms of a selected participant at once, directly from the 'Participants overview' page.



You will be prompted to enter your credentials in order to sign the participant. Additionally you can also select to lock the participant upon signing, by ticking the 'Lock participant' box.

3.6.2 Lock or unlock a visit or form

If you have lock rights, you can also choose to separately lock or unlock a visit or form by choosing the "Unlock this visit (1 and 2)" or "Unlock this form" option.

The screenshot displays the Castor interface for a participant with ID 110007. The participant's status is 'Not Set'. The interface shows a sidebar with navigation options: Participant, Visits, Repeating Data, Surveys, Monitoring, and Randomization. The main content area is titled 'Screening 1. Demographics' and shows a progress bar at 18%. A context menu is open over the 'Screening' section, with two options highlighted: 'Mark visit as missing' (labeled with a red '1') and 'Lock this visit' (labeled with a red '2'). The 'Lock this visit' option is currently selected. The form fields for the 'Demographics' section include: 1.1 Year of birth (2009), 1.2 Gender (Female selected), Height (152.4 cm), Weight (85 kg), Age (36.6), and Country (Netherlands).

4. Study Conduct

The remainder of this manual is dedicated to providing suggestions to maximize the CDMS for managing your data.

4.1 Protocol Amendments

You can keep track of protocol amendments within the CDMS by creating fields that document the protocol or informed consent versions. Doing this allows this information to be documented for each participant.

Screening
2. Informed Consent

Consent info 1

● 2.1 Enrollment Status	<input type="text"/>
● 2.2 Date Created	<input type="text"/> (dd-mm-yyyy)
● 2.3 Date invited	<input type="text"/> (dd-mm-yyyy)
● 2.4 ICF Version	<input type="text"/>
● 2.5 ICF Status	<input type="text"/>
● 2.6 ICF Language	<input type="text"/>
● 2.7 Country	United States
● 2.8 Site	Test Institute
● 2.9 Date of ICF	<input type="text"/> (dd-mm-yyyy)

Consent info 2 (Version update Only)

● 2.10 ICF Version	<input type="text"/>
● 2.11 ICF Language	<input type="text"/>
● 2.12 ICF Status	<input type="text"/>

4.2 Deviations

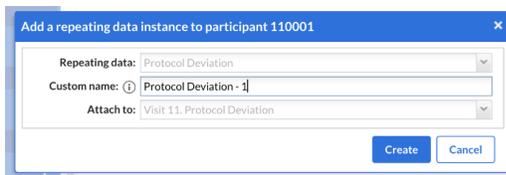
Repeating Data Structures are useful for keeping track of protocol deviations. It is recommended that the add a repeating data button is utilized and dependencies are created where a deviation may occur.

Baseline

7. Baseline (7 +/- 2 days) Visit Date

7.1	Was visit completed?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
7.1.2	Visit Date	<input type="text" value="11-09-2020"/>  (dd-mm-yyyy)	
7.2	Number of days since washout began:	<input type="text" value="10"/>	
 Visit Out of Window			
7.3.1		<input type="button" value="Add a Deviation"/>	

Using the add a repeating data button, the Protocol Deviation repeating data will always be linked to the visit in which the repeating data was created.



You are further able to create notifications on the Repeating Data Event type and choose the Deviation Repeating Data.

4.3 Closeout Activities

Once a study is complete, we recommend performing the following actions:

- 1) [Lock](#) all participants
- 2) [Export a copy](#) of the study data
- 3) Set the study to 'Not Live' in the ['Settings' tab](#)
- 4) Remove all users and study admins can reduce their own [rights](#). It is recommended that study admins leave themselves as the only user, and remove all user rights except 'View', 'Export' 'Manage Participants' and 'Manage Settings'.
- 5) Archive the study. Once the study is 'closed', you can [archive the study](#) in the 'My studies' overview, which will remove it from the overview for all users and prevent users from accessing it in future. Please note you must have 'Manage Settings' rights to be able to archive or un-archive a study.

In case medical coding service was used, please make sure to archive any empty coded repeating data instances and inform your Project manager about the study closure, so we could remove the service.

Castor manages retention periods through its “Document management and retention policy”. Clinical Trial documents as defined by ICH-GCP E6 (R2): Good Clinical Practices Consolidated Guideline, FDA’s 21 CFR Part 11, or local/regional regulations are retained throughout the life cycle of the trial.

5. Further Information

For more information regarding data management, check Castor CDMS’s knowledge base:

<https://helpdesk.castoredc.com>. Additional [ready-to-print instructions](#) based on user roles are also available. If you have any questions or concerns, please contact us at support@castoredc.com