

Castor

Castor CDMS Data Management User Guide

Version 2024.1

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

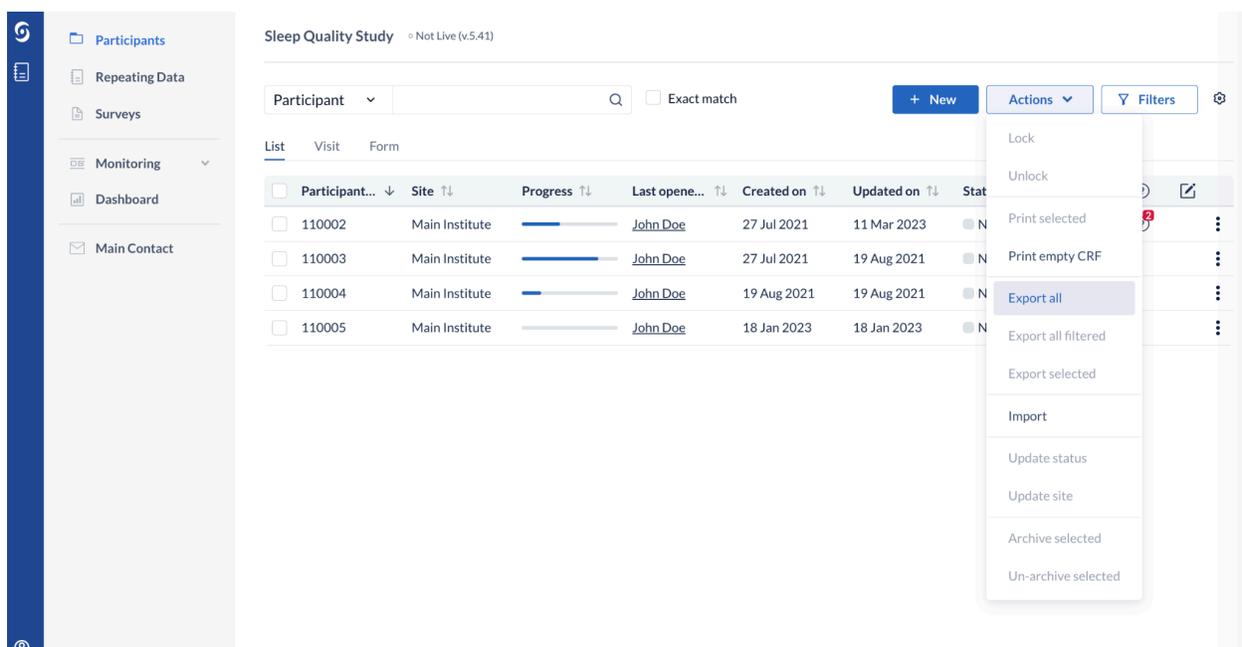
1.1. CRF Review

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

1.1.1. Data Dictionary

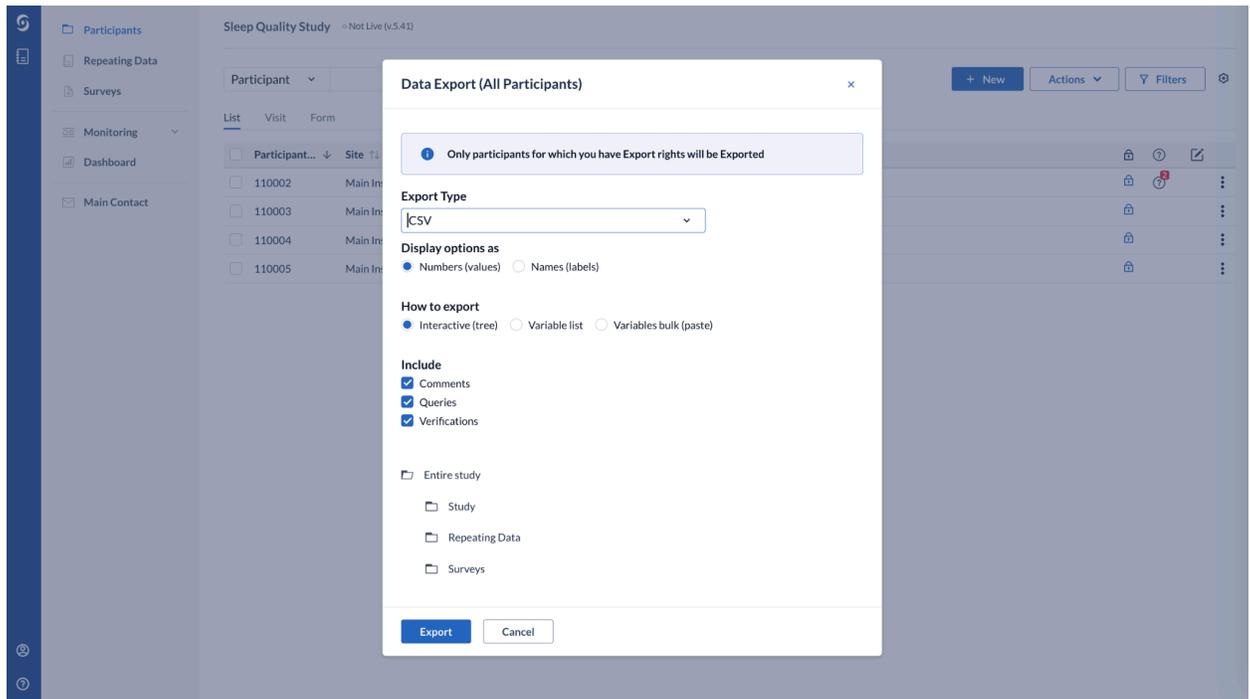
A data dictionary is included with each data export. The data dictionary includes all of the variables within the study, including option groups, and field dependencies.

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:

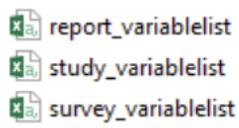
1. Select either Excel or CSV.



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



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



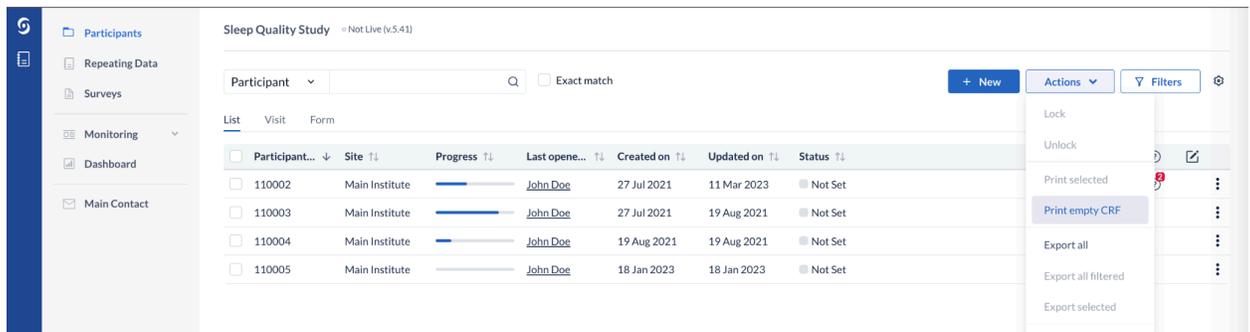
2. Select 'Entire Study'.
3. Click 'Export'. Once the file has been exported successfully the user will receive a completion email. You can select the link located within this email and be directed

to the exported file to download. You can also navigate to the 'Export' tab and see a listing of all available exports to download.

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

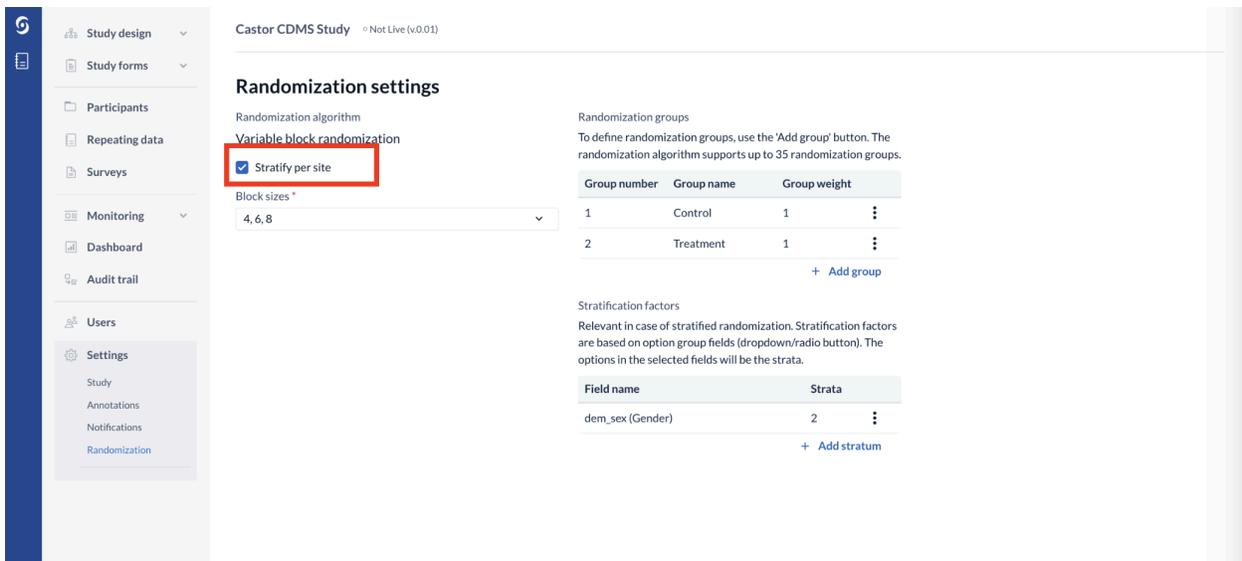
- Select the structure (Study, Repeating Data, Surveys) you would like to print.
- Choose the options you would like to include in the PDF.
- Click 'Print'.

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, block sizes, and fields within the CRF for stratification. Customized randomization settings are available for an additional fee. Please contact your account executive for more information.

The option 'Stratify per site' is enabled by default.



Castor CDMS Study Not Live (v0.01)

Randomization settings

Randomization algorithm
Variable block randomization

Stratify per site

Block sizes *
4, 6, 8

Randomization groups
To define randomization groups, use the 'Add group' button. The randomization algorithm supports up to 35 randomization groups.

Group number	Group name	Group weight	
1	Control	1	⋮
2	Treatment	1	⋮

+ Add group

Stratification factors
Relevant in case of stratified randomization. Stratification factors are based on option group fields (dropdown/radio button). The options in the selected fields will be the strata.

Field name	Strata	
dem_sex (Gender)	2	⋮

+ Add stratum

1.2.1. Randomization permissions

There are two separate user permissions 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.

GF New User Permissions Not Live (v0.11)

Roles & permissions Cancel Save

	Admin	Monitor	Data-entry	Custom Role
Add	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
View	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Edit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Email	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Randomization	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View Randomization	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sign	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lock	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verify	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Query	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Archive	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Export	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send surveys	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
View surveys	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Total permissions	14	3	5	1

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.

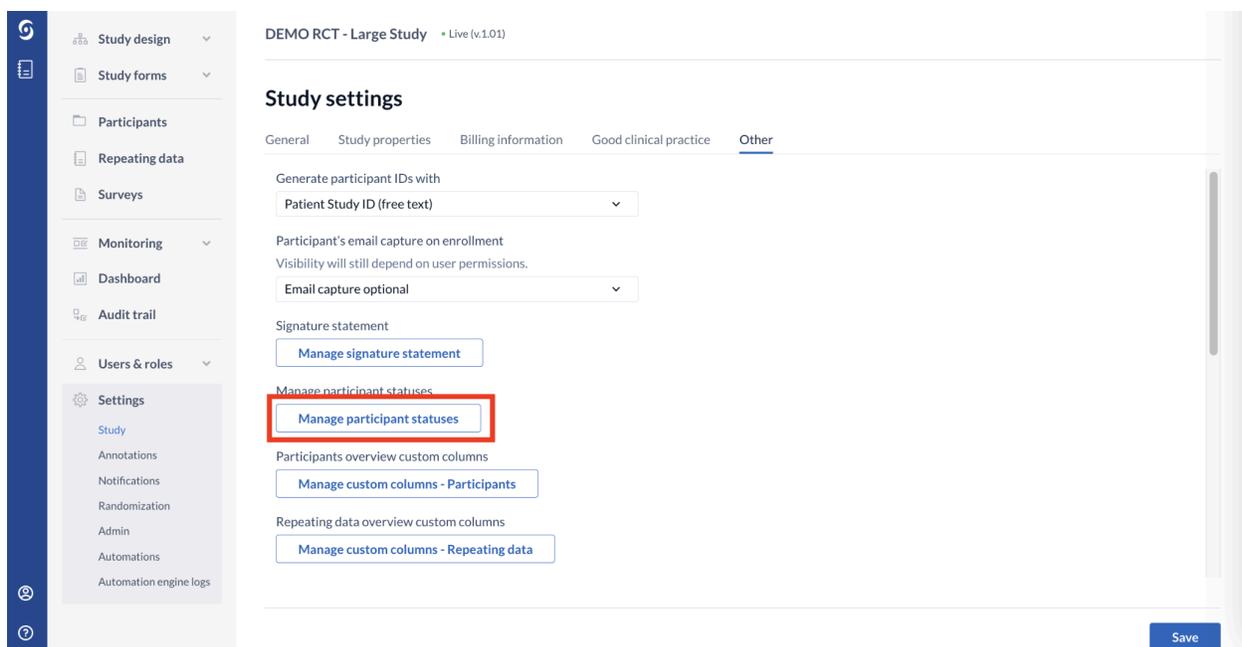
1.5.1 User Acceptance Testing Environment

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 'Settings' permissions can create, update and delete participant statuses from the 'Study' settings, page 'Other' by clicking on the 'Manage participant statuses' button.



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

← Back to participants

Participant ID
██████

63%

Not set

Not randomized

Castor Connect app
Not yet activated

Participant

- Visits
- Repeating data
- Surveys
- Monitoring

Participant ID: 110005 Not Live (v4.51)

Pre Screening I
1. Pre-Screening I

- 1.1 1. Is patient enrolled? Yes No
- 1.3 Randomized? This participant was not randomized yet.
- 1.4 Randomized 0
- 1.5 Upload
- 1.6 Encrypted field This field is encrypted. Click the key icon to view or enter data.

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

- Study structure
- Study forms
- Participants
- Repeating Data
- Surveys
- Monitoring

Castor EDC Study Not Live (v.0.01)

Participant Exact match

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	<input checked="" type="checkbox"/> Enrolled
<input type="checkbox"/> 100002	Test Institute	-	<div style="width: 50%;"></div>	07 Jun 2022	19 Jul 2022	<input type="checkbox"/> 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 

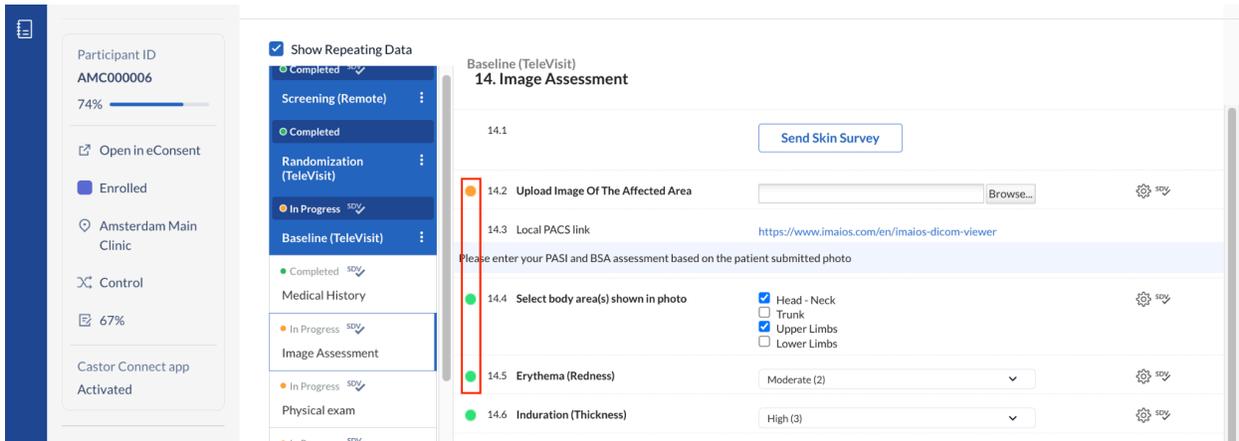
⚠ Date of consent is mandatory. Please provide the date.

- 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).

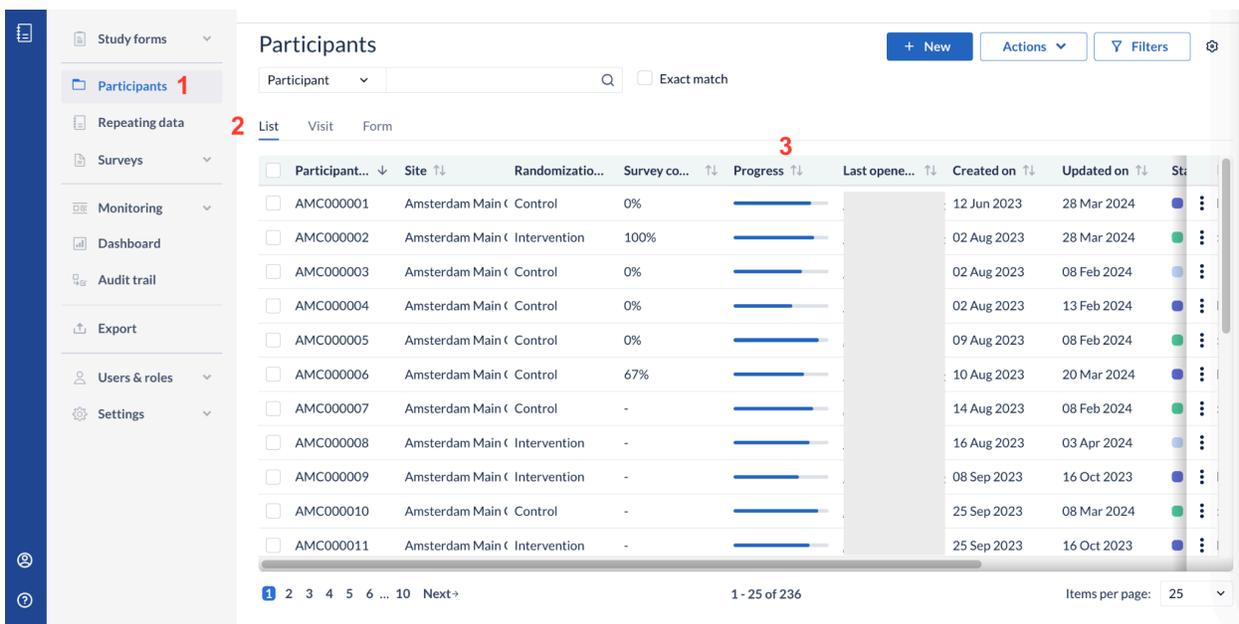
These field level status icons in data entry view are the lowest status level for progress indication in visits, forms, repeating data, and surveys.



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).

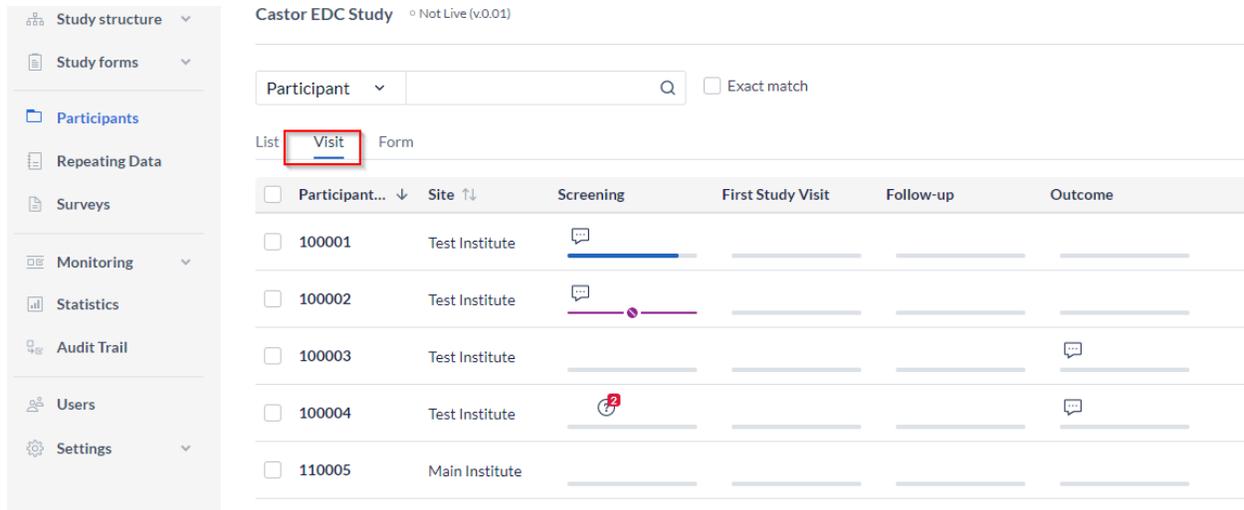


A participant will show as incomplete until required fields in all visits and forms are complete.

- **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.

Participant ID
AMC000004
78% Progress bar

Enrolled

Amsterdam Main Clinic

Control

0%

Castor Connect app
Activated

Participant

- Visits
- Repeating data
- Surveys
- Monitoring

All repeating data

Filter by Repeating Data type:

Filter by name:

Filter by Repeating Data:

Filter by visit:

Filter by status:

[Add a repeating data instance](#)

Status	Repeating Data	Name	Type	Created on	Created by	Assigned to
<input type="radio"/>	Adverse event	Adverse event - 1	Adverse Event	2023-08-02 14:5...		Baseline (TeleVisit) <input type="checkbox"/>
<input checked="" type="radio"/>	Adverse event	Adverse event - 2	Adverse Event	2023-11-02 13:4...		Baseline (TeleVisit) <input type="checkbox"/>
<input checked="" type="radio"/>	Concomitant Me...	Concomitant Me...	Repeated measure	2023-08-02 14:5...		Screening (Remot... <input type="checkbox"/>

Page 1 of 1 | Show 25

Repeating Data 1 - 3 of 3

Repeating Data

[Previous](#) [Next](#)

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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 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. Clicking on the three dot menu allows to access additional menu options for each survey invitation.

The screenshot displays the 'Surveys' management interface. The table lists survey invitations with the following columns: Participant ID, Site, Package name, Status, Parent, Progress, Created on, Available from, Sent on, Completed on, and Sent via. A red box labeled '1' highlights the 'Progress' column, which shows a percentage bar for each survey. Another red box labeled '2' highlights the three-dot menu icon for a survey invitation. A third red box labeled '3' highlights the 'Print survey' option in the dropdown menu that appears when the menu is clicked.

Participant ID	Site	Package name	Status	Parent	Progress	Created on	Available from	Sent on	Completed on	Sent via
AMC000001	Amsterdam Main Cl	Skin Questionnaire	Sent			19 Jan 2024	19 Jan 2024	19 Jan 2024		Castor Connect
AMC000001	Amsterdam Main Cl	Report a headache	Sent			19 Jan 2024	19 Jan 2024	19 Jan 2024		Castor Connect
AMC000001	Amsterdam Main Cl	Anxiety Survey	Sent			19 Jan 2024	19 Jan 2024	19 Jan 2024		Email invite
AMC000002	Amsterdam Main Cl	Quality of Life Survey (SF36)	Completed		100%	02 Aug 2023	02 Aug 2023	02 Aug 2023	02 Aug 2023	Castor Connect
AMC000003	Amsterdam Main Cl	Epilepsy Quality of Life	Created			24 Oct 2023	24 Oct 2023			Castor Connect
AMC000003	Amsterdam Main Cl	Quality of Life Survey (SF36) - V	Viewed			24 Oct 2023	24 Oct 2023	24 Oct 2023		Email invite
AMC000004	Amsterdam Main Cl	Quality of Life Survey (SF36)	Viewed			02 Aug 2023	02 Aug 2023			Castor Connect
AMC000005	Amsterdam Main Cl	Quality of Life Survey (SF36)	Received			12 Oct 2023	12 Oct 2023			Castor Connect
AMC000005	Amsterdam Main Cl	Report a headache	Received			12 Oct 2023	12 Oct 2023	12 Oct 2023		Castor Connect
AMC000005	Amsterdam Main Cl	Skin Questionnaire	Received			12 Oct 2023	12 Oct 2023			Castor Connect
AMC000006	Amsterdam Main Cl	Report a headache	Completed		100%	01 Dec 2023	01 Dec 2023	01 Dec 2023	31 Jan 2024	Castor Connect
AMC000006	Amsterdam Main Cl	Quality of Life Survey (SF36)	Viewed			01 Dec 2023	01 Dec 2023	01 Dec 2023		Castor Connect
AMC000006	Amsterdam Main Cl	Quality of Life Survey (SF36) - V	In Progress		50%	31 Jan 2024	31 Jan 2024	31 Jan 2024		Email invite
AMC000006	Amsterdam Main Cl	Skin Questionnaire	Completed		100%	30 Jan 2024	30 Jan 2024	30 Jan 2024	22 Feb 2024	Castor Connect
AMC000006	Amsterdam Main Cl	Anxiety Survey	Completed		100%	25 Jan 2024	25 Jan 2024	30 Jan 2024	01 Feb 2024	Email invite
AMC000006	Amsterdam Main Cl	Report a headache	Completed		100%	12 Feb 2024	12 Feb 2024	12 Feb 2024	22 Feb 2024	Castor Connect
AMC000012	Amsterdam Main Cl	Skin Questionnaire	Sent			19 Dec 2023	19 Dec 2023	19 Dec 2023		Castor Connect
AMC000012	Amsterdam Main Cl	Skin Questionnaire	Completed		100%	19 Dec 2023	19 Dec 2023	19 Dec 2023	19 Dec 2023	Castor Connect
AMC000012	Amsterdam Main Cl	Report a headache	Sent			19 Dec 2023	19 Dec 2023	19 Dec 2023		Castor Connect
AMC000012	Amsterdam Main Cl	Anxiety Survey	Sent			19 Dec 2023	19 Dec 2023	19 Dec 2023		Email invite
AMC000012	Amsterdam Main Cl	Epilepsy Quality of Life	Received			19 Dec 2023	19 Dec 2023	19 Dec 2023		Castor Connect

2.2. Survey Compliance

‘Compliance’ as a measure, calculated based on the number of surveys completed by a participant compared to the number made available to them to date.

The ‘Survey compliance’ page includes a combined grid displaying participant-level compliance and individual survey packages. Users can apply filters for various parameters and access quick filters for non-compliance participants or recent surveys. An overall compliance number is displayed for each participant.

Participant ID	Site	Participant status	Survey packages scheduled	Survey packages completed	Compliance
> MYC000012	Mayo Clinic	Not set	37	19	51%
> MYC000007	Mayo Clinic	Screened	23	16	70%
> AMC000105	Amsterdam Main Cl	Not set	17	15	88%
> AMC000019	Amsterdam Main Cl	Screened	14	10	71%
> AMC000014	Amsterdam Main Cl	Screened	10	7	70%
> AMC000058	Amsterdam Main Cl	Not set	8	5	63%
> AMC000139	Amsterdam Main Cl	Not set	7	5	71%
> AMC000146	Amsterdam Main Cl	Not set	7	3	43%
> AMC000006	Amsterdam Main Cl	Enrolled	6	4	67%
> KCH000003	King's College Hosp	Complete	6	3	50%
> AMC000169	Amsterdam Main Cl	Screened	5	2	40%
> AMC000012	Amsterdam Main Cl	Enrolled	5	1	20%
> AMC000140	Amsterdam Main Cl	Not set	5	2	40%
> AMC000155	Amsterdam Main Cl	Not set	4	3	75%
> AMC000095	Amsterdam Main Cl	Screened	4	2	50%
> AMC000000	Amsterdam Main Cl	Not set	2	1	25%

Clinicians who have both export permissions and access to the survey compliance listing will be able to request an export of their filtered compliance data by clicking on the ‘Actions’ button and selecting the ‘Export copy’ option. This will become available as a downloadable file in the ‘Exports’ section of the CDMS.

2.3 Data Review

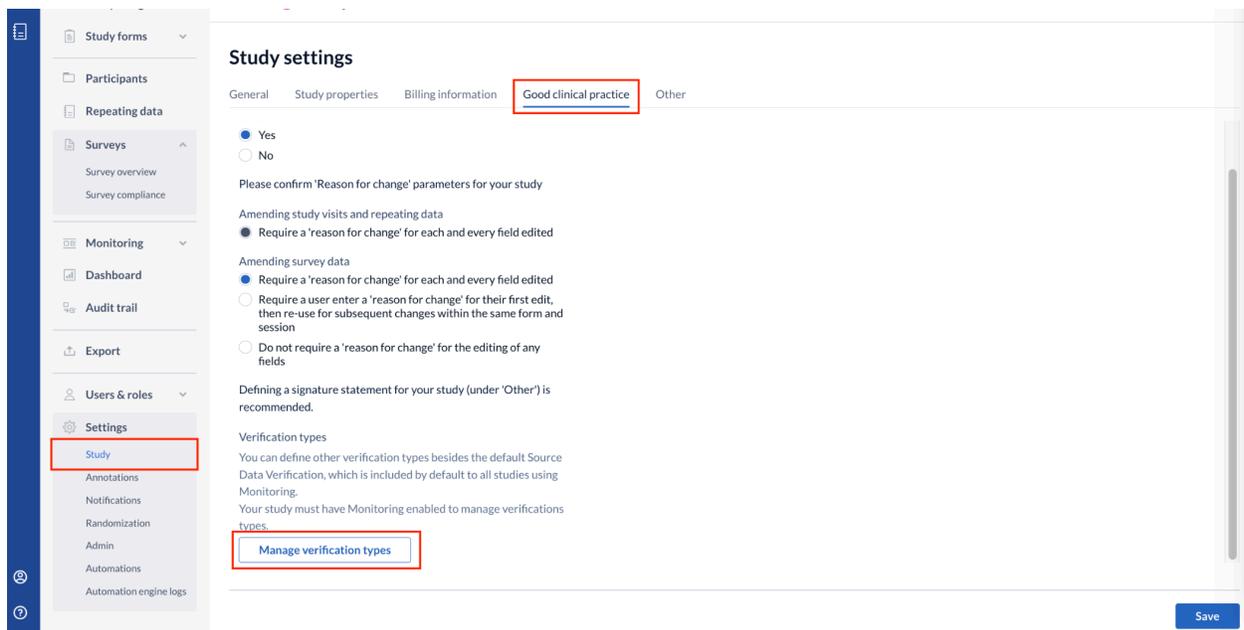
2.3.1 Verification

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.

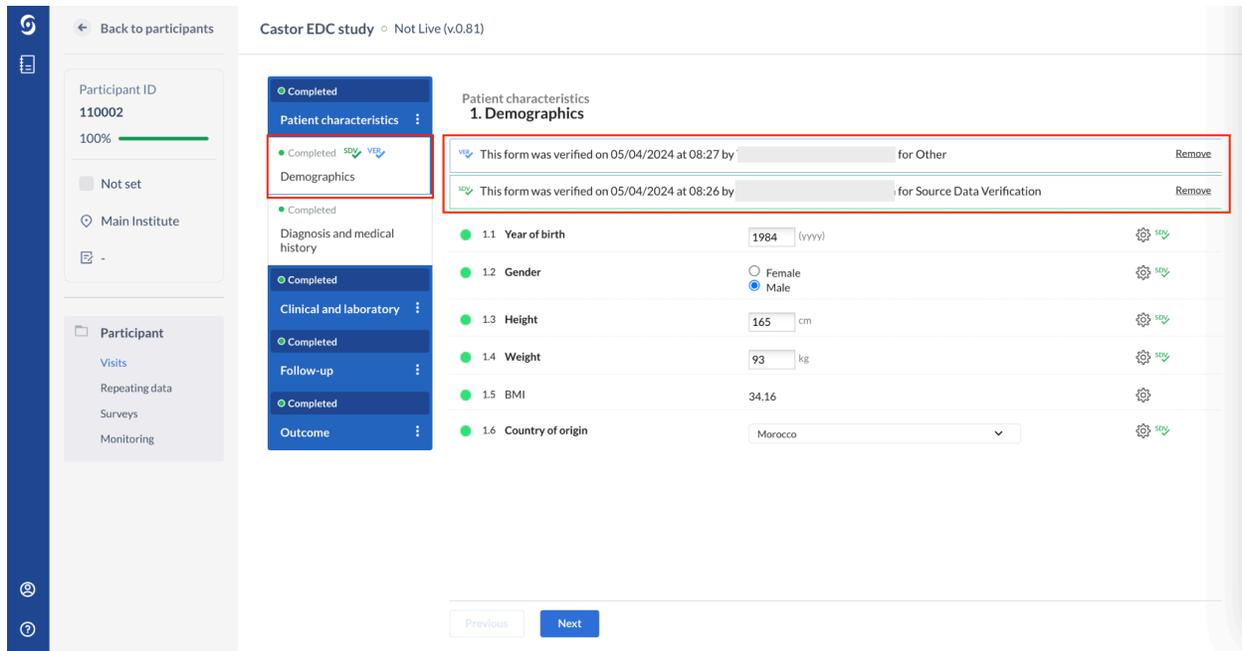
Under 'Manage verification types', located in the 'Good clinical practice' section of the study settings, you can add or edit the verification types in your study:



The screenshot shows the 'Study settings' interface with the 'Good clinical practice' tab selected. The left sidebar contains a 'Settings' menu where 'Study' is highlighted. The main content area shows options for 'Amending study visits and repeating data' and 'Amending survey data', both with 'Require a reason for change' selected. At the bottom of the main content area, the 'Manage verification types' button is highlighted with a red box. A 'Save' button is visible in the bottom right corner.

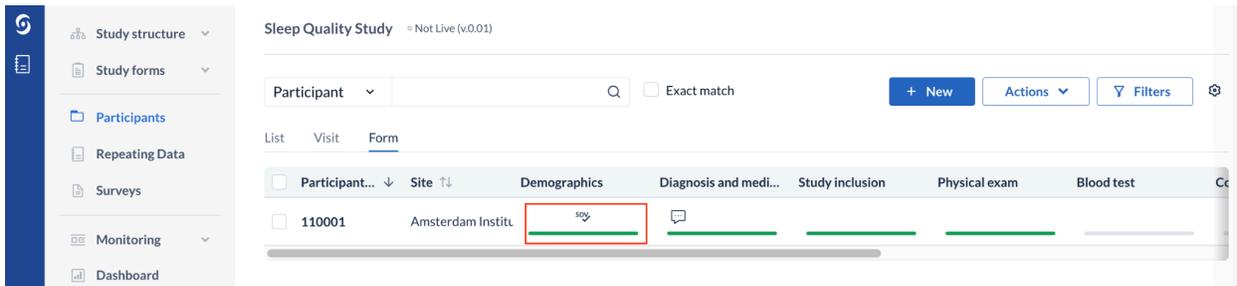
You have the option to SDV all forms in a visit, a form (including all fields or required fields) as well as individual fields. For other custom verification types, you cannot verify individual fields.

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.



The screenshot shows the Castor EDC interface for a study titled "Sleep Quality Study" (version v.0.01). On the left is a navigation sidebar with options: Study structure, Study forms, Participants, Repeating Data, Surveys, Monitoring, and Dashboard. The main area displays a table of participants. The table has columns for Participant ID, Site, Demographics, Diagnosis and medication, Study inclusion, Physical exam, and Blood test. A single participant is listed with ID 110001 at the Amsterdam Institute site. The "Demographics" column for this participant is highlighted with a red box and contains a "show" link. Above the table, there is a search bar for "Participant" with an "Exact match" checkbox, and buttons for "+ New", "Actions", and "Filters".

Participant...	Site	Demographics	Diagnosis and medi...	Study inclusion	Physical exam	Blood test
110001	Amsterdam Instit.	show				

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:

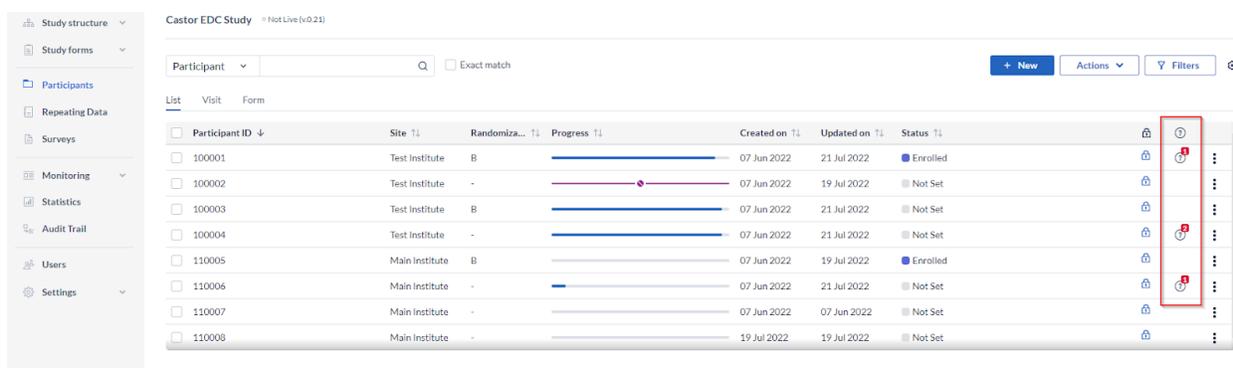
- EU: <https://data.castoredc.com/api>
- US: <https://us.castoredc.com/api>

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

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

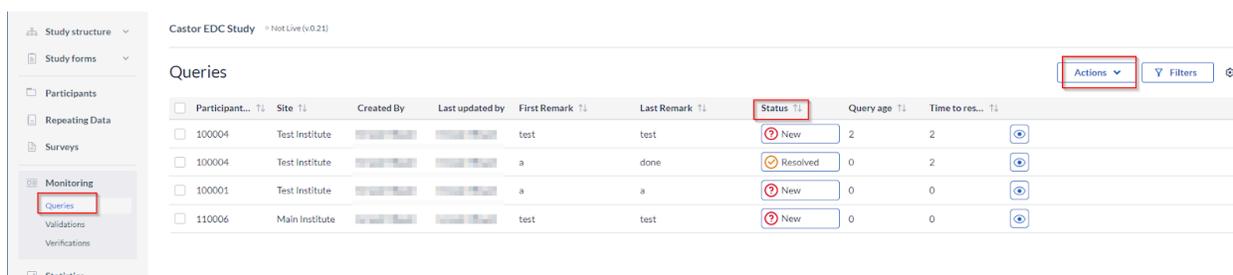
3.3. Data Queries

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



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.



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.



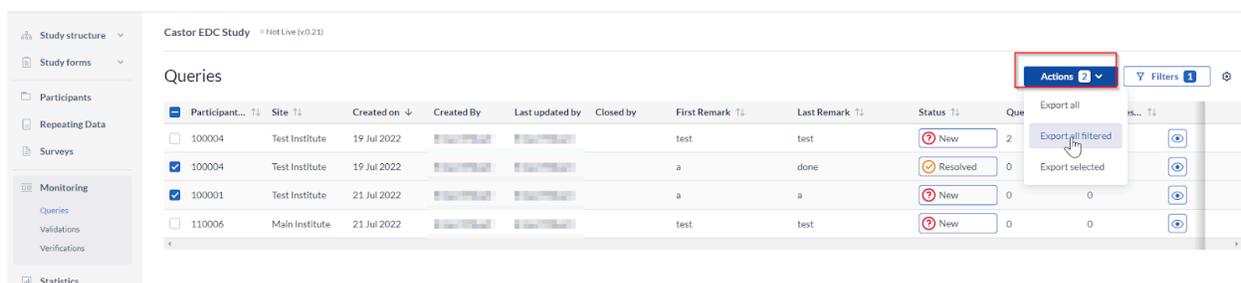
3. Closed.



3.3.1 Exporting Queries

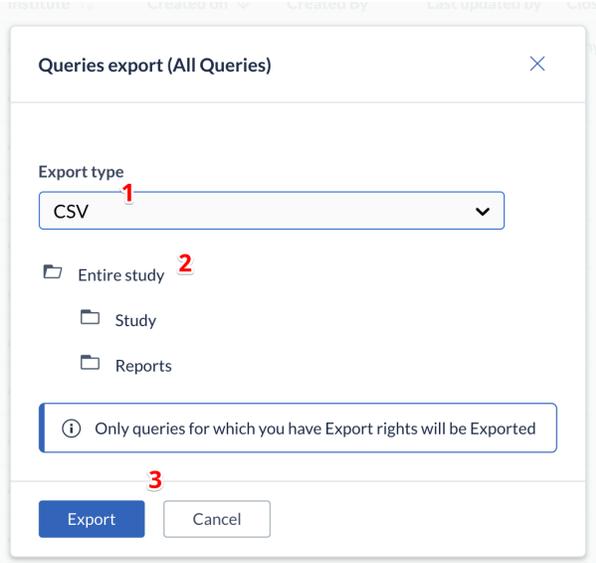
Users with Export rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the forms below:

- 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

1 CSV ▼

2

- Entire study
- Study
- Reports

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

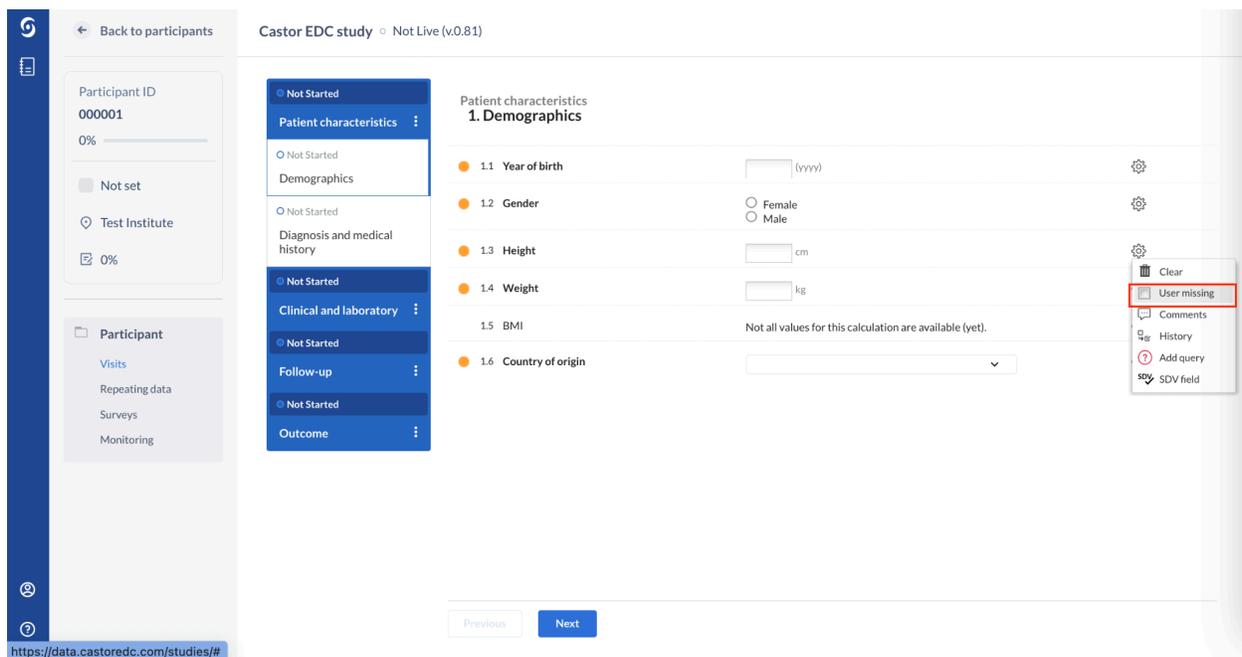
3

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':



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:

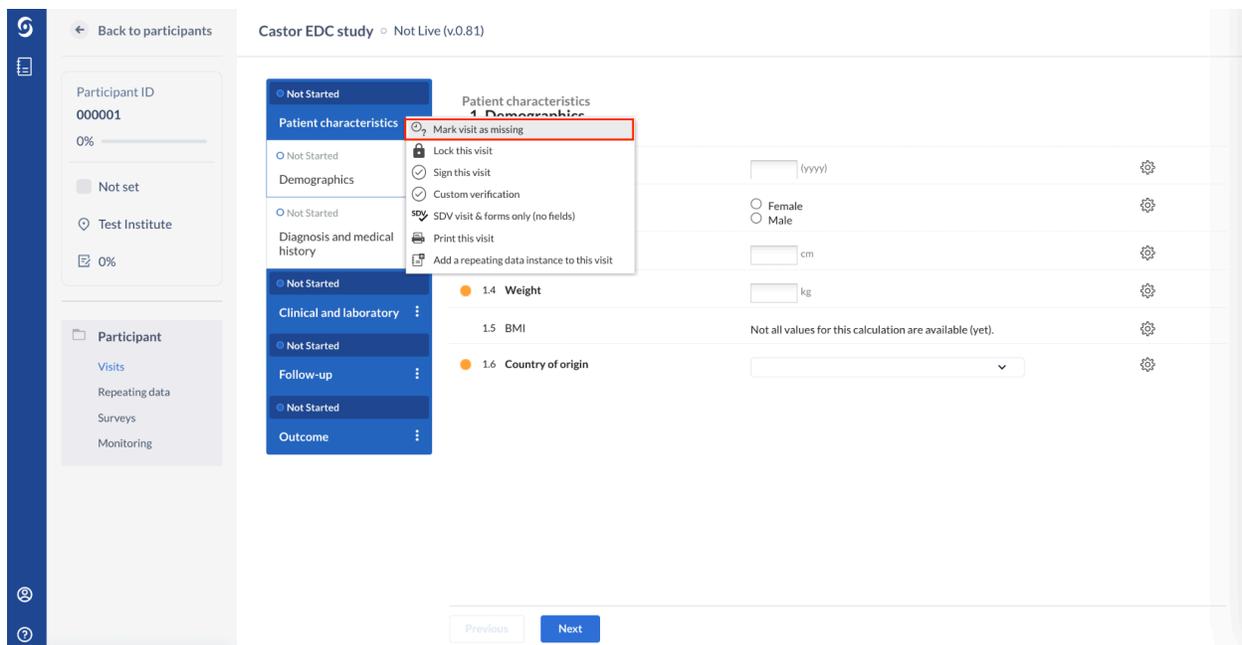
- Measurement failed (-95)
- Not Applicable (-96)
- Not asked (-97)
- Asked but unknown (-98)
- Not done (-99)

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 three dot menu 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:

3.4 Date of birth | 3.4 | dd-mm-

Mark whole phase 'Demographics' as missing?

Choose reason:

Measurement failed (-95)

Not applicable (-96)

Not asked (-97)

Asked but unknown (-98)

Not done (-99)

Comment:

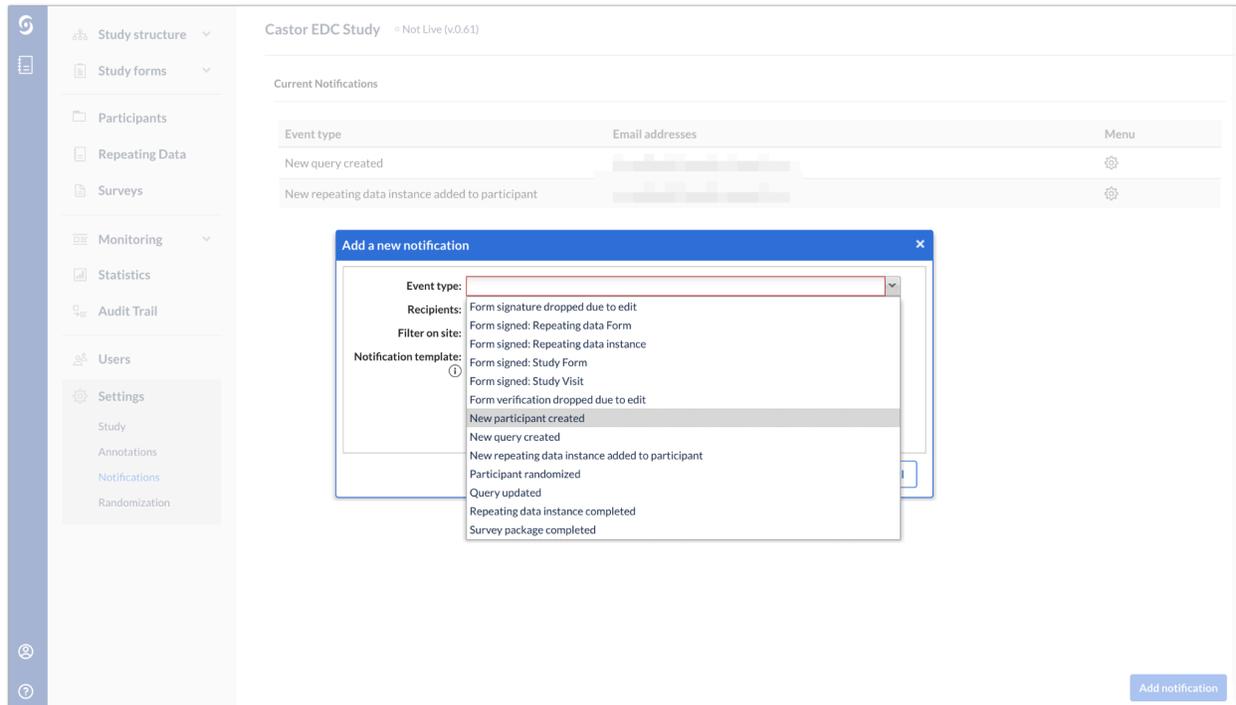
Please note: marking a phase as missing cannot be undone. Setting phase to missing may affect signatures, verifications and Child field dependencies.

3.5. Notifications

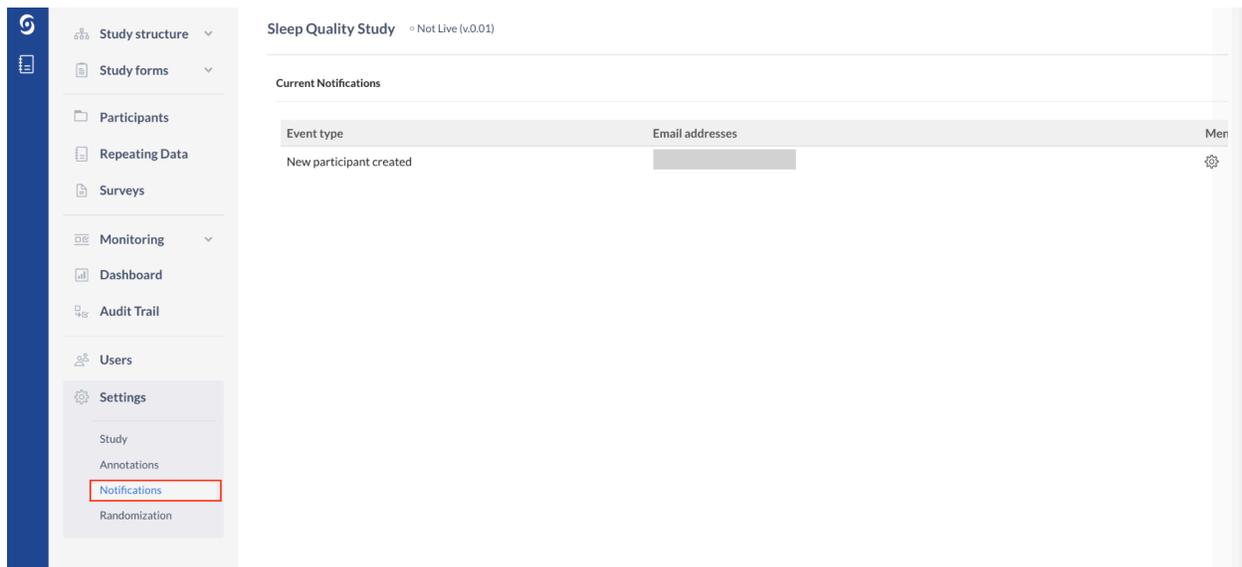
Notifications for specific study events can be created in the study settings. Notifications are not possible for individual fields or completion statuses. Available study events include:

- 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".

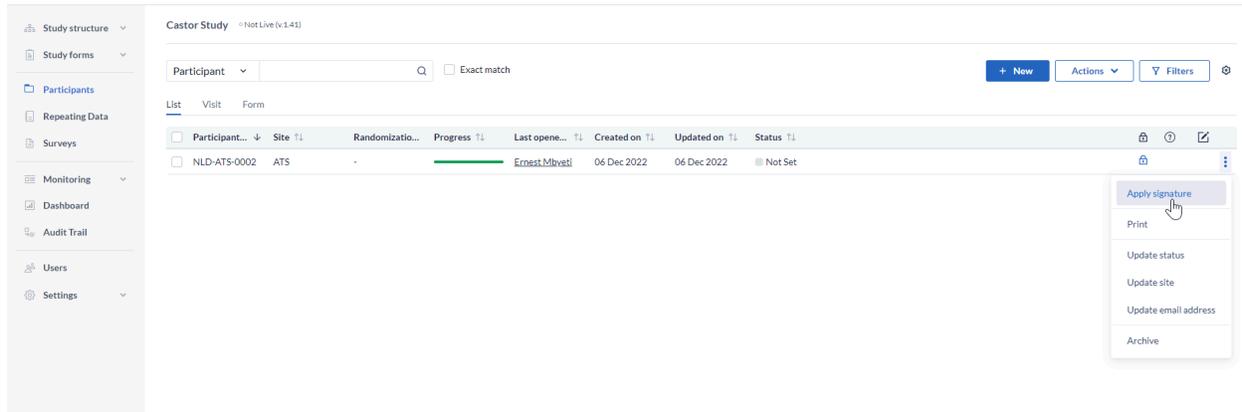
1. When in a participant, click on a form or visit. Click on the three dots that appear to the right.
2. Click on "Sign this visit" for visits or "Sign this form" for forms.

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

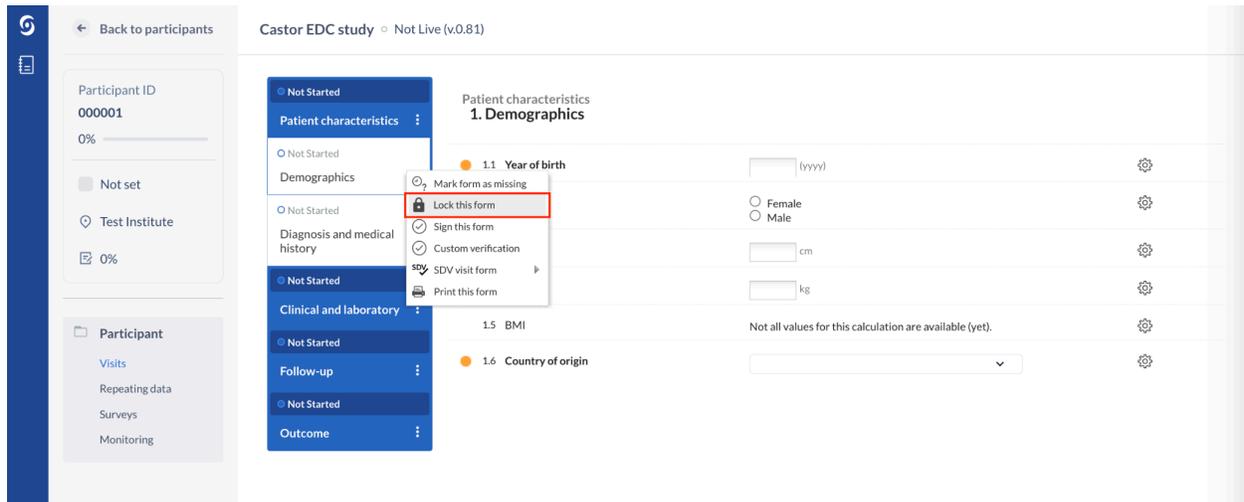
Castor CDMS offers the ability to seamlessly sign all forms of a selected participant at once, directly from the 'Participants overview' page.



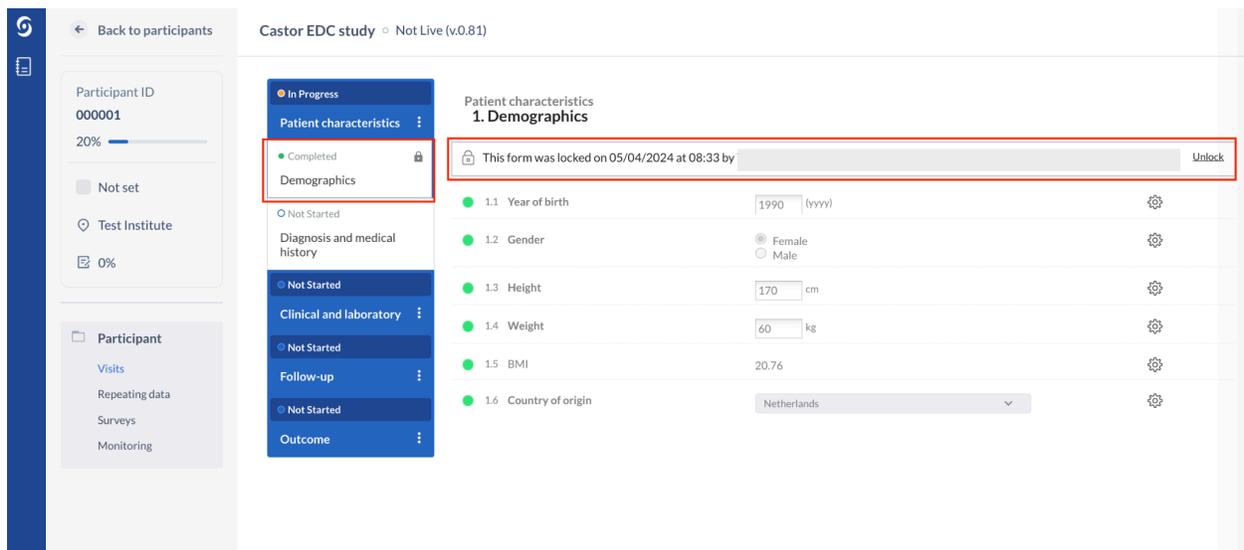
You will be prompted to enter your credentials in order to sign the participant. Additionally you can also select to lock the participant upon signing, by ticking the 'Lock participant' box.

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 "(Un)lock this visit" or "(Un)lock this form" option.



A lock icon will appear on top of the locked form, as well as in the form navigator panel on the left:



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

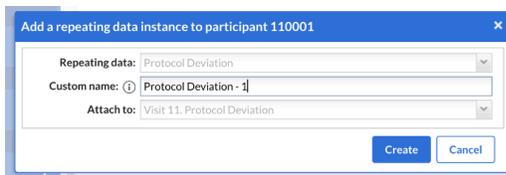
7. Baseline (7 +/- 2 days) Visit Date

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 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.



The dialog box shows the following fields:

- Repeating data: Protocol Deviation
- Custom name: Protocol Deviation - 1
- Attach to: Visit 11: Protocol Deviation

Buttons: Create, Cancel

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