

Castor

Castor CDMS Data Management User Guide

Version 2024.2

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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

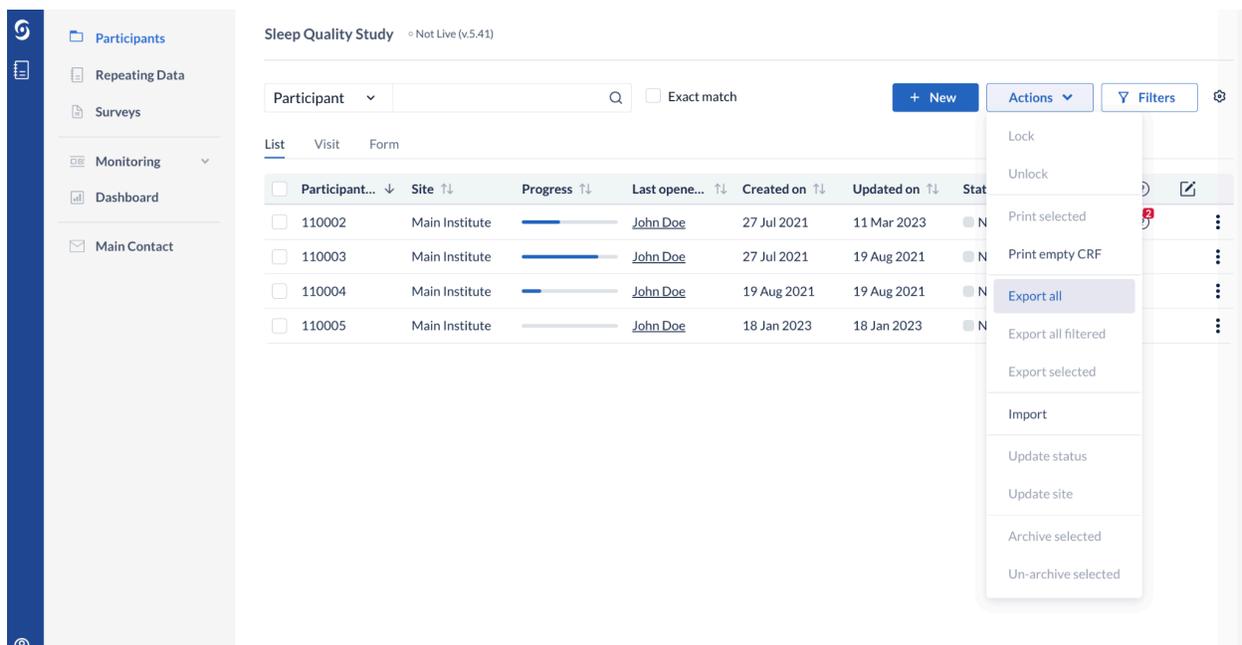
1.1. CRF Review

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.

Data Export (Selected Participants)
×

i Only participants for which you have Export permissions and that are not archived will be exported.

Export Type

CSV
▼

Group data

Do not group data
 Group data by domain

Display options as

Numbers (values)
 Names (labels)

How to export

Interactive (tree)
 Variable list
 Variables bulk (paste)

Include

Comments
 Queries
 Verifications

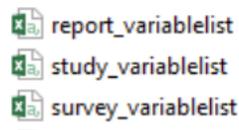
Cancel

Export

- 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.

In case you select a CSV or SAS file type, an option is presented to 'Do not group data' (default) or 'Group data by domain'.

Data Export (Selected Participants) ×

i Only participants for which you have Export permissions and that are not archived will be exported.

Export Type

CSV ▼

Group data

Do not group data
 Group data by domain

When data is grouped by domain, the exported file format follows the following structure, with one line per Visit/Repeating Data instance/Survey instance:

- Participant Id
- Participant Status
- Site Abbreviation
- Randomization Id

- Randomization Group
- Randomized On
- Participant Creation Date
- Visit name
- Visit number (as set on the Study Structure page)
- Type (Visit, Repeating data, Survey)
- Name (of the Visit, Repeating data, Survey)

VS

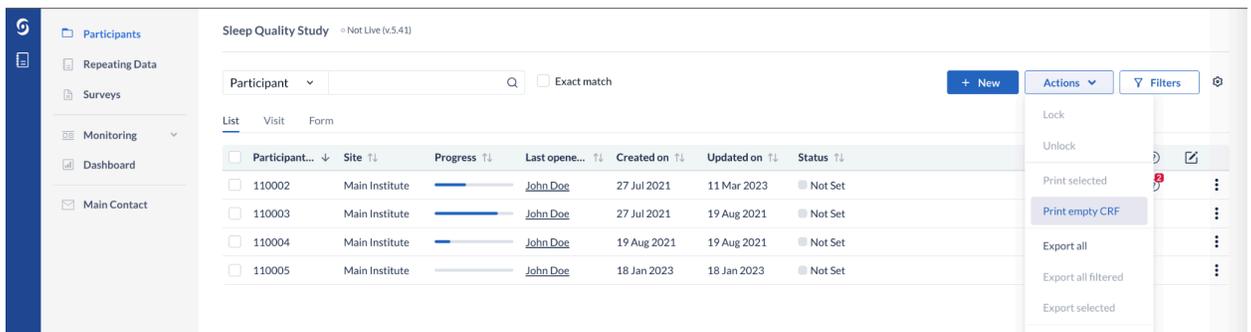
Participant Id	Participant Status	Site Abbreviation	Randomization Id	Randomization Group	Randomized On	Participant Creation Date	Visit name	Visit number	Type	Name	bmi	height	hr	weight
120001	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	23.5	167		65.4
120001	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.9	167	75.3	61.1
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				65.6
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				68.7 63.1
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2				85.9 78.4
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #3				59.5 76.6
120002	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	30.52	166.7		84.8
120002	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	28.7	166.7	81.6	79.7
120002	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				77
120002	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				76.2 79
120003	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	21.56	176.4		67.1
120003	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.9	176.4	85.8	68.3
120003	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				76.3
120003	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				67.9 62.1
120004	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	20.5	162.3		54
120004	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	20.2	162.3	78.3	53.1
120004	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				86.8
120004	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				58.8 68.8
120005	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	24	157.6		59.6
120005	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	24.0	157.6	81.9	59.7
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				91.3
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				65.7 79.4
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2				85.1 61.9
120006	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	22.07	183		73.9
120006	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.4	183	71.7	71.7
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				69
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				78.9 55.8
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2				65.3 57.4
120007	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	21.93	188.6		78
120007	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	11.7	188.6	65.1	41.7
120007	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				70.1
120007	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				62.2 69.5
120008	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	24.11	172.1		71.4
120008	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	23.6	172.1	71.2	69.8
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				75.9
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				63.9 70.8
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2				79.3 86.3
120009	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	18.14	171.9		53.6
120009	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	18.1	171.9	60.8	53.5
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up				84.1
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1				88.9 71.4
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2				68.5 81.2

- All dates (field values & metadata) are exported in YYYY-MM-DD hh:mm (date and time), or YYYY-MM-DD (date) format.
- Checkboxes are exported in the [domain variable name]_[option name] format, with a value of 1 representing a checked option, and 0 representing an unchecked option.
- Number and date fields are exported in the [domain variable name]_number and [domain variable name]_date format.
- Grid fields are exported in the [domain variable name]_[row name]_[column name] format.

- Row and column names are cut off at 15 characters.
- Data marked as missing is handled the same way as our other exports.
- Form blinding permissions are taken into account while exporting data. In case the user is blinded, the related cells are empty in the export.
- View randomization permissions are taken into account while exporting data. Only randomization information from sites where a user has View randomization permissions for, are included in the export.
- In case variable names are generated, they are limited at 64 characters.
- A field variable list is added per domain ([domain abbreviation]_variablelist.[filetype]).
- If the user does not have decrypt permissions for the site the participant is assigned to, the encrypted value will be exported as *encrypted*.

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':



The screenshot shows the 'Participants' tab for a 'Sleep Quality Study' (v.5.41). The interface includes a search bar for 'Participant' with an 'Exact match' checkbox. Below the search bar is a table with columns: Participant, Site, Progress, Last opened, Created on, Updated on, and Status. The table contains five rows of participant data. In the top right corner, there is a '+ New' button and an 'Actions' dropdown menu. The 'Actions' menu is open, showing options: Lock, Unlock, Print selected, Print empty CRF (highlighted), Export all, Export all filtered, and Export selected.

Participant	Site	Progress	Last opened	Created on	Updated on	Status
110002	Main Institute	<div style="width: 100%;"></div>	John Doe	27 Jul 2021	11 Mar 2023	Not Set
110003	Main Institute	<div style="width: 100%;"></div>	John Doe	27 Jul 2021	19 Aug 2021	Not Set
110004	Main Institute	<div style="width: 100%;"></div>	John Doe	19 Aug 2021	19 Aug 2021	Not Set
110005	Main Institute	<div style="width: 100%;"></div>	John Doe	18 Jan 2023	18 Jan 2023	Not Set

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

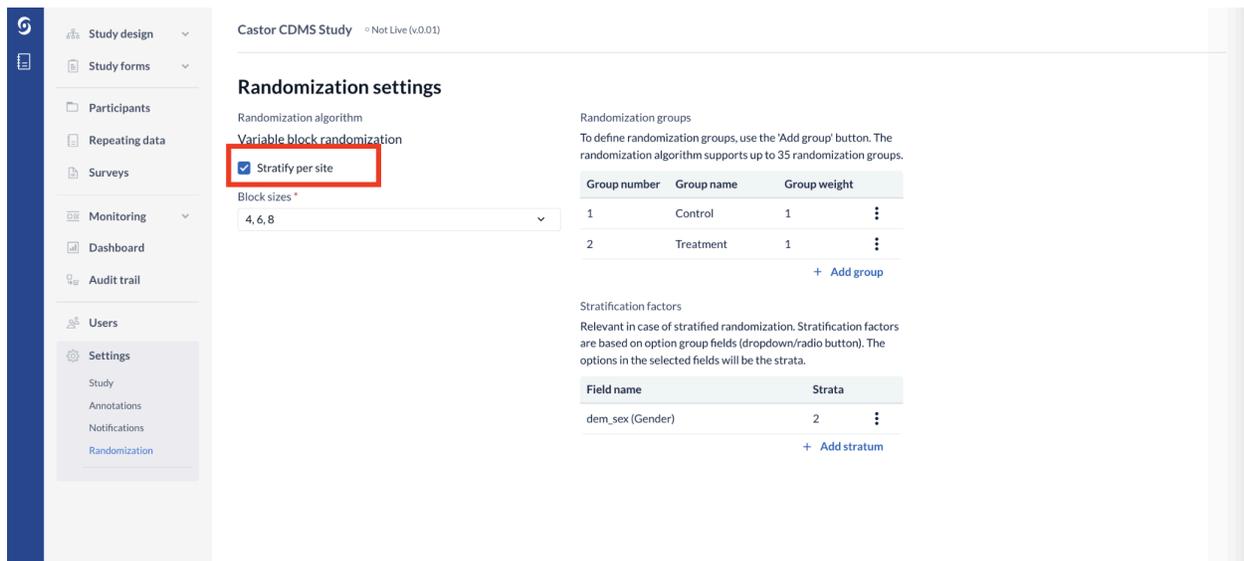
- Select the structure (Study, Repeating Data, Surveys) you would like to print.
- Choose the options you would like to include in the PDF.
- Click 'Print'.

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

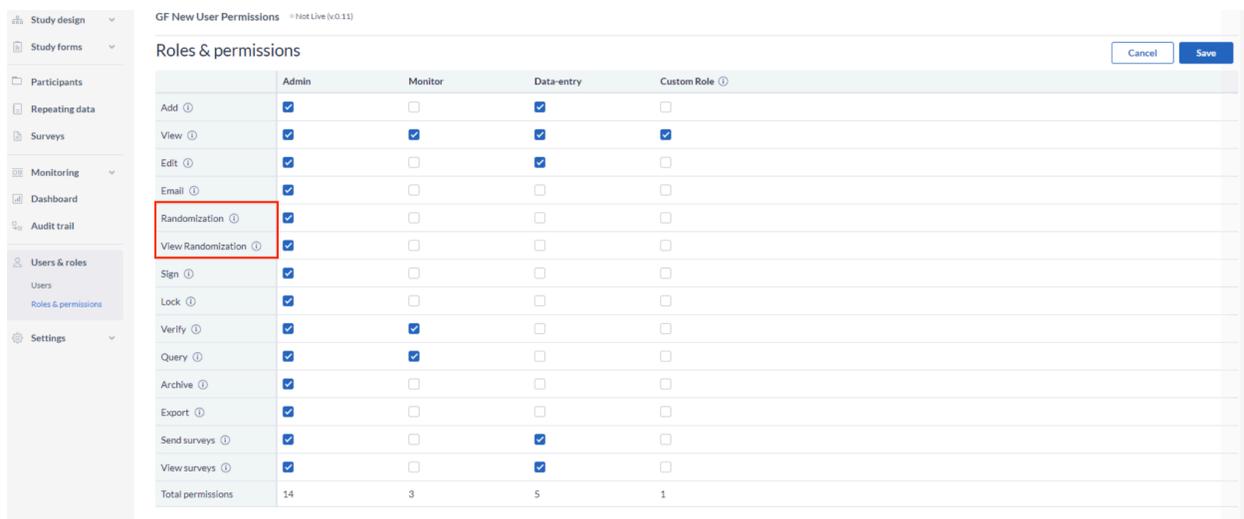
Castor uses a variable block randomization method. Randomization settings can be viewed in the Settings tab. You are able to define randomization groups and weights, block sizes, and fields within the CRF for stratification. Customized randomization settings are available for an additional fee. Please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

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



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.



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.



i Patient can participate, please continue.

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



! 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.



! Medication End Date is before Medication Start Date. Please correct.

- **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:



⊘ This patient cannot participate in the study if not diagnosed.

- 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.

 This patient cannot participate in the study if not diagnosed.

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.

1.4. eLearning

The [Castor Academy](#) contains a structured series of tutorials with step-by-step 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.

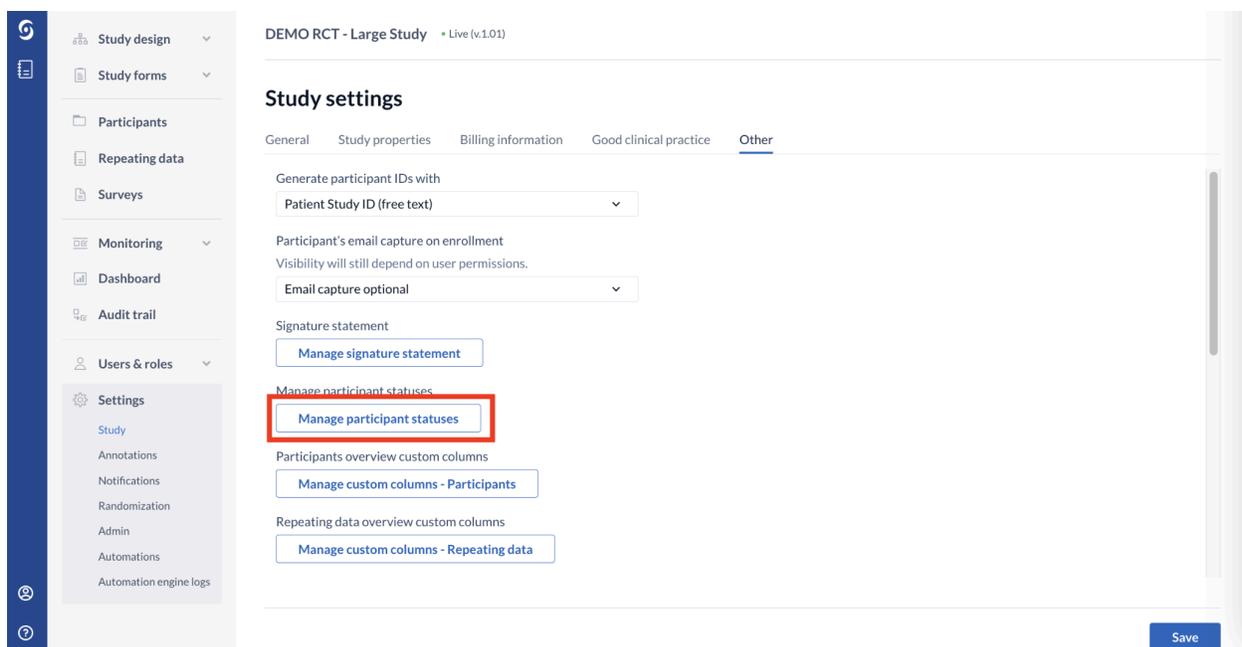
1.5.1 User Acceptance Testing Environment

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

Demo Study ▾ Not Live (v0.01)

Participant ID
110002
50%

In progress

Site One

Participant

- Visits
- Repeating data
- Surveys
- Monitoring

Data collection progress

50%

Show repeating data instances

- Patient characteristics 100% SDV
- Clinical and laboratory 15% SDV
 - Physical exam Not started
 - Blood test** In progress SDV
 - Medication intake Completed
- Follow-up 0%

Clinical and laboratory

4. Blood test

✓ 4.1 Date of blood sample * SDV ⋮
2024-03-11 (yyyy-mm-dd)

* 4.2 Haemoglobin concentration * SDV ⋮
mmol/l

* 4.3 Hematocrit value * SDV ⋮
l/l

* 4.4 Blood white blood cell count * SDV ⋮
*10⁹/L

* 4.5 Blood trombocyte count * SDV ⋮

Back Next

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

Demo Study ▾ Not Live (v0.01)

Participants

+ New Actions Filters

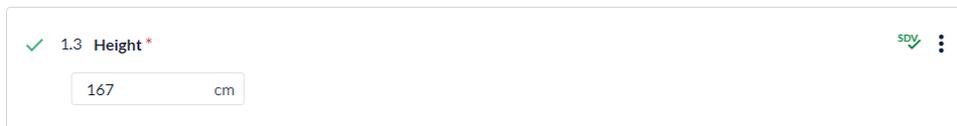
Participant Exact match

Participant	Site	Randomizatio...	Survey co...	Progress	Created on	Updated on	Status	
<input type="checkbox"/> 110001	Site One	-	-	<div style="width: 50%;"></div>	20 Mar 2024	17 Jun 2024	In progress	🔒 🕒 ⋮
<input type="checkbox"/> 110002	Site One	Group B	-	<div style="width: 50%;"></div>	20 Mar 2024	17 Jun 2024	In progress	🔒 🕒 ⋮
<input type="checkbox"/> 110003	Site One	-	-	<div style="width: 100%;"></div>	20 Mar 2024	17 Jun 2024	Completed	🔒 🕒 ⋮
<input type="checkbox"/> 110004	Site One	-	-	<div style="width: 50%;"></div>	20 Mar 2024	17 Jun 2024	In progress	🔒 🕒 ⋮
<input type="checkbox"/> 110005	Site One	-	-	<div style="width: 100%;"></div>	20 Mar 2024	17 Jun 2024	Completed	🔒 🕒 ⋮
<input type="checkbox"/> 110006	Site One	-	-	<div style="width: 50%;"></div>	20 Mar 2024	17 Jun 2024	In progress	🔒 🕒 ⋮

2.2 Progress of completion

Completion for each area of the CRF is generally coded using colored status icons. Shown to the left of each question is the status icon, which indicates whether the question:

- has been answered (green thick):



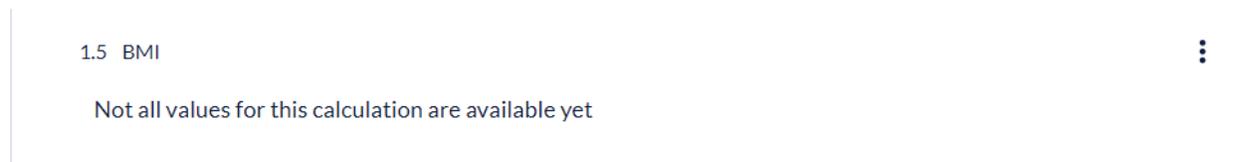
A screenshot of a CRF field for '1.3 Height *'. The field contains the value '167' followed by the unit 'cm'. A green checkmark icon is visible to the left of the question label, and a green 'SDV' icon with a dropdown arrow is to the right.

- data entry is required and no input has been entered yet (red asterisk):



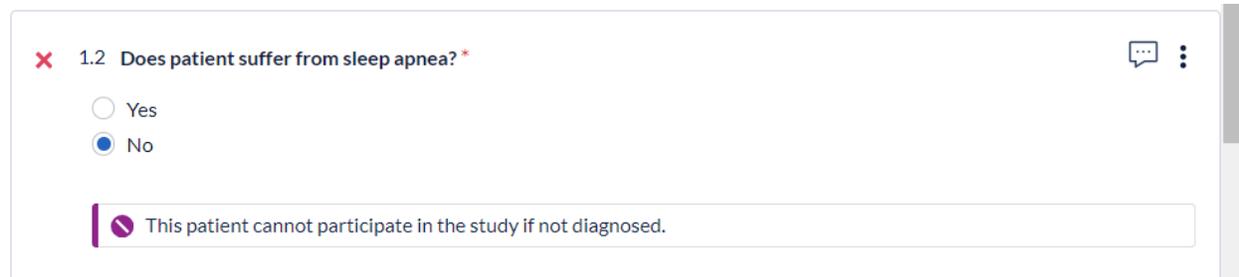
A screenshot of a CRF field for '1.4 Weight *'. The field is empty, with the unit 'kg' to its right. A red asterisk icon is to the left of the question label, and a blue 'SDV' icon with a dropdown arrow is to the right.

- data entry is not required - field shows the value based on calculation (no icon)



A screenshot of a CRF field for '1.5 BMI'. The field contains the text 'Not all values for this calculation are available yet'. There are no status icons.

- the input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message (red cross)



A screenshot of a CRF field for '1.2 Does patient suffer from sleep apnea? *'. The field has two radio buttons: 'Yes' (unselected) and 'No' (selected). A red 'X' icon is to the left of the question label, and a red speech bubble icon with a dropdown arrow is to the right. Below the radio buttons, a red warning message is displayed: 'This patient cannot participate in the study if not diagnosed.'

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).

Participant	Site	Randomization group	Survey co...	Progress	Castor Connect	Gender
000001	Amsterdam Institute 2	-	-		1	1
AMS_000002	Amsterdam Institute	-	50%		1	1
AMS_000005	Amsterdam Institute	-	0%		1	1
AMS_000006	Amsterdam Institute	Control	0%		Missing (not done)	1
AMS_000007	Amsterdam Institute	-	0%		0	Missing (not done)
AMS_000008	Amsterdam Institute	-	0%		0	0
AMS_000009	Amsterdam Institute	-	40%		0	0
AMS_000014	Amsterdam Institute	-	-		1	1
AMS_000016	Amsterdam Institute	Control	-		1	1
AMS_000017	Amsterdam Institute	-	-		1	1
AMS_000018	Amsterdam Institute	-	-		1	1
AMS_000019	Amsterdam Institute	-	-		1	1
AMS_000020	Amsterdam Institute	-	-		1	1

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.

Participants + New Actions Filters

Participant Exact match

List Visit Form

Participant...	Site	Inclusion and Rand...	Baseline	Follow-up visit (2 w...	Follow-up visit (4 w...	End of study
<input type="checkbox"/> 000001	Amsterdam Instit.					
<input type="checkbox"/> AMS_000002	Amsterdam Instit.					
<input type="checkbox"/> AMS_000005	Amsterdam Instit.					
<input type="checkbox"/> AMS_000006	Amsterdam Instit.					
<input type="checkbox"/> AMS_000007	Amsterdam Instit.					
<input type="checkbox"/> AMS_000008	Amsterdam Instit.					

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

Participants + New Actions Filters

Participant Exact match

List Visit Form

Participant...	Site	Inclusion	Demographics	Measurements	Randomization	Drug administration	SAE	Lab results	Me
<input type="checkbox"/> 000001	Amsterdam Instit.								
<input type="checkbox"/> AMS_000002	Amsterdam Instit.								
<input type="checkbox"/> AMS_000005	Amsterdam Instit.								
<input type="checkbox"/> AMS_000006	Amsterdam Instit.								
<input type="checkbox"/> AMS_000007	Amsterdam Instit.								

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 (Progress column).

← Back to participants

Participant ID
110002
58%

In progress

Site One

Group B

-

Participant

Visits

Repeating data

Surveys

Monitoring

Demo Study Not Live (v0.11)

Repeating data + Create Filters

Repeating d...	Instance name	Type	Created on	Created by	Parent	Progress	
Medication	Medication - 13-06-	Repeated measure	13 Jun 2024	John Smith	Follow-up	Completed	🔒 ⋮
Medication	Medication - 13-06-	Repeated measure	13 Jun 2024	John Smith	Clinical and laboratc	Not started	🔒 ⋮
Medication	Medication - 13-06-	Repeated measure	13 Jun 2024	John Smith	No parent	Not started	🔒 ⋮
Medication	Medication - 13-06-	Repeated measure	13 Jun 2024	John Smith	No parent	Not started	🔒 ⋮
Blood pressure	Blood pressure - 13-	Repeated measure	13 Jun 2024	John Smith	No parent	Not started	🔒 ⋮
Blood pressure	Blood pressure - 13-	Repeated measure	13 Jun 2024	John Smith	No parent	Not started	🔒 ⋮
Blood pressure	Blood pressure - 14-	Repeated measure	14 Jun 2024	John Smith	Follow-up	Completed	🔒 ⋮
Adverse Event	Adverse Event - 14-	Adverse Event	14 Jun 2024	John Smith	Clinical and laboratc	Not started	🔒 ⋮
Unscheduled visit	Unscheduled visit - :	Unscheduled visit	14 Jun 2024	John Smith	Follow-up	Completed	🔒 ⋮
Adverse Event	Adverse Event - 14-	Adverse Event	14 Jun 2024	John Smith	Patient characterist	Not started	🔒 ⋮

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 access to additional menu options for each survey invitation.

The screenshot displays the 'Surveys' management interface. The table lists various survey invitations with columns for 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 for a survey invitation, which contains options such as 'Edit invitation properties', 'View survey (un-editable)', 'Open survey in popup', 'Open survey in new window', 'Print survey' (labeled '3'), 'Delete survey', and 'Archive'.

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

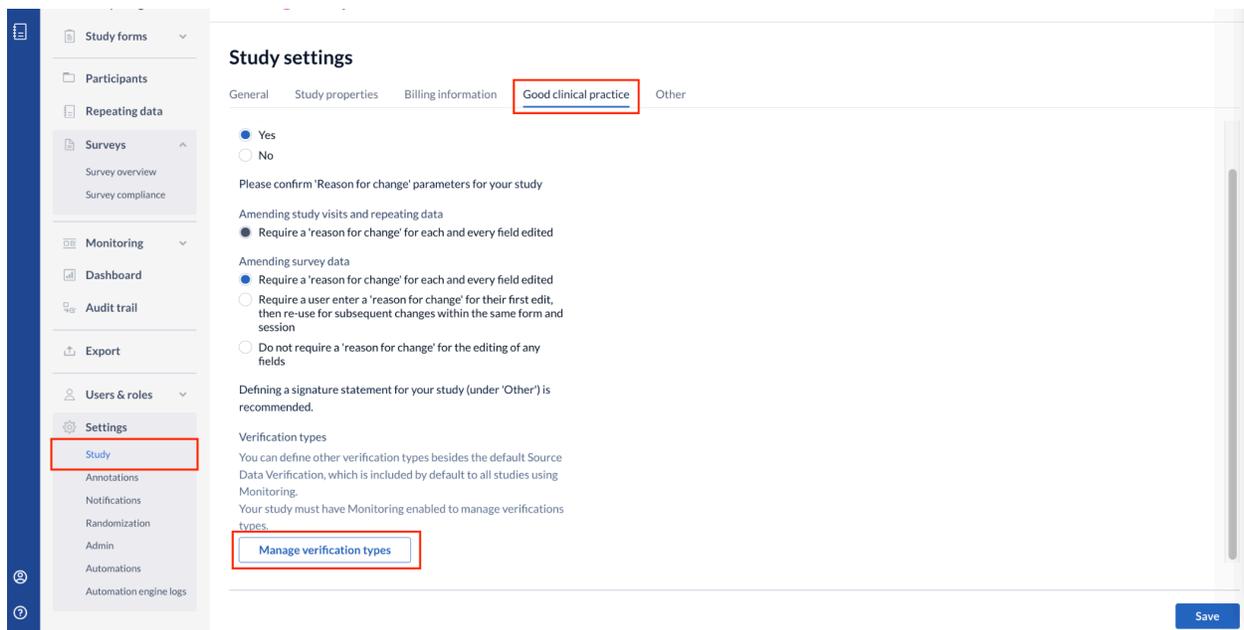
2.3.1 Verification

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.

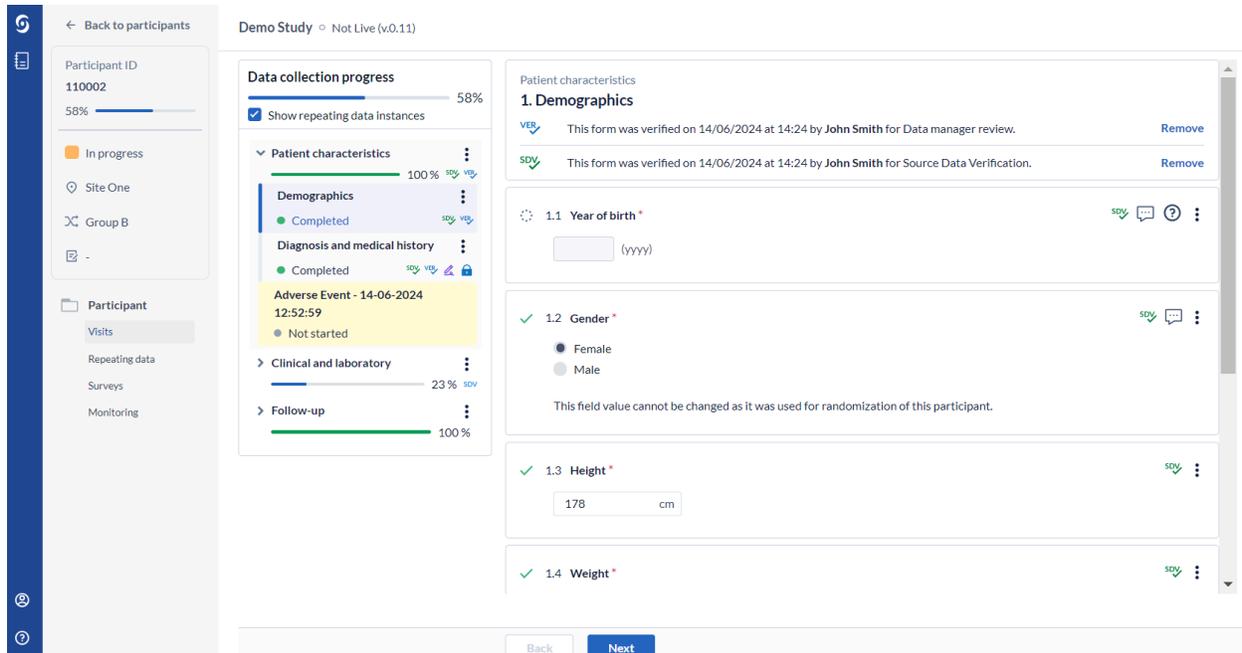
Data verification is linked to Monitoring, so to be able to use it, first enable Monitoring in your study settings. Please note that 'Monitoring' cannot be enabled for retrospective studies.

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:



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.

Participants

Participant
 Exact match

<input type="checkbox"/> Participant...	Site	Demographics	Diagnosis and medi...	Physical exam	Blood test	Medication intake	Physical exam
<input type="checkbox"/> 110001	Site One						
<input type="checkbox"/> 110002	Site One						
<input type="checkbox"/> 110003	Site One						
<input type="checkbox"/> 110004	Site One						
<input type="checkbox"/> 110005	Site One						
<input type="checkbox"/> 110006	Site One						

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.

Participants + New Actions Filters

Participant Exact match

List Visit Form

Participant...	Site	Survey co...	Progress	Created on	Updated on	Status		
<input type="checkbox"/> 110001	Site One	-	<div style="width: 50%;"></div>	20 Mar 2024	03 Apr 2024	In progress	🔒	🔍
<input type="checkbox"/> 110002	Site One	-	<div style="width: 50%;"></div>	20 Mar 2024	14 Jun 2024	In progress	🔒	🔍
<input type="checkbox"/> 110003	Site One	-	<div style="width: 100%;"></div>	20 Mar 2024	20 Mar 2024	Completed	🔒	🔍
<input type="checkbox"/> 110004	Site One	-	<div style="width: 50%;"></div>	20 Mar 2024	20 Mar 2024	In progress	🔒	🔍
<input type="checkbox"/> 110005	Site One	-	<div style="width: 100%;"></div>	20 Mar 2024	20 Mar 2024	Completed	🔒	🔍
<input type="checkbox"/> 110006	Site One	-	<div style="width: 0%;"></div>	20 Mar 2024	20 Mar 2024	Not started	🔒	🔍

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.

Castor EDC Study Not Live (v0.21)

Monitoring **Queries** Actions Filters

Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to res...
<input type="checkbox"/> 100004	Test Institute			test	test	New	2	2
<input type="checkbox"/> 100004	Test Institute			a	done	Resolved	0	2
<input type="checkbox"/> 100001	Test Institute			a	a	New	0	0
<input type="checkbox"/> 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.



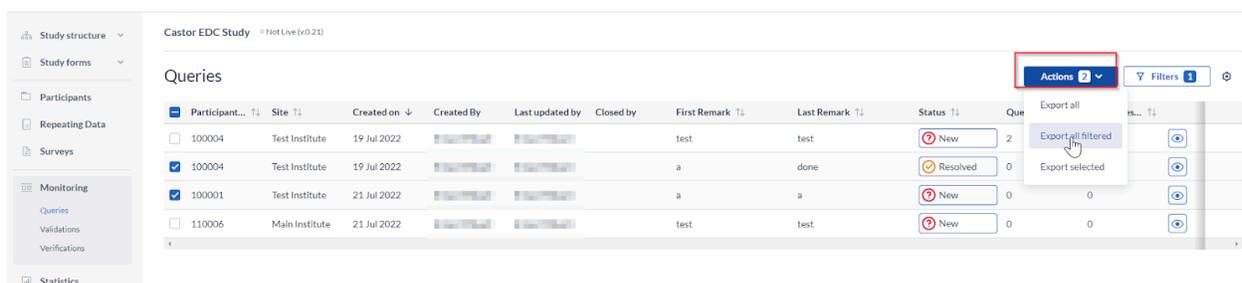
3. Closed.



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 ▼

- 📁 Entire study
 - 📁 Visits
 - 📁 Repeating Data

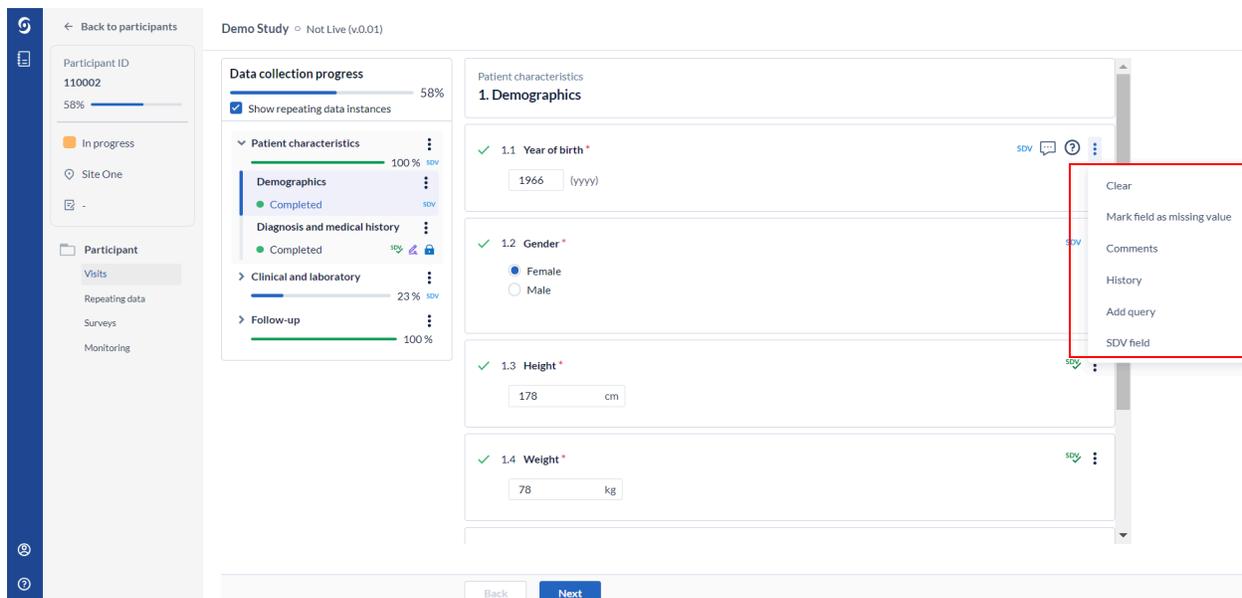
i Only queries for which you have Export permissions will be Exported

Cancel Export

3.4. Missing Pages

3.4.1 Mark field as missing value

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 'Mark field as missing value'. This option can be accessed by clicking on the three dots next to the field and selecting 'Mark field as missing value':



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:

Mark field as missing value
×

Please select a reason for missing the value on field "Year of birth".

Reason *

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

Comment

Cancel

Mark as missing

The field marked as missing will be faded/grayed 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.

⊙
1.1 Year of birth *

SDV
⋮

(yyyy)

If needed, it is possible to remove the 'Mark field as missing value' entry by clicking on the three dots and selecting the checkbox 'Unmark field as missing value'. This will remove the previous 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 value

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:

The screenshot displays the Castor interface for a 'Demo Study' (Not Live, v.0.11). On the left, a sidebar shows the participant ID '110002' with a 58% data collection progress bar. Below this, there are sections for 'In progress', 'Site One', 'Group B', and a 'Participant' folder containing 'Visits', 'Repeating data', 'Surveys', and 'Monitoring'. The main area shows 'Data collection progress' at 58% with a 'Show repeating data instances' checkbox checked. A list of data categories includes 'Patient characteristics' (100% SDV), 'Clinical and laboratory' (23%), and 'Follow-up' (100%). A context menu is open over the 'Patient characteristics' entry, listing actions such as 'Mark visit as missing value' (highlighted with a red box), 'Lock this visit', 'Sign this visit', 'Apply custom verification', 'Remove all SDV', 'Print this visit', and 'Add a repeating data instance'. Below the menu, a data entry for '1.3 Height*' is visible with a green checkmark.

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

Mark visit as missing value ×

Please select a reason for missing the value on visit "Patient characteristics".

Reason *

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

Comment

Marking a visit as missing cannot be undone and may affect signatures, verifications and dependencies related to the visit. Proceed with caution.

Cancel

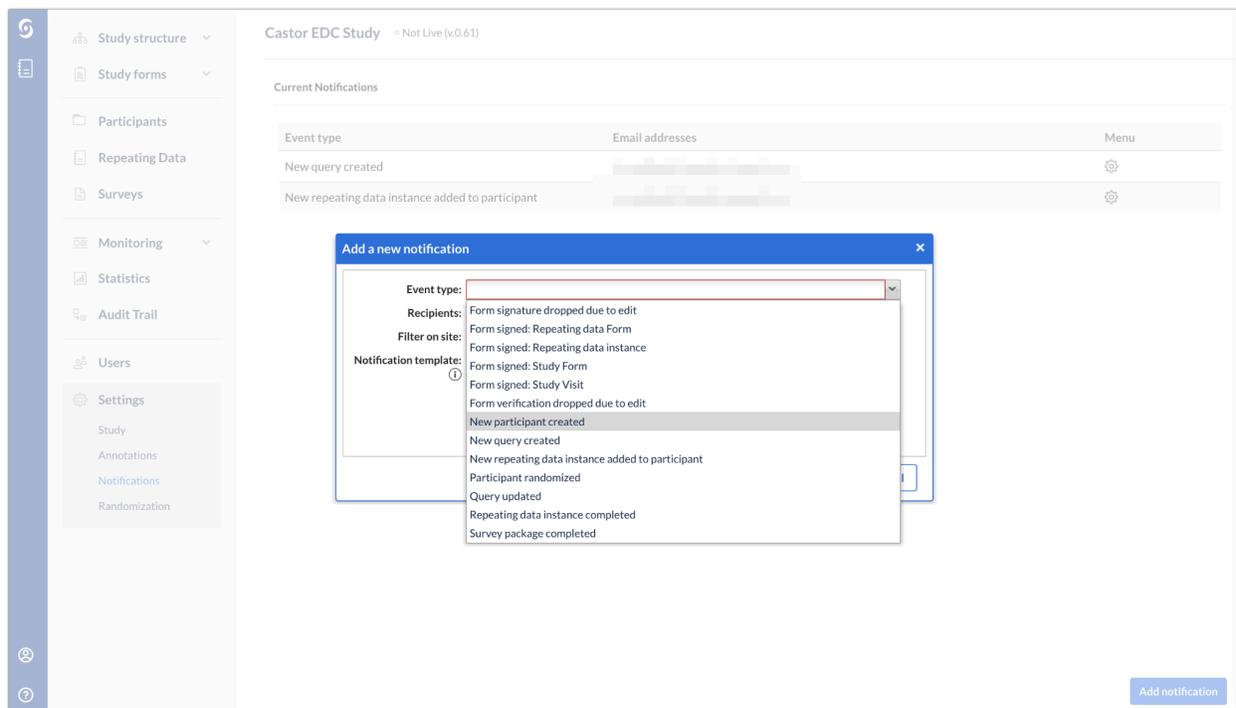
Mark as missing

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:

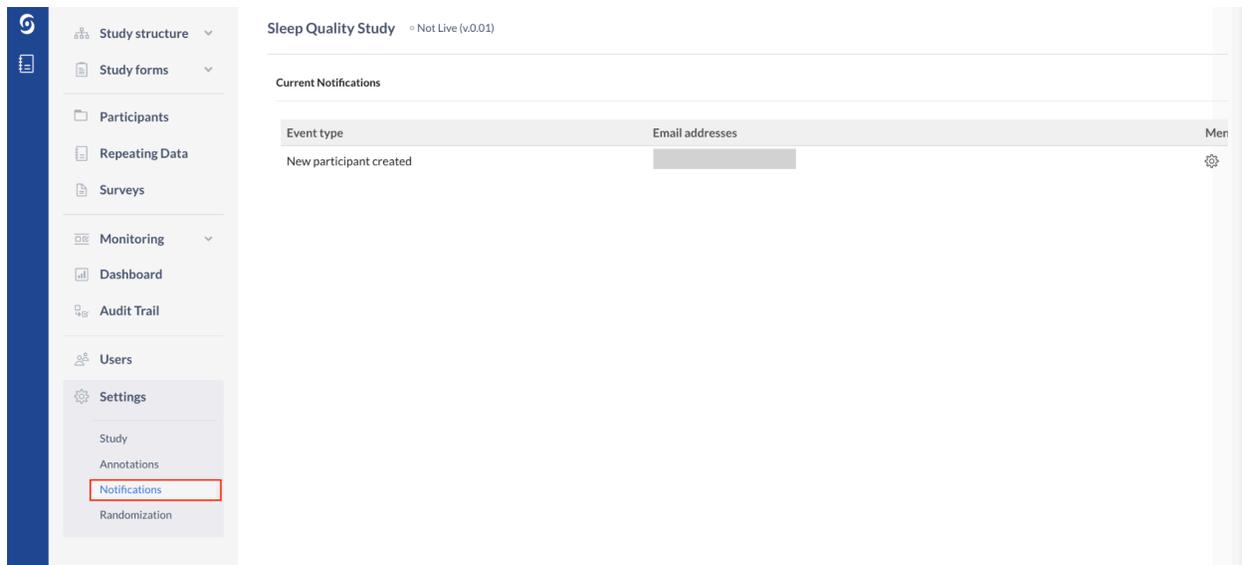
- Field result: Repeating Data
- Field result: Study
- Field result: Survey
- Form signature dropped due to edit
- Form signed: Repeating Data
- Form signed: Repeating Data Form

- 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.

Back to participants

Participant ID
110002
58%

In progress

Site One

Group B

Participant

- Visits
- Repeating data
- Surveys
- Monitoring

Demo Study ◦ Not Live (v.0.11)

Data collection progress

58%

Show repeating data instances

- Patient characteristics 100% SDV
- Clinical and laboratory 23% SDV
- Follow-up 100%

Patient characteristics

1. Demographics

VER This form was verified on

SDV This form was verified on

VISIT

- Mark visit as missing value
- Lock this visit
- Sign this visit
- Apply custom verification
- Remove all SDV
- Print this visit
- Add a repeating data instance

1.3 Height *

- 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.

Data collection progress

58%

Show repeating data instances

- Patient characteristics 100% SDV
- Clinical and laboratory 23% SDV
- Follow-up 100%

Patient characteristics

1. Demographics

- This form was signed on 14/06/2024 at 14:37 by John Smith (connecttraining2023@gmail.com). Remove
- VER This form was verified on 14/06/2024 at 14:24 by John Smith for Data manager review. Remove
- SDV This form was verified on 14/06/2024 at 14:24 by John Smith for Source Data Verification. Remove
- This form was locked on 14/06/2024 at 14:37 by John Smith (connecttraining2023@gmail.com). Unlock

1.1 Year of birth *

(yyyy)

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.

Participants + New Actions Filters

Participant Exact match

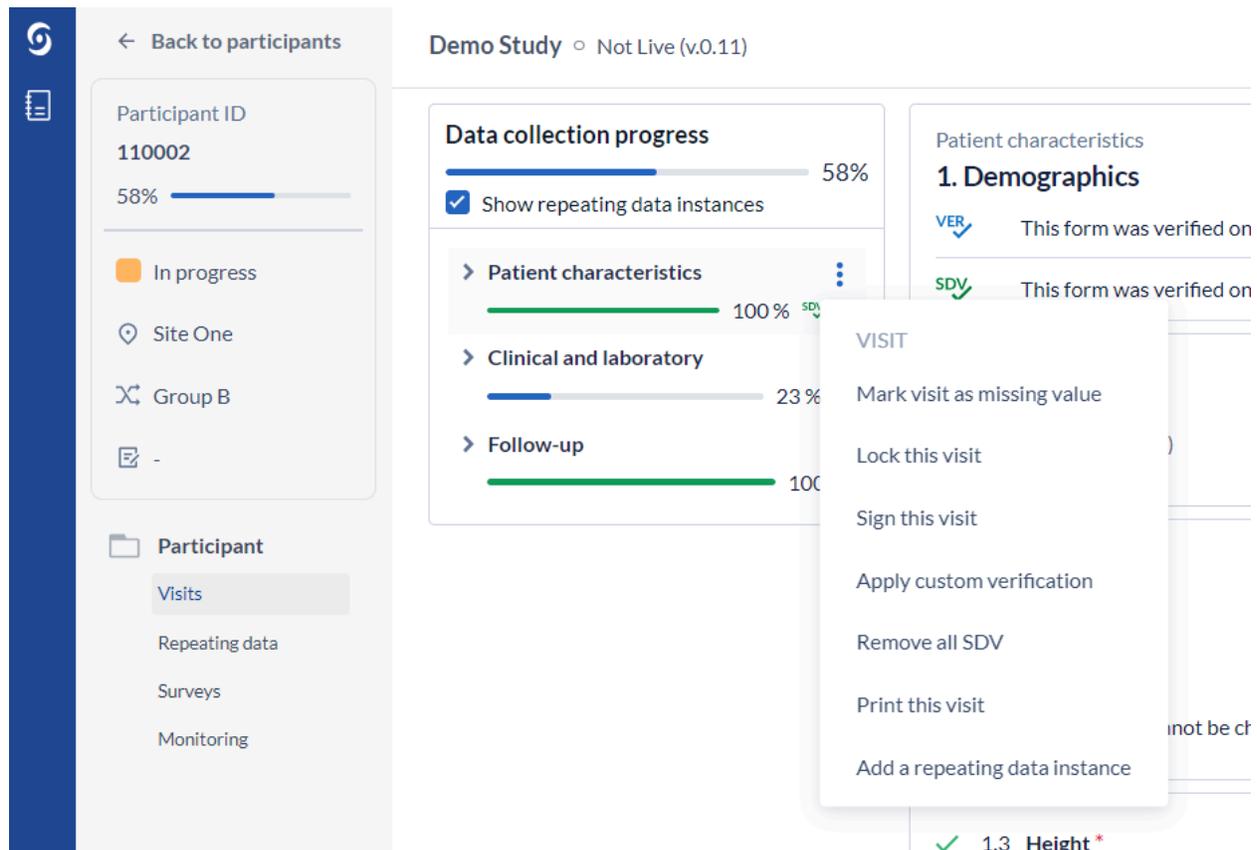
List Visit Form

<input type="checkbox"/>	Participant...	Site	Randomizatio...	Survey co...	Progress	Created on	Updated on	Status	
<input type="checkbox"/>	110001	Site One	-	-	<div style="width: 100%;"></div>	20 Mar 2024	03 Apr 2024	In progress	<ul style="list-style-type: none"> Apply signature Print Export Update status Update site Update email address Archive Delete
<input type="checkbox"/>	110002	Site One	Group B	-	<div style="width: 100%;"></div>	20 Mar 2024	14 Jun 2024	In progress	
<input type="checkbox"/>	110003	Site One	-	-	<div style="width: 100%;"></div>	20 Mar 2024	14 Jun 2024	Completed	
<input type="checkbox"/>	110004	Site One	-	-	<div style="width: 50%;"></div>	20 Mar 2024	14 Jun 2024	In progress	
<input type="checkbox"/>	110005	Site One	-	-	<div style="width: 100%;"></div>	20 Mar 2024	20 Mar 2024	Completed	
<input type="checkbox"/>	110006	Site One	-	-	<div style="width: 0%;"></div>	20 Mar 2024	20 Mar 2024	Not started	

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:

Data collection progress

58%

Show repeating data instances

- > Patient characteristics 100% SDV VER LOCK
- > Clinical and laboratory 23% SDV
- > Follow-up 100%

Patient characteristics

1. Demographics

	This form was signed on 14/06/2024 at 14:37 by John Smith (connecttraining2023@gmail.com).	Remove
<small>VER</small>	This form was verified on 14/06/2024 at 14:24 by John Smith for Data manager review.	Remove
<small>SDV</small>	This form was verified on 14/06/2024 at 14:24 by John Smith for Source Data Verification.	Remove
	This form was locked on 14/06/2024 at 14:37 by John Smith (connecttraining2023@gmail.com).	Unlock

SDV 1.1 Year of birth * SDV CHAT HELP MORE

(yyyy)

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 within a form that document the protocol or informed consent versions. Doing this allows this information to be documented for each participant.

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.

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