Castor

Castor CDMS Data Management User Guide

Version 2024.1

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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

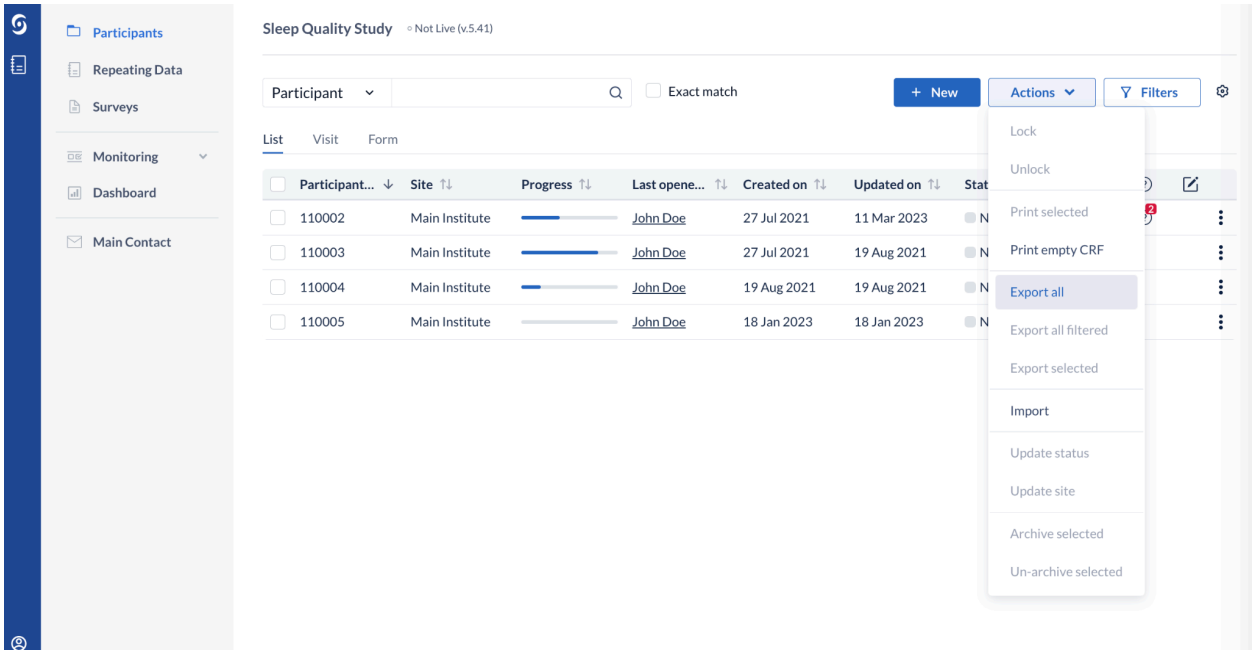
1.1. CRF Review

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

1.1.1. Data Dictionary

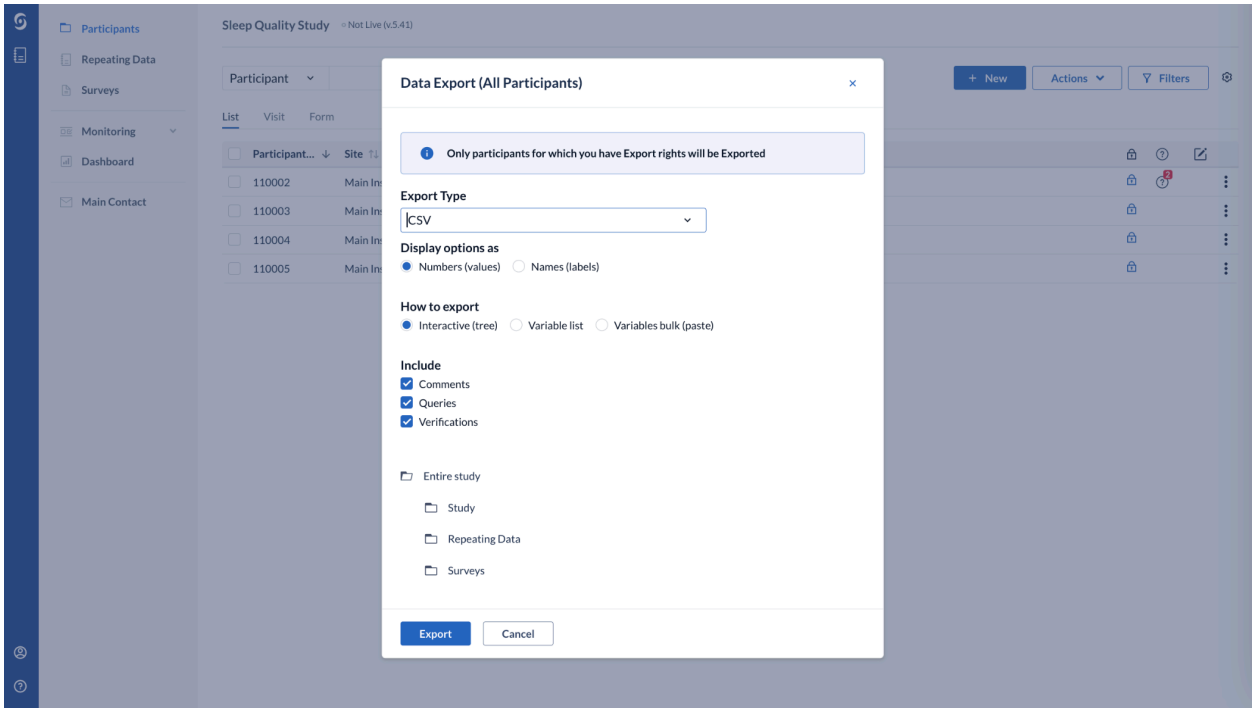
A data dictionary is included with each data export. The data dictionary includes all of the variables within the study, including option groups, and field dependencies.

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.



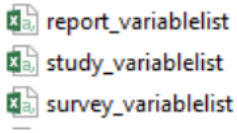
In the 'Data Export' window:

1. Select either Excel or CSV.



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

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



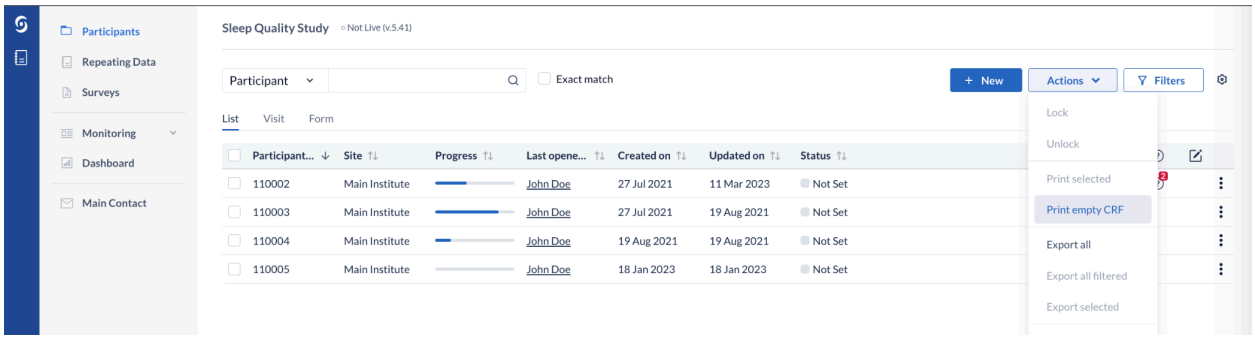
2. Select 'Entire Study'.
3. Click 'Export'. Once the file has been exported successfully the user will receive a completion email. You can select the link located within this email and be directed

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

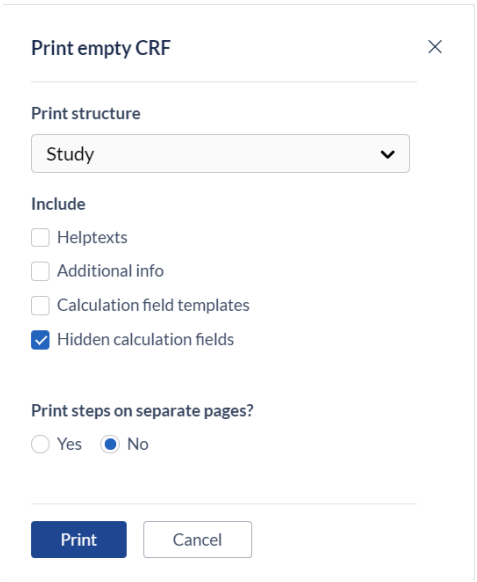
Study variables, repeating data variables, and survey variables will be exported as separate variable lists.

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.



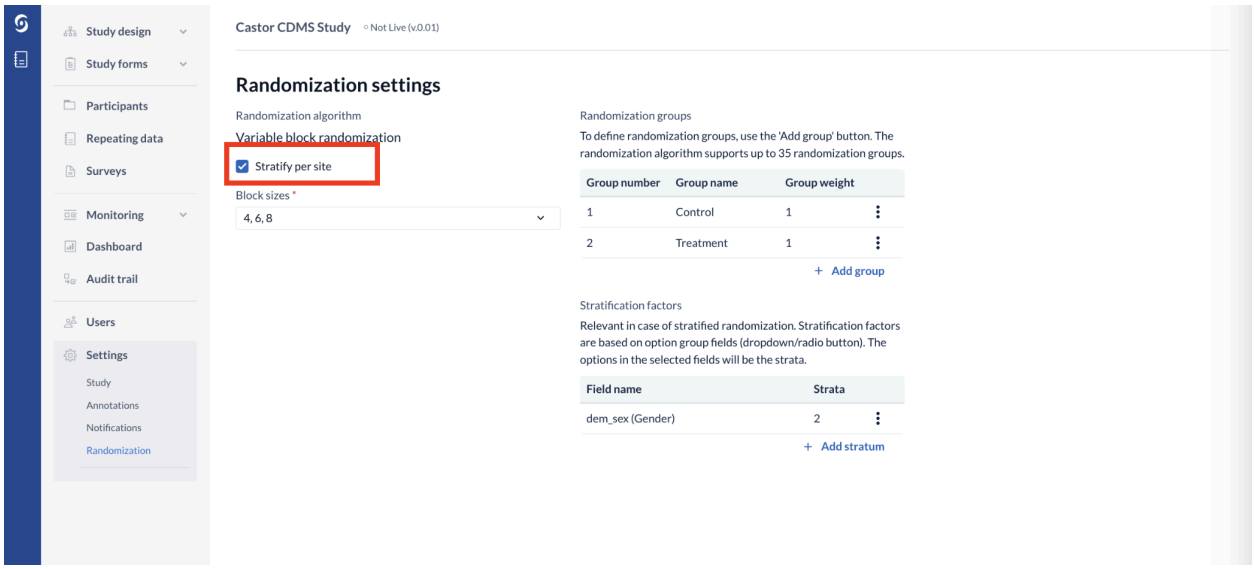
- Select the structure (Study, Repeating Data, Surveys) you would like to print.
- Choose the options you would like to include in the PDF.
- Click ‘Print’.

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.

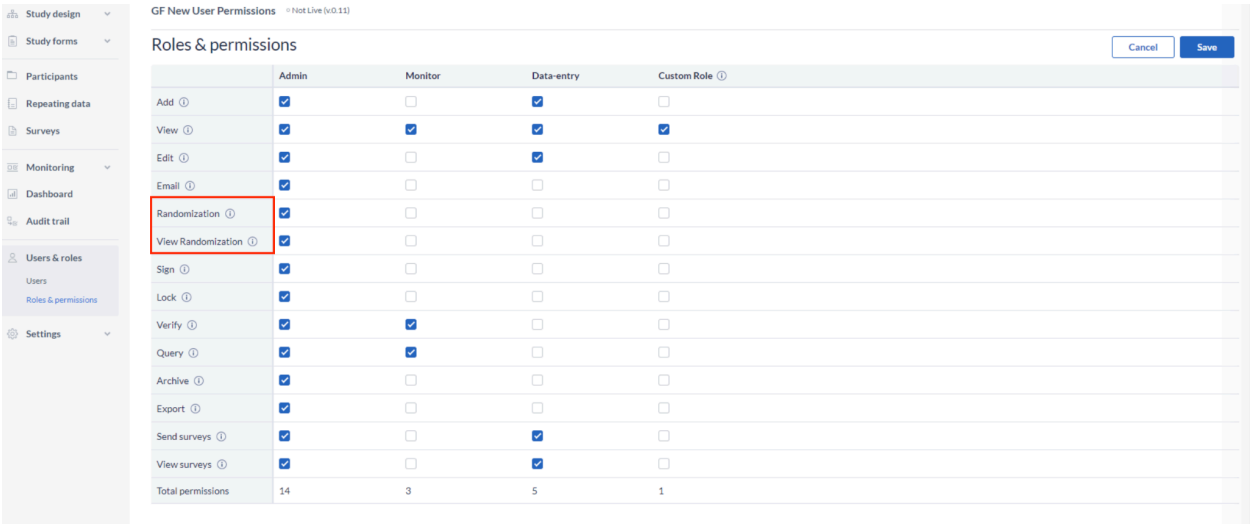
The option ‘Stratify per site’ is enabled by default.



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.

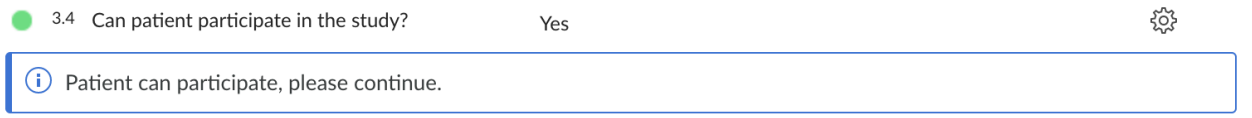
1.3. Data Validations/Edit Checks

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.

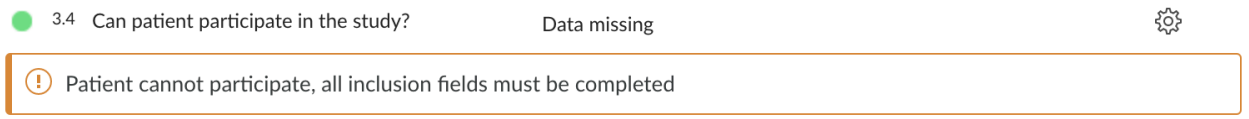
1.3.1. Data validation: Single Field

There are 4 validation types:

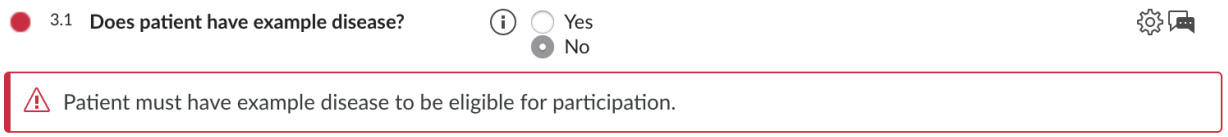
- **Message**: A simple indication message, outlined in blue, that the user needs to take a certain action.



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



- **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.



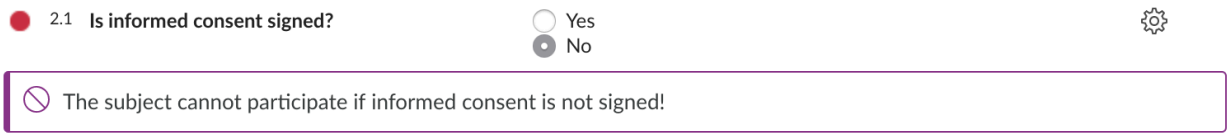
- **Exclusion**: A message in purple that excludes the subject from the study; when this message is visible the user, it is possible to navigate to different forms in a form:

- 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:

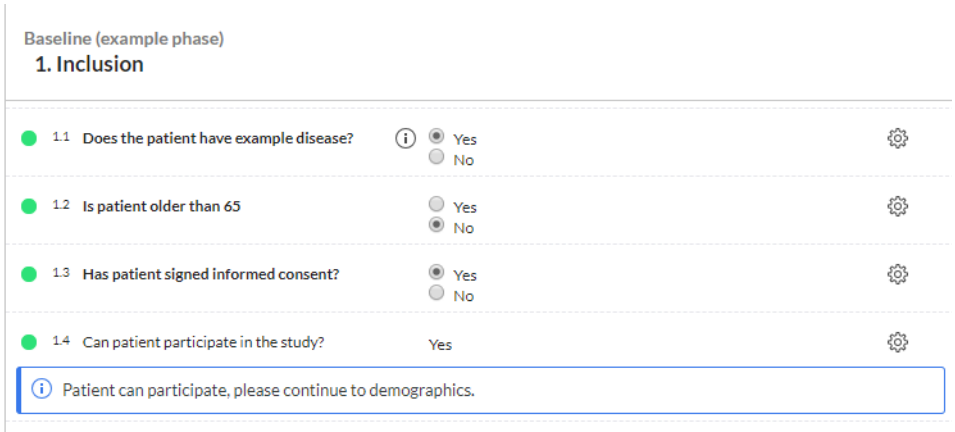
- If an exclusion occurs on a repeating data instance form, data entry is blocked on that repeating data instance form, but not blocked on any other repeating data instances or study data.

  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.



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 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.

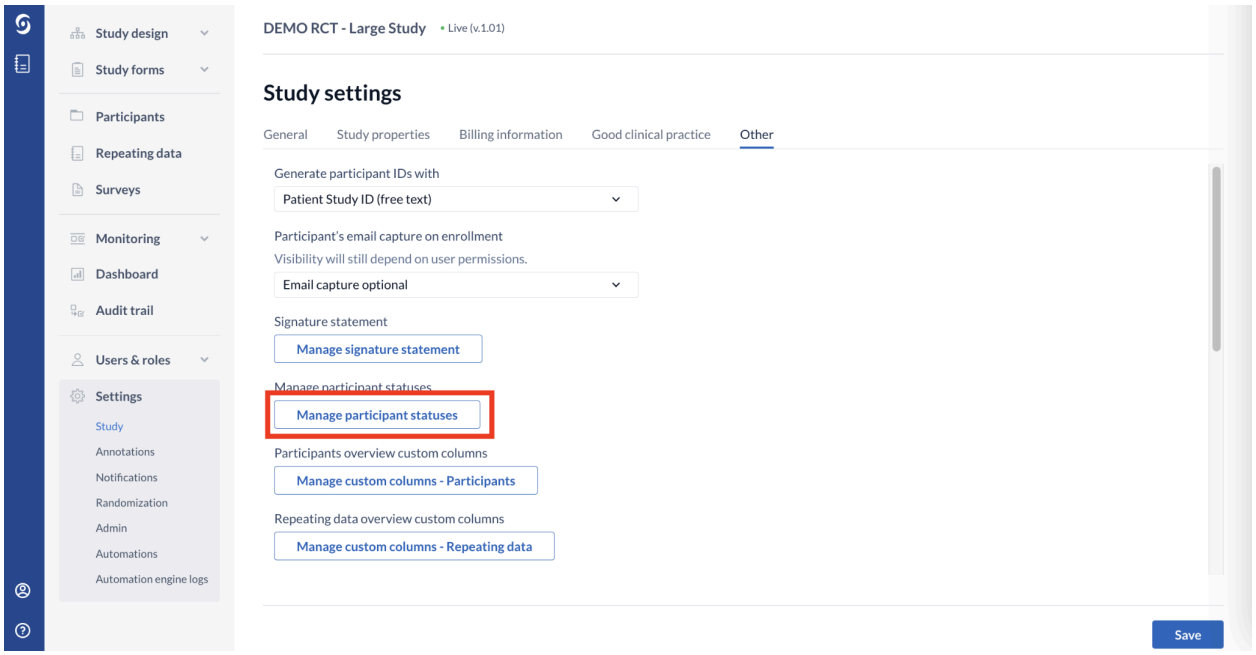
1.5.1 User Acceptance Testing Environment

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.

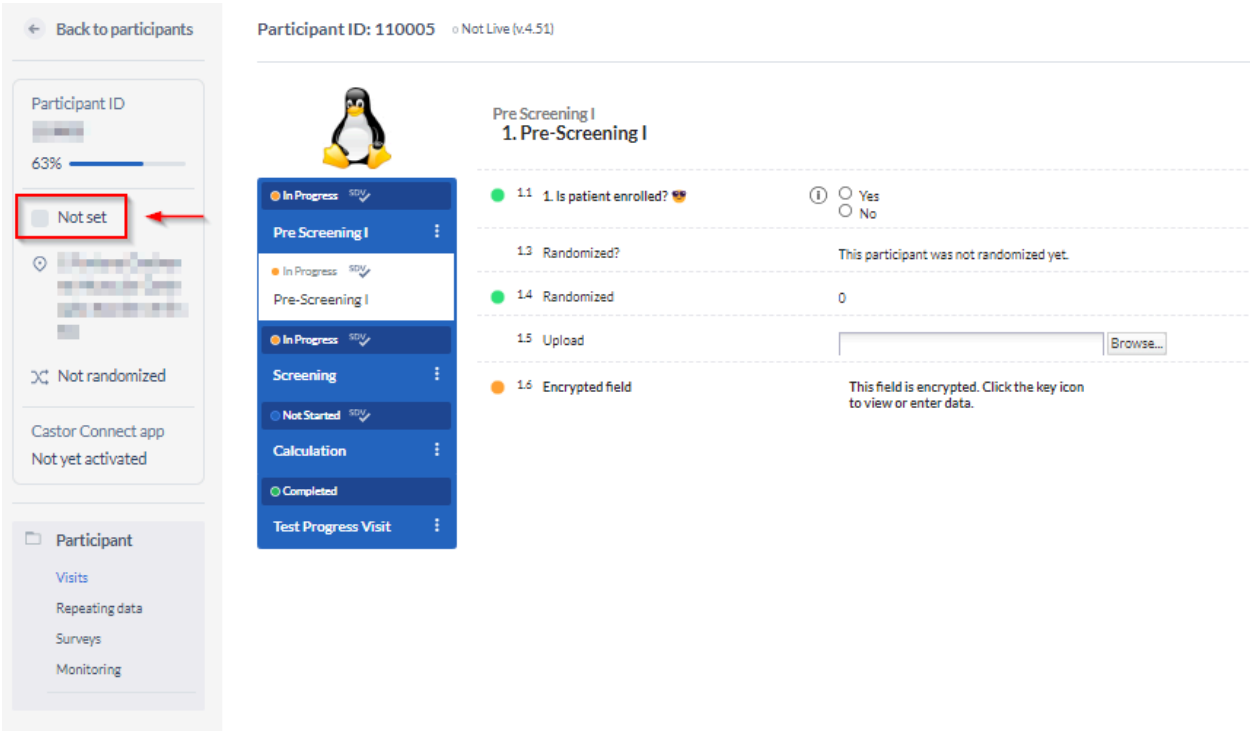
2. Tracking

2.1. Enrollment Status

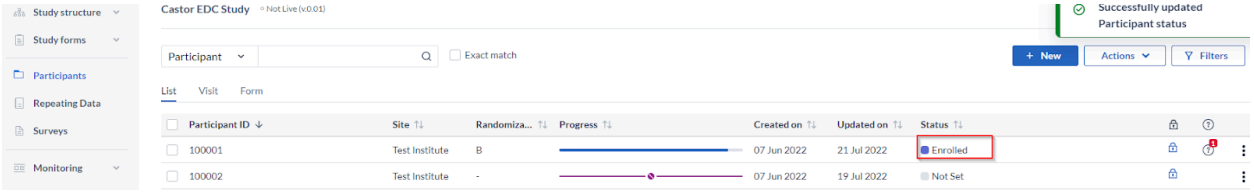
It is possible to track enrollment status using the 'Participant Status' feature in Castor CDMS. Study admins with 'Settings' permissions can create, update and delete participant statuses from the 'Study' settings, page 'Other' by clicking on the 'Manage participant statuses' button.



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



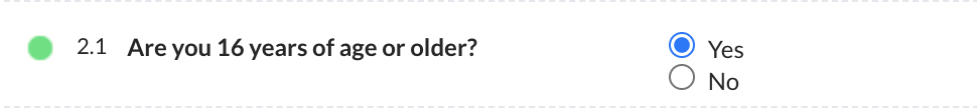
The participant status is also visible in the Participants overview in the Status column.



2.2 Progress of completion

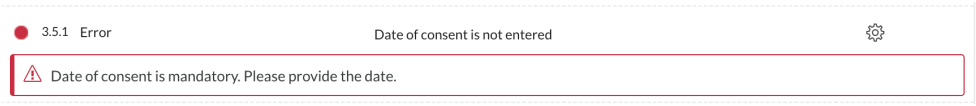
Completion for each area of the CRF is generally coded using colored status icons.

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

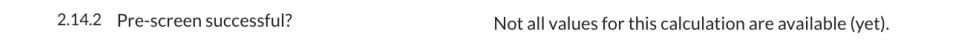


Orange Data is required and no input has been entered yet. For example, field 2.3:

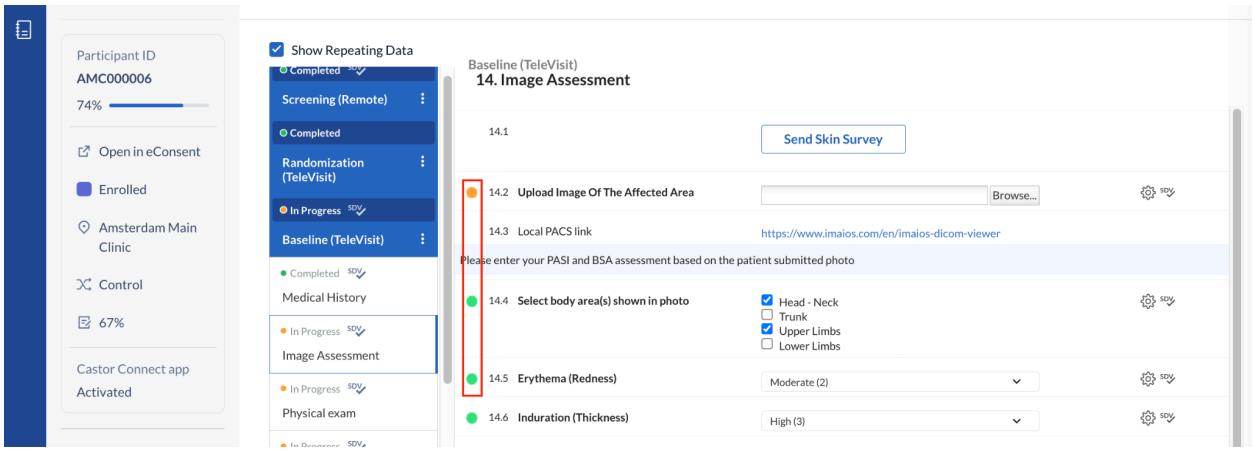
Red The input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message.



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



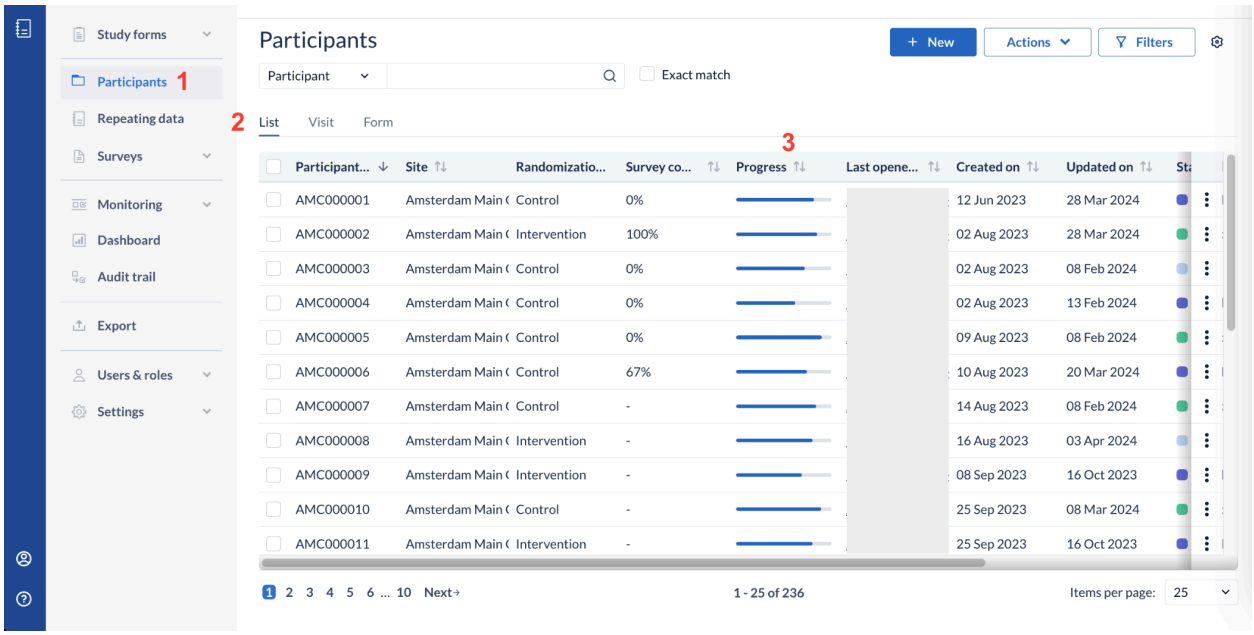
These field level status icons in data entry view are the lowest status level for progress indication in visits, forms, repeating data, and surveys.



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).

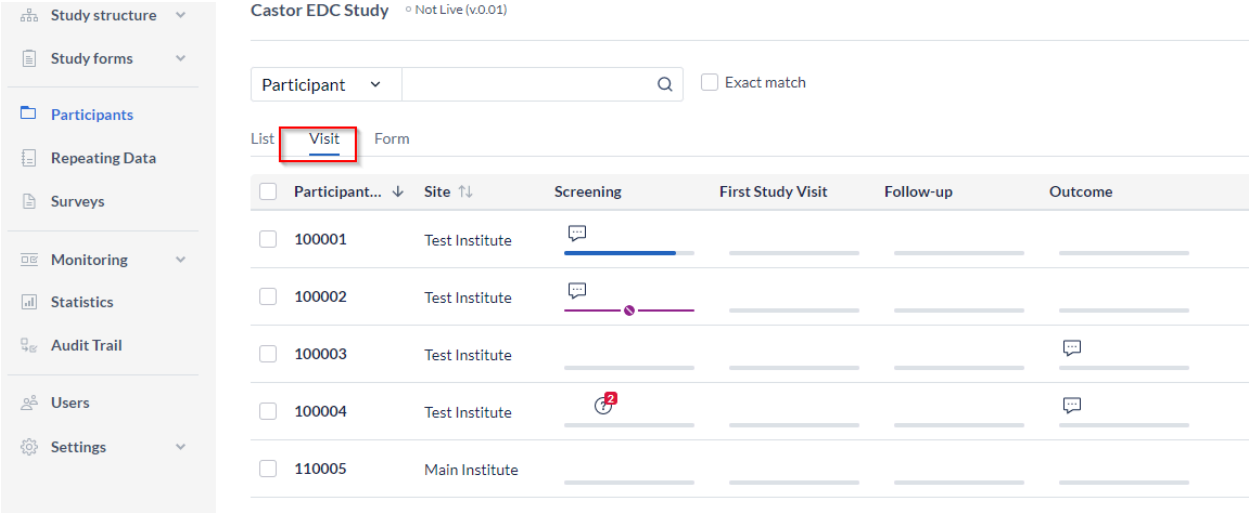


A participant will show as incomplete until required fields in all visits and forms are complete.

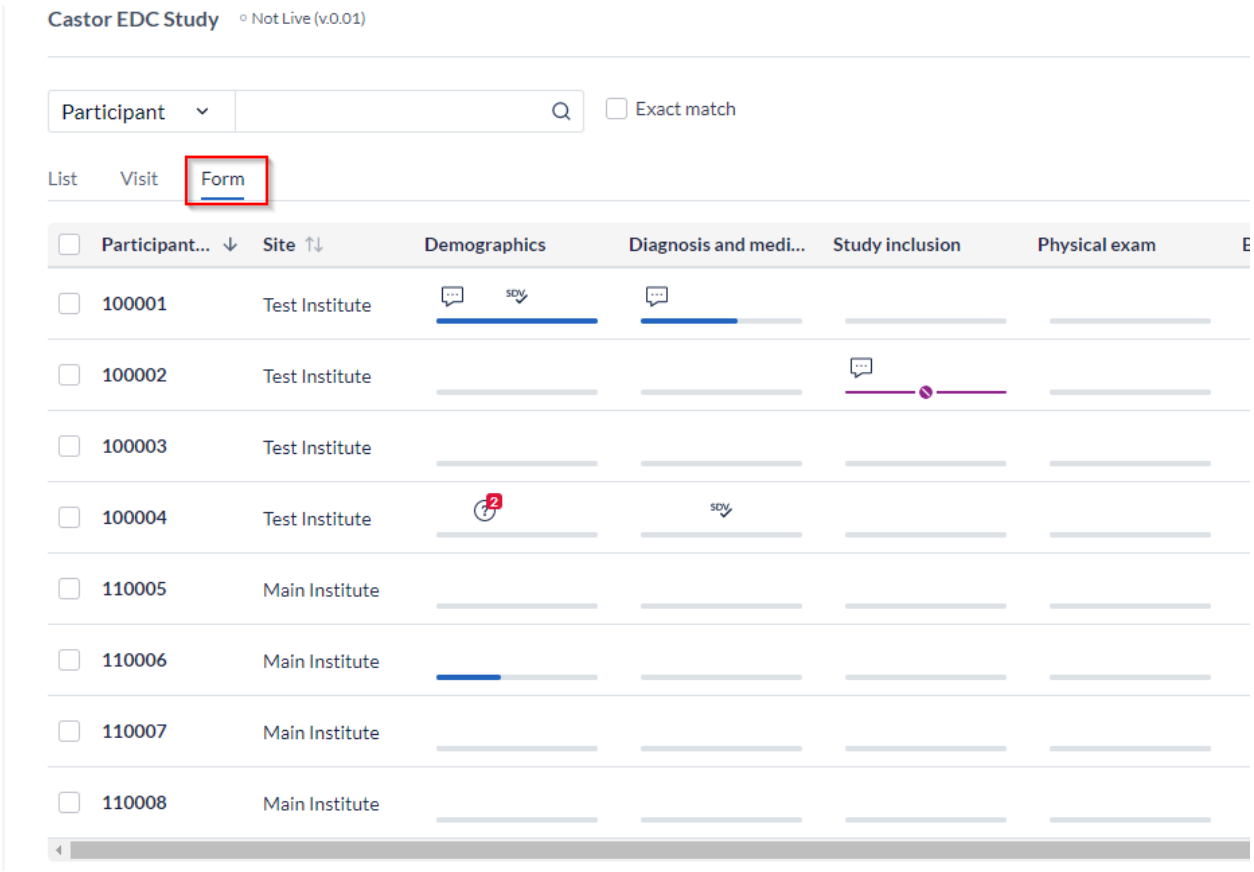
- **Green**: All field values are complete and valid.
- **Gray**: No values have been saved or data entry has not begun.
- **Blue**: Data Entry has started but is not complete.
- **Purple with an icon**: Patient is excluded from the study.

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.

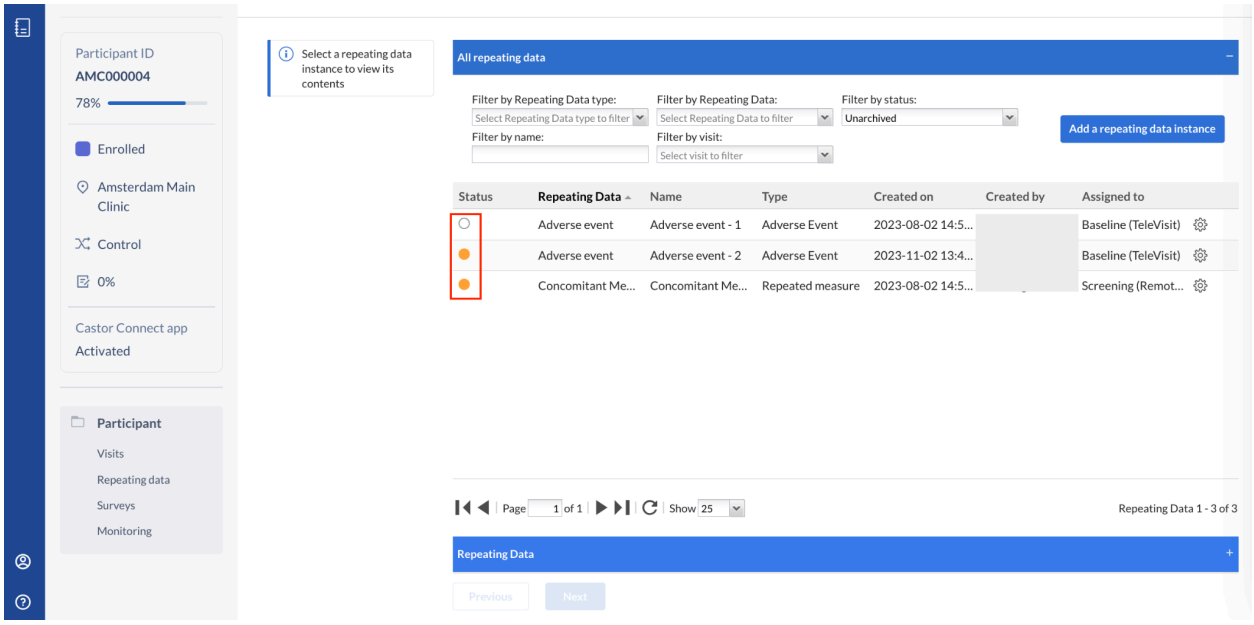


‘Form’ View provides an overview of the progress for each form.


Castor EDC Study
Not Live (v.0.01)
Participant
Exact match
List
Visit
Form
Participant...
Site
Demographics
Diagnosis and medi...
Study inclusion
Physical exam
100001
Test Institute
100002
Test Institute
100003
Test Institute
100004
Test Institute
110005
Main Institute
110006
Main Institute
110007
Main Institute
110008
Main Institute

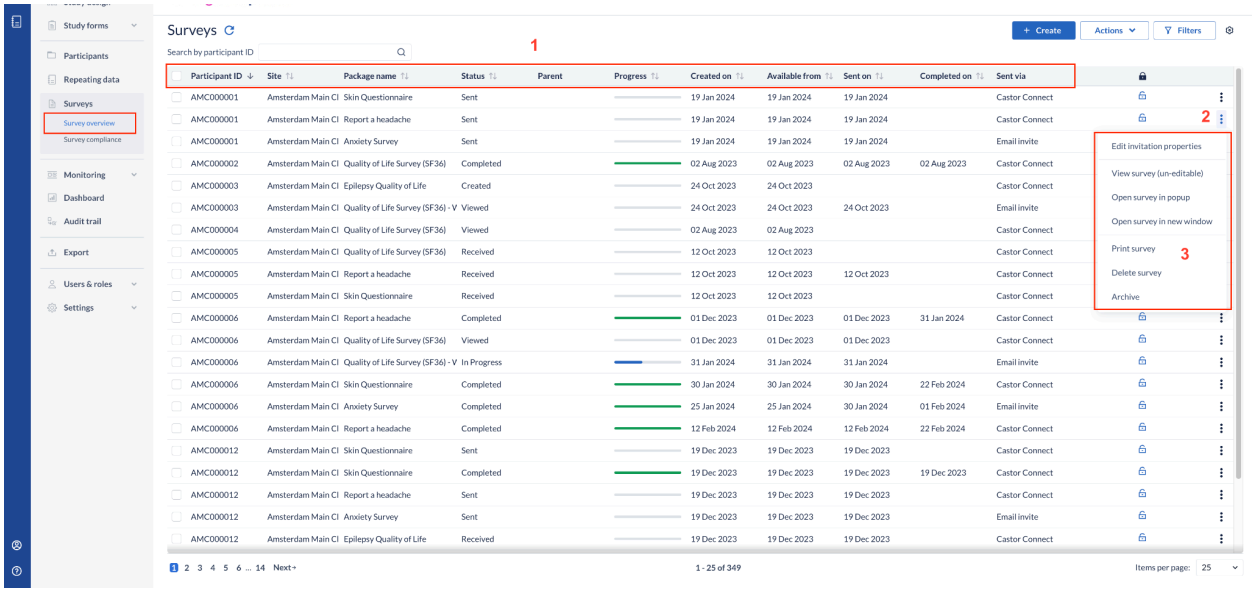
2.2.2 Repeating Data

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.



2.2.3 Surveys

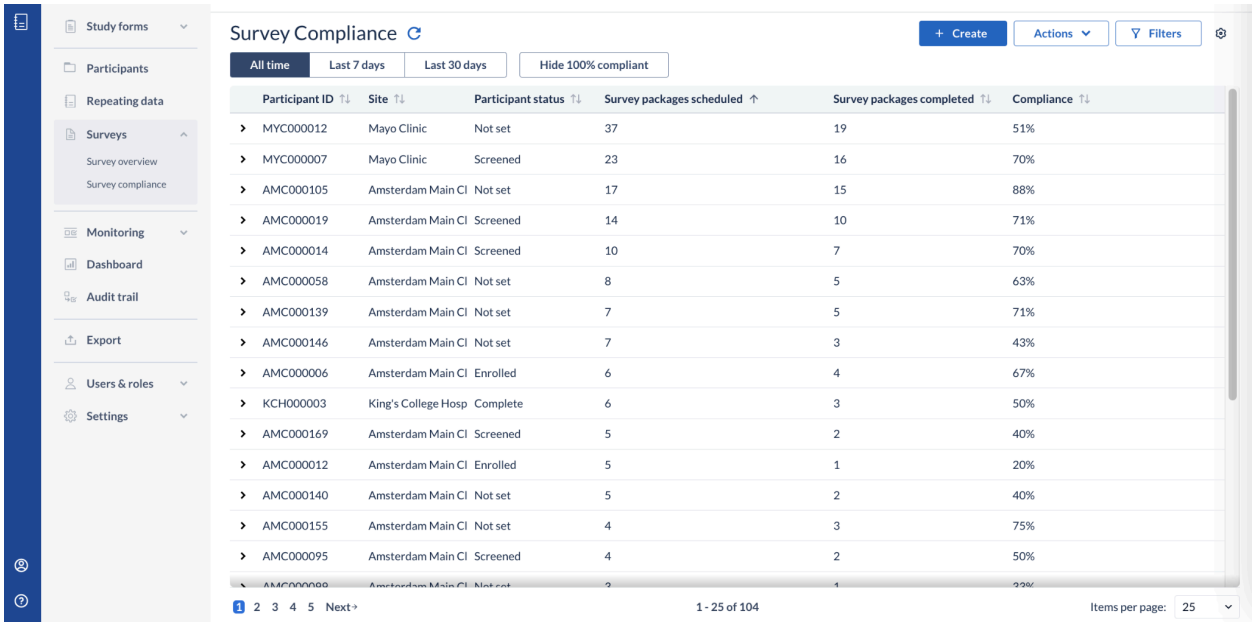
Survey progress is displayed as a percentage of required fields that have been completed in the 'Progress' column in the global Surveys tab (1). You further have the option to automatically lock surveys using the lock icon when a respondent submits a survey and create notifications each time a survey 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.



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.



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

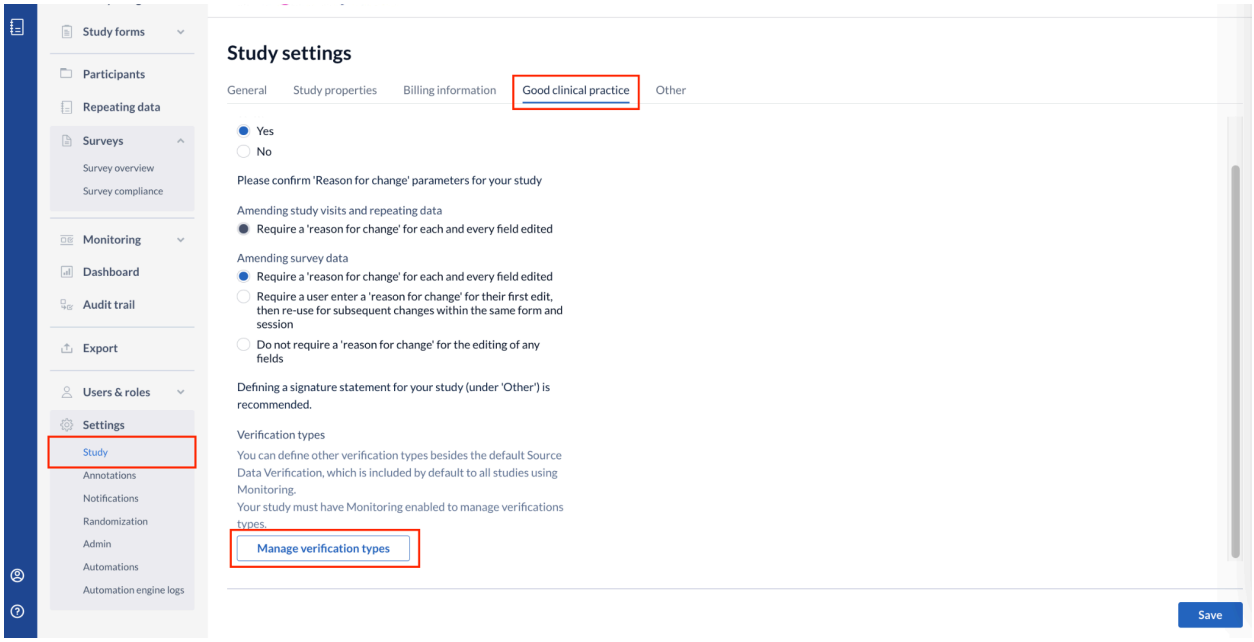
2.3.1 Verification

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.

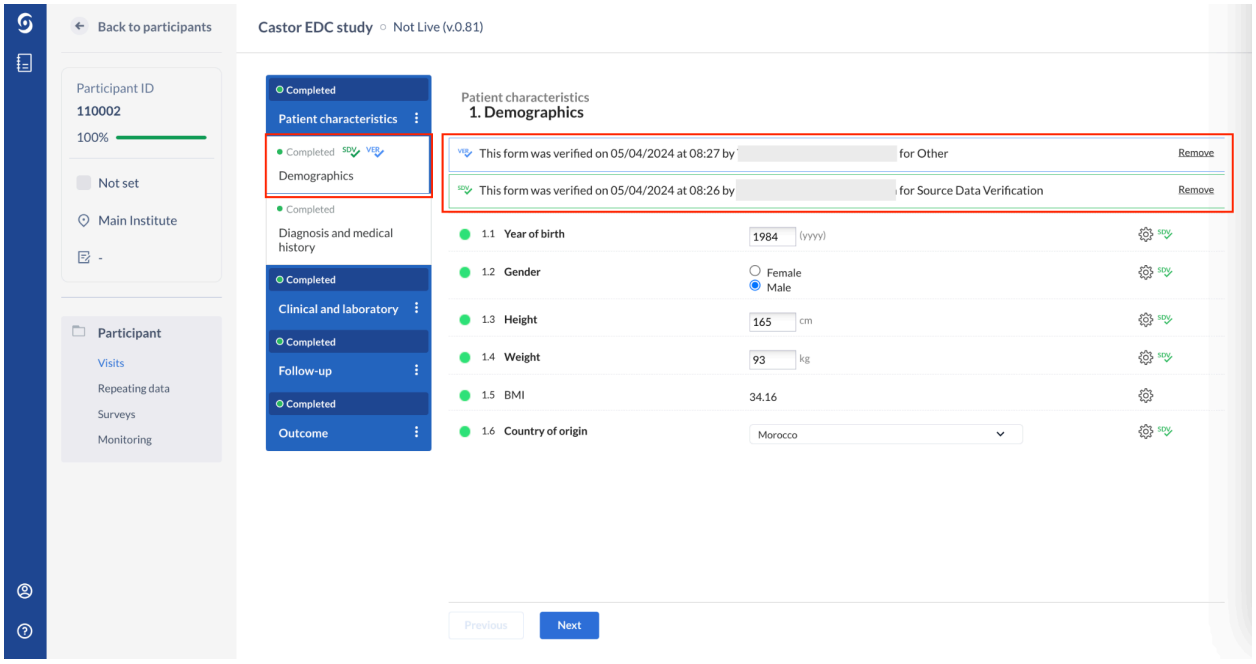
Data verification is linked to Monitoring, so to be able to use it, first enable Monitoring in your study settings. Please note that 'Monitoring' cannot be enabled for retrospective studies.

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.

Study structure
Study forms
Participants
Repeating Data
Surveys
Monitoring
Dashboard
Sleep Quality Study
Not Live (v.0.01)
Participant
Exact match
+ New
Actions
Filters
List
Visit
Form
Participant...
Site
Demographics
Diagnosis and medi...
Study inclusion
Physical exam
Blood test
110001
Amsterdam Institu

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 seperately. It is not possible to 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:

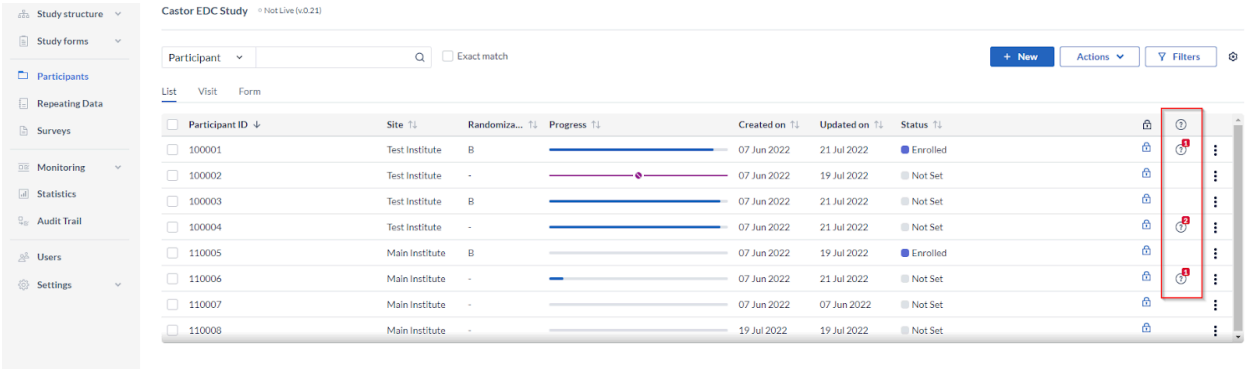
- EU: https://data.castoredc.com/api
- US: https://us.castoredc.com/api

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

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

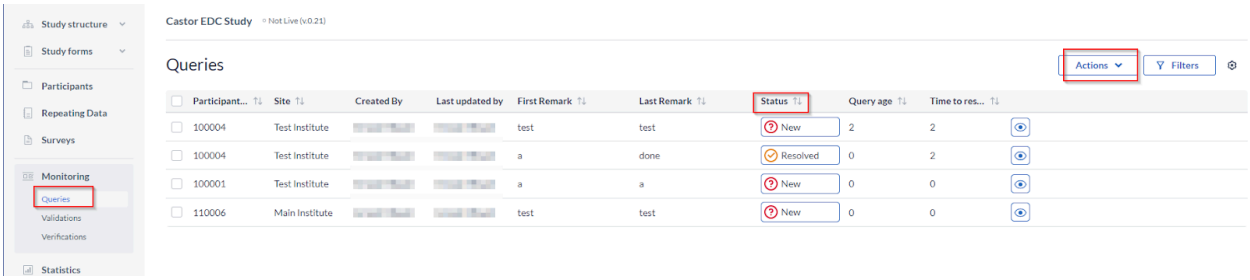
3.3. Data Queries

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.

   New Open Confirmed

2. Resolved.

   Resolved

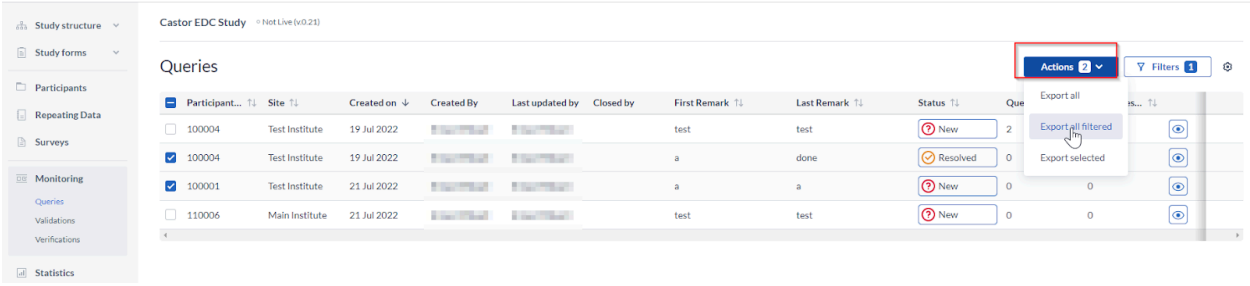
3. Closed.

   Closed

3.3.1 Exporting Queries

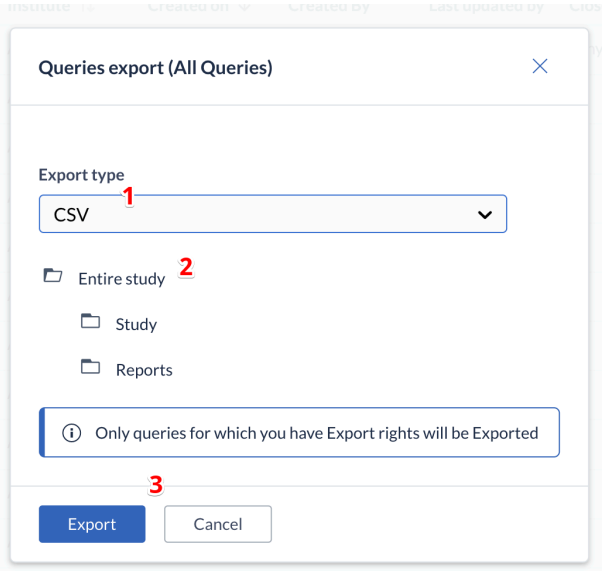
Users with Export rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the forms below:

- 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:

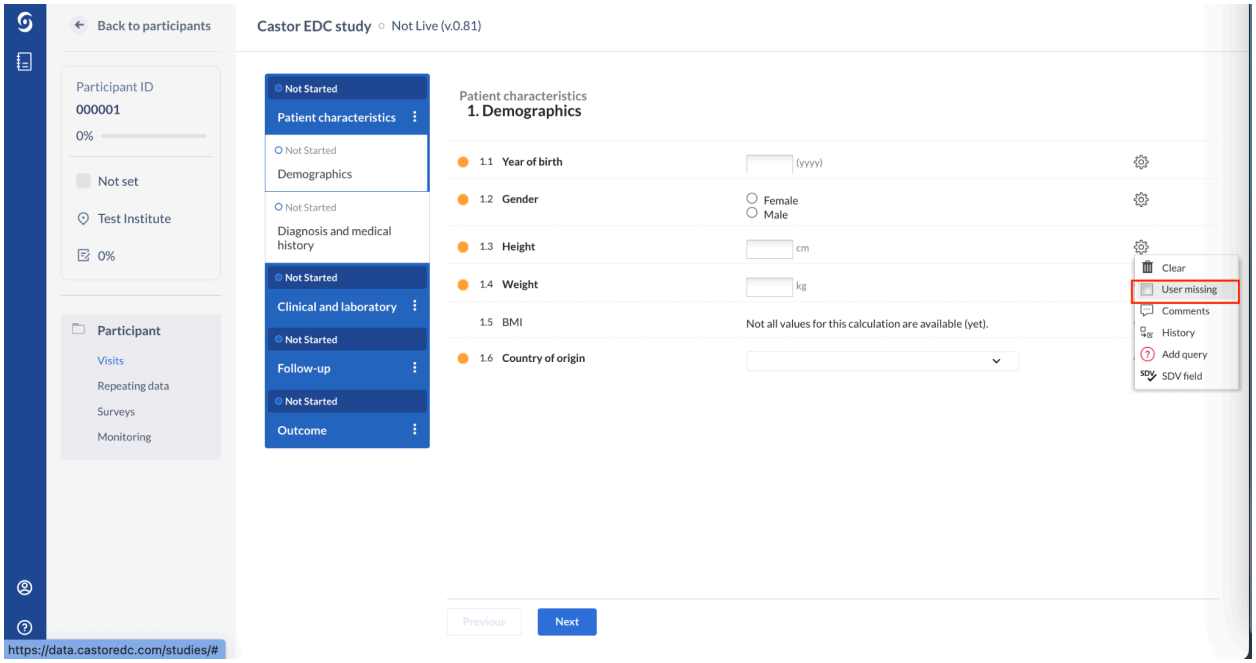
- Export type: choose to export into CSV or Excel (1)
- Export tree: choose if you would like to export queries for entire study, specific study visits or forms in your study or for repeating data, a specific repeating data or a repeating data form (2)
- Export: click on Export button to generate export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



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:

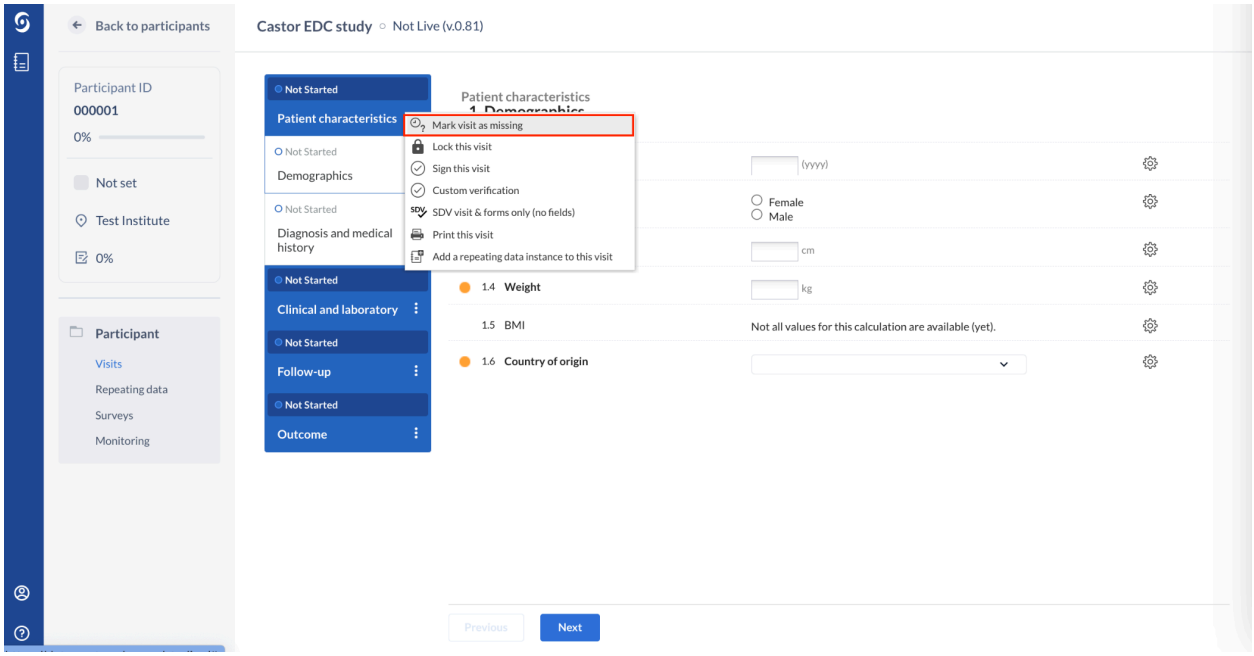
- Measurement failed (-95)
- Not Applicable (-96)
- Not asked (-97)
- Asked but unknown (-98)
- Not done (-99)

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.

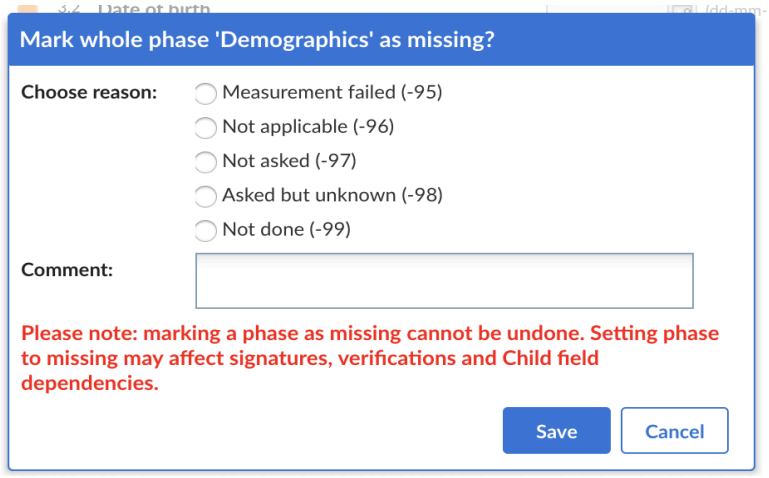
If needed, it is possible to remove the 'user missing' entry by clicking on the cogwheel menu and selecting the checkbox 'User missing' again. This will remove the 'User missing' status and allow entry of data into the field. The comment will be kept and each of these actions will be logged in the audit 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:

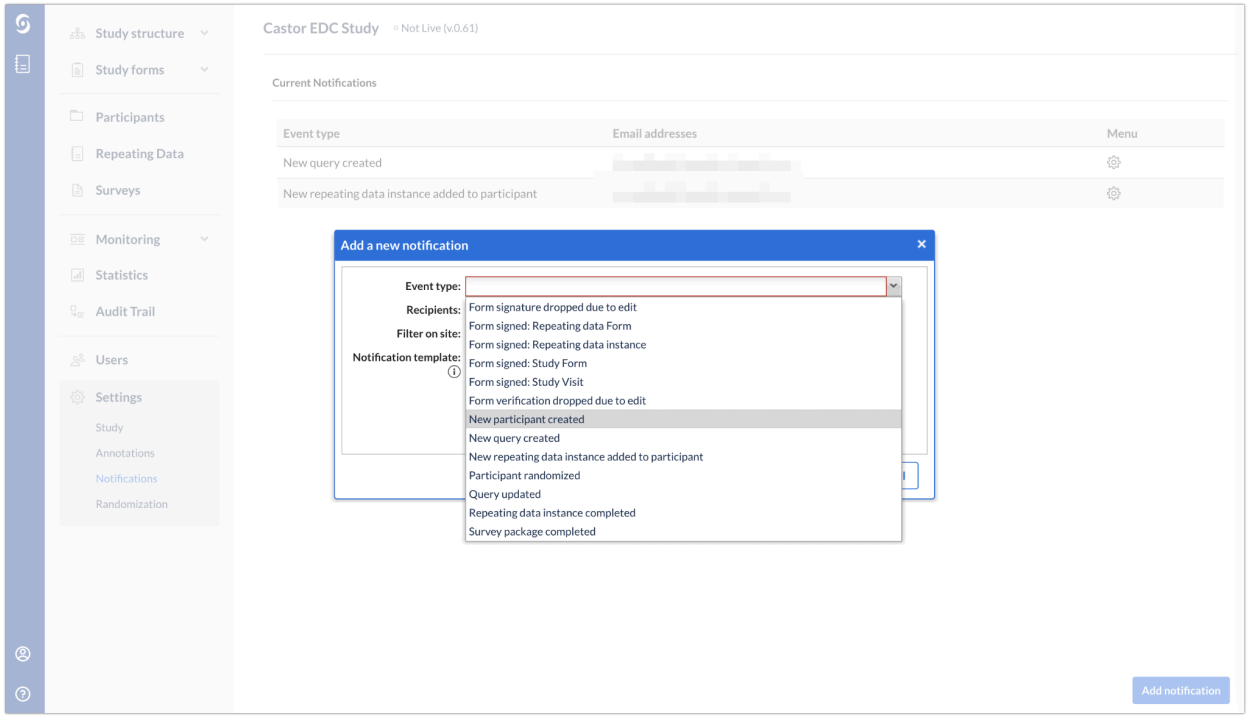


3.5. Notifications

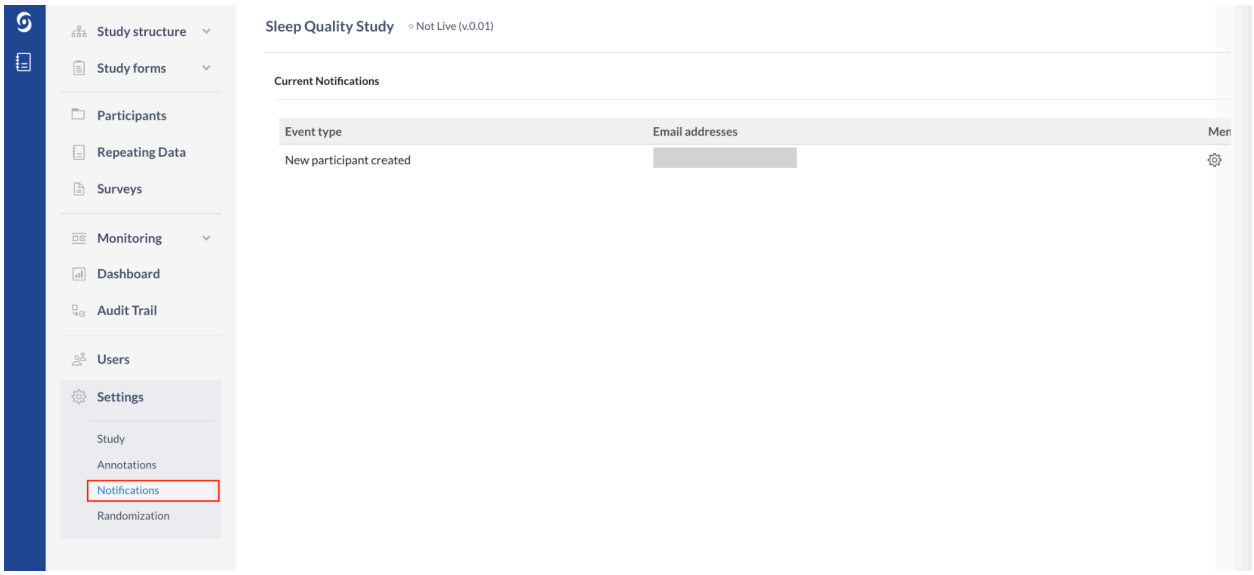
Notifications for specific study events can be created in the study settings. Notifications are not possible for individual fields or completion statuses. Available study events include:

- 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:



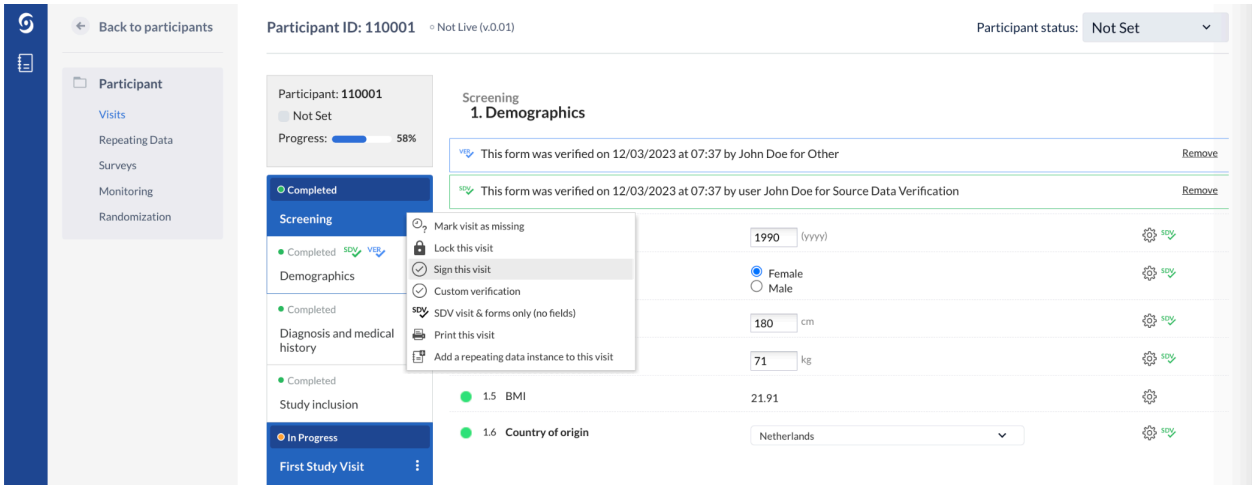
3.6. Signing and Locking

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.

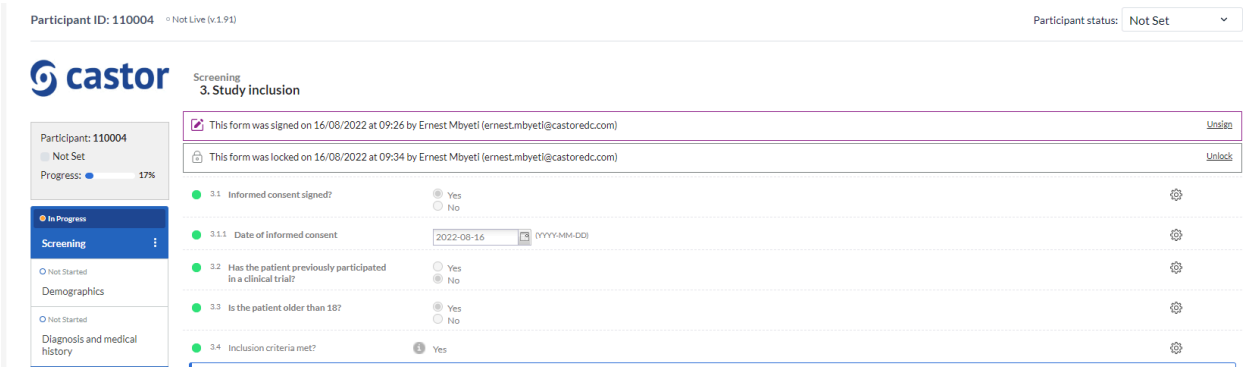
3.6.1 Sign or unsign a visit or form

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.



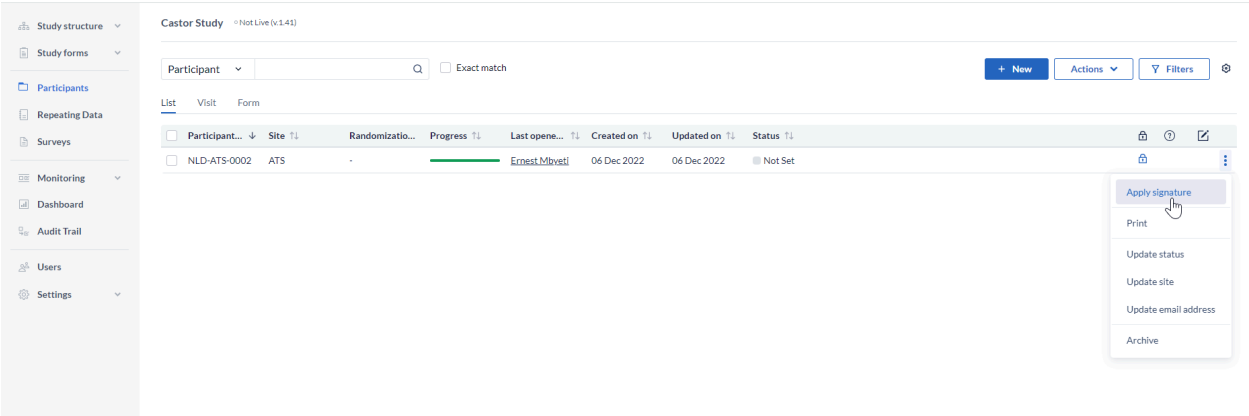
3. Enter your password to confirm your identity. You can choose to also lock the visit/form in the same instance, to prevent further data entry. Click "Sign" to confirm and to sign the visit or form. In order to lock during signing, it is necessary to have the lock user right. For users without the lock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

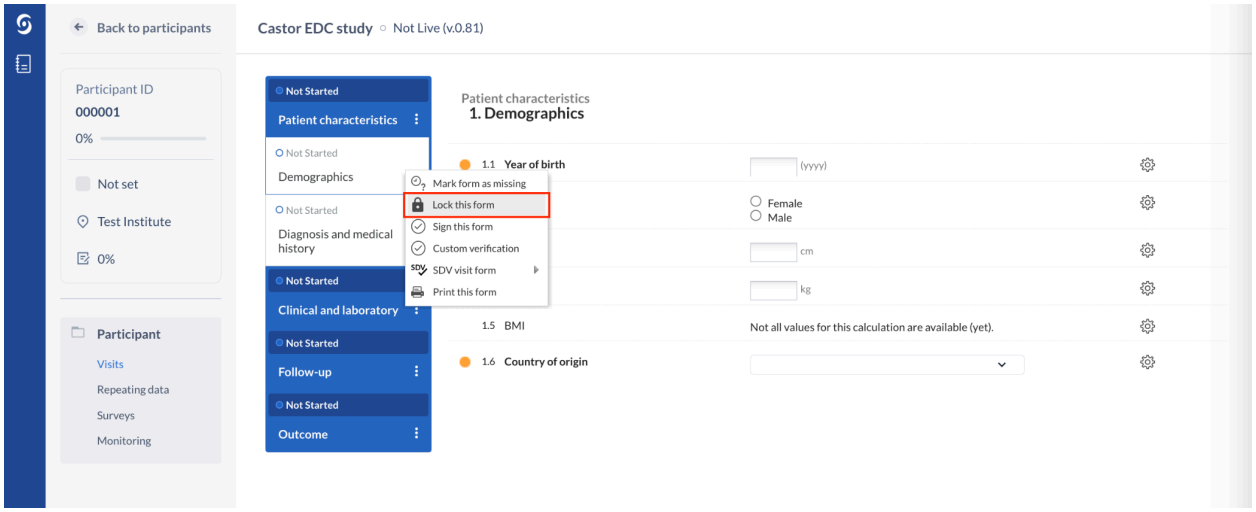
Castor CDMS offers the ability to seamlessly sign all forms of a selected participant at once, directly from the 'Participants overview' page.



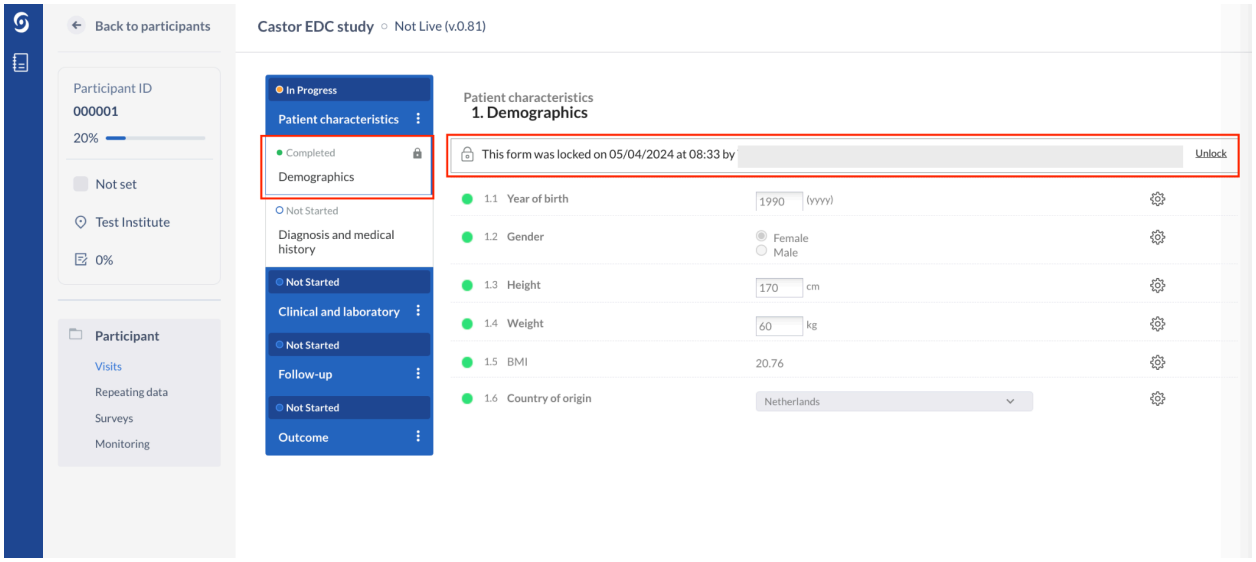
You will be prompted to enter your credentials in order to sign the participant. Additionally you can also select to lock the participant upon signing, by ticking the 'Lock participant' box.

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:

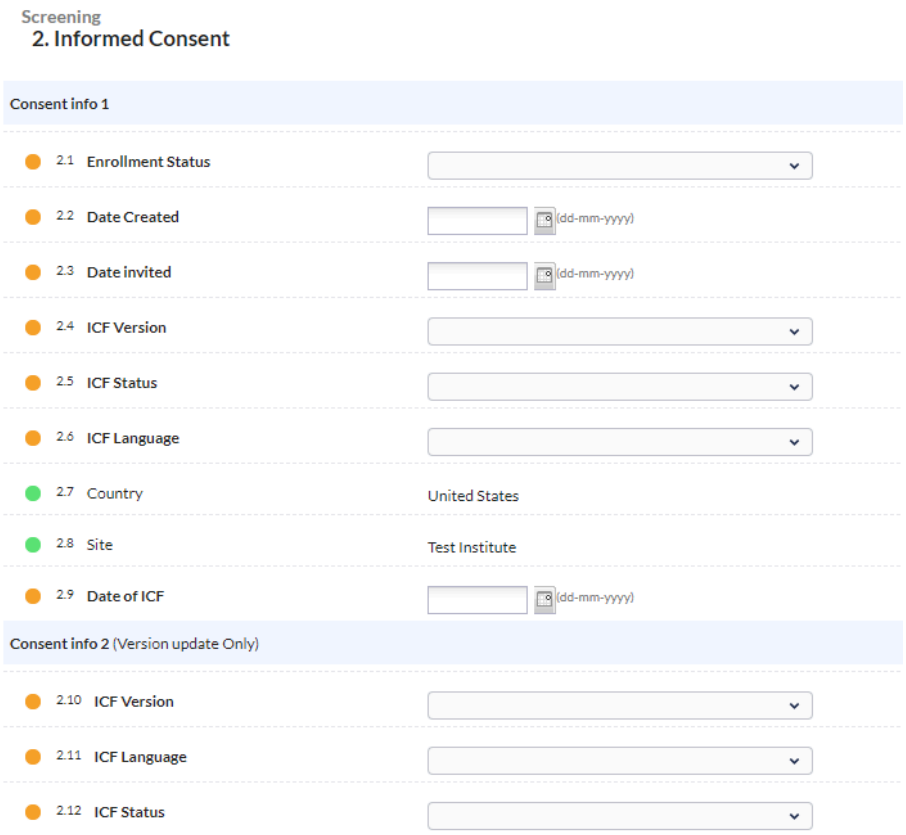


4. Study Conduct

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

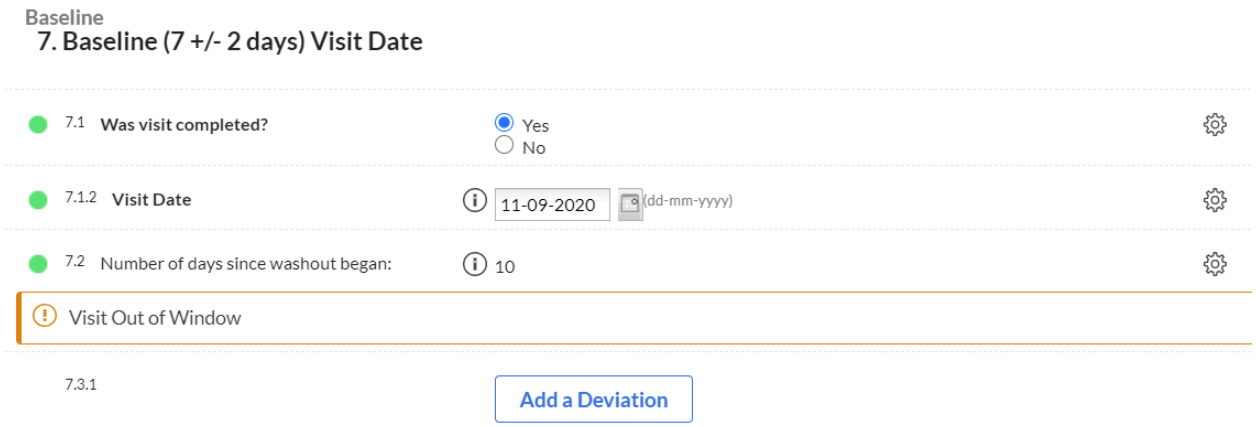
4.1 Protocol Amendments

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.

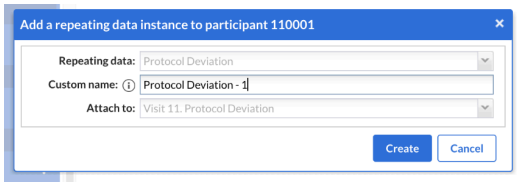


4.2 Deviations

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