Castor

Castor CDMS Monitoring User Guide

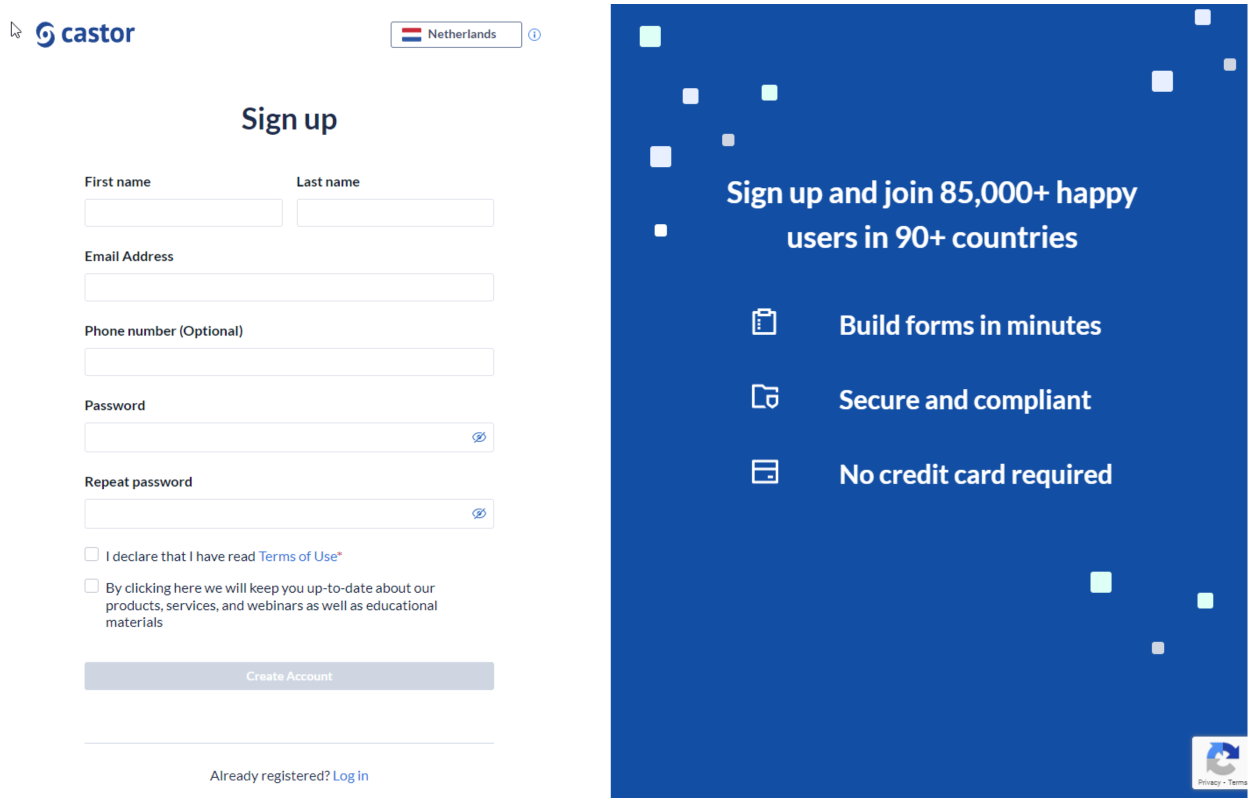
Version 2022.4

1. Register an account

There are two ways to register an account: a) via the registration page b) by being added to a study by a study administrator.

1.1. Registration page

You can go directly to our website to create an account before being invited to a study. You will choose the site to create your account based on the location of your study data. Navigate to one of the URLs below to access the registration page:



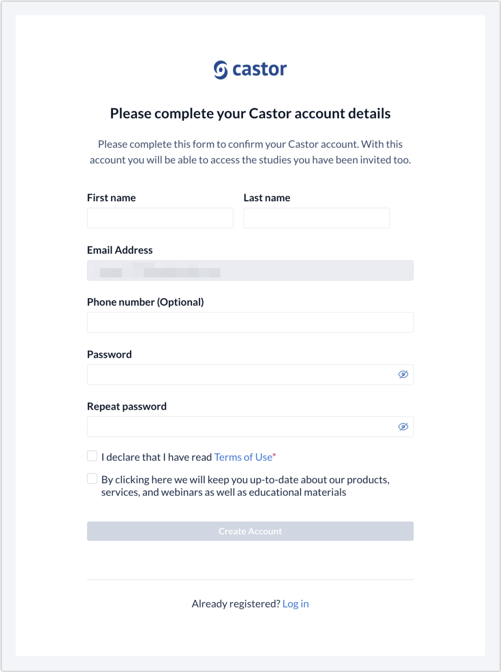
- EU Account: https://data.castoredc.com/register
- UK Account: https://uk.castoredc.com/register
- US Account: https://us.castoredc.com/register
- AU Account: https://au.castoredc.com/register

To register your Castor account:

1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number

1.2. User is added to a study

If a study administrator has added you to a study, you will receive an invitation by email for the study for which you need to do data entry. Click on the activation link in the email and it will redirect you to the registration page. To register Castor account:



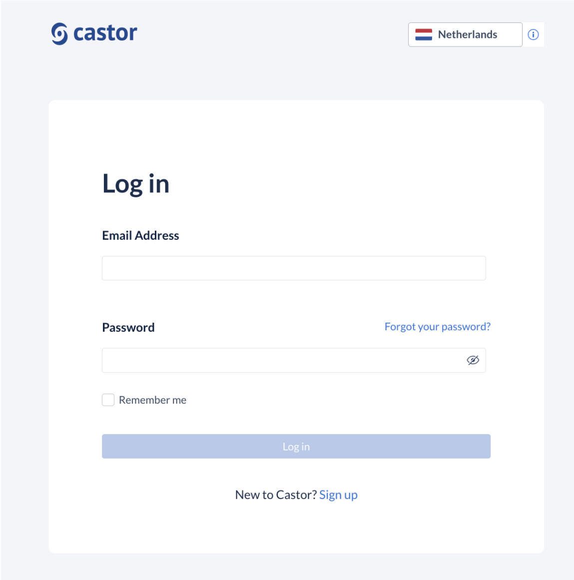
1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.

3. Click on ‘Register’. Shortly after registering your details, an email with an activation link will be sent to the email address you have provided. Click on this link to confirm that the supplied email address belongs to you and verify your account.

2. Log In

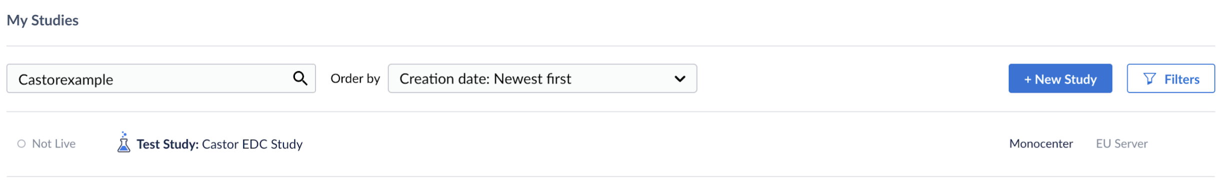
To access the study, log into Castor EDC via https://data.castoredc.com (NL server). If your study is on the US, AU or UK server, you can also directly go to https://au.castoredc.com/register,
http://us.castoredc.com or http://uk.castoredc.com, respectively.

1. Choose the server that is used for your study in order to be able to access the study.
2. Enter your email address and password.
3. Click on ‘Login’.

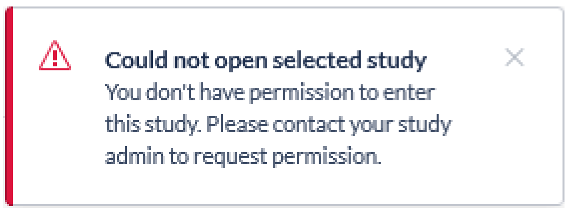


3. Open a study

Once you have logged into Castor EDC, you will see the ‘My Studies’ overview where all of the user studies (databases) are shown. If a study is live (indicated by a green button and ‘Live’ to the left of the study name), you can click on the study name to enter the study.



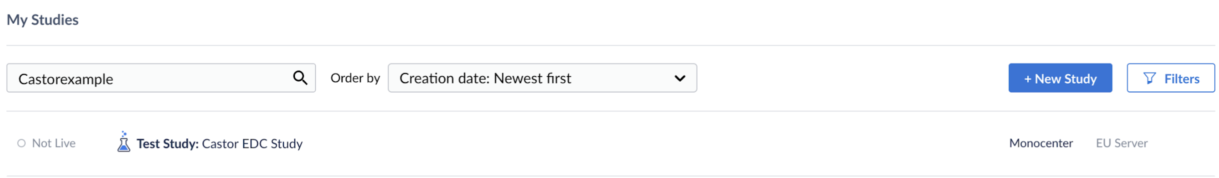
Trying to open a study that is not live will show the following warning:



If the study is still in maintenance mode (the button is blank, and the status says ‘Not Live’) you will only be able to open the study if you have management rights.

3. Access study for Monitoring

Once you have logged into Castor EDC, you will see the 'My Studies' page where all of the studies (databases) you have access to are shown. Only live studies can be accessed by monitors. If a study is live (indicated by a green button next to the study title), you can click on the study name to enter the study and perform your monitoring activities.

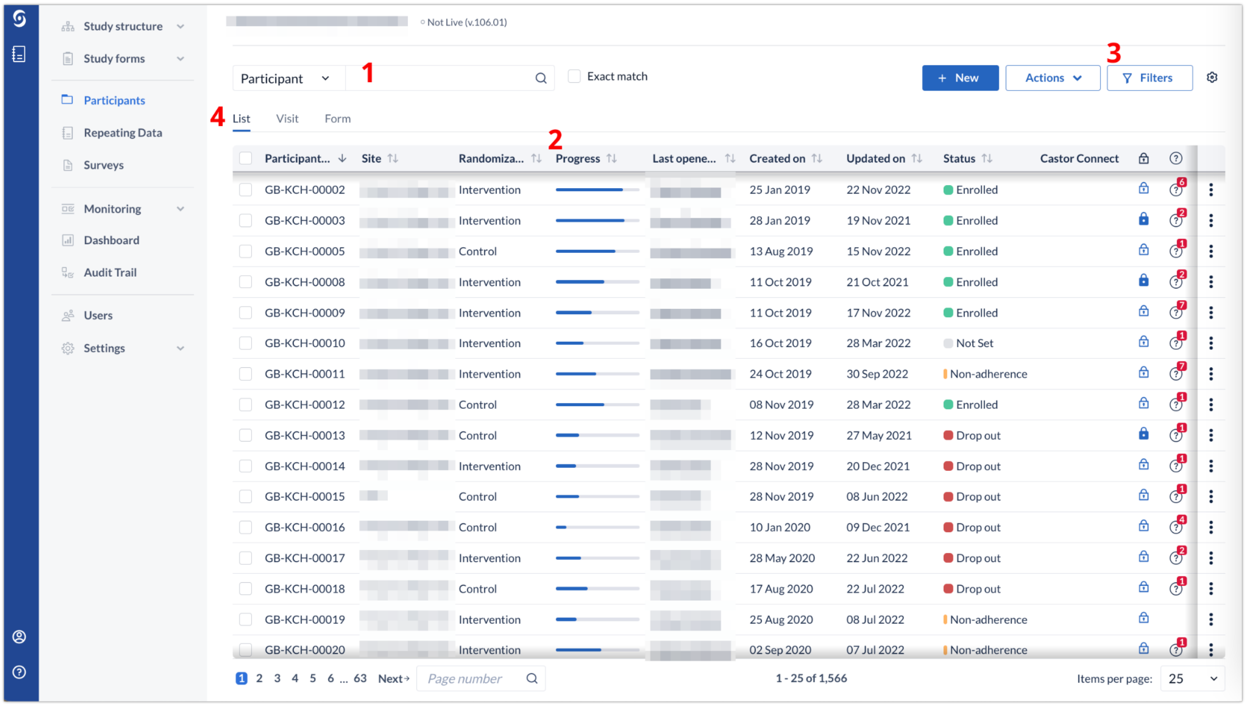


The study will open on the Participants tab. As a monitor, you will most likely see the following tabs:

1. **Participants**: Contains an overview of all participants in the study, where you can access the participants for data review.
2. **Repeating Data**: Contains an overview of all repeating data instances created within the study.
3. **Surveys**: In this tab, there is an overview of all the survey invitations that have been created, sent and filled.
4. **Monitoring**: Queries, validations, and verifications are shown in this tab.

4. The Participants tab

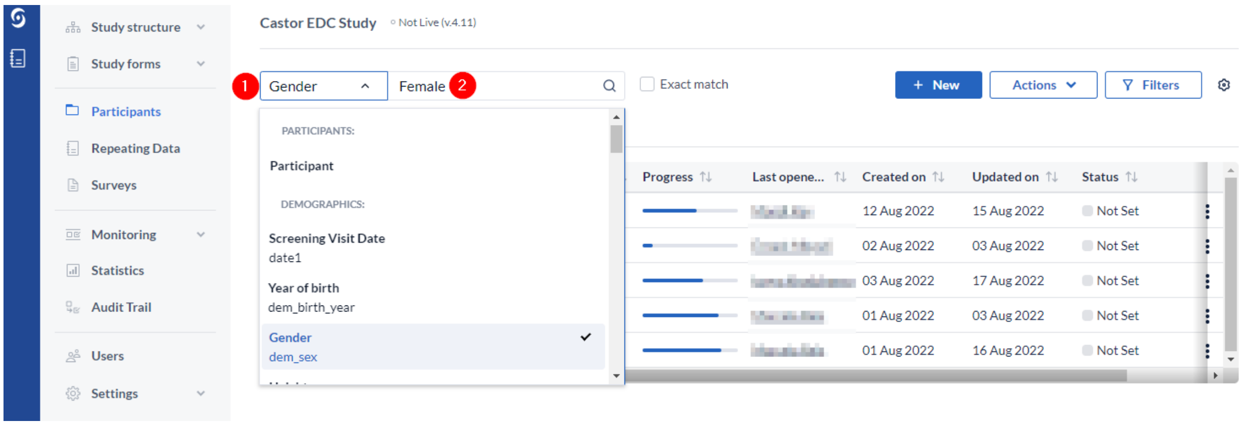
In the Participants tab, a list is displayed showing all participants for the sites to which you have 'View' rights (see Section 6).



1. In the 'Participants' tab, a search box is available, in which it is possible to search for a particular participant ID or . More information on the search is provided in section 4.1.
2. The 'Progress' column will show the status of completion for each participant.
3. By default, all participants are shown, however you can use the 'Filter' button to filter based on various parameters.
4. It is possible to change the view mode to show the progress of the participants by visits or forms. This will display the status of completion of each form for each participant. Double click on any visit or form to directly access it.

4.1. Search for Participants

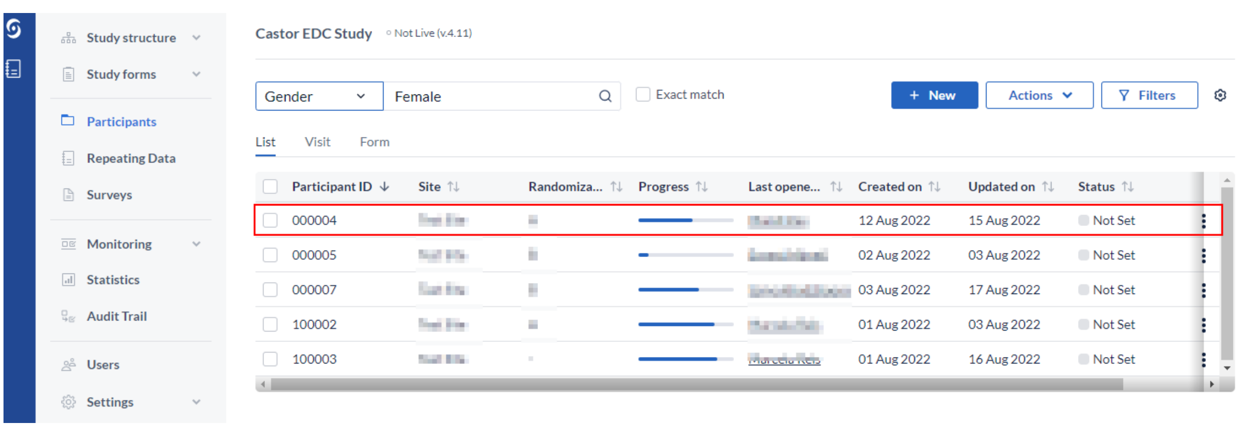
You can use the search bar to find participants that contain certain data, for example if you want to find the participants with a certain age at onset.



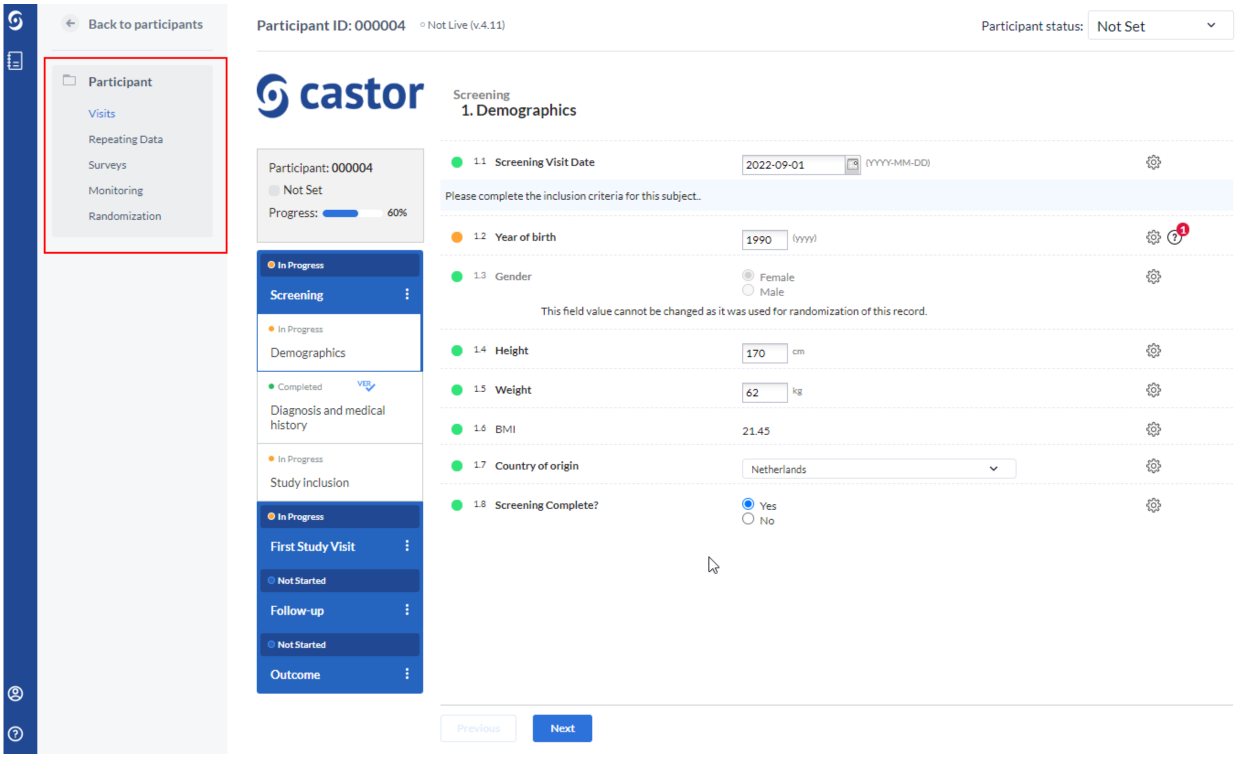
1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the left search box (in this example 'female') and all matching participants will be displayed.

4.2. Accessing a single participant

To open a participant double click the line the participant is on.



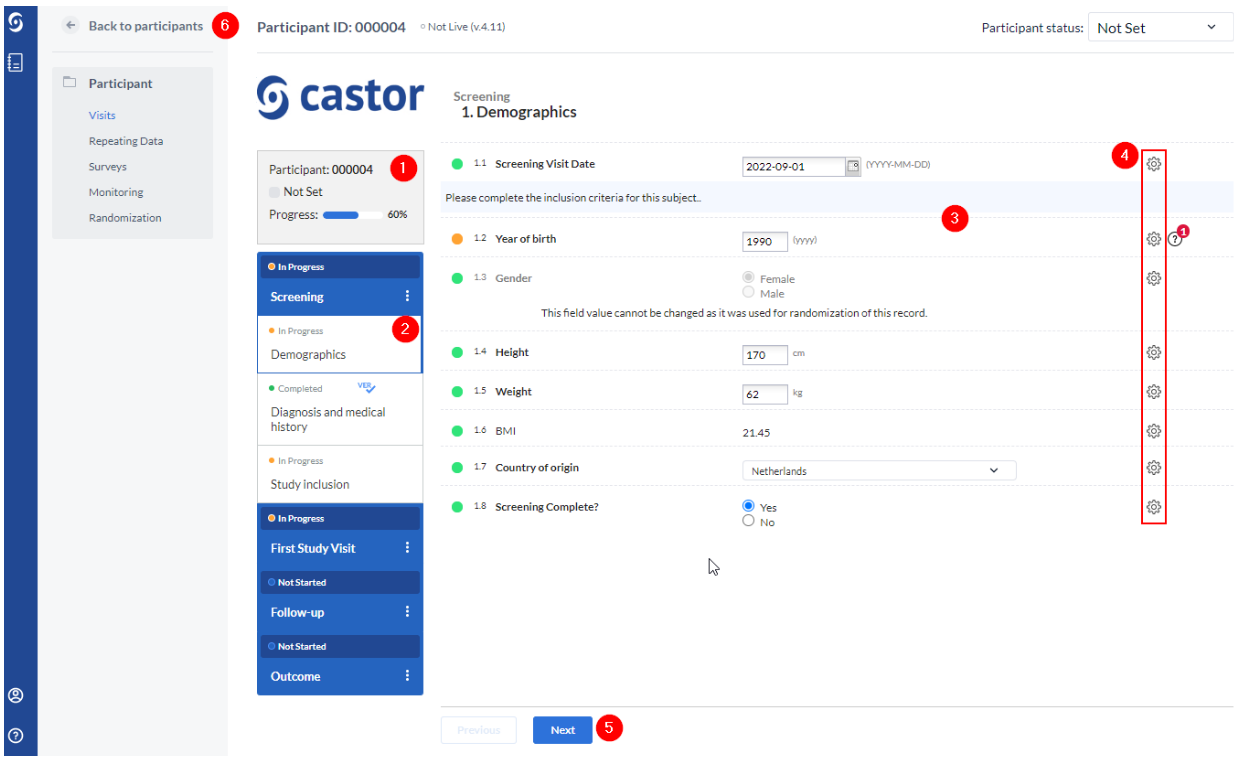
There are a total of 5 available tabs within the participant overview, but which tabs you see depends on the study setup and your specific user rights:



1. **Study tab** - You access this tab by default when you open the participant; this is where you will see the study forms and can navigate between them.
2. **Repeating Data tab** - Contains all repeating data instances that were created for the participant, such as Adverse Event repeating data instances(see 'The Repeating data tab' section below).
3. **Surveys tab** - Contains all surveys that were created or sent to a participant.
4. **Monitoring tab** - Contains an overview of relevant monitoring information, such as queries, verifications, and validations (see 'The Monitoring tab' section below).
5. **Randomization tab** - Contains information on when and by whom the participant was randomized and, in unblinded studies, the randomization allocation.

4.2.1 The Study tab

The Study tab in a participant outlines all the study forms and allows you to navigate between the different pages.



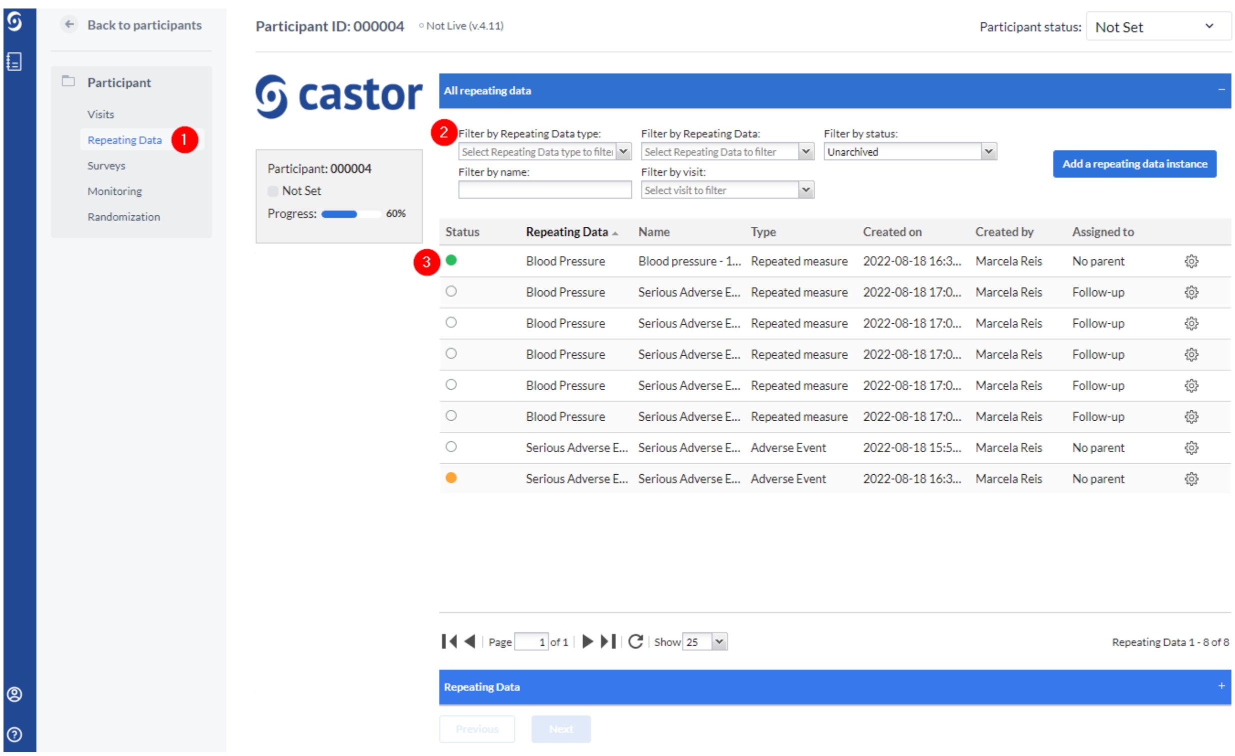
It consists of the following elements:

1. Participant ID, progress of completion, and participant status.
2. An overview of the study forms (visits and forms of the study). Phases consist of forms and each form contains a set of questions. You can click on the form of interest in this panel to start entering the required data. Once you answer a question in the form, you will see a small wheel turning to the left of the field and this means the data is being saved.
3. Data is entered into questions, or fields within the study form (forms).

4. Each field is accompanied by a cogwheel menu, containing options for each participant. In this menu, you can clear the data from a field, add a comment or mark the field as ‘missing’ data.
5. It is possible to navigate to the previous/next form by clicking on ‘Next’ or ‘Previous’. If you reach the first or the last form, these buttons will be grayed out.
6. To exit the participant and return to the participant list, click on the ‘Back to participants’ button.

4.2.2 The Repeating Data tab

Repeating Data forms are used for unscheduled events, such as Adverse Event repeating data instances.

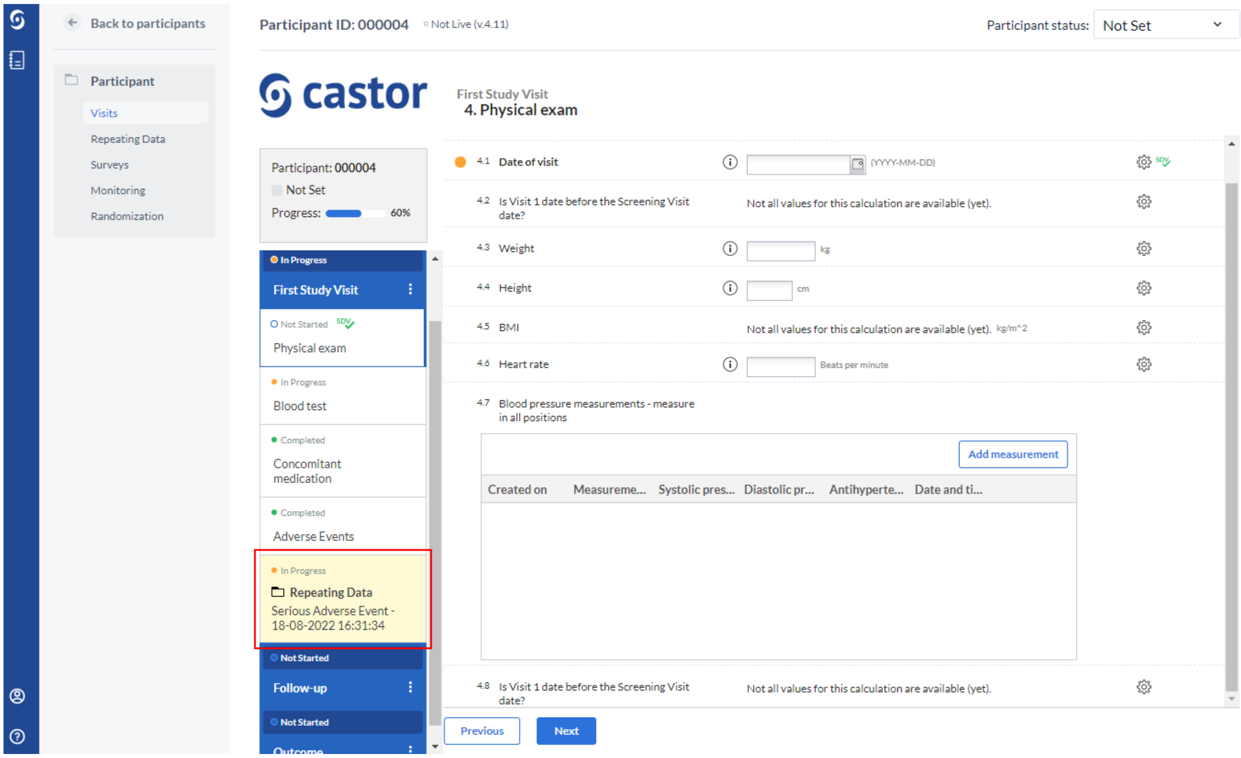


1. The ‘Repeating Data’ tab in a participant will show you all existing repeating data instances for that participant. The global Repeating Data tab in the study overview will list all repeating data instances for all participants.

2. To search for a repeating data instance, you can use the many filter options in the top, such as repeating data type (e.g. unscheduled visit) and parent visit (the visit to which a repeating data is attached to).
3. Double-click the repeating data instance of interest to open it. The dot/icon beside the repeating data instance is used to indicate progress: green indicates the repeating data instance is complete, orange indicates that the repeating data instance is still in progress, and white indicates a repeating data instance has been created but not started. You may also see the 'Add a repeating data instance' button, which is used for adding new repeating data instances to the participant. Additionally, repeating data instances are added directly via a form.

The same data entry and monitoring rules apply for repeating data instances, as for the study forms: Repeating data will have a status indicator which shows their completion and can be queried, signed, and verified.

If a repeating data instance was attached to a visit, it will also be shown in the study overview:



4.3 Important indicators in data entry

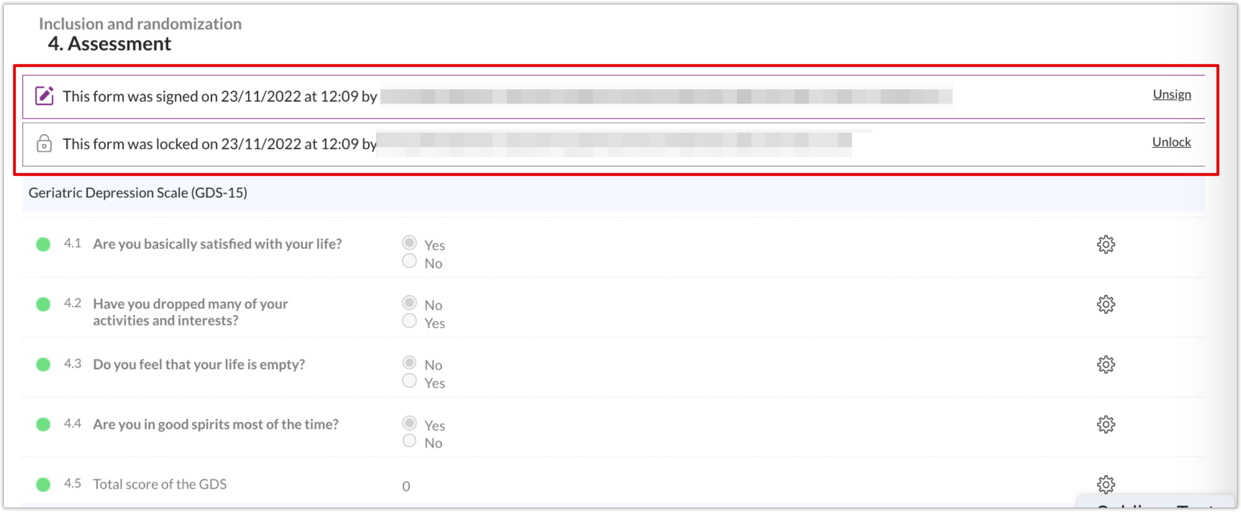
4.3.1 Data validations

Data validations (edit checks) are programmed by the study admin at the beginning of the study. If the entered data in the study or repeating data meets a certain condition, a message will appear indicating this next to the affected field:

Data validation types include errors, messages, warnings, and exclusions. With the exception of errors, existing data validations will be visible in the 'Monitoring' tab under validations.

4.3.2 Signed, locked, and verified forms

While navigating through the study or repeating data forms, if a form was signed or locked, there will be banners indicating it at the top:



The signature, lock and SDV icons will also be displayed next to the form name in the form navigator to the left. (See also: SDV section below).

4.3.3 Field comments and queries

You might also notice a text bubble in certain fields, this indicates an added comment:

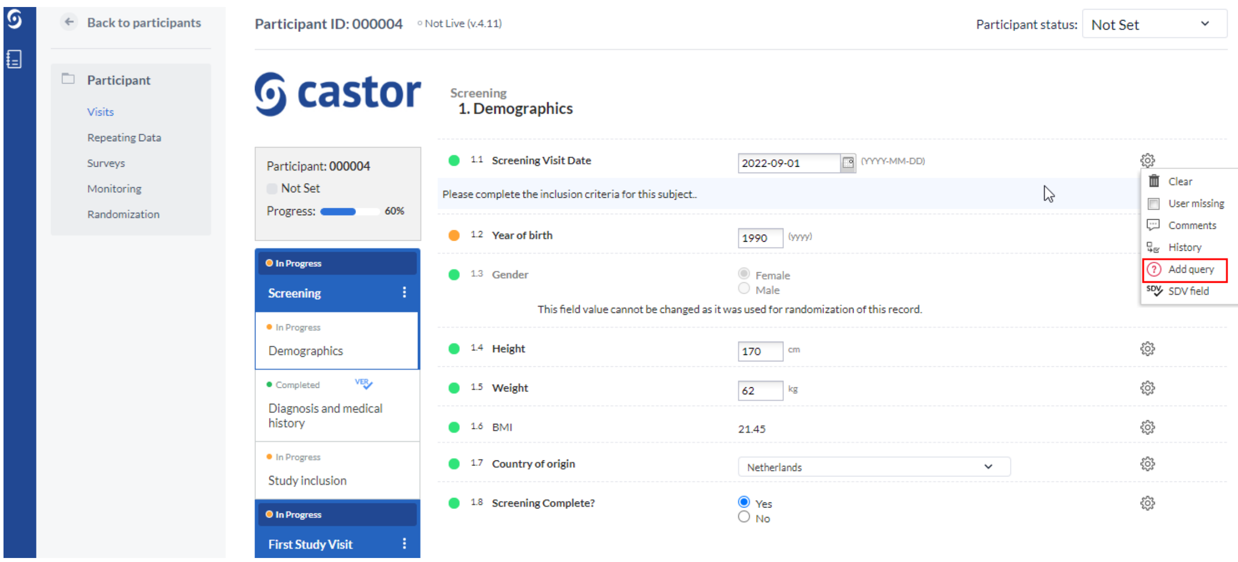
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

When a query is present in a field, the query sign will be shown next to the field (see Monitoring Queries section below).

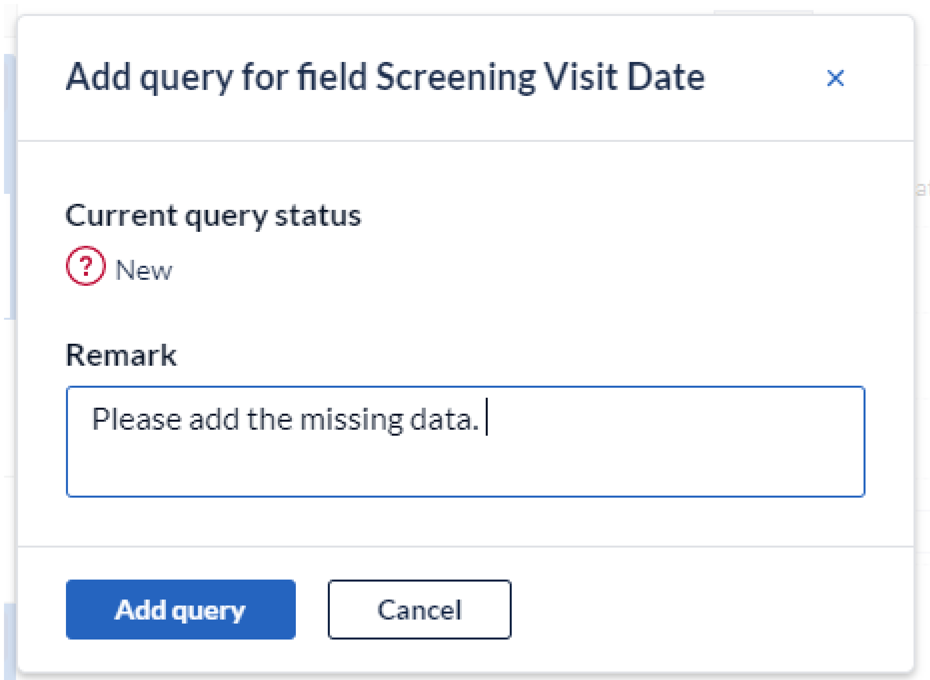
5. Monitoring queries

5.1 Adding queries

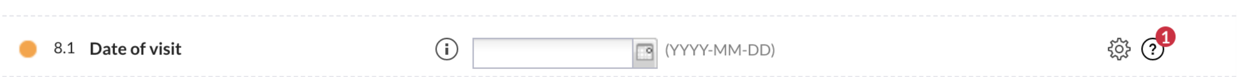
1. To create a query for a field, while in the relevant form, click on the cogwheel icon to the right of the question. From the presented options, choose ‘Add query’:



2. A pop-up window will appear where you can enter your remark. Click on the ‘Add query’ button to save the query.



3. You can also add multiple queries to the same field allowing them to be simultaneously managed by monitors on single data points (fields). Every time a new query is added, it gets an incremental number (eg. Query 1, Query 2, Query n+1) so that users can differentiate while responding to them and/or updating their status.
4. Once you have added a query, you will see that for fields with data, status has been updated to incomplete, as indicated by the orange bullet. The query icon (question mark) will appear next to the field.



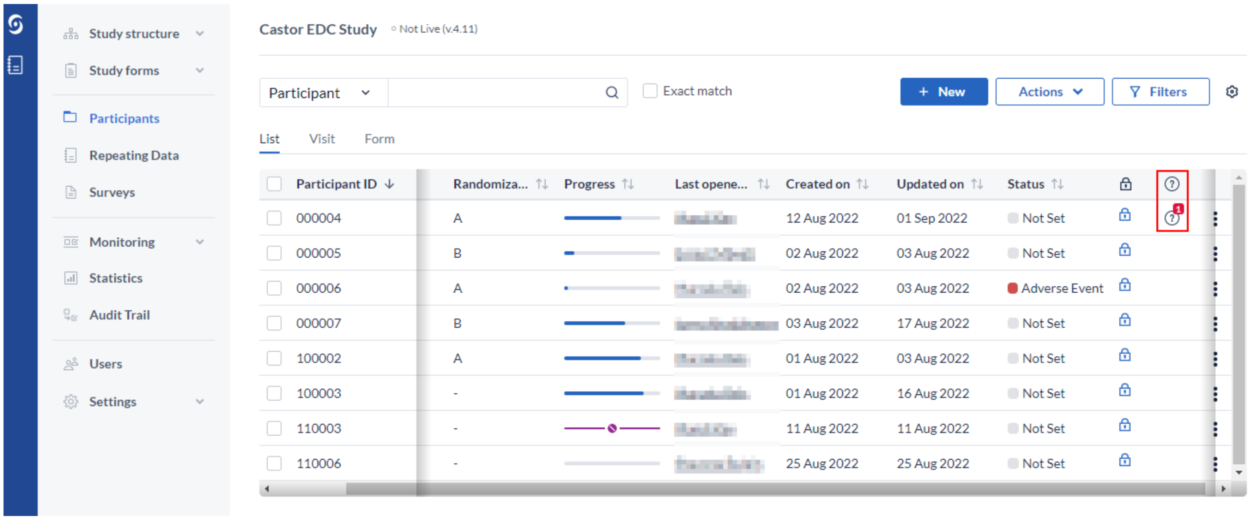
5.2 Query resolution

When an existing query is verified or resolved by a data entry user, they can add their remark by changing the status of the query to one of the following options:

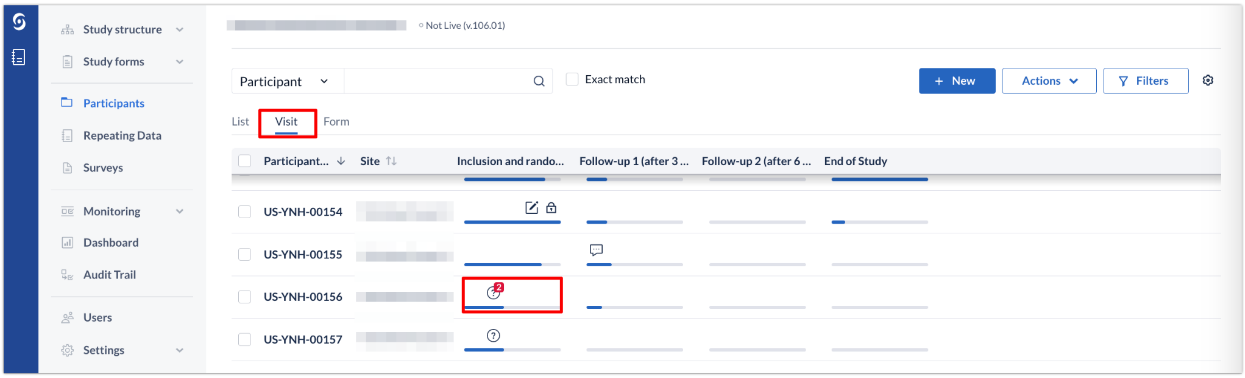
- **New**: This query has not been reviewed.
- **Open**: This query was viewed but a change of status or comment was not made.
- **Unconfirmed**: The user does not agree with the monitor.
- **Confirmed**: The user agrees with the monitor and will try to resolve the issue.
- **Resolved**: The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment.
- **Closed**: The monitor indicates the issue is resolved and marks the query as closed. Only users with query rights can close a query. Only when the query is closed will this field be marked as complete again (green bullet).

5.3. Query overview

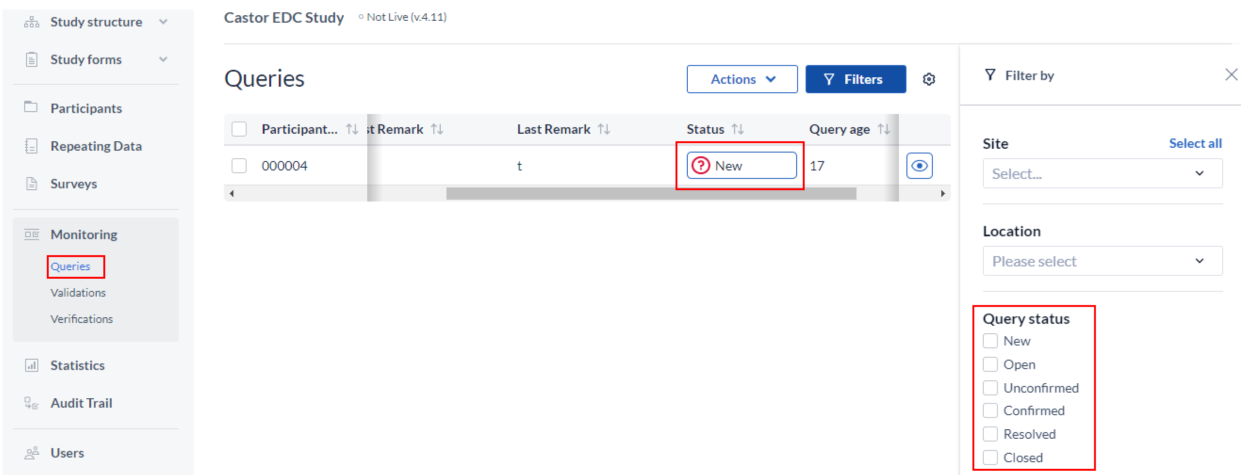
Existing queries are indicated with their respective icon in the 'Participants' list, in the 'Queries' column:



The queries are also indicated in the 'Visit' and 'Form' view mode in the 'Participants' tab:



All queries for a participant and their status are listed and can be reviewed from the participant's 'Monitoring' tab, 'Queries' subtab:



All queries for *all* participants are available in the general Monitoring tab (see Monitoring tab section below).

5.4 Query notifications

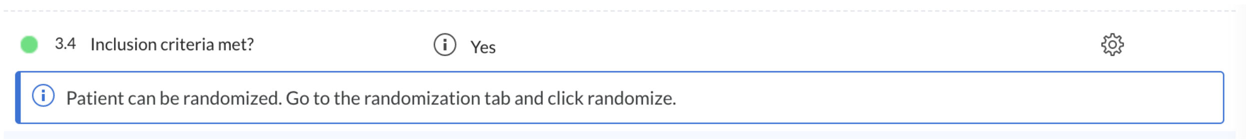
Upon query creation, a notification can be sent to a selected user in the study. All query creation notifications will be sent to that user. This notification needs to be set up by the study admin in the Settings tab.

6. Data Validations

Validations are pre-programmed edit checks that show messages to the data entry users. While navigating through the study forms, you can check if such validations have been activated. These appear as banners attached to a field for which they were programmed.

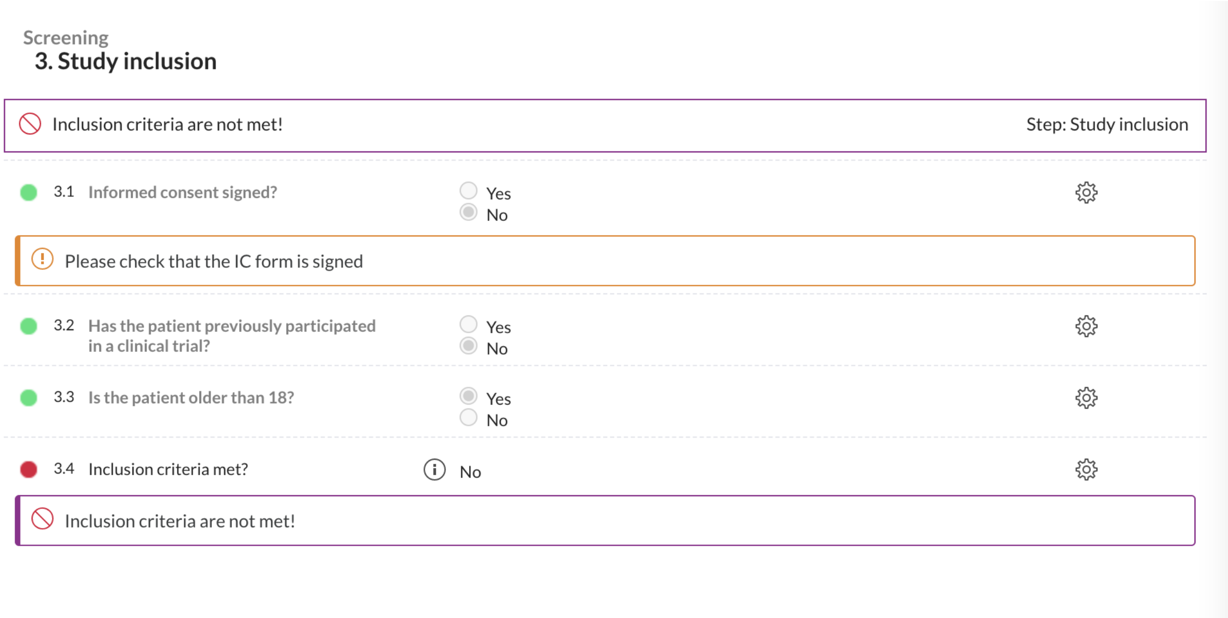
There are three types of validations that can be active:

1. A 'message' type, conveying information to the user:



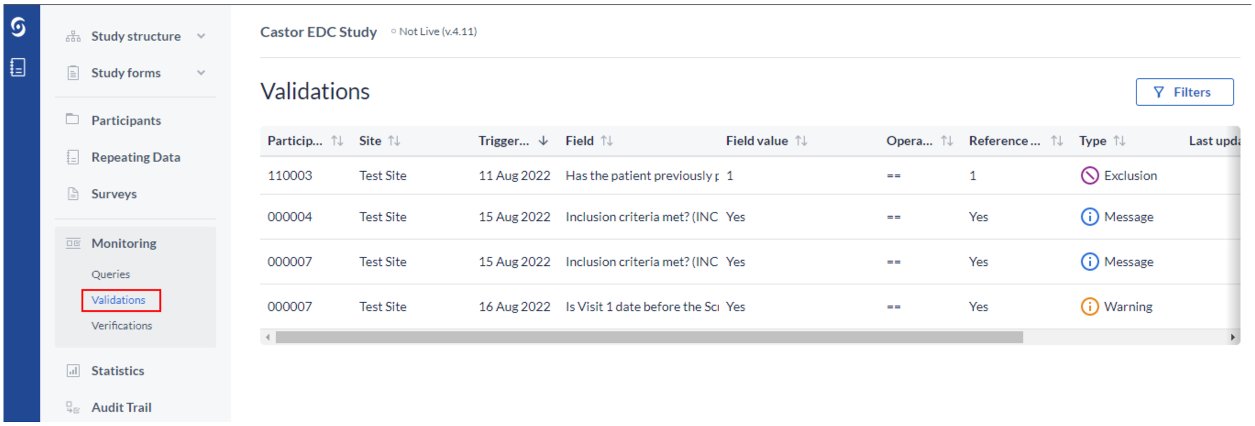
2. A 'warning' type, warning the user:

3. An ‘exclusion’ type, when the entered data does not meet inclusion/exclusion criteria:



When the exclusion validation is active, further data entry or navigation between forms is not possible.

All active validations for a participant are shown in the participant’s Monitoring tab, Validations subtab:



All active validations for *all* participants are available in the global Monitoring tab (see Monitoring tab section below).

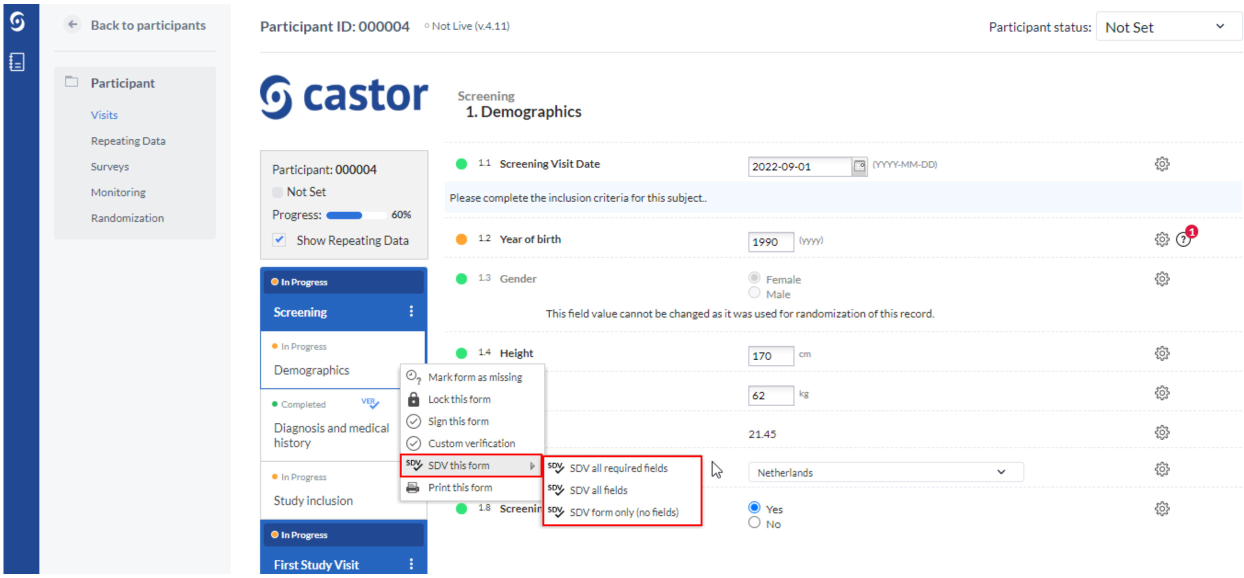
7. Source Data Verification

Study monitors performing source data verification (SDV) are able to mark fields, forms and visits as verified.

7.1. Verify a study form

You can mark a form or visit as verified. To do so:

1. Open the participant where you want to perform SDV or any other data verification that is relevant for your study.
2. In the left panel, click on the visit or form that you want to verify. Click on the three dots next to it and select 'SDV this form' and choose which verification you would like to apply.

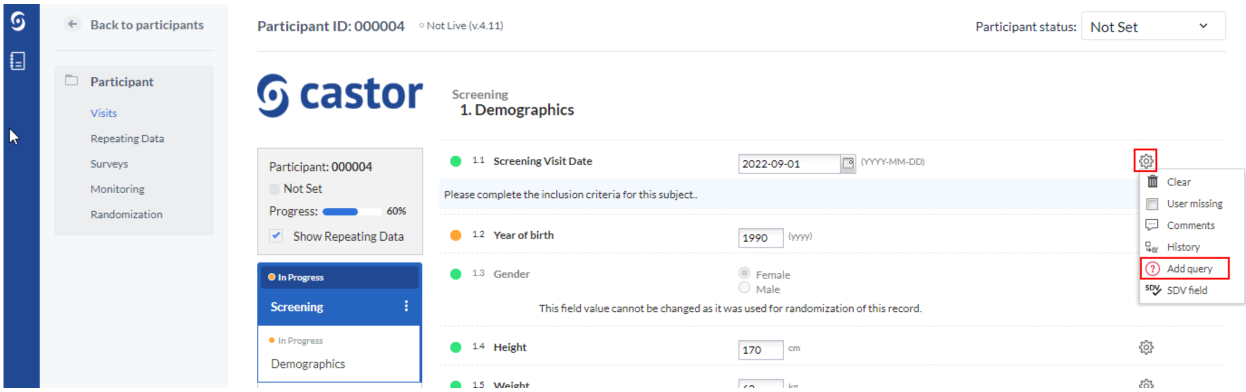


3. Click 'Continue' to save the verification or 'Cancel' to return to the data entry view.

7.2. Mark a field as verified

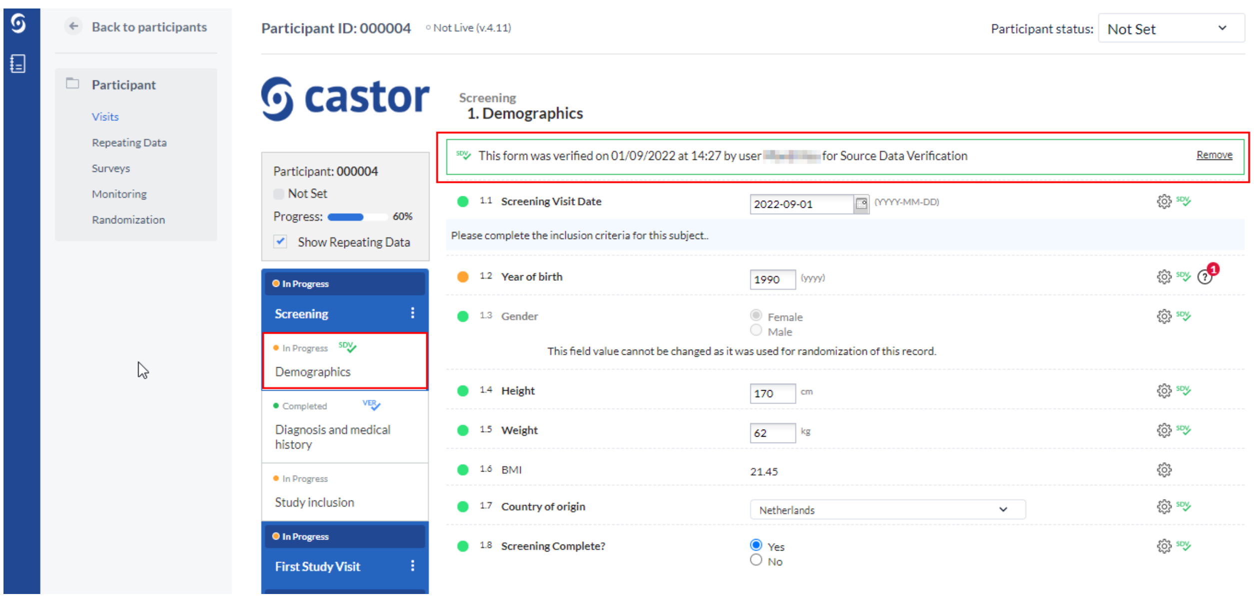
It is also possible to apply SDV to a field. To do so:

1. Click on the cogwheel next to a field where SDV should be applied
2. Choose the option ‘SDV field’



7.3 SDV indicators

In a participant, each verified form will be marked with a green banner indicating the date and time of verification as well as the name of the user who performed verification. In the banner, there is the option to 'remove' the verification - this can be done only by the user who performed the verification.



Reports that are marked as verified have the SDV icon when attached to a visit.

The following logic applies to banners and SDV icons:

- The Step SDV banner is shown when the user chooses any of the options to SDV a form and when all required fields in a form have been individually SDV’d.
- The Step SDV icon is shown on the visit/form navigation bar when the user chooses any of the options to SDV a form or when all required fields in a form have been individually SDV’d.
- When the Step SDV banner is shown, the corresponding form is shown as SDV’d on the Step View of Participant tab

When adding SDV:

- A form is considered SDV'd when all the required fields have been individually marked as SDV'd or if the form has been SDV'd directly by the user;
- A Visit is considered SDV'd when all its forms have been marked as SDV'd;
- A Repeating Data instance is considered SDV'd when all its forms have been marked as SDV'd.

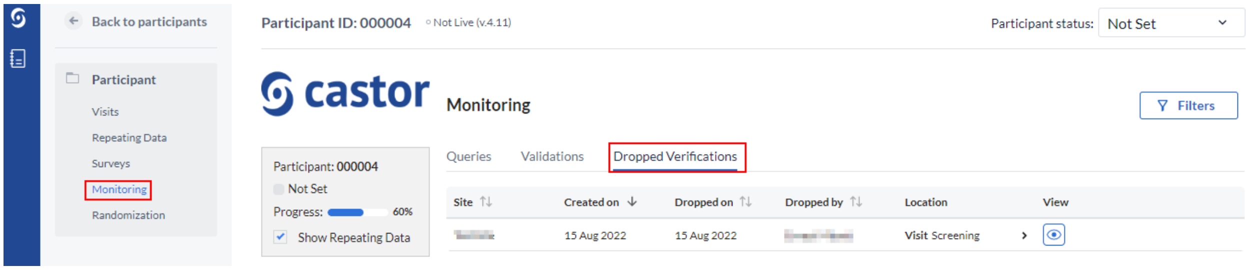
When dropping SDV:

- The Form SDV is removed when the SDV of any of the required fields within that form is removed;
- The Visit SDV is removed when the SDV of any of its child Steps is removed;
- The Repeating Data instance SDV is removed when the SDV of any of its child Steps is removed.

7.4 Modifying data after SDV

After a form is verified, if a user attempts to change data, they will receive a warning and any data modification will cause the form verification to be dropped.

It is also possible for the study admin to set up email notifications whenever form verifications are dropped, to ensure that the appropriate contacts are notified of changes made to verified data. All dropped verifications for a participant are listed in the participant's Monitoring tab, Verifications subtab:



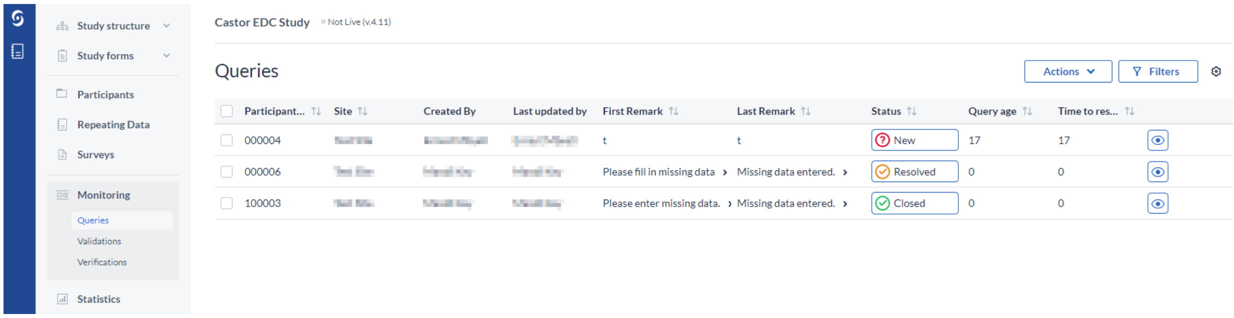
All dropped verifications and pending verifications on required completed fields, for all participants, are available in the general Monitoring tab. (see Monitoring tab section below).

8. The global Monitoring tab

Within the general study overview, you can also access the 'general' monitoring tab, that gives an overview of all the queries, data validations and dropped or pending verifications for all participants in a study. The Monitoring tab within a participants record will include the same sub-tabs, but these will contain only the information relevant for the selected participant.

8.1. Queries subtab

In the Queries subtab you will find an overview of all queries in a study and details associated with them:



- **Participant ID**: ID of a participant where a query has been created.
- **Site**: Site to which the participant is linked.
- **Created by**: User who created a query.
- **Last updated by**: Last user who updated a query.
- **First Remark**: Initial comment which was added when creating a query.
- **Last Remark**: Last comment that was added on the query.
- **Status**: Status of a query. Clicking on the query status will open the query window where you can update the query.
- **Query age**: How long ago was a query created.
- **Time to resolve**: Time required to resolve a query.

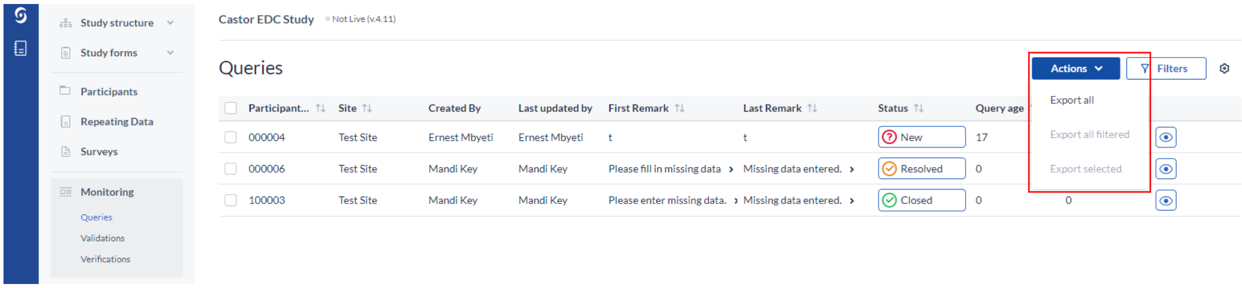
- **View**: Click on the eye icon to view the query in a form where it was created.

Using the 'Filters' button, you can filter by site, location, query status, created by, updated by, created between, days in current status and days since opened.

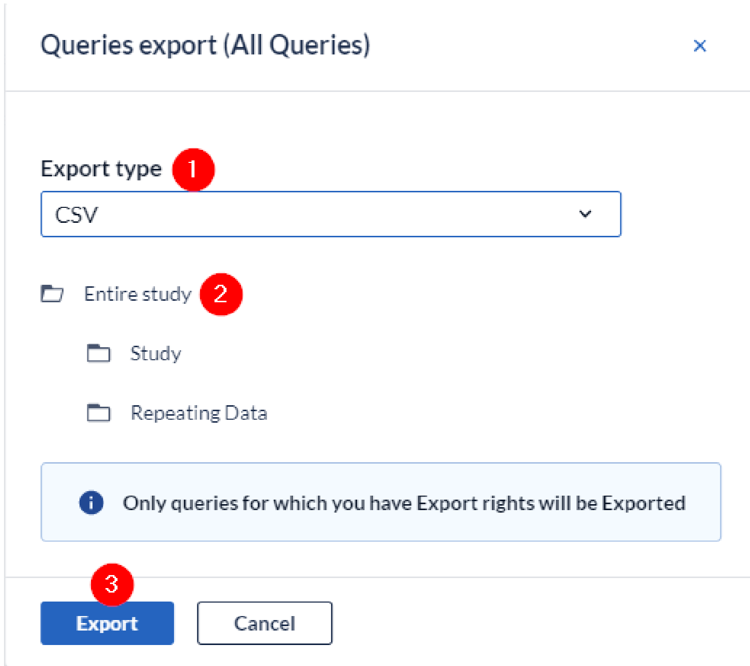
8.2. Exporting Queries

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:

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

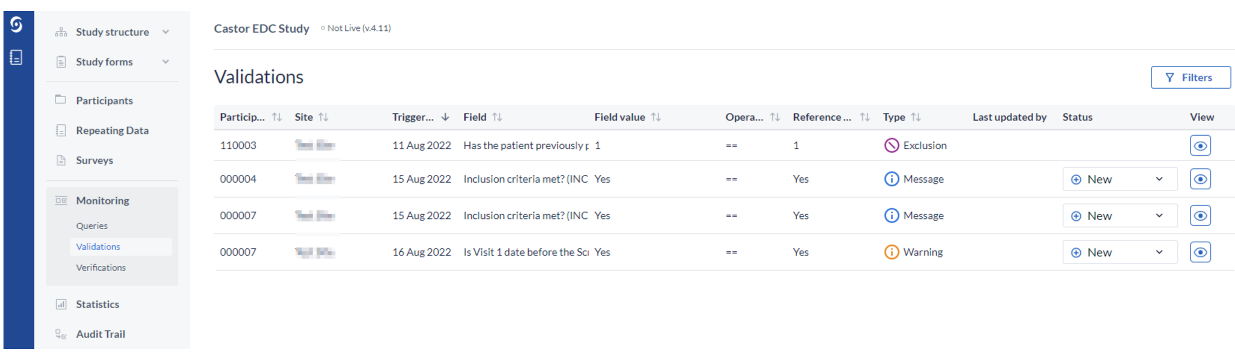


2. In Queries export dialog window, specify:
   - **Export type**: Choose to export into CSV or Excel (1).
   - **Export tree**: Choose if you would like to export queries for the entire study, specific study visits or forms in your study or for repeating data instances, a specific repeating data or a repeating data form (2).
   - **Export**: Click on Export button to generate export of the queries (3).



8.3. Validations subtab

The 'Validations' sub-tab displays all active validation fields in study, repeating data or surveys of the type Exclusion, Warning, and Message.



1. A user can filter validations by type (Exclusion, Warning, Message), by site to show participants with validations which belong to a particular site, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all participants is given with the details of the validation.
3. The operator represents how the field value and the reference value are compared, depending on the setup of the validation message. There are several operators: greater than, greater than or equal to, equal to, smaller than, smaller than or equal

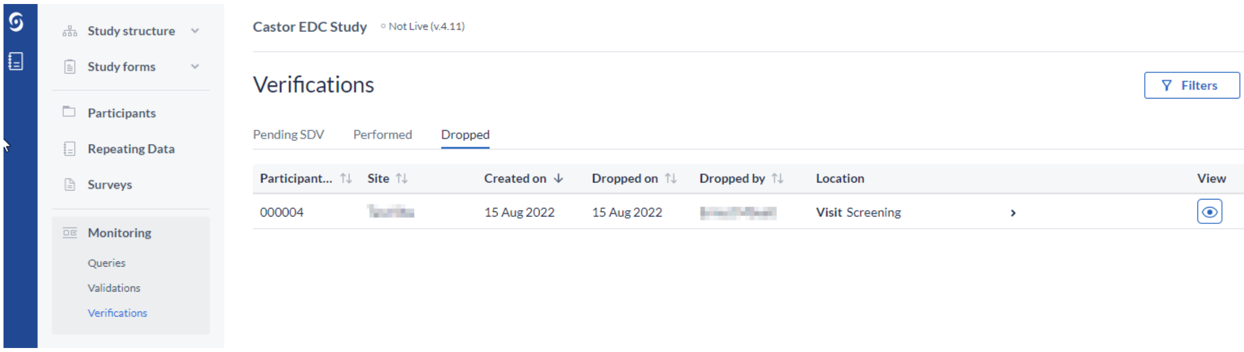
to, not. The 'Reference value' represents the value that is used in comparison to the value that was entered in a field, as defined during the validation setup.

4. It is possible to manage the field's validation using the status feature in the Monitoring tab. You are able to select the following status: New, Reviewed and Completed for the following validation message types: Message, Warning. In this way, it is possible to see the remaining active validations that still need to be evaluated and resolved. Once marked as ‘resolved’, the validation is not shown any longer in the Validations overviews AND in Data entry. But as soon as a user changes the status from ‘resolved’ to ‘reviewed’ or ‘new’, the validation is shown again in data entry.
5. To open the participant and jump to the form with the validation, click on the eye icon in the column 'View'.

8.4. Verifications subtab

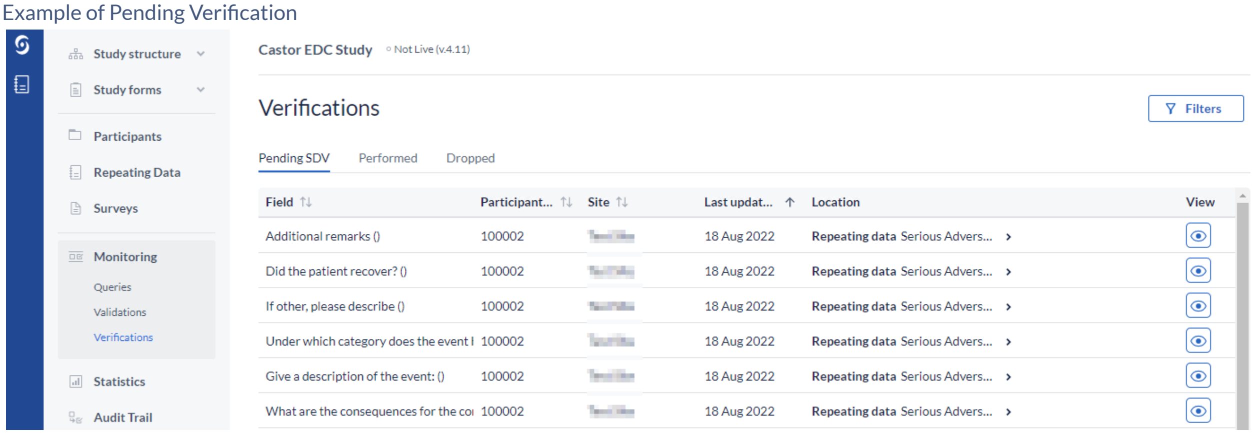
This subtab displays all pending, preformed, and dropped verifications in the study:

Example of Dropped Verification



- Using the Pending, Performed, and Dropped verification tabs under verification will filter each relevant verification.
- Each row shows the participant ID, the site name, creation date, drop date, dropped by and the location of the dropped verification. You can expand the location field by clicking on the carrot within the field to review the Visit, Form, and Field where the verification was dropped, performed, or is pending.
- To open the participant and jump to the form where the verification is located, click on the eye icon in the column 'View'.

Example of Pending Verification



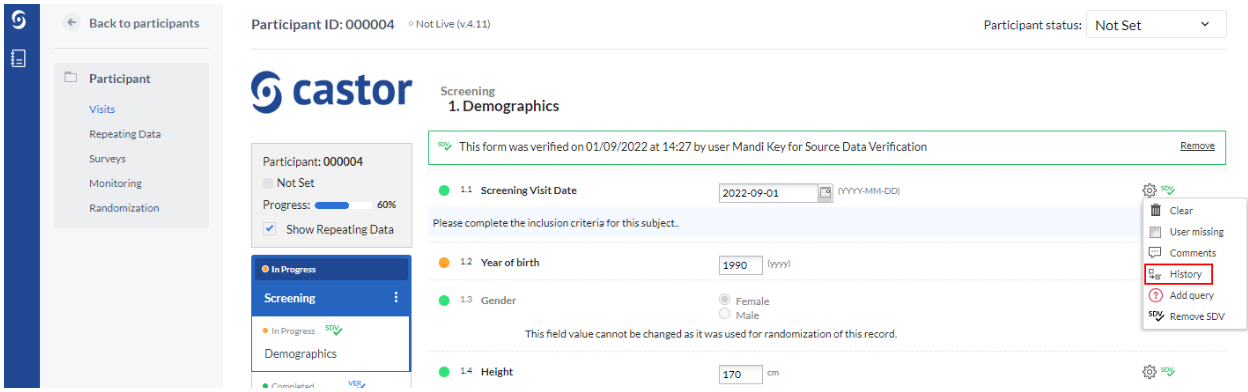
- Using the ‘Filters’ button on the Pending, Preformed, or Dropped tab, you can choose to filter by site, date range,and/or location for the study or for repeating data only.
- Each row shows the participant ID, the site name, last update date, and field location. You can expand the location field by clicking on the carrot within the field to review the Visit, Form, and Field where the SDV resides.
- To open the participant and jump to the form where the verification was added, dropped, or performed click on the eye icon in the column 'View'.

Please note that the Pending SDV tab only includes fields that are required and have been completed. To see all active verifications, go to the Participants tab and use the "Visit" or “Form” view mode. Verified forms will contain a green checkmark. (See Participant tab section below)

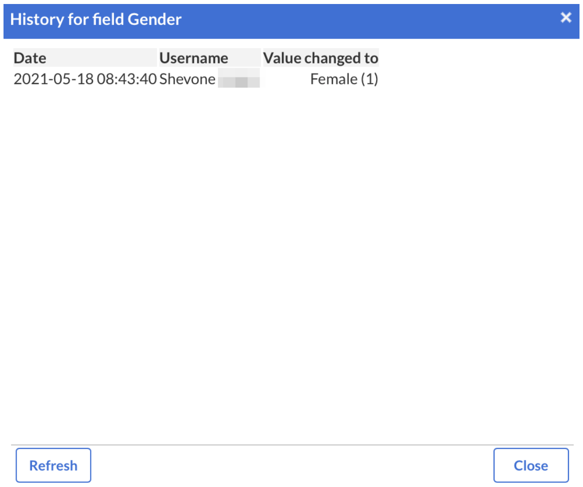
9. Using the Audit Trail

The study audit trail allows for a review of all access and changes made to study settings and data. It is possible to apply a filter to the displayed information based upon the event type, the user and the affected variable (where applicable). Access to the full audit trail is normally available only to study admins with all management rights.

As a monitor, in data entry you can view the audit trail for all participant results. To view the audit trail of a single field, click on the cogwheel next to the field:



A popup will appear detailing the changes to the field. The date, the user who changed the field, and the new value are all displayed:

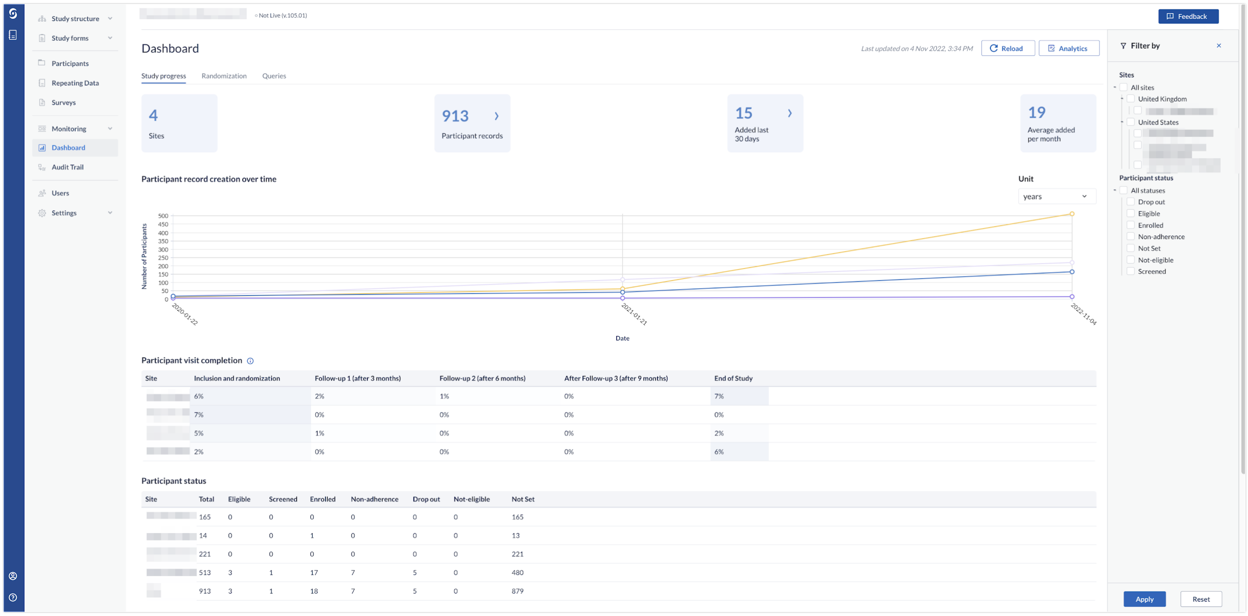


10. The Dashboard tab

The Study Dashboard allows to track the progress of your study, including:

- Participant recruitment
- Data collection progress
- Randomization
- Queries

Please note that the data aggregated in the dashboard is based on your personal viewing rights.



It is possible to filter the dashboards by site and participant status using the 'Filters' button. The filter is saved on a study and user level and will, therefore, still be in place when returning to the dashboard at a later time.

11. Further Information

For more information regarding study monitoring, please check Castor EDC's knowledge base: https://helpdesk.castoredc.com