

Castor

Castor CDMS Monitoring User Guide

Version 2024.2

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11. Further Information

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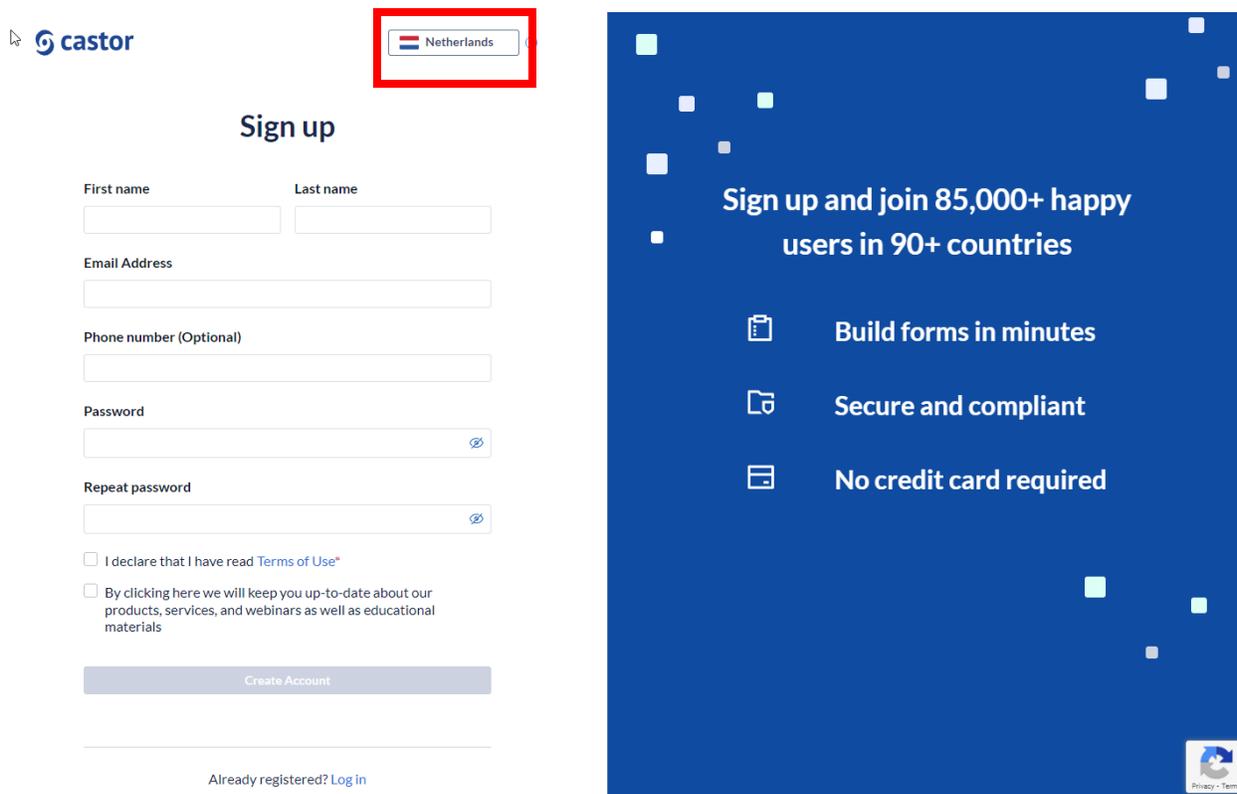
1. Register an account

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. When clicking on the Flag dropdown list, you can change the server location.



The image shows two parts of the registration process. On the left is the 'Sign up' form, which includes fields for 'First name', 'Last name', 'Email Address', 'Phone number (Optional)', 'Password', and 'Repeat password'. Below these fields are two checkboxes: one for 'I declare that I have read Terms of Use*' and another for 'By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials'. A 'Create Account' button is at the bottom of the form, and a 'Log in' link is provided for existing users. A red box highlights the 'Netherlands' flag in the top right corner of the page. On the right is a blue promotional banner with the text 'Sign up and join 85,000+ happy users in 90+ countries' and three bullet points: 'Build forms in minutes', 'Secure and compliant', and 'No credit card required'.

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>

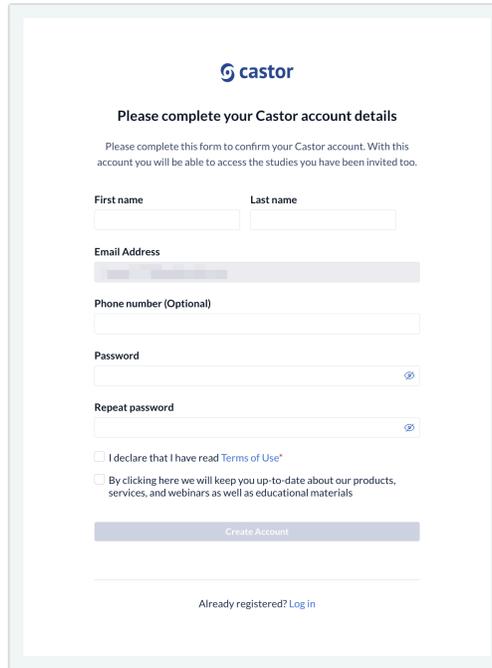
To register your Castor account:

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
4. Accept the 'Terms of Use' and opt-in the email communications (optional)
5. Press the button 'Create Account'

You will receive an email to verify your account. After clicking the link in the email address, you will be prompted to confirm the server where your account will be created.

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:



The screenshot shows a web form titled "Please complete your Castor account details". At the top, it features the Castor logo and a sub-header. Below the sub-header is a short instruction paragraph. The form contains several input fields: "First name" and "Last name" (two separate boxes), "Email Address" (a single box with a greyed-out placeholder), "Phone number (Optional)" (a single box), "Password" (a box with a strength indicator icon), and "Repeat password" (a box with a strength indicator icon). There are two checkboxes: one for "I declare that I have read Terms of Use*" and another for "By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials". A "Create Account" button is positioned below the checkboxes. At the bottom of the form, there is a link for "Already registered? Log in".

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 CDMS 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>, <https://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.
3. Provide your password.
4. Click on 'Login'.

2.1. Activate two-factor authentication

In Castor, you can [configure two-factor authentication \(2FA\)](#) for your account.

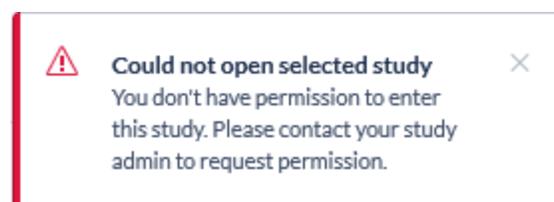
This means that, upon login, you will have to enter an extra authentication code generated by an authentication app on your phone or tablet. This adds an extra layer of security to your Castor account - potential attackers will need not only your account details, but also your physical device with your authentication app to be able to access your account.

3. Open a study

Once you have logged into Castor CDMS, 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.



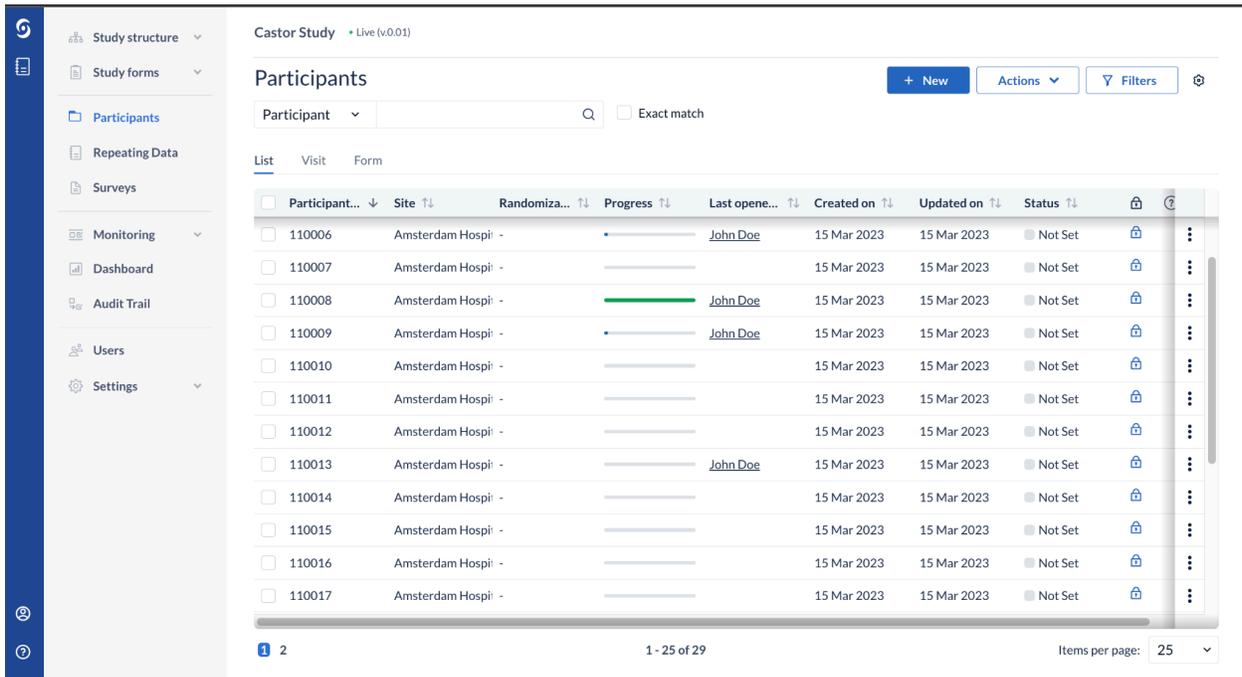
Trying to open a study that is not live will show the following warning:



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

The study will open on the Participants tab.



Castor Study • Live (v0.01)

Participants

+ New Actions Filters

Participant Exact match

List Visit Form

Participant...	Site	Randomiza...	Progress	Last opene...	Created on	Updated on	Status		
<input type="checkbox"/> 110006	Amsterdam Hospii -		<div style="width: 20%;"></div>	John Doe	15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110007	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110008	Amsterdam Hospii -		<div style="width: 100%; background-color: green;"></div>	John Doe	15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110009	Amsterdam Hospii -		<div style="width: 20%;"></div>	John Doe	15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110010	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110011	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110012	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110013	Amsterdam Hospii -		<div style="width: 20%;"></div>	John Doe	15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110014	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110015	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110016	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		
<input type="checkbox"/> 110017	Amsterdam Hospii -		<div style="width: 20%;"></div>		15 Mar 2023	15 Mar 2023	Not Set		

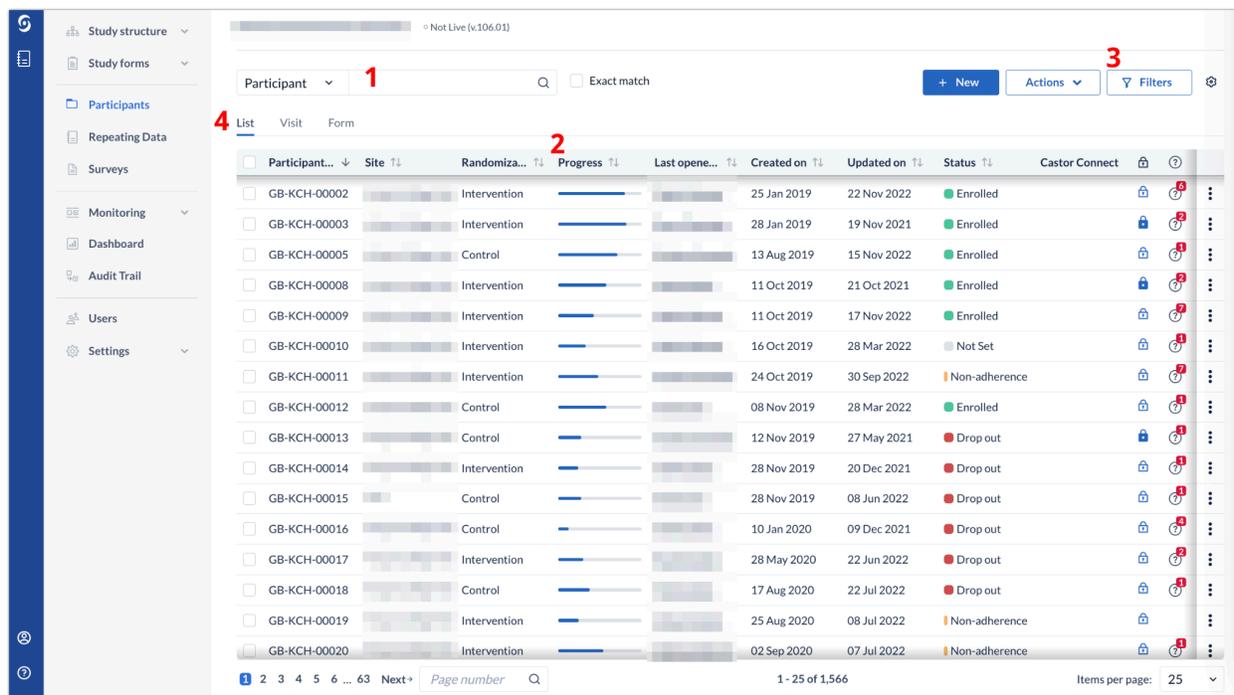
1 2 1 - 25 of 29 Items per page: 25

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

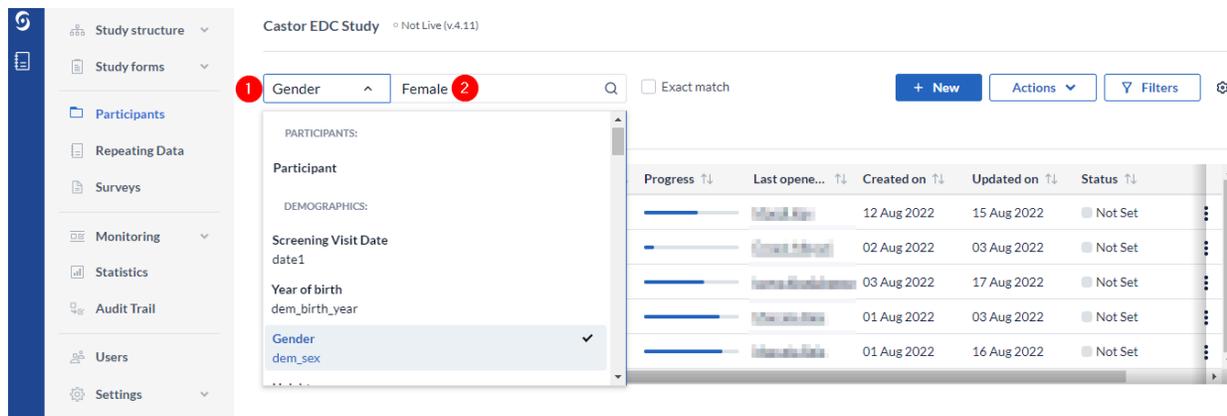
In the Participants tab, a list is displayed showing all participants for the sites to which you have 'View' rights (see Section 6).



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

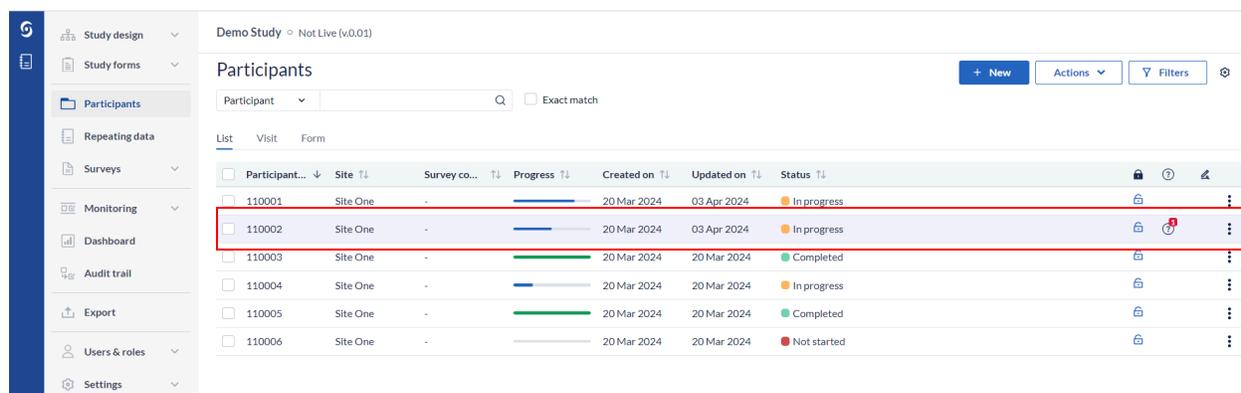
You can use the search bar to find participants that contain certain data, for example if you want to find the participants with a certain age at onset.



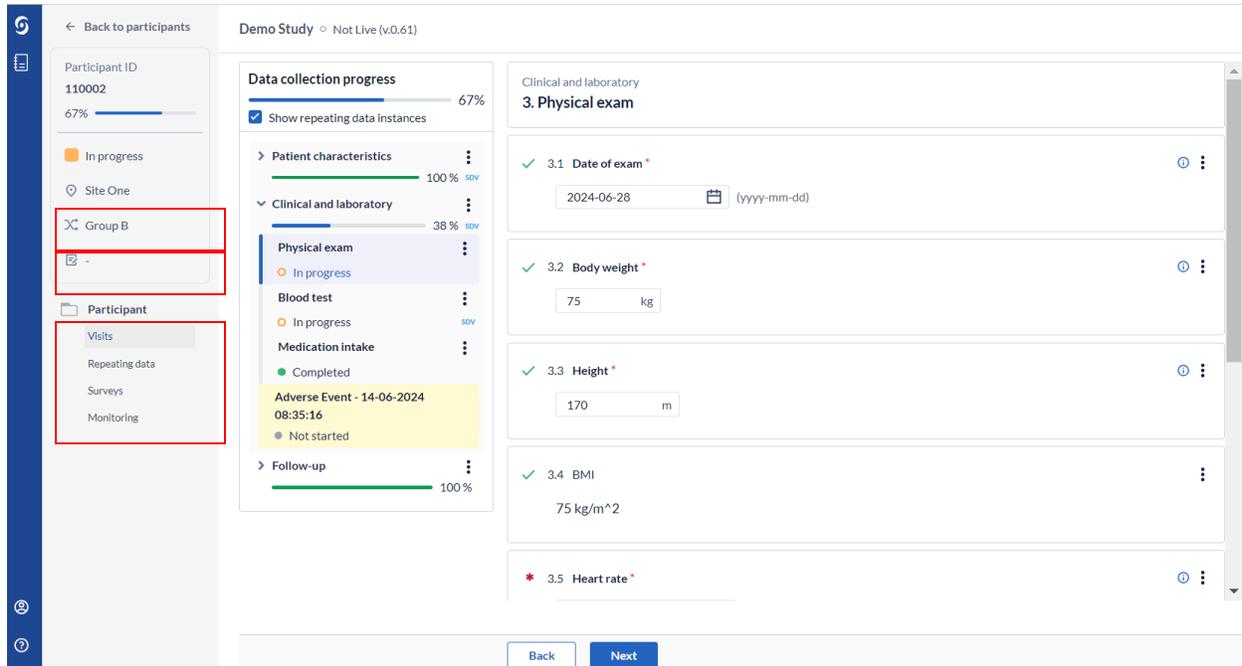
1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the left search box (in this example 'female') and all matching participants will be displayed.

4.2. Accessing a single participant

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



There are a total of 4 available tabs within the participant overview, but which tabs you see depends on the study setup and your specific user rights:



1. **Visits 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 button** - Contains information on when and by whom the participant was randomized and, in unblinded studies, the randomization allocation. This is optional if the study has such a feature.
6. **Overall survey compliance link** (below the Randomization button) - allows to see the status of the surveys in the study.

4.2.1 The Visits tab

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

The screenshot displays the Castor interface for a participant's visit. Key elements include:

- Top Left:** A button labeled "Back to participants" is highlighted with a red box.
- Participant Information:** The participant ID is 110002, and the site is Site One. The progress bar shows 50% completion.
- Data Collection Progress:** A central panel shows progress for various categories: Patient characteristics (100%), Clinical and laboratory (15%), Physical exam (Not started), Blood test (In progress), Medication intake (Completed), and Follow-up (0%).
- Main Form Area:** Titled "4. Blood test", it contains several fields:
 - 4.1 Date of blood sample: A date field with the value 2024-03-11 and a calendar icon.
 - 4.2 Haemoglobin concentration: A text input field with the unit mmol/l.
 - 4.3 Hematocrit value: A text input field with the unit l/l.
 - 4.4 Blood white blood cell count: A text input field with the unit $\times 10^9/L$.
 - 4.5 Blood trombocyte count: A text input field.
- Bottom:** "Back" and "Next" navigation buttons are highlighted with a red box.

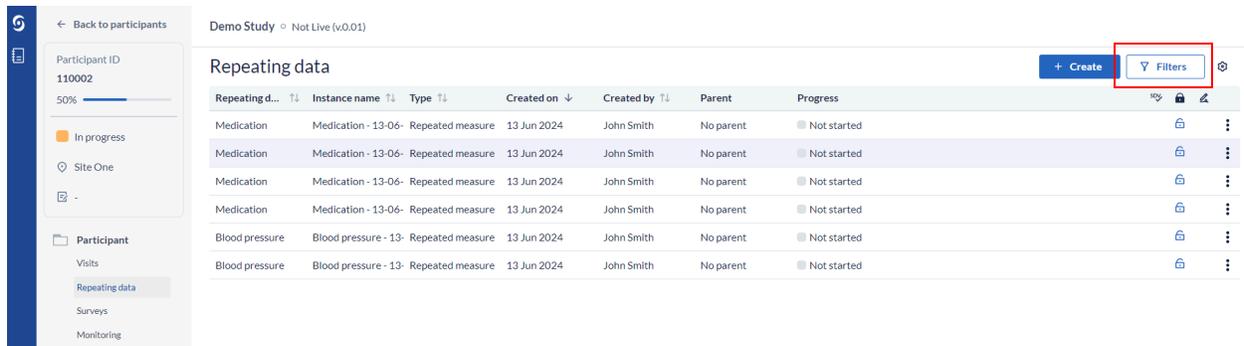
It consists of the following elements:

1. To exit the participant and return to the participant list, click on the 'Back to participants' button.
2. Participant ID, progress of completion, participant status, site, randomization and survey compliance status.
3. An overview of the study forms (visits and forms of the study). Visits 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.

4. Data is entered into questions, or fields within the study form.
5. Each field is accompanied by a 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, apply SDV, raise a query depending on your permissions.
6. 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.

4.2.2 The Repeating Data tab

Repeating Data forms are used for repeated measurements or unscheduled events, such as Adverse Event, Medication history, Blood pressure or any other repeating data.



Repeating d...	Instance name	Type	Created on	Created by	Parent	Progress
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
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

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 "Filters" 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. Click the repeating data instance of interest to open it. Colors in the "Progress column" indicate: green - the repeating data instance is complete, orange - that the repeating data instance is still in progress, and white - a repeating data instance has been created but not started. You may also see the '+Create' 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.

Repeating data instances that are created and attached to a specific parent are shown in the navigation panel. A checkbox 'Show repeating data instances' is presented on top of the navigation, allowing the user to optionally hide children instances that are of type 'adverse event', 'unscheduled visit' or 'measurement' from the visit view.

Repeating data instances are not displayed by default unless this is specifically activated in the study settings. To display the instances of type 'repeated measure', the 'Display repeated measure instances in visit navigator' option needs to be configured in the 'Other' tab of the study settings page.

The screenshot displays the Castor study interface for a participant with ID 110002. The interface is divided into several sections:

- Left Panel:** A navigation sidebar with options like 'Back to participants', 'Participant ID 110002', '50%' progress bar, 'In progress', 'Site One', and a list of data types: 'Participant', 'Visits', 'Repeating data', 'Surveys', and 'Monitoring'.
- Top Section:** 'Data collection progress' for 'Demo Study - Not Live (v0.01)'. It shows a 50% progress bar and a checked checkbox for 'Show repeating data instances' (highlighted with a red box).
- Middle Section:** A hierarchical view of data collection progress:
 - Patient characteristics:** 100% completed (SDV).
 - Demographics:** Completed (SDV).
 - Diagnosis and medical history:** Completed (SDV).
 - Clinical and laboratory:** 15% completed (SDV).
 - Physical exam:** Not started.
 - Blood test:** In progress (SDV).
 - Medication intake:** Completed.
 - Adverse Event - 14-06-2024 08:35:16:** Not started (highlighted with a red box).
 - Follow-up:** Not started.
- Right Panel:** 'Patient characteristics 1. Demographics' form with fields:
 - 1.1 Year of birth: 1967 (SDV)
 - 1.2 Gender: Male (SDV)
 - 1.3 Height: 178 cm (SDV)
 - 1.4 Weight: 78 kg (SDV)
- Bottom:** 'Back' and 'Next' buttons.

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:

 Date of signature cannot be in the future

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:

Unscheduled visit - 17-05-2024 14:35:18

2. Laboratory

	This form was signed on 17/05/2024 at 14:36 by A [redacted] [Castor Support] (A [redacted]@CASTOREDC.COM).	Remove
	This form was verified on 17/05/2024 at 14:41 by A [redacted] [Castor Support] for Source Data Verification.	Remove
	This form was verified on 17/05/2024 at 14:41 by [redacted] Other.	Remove
	This form was locked on 17/05/2024 at 14:40 by A [redacted] [Castor Support] (A [redacted]@CASTOREDC.COM).	Unlock

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).

[← Go to repeating data overview](#)

> Adverse event - 17-05-2024

14:28:11

22 %

SDV ✓

VER ✓





4.3.3 Field comments and queries

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

* 1.1 Year of birth *

SDV   

(yyyy)

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

- 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':

The screenshot shows a patient form titled "Patient characteristics" with a sub-section "1. Demographics". It contains three fields: "1.1 Year of birth" (value: 1967), "1.2 Gender" (value: Male), and "1.3 Height" (value: 178 cm). A dropdown menu is open over the "Year of birth" field, showing options: "Clear", "Mark field as missing value", "Comments", "History", "Add query" (highlighted with a red box), and "SDV field".

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

The pop-up window is titled "Add query for field Year of birth" and has a close button (X). It displays the "Current query status" as "New" with a question mark icon. Below this is a "Remark" field with the placeholder text "Please add missing data". At the bottom, there are two buttons: "Cancel" and "Add query".

- 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.

* 1.1 Year of birth *
SDV   

(yyyy)

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:

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%; background-color: #007bff;"></div>	20 Mar 2024	03 Apr 2024	In progress	🔒	🔍
<input type="checkbox"/> 110002	Site One	-	<div style="width: 50%; background-color: #007bff;"></div>	20 Mar 2024	14 Jun 2024	In progress	🔒	🔍
<input type="checkbox"/> 110003	Site One	-	<div style="width: 100%; background-color: #28a745;"></div>	20 Mar 2024	20 Mar 2024	Completed	🔒	🔍
<input type="checkbox"/> 110004	Site One	-	<div style="width: 25%; background-color: #007bff;"></div>	20 Mar 2024	20 Mar 2024	In progress	🔒	🔍
<input type="checkbox"/> 110005	Site One	-	<div style="width: 100%; background-color: #28a745;"></div>	20 Mar 2024	20 Mar 2024	Completed	🔒	🔍
<input type="checkbox"/> 110006	Site One	-	<div style="width: 0%; background-color: #dc3545;"></div>	20 Mar 2024	20 Mar 2024	Not started	🔒	🔍

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

Participants

Participant Exact match

List Visit Form

Participant...	Site	Patient characterist...	Clinical and laborat...	Follow-up
<input type="checkbox"/> 110001	Site One	<div style="width: 100%; background-color: #28a745;"></div> SDV	<div style="width: 50%; background-color: #007bff;"></div> SDV	<div style="width: 0%; background-color: #6c757d;"></div>
<input type="checkbox"/> 110002	Site One	<div style="width: 100%; background-color: #28a745;"></div> SDV 🔍	<div style="width: 50%; background-color: #007bff;"></div> SDV 🔍	<div style="width: 100%; background-color: #28a745;"></div>
<input type="checkbox"/> 110003	Site One	<div style="width: 100%; background-color: #28a745;"></div> SDV	<div style="width: 100%; background-color: #28a745;"></div> SDV	<div style="width: 100%; background-color: #28a745;"></div>
<input type="checkbox"/> 110004	Site One	<div style="width: 50%; background-color: #007bff;"></div>	<div style="width: 25%; background-color: #007bff;"></div>	<div style="width: 0%; background-color: #6c757d;"></div>
<input type="checkbox"/> 110005	Site One	<div style="width: 100%; background-color: #28a745;"></div> SDV	<div style="width: 100%; background-color: #28a745;"></div> SDV 🔍	<div style="width: 100%; background-color: #28a745;"></div> 🔍
<input type="checkbox"/> 110006	Site One	<div style="width: 0%; background-color: #6c757d;"></div>	<div style="width: 0%; background-color: #6c757d;"></div>	<div style="width: 0%; background-color: #6c757d;"></div>

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

The screenshot shows the 'Monitoring' tab in the Castor interface. The 'Queries' table lists five entries for participant 110002 at Site One, all created by John Smith. The 'Status' column shows 'New' for all entries. The 'Query' column shows '86' for the first entry and '0' for the others. The 'Filter by' sidebar on the right allows filtering by Site, Location, Query status, Created by, Updated by, and Created between.

Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query	View
110002	Site One	John Smith	John Smith	test	test	New	86	
110002	Site One	John Smith	John Smith	test	test	New	0	
110002	Site One	John Smith	John Smith	test	test	New	0	
110002	Site One	John Smith	John Smith	Please add missing data	Please add missing data	New	0	
110002	Site One	John Smith	John Smith	tsst	tsst	New	0	

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 - information' type, conveying information to the user:



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



3. An 'error' type, when the entered data is not accepted or wrong. Prevents saving that field value:

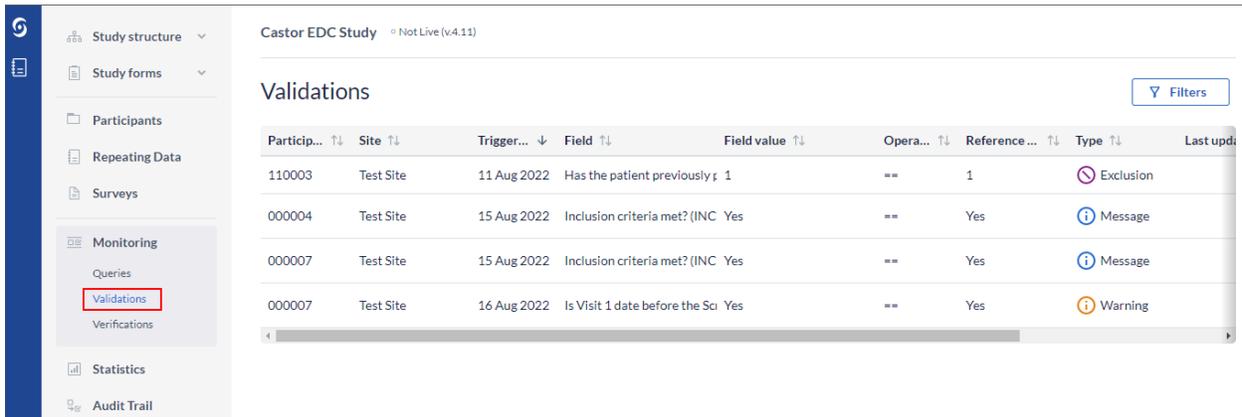


4. An 'exclusion' type, when the entered data does not meet inclusion/exclusion criteria:



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:



Particip...	Site	Trigger...	Field	Field value	Opera...	Reference ...	Type	Last upd:
110003	Test Site	11 Aug 2022	Has the patient previously	1	--	1	Exclusion	
000004	Test Site	15 Aug 2022	Inclusion criteria met? (INC	Yes	--	Yes	Message	
000007	Test Site	15 Aug 2022	Inclusion criteria met? (INC	Yes	--	Yes	Message	
000007	Test Site	16 Aug 2022	Is Visit 1 date before the Sci	Yes	--	Yes	Warning	

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

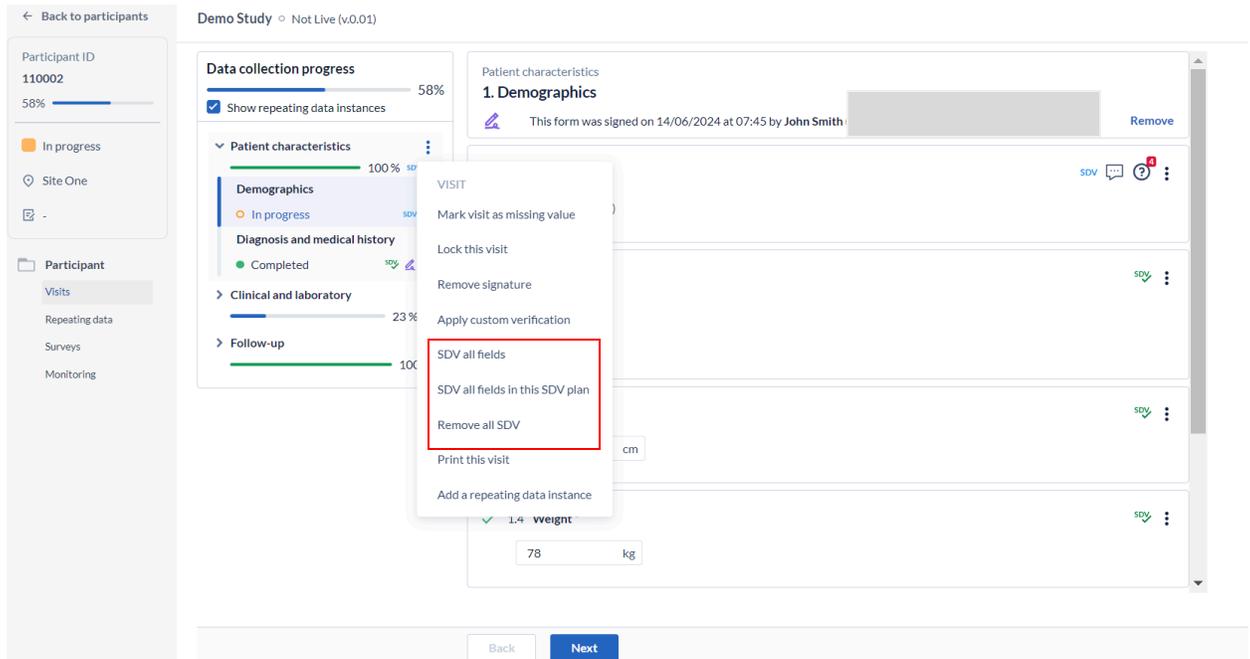
7. Source Data Verification

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

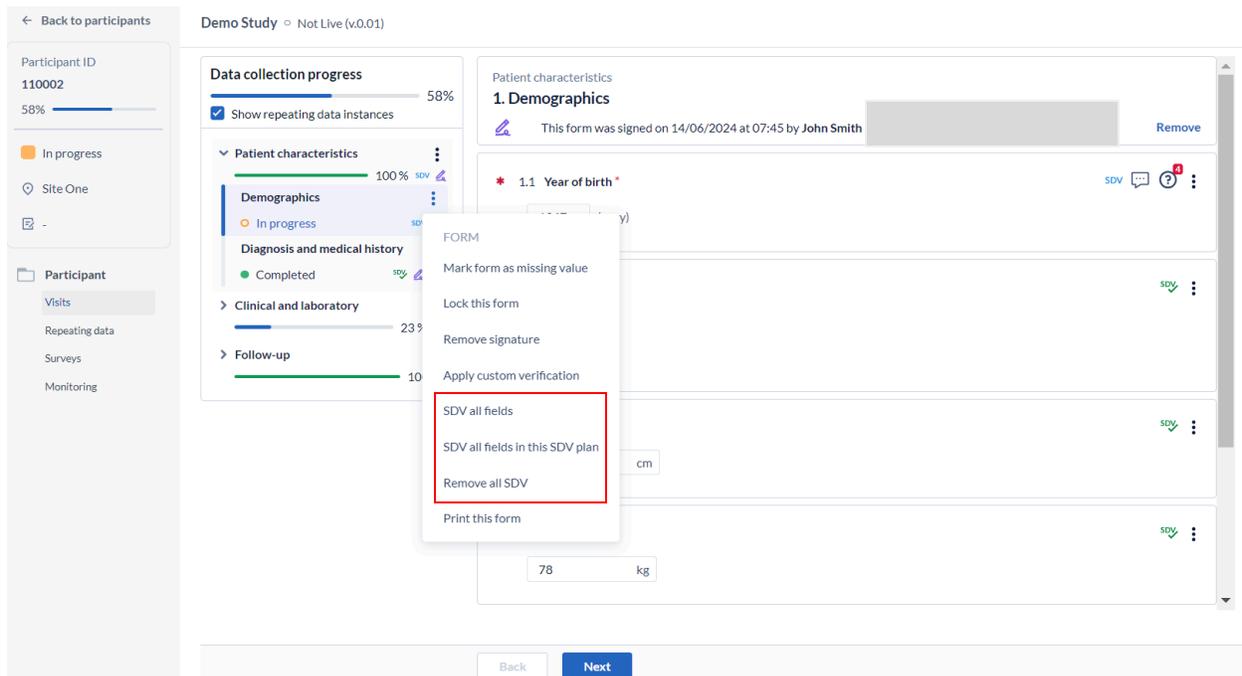
7.1. Verify a visit or a study form

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. When adding SDV for a visit, click on the **three dots next to the visit** name and choose a relevant SDV option:



3. To apply SDV to a form, click on the **three dots next to the form** and select a relevant SDV option:

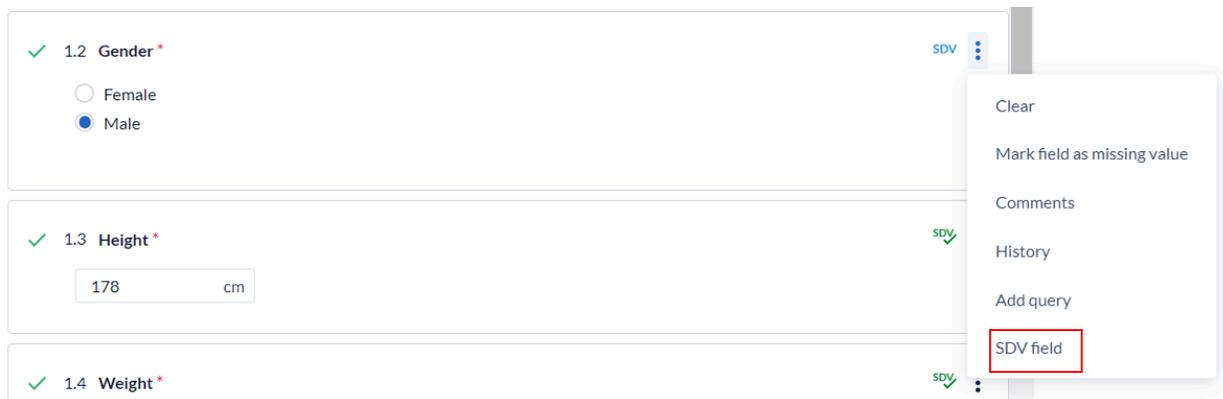


3. Click 'Continue' to save the verification or 'Cancel' to return to the data entry view.

7.2. Mark a field as verified

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

1. Click on the **three dots next to the field**
2. Choose the option 'SDV field'

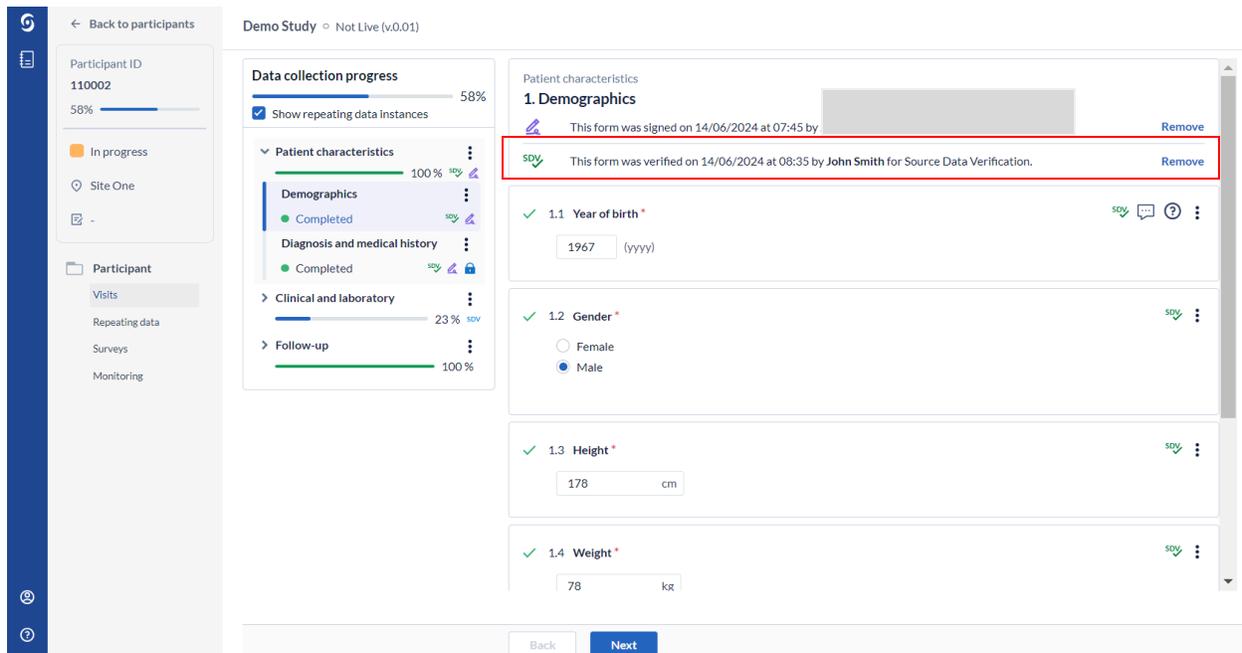


The screenshot shows a data entry form with three fields:

- 1.2 Gender ***: Radio buttons for Female and Male (Male is selected). A blue 'SDV' icon and a three-dot menu are visible to the right.
- 1.3 Height ***: A text input field containing '178' and a unit dropdown set to 'cm'. A green 'SDV' icon and a three-dot menu are visible to the right. The context menu is open, showing options: Clear, Mark field as missing value, Comments, History, Add query, and **SDV field** (highlighted with a red box).
- 1.4 Weight ***: A text input field. A green 'SDV' icon and a three-dot menu are visible to the right.

7.3 SDV indicators

In a participant, each verified form will be marked with a 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 Form 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 Form 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 Form SDV banner is shown, the corresponding form is shown as SDV'd on the Form 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 Forms is removed;
- The Repeating Data instance SDV is removed when the SDV of any of its child Forms 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:

← Back to participants

Demo Study Not Live (v0.01)

Monitoring Filters

Queries Validations Pending SDV Dropped Verifications

Site <small>↑↓</small>	Created on <small>↓</small>	Dropped on <small>↑↓</small>	Dropped by <small>↑↓</small>	Location	View
Site One	14 Jun 2024	14 Jun 2024		Visit Patient cha... >	
Site One	14 Jun 2024	14 Jun 2024		Visit Patient cha... >	

1 - 2 of 2 Items per page: 25

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).

7.5 Source Data Verification – SDV Plans

The SDV plans can be applied to the study builds. One plan can be applied to one study site. When the SDV plan is applied, you can see an SDV icon next to the Visit, Form or field name. These icons indicate which data should be verified.

Data collection progress

25%

Show repeating data instances

- ▼ Patient characteristics 25%
 - Demographics 50% SDV
 - In progress SDV
 - Diagnosis and medical history SDV
 - In progress SDV
- > Clinical and laboratory 8% SDV
- > Follow-up 0%

Patient characteristics

1. Demographics

✓ 1.1 Year of birth * SDV ⋮

1967 (yyyy)

✓ 1.2 Gender * SDV ⋮

Female

Male

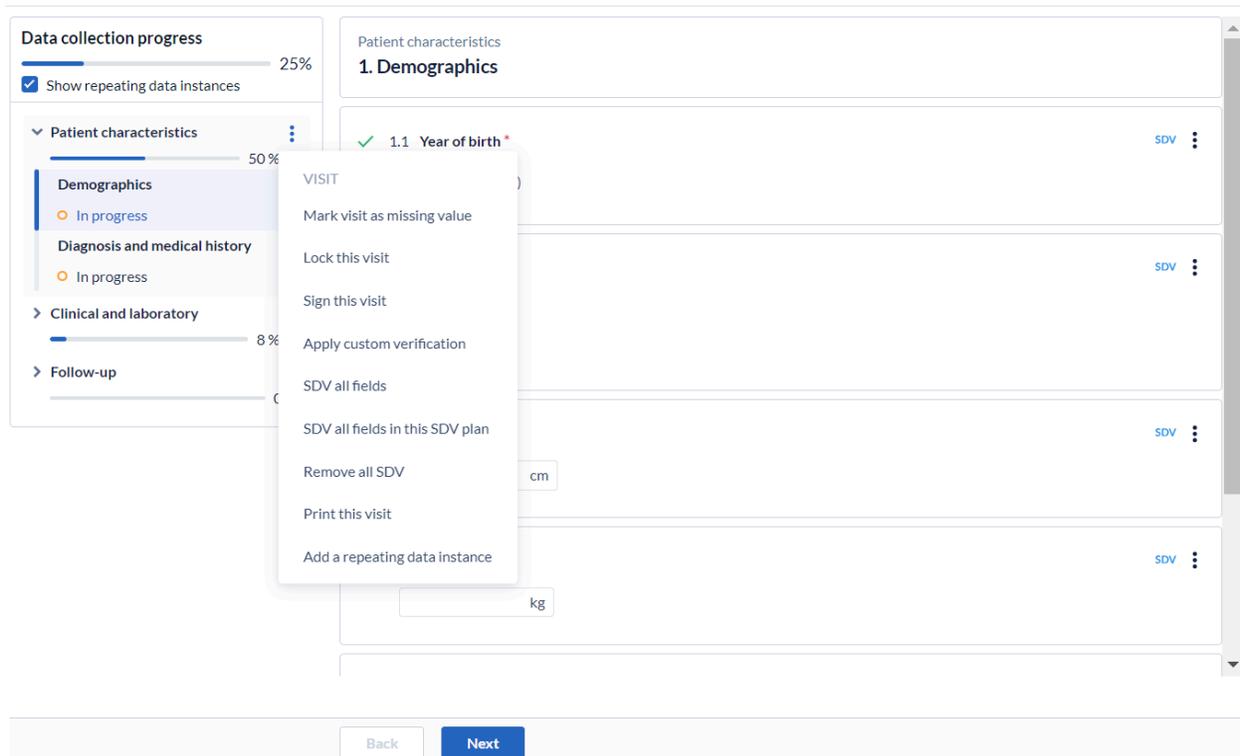
* 1.3 Height * SDV ⋮

cm

* 1.4 Weight * SDV ⋮

kg

1. To apply SDV to a visit or a form, click on the three dot menu next to the visit name and choose the option 'SDV Visit', then choose a relevant SDV option:



Once verified, the SDV icon will turn green and a banner stating that the form was verified will appear.

Data collection progress 33%

Show repeating data instances

- Patient characteristics 70% SDV
 - Demographics
 - In progress
 - Diagnosis and medical history
 - In progress
- Clinical and laboratory 8% SDV
- Follow-up 0%

Patient characteristics

2. Diagnosis and medical history

SDV This form was verified on 14/06/2024 at 08:52 by John Smith for Source Data Verification. Remove

✓ 2.1 Primary renal diagnosis* SDV

Focal glomerulosclerosis

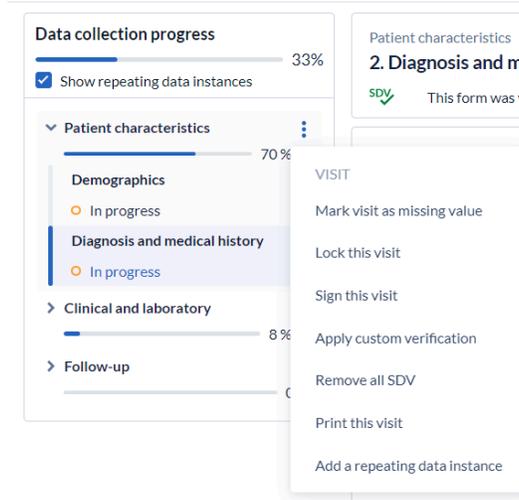
✓ 2.2 History of cardiovascular disease* SDV

No
 Yes
 Unknown

✓ 2.3 History of diabetes* SDV

No
 Yes
 Unknown

- The same logic has been extended at form, visit and repeating data levels. If a form, visit or repeating data instance has no fields requiring SDV, the green SDV icon will be added only after all its fields that can be verified have been verified.
- This optional and additional verification will not influence the SDV progress of your study, as this will only account for the defined SDV plans.
- Using the cogwheel menu on form, visit or repeating data instance levels, you can choose to verify in batch all fields or all fields in the assigned SDV plan. Once a form, visit or repeating data instance has been marked as verified, you can easily remove all source data verifications in bulk by clicking on the three dots next to a visit or a form and choosing the option to 'Remove all SDV':



- A confirmation dialog will appear. Click 'Yes' to proceed. The SDV will be removed. The banner disappeared and the SDV icon's color is blue again.

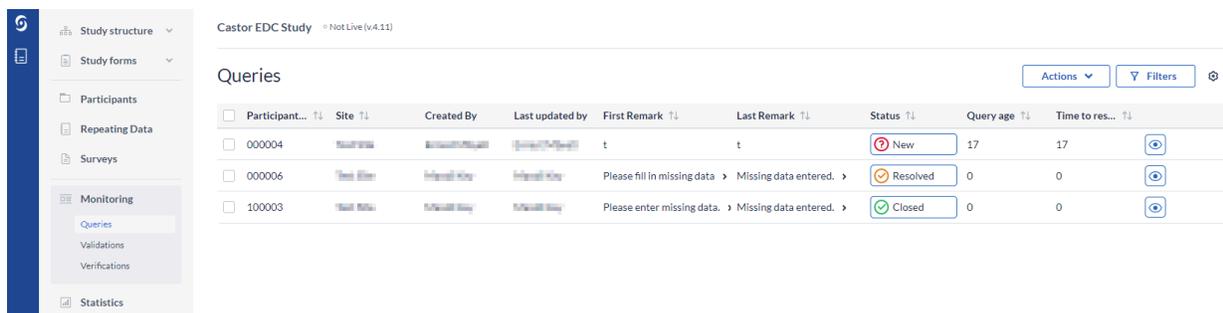


8. The global Monitoring tab

Within the general study overview, you can also access the ‘global’ 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 participant 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...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to res...
000004	Test Site	Michael Key	Michael Key	t	t	New	17	17
000006	Test Site	Michael Key	Michael Key	Please fill in missing data	Missing data entered	Resolved	0	0
100003	Test Site	Michael Key	Michael Key	Please enter missing data	Missing data entered	Closed	0	0

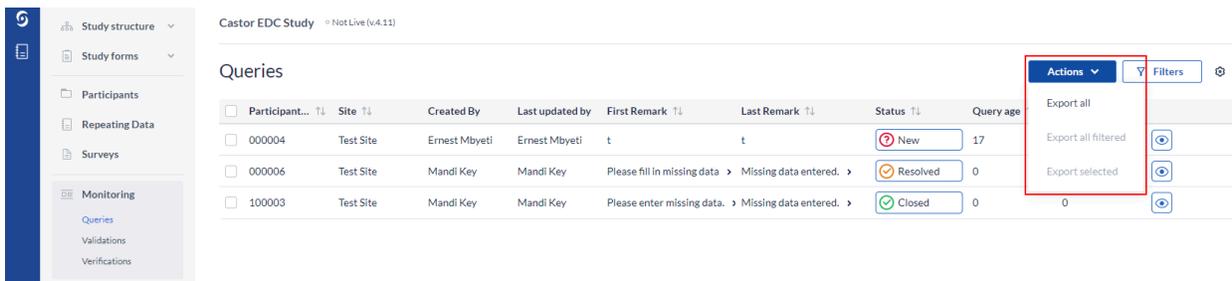
- **Participant ID:** ID of a participant where a query has been created.
- **Site:** Site to which the participant is linked.
- **Created by:** User who created a query.
- **Last updated by:** Last user who updated a query.
- **First Remark:** Initial comment which was added when creating a query.
- **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.



The screenshot shows the Castor EDC Study interface. On the left is a navigation menu with categories like Study structure, Study forms, Participants, Repeating Data, Surveys, and Monitoring. The main area displays a table of Queries. The table has columns for Participant ID, Site, Created By, Last updated by, First Remark, Last Remark, Status, and Query age. Three rows are visible, with statuses 'New', 'Resolved', and 'Closed'. An 'Actions' dropdown menu is open over the table, showing options: 'Export all', 'Export all filtered', and 'Export selected'. A 'Filters' button is also visible in the top right of the table area.

Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age
000004	Test Site	Ernest Mbyeti	Ernest Mbyeti	t	t	New	17
000006	Test Site	Mandi Key	Mandi Key	Please fill in missing data	Missing data entered.	Resolved	0
100003	Test Site	Mandi Key	Mandi Key	Please enter missing data.	Missing data entered.	Closed	0

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).

Queries export (All Queries) ✕

Export type *

- Entire study
- Visits
- Repeating Data

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

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.

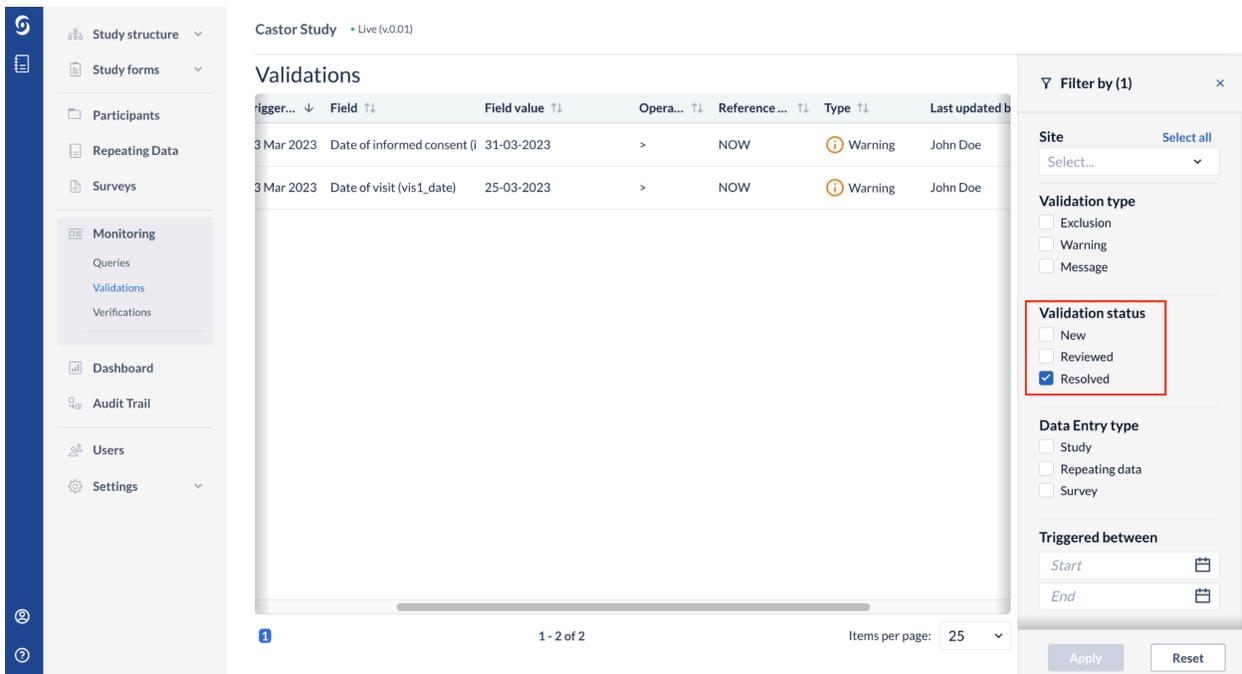
- Study structure
- Study forms
- Participants
- Repeating Data
- Surveys
- Monitoring
 - Queries
 - Validations
 - Verifications
- Statistics
- Audit Trail

Castor EDC Study Not Live (v4.11)

Validations Filters

Particip...	Site	Trigger...	Field	Field value	Opera...	Reference...	Type	Last updated by	Status	View
110003		11 Aug 2022	Has the patient previously	1	==	1	Exclusion			
000004		15 Aug 2022	Inclusion criteria met? (INC	Yes	==	Yes	Message		New	
000007		15 Aug 2022	Inclusion criteria met? (INC	Yes	==	Yes	Message		New	
000007		16 Aug 2022	Is Visit 1 date before the Sci	Yes	==	Yes	Warning		New	

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. You can find the the 'Resolved' validations by using the 'Filters'



The screenshot displays the 'Validations' section of the Castor Study interface. On the left is a navigation sidebar with options like 'Study structure', 'Study forms', 'Participants', 'Repeating Data', 'Surveys', 'Monitoring' (with sub-items 'Queries', 'Validations', 'Verifications'), 'Dashboard', 'Audit Trail', 'Users', and 'Settings'. The main area shows a table of validations with columns: Triggered, Field, Field value, Operator, Reference value, Type, and Last updated by. Two rows are visible, both showing 'Warning' types for 'Date of informed consent' and 'Date of visit'. A 'Filter by (1)' panel is open on the right, showing filters for Site, Validation type (Exclusion, Warning, Message), Validation status (New, Reviewed, Resolved - which is checked and highlighted with a red box), Data Entry type (Study, Repeating data, Survey), and Triggers between (Start, End). At the bottom of the table, it shows '1 - 2 of 2' items and 'Items per page: 25'.

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

Castor EDC Study - Not Live (v4.11)

Verifications Filters

Pending SDV Performed **Dropped**

Participant...	Site	Created on	Dropped on	Dropped by	Location	View
000004		15 Aug 2022	15 Aug 2022		Visit Screening	

- 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

Castor EDC Study - Not Live (v4.11)

Verifications Filters

Pending SDV Performed Dropped

Field	Participant...	Site	Last updat...	Location	View
Additional remarks ()	100002		18 Aug 2022	Repeating data Serious Advers... >	
Did the patient recover? ()	100002		18 Aug 2022	Repeating data Serious Advers... >	
If other, please describe ()	100002		18 Aug 2022	Repeating data Serious Advers... >	
Under which category does the event I	100002		18 Aug 2022	Repeating data Serious Advers... >	
Give a description of the event: ()	100002		18 Aug 2022	Repeating data Serious Advers... >	
What are the consequences for the coi	100002		18 Aug 2022	Repeating data Serious Advers... >	

- 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 (contain data). 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 and user. Access to the full audit trail is normally available only to study admins with all management rights.

Date	Username	User role	Participant ID	Event type	Old value	New value
			A AMC000007	Record opened		
				Audit trail viewed		
				Study opened		
			A AMC000007	Record opened		
			A AMC000006	Record opened		
			A AMC000001	Record opened		
			A AMC000002	Record opened		
				Study opened		
			MYC000012	Survey result		epilepsy_im
			MYC000012	Survey result		epilepsy_im
			MYC000012	Survey result		epilepsy_im
			MYC000012	Survey result		epilepsy_im
			MYC000012	Survey result		feeling_diffe

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 three dots next to the field and select 'History':

The screenshot shows a data entry interface with a sidebar on the left and a main form area. The sidebar includes a 'Data collection progress' section with a 58% completion bar and a list of categories: 'Patient characteristics' (100% completed), 'Demographics' (Completed), 'Diagnosis and medical history' (Completed), 'Clinical and laboratory' (23%), and 'Follow-up' (100%). The main form area is titled 'Patient characteristics' and '1. Demographics'. It contains three fields: '1.1 Year of birth' (value: 1966), '1.2 Gender' (radio buttons for Female and Male), and '1.3 Height'. A dropdown menu is open next to the 'Year of birth' field, showing options: 'Clear', 'Mark field as missing value', 'Comments', 'History' (highlighted with a red box), 'Add query', and 'SDV 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:

Value change history for 'Year of birth' ×

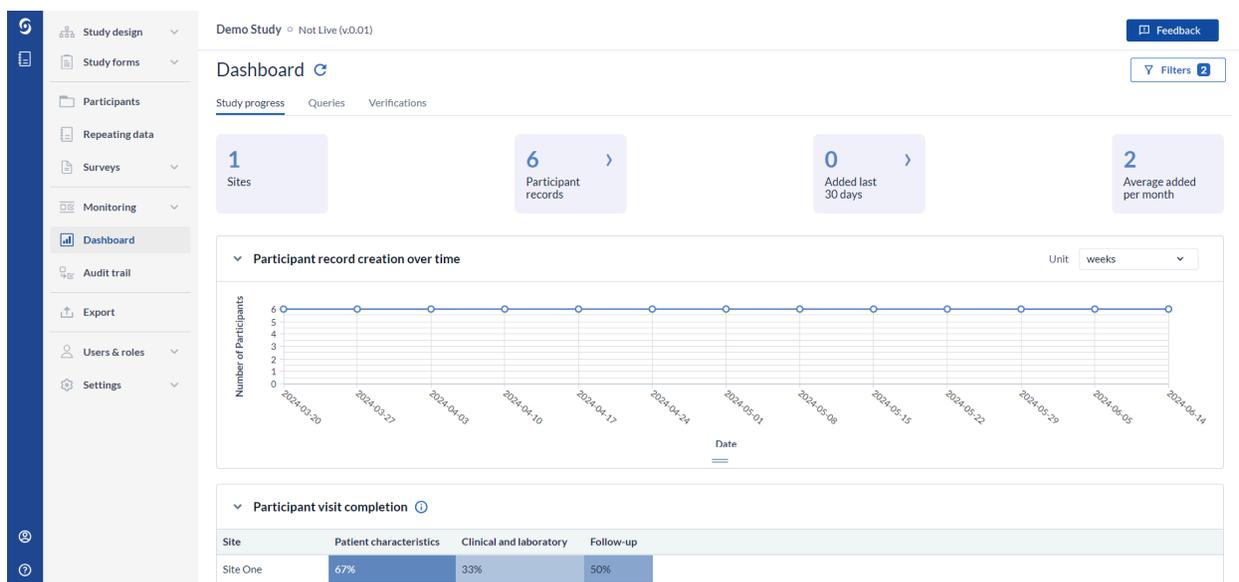
Updated on	Updated by	Value changes to
2024-03-20 11:04:26	John Smith	1967
2024-06-14 09:41:37	John Smith	1966

[Close](#)

10. The Dashboard tab

The [Study Dashboard](#) allows you to track the progress of your study, including participant recruitment, data collection progress, randomization and queries.

Please note that the data aggregated in the dashboard is based on your personal viewing [permissions](#). Before you start analyzing data in the Dashboard use a rounded arrow next to Dashboard title to update the view.



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 CDMS's knowledge base: <https://helpdesk.castoredc.com> or visit Castor Academy <https://academy.castoredc.com/>