

# Castor

## Castor CDMS Monitoring User Guide

Version 2025.2.0.0

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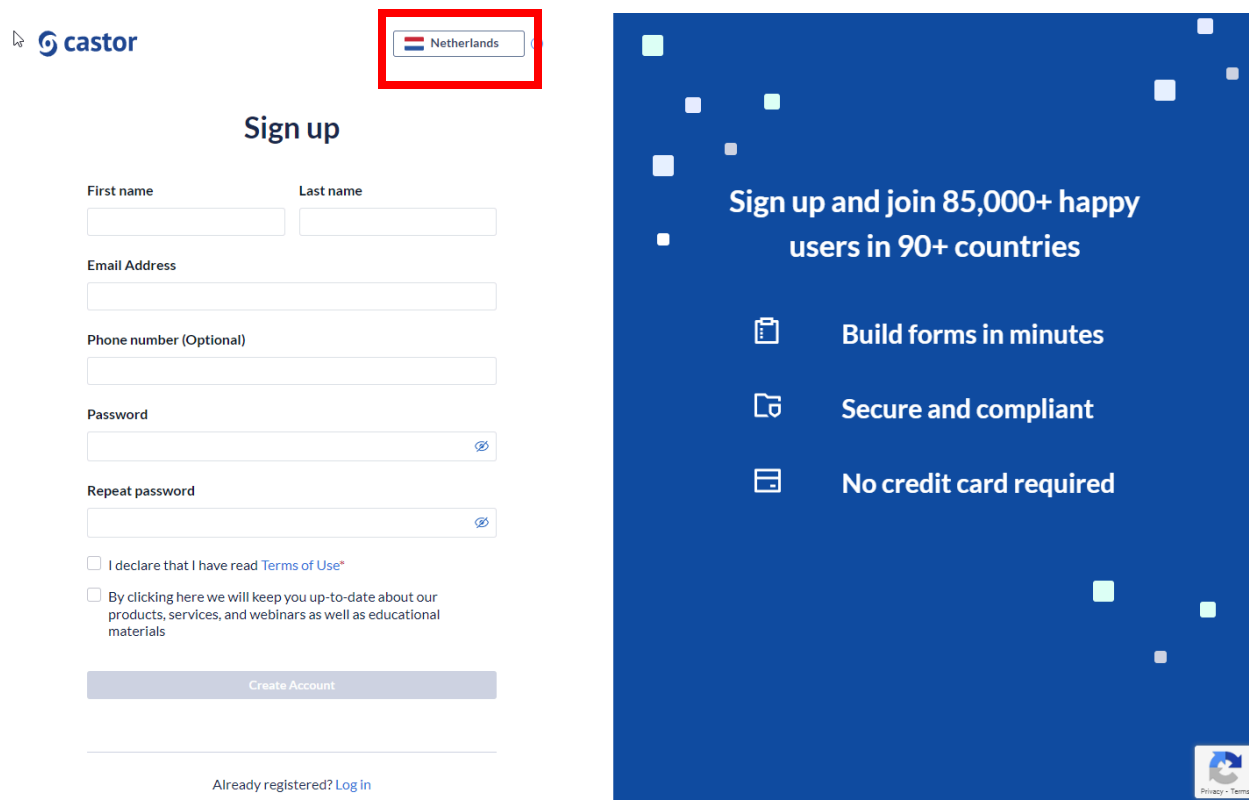
## 1. Register an account


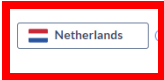
There are two ways to register an account:

- 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.



### Sign up

First name  Last name

Email Address

Phone number (Optional)

Password

Repeat password




☐ I declare that I have read [Terms of Use](#)\*

☐ By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials

[Create Account](#)

Already registered? [Log In](#)

**Sign up and join 85,000+ happy users in 90+ countries**

-  **Build forms in minutes**
-  **Secure and compliant**
-  **No credit card required**

[Privacy](#) [Terms](#)

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'

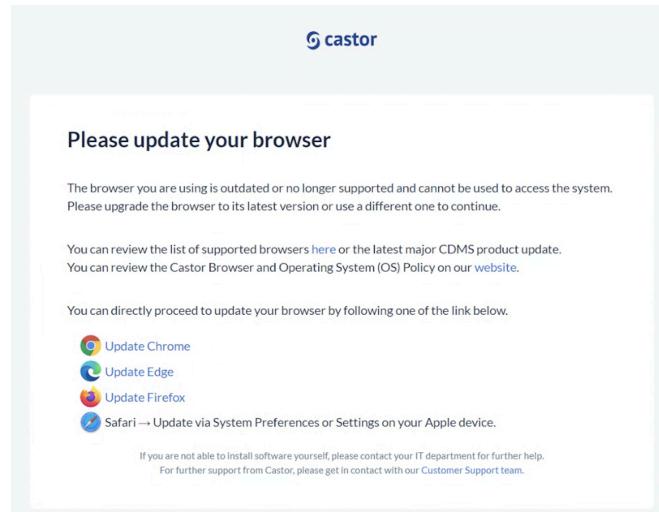
You will receive an email to verify your account. After clicking the link in the email address, you will be prompted to confirm the server where your account will be created.

## 1.2. System Access. Browser & Operating Support Policy

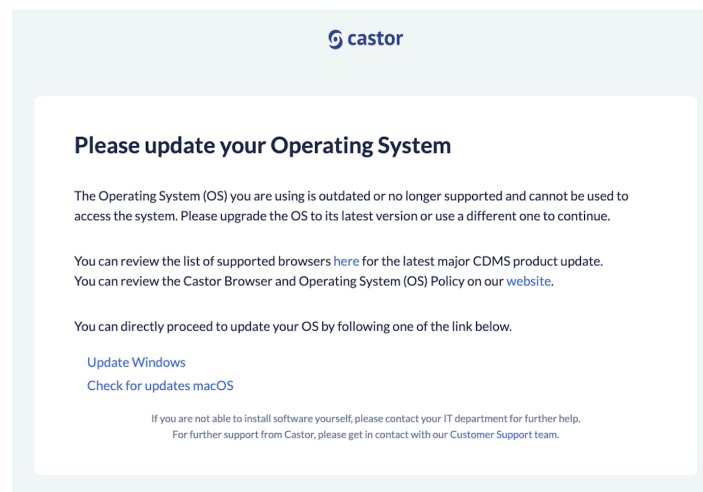
Study teams (clinicians, researchers etc.) accessing CDMS with an unsupported browser or operating system (OS) will now be blocked from logging in and shown a clear error message. This ensures a reliable experience by enforcing access only through allowlisted environments. This change is applicable to all CDMS users that are required to log into the system.

Two new messages have been introduced as part of [Castor's Browser and Operating System Policy](#) enforcement for study teams. If both the OS and browser are unsupported, the OS message takes priority.

**Unsupported Browser Message:**



## Unsupported OS Message:



*Note: The above messages apply only to [clinician-facing CDMS interfaces](#)*

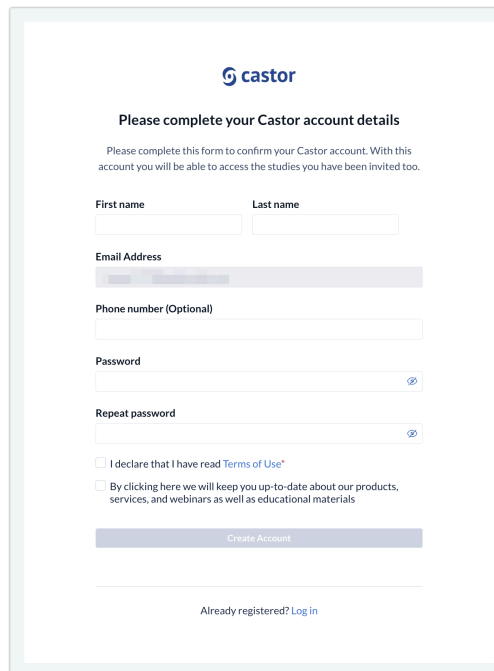
## Supported and validated versions for v2025.2.0.0

### Clinicians:

- Chrome 125 or newer
- Microsoft Edge 124 or newer
- Firefox 127 or newer
- Safari 17 or newer (macOS)
- Safari on iOS 17 or newer

### 1.3. 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 image shows a registration form for a Castor account. At the top is the Castor logo. Below it is the heading "Please complete your Castor account details" followed by a subtext: "Please complete this form to confirm your Castor account. With this account you will be able to access the studies you have been invited too." The form contains several input fields: "First name" and "Last name" (two separate boxes), "Email Address" (a single box with a pre-filled email address), "Phone number (Optional)" (a single box), "Password" (a single box with a strength indicator icon), and "Repeat password" (a single box with a strength indicator icon). Below these fields are two checkboxes: "I declare that I have read Terms of Use\*" and "By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials". At the bottom of the form is a "Create Account" button. Below the button is a link: "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>, <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.
3. Provide your password.
4. Click on 'Login'.

### 2.1. Activate two-factor authentication

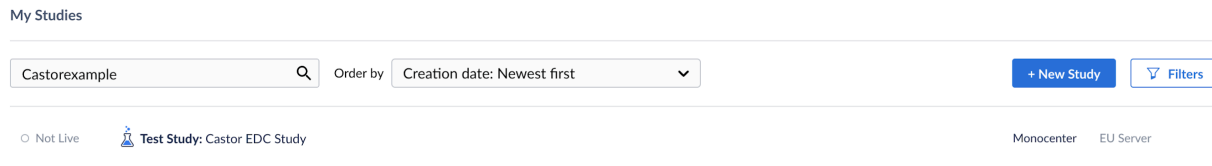
In Castor, you can [configure two-factor authentication \(2FA\)](#) for your account.

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.

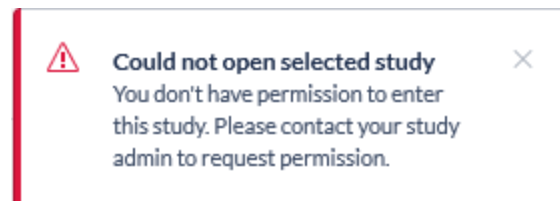


### 3. Open a study

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.



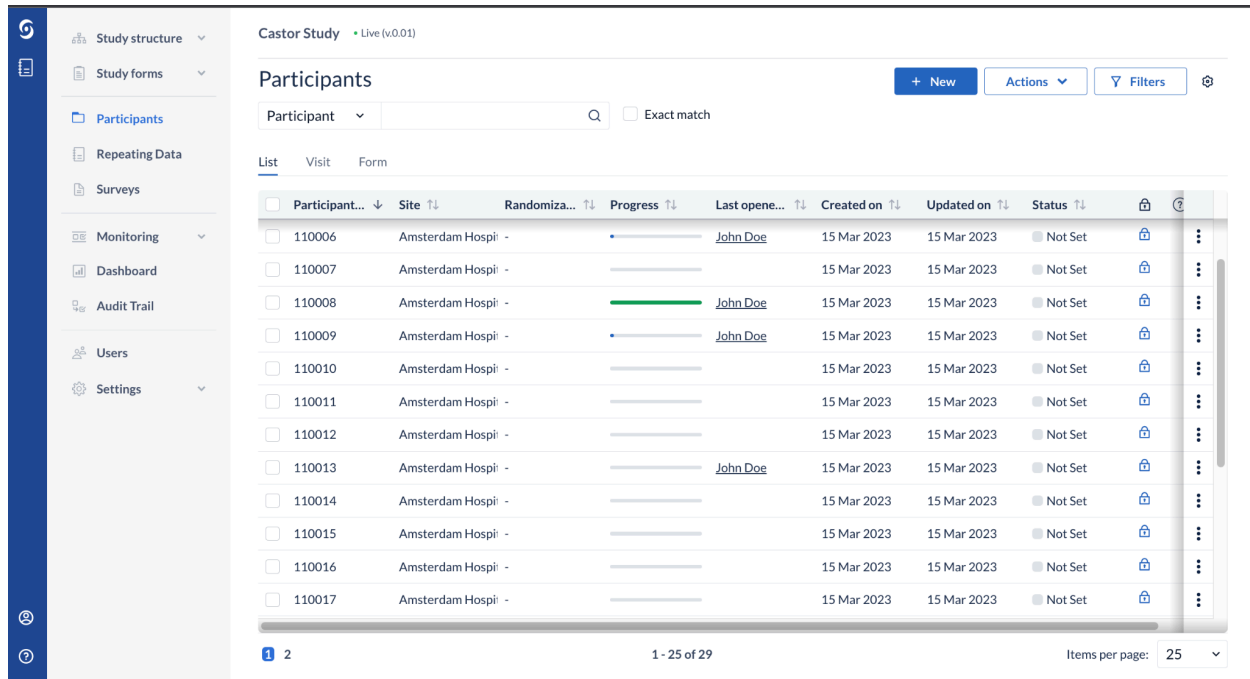
Trying to open a study that is not live will show the following warning:



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.

## 4. Access study for Monitoring

The study will open on the Participants tab.



Castor Study • Live (v.0.01)

Participants

+ New Actions Filters

Participant Q Exact match

List Visit Form

Participant...	Site	Randomiza...	Progress	Last opene...	Created on	Updated on	Status	
110006	Amsterdam Hospi	-	<div><div></div></div>	<a href="#">John Doe</a>	15 Mar 2023	15 Mar 2023	Not Set	
110007	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110008	Amsterdam Hospi	-	<div><div></div></div>	<a href="#">John Doe</a>	15 Mar 2023	15 Mar 2023	Not Set	
110009	Amsterdam Hospi	-	<div><div></div></div>	<a href="#">John Doe</a>	15 Mar 2023	15 Mar 2023	Not Set	
110010	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110011	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110012	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110013	Amsterdam Hospi	-	<div><div></div></div>	<a href="#">John Doe</a>	15 Mar 2023	15 Mar 2023	Not Set	
110014	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110015	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110016	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	
110017	Amsterdam Hospi	-	<div><div></div></div>		15 Mar 2023	15 Mar 2023	Not Set	

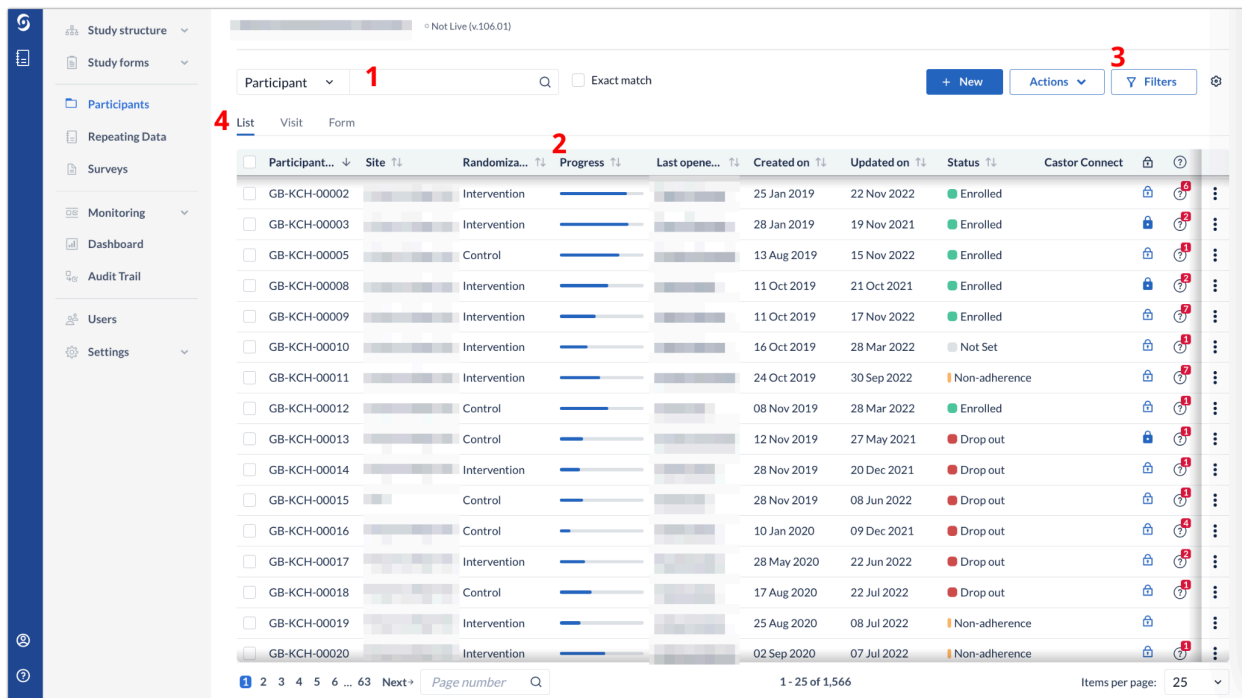
1 2 1 - 25 of 29 Items per page: 25

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.

## 5. The Participants tab

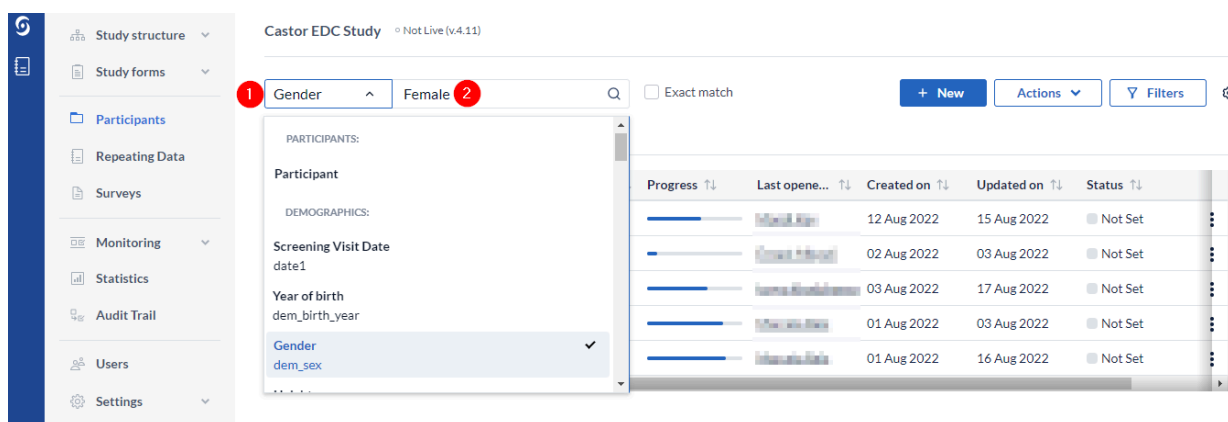
In the Participants tab, a list is displayed showing all participants for the sites to which you have 'View' rights (see Section 6).



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.

## 5.1. Search for Participants

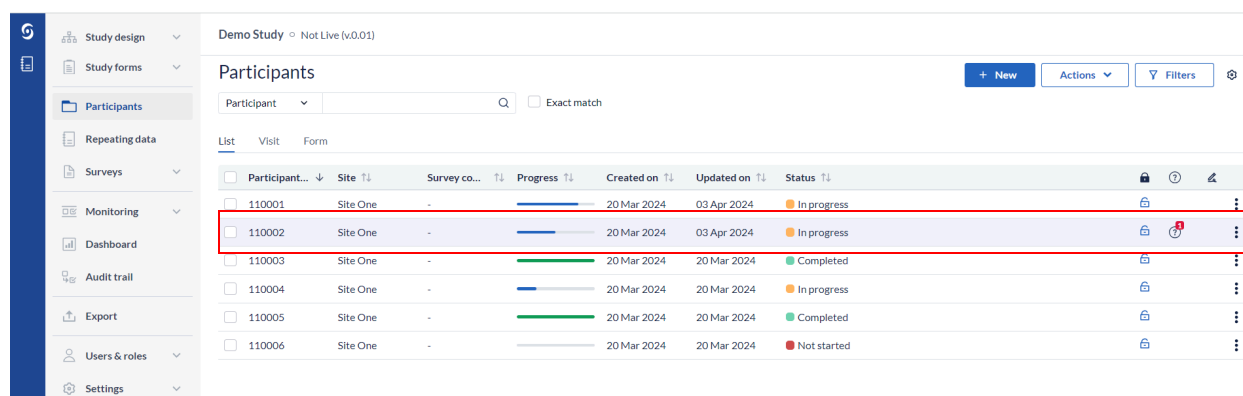
You can use the search bar to find participants that contain certain data, for example if you want to find the participants with a certain age at onset.



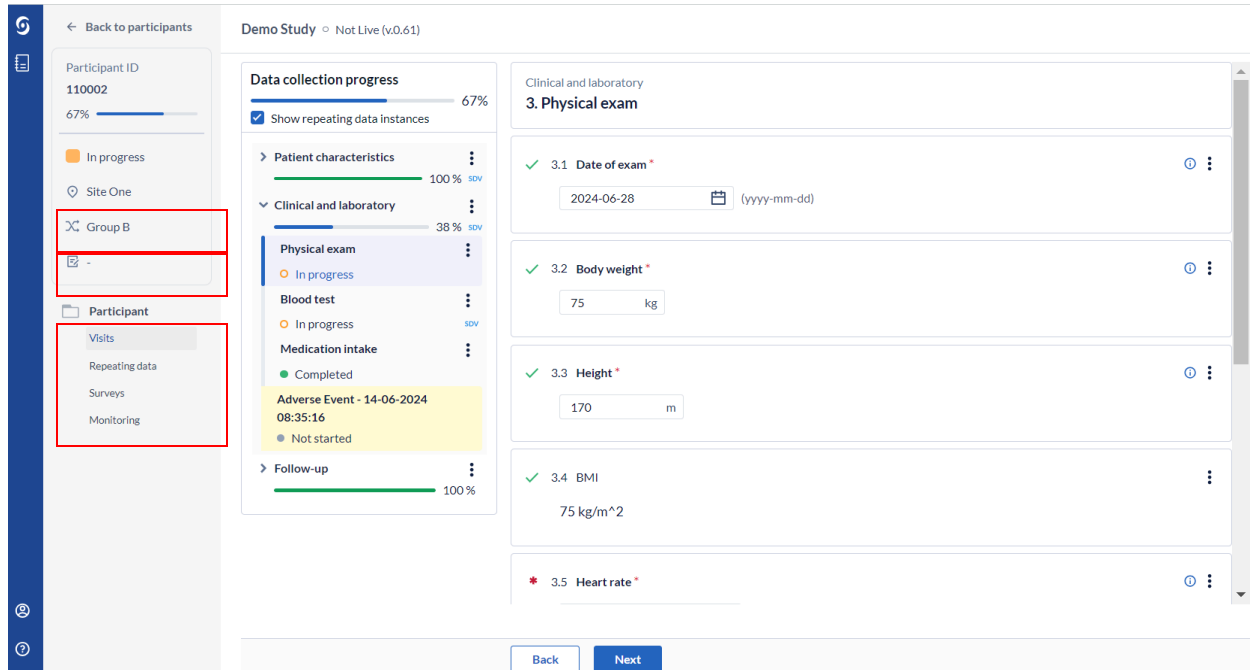
1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the left search box (in this example 'female') and all matching participants will be displayed.

## 5.2. Accessing a single participant

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



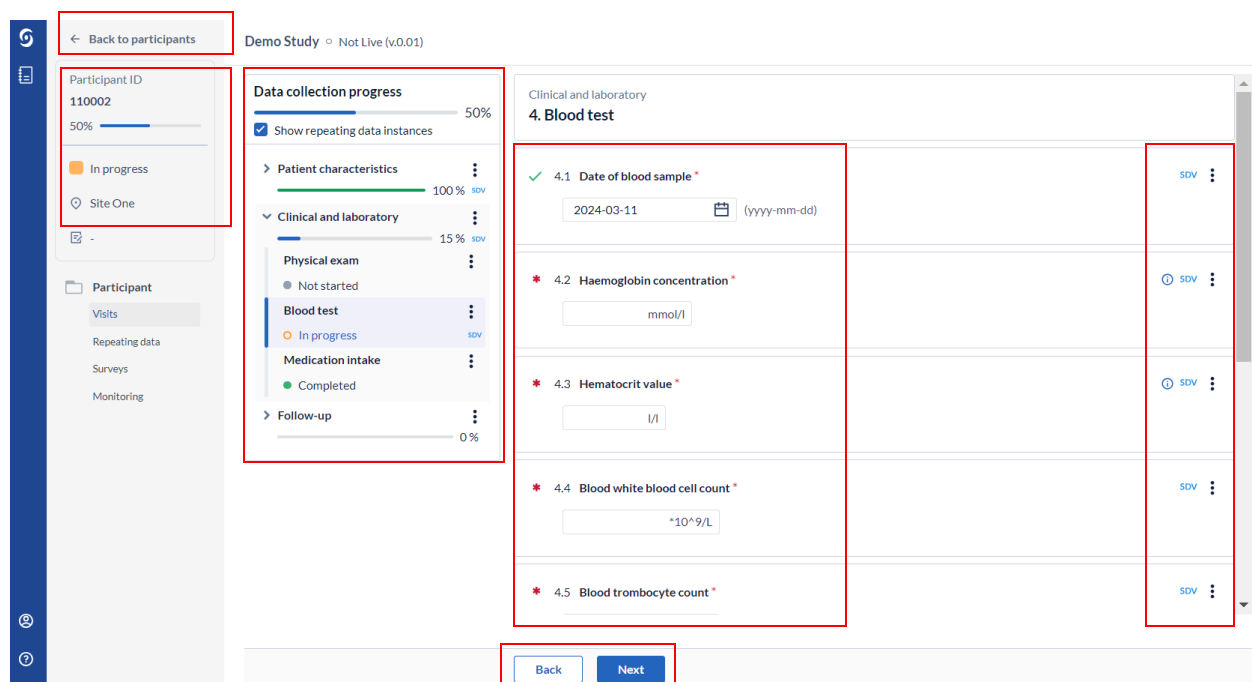
There are a total of 4 available tabs within the participant overview, but which tabs you see depends on the study setup and your specific user rights:



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.

## 5.2.1 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 visits. The sidebar on the left contains navigation links: 'Back to participants', 'Participant ID 110002', '50%' progress bar, 'In progress' status, 'Site One', and a list of study forms including 'Participant', 'Visits', 'Repeating data', 'Surveys', and 'Monitoring'. The central panel shows 'Data collection progress' for 'Demo Study - Not Live (v0.01)'. It includes a 'Show repeating data instances' checkbox and a list of study forms: 'Patient characteristics' (100% SDV), 'Clinical and laboratory' (15% SDV), 'Physical exam' (Not started), 'Blood test' (In progress, SDV), 'Medication intake' (Completed), and 'Follow-up' (0%). The right panel displays the '4. Blood test' form, which includes fields for '4.1 Date of blood sample' (2024-03-11), '4.2 Haemoglobin concentration' (mmol/l), '4.3 Hematocrit value' (l/l), '4.4 Blood white blood cell count' (\*10<sup>9</sup>/L), and '4.5 Blood trombocyte count'. Each field has a corresponding 'SDV' button. At the bottom, there are 'Back' and 'Next' buttons.

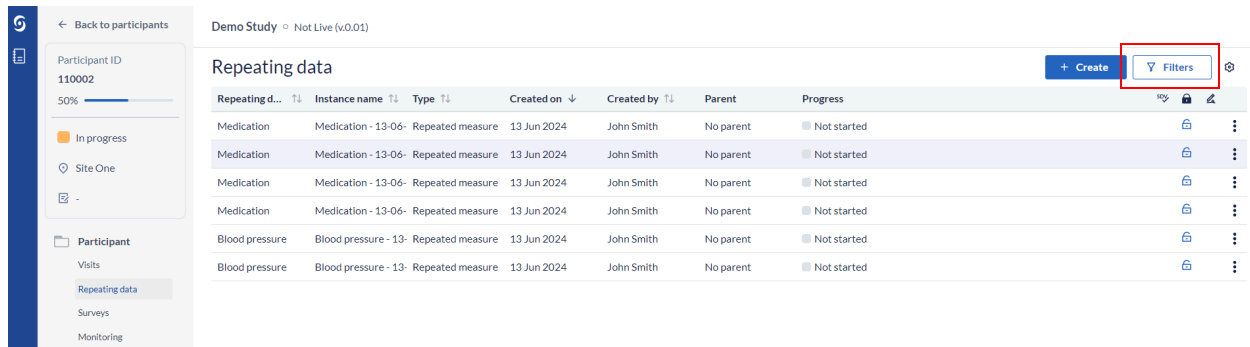
It consists of the following elements:

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.

## 5.2.2 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	

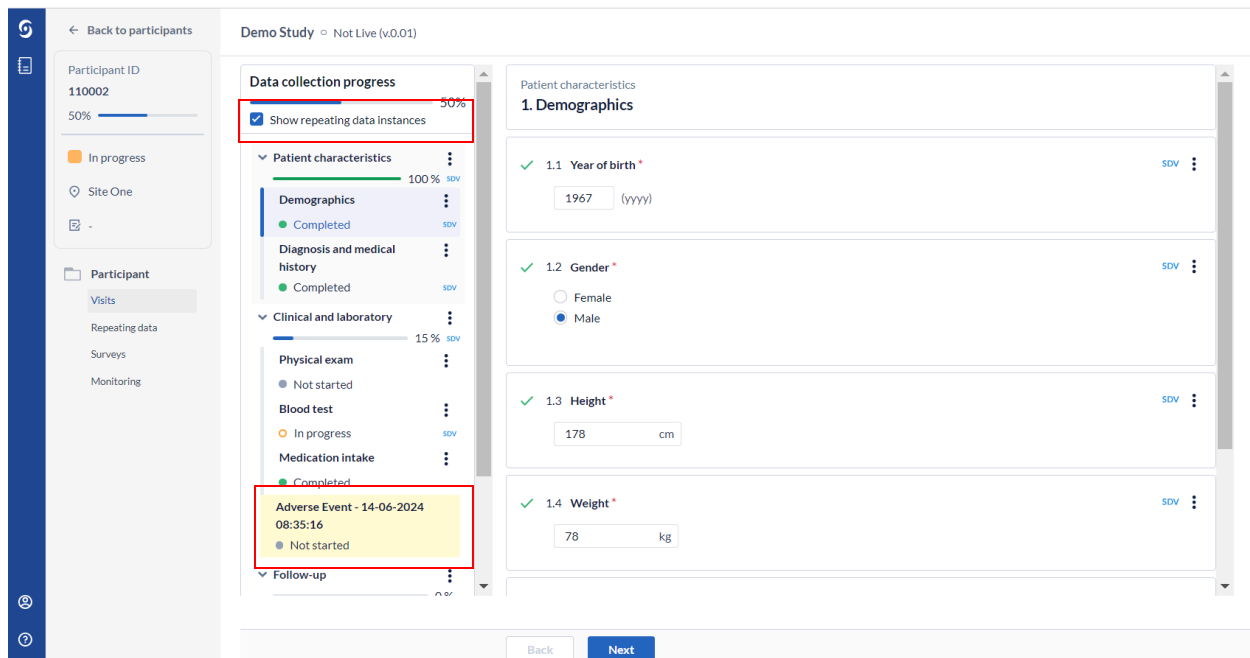
1. The 'Repeating Data' tab in a participant will show you all existing repeating data instances for that participant. The global 'Repeating Data' tab in the study overview will list all repeating data instances for all participants.
2. To search for a repeating data instance, you can use the "Filters" 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 Sidebar:** Contains navigation links for 'Participant', 'Visits', 'Repeating data', 'Surveys', and 'Monitoring'. The 'Participant' section is currently selected.
- Top Bar:** Shows 'Demo Study' and 'Not Live (v0.01)'.
- Data collection progress:** A progress bar indicates 50% completion. A checkbox labeled 'Show repeating data instances' is checked and highlighted with a red box.
- Patient characteristics:** A section titled '1. Demographics' containing four items:
  - 1.1 Year of birth: 1967 (yyyy)
  - 1.2 Gender: Male (selected)
  - 1.3 Height: 178 cm
  - 1.4 Weight: 78 kg
- Repeating data instances:** A section titled 'Patient characteristics' showing a list of instances. The 'Demographics' instance is marked as 'Completed'. The 'Clinical and laboratory' instance is marked as 'In progress'. The 'Physical exam' instance is marked as 'Not started'. The 'Blood test' instance is marked as 'In progress'. The 'Medication intake' instance is marked as 'Completed'. An 'Adverse Event - 14-06-2024 08:35:16' instance is marked as 'Not started' and highlighted with a red box.
- Bottom Bar:** Contains 'Back' and 'Next' buttons.





[← Go to repeating data overview](#)

> Adverse event - 17-05-2024

⋮

14:28:11

22 %

SDV ✓

VER ✓

### 5.3.3 Field comments and queries

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

\* 1.1 Year of birth \*

1967

(yyyy)

SDV

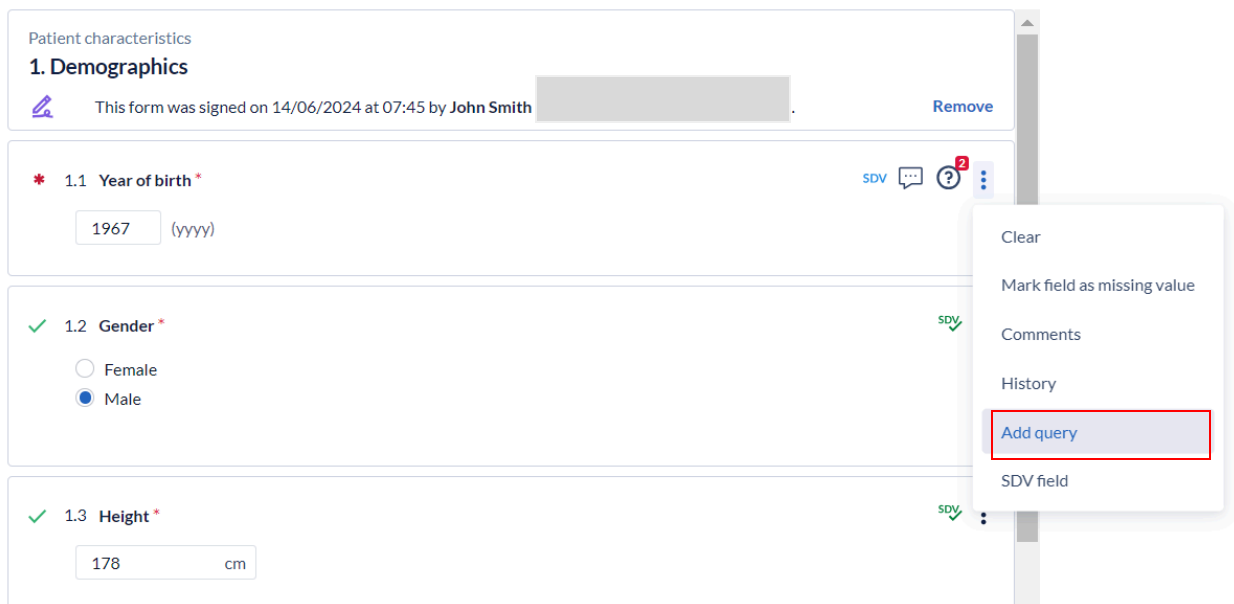
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

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

## 6. Monitoring queries

### 6.1 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':



Patient characteristics

**1. Demographics**

This form was signed on 14/06/2024 at 07:45 by John Smith [redacted] [Remove](#)

**\* 1.1 Year of birth \*** SDV ?

1967 (yyyy)

**✓ 1.2 Gender \*** SDV

☐ Female

☒ Male

**✓ 1.3 Height \*** SDV

178 cm

Clear

Mark field as missing value

Comments

History

**Add query**

SDV field

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

**Add query for field Year of birth** [×](#)

Current query status

? New

Remark \*

Please add missing data

[Cancel](#) [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)

## 6.2 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).

## 6.3. 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

<input type="checkbox"/>	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: 50%; 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

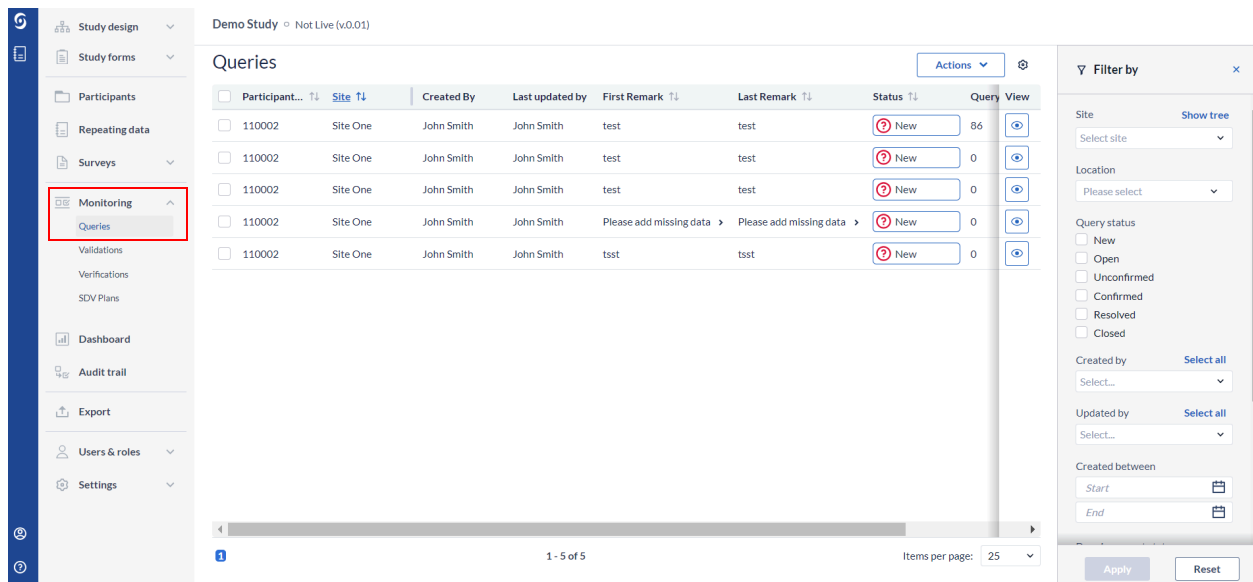
Participant ▾

☐ Exact match

List
Visit
Form

<input type="checkbox"/>	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	
<input type="checkbox"/>	110002	Site One	<div style="width: 50%; background-color: #007bff;"></div> <span style="border: 2px solid red; padding: 2px;">🔍</span>	<div style="width: 50%; background-color: #007bff;"></div> <span style="border: 2px solid red; padding: 2px;">🔍</span>	<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: 50%; background-color: #007bff;"></div>	<div style="width: 100%; background-color: #28a745;"></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: #dc3545;"></div>	<div style="width: 0%; background-color: #dc3545;"></div>	<div style="width: 0%; background-color: #dc3545;"></div>

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



**Monitoring**

**Queries**

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	

1 - 5 of 5

Items per page: 25

**Filter by**

Site: [Show tree](#)  
Select site:

Location: Please select

Query status

- ☐ New
- ☐ Open
- ☐ Unconfirmed
- ☐ Confirmed
- ☐ Resolved
- ☐ Closed

Created by: [Select all](#)  
Select...

Updated by: [Select all](#)  
Select...

Created between

Start:

End:

[Apply](#) [Reset](#)

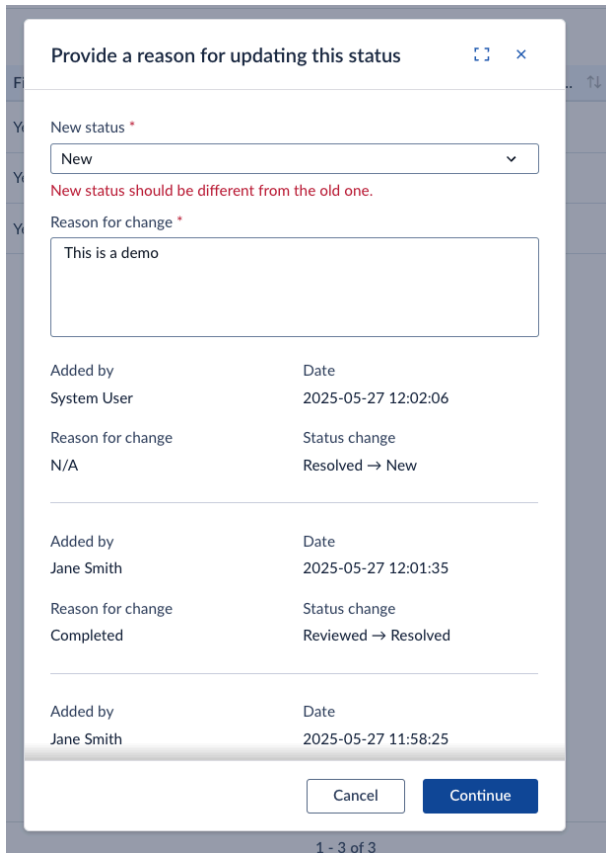
All queries for *all* participants are available in the general Monitoring tab (see Monitoring tab section below).

## 6.4 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.

## 7. Data Validations

Users updating validation statuses in studies with the “**Confirm validation updates**” setting **enabled** will now be prompted to enter a mandatory reason for change. This reason is logged in the Audit Trail.



Provide a reason for updating this status

New status \*

New

New status should be different from the old one.

Reason for change \*

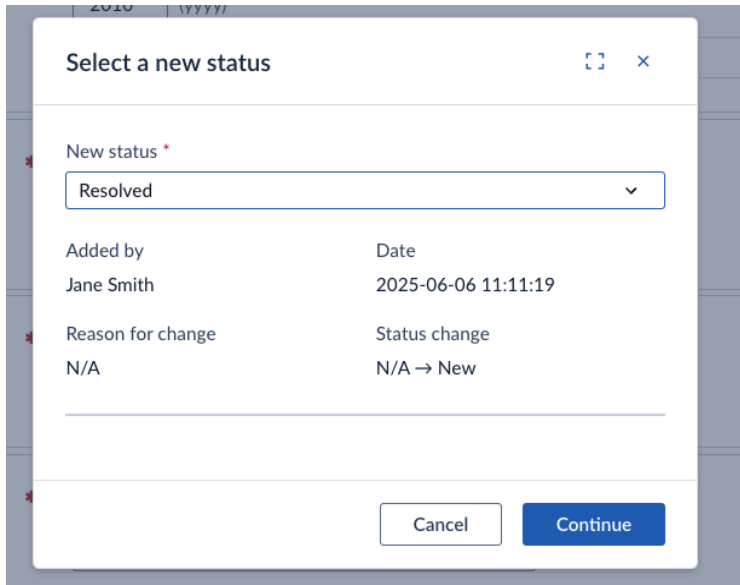
This is a demo

Added by	Date
System User	2025-05-27 12:02:06
Reason for change	Status change
N/A	Resolved → New
Added by	Date
Jane Smith	2025-05-27 12:01:35
Reason for change	Status change
Completed	Reviewed → Resolved
Added by	Date
Jane Smith	2025-05-27 11:58:25

Cancel Continue

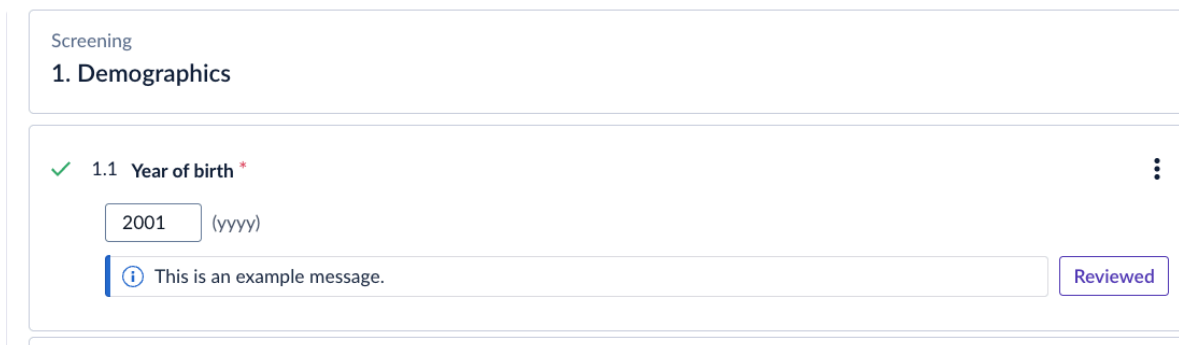
1 - 3 of 3

For system-triggered status changes, the static note "Automatically updated by the system" is recorded automatically. For studies where the “**Confirm validation updates**” setting is **disabled**, the status updates can be completed without inputting a reason.



Users can now update the status of **Information** and **Warning validations** directly within the CRF views in modern Data Entry, eliminating the need to switch to the Validations overview.

If the user does not have 'Validations' permissions, the status button will be read-only. If Monitoring is **disabled**, then this will not shown in Data Entry.



Status changes are permission-based, logged in the Audit Trail, and reflected instantly across all views with confirmation toasts.

If Monitoring is **not enabled** for the study, validation statuses remain read-only.



#### Audit trail

Filters 1

Date	Performed by	User role	Participant ID	Event type	Old value	New value
27 May 2025 12:10:29	System User (email)	—	110003	Validation status updated	reviewed	auto-closed
27 May 2025 12:10:17	Jane Smith (alexan)	—	110003	Validation status updated	new	reviewed

*Applicable only for studies using the newly released using the [updated Validations logic](#) (CDMS v2024.4.0.0):*

Validation status updates include a full change history within the status update modal. Users can view the status change history including who made each change, when it was made, and the reason for it, if the “**Confirm validation updates**” setting is **enabled**. For studies **without the setting enabled**, reasons are omitted or marked as “N/A.” Entries are listed from newest to oldest, providing transparency and auditability directly within the workflow.

Provide a reason for updating this status

New status \*

Auto-closed

Added by

System User

Date

2025-06-02 10:12:03

Reason for change

Automatically updated by the system.

Status change

New → Auto-closed

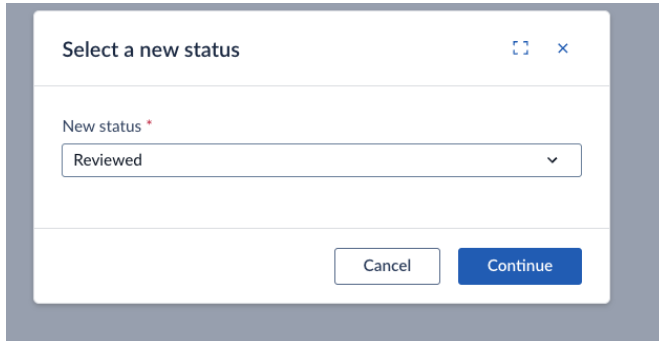
Added by

Jane Smith

Date

2025-06-02 10:11:53

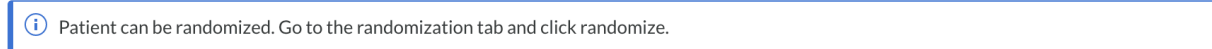
For studies that **have not adopted** the new Validations logic, the validations status change flow remains as before the release. Only some visual changes apply.



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:



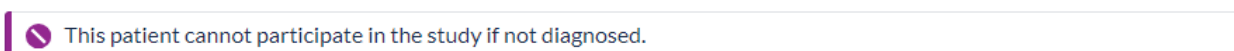
2. A 'warning' type, warning the user:



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

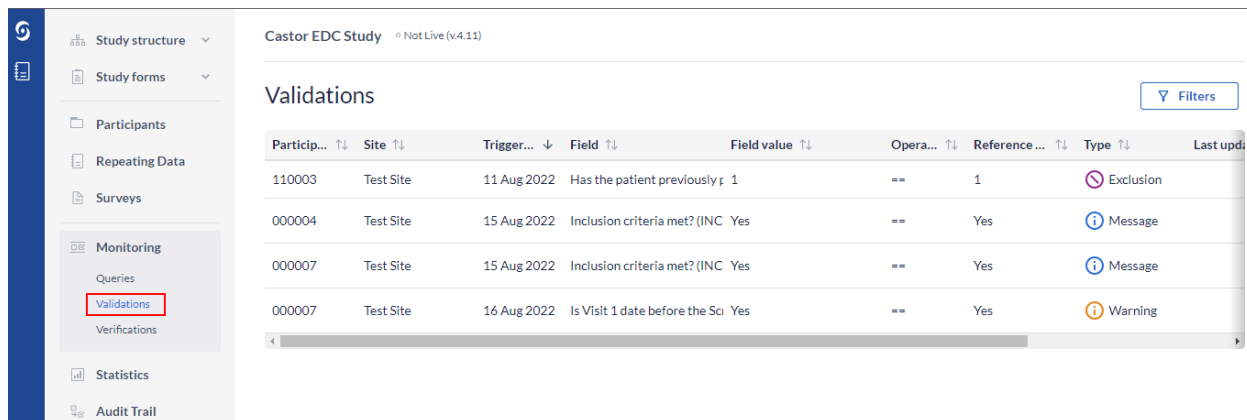


4. An 'exclusion' type, when the entered data does not meet inclusion/exclusion criteria:



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:



Castor EDC Study - Not Live (v4.11)

Validations Filters

Particip...	Site	Trigger...	Field	Field value	Opera...	Reference ...	Type	Last upd...
110003	Test Site	11 Aug 2022	Has the patient previously g	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).

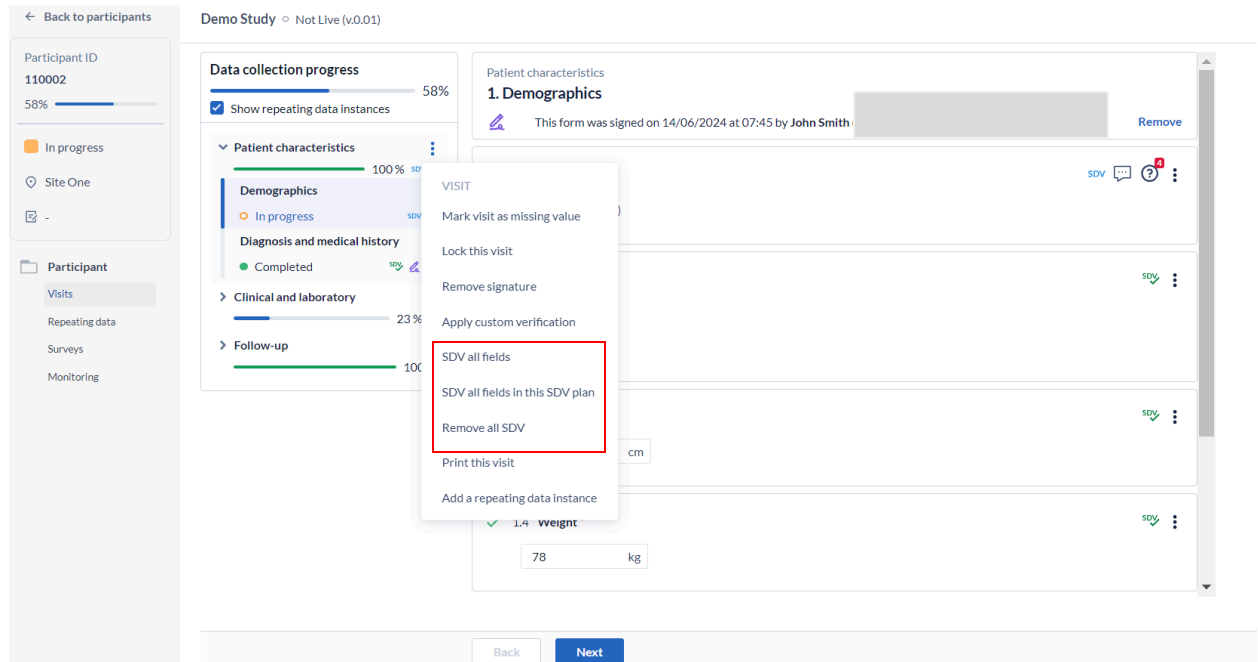
## 8. Source Data Verification

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

### 8.1. Verify a visit or a study form

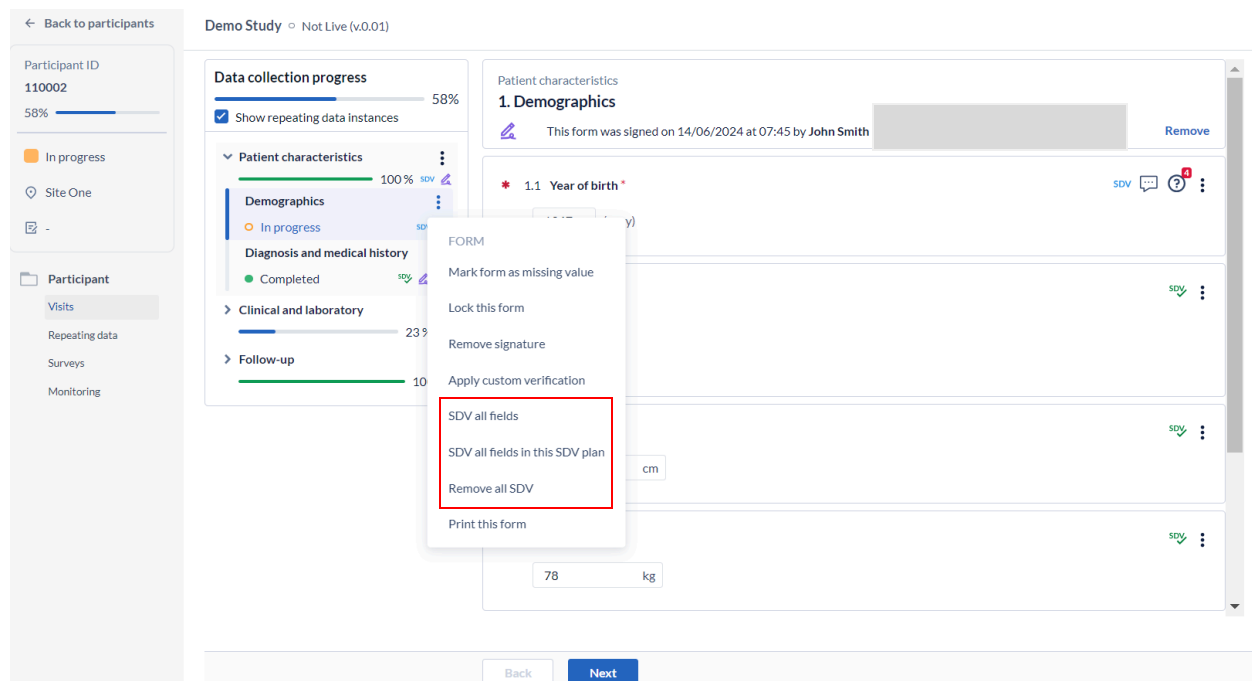
You can mark a form or visit as verified. To do so:

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:



The screenshot shows the Castor interface for a 'Demo Study' (v0.01). On the left, a sidebar shows 'Participant ID 110002' with a 58% data collection progress bar. The main area displays 'Patient characteristics' with a '1. Demographics' form. A context menu is open over the form, listing options: VISIT, Mark visit as missing value, Lock this visit, Remove signature, Apply custom verification, SDV all fields (highlighted with a red box), SDV all fields in this SDV plan (highlighted with a red box), Remove all SDV (highlighted with a red box), Print this visit, and Add a repeating data instance. The form itself shows a 'Year of birth' field with a value of 78.

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



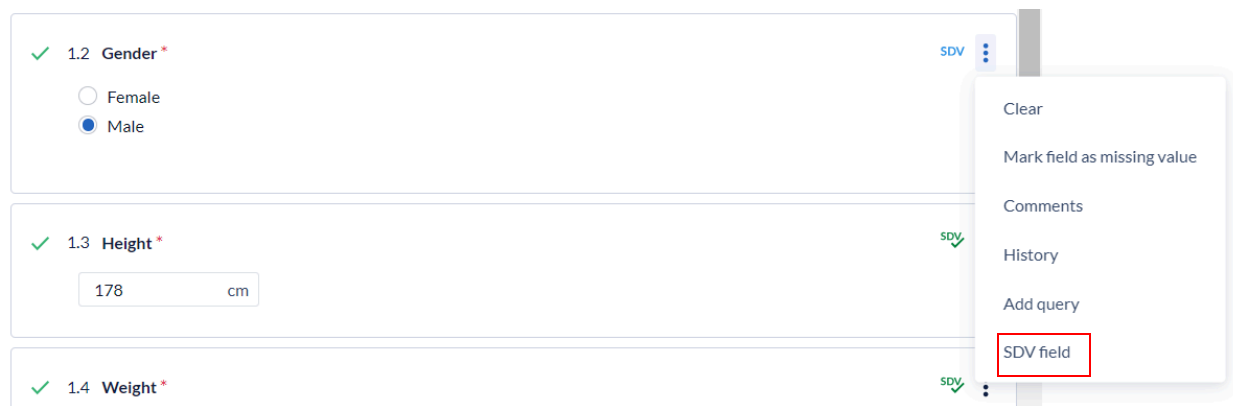
The screenshot shows the Castor interface for a 'Demo Study' (v0.01). On the left, a sidebar shows 'Participant ID 110002' with a 58% data collection progress bar. The main area displays 'Patient characteristics' with a '1. Demographics' form. A context menu is open over the form, listing options: FORM, Mark form as missing value, Lock this form, Remove signature, Apply custom verification, SDV all fields (highlighted with a red box), SDV all fields in this SDV plan (highlighted with a red box), Remove all SDV (highlighted with a red box), and Print this form. The form itself shows a 'Year of birth' field with a value of 78.

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

## 8.2. 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 form with three fields, each with a green checkmark indicating verification:

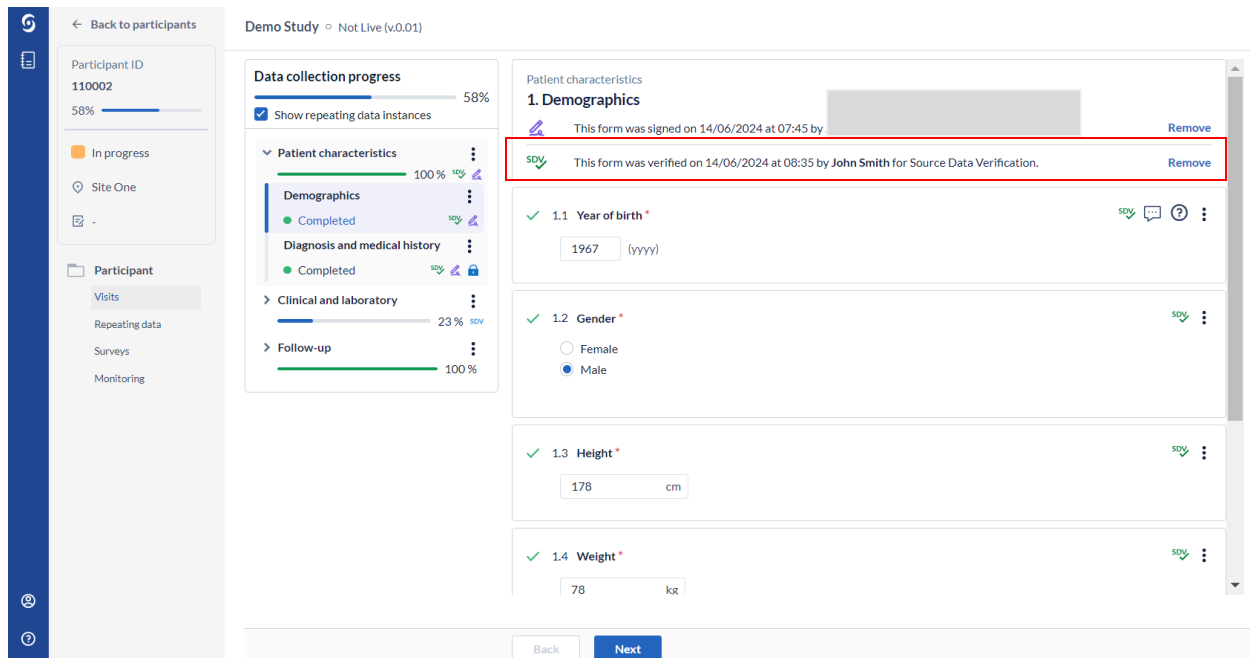
- 1.2 Gender \***: Radio buttons for Female and Male (Male is selected).
- 1.3 Height \***: A text input field containing '178' and a unit dropdown set to 'cm'.
- 1.4 Weight \***: A text input field (empty).

A context menu is open for the Height field, showing the following options:

- Clear
- Mark field as missing value
- Comments
- History
- Add query
- SDV field** (highlighted with a red box)

## 8.3 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.



The screenshot displays the Castor interface for a participant with ID 110002. The left sidebar shows navigation options: Back to participants, In progress (58%), Site One, and a list of data types (Participant, Visits, Repeating data, Surveys, Monitoring). The main content area is titled 'Demo Study - Not Live (v.0.01)' and shows 'Data collection progress' with a 58% completion bar. Below this, a 'Patient characteristics' section lists 'Demographics' (100% completed), 'Diagnosis and medical history' (100% completed), 'Clinical and laboratory' (23% completed), and 'Follow-up' (100% completed). The right panel shows 'Patient characteristics' with a list of forms. A red box highlights a banner for a verified form: 'This form was signed on 14/06/2024 at 07:45 by [redacted]' and 'This form was verified on 14/06/2024 at 08:35 by John Smith for Source Data Verification.' Below the banner, the form fields are visible: 1.1 Year of birth (1967), 1.2 Gender (Male), 1.3 Height (178 cm), and 1.4 Weight (78 kg). Each field has an SDV icon (a green checkmark with 'SDV' text) indicating it has been individually verified.

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.

## **8.4 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:

## 8.5 Source Data Verification – SDV Plans

castoredc.com | 32



**Data collection progress**

25%

☒ Show repeating data instances

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

Patient characteristics

**1. Demographics**

✓

1.1 Year of birth \*

SDV

⋮

(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:

**Data collection progress**

25%

☒ Show repeating data instances

- Patient characteristics**
  - Demographics 50%
  - Diagnosis and medical history In progress
- Clinical and laboratory 8%
- Follow-up

Patient characteristics

**1. Demographics**

✓

1.1 Year of birth \*

SDV

⋮

(yyyy)

⋮

VISIT
 

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

SDV

⋮

cm

SDV

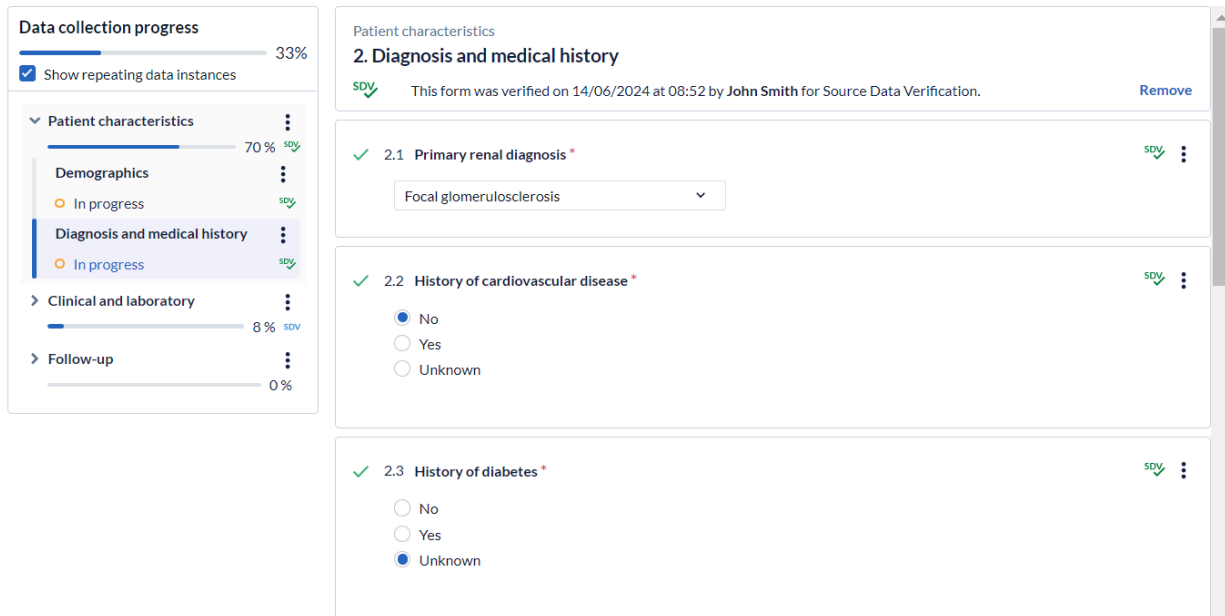
⋮

kg

Back

Next

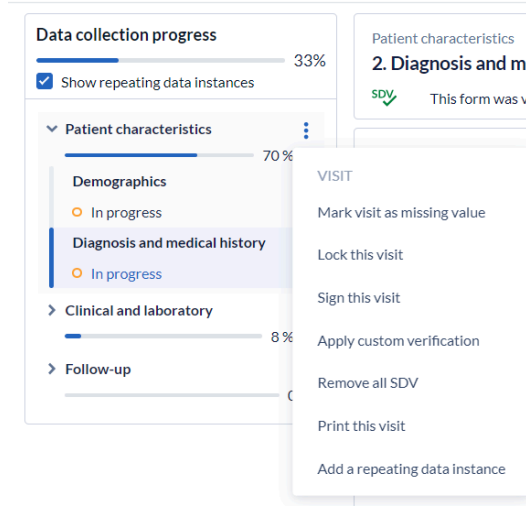
Once verified, the SDV icon will turn green and a banner stating that the form was verified will appear.



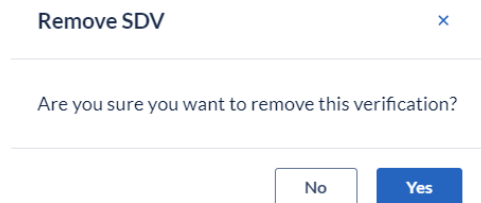
The screenshot displays the Castor interface. On the left, a 'Data collection progress' sidebar shows a 33% completion rate with a 'Show repeating data instances' checkbox. The sidebar lists categories: Patient characteristics (70% SDV), Demographics (In progress), Diagnosis and medical history (In progress), Clinical and laboratory (8% SDV), and Follow-up (0%). The main panel, titled 'Patient characteristics 2. Diagnosis and medical history', shows a green SDV icon and a verification banner: 'This form was verified on 14/06/2024 at 08:52 by John Smith for Source Data Verification.' Below this, three form items are listed, each with a green SDV icon and a three-dot menu:

- 2.1 Primary renal diagnosis \*: Focal glomerulosclerosis
- 2.2 History of cardiovascular disease \*: No (selected), Yes, Unknown
- 2.3 History of diabetes \*: No, Yes, Unknown (selected)

- 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.

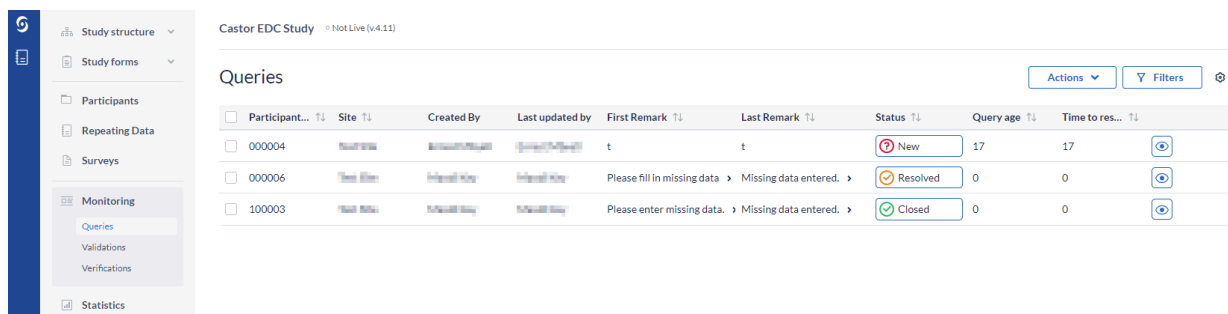


## 9. The global Monitoring tab

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.

### 9.1. 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	Study Site	Created By	Last updated by	t	t	New	17	17	
000006	Study Site	Created By	Last updated by	Please fill in missing data	Missing data entered	Resolved	0	0	
100003	Study Site	Created By	Last updated by	Please enter missing data	Missing data entered	Closed	0	0	

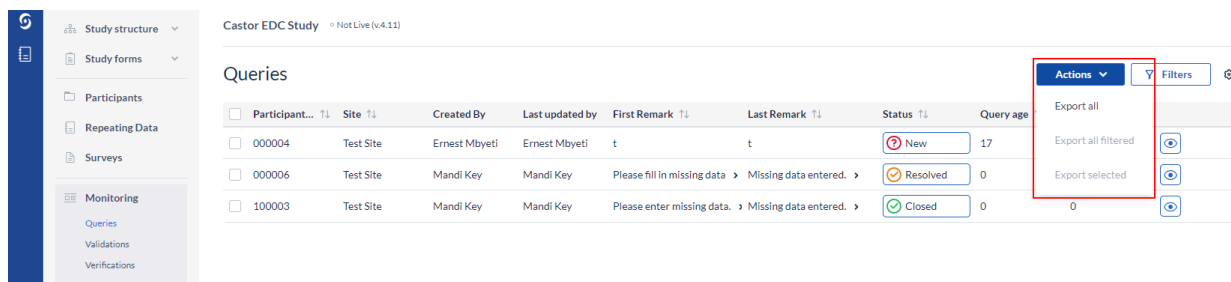
- **Participant ID:** ID of a participant where a query has been created.
- **Site:** Site to which the participant is linked.
- **Created by:** User who created a query.
- **Last updated by:** Last user who updated a query.
- **First Remark:** Initial comment which was added when creating a query.
-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

## 9.2. 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 sidebar with navigation options: Study structure, Study forms, Participants, Repeating Data, Surveys, and Monitoring (selected). The Monitoring section is expanded, showing Queries, Validations, and Verifications. The main area displays the 'Queries' table for 'Castor EDC Study - Not Live (v4.11)'. The table has columns: Participant..., Site, Created By, Last updated by, First Remark, Last Remark, Status, and Query age. Three queries are listed: 000004 (New), 000006 (Resolved), and 100003 (Closed). Above the table, there are 'Actions' and 'Filters' buttons. The 'Actions' dropdown menu is open, showing options: 'Export all', 'Export all filtered', and 'Export selected'.

Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age
<input type="checkbox"/> 000004	Test Site	Ernest Mbyeti	Ernest Mbyeti	t	t	New	17
<input type="checkbox"/> 000006	Test Site	Mandi Key	Mandi Key	Please fill in missing data	Missing data entered.	Resolved	0
<input type="checkbox"/> 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 \*

CSV ▼

Entire study

Visits

Repeating Data

Only queries for which you have Export permissions will be Exported

Cancel

Export

## 9.3. 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

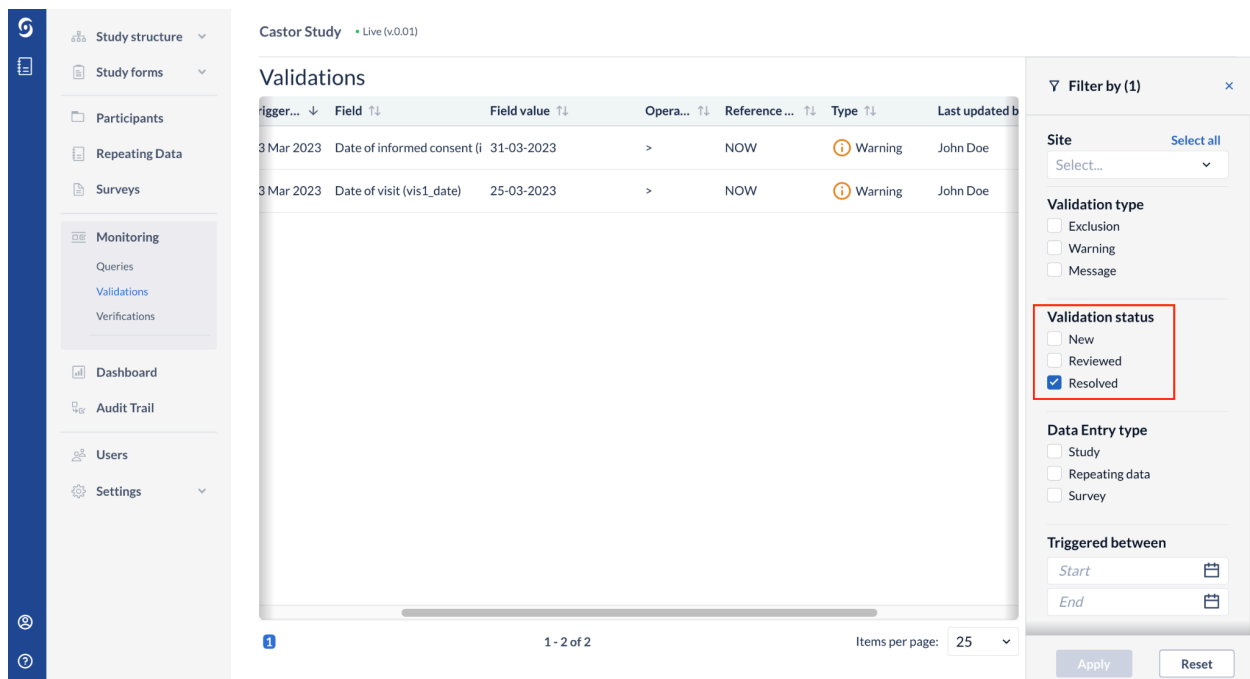
Castor EDC Study Not Live (v4.11)

Validations

Filters

Participa...	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'

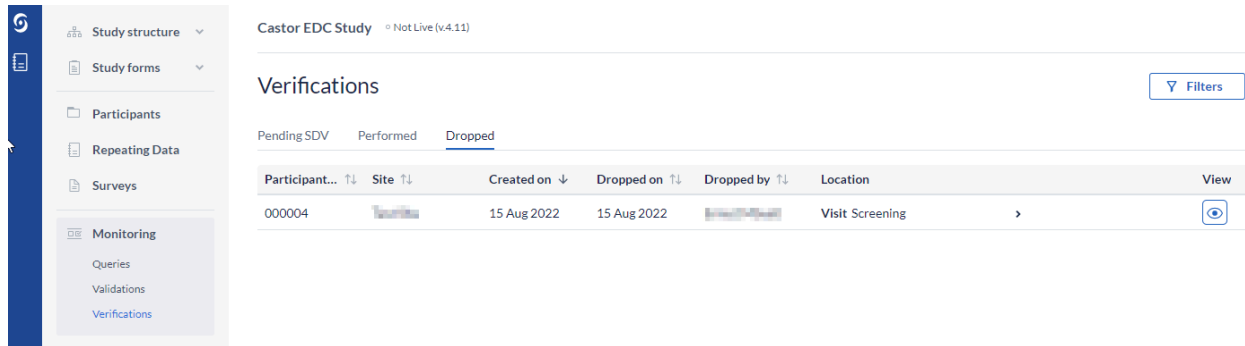


5. To open the participant and jump to the form with the validation, click on the eye icon in the column 'View'.

## 9.4. Verifications subtab

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

Example of Dropped Verification



Castor EDC Study v4.11

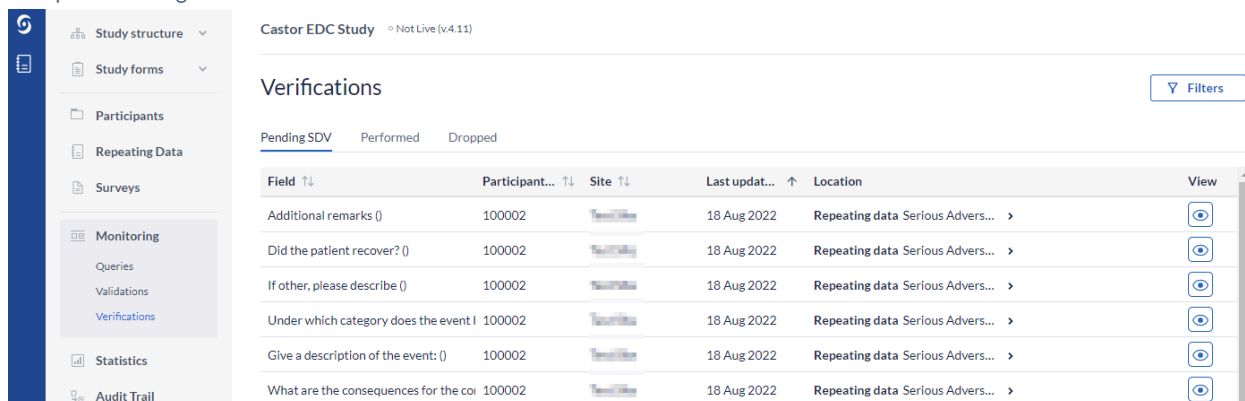
Verifications Filters

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 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... >	

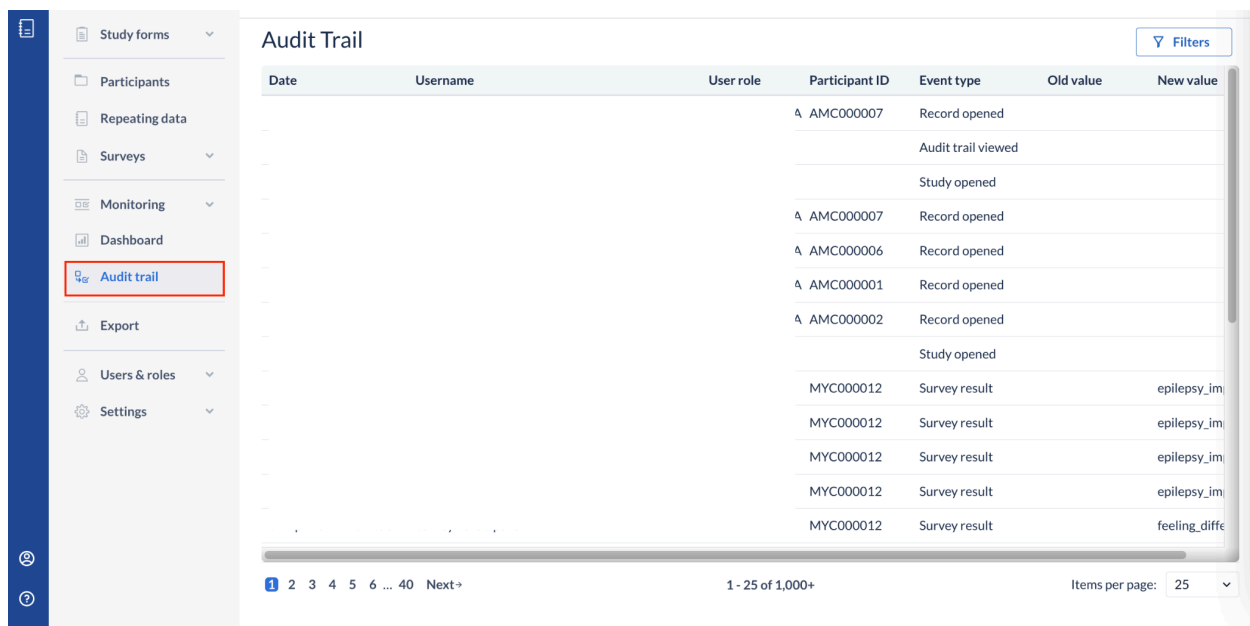


- Using the 'Filters' button on the Pending, Preformed, or Dropped tab, you can choose to filter by site, date range, and/or location for the study or for repeating data only.
- Each row shows the participant ID, the site name, last update date, and field location. You can expand the location field by 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).

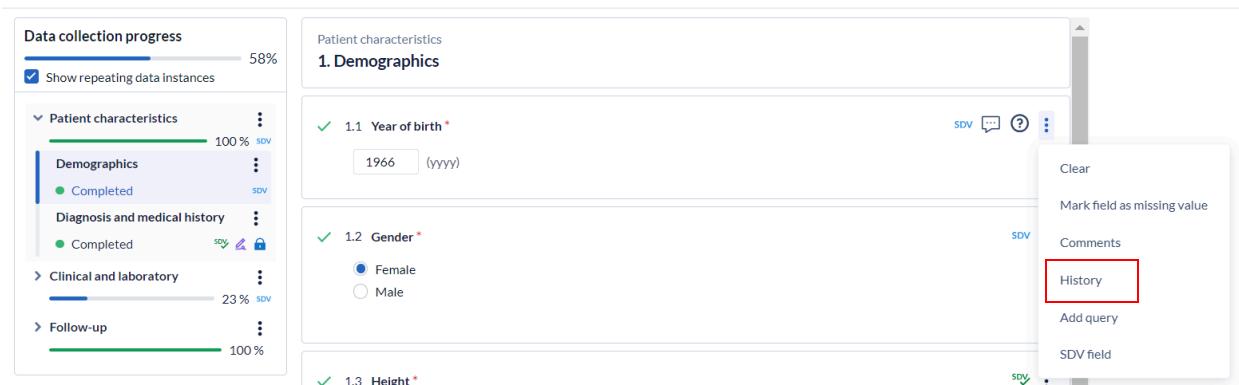
## 10. Using the Audit Trail

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
			AMC000007	Record opened		
				Audit trail viewed		
				Study opened		
			AMC000007	Record opened		
			AMC000006	Record opened		
			AMC000001	Record opened		
			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':



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'

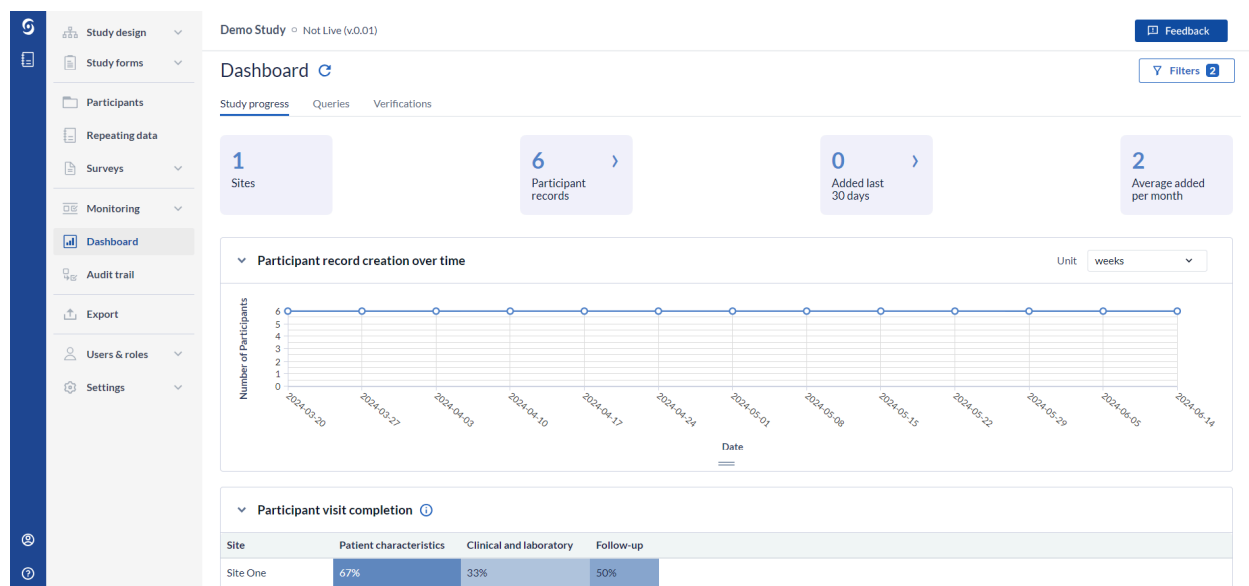
Updated on	Updated by	Value changes to
2024-03-20 11:04:26	John Smith	1967
2024-06-14 09:41:37	John Smith	1966

Close

## 11. The Dashboard tab

The [The Study Dashboard in CDMS](#) 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 \(Define user roles in CDMS\)](#). 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.

## 12. 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/>