

International Watch & Wait database

IWWD 2.0



Castor EDC Data entry Manual



Administrative responsibilities

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<https://www.castoredc.com/electronic-data-capture-system/>

Website IWWD on CAST-cancer.eu

[IWWD-webpage on CAST-cancer.eu](#)

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Logon

IWWD on the Castor website is obtainable via <https://data.castoredc.com/>

Are you new to Castor? Click on the “Sign up” button and create an account.

Fill in your email address and click on ‘*forgot your password?*’ to obtain a new password.

Netherlands is the country of origin where the database is located. So choose Netherlands, or leave Netherlands as it is.

Log in

Netherlands

Email Address

Email address is a required field

Password

Forgot your password?

Password is a required field

Remember me

Log in

New to Castor? Sign up

Your e-mail address is connected to the user role in Castor. You are automatically connected to your institute and you will get the user role “data entry”. Please use your institute e-mail address.

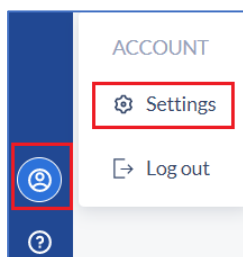
Activate two-factor authentication (2FA).

Since the database contains personal data, 2FA is obligatory. To enable 2FA, first make sure that an authentication app is installed and updated on your phone/tablet.

There are a variety of Authenticator apps that you can download for your smartphone.

A popular example is [Google Authenticator](#), which can be found in Google Play and the iOS App Store, but you can also choose for the Microsoft Authenticator or for Authy.

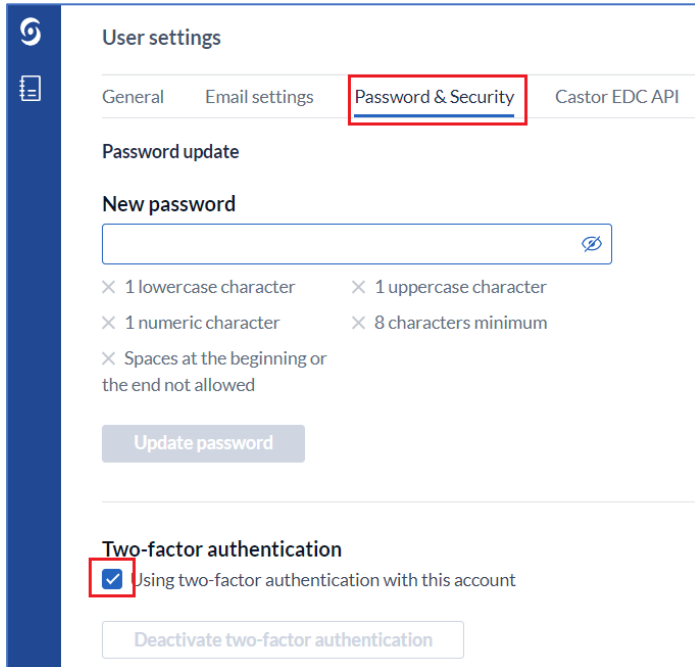
In Castor, go to your Account Settings by clicking on the account icon in the top left corner and selecting 'Settings'.



Then, go to the tab 'Password & Security'.

Under the "Two-factor authentication" section, tick the box for "Using two-factor authentication with this account". Then click the blue button below "Activate two-factor authentication".

Click on the link to see how you can activate 2FA: <https://helpdesk.castoredc.com/2-introduction-and-getting-started/two-factor-authentication>



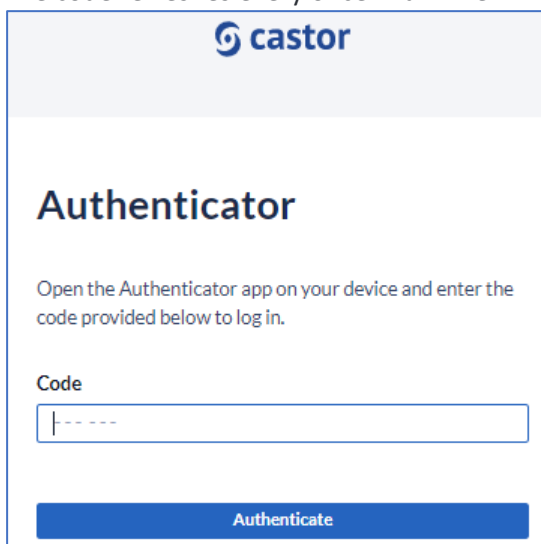
The screenshot shows the 'User settings' page with the 'Password & Security' tab selected. Under the 'Two-factor authentication' section, the checkbox 'Using two-factor authentication with this account' is checked. A 'Deactivate two-factor authentication' button is visible below.

Now follow the instructions on screen, that will ask you first to open/install an Authenticator app on your phone and then to scan the provided QR-code.

Once you have scanned the QR code or entered the key, a 6-digit code will appear in your authentication app. Enter this code into the field and click 'Configure'.

Once configured, CastorEDC will appear in your Authentication app. **Every time you log into Castor, you will need to provide the 6-digit code generated in the Authentication app.**

The code refreshes every once in a while.



The screenshot shows the 'Authenticator' screen with the Castor logo. The text reads: 'Authenticator', 'Open the Authenticator app on your device and enter the code provided below to log in.', and a 'Code' input field with a placeholder '1-----'. An 'Authenticate' button is at the bottom.

More information about 2FA: <https://helpdesk.castoredc.com/article/27-two-factor-authentication>

Import from ProMISe

All patient data that had been entered into the ProMISe data base until closure in April 2022 have been imported into the Castor database.

The structure in Castor is the same as in ProMISe, however, the names differ.

	ProMISe	Castor
Data collected once	PATIENT table	Visits
Treatment data – repeated data	TREATMENT table	Repeating data-> Treatment
Assessment data – repeated data	ASSESSMENT table	Repeating data-> Assessment

In Castor each patient is a Participant record in the Visits.

A Participant can have multiple treatments. Each Treatment is stored in a Repeating data.

A Participant will usually have multiple assessments (follow-ups). Each Assessments is stored in a Repeating data.

Participant:

The data that are collected once for each patient (Participant) can be found in the Visits.

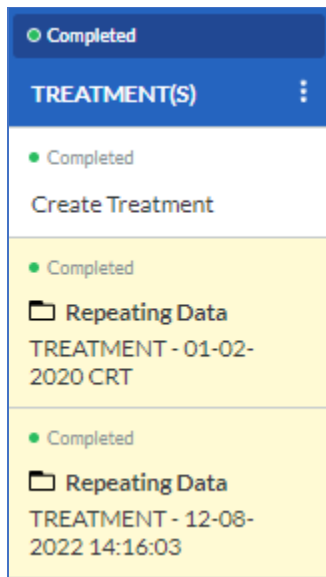
The data are divided in Phases and Steps (chapters).

The screenshot displays the 'WATCH WAIT Database' interface for participant TES-001. On the left, a navigation menu under 'Participant' includes 'Visits' (highlighted with a red box), 'Repeating Data', and 'Monitoring'. The main content area features a circular logo with 'WATCH WAIT Database' and a clock face. Below the logo, participant information is shown: 'Participant: TES-001', 'cCR' status (green dot), 'Progress: 60%' (blue progress bar), and a checked 'Show Repeating Data' option. A vertical list of study phases and steps follows, each with a status indicator (Not Started, In Progress, or Completed) and a three-dot menu icon:

- Not Started: FROM PROMISE
- In Progress: PATIENT IDENTIFIERS & INCLUSION
- Not Started: ADULT COMORBIDITY EVALUATION [ACE-27]
- In Progress: PRIMARY STAGING
- Completed: TREATMENT(S)
- In Progress: RESTAGING AFTER NEOADJUVANT/INDUCTION THERAPY
- Completed: 2nd RESTAGING AFTER ADDITIONAL/CONSOLIDATION TREATMENT / ADDITIONAL WAITING TIME
- Completed: ASSESSMENTS
- Completed: DEATH

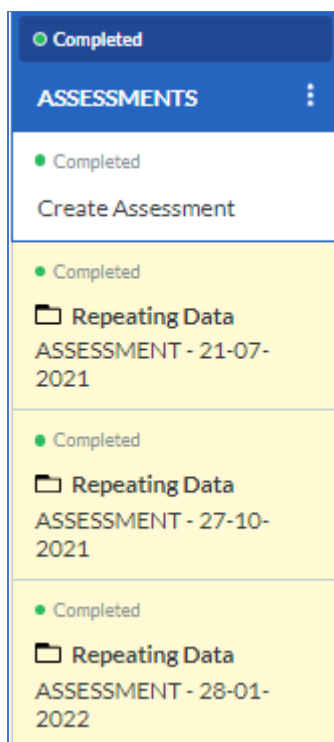
Example overview of all Treatments within a Participant.

Here you can create a treatment or open an existing Repeating data of previous treatments



Example overview of all Assessments within a Participant.

Here you can create an assessment or open an existing Repeating data of previous assessments/follow-up visits



Repeating data-Treatment:

Example of a Repeating data-Treatment with different Phases. One Repeating data is for one treatment(combination)

The screenshot displays the 'WATCH WAIT Database' interface. On the left, a sidebar menu includes 'Participant', 'Visits', 'Repeating Data' (highlighted with a red box), and 'Monitoring'. The main area shows participant information for 'Participant: TES-001', 'cCR' status, a 60% progress bar, and a checked 'Show Repeating Data' option. Below this, three treatment entries are listed, each marked as 'Completed': 'TREATMENT - 01-02-2020 CRT', 'PERIOD AND TYPE OF TREATMENT', 'NEOADJUVANT/INDUCTION TREATMENT', and 'CONSOLIDATION/ADDITIONAL or SALVAGE TREATMENT'. A dialog box titled 'Add a repeating data instance to participant TES-001' is open at the bottom. It contains three fields: 'Repeating data:' with a dropdown set to 'TREATMENT', 'Custom name:' with an information icon and a dropdown set to 'TREATMENT - 05-09-2022 CRT' (highlighted with a red box), and 'Attach to:' with a dropdown set to 'Visit 5. TREATMENT(S)'. 'Create' and 'Cancel' buttons are at the bottom right of the dialog.

Castor EDC by default fills out today's date in the "Custom name" line. You need to change the date into the date of the Treatment and you may add the type of treatment.

Repeating data-Assessment:

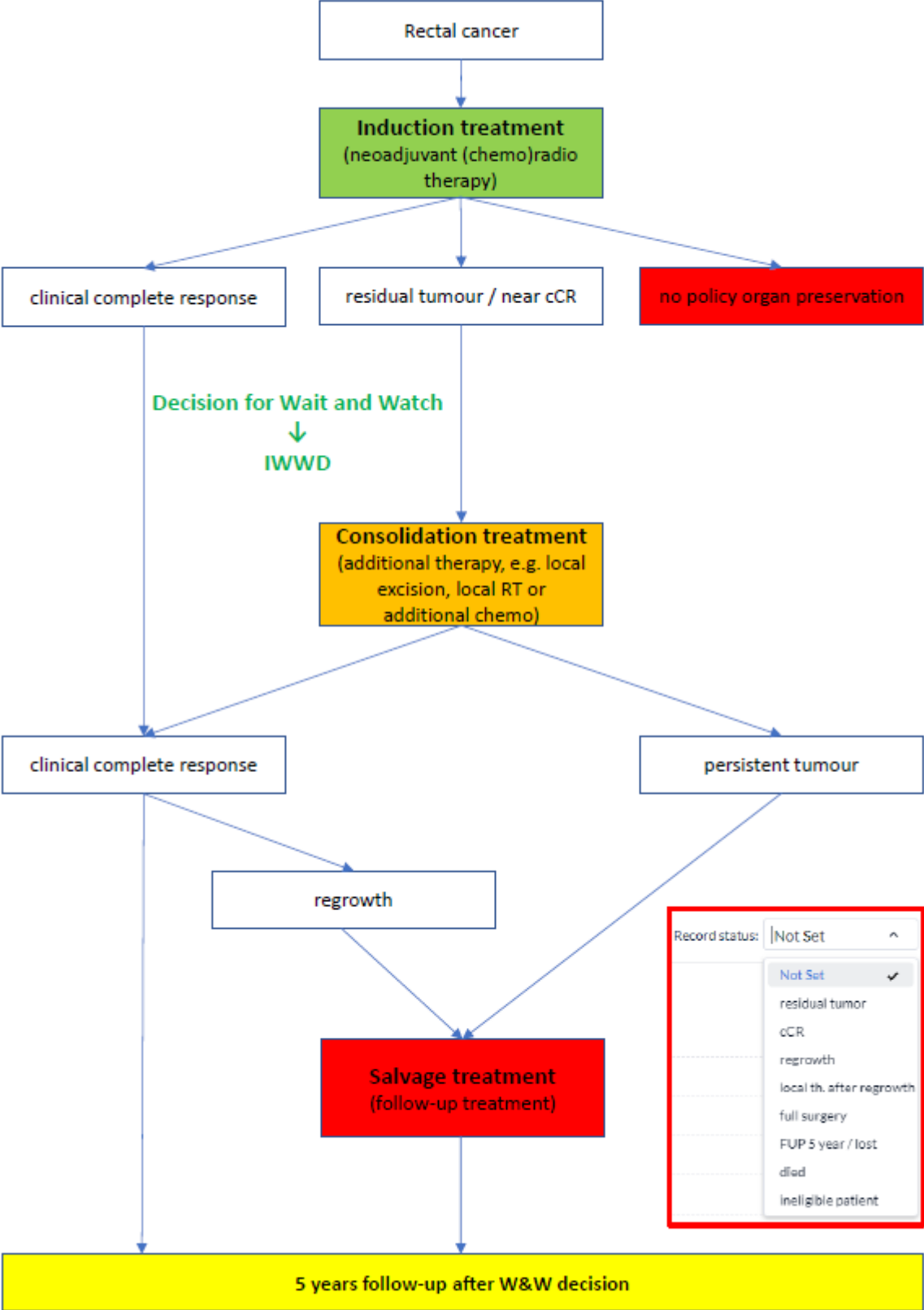
Example of a Repeating data-Assessment with different Phases. One Repeating data is for one assessment date with associated investigations.

The screenshot displays the 'WATCH WAIT' database interface. On the left, a sidebar menu under 'Participant' includes 'Visits', 'Repeating Data' (highlighted with a red box), and 'Monitoring'. The main content area features a circular logo with 'WATCH WAIT' and 'Database' text. Below the logo, a summary box shows 'Participant: TES-001', 'cCR' status, a 60% progress bar, and a checked 'Show Repeating Data' option. A list of completed assessments follows, each with a green dot and the word 'Completed':

- ASSESSMENT - 05-07-2022
- Local Assessment in Follow-up
- Dissemination Investigations in Follow-up
- Morbidity
- Evaluation Disease Status

Castor EDC by default fills out today's date in the "Custom name" line. You need to change the date into the date of the Measurement (follow-up visit).

Flow chart



Basics

After Castor has loaded you will see an overview of your Participants. Click on the “cogwheel” button to add or remove columns of this overview.

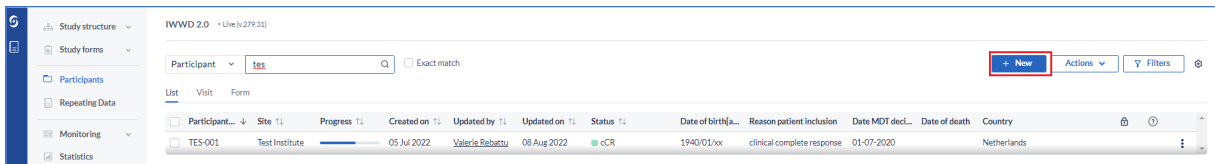
Participant...	Site	Progress	Created on	Updated by	Updated on	Status	Date of birth	Reason patient inclusion	Date MDT decision	Date of death	Country
TES-001	Test Institute		02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1955/06/xx	M1 at diagnosis and local co	12-12-2016		Romania
			02 May 2022	ProMISseNaarCast	06 May 2022	full surgery	1953/03/xx	clinical complete response	13-06-2014		Romania
			02 May 2022	ProMISseNaarCast	06 May 2022	full surgery	1965/12/xx	clinical complete response	09-07-2019		Romania
			02 May 2022	ProMISseNaarCast	06 May 2022	full surgery	1948/11/xx	clinical complete response	14-08-2018		Romania
			02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1938/09/xx	clinical complete response	05-02-2018		Italy
			02 May 2022	ProMISseNaarCast	06 May 2022	full surgery	1946/02/xx	clinical complete response	10-05-2018		Italy
			02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1961/05/xx	clinical complete response	14-06-2019		Italy
			02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1960/11/xx	clinical complete response	27-09-2019		Italy
			02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1969/01/xx	clinical complete response	03-10-2019		Italy
			02 May 2022	ProMISseNaarCast	06 May 2022	Not Set	1970/12/xx	clinical complete response	30-07-2020		Italy
			05 Jul 2022	Valeris Rebatutt	08 Aug 2022	CCR	1940/01/xx	clinical complete response	01-07-2020		Netherlands

Click on the “help” button in the left corner for more support, for example ‘Manuals’.

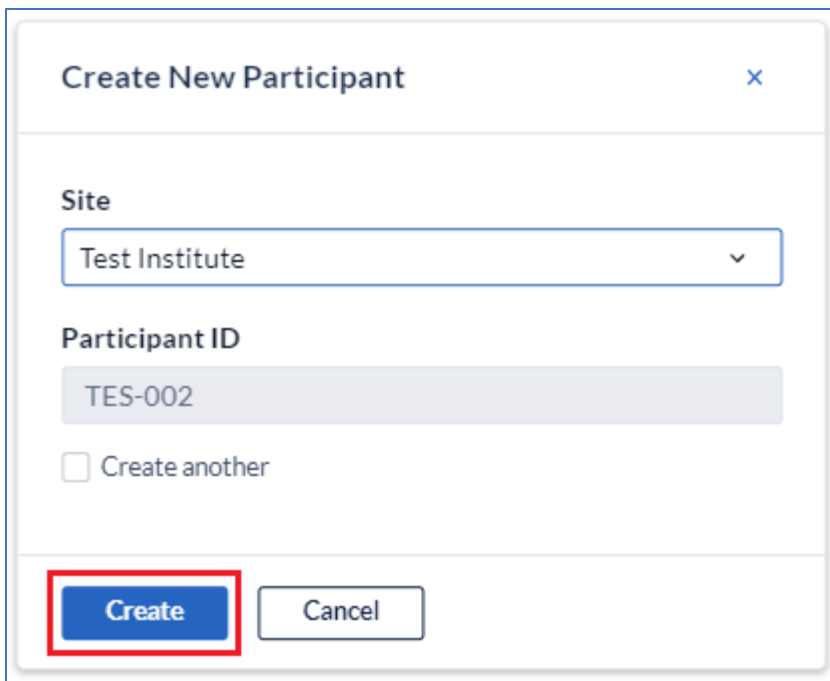
- SUPPORT
- Manuals
- Calculation Helper
- Castor Academy
- Form Exchange
- Ask for support
- Keyboard shortcuts
- Castor v2022.2.0.1
- Privacy
- Terms of Use

Creating a new Participant record

To add a new Participant click on the “+New” button.



Your institute will be visible or select the appropriate institute if you enter data for more hospitals. The Record ID will be filled in automatically and click on “Create”. The Record ID consists of your institute number, followed by a sequential number within your institute.



The 'Create New Participant' dialog box is shown. It has a title bar with a close button (X). The 'Site' dropdown menu is set to 'Test Institute'. The 'Participant ID' field is filled with 'TES-002'. There is a checkbox labeled 'Create another' which is currently unchecked. At the bottom, there are two buttons: 'Create' (highlighted with a red box) and 'Cancel'.

Data entry

After Castor has loaded you will see the overview of your Participants.

To open a Participant, click on the record line.

Participant...	Site	Progress	Created on	Updated by	Updated on	Status	Date of birth	Reason patient inclusion	Date MDI decl...	Date of death
TES-001	Test Institute	<div style="width: 100%;"></div>	05 Jul 2022	Valerie Rebattu	08 Aug 2022	cCR	1940/01/xx	clinical complete response	01-07-2020	
TES-002	Test Institute	<div style="width: 100%;"></div>	05 Sep 2022	Annet Roodhooft	05 Sep 2022	Not Set				

When you open a Participant, the data entry view is displayed:

Participant ID: TES-002 • Live (v.279.31) Participant status: Not Set

WATCH WAIT

3. Patient identifiers

- 3.1 Database [calculated] Original Castor patient
- 3.2 Country Netherlands
- 3.3 Institute Test Institute
- 3.4 Month of birth
- 3.5 Year of birth
- 3.6 Date of birth [anonymised, calculated] Not all values for this calculation are available (vet).
- 3.7 Gender male female
- 3.8 Unique identification number own hospital [encrypted] This field is encrypted and can't be accessed without encrypt or decrypt rights.
- 3.9 Physician [encrypted] This field is encrypted and can't be accessed without encrypt or decrypt rights.

Previous Next

1. Participant number, Participant status (see below) and Progress (=completeness).
2. Phases and Steps. Here you can navigate through the eCRF and see the individual progress per Phase and Step. Steps and Phases can have three different stages of completion:
 - Not Started (white).
 - In Progress (orange).
 - Completed (green).When every required field for a step has been completed, the step icon will show as a green dot.
When every step inside a phase has been completed, the phase will be marked as completed.
3. Field options, here you can perform various actions that apply to only the field on this row, e.g. 'Undo/clear' or 'Set field as missing', add comments.
4. You can use the Next/Previous buttons to navigate through the steps of the Participant.
5. This button returns you to the Participant overview list.

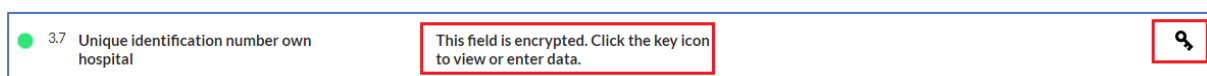
Data will be saved immediately after entering. For the IWWD database GCP is enabled. Adherence to Good Clinical Practice (GCP) requires you to provide a rationale for making changes to entered data after an initial value was already set. Enabling GCP means that any time a user attempts to change previously entered data in a record, they will need to add a reason for change in order to save the

new value. The user has 30 seconds (e.g. to correct typing errors) after the entering of the data to amend or change the value without being required to provide a reason, after this any further amendments must be justified in the dialog window. The reason for change will not be prompted if the data is being entered for the first time, and the 30 second time allowance resets when each change is made.

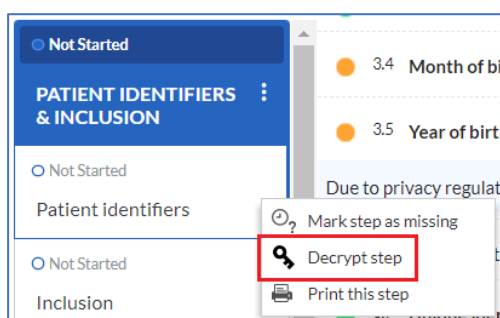
For more information about data entry see: <https://helpdesk.castoredc.com/collect-data/doing-data-entry>.

Encrypted fields

To view or enter data on encrypted fields, the key icon needs to be clicked. This will either reveal the data that has been entered or allow for entering of data.



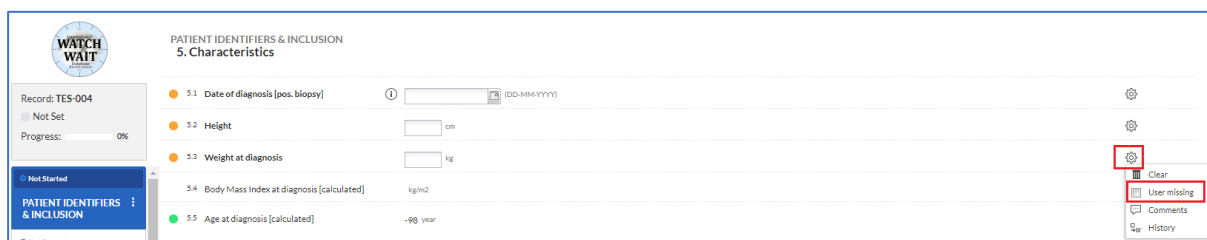
If there are multiple encrypted fields within a step, they can view all fields in the step in bulk via the step navigator. Click on the three dots in the step, then click 'Decrypt step':



For working with encrypted data see also <https://helpdesk.castoredc.com/encryption-module/working-with-encrypted-data>

Missing data

When a value is not applicable or not done or etc., click on the “cogwheel” button and on “User missing” and choose reason for the missing value.



Status

In Castor the current status of the record can be indicated.

In the overview, Status will be shown once you added the column.

Status ↑	Date of birth[a...	Date MDT deci...	Date of death
local th. after regrowth	1940/01/xx	01-01-2022	21-06-2022
died	1960/03/xx	17-06-2022	
cCR			
Not Set	1945/12/xx	02-07-2014	








When you have the Participant record opened, the Status is shown on the top right position of the screen.

By default the Status = Not Set

Since IWWD focusses on organ preservation the Status should give an indication of the **local status**. If the status of the Participant changes from one situation into another, the Participant status should be changed to maintain an up to date overview of your Participants.

Participant status: died ^

- Not Set
- residual tumor
- cCR
- regrowth
- local th. after regrowth
- full surgery
- FUP 5 year or lost
- died ✓
- ineligible patient

	residual tumor	local disease status after induction treatment: residual tumor / near complete response
	cCR	local disease status after induction (and consolidation) treatment: clinical complete response
	regrowth	local disease status after induction (and consolidation) treatment: regrowth after cCR
	local th. after regrowth	local therapy after regrowth: local excision or local radiotherapy
	full surgery	full surgery (APR, LAR, etc.) after regrowth or after previous local therapy. non-operative management failed
	FUP 5 year / lost	Follow-up in IWWD-registry is completed (minimum 5 years) or patient is lost to follow-up (emigrated)
	died	died

When you completed the registration of your new Participant in the IWWD, you change the Participant status to:

residual tumour
or to cCR

When regrowth of the local tumour is assessed, you change the Participant status into regrowth

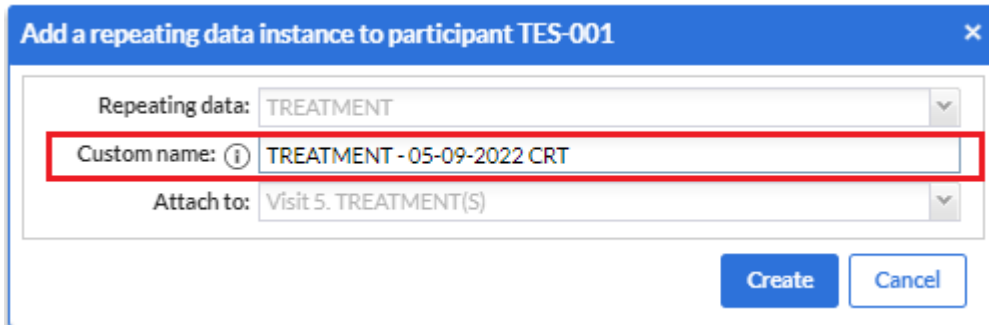
You move on to the next Participant status if it is applicable, to indicate that your Participant underwent

Local therapy after regrowth, or
Full surgery

After full surgery, no further follow-up is required, except for the survival status

“Full surgery”, “FUP 5 year/lost” and “died” are indications of end statuses
The previous statuses are indicating that the data collection is ongoing.

Correcting the date of a Repeating data



Dialog box titled "Add a repeating data instance to participant TES-001".

Repeating data: TREATMENT

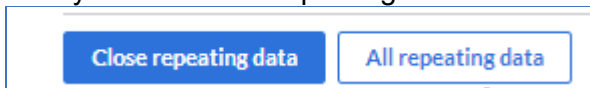
Custom name: TREATMENT - 05-09-2022 CRT

Attach to: Visit 5. TREATMENT(S)

Buttons: Create, Cancel

Castor EDC by default filled out today's date in the "Custom name" line, if you did not change it into the date of the Assessment or the date of the Treatment. There is one way to correct this afterwards:

When you are "inside" a Participant, you click on one of the Repeating Data. Then you click on All repeating data

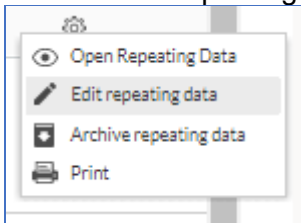


Buttons: Close repeating data, All repeating data

A list of all Assessments and all Treatments of this Participant will appear.

Click on the cogwheel at the end of the line of the Assessment or Treatment that you want to correct.

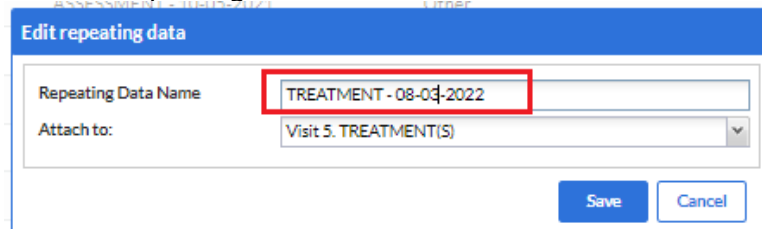
Click on Edit repeating data



Context menu options:

- Open Repeating Data
- Edit repeating data
- Archive repeating data
- Print

Edit the Repeating Data Name and click on the Save button.



Dialog box titled "Edit repeating data".

Repeating Data Name: TREATMENT - 08-03-2022

Attach to: Visit 5. TREATMENT(S)

Buttons: Save, Cancel

Back in the list of All repeating data, you will see the corrected name.

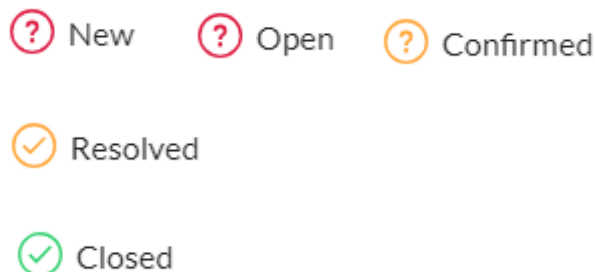
Monitoring / Queries

The 'Monitoring' module allows monitors **or central trial coordinators** to create data queries for fields in a Visit. These data queries or queries are issues the monitor/**central trial coordinator** has identified with the value entered in a field. Queries need to be closed for a record to be marked as complete.

When an existing query is opened, the status is set as New. A normal user can either set the status to:

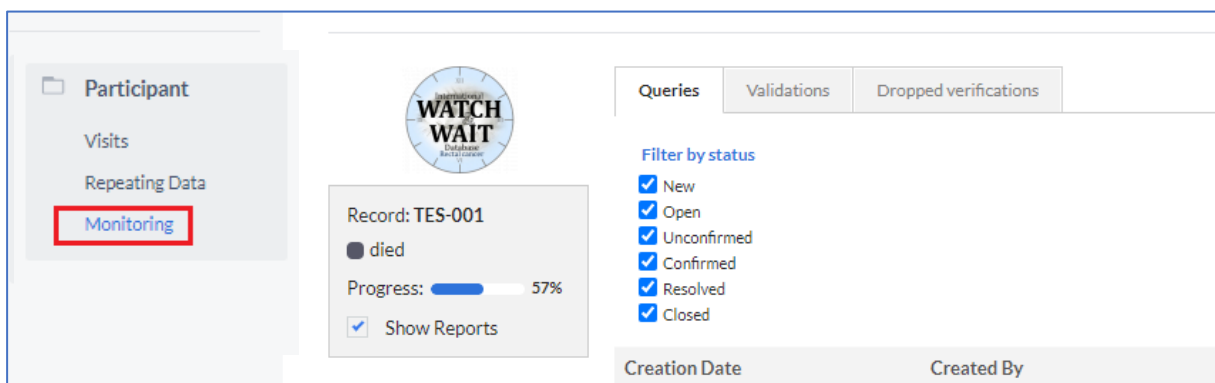
- **Open:** The user has acknowledged/opened the query, and added a remark. The status changes from New to Open.
- **Unconfirmed:** The user does not agree with the monitor.
- **Confirmed:** The user agrees with the monitor and will try to resolve the issue.
- **Resolved:** The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment. In this case the query is not closed which why the step status is shown as amber, and not green - the query is still open.
- [Only with 'Query' right (monitor)] **Closed:** The monitor indicates the issue is resolved and marks the query as closed. The query icon will turn into a green check mark and the progress button of the entire step will be green indicating that the step has been completed - all data entered and there are no open queries.

1. The icon that is displayed next to the field with the query or in the Monitoring tab displays the status of the query:



The status can only be changed when accompanied by a remark.

To update the status of a query, please choose the appropriate status from the drop-down, enter your remark, and press the 'Update' button.



Exit Castor

Click on 'Log out'.

