

# Data Management in Castor EDC

The following manual contains suggestions and ideas for managing your data. The manual uses activities outlined in the [GCDMP](#) as a guide and is divided based on those activities. This manual may reference information provided in our other role specific manuals for Data Entry, Monitoring, and Study Admin.

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# Study Set-up

## CRF Review

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

## Data Dictionary

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

In the Records Overview, click on the 'Actions' button and choose the option to 'Export all' to export all records. If you would like to export only a selection of records, click on the checkbox next to each record or use the 'Filters' button to filter the records based on certain criteria. Afterwards, the options 'Export all filtered' or 'Export selected' will be activated in the 'Actions' menu.

Castor EDC Study ◦ Not Live (v.0.21)

Record ▼

☐ Exact match

+ New

1 Actions ▼

Filters ▼

List	Phase	Step				
<input type="checkbox"/> Record <span>▼</span>	Institute <span>↑↓</span>	Last opened on <span>↑↓</span>	Last opened by <span>↑↓</span>	Randomization gr... <span>↑↓</span>	N	Progress <span>↑↓</span>
<input type="checkbox"/> 000001	Utrecht Institute	19 Feb 2021	Tonya Support	-		<div><div></div></div>
<input type="checkbox"/> 000002	Utrecht Institute	19 Feb 2021	Tonya Support	A		<div><div></div></div>
<input type="checkbox"/> 110001	Utrecht Institute	18 Feb 2021	Tonya Support	B	C	<div><div></div></div>
<input type="checkbox"/> 110002	Amsterdam Institute	15 Dec 2020	Tonya Support	-		<div><div></div></div>
<input type="checkbox"/> 110003	Amsterdam Institute	18 Feb 2021	Tonya Support	B		<div><div></div></div>
<input type="checkbox"/> 110004	Amsterdam Institute	18 Feb 2021	Tonya Support	A		<div><div></div></div>
<input type="checkbox"/> 110005	Amsterdam Institute	15 Dec 2020	Tonya Support	-		<div><div></div></div>
<input type="checkbox"/> 110006	Amsterdam Institute	15 Dec 2020	Tonya Support	-		<div><div></div></div>

Lock

Unlock

Print selected

Export all 2

Export all filtered

Export selected

Import

Update institute

Archive selected

Un-archive selected

In the 'Data Export' window:

1. Select either Excel or CSV.

Data Export (All Records) X

Only records for which you have Export rights will be Exported

Export Type  
CSV

Display options as  
☒ Numbers (values) ☐ Names (labels)

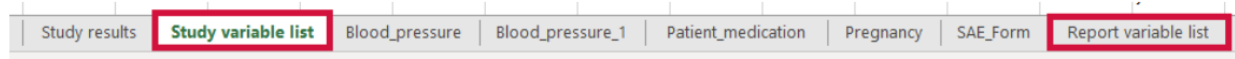
How to export  
☒ Interactive (tree) ☐ Variable list ☐ Variables bulk (paste)

Include  
☒ Comments  
☒ Queries  
☒ Verifications  
☐ Encrypted Fields

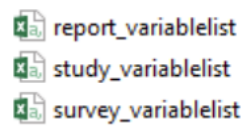
Entire study  
Study  
Reports  
Surveys

Export Cancel

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



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

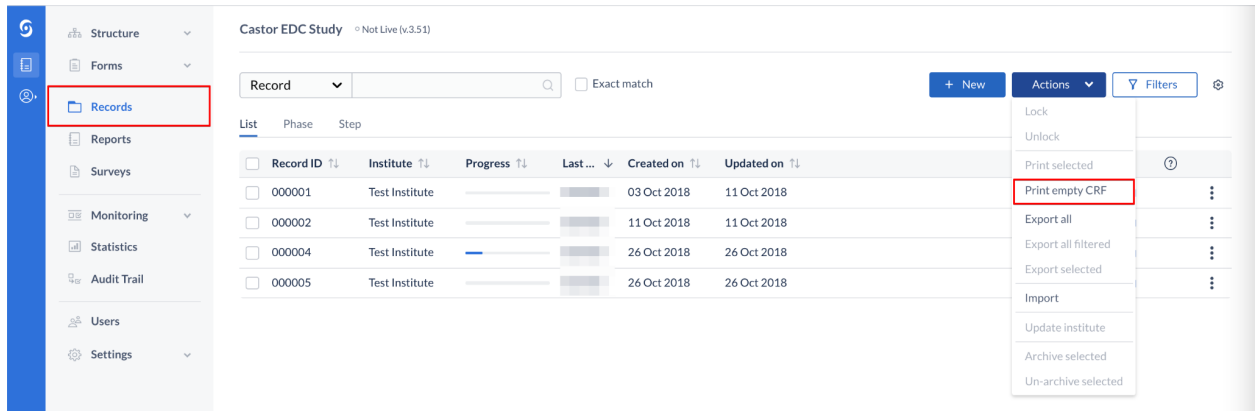


2. Select 'Entire Study'.
3. Click 'Export'.

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

## Blank CRFs

1. Navigate to the 'Records' tab. In the upper right corner, click on the 'Actions' button, then click on 'Print empty CRF':



2. Here you will select the options for your PDF.

The 'Print empty CRF' dialog box is shown. It has a title bar with a close button (X). The 'Print structure' section has a dropdown menu set to 'Study'. The 'Include' section has four checkboxes: 'Helptexts' (unchecked), 'Additional info' (unchecked), 'Calculation field templates' (unchecked), and 'Hidden calculation fields' (checked). The 'Print steps on separate pages?' section has two radio buttons: 'Yes' (unchecked) and 'No' (checked). At the bottom are 'Print' and 'Cancel' buttons.

1. Select the structure (Study, Reports, Surveys) you would like to print.
2. Choose the options you would like to include in the PDF.
3. Click 'Print'.

A new page will open, which contains a preview of the printable study form. You can save this page as a PDF by selecting the option 'Save as PDF' from the available options.

# Randomization Review

Castor uses a variable block randomization method. Randomization settings can be viewed in the Settings tab. You are able to define up to 9 randomization groups and weights (1), block sizes, and fields within the CRF for stratification (2). Customized randomization settings are available for an additional fee. Please contact your account executive for more information.

The option 'Stratify per institute' is set to 'Yes' by default.

The screenshot shows the 'Castor EDC Study' interface with the 'Randomization' settings tab selected in the left sidebar. The main content area is divided into two sections: 'Randomization groups' and 'Stratify by'. The 'Randomization groups' section has a table with columns 'Name', 'Weight', and 'Remove'. Below the table is an 'Add group' button with a red '1' next to it. The 'Stratify by' section has a table with columns 'Field', 'Strata', and 'Remove'. Below the table is an 'Add stratum' button with a red '2' next to it. At the bottom, there are settings for 'Randomization algorithm' (set to 'Variable block randomization'), 'Stratify per institute' (set to 'Yes'), and 'Block sizes' (set to '2, 3, 4'). A 'Save randomization settings' button is located at the bottom left of the main content area.

Name	Weight	Remove
------	--------	--------

[Add group](#) 1

Field	Strata	Remove
-------	--------	--------

[Add stratum](#) 2

Randomization algorithm: Variable block randomization  
Stratify per institute: Yes  
Block sizes: 2, 3, 4

[Save randomization settings](#)

## Randomization User Rights

There are two separate user rights related to randomization in Castor. A user can have none, one, or both rights. The randomization right allows a user to randomize a record. View randomization allows a user to view the randomization allocation for a record. Both rights together will allow a user to both randomize and view the randomization allocation for a record.

User rights for [Admin]													
Institute Rights		Management Rights											
Institute ^	User role	Add	View	Edit	Email	Rand.	View ran.	Sign	Lock	Verify	Query	Archive	Export
All institutes	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Castor 1	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Castor 2	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Castor 3	<u>None</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test Institute	<u>Admin</u>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Please note that users that do not have view randomization rights will be unable to export randomization data when performing data exports.

## Data Validations/Edit Checks

Data validations, or real-time edit checks, are able to be programmed at the field level. A simple or single field validation can be created on the field properties tab. You are able to use these data validations to warn data entry users about a possible error or provide further instructions.

### Data Validation: Single Field

There are 4 validation types:

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

3.4
Can patient participate in the study?
Yes

Patient can participate, please continue.


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

3.4
Can patient participate in the study?
Data missing

Patient cannot participate, all inclusion fields must be completed

- **Error:** A red outlined message can be used to indicate data has been entered that is not accepted or wrong. When the error message type is displayed, the data for that field is not saved. This means that a subsequent field cannot be

dependent on a value that would trigger the 'Error' message.

3.1 Does patient have example disease? ☐ Yes ☒ No 

 Patient must have example disease to be eligible for participation.


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


- if an exclusion occurs on the study form, data entry is blocked on the entire study form and on any report instances. The Exclusion message will be displayed on every form in the study data view with the name of the step where the exclusion has been triggered. The report data view will be greyed out:

 The patient cannot participate in the study Step: Grid Calculations

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

You can use this for validating inclusion and exclusion criteria. Please be aware, that it's not possible to leave fields with exclusion criteria empty (user missing), nor possible to enter values which are outside the boundaries you have set.

2.1 Is informed consent signed? ☐ Yes ☒ No 

 The subject cannot participate if informed consent is not signed!

## Data Validation: Multi-Field

If you would like to validate multiple fields, for example, eligibility criteria, it is necessary to first create a calculation field that considers the variables in the study. For an example calculation, please see the [article](#) in our helpdesk. You can then create a data validation in the field properties on the calculation field.

Baseline (example phase)		
1. Inclusion		
1.1	Does the patient have example disease?	<input checked="" type="radio"/> Yes <input type="radio"/> No
1.2	Is patient older than 65	<input type="radio"/> Yes <input checked="" type="radio"/> No
1.3	Has patient signed informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No
1.4	Can patient participate in the study?	Yes
<div> <i>i</i> Patient can participate, please continue to demographics.         </div>		

## eLearning

Castor Academy ([academy.castoredc.com](https://academy.castoredc.com)) is our eLearning platform. The Academy contains a structured series of videos with step-by-step instructions for each selected Castor feature. Courses are role specific for data entry personnel, monitors, and study builders.

For premium accounts, we offer courses with certifications that require the completion of quizzes after each section is completed. Users are required to pass each quiz with an 80% to proceed to the next section. If a user fails to pass a quiz, they will need to wait 2 weeks in order to retake the quiz. The courses without a certification are also available at no charge to all Castor users.

User accounts on Castor Academy are not linked to user accounts in Castor EDC. Therefore, we at Castor do not enforce the completion of Castor Academy for access to live studies.

To take advantage of the certified courses, please contact your dedicated Customer Success Manager or Support at [support@castoredc.com](mailto:support@castoredc.com).

## User Acceptance Testing (UAT)

Castor does not offer UAT for studies not created by our Professional Services team. However, we have provided guidance documentation in our online manual. This documentation can be reviewed [here](#).

For studies that are created by our Professional Services team, Castor offers two levels of UAT. Basic UAT includes the creation of two test records and ensuring that all edit checks and dependencies work correctly. Basic UAT does not include documentation.

Extensive UAT includes the creation of a data dictionary before study building commences, and an automated UAT process that confirms the existence of fields and tests functionality of each field. Documentation is provided. Extensive UAT should be requested before study building begins and cannot be added later.

## Tracking

### Enrollment Status

Record status is not currently built into Castor. However, it is possible to keep track of your subjects' statuses by creating data points at the enrollment step and during your end of study step.

Record: 000001

Progress:  49%

☒ Show Reports

Completed

Inclusion and Exclusion (V1)

Completed

Demographics

Completed

Inclusion Criteria

Completed

Exclusion Criteria

Completed

Informed Consent

Inclusion and Exclusion (V1)

4. Informed Consent

4.1 Can the patient participate in the study?

Yes. After enrollment, continue to baseline.

4.2 Has patient signed informed consent?

☒ Yes  
☐ No

4.2.1 Date for signed informed consent

01-05-2020

4.2.2 Was the patient enrolled in the study?

☒ yes  
☐ no

Record ID: 110001 Not Live (v.20.91)

Record: 110001

Progress:  52%

In Progress

Inclusion and Exclusion (V1)

In Progress

Baseline (V1)

In Progress

Day 30 Follow Up (+/- 2 Days) V2

Not Started

Day 60 Follow Up (+/- 2 Days) V3

In Progress

Subject Summary

End of Study

15. End of Study

15.1 Has the subject completed their participation in the study?

☒ yes  
☐ no

15.1.1 Was the subject discontinued from the study?

☐ yes  
☒ no

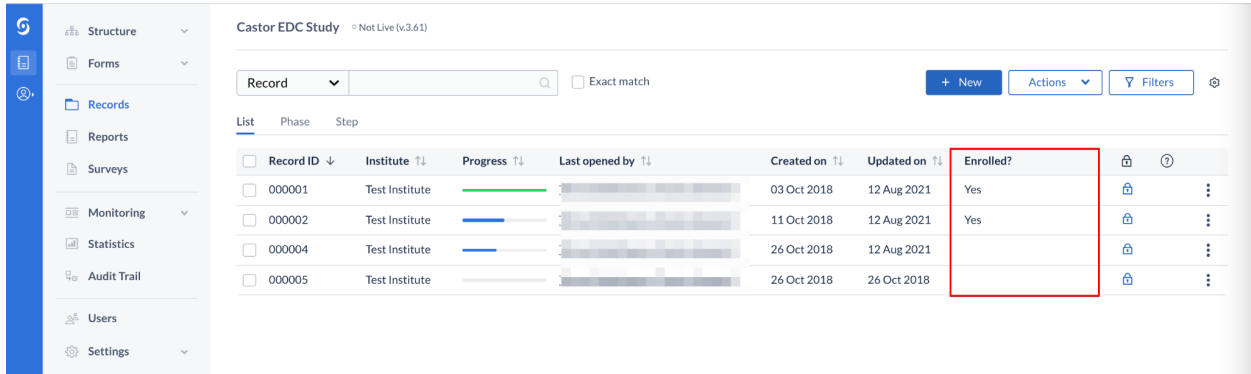
15.1.1.4 Date subject completed participation in study:

Previous

Next

The data in these fields can then be used to customize the records columns in the study settings.

These fields can be used to provide enrollment information on the main Records tab. After creating your question in the form builder, you can [customize](#) your columns so that you can display this information.



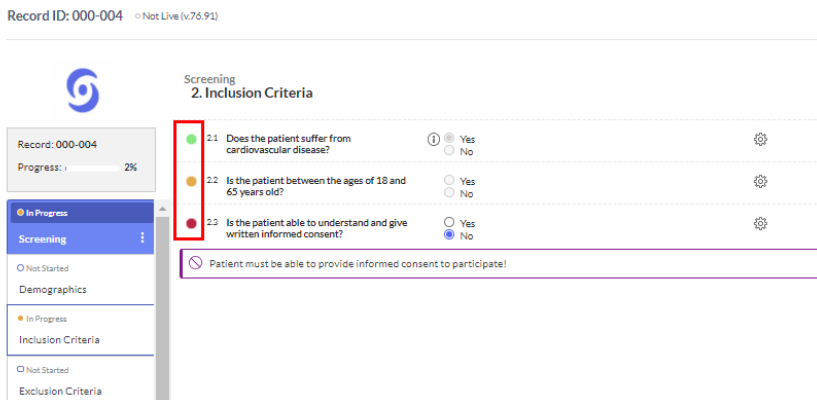
Castor EDC Study - Not Live (v.3.6.1)

Record  ☐ Exact match + New Actions Filters

Record ID	Institute	Progress	Last opened by	Created on	Updated on	Enrolled?
000001	Test Institute	<div><div></div></div>		03 Oct 2018	12 Aug 2021	Yes
000002	Test Institute	<div><div></div></div>		11 Oct 2018	12 Aug 2021	Yes
000004	Test Institute	<div><div></div></div>		26 Oct 2018	12 Aug 2021	
000005	Test Institute	<div><div></div></div>		26 Oct 2018	26 Oct 2018	

## Progress of completion

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



Record ID: 000-004 - Not Live (v.76.91)

Screening  
2. Inclusion Criteria

Record: 000-004  
Progress:  20%

**In Progress**  
Screening  
Not Started  
Demographics  
In Progress  
Inclusion Criteria  
Not Started  
Exclusion Criteria

2.1 Does the patient suffer from cardiovascular disease? ☐ Yes ☐ No

2.2 Is the patient between the ages of 18 and 65 years old? ☐ Yes ☐ No

2.3 Is the patient able to understand and give written informed consent? ☐ Yes ☒ No

⚠ Patient must be able to provide informed consent to participate!

The status icons indicate the status for a field, they have the following meanings:

- **Green:** The value is valid and the field is saved.
- **Orange:** The field is required and no value has been entered yet.
- **Red:** The value is invalid and the field has not been saved.

- **No icon:** The field is not required and no value has been saved.

These field level status icons in data entry view are the lowest status level for progress indication in phases, steps, reports, and surveys. Progress for phases, steps, reports, and surveys are calculated based on the fields that are marked [required](#) in the fields' settings. Fields that are not required are not included in the completion progress.

## Records

Record progress can be viewed on the Record Overview screen (3).

	Last opened on	Last opened by	Randomization gr...	Next phase	Progress	Created by	Created on
<input type="checkbox"/>	19 Feb 2021	Tonya Support	-		<div><div></div></div>	Tonya Support	12 Feb 2020
<input type="checkbox"/>	19 Feb 2021	Tonya Support	A		<div><div></div></div>	Tonya Support	12 Feb 2020
<input type="checkbox"/>	18 Feb 2021	Tonya Support	B	Completed	<div><div></div></div>	Tonya Support	12 Feb 2020
<input type="checkbox"/>	15 Dec 2020	Tonya Support	-		<div><div></div></div>	Tonya Support	15 Dec 2020
<input type="checkbox"/>	18 Feb 2021	Tonya Support	B		<div><div></div></div>	Tonya Support	15 Dec 2020
<input type="checkbox"/>	18 Feb 2021	Tonya Support	A		<div><div></div></div>	Tonya Support	15 Dec 2020
<input type="checkbox"/>	15 Dec 2020	Tonya Support	-		<div><div></div></div>	Tonya Support	15 Dec 2020
<input type="checkbox"/>	15 Dec 2020	Tonya Support	-		<div><div></div></div>	Tonya Support	15 Dec 2020

List view (2) provides an overall view of required fields in the study form. A record will show as incomplete until required fields in all phases and steps are complete.

- **Green:** All field values are complete and valid.
- **Gray:** No values have been saved or data entry has not begun.
- **Blue:** Data Entry has started but is not complete.

Please note that if a record contains an unclosed query, progress will remain incomplete even if all data has been entered.

Phase View provides an overview of the progress for each phase.

Castor EDC Study

Not Live (v.0.21)

Record

Exact match

+ New

Actions

Filters

List

Phase

Step

<input type="checkbox"/> Record	Institute	Screening	First Study Visit	Follow-up	Outcome
<input type="checkbox"/> 000001	Utrecht Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000002	Utrecht Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110001	Utrecht Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110002	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110003	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110004	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110005	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110006	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110007	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 110008	Amsterdam Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

123456...14Next

1 - 25 of 333

Items per page: 25

Step View provides an overview of the progress for each step.

Castor EDC Study

Not Live (v.3.61)

Record

Exact match

+ New

Actions

Filters

List

Phase

Step

Record ID

Institute

Inclusion

Demographics

Measurements

Assessment

<input type="checkbox"/> 000001	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000002	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000004	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000005	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

## Reports

Since each report can have none to many instances for each record, progress for reports does not influence the progress of the record. Like study data, progress is only influenced by those

fields that are required. The color coded status icons indicate the completion status of each report instance.

Record ID: 000-001 Not Live (v77.11)

**All reports**

Record: 000-001  
Progress: 100%

Filter by report type: Select report type to filter  
Filter by report: Select report to filter  
Filter by status: Unarchived

Filter by name: Select phase to filter

Add a report

Status	Report	Name	Type	Created on	Created by	Assigned to	
	Medication	Medication - 22-10-2020 11:01...	Repeated measure	2020-10-22 11:01:56	Niecy Duncan [Admin]	No parent	
	Medication	Medication - 17-12-2020 14:34...	Repeated measure	2020-12-17 14:34:04	Niecy Duncan [Admin]	No parent	
	Medication	Medication - 17-12-2020 14:33...	Repeated measure	2020-12-17 14:33:49	Niecy Duncan [Admin]	No parent	

## Surveys

Survey progress is displayed as a percentage of required fields that have been completed. You further have the option to automatically lock surveys when a respondent submits a survey and [create notifications](#) each time a survey is completed. If a respondent does not complete a survey in one sitting, responses are saved and the respondent can continue answering where they left off.

Manage groups **Bulk Survey Invite**

Filter by institute: All institutes  
Filter by survey package name: Sleep Survey  
Filter by completion status: All  
Filter by parent: None

Filter by record id: On  
Filter by date sent: On  
Filter by date completed: On

Reset

Record	Institute	Package name	Status	Progress	Date created	Date planned	Date sent	Date completed	Menu
<input type="checkbox"/> 000-001	Test Institute	Sleep Survey	Locked	100	2020-12-17			2020-12-17	
<input type="checkbox"/> 000-002	Test Institute	Sleep Survey	In Progress	67	2020-12-17				
<input type="checkbox"/> 000-003	Test Institute	Sleep Survey	Created	0	2020-12-17				

## Data Review

### Verification

In Castor you have the option to verify collected data in your study. The most common example is source data verification (SDV), but you can also define your own verification type depending on the quality control that you want to use for your study data.

The SDV option is included by default if Monitoring is enabled. To use this feature you have to first ensure that the correct study settings are applied and that the correct [user rights](#) are assigned to users in the study.

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

Under 'Manage verification types', located in the 'GCP' section of the study settings, you can add or edit the verification types in your study:

Users

Settings

Study

Metadata

Notifications

Randomization

Admin

Automations

Automation engine logs

GCP

Confirm Changes: Yes

Verification types: Manage Verification Types

Other

Record IDs: Incremental

Clear inapplicable child fields: Yes


Enable beta features: Yes

Enforce 2FA: No

Only show records with exact match: No

You have the option to SDV all steps in a phase, a step (including all fields or required fields) as well as individual fields. For other custom verification types, you cannot verify individual fields.

At the top of each verified page, a banner is displayed with the verification details. This banner is only visible if SDV has been performed on an entire step.



Day 30

11. Day 30 Visit

Record: 000-001

Progress: 98%

Baseline

Completed

Day 30

Day 30 Visit

Evaluations

Laboratory Tests

1 VER This step was verified on 22/12/2020 at 09:14 by Niecy Duncan for Data Management Verification Remove

2 SDV This step was verified on 22/12/2020 at 09:14 by Niecy Duncan for Source Data Verification Remove

11.1 Was visit completed? Yes No

11.1.2 Visit Date 14-01-2021 dd-mm-yyyy

11.2 Day 30 Date Validation 28

Previous

Next

1. A custom verification banner
2. An SDV banner
3. The step verification icons

Phases and steps that have been SDV'd can be seen on the Records overview page when in Phase or Step view. Remember that an entire phase or step would need to have SDV performed in order for the SDV icon to appear.

Castor EDC Study - Not Live (v.3.51)

Record  ☐ Exact match + New Actions Filters

List Phase Step

<input type="checkbox"/> Record ID	Institute	Inclusion and random...	Follow-up 1 (after ...)	Follow-up 2 (after ...)	Follow-up 3 (after ...)	End of Study
<input type="checkbox"/> 000001	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000002	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000004	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/> 000005	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

## Data Processing

### Medical Coding

Castor EDC allows for medical coding of adverse events and concomitant medications. We have implemented an out-of-the-box integration with a Medical Coding platform: MedCodr.

MedCodr is a web based solution for coding medical terms and products to standard dictionaries including MedDRA and WHODrug or custom dictionaries.

It is possible to attach metadata from the MedDRA and WHODrug to Adverse Event (AE) dictionaries. This means that, upon adding terms in a text field in an AE, Medical History, or Concomitant Medication Report, it is possible to use MedCodr (an external service) to browse and attach the correct translation from the MedDRA and WHODrug to these reports.

Once one of the above mentioned reports are created and a term is added to a text field, codes are pushed back to Castor EDC in dedicated coding reports that can be exported separately.

Castor also provides Coding-as-a-Service for when your team does not have the time or capabilities to perform this task.

Medical Coding is a premium feature. If you are interested in adding this service, please contact your account executive or [support@castoredc.com](mailto:support@castoredc.com).

### Loading Electronic Data

There are two methods available to add electronic data to the EDC: CSV import or Application Programming Interface (API).

## CSV Import

You are able to import data into the EDC via CSV. You can import data for one record at a time or for multiple records. For importing via CSV, variable names must exist in the database and there is a limit of 25,000 data points per single import. This limit is much lower for importing encrypted data.

It is possible to import study data and report data only. Study and report data must be imported separately. It is not possible to import the following:

- Survey data
- Queries
- Comments
- Signatures
- Data verifications

Note that in certain circumstances data in the CSV file must be formatted properly for a successful import. Details about these formats can be found in our [online manual](#). Please review [Import Study Data](#) and [Import Report Data](#) for more information about importing.

## Application Programming Interface (API)

Castor EDC allows for linking the EDC database to other applications via API. The API supports authentication and authorization of API calls through the industry standard [OAuth2](#). To start, you will need to create [API credentials](#) in the Account Settings.

It is possible to retrieve (GET) and send (POST) using API endpoints.

These endpoints can be found in our online manual based on the server you are using for your study:

- EU: <https://data.castoredc.com/api>
- US: <https://us.castoredc.com/api>
- UK: <https://uk.castoredc.com/api>
- AUS: <https://au.castoredc.com/api>

If questions arise during your setup, please contact [support@castoredc.com](mailto:support@castoredc.com).

## Data Queries

Data queries can be viewed on the Record Overview for each record. The counter displays only queries that have not been closed.

<input type="checkbox"/> Record	Institute	Last op...	Last op...	Rand...	Progress	Created ...	Created ...	Updated...	Updated...	Q...	Actions
<input type="checkbox"/> 110001	Main Inst...	30 Jun ...		-	<div><div></div></div>		30 Jun 2...	30 Jun 2...			
<input type="checkbox"/> 110002	Main Inst...	30 Jun ...		-	<div><div></div></div>		30 Jun 2...	30 Jun 2...			

The query icon can also be seen when in phase and step view.

The status and comments for each query can be reviewed on the Monitoring tab, Queries subtab.

Structure	Familiarise Yourself With Castor	Not Live (v0.31)
Forms	Queries	Actions Filters
Records		
Reports		
Surveys		
Monitoring		
Queries		
Validations		
Verifications		

Record ID	Institute	Created on	Created By	Last updated by	Closed by	Location	First Remark	Last Remark	Status	Query age	Time to resol	View
<input type="checkbox"/> 110001	Main Institute	20 Jul 2021	Ernest Mbyeti	Ernest Mbyeti		Phase Infor...	test	test	New	0	0	
<input type="checkbox"/> 110002	Main Institute	20 Jul 2021	Ernest Mbyeti	Ernest Mbyeti		Phase Infor...	ok	ok	Resolved	0	0	
<input type="checkbox"/> 110002	Main Institute	20 Jul 2021	Ernest Mbyeti	Ernest Mbyeti	Ernest Mbyeti	Phase Infor...	test	test	Closed	0	0	
<input type="checkbox"/> 110002	Main Institute	20 Jul 2021	Ernest Mbyeti	Ernest Mbyeti		Phase Infor...	test	test	Unconfirmed	0	0	
<input type="checkbox"/> 110002	Main Institute	20 Jul 2021	Ernest Mbyeti	Ernest Mbyeti	Ernest Mbyeti	Phase Infor...	test	test	Closed	0	0	

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

- **Open:** The user has acknowledged/opened the query, and added a remark. The status changes from New to Open.
- **Unconfirmed:** The user does not agree with the monitor.
- **Confirmed:** The user agrees with the monitor and will try to resolve the issue.
- **Resolved:** The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment. In this case the query is not closed which is why the 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.

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

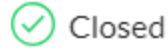
1. Open/Unconfirmed/Confirmed.

New    Open    Confirmed

## 2. Resolved.



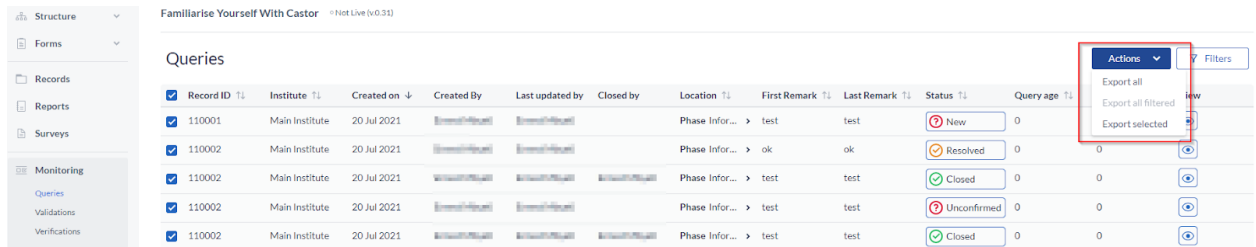
## 3. Closed.



## 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 steps below:

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



The screenshot shows the 'Queries' table in the Castor application. The table has columns for Record ID, Institute, Created on, Created By, Last updated by, Closed by, Location, First Remark, Last Remark, Status, Query age, and a 'New' button. The 'Status' column shows various states: New, Resolved, Closed, and Unconfirmed. The 'Actions' dropdown menu is open, showing three options: 'Export all', 'Export all filtered', and 'Export selected'.

Record ID	Institute	Created on	Created By	Last updated by	Closed by	Location	First Remark	Last Remark	Status	Query age	New
110001	Main Institute	20 Jul 2021				Phase Inform...	test	test	New	0	
110002	Main Institute	20 Jul 2021				Phase Inform...	ok	ok	Resolved	0	
110002	Main Institute	20 Jul 2021				Phase Inform...	test	test	Closed	0	
110002	Main Institute	20 Jul 2021				Phase Inform...	test	test	Unconfirmed	0	
110002	Main Institute	20 Jul 2021				Phase Inform...	test	test	Closed	0	

- In Queries export dialog window, you can specify:
  - Export type: choose to export into CSV or Excel (1)
  - Export tree: choose if you would like to export queries for entire study, specific study phases or steps in your study or for reports, a specific report or a report step (2)
  - Export: click on Export button to generate export of the queries (3)

Queries export (All Queries)

Export type  
CSV

Entire study  
Study  
Reports

Only queries for which you have Export rights will be Exported

Export Cancel

## Missing pages

### User missing

If a data point cannot be answered due to missing data or other known reason, you can address this in the study forms by defining the data as 'user missing'. This option can be accessed by clicking on the cogwheel next to the field and selecting 'User missing':

Back to records

Record ID: 110001 Not Live (v.8.31)

Record  
Study  
Reports  
Surveys  
Monitoring

Record: 110001  
Progress: 53%

Demographics  
3. Patient Demographics

3.1 Gender  
Male  
Female

3.2 Date of birth (dd-mm-yyyy)

Completed  
Baseline  
Not Started  
Demographics

Clear  
User missing  
Comments  
Audit trail  
Queries

A dialog window will open, in which you are prompted to select the most applicable reason for the missing data point and to add a comment. The selected reason will assign the associated value to the field and this value that will also be exported as data values. It is not possible to change the predefined values for missing data. The available values are:

- Measurement failed (-95)

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

The field marked as missing will be faded/greyed in the form, but the status icon will update to show that the field has been completed. A comment will be added to the field, containing the reason entered.

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

## Mark full steps/phases as missing

Full steps and phases can also be marked as missing by selecting Mark phase / step as missing in the data entry navigator using the cogwheel right next to the phase/step:

Record ID: 110001 (v.8.31)

Record: 110001  
Progress: 53%

Demographics  
3. Patient Demographics

3.1 Gender  
3.2 Date of birth

Completed  
Baseline  
Not Started  
Demographics  
Not Started  
Patient Demographics  
Not Started  
Visit 1 and Randomization  
Not Started  
End of Study

Mark phase as missing  
Lock this phase  
Sign this phase  
Mark as verified  
Print this phase  
Add a report to this phase

After 'Mark step/phase as missing' is clicked, a new dialog window will open in which you can provide a reason for the missing information and include a comment:

3/4 Date of birth 1/7/ (dd-mm-)

Mark whole phase 'Demographics' as missing?

Choose reason:

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

Comment:

Please note: marking a phase as missing cannot be undone. Setting phase to missing may affect signatures, verifications and Child field dependencies.

Save

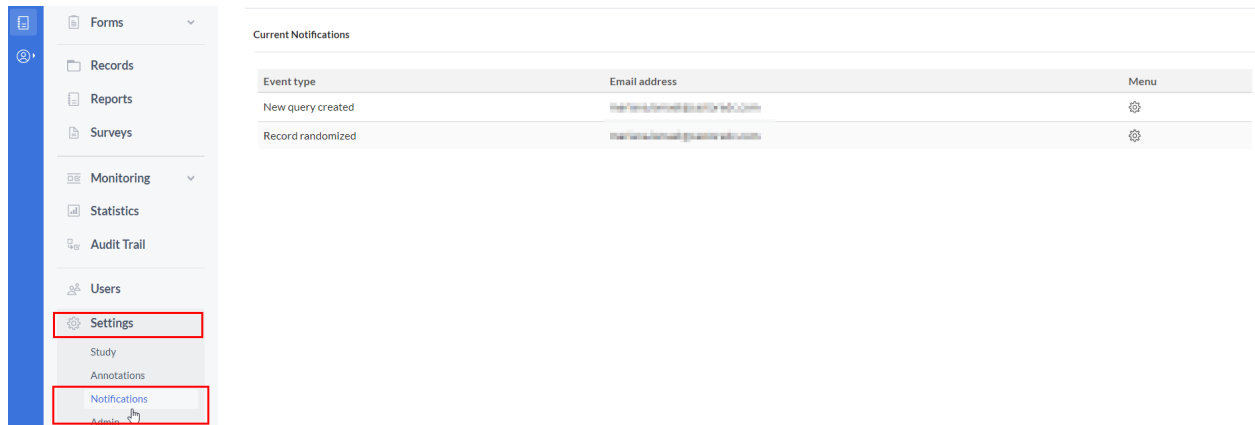
Cancel

## Notifications

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

- Form signature dropped due to edit
- Form signed: Report
- For signed: Report Step
- Form signed: Study Phase
- Form signed: Study Step
- Form verification dropped due to edit (and field form verification dropped due to edit)
- New query created
- New record created
- Query updated
- Record randomized
- Report completed
- Survey package completed
- New report added to record: when selecting new report added to a record, choose from the drop-down menu which is the specific report that you are interested in receiving the notification

1. Recipient: Choose a recipient of the notification email in the drop-down (which shows all users added to the study).
2. Filter on institute: Choose one or multiple institutes for which you want to receive the notifications (i.e. only your own hospital). Leave this field empty if you want to receive notifications for all institutes.
3. Notification template: This is the email text that will be sent when the event occurs. You can modify this as you like. The listed available tags will be replaced by their real values when the notification is sent.
4. Press the 'Save' button to save the notification or the cancel button to return to the notifications overview. This is also where you can find all current the notifications created for your study:



## Signing and Locking

In order to sign or lock a phase, step, or report, it is necessary to have sign and lock user rights. One or both of these rights can be assigned to a user as they are separate rights.

### Sign or unsign a phase or step

You can sign individual phases and steps. Open the record for which you want to sign steps/phases. On the left side you will find the phase and step navigator. In our example, we will sign and lock the step "Inclusion".

1. When in a record, click on a step or phase. Click on the three dots that appear to the right.
2. Click on "Sign this phase" for phases or "Sign this step" for steps.
3. Enter your password to confirm your identity. You can choose to also lock the phase/step in the same instance, to prevent further data entry. Click "Sign" to confirm and to sign the phase or step. In order to lock during signing, it is necessary to have the lock user right. For users without the lock user right, an error message will appear if they attempt to lock.

Record: 000001  
Progress:  76%  
☒ Show Reports

Inclusion\_
2. Inclusion

This step was signed on 11/06/2020 at 16:14 by [Marlene Isom](#) for [Baseline](#)

2.1 Date of assessment  (dd-mm-yyyy)

2.2 Is patient older than 18? ☒ Yes ☐ No

2.3 Patient gender ☐ Male ☒ Female

A warning will be displayed at the top of the data entry screen, warning the user that the current step has been signed and/or locked. It is also possible to unsign a step/phase.

Record: 000001  
Progress:  91%

Patient characteristics
1. Demographics

This step was signed on 11/06/2020 at 12:17 by [Marlene Isom](#) for [Baseline](#) [Unsign](#)

1.1 Year of birth  (yyyy)

## Lock or unlock a phase or step

If you have lock rights, you can also choose to separately lock or unlock a phase or step by choosing the "Unlock this phase" or "Unlock this step" option.

Record: 110001  
Progress:  25%

Baseline
2. Demog

This step is locked

2.1 Age

2.2 Gender

Completed
Baseline

Completed
Inclusion

Completed
Demographics

Completed
Measurement

Not Started

Unlock this step

Sign this step

Mark as verified

Print this step

# Study Conduct

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

## Protocol Amendments

You can keep track of protocol amendments within the EDC by creating fields that document the protocol or informed consent versions. Doing this allows this information to be documented for each record.

### Screening 2. Informed Consent

#### Consent info 1

2.1 Enrollment Status	<input type="text"/>
2.2 Date Created	<input type="text"/> (dd-mm-yyyy)
2.3 Date invited	<input type="text"/> (dd-mm-yyyy)
2.4 ICF Version	<input type="text"/>
2.5 ICF Status	<input type="text"/>
2.6 ICF Language	<input type="text"/>
2.7 Country	United States
2.8 Site	Test Institute
2.9 Date of ICF	<input type="text"/> (dd-mm-yyyy)

#### Consent info 2 (Version update Only)

2.10 ICF Version	<input type="text"/>
2.11 ICF Language	<input type="text"/>
2.12 ICF Status	<input type="text"/>

## Deviations

Reports are useful for keeping track of protocol deviations.

It is recommended that the add a report button is utilized and dependencies are created where a deviation may occur.

Baseline  
7. Baseline (7 +/- 2 days) Visit Date

7.1	Was visit completed?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
7.1.2	Visit Date	<input type="text" value="11-09-2020"/> <small>(dd-mm-yyyy)</small>	
7.2	Number of days since washout began:	<input type="text" value="10"/>	

Visit Out of Window

7.3.1 [Add a Deviation](#)

Using the add a report button, the Protocol Deviation report will always be linked to the phase in which the report was created.

Add a report to record 110002

Report:	<input type="text" value="Protocol Deviation"/>
Custom name:	<input type="text" value="Protocol Deviation - 15-09-2020 14:53:51"/>
Attach to:	<input type="text" value="Phase 2. Baseline"/>

[Create](#) [Cancel](#)

You are further able to create notifications on the Report Event type and choosing the Deviation Report.

## Signing the Record

In a previous section, we showed you how to sign phases and steps. It is not possible to sign a record. However, you can opt to have your investigators sign off on an End of Study phase shown previously.

Record: 000001  
Progress:  4%

Not Started

Screening

In Progress

Baseline

Not Started

Device Details

Not Started

Week 12

Not Started

Week 24

Completed

End of Study

End of Study  
26. End of Study

This step was signed on 31/12/2020 at 15:23 by Niecy Duncan [Admin] (niecy.duncan@castoredc.com) Unsign

This step was locked on 31/12/2020 at 15:23 by Niecy Duncan [Admin] (niecy.duncan@castoredc.com) Unlock

26.1	Has the subject completed their participation in the study?	<input checked="" type="radio"/> yes <input type="radio"/> no	<a>Settings</a>
26.1.1	Was the subject discontinued from the study?	<input checked="" type="radio"/> yes <input type="radio"/> no	<a>Settings</a>
26.1.1.1	Date subject discontinued	<input type="text" value="17-12-2020"/> <small>(dd-mm-yyyy)</small>	<a>Settings</a>
26.1.1.2	Reason for discontinuing	<input type="text" value="Non-compliance"/>	<a>Settings</a>
26.1.1.3	Additional comments:	<div>misuse of study drug</div>	<a>Settings</a>

## Closeout Activities

Once a study is complete, we recommend performing the following actions:

- 1) Lock all records
- 2) Export a copy of the study data
- 3) Set the study to 'not live' in the 'Settings' tab
- 4) Remove all users and study admins can reduce their own rights. It is recommended that study admins leave themselves as the only user, and remove all user rights except 'View', 'Export', 'Manage Records', 'Manage Settings'.
- 5) Archive the study. Once the study is 'closed', you can [archive the study](#) in the 'My studies' overview, which will remove it from the overview for all users and prevent users from accessing it in future.

The data is stored for at least 25 years (depending on local laws).

Our policy is to always match relevant, local regulations. In this case, the new Clinical Trial Regulation will require the Clinical Trial Master File to be stored for 25 years. Castor will ensure that we support storage of data (including the original audit trail) for that time period unless our customers explicitly do not require us to (as they might archive it elsewhere).

### **Further information**

View the Castor EDC video workshop at <https://workshop.castoredc.com/>.

For more information regarding data management, check Castor EDC's knowledge base: <https://helpdesk.castoredc.com>. Additional [ready-to-print instructions](#) based on user roles are also available. If you have any questions or concerns, please contact us at [support@castoredc.com](mailto:support@castoredc.com)