

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

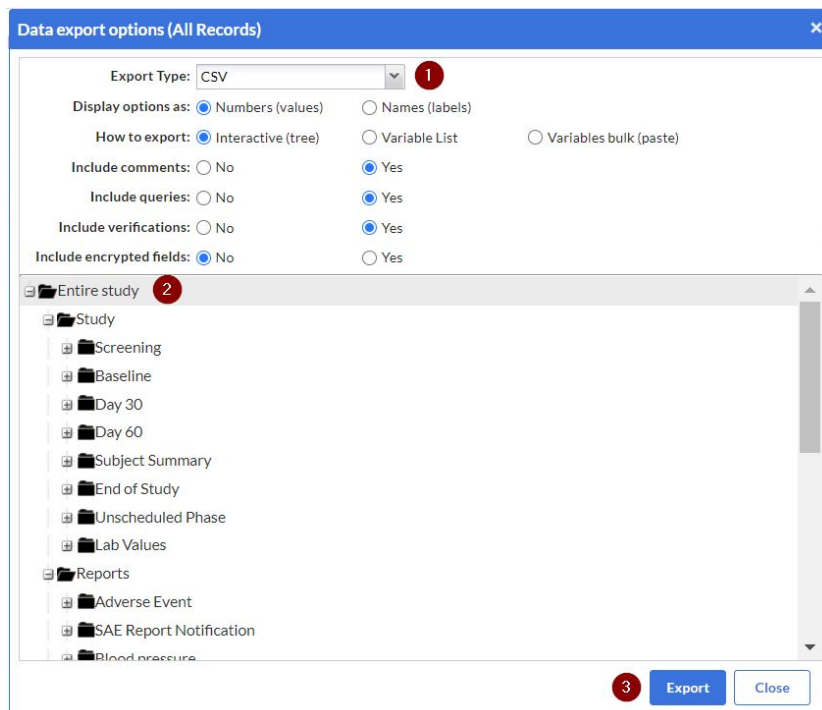
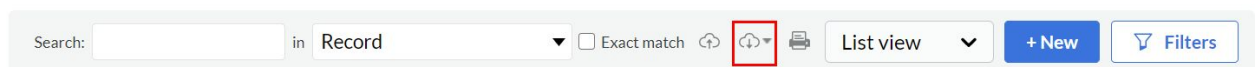
CRF Review

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

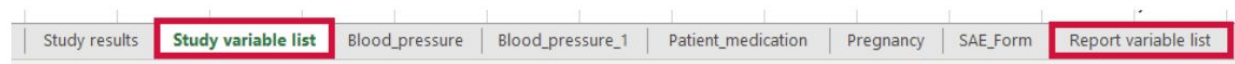
Data Dictionary

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.

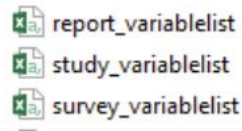
In the Records Overview, click on the 'Export' button.



1. Select either Excel or CSV.
 - An Excel export will produce one workbook with multiple worksheets.



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

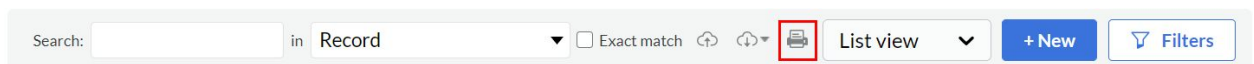


2. Select 'Entire Study'.
3. Click 'Export'.

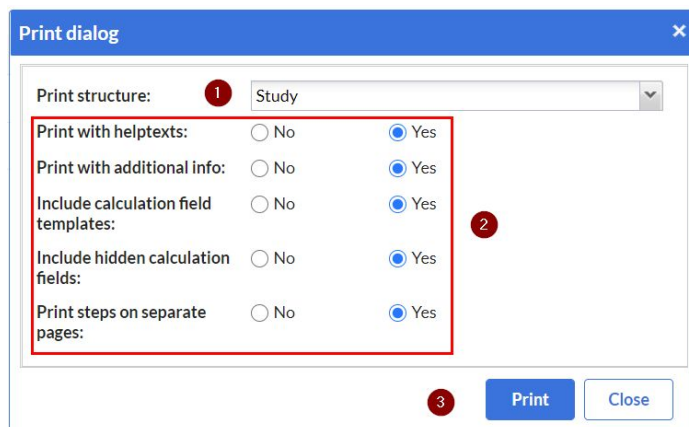
Study variables, report variables, and survey variables will be exported as separate variable lists.

Blank CRFs

1. In the Records Overview, click on the 'Print' icon.



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



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. Randomizations settings can be viewed in the Study 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.

Castor EDC Study - Not Live

Randomization groups

Name	Weight	Remove
Add group 1		

Stratify by

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	None	<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	None	<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	None	<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	None	<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	Admin	<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"/>

Save Close

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 cannot continue to other steps (data entry is blocked). 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 
 Patient can participate, please continue to demographics.		

eLearning

Castor Academy (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.

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.

The screenshot displays the 'Informed Consent' section of a study form. On the left, a sidebar lists various sections: 'Completed' (highlighted in blue), 'Inclusion and Exclusion (V1)', 'Demographics', 'Inclusion Criteria', 'Exclusion Criteria', and 'Informed Consent'. The main area shows the '4. Informed Consent' section with several questions. Question 4.2.2, 'Was the patient enrolled in the study?', is highlighted with a red box and has the 'yes' radio button selected. Other questions include 4.1 (Can the patient participate in the study?), 4.2 (Has patient signed informed consent?), and 4.2.1 (Date for signed informed consent).

Question ID	Question Text	Answer
4.1	Can the patient participate in the study?	Yes. After enrollment, continue to baseline.
4.2	Has patient signed informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No
4.2.1	Date for signed informed consent	01-05-2020 (dd-mm-yyyy)
4.2.2	Was the patient enrolled in the study?	<input checked="" type="radio"/> yes <input type="radio"/> 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:

(dd-mm-yyyy)

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.

Record	Institute	Last opened	Last opened by	Next phase	Progress	Created by	Created on	Updated on	Updated by	Queried	Enrolled	Discontinued	Completed	Actions
<input type="checkbox"/> 000001	Castor 2	14 Apr 2020	Niecy Dunc...		<div></div>	Niecy Duncan...	01 Apr 2020	11 May 2020	Niecy Duncan...		yes	yes	yes	
<input type="checkbox"/> 110001	Castor 1	15 Apr 2020	Niecy Dunc...		<div></div>	Niecy Duncan...	01 Apr 2020	21 Apr 2020	Niecy Duncan...		yes	yes	yes	

Progress of completion

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

Record: 000-004
Progress: 2%

Screening

2. Inclusion 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.

Record	Institute	Last opened	Last opened	Randomized	Progress	Created by	Created on	Updated on	Updated by	Que...	Enrolled	Discontinued	Completed	Gender	Actions
<input type="checkbox"/> 000-001	Test Institute	-	-	-	<div><div></div></div>	Niecy Dunca...	22 Oct 2020	17 Dec 2020	Niecy Dunca...		yes	no	yes	Male	
<input type="checkbox"/> 000-002	Test Institute	-	-	-	<div><div></div></div>	Niecy Dunca...	22 Oct 2020	22 Oct 2020	Niecy Dunca...						
<input type="checkbox"/> 000-003	Test Institute	-	-	-	<div><div></div></div>	Niecy Dunca...	12 Nov 2020	17 Dec 2020	Niecy Dunca...					Female	

List view provides an overall view of required fields in study form data. 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.

Search:

in

Record

Exact match

Phase view

+ New

Filters

<div><input type="checkbox"/></div>	Record	Institute	Screening	Baseline	Day 30	Day 60	Subject Summary	End of Study	Unschedu... <div><div></div></div>	Lab Values
<div><input type="checkbox"/></div>	000-001	Test Institute	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>
<div><input type="checkbox"/></div>	000-002	Test Institute	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>
<div><input type="checkbox"/></div>	000-003	Test Institute	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>

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

Search:

in

Record

☐ Exact match

Step view

+ New

Filters


<input type="checkbox"/>	Record	Institute	Demographics	Inclusion Criteria	Exclusion Criteria	Informed Consent	Randomization	Baseline [...]	Evaluations	Laboratory Tests	Adverse E
<input type="checkbox"/>	000-001	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/>	000-002	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
<input type="checkbox"/>	000-003	Test Institute	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

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

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)



Record: 000-001

Progress: 100%

All reports

Filter by report type:

Select report type to filter

Filter by report:

Select report to filter

Filter by status:




Unarchived

Filter by name:

Filter by phase:

Select phase to filter

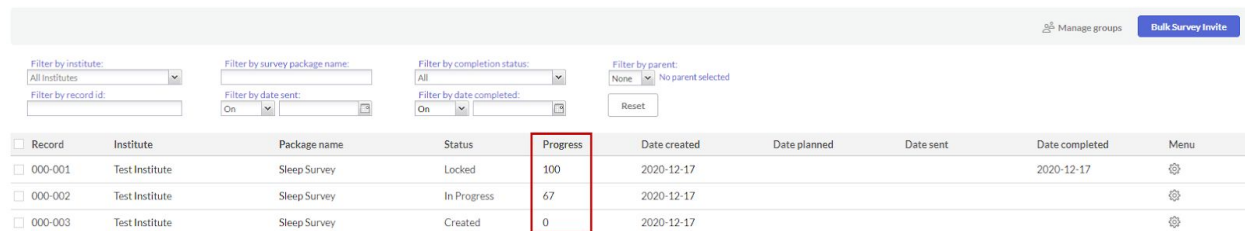
Add a report

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



The screenshot shows the top of the Castor survey management interface. At the top right, there are links for 'Manage groups' and 'Bulk Survey Invite'. Below these are several filter options: 'Filter by institute' (set to 'All Institutes'), 'Filter by survey package name' (empty), 'Filter by completion status' (set to 'All'), 'Filter by parent' (set to 'None'), 'Filter by record id' (empty), 'Filter by date sent' (set to 'On'), 'Filter by date completed' (set to 'On'), and a 'Reset' button. Below the filters is a table with the following columns: Record, Institute, Package name, Status, Progress, Date created, Date planned, Date sent, Date completed, and Menu. The table contains three rows of data, with the 'Progress' column values highlighted in red.

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

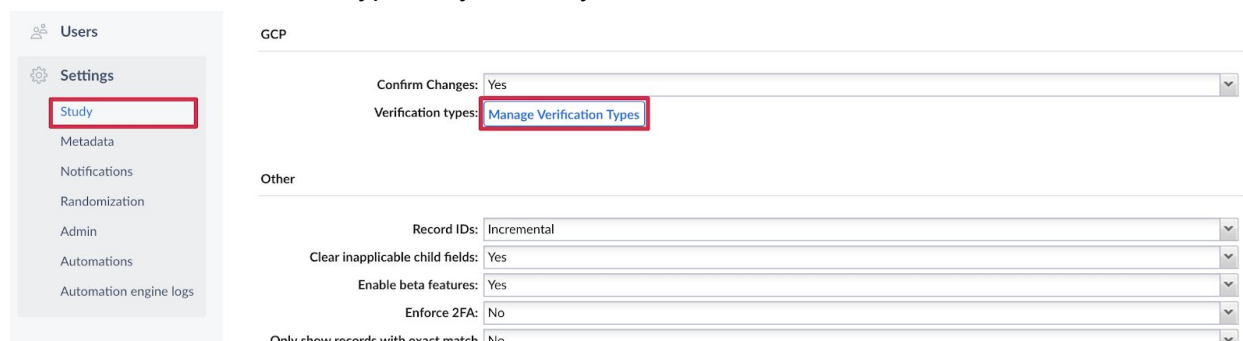
Verification

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:



The screenshot shows the Castor study settings interface. On the left, there is a sidebar with the following menu items: Users, Settings, Study (highlighted with a red box), Metadata, Notifications, Randomization, Admin, Automations, and Automation engine logs. The main content area is titled 'GCP' and contains the following settings: 'Confirm Changes' (set to 'Yes'), 'Verification types' (set to 'Manage Verification Types' and highlighted with a red box), 'Record IDs' (set to 'Incremental'), 'Clear inapplicable child fields' (set to 'Yes'), 'Enable beta features' (set to 'Yes'), 'Enforce 2FA' (set to 'No'), and 'Only show records with exact match' (set to '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 SVD has been performed on an entire step.

Record: 000-001
Progress: 98%

Day 30
11. Day 30 Visit

1. This step was verified on 22/12/2020 at 09:14 by Niecy Duncan for Data Management Verification [Remove](#)

2. 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 (dd-mm-yyyy)

11.2 Day 30 Date Validation

[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.

Not Live (v.77.71)

Search: in Record ☐ Exact match [Phase view](#) [+ New](#) [Filters](#)

<input type="checkbox"/>	Record	Institute	Screening	Baseline	Day 30	Day 60	Subject Summary	End of Study	Unschedu...	Lab Values	Vist
<input type="checkbox"/>	000-001	Test Institute									
<input type="checkbox"/>	000-002	Test Institute									
<input type="checkbox"/>	000-003	Test Institute									
<input type="checkbox"/>	000-004	Test Institute									

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.

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.

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		Not Live (v.77.11)				
Forms						
Records						
Reports						
Surveys						
Monitoring						
Queries						
Validations						
Verifications						
Statistics						
Audit Trail						
Users						
Settings						

Record	Institute	Creation Date	Created By	Location	Last Remark	Status
000-001	Test Institute	22 Oct 2020 10:45		Phase: Day 30 Step: Day 30 Visit Field: Day 30 Date V...	Visit outside of range. Please complete deviation repo...	① Opened
000-001	Test Institute	22 Oct 2020 10:58		Phase: Day 30 Step: Drug Compliance Field: Explain ...	Please explain why investigational product was not re...	① Opened
000-001	Test Institute	22 Oct 2020 10:59		Phase: Baseline Step: Evaluations Field: Was an echoc...	Update is not required.	① Unconfirmed
000-001	Test Institute	22 Oct 2020 11:00		Phase: Baseline Step: Laboratory Tests Field: P-Creati...	Update pending	① Confirmed
000-001	Test Institute	22 Oct 2020 11:00		Phase: Baseline Step: Laboratory Tests Field: INR Value	Value entered. Please close query.	① Resolved
000-001	Test Institute	22 Oct 2020 11:01		Phase: Baseline Step: Laboratory Tests Field: INR Ana...	Done	① Closed
000-001	Test Institute	22 Oct 2020 11:03		Report: Medication Step: Medication Field: Name	Done	① Closed
000-001	Test Institute	22 Oct 2020 11:04		Phase: Baseline Step: Adverse Events Field: Did the s...	Done	① Closed
000-001	Test Institute	22 Oct 2020 11:04		Phase: Baseline Step: Drug Distribution Field: Issue d...	Done	① Closed
000-001	Test Institute	22 Oct 2020 11:05		Phase: End of Study Step: End of Study Field: Has the ...	This phase has successfully completed Source Data Va...	① Closed
000-003	Test Institute	12 Nov 2020 12:47		Phase: Screening Step: Demographics Field: Gender	Closed	① Closed

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.

① New ① Open ① Confirmed

2. Resolved.

① Resolved

3. Closed.



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':

The screenshot displays a study form for Record ID: 110001. On the left, a sidebar contains a 'Record' section with links for 'Study', 'Reports', 'Surveys', and 'Monitoring'. The main content area shows a progress bar at 53% and a section titled '3. Patient Demographics'. Two fields are visible: '3.1 Gender' with radio buttons for 'Male' and 'Female', and '3.2 Date of birth' with a text input field and a calendar icon. A cogwheel icon is positioned to the right of the 'Date of birth' field. A dropdown menu is open from this cogwheel, showing options: 'Clear', 'User missing' (highlighted with a red box), 'Comments', 'Audit trail', and '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)

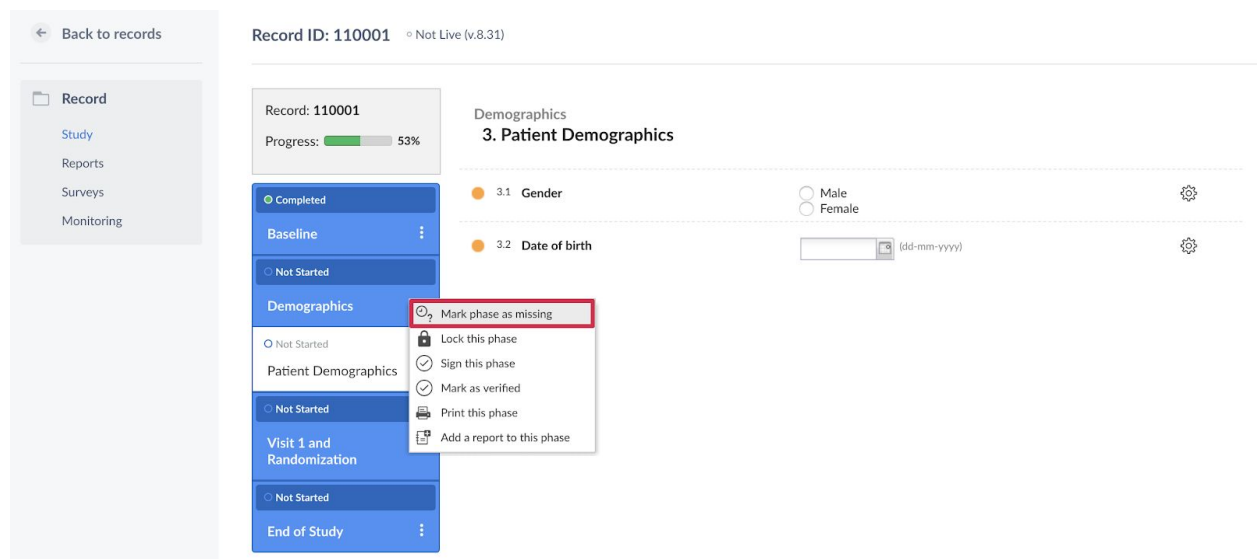
The field marked as missing will be faded/greyed in the form, but the status icon will update to show that the field has been completed. A comment will be added to the field, containing the reason entered.

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 Not Live (v.8.31)

Record: 110001
Progress: 53%

Demographics
3. Patient Demographics

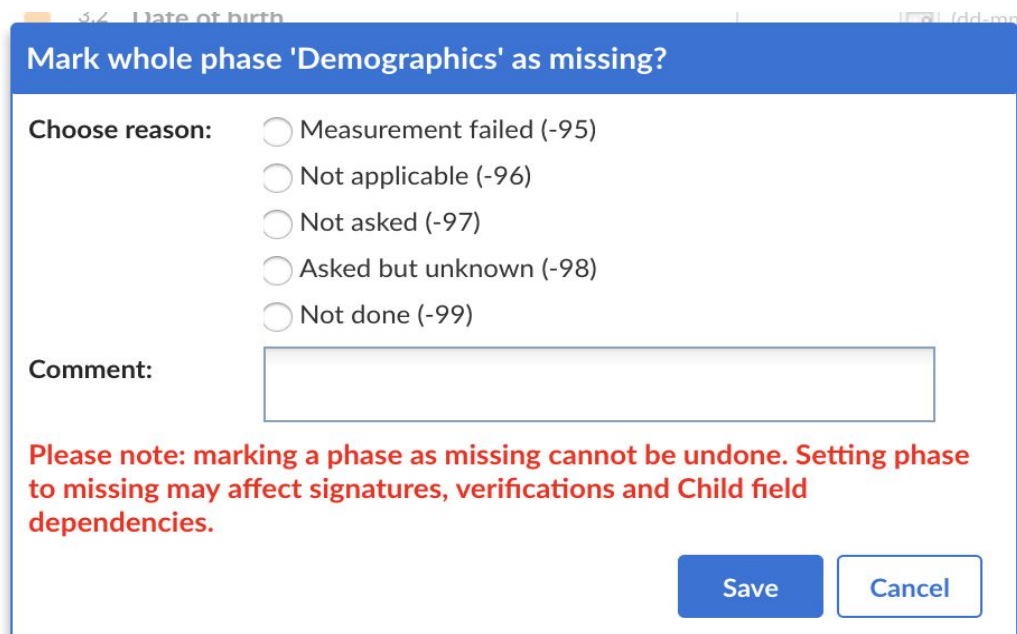
3.1 Gender ☐ Male ☐ Female

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:



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 (see below)
- Form verification dropped due to edit
- New query created
- New record created
- Query updated
- Record randomized
- 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

Add a new notification

Event type: New report added to record

Report:

Recipient: All

Filter on institute: Blood pressure

Notification template: Medication

Unscheduled visit

Available tags:

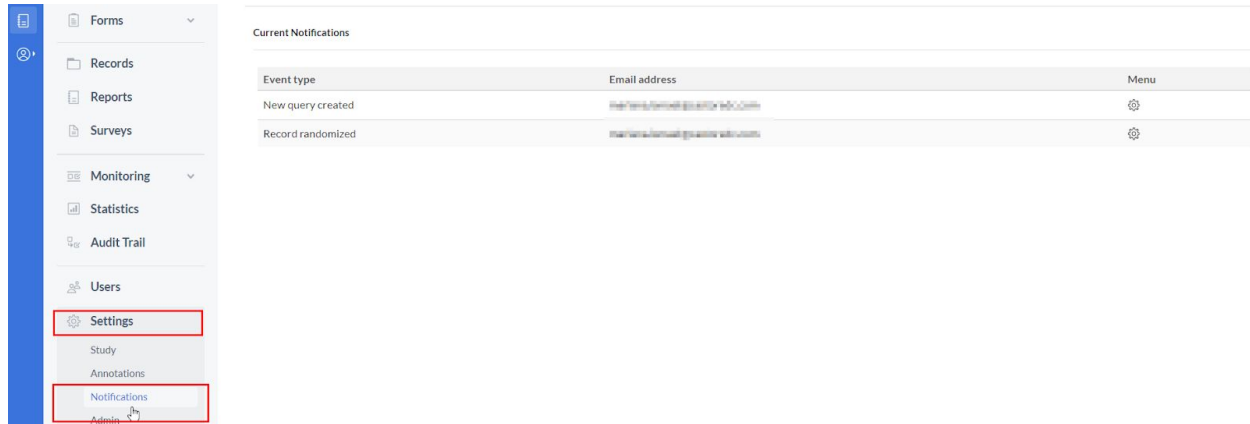
Tag	Description
{recordId}	the record id of the record for which the report was added.
{instituteName}	the institute name of the record for which the report was added.
{reportType}	the type of report that was added.
{reportCustomName}	the custom name given for the added report.
{studyName}	the name of the current study.
{userName}	the name of the user who added the report.
{userEmailAddress}	the email address of the user who added the report.
{eventDate}	the date that this event happened.
{eventTime}	the time of the day that this event happened.

Save

Cancel

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:



The screenshot shows the application's sidebar menu on the left and the 'Current Notifications' table on the right.

Sidebar Menu:

- Forms
- Records
- Reports
- Surveys
- Monitoring
- Statistics
- Audit Trail
- Users
- Settings** (highlighted with a red box)
- Study
- Annotations
- Notifications** (highlighted with a red box)
- Admin

Current Notifications Table:

Event type	Email address	Menu
New query created	maria.s.fernandez@uniovi.es	⚙️
Record randomized	maria.s.fernandez@uniovi.es	⚙️

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

In Progress
Inclusion_
Completed
Informed consent
Completed
Inclusion

Inclusion_

2. Inclusion

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

Completed
Patient characteristics
Completed
Informed consent
Completed
Inclusion

Patient characteristics

1. Demographics

This step was signed on 11/06/2020 at 12:17 by [Marlene Isenhardt](#) 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%

Completed
Baseline
Completed
Inclusion
Completed
Demographics
Completed
Measurement
Not Started

Baseline

2. Demog

This step is locked

2.1 Age
2.2 Gender

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:	Protocol Deviation
Custom name:	Protocol Deviation - 15-09-2020 14:53:51
Attach to:	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? ☒ yes ☐ no [Settings](#)

26.1.1 Was the subject discontinued from the study? ☒ yes ☐ no [Settings](#)

26.1.1.1 Date subject discontinued (dd-mm-yyyy) [Settings](#)

26.1.1.2 Reason for discontinuing [Settings](#)

26.1.1.3 Additional comments: [Settings](#)

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