

Castor

Castor EDC Study Administrator User Guide

Version 2021.6

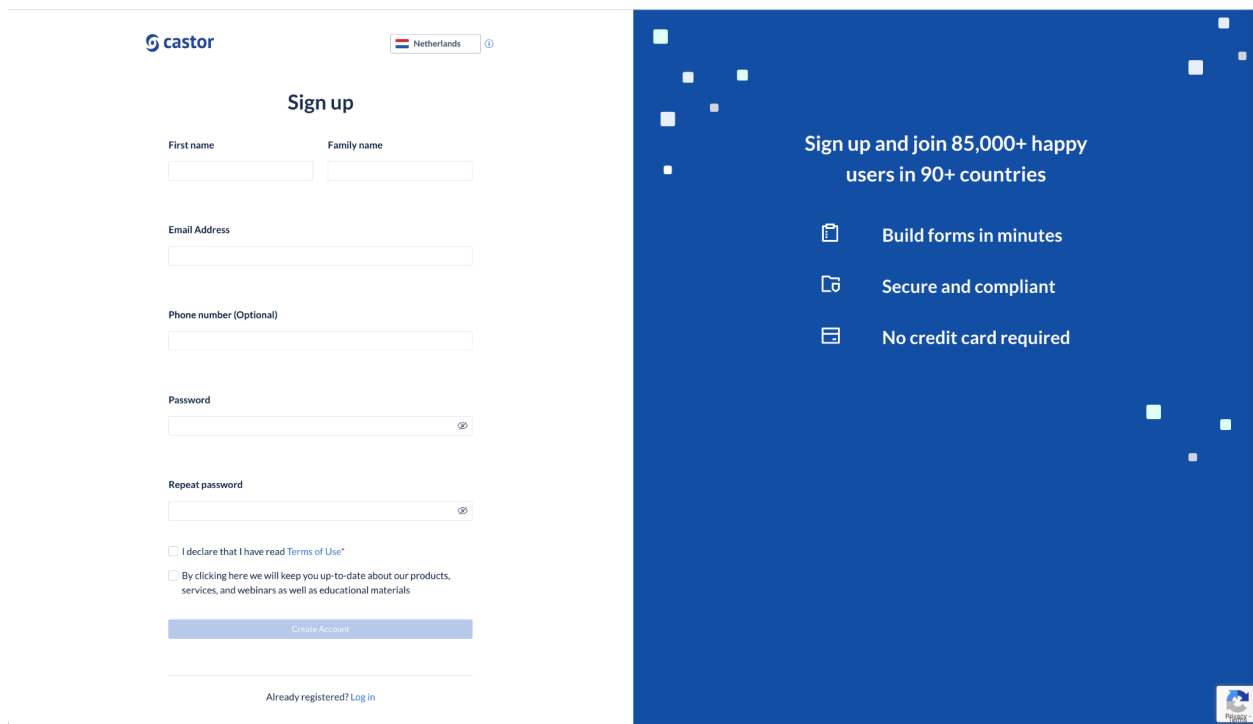
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1. Register an account

There are two ways to register an account: a) via the registration page b) by being added to a study by another study administrator.

1.1. Registration page

You can go directly to our website to create an account before being invited to a study. You will choose the site to create your account based on the location of your study data.



The screenshot shows the Castor registration page. On the left, there is a white registration form with the following fields and options:

- Sign up** header
- First name and Family name input fields
- Email Address input field
- Phone number (Optional) input field
- Password input field with an eye icon for toggling visibility
- Repeat password input field with an eye icon for toggling visibility
- Two checkboxes:
 - ☐ I declare that I have read [Terms of Use](#)*
 - ☐ By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials
- Create Account** button
- Link: [Already registered? Log in](#)

On the right, there is a blue banner with the following content:

- Text: **Sign up and join 85,000+ happy users in 90+ countries**
- Three benefits listed with icons:
 - Build forms in minutes**
 - Secure and compliant**
 - No credit card required**

Navigate to one of the URLs below to access the registration page:

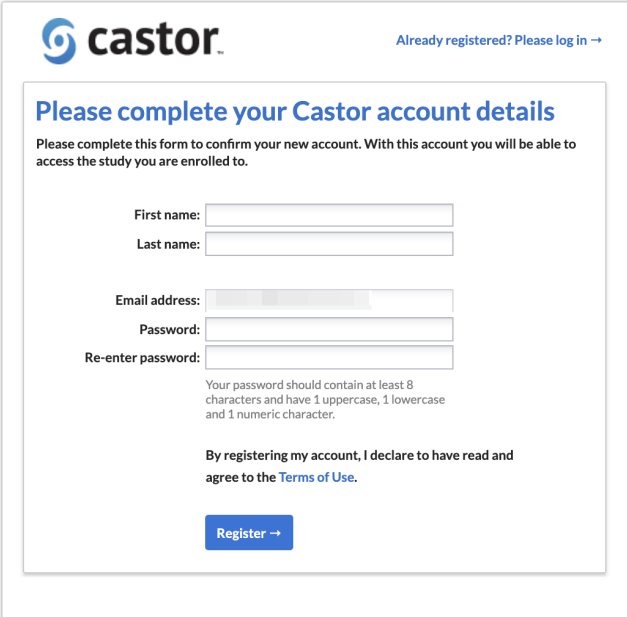
- EU Account: <https://data.castoredc.com/register>
- UK Account: <https://uk.castoredc.com/register>
- US Account: <https://us.castoredc.com/register>
- AU Account: <https://au.castoredc.com/register>

To register your Castor account:

1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number

1.2. User is added to a study

If another study administrator has added you to a study, you will receive an invitation by email. Click on the activation link in the email and it will redirect you to the registration page. To register Castor account:



The image shows a web registration form for a Castor account. At the top left is the Castor logo, and at the top right is a link: "Already registered? Please log in →". The main heading is "Please complete your Castor account details". Below this is a sub-heading: "Please complete this form to confirm your new account. With this account you will be able to access the study you are enrolled to." The form contains several input fields: "First name:", "Last name:", "Email address:", "Password:", and "Re-enter password:". Below the password fields is a note: "Your password should contain at least 8 characters and have 1 uppercase, 1 lowercase and 1 numeric character." At the bottom of the form is a checkbox area with the text "By registering my account, I declare to have read and agree to the [Terms of Use](#)." and a blue button labeled "Register →".

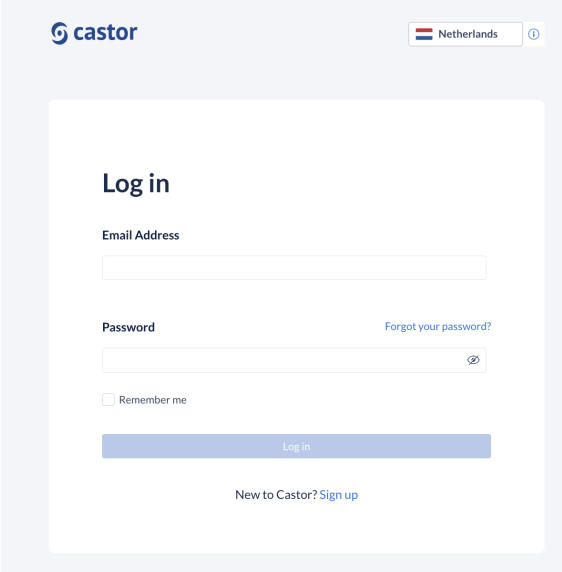
1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be sent to the email address a user has provided. Click on this

link to confirm that the supplied email address belongs to a user and verify a user account.

2. Log In

Log into Castor EDC via <https://data.castoredc.com>. If your study is on the US, AU or UK server, you can also directly go to <https://au.castoredc.com/register>, <http://us.castoredc.com> or <http://uk.castoredc.com>, respectively.

1. Choose the server that is used for your study in order to be able to access the study.
2. Enter your email address and password.
3. Click on 'Login'.



The screenshot shows the Castor EDC login interface. At the top left is the Castor logo. At the top right is a dropdown menu showing the flag for the Netherlands and a help icon. The main content area is titled 'Log in'. It contains an 'Email Address' input field, a 'Password' input field with a 'Forgot your password?' link to its right, and a 'Remember me' checkbox. Below these is a blue 'Log in' button. At the bottom, there is a link that says 'New to Castor? Sign up'.

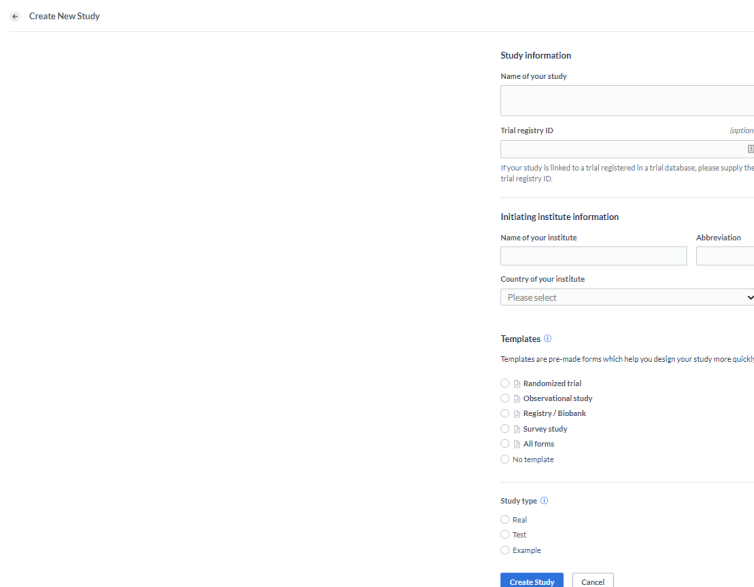
3. Start a study

After logging in, you will be redirected to the page 'My studies', which is an overview of all your studies (databases). If you have none, the list will be empty. You can start by creating a new study.

1. Click on 'New Study'.



2. Fill in the study details:



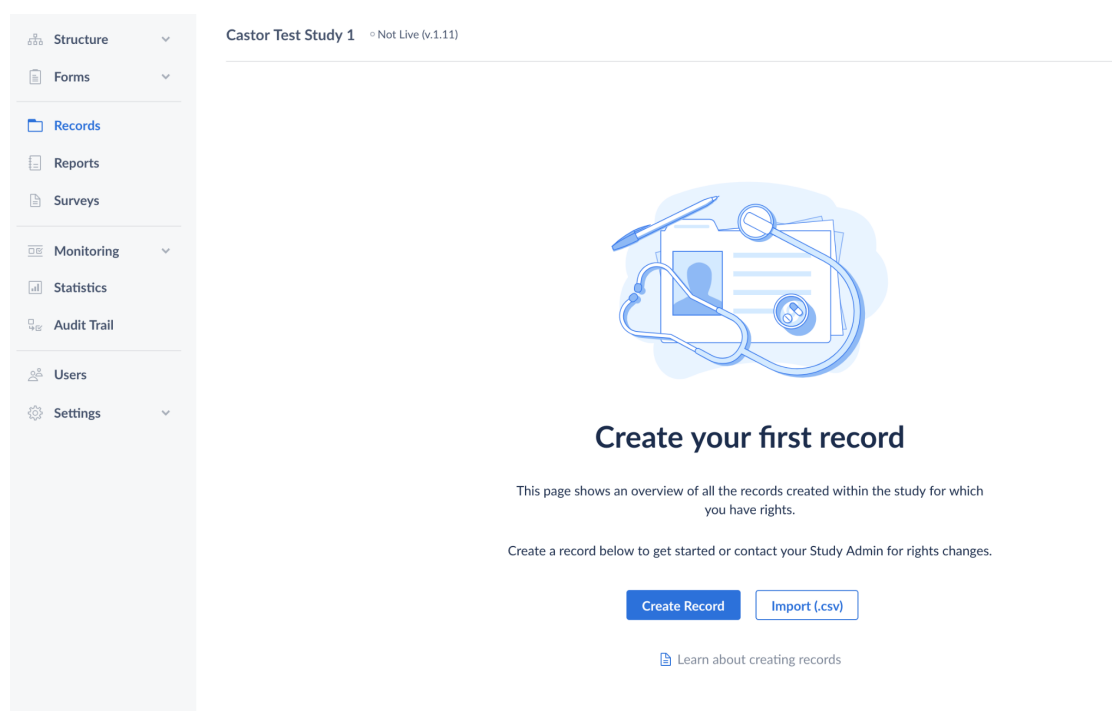
- **Name of your study:** Fill in a study name. The study name can be changed later.
- **Trial registry ID:** Fill in the ID of the trial registry your study is registered in (if applicable, e.g. clinicaltrials.gov)

- **Name of your Institute:** Complete the details of the institute that your study will be associated with.
- **Institute abbreviation:** Enter the institute abbreviation consisting of a minimum of three and maximum of six characters.
- **Institute country:** Choose a country where the institute is located.
- **Templates:** If you are new to Castor, we recommend using these pre-made forms. When you enable this setting, we create your study with some example phases, steps and fields to get you quickly started. Alternatively, you can select 'No template' to build your study from scratch.
- **Study type:** If you are using this study for testing purposes only, choose test study. If you are collecting data, please choose real study.
- When choosing the real study type, Confirm that you have followed the online workshop (<https://academy.castoredc.com>)
- Click on 'Create study'

4. Introduction to Castor EDC

4.1. Manage your study

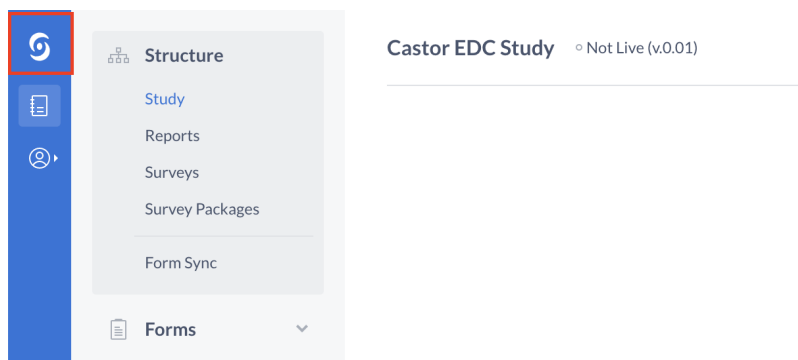
Once you have created your study, the study will open on the Records tab. There can be up to ten tabs visible in the management view, depending on the settings you define for the study:



- **Structure:** This is where you define the structure of your study. This is the first step you take when building your study. There are three types of forms you can use - Study, Reports, and Surveys.
- **Forms:** Here you can create your forms, i.e. your fields (questions).
- **Records:** Here you can create and access records for data entry.
- **Reports:** Here is an overview of all reports added to the study.

- **Surveys:** Here you can find an overview of all the survey invitations that have been created. This tab is only visible if Surveys is set to 'Yes' in Settings.
- **Monitoring:** Queries, validations, and verifications are shown in this tab. This tab is only visible if Monitoring is set to 'Yes' in Settings.
- **Statistics:** This tab shows the number of inclusions and the number of records randomized per institute per group.
- **Audit trail:** This is the complete audit trail for the study. This tab will only be visible for users that have all management rights enabled (i.e. Manage Records, Forms, Users, and Settings).
- **Users:** Here you can invite users to a study and manage their study rights.
- **Settings:** Here all the settings for the eCRF are managed.

If you want to go back to your 'My studies' overview, click on the Castor logo icon in the left upper corner.



4.2. Determine the study structure

Before you can create your questions in Castor, you need to determine what kind of forms you need to use for your study. In Castor we distinguish between 3 types of forms:

- **Study forms:** the actual 'Case Report Form' in which you collect patient data.

- **Reports:** the repeating forms can be used for repeating data such as Adverse Event Reports, medication, and repetitive measurements such as blood pressure. They have a 'one-to-many' (1:N) relation with the record. In your study form you can refer to a report.
- **Surveys:** questionnaires that you can send to participants using their email addresses.

The [Form Sync](#) feature allows for each production study to have a corresponding test environment.

5. Create study forms, reports, and surveys

If you know what kind of form you should use, you can start creating them. The three forms are made in a similar manner.

1. Navigate to the Structure tab.
2. Navigate to a sub-tab:
 - Click on the 'Study' sub-tab to create study forms
 - Click on the 'Reports' sub-tab to create reports
 - Click on the 'Surveys' sub-tab to create surveys

5.1. Create a phase, report, or survey

Phases are periods in a study, e.g. 'Baseline', 'Visit 1' etc. Only study forms have phases; reports and surveys don't.

1. Select 'Study' from the Structure tab.
2. Select 'Add' next to the Phase column.

Structure

Study **1**

Reports

Surveys

Survey Packages

Form Sync

Forms

Records

Reports

Surveys

Monitoring

Statistics

Audit Trail

Users

Settings

Castor EDC Study Not Live (v.0.01)

Phase **+ Add** **2**

Steps **+ Add**

Screening	
First Study Visit	
Follow-up	
Outcome	

- The 'Add a Phase' dialog window will open where you can select the positioning of the phase, name of the phase, and duration.
- Click 'Save' to create a new phase.

Add a phase

Position ⓘ

Place at the top

Phase name* ⓘ

First Visit

Duration (in months) ⓘ

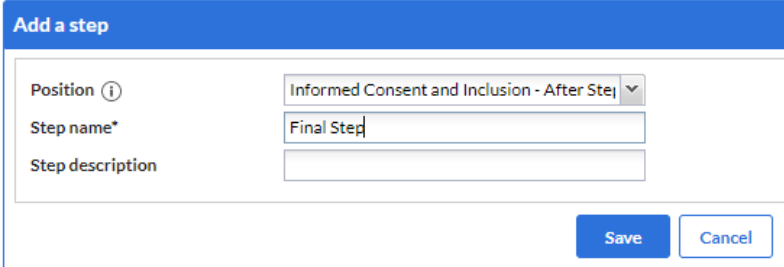
Save

Cancel

5.2. Create a step

Steps are sections inside a phase, report, or survey and contain the actual questions. Steps break up big forms in several 'pages', and make the form user friendly and less bulky. You can create one or several steps, e.g. 'Demographics' or 'Informed Consent at Screening'.

1. Click the 'Add' button in the right panel next to Steps of Screening to add a new step.
2. Define the step properties.
 - Choose the position for the step.
 - Choose the name for the step e.g. 'Informed Consent'.
 - Optional: Choose a description for this step, this text will be added to the top of the step in data entry.
3. Click 'Save'. The step will be shown in the right panel.

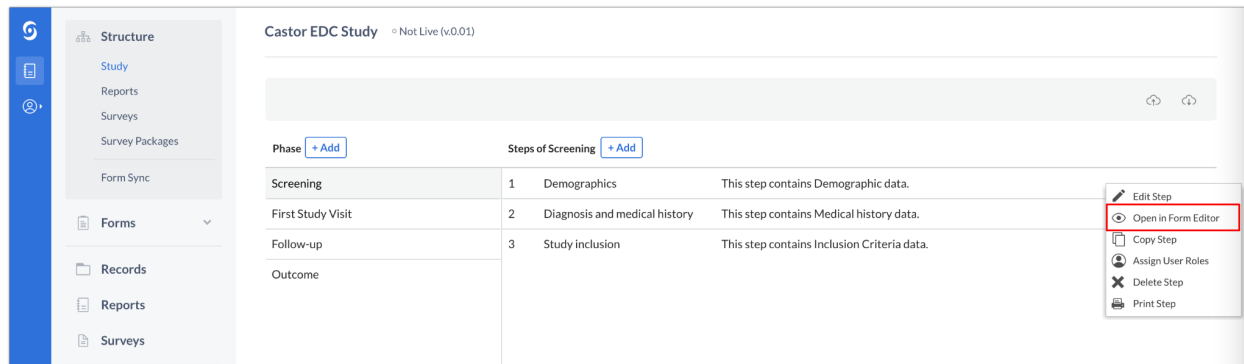


5.3. Create fields

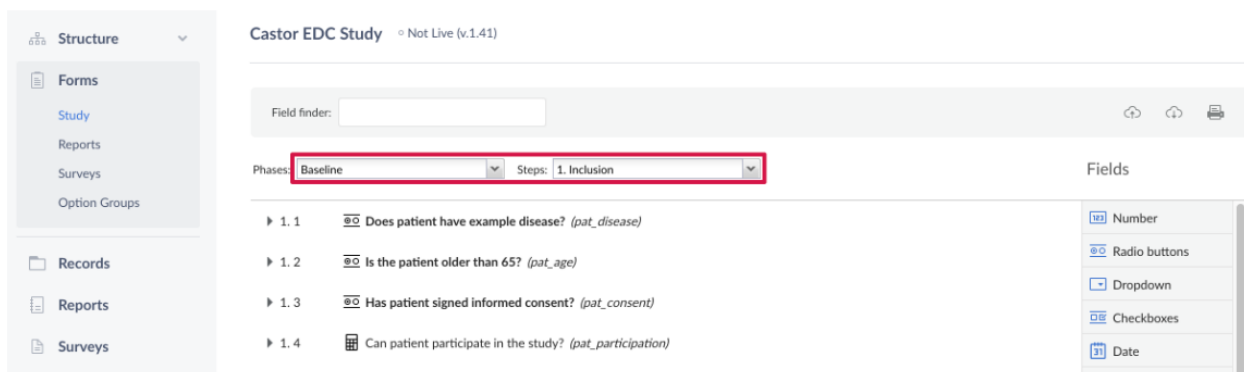
Fields are the actual questions in your form. Each step can have any number of fields, but we advise users to keep the number of fields per step low (below 50), to make sure the forms don't get too long.

1. Navigate to the Structure tab and select the form you would like to add or edit fields for e.g. Study, Reports, or Surveys.
2. Click on the phase, report, or survey you want to add or edit fields for.
3. Select the phase you want to add or edit fields for.

- Click on the cogwheel next to the step you want to add or edit fields for and select 'Open in form editor'.






















- You will be redirected to the 'Forms' tab. This is where you can add and edit fields. You can also select the phase and step from the dropdown menu:



Choose a field type in the right panel of the form builder.

- **Number:** this field can only contain numbers.
- **Radio buttons:** displays an option list from which the user can choose only one option. The buttons can be placed vertically or horizontally.
- **Dropdown:** displays an option list from which the user can choose only one option. If you have a large number of options, this is more convenient than a radio button field. Dropdown fields will turn into a search box which improves data entry performance for studies with large option groups.
- **Checkboxes:** displays an option list from which the user can choose multiple options.
- **Date:** field in which the user can select a date. The date format can be configured in the 'Settings' tab for each site.
- **Year:** displays a year value, the lower limit for the year field is 1891 and the maximum is 2099.
- **Time:** this field can be used to display a time value (hh:mm). By default, time values are listed based upon the 24 hour clock and are divided into 15 minute increments. To add exact time values, type the digits e.g 15:32 into the field manually.
- **Calculation:** used to access variables from your study to calculate values, e.g. a BMI from weight and length.
- **Slider:** useful for VAS-measurements and other numeric values with clear minimum and maximum values.
- **Remark:** this is not a real field, but rather a line of text you can add to your forms to provide the user with more information and structure the form.

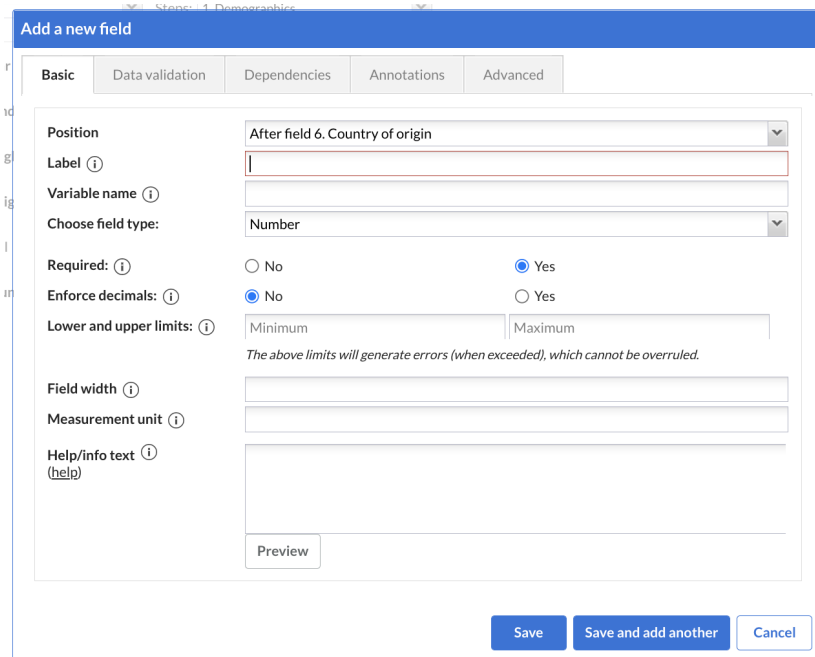
Fields

 Number
 Radio buttons
 Dropdown
 Checkboxes
 Date
 Year
 Time
 Calculation
 Slider
 Remark
 Summary
 QR Code
 Repeated Measure
 Text
 Text (multiline)
 Randomization
 Upload file
 Image
 Grid

- **Summary:** create summaries of collected data in your eCRF.
- **QR Code:** QR codes can contain information about the current logged in user, record institute, record id and record values for any variable in the study.
- **Repeated Measure:** with this field you can quickly add repeated measures in the data entry. When creating a repeated measure field, you can select to display measurements for all linked phases or reports for a specific repeated measure.
- **Text:** a text field that can contain any value (single line). The maximum length for this field is 4196 characters.
- **Text (multiline):** a text field that can contain multiple lines of text. The maximum length for this field is 4196 characters.
- **Randomization:** displays the assigned randomization group of a record in the form (for example, 'placebo' or 'treatment').
- **Upload File:** allows the user to upload a file that belongs to the record or a survey (i.e. an image, pdf, etc.). The maximum file size is 5MB.
- **Image:** The image field serves as a graphical alternative to the Remark field. You can upload an image here that will be displayed inline in the form. SVG image format is not supported.
- **Grid:** field type to group closely related data in a tight interface (table).
- **Date & time:** this field can hold a date and time. Displayed in format dd-mm-yyyy and hh:mm
- **Number & Date:** stores a number value alongside a date, can be used for laboratory results.
- **Add Report Button:** creates a button which allows you to quickly add a certain report in the data entry.
- **Add Survey Button:** creates a button which allows you to quickly add a certain survey in the data entry.
- **Link:** allows to create a link to an external webpage that is generated in the same way as calculation and summary fields are generated, using variables. With this

approach you can create deep-links to external resources like PACS, HIS or other systems.

When adding a new field, or editing an existing one, you will see the field properties screen. Different types of fields have different available basic properties.







Basic properties that need to be filled out are:

- **Position:** determines where the field appears on the form
- **Label:** defines the label that the field has. The label is the actual question (e.g. 'What is the patient's gender?' or 'Gender'). The label has a limit of 1024 characters.
- **Variable name:** a required field that is used when you export or import your data or in calculation fields. This name identifies your variables and must be unique (e.g. 'baseline_gender').
- **Choose field type:** Change the field type.

- **Required:** If you set it to 'Yes', this field will be taken into account when calculating the form completeness.
- **Measurement unit:** This is displayed after the field and shows the user which units are expected, e.g. 'cm' or 'mmol/L'.
- **Help/info text:** This text can be toggled by the user to display additional information about the field. Use this for lengthy explanations. You can add styling to the help text using Markdown tags.
- **Help/info text preview:** Render a preview of the styled text.

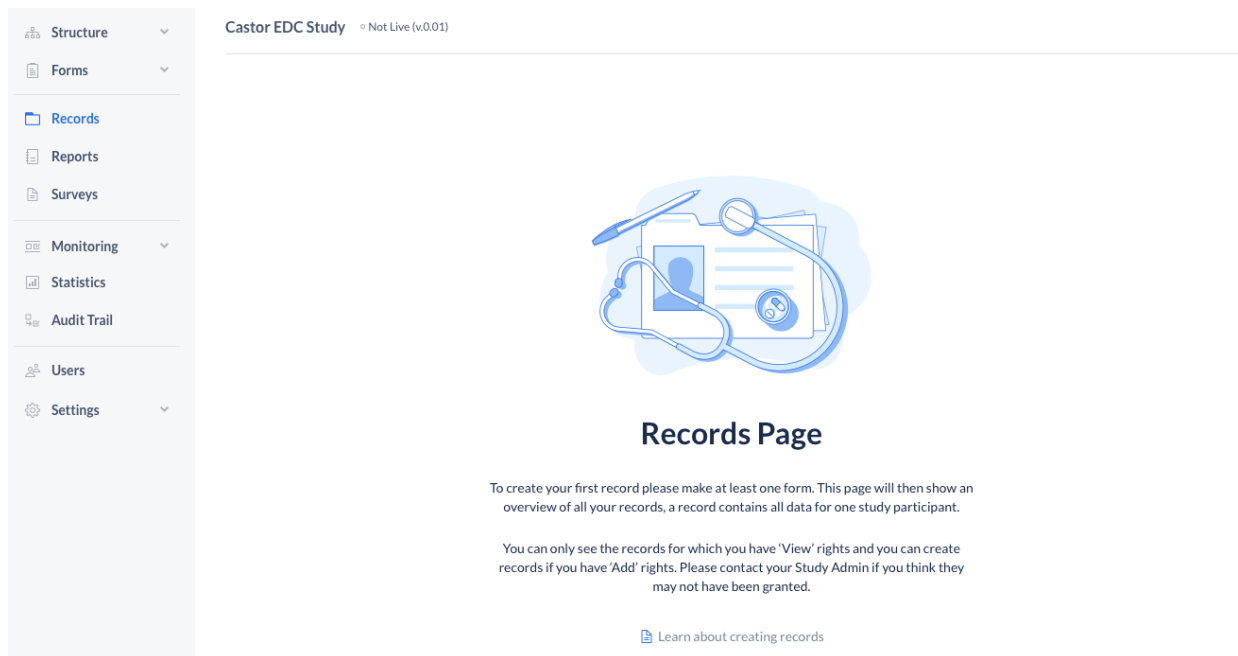
There are four icons on the right hand side of the field which you can use to:

-  Edit a field
-  Copy a field
-  Move a field
-  Delete a field

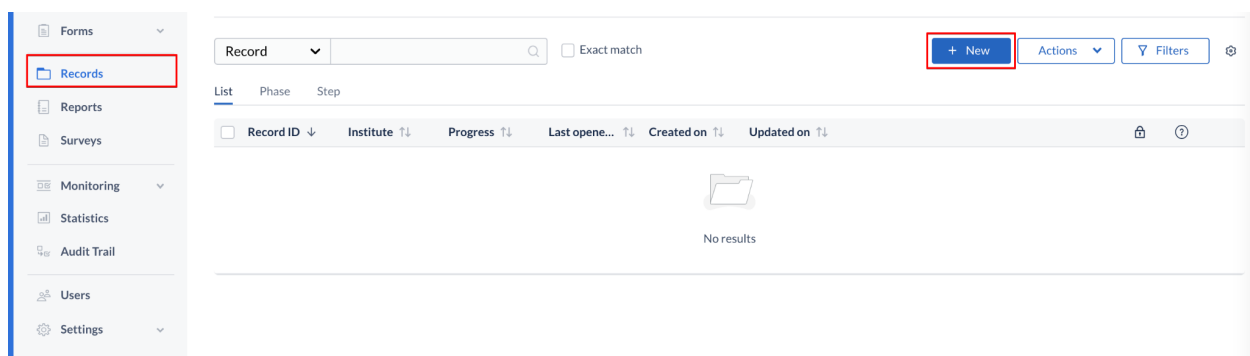
Changing the field type for fields in which data has been collected is limited to only allow compatible field type changes, in order to prevent data loss.

6. Test your forms

Now that you have created your forms, it's time to see how they are functioning. You first need to create a test record. For new studies where the records haven't been created yet, navigate to the Records tab and click on the 'Create Record' button.



If a study contained records previously (for example, a different study team member created and deleted test records), follow the steps below:



1. Click on the 'Records' tab.
2. Click on '+New'. You will be prompted to select an institute. By default, Castor will generate incremental IDs per institute. The 'Create New Record' dialogue box will open and you will select the Institute you wish to add the record to. The record ID will be auto generated. You can customize the record IDs in the Settings tab. Add record's email address in the 'Email address' field if applicable.

3. Click 'Create'. Your record will be created and will open and land on the first phase and step of the record for data entry.

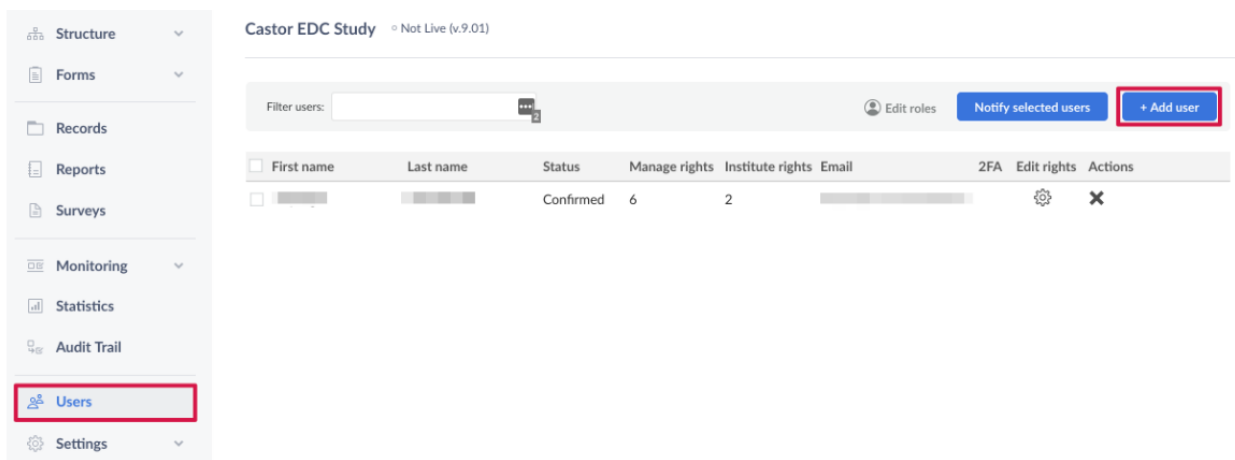
You can now test your form. Enter data to see whether your form is functioning well!

7. Manage Users in your study

The 'Users' tab allows you to create and edit roles, add users to your study, and manage permissions.

7.1. Add a User

1. Navigate to the 'Users' tab.
2. Click on 'Add user' to add someone to the study.



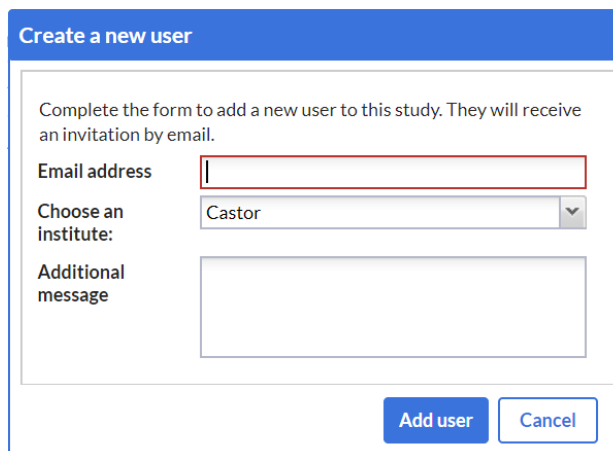
Castor EDC Study v Not Live (v.9.01)

Filter users:

Edit roles Notify selected users **+ Add user**

<input type="checkbox"/>	First name	Last name	Status	Manage rights	Institute rights	Email	2FA	Edit rights	Actions
<input type="checkbox"/>			Confirmed	6	2				

3. A pop-up will be shown. Fill in the user's email address and select an institute to which the user belongs.(If you need to add additional institutes, you may do so when you define the user's rights in the next step). You can also add an additional message to inform them about the invitation.



Create a new user

Complete the form to add a new user to this study. They will receive an invitation by email.

Email address

Choose an institute:

Additional message

Add user Cancel

4. Press 'Add user'.

The added users will be shown in the Users tab. If the user already has a Castor account, the study will be added to their list of studies and their status in the Users tab will be set to 'Confirmed'.

If the user does not have a Castor account, they will receive an email in which they are asked to register before being able to enter your study. They will be listed as 'Invited' if they have not yet signed up. If you want to remind them to join, or when they lose the email you can click the envelope button under 'Actions' to resend the invite.

<input type="checkbox"/>	First name	Last name	Status	Manage rights	Institute rights	Email	Edit rights	Actions
<input type="checkbox"/>	John	Fisher	Confirmed	4	4	john.fisher@castor.com		
<input type="checkbox"/>	John	Smith	Confirmed	6	4	john.smith@castor.com		
<input type="checkbox"/>	John	Smith	Confirmed	1	4	john.smith@castor.com		
<input type="checkbox"/>			Invited	0	0	john.smith@gmail.com		
<input type="checkbox"/>	John	Smith	Confirmed	4	4	john.smith@castor.com		

7.2 Define user rights and roles

After adding a user, you can assign user rights and roles to the new user. Rights are the individual rights that you can define for each user, whereas roles are a set (combination) of rights. By default newly created users do not have any rights within your study.

Click on the cogwheel next to a user (under the column name 'Edit rights') or double click on the user. A pop-up will be shown:

User rights for [redacted]

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	<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"/>
Test Institute	<u>Data-e...</u>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" 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"/>

Save

Close

7.2.1 Institute rights

Rights in Castor are assigned on the institute level. That means that a user can have different rights in one or multiple institutes.

Rights to access records are given per institute. They can be given in two ways:

- by assigning a User role to the user. You can choose one of the pre-defined roles or create your own roles.
- by clicking the checkboxes for each right manually

The record rights per institute are as follows:

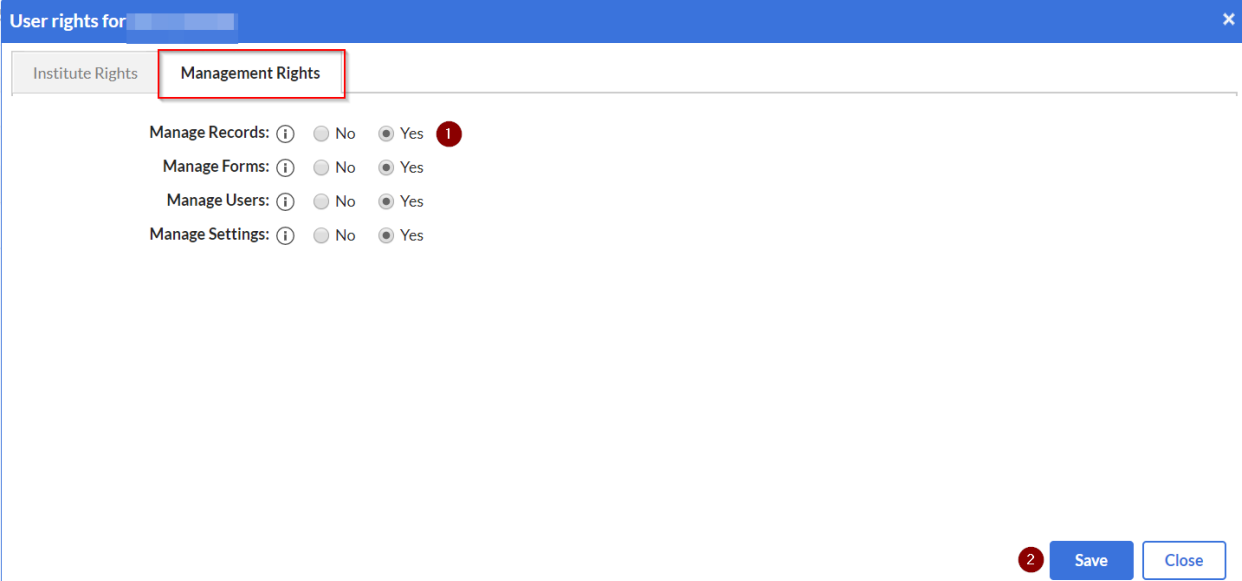
- Add:** Allows the user to create new records. To add a record, you also need a 'View' right.
- View:** Allows the user to view and print records, view queries and comments and print records.
- Edit:** Allows the user to enter and edit data in a record, import study and report data, view and respond to queries and comments. Adding a report also requires Edit rights (instead of Add rights).

- **Email:** Allows the user to view and/or edit the stored email address within a record or within a survey invitation. **Note:** To be able to edit a record email address it is also necessary to have 'Edit' rights.
- **Rand. (randomize):** Allows the user to randomize records.
- **View rand. (view randomization):** Allows the user to view the randomization allocation for a record.
- **Sign:** Allows the user to digitally sign study forms.
- **Lock:** Allows the user to lock records, preventing further data entry, as well as to unlock records.
- **Verify:** Allows the user to perform (source data) verification.
- **Query:** Allows the user to create and close queries (used for monitoring).
- **Archive:** Allows the user to archive and unarchive records.
- **Export:** Allows the user to export data. To be able to export records, you need both 'View' and 'Export' rights.
- **Send surveys:** Allows the user to create and send survey invitations as well as create and manage groups for bulk invites.
- **View surveys:** Allows the user to view and enter survey data
- **Encrypt:** Allows users to view and edit encrypted data.
- **Decrypt:** Allows users to edit encrypted data.

Click 'Save' to save changes. Click 'Close' to discard changes and close the pop-up.

7.2.2. Management rights

The management rights are advanced rights for users that are managing the study (in contrast to only doing data entry). Click on the 'Management rights' tab.



1. Select management rights for the user. The management rights are as follows:

- **Manage Records:** Allows access to the Records, Surveys, and Statistics tabs. The exact data the user will have access to depends on the institute rights. For example, a user who needs to view the records for institute X will need to have 'Manage records' rights, but also 'View' rights for institute X.
- **Manage Form:** Allows the user access to the Form tab.
- **Manage Users:** Allows the user access to the Users tab.
- **Manage Settings:** Allows the user access to the Settings tab.
- **Mange Encryption/Decryption:** Allows to assign Encrypt/Decrypt rights if the Encryption module is enabled in the Settings tab.
- **Note:** To be able to see the Audit trail, you need all management rights.

2. Click 'Save' to save changes. Click 'Close' to discard changes and close the pop-up.

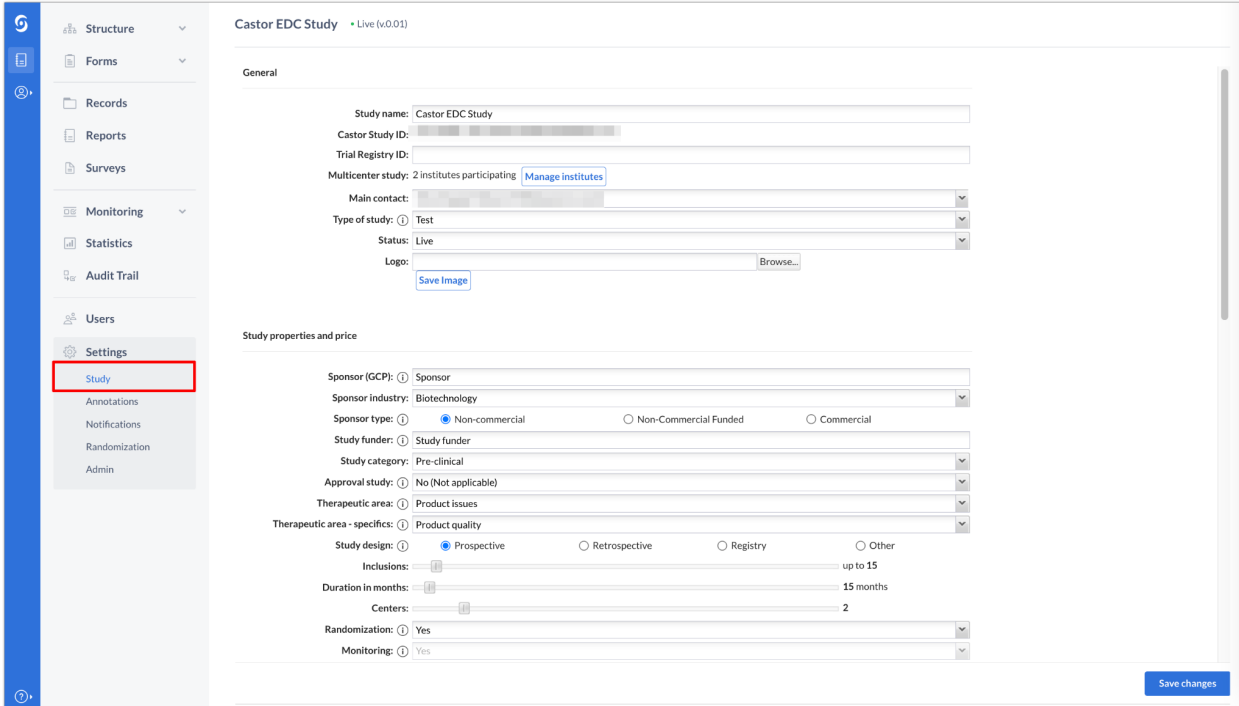
Keep in mind that only users with 'Management rights' will be able to access the study when it is not live.

8. Settings for your study and Going live

Navigate to the 'Settings' tab. In this tab, you can define the settings of your study. There are five categories in the tab: General, Study properties and price, Invoice details, GCP, and Other. When you go live (i.e., before you start collecting data), the sections General, Study properties and Billing details and the user's profile of the main contact (the person setting the study to live) need to be fully completed.

8.1 General Settings

The first section is 'General':



The screenshot displays the 'Castor EDC Study' settings page for a 'Live (v.0.01)' study. The left sidebar contains a 'Settings' menu with 'Study' highlighted. The main content area is divided into two sections: 'General' and 'Study properties and price'.

General Section:

- Study name: Castor EDC Study
- Castor Study ID: [Redacted]
- Trial Registry ID: [Redacted]
- Multicenter study: 2 institutes participating (with a 'Manage institutes' link)
- Main contact: [Redacted]
- Type of study: Test
- Status: Live
- Logo: [Redacted] (with 'Save Image' and 'Browse...' buttons)

Study properties and price Section:

- Sponsor (GCP): Sponsor
- Sponsor industry: Biotechnology
- Sponsor type: Non-commercial (selected), Non-Commercial Funded, Commercial
- Study funder: Study funder
- Study category: Pre-clinical
- Approval study: No (Not applicable)
- Therapeutic area: Product issues
- Therapeutic area - specifics: Product quality
- Study design: Prospective (selected), Retrospective, Registry, Other
- Inclusions: [Slider] up to 15
- Duration in months: [Slider] 15 months
- Centers: [Slider] 2
- Randomization: Yes
- Monitoring: Yes

A 'Save changes' button is located at the bottom right of the form.

- **Study name:** the study name which is displayed on the homepage and above your forms during data entry.

- **Study ID:** unique study identifier, which can only contain alphanumeric characters and dashes and is limited to 250 characters.
- **Trial registry ID:** ID of the trial registry your study is registered in (if applicable, e.g. clinicaltrials.gov).
- **Multicenter study:** manage participating institutes and define custom date formats for each institute. Institute rights are defined in the 'Users' tab.
- **Main contact:** the email address of the contact person who is responsible for the study (usually the study admin). The e-mail address will be listed below the data entry screen, so that other users can contact the study admin.
- **Type of study:** change the study type, as displayed in the My Studies overview. Can be set to Real, Test or Example study. Use 'Real' if you will collect real patient/subject data in the study
- **Status:** determines if the study is accessible for data entry. If the study is not live, data can only be entered for testing purposes via 'Manage records'. Users without management rights cannot enter data if the study is not live.
- **Logo:** Upload a logo for your study. Upload your image by clicking 'Browse...', then click 'Save Image'. The logo will appear in the data entry. You can also include this logo in survey invitations by using the {logo} syntax. We recommend a logo size of 193 x 75 pixels.

8.2 Study properties and price

The next part contains all study details to determine the cost of the study:

Study properties and price

Sponsor (GCP): ① Sponsor

Sponsor industry: Biotechnology

Sponsor type: ① ☒ Non-commercial ☐ Non-Commercial Funded ☐ Commercial

Study funder: ① Study funder

Study category: Pre-clinical

Approval study: ① No (Not applicable)

Therapeutic area: ① Product issues

Therapeutic area - specifics: ① Product quality

Study design: ① ☒ Prospective ☐ Retrospective ☐ Registry ☐ Other

Inclusions: ① up to 15

Duration in months: ① 15 months

Centers: ① 2

Randomization: ① Yes

Monitoring: ① Yes

Surveys: ① Yes

Field encryption: ① No

Premium support: ① No

Per year €362

Total € 453

- **Sponsor (GCP)** : The sponsor of the study is responsible for the initiation, management, and/or financing the study. See **ICH-GCP guidelines**.
- **Sponsor industry**: Specify the sponsor industry of your study.
- **Study type**: Specify if your study is a non-commercial or commercial study.
- **Study funder**: The organization providing the financing for the study.
- **Study category**: Specify the category of your study.
- **Approval study**: Will data from this study be submitted for regulatory approval?
- **Therapeutic area**: The main medical domain that applies to the study.
- **Study design**: Specify the design type of your study.

- **Inclusions:** Specify the number of inclusions in your study (i.e., how many records do you expect in the database?).
- **Duration in months:** the duration of data collection (i.e., how long will your study be active/live?)
- **Centers:** How many centers will be participating/included in your study?
- **Randomization:** Choose if you want to use randomization for your study. Learn more about randomization in your study [here](#) and [here](#).
- **Monitoring:** Choose if you want to use monitoring for your study. Learn more about monitoring in your study in the manual for monitors.
- **Surveys:** Choose if you want to use surveys for your study. Learn more about surveys in
- **Field Encryption:** Select if you will use encryption for your study. If selected, you will be able to encrypt select fields.
- **Payment period:** Specify if you want to pay upfront (with a 10% discount!) or yearly.

For more information on pricing, visit <https://www.castoredc.com/pricing>

8.3 Invoice details

Enter all the billing details for this study, including the address that the invoice for the study will be sent to. Please specify the 'Project number' to ensure the invoice gets declared for the right project:

Invoice details

Billing code ⓘ

No

Billing contact: ⓘ

Organisation: ⓘ

(Billing) department: ⓘ

Street and number:

Postal code:

City:

Country:

Billing contact email: ⓘ

Cost center: ⓘ

Project number: ⓘ

Other payment reference:

International VAT Nr: ⓘ

Billing Code: Navigate to Invoice details under settings. Here you insert your billing code. If your organization has an institute contract, you may contact your local Clinical Trial Unit (institute/organization Research Department) to request the billing code. The Billing Code may also be found on the intranet page of the institute, where applicable.

Invoice details

Billing code ⓘ

Yes

Enter your billing code:

? Don't have a billing code yet? Please contact sales at sales@castoredc.com or +31 20-2440003 and we'll get you up and running in no time!

Cost center (department) no.:

8.4 Good Clinical Practice

You can choose whether to enable GCP for your study:

GCP

Confirm Changes: Yes

Setting a signature statement (below) is recommended when enabling GCP.


Verification types: [Manage Verification Types](#)

- Confirm changes:** If you are using the extra GCP features, you can choose to enable the ‘Confirm changes’ functionality. This will require the user to enter reasons for changes that are made to the data according to GCP requirements.
- Verification types:** manage verification types including adding and deleting source data verification and other verification types. Learn how to set up (Source) Data Verification in the manual for monitors.

8.5 Other

Other


Record IDs: Incremental

Email capture on enrollment:  Email capture optional

Clear inapplicable child fields: Yes

Enable beta features: No

Enforce 2FA: No

Enable signing of locked forms:  Yes

Only show records with exact match when searching: No

Signature statement: [Change signature statement](#)

Manage record status: [Manage record statuses](#)

Records overview custom columns: [Manage custom columns](#)

Study access IP allow list: [Manage list](#)

- Record IDs:** Choose how you want IDs for new records to be generated. You can customize the IDs by selecting 'Custom definition'.
- Email capture on enrollment:** Choose if and how would an email be required for newly created records. Please note that visibility for this option is subject to user rights.
- Clear inapplicable child fields:** When set to 'Yes', this setting clears the inapplicable child fields at change of a field. For example: when changing the gender from female to male, all pregnancy fields are cleared. The system will always ask for confirmation before existing data is being cleared.

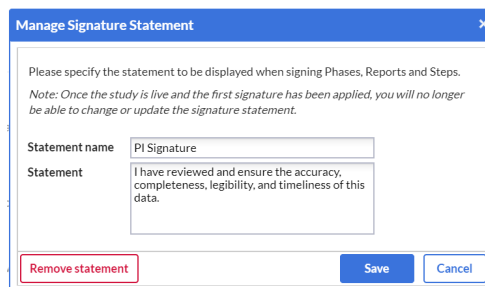
Changing this field will have a consequence

You are changing the value for a field with dependent fields
Are you sure you want to clear the stored value for:
Is patient pregnant?
Months pregnant

Continue
Cancel change

This setting is only for study forms and reports. In surveys, inapplicable child fields are always cleared, regardless of this setting. Changing this setting after you have started the collection of data will not clear inapplicable fields retroactively.

- **Enable beta features:** When set to 'Yes' this setting enables the automation engine functionality.
- **Enforce 2FA:** two factor authentication can be enforced on the study level - when set to 'Yes', users in this study must use two factor authentication for their Castor account to be able to access the study.
- **Enable signing of locked forms:** If enabled, signing of locked forms becomes possible.
- **Only show records with exact match when searching:** Choose whether you want your search for records to match the exact strings you input into the search field in the Records tab.
- **Signature Statement:** This statement will be presented when applying a signature. So, by signing the phase or step, you declare what is written in the signature. Note: after the study has gone live, it is no longer possible to edit the signature.



The dialog box is titled "Manage Signature Statement" and contains the following text and fields:

Please specify the statement to be displayed when signing Phases, Reports and Steps.
Note: Once the study is live and the first signature has been applied, you will no longer be able to change or update the signature statement.

Statement name:

Statement:

Buttons: Remove statement Save Cancel

- **Manage Record status:** This option allows you to create, edit, and delete record statuses.

- **Record overview custom columns:** Add and delete custom columns to the Records tab.
- **Study access IP list:** Whitelist a range of IP addresses in CIDR format. The study will then be accessible from the IP addresses on the list only.

8.6 Setting study to 'Live'

"Going live" in essence means that your study will be running and you can start collecting data. To set your study to live, go to the Settings page of your study and in the top section find the field 'Status' and select 'Live'. Before going live, you need to fill in the fields for 'Study properties and price' and 'Billing'. Please consider the following consequences:

1. The price of the study will be shown and is based on the information you enter in the 'Study properties and price' form. It is important to fill out this form truthfully and as completely as possible. You will receive the full pricing overview by email after you set your study to live. In case you have received a billing code (e.g. if you are from an institute that has a Castor institute license), you will need to enter this in the billing code details section.
2. When you set your study to live, you will no longer have access to your form builder. If you need to make further changes to your CRF, you will have to turn it back 'offline'. Be careful when you do this, as changes will be reflected in already existing records and might affect collected data. Therefore, we recommend that you and your team thoroughly test your eCRF thoroughly before going live.
3. Be aware that after going live you will not be able to delete anything. This is in accordance with Good Clinical Practice (GCP) data. For example, records will need to be archived instead of being deleted. Archived records will not get exported nor influence your study in any way, but will still be traceable/recoverable in case of an

audit. If you would like to archive records and might need to use the data from the archived records in the future, we recommend exporting the data first.

9. Further Information

If you would like to view our Castor EDC video tutorials, you can do so [here](#).

For more information regarding creating and managing study as a study admin, please check Castor EDC's knowledge base: <https://helpdesk.castoredc.com>. If you have any questions or concerns, please contact us at support@castoredc.com