Castor

Castor CDMS Study Administrator User Guide

Version 2022.3

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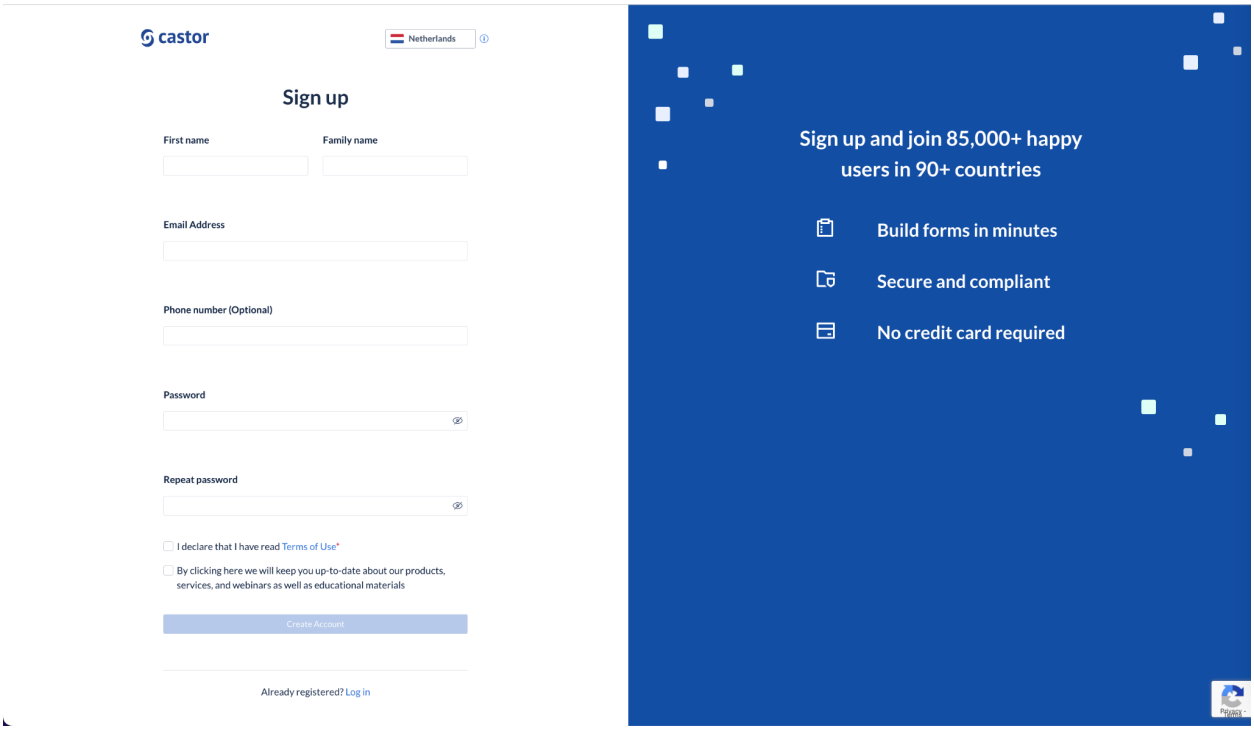
1. Register an account

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.



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

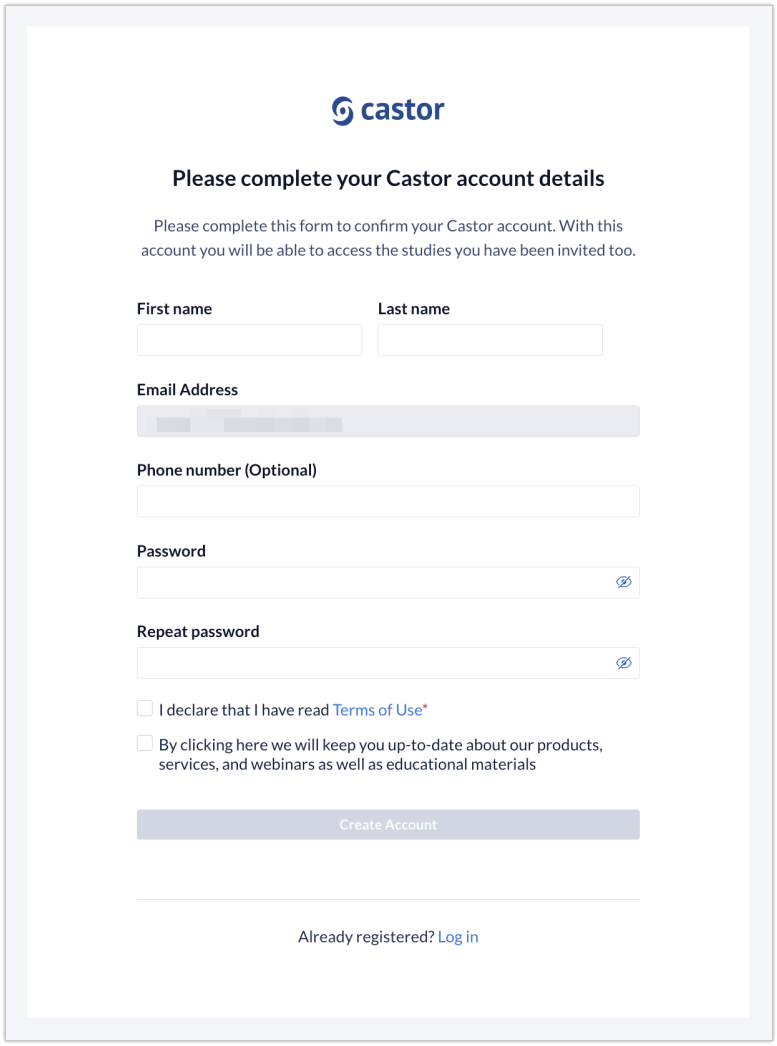
- EU Account: https://data.castoredc.com/register
- UK Account: https://uk.castoredc.com/register
- US Account: https://us.castoredc.com/register
- AU Account: https://au.castoredc.com/register

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 adder to a study

If you have been added 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:

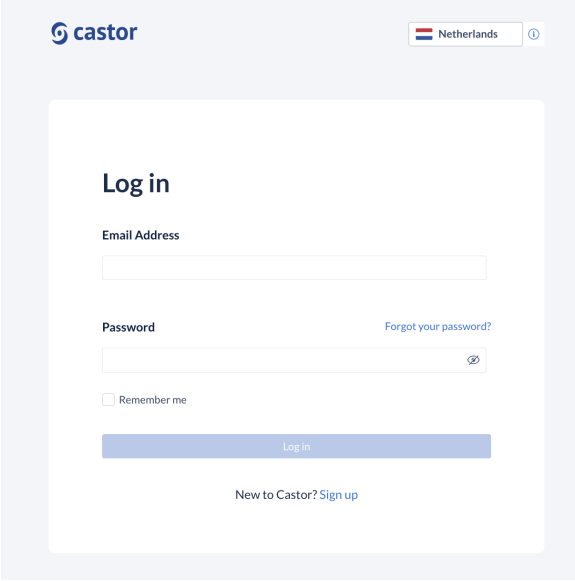


1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Create Account'. Shortly after registering a user details, an email with an activation link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

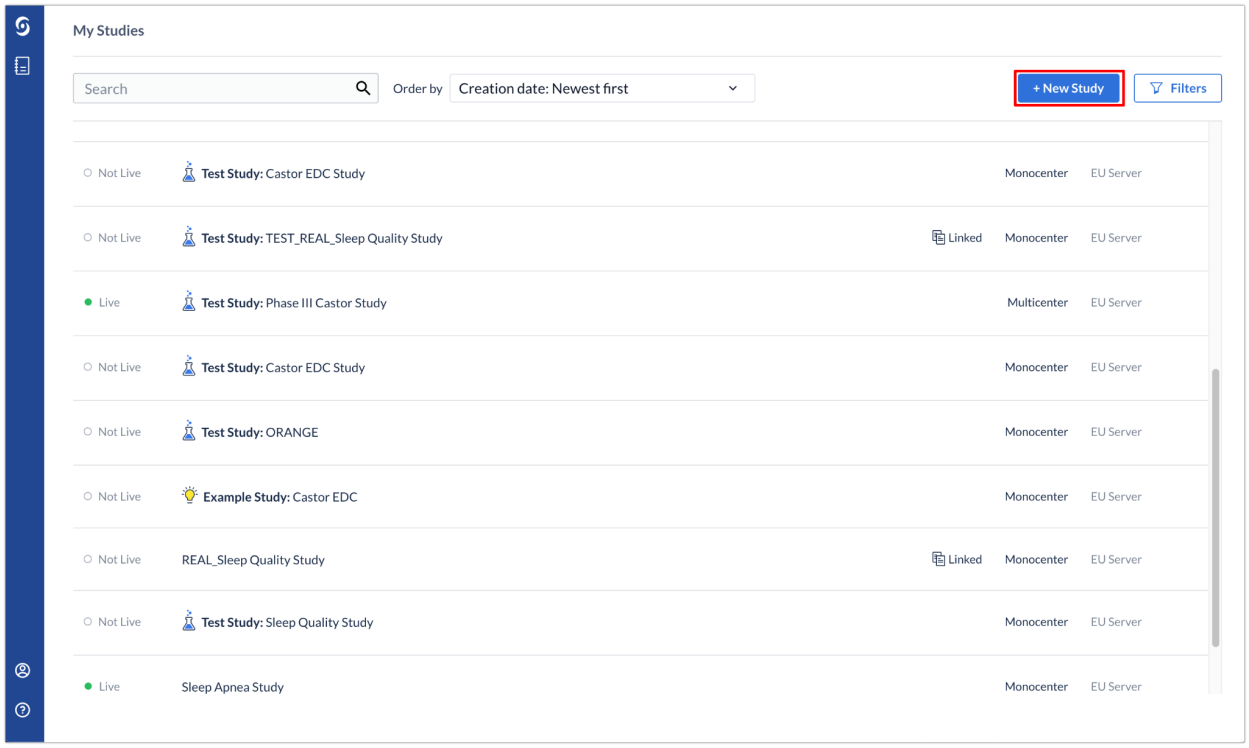
1. Choose the server that is used for your study in order to be able to access the study.
2. Enter your email address and password.
3. Click on 'Login'.



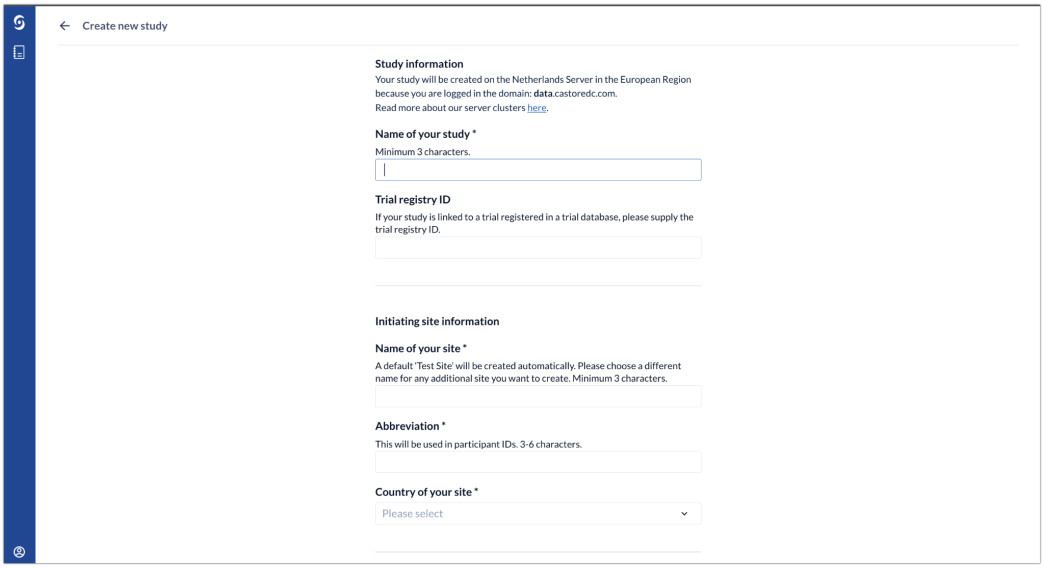
3. Start a study

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:



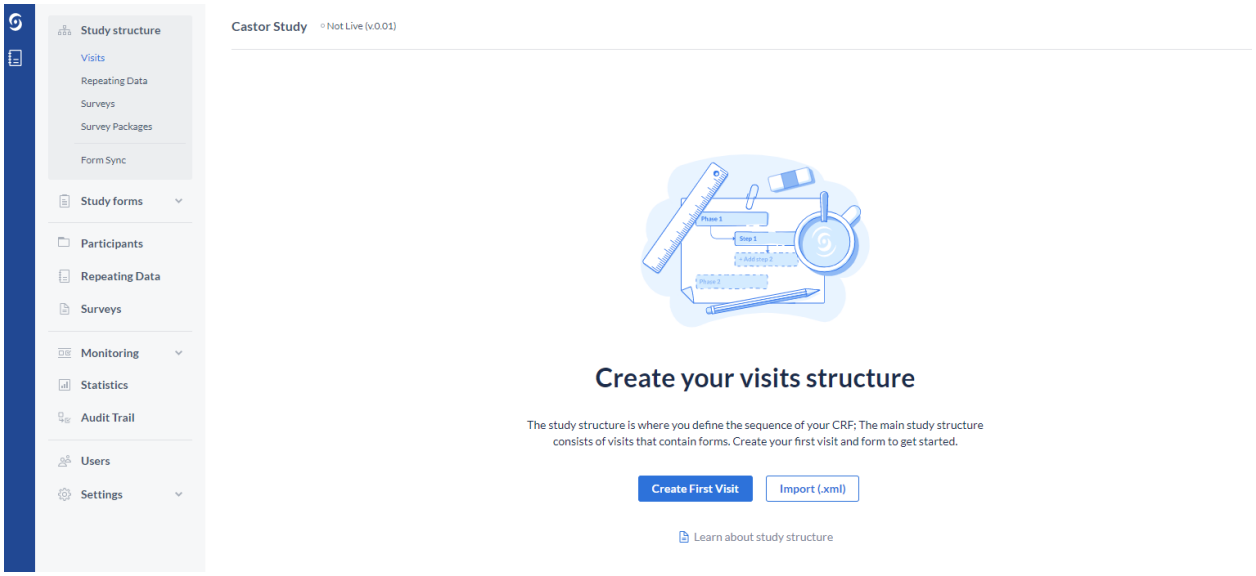
- **Name of your study**: Fill in a study name. The study name can be changed later.
- **Trial registry ID**: Fill in the ID of the trial registry your study is registered in (if applicable, e.g. clinicaltrials.gov)
- **Name of your site**: Complete the details of the site that your study will be associated with.
- **Abbreviation**: Enter the site abbreviation consisting of a minimum of three and maximum of six characters.
- **Country of your site**: Choose a country where the site 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 visits, forms 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

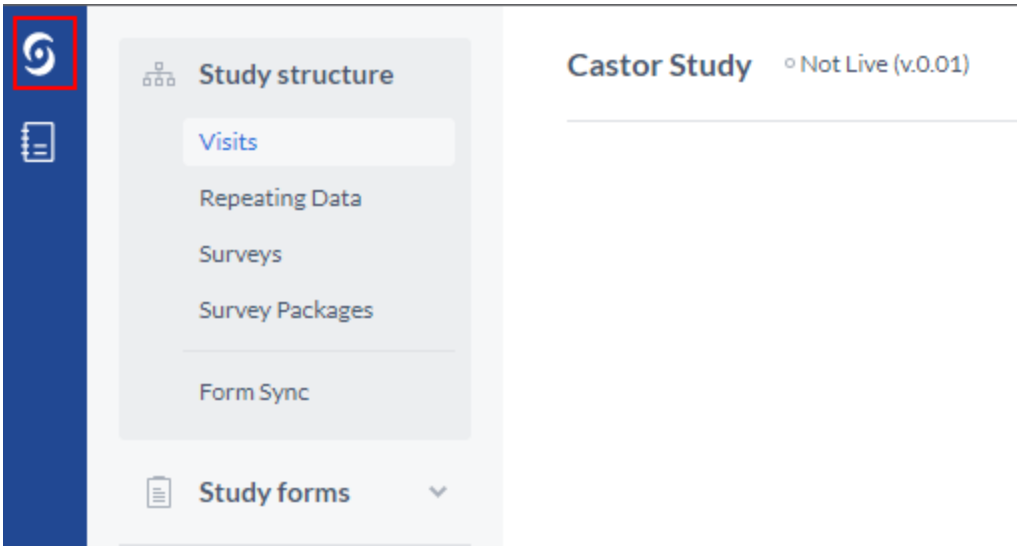
Once you have created your study, the study will open on the Structure tab. There can be up to ten tabs visible in the management view, depending on the settings you define for the study:



- **Study Structure**: This is where you define the structure of your study. This is the first form you take when building your study. There are three types of forms you can use - Study, Reports, and Surveys.
- **Study Forms**: Here you can create your forms, i.e. your fields (questions).
- **Participants**: Here you can create and access participants for data entry.
- **Repeating Data**: Here is an overview of all repeating data 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 participants randomized per site 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 Participants, 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.
- **Repeating Data**: The repeating forms can be used for repeating data such as Adverse Events, medication, and repetitive measurements such as blood pressure.

They have a 'one-to-many' (1:N) relation with the participant. In your study form you can refer to a repeating data instance.

- **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, repeating data, and surveys

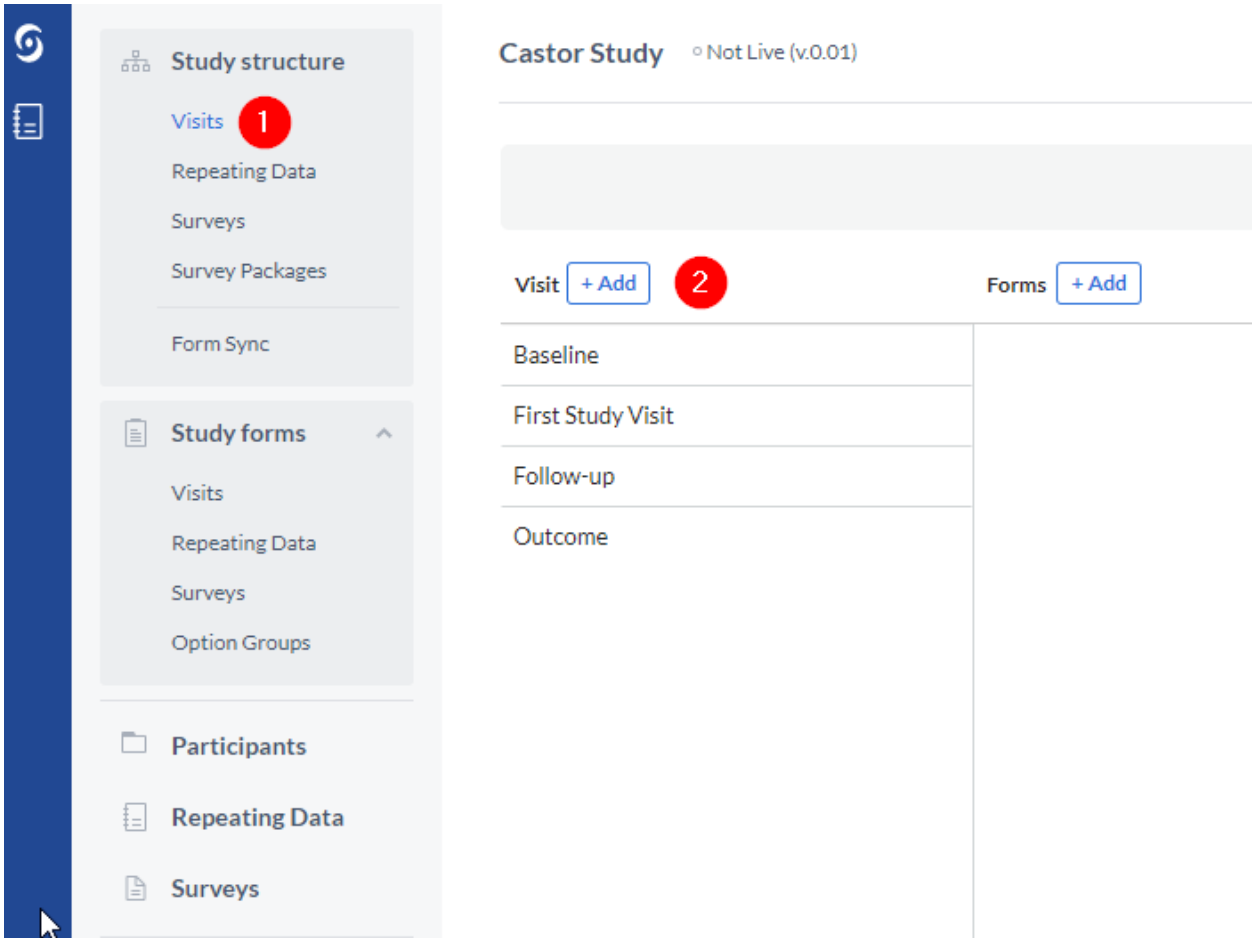
If you know what kind of form you should use, you can start creating them. The three forms are made in a similar manner.

1. Navigate to the Study structure tab.
2. Navigate to a sub-tab:
    - Click on the 'Study Forms' sub-tab to create study forms
    - Click on the 'Repeating Data' sub-tab to create repeating data instances.
    - Click on the 'Surveys' sub-tab to create surveys

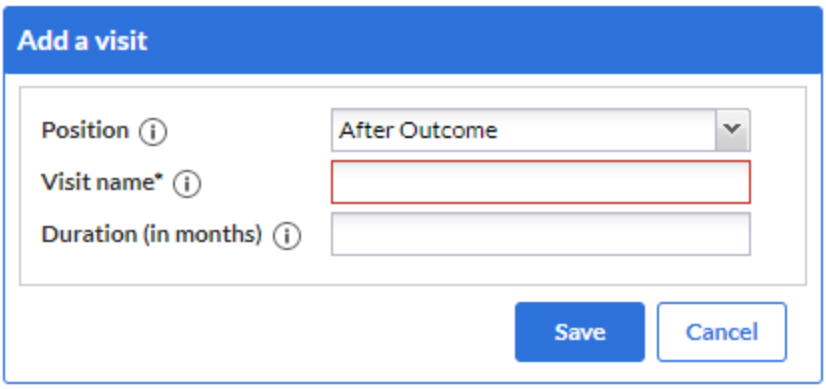
5.1. Create a visit, repeating data, or survey

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

1. Select 'Visit' from the Study structure tab.
2. Select 'Add' next to the Visit column.



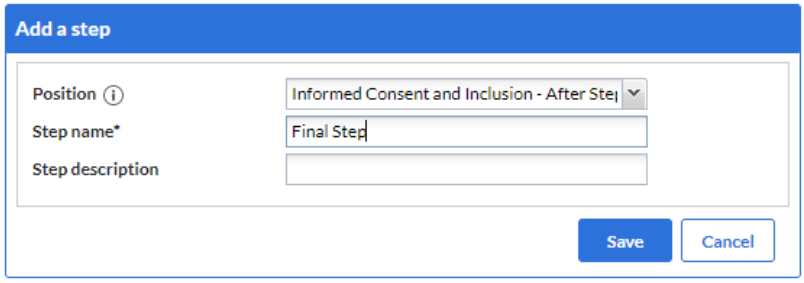
3. The 'Add a visit' dialog window will open where you can select the positioning of the visit, name of the visit, and duration.
4. Click 'Save' to create a new visit.



5.2. Create a form

Forms are sections inside a visit, repeating data, or survey and contain the actual questions. Forms break up big forms in several 'pages', and make the form user friendly and less bulky. You can create one or several forms, e.g. ‘Demographics’ or ‘Informed Consen’t at Screening.

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

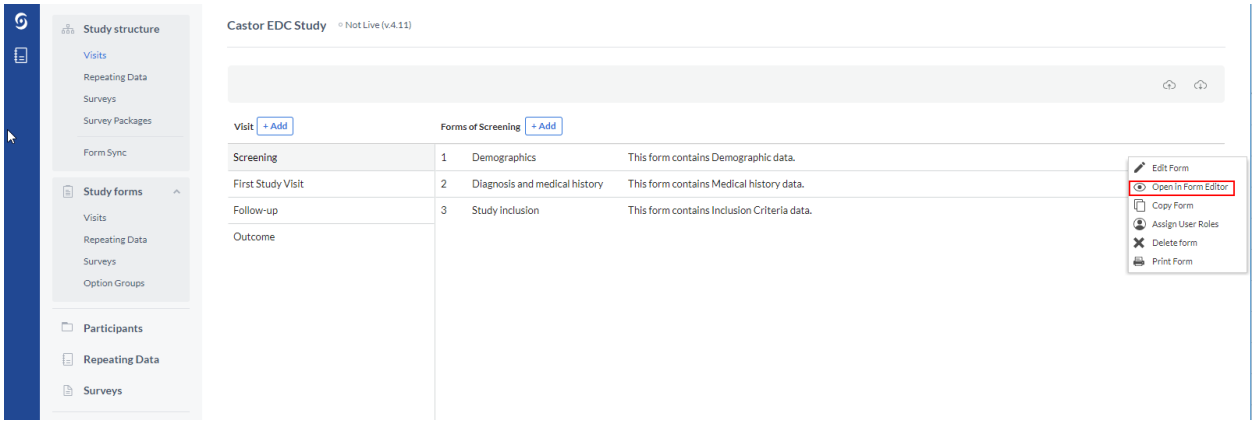


5.3. Create fields

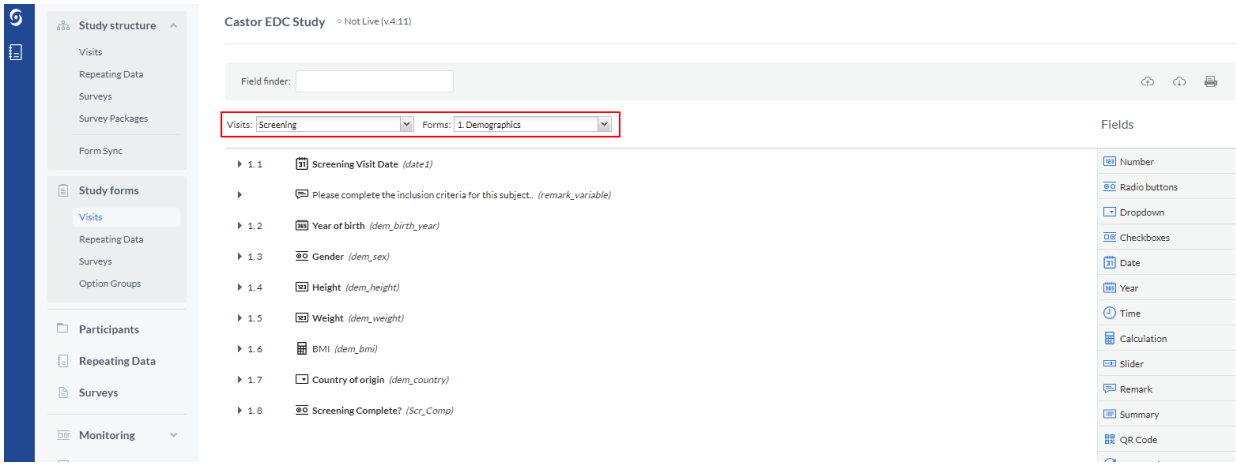
Fields are the actual questions in your form. Each form can have any number of fields, but we advise users to keep the number of fields per form low (below 50), to make sure the forms don't get too long.

1. Navigate to the Study Structure tab and select the form you would like to add or edit fields for e.g. Study, Repeating Data, or Surveys.
2. Click on the visit, repeating data, or survey you want to add or edit fields for.
3. Select the visit you want to add or edit fields for.

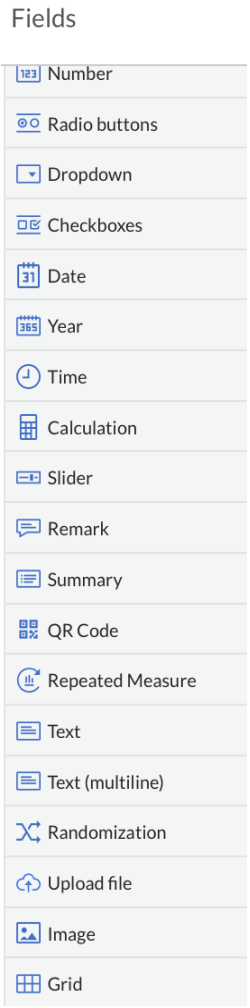
4. Click on the cogwheel next to the form you want to add or edit fields for and select ‘Open in form editor’.



5. You will be redirected to the ‘Study forms’ tab. This is where you can add and edit fields. You can also select the visit and form from the dropdown menu:



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

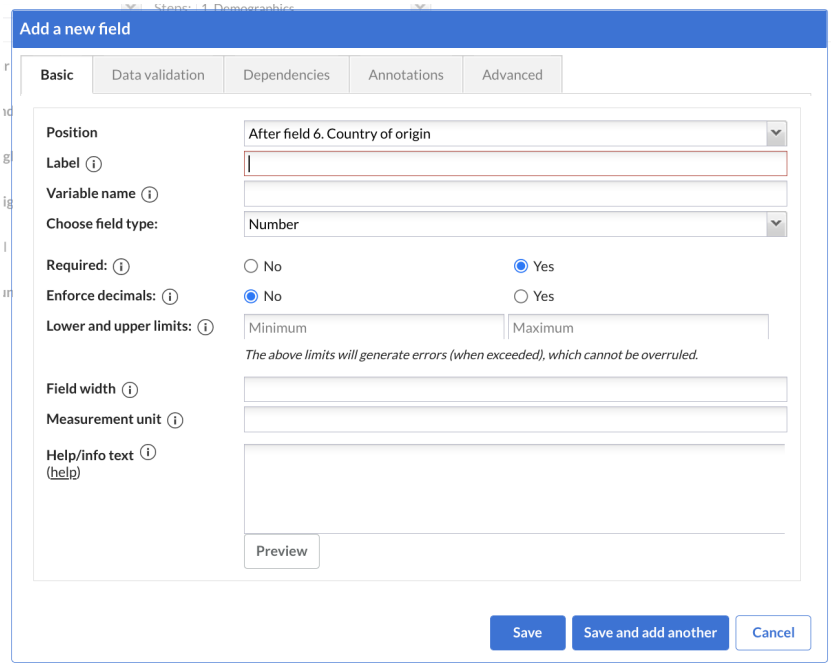


- **Number**: this field can only contain numbers.
- **Radio buttons**: displays an option list from which the user can choose only one option. The buttons can be placed vertically or horizontally.
- **Dropdown**: displays an option list from which the user can choose only one option. If you have a large 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.

- **Summary**: create summaries of collected data in your eCRF.
- **QR Code**: QR codes can contain information about the current logged in user, participant site, participant id and participant 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 visits or repeating data 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 participant in the form (for example, 'placebo' or 'treatment').
- **Upload File**: allows the user to upload a file that belongs to the participant 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.
- **Repeating Data Button**: creates a button which allows you to quickly add a certain repeating data 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'). The variable name has a lime of 64 characters.

- **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

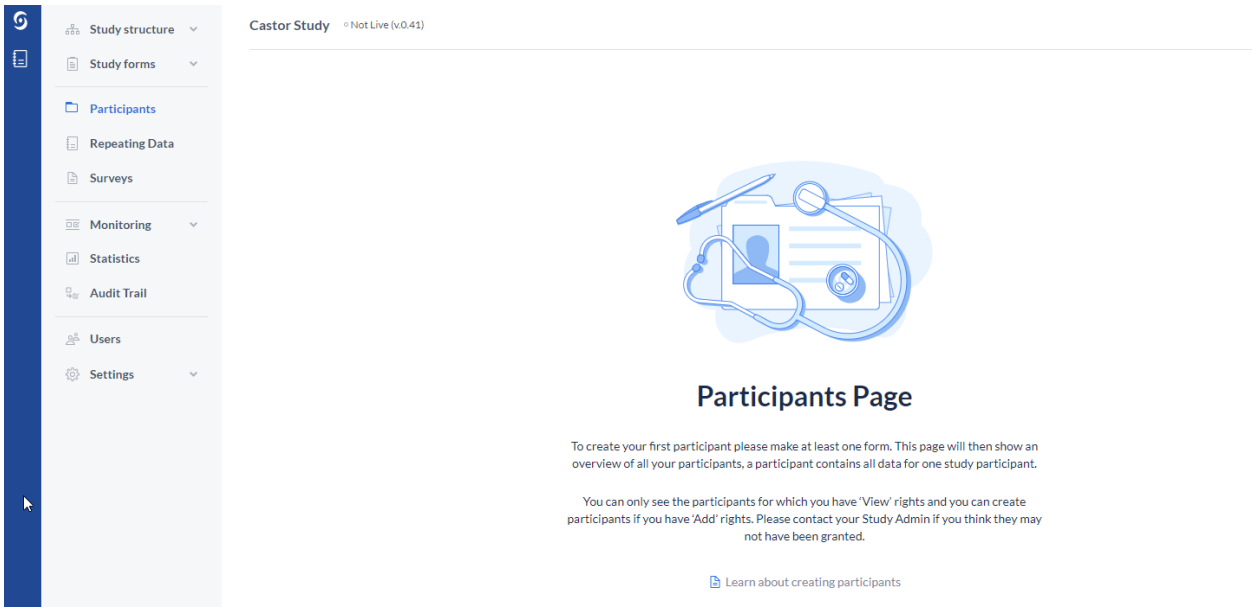
Move a field

Delete a field

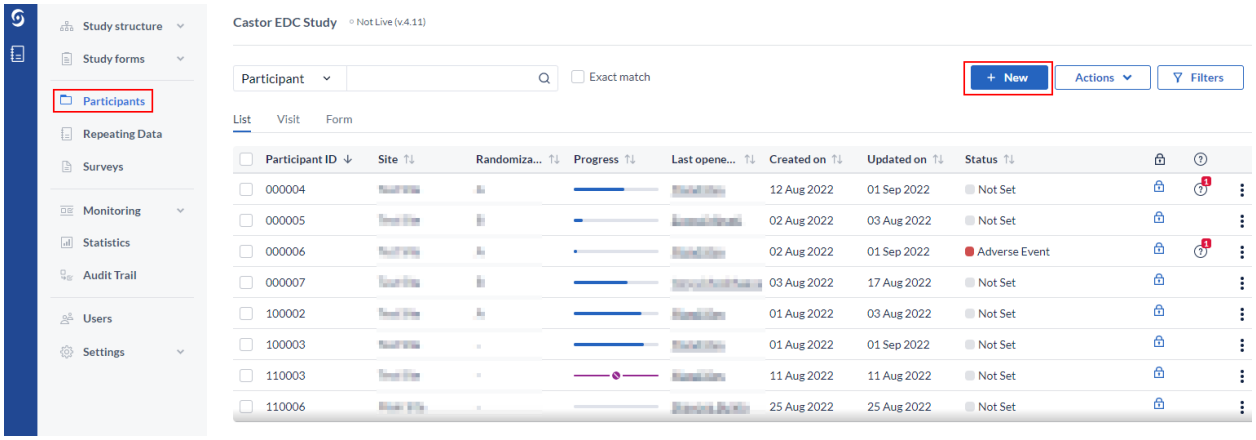
Changing the field type for fields in which data has been collected is limited to only allow compatible field type changes, in order to prevent data loss.

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 participant. For new studies where the participants haven't been created yet, navigate to the Participant tab and click on the 'Create Participant' button.



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



1. Click on the 'Participant' tab.
2. Click on '+New'. You will be prompted to select a site. By default, Castor will generate incremental IDs per site. The 'Create NewParticipant' dialogue box will open and you will select the Institute you wish to add the participant to. The participant ID will be auto generated. You can customize the participant IDs in the

Settings tab. Add participant's email address in the 'Participant email' field if applicable.

3. Click 'Create'. Your participant will be created and will open and land on the first visit and form of the participant for data entry.

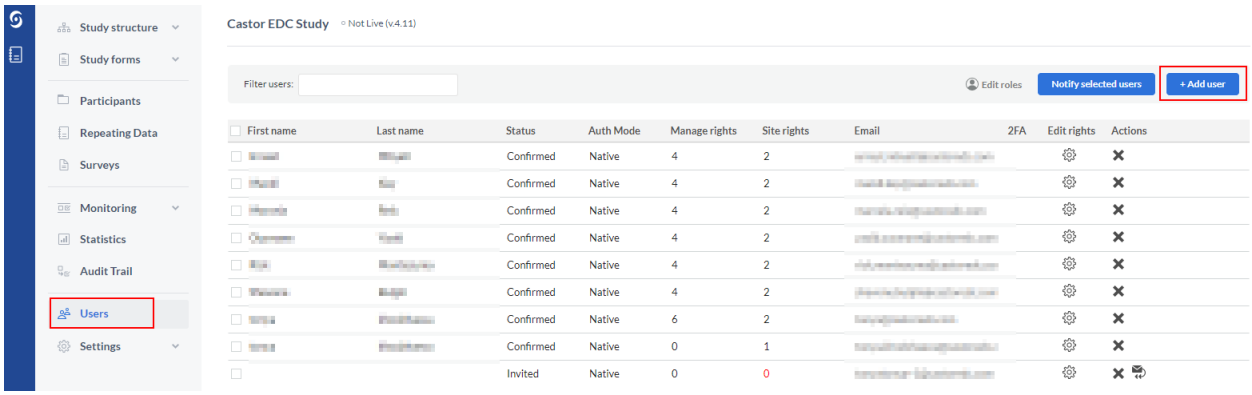
You can now test your form. Enter data to see whether your form is functioning well!

7. Manage Users in your study

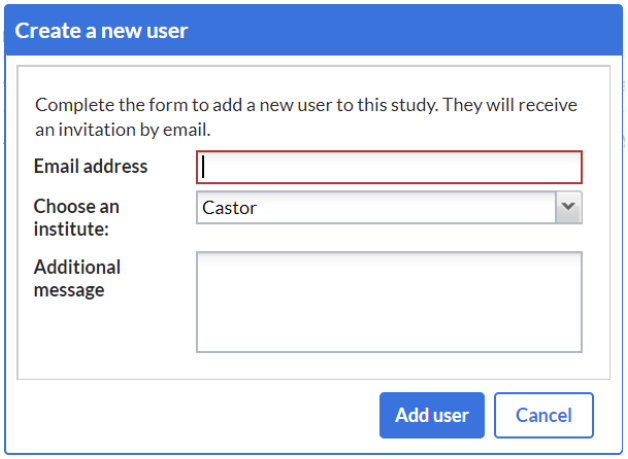
The 'Users' tab allows you to create and edit roles, add users to your study, and manage permissions.

7.1. Add a User

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



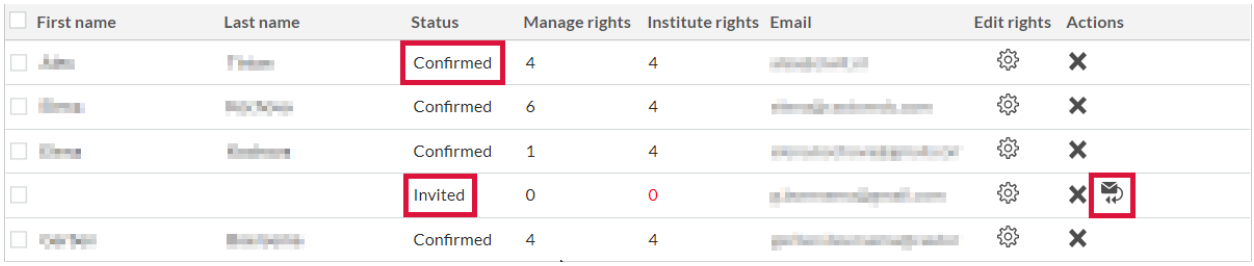
3. A pop-up will be shown. Fill in the user's email address and select a site to which the user belongs. (If you need to add additional sites, you may do so when you define the user's rights in the next form). You can also add an additional message to inform them about the invitation.



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'.

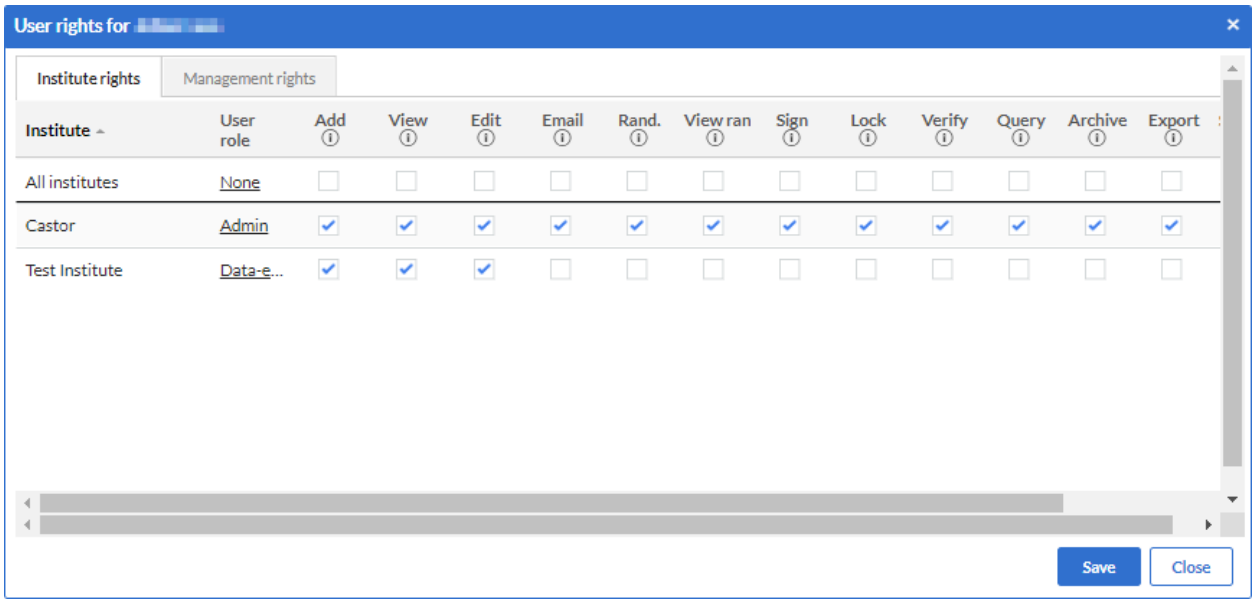
If the user does not have a Castor account, they will receive an email in which they are asked to register before being able to enter your study. They will be listed as 'Invited' if they have not yet signed up. If you want to remind them to join, or when they lose the email you can click the enveloppe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



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:



7.2.1 Site rights

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

Rights to access participants are given per site. 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 participant rights per site are as follows:

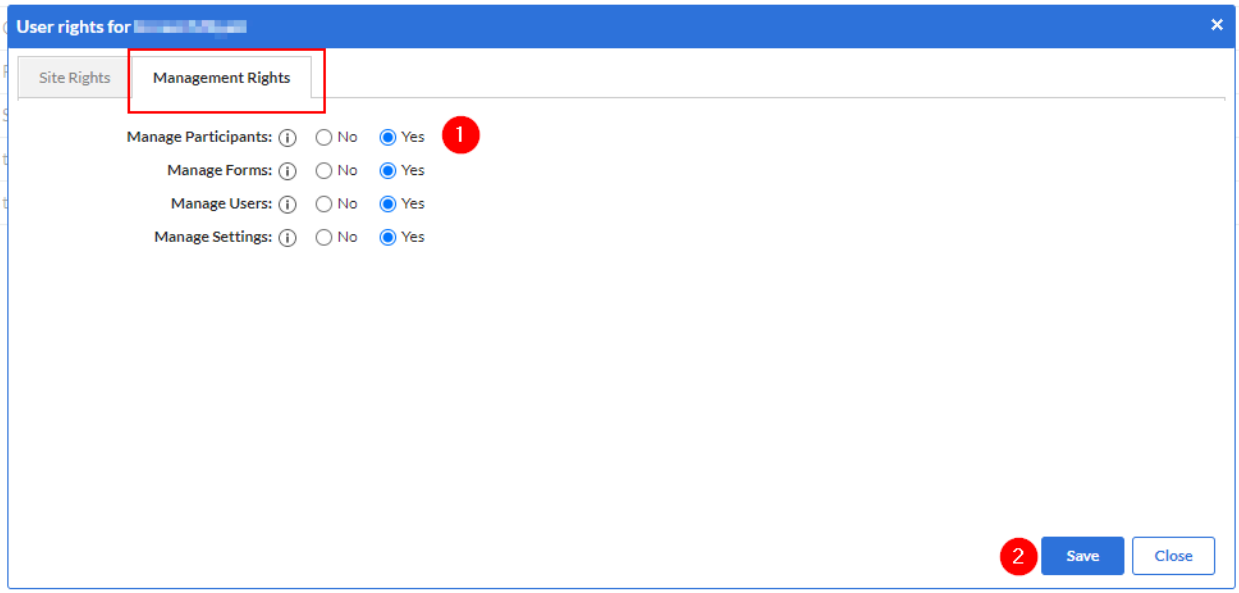
- **Add**: Allows the user to create new participants. To add a participant, you also need a 'View' right.
- **View**: Allows the user to view and print participants, view queries and comments and print participants.
- **Edit**: Allows the user to enter and edit data in a participant, import study and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

- **Email**: Allows the user to view and/or edit the stored email address within a participant or within a survey invitation. **Note**: To be able to edit a participant email address it is also necessary to have 'Edit' rights.
- **Rand. (randomize)**: Allows the user to randomize participants.
- **View rand. (view randomization)**: Allows the user to view the randomization allocation for a participant.
- **Sign**: Allows the user to digitally sign study forms.
- **Lock**: Allows the user to lock participants, preventing further data entry, as well as to unlock participants.
- **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 participants.
- **Export**: Allows the user to export data. To be able to export participants, 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 participants**: Allows access to the participants, Surveys, and Statistics tabs. The exact data the user will have access to depends on the site rights. For example, a user who needs to view the participants for site X will need to have 'Manage participants' rights, but also 'View' rights for site 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.

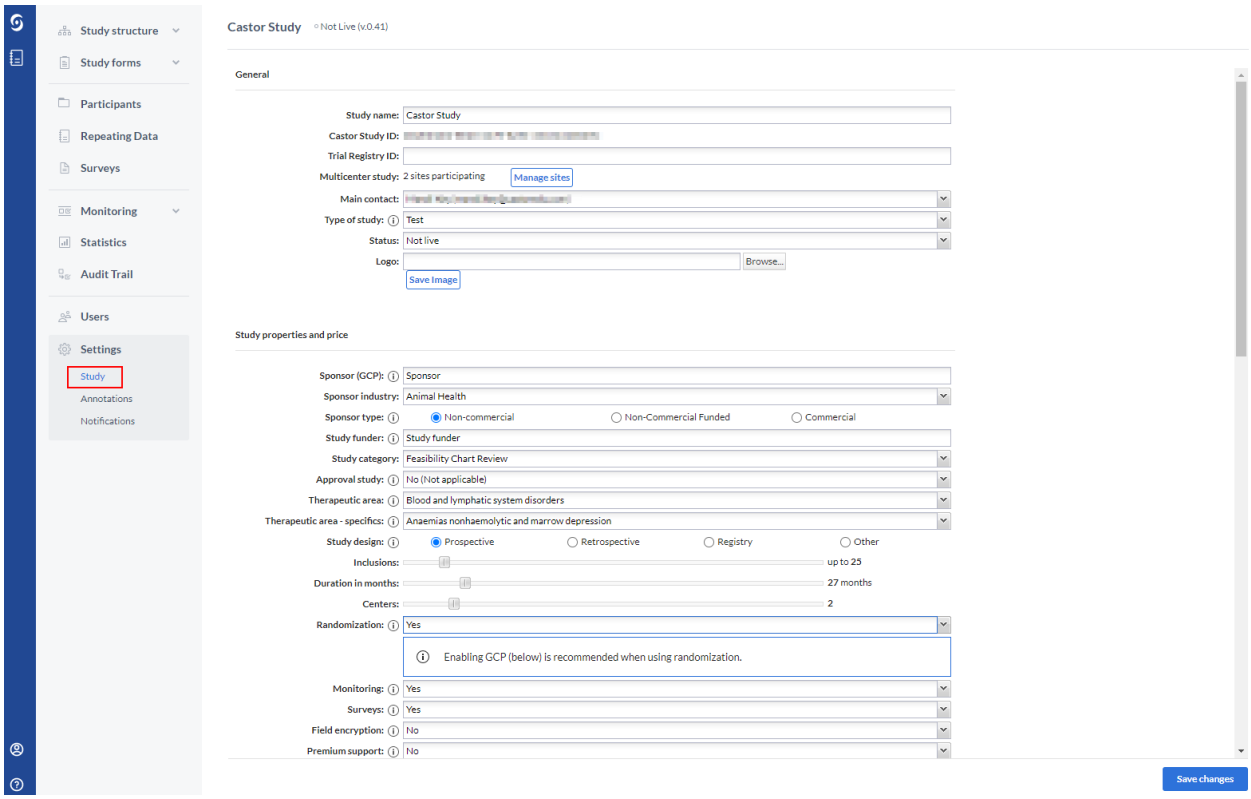
Keep in mind that only users with 'Management rights' will be able to access the study when it is not live.

8. Settings for your study and Going live

Navigate to the ‘Settings’ tab, ‘Study’ sub-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

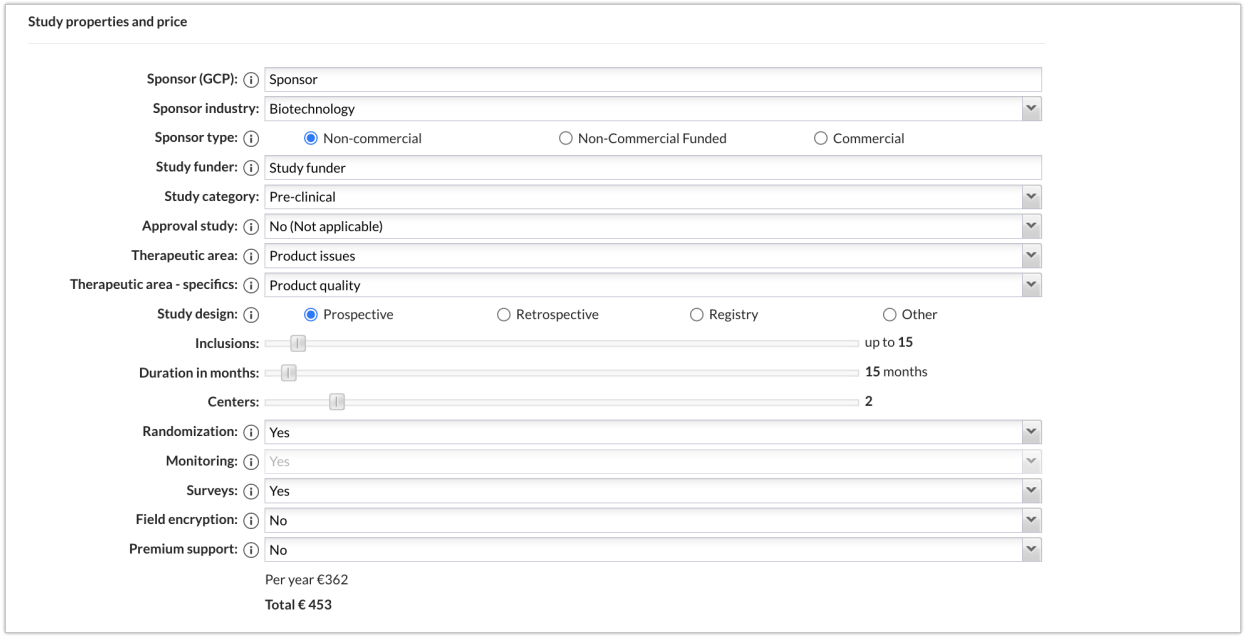
The first section is 'General':



- **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 sites and define custom date formats for each site. 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 participants'. 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:



- **Sponsor (GCP) :** The sponsor of the study is responsible for the initiation, management, and/or financing of 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.

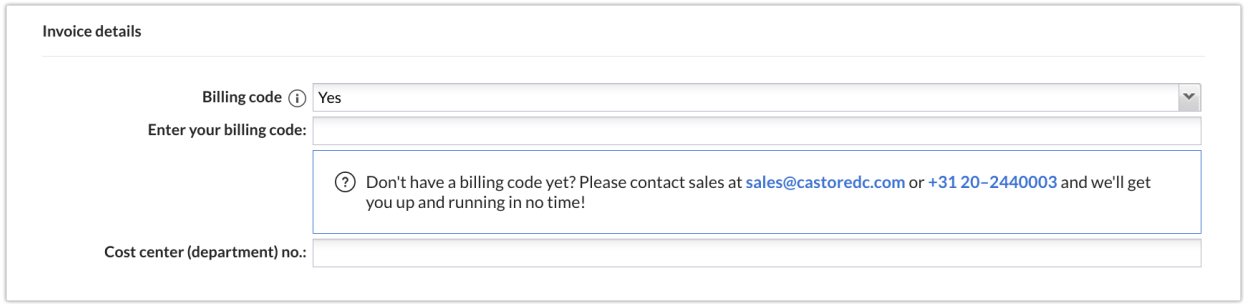
- **Inclusions**: Specify the number of inclusions in your study (i.e., how many participants do you expect in the database?).
- **Duration in months**: the duration of data collection (i.e., how long will your study be active/live?)
- **Centers**: How many centers will be participating/included in your 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

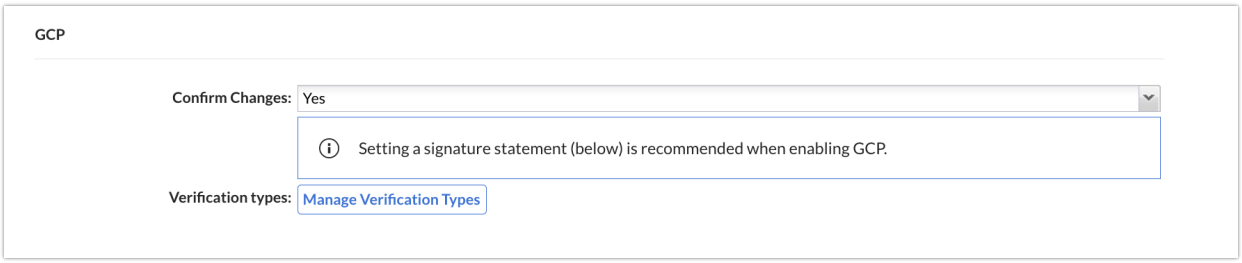
Enter all the billing details for this study, including the address that the invoice for the study will be sent to. Please specify the 'Project number' to ensure the invoice gets declared for the right project:

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



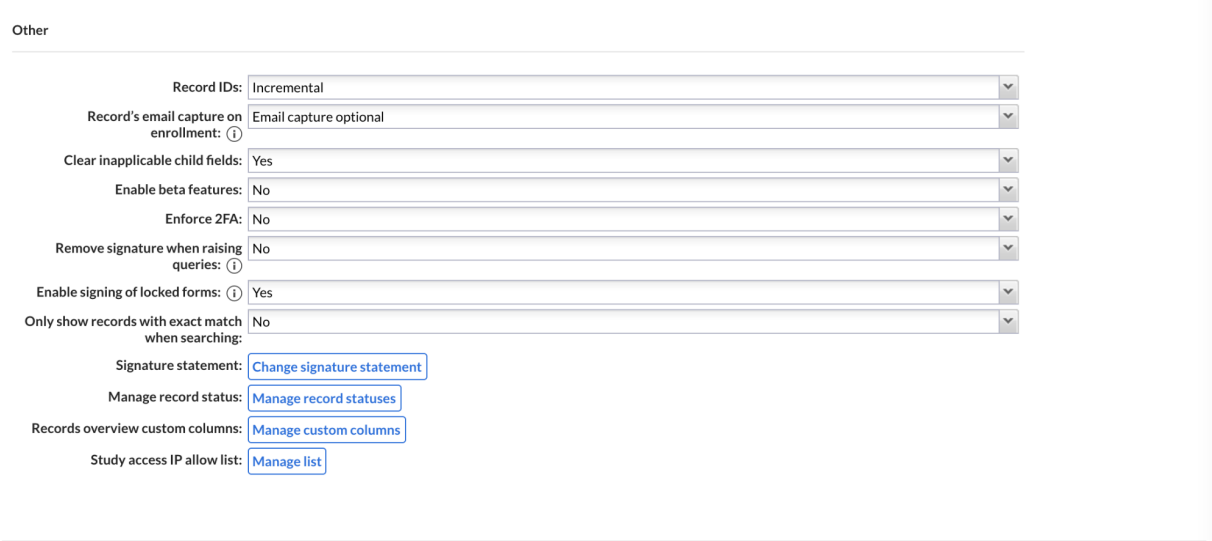
8.4 Good Clinical Practice

You can choose whether to enable GCP for your study:

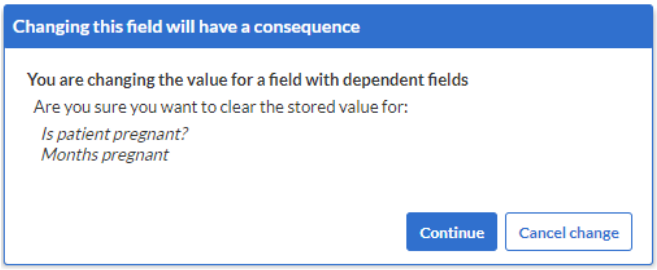


- **Confirm changes**: If you are using the extra GCP features, you can choose to enable the 'Confirm changes' functionality. This will require the user to enter reasons for changes that are made to the data according to GCP requirements.
- **Verification types**: Manage verification types including 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

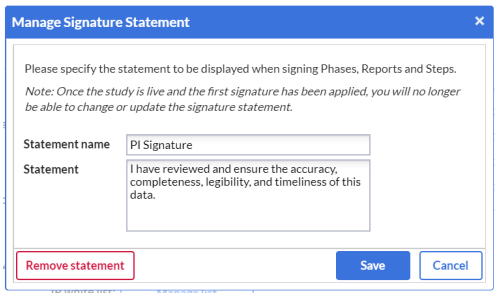


- **Participant IDs**: Choose how you want IDs for new participants to be generated. You can customize the IDs by selecting 'Custom definition'.
- **Email capture on enrollment**: Choose if and how would an email be required for newly created participants. Please note that visibility for this option 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.



This setting is only for study forms and repeating data. 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.
- **Remove Signature when raising queries:** this setting allows automatic removal of a signature when queries are opened on a signed form.
- **Enable signing of locked forms:** If enabled, signing of locked forms becomes possible.
- **Only show participants with exact match when searching**: Choose whether you want your search for participants to match the exact strings you input into the search field in the participants tab.
- **Signature Statement**: This statement will be presented when applying a signature. So, by signing the visit or form, you declare what is written in the signature. Note: after the study has gone live, it is no longer possible to edit the signature.

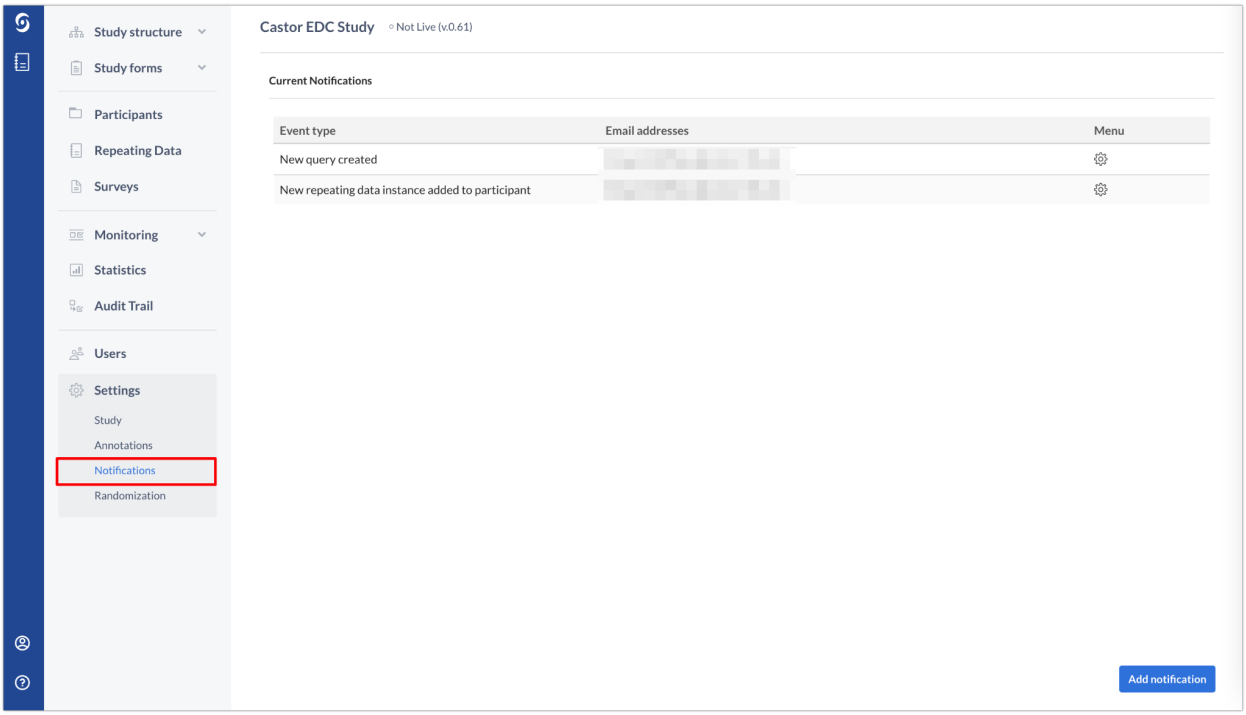


- **Manage Participant status:** This option allows you to create, edit, and delete participant statuses.
- **Participant overview custom columns**: Add and delete custom columns to the participants tab.

- **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 Notifications

Castor CDMS can send you updates via email (notifications) of several predefined events as soon as they happen in the system. To set up notifications, first go to the study 'Settings' tab, then choose the 'Notifications' sub-tab. Here you can add a new notification or edit existing ones:



8.7 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 a site that has a Castor site 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 participants 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, participants will need to be archived instead of being deleted. Archived participants 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 participants and might need to use the data from the archived participants 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