Castor

Castor CDMS Study Administrator User Guide

Version 2025.2.0.0

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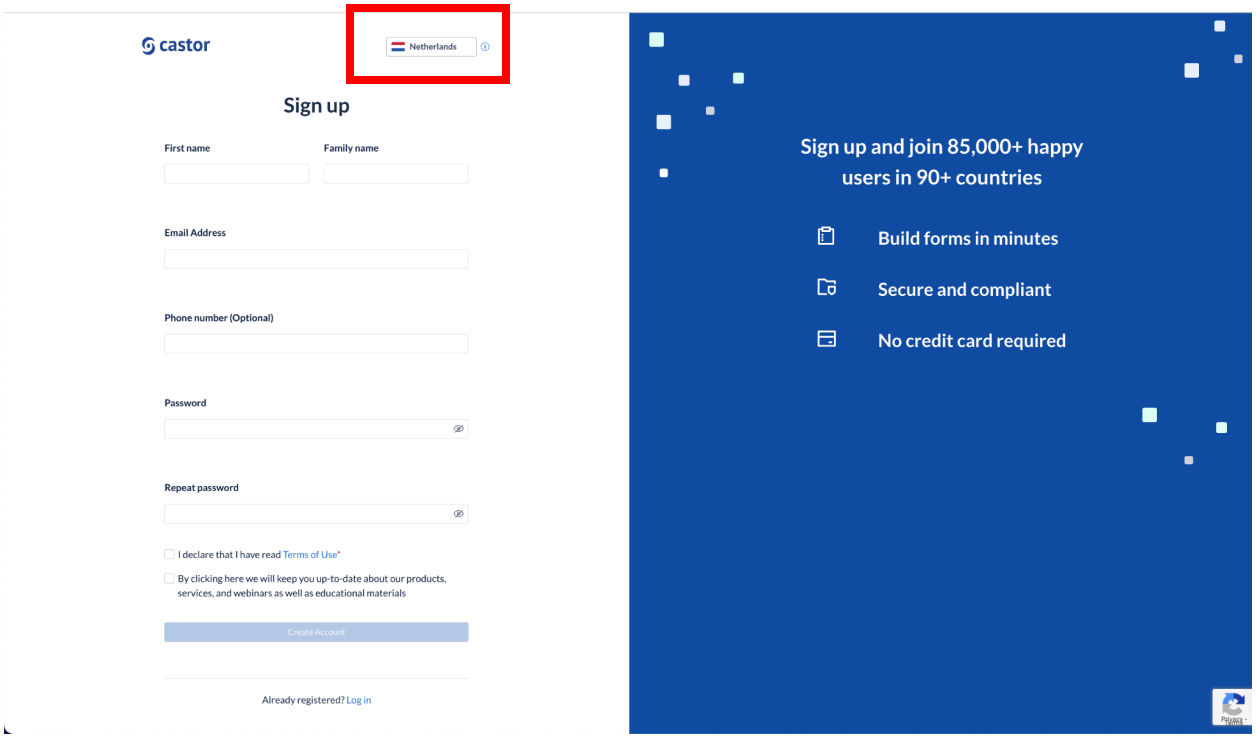
1. Register an account

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. When clicking on the Flag dropdown list, you can change the server location.



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
4. Accept the 'Terms of Use' and opt-in the email communications (optional)
5. Press the button 'Create Account'

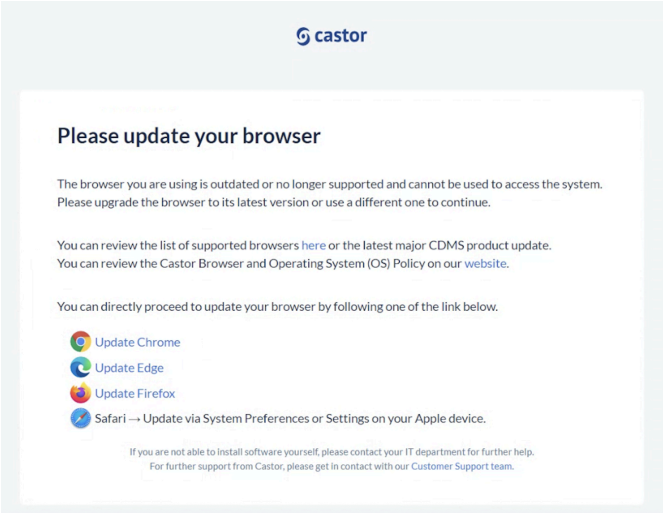
You will receive an email to verify your account. After clicking the link in the email address, you will be prompted to confirm the server where your account will be created.

1.2. System Access. Browser & Operating Support Policy

Study teams (clinicians, researchers etc.) accessing CDMS with an unsupported browser or operating system (OS) will now be blocked from logging in and shown a clear error message. This ensures a reliable experience by enforcing access only through allowlisted environments. This change is applicable to all CDMS users that are required to log into the system.

Two new messages have been introduced as part of Castor's Browser and Operating System Policy enforcement for study teams. If both the OS and browser are unsupported, the OS message takes priority.

Unsupported Browser Message:



Unsupported OS Message:

Note: The above messages apply only to clinician-facing CDMS interfaces

For study participants accessing CDMS functionality (web-surveys), dedicated new messages will only be active by default for new studies created on or after July 1st, 2025. This means that, while the policy is still applicable, participants from existing studies will not encounter these upgrade messages regardless of their browser/OS combination. Upon request, our Support team can activate the warning screen functionality for existing studies.

Supported and validated versions for v2025.2.0.0:

Clinicians:

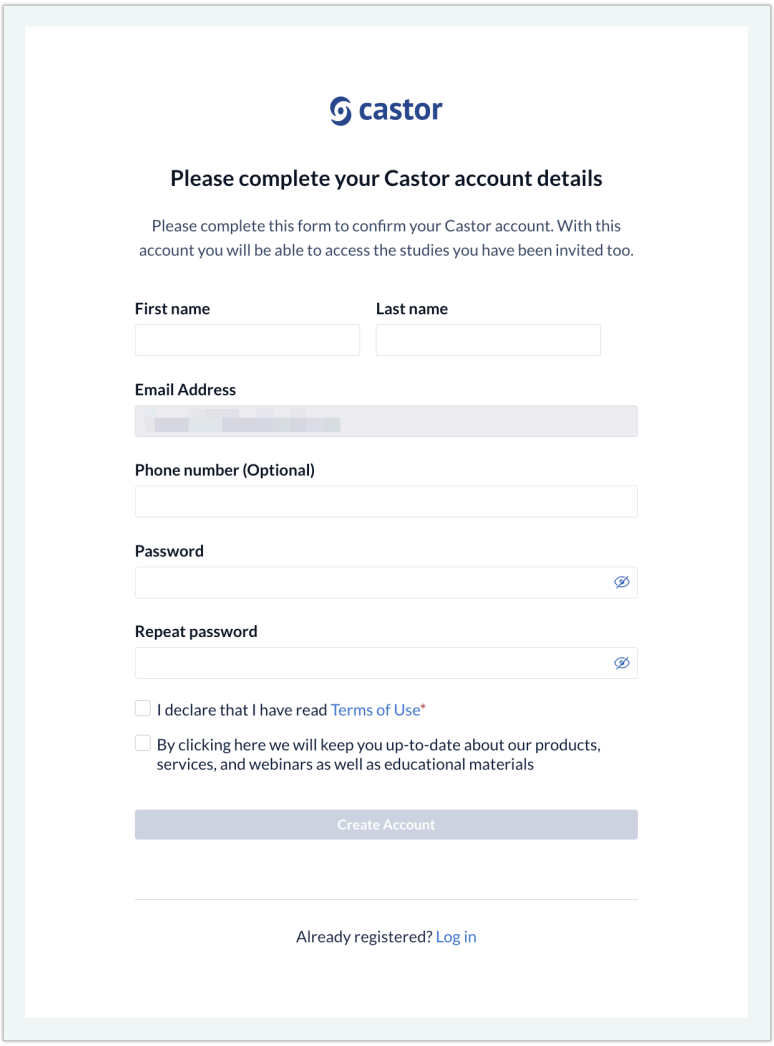
- Chrome 125 or newer
- Microsoft Edge 124 or newer
- Firefox 127 or newer
- Safari 17 or newer (macOS)
- Safari on iOS 17 or newer

Participants:

- Chrome 125 or newer
- Microsoft Edge 124 or newer
- Firefox 127 or newer
- Safari 17 or newer (macOS)
- Safari on iOS 17 or newer
- Samsung Internet 27 or newer

1.3. User is added 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:

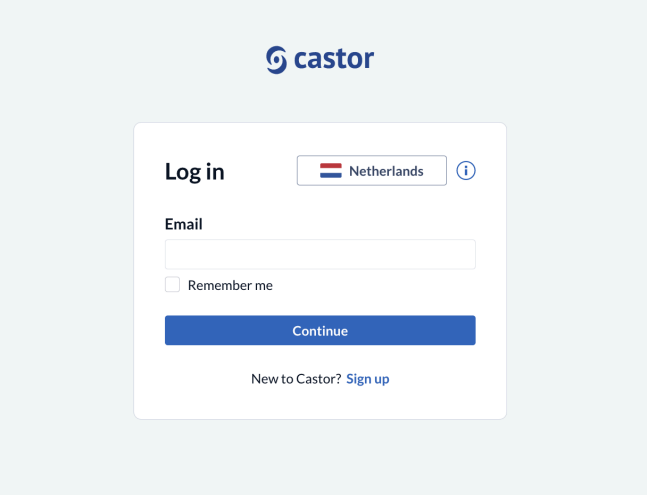


1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Create Account'. Shortly after registering a user details, an email with an activation link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

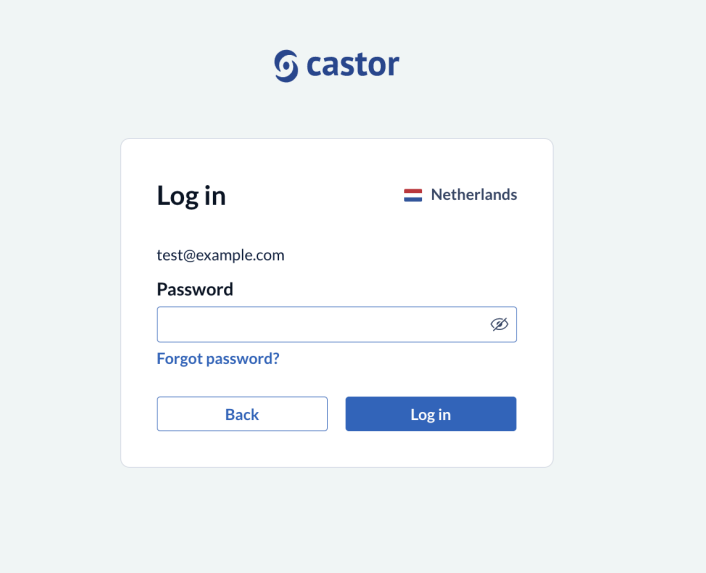
2. Log In

Log into Castor CDMS 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.



3. Enter your password.



4. Click on 'Login'.

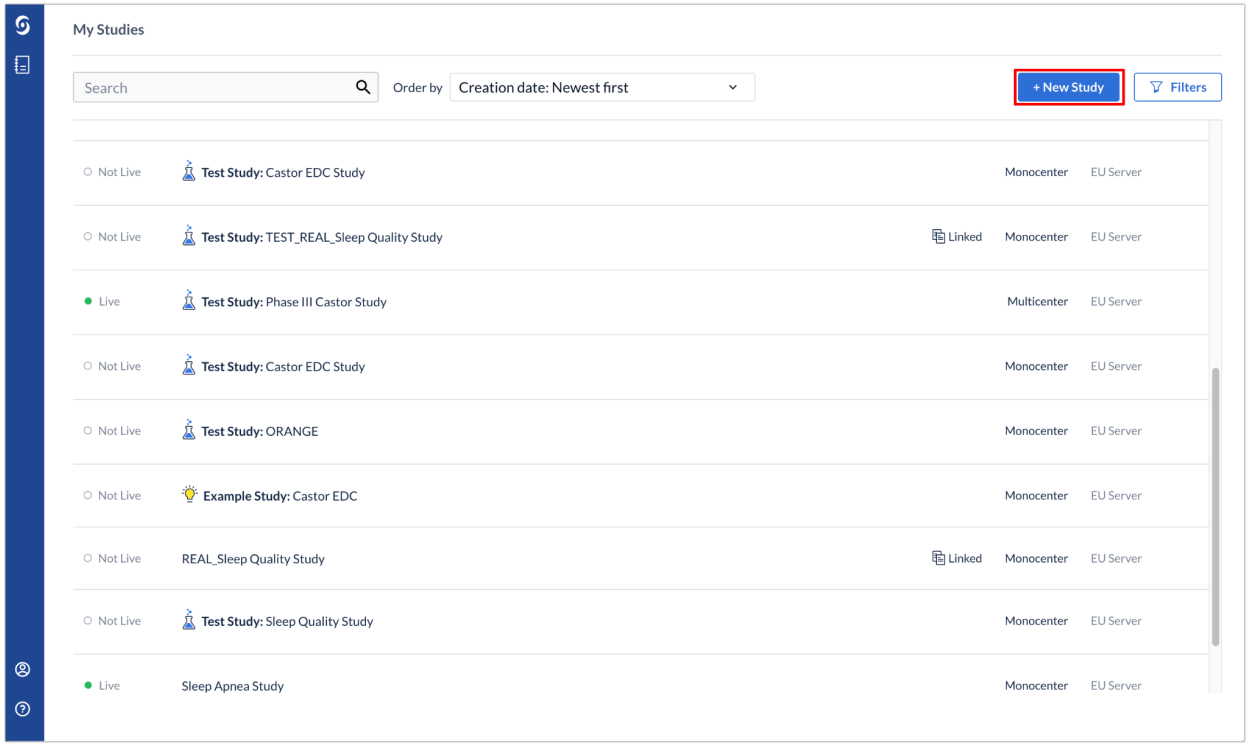
2.1. Activate two-factor authentication

In Castor, you can configure two-factor authentication (2FA) for your account.
This means that, upon login, you will have to enter an extra authentication code generated by an authentication app on your phone or tablet. This adds an extra layer of security to your Castor account - potential attackers will need not only your account details, but also your physical device with your authentication app to be able to access your account.

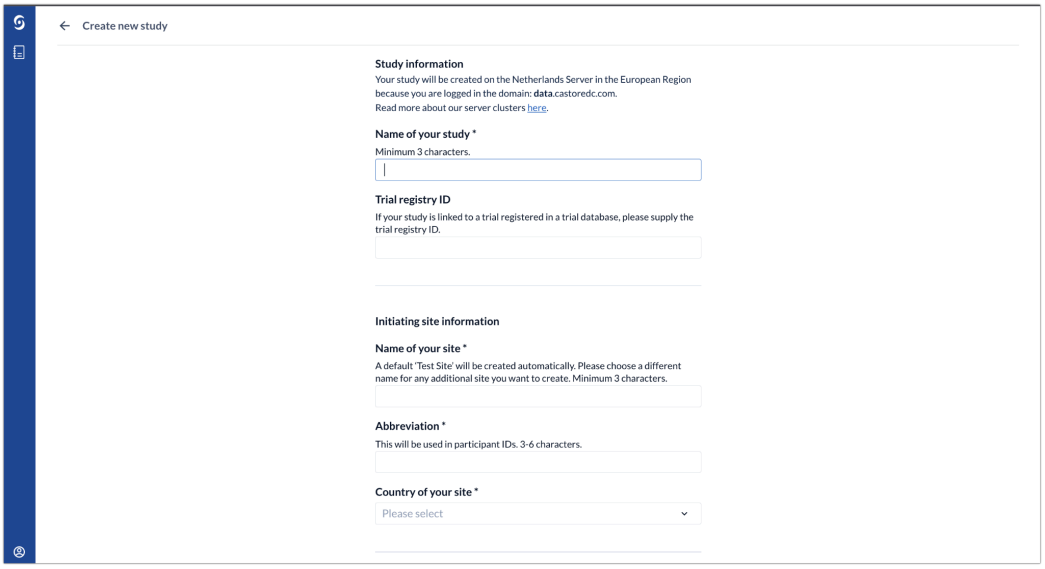
3. Start a study

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:



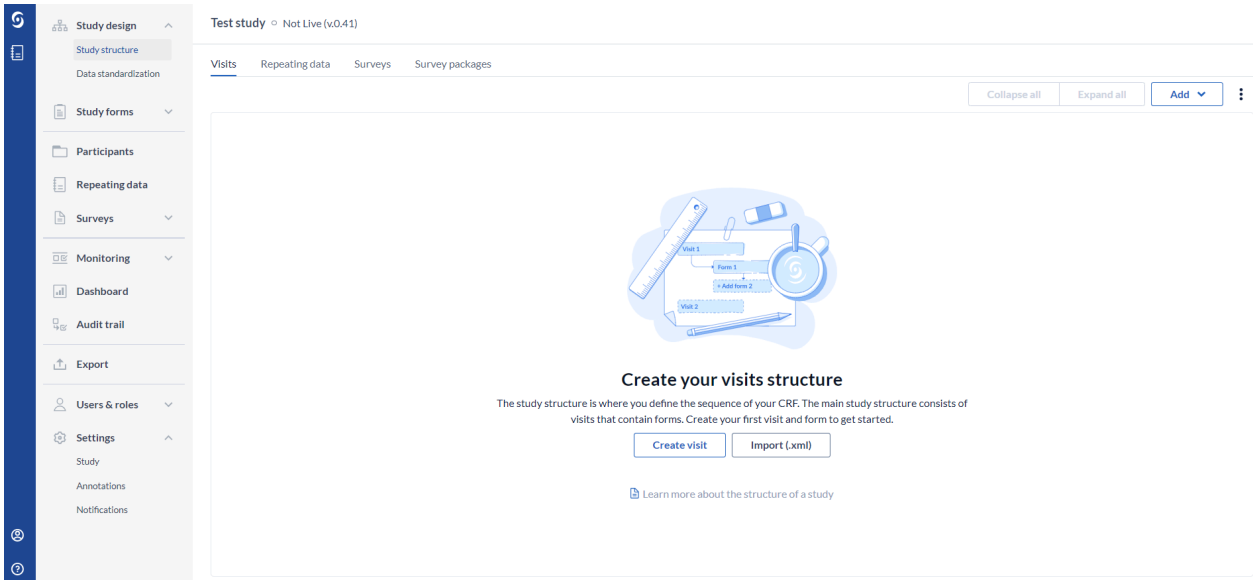
- **Name of your study**: Fill in a study name. The study name can be changed later.
- **Trial registry ID (optional)**: Fill in the ID of the trial registry your study is registered in (if applicable, e.g. clinicaltrials.gov)
- **Name of your site**: Complete the details of the site that your study 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 production study. Choose Example study type if you wish to get familiar with the system.
- When choosing the production study type, Confirm that you have followed the online training (https://academy.castoredc.com)
- Click on 'Create study' button

4. Introduction to Castor CDMS

4.1. Manage your study

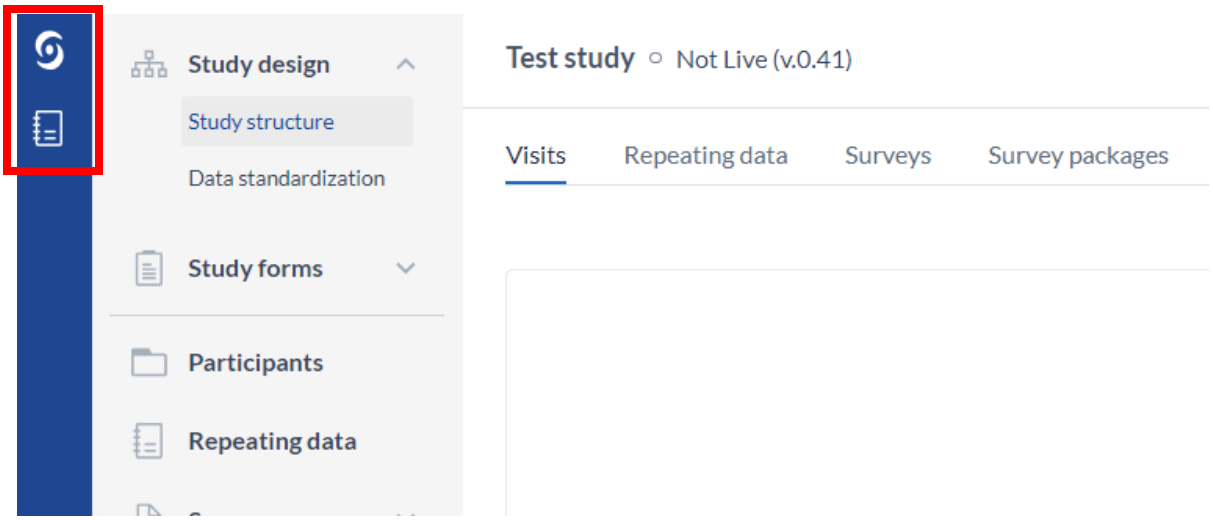
Once you have created your study, the study will open on the Structure tab. There can be up to ten tabs visible in the management view, depending on the settings you define for the study:



- **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.
- **Data standardization**: Here you can see the domains added to your study, and add, edit, and delete domains.
- **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.
- **Dashboard**: 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 manage permissions enabled (i.e. Participants, Forms, Users, and Settings).
- **Export**: Allows to view the export files, this tab is visible for users with the 'Export' permissions.
- **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 or the book 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:

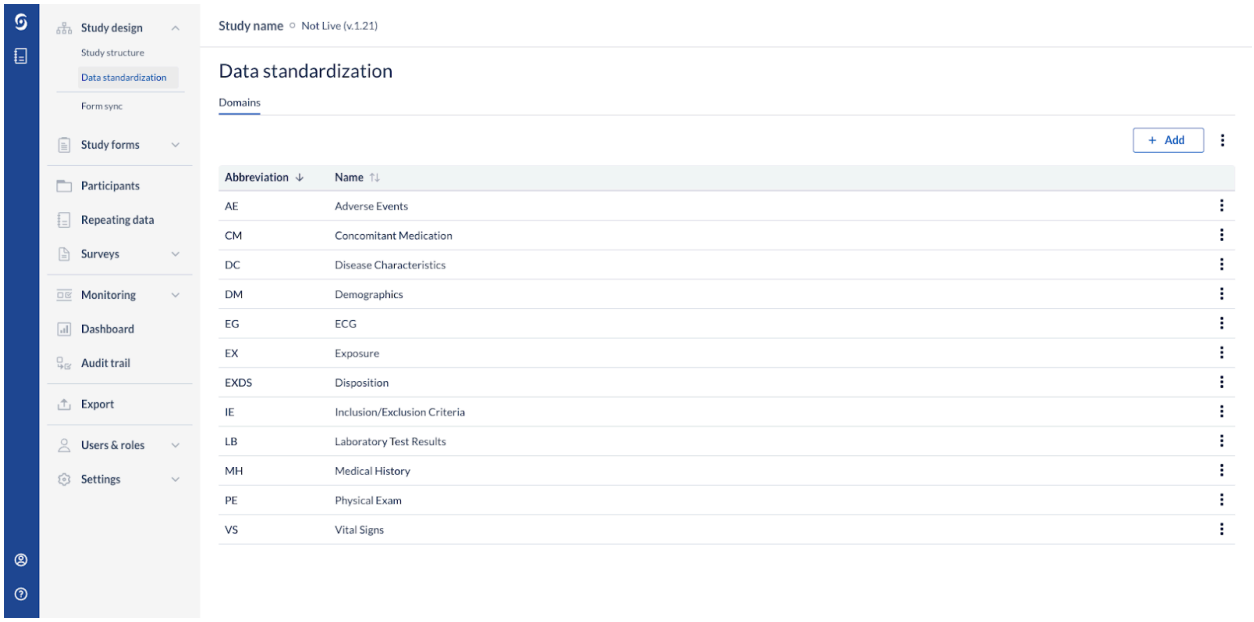
- **Study forms**: The actual 'Case Report Form' in which you collect patient data.
- **Repeating Data**: The repeating forms can be used for repeating data such as Adverse Events, medication, and repetitive measurements such as blood pressure. They have a 'one-to-many' (1:N) relation with the participant. In your study form you can refer to a repeating data instance.
- **Surveys**: Questionnaires that you can send to participants using their email addresses, or share via a general survey link, or via Castor Connect App.

The Form Sync feature allows for each production study to have a corresponding test environment.

4.3. Data Standardization

The Data Standardization allows users to more easily manage the export files and conduct a more effective analysis of variables within the same category. The domain-based export 'regroups' variables by visit (including unscheduled visits and surveys) and domain. It is available for CSV and SAS exports.

Data standardization page is available under the Study design navigation item. On the Data standardization page you can see the domains added to your study, and add, edit, and delete domains.



5. Create study forms, repeating data, surveys and survey packages

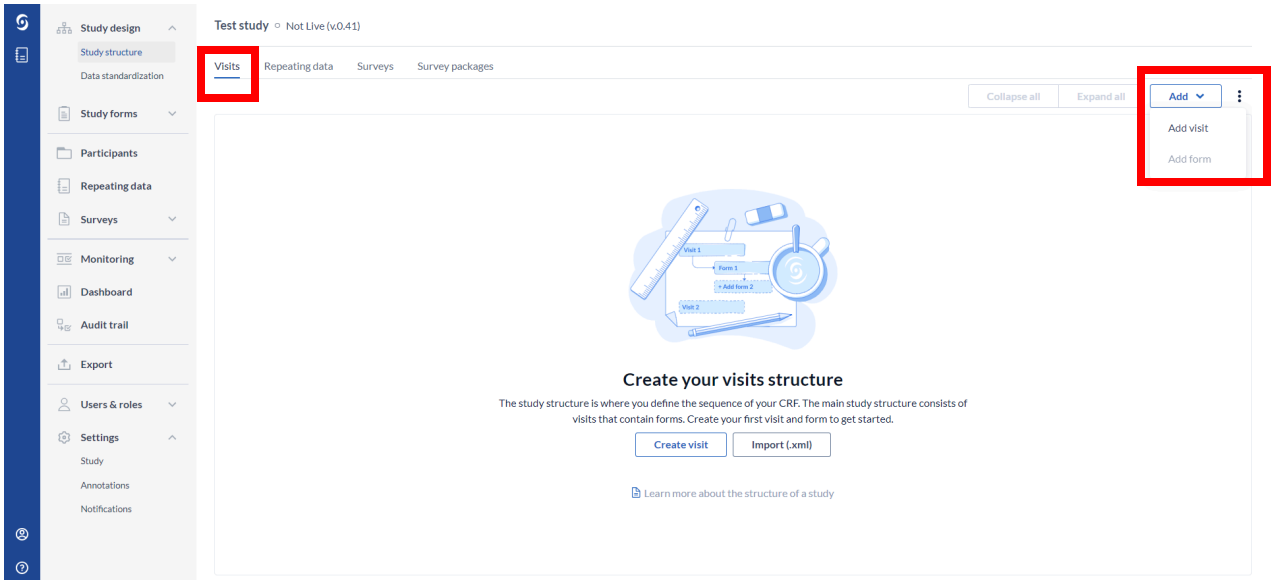
If you know what kind of form you should use, you can start creating them. The three forms are made in a similar manner.

1. Navigate to the 'Study design', then 'Study structure tab.
2. Navigate to a sub-tab:
    - Click on the 'Visits' 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
    - Click on the 'Survey packages' sub-tab to create survey packages. In order to send out a survey to participants, you must create survey packages. Learn more about survey packages in the article '[Creating a survey package for Castor Connect]'

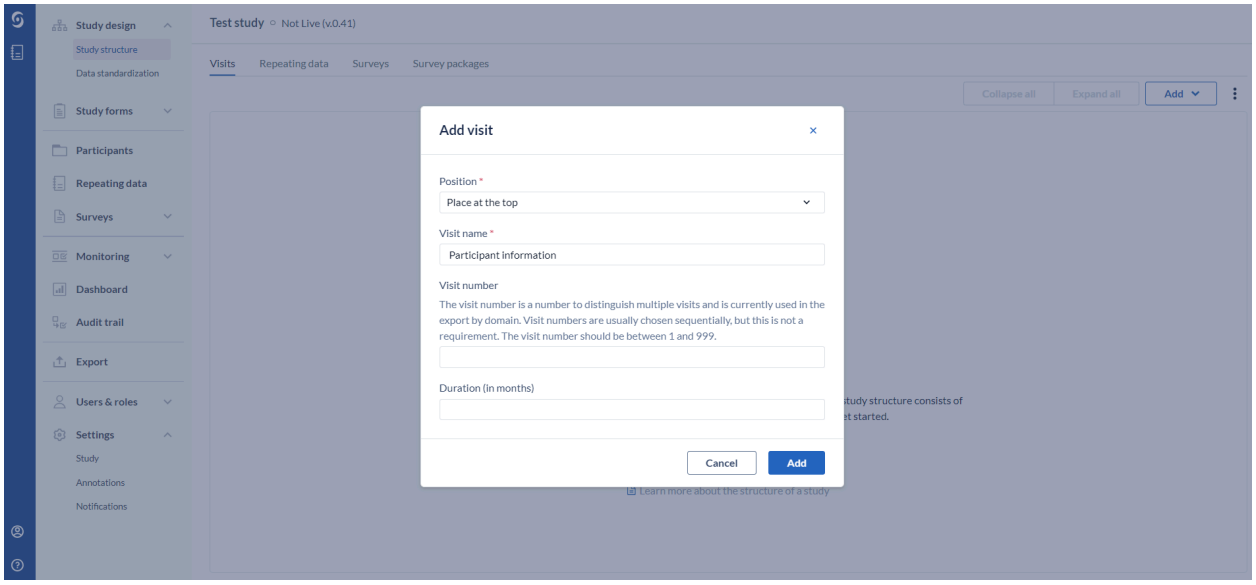
5.1. Create a visit, repeating data, survey or a survey package

Visits 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 design - Study structure tab.
2. Select ‘Add - Add visit’.



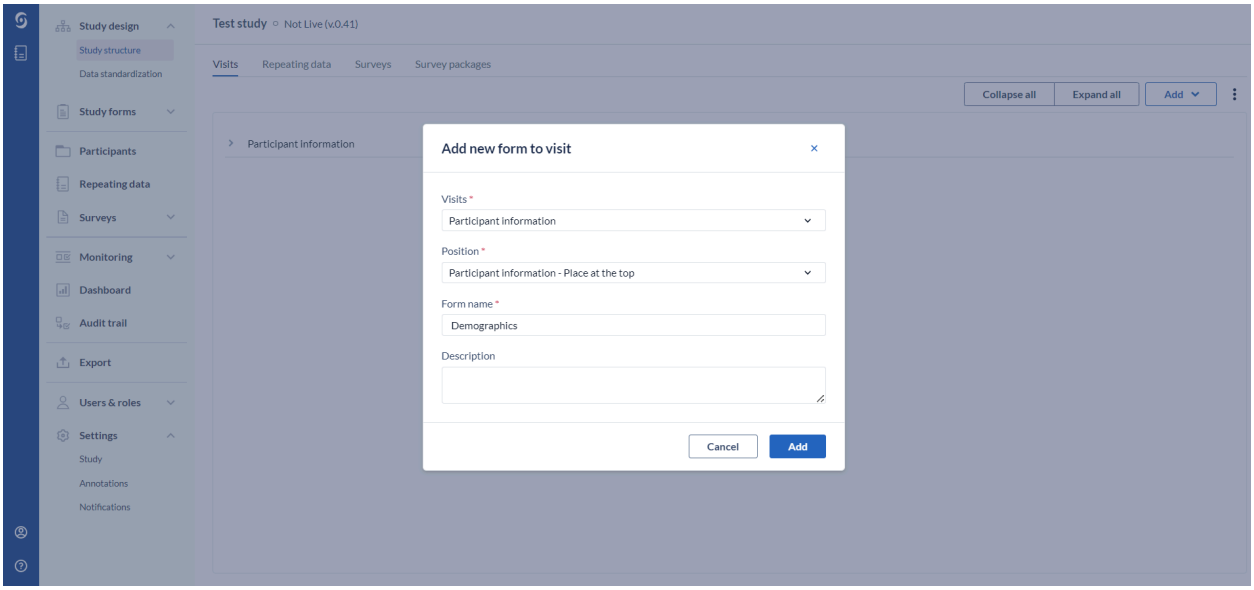
3. The ‘Add visit’ dialog window will open where you can select the positioning of the visit, name of the visit, and duration.
4. Click ‘Add’ to create a new visit.



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 Consent’ at Screening.

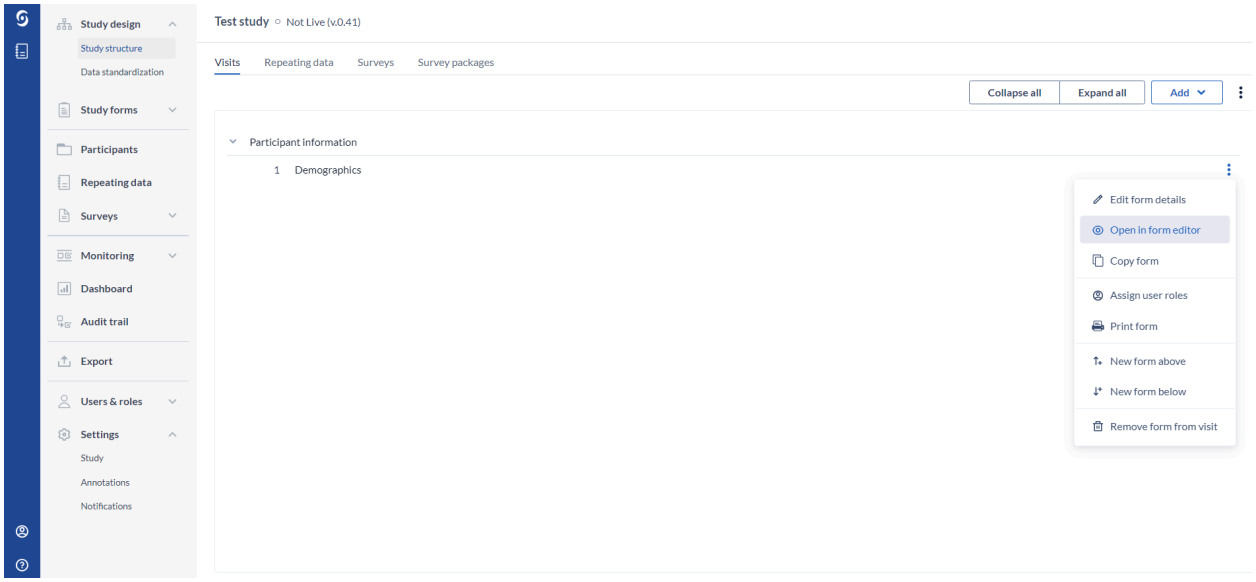
1. Click the ‘Add form’ button in the right panel.
2. Define the form properties.
    - Choose the position for the form.
    - Choose the name for the form e.g. ‘Informed Consent’.
    - Optional: Choose a description for this form, this text will be added to the top of the form in data entry.
3. Click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



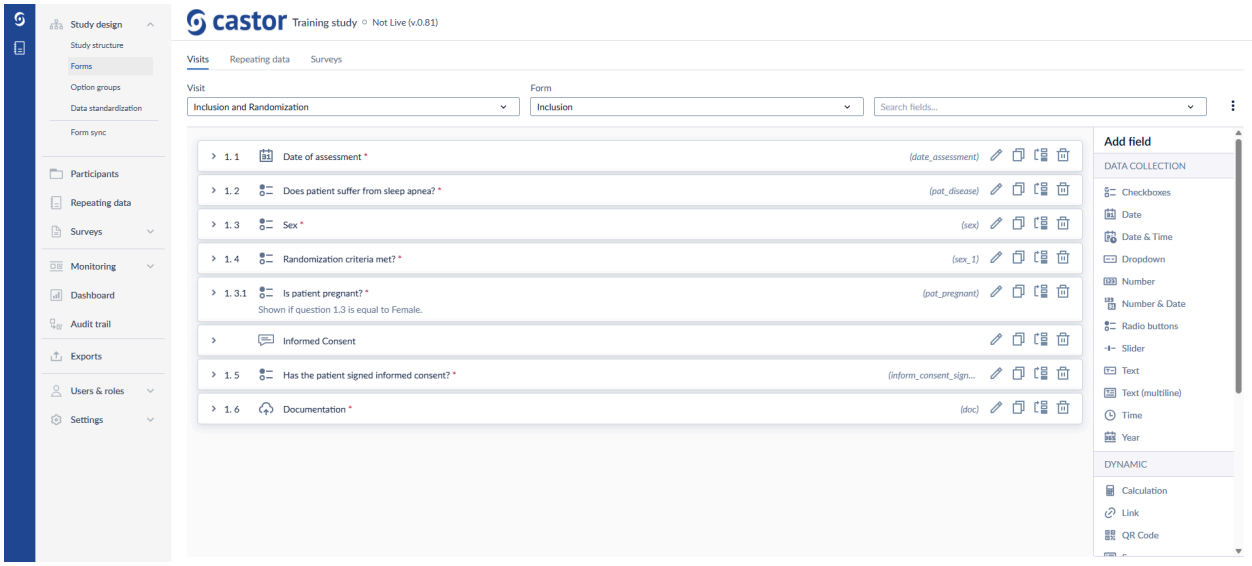
5.3. Create fields

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.

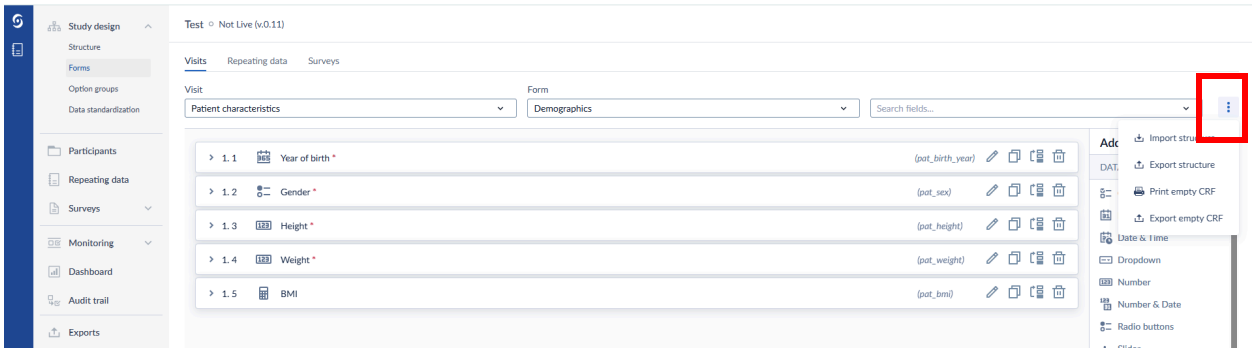
1. Navigate to the Study Structure tab and select the form you would like to add or edit fields for e.g. Visits, Repeating Data, or Surveys.
2. Click on the visit, repeating data, or survey you want to add or edit fields for.
3. Select the visit you want to add or edit fields for.
4. Click on the three dots 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 'Forms' tab. This is where you can add and edit fields. You can also select the visit and form from the dropdown menu:



To Import Structure, Export Structure, and Print Empty CRF or Export empty CRF, select the 3-dot menu next to the search bar.



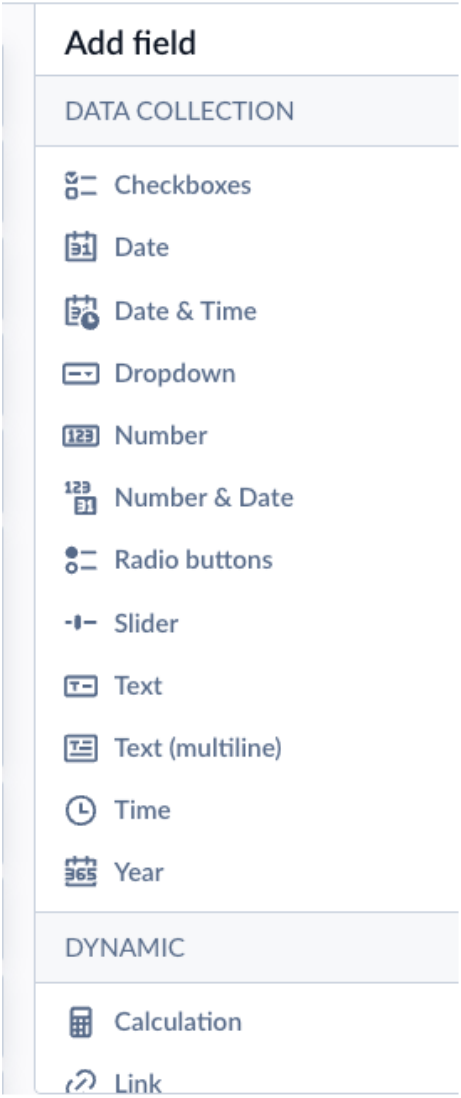
You can request a PDF export of an empty CRF from the Study Structure, Forms, and Option Group pages. When generating the export, you can customize:

- Page size and layout, including title page, table of contents, and whether each form starts on a new page
- Which Visit, Repeating Data, and Survey forms to include

- What information to display, such as hidden calculation fields, field details, and calculation templates

Once the export is ready, it will be available for download from the Exports page.

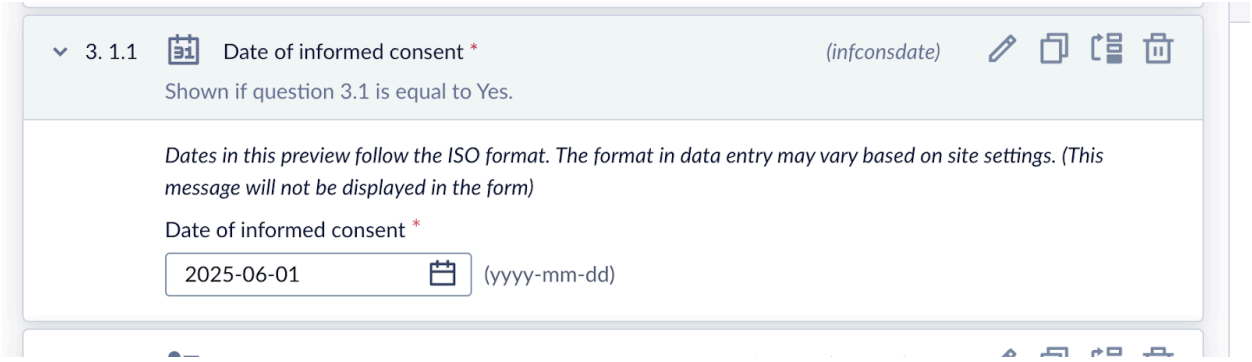
To add a field to the form, choose a field type in the right panel of the form builder.



Available field types:

- **Add Survey Button**: creates a button which allows you to quickly add a certain survey in the data entry.
- **Calculation**: used to access variables from your study to calculate values, e.g. a BMI from weight and length.
- **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.

  The date format in Form Builder field previews is standardized to ISO format (YYYY-MM-DD).

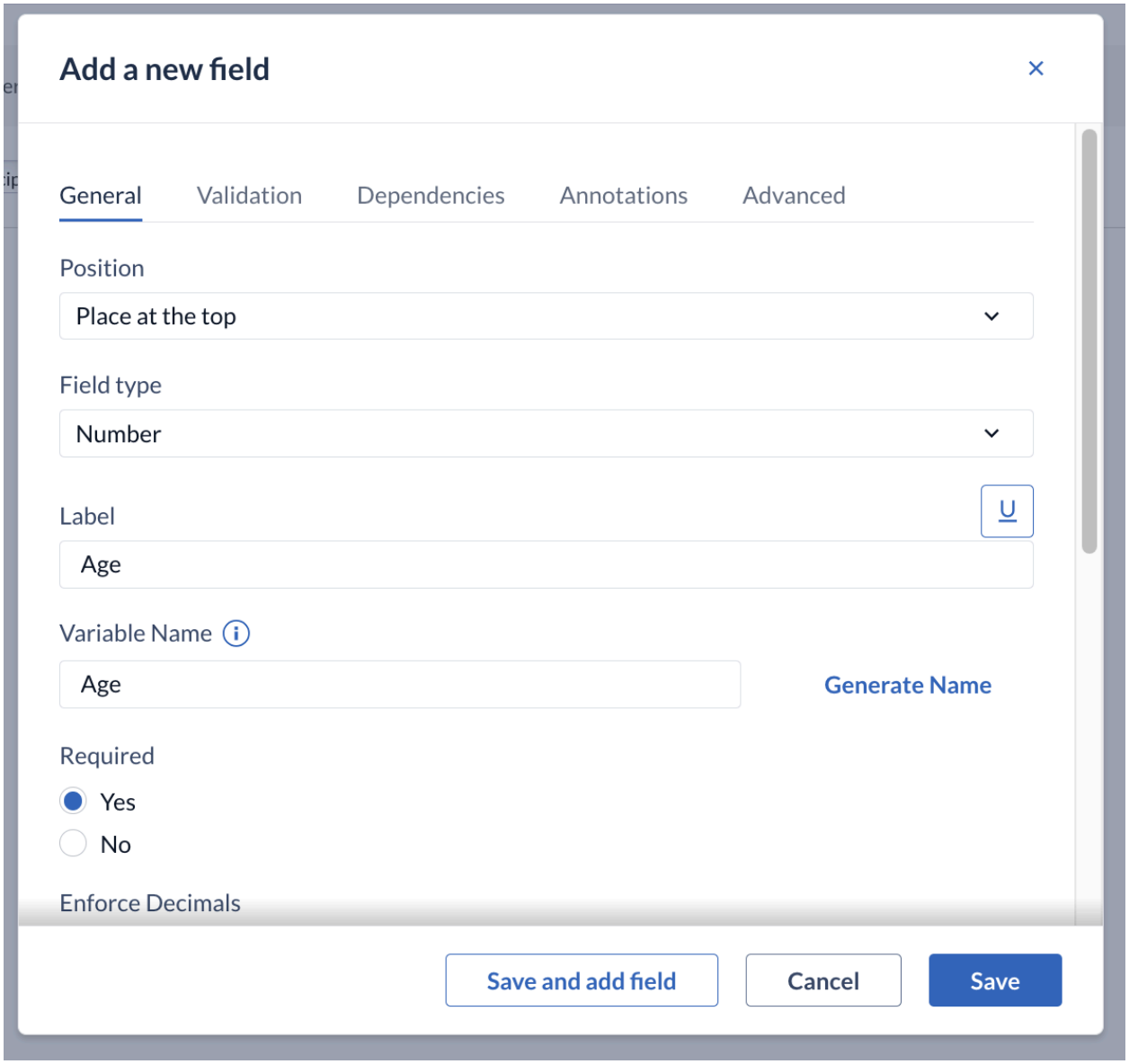


- **Date & time**: this field can hold a date and time. Displayed in format dd-mm-yyyy and hh:mm
- **Dropdown**: displays an option list from which the user can choose only one option. If you have a large number of options, this is more convenient than a radio button field. Dropdown fields will turn into a search box which improves data entry performance for studies with large option groups.
- **Grid**: field type to group closely related data in a tight interface (table).
- **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.

- **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.
- **Number**: this field can only contain numbers.
- **Number & Date**: stores a number value alongside a date, can be used for laboratory results.
- **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.
- **Radio buttons**: displays an option list from which the user can choose only one option. The buttons can be placed vertically or horizontally.
- **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.
- **Randomization**: displays the assigned randomization group of a participant in the form (for example, 'placebo' or 'treatment').
- **Repeating Data Button**: creates a button which allows you to quickly add a certain repeating data in the data entry.
- **Slider**: useful for VAS-measurements and other numeric values with clear minimum and maximum values.
- **Summary**: create summaries of collected data in your eCRF.
- **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.

- **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.
- **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.
- **Year**: displays a year value, the lower limit for the year field is 1891 and the maximum is 2099.

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.

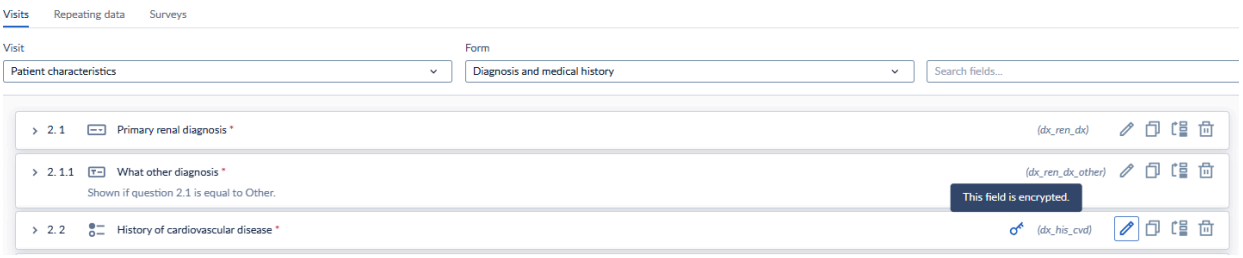
- **Variable name**: a required field that is used when you export or import your data or in calculation fields. This name identifies your variables and must be unique (e.g. 'baseline_gender'). The variable name has a lime of 64 characters. Click on 'Generate Name' to generate a variable name based on the field label.
- **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 a field which you can use to: edit, copy, move delete.

You can also move a field - change its position - using a drag-and-drop feature.

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.

Encryption visibility
Study designers can identify encrypted fields as a dedicated encryption icon is displayed next to field labels. Hovering over the icon reveals a tooltip: *"This field is encrypted."* The indicator updates in real-time when encryption settings change and is fully accessible via keyboard navigation.

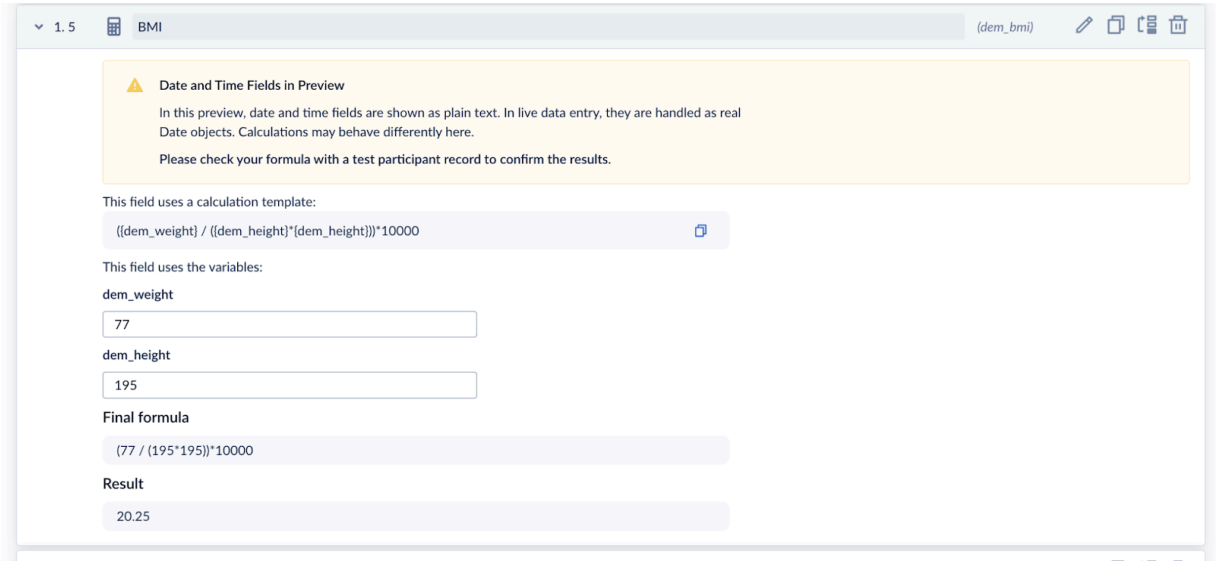


5.3.1 Interactive field preview

The Field Builder features an interactive field preview, allowing real-time interaction when expanding a field card. You can verify field configurations without creating test participants, streamlining form building. Additional options, such as slider orientation, are now directly accessible from the preview.

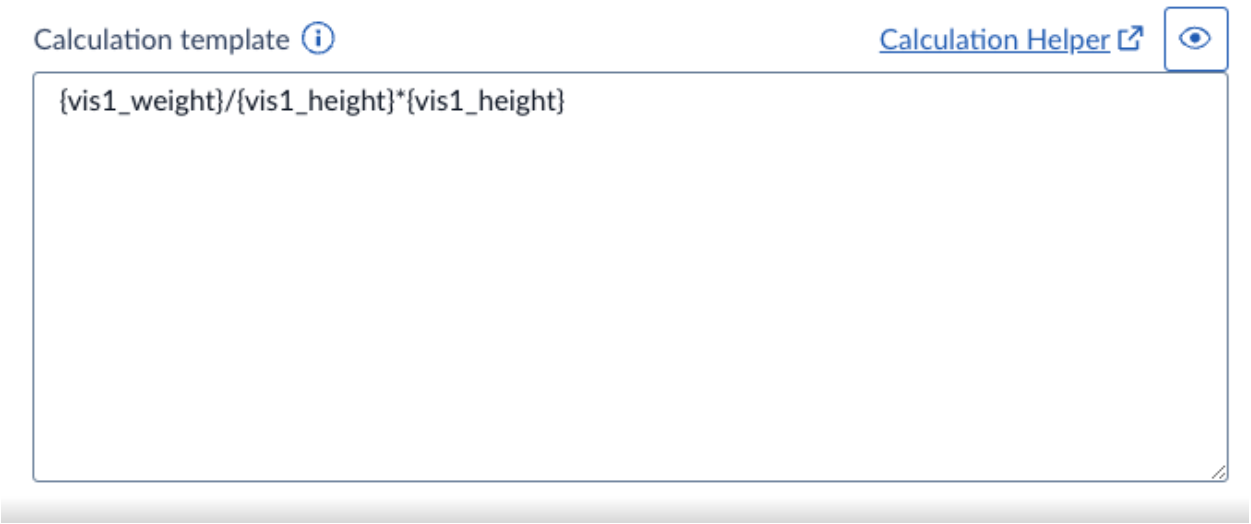
Please note that previews for template-based fields (like Calculations, Summaries, and QR Codes) currently do not carry specific field configurations, and date and time fields are shown as plain text in the preview, which may lead to differences compared to live data entry where dates are treated as Date objects.

A warning message is shown in the preview to highlight this.



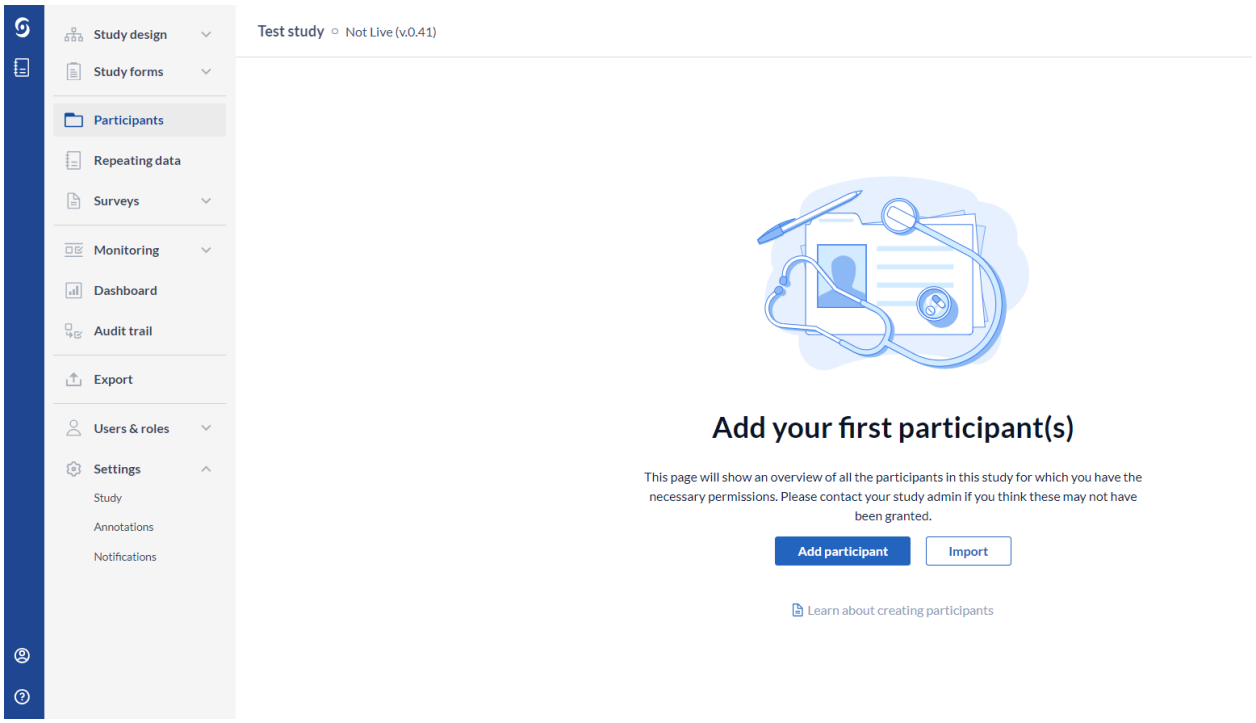
5.3.2 Calculation Helper Tool

You can now access Castor's external Calculation Helper tool directly from the Form Editor when configuring calculation fields. A new "Calculation Helper" button allows quick access in a new tab with the user-inputted calculation template pre-filled, reducing workflow interruptions.

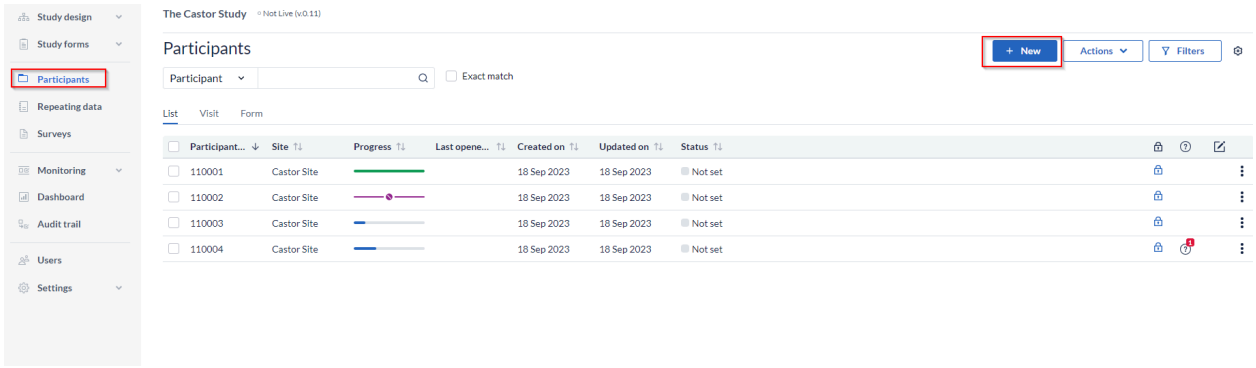


6. Test your forms

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 'Participants' 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 'Participants' 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!

It is possible to separate the production study and test environment automatically by using a Form Sync feature or manually creating a duplicate of a study.

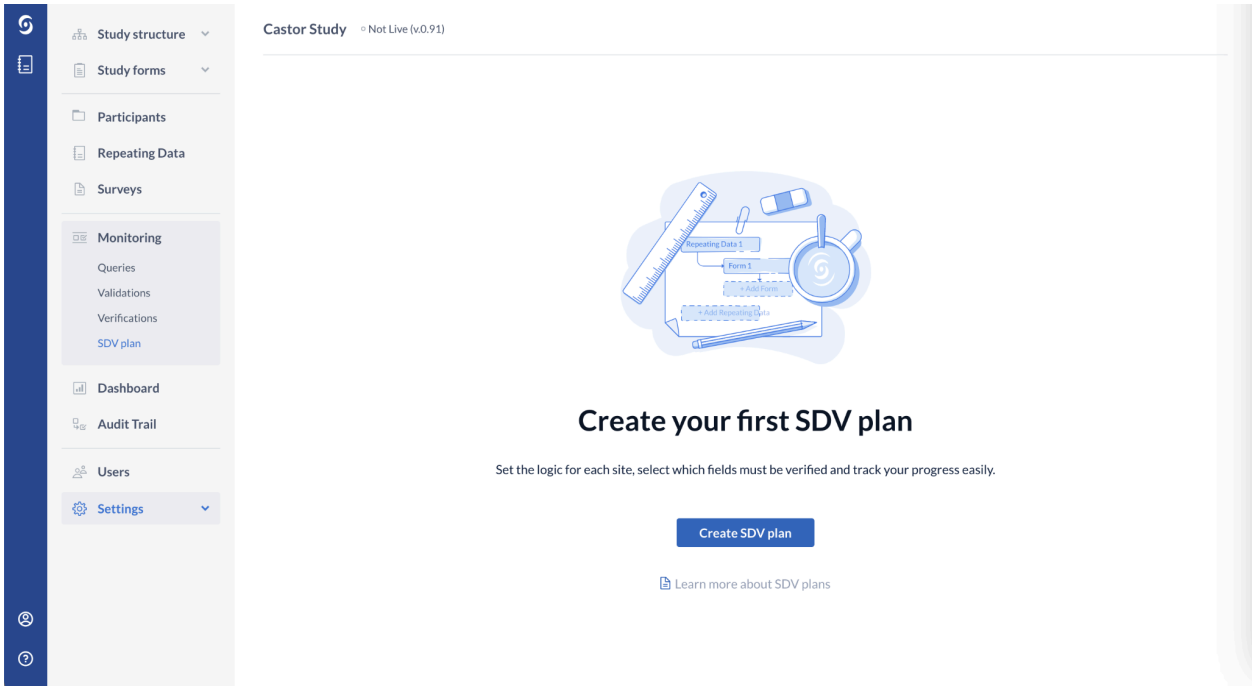
To learn more about creating a duplicate of your study automatically, read the article: Using Test and Production Study Environments in CDMS.

7. Monitoring - Source Data Verification Plans

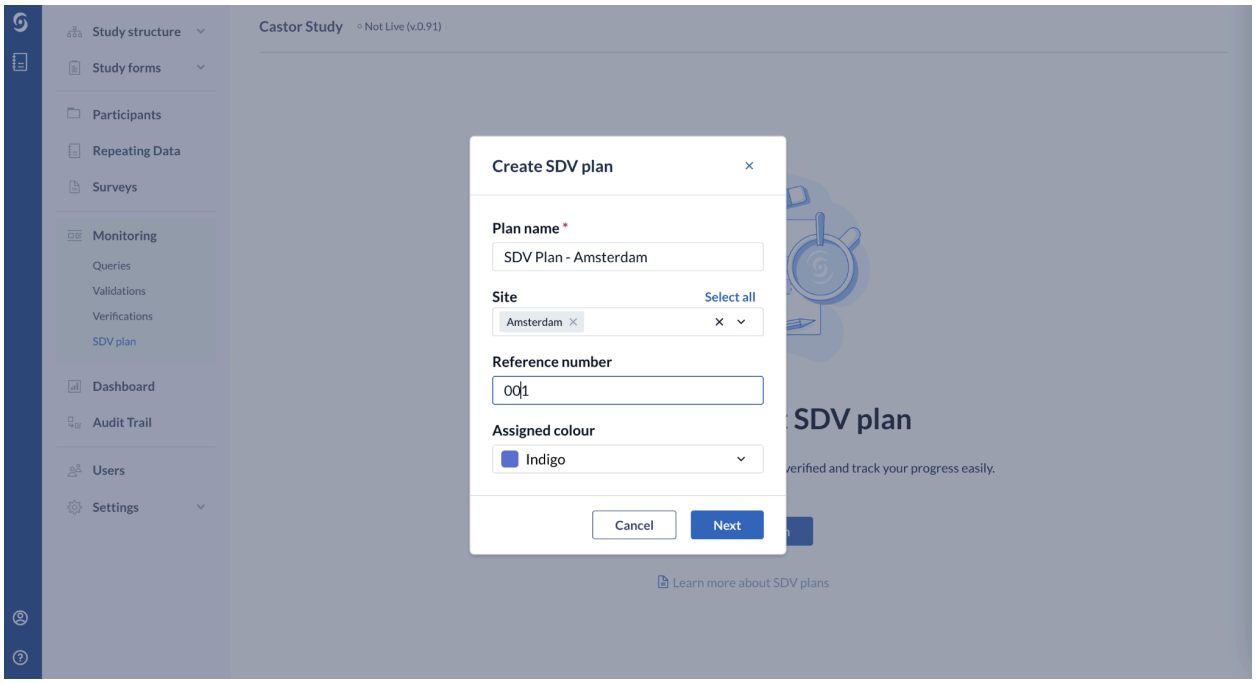
In Castor CDMS, it is possible for study admins to create SDV Plans and specify fields which require source data verification (SDV).

7.1. Building and using SDV Plans

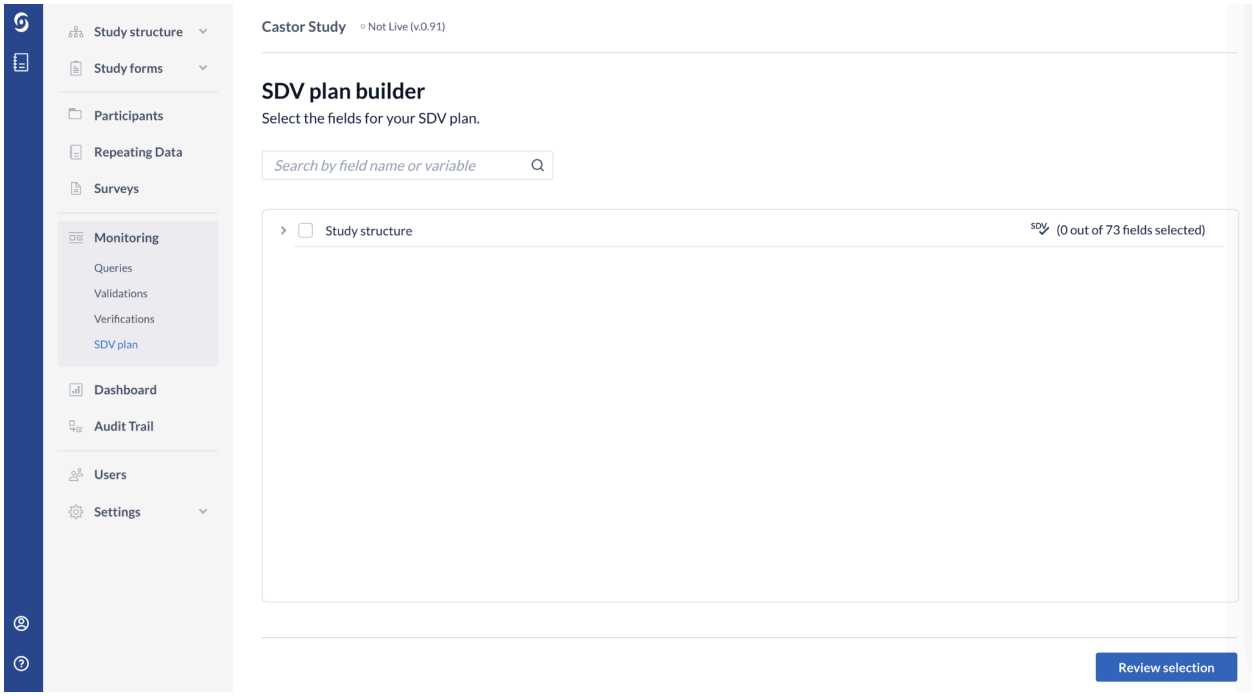
1. If you want to create an SDV plan for a new study, make sure that the Monitoring is selected in study Settings (Study properties).
2. Then, in the Monitoring tab go to 'SDV plans' sub-tab. Then select the 'Create SDV plan' button.



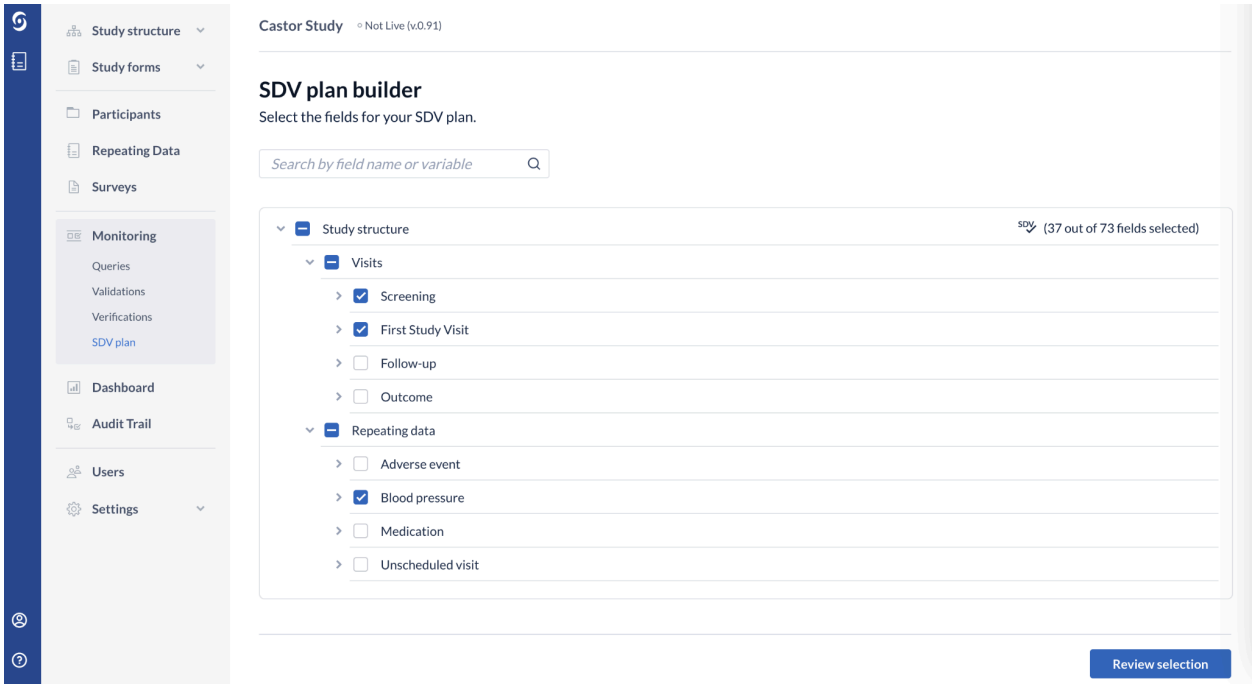
3. In a new pop-up window enter the plan's name and select the site, to which the plan will apply. Note, that only one SDV plan can be created for each site. Expand the list to select the site.



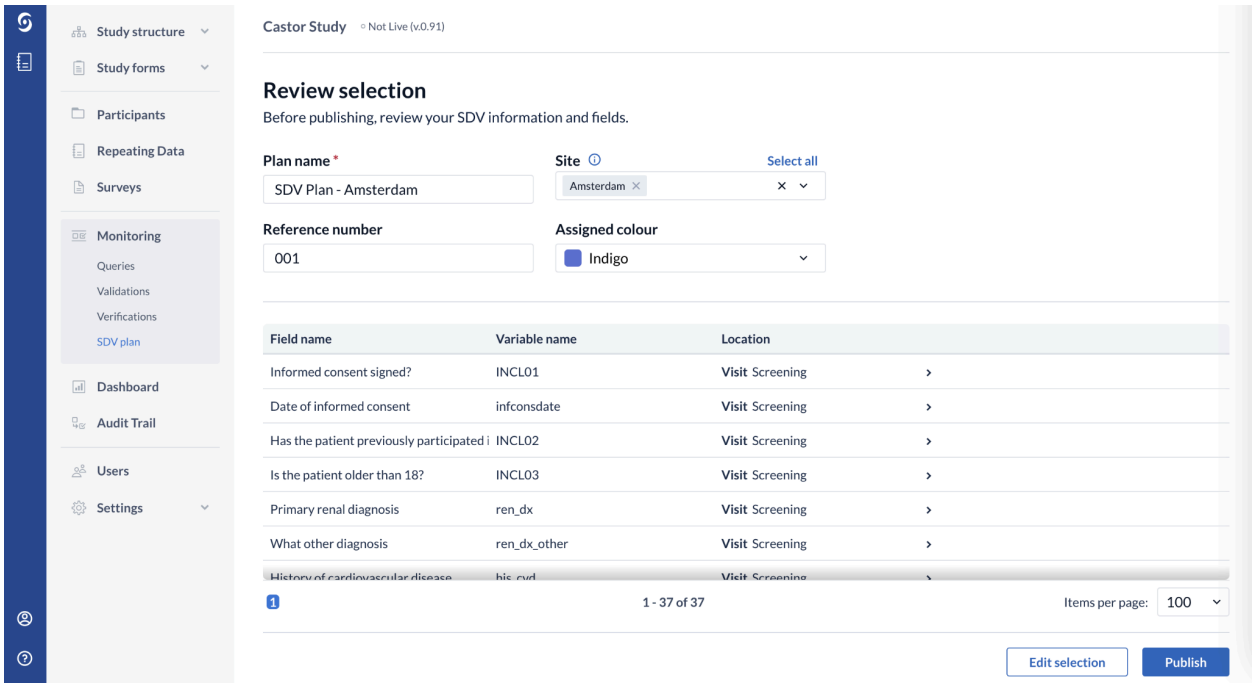
4. Click "Next" to proceed. Afterwards, you will be redirected to the SDV Plan Builder page:



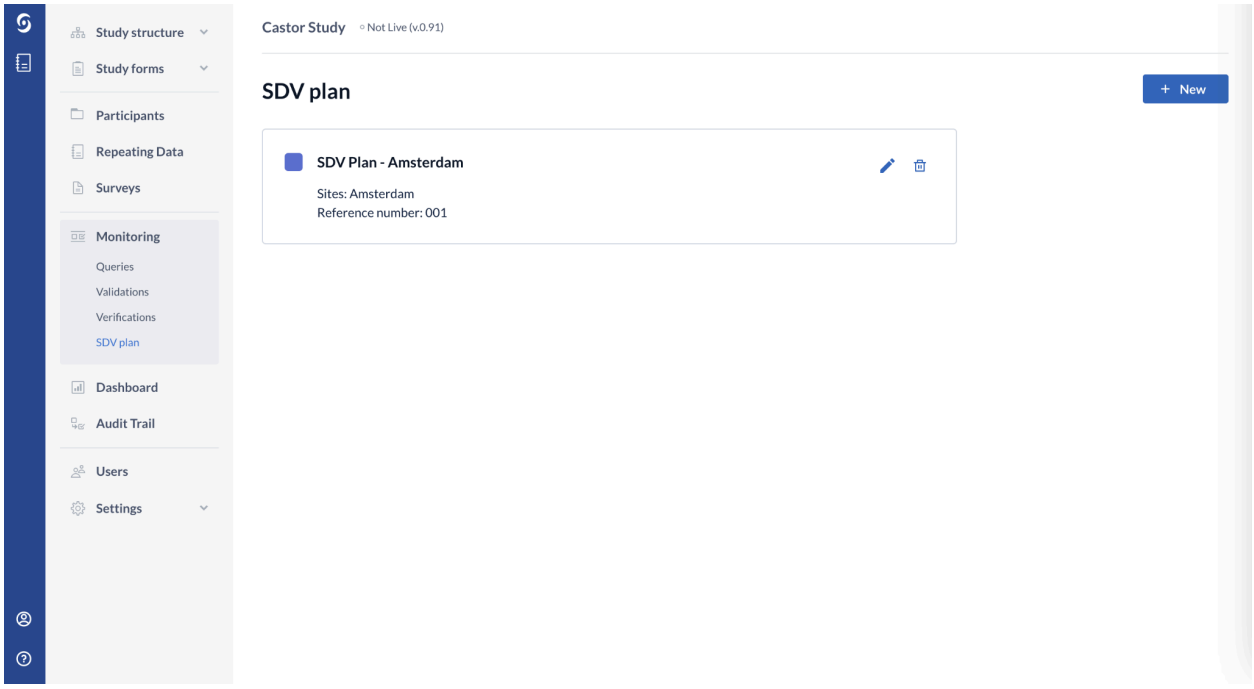
5. Select the fields for your SDV plan by using a search bar or by clicking on the study structure and manually selecting the fields for SDV:



6. Once the fields are selected, click on the "Review selection" button to proceed.
7. In the Review selection page, you will be able to review your SDV information and fields before publishing the SDV plan:



8. Click on "Edit selection" to return to the previous page and adjust the fields for SDV.
9. When ready, click the "Publish" button to publish the SDV plan. Once published, it will be shown in the "SDV plan" page:

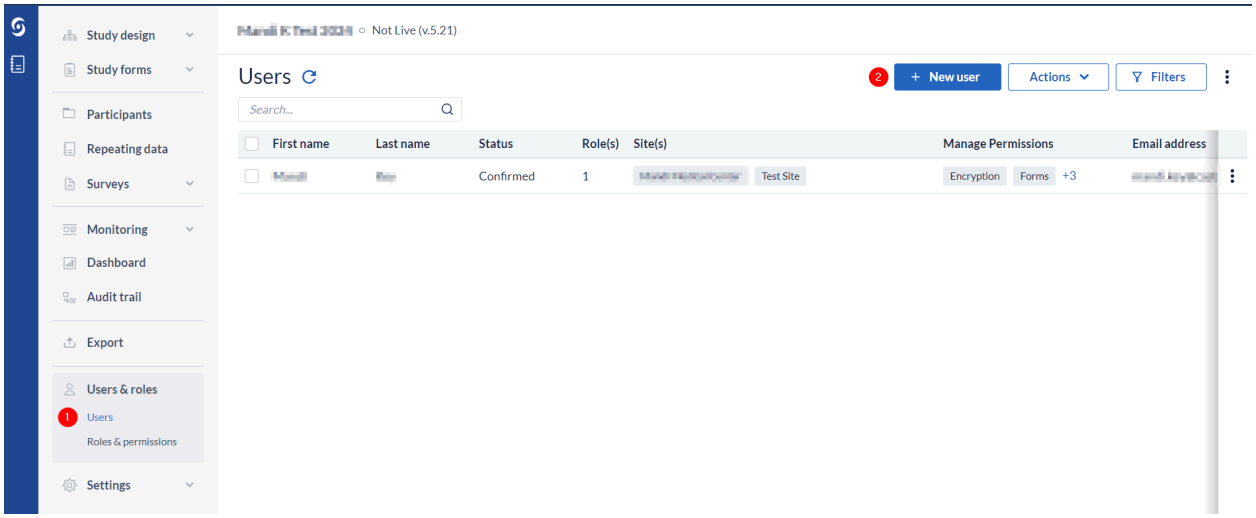


8. Manage Users in your study

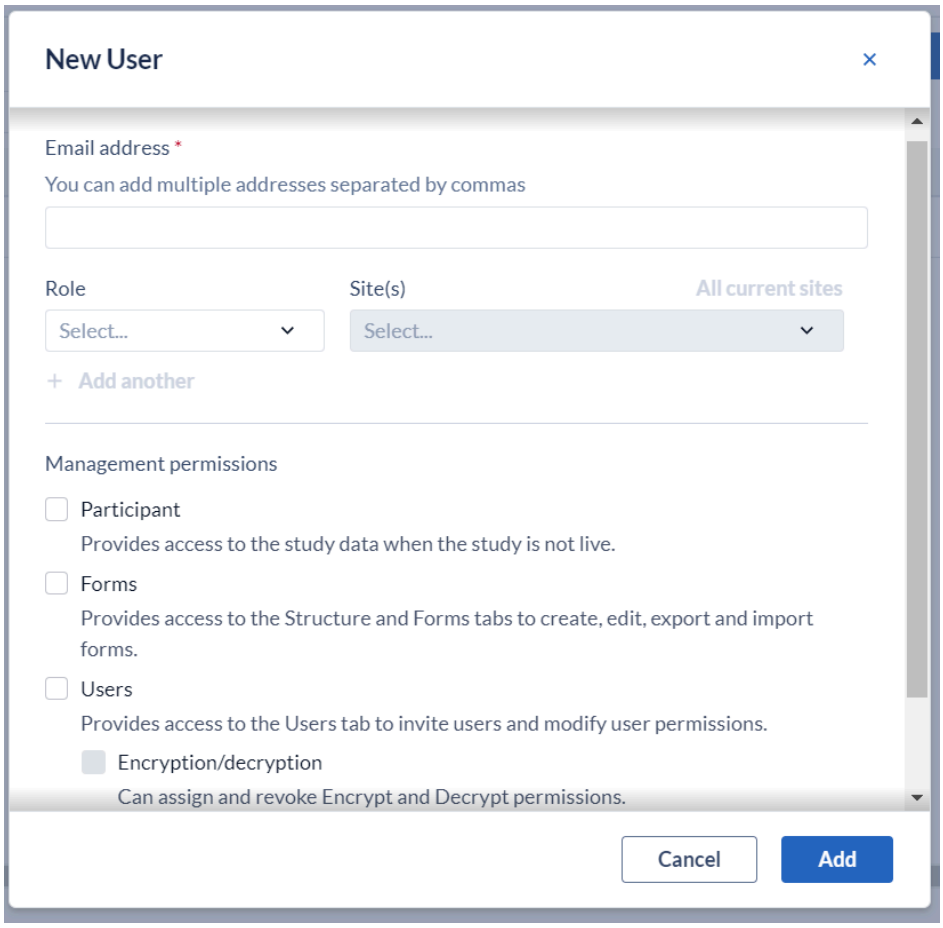
The 'Users' tab allows you to create and edit roles, add users to your study, and manage permissions.

8.1. Add a User

1. Navigate to the 'Users' sub tab under heading 'Users & Roles'.
2. Click on 'New user' to add someone to the study.



3. A pop-up will be shown. Fill in the user's email address and select the role and site(s) to which the user belongs. The new user can be granted selected roles to each individual site by selecting 'add another' in the role section on the New User popup. You can add multiple users at one time by adding each user email address separated by a semicolon

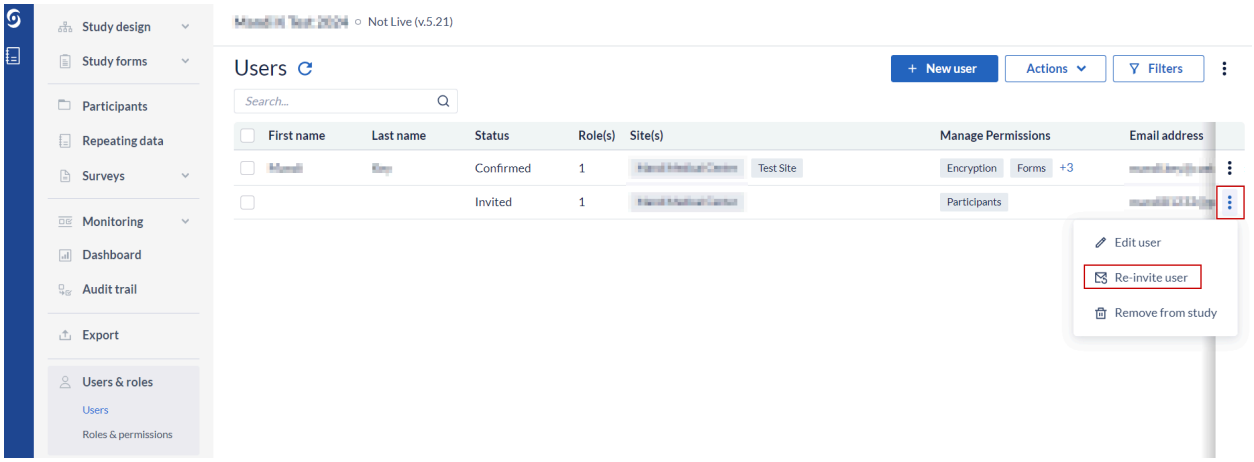


4. Select all applicable management permissions for the user
5. Click 'Add'

The added users will be shown in the Users sub 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 resend the email invitation you can click the three dots to the right of the user record and select 'Re invite

user'.



8.2 Define user permissions and roles

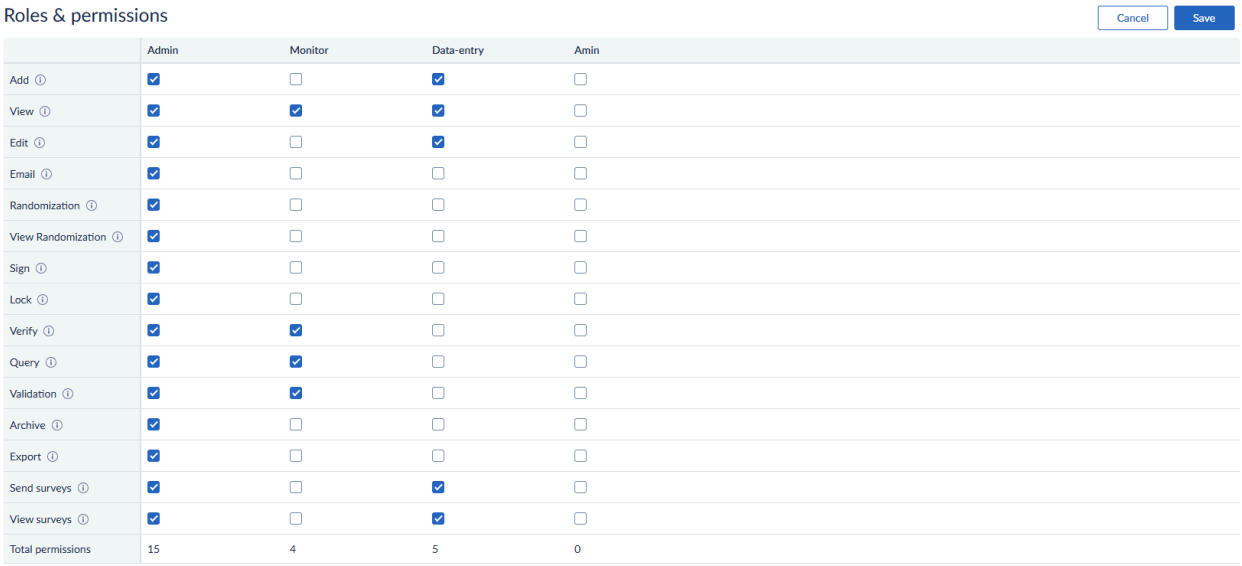
Permissions in Castor are assigned as roles, which means that a user can have different roles in multiple sites.

The 'Roles & permissions' page provides a complete overview of the current roles, but also it gives the possibility to the admins to create Custom Roles, which they can assign to users.
Three pre-existing roles are defined in Castor that reflect the common rights assigned to users:

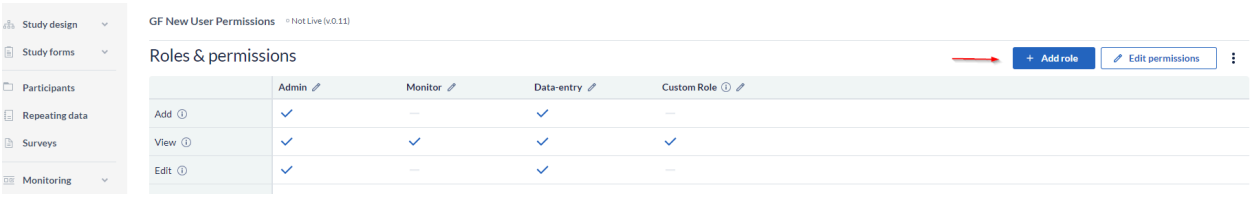
- Admin: has rights for most actions.
- Data-entry: only has rights to add participants, view them, and edit data.
- Monitor: only has rights to view data and create queries.

You can edit these existing roles by selecting the option to Edit permission (top-right corner) and checking or unchecking the right that you want to give or remove for one of the roles.

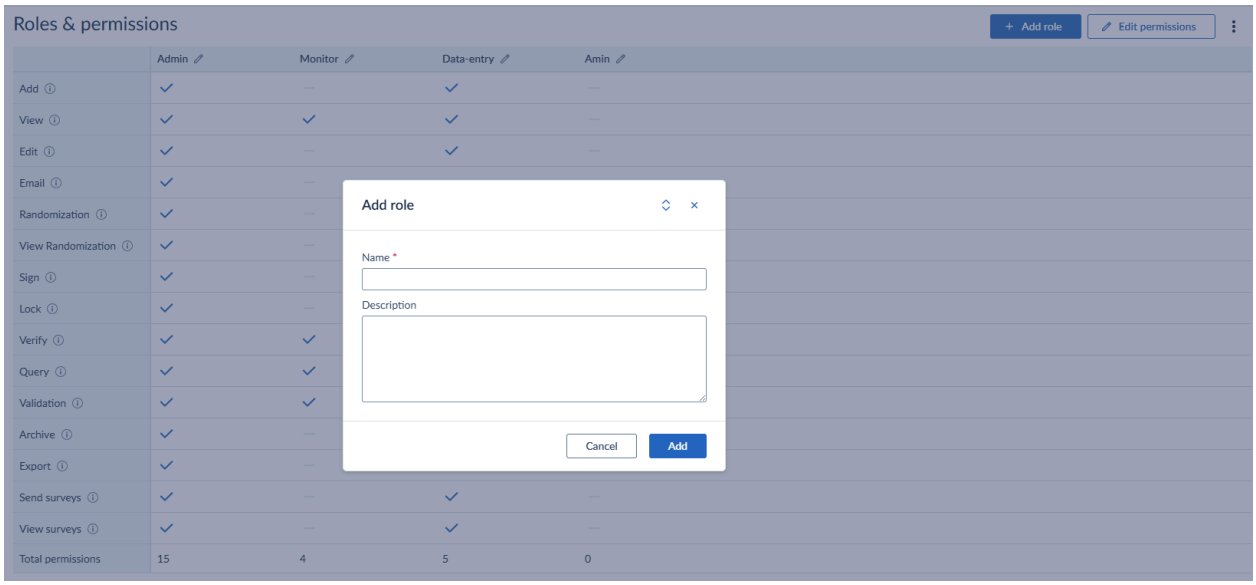
Save the changes, or discard.



You can also create new user roles by clicking on the '+ Add Role' button.



Specify a name in the popup and press 'Add' to create the role, but be aware that you need to assign the rights to your newly created role by selecting the rights.



8.2.1 Site permissions

Permissions 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 by assigning a User role to the user.

The participant permission per site are as follows:

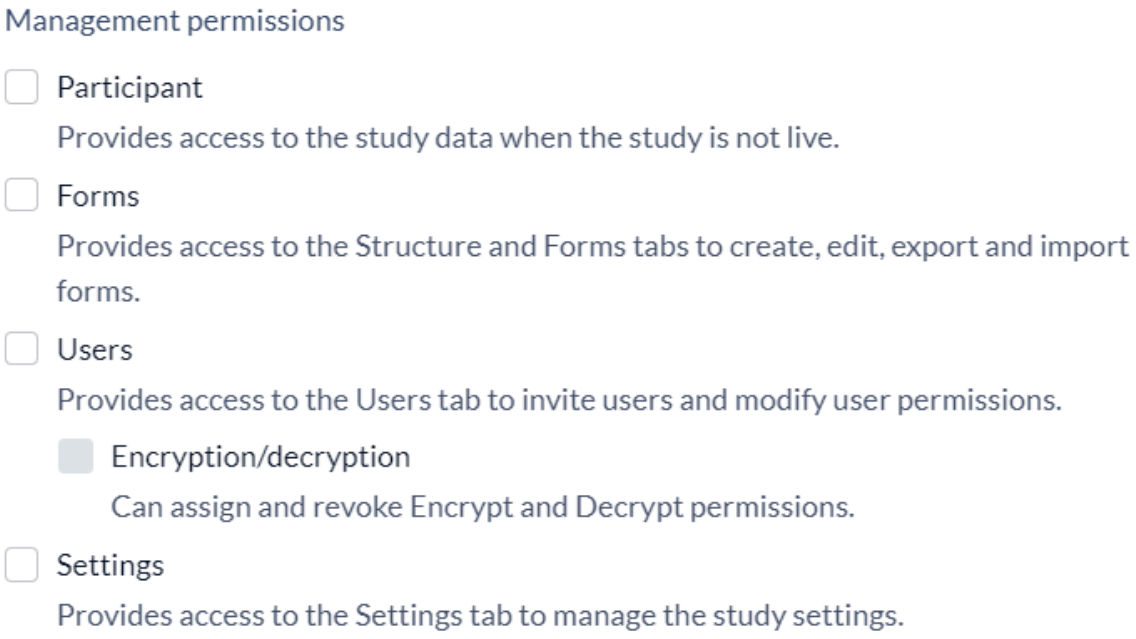
- **Add**: Allows the user to create new participants. To add a participant, you also need a 'View' right.
- **View**: Allows the user to view and print participants, view queries and comments and print participants.
- **Edit**: Allows the user to enter and edit data in a participant, import study and 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).
- **Validation**: Allow the user to review and resolve validations
- **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.

8.2.2. Management permissions

The management permissions are advanced rights for users that are managing the study (in contrast to only doing data entry).



The management rights are as follows:

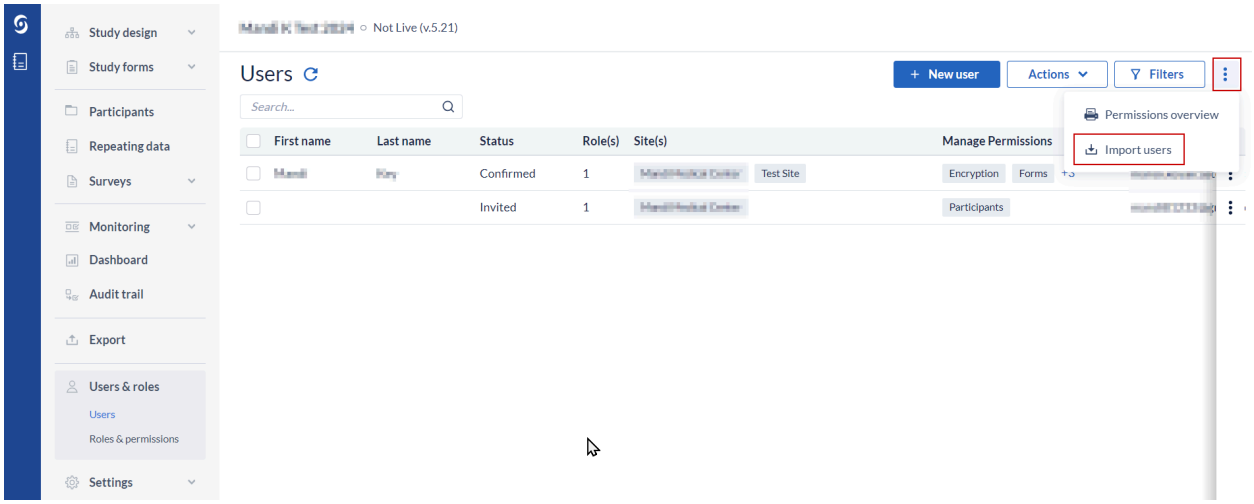
- **Manage participants**: Allows access to the participants, Surveys, and Statistics tabs. The exact data the user will have access to depends on the site permissions. For example, a user who needs to view the participants for site X will need to have 'Manage participants' permissions, but also 'View' permissions for site X.
- **Form**: Allows the user access to the Form tab.
- **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 permissions if the Encryption module is enabled in the Settings tab.
- **Note**: To be able to see the Audit trail, you need all management permissions.

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

8.2.3 Import Users

If there is a need to create many users within your study, these users can be imported into your study using the 'Import Users' option and uploading a CSV file. User rights and permissions can also be assigned to the newly created users via the 'Import User' function.

1. To Import Users select the three dots to the right of the 'Filter' and select 'Import Users'.

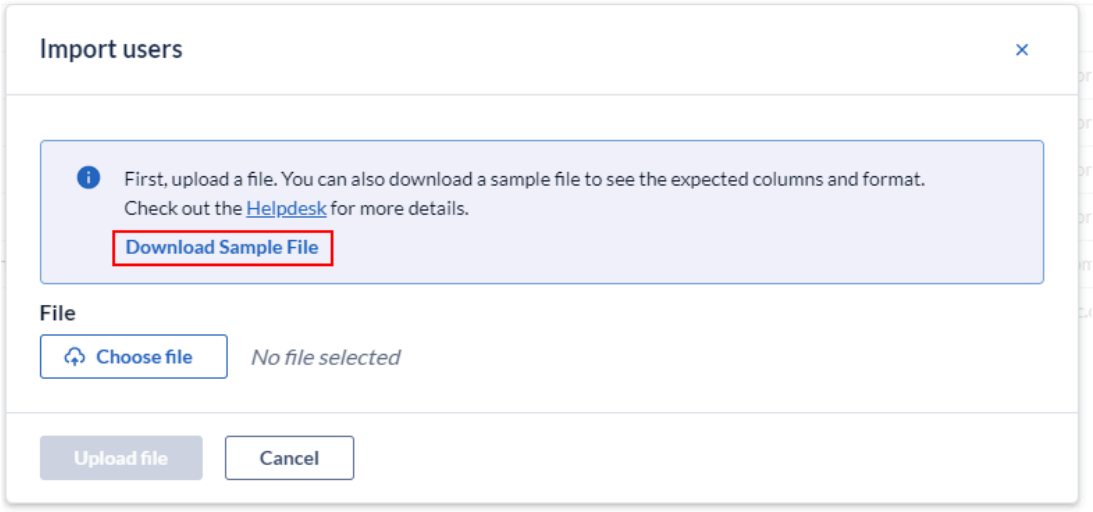


2. Upon selecting 'Import Users' a sample file can be downloaded that can be used to create your import.

Example of User Upload file:

	A	B	C	D	E	F	G
1	Email Address	Auth Mode	Invitation Message	Site Abbreviation	Role	Site Perm	Management Permissions
2	john@doe.com	native	Welcome to our stu	SIA	Admin		24
3	john@doe.com			SIB	Admin	1234	
4	jane@test.com	native		SIA			

3. Once the import file is ready, select 'Choose file' and then 'Upload file'.



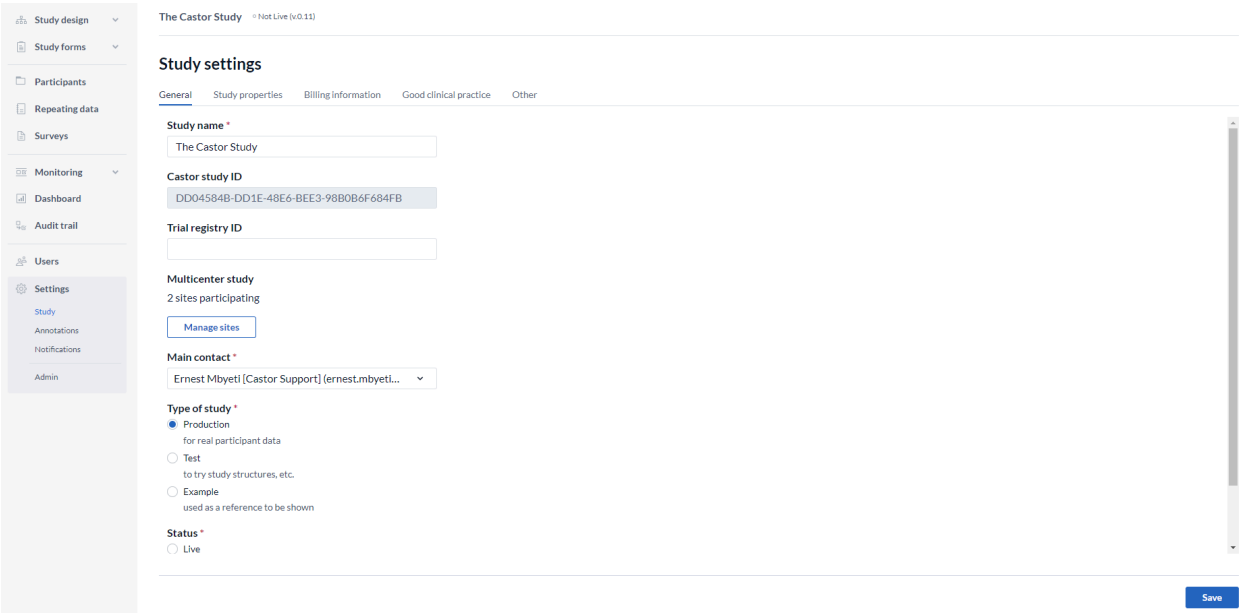
*There is a limit of 50 users that can be imported at one time.

9. 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, Billing Information, GCP, and Other. When you go live (i.e., before you start collecting data), the sections General, Study properties, Billing information and the user's profile of the main contact (the person setting the study to live) need to be fully completed.

9.1 General Settings

The first section is 'General':



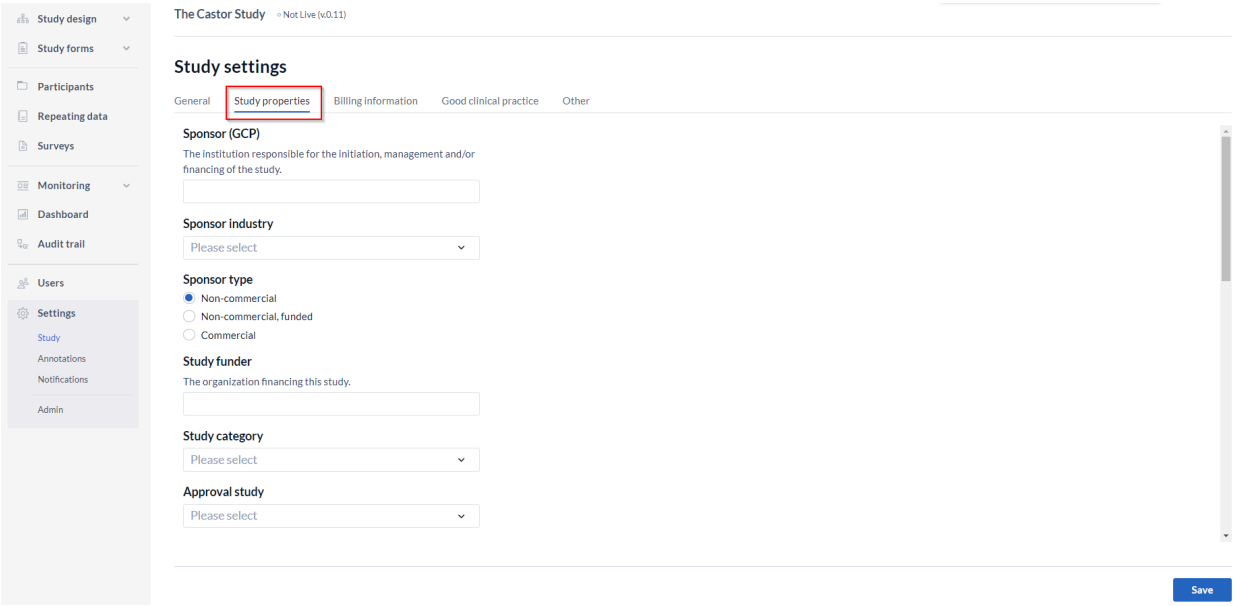
- **Study name**: the study name which is displayed on the homepage and above your forms during data entry.
- **Castor study ID**: unique study identifier which is automatically generated.
- **Trial registry ID**: ID of the trial registry your study is registered in (if applicable, e.g. clinicaltrials.gov).
- **Multicenter study**: manage participating sites and define custom date formats for each site. Site permissions 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 Production, Test or Example study. Use Production if you will collect real

patient/subject data in the study. Use Example study if you would like to familiarize yourself with the system.

- **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.

9.2 Study properties

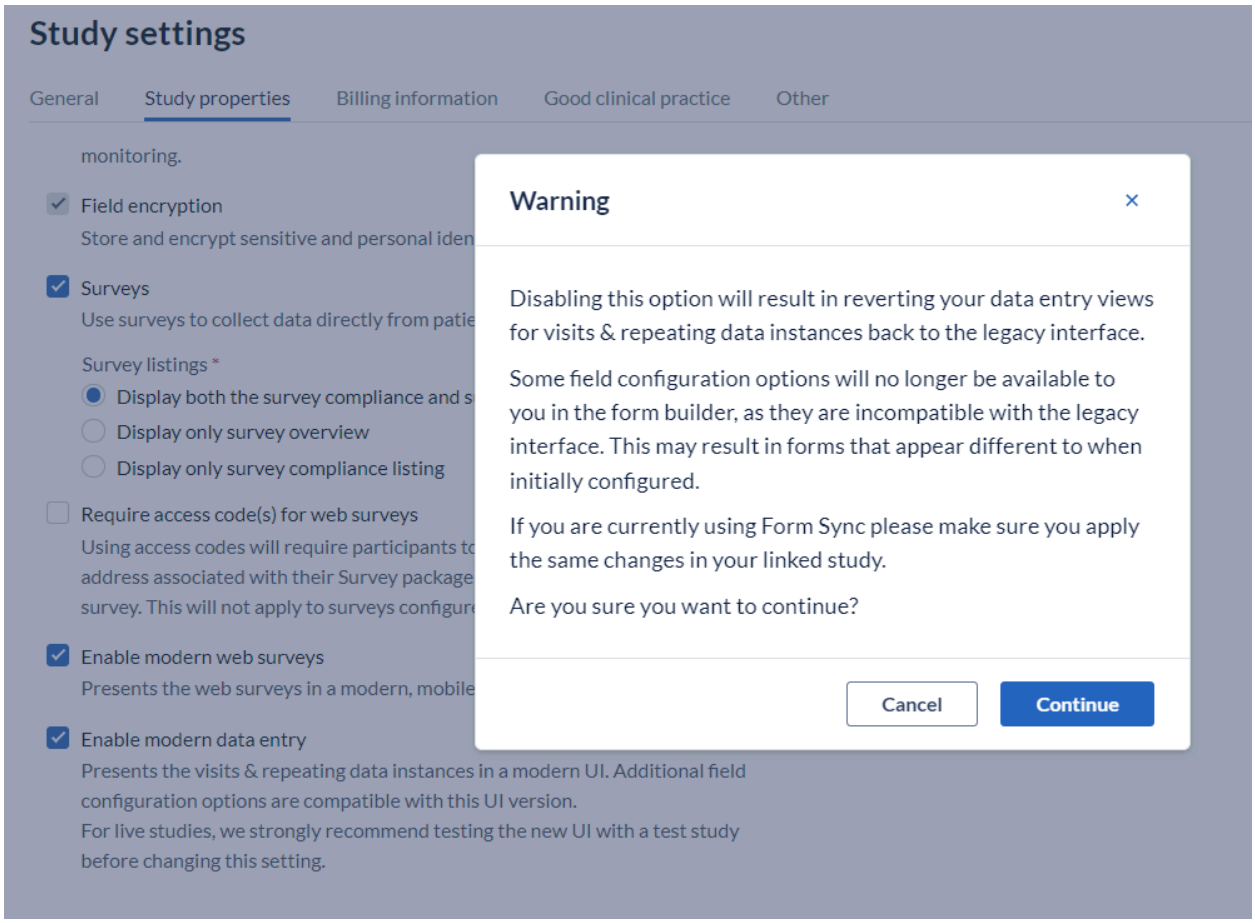
The next part contains all study details to determine the cost of the study:



- **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.
- **Sponsor type:** Specify if your study is a non-commercial , non-commercial funded 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 sites 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 (Randomize a participant in CDMS) and here (Randomization settings in CDMS).
- **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 and define the view for your surveys listing.
    - Survey listings
        - Display both the survey compliance and survey overview listings
        - Display only survey overview
        - Display only survey compliance listing

- **Enable modern web surveys**: Presents the web surveys in a modern, mobile-friendly UI. Available for studies created before the release 2024.2. In new studies the option is auto-enabled.
- **Enable modern data entry:** In studies that were built before the release 2024.2 the option is available. It allows users to see and try out the new interface on their study. A dialog is present when a user disables this, reverting the study's interface back to the legacy views.

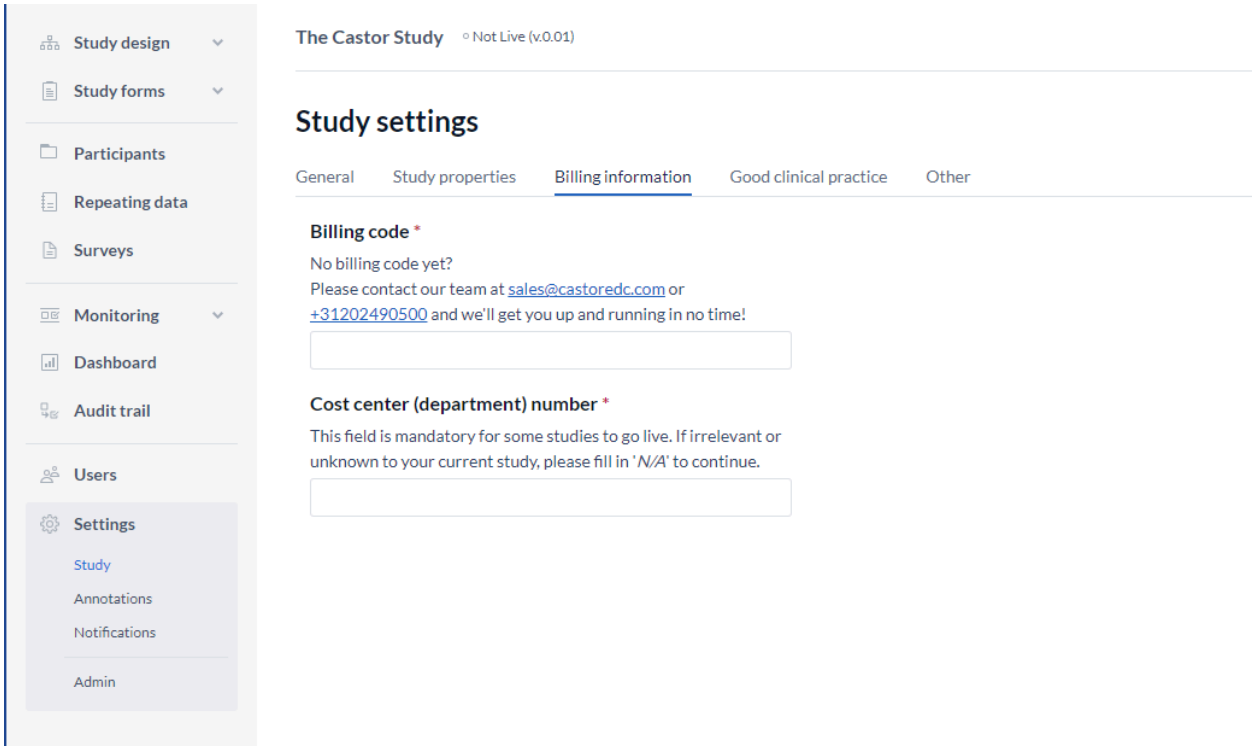


- **Field Encryption**: Select if you will use encryption for your study. If selected, you will be able to encrypt select fields.
- **Require access code(s) for web surveys:** Enabling web survey access codes means that whenever your participant navigates to a web survey that has been sent, they will be required to enter an access code. This access code is sent automatically to the associated email address when a user navigates to the access code screen

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

9.3 Billing information

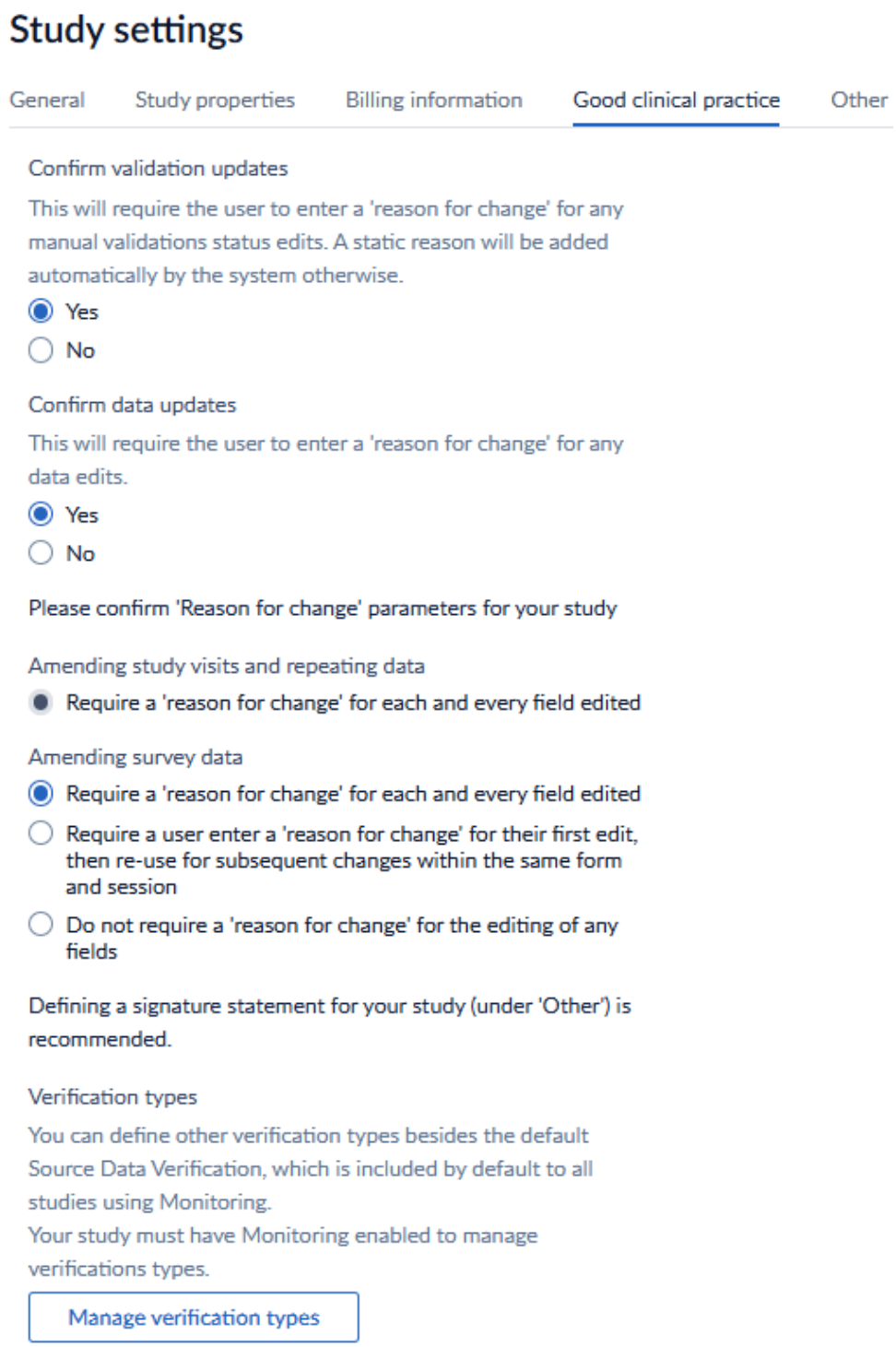
Enter the Billing Code of the study to go live . Please specify the ‘department number’ to ensure the invoice gets declared for the right department:



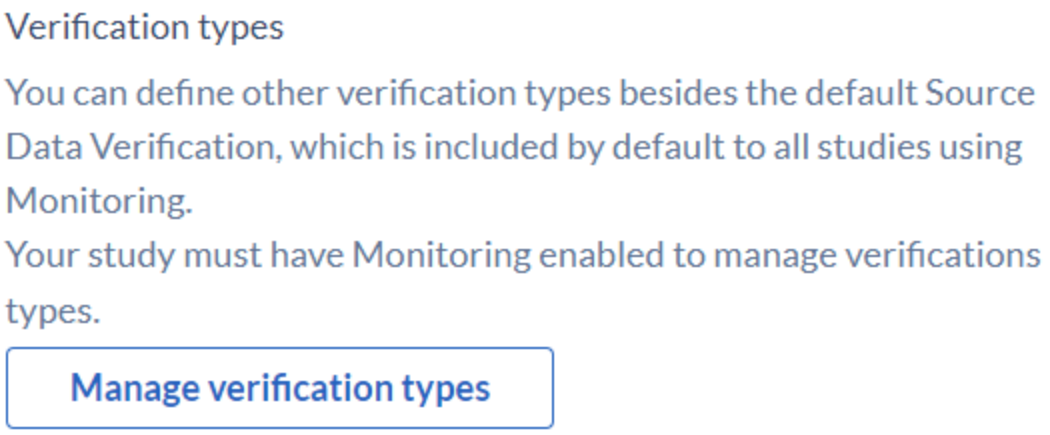
Billing Code: Here you insert your billing code. If your organization has a site contract, you may contact your local Clinical Trial Unit (site/organization Research Department) to request the billing code. The Billing Code may also be found on the intranet page of the site, where applicable.

9.4 Good Clinical Practice

You can choose whether to enable GCP for your study:



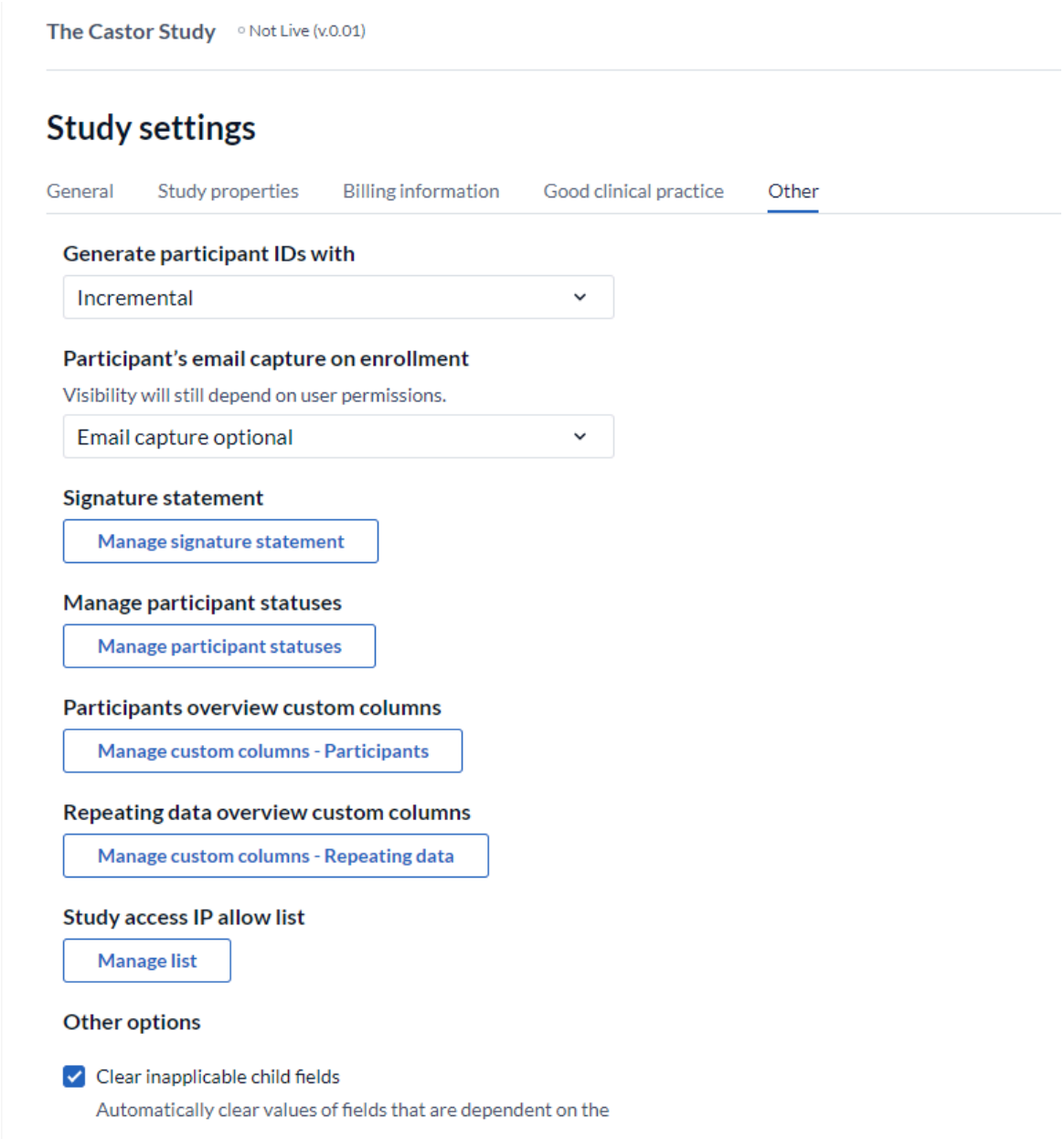
"Confirm validation updates" setting in the 'Good Clinical Practices' tab - enabling this study setting will require a reason for manual validation status edits and will add a static system generated reason for any automatic changes of the validations status (i.e. when a validation is auto-closed after a value update event). This setting is going to be enabled by default for all new studies, created after the release 2025.2.0.0, but kept disabled for the studies created before that release, to prevent any workflow disruptions. Studies created before the release 2025.2.0.0 can opt in by simply toggling it on, as it enhances traceability.



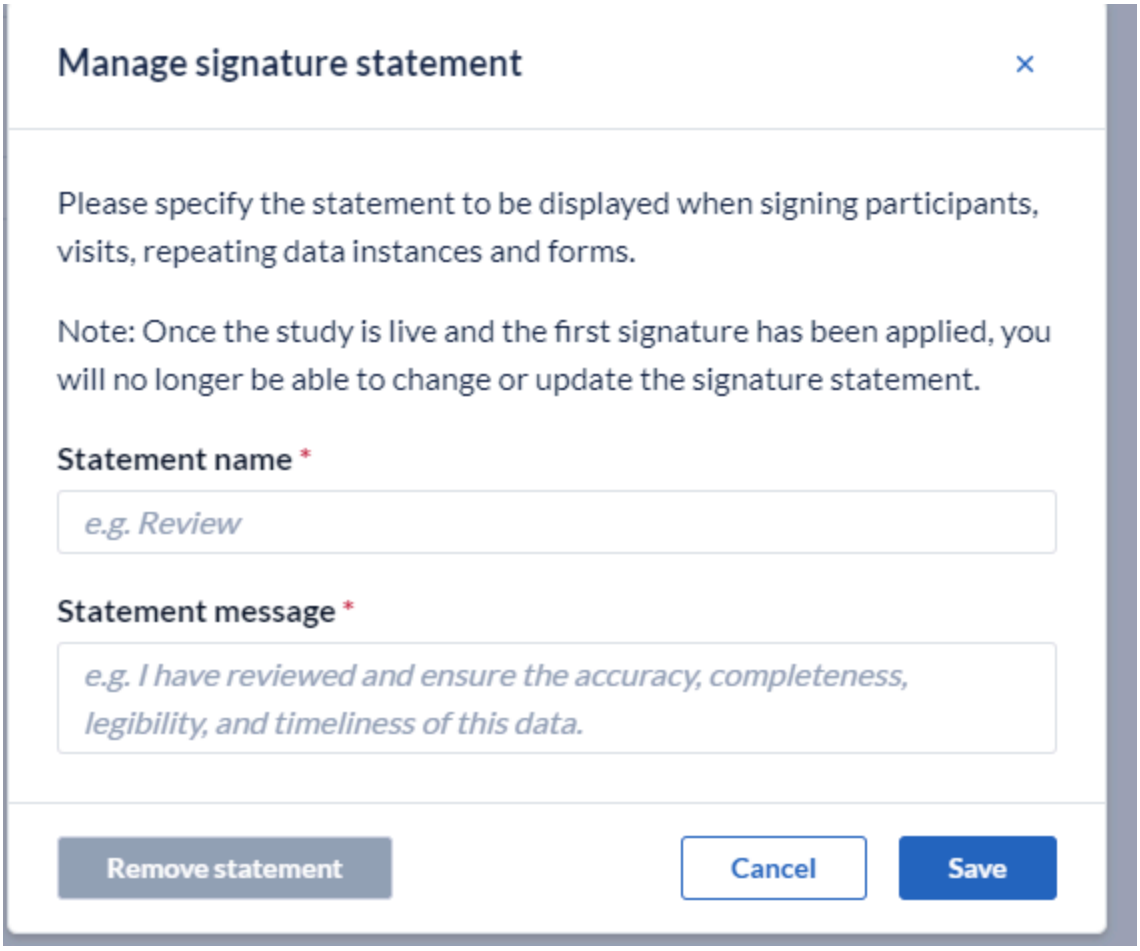
- **Confirm changes**: If you are using the extra GCP features, you can choose to enable the 'Confirm changes' functionality. This will require the user to enter reasons for changes that are made to the data according to GCP requirements.
- **Reason for change:** If you have selected to confirm changes you will then be able to select parameters for Reason for change, either require reason for change for each change event, first change event within timeframe, or no required reason for change.

- **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.

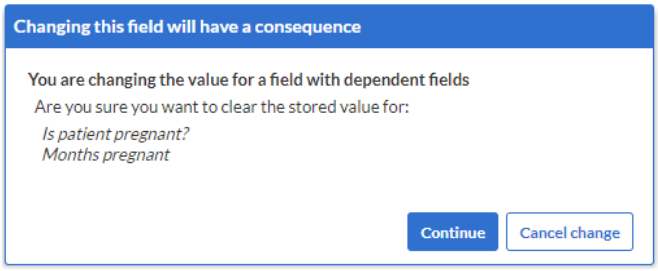
9.5 Other



- **Participant IDs**: Choose how you want IDs for new participants to be generated. You can Customize participant's ID's in CDMS by selecting 'Custom definition'.
- **Participant's 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 permissions.
- **Manage 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 statuses:** This option allows you to create, edit, and delete The Participant Status in CDMS.
- **Manage custom columns - Participants**: Add and delete custom columns to the participants tab.
- **Manage custom columns - Repeating data**: Add and delete custom columns to the global repeating data tab.
- **Study access IP allow list**: Whitelist a range of IP addresses in CIDR format. The study will then be accessible from the IP addresses on the list only.
- **Clear inapplicable child fields**: When enabled, 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.



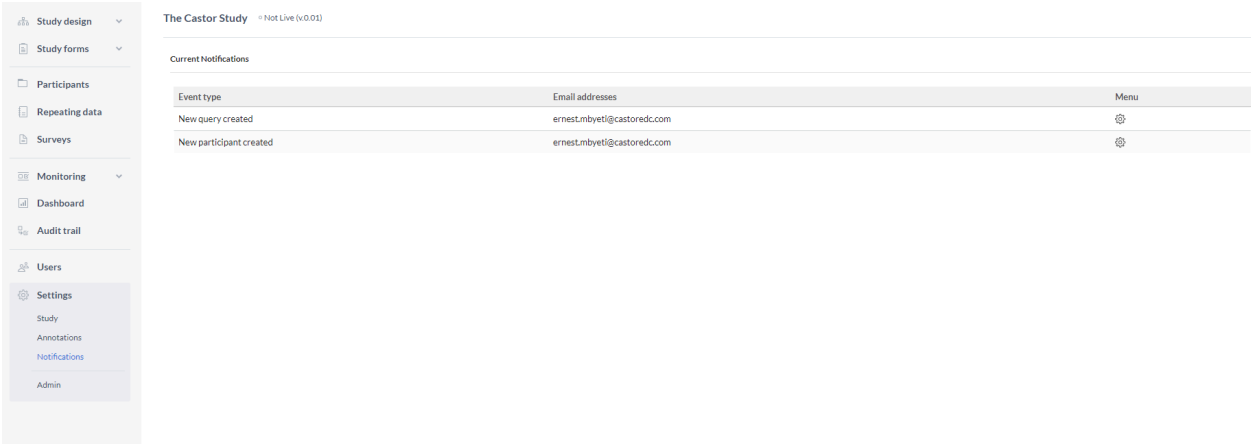
This setting is only for study forms and repeating data. In surveys, inapplicable child fields are always cleared, regardless of this setting. Changing this setting after you have started the collection of data will not clear inapplicable fields retroactively.

- **Enable the Automation Engine (beta)**: 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.
- **Display repeated measure instances in visit navigator**: allows showing the repeating measurement instances in the visit navigator for each participant

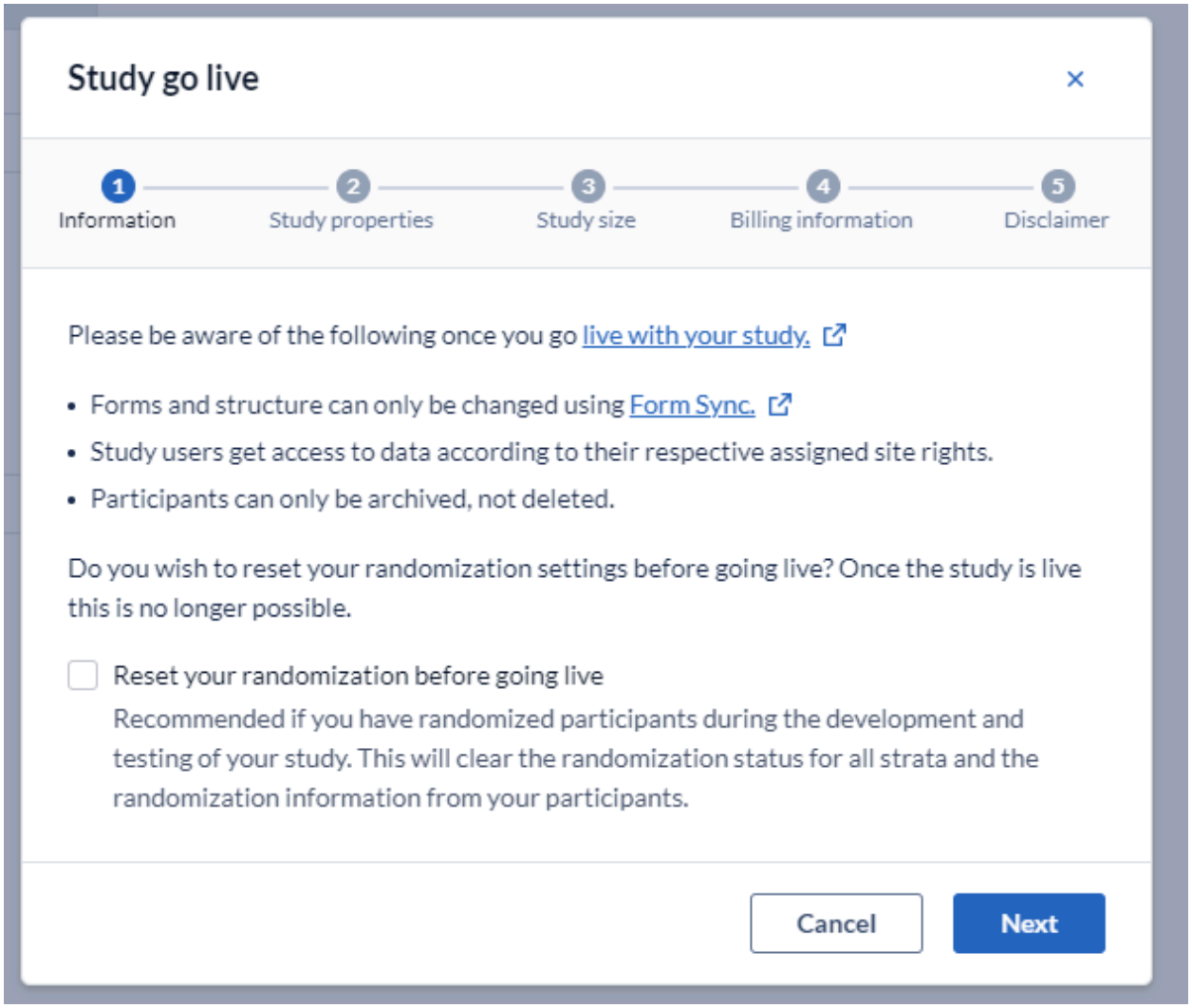
9.6 Notifications

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 (Notifications for study events in CDMS) or edit existing ones:



9.7 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 tab, 'General' section and find the field 'Status' and select 'Live'. Before going live, you need to fill in the fields for 'Study properties' , 'Study size', 'Billing information'. Please consider the following consequences:



1. Setting your study to 'Live' has some implications, please refer to the article 'What does "going live" mean in CDMS?' for more information.

2. Reset your randomization before going live: Recommended if you have randomized participants during the development and testing of your study. This will clear the randomization status for all strata and the randomization information from your participants.
3. 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.
4. 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.

10. Requesting and downloading exports via the API

There are three new API endpoints to request, monitor, and download exports. More information can be found in the API documentation (Castor EDC/CDMS Application Programming Interface (API)).

- **POST /study/{study_id}/export**: This endpoint allows you to submit export requests by specifying the desired export types, formats, filters, and options. Please note that this endpoint is currently in beta and will be improved over the coming releases. Implementation details may change.
- **GET /study/{study_id}/export**: This endpoint allows you to view the status of previously requested exports.

- **GET /study/{study_id}/export/{id}/download**: This endpoint allows you to download completed exports.

11. Further Information

If you would like to view our Castor CDMS video tutorials, you can do so on Castor Academy.

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