Castor

Castor eConsent Organization Admin User Guide

Version 2023.2

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1. Introduction

An organization admin role makes it easier to manage studies within your organization. While all other roles in eConsent are tied to one specific study, this role is set on an organization level and allows to create and manage studies for an organization.

Here is a brief overview of the organization admin role:

- Study team members with an organization admin role can create studies for an organization by using the 'Create new study' button on the study overview page.
- In case the study team member is an organization admin for multiple organizations, the study team member can choose the organization that is associated with the study.
- Study team members with an organization admin role can view all studies from their organization(s) and access them with permissions identical to the study admin role.
- Within the study overview, users can use a search bar to find a study.

2. Obtain access

To begin using Castor eConsent, you must first obtain access. Contact the Castor support team (support@castoredc.com) and express your interest in using eConsent for your study and provide the following information in your request:

- Organization Name: Provide the name of your organization or institution. This ensures that your study is properly associated with your entity.
- Email Address for the Admin Account: Specify the email address that will be associated with the admin account in Castor eConsent. Ensure that this email address is accessible and will be actively monitored by the person responsible for managing the eConsent process.
- Country: Indicate the country where your organization is located. This information is essential for regulatory compliance purposes.
- Region for Information Storage: Choose the region where you would like your eConsent data to be stored. Castor offers options for data storage in the European



- Union (EU) or the United States (US). Consider any data protection or residency requirements when making this selection.
- Integration with Landing Page or Enrollment Portal: Inform Castor if you plan to integrate eConsent with a landing page or enrollment portal. This allows for a seamless participant experience and streamlines the enrollment process.

The Castor Support team will process the request and invite you to the eConsent platform as an Organization admin.

3. Register an account

Invited users will receive an email with a link to access the eConsent platform:



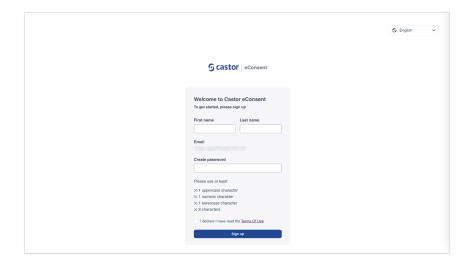
You've been added to a new organization in **eConsent**

You have been added as an Organization Admin for 'Castor Support' in Castor eConsent.

Please log in to create and access studies under that organization.

Log in

You will then be directed to the registration page:



You will need to accept the Terms of Use and provide the following details when registering the account:

- First name
- Last name
- Email will be automatically pre-filled
- Create password

After filling out the details and accepting the Terms of Use, click on the 'Sign up' button to complete the registration.

Should you already have an account registered in eConsent, you will be directed to the eConsent login page where you can log in with your eConsent credentials.

4. Log In

In order to access the eConsent platform after registration has concluded you will need to access the following url's bases on the location of your study, US or Europe:

- US eConsent https://us.castorconsent.com/
- EU eConsent https://eu.castorconsent.com/

Study data is only stored on one of these servers and only one server location can be accessed at a time. If you do not see any studies listed please make sure to check our other server location.

You can toggle between the two study locations by selecting the Europe or USA icons at the top of the page.

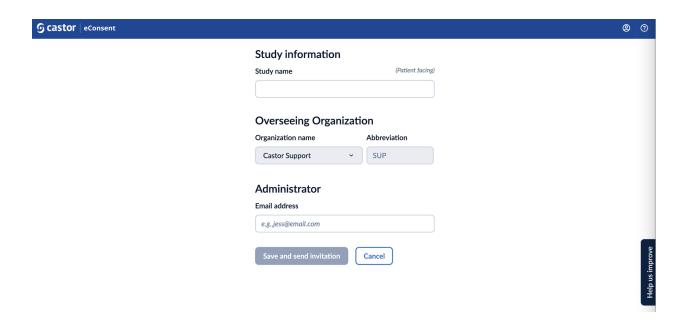
5. Create a study

After logging in, you will be redirected to the 'Studies' overview page from which you can create a new study and see all existing ones.

1. To create a new study, click the 'Create a new study' button:



- 2. Provide the study details:
- Study name (patient facing)
- Organization name (will be prefilled)
- Abbreviation (will be prefilled)
- Email address: Enter the email address of the study administrator

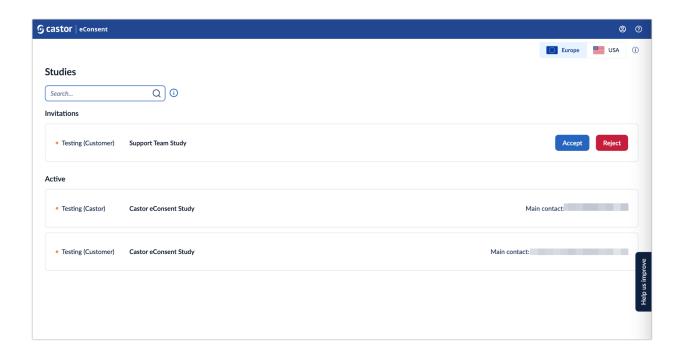


- 3. Press the 'Save and send invitation' button to create a study and send an invite to the study administrator.
- 4. You will be redirected to the 'Settings' tab of the newly created study.

6. Open a study

After logging in, the 'Studies' overview will be displayed with two sections, 'Invitations' and 'Active'. The 'Invitations' section will only appear if you have been sent an invitation and have not yet accepted or rejected the invitation.

Before accessing any studies you will first need to accept the invitation by pressing the 'Accept' button. Rejecting the invitation cannot be undone and you will need to contact the study admin to request a new invite.

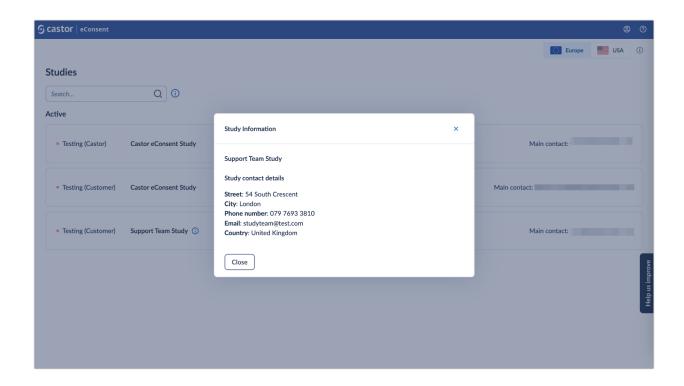


Studies overview consists of the following elements:

- Servers: Here the data storage locations are displayed. There are two server locations available: Europe and the United States. Study data is only stored on one of our servers and only one server location can be accessed at a time. If you don't see any studies please make sure to check a different server location.
- Search bar: it is possible to search by organization name, study contact email address or study name
- Invitations: If you are invited to a study, but you have not accepted the invite yet, the study will be listed in the top panel. It is possible to either accept or reject an invitation to a study. Once you have accepted the invitation, you will be able to open a study.
- Active: once you have accepted an invitation to a study, it will appear in the 'Active' list. The list displays all studies you have access to. For each study, the following information is shown:
 - Status: Testing (Castor), Testing (Customer), Live. Read more about what each status means in the article: Study status in eConsent
 - Study title: name of the study
 - o Main contact: main contact of the study. If the main contact has been invited to the study, but have not accepted the invitation yet, the status will be 'Main contact invited'



Study information: by clicking on the(i) icon, it is possible to view additional study information

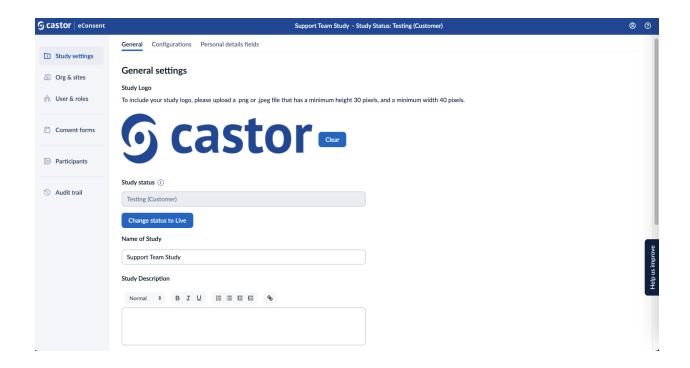


Studies for which an invitation has been accepted will appear in the 'Active' section and it is possible to access the study by clicking on the study row.

7. Setting the study to 'Live'

Only users with the 'Organization admin' and 'Study admin' role can set the study to 'Live'.

Use the Study settings tab, General settings subtab to change the status of your study.



The **Study status** field displays the study status information. Each study progresses through the following statuses:

- Testing (Castor): The study is being tested by Organization admin. Audit trail events during this study status are marked with the status 'Testing (Castor)'.
- Testing (Customer): The study has passed the quality checks by Organization admin and is handed over to the Study Admin to perform User Acceptance Testing (UAT). Audit trail events during this study status are marked with the status 'Testing (Customer)'.
- Live: The study has passed the quality checks by Organization admin and UAT by the Study Admin. All the participant records that were created during both 'Testing' study statuses are automatically archived. Audit trail events during this study status are marked with the status 'Live'.

Once the study status has been changed, it is not possible to revert to the previous status.

8. Further Information

Please check the Study admin user manual for all study-related management activities: Castor eConsent Study Admin User Guide 2023.2

If you would like to view our Castor eConsent video tutorials, you can do so here.

For more information regarding creating and managing study, please check Castor EDC's knowledge base: Castor eConsent Knowledge Base. If you have any questions or concerns, please contact us at support@castoredc.com