cr.gdpr

EUCROF GDPR Code of Conduct for Service Providers in Clinical Research

Platform user guide for CROs

EUCROF
European CRO Federation

Contents

Introduction

This guide is for service providers in clinical research (CROs) who want to submit an application to demonstrate adherence to the EUCROF GDPR Code of Conduct for Service Providers in Clinical Research (the Code).

The guide sets out the different steps in the process with instructions on how to complete the application process.

If you need help with any aspect of the process, please contact the Risk and Compliance Officer (RCO): rco@crgdpr.org

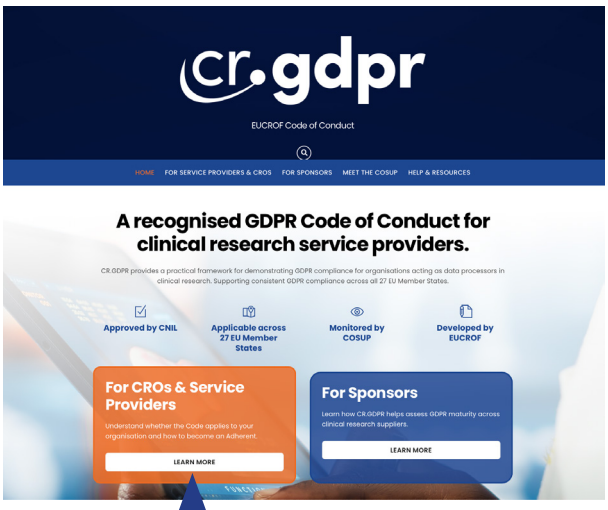
Where to find the platform

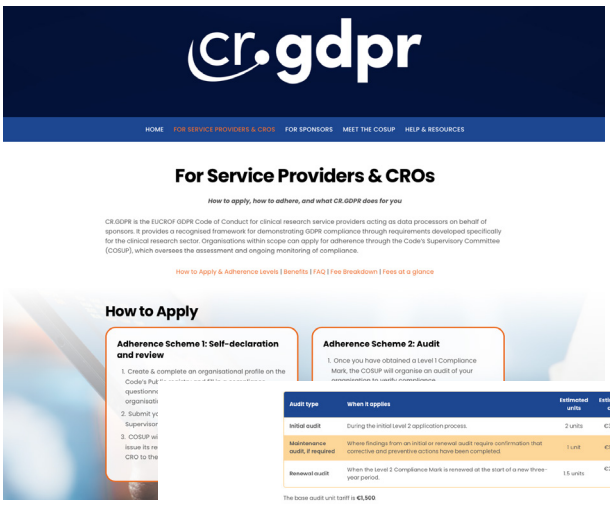
1: The URL for the home page is: https://cro.eucrof.eu

From this page you can either log in if you have already registered / submitted an application, or you can start the process of registering and submitting an application.

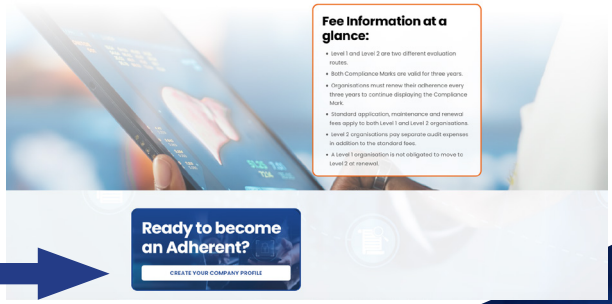
2: On the CR.GDPR website here: https://crgdpr.org/

> Click on 'CROs and service providers'.
> Scroll down the page and click on 'Ready to become an adherent?'
> This link will take you to the platform homepage.



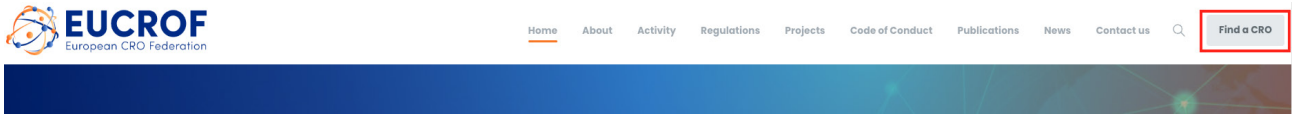


CRO's and service providers

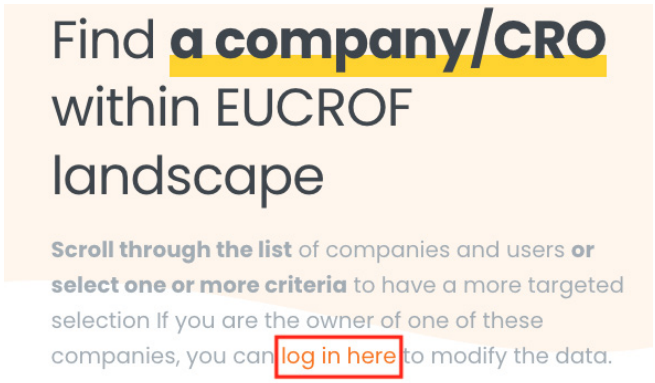


CRO platform

3: From the EUCROF website here: https://eucrof.eu/
> Click on 'Find a CRO'.



> Click on 'Log in here'.



> This will take you to a screen where you either log in if you have already registered / submitted an application, or where you can start the process of registering and submitting an application.
https://cro.eucrof.eu/login

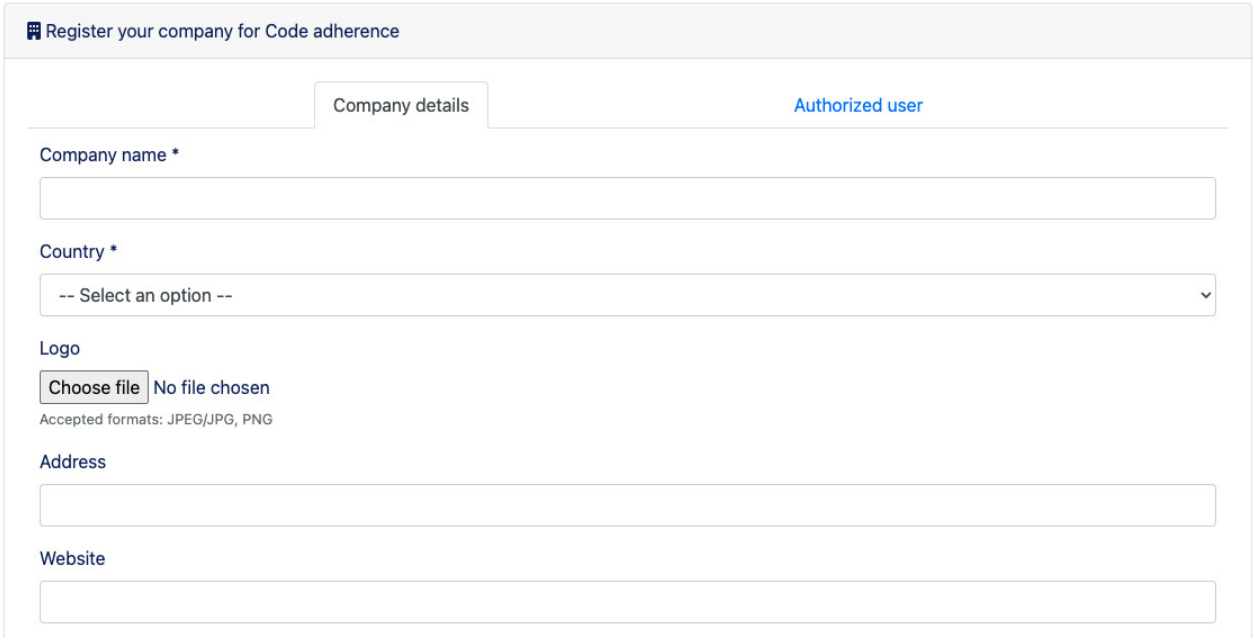
Registering your CRO

Click on 'Adhere to the code of conduct' to get started.

Company information

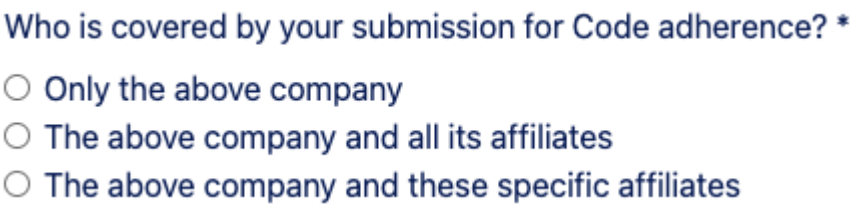
The first step is to register your company. You will need to enter the following information.

- Company name
- Country
- Logo (optional)
- Address (optional)
- Website URL (optional)



Who the submission covers

We then ask you who your submission covers. If you tick 'The above company and these specific affiliates' a free text box will appear for you to specify which affiliates.

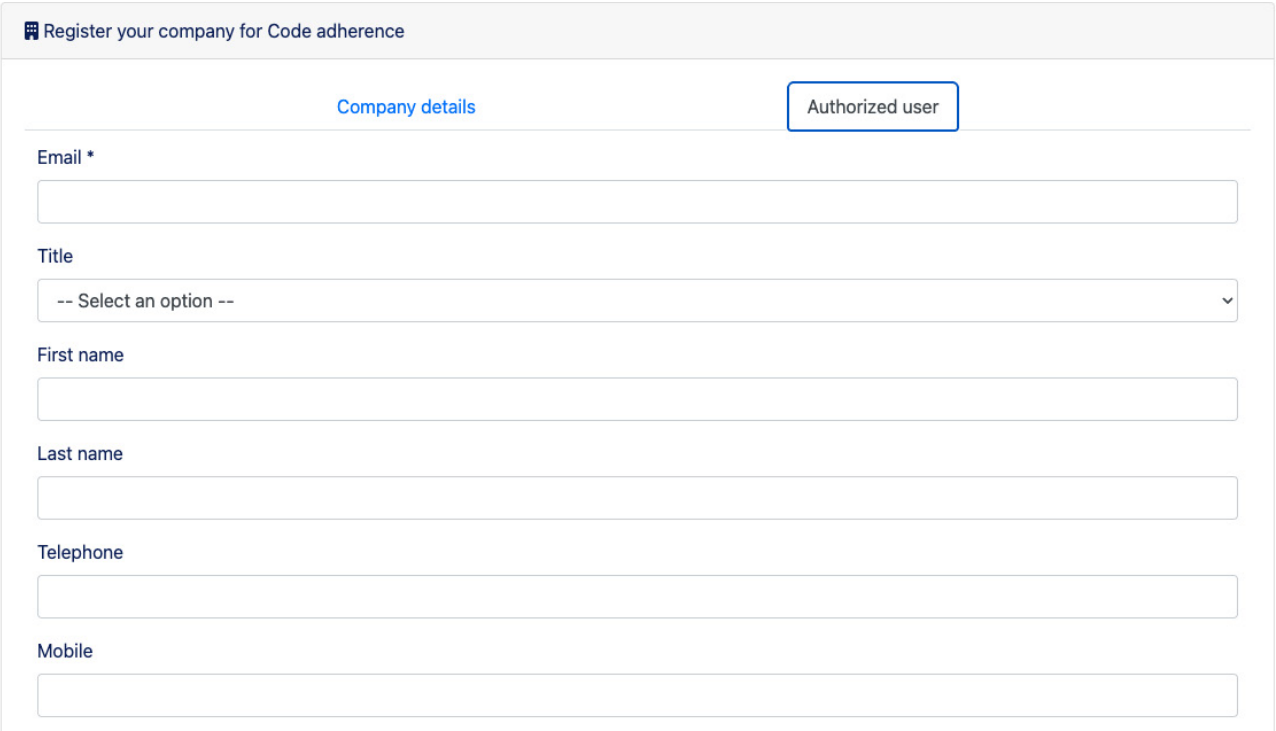


Click 'next' to move to the authorised user information page.

Authorised user information

Now you need to provide the following information for the main authorised user. This is usually the person doing the submission, and the key contact at the company for the submission.

- Email
- Title
- Name
- Phone numbers



If your company has already been registered you will get a message to tell you this.

The authorised user will get an email with an initial password to access the platform. This user will then be able to access the company profile and start the submission process.

You will be immediately asked to change your password.

To log into the platform click 'Login' in the top right corner of the platform home page.

Company information page

This page contains all the key information for the company. It also lists any documents sent or received. From this page you can do the following.

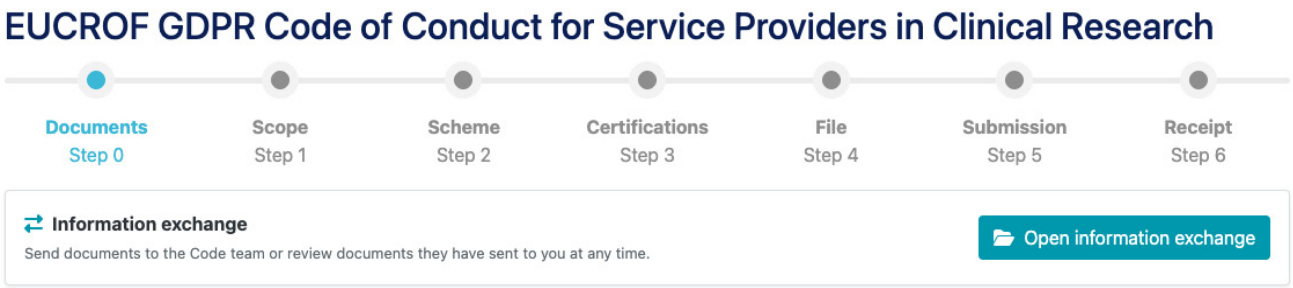
- Edit company information
- Set or edit contacts
- Add back-up users
- Submit an application for code adherence
- Contact the Risk and Compliance Officer for help.

From this page you can also edit the services the CRO provides and submit documents for adherence. However, these steps form part of the submission process, so we advise you not to use these options at the start.

Submit an application for Code adherence

Click this button:

The submission process is a series of steps, and you will see your progress at the top of the page.

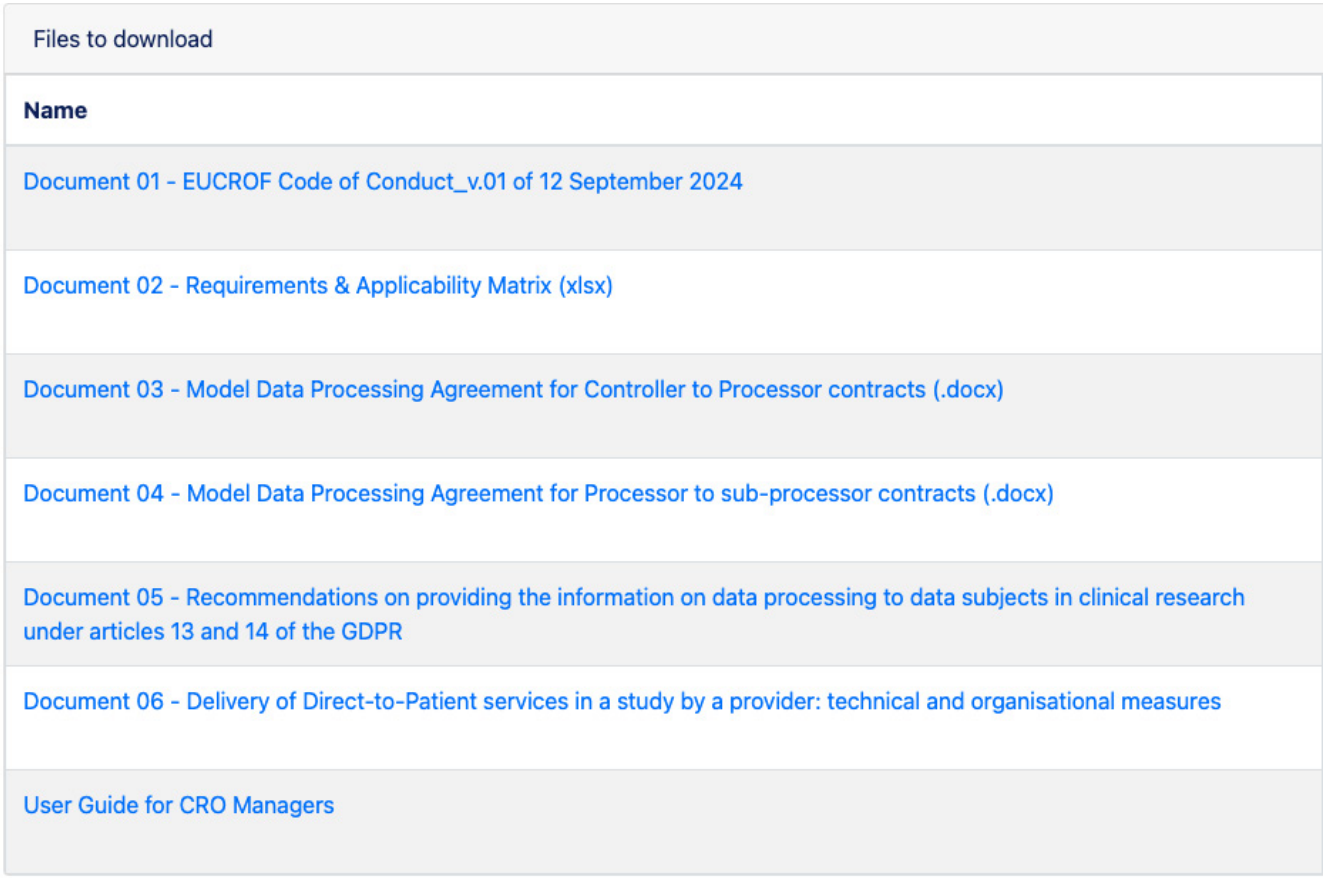


You can save your progress at any time by clicking the 'Save' button at the bottom of each page. To move onto the next step, click 'Next'. To go back a step, click 'Previous'. Once you have submitted your application at step 5 you can't go back.

Overview of the steps

Step 0 - Documents	Here you will find a link to download the following documents. • Document 01 - EUCROF Code of Conduct. • Document 02 - Requirements and Applicability Matrix: each code requirement and which classes of service it applies to. • Document 03 - Model Data Processing Agreement for Controller to Processor contracts • Document 04 - Model Data Processing Agreement for Processor to sub-processor contracts. • Document 05 - Recommendations on providing the information on data processing to data subjects in clinical research under articles 13 and 14 of the GDPR. • Document 06 - Delivery of Direct-to-Patient services in a study by a provider: technical and organisational measures. • This user guide.
Step 1 - Scope	Here you select all the services in scope for your submission.
Step 2 - Scheme	Here you choose whether you are applying for Level 1 or Level 2 adherence, provide your company's global headcount and see the applicable fee. Level 1 is a self-declaration, Level 2 is an audit. You can only apply for Level 2 if you already have a compliance mark for code adherence at Level 1.
Step 3 - Certifications	Here you upload any certifications you have for ISO 9001, 27001 and / or 27701.
Step 4 - File	Here you provide the evidence that you adhere to the Code requirements.
Step 5 - Submission:	Here you accept the terms and submit your application.
Step 6 - Receipt	Here you get confirmation of the submission and next steps.
Information exchange	This allows you to send any extra information or documents the RCO has asked for. From this screen you can see a list of anything you have sent or anything you have received from the RCO.

Step 0 - Documents



- Document 01 - EUCROF Code of Conduct. This is the final, complete published version of the Code.
- Document 02 - Requirements and Applicability Matrix. This sets out each code requirement and indicates which classes of service it applies to. This will help you determine which Code requirements are relevant to your application.
- Documents 03 and document 04 - Model Data Processing Agreements. These are model agreements for controller to processor, and for main processor to sub-processor relationships. These documents are not mandatory but highly recommended. They have to be adapted to the specific context of the contractual relationship with your customer and / or subcontractors.
- Documents 05 and document 06 - Recommendations on providing information to data subjects in clinical research, and Technical and organisation measures for delivery of direct-to-patient services in a study. These documents are guidance documents to help your company.
- This user guide.

When you are ready to move on to the next step, click 'Next'.

Step 1 - Scope

Here you select all the services in scope for your submission. Clicking on 'Show detail' provides more information about that service and what it involves.

Please select the classes of services to be considered in scope of your EUCROF Code GDPR compliance

- ☐ (1) Synopsis, protocol and CRF design [Show detail]
- ☐ (2) ICF design & information leaflet [Show detail]
- ☐ (3) Site selection and contract [Show detail]
- ☐ (4) Data collection [Show detail]
- ☐ (5) Monitoring [Show detail]
- ☐ (6) Medical monitoring [Show detail]
- ☐ (7) Pharmacovigilance and safety reporting [Show detail]
- ☐ (8) Direct-to-patient services [Show detail]
- ☐ (9) Data management [Show detail]
- ☐ (10) Statistical analysis [Show detail]
- ☐ (11) Clinical Study Report (CSR) [Show detail]
- ☐ (12) Financial management [Show detail]
- ☐ (13) Public disclosure [Show detail]
- ☐ (14) Translation of study documents/data [Show detail]
- ☐ (15) Audits [Show detail]
- ☐ (16) Provision of IT-managed services [Show detail]
- ☐ (17) Provision of physical hosting infrastructure [Show detail]
- ☐ (18) User / Technical support & hotline [Show detail]
- ☐ (19) Decommissioning services [Show detail]
- ☐ (20) Maintenance of Trial Master File (TMF) [Show detail]
- ☐ (21) Archiving services [Show detail]
- ☐ (22) Regulatory/Study start up services [Show detail]
- ☐ (23) Arrangement of investigator meetings [Show detail]

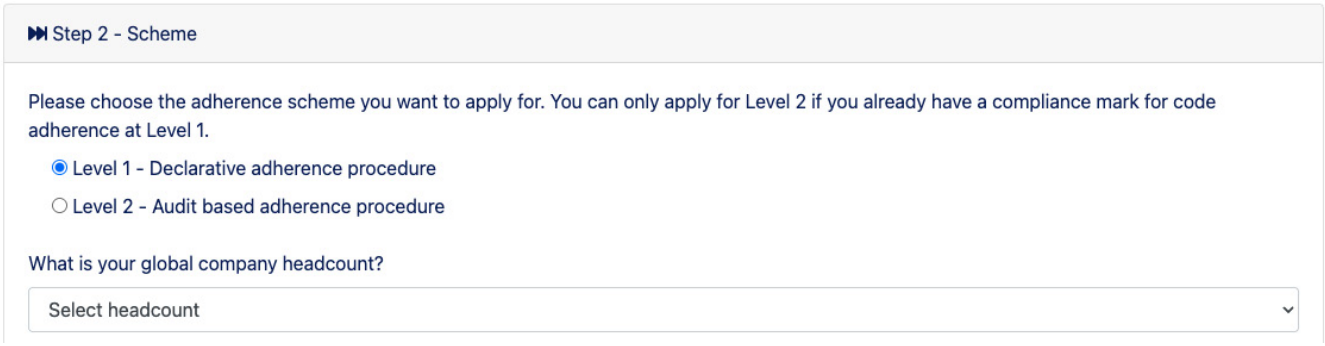
When you are ready to move on to the next step, click 'Next'.

Step 2 - Scheme

Level 1 or Level 2

Here you choose whether you are applying for Level 1 or Level 2 adherence. Level 1 is a self-declaration, Level 2 is an audit.

You can only apply for Level 2 if you already have a compliance mark for code adherence at Level 1.



Global company headcount

You then provide your global company headcount by choosing a range from the drop-down list.

Applicable fee, invoice and payment

Once you provide the headcount information the fee table will appear and you will see the applicable fee for your company. Once you save this stage or move onto the next step you will receive an automatically-generated invoice to pay the fee.

The invoice will be pre-filled with the invoice number, invoice date, customer details and fee amount. Please complete any remaining fields as needed, upload the final invoice through the Information exchange section in the platform, and arrange to pay the fee.

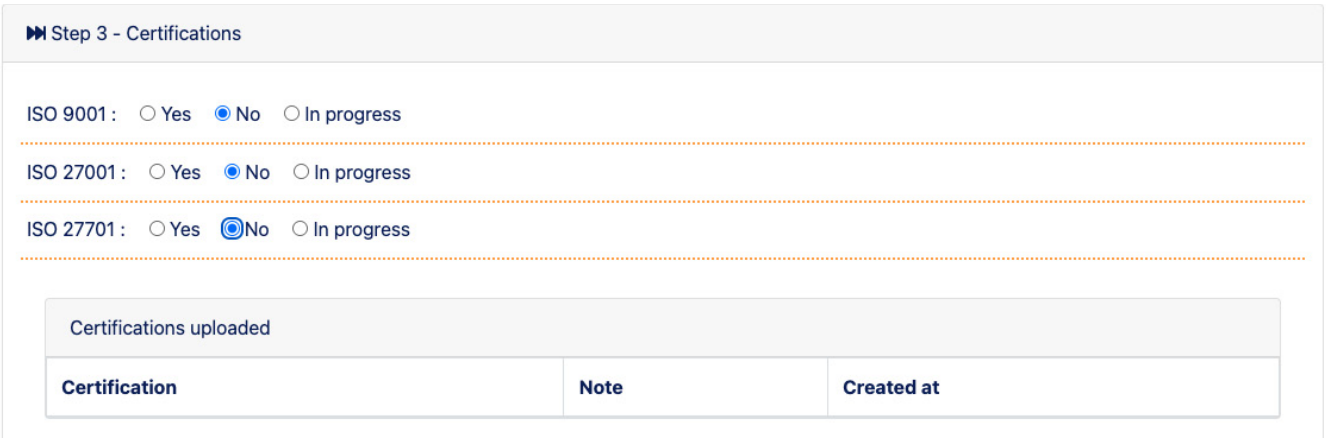
You must pay the fee before the RCO can start to process your application.

Public registry visibility

You choose if you want your company to be on the Code public registry showing the current status of your application.

Step 3 - Certifications

Here you indicate if your company has any certifications for ISO 9001, 27001 and / or 27701 or if you are in the process of being certified. Please upload a copy of any certification your company has.



When you are ready to move on to the next step, click 'Next'.

Step 4 - File

Here you provide the evidence that you adhere to the Code requirements.
You have the choice to:

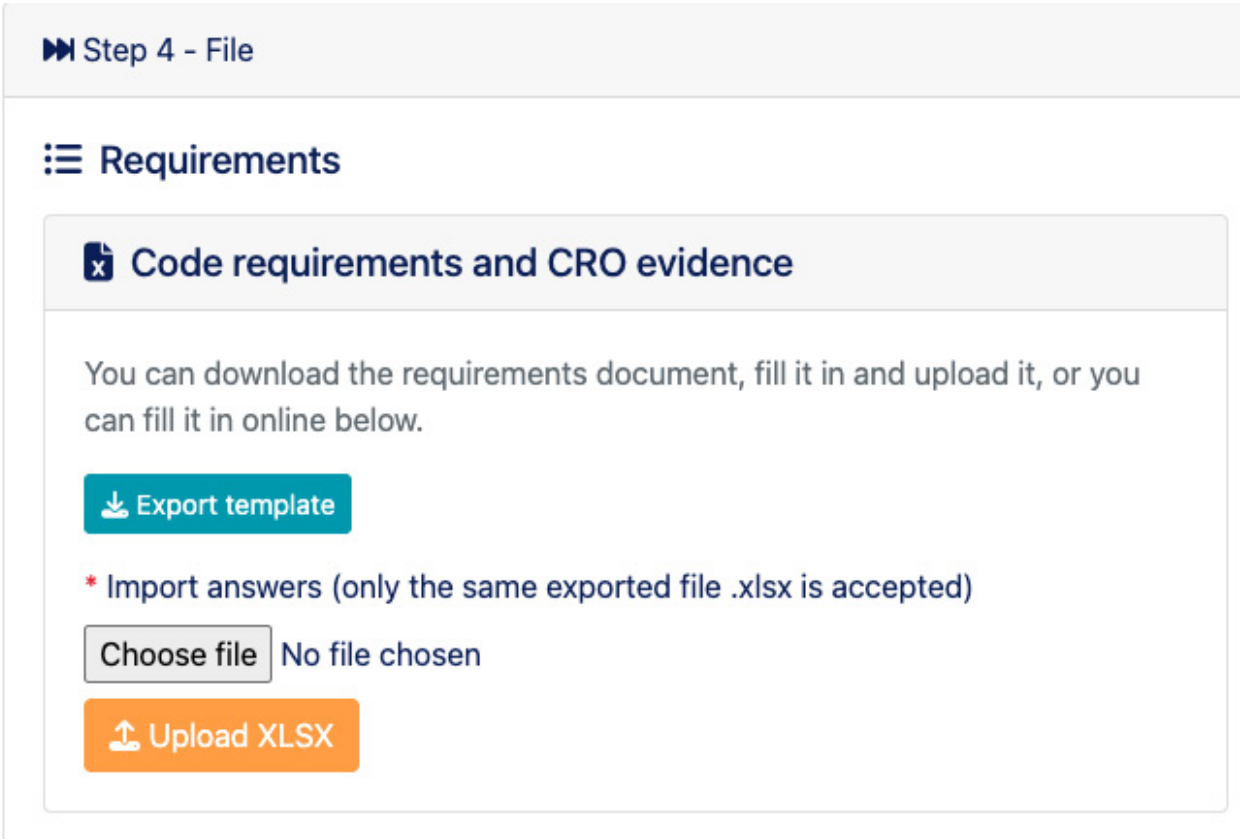
- download the requirements in a spreadsheet, complete it, and upload it; or
- indicate your adherence to each requirement online.

Whichever option you choose, you will only see the applicable requirements based on the service(s) you selected in Step 1 - Scope.

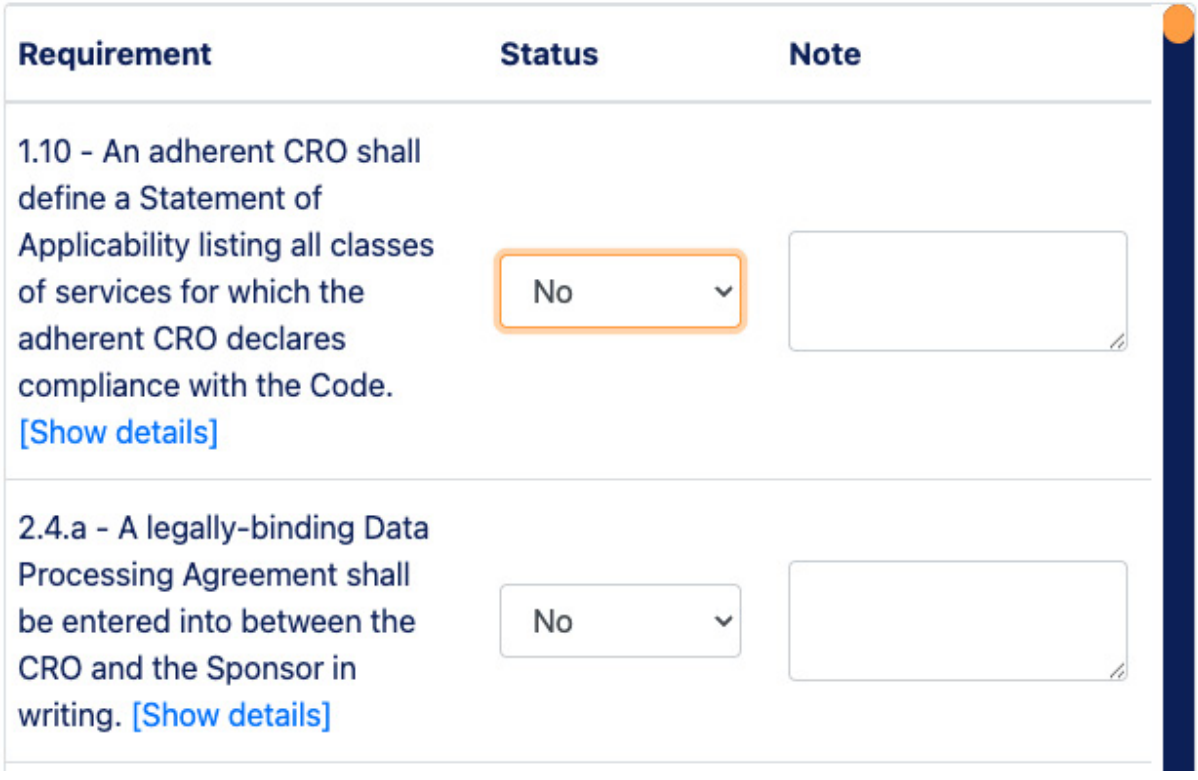
For each requirement indicate your adherence by choosing 'Yes', 'No' or 'In progress' from the drop-down list. You have the option to add notes.

Download option

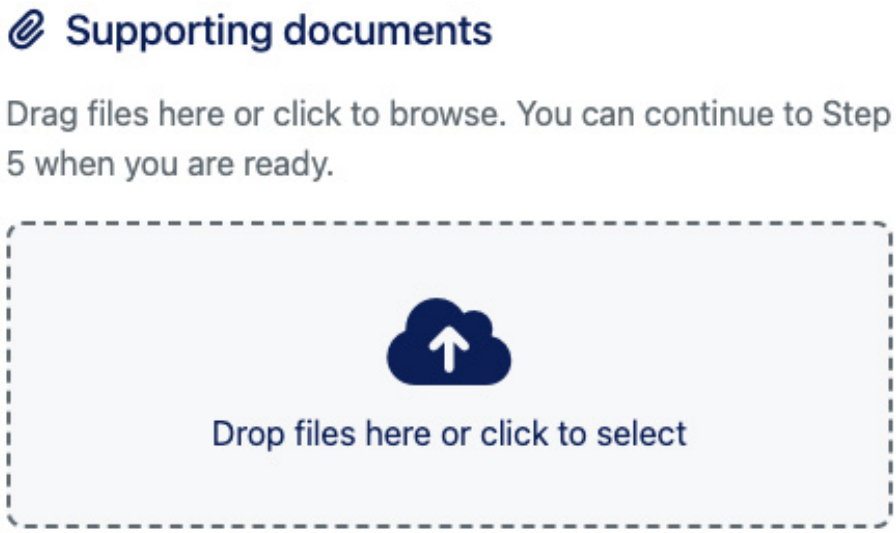
When you upload your completed spreadsheet click 'Choose files' to select the document on your device. Then click 'Upload'. You will get a message to confirm the upload was successful.



Online option



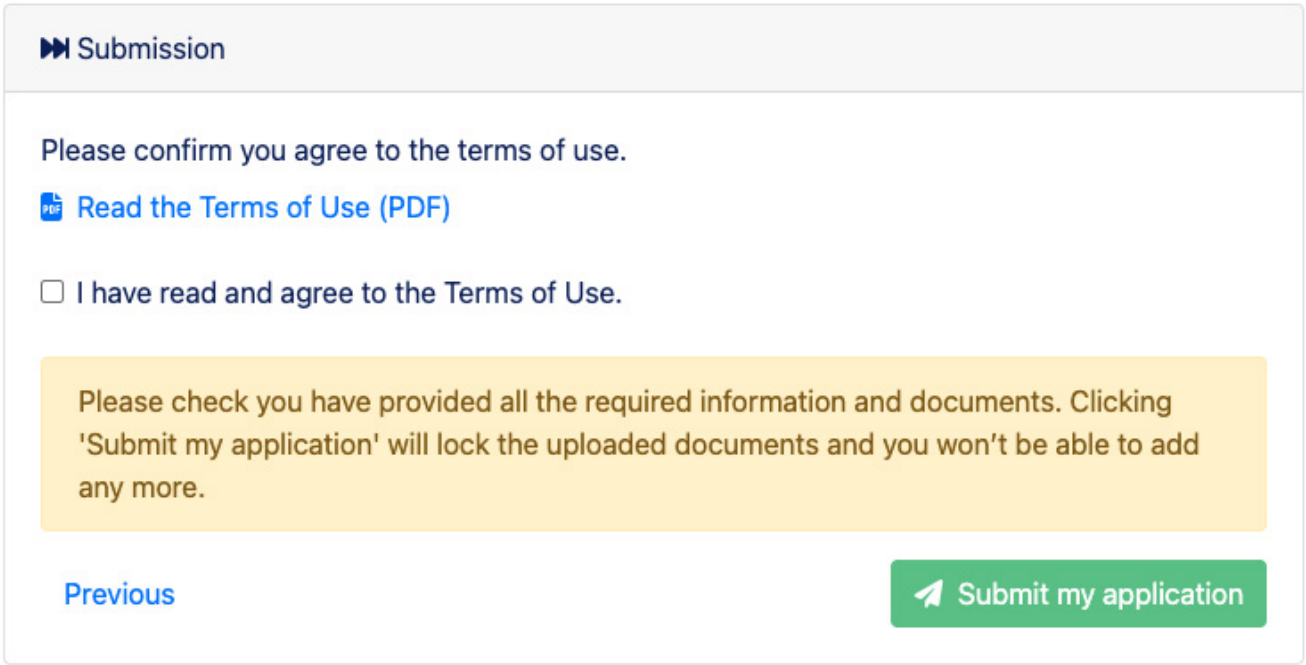
Supporting documents
You can also upload here any supporting documents.



When you are ready to move on to the next step, click 'Next'.

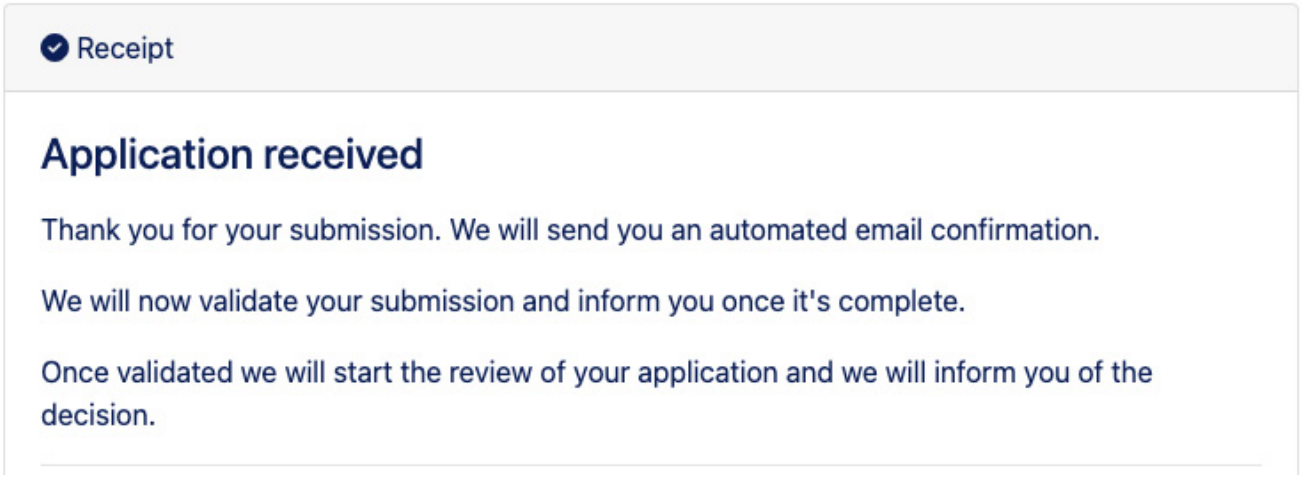
Step 5 - Submission

Please read and accept the terms. After this stage you will not be able to edit any of your submission.



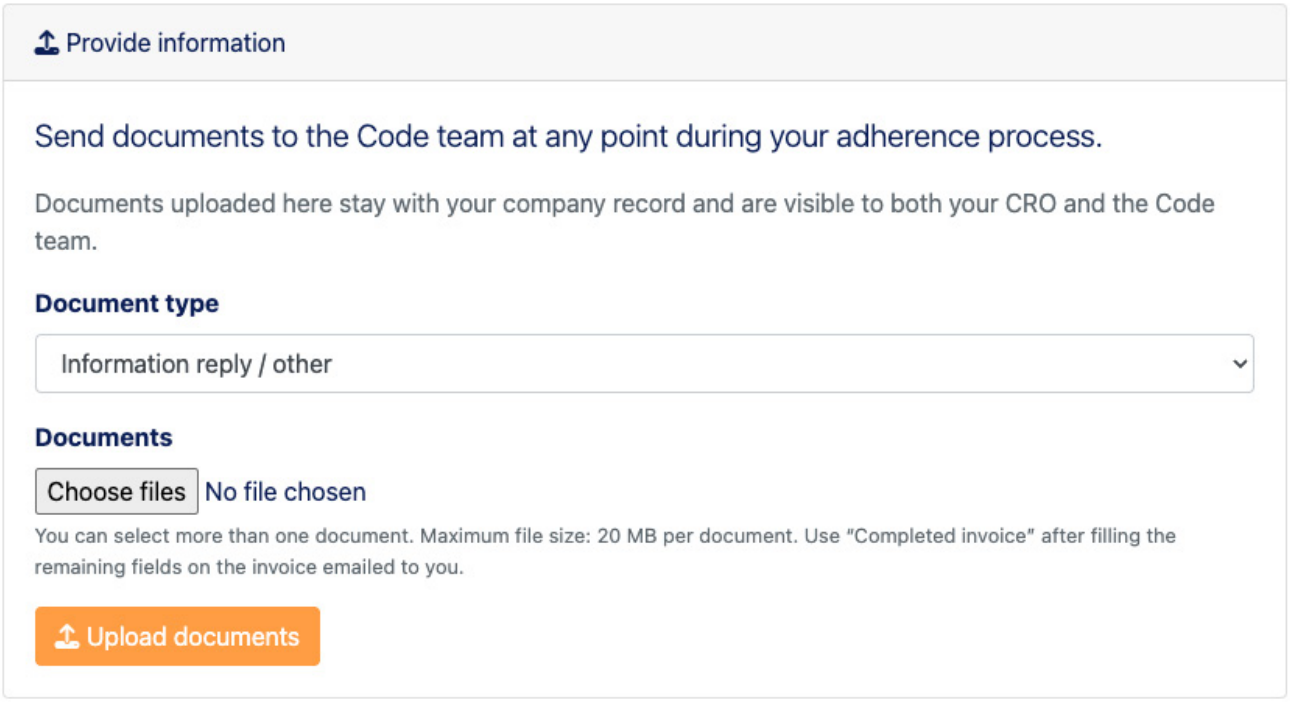
Step 6 - Receipt

You will see confirmation that you have submitted your application and you will get the same confirmation by email. Once the RCO has confirmation that the fee has been paid, they will start the validation process.



Information exchange

This allows you to send any extra information or documents the RCO has asked for. From this screen you can see a list of anything you have sent or anything you have received from the RCO.



When you upload a document click 'Choose files' to select the document on your device. Then click 'Upload'. You will get a message to confirm the upload was successful.

The validation process

Once the RCO has confirmation the company has paid the fee they will validate the application.

This involves checking that you have provided all the required documents and information and that it is adequate to start the assessment.

If the RCO needs more information or clarification they will contact you through the platform. They will send you a validation letter once this step is complete.

The assessment process

The RCO assesses the application against the Code requirements. If the RCO needs more information or clarification they will contact you through the platform.

Once the RCO completes the assessment they prepare a summary report for the COSUP Board, who review the application at their next available meeting.

COSUP Board decision

If the Board requires more information or clarification the RCO will contact you through the platform.

Once the COSUP Board completes their review, they will make one of the following decisions.

- Adherence mark granted
- Adherence mark is granted pending clarifications
- Adherence mark is not granted yet pending implementation of CAPAs
- Adherence mark cannot be granted, and the dossier is rejected.

The RCO will send you the decision letter through the platform.