Demonstrating data protection compliance with CR.GDPR

3rd September 2026

12:00 BST | 13:00 CEST | 14:00 EEST

Meet our speakers

- **Victoria Watts**, Chair of the CR.GDPR monitoring body (COSUP)
- **Christophe Maes**, Vice Chair of the CR.GDPR COSUP
- **Emma Butler**, Risk and Compliance Officer of the CR.GDPR COSUP
- **Stephen McCartney**, Risk and Compliance Officer of the CR.GDPR COSUP



cr.gdpr

Agenda

- What is CR.GDPR and what is its purpose
- How to make an application
- How to make a successful application
- Decision making process
- Questions and Answers

What is CR.GDPR and what is its purpose

Victoria Watts

What is CR.GDPR

- CR.GDPR is the 1st transnational GDPR code of conduct in the area of clinical research.

- Written by the industry, for the industry
  - 8 years of continuous efforts by an international team of expert professionals from a wide variety of backgrounds in clinical research, data protection, IT, auditing, patient advocacy, regulatory and legal.

- CR.GDPR is the specific interpretation, approved by the supervisory authorities, of how the GDPR should be implemented for clinical research by CROs / service providers.

What is the purpose of CR.GDPR

- GDPR requires that the *"controller shall use only processors providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject."*

- Adherence to an approved GDPR Code of Conduct like CR.GDPR is one type of sufficient guarantee that a CRO / service provider could provide to a controller.

What is the purpose of CR.GDPR

We aim to build trust and confidence in the compliance marks granted by the COSUP as evidence of sufficient guarantees.

Transparency

- We have a public registry of adherents who have been awarded compliance marks.
  - https://cro.eucrof.eu/eucrof-code-public-registry

Robustness

- CR.GDPR was fully approved by the CNIL and had a favourable opinion from the EDPB.
- CR.GDPR is overseen by an accredited monitoring body, the COSUP.

So how does CR.GDPR work?

CROs / service providers who want to be recognised as an adherent to CR.GDPR have to submit an application to the COSUP to have their compliance reviewed/audited.

Only CROs and service providers who have been through the adherence process will be permitted to display a CR.GDPR compliance mark and be listed on the public registry.

There are two levels of adherence schemes and 2 levels of compliance marks

- Adherence Scheme 1: **Self-declaration and RCO review**
- Adherence Scheme 2: **Audit**

What is within the scope of CR.GDPR

Who is covered?

- Service providers for clinical research acting as a Data Processor for the research/study sponsor in the frame of a service contract.
- Service providers who are full-service CROs and/or specialised single-service vendors e.g., IT.

What is covered?

- 23 classes of services that a CRO / service provider can deliver.

Whose data are covered?

- Patients & healthcare professionals.

What geographical area?

- 27 European Union Member States.

What can CR.GDPR do for you

Adhering CROs and service providers

- Reduce administrative and operational waste.
- Obtain practical guidance on showing and keeping GDPR compliance.
- Align approaches with other adhering members and selected sub-contractors / partners.
- Display an externally recognized compliance mark for 3 years as sign of high standard study services.

Investigational sites

- Streamline GDPR acceptance of compliant CROs / service providers.
- Use list of CR.GDPR adhering CROs / service providers when assessing reliable CROs to share data with.

Sponsors contracting adhering CROs

- Assess CROs / service providers using the same acknowledged compliance scheme in all 27 EU Member States.
- Reduce expenses in data protection audits of CROs / service providers.
- Easy (online) access to compliance status of selected CROs / service providers.
- Demonstrate appropriate oversight of sufficient guarantees.

Where to find more information

Please visit our website at https://crgdpr.org for more information about the Code itself, the COSUP members, the fees for adherence, and much more…

How to make an application

Emma Butler

How to access the platform

Access the platform directly:
https://cro.eucrof.eu

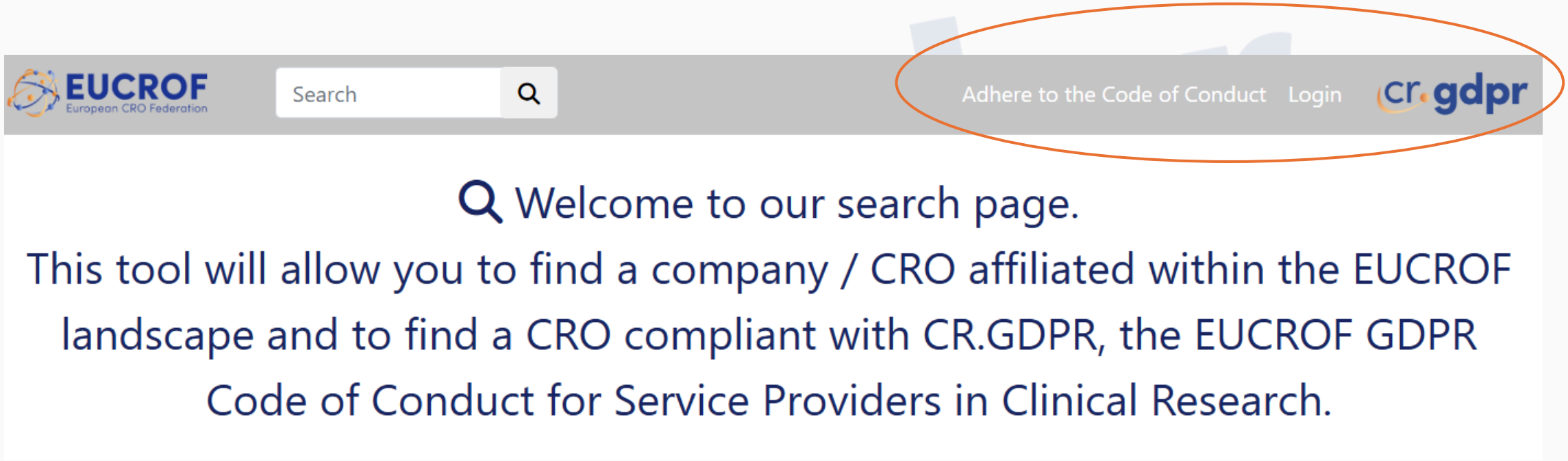
Register and start the application process

Or go through the CR.GDPR website: https://crgdpr.org/

Click on ‘CROs and service providers’

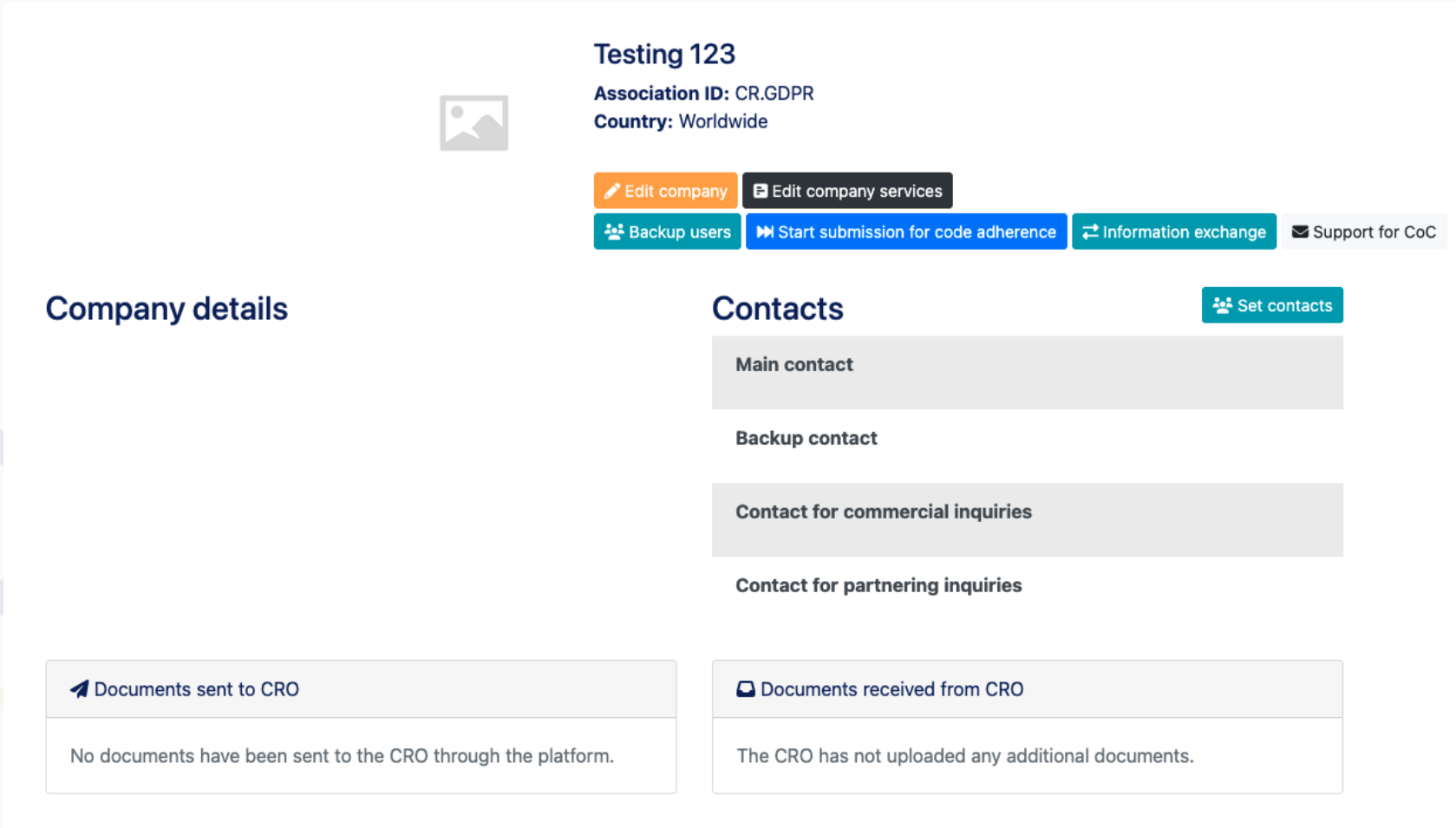
Scroll down the page and click on ‘Ready to become an adherent?’

Register your company

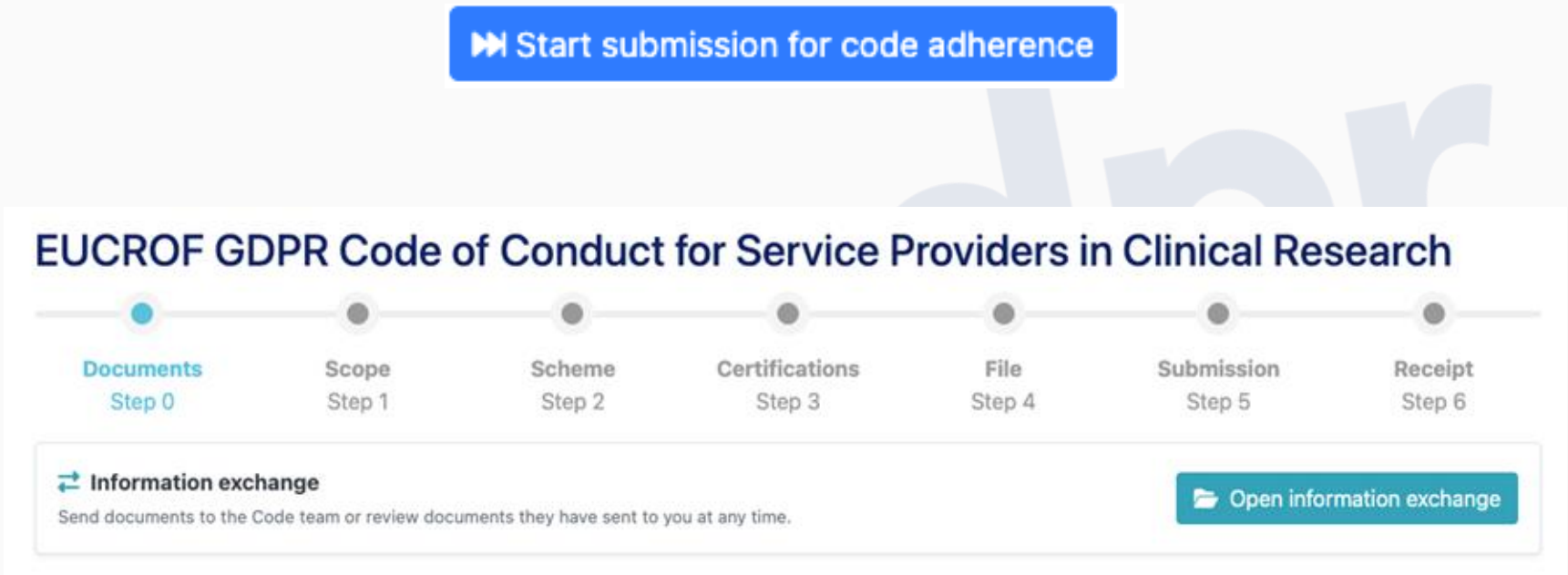


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Register your company



Submit an application for Code adherence

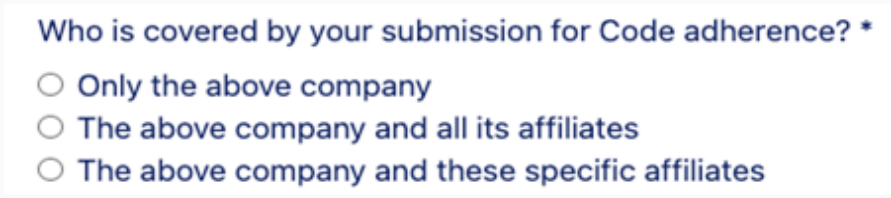


You'll find the platform user guide and Code documents at Step 0.

Step 1 - scope

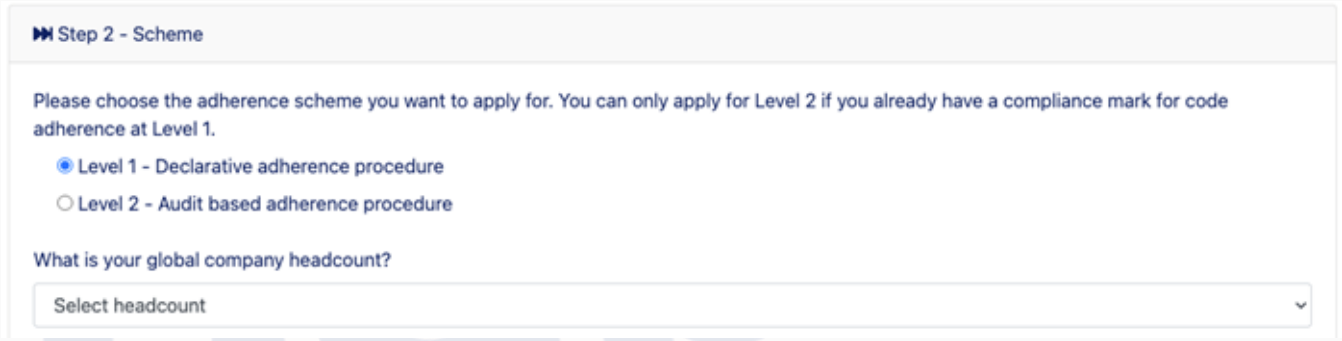
- Select all the services in scope for your submission.
- This is your ‘statement of applicability’ - for Level 1 and Level 2.
- Select who your submission covers.





Step 2 - scheme

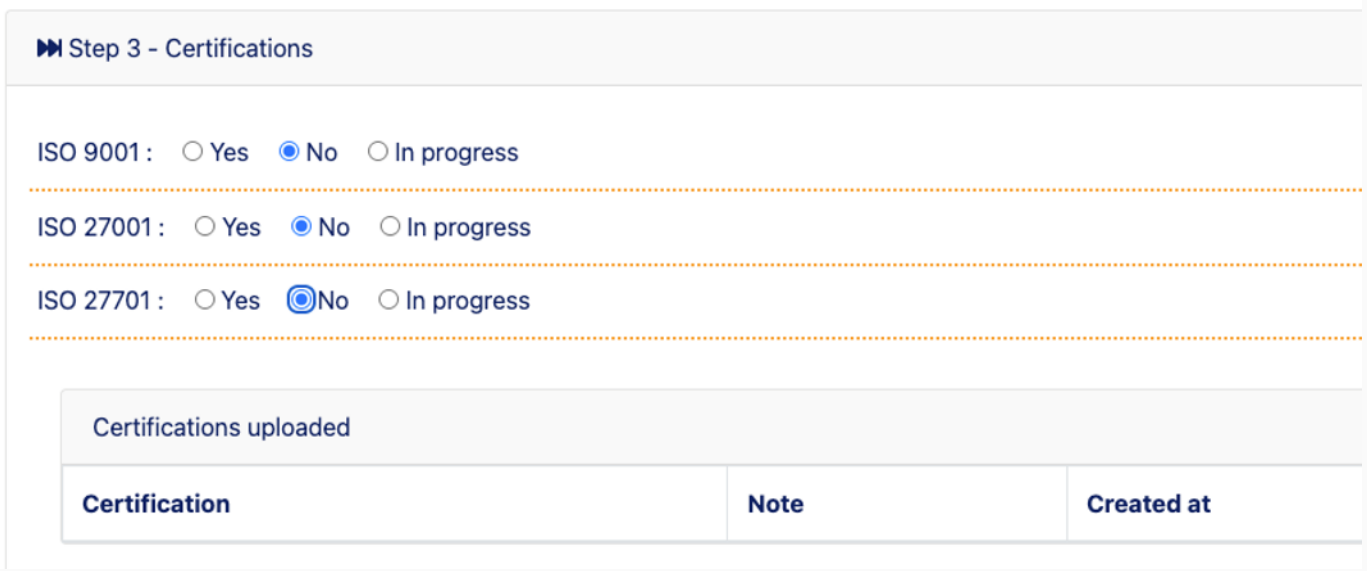
- Choose what level compliance mark you are aiming for.
  - Note: only Level 1 available currently.
- Choose if you want to be visible in the public register during the application.
- Indicate company global headcount.
  - This determines the fee and auto-generates invoice - sent by email.



Note:
You can continue with your application but we cannot start processing it until you have paid the fee.

Step 3 - certifications

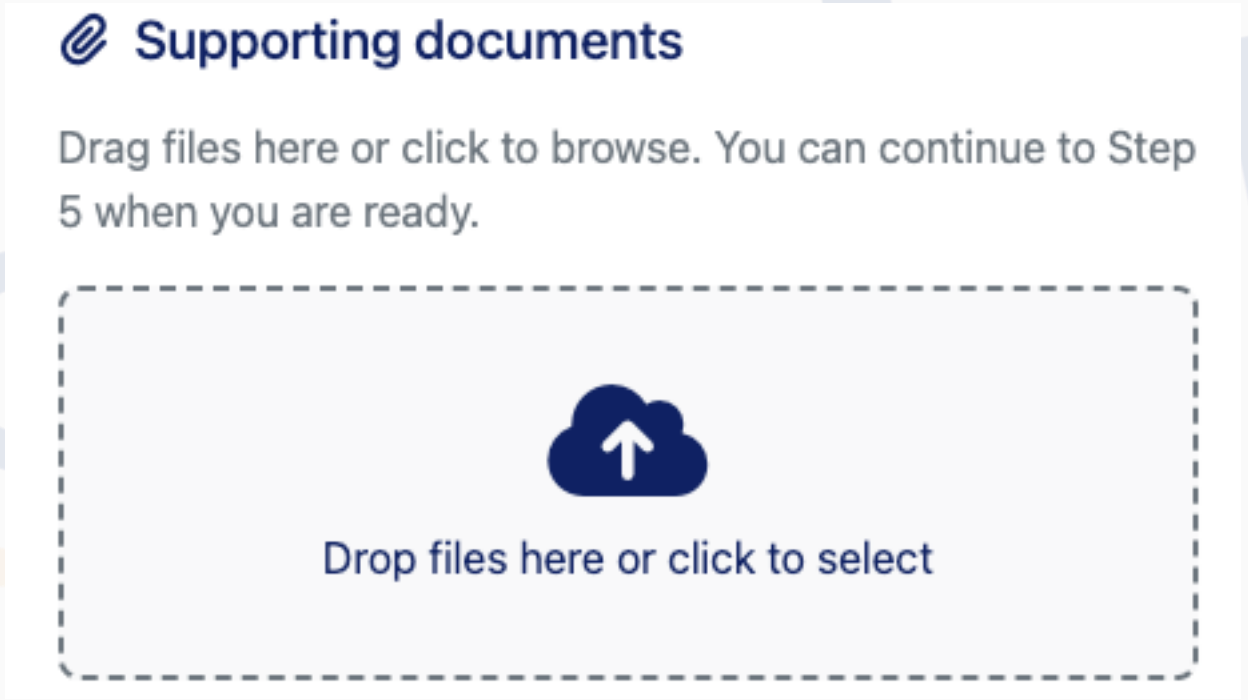
- Indicate if you have any relevant ISO certifications and upload the certificate as evidence.
- Note: these certifications are not mandatory but if you have a certification, it helps.



Step 4 - the main part of the application

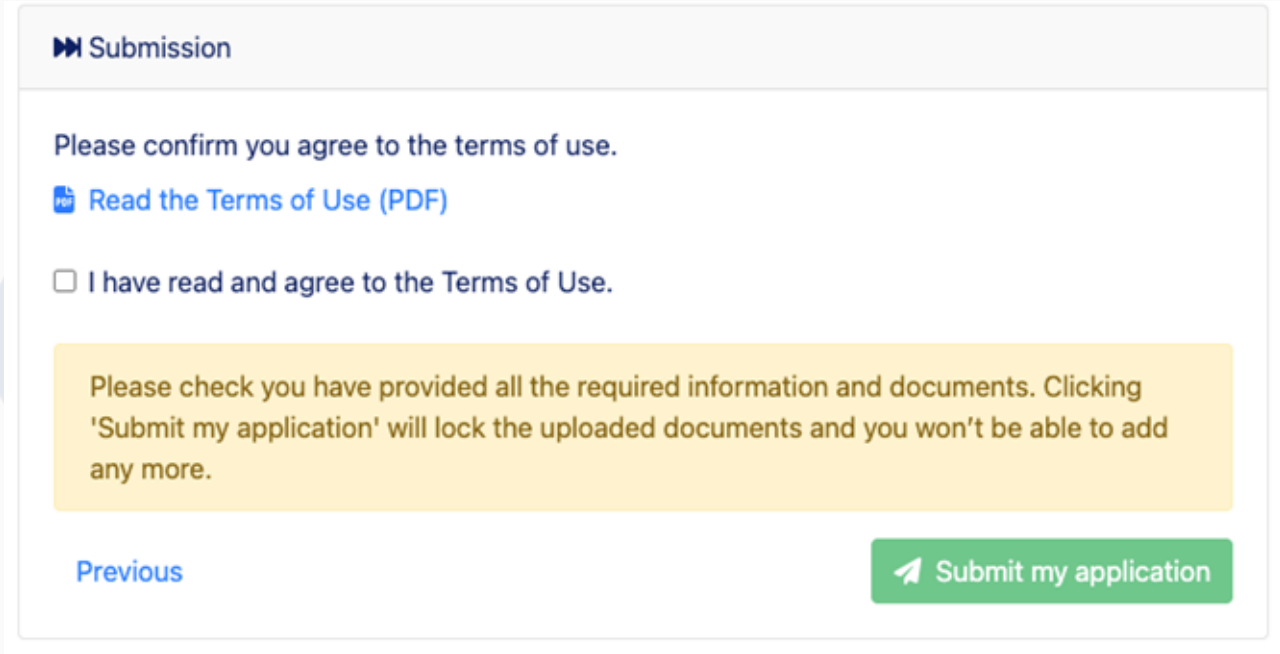
- Provide the evidence that you adhere to the Code requirements.
- You have the choice to:
  - download the requirements in a spreadsheet, complete it, and upload it; or
  - indicate your adherence to each requirement online.
- Whichever option you choose, you will only see the applicable requirements based on the service(s) you selected in Step 1 - Scope.
- For each requirement:
  - indicate adherence by choosing ‘Yes’, ‘No’ or ‘In progress’;
  - add notes explaining how you comply;
  - upload the evidence.

Step 4 - provide your evidence

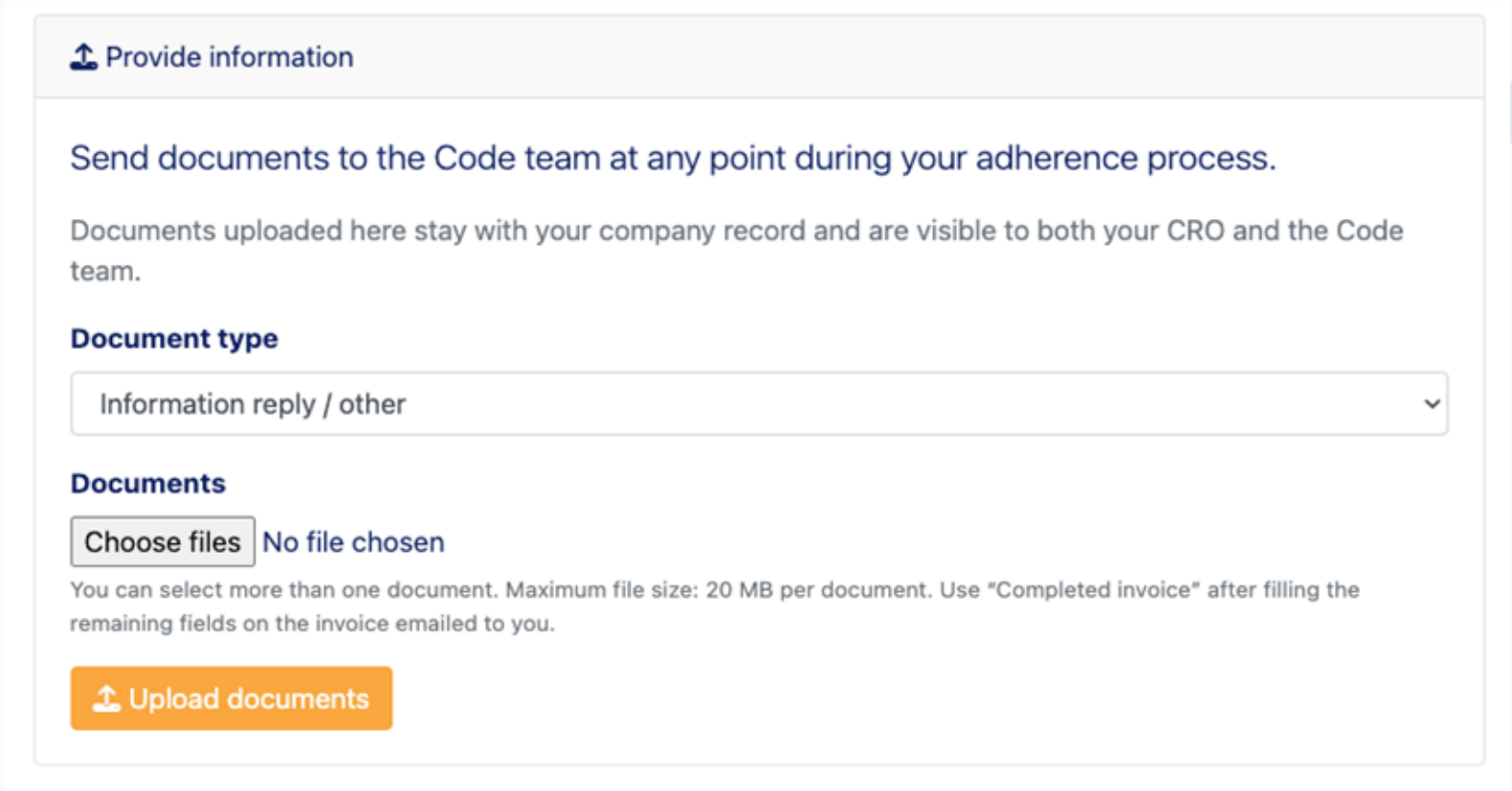


Step 5 - submit

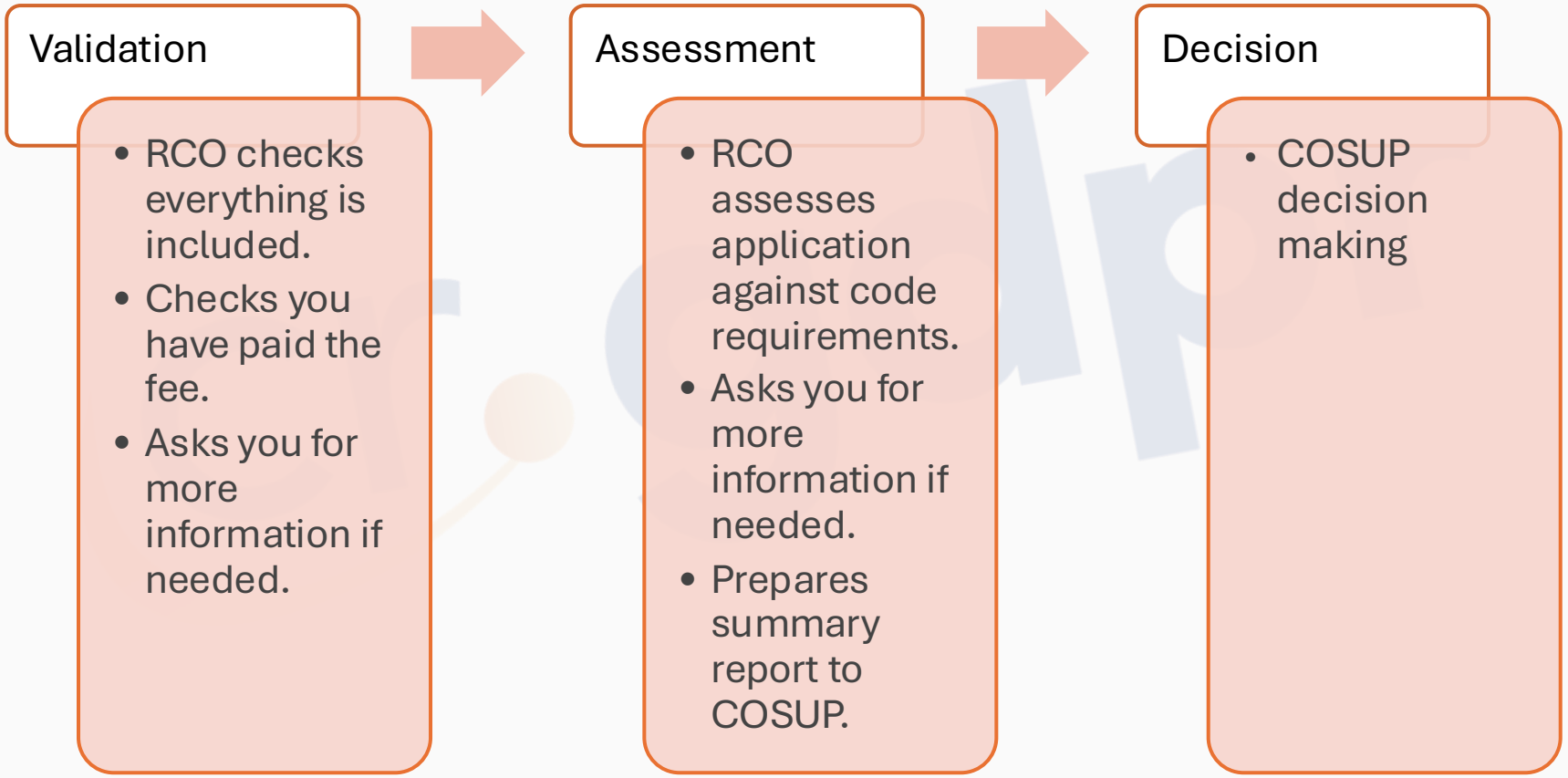
- Agree to the terms.
- Check you have provided all the information.
- After submitting your application is locked.
- Use information exchange to add any further documents.



Information exchange



After submitting an application



How to make a successful application

Stephen McCartney

Hints and tips for a successful application

- RCO can’t start the assessment of your application until you pay the fee.
- Tell us **how** you comply with each code requirement, don’t just tell us you comply.
- If you reference a document to support your application, upload that document.
- If we have further questions, don’t panic. We just want to get your application over the line. You have 10 working days to reply.
- If you are concerned or have further questions, reach out to us at rco@crgdpr.org

Decision making processes

Christophe Maes

WHO

Meet the COSUP members

The supervisory committee makes the decisions collectively.



Victoria Watts

Chair



Christophe Maes

Vice-Chair



Dimitrios Athanasiou

Member



Pierre-Henri Bertoye

Member



Marc Brooks

Member



Ricard Martínez Martínez

Member



Anastassia Negrouk

Member



Ekaterina Smirnova

Member



Pierre Westphal

Member

SCOPE

Decision-making overall process

START

RCO delivers the Summary Report to COSUP at least five working days before the COSUP's meeting.

DECIDE

COSUP reviews the dossier case by case, challenges the evaluation and votes.

END

Decision A, B, C or D is selected. RCO communicates the approved outcome.

SAFEGUARD 1

Conflict-of-interest gate

Actual, potential and perceived conflicts are addressed before substantive dossier review.

1 DECLARE

Disclose any relationship or interest linked to the candidate CRO.

2 ASSESS

Determine whether the member can participate impartially.

3 RECUSE

Where required, do not participate in case discussion or voting.

4 RECORD

Document the declaration, decision, recusal and eligible voters.

SAFEGUARD 2

Independence is essential

The conclusion must follow the dossier evidence and Code criteria, free from applicant or institutional influence.

INDEPENDENT JUDGEMENT

COSUP reaches its own collective conclusion. The RCO informs and supports the discussion but does not decide.

EVIDENCE-BASED

Members review findings, grading and clarifications consistently against the Code.

DOCUMENTED

The Chair structures the conclusion and ensures that only eligible members participate in voting.

WHO DOES WHAT

Separation of responsibilities

RCO evaluates; COSUP challenges and decides; the Chair structures the conclusion.

RCO

Provides report
Explains findings
Supports queries
Communicates outcome

COSUP members

Review beforehand
Challenge grading
Request information
Vote dossier by dossier

Chair / delegate

Moderates
Summarises queries
States outcome
Manages adjournment

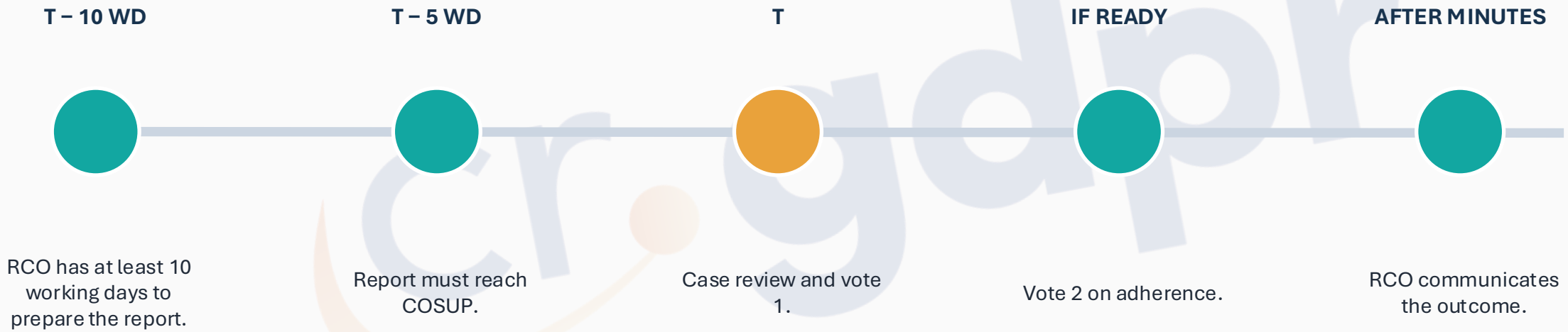
Candidate / SME

Answers queries
Implements CAPAs
Provides specialist input
Does not decide

WHEN

Timeline and cut-offs

The key timing rule is the five-working-day cut-off before a COSUP meeting.



Late reports or answers received fewer than 5 working days before the meeting move to the next meeting.

HOW

Inside the COSUP meeting

Structured challenge converts the RCO evaluation into a decision-ready final summary.



A dossier with pending questions cannot be deemed “Acceptable”.

GOVERNANCE

The two-vote logic

One vote is mandatory. Vote 2 occurs only if the dossier is decision-ready.

VOTE 1 | Final summary

Confirms pending queries, evaluation outcome and final finding grades.

Negative: continue or adjourn.
Positive with queries: no vote 2; return after answers.

READY?

VOTE 2 | Adherence

Only when vote 1 is positive, no pending questions remain and the dossier is ready.

Result: pathway A, B, C or D.

OUTCOMES

Four decision pathways

Each route defines a clear next action.

A

GRANTED

Acceptable; no queries

Inform applicant
Update register

B

GRANTED PENDING CLARIFICATIONS

Acceptable; clarifications only

Reply within 10 WD
Chair confirms A or moves to C

C

NOT YET GRANTED

CAPA required

Normally 3 months
to implement and resubmit

D

NOT GRANTED

Rejected; no queries

Inform applicant
Update register

CLOSE

Five messages to remember

The decision process is independent, evidence-based, collective and transparent, making CR.GDPR a trusted compliance mark.

1. **Independence is a prerequisite, not an afterthought.**
2. **Conflicts of interest are managed before each dossier review.**
3. RCO informs; COSUP decides.
4. Vote 1 aligns the final summary; vote 2 decides adherence.
5. Outcomes A–D define exactly what happens next.

Questions and Answers

Website: https://crgdpr.org
Email: cosup@crgdpr.org