EUDAMED user guide

CI/PS for Sponsors

Playground v 3.11.0
2025

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1 Introduction

The purpose of this user guide is to help you navigate through the Clinical Investigation and Performance Studies (CI/PS) module in EUDAMED.

This guide assumes the reader is acquainted with the Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices, hence no specific rules or other guidance will be provided in relation to certain registration steps.[1]

[1]For a wider understanding on how to use the platform, including FAQs and process infographics, visit the EUDAMED Information Centre.

2 Getting started – access the CI/PS module

Prerequisite to access EUDAMED:

EU Login (ECAS) account

If you do not have an EU Login account, please follow the instructions for creating an account before attempting to use the EUDAMED database.

Click on the following link to arrive to the EUDAMED Playground page

You will be prompted to enter EUDAMED via your EU Login account.

Once logged in, your dashboard will show links to use the *CI/PS* module.

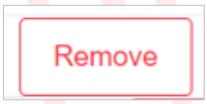
Useful EUDAMED symbols and features:

- **Red asterisk**: mandatory field, e.g.:

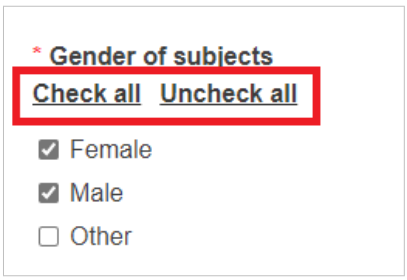
- **Closed red padlock**: information that will not be publicly available when the application or notification becomes public, e.g.:

- **Clear**: to clear the field value:

- **Remove**: to remove a line of the field value, or to remove a sub-section or to remove a document, when additional values, sub-sections or documents were added by the user previously:



- **Check/uncheck all**: to check all or to uncheck all available options for a field where multiple values are accepted:

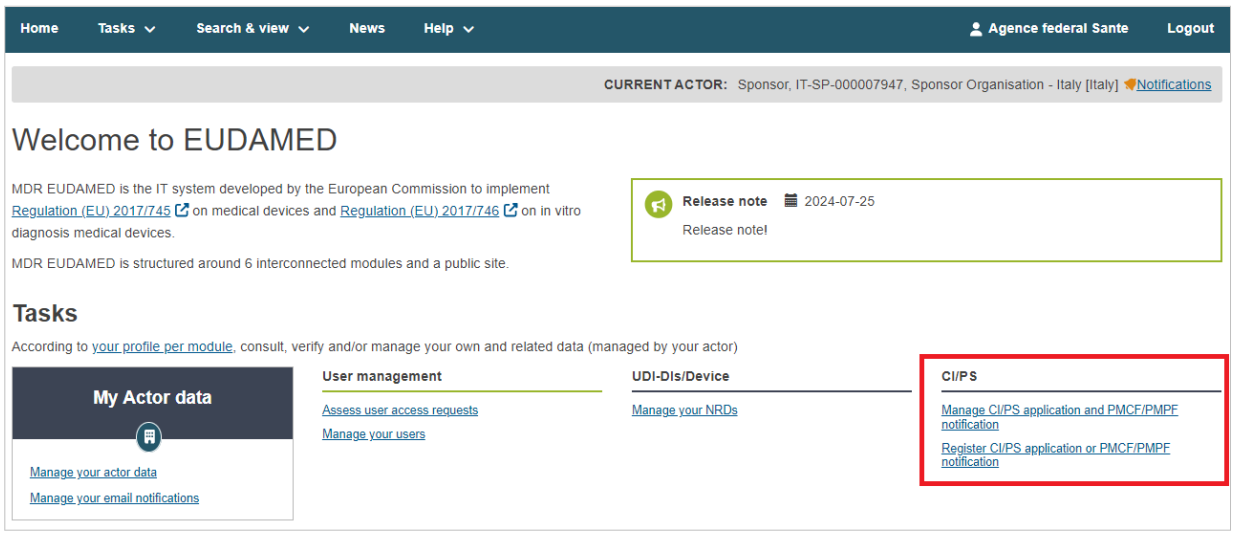


3 Register a CI/PS application

VIDEO: Resubmission of the CI/PS application/notification

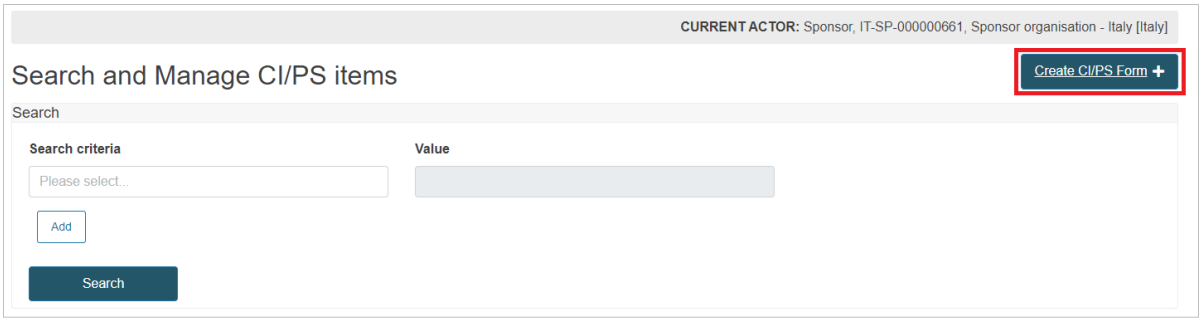
VIDEO: CI/PS Submission for additional countries

NOTE
The system saves the data you enter automatically. There is no **Save** button.

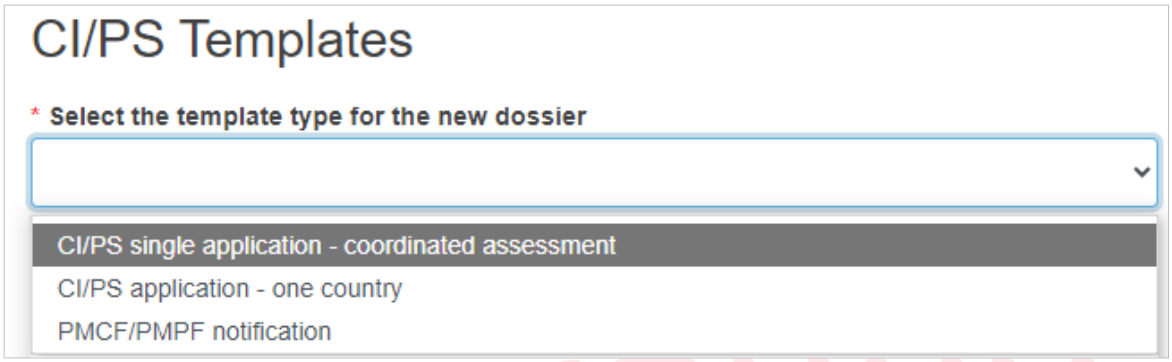


To start, you have two options in the dashboard:

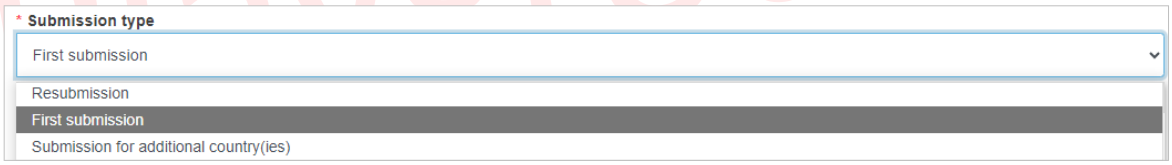
- Click *Register CI/PS application or PMCF/PMPF notification*
- Click *Search and Manage application/notification* and click the **Create CI/PS Form** button at the top right corner.



1. Select the form you want to submit from the drop-down list.



2. Select the **Submission Type** from the drop-down list.



Submission for additional country(ies):

- If you select **CI/PS application – one country** in the field *Select the template type for the new dossier*, this means that the new application will be submitted only to the country which will be selected in step 7 below.
- If you select **CI/PS single application – coordinated assessment**, this means that the new application will be submitted to all countries specified in the dedicated field *Country for this application* in the *Coordinated assessment information* screen.
- If you select **PMCF/PMPF notification**, this means that the new notification will be submitted only to the country which will be selected in step 7 below.

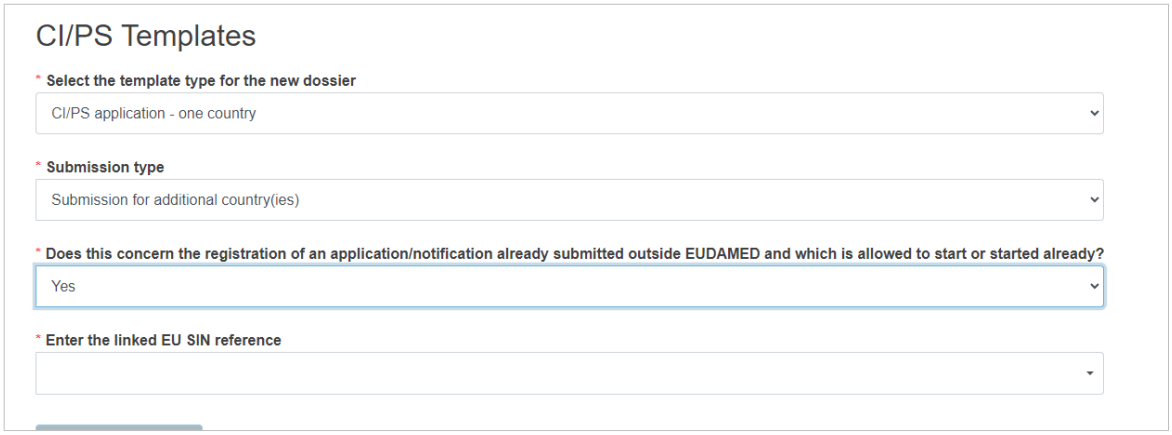
When you create the application for submission to additional country(ies), it will be populated with the information from the latest application (version) that was submitted for that EU SIN. If all the information corresponds with the new submission, you only need to fill in the national information for each new country.
All the fields are editable, except the CI/PS plan code (see support clip CI/PS Submission for additional countries).

Resubmission:

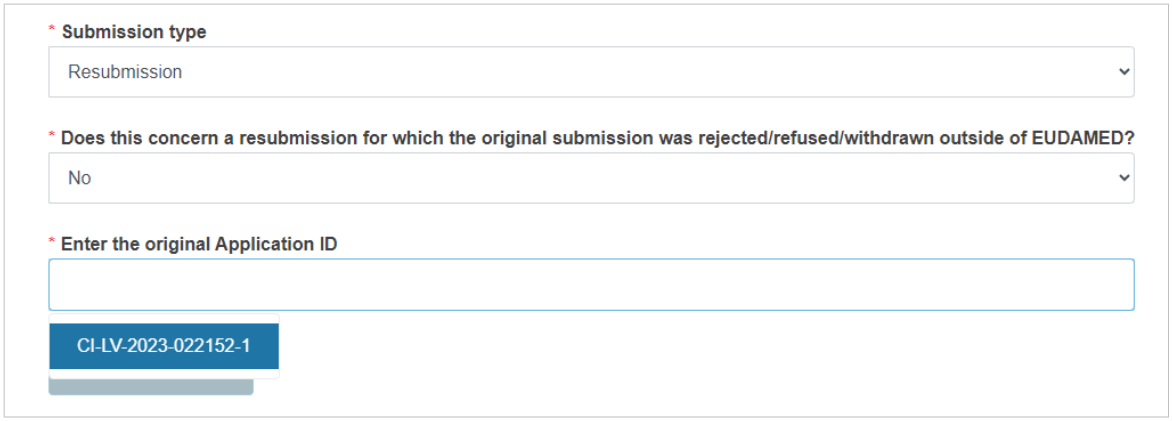
When you create a resubmission, the form will be populated with the information from the original application. You need to adapt the data as appropriate before submitting the new application/notification.
All the fields are editable, except the CI/PS plan code (see support clip CI/PS Resubmission).

3. If you are initiating a first submission in EUDAMED of a CI/PS application – one country or a PMCF/PMPF notification: Reply *Yes* or *No* to the question *Does this concern the registration of an application/notification already submitted outside EUDAMED and which is allowed to start or started already?*

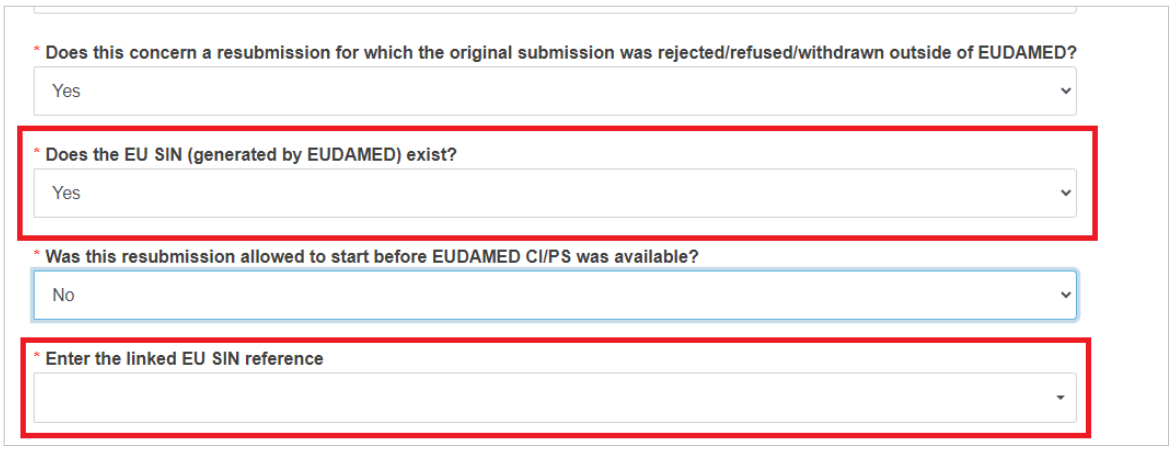
4. If you are **initiating a submission for additional country(ies)**:
Reply *Yes* or *No* to the question *Does this concern the registration of an application/notification already submitted outside EUDAMED and which is allowed to start or started already?*
Reply *Yes* or *No* and **enter the linked EU SIN reference**, by choosing the relevant result from the drop-down list.



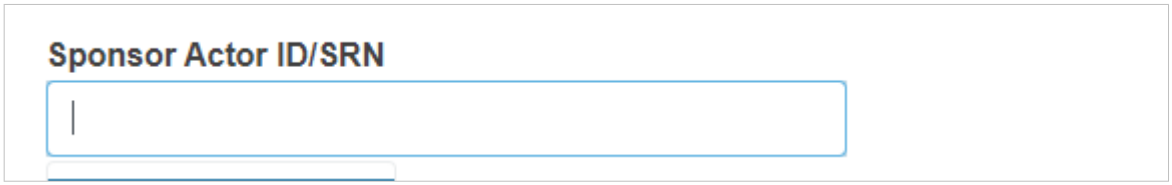
5. If you are **resubmitting an application/notification**:
   Reply *Yes* or *No* to the question *Does this concern a resubmission for which the original submission was rejected/refused/withdrawn outside of EUDAMED?*
   If you reply *No*, **enter the original application ID** by choosing the relevant result from the drop-down list.
   The system will retrieve all the applications/notifications that have been withdrawn by your actor and applications submitted by your actor that have been rejected or refused by the Competent Authority.



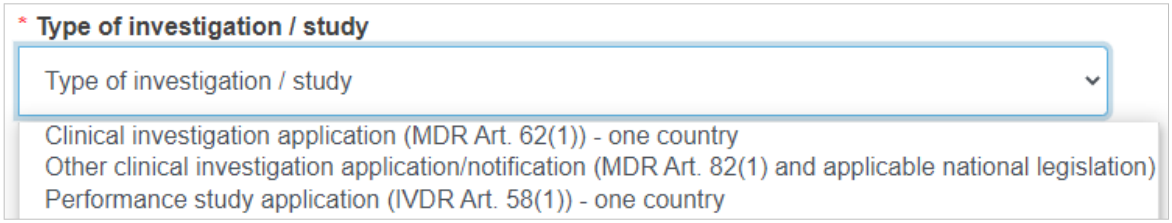
   If you reply *Yes* to the previous question, reply *Yes* or *No* to *Does the EU SIN (generated by EUDAMED) exist?*
   Reply *Yes* or *No* to the question *Was this resubmission allowed to start before EUDAMED CI/PS was available?*
   If you replied *Yes* to the question *Does the EU SIN (generated by EUDAMED) exist?*, you will need to select a value for *Enter the linked EU SIN reference*:



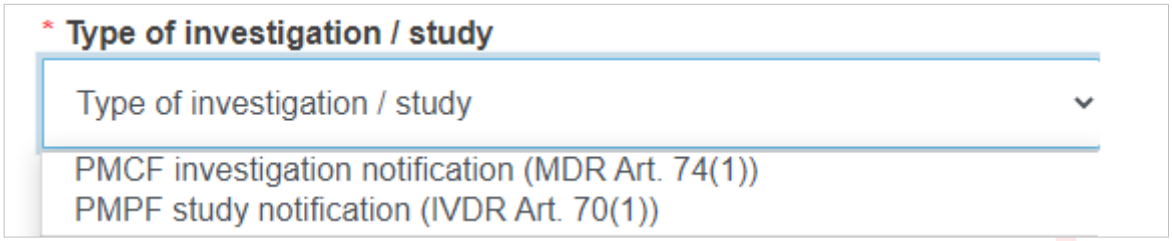
6. Select the proposed **Actor ID/SRN**.



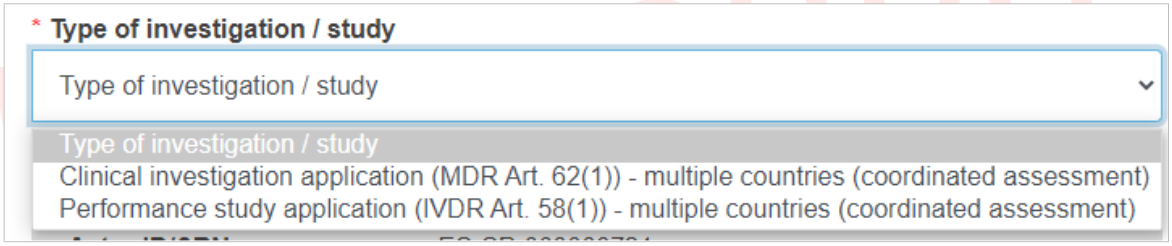
7. In the case where this is a first submission or any submission for which no related EU SIN exists, you need to select the **type of investigation/study** from the drop-down list.



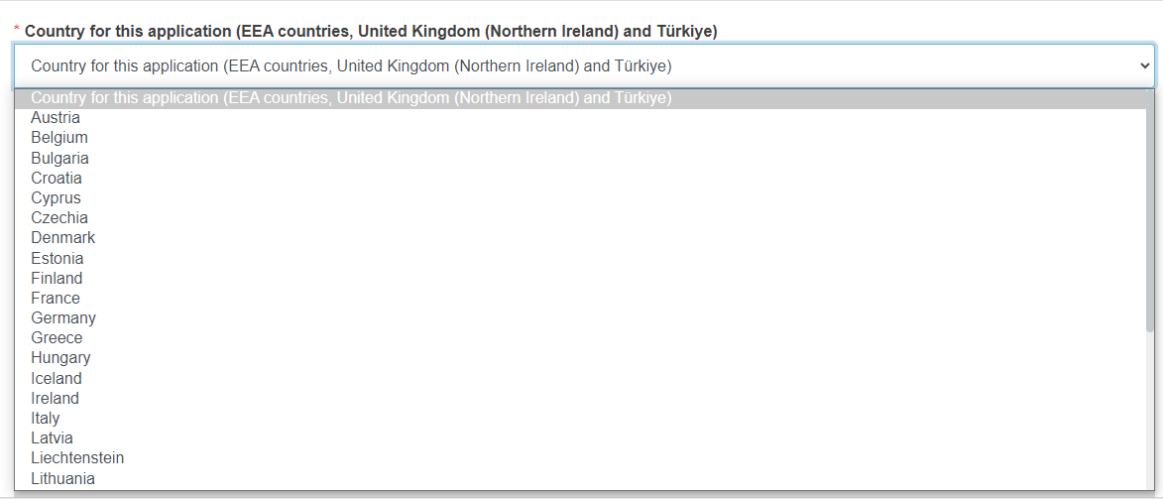
The above view **depends on the form you are submitting**.
For a **PMCF/PMPF notification (first submission)** you will have the following options:



For a **CI/PS single application – coordinated assessment (first submission)** you will have the following options:



8. Select the **country** from the drop-down list. Only EU+ [2] countries are available for selection. This step does not apply to the form type *CI/PS single application – coordinated assessment* or to the *Resubmission* that exists in EUDAMED.



IMPORTANT
If you are **initiating a submission for additional country(ies)**, you cannot submit an application/notification for a country for which an application/notification already exists on the same EU SIN.

9. Click **Create Form** at the bottom of the screen.

Below you can find a table with a summary of the fields that you have to fill in, depending if you are managing a first submission, a resubmission or a submission of additional country(ies):

Submission type	Type of investigation/ study and Applicable legislation	Country for this application	Enter the original Application ID	Enter the linked EU SIN reference
First submission	Yes	Yes[a.]		
Resubmission			Yes	
Submission for additional country(ies)		Yes[b.]		Yes

[a.] Except for CI/PS single application – coordinated assessment.

[2] EEA, Northern Ireland and Türkiye.

[b.] Except for CI/PS single application – coordinated assessment.

3.1 How to complete the application

NOTE
For this guide we are using the CI/PS application - one country form. The other forms available are very similar but we will identify their differences when relevant.

Once you have filled in all the fields as explained in the previous chapter, the system will create a draft record and generate an Application ID, the EU SIN and the National SIN.

The **Application ID** is different for every application or notification and has the following format:

1. **For CI/PS**: CI or PS (identifies if it is a clinical investigation or a performance study). **For PMCF/PMPF**: CF or PF (identifies if it is a post-market clinical follow up or a post-market performance follow up).
2. The country code or 'EU' if it is an application for coordinated assessment
3. The year of initiation of the application/notification
4. Six-digit number that resets every year. There will be a new series of unique identifiers every year, composed by the year and the six-digit number. This composed identifier is unique in the entire system, it is not repeated per country or per type of investigation/study or per sponsor.
5. Application/notification sequence number (in the example CI-BE-2023-022328-1, -1 means that this is the first submission for the given clinical investigation application; in the example CI-AU-2022-000555-2, -2 means that there is a submission for an additional country (Austria) for the same clinical investigation; in the example CF-BE-2023-001119-R2, -R2 means that two resubmissions were done for the same application)

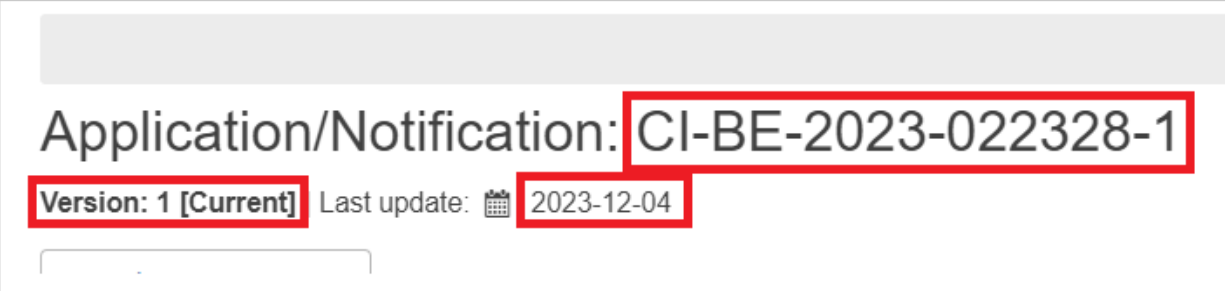
The **EU SIN** is the unique identifier of the investigation/study and will be shared among all resubmissions and submissions for additional country(-ies) that refer to the same first submission. It is built as follows:

The **National SIN**, which is displayed in the National information section, is the same as the EU SIN except for the code 'EU' which is replaced with the relevant country code.

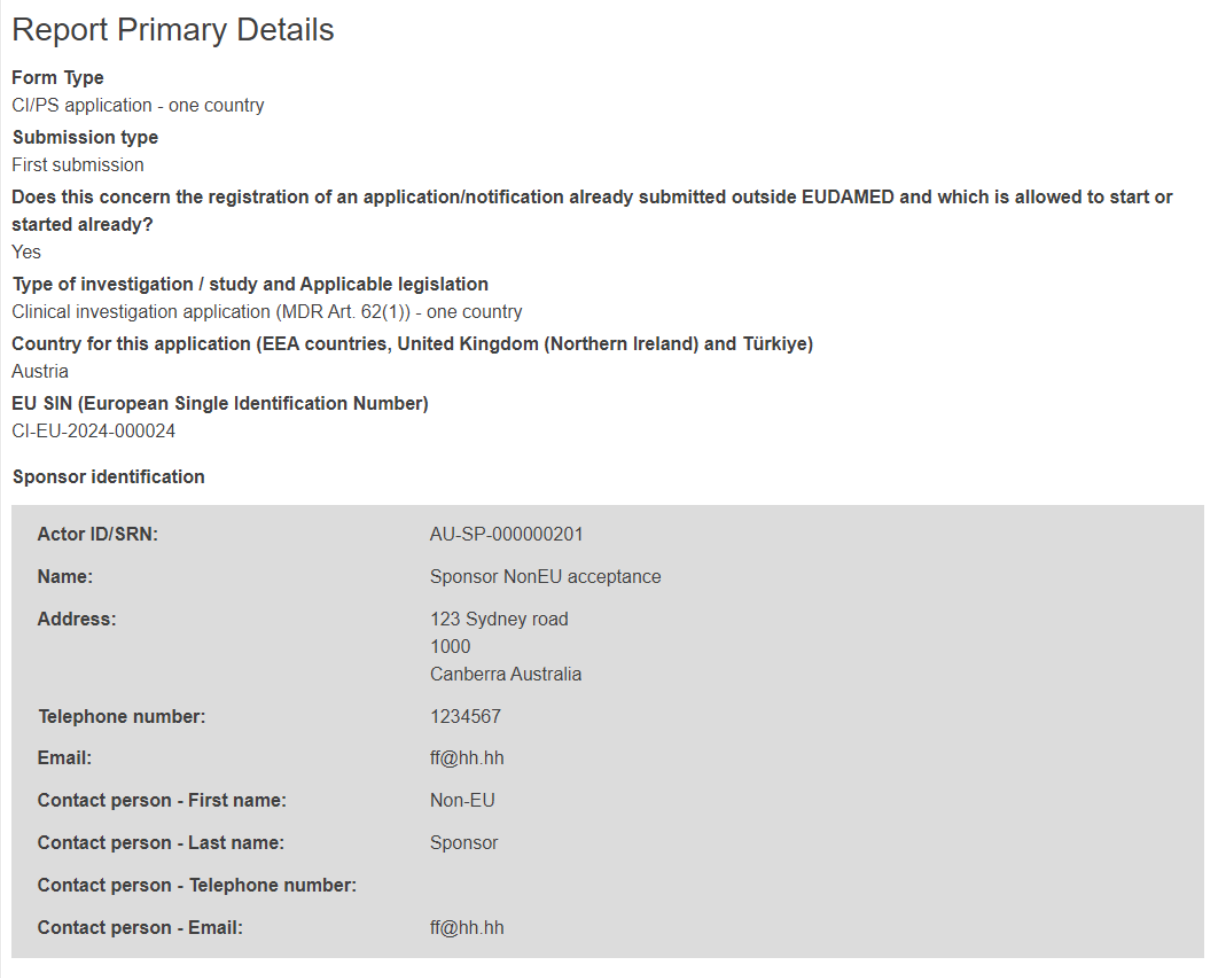
- element 1 above
- EU

- elements 3 and 4 above

At the top of the page you can see the version number of the draft record and the date of the last update.



The first section of the form, named **Report Primary Details**, gives you an overview of the data already entered.



Report Primary Details

Form Type
CI/PS application - one country

Submission type
First submission

Does this concern the registration of an application/notification already submitted outside EUDAMED and which is allowed to start or started already?
Yes

Type of investigation / study and Applicable legislation
Clinical investigation application (MDR Art. 62(1)) - one country

Country for this application (EEA countries, United Kingdom (Northern Ireland) and Türkiye)
Austria

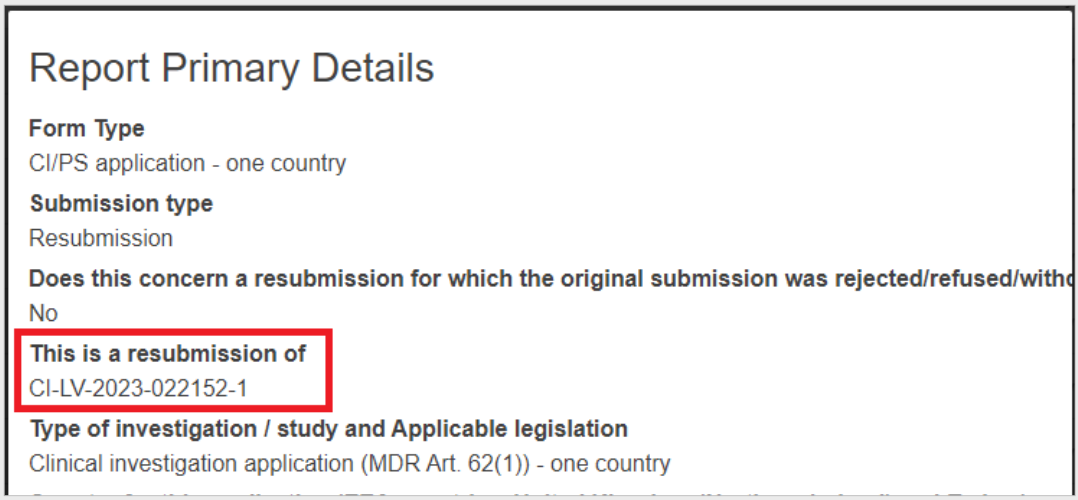
EU SIN (European Single Identification Number)
CI-EU-2024-000024

Sponsor identification

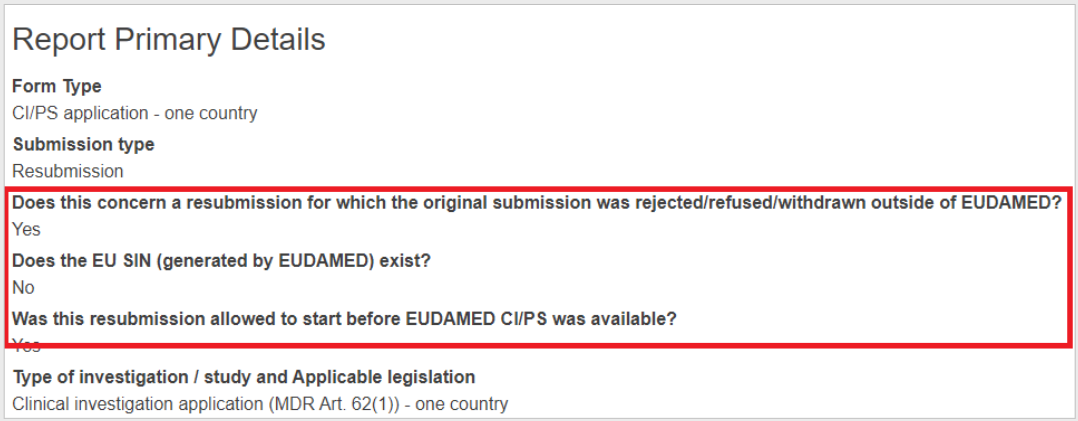
Actor ID/SRN:	AU-SP-000000201
Name:	Sponsor NonEU acceptance
Address:	123 Sydney road 1000 Canberra Australia
Telephone number:	1234567
Email:	ff@hh.hh
Contact person - First name:	Non-EU
Contact person - Last name:	Sponsor
Contact person - Telephone number:	
Contact person - Email:	ff@hh.hh

NOTE

If you are **resubmitting an application**, the report primary details will have an extra field: *This is a resubmission of* which displays the original Application ID for which the current form is a resubmission.



If you are submitting a pre-existing application/notification the report primary details will have the following fields:

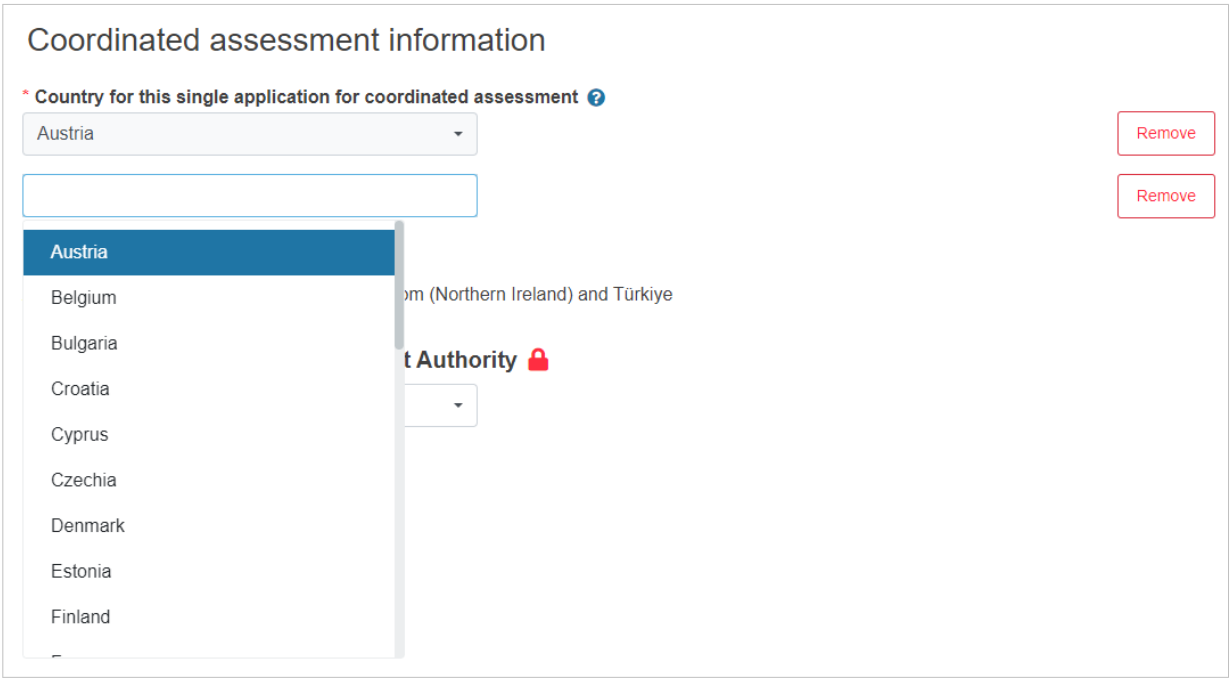


3.1.1 Coordinated assessment information - applicable to the CI/PS single application – coordinated assessment

Click **Coordinated assessment information** from the left menu

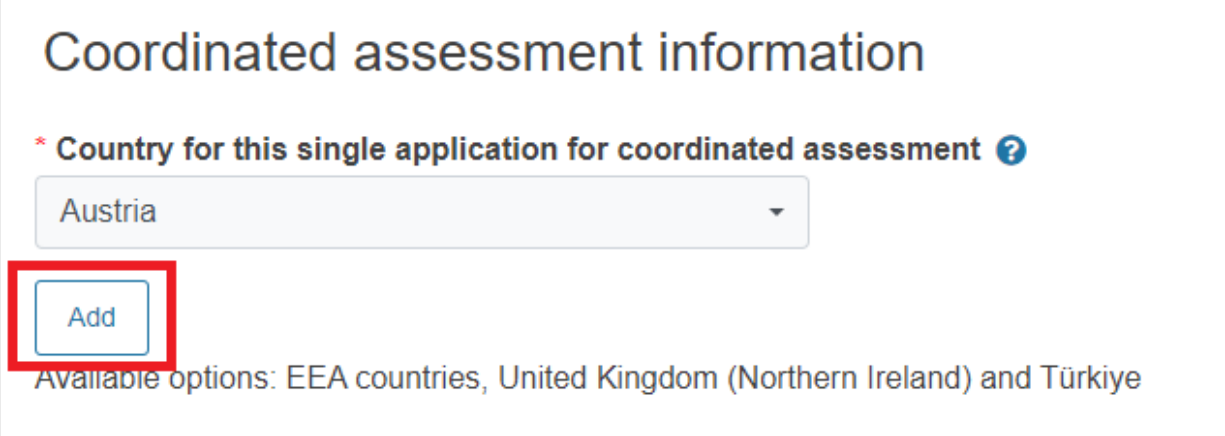
Select the countries from the drop-down **to which the single application will be submitted**.

NOTE
You can only select countries for which the competent authority has declared to be ready to participate in a coordinated assessment procedure.



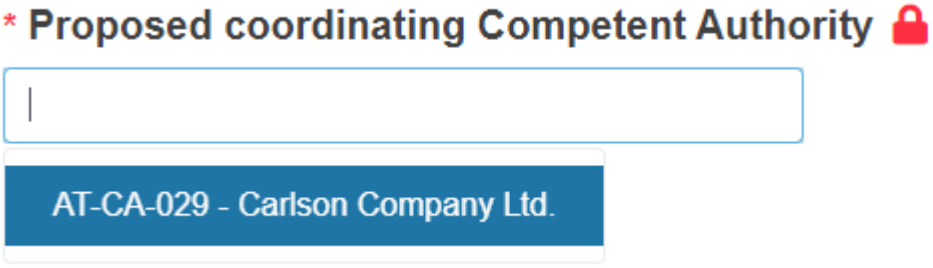
As soon as you select the country, the system will load the national information section specific for the selected country.

To add more countries click **Add**.



NOTE
As soon as a country is selected, the field becomes read only. If you need to correct it before submission, click **Remove** and then **Add**.

Choose the proposed coordinating *Competent Authority* from the drop-down list. You will see only the Competent Authorities linked to the countries that you have selected above and that are available to be the coordinating Competent Authority.



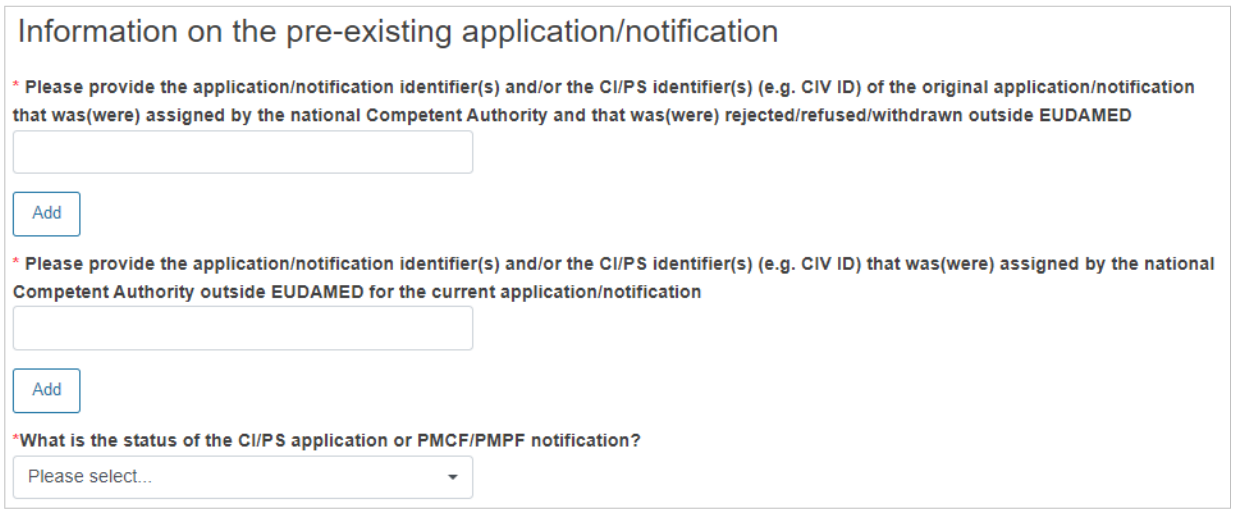
3.1.2 CI/PS identification

Click **CI/PS Identification** from the left menu.

In this section you must identify your CI/PS plan by providing the following information:

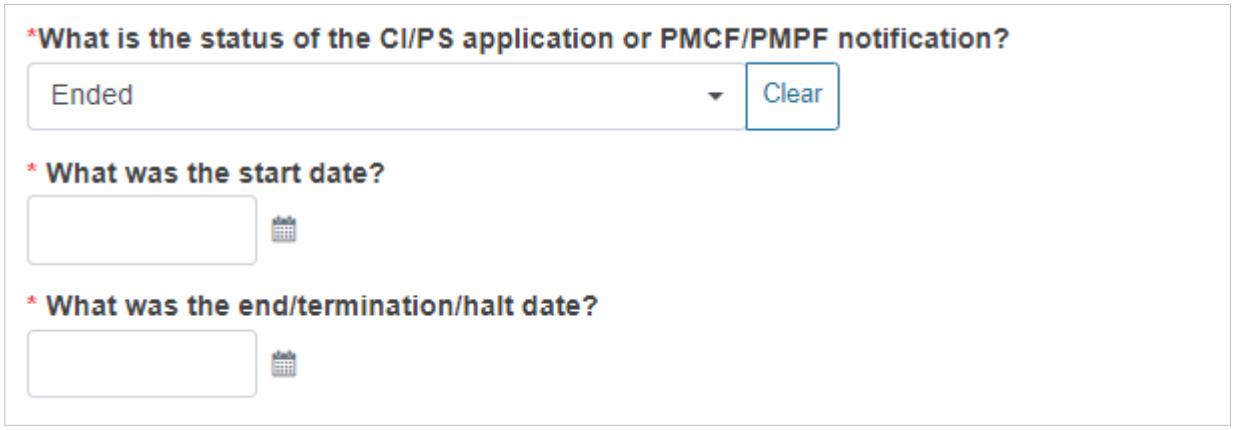
- **CI/PS plan code**: **This value will no longer be editable in a new version of this application or any linked application** (re-submission or submission for additional country/-ies).
- **CI/PS plan version**
- **CI/PS plan date**: You can only choose a date in the past.
- **Full title**
- **Short title**
- **Title for lay people**

If you are submitting a pre-existing application/notification, depending on the information you have provided during the registration step, further details will be requested in the section *Information on the pre-existing application/notification*:



Once the CA accepts the pre-existing application/notification, the state will correspond to the value that is selected in this field.

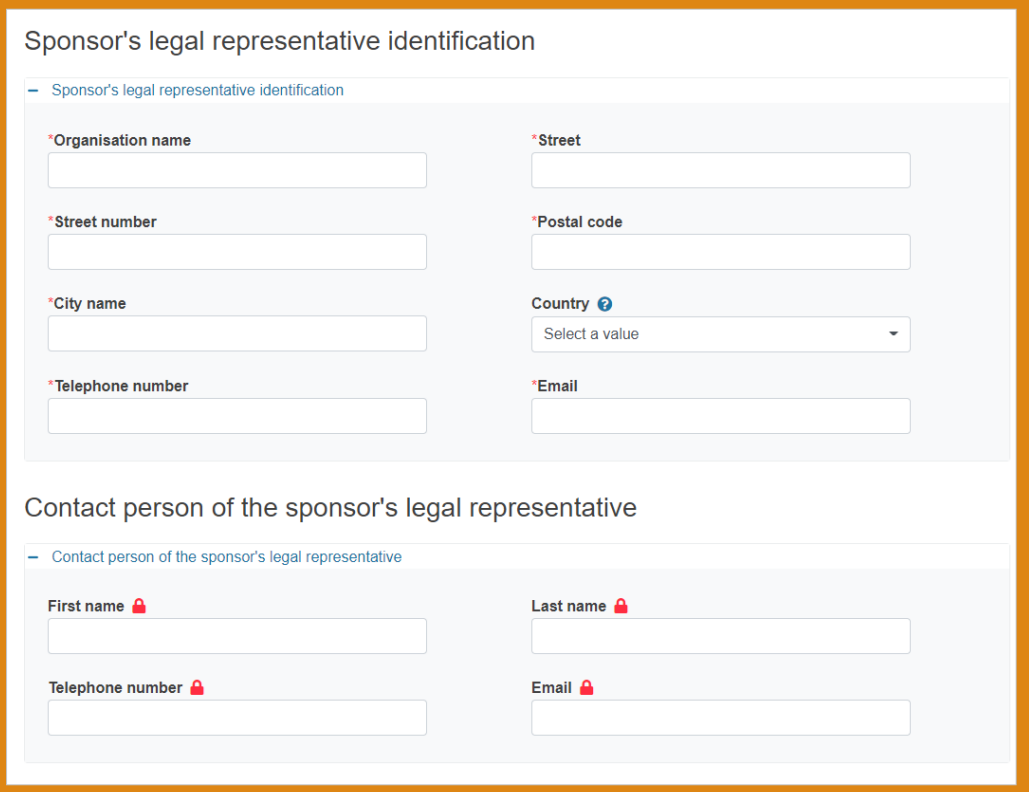
If you choose *Ended*, *Terminated early* or *Temporarily halted* the system will display two new fields, asking you to indicate the start date and the end/termination/halt date.



3.1.3 CI/PS contact person

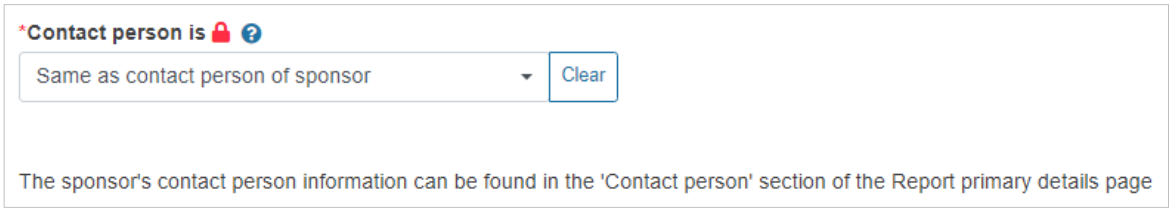
1. Click **CI/PS contact person** from the left menu.

IMPORTANT
If your **organisation is not established in the EEA, United Kingdom (Northern Ireland only) or Türkiye**, you will be asked to provide a **legal representative** and the contact person of the Sponsor's legal representative.



2. Choose the *contact person* of the CI/PS from the drop-down list:
   - **Same as contact person of Sponsor**
   - **Same as contact person of Sponsor's legal representative**: this option will appear **only if you have a legal representative**.
   - **Other**: if you select this option, you will be asked to provide the details of the contact person.

3. If you select *Same as contact person of Sponsor* the below message will be displayed:

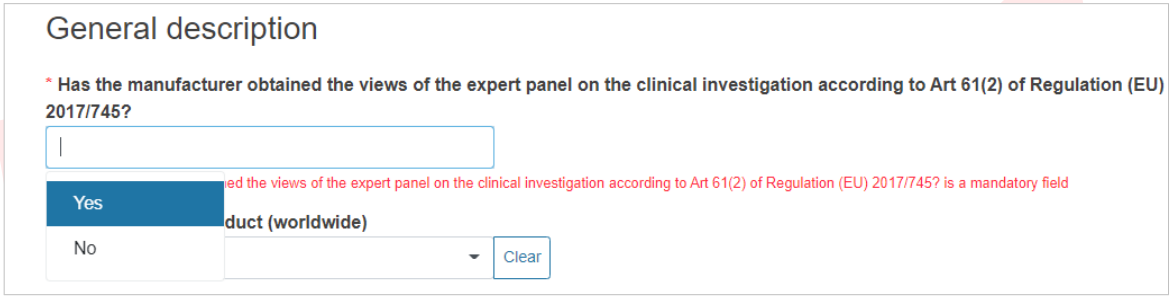


3.1.4 CI/PS Description - part 1

Select **CI/PS description - part 1** from the left menu.

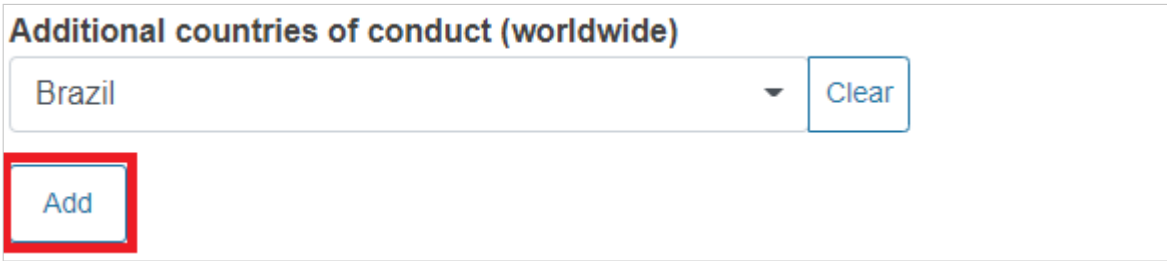
General description

1. Reply to the question *Has the manufacturer obtained the views of the expert panel on the clinical investigation according to Art 61(2) of Regulation (EU) 2017/745?* by selecting *Yes* or *No* from the drop-down list.

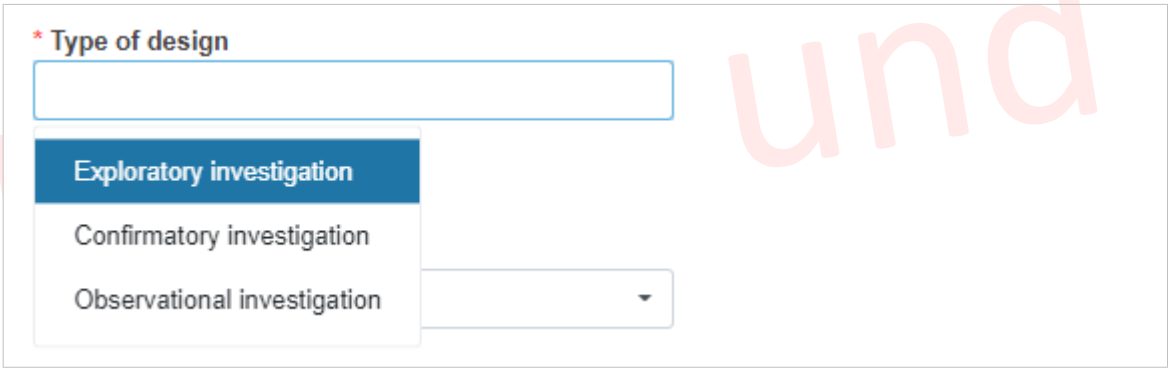


2. Add more countries of conduct, if relevant.

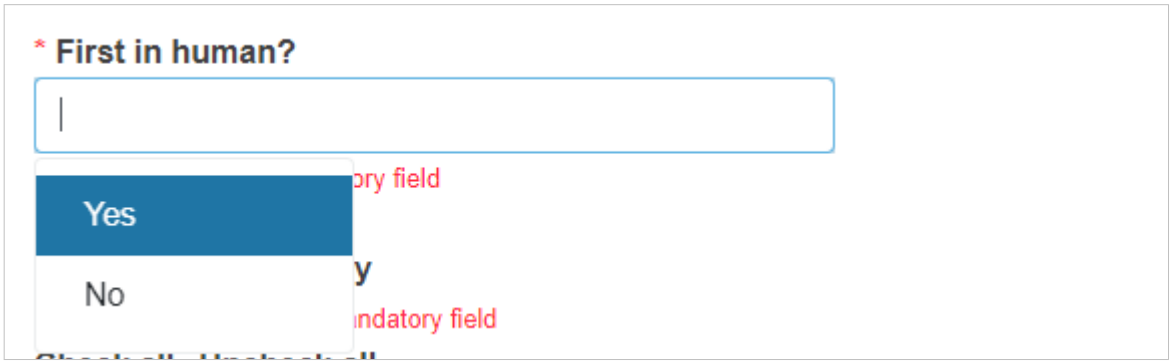
3. You can **add several countries**. To do it click **Add** and select the country from the drop-down list.



4. Select the **type of design**. At least one option must be selected.

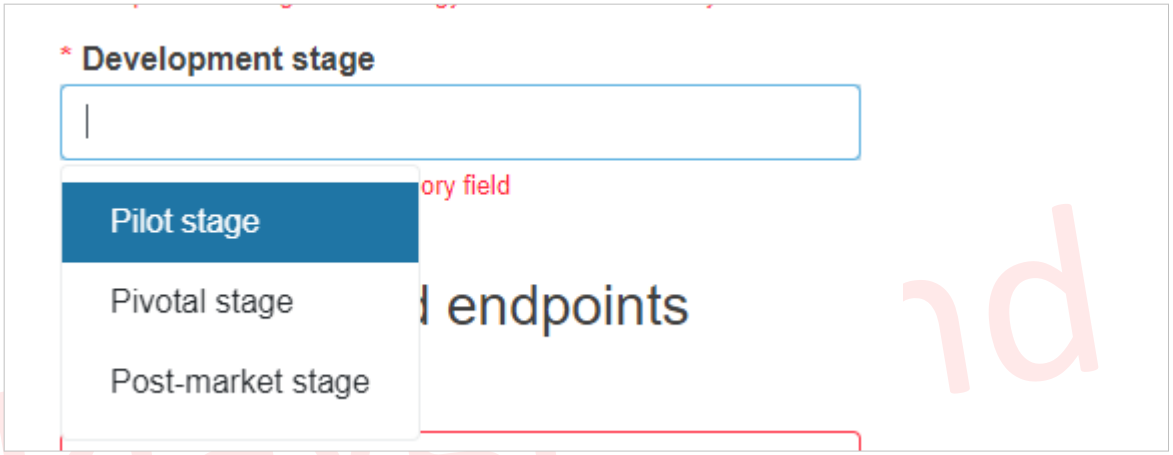


5. Reply *Yes* or *No* to the question *First in human?*



6. Select the *design methodology*. At least one option must be selected.

7. If you select the option *Other* you will be required to provide further information. Select the **development stage** from the drop-down list. You can select only one option.



Objectives and endpoints

Provide the following information:

- Primary
- Secondary objective
- Other objective(s)
- Primary endpoint
- Secondary endpoint
- Other endpoint(s)
- Overall synopsis

3.1.5 CI/PS Description – part 2

Click **CI/PS Description – part 2** from the left menu.

Planned number of subjects

Insert the planned number of subjects in:

- Europe
- Asia
- Africa
- North America
- South America
- Oceania

At the end, you can indicate the total number of subjects.

Dates

In this field, indicate the estimated start and end dates of the CI/PS, when relevant.

To select the date **click on the calendar icon**.

Alternatively, you can insert the date in the format YYYY-MM-DD.

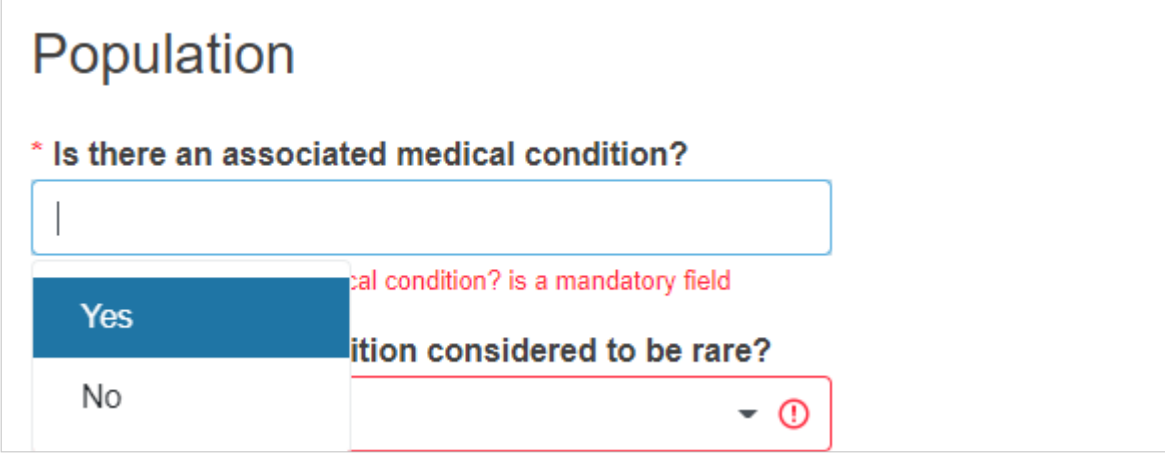
NOTE
The start date cannot be in the past.

IMPORTANT
If you are submitting a **PMCF/PMPF notification** (first version), you have to select an *Estimated start date* which is at least 30 calendar days from the date of submission.

If you are submitting a pre-existing application/notification and in the *CI/PS identification* section you selected the value *Not yet started*, either only the *Estimated end date* will appear or none of the date fields.

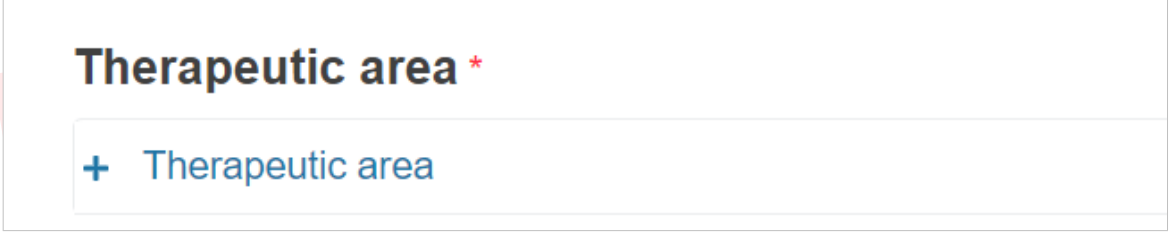
Population

1. Reply *Yes* or *No* to the question Is there an associated medical condition?

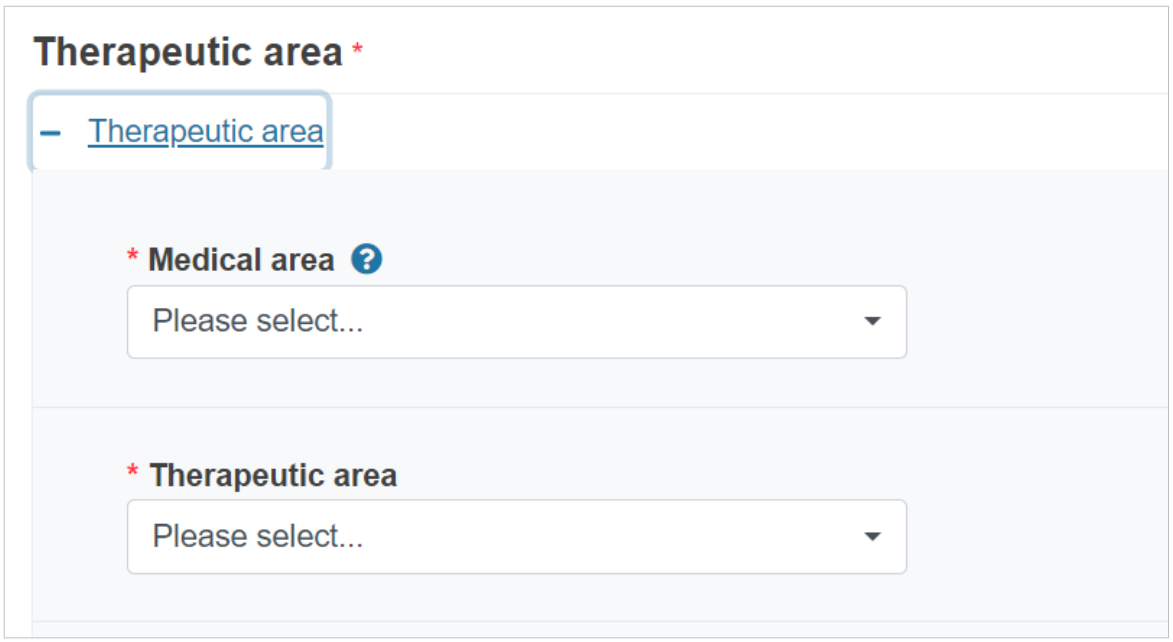


2. **If you reply Yes**, the question *Is the medical condition considered to be rare?* will appear for you to reply.

3. For MDR - Select the **therapeutic area** by clicking **+ Therapeutic area**.

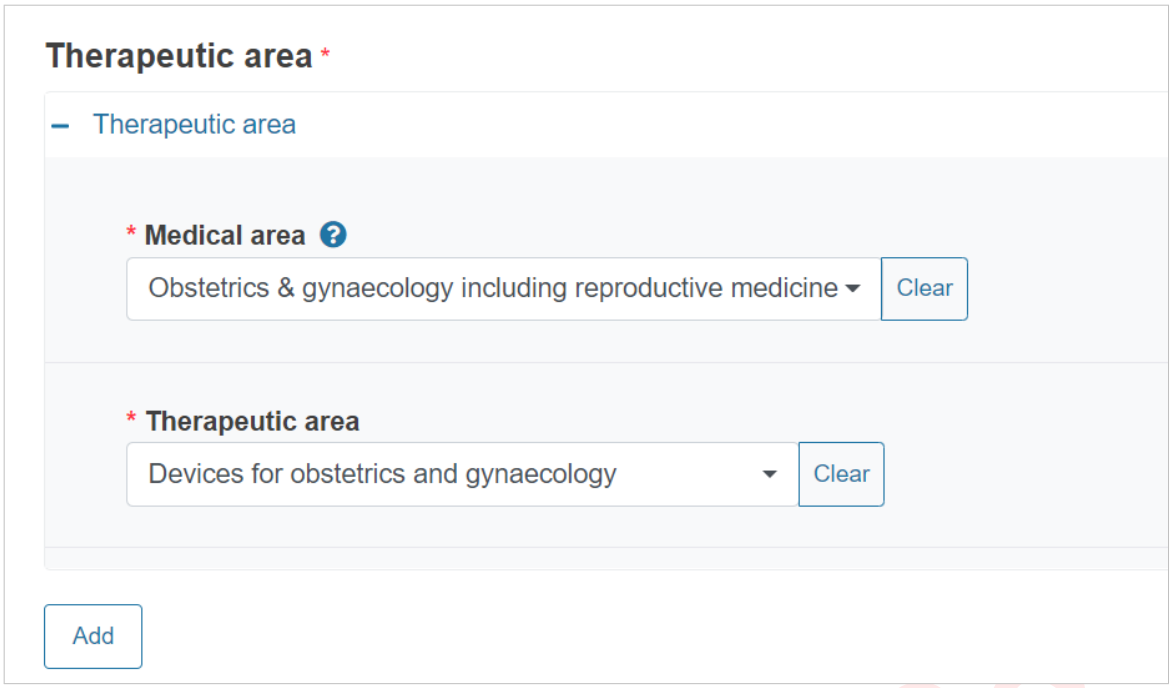


4. A new section will appear for you to **choose the medical and therapeutic areas**.



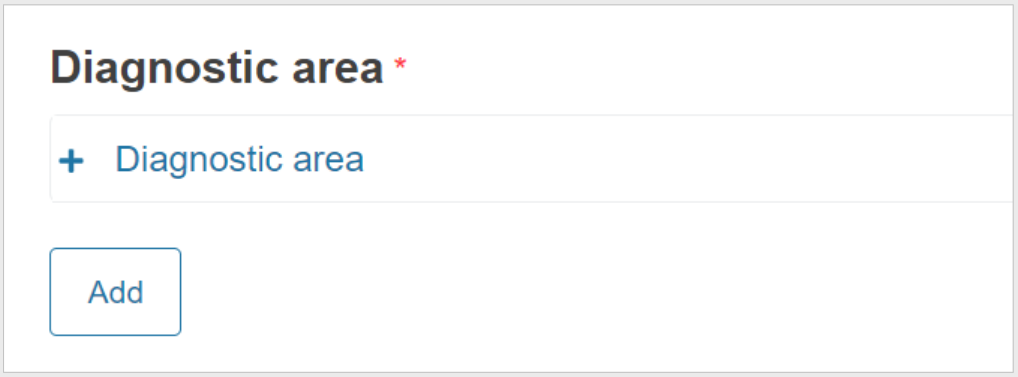
5. The medical area you choose will determine the options you will have under the therapeutic drop-down list.

6. You can **add more therapeutic areas** by clicking **Add**.

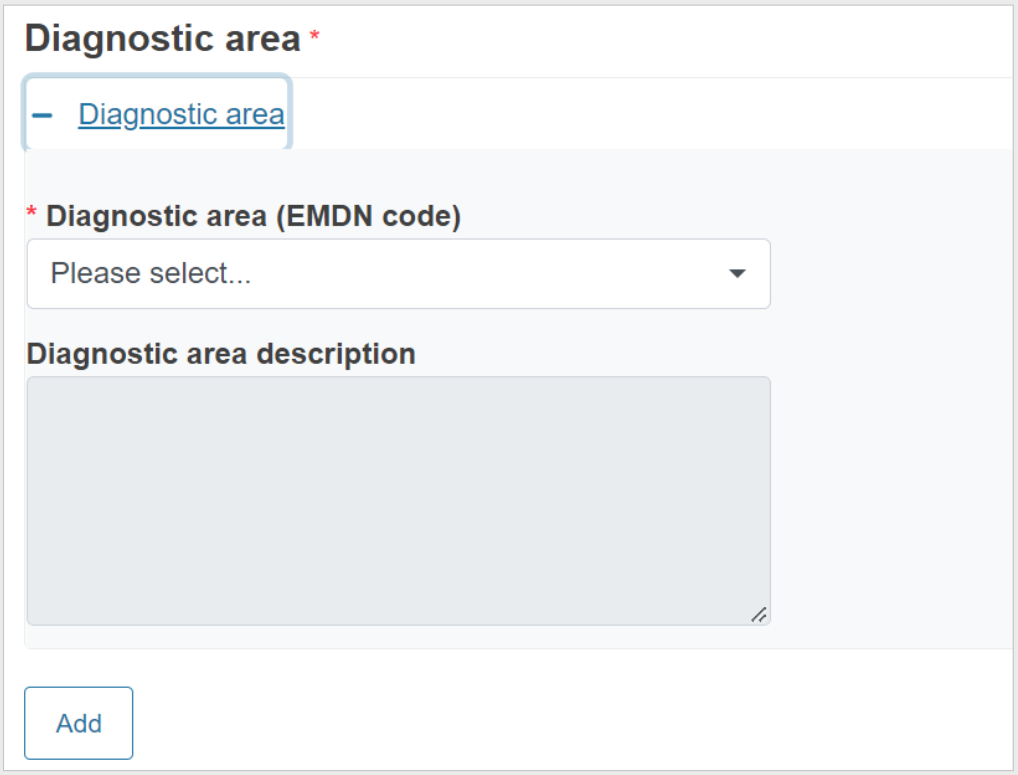


NOTE
In case of Performance Studies (IVDR) the section Diagnostic area will show instead of Therapeutic area.

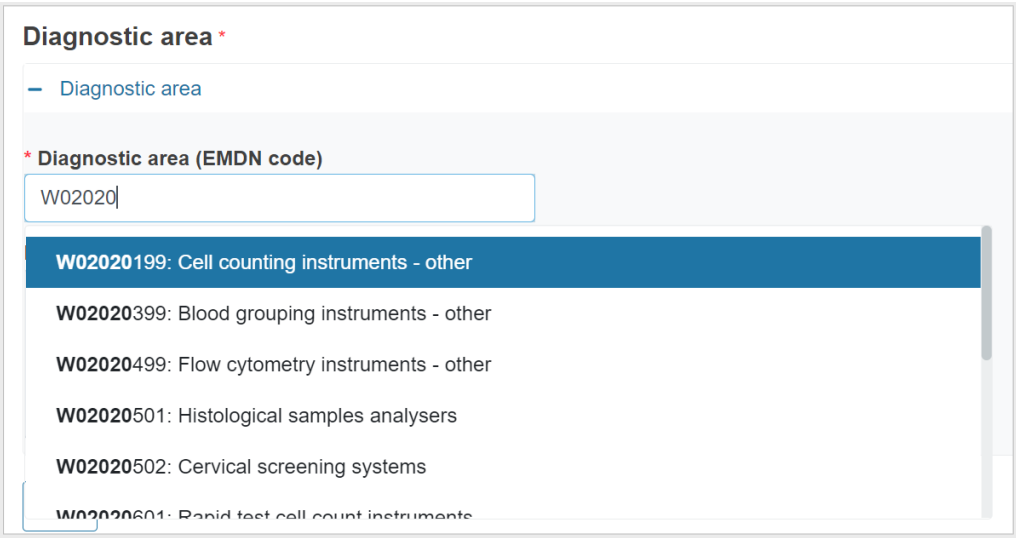
A new field will appear to select the Diagnostic area.



The Diagnostic area codes are the EMDN nomenclature codes for IVD devices. The values are restricted to the EMDN codes starting with “W” (In vitro diagnostic medical devices) at level 3 or 4 of the nomenclature structure. See the European Medical Device Nomenclature (EMDN) for more information.



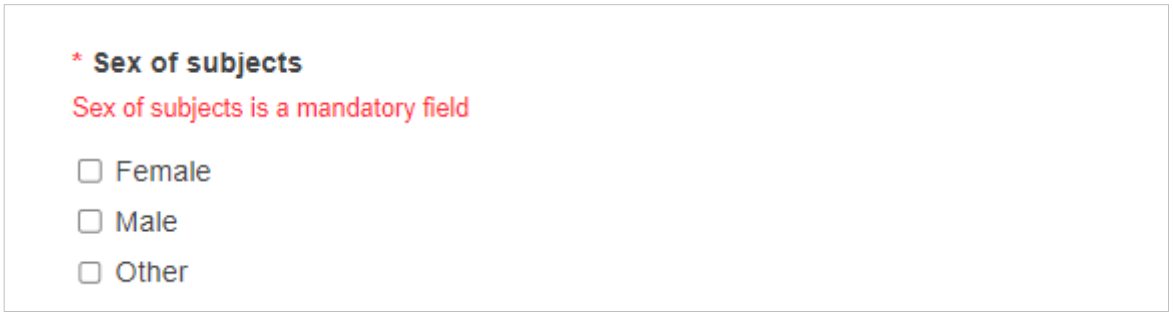
To complete the field and retrieve the description, enter “W” and at least the first 4 digits of the nomenclature code.



The system will display the relevant options to select from.

You can **add several Diagnostic area codes** by clicking *Add*.

7. Provide the **sex of the subjects**.



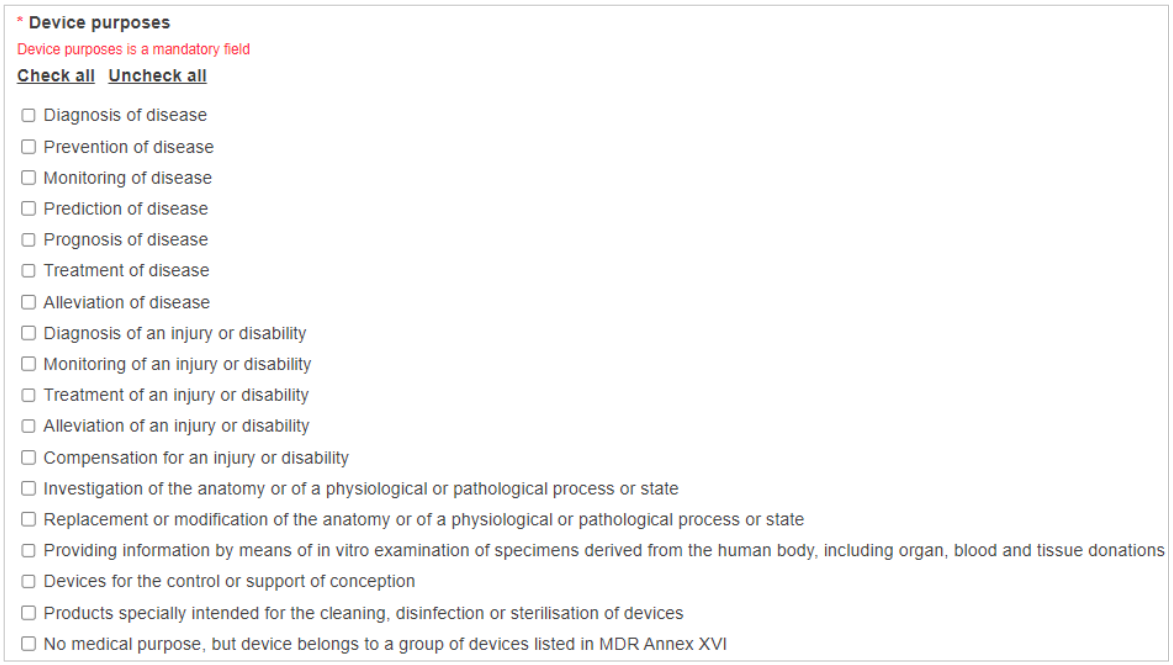
8. Indicate the **inclusion and exclusion criteria**.

9. Choose the **type of subjects**.

10. Choose the **age range**.

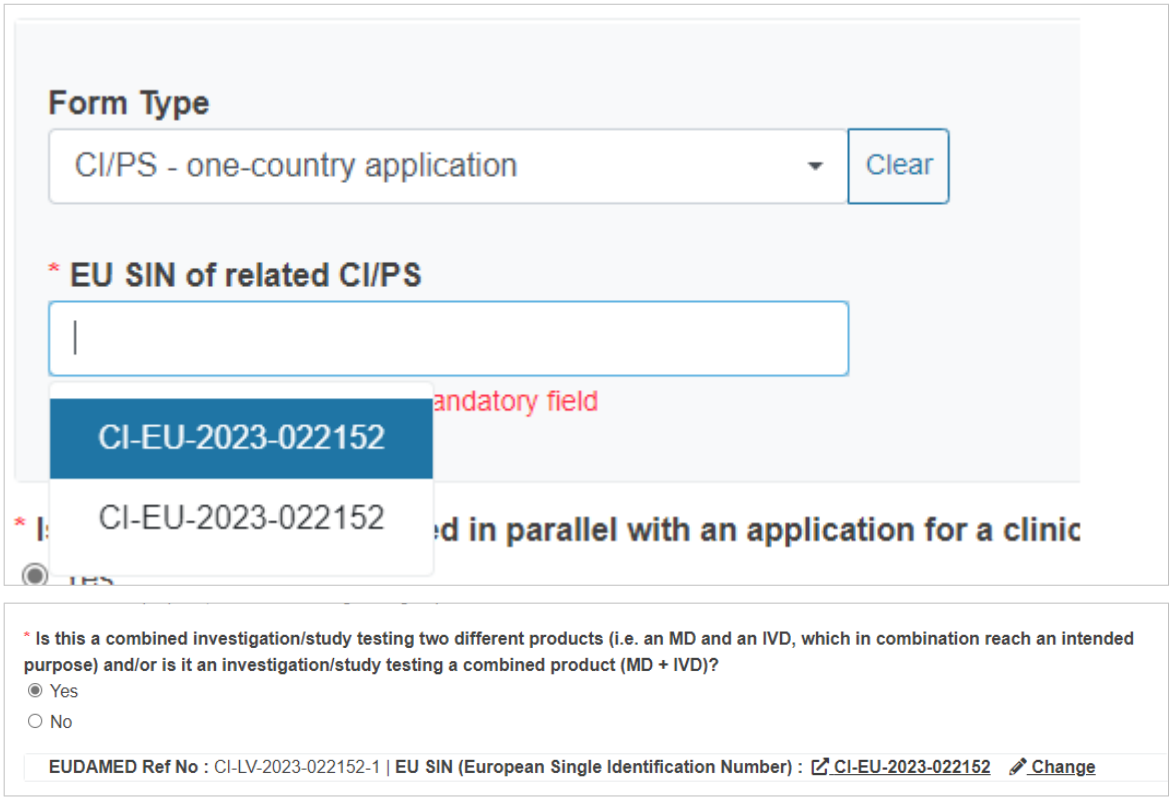
Scope of the investigational/study device

1. Choose the **device purposes**:



2. Reply *Yes* or *No* to the question *Is this a combined investigation/study testing two different products (i.e. an MD and an IVD, which in combination reach an intended purpose) and/or is it an investigation/study testing a combined product (MD + IVD)?*

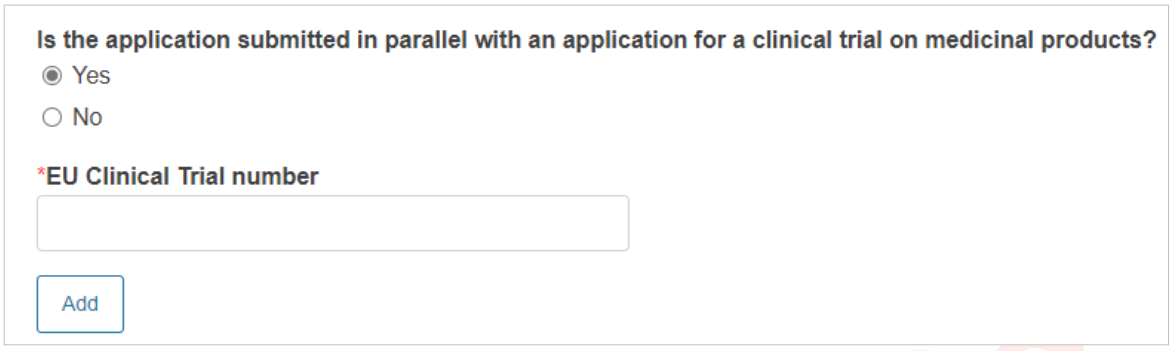
3. If you reply **Yes**, a new section will appear, from where you can select the form type you want to link to the application/notification. Then choose from the drop-down list the EU SIN of the related CI/PS application or PMCF/PMPF notification. The drop-down list only displays forms owned by the current Sponsor.



IMPORTANT
You can only link forms that have been created by your Sponsor actor. You cannot link draft forms.

4. Reply *Yes* or *No* to the question *Is the application submitted in parallel with an application for a clinical trial on medicinal products?*

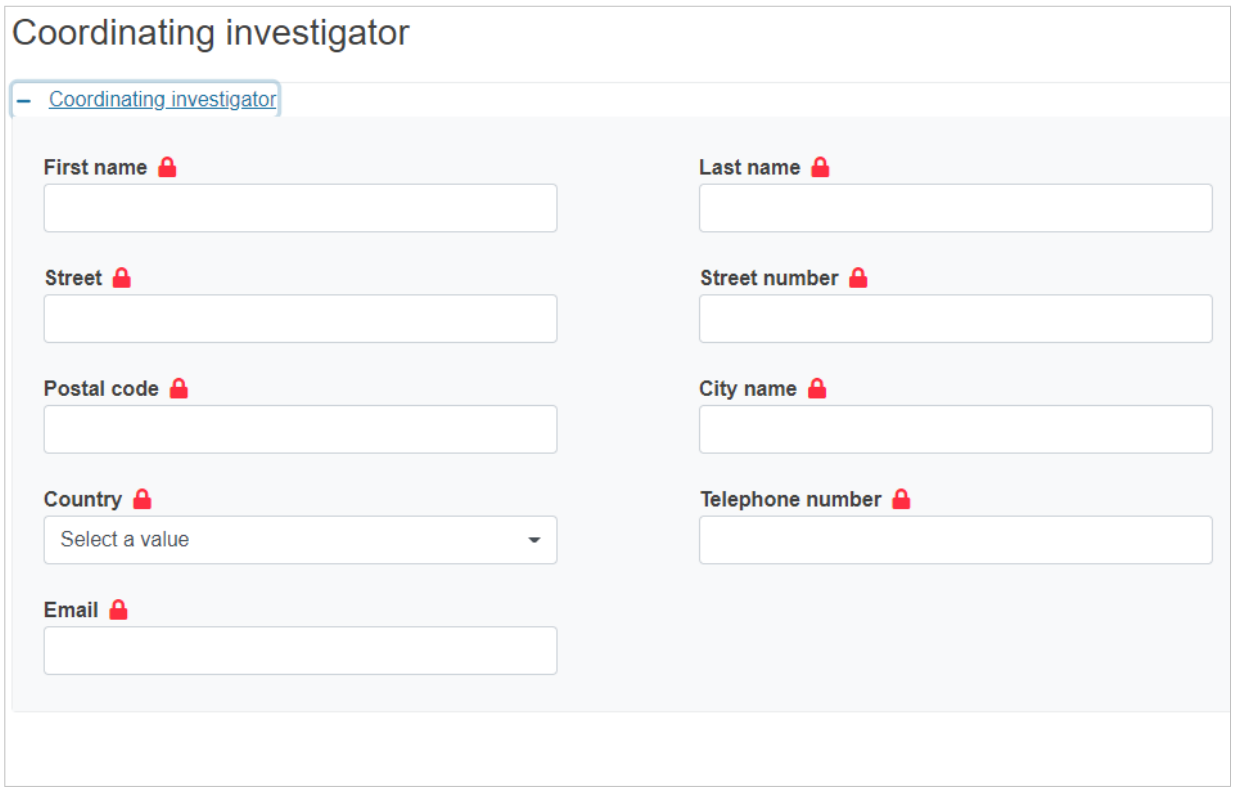
5. If you reply *Yes*, you must **provide EU Clinical Trial number**.



6. To **add other EU clinical trial number** click **Add**.

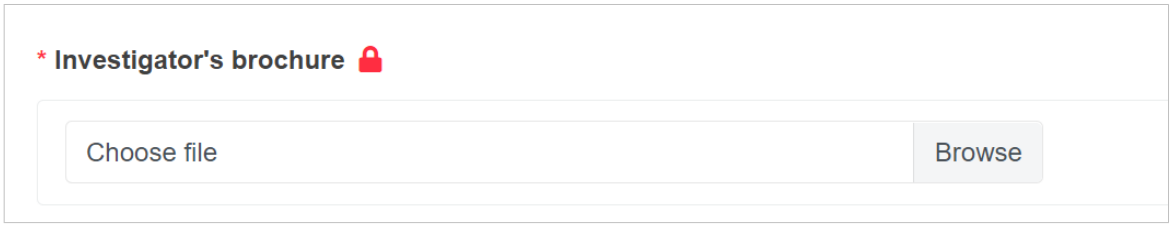
Coordinating investigator

Insert the details of the coordinating investigator.



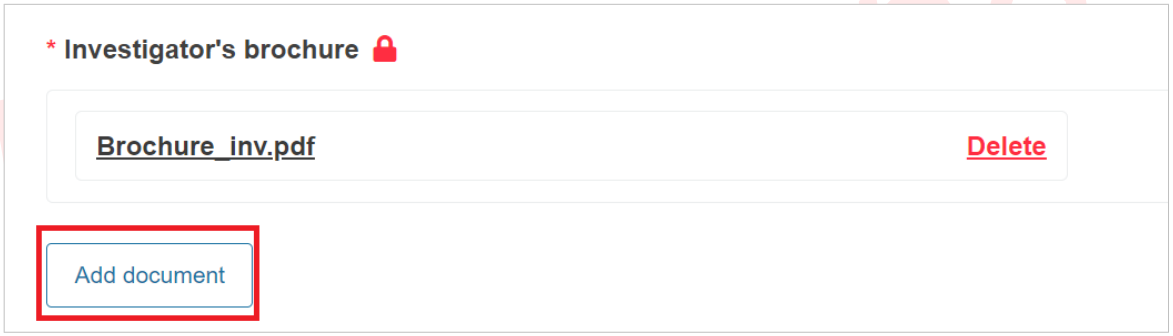
3.1.6 Common documents and statements

1. Click **Common documents and statements** on the left menu.
2. To **upload a document**, click *Browse* and then select it from your computer.



NOTE
All the documents must be uploaded in PDF format.

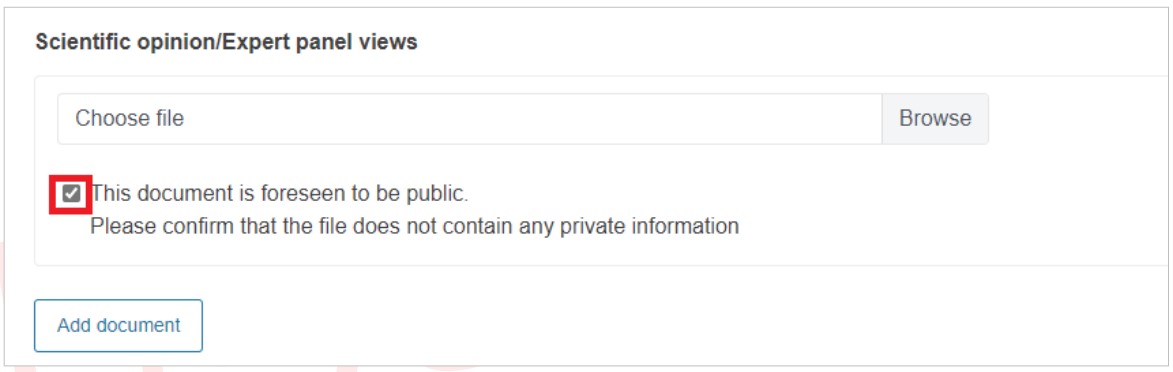
3. You can **add several documents** for each topic. To do it, click *Add document*.



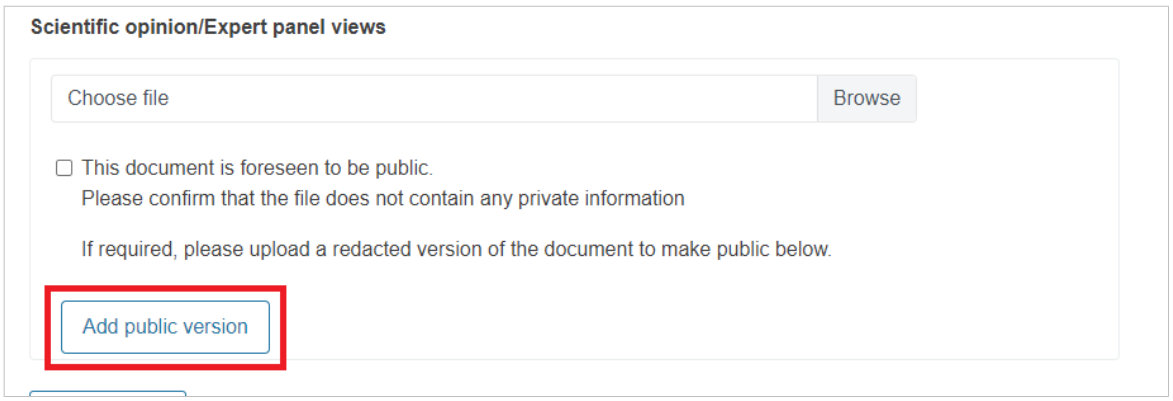
NOTE
The investigator's brochure is not mandatory if you are submitting a PMCF/PMPF notification.

NOTE
Click **delete** to replace the uploaded file with another one, or **remove** to eliminate the document instance (only available when there are at least two file instances).

4. The following documents will **not be publicly available**:
   - Investigator's brochure
   - Clinical investigation/Performance study plan (for CI/PS application only)
   - PMCF/PMPF investigation plan (for PMCF/PMPF only)
   - Technical documentation as risk analysis, test report, etc.
   - Overall synopsis of clinical investigation/performance study (Referenced in MDR Chapter II 3.1.5 in annex XV/IVDR Part A 2.3.2 (g) in annex XIII)
   - Statement of conformity
5. The following documents will be **public**:
   - Scientific opinion/Expert panel views
   - Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/personal information
6. The following documents will be **public only once the End report and summary** of the CI/PS or PMCF/PMPF are published.
   - Clinical investigation/Performance study plan
   - PMCF/PMPF investigation plan
7. For these documents, you will be asked to **confirm that they do not contain private information**. To do it, you must tick the box.

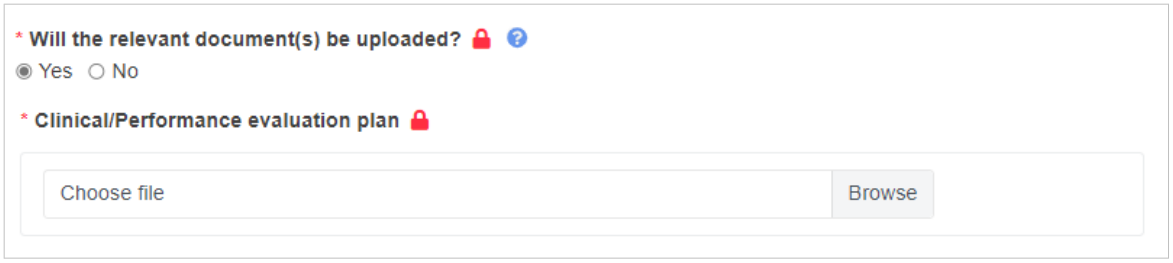


8. If the document has private information, do not tick the box. Instead, you must **upload a redacted version** of the document to make it public.

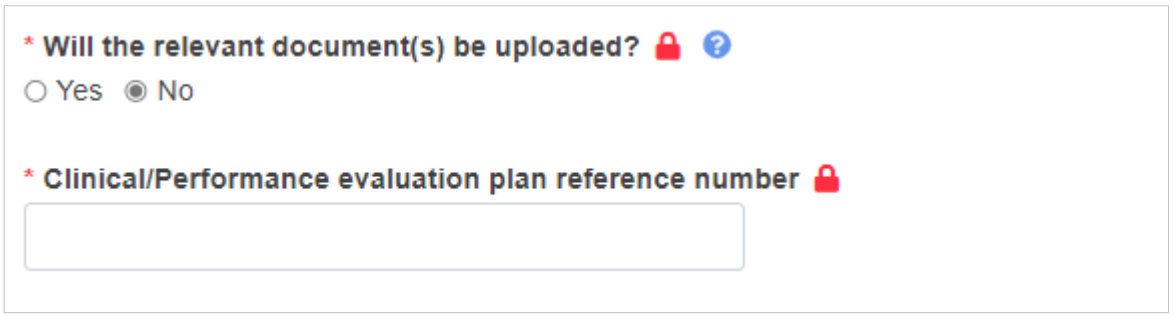


9. On the clinical/performance evaluation plan, reply *Yes* or *No* to the question *Will the relevant document(s) be uploaded?*

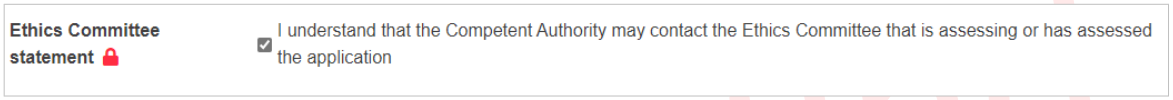
10. **If you reply Yes**, you will be asked to provide the Clinical/Performance evaluation plan.



If you reply No, you will be asked to provide the *Clinical/Performance evaluation plan reference number*.



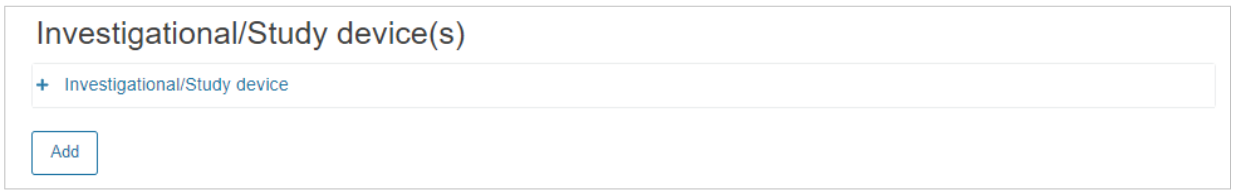
11. At the end of the screen, **acknowledge the Ethics Committee statement**, i.e., the Competent Authority may contact the Ethics Committee that is assessing or has assessed the application.



3.1.7 Investigational/Study device(s)

Click **Investigational/study device(s)** in the left menu.

Click **+ Investigational/Study device(s)** to **expand the section**.

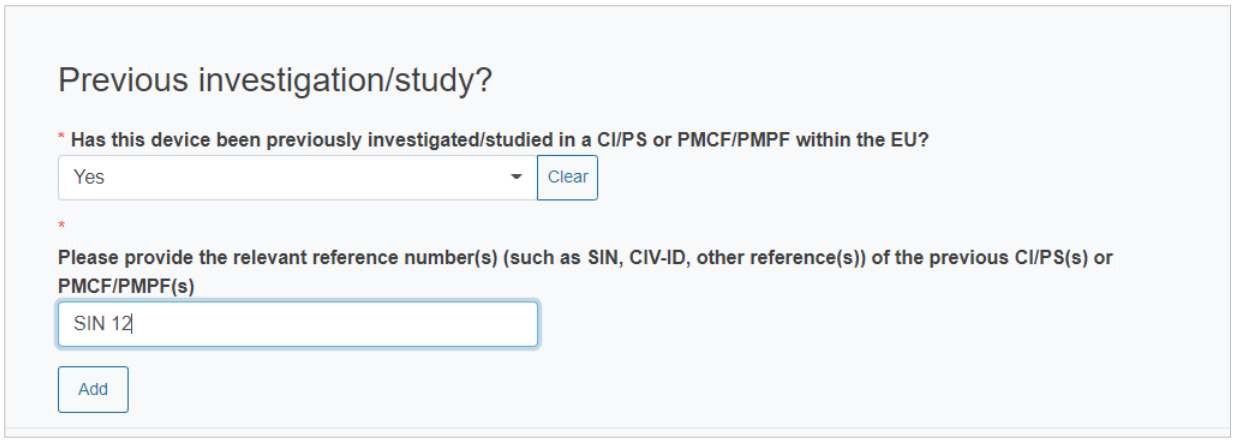


NOTE
For each Investigational/Study device(s), the system generates a new sub-section under the *Language-specific investigational/study device(s) information* header of the *National Information* section with the same identifier as the *Investigational/Study device(s)*.

Previous investigation/study?

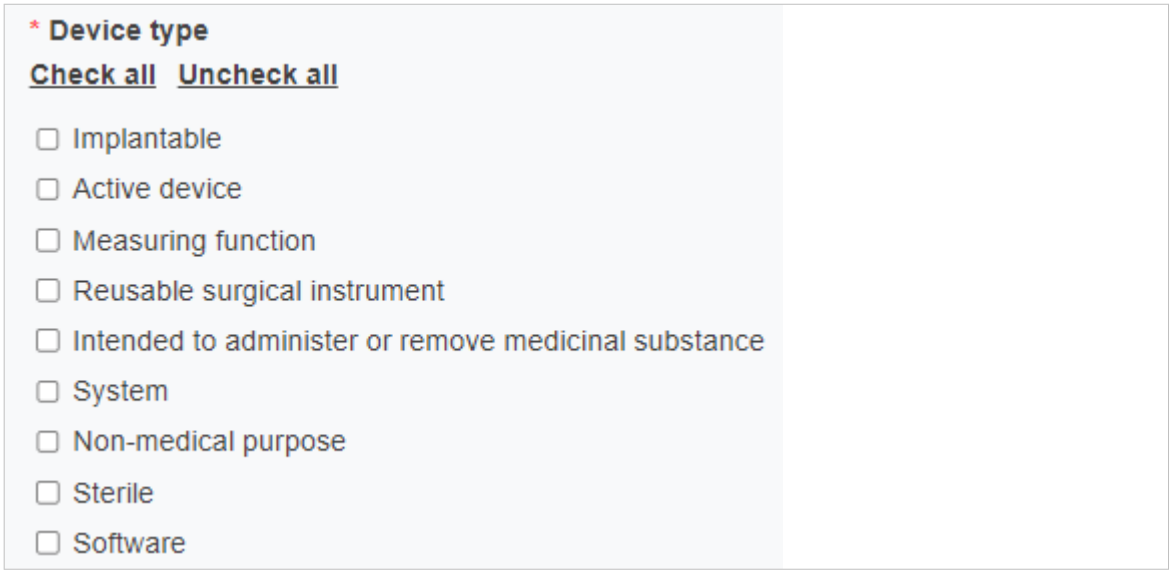
Reply *Yes* or *No* to the question *Has this device been previously investigated/studied in a CI/PS or PMCF/PMPF within the EU?*

If you reply *Yes*, a new field will appear for you to **provide the relevant reference number(s) (such as SIN, CIV-ID, other reference(s)) of the previous CI/PS(s) or PMCF/PMPF(s)**.



Device information

1. Reply *Yes* or *No* to the question *Do any of the following device types apply?*
2. If you reply *Yes*, select the *Device type(s)*:



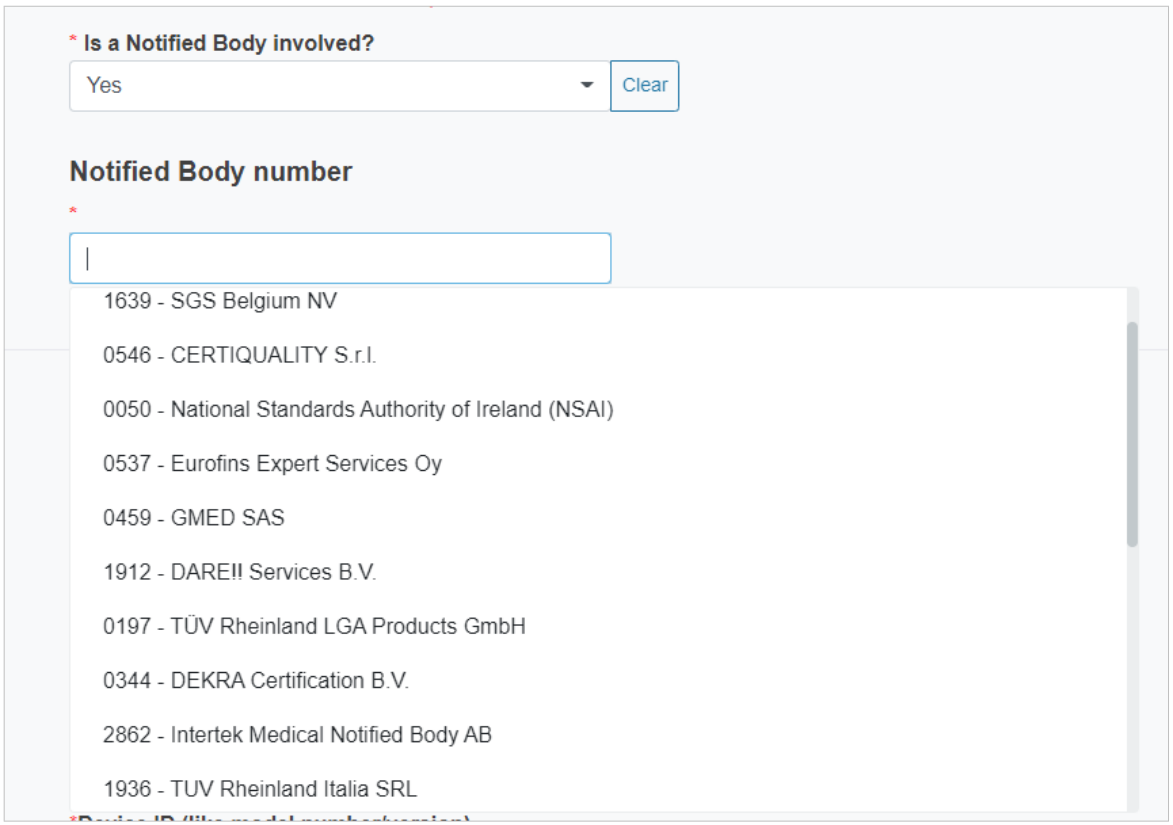
3. Reply to the question *Is the device CE marked?*

4. Based on the response, certain fields will become available (and mandatory) or not:

Is the device CE marked?	Yes	**Is the device registered in EUDAMED?**	Yes	Provide: • Unique Device Identification (UDI-DI / EUDAMED ID) • Confirm that the CE-marked device will be used outside the scope of its CE mark by ticking the box
			No	Provide: • UDI-DI - not registered in EUDAMED • Issuing entity • Confirm that the CE-marked device will be used outside the scope of its CE mark by ticking the box
	No	No further action		

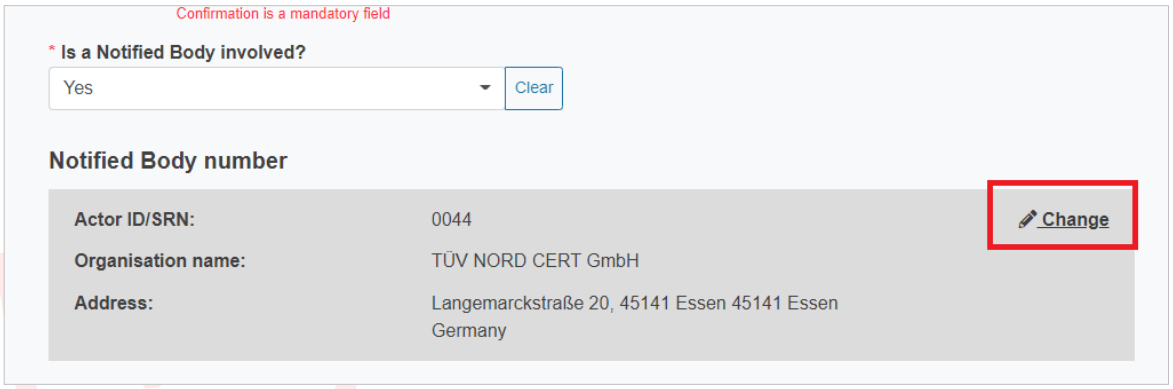
5. Reply *Yes* or *No* to the question *Is a Notified Body involved?*

6. If you reply *Yes*, you must select from the drop-down list the Notified Body number.



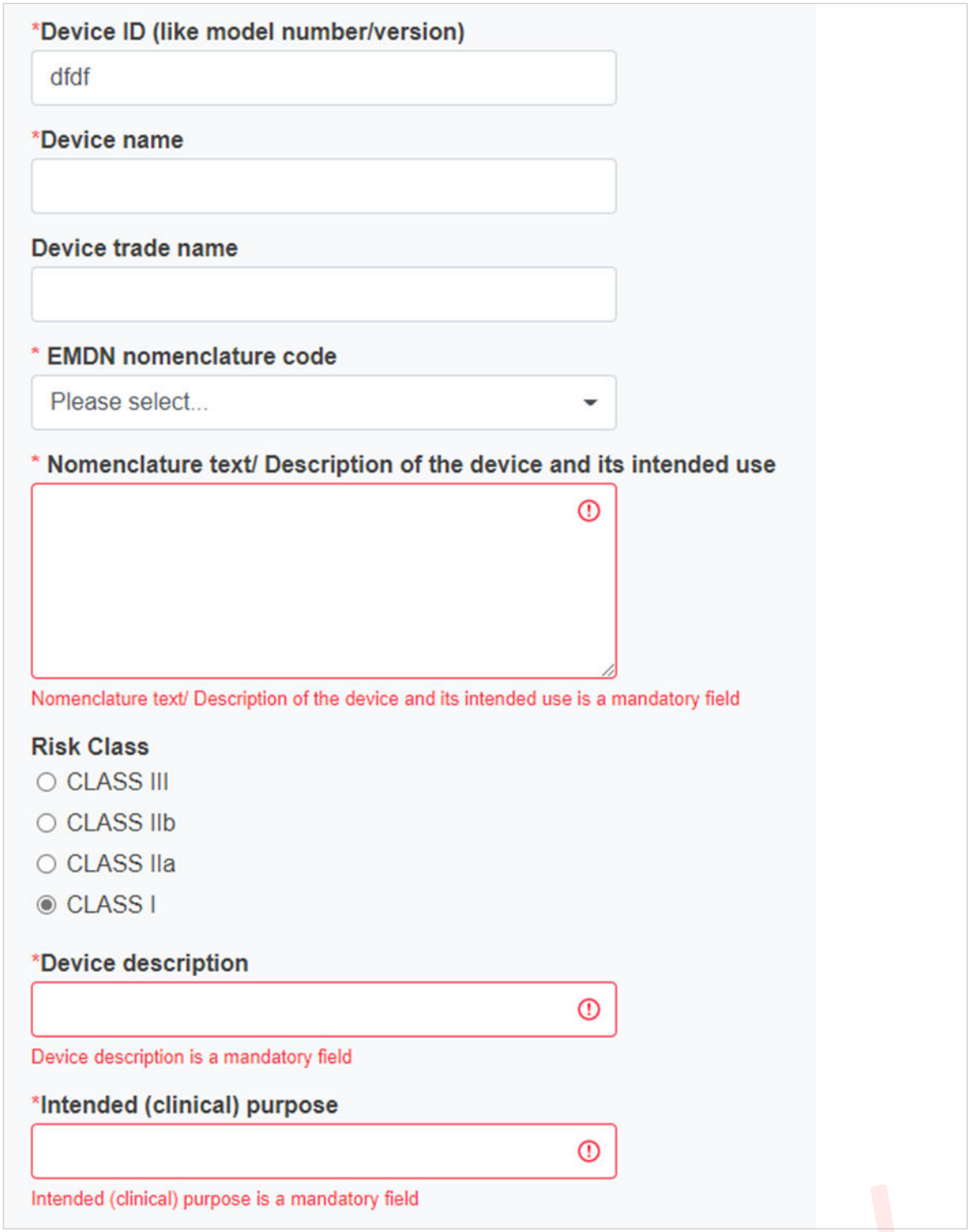
7. Once you select the Notified Body number, its data will be displayed.

8. To **change the Notified Body number** click **Change** at the top right of the grey box.

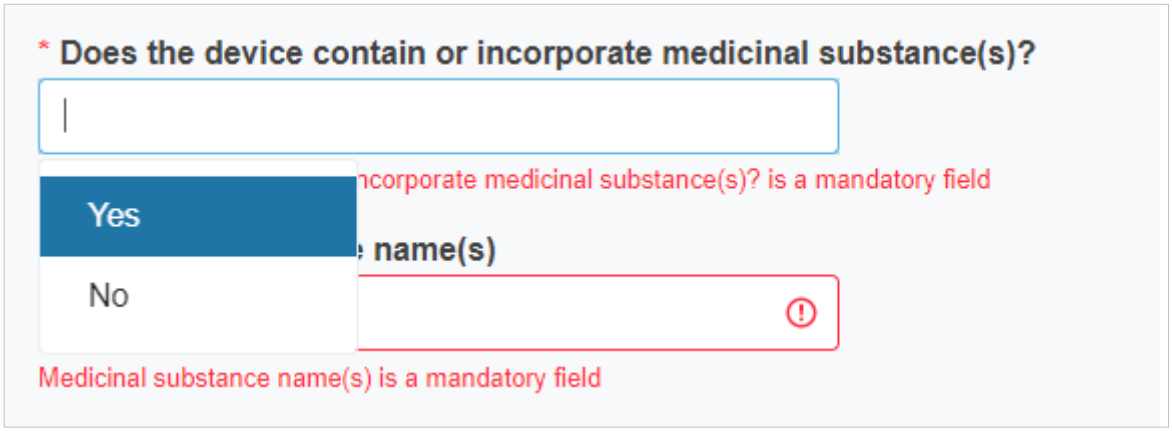


Investigational/Study device details

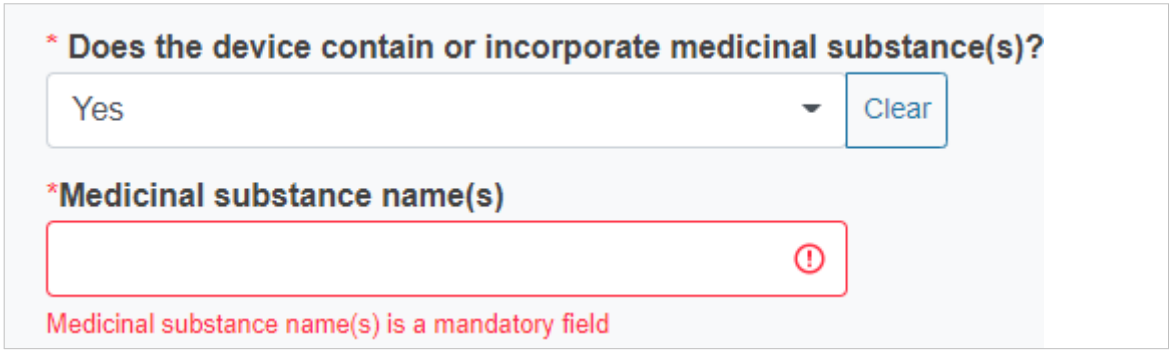
1. In this section provide the details of the device:
   - Device ID
   - Device name
   - Device trade name
   - EMDN nomenclature code
   - Nomenclature text/ Description of the device and its intended use – retrieved automatically based on the code selected
   - Risk class (choose from the list – only one option is possible)
   - Device description
   - Intended (clinical) purpose



2. Reply *Yes* or *No* to the question *Does the device contain or incorporate medicinal substance(s)?*

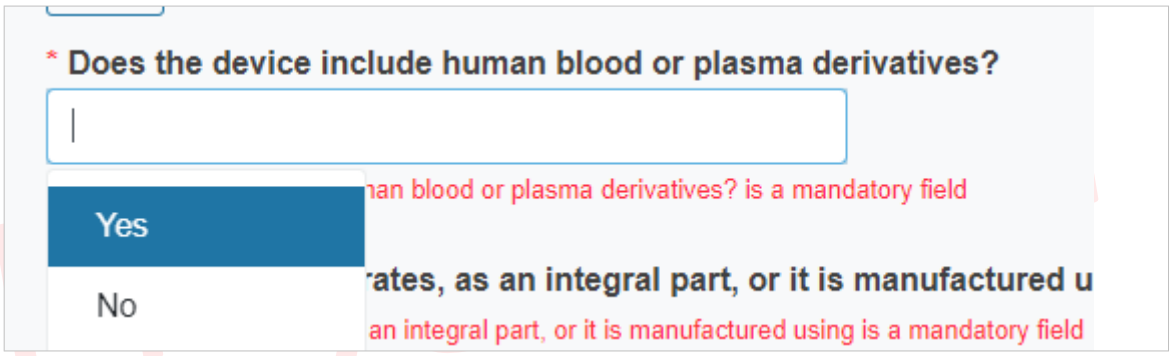


3. If you reply *Yes*, you must **provide the name of the medicinal substance**.



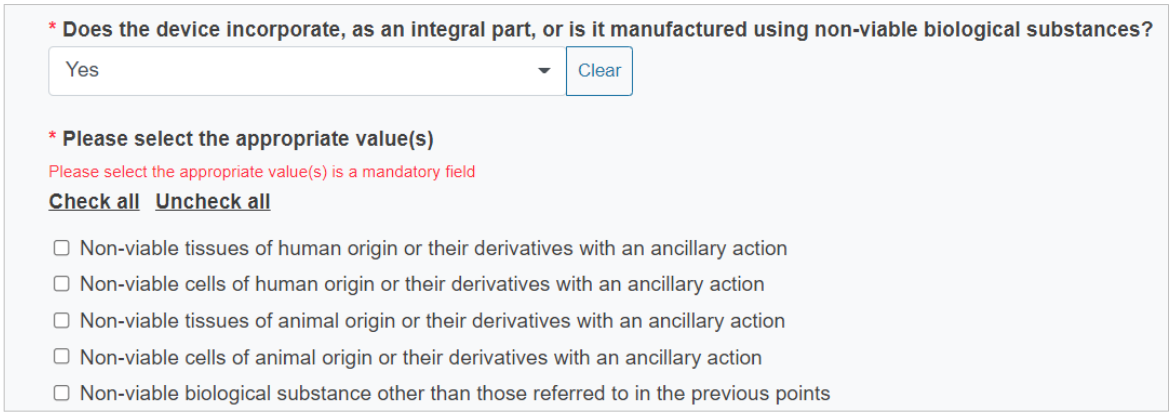
4. To **add more medicinal substances** click **Add**.

5. Reply *Yes* or *No* to the question *Does the device include human blood or plasma derivatives?*

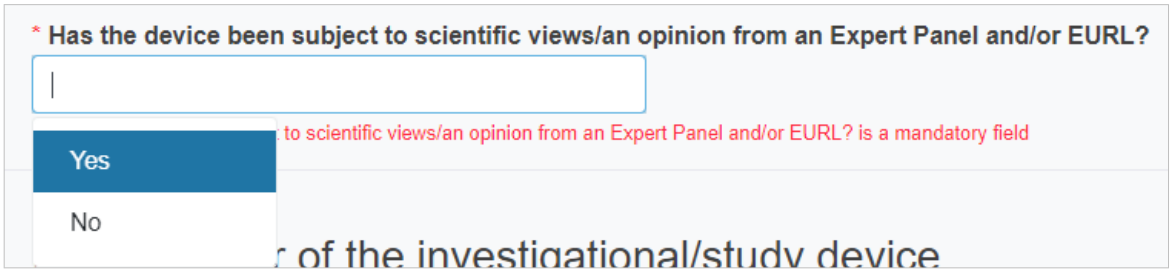


6. Reply *Yes* or *No* to the question *Does the device incorporate, as an integral part, or is it manufactured using non-viable biological substances?*

If you reply *Yes*, you must complete the relevant value(s) for the field *Please select the appropriate value(s)*.
You can select several options.

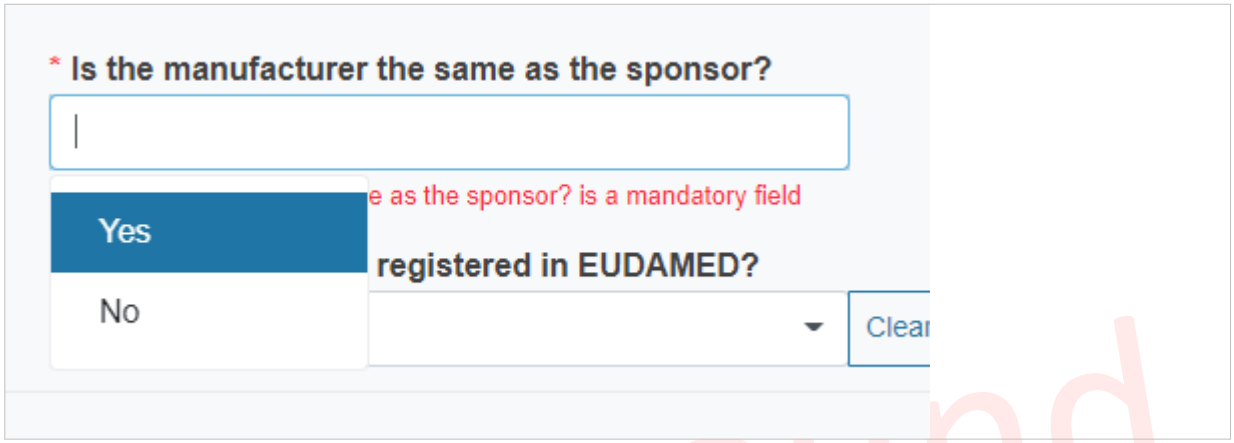


7. Reply *Yes* or *No* to the question *Has the device been subject to scientific views/an opinion from an Expert Panel and/or EURL?*



Manufacturer of the investigational/study device and Manufacturer information

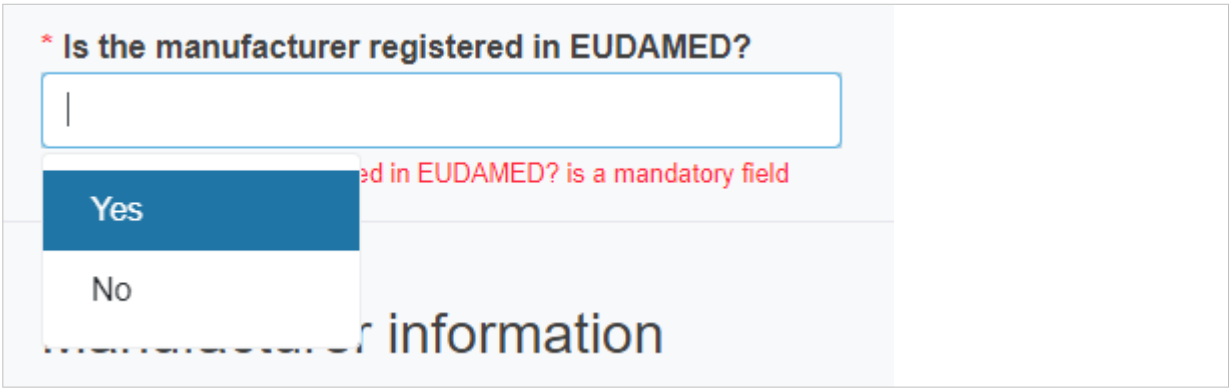
Reply *Yes* or *No* to the question *Is the manufacturer the same as the sponsor?*



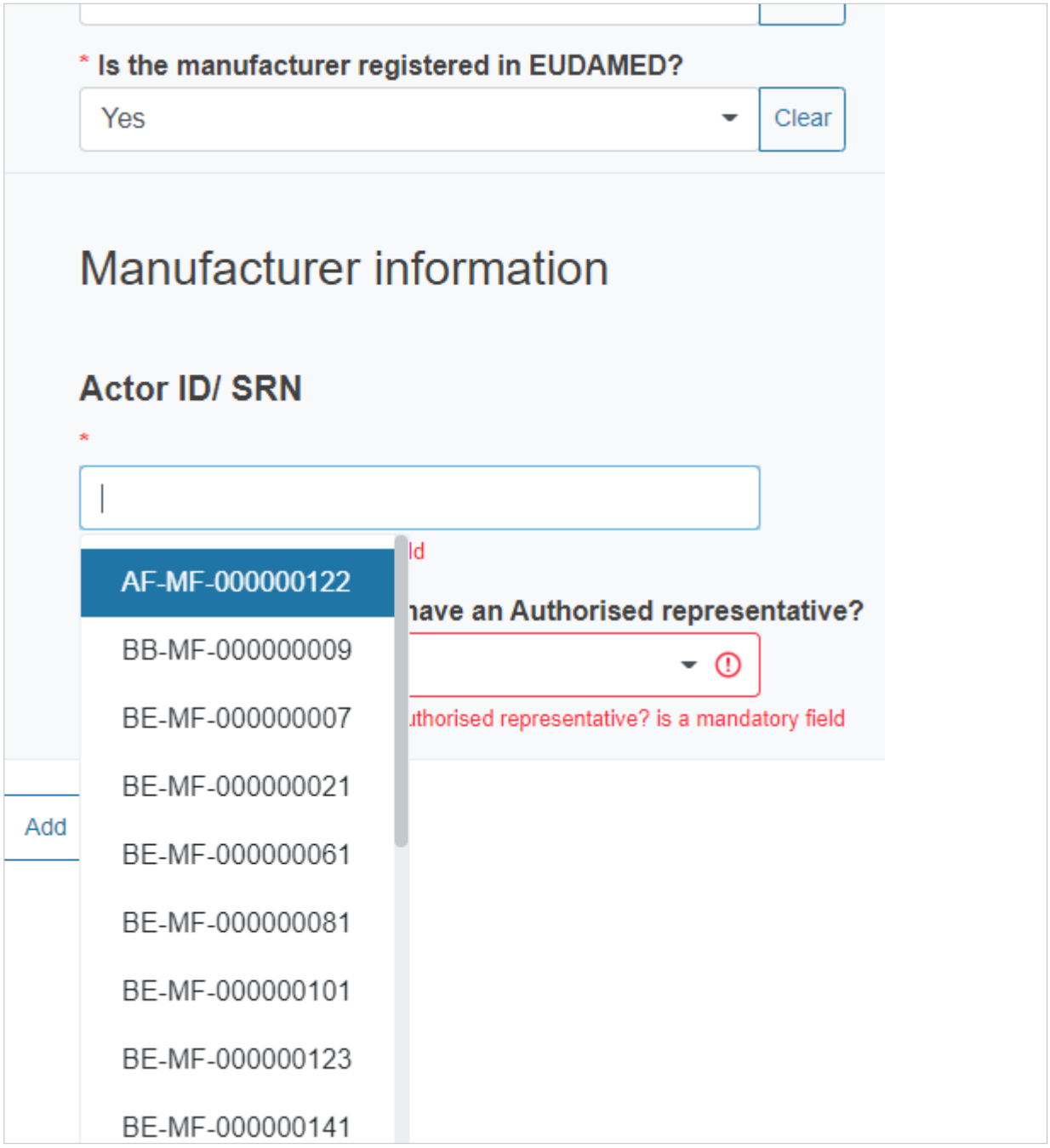
If the device:

- is not CE marked **or**
- is CE marked but it is not registered in EUDAMED,

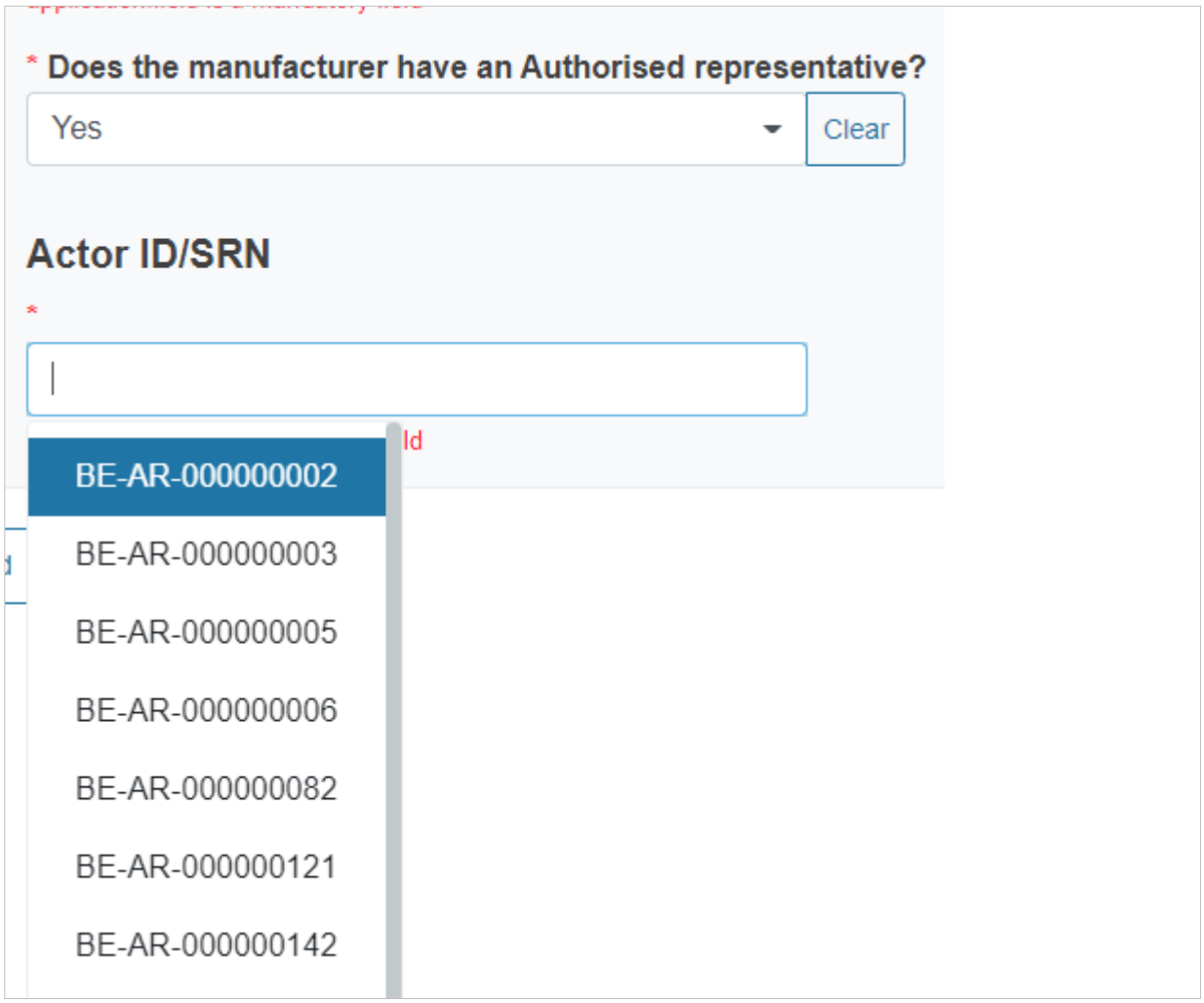
you need to reply reply *Yes* or *No* to the question *Is the manufacturer registered in EUDAMED?*



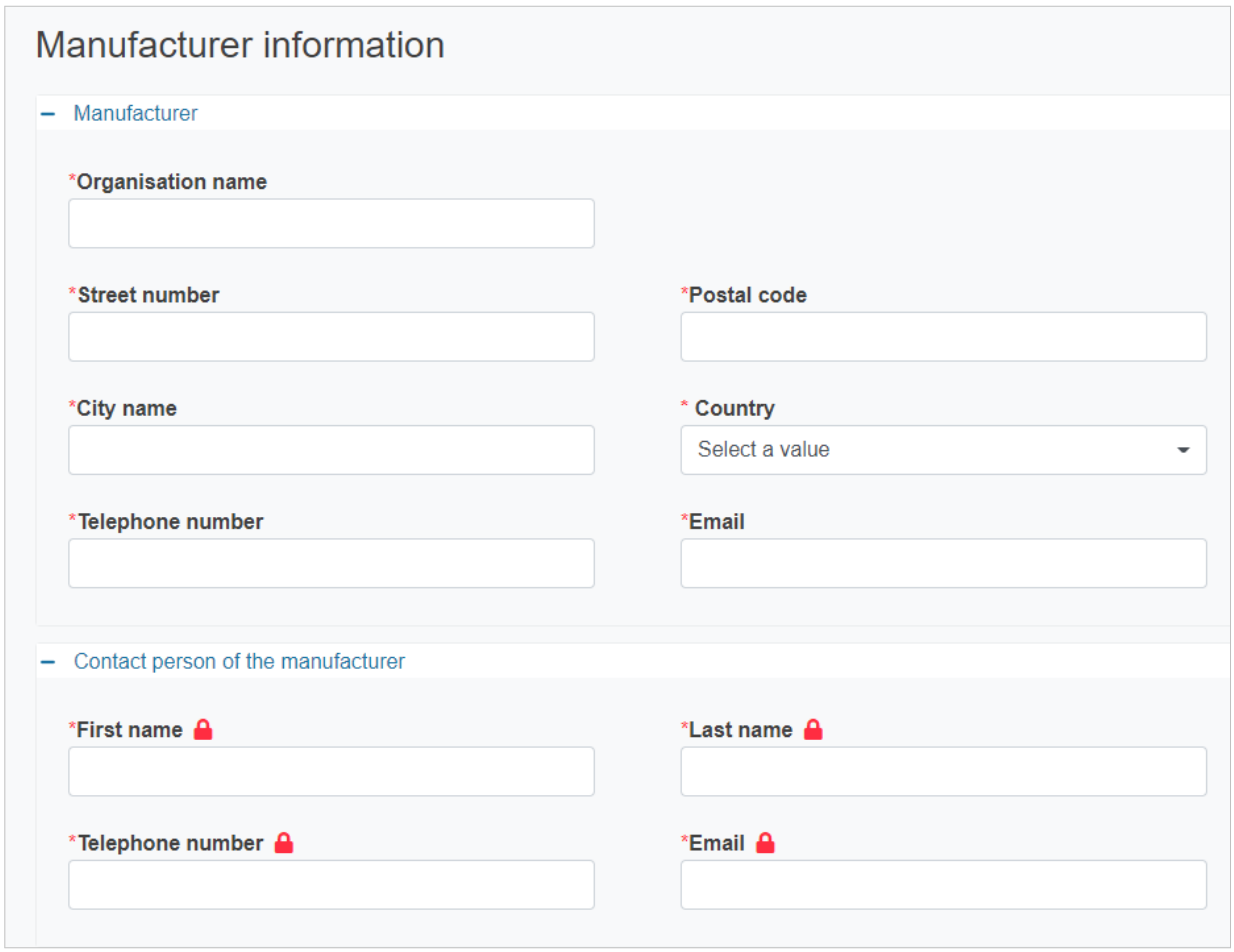
If you reply *Yes*, you will be asked to select from the dropdown list the Actor ID/SRN of the manufacturer.



You will also have to indicate if the manufacturer has an authorised representative. If you reply *Yes*, you must select from the dropdown list its Actor ID/SRN as well.



If the **manufacturer is not registered** in EUDAMED you must provide its details. The details of the contact person will not be made publicly available.



Below you can find a **summary table** where you can check the data you need to provide depending on certain conditions.

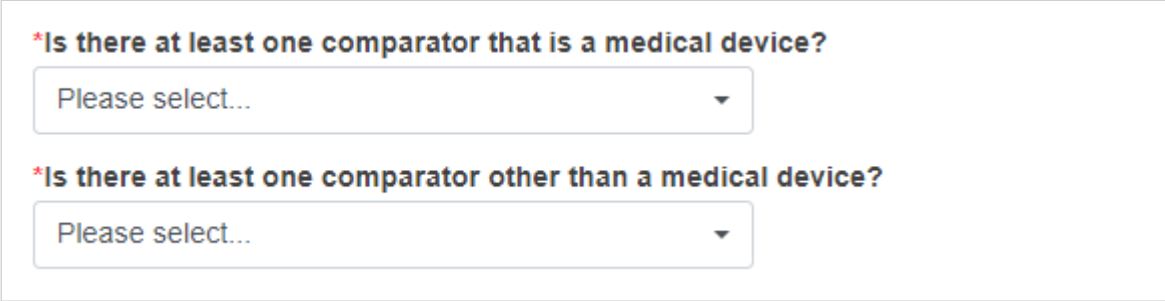
Do I need to provide the following data?	The device is not CE marked - CI/PS only, option not applicable for PMCF/PMPF	The device is CE marked but is not registered in EUDAMED	The device is registered in EUDAMED	
			CI/PS	PMCF/PMPF
UDI-DI/EUDAMED ID			Yes	Yes
UDI-DI - not registered in EUDAMED		Yes		
Issuing entity		Yes		
I confirm that the CE-marked device will be used outside the scope of its CE mark		Yes, for CI/PS only	Yes	
I confirm that the CE-marked device will be used within the scope of its CE mark		Yes, for PMCF/PMPF only		Yes
Investigational/Study device details				
Device ID (like Model number / Version)	Yes	Yes	Yes	Yes
Device name	Yes	Yes	Only if different from registered device data	
Device trade name	Yes	Yes	Only if different from registered device data	
EMDN nomenclature code and nomenclature text	Yes	Yes	Select the EMDN code of the registered device that applies to the current CI/PS	Select the EMDN code of the registered device that applies to the current PMCF/PMPF
Risk Class	Yes	Yes	Yes	
Device description	Yes	Yes	Yes	Yes

Do I need to provide the following data?	The device is not CE marked - CI/PS only, option not applicable for PMCF/PMPF	The device is CE marked but is not registered in EUDAMED	The device is registered in EUDAMED	
Intended (clinical) purpose	Yes	Yes	Yes	Yes
Does the device contain or incorporate medicinal substance(s)?	Yes	Yes		
Does the device include human blood or plasma derivatives?	Yes	Yes	Yes	
Does the device incorporate, as an integral part, or is it manufactured using non-viable biological substances?	Yes	Yes	Yes	Yes
Has the device been subject to scientific views/an opinion from an Expert Panel and/or EURL?	Yes	Yes	Yes	Yes
Manufacturer of the investigational/study device				
Is the manufacturer the same as the sponsor?	Yes	Yes	Yes	Yes
Is the manufacturer registered in EUDAMED	Yes	Yes		

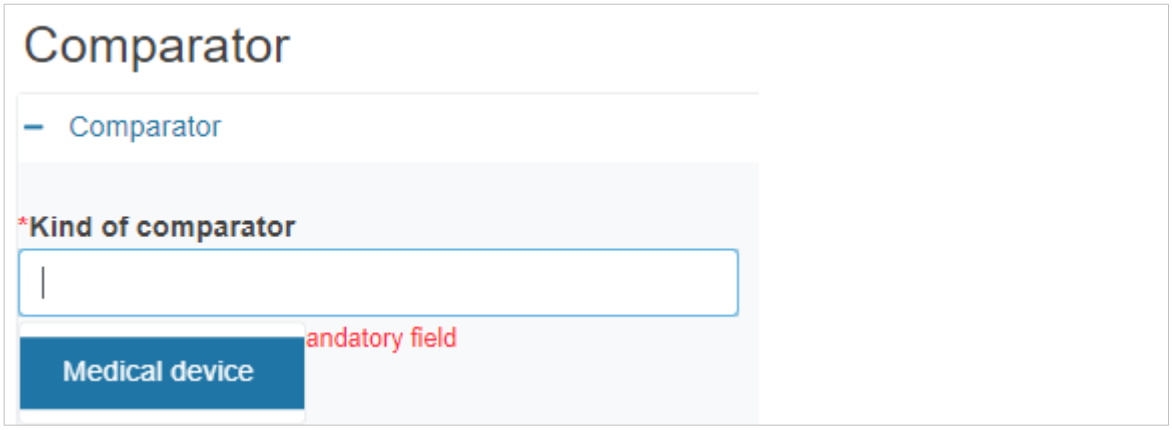
You need to provide the authorised representative details only if the manufacturer is registered in EUDAMED **and** the country of the manufacturer is non-EU.

3.1.8 Comparator

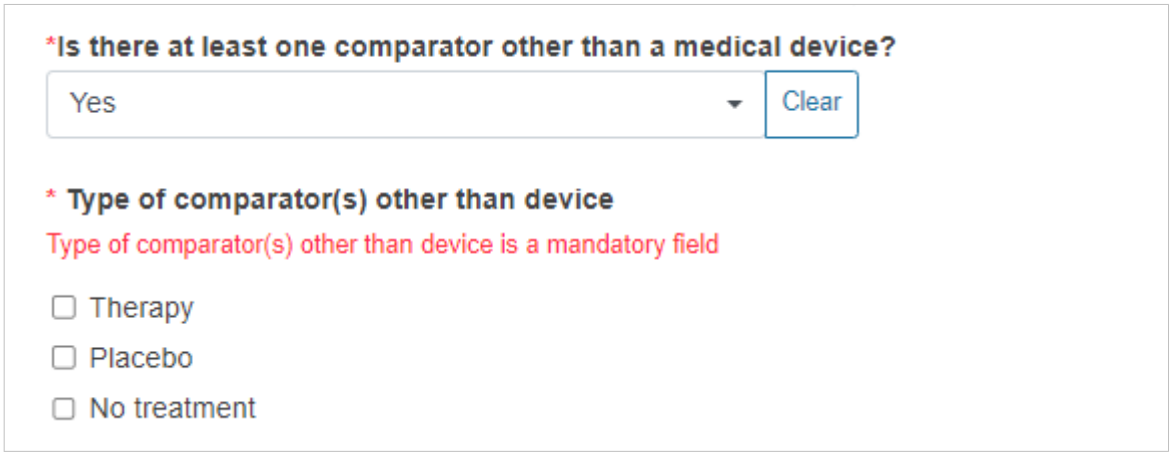
1. Click **Comparator** from the left menu.
2. Indicate if there is at least one Comparator that is a medical device and if there is at least one Comparator other than a medical device, by selecting *Yes* or *No*.



3. If you reply *Yes* to the first question, a new sub-section will appear for you to choose the type of Comparator device, which depends on the legislation selected in the first step.



4. If you reply *Yes* to the second question, the system will display a list for you to choose the type of Comparator. You can select more than one option.



5. The following Comparators require further information:
   - Medical device
   - IVD medical device
   - IVD medical device according to Art 5(5) of the IVDR

6. To fill in the information of the above Comparators, follow the explanation presented in the chapter *Investigational/Study device(s)*.

> **NOTE**
> For each Comparator device, the system generates a new sub-section under the *Language-specific Comparator device(s) information* header of the *National Information* section with the same identifier as the Comparator.

7. Below you can find a summary table where you can check the data you need to provide depending on certain conditions.

Do I need to provide the following data?	The medical device Comparator is not CE marked - CI/PS only, option not applicable for PMCF/ PMPF	The medical device Comparator is CE marked but is not registered in EUDAMED	The medical device Comparator is registered in EUDAMED	
			CI/PS	PMCF/PMPF
UDI-DI / EUDAMED ID			Yes	Yes
UDI-DI - not registered in EUDAMED		Yes		
Issuing entity		Yes		
I confirm that the CE-marked device will be used outside the scope of its CE mark		Yes (PMCF/PMPF)		Yes
Will the CE-marked Comparator medical device be used in the clinical investigation/performance study within the scope of its CE mark?		Yes (CI/PS)	Yes	
Investigational/Study device details				
Device ID (like Model number / Version)	Yes	Yes		
Device name	Yes	Yes		
Device trade name	Yes	Yes		
EMDN nomenclature code and nomenclature text				
Risk Class	Yes	Yes		
Device description	Yes	Yes	Yes	Yes
Intended (clinical) purpose	Yes	Yes	Yes	Yes
Does the device contain or incorporate medicinal substance(s)?	Yes	Yes		
Does the device include human blood or plasma derivatives?	Yes	Yes		
Does the device incorporate, as an integral part, or is it manufactured using non-viable biological substances?	Yes	Yes		
Has the device been subject to scientific views/an opinion from an Expert Panel and/or EURL?	Yes	Yes		
Manufacturer of the investigational/study device				
Is the manufacturer the same as the sponsor?	Yes	Yes		
Is the manufacturer registered in EUDAMED	Yes	Yes		
Manufacturer Actor ID / SRN or Manufacturer details	Yes	Yes		

3.1.9 National information

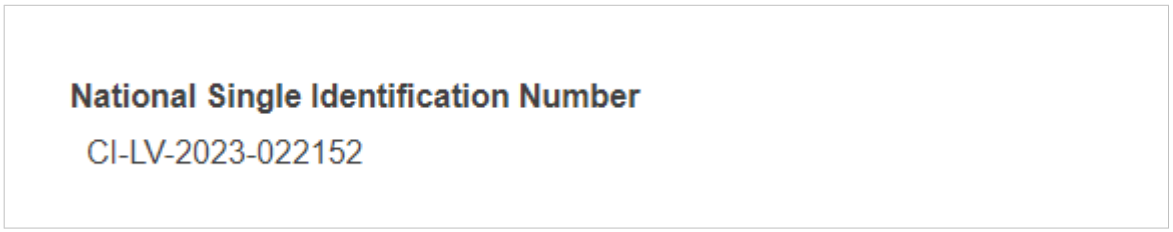
Click **National Information (country name)** in the left menu.

National clinical investigation/performance study information

IMPORTANT

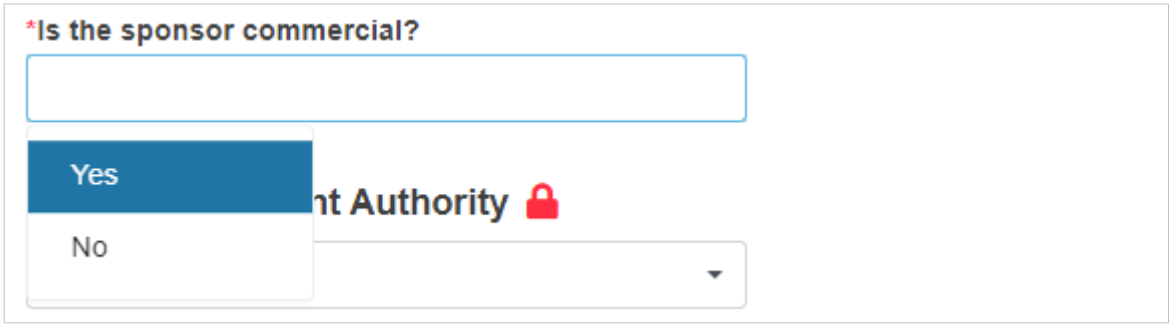
If you are submitting an application for additional country(ies) or a pre-existing application/notification for which an EU SIN exists, this section is not pre-populated and you need to fill in the national information for each additional country(ies).

1. At the top of the screen, every national information section (one per country, in case of an application for coordinated assessment), you can see the national single identification number (SIN).

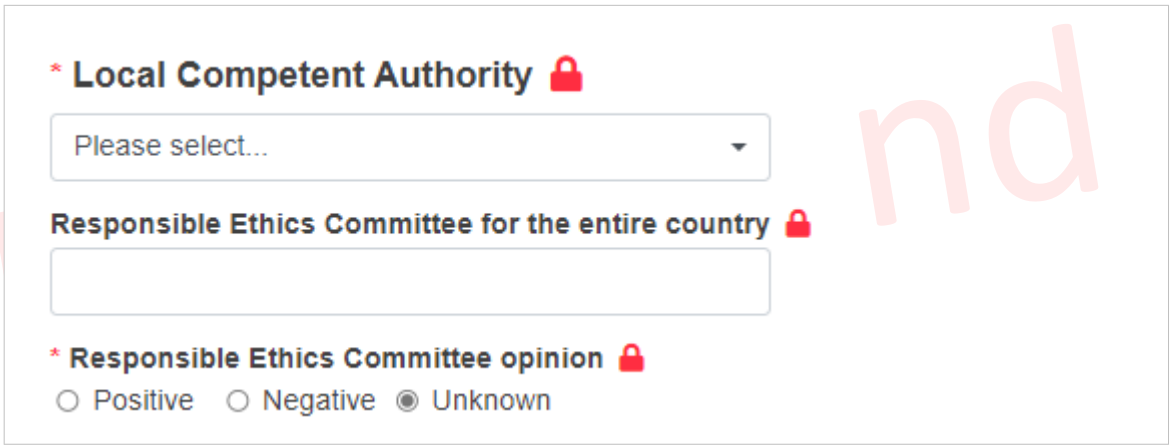


2. Indicate the expected number of subjects for the country.

3. Reply *Yes* or *No* to the question *Is the sponsor commercial?*

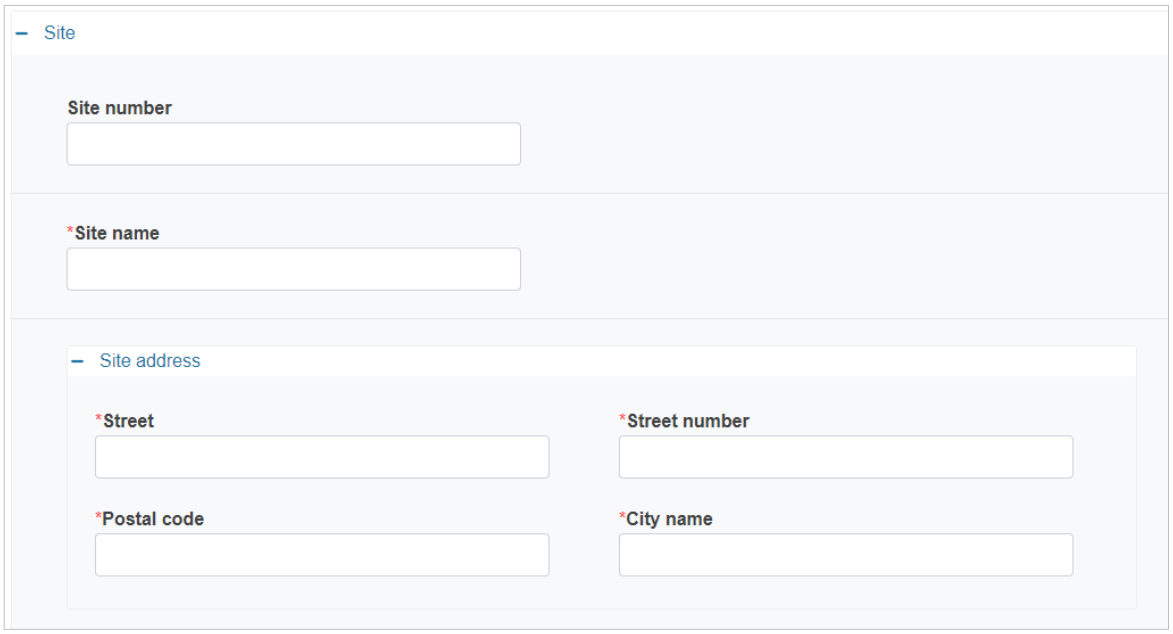


4. Provide the **details of the Local Competent Authority**:
   - Identification of the Local Competent Authority (the system will give you the relevant results) - this value determines the Competent Authority that will validate and authorise (when relevant) the submission
   - Responsible Ethics Committee for the entire country
   - Responsible Ethics Committee opinion (define if is Positive, Negative or Unknown).

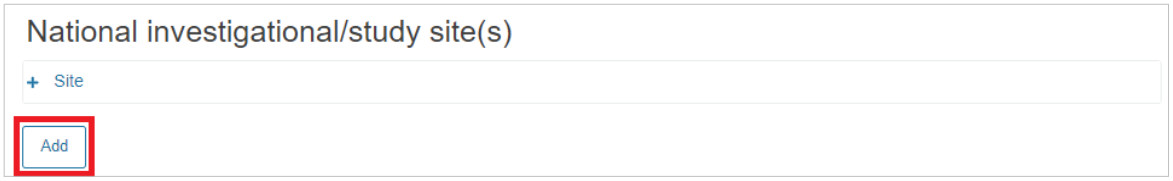


National investigational/study site(s)

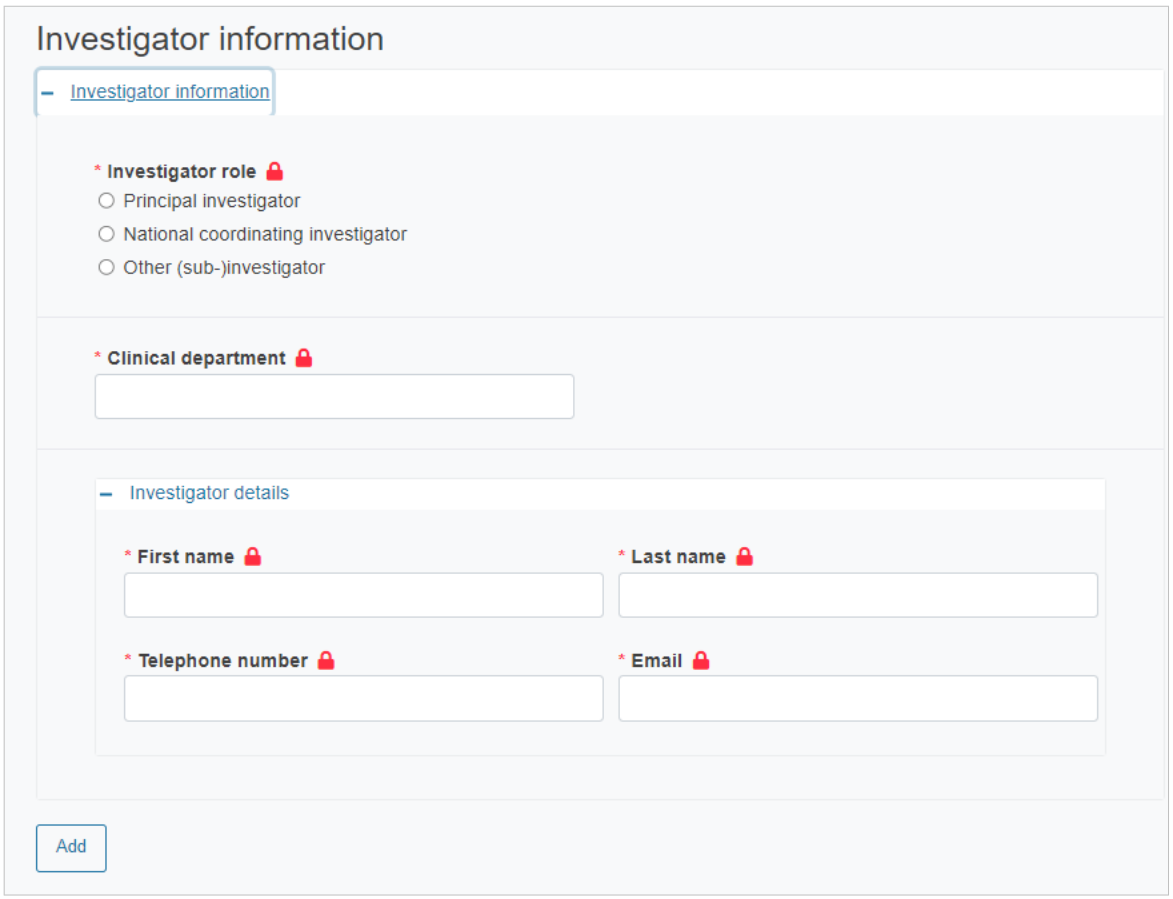
1. Provide the details of the site:
   - Site number
   - Site name
   - Site address



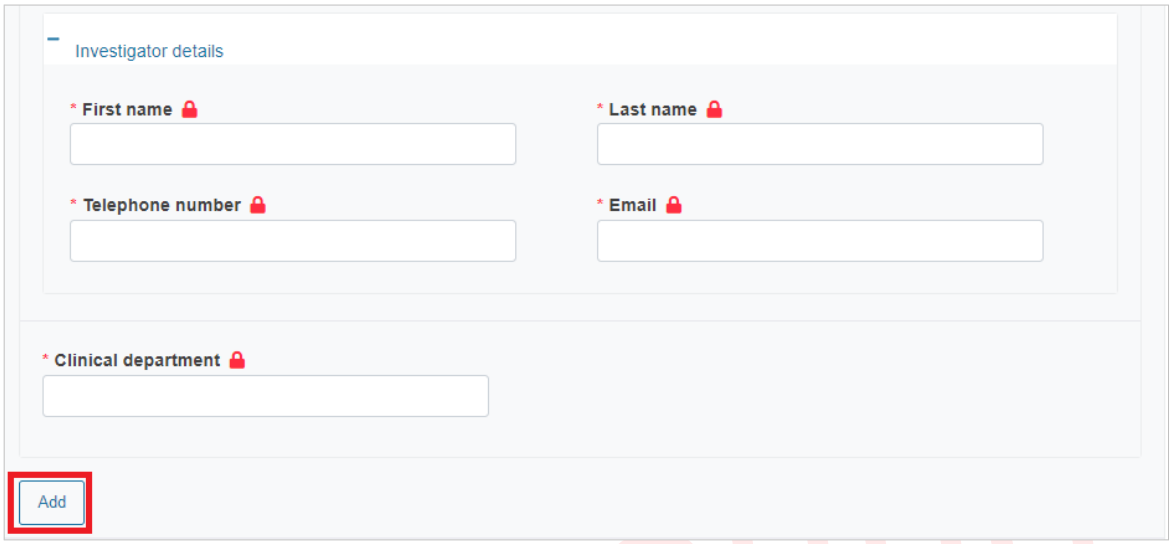
2. To add more sites, click *Add*.



3. Provide the details of the investigator:
   - Investigator role
   - Clinical department
   - Investigator details (first name, last name, telephone number and email)

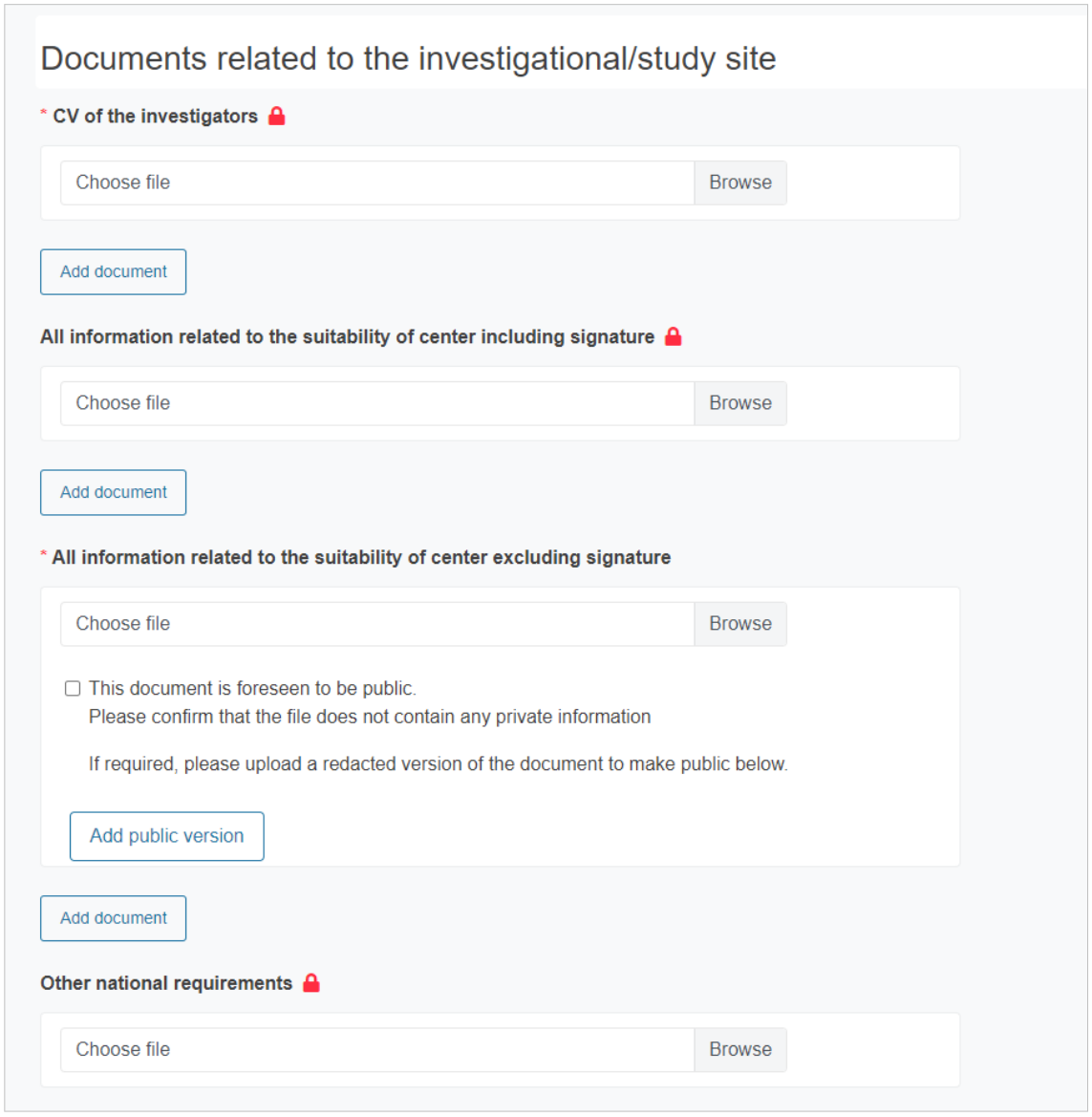


4. To add more investigators you need to have the *Site* section expanded. Then click *Add*.



5. Provide the *Documents related to the investigational/study site*:
   - CV of the investigator
   - All information related to the suitability of center including signature
   - All information related to the suitability of center excluding signature *

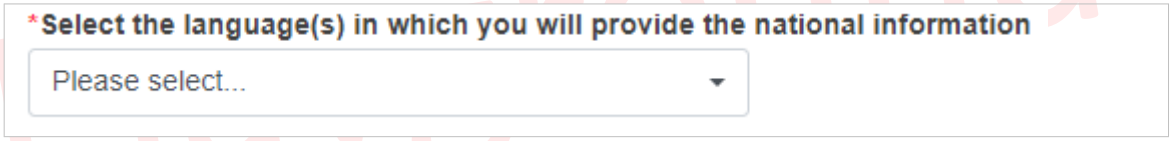
- Other national requirements



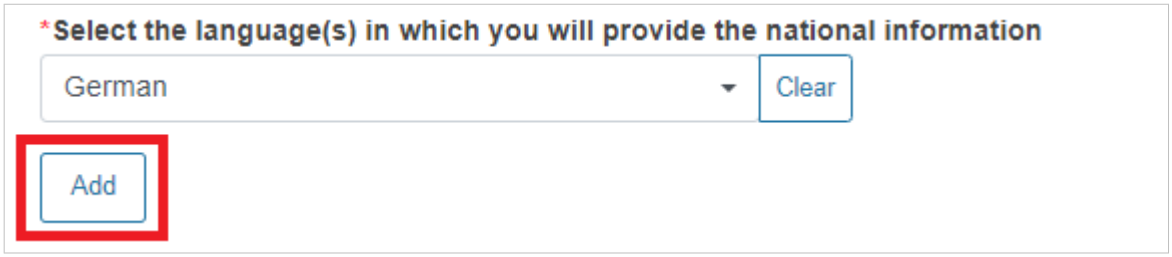
* For this document **you must acknowledge that it does not contain private information**, as it is expected to be public. To do it, tick the box.

6. Select the language(s) in which you will provide the national information from the dropdown list.

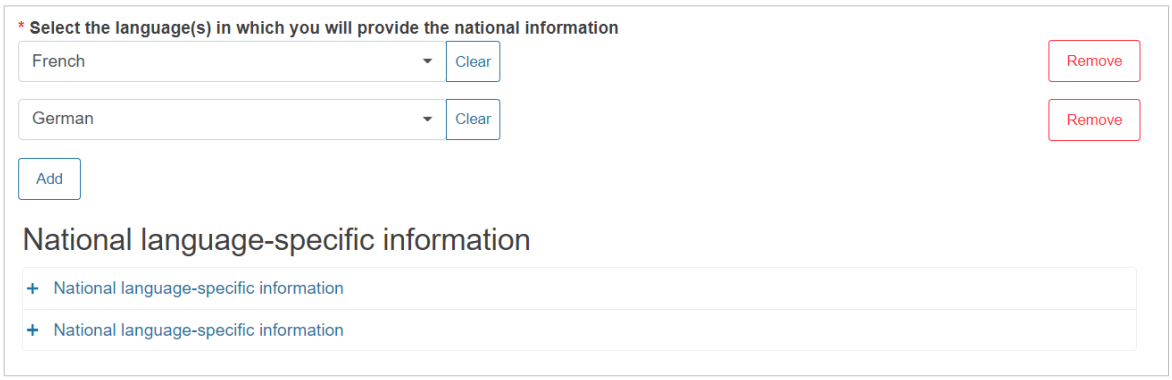
> **NOTE**
> The system filters the national language(s) of the country of the application.



7. You can **add more languages** by clicking **Add**.



8. As soon as a language is defined in the field above, the system will generate the relevant number of dedicated *National language-specific information* sections:



National language-specific information

1. Provide the following information of the CI/PS in the relevant national language:
   - Full title
   - Title for lay people
   - Description for Design methodology – Other – only if this value was selected for Design methodology previously
   - Description for Type of subjects – Other – only if this value was selected for *Type of subjects* previously
   - Primary objective
   - Secondary objective
   - Other objective(s)
   - Primary endpoint
   - Secondary endpoint
   - Other endpoint(s)
   - Overall synopsis
   - Inclusion criteria
   - Exclusion criteria

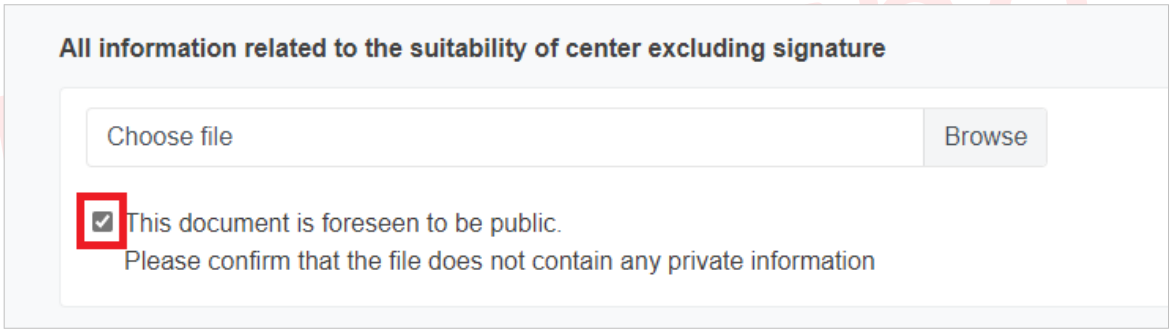
2. National language-specific Investigational/study (and Comparator) device(s) information sections:

3. As soon as the sections *Investigational/Study devices* and *Comparator* are filled in, the system will create the correct number of sub-sections, if any.

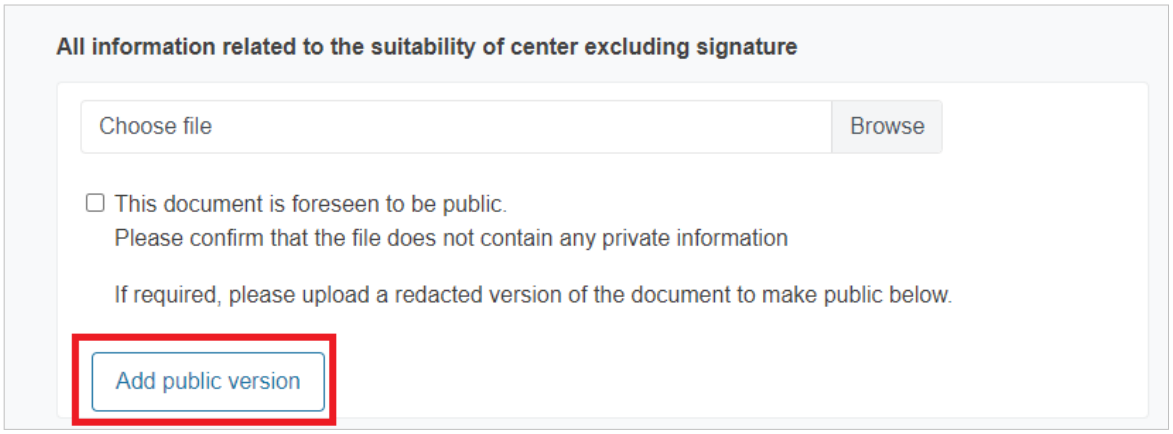
4. For each sub-section (*Investigational/Study device(s)* and *Comparator*), provide the following information in the relevant language:
   - Device name – not applicable to PMCF/PMPF notification or to the Comparator section
   - Device trade name – not applicable to PMCF/PMPF notification or to the Comparator section
   - Device description
   - Intended (clinical) purpose

5. Provide the following documents in the national language:
   - Instruction for use
   - Informed consent/Patient information leaflet *
   - Ethics Committee opinion *
   - Proof of insurance
   - Other national requirements

   * For these documents **you must acknowledge that they do not contain private information**, as they are expected to be public. To do it, tick the box.

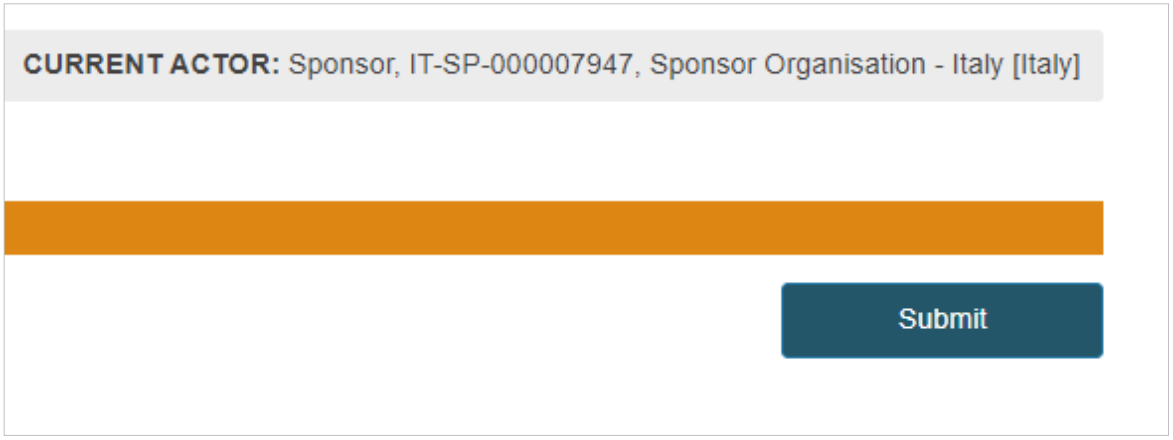


6. If you are uploading a document that is expected to be public and it contains private information, you must **upload a redacted version**. To do it, click *Add public version*.

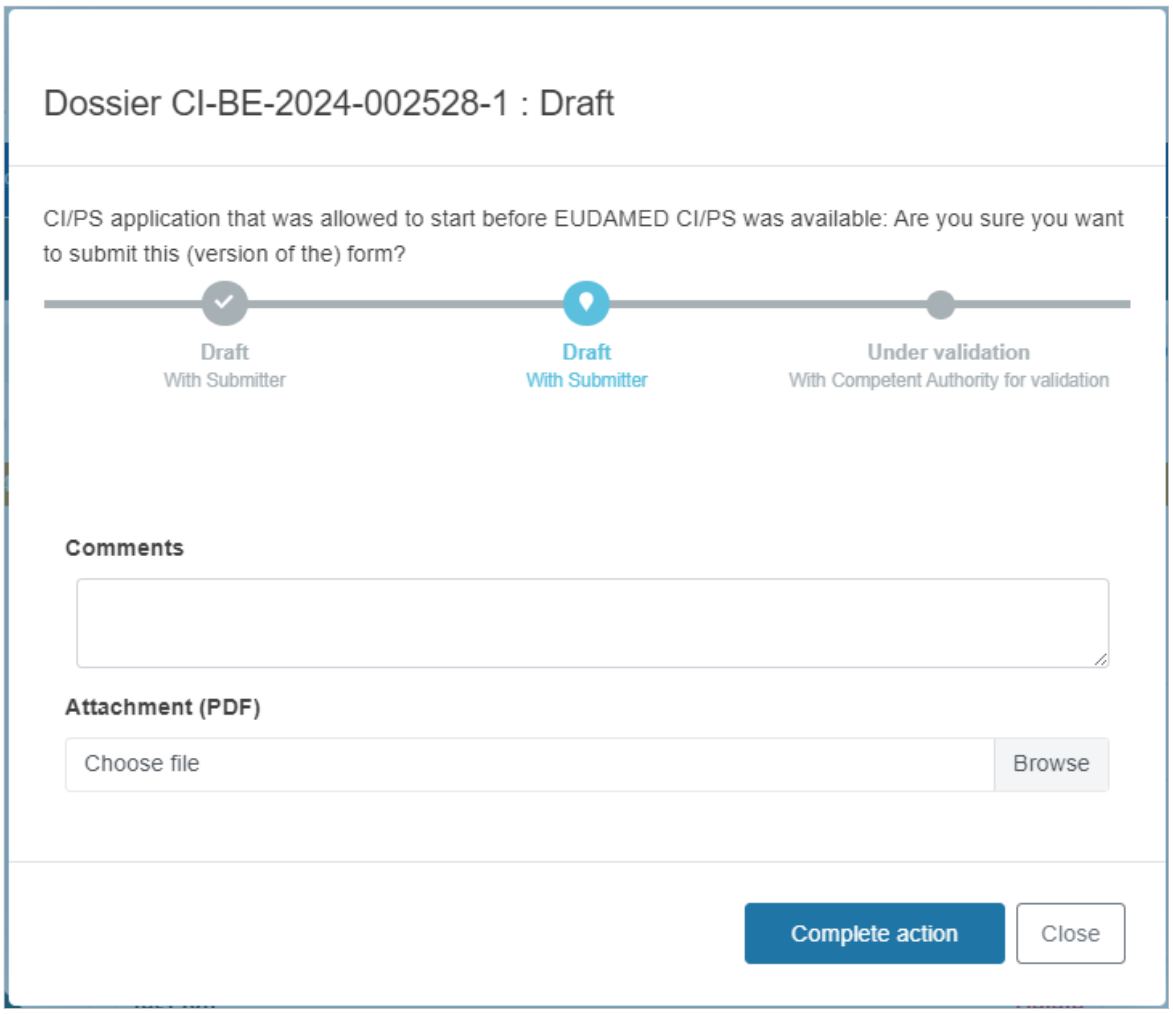


4 Submit an application/ notification

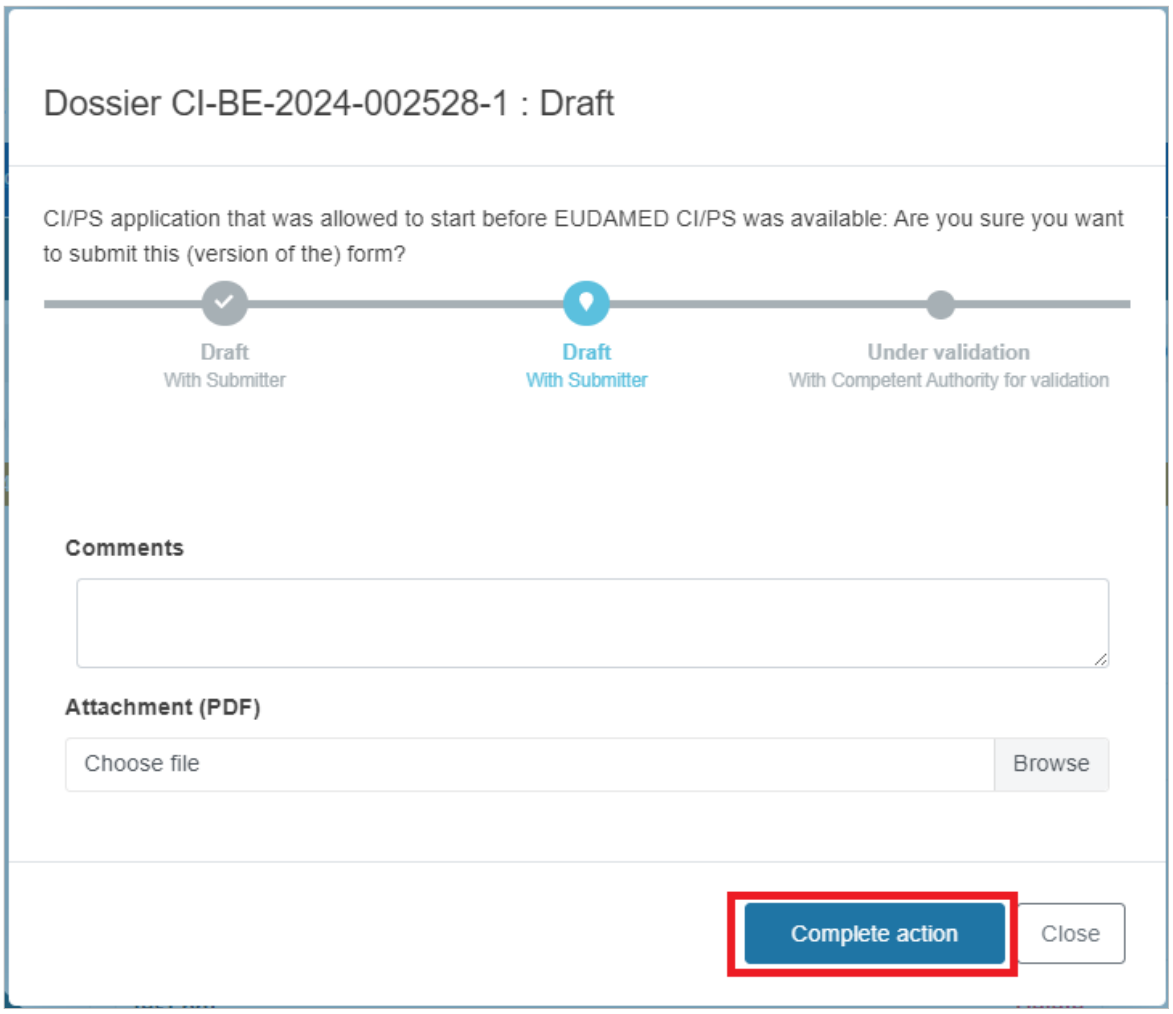
1. Once you have completed the application, click **Submit** at the top right of the screen.



2. A pop-up window will appear for you to complete your action.

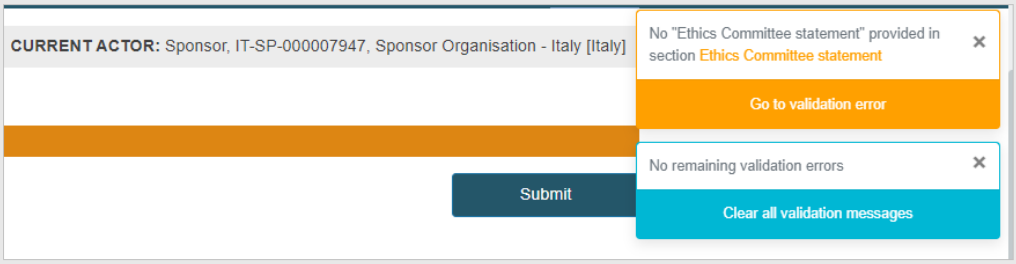


3. If you are not yet ready to submit the application, click **Close**. The record will remain in *Draft* state.
   To confirm the submission, click **Complete action**.

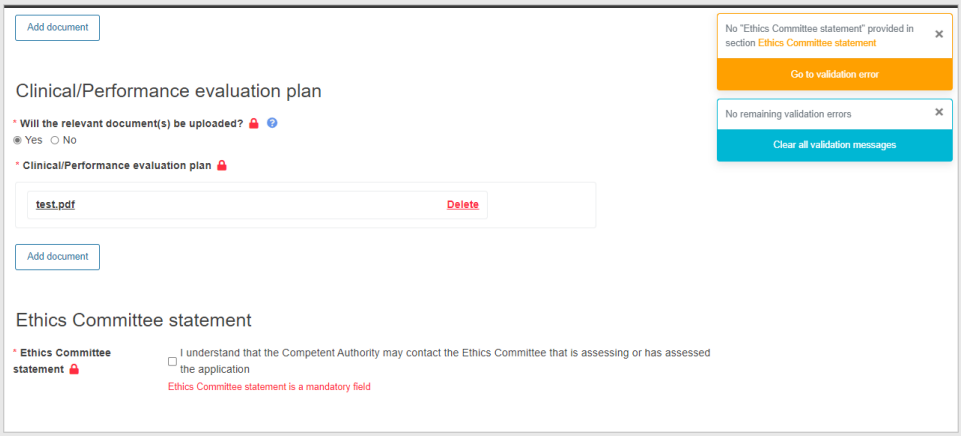

Dossier CI-BE-2024-002528-1 : Draft
CI/PS application that was allowed to start before EUDAMED CI/PS was available: Are you sure you want to submit this (version of the) form?
Draft
With Submitter
Draft
With Submitter
Under validation
With Competent Authority for validation
Comments
Attachment (PDF)
Choose file
Browse
Complete action
Close

WARNING

If there is any field that is not completed correctly, the system will display the blocking error(s) at the right-hand side at the top of the screen.

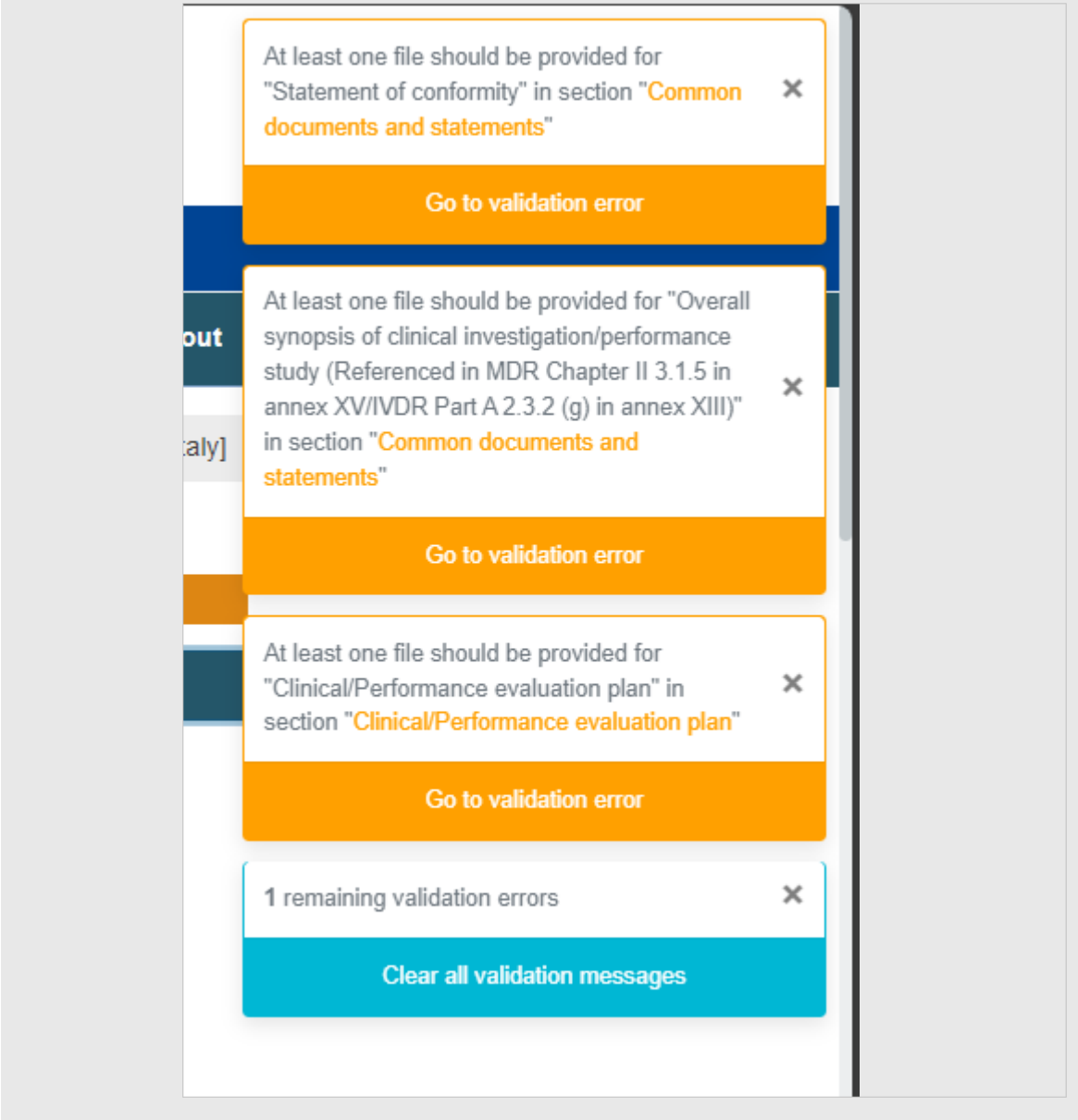


1. Click on *Go to validation error* to be guided to the appropriate section and field that generates the error so that you can directly correct the information.



2. Click on *Clear all validation messages* to hide the messages.

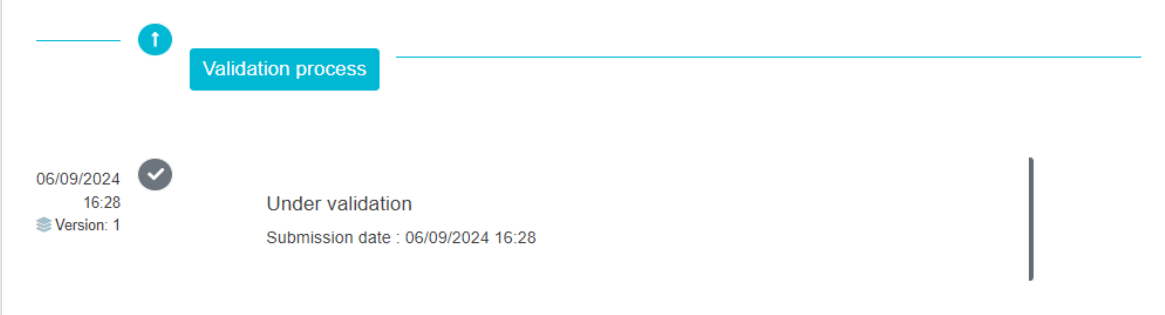
3. If several error messages apply, the system will only show the first 3 error messages in an individual orange box followed by a blue box that tells you how many additional errors remain.
   These additional errors will be displayed gradually once the first 3 errors have been corrected.



4. If there are no blocking errors for submission, the state of your application will change to:
   - *Under validation* - for the CI/PS application - one country
   - *Notified* – for the PMCF/PMPF notification
   - *Awaiting coordinator* – CI/PS single application – coordinated assessment

   You can check it on the *Search and Manage* page.

5. Once you have submitted your application, you can **check the workflow actions and comments** on the *Report history overview* section of the application.
   The workflow section displays the deadline for the competent authority to validate the application or to acknowledge the notification. As long as it is not done, the sponsor cannot perform any further actions.



6. The submission will trigger a notification to the concerned Competent Authority (CA) and the clock starts.
   If you have submitted a PMCF/PMPF notification, the competent authority is notified and should acknowledge it within the deadline. However, if the competent authority does not acknowledge receipt of the PMCF/PMPF notification within the deadline, the PMCF/PMPF is allowed to start.

NOTE
If you are submitting a **CI/PS single application - coordinated assessment** the application will get the state *Awaiting coordinator*.

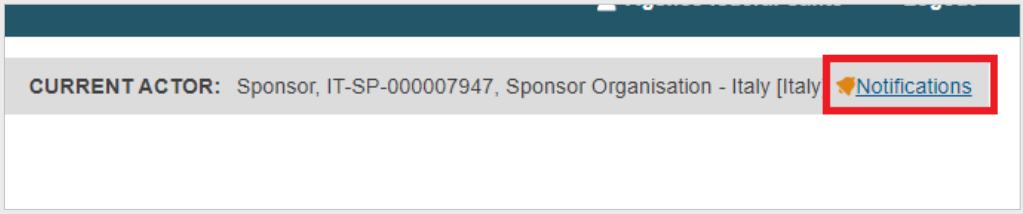
CI/PS single application - coordinated assessment	AT-SP-000000861	PCTA240830090927104 (PVTA240830090927330)	TitleForLayPeople,TFLPTA240830090928380,TitleForLayPeople	2024-08-30	Awaiting coordinator

The *Report history overview* screen will look as follows:

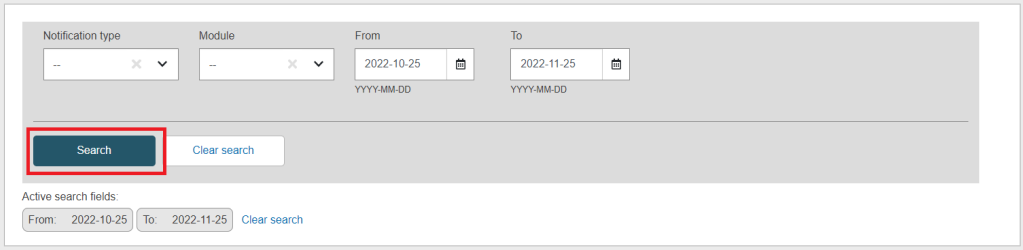
NOTE

You will receive a notification every time there is a change to your application via EUDAMED platform[3]. There are two types of notifications: *Action* and *Information*.

1. Go to the top of the screen and click *Notifications*:



2. Define the parameters to refine your search and then click on *Search*.

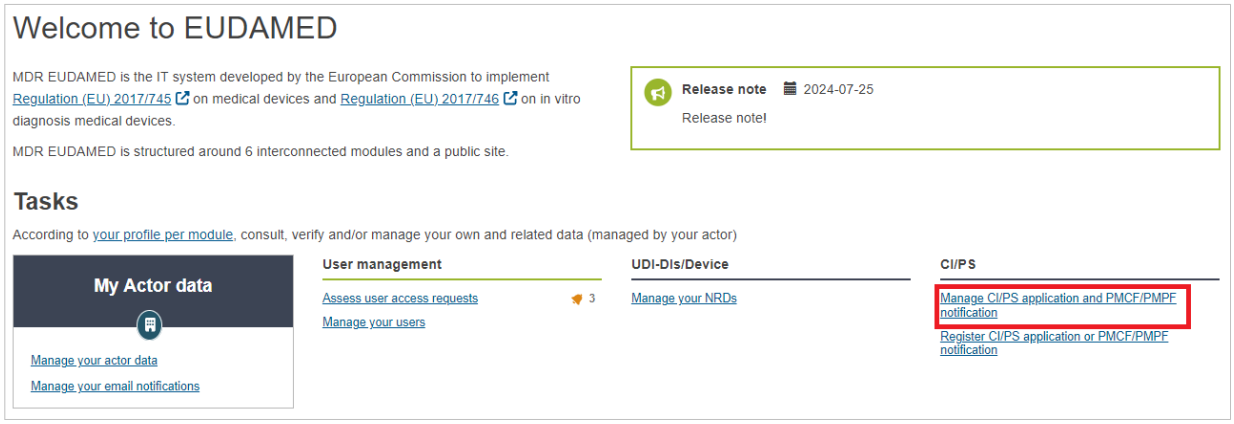


3. The system will present you the relevant results.

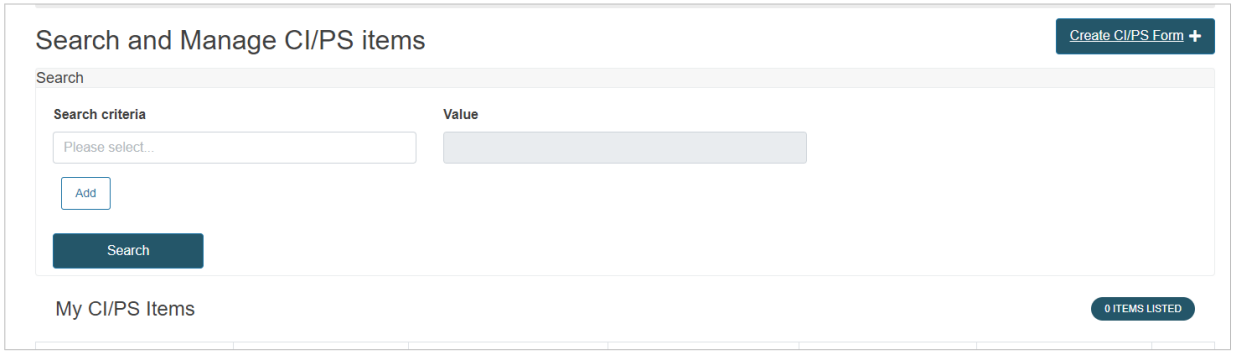
[3]Once the module goes to production, the user will also receive the notifications via email.

5 Search and manage application / notification

Click *Manage CI/PS application and PMCF/PMPF notification*.



You will arrive to the *Search and manage application / notification CI/PS items* page.

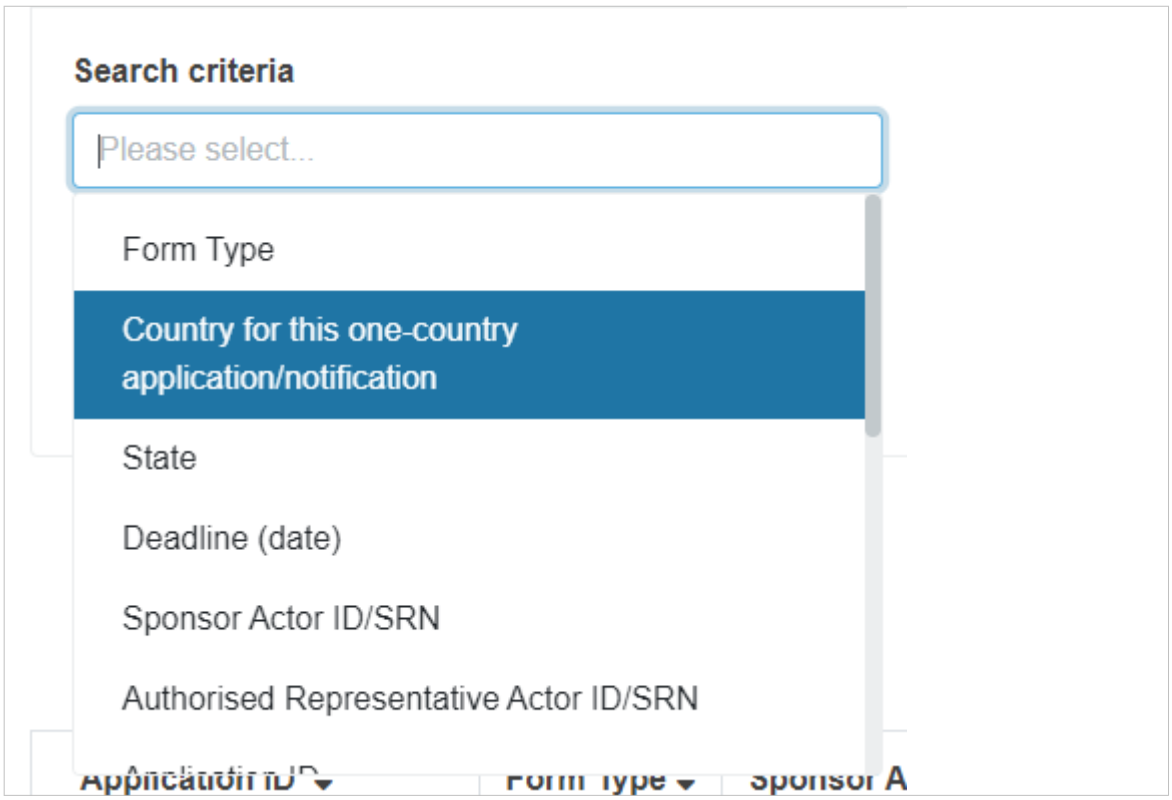


5.1 Search CI/PS items

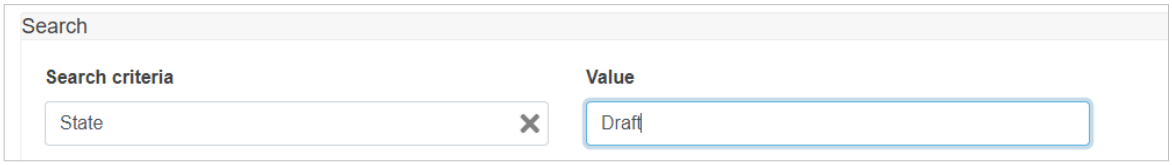
On the *Search and manage* page, depending on your user rights, you can see the records of your Sponsor actor in all states.

To **search a report**, use the search tool and follow these steps:

1. Go to the *Search criteria* field and select the relevant criterion from the drop-down list.

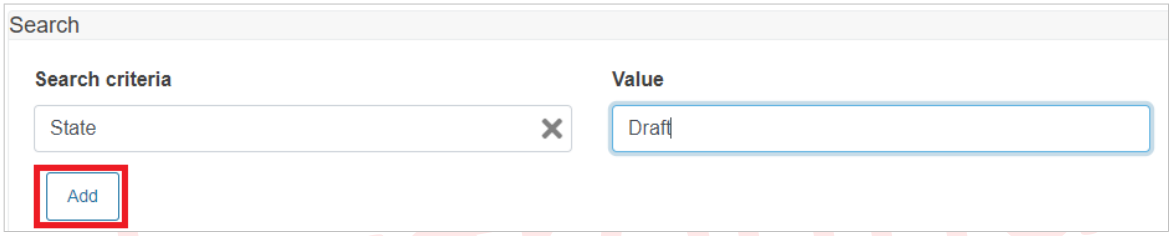


2. Enter the value matching your search criteria, i.e., if you chose *State*, the value could be *Draft, Under validation*, etc.

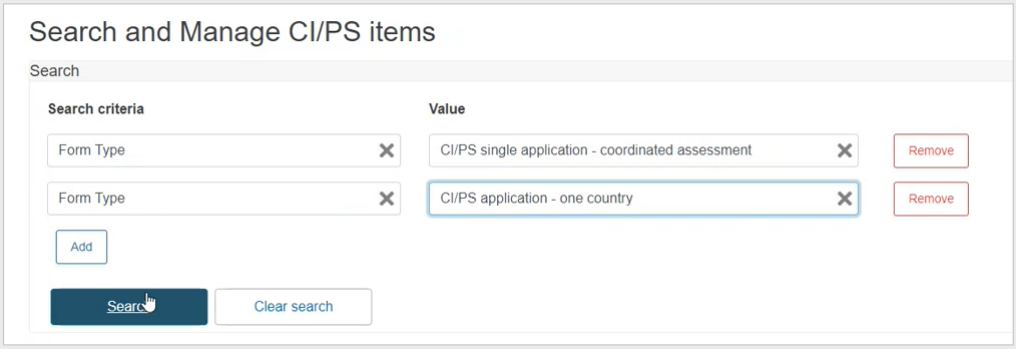


NOTE
In the case where the search criterion refers to a pre-defined list of values, as soon as you start typing in the field *Value*, the system will present the relevant results.

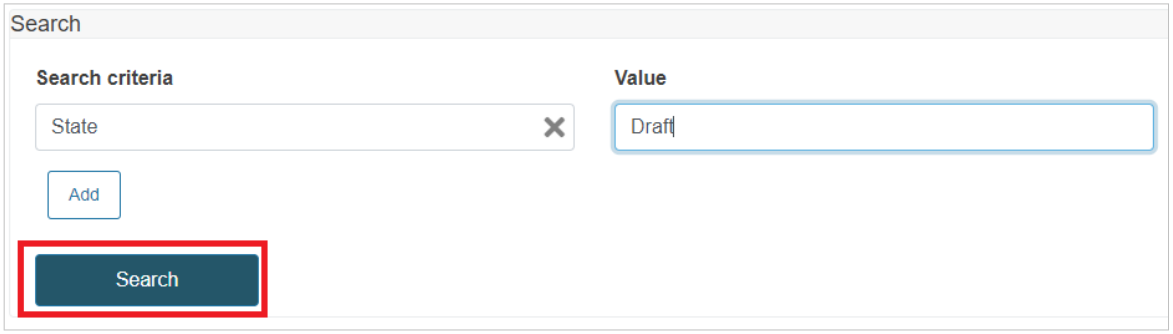
3. Add other relevant search criteria if needed. To do it, click **Add**.

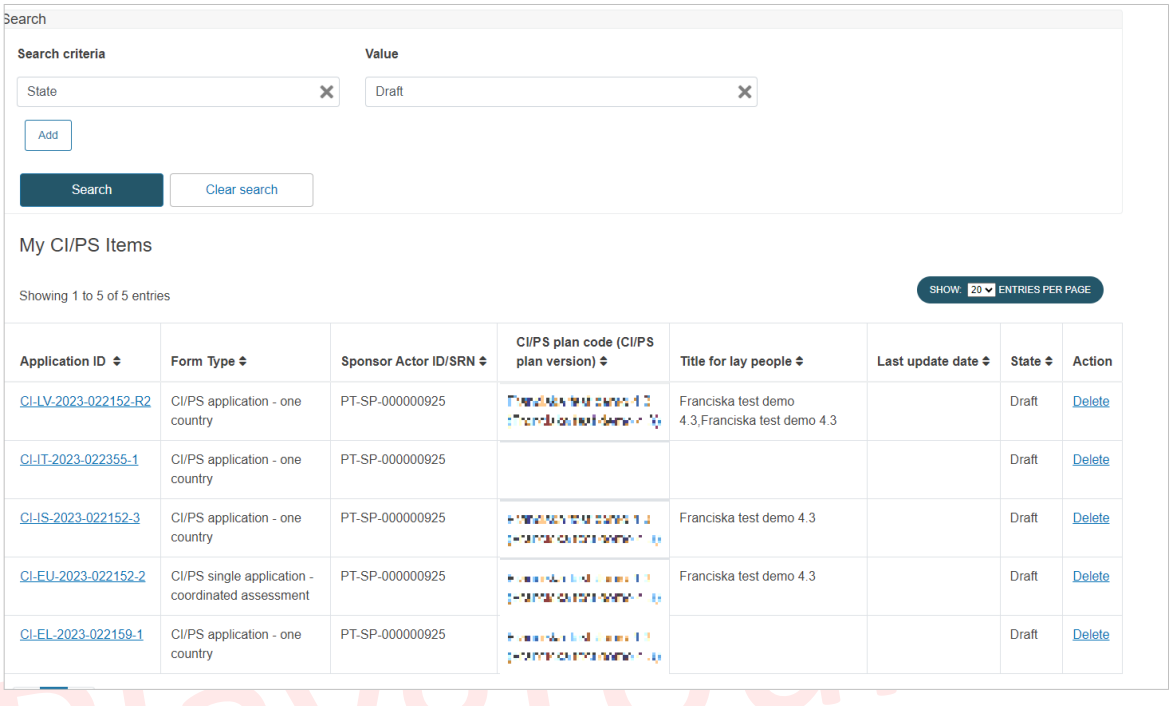


NOTE
You can add the same search criterion several times, with a different value each.



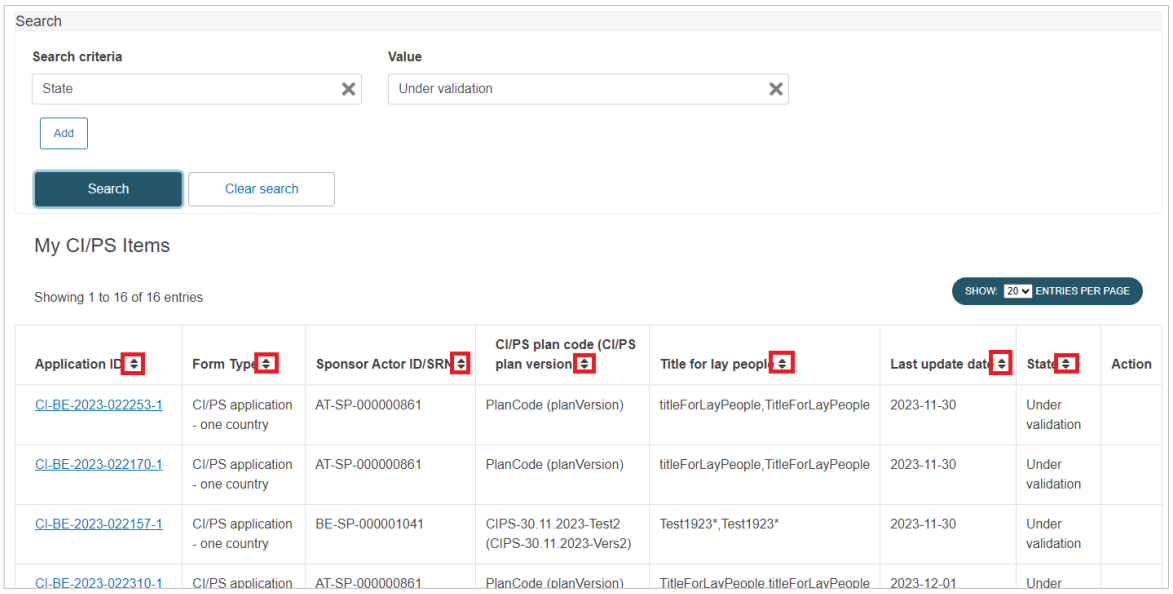
4. Click **Search** and the system will display the relevant results.





NOTE
If you are searching using the criterion *Deadline (date)*, keep in mind that the system will not present applications in state *Authorised*, as no deadlines apply in this case.

The results are sorted by default by date (closest deadline at the top of the search results list). Nonetheless, you can organise the results using the other columns available. To do it, use the arrows next to the title of each column.



At the top of the list with the search results, select how many results you want to show per page:

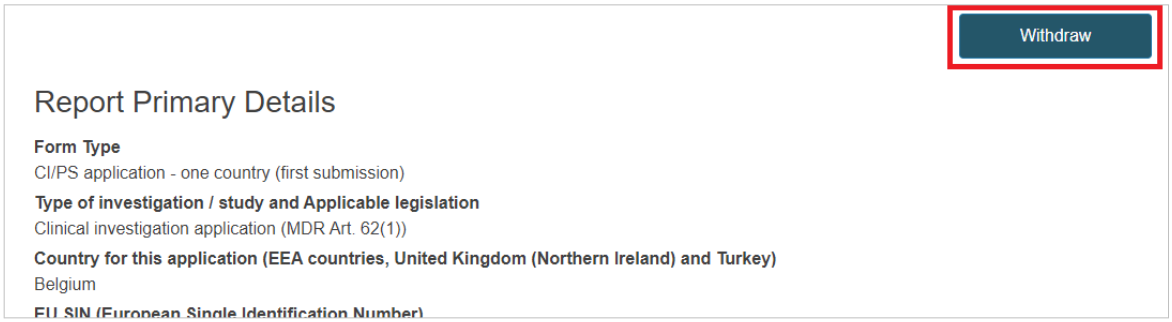
6 Withdraw an application

NOTE
You can withdraw an application/notification at any stage before the CI/PS or PMCF/ PMPF starts.

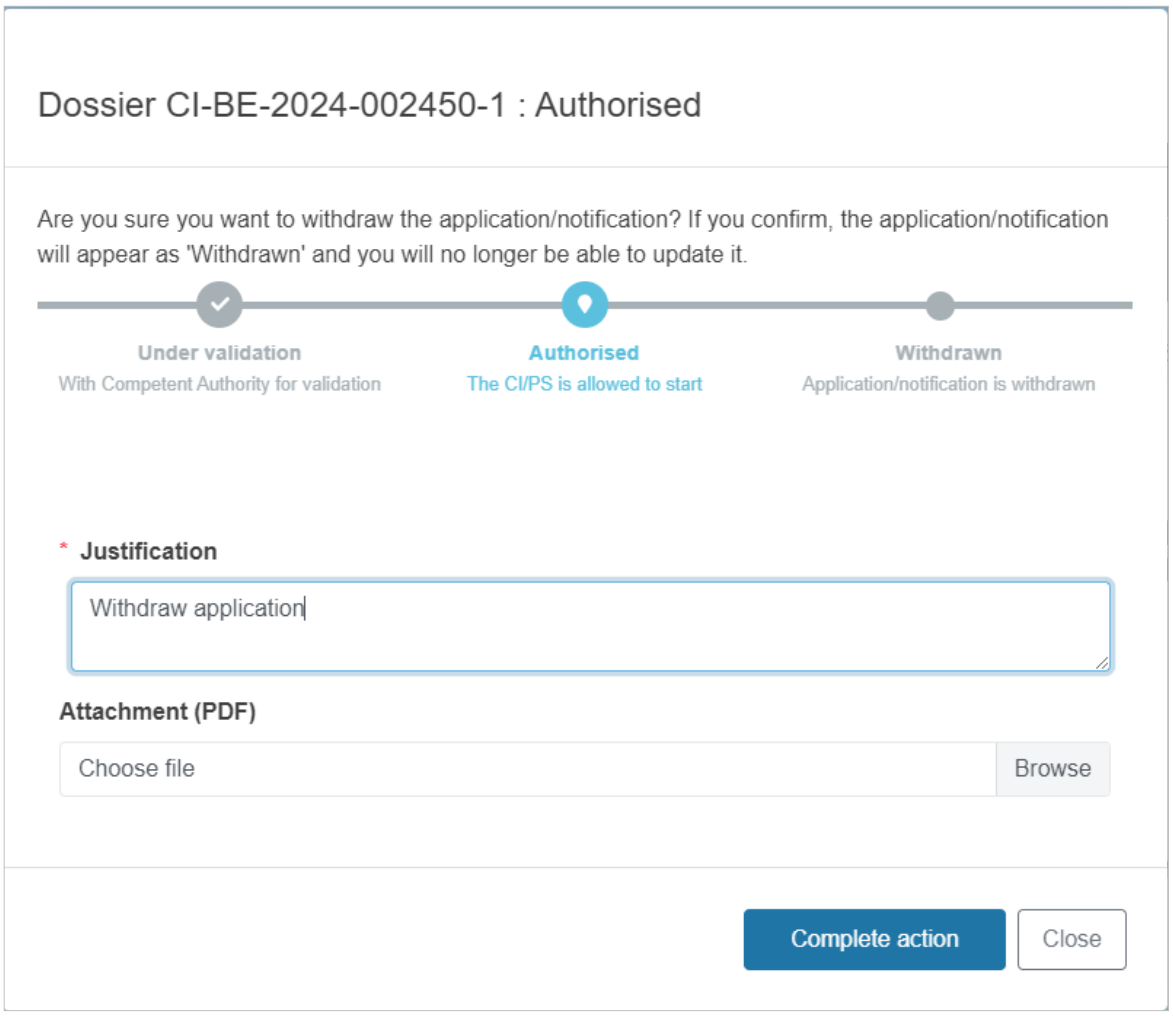
To withdraw an application/notification follow these steps:

1. Search for the application/notification on the *Search and Manage CI/PS items* page.
2. Open the application by clicking on the application ID.

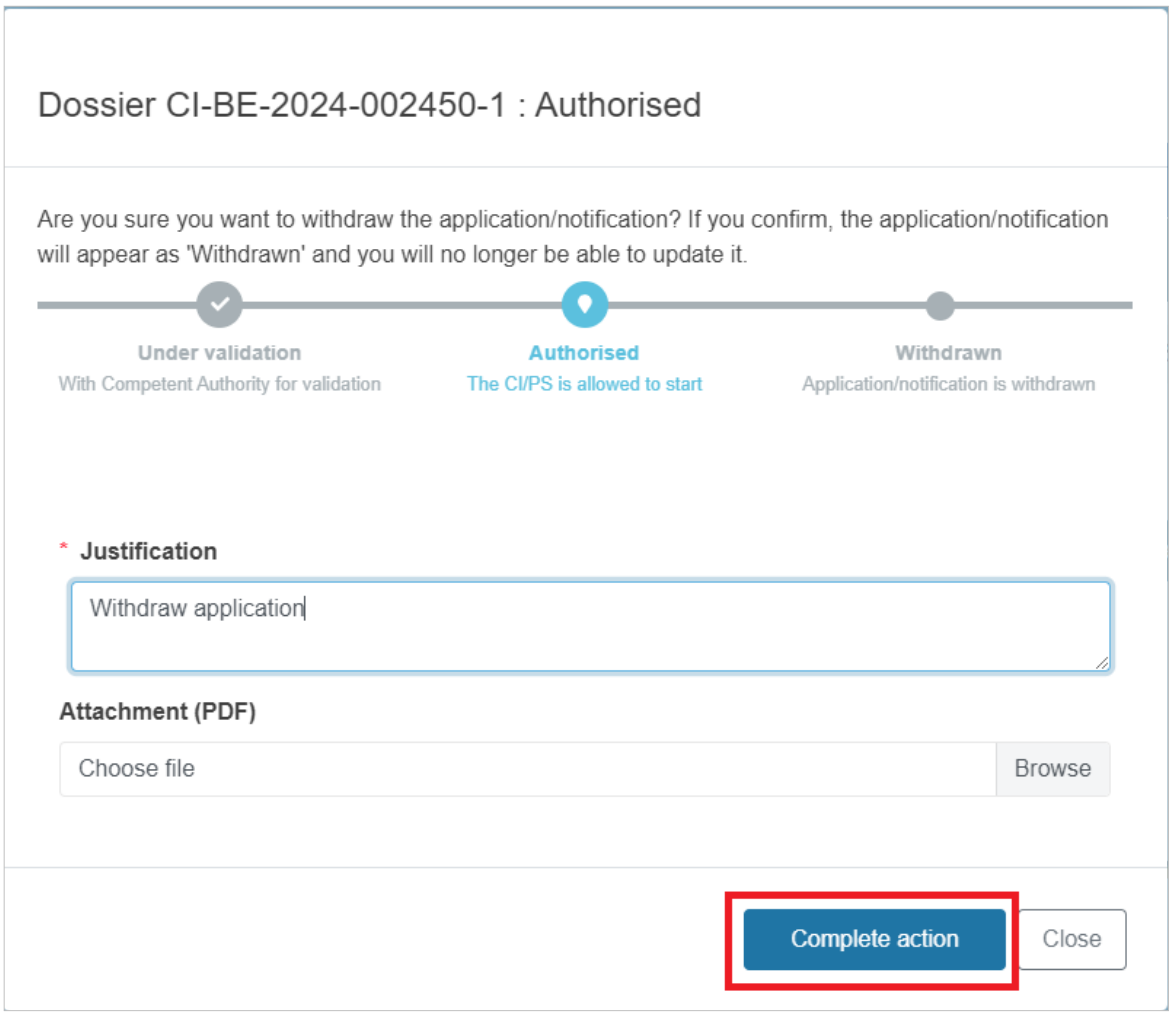
3. Click **Withdraw** at the top right of the page.



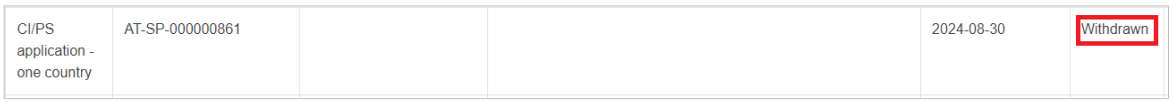
4. A pop-up message will appear for you to complete your action.

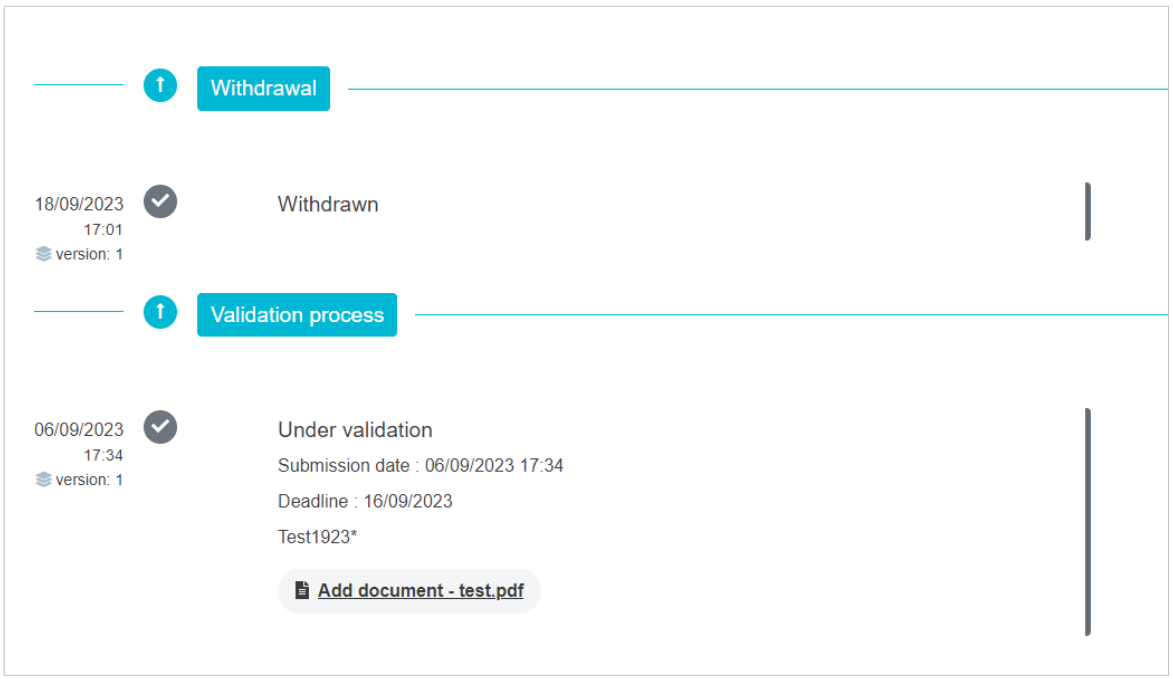


5. Use the *Justification* box to submit any relevant information related to your action.
6. Confirm your action by clicking **Complete action**.



7. The state of the application/notification will change to *withdrawn*. You can check it on the *Search and manage* page or by going to the *Report history overview*.



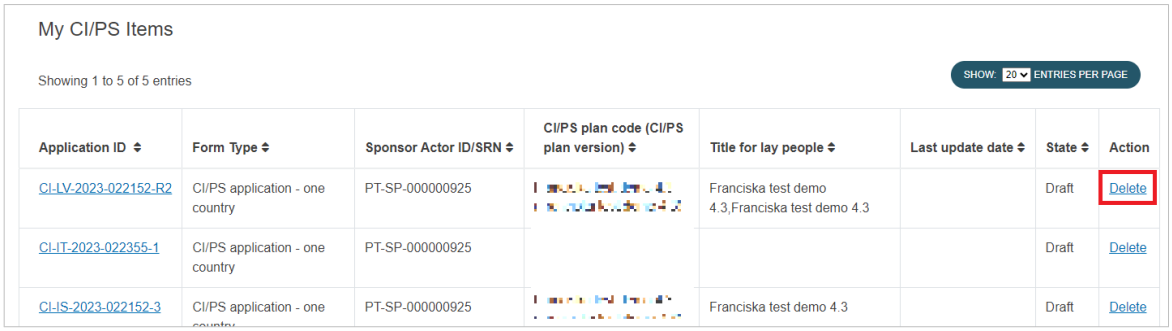


NOTE
Once you have withdrawn an application/notification, it is no longer possible to edit it.

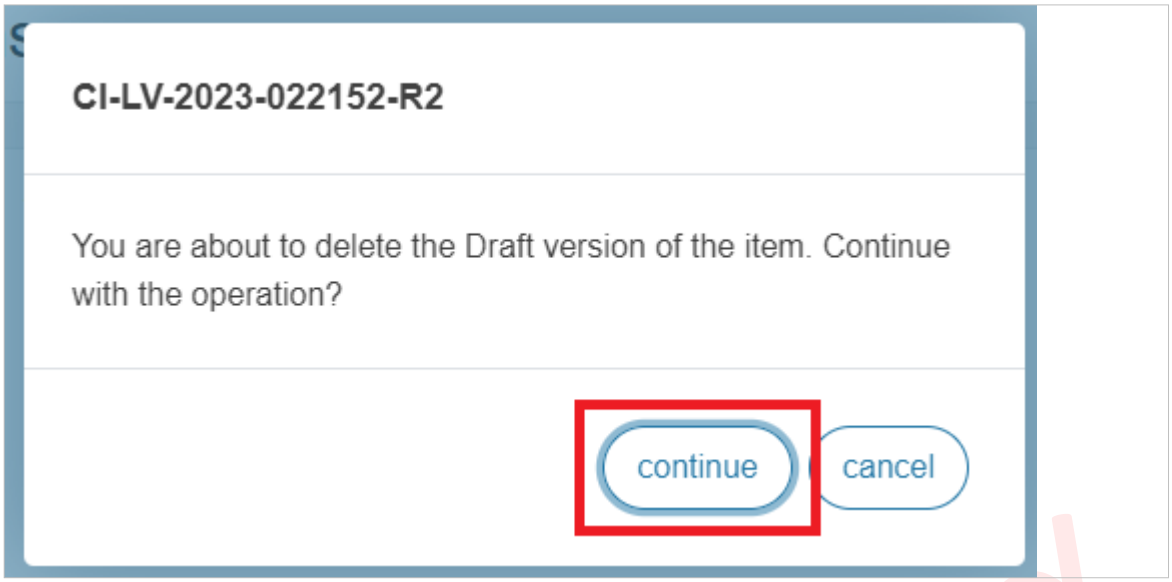
7 Delete a draft application

To **delete a draft application/notification** follow these steps:

1. Go to the *Search and manage CI/PS items* page.
2. Search for the application/notification.
3. Click **Delete** on the *Action* column.



4. A pop-up message will appear for you to confirm your action. Click **Continue** to proceed. Otherwise, click **Cancel**.



5. The application/notification will be deleted and will disappear from the *Search and manage CI/PS items* page.

NOTE
Once you have deleted a draft application/notification, it is no longer possible to recover it.

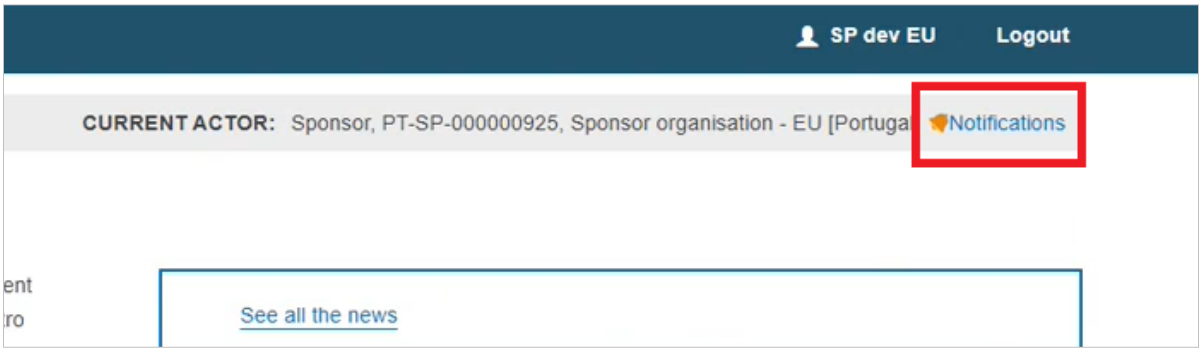
8 Validation rejected - Edit and submit response to Competent Authority

NOTE
You can follow the validation progress in the tab *Report history overview*.

If the **Competent Authority rejected your application** and has requested further information, you will receive a notification in the *Notifications Inbox*.

To check your notifications/actions, follow these steps:

- On the *Welcome to EUDAMED* page, go to the top and click on **Notifications**. Here you can find the relevant notification(s) relating to the status change of the application.



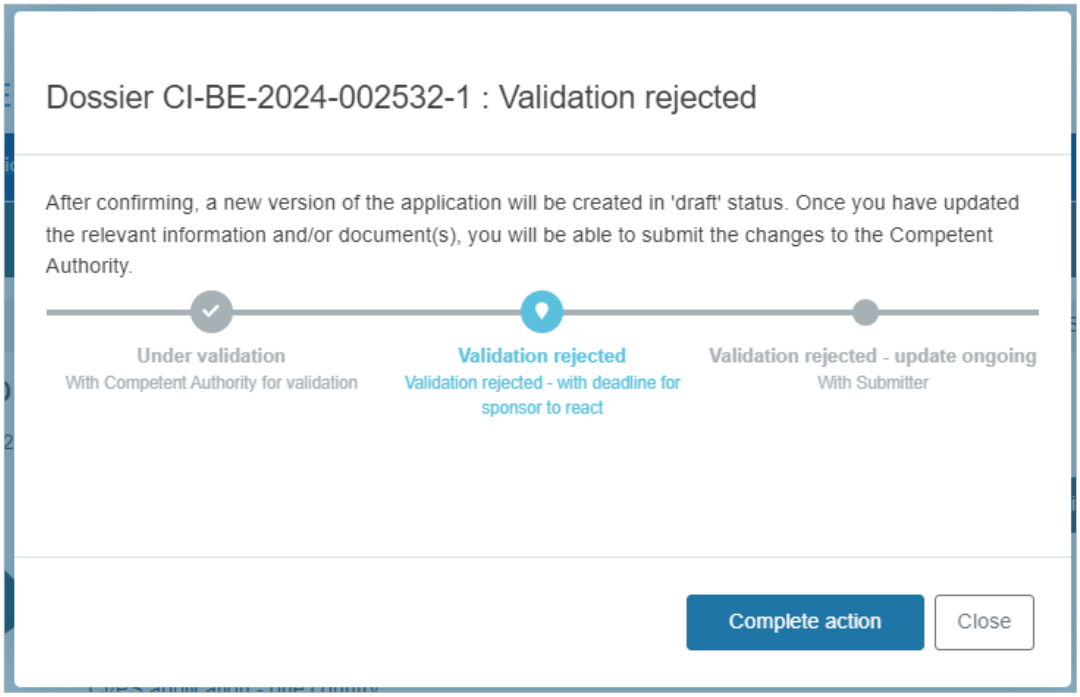
On the *Search and Manage CI/PS items* page, the application will have the state *Validation rejected*. To open the application go to the *Search and Manage CI/PS items* page and click on the application ID.
Once you open it, at the top of the page, you will see the following options:

1. **Create new version**

a. Click on **Create new version**

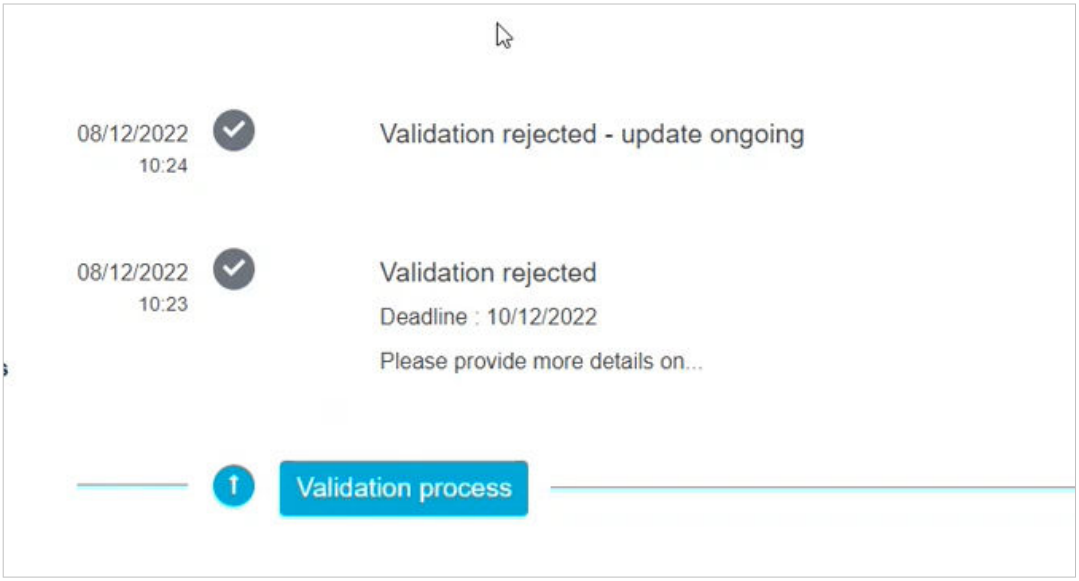
NOTE
In case the Competent Authority rejected a pre-existing application/ notification, the button to *Withdraw* is not available.

b. A pop-up window will appear. Click **Complete action**.



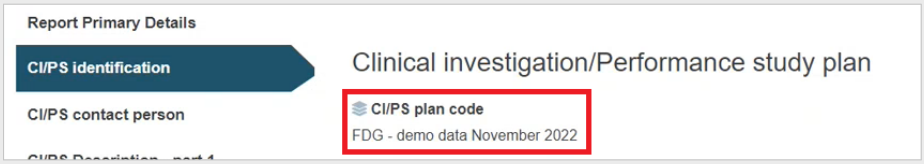
c. A **new version** of the CI/PS application will be created in state *draft*. You can edit it, by clicking **Edit** at the top of the page.

d. As soon as a new version is created, the application will change to *Validation rejected – update ongoing*.



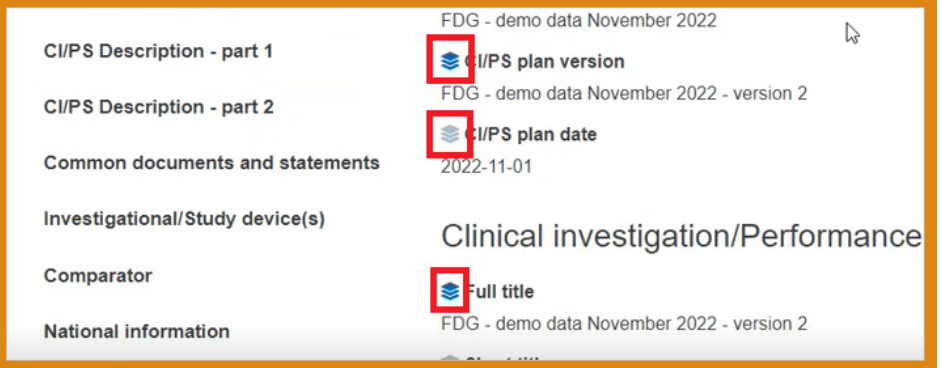
NOTE

The field *CI/PS plan code* under the *CI/PS identification* section is the only field that you cannot edit, as it is the unique identifier of the CI/PS worldwide.

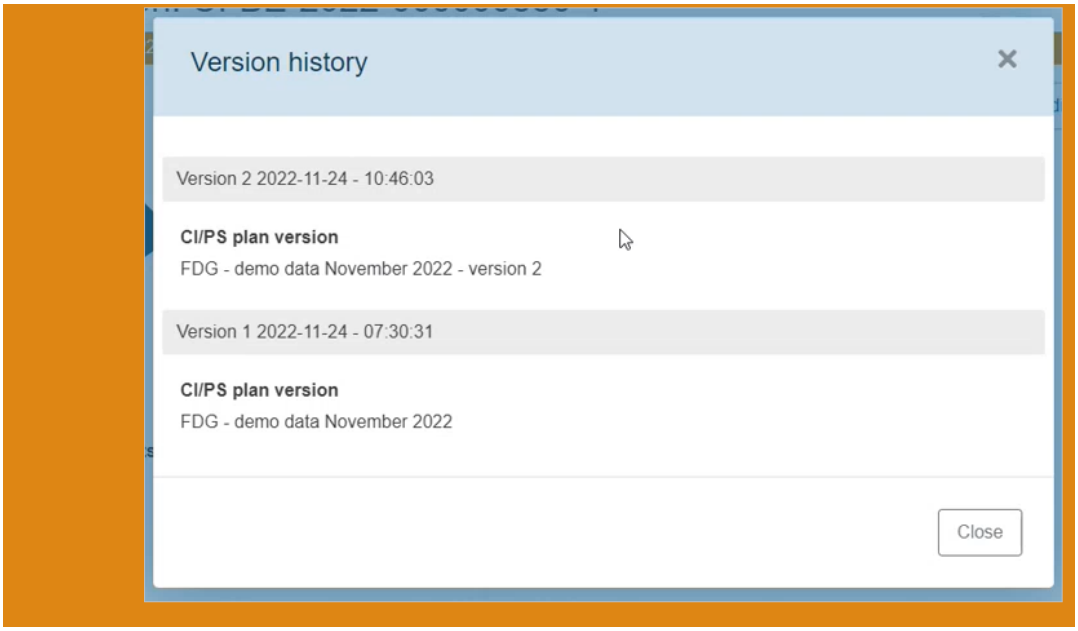


IMPORTANT

In the new version, the fields that have been edited will display a dark blue icon and the fields that have not been edited will display a light blue icon.

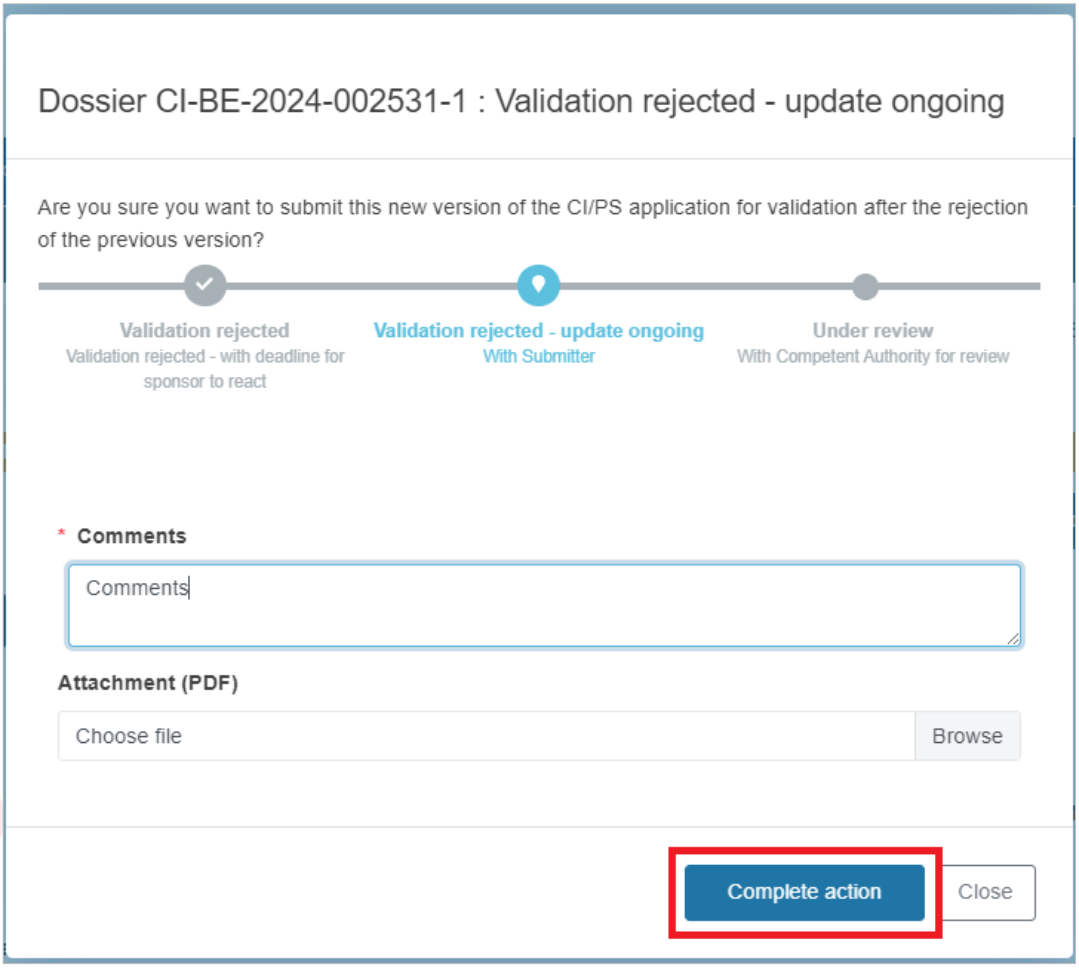


By clicking on the dark blue icon, you have an overview of the version history of that particular field:



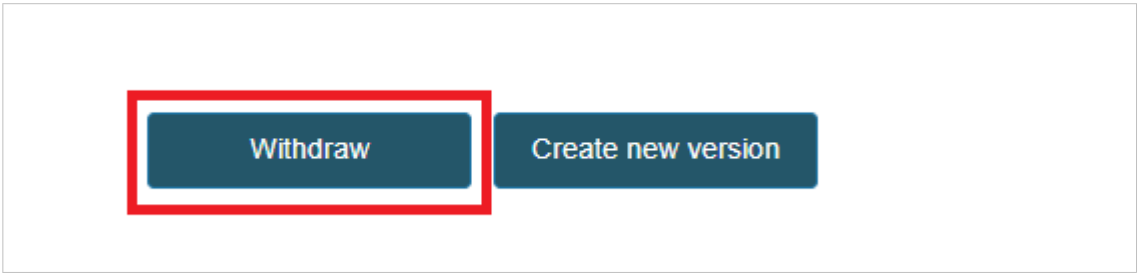
e. Once you have updated the relevant information, submit the changes to the Competent Authority for validation by clicking **Submit response to CA**.

f. A pop-up window will appear for you to provide the relevant comments. Once you are done, click **Complete action**.



g. The new version of the CI/PS application will now have the state *Under review*.

2. **Withdraw**



NOTE
For more information on how to withdraw an application see chapter *Withdraw an application*.

Once the response is submitted to the CA, the Sponsor can only withdraw the application. No further actions are available.
The Sponsor can follow every action taken by the CA by going to the tab *Report history overview*.

9 Pending additional info – provide additional information

The CA can request additional information before the authorisation of the CI/PS application. If it happens, you will receive back the application as *Pending additional info*.

NOTE
There is no deadline for the Sponsor to react.

Once you open the application, at the top of the page, you have the option to:

- Create new version
- Withdraw

To perform the actions above, follow the same steps as described in *Validation rejected - Edit and submit response to Competent Authority [67]*.

Once you have submitted the required information, the application will become Validated (pending authorisation).

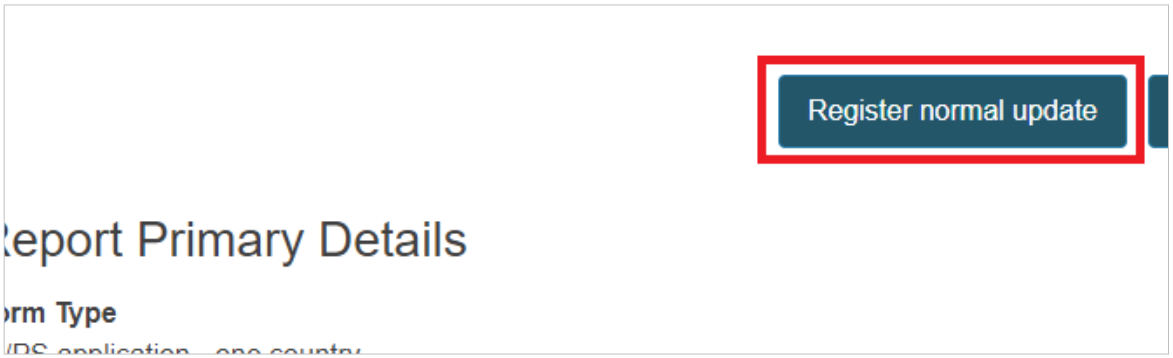
10 Submit normal update

You can submit a normal update to your application/notification when it has one of the following states:

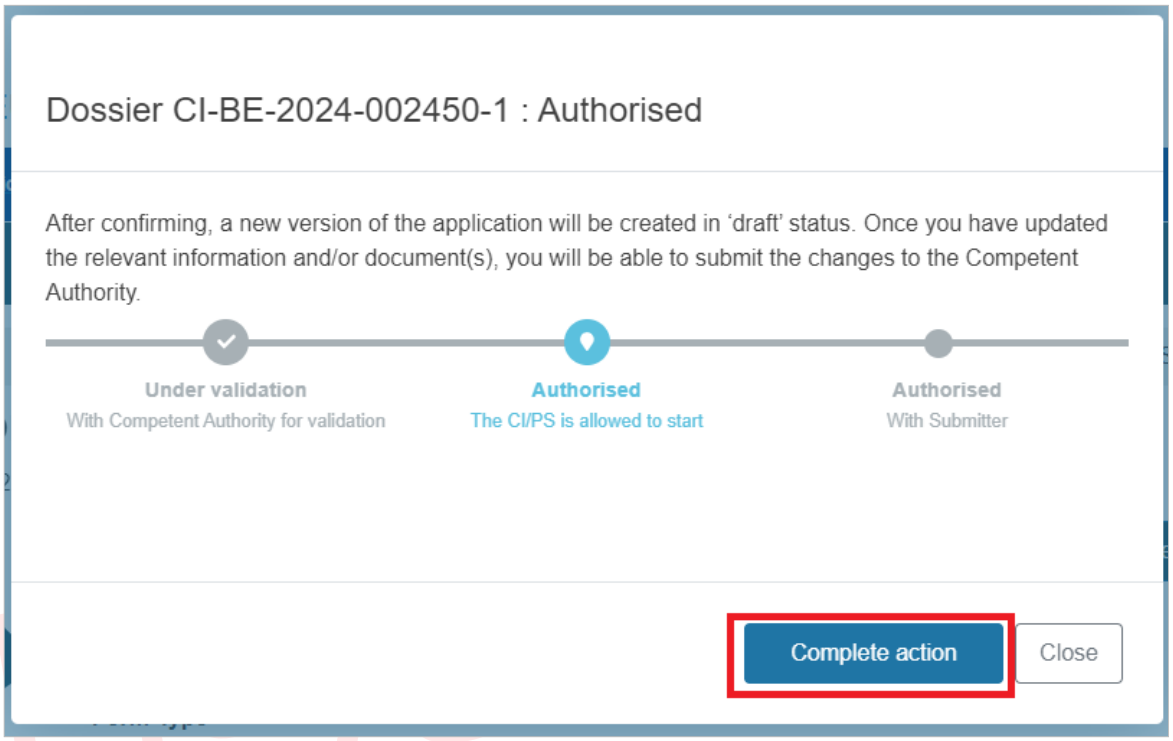
- Notified (published), Acknowledged, Started or Temporarily halted (PMCF/PMPF)
- Validated (may start), Authorised, Started or Temporarily halted (CI/PS)

To do it, follow these steps:

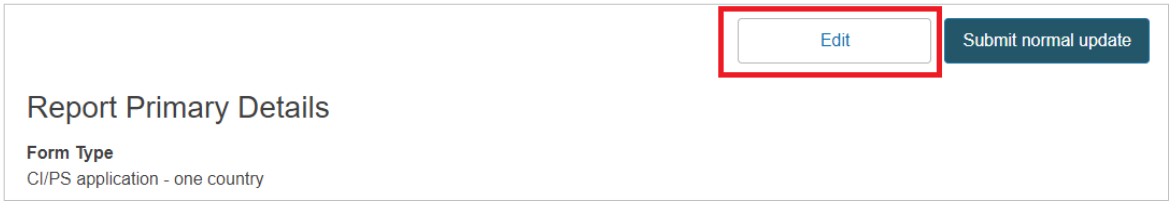
1. Click **Register normal update**.



2. A pop-up window will appear. Click **Complete action** to proceed.



3. A new version of the application will be created as *Draft*. At this stage, you will be able to *Edit* the relevant information in the application.

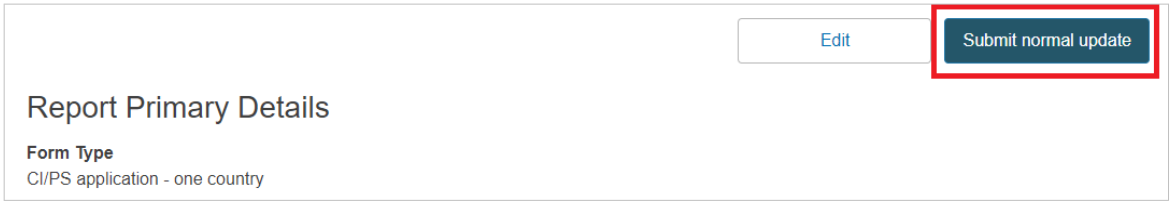


NOTE

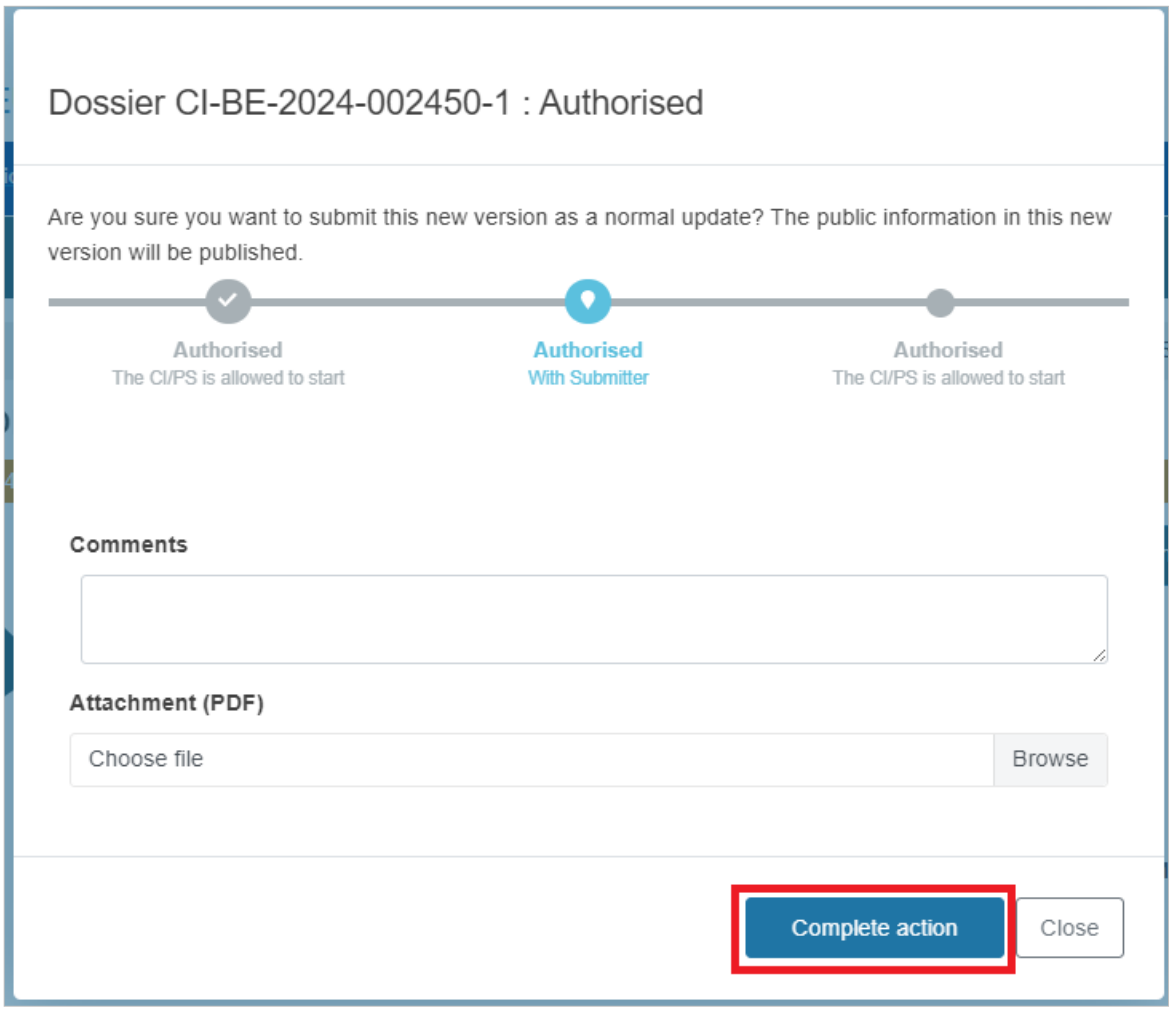
You will not be able to change the value of the field *CI/PS plan code*. In the case of a coordinated assessment, the following fields cannot be edited either:

- the countries to which the coordinated assessment application has been submitted;
- the proposed coordinated Member State.

4. When all appropriate updates have been registered, click **Submit normal update**.



5. A pop-up window will appear for you to provide comments. Once you are done, click **Complete action**.



NOTE
Completing this action will generate a notification to the Competent Authority that a new version has been submitted.

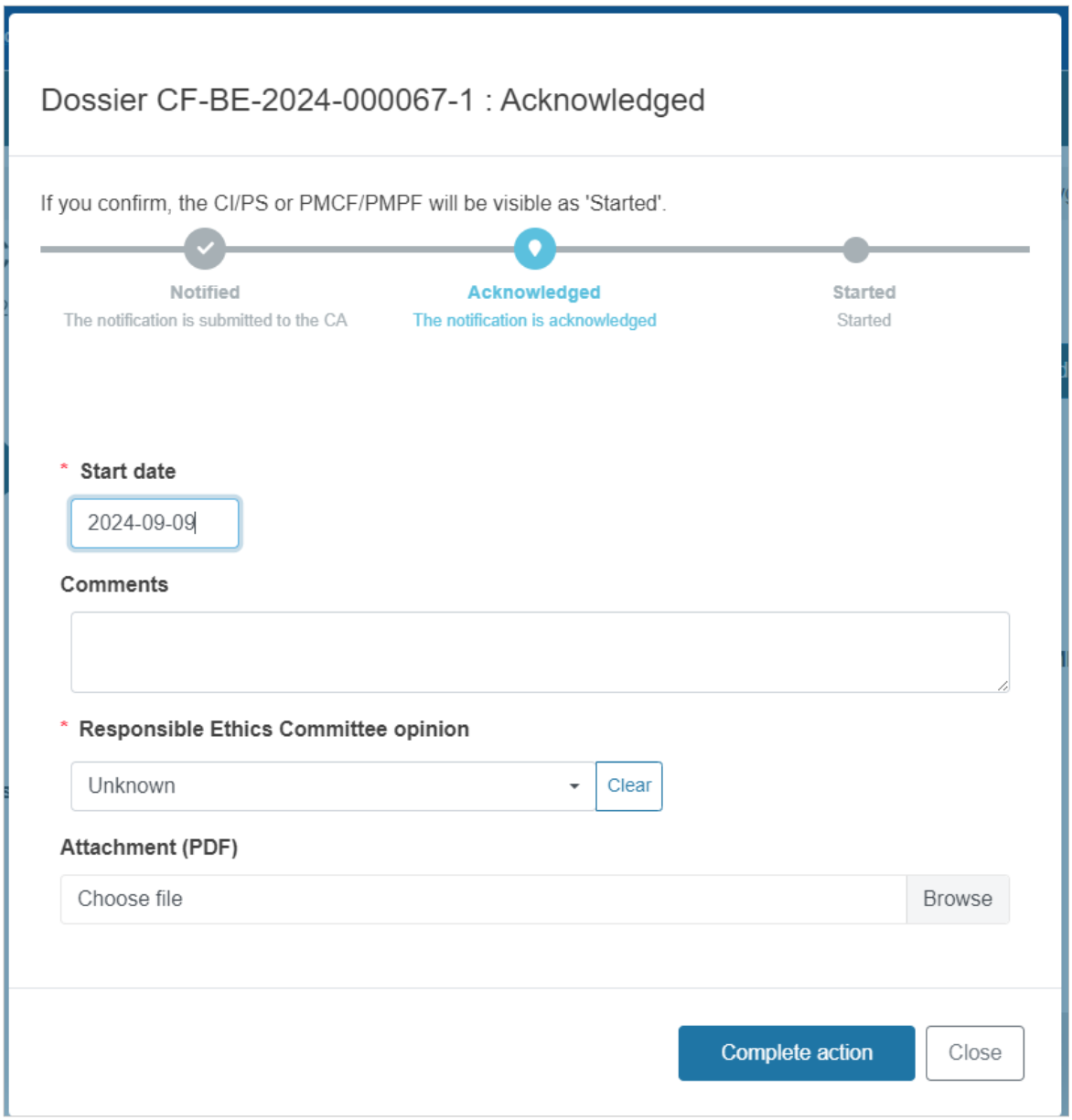
11 Register start date

VIDEO: Register a CI/PS start date

Once the application/notification is authorised to start, you can indicate the start date.

To do it:

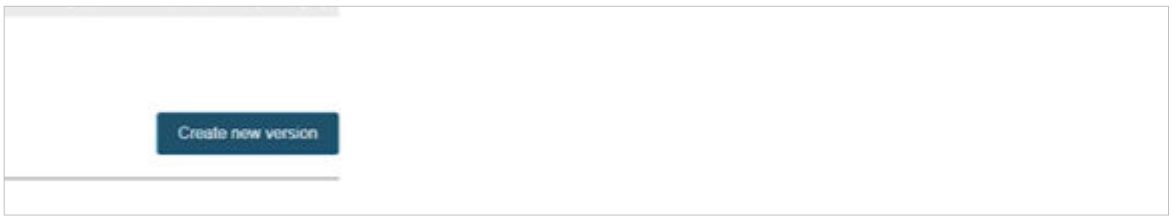
1. Go to the top right corner of the page and click *Register start date*.
2. A pop-up window will appear. Fill in the start date and provide any relevant comments.



IMPORTANT
If the *Responsible Ethics Committee opinion* is *Unknown* until this stage, you must have their positive opinion before registering the start date. Otherwise, the application/notification cannot start.

NOTE
The start date cannot be in the future.

3. Once all the mandatory fields are filled in, click *Complete action*.
4. The application/notification will now have the state *Started*.
5. Once the application/notification has started, you can *Create new version*.



12 Deadlines applying to the CI/PS application – one country

Key date/event	Process description	Deadline	Possibility of extension?	Period can be suspended?
Submission date	Sponsor submits CI/PS application			
Validation date	Time for validation decision by CA	10 days of submission date (FS-CI/PS-003.05)	Yes, + 5 days (LR-CI/PS-025)	
(in case of negative validation decision)	Time for sponsor to provide comments or complete application	10 days of negative validation decision	Yes, + 20 days	
Validation date	Time for CA to provide validation decision after additional comments or completion of application by sponsor	5 days of sponsor's feedback	Yes, + 5 days (LR-CI/PS-025)	
Authorisation date	Time for authorisation decision (assessment) by CA	45 days of validation date	Yes, + 20 days or + 50 days if Class IIb/C or Class III/D	Yes, while waiting for response sponsor: additional comment or complete application

13 Deadlines applying to the PMCF/PMPF notification

Key date/event	Process description	Deadline	Possibility of extension?
Submission date	Minimum period for sponsor to notify PMCF/PMPF investigation/study to the MSC	30 days before starting PMCF/ PMPF	No
	Maximum period for CA to acknowledge receipt of the notification (and to provide comments to sponsor)	30 days of submission date	No

14 Notifications triggered by the system

Identifier and subject of the EUDAMED notification	Recipient(s)	Triggered
CI/PS-001: Submission of CI/PS application - one country	CA selected in the National information section - *Local Competent Authority* field	At submission of the first version of the form
CI/PS-002: Submission of PMCF/PMPF notification - including sponsor validation information	CA selected in the National information section - *Local Competent Authority* field	At submission of the first version of the form
CI/PS-023: Submission of pre-existing CI/PS application - one country	CA selected in the National information section - *Local Competent Authority* field	At submission of the first version of the form for a CI/PS that was allowed to start before EUDAMED CI/PS is available
CI/PS-024: Submission of pre-existing PMCF/PMPF notification	CA selected in the National information section - *Local Competent Authority* field	At submission of the first version of the form for a PMCF/PMPF that was allowed to start before EUDAMED CI/PS is available
CI/PS-026: pre-existing CI/PS application or PMCF/PMPF notification: sponsor submitted response to rejection	CA selected in the National information section - *Local Competent Authority* field	At submission of a response by the sponsor to the rejection of a CI/PS or PMCF/PMPF that was allowed to start before EUDAMED CI/PS is available
CI/PS-042: CI/PS application - one country: outcome of validation process (generic)	Sponsor owner of the form and CA actor selected in the National information section - *Local Competent Authority* field	At submission of the validation decision by the CA (positive or negative)
CI/PS-025: registration of pre-existing CI/PS application or PMCF/PMPF notification was assessed by CA	Sponsor owner of the form	At submission of the CA assessment of a CI/PS or PMCF/PMPF that was allowed to start before EUDAMED CI/PS is available
CI/PS-051: Submission for additional country(ies) - CI/PS one country	All CAs to whom another CI/PS application with the same EU SIN has already been submitted	At submission of a new application for additional countries for the same EU SIN
CI/PS-053: Submission for additional country - PMCF/PMPF notification	All CAs to whom another PMCF/PMPF notification with the same EU SIN has already been submitted	At submission of a new notification for additional countries for the same EU SIN
CI/PS-022: Sponsor submits normal update to CI/PS application or PMCF/PMPF notification	CA selected in the National information section - *Local Competent Authority* field	When the sponsor submits a new version of the application/notification that is not a substantial modification
CI/PS-005: CA extends deadline for validation of CI/PS application - one country	Sponsor owner of the form	When the CA extends the period for validation
CI/PS-006: CA extends deadline for sponsor in CI/PS application - one country	Sponsor owner of the form	When the CA extends the period for the sponsor to react to the initial rejection of the application
CI/PS-007: CI/PS application - one country: sponsor submitted response to rejection	CA selected in the National information section - *Local Competent Authority* field	When the sponsor submits a response to the initial rejection of the application
CI/PS-009: The application is lapsed (no sponsor response before deadline)	Sponsor owner of the form and CA actor selected in the National information section - *Local Competent Authority* field	When the sponsor did not submit a response to the initial rejection of the application before the deadline expired
CI/PS-010: CI/PS application - one country: authorisation outcome	Sponsor owner of the form and CA actor selected in the National information section - *Local Competent Authority* field	At submission of the authorisation decision by the CA (positive or negative)
CI/PS-011: CI/PS application - one country: authorisation refused (corrective measure)	All CAs with CI/PS responsibilities and EC actor	When the CA refuses authorisation of a CI/PS application - one country. This is considered to be a corrective measure and is therefore communicated to all CAs and the EC.
CI/PS-012: Request additional information during authorisation - one country	Sponsor owner of the form and CA actor selected in the National information section - Local Competent Authority field	When the CA submits a request for additional information during the authorisation process
CI/PS-013: Provide additional information during authorisation - one country	CA selected in the National information section - *Local Competent Authority* field	When the sponsor submits a response to the request for additional information from the CA
CI/PS-014: CA extends deadline for authorisation of CI/PS application - one country	Sponsor owner of the form	When the CA extends the period for authorisation
CI/PS-015: PMCF/PMPF - no reaction from CA	Sponsor owner of the form	When the CA does not submit a response to the PMCF/PMPF notification after 30 days
CI/PS-016: PMCF/PMPF is acknowledged by CA	Sponsor owner of the form	When the CA acknowledges receipt of the PMCF/PMPF notification
CI/PS-027: CI/PS application - one country is withdrawn by sponsor	All CAs with CI/PS responsibilities and EC actor	When the sponsor withdraws the CI/PS application

Identifier and subject of the EUDAMED notification	Recipient(s)	Triggered
CI/PS-029: PMCF/PMPF notification is withdrawn by sponsor	All CAs with CI/PS responsibilities and EC actor	When the sponsor withdraws the PMCF/PMPF notification
CI/PS-018: Sponsor defined (re)start date for a participating country	CA selected in the National information section - *Local Competent Authority* field	When the sponsor submitted the start date or the restart date of a CI/PS or PMCF/PMPF
CI/PS-008: Sponsor actor data ready for publication	Sponsor for which the actor data was 'validated' implicitly	When the CA positively validates a CI/PS application or acknowledges receipt of a PMCF/PMPF notification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