EudraCT protocol: filling in a third country file

These instructions regard third country files only. As of 31 January 2025, the creation and amendment of EU/EEA CTAs is no longer possible through EudraCT, since any ongoing trial in EU/EEA needs to be recorded on CTIS.

The present part of the user manual provides instructions on the following EudraCT processes:

1. Create a Third country file (this can be done after the creation of an EudraCT number)

2. Save XML of a third country file

3. Save PDF version of a Third Country file

4. Load a Third Country file

5. Completing a Third Country file (see the detailed list of fields)

6. Validate a third country file

Click on the relevant link to go to the relevant instructions. After having validated the third country file, the user can submit it as described here.

A full overview of EudraCT processes is provided in the EudraCT step-by-step guide. In case support is needed, see here.

Create a draft third country file

Once having [created an EudraCT number](), you can create a third country file.

1. From the EudraCT application https://eudract.ema.europa.eu/results-web/ click on 'Create' and select 'Clinical Trial Protocol' then 'Third Country file'. The Initial Required Information section appears: insert the EudraCT Number for the third country file in the free text field

2. Click on 'create' and the Clinical Trial third country file Menu appears with all the sections that need to be completed.

Save XML of the third country file

In case you did not log in EudraCT while filling in a a third country file, **it is important to save the file locally because the file is not saved online within the application.** If you exit the EudraCT without saving the full third country data as XML file, any newly inserted data is lost.

To save a third country file as an XML file, the file needs to have been just [created]() or just [loaded]() on EudraCT.

1. Click on the option Save as XML at the top right corner of the page:

2. Click on 'click here to Download XML' and click on 'Save' to save the file locally.

The third country file in XML format is now saved locally. In case you would like to change its content, you need to upload it again (see '[Load a Third Country file]()').

Save the PDF version of a Third Country file

To save a third country file as a pdf file, the file needs to have been just created (see section 'Create the draft Third country file') or be loaded on EudraCT (see section 'Load a Third Country file').

1. Click on the option Save pdf at the top right corner of the clinical trial application menu
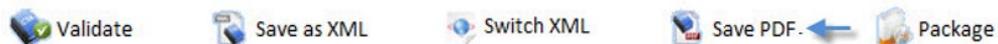
2. Click on 'Download current form' and click on Save to save the file locally.

The third country file in pdf format can now be stored locally.

Load a Third Country file

A locally saved Third Country file in XML format can be loaded again, after having been saved as XML file locally during its completion. Any user can load a Third Country using the application: a user does not need to log in the system load an XML file.

1. From the EudraCT application https://eudract.ema.europa.eu/results-web/ , click on 'Load' at the top right corner, select 'Clinical Trial' then '3rd Country', and the relevant XML Upload screen appears:

2. Click on 'add' and find the XML file in your workstation's available areas.

3. Click on 'Open' and the file path is saved to the application:

4. Click on 'upload'.

   - XML file update report: Success - The file is uploaded to the application, where you may edit or review it from the Menu, where it will now be loaded.

   - XML file update report: Failure - If the file does not load for some reason, an error message appears, giving details. Ensure that the file you are trying to upload is present and adheres to the schemas before trying again. Ensure also that it is the correct type (Third Country, not EEA CTA) and that it is associated to a EudraCT number. For questions, refer to the Frequently Asked Questions.

You can now update the third country file as described in the section below. If your updates are performed while you are not logged in, you must download and save the relevant XML file locally. If you exit the EudraCT without saving the full third country data as XML file, any newly inserted data is lost.

Filling in a Third Country file or a EU/EEA CTA

This section describes how to fill in the content of a third country file, after its creation. Note, in case you are not logged in EudraCT:

- After having created the file, it is recommended to save it locally as XML often while completing it, since the file is not saved online on the application.

- The session timeout for EudraCT is set to 30 minutes. After 30 minutes of inactivity you are automatically logged out and any changes made are lost unless they have been saved. To avoid any loss of data you need to save your protocol content as XML file often.

Click on the relevant section of the third country file to view detailed instructions for completing it.

1. Section A. Trial Identification

Section A requires the third country data provider to provide information to identify the clinical trial.

1. A.2: The EudraCT number, <u>obtained previously through the EudraCT website</u>, is added automatically after entry in the Initial Required Information screen.

2. A.3: click on the free text field and enter the full title of the clinical trial (up to 2000 characters). The title should be identical to the one specified in the study protocol and/or to the other documents submitted as part of the Clinical Trial Application dossier. Note: If this trial is included in more than one agreed PIP, provide one PIP decision number in field A.8 "EMA Decision number of Paediatric Investigation Plan" and enter all other PIP decision numbers in field A.3 after the clinical trial title.

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on ✚ in case a further language needs to be added or ✖ if you wish to delete a previously added language translation

3. Click in the free text field and enter the title of the clinical trial in non-technical terms, suitable for comprehension by individuals without medical/pharmaceutical training, up to 500 characters.

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on ✚ in case a further language needs to be added or ✖ if you wish to delete a previously added language translation

4. Click on the free text field and enter a shortened title of the clinical trial, if available. This abbreviated title should be identical to the one mentioned in the protocol (A.3.2).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on ✚ in case a further language needs to be added or ✖ if you wish to delete a previously added language translation

5. A.4.1: Click on the free text field and enter the sponsor protocol number, which is assigned by the sponsor. This should be identical to the protocol number provided when the EudraCT number was obtained, and which appears on the receipt of confirmation of the EudraCT number and should remain unchanged throughout the study. The protocol number should not contain any date or blanks and should remain identical throughout the duration of the trial.

6. If the trial is registered on the ISRCTN registry, type in the International Standard Randomised Controlled Trial Number in field A.5.1.

7. If the trial is registered on 'ClinicalTrials.gov', type the ClinicalTrials.gov identifier (the format for this identifier is "NCT" followed by an 8-digit number, e.g.: NCT00000419) in field A.5.2.

8. If the trial is registered on the WHO Clinical Trials Portal, please enter the WHO International Clinical Trials Registry Platform's (ICTRP) Universal Trial Number (A.5.3).

9. If other identifiers are available click on the left-hand field and enter the name of the identifier, then enter the identification number for this trial in the right-hand field. Click 🔲 button to add additional fields and click the ✖ button to delete fields added in error (A.5.4).

10. A.7: Select 'Yes' for a trial part of a paediatric investigation plan (PIP) or otherwise, choose 'No'. A paediatric investigation plan is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of the medicine for children (A.7).

11. A.8: Enter the European Medicines Agency's decision number for the Paediatric Investigation Plan (PIP) where available. The value entered should have the format: **P/xxx/yyyy** where '**xxx**' is 1,2 or 3 digits and '**yyyy**' represents years. The system currently allows entry of only one decision number per clinical trial (A.8 - Conditionally Mandatory - if A.7 is 'Yes', A.8 must be completed.). If this trial is included in more than one agreed PIP, please provide one PIP decision number in field A.8 "EMA Decision number of Paediatric Investigation Plan" and enter all other PIP decision numbers in field A.3 "Full title of the trial" after the clinical trial title.

Note: The EMA PIP decision number appears on the title page of the Agency's decision on a PIP in the format P/xxx/yyyy underneath the title "European Medicines Agency decision" (it is usually printed in the top right corner of the title page.). The EMA PIP decision number is not the same as the EMA PIP procedure number which is formatted EMEA-xxxxxx-PIPxx-yy and which appears on summary reports, opinions, etc.

The section is now complete. It is suggested you move to the next section of the Clinical Trial Menu ("B. Sponsor Identification") or return to the main Menu.

2. Section B. Sponsor Identification

The following steps are necessary to fill in the fields of Section B Sponsor Identification of an EudraCT third country file. Once having selected Section B, click on 🔲 'Add Sponsor' to add a Sponsor. Once the whole section is complete, the Sponsor Details appear on a table in this section.

B.1 - Sponsor Organisation

Include the details for section B.1 Sponsor Organisation. Enter details through the user interface, then click on other blue heading to open other uncompleted sections.

Click on 'Done' when the section is completed and you return to the section overview level, where additional sponsors may be added, or existing sponsor details edited or deleted.

1. Click in the free text field and enter the name of the sponsor of the trial. Sponsor is defined in article 2 (e) of Directive 2001/20/EC , as "an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial"(B.1.1).

2. In field B.1.3.4. click the drop-down list to select the Country in which the sponsor's organisation is based.

B.3.1 and B.3.2 Status of the sponsor

Click the drop-down list to select relevant option describing the status of the Clinical Trial's sponsor (B.3.1/B.3.2 - Mandatory field). Tip: a commercial sponsor is a person or organisation that takes responsibility for a trial which is part of the development programme for a marketing authorisation of a medicinal product at the time of the application.

B.4 Source(s) of Monetary or Material Support for the clinical trial

This section should identify the major organisations providing monetary or material support for the conduct of the trial. In many cases this will be the same as the sponsor. Where there are other organisations providing significant funding or material support these should be identified (e.g., where a funding organisation or pharmaceutical company provide support for a non-commercial trial (including (but not limited to) funding, design, implementation, data analysis and reporting).

1. Include the name of the Organisation (or individual) who is providing the finance or resources for the clinical trial in field B.4.1.

2. Include the country name of the Organisation (or individual) who is providing the finance or resources for the clinical trial in field B.4.2.

Click 🛨 to add other organisations. Click ✖ to delete any entries added in error. Click on 'done' when the section is completed and you return to the section overview level, where additional sponsors may be added, or existing sponsor details edited or deleted.

B.5 Contact point designated by the sponsor for further information on the trial

The contact point will be made publicly available and is the place to which members of the public can address requests for information about the trial. Note: The contact point may be at the sponsor, a trial site or another organisation, and there may be one per concerned Member State or one in the EEA.

1. Enter the name of the organisation in field B.5.1.

2. Provide a functional contact point rather than the name of a person in field B.5.2.

3. In free text fields B.5.3, provide the full postal address

4. Click the drop-down list to select the Country in which the contact point is based (B.5.3.4).

5. In free text fields B.5.4 to B.5.5, enter the contact details (phone number, fax). The contact details (phone number, fax,) are those of the further information contact in section B.5 (B.5.4-B.5.5 -Conditionally mandatory - include at least one of B.5.4-B.5.6.). Note: include the international or applicable area codes.

6. When entering the email address in the free text field please be aware that functional emails are preferred to personal ones E.g.: regulatory@corporate.com or renalcancer.ct-unit@hospital.org) (B.5.6 - Conditionally mandatory - include at least one of B.5.4-B.5.6.).

Section B is now complete. It is suggested you move to the next section of the Clinical Trial Menu ("B. Sponsor Identification") or return to the main Menu.

3. Section C. Third country data provider Identification

C.1 Request to receive a copy of CT Information data as XML

1. C.1.5 Request to receive a copy of CT Information as XML: click a radio button to indicate if you'd like copy of the CTA data downloaded from EudraCT as XML.

   Note: C.1.5.1 is mandatory and if the answer is 'Yes' then C.1.5.1.1 should contain at least one email address.

2. If you answered 'Yes' to C.1.5.1, then you may provide up to 5 email addresses to which copies of the CTA XML file will be sent via EudraLink. (C.1.5.1.1 - Conditionally mandatory - include at least one email address).

3. Note: These email addresses must have Eudralink accounts for secure password protected delivery unless you answer 'No' to C.1.5.1.2 for delivery without password protection.

4. Select 'Yes' if you require secure email delivery of the XML.

5. For Validation Guidance: C.1.5.1.2 is a mandatory: If C.1.5.1 is answered 'No' C.1.5.1.2 answer should also be 'No'. If C.1.5.1 is 'Yes', C.1.5.1.2 may be either 'Yes' or 'No'.C.1.5.1.2. by default is blank. Note: Ensure that this field does not contain any spaces within or outside the body of the email address, or rubbish data (e.g. XXXX). Failure to do so, may cause issues with the validity of the XML

Click 'Done' button when the sub-section is complete.

4. Section D. IMP Identification

Click on 'add IMP' and complete all questions concerning information relating to the identification of the Investigational Medicinal Product(s) (IMPs) to be used in the Clinical Trial. If most of the answers are the same for any additional IMP(s) (e.g., three tablets of different strength), then enter one IMP, use the 'Copy IMP' function in the IMP Details screen, which appears once the first IMP has been added. You may then edit the relevant fields in the copy to update the information (e.g. Strength). **Sections D.3.8 to D.3.10 are available via the 'add active substance' function, after having added an IMP.**

D.1/D.2 IMP Identification and Status Details

1. Choose the Investigational Medicinal Product Category from the drop-down list. Click on the drop-down list to select relevant option (D.1.2 and D.1.3). If there is no clear 'Test IMP' or 'Comparator' in your study design, indicate all Investigational Medicinal Products (IMPs) as 'Test IMP'. Each strength and pharmaceutical form should be recorded as a separate Investigational Medicinal Product (use "copy IMP" and edit the strength of each active substance and/or pharmaceutical form of the IMP).

2. In Section D.2, the information provided should be that which specifically relates to the actual product being used in the trial in the Member State to which the CTA is addressed. For example, if the CTA is submitted in France, the IMP has a MA in France and Germany, and the sponsor chooses to use the IMP registered in Germany for the purposes of the trial, it is the German trade name/MAH/MA number that should be mentioned in this section.

3. When you answer D.2.1, if you select the 'No' option then go to D.3.
   If 'Yes' then complete section D.2.1.1.1 to D.2.1.1.4.

UNLESS the IMP has a Marketing Authorisation in the Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol. In such a case, complete D.2.1.2 with the name of the Member State to which the application is submitted, answer 'Yes' to D.2.1.2.1, and then go to section D.2.2. Tip: If the Investigational Medicinal Product has a Marketing Authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2, below.

4. If the IMP has a Marketing Authorisation in the country from which it is sourced for use in this Clinical Trial, complete section D.2.1.1. with the information relevant to the country from which the product has been sourced.

5. In free text field D.2.1.1.1, if the IMP has a Marketing Authorisation in the country from which it is sourced for use in this clinical trial, specify the Product Name as registered by the Marketing Authorisation Holder (MAH). It is available from the Summary of Product Characteristics (SmPC), or product labelling.

6. In free text field D.2.1.1.1.1, specify the EudraVigilance Product Code here when available (see instructions below 'D. MPD Add Active Substance - to Add an Active Substance(s) to an IMP').

7. In free text field D.2.1.1.1.2, specify the Name of the Marketing Authorisation holder, which is available from the Summary of Product Characteristics (SmPC), or Product Labelling.

8. In free text field D.2.1.1.1.3, specify the Marketing Authorisation number, which is issued when a Marketing Authorisation is granted in a MS. It is available from the Summary of Product Characteristics (SmPC) or Product Labelling.

9. In section D.2.1.1.4:

    *   Answer 'Yes' if there are any trial-specific operations that could affect the product quality, such as modification of the pharmaceutical form (e.g. over-encapsulation, colour, dilution, re-tableting for blinding etc.) or removal from the primary packaging and repacking (e.g. removal from a blister and putting in a bottle). If the blinding consists in over encapsulating tablets, trial specific coating (modified colour, or debossing), this information should be reported here.

    *   Answer 'No' If the product has only been relabelled or repackaged.

10. In section D.2.1.2, click on the drop-down list to specify the name of the country where the holder was granted the Marketing Authorisation of the actual Investigational Medicinal Product to be used in the clinical trial in the Member State concerned by the application.

    *   If the Investigational Medicinal Product has a Marketing Authorisation in several countries, enter the name of the country (or of one of the countries, if one of them is a Member State, choose this one) that granted the Marketing Authorisation for the actual Investigational Medicinal Product to be used in the trial in accordance with section D.2.1.1.2.

    *   Where the product is a Centrally Authorised Product, give the Member State in which the product was intended to be marketed (i.e. the one for which it is labelled) or, if bulk product is used, choose one of the Member States.

11. In section D.2.1.2.1, answer 'Yes' if the Marketing Authorisation of the IMP to be used in the clinical trial in the Member State concerned by the application was granted by the same Member State. Answer 'No' if the Marketing Authorisation was granted by another country.

12. Complete section D.2.2 when the IMP has a Marketing Authorisation in the Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol. Tip: You should also have answered 'Yes' to D.2.1 and have completed D.2.1.2 with the name of the Member State to which the application is submitted, and 'Yes' to D.2.1.2.1.

13. Section D.2.2.1 should be answered 'Yes' when the protocol only identifies the INN and the investigator can use whichever brand is locally available.
    The protocol of the clinical trial may specify only the INN of the product used in the trial (for example 'paracetamol') when, for the same active substance there are several different trade names available in the Member state concerned and no one of them is specified by the protocol. Note: If 'Yes', give active substance in section D.3.8 or D.3.9 from the IMP details field (see instructions below 'D. MPD Add Active Substance - to Add an Active Substance(s) to an IMP').

14. If D.2.2.1 is answered 'Yes' then D.2.2.2 may be 'Yes' or 'No'.
    Select 'Yes' if, in the protocol, treatment regimens for the Investigational Medicinal Product allow different combinations of marketed products (only defined by their INN) used according to local practice at some or all investigator site in the concerned Member State (this case is frequently observed in oncology or HIV clinical trials). In this case each site might have a different combination compared to other sites. Note: if 'Yes', give active substance in section D.3.8 or D.3.9 from the IMP details field.

15. If D.2.2.1 is answered 'Yes' then D.2.2.3 must be 'No'. However, if the answer to this field is 'Yes' then D.2.2.1, D.2.2.2 and D.2.2.4 should be 'No'. Note: if 'Yes', write the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.3

16. If D.2.2.1 is answered 'Yes' then D.2.2.4 must be answered 'No'.

17. Answer D.2.5 according to the [Community register on orphan medicinal products (Regulation (EC) no. 141/2000)](#).
    If the D.2.5 was answered 'Yes', please enter the orphan drug designation number in D.2.5.1. Tip: The orphan drug designation number is available on [Community Register of orphan medicinal products](#) . Note: This is in reference to the regulation (EC) No.141/2000 on Orphan Medicinal Products.

D.3 Description of the IMP

1. Complete D.3.1 only when there is no trade name. This is the name routinely used by a sponsor to identify the Investigational Medicinal Product in the CT documentation (e.g., in the protocol, IB etc.). Note: it is mandatory to complete D.3.1.and/or D.3.2 if question D.2.1 was answered 'No'.

2. Complete D.3.2 only when there is no trade name. This is a code assigned by the sponsor which represents the name routinely used by the sponsor to identify the product in the trial's documentation. For example, a code may be used for combinations of drugs or drugs and devices. Note: it is mandatory to complete D.3.1.and/or D.3.2 if question D.2.1 was answered 'No'.

3. In D.3.4, select the pharmaceutical form of the actual Investigational Medicinal Product to be used in the clinical trial from the drop-down menu. Note: mandatory field unless D.2.2 is 'Yes'.

4. Answer D.3.4.1 with 'Yes' if the formulation is specifically for paediatric usage.

D.3.7 Routes of administration for this IMP

This sub-section simply contains Routes of Administration for the selected Investigational Medicinal Product.

1. To select one Route of Administration, click the country and then click 'Copy'.

2. To select more than one Route of Administration hold CTRL then click the Routes of Administration and then click 'Copy'. Use the scroll bar at the side of the window to move to other options. Note: This is a Mandatory field if your precise term is not available use the free text field and include it in your cover letter.

Selecting 'D.3.11 Type of IMP' opens the relevant section and only then can sections D.3.8 to D.3.10 for active substances be accessed by selecting 'add active substance' for this IMP at the IMP Identification Index screen.

D.3.11 Type of IMP

In this sub-section it is possible to provide details on the type of the selected Investigational Medicinal Product.

1. In field D.3.11.1, select 'Yes' if the Investigational Medicinal Product is obtained by chemical synthesis. Note: in some cases, where there are two or more active substances in one Investigational Medicinal Product, it is possible that both D.3.11.1 and D.3.11.2 are marked 'Yes'.

2. In field D.3.11.2, select 'Yes' for Investigational Medicinal Products (IMPs) where the active ingredient(s) are biological product(s) of human or animal origin, or contain biological components of human or animal origin, or the manufacturing of which requires such components. Note: In some cases, where there are two or more active substances in one IMP, it is possible that both D.3.11.1 and D.3.11.2 would be marked 'Yes'. Also, if D.3.11.2 is marked 'Yes', ensure that D.4 is completed.

3. If the IMP is considered an Advanced Therapy Investigational Medicinal Product (ATIMP), select 'Yes' for D.3.11.3. Note: If this field is marked 'Yes', ensure that the following five sub-questions below, as well as section D.5 is completed.

4. If the proposed clinical trial entails a somatic cell therapy medicinal product, select 'Yes' for D.3.11.3.1.

5. Select 'Yes' for D.3.11.3.2 if this Advanced Therapy IMP is a gene therapy medicinal product.

6. Select 'Yes' for D.3.11.3.3 if this Advanced Therapy IMP is a tissue engineered medicinal product.

7. Select 'Yes' for D.3.11.3.4 if the Advanced Therapy IMP is a combined product involving a medical device?

8. Select 'Yes' for D.3.11.3.5, if the Committee on Advanced Therapies (CAT) has issued a recommendation for classification for this IMP.

9. Click on the free text field and specify the Committee on Advanced Therapies (CAT) classification and reference number, if D.3.11.3.5 was 'Yes'.

10. Select 'Yes' for D.3.11.4 if this IMP includes a medical device but does not involve an advance therapy medicinal product.

11. Select 'Yes' for D.3.11.5 if this IMP is a radiopharmaceutical medicinal product.

12. Select 'Yes' for D.3.11.6 if this IMP is an immunological medicinal product (such as a vaccine, allergen, immune serum, etc.), whether it is for prophylactic or therapeutic use.

13. Select 'Yes' for D.3.11.7 if the IMP is a medicinal product derived from human blood or plasma. Note: If this question is answered 'Yes', D.3.11.2 should also have been answered 'Yes'.

14. Select 'Yes' for D.3.11.8 if the IMP is of biological or biotechnological origin but does not fit any of the categories listed above and is obtained by extraction from biological material. Note: If this question is answered 'Yes', D.3.11.2 should also have been answered 'Yes'.

15. Select 'Yes' for D.3.11.9 if the IMP was produced using recombinant technology. Note: If this question is answered 'Yes', D.3.11.2 should also have been answered 'Yes'.

16. Select 'Yes' for D.3.11.10 if this IMP contains Genetically Modified Organisms. Note: If this question is answered 'Yes', D.3.11.2 should also have been answered 'Yes'. The following two questions should be completed only if the Investigational Medicinal Product is a medicinal product containing genetically modified organisms.

17. Answer D.3.11.10.1 only if the IMP is a medicinal product containing genetically modified organisms.

18. Answer D.3.11.10.2 only if the IMP is a medicinal product containing genetically modified organisms.

19. Select 'Yes' for D.3.11.11 if this IMP contains an active substance of herbal origin.

20. Select 'Yes' for D.3.11.12 if this IMP is a homeopathic medicinal product.

21. Select 'Yes' for D.3.11.13 if the proposed clinical trial entails a medicinal product of a type not detailed above (e.g. medicinal gas).

22. If this is an 'Other' type of IMP, in D.3.11.13.1, specify the type of IMP in the free text field.

23. In D.3.12 free text field, enter the mode of action of the active substance of this medicinal product (up to 500 characters). Abbreviation should be avoided if possible.

IMP Details table

Once an IMP is added, it appears in the IMP Details' table of section D. IMP Identification:

From this table, you can choose:

- 'Add IMP' at the top to add another IMP (after all details are added, another IMP will appear in the IMP details' table)

- 'Edit IMP', in case you wish to review and edit the IMP that was already added.

- 'Delete IMP' beside the IMP in the table. A warning dialogue appears: click 'Yes' to delete the IMP, otherwise click 'No'. The updated IMP Details screen appears. Note: Active substances can be deleted from the parent IMP in the same way.

- 'Copy IMP' beside the IMP in the table that you wish to duplicate. The entry appears in duplicate directly below the original IMP in the IMP Details table. You can then click on 'Edit IMP' to make any necessary changes to the IMP copy.

- 'Add active substance', section 'D. MPD Add Active Substance' opens and you can search for an active substance in order to add it to the IMP Details.

D. MPD Add Active Substance - to Add an Active Substance(s) to an IMP

Once having clicked on 'add active substance', the following screen is shown:

D. MPD Add Active Substance

Search for active substance using either the name or EV code. Use the EV Code in preference to the substance name.

- ⦿ Active Substance name
- ○ Substance EV code   equals

Search   Return

1. Click the drop-down to choose the filter to be applied to the 'Active Substance name'. The options are 'contains', 'equals' or 'starts with' (operators). Now click in the free text field on the right and specify the active substance name, or part thereof, based on your filter criteria. Alternatively, click on 'Substance EV code' and specify the 'Substance EudraVigilance Code' in the free text field, which must be an exact match. Note: the search for EV Number is always an 'equals' search.

2. When your search criteria are complete, click on 'Search'. A successful search returns a list of results:

MPD Search Results

Substance Name (EN) ⇕	Source ⇕	EV Code ⇕	CAS No. ⇕	CBD	Substance Category ⇕	Status ⇕	
Acetylaminonitropropoxybenzene Names	INN	SUB71211	0000553-20-8	Details	AUTHORISED	CURRENT	⊕
ACETYLCHOLINESTERASE Names		SUB32167	9000-81-1	Details	AUTHORISED	CURRENT	⊕
N,S-diacetyl methyl cysteinate Names		SUB73252		Details	AUTHORISED	CURRENT	⊕
2'-((2-(4-Methoxyphenyl)acetylamino)methyl)biphenyl-2-carboxylic acid (2-pyridin-3-yl-ethyl)amide Names		SUB267566		Details	AUTHORISED	CURRENT	⊕
ACETYL ACETONE Names		SUB120168	123-54-6	Details	AUTHORISED	CURRENT	⊕

If your active substance is not available from this search, it needs to be added in the XEVMPD through opening a ticket in the EMA Service Now Request SMS services - Employee Center (europa.eu) (to log in: please add the extension '@id.ema.europa.eu' to the EMA username; non-registered users can create an EMA account first). You need to request the registration of the concerned substance by filling in the Excel file (using this template) and attaching the respective Investigator Brochure. Note that this service has a service level agreement (SLA) of 5-10 working days. You will have the option to update any information on the new substance once registered, as per above steps. More details in the Frequently Asked Questions.

3. Click on the button to add the active substance to the IMP Details. There is no limit to the number of active substances that can be added in this way.

Once you successfully found and added the active substance, the IMP Details table appears with the item added.

D.3.8 to D.3.10 IMP Identification Details (add Active Substances)

As per above-described process, in order to add an 'active substance' you need first to add an IMP in section D of the CTA ("IMP identification"). Once details of the IMP have been added in sections D.1 to D.7, you can go back to the main section D and click on the tab "Add active substance". Once having searched for and found the Active Substance, sections D.3.8 to D.3.10 will automatically open and can be updated. For more information, see " D. MPD Add Active Substance - To Add an Active Substance(s) to an IMP". Sections D.3.8 to D.3.10 are mandatory and public fields, therefore they must be answered. Note: It is not necessary to answer D.3.8 if D.2.2.3, D.2.2.4 are answered 'Yes'.

In case the following free text fields are not already pre-filled, it is possible to fill them in as follows:

1. D.3.8, to specify the International Non-proprietary Names (INN) /Proposed INN. For marketed products, the INN is available in the SmPC. For EU marketed products, the INN is available in section 2 of the EU SmPC entitled "Qualitative and quantitative composition".

2. Another descriptive name may be used in specific situations, for example for products of biological or biotechnological origin that have no INN or proposed INN, or where it is an alternative name which is not registered as INN or proposed INN

3. D.3.9.1, to specify the CAS number: if available, specify this active substance's CAS number (a unique numeric identifier for chemical entities) in field D.3.9.1. CAS' format is nnnnnn-nnn-c where c is a check digit and leading zeros may be suppressed (up to 12 characters). For more information, please check http://www.cas.org

4. D.3.9.2, to specify the active substance's (AS) current sponsor code (up to 100 characters).

5. D.3.9.3, to specify another descriptive name for biological/ biotechnological Products that do not have an INN or Proposed INN (up to 500 characters).

6. D.3.9.5, to include the full molecular formula for the active substance.

7. D.3.9.6, to include the accepted chemical/biological description of the Active Substance.

8. Complete details relating to the active substance's strength using fields D.3.10.1 to D.3.10.3. Note: in this section the strength / concentration should be given for each different pharmaceutical form and/or strength of the Investigational Medicinal Product being used in the trial (for example amount of active substance per tablet) and not the dose administered to the subject. Note on 3.10.1: if a unit for your product is not available in the list, please provide an explanation regarding the unit value in section D.3.9.6.

The sub-section is now complete.

Section D.8 Placebo Information

Once the IMP is added, it is possible to add any Placebo information, if present. After selecting "Section D.8 Placebo Information", 'Add Placebo' is selected and the D.8 Information on the Placebo screen appears.

1. Select the relevant Pharmaceutical form and Route of administration from drop-down lists D.8.3 and D.8.4.

2. In D.8.5, click on the check box beside the IMP that the placebo you are entering information for is related to. This allows placebos to be added to Clinical Trials containing multiple IMPs. Once selected, other IMPs move down the screen.

3. In D.8.5.2 click the relevant radio button to indicate whether the placebo is identical to the IMP (aside from the absence of the active substance). Note: This is a MANDATORY FIELD and if it is 'Yes', D.8.5.2.1 should be completed.

4. In free text field D.8.5.2.1, specify any other major ingredients in the placebo if D.8.5.2 was marked 'Yes'.

The section is now complete. Click 'Done' to return to the D.8 Placebo Information page. You can edit   or delete   placebos from the Placebo Details table in section D.8.

5. E. General Information on the Trial

E.1 Medical condition or disease under investigation

This sub-section is intended to detail the medical condition or disease under investigation.

1. In E.1.1, click on the free text field and enter:
   - In the case of healthy volunteer trials, state 'healthy volunteers' as well as the intended indication for the product under development, which should be provided in parentheses.
   - If the trial is to be conducted on patients, only the name of the disease, which is the indication for which the Investigational Medicinal Product is administered, is required.

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on   in case a further language needs to be added or   if you wish to delete a previously added language translation

2. Click on the free text field E.1.1.1 and include a description of the medical condition in non-medical language - e.g. Avian Influenza Virus A (H5N1) might be described as Bird Flu.

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on   in case a further language needs to be added or   if you wish to delete a previously added language translation.

3. In E.1.1.2, click the drop-down list, then select the Therapeutic Area from the list of options. If an option is too long for the drop-down box, move your mouse over it and the entire option appears in a tooltip. Note: This list is based upon on one taken from the Medical Subject Headings list (MeSH®). MeSH® is the National Library of Medicine's controlled vocabulary thesaurus, it consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity.

4. To add new MedDRA® data in field E.1.2, enter search details for the MedDRA® term and/or level on the following page. Alternatively enter the classification code you wish to add. Then click 'Search' button. You should routinely use the level 'LLT' (Lowest Level Term).

Click on the adjacent check box to select found terms from the Results list, then click 'Add Selected' button to add them to the CTA.

5. E.1.3 Is any of the conditions being studied a rare disease?: if, in the view of the sponsor, the indication investigated in the clinical trial answers the rare disease definition, select 'Yes'. If not, the applicant should select 'No'. Definition: A rare disease concerns a restricted number of patients in the general population and shows evidence of gravity (because it is life-threatening, invalidating or serious and chronic). The limit accepted in Europe is 1 / 2000 person affected by the disease. Note: Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation: COM/436/01.

E.1.2 MedDRA information

For more information on MedDRA see: https://www.meddra.org/.

1. To add new MedDRA data, enter search details for the MedDRA term and/or level.

   Detailed MedDRA Search Instructions: First set the Term filter, using the filter drop-down options to narrow or widen your search look-up. Click in the Term free text field (on the right) and enter the MedDRA term (or part of a term). Next, set the level in the MedDRA hierarchy you wish to search at then click the 'Search' button. Alternatively, enter the classification code you wish to add. Then click the 'Search' button. Note: It is recommended that users should routinely use the Lowest Level Term (LLT).

   Key to MedDRA Hierarchy Codes

   - SOC (System Organ Class)

   - HLGT (High Level Group Term)

   - HLT (High Level Term)

   - PT (Preferred Term)

   - LLT (Lowest Level Term).

2. If your search criteria allow, a Results list appears beneath the Search window. Note: If the results run over more than one page, use the navigation buttons at the bottom of the list.

3. Click the adjacent check box to select found terms from the Results list, then click 'Add Selected' button at the bottom of the Results list to add them to section E.1.2 MedDRA information section of the CTA:
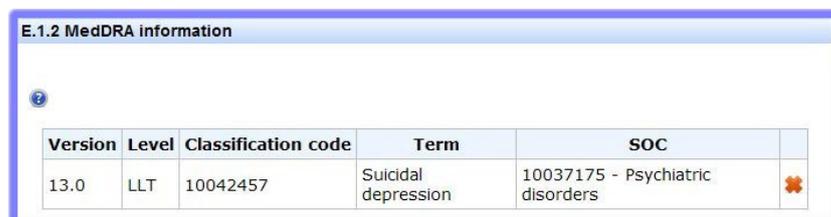
Version	Level	Classification code	Term	SOC	
13.0	LLT	10042457	Suicidal depression	10037175 - Psychiatric disorders	✖

4. Repeat the above process to add additional terms, as necessary.

E.2 Objective of the Trial

This sub-section details the objectives of the Clinical Trial.

1. Click on the free text field E.2.1 and include a description of the main objectives of the trial, if applicable. The main (primary) objectives of the trial should be described in this section. The wording used here should be consistent with the wording in the protocol.

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation.

2. Click on the free text field E.2.2 and include a description of the secondary objectives of the trial, if applicable (up to 1000 characters). The wording of the objective(s) mentioned here should be consistent with the wording in the protocol.

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

3. In field E.2.3, select 'Yes' if a sub-study is planned and if this sub-study is taking place in the Member State concerned by the application. If not, select 'No'. Note: A sub-study, or ancillary study, is a study performed on a sub-group of the subjects included in the clinical trial. For example, a pharmacokinetics or pharmacogenetic sub-study may include a sample of the patients participating in the clinical trial.

4. Click on the free text field E.2.3.1 and include the details of each sub-study (up to 4000 characters). If a sub-study does not have a title, the nature of the sub-study should be entered here instead of a title (for example: pharmacogenomic study).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

E.3 Principal inclusion criteria, E.4 Principal exclusion criteria and E.5 End point(s)

This sub-section details the criteria surrounding inclusion in or exclusion from the Clinical Trial, as well as end points in the Clinical Trial.

1. Click on the free text field E.3 and list the details of the most important reasons for the inclusion of subjects in the clinical trial (up to 5000 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation.

2. Click in the free text field E.4 and list the details of the most important reasons for exclusion of subjects from the clinical trial from among the exclusion criteria described in the protocol (up to 5000 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

Warning: Exclusion criteria should not be described as the contrary of the inclusion criteria listed in the free text field E.3.

Warning: The principal exclusion criteria should not be mistaken for the criteria of study termination or treatment halt.

3. Click in the free text field E.5.1 and list the primary end points of the clinical trial (up to 5000 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

   Warning: the primary end point(s) should not be mixed with the objectives described in the section E.2.1. For example, for a trial which objective is to evaluate the efficacy of a treatment for hypercholesterolemia, the primary end point could be a 20% decrease of the cholesterol level.

4. Click in the free text field E.5.1.1.and include a time point for each of the primary end points detailed in the section above (up to 800 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

   Click in the free text field E.5.2 and list the secondary end points of the clinical trial (up to 5000 characters). Warning: The secondary end point(s) should not be mixed with the objectives described in the section E.2.1.

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

5. Click in the free text field E.5.2.1 and include a timepoint for each of the secondary end points detailed in the section above (up to 800 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

E.6 and E.7 Scope of the Trial, Trial Type and Phase

E.6 is a mandatory section and each sub question should be answered. Take into account all the objectives of the Clinical Trial (not only the primary objectives) and all the assessments conducted during the clinical trial.

1. Select 'Yes' for E.6.1 if the assessment of the IMP efficacy as a diagnostic tool is within the clinical trial objectives.

2. Select 'Yes' for E.6.2 if the assessment of the IMP efficacy as a prophylactic preventive intervention is within the clinical trial objectives.

3. Select 'Yes' E.6.3 if the assessment of the IMP efficacy as a therapeutic intervention is within the clinical trial objectives.

4. Select 'Yes' for E.6.4 if the study includes the assessment of the safety of use of the IMP(s).

5. Select 'Yes' for E.6.5 if the study assesses efficacy of the IMP(s).

6. Select 'Yes' for E.6.6 if the study will determine pharmacokinetic parameter of the IMP(s).

7. Select 'Yes' for E.6.7 if the study will determine pharmacodynamics of the IMP(s).

8. Select 'Yes' for E.6.8 if the study will determine bioequivalence of two or more IMP(s). Note: you should also mark 'Yes' in E.7.1.2.

9. Select 'Yes' for E.6.9 if the study will determine dose-response patterns of the IMP(s).

10. Select 'Yes' for E.6.10 if the study will involve pharmacogenetic research of the IMP(s).

11. Select 'Yes' for E.6.11 if the study will involve pharmacogenomic research of the IMP(s).

12. Select 'Yes' for E.6.12 if the study will involve pharmacoeconomic research of the IMP(s).

13. Select 'Yes' for E.6.13 if the Clinical Trial's scope is other than those options available above. If applicable then complete the free text field E.6.13.1, below.

14. Click in the free text field E.6.13.1 and include details of the trial scope, if E.6.13 is 'Yes' (up to 500 characters).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on ➕ in case a further language needs to be added or ✖ if you wish to delete a previously added language translation

E.7 Trial and Phase - Further Information

1. For E.7.1, human pharmacology (Phase I) trials are the first stage of testing in human subjects, generally comprising a small group of healthy volunteers. This phase includes trials designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug. Note: If 'Yes' is selected, one item from E.7.1.1. to E.7.1.3. should be marked 'Yes' too.

2. In E.7.1.1, select 'Yes' if in this trial it is the first time that the IMP will be administered to humans. Future trials will not be considered as a first administration to humans, in any country. Select 'No' in the case of new generics or new formulations of a medicinal product. Warning: If the medicinal product has been administered to humans in a previous trial, the trial in the present application cannot be considered a first administration to humans, even if this trial is the first administration to a new population or in a new indication. For example, if previous trials have been conducted on adults, and if the new trial is conducted on children, this new trial (concerned by the present application) cannot be considered the first administration to humans.

3. In E.7.1.2, select 'Yes if this trial is a bioequivalence study. Otherwise, select 'No'.

4. In E.7.1.3, select 'Yes' if the phase 1 trial is neither a first administration to humans nor a bioequivalence study. Then complete the free text field 'Trial type Other specification' below.

5. If E.7.1.3 was answered 'Yes', click in the free text field and include details of the trial type (up to 100 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation.

6. In E.7.2, select 'Yes, if the Clinical Trial is a therapeutic exploratory (Phase II) trial. These trials are performed on larger groups and are designed to assess how well an Investigational Medicinal Product works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients.

7. In E.7.3, select 'Yes, if the Clinical Trial is a therapeutic confirmatory (Phase III) trial. Therapeutic confirmatory (Phase III) trials are randomized clinical trials on large groups, designed to be a definitive assessment of how effective the drug is, in comparison with current best alternative treatment.

8. In E.7.4, select 'Yes, if the Clinical Trial is a Therapeutic use (Phase IV) trial. A therapeutic use (Phase IV) trial involves products with a marketing authorisation.

E.8 Design of the Trial

This is a mandatory section, and each sub question should be answered.

1. If E.8.1 is 'Yes', E.8.1.1-E.8.1.7.1 applying to the design of the trial should be completed. Note: In a controlled trial, the tested product is compared to a reference treatment. The reference treatment can be, for example, a placebo, a product known to be effective, a surgical procedure, or a different dose of the same product.

2. In E.8.1.1, if each subject in the trial is randomly assigned to receive either the study treatment or a placebo, select 'Yes'.

3. In E.8.1.2, if the investigators and the subjects know which treatment is given, select 'Yes'.

4. In E.8.1.3, if the subjects (healthy volunteers or patients) included in the trial don't know which treatment they are given, select 'Yes'.

5. In E.8.1.4, if the investigators and the subjects included in the trial (healthy volunteers or patients) don't know which treatment is given, select 'Yes'.

6. In E.8.1.5, select 'Yes', if the trial compares groups of subjects concurrently, each group receiving different dose or treatment.

7. In E.8.1.6, select 'Yes', if comparing two (or more) treatments in which patients are switched to the alternative treatment after a specified period of time.

8. In E.8.1.7, if there is another methodological characteristic to the trial design, select 'Yes' and complete free text field E.8.1.7.1 with a description.

9. In E.8.1.7.1, click in the free text field and include details of the trial design (up to 100 characters).

   Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

10. In E.8.2.1, select 'Yes' if the comparator drug is another medicinal product.

11. In E.8.2.2, select 'Yes' if the comparator drug is a placebo. Warning: if the placebo is only used in the trial in order to maintain the blind, the placebo should not be considered as a comparator and 'No' should be selected.

12. In E.8.2.3, if the comparator is neither another medicinal product nor a placebo, select 'Yes' here and provide details in the free text field below.

13. In E.8.2.3.1, click in the free text field and include details of comparators which are neither other medicinal products nor placebos - e.g., a medical device, a surgical procedure, the lack of treatment, a different treatment schedule, different dosage of the same product (up to 100 characters).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on 🞢 in case a further language needs to be added or ✖ if you wish to delete a previously added language translation

14. In E.8.2.4, click in the free text field and include the number of treatment arms (groups) in the trial (up to 10 characters).

    Note on Section E.8.2: In a comparative trial, the investigational product or marketed product is compared against a standard drug (or placebo). The standard (or reference) or placebo medication is called the comparator drug. Ref: "Comparator drug". Pharmaceutical Medicine Dictionary. Philadelphia: Elsevier Health Sciences, 2001. Credo Reference. Web. 26 January 2010.
    Warning: if the placebo is not used as a comparator but is only used in the trial in order to maintain the blind, the placebo should not be considered as a comparator and 'No' should be ticked for the item E.8.2.2.

15. In E.8.3, select 'Yes' if the trial is conducted in a single centre (clinical trial site) in the Member State concerned by the application.

16. In E.8.4, select 'Yes' if the trial is conducted in multiple sites in the concerned Member State. In this case, the number of sites in the Member State concerned should be entered in section E.8.4.1, below.

17. Click in the free text field E.8.4.1 and include the number of sites in the Member State concerned where the trial will take place (up to 2 numbers).

18. In E.8.5, select 'Yes' if the trial will be conducted in more than one Member State of the EEA.

19. In E.8.5.1, click in the free text field and include the number of sites in the European Economic Area where the trial is planned to take place (up to 2 numbers). Note: include the sites in the Member State concerned in your total.

20. In E.8.6.1, select 'Yes' if the trial involves Investigator Sites in at least one Member State and at least one third country. A third country means a country which is not a Member State of the EU/EEA.

21. In E.8.6.2, select 'Yes' if the trial only involves Investigator sites in third countries. Note: a third country means a country which is not a Member State of the EU/EEA.

22. In E.8.6.3, select the countries if either of the previous two questions were answered 'Yes'. Multiple selection of Options: to select one value, click the value and then click 'Copy'.

To select more than one value, hold CTRL then click the other value you wish to select, then click 'Copy'. To delete all selected values from the right-hand field, click 'Remove All' button. Note: The above technique can be used for any options organised in the same format of two fields.

23. In E.8.6.4, click in the free text field and include the number of sites outside the European Economic Area where the trial is planned to take place (up to 2 numbers).

24. In E.8.7, select 'Yes' if an independent data monitoring committee will be used for this trial.

25. In E.8.8, click in the free text field and, if it is the last visit of the last subject, enter 'LVLS'. If it is not 'LVLS', provide the definition and justification (up to 500 characters).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

26. In E.8.9, the duration should be measured from the 1st inclusion until the last visit of the last subject (LVLS).

27. In E.8.9.1, click in each field and enter relevant numbers for years, months and days (up to 2 numbers per field).

28. In E.8.9.2, click in each field and enter relevant numbers for years, months and days (up to 2 numbers per field). Note: E.8.9.2 should not be answered if the clinical trial takes places in a single country (i.e., E.8.5 and/or E.8.6.1 are answered 'No'.).

29. In E.8.10.1, enter the date on which recruitment of subjects for the trial is planned to commence in the MS concerned in the following format: YYYY-MM-DD. Tip: alternatively, click on the calendar and select the start date.

30. In E.8.10.2, enter the date on which recruitment of subjects for the trial is planned to commence in all countries in the following format: YYYY-MM-DD. Tip: alternatively, click the calendar and select the start date. Note: E.8.10.2 should not be answered if the clinical trial takes places in a single country (i.e. E.8.5 and/or E.8.6.1 are answered 'No'.).

Once the entire section is completed to your requirements, including all sub-sections, you can move to the next section ("F. Population of Trial Subjects").

6. F. Population of Trial Subjects

F.1 Age Range

1. If there are no subjects under 18 it is sufficient to answer 'No' to F.1.1 and then answer questions relevant to adults and elderly, which begins at F.1.2 (Adults (18-64 years) step 15, below).

2. Subjects under 18: when considering F.1.1, any subject of 18 years or older is considered an adult for the purposes of clinical trials. If 'Yes' is selected, all fields from F.1.1.1. to F.1.1.6. should be completed. E.g.: If subjects aged 2 to 11 are enrolled in the trial, select 'Yes' for F.1.1.5. and 'No' for F.1.1.1, F.1.1.2, F.1.1.3, F.1.1.4 and F.1.1.6.).

3. Click on the text field on the left of F.1.1 and enter relevant number of subjects (up to 10 numerals).

4. In F.1.1.1, select 'Yes' if the subjects are unborn infants, still in the womb.

5. In F.1.1.1.1, click in the field and enter relevant number of subjects (up to 10 numerals).

6. In F.1.1.2, select 'Yes' if the subjects are not more than 37 weeks from their conception.

7. In F.1.1.2.1, click in the text field and enter relevant number of subjects (up to 10 numerals).

8. In F.1.1.3, select 'Yes' if the subjects are new-born babies aged 0-27 days.

9. In F.1.1.3.1, click in the text field and enter relevant number of subjects (up to 10 numerals).

10. In F.1.1.4, select 'Yes' if the subjects are aged 28 days to 23 months.

11. In F.1.1.4.1, click on the field and enter relevant number of subjects (up to 10 numerals).

12. In F.1.1.5, select 'Yes' if the subjects are aged 2 to 11 years.

13. In F.1.1.5.1, click in the field and enter relevant number of subjects (up to 10 numerals).

14. In F.1.1.6, select 'Yes' if the subjects are aged 12 to 17 years.

15. In F.1.1.6.1, click on the field and enter relevant number of subjects (up to 10 numerals).

16. Adult Subjects: In F.1.2, select 'Yes' if the subjects are aged 18 to 64 years.

17. In F.1.2.1, click in the field and enter relevant number of subjects (up to 10 numerals).

18. In F.1.3, select 'Yes' if the subjects are aged 65 years or more.

19. In F.1.3.1 click in the field and enter relevant number of subjects (up to 10 numerals).

The subsection is complete. Now complete sections F.2-F.5, as outlined below.

F.2 Gender

Identify the sex of the subjects of the Clinical Trial (both below sections are mandatory).

1. In F.2.1, select 'Yes' if the trial includes female subjects.

2. In F.2.1, select 'Yes' if the trial includes male subjects.

The subsection is complete. Now complete sections F.3-F.5, as outlined below.

F.3 Group of trial subjects

Identify the detailed constituents of the group of subjects in the Clinical Trial.

1. In F.3.1, select 'Yes' if the trial includes subjects in good health.

2. In F.3.2, select 'Yes' if the trial includes subjects, who are currently patients.

3. In F.3.3, select 'Yes' if the trial includes subjects (healthy volunteers or patients), who are considered to be part of a vulnerable population (see ICH GCP E(6) definition of 'Vulnerable Subjects'). Tip: If 'Yes', complete sections F.3.3.1-F.3.3.7.1.

4. In F.3.3.1, select 'Yes' if the trial includes women subjects who have the potential to give birth and are not using contraception.

5. In F.3.3.2, select 'Yes' if the trial includes women subjects who have the potential to give birth and are using contraception.

6. In F.3.3.4, select 'Yes' if the trial includes women subjects who are breastfeeding.

7. In F.3.3.5, select 'Yes' if an emergency situation, where urgent care is needed for the patient and this involves enrolment in the trial (for example: myocardial infarction, or head injury).

8. In F.3.3.6, select 'Yes' if subjects who are incapable of giving consent personally are to be enrolled in the trial. For example: subjects incapable of giving consent for physical or physiological reasons, or reasons linked to their medical condition (e.g., coma, mental disability and in accordance with national requirements); subjects under-age incapable of giving consent personally; subjects with a condition which makes them incapable of giving consent personally and who need urgent care. In this last case, select 'Yes' for F.3.3.5, above. Note: This section is for subjects who are vulnerable for reasons other than their age alone. Children are already identified under F.1.1, but institutionalised, or mentally handicapped children should be mentioned in the free text field, F.3.3.6.1.

9. In F.3.3.6.1, click in the free text field and include details of the groups of population subjects incapable of giving consent. Note: This section is for subjects who are vulnerable for reasons other than their age alone. Children are already identified under F.1.1, but institutionalised, or mentally handicapped children should be mentioned here (up to 250 characters).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

10. In F.3.3.7, select 'Yes' if other categories of vulnerable subjects will be enrolled in the trial. For example, subjects who are in prison or subjects hospitalised without their consent.

11. If 'Yes', complete section F.3.3.7.1 by adding details. In F.3.3.7.1, click in the free text field and include details of the other category of vulnerable populations (up to 100 characters).

    Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

If the above steps are completed, including mandatory fields. the subsection is complete. Now complete sections F.4-F.5, as outlined below.

F.4 Planned number of subjects to be included

Identify exact numbers of subject to be included in the Clinical Trial. The information entered in this section should match the information presented in sections E.8.3.and E.8.4, as applicable.

1. In F.4.1, click in the free text field and include details of the planned number of subjects to be included in the Member State to which the application is submitted (up to six numerals).

    Note: F.4.2.1 and F.4.2.2 should not be answered if the clinical trial takes places in a single country (i.e. E.8.5 and/or E.8.6.1 are answered 'No'.).

2. In F.4.2.1, click in the free text field and include details of the planned number of subjects to be included in the EEA (including the concerned Member State) in toto (up to six numerals).

3. In F.4.2.2, click in the free text field and include details of the planned number of subjects to be included in the entire world (up to six numerals).

If the above steps are completed, including mandatory fields, the subsection is complete. Now complete section F.5, as outlined below.

F.5 Post trial treatment details

Identify any planned patient treatment or care, post Clinical Trial.

Click in the free text field and include details of post-trial treatment or care, if not already provided in the protocol (up to 500 characters).

Add Content in Another Language: it is possible to add the text in another language than English, through filling in the relevant free text field; the relevant language needs to then be specified from the dropdown menu. Click on in case a further language needs to be added or if you wish to delete a previously added language translation

If the above steps are completed, including mandatory fields, the subsection is complete.

When all five sections are completed (in any order), click on 'Done' and you return to the Clinical Trial Application Menu. Once the entire section is completed to your requirements, including all sub-sections, it is suggested you move to the next section ("G. Clinical Trial Sites/Investigators in the Member State").

7. G. Clinical Trial Sites information

G.4 Networks to be involved in the Trial

Include details of any Clinical Investigator Network involved in the Clinical Trial. In order to enter details of any Clinical Investigator Network involved in the Clinical Trial, click Add Trial Network and the G.3. Central Technical Facilities Details screen appears.

1. In free text fields G.4.1, include the name of the organisation of any Clinical Investigator Network involved in the Clinical Trial, if applicable.

2. In field G.4.3.4, click the drop-down list to select the relevant country from drop-down list.

If the above steps are completed, the subsection is complete. Click on 'Done' and you return to the G. Clinical Trial Sites information screen.

8. H. Ethics Committee Information

Choose the country where the trial of your third country file was first authorised from the dropdown menu, in order to complete section H.4.1.

If the above steps is completed, the subsection is complete.

When all the fields are completed, click on 'Done' and you return to the Clinical Trial Menu.

Validate a third country file

Once the the third country file is completed, it needs to be validated. All users of EudraCT can perform a validation on a third country file: it can be done whilst being logged in or not. Steps:

1. The third country file is loaded in EudraCT.

2. Click on 'Validate' in the Clinical Trial Menu the Task Bar at the top right of the screen and the loaded file is validated against the business rules and the Application Validation Results screen appears.

3. In case of validation errors, in order to expand an individual section, click the arrow alongside a particular section. The folder expands (click the arrow again to close the section). To drill down further click subsequent arrows. Alternatively, use the Expand All / Collapse All links at the top of the Validation Results page. In order to solve the validation errors, follow the instructions provided. For questions, refer to the Frequently Asked Questions.

Support needed?

For questions, refer to our Frequently Asked Questions. If the answer to your question is not there, Contact us.