EudraCT protocol: filling in an EU/EEA CTA or a third country file

As of 31 January 2023, all initial clinical trial applications in the EU/EEA must be submitted through the Clinical Trials Information System. EudraCT needs to be used by sponsors for amendments to EU/EEA EudraCT CTAs submitted before 31 January 2023, creation and submission of third country files of PIP/Art 46 trials conducted exclusively outside of the EU/EEA, and submission of results of EudraCT trials. The present document provides instructions to sponsors on the following EudraCT processes:

1. Load a Clinical Trial Application or Third Country file
2. Create a Third country file (this can be done after the creation of a EudraCT number)
3. Filling in a Third Country file or a EU/EEA CTA amendment (see the detailed list of fields)
4. Save XML of CTA or third country file
5. Save PDF version of CTA or Third Country file
6. Validate a CTA/third country file

After having filled in and validated a EudraCT EU/EEA CTA or a third country file, the user can create a submission package (this is mandatory in case of submission of amendments to EU/EEA CTAs).

Note: in case a EudraCT trial is going to be conducted in additional EU/EEA member state(s), to which a EudraCT CTA was not submitted before 31 January 2023, the trial needs to be transitioned to CTIS, first, since this is considered a new trial application for this member state.

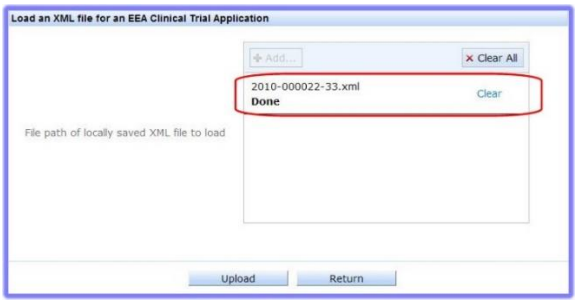
A full overview of EudraCT processes is provided in the EudraCT step-by-step guide. In case support is needed, see here.

Load a Clinical Trial Application or Third Country file

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

1. From the EudraCT homepage, click on EudraCT tools & Login and then click on 'Load' at the top right corner, select 'Clinical Trial' then 'EEA' or '3rd Country', depending on the type of XML you wish to load. **For EEA CTA only**: confirm that you need to load a EU/EEA CTA XML file which was submitted before 31 January 2023, in order to amend it (if this is not selected, you will need to perform your submission through the CTIS). The relevant XML Upload screen appears:

2. Click on 'Add', select 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 CTA Menu, where it will now be loaded.
    - XML file update report: Failure - if the file does not load, 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 (EEA/Third Country) and is associated to a EudraCT number. For questions, refer to the Frequently Asked Questions.

You can now fill in the Clinical Trial Application or the third country file. Once the updates are performed, **you must download and save the relevant XML file locally**. If you exit the EudraCT without saving the full application or third country data as XML file, any newly inserted data is lost.

Create a Third country file (or a CTA, under exceptional circumstances)

Once having created a EudraCT number, you can create a third country file. With regards to creating a new EU/EEA Clinical Trial Applications (CTAs), as of 31 January 2023, this option is given to sponsors only in case they have lost the XML file of the EudraCT CTA that was submitted to the National Competent Authority before 31 January 2023. **This option must not be used to create initial applications of EU/EEA trials, including new applications of additional member states for existing EudraCT trials: the use of the Clinical Trial Information System is mandatory for this purpose.**

1. From the EudraCT homepage, click on EudraCT tools & Login and then click on 'Create' and select 'Clinical Trial Protocol' then 'EEA' or 'Third Country file', depending on the type of XML you wish to create. The following appears:
    - **For EEA CTA only**: confirm that you need to create a CTA to perform an amendment to a EudraCT CTA which was submitted before 31 January 2023 (if this is not the case, you will need to perform your submission through the CTIS). Afterwards, use the drop-down to select the National Competent Authority of the CTA that needs to be amended.
    - **For third country files and EEA CTA amendments**: insert the relevant EudraCT Number in the free text field (see section on EudraCT number creation for third country files, or use the EudraCT number of the EEA CTA that needs to be amended)
2. Click on 'create' and the Clinical Trial Application Menu appears with all the sections that need to be completed as described in Completing a Third Country file or a EU/EEA CTA.

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

This section describes how to fill in the full content of a third country file, once created, or how to fill in the parts of a CTA that need to be amended, after having loaded it. **As of 31 January 2023, all initial clinical trial applications in the EU/ EEA must be submitted through the Clinical Trials Information System**. Amendments to EU/EEA CTAs that were previously submitted through EudraCT can still be performed as detailed in the present section.

Note:

- After having created the third country file, or having loaded the EU/EEA CTA, it is recommended to save it locally as XML often while completing it, since it is not saved on the EudraCT application.
- **The session timeout for EudraCT is set to 30 minutes**. After 30 minutes of inactivity, any changes made are lost unless they have been saved locally as XML: to avoid any loss of data you need to save your protocol content as XML file often.

Once filled in, the CTA or the third country file needs to be validated, before being submitted to the NCA (in case of CTA amendment) or submission to EudraCT (in case of third country file).

Click on the relevant section of the CTA/third country file to view details for its completion:

1. Section A. Trial Identification

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

1. A.1: this field is not present in third country file and refers to the National Competent Authority of the EU/EEA Member State to which the Clinical Trial Application needs to be submitted. As of 31 January 2023, **it is not possible to create a new CTA for an additional member state to be added to an EudraCT trial**. In this case, the trial needs to be transitioned to CTIS first (this is considered a new trial application for this member state) and then the new member state can be added within the Clinical Trial Information System.
2. A.2: the EudraCT number, obtained previously through the EudraCT public web site, is added automatically (either after its entry in the Initial Required Information screen, for third country files, or from the loaded EEA CTA). Note: In the case of a resubmission (see section A.7), this field should contain the same EudraCT number as in the first submission.
3. A.3: click in 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
4. 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
5. 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

6. 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.

7. Click in the free text field and enter the sponsor protocol version, which is assigned by the sponsor (up to 10 characters). This should be identical to that appearing in the protocol, though may change according to any updates and amendments to the final protocol. If none is available, please leave blank (A.4.2).

8. Click on the calendar to select the date of the protocol in the following format: YYYY-MM-DD. The sponsor protocol date is assigned by the sponsor and should be identical to that appearing in the protocol. Any translation of the protocol should be assigned the same date as in the original document. This date may change according to any updates and amendments to the final protocol. However, the date included in this form should always be the date of the protocol which received the initial authorisation. Any other updates on the protocol date should only be provided in the corresponding significant amendment form when applicable (A.4.3 - Mandatory field). Reference: footnote 3 on page 16 of the Commission Guidance on clinical trial dossier for competent authorities published 30th March 2010).

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

10. 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.

11. 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).

12. 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).

13. Field A.6 of the EudraCT EU/EEA CTA (not present in the third country file): by default, this is set to 'No'. Next to 'Indicate the resubmission letter or else' click the drop-down list to select 'First submission', for an amendment to a first submission. As of 31 January 2023, if this is an amendment to a resubmission file that was submitted before 31 January 2023, select the correct resubmission letter to change field A.6 to 'Yes'. In case the initial EudraCT application has been withdrawn by the applicant or refused by the competent authority, the new application needs to be submitted through the Clinical Trial Information System. 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).

14. 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 Application ("B. Sponsor Identification") or return to the Clinical Trial Application Menu.

2. Section B. Sponsor Identification

The following steps are necessary to fill in the fields of Section B Sponsor Identification of an EudraCT EU/EEA Clinical Trial Application or 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).

   Note: The sponsor contact should be a person who works within the company/organisation mentioned in section B.1.1 (it should not be a person working in an applicant company appointed by the sponsor (or by its legal representative) to submit the application to the National Competent Authority - applicant information is in section C) (B.1.2).

2. Enter the full name of the contact in B.1.2.1 to B.1.2.3. The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter 'Elizabeth' for 'Ana Elizabeth' (B.1.2.2). Tip: use B.1.2.3 Family Name field to record a functional role, as well as a surname (e.g. Head of regulatory affairs etc.).

3. In free text fields B.1.3, provide the full postal address to be used in case the concerned National Competent Authority/Ethics Committee needs to contact the sponsor by post (B.1.3.1, B.1.3.2).

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

5. The contact details (phone number, fax) are those of the sponsor contact mentioned in section B.1.2. Please include the international or applicable area codes (B.1.4, 1.5 - Conditionally mandatory - include at least one of B.1.4-B.1.6.).

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.1.6 - Conditionally mandatory - include at least one of B.1.4-B.1.6.).

B.2 Legal Representative (section not applicable to third country files)

This section is only applicable to amendments to EU/EEA EudraCT CTA for which the initial submission was submitted to the relevant National Competent Authority before 31 January 2023. According to Article 19 of Directive 2001/20/EC, "the sponsor or a legal representative of the sponsor must be established in the Community". If the sponsor is not established in the EEA, they should appoint a legal representative established in the EEA. Like the sponsor, the legal representative can be an individual, company, institution, or organisation. Enter details in this section if required to comply with Article 19 of Directive 2001/20/EC and complete any other fields. Please note that only one legal representative in the EEA can act on behalf of one sponsor for the purpose of a given clinical trial (B.2).

1. B.2.1 - Enter the name of the Legal Representative (organisation or individual) in the field.
2. Enter the full name of the contact in B.2.2.1 to B.2.2.3. Tip: use B.2.2.3 Family Name field to record a functional role, as well as a surname (e.g. Head of regulatory affairs etc.).
3. In free text fields B.2.3, provide the full postal address to be used in case the concerned NCA/EC needs to contact the legal representative by post
4. In field B.2.3.4. use the drop-down list to select the Country in which the Legal Representative's organisation is based. Tip: when the drop-down in open, use the first letter of the Country to toggle through the countries with that initial letter.
5. In free text fields B.2.4 to B.2.6, enter the contact details (phone number, fax, e-mail) of the legal representative mentioned in section B.2.2 (conditionally mandatory - include at least one of B.2.4-B.2.6.). Note: include the international or applicable area codes.

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 Application ("B. Sponsor Identification") or return to the Clinical Trial Application Menu

3. Section C. Applicant Identification/ Third country data provider Identification

In case of amendments to EudraCT EU/EEA CTA: complete the details of the Applicants to both the National Competent Authority (C.1) and the Ethics Committee (C.2).

In case of completion of third country files: refer only to steps 9-11 of section C.1.

C.1 Request for Authorisation to Competent Authority

Enter details for section C.1 Applicant Identification - Request for the National Competent Authority then click on 'done' when the sub-section is complete. The NCA Applicant Contact (or contact person) should be a practical contact and might not be the signatory of the application but may be the same person as the one mentioned in section B.1.2 if the sponsor is the applicant (or in section B.2.2 if the legal representative is the applicant). The family name, at least, should be provided in C.1.4.2, or be completed with a function (e.g. Head of regulatory affairs). All the fields should be completed even when this repeats the sponsor or legal representative information from B.1 and B.2.

1. Click the drop-down list to choose the relevant option, dependent upon whether the applicant is the sponsor, the legal representative of the sponsor or the individual or organisation appointed by the sponsor to submit the application (C.1.1, C1.2, C.1.3).
2. Section C.1.4 concerns the Applicant to the National Competent Authority (NCA) and is the party with whom the NCA will routinely correspond. Enter the details of the legal applicant (who will sign the form). Tip: The legal applicant may be the sponsor, the legal representative if the sponsor is established outside the EEA, or an individual or company appointed by the sponsor (or by its legal representative) to submit the application to the NCA. The applicant must be based in the European Union. The NCA Applicant Contact may be a different individual at the same Location/Organisation, if necessary.

3. In free text field C.1.4.1, enter the full, official name of the Applicant Organisation.
4. In free text fields C.1.4.2.1- C.1.4.2.3, enter the NCA Applicant Contact (or contact person). Functional emails are preferred to personal ones.
5. In free text fields C.1.4.3, provide the full postal address.
6. For field C.1.4.3.4, click the drop-down list to select the Country in which the applicant organisation is based.
7. In free text fields C.1.4.4 to C.1.4.5, enter the contact details (phone number, fax). The contact details (phone number, fax,) are those of the National Competent Authority Applicant Contact mentioned in section C.1.4.2. Note: include the international or applicable area codes.
8. 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.
9. 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).
10. 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.
11. Select 'Yes' if you require secure email delivery of the XML.
12. 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.

C.2 Request for Opinion of the Ethics Committee

Enter details for section C.2 Request for Opinion of the Ethics Committee then click 'Done' button when the sub-section is complete. This section is not mandatory. It should be completed for applications to ethics committees in those Member States where the Ethics Committee requests this form as part of the application to them.

1. Click the drop-down list to choose the relevant option, dependent upon whether the applicant is the sponsor, the legal representative of the sponsor, the coordinating/principal investigator or the individual or organisation appointed by the sponsor to submit the application (C.2.1 and C.2.2 and C.2.3 and C.2.4).
2. In section C.2.5, enter the details of the Applicant to the Ethics Committee. This should be the legal Applicant. In the free text field C.2.5.1, enter the full, official name of the Applicant Organisation.
3. In free text fields C.2.5.2.1 - C.2.5.2.3, enter the NCA Applicant Contact (or contact person). Note: The Contact person (C.2.5.2) may be a different individual at the same Location/ Organisation. The Phone, Fax and E-mail should be those of the Contact person.

4. In free text fields C.2.5.3, please provide the full postal address.
5. For field C.2.5.3.4, click the drop-down list to select the Country in which the applicant organisation is based.
6. In free text fields C.2.5.4 to C.2.5.6, enter the contact details (phone number, fax). The contact details (phone number, fax, email) are those of the Applicant Contact mentioned in section C.2.5.2. Note: include the international or applicable area codes.

This section is now 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 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. In D.2.3.2, if 'Yes' is selected, please provide justification for using simplified dossier in the covering letter. Tip: Refer to the guidance CT1 Section 2.7.3 and Table 1.

18. In section D.2.4, the term 'authorised' should be understood in the context of Directive 2001/20/EC (i.e., an authorisation, according to Directive 2001/20/EC, has been given for a trial using this Investigational Medicinal Product).

19. In section D.2.4.1, add the Member States where the use of the IMP has been previously authorised. 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.

20. 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.

21. Answer D.2.6 as appropriate. If 'Yes', please answer D.2.6.1.1 and D.2.6.1.2 depending on the source of the scientific advice. This scientific advice may be given by a National Competent Authority or by the CHMP (European Medicines Agency) or both.

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. If the product has a Marketing Authorisation in the concerned Member State, include the Anatomical, Therapeutic, Chemical (ATC) code. This is available from the Summary of Product Characteristics (SmPC). Click to add an ATC code field. Click again, to include an additional ATC code. Note: it is mandatory to include at least one ATC code in this field if question D.2.2.3 is answered 'Yes'.
4. 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'.
5. Answer D.3.4.1 with 'Yes' if the formulation is specifically for paediatric usage.
6. In D.3.5, Include the duration of administration of the Investigational Medicinal Product to a subject. (e.g., if it is intended, in accordance with the protocol, to treat a subject for 3 weeks, specify 'three weeks'). If the Investigational Medicinal Product is not administered on a continued basis, specify the rhythm of the product administration. For example, regarding a clinical trial in oncology, if the treatment is administered at day 1 and day 2 every four weeks, specify 'D1 and D2 every four weeks', mentioning the maximum number of cycles foreseen. This field should NOT be completed by simply indicating 'See protocol'. Warning: The treatment duration (period of time during which the patient is administered with the Investigational Medicinal Product) is not the same as the period of participation of a patient (period of time during which the subject is followed up within the context of the clinical trial). Note: Mandatory field unless D.2.2 is 'Yes'.
7. In D.3.6.1, specify whether the dose is per day or a total dose, using the radio buttons (also D.3.6.2). Note: The read only field above the radio buttons displays historical data if an xml created prior to EudraCT v8.1.0.1 is loaded.
8. Click on the free text field 'D.3.6.1 Specify total dose (number and unit)' and specify the amount of IMP (numeric quantity) administered per dose. Use the drop-down list directly below the text field to specify units.
9. In 'D.3.6.1 Route of administration (relevant to the first dose)', click the drop-down list to specify the route of administration related to the first dose.
10. In 'D.3.6.2 Specify per day or total', choose the most appropriate answer from 'Dose per day' or 'Total dose' using the radio buttons. Note: The read-only field above the radio buttons displays historical data if an xml created prior to EudraCT v8.1.0.1 is loaded.
11. In 'D.3.6.2 Specify total dose (number and unit)' click in the free text field and specify the amount of IMP (numeric quantity) administered per dose. Use drop-down list at the next field (D.3.6.2 Route of administration (relevant to the maximum dose)) to specify units.
12. In D.3.6.2 Route of administration (relevant to the maximum dose), use the drop-down list to specify the units of the dose being described.
13. In D.3.6.2, click the drop-down list to select the Route of Administration which the maximum dose refers to.

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 from there, if applicable, sections D.4, D.5 and D.6. 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.
24. Select 'Yes' in D.3.13 if the active substance contained in this IMP is to be administered for the first time in a clinical trial (first-in-human (FIH) clinical trial). Note: If you answer D.3.13 'Yes', you should also answer 'Yes' in E.7.1.1. and also complete question D.3.6.1.
25. Click in D.3.13.1 free text field and enter any risk factors identified in accordance with the first in human guidance.

IMP Details table

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

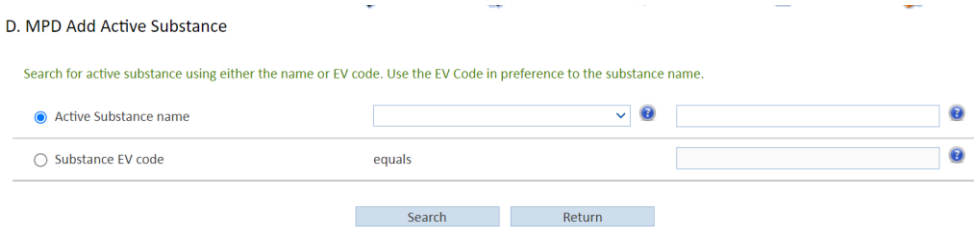
From this table, you can choose:

- '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:



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.

D.9 Site(s) where the qualified person certifies batch release – applicable only to amendments to EU/EEA EudraCT CTA

This section is not applicable to the creation of third country files. It is only present for the EU/EEA EudraCT Clinical Trial Application, and it records the Sites responsible for final Qualified Person (QP) Release of the IMPs prior to distribution to Investigators. Click 'Add Responsible Site' if the Clinical Trial Application requires it. Otherwise click the 'D.9.1 IMPs and placebos for which no responsible site needs to be identified' link to complete that section. The details of the sub-sections can be viewed below.

D.9.1 IMPs and placebos for which no responsible site needs to be identified

This section is used to identify IMPs and placebos which comply to all the below conditions:

- Have a Marketing Authorisation (MA) in the EU and
- Are sourced from the EU market and
- Are used in the trial without modification (e.g., not over-encapsulated) and
- The packaging and labelling are carried out for local use only as per article 9.2. of the Directive 2005/28/EC (GCP Directive).

If all the above conditions are met, you can click on the tick box (D.9.2), and in the 'Finished IMP' table directly beneath D.9.2 select the IMPs and placebos which meet the above criteria. Click then on ‘Done’ to return to D.9 Site(s) where the qualified person certifies batch release.

The section is now complete and the details of D.9.1 are added to the Clinical Trial Application.

Add Responsible Site

This section requires the addition of sites and individuals required to certify a batch release for the Clinical Trial. Note: where products are to be identified under D.9.2, all sub-questions (D.9.2.1 to D.9.2.4) are mandatory, except post code when none exists for that address.

1. In D.9.2.1 and D.9.2.2 (which is one field), click the drop-down list, then select the Responsible Site Role from the list of options.
2. In D.9.2.3 click in the free text field and enter the name of the organisation responsible of the product release for its use in the concerned clinical trial.

3. Enter the full address for the site responsible for the product release in D.9.2.4.1 to D.9.2.4.4
4. Click in the free text field D.9.2.5 and enter the manufacturer's authorisation number (up to 100 characters). Note: If there is no manufacturing authorisation number but the site is authorised — enter 'Site authorised' — this is applicable in some Member States (e.g. Germany) where no manufacturing authorisation number is issued.
5. In D.9.2.5.1, click in the free text field and enter the reasons why an authorisation was not given (up to 500 characters), if applicable.
6. Click on 'Next' to advance to the 'Finished IMP' table. To select the IMPs and placebos which are to be certified as part of the batch release for the Clinical Trial, click the check box under 'Associate' check.

The section is now complete and the details of D.9.2 (Add Responsible Site) are added to the Clinical Trial Application. Once responsible site information is added the Placebo Information Details table appears on D.9 Site(s) where the qualified person certifies batch release page:

You may edit or delete responsible sites from the Responsible Sites Details table in section D.9. You can add additional Responsible Sites as well as IMPs and Placebos for which no responsible site needs to be identified.

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.

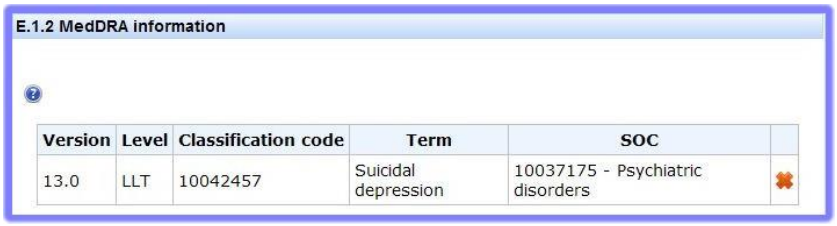
   Detailed MedDRA Search Instructions: First set the Term filter, using the filter drop-down options to narrow or widen your search look-up. Click in the Term free text field (on the right) and enter the MedDRA term (or part of a term). Next, set the level in the MedDRA hierarchy you wish to search at 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:



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.
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 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 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, 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/Investigators in the Member State

Section G. of an EudraCT EU/EEA **Clinical Trial Application** to be amended is composed of four sections: Investigators, Central Technical Facilities, Clinical Trial Networks and Sponsor's Subcontractor Facilities. Section G. of a **third country file** is composed of only one section, Clinical Trial Networks. Click the  beside each relevant option to begin adding a new entry. To edit any previously made entries within any of the subsections, click the  icon beside the relevant entry. To delete any previously made entries within any of the subsections, click the  icon beside the relevant entry.

G.1 and G.2 Investigator Details

Complete the Investigator Sites in this Member State only. At least one (the principal of a single centre or coordinator of a multiple centre trial) should be added. To enter Investigator details, click Add Investigator and the G.1 and G.2 Investigator screen appears.

1. First, click the drop-down list, then select the investigator's role from the available options.
2. In G.1.1/G.2.1 free text field, insert the Investigator's given name, which is also known as first name or forename.
3. In G.1.2/G.2.2 free text field, click in the free text field and include the investigator's middle name. The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter 'Elizabeth' for 'Ana Elizabeth' (up to 100 characters).
4. In G.1.3/G.2.3, click in the free text field and include the investigator's family name, which is also known as the surname.
5. In G.1.4/G.2.4, click in the free text field and include the investigator's professional qualifications (up to 50 characters).
6. In G.1.5/G.2.5 (Institution Name), click in the free text field and include the full name of the Institution or Organisation that the investigator works for.
7. In G.1.5/G.2.5 (Institution Department Name), click in the free text field and include the full name of the department of the above-named Institution or Organisation that the investigator works in.
8. In G.1.5.1/G.2.5.1, click in the free text field and include the building name and/or number and street name.
9. In G.1.5.2/G.2.5.2, click in the free text field and include the town or city where the investigator is based.
10. In G.1.5.3/G.2.5.3, click in the free text field and include the address' post code (where applicable).
11. In G.1.5.3/G.2.5.3, select the relevant country from drop-down list.
12. In G.1.6/G.2.6, click in the free text field and include the contact details (phone number, fax, e-mail) of the investigator mentioned in section G.1.1/G.2.1-G.1.3/G.2.3).
13. In G.1.7/G.2.7, click in the free text field and include the contact details (phone number, fax, e-mail) of the investigator mentioned in section G.1.1/G.2.1-G.1.3/G.2.3).
14. In G.1.8/G.2.8, click in the free text field and include the contact details (phone number, fax, e-mail) of the investigator mentioned in section G.1.1/G.2.1-G.1.3/G.2.3).

If the above steps are completed, including mandatory fields, the subsection is complete. When all the fields are completed, click on ‘done’ and you return to the G. Clinical Trial Sites/Investigators in the Member State screen.

G.3 Central Technical Facility Details

1. Only central facilities who supply services for at least this Member State should be included. The facility may be in this Member State, another Member State, or a Third Country. To enter Investigator details, click Add Central Technical Facility and the G.3. Central Technical

Facilities Details screen appears. Note: Central Technical Facilities includes central laboratories and central ECG or image processing facilities.

2. In G.3.1 Name of Organisation, click on the free text field and include the full name of the Institution or Organisation that the Central Technical Facility (CTF) is a part of.
3. In G.3.2 Central technical facility organisation department, click in the free text field and include the full name of the specific department within the Central Technical Facility.
4. Enter the full name of the contact in G.3.3.1 to G.3.3.3.The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter 'Elizabeth' for 'Ana Elizabeth' (G.3.3.2). Tip: Use G.3.3.3 Family Name field to record a functional role, as well as a surname (e.g. Head of regulatory affairs etc.).
5. In free text fields G.3.4, provide the full postal address of the above identified Central Technical Facility.
6. In field G.3.4.4 click the drop-down list to select the Country in which the Central Technical Facility is based.
7. The contact details (phone number, fax) are those of the contact person mentioned in section G.3.3. Please include the international or applicable area codes (G.3.5, G.3.6).
8. When entering the email address in the free text field please be aware that functional emails are preferred to personal ones(e.g. like regulatory@corporate.com or renalcancer.ct-unit@hospital.org) (G.3.7).
9. In field G.3.8.1, select 'Yes' if the CTF will provide routine clinical pathology testing.
10. In field G.3.8.2, select 'Yes' if the CTF will provide clinical chemistry analysis or testing.
11. In field G.3.8.3, select 'Yes' if the CTF will provide Clinical haematology analysis or testing.
12. In field G.3.8.4, select 'Yes' if the CTF will provide Clinical microbiology analysis or testing.
13. In field G.3.8.5, select 'Yes' if the CTF will provide histopathology analysis or testing.
14. In field G.3.8.6, select 'Yes' if the CTF will provide serology/ endocrinology analysis or testing.
15. In field G.3.8.7, select 'Yes' if the CTF will provide analytical chemistry.
16. In field G.3.8.8, select 'Yes' if the CTF will provide ECG analysis/ review.
17. In field G.3.8.9, select 'Yes' if the CTF will provide medical image analysis/ review - X-ray, MRI, ultrasound, etc.
18. In field G.3.8.10, select 'Yes' if the CTF will provide Primary/ surrogate endpoint test.
19. In field G.3.8.11, select 'Yes' if the services provided by a central technical facility are not covered in the above options. Then complete the free text field below.
20. In field G.3.8.11.1, click in the free text field and include the services provided by a CTF (up to 100 characters).

G.4 Networks to be involved in the Trial

Include details of any Clinical Investigator Network involved in the Clinical Trial. 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. Tip: Additional networks may be added in the G. Clinical Trial Sites/Investigators in the Member State screen.
2. Enter the full name of the contact in G.4.2.1 to G.4.2.3. The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter 'Elizabeth' for 'Ana Elizabeth' (G.4.2.2). Tip: use G.4.2.3 Family Name field to record a functional role (e.g., Head of regulatory affairs etc.).
3. In free text fields G.4.3.1-G.4.3.3, please provide the full postal address of the above identified Central Technical Facility.
4. In field G.4.3.4, additionally, click the drop-down list to select the relevant country from drop-down list.
5. In field G.4.4-4.6, the contact details (phone number, fax, e-mail) are those of the network contact mentioned in section G.4.2. Please include the international or applicable area codes and email address.
6. When entering the email address in the free text field please be aware that functional emails are preferred to personal ones (e.g. like regulatory@corporate.com or renalcancer.ct-unit@hospital.org) (G.4.6).
7. In field G.4.7, click in the free text field and include the activities performed by the trial network pertaining to the CTA (up to 2000 characters).

If the above steps are completed, including mandatory fields, the subsection is complete. When all the fields are completed (in any order), click on ‘Done’ and you return to the G. Clinical Trial Sites/Investigators in the Member State screen.

G.5 Organisations to whom the sponsor has transferred trial related duties and functions

Only central CRO facilities supplying services for at least this Member State should be entered (not e.g., individual field-based CRAs). The facility may be in this Member State, another Member State, or a Third Country. To enter details of any Sponsor's Subcontractor Facility involved in the Clinical Trial, click Add Sponsor's Subcontractor Facilities and the 'G.5.Organisations to whom the sponsor has transferred trial related duties and functions' screen appears.

1. In field G.5.1.1, click in the free text field and include the full name of the Institution or Organisation to which the Sponsor has transferred Clinical Trial related duties and functions.
2. In field G.5.1.2, click in the free text field and include the full name of the department of the above-named Institution or Organisation to which the Sponsor has transferred Clinical Trial related duties and functions.
3. In field G.5.1.3.1, click in the free text field and include the contact person's given name, which is also known as first name or forename.

4. In field G.5.1.3.2, click in the free text field and include the contact person's middle name. This refers to the second given name and does not refer to any part of the family name. For example, enter 'Elizabeth' for 'Ana Elizabeth'. Note: the middle name is not mandatory.
5. In field G.5.1.3.3, click in the free text field and include the contact person's family name, which is also known as Surname. Tip: use this field to record a functional role, as well as the family name.
6. In free text fields G.5.1.4.1-5.1.4.3, please provide the full postal address of the above identified Sponsor's Subcontractor Facility.
7. In field G.5.1.4.4 click the drop-down list to select the Country in which the identified Sponsor's Subcontractor Facility is based.
8. The contact details (phone number, fax) are those of the subcontractor contact mentioned in section G.5.1.3. Please include the international or applicable area codes (G.5.1.5, G.5.1.6).

   When entering the email address in the free text field please be aware that functional emails are preferred to personal ones (e.g., like regulatory@corporate.com or renalcancer.ct-unit@hospital.org) (G.5.1.7).
9. In field G.5.1.8, select 'Yes' if the sponsor will delegate all tasks of sponsor.
10. In field G.5.1.9, select 'Yes' if the vendor will undertake monitoring duties.
11. In field G.5.1.10, select 'Yes' if the vendor will undertake regulatory duties (e.g. preparation of applications to CA and Ethics Committee).
12. In field G.5.1.11, select 'Yes' if the vendor will undertake investigator recruitment/selection duties.
13. In field G.5.1.12, select 'Yes' if the vendor will undertake treatment randomisation duties or duties include the setup, maintenance, and operation of automated Interactive Response systems, like IVRS (voice), IWRS (Internet/world wide web based) or hybrid ones.
14. In field G.5.1.13, select 'Yes' if the vendor will undertake Data Management duties.
15. In field G.5.1.14, select 'Yes' if the vendor will undertake electronic data capture (EDC) duties.
16. In field G.5.1.15, select 'Yes' if the vendor will undertake drug safety duties that involve SUSAR reporting.
17. In field G.5.1.16, select 'Yes' if the vendor will perform Quality Assurance auditing.
18. In field G.5.1.17, select 'Yes' if the vendor will undertake statistical analysis.
19. In field G.5.1.18, select 'Yes' if the vendor will undertake medical writing duties.
20. In field G.5.1.19, select 'Yes' if the vendor will undertake other duties subcontracted not mentioned above.
21. In field G.5.1.19.1, click in the free text field and include other duties performed by the subcontractor on behalf of the sponsor, if not detailed in the above options (up to 100 characters).

If the above steps are completed, including mandatory fields, the subsection is complete. When all the fields are completed, click on ‘Done’ and you return to the G. Clinical Trial Sites/Investigators in the Member State screen.

8. H. Competent Authority/Ethics Committee Information

For third country files: choose the country where the trial was first authorised from the dropdown menu, to complete section H.4.1.

For **EudraCT EU/EEA CTA**: complete the current status of the application to the Ethics Committee / National Competent Authority, through referring to the below instructions.

H. National Competent Authority

Only one NCA and Ethics Committee may be added per CTA. Complete the current status of the application to the National Competent Authority.

1. In field H.2.1, click in the free text field and enter the full name of the NCA concerned with the Clinical Trial Application.
2. In free text fields H.2.2, please provide the full postal address of the above identified NCA.
3. In field H.2.2.4, click the drop-down list to select the Country in which the NCA is based.
4. In field H.2.2.4, enter the date on which the application was submitted to the National Competent Authority concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar  and select the start date.
5. In field H.3.1/H.3.2/H.3.3, select the status of the NCA Authorisation from drop-down list.
6. If the status selected was 'Given' in the above field, please enter the date on which the application was authorised by the National Competent Authority in field H.3.3.1 in the following format: YYYY-MM-DD. Alternatively, click the calendar  and select the start date.
7. In field H.3.3.2/H.3.3.3, click the drop-down arrow to select whether the authorisation was accepted, or not accepted by the applicant.
8. If 'not accepted' was chosen above, click in the free text field H.3.3.3.1 and include reasons for non-acceptance by the applicant of National Competent Authority Authorisation (up to 1000 characters).
9. If 'not accepted' was chosen above, click in the free text field H.3.3.3.2 and enter the date on which the application is expected to be resubmitted to National Competent Authority in the following format: YYYY-MM-DD. Alternatively, click the calendar  and select the expected date of the resubmission

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

H. Ethics Committee

Complete the current status of the application to the Independent Ethics Committee.

1. In field H.2.1, click in the free text field and enter the full name of the Ethics Committee concerned with the Clinical Trial Application.
2. In free text fields H.2.2, please provide the full postal address of the above identified Ethics Committee.
3. In field H.2.2.4, click on the drop-down list to select the Country in which the Ethics Committee is based.

4. In field H.2.2.4,enter the date on which the application was submitted to the Ethics Committee concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
5. In field H.3.1/H.3.2/H.3.3, select the status of the Ethics Committee's opinion from drop-down list.
6. If the status selected was 'Given' in the above field (H.3.1/H.3.2/H.3.3), in field H.3.3.1 please enter the date on which the Ethics Committee concerned gave their opinion in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
7. In field H.3.3.2/H.3.3.3, click the drop-down arrow to select whether the opinion given by the Ethics Committee was favourable, or not.
8. If 'not favourable' was chosen above, click in the free text field H.3.3.3.1 and include reasons for the non-favourable Ethics Committee Opinion (up to 1000 characters).
9. If 'not favourable' was chosen above, click in the free text field H.3.3.3.2 and enter the date on which the application is expected to be resubmitted to the Ethics Committee in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the expected date of the resubmission.

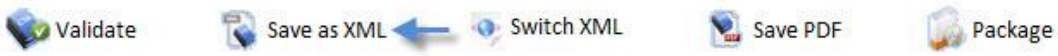
If the above steps are completed, including mandatory fields. the subsection is complete. When all the fields are completed, click on 'Done' and you return to the Clinical Trial Application Menu.

Save XML of CTA or third country file

While filling in a Clinical Trial Application or a third country file, **it is essential to save the file locally because the file is not saved online within the application.** If you exit the EudraCT without saving the full application or third country data as XML file, any newly inserted data is lost.

To save a CTA or third country file as an XML file, it needs to have been created or loaded on EudraCT.

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



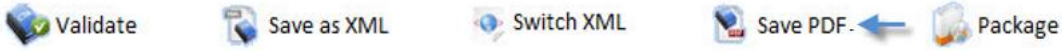
2. Click on 'click here to Download XML' and click on 'Save' to save the file locally.

The CTA or 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 Clinical Trial Application or Third Country file').

Save PDF version of CTA or Third Country file

To save a CTA or third country file as a PDF file, it needs to have been created or loaded on EudraCT.

1. Click on the option 'Save PDF' at the top right corner of the page:



2. Click on 'Download current form' and click on 'Save' to save the file locally.

The CTA in pdf format can now be sent to the relevant National Competent Authority(ies) as required. The third country file in pdf format can be stored locally.

Validate a CTA/third country file

Once the CTA or the third country file is filled in, it needs to be validated. All users of EudraCT can perform a validation through using the EudraCT application. Steps:

1. The CTA/third country file is loaded on EudraCT and its details can be seen on the left-hand side of the screen.
2. Click on 'Validate' in the Clinical Trial Application Menu the Task Bar at the top right of the screen and the loaded file is validated against the business rules; 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.

Once all the validation rules are solved, the file can submitted to the NCA (in case of CTA amendment) to EudraCT (in case of third country file).

Note on CTA amendments: under exceptional circumstances and if duly justified to the relevant National Competent Authority, applicants may create a submission package with a CTA that does not meet all the validation rules. It is expected that such issues are kept to an absolute minimum and should be accompanied by an explanation in the covering letter for the submission. This will help NCAs and Ethics Committees to ensure a more efficient processing of the Clinical Trial Application.

Support needed?

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