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EudraCT & EU CTR Frequently asked questions

This document provides answers to the most frequently asked questions received on the EudraCT database and on its public interface, the European Clinical Trial Register (EU CTR).

If the answer to your question is not here, please contact the Service Desk using the user credentials for a system hosted by EMA. Non-registered users can refer to this link and click on "Create an EMA account". Please specify "EudraCT" in the title of your request.

Sponsor are advised to liaise with the relevant National Competent Authority (NCA) for trial's authorisation and insertion in EudraCT/EU CTR, including inserting the relevant NCA decision and/or Ethics Committee opinion, as well as to update the content of the Clinical Trial Application and the trial status (see question 3.).

The entire process of registration of a clinical trial in the database and of updating of its information is described in the page Registering a trial and updating its information.

The steps required in order to post results are described in the Tutorials on posting results.

Specific instructions on the use of the EudraCT application can be found in the EudraCT user manual.

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General Questions

1. What types of studies do you register in EudraCT?

The EudraCT database covers **only interventional clinical trials** using investigational medicinal products (IMP) conducted in the EU/EEA and outside the EU/EEA if they are part of an agreed PIP (Paediatric Investigation Plan) or in scope of Art 46 of the paediatric regulation (see question 94.). For non-interventional clinical trials, refer to ENCEPP database. Registration on the ENCEPP database is on a voluntary basis. For trials on medical devices, active implantable medical devices, and in vitro diagnostic medical devices as defined in Community legislation, you are recommended to follow procedures on devices in place in the country where the clinical trial is conducted/will be conducted.

2. What is the legal basis of the EudraCT database?

The legal basis for the EudraCT database is provided in article 11 of Directive 2001/20/EC.

Two Regulations partially derogate art 11, disclosing data contained in EudraCT to the public and including data on paediatric subjects:

- Article 57(2) of Regulation (EC) No 726/2004: legal basis for public disclosure of EudraCT trials in EU CTR (refer to question 16.)

- Article 41 of Regulation (EC) No 1901/2006: legal basis for the inclusion in EudraCT of data on Paediatric clinical trials authorized only in third countries, and for their public disclosure. (refer to question 94.)

The requirements on posting of clinical trial results are defined in the Commission Guideline 2012/C 302/03- "Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006" (hereinafter: "Commission Guideline on results posting").

More information on the legislative requirements on clinical trials can be found in EudraLex - Volume 10

More information on the latest developments for clinical trials is available on the European Commission website on clinical trials.

3. For what issues shall I contact the National Competent Authorities (NCAs)?

Sponsor needs to liaise with the NCA directly and not with EMA, in order to:

- Authorise a trial and insert it in EudraCT, so that it is visible in EU CTR, see question 26.

- Updates on the NCA decision or IEC opinion in EudraCT, so that the trial can be visible in EU CTR, see question 4.

- Updates to the clinical trial application published in EU CTR are needed, see question 8. 36.

- Updates of the trial status, see question 31.

- Extension of deadline for results posting, see question 73. and 75.

Contact details are here: National Competent Authority(ies).

Questions about publication in EU CTR

4. Why can I not find a trial in the European Clinical trial Register (EU CTR)?

The reasons could be the following:

- The Clinical Trial Application (CTA) of the trial was not sent to the National Competent Authority (NCA), or it was not uploaded by the NCA; after having created the XML file of the CTA, the sponsor is responsible to send it to the NCA(s) of the EU Member State(s) where the trial will be authorised. Sponsors are advised to liaise with the NCA(s) regarding this.

- Information regarding the NCA approval or the Ethics Committee Opinion was not inserted by the NCA. Sponsors are advised to liaise with the NCA(s) regarding this.

- The trial is a phase 1 trial conducted in adults. All phase 1 trials, conducted solely in adults and which are not part of a Paediatric Investigation Plan (PIP), are not public in the EU CTR. Please refer to European Guidance 2008/C 168/02 Art. 3 para 2 . See question 6.

If you cannot find trial results of a trial, refer to question 56.

5. What is the information that is made public?

The list of CTA fields that are made public in EU CTR and that are not part of an agreed PIP can be found in this document. The list of CTA fields that are made public in EU CTR and that are part of an agreed PIP can be found in this document.   Phase 1 trials conducted solely in adults are not made public in EU CTR, See question 6. Results information is all made publicly available as posted by the sponsor.

6. Are phase 1 trials public in EU CTR?

Phase 1 trials, conducted solely in adults and that are not part of an agreed PIP, are not public in the EU CTR. Phase 1 trials conducted on paediatric subjects and/or part of a PIP are public. Please refer to the European Guidance 2008/C 168/02 Art. 3 para 2 [...Moreover, **phase I trials**, certain details of the characterisation of the investigational medicinal products, certain details of the clinical trial design, information on batch release aspects, legal status of the sponsor, clinical trial sites and any personal related information **are excluded from publication**].,

7. When is a study protocol Clinical Trial Application published in EU CTR?

Publication of Clinical Trial Application (CTA) related information is done automatically in our EU CTR when the National Competent Authority updates the information regarding their approval and approval date, as well as of the Ethics Committee opinion and opinion date. Sponsors should receive a notification regarding this approval. Therefore, it is not possible to establish the exact date/time of this action, because the NCA can input NCA authorisation/date and IEC opinion/date on different time/date.

Publication of results related information is done after 2 weeks from posting date, see question 56.

8. How can I amend the information published in EU CTR?

In case of protocol (CTA) information: the sponsor should submit an updated XML file of the CTA to the National Competent Authority (NCA), so that they can upload this information in EudraCT. The sponsor can click on "EudraCT number, CTA & Login for posting results", then "load → EEA CTA", add the CTA XML file, perform the changes and save the CTA file locally). The amended XML of the CTA form will then need to be submitted to all the relevant National Competent Authority(ies) where the trial is ongoing. Please note that information contained in the cover page of the trial correspond to the CTA of the first member state listed. In case of a third country trial, the sponsor can perform the changes directly in EudraCT, through logging in, modifying the third country file and clicking on "Submit". Further information can be found in question 30.

In case of results information: an updated version of the results should be posted in EudraCT, through logging in here EudraCT number, CTA & Login for posting results, performing the changes through editing the already posted version, and clicking on "post results", refer to question 78.

More information here Registering a trial and updating its information.

9. What does 'start date' refer to in the EU CTR?

The 'start date' on the EU CTR refers to the date in which the study was authorised to proceed (latest date between the NCA approval and the Ethics Committee opinion dates). For trials marked as "outside of EU/EEA" (see question 94.), it is the date in which the study was uploaded in EudraCT by the third country data provider.

10. What is the "Date on which this record was first entered in the EudraCT database?

This is the date when the National Competent Authority uploaded the CTA in the system. This is not the date of the authorisation. The date of authorisation is visible in section N when you search for a trial and click on the country code and go to the detailed view of the trial in the EU CTR.

11. How can I mark my trial as completed or prematurely ended in EU CTR?

Refer to question 31. .

12. When are the results published?

Study results are published after 2 weeks from the posting date. See question 56. Please note that, after the trial results are published, it is not possible to retrieve the posting date, but only the publication/finalisation date.

13. As a researcher, can I access the raw registry data in order to run data analysis?

The EMA does not offer any special Application Programming Interface (API) or web service to external parties to extract data from the register. The EU clinical trial register is not an analytical tool. Refer to question 14. for more details on how to download clinical data.

14. Is it possible to download all the clinical trial information contained in the EU CTR?

At present you can download by:

- number of trials:

- • on current page (all the trial displayed on one page);
- • selected trials only (selection of specific trials from the list using the 'selection' box only);

- download content:

- • Summary details;
- • Full trial details (option to download full information for each of the member states/countries involved in the trial in case multi-state trials are shown in the search results).

Current download is available only as Plain text. It is also possible to create customised searches and subscribe to these searches via RSS (Really Simple Syndication) feeds.

15. When clicking on "RSS feed" using Chrome, it displays an error message

This is a known issue in Chrome, the browser does not support RSS (Really Simple Syndication) feeds. The functionality can be used either in Internet Explorer browser or with a Chrome plugin. It is possible to subscribe to the feed through it by copying the URL to the feeder.

16. What is the legal basis for the publication of data in EU CTR?

The publication of the trial protocol data is performed by adhering to business rules established to apply the EC guidelines on the publication of trial information in accordance with Article 57 (2) of Regulation (EC) No 726/2004 and its implementing guideline 2008/C168/02 and Article 41 of Regulation (EC) No 1901/2006 and its implementing guideline 2009/C28/01. It is recommended to read carefully all the information on the publication of clinical data fields from the EudraLex website. Requirements for posting and publication of results are outlined in the Commission Guideline on results posting.

Off note: policy 070 sets out the requirements for the publication of clinical data of clinical studies submitted to the Agency in the context of Marketing Authorization applications for human medicines under the centralized procedure.

Questions about EudraCT number

17. How can I apply for an EudraCT number?

Please refer to the user manual: Create a EudraCT number. The system will automatically issue an EudraCT number. The sponsor is advised to take a screenshot of this number. In addition, the system sends an email confirmation to the applicant (please check your spam folder/filer settings). The automated message cannot be re-sent by the system.

18. What if I did not receive the automated email on the EudraCT number?

EudraCT numbers are automatically generated and will take anywhere up to 24 hours to arrive at a requestor's Inbox You can contact your IT department to confirm that emails received are not being filtered, blocked or moved. It is possible that you have not received the EudraCT due to your email system blocking or filtering the email from us, your email mailbox is full and over its quota or the email address you provided was either invalid or incorrectly spelled. The subject of this email is 'Application for EudraCT Number' and it is sent from the email address noreply@eudract.ema.europa.eu.

The automated message cannot be re-sent by the system. You can contact the Service Desk and ask a screenshot as demonstration of your study assignment, that can be provided to the NCA. You need to use your user credentials for a system hosted by EMA. Non-registered users can refer to this link and click on "Create an EMA account".

One alternative option is to re-apply for a new EudraCT number; you will be asked to overwrite it (see question 22. Choose "yes" and then continue. You can request a new EudraCT number only if you have not yet submitted the clinical trial application (CTA) form to the NCA.

19. I asked for an EudraCT number, but I cannot see it in the system. Why?

A trial can be seen in the system only if the Clinical Trial Application is uploaded by the National Competent Authority. Refer to question 26.

20. The sponsor's protocol code changed. How do I modify it in EudraCT?

The sponsor's protocol code number is a number assigned by the sponsor to the trial protocol and it can be modified at any time.

If you have only applied for the EudraCT number and you haven't submitted the CTA form to the National Competent Authorities (NCAs), you should ask for another EudraCT number.

If you have already submitted the CTA form to the NCA, then you need to liaise directly with the NCA to notify this change, providing them with an updated XML file of the CTA (see question 36.). The EudraCT number should remain the same because it is a unique identifier of the trial.

21. I would like to delete the EudraCT number I applied for.

If no Clinical Trial Application (CTA) was sent to any NCA, no deletion is necessary, as the EudraCT number will stay unused. For recording purposes, it is not possible for us to delete a EudraCT number. The trial will not be present in our database as no CTA was submitted. No action from your side is needed.

22. I applied for an EudraCT number, but the system informs me that the same sponsor protocol code was already used.

The reason for this message is that someone has requested an EudraCT number in the past with the same protocol code. Please liaise internally in your organisation in order to know if a clinical trial application for this protocol code was already used for a clinical trial application (CTA) that was submitted to a National Competent Authority (NCA). If the trial protocol code has not been used by your organisation in the past for a CTA, then you can use it.

23. What is an EudraCT number and how long is an unused EudraCT number valid for?

A EudraCT number identifies the protocol for a trial, whether conducted at a single site or at multiple sites in one or more Member States. This number is a unique identifier of the trial and once issued, it never expires. It identifies a specific trial.

24. Is it required to identify the EudraCT number in the informed consent form?

It is not required to identify the EudraCT number in the consent form. However, adequate study identifier should be documented on the form.

Questions about Clinical Trial Application (CTA)

25. How can I apply for the authorisation of a clinical trial in EU/EEA?

Directive 2001/20/EC establishes specific provisions regarding the conduct of interventional clinical trials, including multi-centre trials on human subjects involving medicinal products.

Before commencing a clinical trial, a sponsor is required to submit a valid request for authorisation to the Competent Authority(ies) of the Member State(s) in which the sponsor plans to conduct the study. The response from the Competent Authority, whether the request for authorisation is positive or negative, could take up to 60 days.

The sponsor should submit a signed cover letter with the application. Its subject line should contain the EudraCT number and the sponsor protocol number with the title of the trial. **The XML file created through the EudraCT website needs to be attached to the application (**see question 26.)

Sponsor may not start a clinical trial until the Ethics Committee has issued a favourable opinion and the Competent Authority of the Member State concerned has not informed sponsor of any grounds for non-acceptance.

26. How do I register a trial in EudraCT?

You need to create a Clinical Trial Application (CTA) using the EudraCT website. The entire process is described here. Sponsors need to request a EudraCT number and create a CTA. Please note that **in case you would like to save your CTA while you are completing it, you will need to download it and save it locally**. In order to go on with its completion, you will need to upload it again, since you are not logging in the website (the EudraCT application is only a tool for creating a CTA).

The CTA XML file will then need to be sent to the National Competent Authority(ies), where you are asking for authorisation of the trial. Once the NCA(s) upload(s) the trial in EudraCT, and the relevant information on NCA approval and Ethics Committee Opinion are inserted, the trial will be visible in EU CTR (except for phase 1 trials in adults, see question 6.).

27. Where is the CTA that I was creating through the EudraCT website?

A clinical trial application (CTA) that is created by a sponsor is not saved in the EudraCT website. The sponsor does not log in in order to create it and it is responsibility of the sponsor to save it locally.

If you are a sponsor and you are preparing the CTA form, you do not need the access to EudraCT, unless you are a third country data provider preparing the clinical trial application form for a trial conducted in third country and which is part of a PIP (Paediatric Investigation Plan).

Please refer to question 26. and Registering a trial and updating its information for the relevant steps.

If you are preparing the clinical trial application form (namely "third country file") for a third country trial, refer to question 97. and the second part of the webpage Registering a trial and updating its information.

28. Can I save an incomplete XML of a Clinical Trial Application?

Yes, but only locally (in your computer) and not in the EudraCT website. It is recommended for sponsor to save locally the incomplete Clinical Trial Application to amend it if needed. See question 26. and 27.

29. Can I save an incomplete third country file on EudraCT?

Yes, it can be saved in EudraCT. To amend a third country XML file sponsor can download an existing third country XML file on the EudraCT website, edit and upload again the revised XML file to EudraCT. However, it is strongly recommended to save XML file/amended XML file also in your PC.

30. How do I update information of my CTA (protocol)?

The sponsor needs to submit an updated CTA XML file to the National Competent Authority(ies) (NCAs), see question 8. . The NCA approves it through uploading it in EudraCT. It is responsibility of the NCA to update the information, provided by the sponsor through a request for amendment.

If the trial is multi-county, the sponsor must provide this information to each Member State, and they will have to enter the same information in EudraCT for each country.

In case of a third country trial, the sponsor can perform the changes directly in EudraCT, through logging in, modifying the third country file and clicking on "Submit".

31. How do I mark my trial as "completed" or "prematurely ended"?

The sponsor is required to prepare the End of Trial (EoT) Notification Form and submit it to the relevant NCAs. The concerned NCA(s) is (are) responsible to amend the information on the status of the trial in the EudraCT system. Further information on the End of trial can be found in the [CT-1 Guidance](#).

CTA XML file and CTA amendments

32. How can I retrieve the XML file of my CTA?

The EudraCT application is only a tool for creating a CTA. since you are not logging in the website, no file is saved there. It is responsibility of the sponsor to save the XML file once completed it. Please refer to instructions [Registering a trial and updating its information](#)

Please note that in case you would like to save your CTA while you are completing it, you will need to download it. In order to go on with its completion, you will need to upload it again.

The CTA will then needed to be sent to the [National Competent Authority(ies)](#), who will be responsible to upload your trial in EudraCT. Once they upload the trial in EudraCT, it will be visible in EU CTR.

33. Can I submit a CTA to the NCA(s) for which some errors have not been solved as identified in the validation error report?

Sponsor must resolve errors in the business validation rules before submitting the CTA to the NCA. The NCA might not accept the application form if any outstanding issues have not been resolved in advance.

34. Where is the XML schema of a clinical trial application?

The EudraCT Clinical Trial Application (CTA) form schema (.xsd) is available in the Technical Information section of the supporting documentation pages of the EudraCT CTA & results documentation page.

35. If the sponsor changes during the trial, what do I do?

In order to change the sponsorship for a trial, there should be an agreement between the former sponsor and the new sponsor, which will need to be communicated to the National Competent Authority(ies) where the trial is conducted. There is no specific form to fill out, however in case the trial is still ongoing, the sponsor needs to submit an updated XML file of the CTA, as this is a substantial amendment (see question 36.)

For results information, the new sponsor can change the sponsors' details directly in the results data model.

36. How can I amend information of my CTA through a substantial amendment?

Examples of substantial amendments are amendment to the protocol such as change in the title of the trial, include additional sites/countries etc). Sponsor has to notify the National Competent Authority (NCA) of the substantial amendment via the 'Substantial Amendment Notification Form' For more information on the concept of 'substantial amendment, refer to CT-1 Guidance .

In addition, sponsor should amend the original XML CTA file and submit it with the substantial amendment form to the NCA(s) in order to amend the information in the public domain (EU CTR), see question 8. . The National Competent Authority(ies) is(are) responsible to amend the system and upload the amended XML CTA file in EudraCT to supersede the previous information.

37. I did not register my trial in EudraCT when it started. Is a retrospective trial registration possible in EudraCT?

For any enquiry on the retrospective registration of a clinical trial, a sponsor needs to liaise directly with the National Competent Authority(ies) of the Member State(s) where the trial is authorised.

38. Is it necessary to enter information on Non-Investigational Medicinal Products (NIMPs) in the clinical trial application form?

For interventional clinical trial on medicinal product(s) it is required to fill in the Clinical Trial Application form, but it is not required to include information on NIMPs in the application.

39. How to amend information on paediatric population included incorrectly in the original clinical trial application form?

This amendment is considered a 'substantial amendment'. See question 36.

40. How many languages does EudraCT support?

Although EudraCT supports entry of clinical trial data in any EU language, it is advisable that sponsors provide the information, such as for the title of the trial, also in English.

41. How do I provide adverse event reports on my ongoing clinical trial?

As stated in the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (OJ 2011/C 172/01), paragraph 7.9. Format of report, section 104: "- the Sponsor should provide, before completing the clinical trials application form, information on the IMP in the EudraVigilance Medicinal Product Dictionary ('EVMPD')". Investigational Medicinal Product should be input as a new Development Medicinal Product in the XEVMPD. Users registered with EudraVigilance should send an XEVPRM with the operation type 'insert' for a new development product in the XEVMPD.

Providing that the insert was successful, the corresponding EVCODE will be sent automatically to the sender's organisation ID via XEVPRM acknowledgement. If the sender is a WEB Trader user, the XEVPRM Acknowledgement will go to the WEB Trader Inbox. Gateway users should check with their Gateway providers where their XEVPRM Acknowledgements are stored.

For information on how to register with EudraVigilance, see the EudraVigilance registration webpage Note that you need to use the EVCODE for the new development.

Section A

42. Do sections A.4.1 and A.4.2 need to be amended when submitting a substantial amendment to the NCA(s)?

If the substantial amendment involves changes to entries on the clinical trial application (CTA) form, a revised XML file of the CTA including amended data should be submitted alongside the substantial amendment form. In this case, A.4.1 & A.4.2 (revised XML CTA form) and B.4 (in the substantial amendment form) should contain the updated-proposed protocol number and version of the trial. E1 (in the substantial amendment form) should include the sponsor's substantial amendment code number, version and date.

43. I cannot update section A.8 with the decision number of the PIP.

If, when updating section A.8 with the number of the Paediatric Investigation Plan, the following message is displayed "the value entered should have the format P/xxx/yyyy, where "xxx" is 1, 2 and 3 digits and "yyyy" represents years", the sponsor is advised to delete the first leading zero so that the PIP decision number complies with the format allowed in EudraCT, i.e.: P/xxx/yyyy.

Section B

44. What is a legal representative?

As per the CT-1 Guidance "the legal representative may be an individual person or a representative of a corporate entity does not have to be a legally qualified person should be willing to act as the agent of the sponsor in the event of any legal proceedings instituted in the EEA (for example, for service of legal documents) should be established and contactable at an address in the EEA does not assume any of the legal liabilities of the sponsor(s) for the trial by virtue of the role of legal representative and does not therefore require insurance or indemnity to meet such liabilities, but may in some cases enter into specific contractual arrangements to undertake some or all of the statutory duties of the sponsor in relation to the trial, in which case the legal representative would also be regarded as a co-sponsor and would then require insurance or indemnity cover" .

45. How can I fill in section B.2 (legal representative)?

In order to activate the legal representative section in the system, a country that is not under EU/EEA law needs to be specified in section B.1.3.4. If the main sponsor of a clinical trial is not based in the European Economic Area (EEA), the system will allow the sponsor to nominate a legal representative that is based in the EEA.

Section D

46. How do you add an active substance in EudraCT?

If the new substance is not available through the search functionality in EudraCT (section D "IMP identification" of the CTA, please refer to question 47.), The sponsor should write to EMA Service Desk using the user credentials for a system hosted by EMA, requesting the registration of the concerned substance by filling in the Excel file (using this template) and attaching the respective Investigator Brochure. Non-registered users can refer to this link and click on "Create an EMA account". Please 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. By registering the active substance at this stage, you will ensure that the CTA form is complete before you provide it to the National Competent Authority (NCA) and include the correct EVCODE and substance name. Further information can be found in the Frequently Asked Questions document published on the EMA website.

47. How do you fill in sections D.3.8 to D.3.10 of the CTA?

To add an 'active substance' sponsor needs 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, the sponsor can go back to the main section D and click on the tab "Add active substance". Once having searched for the Active Substance, sections D.3.8 to D.3.10 will automatically open and can be updated. The sponsor should provide either the active substance name or the substance EV code in order to complete sections D.3.8 to D.3.10.In the event that your active substance is new and therefore not available through the search functionality in EudraCT, sponsor should send a ticket to EMA Service Desk portal, see question 46. Sections D.3.8 to D.3.10 are mandatory and public fields, therefore they must be answered.

48. How do I solve my validation errors in section D? (e.g. D.2.1, D.3.8)

Please refer to questions 46. and 46. In addition, if 'D.2.1 IMP has MA' is answered "No": please select "not answered" for all further questions in D.2.1 or D.2.2 (except for D.2.1.2.1, see below). Regarding autofill in of the member state and setting D.2.1.2.1 =Yes, If the IMP does not have a marketing authorisation which is the default setting, please remove the country and set D.2.1.2.1 = No to avoid the validation rule error.

Section E

49. In case the trial lasts longer than initially scheduled, shall section E.8.9 "Initial estimate of the duration of the trial" be amended?

The sponsor should amend the information in the CTA of the trial in a manner that extends its duration then the estimate should be amended at the same time, as part of the same amendment (substantial

amendment). The amended XML file of the CTA should be submitted to the relevant NCA(s), see question 8.

50. In case the number of involved Member States/Sites changes, shall section E.8.4.1-8.5.1 be amended?

The CTA(s) sent to the initial National Competent Authorities can be left as they are.

51. In case the start of recruitment date is different, shall section E.8.10 "Proposed date of start of recruitment" be amended?

The data field in E.8.10 should remain the same as initially reported. This means that, an ex post adaptation is not required. E.g.: initially E.8.10 is given as 01.03.2013; However, the real recruitment starts only on 01.10.2013. In case an amendment is submitted in December 2013, the data field in E.8.10 don't need to be updated to 01.10.2013.

Section G

52. Section G.3 – is it possible to further define the expectations for the "main" criteria?

Only central facilities supplying services for at least a Member State, should be inserted in these fields. These are the central lab(s) contracted for assessments related to primary and secondary objectives are reported. The facility may be in this Member State, another Member State or a 3rd Country. Central Technical Facilities include central laboratories and central ECG or image processing facilities.

Field G.3.3.3 can be used to record the functional role of the person, if applicable. For sections G.3.5-G.3.6: the contact details are those of the central technical facility contact mentioned in section G.3.1. The international and applicable area codes need to be included. A functional email address can also be specified in field G.3.7.

53. Section G.5 – what is it meant by "major" 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 3rd Country. Note that the answer to question 'G.5.1 Has the sponsor transferred any major or all the Sponsor's trial related duties and functions to another organisation or third party' will be filled in automatically by the system once the details of the first subcontractor have been entered.

Questions about results

How to post results

54. How do I post results for my trial?

The process for posting results in EudraCT is described here. You need to create an EMA account, then use your EMA account credentials to activate your results user account (log in here and click on "become a results user", then log out and log in again). Afterwards, kindly request assignment to be the primary user for your trial (download and fill in the form, then log in here, click on "your page" and "request assignment", fill in the same information as per the form and upload the filled in form).

Once you have your trial assigned, you can start uploading results for your trial as a summary attachment or a full data set (refer to question 55.). In case you are requested to upload a full data set and you encounter errors or warnings during the process, the validation rules could be of help (look for your error/warning and see the relevant "rule description"). After you have uploaded your results, please make sure to post them by clicking on "post results" at the top right corner of the webpage.

55. Can I post my results as pdf file?

The result-related information is posted to EudraCT in one or both of two modalities: full data set and/or summary attachment.

The modality of posting (full data set/summary attachment) for completed trials is described in this document. If a study is completed before 21/07/2013 and was not an Art.46 or part of a Paediatric Investigation Plan (PIP), then a summary attachment is sufficient. In all other cases, a full data set must be provided.

For trials that never started or that terminated early ("prematurely ended"), sponsors can post a pdf document stating the reasons for the missing or partial results of these trials. see question 70.)

A summary attachment could be as CSR synopsis for instance. The system allows different types of formats: PDF, DOC, DOCX, RTF, TXT, PPT, PPTX, XLS, XLSX, TIFF, TIF, PNG, GIF, JPEG, JPG, and BMP. Maximum file size: 50MB per file.

The content of results information is detailed in guideline 2009/C28/01, applicable to paediatric and non-paediatric trials, as per section 3 of the guideline on posting results. According to section 3.2 of guideline 2009/C28/01 the content of summary attachment that is to be posted in EudraCT needs to be set out in line of the ICH Guideline E3, Clinical Study Reports.

56. Why are my results not public in EU CTR?

Reasons could be among the following:

- Your results are still in "draft". Please check that your results are "posted" and not still in "draft" status. If this is the case, the sponsor needs to click on "post results" at the top right corner of the results' page

- Your results were posted less than two weeks ago. Please note that trial results are published after two weeks from the posting date (which is not visible on the EU CTR).

- Your results are of a phase 1 trial in adult population, hence information on protocol and results will not be visible publicly (see question 6.).

57. Are results required for phase 1 studies conducted solely in adults?

Yes, they are required. However, they will be visible only to National Competent Authorities, EMA and European Commission. Phase 1 trials conducted solely in adults will never be made public, even after the submission of their results (refer to question 6.).

58. When should results for PIP and/or paediatric trials be submitted?

Result-related information for paediatric trials should be posted to EudraCT within 6 months of the end of the trial. Result-related information for non-paediatric trials included in an agreed PIP should be posted within 12 months of the end of the trial. This is irrespective of whether the product is authorised or not. See this document.

59. Where are the legal requirements for results submission in EudraCT?

The European Commission has published a guidance which describes the inclusion of clinical trial results and it is available here: Commission Guideline on results posting.

In addition, a joint letter has been published on the EudraCT website: Joint Letter by the European Commission, EMA and HMA.

60. Should the information regarding study results be anonymized?

In case the full data set is required (see question 55.), no anonymization is possible. In case posting the summary attachment is sufficient, the Commission Guideline does not refer to anonymization of the Commercially Confidential Information (CCI) or personal information. In this case, it is responsibility of the sponsor to amend the relevant information, in order to protect personal data and Commercially Confidential Information, as long as the mandatory information required for the full data set is available from the summary attachment.

61. Do results for paediatric trials need to be provided within 6 months also prior to marketing authorisation of the product concerned?

Result-related information for paediatric trials should be posted to EudraCT within 6 months of the end of the trial. This is irrespective of whether the product is authorised or not. Refer to this link for additional information on submitting results of paediatric studies.

Sponsors' registration for posting results

62. How do I register as a result user in the EudraCT system?

After having created a EMA account, the sponsor needs to log in the website https://eudract.ema.europa.eu/results-web/, click on "become a results user" and then log out and log in again, for the role to be activated. Afterwards, the sponsor can log in again and ask for assignment to be the primary user of a trial as per step 2 of instructions Tutorials on posting results.

63. How do I have a trial assigned as primary user?

Before having a clinical trial assigned as primary user, a Sponsor needs first to have a EMA account activated as results user, see question 62. .

Afterwards, the sponsor needs then request assignment to be the primary user for the trial as described in step 2 of the above linked instructions (download and fill in the form https://eudract.ema.europa.eu/docs/guidance/EudraCt%20Request%20March2019.pdf then log in here https://eudract.ema.europa.eu/results-web/, click on "your page" and "request assignment", fill in the same information as per the form and upload the filled in form). The request is then processed by EMA within a few working days. Once the request is accepted, the sponsor is notified and can then log in EudraCT and post results of the trial. The primary user can then nominate back up users and delegated preparers, see Delegation for results. **Sponsors are reminded to click on "post results" at the end of the process.**

64. My username/password/security questions don't work, what shall I do?

Refer to EMA Account Management webpage.

65. I asked for assignment of a trial as primary user, but the following message appears "The EudraCT number that you have entered does not exist in the system".

If a trial cannot be found in EudraCT when requesting assignment, it could be due to the following:

- The sponsor has not submitted the Clinical Trial Application (CTA) form to the National Competent Authorities (NCAs);

- the CTA form was submitted by sponsor but not uploaded into the system by the NCA, probably due to on-going evaluation of the application form;

We recommend the sponsor to ensure that the CTA package created through EudraCT (see question 26.) was submitted to the NCA(s); afterwards, the sponsor can liaise directly with the National Competent Authority regarding this.

The entire process is described here Registering a trial and updating its information .

66. Why was my request for assignment to a trial rejected?

There may be various reasons why an assignment to a trial has been rejected such as the letter is dated longer than 1 month from the date of submission, the name of the user does not match user account, the e-mail address is not credible etc.

It is important to use a dedicated template to submit the letter, available from the following link

https://eudract.ema.europa.eu/docs/guidance/EudraCt%20Request%20March2019.pdf

67. When nominating a back-up user or delegated preparer, this message is displayed: "A EudraCT results user with this username and email address cannot be found "

This means that **this account does not have a results user role**, this why you can't find it. Your colleague needs to use his EMA account credentials to activate his results user account, as specified in step 1 of the Tutorials on posting results webpage (click on each blue word to open relevant instructions - log in here and click on "become a results user", then log out and log in again). Once he has done so, you will be able to nominate him as back up user.

68. The current primary user of my trial left my company, what do I do?

In case there is a back-up user, she/he can remove the primary user directly in the system, and nominate a new one, see Delegation for results.

If there is no back up user, the sponsor needs to contact the Service Desk using the user credentials for a system hosted by EMA. Non-registered users can refer to this link and click on "Create an EMA account". Please specify "EudraCT" in the title of your request. In the request, the sponsor needs to state the trial number and the justification for which the primary user needs to be replaced. Please note that a person that is nominated as primary user, needs to be results user first (see question 62.).

Prematurely ended trials

69. My trial never recruited participants, never started or it ended prematurely, what do I do?

The sponsor needs to notify the National Competent Authority (NCA) of the premature end of the trial by filling in the End of Trial notification form and asking them to set the trial status as "prematurely ended" . Results for this trial need to be posted as pdf document, see question 70.

70. If my trial is never started or has ended prematurely, shall I post results?

Yes. Sponsors of trials that are "prematurely ended" should post a pdf document in the results section of EudraCT:

- For trials that were approved but never started, sponsors are required to state the reasons for the premature interruption in the pdf document

- For trials that started and terminated early, sponsors are required to state the reasons for the early interruption, together with any partial result, if available, in the pdf document

In order to know how to post your document, please refer to instructions. After you have uploaded your document, please make sure to post it by clicking on "post results" at the top right corner of the webpage.

71. Is there a template of the pdf that needs to be posted when a trial ended prematurely?

No template is present, you can use your company's headed paper and justify why the trial has never started or has prematurely ended. Any results that are present need to be included in the document.

Timing of results posting and postponement of deadline

72. What is the timing of posting for my results?

Refer to this document. In line with the Commission Guideline on results, for trials conducted on adults only, sponsors need to post results within 12 months from the End of Trial date. For trials conducted also on paediatric subjects, sponsors need to post results within 6 months from the End of Trial date.

73. Can I ask for postponement of the deadline for my results submission?

There is no requirement for the sponsor of a clinical trial to notify the Agency of the late submission of clinical trial results. It is legal responsibility of the sponsor to notify the relevant National Competent Authorities on this matter. It is responsibility of the National Competent Authority to agree on any postponement or to follow up on any missed submission. We kindly advise you to inform them about this. In case results will not be submitted on time, you may receive only reminders from EMA.

74. What are the implications for not posting results or for a late posting?

There may be implications at National level. EMA is not responsible to apply a penalty to sponsors who are not fulfilling the legal requirements to provide results in EudraCT. All the results for phase I-IV clinical trials are required to be posted to EudraCT as per the [Commission Guideline](#) on results posting.

75. Can an extension be granted for posting of paediatric trials results?

Commission Guideline 2009/ C 28/01 in Section 2.2.2 states that result-related information for paediatric trials should be submitted to the EMA, for entry into EudraCT, no more than six months after the trial has ended, whether the trial has been completed or prematurely terminated, whichever occurs first. However, notwithstanding the above, if (a) the clinical trial does not fall within the scope of Article 46(1) of the Paediatric Regulation, and (b) it is for objective scientific reasons not possible to submit the result-related information within six months, which has been demonstrated by the submitting party, result-related information for paediatric trials may be submitted to the EMA, for entry into EudraCT, at the latest within twelve months after the trial has ended, whether the trial has been completed or prematurely terminated, whichever occurs first.

This means that an extension to the 6-month rule can be granted only for trials which are not in scope of Art. 46(1) of the Paediatric Regulation. [Article 46(1) trials are paediatric trials initiated on or after 26 January 2007 which involves the use of a medicinal product covered by a European marketing authorisation and which are sponsored by the marketing authorisation holder].

This specific scenario must be discussed with the National Competent Authority/ies of the Member State(s) concerned by the application. There is currently no specific template to apply for the extension.

76. Will late results or missing results be flagged in the EU CTR?

Currently the system does not flag results provided late or not provided. The EMA has put in place a manual process, by which sponsors receive an email reminding to provide missing results in EudraCT.

Please note that it is responsibility of the National Competent Authority to monitor results' compliance according to art 4.7 of the Commission guideline 2012/302 03/EC "Member States should verify that for clinical trials authorised by them the result-related information is posted to the Agency".

Update of trial details

77. What do the statuses draft/posted/finalised of trial results mean?

The trial results in EudraCT have the following three statuses: "draft" (when results are being prepared), posted (when the results have been posted, after having passed the validation stage) and finalised (when the results are final and published if the trial record meets the publication rules).

78. How do I edit results information?

When results are in draft, the data can be updated at any time. When they are in "posted" they can be edited for two weeks from posting date, before they become finalised. When results are in finalized status, they can be updated if the option "update" is present, and with the creation of a new version. After two weeks from posting, the new version will be published in the EU CTR. A link to the old version will remain published in the EU CTR to keep track of the changes and for transparency reason.

79. How to update sponsor details if the sponsor changes after the end of the trial?

Change in sponsorship is not within the remit of the EMA. It is possible to update the amended information for the sponsor directly into the results module in EudraCT. The system allows sponsors to change some information in relation to the sponsor's details. However, this change will be reflected only in the results module of the trial published in EU CTR. In order to update the information of the trial as shown in the EU CTR search webpage, the sponsor needs to submit an updated XML of the CTA to the first member state appearing in the EU CTR webpage.

When the sponsor results user prepares the letter for assignment of trials to post results, it is important to clarify the change in sponsorship in the letter before uploading it in EudraCT. This will speed up the automated process.

80. Can I discard version 2 of my results (finalised), and keep version 1?

The EMA does not allow removal of data provided by the sponsor in EudraCT. All the versions of results remain in the system for transparency reason. If there is a change in a value in V1, this will be clearly stated in the justification sponsors have to give when updating the version of the results. Results can be updated with the creation of a new version, that need to be posted.

Questions on reporting the full data set

81. How can I solve errors and warnings after validating my results?

In order to know how to solve your errors/warnings, you can consult the validation rules (look for your error/warning and see the relevant "rule description"). Errors need to be solved according to the rules, while for warnings a justification is sufficient, to be provided when clicking on "validate full data set" and then "save" afterwards.

82. How do I report a statistical analysis for a single arm study design?

In order to report a statistical analysis related to a specific endpoint it is required to define at least two comparison groups. In order to report a single arm trial, a workaround needs to be performed. One of the two comparison groups can be defined in the subject disposition, and the other(s) in section "baseline characteristics" within the "Subject analysis set" functionality. You can then select both comparison groups in each "Endpoint definition" section. Please note that this is a workaround in order to accommodate reporting of single arm trials results.

83. How can I prepare results for a cross-over study design?

Currently the system cannot accommodate this specific scenario. There are several ways to report cross over study using workarounds, depending on the need of the reporting groups for endpoints and

statistical analysis. Option 1: One overall period could be used to detail the design and arms. With this choice, milestones (e.g. wash out) can be included. Each arm should document the number of subjects who started and the number who completed. Option 2: Several periods could be used to detail the design and arms. Each arm should document the number of subjects who started and the number who completed. Option 3: One overall period could be used to detail the design and arms. In this case, when providing subject disposition, the fact that the arms are not mutually exclusive should be ticked as "yes". Each arm should document the number of subjects who started and the number who completed.

84. I have no information on the age of some patients. How do I include them in the full data set analysis?

It is a concern that there is no age information for two patients. For this, the EMA recommends sponsors to contact the investigator site to clarify this issue. It is responsibility of the sponsor and of the investigator to collect accurate information about patients joining a trial. Unfortunately, it is not possible for the Agency to give the permission to omit a patient, as this is the responsibility of the sponsor/investigator. If this is not possible and you do not wish to remove this patient, it is possible to use the average age of the group as the age for those patients.

85. How can I distinguish between the number of subjects treated and enrolled in the results data model?

The system cannot differentiate between treated and enrolled. The help provided within the system indicated that it is expected that the number of subject enrolled be provided for the overall worldwide total of subjects. The same applies to the provision for the number of subjects in the period (number of subjects enrolled).

Therefore, the total number of subjects reported in the baseline period or period 1 is expected to be the same as the total number provided for the overall worldwide figure.

It is expected that if 10 subjects were enrolled worldwide, then period 1 be provided for these 10 subjects. In case, it is not and less subjects are declared for the baseline characteristics, then a justification should be provided.

86. What does the 'friendly description' mean in the result data model?

The 'friendly description' is used by the sponsor to identify the results for a specific trial, however this is not a mandatory filed. The friendly description will not be visible on the public domain. This feature is only for internal user for Sponsors.

87. If I have multiple preferred terms in the AE section, how do I ensure this is not considered duplication, but a single AE term referred to two different SOCs?

The release 10.4.0.0 caters for this scenario. In this case, the system will consider the term a new AE term belonging to a different System Organ Classes (SOCs) and there will not be any error when validating the results.

88. Is there a way to enter percentages in the adverse events fields?

Although the data entry process doesn't allow for percentages to be entered for Adverse Events and Serious and Non-Serious Adverse Events, they are automatically calculated when the database is exported as a PDF.

89. When I prepare results and view the PDF version, I see a note at the end of the page. What is this note about?

The 'note' appearing in the PDF file refers to cases when the sponsor provides a justification for a warning in the system. In case there is no justification, then the note appears blank in the pdf file without any information there.

If you need to enter a comment or additional information on the results, you can use the section 'More Information' in the results data model under 'Limitations and Caveats'.

90. Is it possible to have the XML file of my results?

Sponsors are advised to download the XML file of their results when they are ready, before clicking on "post results". Afterwards, it is possible to download the XML file only when results are in "posted" status (up to 2 weeks from posting date) and not when they are in "finalised" status (see question 77.).

Training material for results posting

91. Is there any training material for posting the full data set of results?

Yes, the training material is under the [Training page](#) of EudraCT. You can use the training environment in order to practice in results posting, see question 92.

Instructions on how to post results are provided [here](#) .

In order to know how to solve your errors/warnings, you can consult the [validation rules](#) (look for your error/warning and see the relevant "rule description").

You can also see some examples on how other studies are reported in our EU CTR website (go to webpage https://www.clinicaltrialsregister.eu/ctr-search/search, then select "search tools", date range between 1st August 2013 and today, and "results status" as "trials with results", then click on "search").

The [data dictionary](#) could also be of help.

If you encounter specific problems that you cannot solve with looking at the validation rules or the above tips, you can open a query with our Service Desk (see question 106.), mentioning the clinical trial number or, better, attaching the XML file of the results (click on "download XML" at the top right corner of your trial's page).

92. How do I use the training environment?

You can request an EudraCT number in the training environment, as per the presentation linked in the first bullet point of [EudraCT Training page](#). Once you have a trial number and the trial assigned, you can practice in inserting results there. In case you need to practice with results of a certain trial (e.g. number 2007-123456-12), you can:

1. Download the XML file of the results of the trial 2007-123456-12 from EudraCT production environment, unzip it, open it using notepad and look for the word "number" (CTRL+F=number) and, once found, delete the EudraCT number 2007-123456-12

2. copy the trial number assigned to you in the training environment

3. paste the trial number assigned in the training environment in the same location where number 2007-123456-12 was deleted. Save this XML.

4. in the training environment, click on "upload XML" at the top right corner of the trial assigned, and upload the XML that was just saved.

Now results in the training environment are the same as results uploaded in EudraCT (except for the trial number, of course). Please note that an XML file of results can be downloaded by the sponsor only if results are still in "draft". Please note that it is not possible to assign a "delegated preparer" in the training environment.

93. How do I request an EudraCT number in my training environment?

A real EudraCT number cannot be used. After registering as a result user in the training environment the system will assign the result user a 'dummy EudraCT number', through following steps detailed in presentation of the first bullet point of the Training page. Further information in question 92.

Questions about third country trials

94. When does a trial conducted only in a third country (non-EEA country) need to be reported in EudraCT?

A trial conducted only in a third country needs to be reported in EudraCT if it fulfils at least one of the following criteria:

- The trial is part of an agreed PIP

- The trial is in scope of Article 45 of the Paediatric [Regulation (EC) No 1901/2006](#) (historical trials)

- The trial is in scope of Article 46 of the Paediatric [Regulation (EC) No 1901/2006](#)

If none of the above criteria applies, then the trial does not need to be reported in EudraCT even if it includes paediatric subjects.

Uploading a third country file

95. How do I upload a protocol of a third country file?

In order to upload the protocol, please create a "third country file", through clicking on "create" - "protocol" and "third country file" in [this webpage](#).

Please note that in case you would like to save your file while you are completing it, you will need to download it. In order to go on with its completion, you will need to upload it again, since you are not logging in the website (the EudraCT application is only a tool for creating the third country file).

Afterwards, you can upload the protocol as third country file through logging in here https://eudract.ema.europa.eu/results-web/ .

Refer to [Registering a trial and updating its information](#) , section "For a trial to be conducted outside of the EEA, but part of a Paediatric Investigation Plan (PIP):"

More information in [this document](#).

At the end of your study you will need to submit results as per [instructions](#).

96. How do I get a username and password to be a third country data provider (PIP addressee and Article 46 data provider)?

In order to register a third country data provider, please submit a scanned letter to the [Service Desk](#) using the user credentials for a system hosted by EMA and requesting authorisation of a person's Eudralink credentials for the upload of third country clinical trial data to EudraCT. Non-registered users can refer to [this link](#) and click on "Create an EMA account" before raising a ticket using the service desk portal.

This letter should be on headed paper of the PIP addressee/marketing authorisation holder/sponsor, signed by a representative of the PIP addressee/marketing authorisation holder/sponsor and contain a clear statement that the person named in the letter is to be given permission to provide protocol clinical trial data to the EudraCT database as well as a declaration that only data of trials will be uploaded for which the company/user is the PIP addressee/marketing authorisation holder/sponsor. The letter should also contain the following information about the user: name, address, e-mail, and

optionally telephone, telefax. Additional information can be found here [Registering a trial and updating its information](#) and [https://eudract.ema.europa.eu/help/Default.htm#eudract/user_roles_ov.htm](#) .

97. I am a third country data provider (PIP addressee). How do I prepare protocol-related third country information for inclusion in EudraCT?

In order to post a third country clinical trial file the sponsor needs a user ID, password and the third country data provider user role (see question 98.). Once these credentials have been obtained, the sponsor can post the third country trial file by logging on to EudraCT public site and creating a new third country file for a trial for which there is no XML or by editing an existing XML file for the same trial. Once the XML file is prepared, it is recommended to save it locally on the sponsor's own system. See question 95. 97. Unlike EEA CTA XML files, third country files are not processed by NCAs but are posted by the PIP addressee using EudraCT.

98. I hold an agreed PIP. When should I submit protocol-related third country trial information?

In accordance with the European Commission a third country file should be submitted no later than one month after, either the EMA decision agreeing a PIP, or the first approval/positive opinion of the trial by a third country competent authority and/or third country ethics committee, whichever is the latest. See relevant information in [this document](#).

99. How do I amend my third country file that is already uploaded?

The sponsor should log in the EudraCT site, perform the changes of the trial XML file, upload the revised XML file to EudraCT, click on "submit".

Specific questions on different scenarios

100. If a clinical trial in an agreed PIP comprises sites inside the EEA as well as in third countries, do I need to upload third country information?

Yes. If the clinical trial comprises sites inside the EEA as well as in third countries, third country information has to be posted directly to the EudraCT database in addition to the EEA CTA, which is submitted to the NCA(s). You can use the same EudraCT number for EEA CTA(s) and the third country file of the same trial.

101. If a trial in scope of Article 46 comprises sites inside the EEA as well as in third countries, do I need to upload third country information/results?

No. If the clinical trial comprises sites inside the EEA as well as in third countries, no third country information need to be posted (unless the trial is also part of an agreed PIP, in which case third country information needs to be posted). However, results will need to be posted for these trials using the same EudraCT number of the EEA CTA which was previously submitted to the NCA(s).

102. Do I have to upload a third country protocol for a paediatric trial conducted outside of the EU if there is no marketing authorization for that product in the EU?

No, unless the trial is included in an agreed PIP.

103. Which paediatric studies fall under Article 45 of Regulation (EC) No 1901/2006 and are in scope of EudraCT?

Paediatric studies in respect of products covered by an EU marketing authorisation on 26 January 2007 and completed before or on 26 January 2007 (Article 45 (1)) were to be submitted for publication via the European Clinical Trials Register (EU-CTR) by 21 July 2016.

104. Do the requirements for posting clinical trial information in EudraCT apply only to trials conducted in the EEA or also to those conducted outside the EEA?

The requirements for posting information apply to all registered clinical trials with at least one investigator site in the EEA as well as to paediatric and non-paediatric trials included in an agreed PIP, even if they are conducted outside the EEA.

105. Am I required to post protocol-related third country information only for paediatric trials included in an agreed PIP or for any trial carried out in third countries and contained in an agreed PIP?

You are required to post a third country file for any interventional clinical trial carried out in third countries and contained in an agreed PIP regardless whether the trial includes paediatric subjects or not.

Questions about support, username/password and IT

106. How can I ask for support?

If the answer to your question is not here, please contact the Service Desk using your user credentials for a system hosted by EMA. Non-registered users can refer to this link and click on "Create an EMA account". Please specify "EudraCT" in the title of your request.

107. I have issues when logging in and I can't contact the Service Desk for this reason

Refer to EMA Account Management webpage.

108. Entering information in the database is particularly slow. Any suggestion?

An option could be to try a different browser (e.g. Google Chrome) when using the EudraCT application.

109. Where can I find the technical documentation (i.e. release note) in EudraCT?

Technical documentation is visible under the 'Technical documentation' page.