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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 Now](#), adding the extension @id.ema.europa.eu to your EMA username. For non-registered users: create an [EMA account](#).

**Any European Union (EU)/European Economic Area (EEA) trial with a foreseen Last patient last visit after 30 January 2025 is required to transition to the [Clinical Trials Information System \(CTIS\)](#) to comply with [Regulation \(EU\) 536/2014](#). This needs to be done **as soon as possible**, since this deadline includes the time necessary for completion of the Member State(s) procedure, which can take up to 3 months. More information in question 3.**

**As of 31 January 2023, all initial clinical trial applications in the EU/EEA must be submitted through the [Clinical Trials Information System](#).** The use of the EudraCT database is now limited to the tasks described in question 2.

With regards to trials for which the Clinical Trial Application (CTA) was submitted to the [relevant National Competent Authority \(NCA\)](#) before 31 January 2023, **sponsors are advised to liaise with the NCA directly** for trials' uploading and updating on EudraCT/EU CTR (insertion of pending NCA decision and/or Ethics Committee opinion, CTA amendments and updating of the trial status), see question 5.

The entire process of updating protocol and results information of an EudraCT clinical trial is described in the [EudraCT step-by-step guide](#). Specific instructions are provided in the [User manual](#). The steps required to post results are described in the [Tutorials on posting results](#).

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# General Questions

## 1. What types of studies are registered in EudraCT?

The EudraCT database covers **only interventional clinical trials** using investigational medicinal products (IMP):

- submitted to the National Competent Authorities (NCAs) of the European Union (EU)/European Economic Area (EEA) from 1 May 2004 to 30 January 2023 under [Directive 2001/20/EC](#).
- conducted outside of the EEA and part of a Paediatric Investigation Plan (PIP) and/or conducted under Article 45 and 46 of [Regulation \(EC\) No 1901/2006](#) (see question 98. ).

EU/EEA interventional clinical trials for which an application was submitted under the Clinical Trial Regulation 536/2014 are stored in the [Clinical Trials Information System \(CTIS\)](#). CTIS also contains former EudraCT trials which were [transitioned to CTIS](#): see question 3.

With regards to 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. As of 31 January 2023, which actions can users still perform on EudraCT?

As per [EudraCT step-by-step guide](#), the [use of the EudraCT database](#) is now limited to:

- the performance of amendments to EU/EEA Clinical Trial Applications for which the initial submission was done before 31 January 2023 (see question 27. )
- the upload of third country files of trials conducted **exclusively** outside of the EU/EEA that are part of a Paediatric Investigation Plan (PIP) and/or in scope of Article 46 of the Paediatric [Regulation \(EC\) No 1901/2006](#) (so called "third country files") (see question 98. )
- the update of EudraCT trial statuses by National Competent Authorities (see question 30. )
- the [submission of results](#) of EudraCT trials by sponsors (see question 54. )

## 3. When does an EudraCT trial need to transition to CTIS?

Sponsors of EU/EEA EudraCT trials that are expected to continue after 30 January 2025 are required to [transition those trials from EudraCT to CTIS at their earliest convenience](#). **Sponsors should note that the Member State(s) procedure, which can take up to 3 months, also needs to be completed before the above deadline.** To know how to transition your trial, see [CTIS: how to get started and how to transition a trial](#). In addition, only interventional clinical trials that have at least one active site in the EU/EEA need to be transitioned.

In case a new EU/EEA-country needs to be added to a EudraCT trial, the EudraCT trial needs to be [transitioned to CTIS](#) first, as this is considered a new trial application for this member state (see [Guidance for the transition of clinical trials](#)).

Trials that are (foreseen to be) completed by 30 January 2025, and that for which no EU/EEA Member State was added after 30 January 2023, can remain on the EudraCT database, and do not need to be transitioned to CTIS, see question 10. If an end of trial notification has been submitted in all EU/EEA member states, but the global end of the trial has not been notified, **the trial does not need to be**

**transitioned:** in this case, trial results are expected via EudraCT within 12 months from its global end of the trial date (6 months in case the trial includes paediatric subjects).

**In case of a multi-country trial that needs to be transitioned to CTIS, sponsors should ensure the harmonisation of their clinical trial under the Directive through EudraCT**, prior to transitioning their trial to CTIS. More information on transition trials can be found [here](#).

#### **4. 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 25. )
- 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 (see question 98. )

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").

As of January 31<sup>st</sup>, 2022, the [clinical trial Regulation \(EC\) 536/2014](#) repealed Directive 2001/20/EC: for more information, see [Clinical Trial Regulation](#) and [EudraLex - Volume 10](#)

#### **5. For what issues shall the sponsor contact National Competent Authorities (NCAs)?**

For trials that were submitted to the relevant NCA before 31 January 2023, the sponsor needs to liaise with the NCA directly and not with EMA, in order to:

- Uploading the CTA and updating the NCA decision or IEC opinion on EudraCT, so that the trial can be visible in EU CTR, see question 13.
- Updating the clinical trial application published on EU CTR, through submitting a CTA amendment, see question 27.
- Updating the trial status (e.g., marking the trial as 'completed'), see question 30.
- Extending the deadline for results posting, see questions 73. and 75.

Contact details of the NCAs can be found here: [National Competent Authority\(ies\)](#).



## Questions about transition trials and CTIS

### **6. Under which conditions must a trial be transitioned to CTIS?**

Refer to question 3.

### **7. How can I transition my trial to CTIS?**

Sponsors who need to transition their trial to CTIS need to follow the instructions provided in document [CTIS: how to get started and how to transition a trial](#) and [module 23 on transition trials](#). In case of a multi-country trial that need to be transitioned to CTIS, sponsors should ensure the harmonisation of their clinical trial under the Directive through EudraCT, prior to transitioning their trial to CTIS.

Please find below a collection of resources to assist sponsors throughout this process.

- section 5 of the [CTIS sponsor's handbook](#)
- [Guidance for the transition of clinical trials](#) published by the European Commission under EudraLex volume 10
- [CTCG's best practice guide](#) and [cover letter template](#) for sponsors of transitional trials
- Module 23 of the [CTIS online training programme](#)
- Bitesize talk: [How to submit a transitional trial in CTIS](#) (including [presentation](#))
- Bitesize talk: [Transitional trials and additional Member State concerned \(MSC\) application](#) (including [presentation](#))
- Clinical Trials Information System Webinar: [Second Year of Transition](#) (including [presentation](#))

### **8. What happens to EudraCT trials that are transitioned in CTIS? Are results expected to be submitted in EudraCT and CTIS?**

Clinical Trial Applications of trials that are [transitioned from EudraCT to CTIS](#) are marked as '[Trial now transitioned](#)' in EudraCT by the relevant National Competent Authority. **Results of these transitioned trials need to be submitted through CTIS and not through EudraCT.**

Only the member states where the trial is still active should be transitioned to CTIS. In case a trial is completed in some countries under the Directive 2001/20, while it is transitioned to CTIS under Regulation 536/2014 for other countries, its results will be expected on CTIS and not on EudraCT.

### **9. Can sponsors submit initial EU/EEA Clinical Trial Applications through EudraCT after 31 January 2023?**

No. **As of 31 January 2023, all initial trial applications in the European Union (EU)/European Economic Area (EEA) must be submitted through CTIS.** In case a new EU/EEA-country needs to be added to a EudraCT trial, the EudraCT trial needs to be [transitioned to CTIS](#) first, as this is considered a new trial application for this member state (see [Guidance for the transition of clinical trials](#)) . Recording of trials conducted exclusively outside of the EU/EEA, as well as EudraCT trials' updates need to be done through EudraCT: see question 2.

## **10. Can sponsors keep their trials on EudraCT until 30 January 2025?**

Yes, if the last patient last visit of the trial is foreseen to be before 31 January 2025. Trials that are foreseen to be completed after 30 January 2025, need to transition to CTIS at the sponsor's earliest convenience. **Sponsors are strongly advised not to ask for their trials' transition closer to the deadline of 30 January 2025:** note that this deadline includes the Member State's procedure to transition the trial (refer to question 3).

EU/EEA EudraCT trials for which the CTAs were submitted before 31 January 2023, and for which the completion/premature end is foreseen before 31 January 2025, can continue to be conducted under the Directive 2001/20 without transitioning to CTIS. Amendments on these trials need to be performed through EudraCT (see question 27. ), as well as their update of trial status (see question 30. ), and results information (see question 54. ). As of 31 January 2023, trials that are conducted exclusively outside of the EU/EEA and that are part of a Paediatric Investigation Plan (PIP) and/or are conducted under Article 45 or 46 of [Regulation \(EC\) No 1901/2006](#) are recorded on EudraCT only: see question 98.

## **11. Will EudraCT be dismissed?**

No. EudraCT will remain active as it stores all interventional clinical trials on medicinal products submitted to the EU/EEA NCAs from 1 May 2004 until 30 January 2023 under [Directive 2001/20/EC](#), as well as all trials conducted outside of the EEA that are part of a Paediatric Investigation Plan (PIP) and/or are conducted under Article 45 or 46 of [Regulation \(EC\) No 1901/2006](#). Until 30 January 2025, the database will keep recording EudraCT trials ongoing in EU/EEA and relevant updates (amendments, trial status update). After 30 January 2025, results of EudraCT trials will continue to be uploaded on EudraCT.

## **12. Where can I find more information on CTIS?**

See question 7. and in particular document [CTIS: how to get started and how to transition a trial](#). Additional links are here: [legislation](#), [CTIS homepage](#), [training material](#), [sponsor handbook](#).

## Questions about publication on EU CTR

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

The reasons for not finding a trial through the [‘search’ page of EU CTR](#) could be due to 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 (refer to [European Guidance 2008/C 168/02](#) Art. 3 par. 2 and [Commission Guideline 2012/C 302/03](#), Art. 5). See question 15.
- The trial was submitted under the Clinical Trials Regulation through [CTIS](#).

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

### **14. What is the EudraCT information that is made public on EU CTR?**

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 15. For public trials, results information is all made publicly available as posted by the sponsor.

### **15. Are EudraCT phase 1 trials conducted solely on adults public on 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**]. Note: trials that are marked as phase 1 as well as other phases in EudraCT are published on EU CTR (e.g., phase1+2 trials on adults are made publicly available through EU CTR).

### **16. When was a study protocol Clinical Trial Application published on 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.

### **17. How can I amend the information published on 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 see question 27. Once uploaded and approved, the updated information will be displayed publicly in case the trial is already publicly available (see question 13. ). Note that information contained in the EU CTR cover page of the trial corresponds to the CTA of the first member state listed.

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

**In case of results information:** an updated version of the results should be posted in EudraCT, through logging in the [EudraCT tools and login page](#), performing the changes through editing the already posted version, and clicking on "post results", refer to question 78.

More information in the [EudraCT step-by-step guide](#).

### **18. 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 98. ), it is the date in which the study was uploaded in EudraCT by the third country data provider.

### **19. 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.

### **20. How can a trial be marked as completed or prematurely ended on EU CTR?**

Refer to question 30.

### **21. When are the results published?**

Study results are published after two weeks from their posting date in EudraCT. 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.

### **22. As a researcher, can I access the raw registry data 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 23. for more details on how to download clinical data.

### **23. 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.

### **24. 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.

### **25. 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 0070 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 EU/EEA Clinical Trial Application (CTA)

### **26. Can I create new EU/EEA CTAs using EudraCT?**

The creation of new EU/EEA CTAs using the EudraCT Application for trials that need to be authorised in the EU/EEA is not allowed. The functionality of creating new EU/EEA CTAs is available on EudraCT and must be used only in case an amendment needs to be performed on a CTA that was submitted to the relevant NCA(s) before 31 January 2023, but the original CTA XML file cannot be modified through the 'load' option (i.e., in case the original XML was lost).

As of 31 January 2023, all initial trial applications in the European Union (EU)/European Economic Area (EEA) must be submitted through [CTIS](#). In case a new EU/EEA-country needs to be added to a EudraCT trial, the EudraCT trial needs to be [transitioned to CTIS](#) first: more information in question 3.

Creation of third country files of trials conducted exclusively outside of the EU/EEA must be performed through EudraCT: see the bottom part of the [EudraCT step-by-step guide](#).

### **27. How do I update information of my CTA (protocol)?**

To amend an EU/EEA EudraCT CTA that was submitted before 31 January 2023, the sponsor should submit an updated XML file of the CTA to the National Competent Authority(ies) (NCAs) where the trial is authorised, so that they can upload this information in EudraCT. As per [user manual](#), the sponsor needs to click on "[EudraCT tools and login](#)", then "load →EEA CTA", add the CTA XML file, perform the changes, and save the CTA file locally. The amended XML of the CTA will then need to be submitted to all the relevant National Competent Authority(ies) of the Member States where the trial is approved (if substantial, see question 36. ). The NCA approves it through uploading it in EudraCT. It is the responsibility of the NCA to update the information provided by the sponsor through a request for amendment. Once uploaded and approved, the updated information will be displayed publicly in case the trial is already publicly available (see question 13. ).

If the trial is multi-country, the sponsor must provide the updated CTA XML file to the National Competent Authority of each involved Member State. Each competent authority will have to upload this information on EudraCT for their 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".

### **28. Where is the CTA/third country file that I was working on, while using EudraCT?**

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 the sponsor exits the EudraCT without saving the full application or third country data as XML file, any newly inserted data is lost. The sponsor does not log in to amend the protocol information and it is the responsibility of the sponsor to save the XML locally. The [user manual](#) provides instructions on how to save the XML file of a CTA/third country file.

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

A full overview of EudraCT processes is provided in the [EudraCT step-by-step guide \(see bottom of the page on creation of third country trials\)](#).

### **29. Can I save an incomplete XML of a Clinical Trial Application? What about an incomplete third country file?**

Sponsors can save an incomplete XML of a Clinical Trial Application only locally (on their computer) and not in the EudraCT website. It is recommended for sponsors to save locally their Clinical Trial Application(s) during its completion and at the end, in order to be able to amend it in a second moment. See question 27. and [user manual](#).

On the contrary, a third country file can be saved in EudraCT. To amend a third country XML file, sponsors can download an existing third country XML file from the EudraCT website, edit and upload again the revised XML file to EudraCT. However, it is strongly recommended to save an (amended) XML file also on your computer.

### **30. 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 update the status of the trial in the EudraCT system. Further information on the End of Trial can be found in the [CT-1 Guidance](#).

The trial status of third country files does not need to be updated.

### **31. Once I ask for an EudraCT number or a CTA amendment, I see the error "User details could not be loaded! Please contact Administrator!"**

The sponsor's access to EudraCT is foreseen only in case results need to be uploaded. No access is needed to upload EU/EEA Clinical Trial Applications amendments in EudraCT, or when asking for an EudraCT number. To avoid this error message, sponsors should log out of EudraCT and use the options in page 'tools and login' while being not logged in the application. Further information on how to amend a CTA can be found in question 27.

#### **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, no information is saved there. It is the responsibility of the sponsor to save the XML file on a local drive.

If you want to save your CTA while you are completing it, you will need to download it and save it on your local drive. To continue with its completion, you will need to upload it again.

The completed CTA must be sent to the [National Competent Authority\(ies\)](#), who will be responsible to upload the CTA in EudraCT. Once they upload the CTA 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?**

The 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 [Supporting documents](#) page.

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

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. If the trial is still ongoing, the sponsor should also submit an updated XML file of the CTA, as this is a substantial amendment (see question 27. and 36. ).

If a trial is completed, the above process is also recommended to ensure that the correct sponsor information is reflected in EudraCT and EU CTR. It is also possible to update the sponsor information through the results data model. However, the updated details will only show in the results sections of EudraCT and EU CTR, not in any other field (e.g., not in the CTA or trial information).

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

Examples of substantial amendments are amendments to the protocol such as, a change in the title of the trial, include additional sites/countries etc. The 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, sponsors should amend the original XML CTA file and submit it with the substantial amendment form to the NCA(s) to amend the information in the public domain (EU CTR), see question 17. and 27. . 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. 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. Please liaise directly with the NCA to notify this change, providing them with an updated XML file of the CTA (see questions 27. and 36. ). The EudraCT number should remain the same because it is a unique identifier of the trial.

### **38. 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.

### **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 questions 17. , 27. and 36.



#### **40. How many languages does EudraCT support?**

Although EudraCT supports entries 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 EudraCT clinical trial?**

Refer to the [Reporting requirements under the Clinical Trials Directive](#).

**Suspected unexpected serious adverse reactions (SUSARs)** should be reported to [EudraVigilance](#) instead of separately to national competent authorities in each EU / EEA country where related clinical trials are running. This rule came into effect on 31 January 2022. For some countries, sponsors should report SUSARs also to national ethics committees (sponsors are advised to review the relevant national legislation).

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.

**All other safety related information** should be reported to the [national competent authorities](#) of the EU Member States / EEA countries and ethics committees via national processes.

#### **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?**

In case a sponsor is not established in any of the EU/EEA countries, the sponsor needs to appoint a legal representative which resides in the EU/EEA territory. The legal representative acts as the agent of the sponsor in the event of any legal proceedings instituted in the EEA (for example, for service of legal documents). Contractual arrangements between the sponsor and the legal representative need to be in place in order to undertake some or all of the statutory duties of the sponsor in relation to the trial.

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

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, see question 47. ), the sponsor needs to open a request through the EMA Service Now [Request SMS services](#) (to log in Service Now: please add the extension '@id.ema.europa.eu' to the EMA username; non-registered users can create an [EMA account](#) first). The sponsor should request the registration of the concerned substance by filling in the Excel file (using [this template](#)) and attaching the respective Investigator Brochure. 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 "Add active substance" on the right-hand side of the IMP name. Active substances should be added for each IMP.

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, the sponsor should send a ticket to EMA Service Now 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)**

In order to solve the error "D.2.2.3 The products to be administered as IMPs are defined as belonging to an ATC group): It is mandatory to identify at least one active substance for every IMP except when D.2.2.3 Products to be administered as IMP belonging to ATC Group or D.2.2.4 Other are answered Yes.", please refer to questions 46. and 47.

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.

If your validation error mentions that your IMP should have at least 1 active substance, please refer to question 48.

#### **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 17.

#### **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 does not 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 one Member State, should be inserted in these fields. These are the central laboratory(ies) contracted for assessments related to primary and secondary objectives, and in which the measurement or assessment of the main evaluation criteria are centralised. 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. More than one facility can be added in this section.

### ***53. Section G.5 – what is 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 on EudraCT is described [here](#). You need to [create an EMA account](#) through the [EMA self-registration form](#), 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, you need to [validate your results](#): 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 (summary attachment) only?**

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

If a study is completed before 21/07/2013 and it was not conducted under Art 45, 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 a 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 the results I posted on EudraCT not public on 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 15. ).

### **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 15. ).

### **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 the responsibility of the sponsor to amend the relevant information 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 on the EudraCT system?**

As per [user manual on results user role activation](#): after having [created a EMA account](#), the sponsor needs to log in to the [EudraCT tools and login page](#), 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 to have an [EMA account activated with the results user role](#), see question 62.

Afterwards, the sponsor needs to [request assignment to be the primary user](#) for the trial as described in step 2 of the [Tutorials on posting results](#) (download and fill in the [form](#) then log in the [EudraCT tools and login page](#), 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 create the results data module of the trial.

Please note that only 1 primary user can be assigned per trial. Assigned primary users can proceed with uploading results, as well as with adding other users to their trial as back-up, for results entering and/or posting purposes, see [Delegation for results](#).

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

Refer to [EMA Account Management](#) webpage. Please note that it is no longer possible to change the e-mail address of your account. If you no longer have access to your account's e-mail address, a new EMA account must be created (see [user manual](#) on how to create an EMA account).

#### **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 the 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 was created](#) through EudraCT and submitted to the NCA(s). The sponsor should liaise directly with the [National Competent Authority](#) if the CTA was submitted to the NCA, but the trial cannot be found in the system. A full overview of EudraCT processes is provided in the [EudraCT step-by-step guide](#) while the detailed instructions are in the [user manual](#).

#### **66. I asked for assignment of a trial as primary user, but the following message appears "20xx-xxx-xxx: EudraCT number has already been assigned to a primary user"**

This means that the trial was already assigned to a primary user. The sponsor results user needs to:

- check if the trial was already assigned to his/her account, through going to “your page” and see if the trial number is listed among the “draft results” or under the “posted and finalised results” link.
- check internally whether a colleague already asked to have the trial assigned as primary user. If this is the case, the primary user can nominate a back-up user or a delegated preparer and poster, see [Delegation for results](#).
- ask the [EMA Service Now](#) to be replaced as primary user for the trial: refer to question 68.

**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**. Your colleague needs to use their EMA account credentials to activate their 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 they have done so, you will be able to nominate them as back up user. Detailed instructions in the user manual's sections ([results user role activation](#), [delegation for results](#)).

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

The sponsor should check internally whether a back-up user is assigned for the trial. In case there is a back-up user, they 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 [EMA Service Now](#), adding the extension @id.ema.europa.eu to the EMA username. For non-registered users: create an [EMA account](#). It is important to choose the page "Request a EudraCT Service". In the request, the sponsor needs to specify the following:

- **EudraCT number** of the trial
- The **username** and **email address** of the EMA account of the new primary user to be nominated for the trial. Please note that the person that is nominated as primary user, needs to be results user first (see question 62. ).
- the **justification** for which the primary user needs to be replaced (e.g., he/she is no longer employed in the company)
- name of the current primary user, who is no longer with your company (not mandatory, only if known)

**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 a pdf document, see question 70.

**70. If my trial never started or 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



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?**

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, in line with [Paediatric Regulation \(EC\) No 1901/2006](#).

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

It is the legal responsibility of the sponsor to notify the relevant National Competent Authorities on this matter. It is the 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 cannot be submitted on time, you may receive reminders from EMA. If you receive a reminder from the EMA, and the proposed deadline for results posting cannot be met, you need to reply to the reminder with a justification of late results posting.

### **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.

If results are not posted within the expected timelines, and no justification for late reporting is provided to the EMA upon receipt of the reminders mentioned in question 73. the EudraCT number of the trial may be listed in the List of trials for which National Competent Authorities and EMA could not reach sponsors, or for which sponsors could not follow up on reminders to post results. This list is published on the [EU CTR website](#) and updated on a regular basis.

### **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 EU CTR does not flag trials for which results are provided late. The EMA sends reminders to sponsors of trials for which results are missing. If results are still not posted after receiving those reminders, the EudraCT number of your trial may be listed in the List of trials for which National Competent Authorities and EMA could not reach sponsors, or for which sponsors could not follow up on reminders to post results. This list is published on the [EU CTR website](#) and updated on a regular basis.

Please note that it is the 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 in EU CTR provided that the trial record meets the publication rules).

## **78. How can the sponsor edit results information?**

When results are in draft, their data can be updated at any time. The dates on which draft results are created or updated are not recorded on EudraCT.

When results are in "posted" status, they can be edited for two weeks from the posting date, before they become finalized. This will revert the status from "posted" to "draft". The date on which the results were initially posted is not recorded in EudraCT. A new posting date will be visible when the results are posted again.

Two weeks after the posting date, the results will automatically be in "finalized" status in EudraCT and published on the EU CTR. Only the publication date will be registered both in EudraCT (finalization date) and EU CTR. When results are in finalized status, they can no longer be updated, however, a new results version can be created after finalization of the first version. Two weeks from posting the new version, it 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 reasons. It is not possible to delete a results finalised version from EudraCT or EU CTR.

The detailed process is described in the relevant [user manual's section](#).

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

Changes 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. 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 of trial assignment.

## **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 reasons. 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. What is the difference between 'summary attachment' and 'full data set'?**

In the 'Index' section of an EudraCT trial's results, sponsors can read the two different modalities of posting results of an EudraCT trial:

- with 'summary attachment' it is meant a document that is attached to the results module of the EudraCT application, through the option 'attach summary'. The document is generally in pdf format, but it can be in other formats (e.g., JPG, DOC, DOCX).
- the 'full data set' is the set of fields that need to be filled in using the EudraCT application. Sections of the full data set can be viewed on the left-hand side of the results interface ('Trial Information', 'Subject disposition', 'Baseline characteristics', 'End points', 'Adverse events', 'More information'). Those sections need to be filled in as per [Data dictionary](#). In case of errors/warning during the process, see question 82.

In most of the cases it is not possible for the sponsor to post results as a 'summary attachment' only: the modality of results posting (summary attachment versus full data set) is described in question 55. and in the [Tutorials on posting results](#).

## **82. 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. Once all errors and warnings are solved, all validation rules are passed. At this point, the sponsor needs to click on "post results" at the top right corner of the screen.

### **83. How do I report a statistical analysis for a single arm study design?**

To report a statistical analysis related to a specific endpoint it is required to define at least two comparison groups. To report a single arm trial, a workaround needs to be performed. There are two options:

1. The statistical analysis for an endpoint is not mandatory. You could choose to delete the statistical analysis (go to the analysis page, scroll down, and select "delete statistical analysis"). This will generate a warning which you can reply to with a justification for not entering the analysis.
2. If you choose to report the statistical analysis, 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 to accommodate reporting of single arm trials results.

### **84. 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 question "Are the arms mutually exclusive?" should be ticked as "no". Each arm should document the number of subjects who started and the number who completed. As this is a workaround, the total number of subjects in this case will not represent the actual number of subjects, but it will be the sum of each arm's subjects.

### **85. Do all endpoints of a trial need to be included?**

Only the most important endpoints, corresponding to those ones initially defined by the sponsor in section E.5 END POINT(S) of the CTA, need to be reported in EudraCT through the full data set section. In case not all endpoints can be reported through the full data set, for example, in case some of them are not met, it is possible to include those ones that cannot be reported in a pdf file to be attached as a 'summary attachment'.

### **86. In the Subject disposition – Arm section, I have issues with specifying the number of subjects joining or non-completing a trial: what can I do?**

Once the sponsor clicks on "go to page" nearby the relevant error in the "validation report", the system will show the "arm" page. In the "milestones" section of this page, the sponsor needs to use the "subject non completion reason" or the "subject joining reasons" option, where, after selecting the reason and indicating the number of subjects, **the sponsor needs to click on the "plus" nearby the number to add the number of subjects**. Once this section is completed, the sponsor can click on "done".

### **87. I have an error message regarding the total number of subjects affected by (non) serious adverse events, e.g. "The total number of subjects affected by the non-serious adverse events is less than the total"**

***number of subjects affected by non-serious adverse events for the reporting group. Account for all subjects affected or correct the total number of subjects for the reporting group”: how can I solve it?***

Note that there has to be a numerical correspondence between:

- the number of 'Subjects affected by (non)-serious adverse events' ('for this reporting group, provide the following totals:') declared in the 'Adverse event reporting groups' definition section, that is in the centre of the 'adverse events' page
- the number declared in the 'serious adverse events' or 'Non-serious adverse events' sections, that are at the bottom of the 'adverse events' page.

The sum of all the adverse events must be equal or less than the sum of each person's adverse event, as a person can have more than one adverse event. As per [validation rule](#): "For each reporting group, the total number of subjects affected by all non-serious adverse event, collectively, must not be less than the 'total number of subjects affected by non-serious adverse events' for the reporting group". To solve the errors, note that the sum of each (non) serious adverse event per product needs to correspond to the total values. The threshold is applicable to all values (i.e., the field "Subjects affected by non-serious adverse events" should count subjects affected by non-serious adverse events above the threshold).

***88. 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 the 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.

***89. 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.

***90. 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 field. The friendly description will not be visible on the public domain. This feature is only for internal user for Sponsors.

### **91. I click on "save" but the system doesn't save data entered on results**

This issue usually occurs when in the endpoint section the measurable unit of a specific endpoint is not chosen but it is typed in only with one character, while the characters should be at least two (e.g., the sponsor should type "percentage" instead of "%", or "litre" instead of "L"). It is advisable to choose the unit from the dropdown list.

If the issue persists, the sponsor can click on "download XML" at the top right corner of the website, before clicking on "save" and after having entered the data. The XML can then be sent to [EMA Service Now](#) for further assistance (see question 115. ).

### **92. 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.

### **93. 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'.

### **94. 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***

### **95. Is there any training material for posting the full data set of results?**

Instructions on how to post results are provided [here](#). The training material is under the [Training page](#) of EudraCT. You can use the linked training environment to practice in results posting, see question 96.

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 [EU CTR search page](#), 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 [EMA Service Now](#) (see question 115. ), 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).

### **96. How do I use the training environment?**

You can request an EudraCT number in the [training environment](#), as per the [user manual section on EudraCT Training page](#). Once you have a trial number and the trial assigned, you can practice 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.

### **97. 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 the [user manual section on training environment](#); further information in question 96.

## Questions about third country trials

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

A trial conducted solely **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. **If a PIP/Art 46 trial is conducted in the EU/EEA as well as outside of the EU/EEA, this trial needs to be reported through the [Clinical Trials Information System](#) only.**

### **99. How can I record a trial conducted exclusively in third countries on EudraCT?**

The process of recording a third country file in EudraCT is described at the bottom of the [EudraCT Step-by-step guide](#) as well as in the [EudraCT user manual](#). The following questions may answer the most common doubts a sponsor has during this process.

#### **Generating a EudraCT number for a third country file**

### **100. How can I apply for an EudraCT number?**

From 31 January 2023, EudraCT numbers can be created only for the creation of third country files of trials that are conducted exclusively outside of the EU/EEA. The process is described in the relevant [user manual's section](#) and in the bottom part of the [EudraCT Step-by-step guide](#).

### **101. 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. The subject of this email is 'Application for EudraCT Number', and it is sent from the email address [noreply@eudract.ema.europa.eu](mailto:noreply@eudract.ema.europa.eu). 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. **If the email cannot be found**, you can contact the [EMA Service Now](#), adding the extension [@id.ema.europa.eu](mailto:@id.ema.europa.eu) to the EMA username. For non-registered users: create an [EMA account](#). Once logged in, it is important to select "Request a EudraCT Service". In the text, please specify the EudraCT number that was assigned to your trial, the sponsor protocol code, and the email address to which you would like the message to be sent.



### **102. I asked for a EudraCT number, but I cannot see it in the system. Why?**

EudraCT numbers are not automatically stored in EudraCT. Only when the relevant EU/EEA CTA or third country file is uploaded in EudraCT, the number appears in the system, and it is eventually displayed on EU CTR. More information in the [EudraCT step-by-step guide](#) and in question 106.

### **103. I would like to delete the EudraCT number I applied for.**

If no Clinical Trial Application (CTA) was sent to any NCA, or if no third country file was uploaded in the system, 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.

### **104. What is a 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.

### **105. 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.

#### **Uploading a third country file**

### **106. How do I create a protocol of a third country file?**

Refer to the [EudraCT step-by-step guide](#), section "For a trial to be conducted exclusively outside of the EEA, but part of a Paediatric Investigation Plan (PIP)/Art 46 of paediatric regulation:". Specific instructions are provided in the [User manual](#)'s relevant section ([EudraCT number assignment](#), [protocol completion](#)).

To create the protocol, after assignment of the EudraCT number, 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. To go on with its completion, you will need to upload it again, since you are not logging on 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](#) as a third country data provider, see question 107. At the end of the trial, you will need to submit results as per [instructions](#).

### **107. How do I get a username and password to be a third country data provider (PIP addressee and/or Article 46 data provider)?**

Refer to the relevant [user manual section](#). To register as a third country data provider, please submit a scanned letter with your request to the [EMA Service Now](#), adding the extension @id.ema.europa.eu to the EMA username. For non-registered users: create an [EMA account](#). Once logged in, it is important to

select "Request a EudraCT Service", requesting authorisation of a person's Eudralink credentials for the upload of third country clinical trial data to EudraCT.

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 in the [EudraCT step-by-step guide](#).

**108. I am a third country data provider: how do I prepare protocol-related third country information for inclusion in EudraCT?**

Refer to the bottom of the [EudraCT step-by-step guide](#). Once the [third country file has been created](#), the sponsor user needs a [user ID, password](#) and the [third country data provider user role in order to submit the file through EudraCT](#) (see question 107. ). It is recommended that the sponsor saves the third country file locally on the sponsor's own system, see question 106. Unlike EEA CTA XML files, third country files are not processed by NCAs but are posted by the sponsor using EudraCT.

**109. I hold an agreed PIP and/or I conducted a trial under Art 46 of the paediatric regulation. 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. Any amendment to the protocol also needs to be submitted in accordance with the same timeline, see question 110.

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

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

**Specific questions on different scenarios**

**111. If a clinical trial in an agreed PIP or under Art 46 of the paediatric regulation comprises sites inside the EEA as well as in third countries, do I need to upload third country information?**

No. **If a trial is conducted in the EU/EEA as well as outside of the EU/EEA**, this trial needs to be reported through the [Clinical Trials Information System](#) only.

**112. 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.

**113. 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.

**114. 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 only in third countries and contained in an agreed PIP?**

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

## Questions about support, username/password, and IT

### **115. How can I ask for support?**

If the answer to your question is not here, you can contact the [EMA Service Now](#), adding the extension @id.ema.europa.eu to the EMA username. For non-registered users: create an [EMA account](#).

### **116. I have issues when logging in and I can't contact the Service Now for this reason**

Refer to [EMA Account Management](#) webpage.

### **117. 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.

### **118. Where can I find the technical documentation (i.e., release note) on EudraCT?**

Technical documentation is visible at the bottom of [this page](#).