



## EudraCT & EU-CTR Question and Answer table

### Frequently Asked Questions & Answers (FAQs) – V1.1 (December 2017)

Note: Additional information on the EudraCT functionalities (user interface, navigation) is available in the Help tab on the EudraCT public website: <https://eudract.ema.europa.eu/help/Default.htm>

Additional information on the legal requirements for clinical trials is available in EudraLex Volume 10 <https://ec.europa.eu/health/documents/eudralex/vol-10/>

Additional information on paediatric clinical trials is available on the EC website [https://ec.europa.eu/health/human-use/paediatric-medicines/developments\\_en](https://ec.europa.eu/health/human-use/paediatric-medicines/developments_en)

More information on the latest developments for clinical trials is available on the EC website [https://ec.europa.eu/health/human-use/clinical-trials/developments\\_en](https://ec.europa.eu/health/human-use/clinical-trials/developments_en)

Item no.	Question	Answer
<b>GENERAL INFORMATION</b>		
1.	How long is an unused EudraCT number valid for?	A EudraCT number is a unique identifier of the trial and once issued, it never expires. It identifies a specific trial.
2.	How many languages are supported in EudraCT?	Although EudraCT supports entry of clinical trial data in any EU language, it is recommended for sponsor to provide the information, such as for the title of the trial, also in English.



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3.	EudraCT application displayed a technical error, what should I do?	Please report details of the technical error via the EMA Service Desk portal: <a href="https://servicedesk.ema.europa.eu">https://servicedesk.ema.europa.eu</a>
4.	Is a retrospective trial registration possible in EudraCT?	For any enquiry on the retrospective registration of a clinical trial, sponsor has to liaise directly with the National Competent Authority of the Member State where the trial was conducted. Refer to the following link: <a href="https://eudract.ema.europa.eu/nca_contacts.html">https://eudract.ema.europa.eu/nca_contacts.html</a>
5.	Where can I obtain the XML schema to prepare a clinical trial application?	The EudraCT Clinical Trial application form schema (.xsd) is available in the Technical Information section of the supporting documentation pages of the EudraCT website: <a href="https://eudract.ema.europa.eu/protocol.html">https://eudract.ema.europa.eu/protocol.html</a>
6.	Are trials using medical devices required to be included in the EudraCT database?	Directive 2001/20/EC does not apply to medical devices, active implantable medical devices, and in vitro diagnostic medical devices as defined in Community legislation. You are advised to follow procedures on devices in place in the country where the clinical trial is conducted/will be conducted. Contact the National Competent Authority of the country(ies) concerned for further details: <a href="https://eudract.ema.europa.eu/nca_contacts.html">https://eudract.ema.europa.eu/nca_contacts.html</a>
7.	How do I register a trial in EudraCT?	Directive 2001/20/EC establishes specific provisions regarding the conduct of interventional clinical trials, including multi-centre trials on human subjects involving medicinal products.  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.

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		<p>Before commencing a clinical trial, sponsor shall be required to submit a valid request for authorisation to the Competent Authority of the Member State 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.</p> <p>Before submitting an application to the National Competent Authority, the applicant should obtain a unique EudraCT number from the EudraCT Community Clinical Trial System by the procedure described in the Help file:</p> <p><a href="https://eudract.ema.europa.eu/help/Default.htm#eudract/create_eudract_no.htm">https://eudract.ema.europa.eu/help/Default.htm#eudract/create_eudract_no.htm</a></p> <p>This number identifies the protocol for a trial, whether conducted at a single site or at multiple sites in one or more Member States.</p> <p>To obtain the EudraCT number automatically from the database the applicant will need to provide a few items of information.</p> <p>The applicant should submit a signed cover letter with the application. Its subject line should contain the EudraCT number and the invariable sponsor protocol number (if available) with the title of the trial.</p> <p>Please note that the concept of sponsor and Legal Representative of the sponsor are both in the CT1 guidance attached and in the Directive as well.</p> <p>From a practical point of view you need to follow the instructions below:</p>

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		<ul style="list-style-type: none"> <li>• sponsor can create, save xml/pdf files of Clinical Trial Applications locally only after obtaining a EudraCT Number from the system;</li> <li>• sponsor has to load locally saved Clinical Trial Applications to complete, validate, compare or use to prepare a package for submission to a National Competent Authority;</li> <li>• sponsor has to click on “create” EudraCT number and fill in the information;</li> <li>• The system will automatically issue an EudraCT number sending an email confirmation to the applicant (please check your spam folder/filer settings). The automated message cannot be re-sent by the system;</li> <li>• The applicant can now create, save and submit the CTA as per the above mentioned instructions.</li> </ul> <p><b>Note: Sponsor is unable to save xml files to the EudraCT system. Only National Competent Authorities are able to do this upon submission of the xml file.</b></p>
<b>PROTOCOL INFORMATION</b>		
8.	Can I save an invalid or incomplete Clinical Trial Application?	Yes, but only locally and not in the EudraCT system. It is recommended for sponsor to save locally the incomplete Clinical Trial Application to amend it if needed.
9.	Can I save an invalid or incomplete third country XML file on EudraCT? How to make amendments in a completed third country file?	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 public website, edit and upload again the revised XML file to EudraCT. <b>It is strongly recommended</b>

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		<b>to save XML file/amended XML file also locally.</b>
10.	Can I prepare a Clinical Trial Application submission with a clinical trial application that does not meet all of the business rules as identified in the validation error report?	Sponsor has to resolve errors in the business validation rules before submitting the CTA to the NCA. The NCA might not be able to accept the application form if any outstanding issues have not been resolved in advance.
11.	How to register a new substance in EudraCT?	<p>In the event that the new substance is not available through the search functionality in EudraCT, it is advised to register the new substance in the XEVMPD following the link provided on the EudraCT application. The EMA can offer punctually to sponsor not yet registered with EudraVigilance to register the new substance on their behalf. For this step, please follow the link</p> <p><a href="https://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000687.jsp">https://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000687.jsp</a> and complete the required form and send it by email to the EudraVigilance team. It should not take more than three to five working days if the form is complete.</p> <p>Sponsor has the option to update any information on the new substance once registered. By registering the active substance at this stage, sponsor will ensure that the CTA form is complete before submitting it to the National Competent Authority (NCA) and include the correct EVCODE and substance name.</p> <p>Information on how to submit a new substance in section XII/002 of the Extended EudraVigilance Medicinal Product Report Message (XEVPRM) can be found in the Frequently Asked Questions document published on the EMA website:</p> <p><a href="http://www.ema.europa.eu/docs/en_GB/document_library/O">http://www.ema.europa.eu/docs/en_GB/document_library/O</a></p>

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		<a href="ther/2014/09/WC500172599.pdf">ther/2014/09/WC500172599.pdf</a>
12.	What types of studies need to be registered in EudraCT?	<p>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). For non-interventional clinical trials, it is advised to refer to ENCEPP database <a href="https://www.encepp.eu/">https://www.encepp.eu/</a>. Registration on the ENCEPP database is on a voluntary basis.</p> <p>More information on the legislative requirements can be found in EudraLex - Volume 10 Clinical trials guidelines, Chapter VI - Legislation: <a href="https://ec.europa.eu/health/documents/eudralex/vol-10_en">https://ec.europa.eu/health/documents/eudralex/vol-10_en</a></p>
13.	How to add a new active substance in EudraCT?	To add a new 'active substance' sponsor has go to the IMP screen, and there a green text is displayed explaining how to get to the active substance screen. Click 'Add IMP' to start the first Investigational Medicinal Product or create another one. To add an Active Substance (section D.3.8 to D.3.10) for this IMP clicks 'Add Active Substance'. In the event that the new substance is not available through the search functionality in EudraCT, sponsor is advised to register the new substance in the XEVMPD following the link provided on the EudraCT application.
14.	How to search for clinical trials registered in EudraCT?	The information on registered authorised clinical trials is accessible via the European Clinical Trials Register <a href="https://www.clinicaltrialsregister.eu/ctr-search/search">https://www.clinicaltrialsregister.eu/ctr-search/search</a>
15.	Is it necessary to enter information on NIMP 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

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		not required to include information on NIMPs in the application.
16.	How to populate the legal representative question in EudraCT?	<p>In order for the legal representative section to be activated in the system sponsor has to provide the country in section B.1.3.4. If the main sponsor of a clinical trial with a medicinal product is not based in the European Economic Area (EEA), for example, an American or Japanese company, it is a statutory requirement to appoint a legal representative based in the EEA for the purposes of the trial.</p> <p>As per the CT-1 Guidance (<a href="https://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf">https://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf</a>) <i>“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”</i></p>
17.	How to contact the national competent authorities?	Contact details are available on the EudraCT public website: <a href="https://eudract.ema.europa.eu/nca_contacts.html">https://eudract.ema.europa.eu/nca_contacts.html</a>

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18.	How to amend information on paediatric population included incorrectly in the original clinical trial application form?	<p>In this specific scenario the amendment is considered a 'substantial amendment'. Therefore the sponsor needs to prepare a substantial amendment notification form and submit the document along with an amended CTA XML file to the relevant National Competent Authorities.</p> <p>More information on the substantial amendment notification form can be found in EudraLex - Volume 10 Clinical trials guidelines, Chapter I:  <a href="https://ec.europa.eu/health/documents/eudralex/vol-10_en">https://ec.europa.eu/health/documents/eudralex/vol-10_en</a></p>
19.	Is it required to identify the EudraCT number in the 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.
20.	What action is required when the clinical trial is complete?	<p>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.</p> <p>More information can be found in EudraLex - Volume 10 Clinical trials guidelines, Chapter I:  <a href="https://ec.europa.eu/health/documents/eudralex/vol-10_en">https://ec.europa.eu/health/documents/eudralex/vol-10_en</a></p>
<b>RESULTS INFORMATION</b>		
21.	Am I required to post clinical trial results?	<p>Sponsor is required to provide results for clinical trials registered in EudraCT.</p> <p>The European Commission has published guidance which describes the inclusion of clinical trial results and it is available here: Commission Guideline — 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</p>



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		(EC) No 1901/2006) <a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a>
22.	What is the timing of posting for the results?	Refer to Commission Guideline 2012/C 302/03 <a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a>  More information is available here <a href="https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modality%20and%20timing%20of%20posting_V3.pdf">https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modality%20and%20timing%20of%20posting_V3.pdf</a>
23.	Do results for PIP and/or paediatric trials need to be provided within 6 months of the end of the trial? Does this accelerated timeline only refer to trials after marketing authorisation?	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. (Refer to Question 31 regarding a potential extension.)
24.	What are the different statuses of trial results in EudraCT?	The trial results in EudraCT have the following three statuses: draft (when results are being prepared), posted (when the results have passed the validation stage) and finalised (when the results are final and are published if the trial record meets the publication rules). When results are in draft, the data can be updated at any time. When results are in finalized status, they can be updated with the creation of a new version. The new version as well as the old version will be published in the EU CTR to keep track of the changes and for transparency reason.
25.	Are results required in EudraCT for phase 1 studies? Are they made publicly available in the EU CTR?	All the results for phase I-IV clinical trials are required to be posted to EudraCT. However, Phase 1 trials, conducted solely

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		<p>in adults and that are not part of an agreed PIP, are not made public in the EU CTR. Please refer to Article 5 of the Commission Guideline 2012/C 302/03  <a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a></p> <p>The publication of the records in the European Clinical Trials Register (EU-CTR) is 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. Documentation available in Chapter V – Volume X of EudraLex  <a href="https://ec.europa.eu/health/documents/eudralex/vol-10/">https://ec.europa.eu/health/documents/eudralex/vol-10/</a></p> <p>In particular, as per the European Guidance 2008/C 168/02 Art. 3 para 2 [...Moreover, <b>phase I trials</b>, 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 <b>are excluded from publication...</b>]  <a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf</a></p>
26.	How do I register as primary user?	<p>To become a primary user on behalf of an organisation/sponsor a user first needs to request assignment of the relevant trial by registering as a result user. More information can be found from the following link  <a href="https://eudract.ema.europa.eu/docs/training/EudraCT%20V10%20results-%20getting%20started%20and%20request%20for%20trial%20assignment.ppt">https://eudract.ema.europa.eu/docs/training/EudraCT%20V10%20results-%20getting%20started%20and%20request%20for%20trial%20assignment.ppt</a></p>
27.	Why my request for assignment to a trial has been rejected?	<p>There may be various reasons why an assignment to a trial has been rejected such as the letter is dated longer than 1</p>

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		<p>month from the date of submission, the letter was not prepared on the sponsor's headed paper, the name of the user does not match user account, the e-mail address is not credible etc. It is important to always use a dedicated template to submit the letter, available from the following link</p> <p><a href="https://eudract.ema.europa.eu/docs/forms/template%20letter_clinical%20trial%20assignment%20request%20for%20result%20preparation%20and%20posting.doc">https://eudract.ema.europa.eu/docs/forms/template%20letter_clinical%20trial%20assignment%20request%20for%20result%20preparation%20and%20posting.doc</a></p> <p><b>Functional email address is not accepted.</b></p>
28.	What is the format for uploading results to EudraCT?	<p>The result-related information can be posted to EudraCT in one or both of two modalities: full data set and/or summary attachment. 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.</p>
29.	When does a full data set need to be entered and when does a CSR synopsis fulfil the results requirements?	<p>For studies that ended on or after the date of the finalisation of the programming (21 July 2014), a full data set is mandatory.</p>
30.	Can an extension be granted for posting of paediatric trials results?	<p>Commission Guideline 2009/ C 28/01 in Section 2.2.2 states that <i>result-related information for paediatric trials should be submitted to the EMEA, 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</i></p>

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		<p><i>submitting party, result-related information for paediatric trials may be submitted to the EMEA, 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.</i></p> <p>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].</p> <p>This specific scenario has to 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.</p>
31.	How to deal with posting results in case no patients have entered a study?	<p>The National Competent Authority (NCA) needs to be notified of the premature end of the trial by filling in the End of Trial notification form. In case no subjects were recruited it is not appropriate to complete the full dataset for results. However there is currently no functionality for sponsors to inform that recruitment never started. If this is an old trial and there is an end of trial/withdrawal reported by sponsor, a comment should be entered by the NCA that no subjects were recruited. Sponsor should liaise with the NCAs of the Member State(s) concerned by this application.</p>
32.	How to update sponsor details in the event of changing the sponsor of a clinical trial?	<p>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</p>

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		system allows sponsors to change some information in relation to the sponsor's details. When primary 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 allow the team involved in the approval/rejection of the letter to process the request smoothly without delay.
33.	If we have multiple preferred terms in the AE section, how do we 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 SOC and there will not be any error when validating the results.
34.	For one of my study that was earlier released on EudraCT, a new version was created for a single change in the value.  However, the single value needs no correction hence we would like to discard the version 2.	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.
35.	How to create EudraCT numbers in the test environment?	After registering as a result user in the training environment the system will assign the result user a 'dummy EudraCT number'. <u>A real EudraCT number cannot be used</u> . A useful presentation is published on the external website 'How to request a new EudraCT number in the Training environment' <a href="https://eudract.ema.europa.eu/training.html">https://eudract.ema.europa.eu/training.html</a>
36.	Late results summary submission: Is there any process for notifying of a result summary that will not meet the deadline?  What are the implications for not posting results on the EU Register or posting late?	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 relevant National Competent Authorities to liaise with the sponsors for compliance with the Commission Guideline 2012/C 302/03.

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		(Refer to Question 31 regarding a potential extension.)
37.	Is there a penalty for falling to register or submit clinical study reports to EudraCT?	<p>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 — 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).</p> <p>Section 4.7. 'Non-compliance, factual inaccuracy' of the Commission Guideline states the following: Member States should verify that for clinical trials authorized by them the result-related information is posted to the Agency."</p> <p><a href="https://ec.europa.eu/health/documents/eudralex/vol-10/">https://ec.europa.eu/health/documents/eudralex/vol-10/</a></p> <p>Refer to the document published on the external website 'Trial results - Modalities and timing of posting' <a href="https://eudract.ema.europa.eu/result.html">https://eudract.ema.europa.eu/result.html</a></p>
38.	Am I required to post clinical trial results at this stage?	<p>The European Commission has published guidance which describes the inclusion of clinical trial results and can be found here: Commission Guideline — 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).</p> <p><a href="https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a></p>

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39.	What are the required modalities and timings of posting result-related information for different trial types?	Refer to the Commission Guideline (2012/C 302/03) <a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a> and the document "Trial results: Modalities and timing of posting" <a href="https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting_V3.pdf">https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting_V3.pdf</a>
<b>EU CLINICAL TRIAL REGISTER (EU CTR)</b>		
40.	Why is a clinical trial not visible in the EU CTR?	<p>This could be due to the following:</p> <ul style="list-style-type: none"> <li>• sponsor has not submitted the Clinical Trial Application form to the National Competent Authorities;</li> <li>• The application form was submitted by sponsor but not uploaded into the system by the National Competent Authority probably due to on-going evaluation of the application form;</li> <li>• It is a phase 1 trial in adult population (refer to Q.25).</li> </ul> <p>We recommend you to liaise directly with the National Competent Authority regarding this.</p> <p><b>Note: The approval from the National Competent Authority and the Ethics Committee triggers the publication of clinical trial information in the EU CTR.</b></p>
41.	Is it possible to download all the clinical trial information contained in the EU CTR?	<p>At present sponsor can download</p> <p>- number of trials:</p> <ol style="list-style-type: none"> <li>1. on current page (all the trial displayed on one page);</li> <li>2. selected trials only (selection of specific trials from the list using the 'selection' box only);</li> </ol>

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		<p>- download content:</p> <ol style="list-style-type: none"> <li>1. Summary details;</li> <li>2. 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).</li> </ol> <p>Current download is available only as Plain text.</p> <p>It is now possible to create customised searches and subscribe to these searches via RSS (Really Simple Syndication) feeds.</p>
42.	Is it possible to request changes to the information displayed in EU CTR by the applicant or sponsor?	<p>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 (Chapter V):</p> <p><a href="https://ec.europa.eu/health/documents/eudralex/vol-10/">https://ec.europa.eu/health/documents/eudralex/vol-10/</a></p>
43.	Is all protocol data published in the EU CTR?	<p>Protocol data for all types of investigational studies/trials needs to be entered in the EudraCT database, however phase I trials data is not to be made public on EU CTR, unless it is part of an agreed PIP. Although the information is not made public, it is a legal requirement for sponsor to provide the results of the trial.</p>



Item no.	Question	Answer
		<p>Legal requirements below</p> <p><a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf</a></p>
44.	Where is the list of protocol related fields (CTA/third country form) to be made public in EU-CTR?	<p>The list of fields to be public in the European Clinical Trials Register is 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.</p> <p>In addition the approval from the National Competent Authority and the opinion from the Ethics Committee will trigger the publication of the trial protocol in the EU CTR.</p> <p>For further information refer to Chapter V in EudraLex Volume 10</p> <p><a href="https://ec.europa.eu/health/documents/eudralex/vol-10/">https://ec.europa.eu/health/documents/eudralex/vol-10/</a></p>
<b>PAEDIATRIC CLINICAL TRIAL INFORMATION (PROTOCOL AND RESULTS)</b>		
45.	How do I obtain a user ID and password for a third country data provider (PIP addressee)?	<p>Follow the instructions in the 'Help file' for EudraCT user roles <a href="https://eudract.ema.europa.eu/help/Default.htm#eudract/results_user_role.htm">https://eudract.ema.europa.eu/help/Default.htm#eudract/results_user_role.htm</a></p> <p>All people registered as "person authorised to upload 3rd country clinical trial data to EudraCT" in the respective PIP application can use their Eudralink credentials to access EudraCT.</p> <p>If the Eudralink credentials have not been authenticated or if another person in the organisation will carry out the task of the PIP addressee in relation to EudraCT, a signed letter has to be submitted to <a href="mailto:paediatrics@ema.europa.eu">paediatrics@ema.europa.eu</a> requesting authorisation of a person to upload third country clinical trial</p>

Item no.	Question	Answer
		data to EudraCT.
46.	I am a third country data provider (PIP addressee). How do I prepare protocol-related third country information for inclusion in EudraCT?	<p>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. (Follow the instructions in the 'Help file' for EudraCT user roles).</p> <p><a href="https://eudract.ema.europa.eu/help/Default.htm#eudract/user_roles_ov.htm">https://eudract.ema.europa.eu/help/Default.htm#eudract/user_roles_ov.htm</a></p> <p>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.</p> <p>Unlike EEA CTA XML files, third country files are not processed by NCAs but are posted by the PIP addressee using EudraCT.</p>
47.	I hold an agreed PIP. When should I submit protocol-related third country trial information?	<p>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.</p>
48.	If a clinical trial in an agreed PIP comprises sites inside the EEA as well as in third countries do I still need to post third country information?	<p>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 NCAs. The same EudraCT number should be used for EEA CTA(s) and the third country file of the same trial.</p>

Item no.	Question	Answer
49.	For which trials am I required to post third country information?	In addition to all interventional clinical trials with at least one investigator site in the EEA the requirements for posting information apply also to interventional clinical trials that are included in an agreed PIP (regardless whether the trial includes paediatric subjects or not), even if conducted outside the EEA.
50.	I tried to update the EudraCT application in section A.8 with the decision number of the paediatric investigation plan, but I get the message "the value entered should have the format P/xxx/yyyy, where "xxx" is 1, 2 and 3 digits and "yyyy" represents years". What should I do?	We recommend sponsors to delete the first leading zero so that the PIP decision number complies with the format allowed in EudraCT, i.e.: P/xxx/yyyy. It is envisaged that the required data format in this field will be updated in the future release of the system.
51.	Is there a requirement to enter third country protocol related information in the EudraCT database for any 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.
52.	Are results for paediatric trials to be provided within 6 months also prior to marketing authorisation of the product concerned or does this accelerated timeline only refer to trials after marketing authorisation?	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.
53.	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.
54.	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	The requirements for posting information apply to <u>all registered clinical trials</u> with at least one investigator site in the EEA as well as to paediatric and non-paediatric trials

Item no.	Question	Answer
	EEA?	included in an agreed PIP, even if they are conducted outside the EEA.
<b>55.</b>	If my third country file previously uploaded requires amendments what should I do?	Go to the EudraCT public site, load and edit your current XML file and upload the revised XML file to EudraCT.
<b>56.</b>	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.