EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraCT Training 30th Oct 2014 – Question and Answer

Q1: Do we even have to include CT in the paediatric population when performed between 2004 and 2007?
A1: Yes, if the paediatric trials are included in an agreed PIP

Q2: How far in time do we need to go back to publish results of "old" trials which ended before 21/7/2013
A2: Results can only be provided for a trial that has been submitted and is registered in EudraCT. This applies to trials which include at least one site in the EU as clinical trials conducted in third countries which are linked to European paediatric drug development.

Q3: "Draft can be changed at any time", but categories or end points cannot without losing all data, is it right?
A3: Yes it is correct.

Q4: If attaching a summary only for an applicable CT is there any information required in the tabulated section, i.e.: under trial description?
A4: Summary report should contain all the information regarding the study (study design, Sponsor information, study phase…)

Q5: One of the possibilities for automatic assignment is to have the e-mail listed as applicant in the CTA - but does that have to be in the last submitted CTA for the country? I.e. if our e-mail was listed at a certain time point and then replaced by another at a subsequent submission, can that person (previous applicant) still be automatically assigned?
A5: For the automatic assignment the system checks whether the user matches the email address which appears in any CTA versions.
If the system cannot find this match then the user has to follow the process of the trial assignment via letter.

Q6: What is the rationale to upload results for phase 1 trials in adults which, however, are not published?
A6: it is a requirement as stated in the European Guideline 2008/C 168/02 Art. 3 http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf and this enables national competent authorities to view the results and it is his is clearly stated in the

Q7: Do comments from member states need to be addressed to have results posted?
A7: Sponsors can only post validated results. There is a timeframe of 15 days between the time the results are posted and before they are made public.

Q8: To gain access to CTs via protocol (vs. letter), does the actual individuals name who is making the request need to be listed in the CTA?
A8: it is not required that the individual name and email address is documented on the CTA if the request is made through the upload of a letter.

Q9: We have a EudraCT number but the system says it does not exist. The help desk has researched it several times and the system still says it does not exist. What can be done in this case?

A9: It could be that the Sponsor has not submitted the CT Application to the National Competent Authorities and in this case the trial is not present in EudraCT.

Q10: How do we access the EudraCT database to look for registered clinical trials?
A10: The information on registered/authorised clinical trial is accessible via the European Clinical Trials Register https://www.clinicaltrialsregister.eu/ctr-search/search

Q11: How would member states submit questions and how would we receive feedback on the answers to those questions (including those asked by other member states)?
A11: the national competent authority would contact the sponsors using the same route as the one they have used to contact the sponsor during the assessment or the supervision of the trial.

Q12: What about trials that were registered in EudraCT but never started, i.e. no patients were included in the trial? Are there any results to be provided? If yes, what would the contents be?
A12: for these trials, if an attachment only can be provided, then this explanation should be provided in the attachment. For the other trials that may not have completed, then the sponsor cannot provide any data as the data model is not suited to trials that have not started.

Q13: Could you confirm that it takes 25 WDs to request assignment to trials for the purpose of posting results?
A13: Yes, as per recent update, it takes 25 WDs for the registration team to process the request and provide an approval/rejection to the request for trial assignment.

Q14: For withdrawn studies or early terminated studies, is there any specific process?
A14: for these trials, if an attachment only can be provided, then this explanation should be provided in the attachment. For the other trials that may not have completed, then the sponsor should provide the data that were collected in the result data model.

Q15: Is there a link between this new EudraCT process and ICMJE Publication (as with ct.gov)?
A15: The sponsor has the possibility to provide a PubMed reference in the result datamodel

Q16: On CT.gov you can list a collaborator, is there any place to list this in EudraCT?
A16: There is a provision for the sponsor to list the public contact and scientific contact point with also other co-sponsors.

Q17: Regarding compliance with posting deadlines - will this be defined by the date of sponsor posting or the date the results are finalised?
A17: It is when the results are posted.

Q18: At which time point do we need to register a 3rd country file in preparation for results posting in case we are not sure if subjects under 18 years will ever be included?
A18: The PIP study regardless of the population included should be registered as soon as possible.

Q19: Can you clarify whether a study would be considered paediatric if a paediatric patient was included in error?
A19: if the paediatric subject was included in error, the trial is not to be considered a paediatric trial.

Q20: Are the results released to the public before product is approved?
A20: the provision for posting results in EudraCT is irrespective of whether the product is authorised or not.

Q21: With regard to the attached summary - does that get uploaded to EU CTR as well, i.e. it will be made public so should be redacted?
A21: The attached summary is made public in the EU CTR. The document may be redacted if needed.

Q22: If you begin populating the full data set, can you subsequently revert to synopsis only?
A22: It is possible to choice to post only the synopsis although data have already been provided in the structured data model.

Q23: Which languages will be accepted, in particular for finished (old) studies where no English synopsis is available?
A23: It is recommended that if not provided in English, the attachment be in the language of the country where the trial was conducted and the language be an official language of the EU.

Q24: Will all results entered in EudraCT be accessible thereafter via the clinical trial register?
A24: All phase trial results have to be provided but only phase II to IV will be published in the Register. Phase 1 trial results won't be published as per the European Guideline 2008/C 168/02 Art. 3.

Q25: 85 years and over is new age range compared to CTA.
A25: Yes, this is correct. The age range has been updated further to consultation with patient groups.

Q26: Can you confirm the timeline, i.e. 12 months following trial end, is that the LSLV? If so, what about oncology trials which may have a 2-3 year safety follow-up, is it 12 months from the end of the follow-up?
A26: In most cases the end of the trial date corresponds to the LSLV. However, the EOT may be described in a different way in the protocol and the EOT notification should be done following the procedures described in the protocol.

Q27: Is it mandatory to set up subject analysis sets?
A27: No, subject analysis set is optional and it to be used at the discretion of the sponsor.

Q28: The statistical analysis detail - does this need to be completed for EVERY endpoint, including exploratory?
A28: The functionality is there for the sponsor to complete but is not mandatory.

Q29: For phases 1 trial, within group analysis is performed thus only one arm participates in the statistical analysis but this creates an error. How can we deal with this issue? Do we have to disclose such analysis?
A29: this reporting requirement needs to be further analysed.

Q30: Can we upload SAE and AE tables instead of filling in the form manually bearing in mind there could be hundreds of AEs.
A30: Yes, there is an option to upload an XML file only for AE/SAE.

Q31: When reporting statistical analysis for cross-over trials, the number of subject analysed is automatically computed by the system which is usually double the number of patients actually analysed. Could this be amended?
A31: this particular functionality needs to be further examined.

Q32: "Component categories List have invalid value expression null" Why do we get this when removing categories from the list? When we receive this message the only thing we are allowed to do is logout, any way to prevent it?

A32: we recommend that you contact the EudraCT service desk EudraCT@ema.europa.eu to report such issue.

Q33: Typing in data manually has a high risk of mistakes. Is there any possibility of uploading data? When saving the draft file which format is it - xml file?
A33: Yes, there is an option to upload an XML file which includes the data.

Q34: For oncology studies it is very common that the number of subject that completed the trial is 0, yet again this creates an error within EudraCT, how can this be solved?
A34: This particular functionality needs to be further examined as it appear that the completed field does not allow for the number "0" to be included.

Q35: What is the minimum time you estimate for completing the full data set for a simple trial?
A35: It depends on the type of trial and the number of SAE and AE that need to be reported.