General

Q1: Can the results still be edited when status is "finalised"?
A1: Yes and the functionality is "update" and a new draft version is prepared based on the last version finalised.

Q2: How are trials assigned to a primary user?
A2: Process to become a results user can be found following this link https://eudract.ema.europa.eu/document.html

Q3: Can there be only 1 back-up user? What about preparer and preparer/poster, can there be several people assigned to those roles?
A3: The primary user can assign one back up user and as many as necessary preparer users and preparer/poster users.

Q4: Can a results user be automatically assigned if his/her e-mail address was entered in section C.1.5.1.1.of the Annex 1 form?
A4: The automated assignment based on protocol information applies to the following fields: B1.6, B.2.6, C1.4.6, C.2.5.6.

Q5: Do we have to post the CSR synopsis for old trials on the EudraCT database?
A5: Requirements to post summary attachment are clearly stated in the document using the link below.
https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting.pdf

Q6: Is it still required to submit CSR for trials that ended on or after 21 July 2013 and for which we are posting the results on EudraCT?
A6: Sponsor can start entering the results related data at any time once they have been assigned the trial and they should post the data in EudraCT according to the timing described in the EC guideline which applies after the end of trial.

Q7: How do we get access to the UAT environment?
A7: The EudraCT training environment is available using the following URL: https://eudract-training.ema.europa.eu/

Q8: How do we claim trials conducted by other sponsors if trials/products have been in-licensed (and vice versa)?
A8: When providing the trial assignment via letter, the "new" sponsor should provide evidence of such a claim as an attachment to the assignment letter.

Q9: Once we attach the CSR Synopsis and submit it in EudraCT, do we still need to submit to other Competent Authorities & Ethics Committees?
A19: as described in section 4. Of the commission guidance on results, the posting of the results in EudraCT is considered as the submission of the clinical trial summary report as part of the end-of-trial-declaration to national competent authorities as set out in Section 4.3 of the detailed guidance CT-1.

Q10: How to update the applicant if emails have changed for sponsor/local contact/legal rep after the last submission (amendment or EoT submission)
A10: The sponsor can prepare an update to the initial application and submit it to the relevant national competent authority (ies).

Q11: I understand the data will be prepopulated from the CTA of the first country that uploaded the CTA in EudraCT, but will the data be prepopulated from the first CTA uploaded in that country or the last (in case fields were updated with amendments and revised CTA submitted)?

A11: Data prepopulated come from the country which first approved the trial and the latest CTA information are uploaded in EudraCT.

Q12: If we have already submitted a CSR between July 2013 and July 2014, do we need to go back and post the results in EudraCT?
A12: Yes, all trials registered in EudraCT need eventually to display results.

Q13: Is it correct that only the fields with a red asterisk are mandatory to be filled?
A13: Yes, correct. However some fields may be conditionally required and would need to be completed in some cases.

Q14: Do data in all fields become public or only some of it?
A14: All data provided in relation to CT results are published on the EU Clinical Trials Register.

Q15: Are there any plans to pull at least the product information in from the existing application (XML) and then amend if required. This data already exists
A15: The product information should be entered in the results data model and cannot be extracted from the CTA information as period/arm are not provided.

Q16: The Commission Guideline 2012/C 302/03 states under section 4: … Moreover, this posting is considered as the submission of the clinical trial summary report as part of the end-of-trial-declaration to national competent authorities as set out in Section 4.3 of detailed guidance CT-1…
Does this mean that the sponsor submits to the competent authorities only the end-of-trial declaration but uploads results-related information on the EudraCT database displacing the need of submitting the summary report one year after end of trial to the competent authorities? Does this apply to Phase I as well as to Phase II-IV trials?
A16: This is correct and also applies to phase 1 trial.

Q17: How should be dealt with for clinical trials that ended prior to the 21 June 2014 for which the sponsor is not in business any more (e.g. due to liquidation, insolvency, mergers, etc.). To whom is imposed the obligation for posting of clinical trial results in such cases?
A17: The obligation to post results remains and the new sponsor who has taken over the trials has the responsibilities to provide results-related information.

Q18: In cases where the sponsor has its registered business outside the European Economic Area, would obligations be imposed to the legal representative in the sense of Art 19 of Directive 2001/20/EC, even if the sponsor is not operational any more for whatever reasons or if the contractual agreement between the sponsor and the legal representative has ended before?
A18: If the trial has at least one site in the EU/EEA the new sponsor becomes the legal responsible party to provide results-related information.

Q19: Which sanctions might be applied by Member States and/or the EMA in case clinical trial reports for clinical trials that ended prior to the 21 June 2014 would not be provided and what would be the legal basis for these?
A19: The member states regulations should be consulted to check the sanctions that may be applied.

Q20: Is it correct that pivotal studies in adults that are completely conducted outside the EU/EEA are not to be uploaded to EudraCT, even if these are part of an EU Dossier? Can the EMA confirm that the mentioned studies are out of scope of the Commission Guideline 2012/C 302/03?
A20: Only interventional clinical trials on medicinal products with at least one clinical trial site in the EU/EEA and outside of the EU/EEA if they are part of a PIP (Paediatric Investigation Plan) are to be included in the EudraCT system. Adult trials conducted

completely outside the EU/EEA and that are not part of a PIP do not fall into the scope of Directive 2001/20/EC.

Q21:Are clinical trials (non-paediatric) which started before the implementation of the directive 2001/20/EC into national law (e.g. phase I study started in 2003 in Germany, implementation into national law took place end of June 2004) but ended afterwards (for the very same study in 2007) in the scope of the Commission Guidance 2012/C 302/03)?
A21: any trials (and not in scope with the paediatrics regulation) that have not been registered in the EudraCT database are not in scope the Commission Guidance 2012/C 302/03).

Q22: Are we obliged to submit results from bioequivalence studies as well?
A22: Sponsors have to provide results for all trials registered in EudraCT including phase I BA/BE studies with healthy volunteers.

Q23: Which date is used regarding the compliance deadline, the posting date or the finalisation date?
A23: The posting date

Q24: In case of interim and final analyses (i.e 2 different reports) does the completes results cancel/replace the firsts results of the interim analysis previously entered or is there a way to manage this
A24: No, both reported results would be published. The more recent one would appear as "current".

Phase 1 and paediatrics studies

Q25: How can Phase 1 CT results be provided?
A25: Sponsors should provide results for all phase 1 clinical trials registered in EudraCT in the same way as for any other trials. Detailed information can be found on the EudraCT public site https://eudract.ema.europa.eu/document.html

Q26: How about PIP trials that are conducted in third countries? They do not have CA/IEC opinion in the EudraCT system. Do the results still get published?
A26: Paediatric interventional clinical trials that are part of a PIP and exclusively conducted in third country (ies) are uploaded in the database by the PIP addressee and would not have CA/IEC opinion. However, results are to be provided in the same way as for any other trials.

Q27: Do Sponsors need to provide structured data for all paediatric populations or just PIPs?
A27: Refer to the following document
https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting.pdf

Q28: What is meant with Phase 1 study in adults (not part of PIP): are they published? Do I read PIP as paediatric implementation plan?
A28: Sponsors have to provide results for phase 1 trials in adults in the same way as for any other trials registered in the EudraCT database. Phase 1 trials in adult are not public. Therefore the results will not be made public but are available to National Competent Authority. PIP is Paediatric Investigation Plan.

Q29: Phase I studies: Is it correct that although results of phase I studies will not be published sponsors need to post the result-related information? Is it correct that national competent authorities uploaded the protocol-related information of these Phase I studies upon approval and that as soon as sponsor starts posting the result-related information the protocol-related information will be uploaded automatically so as to facilitated the entry of the results by the sponsor?

A29: Yes, both assumptions are correct. As per the Commission Guideline 2012/C 302/03 results related information for all trials in EudraCT have to be provided but phase 1 trials won't be made publicly available. In addition, the system has been developed in such a way that the protocol-related information will be automatically uploaded in the results from the CTA.

Q30: Studies Art 45 is to be submitted based on structure data or attachment only?
A30: Paediatric trials in respect of products covered by an EU marketing authorisation and completed by 26 January 2007 are in scope of EudraCT. A study summary should be submitted to the EudraCT for publication.

Q31: For 3rd country PIP studies, do we need to upload the protocol registration details prior to uploading the results, or can we provide both at the same time?
A31: In accordance with the European Commission, a third country file should be submitted no later than one month after, either the European Medicines Agency 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. 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.

Q32: Is submission of results to Paediatrics a separate concept, not considered the same as the submission to competent authorities, and thus not covered by the Guidance statements about submission of results via EudraCT? So for instance, if true, then PIP trials and Article 46 trials also need to submit results at least twice…
A32: The submission of results to competent authorities for assessment and the submission of results for publication in the European Clinical Trials Register are two different things. The requirements for the latter (i.e. publication) are set out in Commission Guideline 2012/C 302/03 and in the documents called "Modalities and timing of posting…".
The requirements for submission for assessment are mentioned under points 4 and 5.

Q33: Although Article 45 results were supposed to be submitted by 27 Jan 2008, submission requirements were postponed until recently. Is there a timeline and/or deadline for submission of Article 45 results for assessment, since the "Trial results: Modalities and timing of posting" would be misleading?
A33: The submission deadline for Art.45 studies for assessment by the competent authority was 27 January 2008. This deadline has not been changed. Please see link here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000038.jsp&mid=WC0b01ac0580025ea5
However, the deadline for submission for is set out in Commission Guideline 2012/C 302/03.

Q34: I thought Article 46 results submissions for assessment had been delayed, similar to Article 45. Maybe I really missed the boat on that one. But if not, and submissions are only recently required, is there a timeline and/or deadline for their retroactive submission (where applicable), since the "Trial results: Modalities…" is about EudraCT?
A34: The Art.46 study data should be submitted for assessment by the competent authority within 6 months of their completion. If the deadline has been missed it is recommended to submit the data as soon as possible.
For queries related to study format submission, depending on whether it is for centrally authorised or mutual-recognition, decentralized and nationally authorised medicines, please refer to
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000038.jsp&mid=WC0b01ac0580025ea5 and the following section:

"Article 46 requires marketing-authorisation holders to submit information on studies conducted in children of authorised medicines that have been completed since the Paediatric

Regulation came into force on 26 January 2007 and are sponsored by the marketing-authorisation holder. Information must be submitted within six months of completion of each study. Information on how to submit these studies for centrally authorised medicines is available on Article-46 paediatric study submission: questions and answers. For mutual-recognition, decentrally and nationally authorised medicines, see the
Best practice guide Article 46 - European Union worksharing procedure."

Q35: There is no mention of exclusion for those Article 45 studies that have already been submitted for inclusion in the Article 45 Paediatric Studies database, which are also already disclosed in the EU CTR. Is this an oversight, or do MAHs need to resubmit these files if not part of a PIP?
A35: Only those Article 45 trials which are part of an agreed PIP need to be posted to EudraCT (with the full dataset) even if they have been submitted for publication in the Article 45 database previously.

Q36: I thought EudraCT had been updated to support the direct submission of Article 45 results files, reducing the burden for the Paediatrics group in managing submissions. If so, is submission by email to make it easier for MAHs, or is EudraCT not equipped for Article 45 results "standalone" submissions?
A36: Unfortunately there were no resources to build this functionality into EudraCT. Therefore, any submitted Article 45 results will be uploaded to the system by the Agency. (Exception: Article 45 results of studies that are part of an agreed PIP are to be posted to EudraCT by the PIP addressee.)

Q37: If Article 45 results have not been previously submitted AND are included in a PIP, must the results be emailed to Paediatrics in addition to submitting protocol and full results via EudraCT?
A37: From a practical point of view it would seem reasonable to only post the results to EudraCT (full data set) in such cases. However, the results also need to be submitted to the Agency for assessment.

Q38: Are clinical trials which fall under Article 45 and Article 46 of regulation 1901/2006 and started before 2004 (these studies where classified retrospectively after approval of the bio-similar by EMA as Art. 45/46 studies) in the scope of the Commission Guidance 2012/C 302/03?
A38: Yes, please refer to the modalities and timing of posting document on the EudraCT website.

Trial Information

Q39: Trial Information Page: we need a "justification" for validation error messages or "unknown/missing" field to reconcile when age group breakdown info isn't available for all enrolled participants?
A39: A justification has to be provided in case a warning message has been detected during the validation of the results. The comment entered by the Sponsor as a justification will be published along the results in the EU CTR further to posting.

Q40: There is not a field for "State". Should we enter state with the city/town?
A40: The "State" is not required in the address. However, the user can provide further information in the field "city".

Q41: Is final analysis date equal to last subject last visit date or the date of the final CSR?
A41: LSLV corresponds to the End of Trial date and the date of analysis to be reported is the date for the cut-off data point for the reported analysis.

Q42: If we are reporting data up to a final date that occurs AFTER the primary completion date, do we need to select "No" for that field?

A42: In this scenario, it is not the analysis of the primary completion data that is being provided and question "Is this the analysis of the primary completion data? should be answered "no".

Q43: Do we need to list all countries worldwide separately or just EEA countries?
A43: The list of the countries where the trial was conducted should be provided even if outside of the EEA.

Q44: What options do we have if we do not have age breakdown info for all enrolled patients? You currently get a validation error message if that is the case. Are there plans to add a justification field for this section?
A44: In the section protocol information, the age breakdown categories are the ones from the CTA form. It is recommended that the age range breakdown categories be populated as accurately as one can determine.

Q45: Should date of analysis be 'database lock date' in case of final analysis?
A45: The date of analysis to be reported is the date for the cut-off data point for the reported analysis.

Subject disposition

Q46: Does the reason for non-completion need to be included for each patient that did not complete the treatment?
A46: A reason for non-completion has to be provided for each subject that would not have completed a period.

Q47: If there is a Phase1/Phase 2 study, how to report the subject disposition as the subjects in each phase are unique. This can be done by creating 2 periods while reporting in ClinicalTrials.gov, however, here if these are reported as 2 periods, there is no option to report baseline for overall subjects. Instead we can report the baseline only for first period as it is automatically populated as number of subjects while reporting baseline. Please guide how to deal with such cases.
A47: The user can prepare a subject analysis set and report some baseline characteristics for this additional reporting group.

Q48: Baseline data in some studies is available for treated participants but not for started (randomized). Please suggest if it is okay to report the treated as started so that they can be selected while reporting the baseline characteristics?
A48: The user can prepare several periods and select the one for which they are able to report the baseline characteristics.

Q49: Is it true that if we have 3-way cross-over study, we can report only one overall period?
A49: There are several ways to report cross over study 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 subject 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 subject who started and the number who completed:

Option 3: One overall period could be used to detail the design and arms. In this case, when providing subject disposition, the fact that the arm are not mutually exclusive should be

ticked as yes. Each arm should document the number of subject who started and the number who completed:

Q50: What do you do if you have really separate baseline periods; for example in multiple-period DDI studies?
A50: The data model is provided in order for the user to report the summary results. The user should use the current functionalities in order to best report the summary results in an informative way. A subject analysis set could be created for the need to report baselines characteristics for an additional group of subjects.

Q51: Are there any plans to add a selection field for the route of administration and pharmaceutical form fields so you can start typing the name and not have to scroll through the list?
A51: This suggestion will be further considered

Q52: In the Baseline Characteristics section there is an option to enter data for a subject analysis set. For a 2-arm study it would be more standard to enter the data for the analysis for each arm, rather than for the total analysis set. Is this possible?
A52: It is recommended that for a 2 arm study, the user provides in the subject disposition section, the period including the arm to enable the reporting of the baselines characteristics that can be reported per arm for the all period.

Endpoint

Q53: In the Endpoints section, it would be good if the user could reorder endpoints and categories within tables, as well as being able to copy/duplicate Endpoints. Any plans to add?
A53: This suggestion will be further considered.

Q54: There is also an issue with revising endpoint parameters in a saved endpoint (Countable or measurable endpoint, Countable units, Measurable units, type, or precision/dispersion type, categories). Parameters are greyed out after saving and the only way to change is by unchecking the "Ready for collecting values" box, thereby deleting all entered data in the table. Is there a way around this or a plan to change this? This makes editing one's own record extremely time-consuming.
A54: There is no work around this functionality. All endpoint parameters should be defined prior to collection of data.

Q55: When creating subject analysis set under an endpoint, the subject analysis set appears in the baseline characteristics. Is it acceptable not to report baseline characteristics for a subject analysis set since we have already reported baseline characteristics for all randomized subjects?
A55: Yes, it is not necessary to report baseline characteristics for a subject analysis set although it has been created and use for in the endpoint section.

Q56: If the arms for reporting endpoints are different from the arms used for reporting baseline characteristics, how do we add arms to the endpoints as we can only select from already defined arms?
A56: Additional reporting groups can be created with the functionality "subject analysis set" and the endpoint results can be reported for that particular group prepared.

Q57: For endpoints, are the requirements the same as for ct.gov in that we have to report primary and secondary endpoints identified in the protocol only? Any exploratory or tertiary endpoints are not reported?

A57: The user should use the current functionalities in order to best report the summary results in an informative way. If several endpoints including primary, secondary and other should be reported, then the functionalities are there to enable the reporting.

Q58: Do we have to enter data information related to the endpoint of a sub-study?
A58: The user should use the current functionalities in order to best report the summary results in an informative way. Data related to a sub group of patients in a study can be reported using the result data model.

Q59: Please review the entry of data values when both 'reporting group' and 'subject analysis set' are selected. (It appears that the same data would then need to be added twice--once for reporting groups and once for the subject analysis set, which seems confusing).
A59: The user has to select the reporting group based on information already entered in the subject disposition section and in the subject analysis set if one was created. Then the values should be reported for the groups selected.

Q60: I see a section for 'charts' where you have the ability to add figures, etc, in which situations would you do this? When is it acceptable or desired?
A60: This functionality is provided in case the user would like to further illustrate the reporting of the results.

Adverse event

Q61: What is the current version of EUTCT code list for MedDRA system organ class used with AE section of XML?
A61: The current version of EUTCT Version is 5.8.5.

Q62: What is definition of "Total number of deaths resulting from adverse events" under Arm AE summaries---does this refer to drug-related deaths?
A62: Yes, this is correct

Q63: It will be impossible to enter SAEs on an individual basis for certain disease sites as there could be 100's per trial. How can we handle this issue?
A63: The user should use the current functionalities in order to best report the summary results in an informative way.

Q64: What if, especially for the older studies, you do not have a separate analysis of non-serious adverse events? How this would be addressed/handled within the record?
A64: The user should use the current functionalities in order to best report the summary results in an informative way and report on non serious adverse events and serious adverse events if the result data model is used to report the results. Otherwise for older trials that do not include a paediatrics population then the submission of an attachment is sufficient.

Q65: MedDRA version is mandatory for AEs, however there are studies where the version may not be available, how to deal with such cases?
A65: The user should use the current functionalities in order to best report the summary results in an informative way. When the data model is used to report the results, the type of dictionary (MedDRA, SNOMED or other) should be indicated as well as its version. Note that the dictionary type and version can be amended for each AE/SAE as required.

Q66: Can we report the total number of adverse events including SAE for NSAE?
A66: This is not the concept presented in this data mode. Non-serious adverse event do not include numbers related to SAE.

Attachment and download

Q67: Is it acceptable for a Sponsor to redact CSR information that is considered as commercially sensitive for 'old studies', prior to posting this information as an attachment?
A67: Yes it is acceptable.

Q68: Can we produce a Word or PDF document of the entire results record so we can send to the team for review and approval without going through the system?
A68: A pdf can be downloaded from the system. This document can be used for QC internally at the organisation before the results are submitted.

Q69: Can you use the download xml for upload (with some modifications to the record in the xml)?
A69: There is an option to upload XML and download XML.