EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Q&A – EudraCT – Results Webinar #6 – session 24 February 2016

Q1: Are you adding this updated timeline into modalities document? Even if this revised timeline is temporary still it will be highly beneficial and crucial to add to modalities document because the external researcher will refer to this on compliance matrix.

A1: It is not our current intention to add the timelines for this incident to the Modalities and timing document. Where revised timelines have been invoked, there is a note in the system that states that the trials are compliant with those revised timelines, referencing the period that the system was not available.

Q2: Why you are using "this" version? Why not current version? Label states "this" version in the public but it should be labelled "current" version.

A2: "This" version has been selected as subsequent versions, which would then become current, would not be affected. The messages have been designed to make clear the versions which have been affected.

Q3: In a message from EMA (which arrived late in January 2016 in an excel table), we have received a message to clarify some text within a study result entry. It has to do with an explanation of a missing patient from a particular treatment arm. The reason has the ID 22737 and ID 7478. There is no explanation what these IDs stand for. Where could we find the explanations for the reason ID?

A3: These IDs are the internal primary keys of the entries. They are included in case there is a need for technical follow-up with the EMA technical team in specific instances. From the duplicate identification perspective, the EudraCT number, period title, arm title and non-completion reason text are considered to be enough to identify the entry.

Q4: Is there an issue with the EUDRACT database with regard to validating the entry, while entering the data. I have experienced today in particular a problem when validating the data. The database either crashes on me and I have to re-enter my credentials or I stay on line but am on the first page. Is there any workaround?

A4: Please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the XML being uploaded into the system, a screenshot of the validation errors (if available), and a visualisation of what the correct representation would look like.

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Q5: Can primary user/back-up user has functionality to bulk assignment of records to a user?

A5: No. Assignment of users is on an individual and trial by trial basis.

Q6: Can a primary user assign more than one backup user?

A6: No, only one primary user and one back up user per trial.

Q7: Also, [we] would like to have a search box in the Draft screen of [the] user assignment page. This functionality currently exists for the Finalized/posted screen.

A7: Implementation of this functionality constitutes a change to the system. The request will be recorded and considered in the context of development scheduling according to priority and availability of development resource.

Q8: Can a Sponsor primary user assign a back-up in a CRO?

A8: A primary user has the duty to administer the users and manage their access to a trial on behalf of the sponsor. It is the responsibility of the sponsor to identify a suitable primary user and there is no business rule that requires a primary user or back-up user to be a sponsor staff member.

Q9: For those trials for which the submission deadline on EudraCT has been postponed due to the recent unavailability of EudraCT (originally results should have been posted on e.g. February 15, 2016, but that has now been postponed to 13 July 2016), should the sponsors in addition submit the clinical trial summary reports (CTR synopsis) to the competent authorities and ethics committees within one year of the end of trial (i.e. by February 15, 2016 in the above example) in order to comply with the 'Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)'?

A9: It is recommended to liaise with the national competent authority of the countries where the trial was authorised in order to ascertain their national requirements.

Q10: What is the preferred method for adding a back-up user where a trial is now in finalised status?

A10: By creating a draft version, the primary user will be able to assign a back-up user to the trial. There is also an option to ask the service desk to assign a new user.

Q11: Is there any guidance given on minimal expected dataset for early terminated studies?

A11 There is currently no guidance on the provision of results reporting for trials that have ended early. As it stands, there is no functionality in the EudraCT system to enable the Member State/National Competent Authority or the sponsor to indicate that no results are provided because the trial has ended early. It is recommended that sponsors liaise with the national competent authorities of

the member state(s) that have authorised the trial when reporting the early termination indicating whether summary results in a structured form can be reported to EudraCT.

Q12: Please can you repeat again for which studies justification wording needs to be provided if timelines were not met?

A12: Two categories of trials are affected:

- Results sets that fell due in the period that the system was closed (31 July 2015 to 12 January 2016)
- Results sets that fall due in the two months following re-opening of the system (13 January 2016 to 13 March 2016)

Q13: Regarding the upload of results summary: Can one run into problems regarding publication of the results in peer reviewed journals when the results have already been published in EudraCT and vice versa?

A13: The obligation to submit summary results to EudraCT is laid out in 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; (2012/C 302/03). The intention is not to impede the peer review of scientific articles or their publication.

Q14: For the total number of subjects with non-serious AEs, should the number be the total number of subjects experiencing a non-serious AE in the trial overall or the number above the specified threshold of reporting?

A14: The number of subjects experiencing non-serious AE should match the number exposed for the reporting group. Therefore, it is the number above the specified threshold of reporting.

Q15: Can it be considered for future release for hyperlinks to be added from the ERRORs listed on the validation page to take user to actual page/field where the error occurs?

A15: Implementation of this functionality constitutes a change to the system. The request will be recorded and considered in the context of development scheduling according to priority and availability of development resource.

Q16: Is it mandatory to remove PII (Personally Identifiable Information), while uploading already released result summaries?

A16: Personally Identifiable Information should not be provided while uploading information in EudraCT.

Q17: How to enter a trial which was cancelled prior to enrolment of any patients i.e. no results data is available?

A17: There is currently no guidance on the provision of result reporting for trials that have ended early. As it stands, there is no functionality in the EudraCT system to enable the MS/NCA or the sponsor to indicate that no result is provided because the trial has ended early. It is recommended that sponsors liaise with the national competent authorities of the member state(s) that have authorised the trial when reporting the early termination indicating that summary results cannot be provided as no subjects were recruited.

Q18: If there is a "potential error" will the "currently produced pdf" will be sufficient in determining problems?

A18: The pdf version downloaded from the system accurately represents the data as held within the system. Comparison of the data in the pdf file downloaded from the system currently with source data held by the sponsor provides a sound basis.

Q19: If a Sponsor has 'no potentially affected results sets', is the Sponsor still required to check the results data sets in EudraCT?

A19: The Agency is advising sponsors to review all trials have been posted in the system as a precautionary measure.

Q20: If there are errors in the entry - is it possible to save the entry? The system allowed me to keep on entering further data following an erroneous entry and then not permitting me to save when I tried to.

A20: Those entering data are advised to save frequently. Where an error occurs on saving, the system notifies the user. Data input since the previous save action will then not be saved.

Q21: Will the responses be made available for the questions that you said you would reply to in writing?

A21: Yes. The written questions and answers are published on the training page of EudraCT.

Q22: If during the review of the posted results the sponsor notices an error not due to the system error in EudraCT, but due to an oversight by the results user, is it possible to post a new version?

A22: This answer applies to trials that were finalized in EudraCT – Results (or posted for finalization) as of 31 July 2016. The steps to take are:

1. Create a new version of the results set (Update option against a finalized results set)
2. Specify in the "Version creation reason" the reason that a new version is needed. This may include text such as "Correction of SAE data" or "Correct to align with submissions to [another register]".
3. Make the necessary changes, validate and post in the standard manner.
4. Using the notification described in section 8.3 of the Instructions to sponsors document, notify the Agency that an updated results set has been posted. **Include in that notification additional text informing the Agency that the new version contains amendments**

unrelated to the system errors and quote the text included in the "Version creation reason" field.

The Agency will remove the tags from any previous versions and restore them to public view. The new version, when published at the end of the two week pipeline period, will supersede any previous versions in the usual way. Any previous versions will remain available, reflecting the normal behaviour of the system. The Agency will notify the submitter that the appropriate action has been taken, using the notification format described in section 8.4 of the "Instructions for sponsors", **noting the particular circumstances of the case**.

Q23: When we say 'posted into public' please could you advise which web site or which material is referred to? I am wondering where the validated results are being posted.

A23: The EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/)

Q24: Are any particular web browsers recommended for posting of results?

A24: EudraCT – Results has been formally tested using Microsoft Internet Explorer and Mozilla Firefox.