EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Q&A – EudraCT – Results Webinar #3 – session 3 February 2016

Q1: We are facing an error while uploading XML file in EudraCT, error states - End Point: Dispersion value is negative.

A1: In this case we recommend sponsors to provide a screen shot of the error and open a call via the new IT service desk tool http://servicedesk.ema.europa.eu/jira/servicedesk/customer#portals.

Q2: For those results removed from public view, which is responsible for re-posting? Will the EMA notify individual sponsors about these studies?

A2:Please refer to the Instructions to sponsors document in which the processes are described.

Q3: What is the penalty for not publishing the 'Results' on time?

A3: A penalty will be applied at a national level from the National Competent Authorities.

Q4: What about studies due 21 July 2015 that could not be posted due to bugs in the system and then the system closed before the bugs were resolved?

A4: Where these issues have been notified to EMA, they are under discussion in the context of planning for potential future versions of the system. Compliance with submission timelines will be addressed in this context on the basis of notifications received.

Q5: While Qcing a results set for a study identified as a "Potential category issue" other revisions were identified that are not related to the system error. What are the steps to take in this situation? The following tag does not exactly apply since the revised version is not related to a system error "Due to a system error, the data reported in this version is not correct and has been removed from public view".

A5: 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]".

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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**.

Q6: Regarding approvals from ECs and CAs. Could you tell me something more about this? Does this mean that sponsors have to upload, together with the results, all approval letters? Will such letter be in public view?

A6: Sponsor does not have to upload approval letters from CA and Ethics Committee together with the results because this is not a legal requirement.

Q7: Results that are due between 14 Jan 2016 and 13 Mar 2016 that are submitted in that time frame (on time) do they need to be identified an email need to be specifically identified in an email from the Sponsor to the EMA?

A7: If the results have been provided on time as per the ordinarily applicable timelines there is no need for sponsors to notify the EMA.

Q8: Do public finalized results need to be QC'd by sponsors?

A8: The Agency is advising sponsors to review all trials that have been posted (and are therefore now finalized) in the system as of 31 July 2015 as a precautionary measure. .

Q9: Will the results of phase I/II trials be made public or are they exempted?

A9: Phase I/II trials are made publicly available following business rules for publication of trials in the EU CTR.

Q10: Have you done corrections even on results that were still in 'Draft' version?

A10: EMA is not responsible to correct data on results. Sponsors have been notified of the errors identified by the Agency and they have been asked to correct them. Some of these affected results were posted and published others were posted but not published as of 31 July 2015, which is the date of the system closure.

Q11: Can the issue about the results appearing in different order from section to section be placed on the EudraCT front page?

A11: The issue with the trials potentially affected by timestamp issues and category issues has been provided in the presentation published on the external website https://eudract.ema.europa.eu/training.html. The issue with data ordering will be illustrated in the presentation for the fourth webinar.

Q12: With regard to potential errors, a Yes is not a guarantee of an issue. Is a No also not absolute - as in there could be problems with the data? Or is a No in the column, or if you fell into category 1 from Instructions to sponsors (no potentially affected results). Is this a guarantee that the data is good and basically, no review is needed? For example of the former, could a record be identified as not affected by timestamp or category, but the new pdf data differs from the original pdf data?

A12: A "Yes" means that the data may have been affected by the relevant issue as analysis of the data showed symptoms indicating that an error may have occurred. A "No" shows that no such symptoms were identified. However, the fact that no symptoms were identified does not exclude that the trials results set may have been affected. The Agency is advising sponsors to review all trials in the system as of 31 July 2015, whether in Draft or Finalized, that have structured data in the relevant sections of the full results set as a precautionary measure.

Q13: Many of the DRAFT records in the list that was sent to the Primary User had no data entered before the system went down. Do these need to be identified in an email from the sponsor to the EMA when they are released for the first time?

A13: Where trials results were in Draft as of 31 July 2015, there is no need to inform EMA of posting for finalization unless for a first version, there is a need to highlight compliance with the revised timelines.

Q14: Are the timestamp and/or category issues likely occurring in the trials affected due to outage? Or is it affecting all the newly drafted studies as well?

A14: The identified issues should not affect newly drafted studies.

Q15: Tagging of result set - Does sponsor need to do tagging? If so, how to do it in EudraCT database.

A15: The tagging is done by EMA.

Q16: Where is the training page of the EudraCT application?

A16: https://eudract.ema.europa.eu/training.html

Q17: I have uploaded an xml and received error "validation rule "Duplicate NOT_COMPLETED_REASON. other Reason..." The cause was reason 'Screen failure' in two different sections, SD> PreAssign and SD> PostAssign. Is this an intended interpretation of the 'Duplicate

NOT_COMPLETED_REASON.other otherReason' rule or some over zealousness in the sites upload validation? I have submitted a ticket for this but do not have a response as yet

A17: The validation is operating as designed. The system works by defining the non-completed reason once, and then re-using the same defined reason as a controlled term with the same identifier throughout the rest of the results set. Where the text of such a non-completed reason (e.g. "adverse event – severe rash") is put in a second time, the system accepts re-submission of the text, but treats it as a new non-completion reason with its own identifier. This leads to display issues, particularly in tabular representations of results, where data do not line up against one instance of the text, but two, leading to comparative data being displayed on different lines. Thus taking the example of "adverse event – severe rash", the data relating to one reporting group will be displayed on a separate line from those relating to a second reporting group as the system considers each definition of "adverse event – severe rash" as a different reason.

Q18: Are there exemptions for investigator initiated trials where no one is in the position to fill out the full data set - would it be possible to only upload the trials results without filling out the full data set - and how could we do it?

A18: As per the Commission Guideline 2012/302-03 results have to be provided for all trials registered in EudraCT. Training material is provided in the EudraCT public website to support this activity. In particular the document Trial Results – Modalities and timing of posting is the main one for sponsors to know whether the trial results have to be provided as full data set or only attachment https://eudract.ema.europa.eu/result.html.

Q19: Do the results on the screen and in the pdf version appear identically?

A19: Yes, correct. The only difference is in the layout of the view mode.

Q20: Submitted trial ownership request 9 months ago...sent 3 reminders again. Are you experiencing a workload re: trial ownership request?

A20: Currently we have a queue of requests submitted in January 2016. If your request was an old one we recommend you to resubmit it because there might have been some issues when the system was down.

Q21: Will we also have some real examples shown - training session for specific type of trials? Are you planning anything like that for these webinars?

A21: This is out of the scope for these webinars. However Q&A and additional training material can be found in the external website https://eudract.ema.europa.eu/training.html.

Q22: There are several ways to try to fit cross-over trials into the system. Do you have a preferred method that you would recommend?

A22: It is up to the sponsor to provide meaningful results in the public domain. The Agency is not in a position to give advice on how to present the results of individual clinical trials.

Q23: What was the official date the system stopped functioning and when did it get back up & running again?

A23: Access to the system was withdrawn on 31 July 2015 and it was reopened on 13 January 2016.

Q24: For finalized studies [identified] a[s] potentially affected were the xml´ modified or will the[y] modified by the system when I create a new version.

A24: No changes were made to the XML schema, and no changes were made to the data held with the single exception of the script that was run to eliminate duplicate non-completion or joining reasons (See the Instructions for sponsors document). Please note the additional validation violation messages for XML upload described in the release notes for version 10.2.1.0.