



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Q&A – EudraCT – Results Webinar #1 – session 20 January 2016

Revision 1, 5 February 2016

- Answer to Q5 updated
- Answer to Q7 updated

Q1: Will the slide deck be available for download?

A1: The slide deck will be posted on the EudraCT Training page.

Q2: Can you please confirm that if no list of trials have been received, that means that the system failure had probably not affected the results already posted?

A2: A list of trials has been provided to each primary user to whom potentially affected trials have been assigned. If no list of trials has been provided, then the Agency did not identify any symptoms indicating that the data may have been affected. The fact that no symptoms were identified does not exclude that trials results sets may have been affected and the Agency is advising sponsors to review all trials have been posted in the system as a precautionary measure.

Q3: If a Primary User is no longer at a company, can their email containing the list of studies be made available to another primary user at that sponsor?

A3: If a Primary User is no longer at a sponsoring company, then either the backup user may be assigned as the Primary User and may request the email containing the list of studies, or an appropriate representative of the sponsor may request the email containing the list of studies. That representative may be another Primary User at the sponsoring company.

Q4: What algorithm did you use to identify study records with category issues ?

A4: A two step query was used: (1) Identify all areas in the results set where categories occur; (2) Identify those trials where these areas had been edited subsequent to first creation.

Q5: Is it possible that the back-up user or delegated preparer/poster of a study record send the notification email to EudraCT after posting the results?

A5: The notification email is to be sent by any EudraCT – Results User to whom the trial is assigned.



Q6: Please confirm if a study does not have a potential issue identified that QC of the results for that study is not required and we should go through the steps to make the results public?

A6: The Agency is advising sponsors to review all trials have been posted in the system as a precautionary measure

Q7: Based on the potential issues information that was given to the primary users, we went ahead and requested a new version so the writers could gain editing access to the study. However, when reviewing the results it appears that there are no issues with the study. Do I just call out that another version was created when I send the template email stating that study is ready for re-release?

A7: The new draft is left in "Draft" status with the justification "Update initiated unnecessarily; No errors found in results flagged as being potentially affected by errors in the system" and the standard process to restore the status of finalized results sets not requiring correction (using the notification set out in section 8.1 of the Instructions for sponsors) is used.

Q8: In Subject Disposition> Periods> Arms> Subject joining reasons- 'Late Recruitment' can be selected only once, as if to say, "there can only be one reason for late recruitment per arm". It seems possible there could be more than one?

A8: On top of the subjects that started initially in the reporting group, the user can account for the subjects that have joined after the initial start. In this case, the user would need to select the reason from a drop down menu. The reasons can be multiple and are "late recruitment, joined from another group, other please specify". If the user chooses "late recruitment" or "other please specify", they have to record further information in a text box. The late recruitment is the reason and additional text has to be provided.

Q9: What is the timing for notification of releases back to the EMA? How often should we send notifications for trials that should have been posted in the down time period and are currently being posted now?

A9: Notifications should be sent to EMA within 48 hours of posting.

Q10: Have there also been made adjustments to the characteristics of results sections itself? E.g. is it possible not to select a baseline period (e.g. for BE studies)?

A10: No adjustments have been made to the characteristics of results sections. Business rules and the operation of the system remain unchanged except for the addition of the new validation violation messages for XML upload set out in the release notes for version 10.2.1.0.

Q11: Is it necessary to review also results posted as uploaded pdfs (e.g. CTR synopsis)?

A11: Where summary results have been uploaded as a PDF and none of the details in the sections making up the full data set have been provided, there is no need to review the results. Where partial details have also been provided in the sections making up the full data set, review is advised.

Q12: When creating a new version, we should provide the rationale, what should be entered?

A12: "Data correction due to a system error in EudraCT – Results"

Q13: Are you aware that in some cases, there is an issue with the display of reporting groups? I noticed that for one of my studies, when I generated a PDF preview, the reporting group order was switched in the adverse events section versus the rest of the record. There was no problem or switching of the data, it was strictly an order of the display of the reporting groups. Will this be remedied in a future release?

A13: See known errors in release notes for version 10.2.1.0. The Agency is planning to remedy this issue.

Q14: Just so you are aware, when creating a pdf it is still dropping text.

A14: Where an issue is encountered, please contact the EMA Service Desk with details.

Q15: Will Q&A be available also from the coming webinars?

A15: Yes

Q16: Just to mention, if there is a way to allow a value of NA for entry it is critical to correct presentation of time to event endpoints in which the value is not reached. This is available in CT.gov.

A16: Currently, when defining the end points to be reported in a measurable fashion, it is expected that the calculations have been done for the groups reported and for all timeframes/categories selected. Values should be available when reporting an arithmetic mean, a median, a least square mean, a geometric mean or a log mean. It is not understood how "not applicable" could be reported when the user has defined that they want to report for example the arithmetic mean for a reporting group. It may be that the categories selected within the reporting do not all have values collected/calculated. In this event the user should review the reporting method used and decide to report the endpoint in such a way that all values are provided.

Q17: Is there a way to create a new version without re-entering all the data in all the 6 sections of the database?

A17: Clicking on "Update creates a draft which contains the data as contained in the finalized version ready for modification.

Q18: Statistical analysis cannot be within-groups (validation generates an error; at least 2 reporting groups must be selected). Will this be changed in the future to allow within-groups analyses?

A18: It is correct that the application does not allow the capture of a statistical analysis performed within a group or against standard practice not defined within the subject disposition. This option needs to be further analysed before it is implemented in the data model. Please note that although the functionality does not exist and that the user cannot report this particular statistical analysis, the results can still be posted and published.

Q19: Is the next webinar a follow up of this one or a repetition?

A19: The approach to each of the subsequent webinars is to review the Instructions to sponsors to the extent necessary, and then to address questions, building on the foundations of questions already posed and answered.