EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Q&A – EudraCT – Results Webinar #2 – session 27 January 2016

Q1: Will the slide deck be available for download?

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

Q2: Concerned that we are still unable to upload stats for one analysis group (which you can do in CTgov). It is important to have stats primary endpoint which gives info about the power of the study. Please could you advise when this will be implemented and what we can do in the meantime?

A2: if the trial includes only one arm or one reporting group, results can be prepared and endpoints can be reported upon for this reporting group/arm. The statistical analysis being optional, they can finalise the results. However, the limitation is with the statistical analysis which requires at least two arms/two reporting groups. The improvement of the application on this topic is currently being considered.

Q3: When will missing trailing zeros issue be resolved?

A3: The Agency is working on the current release. The next step will be to prioritise and schedule issues raised, at which time short term timing will be clarified.

Q4: We are unable to add user in EudraCT for our new team members who have created their EudraCT ID recently.

A4: If you want to add additional users for preparing and posting results you need to ensure that the other users are registered results users. Users are not available to Primary or backup users to assign to trial results unless they have been previously registered as results users with EMA.

Q5: We are unable to manage assigned users and to add other users.

A5: Please refer to the presentation published on the external website to manage users.
https://eudract.ema.europa.eu/training.html

Q6: We have issues with safety reporting. It seems that when we use a different dictionary than MedDRA we have to use SOC (but we don't have SOC identification).

A6: You can report a different dictionary as specified in the picklist or you can choose 'Other' and enter the preferred dictionary. The SOC has to be used regardless of whether you are using MedDRA or another dictionary.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5560
Send a question via our website www.ema.europa.eu/contact

Q7: What is the deadline for sponsors to send confirmation back to EMA for previously finalized results to be published again?

A7: The deadline for posting results affected by the unavailability of the system is 13 July 2016. Two situations may arise:

- A finalized results set in the system is correct and EMA is to be requested to restore the results to public view: In this case, the deadline for submission of the notification to EMA is midnight (UK time) on 13 July 2016;
- A version of the results set is to be posted – either correcting data affected by the system, or a new set of results submitted in compliance with timelines revised as a consequence of the unavailability of the system. In both cases, the requirement is that the results set is posted within the system before midnight (UK time) on 13 July 2016. EMA is to be notified of posting within 48 hours of the relevant results set being posted.

Q8: Please confirm that when a primary user has left the company a new primary user can be assigned by the backup user, and then that new primary user can send you an email requesting the list that was sent to the original primary user.

A8: Note that the back-up user can remove the primary user who left the company and become primary user. The new primary user may request the list that was sent to the original primary user.

Q9: Please confirm whether the results of Phase 1 studies are available for public viewing.

A9: As per the European Guidance 2008/C 168/02, phase I trials are excluded from publication in the EU Clinical Trials Register and the information is not available to the public.

Q10: In the documents about revised deadlines there is a gap between March and July 2016. Please could you explain this in further detail?

A10: March and July 2016 are deadlines for different things: The March deadline limits the period that defines the affected results sets; The July deadline marks the point by when all affected results sets are to have been addressed and resolved. The presentation at the webinar of 3 February 2016 presents the timeline in a different way which explains the gap.

Q11: Can you copy the data entered in the training environment into the production environment?

A11: The training environment is for training purposes only and therefore the information provided should not be transposed into the production environment. This is because identification and other elements of the data are not the same, and manual editing of the xml outside the system could invalidate the xml.

Q12: Can I alter dates in the training environment?

A12: Yes, data can be modified both in training and production environment.

Q13: Once the rationale and changes for a new version of a previously-posted study is provided, is it possible to update rationale new version is created? This refers to a finalized study where there is an option to create new version.

A13: In this case you have to create another version and amend the rationale.

Q14: You mentioned an exception to the 13 March 2016, but did not discuss it. Please clarify.

A14: The exception to the 13 March 2016 deadline is those trials categorised as to be posted ≤ 24 months after finalisation of the programming. Please see the presentation (Slide 3) and the table in section 2 of the Instructions to sponsors.

Q15: Can data be validated in the training environment?

A15: Yes, correct.

Q16: I have received validation errors for one of our studies due to missing data for the end point values for reporting groups (arithmetic mean and standard deviation). The fields were left blank intentionally as the data is not available due to early termination of the trial. The relevant table includes the following note: 'This study was prematurely terminated. No statistical analyses were completed.' Due to the validation error, I am unable to post the results. Could you please advise me how can this section be bypassed or what should be included?

A16: Please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the XML downloaded from the system, a screenshot of the validation errors, and a visualisation of what the correct representation would look like.

Q17: Justifications that were entered in the validation area have been removed during the system update. Do we need to specify that the text was added back in as part of the rationale when re-submitting and notifying EMA?

A17: This question refers to justifications entered into the system in response to questions raised by the system on validation. These justifications are retained in the system and are specific to each version of the results. They are within the system (rather than the data themselves) and tied to the version in respect of which the validation questions were raised and answered. Thus, on creation of a new version, the justifications will not be linked to that new version. When validating the new version, the same justifications may need to be repeated, unless the data have been updated or modified and no justification is needed.

Q18: The reporting groups for end points are auto populated from subject disposition. This is not appropriate for my study and I have added subject analysis sets. Is this the correct approach?

A18: The reporting of endpoints data in the application enables the user to select the reporting groups already defined in the subject disposition section or use the subject analysis set as reporting group. This functionality was developed to accommodate certain trials and it is thought to be correct.

Q19: If Primary User is no longer with organization, could back up user assign new team member as a Primary User? If yes, how we could do this, kindly guide.

A19: The back-up user can assign himself/herself as a primary user however he/she cannot assign any other users as primary user. Once assign as the primary user, he/she can manage other users and assign a new back up user.

Q20: Could you please advise how studies that are terminated prematurely are captured on the EudraCt website?

A20: The premature end of a trial is entered in the EudraCT system by the National Competent Authority (NCA) once the sponsor has submitted the End of Trial Notification form to the NCA . The sponsor can prepare and provide results at any time even if the trial has ended prematurely.

Q21: In 'posted and finalized results' section you can search and filter by the EudraCT number. Can this search tool be made also available for the listed trials in 'your page' section?

A21: EMA has to consider impact and possibility to enhance the system in this regard.

Q22: We have a study with multiple arms and some of the endpoints were assessed only in specific arms (not in all the arms). Even after adding the justification to resolve the validation errors, we were not able to release the results. The error is "The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Either resolve this issue or provide a justification". How do we resolve this issue?

A22: Please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the XML downloaded from the system, a screenshot of the validation errors, the text of the justification message, and a visualisation of what the correct representation would look like.

Q23: The training environment does not accept the EudraCT number and shows an error message that the 'EudraCT number is invalid'. Please provide guidance to assign a study in the training environment? Is a letter supporting the request required?

A23: Sponsors cannot use a real EudraCT number in the training environment. When registered in the training environment, the system assigns random EudraCT numbers to the sponsor to be used for training purposes. Studies can be assigned by the user in person directly by clicking on "*Register (only for users who want to provide results data)*" which is located under the login section. The next screen provides the necessary instructions.

Q24: Who can we contact for endorsement of 13th July 2016 in exceptional circumstances - IT helpdesk does not provide this?

A24: Sponsors are required to assess the submission date of the trial in the context of the "Trial results: modalities and timing of posting" document posted on the EudraCT website. The extended

deadlines described in the announcement on the website and in the "Instructions to sponsors" document are applied in the context of the underlying requirements. If there are queries relating to circumstances that appear to fall outside the defined parameters, they should be submitted to EMA via the Service Desk Portal at https://servicedesk.ema.europa.eu/.

Q25: The email "EU instructions for primary users" went to an associate who is no longer at our company. Please provide an update as to when the email will be forwarded and also when access of these studies will be transferred to my EudraCT account.

A25: The EMA has already contacted all registered users as well in case the primary user is no longer working for that company.

Q26: If we as sponsors haven't made any updates of the initially released data sets, then we can't have potentially affected trials?

A26: In principle, if a sponsor has made no changes to data input initially, that is correct. However sponsors have to authorise the EMA to publish those results, and edits to data while trials were in draft may have affected data.

Q27: Do timestamp issues affect data already inputted before system closure but not posted? And so should all this entered data be re-checked?

A27: Time stamp issues may affect data that is in draft. The illustration on lines 6 and 7 of the table on slide 5 of the presentation given on 27 January illustrates cases where trials that have been edited but not posted displayed symptoms that indicated that an error in the timestamp issues classification may have occurred.

Q28: Could we update the study which is in posted results section and showing only View Option; since we would need to update the data for those particular studies with updated data (safety).

A28: In this particular case sponsor has to create a new version and make the necessary amendments.

Q29: In the 'Instructions for sponsors' document - Section 8.5. Sponsor notification to EMA: Results set submitted in compliance with revised timelines: Where finalized results have been posted in respect of a results set: a) whose submission deadline fell due between 31 July 2015 and 12 January 2016 and which have been submitted between 13 January 2016 and 13 July 2016;OR b) whose submission deadline fell due between 13 January 2016 and 13 March 2016 and which have been submitted between 14 March 2016 and 13 July 2016;

for category b – what do we do when the submission deadline falls between 13 January 2016 and 13 March 2016 and which have been submitted between 13 January 2016 and 13 July 2016, NOT "14 March 2016 and 13 July 2016" as the category specifies? How do we note such cases, since there is no separate category for them listed in the template letter?

A29: The question implies that the study which fell due between January and March is submitted within that timeframe. If such is the case, compliance with the standard reporting timeframes has been

achieved and there is no need to note that a study has been submitted in accordance with revised timelines.

If, on the other hand, the study falls due between January and March, and is submitted between March and July, then EMA should be notified that results are being submitted in compliance with revised timelines.

Q30: We have a study that ended Jan 2015. Can we post the result by 13 Jun 2016?

A30: If the study ended in January 2015, the standard reporting timeframe would require that results are submitted within 12 months – i.e. by January 2016. The due date therefore falls within the period identified as "affected results", and results are to be posted by 13 July 2016.

Q31: Is there a kind of forum platform where users can exchanged their issues (and how we can resolve them) related to results submission?

A31: This has not been planned. We are providing these webinars for sponsors to share information and resolve issues with regards to result-related data in EudraCT.

Q32: We have a scenario where the number of subjects starting the extension period is not consistent with the number completing the preceding period. Even after adding the justification for the validation error, the results could not be released. Please suggest how to resolve this issue?

A32: Please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the XML downloaded from the system, a screenshot of the validation issues, and a visualisation of what the correct representation would look like.

Q33: ITServiceDesk@ema.europa.eu - when is that to be used?

A33: As of 1st February 2016 the Agency has launched the new EMA Service Desk Portal as a single point of contact for external enquiries on EudraCT/EU CTR. EMA Service Desk portal is available at https://servicedesk.ema.europa.eu. A transition period until 1st March 2016 is in place to facilitate the process in the new system therefore the ITServiceDesk@ema.europa.eu mailbox is still in place and can be used to raise calls.

Q34: We submitted a synopsis for 21st July 2015 deadline but discovered this was rejected and we needed to submit a full field results posting. We started to do this and then system went down - can we assume 13th July 2016 is our new deadline?

A34: Yes, correct.

Q35: We registered a phase II study (draft) prior to the closure of the system. Is it normal that it is not displayed on EU-CTR?

A35: Sponsors have to validate the results before posting them. When posted, it takes 2 weeks for the results to be finalised and be visible in the public domain.

Q36: Is pdf of publication enough?

A36: Please refer to the document published on the external website 'Trial results – Modalities and timing of posting ' https://eudract.ema.europa.eu/result.html.

Q37: I am yet to receive a reply. I am unable to upload study report as the EudraCT website is showing uploading through a fake path.

A37: The system has been programmed to display the message including the words "fake path" in the message displayed in the dialogue box. In the same dialogue box, once the action has been executed, the word "Done" is displayed. If these circumstances do not describe what happens when you try to upload a document, please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the document, and a screenshot of the point at which upload fails.

Q38: Do the timestamp and category errors only affect data that were uploaded in XML- so results entered manually are unaffected?

Q38: This issue affect both data which have been uploaded as XML and results entered manually in EudraCT.

Q39: Is there a training environment accessible for non-registered users? We would like to inform our teams on the structures and requirements of the EudraCT Results database.

A39: The Training environment is available to all. However, to prepare and post results, it is necessary to be a registered results user.

Q40: Regarding issue which we were facing for addition of new user for new team members, an error is occurring - A EudraCT results user with this username and email address cannot be found. Primary User only trying to add new user in this case.

A40: In this particular scenario the new user has to be registered as a result user.

Q41: Have the studies that in draft on 31 July 2015 been affected?

A41: Potentially they could be affected.

Q42: Does the rationale for a newly-created version of a finalized study get seen in the public domain after posting the new version or is it for internal use only?

A42: The update information regarding the rationale for newly-created versions is published as part of the results set on the EU Clinical Trials Register in the field entitled "Version creation reason".

Q43: Re justifications - In every study that we have checked, all of the justifications entered in the draft and posted and finalised studies have been removed. All justifications are now blank. (e.g., a primary end point without a statistical analysis requires a justification in the validation area).

A43: Please see the answer to question 17 above. If necessary, please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the version number, a screenshot of an example validation issue, the text of the justification message and a visualisation of what the correct representation would look like.

Q44: Do we have to subtract the 15 days EMA needs to post submitted results from the 13 July timeline, to ensure that the study is posted on 13 July? Or is the 13 July timeline to be understood when studies have to be submitted to EMA?

A44: The 13 July 2016 is the deadline for sponsor to submit results into EudraCT; the 15 days period is the time for the finalisation of the results into the public domain.

Q45: We have a scenario where the number of subjects starting the extension period is not consistent with the number completing the preceding period. Even after adding the justification for the validation error, the results could not be released. Please suggest how to resolve this issue?

A45: Please provide the specifics via https://servicedesk.ema.europa.eu/. Ideally, we would wish to be provided with the EudraCT number, the XML downloaded from the system, a screenshot of the validation issues, the text of the justification message and a visualisation of what the correct representation would look like.

Q46: How can a sponsor give approval that we are happy to move studies from draft to finalised.

A46: The system allows for the download of PDF and the assignment of delegated users. Sponsors may use either of these features to make available the information for internal approval. Once that approval has been given, "posting" the results moves the studies from draft to finalized. Finalization and publication (unless exempt from publication) follows two weeks after posting.