EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Q&A – EudraCT – Results Webinar #5 – session 17 February 2016

Q1: Do we need to send these notification to EMA per study or can [a number] be clubbed together in one mail?

A1: Notifications may be sent singly or grouped as suits the sponsor. EMA has stipulated that such notifications should be sent within 48 hours of posting.

Q2: Generally speaking, what happens to a sponsor if it doesn't observe the deadline established by EMA for errors correction / communication to EMA (July 13th 2016)?

A2: Penalties will be applied at a national level according to the National Law of the Member States concerned.

Q3: This is with regard to retrospective result submission. There could be instances that studies in question are very old for the Sponsor, or due to various company acquisitions that might have occurred in past, source documents are unavailable for results to be submitted as per EMA guidelines. Kindly guide us on the scenario for such retrospective studies for which results cannot be summarized by a Sponsor.

A3: Such retrospective submissions fall into two categories: Those for which details are held within EudraCT as a consequence of the application of Directive 2001/20 (EC), and those that are not. Full details are required for the former; no results reporting is required for the latter.

Q4: If a study was due by 21 July 2015, but the sponsor was going to submit within the additional 3 month grace period but then the system error occurred, what would happen in that case? Would that study have a revised date as 31 July 2016 as well?

A4: There was no additional 3 month grace period in operation prior to 31 July 2016 (the date the system became unavailable).

Q5: Where is the Instructions for sponsors document referred to in your slides?

A5: The Instructions for sponsors document has been sent to all primary users to whom trials were assigned at the point at which the system became unavailable.

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Q6: Is it possible to assign a new backup user to multiple or all trials at once via the service helpdesk? Would it be possible to assign more than 1 backup user per trial?

A6: (1) It is not possible to assign a backup user to multiple trials at once via the Service Desk. (2) More than one backup user may be assigned to a trial and sponsors are highly encouraged to use the automated assignment features in order to gain assignment quickly and efficiently.

Q7: Rerunning a validation report after leaving a study record and then returning, identifies several "incomplete" errors across many fields (blinding implementation, recruitment details, limitations and caveats) that did appear upon the first validation. Study record data was not changed in the interim. This affects several of our records.

A7: 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.

Q8: We understand that arm-shuffling issues are still there, although data remains intact; upon raising tickets or may be upon sharing xml - can it be sorted out?

A8: This issue is not one that can be corrected on a case-by-case basis. Resolution of this issue is under consideration in the context of development scheduling according to priority and availability of development resource.

Q9: What can be done if a validation message comes back for an endpoint that has incomplete values? for example, if one of the study arms had an N of 0 for a particular PK endpoint?

A9: 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.

Q10: In case the results are delayed on EudraCT due to delay in generation of the source document (CSR), is there any provision to provide any justification to EMA, as there is provision on Clinicaltrial.gov?

A10: In the event of delay in the provision of the results, it is recommended that the sponsor liaises with the national competent authorities of the country(ies) where the trial was authorised. In the EudraCT results database, the sponsor may wish to include a statement in the section limitations and caveats.

Q11: For the current version of the EudraCT, is the statistical analysis accepted for a single arm study, as in the previous version it was not accepted?

A11: No new functionality has been added to the system in this release. Statistical analysis results in the circumstances described cannot be submitted as structured data and a document can be uploaded in the section “endpoint” if required.