



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Q&A – EudraCT – Results Webinar #4 – session 10 February 2016

Q1: If a study is removed from public view and in EudraCT database under finalized section, study status is "VIEW". How to proceed for such studies? If we need to do any update, how we could make it?

A1: If there is a need to update the study, the standard process using the "update" link in the column on the far right of the tabular representation should be used. Clicking on the "update" link creates a new, editable version on the basis of the last finalised version.

Q2: Can I replace a primary user by the assigned backup user or any other registered results user or can this replacement of the primary user only be carried out by EMA?

A2: Primary user re-assignment can be managed by either the primary user or the backup user. The only time primary user re-assignment has to be carried out by EMA is when only a primary user has been assigned to a trial, and that primary user is no longer able to access the trial.

Q3: Where in the system can due dates and tags be seen?

A3: Due dates are not displayed within the system. Due dates are calculated by reference to the "[Trial results: Modalities and timing of posting](#)" document. For the tagging, please see the relevant slides from the webinars run in the context of the reintroduction of the system.

Q4: Are these webinars a series of training or repeat sessions of same content?

A4: The approach to each webinar 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.

Q5: Please show the tag for a study where errors were not found due to the system but changes were made to the results due to revised data since the original posting (eg. NIH changes to the FDAAA version, new tables generated, etc.).

A5: Where these are the changes made, there is no system tag (i.e. one with yellow highlighting). The field "Version creation reason" is used by the sponsor to specify the reason that the changes were made.



Q6: In order to check a potentially study in status finalized I have to create an update and to provide a reason for that update. Which reason I should enter assuming I will not later identify an error?

A6: The review can be undertaken using the "View" functionality and it is not necessary to create a new version. When viewing the results, an option to download PDF is presented in the form of a button towards the bottom of the screen. This can be used to generate a PDF version for printing and offline review.

Q7: If data are entered manually, is the xml extracted from the EudraCT than an exact representation?

A7: Yes

Q8: If a primary user is replaced by the backup user, do we need to upload a new letter of authorisation?

A8: No

Q9: To summarise on the earlier question re non-compliance in posting Results, - the penalty for not being on time with the posting (Not due to system being down) --> is the tagging which clearly visible at the top of the EudraCT entry - stating that the sponsor is non-compliant. Is that correct?

A9: For the purposes of this exercise, the Agency is tagging results sets that could not be submitted in accordance with ordinarily applicable timelines as follows "Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines". The functionality for tagging results for late submission is in the list of enhancements that will be scheduled for development according to priority and availability of development resource.

Q10: The EudraCT database still has shuffling issues. For example, if my study has 5 reporting arms A, B, C, D and E. I create the arms in sequence, however database shuffles these in to random order (B, C, D, A, E). Are you working to resolve this issue?

A10: This has been highlighted as a known error and is under consideration in the context of development scheduling according to priority and availability of development resource.

Q11: System creates validation errors for single arm studies stating with regards to comparison groups how do we address this issue?

A11: In this specific case you can post the result without entering the details of the statistical analysis. The system cannot currently accommodate one arm study.

Q12: If we have to report Not Calculated or Not Available in any section of endpoint section. How we can report that?

A12: For data quality purposes the N/A or not calculated is not allowed in the system. Sponsors should be able to provide correct and meaningful data for results.