



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2013
EMA/722850/2013

EudraCT V9 Workshop – Validate and post results in EudraCT 20th November 2013 Q&A documents

Q: Do you have schematron validation file, similar to Eudra CTA?

A: We will not use schematron to validate results. Validation of the results can be performed only in the system.

Q: Will the justification for Warning be public?

A: Yes, correct.

Q: How often will the rules be updated?

A: There are more than 250 validation rules in the system. New rules will possibly be introduced later on if needed.

Q: If a justification for warning is not provided, would the user be able to post the results?

A: No, the justification has to be provided at the time of validation of the results.

Q: What are the rules to attach a summary OR enter full data set or both?

A: The rules are set out in the European Commission Guideline 2012/C 302/03.

Q: Are there any plans to have QA review by EMA of the postings in the future?

A: In the Agency, there is a system with functionalities to perform a review of posted results.

Q: What is the procedure for reporting feedback/findings about the use of the system?

A: For providing feedback, enquiring about a specific topic or reporting a technical issue, send a message to the following mailbox: eudract@ema.europa.eu

Q: Can you upload xml with justifications to the system?

A: The XML upload does not affect the justification/error/warnings. Once the XML is uploaded, the validation should be performed and justification can be entered manually in the system.

Q: Do we have to deal with warnings first and then take care of them in EudraCT UI?

A: Before posting the results, the sponsor has to resolve the errors and warnings in order to resolve any validation issues in EudraCT.

Q: Can you add justifications on the actual screen with the issue, or only in the validation screen?

A: The justifications can only be providing at the time of validation within the validation functionality.

Q: If there is an error or a warning - does it always appear on the page as 'Orange' background?

A: The warning is highlighted in orange, whereas the error in red. In particular for errors if you click on 'go to error' the link will direct you to the error page where the field to be updated has orange background.

Q: If you need to edit the justification, where will the text box be available?

A: The justifications can be edited in the validation screen.

Q: If the justification for warning is provided on the validation report page and the user navigates away to another page, would the justification be automatically saved?

A: The justification is not saved automatically by the system so if you leave the screen without saving the justification is lost.

Q: Could you please confirm that there is no need to report Phase I results unless the study is part of a PIP?

A: The results have to be reported for all trials regardless of phases or whether they are part of a PIP.

Q: When you enter the number of adverse events or serious adverse events the first time, can that number be automatically populated to later screens requiring the same information? This could reduce the number of errors and moving between screens to correct errors.

A: Some data entered by the user in the adverse event section (the number of subjects exposed for a reporting group) are carried forward to the next section. The data can be edited and modified if necessary in that section.

Q: Are deaths not considered to be serious adverse events?

A: Yes, they are considered SAEs but there are exceptions for specific trials especially oncology trials.

Q: Will spelling be checked as part of the validation?

A: The system does not have any spell check but the user can use the 'Add-on' feature within Firefox/Windows.

Q: Are justifications only visible in the validation report? Can you see the justification in the data entry portion of the record?

A: The justifications are only visible in the validation report.

Q: Is there a way to preview the full dataset identical to the public view?

A: The 'Preview' feature is available in EudraCT and it will be updated to resemble the public view in the future iterations foreseen in 2014.

Q: Is there a link for the commission guidelines?

A: EudraLex Chapter V (http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf)

Q: Would the posting of result apply in the future to clinical trial with medical device?

A: No, the EudraCT database only includes interventional trials.

Q: Are we able to access a test environment?

A: The testing environment is not publicly available. The EMA is considering the development of a Sandbox, which can be used for training and familiarisation purposes.

Q: Will the future test environment contain copies from production, like the CT.gov test system?

A: This point is still under evaluation and internal discussion.

Q: Is there a structure for a XML file available that is to be transferred into the EudraCT database?

A: A draft XML file structure is now available in the documentation section on the EudraCT website.

Q: Will the results posted also be required retrospectively (back to 2004)? It was my understanding that moving forward entering results on EudraCT will replace the submission of CSR synopsis to regulatory authorities - but not retrospectively because the CSR synopses were already submitted to CA...

A: For older trials, not involving paediatric population and agreed PIPs, results can be provided as attachments only.

Q: Are full data sets not required for recently completed and upcoming trials if they involve adults subjects only and no PIP?

A: Only results for trials in scope of Article 45 of Regulation (EC) No 1901/2006 and trials completed more than 1 year prior to the end of programming of the system, which are not part of an agreed PIP nor in scope of Article 46 of Regulation (EC) No 1901/2006, are to be posted, as a minimum, with a

synopsis or more summary attachments. For all other trials, the full dataset is the minimum requirement for posting results.

Q: Is there a way to delete all results data and start over, before posting has occurred?

A: Before posting results, the user can manually delete all results data.

Q: Other than upload XML, are there any plans for any API for posting results and for entering justifications?

A: There are currently no plans for the Agency to provide an upload service API (application programming interface) or support receipt of results through a Gateway-style solution.

Q: What rule to judge including FULL dataset or not for posting?

A: The full dataset can be posted for any type of trial, on condition that there is a protocol in EudraCT. If only summary attachments are posted, then the system asks up to four questions about the trial to determine whether this is allowed. If the trial does not conform to the requirements for posting only a summary attachment, the system prevents the user from posting an attachment only for that trial.

Q: How to handle publications that is allowed by Art.45 for which we are not the copyright owner?

A: The Sponsor must have the copyright owner's permission to use a publication in the results of their clinical trial.

Q: Is global end of trial LSLV or primary completion date?

A: The global end of trial usually corresponds to the last subject last visit (LSLV).

Q: All studies with EudraCT number need full data set if their LPLV falls within 1 year prior to mid-2014 and going forward

A: The above statement is correct.

Q: If you make changes within the 15 day period, is there a publicly available audit trail to track the changes?

A: If changes are made by the user within the 15 days period, the results are not yet made public. The results will change from a state of "posted" to a draft state and can be modified by the user. However to post the results, the user will need to validate and actively post the result again.

Q: How to update the results once they are published?

A: Sponsor can update results after publication by preparing another version of the results. The new version will be published and will supersede the old one. All versions (old and new) will be made available on the EU CTR.

Q: Is the 15 day wait, business or calendar days for review of results before finalisation?

A: The timing between posting and finalisation/publication of the results on the EU CTR is 15 calendar days.

Q: If you un-post a full data set, and then repost a few days later, does the 15 day clock start over?

A: Yes, the 15 day clock starts over.

Q: Is it at most 15 days or at least 15 days?

A: At most 15 calendar days.

Q: How to manage the preparation of the results for a trial that was submitted to several countries?

A: If a trial has multiple CTAs submitted to several countries, only one set of results is prepared and published for the trial.

Q: Did you say that an OLD trial is a trial that ends 1 year before the implementation of the database (which is anticipated to be in 2014), and that OLD trials can post a PDF synopsis for results instead of a full data set?

A: Unless the trial is part of an agreed Paediatric Investigation Plan or is in scope of Article 46 of Regulation (EC) No 1901/2006 then the above statement is true.

Q: If final results data are available for a trial, can we update the record and re-submit, or do we need to ask a new results posting request to EMA?

A: Once the user has been assigned to a trial, the user can update the results at any time. There is no need to contact the EMA.

Q: If the primary completion date in an adult phase 2 study was in 2005 and the overall LSLV in 2014, is this trial considered an OLD study?

A: In compliance with the guidance 2012_302-03, it is the global end of trial that kicks off the requirements for results to be provided as per a specific timing and as per a certain format (full data set and/or attachment).