Q&A – EudraCT Results training – session 16th December 2014

Q1: When can public see data and when can only EMA see data?
A1: Results data can be viewed in the European Clinical Trials Register (EU CTR) once they are finalised. National competent authority and EMA staff can view the results data when they are draft, posted or finalised.

Q2: Do all opinions from CA/IEC need to be added or is just 1 enough?
A2: The opinion and decision from the competent authority and ethics committee are required for the records to be made public.

Q3: Please confirm there is no QA review, just the system validation
A3: There is an automated validation. Scientific validation may be performed at the level of the National Competent Authorities; the Agency staff does not perform scientific validation of the results.

Q4: Can results be posted even if not all CMS have the trial status turned to "completed" i.e. does this prevent the sponsor from posting the results
A4: Results can be prepared and posted for interim analysis even if the trial has not yet reached its end date.

Q5: After the initial 14 days in the "posted" period (when sponsor can withdraw posting and return it to draft) - is there any later opportunity for sponsor to retract posting and return it to draft?
A5: No, once the results are finalised, those can only be superseded by providing a new version in the system. Previous versions of the results remain in the register

Q6: Does summary attachment mean CSR synopsis?
A6: Yes, this could be an option.

Q7: What about providing results for retrospective trials?
A7: if the trial is registered in EudraCT, the sponsor should provide results.

Q8: If the national competent authority has received the EoT notification and still not modified the status of the trial to "complete" does it prevent the sponsor from posting the results?
A8: the sponsor can prepare and post the results, however the data will not be made public until the record is made public.

Q9: Will all entered data become public? Or is there special algorithms embedded that selects only certain data to become public?
A9: All clinical trial results will be made publicly available via the EU CTR

Q10: Do you know how long national reporting requirements, e.g. §42b BfArM, will have to be followed? Will the results already submitted to these portals be transferred to EudraCT?
A10: Currently there is no mechanism in place to transfer data from other registries to EudraCT or vice versa.

Q11: Can you please confirm that a pdf of results for trial results entered into ClinicalTrials.gov would be accepted for 'old' trials?

A11: Yes this is acceptable

Q12: Please confirm if all primary and secondary endpoints included in the CSP must be posted or is it just the key endpoints that need to be entered?
A: It is recommended that the data for the key end points be provided in the results.

Q13: When will the timeline change to 25 calendar days?
A13: The timeline has already been changed to 25 calendar days due to high volume of requests from sponsors.

Q14: Can you please include a link to the XML Schema that you mentioned in the final QA document?
A14: The XML schema details can be found here
https://eudract.ema.europa.eu/document.html under the section 'Result related documentation'.

Q15: For retrospective 3rd party country paediatric studies that do not have EudraCT numbers, will we need to register the protocol?
A15: If the 3rd country trial falls into the scope of art. 46, it should be registered in EudraCT using the 3rd country file functionality.

Q16: Is there an easy way to search for all studies by a certain sponsor so that the sponsor can post results to those without going through each study search individually?
A16: A search can be performed in the register by typing the name of the sponsor.

Q17: In the CTA xml we already fill in the trial information details, why is this not linked to the Trial information on the results page so that we don't have to enter the data twice.
A17: in trial information, several fields are pre-populated from the CTA information.

Q18: Not including planned number of subjects on the EudraCT form for a CTA would file validation; how is it that this data is not available? Is it because older versions of EudraCT did not ask those specific questions?
A18: if the planned number of subjects has been provided in the CTA, then the information is pre-populated in the trial information section. The user has to provide the actual number of subject enrolled.

Q19: Could you please give an example of when you may have more than one overall period for a study?
A19: The sponsor may wish to provide the results by preparing the first period including all subjects which can be the baseline period and by preparing additional periods to further define the trial design. This may be of interest in the events that endpoints should be reported for the arms included in the additional periods.

Q20: Can you add more than one IMP to an arm?
A20: Yes, this can be done

Q21: Why is the product information not taken from section D of the EudraCT form? It would be easy to select which products are used in each arm if the products were already available in the system.
A21: the IMP information is not provided per arm. Therefore, it is not possible to pre-populate the information in the result.

Q22: As results are to be posted after the end of trial, please could you clarify why there is capacity for results of an interim analysis to be posted BEFORE the end of a trial? In addition there is an option to declare that data continues to be collected after the trial has ended, however it is clear from our CA that this is not allowed?

A22: The provisions in relation to the timing of posting were prepared in view of the requirements documented in the European Commission guideline 2012/C 302/03 (section 4.3).

Q23: With regard to the products that have to be assigned. Is there a connection to the developmental products in the EudraVigilance database?
A23: Unfortunately there is no link to the product registered in the EudraVigilance system.

Q24: Can the Ct.gov xml be uploaded and then the additional required data entered?
A24: No, the EudraCT system cannot accommodate XML files from CT.gov.

Q25: Could the endpoints not be derived from the EudraCT form used for the CTA?
A25: The information related to end points in the results is more detailed and include several fields that should be completed.

Q26: Please clarify systematic and non-systematic assessment types?
A26: systematic assessment should be selected when the monitoring of adverse events is done in a systematic fashion and they are collected on a routine basis. Non-systematic assessment means that subjects may have reported the adverse event.

Q27: If you don't have a result for a particular endpoint - data is not available for a particular arm, what is your recommendation for entering that?
A27: If you don't have data for a particular endpoint, you should not report on this endpoint.

Q28: If data are not available, would entering 0 be appropriate, even if 0 is not the actual data, since we do not have the option to enter N/A?
A28: it is expected that the results are provided for each endpoint. "Not applicable" is not an allowed value.

Q29: Can you copy and paste end points for those with a large amount of data i.e. adverse events?
A29: This option is not available in the system.

Q30: Is there any way to have an electronic upload of the information? The entry of all these data by hand is very unreliable and time consuming.
A30: The sponsor can upload an XML to populate all the fields or select to upload XML for the adverse event information.

Q31: What Sponsor information is required to be stated in the protocol as part of EMA reporting requirements i.e. medical monitor?
A31: in the trial information section, the sponsor should provide a scientific and public contact points.

Q32: Is it required to identify the EudraCT # in the consent form?
A32: it is not required to identify the EudraCT number in the consent form. However adequate study identifiers should be documented on the form.

Q33: How to provide results for cross-over study?
A33: In relation to your scenario on how to report cross-over studies note that there are several ways to report it depending on the need of the reporting groups for endpoints and statistical analysis.
Option 1: One overall period could be used to detail the design and arms. With this choice, milestones (e.g. wash out) can be included. Each arm should document the number of subject who started and the number who completed.
Option 2: Several periods could be used to detail the design and arms. Each arm should document the number of subject who started and the number who completed.
Option 3: One overall period could be used to detail the design and arms. In this case, when

providing subject disposition, in this case the arms are not mutually exclusive and the answer to the question "are the arms mutually exclusive?" should be responded "no". Each arm should document the number of subjects who started and the number who completed. However, there is a system limitation at the moment with this option for the reporting of the statistical analysis. There is an automated sum up of the arms population that is performed by the system which is not valid for this option. The result can be reported by omitting the statistical analysis.