



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EudraCT V9 Workshop – Managing users and prepare results in EudraCT 15th November 2013 Q&A documents

Q: Can there be multiple users with the same role for the same study?

A: There can be more than one delegated preparer and delegated preparer and poster, but there can only be one primary user and one back-up user.

Q: Can the delegation only be on the EudraCT number or will the tabulation also show the sponsor ID for a trial?

A: The delegation is per EudraCT number

Q: On "Your Page" as a primary user, can I see whom I assigned which study? Do I have to navigate somewhere else to find this information?

A: On "Your Page" the user can see the other users assigned to a specific trial clicking on the link 'Manage Assigned Users'.

Q: Can a single email address be used for multiple users (primary, back up, preparer, etc)?

A: The email address is for an individual user and it identifies a specific user. Each user has her/his own email address used for the registration process.

Q: You said the primary user was already assigned. Is the primary user the person who originally entered the trial in EudraCT? If so, can EudraCT be reassigned?

A: The primary user is the person who is officially appointed by the sponsor to prepare results in EudraCT.

Q: Does a user in order to be added as, e.g. poster, need to be a registered results user in EudraCT? Does the primary user need to know the exact name of the users to whom he/she wants to delegate the trial?

A: To become a result user, the user needs to register with EudraCT unless he/she has already got Eudralink credentials. Then the primary can delegate tasks to the user by selected their name and email address if they have already been delegated trials in the past or the primary user will need to enter their name and email address.

Q: Does the back-up user and user you delegate to need to go through a registration process first as you described at the last webinar (as the primary user has done)?

A: Any user has to be registered first in order to become a results user. Afterwards the primary user can appoint other users in the roles of back-up, delegated preparer, delegated preparer & poster.

Q: Can primary and back-up user access a trial at the same time and does back up user has all the rights as primary user?

A: The results can be edited once at a time. If results are edited, the other users can only view the results. A back-up user does have the same rights as Primary user. A Primary & back-up user can delete appointed users and name new users.

Q: Do all results users/preparers need their own EudraCT Account?

A: Anyone needs to have own EudraCT account.

Q: Who can change the primary user?

A: The Primary user can remove himself/herself from the trial or the back-up user can remove the primary user.

Q: Can there be an error message pop-up indicating that if the sole user (primary or backup) is going to delete them, no one will be able to enter results?

A: There is a confirmation box that needs to be checked in before the user is removed. Also an email is sent to the primary user and the back-up user to inform them of the decision taken.

Q: We have a mail box for clinical trial disclosure where everyone working with disclosure has access; this is convenient for instance when people are on holiday. Is it possible to give two mail addresses?

A: The email-address belongs to a specific results user and it cannot be exchanged. For audit reasons, we strongly advise against the use of shared mailboxes in EudraCT. We recommend that all users register as individuals and do not share user accounts.

Q: As primary user, do the delegated users defined once for 1 trial will appear as option for users for my other trials?

A: The delegated users to your trials are provided as options so you can quickly assigned them again to different trials.

Q: Could the back-up user remove the primary user? (In case the primary user is no longer available)

A: yes that is correct.

Q: If a CRO or Consultant is working with multiple sponsors, would they have multiple EudraCT accounts - one per sponsor?

A: the EudraCT account is at individual level, one account for one results user.

Q: Can we transfer or share individual trial records with/to other pharmaceutical companies if there are company mergers or if there is a co-development partner?

A: The sponsor retains the right to manage the assignment of clinical trials to any individual they feel it necessary to share the responsibility for preparing or posting the results irrespective of the company they work for.

Q: I assume we need to submit a single request for each batch of 50 studies, but I'm wondering if a user can be the primary user for 150 studies, for example.

A: Yes this is correct. There is no limitation on the number of EudraCT numbers assigned to a results user, whether primary user or other users.

Q: Sounds like in EudraCT, trials are tracked to individuals. This is different from CT.gov, where trials are tracked to the sponsor.

A: Yes, you are correct it is the individual that is assigned to the results rather than the Organisation. ClinicalTrials.gov records the association between the protocol and organisation which enabled them to take this approach. The same is not true for the EMA.

Q: Can a primary user access a trial at the same time as a delegated preparer. Can 1 trial have 2 delegated preparers?

A: A user can only have one role for a designated trial. The user can be a primary user, a back-up user or a delegated preparer or a delegated preparer and poster.

Q: On the trial information page reference to a national CTA was made - will this always be available and link to the original CTA form?

A: Yes, that's correct. There is a link on the Trial Information page from which the user can access information contained in the CTA form used to pre-populated the information when the result record is accessed for the first time.

Q: Are there character number limits for the various fields? (e.g. title)

A: Yes, there are and they are specified in the EudraCT result related data dictionary [<http://eudract.eudra.org/document.html>]

Q: Can you 'discard changes' after saving "changes"?

A: You can discard changes before saving changes. Discarding changes after saving has no effect.

Field Code Changed

Q: Will the friendly description be visible on public domain once the results are posted?

A: No, the friendly description will not be visible on the public domain. This feature is only for internal user for Sponsors.

Q: Do you have best practice advice for the title of the attached results summary?

A: We recommend meaningful, simple and clear title.

Q: Will the summary attachment option be available only for those studies that are applicable to the transition rules for retrospective results posting? Or for any study and the sponsor will simply have to know whether the summary option is actually applicable to a given study?

A: The option to provide summary attachment(s) is available for all trials. According to the modality of posting, an attachment can be sufficient for some of the trials that have ended in the past but going forward the full data set will be required. The system has been built in such a way to allow the posting of simply an attachment for trials that fulfil the criteria described in the commission guideline or the full datasets for the other trials with the option to provide attachment(s) also.

Q: If there are multiple national CTAs for one study, does the results preparer need to select one national CTA to display?

A: The preparation and posting of results data is per EudraCT number and not per single clinical trial application form. The user does not need to select a particular CTA.

Q: Would the relevant information from the CTA be populated in the results section to which it is linked?

A: There are some fields which will be taken from the CTA form and they will be displayed as soon as the results user will enter the results in EudraCT.

Q: How do you know when both Regulatory Authority and EC in a country approve the CTA for the first time?

A: The National Competent Authority has the responsibility to enter the approval by the authority and the ethics committee opinion in EudraCT. This information is required to enable the trial information to be made public on the EU CTR.

Q: Contact point: will just an email address be acceptable? In the CTA it obviously is...

A: The information about the contact point has to be provided in the Trial Information section under 'Scientific contact point' and 'Public contact point'. If the information has been provided in the CTA, it will be prepopulated and can be edited by the user.

Q: Do actual names need to be entered, or can a title / role be entered in the contact field

A: in the Scientific and Public contact point the functional contact point has to be provided.

Q: How often do you need to save during data entry and does the database time out the user (log out)?

A: It is recommended to save regularly; the system has been set up to time out the user after 30 minutes of inactivity. If during this period the results user has not saved the entries these will be lost.

Q: Editing prepopulated data: Will this overwrite existing protocol information in EU-CTR?

A: The protocol record will not be changed by editing the pre-populated fields in the trial information of the results-related information.

Q: Do we need EudraCT # for legacy Art.45 Trials?

A: This remains under discussion within the Agency.

Q: Is it possible to have multiple primary completion dates?

A: No, there is only one primary completion date to be completed in the EudraCT data model.

Q: Will all the fields that we looked at, be visible to the public?

A: All the fields for results will be made publicly available in the EU CTR

Q: When you say global end of trial date, would it mean study follow-up completion or study completion date and not LSLV.

A: The global end of trial usually corresponds to last patient last visit LSLV.

Field Code Changed

Q: If a country is added and it has not been documented in the CTA, would CTA need an update as well (without planned numbers in this case)?

A: In case of a substantial amendment is introduced in the study, the national competent authority of the country where the trial is taking place should be notified. In the event that the information on the additional country has not been captured in EudraCT, the user can document the additional country in the trial information section of the results in EudraCT v9.

Q: Is the breakdown for age mandatory for all trials?

A: Yes, the breakdown for age is mandatory for all trials

Q: Can we have a customized category for the "Age breakdown" field? Because is it possible that the company used age category is different than what you showed here

A: The age category in the trial information section is the one used in the CTA for which the sponsor has provided the planned number of subjects. In the results information, the actual number of subjects enrolled should be provided.

Q: Are any of the fields in subject disposition mandatory? None of the sub headings have a red asterisk indicating such.

A: There are certain fields in Subject Disposition in the Periods/Arms where specific fields are mandatory

Q: Is there a sham option for device trials, like the placebo for drugs?

A: Devices are not in scope of the Directive 2001/20/EC which focuses only on interventional clinical trials on medicinal products.

Q: Do you have to re-enter the product for each arm or can you pick it from products populated earlier from another arm in the study?

A: The way to achieve the copying of products is to add all the arms and products in period 1, then use the feature that copies arms into period 2, and period 3, etc... which will copy the arms and any products within the arms to those periods.

Q: Would this system be compatible with old version of the EudraCT application form?

A: The system dedicated to results does not need to be compatible with the CTA application form as it is a distinct and different system.

Q: Are reasons for non-completion optional or conditionally required based on the number of subjects started and completed the period?

A: In case the number of subject completed is less than started, the sponsor has to provide a subject non-completion reason. Therefore this field is conditionally required.

Q: Is the "select baseline period" checkbox mandatory?

A: Yes, the baseline period checkbox is mandatory for at least one period.

Q: If you have a phase 1 healthy volunteer study with several periods, where in each period a new group of subjects is recruited, would you like to have baseline characteristics for each period separately? Can this be done or do you have to select the baseline characteristics from the first period?

A: It is recommended that one period be created to cover for all the subjects recruited in the trial (e.g. one overall study period). This period should be checked as the baseline period and will ultimately be used to report the baseline characteristics.

Q: If my trial has 4 visits - screening, baseline, week 24 and week 48, would I enter 2 periods - baseline to week 24 and week 24 to week 48 or just one period baseline to week 48 - treatment is the same throughout?

A: It is recommended that one period be created to cover for all the subjects recruited in the trial and that intermediate milestone within the period be created to accommodate for week 24, week 24-48.

Q: In the baseline it shows Reporting Group 1 and Reporting Group 2 as column heads instead of actual name of treatment. This may cause the user to constantly refer back to which reporting group is labelled as the IMP or placebo, etc.

A: The labels are directly above the fields containing the values so will be on the same scrollable area of the page. When the user hovers over the values box, highlighting is applied to the label.

Field Code Changed

Q: Could you confirm that all the items required will be available as an Excel list? Which information is required and to retrieve this information for completion...

A: The data mapping is available on the website under 'Documentation'/Result related documentation'/EudraCT result related data dictionary.

Q: When this EudraCT 9 will be released?

A: the EudraCT V9 has been released on 10th October 2013

Q: Is it the final version?

A: The EudraCT V9 is the current version; there will be future releases to accommodate additional functionalities in the near future.

Q: Will the Agency provide more guidance on how to enter the results according to the study design of the trial (e.g. two or more period cross-over trials)?

A: The Agency will provide additional guidance to sponsors in a nearer future.

Q: If you create a subject analysis set in baselines, is it then mandatory to provide data? The section doesn't have a red asterisk, but the data entry fields do.

A: It is not mandatory to create a subject analysis set. If the user starts completing the information then all fields in that section that are marked with a red asterisk are required.

Q: When a project is sold to another sponsor during or after development, can the new sponsor then claim the trials conducted by the previous sponsor for result reporting?

A: Trials can be claimed by the new entity and if the name is of the sponsor has changed, we advise that the requestor provides an explanation in the request for assignment letter.

Q: Is there a test version of the EudraCT data base available?

A: The EMA is looking into providing a test version of the EudraCT system to enable sponsors to simulate the data entry of results as well as testing the XML upload.

Q: Can there be more than one primary endpoint?

A: The system does not prevent the user from providing more than one primary end point.

Q: Do all primary and secondary endpoints as specified in the protocol need to be reported?

A: The system allows the user to enter the primary and secondary endpoints as it is intended for the results to be reported. There is currently no link with the primary and secondary endpoints as specified in the protocol. The user is requested to provide results for one primary endpoint at least and in the event that a trial has prematurely ended, the user would be requested to provide a justification for not providing the results of the primary endpoint.

Q: If we are uploading a synopsis at the summary attachment area, do any other required fields need to be populated?

A: If the sponsor is submitting a synopsis only and that modality of posting is permitted for that trial, there is no need to provide the full data set. In order to post the results, you will need to confirm that the trial is not part of an agreed Paediatric Investigation Plan, confirm whether or not the trial is in scope of Article 45 or Article 46 of Regulation (EC) No 1901/2006 and you will need to confirm the global end of trial date.

Q: Causally-related according to whom? - Physician or sponsor?

A: The causality is assigned by the physician and reported as such for the serious adverse event (SAE).

Q: While reporting dictionary for a specific adverse event, asterisk does not appear on dictionary name and version. Are these optional there or still mandatory?

A: All the mandatory/optional and conditionally required fields are listed in details in the data dictionary.

Q: Is the threshold for non-serious AEs fixed at 5% or could it be determined differently?

A: The threshold for non-serious AE reporting can be any value between 0% and 5%.

Q: Is there a process for releasing the data after you have entered them as there is at CT.gov?

Field Code Changed

A: The action 'post results' will allow user to post the results which will be published in the EU CTR within 15 calendar days.

Q: Could we download a copy of results in .pdf to use as a reference to what results looks like?

A: The download .PDF feature is available both in 'Your Page' and in the Index page. In 'Your Page' the user has the ability also to 'view' the results and eventually download in .PDF.

Q: Are fatalities same as death?

A: Yes, correct

Q: Does the system automatically save the data?

A: The system does not save data automatically so it is strongly recommended to save data all the time. The system does log the user out after 30 minutes of inactivity.

Q: Is it enough only to post the summaries for 'old' studies?

A: Currently for some of the trials that have ended in the past and before the finalisation date of the programming of EudraCT V9, there is an option to provide only summary attachment(s).

Q: If there is no test instance available at the moment, is there any way for a non-sponsor (e.g. technology vendor providing disclosure tools to sponsors) to get into the system and see how it works in detail?

A: The Agency is considering providing a sandbox to allow Sponsors to taste how it works with the system. Future implementation will be available next year.

Q: How often can a sponsor access a record in case there is an update, e.g. reporting interim analysis and 6 months later the final analysis?

A: The result data can be updated at any time.

Q: In the Adverse Event section on EudraCT there are areas where the required asterisk is not present. In the data dictionary, there are fields listed as either R= conditionally required or M= mandatory. What is the difference and how do we know when to populate specific fields based on these differences?

A: In the data dictionary, we have indicated "R" when a field is conditionally required. In the adverse event section, if no event is provided then the fields do not need to be completed.

Field Code Changed