



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2013
EMA/712170/2013

EudraCT V9 Workshop – Getting started with EudraCT to prepare and post results

30th October 2013

Q&A documents

Q: Can I use my Eudralink credentials that I currently use to submit CTA forms to become a result user in EudraCT?

A: Yes, in order to become a EudraCT results user, you can use your Eudralink credentials. In case you do not yet have an ECD account you will need to register (i.e. an ECD account would be created) before you can become a result user.

Q: Is there going to be only one primary user per sponsor?

A: There is one primary user per trial. The Sponsor can have any number of primary users.

Q: Is the account registration specific to one individual person or for one company?

A: The log in credentials (password and username) is for an individual who has registered with the Agency under their name having provided their individual email address.

Q: Can several users request assignment to the same trial?

A: A trial is only assigned to one primary user. If a trial is already assigned to a primary user, other users will not be able to request assignment to the same trial.

Q: What is the purpose of the trial assignment?

A: The assignment is to enable the primary user to prepare and post results for a particular trial but to also delegate the trial to a back-up user and other users (e.g. preparer, preparer/poster).

Q: Is it possible to populate the list of EudraCT numbers from CTA-XML or does the list of EudraCT numbers need to be keyed in again?

A: The list of EudraCT numbers can be keyed, or cut and pasted from the request assignment letter to the system.

Q: Why would you reject a request for a trial assignment?

A: A request for assignment can be rejected due to a lack of information at the time of the request. For example, if the letter prepared and uploaded does not comply with the template that is currently available on the EudraCT website, then the request is rejected. Also, if the trial has already been assigned to another user, the request would be rejected.

Q: Is there a process to change the person assigned as primary user?

A: In the "manage user" feature, the primary user has the ability to remove themselves from the list of user for a particular trial. Also, the back-up user can remove the primary user. Subsequently, the primary user would be removed and not entitled to access the result record for the trial. When the primary user is removed, the back-up user automatically becomes the primary user and can assign a new backup user.

Q: Which sponsor name should be used if there is a different sponsor in each participating EU country within one trial?

A: It is recommended that the sponsor as named on the clinical study report is used to prepare the request for trial assignment.

Q: What guarantee do you have that the letter you receive was indeed sent by the sponsor's employee or delegates?

A: The trial request assignment is performed by providing a letter that should match the requirements of the template letter but also the information related to the primary user should be documented in the letter. The person signing the letter confirms that they are authorised to submit results.

Q: What do we do if the person is the primary role for a trial who resigns and leave the company?

A: It is the responsibility of the primary user to remove themselves from the assignment. If not done by a primary user, the back-up user can remove the primary user. The responsibility for managing user remains exclusively with the Sponsor.

Q: Can a user working for CRO/other company remove themselves from the assignment as opposed to the Sponsor?

A: Sponsor can delegate responsibility to prepare results to a CRO and it is recommended that there is a formal/legal agreement.

Q: Does a primary user automatically have the rights to prepare and post results himself/herself?

A: A primary user can prepare and post results, as well as delegate to another user with either preparer and poster role or solely the preparer role.

Q: Is there a time for archiving a record and assignment?

A: Trial assignment requests are saved in the system indefinitely until further notice.

Q: Can you please clarify again the role of preparer and poster? Can this person manage other accounts?

A: A delegated preparer/poster user cannot manage other accounts, only the primary and back-up users can do that.

Q: Do trial results stay in EudraCT forever?

A: Yes.

Q: Is the primary user role similar to the administrator role in CT.gov?

A: the Primary user role may be affiliated to the Responsible party in the NIH (the responsible party could be named as a person or as an organisation where the role is the Administrator) unless the Responsible party is not named individual, it would be associated to the Administrator role.

Q: Do you need to have a person assigned forever?

A: A user is assigned for an indefinite period unless he/she is removed by the Sponsor.

Q: Can the primary user do a bulk assignment for multiple trials (say several dozens of trials at a time) to his/her team members as preparers, or does he/she have to do that one trial at a time?

A: The primary user can request trial assignment for up to a maximum of 50 EudraCT numbers per assignment letter. There are currently no features for a primary user or back-up users to bulk assign trials to delegated users.

Q: Do you finalise results at once or by endpoint? In other words, would you have an assigned person in the year 1, then finalise and re-assign somebody for uploading results of secondary endpoints - in cancer trials this may come 10 years afterwards.

A: When the results are published for a specific trial they can be updated later on, in particular for follow-up analyses. Sponsors have the ability to edit/update the results at any time and publish a subsequent version of the results.

Q: Can a sponsor ask for a list of users and trials?

A: There are currently no features in EudraCT to allow Sponsor to obtain a list of results user per trial.