Submission of Clinical Trial Results in EudraCT- Sponsor guidance

As of 21st July 2014, it became mandatory for sponsors to post clinical trial results in the European Clinical Trials Database (EudraCT). These summary results will become available to the public.

Sponsors will now be obliged to post results in EudraCT for any interventional trials registered in EudraCT and that have ended within a certain period of time:

- For any interventional clinical trials that ended on or after 21 July 2014, sponsors will have to post results within six or twelve months following the end of the trial, depending on the type of trial concerned;
- For trials that ended before that date, sponsors will need to submit the results retrospectively.
    - For trials that ended before 21st July 2013, a copy (PDF) of the clinical study report can be uploaded to the EudraCT.
- For trials that ended after 21st July 2013, a full dataset of the trial result is required to be uploaded in line with one year of the finalisation of the programme i.e. by 21st July 2015.

In order for results to be uploaded a user needs to be registered with EudraCT and assign the trial (EudraCT number) to their account if they are not the account which originally applied for the EudraCT number. This user will then be able to post trial results.

Account details

In order to prevent the need for assigning several different accounts to one trial in case of individuals moving roles, the CTIMP's team will have one account for uploading results related information and comply with the new requirements. All members of the CTIMP's team should log in using the below details.

Username: s3q4y7

Email: ctimps@ucl.ac.uk

Password: Ctimps2015

JRO Guidance

For all trials that have been declared ended after 21st July 2013, the final report will need to be uploaded to EudraCT following a pre-determined dataset that has been complied by the EMA http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf . At the end of trial the SRA/RM ATMP will send the site the dataset document and remind them that the end of trial report is to be uploaded within one year of the declaration of the EOT. The SRA/RM will also request that the site CI or delegated individual registers on the EudraCT database https://eudract.ema.europa.eu/help/Default.htm#eudract/register.htm . The CI will then provide the JRO with their username and registered email address for the EudraCT system (see separate Investigator guidance).

The SRA/RM ATMP will then allocate that username and individual as a **Delegated Preparer** for that trial. A **Delegated Preparer** is able to perform the tasks that would lead to the preparation of

results in the EudraCT system; these include uploading a summary attachment, downloading of report, data entry of full data set and validation of the results. The delegated individual should work alongside the trial statistician in order to complete this mandatory data to be made publicly accessible.

The delegated individual will then be responsible for the uploading of the final report according to the full dataset guidance, as per the link above. Such information which is pertinent will be subject disposition, contact for the study, AE data, and amendment information. The delegated preparer will upload all of this information, validate the dataset (which is automated in EudraCT), then the primary user which is ctimps@ucl.ac.uk will be able to post results once review of the information is complete.

Assigning a EudraCT to CTIMPs account

When a Clinical Trial is moving through the sponsorship pathway the SRA/RM ATMP will now be responsible for registering for a EudraCT number using the ctimps@ucl.ac.uk account. This will ensure that, the EudraCT number is assigned to the correct account in order to allow final study reports to be uploaded within one year of the end of trial.

Any trials which were registered prior to the implementation of the new guidance, the EudraCT numbers will be assigned to the sponsor's account retrospectively. This has been completed for all older trials however for any trials which have been missed or the CI registers for a EudraCT number prior to JRO involvement, the number will need to be assigned to the ctimps@ucl.ac.uk.

To assign a EudraCT number a template letter to request assignment needs to be completed and signed off by the sponsor. The letter contains the full trial title, the EudraCT number and the trial sponsor. The template letter is found here Template EMA letter request.doc. This letter then needs to be uploaded to EudraCT following these steps https://eudract.ema.europa.eu/help/Default.htm#eudract/clinical_trial_assignment.htm

The EMA will then email ctimps@ucl.ac.uk once the trial has been assigned to this account. The results related information can then be uploaded.

Assigning a user

The SRA/RM ATMP will be responsible for assigning users to the trial for the preparation of trial results. In order to assign a user select the corresponding EudraCT number on the ctimps@ucl.ac.uk account and select 'manage assigned users'. https://eudract.ema.europa.eu/help/Default.htm#eudract/delegation_for_results.htm. Ensure the individual is assigned as the **delegated preparer.**

The SRA/RM ATMP will then notify the delegated individual that they have been assigned as a user and can now upload the data for that trial. The user must upload the mandatory dataset; however they can also upload a summary report as a PDF if they also want to include this.

The full dataset must be completed within one year of the declaration of EOT.

Post results

Once the CI or delegate has uploaded the data, the SRA/ATMP should be notified that the data has been uploaded and validated. The information should be reviewed by the SRA/RM ATMP and the checklist completed. Once the SRA/RM ATMP is satisfied with the information the results should be posted to EudraCT, no later than one year after the end of trial has been declared. Information regarding how to post is found here https://eudract.ema.europa.eu/help/Default.htm#eudract/posted_results.htm

The data will be made public within 15 days.

SRA/RM ATMP should print the proof of upload and file in the sponsor file alongside the PDF copy of the report which can be saved and printed from EudraCT. The proof of upload and PDF report should be sent to the CI for filing in the TMF.

The MHRA should then be notified by email that the report has been uploaded to EudraCT. The MHRA have requested that the sponsor should send a **short** confirmatory email to CT.Submission@mhra.gsi.gov.uk once the end of trial study report has been uploaded, with '*End of trial study report: EudraCT XXXX-XXXXXX-XX*' as the subject line.

The CI is delegated the responsibility of sending the PDF summary result to the ethics committee, and sending the SRA/RM ATMP the relevant correspondence.

CTU Trials

For those trials in which a CTU are delegated the responsibility of the final study report, the lead contact or delegate within the CTU should be delegated as a **results preparer** who will then be responsible for compiling the full dataset. The sponsor will be responsible for posting the results to EudraCT as above.

A template email has been compiled which contains the information on how this will be done and how to register themselves as a user.