

## **Submission of Clinical Trial Results in EudraCT- Investigator/Statistician Guide**

As of 21<sup>st</sup> 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.

In order for this obligation to be met, the CI will be delegated the responsibility of completing the full dataset of results in the EudraCT system. The CI can delegate an individual to upload this information however the CI needs to maintain oversight and overall responsibility of the information. The information contained in the final report should be completed alongside the study statistician.

The CI/nominated individual needs to provide the JRO SRA/ATMP Manager with their 'user details' so that they can prepare the report in EudraCT. Please register as a 'user' as shown below, please pass on this information to other members of the trial team that will also need access to the dataset e.g. Statistician.

### **Registering as a User**

In order to register as a results user for EudraCT complete the steps as shown here: <https://eudract.ema.europa.eu/help/Default.htm#eudract/register.htm>. The user will need to complete their details as well as details of the organisation that they work for i.e UCL.

The system will send an email to the registered email address confirming your user name and the account will need to be activated prior to being in use. This email may go in to the junk email folder. If you have not received this email please contain [eudract@ema.europa.eu](mailto:eudract@ema.europa.eu) with your details and they will be able to assist you. The JRO does not manage these accounts.

Once the account has been set-up and activated please contact the SRA with your username and email address, they will then give you access to your trial dataset, as a **delegated preparer**. A **delegated preparer** is able to perform the tasks that would lead to the preparation of results in the EudraCT database.

### **Full dataset**

Once access had been gained for a trial, results related information can be uploaded following a pre-determined dataset that has been compiled by the EMA  
[http://ec.europa.eu/health/files/eudralex/vol-10/2013\\_01\\_22\\_tg\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf)

The Full dataset contains information regarding the amount of participants, the study design, AE information, and the statistical findings. Details of any substantial amendments submitted in the trial will also need to be included.

In addition to this you can also upload a summary report for extra detail as a PDF; this will also be made available to the public. The full dataset must be completed within one year of the declaration of EOT.

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Once all the information has been added to the system, you will need to validate the information which is shown here:

[https://eudract.ema.europa.eu/help/Default.htm#eudract/validate\\_results.htm](https://eudract.ema.europa.eu/help/Default.htm#eudract/validate_results.htm). Validating will ensure that all information has been completed accurately and all mandatory information included. Once validation has been completed all information has been reviewed and agreed by the CI if they are not the results user, please notify the SRA/ATMP manager who will check the data and post the results.

Once the results have been published the data will be made public within 15 days. The SRA/ATMP Manager will send you proof of upload as well as a PDF copy of the report. The CI or delegate should send the final report to the ethics committee and R&D copying in the SRA/ATMP Manager. The final report should then be filed in the corresponding section of the TMF.