

Subject line: EudraCT clinical trial results are still in draft

Dear Sponsor,

Results for your trial EudraCT xxxxxx – full title – sponsor code are still in “draft” in EudraCT.

We kindly ask you to post your trial results in the EudraCT database, in order to comply with the [European Commission Guideline](#) on results posting and as requested in the [Joint Letter by the European Commission, EMA and HMA](#) . Publication on external sources or having sent the report to National Competent Authorities is not sufficient. The guideline is applicable retrospectively.

In case no results or only partial results are available, please post a pdf document justifying the missing/partial results for your trial (see step 4 below).

Please see below helpful [instructions](#):

1. Contact the primary user of your trial. The primary user is the person who has an [EMA account](#), activated with the results user role and who has requested assignment for the trial as per step 2 of the [tutorials on posting results](#)
 - It could be that the trial has also a back-up user assigned. You can investigate it in your institution and liaise with the back-up user as well.
2. The primary user can [log in](#) the EudraCT website using EMA credentials
 - in case of login problems (inactive accounts/forgotten password): refer to [EMA account management](#)
3. The primary user looks for the above-mentioned trial number in “your page” and clicks on “edit”
4. The primary user can **upload results** as:
 - a summary attachment (e.g. pdf file), if the end of trial date of your trial is before 21st of July 2013 and your trial is not part of a PIP/Art 46 or in case your trial was prematurely ended, no subjects recruited or only partial results are available
 - a full data set, in all other cases. In case you encounter errors or warnings during the process, the [validation rules](#) could be of help (look for your error/warning and see the relevant “rule description”).
5. The primary user needs to ensure to **post** the trial results by clicking on “post results” at the top right corner of the webpage.

For questions, please refer to our [Frequently Asked Questions](#) . If the answer to your question is not there, [Contact us](#).

For your information, results of phase 1 trials conducted in adults that are not part of an agreed PIP still need to be posted in EudraCT.

Thank you very much for posting results, the EMA highly appreciates it.

EudraCT team

European Medicines Agency

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