

Subject line: EudraCT clinical trial results not posted

Dear Sponsor,

Results for your trial EudraCT xxxxxx – sponsor code – full title have not been posted in EudraCT.

We kindly ask you to provide 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 the below detailed [instructions](#):

1. Set up an [EMA account](#):
 - kindly allow some time (at least 2 hours) for the activation of the EMA account – it is **not** accessible immediately after setting it up.
 - in case of login problems (inactive accounts/forgotten password): refer to [EMA account management](#)
2. Register as results user ([log in](#) using EMA credentials, click on “become a results user”, log out and [log in](#) again).
3. Request assignment to be the primary user for your trial (download and fill in the [form](#) , then [log in](#), click on “your page” and “request assignment”, fill in the same information as per the form and upload the filled in form). Your request will be processed soon. Once you are assigned, you can ask another person to set up an EMA account and register as results user (see step 1) and [nominate him/her as back-up user](#)
4. Once you have your trial assigned, you will see it in “your page”, and you 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. After you have uploaded your results, please make sure to [post them](#) 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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