EudraCT results: posting of results

Once results are uploaded as summary attachment and/or full data set, as applicable, results can be posted in EudraCT, as per step 6 of <u>Tutorials on posting results</u>. Note: before posting, all validation rules need to be solved in case results are posted as a full data set, see <u>validation for results</u>. A full overview of EudraCT processes is provided in the <u>EudraCT step-by-step guide</u>. In case support is needed, see <u>here</u>.

Post results

1. Once logged in 'your page', select the relevant trial and click on 'Edit':

EudraCT number +	Version	Sponsor name +	Friendly description +	Last saved +	Status +	Options
2007-002716-26	1			18-0ct-2013	Draft	Edit View Manage assigned users

2. Afterwards, click on 'post results' at the top right corner of the trial's page:

			1			
Save	Discard changes	Validate full data set	Post results	Upload XML	Download XML	Download PDF

3. The user will then need to confirm that the modality of posting (summary attachment vs full data set) is correct, and then declare whether the trial was prematurely ended or not, if it was part of a paediatric investigation plan, or conducted under Article 45 or 46 of the paediatric regulation 1901/2006.

Post results > Composition
This version of the results for this clinical trial is composed of the full data set and a summary provided as one or more attachments. If you wish to continue with the posting process, proceed. Otherwise, consider the two points below.
1. If your intention is not to include the full data set and to only post the summary attachment(s) in this version of the results, indicate below that the full data set should not be included, then proceed. (The data will be retained in the system for your future use in either case.)
C Include the full data set 💿 Do not include the full data set
 If your intention is not to include the summary attachment(s) and to only post the full data set, cancel and return to the index page to remove the attachment(s).
Proceed Cancel

Post results > Modality of posting

You will now be asked up to 4 questions about the clinical trial. Provide an answer to each question to ascertain whether the modality of posting used (one or more summary attachments only) is permitted.

- Is this clinical trial part of an agreed paediatric investigation plan (PIP)? No
- Does article 45 of Regulation (EC) No 1901/2006 apply to this trial? No
- Does article 46 of Regulation (EC) No 1901/2006 apply to this trial? No
- When was the global end of the trial? 30/08/2010

Previous	Cancel	Next
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- 4. If all the answers provided are correct, the user will be able to post results, after having accepted the terms of agreement.
- 5. The results have been successfully posted to EudraCT:

Post results - success

Data for this version of the results of the clinical trial have be	een posted to EudraCT
This version of the results will be made public within the next 15 days, in accordance with the further editing.	e European Commission guideline [2012/C 302/03]. During this period you will be able to cancel the posting of this version of the results to enable
IMPORTANT: Result-related data will be made public if, in addition to European Commission guideline, at i See the table below for more information.	least one of the protocol-related records for this trial has also been made public in the EU clinical trials register.
CTA Member state name/Third country file	EU clinical trials register publication status
CTA: Finland - Fimea	published
CTA: Italy - Italian Medicines Agency	unpublished
Contact the national competent authority in the relevant member state if you have question	ns about the publication status of the clinical trial applications for this trial.

OK

The results will be in 'posted status' for two weeks after posting. After two weeks, results will be in 'finalised' status and can be viewed on the EU CTR if the protocol (CTA or third country file) related records are published. Please note: results of phase I clinical trials conducted solely on adult or to trials that do not have the NCA/Ethics Committee data inserted, will not be made public on <u>EU Clinical Trial</u> <u>Register</u> since the relevant CTA/third country file is also not public.

Note: during the two weeks period of 'posted status', the sponsor has the possibility to retract the publication through <u>updating them</u>, so that the previous version is not published. If so, the results status returns to "draft". In case, instead, the two weeks have passed and the status of the results to be updated is on 'finalised', when <u>updating those results</u> a second version of results will be created which will be added to the first one when published.

Support needed?

For questions, refer to our <u>Frequently Asked Questions</u>. If the answer to your question is not there, <u>Contact us</u>.