Posting clinical trials and their results on the EU Clinical Trials Register

During late spring/summer of 2021, Research support was involved in helping OUH researchers publish their studies and the study results in the EU Clinical Trials Register (EUCTR). Below questions that came up from study teams, both general and on entering data in the system, and the answer to those questions.

This document will be updated if new issues or other relevant information appears.

If you have further questions or need support for publishing in the EUCTR, contact persons are Erica Ponzi, statistician, and Filip Segers, monitor, both from the Department of research support for clinical trials (CTU).

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General

Q When do I have to report my study on EU CTR?

A Studies have to be reported on EU CTR the latest one year after the last patient's last visit. For pediatric studies, this limit is six months after the last patient visit.

Q How do I report my study on EU CTR?

A Here are the EU CTR detailed webpage instructions and guidelines on the publication of results on EU CTR You will have to set up a EMA account and register as a "result user". You need to be the primary user for your trial, and will be able to upload results from your personal page. Remember to post results when you finish!

Q The former PI responsible for the study has changed jobs or has quit/retired. How do I obtain rights as a primary user to be able post the study results?

A Make sure you have an EMA account and are registered as a result user. Then fill out and send in the form "*Request assignment to be the primary user for your trial*":

https://eudract.ema.europa.eu/help/Default.htm#eudract/clinical_trial_assignment.htm

This needs to be filled out and signed by the Sponsor (OUS), stating that you are the responsible person ("primary user") and reporting the EUDRACT number of the study. You will get an answer from EUdraCT in a few days and will be able to register results from the webpage.

Q I have already sent my "End of study declaration" to SLV, do I also have to report to EU CTR?

A Yes, EU CTR and SLV registration are two different processes and need to be completed independently.

Q If summary results from my trial are posted, can this prevent me from publishing in an academic journal?

A No, the International Committee of Medical Journal Editors (ICMJE) has explicitly stated that summary results posted onto trial registries will not be considered to be prior publication. See http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/overlapping-publications.html

"The ICMJE will not consider as prior publication the posting of trial results in any registry that meets the criteria noted in Section III.L. if results are limited to a brief (500 word) structured abstract or tables (to include participants enrolled, key outcomes, and adverse events). The ICMJE encourages authors to include a statement with the registration that indicates that the results have not yet been published in a peer-reviewed journal, and to update the results registry with the full journal citation when the results are published."

And section III L in 2017_dec_urm.pdf (icmje.org)

"The ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/network/primary/en/index.html) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP.

[…]

The ICMJE will not consider as prior publication the posting of trial results in any registry that meets the above criteria if results are limited to a brief (500 word) structured abstract or tables (to include trial participants enrolled, baseline characteristics, primary and secondary outcomes, and adverse events)."

Q We have changed the global end of trial. How can I update this information?

A You can change the global end of trial date through uploading a new version of the results of your trial and updating the date.

Q I have a publication related to the study, can I upload that instead?

A If your study ended after 21 July 2014, a structured report of the results to EU CTR is needed regardless. If your study was completed before 21 July 2014, uploading the publication is sufficient and you do not need a structured report to EU CTR. Remember to report the publication both to SLV and EU CTR.

Q My study got approved but was prematurely stopped. Do I have to report the results on EU CTR?

A Yes, you need a summary of the results and a statement of the reason for the premature interruption of the study.

Q I have uploaded my trial results but I am getting error messages from EU CTR. What should I do?

A If you encounter error or warning messages, you can consult the validation rules and look for your error message. If your error message is not there, you can contact EMA or send us an email at CTU@ous-hf.no.

Q I am uploading my results: do I have to report all outcomes?

A You can upload all outcomes if you wish, but only primary outcomes are required.

Q I am uploading my results: do I have to report all adverse events?

A Yes, all adverse events have to reported. This includes serious and non-serious adverse events, and drug related and non-drug related adverse events. Note that the number to be reported is the number of patients affected by adverse events, not the number of events (so report only once if the same patients has the same AE twice or more times.) Information about the grading of the events is not necessary in the report.

On entering data in the system

Q I am uploading my results: what are the patients who "have finished the arm"?

A Here you should include all patients who got to the end of this study period. Patients that are recorded at this time point should be included, patients that discontinue the study or withdraw should be excluded. Patients with protocol deviations should be included unless the protocol deviation determines their exclusion from the study.

Q I am uploading my results: when I upload information about categorical characteristics I get errors about non-corresponding numbers, what do they mean?

A Remember to include all possible values for the category (e.g. not only number of smokers, but also number of non-smokers), so that the counts sum up to the total number of patients. Add the "not recorded" category value if the value is missing for some patients.

Q I am uploading my results: I get an error about incomplete endpoint values. What does it mean?

A You need to report the endpoint values for all patient groups (treatment group, control group, other possible relevant groups), and the overall values for all analysis populations (per protocol, intention to treat,…) that you include in the report.

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