EudraCT protocol: third country file submission

Third country files need to be submitted through EudraCT only in case they are conducted exclusively outside of the EU/EEA and are part of a Paediatric Investigation Plan and/or under Art. 46 of the Regulation (EC) No 1901/2006. New EU/EEA Clinical Trial Applications of PIP/Art 46 trials to be conducted in EU/EEA as well as outside of the EU/EEA need to be created through the Clinical Trial Information System.

In order submit the third country file through EudraCT, after having created it and filled it, you need to have an EMA account and ask for it to be assigned with the role of a third country data provider. Afterwards, you can proceed with submitting the third country file.

A full overview of EudraCT processes is provided in the EudraCT step-by-step guide. In case support is needed, see here.

Registration as third country data provider

To register as a third country data provider, you need to create an EMA account, first. Afterwards, you need to open an EMA Service Now query (to log in: **add the extension @id.ema.europa.eu to your EMA username**). Once logged in the Service Now, click on "Applications", select "EudraCT" among the Applications topics and then select "Request a EudraCT Service". You can then to submit a scanned letter with your request to become a third country data provider on EudraCT. This letter should be on headed paper of the PIP addressee/marketing authorisation holder/sponsor, signed by a representative of the PIP addressee/marketing authorisation holder/sponsor and contain a clear statement that the person named in the letter is to be given permission to provide protocol clinical trial data to the EudraCT database as well as a declaration that only data of trials will be uploaded for which the company/user is the PIP addressee/marketing authorisation holder/sponsor. The letter should also contain the following information about the user: name, address, e-mail, and optionally telephone. Once you have the role assigned by the Service Now, you can proceed with the submission of your third country file through EudraCT, see below.

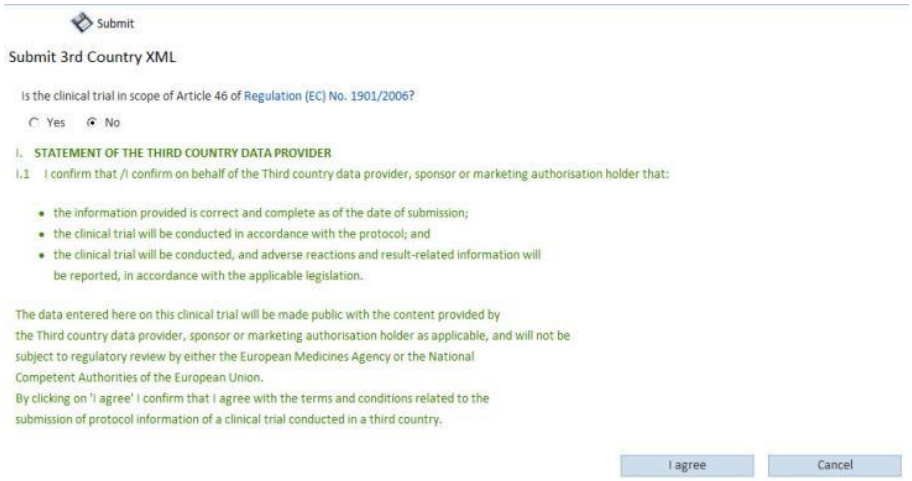
Submission of a third country file

This action should be performed only after the third country file has been created, completed and validated. If you are not sure if the file has been validated, you can upload it and validate it again.

Third country data providers are responsible for the content of any third country file submitted through EudraCT. See steps to perform, once having assigned a third country data provider user role:

1. Log into EudraCT with the EMA account credentials associated with the third country data provider role.
2. Load the third country file you want to submit
3. Validate the third country file

4. Click on the option ‘Submit’ at the top of the screen, after having validated the file
5. A statement is then shown. You need to agree with the statement to submit your third country file through EudraCT:



The application has been submitted successfully. The third country file is now stored in the EudraCT system.

Support needed?

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