# EudraCT protocol: third country file submission

After having created and filled in a third country file, you need to gain the role of a third country data provider to your EMA account and then to submit the file through EudraCT. This needs to be done for trials conducted exclusively in third countries and part of a Paediatric Investigation plan and/or conducted under Art 46 of the paediatric Regulation (EC) No 1901/2006.

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, first of all you need to create an EMA account, as per user manual on EMA account creation. For this purpose, you will need to either install the 'Microsoft Authenticator' app on your phone or using other authentication options, in order to log in EudraCT. In case of issues with logging in, you can recover password here, as per instructions. Afterwards, you need open an EMA Service Now query (to log in: **add the extension @id.ema.europa.eu to your EMA username).** You can then 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. The user to be nominated as third country data provider needs to have an EMA account.

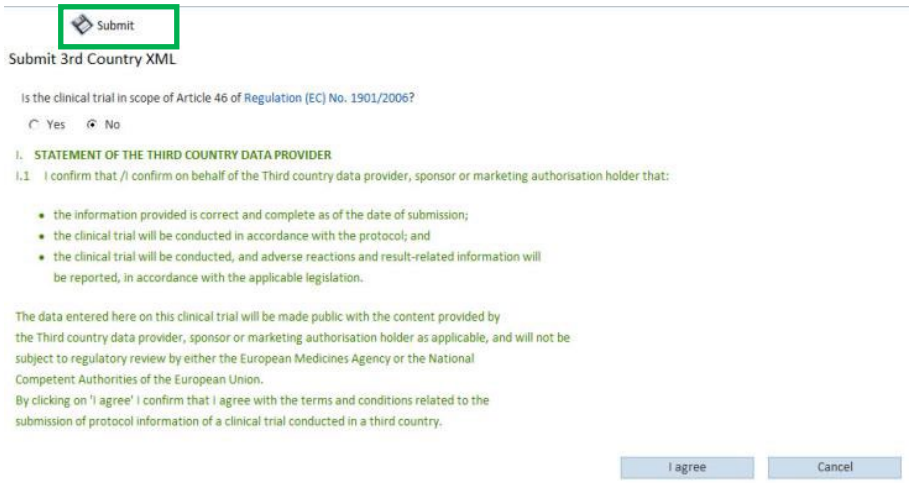
## Submission of a third country file

This action should be performed only after the third country file has been completed and validated. If you are not sure that the third country file has been validated, select Validate and refer to section 'Validate a CTA/third country file.

Third country data providers are responsible for the content of any submission.

1. Log into EudraCT under the third country data provider role. When logging in, **add the extension @id.ema.europa.eu to your EMA username**.
2. Load the third country clinical trial you want to submit.
3. In the clinical trial application menu, check that the information on the left hand-side of the screen is correct, and ensure that the content of the third country file has been validated.
4. Once validated, the task bar at the top of the screen includes the option to 'Submit'.

5. A statement is then shown. You need to agree with the statement in order 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.