EudraCT protocol: EudraCT number creation

The assignment of an EudraCT number to your clinical trial is the first step needed to create a EudraCT third country file. Note: as of 31 January 2023, **EudraCT numbers need to be created only for the purpose of creation of third country files of trials to be conducted exclusively outside of the EU/EEA and that are part of a Paediatric Investigation Plan and/or under Art. 46 of the paediatric regulation 1901/2006**. New EU/EEA Clinical Trial Applications of trials to be conducted in EU/EEA need to be created through the Clinical Trial Information System: this includes PIP/Art 46 trials that are also conducted in third countries.

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

EudraCT number generation

Steps:

1. From the EudraCT homepage, click on EudraCT tools & Login and then select 'Create' and 'EudraCT number'
2. Confirm that you want to request a EudraCT number for a trial conducted exclusively outside of the EU/EEA and part of a Paediatric Investigation Plan (PIP) and/or in scope of Article 46 of the Paediatric Regulation (EC) 1901/2006. In case, instead, you need to request a EudraCT number for a EU/EEA trial, this is not possible, and you will be re-directed to the Clinical Trial Information System.
3. Enter the name of the organisation the EudraCT number request is for, in the 'Requestor's organisation name' field.
4. Enter the town/city in which the organisation's office is located, in the 'Requestor's organisation town/city' field. This should relate to the office where the planned Clinical Trial is to be run from (rather than the global headquarters, for example).
5. Use the drop-down menu to select the country in which the organisation's office is located.
6. Insert the Sponsor's Protocol Code Number. This number is not generated by the EudraCT system, but it is created by the sponsor. It should be entered in the format as specified by the sponsor's organisation and it must be completed. Note: in case the inserted protocol code was already used in the past by your o other organisations, a warning message appears: ensure that your organisation has not already created a third country file with this protocol. If the trial protocol code has not been used by your organisation in the past, then you can use it.
7. In the 'Requestor name' field, enter your first name; in the 'Requestor last name' field, enter your last name (family name).
8. Enter the e-mail address where the EudraCT number should be sent. Any valid e-mail address is acceptable and need not be the requestor's e-mail.

9. For security reasons, enter the letters and numbers displayed in the window next to the text field. This entry is case sensitive and mandatory. If you cannot read the text in the picture, click on 'New Image' to refresh the security image.
10. Confirm that the EudraCT Number is to be used for a for a clinical trial conducted exclusively outside of the EU/EEA
11. Confirm that the EudraCT Number is to be used for a clinical trial that is part of an agreed Paediatric Investigation Plan (PIP) and/or for a clinical trial in scope of Art. 46 of the Paediatric Regulation (EC) No 1901/2006.
12. Click on 'Get EudraCT number': the EudraCT Number is generated and appears on the web page. It is recommended to take a screenshot of the EudraCT number assignment.
13. The EudraCT number is also sent to the specified email address.
14. Click the OK button to return to the home page and fill in a Third country file.

Support needed?

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