

Step 1

Apply for security code

Visit the website and follow the procedures to obtain a security code. This is for one protocol and is valid for 24 hours.

Step 2

Apply for EudraCT number

Obtain a EudraCT number for your study from the EudraCT website. This protocol-unique number must be quoted on the applications for Clinical Trial Authorisation and ethics committee (IEC) opinion, amendments and end of trial notification.



Step 3

Complete application for Clinical Trial Authorisation and ethics opinion

Once all documents and information are available you must apply for Clinical Trial Authorisation (CTA) and obtain a favourable IEC opinion. Complete the forms on the EudraCT website, save as an XML file on a local computer and print off the forms as PDFs.

Step 4

Prepare essential information and supporting documents

You will need to submit study documents such as the final protocol, Investigator's Brochure (IB) and investigational medicinal product dossier (IMPD).

Step 5

Apply for CTA and ethics opinion

This may be done in parallel and for most medicinal products (except products like gene or cell therapies and biotech products) takes a maximum of 60 days after receipt of a valid application. The application forms, together with supporting documents (and in the case of the CTA application a disc containing core data in XML format), are sent to the competent authority (CA) and the appropriate IEC in each of the Member States where the trial is to be carried out.



Procedures for interventional clinical trials on medicinal products in humans

to be conducted in at least one European Member State
All documents can be obtained from the website:

<http://eudract.emea.eu.int>

Step 6

Perform study in accordance with GCP and GMP

The trial must be performed in accordance with internationally recognised good clinical practice (eg. ICH GCP) and all medicinal products used in the study should have been prepared to the standards of GMP.

Step 7

Notification of amendments

Once authorisation has been obtained, sponsors have to decide if any change is substantial (as defined in the detailed guidance). Substantial amendments should be notified to the CAs and/or IECs concerned using the standard form available from the EudraCT website.

Step 8

Reporting adverse reactions

The investigator must report immediately to the sponsor all serious adverse events (SAEs). The sponsor must report expediently, using the EudraVigilance database, all suspected unexpected serious adverse reactions (SUSARs). Annual safety reports must also be prepared by the sponsor and submitted to the CAs and IECs concerned.

Step 9

Notification of the end of the study

Use the standard form on the EudraCT website to notify the CA and IEC that the trial has ended. You should do this within 90 calendar days unless the trial has terminated early, in which case you must report it within 15 calendar days.

Step 10

Ensure essential documents are maintained and archived and submit a report of the study

All essential trial documents should be carefully filed, retained and securely archived. A report of the study should be prepared and submitted to the CA and IEC within 1 year of the study ending.