ECTR European Clinical Trial Regulation

CLINICAL TRIALS

THE PROCESS FOR STARTING UP CLINICAL TRIALS WILL CHANGE

The ECTR will change the process for starting up clinical trials in Europe. This has consequences for everyone who is involved in this type of research. This folder explains what is going to change.

Dutch Ambition

The introduction of the ECTR offers the Netherlands the opportunity to become even more attractive for international clinical trials.

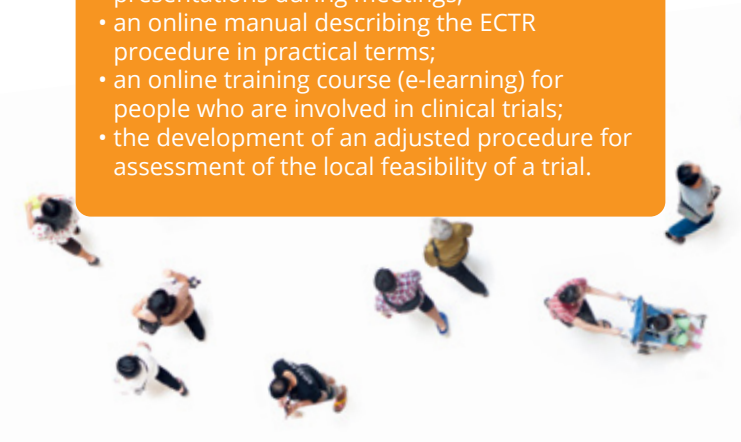
When the ECTR comes into effect in Europe, the Netherlands is:

- capable to complete assessments of clinical trials (well) within the time frames set by law;
- optimally suited for the execution of clinical trials;
- highly in demand with drug developers to conduct these trials.

The Dutch Central Committee on Research Involving Human Subjects (Centrale Commissie Mensgebonden Onderzoek, CCMO), the Dutch Clinical Research Foundation (DCRF) and the Ministry of Health, Welfare and Sport (VWS) are working together in order to successfully implement the ECTR in the Netherlands.

Organizations that are working on clinical trials should prepare themselves for the ECTR requirements. The CCMO and the DCRF are supporting them to do so, through:

- presentations during meetings;
- an online manual describing the ECTR procedure in practical terms;
- an online training course (e-learning) for people who are involved in clinical trials;
- the development of an adjusted procedure for assessment of the local feasibility of a trial.



What is the ECTR?

ECTR stands for European Clinical Trial Regulation. This is European legislation that regulates clinical trials in the European Union (EU) – and therefore in the Netherlands.

The purpose of the ECTR is:

- to simplify and accelerate clinical trials within the EU in order to make new treatment options available sooner;
- to keep the EU attractive for sponsors of clinical trials.

The ECTR describes:

The medical ethics review process
- The maximum lead times of the review process for clinical trials will be equal for all EU countries. As a result, all sites in participating countries can start recruiting subjects at the same time.
- Study protocols and other study-related documents will be submitted centrally and electronically in the EU. The European Medicines Agency (EMA) is developing a web portal and a database specifically for this purpose.

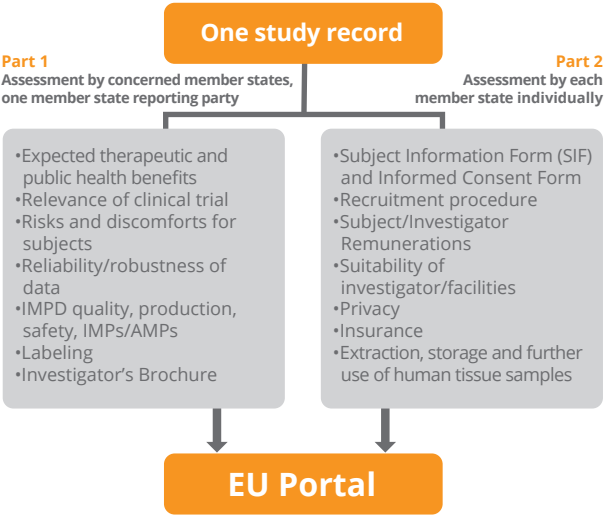
Safety reporting
- The assessment of safety reports will be done per product instead of per study. One EU member state will become responsible for the safety reporting for each investigational drug.
- Sponsors must report SUSARs directly in the EudraVigilance database.

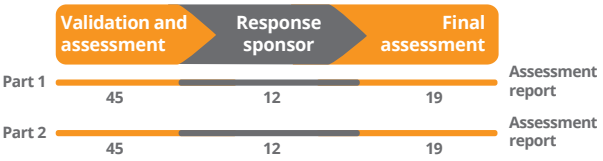
The publication of trial data
- Trial-specific information will be disclosed via the EU web portal. Decision rules determine when specific information will be disclosed.

The ECTR will come into effect six months after the EU web portal and the database become available. The exact date is currently unknown.

Review process of clinical drug trials in the EU

The assessment of Part 1 and Part 2 are carried out parallel to, or after each other. The maximum periods for the assessment of Part 1 and Part 2 are identical.





Under the ECTR, maximum terms are applicable for the phases of the medical ethics review. After the first period with the maximum of 45 calendar days, the MREC may request additional information from the sponsor once. The sponsor then has a maximum of 12 calendar days to respond to this request. The final assessment subsequently occurs within 19 calendar days and then the reporting member state draws up the assessment report.

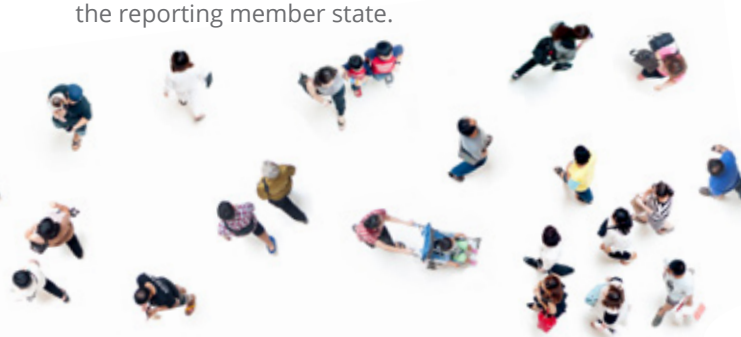
Review in two parts: Part 1 and Part 2

The ECTR divides the reviewing process into two parts.
- Part 1 contains the assessment of the medical scientific method and of the product.
- The assessment of Part 2 concerns the national issues such as the information letter for research subjects, insurance and privacy aspects. Part 2 also includes the remunerations to research subjects and investigators and the suitability of investigators and site facilities.

Multinational Clinical Trials
In the case of multinational clinical trials, the concerned member states jointly conduct the assessment of Part 1. Per study proposal one member state is the so-called reporting member state. This member state, in agreement with the reviewing committees in the other concerned member states, establishes the assessment report regarding Part 1. Each member state provides a separate assessment of Part 2. The approval of Part 1 applies to all the concerned member states. The approval of Part 2 applies to all the participating centers in the concerned member state.

CCMO
In the Netherlands, the Central Committee on Research Involving Human Subjects (CCMO) is responsible for setting up the medical ethics review process. The medical ethics review of the trial is conducted by specially selected medical research ethics committees (MRECs).

The CCMO has established a National Clinical Trial Office ('Landelijk Bureau') that offers administrative support to the MRECs involved in the assessment of multinational studies for which the Netherlands is the reporting member state.



March 2020

ECTR European Clinical Trial Regulation

Would you like to stay informed? Follow the developments via the DCRF and CCMO websites. You can also register to receive their newsletters.

DUTCH CLINICAL RESEARCH FOUNDATION

www.dcrfonline.nl/clinical-trial-regulation
secretariaat@dcrfonline.nl

CENTRAL COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS (CCMO)

www.ccmo.nl
ccmo@ccmo.nl
Twitter: @_CCMO

Ministerie van Volksgezondheid, Welzijn en Sport

DCRF Dutch Clinical Research Foundation

ccmo Centrale Commissie Mensgebonden Onderzoek