EU Clinical Trial Regulation (536/2014)
- Normal Clinical Practice-

Centrale
Commissie
Mensgebonden
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CTR training EMA – HMA - COM

March 9-10, 2021

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Article 2.2.2 - Definitions

Clinical trial' means a clinical study which fulfils any of the following conditions:

(a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;

(b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or

(c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

Article 2.3 - Definitions

Low-intervention clinical trials

- the investigational medicinal products are used in accordance with the terms of the marketing authorisation; **or**
- the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; **and**
- the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned

Article 6.1 - Assessment

- .....
- the risks and inconveniences for the subject, taking account of all of the following:
  - — the characteristics of and knowledge about the investigational medicinal products and the auxiliary medicinal products;
  - — the characteristics of the intervention compared to normal clinical practice;
  - — the safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan;

Article 8.2a, 19.2a, 23.2a – Decision

Article 14.4a – Additional MS

Opt-out MS

- .....
- when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;

Article 48 - Monitoring

In order to verify that ..... requirements of this Regulation, the sponsor shall adequately monitor the conduct of a clinical trial. The extent and nature of the monitoring shall be determined by the sponsor ..... characteristics:

(a) whether the clinical trial is a low-intervention clinical trial;

(b) the objective and methodology of the clinical trial; and

(c) the degree of deviation of the intervention from normal clinical practice.

Normal Clinical Practice

Article 2.6 – Definition

Normal clinical practice' means the treatment regime typically followed to treat, prevent, or diagnose a disease or a disorder;

What is not considered normal clinical practice (1)

- Administration of a medicinal product without a marketing authorisation in the EEA
- Administration of a medicinal product in healthy volunteers or in patients without clinical indication or medical need
- Other unproven interventions as defined in Article 37 of the Declaration of Helsinki
- Blinding or randomisation of treatment allocation
- Additional or more frequent/increased diagnostic or monitoring procedures or sampling performed solely for the purposes of the clinical study.
- Any procedures not considered clinical practice for the individual patient within the framework of the National Healthcare System of the Member State concerned with the clinical study.

What is not considered normal clinical practice (2)

With regard to off-label use of medicinal products with a marketing authorisation in the EEA it is within the competence of each Member State to determine if established off-label use in principle is considered within their normal clinical practice and can be investigated in a non-interventional study or not.

Sponsors are recommended at the planning stage of such a clinical study/clinical trial to seek advice from all Member States where the study/trial is intended to take place. A clinical trial application should then be submitted to all Member States where the conduct of a non-interventional study is not possible.

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information

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