Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 2

Definitions

1 For the purposes of this Regulation, the definitions of 'medicinal product', 'radiopharmaceutical', 'adverse reaction', 'serious adverse reaction', 'immediate packaging' and 'outer packaging' set out in points (2), (6), (11), (12), (23) and (24), respectively, of Article 1 of Directive 2001/83/EC apply.

2 For the purposes of this Regulation, the following definitions also apply:

(1) 'Clinical study' means any investigation in relation to humans intended:

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

(b) to identify any adverse reactions to one or more medicinal products; or

(c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining the safety and/or efficacy of those medicinal products;

(2) '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.

(3) 'Low-intervention clinical trial' means a clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products, excluding placebos, are authorised;

(b) according to the protocol of the clinical trial,

(i) the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or

(ii) 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

(c) 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;

(4) 'Non-interventional study' means a clinical study other than a clinical trial;

(5) 'Investigational medicinal product' means a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial;

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

(7) 'Advanced therapy investigational medicinal product' means an investigational medicinal product which is an advanced therapy medicinal product as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[1];

(8) 'Auxiliary medicinal product' means a medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational medicinal product;

(9) 'Authorised investigational medicinal product' means a medicinal product authorised in accordance with Regulation (EC) No 726/2004 or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an investigational medicinal product;

(10) 'Authorised auxiliary medicinal product' means a medicinal product authorised in accordance with Regulation (EC) No 726/2004, or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an auxiliary medicinal product;

(11) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(12) 'Member State concerned' means the Member State where an application for authorisation of a clinical trial or of a substantial modification has been submitted under Chapters II or III of this Regulation respectively;

(13) 'Substantial modification' means any change to any aspect of the clinical trial which is made after notification of a decision referred to in Articles 8, 14, 19, 20 or 23 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial;

(14) 'Sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial;

(15) 'Investigator' means an individual responsible for the conduct of a clinical trial at a clinical trial site;

(16) ‘Principal investigator’ means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;

(17) ‘Subject’ means an individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control;

(18) ‘Minor’ means a subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent;

(19) ‘Incapacitated subject’ means a subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law of the Member State concerned;

(20) ‘Legally designated representative’ means a natural or legal person, authority or body which, according to the law of the Member State concerned, is empowered to give informed consent on behalf of a subject who is an incapacitated subject or a minor;

(21) ‘Informed consent’ means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial;

(22) ‘Protocol’ means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. The term ‘protocol’ encompasses successive versions of the protocol and protocol modifications;

(23) ‘Investigator's brochure’ means a compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product or products in humans;

(24) ‘Manufacturing’ means total and partial manufacture, as well as the various processes of dividing up, packaging and labelling (including blinding);

(25) ‘Start of a clinical trial’ means the first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol;

(26) ‘End of a clinical trial’ means the last visit of the last subject, or at a later point in time as defined in the protocol;

(27) ‘Early termination of a clinical trial’ means the premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with;

(28) ‘Temporary halt of a clinical trial’ means an interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it;

(29) ‘Suspension of a clinical trial’ means interruption of the conduct of a clinical trial by a Member State;

(30) ‘Good clinical practice’ means a set of detailed ethical and scientific quality requirements for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials ensuring that the rights, safety and well-being of subjects are protected, and that the data generated in the clinical trial are reliable and robust;

(31) ‘Inspection’ means the act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other

resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

(32) ‘Adverse event’ means any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment;

(33) ‘Serious adverse event’ means any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death;

(34) ‘Unexpected serious adverse reaction’ means a serious adverse reaction, the nature, severity or outcome of which is not consistent with the reference safety information;

(35) ‘Clinical study report’ means a report on the clinical trial presented in an easily searchable format, prepared in accordance with Annex I, Part I, Module 5 of Directive 2001/83/EC and accompanying an application for marketing authorisation.

3 For the purposes of this Regulation, a subject who falls under the definition of both ‘minor’ and ‘incapacitated subject’ shall be deemed to be an incapacitated subject.

(**1**) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

Status:
Point in time view as at 16/04/2014.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Article 2.