

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)

CHAPTER 1

SUBJECT-MATTER

Article 1 (1) This Directive lays down the following provisions to be...

CHAPTER 2

GOOD CLINICAL PRACTICE FOR THE DESIGN, CONDUCT, RECORDING AND REPORTING OF CLINICAL TRIALS

SECTION 1

GOOD CLINICAL PRACTICE

Article 2 (1) The rights, safety and well being of the trial...
Article 3 The available non-clinical and clinical information on an investigational medicinal...
Article 4 The protocol referred to in point (h) of Article 2...
Article 5 All clinical trial information shall be recorded, handled, and stored...

SECTION 2

THE ETHICS COMMITTEE

Article 6 (1) Each Ethics Committee established under Article 6(1) of Directive...

SECTION 3

THE SPONSORS

Article 7 (1) A sponsor may delegate any or all of his...

SECTION 4

INVESTIGATOR'S BROCHURE

Article 8 (1) The information in the investigator's brochure, referred to in...

CHAPTER 3

MANUFACTURING OR IMPORT AUTHORISATION

- Article 9 (1) Authorisation, as provided for in Article 13(1) of Directive...
- Article 10 (1) In order to obtain the authorisation the applicant must...
- Article 11 (1) The competent authority shall issue the authorisation only after...
- Article 12 (1) In order to ensure that the requirements laid down...
- Article 13 The holder of the authorisation shall at least comply with...
- Article 14 If the holder of the authorisation requests a change in...
- Article 15 The competent authority shall suspend or revoke the authorisation, as...

CHAPTER 4

THE TRIAL MASTER FILE AND ARCHIVING

- Article 16 The documentation referred to Article 15(5) of Directive 2001/20/EC as...
- Article 17 The sponsor and the investigator shall retain the essential documents...
- Article 18 Any transfer of ownership of the data or of documents...
- Article 19 The sponsor shall appoint individuals within its organisation who are...
- Article 20 The media used to store essential documents shall be such...

CHAPTER 5

INSPECTORS

- Article 21 (1) The inspectors, appointed by the Member States pursuant to...
- Article 22 In order to ensure the presence of skills necessary for...

CHAPTER 6

INSPECTION PROCEDURES

- Article 23 (1) Good clinical practice inspections may take place on any...
- Article 24 Member States shall make publicly available within their territories the...
- Article 25 Member States shall provide for sufficient resources and shall in...
- Article 26 Member States shall establish the relevant procedures for verification of...
- Article 27 Member States shall establish the relevant procedures for the following:...
- Article 28 Member States shall maintain records of national and, if applicable,...
- Article 29 (1) In order to harmonise the conduct of inspections by...
- Article 30 (1) Member States shall lay down all necessary rules to...

CHAPTER 7

FINAL PROVISIONS

- Article 31 (1) Member States shall bring into force the laws, regulations...
Article 32 This Directive shall enter into force on the twentieth day...
Article 33 This Directive is addressed to the Member States.
Signature

Status: This is the original version (as it was originally adopted).

- (1) OJ L 121, 1.5.2001, p. 34.
- (2) OJ L 262, 14.10.2003, p. 22.
- (3) OJ L 311, 28.11.2003, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).