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)

ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION

17. The protocol shall at least include:
18. If a clinical trial is conducted with an active substance...
19. With regard to the notification of adverse events, the protocol...
20. The protocol shall describe the procedures for:
21. In case the sponsor intends to submit a single safety...
22. Issues regarding labelling and the unblinding of investigational medicinal products...
23. The protocol shall be accompanied by the Charter of the...
24. The protocol shall be accompanied by a synopsis of the...

E. INVESTIGATOR'S BROCHURE (IB)

25. An IB, which has been prepared in accordance with the...
26. The purpose of the IB is to provide the investigators...
27. The information in the IB shall be presented in a...
28. If the investigational medicinal product is authorised, and is used...
29. For a multinational clinical trial where the medicinal product to...
30. If the IB is not an SmPC, it shall contain...

F. DOCUMENTATION RELATING TO COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP) FOR...

31. As regards documentation relating to GMP compliance, the following shall...
32. No documentation needs to be submitted where the investigational medicinal...
33. If the investigational medicinal product is not authorised, and does...
34. In all other cases, a copy of the authorisation referred...
35. For processes related to investigational medicinal products set out in...

G. INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD)

36. The IMPD shall give information on the quality of any...

1.1. Data relating to the investigational medicinal product

Introduction

37. Regarding data, the IMPD may be replaced by other documentation...
38. Each section of the IMPD shall be prefaced with a...
39. The information in the IMPD shall be concise. The IMPD...

Quality data

40. Quality data shall be submitted in a logical structure such...

Non-clinical pharmacology and toxicology data

41. The IMPD shall also contain summaries of non-clinical pharmacology and...
42. Non-clinical pharmacology and toxicology data shall be submitted in a...
43. The IMPD shall provide a critical analysis of the data,...
44. The IMPD shall contain a statement of the good laboratory...
45. The test material used in toxicity studies shall be representative...

Data from previous clinical trials and human experience

46. Data from previous clinical trials and human experience shall be...
47. This section shall provide summaries of all available data from...

Overall risk and benefit assessment

48. This section shall provide a brief integrated summary that critically...

ANNEX II

APPLICATION DOSSIER FOR SUBSTANTIAL MODIFICATION

ANNEX III

SAFETY REPORTING

ANNEX IV

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL

The summary of the results of the clinical trial shall...

A. CLINICAL TRIAL INFORMATION:

B. SUBJECT DISPOSITION:

C. BASELINE CHARACTERISTICS:

D. END POINTS:

E. ADVERSE EVENTS:

F. ADDITIONAL INFORMATION:

ANNEX V

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL FOR LAYPERSONS

The summary of the results of the clinical trial for...
Clinical trial identification (including title of the trial, protocol number,...

ANNEX VI

LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS

A. UNAUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

A.1. General rules

1. The following particulars shall appear on the immediate and the...
2. Symbols or pictograms may be included to clarify certain information...
3. The address and telephone number of the main contact shall...

A.2. Limited labelling of immediate packaging

A.2.1. Immediate and outer packaging provided together

4. When the product is provided to the subject or the...

A.2.2. Small immediate packaging

5. If the immediate packaging takes the form of blister packs...

B. UNAUTHORISED AUXILIARY MEDICINAL PRODUCTS

6. The following particulars shall appear on the immediate and the...

C. ADDITIONAL LABELLING FOR AUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

7. In accordance with Article 67(2), the following particulars shall appear...

D. REPLACING OF INFORMATION

8. The particulars listed in sections A, B and C, other...
9. The particulars referred to in the following points shall not...

ANNEX VII

CORRELATION TABLE

(**1**) OJ C 44, 15.2.2013, p. 99.

(**2**) Position of the European Parliament of 3 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

(**3**) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

(**4**) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

(**5**) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**6**) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1.)

(**7**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(**8**) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(**9**) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(**10**) OJ C 253, 3.9.2013, p. 10.

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.