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 IV

APPLICATION DOSSIER

Article 25

Data submitted in the application dossier

1 The application dossier for the authorisation of a clinical trial shall contain all required documentation and information necessary for the validation and assessment referred to in Chapter II and relating to:

a the conduct of the clinical trial, including the scientific context and arrangements taken,

b the sponsor, investigators, potential subjects, subjects, and clinical trial sites;

c the investigational medicinal products and, where necessary, the auxiliary medicinal products, in particular their properties, labelling, manufacturing and control;

d measures to protect subjects;

e justification as to why the clinical trial is a low-intervention clinical trial, in cases where this is claimed by the sponsor.

The list of required documentation and information is set out in Annex I.

2 The application dossier for the authorisation of a substantial modification shall contain all required documentation and information necessary for the validation and assessment referred to in Chapter III:

a a reference to the clinical trial or clinical trials which are substantially modified using the EU trial number referred to in the third subparagraph of Article 81(1) (the 'EU trial number');

b a clear description of the substantial modification, in particular, the nature of and the reasons for substantial modification;

c a presentation of data and additional information in support of the substantial modification, where necessary;

d a clear description of the consequences of the substantial modification as regards the rights and safety of the subject and the reliability and robustness of the data generated in the clinical trial.

The list of required documentation and information is set out in Annex II.

3 Non-clinical information submitted in an application dossier shall be based on data derived from studies complying with Union law on the principles of good laboratory practice, as applicable at the time of performance of those studies.

4 Where reference is made in the application dossier to data generated in a clinical trial, that clinical trial shall have been conducted in accordance with this Regulation or, if conducted prior to the date referred to in the second paragraph of Article 99, in accordance with Directive 2001/20/EC.

5 Where the clinical trial referred to in paragraph 4 has been conducted outside the Union, it shall have been conducted in accordance with principles equivalent to those of this Regulation as regards the rights and safety of the subject and the reliability and robustness of the data generated in the clinical trial.

6 Data from a clinical trial started as from the date referred to in the second paragraph of Article 99 shall only be submitted in an application dossier if that clinical trial has been registered prior to its start in a public register which is a primary or partner registry of, or a data provider to, the WHO ICTRP.

Data from a clinical trial started before the date referred to in the second paragraph of Article 99 shall only be submitted in an application dossier if that clinical trial is registered in a public register which is a primary or partner registry of, or a data provider to, the WHO ICTRP or if the results of that clinical trial have been published in an independent peer-reviewed scientific publication.

7 Data submitted in an application dossier which do not comply with paragraphs 3 to 6 shall not be considered in the assessment of an application for authorisation of a clinical trial or of a substantial modification.

Article 26

Language requirements

The language of the application dossier, or parts thereof, shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting, for the documentation not addressed to the subject, a commonly understood language in the medical field.

Article 27

Update by way of delegated acts

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in respect of amending Annexes I and II in order to adapt them to technical progress or to take account of international regulatory developments in which the Union or the Member States are involved, in the field of clinical trials.

Status:
Point in time view as at 31/01/2020.

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, CHAPTER IV.