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 VII

SAFETY REPORTING IN THE CONTEXT OF A CLINICAL TRIAL

Article 45

Technical aspects

Technical aspects for safety reporting in accordance with Articles 41 to 44 are contained in Annex III. Where necessary in order to improve the level of protection of subjects, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to amend Annex III for any of the following purposes:

(a) improving the information on the safety of medicinal products;

(b) adapting technical requirements to technical progress;

(c) taking account of international regulatory developments in the field of safety requirements in clinical trials, endorsed by bodies in which the Union or the Member States participate.

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 45.