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 XI

SPONSOR AND INVESTIGATOR

Article 71

Sponsor

A clinical trial may have one or several sponsors.

Any sponsor may delegate, in a written contract, any or all of its tasks to an individual, a company, an institution or an organisation. Such delegation shall be without prejudice to the responsibility of the sponsor, in particular regarding the safety of subjects and the reliability and robustness of the data generated in the clinical trial.

The investigator and the sponsor may be the same person.

Article 72

Co-sponsorship

1 Without prejudice to Article 74, where a clinical trial has more than one sponsor, all sponsors shall have the responsibilities of a sponsor set out in this Regulation, unless the sponsors decide otherwise in a written contract setting out their respective responsibilities. Where the contract does not specify to which sponsor a given responsibility is attributed, that responsibility shall lie with all sponsors.

2 By way of derogation from paragraph 1, the sponsors shall be jointly responsible for establishing:

- a a sponsor responsible for compliance with the obligations of a sponsor in the authorisation procedures set out in Chapters II and III;
- b a sponsor responsible for being a contact point for receiving all questions from subjects, investigators or any Member State concerned regarding the clinical trial and providing answers to them;
- c a sponsor responsible for implementing the measures taken in accordance with Article 77.

Article 73

Principal investigator

A principal investigator shall ensure compliance of a clinical trial at a clinical trial site with the requirements of this Regulation.

The principal investigator shall assign tasks among the members of the team of investigators in a way which is not compromising the safety of subjects and the

reliability and robustness of the data generated in the clinical trial at that clinical trial site.

Article 74

Legal representative of the sponsor in the Union

1 Where the sponsor of a clinical trial is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative shall be deemed to be a communication to the sponsor.

2 Member States may choose not to apply paragraph 1 as regards clinical trials to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical trial who shall be the addressee for all communications with the sponsor provided for in this Regulation.

3 As regards clinical trials to be conducted in more than one Member State, all those Member States may choose not to apply paragraph 1 provided that they ensure that the sponsor establishes at least a contact person in the Union in respect of that clinical trial who shall be the addressee for all communications with the sponsor provided for in this Regulation.

Article 75

Liability

This Chapter shall not affect the civil and criminal liability of the sponsor, investigator, or persons to whom the sponsor has delegated tasks.

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 XI.