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 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.

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 72.