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 III

AUTHORISATION PROCEDURE FOR A SUBSTANTIAL MODIFICATION OF A CLINICAL TRIAL

Article 22

Assessment of a substantial modification of aspects covered by Parts I and II of the assessment report — Assessment of the aspects covered by Part II of the assessment report

1 Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 38 days from the validation date.

2 During the period referred to in paragraph 1, the Member State concerned may request, with justified reasons, additional information from the sponsor regarding this substantial modification as far as its territory is concerned.

3 For the purpose of obtaining and reviewing the additional information referred to in paragraph 2 from the sponsor in accordance with the third and fourth subparagraph, the Member State concerned may extend the period referred to paragraph 1 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide the requested additional information within the period set by the Member State concerned in accordance with the second subparagraph, the application shall be deemed to have lapsed in that Member State.

The request for additional information and the additional information shall be submitted through the EU portal.

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 22.