

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 VI

**START, END, TEMPORARY HALT, AND EARLY
TERMINATION OF A CLINICAL TRIAL**

Article 37

**End of a clinical trial, temporary halt and early
termination of a clinical trial and submission of the results**

1 The sponsor shall notify each Member State concerned of the end of a clinical trial in relation to that Member State through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in relation to that Member State.

2 The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in the last Member State concerned.

3 The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned and in all third countries in which the clinical trial has been conducted through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in the last of the Member States concerned and third countries in which the clinical trial has been conducted.

4 Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV.

It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of that summary is set out in Annex V.

However, where, for scientific reasons detailed in the protocol, it is not possible to submit a summary of the results within one year, the summary of results shall be submitted as soon as it is available. In this case, the protocol shall specify when the results are going to be submitted, together with a justification.

In addition to the summary of the results, where the clinical trial was intended to be used for obtaining a marketing authorisation for the investigational medicinal product, the applicant for marketing authorisation shall submit to the EU database the clinical study report within 30 days after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for marketing authorisation has withdrawn the application.

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 37. (See end of Document for details)

For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of those data.

5 The sponsor shall notify each Member State concerned of a temporary halt of a clinical trial in all Member States concerned for reasons not affecting the benefit-risk balance through the EU portal.

That notification shall be made within 15 days from the temporary halt of the clinical trial in all Member States concerned and shall include the reasons for such action.

6 When a temporarily halted clinical trial referred to in paragraph 5 is resumed the sponsor shall notify each Member State concerned through the EU portal.

That notification shall be made within 15 days from the restart of the temporarily halted clinical trial in all Member States concerned.

7 If a temporarily halted clinical trial is not resumed within two years, the expiry date of this period or the date of the decision of the sponsor not to resume the clinical trial, whichever is earlier, shall be deemed to be the date of the end of the clinical trial. In the case of early termination of the clinical trial, the date of the early termination shall be deemed to be the date of the end of the clinical trial.

In the case of early termination of the clinical trial for reasons not affecting the benefit-risk balance, the sponsor shall notify each Member State concerned through the EU portal of the reasons for such action and, when appropriate, follow-up measures for the subjects.

8 Without prejudice to paragraph 4, where the clinical trial protocol provides for an intermediate data analysis date prior to the end of the clinical trial, and the respective results of the clinical trial are available, a summary of those results shall be submitted to the EU database within one year of the intermediate data analysis date.

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 37.