

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 VIII

### **CONDUCT OF A CLINICAL TRIAL, SUPERVISION BY THE SPONSOR, TRAINING AND EXPERIENCE, AUXILIARY MEDICINAL PRODUCTS**

#### *Article 58*

##### **Archiving of the clinical trial master file**

Unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial. However, the medical files of subjects shall be archived in accordance with national law.

The content of the clinical trial master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities.

Any transfer of ownership of the content of the clinical trial master file shall be documented. The new owner shall assume the responsibilities set out in this Article.

The sponsor shall appoint individuals within its organisation to be responsible for archives. Access to archives shall be restricted to those individuals.

The media used to archive the content of the clinical trial master file shall be such that the content remains complete and legible throughout the period referred to in the first paragraph.

Any alteration to the content of the clinical trial master file shall be traceable.

**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 58.