

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 55

Investigator's brochure

- 1 The sponsor shall provide the investigator with the investigator's brochure.
- 2 The investigator's brochure shall be updated where new and relevant safety information becomes available, and shall be reviewed by the sponsor at least once per year.

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 55.