

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 I

GENERAL PROVISIONS

Article 3

General principle

A clinical trial may be conducted only if:

- (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and
- (b) it is designed to generate reliable and robust data.

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 3.