

# Clinical Study

## REGULATION (EU) No 536/2014

[https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)

'Clinical study' means any investigation in relation to humans intended:

- (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
  - (b) to identify any adverse reactions to one or more medicinal products; or
  - (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;
- with the objective of ascertaining the safety and/or efficacy of those medicinal products;