

Clinical Trial

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

'Clinical trial' means a [clinical study](#) which fulfils any of the following conditions:

- (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
- (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
- (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.