

Clinical study

A clinical study is a scientific investigation in which participants receive a health-related intervention, such as a medicine, in order to learn about (discover or verify) how it works and interacts with the body (clinical, pharmacological, pharmacodynamic, and pharmacokinetic effects), or to identify any adverse reaction in order to understand the safety of and/or how well the medicine works (efficacy).

Previously, the terms clinical study and clinical trial were used synonymously. Refer to Regulation 2014/536 for more information.