Clinical trial

A clinical trial is a clinical study in which participants are assigned according to a pre-defined therapeutic strategy or plan (protocol) to receive a health-related intervention, such as a medicine, in order to investigate its effects on health outcomes, usually compared to another (or sometimes no) treatment.
Clinical trials are used to evaluate clinical practices that do not fall within the current practices of a country, or to evaluate a new medicine (investigational medicinal product).
Clinical trials are used to generate data on the safety and efficacy of the intervention. Clinical trials are conducted only after a regulatory authority approval and ethics committee review. Clinical trials are often characterised in Phases from I (first-in-human), II (exploratory), III (confirmatory) to IV (post approval).
Previously, the terms clinical study and clinical trial were used synonymously. Refer to Regulation 2014/536 for more information.