

Non-interventional observational study

In epidemiology and statistics, an observational study draws conclusions about the possible effect of a treatment on participants, where the assignment of participants into a treatment group versus a control group is outside the control of the investigator. In a non-interventional observational study, no additional diagnostic or monitoring procedures are applied to the patients, and epidemiological methods are used for the analysis of collected data (as per Article 2(c) of 2001/20/EC). It is not a randomised, controlled trial (RCT).

However, in some cases, observational studies are the most appropriate design – for example, if the condition being studied is rare. Sometimes non-interventional studies are the only ethical approach, for example if the effect of an environmental risk factor such as asbestos is being studied, it would be unethical to deliberately expose participants to asbestos.

There are three types of non-interventional study, which are defined separately in this glossary. They are:

- Cohort studies
- Cross-sectional studies
- Case-control studies