Definition of Observational Drug Study (ODS)

Any research that involves the collection of individual data related to the health of people, provided that it does not fulfil any of the conditions required to be considered a clinical trial, as established in article 2.1. i) of Royal Decree 1090/2015, dated 4 December, which regulates clinical trials with drugs, Ethics Committees for drug research and the Spanish Registry of Clinical Studies, and is carried out with one of the following purposes:

1. Determining the beneficial effects of drugs, as well as their modifying factors, including the perspective of patients, and their relationship with the resources used to achieve them.

2. Identifying, characterising, or quantifying adverse drug reactions and other risks to the safety of patients related to their use, including possible risk factors or effect modifiers, as well as measuring the effectiveness of risk management measures.

3. Obtaining information about medication use patterns in the population.

Observational studies with drugs should aim to complement the information already known about the drug without interfering with usual clinical practice.

Observational drug study for prospective monitoring

Any observational drug study in which subjects are monitored for a period of time until the outcome variable is reached, and this has not yet occurred at the start of the study.