# WHAT IS A CLINICAL TRIAL?

A clinical trial is an investigative study that aims to evaluate the safety and efficacy of new drugs or new combinations of drugs. In vaccines and monoclonal antibodies clinical trials, the immune response is also evaluated.

To conduct a clinical trial with medicines, approval is required from a Research Ethics Committee and the Ministry of health.

Clinical trials are classified into 4 phases:

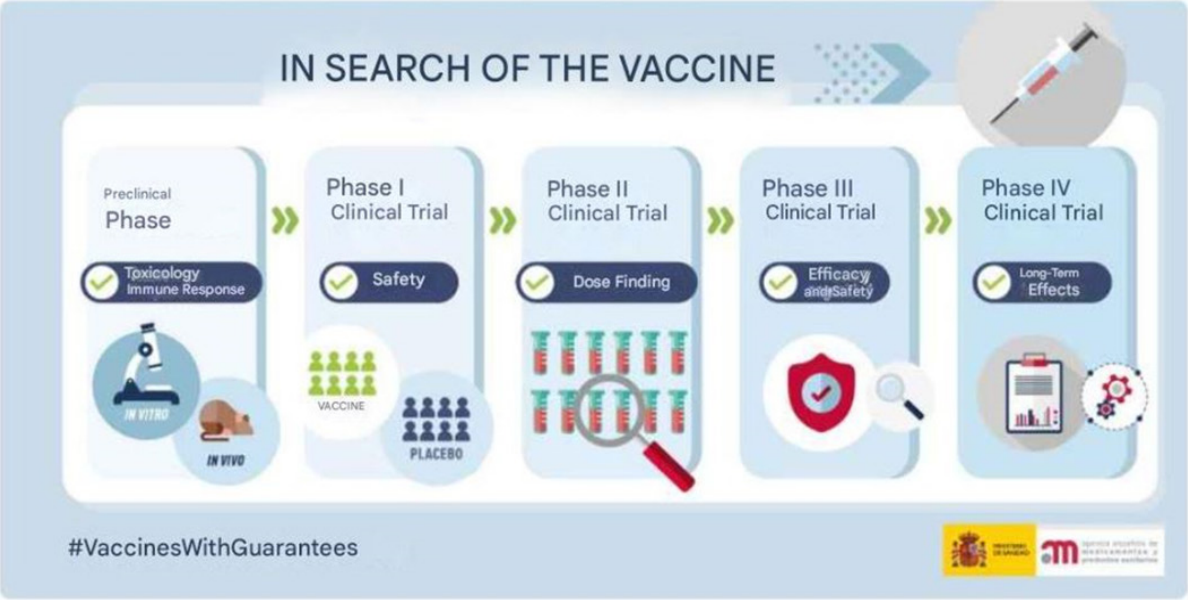


*Image adapted and translated from https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid-19/vacunas-contra-la-covid-19/desarrollo-de-vacunas/

Although the primary objective of each phase is different (as shown on the image), the safety of the vaccine under study is evaluated in all phases.

Phase I clinical trials involve tens of healthy individuals; phase II hundreds of individuals; and phase III thousands of individuals including those with stable chronic conditions. Phase III is the phase prior to approval for public use. Phase IV clinical trials are conducted once the vaccine is on the market.

In our centre, majority of the clinical trials that we conduct are in Phase II and III.

## WHO CAN PARTICIPATE?

- Healthy individuals or those with a medical condition depending on the requirements of each specific study.
- Participation is absolutely VOLUNTARY. You can say NO or withdraw at any time without repercussions to the relationship with your healthcare provider.
- Before including a volunteer in a clinical trial, each person's status is assessed to ensure that they can safely participate.

## WHAT DOES IT ENTAIL TO PARTICIPATE IN A CLINICAL TRIAL?

- Sign an informed consent form.
- Attend face to face visits or answer telephone visits.
- Assessment of the volunteer's suitability to participate. Questions are asked about medical history and treatments.
- Physical examination, blood analysis or other tests are performed depending on the study being carried out.
- Administration of an investigational vaccine or monoclonal antibody, comparator or placebo, usually through random allocation.
- Periodic follow-up visits.
- Allow medical personnel to access your medical information.

## WHAT ARE THE ADVANTAGES OF PARTICIPATING IN A CLINICAL TRIAL?

- Have the possibility to access a new vaccine.
- Receive close follow-up from the research team.
- Contribute to the discovery of a new vaccine or monoclonal antibody.
- Contribute to the prevention of infectious diseases.

## HOW CAN I PARTICIPATE?

If you are interested to participate in a clinical trial about vaccines and monoclonal antibodies for the prevention of infectious diseases, please register on the following form.

If you meet the eligibility criteria for a clinical trial, a member of the research team will contact you.

**For more information, please contact**
**the research team by telephone at 634 265 812**
*(Monday to Friday from 9:00 to 15:00h)*

**OR email us at: cvac@clinic.cat**