

# Clinical Trials

Step by step toward  
a brighter future



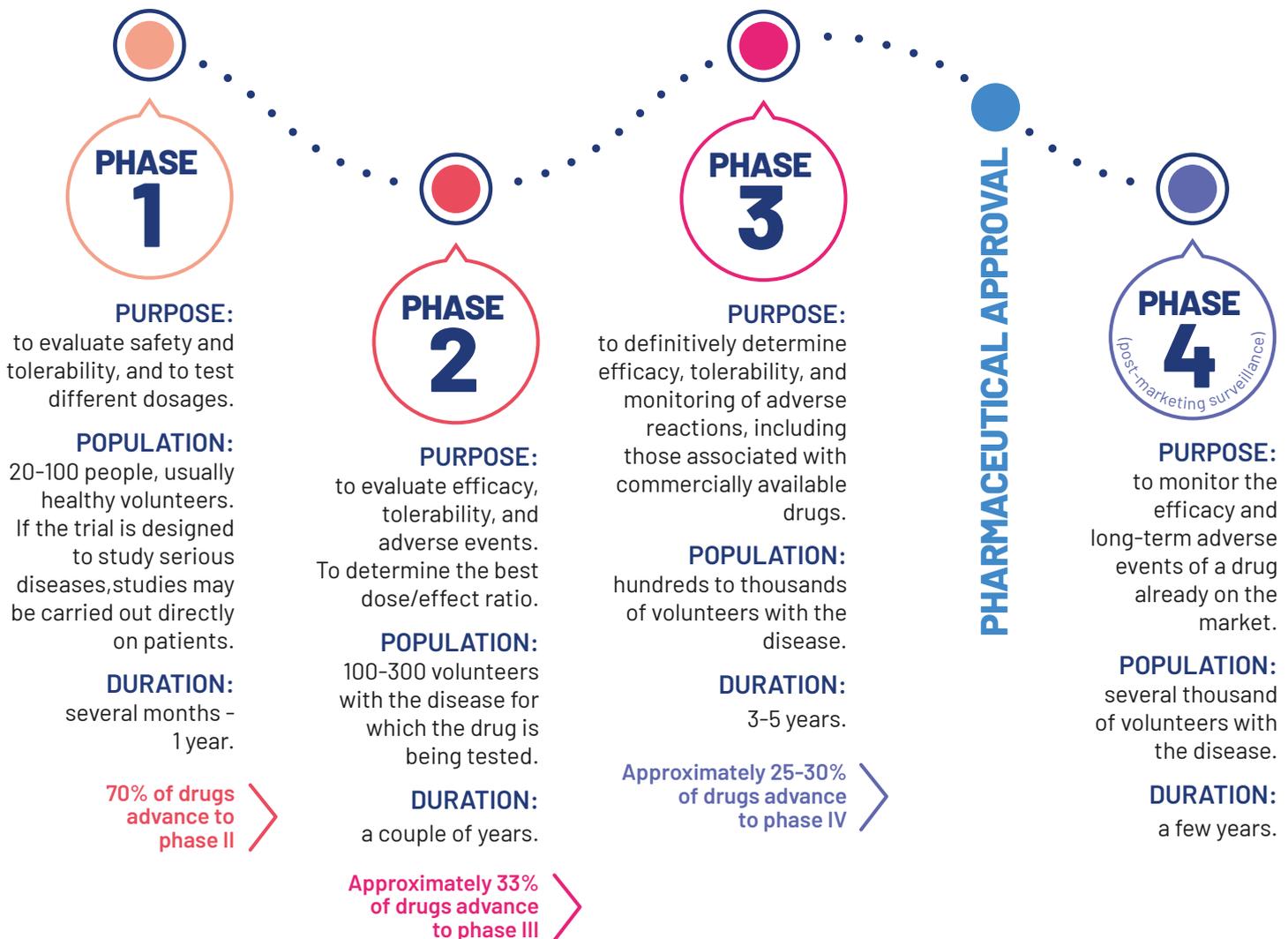
**Clinical trials are the beating heart of medical research**, a crucial step in the process of developing new treatments and therapies for a wide range of diseases and clinical conditions. They provide an opportunity for patients to access **cutting-edge treatments** and contribute to the **advancement of medicine**.

To be marketed, any drug must be studied in humans. After the development phase and preclinical studies in the laboratory and on animal models, the clinical study begins: the study in humans is aimed at defining or verifying the effects of a new drug or an existing drug for new therapeutic uses, to ascertain its safety, tolerability and efficacy.

Clinical studies can be also performed on medical devices, cosmetics, surgical procedures, or behavioral interventions.



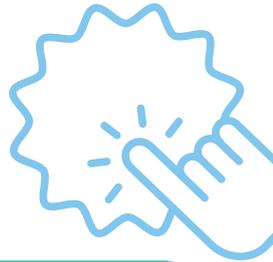
**Clinical trials for new molecules involve four phases:**



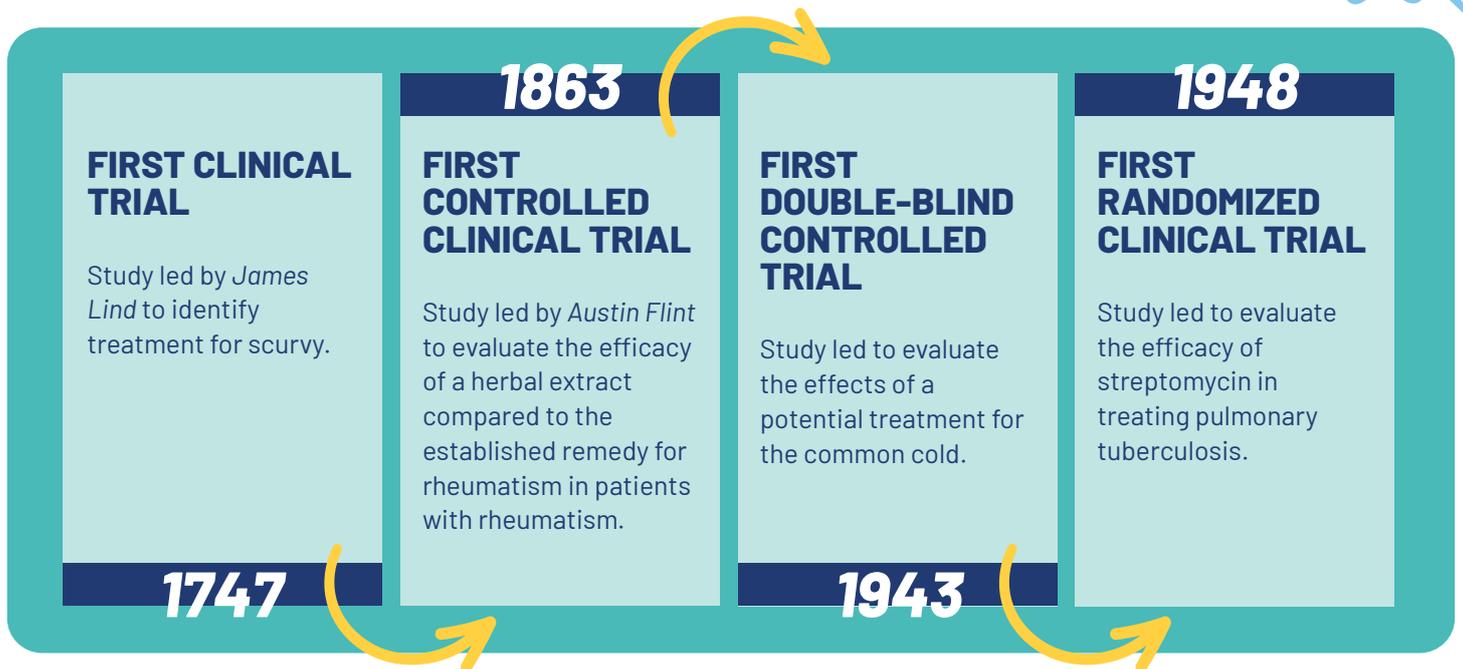
All clinical trials, before being conducted, require the **approval of an Ethics Committee (EC)**, an independent body that evaluates the ethical and scientific aspects of the trial to ensure and protect the rights, safety and well-being of the people involved.

Clinical trials are designed to **provide patients with increasingly effective and innovative therapeutic or diagnostic solutions**, to **fight diseases** and **improve individuals' quality of life**. Participating in a clinical trial can be an important opportunity to access innovative therapies.

However, the decision to participate in a clinical trial is a personal and informed decision that should be made by consulting the own referring physician.



## Evolution of clinical trials throughout history



Over the **past decades**, clinical trials have become increasingly sophisticated, with the use of cutting-edge technologies such as **artificial intelligence**, which enables the use of **big data** and techniques to study an individual's genetic heritage. Moreover, the use of new tools, such as telemedicine to reach patients living in remote areas, has made clinical trials more accessible and inclusive.

## Clinical trials' glossary

### CONTROL

"Control" is a placebo, a substance with no specific therapeutic effect.

A *controlled* clinical trial shows that an active treatment is more effective than a sham treatment, minimizing the placebo effect.

*[Control may also be a therapy of established efficacy]*

### DOUBLE-BLIND

The "*double-blind*" mode is a strategy in which the physician is unaware of what they are administering, and the patient is unaware of what they are receiving. This minimizes the risk of influencing the outcome of the research.

## RANDOMIZATION

Random assignment of subjects to two or more treatment groups. A *randomized* clinical trial ensures that all variables are evenly distributed among the groups.

## INTERVENTIONAL STUDY

A study involving the participation of patients in which an intervention – a potential drug, medical device, or procedure – that is believed to be better than the one used in clinical practice is administered to evaluate its efficacy and safety.

## OBSERVATIONAL STUDY

A study limited to recording, describing and analyzing what happens to patients treated during normal clinical practice, within a specified observation period.

## Clinical trials by the numbers

The *International Clinical Trials Registry Platform (ICTRP)* promoted by the World Health Organization (WHO), records clinical trials worldwide and ensures that the data is accessible to healthcare professionals, with the aim of improving transparency and strengthen the validity of trials.



From 1999 to 2022, **744,100 clinical trials** were registered worldwide, of which **577,531 were related to new treatments** (therapeutic, diagnostic, surgical). Among these, 271,906 can be identified in one of the four phases of clinical trials (51,755 phase I, 95,790 phase II, 75,475 phase III, 48,886 phase IV).

Which countries are the most active in this area? The **United States** ranks first with **142,300 studies**, followed by **China** with **64,194** and **Japan** with **47,059**. Only 11% of trials are conducted in pediatric populations.

## Angelini Pharma's contribution to global health

Angelini Pharma is constantly committed to clinical research to develop innovative solutions, mainly in two important areas of health: **Brain Health** and **Consumer Healthcare**.

In 2024, there will be **23 clinical trials** sponsored by Angelini Pharma:

- **18 active** in 13 countries: 7 interventional trials on drug, including 3 pediatric studies; 6 observational trials on drug; 4 clinical investigations on medical devices; 1 clinical study on cosmetics;
- **5 to be activated**: 1 interventional trial on drug; 3 observational trials on drug; 1 clinical study on cosmetics.

### Angelini Pharma clinical trials by type (2024)



Observational trials on drug



Interventional trials on drug

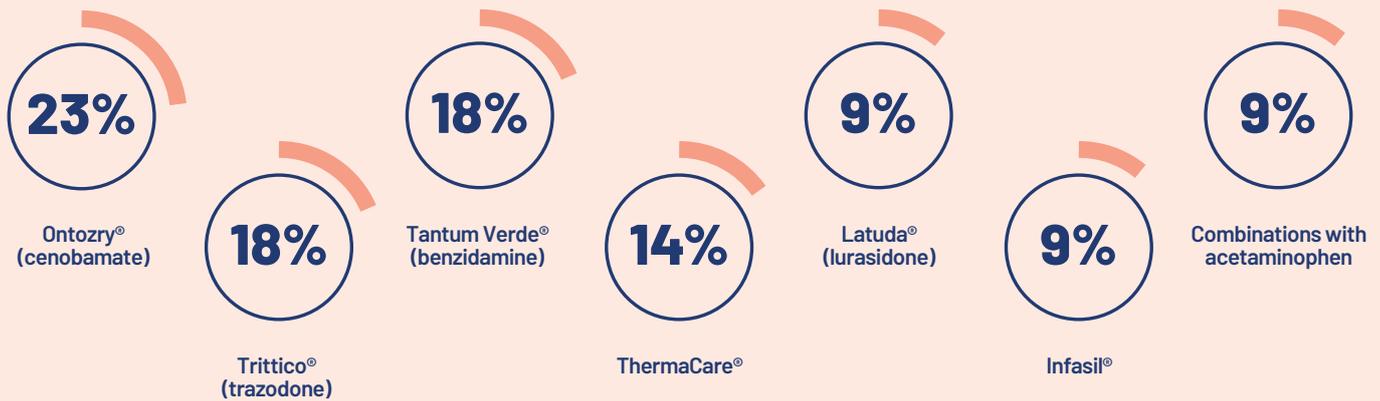


Interventional clinical investigation on medical device



Clinical study on cosmetics

## Angelini Pharma clinical trials by product (2024)



All studies engage different research groups and specialists and involve collaboration with scientists and physicians to ensure that clinical research is driven by the needs of patients.

### References:

- AIFA - La sperimentazione clinica dei farmaci - <https://www.aifa.gov.it/sperimentazione-clinica-dei-farmaci>
- FDA - The drug development process - <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process>
- FDA - The drug development process/Clinical research - <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>
- World Health Organization (WHO) - Global Observatory on Health and R&D - <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group>
- Bhatt A. Evolution of clinical research: a history before and beyond James Lind. PICR Jan (2010); 1(1):6-10
- AIFA - ABC degli studi clinici - <https://www.aifa.gov.it/sites/default/files/bif000133.pdf>
- Ministero della Salute - ABC degli studi clinici. Sperimentazioni controllate e randomizzate (RCTs) - [https://www.salute.gov.it/imgs/C\\_17\\_pubblicazioni\\_242\\_allegato.pdf](https://www.salute.gov.it/imgs/C_17_pubblicazioni_242_allegato.pdf)
- NHI, National Institute of Aging - What Are Clinical Trials and Studies? - <https://www.nia.nih.gov/health/clinical-trials-and-studies/what-are-clinical-trials-and-studies>
- World Health Organization (WHO) - Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2022) - <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development>