

• *4 Phases of*
**CLINICAL
TRIALS**

All investigational therapies are tested in clinical trials to see how safe they are and how well they work in people living with medical conditions.

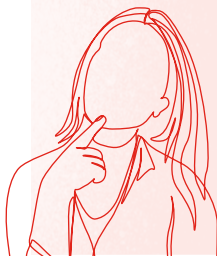
Clinical trials rely on people to volunteer as participants. Volunteers are essential to the research and development process, providing valuable impact for generations to come.

Clinical trials typically take place over

4 different Phases.

Each Phase needs to be successfully completed before moving on to the next one.

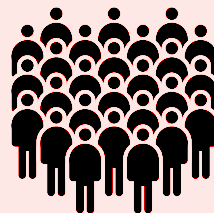
Phase 1



Phase 1 studies usually involve small groups of healthy volunteers. However, in areas like cancer research, patients often participate, as the investigational therapy being studied is intended for those with the medical condition.

It is in Phase 1 studies that an investigational therapy is first given to people. Researchers will look at:

- how the human body reacts
- if an investigational therapy is **safe for people**
- the **best dose** to use, and
- **how** it should be used.



20 - 100¹
participants

≤ 1
year

Phase 2

Phase 2 studies involve larger numbers of volunteers living with the medical condition being studied. In these studies researchers learn more about how safe an investigational therapy is, its effects in the body, and how well it works.

If the investigational therapy is seen to be **safe**, it usually moves to Phase 3.



100 - 300¹
participants

1 - 2
years

Phase

3

Phase 3 studies are carried out in large numbers of volunteers that have the medical condition being studied. These studies can last for many years. They compare the investigational therapy with a placebo or existing therapies to see if it:

- is **effective**, and
- remains **safe**



After the Phase 3 study is complete, health authorities review the clinical trial results and decide if it will become an approved therapy. Sometimes, phases 2 and 3 are combined into a single, hybrid trial.

300 - 3,000¹
participants

1 - 4
years

Phase

4



Phase 4 studies help us understand more about the **long-term safety** and effectiveness of the approved therapy across a large population of people living with the medical condition.



They can be carried out after the therapy has been approved for use in patients.

3,000+¹
participants

1 - 4+
years

Did you know?

In a typical year,
there can be

**up to
6,000**

clinical trials active in
the U.S. alone.²

The U.S. FDA
approves an average of

**45-50
new treatments**

each year.³

Clinical trial development
times, from Phase 1 studies
to when treatments are
approved, can range from

**5-20
years.**⁴

References

1. U.S. Food and Drug Administration. (2018, January 4th). Step 3: Clinical Research. FDA. <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>
2. World Health Organization. (2024, June). Number of clinical trials by year, country, WHO region and income group (1999-2024). WHO. <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>
3. U.S. Food and Drug Administration. (2025, February). Novel Drug Approvals at FDA. FDA. <https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda>
4. Brown, D.G., Worst, H.J., Kapoor, A., Kenna, L.A., Southall, N. (2022). Clinical development times for innovative drugs. *Nat Rev Drug Discov.*;21(11):793-4 <https://doi.org/10.1038/d41573-021-00190-9>