

What are clinical trials?

In 1962, the U.S. government passed a law that required the Food and Drug Administration (FDA) to test all new treatments to show they **work** (are effective) and are **safe** for people to use.

These tests are called **clinical trials**.

Since then, the FDA has approved more than:

20,000 Medicines, such as for high blood pressure
6,700 Medical devices, such as pacemakers
90 Vaccines, such as the flu shot



Clinical trials rely on **volunteers** to study new treatments

In a clinical trial, doctors and other staff give treatments to volunteers based on a specific plan. Experts review this plan to make sure volunteers are safe.



➤ Researchers must give volunteers complete information about the clinical trial before they agree to take part. This is called **informed consent**.
 Volunteers can leave the trial at any time.



292,766

volunteers participated in clinical trials worldwide for new possible drugs between 2015 to 2019



102,486





of those volunteers were in the U.S.



Clinical trials take place all over the nation and are sponsored by many types of organizations, such as the government, hospitals, drug companies, and research centers.

Clinical trials move in **phases** to ensure safety and effectiveness

➤➤ **Phases allow careful testing of new possible treatments.**
 Each phase answers different and important questions.

Phase 1	Phase 2	Phase 3		Phase 4
Months	Months to 2 years	1 to 4 years	Months	Many years
 10s of volunteers	 100s of volunteers	 1000s of volunteers	FDA Approval	 Countless volunteers
Questions to answer: ➤ Is it safe for people? ➤ How much of the treatment is needed?	Questions to answer: ➤ How well does it work? ➤ Are there new safety concerns?	Questions to answer: ➤ Does it work better than the current treatment? ➤ Are there new safety concerns?		Questions to answer: ➤ Does it work for all types of people? ➤ Are there new safety concerns?

Sources:

- www.fda.gov/AboutFDA/Transparency/
- <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>
- www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
- FDA. 2015-2019 Drug Trials Snapshots Summary Report: Five-year Summary and Analysis of Clinical Trial Participation and Demographics. November 2020.
- https://www.fda.gov/media/143592/download?utm_medium=email&utm_source=govdelivery

Interested in volunteering for a clinical trial? Visit:
www.melanoma.org/clinical-trials

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