

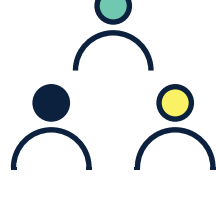
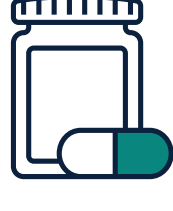


# From trial to treatment

How clinical trials help identify new treatments to save and improve lives<sup>1</sup>

## What are clinical trials?







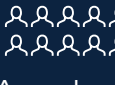
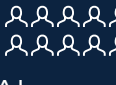
Clinical trials are research studies with volunteers designed to learn more about how our bodies respond to medicines or other treatments.<sup>1</sup> Clinical trials test possible drugs, vaccines or medical devices to see if they work.<sup>2</sup> It may take many clinical trials all around the world to understand which treatments work and how they work.



Clinical trials are a key part of the drug development process and can support our goals to:

- Save and improve lives
- Learn more about how our bodies may respond to medicines or other treatments
- Find new and better ways of keeping people healthy

### Clinical trials happen in 4 phases<sup>3</sup>

	Phase 1 <sup>4,5</sup>	Phase 2 <sup>4,5</sup>	Phase 3 <sup>4,5</sup>	Phase 4 <sup>4,5</sup>
<b>Questions it may answer:</b>	 Is the treatment safe? How much of it is needed? Are there any side effects?	 How well does the treatment work? Is it safe and what are the potential side effects? How much of it is needed?	 How well does the treatment work over time? Is it safe? How much of it is needed? Are there any new side effects? Does the new treatment work better than an existing treatment or a placebo? (A placebo looks like the trial treatment, but has no active medication)	 <b>Government agency review and approval:</b> Drug maker applies for approval. A treatment must be approved before doctors can prescribe it. How well does the treatment work over time? Does it work well for all types of people? Are there any new side effects? Can it work to treat other diseases?
<b>Who takes part:</b>	 A small group (about 20 to 100) of usually healthy people	 A larger group (about 100 to 500) of healthy people, or people with a certain disease	 A new, larger group (about 1,000–5,000) of people	 A large group (thousands) of people who have been prescribed the new treatment
<b>How long it takes:</b>	6 months to 1 year	6 months to 1 year or more	1 to 4 years	Ongoing for many years

## Clinical trials take time and resources:

- A treatment may take several years to move from a Phase 1 trial to government approval for doctors to prescribe it<sup>3</sup>
- Clinical trials require financial investment from sponsors.<sup>1,5</sup> Merck is the sponsor of a variety of clinical trials in different diseases and conditions
- Thousands of people in many countries contribute to clinical trials, including patients, researchers, health care professionals and support staff<sup>2</sup>

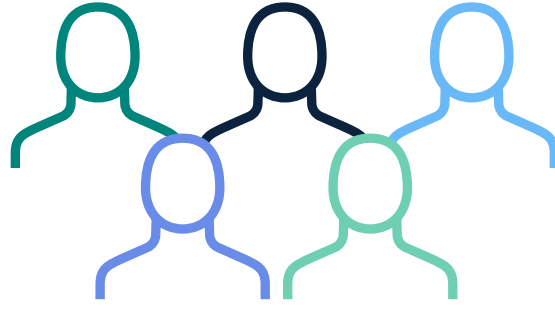


## Why are clinical trials needed?

Clinical trials are needed to find new treatments to improve people's health and save lives.<sup>1</sup> New treatments must be tested in clinical trials before government agencies can approve them for doctors to prescribe to people.<sup>1,5</sup>

## Clinical trials need a diverse group of volunteers to take part

Different people may have different reactions to the same treatment, based on their age, gender, weight, race, ethnicity, and other factors.<sup>6,7</sup> Clinical trials rely on volunteers to take part, and it's vital that these people come from diverse backgrounds to help ensure that our research reflects the various communities that we serve.<sup>6,7</sup> By including people from diverse backgrounds, clinical trials can help make sure treatments are safe and work well for people from all different communities.<sup>2,6</sup>



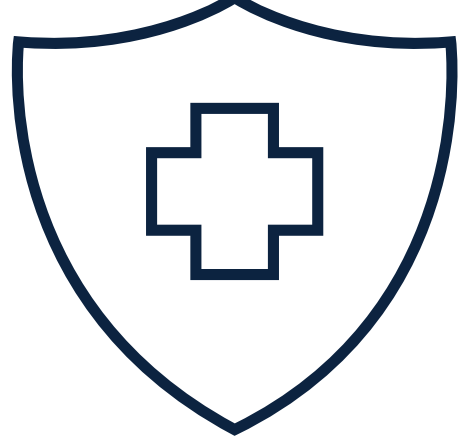
## There are many reasons why people volunteer for clinical trials

### By taking part in a clinical trial, you can:<sup>1</sup>

- + Learn more about your health condition and take an active role in your own health care
- + Help future patients by advancing medical research

### Clinical trials may also have some risks, such as:<sup>1,5</sup>

- ✗ Unwanted side effects
- ✗ The treatment may not work or, in some trials, you may not receive the treatment being studied
- ✗ Extra time and attention for trial-related tasks and visits



## Clinical trials show which products are safe and work well in patients<sup>5</sup>

- Did you know that most products that undergo laboratory testing never make it to human testing in clinical trials?<sup>1</sup>
- Of the ones that enter clinical trials, only 12% will be approved by a government agency.<sup>8</sup>



We are grateful to the thousands of volunteers who take part in our clinical trials

## References:

1. Clinical research versus medical treatment. U.S. Food and Drug Administration. <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment>. Accessed February 12, 2023.
2. Inside clinical trials: Testing Medical Products in people. U.S. Food and Drug Administration. <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/inside-clinical-trials-testing-medical-products-people>. Accessed February 12, 2023.
3. The drug development and approval process. FDAREview.org. <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/inside-clinical-trials-testing-medical-products-people>. Accessed February 12, 2023.
4. What are clinical trials? Merck Clinical Trials. <https://www.merckclinicaltrials.com/about/>. Published October 18, 2022. Accessed February 12, 2023.
5. About clinical trials. CenterWatch. <https://www.centerwatch.com/clinical-trials/overview>. Accessed February 12, 2023.
6. Clinical trial diversity. U.S. Food and Drug Administration. <https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity>. Accessed February 12, 2023.
7. Clinical trial diversity - food and drug administration. U.S. Food and Drug Administration. <https://www.fda.gov/media/106965/download>. Accessed February 12, 2023.
8. Modernizing drug discovery development and approval. PhRMA. <https://www.phrma.org/research-and-development/modernizing-drug-discovery-development-and-approval>. Accessed February 12, 2023.