

A Guide to Clinical Trials for People Over 65

Finding Treatments Together

Why are clinical trials important?

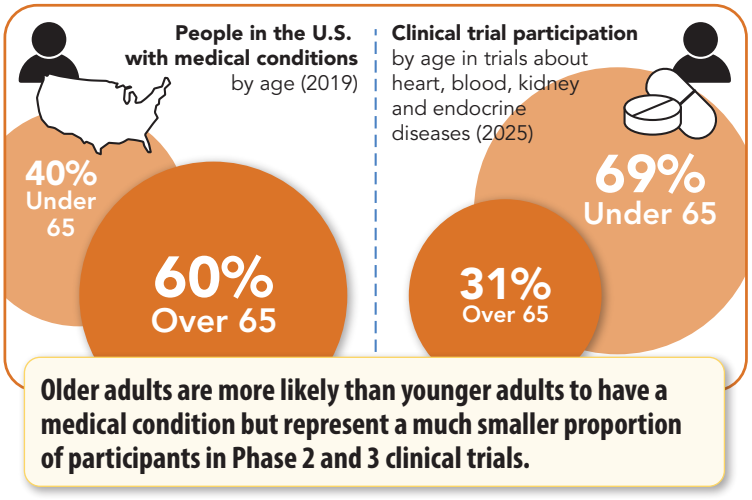
Clinical trials are the best way to find out if new treatments or vaccines work and how safe they are. If clinical trials show that a new treatment works and is safe, then it can be approved to be used by the people who need it.

Why should clinical trials have diverse participants?

Treatments or vaccines may affect people of different races, ethnicities, ages, genders, or sexes in different ways. It's important for everyone to be involved in clinical trials so we know how new treatments work and if they are safe for people from every community.

In the U.S., about 61% of people who have cancer are over 65 years old. Yet only about 26% of participants in clinical trials for cancer treatments are in this age group. Diseases affect people over 65 more than any other age group, but compared to other age groups, there is not as much information about which treatments work best for them.

People over 65 have been underrepresented in clinical trials.



Older adults are more likely than younger adults to have a medical condition but represent a much smaller proportion of participants in Phase 2 and 3 clinical trials.

sources: FDA Drug Trials Snapshots Summary Report; United States Census Bureau

Why have people over 65 been underrepresented in clinical trials?

Ageism

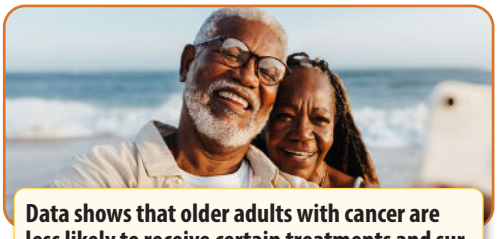
Ageism is discrimination against people due to negative or untrue beliefs based on their age. For example, many healthcare professionals use oversimplified language when speaking to older adults due to an ageist belief that people over 65 may not be able to understand as clearly as other adults. Ageism from researchers or healthcare professionals can have poor effects on the health and wellbeing of people over 65.

Ageism can keep healthcare professionals from sharing all of the treatment options they would usually share with younger patients. Data shows that older adults with cancer are less likely to receive certain treatments and surgeries even when they may help them.

On the other hand, ageism can also cause healthcare professionals to think that older patients need more treatment than they actually do. This can cause them to give patients over 65 more treatment than they need, even when the risks of those treatments outweigh the benefits. This can lead to other medical problems.

Barriers

Many people over 65 may have medical conditions or encounter other barriers that may make it difficult or unsafe for them to participate in certain clinical trials.



Data shows that older adults with cancer are less likely to receive certain treatments and surgeries even when they may help them.

source: https://ascopubs.org/doi/10.1200/OP.24.00324

Some of the barriers that make it more difficult for people over 65 to participate include eyesight problems and accessibility issues. When looking for clinical trials, you can ask if the researchers and staff are taking steps to overcome these barriers. Here are some sample questions:

- Are the documents available in large type?
- Does the trial site have ramps and handrails for accessibility?
- Will transportation be provided to and from the trial site?
- Will my caregiver be included at every stage of the clinical trial process?

There are websites to make searching for clinical trials easier. These sites have filters to show trials specifically for people over 65.

How are you protected if you participate?

Federal laws protect the safety of clinical trial participants. Clinical trials must:

- Follow laws and guidelines that make sure trials are ethical.
- Include a process called informed consent to fully inform people about a trial before they can agree to be in it.
- Be approved by an expert group called an institutional review board (IRB) that makes sure the trial is as fair and as safe as possible.

Mistrust of clinical research and healthcare

Some people mistrust doctors, researchers, or the healthcare system. Many people over 65 witnessed or experienced clinical researchers treating trial participants poorly in the Tuskegee Syphilis Study (1932–1972). In that trial, researchers withheld a treatment for syphilis from Black male participants.

This unjust treatment led to changes in the way that clinical trials are run and how participants are protected. But, clinical research professionals are still working to build back trust with all communities and show that they are taking the necessary steps to maintain the safety of all participants.

Being in a trial is your choice

When you sign an informed consent form to participate in a trial, you are not signing your rights away. Being in a trial is optional. **You can stop at any time and for any reason**. The trial staff will help you do this safely.

What are some of the risks and benefits?

Possible risks

- The treatment in the trial may not help you.
- You may have side effects from the trial treatment.
- You may have frequent testing or blood draws.
- You will need to set aside time for participation.

Possible benefits

- You may have access to treatments for your condition before they are available to other patients.
- You will help researchers learn more about how a treatment affects your community.
- Your health will be watched by the trial doctors and nurses.

If you are thinking about participating in a clinical trial, be sure to talk with your doctor and loved ones to see if the trial is right for you.

What are other ways you can get involved?

Not all clinical trials test an investigational new treatment or vaccine. Observational studies collect information about people's health during their normal care. This helps researchers learn more about specific health issues.

Joining a clinical trial that tests a new treatment for an illness or condition is only one way to participate in clinical research. Here are other ways to get involved:

- Volunteer for an observational study that only collects health data.
- Join a trial as a "healthy volunteer" so researchers can collect data on how a new treatment acts in the body before giving it to patients.
- Sit on a patient advisory board that helps ensure that trials have the participants' best interests in mind.
- Talk with your family and friends to raise awareness about clinical research in your community.

How can you find more information?

Patient support groups may be able to tell you about clinical trials for your condition. If you would like to learn more about our search clinical trial services, call **1-877-MED-HERO** or visit https://www.ciscrp.org/search-clinical-trials

For more information from CISCRP's *Finding Treatments Together* series and for translations of this brochure, go to: www.ciscrp.org/findingtreatmentstogether.

This brochure was co-developed together with a diverse group of people and experts who have experience working with diverse communities.

It was also reviewed and tested with patients, the public, and health professionals. They all helped to make sure it is clear, non-biased, and culturally appropriate.

CISCRP

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376

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