Women in Clinical Trials

A journey through the past, present, and future of women's representation in clinical research in the U.S.

What are clinical trials?

Clinical trials are used to test new treatments to see how well they work and how safe they are for the people who need them. These treatments can be drugs, vaccines, diets, or medical devices. Clinical trials help us find better ways to reduce disease symptoms, prevent illness, and diagnose medical conditions.

Why do we need women in clinical trials?

Clinical trials need participants who represent the people who will use the treatment. Treatments can affect people's bodies in different ways because of factors like sex, gender, race, and age. For example, liver injuries caused by medication are more likely to happen in women than in men. The only way we can know if a treatment works for women is if women participate in clinical trials.

But, for a long time, very few women were included in clinical trials. Let's take a walk through history to better understand why fewer women have participated in clinical research and why researchers have not studied women's health issues enough.

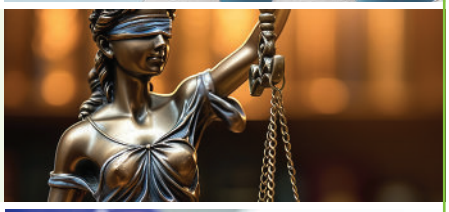
Source: https://pubmed.ncbi.nlm.nih.gov/18929073/

Until the end of the 20th century, there were very few women (or minorities) working in medicine and science. Women's health issues were given low priority.

1950s and 1960s – Many pregnant women took a drug called thalidomide for morning sickness. But, it caused their babies to be born with serious disabilities. This created a fear of including women in clinical trials.

1977 – The Food and Drug Administration (FDA) created a policy to keep all women of childbearing age from participating in early phases of clinical trials, even women who were taking birth control. This caused a serious shortage of information on how drugs affect women.

1986 – The National Institute of Health (NIH) created a policy encouraging scientists to include women (and minorities) in their research. In 1993, this policy became a law.



1990s – The NIH launched the Women's Health Initiative. Within 15 years, they enrolled over 150,000 women who finished menopause to participate in research on new treatments to lower the risk of bone problems, heart disease, and certain types of cancer.

Recently – By 2019, about 40% of the people participating in clinical trials for cancer, cardiovascular disease, and psychiatric disorders were women. The ultimate goal is for clinical trials to represent the U.S. population with women making up 50% of the participants.

While there has been a lot of progress, today some women still mistrust doctors, researchers, and the healthcare system because of discrimination. An example of discrimination is when women bring up problems to their healthcare providers and they are judged or not taken seriously.

Women who are a part of other minority communities, including Black women and trans women, may experience even more discrimination. Common misconceptions among medical professionals, such as the belief that Black people can tolerate more pain, continue to prevent women from participating in research.

Sources: https://orwh.od.nih.gov/ toolkit/recruitment/history and https://www.aamc.org/news/how-we-fail-black-patients-pain

We need women to participate in clinical trials, so that they can receive the best possible healthcare.

There are over 700 diseases that affect both men and women but are often caught later in women because we do not have enough research that includes women.

As of 2020, only 5% of funding for research is spent on women's health research. 4% is spent on women's cancer. 1% is spent on any other condition.

Sources:
https://www.cpr.ku.dk/cpr-news/2019/study-across-diseases-women-are-diagnosed-later-than-men/
https://doi.org/10.1038/s44222-024-00253-7

Looking towards the future

The next step toward progress is more clinical trials on health issues that primarily affect women. In March 2024, the US government directed $12 billion to women's health research. This means that organizations like the NIH and the Department of Health and Human Services (HHS) have more motivation and resources than ever to focus on women's health research.

Source: https://irp.nih.gov/catalyst/32/3/president-biden-requests-12b-for-research-on-womens-health

What are the risks and benefits of participating in clinical trials?

Participating in a clinical trial can be an important decision. Here are some things to consider to determine if it is right for you:

Possible Benefits

- You may have early access to new treatments for your condition
- You will help researchers learn more about how a treatment affects women
- Your health will be watched by the trial doctors and nurses

Possible Risks

- The trial treatments may not work for you
- You may have side effects from the trial treatments
- You may have frequent testing or blood draws
- You will need to set time aside to participate

Being in a clinical trial is always optional.
You can stop a trial at any time for any reason.

How to participate in a clinical trial

- For a guide to deciding if joining a clinical trial is right for you, check out our "**Should I Participate in a Clinical Trial**" brochure on our website at www.ciscrp.org/should-i-participate/.
- For information on how to find clinical trials, check out our "**How to Find A Clinical Trial**" brochure on our website at www.ciscrp.org/how-to-find-a-clinical-trial/.
- Talk to your healthcare provider about what trials might be right for you.

For more information

- For more information about **treatments working differently in women**: https://pubmed.ncbi.nlm.nih.gov/18929073/
- For more information about the **history of women in clinical research**: https://orwh.od.nih.gov/toolkit/recruitment/history
- For more information about **funding and women's health research**: https://www.nature.com/articles/s44222-024-00253-7

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.

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