# Disparities in Oncology Clinical Trial Enrollment

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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## Introduction

Clinical trials are used all over the world to study, prevent, screen for, diagnose, and manage new treatments for all types of health conditions. They are important for the constant improvement and development of modern medicine. However, like all other aspects of medicine, disparities still exist, especially between genders. Women were excluded from any clinical trial until 1986, as it was believed that participating in clinical trials could harm their childbearing potential. In the 1990s, the Women's Health Initiative was launched, and it helped kickstart clinical trials that studied post-menopausal conditions. It wasn't until 1994 that the National Institute of Health (NIH) wrote a policy into federal law (*History of Women's Participation in Clinical Research*, n.d.).

Not including equal amounts of gender representation in their clinical trial enrollments had many implications. First, women's health was put on the back burner and wasn't being researched. For example, it was only until this past decade that monumental advances in gynecological oncology treatments were made (Vilches et al., 2024). Second, since women weren't involved as patients in these trials, there was a lack of research on how various treatments affect women differently, leading to a lack of women-specific symptoms and treatments. Lastly, research funding still hasn't caught up to equal research, aiding in the current gap of knowledge. This lack of research is still present today and is showcased in the lack of equality for genders in research participation.

I will use the Social Construction of Technology (SCOT) theory to analyze this question of gender disparity. More specifically, I will be looking at the gender biases in clinical research trials and how that has led to inequality in cancer trials. Gender biases in clinical trials will be the

technology for SCOT with cancer trial enrollment as the case study. Even though it has been 30 years since they made it a law to include women in clinical trials, there is monumental evidence that the gap has not been closed. How can we use history to close this fundamental gap?

**Literature Review**

Inequality in clinical trial participant enrollment has been happening since the decision not to allow women into trials. Currently, there is research looking into how sex, gender, race, etc., affect patient participation and why this occurs in all clinical trials. Oncology trials are a bit different compared to other trials because some cancer trials are only targeted for a certain cancer that is gender-specific (like female reproductive cancers). So, research for this paper uses data that takes this factor into account when trying to answer the question of research enrollments.

The first group of research is from the *American Cancer Society Journal*, called "Assessment of gender representation in clinical trials leading to FDA approval for oncology therapeutics between 2014 and 2019: A systematic review-based cohort study." This journal article reviews gender representation in clinical trials seeking FDA approval between 2014 and 2019 (Dymanus et al., 2021). In the article, the authors highlight data that proves women are less represented in certain cancer clinical trials, using data collected from PubMed and the NIH clinical research trial registry (Dymanus et al., 2021). They eliminated trials that were for gender-based cancer (like ovarian) and trials that didn't provide genders for enrollees, eliminating the question of whether enrollment was based on enrollment necessities (Dymanus et al., 2021). They then found that women were only represented at 39.7%, even when incidence rates were higher in a certain disease for women (Dymanus et al., 2021).

The second group of research is also from the *American Cancer Society Journal*, called "The missing data: A review of gender and sex disparities in research." This article discusses the clinical trial gaps in gender and racial inclusion, alongside funding, with a particular specificity in gynecologic oncology (Karpel et al., 2025). They found that women have lower inclusion rates despite having a higher burden of disease across many disease types "(41% female participants vs. 51% female population disease burden)" (Karpel et al., 2025). This was shown in a different study that found that from 2003 to 2016, lung, melanoma, and pancreatic cancers had lower female enrollments despite having a higher prevalence of cancer (compared to men) (Karpel et al., 2025). They also found that in a study of oncology trials that led to Food and Drug Administration (FDA) approval in 2018, only 38% were female (Karpel et al., 2025).

The third group of research found that cooperative groups conducting research had a much lower percentage of gender compared to burden compared to the noncooperative groups, also being used in the study (Ludmir et al., 2019). A cooperative group in clinical trial terms means the trial is being conducted by one single group at many sites across the country at the same time ("Clinical Trials," n.d.). They also found that out of 168 trials, enrollment of women was 6.8% lower compared to the amount of burden of disease (Ludmir et al., 2019). This proves that matters need to be taken up with the noncooperative groups that involve multiple parties (such as financiers from an industry group) in a clinical trial, so that an established amount of equal gender enrollment is stated across one or many sites.

These articles found similar evidence of gender enrollment inequalities. Despite the reversal of the NIH ban, the implications of having women in their trials, such as the thought that multi-gender enrollment would cost the study more, have led to fewer women being represented in trials that affect them more, with numerical data to prove their theories. These studies go on to

discuss the implications of these numbers and how to help continue the improvement of enrollment numbers in the future, with considerations such as funding differences in diseases and changing the enrollment criteria for clinical trials before they are approved by the FDA. However, these don't fully address the root of the problem, which is fixing research inequalities to fix enrollment numbers.

**Conceptual Framework**

The Social Construction of Technology (SCOT) theory was created by Wiebe Bijker and Trevor Pinch in 1984 ("Social Construction of Technology (SCOT)," n.d.). It is the theory of the relationship between technology and society, analyzing the technical changes in society and how they are all interconnected and how they influence society ("Social Construction of Technology (SCOT)," n.d.). Interpretive flexibility, the principle of symmetry, relevant social groups, and stabilization are all subconcepts of this theory ("Social Construction of Technology (SCOT)," n.d.). Interpretive flexibility describes the process where each technological creation is up to individual interpretation, which changes how each individual sees the SCOT theory working. The principle of symmetry describes looking equally at successful and failure cases when analyzing a technology. Relevant social groups describe all of the members of a particular group, all attached to one distinct technology. Lastly, stabilization describes when a technology has been solved, and everyone refers to the technology's problem as solved. Criticisms involved in this technology include the lack of constraints that the physical world poses that are neglected in this analyzation and that the definition used for determining the group of associated people leave a wide gap in people who use/are affected by the technology that don't get used in the theory because they don't fit the definition ("Social Construction of Technology (SCOT)," n.d.).

For this paper, I will be using gender inequalities in clinical research to analyze how this has led to an inequality in trial enrollments between genders in oncology trials. I will be using social groups as described by SCOT to analyze this technology's role in current society and how these social groups have shaped the technology into what we know it as today.

**Analysis**

The steps that caused the current research situation can be traced back to many different branches, all dating back to the 1960s. Things such as a lack of funding, government mandates (or lack thereof), lack of research, and not updating historic procedures have all led to a current-day situation where oncology clinical trials have an uneven amount of enrollment based on gender, which is affecting current research capabilities. Not having equal amounts inhibits researchers from finding distinctions in care and treatments between genders. It allows researchers and physicians to keep the current standards and ideologies that men and women are created equal biologically (even though it has been proven that they are not) and to treat them as such. So, I will be using disparities in enrollment groups to analyze social groups, interpretations, and interests (interpretive flexibility), the principle of symmetry, the process of closure (stabilization), and the potential for evolution or resistance, as these are the key factors of the SCOT theory.

Social Groups

Many social groups can be attributed to the SCOT theory of enrollment inequalities. First is the hospital social group. These are the hospital networks that these doctors work in that oversee all of these patients and the doctors. They do the employee hiring, patient management,

and approve and help fund all clinical trials. Within this social group are many subsections. First, there are the doctors who contribute a lot of their time and effort to clinical trials and patients. They are the ones overseeing the clinical trials, approving patients to be enrolled, seeing patients in their clinics, and diagnosing patients. Next are the clinical research coordinators, who work closely with the sponsors of the clinical trials and the doctors to ensure that the protocol of the clinical trials is being followed as precisely as possible. They also help with acuity levels (a specific number of patient enrollment set by the protocol when first approved, that the site of the clinical trial has to meet within a certain amount of time).

Second is the social group of the government and its impact on healthcare. First, the government is the one who oversees all of the national funding, including how much goes towards medical research. The government was also the first to mandate that women should not be allowed into clinical trials, pushing the motive that the hormonal imbalances of women, along with their childbearing abilities, made them unsuitable and unsafe for clinical trials. They didn't want another incident like the Thalidomide incident of the 1950s. They also control the subgroup that is the National Institute of Health (NIH). They were the ones to push women back into clinical trials and officially into law in the 1990s. They are the ones who started the Women's Health Initiative, trying to push forward women's research since none had been conducted while women were not allowed in clinical trials. They are also one of the organizations that help organize clinical trials and identify problem diseases, and the data that goes along with the diseases. Their main goal, though, is spreading out the national health funding. In a report released in 2025, women's research was only allotted 8.8% of the national funds (Karpel et al., 2025). Not funding women's research properly will continue the trend of not researching women's health properly, including ways to involve more women in clinical trials. The next

subgroup is the FDA. They are the ones who officially approve clinical trials and push them into being a standard of care treatment option. They make sure companies are following protocols for their safety and the safety of patients. They also mandate that everything is as straightforward as possible and regulate data to make sure that a drug is helping patients. Next is the International Review Board (IRB), which helps mandate and write clinical trial protocols. They also approve any and all updates, including the accrual numbers, and help close a study safely. They also help to mandate who is included and excluded from trials, leading to an unbalanced number of enrollees. Lastly, the insurance companies and employers interact with the charges and procedure expenses from the clinical trials. They help patients pay and make sure they are not billing patients with extra charges that the study should be paying for.

The next big social group is the pharmaceutical companies. These companies design, innovate, and create the product. They come up with the money and investors to supply all of the necessary funds and supplies to take their drug from an idea to a phase 1 clinical trial to an FDA-approved drug. They also help set guidelines and protocols for their drugs, which include who is included or excluded, which could potentially lead to a gender enrollment bias. Within this pharmaceutical company group is a subgroup of lab researchers. These lab researchers are the ones making and testing the design. They use standard of care knowledge to create these drugs, which are often based on male-only data and biological functions. This can affect the adverse events that patients experience (due to a difference in biological compositions) in clinical trials and the procedures that are conducted, often leading to fewer women wanting to join the trial.

The last social group is the patients. These are the men and women receiving the treatments, making the final decision to join a clinical trial or not. They listen to doctors, clinical

research coordinators, and pharmaceutical companies to make decisions. They also have a subgroup called their friends and family, who also help them make decisions and listen to all of the advice given to them. Their decisions can also be based on insurance, financial, or political standings, not just the health of their loved one. Sometimes, certain procedures, extra laboratory tests, or additional symptoms may all persuade people to stray away from a clinical trial, and some clinical trials aren't offered to some women because of these additional circumstances.

Interpretations and interests (Interpretive flexibility)

This technology has a complicated interpretive flexibility because no one reason has caused the current status of trials. SCOT could analyze this technology and blame it on the original ideology that women are not as important as men in society. It could originate back to the original idea that drugs and treatments were not safe for women due to their childbearing abilities, and the fact that the thalidomide drug caused such drastic effects on children born while a mother was taking it. You could also analyze this issue and pinpoint it to the fact that even though the NIH said that it was safe for women to be included in trials, it was not written into law until the 1990s. It could also be traced back to the point that they already have "knowledge" on all of these diseases (even though they are male-only based practices). Therefore, there is a lot of interpretive flexibility to cause this technology to shape society and for society to have shaped it.

Principle of Symmetry

There have been many researchers who have tried to figure out and pinpoint how to fix this problem. None have been successful, but none have really tried either. Many discuss in their

papers things that affect the numbers and ways to change them. Some oncology researchers believe that fixing funding to specific gender-based diseases, fixing funding to include more female investigators, mandating that clinical trials include a certain threshold of each gender to qualify for FDA approval, and changing protocols to reflect the burden of disease vs enrollment numbers. However, there is still no mandate or rule that states that a clinical trial needs to have 50/50 enrollment between genders. Nor are there mandates about enrolling patients based on burden of disease on a certain group.

Process of closure (Stabilization)

For my research question, stabilization happens when trials, pharmaceuticals, procedures, and diagnoses all start to be based on male-only data. Since women weren't allowed or had very low enrollment rates, most studies solely focused on male patients and how a certain treatment or trial affected them. They then used this data to also diagnose, treat, and create clinical trials for diseases that also affected women (like oncology) without taking into consideration any biological differences. This made men the elite biological group, solely using them as the medical model for their trials. Thus, stabilization happened in SCOT until now, when women are starting to fill more spots in clinical trials.

Potential for evolution or resistance

Using SCOT, the technology of inequalities of enrollment in clinical trials based on gender has lots of potential for evolution, but will likely come with resistance. The background knowledge for this problem could be changed from non-gender-specific or male-only knowledge to gender-specific disease care, making clinical trials more accessible to both genders. There

could also be state or federal mandates that require certain gender enrollments for trials based on the burden of disease that affects each group. Spreading awareness about clinical trials and providing additional support to clinical trial participants could help encourage more women to enroll. Limiting financial barriers to treatment, like gas money or hotel stays for treatment, along with the actual cost of treatment (whether visits and standard of care treatments are insured or not), could be a way to evolve clinical trials to push for more enrollment. Pushing for more funding for women's research and prioritizing giving funds to more women researchers could help aid in enrollment numbers since there will be more knowledge out there for patients and doctors to make better decisions ("Women in Clinical Trials," n.d.).

**Conclusion**

The gender gap in clinical trial enrollments in oncology can be traced back to many things, as discussed above. It is a relevant problem in today's world, especially with the current political environment. With research funding getting scrapped left and right, making the most of the research that's left is the most important factor. One of the ways to accomplish this is to include equal numbers of participants by gender, so that the adverse effects, pharmaceutical differences, and effect of treatment can be studied over a larger group of people. It would also help get the drug to market approval because it would more easily show that it helps all parties involved, not just men. All in all, though, promoting equality in healthcare is a never-ending battle that will hopefully be continuing to change throughout the future.

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