

Diversity in Clinical Trials



Importance of Diverse Representation in Clinical Trials

It is important to enroll patients with diverse backgrounds such as ethnicity, race, age, and gender, as differences between people can lead to different responses to the same medication.

White people make up 58% of the U.S. population and 75% of clinical trial participants. This means other racial and ethnic groups, including Black, Hispanic, and Asian only make up 25% of clinical trial participants.

Medical communities are continuously working to implement better practices to reduce barriers to participation for diverse populations.



The Otsuka Difference

Otsuka puts participants first in clinical trials by:

- Developing a community-centric clinical trial awareness campaign
- Assessing doctors who may run an Otsuka trial to understand their reach into diverse communities
- Sending quarterly Diversity, Equity and Inclusion digests to doctors conducting Otsuka clinical trials to educate on different diversity topics
- Capturing both sex at birth and gender identity on patient forms
- Implementing a protocol review board to ensure clinical trial teams are taking steps to think about diversity and inclusion in the development of the clinical trial design



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Some Key Events That Led to Regulations

Involuntary Sterilization (1930s-1970s)¹:

- Nearly one-third of the women in Puerto Rico were coerced into sterilization when government officials claimed that Puerto Rico's economy would benefit from a reduced population.
- This also happened to other groups such as American Indians, Hispanic/Latinos, and African Americans

Henrietta Lacks (1951)²:

- African American cancer patient had tumor cells biopsied for scientific research without consent
- Her "HeLa cells" led to medical findings without any consent from or compensation to the Lacks family

Tuskegee Syphilis Study (1932-1972)³:

- This government-funded study recruited Black men who were told they would be treated for "bad blood"
- Researchers did not provide participants an informed consent, did not provide any treatment, and did not tell the participants they had Syphilis or offer treatment when it became available

The Willowbrook State Developmental Center (1947-1987)⁴:

- Participants were infected with Hepatitis and then given experimental vaccines
- Study participation was required for school acceptance and risks were not fully explained to parents

Otsuka contributes to the health of people around the world by continuously creating new value. We recognize that in order to continue sustainable growth, all business activities must be founded on respect for human rights. We acknowledge the historical human rights violations that have occurred as a result of clinical trials, and strive to do better, which includes complying with all regulations designed to protect patients and the integrity of the clinical trial process.



Safety Guardrails in Clinical Trials

Safety guardrails were created for clinical trials as a result of past events to prevent the exploitation of study participants in the future.



Good Clinical Practice (1997)

An international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve human participants



Office of Human Research Protections (OHRP) (2000)

Helps protect the rights, welfare, and well-being of healthy volunteers and patient participants



Food and Drug Administration (FDA) (1961)

Provides oversight for clinical trials that are testing new medicines or medical devices



Institutional Review Board (IRB) (1974)

Ensures that the risks are minimal compared with the potential benefits



Data and Safety Monitoring Board (DSMB)

Reviews data from a clinical trial for safety problems or differences in results among different groups



Informed Consent (1947)

A patient must provide Informed consent in order to enroll in a clinical trial. During the consent process, the patient learns details about the purpose of the study, what will be asked of them, along with the risks of participating

1. <https://journeys.dartmouth.edu/lats3ramsden/2018/04/20/reproductive-injustices-against-latina-women-in-the-1900s/>

2. <https://www.hopkinsmedicine.org/henriettalacks/>

3. <https://www.cdc.gov/tuskegee/timeline.htm>

4. <https://disabilityjustice.org/the-closing-of-willowbrook/>