Bliss COLLECTIVE

# REPRESENTATION IN CLINICAL TRIALS

## Why Representation Matters

**Systemic and systematic bias has created deep inequities in healthcare and clinical research. By understanding clinical trials, patients can access more treatment options and help ensure future care reflects everyone.**

### Who Is Most Underrepresented?

In women's oncology clinical trials, the groups most consistently and severely underrepresented are racial and ethnic minority women in the Black, Indigenous, and people of color (BIPOC) communities.

### Black Women

- One of the most medically underrepresented groups in clinical trials.
- Leads to **gaps in data** and treatments that may be less effective—or less safe.
- **Representation is critical** for developing treatments that work for everyone.

### Policies Driving Change

**FDA Diversity Guidance (2022)**

**Consolidated Appropriations Act (2022)**

- Unified protections across federal agencies.
- Strengthened safeguards for vulnerable populations:
  - Pregnant women
  - Fetal & neonatal persons
  - Children
  - Prisoners
- Established expert-led councils to review research policies and participant protections.

### What Are Diversity Action Plans?

Sponsors (usually pharmaceutical or device companies) must now submit **diversity action plans** before new treatments can be approved.

These plans outline:

- How participant demographics will match the populations most impacted by the disease.
- Strategies to include historically excluded and underrepresented groups.
- How treatments will be evaluated across **all types of people** for safety and effectiveness.

**Better Representation = Better Science**

### A Stronger, More Ethical Research Framework

Recognizing past ethical failures creates safeguards for the future. Expert oversight, strong laws, and informed patients drive accountability

Today's framework ensures clinical trial participation is:

- Voluntary
- Safe
- Just
- Ethical

**Equity, safety, and justice must guide every clinical trial.**

Acknowledging and understanding the previous failures and ethical errors in medicine allows us to identify ways to ensure that unethical activities are not repeated. With the help of these expert-led groups, guidelines, laws, and patients like you driving change and accountability, a framework has been established to ensure that clinical trials are ethical and just and that clinical trial participants are voluntary and well-informed. Safety and justice, especially for historically underrepresented and vulnerable populations, will continue to be a key underlying feature of all clinical trials.

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