The Columbia University Irving Medical Center (CUIMC) Diversity in Clinical Trials Training Program: A novel approach to improving inclusivity and generalizability of clinical research

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BACKGROUND

- While clinical trials are essential to improving health outcomes, lack of diversity among participants limits generalizability of research and perpetuates disparities
- New FDA requirements aim to align study demographics with overall population, but other approaches are needed
- Future trialists need explicit training in recognizing and mitigating barriers to access at every step of a clinical trial, from design to publication
- Under the Columbia/Pfizer Initiative for Clinical Trial Diversity, the creation of the Diversity in Clinical Trials Training aims to address these needs

GOALS

This program aims to:

- Provide foundational training on clinical trial design and execution while integrating concepts of health equity
- Explores barriers to accrual from underrepresented populations
- Address barriers through thoughtful study design, community partnerships, and industry collaboration
- Prepare participants to lead clinical research that is high quality, inclusive, and equitable

SOLUTIONS/METHODS

- 8 week hybrid program
- Participants from Columbia, Yale, Cornell
- Topics included translational medicine, statistical considerations, the informed consent process, regulatory framework, adverse event reporting, industry partnerships, patient and community advocacy, implicit bias, and overcoming barriers
- Sessions included lectures, workshops, interactive case studies, and panel discussions
- Feedback was elicited with anonymous surveys at the beginning, midpoint, and conclusion and used to inform future iterations

OUTCOMES

- 88 total participants (38 participants attended the required five out of eight sessions across 16 departments)
- 58% were from Oncology, 16% from Medicine, 11% from Pediatrics, 9% from Psychiatry

OUTCOMES (Cont.)

Participants were at different stages in their career:

- 39% clinical fellows and faculty
- 47% staff
- 13% being participants from other institutions
- 32% reported no formal training in clinical trials, though 48% had some “on-the-job” research experience

Significant barriers to becoming a clinical investigator (reported through the pre-program survey):

- 81% said **limited opportunities for a comprehensive clinical trial training program**
- 77% reported time constraints due to other clinical, research and/or teaching responsibilities
- 58% reporting financial barriers

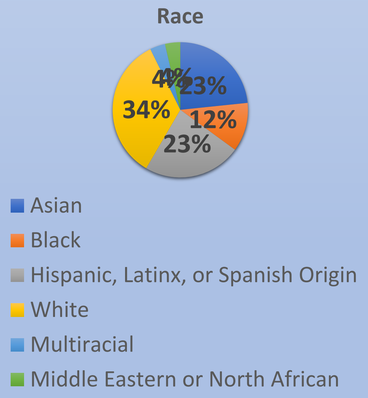
Post-program survey reports:

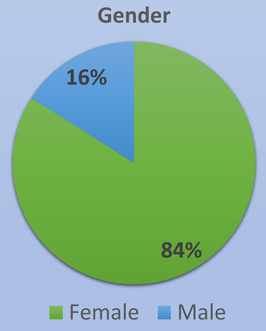
- 70% would like interactive workshops
- 60% want to see a library of resources
- 55% would like information session in a future iteration of our training program

Demographic Information:

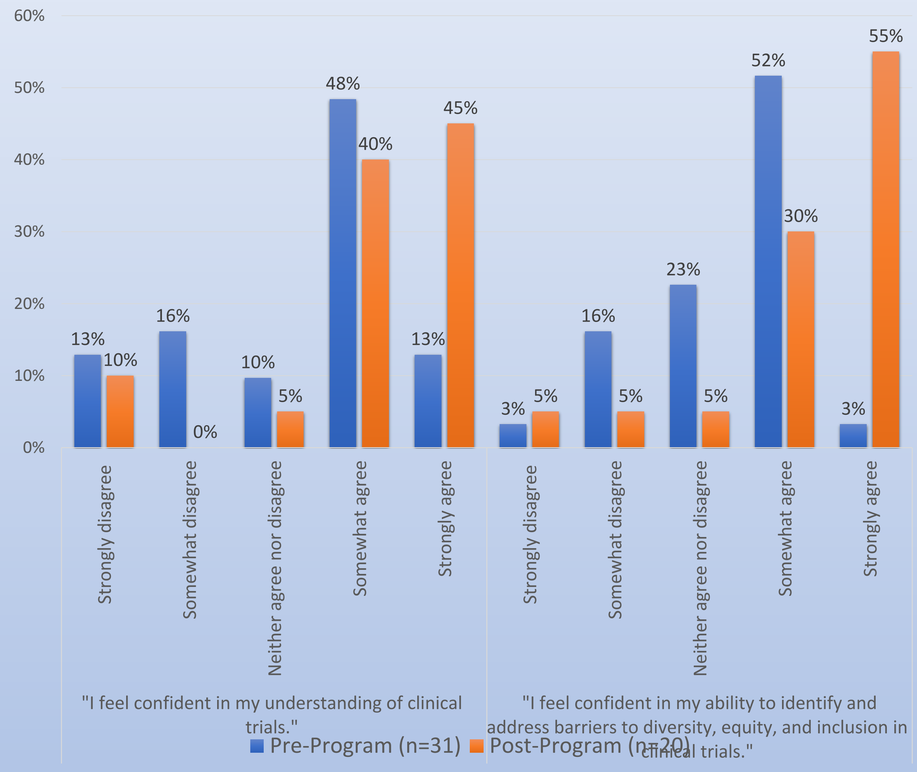
Race and gender:** **Self identified, adds up to >100%

Out of the 19 who answered the demographic questions





Pre and Post Survey Results Comparison:



LESSONS LEARNED/FUTURE DIRECTION

- Feedback indicates this program **addresses an unmet education need**
- Plan to expand the program's reach to **regional academic institutions**
- Plan to **address regional disparities** (i.e., rural and native populations)
- Add sessions on **barriers to LGBTQ involvement** in trials and sessions on **authorship and publication**
- Collect long-term data on our participants to understand what percentage ultimately pursue a career in clinical research