Category: Training, Career Development, and Staff Retention - Work in progress

The Columbia University Irving Medical Center Diversity in Clinical Trials Training Program: A Novel Approach to Improving Inclusivity and Generalizability of Clinical Research

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1. Background

While clinical trials are essential to improving health outcomes, lack of diversity among participants limits the generalizability of results and may perpetuate disparities. New Food and Drug Administration (FDA) requirements aim to align study demographics with those of the overall population, but other approaches are needed. To ensure greater inclusivity and better science, future trialists require more than just a strong foundation in the methods and conduct of hypothesis-driven research; they also need to recognize and mitigate barriers to access at every step, from trial design to publication.

2. Goals

This program aims to provide foundational training on clinical trial design and execution while integrating concepts of health equity in clinical research. It explores barriers to accrual from underrepresented populations and encourages participants to address these through thoughtful study design, community partnerships, and industry collaboration. Program participants will be better prepared to lead clinical research that is high quality, inclusive, and equitable.

3. Solutions and Methods

The first iteration of this eight-week program was launched in Spring 2023, and each session was live. During its second year, a hybrid structure accommodated participants from regional academic institutions, including Weil Cornell Medicine and Yale School of Medicine. 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.

4. Outcomes

For the first cohort, there were 44 total participants across 13 departments. Most (58 percent) were from Oncology, 16 percent from Medicine, 11 percent from Pediatrics, 9 percent from Psychiatry. Participants were at different stages in their career: 27 percent clinical fellows, 18 percent faculty and 54 percent staff. A majority (56 percent) reported no formal training in clinical trials, though 50 percent had some “on-the-job” research experience. Feedback from our first cohort has been overwhelmingly positive, with 90 percent of respondents reporting they would recommend this course to their colleagues. Data collection from our second year is ongoing.

5. Lessons Learned and Future Directions

Participant feedback indicates that this program is addressing an unmet educational need. Based on recommendations from the first cohort, changes were made to the format and new topics introduced. We will continue to refine our approach in subsequent iterations and plan to expand the program’s reach with a judicious roll-out to other institutions. With such an expansion, we anticipate the need for greater attention to regional disparities (i.e., rural and native populations). Barriers to LGBTQ involvement in trials and sessions on authorship and publication have also been proposed as topics for

next year. We also plan to collect long-term data on our participants to understand what percentage ultimately pursue a career in clinical research.