Category: Community Outreach and Engagement & Diversity, Equity, and Inclusion - Work in Progress

A Multimodal Approach to Increasing Participation of Underrepresented Communities in Investigator-Initiated Cancer Clinical Trials

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1. Background
Cedars-Sinai Cancer serves a highly diverse catchment area, yet clinical trial participants do not always reflect the breadth of this diversity. Underrepresented populations do not participate at expected rates due to burdensome research procedures, restrictive eligibility criteria, cultural or language barriers, and other factors. The result is a research population that is not representative of the catchment area, impacting generalizability of results. Investigator-initiated trials (IITs) provide an opportunity to design and customize trials to meet the needs of historically marginalized populations by actively addressing barriers to participation for underresourced communities and designing trials that engage specific groups that have been economically/socially marginalized.

2. Goals
Develop a multimodal approach to IIT design that encourages diversity, equity, and inclusion (DEI) in all areas of protocol design, resulting in protocols that complement the overall cancer research portfolio and support DEI enrollment goals.

3. Solutions and Methods
A collaboration was formed between Cedars-Sinai Cancer's IIT Development Program, Clinical Trials Equity Program, and investigators to design strategies to support DEI accrual goals throughout the trial process, from protocol design to recruitment and retention, trial conduct, analysis, and reporting.

4. Outcomes
Multiple strategies are ongoing involving protocol development with DEI objectives, support of underserved patients, and increasing clinical trial awareness. The IIT protocol template was revised to include a section on expected enrollment targets by gender, race, and ethnicity. At the time of the initial IIT committee review, the principal investigator details how the trial addresses the needs of our catchment area and how to support enrollment of underrepresented groups; and reviewers comment on whether the trial supports our catchment area and underrepresented populations. To address language translation of informed consent forms, questionnaires, and other patient-facing study documents, the institution implemented a process to fund translation expenses for research where language translation was not budgeted. During the enrollment period, study teams offer patients an Inclusive Demographics for Research (IDR) questionnaire, which gathers granular demographic information allowing for measurement of progress towards DEI goals. Furthermore, a virtual, self-paced training is offered to all researchers, providers, scientists, and faculty, to develop a deeper understanding of health equity, our cancer catchment area, underserved communities of color, benefits of inclusive research, barriers for communities of color to participate in research, resources to support diverse enrollment, and education and awareness tactics to engage with communities of color for research consideration and enrollment. Based on these interventions, analysis of our accrual data for the Latinx population demonstrated increased in enrollment to interventional treatment trials from 11.1 to 18.3 percent (+7.2 percent), interventional and non-interventional non-therapeutic accruals have increased by 4 percent and 5 percent respectively in the past year.

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5. Lessons Learned and Future Directions

Future directions include conducting real-time assessment of progress toward DEI goals, utilizing data gathered from the IDR questionnaire to refine outreach strategies, and continuing to engage participants from diverse backgrounds to understand motivating factors and barriers to clinical trial enrollment. We will expand our focus to enhance resources to improve enrollment of our underserved Asian and Black communities.

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