Category: Finance/CCSG/PRMS – Work in Progress

Monitoring Study Enrollment Demographics: PRMS-COE Collaboration at University of Colorado Cancer Center (UCCC)

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1. Background

The National Cancer Institute (NCI) is dedicated to ensuring access to clinical trials opened at NCI-Designated Cancer Centers for all demographic populations. In November 2019, the Funding Opportunity Announcement for P30 Cancer Center Support Grants (CCSG) was revised to include additional monitoring responsibilities for the protocol review and monitoring system (PRMS). More specifically, PRMS was newly tasked with evaluating how the inclusion of minorities and other underrepresented populations into clinical trials is considered and monitored in open protocols.

2. Goals

With the new NCI requirements to evaluate the potential for inclusion of underrepresented populations in new clinical trials and to monitor open protocols, PRMS endeavored to roll out a collaborative review process to include key stakeholders, such as the University of Colorado Cancer Center (UCCC) Office of Community Outreach and Engagement (COE).

3. Solutions and Methods

- Input new questions into the scientific review committee form:
    - Are the eligibility criteria broad enough to be inclusive of all demographics?
    - Does the study include satellite/regional hospitals?
    - Does the study provide documents or consents in languages other than English?
- Hold regular meetings between PRMS and COE to determine:
    - Demographic definitions are aligned for race, ethnicity, rurality, and socioeconomic status
    - Areas for enhancement on the PRMS submission form related to potential barriers to enrollment
    - Workflow solutions for relaying PRMS submission requests or identified barriers to COE team
- Revise the PRMS submission form:
    - Input Colorado cancer demographics table for reference
    - Principal investigator (PI) required to indicate whether demographic enrollments are expected to be higher, lower, or the same as Colorado
    - PI able to identify potential barriers for enrolling a diverse population, such as access; language or literacy; cultural or religious; or other barriers
    - PI able to request COE support directly
    - COE list of local resources provided
- Create custom report from our clinical trial management system, OnCore, to review demographic enrollment and study data:
    - Age, Gender, Race, Ethnicity, and Rurality
    - Reports sent to Disease Based Teams (DBTs) biannually
        - Reports include demographics above; list of studies from which the demographic data was extracted; 6-month trend report; Colorado population demographics; clinic demographics (i.e., who is walking in); a DBT comparison

graph for Hispanic/Latino enrollments; and information on how to request English-to-Spanish translation as well as assistance with strategies to make protocol engagement culturally and literacy appropriate

4. Outcomes

New PRMS review and monitoring processes were rolled out in July 2020 to incorporate evaluating newly submitted trials for demographic expectations, ensuring study inclusivity, and providing biannual monitoring reports to DBTs. PRMS has distributed four 6-month reports to DBTs.

5. Lessons Learned and Future Directions

There has been a recent strong push to ensure diversity, equity, and inclusion in cancer clinical trials. Monitoring DBT enrollment demographics has brought awareness of enrollment demographics to UCCC PIs, allowed UCCC to identify areas of need, and informed COE with data to target teams needing more assistance. The ultimate goal is to increase enrollment of underrepresented populations to studies open within the UCCC. Future metrics will determine whether these monitoring efforts have been fruitful.