

## **PRMS - COE Collaboration to Improve Diversity Awareness in Clinical Trial Enrollments 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 Cancer Center Support Grant (CCSG) was updated to include additional monitoring responsibilities for the Protocol Review and Monitoring System (PRMS). More specifically, PRMS was tasked with evaluating how the inclusion of minorities and other underrepresented populations into clinical trials is considered and monitored in open protocols. At this same time, increasing diversity in clinical trial enrollments was made a top priority at the University of Colorado Cancer Center (UCCC).

### **2. Goals**

In collaboration with the UCCC Office of Community Outreach and Engagement (COE), PRMS implemented a multi-pronged approach in 2020 aimed at increasing awareness of diversity and inclusion in clinical trials and measuring the current state of clinical research enterprise knowledge regarding best practices related to recruitment of diverse patient populations.

### **3. Solutions and Methods**

1. Revised the PRMS submission form to include:
  - a. Required study teams to indicate expected demographic enrollment for interventional trials
  - b. Provided catchment-area demographics within the PRMS submission form
  - c. Added questions on potential barriers to enrollment and how barriers could be addressed and resolved; relayed any identified barriers to COE
2. PRMS provided demographic enrollment data on race, ethnicity, gender, age, and rurality to Disease Based Teams every 6 months
3. PRMS and COE partnered on live presentations to individual Disease Based Teams (DBTs) to share demographic enrollment data and COE resources available to teams
4. Surveyed UCCC faculty and staff on the current state of clinical trial diversity awareness and use of best practices using the validated Diversity Site Assessment Tool (DSAT) before and after items 2 and 3 above; the DSAT's purpose is to evaluate a site's practice in study enrollment and performance in order to pinpoint areas of opportunity to successfully recruit a diverse population to clinical trials

### **4. Outcomes**

DSAT scores showed improvement in three areas of diversity awareness one year after implementing the PRMS-COE activities. These defined areas include 1) Site Overview; 2) Site Recruitment and Outreach; and 3) Patient Focused Services. Higher scores in each category are reflective of a site that is aware of general diversity best practices. In addition, PRMS-COE assisted 9 DBTs with support for identified barriers. Notably, UCCC increased Hispanic/Latino enrollments to interventional trials over this same period from 6.9 percent in FY2020 to 11.2 percent in Fiscal Year (FY) 2022.

### **5. Lessons Learned and Future Directions**

The collaboration between PRMS and COE to increase diversity awareness in clinical trial enrollments has contributed to a measured improvement in awareness as well as positive outcomes as indicated by an increase in Hispanic/Latino enrollments at UCCC. The results of the DSAT identified targeted areas where we can focus our efforts on staff education and improved awareness to achieve our goal of aligning best practices for enrolling diverse populations to our trials. This is an ongoing effort, and continued monitoring to increase diversity awareness will remain a top priority at our center.