

A Dual Prospective–Retrospective Review Framework Enhancing Representation and Accessibility in Cancer Clinical Trials

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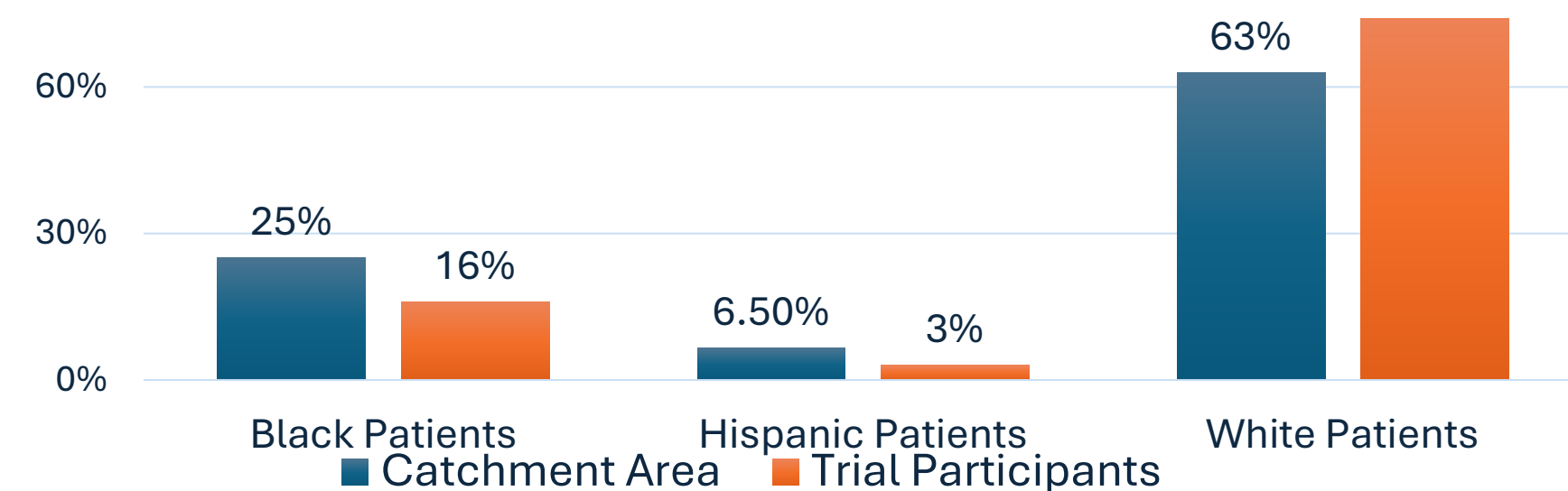


1. Introduction / Rationale



Representation in cancer clinical studies strengthens validity and impact.

DCI Clinical Trial Enrollment



- Underrepresentation in clinical trials is driven by barriers like restrictive eligibility, limited awareness, mistrust, and logistical challenges.
- Ensuring studies reflect the populations affected is essential to evaluate therapeutic efficacy and identify biology associated with response.

Approach

Two complementary institutional review processes:



Retrospective PRMC Review (Start date – July 2025)

Investigator-initiated trials (IITs) enrolling ≥ 10 participants, but $<10\%$ from underrepresented groups.

Comprehensive review of protocols to identify barriers (eligibility, referral, logistics)
Meet with clinical research teams to discuss strategies and enhance recruitment.



Prospective PRMC Review (Start date – Sep 2025)

“Representation Reviewer” embedded into PRMC for new investigator-initiated trials.

Review occurs before activation → allows proactive adjustments.

3. Progress to Date

19 Total Reviews (IITs) = 9 Retrospective + 10 Prospective



Improved recruitment planning

• **E.g.** Recommended partnering with DCN regional clinics to support referrals from rural communities, helping expand access

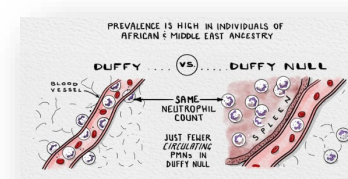


• **E.g.** Recommended development of plain language, low literacy, culturally accessible study materials to improve understanding and comfort

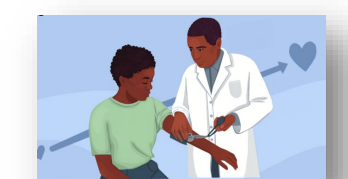


Protocol design adjustments

• **E.g.** Recommended expanding neutrophil count eligibility criteria to align with recent findings on the Duffy-null phenotype, which is common among Black individuals and associated with healthy, but lower baseline neutrophil levels



• **E.g.** Recommended review of hypertension criteria for unnecessary restrictiveness since elevated hypertension prevalence among Black adults can disproportionately limit participation



4. Future Directions

- Continue systematic data collection to evaluate the effectiveness and impact of the review process.
- Track key metrics to identify areas for improvement across study planning, protocol development, and recruitment strategies.
- Further develop resources, tools, and guidelines to support representative study design at all stages of the trial lifecycle.
- Create a centralized menu/directory of support options and best-practice resources for study teams to use during protocol development and study implementation.

5. Key Takeaways

Representation initiatives embedded into the protocol development and implementation process

- Promotes earlier action on recruitment barriers
- Builds a scalable model for institutional change
- Positive relationship building between COE and clinical research teams around representation in clinical trials

Contact

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