Category: Community Outreach and Engagement, and Community Representation and Inclusion – Work in progress

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

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1. Background

Diverse patient representation is essential for ensuring that cancer clinical trial results are both scientifically rigorous and broadly generalizable. A review of enrollment to clinical trials at Duke Cancer Institute (DCI) identified gaps between catchment area demographics and trial enrollment patterns suggesting possible structural and procedural limitations affecting trial accessibility. Traditional approaches that intervene only after activation often fail to address upstream design decisions that shape trial participation. To overcome this gap, DCI developed a comprehensive institutional model integrating both retrospective review and prospective scientific oversight to embed representation considerations across the life cycle of investigator-initiated trials (IITs). This model establishes a scalable, systematic framework that enhances scientific precision, improves operational feasibility, and strengthens institutional research quality.

2. Goals

Implement an institutional review system that expands representation across IITs at both pre-activation and post-accrual stages.

Detect and correct structural, scientific, and logistical barriers limiting accessibility.

Integrate structured consultations to support investigators and clinical research staff in implementing recommendations.

Create an exportable model that can be adopted by peer cancer centers to improve trial generalizability.

3. Solutions and Methods

DCI launched a dual-review architecture uniquely integrating retrospective performance analysis with prospective scientific review through the DCI Protocol Review and Monitoring System (PRMS).

A. Retrospective Review

The DCI Clinical Research Representation (CRR) team conduct structured reviews of IITs enrolling ≥10 participants but demonstrating <10 percent representation from catchment-relevant demographic groups. We analyze eligibility thresholds, visit burden, logistical constraints, referral patterns, and clarity of study materials and recommend solutions.

The CRR team hosts consultations with investigators and study teams walk through findings, discuss implementation strategies, troubleshoot barriers, such as protocol eligibility criteria and patient recruitment methods, and align study operations with real-world access needs. For example, we

encouraged teams to leverage the Duke Cancer Network's affiliated rural clinics to expand recruitment and enrollment opportunities within communities that are historically underserved and underrepresented, ensuring study operations align with real-world access needs.

B. Prospective Review

A Representation Reviewer is integrated directly into PRMS oversight of all new IIT submissions, ensuring that representation considerations are evaluated at the point of scientific review. This integrated review assesses eligibility design, visit complexity, recruitment pathways, and anticipated logistical barriers, allowing early modifications—such as protocol amendments or alternate recruitment strategies—that strengthen trial accessibility before activation.

We consult with investigators during protocol development to refine study design, anticipate challenges, and integrate representation considerations.

4. Outcomes

In the first year, we completed a pilot review of 18 IITs (9 retrospective; 9 prospective). Across these studies, the Representation Reviewers made specific operational recommendations, including protocol-level adjustments to eligibility criteria and visit schedules, as well as alternative recruitment pathways tailored to catchment-relevant populations. Several teams implemented these recommendations—for example, expanding recruitment to affiliated community clinics and revising patient-facing materials to improve clarity and accessibility.

Engagement with the consultation process has been strong, with investigators proactively seeking early support prior to protocol submission. While it is too early to assess changes in representation outcomes, the pilot phase demonstrates that structured reviews and targeted recommendations are feasible, well-utilized, and able to shape study design and recruitment planning at stages where changes can meaningfully influence enrollment trajectories.

5. Lessons Learned and Future Directions

Prospective CRR integration within the DCI PRMS accelerates impactful adjustments, while retrospective analyses provide essential feedback loops to study teams. Consultations support study teams in applying recommended changes by translating scientific objectives into operational steps that can be implemented within real-world clinical workflows. Next steps include expanding longitudinal metrics, assessing the impact on trial representation, enhancing the procedural workflow to encompass industry-sponsored studies, and improving the workflow through iterative feedback from collected data metrics and enrollment trends.