

## **Hybrid Decentralization of Early Phase Cancer Clinical Trials to Enhance Study Recruitment of Underrepresented Minorities**

C. Wiess, A. Rodrigues, I. Palma, D. Wall, P. LoRusso

*Yale Cancer Center, Yale School of Medicine*

### **1. Background**

Poor accrual of underrepresented minorities (URM) to clinical trials is a concern in cancer drug development, not only due to their lack of access to novel agents, but also the fact that limited diversity may fail to identify groups who could benefit, or have increased toxicity from, novel agents. This worry is even more predominant with early phase cancer clinical trials (EPCCT). EPCCT are often conducted in centralized locations, and, due to their complexity, require frequent safety assessments and extensive protocol requirements. Geographic location of trial execution is a major challenge for these patients. As such, the majority of URM patients are treated close to home in community clinics.

### **2. Goals**

This project aims to implement a hybrid decentralization model (HDM), bringing feasible EPCCT components into community clinics where many URM patients already receive their treatment. The overall goal is to determine if, by bringing the trials to the patients, an increase in recruitment and retention will occur. We are opening two EPCCT clinics in community clinics in Connecticut: one in Fairfield County (12.9 percent Black, 20.5 percent Hispanic) and one in Hartford County (15.8 percent Black, 18.9 percent Hispanic).

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

Infrastructure was established to support EPCCT at the community clinics, including dedicated space in the community clinic, a streamlined referral mechanism to schedule consults, and a feasibility assessment tool to allow for review of clinic capabilities to compliantly support protocol required visits; this tool provided a roadmap confirming which study visits must occur at the main Phase I Unit and which could occur at the community clinic. Feasibility considerations included, but were not limited to, drug administration route, timing and acuity of post-dose assessments, and onsite departments available (imaging, radiation, cardiology, ophthalmology, etc.).

To accommodate the multi-facility approach to Experimental Therapeutics Clinical Trials Network trials, formal guidance was drafted in collaboration with the National Cancer Institute, allowing participants to move between the community clinic and the main Phase I Unit without formally transferring the patient in the Cancer Trials Support Unit. Additionally, collaboration with study sponsors secured approval for key trials to be opened at the clinic, with appropriate steps taken to notate it as a participating location at the protocol level to ensure regulatory compliance.

Technological support was obtained through collaboration with Yale New Haven Hospital to allow EPCCT research staff to remotely manage protocol required visits. Community clinic research staff were identified, trained, and delegated to provide required onsite support including, but not limited to, video telecommunications setup, oral drug accountability, and PRO completion. Transportation and Structural and Social Determinants of Health resources were established for participants requesting assistance.

### **4. Outcomes**

As of March 7, 2023, EPCCT trialist consultations at the Fairfield County clinic serviced an URM

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population, including 21 percent Black and four percent Hispanic. Twenty-five percent of patients seen have consented to an EPCCT.

**5. Lessons Learned and Future Directions**

The HDM will be expanded to a Harford County community clinic. To ensure data integrity and patient safety, deviations and serious adverse events will be assessed and compared between the standard centralized model and HDM.

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