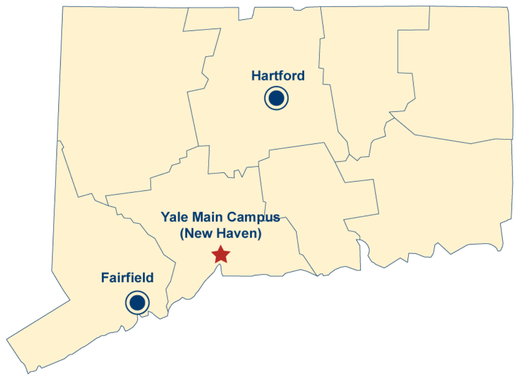
Hybrid Decentralization of Early Phase Cancer Clinical Trials to Enhance Study Recruitment of Underrepresented Minorities

Christina Wiess, BA, CCRP, Amy Rodrigues, CCRP, Ingrid Palma, MHS, Diane Wall, MSN, RN, Patricia LoRusso, DO

Goals

Aim: to implement a hybrid decentralization model, bringing feasible early phase cancer clinical trials components into community clinics where many underrepresented minority patients already receive their treatment.

Goal: to determine if, by bringing the trials to the patients, an increase in recruitment and retention will occur.



Background

- Poor accrual of underrepresented minorities 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.
- Early phase cancer clinical trials 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 underrepresented minority patients are treated close to home in community clinics.

Solutions and Methods

We are opening two early phase cancer clinical trials clinics in community clinics in Connecticut: one in Fairfield County (12.9% Black, 20.5% Hispanic) and one in Hartford County (15.8% Black, 18.9% Hispanic).

Infrastructure was established to support early phase cancer clinical trials at the community clinics, including:

Clinical Presence
- Dedicated space in the community clinic
- Streamlined referral mechanism to schedule consults

Feasibility
- Feasibility assessment tool to allow for review of clinic capabilities, considerations of which included, but were not limited to:
  - ❑ Drug administration route
  - ❑ Timing and acuity of post-dose assessments
  - ❑ Onsite departments available (imaging, radiation, cardiology, ophthalmology, etc.)

Technology
- Technological support obtained from Yale New Haven Hospital to allow EPCCT research staff to remotely manage protocol required visits

Stakeholder Collaboration
- To accommodate multi-facility approach to Experimental Therapeutics Clinical Trials Network (ETCTN) 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 CTSU.
- Secured study sponsors' 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.
- 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.

Structural and Social Determinants of Health
- Each participant is being screening for structural and social determinants of health.
- Required resources were established for participants requiring assistance, including Uber Health

Outcomes

- As of 5/10/2023, early phase cancer clinical trialist consultations at the Fairfield County clinic serviced an URM population including 21.6% Black and 5.4% Hispanic.
- As of 5/10/2023, 40.5% of patients seen by an early phase cancer clinical trialist consultations at the Fairfield County clinic have consented to an early phase cancer clinical trial, with 26.7% of consented patients being Black.
- As of 5/10/2023, 80.0% of the patients consented to an early phase cancer clinical trial have been deemed eligible for and started treatment.

Lessons Learned and Future Directions

- The hybrid decentralization model will be expanded to a Hartford County community clinic.
- Structural and Social Determinants of Health will continue to be evaluated for appropriate intervention.
- To ensure data integrity and patient safety, deviations and SAEs will be assessed and compared between the standard centralized model and the hybrid decentralization model.

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Contact

Christina Wiess
Assistant Director, Clinical Operations
Clinical Trials Office
Yale Cancer Center
100 Church Street South, Suite 160A
New Haven, CT 06519

Christina.wiess@yale.edu