Hybrid Operations to Promote Equity (HOPE)- Bringing Trials Closer to **Patients**

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

UNC CANCER CARE

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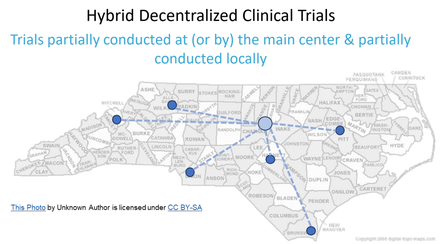
Background & Goals

Addressing socioeconomic, cultural, and environmental barriers to clinical trial enrollment can help ensure the generalizability of results to real-world populations. Patients benefit from more proximally located appointments since many rural households in the US lack access to a car, and rural communities often lack reliable public transportation to travel to distantly located healthcare facilities. The financial burden on patients is amplified by the distance causing missed work and travel expenses related to gas and hotel rooms. Caregivers, who frequently shoulder the logistical and financial strain of accompanying cancer patients to appointments, face compounded challenges, including time away from work and increased stress. These barriers exemplify the need to partner with local healthcare providers (HCPs) to move clinical trial visits closer to cancer patient homes and away from distantly located academic centers.

The goals of the project were to create a hybrid operations to promote equity (HOPE) network of referring physicians for inclusion of patients on hybrid decentralized clinical trials (DCTs) where most, if not all, assessments/visits may be conducted by local HCPs (**Figure 1**).

Figure 1. Hybrid Decentralized Clinical Trials



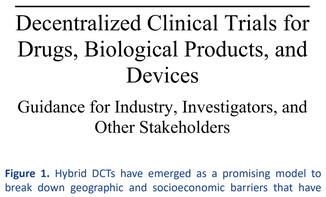


Figure 1. Hybrid DCTs have emerged as a promising model to break down geographic and socioeconomic barriers that have historically restricted participation while maintaining the rigorous oversight of traditional trials. Unlike fully decentralized clinical trials, hybrid DCTs balance remote and in-person study activities, leveraging local health care providers (HCPs) to perform routine clinical tasks while reserving complex procedures that require extensive knowledge of the protocol for specialized trial sites.

Key Innovation: This work differs from expansion of clinical research across cancer network hospitals in that the locations are not all fully owned by LCCC (e.g., one location is a competing healthcare network) and these locations are not considered engaged in research per the regulatory definition and thus do not require contractual agreements or integration into one succinct medical system. Any location or local HCP may collaboratively manage patients with the remote clinical trial team, at any time, without regulatory and contractual barriers.

Hypothesis: *Bi-directional educational engagement of local HCPs on hybrid DCT infrastructure and co-creation of user-friendly tools to identify opportunities (e.g., open to accrual studies) will create a network of referring physicians primed to educate and refer local patients to clinical trial opportunities where most assessments may be done locally.*

Solutions & Methods

The UNC Lineberger Clinical Trials Office (CTO) and Office of Community Outreach and Engagement (COE), partnered to visit community hospitals across North Carolina (NC) (**Figure 2**).

Figure 2. HOPE Team Structure

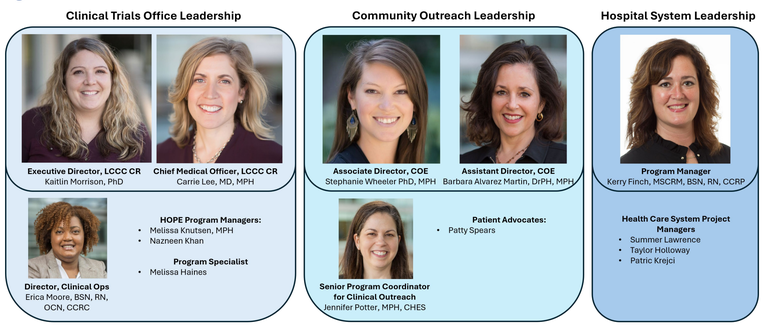


Figure 2. HOPE Leadership Team was made of Clinical Trials Office (CTO) Leadership and Community Outreach & Engagement Leadership (COE). We worked collaboratively with partners in the UNC Health System (Office of Clinical Research) to make connections with local community partners across the state.

Complementary skills and partnerships were necessary for HOPE team success.

Thirty minute pre-visit virtual meetings were conducted to introduce the HOPE tour team to the community hospital team, gain buy-in for the visit and discuss visit logistics (**Table 1**). **The most important element of the pre-visit meetings was building relationships to secure excitement and freely given invitation to travel to their location for an in-person HOPE visit.**

Solutions & Methods

Table 1. Pre-Visit Virtual Meeting Agendas

Agenda Topic	Description
Introductions	Sharing names & roles of HOPE team & prospective community partners

Purpose	• Sharing goals & intentions of the HOPE tours- Listening tour:
	  • Learn about the site & the work they are doing
	  • Learn about their wants & needs
	  • Discover what has worked well from them & any barriers
	  • Share a collaborative opportunity that may be of interest to them
	• Dispelling misconceptions of intentions:
	  • Not there to take over or stop what they are currently doing

Gained Buy-In	• Asked if the location was willing to host us • Asked what a successful visit would look like to them • Shared draft agenda & asked for feedback
Logistics	• Identification of a key contact to determine visit date • Discussion of visit details: 1) Conference room availability, 2) Local lunch delivery ideas, 3) Hybrid or all in-person, 4) Optimal visit length, 5) Projected # of attendees, 6) Suggested attendee roles, 7) Dress code, 8) Room technology, 9) Hot button topics to avoid
Next Steps	Saying goodbyes & sharing promises to provide visit agenda & listening questions in advance

Visit locations were chosen considering multiple factors: 1. Presence of a local oncology HCP, 2. Feedback from UNC Health system project managers on the hospitals' desire to have local trial opportunities for their patients, 3. Race, ethnicity, age, and gender demographics, 4. Geographic spread across the state, 5. Poverty index, 6. Households without internet access, and 7. Established research collaborations demonstrated in ongoing jointly run studies (**Figure 3**).

Figure 3. HOPE Tour Locations

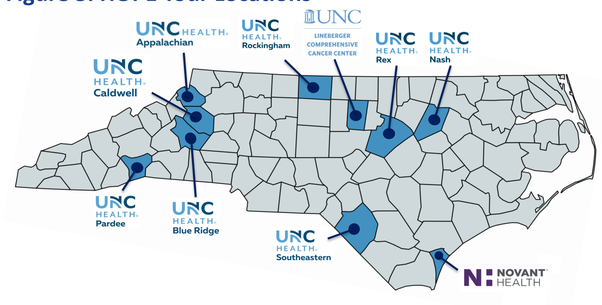


Figure 3. HOPE tour locations visited over a 6-month period. North Carolina (NC) is the most rural of the nation's 10th most populus states (with 34% of its population living in rural areas) and its cities are less populated making it a state of small towns[1]. The spread of diverse populations across the state results in healthcare barriers that cause significant mortality disparities between rural and urban patients, and minority and white patients. The geographic spread of patients also adds many barriers to access including transportation. As NC is a 550 mile long state, UNC Health Pardee is a 4 hr drive one-way from the mountains to UNC Lineberger, while Novant Health- New Hanover is a 2 hr 20 min drive one-way.

Visits were conducted over a 8-month period. Each visit was limited to 3 hours to respect local HCP clinic schedules and agendas were designed to maximize provider engagement and education (**Table 2**). The proximally close and established collaborator UNC Health Rex served as a pilot bus tour stop, to vet the content and timing of the agenda.

Table 2. HOPE Tour Meeting Agenda

9:45am	UNC Team Arrival
9:45am-10:30am	Tour: Facilities & Patient Resources
10:30am-10:45am	Introductions, Overarching Objectives, & Intentions
10:45am-12:00pm	Listening Session
15-minute Break	
Lunch Provided 12:15pm-12:45pm	Introduction to Hybrid Decentralized Clinical Trials
12:45pm-1:15pm	Current Hybrid DCT Opportunities
15-minute Break	
1:30pm-1:45pm	Sharing of Resources
1:45pm-2:00pm	Wrap-Up: Establish Communication Plan for Future Engagement/Collaboration • What is one things that stuck with you about hybrid DCTs? • What is one thing that excites you about hybrid DCTs? What concerns or confuses you about them? • What insights are emerging about how hybrid DCTs could work at your site?

Table 2. The agenda was designed to be interactive and to solicit feedback from the local teams. The tour was used for the local site to show off their infrastructure and for the HOPE team to learn about available patient resources. Introductions were given based on the outline in **Table 1**. During facilitated listening sessions local teams shared perceived barriers and facilitators to clinical research participation. This session was intentionally placed prior to sharing the proposed hybrid DCT collaboration in order to tailor collaboration proposals and plans based on local needs, facilitators and barriers. A short, practical and simple introduction was given about hybrid DCT operations (**Figure 4**), and then 2-3 open or upcoming hybrid DCT trials were presented in 2-3 slides focused on local HCP and patient perspectives. The trials to presented were chosen based off of learning from the pre-visit virtual meetings as locations shared their desired outcomes from the tour, highlighting what trials they desired for their local patients. Resources were shared to connect patients and providers to hybrid DCT opportunities. These resources were user tested during visits and updated accordingly. Wrap up included establishing next steps for the collaboration and soliciting feedback on the hybrid DCT program/methodology.

Key Collaboration: Listening session was ended by asking each member of the local team to share their personal or their team's "super power". This exercise engaged all local teammates and expanded our learnings about the local site (and their learning about one another). It infused a positive vibe into the visit heading into afternoon sessions.

Solutions & Methods

Figure 4. Practical, Patient-Focused Local HCP Training on Hybrid DCTs

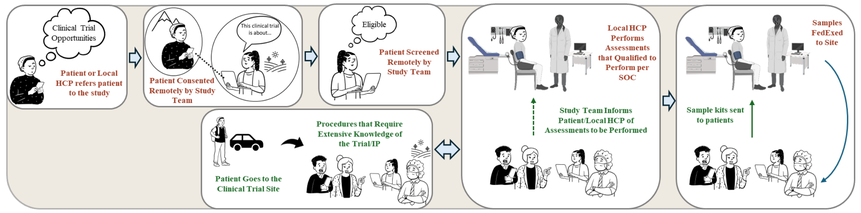


Figure 4. Training was designed to focus on the patient journey and collaboration between UNC and the HOPE network.

Outcomes

Nine community hospitals were visited with 120 local administrators and providers participating in the tour. All locations identified local champions and >1 open/upcoming hybrid DCT of interest that they are anxious to refer patients to for enrollment. All local HCPs emphasized the need for local trials as a metric of quality cancer care. The first center visited, which was also the pilot hybrid DCT launch site, has thus far enrolled 23 patients via hybrid DCT methodologies over the 1-year pilot period.

Key Innovation: Iterative nature of the HOPE tour: ***data-gathering initiative and an adaptive framework for refining hybrid DCT operations***.
Rather than a 1-time assessment, the HOPE tour employed a cyclic process in which insights from local HCPs directly informed protocol modifications, operational workflows, educational strategies and conduct of future HOPE visits. Embedding iteration ensured that hybrid DCT implementation was not only feasible but also aligned with the practical realities of community-based clinical research.

Table 3. Key Highlights from Facilitated Listening Sessions

Highlighted Local Patient Resources	Notable clinical research facilitators	Notable clinical research barriers
•Free parking •Lunch provided in infusion •Transportation resources •Local culturally and grade-level appropriate education •Technology rooms & support for remote visits •Strong foundation and local patient advocate support (e.g., wig bank non-profit supporting patients) •Flexible visit schedules where patients seen upon arrival even if not at scheduled visit time	•Existing research collaborations with LCCC •Existing clinical research infrastructure •Motivated local research coordinators who lack bandwidth for additional engaged research, but embrace additional hybrid DCT opportunities for their patients where they can refer out to a centralized research team •Prior experience in clinical research even if not ongoing •Stable local HCPs •Motivated local HCPs to champion research •Local HCPs who have previously served as PIs •Strong support from clinical leadership •Strong C Suite support •Strong community support	•Lack of research education among patients and community •Physical space constraints •Different EMR •Lack providers who are research champions •Overburdened local HCPs who lack additional time for even minor additions (e.g., recommending a study to their patient) •Local HCPs who prefer status quo treatments for comfort •Local HCPs employed by a competing healthcare system within a different healthcare system facility

Table 3. Insights provided critical guidance for adapting hybrid DCT operations to meet the realities of community-based care for each site.

Lessons Learned & Future Directions

Figure 5. Simplified Patient Education Materials

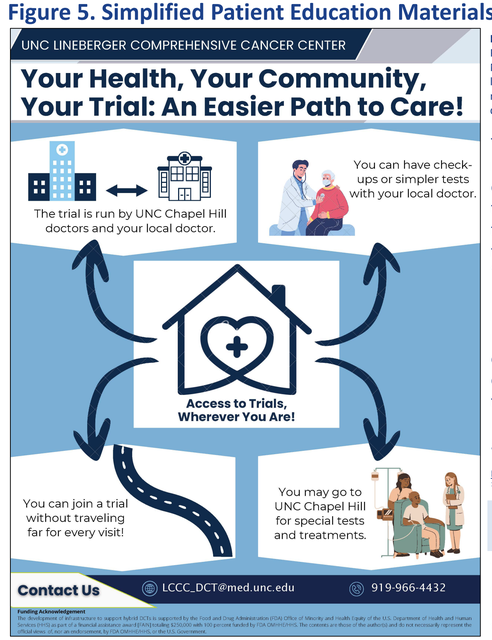


Figure 5. Simplified educational materials were co-designed with the Patient Advocates in Research Council (PARC) and the FDA Office of Minority Health and Health Equity to enhance their applicability to lower-level educational needs. More advanced versions of the educational materials were also provided for higher educational-level patients who desire to have more details about the methodology.

The extent of available local community resources supporting local patients even in poor counties was unexpected. Many local HCPs had transportation services, free lunches and technology rooms that could be used by patients for remote visits. They consider themselves "neighbors caring for neighbors" taking great pride in their teamwork approach. When patients must travel to distant clinical trials sites, similar resources are often not available outside their communities. Additionally, patients in many communities had lower-level educational needs than anticipated (2nd grade) resulting in redesigning patient education materials (**Figure 5**).

References:
[1] (NC Department of Transportation, NC FIRST Commission, November 2019).

Key Insight: Keeping patients local not only reduces socioeconomic, culture and transportation barriers, it restores access to local community resources.

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