UNC LINEBERGER COMPREHENSIVE CANCER CENTER

UNC CANCER CARE

Hybrid Operations to Promote Equity (HOPE)

Establishing Oncology Hybrid DCTs Across NC

J. Kaitlin Morrison, PhD
Executive Director, UNC Lineberger Clinical Research
Assistant Professor of Medicine- Hematology

Disclosures

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Clinical Research Not Readily Accessible Despite Importance

Cancer clinical trials are emblematic of high-quality care[1,2]

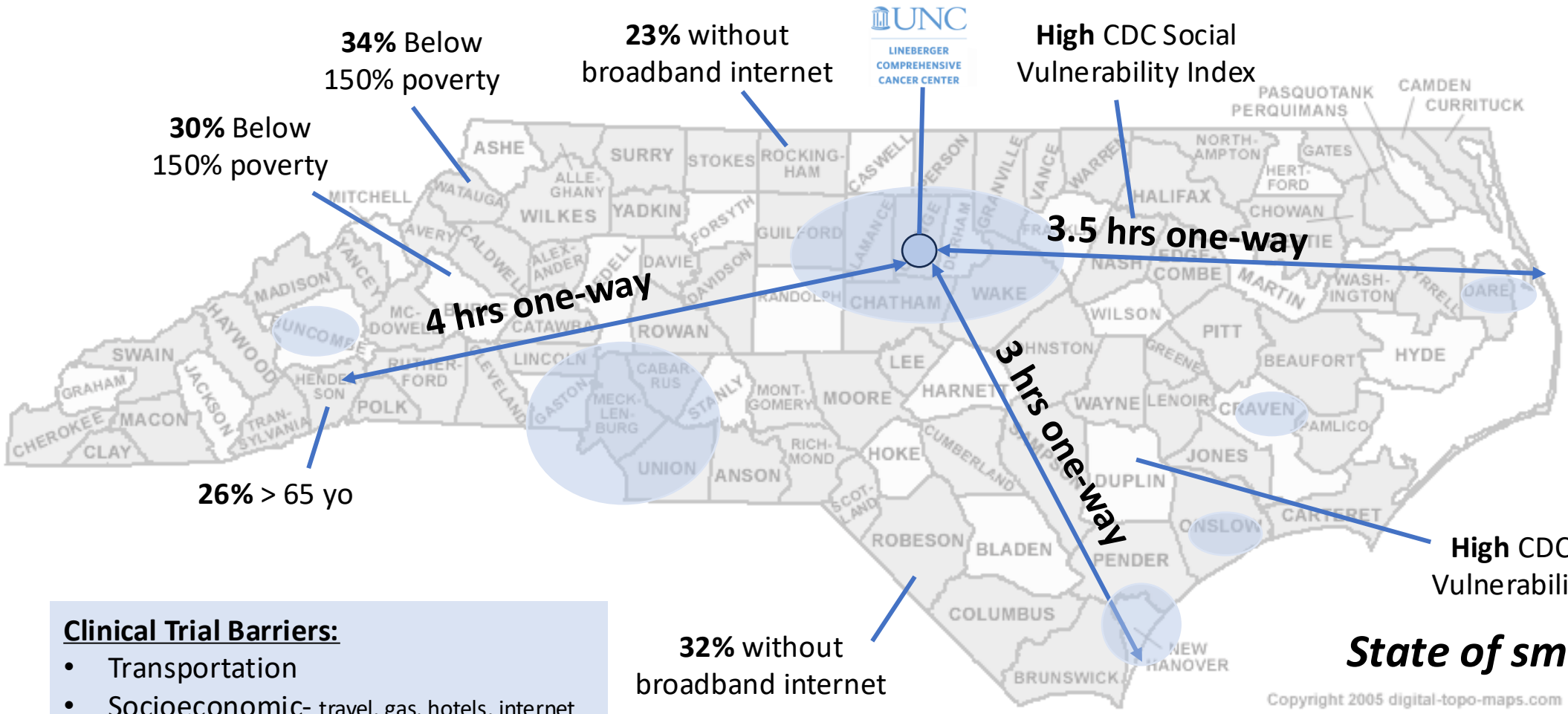
Many patients are distantly located from Academic Medical Centers (AMCs) with treatment trials.

Open to accrual phase I-III cancer treatment trials[3]:

- **70%** of US counties had **no** reported **active trials**
- **86%** of **nonmetropolitan counties had no trials**
- Clinical trial **availability varied by social vulnerability**
- **20%** of US counties **have local cancer care, but no clinical trials**

1. Patel MI, Lopez AM, Blackstock W, et al: Cancer Disparities and Health Equity: A Policy Statement From the American Society of Clinical Oncology. J Clin Oncol 38:3439-3448, 2020
2. (NCCN) NCCN: NCCN Clinical Practice Guidelines in Oncology: Category 1 Guidelines, 2025
3. M. Kelsey Kirkwood et al. State of Geographic Access to Cancer Treatment Trials in the United States: Are Studies Located Where Patients Live?. *JCO Oncol Pract* **21**, 427-437(2025).DOI:10.1200/OP.24.00261

Problem Statement—Many patients are distantly located from AMCs with treatment trials



Clinical Trial Barriers:

- Transportation
- Socioeconomic- travel, gas, hotels, internet
- Time off Work
- Cultural/Educational

550-miles long

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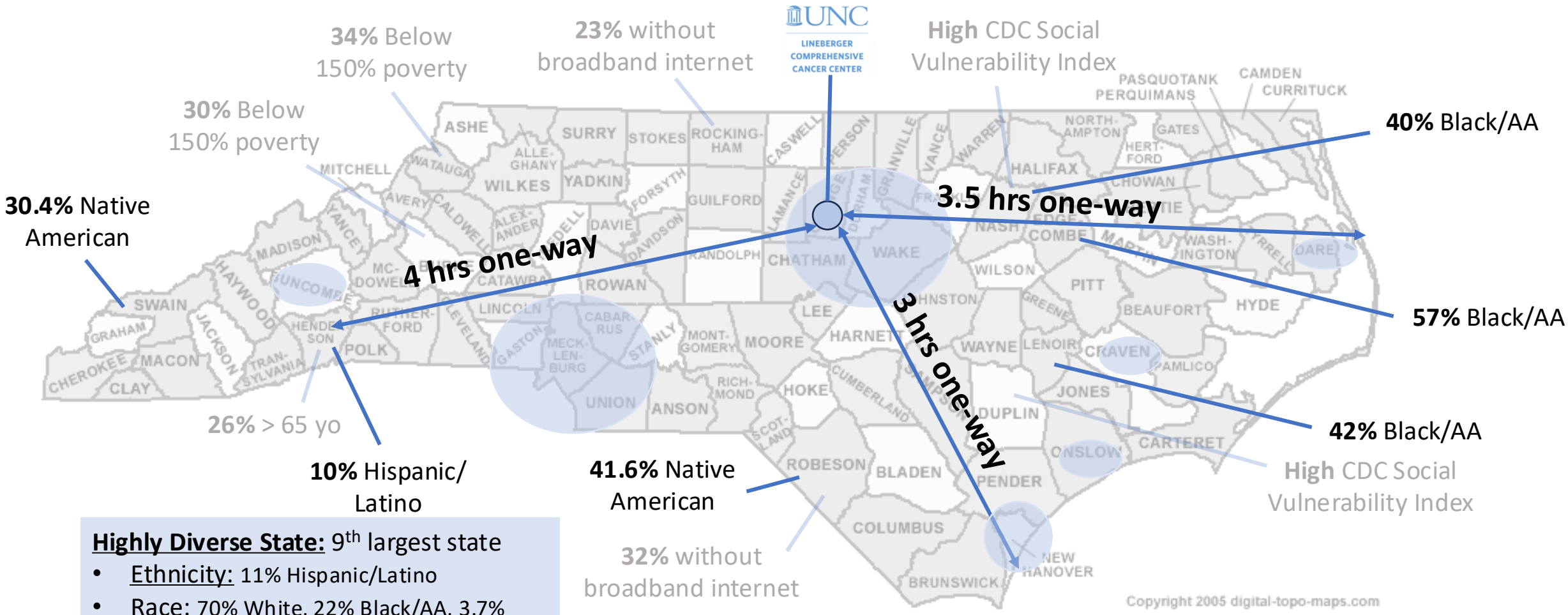

Highly Diverse State: 9th largest state

- Ethnicity: 11% Hispanic/Latino
- Race: 70% White, 22% Black/AA, 3.7% Asian, 2.7% More than 1 race, 1.6% American Indian
- Age: 22% < 18, 61% 18-65, 18% > 65

550-miles long

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

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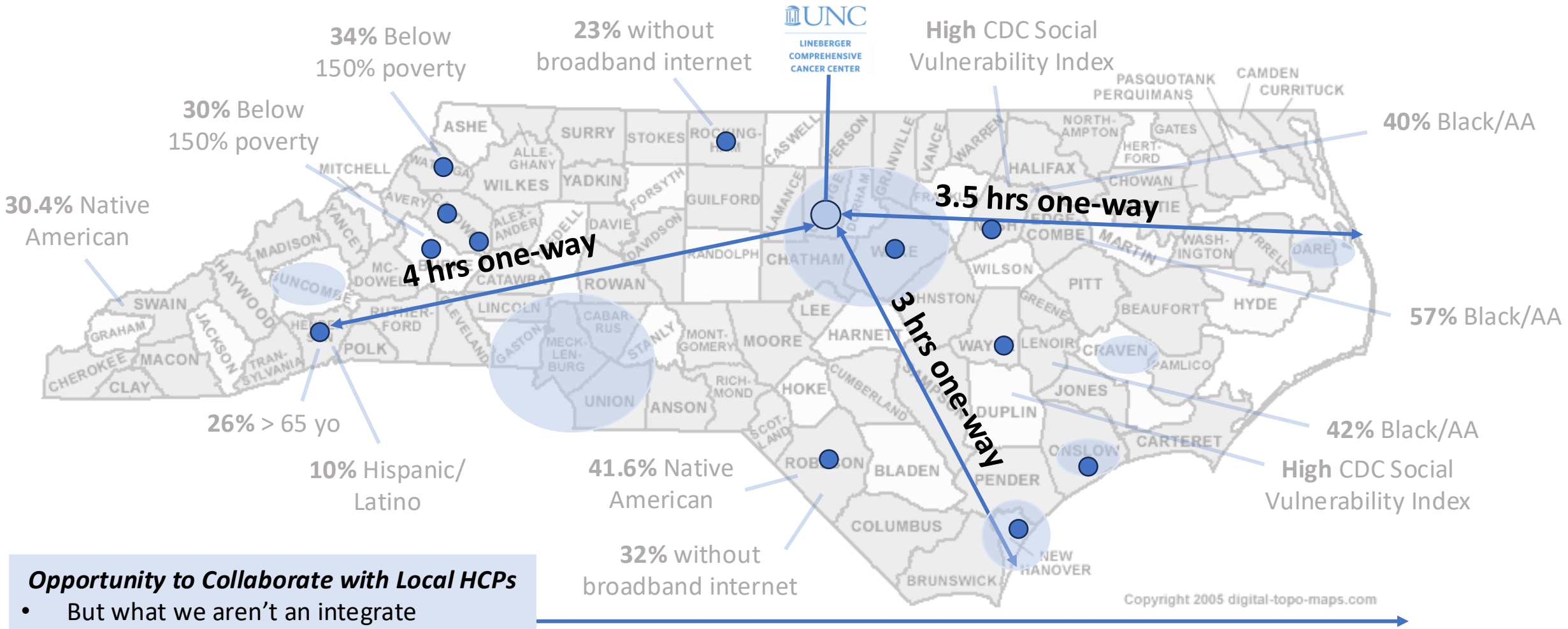

Opportunity to Collaborate with Local HCPs

- But what we aren't an integrate Healthcare system
- But we aren't legally/contractually primed to conduct research

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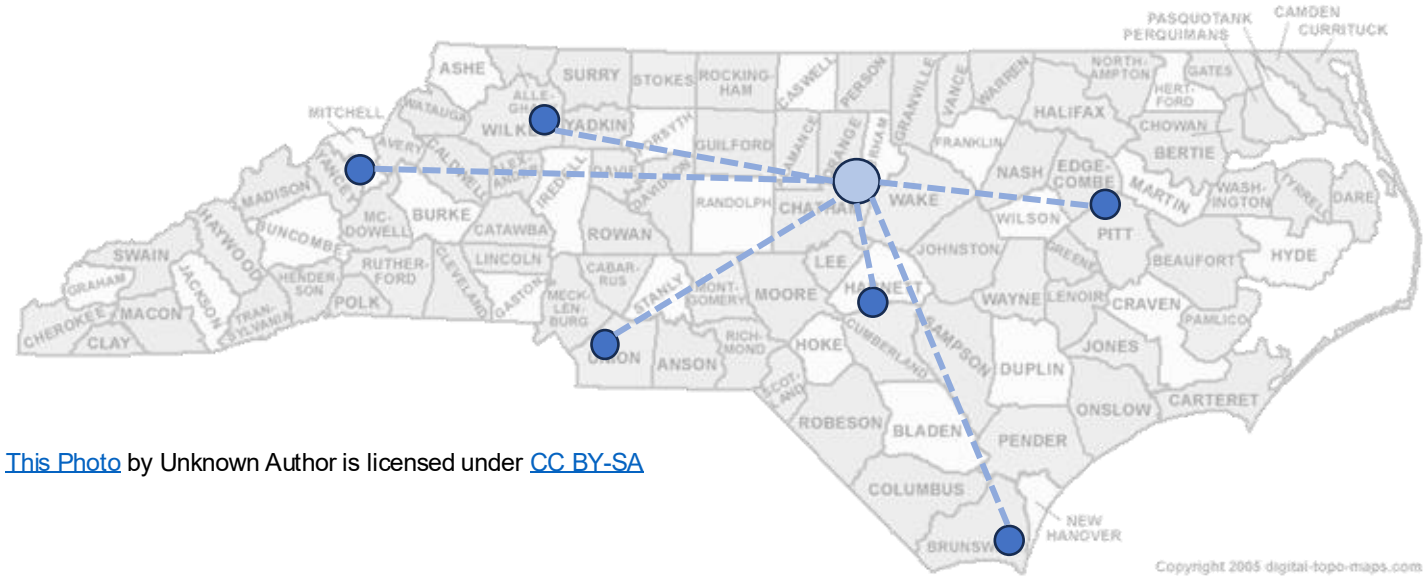
Hybrid DCTs- One Strategy for Extending Trials to the Community

Current Clinical Research Landscape

Many structural/systemic, institutional, clinical/research team barriers

Locations that are not UNC Hospitals that are Located Closer to the Patients that we Serve

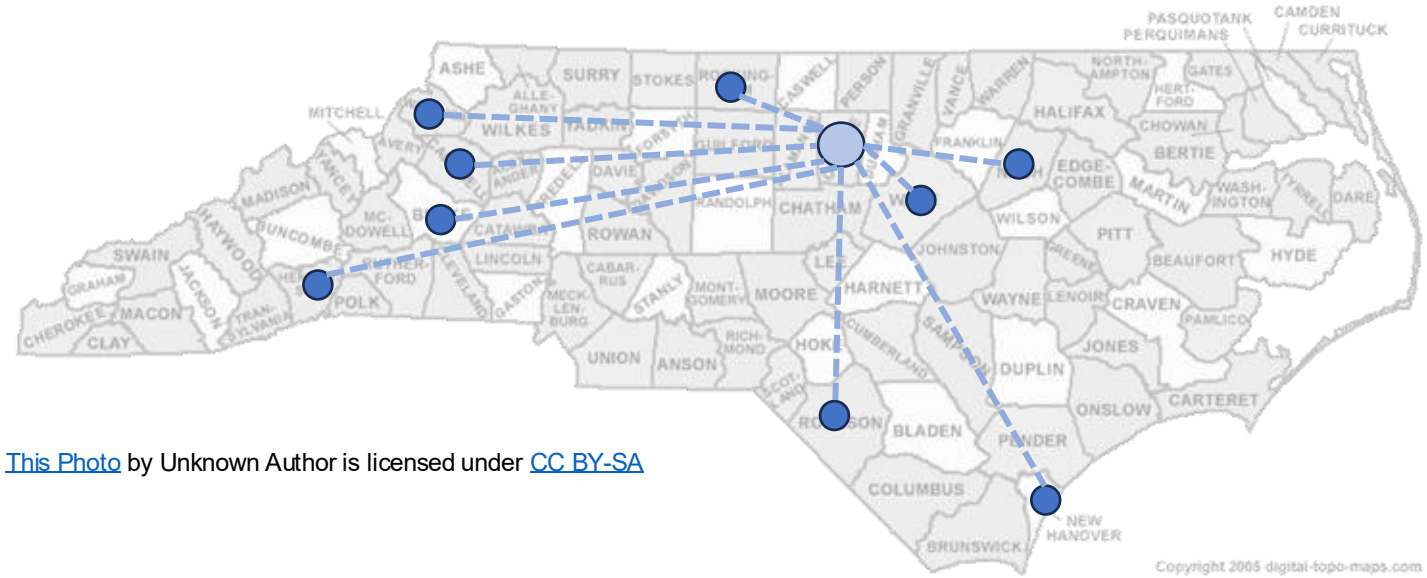


This isn't a UNC problem—data shows that this is a clinical research problem

Hybrid DCTs- One Strategy for Extending Trials to the Community

Hybrid Decentralized Clinical Trials

Trials partially conducted at (or by) the main center & partially conducted locally



GUIDANCE DOCUMENT

Conducting Clinical Trials With Decentralized Elements

SEPTEMBER 2024

- Complex tasks that require extensive knowledge of the IP
- Tasks more closely related to clinical practice. Many not be considered engagement in research

Hybrid DCTs- One Strategy for Extending Trials to the Community

Local HCPs and locations NOT engaged in research!

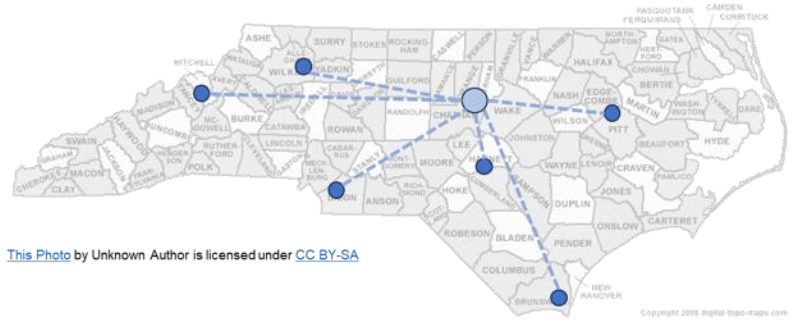
3 Flavors:

1. Local physicians perform procedures that they are qualified to perform in clinical practice (e.g., PEs, reading radiographs, obtaining vitals) AND all procedures billed as standard of care (SOC)
   - No contracts, payments, local IRB oversight, any physician/ location can participate at any time.
   - Study overseen remotely by sponsor (no local PI)
2. Local physicians perform procedures that they are qualified to perform in clinical practice (e.g., PEs, reading radiographs, obtaining vitals) AND some of these assessments are on a fee-for-service basis (not SOC)
   - No local IRB oversight or complex contracts
   - Vendor agreements for payment
   - Study overseen remotely by sponsor (no local PI)
3. Investigational product infused (under IND—not per SOC) OR other complex procedures that require study-specific training performed by local sites
   - Engaged clinical research
   - Current solution is to open multicenter trials

LCCC Clinical Research- Extending Trials to the Community

Hybrid Decentralized Clinical Trials

Trials partially conducted at the main center & partially conducted locally



Advantages for Community Hospitals:

- ACCRUAL!
- ACS Commission on Cancer Accreditation allows you to count accruals even when referred to other centers for the trial!
- Require less infrastructure locally to run trials
- Less onerous for HCPs
- Local centers keep $ from SOC procedures
- Can offer a greater # of clinical trials to their patients
- Other opportunities- publications, protocol development, etc.

LCCC Clinical Research- Extending Trials to the Community

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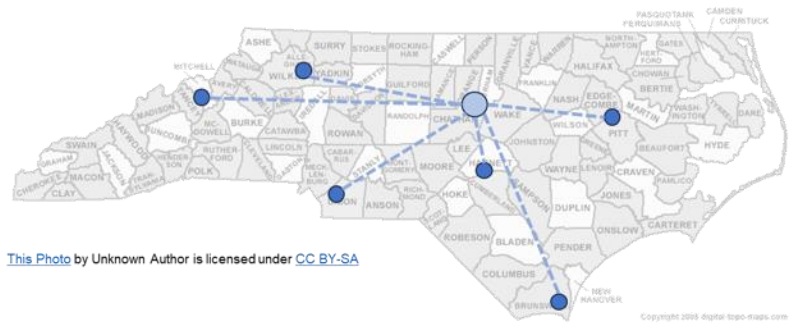


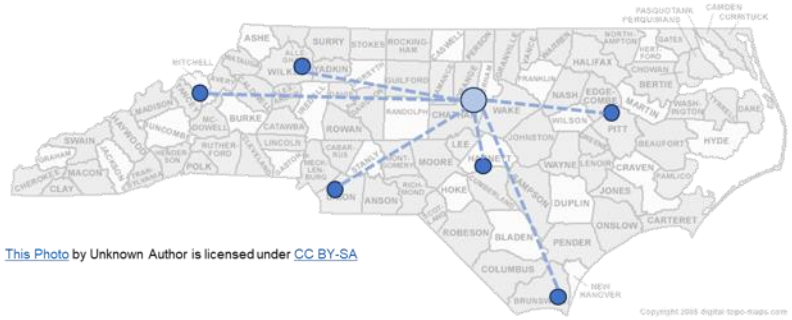
Advantages for UNC:

- ACCRUAL!
- Extend our reach into our catchment area
- Bring the research to our diverse patient populations
- Cheaper to run these trials over multicenter trials (1 regulatory approval)

Hybrid DCTs- Extending Clinical Trial Opportunities to the Community

Hybrid Decentralized Clinical Trials

Trials partially conducted at the main center & partially conducted locally

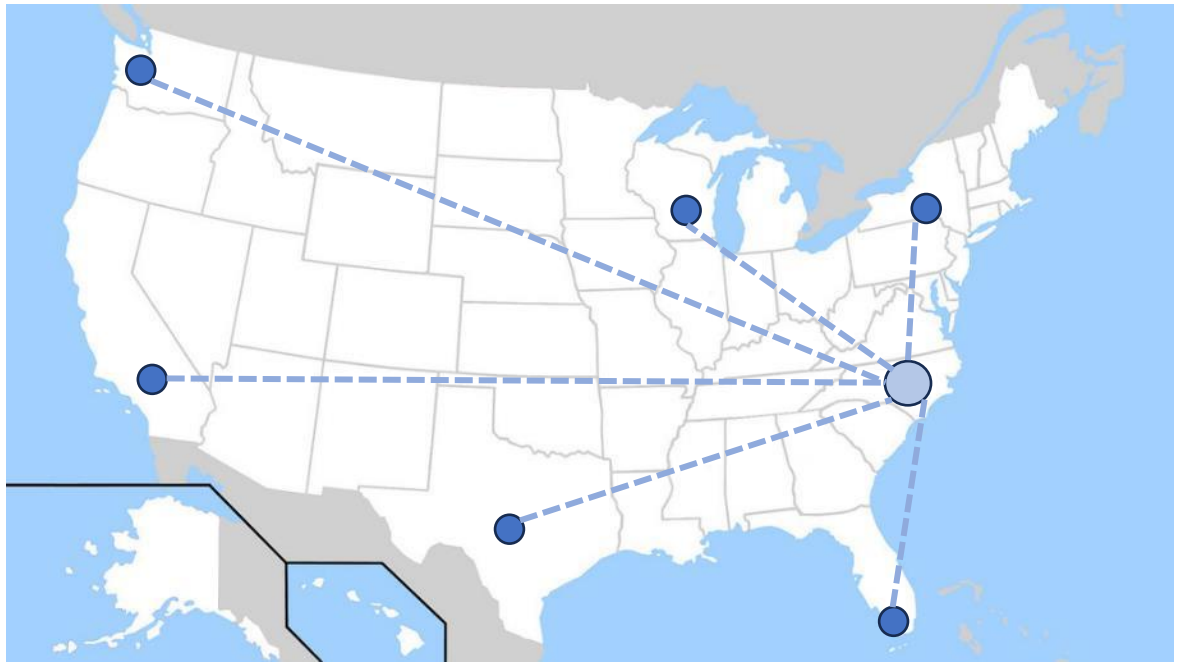


Advantages of this approach
• Expand access to more diverse patient populations
• Improve efficiencies
• Enhanced convenience for trial participants
• Reduced burden on caregivers
• Facilitates research on rare diseases
• Facilitate research with diseases affecting populations with limited mobility or access to traditional trial sites
• Improved trial participant engagement, recruitment, enrollment and retention of a meaningfully diverse clinical population
• Use of local health care providers (HCPs) may reduce culture or linguistic barriers to participation in clinical trials

Hybrid Decentralized Clinical Trials- LCCC Successful Experience- CAR T

Hybrid Decentralized Clinical Trials

Trial partially conducted at the main center & partially conducted locally



Procurement, Lymphodepletion, Infusion, DLT Monitoring

Long-Term FU (e.g., scans, physicals, blood collections

- Patients come to UNC for screening/treatment/short-term follow-up
- Subjects seen locally for long-term FU
  - Patients contacted by SC and told it is time to schedule local appointment & labs
  - SC asks about long-term gene therapy side effects
  - Collect local records
  - Check in with local HCP about potential long-term side effects (HCP provided a list of side effects to look out for)
  - Subject provided with kit for blood collection/shipment
- Set up based on allowances in FDA Guidance: *Long Term Follow-Up After Administration of Human Gene Therapy Products*
- In process of analyzing compliance data

>200 patient enrolled across 17 protocols. ~95% using hybrid decentralized methods (~139)

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Goal—Hybrid Operations to Promote Equity (HOPE)

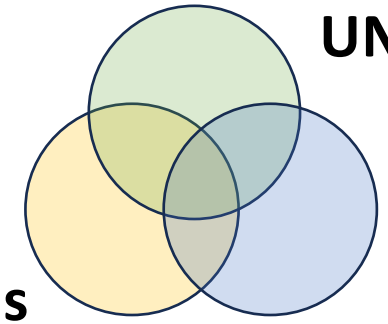
Goal: Create a HOPE network of referring physicians for inclusion of patients on hybrid DCTs where most, if not all, assessments/visits may be conducted by local HCPs

Hypothesis: **Bi-directional educational engagement** of local HCPs on hybrid DCT **infrastructure** & **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 & refer local patients to clinical trial opportunities where most/all assessments may be done locally

- **Not requiring a formal network with legal/contractual priming**
- **Not requiring engagement in research**

Operationalizing HOPE

- **Build your team**



- **Identify potential partners**

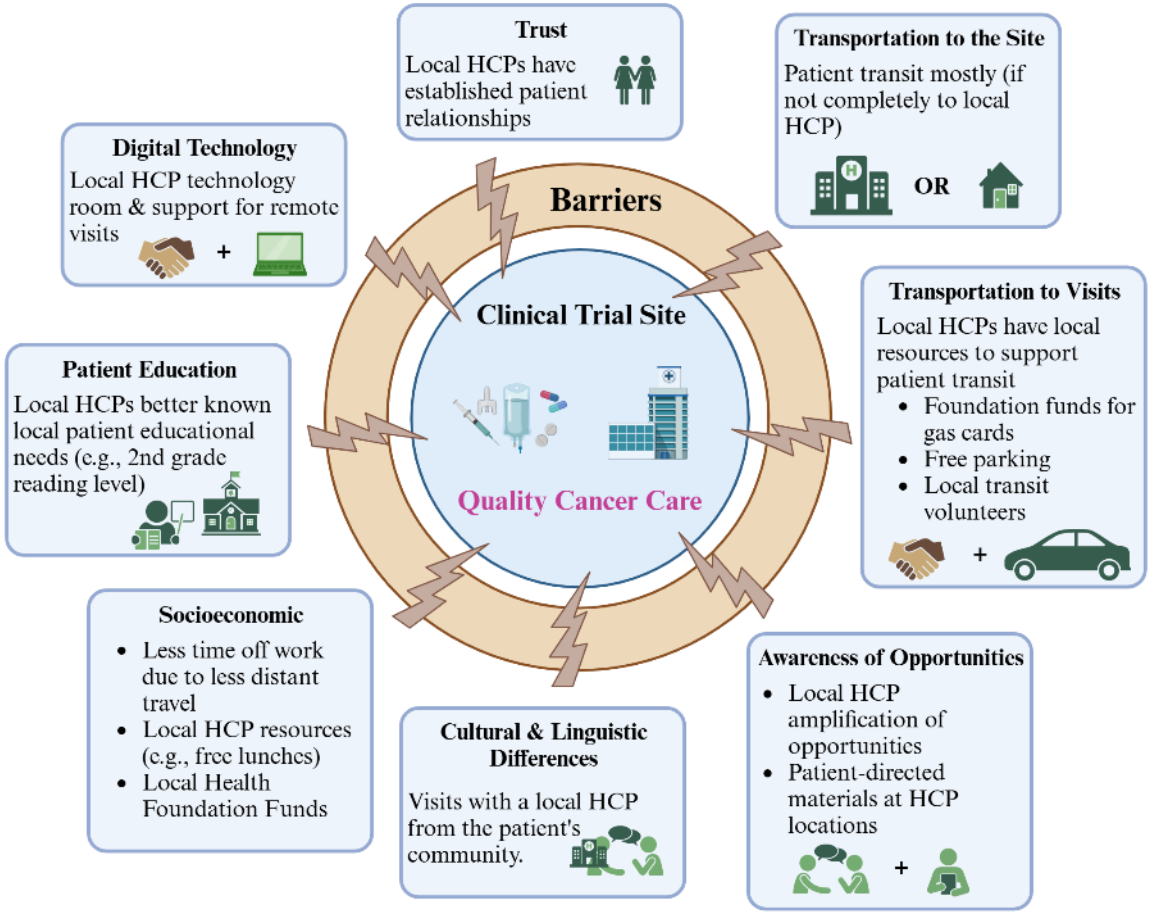
- **Virtual introductions**
  - Mission, Invitation, Agenda, Logistics (e.g., food, space, attire), Hot button topics

Operationalizing HOPE

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?

- **Structure**
  - **~3 hours**
  - **Going to the locations**
  - **Flexible for local needs—targeted time for local HCPs**
  - **Saying "yes" to whomever wanted to meet with us**
  - **Iterative process—lessons learned integrated into future visits**
- **Tips for success:**
  - **Tour**
  - **Facilitated listening session—including "superpowers"**
  - **Wrap-up with questions about the future, concerns & excitement**
- **Results:**
  - **Visited with 120 local administrators & providers**
  - **C-suite, provider & patient advocate buy-in**

Lessons Learned—Restoration of Access to Local Support



- **Local hospitals had tailored solutions for local barriers**
- **All local teams highly valued research:**

  Research = Quality Cancer Care
- **Many local HCPs viewed research as a market differentiator**
- **Flexibilities in clinical trial design allow for local adaptability**
- **Lower-level educational needs than anticipated (2nd grade)**

"Neighbors caring for Neighbors"

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Lessons Learned—Restoration of Access to Local Support

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UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Patient or Local HCP refers patient to the study

DCT Weaknesses: *Separation from the clinical trial site = Limited patient/provider awareness*

Methodologies Targeting Awareness:

1. **Provider-Directed QR Codes in Clinic Workrooms**
2. **Patient-Directed QR Codes in Patient Exam Rooms**
3. Remote Screening ***IF*** Have Same Instance of EMR
4. Patient & Provider Educational Materials

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

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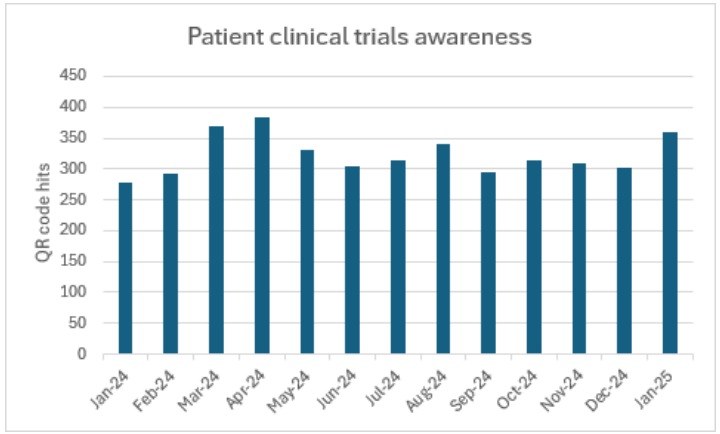
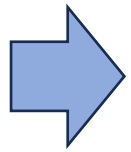
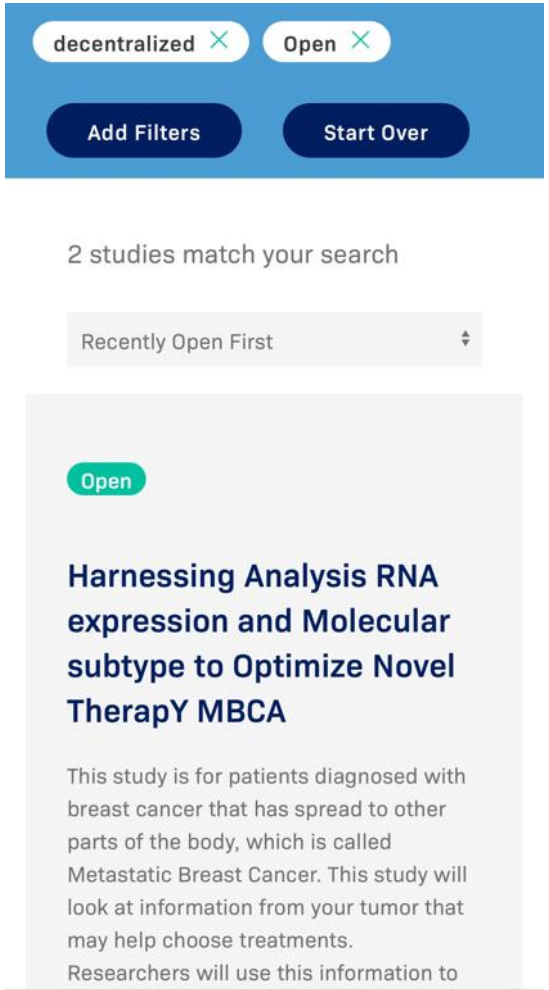


Within last year:

- Physician-directed: 206 hits
- Patient-directed: 5,107 hits





Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Patient or Local HCP refers patient to the study

Barrier: *2nd Grade Reading Level*

Solution: **Simplified Educational Materials**

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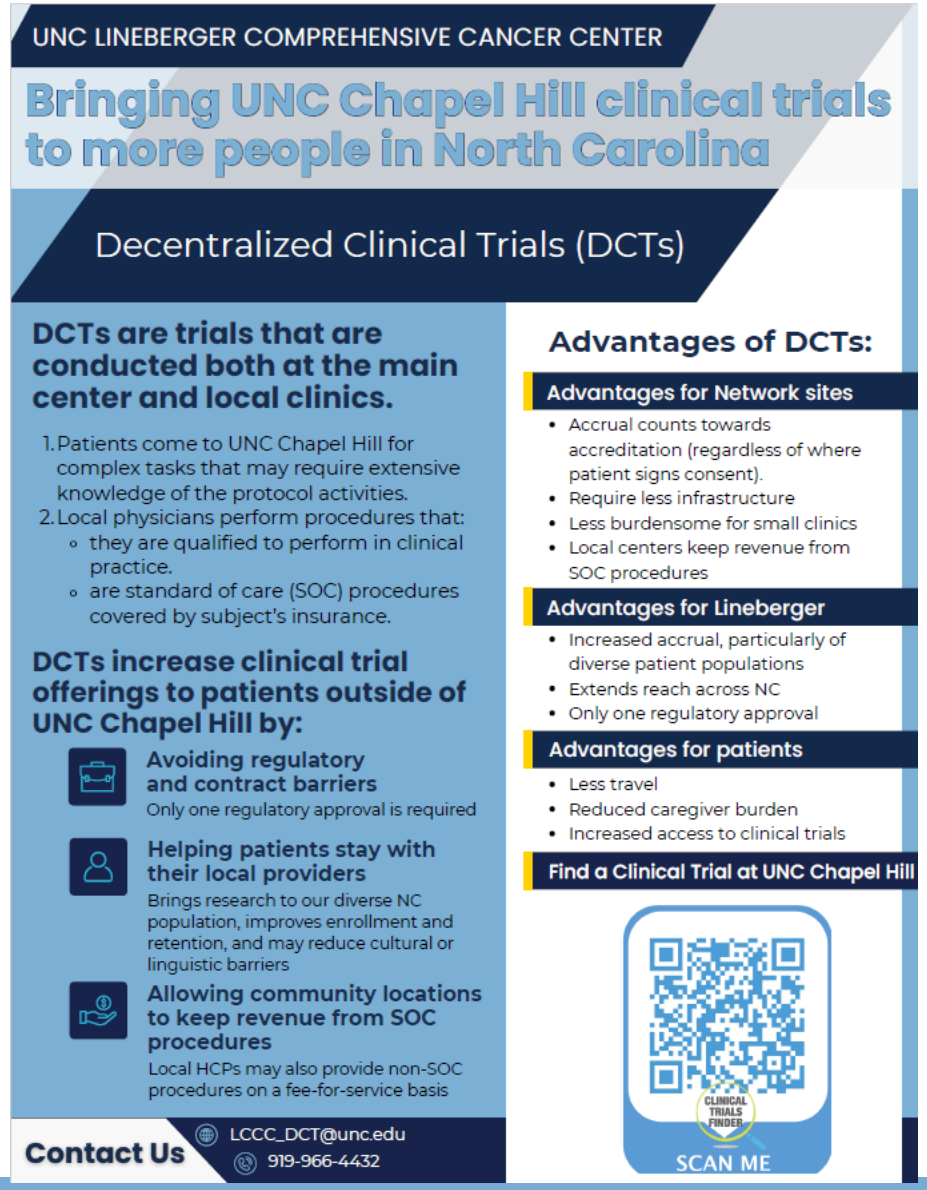
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor



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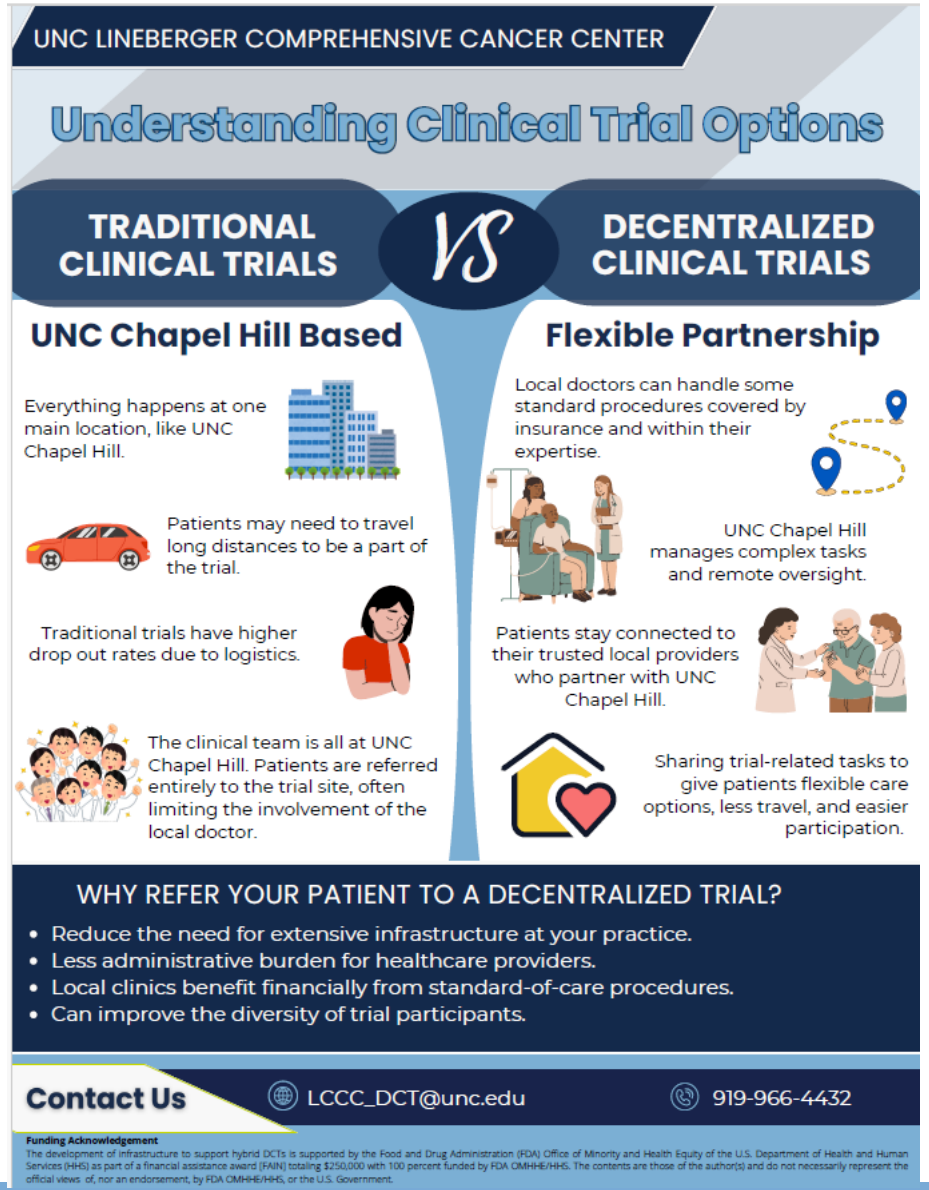

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Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Patient or Local HCP refers patient to the study

Patient Consented Remotely by Study Team

Process: HIPAA-compliant Video Calls & Electronic platforms (e.g., Veeva)

DCT Weaknesses: *Access to Internet & Tech Savviness*

Methodologies Targeting Consent:

1. **"Zoom Rooms" in community hospitals**

1. **Local educators and/or nurses assisting with tech set up**

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Patient or Local HCP refers patient to the study

Patient Consented Remotely by Study Team

Patient Screened Remotely by Study Team

Methodologies for Screening:

1. **Screening via same instance of EMR**

2. **Care Everywhere Module in Epic**
   Health System Research Policy Updates- *Used for patient's care coordination directing investigational research oversight of a UNC patient*

3. **Risk-Based Use of Paper Records**

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

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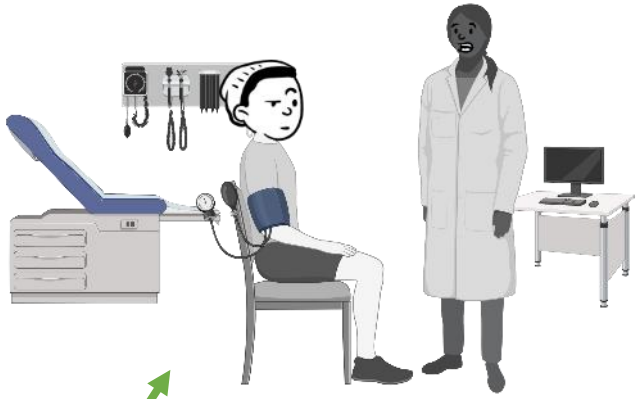
Patient Screened Remotely by Study Team



Local HCP Performs Assessments that Qualified to Perform per SOC

Methodologies to Consider for Local HCPs:

- "Launch" meetings providing education to local providers on a new opportunity

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

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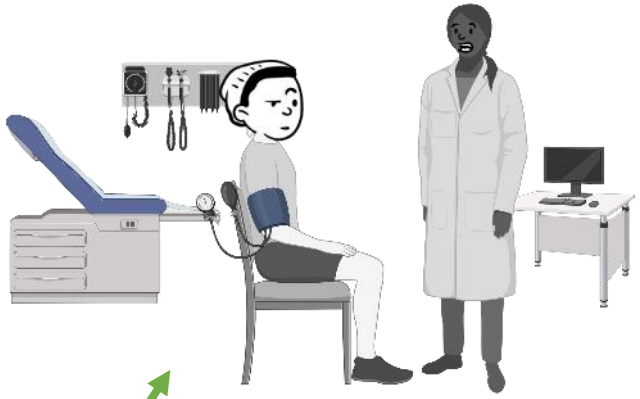

Local HCP Performs Assessments that Qualified to Perform per SOC

Study Team Informs Patient/Local HCP of Assessments to be Performed

Methodologies for Local Patient Care:

- Patient Calendars
- Patient Educational Handouts

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

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IRB Approved at the Protocol Level Mar 19, 2024

GUIDE TO YOUR CAR T-CELL THERAPY

CELL PROCUREMENT – We will collect blood from you to make modified T cells that are able to fight and kill the tumor cells. You may need to undergo apheresis, a blood collection process that helps us collect enough T cells from your blood.

During the time your T-cells are being modified, you may continue further chemotherapy as needed. We will contact you once your CAR T-cells are ready.

We will recheck your eligibility before you start lymphodepletion chemotherapy and before administering the iC9-CAR.B7-H3 T-cells. If you are eligible, we will ask you to sign the Main Treatment consent form.

LYMPHODEPLETING CHEMOTHERAPY – You will receive Fludarabine and Cyclophosphamide for 3 consecutive days.

PRE-INFUSION SCREENING – We will ensure you still meet eligibility criteria before receiving the modified iC9-CAR.B7-H3 T-cells.

iC9-CAR.B7-H3 T-CELL ADMINISTRATION – The cells will be given through IV infusion over 5 – 10 minutes. You are required to stay at the hospital for at least 4 hours after the cells have been given. We will be collecting research labs before and after the iC9-CAR.B7-H3 T-cells are administered. If you are not showing any symptoms of distress, you will be discharged home/to your local accommodations.

During the first 4 weeks of your follow-up, you are at increased risk for experiencing cytokine release syndrome, neurotoxicity, and/or other severe symptoms and will be required to stay within close proximity of UNC Hospital. If you live within 30 miles driving distance of UNC Hospital, you may stay at home between your scheduled assessments. If you must travel more than 30 miles to UNC Hospital, you must stay at the SECU Family House or in similar local accommodations during this time. If you have a medical condition requiring inpatient care or if the treating team believes that outpatient care will pose an unnecessary risk to you, you will remain inpatient for treatment and study visits until any conditions requiring inpatient care have resolved.

After Discharge:
If you have any signs of fever (38.0°C /100.4°F or higher), chills or sweats, or any new symptoms after the infusion, please immediately call the phone number below to speak with a provider and determine what steps need to be taken.

FOLLOW-UP – You will have a clinic visit once weekly for weeks 1-4 and at 6 weeks after the iC9-CAR.B7-H3 T-cell administration. Follow-up visits will continue every 3 months for the first year, every 6 months for the next 5 years, and then annually for up to 15 years. Visits after month 3 can occur with your local healthcare provider.

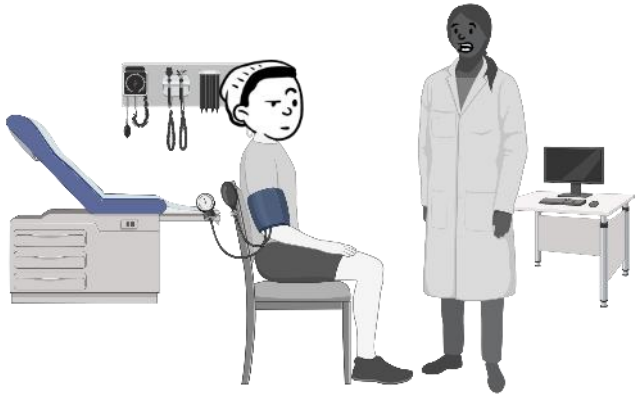
If you experience cytokine release syndrome, neurotoxicity, or other severe symptoms as a result of iC9-CAR.B7-H3 T-cell administration, contact the study team immediately.

Monday –Friday (8am-4pm) – call the **BMT clinic** at **984-974-8349.**

Nights, weekends, holidays– call the inpatient unit at 984-974-8280 and ask to speak to the *hematology/oncology on-call fellow.*

When you call, identify yourself as a "CAR T-Cell therapy patient."

LCCC 2128-ATL v. 2023 November



Local HCP Performs Assessments that Qualified to Perform per SOC

Study Team Informs Patient/Local HCP of Assessments to be Performed

Methodologies for Local Patient Care:

- Patient Calendars
- Patient Educational Handouts

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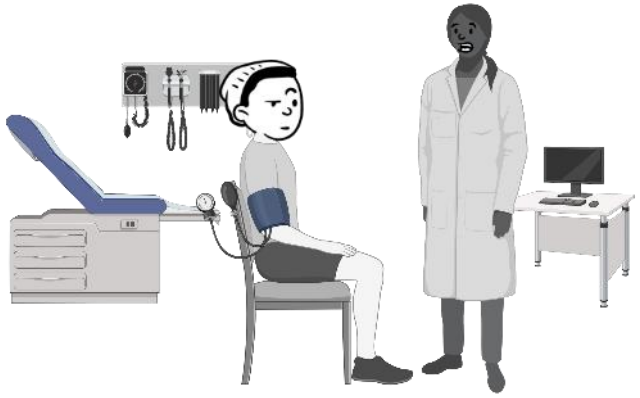
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Compliance Oversight:

- **Study-Specific & Overarching Monitoring Plan**—adjusted to watch compliance more closely & identify Risks to this approach

- **eCRFs—**adjusted to:
  - Capture visit locations (e.g., remote, local HCP, study site)
  - Capture key enhanced demographics
  - Include types of categories deviations & reason for deviations (e.g., patient convenience, patient compliance, travel issues)*

*Planned analysis of deviations across studies comparing visit locations & protocol adherence



Local HCP Performs Assessments that Qualified to Perform per SOC

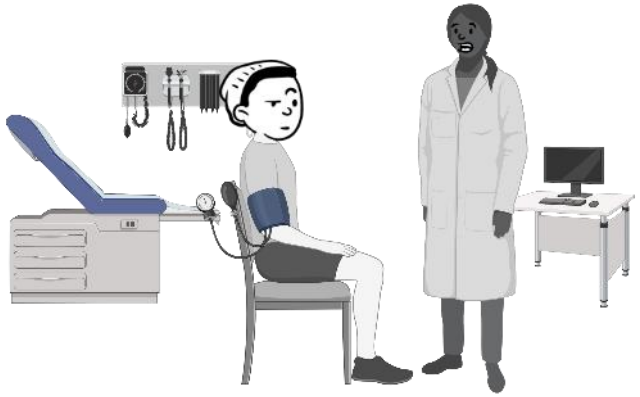
Study Team Informs Patient/Local HCP of Assessments to be Performed

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

DCT Weaknesses: *Overly complex protocols*

Development Considerations:

- **Simplify! Exclude excess!**
- **Mirror SOC as much as possible**
- **Consider billing coverage analysis implications**



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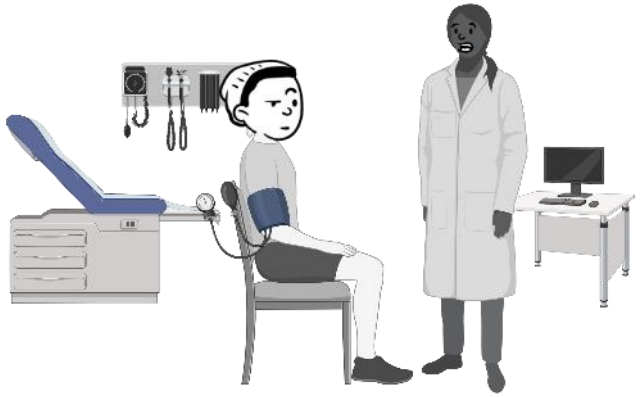
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

DCT Weaknesses: *Overly complex protocols*

Development Considerations:

- **Reliance on package inserts**
- **Limit dose modification language**
- **Simplify! Exclude excess!**



Local HCP Performs Assessments that Qualified to Perform per SOC

Instructions on Commercially Available Regimen

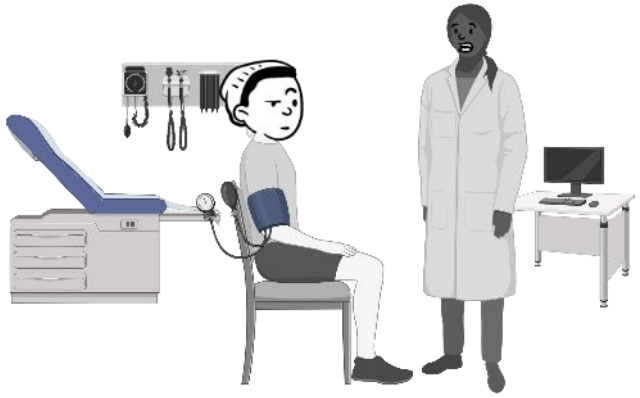
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Process: SC ships oral drug to patient

DCT Weaknesses: *Reliable patient home addresses & digital access to pill diaries*

Methodologies Targeting Oral Drugs:

- **Shipment to local HCP in care of the patient**
- **Local HCP scanning pill diaries into EMR**
- **Paper pill diaries reviewed on SC video call**
- **Additional local resources (e.g., on site library)**
- **Local FedEx identified for return**



Local HCP Performs Assessments that Qualified to Perform per SOC

Oral Drug Shipped & Returned

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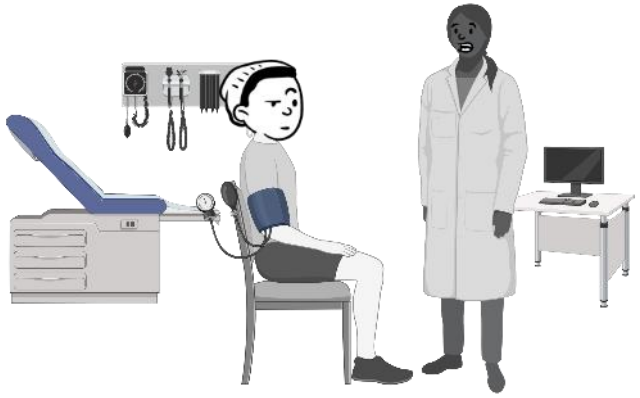
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Process: AE communication plan established upfront with local HCPs

DCT Weaknesses: *Patients share AEs with local providers & not study team*

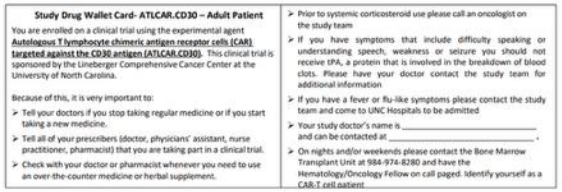


Local HCP Performs Assessments that Qualified to Perform per SOC

AEs Shared & Addressed

<u>Methodologies Targeting AEs:</u>

- **Patient emergency cards**
- **Upfront redundant communication:**
  - Instruct patients to contact study team
  - Share AEs directly with study team



Study Drug Wallet Card- ATLCAR.CD30 – Adult Patient

You are enrolled on a clinical trial using the experimental agent **Autologous T lymphocyte chimeric antigen receptor cells (CAR) targeted against the CD30 antigen (ATLCAR.CD30)**. This clinical trial is sponsored by the Lineberger Comprehensive Cancer Center at the University of North Carolina.

Because of this, it is very important to:

- Tell your doctors if you stop taking regular medicine or if you start taking a new medicine.
- Tell all of your prescribers (doctor, physicians' assistant, nurse practitioner, pharmacist) that you are taking part in a clinical trial.
- Check with your doctor or pharmacist whenever you need to use an over-the-counter medicine or herbal supplement.
- Prior to systemic corticosteroid use please call an oncologist on the study team
- If you have symptoms that include difficulty speaking or understanding speech, weakness or seizure you should not receive tPA, a protein that is involved in the breakdown of blood clots. Please have your doctor contact the study team for additional information
- If you have a fever or flu-like symptoms please contact the study team and come to UNC Hospitals to be admitted
- Your study doctor's name is _____ and can be contacted at _____.
- On nights and/or weekends please contact the Bone Marrow Transplant Unit at 984-974-8280 and have the Hematology/Oncology Fellow on call paged. Identify yourself as a CAR-T cell patient

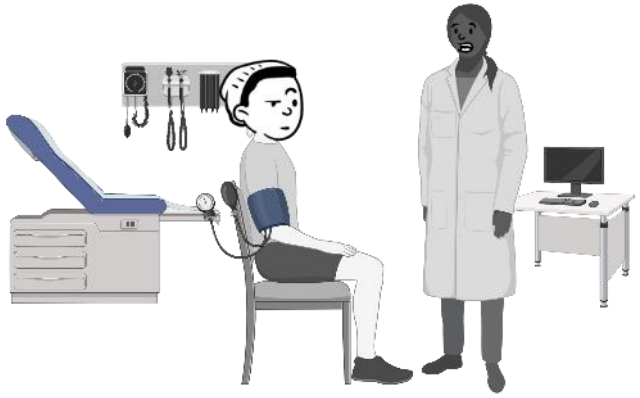
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Process: Sample kit with picture instructions provided to patient for local phlebotomist

DCT Weaknesses: *Processes for payment of local sample collection*

Methodologies for Samples:

- **Piggyback on SOC blood collections**



Local HCP Performs Assessments that Qualified to Perform per SOC

Sample Kits Shipped & Sample Returned

Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Lab Instructions for LCCC 1829: HARMONY

Lab manual version 2.0 dated 18 Sept 2023

Thank you very much for your continued participation in HARMONY.

At the scheduled doctor's visit, please have an appropriate staff member collect the blood for shipping to UNC-TPF.

Patient Subject ID_____

Date of Draw: _____ **Time Drawn:** _____

Kit Includes:

- 1x10mL Steck cfDNA tube
- FedEx Label for overnight shipping (if applicable) – some sites will use a courier in lieu of FedEx
- Packaging materials for shipping back to UNC-TPF Lab

Time Points:

__ Baseline ___ 6 month intervals (month _____)

(Please complete the information requested on the pre-affixed label on the tube and specimen bag)

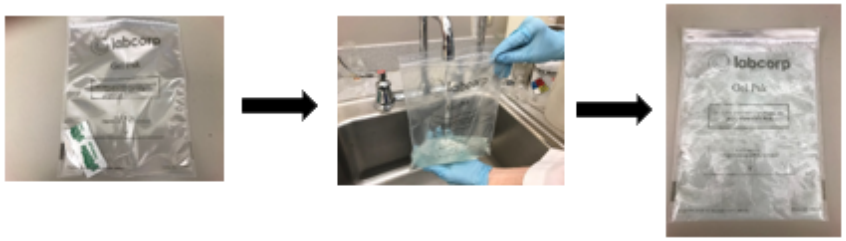
- *Patient Subject ID*
- *Date of Specimen Collection*
- *Time of Collection*

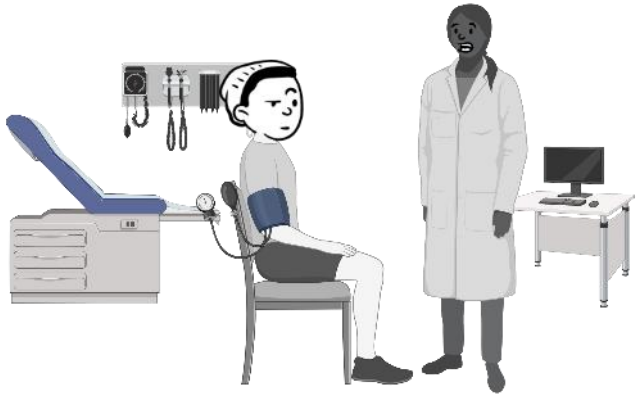
Processing Instructions:

1. Once the blood is collected, invert vacutainer 5-8 times taking care not to shake the vacutainer. Do not spin and do not place the blood in a refrigerator or dry ice.

Packaging Instructions:

2. Fill Gel Pack with water to fill line (outlined below)
   a. Once filled please ensure all air is removed, and the bag is securely closed.
      i. **DO NOT** place blood tubes inside gel pack.





Local HCP Performs Assessments that Qualified to Perform per SOC

Sample Kits Shipped & Sample Returned

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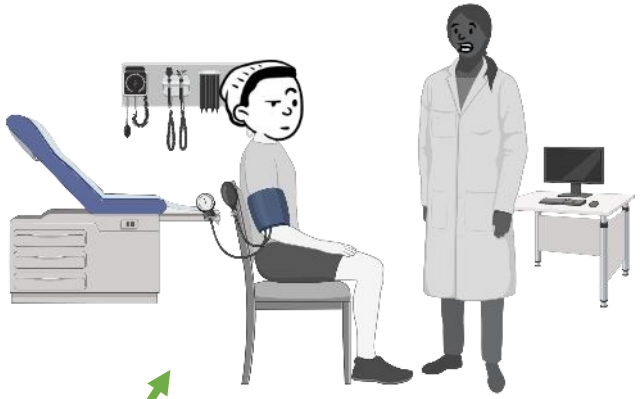
Hybrid DCTs- Path of the Patient & Oversight by the Sponsor

Patient or Local HCP refers patient to the study

Patient Consented Remotely by Study Team

Patient Screened Remotely by Study Team



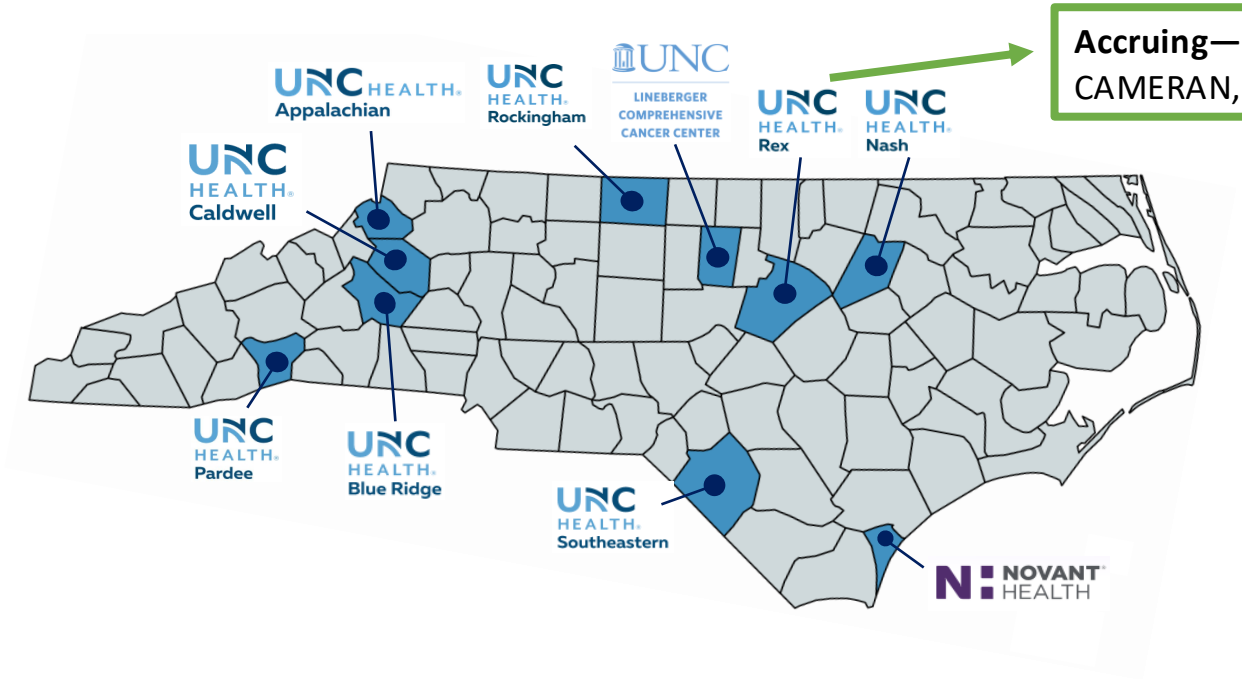
Local HCP Performs Assessments that Qualified to Perform per SOC

Patient Goes to the Clinical Trial Site for Procedures that Require Extensive Knowledge of the Trial/Investigational Product

Hybrid DCTs- Example Partnership with a Local HCP

Remote by Study Team	Local HCP	Fee for Service
• Eligibility • Informed Consent • Pill Diary • Toxicity Assessment • Medical Record Abstraction • Mailed Oral Drug	• PE • Performance Status • Medical History • Labs • Scans	• Myocardial perfusion imaging • Blood cardiac panel • TSH

Outcomes—Pilot Study Success



Accruing—Actively accruing to CAMERAN, HOPE & **HARMONY**

- Enrolled **20 patients** on pilot study in 1-year period (23 at AMC over same period)

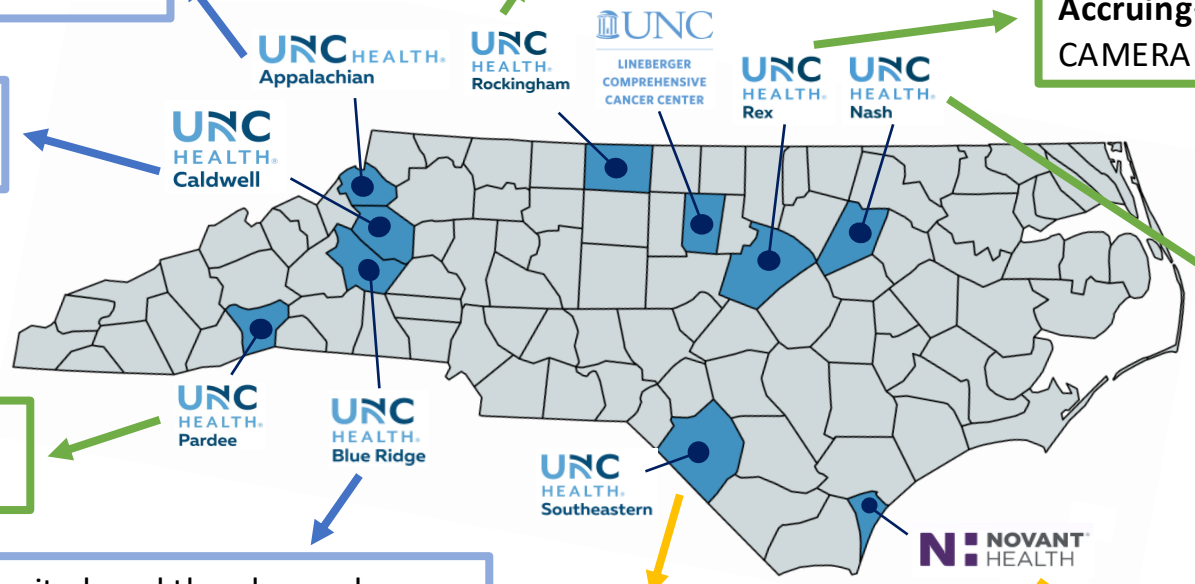
Outcomes—Broader Application on the Horizon

Motivated—Want to accrue to these studies. Already met with their legal council to get things rocking and rolling

Launched!—Actively screening for accrual for CAMERAN

Accruing—Actively accruing to CAMERAN, HOPE & HARMONY

Excited—Very interested in prevention studies



Launched—Actively screening to PROGRESS

Accruing—Actively accruing to HARMONY

Interested—C suite loved the plan and sees this as a market differentiator

Motivated—Excited about an upcoming study to use a new scanner that they are proud of

Invested—UNC/Novant Capacity Building Grant for upcoming Rad/Onc studies

76 patients consented
69 enrolled
Over 2 yrs (median: 0.54; range 0.2.5-2)

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HOPE for the Future—Next Steps

- **Bi-monthly newsletter**
  - Highlighting wins!
  - Sharing tips
  - Enhancing trial awareness
  - Creating a little competition between locations
- **Virtual bi-annual meeting**
  - Create community
  - Share results and wins
- **Growing Portfolio**
  - >20 trials opening this year
  - Increasingly complex operations

HOPE Network Connection

Hello HOPE Provider Network-

We hope you are enjoying your summer! This is the 2nd of our planned bi-monthly update on our hybrid DCT initiative where you will find info on open trials, site status, and other details.

If you have any questions, suggestions OR want to launch any of these studies at your center please reach out to **lccc_dct@med.unc.edu**

Open Hybrid DCT Studies:

Indication	Trial Name	Trial Details
Breast	**LCCC 1829: HARMONY** Harnessing Analysis RNA expression and Molecular subtype to Optimize Novel TherapY MBCA	**Blood Draw Study at Baseline and Every 6 Months** • PAM50/RNA sequencing for 1st line met pts • Both patient & local physician consented—provider preference testing **Brief Key Inclusion:** • 1st line met patients (no later)
Breast	**LCCC 2104: CAMERAN** Compare Adjuvant Monotherapy w Endocrine or Accelerated Partial Breast Irradiation After Lumpectomy	**Randomized Treatment, Quality of Life Survey Study** • HER+/HR- Adjuvant • Low risk localized ER+ breast cancer randomizing to either partial breast irradiation vs. endocrine therapy **Brief Key Inclusion:** • Women >65 y.o. • ER+, HER2- • IDC Grade 1 or 2

CLICK HERE To learn more about these and other studies

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Thank You

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- **UNC Lineberger Clinical Trials Office Team:**
  - Shaw Scott, JD
  - Erica Moore, BSN, RN, OCN
  - Megan Laffan
  - Erin Kelly
  - Brian Burgess
  - Blair Adams
  - Julianne Maccarone
  - Leila Kiefer, PhD
  - Allison Camp, PhD
  - Adan Maldonado-Nolasco
  - Jessica Huamani-Bundy
  - Melissa Haines
  - Erin Crecelius

- **Hybrid DCT Pilot Investigators**
  - Sam Rubenstein, MD
  - Lisa Carey, MD
  - Shivani Sud, MD
  - Colette Shen, MD
  - Dana Casey, MD

- **UNC Lineberger Community Outreach & Engagement:**
  - Jennifer Potter
  - Stephanie Wheeler, PhD, MPH
  - Barbara Alvarez-Martin, DrPH, MPH

- **UNC Health Team:**
  - Kerry Finch MSCRM, BSN, RN, CCRP
  - Individual Site-Specific Project Managers

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Evaluation

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
NRP
Network for Research Professionals

Post-session evaluation:

https://go.unc.edu/NRPAprEval

or scan the QR code.

Attendance Certificate: An option to **download** certificate, BEFORE submitting the eval, is found at the end of the post session eval survey.

Email: NRP@unc.edu if further questions or suggestions for future education.

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Questions?