Hybrid Decentralization as a Model for Early Phase Clinical Trial Recruitment

Patricia Mucci LoRusso, D.O., Ph.D.(h)
Professor of Medicine
Associate Center Director: Experimental Therapeutics
Yale University/Yale Cancer Center

YaleNewHavenHealth
Smilow Cancer Hospital

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Patricia LoRusso, DO, PhD (h)

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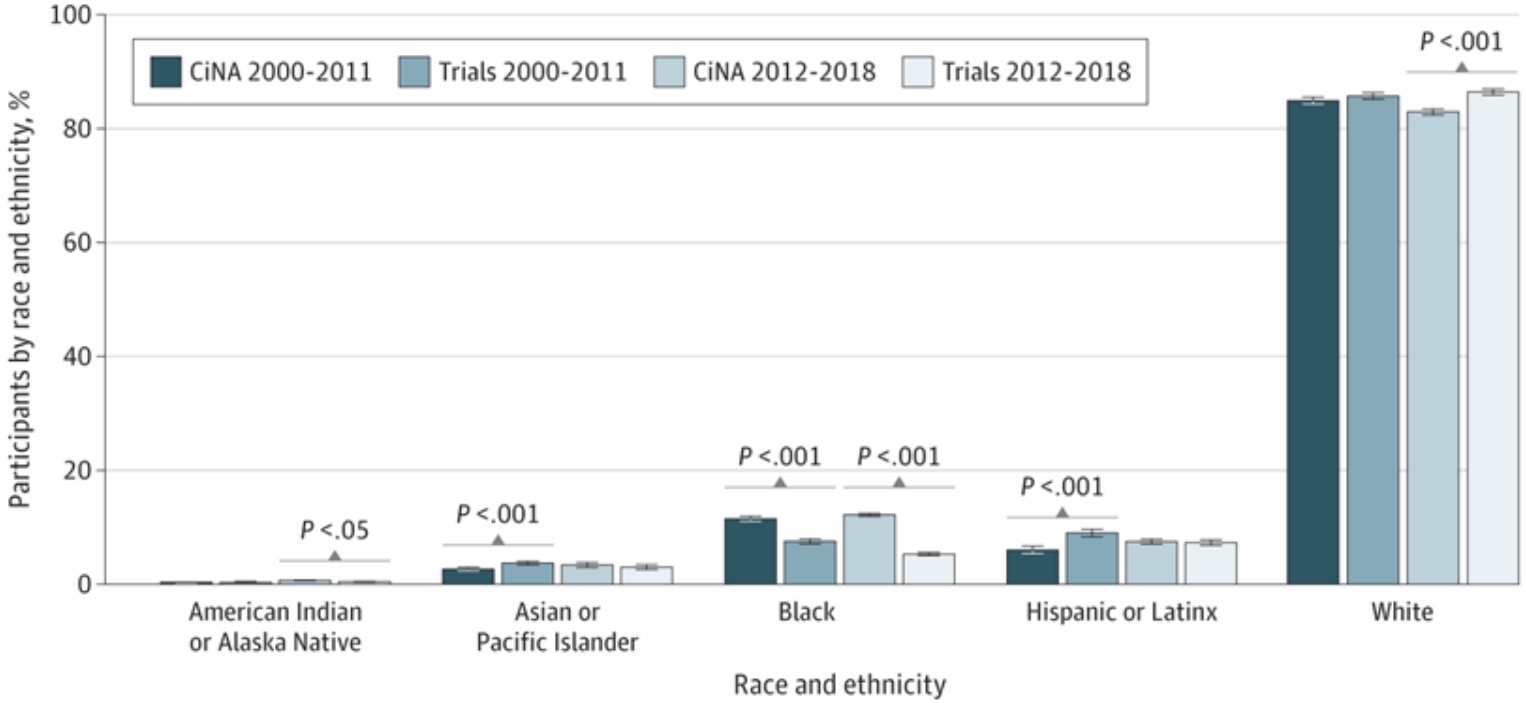
Incidence by Race and Ethnicity in Phase 1 Cancer Drug Trials Compared With Cancer in North America (CiNA) Incident Cancer Cases, 2000-2018



- 8309 participants assessed from 221 Phase I Clinical Trials Recruited in the United States
- Almost half of Phase I cancer clinical trials in the US had NO Hispanic or Latin American subjects
- 42% had NO black patients

Dunlop et al. JAMA 2022; 5(11)
https://pharmaphorum.com/news/study-exposes-lack-of-diversity-in-us-cancer-trials

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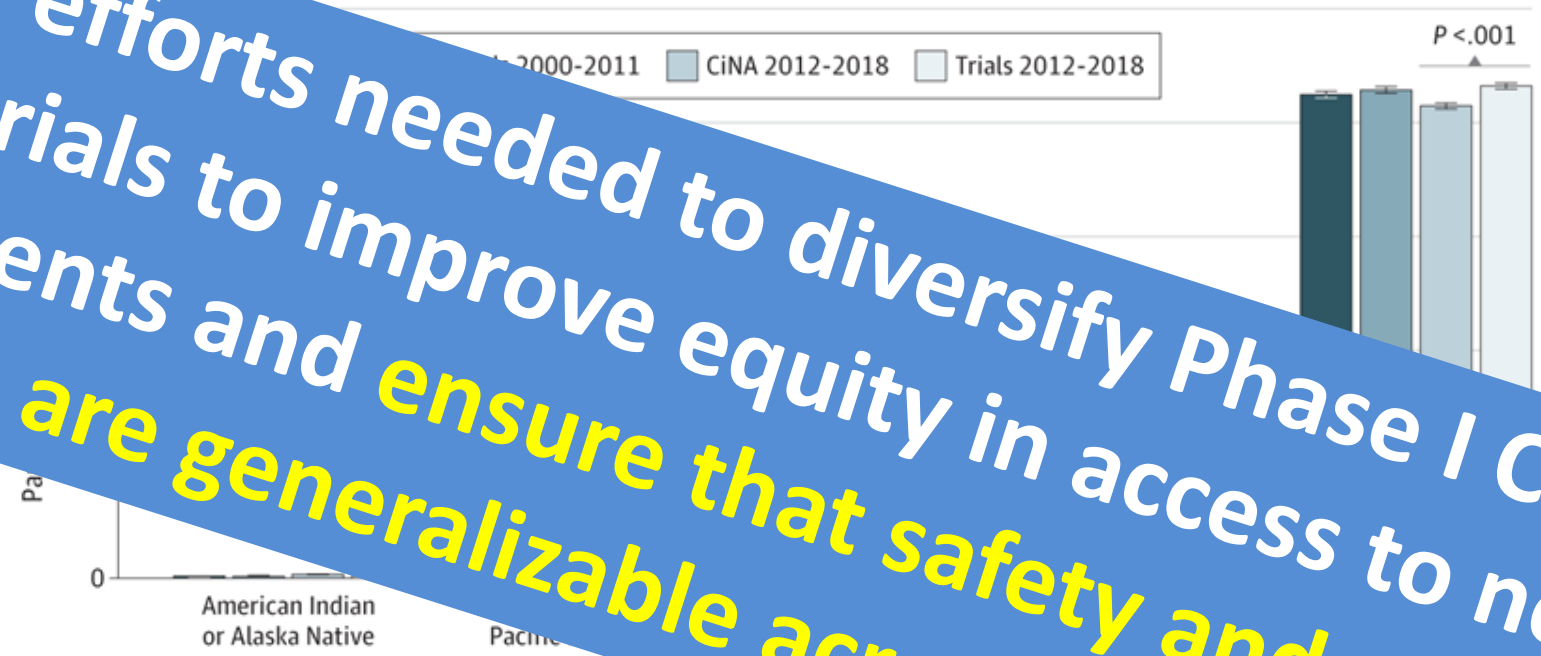

More efforts needed to diversify Phase I Cancer drug trials to improve equity in access to new treatments and ensure that safety and efficacy findings are generalizable across populations

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The Burden of Cancer is not Equally Shared

- Clinical trial URM representation: 4%
  - Significantly lower for Early Phase Clinical Trials
- **URM clinical trial recruitment importance:**
  - **Understand potential PK/PG/PD, efficacy and toxicity differences**
  - **Seeing greater therapeutic benefit in novel agents in early phase trials**
  - **All eligible patients should be offered early phase trials when appropriate**

U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots
Nazha B, Mishra M, Pentz R, Owonikoko TK. American Society of Clinical Oncology Educational Book. Volume 392019. p 3-10.

Project Vision

We proposed a **“hybrid decentralization”** early phase clinical trial (EPCT) model, employing a process whereby many of the components of a clinical trial are executed closer to the patient’s home, using procedures that varied from the traditional cancer center EPCT model whenever possible, rather than having patients always traveling to a centralized site.

Yale Cancer Center Catchment Area

State of Connecticut

- 3.6 million residents in 8 counties
- **3rd smallest** by area; **4th most densely populated**
- **Highest** per capita **income**; **2nd highest** income **inequality**
- Demographics similar to US; structurally marginalized populations are majority within several urban areas
- One of the **fastest aging** populations in the US

Expanded Smilow Network

- **16 Smilow Network sites** across CT & into RI

Structurally marginalized populations in Connecticut cities

	% Living in poverty	% Black or African American	% Latinx or Hispanic
US	10.5	13.4	18.5
Connecticut	10.1	12.2	16.9
Bridgeport	21.8	35.1	40.8
Hartford	28.1	37.7	44.3
New Britain	21.7	12.8	43.3
New Haven	26.5	32.6	31.2
New London	24.5	15.0	33.4
Waterbury	23.4	21.7	37.4
Windham	24.6	6.2	41.1

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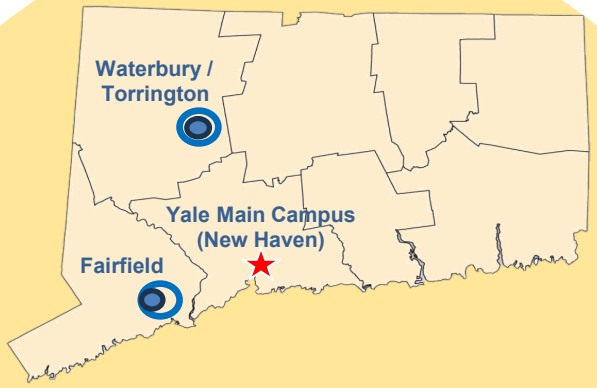
Utilization of a Hybrid Decentralization Model to Enhance Access and Recruitment of Underrepresented Minorities to Early Phase Clinical Trials

Hybrid Decentralization Model



Bridgeport
35.1% Black
40.8% Hispanic

Waterbury:
21.7% Black
37.4% Hispanic

Aim 1: To conduct a multi-level assessment of the unique facilitators and barriers to recruitment of URM populations to early phase cancer clinical trials, addressing patient, provider, health system/policy, and community-level influences

Aim 2: To implement a sustainable hybrid decentralization clinical trials model which will:

a. Increase recruitment of URM patients to early phase oncology clinical trials

b. Maintain patient safety and data integrity of early phase clinical trials

Aim 3: To evaluate the patient, provider, health system, and community partner experience of the hybrid decentralization model and assess its ability to address barriers to early phase trial inclusion of URM patients

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Study Aim 1

To conduct a multilevel assessment to determine the unique facilitators and barriers to recruitment of Black and Hispanic/Latine patients to early phase cancer clinical trials, addressing patient, provider, health system/policy, and community-level influences

Aim Lead: Jessica B. Lewis, PhD, MFT
Deputy Director, Center for Community Engagement &
Health Equity, Yale Cancer Center

Methods: Qualitative Interviews & Online Surveys

Semi-structured In-depth Interviews

Patients (n=29)

- **Black or Hispanic/Latine patients with metastatic cancer** receiving treatment at our Network Sites in Trumbull/Bridgeport & Hartford, referred by cancer care team

Providers (n=33)

- **Physicians & staff** members providing care at Trumbull/Bridgeport & Hartford Care Centers
- New Haven **providers who refer** to early phase trials & **patients on trials**

➢ Rapid Qualitative Inquiry approach for data collection, management & analysis

Online Surveys

Providers (n=81)

- **Oncologists & Advance Practice Providers** providing oncology care across all Smilow Network Care Centers, including Smilow Cancer Hospital

Patient Interview Themes

Informational influences:

- Cancer etiology, treatment options, including trials
- Health literacy & provider communication
- Media: You Tube channels, podcasts, multilingual resources

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- Unmet social needs: Transportation, food insecurity, housing instability, health insurance issues, inadequate interpretation services
- Benefits of trials: close monitoring

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Emotional Influences:

- Trusted advisors: Caregivers/Physicians/Peers
- Hope; motivation to get better; try anything
- **Altruism/Desire to help their community**
- Need for control
- Experiences of racism and racial trauma
- Trust/Mistrust
    - Guinea pig
    - Will not get the same medicine as White patients
    - Feel talked down to, like a number

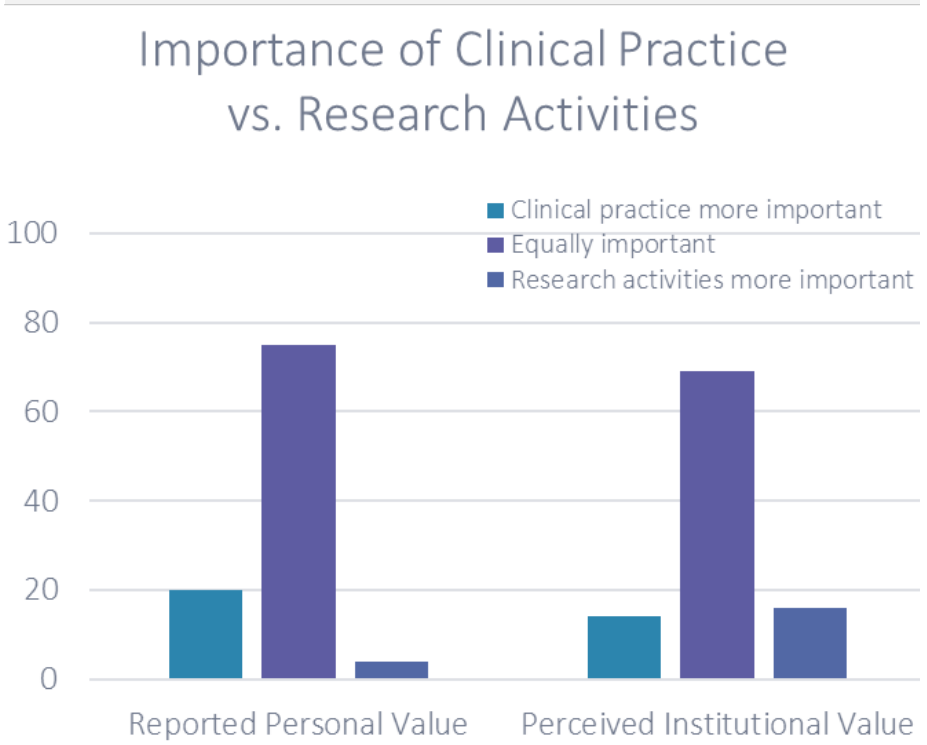
Provider attitudes toward early phase cancer clinical trials

Positive Attitude

- 87% strongly endorsed importance of on-site early phase cancer clinical trials
- 80% *very/extremely likely* to refer eligible patients to early phase trials

Knowledge Gaps

- 25% of providers reported they were *not at all* or *slightly* knowledgeable about early phase cancer clinical trials
- 51% providers were *not at all* or only *slightly* informed about what early phase clinical trials were open in their system



Study Findings: Patient needs for participation

Patients want more **information** about cancer etiology, treatment options & trials

- Multi-media
- Multi-lingual
- At their health literacy level

Patients need an **invitation** to trials

Patients need help with their **unmet social needs**: food, transportation, housing, language, insurance

Patients need to feel a **trusting positive relationship** with the health system and with research

Study Findings: Provider needs to support participation

Providers need more **time & support** to have conversations about trials

Providers want to know patients have their **social needs met** so a trial does not burden them

Providers & staff want more **information about particular trials** for which patients may be a fit

Staff needs more **information about early phase trials** to support participation

Providers & staff want patient and **community trust** to support the conversation

Study Aim 2

Implement a sustainable hybrid decentralization clinical trials model which will:

a. **Increase recruitment of URM patients to early phase oncology clinical trials**
b. **Maintain patient safety and data integrity of early phase clinical trials**

Aim Leads: Dr. Patricia LoRusso, D.O., Ph.D. (h)
Dr. So Yeon Kim, M.D.

Latest Trumbull Numbers

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Patient's Race/Ethnicity & Health Insurance Type
From November 10th , 2023 to September 1st , 2025

	White Non-Hispanic Male	White Hispanic Male	Not Reported Race Hispanic Male	White Hispanic Female	White Non-Hispanic Female	Black Non-Hispanic Male	Black Non-Hispanic Female	Middle Eastern Non-Hispanic Female	Asian Non-Hispanic Female	Asian Hispanic Female	Asian Preferred Not To Share Ethnicity Male & Female	Not Reported/ Preferred Not to Share Race and/or Ethnicity and/or Gender	Insurance Type Total
Medicaid/ Uninsured	1	0	2	1	4	0	6	1	0	0	0	0	**15 (12%)**
Medicare	4	0	0	0	26	0	3	0	0	0	0	2	**35 (26%)**
Private	14	1	0	3	40	3	13	0	1	1	2	4	**82 (62%)**
Patient Total	**19 (13%)**	**1 (1%)**	**2(2%)**	**4 (4%)**	**70 (52%)**	**3 (3%)**	**22 (15%)**	**1 (1%)**	**1 (1%)**	**1 (1%)**	**2 (2%)**	**6 (5%)**	**132**

Latest Trumbull Numbers (Cont.)

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Patients Consented and had Completed a 1st Visit & Health Insurance Type From November 10th , 2023 to September 1st , 2025													
	White Non-Hispanic Male w/ Private	White Non-Hispanic Male w/ Medicare	White Hispanic Male w/ Private	White Not Reported Ethnicity Male w/ Medicare	White Non-Hispanic Female w/ Medicare	White Non-Hispanic Female w/ Private	White-Non-Hispanic Female w/Medicaid	White Hispanic Female w/ Private	Black Non-Hispanic Female w/Private	Black Non-Hispanic Female w/Medicare	Black Non-Hispanic Female w/ Medicaid/ Uninsured	Asian Preferred Not to Share Ethnicity Male w/ Private	Asian Hispanic Female w/ Private
Patient Number 46 of 132 (%)	7 (14%)	1 (2%)	1 (2%)	1 (2%)	9* (21%)	14 (34%)	2 (5%)	1 (2%)	5 (12%)	1 (2%)	2 (5%)	1 (2%)	1 (2%)

Educational Tools

In Clinics Now: Patient Facing Educational Brochure (Right)

Medical Research Changes Lives

Help Make a Difference by Participating in a Clinical Trial

REASONS OUR PATIENTS JOIN:

- They want access to the most cutting edge, newest treatments available to fight their cancer.
- They want to contribute to science and discovery to help the next generations of cancer patients.
- They like the close monitoring of their cancer, their treatments, and side effects.
- They want to make sure that researchers are including people from their communities in studies so that we can know how new treatments work for everyone

FOR MORE INFORMATION PLEASE CALL:
Yale Cancer Center Clinical Trials Office
(203) 785-5702

smilowcancerhospital.org

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Introduction to Clinical Trials

What Are Clinical Trials?
Clinical trials are research studies that involve patient volunteers and allow healthcare providers and patients access to the latest medicines and treatments before they are approved for wider use. These studies answer important questions such as, "What are the side effects of a medicine?" or "Which treatment is better?" All medicines that are currently approved were first available to patients through clinical trials.

Many new treatments are designed based on what has worked in the past, in efforts to improve care. You may be interested in or asked if you'd like to enter a trial and it is important to learn as much as possible about the trial. Your doctor will explain the trial you are eligible to participate in; please ask as many questions as you would like so you fully understand the trial before deciding to participate.

Clinical trials may help researchers find new ways to treat, diagnose, and prevent cancer, and manage the symptoms of cancer or the side effects from cancer treatment. The Food and Drug Administration (FDA) approves all trials in different phases before patients can be treated, and patients are closely monitored throughout all phases.

PHASES OF A CLINICAL TRIAL INCLUDE:

PHASE 1 (also known as Early Phase)

- Phase 1 trials test new treatments by themselves or in combination for the first time in human volunteers. Only small numbers of volunteers join these trials.
- The purpose of these trials is to assess the safety of the new treatment, find the right amount of medicine to give, and determine how it should be given (when and how).
- Phase 1 trials find out important pieces of information including how the new treatment interacts with the body and fights cancer.

PHASE 2

- If the goals of a Phase 1 trial are met, a Phase 2 clinical trial is often done to further decide if the new treatment is effective for fighting certain types of cancer.
- As in a Phase 1 trial, a Phase 2 clinical trial continues to look for any side effects of the treatment.

PHASE 3

- Phase 3 clinical trials compare the safety and effectiveness of the new treatment compared with what patients are currently getting.
- These trials include large numbers of patient volunteers.
- If the new treatment is as effective or more effective than the treatment patients are currently getting, it may be approved by the FDA as a new cancer therapy.

PHASE 4

- A Phase 4 clinical trial happens after the treatment is approved by the FDA as a new standard treatment.
- It may also be done to further assess safety over a longer period of time in a larger group of patients, or in a group of patients that may not have been included in the original Phase 3 trial.

TYPES OF TREATMENTS IN CLINICAL TRIALS:

- *Immunotherapy* – medicine that uses the body's immune system to recognize cancer cells as invaders, and kill them.
- *Chemotherapy* – a medicine that kills cancer cells directly.
- *Targeted therapies* – medicine that targets a certain protein found in the body or cancer cells to stop cancer growth.

DECIDING TO PARTICIPATE:

- Participation is your choice; you can always stop the study at any time for any reason.
- Participating in a clinical trial is a chance to join research that may lead to new discoveries and treatments that may improve outcomes for cancer patients.
- The treatment in a clinical trial may work to treat your cancer with different side effects than usual cancer treatment.
- People who participate in clinical trials have increased clinic visits and are monitored more closely during the course of their treatment for any side effects or other concerns that may not have been expected.

STEPS FOR PARTICIPATION:

LEARN MORE

- If you are interested in learning more about clinical trial opportunities, you will be referred to the clinical trial team to meet, discuss clinical trials, and answer your questions.
- A doctor will decide if a trial is a good match for you and will recommend one if they think there is a good fit.
- You will learn about the trial and review an information form with the clinical trial team that goes over the details of participation.

JOIN

- If you are interested in learning more about clinical trial.
- If you are interested in participating, you will be invited to sign a consent form indicating that you understand the information provided to you.
- Following consent, you will enter the screening period – that means you will have tests done to confirm you and the trial are a good match, which could include a physical exam, labs, imaging, possible biopsy, and other tests, depending on the requirements of the trial.

START TREATMENT

- You will start treatment – this is similar to other treatment visits, but there will be additional visits and assessments to monitor your health and well-being very closely throughout the trial and learn more about the new treatment.

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Educational Tools (Cont.)

Akin to a "Golden Book" Patient Facing "Mythbusters" Booklet

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Project Timeline

- Hire/Train Staff
- Prepare Survey Design
- Conduct Qualitative Interviews
- Develop Tools & Processes
- Finalize Contracts and Equipment
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- Recruit Community Champions
- Onboard at Satellites
- Consultation with Community Advisory Board
- Develop SSDoH screening and referrals
- Open Satellite Clinic #1
- Recruit Patients

Project Timeline

Year 1

- Hire/Train Staff
- Prepare Survey Design
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- Set up CTO/Clinic Infrastructure

Year 2

- Recruit Community Champions
- Onboard at Satellites
- Consultation with Community Advisory Board
- Develop SSDoH screening and referrals
- Hire / Train Patient Navigators
- Open Satellite Clinics
- Recruit Patients

Year 3

- **Identified Need for a RN Patient Navigator**
- **Reassessed utilization of community champions**
- **Open Waterbury/Torrington second site (10//01/2025)**
- **Begin follow-up treatment at Trumbull**
- **Developed/distribute educational tools**

Year 4

- Conduct Qualitative Interviews
- Data Analysis
- Adapt Hybrid Model to Scale
- Report Findings

Identified (& Focused) Challenges:

- ❑ Supplemental Funds for Patients in Financial Need
- ❑ Registered Nurse Navigator
- ❑ Interdepartmental Team Communication
- ❑ Continuum of APP Support
- ❑ Patient/Staff Education
- ❑ Restructuring
- ❑ Physician Referrals
- ❑ Co-Morbidities

Conclusion

- Bringing program to the patient has increased recruitment benefiting all patients
- Identifying and overcoming social barriers important for patient retention
- Frequent communication or contact with network physicians significant benefit in patient referrals

Thank You!!!!