



Wake Forest University
School of Medicine



Atrium Health
Levine Cancer

NCI

Comprehensive
Cancer Center

Breaking Barriers: Bridging Disparities in Clinical Trials for Health Equity

NCOA/SCOS Joint 2024 Meeting

Jimmy Ruiz, MD

Professor of Medicine

Assistant Director for Clinical Research

Section of Hematology and Oncology

Winston-Salem, NC

Disclosures

Consulting and Honoraria:

Sanofi

BMS

Genzyme

Pfizer

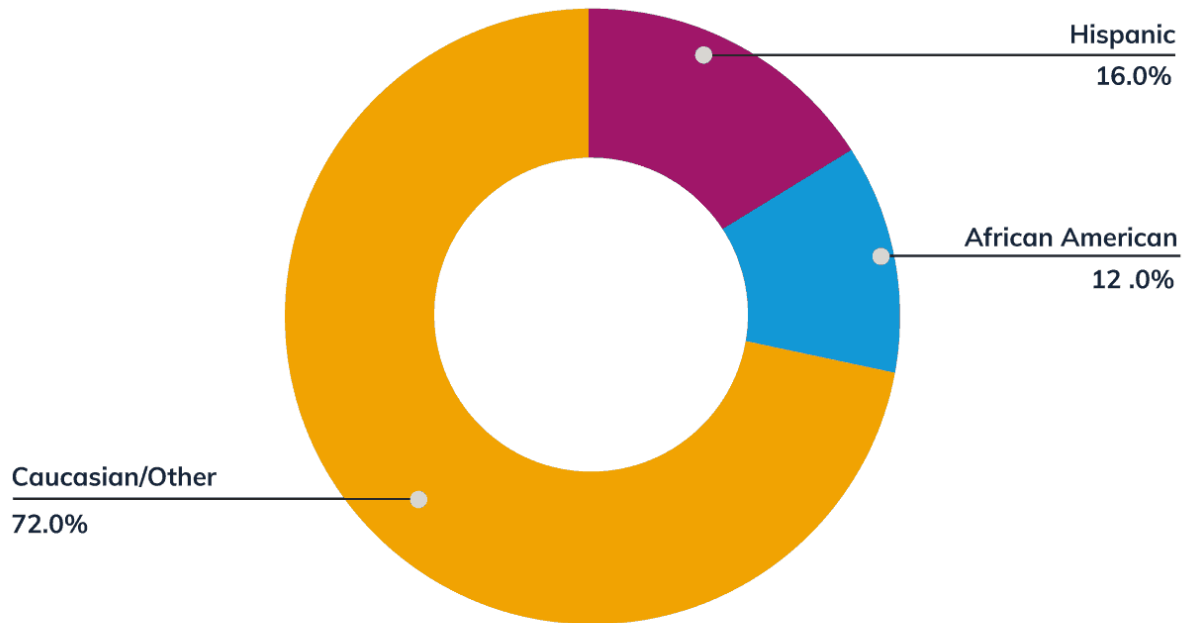
Speaker:

Jazz

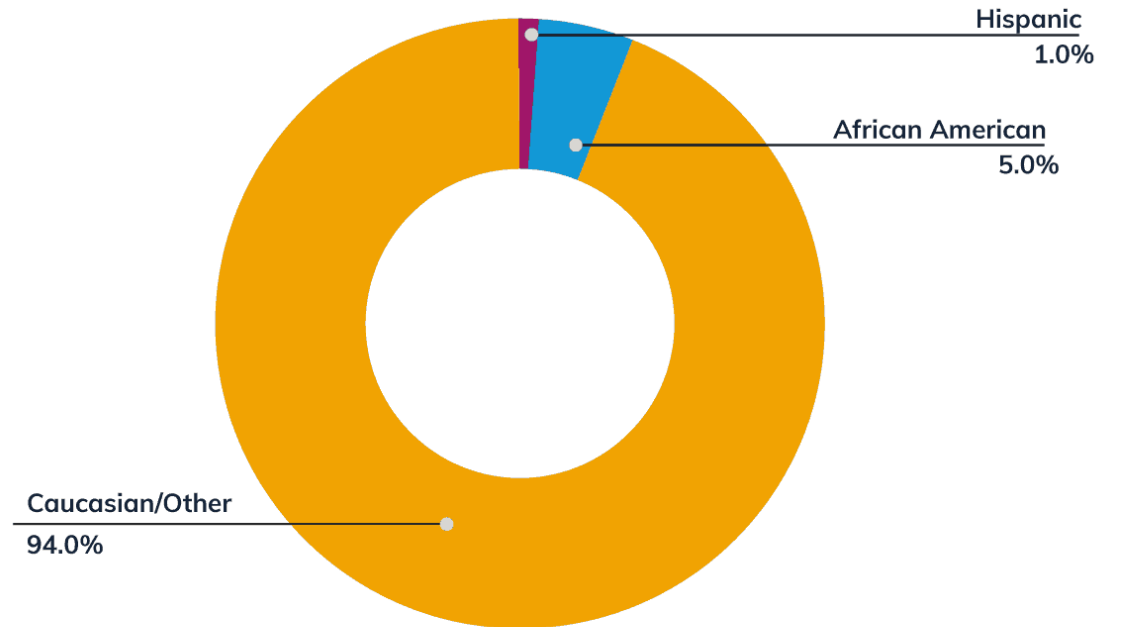


Clinical Trial Representation by Race and Ethnicity

United States Population



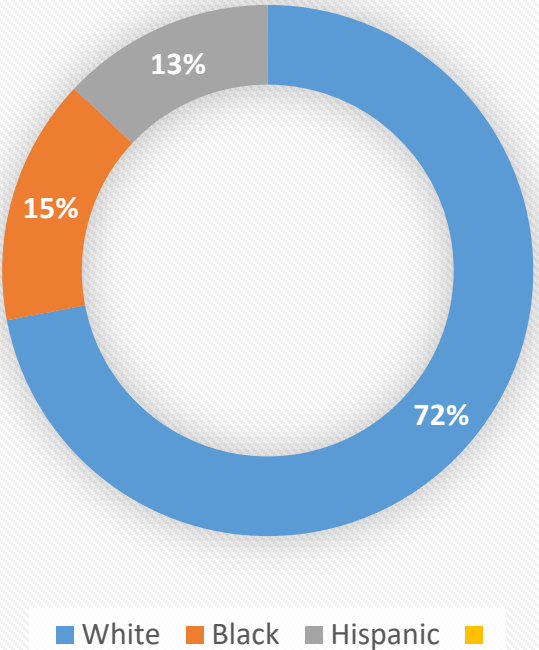
Clinical Trial Participants



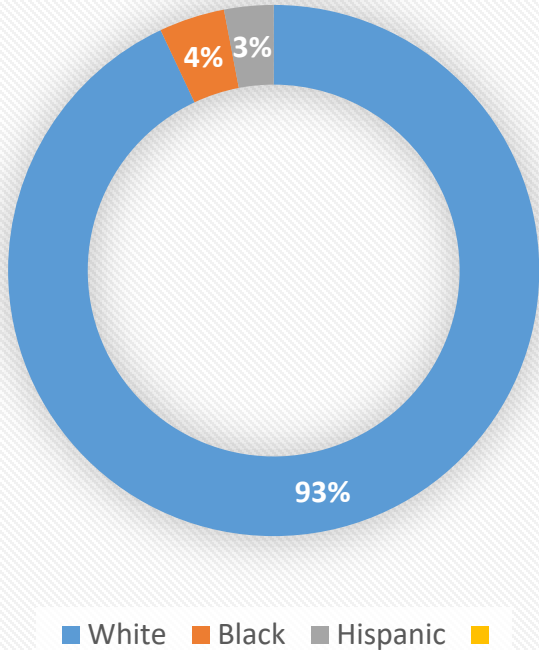
**Sourced from <https://www.sciencedirect.com/science/article/pii/S0146280618301889>*

Cancer Therapeutic Trials

Cancer Population



Cancer Clinical Trial Enrollment



*Duma N, et al. JCO Oncol Pract 14: e1-e10, 2018
Unger JM, et al. J Natl Cancer Inst 111:245-255, 2019*

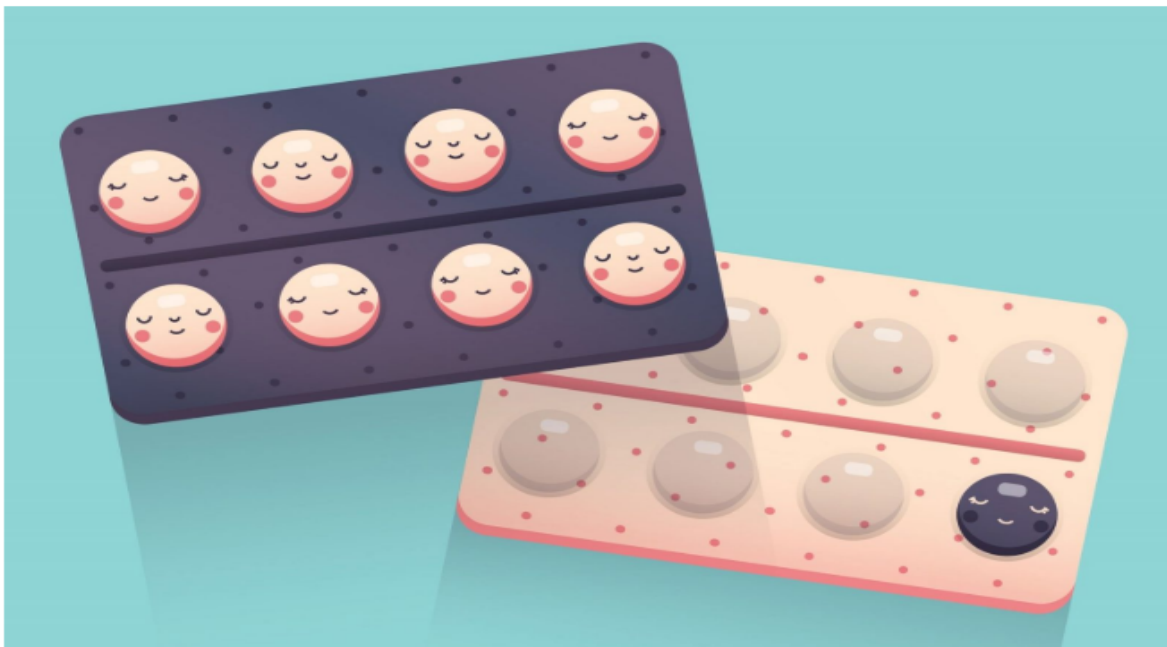
Diversity in clinical trials: Why is this important?

- Paucity of information on multi-ethnic patient bases
- Segments of the population are not included in clinical trials and do not meet statistical significance

Question: Possible to determine if the therapy in question will work?

- Pharmacogenetic research in the past few decades has uncovered significant differences among racial and ethnic groups
 - Metabolism
 - Clinical effectiveness
 - Side-effect profiles

Burroughs VJ et al. J Natl Med Assoc. 2002 Oct;94
Pirmohamed, M. *Nat Rev Genet* **24**, 350–362 (2023)



Chiara Morra for ProPublica

Black Patients Miss Out On Promising Cancer Drugs

A ProPublica analysis found that black people and Native Americans are under-represented in clinical trials of new drugs, even when the treatment is aimed at a type of cancer that disproportionately affects them.

by Caroline Chen and Riley Wong, Sept. 19, 2018, 5 a.m. EDT

This story was co-published with [Stat](#).

It's a promising new drug for multiple myeloma, one of the most savage blood cancers. Called Ninlaro, it can be taken as a pill, sparing patients painful injections or cumbersome IV treatments. In a video sponsored by the manufacturer, Takeda

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“Stark under-representation of Black patients is widespread in clinical trials for cancer drugs, even when the type of cancer disproportionately affects them.”

Diversity in clinical trials: Why is this important?

- FDA wrote that *“meaningful differences may exist in multiple myeloma disease biology, presentation, and response to treatment in blacks compared to whites.”*
- Black patients make up **20 %** of U.S. multiple myeloma diagnosis and are twice as likely as white Americans to be diagnosed
- Account for **4.5 %** of participants in multiple myeloma trials since 2003.

Diversity in clinical trials: Why is this important?

Impact on Scientific Innovation and Progress

“Population disparities always increase when there is scientific progress”

- Screening & treatment of breast cancer
- Screening & treatment of colorectal cancer
- Now we are seeing it again
 - Precision Medicine (Oncology)
 - Immunotherapy
 - Lung cancer screening



Dr. Otis Brawley

Delayed Medical Advances in Rural and Communities of Color

Unequal Access to Innovative Treatments

Aldrighetti CM, et al. *JAMA Netw Open*. 2021

Gupta, et al. *Sci Rep* 13, 8190 (2023)

Haddad DN, et al. *Ann Am Thorac Soc*. 2020

Factors Contributing to Disparities

- Socioeconomic
- Racial and Ethnic
- Geographic
- Barriers to Participation

Clinical Trial Participation

Site selection

Structural
barriers

Racism

Medical/psychiatric
conditions

Knowledge
& attitudes

Social determinants
of health

Trial
operations

Eligibility criteria

Systematic biases

Other

Discrimination



Barriers to Enrollment into Clinical Trials



Patients

- **Mistrust**
- **Lack of information**
 - **Comfort with CT process**
 - **CT awareness**
- **No local availability**
- **Trial does not match disease**
- **Financial Costs**
- **Language and/or Communication**

- **Strict Eligibility**
 - **Performance status**
 - **Comorbidities**
- **Numerous trial visits**
- **Additional tests**



Clinical Trial Protocol



Physicians

- **Clinician Biases**
- **Logistical Reasoning**
- **Limited Time**
- **Limited Resources**
- **Lack of automation**

- **Trial Locations**
- **Types of Trials**
- **Diversity of Research and Support Staff**

Cancer Center



Research Institutions



Patients

Mistrust

Tuskegee Syphilis study





Patients
Mistrust

Parallels with COVID-19

CALIFORNIA

California fails to protect Latino workers as coronavirus ravages communities of color

☰ 🔍

INSIDER

Black and brown people make up two-thirds of US coronavirus deaths below age 65, a new study found

Aria Bendix Jul 11, 2020, 8:51 AM

The San Diego Union-Tribune

Subscribe
\$4 for 4

San Diego Blacks and Latinos most likely to lose jobs and live in COVID hot spots, data shows



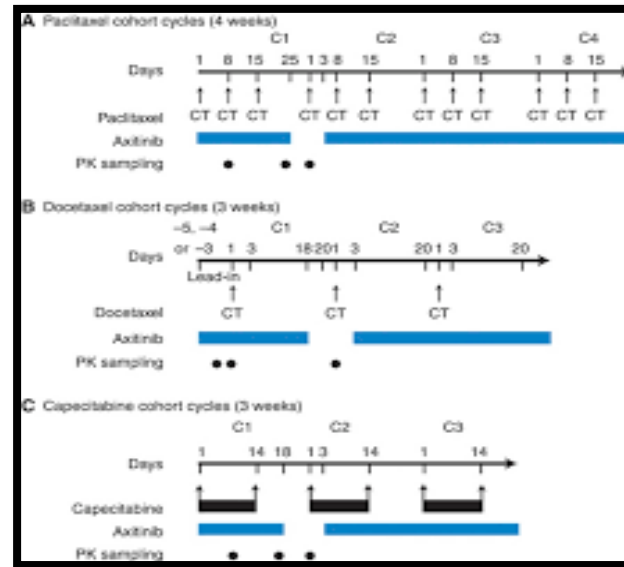


Patients

Language and/or Communication

Meaning of “Trial”

Meaning of Treatment “Cycle”

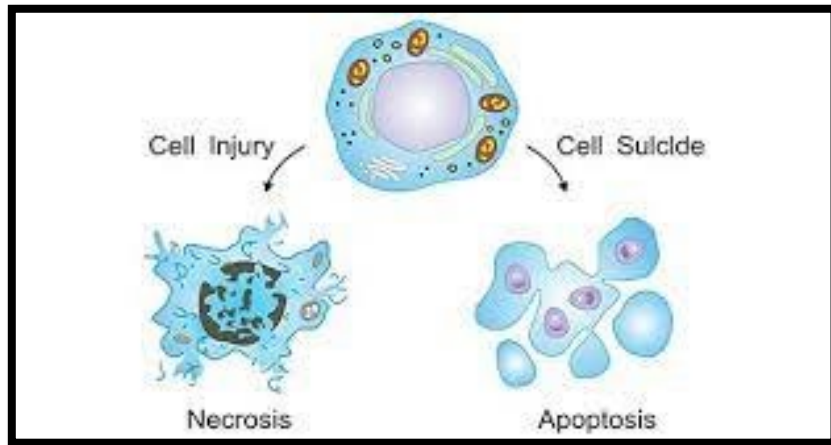




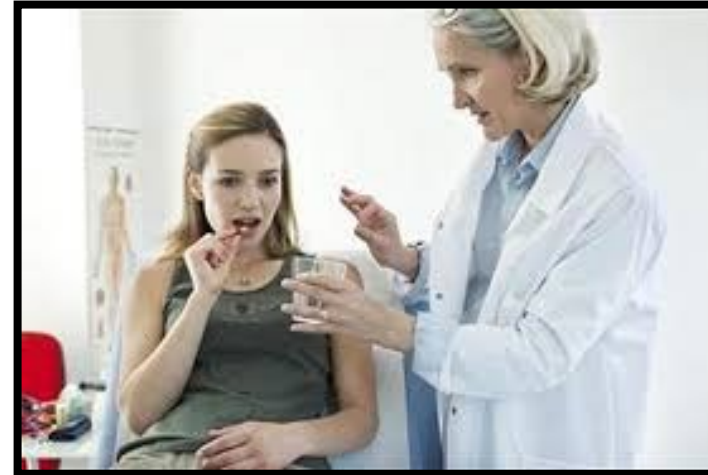
Patients

Language and/or Communication

Meaning of “Cell”



Meaning of “Study or Experiment”



Addressing Disparities in Clinical Trials



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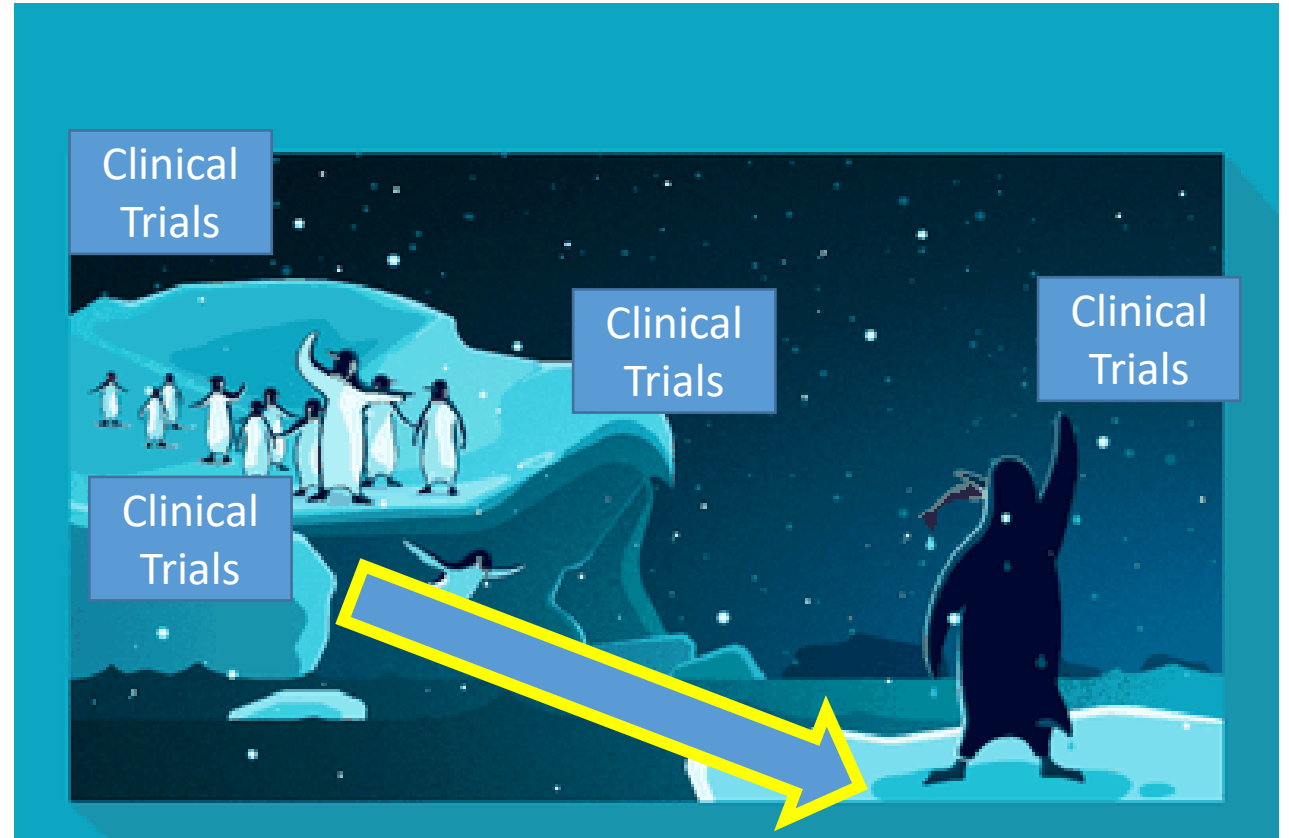
Cancer Center



Research Institutions

Addressing Disparities in Clinical Trials

- Distance
- Centralized Approach to Clinical Trials



Addressing Disparities in Clinical Trials

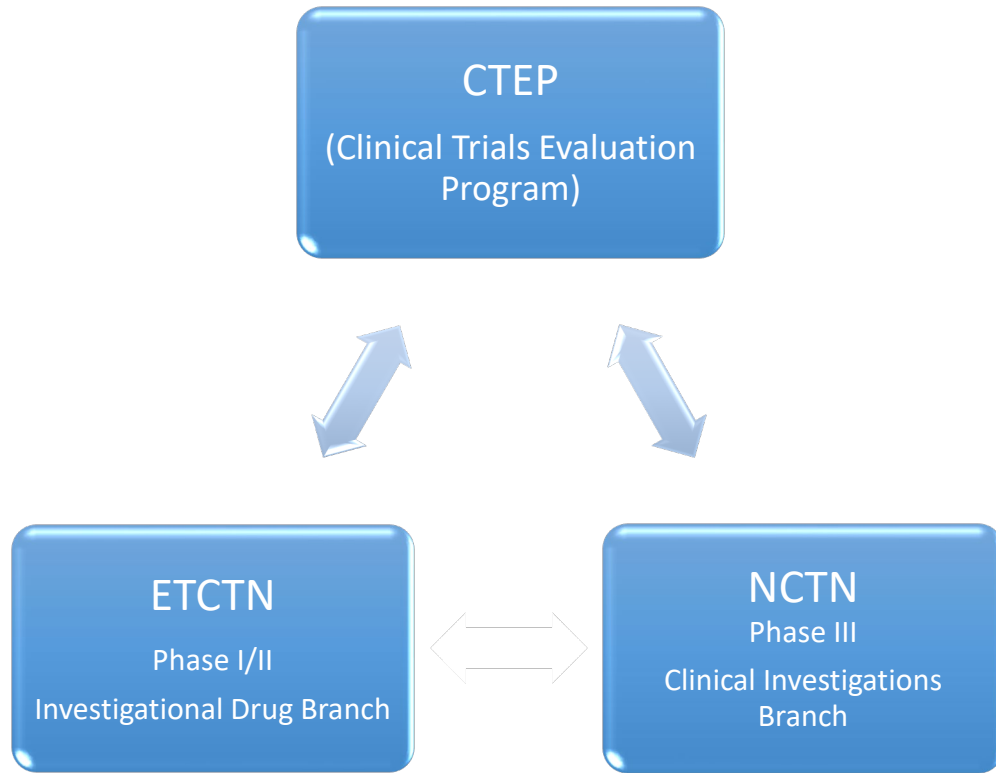
CATCH-UP.2020 Overview
*(Create Access to Targeted Cancer
Therapy for Underserved Populations)*

- **AIMS:**
 - Offer and enroll patients to Experimental Therapeutics Clinical Trials Network Studies
 - Specific goals
 - 24 patients
 - 12 from underserved populations
 - Focus on minority/underserved populations (includes rural populations)
 - Develop earlier career faculty

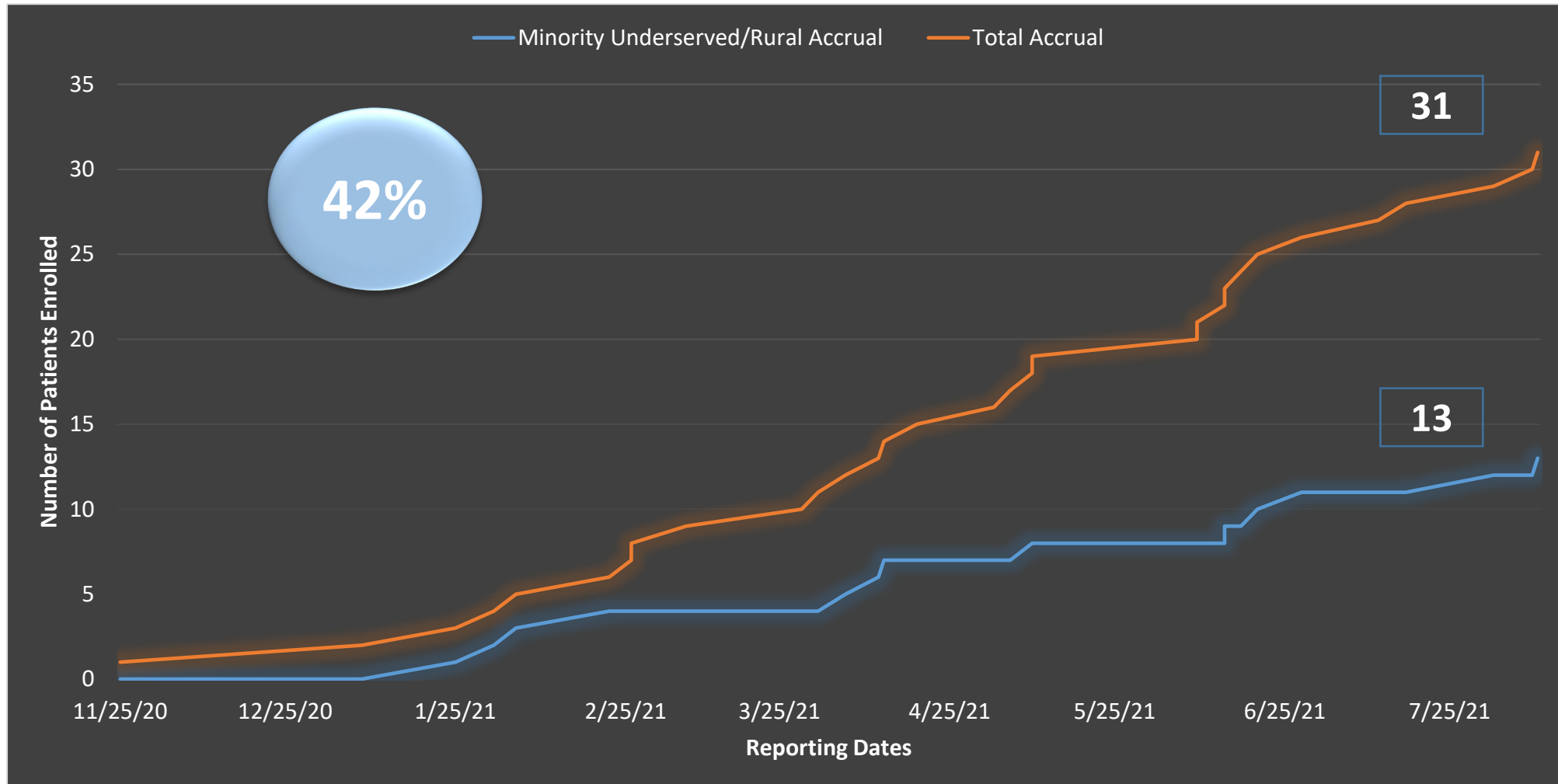


Addressing Disparities in Clinical Trials

Experimental Therapeutics Clinical Trial Network (ETCTN)



WFBCCC: CATCH-UP ACCRUAL



and beyond..

CATCH-UP.2020: Expanding network accrual tools

- ETCTN trials open at Clemmons, Wilkes, and Statesville
- Co-management of trial patients with outreach providers (10302)
- On-going:
 - Population Health Navigation
 - Weekly Newsletter to Outreach sites and local providers
 - Schedule “screening” of Outreach Clinics
 - Systematic identification with Wake Forest Precision Oncology Initiative



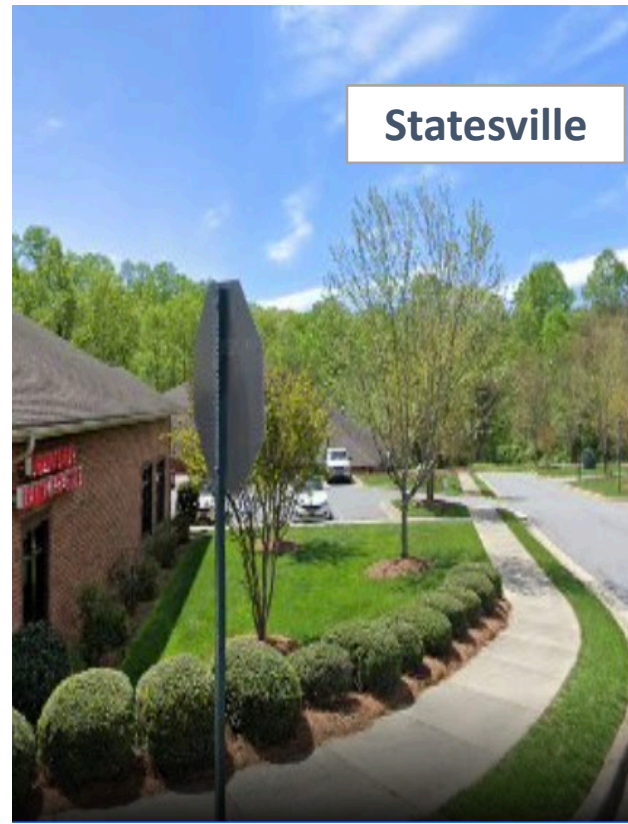
Wilkes



Statesville



Clemmons

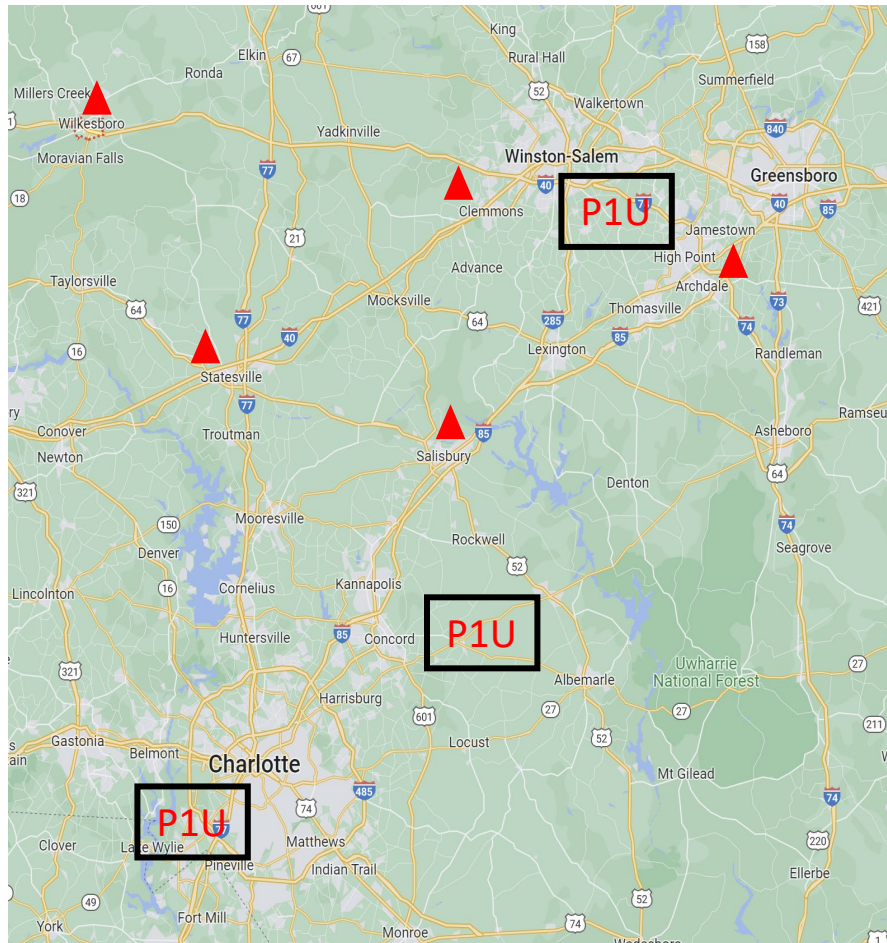




Experimental Therapeutics Clinical Trials Network
Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

Accrual to early phase trials and expanded access to this therapeutic option for underserved populations



Phase 1 Unit

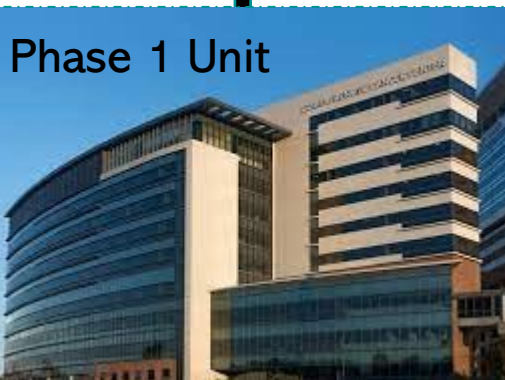


Charlotte

Phase 1 Unit



Concord



Winston-Salem

Addressing Disparities in Clinical Trials



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Cancer Center



Research Institutions

Patient Health Navigators

Population Health Navigators included in:

- Research team meetings
- Patient workflow both at Main Campus and Outreach sites

Alexis Daniels, MS

African-American Patient Navigator

aadaniel@wakehealth.edu



Maria Combs, JD, OPN-CG

Hispanic Patient Navigator

marcombs@wakehealth.edu



Emily Copus, MSW, OPN-CG

Rural Patient Navigator

eabritt@wakehealth.edu



Patients

Lack of information: Provide comfort with CT process through education, provide CT awareness, pull resources for financial costs, and provide the needed cultural touch (diversity of research staff).

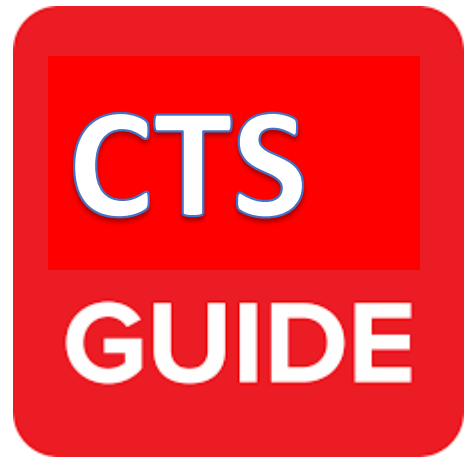
CTSGUIDE: Clinical Trial Selector GUIDE

Wake Forest Baptist Health School of Medicine Innovations Explore Our System



This site is intended for health care providers to identify open clinical trials. If you are a patient or a member of the community, please visit BeInvolved for clinical trial information and search options.

Treatment Interventional Non-Interventional Search How to



Physicians

Address Limited Time and Lack of automation

Treatment

Sarcoma

Lung

Hematologic

Gastrointestinal

Breast

Genitourinary

Gyn/Onc

Phase 1 and Precision Medicine

Cancer Control and Survivorship

Pediatric

Brain

Melanoma

Stage IV

Neuropathy following Taxane or Platin...

[CCCWFU98116] Nicotinamide Riboside (NR) in Paclitaxel-Induced Peripheral Neuropathy

ER/PR+ Her2- 1st line and 2nd li...

[WFB00074219] A Phase III, Randomized, Double-Blind, Placebo-Co...

[WFB00074120] A randomized, multicenter, double-blind phase 3 s...

Stage III

Residual disease after Neo Adjuva...

[NR0-09005/01418] A Randomized, Phase III Trial to Evaluate the...

Neo Adjuvant 1st line

[CCCWFU74218] I-SPY 2 TRIAL: In vestigation of Serial Studies to...

Neuropathy following Taxane or Platin...

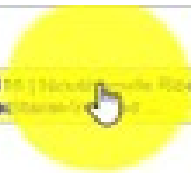
High Risk Adjuvant/Neoadjuvant

DCIS

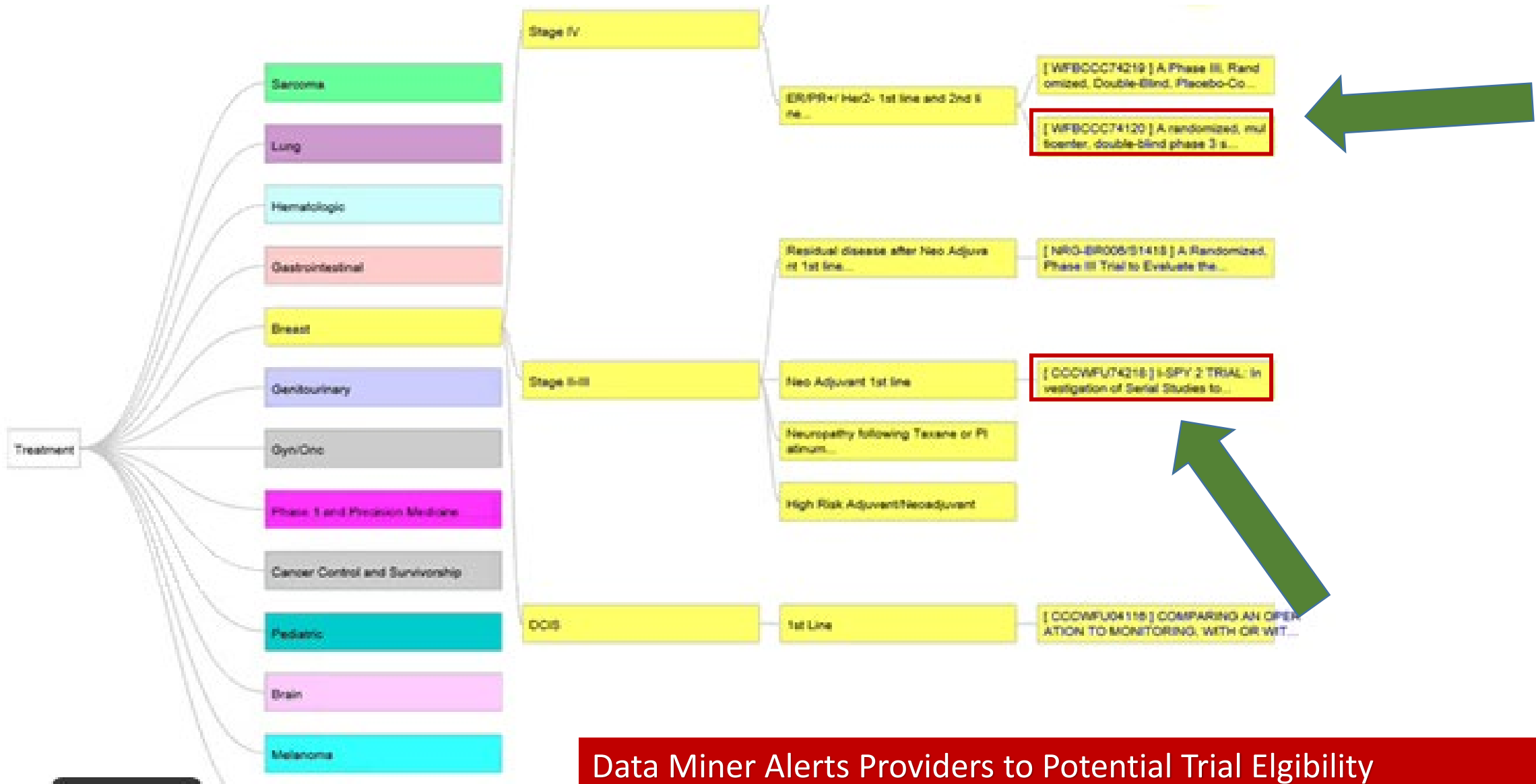
1st Line

[CCCWFU04116] COMPARING AN OPER ATION TO MONITORING, WITH OR WIT...

[CCCWFU98116] Nicotinamide Riboside (NR) in Paclitaxel-Induced Peripheral Neuropathy



Automation is KEY !



Sarcoma

IRB Number: IRB00053194

OnCore No: CTSUEA6134

NCT Number: NCT02224781

Title: A Randomized Phase III trial of Dabrafenib + Trametinib followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients With Advanced BRAFV600 Mutant Melanoma

Therapeutic Level: interventional

Email

Principal Investigator

Pierre Triozzi
ptriozzi@wakehealth.edu

Study Contact

Angela Howell anhowell@wakehealth.edu
Rebecca Dellinger-Johnston radellin@wakehealth.edu
Matthew Eber meber@wakehealth.edu

Co-Investigator(s)

Treatment

Description

Primary Objective

To determine whether initial treatment with either combination ipilimumab + nivolumab (with subsequent dabrafenib in combination with trametinib) or dabrafenib in combination with trametinib (with subsequent ipilimumab + nivolumab) significantly improves 2 year overall survival (OS) in patients with unresectable stage III or stage IV BRAFV600 mutant melanoma

2.2 Secondary Clinical Objectives

2.2.1 To evaluate the impact of initial treatment on median OS and Hazard Ratio for death.

2.2.2 To determine whether initial treatment choice significantly improves 3 year OS.

2.2.3 To evaluate the anti-tumor activities (RECIST-defined response rate, median PFS) and safety profiles of ipilimumab + nivolumab and dabrafenib-trametinib in a Cooperative Group trial of patients with V600 mutant melanoma.

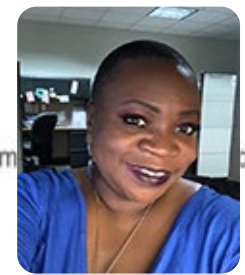
To evaluate the activity (RECIST-defined response rate, median PFS) and safety of dabrafenib + trametinib in patients who have had disease progression on ipilimumab + nivolumab and in comparison to its activity and safety in ipilimumab + nivolumab naive patients.

Brain

Melanoma

IRB Number: IRB00053194
OnCore No: CTSUEA6134
NCT Number: NCT02224781
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Therapeutic Level: interventional

Email Sent to Patient Health Navigator



vs. ipilimumab + nivolumab followed by dabrafenib + trametinib at Progression With Advanced BRAFV600 Mutant Melanoma

Email



Principal Investigator

Pierre Triozzi
ptriozzi@wakehealth.edu

Co-Investigator(s)

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Rebecca Dellinger-Johnston radellin@wakehealth.edu
Matthew Eber meber@wakehealth.edu

Description

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Email Sent to Study Coordinator Pool

Addressing Disparities in Clinical Trials



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Physicians

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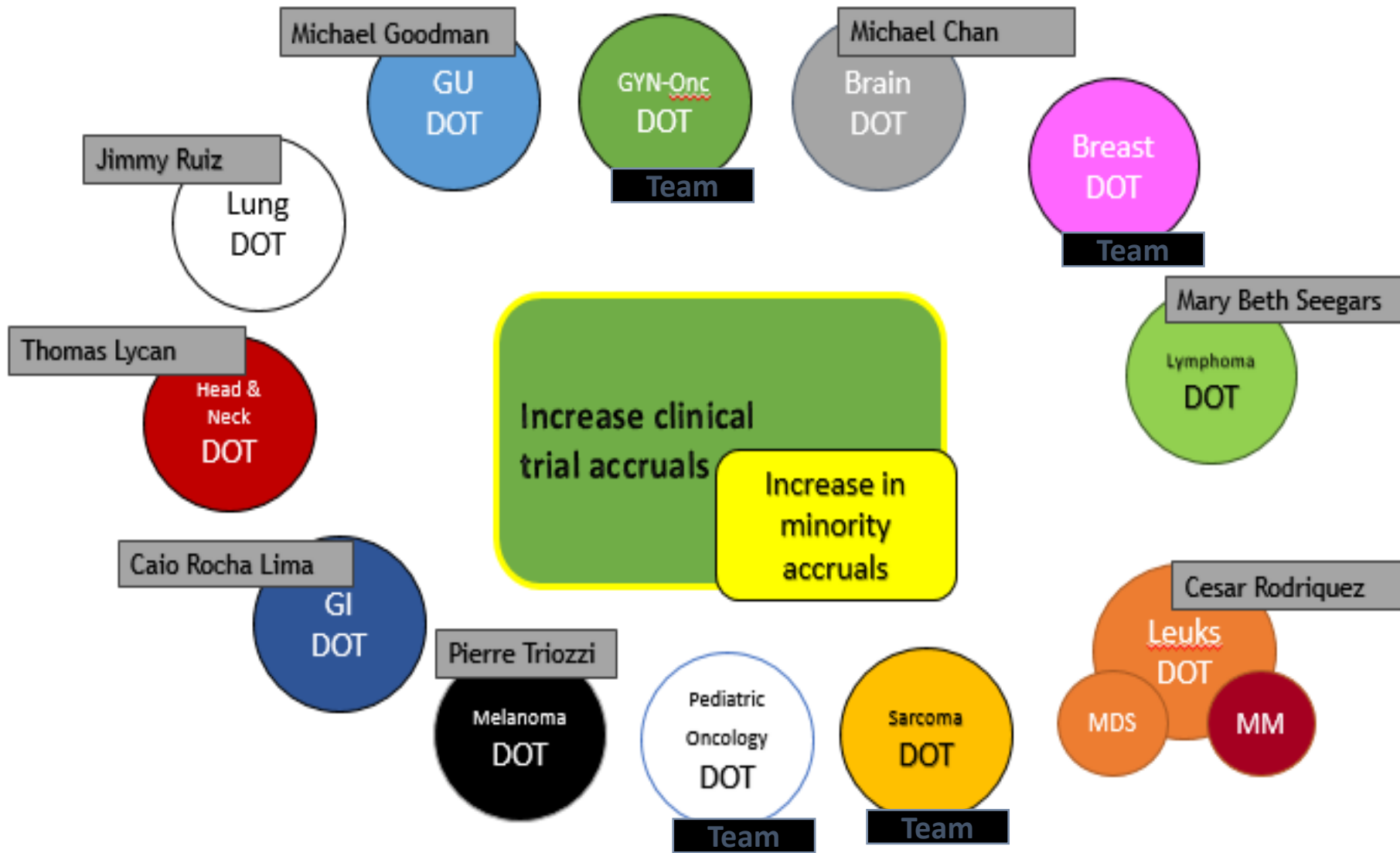
Cancer Center



Research Institutions



Clinical Trial Protocol



- Review clinical trial accruals
- Expectations for minority, women, and rural enrolled subjects
- Barriers to enrollment

Champions for Diversity for Clinical Trial Participation



Cancer Center
Research Institutions

DOT - Champion for Diversity

- One member of DOT assigned to role of Champion for Diversity (CD)
- Each DOT CD invited to participate in the OCHE Advisory Group
- Dr. Micheal Chan

**Neuro-Onc DOT
Champion for Diversity**





Office of Cancer Health Equity

Cancer can affect anyone, at any time. We believe that everyone should have an equal chance of surviving cancer.

Collaborating in the Hispanic Community

The Office of Cancer Health Equity partners with Cancer Services, Inc. to support the Hispanic community. Maria Combs, our Hispanic Patient Navigator, works closely with Gloria Galeano Hall, bilingual Patient Advocate at Cancer Services. They attend Hispanic community outreach events and serve as facilitators of the Hispanic cancer support group as well as the Cancer Transitions survivorship program.



Gloria Galeano Hall and the entire Hispanic Support Group



Dr. Jimmy Ruiz, Assistant Director of OCHE, leading the discussion at Cancer Transitions.



Goals for improved access and minority enrollment to clinical trials

- CTs are accessible, affordable, and equitable for patients
- Design efficient CTs that are integrated into clinical care
- Simplify, streamline, and standardized protocol requirements
- Recruit, retain, and support a well trained diverse clinical trial team
- Institute oversight and review clinical trial results

