



Yale Center for
Clinical Investigation

Understanding Health Equity in Clinical Trials

FDA Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee Meeting- September 6, 2023

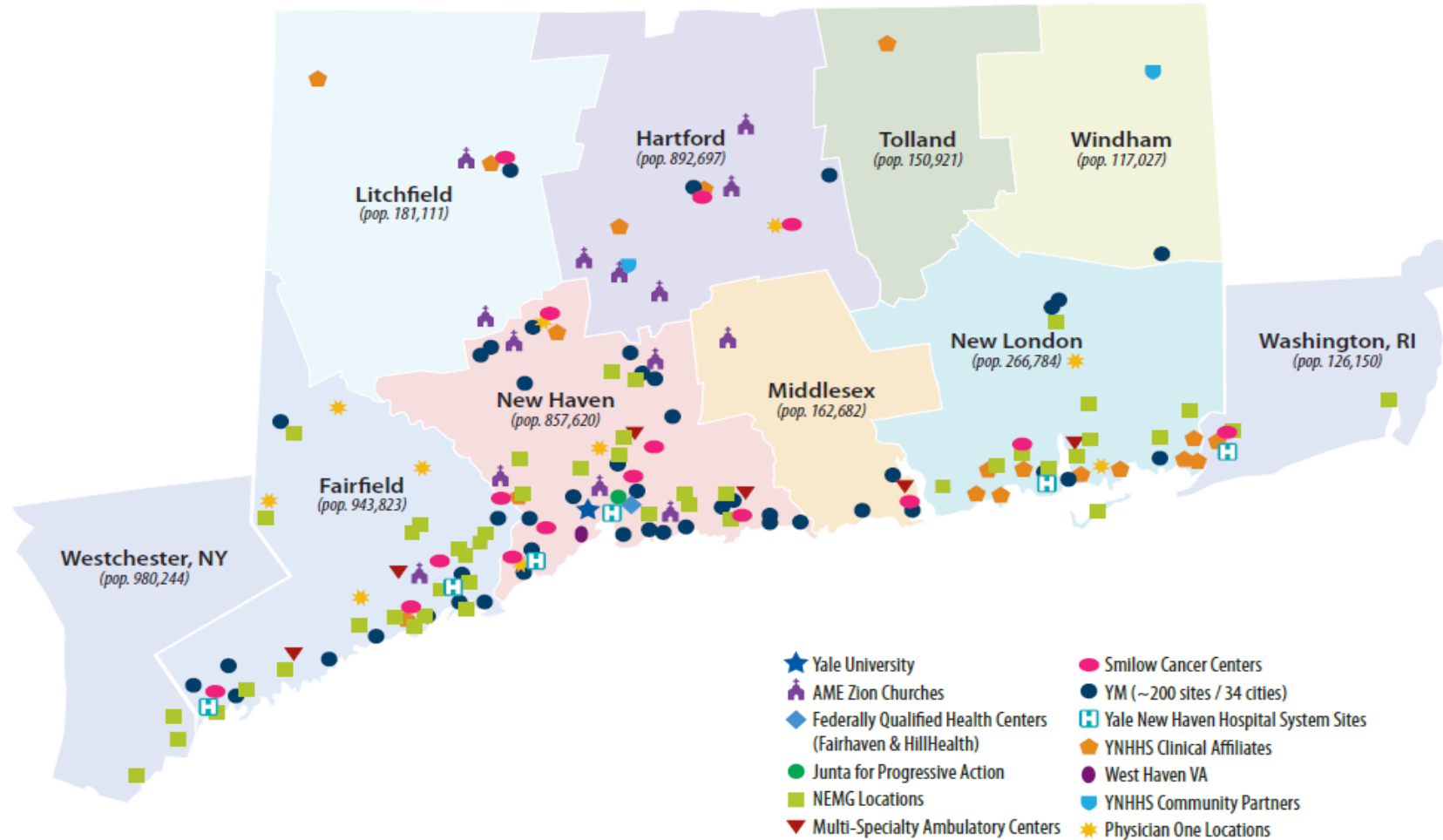
Tesheia Johnson, MBA, MHS
Director for Clinical Research, Yale School of Medicine
Deputy Director and Chief Operating Officer
Yale Center for Clinical Investigation

Disclosures

- I have no relevant financial relationships to disclose.

Our Clinical Research Hub

- **Yale University**
 - Yale Medicine, including ~300 specialty practices
 - Yale Health Plan
- **Community partnerships**
 - AME Zion Churches of Connecticut
 - More than 30 community-based organizations
- **Yale New Haven Health System (2530 beds)**
 - Yale New Haven Hospital (1561 beds)
 - Greenwich Hospital
 - Bridgeport Hospital
 - New England Medical Group (NEMG), including 271 care sites
 - Lawrence + Memorial
- **Federally Qualified Health Centers**
 - Fair Haven Community Health Center
 - Cornell Scott Health Center
- **Close clinical and research collaborations with VA Hospital at West Haven**



Patient Population Race & Ethnicity at Yale

2021 US Census Demographics

- ▶ 60.1% White
- ▶ 18.5% Hispanic/Latinx
- ▶ 13.4% Black/African American
- ▶ 5.9% Asian
- ▶ 1.3% Native American/Alaskan
- ▶ 0.2% Pacific Islanders
- ▶ 2.8% Two or More, Other

2021 Yale Patient Demographics

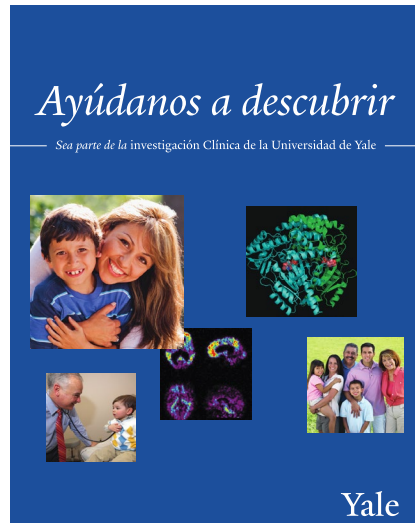
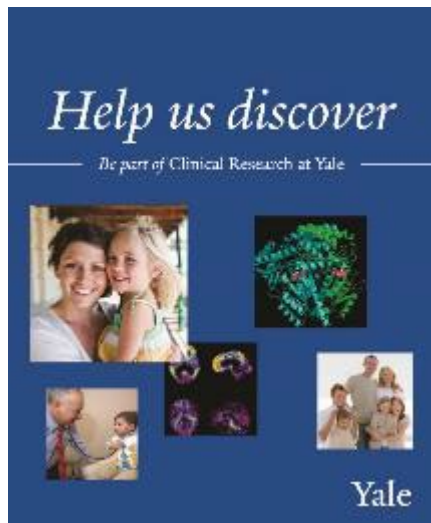
- ▶ 65.7% White
- ▶ 15.3% Hispanic/Latinx
- ▶ 13.8% Black/African American
- ▶ 3.0% Asian
- ▶ 0.3% Native American/Alaskan
- ▶ 0.3% Pacific Islander
- ▶ 10.6% Other
- ▶ 6.3% Unknown

Yale COVID Inpt Demographics

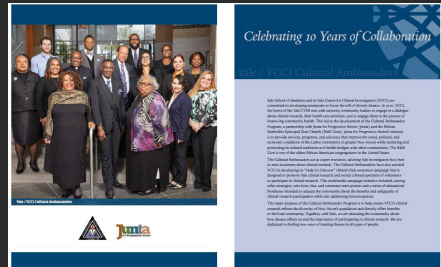
- ▶ 43.9% White
- ▶ 26.1% Hispanic/Latinx
- ▶ 24.8% Black/African American
- ▶ 1.8% Asian
- ▶ 0.04% Native American/Alaskan
- ▶ 0.06% Pacific Islanders
- ▶ 3.3% Other

Integrated Approaches to Recruitment: “Help us discover” clinical research awareness campaign

- Database of volunteers
- Cultural Ambassadors
- Advertising and media
- New clinical research recruitment call center
- Integrate community practices
- Community based health fairs and clinics
- Epic telehealth engagement
- Social media outreach
- **NEW** Radio shows focused on health
- **NEW** TV shows focused on health



Celebrating more than 13 Years of Collaboration



Yale / YCCI Cultural Ambassadors
and FDA's Office of Minority Health and Health Equity

10TH ANNIVERSARY
Celebration & Gala

February 28, 2020
Omni Hotel, New Haven, CT



THE 2ND INNOVATION AND DIVERSITY SUMMIT
Yale School of Medicine and FDA's Office of Minority Health and Health Equity

Friday, February 28th
7:30 am to 4:14 pm
Harkness Auditorium | 333 Cedar Street, New Haven

The Innovation and Diversity Summit: Patient-Centered Approaches to Care and Research, a collaboration of Yale School of Medicine and our partners at the FDA Office of Minority Health and Health Equity and the YCCI Cultural Ambassadors for Clinical Research, will focus on raising awareness about the need for diverse participation in clinical trials and innovative patient-centered approaches to care and research. Our goal is to bring stakeholders from the government, industry, academia, and community to generate discussion about innovation and clinical trial diversity and raise awareness.

Keynote Speakers

Frederick M. M. MD, Director, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration
Gary H. Gibbons, MD, Director of the National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH)

Diversity and Innovation at FDA

CAFT Hilda A. Arango, Associate Commissioner for Minority Health, Division, Office of Minority Health and Health Equity, U.S. Food and Drug Administration
RADM Denise Hinton, Chief Scientist, U.S. Food and Drug Administration
William Lutz, MD, PhD, Lead Medical Officer, Professional Practice and Stakeholder Engagement, Office of the Center Director, CBER, U.S. Food and Drug Administration

Diversity and Innovation at Yale School of Medicine

Nancy Brown, MD, Dean, Yale School of Medicine
Rishi Teich, MD, Deputy Dean for Scientific Affairs (Clinical Departments) Chair, Department of Laboratory Medicine, Center for YCCI Co-Principal Investigator, Yale CTSA
John Krystal, MD, Chair, Department of Psychiatry, Chief of Psychiatric and Behavioral Health at Yale New Haven Hospital, Co-Director, YCCI, Co-Principal Investigator, Yale CTSA
Allen Haines, MD, FAAP, Chief Medical Information Officer, Yale School of Medicine and Yale New Haven Health
Sandra E. Johnson, MBA, MPH, Deputy Director and Chief Operating Officer of YCCI, Associate Director for Clinical Research for Yale School of Medicine, Representative from Yale Cultural Ambassadors Program, AME Zion Church and JCC

Panel Discussion

Leslie L. Clark, MD, FACG, FAACP (Health & Co., Inc.) | Naindar Chopra (Hugoboss | Dr. Marie-Claude Raymond (BioGenidev | Together) | Paul Underwood, MD, FACC, FPCAI (Dorwin Scientific) | Nivela Bialik (Covance Koch) | Sandra Amaro (Pharm) | Julian Sandwell, MD (Dorwin Scientific | Representative from Yale Cultural Ambassadors Program (AME Zion Church and JCC))

YCCI is proud to join the CTSA Center for the National Center for Advancing Translational Science (NCATS), a component of the National Institutes of Health (NIH).

To learn more about the event, view the agenda, and/or RSVP, please click on the QR code or visit: <https://medicine.yale.edu/ycci/news/summit>
For questions call (203) 785-5482.

Yale



Key features of the Ambassador program

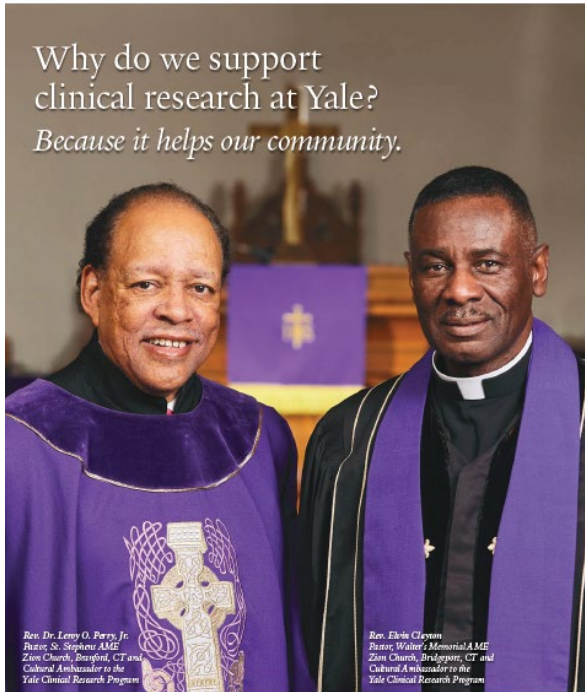
The Program:

- Selection by the community
- Commitment is not to a specific trial, but to the organization
- Compensation for training and engagement
- Minimum training
- Actual training
 - Over 200 hours
 - Community Health Care Worker certification
 - Continual education – (repeat training 2-4 years)
- How to engage faculty

Benefits:

- Community Education and Awareness of Trials
- Working with the community to make clinical research accessible to the communities, including activities around decentralized trials
 - Church and community locations
- Address patient burden and how to help uptake these issues/needs

Why do we support clinical research at Yale?
Because it helps our community.



Rev. Dr. Leroy O. Perry, Jr.
Pastor, St. Stephen AME
Zion Church, Branford, CT and
Cultural Ambassador to the
Yale Clinical Research Program

Rev. Edwin Clayton
Pastor, Walter's Memorial AME
Zion Church, Bridgeport, CT and
Cultural Ambassador to the
Yale Clinical Research Program

Be part of Clinical Research at Yale.

Each of us benefits every day from clinical research. Your blood pressure medicine, your child's asthma inhaler, the latest Alzheimer's drug that your mom is taking – all of these are available to you because of clinical studies that show they are safe and effective. The African American community has higher rates of many diseases like asthma, diabetes, and certain cancers – yet we're underrepresented in research programs. As cultural ambassadors for the Yale School of Medicine, we are committed to supporting medical research. We urge you to do your part by volunteering for a clinical trial. Hundreds of opportunities are available. Help make a difference.

Visit us at www.yalestudies.org, where you can review available trials and build your personal profile. Or call 1-877-978-8343 for more information.

HELP US DISCOVER **Yale**

Why do we support clinical research at Yale?
Because it helps our community.



Staff of Jesus for Progressive Action

Be part of Clinical Research at Yale.

Each of us benefits every day from clinical research. Your blood pressure medicine, your child's asthma inhaler, the latest Alzheimer's drug that your mom is taking – all of these are available to you because of clinical studies that show they are safe and effective. The Latino community has higher rates of many diseases like diabetes, heart disease, and asthma – yet we're underrepresented in research programs. As cultural ambassadors for the Yale School of Medicine, we are committed to supporting medical research. We urge you to do your part by volunteering for a clinical trial. Hundreds of opportunities are available. Help make a difference.

Visit us at www.yalestudies.org, where you can review available trials and build your personal profile. Or call 1-877-978-8343 for more information.

HELP US DISCOVER **Yale**

Example: 2020 focus on heart disease and stroke



A device example: Special campaign partnered with cardiologist to educate community on a one-time implant to protection against stroke risk

<https://medicine.yale.edu/ycci/researchspectrum/cer/research/ambassadors/tfrs/>



Allowing Communities To Not Just Survive, But To Thrive

Rev. Elvin Clayton, Pastor, Walters Memorial AME Zion Church and Yale Cultural Ambassador for Clinical Research
https://www.youtube.com/watch?v=-OkeASrW_TQ



Rev. Elvin Clayton
Pastor, Walter's Memorial AME Zion Church
YCCI Cultural Ambassador



If you want to hear the voice of the voiceless...

Racial Equality in Clinical Trials - Yale Center for Clinical Investigation

Cultural Ambassador, Yale leaders, FDA speak about diversity in clinical trials

<https://www.youtube.com/watch?v=DsXmxNnKMLg>

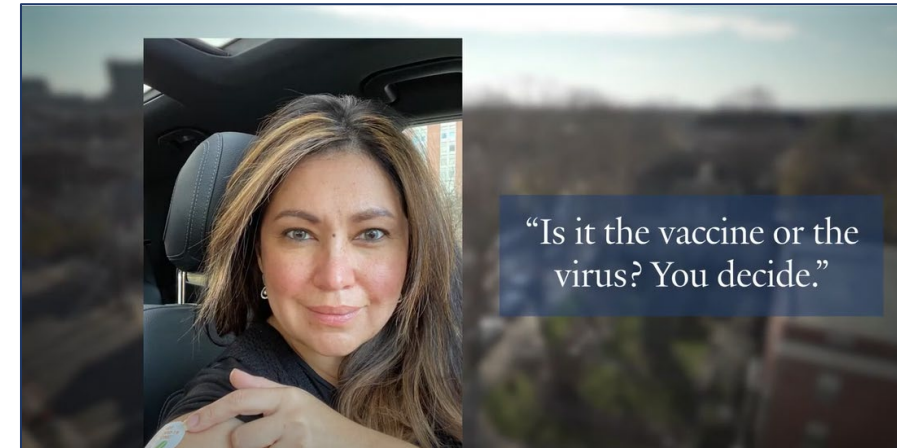


Science and Faith Come Together...

We are urging everyone to get the vaccine

Rev. Dr. Leroy Perry, Pastor, St. Stephens AME Zion Church and Yale Cultural Ambassador for Clinical Research

<https://www.youtube.com/watch?v=l2MPE-kYW8I>



“Is it the vaccine or the virus? You decide.”

Sandra Trevino-Ranalli, M.S.S.W., L.C.S.W. and Yale Cultural Ambassador for Clinical Research

<https://www.youtube.com/watch?v=aMnj8LdrTUQ>



My brother you might not be around...we don't have the luxury of waiting to see

Response to why don't we wait and see how others make out with the vaccine.

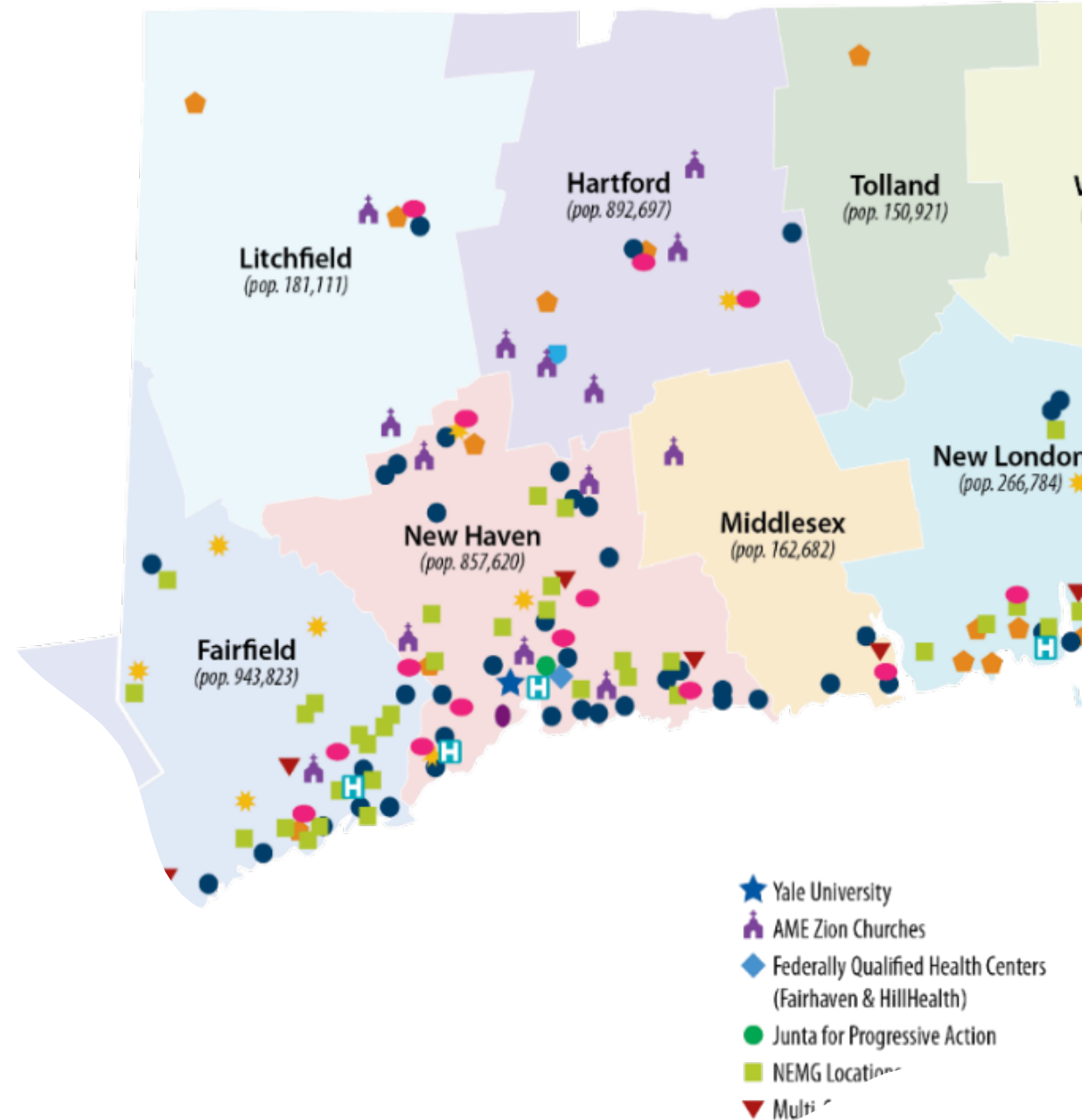
Rev. Dr. Leroy Perry, Pastor, St. Stephens AME Zion Church and Yale Cultural Ambassador for Clinical Research

<https://www.youtube.com/watch?v=mh2bK3iFAOs>



More than a decade of Clinical Research Growth and Successes

- 8% of new patients come to Yale initially for research, 75% adoption of patient portal.
- 950% increase in industry research
- FY22 ~30K individuals participated in clinical trials, with ~32% identifying as person of color (up from 2-4% in 2010)
- 2016- present
 - Yale conducted ~5K clinical trials (42% therapeutic / 58% non-therapeutic), with total accrual ~70K participants.
 - Over the past five years ~26% of our total enrollment has been from underrepresented minorities (FY20 was ~30%). When you compare therapeutic vs. non-therapeutic (~24% therapeutic URM / ~27% non-therapeutic URM) –
 - For studies with the **Cultural Ambassadors engaged over the past 5 years ~61%** of our total enrollment has been from underrepresented minorities, when you look at therapeutic vs. non-therapeutic (52% therapeutic / 67% non-therapeutic).
 - **99% retention rate total and 97% URM**



Our Partnership:

FDA Office of Minority Health and Health Equity and Yale

MOU 225-18-015

1. Collaborations to cultivate and advance the *Yale Cultural Ambassadors Program* and the engagement of community partners to increase participation of diverse underserved populations in clinical research;
2. Advancing education and participation of diversity of the ...scientific workforce ...including clinical trials;
3. Advancing student education...into...biomedical science... including student internships and faculty sabbatical;
4. Opportunities for FDA staff to serve as adjunct faculty or on advisory boards;
5. Opportunities to convene joint meetings for education and research;
6. Opportunities for Yale students, trainees, and faculty training in the regulatory science pathways;
7. Research and evaluation collaborations;
8. Cooperative international initiatives; and
9. Accessing unique facilities and equipment for scientific endeavors.

<https://www.fda.gov/about-fda/academic-mous/mou-225-18-015>

Selected Accomplishments:

- *Innovation and Diversity Summits, focus Patient-centered Approaches to Care and Research*
- Joined Yale work to expand community engaged clinical trials network in Puerto Rico.
- Joint presentations at minority serving groups and organizations, including Black Nurses Association
- FDA hosting of Yale Clinical and Translational Science Interns for 4-week externships at OMHHE.
- Joint FDA-Yale DIA publication, “*Advancing Clinical Trial Diversity Through Community Engagement*”
- *Diversity and Innovation in Clinical Trials Summit*

THE INNOVATION AND DIVERSITY SUMMIT:
Patient-Centered Approaches to Care and Research

Friday, October 5th
7:00 am to 2:30 pm | Lunch will be provided
Harkness Auditorium | 333 Cedar Street, New Haven

The Innovation and Diversity Summit, a collaboration of Yale School of Medicine and our partners at the FDA Office of Minority Health, will focus on raising awareness about the need for minorities and subpopulation participation in clinical trials; patient-centered approaches to care and research; and the role of technology in both areas. Our goal is to bring stakeholders from governmental agencies, industry, academia, and the community together to provoke discussion about innovation and clinical trial diversity and raise awareness.

Presentations

FDA Speakers
 RADM Denise Hinton, Chief Scientist, FDA
 CAPT Richardae Araujo, Associate Commissioner for Minority Health, FDA

Diversity and Innovation: The Yale Evolution
 Allen Hsiao, MD, FAAP, Chief Medical Information Officer, Yale School of Medicine and Yale New Haven Health
 Teshia Johnson, MBA, MHS, Deputy Director and Chief Operating Officer of YCCI, Associate Director for Clinical Research for Yale School of Medicine

Historical Perspective on Henrietta Lacks
 Representatives from Henrietta Lacks Family

Historical Perspective on Minorities in Research
 Quincy J. Byrdsoong, PhD, CIP, OCEP, Executive Director for Research Administration, Wellstar Research Institute

Regulatory Perspectives
 Linda Coleman, JD, CIP, CHC, CHRC, OCEP-I, Director, Human Research Protection Program, Yale University

Community and Patient-Centered Approach to Cardiovascular Health and Research
 Erick Velazquez, MD, FACP, FACC, FASE, FAHA, Professor of Medicine and Chief, Cardiovascular Medicine, Yale University

Panel Discussion

 To learn more about the speakers, view the full agenda, and/or RSVP, please



From left to right: Intern Shiny Weerakoon (YSPH student); RADM Richardae Araujo, PharmD MS, Director FDA OMH; Intern Asia Brown (YSPH student);

FDA Office of Minority Health and Health Equity Clinical Trials Diversity Research awarded to Yale

Competitive contract from the FDA Office of Minority Health and Health Equity entitled *Leveraging Community Engagement and Electronic Health Record Strategies to Promote Diverse Participation in COVID-19 Clinical Trials* (Contract # 75F40120C00174).

- **Aim1:** Understand factors or combination of factors that contribute to COVID-19 morbidity and mortality in minority populations
- **Aim 2:** Utilize real time data and EHR data to provide population health management and access to COVID-19 and other clinical trials information, including integration of community level social determinants of health information
- **Aim 3:** Understanding ways to amplify linguistically and culturally appropriate information related to COVID-19 and general research awareness, participation, and retentions as well as prevention strategies.

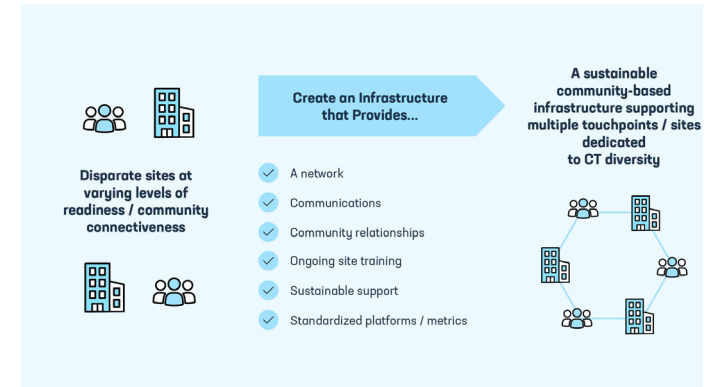
This project is supported by the Food and Drug Administration (FDA) Office of Minority Health and Health Equity of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling \$3.3M. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

Community –Industry Partnerships

Equitable Breakthroughs in Medicine Development: Program overview

Overview: This is an 18-month initiative to help underrepresented patients be more involved in clinical research and new medical treatments. This effort seeks to connect diverse communities, patients, providers, health partners, community organizations, academic institutions, and clinical trial sponsors, to pilot a network of 10 sustainable, connected, community-based trial sites

- **Key goals over the 18-months:**
 - Showing **proof of concept** for a comprehensive, collaborative network of sustainable, connected, community-based sites supporting clinical trial diversity in underserved communities
 - Partnering with **trusted messengers and community leaders** to raise education, awareness and support for clinical trial participation
 - Providing the **resources and technical support** for local sites to be successful, sustainable, and thrive
 - Build **training opportunities and mentorship** for investigators and staff



**EQUITABLE
BREAKTHROUGHS
IN MEDICINE DEVELOPMENT™**

<https://medicine.yale.edu/ycci/researchspectrum/collab/equitable-breakthroughs-medicine-development/>

A few thoughts from our experiences relevant to the meeting goals... *Community engagement and bidirectional partnership has been key to our tremendous progress.*

- Knowledge alone is not power!
 - Long term investment on both sides in structure, organization, evaluation is required.
 - There should be active engagement around FDA regulations...lack of understanding of the meaning of the regulation can become an issue when building trust.
 - Important questions:
 - What do your partners get out of the relationship? How can it be bidirectional?
 - How do you activate community group partnerships?
 - What is the long-term commitment (***training has been key***)
 - The activities should include direct to patient education and awareness, which is age, linguistically, and culturally appropriate and tailored to the audience by method of communication.
- Decentralized trials have the potential to bring research closer to the community.
 - However patient burden must be considered; study task cannot just simply shift from the research site to the patient home.
 - Multiple technology solutions can add to participant burden, expense, and lack of satisfaction with the trial experience.
- Leveraging and partnering with FDA offices, universities/ health system, advocacy groups, and community group engagement programs can lead to better understanding of the meaning and purpose of research regulation, along with enhanced trust in the FDA review process with the potential for improvements in uptake post approval by all populations.



Additional Background Information



Yale Center for
Clinical Investigation

Partnering
with the
Cultural
Ambassadors

facebook Sign Up

Email or Phone Password Log In

The Tom Ficklin Show: Covid-19 Vaccines, Treatments and Research



7:05

.....Thank you for tuning into WNHH-LP 103.5FM/Facebook.com/NewHavenIndepe

The Tom Ficklin Show: Covid-19 Vaccines, Treatments and Research

New Haven Independent was live.
December 21, 2020 · 🌐

The Tom Ficklin Show: Covid-19 Vaccines, Treatments and Research
newhavenindependent.org

536 Views

4 Likes 4 Comments 12 Shares

December 21, 2020
COVID 19 - Vaccines,
Treatments, and Research

*Dr. Marcella Nunez-Smith,
Dr. Charles Dela Cruz, Tesheia
Harris, Reverend Perry, and
Reverend Clayton*

October 19, 2020
COVID 19 – Clinical Research

*Dr. Charles Dela Cruz, Tesheia
Harris, and Reverend Clayton*

facebook Sign Up

Email or Phone Password Log In

The Tom Ficklin Show | Covid Clinical Research



3:58

now? feel free to comment, and join in the fun..... Thank yo

The Tom Ficklin Show | Covid Clinical Research

New Haven Independent was live.
October 19, 2020 · 🌐

The Tom Ficklin Show | Covid Clinical Research
newhavenindependent.org

306 Views

3 Likes 1 Comment 10 Shares

Share

Tom Ficklin Radio Show partnership

Take ownership of your health...your life depends on it.

TAKE OWNERSHIP OF YOUR HEALTH...YOUR LIFE DEPENDS ON IT



The Tom Ficklin Radio Show, the Yale Center for Clinical Investigation (YCCI), and their AME Zion Church Cultural Ambassadors for Research at Yale, have launched a new partnership to raise awareness in the minority community on health promotion topics and how to access cutting-edge clinical research.

Topic: COVID Vaccine Hesitancy

with Dr. Brita Roy, Yale Medicine and Dr. Thomas Balcezak, YNH
MONDAY, MARCH 15, 2021 AT 11 AM, WNHH 103.5 FM

Dr. Roy and Dr. Balcezak will join the Cultural Ambassadors to speak about the impact of COVID19 in communities of color and the elderly. They will speak about testing, treatment, vaccine distribution efforts, and what they are doing to address vaccine hesitancy in our community.

Guest Speakers



Brita Roy, MD, MPH, MHS

Assistant Professor of Medicine (General Medicine) and Epidemiology (Chronic Diseases); Director of Population Health (Yale Medicine)



Thomas Balcezak, MD

Chief Clinical Officer and Executive Vice President, Yale New Haven Health

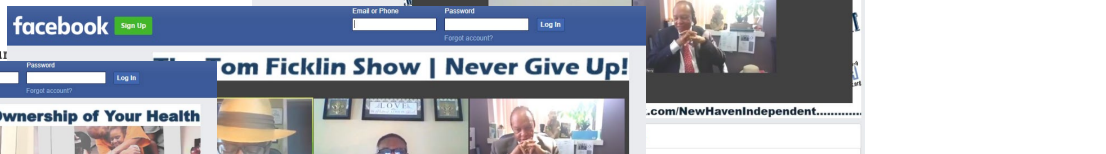
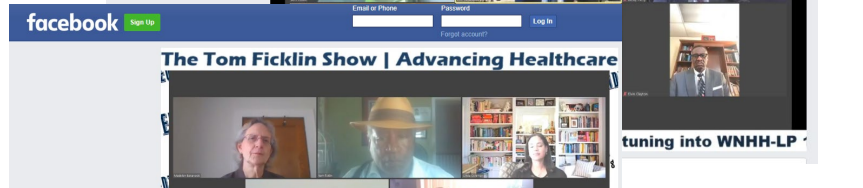


Reverend Elvin Clayton

Pastor, Walter's Memorial AME Zion Church



Sun Distr Conf



See a full listing of past shows:

<https://medicine.yale.edu/ycci/researchspectrum/cer/research/ambassadors/tfrs/>

January 2020 - March 2021

March 8th - [A Conversation with Dr. Darin Latimore](#) Deputy Dean and Chief Diversity Officer, Yale School of Medicine
 March 15th - [COVID Vaccine Hesitancy](#) Dr. Brita Roy, Dr. Thomas Balcezak, Reverend Clayton, and Sundae Black
 February 15th - [A Conversation with Dr. Keith Churchwell](#) With Reverend Perry and Reverend Clayton

August 2020 - December 2020

December 14th- [Fatherhood Initiative Program](#) With Dr. John Krystal, Hon. Michael L. Ferguson, Anthony Judkins, Reverend Perry, and Reverend Clayton
 December 21st - [COVID 19 - Vaccines, Treatments, and Research](#) With Dr. Marcella Nunez-Smith, Dr. Charles Dela Cruz, Reverend Perry, and Reverend Clayton
 November 9th - [Cancer Diagnoses and Screenings in Communities of Color](#) With Dr. Roy Herbst and Dr. Brita Roy
 November 2nd - [Taking Charge of Your Health](#)
 A Conversation with Dr. Nancy J. Brown, Dean, Yale School of Medicine With Reverend Perry and Reverend Clayton
 October 19th - [COVID Clinical Research at Yale with Dr. Charles Dela Cruz](#)
 September 21 - [Cardiovascular Health with Dr. Eric Valazquez](#)
 September 14 - [COVID Vaccine Questions Answered](#) with Leading Researcher, Dr. Onyema Ogbuagu, Yale With Dr. Onyema Ogbuagu, Reverend Perry, and Reverend Clayton
 August 24 - [Taking Charge of Your Health](#) with Dr. John Krystal, Reverend Perry, and Reverend Clayton
 August 10 - [Advancing Health Care through a Community and University Partnership in Research: The Role of the Yale HRPP and IRB](#)
 with Madelon V. Baranowski, Linda M. Coleman and Reverend Perry and Reverend Clayton
 August 3 - [Be Smart, Be Prepared, Be Proactive During this Global Crisis](#) with Dr. Marcella Nunez-Smith and Maurice Williams

January 2020 - July 2020

July 6 - [Community Engagement and Education for Pneumonia Prevention](#) with Yale Cultural Ambassadors
 June 15 - [Celebrating Men's Health Month](#) with Yale Cultural Ambassadors
 June 8 - [A Conversation with Yale's Dr Marcella Nunez-Smith](#)
 March 30 - [Take Ownership of Your Health During This Global Crisis](#) with Reverend Perry, Reverend Clayton and Sundae Black
 February 17 - [Tenth anniversary of the Yale Cultural Ambassadors Program and The Innovation and Diversity Summit at Yale](#)
 February 3 - [Health Disparities](#) with Reverend Perry, Reverend Clayton
 January 20 - [Prostate Cancer](#) with Daniel P. Petrylak, MD, Reverend Clayton, and Tesheia Johnson
 January 13 - [Importance of Diversity in Clinical Trials and AME Zion Initiatives](#) with Reverend Perry and Reverend Clayton

New Partnership Launched Yale and “*Tu Salud Tu Familia*” (Your Family Your Health)

Launched on last Saturday October 9, 2021, in the
Connecticut market

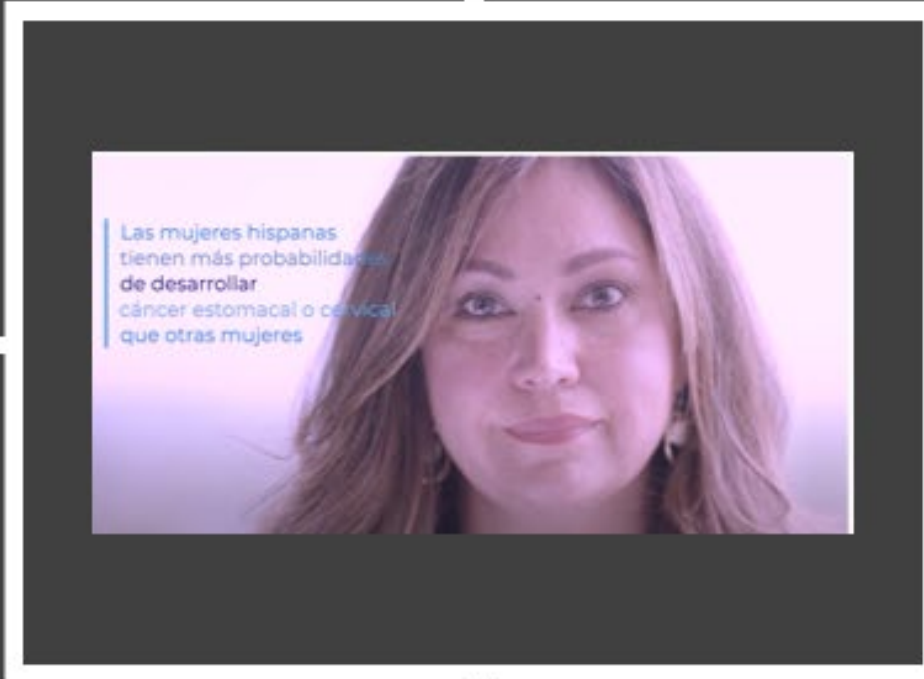


*The partnered show on bariatric surgery featuring Yale School of Medicine faculty Drs.
John Morton and Jorge Moreno received a 2022 Emmy*



Cirugía bariátrica - Tu Salud Tu Familia

<https://medicine.yale.edu/news-article/yale-weight-loss-program-goes-primetime-surgery/>



Young Ambassador



<https://www.youtube.com/watch?v=SQdz-jCZKh0>



Yale Center for
Clinical Investigation

Workforce Development: Clinical and Translational Research Internship

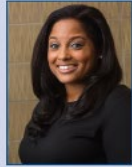
MEET OUR YCCI PAST INTERNS



Doug Streat, 2017 YCCI Intern

"Working at YCCI was one of the most formative parts of my public health training. It's not often that students get the chance to interact with senior leaders of large health organizations and directly influence the trajectory of those organizations, but YCCI gives its interns the chance to do just that. I learned skills and content in my work at YCCI that I still leverage every day in my work today."

Doug is currently vice president and chief of staff at Aledade, a 500-employee Series D primary care startup based in Bethesda, MD with operations in 30 states.



Latoya Howard, 2008 & 2009 Summer YCCI Intern

"The YCCI internship experience was instrumental in my career and I am forever grateful for the opportunity."

Latoya decided to stay at Yale in clinical research, has been promoted several times, and is current a Senior Regulatory Analyst with the Yale Human Research Protection Program.



Josh Tan, 2017 YCCI Intern

"My internship with YCCI was a highlight of my MPH program. The Center gave me the opportunity to lead my own project while providing extensive support for me to succeed. Not only did I have the opportunity to engage with senior leaders of a premier healthcare organization, but also contributed to a project that made transformative impacts to clinical trial operations going forward. This experience broadened my horizon on career options and taught me skills transferable to my future roles."

Josh is currently a strategy associate with Pfizer Inc.



Geisa Wilkins, 2020 YCCI Intern

"YCCI has given me numerous opportunities for hands-on experience. Working as a Clinical Research Intern gave me a preview into all the facets of research at YCCI. Working with the YCCI team was the best opportunity for my professional career, and it could be a great experience for you as well."

Geisa is one of the newest members of the YCCI clinical research team, recently accepted a position as a YCCI Recruitment Specialist.



Asia Brown, 2017 YCCI Intern

"I am thankful for the opportunities I had to weigh in on strategic insights, which has prepared me for the work I'm currently doing. The YCCI takes care of their interns to ensure you get the experience and exposure you desire!"

Asia is currently a nonprofit strategy consultant at Wellspring Consulting.



Cassandra Lincoln, 2017 YCCI Intern

"My internship experience with YCCI was a highlight of my time at Yale. It was exciting to learn from and work with senior leadership and faculty across the university and contribute meaningful work to cutting-edge clinical research. The program provided me not only with substantive knowledge about clinical trial operations and management, but also with a network of mentors invested in my professional growth. Over the course of the internship, I learned how to better communicate, drive to consensus, and present actionable recommendations."

Cassandra is currently a student at Stanford Law School, studying the intersection of healthcare and the law.

Results to date:

- ▶ 2009 - Launched an informal program
- ▶ 2016 - Clinical and Translational Research Internship
- ▶ 2021 - Expanded number of interns



- ▶ 2018 - Expanded to include a 4-week externship with the FDA Office of Minority Health and Health Equity

Results to date:

- ▶ To date we have been able to support a small number of interns. With expanded fund, we would build on our past success which includes **estimate ~57% minority, ~70% female; and 83% who are still engaged in research / health care / health management, with ~20% deciding to remain in research careers at Yale.**

HELP US DISCOVER | Be Part of Clinical Research at Yale.

Yale

<http://www.yale.edu/hronline/careers/application/external/index.html>

Collectively investing in the next generation:

YCCI Clinical and Translational Research Exposures Pilot Summer Internship Program



- ~1500 students from around the world, with just ten days to advertise
- More than 400 full applications, along with letters of recommendation for participation in the program
- *Interns, age 15-20, from ~20 different states, Canada, and Puerto Rico.*
- *~30-40% are minority, ~50% female; and 20% from rural areas with limited similar opportunities.*
- *Further for many of the students, this will be there first internship opportunity.*

Our diversity in clinical trials work highlighted by Merck, J&J, MRCT, and The Health Management Academy

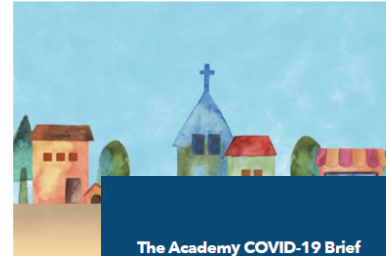
1. Improve Diversity in Clinical Trials. <https://mrctcenter.org/diversity-in-clinical-trials/>. Accessed 2020 October 15
2. Think Medium: Access to Clinical Research and an Approach to Advancing Health Equity https://www.youtube.com/watch?v=y_hsnrNmu8o December 30, 2020, episode 72, of the *Fireside Chat with Gary Bisbee* is entitled “[Yale Cultural Ambassador Program: Access to Clinical Research and an Approach to Advancing Health Equity.](https://www.firesidechatpodcast.com/)” (<https://www.firesidechatpodcast.com/>)
4. Increasing Diversity In Clinical Trials: The Critical Role Of Community Partnerships & Collaborations By Luther T. Clark, M.D., Madeline Geday, Adrelia Allen, Senaka Peter, Mary Elmer, Kelly Donlon Hoy, and Vivian Ogbonnaya, Merck & Co., Inc. **October 6, 2020** Accessed at <https://www.clinicalleader.com/doc/increasing-diversity-in-clinical-trials-the-critical-role-of-community-partnerships-collaborations-0001>
5. Ambassadors are also to be featured in an upcoming J&J publication



Increasing Diversity In Clinical Trials: The Critical Role Of Community Partnerships & Collaborations

By Luther T. Clark, M.D., Madeline Geday, Adrelia Allen, Senaka Peter, Mary Elmer, Kelly Donlon Hoy, and Vivian Ogbonnaya, Merck & Co., Inc.

Clinical trial results provide the critical evidence base for evaluating the safety and efficacy of new medicines and medical products. When the research study population reflects the characteristics of the population for whom treatment is intended, those individuals who subsequently use the medicines are better served and we advance better health outcomes. If clinical trial participants do not reflect the intended use population, results may be less informative and may not be generalizable.



The Academy COVID-19 Brief

Yale's Cultural Ambassador Program Bolsters Minority Participation in Clinical Trials

Yusuf Mirad, Director, Healthcare Programs
Brian Contas, General Manager

The Yale School of Medicine (YSM) and the Yale Center for Clinical Investigation (YCCI) have spearheaded innovative strategies to bolster minority participation in clinical trials, an issue that has handicapped providers' efforts to eliminate racial health disparities in the United States. Yale's Cultural Ambassador program and its investment in engagement tactics leveraging its electronic medical record are at the core of Yale's approach, driving growth of underrepresented minority (URM) participation in clinical research from 3% to 30% between 2010 and 2019. Today, their platform approach plays an integral role in COVID-19 vaccine trials. More broadly, Yale's experience provides a framework for systems eager to enhance health equity efforts beyond just clinical trial diversity – the Ambassador program is an invaluable resource for drafting communications on topics involving race; determining community-level needs regarding social determinants of health; evaluating optimal sites for research; and building sustainable models of trust to address the root causes of health disparities.

A Brief History of the Cultural Ambassadors Program

- ◆ In 2008, YCCI hosted focus groups with roughly 1,000 participants from diverse ethnic and socioeconomic backgrounds, with ages ranging from 19 to 81 years old. Participants were asked about medical treatments with which they were familiar, what they knew about how such treatments were developed and what would motivate them to participate in clinical trials. They were also asked to react to advertisements recruiting volunteers, and words used to describe clinical trials and participants. The focus group discussions revealed high levels of **mistrust** among minorities that posed a barrier to participation in clinical trials. Several factors contributed to this, including a lack of clinical research literacy, misinformation about the research process, rights of participants and the use of data. Researchers also identified specific barriers for different communities. In the minority specific focus groups, both **African American and Hispanic** individuals expressed a general distrust of the medical profession and views that clinical trials participation meant being a guinea pig.
 - For **Hispanic** individuals, many of whom have non-English speaking relatives, it was noted that there was a scarcity of recruitment materials in Spanish, and so these individuals also noted fear in the community that participating in clinical trials may threaten legal residency status.
 - For **African American** individuals, many raised the issues of past abuses (Tuskegee), as well as cultural barriers such as home remedies as better treatment options, and the view by some in the community that asking for help or seeking care for illness was a sign of weakness especially among some minority males.Both groups also expressed a desire to engage with physicians and staff members who represented their ethnicity.
- ◆ In 2010, YCCI met with **community leaders** from Junta, a Latino community-based non-profit in New Haven, and the African Methodist Episcopal Zion Church (AME Zion), one of the oldest African American congregations in the country. One year later, the Cultural Ambassadors Program was born.
- ◆ In 2011, Yale launched the “**Help Us Discover**” Initiative. This program centered around working directly with local faith and advocacy leaders in collaboration with Yale faculty to strategize around recruitment and increase access to Yale's clinical trials program.
- ◆ In March 2015, the “Help Us Discover” program was integrated with Yale's Epic electronic health record (EHR). To achieve direct-to-patient engagement using the EHR, Yale developed a research section in the MyChart patient portal. Through this portal, patients learn about research opportunities matched to their profile and can flag their interest in



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Yale Center for
Clinical Investigation

Our diversity in clinical trials work highlighted by PhRMA

<https://www2.deloitte.com/us/en/insights/industry/life-sciences/lack-of-diversity-clinical-trials.html>
11 November 2021



Enhancing clinical trial diversity

Stakeholder perspectives on advancing research through representative clinical trials

Enhancing clinical trial diversity

CASE STUDY

The Yale Center for Clinical Investigation (YCCI) created a cultural ambassador program comprising community-based partnerships with the African Methodist Episcopal Zion (AME Zion) Churches of Connecticut and several Hispanic or Latin leaders in the area including the Junta for Progressive Action. These relationships were formed after candid discussions regarding the need for more diverse participants and the benefit to both the individuals and the community.

Key features of cultural ambassadors include:

- Engaging in advocacy and education efforts in the community, driving awareness of the importance of clinical research;
- Serving as bidirectional partners appointed by community leaders;
- Focusing on building trust-based relationships, increasing health system engagement and contributing to improved overall health;
- Being committed to the organization, not to a specific trial and members train over 200 hours and community health care worker certification.

The cultural ambassadors meet monthly with clinical trial researchers who explain the research and are receptive to feedback from the ambassadors. Because these ambassadors are respected leaders in their communities, when they reach out to individuals who they think would be good candidates for a study, they have a higher rate of success in recruiting and retaining them in the study. The cultural ambassador program has enabled success over the past 10 plus years. In fiscal year 2020, the Yale School of Medicine sponsored more than 2,111 active trials, with approximately 27,800 participants, including approximately 31% underrepresented minorities. In some individual studies, with direct support of the cultural ambassador, underrepresented minorities represent more than 50% of total enrollment. Workshop participant Teshia Johnson, deputy director and chief operating officer of YCCI stated, "The cultural ambassador enabled us to be significantly successful in not only connecting with the needs of the community and understanding the priorities of the community and bringing that insight into our research and projects, but also helped us to think very sensitively about the cultural and language aspects of what we are doing in our research enterprise."

Source: The Deloitte Center for Health Solutions Industry stakeholder interview conducted in February 2021; PhRMA, "Partnering for health equity: Advancing research through representative clinical trials," June 8-9, 2021.

What's different about this effort?

**EQUITABLE
BREAKTHROUGHS**
IN MEDICINE DEVELOPMENT™



<https://phrma.org/Equity/clinical-trial-diversity>

- This is an industry-wide effort and initiative with patients, health care providers, communities, clinical trial sponsors, health systems, and academia.
- It has a specific focus on mentorship for staff at clinical trial sites, sustainable support for local community-based sites and partnership with communities of color that have historically been underrepresented.

*Our goal is to show proof of concept over an 18-month period for a **sustainable, community-based infrastructure** that tears down the systemic barriers underserved patients often face when it comes to clinical trials, and to address issues of mistrust head on.*

<https://medicine.yale.edu/ycci/researchspectrum/collab/equitable-breakthroughs-medicine-development/>

Questions



Yale Center for
Clinical Investigation