

Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM – 12noon ET



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

LEARNING IN: A WEBINAR SERIES

Disclaimer

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October 14, 2020	Community Awareness, Access, Knowledge
October 28, 2020	Workforce Development
November 11, 2020	Study Design, Eligibility, Site Selection & Feasibility
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January 13, 2021	Data Standards and Analysis
January 27, 2021	Stakeholder Roles and Responsibilities
February 10, 2021	Role of Data in Diversity: Genetics & Real World Data

COMMUNITY AWARENESS, ACCESS, KNOWLEDGE

October 14, 2020
11AM – 12noon ET

Tesheia Johnson, MBA, MHS

Associate Director for Clinical Research
Yale School of Medicine
Deputy Director and Chief Operating Officer
Yale Center for Clinical Investigation



Jessica S. Scott, MD, JD

Head of R&D Patient Engagement Office
Takeda Pharmaceutical Company



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Practical Approaches to improving Diversity in Clinical Trials

Agenda

- MRCT Center introduction
- Introduction to Achieving Diversity, Inclusion, Equity In Clinical Research Project
- Community Awareness, Access, and Knowledge as presented in the Guidance and Toolkit
- Presentations by:
 - Tesheia Johnson, MBA, MHS
 - Jessica Scott, M.D., J.D.



The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

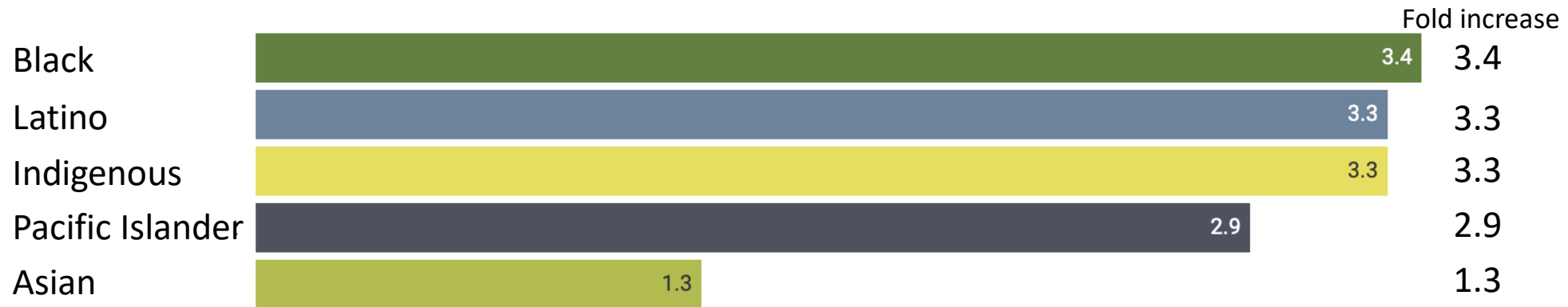
Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



Health disparities by race and ethnicity in the COVID-19 pandemic

Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites



<https://www.apmresearchlab.org/covid/deaths-by-race>

But are underrepresented in research



The NEW ENGLAND
JOURNAL of MEDICINE

Perspective
AUGUST 27, 2020

Racial Disproportionality in Covid Clinical Trials

Daniel B. Chastain, Pharm.D., Sharmon P. Osae, Pharm.D., Andrés F. Henao-Martínez, M.D., Carlos Franco-Paredes, M.D., M.P.H., Joanna S. Chastain, Pharm.D., and Henry N. Young, Ph.D.

News & Analysis

Medical News & Perspectives

Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials

Mary Chris Jaklevic, MSJ

<https://jamanetwork.com/journals/jama/fullarticle/2769611>





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ACHIEVING DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

Guidance Document

Barbara E. Bierer, MD
Sarah A. White, MPH
Laura G. Meloney, MPH, MS
Hayat R. Ahmed, MS
David H. Strauss, MD
Luther T. Clark, MD



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ACHIEVING DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

Toolkit

Barbara E. Bierer, MD
Sarah A. White, MPH
Laura G. Meloney, MPH, MS
Hayat R. Ahmed, MS
David H. Strauss, MD
Luther T. Clark, MD

Achieving Diversity, Inclusion,
Equity In Clinical Research

Guidance and Toolkit

mrctcenter.org/diversity-in-clinical-trials

Released 6 August 2020



Leadership

- RADM Richardae Araujo, PharmD, MS, U.S. FDA
- Barbara E. Bierer, MD, MRCT Center
- Luther T. Clark, MD, Merck & Co., Inc.
- Milena Lolic, MD, U.S. FDA
- David H. Strauss, MD, Columbia University
- Sarah White, MPH, MRCT Center

MRCT Center staff:

- Carmen Aldinger, PhD, MPH
- Hayat Ahmed, MS
- Laura Meloney, MS, MPH
- Joshua Smith-Sreen, MBE

And the invaluable contributions of >50 workgroup members, representing:

- Patients, Patient Advocates
- Academia
- Pharmaceutical companies
- CROs
- Non-profit organizations
- Trade associations
- Government agencies
- Research institutes

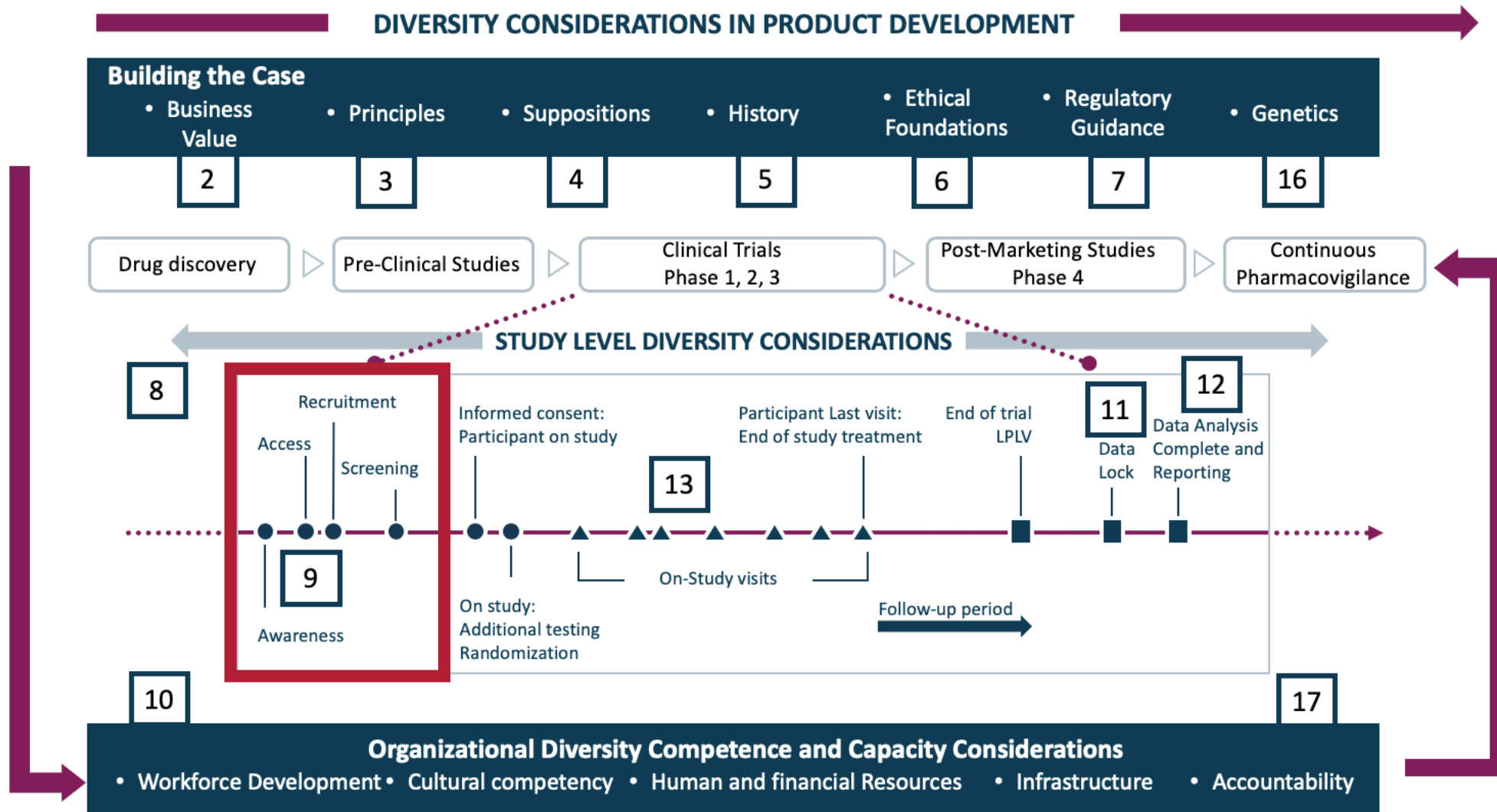
Each serving in their individual capacity.

- Multi-stakeholder contributions and consensus
- Practical and actionable recommendations
- Accountability section considers how each stakeholder can change the paradigm
- Toolkit provides adaptable resources not easily found elsewhere



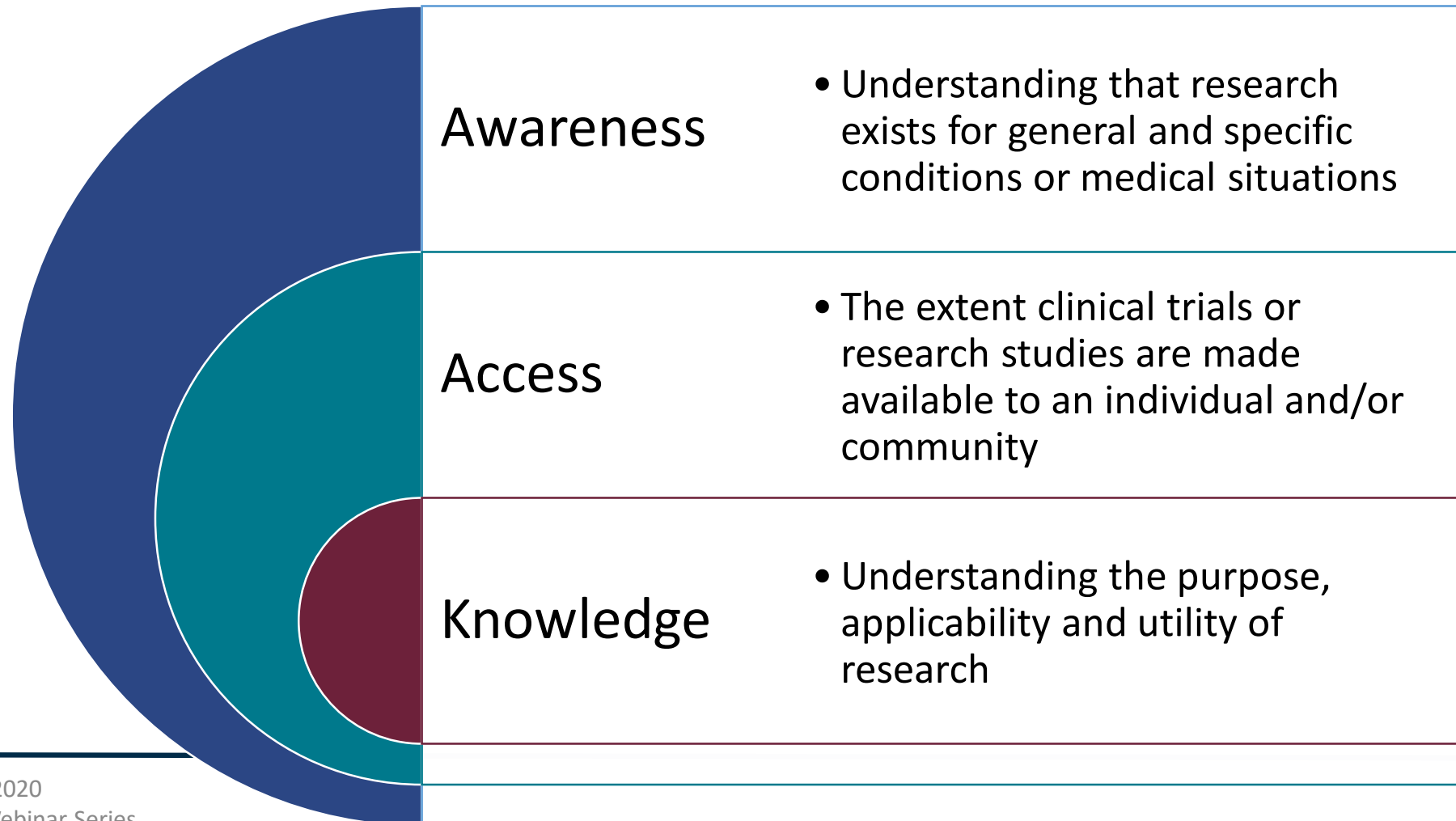
mrctcenter.org/diversity-in-clinical-trials

Focusing on Community Awareness, Access, Knowledge



Willingness

Willingness to participate in clinical research depends upon three intersecting elements that impact the researcher, participant and the community:



Individuals must be invited



Patient and community engagement support diverse participation

Forming Relationships

The patient and community to be in key leadership roles, as advisors, and as consultants

Training and Support

Patient perspective to influence research priorities and questions

Shared Goals

Seek input to tailor study design and conduct to improve access, enrollment, and retention

Sustained partnerships



Community collaboration

Engagement Strategies

- Engage minority healthcare physicians and staff
- Engage those who are self-identified with the community at issue, including minority PIs and study staff
- Attend community events
- Establish a presence at community centers and clinics by offering free health screenings

Diverse Participant Engagement Strategies

A checklist for sponsors, CROs and investigators on the four stages of clinical research

Priority setting

- ☐ Build relationships with communities of potential participants
- ☐ Ensure essential research questions are relevant to target population
- ☐ Ensure outcomes are relevant and meaningful to target population
- ☐ Incorporate participant voice in study decision-making

Study design

- ☐ Incorporate novel study designs that support diverse enrollment
- ☐ Implement review processes for informed consent and outcome measures
- ☐ Utilize social networks to aid in study recruitment

Conduct

- ☐ Create understandable, health literate study materials in languages relevant to target population
- ☐ Nurture patient and researcher/study team relationship

Dissemination

- ☐ Create understandable, health literate dissemination materials in languages relevant to target population
- ☐ Interpret study results for patients from diverse backgrounds
- ☐ Prioritize outreach to additional audiences
- ☐ Share results widely, considering all types of media outlets



Engagement strategies across different stages of research

Awareness Raising Initiatives to Promote Diverse Participant Engagement: a model checklist for implementers

Build community and local partnerships

- ☐ Reach out to local institutions, groups, community leaders, clinics and clinicians
- ☐ Create community advisory boards to inform research design and outcomes
- ☐ Hire and train community members as staff
- ☐ Attend and integrate into community events, when possible

Provide educational activities

- ☐ Host a luncheon, health fair or expo for the community or hospital
- ☐ Provide on-site educational programs and print materials

Advertising strategies

- ☐ Create understandable, health literate study materials in languages relevant to target population
- ☐ Place study adverts in locations frequented by the target study population
- ☐ Consider all places media outlets: radio, TV, internet and social media

Integrate research into everyday life

- ☐ Consider decentralizing the trial to ease direct participation requirements
- ☐ Provide necessary provisions to encourage participation (i.e., transport or refunds) and reduce burdens
- ☐ Maintain a consistent presence in the community or with the target population

Recommendations for stakeholders

For Sponsors, Investigators, Providers and Healthcare Institutions

- Establish community presence
- Commit to long-term partnerships with local trusted organizations to sustain connectivity with the community
- Appreciate the value of community insight
- Develop educational programs/resources to support research literacy and address knowledge/awareness gaps
- Educate community members broadly on clinical research and for specific trials (prior to recruitment)
- Consider dedicated recruitment coordinators for research sites able to travel to public locations (e.g., health fairs, free clinics)
- Consider financial needs of the community partner, and the participant (e.g. reimbursement, compensation) and include these needs in grant funding applications and budgets as necessary
- Treat community engagement as bi-directional: sponsors, investigators, and research study teams should not “visit” a community with an “ask” without expecting to be responsive, and potentially give of themselves, in return

Recommendations for stakeholders

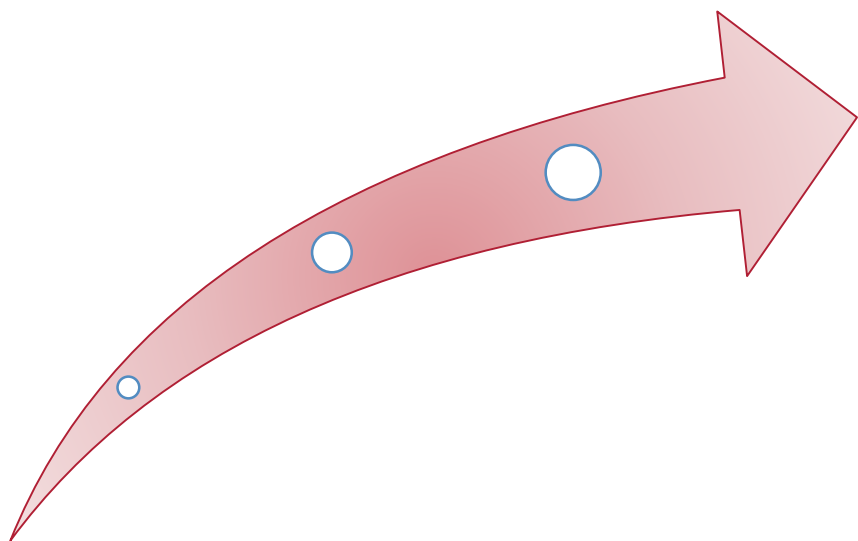
For Patients, Community Organizations, and the Public

- Help patients, potential participants, and the public become aware of clinical research
- Advise others that the current lack of diversity in clinical trials can limit clinical decision making – i.e., “if patients like us are not in clinical trials, we have no data on how these drugs or devices will work for us and our family, and this limits our ability – and our clinicians’ – to make decisions.”
- Increase the involvement of patient advocacy organizations in promoting diverse inclusion of participants in clinical research and providing awareness materials for the public regarding the benefit of clinical research.

Key Performance Indicators

The importance of metrics

Progress takes time



Participant & Community Engagement – Potential Key Performance Indicators (KPIs)

Output indicators

- ☐ Process established for target subpopulation(s) to voice inclusion during trial design
- ☐ Number of partnerships established with patient advocacy and community organizations relevant to target subpopulation(s)
- ☐ Number of in-person meetings held with patients of target subpopulation(s) to guide study design and recruitment planning
- ☐ Proportion of participant-facing materials reviewed by patients and advocates of target subpopulation(s)
- ☐ Proportion of clinical trials with patient feedback processes at the end-of-study with patients of target subpopulation(s)
- ☐ Community advisory boards established for target subpopulation(s)

Outcome indicators

- ☐ Adjustment to study protocol and/or recruitment materials made based on target subpopulation(s) engagement activities
- ☐ Target subpopulation(s) input represented at annual review
- ☐ Proportion of subpopulation(s) relationship sustained across more than one trial

Today's speakers



Tesheia Johnson, MBA, MHS

Associate Director for Clinical Research, Yale School of Medicine

Deputy Director and Chief Operating Officer, Yale Center for Clinical Investigation

Diversity Leaning In - Community and Participant Engagement

The Yale Model: *Leveraging the EHR, Research Systems, Community Partnerships, and Centralization to Promote Diversity in Clinical Trials*

Tesheia Harris, MBA, MHS (formerly Johnson)

Chief Operating Officer and Deputy Director , Yale Center for Clinical Investigations
Director of Clinical Research , Yale University School of Medicine

October 14, 2020

Clinical Footprint = EHR Footprint



Yale
NewHaven
Health
Greenwich
Hospital



Yale
NewHaven
Health
Bridgeport
Hospital



YaleNewHaven**Health**
Yale New Haven Hospital
Yale New Haven
Children's Hospital Smilow Cancer
Hospital



Yale
NewHaven
Health
Lawrence + Memorial
Hospital



Yale
NewHaven
Health
Westerly Hospital



Yale
NewHaven
Health
Northeast
Medical Group



Yale Medicine



Yale Health Center



+ Community
Connect

By the Numbers at a Glance (FY 2018)

\$5.5B
revenue*

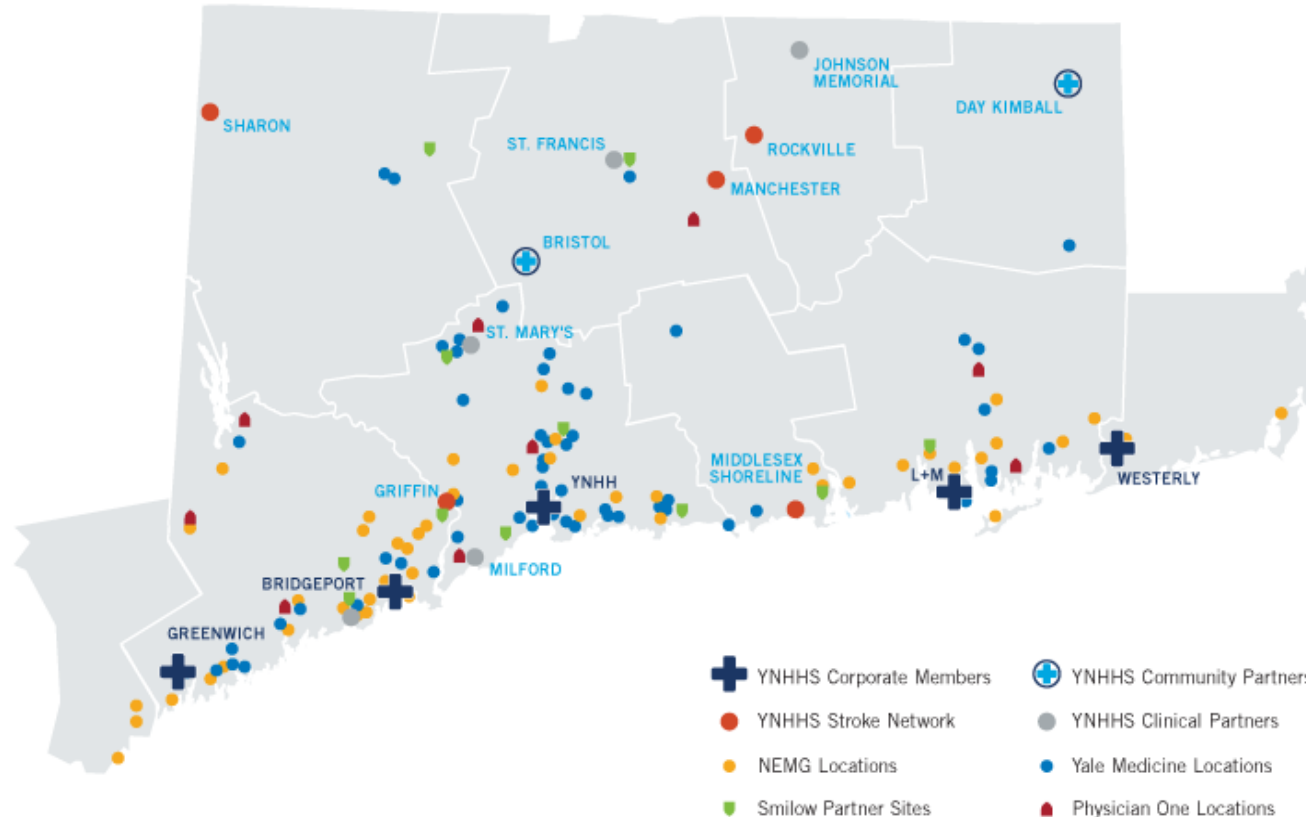
2,563
beds

271
care sites

6
hospital
campuses

8,113
medical staff

25,800
employees



462,998
ED visits

182,655
inpatient admits

2.4M
ambulatory encou

1,997 active
research studies
~5,000 IRB protoc

~\$387M
NIH grants

\$790M total
research funding



HIMSS Analytics

STAGE
7

CHIME
HealthCare's
**most
wired**

**BEST
HOSPITALS**
U.S. News
2018-19

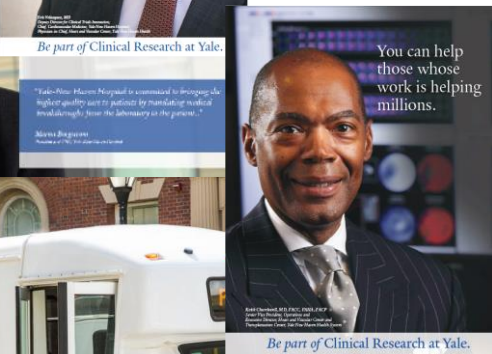
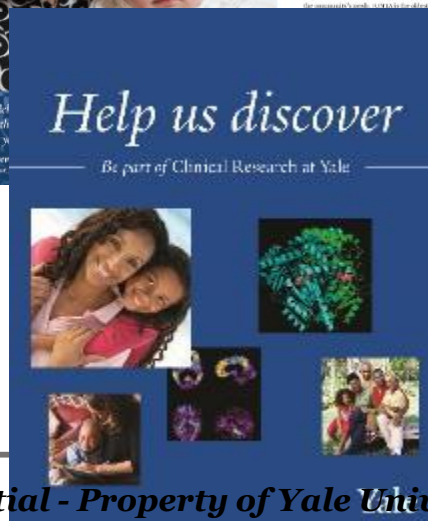
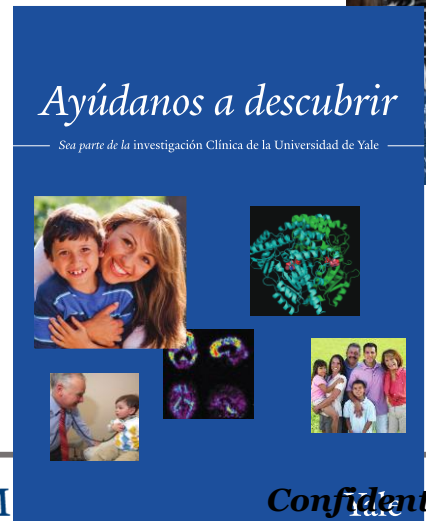
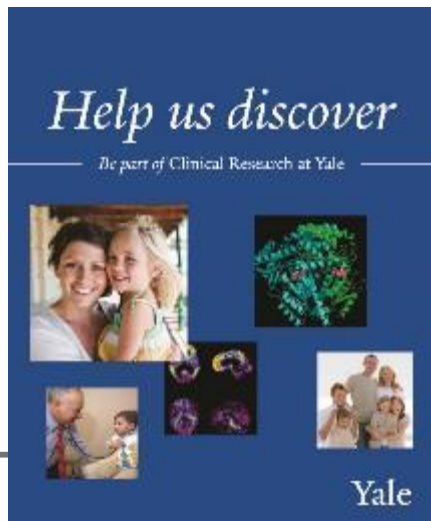
*Also includes Yale Medicine

Current Clinical/EHR Footprint = Clinical Research “Lab”

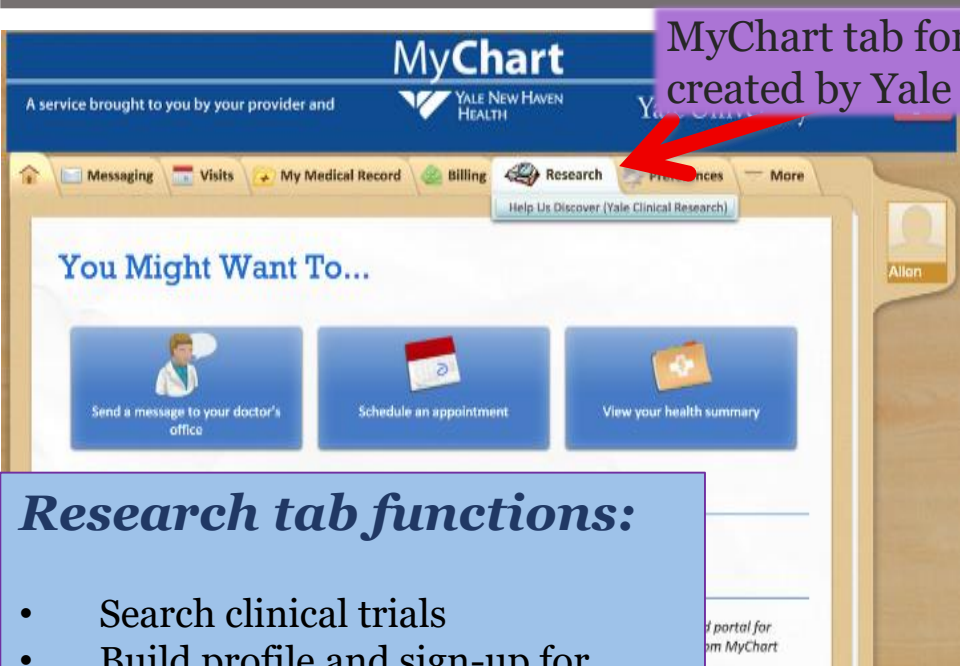
Critical Indicators	Yale-New Haven	Bridgeport	Greenwich	L&M	Westerly	Northeast Medical	TOTAL
Licensed Beds	1,569	383	206	280	125	N/A	2,563
Inpatient Discharges	78,529	18,208	12,538	13,808	3,632	N/A	126,715
Outpatient Encounters	1,187,405	277,043	289,860	430,988	114,395	402,000	2,692,691
Emergency Dept Visits	223,987	102,624	38,828	79,001	18,558	N/A	462,998
Net Patient Service Rev.	\$2.4B	\$439M	\$349M	\$314M	\$63M	\$123M	\$ 3.7B
Medical Staff	4,080	1,150	601	493	101	660	7,085
Employees	12,428	2,619	1,636	2350	612	1,050	20,692

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
- ▶ **NEW** Integrate community practices
- ▶ **NEW** Epic telehealth engagement



Leveraging MyChart Patient Portal for Research and Direct to Patient Messaging



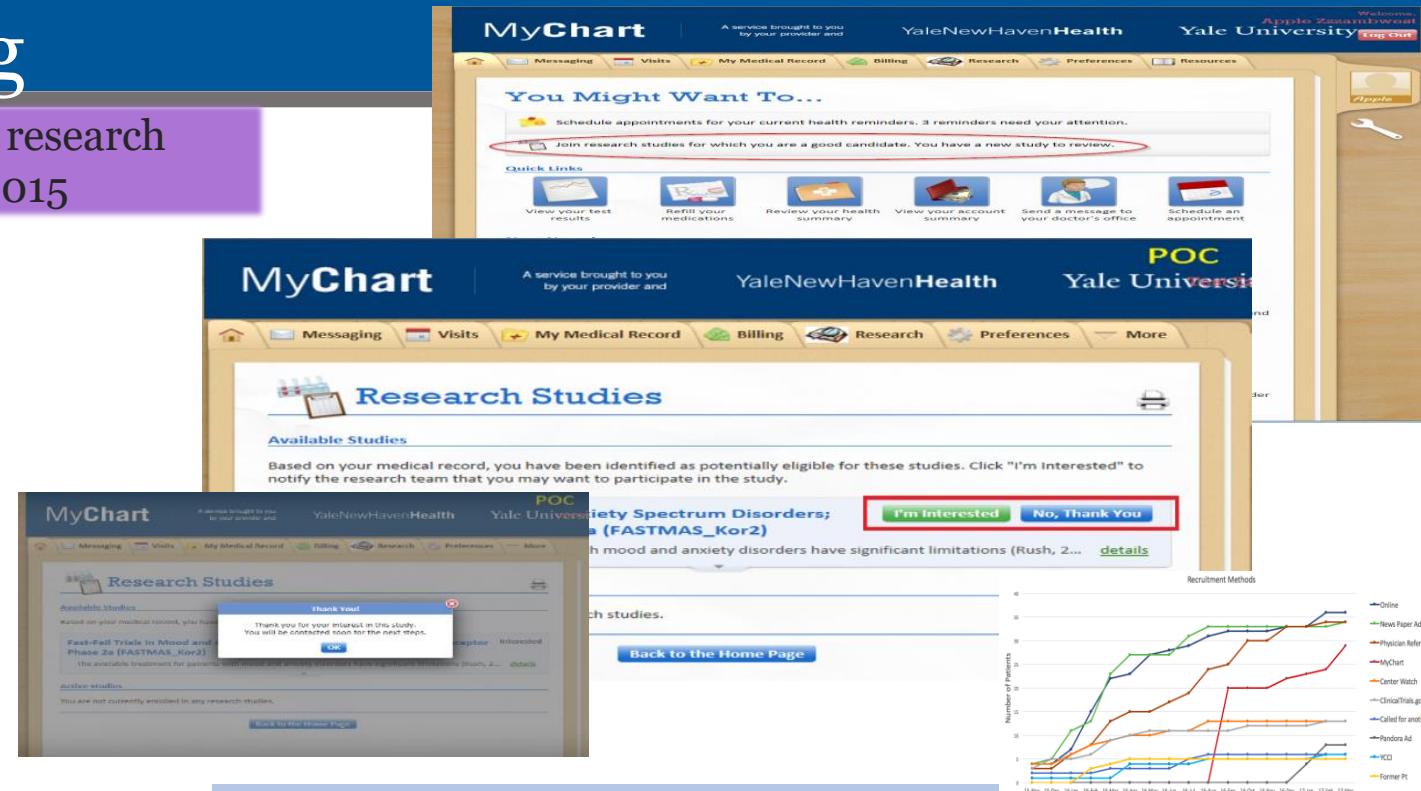
MyChart tab for clinical research created by Yale March 2015

Research tab functions:

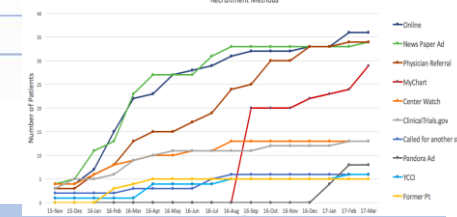
- Search clinical trials
- Build profile and sign-up for trials
- Opt Out of research

More than 5,000 recruited with no advertisement, twice the number recruited through traditional ads

Only **481** opt outs since March 2015



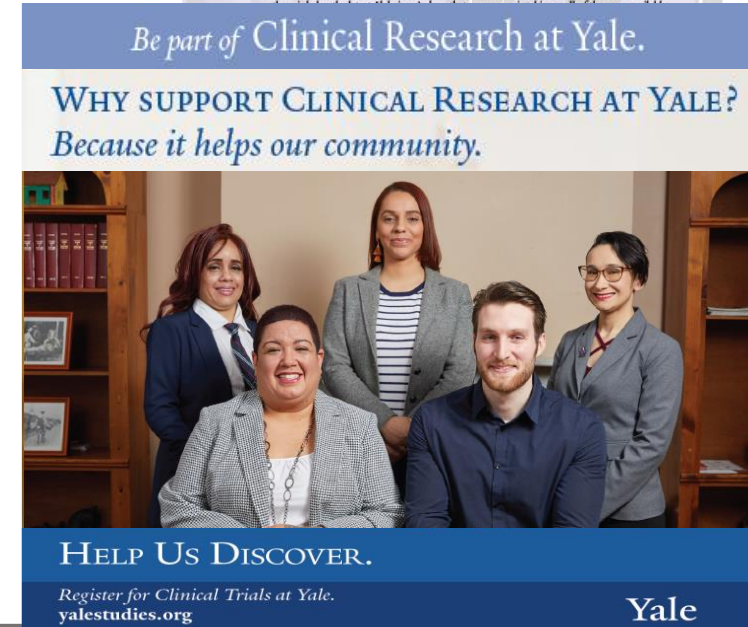
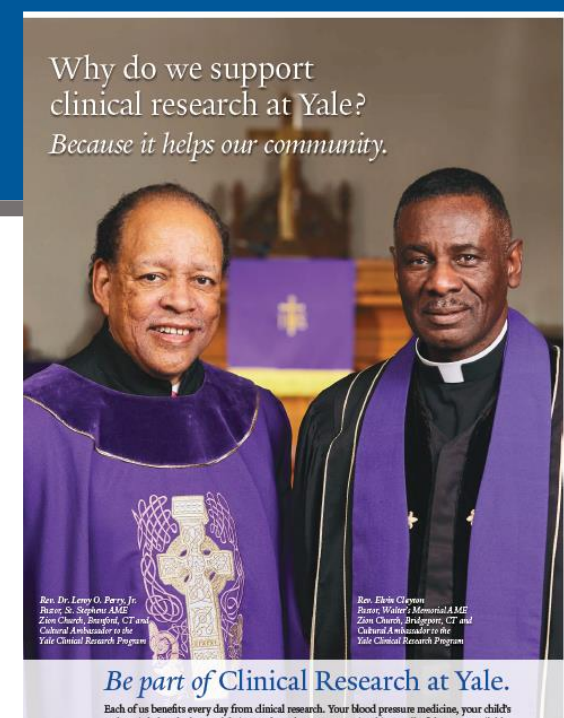
- Over 1000 consenting to studies
- Halo Effect: ~700 interested “failed” screening, ultimately enrolled in other studies



Leveraging Engagement: Innovation in recruitment of diverse patient populations

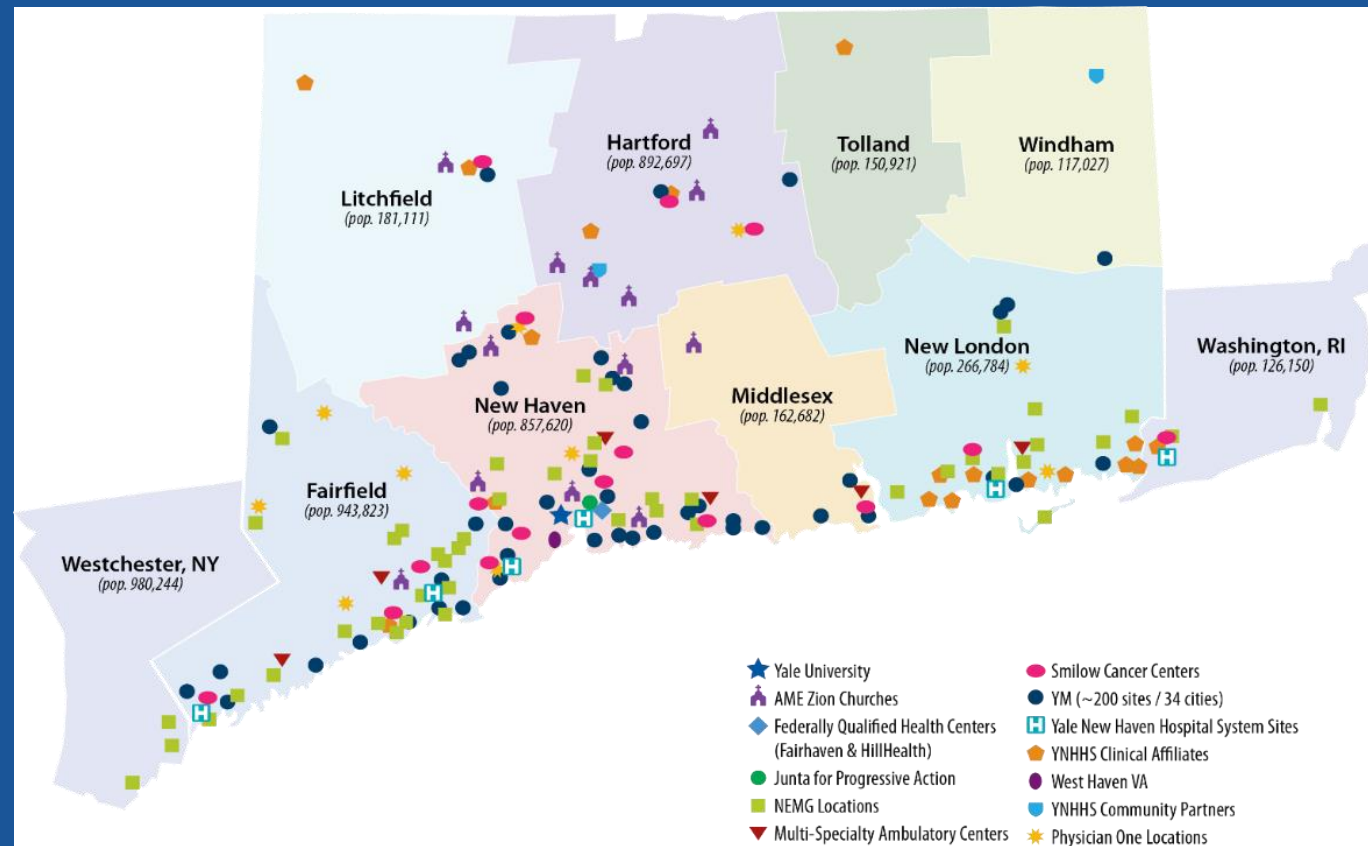
Cultural Ambassador program role includes:

- ✓ Bidirectional collaboration, with community setting priorities
- ✓ Express community needs, ideas, and interest
- ✓ Recruitment campaign development advice
- ✓ Recruitment plan development
- ✓ Recruitment support for special populations
- ✓ Study design support
- ✓ Translations of study material and informed consent
- ✓ Community Grand Rounds held monthly



Clinical Research Growth

8% of new patients
come to Yale
initially for
RESEARCH



In FY20, more than 30% of all accrual across
Yale studies was historically underrepresented
populations

Our Partnerships

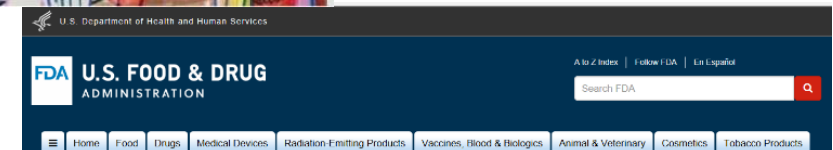
FDA Office of Minority Health Equity and Yale University



<https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/ucm603678.htm>



1. Collaborations to cultivate and advance **the Yale Cultural Ambassadors Program** and the engagement of community partners to increase participation of diverse and historically under represented or underserved populations in clinical research.



About FDA
Home > About FDA > Partnerships: Enhancing Science Through Collaborations With FDA > Memoranda of Understanding (MOUs) > Academia MOUs

MOU 225-18-015

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Memorandum of Understanding Between U.S. Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, Office of Minority Health; and Yale University

I. Purpose

The United States Food and Drug Administration (FDA) and Yale University (New Haven, Connecticut), share interests in promoting scientific progress through exchange of scientific capital in public health, epidemiology and research. Both institutions foresee benefits from scientific training for community members, patient communities, health care providers, academicians, and students to foster a well-grounded foundation in interdisciplinary science on which scientific learning can grow. This Memorandum of Understanding (MOU) forms the basis for the initial relations between FDA and Yale University (Yale) to promote shared interests in various science-based academic initiatives, fellowships, internships, sabbaticals, research and scientific education.

Today's speakers



Jessica Scott, M.D., J.D.
Head of R&D Patient Engagement,
Takeda



Patient and Community Engagement



October 14th, 2020

Jessica Scott, MD, JD

Head of R&D Patient Engagement

Takeda

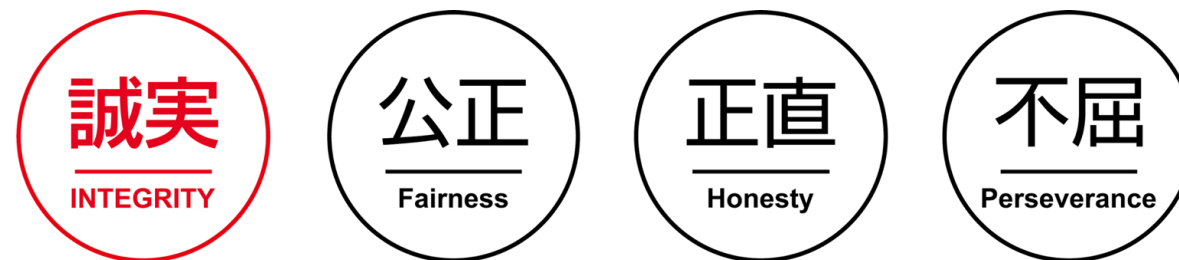
Corporate Philosophy



Since our founding in 1781, our integrity-centered values have guided us in everything we do.

Takeda-ism continues to guide us in our pursuit of better health for people worldwide.

VALUES TAKEDA-ISM



OUR PRIORITIES

We take action and make decisions by focusing on our four priorities, in order of:

- 1
Putting the patient at the center
- 2
Building trust with society
- 3
Reinforcing our reputation
- 4
Developing the business

A photograph showing a person in a pink hoodie hugging a person in a blue jacket from behind. The person in the pink hoodie is wearing a watch and has their arms around the person in the blue jacket. A black Canon camera is visible in the bottom left corner. The text "What does this mean in practice?" is overlaid in the center of the image.

What does this mean in practice?

Changing Mindset through KPI Evolution



Moving from
Developing medicines
for patients to
developing medicines
with patients

Patient Engagement Plan

A proactive road map for
how and when the
patient/community
perspective

will be incorporated into
development of a new
medicine



Our Goals

Patient Centric
Culture

All R&D Employees complete
Patient-themed Activities (FY18)

All Program Teams must have
Patient Engagement Activities (FY19)
Patient Engagement Plans* (FY20)

Patient Engagement and Diversity



How we partner is critical to our mutual success

- Deep listening through 2-way dialogue
- Shows respect, affirms dignity
- Encourages people to share what is truly important to them
- Helps us navigate toward developing more medicines of value



Health equity issues lead to diversity challenges in trials



- Strengthening communities and building capacity
- Deep listening and partnership in communities
- Capability building helps build trust
- Demonstrate commitment

A close-up photograph of two hands, palms up, holding a large number of small, bright, glowing white particles. The background is dark with a bright, radial sunburst effect emanating from behind the hands, creating a warm, golden glow. The text "Thank you" is centered over the image in a red, sans-serif font.

Thank you

Jessica Scott, MD, JD
Head of R&D Patient Engagement

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Discussion and Questions

Join us:



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