Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays 11AM - 12noon ET

LEANING IN: A WEBINAR SERIES
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The MRCT Center is supported by voluntary contributions (www.MRCTCenter.org) and grants.
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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
December 9, 2020  Study Conduct (Recruitment, Retention)
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

LEANING IN: A WEBINAR SERIES
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.
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

<table>
<thead>
<tr>
<th>Race/Community</th>
<th>Fold Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>3.4</td>
</tr>
<tr>
<td>Latino</td>
<td>3.3</td>
</tr>
<tr>
<td>Indigenous</td>
<td>3.3</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>2.9</td>
</tr>
<tr>
<td>Asian</td>
<td>1.3</td>
</tr>
</tbody>
</table>

But are underrepresented in research

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.

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

Leaning In Webinar Series

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Achieving Diversity, Inclusion, and Equity in Clinical Research

Guidance and Toolkit

mrctcenter.org/diversity-in-clinical-trials

Released 6 August 2020

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
Leadership

• RADM Richardae Araojo, 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

DIVERSITY CONSIDERATIONS IN PRODUCT DEVELOPMENT

Building the Case
- Business Value
- Principles
- Suppositions
- History
- Ethical Foundations
- Regulatory Guidance
- Genetics

Drug discovery → Pre-Clinical Studies → Clinical Trials Phase 1, 2, 3 → Post-Marketing Studies Phase 4 → Continuous Pharmacovigilance

STUDY LEVEL DIVERSITY CONSIDERATIONS

Organizational Diversity Competence and Capacity Considerations
- Workforce Development
- Cultural competency
- Human and financial Resources
- Infrastructure
- Accountability

Recruitment
Access
Screening
Awareness
Informed consent: Participant on study
Participant Last visit: End of study treatment
End of trial LPLV
Data Analysis Complete and Reporting
Follow-up period
On-study visits
On-study: Additional testing
Randomization

14 October 2020
Leaning In Webinar Series
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Willingness to participate in clinical research depends upon three intersecting elements that impact the researcher, participant and the community:

**Awareness**
- Understanding that research exists for general and specific conditions or medical situations

**Access**
- The extent clinical trials or research studies are made available to an individual and/or community

**Knowledge**
- Understanding the purpose, applicability and utility of research
Individuals must be invited

WHO ME!? I THOUGHT YOU'D NEVER ASK.
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

<table>
<thead>
<tr>
<th>Diverse Participant Engagement Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>A checklist for sponsors, CROs and investigators on the four stages of clinical research</td>
</tr>
</tbody>
</table>

#### 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

<table>
<thead>
<tr>
<th>Build community and local partnerships</th>
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<tbody>
<tr>
<td>- Reach out to local institutions, groups, community leaders, clinics and clinicians</td>
</tr>
<tr>
<td>- Create community advisory boards to inform research design and outcomes</td>
</tr>
<tr>
<td>- Hire and train community members as staff</td>
</tr>
<tr>
<td>- Attend and integrate into community events, when possible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Provide educational activities</th>
</tr>
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<tbody>
<tr>
<td>- Host a luncheon, health fair or expo for the community or hospital</td>
</tr>
<tr>
<td>- Provide on-site educational programs and print materials</td>
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<table>
<thead>
<tr>
<th>Advertising strategies</th>
</tr>
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<tbody>
<tr>
<td>- Create understandable, health literate study materials in languages relevant to target population</td>
</tr>
<tr>
<td>- Place study adverts in locations frequented by the target study population</td>
</tr>
<tr>
<td>- Consider all places media outlets: radio, TV, internet and social media</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Integrate research into everyday life</th>
</tr>
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<tbody>
<tr>
<td>- Consider decentralizing the trial to ease direct participation requirements</td>
</tr>
<tr>
<td>- Provide necessary provisions to encourage participation (i.e., transport or refunds) and reduce burdens</td>
</tr>
<tr>
<td>- Maintain a consistent presence in the community or with the target population</td>
</tr>
</tbody>
</table>
### 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

<table>
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<tr>
<th>Participant &amp; Community Engagement – Potential Key Performance Indicators (KPIs)</th>
</tr>
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<tbody>
<tr>
<td><strong>Output indicators</strong></td>
</tr>
<tr>
<td>- Process established for target subpopulation(s) to voice inclusion during trial design</td>
</tr>
<tr>
<td>- Number of partnerships established with patient advocacy and community organizations relevant to target subpopulation(s)</td>
</tr>
<tr>
<td>- Number of in-person meetings held with patients of target subpopulation(s) to guide study design and recruitment planning</td>
</tr>
<tr>
<td>- Proportion of participant-facing materials reviewed by patients and advocates of target subpopulation(s)</td>
</tr>
<tr>
<td>- Proportion of clinical trials with patient feedback processes at the end-of-study with patients of target subpopulation(s)</td>
</tr>
<tr>
<td>- Community advisory boards established for target subpopulation(s)</td>
</tr>
<tr>
<td><strong>Outcome indicators</strong></td>
</tr>
<tr>
<td>- Adjustment to study protocol and/or recruitment materials made based on target subpopulation(s) engagement activities</td>
</tr>
<tr>
<td>- Target subpopulation(s) input represented at annual review</td>
</tr>
<tr>
<td>- Proportion of subpopulation(s) relationship sustained across more than one trial</td>
</tr>
</tbody>
</table>
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 New Haven Health
- Greenwich Hospital
- Bridgeport Hospital

Yale New Haven Health
- Yale New Haven Hospital
- Smilow Cancer Hospital

Yale New Haven Health
- Yale New Haven Children's Hospital
- Lawrence + Memorial Hospital

Yale New Haven Health
- Westerly Hospital

Yale Medicine

Yale Health Center

Fair Haven Community 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 encounters  
1,997 active research studies  
~5,000 IRB protocols  
~$387M NIH grants  
$790M total research funding

*Also includes Yale Medicine
Current Clinical/EHR Footprint = Clinical Research “Lab”

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

Confidential - Property of Yale University School of Medicine - Reuse not permitted
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
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.
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
What does this mean in practice?
Changing Mindset through KPI Evolution

Moving from Developing medicines for patients to developing medicines with patients

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 Plan
A proactive road map for how and when the patient/community perspective will be incorporated into development of a new medicine
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
Community Engagement for Greater Diversity

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
Thank you

Jessica Scott, MD, JD
Head of R&D Patient Engagement
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REGISTER
Discussion and Questions