Moderator:

• Kristin West, Director, Research Ethics & Compliance, COGR

Panelists:

• Milena Lolic, MD, MS
  Office of Chief Scientist
  Office of the Commissioner, FDA

• Robert Fullilove, EdD
  Associate Dean for Community & Minority Affairs
  Professor of Clinical Sociomedical Sciences
  Co-Director, Cities Research Group
  Columbia University

• Efren Flores, MD
  Assistant Professor of Radiology, Harvard Medical School
  Officer, Radiology Community Health & Equity
  Radiologist, Thoracic & Emergency Divisions
  Faculty, The Mongan Institute
  Massachusetts General Hospital

• Martha Jones, MA, CIP
  Vice President, Human Research Affairs
  Mass General Brigham

• Megan Kasimatis Singleton, JD, MBE, CIP
  Associate Dean, Human Research Protections and
  Director of the Human Research Protections Program
  Johns Hopkins University School of Medicine
Advancing Trials Diversity Through Data Transparency

Milena Lolic, M.D., M.S.
OCS-FDA

Council on Governmental Relations Virtual Meeting
February 24, 2021
Disclaimer

• This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA

• No conflicts of interest to declare
Judging the Trial Data

- Rare disease
- ?
- Screen failure rates
- Barriers
- Drop-out rates
- Limited subpopulation conclusions
Guidance Documents for Industry
Drug Trials Snapshots
Transparency effort since 2015

• Web-based information about participation in clinical trials that supported the FDA approval of new drugs*
• Includes trial design, overall and subgroup assessments of safety and efficacy
• Dual format (for consumers and professionals)

*New Molecular Entities and original Biologic Licensing Applications
<table>
<thead>
<tr>
<th>Drug Trials Snapshot</th>
<th>Active Ingredient</th>
<th>Date of FDA Approval</th>
<th>What is it Approved For</th>
<th>Prescribing Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCRUFER</td>
<td>ferric maltol</td>
<td>July 25, 2019</td>
<td>Treatment of low iron stores</td>
<td>Accrufer</td>
</tr>
<tr>
<td>ADAKVEO</td>
<td>crizantuzumab-tmza</td>
<td>November 15, 2019</td>
<td>Treatment of vasculitis crises in patients with sickle cell disease.</td>
<td>Adaakveo</td>
</tr>
<tr>
<td>ADDYI</td>
<td>flibanserin</td>
<td>August 18, 2015</td>
<td>Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women</td>
<td>Addyi</td>
</tr>
<tr>
<td>ADLYXIN</td>
<td>lixisenatide</td>
<td>July 27, 2016</td>
<td>Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise</td>
<td>Adlyxin</td>
</tr>
<tr>
<td>AEMCOLO</td>
<td>rifaximin</td>
<td>November 16, 2018</td>
<td>Treatment of traveler's diarrhea in adults</td>
<td>Aemcollo</td>
</tr>
<tr>
<td>ALMOVIC</td>
<td>erenumab-aooe</td>
<td>May 17, 2018</td>
<td>Preventive treatment of migraine in adults</td>
<td>Almovig</td>
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<tr>
<td>AJOVY</td>
<td>fremanezumab-vfm</td>
<td>September 14, 2018</td>
<td>Preventive treatment of migraine in adults</td>
<td>Ajovy</td>
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<tr>
<td>AKLIEF</td>
<td>trifarolene</td>
<td>October 4, 2019</td>
<td>For the topical treatment of acne vulgaris in patients 9 years of age and older</td>
<td>Aklief</td>
</tr>
<tr>
<td>AKYNEO</td>
<td>fosnetpitant and palonosetron</td>
<td>April 19, 2018</td>
<td>Prevention of the nausea and vomiting that happens right away or later in adults receiving certain antinecancer medicines (chemotherapy)</td>
<td>Akynezo</td>
</tr>
<tr>
<td>ALECENSA</td>
<td>Alecitinl</td>
<td>December 11, 2015</td>
<td>Treatment of metastatic non-small cell lung cancer</td>
<td>Alectensa</td>
</tr>
</tbody>
</table>
# DTS Summary 2015-2020

<table>
<thead>
<tr>
<th></th>
<th>WOMEN</th>
<th>WHITE</th>
<th>ASIAN</th>
<th>BLACK or AA</th>
<th>HISPANIC</th>
<th>AGE 65 and OLDER</th>
<th>USA</th>
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<tbody>
<tr>
<td>2015</td>
<td>40%</td>
<td>79%</td>
<td>12%</td>
<td>5%</td>
<td>-</td>
<td>37%</td>
<td>28%</td>
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<tr>
<td>2016</td>
<td>48%</td>
<td>76%</td>
<td>11%</td>
<td>7%</td>
<td>-</td>
<td>21%</td>
<td>43%</td>
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<tr>
<td>2017</td>
<td>55%</td>
<td>77%</td>
<td>11%</td>
<td>7%</td>
<td>14%</td>
<td>32%</td>
<td>34%</td>
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<tr>
<td>2018</td>
<td>56%</td>
<td>69%</td>
<td>10%</td>
<td>11%</td>
<td>14%</td>
<td>15%</td>
<td>47%</td>
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<tr>
<td>2019</td>
<td>72%</td>
<td>72%</td>
<td>9%</td>
<td>9%</td>
<td>18%</td>
<td>36%</td>
<td>40%</td>
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<tr>
<td>2020</td>
<td>56%</td>
<td>75%</td>
<td>6%</td>
<td>8%</td>
<td>11%</td>
<td>30%</td>
<td>54%</td>
</tr>
</tbody>
</table>
Global Demographics

**Sex Distribution**
- Female: 51%
- Male: 49%

**Race Distribution**
- White: 76%
- Asian: 11%
- Black or African American: 9%
- Other: 4%
- Missing: 1%

**Age Distribution**
- < 65 Years: 69%
- ≥ 65 Years: 31%

**Ethnicity Distribution**
- Hispanic or Latino: 20%
- Not Hispanic or Latino: 13%
- American Indian or Alaska Native: 67%
US Participation by Race
Ethnicity Distribution

Global
Total Participants = 292,537
(Country data missing for 229 participants)

United States
Total Participants = 102,595

Rest of the World
Total Participants = 189,942
A total of 4,922 patients participated in the trials that led to the approvals of 18 new drugs. Overall,

- 50% of all participants were women,
- 73% were White,
- 14% were Asian,
- 5% were Black or African American,
- 5% were Hispanic,
- 44% were 65 years and older, and
- 41% were from the sites in United States.
Race Distribution in DM Trials

- United States:
  - White: 80%
  - Asian: 14%
  - Black or African American: 3%
  - Other: 2%
  - American Indian or Alaska Native: 1%

- Rest of the World:
  - White: 67%
  - Asian: 27%
  - Black or African American: 4%
  - Other: 2%
  - American Indian or Alaska Native: < 1%
Ethnicity Distribution in DM Trials

United States
Total Participants = 7,350

- 77% Not Hispanic or Latino
- 23% Hispanic or Latino
- < 1% Missing

Rest of the World
Total Participants = 24,211

- 81% Not Hispanic or Latino
- 17% Hispanic or Latino
- 2% Missing
Barriers to Participation

• Lack of awareness
• Mistrust of the medical system
• Inadequate recruitment effort
• Language barrier
• Barriers to the enrollment in clinical trials
  o enrollment criteria
  o sites selection
  o time and resource constrains
COVID-19 and Diverse Population

• FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19; June 2020
  o “FDA strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”

• FDA Guidance for Industry on COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; May 2020
  o “Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.”
Remdesivir Trials

- Men (1,294 patients) 37%
- Women (749 patients) 63%

- White (1,170 patients) 57%
- Black or African American (368 patients) 14%
- Asian (282 patients) 18%
- American Indian or Alaska Native (12 patients) 9%
- Native Hawaiian or Other Pacific Islander (8 patients) 1%
- Other* (203 patients) <1%

- Less than 40 years (252 patients) 21%
- 40-64 years (1,080 patients) 74%
- 65-74 years (420 patients) 14%
- 75 years and older (291 patients) 12%
- Not reported (92 patients) 5%
Moderna Trials

- **Gender Distribution**
  - Men: 15,995 participants (47%)
  - Women: 14,355 participants (53%)

- **Race Distribution**
  - White: 24,023 participants (73%)
  - Black of African Americans: 3,090 participants (10%)
  - Asian: 1,385 participants (5%)
  - American Indian or Alaska Native: 230 participants (<1%)
  - Native Hawaiian or other Pacific Islander: 66 participants (1%)
  - Other/Multiracial: 1,556 participants (5%)

- **Age Distribution**
  - <65 years: 22,830 participants (78%)
  - ≥65 years: 7,520 participants (21%)

- **Hispanic or Latino**
  - Hispanic or Latino: 6,234 participants (21%)
  - Not Hispanic or Latino: 23,834 participants (78%)
  - Not reported: 282 participants (1%)
Achieving Health Equity in Preventive Services

Screening rates are higher with

• patient navigator for colorectal, breast, and cervical cancer;

• telephone calls and prompts for colorectal cancer; and

• reminders with lay health workers for breast cancer.
<table>
<thead>
<tr>
<th>Research and Collaboration</th>
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<tbody>
<tr>
<td>• Intramural Research</td>
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<tr>
<td>• Extramural Research</td>
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<tr>
<td>• FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects</td>
</tr>
<tr>
<td>• Broad Agency Announcement (BAA)</td>
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<tr>
<td>• Summer Science Teacher Training Program</td>
</tr>
<tr>
<td>• Internships and Fellowships</td>
</tr>
<tr>
<td>• Academic Collaborations</td>
</tr>
<tr>
<td>• FDA &amp; HHS Working Groups &amp; Collaborations</td>
</tr>
<tr>
<td>• Stakeholder Input into Research Agenda</td>
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<tr>
<th>Outreach and Communication</th>
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</thead>
<tbody>
<tr>
<td>• Programs/Initiatives/Campaigns</td>
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<tr>
<td>• Diversity in Clinical Trials Initiative</td>
</tr>
<tr>
<td>• Language Access Program</td>
</tr>
<tr>
<td>• Health Education Materials</td>
</tr>
<tr>
<td>• Social Media</td>
</tr>
<tr>
<td>• Newsletter &amp; E-alerts</td>
</tr>
<tr>
<td>• Website</td>
</tr>
<tr>
<td>• Health Equity Lecture Series &amp; Webinars</td>
</tr>
<tr>
<td>• Stakeholder Meetings/Symposiums</td>
</tr>
</tbody>
</table>
Thank you
Resources

• Drug Trials Snapshots
  https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots
• NIH Clinical Trials
  https://www.ClinicalTrials.gov
• FDA Guidances
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents
• FDA Advisory Committee
  https://www.fda.gov/advisory-committees/advisory-committee-calendar
• Office of Minority Health and Health Equity
  OMHHE@fda.hhs.gov
IMPROVING DIVERSITY IN CLINICAL TRIALS: HOW DO WE DO THAT?

ROBERT E FULLILOVE, EdD
Columbia University
Positionality: what’s my credibility?

- I have had more than a little experience with our nation’s struggles with diversity and with efforts to have anti-racist approaches to medicine and public health

- For this topic, it is important to understand that the resistance to participate in scientific research in the Black community involves more than an awareness of the Tuskegee Syphilis Study.
WAITING ROOM
FOR COLORED ONLY
BY ORDER
POLICE DEPT.
Figure 5. Afro-American Sons and Daughters Hospital circa 1950
(Reproduced with permission; Afro-American Sons & Daughters; Joseph C. Thomas, author)
Figure 3. Robert Elliott Fullilove, MD
(Reproduced with permission; Afro-American Sons & Daughters; Joseph C. Thomas, author)
During the very terrible epidemic of the flu that claimed my mother's life, my father spent three days and nights going from one plantation to another, without going home at all. He would finish at one house where all the members were down with the flu, and there would be somebody waiting there to take him to another house where all the members were sick. And, surprisingly enough, although we had it, she died of it, he never contracted at all.
Julius Rosenwald Fellows
MGH Dates of Note: 1938-1940

Harold E. Farmer, MD
Internal Medicine, 1938
1932 – Graduated from University of Pennsylvania School of Medicine

Robert E. Fullilove, Jr., MD
Urology, 1940
• 1934 – Graduated from Howard Medical School
• First African American elected president of the Essex County Medical Hospital

Robert Fullilove, MD (above), courtesy of his son, Robert Fullilove, PhD
My Dad’s first publication: JAMA, 1943

"SYPHILIS AND THE NEGRO"

Robert E. Fullilove Jr., M.D.

Author Affiliations

"SYPHILIS AND THE NEGRO"

To the Editor,—The article by Dr. Smillie in the June 5 issue of The Journal concerning syphilis and the Negro, and the editorial comment, serve to give needed emphasis to an important problem. But in characterizing the problem as a purely Negro one there is grave danger of overlooking some important facts concerning the treatment and prevention. Why is the syphilis rate so much higher in the Negro than in the white? To quote Dr. Smillie, "Among the whites syphilis has become, in the great majority of cases, a disease of the ignorant, the careless, the criminal and the social outcast." Do not the same conditions apply to syphilis in any group? The Negro is discriminated against economically and educationally; it would be difficult to find conditions more favorable to the development of crime, carelessness and social ostracism than the poverty and ignorance engendered by the wage and educational differentials that are too often the lot of the Negro. In this connection the chart published with your editorial comment (p. 378) is quite significant. It shows educational deficiencies as a cause, second only to syphilis, of rejection of Negro males by Selective Service local boards, whereas this factor did not appear in the first ten causes of rejection in the white group. This is more than a mere coincidence. It would be a serious mistake to attempt to treat this problem by merely dispensing large quantities of antisypilitic drugs without at the same time attempting to cure some of the serious socioeconomic conditions underlying it.

Robert E. Fullilove Jr., M.D., New Orleans.
Books by Mindy Thompson Fullilove, MD

Root shock
2004

Urban Alchemy: Restoring What We Can Do About It
2013

The house of Joshua
1999

Homeboy Game to Orange
2008

From Enforcers to Guardians
2020
The summer of 1964 saw steady strides forward in the struggle for justice and equality. Civil rights organizations established a summer program to help African Americans register to vote in Mississippi. The Mississippi Freedom Democratic Party was born to challenge the traditional Democratic Party in the state, which was dominated by segregationists. And in July the Civil Rights Act proposed by President John F. Kennedy before his assassination was signed into law by President Lyndon Johnson.
Perceptions of scientific research

• Science has become “just another voice in the room”

• It is no longer perceived as a source of undeniable truth

• In communities of color, residents question: “what has scientific research done concretely for me or mine?”
The pandemic has demonstrated how poorly medicine and science have served communities of color. Residents of such communities are overrepresented among cases, hospitalizations, and mortality rates. Vaccine distribution has not fared any better: poor access, limited availability, well-documented abuses, and a history of vaccine hesitancy are just some of our current challenges.
Relevant comments from community members

• “I only see you when you want something. You want me in an experiment that you say will help me and my community.”

• ”But if you want to help my community, do something first about unemployment, housing, educational opportunities, and these racist cops....”
What is the most important first step?

• Creating a sense of trust that we are in communities of color to do more than conduct research

• Without a coordinated effort to be in such communities to be visible allies working on ALL of the community’s problems, our silos will keep us from creating effective collaborations
What’s needed?

• A Marshall Plan for community public health interventions

• COVID-19 provides the perfect opportunity to collaborate

• A concerted plan to eliminate the health disparities and the social determinants of health that COVID-19 has exploited is urgently needed
What is needed?

• Concerted efforts to deal with all of the health needs of the community are a fundamental component of creating trust.

• Impossible? Too difficult to organize? Our silos prevent collaboration? Ok, but...

• Necessity is the Mother of Invention...and so is our need to get on top of this pandemic....
Promoting diversity and equity in clinical trials

Efrén J. Flores, MD
Assistant Professor of Radiology, HMS
Officer, Radiology Community Health & Equity
Faculty, The Mongan Institute
Radiologist, Massachusetts General Hospital

@EJFLORESMD
Quote from individual interview with Hispanic/Latina “passive refuser” for a clinical trial: “Before talking to you, no one has asked me to participate in research”
"They don’t want to be anyone’s guinea pig."
- Patient Navigator

"No, I’ve never been offered a research study"
- Patient

"Many of them don’t have Patient Gateway. Some of them don’t even have smart phones"
- Provider

"Medicaid does not want to give you MRIs and CT scans. You have to be on your deathbed."
- Patient

"I mean, how do you just go about asking a doctor to get a lung screen?"
- Patient

"I don’t have a computer. I don’t have internet access or anything like it."
- Patient
MEETING PATIENTS WHERE THEY ARE
Radiology Race, Equity, Access & Community Health (R²EACH) Care Delivery Transformation Initiative
Despite some lower adoption, blacks and Hispanics own smartphones at similar shares to whites

% of U.S. adults in each group who say they have the following

- **Desktop or laptop computer:**
  - White: 82
  - Black: 79
  - Hispanic: 79

- **Home broadband:**
  - White: 82
  - Black: 79
  - Hispanic: 61

- **Smartphone:**
  - White: 80
  - Black: 82
  - Hispanic: 79

- **Tablet computer:**
  - White: 58
  - Black: 53
  - Hispanic: 43

- **All of the above:**
  - White: 40
  - Black: 33
  - Hispanic: 28

Note: Those who did not answer are not shown. Whites and blacks include only non-Hispanics. Hispanics are of any race.

PEW RESEARCH CENTER

- Digital outreach and telemedicine can be a vehicle to promote equity and diversity
- Transforming recruitment and engagement in research requires a new approach
Promoting diversity and equity in research and clinical care

Latino Provider

Latina Patient

Simpler language with more visuals

LUNG CANCER SCREENING
ARE YOU ELIGIBLE?

EXÁMENES DE DETECCIÓN DE CÁNCER DE PULMÓN
¿ES USTED CANDIDATO?

¿SU EDAD?

¿FUMA?

Tobacco Counselor

Access to Local Resources

Free Nicotine Patches

CONVERSE CON SU MÉDICO SOBRE SU RIESGO DE PATAR EL RIESGO DE DE PADER CÁNCER DE PULMÓN Y SI LAS PRUEBAS DE DETECCIÓN SON APROPIADAS PARA UD.

EARLY DETECTION SAVES LIVES

A 15-MINUTE EXAM COULD SAVE YOUR LIFE

PAINLESS
NON-INVASIVE
NO PREPARATION
COVERED BY MOST INSURANCE

LA DETECCIÓN TEMPRANA SALVA VIDAS

UN EXAMEN DE 15 MINUTOS PUEDE SALVARLE LA VIDA

SIN DOLOR
NO INVASIVO
SIN PREPARACIONES
LA MAYORÍA DE LOS SEGUROS OFRECEN COBERTURA

@EJFLORESMD
DO THINGS DIFFERENTLY
OUR WORK IS NOT DONE UNTIL NO ONE IS LEFT BEHIND
Mass General Brigham Center of Excellence: Aspirations

• Create a nationally-recognized model
  • Where DEI is the *norm*, not the exception in our research
  • Brings together the innovation, expertise and individual efforts in DEI into a system-wide infrastructure
  • Facilitates actions (initiatives) that result in real and sustainable change in how we conduct research

• Parallels and integrates with clinical initiatives to
  • Remove healthcare disparities
  • Support health care equity goals
  • Improve the lives of our patients and our communities

• Create an infrastructure both locally and nationally for organization, discussion, education, and collaboration
Model Based on Successful Mass General Brigham Center for COVID Innovation

https://covidinnovation.partners.org/

**Steering Committee**
- Overarching Goals
- Identify Pillars
- Manage Funds

**Pillars**
- Led by Co-Chairs
- Facilitate system-wide organization, integration and collaboration

**Action Groups**
- Led by Chairs/Co-Chairs
- Develop and implement projects & research

**HRA/CAO + System-wide Representatives**
- Overarching Goals
- Identify Pillars
- Manage Funds
### Research Infrastructure
- Research Review Committees (IRB, SRC, etc)
- Research Staffing
- Partnerships
  - Industry
  - Private
  - Government
- Community
- Funding
- Data and Analytics

### Research Participant Experience
- Recruitment
- Retention
- Community Engagement
- Connecting to patient experience

### Education
- Conferences
- Symposia/Workshops
- Publications
- Toolkits

### Policy & Regulation
- Local
- State
- Federal ★

### Research Methods & Implementation
- Study Design
- Protocol Development
- Instruments and Measurement
- Analysis Methods
Bringing “Siloed” Efforts Together

- Patient Gateway & Clinical Services
- Participant & Clinician Education
- Direct Patient Contact
- Research Navigation Office
- Community Engagement
- Rally
Key Takeaways

• The DEI Pandemic: needs the same priority and action
• Efforts must have institutional-level coordination, leadership and support
• Lessons from Babar: When your village is burning – Act!
Task Force on Diversity, Equity & Inclusion in Research

Megan Kasimatis Singleton, JD, MBE, CIP
Associate Dean, Human Research Protections

February 24, 2021: COGR
White Coats for Black Lives
Racial Justice Report Card
2019

Johns Hopkins University School of Medicine

14. ANTI-RACISM IRB POLICIES

C

There are no specific IRB policies related to race or racism, including no requirements related to how race is defined in research protocols.
# The Charge of The Task Force

<table>
<thead>
<tr>
<th>Sub-Committee</th>
<th>Assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race/Ethnicity</td>
<td>• Define a vision for diversity, equity and inclusion in research</td>
</tr>
<tr>
<td></td>
<td>• Identify barriers and facilitators to achieving this vision</td>
</tr>
<tr>
<td>Limited English Proficiency</td>
<td>• Outline recommendations to ensure this vision could be achieved</td>
</tr>
<tr>
<td>Gender</td>
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<td>Disabilities</td>
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<tr>
<td>Research Across the Lifespan</td>
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</tbody>
</table>

Comprised of over 35 members including community members, faculty, researchers, research staff, IRB members and staff
Current Progress/Next Steps

• Full Task Force and subcommittees have met monthly between September- January
• Each subcommittee drafted preliminary recommendations and Task Force members provided feedback
• Recommendations are being compiled into a single report with cross-cutting themes
• Sessions will be held to obtain feedback on recommendations and next steps
• An implementation oversight group will be defined
Preliminary Considerations

• Assessments have to be comprehensive and continuous
• Small changes can have a great impact
• Sustainable change will require resources
Mechanisms to get involved

- Help support researchers seeking a forum to discuss barriers to diversity, equity & inclusion in research at your organization
- Consider whether your office/organization’s policies and practices support or impede diversity, equity & inclusion in research
- Support the creation of new pathways to enhance diversity, equity and inclusion in research
- Participate in national efforts to improve diversity, equity & inclusion in research
Q & A
Next Session: NSF Director (Guest Speaker) Tomorrow @ 12:30 EST

Visit us at www.cogr.edu

Thank You