DIA

Diversity, Equity, and Inclusion in the Drug Development Lifecycle Meeting

Virtual | April 27

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Overview

DIA's *Diversity, Equity, and Inclusion in the Drug Development Life Cycle Meeting* will lead the way in sharing knowledge and fostering coalitions to build greater diversity, equity, and inclusion in the drug development lifecycle. Moving beyond describing the problems that exist in this space, the meeting will emphasize approaches and solutions in which our field has been investing. The meeting will include interactive and compelling discussions and exercises that will lead to a better understanding of how we can improve as an industry to encourage accountability and sustainability of efforts. An important purpose of the meeting is to advance dialogue among thought leaders from industry, clinical research sites, patient engagement, academia, the FDA, and public policy to spur additional ideas to move the field forward.

Who Should Attend

Professionals involved in:

- Clinical Research
- Clinical Operations
- Data transparency/data sharing
- Diversity, Equity and Inclusion
- Health Outcomes
- Medical Affairs and Communication
- Patient Advocacy
- Patient Engagement/Patient Support
- Professional Education, Training and Development
- Public Policy
- Research and Development
- Regulatory Affairs
- Strategic Planning

Schedule At-A-Glance

DAY ONE | TUESDAY, APRIL 27

Sessions will be held in ET

10:00-10:30AM	Welcoming Remarks and Keynote Address
10:30-11:30AM	**Session 1:** Increasing Diversity in Drug Discovery and Early Development
11:30-11:45AM	Break
11:45AM-12:45PM	**Session 2:** Exploring the Role of IRBs and IECs in Assuring Appropriate Representation in Research and Development
12:45-1:15PM	Break
1:15-2:30PM	**Session 3:** CONCURRENT SESSIONS
	Session 3a: Change Management – From Insights Into Action
	Session 3b: Weaving a Tapestry: Multifaceted Perspectives for Enrollment and Retention of Diverse Populations in Clinical Trials
2:30-2:45PM	Break
2:45-4:00PM	**Session 4:** Clinical Trial Diversity and Inclusion: Perspectives from FDA, Industry, and Clinical Research Sites
4:00-4:15PM	Break
4:15-5:15PM	**Session 5:** Access to Clinical Trials and Post-Marketing Equity for Traditionally Underrepresented Populations: What are Best Practices?
5:15-5:45PM	Networking Lounge
5:45PM	Conference Adjourns

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Recognize how to engage and be proactive to the needs of diverse communities to build trust and combat misinformation
- Identify strategies that work towards efforts of diversity, equity and inclusion with relation to the drug development lifecycle
- Restate dialogue regarding the importance of genomics in discovery science and early clinical development
- Apply how to engage Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs) on diversity, equity, and inclusion efforts within clinical trials and throughout the drug development lifecycle
- Explain the conscious decision making it takes for a company to pursue diversity in clinical trials
- Evaluate the challenges that impact diversity recruitment, enrollment, and retention in clinical trials
- Describe FDA efforts to advance the inclusion of minorities and women in clinical trials
- Identify industry efforts that support clinical trial diversity
- Explain clinical research site activities that advance clinical trial diversity through community engagement
- Discuss how to engage and support health equity and access during the post-marketing phase of the drug development lifecycle

Continuing Education

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2. Complete a Verification of Attendance Form
3. Send back to **CE@DIAglobal.org** by May 4, 2021
4. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Tuesday, May 11, 2021**.

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Continuing Education Credit Allocation

Diversity, Equity, and Inclusion in the Drug Development Lifecycle Meeting: UAN 0286-0000-21-041-L04-P, ACPE 5.5., CEUs 55

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Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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DAY ONE | TUESDAY, APRIL 27

Sessions will be held in ET

10:00-10:30AM

Welcoming Remarks and Keynote Address

Robert Fullilove, EdD, Associate Dean, Community and Minority Affairs, Columbia University

Join Dr. Robert Fullilove in our featured fireside chat where he will discuss how to engage diverse communities, build trust, combat misinformation, and be proactive to the needs of diverse populations.

10:30-11:30AM

Session 1: Increasing Diversity in Drug Discovery and Early Development

Session Chair

Nicole Richie, PhD, Global Head Health Equity and Population Science, Clinical Development, Genentech

Understanding that different demographics contribute to an individual's susceptibility to disease, is an important factor in determining how people respond to medicinal products. Although omics is now widely utilized as a tool to inform and accelerate both an understanding of disease process, medicinal response, and the identification of new therapeutic targets, most data from diverse populations is lacking, leading to challenges in determining the full spectrum of variation that contributes to disease or drug response. This session will identify and discuss current strategies to include more diversity in early drug development to advance discovery work.

Speakers

Latha Palaniappan, MD, MS, Professor, Stanford University School of Medicine

Mark McCarthy, MD, MA, FRCP, Executive Director, Human Genetics; Staff Scientist, Genentech

Lucia Hindorff, PhD, MPH, Program Director, National Human Genome Research Institute (NHGRI)

11:30-11:45AM

Break

11:45AM-12:45PM

Session 2: Exploring the Role of IRBs and IECs in Assuring Appropriate Representation in Research and Development

Session Chair

Barbara Bierer, MD, Faculty Director, MRCT Center; Professor of Medicine, Harvard Medical School

Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs) arose from the recognition that laws were needed to protect human rights in clinical research studies and these bodies now play an important role in assuring these protections are in place a priori and maintained throughout clinical studies. In this session we will explore questions around whether IRBs and IECs may be able to contribute to

improving inclusion of representative populations in clinical research and trials. Some questions to be asked include: Can IRBs and IECs play a part in identifying issues surrounding diversity? Can IRBs and IECs aid in ensuring accurate representation of the target patient population that is representative of the explored disease? These ideas will be explored in this session as it applies to the pre-clinical phase, and beyond, of the drug development lifecycle.

Speakers
Monica Baskin, PhD, Associate Director for Community Outreach and Engagement, O'Neal Comprehensive Cancer Center, School of Medicine

Michele Russell-Einhorn, JD, Chief Compliance Officer and Institutional Official, Advarra

12:45-1:15PM **Break**

1:15-2:30PM **Session 3:** CONCURRENT SESSIONS

Session 3a: Change Management – From Insights Into Action

Session Chair
Dyan Bryson, MBA, Patient Engagement Strategist/Patient Advocate, Inspired Health Strategies

What does it take for a company to achieve change management on diversity and inclusion (D&I) efforts? What is the momentum needed within a company to take on D&I efforts? What tools and resources currently exist? How does one engage with the CEO and leadership on these efforts? These questions and more will be explored as you join experts who have tackled these challenges and will provide solutions that work towards change management best practices of D&I efforts, driving insights into action.

Business Model Evolution – Putting the Patient at the Center
Anthony Yanni, MD, Executive Vice President, Patient Centricity, Astellas

Getting it Done: Clinical Trial Diversity
Jessica Scott, JD, MD, Head of R&D Patient Engagement Office, Takeda Pharmaceutical Company

Donna Schwarz, MA, Founder, Schwarz Consulting

Clinical Trial Diversity: The Supplier Perspective
Adam Brown, Founder and Chief Executive Officer, ClinArk

Danielle Coe, Founder and CEO, Black Women in Clinical Research

Marya Shegog, MPH, Health Equity and Diversity Coordinator, The Lazarus Project

Session 3b: Weaving a Tapestry: Multifaceted Perspectives for Enrollment and Retention of Diverse Populations in Clinical Trials

Session Co-Chairs
Monique Adams, PhD, MS, Director, Clinical Innovation Lead, Janssen

Diana Foster, BSN, PhD, MBA, Chief Executive Officer, Total Clinical Trial Management; Vice President, Strategy and Development, Society for Clinical Research Sites

Amy Sitnick, MA, Vice President, Marketing, Greenphire

In this interactive session, presenters will showcase their wide-ranging experience and offer proven techniques to further engage diverse participants in clinical trials. Beginning with an analysis of the barriers that may limit diverse participation in clinical trials, the presenters will focus on successful strategies for awareness, recruitment, and participant retention. Whether you are a sponsor, CRO, site or other industry representative, you will not want to miss this opportunity to hear best practices you can implement within your organization to improve clinical trial outcomes for all.

Speakers
LaShell Robinson, MS, Clinical Operations Lead Diversity and Inclusion in Clinical Trials, Janssen Pharmaceuticals

Lorena Kuri, MBA, Head, Diversity Strategy, Bristol Myers Squibb

Karri Venn, PMP, President, LMC Manna Research

Kristine Baffo, Senior Project Manager, Inside Edge Consulting Group

2:30-2:45PM	**Break**
2:45-4:00PM	**Session 4:** Clinical Trial Diversity and Inclusion: Perspectives from FDA, Industry, and Clinical Research Sites **Session Chair** **RADM Richardae Araojo, PharmD, MS**, Associate Commissioner and Director, Office of Minority Health and Health Equity, FDA Join leaders from the FDA's Office of Minority Health and Health Equity, the FDA's Office of Women's Health, alongside representatives from industry and clinical research sites for a thought-provoking session that explores strategies that work towards enhancing the diversity of clinical trial populations. **Speakers** **Kaveeta Vasisht, DrMed, MD, PharmD**, Associate Commissioner and Director, Office of Women's Health, FDA **Cassandra Smith, MBA**, Director, Diversity and Inclusion in Clinical Trials, Janssen Research & Development **Fabian Sandoval, MD**, Chief Executive Officer and Research Director, Emerson Clinical Research Institute, Inc.
4:00-4:15PM	**Break**
4:15-5:15PM	**Session 5:** Access to Clinical Trials and Post-Marketing Equity for Traditionally Underrepresented Populations: What are Best Practices? **Session Chair** **Charlotte Jones-Burton, MD, MS**, Vice President, Otsuka Pharmaceutical Post-marketing and pharmacovigilance efforts are important to ensure the safety and efficacy of an approved drug or biologic. COVID-19 has disproportionately impacted traditionally underrepresented populations and post-market monitoring is lending insight to how these populations are responding to available products. This session will focus on best practices with respect to access to clinical trials and post-marketing equity for traditionally underrepresented populations. The following questions will be explored in this session: How do we engage and ensure health equity and access to traditionally underrepresented populations? Who is the trusted messenger and what is the fix when things do not go right? **Panelists** **Sunita Dhar, MD**, Executive Medical Group Director, Genentech **Lionel Phillips, MBA**, President, Inside Edge Consulting
5:15-5:45PM	**Networking Lounge** Join DIA's Diversity and Inclusion Community Chair in our Networking Lounge following the meeting. This is your chance to turn your cameras on, unmute your microphone, and talk freely with other participants! What takeaways did you gain from the day? What examples can you share that can benefit others? We really want to use this time for casual conversation amongst the group.
5:45PM	**Conference Adjourns**