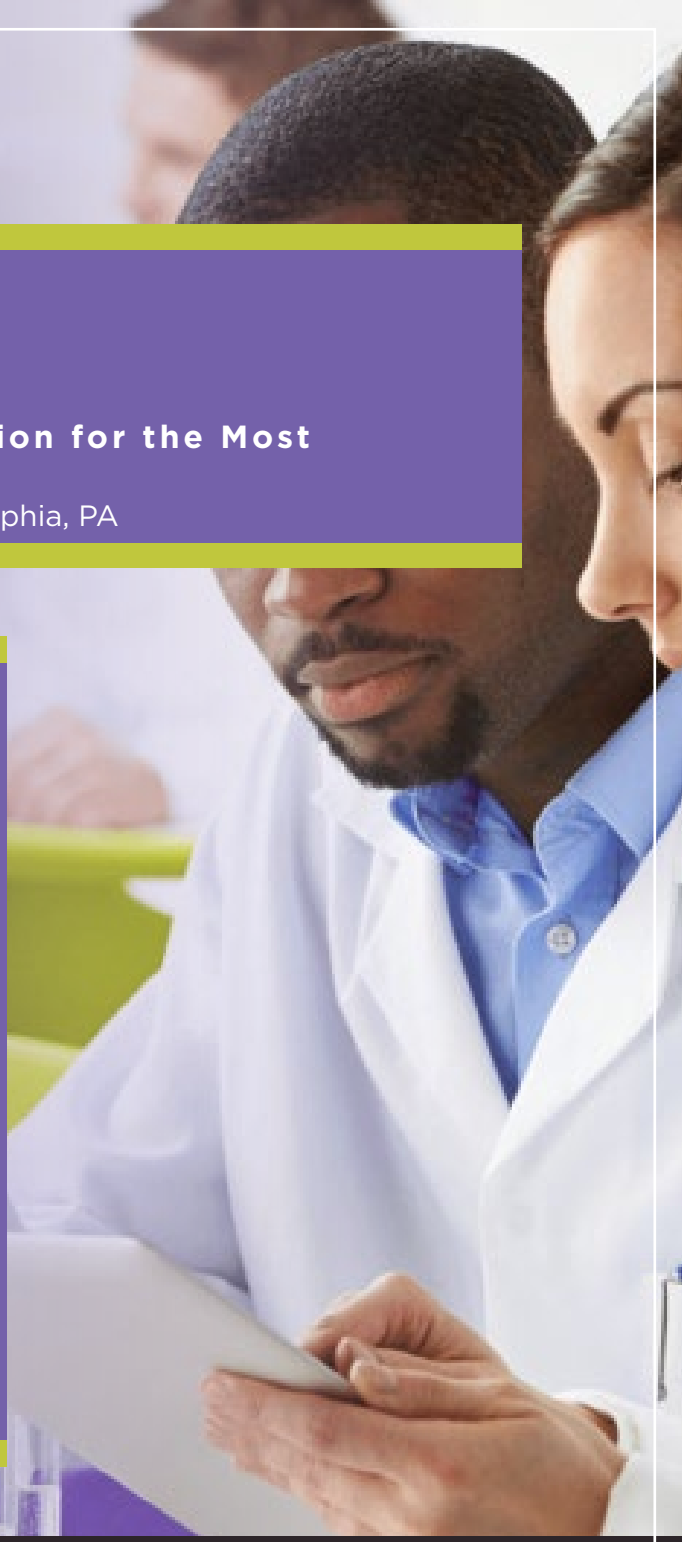
DYNAMIC GLOBAL EVENTS

3rd Diversity in Clinical Trials Summit

Interpreting FDORA and Putting it Into Action for the Most Effective Clinical Trials

May 15-16, 2024 | The Inn At Penn, A Hilton Hotel | Philadelphia, PA



All-New Insights On Your Biggest Diversity In Clinical Trials Challenges!

- **Evaluate your Efforts in Trial Diversity, What Is Working, and What Is Not**
- **Take a Fresh Perspective Where Teams Are Focusing Less on Nuts & Bolts and More On Patient Care In Clinical Trials**
- **Past, Present, and Future – Addressing Historical Obstacles to Diversity in Clinical Trials**
- **Act on FDA Guidance, Establish Clinical Study Enrollment Goals and Practice the Use of Disease Prevalence or Incidence Data**
- **Explore Why Research Must Include Mapping Out the Biocultural Journeys of Target Populations**
- **Gain Insight to Key Opportunities for Investigator Sponsored Research & Clinical Trial Diversity**
- **Clinical Development Considerations for Population Specific Inclusion and Analysis**
- **Make your Team Part of the Increased Awareness and Action that have Improved Representation in Recent Years**

Featured Speakers

David Blackwell
Director, Drug Safety Evaluation
PFIZER

Ramona Burress
Head of Patient Engagement & Insights - Center for Health Equity and Patient Affairs
TAKEDA

Stephen Framil
Corporate Accessibility Lead
MERCK

Nicole Richie
Vice President and Global Head Health Equity and Population Science
GENENTECH

DISTINGUISHED SPEAKING FACULTY

Aparna Ahuja
Divisional Vice President Medical, Clinical and Scientific Affairs ID Rapid Diagnostics
ABBOTT

David Blackwell
Director, Drug Safety Evaluation
PFIZER

Eucharia Borden
VP of Programs & Health Equity
FAMILY REACH

Ramona Burress
Head of Patient Engagement & Insights - Center for Health Equity and Patient Affairs
TAKEDA

Stephen Framil
Corporate Accessibility Lead
MERCK

Ashwin Mathew, MBA
Director, Global Demographics & Diversity Analytics
GSK

Korin Martin
Director, Project Management Office
MERCK

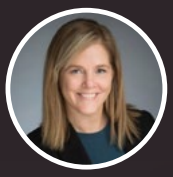
Joanne Nicholls, Ed.D
Director, Clinical Research Corporate Clinical Research
NOVANT HEALTH

Tyrone Quarterman
Senior Manager of Health Equity, Diversity, Equity, and Inclusion, University Affairs
MYRIAD GENETICS

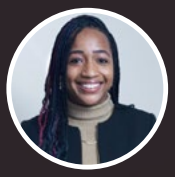
Maria Restrepo, Ph.D.
Program Director, Diversity in Clinical Trials
MEDTRONIC

Nicole Richie
Vice President and Global Head Health Equity and Population Science
GENENTECH

Veronica Sandoval
Principal, Patient Inclusion & Health Equity
Chief Diversity Office
GENENTECH



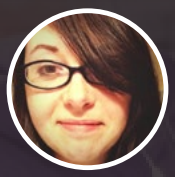
Jennifer Scheller
VP, Head of Clinical Sites, Data Management & Quality
MERCK



Ebony Scott
Senior Manager, Patient & Community Engagement Digital Optimization
WALGREENS

Erik Sokolowski
Senior Director, Head of Global Trial Optimization
ALNYLAM PHARMACEUTICALS

Carla Tardif
CEO
FAMILY REACH



Katie Wade
Director, Research Process & Infrastructure, Medical Research Operations
BIOGEN

Clinical Trial Diversity action plans as expected by FDA are no longer on the horizon—they are here! Facing an unprecedented regulatory focus on community representation in clinical trials, have you taken the necessary time to prepare your teams to change their entire clinical recruitment outlook?

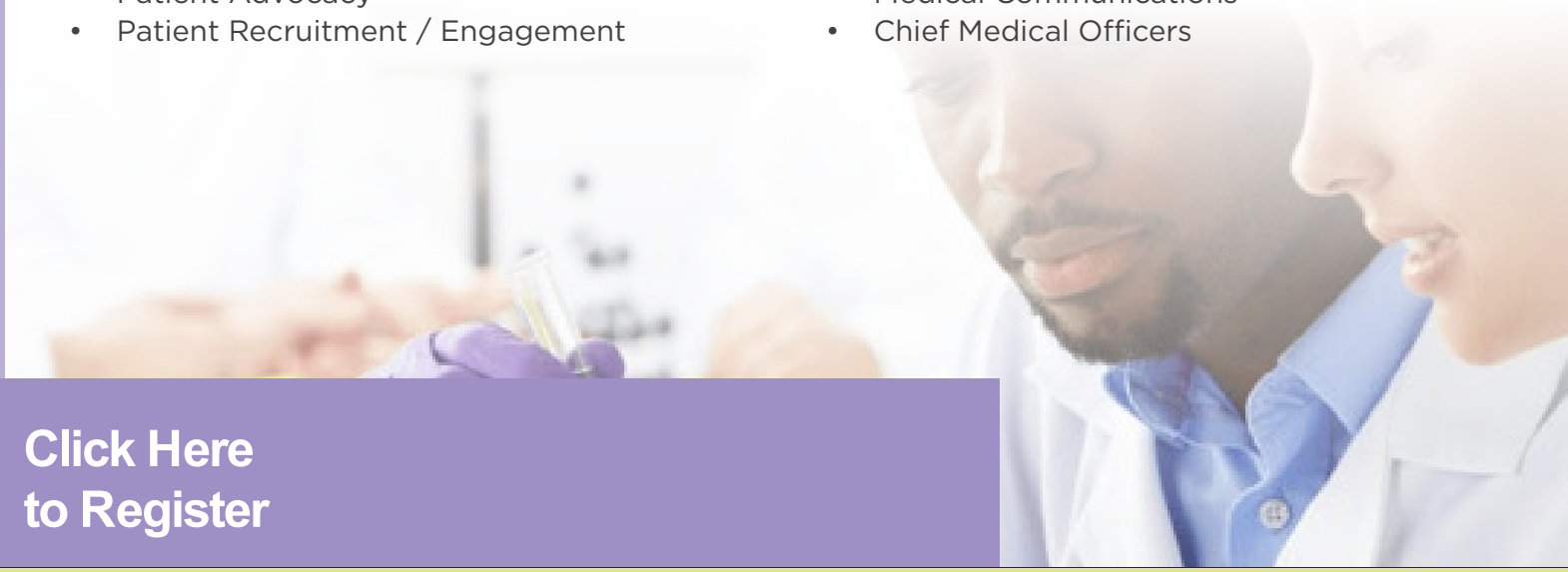
DGE is proud to invite you and your colleagues to attend the **3rd Diversity in Clinical Trials Summit** -the most in-depth conference available for:

- Gaining full understanding of the FDA's action plans and FDORA
- Acknowledging the problems of DCT in the past, current efforts to overcome these issues and raising the bar for future goals and achievements
- Gaining insight into how trial diversity helps you best serve patients and develop the most effective treatments

WHO WILL ATTEND

Professionals working in biotech, pharma and medical device and diagnostics:

- Clinical Trials / Trial Design
- Clinical Operations / Research / Development / Data
- Decentralized Trials
- Patient Centricity
- Patient Experience
- Patient Advocacy
- Patient Recruitment / Engagement
- Public Affairs / Policy
- MSL / KOL
- HEOR
- Site Management
- Real World Evidence / Real World Data
- Medical Affairs
- Medical Communications
- Chief Medical Officers



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DAY ONE
WEDNESDAY, MAY 15, 2024

ALL TIMES ARE IN EST

8:00 *Registration & Log In*

8:45 *Chairperson's Opening Remarks*

9:00 **FIRESIDE CHAT: Create a Team that Shapes Personalized Medication: Integrating Diversity in Clinical Trials through Patient-Focused Drug Development**

Increase enrollment and retention of patients from racially and ethnically diverse populations by Identifying and engaging the most promising sites in underserved communities. Grasp a patient-centric approach by seeking patient input throughout the development process.

- Understand and overcome the challenges and barriers to trial diversity
- Consider game changing real-world examples where patient-focused approaches improved diversity
- Participate in a strategy shifting discussion about how technology and Social Determinants of Health (SDOH) data analytics can play a role in success

Ramona Buress, Head of Patient Engagement & Insights - Center for Health Equity and Patient Affairs, **TAKEDA**

Veronica Sandoval, Principal, Patient Inclusion & Health Equity, Chief Diversity Office, **GENENTECH**

9:45 **KEYNOTE: Evaluate your Efforts in Trial Diversity, What Is Working, and What Is Not**

2024 is the year where we measure organizational diversity in clinical trials. Now that FDORA is approaching finalization, the goals put in place according to an earlier FDA action plan two years ago must be re-evaluated and taken to the next step.

- Acknowledge how unequal treatment based on race and socioeconomic status led to distrust for the medical community and clinical research in many communities of color
- Gain insight into new policies for transparent research and equal trial access as we learn from the mistakes of history
- Discover how to lower health disparities by enrolling a wide range of participants in our clinical trials to make sure our vaccines and medicines work across ethnicities, races, and genders

Jennifer Scheller, Vice President, Head of Clinical Sites, Data Management & Quality, **MERCK**

10:30 *Break*

11:00 **Take a Fresh Perspective Where Teams Are Focusing Less on Nuts & Bolts And More On Patient Care In Clinical Trials**

Recognize that feedback from real-world clinical experience is crucial for comparing and improving the use of drugs, vaccines, medical devices

- Acknowledge how to take advantage of the far broader options now available to trial sponsors
- Go over at length the hurdles of Social Determinants of Health (SDOH) and see why they must be understood to be solved
- Engage in a conversation about how the industry must spearhead the movement to move beyond this

David Blackwell, Director, Drug Safety Evaluation, **PFIZER**

11:45 **Past, Present, Future: Address Historical Obstacles to Diversity in Clinical Trials**

To achieve greater diversity and inclusion in clinical trials, we must understand the history behind a major issue in disadvantaged populations: medical mistrust.

- Understand the Past and explore historic examples of medical mistreatment, particularly as they relate to clinical and scientific research
- Address the Present and recognize the remnants of past failures and give credit to advancements and progression in the proper direction
- Prepare for the Future, discuss opportunities for improvement and identify key resources for development while establishing boundaries to avoid repeating history

Tyrone Quarterman, Senior Manager of Health Equity, Diversity, Equity, and Inclusion, University Affairs, **MYRIAD GENETICS**

12:30 *Lunch*

1:45 **Act on FDA Guidance, Establish Clinical Study Enrollment Goals and Practice the Use of Disease Prevalence or Incidence Data**

- Adhere to the very latest FDORA guidance and achieve meaningful representation in clinical studies, while relying on all stakeholders to do their part
- Discuss how and when to collect and present the prevalence or incidence data on a disease or condition by demographic subgroup
- Gain critical insights into the best possible data sources and assessment methodologies
- Explore a pragmatic approach that balances FDA's intent to increase diversity in clinical trials with bringing urgent medical treatments to patients as soon as possible

Ashwin Mathew, Director, Global Demographics & Diversity Analytics, **GSK**

2:30 **Internalize how Trial Accessibility Helps Identify Potential New Treatments to Improve People's Health and Save Lives**

Prioritize the need to go beyond the lab and into the community by working with HBCUs, houses of worship, patient organizations, and community leaders. This will require increasing education and pursuing new partnerships.

- Learn why progress is due in large part to the important and tough scientific questions that are set out to answer with trials and collaborations
- Understand the key importance of clinical trial accessibility in that they may take many trials all around the world to understand which treatments work and how they work
- Explore why participation in clinical trials is a primary route by which patients get access to investigational medicines and contribute to the collection of safety

and efficacy data needed to support regulatory approval worldwide

Stephen Framil, Corporate Accessibility Lead, **MERCK**

3:15 *Break*

3:45 **KEYNOTE: How the External Council for Advancing Inclusive Research Responded to FDA Guidance**

- Review the causes of health disparities – locally and globally
- Explore how social and biological factors impact outcomes, and how exclusion criteria must change in response to this
- Tease out multifactorial causes for differences in outcomes

Nicole Richie, Vice President and Global Head Health Equity and Population Science, **GENENTECH**

4:30 **Explore Why Research Must Include Mapping Out the Biocultural Journeys Of Target Populations**

Prioritize the common goals of DCT that ensure the clinical study of a drug or device reflects the diversity of the population for which it is being developed. Understand how this approach can aid the development of research scientific aims that serve the population.

- Understand why for the importance stretches beyond the patients who will ultimately use the drug or device
- Grasp how this is also of huge interest to industry, clinicians, study participants, health care systems and academia
- Learn the necessity of being a leader with an approach that can aid the development of research scientific aims that serve the population

Maria Restrepo, Program Director, Diversity in Clinical Trials, **MEDTRONIC**

5:15 *Day One Concludes*

DAY TWO
THURSDAY, MAY 16, 2024

ALL TIMES ARE IN EST

8:00 *Registration & Log In*

8:30 *Chairperson's Recap of Day One*

8:45 **Explore the Key Opportunities for Investigator Sponsored Research & Clinical Trial Diversity**

Investigator Sponsored Research is an area that may not be considered in most Clinical Trial Diversity initiatives, but it can present a unique opportunity. For companies that fund ISR, incorporating diversity and inclusion into an ISR program complements a commitment to diversity.

- Understand the reasons to incorporate diversity in ISR and options to make it happen.
- Grasp the opportunities for investigators studying health inequities
- Consider next steps and how to measure the impact of diversity in an ISR program while enhancing the diversity in patient recruitment

Katie Wade, Director, Research Process & Infrastructure, Medical Research Operations, **BIOGEN**

9:30 **Recognize How Retail Pharma Partners can Boost Community Engagement and Representation**

- Gain an insider's perspective with a complete overview of health disparities and one of the most pressing areas of diverse trials: Social Determinants of Health (SDOH)
- Learn from large direct to consumer/patient community engagement by highlighting the Walgreens Clinical Trials approach
- Grasp key lessons of community engagement from the second-largest pharmacy store chain in the United States

Ebony Scott, Senior Manager, Patient & Community Engagement Digital Optimization, **WALGREENS**

10:15 *Break*

10:45 **FIRESIDE CHAT: Explore Why Research Must Include Mapping Out the Biocultural Journeys Of Target Populations**

Participate in a discussion about how to create an ethnically sensitive Clinical Trial Brochure. Learn to leverage insights from our Employee Resource Group (ERG) members to understand the mosaic perspective of diverse patient journeys and tailor the brochure content accordingly.

- Lead large-scale strategic initiatives aimed at improving the efficiency of clinical trials by implementing innovative processes and technology
- Explore ways to play an instrumental role in the Diversity and Inclusion in Clinical Trials
- Actively work to diversify participation in clinical trials while promoting equal representation within the field and lead efforts in developing and mapping out processes to achieve these goals

Korin Martin, Director, Project Management Office, **MERCK**

Erik Sokolowski , Senior Director, Head of Global Trial Optimization, **ALNYLAM PHARMACEUTICALS**

11:30 **Make Your Team Part of The Increased Awareness and Action That Have Improved Representation and Testing In Recent Years**

Unnecessary prescriptions are producing antibiotic-resistant bacteria. Find out if access to point-of-care testing can change the picture

- Gain insight into adapting the draft guidance which provides a framework for a Diversity Plan focused specifically on racial and ethnic characteristics
- Understand how to support the objectives of this new guidance by highlighting methodological implementation of the Diversity Plan
- Discover how to put in place the opportunities for studies to facilitate their implementation and expansion

Aparna Ahuja, Divisional Vice President Medical, Clinical and Scientific Affairs, ID Rapid Diagnostics, **ABBOTT**

12:15 *Lunch*

1:30 **Explore why Your Company Should be Governed by Institutional Review Boards**

- Address why certain therapy programs must be a central issue and discuss why your organization must be very keen on broadening patient access to technology
- Discover our top priority: to protect the rights, dignity, privacy, and welfare of our medical research participants
- Ensure clinical trial participants are informed appropriately while upholding legal and ethical standards of conduct
- Learn why your diverse recruitment strategy must address patient needs and risk/benefit ratios

Joanne Nicholls, Ed.D, Director, Clinical Research Corporate Clinical Research, **NOVANT HEALTH**

2:15 **Make your Team Part of the Increased Awareness and Action that have Improved Representation in Recent Years**

Discover why we are committed to helping people from all backgrounds address their health needs and ensuring that our research reflects the people we serve

- Get to the essence of why diversity in clinical trials is so important and understand how different people different reactions to the same medicine may have based on their age, gender, weight, race, ethnicity and other factors
- Explore why clinical trials rely on volunteers to participate, and they can help show if the medicines and vaccines are safe and work well for people from all different communities
- Identify the key partners for obtaining and managing necessary data while normalizing the of sharing ideas, experiences, and best practices

Amanda Bishop, Diversity Program Lead, **MERCK**

3:00 **Putting People First: Removing Financial Barriers to Clinical Trials**

- Learn how to remove barriers like housing, transportation, and food insecurity impacting a patient's access to clinical trials
- Discover how a national nonprofit is building community-level partnerships to build trust and reach diverse patient populations
- Increase patient engagement through targeted initiatives rooted in cultural humility

Carla Tardif, CEO, **FAMILY REACH**

Eucharia Borden, VP of Programs & Health Equity, **FAMILY REACH**

3:45 *Conference Concludes*

"The conference was well organized, and the topic was comprehensively covered"
-Associate Director, Regulatory Affairs, Boehringer -Ingelheim

"Many opportunities for networking. I would recommend this event to my colleagues."
-Associate Director, Diversity, Equity, and Inclusion in Clinical Trials, Janssen

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3rd Diversity in Clinical Trials Summit

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May 15-16, 2024 | The Inn At Penn, A Hilton Hotel | Philadelphia, PA

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