DAY ONE - Monday, May 22, 2023

8:15 am

Registration and Coffee/Tea

8:45 am

Co-Chair Opening Remarks

Shalini V. Mohan, MD
Executive Director, Head of Health Equity and Inclusive Research (HEIR) | US Medical Affairs, **Genentech**

Denise C. Snyder, MS, RD, LDN
Associate Dean of Clinical Research, **Duke University School of Medicine**

9:00 am

Building a Business Case: Evaluating and Strategizing the Financial Economics of Clinical Care in the Research Setting

This session addresses:

- The underlying cost issues in clinical research due to growing protocol complexity, a rise in regulations/guidance and increasing time and financial pressures on clinician-investigators
- Regulatory issues
- How you can help health providers to develop the business case to conduct clinical trials
- Building capacity in the community
- What can be acted upon?

Donna O'Brien
National Advisor, **Manatt Health**

Henry Wei, MD
Head of Development Innovation, **Regeneron**

Marianne Hamilton Lopez
Senior Research Director, Biomedical Innovation, **Duke-Margolis Center for Health Policy**

9:40 am

Keynote: The Future of Integrated Health

As CEO of Wake Forest Baptist and Dean of the School of Medicine, Dr Freischlag has the overall responsibility for the health system's clinical, academic and innovation enterprises and its annual operating budget of $3 billion. In this keynote talk, Dr Freischlag will provide her thoughts on the future of integrated health in the United States. She will also address:

- The transformation of a health system as a Learning Health Organization
- The role of clinical research in empowering health care consumers with choice and why this is important to integrate research participation within the continuum of care
- What work is underway within integrated health systems to better address racial and socioeconomic disparities and what are some of the bold change imperatives in play

Julie Freischlag, MD
CEO, **Atrium Health Wake Forest Baptist,**
Dean, **Wake Forest School of Medicine**

10:10 am

How the Henry Ford Health System Integrated Clinical Trials into Clinical Care Across their Entire System

The Henry Ford Health System has prioritized clinical trials across their entire system to expand their clinical research. They accomplished this by utilizing a three-step strategy including centralizing clinical trial activity, directing funds and motivating clinicians. In this session, they address the following:

- A three-step system
- Implementing operational changes by bringing four sites into one and doubling the number of patients in a diverse population with access to clinical research
- Establishing a five-year strategic plan to triple the amount of patients, embed research and education into clinical care

Jennifer (Gibson) Levy
Vice President, Education, **Henry Ford Health System**

Donna O'Brien
National Advisor, **Manatt Health**

David Lanfear, MD
VP Clinical and Translational Research, **Henry Ford Health System**

10:45 am - 11:15am

Grand Opening of the CRAACO® Cafe & Networking Break

- Tea / Coffee & Breakfast
- Meet the Exhibitors
- Peer-to-Peer Networking

11:15 am

The Patient Experience: A Mother and Daughter Perspective on Clinical Trials

A mother and daughter together have experienced six clinical trials including asthma, COVID-19, arthritis, mental health and blood trials. In this fireside discussion, we learn from their perspective on how industry can improve the clinical trial experience for patients.

Moderated by:
Desire'e Dickerson
Manager of Clinical Trial Operations, **Javara**

Fawn Volz
Patient Advocate

Auburn Volz
Patient Advocate

11:45 am

Novartis' Approach to Making Patients Feel Valued in Clinical Research

Novartis is investing time, energy and resources into how they are making patients feel valued and supported. This session addresses:

- Implementing a program that engages patients, incorporating their journey while realizing business objectives including long-term participation and compliance
- Partnering with medical and clinical operations teams to streamline the patient experience by evaluating the study from the patients' perspective
- Case study on the GRATITUDE project

Lani Hashimoto
Associate Director, Patient Engagement Management, **Novartis**

12:10 pm

Technology Strategies to Bridge the Gap Between Healthcare and Clinical Research

Integrating clinical care and clinical research requires a solid data and technology strategy. In this session we will discuss:

- Overview of CRAACO framework
- Operational and technology considerations
- Discussions on possible technology solutions

Pranathi Vangeepuram
VP of Products, **Javara**

Kathy Cole
Senior Director, eClinical Solutions, **Javara**

12:35 pm - 1:40 pm

Lunch & Networking Break

- Lunch
- Meet the Exhibitors
- Peer-to-Peer Networking

1:40 pm

Democratizing Access: Enabling All Care Locations to be Research Locations

We share the common goal of democratizing access for patients and physicians to get access to clinical research, but what are inroads being made and how? In this session:

- Explore the barriers in healthcare settings supporting research
- Identify barriers such as current definitions of "sites" and interpretations of "1572s"
- Share strategies and solutions for navigating today's environment
- Define a future where all healthcare settings are spaces for patients to engage in research

Led by:
Angela Radcliffe
Digital Performance Improvement and Innovation Research IT, **Bristol Myers Squibb**

Panelists:
Shelly Barnes
Global Clinical Innovations Lead, **UCB**

Jamie Harper, MHA, CCRP
Vice President, Site Solutions & Engagement, **WCG**

Scott Stout
CEO, Co-Founder, **MedVector**

2:20 pm

Insurance and Challenges with Clinical Trials

Lucy R. Langer, MD, MSHS
National Medical Director of Oncology and Genomics, **UnitedHealthcare**

Donna O'Brien
National Advisor, **Manatt Health**

2:40 pm

Mitigating Site Identification and Selection Risk by Leveraging Healthcare-First Sites

This session addresses how to overcome the challenges in the current site identification and selection process and how past clinical trial experience impacts newly formed sites and new investigators. Elligo will share how they partner with healthcare-first physicians to bring clinical research as a care option to their patient populations while mitigating risk. More specifically:

- Pairing physicians with end-to-end support from a best-in-class research team while leveraging proprietary technology matching trial opportunities within their patient population

Sean Rice
Vice President Trial Placement Services, **Elligo**

2:55 pm

Enabling Patients to Participate in Clinical Trials Closer to their Homes

In this presentation, we discuss the definition of community research sites, their value in the ecosystem of sites overall, including academic medical centers, dedicated research sites and community research sites. The benefit of community sites is that they provide greater access for patients to participate in clinical trials closer to home including in clinical practices where they already receive their healthcare. More specifically:

- How to include community research sites in site engagement planning, especially now that sponsors will need to submit diversity action plans in pivotal studies
- Understanding the difference in working with community research sites to achieve success with site feasibility, budgeting, study-start-up and patient recruitment
- Practical tips on how to work with community sites

Dana Edwards
COO, **Circuit Clinical**

3:10 pm - 3:40 pm

Afternoon Break

- Meet the Exhibitors
- Peer-to-Peer Networking
- Preview silent auction items

3:40 pm

Hospital System-Community Integration that Builds Trust, Drives Awareness, and Creates Clinical Trial Choices

Oregon Health & Science University will share their progress in how they are integrating with communities, what important considerations there are when engaging with community hospitals and also discuss their work trying to build an Affiliate Program Network for greater clinical trial access. More specifically:

- How OHSU addresses the challenges of working with non-academic hospitals, as well as smaller community hospitals in rural areas
- Collaborating with Johns Hopkins Clinical Research Network, and other established hospitals with clinical collaborations, to address common hurdles
- Partnering with community executives, creating a collaborative partnership through an educational approach to build a strong affiliate research program

Madeline Sparks Cresswell, MBA
Affiliate Research Program Manager, **Oregon Health & Science University**

4:05 pm

How to Connect with Primary and Multi-Specialty Care Medical Practices to Catalyze Access to Clinical Trials for Underserved Patients

- Personal experiences with early phase studies and how trust and kindness led to a career in helping patients
- A case study that yielded unexpectedly in an increased number of traditionally underrepresented volunteers
- Exploration of the difference between an expert and a trusted source
- Suggestions on how to connect with community providers and recruit their patients

Greg Sweatt
Senior Director of Provider Networks, **Optum**

4:20 pm

How Genentech is Engaging Community Based Hospitals and Clinics for Greater Patient Diversity, Access and Inclusion

Genentech takes us through their pilot program of decentralized models of trials to empower patients and decrease potential unconscious bias that may hinder participation of historically underrepresented populations.

Specifically addressing:

- How Genentech is committed to recruiting more representative populations into clinical research
- Advancing knowledge of clinical outcomes in patients across race/ethnicity and gender by leveraging Genentech's unique portfolio and data assets
- Developing new approaches for supporting populations currently understudied in genomic and clinical research
- Collaborating with our External Council for Inclusive Research to establish new standards and principles for inclusive research at Genentech

Shalini V. Mohan, MD
Executive Director, Head of Health Equity and Inclusive Research (HEIR) | US Medical Affairs, **Genentech**

4:40 pm

Reducing Barriers to Patient Entry in DCT Diagnostic & Observational Studies: Offering a Possible Gateway to Subsequent Patient Involvement in Therapeutic Trials

Addario Lung Cancer Medical Institute (ALCMI) is a consortium that includes 25 major US academic medical centers, and partners with the GO2 for Lung Cancer Foundation to expand clinical research. They have been deploying decentralized clinical trial strategies. In this session:

- About the partnerships and DCT technology to better support patients in clinical trials
- Helping bring trials closer to the patients
- How DCTs are elevating a patient's first-time participation in DCTs
- Patient perspective

Richard Erwin
Executive Director, **Addario Lung Cancer Medical Institute (ALCMI)**

Andrew Ciupek
Associate Director, Clinical Research, **GO2 for Lung Cancer Foundation (GO2)**

Terri Conneran
Lung Cancer Survivor and Founder & Advocate, **KRAS Kickers Patient Group**

5:15 pm

Networking Reception and Silent Auction

Please join us for the CRAACO Networking Reception. We are pleased to announce that there will be a silent auction to benefit the Greater Gift Foundation.

Greater Gift

This reception is graciously hosted by

CIRCUIT CLINICAL · ELLIGO HEALTH RESEARCH · JAVARA

DAY TWO - Tuesday, May 23, 2023

8:45 am

Coffee/Tea

9:00 am

Co-Chair Opening Remarks

Shalini V. Mohan, MD
Executive Director, Head of Health Equity and Inclusive Research (HEIR) | US Medical Affairs, **Genentech**

Denise C. Snyder, MS, RD, LDN
Associate Dean of Clinical Research, **Duke University School of Medicine**

9:15 am

Addressing the Workforce Issues in Clinical Trials: Strategies for Building a Successful Clinical Research Team in the Care Setting

There are huge concerns around workforce shortages throughout the clinical ecosystem. This session address actions that can be taken to elevate this growing problem. More specifically:

- Defining a standard of expertise and competency in clinical research to overcome the problem of individual requirements at each pharmaceutical company
- Integrating clinical research into medical and nursing training to promote the field and increase participation in PI
- Building awareness of the clinical research profession as an integral part of medical advancement
- Implementing a global program of excellence
- Creating a workforce program that increases retention rates among PIs

Susan Landis
Executive Director, **Association of Clinical Research Professionals**

Michelle Rowe, RN
VP, Operations, **HCA Healthcare Research Institute**

9:45 am

Non-Traditional Hiring: Alternatives in Clinical Research Hiring: Duke's Workforce Resilience Program in the Care Setting

Hiring, maintaining and growing your clinical workforce is one of the most challenging issues in establishing a clinical trial. In this session, our speakers address:

- Duke's Workforce Resilience program (WeR) to hire clinical staff from non-traditional areas, enabling augmentation of teams
- By implementing both a training and mentoring program, Duke has created a program which has increased hiring and established a tier advancement allowing for a higher retention rate of their clinical staff

Barbara Estay
Clinical Research Specialist Sr, **Duke Office of Clinical Research (DOCR) at Duke University School of Medicine**

Sally Taylor
Research Program Leader, **Duke Office of Clinical Research (DOCR) at Duke University School of Medicine**

Sherry Huber
Clinical Research Nurse Coordinator, Team Lead, **Duke Office of Clinical Research (DOCR) at Duke University School of Medicine**

10:25 am

Networking Break

- Tea/Coffee & Breakfast
- Meet the Exhibitors
- Peer-to-Peer Networking

11:00 am

Integrating and Strengthening Clinical Research Teams by Evaluating Knowledge and Skill Gaps Across Individuals

This session addresses specific solutions to retaining clinical research teams from two leading academic medical centers. More specifically:

- Identifying the challenges including foundational on-boarding, logistics, institutional champions, mentorship and clear career paths in order to create a program of growth and retention
- Evaluating framework knowledge and skill gaps within and across individuals
- Implementing diversification of workforce competency
- Forging solutions with integration among teams, improved communication and overall workforce engagement and resilience activities
- Creating a path to advancement and providing growth opportunities to increase staff retention

Denise C. Snyder, MS, RD, LDN
Associate Dean of Clinical Research, **Duke University School of Medicine**

Laura Viera, MA, CCRP
Co-Director, Clinical Research Support Office, **UNC School of Medicine**

11:25 am

Case Study: Growing and Diversifying the Clinical Research Workforce: "A Two-Pronged Approach"

Under-representation of diverse groups in the clinical research workforce contributes to the under-representation of diverse clinical trial participants. To help grow and diversify the clinical research workforce, the Association of Clinical Research Professional (ACRP)'s Early Talent Training Program was implemented to introduce high school and community college students to the clinical research profession, offering a core research curriculum. The second program implemented focuses on coordinating ACRP's Clinical Research Coordinator (CRC) foundational competency training to clinical trials sites located in, and serving underrepresented groups. This session discusses these programs, results and future expectations. Merck's Kelly Clark will be joined by a special guest, one of the student participants, Darius D. Fullenwinder.

Kelly Clark
Head of US Partnerships and Global Site Development, **Merck**

Susan Landis
Executive Director, **Association of Clinical Research Professionals**

Darius D. Fullenwinder
Student Participant, **Merck's Program**

12:00 pm

Applying Digital Innovation to Streamline Clinical Research in the Care Setting – Developing Practical Experiments to Test and Learn

Improving collaboration between the Clinical Research and Clinical Care Setting for the Improvement of the Patient Experience requires approaching the adoption of new tools, technologies, and mindsets in a pragmatic and actionable way. This facilitated, hands-on session will leverage roundtable discussion, microlessons, and hands-on activities to:

- Explore current digital technologies that are driving innovation in how we do drug discovery and development such as large language models and the role of AI, clinical operations workflow automation, wearables, and predictive analytics
- Teach a rapid innovation framework that will foster a test and learn mindset you can take back to your teams!
- Provide an opportunity to practice the framework through the development of an experiment to deliver a practical next step for applying digital innovation in your organization.

Angela Radcliffe
Digital Performance Improvement and Innovation Research IT, **Bristol Myers Squibb**

12:30 pm

Lunch & Networking Break

- Lunch
- Meet the Exhibitors
- Peer-to-Peer Networking

1:40 pm

How Veradigm and ICON are Collaborating to Bring Physicians and Patients Greater Access to Clinical Trials

In this session, Veradigm and ICON discuss how their partnership is enabling more physicians and their patients access to clinical research. In this session, they address:

- Applying analytics to EHR data in order to assess patient eligibility
- Integrating systems to allow for automated data transfer from EHR to EDC
- Decreasing the burden of physician participation with support, standardization and automation
- Increasing the number of physicians participating in research
- Recruiting at a faster pace

Louisa Roberts
VP Corporate Development and Strategic Partnerships, **ICON**

Mac Bonafede
VP RWE, **Veradigm**

2:00 pm

Clinical Care to Research Data: The Need for A Dynamic Collaboration for Collecting and Sharing Data

The acquisition and use of EHR data for prospective clinical research has remained largely separate from data collection routine care. Through the implementation of standards these processes can be modernized, benefiting all stakeholders across the research enterprise. This session addresses:

- The challenges and opportunities in collecting data as clinical trials become more localized and multi-site
- How VULCAN, a research community collaboration, creates interoperability standards for the exchange of healthcare data – bridging clinical research into the broader healthcare ecosystem

Led by:
Conor Kane
Senior Director, **Janssen Clinical Innovation**

Panelist:
Catherine Diederich, Ed.D., MMCi
Master of Management in Clinical Informatics, **Duke University School of Medicine**

Anita Walden
Assistant Director for the Center for Data to Health V. Associate Professor, **University of Colorado Anschutz**

2:35 pm

How Sanofi is Partnering with Hospital Systems to Leverage EHRs for Patient Matching from Care to Research

Using fully compliant data privacy EHR queries to build clinical site networks with the highest recruitment potential, requires multi-stakeholder collaboration. In this session, we address:

- Developing patient cohort selection criteria by using a combination of protocol eligibility and proxy criteria to address the challenge of data limitation
- Leveraging AI and Machine Learning to automate patient cohort selection criteria for utilization in clinical sites
- The latest report from the IMI EU PEARL consortia project on developing innovative capabilities in leveraging EHRs for patient-matching in clinical trials

Led by:
Nadir Ammour
Global Lead for External Engagement; Project Leader, EHRs Patient Matching, **Sanofi**

Panelist:
Christel Daniel, MD
Associate Director at Assistance Publique, **Hôpitaux de Paris (AP-HP)**

3:05 pm

Co-Chair Closing Remarks

Shalini V. Mohan, MD
Executive Director, Head of Health Equity and Inclusive Research (HEIR) | US Medical Affairs, **Genentech**

Denise C. Snyder, MS, RD, LDN
Associate Dean of Clinical Research, **Duke University School of Medicine**

3:15 pm

CRAACO Concludes