DIA

Master Protocols and Complex Innovative Design

November 4-5 | Virtual

PROGRAM CHAIRS

Daniel Millar, MBA
Senior Director, Strategic Business Transformation, Quantitative Science,
Janssen Research & Development, LLC

Robert Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track
Georgetown University Medical Center

Fanni Natanegara, PhD
Research Advisor
Eli Lilly and Company

PROGRAM COMMITTEE

Zoran Antonijevic, MSc
Vice President, Statistical Consulting
Abond CRO Inc.

Michelle Detry, PhD
Director, Adaptive Trial Execution & Senior Statistical Scientist
Berry Consultants LLC

Kristin Dolinski
Deputy Vice President, Science and Regulatory Advocacy
PhRMA

AnnCatherine Downing, PharmD
Senior Research Advisor – Clinical
Eli Lilly and Company

Anne-Marie Duliege
Chief Medical Officer
Pancreatic Cancer Action Network

Yi Liu, PhD
Executive Director Biostatistics
Nektar Therapeutics

Cristiana Mayer, DrSc, PhD
Head of Biostatistics
Johnson & Johnson Vision

Pritibha Singh, BS, MBA, MS
Global Program Associate Director - Oncology Hematology Development Unit
Novartis, Switzerland

Rui (Sammi) Tang, PhD
Vice President, Global Head of Biometric of Oncology
Servier Pharmaceuticals

Overview

The evolution of clinical trial designs has accelerated since the onset of the pandemic to meet patient and logistical need. While elements of randomized control trials remain a gold standard, clinical trials continue to transform, building on innovations in study design and statistical approaches, as well as regulatory flexibilities, with the promise of bringing new medicines to patients more quickly than ever.

Supported by advancement in clinical trial operations, development of digital technologies along with strong partnerships and collaborations amongst key stakeholders, clinical trials are poised to reach more people and add efficiency to clinical drug development. Master protocol and complex innovative designs continue to provide frameworks that hold enormous promise for engaging patients more productively, increasing overall efficiency and improving successful outcomes.

DIA's *Master Protocols and Complex Innovative Design* Meeting will bring together a truly multidisciplinary group of experts in clinical trial planning, execution, and analysis to share and discuss both the common and unique challenges and opportunities in the adoption of master protocols and complex innovative design. Join industry, patient, regulatory agency, other government, and NGO representatives to examine the growing body of knowledge, experience, and resources available to better meet patient needs through successful implementation of innovation in clinical trial designs.

Who Should Attend?

Professionals within biopharmaceutical and medical device research, regulatory agencies, and patient organizations, who are involved in:

- Clinical Data Management, Clinical Operations, Clinical Research
- Good Clinical Practice
- Health Economics and Outcomes Research
- Medical Affairs
- Pharmacology
- Patient Engagement
- Regulatory Affairs
- Research and Development
- Rare/Orphan Diseases
- Statistics
- Strategic Planning
- Trial Design

DAY ONE | FRIDAY, NOVEMBER 4

10:00-10:15AM	**Welcome and Opening Remarks**
10:15-10:45AM	**Session 1:** Keynote – Patient Advocacy
10:45-11:00AM	Break
11:00AM-12:15PM	**Session 2:** Decision Making for Master Protocols
12:15-12:45PM	Break
12:45-2:00PM	**Session 3:** The Art of Implementing and Conducting Platform Trials
2:00-2:15PM	Break
2:15-3:30PM	**Session 4:** Innovative Uses of Alternative Data Sources
3:30-3:45PM	Break
3:45-5:00PM	**Session 5:** Challenges in the Integration of Digital Data and Telemedicine to Clinical Trials

DAY TWO | FRIDAY, NOVEMBER 5

9:50-10:00AM	Welcome Remarks
10:00-11:15AM	**Session 6:** Global Regulatory Discussion - Perspectives from Cross-Region Regulatory Authorities
11:15AM-11:30AM	Break
11:30-12:45PM	**Session 7:** Complex Innovative Trial Designs: From Pilot to Practice
12:45-1:30PM	Break
1:30-2:45PM	**Session 8:** Innovative Designs for Acute Myeloid Leukemia: Patient, Sponsor, and Investigator Perspectives
2:45-3:00PM	Break
3:00-4:15PM	**Session 9:** Clinical Research in a Global Pandemic: Lessons Learned for Drug Development
4:15-4:30PM	Closing Remarks

Learning Objectives

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

- Articulate the challenges and opportunities for the use of complex innovative design and master protocols
- Explain how master protocols and CIDs contribute to increased efficiency and other enhancements of medical product research to ultimately accelerate patient access to innovative therapies
- Describe the purpose, anticipated outcomes, and progress to date of the FDA CID Pilot Program
- Discuss the views of global regulatory authorities (e.g., FDA, EMA, etc.) on CIDs and their suitability/applicability for clinical research in their respective regions; explore aspects and further opportunities for alignment among global regulatory agencies in regard to CID adoption
- Examine several examples of master protocol designs, complex adaptive designs, and designs using Bayesian techniques, and discuss their regulatory suitability, potential challenges, and benefits for patients and medical product developers
- Summarize learnings from the use of master protocols to develop vaccines and therapeutics for COVID-19 and how they apply to developing interventions for other indications

Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 10.75 contact hours or 1.075 continuing education units (CEU's). Type of Activity: Knowledge

ACPE credit is available if you attend the Master Protocol Workshop live virtual November 4-5, 2021. Credit will not be awarded for watching the sessions On Demand post-conference.

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, DECEMBER 17, 2021

Continuing Education Allocation

November 4 Day 1: Master Protocol and Complex Innovative Design: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-21-084-L04-P

November 5 Day 2: Master Protocol and Complex Innovative Design: 5.25 contact hours or .525 CEUs Type of Activity: Knowledge, 0286-0000-21-085-L04-P

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by **Friday, December 17, 2021**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net.**

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend one or both days of the workshop, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Friday, November 19, 2021**.

If you are claiming ACPE credit for this event you must:

1. Complete a Verification of Attendance Form

2. Send back to **CE@DIAglobal.org** by **November 12, 2021**

3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Friday, November 19, 2021.

To access My Transcript:

- Visit DIAglobal.org
- Sign In with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select My Account from the menu
- Select My Transcripts then Manage My Transcripts

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

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

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

TO ACCESS MY TRANSCRIPT

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

DAY ONE | FRIDAY, NOVEMBER 4

Sessions held in ET

10:00-10:15AM

Welcome and Opening Remarks

Speakers/Session Chairs

Robert Beckman, MD, Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Daniel Millar, MBA, Senior Director, Strategic Business Transformation Quantitative Sciences, Janssen Research & Development, United States

Fanni Natanegara, PhD, Research Advisor, Eli Lilly and Company

10:15-10:45AM

Session 1: Keynote – Patient Advocacy

Session Co-Chairs

Zoran Antonijevic, MSc, Vice President, Statistical Consulting, Abond CRO Inc.

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development, United States

Families in the rare disease community are familiar with the complicated, and often frustrating, clinical trial process. How can we make clinical trials faster, less burdensome, and open to all comers, no matter the stage of disease? Would it be possible to understand the individual's response to a compound or biologic (intervention) more quickly? Would it be possible to have less exposure to placebo? To initiate testing of combinations of promising therapeutics earlier? To get to a go/no-go more quickly? Could we learn from our recent experience with COVID-19?

One potential pathway to overcoming obstacles in clinical trials for rare disease therapeutics is to address trial protocols, and a master protocol is one innovative approach that may have advantages. Experiences from their use for COVID-19 and in the development of approaches for Duchenne Muscular Dystrophy can inform their uses for rare indications.

Learning Objectives

- Recognize the benefits of master protocols from a patient perspective
- Explain core patient-centric principles that can drive meaningful outcomes and uptake
- Evaluate existing opportunities to create further efficiency in clinical trials

Speaker
Patricia Furlong, BSN, Founding President and CEO, Parent Project Muscular Dystrophy

10:45-11:00AM **Break**

11:00AM-12:15PM **Session 2:** Decision Making for Master Protocols

Session Co-Chairs
Robert Beckman, MD, Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University

Zoran Antonijevic, MSc, Vice President, Statistical Consulting, Abond CRO Inc.

The session will present basic principles of decision analysis for optimization of clinical trials, programs and portfolios with an emphasis on efficiency. Example applications will include standard protocols and portfolios but will also focus on master protocols. A perspective on this topic from Europe's EU-Pearl Program will also be presented. Finally, the roles of patients and trial participants as decision makers will be discussed.

Learning Objectives

- Understand key concepts related to decision making for clinical trials, master protocols, and portfolios
- Apply selected aspects of decision making with emphasis on master protocols
- Understand Europe's EU PEARL program and approach to decision making in master protocols.
- Define the role of patients as decision makers

Zoran Antonijevic, MSc, Vice President, Statistical Consulting, Abond CRO Inc.

Robert Beckman, MD, Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Martin Posch, PhD, Professor, Medical University of Vienna

Gianna McMillan, **PhD,** Bioethics Institute, Associate Director, Loyola Marymount University

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

12:45-2:00PM **Session 3:** The Art of Implementing and Conducting Platform Trials

Michelle Detry, PhD, Director, Adaptive Trial Execution & Senior Statistical Scientist, Berry Consultants LLC

Anne-Marie Duliege, Pancreatic Cancer ActionNetwork, Chief Medical Officer

This session will present the main strategic and operational considerations during the preparation and implementation of platform trials. Platform trials require an intense collaboration among numerous groups that differs from the standard clinical trial infrastructure. Their viewpoints must be integrated to meet the common goal of the platform. The speakers will describe their roles in the design and conduct of various ongoing platform trials, as well as some of the challenges they may face.

Learning Objectives

- Understand the role of the various partners required to conduct a platform trial, and their contributions to the value of this trial
- Identify the unique perspectives and operational challenges involved in conducting a platform trial
- Understand the importance of an intense collaboration between the partners to address these challenges and contribute to an optimal conduct of a platform trial

Identifying the Right Industry Partners: The Role of the Sponsor
Meredith Buxton, PhD, MPH, Chief Operating Officer, Global Coalition For Adaptive Research

Advancing the Science: The Perspective of an Investigator
Vince Picozzi, Virginia Mason Franciscan Health

Advancing the Science: Joining a Platform Trial: The Perspective of the Biopharma Partner
Ewa Carrier, Executive Director, Fibrogen

Sponsor and the CRO
Len Rosenberg, PhD, RPh, Head of Clinical Operations, Beat AML, a division of The Leukemia and Lymphoma Society

The Critical Role of the Blinded Statistician: Role and Interactions with the FDA
Melanie Quintana, PhD, Statistical Scientist, Berry Consultants, LLC

The Patient's Perspective and the Role of Patients Advisory Group
Sabrina Paganoni, MD, PhD, Assistant Professor, Harvard Medical School, Healey Center for ALS at Mass General

2:00-2:15 PM — **Break**

2:15-3:30PM — **Session 4:** Innovative Uses of Alternative Data Sources

Session Chairs
Pritibha Singh, MBA, MSc, PMP, Global Program Associate Director - Oncology Hematology Development Unit, Novartis, Switzerland

Advancements in use of big data, including applications such as historical controls and synthetic arms, enabled by applications of AI and machine learning, continue to transform clinical trials and research. While the aim continues to be to leverage all data to generate insights, these new approaches come with challenges due to use of data from multiple modalities. Emerging examples of combining multimodal data to generate insights and drive decision making will be shared, and the possibilities that exist through use of these advancements in data use and application will be explored.

Learning Objectives

Describe what different types of data modalities in healthcare can be combined Recognize what sorts of insights drive decision-making from multimodal data Discuss applications of AI and Machine Learning in healthcare

Speakers
Pritibha Singh, MBA, MSc, PMP, Global Program Associate Director - Oncology Hematology Development Unit, Novartis, Switzerland

HOME: A Pilot Natural History Study of Metachromatic Leukodystrophy to Augment Controls for Regulatory Consideration
Hussein Ezzeldin, PhD, Senior Staff Fellow, U.S. Food and Drug Administration (FDA)

Historical Control Borrowing in Clinical Trial Analyses
Duncan Rotich, PhD, Senior Manager Biostatistics, Bristol Myers Squibb

Speaker
Jo Aggarwal, Founder and CEO, Wysa

3:30-3:45PM — **Break**

3:45-5:00PM

Session 5: Challenges in the Integration of Digital Data and Telemedicine to Clinical Trials

Session Co-Chairs
Fanni Natanegara, PhD, Research Advisor, Eli Lilly and Company

Rui (Sammi) Tang, PhD, Vice President, Global Head of Biometric, Oncology, Servier Pharmaceuticals

The digital revolution has transformed many areas of our life including pharmaceutical drug development to enhance efficiency and optimize value in clinical trials. The session is meant to draw more attention in the face of the coronavirus disease 2019 (COVID-19) outbreak, which has caused unprecedented disruption in the conduct of clinical trials and presented considerable challenges and opportunities for clinical trialists and data analysts. Speakers will present opportunities with virtual, remote, digital, or decentralized clinical trials as viable options to enhance efficiency in drug development and, more importantly, in offering diverse patients easier and attractive means to participate in clinical trials. Case studies will be shared to highlight benefit and challenges in using digital data and telemedicine to clinical trials including data acquisition, processing, and analysis in a virtual trial setting. Issues of patient safety, measurement validity, and data integrity will be reviewed, and considerations are put forth with reference to the mitigation of underlying regulatory and operational barriers.

Learning Objectives:

- Articulate principles of decentralized clinical trials and remote data collection in clinical trials
- Develop and evaluate options for implementing telemedicine and digital health tools
- Identify challenges and potential solutions to remote data collection
- Describe ownership and sharing of digital data when multiple sponsors are involved in master protocol
- Identify benefit and obstacles of bringing the trials to the patients; technique status in DCT trials constrain and advancement

Venkat Sethuraman, PhD, MBA, Senior Vice President, Global Biometrics and Data Sciences, Bristol Myers Squibb

Mercedeh Ghadessi, MS, MSc, Principal Statistician in Biomarker and Data Insight Bayer

Linda Simba, Eli Lilly and Company

DAY TWO | FRIDAY, NOVEMBER 5

9:50-10:00AM

Welcome Remarks

10:00-11:15AM

Session 6: Global Regulatory Discussion - Perspectives from Cross-Region Regulatory Authorities

Session Co-Chairs
Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development

Pritibha Singh, MBA, MSc, PMP, Global Program Associate Director - Oncology Hematology Development Unit, Novartis, Switzerland

Master Protocols and Complex Innovative Designs have been increasingly embraced by drug developers, patient advocates and regulators to overcome limitations of traditional clinical development approaches. Experience from the COVID-19 pandemic as well as sponsor consultation with multiple global regulator authorities has highlighted the importance of harmonized regulatory processes and standards which enable innovation for patients. This session will address important aspects of regulatory requirements.

Learning Objectives

- Identify similarities and differences in regulator experience, procedures, and opportunities for consultation

- Understand how the regulatory environment for Master Protocols and Complex Innovative Designs has evolved
- Identify specific points of attention to be successful with Master Protocol approaches and Complex Innovative Designs to meet regulatory requirements

Speakers
Nicholas Richardson, DO, MPH, Medical Officer, Division of Hematologic Malignancies, FDA

Kazuhiko Mori, Managing Director, Japan Pharmaceutical Manufacturers Association (JPMA)

Effective use of Complex Innovative Designs; MHRA Experience with Platform Trials
Kirsty Wydenback, DrMed, MSc, Expert Medical Assessor at Medicines and Healthcare products, MHRA, United Kingdom

11:45AM-12:15PM **Break**

11:30-12:45PM **Session 7:** Complex Innovative Trial Designs: From Pilot to Practice

Session Co-Chairs
Kristin Dolinski, Deputy Vice President, Science and Regulatory Advocacy, PhRMA

Yi Liu, PhD, Executive Director Biostatistics, Nektar Therapeutics,

Dionne Price, PhD, Director of Division of Biometrics IV in the Office of Biostatistics, CDER/FDA

Complex innovative designs (CIDs) for clinical trials provide sponsors the opportunity to design and implement more efficient trials that can enhance and potentially expedite the drug development process compared to conventional designs, thereby bringing new medicines to patients sooner. The U.S. Food and Drug Administration demonstrated its encouragement for such clinical trial innovations through the creation of the CID Pilot Meeting Program; the purpose of the pilot is to support the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. The pilot, agreed to as a performance goal under PDUFA VI, gives sponsors whose meeting requests are granted by the Agency an important opportunity to have increased interaction with FDA staff to discuss their proposed CID approaches. Since its introduction, many sponsors have interacted with FDA through this program to gain alignment on their proposed novel CIDs. This session will provide attendees with an overview of the FDA CID Pilot Meeting Program and feature discussion of specific case examples. Recent advances in novel design concepts will also be discussed.

Learning Objectives

- Discuss the status of the FDA CID Pilot Meeting Program and outline its future directions
- Summarize case examples of the FDA CID Pilot Meeting Program and identify areas that may require additional discussion with FDA
- Describe and apply novel clinical trial design concepts and explain how they can increase efficiency in drug development

PDUFA VI CID Pilot Program Update
Dionne Price, PhD, Director of Division of Biometrics IV in the Office of Biostatistics, CDER/FDA

Label Enabling Dynamic Borrowing with External Control for OS – FDA Complex Innovative Designs Pilot
Jiawen Zhu, PhD, Senior Principal Statistical Scientist, Genentech/Roche

Herbert Pang, PhD, MBA, Expert Statistical Scientist, Genentech/Roche

A Bayesian phase I/II platform design for co-developing drug combination therapies for multiple indications
Ying Yuan, PhD, Bettyann Asche Murray Distinguished Professor, University of Texas MD Anderson Cancer Center

The 2-in-1 Design and its Extensions and Applications
Cong Chen, PhD, Director, Early Oncology Development Statistics, Merck Co., & Inc.

12:45-1:30PM **Break**

1:30-2:45PM **Session 8:** Innovative Designs for Acute Myeloid Leukemia: Patient, Sponsor, and Investigator Perspectives

Session Chairs
Robert Beckman, MD, Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

The session will introduce the audience to two innovative clinical study designs for acute myeloid leukemia (AML), an n-of-1 design (Multiomics Precision Medicine) and a master protocol (BEAT AML) and culminate in a panel discussion which will use these examples to illuminate complex innovative designs from the perspectives of patients, trial participants, sponsors, and investigators.

Learning Objectives

- Understand the concept of n-of-1 designs
- Understand how patients and trial participants view n-of-1 designs; how they may benefit and what are potential pitfalls
- Understand how investigators might work with patient communities and trial participants when designing and executing master protocols and n-of-1 designs
- Understand the view of the Sponsor participating in a complex innovative design

Precision Medicine Treatment in Older AML
Amy Burd, PhD, Vice President, Research Strategy, The Leukemia & Lymphoma Society

Multi-Omic and Functional Drug Screening Approach to Treatment
Pamela Becker, MD, PhD, Professor of Clinical Medicine University of California Irvine

Speakers
Uma Borate, MD, Associate Professor the Ohio State University

Kevin Harrang, JD

Jorge DiMartino, MD, Chief Medical Officer, Kronos Bio

Tony Blau, MD, Founder and Chief Executive Officer All4 Cure

Ken Dixon, MD, Founder, Chief Medical Officer, SpeciCare

Crystal Reinhart, PhD, Center for Prevention Research and Development, School of Social Work, University of Illinois at Urbana-Champaign

2:45-3:00PM **Break**

3:00-4:15PM **Session 9:** Clinical Research in a Global Pandemic: Lessons Learned for Drug Development

Session Co-Chairs
Cristiana Mayer, DrSc, PhD, Head of Biostatistics, Johnson & Johnson Vision

AnnCatherine Downing, PharmD, Senior Research Advisor – Clinical, Eli Lilly and Company

Rui (Sammi) Tang, PhD, Vice President, Global Head of Biometric, Oncology, Servier Pharmaceuticals,

Traditional ethical principles that guide clinical research remain the guiding compass for physicians, patients, public health officials, investigators, drug developers, and the public. Accelerating the process of delivering safe and effective treatments and vaccines for areas of unmet medical need is a moral imperative. The COVID-19 pandemic has resulted in innovative new approaches in clinical research and brought vaccine and drug development into mainstream consciousness. Some of the innovations offer new insights into trial design, conduct, data sharing, and regulatory interactions that are broadly applicable. This session will highlight COVID-19 clinical research examples with an emphasis on practices that should be carried forward to speed new therapies to patients.

Learning Objectives

- Outline multiple research efforts for the prevention and treatment of COVID-19
- Describe innovative approaches utilized and found most efficient driven by the COVID-19 pandemic
- Identify transferable learnings from COVID-19 research into other research programs

Speakers

The Race Towards the COVID-19 Vaccine: The Janssen Example
An Vandebosch, PhD, Senior Scientific Director, Statistical Modeling and Methodology, Janssen R&D, Belgium

Developing and Registering a Treatment for COVID-19 (Bamlanivimab): Program Lessons Learned from the first FDA Emergency Use Authorization Treatment for COVID
Kristi Huntington, MS, Sr. Advisor, Pharmaceutical Project Management, Eli Lilly and Company

Lisa LaVange, PhD, Professor and Associate Chair, Department of Biostatistics, University of North Carolina at Chapel Hill

Steve Webb, The George Institute for Global Health, Australia

4:15-4:30PM **Closing Remarks**