

Heart Failure Collaboratory Fall 2024 Think Tank Meeting: New Initiatives
Friday, September 13, 2024 | 8:45am – 12:00pm ET | Via Zoom

8:45 – 8:50am

WELCOME AND OPENING REMARKS

Christopher O'Connor, MD

Part 1: NOVEL STATISTICAL CONCEPTS PROPOSAL
Moderators: Mona Fiuzat, PharmD, Scott Solomon, MD, Christopher O'Connor, MD

8:50 – 9:00am

Introduction: Why do we need “Novel Statistical Concepts”?
Scott Solomon, MD; Janet Wittes, PhD

9:00 – 9:30am

New Quantitative Methods for Cardiovascular Clinical Trials (30 minutes)
Natasha Muhlemann, MD, MBA

- Application of Bayesian methods to clinical trials – case examples
- Strategies & methods when mortality is a competing risk
- ML-based predictive modelling to decrease the uncertainty in effects estimated from randomized trials – illustration of prognosis covariate adjustment (PROCOVA) used for RCT with MACE

9:30 – 10:00am

Discussion, Proposal: New Statistical “Quant” Working Group (30 minutes)
Discussion: ALL HFC Participants

Panelists: Bill Abraham, Vanessa Blumer, Biykem Bozkurt, Javed Butler, Maria Rosa Costanzo, Akshay Desai, Michael Felker, Charu Gandotra, James Januzzi, JoAnn Lindenfeld, Milton Packer, Mitch Psocka, Meir Shinnar, Norman Stockbridge, Bram Zuckerman

Statistical Panel: Brian Claggett, Jennifer Clark, Jason Connor, David DeMets, Tom Fleming, Eric Leifer, Chris Lindsell, Devan Mehrotra, Cyrus Mehta, Stuart Pocock, Ben Saville, LJ Wei, Janet Wittes

Part 2: THE ROLE OF AI IN THE FUTURE OF HF TRIALS – Brief Update

10:00 – 10:10am

Update: The Role of AI in the Future of HF Trials
Learnings from Special Focus; Manuscript Update (10 minutes)
Jon Cunningham, MD

10:10 – 10:20 am

BREAK

Part 3: PHASE 2 STUDY ENDPOINTS IN HF DEVELOPMENT PROGRAMS
Moderators: William Abraham, MD, Christopher O'Connor, MD, Mona Fiuzat, PharmD

10:20 – 10:50am

Phase 2 Study Endpoints (30 min)
Doug Mann, MD; Scott Solomon, MD

10:50 – 11:50pm

Discussion, Proposal: HFC Position Paper (60 minutes)
Discussion: ALL HFC Participants

Panelists: Biykem Bozkurt, Michael Bristow, Peter Carson, Michael Felker, Barry Greenberg, James Januzzi, Marv Konstam, Anu Lala, JoAnn Lindenfeld, Robert Mentz, Chinwe Okoro, Mitch Psocka, Scott Solomon, Norman Stockbridge, Sairah Thommi, Aliza Thompson, Minnow Walsh, Celia Witten, Bram Zuckerman
Statistical Panel: Brian Claggett, Jason Connor, David DeMets, Tom Fleming, Eric Leifer, Chris Lindsell, Stuart Pocock, Ben Saville, Janet Wittes

11:50 - 12:00pm

Next Steps, WRAP UP AND ADJOURN

Christopher O'Connor, MD

Invited Speakers and Panelists

William Abraham, MD

*Professor of Medicine, Physiology, Cell Biology
College of Medicine Distinguished Professor
Division of Cardiovascular Medicine
Ohio State University*

Vanessa Blumer, MD

*Advanced Heart Failure and Transplant Cardiologist
Associate Director, Heart Failure Research
Medical Co-Director, Heart Failure Research
Inova Schar Heart and Vascular*

Biykem Bozkurt, MD, PhD

*Professor of Medicine
Director, Winters Center for Heart Failure Research
Associate Director, Cardiovascular Research Institute
Vice-Chair of Medicine, Baylor College of Medicine*

Michael Bristow, MD, PhD

*Professor of Medicine (Cardiology)
University of Colorado Anschutz Medical Campus
Director, Pharmacogenomics Section
CU Cardiovascular Institute*

Javed Butler, MD, MPH, MBA

*SVP, Baylor Health System
President, Baylor Scott & White
Research Institute*

Peter Carson, MD

*Heart Failure Cardiologist
Washington, DC VMAC (Retired)*

Brian Claggett, PhD

*Chief Statistician, Cardiac Imaging Core
Laboratory and Clinical Trials Endpoints Center
Brigham and Women's Hospital
Assistant Professor, Harvard Medical School*

Jennifer Clark, PhD

*Statistical Team Leader for the Cardiology &
Nephrology Statistical Review Team
CDER, U.S. FDA*

Jason Connor, PhD

*President & Lead Statistical Scientist
ConfluenceStat LLC*

Maria Rosa Costanzo, MD

*Medical Director, Advocate Medical Group
Midwest Heart Specialists
HF and PAH Programs Medical Director, Edward
Hospital Center for Advanced Heart Failure*

Jon Cunningham, MD

*Heart Failure Cardiologist
Brigham and Women's Hospital*

David DeMets, PhD

*Max Halperin Emeritus Professor of Biostatistics
University of Wisconsin – Madison*

Akshay Desai, MD, MPH

*Medical Director, Cardiomyopathy and Heart Failure
Program, Advanced Heart Disease Section
Associate Professor, Harvard Medical School
Brigham and Women's Hospital*

Andrew Farb, MD

*Medical Officer
CDRH, U.S. FDA*

Michael Felker, MD, MHS

*Professor of Medicine
Director, Cardiovascular Research, DCRI
Vice-Chief of Cardiology for Clinical Research
Duke University School of Medicine*

Tom Fleming, PhD

*Professor Biostatistics and Statistics
University of Washington*

Mona Fiuzat, PharmD

*Associate Professor of Medicine
Duke University School of Medicine
Senior Scientific Advisor, CDER, U.S. FDA*

Charu Gandotra, MD

*Medical Officer
CDER, U.S. FDA*

Barry Greenberg, MD

*Director, Advanced Heart Failure Treatment Program
Professor of Medicine
UC San Diego Health*

James Januzzi, MD

*Hutter Family Professor of Medicine
Harvard Medical School*

Marv Konstam, MD

*Chief Physician Executive, The CardioVascular Center
Tufts Medical Center*

Anu Lala, MD

*Assistant Professor of Medicine
Icahn School of Medicine at Mount Sinai*

Eric Leifer, PhD

*Mathematical Statistician
Office of Biostatistics Research, NHLBI*

JoAnn Lindenfeld, MD

*Professor of Medicine
Advanced Heart Failure and Transplantation
Vanderbilt Heart and Vascular Institute*

Christopher Lindsell, PhD

*Professor and Co-Chief of Biostatistics
Duke University
Director, Data Science & Biostatistics, DCRI*

Douglas Mann, MD

*Ada L. Steiner Professor in Cardiology
Professor of Cell Biology and Physiology
Washington University School of Medicine*

Devan Mehrotra, PhD

*Vice President, Biostatistics, Merck & Co.
Adjunct Professor, Biostatistics
University of Pennsylvania*

Cyrus Mehta, PhD

*Co-Founder and President, Cytel Inc.
Adjunct Professor of Biostatistics
Harvard T.H. Chan School of Health*

Robert Mentz, MD

*Associate Professor
Chief, Heart Failure Section
Associate Program Director, Duke Cardiovascular
Disease Fellowship, Duke University*

Natasha Muhlemann, MD, MBA

*Vice President, Strategic Consulting
Cytel*

Christopher O'Connor, MD

*President, Inova Schar Heart and Vascular
Professor of Medicine
Duke University School of Medicine*

Chinwe Okoro, MD

*Office of Therapeutic Products
CBER, U.S. FDA*

Milton Packer, MD

*Distinguished Scholar in CV Science
Baylor Heart and Vascular Institute*

Stuart Pocock, PhD, MSc

*Professor, London School of Hygiene and Tropical
Medicine*

Mitchell Psootka, MD, PhD

*Section Chief, Heart Failure and Transplant Director,
Infiltrative Cardiomyopathy Center
Inova Schar Heart and Vascular
Medical Officer
DCN, U.S. FDA*

Ben Saville, PhD

*President and Lead Statistical Scientist
Adaptix Trials LLC*

Meir Shinnar, MD, PhD

*Medical Officer
CDRH, U.S. FDA*

Scott Solomon, MD

*The Edward D. Frohlich Distinguished Chair
Professor of Medicine, Harvard Medical School
Director, Noninvasive Cardiology
Brigham and Women's Hospital*

Norman Stockbridge, MD, PhD

*Director, Division of Cardiovascular and Renal
Products
CDER, U.S. FDA*

Sairah Thommi, MD

*Medical Officer
CBER, U.S. FDA*

Aliza Thompson, MD, MS

*Deputy Director, Division of Cardiology and
Nephrology
CDER, U.S. FDA*



Mary (Minnow) Walsh, MD

*Medical Director, Heart Failure and Cardiac
Transplantation
St. Vincent Heart Center*

LJ Wei, PhD

*Professor of Biostatistics
Harvard T.H. Chan School of Public Health*

Celia Witten, MD, PhD

*Director of the Office of Cellular, Tissue and Gene
Therapy, CBER, U.S. FDA*

Janet Wittes, PhD

*Principal
Wittes LLC*

Bram Zuckerman, MD

*Director, FDA Division of Cardiovascular Devices
CDRH, U.S. FDA*