

**HFC MEETING:**

**Novel Statistical Concepts for HF Drug and Device Development  
Friday, October 14, 2022, 8:30 am ET – 1:15 pm ET | Remote Meeting: Zoom**

<p><b>8:30 – 8:35 AM</b></p>	<p><b>Welcome and Overview</b> <i>Scott Solomon, MD, Christopher O'Connor, MD, Janet Wittes, PhD</i></p>
<p><b>Session 1</b> <b>8:35 – 9:15 AM</b></p>	<p><b>Part 1: Hazard Ratio Drift</b> <b>Moderators: JoAnn Lindenfeld, MD, Christopher O'Connor, MD</b> 8:35 – 8:55: <i>Jordan Pomeroy; LJ Wei</i></p> <p><i>Background and Concept</i> <i>Internal / inherent issues with Cox Models</i> <i>External influences not related to methodology (ex: COVID, war)</i></p> <p><b>Examples:</b> 8:55 – 9:00: <i>DELIVER (Scott Solomon, Brian Claggett)</i> 9:00 – 9:05: <i>STICH (Chris O'Connor, Kevin Anstrom)</i> 9:05 – 9:10: <i>GUIDE-HF (JoAnn Lindenfeld, John Henderson)</i> 9:10 – 9:15: <i>Potential solutions to mitigate issues (LJ Wei, Jordan Pomeroy)</i></p>
<p><b>9:15 – 10:45 AM</b></p>	<p><b>Part 1 Panel Discussion</b> <b>Open Discussion (45 min)</b> <b>Regulatory Perspectives and Implementation (45 min)</b></p> <p><i>Statistical Panel: Greg Alexander, Kevin Anstrom, Brian Claggett, Jason Connor, David DeMets, Eric Leifer, Cyrus Mehta, Mark Rothmann, Ben Saville, Yanping Qu, LJ Wei, Jialu Zhang</i></p> <p><i>Panel: William Abraham, Phil Adamson, Stefan Anker, Biykem Bozkurt, Javed Butler, Marty Lefkowitz, John McMurray, Robert Mentz, Marc Pfeffer, Scott Solomon, Norman Stockbridge, Michael Zile, Bram Zuckerman</i></p>
<p><b>10:45 – 11:00 AM BREAK</b></p>	
<p><b>Session 2</b> <b>11:00 – 11:40 AM</b></p>	<p><b>Part 2: Contemporary Challenges in Clinical Trial Design – Focus on Estimands</b> <b>Moderators: Scott Solomon, MD, Janet Wittes, PhD</b> 11:00 – 11:40: <i>Vanessa Blumer; Devan Mehrotra</i> <i>Introduction and Clinical Perspective - Vanessa Blumer, MD</i> <i>Statistical Concepts, Examples– Devan Mehrotra, PhD</i></p>



<b>11:45 – 1:15 PM</b>	<p><b>Part 2 Panel Discussion</b> <b>Open Discussion (45 min)</b> <b>Regulatory Perspectives and Implementation (45 min)</b></p> <p><i>Statistical Panel: Kevin Anstrom, Brian Claggett, Jason Connor, David DeMets, Eric Leifer, Kerry Lee, Cyrus Mehta, Mark Rothmann, Ben Saville, Yanping Qu, LJ Wei, Jialu Zhang, Greg Alexander</i></p> <p><i>Panel: William Abraham, Vanessa Blumer, Michael Felker, Anu Lala, JoAnn Lindenfeld, Bettina Kraus, John McMurray, Devan Mehrotra, Chris O'Connor, Marc Pfeffer, Mitch Psootka, Norman Stockbridge, John Teerlink, Bram Zuckerman</i></p> <p><b>Discussion:</b></p> <ol style="list-style-type: none"><li>1. Rescue Medication</li><li>2. Stopping Treatment</li><li>3. Crossover</li><li>4. Subgroups</li></ol>
<b>1:15 PM</b>	<p><b>Closing Remarks and Adjourn</b> <i>Scott Solomon, MD, Janet Wittes, PhD, Christopher O'Connor, MD</i></p>



## PROGRAM CHAIRS

### **Mona Fiuzat, PharmD**

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

### **Christopher O'Connor, MD**

*CEO and Executive Director  
Inova Heart & Vascular Institute  
Professor of Medicine  
Duke University School of Medicine*

### **Scott Solomon, MD**

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

### **Janet Wittes, PhD**

*Statistician  
Former President, Statistics Collaborative, Inc*

## FACULTY AND STATISTICAL PANEL

### **William Abraham, MD**

*Distinguished Professor  
Division of Cardiovascular Medicine  
Ohio State University*

### **Philip Adamson, MD**

*Divisional Vice President and Chief Medical Officer  
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### **Greg Alexander, PhD**

*Director, Biostatistics Division  
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### **Kevin Anstrom, PhD**

*Professor, Department of Biostatistics  
Director, Collaborative Studies Coordinating Center  
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### **Vanessa Blumer, MD**

*Advanced Heart Failure and Transplant Cardiology  
Fellow, Cleveland Clinic Foundation*

### **Biykem Bozkurt, MD, PhD**

*Cain Chair and Professor of Medicine  
Dean of Faculty Development  
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### **Javed Butler, MD, MPH, MBA**

*SVP, Baylor Scott & White Health System, President,  
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### **Brian Claggett, PhD**

*Chief Statistician, Cardiac Imaging Core  
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### **Jason Connor, PhD**

*President & Lead Statistical Scientist  
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### **David DeMets, PhD**

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### **John Henderson, MSc**

*Sr. Manager Clinical Research & Statistician  
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*Professor of Medicine & Consultant Cardiologist  
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*Associate Professor of Medicine, Duke University  
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