

HFC MEETING: Novel Statistical Concepts for HF Drug and Device Development
Friday, November 1, 2024, 8:15 am ET – 1:15 pm ET | Remote Meeting: Zoom

8:15 – 8:20am	WELCOME AND OVERVIEW
<i>Scott Solomon, MD, Christopher O'Connor, MD, Janet Wittes, PhD</i>	
Part One: 8:20 – 10:40am	Part One: Trial Data “Borrowing” <i>Moderators: JoAnn Lindenfeld, MD, Christopher O'Connor, MD</i>
<p>8:20 – 9:00</p> <p>9:00 – 9:40</p>	<p>Background and Concept <i>Introductory briefings:</i></p> <ul style="list-style-type: none"> - <i>Applying Bayesian vs. Frequentist Approaches to various problems (John Bittl) (8:20 – 8:30)</i> - <i>What is borrowing? Bayesian borrowing for Dummies (Jason Connor) (8:30 – 8:40)</i> - <i>Pros/Cons of each approach: Janet Wittes (Frequentist) (8:40 – 8:50); Scott Berry (Bayesian) (8:50 – 9:00)</i> <p>Examples (Tentative)</p> <ul style="list-style-type: none"> - <i>RESPONDER-HF, CORVIA (Amy Crawford, Jan Komtebedde,) (9:00 – 9:10)</i> - <i>Galactic 2.0, Cytokinetics (Fady Malik) (9:10 – 9:20)</i> - <i>Optimizer Device – Frequentist “Borrowing” Example vs. Bayesian approach that was used (William Abraham, JoAnn Lindenfeld, Ben Saville) (9:20 – 9:30)</i> - <i>Bayesian re-analysis of PARAGON (John Bittl, Brian Claggett) (9:30 – 9:40)</i>
9:40 – 10:40	<p>Part One Open Discussion, Regulatory Perspectives and Implementation - ALL HFC MEMBERS (9:40 – 10:40)</p> <p>Statistical Panel: <i>Scott Berry, Brian Claggett, Jason Connor, David DeMets, Thomas Fleming, Folke Folkvaljon, Telba Irony, Eric Leifer, Devan Mehrotra, Natasha Muhlemann, Ben Saville, LJ Wei, Janet Wittes</i></p> <p>Clinical Panel: <i>William Abraham, John Bittl, Maria Borentain, Biykem Bozkurt, Javed Butler, Akshay Desai, Jan Komtebedde, Anu Lala, Fady Malik, Robert Mentz, Milton Packer, Lothar Roessig, Scott Solomon, John Teerlink, Muthiah Vaduganathan</i></p> <p>FDA Panel: <i>Keith Aaronson, Gregory Alexander, Jennifer Clark, Andrew Farb, Charu Gandotra, Mori Krantz, Laura Lu, Nelson Lu, Li Ming Dong, Jordan Pomeroy, Mitch Pstotka, Mark Rothmann, Yanping Qu, Lilly Yue, Jialu Zhang, Yu (Audrey) Zhao, Norman Stockbridge, Bram Zuckerman</i></p>
10:40 – 10:50	BREAK



Part Two: 10:50 – 11:40am	Part Two: Interim Analysis <i>Moderators: Janet Wittes, PhD, Scott Solomon, MD</i>
10:50 – 11:10	<i>Interim Analysis – Who is paying for the free lunch? What does it mean that Bayesian analysis has “no alpha penalty”? (Telba Irony) (10:50 – 11:10)</i>
11:10 – 11:40	<i>Part Two Discussion - ALL (11:10 – 11:40)</i>
Part Three: 11:40 – 1:15pm	Part Three: Expanded endpoints in HF – “other things that matter” <i>Moderators: Janet Wittes, PhD, Scott Solomon, MD</i>
11:40 – 12:10	Expanded endpoints in HF – “other things that matter” (Scott Solomon, Muthiah Vaduganathan) (11:40 – 12:10) <i>ex: initiation or augmentation of oral diuretics, other clinically meaningful events</i>
12:10 – 1:15	Part Three Open Discussion, Regulatory Perspectives and Implementation – ALL HFC MEMBERS (12:10 – 1:15) Statistical Panel: Scott Berry, Brian Claggett, Jason Connor, David DeMets, Thomas Fleming, Folke Folkvaljon, Telba Irony, Eric Leifer, Natasha Muhlemann, Frank Rockhold, Ben Saville, LJ Wei, Janet Wittes Clinical Panel: William Abraham, Amrut Ambardekar, Ankeet Bhatt, Vanessa Blumer, Bobbi Chapman, Ricardo Rocha, Javed Butler, Maria Rosa Costanzo, Barry Greenberg, Carine Hamo, Jim Januzzi, Mariell Jessup, Marv Konstam, Anu Lala, JoAnn Lindenfeld, Robert Mentz, Rhonda Monroe FDA Panel: Keith Aaronson, Gregory Alexander, Jennifer Clark, Charu Gandotra, Mori Krantz, Laura Lu, Nelson Lu, Li Ming Dong, Jordan Pomeroy, Mitch Psootka, Yanping Qu, Mark Rothmann, Fortunato Fred Senatore, Norman Stockbridge, Aliza Thompson, Lilly Yue, Jialu Zhang, Yu (Audrey) Zhao, Bram Zuckerman
1:15pm	CLOSING REMARKS AND ADJOURN

Scott Solomon, MD, Christopher O’Connor, MD, Janet Wittes, PhD

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