



Heart Failure Collaboratory Special Focus Meeting
Interpreting and Implementing New Clinical Trials Data
FDA White Oak Campus, Great Room
March 6th, 2020

8:00 am – 8:40 am SECURITY, BREAKFAST AND REGISTRATION

8:45 am – 8:55 am WELCOME AND OPENING REMARKS

Javed Butler, MD, MPH, MBA
Christopher O'Connor, MD
JoAnn Lindenfeld, MD
Mona Fiuzat, PharmD

8:55 – 9:00am State of the Union: HF Collaboratory
Mona Fiuzat, PharmD

Part I: Baseline Care

Moderators: Javed Butler, MD, MPH, MBA, Marvin Konstam, MD

9:00 – 9:10 am Review of baseline care reported in heart failure trials
Muthiah Vaduganathan, MD, MPH
a. Medications and Dosing
b. Devices
c. Other (MR, ischemia, iron etc.)

9:10 – 9:20 am HF-ARC: Defining Optimal GDMT
Mona Fiuzat, PharmD

9:20 – 9:25 am HF-ARC: Defining Optimal Device Therapy
William Abraham, MD

9:25 – 9:30 am The Lean CRF: what should be standard reporting in clinical trials
Mitch Psotka, MD, PhD

9:30 – 9:35 am How to interpret clinical trials results when baseline care is not GDMT (or not reported)?
John Teerlink, MD

9:35 – 10:20 am Panel Discussion (45 min)
Panelists: Christopher O'Connor, MD, Emily Zeitler, MD, MHS, Muthiah Vaduganathan, MD, MPH, Mona Fiuzat, PharmD, William Abraham, MD, John Teerlink, MD, Mitch Psotka, MD, PhD, Bram Zuckerman, MD

10:20 – 10:40 am BREAK

Part II: Statistical Considerations

Moderators: Bram Zuckerman, MD, Janet Wittes, PhD

- 10:45 – 10:55 am** **How to interpret and design interaction analysis: Statistical considerations for power, pre-specification, and analytic plan**
Janet Wittes, PhD
- 10:55 – 11:05 am** **When and how to use secondary endpoints for indication or clinical decision making**
Scott Solomon, MD
- 11:05 – 11:20 am** **Case examples and how to interpret**
JoAnn Lindenfeld, MD and Janet Wittes, PhD
- a. ARNI and MRA
 - b. SGLT2i and ARNI
 - c. Females – Paragon
- 11:20 – 12:05 pm** **Panel Discussion (45 min)**
Panelists: Scott Solomon, MD, William Abraham, MD, JoAnn Lindenfeld, MD, Eric Leifer, PhD, Norman Stockbridge, MD, PhD, Marty Lefkowitz, MD, Michael Bristow, MD, PhD, Marvin Konstam, MD

12:05 – 12:55 pm

LUNCH

Part III: Clinical Guidance and Future Trials

Moderators: Mona Fiuzat, PharmD, Randall Starling, MD

- 1:00 – 1:25 pm**
(5 min each) **Clinical guidance when baseline therapy not optimal or tested (pros and cons)**
- a. Use all drugs – Gregg Fonarow, MD
 - b. Secondary data analysis of trial database and Risk score based – William Abraham, MD
 - c. Biomarker based – Michael Felker, MD, MHS
 - d. Genetic based – Michael Bristow, MD, PhD
- 1:30 – 1:50 pm** **Future Trials (5 min each)**
- a. Sequencing trials – Peter Carson, MD
 - b. Withdrawal trials (ethical consideration) – Christopher O'Connor, MD
 - c. RWE – ARNI vs. SGLT2i – Gregg Fonarow, MD
- 1:50 – 2:35 pm** **Panel Discussion (45 min)**
Panelists: Gregg Fonarow, MD, Peter Carson, MD, William Abraham, MD, Christopher O'Connor, MD, Orly Vardeny, PharmD, MS, Michael Felker, MD, MHS, Jaime Murillo, MD, Deborah Smith, MD, MPH
- 2:35 – 2:55 pm** **Conclusion and Next Steps**
Javed Butler, MD, MPH, MBA
HFC Chairs: Christopher O'Connor, MD Norman Stockbridge, MD, PhD, Bram Zuckerman, MD, Mona Fiuzat, PharmD, JoAnn Lindenfeld, MD

3:00 pm

Adjourn

Participant List

William Abraham, MD

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

Naomi Aronson, PhD

Executive Director
Clinical Evaluation, Innovation and Policy
Blue Cross Blue Shield Association

Ankeet Bhatt, MD, MBA

Cardiovascular Disease Fellow
Brigham and Women's Hospital
Harvard Medical School

Michael Bristow, MD, PhD

Professor of Medicine (Cardiology)
University of Colorado Division of Cardiology
President and CEO, ARCA Biopharma

Javed Butler, MD, MPH MBA

Chair of the Department of Medicine
University of Mississippi Medical Center

Peter Carson, MD

Clinical Professor, Georgetown University
Chief, Heart Failure Service
Washington DC Veterans Affairs Medical Center

Annunziata Cotugno, MD

Visiting Research Scholar
Inova Heart and Vascular Institute

Ersilia DeFilippis, MD

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(OHT-2)
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Co-Director, UCLA Preventative Cardiology Program
Co-Chief, UCLA Division of Cardiology
The Eliot Corday Chair in Cardiovascular Medicine and
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UCLA Health

Stephen Greene, MD

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Mathematical Statistician
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Professor of Medicine
Vanderbilt University

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Value Creation Team
UnitedHealthcare

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Visiting Research Scholar
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Advanced Heart Failure, Transplant, and Pulmonary
Hypertension
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Laboratory,
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for Drug Evaluation and Research
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Medical Director, Office of Clinical Affairs
Blue Cross Blue Shield Association

Scott Solomon, MD
The Edward D. Frohlich Distinguished Chair
Professor of Medicine, Harvard Medical School
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Mary Ross Southworth, PharmD
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U.S. Food and Drug Administration

Janet Wittes, PhD
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Acting Director, Rare Disease Group, OND/CDER
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Norman Stockbridge, MD, PhD
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Francisco (UCSF)
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Emily Zeitler, MD, MHS

*Assistant Professor of Medicine
Cardiac Electrophysiology
Dartmouth-Hitchcock Medical Center*

Bram Zuckerman, MD

*Director, FDA Division of Cardiovascular Devices
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Industry Attendees

Abbott

Philip Adamson, MD

Amgen

Jose Flores Arredondo, MD
John Groake, MD

Arena Pharmaceuticals

Brandon Walsh, PhD

AstraZeneca

Jersey Chen, MD, PhD
Joan Buenconsejo, PhD
Richard George, MD
Per Johanson, MD, PhD
Craig Zecher

Bayer

Lothar Roessig, MD

Boehringer Ingelheim Pharmaceuticals

Mark DeBellis, MS
Robb Kociol, MD, MA

CVRx

Dean Bruhn-Ding, BS
Liz Galle, BS, MPH

Cytokinetics

Stuart Kupfer, MD
Fady Malik, MD, PhD

Eli Lilly and Company

Chunmei Zhou, MS

Masahiro Murakami, MD, PhD

Wei Ni, PhD Pharmacology

Marija Popovic, PhD

Jeffrey Riesmeyer, MD

Jennie Walgren, PhD

FIRE1 Foundry

Louise Corcoran, B.E., MEngSC

Impulse Dynamics

Angela Stagg, BS

Ishu Rao, MD

LivaNova

Lorenzo DiCarlo, MD

Medtronic

Dan Schaber, PharmD

MyoKardia

Jay Edelberg, MD

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Novartis

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XyloCor Therapeutics

Al Gianchetti