



HFC Special Focus Meeting: Optimal Background Medical Therapy for Clinical Trials

10:00am – 12:20pm ET, March 12, 2021

Remote Via Zoom

10:00 – 10:05am WELCOME AND OPENING REMARKS

Christopher O'Connor, MD
Norman Stockbridge, MD, PhD
Bram Zuckerman, MD
Mona Fiazat, PharmD

10:05 – 10:15am Regulatory Perspectives

10:05 – 10:10am *Drugs, Norman Stockbridge, MD, PhD, Ellis Unger, MD*
10:10 – 10:15am *Devices, Bram Zuckerman, MD*

10:15 – 10:25am Debate

10:15 – 10:20am *We NEED minimum standard of baseline care for future HFREF trials, Javed Butler, MD, MPH, MBA*
10:20 – 10:25am *We DO NOT NEED minimum standard of baseline care for future HFREF trials, Christopher O'Connor, MD*

10:25 – 11:05am Optimal Background Medical Therapy for Clinical Trials

A case for or against drug being considered in baseline standard therapy for future trials (yes or no, in some cases)
Moderators: *Javed Butler, MD, MPH, MBA, JoAnn Lindenfeld, MD*

10:25 – 10:30am *Basic Necessities, Gregg Fonarow, MD*
10:30 – 10:35am *New Drugs: SGLT2 Inhibitors, John McMurray, MD*
10:35 – 10:40am *Vericiguat, Christopher O'Connor, MD*
10:40 – 10:45am *Omecamtiv, John Teerlink, MD*
10:45 – 10:50am *Revisiting the OMT Score Proposal, Mona Fiazat, PharmD*
10:50 – 10:55am *HFpEF – Should there be a standard? Scott Solomon, MD*
10:55 – 11:00am *Iron Replacement, Robert Mentz, MD*
11:00 – 11:05am *Standard Device Therapy, JoAnn Lindenfeld, MD*

11:05 – 11:15am BREAK

11:15 – 12:15pm PANEL DISCUSSION

Moderators : *Mona Fiazat, PharmD, Christopher O'Connor, MD*
Panelists: *Gregg Fonarow, John McMurray, John Teerlink, Scott Solomon, Norman Stockbridge, Bram Zuckerman,*

Richard Jacob, Javed Butler, Mitchell Psocka, Ellis Unger, JoAnn Lindenfeld, William Abraham, Orly Vardeny, Muthiah Vaduganathan, Jaime Murillo, Robert Mentz, Janet Wittes, Eric Leifer, Ersilia DeFilippis, Robert Temple

Panelist questions:

- 1. Position on the debate*
- 2. What is minimal standard ?*
- 3. What % on SGLT2i ?*
- 4. Statistical power for interaction analysis ?*
- 5. What % with ICD ?*
- 6. Should standard be different for drug vs. device trial ?*

12:15 – 12:20pm

WRAP UP AND ADJOURN

Mona Fiuzat, PharmD

Christopher O'Connor, MD

Norman Stockbridge, MD, PhD

Bram Zuckerman, MD

Speakers and Panelists

William Abraham, MD

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

Javed Butler, MD, MPH, MBA

*Chair of the Department of Medicine
University of Mississippi Medical Center*

Cynthia Chauhan

Patient Representative

Ersilia DeFilippis, MD

*Cardiology Fellow
Columbia University Irving Medical Center*

Michael Felker, MD, MHS

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

Mona Fiuzat, PharmD

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

Gregg Fonarow, MD

*Director, Ahmanson-UCLA Cardiomyopathy
Center
Co-Director, UCLA Preventative Cardiology
Program
Co-Chief, UCLA Division of Cardiology
The Eliot Corday Chair in Cardiovascular
Medicine and Science. UCLA Health*

Richard Jacob

Patient Representative

Joerg Koglin, MD, PhD

*Vice President, Global Clinical Development
Merck & Co, Inc*

Martin Lefkowitz, MD

*VP, Cardiovascular Therapeutic Area Head
Novartis*

Eric Leifer, PhD

*Mathematical Statistician
Office of Biostatistics Research
National Heart, Lung and Blood Institute*

JoAnn Lindenfeld, MD

*Professor of Medicine
Samuel S. Riven, MD Director in Cardiology
Director, Section of Advanced Heart Failure and
Transplantation
Vanderbilt Heart and Vascular Institute*

Fady Malik, MD, PhD

*Executive Vice President, Research and
Development
Cytokinetics*

John McMurray, MD, OBE BSc (Hons) MB ChB (Hons)

*Professor of Medical Cardiology & Honorary
Consultant Cardiologist
Institute of Cardiovascular & Medical Sciences
BHF Cardiovascular Research Centre
University of Glasgow*

Robert Mentz, MD

*Chief, Heart Failure Section - Duke University
Medical Center
Associate Program Director - Duke
Cardiovascular Disease Fellowship
Editor-in-Chief, Journal of Cardiac Failure -
Official Journal of the HFSA*

Jaime Murillo, MD

*Executive Vice President
Chief Medical Officer
CardioMetabolic UHG R&D
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Christopher O'Connor, MD

*President, Inova Heart & Vascular Institute
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Duke University School of Medicine*

Mitchell Psotka, MD, PhD

*Section Chief, Heart Failure and Transplant
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Lothar Roessig, MD

*Clinical Development Group Head, VP
Bayer*

Dan Schaber, PharmD

*Bakken Fellow
Vice President, Heart Failure Clinical Research
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Scott Solomon, MD

*The Edward D. Frohlich Distinguished Chair
Professor of Medicine, Harvard Medical School
Director, Noninvasive Cardiology
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Norman Stockbridge, MD, PhD

*Director, Division of Cardiovascular and Renal
Products
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John Teerlink, MD

*Professor of Medicine
University of California, San Francisco (UCSF)
Director of the Heart Failure Program and of the
Clinical Echocardiography Laboratory
San Francisco Veterans Affairs Medical Center*

Robert Temple, MD

*Deputy Center Director for Clinical Science
Acting Deputy Director of the Office of Drug
Evaluation-I
U.S. FDA*

Ellis Unger, MD

*Director, Office of Drug Evaluation-I
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Muthiah Vaduganathan, MD, MPH

*Instructor of Medicine
Center for Advanced Heart Disease
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Orly Vardeny, PharmD, MS

*Associate Professor of Pharmacy and Medicine
University of Minnesota*

Janet Wittes, PhD

*President
Statistics Collaborative, Inc*

Clyde Yancy

*Vice Dean for Diversity and Inclusion
Chief of Cardiology, Department of Medicine
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Bram Zuckerman, MD

*Director, FDA Division of Cardiovascular Devices
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Attendees

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President and CEO, ARCA Biopharma*

Robert Cole, MD

*Co-Director, Advanced Heart Failure, Cardiac
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Director of Heart Failure and Cardiac Transplant
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FDA Attendees

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