

HFC Working Group/Think Tank Meeting | April 26, 2024 | 11:30am – 6:30pm ET

Hybrid Meeting: Ritz Carlton Pentagon City, VA/ Zoom

11:00 – 11:30 AM	REGISTRATION
11:30 – 1:00 PM	Lunch and Presentation of HFC Lifetime Achievement Award Ambassador Room Honoree: Norman Stockbridge, MD, PhD
1:10 – 1:15 PM	WELCOME AND OPENING REMARKS Diplomat Room <i>Christopher O'Connor, MD, JoAnn Lindenfeld, MD</i>
HFC UPDATES	
1:15 – 1:20 PM	State of the Union – HFC <i>Mona Fiazat, PharmD</i>
WORKING GROUP REPORTS AND DISCUSSION <i>Moderators: Mona Fiazat, Chris O'Connor, JoAnn Lindenfeld</i>	
1:20 – 1:30 PM	Regulatory Policy and Implementation Science: Drugs and Devices <i>William Abraham, MD, Scott Solomon, MD, JoAnn Lindenfeld, MD</i>
1:30 – 1:40 PM	Discussion (All)
1:40 – 1:45 PM	Research Culture <i>Christopher O'Connor, MD, Michael Bristow, MD, PhD</i>
1:45 – 1:55 PM	Discussion (All)
1:55 – 2:00 PM	Representative Populations <i>Vanessa Blumer, MD</i>
2:00 – 2:10 PM	Discussion (All)
2:10 – 2:15 PM	Digital Health <i>Mitchell Psotka, MD, PhD</i>
2:15 – 2:25 PM	Discussion (All)
2:25 – 2:45 PM	General Discussion (All)
2:45 – 3:05 PM	BREAK
DEVELOPMENT DEEP DIVE: DRUGS, DEVICES, GENE THERAPIES, NEW TECHNOLOGIES <i>Moderators: Christopher O'Connor, MD, Bill Abraham, MD, JoAnn Lindenfeld, MD</i>	
3:05 – 3:15 PM	Roundtable Recap: Drug, Device Development Deep Dive <i>William Abraham, MD</i>
3:15 – 4:15 PM	Drug Development, Gene Therapies Deep Dive Disease Modification in Hypertrophic Cardiomyopathy 3:15 – 4:15 <i>Stephen Heitner, MD (Cytokinetics)</i> <ul style="list-style-type: none"> ➤ HCM is an uncommon disease and studies conducted are relatively small. ➤ Prospective studies have focused on improvements in feel and function. ➤ Changes in biomarkers and/or cardiac structure have been linked to symptoms and physical performance, but not hard/clinical outcomes. ➤ Longer-term follow up unlikely to generate evidence = to traditional levels of "significance". ➤ Contemporary data from the SHaRe registry, HCMR study do have some clinical endpoints.

4:15 – 5:45 PM **Device Development Deep Dive**
Evidence generation and guidelines

John Laschinger, MD (Edwards Lifesciences) 4:15 – 4:45

- Discussion on endpoints viewed as most valuable to the HF physicians with regards to device therapies and size limitations of trials.

Philip Adamson, MD, MSc (Abbott) 4:45 – 5:45

- What is the level of evidence needed for guideline recommendations?
- How to reconcile guidelines with evidence needed for FDA approval

5:45 PM **WRAP UP AND ADJOURN**

*Christopher O'Connor, MD, JoAnn Lindenfeld, MD, Mona Fiuzat, PharmD
Norman Stockbridge, MD, PhD, Bram Zuckerman, MD*

6:00 – 8:00 PM **RECEPTION**

Speakers

William Abraham, MD

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

Philip Adamson, MD, MSc

*Divisional Vice President and Chief Medical Officer
Heart Failure Division
Abbott*

Vanessa Blumer, MD

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

Michael Bristow, MD, PhD

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

Mona Fiuzat, PharmD

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

Stephen Heitner, MD

*VP, Clinical Research & Therapeutic
Area Lead, Cardiovascular
Cytokinetics*

John Laschinger, MD

*Senior Vice-President of Medical Affairs
Advanced Technology
Edwards Lifesciences*

JoAnn Lindenfeld, MD

*Professor of Medicine
Director, Heart Failure and Transplant Section
Vanderbilt Heart and Vascular Institute*

Christopher O'Connor, MD

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

Mitchell Psotka, MD, PhD

*Section Chief, Heart Failure and Transplant Director,
Infiltrative Cardiomyopathy Center
Inova Schar Heart and Vascular*

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*

Bram Zuckerman, MD

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

2024 HF Collaboratory Working Groups

Digital Health/eHealth and Technology Working Group

Chair: Mitch Psootka, MD, PhD, Chair, (Inova)

Members: Steen Abildstrøm, MD, PhD (NovoNordisk), Tariq Ahmad, MD, MPH (Yale), Ankeet Bhatt, MD, MBA, ScM, (Kaiser Permanente), Isabella Cavagna (Inova, Intern), Martin Cowie, MD (AstraZeneca), Jon Cunningham, MD (Brigham and Women's), Matt Dimond (Loyola Medical School, Intern), Mona Fiuzat, PharmD (Duke), David Kao, MD (University of Colorado), Mark Kittipibul, MD (Duke University), Elizabeth Kunkoski, MS (FDA), Trejeeve Martyn, MD (Cleveland Clinic), Wei Ni, PhD (Eli Lilly), Christopher O'Connor, MD (Inova), Leonard Sacks, MD (FDA, CDER), Elise Shalowitz, MS (University of Colorado), Abhinav Sharma, MD, PhD (McGill University), Whit Tingley, MD, PhD (Tenaya Therapeutics)

Regulatory Policy and Implementation Science: Drugs Working Group

Chair: Scott Solomon, MD, Chair (Brigham and Women's)

Members: Heather Applegate (HFC), Ankeet Bhatt, MD, MBA, SM (Kaiser Permanente), Robert Blaustein, MD, PhD (Merck), Maria Borentain, MD (Bayer AG), Javed Butler, MD, MPH, MBA (Baylor Health System), Jim Carr, PharmD (Stealth Biotherapeutics), Peter Carson, MD (Former, VAMC DC), Isabella Cavagna (Inova, Intern), Matt Dimond (Loyola School of Medicine), Michael Felker, MD, MHS (Duke), Mona Fiuzat, PharmD (Duke), Al Gianchetti, MBA (Xylocor Therapeutics), Richard George, MD (Regeneron), Barry Greenberg, MD (UCSD), Carine Hamo, MD (NYU Langone Health), James Januzzi, MD (Mass General), Mohammed Jessa, PhD (AstraZeneca), Shahzeb Khan, MD (Duke), Marvin Konstam, MD (Tufts), Mori Krantz, MD (FDA), Bettina Kraus, MD (Boehringer Ingelheim), Anu Lala- Trindade, MD (Mount Sinai), Marty Lefkowitz, MD (Novartis Pharmaceuticals), Phil Mendys, PharmD (Pfizer), Darren McGuire, MD (UTSW Medical Center), Masahiro Murakami, MD, PhD (AstraZeneca), Christopher O'Connor, MD (Inova), Jordan Pomeroy, MD, PhD (FDA), Mitch Psootka, MD, PhD (Inova), Ricardo Rocha, MD (Intellia), Lothar Roessing, MD (AskBio), Amy Sehnert, MD (BMS), Steven Simonson, MD (Windtree), Shalabh Singhal, MD (SalubrisBio), Norman Stockbridge, MD, PhD (FDA), John Teerlink, MD (UC, SF), Ellis Unger, MD (Former FDA)

Regulatory Policy and Implementation Science: Devices Working Group

Chairs: William Abraham, MD, Chair (Ohio State University), JoAnn Lindenfeld, MD, Co-Chair (Vanderbilt University)

Members: Keith Aaronson, MD (FDA), Amrut Ambardekar, MD (University of Colorado), Heather Applegate (HFC), Vanessa Blumer, MD (Inova), Roberta Bogaev, MD (Abiomed, Inc.), Biykem Bozkurt, MD (Baylor), Isabella Cavagna (Inova, Intern), Alan Cheng, MD, MBA (Medtronic), Matt Dimond (Loyola School of Medicine), Mona Fiuzat, PharmD (Duke University), Marat Fudim, MD (Duke University), Richard Jacob (Patient Representative), John Laschinger, MD (Edwards), Rhonda Monroe (Patient Representative), Mauro Moscucci, MD (FDA), Christopher O'Connor, MD (Inova), Mitch Psootka, MD, PhD (Inova), Ben Saville, PhD (Adaptix Trials), Meir Shinnar, MD, PhD (FDA), Randall Starling, MD, MPH (Cleveland Clinic/ FDA), Paul Verrastro (CVRx), Bram Zuckerman, MD (FDA)

Representative Population

Chairs: Orly Vardeny, PharmD, MS, Chair (University of Minnesota), Vanessa Blumer, MD, Co-Chair (Inova) **Members:** Phil Adamson, MD, (Abbott), Rosalyn Adigun, MD (FDA), Mark Booras (Patient Representative), Piper Dankworth (Patient Representative), Matt Dimond (Loyola School of Medicine), Ersilia DeFilippis (Columbia University), Yasmire Evans (Mt. Sinai, Intern), Mona Fiuzat, PharmD (Duke), John Godwin (Patient Representative), Christian Guilliod (University of Miami), Mariell Jessup, MD, (AHA), Eric Leifer, PhD (NIH, NHLBI), JoAnn Lindenfeld, MD (Vanderbilt), Martin Mendoza, MD (HHS), Sumeet Mitter, MD (Inova), Christopher O'Connor, MD (Inova), Ileana Pina, MD (FDA), Allman Rollins, MD (Inova), Carlos Santos Gallego (Mt. Sinai, Research Fellow), Fred Senatore, MD, PhD (FDA), Ken Stein, MD (Boston Scientific), LeTanya Tomlinson, RN, BSN, MHSA (Tenaya Therapeutics), Muthiah Vaduganathan, MD (Brigham and Women's), Laura Williams (Patient Representative), Clyde Yancy, MD, MSc (Northwestern), Quentin Youmans (Northwestern)

Research Culture/Networks/Societies

Chairs: Christopher O'Connor, MD, Chair (Inova), Michael Bristow, MD, PhD, Co-Chair (University of Colorado, ARCA Biopharma)

Members: Vanessa Blumer, MD (Inova), Cynthia Chauhan (Patient Representative), Maria Rosa Costanzo, MD (Midwest CV Institute), Martin Cowie, MD (AstraZeneca), Matt Dimond (Loyola Medical School, Intern), Yasmire Evans (Mt. Sinai, Intern), Mona Fiuzat, PharmD (Duke University), Megha Gupta (Duke, Intern), Kim Kiel-Eckert (Patient Representative), Anu Lala-Trindade, MD (Mount Sinai), Scott Lundgren, MD (University of Nebraska), Fady Malik, MD, PhD (Cytokinetics), Robert Mentz, MD (Duke University), Jill Amstutz, MBA (WhiteSwell), Patrice Nickens, MD (NIH NHLBI), Sheila Tynes (HFC), Minnow Walsh, MD (St. Vincent Heart Center), David Whellan, MD, MHS (Thomas Jefferson University), Amin Yehya, MD (Sentara Advanced Heart Failure Center)