

HF Collaboratory Working Group/Think Tank Meeting: Focus on Acute Heart Failure

April 22, 2022 | 8:30am – 12:00pm ET

Hybrid Meeting: Fairview Marriott, Falls Church, VA/ Zoom

8:00 – 8:30 AM

BREAKFAST

8:30 – 8:35 AM

WELCOME AND OPENING REMARKS

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

8:35 – 8:55 AM

HFC UPDATES AND WORKING GROUP REPORT OUTS

8:35 – 8:40 AM

State of the Union – HFC

Mona Fiuzat, PharmD

8:40 – 8:50 AM

HFC COVID CRF Data Collection Update

Ankeet Bhatt, MD, MBA, Scott Solomon, MD, Orly Vardeny, PharmD, MS

8:50 – 8:55 AM

Q & A

8:55 – 10:00 AM

WORKING GROUP REPORTS and DISCUSSION

8:55 – 9:10 AM

Regulatory Policy and Implementation Science: Drugs and Devices

William Abraham, MD, Scott Solomon, MD, JoAnn Lindenfeld, MD

9:10 – 9:20 AM

Research Culture and Societies

Christopher O'Connor, MD, David Whellan, MD, Michael Bristow, MD, PhD

9:20 – 9:30 AM

Representative Populations

Orly Vardeny, PharmD, MS, Muthiah Vaduganathan, MD, MPH

9:30 – 9:40 AM

Digital Health

Tariq Ahmad, MD, MPH, Mitchell Psotka, MD, PhD

9:40 – 10:00 AM

Discussion

10:00 – 10:15 AM

BREAK

10:15 AM – 12:00 PM	FOCUS ON ACUTE HEART FAILURE (AHF) Moderators: <i>Christopher O'Connor, MD, Mona Fiuzat, PharmD, John Teerlink, MD</i>
10:15 – 10:20 AM	FDA Perspective (2 minutes each) CDRH – <i>Bram Zuckerman, MD</i> CDER – <i>Norman Stockbridge, MD, PhD</i>
10:20 – 10:50 PM	AHF: Consensus Recommendations Update <i>Nomenclature, Therapeutic Considerations, Trial Considerations and Endpoint Considerations</i> <i>Carine Hamo, MD, Anu Lala-Trindade, MD</i>
10:50 – 12:00 PM	Discussion Panelists: <i>William Abraham, Tariq Ahmad, Naomi Aronson, Biykem Bozkurt, Michael Bristow, Javed Butler, Peter Carson, Cynthia Chauhan, Lea Drye, Michael Felker, Nasrien Ibrahim, Mariell Jessup, Marvin Konstam, JoAnn Lindenfeld, Robert Mentz, Jaime Murillo, Mitchell Psotka, Scott Solomon, Norman Stockbridge, Ellis Unger, Muthiah Vaduganathan, Orly Vardeny, Clyde Yancy, Bram Zuckerman</i>
12:00 PM	WRAP UP AND ADJOURN <i>Christopher O'Connor, MD</i> <i>JoAnn Lindenfeld, MD</i> <i>Mona Fiuzat, PharmD</i> <i>Norman Stockbridge, MD, PhD</i> <i>Bram Zuckerman, MD</i>
12:00 – 1:00 PM	Lunch and Presentation of HFC Lifetime Achievement Award Honoree: Ellis Unger, MD Former Director, Office of Drugs (1), Center for Drug Evaluation and Research, U.S. FDA

HF Collaboratory Program Chairs

Mona Fiuzat, PharmD

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

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*

Christopher O'Connor, MD

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

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*

Faculty and Panelists

William Abraham, MD

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

Tariq Ahmad, MD

*Medical Director, Heart Failure and Transplant
Associate Professor of Medicine
Yale New Haven Health System*

Naomi Aronson, PhD

*Executive Director
Clinical Evaluation, Innovation and Policy
BlueCross BlueShield Association*

Ankeet Bhatt, MD, MBA

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

Biykem Bozkurt, MD, PhD

*The Mary and Gordon Cain Chair
W.A. "Tex" and Deborah Moncrief, Jr., Chair
Professor of Medicine
Medical Care Line Executive, DeBakey VA Medical
Center
Director, Winters Center for Heart Failure Research
Associate Director, Cardiovascular Research Institute
Vice-Chair of Medicine, Baylor College of Medicine*

Michael Bristow, MD, PhD

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

Javed Butler, MD, MPH, MBA

*SVP, Baylor Scott & White Health System, President,
Baylor Scott & White Research Institute*

Peter Carson, MD

*Cardiologist
Washington, DC VAMC (Retired)*

Cynthia Chauhan

Patient Representative

Lea A. Truman Drye, PhD

*Director, Clinical Science Services
Office of Clinical Affairs
Blue Cross and Blue Shield Association*

Michael Felker, MD, MHS

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

Carine Hamo, MD

*Cardiology Fellow
Icahn School of Medicine at Mount Sinai*

Mariell Jessup, MD

*Emeritus Professor of Medicine
University of Pennsylvania
Chief Science and Medical Officer
American Heart Association*

Marvin Konstam, MD

*Chief Physician Executive, The CardioVascular Center
Tufts Medical Center*

Anu Lala-Trindade, MD

*Assistant Professor of Medicine
Icahn School of Medicine at Mount Sinai*

Robert Mentz, MD

*Associate Professor
Chief, Heart Failure Section
Associate Program Director, Duke Cardiovascular
Disease Fellowship
Duke University*

Jaime Murillo, MD

*Senior Vice President & CMO at Optum Labs
UnitedHealth Group*

Mitchell Psotka, MD, PhD

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

Scott Solomon, MD

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

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*

Muthiah Vaduganathan, MD, MPH

*Instructor of Medicine
Center for Advanced Heart Disease
Brigham and Women's Hospital*

Orly Vardeny, PharmD, MS

*Associate Professor of Pharmacy and Medicine
University of Minnesota*

David Whellan, MD

*James C. Wilson Professor of Medicine, Associate
Provost for Clinical Research, Thomas Jefferson
University
Associate Dean for Clinical Research, Sidney Kimmel
Medical College
Executive Director, Jefferson Clinical
Research Institute*

Ellis Unger, MD

*Cardiologist
Former Director, Office of Drugs (1)
CDER, U.S. FDA*

Clyde Yancy, MD, MSc

*Vice Dean for Diversity and Inclusion
Chief of Cardiology, Department of Medicine
Northwestern Feinberg School of Medicine*

2022 HFC Working Group Members

Digital Health/eHealth and Technology Working Group

Chairs: Tariq Ahmad, MD, Chair (Yale) and Mitch Psotka, MD, PhD, Chair, (Inova)

Members: Mona Fiuzat, PharmD, (Duke), Jonathan Fox, MD, PhD, (Eidos Therapeutics), Nasrien Ibrahim, MD, (Inova), David Kao, MD, (University of Colorado), Harlan Krumholz, MD, MS (Yale), Elizabeth Kunkoski, MD, (FDA), Maulik Majmudar, MD, (Biofourmis), Wei Ni, PhD (Eli Lilly), Richard Nkulikiyinka, MSc, MB BChir, MRCP (Bayer AG), Christopher O'Connor, MD (Inova), Leonard Sacks, MD, (FDA, CDER), Abhinav Sharma, MD, PhD (McGill University), Whit Tingley, MD, PhD, (Tenaya Therapeutics), Paul Varghese, MD, (Google Life Sciences), Vanja Vlainic, MSc, (Bayer AG)

Regulatory Policy and Implementation Science: Drugs Working Group

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

Members: Ankeet Bhatt, MD, MBA (Brigham and Women's), Robert Blaustein, (Merck), Maria Borentain, MD (BMS), Javed Butler, MD, MPH, MBA (Baylor Health System), Michael Felker, MD, MHS (Duke), Mona Fiuzat, PharmD (Duke), Al Gianchetti (Xylocor Therapeutics), Carine Hamo, MD (Mt. Sinai), Nasrien Ibrahim, MD (Inova), James Januzzi, MD (Mass General), Mohammed Jessa, PhD (AstraZeneca), Shahzeb Khan, MD (Duke), Joerg Koglin, MD, PhD (Merck), Marvin Konstam, MD (Tufts), Bettina Kraus, MD (Boehringer Ingelheim), Anu Lala-Trindade, MD (Mount Sinai), Chung Lee-Sogaard, PhD (Pfizer), Marty Lefkowitz, MD (Novartis Pharmaceuticals), Masahiro Murakami, PhD (AstraZeneca), Christopher O'Connor, MD (Inova), Jordan Pomeroy, MD (FDA), Mitch Psotka, MD, PhD (Inova), Lothar Roessing, MD (Bayer), Steven Simonson, MD (Windtree), Howard Surks, MD (Cardurion), Norman Stockbridge, MD, PhD (FDA), John Teerlink, MD (UC, SF), Ellis Unger, MD (Former FDA), Brandon Walsh, PhD (Arena Pharmaceuticals)

Regulatory Policy and Implementation Science: Devices Working Group

Chairs: William Abraham, MD, Chair (Ohio State University), Robert Kazmierski, PhD, Co-Chair (FDA/CMS), JoAnn Lindenfeld, MD, Co-Chair (Vanderbilt University)

Members: Amrut Ambardekar, MD (University of Colorado), Vanessa Blumer, MD (Duke), Roberta Bogaev, MD (Abiomed, Inc.), Biykem Bozkurt, MD (Baylor), Peter Carson, MD (Former, VAMC DC), Lorenzo DiCarlo, MD (LivaNova PLC), Mona Fiuzat, PharmD (Duke University), Elizabeth Galle, MPH (CRVx), Steven Goedeke, MS (Cardionomic), Nasrien Ibrahim, MD (Inova), Richard Jacob (Patient Representative), John Laschinger, MD (Edwards), Christopher O'Connor, MD (Inova), Mitch Psotka, MD, PhD (Inova), Ben Saville, PhD (Berry Consultants), Dan Schaber, PharmD (Medtronic), Meir Shinnar, MD, PhD (FDA), Angela Stagg (Impulse Dynamics), Randall Starling, MD, MPH (Cleveland Clinic/ FDA), Emily Zeitler, MD (Dartmouth), Bram Zuckerman, MD (FDA)

Representative Populations

Chairs: Orly Vardeny, PharmD, MS, Chair (University of Minnesota), Muthiah Vaduganathan, MD, MPH, Chair (Brigham and Women's Hospital)

Members: Phil Adamson, MD, (Abbott), Lawton Cooper, MD (Retired NIH, NHLBI), Piper Dankworth (Patient Representative), Ersilia (Silia) DeFilippis, MD (Columbia), Melvin Echols, MD (Morehouse SOM), Mona Fiuzat, PharmD (Duke), John Godwin (Patient Representative), Nasrien Ibrahim, MD (Inova), Mariell Jessup, MD, (AHA), Dalane Kitzman, MD (Wake Forest), Eric Leifer, PhD (NIH, NHLBI), JoAnn Lindenfeld, MD (Vanderbilt), Martin Mendoza, MD (HHS), Richard Nkulikiyinka, MSc, MB BChir, MRCP (Bayer AG), Christopher O'Connor, MD (Inova), Mitch Psotka, MD, PhD (Inova), Fred Senatore, MD, PhD (FDA), Ken Stein, MD (Boston Scientific), John Teerlink, MD (UC, SF), LeTanya Tomlinson, RN, BSN, MHSA (Tenaya Therapeutics), Laura Williams (Patient Representative), Clyde Yancy, MD, MSc (Northwestern), Debbie Zeldow (HFSA)

Research Culture/Networks/Societies

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

Members: Tomas Andersson, MD, (AstraZeneca), Cynthia Chauhan (Patient Representative), Maria Rosa Costanzo, (Midwest CV Institute), Mona Fiuzat, PharmD (Duke University), Anders Gabrielsen, MD, PhD (AstraZeneca), Nasrien Ibrahim, MD (Inova), Anu Lala-Trindade, MD (Mount Sinai), Fady Malik, MD, PhD (Cytokinetics), Robert Mentz, MD (Duke University), Linda Nelson, BSN, MBA (WhiteSwell), Patrice Nickens, MD (NIH NHLBI), Mitch Psotka, MD, PhD (Inova), Minnow Walsh, MD (St. Vincent Heart Center), Amin Yeyha, MD (Sentara Advanced Heart Failure Center), Debbie Zeldow (HFSA)