

DSMB ACADEMY TRAINING PILOT WORKSHOP

Sunday, June 11 6:30 – 9:00 pm	Welcome Dinner J. Hollinger's Waterman's Chophouse <i>8606 Colesville Rd Silver Spring, MD 20910 (walking distance to hotel)</i> Hotel: COURTYARD BY MARRIOTT, SILVER SPRING DOWNTOWN <i>8506 Fenton Street, Silver Spring, MD 20910</i>
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(7:15 am Shuttle to FDA) 8:00am – 4:50pm ET, Monday, June 12, 2023 |

FDA White Oak Campus, Great Room
10903 New Hampshire Ave, Silver Spring, MD 20993

8:00 – 8:30 am	SECURITY ENTRANCE, REGISTRATION, COFFEE <i>Bus Departs Hotel at 7:15 am</i>
8:30 – 8:40 am	Welcome, opening remarks: Christopher O'Connor, MD, David DeMets, PhD Dr. Califf – to stop by meeting for remarks in afternoon
8:40 – 10:30 am	Didactic Review (120 min) <i>David DeMets, Janet Wittes, Thomas Fleming</i> 8:40-9:00: Introduction, what trials do or do not need DMCs? (David DeMets) 9:00–9:30: Overview of topics from didactic videos, highlights and best practices (Tom Fleming) 9:30-9:45: What constitutes good quality reports and output? (Janet Wittes, 15 min) 9:45-10:00: Sponsor involvement/structure, contract negotiations, charters (David DeMets, 15 min) 10:00 – 10:30: Q&A (30 min)
10:30 – 11:00 am	COFFEE BREAK
11:00 – 11:45 pm	DSMB Memorable Experiences and Lessons Learned (45 min) -JoAnn Lindenfeld (5 min) -Chris O'Connor (5 min) -Michael Bristow (5 min) - FDA Experiences (15 min): Bram Zuckerman/Andrew Farb; Norman Stockbridge - Clyde Yancy: Comment on Trial Diversity and DSMB role (5 min) - Open Comments (10 min)
11:45 – 12:45 pm	LUNCH
12:45 – 2:45 pm	Breakout Groups – 8 groups / Case Reviews Christopher O'Connor / Maria Rosa Costanzo – 1 Clyde Yancy / Michael Felker - 2 Marvin Konstam / Nancy Sweitzer – 3 John Teerlink / Biykem Bozkurt – 4 JoAnn Lindenfeld / William Abraham - 5 Barry Greenberg / Peter Carson - 6 Michael Bristow / Mariell Jessup - 7

	Michael Mack – 8 <u>Statisticians:</u> 1. David DeMets 2. Frank Rockhold 3. Brian Claggett 4. Janet Wittes 5. Thomas Fleming 6. Thomas Cook 7. Ben Saville 8. Jason Connor
2:45 – 3:45 pm	Lessons Learned + Case Reviews + (60 min) Moderator: Christopher O'Connor 2:45 – 3:00: Lessons Learned (David DeMets) 3:00 – 3:15: Case 1. CT Trial (Frank Rockhold, Dave DeMets, 15 min) 3:15 – 3:30: Case 2. L.AH Trial: Tom Fleming (15 min) 3:30 – 3:45: Case 3. BL Trial: Jason Connor, Janet Wittes (15 min)
3:45 – 4:00 pm	WRAP UP, NEXT STEPS, ADJOURN: <i>Christopher O'Connor, MD</i>

Speakers and Panelists

William Abraham, MD

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

Biykem Bozkurt, MD, PhD

*The Mary and Gordon Cain Chair Professor
Associate Provost of Faculty Affairs, Senior Associate
Dean of Faculty Development
Director, Winters Center for Heart Failure Research
Vice-Chair of Medicine, Baylor College of Medicine*

Michael Bristow, MD, PhD

*Professor of Medicine, Division of Cardiology
Director of Pharmacogenomics, University of
Colorado
President and CEO, ARCA Biopharma*

Peter Carson, MD

*Cardiologist
Washington, DC VAMC (Retired)*

Brian Claggett, PhD

*Chief Statistician, Cardiac Imaging Core
Laboratory and Clinical Trials Endpoints Center
Brigham and Women's Hospital
Assistant Professor
Harvard Medical School*

Jason Connor, PhD

*Founder and Lead Statistical Scientist
ConfluenceStat, LLC*

Thomas Cook, PhD

*Professor of Clinical Health Sciences
Department of Biostatistics and Medical Informatics
University of Wisconsin-Madison*

Maria Rosa Costanzo, MD

*Medical Director, Advocate Medical Group
Midwest Heart Specialists
HF and PAH Programs Medical Director, Edward
Hospital Center for Advanced Heart Failure*

David DeMets, PhD

*Max Halperin Emeritus Professor of Biostatistics
University of Wisconsin*

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

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

Thomas Fleming, PhD

*Professor of Biostatistics and Statistics
University of Washington*

Barry Greenberg, MD

*Director, Advanced Heart Failure Treatment Program
Distinguished Professor of Medicine
University of California*

Mariell Jessup, MD

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

JoAnn Lindenfeld, MD

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

Marvin Konstam, MD

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

Michael Mack, MD

*Medical Director of Cardiothoracic Surgery
Baylor Scott & White Health
Chair, BSW Heart Hospital, Plano Research Center*

Christopher O'Connor, MD

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

Frank Rockhold, PhD

*Professor of Biostatistics & Bioinformatics
Duke University*

Ben Saville, PhD

*Director & Senior Statistical Scientist
Berry Consultants*

Norman Stockbridge, MD, PhD

*Director, Division of Cardiology and Nephrology
CDER, U.S. FDA*

Nancy K. Sweitzer, MD, PhD

*Professor and Vice-Chair for Clinical Research,
Department of Medicine
Associate Director, Clinical Translational Sciences
Program
Director of Clinical Research, Cardiology Division
Washington University School of Medicine
Editor in Chief, Circulation: Heart Failure*

John Teerlink, MD

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

Janet Wittes, PhD

*Statistician
President, Wittes LLC*

Clyde Yancy, MD, MSc

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

Bram Zuckerman, MD

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

Training Participants

Amrut Ambardekar, MD

*Medical Director Cardiac Transplant Program
Director of Clinical Research Division of Cardiology
University of Colorado*

Brett Atwater, MD

*Director, Electrophysiology
Director, Electrophysiology Research
Inova Heart and Vascular Institute*

Ana Barac, MD, PhD

*Director of Cardio-Oncology Program
Inova Heart and Vascular Institute
Professor of Medicine, Georgetown University*

Vanessa Blumer, MD

*Fellow, Advanced Heart Failure and Transplant
Cardiology
Cleveland Clinic Foundation*

Jamie Dwyer, MD

*Associate Dean for Clinical Research,
Professor of Medicine
Director of the Data Coordinating
University of Utah Health*

Carine Hamo, MD

*Assistant Professor of Medicine, Cardiology
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*Heart Failure and Transplant Cardiologist
Commonwealth Fund Fellow in Minority Health
Policy, Harvard University*

Karola Jering, MD

*Instructor in Medicine
Brigham and Women's Hospital*

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*Heart Failure and Transplant Cardiologist
Assistant Professor of Medicine Icahn School of
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Sabra Lewsey, MD, MPH

*Advanced HF Cardiologist
Assistant Professor of Medicine
Johns Hopkins Medicine*

Anekwe Onwuanyi, MD

*Professor of Medicine/Chief of Cardiology
Morehouse School of Medicine
Advanced Heart Failure Consultant
Medical Director, Heart Failure Program
Grady Health System*

Mitchell Psotka, MD, PhD

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

Matthew Sherwood, MD

*Physician Supervisor, Interventional Cardiology and
Structural Heart Disease
Director, LAAC/WATCHMAN Program
Co-Director, Structural Heart Disease Program and
Cardiac Catheterization Lab
Inova Heart and Vascular Institute*

Jenica Upshaw, MD

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Associate Director, T1 Center for CV Therapeutics
Associate Professor, Division of Cardiology
Northwestern Medicine*

Amin Yeyha, MD

*Advanced HF and Transplant Cardiologist
Sentara Healthcare*