

HFC - DSMB ACADEMY TRAINING WORKSHOP

Sunday, June 9 6:00 – 9:00 pm	Welcome Dinner The Watermark Hotel 1825 Capital One Drive South McLean, VA 22102 <i>*Dinner will be in the Elevate Meeting Room located next to Wren restaurant</i>
8:30am – 4:45 pm ET, Monday, June 10, 2024 (7:45 am Shuttle from Hotel to Conference Center) Inova Center for Personalized Health (ICPH) Conference Center (Room 3) 8100 Innovation Park Drive Fairfax, VA 22031	
6:45 – 7:30am	Breakfast offered at hotel for guests with rooms (Watermark Hotel, the Avery – 9 th floor)
7:45am	7:45am SHUTTLE DEPARTS from Watermark Hotel to ICPH
8:00 – 8:30 am	REGISTRATION, CONTINENTAL BREAKFAST/COFFEE (Atrium, ICPH)
8:30 – 8:35 am	Welcome, opening remarks: Christopher O'Connor, MD, David DeMets, PhD
8:35 – 10:25 am	Didactic Review <i>David DeMets, Janet Wittes, Thomas Fleming</i> 8:35-8:55: Introduction, what trials do or do not need DMCs? (David DeMets, 20 min) 8:55–9:25: Overview of topics from didactic videos, highlights and best practices (Tom Fleming, 30min) 9:25-9:40: What constitutes good quality reports and output? (Janet Wittes, 15 min) 9:40-9:55: Sponsor involvement/structure, contract negotiations, charters (David DeMets, 15 min) 9:55 – 10:05: Regulatory Perspectives (Norman Stockbridge, Andrew Farb, 5 min each) 10:05 – 10:25: Q&A, Discussion (20 min)
10:25 – 10:50 am	COFFEE BREAK (Atrium)
10:55 – 11:45 am	DSMB Lessons Learned from TOPCAT 10:55 – 11:10 TOPCAT Trial (15 min) <i>Michael Bristow; Brian Claggett</i> 11:10 – 11:30 - Q&A, Discussion (20 min) 11:30 – 11:35 Diversity Considerations (5 min) <i>Wayne Batchelor</i> 11:35 – 11:45 Q&A, Discussion (10 min)
11:45 – 12:30 pm	LUNCH (Atrium)

12:30 – 4:15 pm	Breakout Groups – Case Reviews (1 hour each, 15 min transition) x 3 rotations 12:30 – 1:30; 1:45 – 2:45; 3:00 – 4:00 (15 min wrap up, transition) Christopher O’Connor, Anu Lala – 1 Michael Felker, Jane Wilcox - 2 Biykem Bozkurt, David Whellan – 3 JoAnn Lindenfeld, Alex Mebazaa - 4 William Abraham, Vanessa Blumer – 5 Peter Carson, Ana Barac – 6 Michael Bristow, Mona Fiuzat – 7 Wayne Batchelor, Matt Sherwood - 8 <u>Statisticians:</u> 1. David DeMets – 7, 2, 4 2. Frank Rockhold – 1, 7, 2 3. Brian Claggett – 4, 3, 6 4. Janet Wittes – 8, 4, 7 5. Thomas Fleming – 6, 5, 3 6. Chris Lindsell – 3, 6, 5 7. Eric Leifer – 2, 8, 1 8. Jason Connor – 5, 1, 8
4:15 – 4:45 pm	Lessons Learned, Final Thoughts (30 min) David DeMets, Tom Fleming, Janet Wittes
4:45 pm	ADJOURN: Christopher O’Connor, MD

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*

Ana Barac, MD, PhD

*D’Aniello Chair, Cardio-Oncology
Inova Schar Cancer & Inova Schar Heart and Vascular
Professor of Medicine (Adjunct), Georgetown
University*

Wayne Batchelor, MD, MHS

*Director of the Interventional Heart Program, Inova
Health System, Director of Interventional Heart
Disease Research, Education, and Innovation,
Associate Director, Inova Schar Heart and Vascular
Adjunct Professor of Medicine, Duke University*

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*

Biykem Bozkurt, MD, PhD

*The Mary and Gordon Cain Chair Professor
Director, Winters Center for Heart Failure Research
Vice-Chair of Medicine, Baylor College of Medicine*

Michael Bristow, MD, PhD

*Professor of Medicine (Cardiology)
University of Colorado Anschutz Medical Campus
Director, Pharmacogenomics Section
CU Cardiovascular Institute*

Karim Calis, PharmD, MPH

*Senior Scientist, Director of Clinical Research and
Compliance, Office of the Clinical Director, Division of
Intramural Research
NICHD/NIH*

Peter Carson, MD

*Cardiologist
Washington, DC VAMC (Retired)*

Brian Claggett, PhD

*Chief Statistician, Cardiac Imaging Core
Lab 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*

David DeMets, PhD

*Max Halperin Emeritus Professor of Biostatistics
University of Wisconsin*

Andrew Farb, MD

*Chief Medical Officer
CDRH, U.S. FDA*

Michael Felker, MD, MHS

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

Mona Fiuzat, PharmD

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

Thomas Fleming, PhD

*Professor of Biostatistics and Statistics
University of Washington*

Anu Lala, MD

*Heart Failure and Transplant Cardiologist
Assistant Professor of Medicine
Icahn School of Medicine at Mount Sinai*

Eric Leifer, PhD

*Mathematical Statistician, Office of Biostatistics
Research NHLBI, NIH*

JoAnn Lindenfeld, MD

*Professor of Medicine
Heart Failure and Transplant Cardiologist
Vanderbilt Heart and Vascular Institute*

Christopher J. Lindsell, PhD

*Director, Data Science and Biostatistics, Duke Clinical
Research Institute, Professor and Co-Chief, Division
of Biostatistics, Duke University*

Christopher O'Connor, MD

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

Alexandre Mebazaa, MD

*Professor of Medicine
Université Paris Cité, Paris, France*

Frank Rockhold, PhD

*Professor of Biostatistics & Bioinformatics
Duke University*

Yves Rosenberg, MD, MPH

*Branch Chief, Atherothrombosis and Coronary Artery
Disease, NHLBI/NIH*

Matthew Sherwood, MD, MHS

*System Chief of Structural Heart Disease Program
Co-Director of the Cardiac Catheterization
Laboratory
Director of the LAAC/WATCHMAN Program
Inova Schar Heart and Vascular*

Norman Stockbridge, MD, PhD

*Director, Division of Cardiovascular and Renal
Products, CDER, U.S. FDA*

David J. Whellan, MD MHS

*Executive Director, Jefferson Clinical Research
Institute, James C. Wilson Professor of Medicine
Deputy Provost of Research Affairs, Thomas Jefferson
University, Chief Operating Officer, PIER Consortium*

Jane Wilcox, MD, MSc

*Chief, Heart Failure Treatment and Recovery
Associate Director, T1 Center for CV Therapeutics
Associate Professor, Division of Cardiology
Northwestern Medicine*

Janet Wittes, PhD

*Statistician
President, Wittes LLC*

Training Participants

Ahmad Abdul-Aziz, MD

*Advanced HF, Critical Care Cardiologist
Inova Schar Heart and Vascular*

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*Associate Physician, Cardiologist
Kaiser Permanente San Francisco Medical Center*

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*Heart Failure and Transplant Cardiologist
Brigham and Women's Hospital, Heart and Vascular
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Henry Ford Health*

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*Heart Failure and Transplant Cardiologist
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*Assistant Professor, Medical Education, UVA
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*Director, Infiltrative and Restrictive Cardiomyopathy
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Division of Cardiovascular Medicine
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*Assistant Professor of Medicine
Advanced Heart Failure & Transplant Cardiology
Director of Pathway Programs and Student Support
Northwestern University Feinberg School of Medicine*

Amanda Vest, MD

*Section Head, Heart Failure and Transplantation
Cardiology, Cleveland Clinic, Cleveland OH*

Guests

Rosalyn Adigun, MD, PharmD

*Advanced Heart Failure/Transplant Cardiology,
Mayo Clinic
Medical Officer, DCN, CDER, U.S. FDA*

Scott D. Berkowitz, MD

*Medical Officer
DCN, CDER, U.S. FDA*

Joan Buenconsejo, PhD, MS

*VP of Neuroscience/Cardiovascular Biostatistics
Bristol Myers Squibb*

Selena DeConti, PharmD, MPH

*Associate Director for Safety
DCN, CDER, U.S. FDA*

Justin Godown, MD

*Medical Director, Cardiovascular Research
Cytokinetics*

Austin Hu, MD

*Medical Officer
CDER, U.S. FDA*

Mauro Moscucci, MD, MBA, MPH

*Medical Officer
CDRH, U.S. FDA*

Emily Neumann, BSN, RN

*Medical Science Liaison
Abiomed*

Yaa Oppong, MD

*Clinical Reviewer
DCN, CDER, U.S. FDA*

Patricia Ely Pizzato, MD

*Medical Director, Early Clinical Development CVRM
AstraZeneca*

Thomas Rano, PhD

*Clinical Scientist Team Lead- Cardiovascular
Bristol Myers Squibb*

Melissa Samendinger, RN, MS

*Senior Manager, Clinical Safety
J&J MedTech
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*Global Development Medical Director
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