

## HFC - DSMB ACADEMY TRAINING WORKSHOP

<b>Sunday, June 9</b> <b>6:00 – 9:00 pm</b>	<b>Welcome Dinner</b> <b>The Watermark Hotel</b> <i>1825 Capital One Drive South</i> <i>McLean, VA 22102</i>
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**8:30am – 4:45 pm ET, Monday, June 10, 2024**

**(8:00 am Shuttle from Hotel to Conference Center)**

Inova Center for Personalized Health (ICPH) Conference Center (Room 3)  
8100 Innovation Park Drive  
Fairfax, VA 22031

<b>7:00 – 7:45am</b>	<b>Breakfast offered at hotel (Watermark Hotel, the Avery – 9<sup>th</sup> floor)</b>
<b>8:00am</b>	<b>8:00 am Shuttle from Watermark Hotel to ICPH</b>
<b>8:00 – 8:30 am</b>	<b>REGISTRATION, COFFEE (Atrium, ICPH)</b>
<b>8:30 – 8:35 am</b>	<b>Welcome, opening remarks: Christopher O'Connor, MD, David DeMets, PhD</b>
<b>8:35 – 10:30 am</b>	<b>Didactic Review</b> <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)
<b>10:25 – 10:50 am</b>	<b>COFFEE BREAK (Atrium)</b>
<b>10:55 – 11:45 am</b>	<b>DSMB Lessons Learned from TOPCAT</b> <b>10:55 – 11:10 TOPCAT Trial (15 min)</b> <i>Michael Bristow; Brian Claggett</i> 11:10 – 11:30 - Q&A, Discussion (20 min)  <b>11:30 – 11:35 Diversity Considerations (5 min)</b> <i>Wayne Batchelor</i>  11:35 – 11:45 Q&A, Discussion (10 min)
<b>11:45 – 12:30 pm</b>	<b>LUNCH (Atrium)</b>
<b>12:30 – 4:15 pm</b>	<b>Breakout Groups – 8 groups / Case Reviews (75 min. each) x 3 rotations</b> 12:30 – 1:45; 1:45 – 3:00; 3:00 – 4:15

	<p>Christopher O'Connor, Anu Lala – 1  Michael Felker, Jane Wilcox - 2  Biykem Bozkurt, David Whellan – 3  JoAnn Lindenfeld - 4  William Abraham, Vanessa Blumer – 5  Peter Carson, Ana Barac – 6  Michael Bristow – 7  Wayne Batchelor, Matt Sherwood - 8</p> <p><u>Statisticians:</u></p> <ol style="list-style-type: none"> <li>1. David DeMets – 7, 2, 4</li> <li>2. Frank Rockhold – 1, 7, 2</li> <li>3. Brian Claggett – 4, 3, 6</li> <li>4. Janet Wittes – 8, 4, 7</li> <li>5. Thomas Fleming – 6, 5, 3</li> <li>6. Chris Lindsay – 3, 6, 5</li> <li>7. Eric Leifer – 2, 8, 1</li> <li>8. Jason Connor – 5, 1, 8</li> </ol>
<b>4:15 – 4:45 pm</b>	<p><b>Lessons Learned, Final Thoughts (30 min)</b>  <i>David DeMets, Tom Fleming, Janet Wittes</i></p>
<b>4:45 pm</b>	<p><b>ADJOURN: Christopher O'Connor, MD</b></p>

### 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**

*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*

**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, Division of Cardiology  
Director of Pharmacogenomics, U. of Colorado  
President and CEO, ARCA Biopharma*

**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, Office of Cardiovascular  
Devices (OHT-2), Center for Devices and Radiological  
Health (CDRH)  
U.S. FDA*

**Michael Felker, MD**

*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, Editor In Chief,  
Journal of Clinical and Translational Science*

**Christopher O'Connor, MD**

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

**Frank Rockhold, PhD**

*Professor of Biostatistics & Bioinformatics  
Duke University*

**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*

**Bram Zuckerman, MD**

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

## Training Participants

### **Ahmad Abdul-Aziz, MD**

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

### **Ankeet Bhatt, MD**

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

### **Jonathan Cunningham, MD**

*Heart Failure and Transplant Cardiologist  
Brigham and Women's Hospital, Heart and Vascular  
Center*

### **Jennifer Cowger, MD**

*Section Head of Advanced Heart Failure, Transplant,  
and Mechanical Circulatory Support  
Henry Ford Health*

### **Melissa Daubert, MD**

*Medical Director, DCRI Imaging Program  
Associate Professor of Medicine  
Duke University Medical Center*

### **Hanna Gaggin, MD**

*Heart Failure and Transplant Cardiologist  
Massachusetts General Hospital  
CV Research Center, Mass General Research Institute*

### **Marlena Habal, MD**

*Assistant Professor, Department of Medicine  
NYU Grossman School of Medicine*

### **Manreet Kanwar, MD**

*Director, MCS and Transplant  
Co-Division Chief, HF and PH  
Pitt/Allegheny Health*

### **Tre Martyn, MD**

*Heart Failure and Transplant Cardiologist  
Cleveland Clinic*

### **Garima Sharma, MD**

*Director of Cardio-Obstetrics Program and Director  
of Cardiovascular  
Women's Health, Inova Schar Heart and Vascular  
Adjunct Associate Professor of Medicine, Johns  
Hopkins University School of Medicine*

### **Shashank Sinha, MD, MSc**

*Assistant Professor of Medical Education, University  
of Virginia School of Medicine  
Medical Director, Cardiac Intensive Care Unit,  
Cardiology, Director, Cardiovascular Critical Care  
Research Program Advanced Heart Failure,  
Mechanical Circulatory Support, and Transplant  
Cardiologist, Inova Schar Heart and Vascular/Inova  
Fairfax Medical Campus*

### **Nosheen Reza, MD**

*Assistant Professor of Medicine, CV Medicine  
University of Pennsylvania*

### **Sumeet Mitter, MD, MSc**

*Director, Infiltrative and Restrictive Cardiomyopathy  
Center Associate Director of Cardiomyopathy  
Research  
Inova Schar Heart and Vascular*

### **Nadia Sutton**

*Assistant Professor of Medicine  
Division of Cardiovascular Medicine  
Vanderbilt University*

### **Quentin Youmans, MD**

*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**

*Director, Advanced HF Program; Medical Director  
Cardiac Transplantation Program; Cleveland Clinic  
Associate Professor, Tufts University*