

The Mayflower Hotel

CVCT
Washington DC, **US**

26TH Global
Cardio VASCULAR
Clinical Trialists WORKSHOP

DECEMBER

2025

SUNDAY 7

The Mayflower Hotel

CVCT

Washington DC, **US**

MEETING VENUE

The Mayflower Hotel
1127 Connecticut Avenue NW,
Washington, DC 20036, USA

ONSITE CONTACTS

Patrick Wahby & Petra Niehoff
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TECHNICAL INFORMATION

To facilitate the progress of the meeting, we ask that you give your presentation to the technician in the meeting room 30 minutes before the session begins (or during the coffee breaks).

LOGISTICS AND TECHNICAL ORGANIZATION OVERCOME

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SCIENTIFIC PROGRAM

SCIENTIFIC PROGRAM

TOPIC 1 - 9.00-10.30

WHAT DOES IT TAKE TO VALIDATE AND ACCEPT OTHER SURROGATES FOR CV PREVENTION TRIALS?

- lowering BP, and Lowering blood lipid levels may be sufficient for regulatory approval of an antihypertensive drug and a lipid lowering drug, respectively
- Glucose control is no longer accepted as a surrogate for approving glucose lowering T2D drugs.
- What does it take to validate and accept other surrogates for CV prevention trials?
- What does it take to validate and accept surrogates for Device trials?
- Approaches to statistical validation and Generalisability of a surrogate endpoint

Chairperson: **Faiez Zannad** (Paris, FRA)

Speaker: **Javed Butler** (Dallas, TX, USA)

Discussants: **Joao Ferreira** (Porto, POR), **Christopher Granger** (Durham, NC, USA), **Odd Erik Johansen** (Roche, USA)

COFFEE BREAK

10.30 - 11.00

TOPIC 2- 11.00-12.30

WHAT SHOULD HAPPEN TO PATIENTS AT TRIAL TERMINATION? RATIONALE, PRACTICE AND ETHICS OF WITHDRAWING INVESTIGATIONAL THERAPY AT THE TERMINATION OF A TRIAL

- Most new investigational drugs trials stop study medications in all patients at the last visit.
- Post withdrawal, patients' condition may deteriorate, if the drug was effective
- More attention to post withdrawal data collection (e.g. EMPEROR)
- Extension studies are not always feasible
- Pros and cons and feasibility of open label extension studies?

Chairperson: **Christopher Granger** (Durham, NC, USA)

Speaker: **Frank Rockhold** (Durham, NC, USA)

Discussants: **Marc Humbert** (Paris, FRA), **Lothar Roessig** (AskBio/bayer, GER), **Chloe Wilson** (The Lancet)

LUNCH BREAK

12.30 - 13.30

TOPIC 3 - 13.30-15.00

ACHIEVING MULTIPLE INDICATIONS/APPROVALS USING A SINGLE TRIAL: DESIGN, STATISTICAL AND REGULATORY CONSIDERATION FOR MULTIPLE ENDPOINTS TRIALS

- Multiple separate trials of a single agent are usually needed seeking separate respective indications, e.g., SGLT2i: as T2D drug, HF drug, CKD drug. e.g., GLP1RA: weight loss, CV, CKD, MASLD claims of benefits
- How to design trials which may have multiple endpoints, targeting different indications?
- How to achieve regulatory approval

Chairperson: **Joao Ferreira** (Porto, POR)

Speaker: **Aliza Thompson** (FDA, USA)

Discussants: **Scott Berry** (Berry Consultants, USA), **Odd Erik Johansen** (Roche, USA), **Janet Wittes** (Wittes LLC, USA)

COFFEE BREAK

15.00 - 15.30

TOPIC 4 - 15.30-1700

IS THERE LIFE BEYOND A “FAILED” PRIMARY ENDPOINT?

- The principle is strict adherence to type I error control. A frequentist interpretation would consider any remaining endpoint to be inconclusive and ‘hypothesis-generating’, as the risk of false discovery cannot be ignored.
- Conclusions by Journals and Regulators generally comply
- But are there exceptions when secondary findings are influential? Can clinical conclusions in select circumstances still be drawn?
- Examples include: VICTOR, PARAGON-HF, RELIEVE-HF, STICH

Chairperson: **Stuart Pocock** (London, UK)

Speaker: **Milton Packer** (Dallas, TX, USA)

Discussants: **Carolyn Lam** (Singapore, SIN), **Douglas Mann** (St Louis, MI, USA), **Yogesh Reddy** (Rochester, Minnesota, USA), **Jan Tijssen** (Amsterdam, NED)

ADJOURN

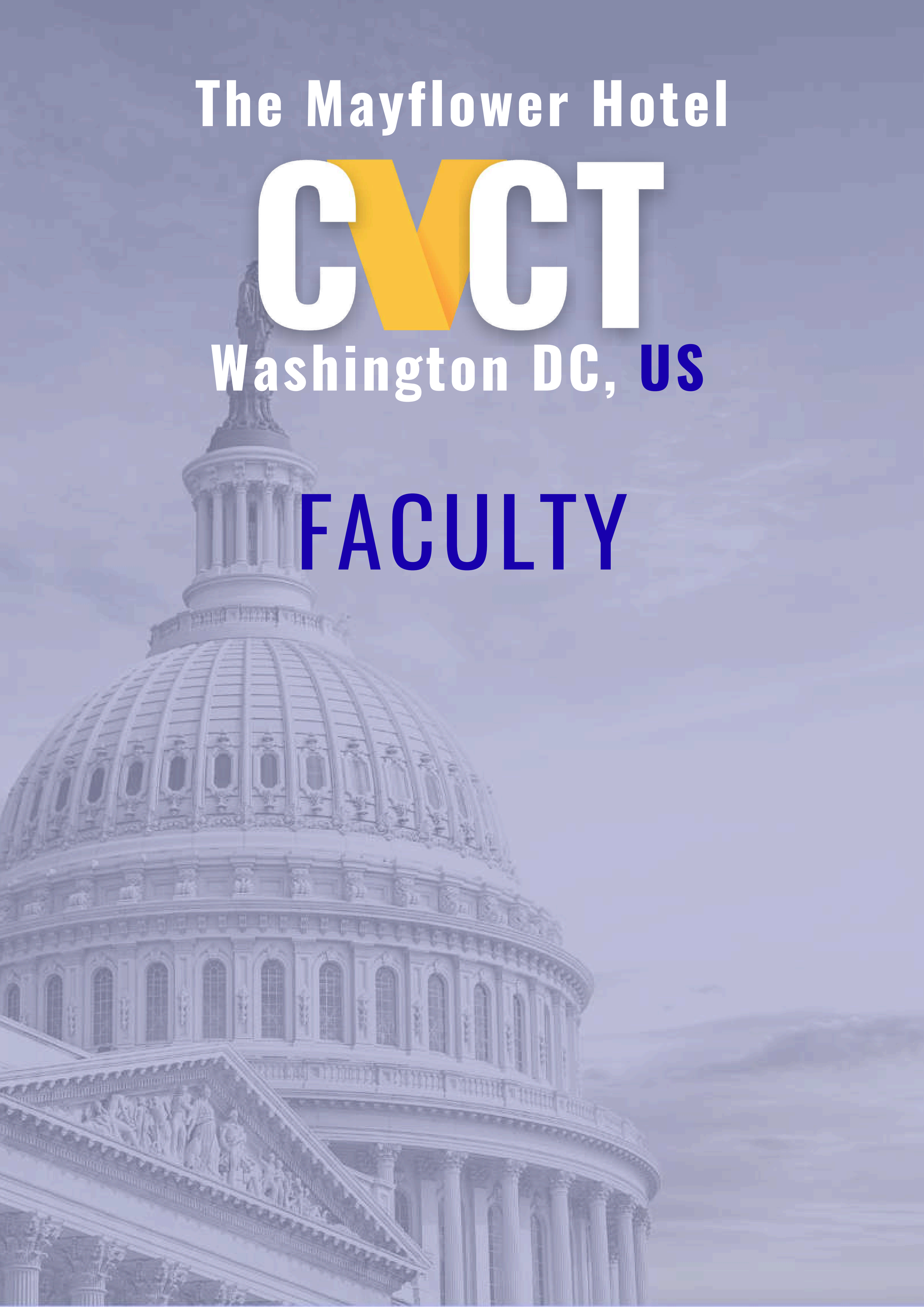
17:00

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FACULTY



Academy



Javed Butler (Dallas, TX, USA)

President of Baylor Scott and White Research Institute and Senior Vice President of Baylor Scott and White Health



Rob Califf (Bethesda, MA,USA)

Duke University



Asita De Silva (Kelaniya, LK)

University of Kelaniya



Mads Engelmann (Copenhagen, DEN)

International Medical Vice President at Novo Nordisk A/S



Joao Ferreira (Porto, POR)

Professor at the Faculty of Medicine of Porto University in Portugal



Christopher Granger (Durham, NC, USA)

Professor of Medicine in the Division of Cardiology at Duke University .



Guiomar Mendieta Badimon (Barcelona, ESP)

Cardiovascular Imaging Fellow and Clinical Cardiology specialist at Hospital Clinic, Barcelona, and a Clinical Scientist at IDIBAPS and CNIC in Spain



Marc Humbert (Paris, FRA)

Head of Pulmonology and Intensive Care at Kremlin-Bicêtre Hospital



Peter Juni (Oxford, UK)

Professor of Medicine and Clinical Trials, University of Oxford



Sanjay Kaul (Los Angeles, CA, USA)

Cedars-Sinai Medical Center



Mohammad Shahzeb Khan (Dallas, TX, USA)

Baylor Scott and White



Paulus Kirchhof (Hambourg, GER)

Cardiologist and researcher at the Department of Cardiology, University Heart and Vascular Center Hamburg, University Medical Center Hamburg-Eppendorf



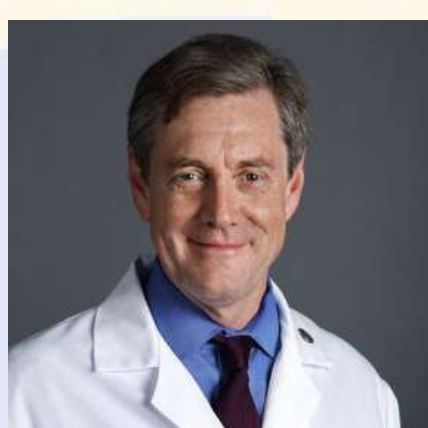
Carolyn Lam (Singapore, SIN)

Senior Consultant Cardiologist at the National Heart Centre Singapore and a Full Professor at Duke-National University of Singapore



Darren McGuire (Dallas, TX, USA)

MD Distinguished Chair in Cardiovascular Science; Distinguished Teaching Professor of Medicine with Tenure at UT Southwestern; Deputy Editor, Circulation



Douglas Mann (St Louis, MI, USA)

Professor of Medicine at Washington University



Alexandre Mebazaa (Paris, FRA)

Appointed by the “Université Paris Cité” and is the Chair of the Department of anesthesia and critical care department of two hospitals



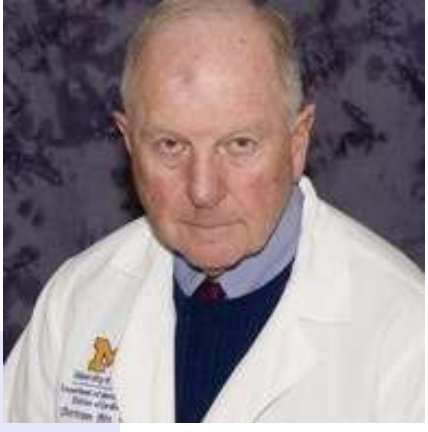
Roxana Mehran (New York, NY, USA)

Endowed Mount Sinai Professor in Cardiovascular Clinical Research and Outcomes at the Icahn School of Medicine at Mount Sinai



Milton Packer (Dallas, TX, USA)

Distinguished Scholar in Cardiovascular Science at Baylor University Medical Center in Dallas.



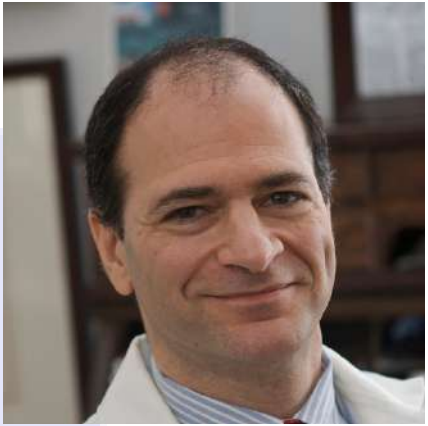
Bertram Pitt (Ann Arbor, MI, USA)

Professor of Medicine Emeritus at the University of Michigan



Stuart Pocock (London, UK)

Professor of Medical Statistics at the London School of Hygiene and Tropical Medicine



Paul Ridker (Boston, MA, USA)

Brigham and Women's Hospital



Yogesh Reddy (Rochester, Minnesota, USA)

Cardiology fellow, Mayo Clinic



Frank Rockhold (Durham, NC, USA)

Professor of Biostatistics and Bioinformatics at Duke University and Faculty Director of Biostatistics at the Duke Clinical Research Institute



Scott Solomon (Boston, MA, USA)

Professor of Medicine, The Edward D. Frohich Distinguished Chair at Harvard University / Brigham and Women's Hospital



Jan Tijssen (Amsterdam, NED)

Expert in Epidemiology and Biostatistics, with a Ph.D. in clinical pharmacology



Subodh Verma (Toronto, CAN)

Cardiac Surgeon, St. Michael's Hospital | Canada Research Chair in Cardiovascular Surgery | Professor, University of Toronto | Associate Editor, JTCVS



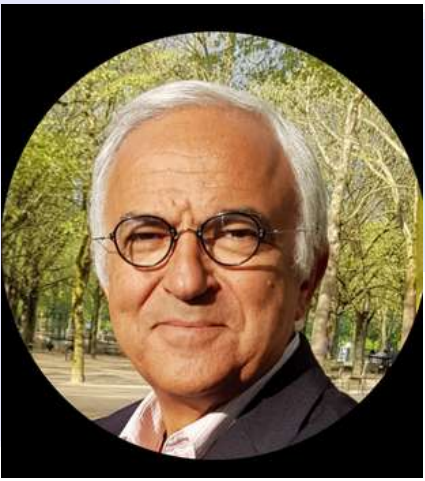
Stephen Wiviott (Boston, USA)

Global Clinical Head at AstraZeneca



Clyde Yancy (Chicago, IL, USA)

Vice-Dean, Health Equity, Professor & Chief of Cardiology, Northwestern University, Feinberg School of Medicine & Assoc. Dir., Bluhm Cardiovascular Institute, Northwestern Medicine



Faiez Zannad (Paris, FRA)

PEmeritus Professor of Therapeutics at the University of Lorraine, Formerly Head of the Division of Heart Failure and Hypertension, and Director of the Inserm clinical Investigation Center at Institut Lorrain du Coeur et des Vaisseaux, Nancy, France

Industry



Scott Berry (Berry Consultants, USA)

President and Senior Statistical Scientist at Berry Consultants



Robert Blaustein (Edgewise, USA)

Chief Development Officer at Edgewise Therapeutics



Roberta Chapman (J&J, USA)

Abiomed/J&J MedTech



Martin Cowie (Astrazeneca, USA)

Senior Vice President & Head of Late CVRM R&D at AstraZeneca in Boston



Bart Gerritse (Medtronic, USA)

Distinguished Statistician, Technical Fellow and Bakken Fellow



Allison Connolly (Abbott, USA)

Director at Abbott



Odd Erik Johansen (Roche, USA)

F.Hoffman-La Roche Ltd.



Samir Awasthi (Anumana, USA)

VP of Clinical Research at Anumana



Christopher O'Donnell (Novartis, USA)

Global Head Cardiovascular and Metabolism Translational Medicine at Novartis BioMedical Research



Juergen Prochaska (Boehringer Ingelheim, GER)

Global Clinical Development at Boehringer Ingelheim



Lothar Roessig (AskBio/bayer, GER)

SVP Integrated Product Team Lead, Congestive Heart Failure at AskBio



Kenneth Stein (Boston Scientific, USA)

Senior Vice President and Global Chief Medical Officer at Boston Scientific



Norman Stockbridge (S & S Consulting, USA)

S & S Consulting Partners



Janet Wittes (Wittes LLC, USA)

Founding Director of the Richard and Susan Smith Center for Outcomes Research at Janet Wittes, PhD, is a biostatistician at Wittes LLC

Regulatory



Alison Cave (MHRA, UK)
MHRA



Jennifer Clark (FDA, USA)



Andrew Farb (FDA, USA)

Chief Medical Officer in the Office of Cardiovascular Devices at the FDA's Center for Devices and Radiological Health (CDRH)



Fortunato Senatore (FDA, USA)



Charu Gandotra (FDA, USA)

Clinical Team Leader in Division of Cardiology and Nephrology, Associate Professor, College of Medicine, Howard University Adjunct Clinical Faculty, Howard University Hospital



Ileana Piña (FDA, USA)

Professor at Thomas Jefferson University and an Adjunct Professor of Biostatistics and Epidemiology at Case Western University



John Sharretts (FDA, USA)

Director of the Division of Diabetes, Lipid Disorders, and Obesity (DDLLO) at the FDA



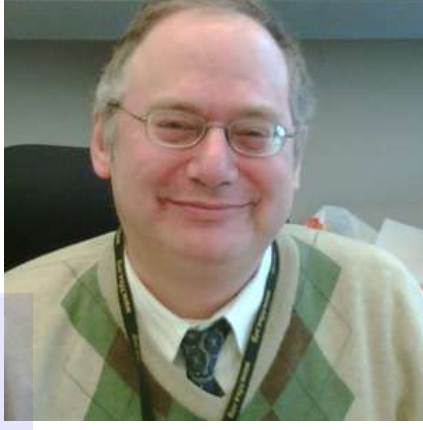
Aliza Thompson (FDA, USA)

Deputy Director of the Division of Cardiology and Nephrology at the FDA, overseeing the review of drugs and biologics for cardiovascular and kidney diseases.



Changfu Wu (FDA, USA)

Senior scientific reviewer at the FDA's Center for Devices and Radiological Health, specializing in heart valve devices and ventricular assist devices



Bram Zuckerman (FDA, USA)

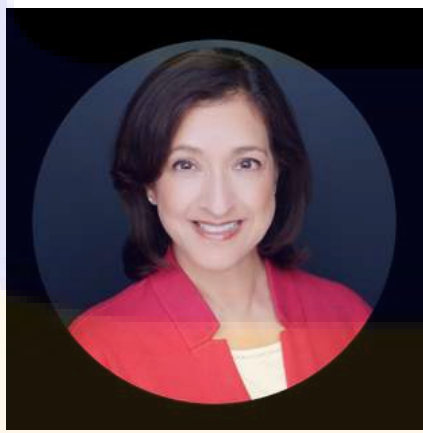
Director of the FDA Office of Cardiovascular Devices. His interests include clinical trial design and medical device development

NIH



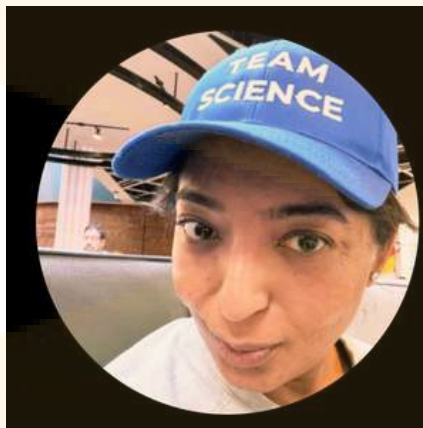
Yves Rosenberg – NIH

Chief of the Atherothrombosis and Coronary Artery Disease Branch at the National Heart, Lung, and Blood Institute, part of the US National Institutes of Health (Bethesda, MD)



Vandana Sachdev – NIH

NHLBI/DCVS



Tania Kamphaus – FNIH

Foundation for NIH

Editors



Michael Basson (Nature Medicine, USA)

Interventional cardiologist, researcher, and educator, serving as CEO of the Baim and PERFUSE research institutes at Harvard Medical School



Jane Leopold (NEJM)

Associate Professor of Medicine at Harvard Medical School and an interventional cardiologist at Brigham and Women's Hospital, where she directs the Women's Interventional Cardiology Health Initiative



Chloe Wilson (The Lancet)

Senior Medical Editor at The Lancet



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<https://www.globalcvctforum.com/cvct-workshop>