CSRC/MDEpiNet PASSION/HVC
Collaborative Communities Thinktank On Prospective Registry-Facilitated Clinical Trials

U.S. FDA Headquarters
Thursday 12-December, 2024
07:00-5:30 pm

I. 07:00-07:30 Arrival & Security Escorts

II. **07:30-07:45 Welcome & Introductions**
Bram Zuckerman (*U.S. Food and Drug Administration*), Norman Stockbridge (*U.S. Food and Drug Administration*), Mitchell Krucoff (*Duke Clinical Research Institute*)

III. 08:00-8:30 Workstream on Global Regulatory Acceptance
Moderators: Aaron Lottes (Purdue University), Ernest Spitzer (Cardialysis)

a. 08:00-08:10 Workstream Overview & Update
Melanie Raska (Boston Scientific)

b. 08:10-08:15 TVT Experience, Perspectives from Edwards
Chie Iwaishi (*Edwards*)

c. 08:15-08:20 TVT Experience, Perspectives from Abbott
Jeeyun Kim (*Abbott*)

d. 08:20-08:30 Discussion
Lead Discussants: Ken Cavanaugh (U.S. Food and Drug Administration), Josh Smale (R3 Vascular), Eric Boersma (Erasmus University Medical Center)

IV. 08:30-09:00 Workstream on Operational Registry Integration Strategies & Solutions
Moderators: Ernest Spitzer (Cardialysis), Rebecca Torguson (U.S. Food and Drug Administration)

a. 08:30-08:40 Workstream Overview & Update
James Tcheng (*Duke Clinical Research Institute*)

b. 08:40-09:00 Discussion
Lead Discussants: Dominic Allocco (Shockwave), Jeffrey Popma (Cardiovascular Research Foundation), Christine Rutan (American Heart Association)

V. 09:00-12:30 Workstream on Cardiogenic Shock I-III

a. ***09:00-09:45 Shock I***: AHA Shock Registry Safety Validation Use Case
Moderators: Nicole Gillette (*U.S. Food and Drug Administration*)*, Eric Klavetter (Medtronic)*

i. 09:00-09:10 AHA Shock Registry Update
Christine Rutan (*American Heart Association*)

ii. 09:10-09:20 Safety Validation Use Case Protocol
David Morrow (*Mass General/Harvard*)

iii. 09:20-09:30 Safety Validation Use Case: Statistical Analysis Plan
Andrew Althouse (*Medtronic*)

iv. 09:30-09:45 Discussion
Lead Discussants: Meir Shinnar (U.S. Food and Drug Administration); Andres Beiras (Getinge); Shaina Costello (American Heart Association), Charles Simonton (Abiomed), Abdulla Damluji (Johns Hopkins University)

b. ***09:45-11:00 Shock II:*** MCS Safety: Cerebral Flow, Pulsatility, Vascular Access, Renal Injury – What Are The Priorities?
Moderators: Kartik Sundareswaran (Abbott), Bram Zuckerman (*U.S. Food and Drug Administration*)

i. 09:45-09:55 Mortality Benefit with Added Risks: What Does DanGer Tell Us?
Holger Thiele *(University of Leipzig*)

ii. 09:55-10:05 MCS Safety Priorities: Academic Perspective
Navin Kapur (*Tufts Medical Center*)

iii. 10:05-10:15 MCS Safety Priorities: FDA Perspective
Mauro Moscucci (*U.S. Food and Drug Administration*)

iv. 10:15-11:00 Discussion
Lead Discussants: Joaquin Cigarroa (Oregon Health Sciences), Imran Aslam (Duke University), Alex Truesdell (Virginia Heart/Inova), Tim Henry (Christ Hospital), Charles Simonton (Abiomed)

11:00-11:15 BREAK

c. ***11:15-12:30 Shock III*:** Re-usable EFIC Infrastructure for Prospective Cardiogenic Shock Trials: What Might That Look Like in the USA?
Moderators: Charles Simonton (Abiomed); Mitchell Krucoff (Duke Clinical Research Institute)

i. 11:15-11:25 EFIC for Cardiogenic Shock and USA Prospective Shock Studies: Lessons Learned and Future Thinking
Graham Nichol (*University of Washington*)

ii. 11:25-11:35 “Re-usable” EFIC Infrastructure for Shock Studies: An FDA Perspective
Pablo Morales (*U.S. Food and Drug Administration*)
iii. 11:35-11:45 Could sIRB Play a Role Supporting “Re-usable” EFIC Infrastructure for Prospective
Amanda Higley (*Advarra*)
iv. 11:45-12:30 Discussion
Lead Discussants: Neal Dickert (Emory); David Morrow (Harvard/MGH); Ron Waksman (Medstar); Nick West (Shockwave); Changfu Wu (U.S. Food and Drug Administration), Eric Klavetter (Medtronic); Carie Facemire (Abiomed)

12:30-1:00: LUNCH BREAK

VI. 1:00-2:30 Workstream on DEI Action Plans for IDE Studies

Moderators: Misti Malone (U.S. Food and Drug Administration), Dan Stephens (Boston Scientific)

a. 1:00-1:10 An Overview of FDA DEI Guidance
Brittany Caldwell (*U.S. Food and Drug Administration*)
b. 1:10-1:20 Class III CV Device Regulatory Science as a Context for DEI in Research
Mitchell Krucoff (*Duke Clinical Research Institute*)
c. 1:20-1:30 Strategies for Success Moving the DEI Needle in CV Research
Megan Coylewright (*ACC Cardiosmart*)
d. 1:30-1:40 Overview of the IDE DEI Action Plan Workstream Deliverables
Wayne Batchelor (*Inova*)
e. 1:40-2:10 Industry Landscape Roundtable: What Are We Doing for IDE DEI APs?
i. 1:40-1:45 Boston Scientific – Janar Sathananthan
ii. 1:45-1:50 Abiomed/J&J Medtech – Roberta (Bobbi) Chapman
iii. 1:50-1:55 Abbott Vascular – Kelly Greer
iv. 1:55-2:00 Medtronic – Manuela Negoita
v. 2:00-2:05 Edwards – Kathy Akagha
vi. 2:05-2:10 R3 Vascular – Josh Smale
f. 2:10-2:30 Wrap Up Discussion
Lead Discussants: Nada Hanafi (MedTech Strategies), Jaime Raben (U.S. Food and Drug Administration), Anthony Fletcher, (Association of Black Cardiologists, Inc.) Tracy Wang (PCORI), Roseann White (3rd Opinion Statistical Consulting)

VII. 2:30-3:45 Workstream on "Clinically Relevant" Periprocedural MI

Moderators: Eric Chen (Abbott); Ron Anson (American College of Cardiology)

a. 2:30-2:40 Redefining PPMI: FDA Perspective
Lydia Glaw (*U.S. Food and Drug Administration*)

b. 2:40-2:50 Clinically Relevant PPMI: Clinical Protocol to Date
Mitchell Krucoff (*Duke Clinical Research Institute*)

c. 2:50-3:00 Biochemical Objectives & Methods
Gillian Murtagh (*Abbott*)

d. 3:00-3:10 Industry Perspective: Value of a Collaborative Approach to Clinically Relevant PPMI Use Case
Dominic Allocco (*Shockwave*)

e. 3:10-3:45: Discussion
Lead Discussants: Rafael Cavalcante (Boston Scientific), Semih Oktay (CardioMed Device Consultants), Ethan Korngold (Abbott), Ron Waksman (MedStar), Fran Thorpe (American College of Cardiology)

VIII. 3:45- 5:00 Workstream on Long-long Heart Valve Follow Up

Moderators: Michael Bowdish (Cedars-Sinai), Christine Rutan (American Heart Association)

a. 3:45-3:55 Ten Year Heart Valve Follow Up: FDA Perspective
Changfu Wu (*U.S. Food and Drug Administration*)

b. 3:55-4:05 Ten Year Heart Valve Follow Up: Industry Perspective
Erin Spinner (*Abbott*)

c. 4:05-4:15 Long-long Workstream: Overview & Deliverables
Sreek Vemulapalli (*Duke University*)

d. 4:15-4:25 Biostatistical Considerations
Roseann White (*3rd Opinion Statistical Consulting*)

e. 4:25-5:00 Discussion
Lead Discussants: Jeffrey Popma (Cardiovascular Research Foundation), Graeme Hickey (Medtronic), Kathy Akagha (Edwards), Bram Zuckerman (U.S. Food and Drug Administration), Rebecca Torguson (U.S. Food and Drug Administration)

IX. 5:00-5:30 Next Steps & Adjournment

Moderators: Bram Zuckerman (U.S. Food and Drug Administration), *Mitchell Krucoff (Duke Clinical Research Institute)*

Lead Discussants:

- Michael Bowdish (*Cedars-Sinai*)
- Megan Coylewright (*ACC Cardiosmart*)
- Christine Rutan (*American Heart Association*)
- Andrew Farb (*U.S. Food and Drug Administration*)

- Roseann White (*3rd Opinion Statistical Consulting*)