



AGENDA

CSRC CRF Open Forum Meeting

10903 New Hampshire Avenue, Silver Spring, Maryland 20993

White Oak Facility, FDA Headquarters • Silver Spring, MD • December 11, 2012

7:30am-8:00am – Registration and Breakfast

8:00am-8:25am (Moderators: John Finkle, MD (GlaxoSmithKline) and Mary Beth Sabol, MD (GlaxoSmithKline))

- Concept behind/need for CV CRFs from Industry Perspective: *John Finkle, MD (GlaxoSmithKline)* 5min
- Brief intro to forms and current concepts: *Mary Beth Sabol, MD (GlaxoSmithKline)* 5min
- CEC committees and how this type of data collection differs from typical CV outcomes trials: *Kenneth Mahaffey, MD (Duke University)* 5min
- FDA perspective on coordination of these forms with other efforts: *Karen Hicks, MD (FDA)* 5min
- Academia/Investigator: *Daniel Lenihan, MD (Vanderbilt)* 5min

8:25am-8:50am – Cardiovascular and Death Forms: Goals & Objectives (Moderator: Mary Beth Sabol)

Broad basic questions to be addressed:

- What is the purpose of the forms?
- What information do we want to gather?
- Source data verification vs source documentation
- **Panel Discussion with Plenary Speakers**

8:50am-12:05pm – Review Forms

- **Death** (8:50-9:35)
 - FDA: *Ellis Unger, MD (FDA)*
 - CSRC: *Mary Beth Sabol, MD (GlaxoSmithKline)*
- **MI/Unstable Angina** (9:35-10:20)
 - FDA: *Karen Hicks, MD (FDA)*
 - CSRC: *James Tcheng, MD (Duke University)*

- **Break** (10:20-10:35)
- **Heart Failure** (10:35-11:20)
 - FDA: *Shari Targum, MD (FDA)*
 - CSRC: *Daniel Lenihan, MD (Vanderbilt)*
- **Arrhythmias** (11:20-12:05)
 - FDA: *Norman Stockbridge, MD, PhD (FDA)*
 - CSRC: *John Finkle, MD (GlaxoSmithKline)*

- **Break to pick up bagged lunch** (12:05-12:20)

12:20pm-3:30pm – Working Lunch & Review Forms

- **Deep Venous Thrombosis & Pulmonary Embolism** (12:20-12:50)
 - FDA: *Norman Stockbridge, MD, PhD (FDA)*
 - FDA: *Karen Hicks, MD (FDA)*
 - CSRC: *Daniel Lenihan, MD (Vanderbilt)*
- **Pulmonary Hypertension** (12:50-1:20)
 - FDA: *Preston Dunnmon, MD (FDA)*
- **Stroke/TIA** (1:20-1:50)
 - FDA: *Karen Hicks, MD (FDA)*
Billy Dunn, MD (FDA)
John Marler, MD (FDA)
 - CSRC: *Philip Sager, MD (Pharmaceutical Consultant)*

- **Break** (1:50-2:00)

- **Valvulopathy** (2:00-2:30)
 - FDA: *Shari Targum, MD (FDA)*
- **Peripheral Arterial Thromboembolism** (2:30-3:00)
 - FDA: *Karen Hicks, MD (FDA)*
 - CSRC: *Kenneth Mahaffey, MD (Duke University)*
- **Revascularization** (3:00-3:30)
 - FDA: *Karen Hicks, MD (FDA)*
 - CSRC: *James Tcheng, MD (Duke University)*

3:30pm-3:45pm – Wrap Up & Next Steps