

AGENDA

**Cardiac Disease and Safety in Clinical Research: Integrating Cardiology and Oncology  
Clinical Trials with Practice  
CSRC and ICOS Annual Meetings**

White Oak Facility, FDA Headquarters • Silver Spring, MD • October 5-6, 2011

**October 5, 2011 CSRC Annual Meeting**

**7:30-8:00 AM**

Registration and Continental Breakfast

**8:00-8:15 AM**

Welcome & Agenda Overview: *Mitchell Krucoff, MD (Duke)* 5 min.  
CSRC: What is CSRC & How Do We Work?: *John Finkle, MD (GSK)* 5 min.  
ICOS: Who We Are & What We Do: *Daniel Lenihan, MD (Vanderbilt)* 5 min.

**8:15-9:15 AM**

Reports from the CSRC Committees  
Moderators: *Paul Kligfield, MD (Cornell)*; *Theresa Wright, MD (Lilly)*

- White Papers: *Ignacio Rodriguez, MD (Roche)* 5 min.
- Scientific Oversight Committee: Accomplishments and New Initiatives: *Benjamin Eloff, PhD (FDA)* 5 min.
- ECG Database: *Paul Kligfield, MD (Cornell)* 10 min.
- Public Programs Update: *Philip Sager, MD (Consultant)* 10 min.
  - Thinktank Conclusions & Actions from Meetings
  - Future Thinktanks
- CSRC Membership: Expanding to Meet Your Needs: *Theresa Wright, MD (Eli Lilly)* 5 min.

**9:15-10:00 AM**

**Plenary Session**

Moderators: *Mitchell Krucoff, MD (Duke)*; *Norman Stockbridge, MD, PhD (FDA)*

- DIA Priorities for the Future: *Paul Pomerantz, MBA* 10 min.
- ACC Priorities and the CSRC: *Jack Lewin, MD* 10 min.

**10:00-10:15 AM Break**

**10:15-11:45 AM**

**Current Safety Issues, Product Development, and Impact on Product Development: How Can We Facilitate Innovation?**

Moderators: *Rick Turner, PhD (Quintiles)*

- FDA CDER Perspective: *Douglas Throckmorton, MD (FDA)* 5 min
- Device Development Perspective: *Justin Mortara, PhD (Mortara Instrument)* 5 min.
- Pharmaceutical Development Perspective: *Rick Sax, MD (Quintiles)* 5 min.

- Alignment of Product Development & Cardiovascular Safety: *Matthew Killeen, PhD (Decision Resources, LLC)* 5 min.
- Lessons in Device Innovation: An Academic View: *Mitchell Krucoff, MD (Duke)* 5 min.
- FDA Device Viewpoint: *Owen Faris, PhD (FDA)* 5 min.

Panel: All Speakers plus *Paul Pomerantz, MBA*, *Jack Lewin, MD*, and *Philip Sager, MD*

**11:45-12:15 PM Lunch**

**12:15-1:45 PM**

**Hot Topics Mini-Symposium I: Innovation in Collecting Safety Data via Novel Randomized Trial Approaches or Other Techniques**

Moderators: *Cindy Green, PhD (Duke)*; *Philip Sager, MD (Consultant)*

- FDA Viewpoint: *Matthew Soukup, PhD (FDA)* 5 min.
- NIH Viewpoint for Innovative Trials: *Denise Bonds, MD, MPH (NIH)* 5 min.
- Pharmaceutical Development Perspective: *Anders Svensson, MD, PhD (Roche)* 5 min.
- Targeted CV Safety Follow-up: *John Finkle, MD (GSK)* 5 min.
- FDA Device Viewpoint: *Owen Faris, PhD (FDA)* 5 min.
- Device Development Perspective: *Hans-Peter Stoll, MD (J&J)* 5 min.
- Academic Viewpoint: *Thomas Suter, MD (Bern University)* 5 min.

Panel: All Speakers

**1:45-2:00 PM Break**

**2:00-3:30 PM**

**Hot Topics Mini-Symposium II: Cardiac Safety & Blood Pressure: Do we need Thorough BP Studies? If so, for all drugs or only for certain drugs?**

Moderators: *Norman Stockbridge, MD, PhD (FDA)*; *Adel Nada, MD (Abbott)*

- FDA: What is the Issue?: *Robert Fiorentino (FDA)* 10 min.
- Industry View: *Robert Blaustein, MD, PhD (Merck)* 5 min.
- Measurement Techniques: Manual vs. Automated: What is the ideal approach?: *Jeff Heilbraun, MS (Corelab Partners)* 5 min.
- Statistical View (How to evaluate Blood Pressure Increases by Incorporating the drug's benefit): *Cindy Green, PhD (Duke)* 5 min.
- Practical Aspects of BP Assessment: *Larry Satin, MD (Cardiocre)* 5 min.

Panel: All Speakers plus *Eric Michelson, MD*



AGENDA

**Cardiac Disease and Safety in Clinical Research: Integrating Cardiology and Oncology Clinical Trials with Practice**

**CSRC and ICOS Annual Meetings**

*White Oak Facility, FDA Headquarters • Silver Spring, MD • October 5-6, 2011*

**3:30-3:50 PM Break**

**3:50-5:15 PM**

**CSRC Future Directions 1:**

**Strategic Relationships and Collaborations**

*Moderators: Ignacio Rodriguez, MD (Roche); John Finkle, MD (GSK)*

- How our organizations are aligned and how can we more closely collaborate?
  - ICOS and the CSRC – *Joseph Carver, MD* 5 min.
  - ACC and the CSRC – *Kathleen Hewitt, MSN* 5 min.
  - DIA and the CSRC – *Paul Pomerantz, MBA* 5 min.
  - HESI and the CSRC – *Syrl Pettit, MEM* 5 min.

Discussion: 20 min.

**CSRC Future Directions 2:**

**Open Discussion on Procedures, Priorities, Proposals for Research, White Papers, and Thinktanks**

Open Discussion: What additional areas should the CSRC focus on in 2012 that are high impact for Public Health? How do we measure our impact? Procedures, Priorities, and Proposals for Research, White Papers, and Thinktanks.

**5:15 PM**

**Adjourn**

**Following the Meeting:**

**6:30-8:30 PM**

Meet and Greet Reception at the Sheraton Washington North Hotel

**7:30-9:00 PM**

CSRC Executive Committee Meeting

ICOS Executive Committee Meeting



AGENDA

**Cardiac Disease and Safety in Clinical Research: Integrating Cardiology and Oncology  
Clinical Trials with Practice  
CSRC and ICOS Annual Meetings**

White Oak Facility, FDA Headquarters • Silver Spring, MD • October 5-6, 2011

**October 6, 2011 ICOS Annual Meeting**

**7:30-8:00 AM**

Registration and Continental Breakfast

**8:00-8:10 AM**

The History of the International CardiOncology Society (ICOS): *Carlo Cipolla, MD (IEO) and Daniel Lenihan, MD (Vanderbilt)*

**8:10-10:00 AM**

**Session I: What is Cardiotoxicity and How Does this Impact Clinicians and Their Patients?**

*Moderators: Michael Ewer, MD (MD Anderson); Michael Fisch, MD (MD Anderson); Mitchell Krucoff, MD (Duke)*

- Is there such a thing as late cardiotoxicity – or just poorly recognized cardiac injury?: *Daniela Cardinale, MD (IEO)* (20 min)
- How can Cardiology help in the development & conduct of a clinical trial for Oncology?: *Thomas Suter, MD (Bern)* (20 min)
- New Developments in Echocardiographic Detection: *Carol Chen, MD (Sloan-Kettering)* (20 min)
- Anti-angiogenic & anti-VEGF therapy: A Cardiovascular view of the disturbed balance between vascular protection and Anti-angiogenesis: *Bonnie Ky, MD (UPHS)* (20 min)
- FDA View: How does Cardiotoxicity impact drug approval?: *Patricia Cortazar (FDA)* (20 min)
- 2 Case Scenarios & Decisions that Arise: *JB Durand, MD (MD Anderson)* (Panel Members Discussion)

Panel Discussion: All Speakers

**10:00-10:20 AM Break**

**10:20-12:00 AM**

**Session II: Recent Development in the Overlap of Cardiology & Oncology**

*Moderators: JoAnn Lindenfeld, MD (Denver); Joanna Brell, MD (NIH); Philip Sager, MD (Consultant)*

- High dose chemotherapy & stem cell transplantation – How do Oncology & Cardiology Interact with these patients?: *Fabio Ciceri, MD (HSR)* (20 min)
- Are Cardiologists Responding Appropriately to Oncology Colleagues? *Ron Witteles, MD (Stanford)* (20 min)
- QT Monitoring during Oncology Trials – Can we realistically expect to learn anything?: *Carlo Cipolla, MD (IEO)* (20 min)
- Harmonizing QT interval requirements for clinical research and cardiac safety worldwide: *Daniel Bloomfield, MD (Merck)* (20 min)

- Case Presentation: *Alan Kono, MD (Hitchcock)*
- Panel Discussion: All Speakers

**12:00-12:40 PM Lunch**

**12:40-2:20 PM**

**Session III: Future for Research in CardiOncology**

*Moderators: John Finkle, MD (GSK); Paige McDonald, PhD (NIH); Richard Steingart, MD (Sloan-Kettering)*

- Can Cardiac Biomarkers, such as troponin, give us better information for the detection of cardiotoxicity?: *Maria Teresa Sandri, MD (IEO)* (20 min)
- Research Opportunities that arise in the overlap between Cardiology & Oncology: *Giuseppe Curigliano, MD, PhD (IEO)* (20 min)
- Can point of care cardiac biomarker testing guide cardiac safety during oncology trials?: *Daniel Lenihan, MD (Vanderbilt)* (20 min)
- FDA View: How do we integrate upcoming research into oncology drug development?: *Gideon Blumenthal, MD (FDA)* (20 min)

Panel Discussion: All Speakers

**2:20-2:30 PM Break**

**2:30-4:40 PM**

**Session IV: Mechanisms for Cardiac Toxicity & Possible Treatments**

*Moderators: Thomas Force, MD (Jefferson); Aarif Khakoo, MD (MD Anderson); Theresa Wright, MD (Eli Lilly)*

- Mitochondrial Mechanisms & Markers of Cardiotoxicity: *Marco Giorgio, MD (IEO)* (20 min)
- MAO Inhibitors for Protection & Treatment of Cardiotoxicity: *Fabio Di Lisa, MD (Padova)* (20 min)
- Does Understanding the biology of cardiac injury & repair from cancer therapy lead to new cardiac therapy?: *Carrie Geisberg, MD (Vanderbilt)* (20 min)
- Early Phase trials in Oncology – Concern for Cardiovascular Toxicity?: *Apostolia Tsimberidou, MD (MD Anderson)* (20 min)
- FDA View: Getting to the heart of the matter – Partnerships for understanding Cardiotoxicity: *Benjamin Eloff, PhD (FDA)* (20 min)
- Case Presentations: *Charlie Porter, MD (Kansas)*

Panel Discussion: All Speakers

**4:40-4:50 PM**

Closing Remarks: *Joseph Carver, MD (UPHS); Daniel Lenihan, MD (Vanderbilt); and Carlo Cipolla, MD (IEO)*