Cardiac Safety Research Consortium

CSRC Annual Meeting 2012

10903 New Hampshire Avenue, Silver Spring, MD 20993

White Oak Facility, FDA Headquarters • Silver Spring, MD

Sunday, December 9 at 7:30pm– Reception in the Capitol Ballroom, DoubleTree Hotel *(8727 Colesville Road, Silver Spring, MD)*

Monday, December 10 - 7:30am-8:00am
Registration and Continental Breakfast

8:00am-8:35am – CSRC 2012

- Welcome and Agenda Overview: *Philip Sager, MD (Consultant)* 5min
- CSRC Mission, How We Work, and Major 2012 Accomplishments: *Mitchell Krucoff, MD (Duke)* 10min
- Discussion 20min

8:35am-12:15pm – Critical Issues in the Assessment of Drug-Induced CV Safety *(Co-Chairs: Norman Stockbridge, MD, PhD (FDA); Philip Sager, MD (Consultant)*

This session will focus on the need and best practices for CV Safety assessments, including the use of outcome studies in the evaluation of new chemical entities and will highlight new approaches & technologies that may impact the need for outcome trials.

- CV Safety Assessment in Drug Development – The Need of Individual Dedicated Studies vs. Monitoring Throughout Development & Risk Management: *Peter Kowey, MD (Lankenau)* 15min
- The Current Heuristic Approach – Strengths & Weaknesses/CV Assessment in Low Risk Patients when there is no prior signal: *Michael Lauer, MD (NIH)* 15min
- CV Outcome Studies in GI Indications to Determine Patient Safety: *Joyce Korvick, MD (FDA)* 15min
- Sentinel Initiative: Ability of Active Surveillance to Capture Major Cardiac Adverse Events: *Monika Houstoun, D.Pharm (FDA)* 15min
- The Use of Existing Large Databases to Better Understand Population and Drug CV Risk: *Mary Parks, MD (FDA)* 15min

9:55am-10:05am – Break

- Innovations in Devices to Facilitate CV Safety Assessment: *Rich Fogoros, MD (Corventis)* 15min
- Missing Data in Outcome Trials – Implications and Prevention: *Jim Neaton, PhD (UMN)* 15min
- CV Safety – What is the Role of CV Adjudication, Key Issues, and When is it Indicated?: *Jonathan Seltzer, MD (Applied Clinical Intelligence)* 15min
- How Broad of an Assessment is Necessary When the Data is Sparse for CV Events and Death in Non-Cardiac Studies: *Mary Beth Sabol, MD (GSK)* and Commentary: *Karen Hicks, MD (FDA)* 15min
- Panel Discussion: All Speakers plus *Robert Temple, MD (FDA); John Finkle, MD (GSK)* 80min

12:20pm – Break and Get Working Lunch

12:45pm-2:30pm – CSRC Future Directions *(Co-Chairs: John Finkle, MD (GSK); Theressa Wright, MD (Eli Lilly)*

- Abstract Presentations from CSRC Membership Regarding New Potential CSRC Initiatives:
  - White Paper on Cardiac Safety in the Development of COPD Drugs: *Pierre Maison Blanche (Biomedical Systems) and Antonio Ferrari (Chiesi)* 12min
  - Prospective early clinical QT study of a test set of marketed drugs to evaluate QT interval response without a TQT study: *Charles Benson (Eli Lilly) and Nenad Sarapa (Consultant)* 15min
  - CV Safety Consultations in Pharmaceutical Organizations: *Roger Mills (Janssen) and Kathryn Gargiulo (Janssen)* 12min
- How Can the CSRC Be More Involved in Device Issues?: *Bram Zuckerman, MD (FDA)* 15min
- Safety Outcome Studies – Key Principles and Case Examples: *Robert Temple, MD (FDA)* 15min
- Panel and Open Discussion: High Impact Public Health Focuses for CSRC in 2013? How Do We Measure Our Impact?

2:30pm-2:45pm – Break

2:45pm-5:15pm – Critical Issues in the Assessment of Drug-Induced CV Safety

- **QT/Arrhythmia Issues: Can the Thorough QT Study Be Replaced? *(Co-Chairs: Borje Darpo, MD, PhD (Consultant); Ignacio Rodriguez, MD (Roche)***
  - Regulatory Perspective: *Norman Stockbridge, MD, PhD (FDA)* 15min
  - QT/PK Modeling to Replace the TQT – Science, Implications, and Pathways Forward: *Borje Darpo, MD, PhD (Consultant)* 15min
  - Panel Discussion 30min
- **Is More Intensive Evaluation of BP Increases Needed During Drug Development? *(Co-Chairs: William White, MD (UCHC); Mary Jane Geiger, MD (Relypsa)***
  - Overview: *William White, MD (UCHC)* 15min
  - State-of-the-art BP Assessments: *Eoin O'Brien (dabl)* 15min
  - Panel Discussion: All Speakers plus *Philip Sager, MD (Consultant)* and *Eric Michelson, MD (Astrazeneca)* 45min

5:15pm-5:30pm – Wrap Up & Next Steps