

Cardiac Safety Research Consortium Adjudication Thinktank

Philip Sager, MD, FACC, FAHA, FHRS
Pharmaceutical Consultant
Chair, Scientific Programs Committee,
Cardiac Safety Research Consortium
Consulting Professor of Medicine
Stanford School of Medicine

Program Committee

Jonathan Seltzer
Mary Jane Geiger
Philip Sager
Monica Bengus
Ralph Brindis
John Finkle
Jonathan Goldman
Stephen Grant

Jae Kim
Peter Kowey
Dan Lenihan
Kenneth Mahaffey
Krucoff Mitchell
Valarie Morrow
Dena Ramey
William B. White

Program Committee

Jonathan Seltzer

Mary Jane Geiger

Philip Sager

Monica Bengus

Ralph Brindis

John Finkle

Jonathan Goldman

Stephen Grant

Jae Kim

Peter Kowey

Dan Lenihan

Kenneth Mahaffey

Krucoff Mitchell

Valarie Morrow

Dena Ramey

William B. White

Why Have This Meeting?

- CV Adjudication is being widely employed
- Lack of data-driven consensus on the role and techniques of CV adjudication
 - Time for a critical examination
- When is adjudication appropriate and where does it add tangible value
- What is the role of PI expertise
- How are events identified and ascertained

Meeting Overview

5

Think Tank Structure

- Short provocative presentations
- Ample discussion time
- Room logistics

Presenters have promised to stay within their allotted time limit 😊

Moderators

Hope for a lasting impact

Publication

Speakers and Audience Participation

- Discussion is key!
 - Discussant taken in the order they are self-identified
 - Virtual round table
 - Microphones- for questions and discussion

CSRC Annual Meeting



Cardiac Safety Research Consortium
www.cardiac-safety.org



December 12-13, 2013
CSRC/ICOS Annual Meeting
Renaissance Hotel

- Critical Issues in Drug Development
 - Janet Woodcock and Robert Califf
- The new paradigm to replace the TQT
- The use of FIM PK/PD modeling to replace the TQT
- How personalized medicine and biomarkers can impact development
- Cardio-Oncology

CSRC Annual Meeting



Cardiac Safety Research Consortium
www.cardiac-safety.org



December 12-13, 2013
CSRC/ICOS Annual Meeting
Renaissance Hotel

- Critical Issues in Drug Development
 - Janet Woodcock and Robert Califf
- The new paradigm to replace the TQT
- The use of FIM PK/PD modeling to replace the TQT
- How personalized medicine and biomarkers can impact development
- Cardio-Oncology