

EXPERT FACULTY:

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Theresa Wright, MD
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Cardiac Safety Research Consortium
and
International CardiOncology Society



Proudly Present:



CSRC and ICOS Annual Meetings

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

October 5 and 6, 2011

FDA White Oak Facility
Great Room, Building 31

10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Agenda

October 5, 2011 - CSRC Annual Meeting

8:00-8:30 Introductory Session

Welcome & Agenda Overview

CSRC: What Is CSRC and How Do We Work

8:30-9:45 Reports from the CSRC Committees

- CSRC Membership: Expanding to Meet Your Needs
- SOC and White Papers
- New Initiatives
- Public Programs Update

9:45-10:00 Break

10:00-11:45 PLENARY SESSION: Current Safety Issues, Product Development, and Impact on Product Development

- FDA Set the Stage Talk
- Industry Perspective- Alignment of product development and CV Safety
- Device Development Perspective
- Pharmaceutical Development Perspective
- Perspective on Data Sharing
- FDA CDER Perspective
- FDA CDRH Perspective

11:45- 12:15 Working Lunch

12:15-1:45 Hot Topics Mini-Symposium I: Innovation in Collecting Safety Data via Randomized Trials

- FDA Viewpoint
- NIH Viewpoint (RFP) for Innovative Trials
- FDA Device Viewpoint
- Device Development Perspective
- Pharmaceutical Development Perspective
- Academic ICOS Viewpoint
- Academic Viewpoint
- Post-marketing Efforts to collect robust safety data viewpoint

1:45-2:00 Break

2:00- 3:30 Hot Topics Mini-Symposium II: Cardiac Safety and Blood Pressure

- FDA: What is the Issue?
- Statistical viewpoint
- Industry View
- Academic View: What should we measure; what is important?
- Measurement techniques (Manual vs Automated; what type, what is the ideal approach)
- Practical aspects of BP assessment
- NIH View

3:30-4:00 Break

4:00- 5:15 CSRC Future Directions: Open Discussion on Procedures, Priorities, Strategic Relationships CSRC; Proposals for Research, White Papers, Think Tanks

How are our organizations aligned and how can we more closely collaborate?

- ICOS and the CSRC
- ACC and the CSRC
- HESI and the CSRC

October 6, 2011 - ICOS Annual Meeting

8:00-8:10 The History of ICOS

8:10 – 10:00 What is Cardiotoxicity and How does this impact clinicians and their patients

- Is there such a thing as late cardiotoxicity-or just poorly recognized cardiac injury?
- How can Cardiology help in the development and conduct of a clinical trial for Oncology?
- New Developments In Echocardiographic Detection
- Anti-angiogenic and anti-VEGF therapy: A Cardiovascular view of the disturbed balance between vascular protection and anti- angiogenesis
- FDA perspective: How does cardiotoxicity impact drug approval?
- 2 Case Scenarios and Decisions that arise

10:00-10:20 Break

10:20-12:00 Recent Developments in the Overlap of Cardiology and Oncology

- High dose chemotherapy and stem cell transplantation: How do Oncology and Cardiology Interact in these patients?
- Are Cardiologists Responding Appropriately to Oncology Colleagues?
- QT monitoring during Oncology trials-can we realistically expect to learn anything?
- Harmonizing QT interval requirements for clinical research & cardiac safety worldwide

Case Presentation

12:00-12:40 Lunch

Session 3: Future for Research in CardiOncology

- Can cardiac biomarkers, such as troponin, give us better information for the detection of cardiotoxicity?
- Research Opportunities that arise in the overlap between Cardiology & Oncology
- Can point of care cardiac biomarker testing guide cardiac safety during oncology trials?
- FDA perspective- How do we integrate upcoming research into oncology drug development

Break: 2:20-2:30

Session 4: Mechanisms for Cardiac Toxicity and Possible Treatments

Possible Treatments

- Mitochondrial mechanisms and markers of cardiotoxicity
- MAO Inhibitors for protection and treatment of cardiotoxicity
- Does understanding the biology of cardiac injury and repair from cancer therapy lead to new cardiac therapy?
- Early phase trials in Oncology-any concern for CardioVascular toxicity?
- FDA Perspective-Getting to the heart of the matter: partnerships for understanding cardiotoxicity.

4:30- 4:50 Next Steps/ Closing Remarks

6:30- 8:30 Meet and Greet Reception at Sheraton Washington North

REGISTRATION

Industry Members: \$850/\$500

Industry Non-members: \$1450/
\$950

Academic Societies & Non-Profits:
\$425/\$250

Government: \$200/\$150

To register, please visit
www.cardiac-safety.org. Please
direct registration questions to
Eva Hill at (919)-668-5927 or
eva.hill@duke.edu.

CME CREDITS

Application for CME credit has
been filed with the American
Academy of Family Physicians for
Day 2 of the meeting/the ICOS
Annual Meeting. Determination of
credit is pending.

CONFERENCE HOTEL

Sheraton Washington North

Phone Number: 301-937-4422

Please reference "CSRC &
ICOS."

CANCELLATION POLICY

Written notification of cancellations
must be received on/before 9/30/11.
Cancellations received from 10/1/11-
10/3/11 will be subject to a \$100 fee.
Cancellations received after 10/3/11
will not be refunded. In the unlikely
event the program is canceled or
postponed, we will not be responsi-
ble for any travel costs or expenses,
including cancellation/change penal-
ties assessed by airlines, travel agen-
cies or hotels.



Visit the CSRC at: www.cardiac-safety.org

Visit ICOS at: www.cardioncology.it/home

Email...

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