

Cardiac Safety Research Consortium

Duke Clinical Research Institute (DCRI)



**Translational Medicine Meets Critical Path:
Cardiac Safety “Hot Topics” Thinktank 2008
October 6-7, 2008**

**An Educational Collaboration between the Health
Environmental Sciences Institute
(HESI), the Cardiac Safety Research Consortium
(CSRC) and the U.S. FDA**



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Cardiac Safety “Hot Topics” Thinktank 2008
October 6-7, 2008**

Monday 6 October (Morning)

- **08:00-09:35** **Open Session**
- **09:35-10:45** **Cardiotoxicity and Troponin: Where Do They Fit in Drug Development?**
- **10:45-11:00** **Break**
- **11:00-12:30** **Preclinical and Clinical Testing for QT Proarrhythmia: How Do They Relate to one Another and to Risk of Life-Threatening Arrhythmic Events?**



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Monday 6 October (Afternoon)

- **12:30-13:45** **Working Lunch**
- **13:45-15:15** **Preclinical and Clinical Evaluation of
Non-QT Proarrhythmia**
- **15:15-15:30** **Break**
- **15:30-17:00** **Biologics and Large Molecules: How do
we Evaluate Proarrhythmia and
Myotoxicity when Thorough QT Cannot Be
Performed?**
- **17:00-17:30** **Summarizing Day 1**
- **17:30** **Adjournment**



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Agenda Tuesday 7 October

- **08:00-09:30** Risks & Benefits Developing Drugs with Safety Signals-
What Are the Challenges?
- **09:30-11:00** New Horizons of Cardiac Safety Programs: Do We Need
“Thorough” Blood Pressure, Heart Rate, Platelet and
Lipid Studies?
- **11:00-12:30** Wrap Up: Where Do We Go From Here-Priorities & Next
Steps?
- **12:30** Adjournment