



**HESI TECHNICAL COMMITTEE ON CARDIAC SAFETY
PROARRHYTHMIA WORKSHOP
OCTOBER 4, 2012**

HYATT REGENCY - PHOENIX, ARIZONA

The Health and Environmental Sciences Institute (HESI) cordially invites you to participate in the HESI Technical Committee on Cardiac Safety Proarrhythmia Workshop October 4, 2012 at the Hyatt Regency following the SPS Annual Meeting in Phoenix, Arizona.

This workshop provides a unique opportunity to hear and discuss analyses generated by internationally recognized scientific consortia regarding the concordance of nonclinical/clinical safety pharmacology cardiovascular data. Agenda highlights include:

- Conclusions of analyses on the HESI-US FDA joint data evaluation of nonclinical to clinical concordance of 112 compounds submitted as INDs and NDAs;
- Results of the HESI literature analysis review of 135 compounds to assess concordance of nonclinical and clinical endpoints;
- Updates from the TI Pharma joint public-private research partnership on concentration-effect (PKPD) modeling research;
- Recent findings of the ABPI-Animal Model Framework assessment of predictivity of preclinical animal models; and
- Discussions of future needs and opportunities for cross-consortia collaboration.

REGISTRATION

Registration is free but space is limited! Register online by **August 15, 2012**:
<http://www.surveymonkey.com/s/ProA2012>

ABOUT THE TECHNICAL COMMITTEE ON CARDIAC SAFETY

Mission:

- To develop and disseminate improved data, approaches, and resources for the evaluation of preclinical and clinical cardiac toxicity.
- Bring preclinical scientists and clinicians together to address issues of contemporary concern relative to clinical cardiac safety.

ABOUT HESI

Mission: Engage scientists from academia, government and industry to identify and resolve global health and environmental issues.

Vision: Creating science-based solutions for a sustainable, healthier world.

Contact: Ms. Jennifer Pierson (jpierson@hesiglobal.org) for more information.



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Draft Agenda

- 12:30 p.m. Welcome and Lunch (lunch provided)
- 1:00 p.m. Cardiac Safety and New Drug Attrition: Setting the Stage for Better Predictivity
- 1:30 p.m. Overview - Initiatives to Assess Nonclinical to Clinical Prediction of QT Effects
- 1:45 p.m. Presentation of ABPI-Animal Model Framework
- 2:30 p.m. Presentation of TI Pharma PKPD Assessment
- 3:15 p.m. Update from EMA on European Concordance Project Objectives
- 3:45 p.m. Break
- 4:00 p.m. Presentations of HESI IND/NDA Database Concordance Analysis Initiative:
A. Literature Analysis Concordance Project
B. Database Analysis Approaches and Assumptions
C. Results and Interpretation
- 5:00 p.m. Dinner Break (light dinner provided)
- 5:20 p.m. Cross-Initiative Panel Discussion
A. Opportunities
B. Gaps
C. Recommendations
D. Improving predictivity, what have we learned?
- 7:45 p.m. Concluding Remarks
- 8:00 p.m. Adjourn