
ILSI Health and Environmental Sciences Institute: HESI

HESI MISSION:

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

October 2011

HESI and CSRC

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- Common participant base (pharma companies, FDA, academe, clinicians)
 - HESI has diverse membership with greater numbers of non-clinical participants emphasizing clinical translation;
 - CSRC more heavily weighted to clinical.
 - Common interests: reducing drug attrition associated with CV effects, CV risks in diabetic populations, cardio-oncology, pediatric and long term dosing effects, etc.



HESI-CSRC TIMELINE

2007 – Introductions

2008 – October 6-7, 2008: HESI-CSRC Cardiac Safety Think Tank. "Translational Medicine Meets Critical Path: Cardiac Safety "Hot Topics"

2009 – Piccini JP, et al, **Current challenges in the evaluation of cardiac safety during drug development: Translational medicine meets the Critical Path Initiative.** *Am Heart J.* 2009;158(3):317–326.

2010- HESI participates in/meets with CSRC Exec Team to discuss possible collaborations

2011 – HESI-CSRC Joint Panel Discussion at HESI Cardiac Safety Annual Meeting (June 2011), HESI attends CSRC ICOS meeting (Oct 2011)

2012?



HESI Cardiac Safety Committee

➤ **HESI Cardiac Safety Committee currently active in:**

- Assessing concordance of nonclinical repolarization and clinical QT measures;
- Translational biomarkers of hemostasis;
- Integrated approaches to increasing predictivity of nonclinical models for clinical outcomes
 - current emphasis on measures of heart rate, arterial blood pressure and myocardial contractility



Opportunities for Partnership

- HESI cardiac initiatives focusing on translation of nonclinical endpoints often struggle to obtain sufficient clinical data for comparison.
- Can future CSRC partnership help us both in this regard?

