

Scientific Programs Update

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Purpose

To drive the formation of scientific forums to foster collaboration that results in research, White Papers publications, scientific manuscripts, and scientific exchange



Annual Program Committee

- Robert Blaustein
- Corina Dota
- Ben Eloff
- John Finkle
- David Gutstein
- Kathleen Hewitt
- Matthew Killeen
- Mitch Krucoff
- Juan Maya
- Valarie Murrow
- Philip Sager
- Cyril Petit
- Norman Stockbridge
- Rick Turner



ACADEMIA

DIA

INDUSTRY

HESI

FDA

ACC

HRS

ICOS

**HEALTH
CANADA**

CROs



THINK TANKS

- Get Together key stakeholders
- Usually one day meeting
- Short provocative presentations
- Focus is on the discussion
- Identify key issues and discuss ways to move the science forward
- Actionable items to foster collaborative work



Key Events- 2011

- Annual Meeting
- Diabetes Drug Development Think Tank
- TREATT Think Tank – Study of Access Site Enhancement for PCI for Women (SAFE-PCI For Women)
 - CSRC, ACC, NIH, FDA, NCRI
- QT Assessment in Early Clinical Development – Feb. 2
 - Can the Predictive Value be Enhanced to be Similar to That of a TQT study



Diabetes Drug Development Think Tank

- Novel approaches to CV Safety assessment in Diabetes Drug Development
 - Collaborative paper detailing how a single study that spans Phases 3 and 4 of development or that uses meta-analyses of ongoing studies, to support regulatory approval
 - Team is starting work led by Mary Jane Geiger
- Analyzing existing databases from large trials to determine the safety characteristics of the diabetic population and permit smarter future trial designs
- Scientific research into how patient and physician values might add to the Benefit:Risk Assessment
 - Preliminary scoping of the issues with the ADA
- Future discussions at the DIA-CSRC Diabetes Meeting and a follow-up Think Tank in 2012



Potential Future Think Tanks

- Safety aspects of blood pressure increases during drug development
- Cardiovascular imaging for safety assessment
- Trans-radial catheterization
- Diabetes drug development #2
- Biologics and CV Safety
- Cardiotoxicity- LV Function
- Troponins as a CV Risk Biomarker



PLEASE SHARE YOUR IDEAS!

