H E S I

ILSI HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

HESI TECHNICAL COMMITTEE ON GENOMICS IN MECHANISM BASED RISK ASSESSMENT
PLENARY MEETING
WESTIN CITY CENTER
1400 M STREET, NW
WASHINGTON, DC
NOVEMBER 7-8, 2007

AGENDA

November 7

8:30 a.m. Continental Breakfast

9:15 a.m. Welcome and Introduction to Session– C. Afshari, Amgen (confirmed)

Presentation of Results from HESI Genomics Programs

9:30 a.m. Baseline Animal Database Program – K. Thompson (FDA), M. Boedigheimer (Amgen), R. Wolfinger (SAS) (confirmed)

11:00 a.m. State of the Science Survey Results – A. Vickers (Allergan) (confirmed)

12:00 p.m. Lunch

1:00 p.m. Genotoxicity Program – J. Aubrecht, Pfizer (confirmed)

2:30 p.m. Break

2:45 p.m. A 6-Week Study of Rodent Cardiotoxicity: Exploring mechanisms of toxicity via traditional toxicity endpoints, cardiac troponin, and microarray *(H. Hamadeh (Amgen), J. Lyon (GSK)) (confirmed)*

a. Study Design and Tox Results
b. Microarray analysis
c. Troponin results
d. Mechanistic interpretations at the 'point of departure'

5:00 p.m. Wrap-Up Discussion and Adjourn Day 1

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November 8, 2007

8:30 a.m.	Continental breakfast
8:30 a.m.	Welcome and Review of Day One
8:45 a.m.	Presentation of New Program Proposals for HESI Genomics Committee 2008: Description of Process and Timelines
9:00 a.m.	Proposal 1: Application and Interpretation of Genomics in Non-Rodent Species. Presenter: Dr. Jim Stevens, Lilly (confirmed)
9:30 a.m.	Proposal 2: Practical Experiences in Applying Toxicogenomics to Risk Assessment: A workshop/case-study approach. Presenter: Dr. Cynthia Afshari, Amgen. (confirmed)
10:00 a.m.	Proposal 3: Use of Genomics to Predict Cardiovascular Risk. Presenter: Dr. Brian Berridge, GSK (confirmed)
10:30 a.m.	BREAK
10:45 a.m	Proposal 4: Use of toxicogenomics in developmental models to evaluate proliferative potential of compounds. Presenter: TBD but BMS has confirmed to provide someone.
11:15 a.m.	Proposal 5: Genomics to validate an in vitro testing paradigm for carcinogenicity. Presenter: Dr. Jiri Aubrecht, Pfizer (confirmed).
11:45 a.m.	Proposal 6: Genomic analysis of cancer signaling pathways. Dr. Don Delker, USEPA. (confirmed)
12:15 a.m.	Discussion of Proposals Presented and Additional Input
12:45	LUNCH (Steering Committee to meet in Closed Session)

1:45 p.m. –3:45 Other Ongoing Activities in the Field of Toxicogenomics

a. *FDA Research and Regulatory Priorities – Dr. Felix Freuh, FDA, CDER (Confirmed)* (20 min. update)
b. *EPA Research and Regulatory Priorities- Dr. Norman Birchfield, EPA's office of the Science Advisor (confirmed)* (20 min. update)
c. *EMEA Research and Regulatory Priorities- Dr. Jean-Marc Vidal, EMEA (confirmed)* (20 min. update)

d. Japan NIH or Other Japanese Government Science Agency –Dr. Jun Kanno (confirmed)- 30 minutes
e. C-Path – Dr. William Mattes (C-Path) – confirmed (15 min)
f. Inno-med – (speaker TBD, participation confirmed) (15 min)

3:45 – 4:15 Perspectives on the Application of Genomics to Risk Assessment: *This session will feature panelists discussing their current experience with TGx and Risk Assessment in a moderated panel discussion: (Chair- Dr. George Orphanides, AstraZeneca)*

A. What are current regulatory requirements/experience around the incorporation of these data?
B. Where does the technology show the greatest value?
C. Where are you seeing genomic data applied?
D. Where are there needs in the field?
E. Are TGx improving the ability to do risk assessment?

4:15 p.m. Adjourn

4:15 - 5:30 Opportunity for HESI Genomics Committee working groups to convene at HESI offices for discussion if requested.

6:00 p.m. Networking Dinner (location to be announced)