Summer 2009-Summer 2010

[°] HESI OUTREACH

[°] HESI OUTREACH IN

EUROPE

Work with ECETOC

- ECETOC / ILSI / CEFIC MOA Workshop on "Using Mode of Action Information to Improve Regulatory Decision Making"
- Held November 2 3 in London, UK
- ~50 participants from academia, industry, government in N. America, Europe, and Japan
- Purpose & Objectives:
 - To achieve a core consensus on the principles and ways forward
 - To build and strengthen relationships across this community
 - To highlight progressive practice in the use of MOA
 - To create forward momentum
- Publication in preparation



Work with WHO

- HESI Mixtures project working with WHO/IPCS to provide case-studies for their Combined Exposures Framework
 - M. Embry attended planning meeting February 2010
 - Joint WHO/OECD/HESI International Workshop on Risk Assessment of Combined Exposures to Multiple Chemicals to be held February 2011
- WHO working with HESI, ILSI, and ECETOC to develop a global "umbrella plan" for activities on Mode of Action of chemicals, including the establishment of a Mode of Action Database.
 - Planning meeting to be held October 2010 (M. Embry to attend)

Involvement with OECD

- OECD Project 2.30: Fish testing framework initiated in early 2010 (lead: USEPA)
- Goals:
 - Review regulatory needs and data requirements for fish testing and the currency of existing OECD Test Guidelines
 - Support animal welfare concerns by identifying unnecessary test methods, minimizing the number of in vivo fish tests, and ensuring the optimal use of data derived from in vivo studies.
- M. Embry a member of project steering team
- Workshop to be held September 2010

Involvement with OECD

- OECD ad hoc working group on Fish Embryo Toxicity Test Validation (FET)
- FET is an alternative for the OECD 203 Fish Acute Toxicity test
- Currently a draft OECD Test Guideline
- Goals:
 - Assess transferability of the method
 - Assess intra- and inter-laboratory reproducibility
- Involves 6 laboratories testing 6 chemicals for Phase I
- Additional substances will be tested in Phase II
- HESI is serving as an external monitor

Involvement with OECD

- OECD Expert Group on the Extended Onegeneration Reproductive Toxicity Study (lead: USEPA)
- Goal: Develop and implement a new protocol to address repro tox, with endpoints addressing DIT, DNT and endocrine function
- Process:
 - Series of regular teleconferences over the last two years
 - Ist face-to-face meeting Oct. 2008 Paris France
 - 2nd face-to-face meeting Oct. 2009 Paris, France
 - 3rd face-to-face meeting June, 2010 The Netherlands
- M. Holsapple is a member of expert group

Meeting participation

- Eurotox/IUTOX 2010
 - HESI-sponsored speaker: Prof. S. Kyrtopoulos,
 "Mechanism-based environmental health research in the age of genomics"
- SETAC Europe
 - HESI is now a SETAC global partner
 - Recognition at 2010 meeting in Seville
 - 7 HESI project-related presentations at the 2010 SETAC Europe meeting

EMA and Safety Working Party

- EMA Offices, London, England
- December 7, 2009
- M. Bonnefoi and S. Pettit
- 2 Presentations on HESI structure, goals, and opportunities for collaboration

• Outcomes:

- First EMA submission to Emerging Issues
- Commitment to greater scientific engagement in HESI via EMA staff
- Insights to changing 'focus' of EMA staff

[°] HESI OUTREACH IN

ASIA

First 'Asia-Friendly' Webinar

- First HESI webinar targeted to HESI participants based in Asia (8 pm EST, 9 am Tokyo)
- 14 participants
 - Daichi Sankyo
 - Astellas
 - Eisai
 - Takeda
 - RIKEN Yokohama Institute
 - ILSI Southeast Asia (Singapore)
 - HESI Staff and BOT (Bonnefoi, Doerrer, Pettit, and Takei)

First 'Asia-Friendly' Webinar

Agenda

- <u>Welcome</u> M. Bonnefoi, sanofi, HESI President
- <u>Scientific Mapping Update</u> N. Doerrer, HESI Associate Director
- <u>Project Recruitment at HESI (RAI and EI)</u> S. Pettit, HESI Associate Director
- Discussion and Q&A

Feedback

- Timing and format was appreciated request to do similar format again.
- Content spurred questions and discussions around RAI opportunities.
- Interest in new Imaging project noted.



HESI to China

Novel Approaches in Preclinical Safety Evaluation: Development and Progress

A joint workshop of the

Chinese National Center for Safety Evaluation of Drugs (sFDA)

and the

ILSI Health and Environmental Sciences Institute

September 26 –27, 2010 Beijing, China

Some specifics...

- Initial contact with Dr. Li Bo, Director NCSED, via R.D. Sarazan (DSI)
- Workshop jointly designed by HESI staff and NCSED staff via phone/email;
- Tentative agenda compiled, invitations from sFDA to speakers in progress;
- Opportunity to
 - Engage and learn from a previously uninvolved regulatory/research body;
 - Highlight HESI science in a geographic area new to HESI, but critical to pharma industry;
 - Discuss HESI organization with sFDA staff;
 - Participate in 60th Anniversary celebration of sFDA
 - Engage in-country scientists from HESI member companies (or prospective member companies)
 - Topics: Biomarkers, Cardiac Safety, Imaging, IVGT, Immunotox
 - Possible participants: Holsapple, Bonnefoi, Pettit, Aubrecht, Harpur, Sarazan, Slikker, Paules, TBD....

