Insights

Your Monthly Update of News and Notes from HESI

July 2013

HESI RISK21 Workshop in Japan. On 5 July 2013, the HESI Risk Assessment in the 21st Century (RISK21) Technical Committee organized a workshop in Tokyo with nominal support by the Society for Risk Analysis Japan. Over 60 scientists from government, academia, and industry participated in the workshop, which created an international and multi-disciplinary forum to exchange information regarding current approaches, challenges, and opportunities in chemical risk assessment. The status of chemical risk assessment in Japan was presented by representatives from the National Institute of Health Sciences, the National Institute of Environmental Studies, and the National Institute of Advanced Industrial Science and Technology. Academic researchers discussed emerging issues in Japan, including nanomaterial hazard evaluation and risk assessment of pharmaceuticals in the environment. Leaders of the HESI RISK21 Technical Committee presented new strategies and approaches of chemical risk assessment with case studies, and stimulated discussion among the participants on their applicability in Japan and globally. The workshop ended with a panel discussion regarding how to promote dialogue to foster international harmonization in strategic approaches to chemical risk assessment. Workshop materials, presentation slides, and other information are available here. For more information, contact Dr. Michelle Embry (membry@hesiglobal.org), Dr. Jennifer Tanir (jtanir@hesiglobal.org) or Ms. Ayako Takei (atakei@hesiglobal.org), HESI Scientific Advisor in Japan.

Dr. Timothy Pastoor (Syngenta), co-chair of RISK21 Technical Committee presented the RISK21 Roadmap and Matrix in Japan.

HESI-CSRC-FDA Workshop. HESI, FDA, and the Cardiac Safety Research Consortium convened the workshop *Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study*, at the FDA White Oak Facility on 23 July 2013. Over 180 scientists from government, academia and industry attended and discussed a comprehensive panel of ion channel assays, *in silico* modeling and stem cell assays to assess proarrhythmic risk. This would represent a new paradigm that has real potential for obviating the need for clinical Thorough QT studies, making cardiovascular risk assessment more efficient. The HESI Proarrhythmia Working Group will further explore a potential assay panel and next steps to validating the assays. Please contact Ms. Jennifer Pierson (jpierson@hesiglobal.org) for more information.

UPCOMING HESI WORKSHOPS

HESI, EPA, and NIEHS Co-Sponsor Workshop on Translational Alternative Models and Biomarkers Predictive of Drug or Chemical Cardiovascular Risk. As a result of the broad current interest in cardiovascular toxicity, the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), HESI, and EPA are collaborating to present a workshop addressing development of new methods to assess and predict whether substances might affect cardiovascular safety in humans. The workshop will be held 10-11 October 2013 at NIEHS. Information and registration available here.

Advances in Assessing Adverse Epigenetic Effects of Drugs and Chemicals. The HESI Technical Committee on the Application of Genomics to Mechanism-Based Risk Assessment is organizing this workshop in Washington, DC, on 18 November 2013. This workshop will focus on epigenetics and its potential implications for toxicology and will feature a review of the current status of different areas of epigenetics research, an overview of available methods, and then use of case studies to expand on topics with potential relevance for toxicological assessment. Please contact Dr. Raegan O'Lone (rolone@hesiglobal.org) for additional information.

HESI Co-Sponsors SOT CCT FutureToxII Workshop. The HESI Project Committee on Distinguishing Adverse from Non-Adverse/Adaptive Effects will co-host a 16-17 January 2014 Society of Toxicology (SOT) Contemporary Concepts in Toxicology (CCT) Workshop titled *FutureToxII: In Vitro Data and In Silico Models for Predictive Toxicology*, in Chapel Hill, NC. FutureToxII will provide a forum to address progress and advances toward a paradigm where improvements to predictivity and concordance are based on *in vitro/in silico* approaches that are integrated with systems biology. An overarching goal is to clarify the usefulness and validity of new and emerging technologies and approaches, so that expectations can be managed in both the regulatory and regulated scientific communities. Breakout groups will provide an opportunity for detailed scientific discussion on how the biological pathways of interest will be elucidated, characterized, and qualified for "Adverse Outcome Pathways" (AOPs) and their applications in basic research and safety assessments. The Organizing Committee for the FutureToxII workshop includes Dr. Douglas Keller (Sanofi US), Co-Chair of the HESI Adverse/Adaptive Project Committee, and Ms. Nancy Doerrer (HESI). Sponsors include SOT, Elsevier, the Hamner Institutes for Health Sciences, HESI, and the University of North Carolina. Registration is open. Click **here** for more information.

HESI at International Congress of Nutrition

Dr. Gregory Ladics (DuPont), Co-Chair of the HESI Protein Allergenicity Technical Committee (PATC), will present an overview of scientific approaches to evaluating novel proteins expressed in biotechnology products and the development of reliable and accurate methodologies for characterizing the allergenic potential of novel proteins at a Food Allergy session on 19 September 2013 at the 20th International Congress of Nutrition (ICN 2013) in Granada, Spain. The Food Allergy session is jointly sponsored by HESI, ILSI Europe, and ILSI North America. Two other ILSI-sponsored sessions will be held at ICN 2013 (15-20 September 2013), and multiple ILSI branches, including HESI, will co-host a booth at the meeting (#47). Click **here** for more information about HESI and ILSI activities at ICN 2013.

Imaging in Drug Distribution. The HESI Project Committee on the Use of Imaging for Translational Safety Assessment is forming a new group on Drug Distribution, focusing on the use of imaging in understanding the drug distribution and delivery of small molecules. If you would like more information or are interested in participating, please contact Dr. Connie Chen (cchen@hesiglobal.org).

New HESI Publication.

Saldutti LP, Beyer BK, Breslin W, Brown TR, Chapin RE, Campion S, Enright B, Faustman E, Foster PMD, Hartung T, Kelce W, Kim JH, Loboa EG, Piersma AH, Seyler D, Turner KJ, Yu H, Yu X, and Sasaki JC. (2013). *In vitro* testicular toxicity models: Opportunities for advancement via biomedical engineering techniques. ALTEX. 30: 353-377.

Call for Data – Clinical Data Compilation Project. The HESI Immunotoxicology Technical Committee Cytokine Release Assays (CRA) work group is interested in collecting CRA data, in conjunction with clinical cytokine release data/infusion reaction information, to better understand the utility of the CRA assays to provide hazard identification for the drug in the clinical setting. The aim is to collect data across multiple organizations to provide a large data set for analysis toward enhancing understanding of the correlation of preclinical and clinical outcomes with respect to cytokine release assessments. If you are interested in contributing data toward this program or have any questions, please contact Dr. Raegan O'Lone (rolone@hesiglobal.org) by **31 July 2013**.

Deadline extended! Call for abstracts for poster presentations –Workshop on *Cytokine Release: State-of-the-Science, Current Challenges and Future Directions* – Submission deadline now 23 August 2013. This workshop, organized by the HESI Immunotoxicology Technical Committee, will be held in Silver Spring, Maryland, on 22 October 2013. This one-day workshop will focus on cytokine storm risk assessments, engaging scientists in discussion of current technologies, practices and scientific challenges. More information can be **here**. Please contact Dr. Raegan O'Lone (rolone@hesiglobal.org) with questions.

New HESI Staff. Please join us in welcoming Alex Keller as a Scientific Program Associate for HESI. Alex comes to HESI with a background in analytical chemistry laboratory research, and holds a BS in Environmental Science with minors in Chemistry and Biology from Duke University.

ILSI Health and Environmental Sciences Institute (HESI)
1156 Fifteenth Street, NW
Suite 200
Washington, DC 20005-1743
202.659.3306 phone
202.659.3617 fax

Please visit us at our website, on YouTube or follow us on Twitter to receive announcements on new publications, upcoming meetings and conferences, and other news.

FROM THE EXECUTIVE DIRECTOR

"A fantastic model of collaboration: thinking partners who aren't echo chambers."

-Margaret Heffernan, CEO and author*

In many ways, HESI's organizational practices and successes are driven by just this ethic. Take a look at the diversity of partners and disciplines engaging in and co-sponsoring HESI activities in this month's Insights. It is easy and comfortable to stay within disciplinary and sector boundaries, but the health issues that HESI seeks to address require all of us to reach outside of this zone. HESI creates a forum for challenging our 'thinking partners' to develop and apply the best science for human and environmental health.

**Check out Heffernan's TED talk on this subject here.*