June 2013

2013 HESI Annual Meeting. A successful HESI Annual Meeting was held 11-13 June 2013 in Alexandria, Virginia, USA. Over 80 global thought leaders participated, with almost half of the attendees from the public sector (government and academia). Meeting participants learned about HESI's role in translating science from research to application, shared perspectives on current and pending scientific challenges, and engaged in interactive discussions that will help influence HESI's future scientific direction.

The Keynote Lecture was delivered via live video link by Dr. Robert Langer, Massachusetts Institute of Technology and 2013 winner of the US National Medal of Technology and Innovation. Dr. Langer spoke on "Biomaterials and Biotechnology: From the Development of Controlled Drug Delivery Systems to the Foundation of Tissue Engineering." His presentation sparked discussion on the pioneering application of technology through multi-disciplinary collaboration. In another high-profile lecture, Dr. Hal Zenick, Director of the US EPA National Health and Environmental Effects Research Laboratory, described "Strategic Directions for EPA's Research," which outlined objectives and programs of direct relevance to HESI and its stakeholders. And Ms. Heather Joseph, Scholarly Publishing and Academic Resources Coalition, gave a thought-provoking presentation on "Open Access and Publishing: The New Frontier in Science?" The leadership of three HESI committees (Cardiac Safety, Sustainable Alternatives, and Immunotoxicology) reported on exciting initiatives that exemplified translational approaches to improving human and environmental health. Annual Meeting participants also had the opportunity to hear more about the scope and impact of HESI's scientific portfolio, provide input on implementing HESI's strategic plan, and engage in small group discussions on emerging scientific issues and priorities.

Click <u>here</u> for a link to the June 2013 HESI Annual Meeting presentations.

Respiratory Sensitizers Project Adopted! The HESI Immunotoxicology Technical Committee formally adopted the Respiratory Sensitizers project through the HESI Emerging Issues process. This new workgroup is planning a workshop for Spring 2014 to address the need for a science-based, standardized methods and assessment framework for the identification and characterization of respiratory sensitizers with respect to risk assessment and risk management. If you are interested in participating or have further questions, please contact Dr. Connie Chen (cchen@hesiglobal.org).

Green Chemistry & Engineering Conference. The progress of the HESI Sustainable Alternatives Subcommittee was well received at the 17th Annual Green Chemistry & Engineering Conference on 18-20 June 2013 in North Bethesda, MD. During the "What is an Alternative Assessment?" session, with an audience of about 75 attendees including leaders in this field, presentations were given by Dr. Derek Muir (Environment Canada), Prof. Royce Francis (George Washington University) and Dr. David Constable (ACS Green Chemistry Institute®) on behalf of the subcommittee. HESI also enhanced its visibility with new audiences by sponsoring the ACS GCI Roundtable Poster Reception and discussing a poster about the subcommittee and HESI with potential future participants. If you are interested in this subcommittee, please contact Dr. Jennifer Young Tanir (jtanir@hesiglobal.org).

Japan SOT. On 19 June 2013, Ms. Syril Pettit delivered a talk on the "Translational Science Knowledge-Cycle" to the JSOT plenary. This presentation highlighted opportunities to improve our translation of new science into meaningful application and reflected perspectives from the December 2012 HESI CITE workshop. Later on the 19th, the work of the HESI Cardiac Safety Proarrhythmia program was featured in a presentation by the project co-chair Dr. John Koerner of the USFDA during an extended session on non-clinical to clinical data translation.

UPCOMING HESI WORKSHOPS

Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study.

Registration is now OPEN. CSRC, FDA, and the HESI Committee on Cardiac Safety will co-host this workshop at the FDA White Oak Facility on 23 July 2013. Workshop participants will examine and discuss a new paradigm, focusing on a comprehensive assessment of ion channel effects to determine actual proarrhythmic risk. Register online and view a draft agenda and travel logistics here. Please contact Ms. Jennifer Pierson (jpierson@hesiglobal.org) for more information.

Advances in Assessing Adverse Epigenetic Effects of Drugs and Chemicals. The HESI Committee on 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 on toxicology, and will feature a review of the current status of different areas of epigenetics research, an overview of available methods, and then use 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 at IUTOX. The Risk Assessment in the 21st Century (RISK21) Technical Committee and the Genetic Toxicology Technical Committee (GTTC) have organized and sponsored symposia at the International Congress of Toxicology 2013 (ICT 2013) which will be held in Seoul, South Korea on 30 June – 4 July 2013.

Symposium: RISK21: Accurate, Resource Appropriate Risk Assessment, on 1 July 2013 at 14:00-15:30.

- Prof. Alan Boobis (Imperial College London, UK), "Why the Need for RISK21?"
- Dr. Timothy Pastoor (Syngenta, USA), "The RISK21 Roadmap and Matrix"
- Dr. Douglas Wolf (US EPA, USA), "RISK21 Case Studies"
- Prof. Angelo Moretto (University of Milan, Italy), "Applications to Cumulative Risk"

Symposium: Are There Thresholds for Genotoxicity?, on 2 July 2013 at 15:30 - 17:00.

- Dr. Anthony Lynch (GlaxoSmithKline, UK), "Impact of Moving From a Qualitative to Quantitative Approach on Genotoxicity Risk Assessment"
- Dr. Bhaskar Gollapudi (Retired Dow Chemical Co., USA), "A Critical Assessment of Low Dose Response in Genetic Toxicology"
- Prof. George Johnson (Swansea University, UK), "Mechanisms Underlying the Non-Linear Dose-Responses for DNA-Reactive Genotoxicants"
- Dr. Takehiko Noemi (National Institute of Health Sciences, Japan), "DNA Repair and Translesion DNA Synthesis as Constituents of "Threshold" of Genotoxicity"
- Dr. Shoji Fukushima (Japan Bioassay Research Center, Japan), "Threshold of Genotoxic Carcinogens: Conclusion from Mechanism-Based Carcinogenicity Studies"

HESI at Japan Teratology Society Meeting. The Developmental and Reproductive Toxicology (DART) Technical Committee has been invited to present its activities at the 21-23 July 2013 Japanese Teratology Society Annual Meeting in Osaka, Japan. Dr. Kok-Wah Hew (Takeda) will speak on behalf of the DART committee at an educational session.

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 work group aims 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.

Call for abstracts for oral and poster presentations – Workshop on Cytokine Release: State-of-the-Science, Current Challenges and Future Directions – Submission deadline 22 July 2013. This workshop, organized by the HESI Immunotoxicology Technical Committee, will be held in the Washington, DC, area 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 found online here. Please contact Dr. Raegan O'Lone (rolone@hesiglobal.org) with questions.

2014 is HESI's 25th anniversary!

Mark your calendars now for an exciting Annual Meeting focusing on future opportunities and celebrating past successes on 10-12 June 2014 in the Washington, DC, area.

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







FROM THE EXECUTIVE DIRECTOR

Many thanks to all those who contributed to the design and execution of this year's HESI Annual Meeting. One of our goals was to greatly increase opportunities for input and discussion at this meeting, and we believe that we have moved successfully in this direction! If you attended the meeting, please do complete the online survey you will receive via email to provide feedback. If you didn't attend, please visit the presentation page as there is some great material to view, and be sure to join us in person next year!

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