March 2013

New Projects

New Emerging Issues Projects Referred to Immunotoxicology and Cardiac Safety Committees. The HESI Emerging Issues Committee (EIC) recently met to review proposals received through the annual emerging issues survey process. A 2013 trial process was approved that supports adoption of relevant new programming areas as adjuncts to existing HESI committees. This process will allow new issues to initiate more rapidly by taking advantage of an existing committee's standing infrastructure and expertise and by providing some oversight and support to help initiate the project. In as years past, participation on a HESI Emerging Issues project will be free for approximately the first year of the project for any HESI member. Two proposals received through the annual emerging issues process were referred to existing HESI committees for further consideration using the 2013 trial process:

- **Standard Methods for Identification of Potential Respiratory Sensitizers.** This project aims to identify currently available methods for detecting potential respiratory sensitizers, discuss the strengths and limitations of these methods, identify key research needs, and develop a standard, validated method for accurate hazard identification. The project will be vetted by the HESI Immunotoxicology Technical Committee for potential initiation in 2Q 2013. If you are interested in this project, contact Dr. Raegan O’Lone (rolone@hesiglobal.org)

- **Development of a Comprehensive In Vitro Prenatotoxicity Assay.** After completing a retrospective preclinical to nonclinical concordance data analysis on a joint HESI/TOXNET database, the Prenatotoxicity Working Group is moving forward to further assess the underlying mechanistic responses and compound compounds. They will also focus on evaluating and comparing current industry practices of cardiac toxicology screening and will design a more predictive nonclinical assay to detect proarrhythmic risk of drugs. The project will be conducted under the umbrella of the HESI Cardiac Safety Technical Committee. If you are interested in this project, contact Ms. Jennifer Pierson (jpierson@hesiglobal.org)

In Other News

The recent HESI workshop on Developing Guidance for Alternatives Assessment (8-February 2013) was featured in the March 2013 issue of the Environmental Factor by the National Institute of Environmental Health Sciences (NIEHS). The article “Public-private group explores sustainable alternatives” summarizes the presentations, discussions, and outcomes from this workshop, held at the NIH in February, focused on the project for identifying sustainable alternatives to chemicals of concern. Contact Dr. Jennifer Tanir (jtanir@hesiglobal.org) to learn more.

A paper by the Genetics Toxicology Technical Committee, “Quantitative approaches for assessing genetic toxicity in non-human primates,” was distinguished as one of the top papers advancing the Risk Assessment of Substance in 2012 by the Risk Assessment Specialty Section of the Society of Toxicology.

In addition to the Emerging Issues process, stakeholders will also initiate programs of work to meet evolving scientific challenges throughout the year. Read below to see which new projects are starting and contact us if you’d like to be involved!

Cardiac Safety Technical Committee Begins Discussion of Predictive Cardiovascular Strategies – Alternative Animals. The Cardiac Safety Technical Committee is revisiting some of the recommendations from the recent publication in Regulatory Toxicology and Pharmacology, “Innovative and translational nonclinical in vivo cardiac safety assessment opportunities,” which is focusing on alternatives for cardiovascular risk evaluation and what patient susceptibilities may be applicable to animal modeling. This group is looking for interested scientists in both the nonclinical and clinical arena. HESI members interested in this new cardiac topic should contact Ms. Jennifer Pierson (jpierson@hesiglobal.org)

New Research Program on Translational Biomarkers for Neurotoxicity. HESI is launching a new research program on translational biomarkers of neurotoxicity. The project will engage US and international regulatory agencies, academics, and industry scientists to identify and evaluate circulating markers of neurotoxicity that may be translated from animal models to the clinic to assess safety. The project will hold its first meeting on 18-20 April 2013 and begins by identifying prototypic neurotoxicants and surveying current practices. Interested partners should contact Ms. Jennifer Pierson (jpierson@hesiglobal.org)

Genetic Toxicology Technical Committee (GTTC) Initiates New Projects. During its recent annual meeting in spring meeting, 16-18 April 2013, the GTTC will brainstorm about the topics of their six new work groups. Collected information, data interpretation, and framework of new test methods, and review previous work in genotoxicity, new compounds: novel mechanisms, and non-linear evaluation of new compounds: biologics. If you have genotoxicity toxicology expertise and are interested in exploring involvement in these new areas or in the existing work groups quantitation, informative existing research that could be applied, please contact Dr. Jennifer Tanir (jtanir@hesiglobal.org).

New HESI Publication


**DEADLINE Approaching for HESI Data Collection on Developmental and Reproductive Study Pracitces.** The extended deadline for the HESI DART Technical Committee for submitting data for two projects is fast approaching. 1) Birth Control in Clinical Trials, and 2) Rabbit 2B Species. If you are interested in contributing data to these projects, contact Dr. Caroline Chen (cchen@hesiglobal.org). The forms can also be downloaded from: [here](https://hesi.org).

New HESI Members

Welcome to GE Healthcare which joined HESI as a 2013 Sponsor organization and has already become very active in the Cardiac Safety and Neurotoxicology programs. Welcome back to Biogen who took a hiatus from HESI in 2012 and has now returned!

FROM THE EXECUTIVE DIRECTOR

Please plan on joining us 13-12 June, 2013 for HESI’s Annual Meeting in Alexandria, Virginia. For the first time this year, the meeting is free for all HESI public and private sector members to encourage your participation and thank you for your support. Be there to encourage HESI’s 40th birthday and to shape the future plans for HESI. Looking forward to seeing you there!