



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 programmatic areas as adjuncts to existing HESI committees. This process will allow new projects to initiate more rapidly by taking advantage of an existing committee's standing infrastructure and expertise and by providing some financial support to help initiate the project. As in 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* Proarrhythmia Assay. After completing a retrospective preclinical to nonclinical concordance data analysis on a joint HESI/FDA IND/NDA database, the Proarrhythmia Working Group is moving forward to further assess the underlying mechanisms of discordant compounds. They will also focus on evaluating and comparing current industry practices of cardiac ion channel 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 addition to the Emerging Issues process, standing HESI Committees also initiate new programs of work to meet evolving scientific challenges throughout the year. Read below to see what new programs are starting and contact us if you'd like to be involved!

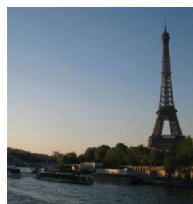
Cardiac Safety Technical Committee Begins Discussion Around a New Workstream – Predictive Cardiovascular Strategies – Alternative Animal Modeling. The Cardiac Safety Technical Committee is revisiting some of the recommendations from a recent publication in *Regulatory Toxicology and Pharmacology*, "[Integrated and translational nonclinical in vivo cardiovascular risk assessment: gaps and opportunities](#)." This group is focusing on alternative animal models 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 safety 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 meetings in March 2013 and begin 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 Work Groups. During its annual spring meeting, 16-18 April 2013, the [GTTC](#) will brainstorm about the topics of their six new work groups: 1) data interpretation, 2) framework for adoption of new test methods, 3) "clean sheet" testing strategy, 4) evaluation of new methods in germ cells, 5) evaluation of new compounds: nanomaterials, and 6) evaluation of new compounds: biologics. If you have genetic toxicology expertise and are interested in exploring involvement in these new areas or in the existing work groups (quantitative, improving existing assays, and new approaches), please contact Dr. Jennifer Tanir (jtanir@hesiglobal.org).

UPCOMING HESI EVENTS

Workshop on "Moving Forward in Human Cancer Risk Assessment in the Genomics Era 2.0" 16-17 May 2013 at the OECD Congress Center, Paris, France. Co-organized by the HESI Application of Genomics to Mechanism-based Risk Assessment Technical Committee and the Maastricht University, Dept of Toxicogenomics. **Registration is now open.** For more information, please click [here](#) or contact Dr. Raegan O'Lone (rolone@hesiglobal.org).



New HESI Publication

Kresja CM, Neradilek MB, Polissar NL, Cox N, Clark D, Cowan L, Bussiere J, Lebrec H. 2013. [An inter-laboratory retrospective analysis of immunotoxicological endpoints in non-human primates: Flow cytometry immunophenotyping](#). *Journal of Immunotoxicology*, Early Online.

DEADLINE Approaching for HESI Data Collection on Developmental and Reproductive Study Practices.

The extended deadline of 31 March 2013 for the HESI DART Technical Committee for submitting data for two projects is fast approaching: 1) Birth Control in Clinical Trials, and 2) Rabbit 2nd Species. If you are interested in contributing data to these projects, contact Dr. Connie Chen (cchen@hesiglobal.org). The forms can also be downloaded [here](#).

In Other News

The recent HESI workshop on Developing Guidance for Alternatives Assessment (7-8 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 assessment](#)" summarizes the presentations, discussions, and outcomes of the workshop, held at NIEHS, which focused on the process for identifying sustainable alternatives to chemicals of concern. Please contact Dr. Jennifer Tanir (jtanir@hesiglobal.org) to learn more. (Workshop attendees are pictured below.)



A paper by the Genetic Toxicology Technical Committee, "[Quantitative approaches for assessing dose-response relationships in genetic toxicology studies](#)," was distinguished as one of the Best Papers Advancing the Science of Risk Assessment in 2012 by the Risk Assessment Specialty Section of the Society of Toxicology.



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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 11-12 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 for HESI. Be there to learn about HESI's scientific portfolio, discuss evolving scientific challenges for your sector and across the global science community, and shape the future plans for HESI. Looking forward to seeing you there!

Sybil D. Pettit