



October 2012

HESI Bioaccumulation Workshop Report Becomes SETAC Globe's Most Highly Viewed Article Ever! According to Dr. John Toll, Editor-in-Chief of the SETAC Globe, the report from the May 2012 HESI expert workshop on in vivo methods for bioaccumulation assessment has received more views and 'social media' networking connections than any prior report published on the site! The workshop focused on links between whole organism in vivo bioaccumulation endpoints with in silico, in vitro, and in situ (field) approaches. Click [here](#) to view the article.

HESI Science Featured in Plenary Lecture at 2nd Annual China SOT Meeting. Dr. Serrine Lau, University of Arizona and HESI Treasurer, presented the plenary lecture at the 2nd Annual China SOT meeting on 24 October 2012 in Chengdu, China. Dr. Lau's talk featured an overview of the HESI organization and its innovative biomarker initiatives, as well as biomarker-related research conducted at the Southwest Environmental Health Sciences Center that she directs. This is the second time HESI has been featured in a plenary lecture at the China SOT (Syril Pettit spoke at the 2011 meeting). HESI looks forward to continued opportunities to engage with this important scientific community.

NEW Translational Safety Biomarker Assessment of Neurotoxicity Subcommittee Initiated. In mid-October, the HESI Emerging Issues Committee (EIC) reviewed rankings submitted by HESI stakeholders on two high priority proposals selected in this year's emerging issues survey process. The project on *Translational Safety Biomarker Assessment of Neurotoxicity* was approved for HESI action based on its scientific value and impact. Public and private sector leadership and a steering team composed of expert academic, government, and industry scientists will be identified in the next two months to scope out the objectives and primary focus of the project. For more information about the project, click [here](#) to see two presentations given at the June 2012 HESI Annual Meeting in Prague. To learn more about, or participate in, the new neurotoxicity biomarker project, contact Ms. Nancy G. Doerrer (ndoerrer@hesiglobal.org).

RISK21 Project Featured at October Society of Toxicology FutureTox Workshop. At an 18-19 October 2012 Society of Toxicology Contemporary Concepts in Toxicology workshop in Arlington, Virginia, Dr. Timothy Pastoor (Syngenta, HESI RISK21 Technical Committee Co-Chair) presented a roadmap developed over the last two years by the HESI Risk Assessment in the 21st Century (RISK21) Technical Committee. The RISK21 roadmap blended well with the theme of the workshop, which was designed to address the challenges and opportunities associated with integration of 21st century toxicity testing technologies and tools into improved, science-informed hazard prediction and risk assessment. The RISK21 roadmap – a tiered, exposure-based, iterative approach to risk assessment – is near completion, and will be described in detail in manuscripts for publication during the next year, as well as in numerous international meetings throughout 2013. Dr. Michael Dellarco (National Institute of Child Health and Human Development) also cited the work of RISK21 in his remarks as chair of the exposure session at the workshop. The SOT FutureTox Workshop was co-sponsored by HESI. For more information about RISK21, contact Dr. Michelle Embry (membry@hesiglobal.org).

Cardiac Safety Program Announces New Publications and Presentations. The HESI Technical Committee on Cardiac Safety is pleased to announce the acceptance of two publications in the last few weeks:

- *Current Practices in Preclinical Drug Development: Gaps in Hemostasis Testing to Assess Risk of Thromboembolic Injury.* E. Schultze et al. Published online at Toxicologic Pathology, September 2012.
- *Integrated and Translational Nonclinical In Vivo Cardiovascular Risk Assessment: Gaps and Opportunities.* B. Berridge et al. Accepted for publication in Regulatory Toxicology and Pharmacology, September 2012.

The Committee also held a successful symposium to roll out the results of the HESI-FDA joint effort to analyze nonclinical to clinical concordance of IND/NDA data on potentially proarrhythmic drugs at the Safety Pharmacology Society

Meeting in early October. The results of this study will be presented as a poster at the American College of Toxicology Annual Meeting in Orlando, Florida, on November 5, and submitted for publication in early 2013.

Concordance of Non-Clinical and Clinical Arrhythmia Data.

On 4 October 2012, the HESI Technical Committee on Cardiac Safety convened the Proarrhythmia Workshop in Phoenix, Arizona. Attendees heard presentations on the results of the HESI-FDA proarrhythmia data evaluation project and updates about related initiatives conducted by the European Medicines Healthcare Products Regulatory Agency, Animal Model Framework Program, and TI-Pharma consortium.

Emerging Issue Workshop: Evaluating Causality in Epidemiology.

On 22-23 October 2012, the Epidemiology Subcommittee convened a HESI Emerging Issue Workshop with experts in epidemiology, toxicology, and exposure measurement. The workshop stimulated a dialogue regarding the methods and issues related to evaluating causality, as well as interpretation of evidence from epidemiology. The Subcommittee plans to publish recommendations in a manuscript in 2013.

Join the Next HESI Asia Outreach Webinar on November 2.

The next ASIA outreach webinar, featuring a presentation by Dr. Alan Boobis (Imperial College London) on **Toxicity Testing in the 21st Century: Challenges and Opportunities**, will take place on 2 November 2012. For information on how to join the webinar, contact Cynthia Nobles (cnobles@hesiglobal.org). The webinar will be held at 4:00 p.m. (Beijing), 5:00 p.m. (Tokyo), 8:00 a.m. (UK), and 4:00 a.m. (US, EDT).

Committee Renewal. Congratulations to the HESI Animal Alternatives in Environmental Risk Assessment Project Committee on its successful renewal after an October review by the HESI Board Program Strategy and Stewardship Committee. The committee was re-chartered based on its scientific impact, productivity, and broad focus. To learn more about the Animal Alternatives Project Committee, contact Dr. Michelle Embry (membry@hesiglobal.org).

From the Executive Director: The activity during the month of October for HESI has been amazing (six different public workshops - four in the US and two in Europe!), so many thanks to all of the committee members, chairs, and staff who have worked so hard to make this happen. HESI's success is often driven by unquantified efforts – but they do not go unrecognized or unappreciated. We also look forward to a strong finish to 2012 with the first HESI 'Combining Interdisciplinary and Translational Expertise' (CITE) workshop to be held in early December. This event will launch new strategic efforts to build HESI's role in fostering creative, resource-effective, and multidisciplinary approaches to public private partnership. Watch this space for links to video from the meeting by early January!

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Upcoming HESI Events

HESI RISK21 Exposure Science at ISES. The Risk Assessment in the 21st Century (RISK21) Technical Committee will sponsor and share its new approaches to exposure science at the 22nd Annual Meeting of the International Society of Exposure Science (ISES) in Seattle, Washington, on 28 October – 1 November 2012. Join the open discussion on RISK21 on Tuesday, October 30, at 5:30-7:00 pm (Puget Sound room). Other RISK21 presentations include: poster #41 on Tuesday by B.J. Gaborek et al., "Rapid and Tiered Exposure Predictions for Occupational Populations"; poster #57 on Wednesday by R. Zaleski et al., "Assessing Consumer Exposure Models for Developing Exposure Bands"; and presentation #THF1-4 on Thursday by R. Zaleski et al., "RISK21: Advancing Exposure Science to Meet the Needs of Risk Assessment in the 21st Century."

Genetically Diverse Mouse Models in Drug Safety Testing Strategies Workshop. 28 November 2012, Washington, DC. This workshop will address a variety of models that capitalize on the diversity of genetic variability and knowledge available in the mouse, including discussion of practical aspects of the proposed context of use for safety assessment and best practices for using these models in pharmaceutical development. Organized by the HESI Application of Genomics to Mechanism-Based Risk Assessment Technical Committee. For additional information, contact Dr. Raegan O'Lone (rolone@hesiglobal.org).

Participate in HESI Data Collection on Developmental and Reproductive Study Practices.

The HESI Developmental and Reproductive Toxicology (DART) Technical Committee seeks data for two projects: 1) Birth Control in Clinical Trials, and 2) Rabbit 2nd Species. The objective of the Birth Control project is to understand current industry practices for contraception requirements for both women and men in clinical trials, the governance processes set-up to promote consistency and/or compliance with contraception requirements, and the effectiveness of current contraception practices in preventing pregnancies during clinical trials. The objective of the Rabbit 2nd Species project is to evaluate developmental toxicology data from pharmaceutical compounds that have been tested in the rat and rabbit. The DART Committee is building a database to facilitate the analysis of concordance between the two species. If you are interested in contributing data to these projects, contact Dr. James Kim (jkim@hesiglobal.org) to obtain survey/data entry forms. The forms will also be available for download from HESI's website in the near future.



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