



# Insights

Your Monthly Update of News and Notes from HESI



## March 2015

**GTTC Wins Best Paper Award.** The HESI Genetic Toxicology Technical Committee (GTTC) paper by [Johnson, et. al.](#), entitled “Derivation of Point of Departure (PoD) Estimates in Genetic Toxicology Studies and Their Potential Applications in Risk Assessment” (Environmental and Molecular Mutagenesis 55:609-623) has been selected by the Society of Toxicology’s Risk Assessment Specialty Section as one of the Best Papers published in 2014 Advancing the Science of Risk Assessment.

### HESI at SOT

#### Monday, March 23

12:00 PM to 1:30 PM—**HESI Luncheon Seminar** (Marriott Marquis Marina Ballroom D): “Towards Predictive Biology with Extreme Computing – and Interdisciplinary Research,” presented by Dr. Frederick Steitz, Director, HPC Innovation Center, Lawrence Livermore National Laboratory. This event is free but requires pre-registration. Register online [here](#).

2:00 PM to 4:45 PM—**Symposium Session** (Convention Center Ballroom 6C): “Cardio-Oncology Concerns Encourage Novel Approaches to Pharmaceutical Risk Assessment Advancing Clinical and Translational Toxicology,” chaired by Myrtle Davis, NIH/NCI, and Brian R. Berridge, Safety Assessment, GlaxoSmithKline.

#### Tuesday, March 24

9:00 AM to 12:30 PM—**Poster Session: Biomarkers** (Convention Center, Exhibit Hall): *Technical Best Practices for Urinary Biomarker Evaluation*, presented by T.Y. Yang, B. Riefke, L.T. Rosini Marthaler, R. Khan-Malek, E. Harpur, and R. O’Lone. Poster no. 651, abstract no. 1220.

#### Wednesday, March 25

9:00 AM to 12:30 PM—**Poster Session: Developmental Toxicology I** (Convention Center, Exhibit Hall): *A Comparison of Rat and Rabbit Developmental Toxicity Study Outcomes of More Than 400 Pharmaceutical Compounds*, presented by A.H. Piermsa, P.T. Theunissen, S. Beken, G.D. Cappon, C.L. Chen, and J. Stewart. Poster no. 114, abstract no. 1711.

## UPCOMING EVENTS

**Webinar—Pediatric Investigational Plans: Experiences with Immunomodulatory Drugs (30 March 2015).** The Immunotoxicology Technical Committee is sponsoring a series of webinars on Clinical Immunotoxicology toward bridging the gap between clinical and nonclinical evaluations on human immune monitoring. The next webinar (30 March at 11:00 AM Eastern) will address the topic of pediatric investigative plans for biotherapeutic, specifically immunomodulatory, agents. A review of current preclinical challenges and strategies, regulatory policy perspectives, and case studies will be presented. If you are interested in learning more about this webinar or the webinar series, contact Dr. Connie Chen ([cchen@hesiglobal.org](mailto:cchen@hesiglobal.org)).

**Registration Is Open—Fetal Imaging in Regulatory Developmental Toxicity Studies (20–21 April 2015).** The HESI DART committee is sponsoring a workshop in Arlington, Virginia, on the topic of developing and using specific imaging technologies (e.g., micro-CT, MRI) for alternative methods for evaluating structural birth defects in animal models. The workshop will introduce and discuss image capture technology relative to existing fetal evaluation methodology, understand the regulatory community's perspective and path for acceptance of results using imaging technology, discuss minimal acceptable criteria for imaging to comply with Good Laboratory Practices and Computer Validations requirements, and develop criteria to demonstrate concordance between new and existing examination methods and between testing results. Visit the [workshop website](#) for more details or contact Dr. Connie Chen ([cchen@hesiglobal.org](mailto:cchen@hesiglobal.org)).

**Registration is Open—Labels without Categories: A Workshop on FDA's Pregnancy and Lactation Labeling Rule (20–21 May).** FDA recently finalized its Pregnancy Labeling and Lactation Labeling Rule (PLLR), which changes the organization of the current Pregnancy and Nursing Mothers section of the US package insert of prescription drugs. Among the many changes are the omission of the current letter categories, reformatting of the sections with inclusion of clinically relevant human and animal data, and written summaries of available safety data. In response to these changes, the DART Technical committee is sponsoring a 2-day workshop that will provide a forum to discuss the impact of the PLLR and train relevant industry professionals on how to write labels according to the new rule. The workshop will be held 20–21 May in Arlington, Virginia. Visit the [workshop website](#) for more information or contact Dr. Connie Chen ([cchen@hesiglobal.org](mailto:cchen@hesiglobal.org)) for more details. *This workshop is also eligible for HESI's Future Leaders Travel Award. Click [here](#) for additional details.*

## HESI STAFFING NEWS



### Welcome Melissa Gilden!

Melissa earned her B.S. in Interdisciplinary Studies with a Women's Health concentration from University of Maryland, Baltimore County, in 2010. In February 2015, she joined HESI as a Scientific Program Associate supporting committees on Neurotoxicology, Nephrotoxicology, Genomics, and Cardiac Safety. Prior to joining HESI, Melissa worked as a Regulatory Associate at Precision for Medicine in Bethesda, Maryland, providing client support for medical device submissions to the US FDA and clinical trial management.

#### 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

I recently had the opportunity to visit with a number of HESI stakeholders based in and around Tokyo, Japan. Not only did I reconnect with many scientists (pharmaceutical and chemical industry, Pharmaceuticals Medical Devices Agency, National Institute of Health Sciences, etc.) that are actively participating in HESI's research programs, but I also enjoyed making new connections. Ayako Takei, HESI's science advisor in Japan, and I both paid first-time HESI visits to the Japanese National Institute for Environmental Studies, the National Institute of Technology and Evaluation Chemical Management Center, and the University of Tokyo Graduate School of Public Policy. Based on these discussions, we look forward to several new participants who will engage in HESI science. We extend many thanks to all of the individuals who spent time with us last week in Tokyo and continue to show such great support for HESI's global scientific mission.