



Insights

Your Monthly Update of News and Notes from HESI



June 2014

Opportunity to Join New HESI Study on Biomarkers of Neurotoxicity. Environmental toxicants and a growing inventory of industrial chemicals that have been linked to neurological damage and attrition due to neurotoxicity represent a significant issue in all stages of drug development. The HESI Subcommittee on Translational Biomarkers of Neurotoxicity recognizes current challenges associated with traditional assessment methods for neurotoxicity (e.g., behavioral and histopathology), including sensitivity and specificity as well as invasive sampling. The team has drafted an initial experimental protocol that will evaluate possible fluidic and imaging biomarkers and compare them to the current histology methods. The study includes rethinking biomarkers from traditional functional end points and sectioning, and it will address gaps in sensitivity and specificity of biomarkers across modalities. This project is at a pivotal point. Now is a great time to learn more and join the group. HESI members may contact Ms. Jennifer Pierson (jpierson@hesiglobal.org) for additional information.

HESI is pleased to welcome Nutrinova Nutrition Specialties & Food Ingredients GmbH, a business of Celanese, as a new corporate sponsor of HESI. The company is active on the HESI Sustainable Chemical Alternatives Technical Committee.

UPCOMING EVENTS



[2014 HESI Annual Meeting and 25th Anniversary](#) (10–12 June; Washington, DC). We look forward to celebrating HESI's 25th Anniversary with you at the Annual Meeting! Visit the [website](#) for the final program of events.

[18th Annual Green Chemistry & Engineering Conference](#) (17–19 June; Bethesda, Maryland). The Sustainable Chemical Alternatives Technical Committee will present poster #333 titled "Multi-Stakeholder Recommendations for Sustainable Chemical Alternatives Assessment." In addition, the HESI Risk Assessment in the 21st Century (RISK21) project will be highlighted in a poster during the American Chemical Society Green Chemistry Institute Roundtable Poster Reception. For more information, contact Dr. Jennifer Young Tanir (jtanir@hesiglobal.org).

[54th Annual Meeting of the Teratology Society](#) (28 June–2 July; Bellevue, Washington). The Developmental and Reproductive Toxicology (DART) Technical Committee is sponsoring a symposium titled "Cross-Industry Data Survey of the Value of Rabbit Developmental Toxicity Data in the Risk Assessment for Pharmaceuticals" on Sunday, 29 June. For more information, contact Dr. Connie Chen (cchen@hesiglobal.org).

41st Annual Meeting of the Japanese Society of Toxicology (2–4 July; Kobe, Japan). HESI committees have several activities throughout the conference.

Wednesday, July 2

9:00 AM – 12:00 PM: Workshop; Examples and Possibilities of Imaging Application in Drug Development

- “Evaluation of drug-induced cardiac toxicity, HESI Technical Committee on Imaging for Translational Safety Assessment,” Dr. Katsuyuki Kazusa (Astellas)

1:30 PM – 2:30 PM: Special Lecture

- “Current topics on nonclinical safety assessment of human pharmaceuticals from a European perspective,” Dr. Jan-Willem van der Laan (CBG-MEB)

2:30 PM – 5:30 PM: Symposium: Safety Assessment of Vaccines

- “Safety of vaccine adjuvants: Focus on autoimmunity workshop report,” Dr. Sarah Gould (Sanofi)
- “Nonclinical evaluation of adjuvants and adjuvanted vaccines; Background of the WHO-guideline”, Dr. Jan-Willem van der Laan (CBG-MEB)

Thursday, July 3

4:10 PM – 6:10 PM: Workshop; Paradigm Shift for Reproductive and Developmental Toxicity Assessment of Pharmaceuticals

- “A comprehensive data survey of the relative value of rat versus rabbit developmental toxicity data in the risk assessment for pharmaceuticals,” Dr. Jan-Willem van der Laan (CBG-MEB)

Friday, July 4

1:30 PM – 2:30 PM: Poster Presentation

- “Translational biomarkers of neurotoxicity: an ILSI HESI consortium perspective on identifying and assessing biomarkers,” Dr. Yuko Sekino (Japan National Institute of Health Sciences)



Last Chance to Register — [Workshop on Genetic Toxicology at the Crossroads: From Qualitative Hazard Evaluation to Quantitative Risk Assessment](#)

The HESI Genetic Toxicology Technical Committee is organizing this satellite workshop following the European Environmental Mutagen Society 2014 Annual Meeting on 10–11 July 2014 in Lancaster, United Kingdom. It is becoming increasingly apparent that the genetic toxicology community should move away from qualitative hazard-based approaches to quantitative risk-based methodologies to facilitate data interpretation in the context of informing human risk. The workshop will bring together experts in the fields of genetic and general toxicology, risk assessment, and computational biology representing industry, academia, and government to address and make recommendations on a path forward on this topic, including the identification of any key data gaps in our knowledge that require further research. For more information, visit the workshop [website](#) or contact Dr. Jennifer Young Tanir (jtanir@hesiglobal.org).

54th Annual Meeting of the Japanese Teratology Society (25–27 July; Sagamihara, Japan).

Dr. Kok-Wah Hew will give a presentation on the DART Technical Committee’s work on the value of the rabbit developmental toxicity data in risk assessment for pharmaceuticals. For more information, contact Dr. Connie Chen (cchen@hesiglobal.org).

Recent Publications.

Forbes B, O'Lone R, Allen PP, Cahn A, Clarke C, Collinge M, Dailey LA, Donnelly LE, Dybowski J, Hassall D, Hildebrand D, Jones R, Kilgour J, Klapwijk J, Maier CC, McGovern T, Nikula K, Parry JD, Reed MD, Robinson I, Tomlinson L, Wolfreys A. (2014). [Challenges for inhaled drug discovery and development: Induced alveolar macrophage responses](#). *Adv Drug Deliv Rev.* 71C: 15–33.

The DART Technical Committee has published the following series of manuscripts describing the results of several experiments designed to assess the potential extent of maternal and embryo-fetal exposure and developmental toxicity resulting from drugs that may be present in seminal fluid:

Beyer BK, Cao J, Ying X, DeLise AM. (2014). The use of optical imaging to assess the potential for embryo-fetal exposure to an exogenous material after intravaginal administration. *Reprod Toxicol*. In press.

Breslin WJ, Hilbish KG, Page TJ, Coutant DE. (2014). [Assessment of fetal exposure risk following seminal excretion of a therapeutic IgG4 \(T-IgG4\) monoclonal antibody using a rabbit model](#) [published online ahead of print 2014 May 23]. *Reprod Toxicol*. pii: S0890-6238(14)00080-X. doi: 10.1016/j.reprotox.2014.05.004.

Hui JY, Hoffmann M, Kumar G. (2014). [Embryo-fetal exposure and developmental outcome of thalidomide following oral and intravaginal administration to pregnant rabbits](#) [published online ahead of print 2014 May 22]. *Reprod Toxicol*. pii: S0890-6238(14)00078-1. doi: 10.1016/j.reprotox.2014.05.002.

Moffat GJ, Davies R, Kwon G, Retter MW, Chellman GJ, Kanapuram S, Moore M, Loomis M, Wang W, Pyrah IT. (2014). [Investigation of maternal and fetal exposure to an IgG2 monoclonal antibody following biweekly intravaginal administration to cynomolgus monkeys throughout pregnancy](#) [published online ahead of print 2014 May 22]. *Reprod Toxicol*. pii: S0890-6238(14)00079-3. doi: 10.1016/j.reprotox.2014.05.003.



Staffing News. Please join us in welcoming Kyle A. Brunette to the HESI staff as a Scientific Program Associate! Kyle earned his BS in Biology from Florida

Gulf Coast University, and most recently served as a research assistant at the Naval Medical Research Center in the Department of Regenerative Medicine.

ILSI Health and Environmental Sciences Institute
1156 Fifteenth Street, NW Suite 200
Washington, DC 20005-1743
202.659.3306 phone
202.659.3617 fax

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FROM THE EXECUTIVE DIRECTOR

One of my favorite parts of preparing for the 25th Anniversary Annual Meeting was the opportunity to delve deeply into HESI's early history and participants. As a result, I feel more strongly than ever that we can be proud of both the organization that HESI is today as well as the organization that we were 25 years ago. HESI's commitment to convening top-notch scientists from across sectors has been unwavering from day one.