



Insights

Your Monthly Update of News and Notes from HESI



February 2015

Featured News. HESI's Executive Director, Ms. Syril Pettit, will travel to Japan later this month to connect with a variety of partner organizations about current HESI science projects and to give a lecture at the University of Tokyo. Her lecture will be featured at the Global Leader Program for Social Design and Management Platform Seminar and will highlight the HESI CITE (Combining Interdisciplinary and Translational Expertise) initiative. Read more about the lecture [online](#) and learn more about the CITE initiative on the [HESI website](#).

DART Is Looking for Additional Partners. The DART committee is testing the consensus list of developmental toxicants, a validation list of positive and negative developmental exposures (based on available TK data) and we need your help! The workgroup is using this list to evaluate real-life laboratory conditions and the performance of alternative *in vitro* systems, starting with zebrafish. The consensus list paper is open access and can be downloaded [here](#). If you would like to learn more about or are interested in participating in this effort, contact Dr. Connie Chen (cchen@hesiglobal.org).

New HESI Member. HESI welcomes Novozymes as a new corporate sponsor! Novozymes is active in the Sustainable Chemical Alternatives Technical Committee.

UPCOMING EVENTS

Registration Is Open – Fetal Imaging in Regulatory Developmental Toxicity Studies (20–21 April 2015; Arlington, Virginia). The HESI DART committee is sponsoring a workshop 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 minimally acceptable criteria for imaging to comply with Good Laboratory Practices and Computer Validation requirements, and develop criteria to demonstrate concordance between new and existing examination methods and between testing results. [Click here to register](#). See the [workshop website](#) for more details or contact Dr. Connie Chen (cchen@hesiglobal.org).

Save the Date – Labels without Categories: A Workshop on FDA's Pregnancy and Lactation Labeling Rule (20–21 May 2015; Arlington, Virginia). 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 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. Visit the [workshop website](#) for more information or contact Dr. Connie Chen (cchen@hesiglobal.org) for more details. *This workshop is also eligible for HESI's Future Leaders Travel Award. Click [here](#) for additional details.*

Save the Date – 2015 HESI Annual Meeting! HESI's Annual Meeting will be held 9–11 June 2015 in Washington, DC. More details will be posted on the website soon.

PUBLICATIONS

McClain S, Jones W, He X, Ladics G, Bartholomaeus A, Raybould A, Lutter P, Xu H, Wang X, Jia X, Chen J. (2015). Agricultural biotechnology safety assessment. *Chi J Prev Med* 49, 78–87.

van der Laan JW, Gould S, Tanir JY; (2015). Safety of vaccine adjuvants: focus on autoimmunity. *Vaccine* (accepted 26 January 2015).

van Ree R, Poulsen LK, Wong GWK, Ballmer-Weber BK, Gao Z, Jia X, Chen J. (2015). Food allergy: definitions, prevalence, diagnosis and therapy. *Chi J Prev Med* 49, 87–92.

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FROM THE EXECUTIVE DIRECTOR

Last week, HESI's Emerging Issues Committee (EIC) met in Washington, DC to discuss recently launched projects as well as new proposals submitted to the organization. It was exciting to see both the quality and diversity of scientific issues brought forward. The topic areas to be presented for voting by the membership in June will be officially announced next month (once we finalize a few details!) but look for exciting new opportunities in areas such as pediatrics, therapeutic stem cells, exposure assessment, and risk assessment quality evaluation.