



September Insights

HESI at the 2016 Safety Pharmacology Society Annual Meeting

HESI Cardiac Safety and NeuTox Committee work will be featured in several different presentations at the SPS Annual Meeting in Vancouver, Canada 18-21 September 2016. Please contact Jennifer Pierson (jpierson@hesiglobal.org) for additional information.

Monday, 19 September 2016

Poster Presentations

- —15:15-15:45: Poster 107, Can Nondinical Repolarization Assays Predict the Results of Clinical Thorough QT Studies? A HESI-FDA Retrospective Analysis (Eunjung Park, PhD, US FDA, HESI Cardiac Safety Committee)
- 15:15-15:45: Poster 191, Cardiac Contractility: Correction Strategies Applied to Telemetry Data From a HESI-Sponsored Consortium (Simon Authier, PhD, CiToxLAB, HESI Cardiac Safety Committee)
- —15:15-15:45: Poster 201, An Assessment of Drug-Induced Changes in Cardiac Inotropy and Lusitropy Parameters in Dogs: Results From a HESI-Sponsored Consortium (Michael Pugsley, PhD, Purdue Pharma, HESI Cardiac Safety Committee)

Tuesday, 20 September 2016

Symposium on Translational Biomarkers: Bridging the Gap

- —15:45–16:15: Brief History of the ILSI/HESI Subcommittee on Translational Biomarkers of Neurotoxicity and an Early Report of the Collaborative Biomarker Project (Syed Imam, PhD, NCTR/FDA, HESI NeuTox Committee)
- —16:15–16:45: Glial Fibrillary Acidic Protein (GFAP) and Related Astroglial Proteins as Biomarkers of Neurotoxicity (James O'Callaghan, PhD, CDC/NIOSH, HESI NeuTox Committee)

View the full agenda [online](#).

HESI at the 2016 Environmental Mutagenesis and Genomics Society Annual Meeting

There will be several presentations and discussions related to the work of the HESI Genetic Toxicology Technical Committee (GTTC) at the [EMGS Annual Meeting](#) in Kansas City, Missouri, on **24–28 September 2016**. Please contact Jennifer Tanir (jtansir@hesiglobal.org) for additional information.

Saturday, 24 September 2016

Workshop: Continued Progress in Developing the Pig-a Gene Mutation Assay for Use in Regulatory Science

- —12:00 Noon: Introduction and Overview of Progress Towards an OECD Test Guideline (Robert H. Heflich, National Center for Toxicological Research, US FDA)
- —12:20 PM: 3R's Friendly Approach to Learning the Pig-a Assay and Demonstrating Laboratory

- Proficiency (Javed A. Bhalli, Covance Laboratories Inc.)
- 12:45 PM: Evaluation of Nongenotoxic Rodent Liver Carcinogens With the Pig-a Assay in Blood and Germ Cells (Zhiying Ji, The Dow Chemical Company)
- 1:10 PM: Molecular Analysis of Pig-a Mutations (Vasily N. Dobrovolsky, National Center for Toxicological Research, US FDA)
- 1:35 PM: GPI Anchor-Deficient L5178Y Cells (Jeffrey C. Bemis, Litron Laboratories)
- 2:00 PM: Break
- 2:15 PM: Japanese Interlaboratory Trial Update (Takafumi Kimoto, Teijin Pharma)
- 2:40 PM: Pig-a as a Translational Biomarker of Human Gene Mutation (Stephen D. Dertinger, Litron Laboratories)

Monday, 26 September 2016

- 12:30–2:00: Pig-a Interest Group Discussion (location: Shawanee Room)

Tuesday, 27 September 2016

Symposium 12, Genotoxicity of Nanomaterials: At the Crossroads

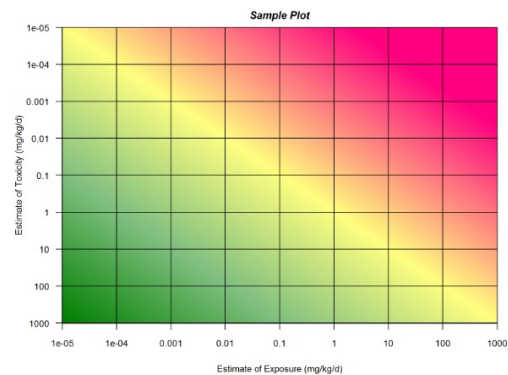
- 2:55 PM: A Revised Genotoxicity Test Battery for Nanomaterials (Rosalie K. Elespuru, US Food and Drug Administration)

Posters

- McDaniel LP, Klimas C, Dertinger SD, Tanir JY, Gollapudi BB, Kenny JD, Dobrovolsky VN, Polli JE, Heflich RH. Development of a Pig-a Gene Mutation Database.
- Tanir JT, Schuler M, van Benthem J. Current Activities of the HESI Genetic Toxicology Technical Committee.

RISK21 2.0

The HESI RISK21 committee is pleased to announce the launch of the new and improved RISK21 2.0 online webtool and user guide. The new webtool features enhancements such as multiple display options for drawing and labeling custom plots to visualize risk data. The RISK21 webtool application allows users to input estimated exposure and toxicity data for each chemical and will plot the intersection area, overlaying a risk matrix represented as a heat map. To explore the new webtool, please visit www.risk21.org.



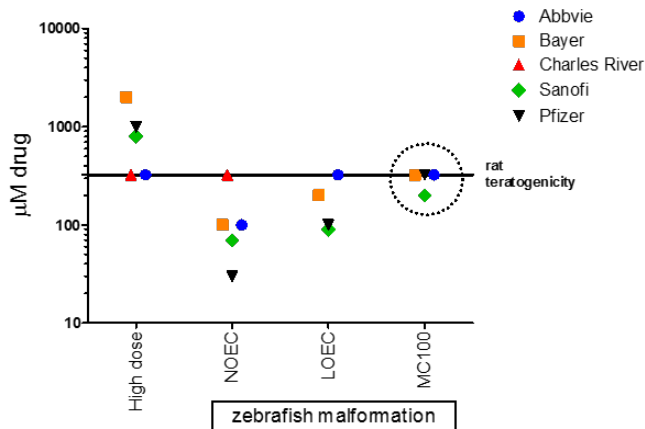
Heat map

Looking for Additional Partners!

DART

A HESI Developmental and Reproductive Toxicology (DART) workgroup has completed the first round of testing of the consensus list of developmental toxicants in the zebrafish embryogenesis assay. The initial results were very promising (see the image below for representative results) and the workgroup would like to add to the number of participating labs to help us complete the testing. If you have a zebrafish embryogenesis assay running in your lab and would like to contribute, we invite your participation! Note that the participating labs are all running different assays and protocols, so any zebrafish developmental tox assay would be a valuable addition! Please contact Connie Chen (cchen@hesiglobal.org) if you would like addition information or are interested.

Comparing zebrafish water to rat plasma: Teratogenicity of caffeine



DART DASTON results.

2016 ILSI Fellows

The 2016 ILSI Fellows presented the results of their projects related to food safety and risk analysis to staff at ILSI and HESI on 22 August 2016. The 2016 ILSI Fellows are individuals who were nominated by ILSI Branches and received a fellowship to participate in the Summer Extended Fellowship in Food Safety Risk Analysis at the University of Maryland's Joint Institute for Food Safety and Applied Nutrition (JIFSAN). The fellows have been at JIFSAN for the entire summer participating in the JIFSAN program. Drs. Michelle Embry and Jennifer Tanir from HESI visited the fellows at JIFSAN on 15 July 2016 to give an overview and demonstration of the RISK21 framework and matrix webtool, which the fellows used in their projects as a method for comparing toxicity and exposure information.



(Left to Right) Dr. Dung Le Hong (Department of Food Chemistry, National Institute of Nutrition, Hanoi, Vietnam), Ms. Chali Srinimnaun (Food and Drug Administration, Ministry of Public Health, Nonthaburi, Thailand), Dr. Jiang Liang (Nutrition and Food Hygiene, China National Center for Food Safety Risk Assessment, Beijing, China), Dr. Haixia Sui (Department of Risk Assessment, China National Center for Food Safety Risk Assessment, Beijing, China), Dr. Suzie Harris (Executive Director, ILSI, Washington, DC), Dr. Ruby Apilado (Department of Science and Technology, Food and Nutrition Research Institute, Taguig City, The Philippines), and Dr. Clare Narrod (Risk Analysis Program Manager/Impact Evaluation Project Lead, JIFSAN, College Park, Maryland).

Upcoming Events

HESI Protein Allergenicity Workshop

NON-IG E MEDIATED IMMUNE REACTIONS TO FOODS:
RESEARCH NEEDS AND SCIENTIFIC APPROACHES TO ASSESSING SAFETY.
A FAAM 2016 pre-meeting workshop, organized by:
ILSI Health & Environmental Sciences Institute (HESI)
Protein Allergenicity Technical Committee (PATC)



12-13 October, 2016
Sheraton Roma Hotel & Conference Centre,
Rome, Italy.



Join us on **12–13 October 2016** to learn about the current approaches and possible gaps in the characterization and detection of proteins anticipated to trigger non-IgE responses, including the etiology of celiac disease as well as the role of dietary proteins in inducing/triggering this disease. Participants will also consider whether the safety assessment of foods derived from genetically modified crops should include considerations related to non-IgE-mediated food allergy. The workshop includes the participation of a multisector panel of speakers from the Leiden University Medical Centre, the Children's Hospital of Philadelphia, the European Laboratory for the Investigation of Food-Induced Diseases, EFSA, and representatives from the agrobiotech industry.

A description of the meeting, preliminary agenda with confirmed speakers, and registration link are available [here](#). All are welcome (this event is open to the public and registration is free). We look forward to seeing you there!

Recent Publications

Lorge E, Moore MM, Clements J, O'Donovan M, Fellows MD, Honma M, Kohara A, Galloway S, Armstrong MJ, Thybaud V, Gollapudi B (2016) Standardized cell sources and recommendations for good cell culture practices in genotoxicity testing. *Mutation Research*. 809: 1–15. [Read more](#).

FROM THE LEADERSHIP

It is 13 years since I first participated in HESI, joining the nascent safety biomarker project steering group. Since then I have been thoroughly schooled in all aspects of HESI's operation; the Technical Committees, the Emerging Issues committee and more recently the Board of Trustees (BOT) and its governance committees. Over this time HESI has continuously evolved, seeking ways to deliver its mission more effectively. However, the pace of change has accelerated under the visionary and dynamic leadership of Executive Director, Cyril Pettit. Earlier this year the BOT adopted several changes in the [governance](#) structure bringing it more completely and explicitly in line with the public-private partnership that is at the very core of HESI's being and that operates at all levels of its organisation. One element of these changes directly impacted the present leadership. No longer do we have only a private sector track to become President in parallel with a public sector track to Chair of the BOT. Rather both leadership roles alternate between public and private sectors, with the proviso that both leadership positions are never simultaneously from the same sector. Tim Pastoor (from the private sector and current President) and I (from the public sector and current Chair of the BOT) were the last to be elected under the old system and the first to transition under this new structure. Both Tim and I were strongly supportive of this change and have adjusted with ease to its reality. While the bylaws stipulate the Chair presides over the BOT and the President presides over the Assembly, in practice we work closely as a leadership 'duo', discussing all aspects of HESI's daily operation and future development, seeking progress for key programs such as implementation of the strategic plan and its many key components. I am confident that in the long term HESI will benefit from this new organisational structure. It is a great privilege to be able to serve HESI through these exciting times.



Ernie Harpur, HESI Chair

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