



Insights

Your Monthly Update of News and Notes from HESI



December 2015

As 2015 draws to a close, HESI is thankful for another wonderful year made possible by our members and partners.

This month's *Insights* offers a look back through some 2015 highlights.



2015 Highlights

January

Strategic Planning Process. HESI's current strategic plan is set to expire at the end of 2015. With that in mind, HESI began a new round of strategic planning at the January Board of Trustees meeting and the June HESI Annual Meeting. HESI sought feedback on present and future organizational challenges and future goals, which resulted in the development of a draft plan. The HESI Board of Trustees will be approving the draft plan in 2016.

February

HESI Japan Outreach. HESI's Executive Director, Ms. Syril Pettit, traveled to Japan 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 was featured at the Global Leader Program for Social Design and Management Platform Seminar and highlighted 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](#).

March

GTTC Wins Best Paper Award. The HESI Genetic Toxicology Technical Committee (GTTC) 2014 [article](#) by Johnson et al. [Derivation of point of departure (PoD) estimates in genetic toxicology studies and their potential applications in risk assessment. *Environ Mol Mutagen*. 55(8):609–623] was 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. It was also awarded the EMM Editor's Choice.

April

HESI PATC Workshop in Paris. The HESI Protein Allergenicity Technical Committee (PATC) held the "Molecular and Genetic Basis of Potential Unintended Effects in Modified Plants" workshop in Paris, France, on 14 April 2015. This workshop was attended by over 60 industry, regulatory, and research scientists from around the globe. Through a series of sessions, participants gained information on topics ranging from the molecular and genetic basis of unintended effects to the potential consequences of those effects on food and feed safety assessment. The workshop presentations are available on the HESI [website](#).

May

HESI at SETAC Europe. Several HESI projects were highlighted at the May 2015 Annual SETAC Meeting in Barcelona, Spain, including (1) the Bioaccumulation Technical Committee *in vitro* ring trial, and (2) Animal Alternatives in Environmental Risk Assessment presentations on "Harmonizing the Harmonized Test Guidelines: Fish Developmental Biology Terminology and Animal Testing Implications," "Ecotoxicological Threshold of Concern (Eco-TTC): Development of an Approach to Assist in Environmental Hazard Assessment," and "The Fish Embryo Toxicity Test as an Alternative to the Larval Growth and Survival Test: Test Sensitivity and Alternative End points in Zebrafish and Fathead Minnows."

June

2015 HESI Annual Meeting. The HESI Board of Trustees and staff welcomed over 115 global thought leaders to the 2015 HESI Annual Meeting, held 9–12 June 2015, in Washington, DC. Participants represented both public-sector institutions (government, academia, research institutes, and NGOs) and private organizations. The meeting also featured thought-provoking presentations from three of the current HESI scientific committees as well as a CITE session with invited speakers from the Harris Group, the African Insect Science for Food and Health Center, and the Institute for Health Metrics and Evaluation. Visit the [HESI website](#) to view some of the presentations and meeting materials.

July

New DART Project on Nonclinical Neonatal Pediatric Animal Models. The Developmental and Reproductive Toxicology (DART) Technical Committee adopted a new project through the Emerging Issues process on the topic of nonclinical efficacy and safety studies to support neonatal therapeutics. The project aims to 1) identify major gaps in preterm and term neonatal drug developmental and neonatal animal models of human disease and 2) address how to best leverage neonatal nonclinical models to support safety and proof of concept for human neonatal disease. The project ultimately aims to develop relevant study designs and data that can be obtained from nonclinical models. Contact Connie Chen (cchen@hesiglobal.org) for more information.

August

HESI and NASA Collaborate. HESI became a member of the NASA Human Health and Performance Center (NHHPC) in 2014. Although NASA may sound like an unlikely partner for HESI, many of the NHHPC goals align with HESI's mission. Both NHHPC and HESI share a goal of convening partners from industry, government, academia, and nonprofit organizations to advance and improve human health through collaborative science. The most recent partnership focuses on medicine stability and shelf-life—what NASA is calling the MoSAIC (Medicine Stability Innovation Collaboration) project. The implications of this project would not only affect medicines provided to NASA astronauts, but it would also benefit the developing world where access to medications is often lacking. Learn more and read the full newsletter [here](#).

September

FDA-HESI Safety Science Forum. HESI entered into a MOU with FDA in 2014 and through this agreement, HESI is organizing a series of educational lectures on contemporary safety science issues at the US FDA White Oak campus in Maryland. The first in the Safety Science Forum series was a two-part lecture on “Human Stem Cell–Derived Cardiomyocytes: Evolving Roles in Drug Safety and Discovery,” held on 17 September 2015. Drs. Gary Gintant (AbbVie) and Mark Mercola (University of California) presented on uses and limitations of human-induced pluripotent stem cell–derived cardiomyocytes in both basic research and the drug development process.

October

HESI Emerging Issues—Two New Programs Launched for 2016! HESI announced the launch of two new Emerging Issues proposals. In the first program, the CT-TRaCS Committee (Cell Therapy – TRacking, Circulation, & Safety) will bring together an interdisciplinary team of scientists to discuss and evaluate current approaches (and gaps) in preclinical methods to assess cell therapeutic safety and to explore the development of new approaches and strategies. HESI anticipates this project will officially begin in January 2016. If you are interested in participating in this program, please contact Ms. Cyndi Nobles (cnobles@hesiglobal.org).

The second program focuses on Big Data and Exposure. A small advisory team, led by HESI's Associate Director for Environmental Science, Dr. Michelle Embry, was chartered by the Emerging Issues Committee to begin to tackle this challenge via development of actionable project areas for specific discussion by interested HESI stakeholders in early 2016. If you are interested in participating in these 2016 discussions, please contact Brianna Farr (bfarr@hesiglobal.org).

November

RISK21 Outreach in Asia. A RISK21 outreach team, composed of Alan Boobis (Imperial College London), Samuel Cohen (University of Nebraska Medical Center), Michelle Embry (HESI), Angelo Moretto (University of Milan), and Tim Pastoor (PSC), gave three highly successful and interactive RISK21 hands-on workshops in Taiwan and China the week of 19–25 October. The workshops introduced the RISK21 project and provided the participants with case study–led instruction on the use of the RISK21 web tool (available at www.risk21.org).

December

New Year, New Projects!

The HESI Genomics Committee is initiating several new workstreams, including the following:

- (1) *miRNA Atlas (Phase 2)*. The committee has conducted an experimental program to assess microRNAs (miRNAs) in control rat tissues to generate an atlas of baseline miRNA expression. This program was initiated to enhance the understanding of normal tissue distribution of miRNAs in the rat, aid in interpretation of miRNA changes upon drug-induced injury, and facilitate biomarker discovery for drug-induced injury. The first phase of this program, utilizing a next-generation sequencing approach to explore expression of ≥ 20 tissues in the rat and generate the atlas, has been completed, with the manuscript describing the findings anticipated by year end. Utilizing the findings from the atlas program, and identification of tissue-enriched and tissue-specific miRNAs, the committee is exploring a second phase of work to evaluate specific candidate miRNAs as putative markers of injury.
- (2) *NGS Standard Development for the Assessment of FFPE RNA*. The recently published 2015 [article](#) by Webster et al. [Mining the archives: a cross-platform analysis of gene expression profiles in archival formalin-fixed paraffin-embedded (FFPE) tissues. *Toxicol Sci.* 148(2):460–472. doi: 10.1093/toxsci/kfv195] described efforts to evaluate next-generation sequencing as a method for transcriptomic profiling of FFPE tissues. Building on this work, the new project will address quality of RNA isolated from FFPE samples and provide improved methods for applying RNA sequencing (RNA-seq) to archival samples. This work aims to (1) evaluate formalin effects on RNA-seq profiles, (2) develop metrics for quality assessment of FFPE RNA, and (3) investigate methods for improving quality of RNA and RNA-seq data from FFPE samples.

If you are interested in more information or wish to become involved in these projects, please contact Dr. Raegan O'Lone (rolone@hesiglobal.org).

The HESI Sustainable Chemical Alternatives Technical Committee has also started two new projects:

- (1) Pilot study for integrating exposure into alternatives assessment, and
- (2) Developing a scoping document for identifying and filling data gaps.

A summary of the two projects is included in the recent SETAC North America Annual Meeting [poster](#).

If you are interested in participating in these projects or would like additional information, please contact Dr. Jennifer Tanir (itanir@hesiglobal.org).

2015 BY THE NUMBERS



FROM THE EXECUTIVE DIRECTOR

I would like to conclude 2015 with a simple thank you to all of those who have contributed their time, energy, and creativity to HESI to make it the vibrant organization that it is today. We are no doubt poised for some great new achievements in 2016 as well. Best wishes for a happy and healthy New Year.

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

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