



Insights

Your Monthly Update of News and Notes from HESI



September 2015

HESI Awarded Grant from FDA. HESI is pleased to announce that the Cardiac Safety Committee (CSC) was recently awarded funds through an FDA Broad Agency Announcement (BAA) competitive grant program. The HESI proposal titled “Validating Human Stem Cell Cardiomyocyte Technology for Better Predictive Assessment of Drug-Induced Cardiac Toxicity” aims to address FDA CDER’s research area 1.1 (“Develop better models of human adverse response”). The awarded funding will help support a study that follows a smaller pilot study conducted by the CSC Myocyte Subteam, which explored stem cell cardiomyocytes use on microelectrode array (MEA) and voltage sensitive dye/optical (VSO) platforms. The HESI CSC will provide in-kind and direct support for the experimental study, data analysis, and program management. For more information about this project or the CSC, contact Ms. Jennifer Pierson (jpierson@hesiglobal.org).

HESI Participates in NCATS First Microphysiological Systems Workshop. HESI participated in the first “Microphysiological Systems Workshop: Working with Industry and Other Stakeholders,” hosted 27–28 August 2015 by the NIH National Center for Advancing Translational Sciences (NCATS). This meeting, attended by multiple stakeholder groups, featured progress in tissue chip development, discussion of potential applications of tissue chips for drug development, and considerations for generating data and validation. HESI presented “Building a Technology Integration Strategy,” which included sharing past experience and points for consideration with regard to collaborative efforts to facilitate evaluation and application of new technologies, and participated in a panel discussion on opportunities for tissue chips.

UPCOMING EVENTS

HESI Genetic Toxicology at EMGS Annual Meeting (26–30 September 2015). The Environmental Mutagenesis and Genomics Society (EMGS) Annual Meeting will be held in New Orleans, Louisiana. Activities of the HESI Genetic Toxicology Technical Committee will be featured in several sessions:

- Saturday, 26 September, 2:05–2:40 (during Workshop 3): “ILSI-HESI Nanomaterials Team’s Recommendations with Regards to Suitability of Standard Genotoxicity Assays for Genotoxicity Testing of Nanomaterials: Results from a Comprehensive Literature Review,” presented by Dr. Stefan Pfuhler, The Procter & Gamble Company.
- Sunday, 27 September, 4:30–6:00 (Poster Session): “P83 Recent Advances by the HESI Genetic Toxicology Technical Committee,” presented by Dr. Jennifer Y. Tanir, HESI.
- Monday, 28 September, 10:00–12:30: Symposium 4: “Mutagenicity as an Apical Endpoint for Risk Assessment,” chaired by Dr. Paul A. White, Health Canada and Prof. George Johnson, Swansea University.

- “The Journey towards a New Paradigm in Genetic Toxicology,” presented by Dr. B. Bhaskar Gollapudi, Exponent, Inc.
- “The Combined, Covariate BMD Approach: Utility for Potency Comparisons and Mode-of-Action Evaluation in Genetic Toxicology,” presented by Dr. John W. Wills, Health Canada.
- “Quantitative Assessment of Genetic Toxicology Data: A Global Perspective,” presented by Prof. George Johnson, Swansea University.
- “A Case for Mutagenicity as an Apical Endpoint to Derive Permissible Exposure Levels,” presented by Dr. Robert Heflich, National Center for Toxicological Research, US FDA.
- “Risk Assessment and Risk Management Decisions Based on Mutagenicity Data,” presented by Dr. Kerry Dearfield, Food Safety and Inspection Service, USDA.
- Monday, 28 September, 12:30–1:40: Meeting of the Pig-a Interest Group (Grand Chenier room).
- Tuesday, 29 September, 8:05–8:20: Presentation during Risk Assessment SIG Breakfast Meeting, “Recent Advances by the HESI Genetic Toxicology Technical Committee,” presented by Dr. Jennifer Y. Tanir, HESI.

For additional information, please contact Dr. Jennifer Y. Tanir (jtanir@hesiglobal.org) or visit the [EMGS Annual Meeting website](#).

HESI Science Featured at SPS Annual Meeting (29 September–1 October 2015). The Safety Pharmacology Society (SPS) Annual Meeting is being held in Prague, Czech Republic. The HESI CSC will present data from the Integrative Strategies Working Group contractility study and the Cardiac Biomarkers Working Group proof-of-concept 1 study:

- Tuesday, 29 September, 10:00–10:30: “HESI Update on Contractility Endpoints,” presented by Dr. Michael Pugsley, Purdue Pharma.
- Tuesday, 29 September, 13:00–14:00: “Biomarkers of Hypercoagulability in Rat Sepsis-Induced Model of Non-Overt Disseminated Intravascular Coagulation (DIC),” presented by Dr. Stan Parish, HESI.

There will also be a special CiPA Session on Thursday, 1 October. Learn more at the [SPS website](#).



2015 HESI Staff Retreat in action. From left to right: Connie Chen, Brianna Farr, Stan Parish, Jennifer Tanir, Jennifer Pierson, Cyndi Nobles, Oscar Bermudez, and Raegan O’Lone

RECENT PUBLICATIONS

Roberts RA, Aschner M, Calligaro D, Guilarte TR, Hanig JP, Herr DW, Hudzik TJ, Jeromin A, Kallman MJ, Liachenko S, Lynch JJ, Miller DB, Moser VC, O'Callaghan JP, Slikker W Jr, and Paule MG (2015) Translational biomarkers of neurotoxicity: a HESI perspective on the way forward. *Toxicol Sci* (In Press).

Stewart J, Breslin WJ, Beyer BK, Chadwick K, De Schaepdrijver L, Desai M, Enright B, Foster W, Hui J, Moffat GJ, Tornesi B, Van Malderan K, Wiesner L, and Chen CL (2015) Birth control in clinical trials: industry survey of use current practices, governance and monitoring. *Therapeutic Innovation & Regulatory Science* (In Press).

FROM THE EXECUTIVE DIRECTOR

In August, we convened our annual HESI staff retreat in nearby Arlington, Virginia. During the retreat, the staff commit to 8 hours of focused — albeit informal — discussion to address issues ranging from committee management, to staff development, to organizational strategy. The 2015 session, as in years past, proved incredibly valuable and generated some great suggestions that will help to optimize HESI's operations. This year I was particularly struck by the affinity of the staff for both the organization's mission and each other. As Director, I couldn't ask for more than this nexus of initiative, enthusiasm, creativity, and comradery. It will undoubtedly serve HESI very well in the months and years to come!

Spil D. Robert

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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