



**August 2012**

**HESI Outreach in Japan.** During the first week of July, HESI visited with dozens of scientists from HESI sponsors around Japan including Sumitomo, Astellas, Daiichi-Sankyo, Takeda, and Mitsubishi-Tanabe. On-site meetings were held with staff from the Japan National Institute of Health Sciences, RIKEN, and the ILSI Japan office, and a lecture by Ms. Syril Pettit on “Collaborative Approaches to Improve Cardiovascular Safety Assessment” was delivered to the Japanese Pharmaceutical and Medical Devices Agency (PMDA). We received positive feedback on HESI’s programs, and offer our thanks to these organizations for their expanding participation in HESI and gracious hospitality during our visit!

**REGISTER NOW! We are excited to offer several innovative scientific workshops this fall...**

**Concordance of Non-Clinical and Clinical Arrhythmia Data.** 4 October 2012 in Phoenix, Arizona. The purpose of the workshop is to review results of the HESI-FDA proarrhythmia data evaluation project and hear updates about related initiatives conducted by the European Medicines Healthcare Products Regulatory Agency, Animal Model Framework Program, and TI-Pharma consortium. Sponsored by the HESI Technical Committee on Cardiac Safety. Click [here](#) for additional details.

**Adjuvants and Vaccines: Focus on Autoimmunity.** 18-19 October 2012 in Amsterdam, The Netherlands. The workshop will assess the state of knowledge with regard to the potential association between adjuvants and autoimmune responses; pool data across available literature including *in vitro*, animal, and human data; and develop recommendations for future evaluation. Sponsored by the HESI Vaccines and Adjuvants Safety Project Committee with additional support from the HESI Immunotoxicology Technical Committee. Click [here](#) to access details and registration information.

**Pluripotent Stem Cells: Applications for Cardiovascular Risk Assessment.** 30-31 October 2012 at the Amgen, Inc. Campus, Cambridge, Massachusetts. This meeting will evaluate current and potential future use of stem cell

platforms and associated technologies in the cardiovascular (CV) risk assessment of pharmaceuticals and/or environmental chemicals. Co-sponsored by the HESI Cardiac Safety Technical Committee and the Safety Pharmacology Society. Click [here](#) for workshop details. To register, click [here](#).

**Challenges for Inhaled Drug Discovery and Development: Induced Alveolar Macrophage Responses.** 30-31 October 2012 in Stevenage, United Kingdom. The workshop will bring together global groups working to discuss current knowledge and methods, gaps and research needs, and best practices with regard to drug-induced macrophage responses during inhaled product development. Co-organized by the HESI Immunotoxicology Technical Committee and the Academy of Pharmaceutical Sciences Great Britain. Contact Dr. Raegan O’Lone ([rolone@hesiglobal.org](mailto:rolone@hesiglobal.org)) for additional information.

**Genetically Diverse Mouse Models in Drug Safety Testing Strategies.** 28 November 2012 in Washington, DC. This workshop will address a variety of models that capitalize upon the diversity of genetic variability and knowledge available in the mouse, including discussion of practical aspects of the proposed context of use for safety assessment and best practices for use of these models in pharmaceutical development. Organized by the HESI Application of Genomics to Mechanism-Based Risk Assessment Technical Committee. Contact Dr. Raegan O’Lone ([rolone@hesiglobal.org](mailto:rolone@hesiglobal.org)) for additional information.

**Publication of Committee-Developed Protocol.** The HESI Bioaccumulation Project Committee has published “Assessment of Metabolic Stability Using the Rainbow Trout (*Oncorhynchus mykiss*) Liver S9 Fraction” in the August 2012 issue of *Current Protocols in Toxicology*. The protocol was developed as part of the Committee’s work to assess the *in vitro* fish liver S9 assay to optimize the prediction of bioaccumulation. Financial support was provided by the European Commission via the study contract CCR.IHCP.C434207.X0 and CEFIC (European Chemical Industry Council) via CEFIC –LRI ECO6.2 (Contract #LRI-

ECO6.2-ILSIHESI-0804). The protocol describes the isolation of S9 fractions from trout livers, assessment of metabolic stability using a substrate depletion approach, and expression of the result as *in vivo* intrinsic clearance. Potential applications of these methods in the field of ecotoxicology include prediction of metabolism impacts on chemical accumulation by fish, evaluation of emerging chemical contaminants, and improved interpretation of *in vivo* toxicity testing results. The protocol is available free of charge by clicking [here](#).

**Participate in HESI Data Collection on Developmental and Reproductive Study Practices.** The Developmental and Reproductive Toxicology (DART) Technical Committee is currently soliciting data for two projects: 1) Birth Control in Clinical Trials, and 2) Rabbit 2<sup>nd</sup> Species. The objective of the Birth Control project is to understand current industry practices for contraception requirements for both women and men in clinical trials, the governance processes set up to promote consistency and/or compliance with contraception requirements, and the effectiveness of current contraception practices in preventing pregnancies during clinical trials. The objective of the Rabbit 2<sup>nd</sup> Species project is to evaluate developmental toxicology data from pharmaceutical compounds that have been tested in the rat and rabbit. The DART Committee is building a database to facilitate the analysis of concordance between the two species. If you are interested in contributing data to these projects, please contact Dr. James Kim ([jkim@hesiglobal.org](mailto:jkim@hesiglobal.org)) to obtain survey/data entry forms. The forms will also be available for download from HESI's website in the near future.

**Committee Renewals.** Congratulations to the HESI Project Committee on Translational Imaging on its successful renewal after the Stewardship Program Review by the HESI Board Program Strategy and Stewardship Committee. The program was commended for its innovative and multi-disciplinary approach to applying imaging technologies to progress drug development and safety for cardiovascular, neural, and liver applications. If you are interested in learning more about this program or joining the committee, please contact the program manager, Dr. James Kim ([jkim@hesiglobal.org](mailto:jkim@hesiglobal.org)).

**HESI at American Chemical Society Meeting.** On 22 August 2012, Dr. Jennifer Young (HESI), on behalf of the HESI Frameworks for Alternative Chemical Assessment and Selection of Safer, Sustainable Alternatives Subcommittee, will present on "Alternatives Assessment: Going Beyond Hazard" at the 244<sup>th</sup> American Chemical Society National Meeting & Exposition in Philadelphia, Pennsylvania.

*From the Executive Director: As you can see from the list of upcoming HESI workshops, summertime does not equal a slowdown in HESI activity! Staff and committee members are hard at work to meet 2012 program goals and initiate plans for the coming year. To date, commitments for more than \$1,000,000 in novel multi-site laboratory studies in 2013 have been confirmed with many more pooled resource allocations still to be finalized. Here's to the power of partnership!*

*Spil D. Reiche*



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