September 2012

RISK21 highlighted at the 8th Congress of Toxicology in Developing Countries in Bangkok, Thailand. On 11 September 2012 in a symposium session on New Approaches to Toxicity Testing and Risk Assessment, Dr. Samuel Cohen (University of Nebraska Medical Center, HESI Board member, and Chair of the ILSI Board of Trustees) gave an invited presentation on the RISK21 Project. Dr. Herman Autrup, HESI Vice-Chair, also presented at the meeting. The meeting yielded opportunities for informal discussions about HESI with our ILSI Southeast Asia colleagues and other regionally based scientists. We look forward to building on these interactions through future activity and partnership.

HESI Partners with ILSI South American Branches on Food Safety Meetings. On 6-7 November in Brasilia, leaders of the HESI Protein Allergenicity Technical Committee (PATC) will present key information about allergenicity safety assessments and new methods to Brazilian regulators and scientists. The meeting, hosted by ILSI Brasil, includes speakers from HESI, the ILSI Center for Environmental Risk Assessment, and the ILSI International Food Biotechnology Committee. On November 8, the PATC leadership will present similar information in Buenos Aires to Argentine scientists at a meeting hosted by ILSI Argentina. For more information, contact Ms. Nancy G. Doerrer (ndoerrer@hesiglobal.org).

HESI Committee Renewal. Congratulations to the HESI Immunotoxicology Technical Committee (ITC) on its successful renewal after a September review by the HESI Board Program Strategy and Stewardship Committee. The committee was re-chartered for an additional three years based on its robust and impactful portfolio. To learn more about the ITC, contact Dr. Raegan O'Lone (rolone@hesiglobal.org).

HESI IVGT Research Featured at Environmental Mutagen Society Annual Meeting. The HESI In Vitro Genetox (IVGT) Project Committee held a symposium titled "Next Generation Risk Assessment and Regulatory Policies" on September 10 at the EMS meeting in Bellevue, Washington. The symposium featured Dr. Bhaskar Gollapudi (retired, Dow Chemical Co., and former co-chair of the IVGT committee), Dr. Vincent Cogliano (US EPA), Dr. Donna Mendrick (US FDA), Dr. J. David Miller (Carleton University), and Dr. Mark Rothstein (University of Louisville).

Welcome to New HESI Sponsor! Please join us in welcoming Quintiles to HESI. Quintiles is a clinical research organization with extensive expertise in both drug development and clinical studies. We look forward to the company's active involvement with the HESI Cardiac Safety Committee and the valuable addition of expertise. Welcome, Quintiles!

From the Executive Director: *HESI's international participation – and its role as the global branch of ILSI – creates a unique opportunity to contribute to science on a global scale. In this month's Insights, it is evident that HESI takes this mission seriously and engages not only in North America, Europe, and Japan – but throughout Asia and South America as well. In collaboration with ILSI's regionally based branches and other HESI contacts, we look forward to building new partnerships to further the reach of HESI's scientific programs, engage new perspectives and expertise, and address critical public health needs through quality science.*

Syril D. Pettit

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. The registration deadline has been extended through 28 September! 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. The special room rate ends 17 September.

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. Please click here for program and registration details or contact Dr. Raegan O'Lone (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. Please click here or contact Dr. Raegan O'Lone (rolone@hesiglobal.org) for additional information.

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 2nd 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 2nd 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) to obtain survey/data entry forms. The forms will also be available for download from HESI's website in the near future.

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 risk assessment of pharmaceuticals and/or environmental chemicals. Co-sponsored by the HESI Cardiac Safety Technical Committee and the Safety Pharmacology Society. The poster abstract submission deadline has been extended to 14 September and the hotel room block is now open! Click here for workshop details. To register, click here.

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