February Insights

HESI Office Move

HESI offices have moved to their new location at:

740 15th Street NW, Suite 600
Washington, DC 20005

Please ensure that all written communications are mailed to this address.

Ruth Roberts Awarded SOT 2018 Founders Award

HESI member Ruth Roberts was recently awarded the SOT 2018 Founders Award. The award is presented to a member of the Society of Toxicology who has demonstrated outstanding leadership in fostering the role of toxicological sciences in safety decision making through the development and/or application of state-of-the-art approaches that elucidate, with a high degree of confidence, the distinctions for humans between safe and unsafe levels of exposures to chemical and physical agents. We thank and congratulate Ruth for all of her great work!

CiPA Model Now Available as Open Source Code

The HESI Cardiac Safety Committee has been actively working to gather data in support of the Comprehensive In Vitro ProArrhythmia (CiPA) Initiative, which aims to improve the drug development process by using new *in vitro* and *in silico* technologies to assess cardiac proarrhythmic risk. The Food and Drug Administration (FDA) has spearheaded the development of an *in silico* computer model and recently tested and validated this model using data generated by a HESI Cardiac Safety Subteam. Preliminary results were presented at the 2017 Safety Pharmacology Society Annual Meeting and proved that the *in silico* model is able to accurately bin compounds into high, medium, and low proarrhythmic risk categories. The FDA is finalizing the validation study and will publish the results soon. The details of the model and training results are published here. In the meantime, the FDA released the model as open source code, making it available to everyone. This is a major step forward for the CiPA Initiative and all involved are to be congratulated. For more information, visit the CiPA website or email Jennifer Pierson (jpierson@hesiglobal.org).

CT-TRACS Events

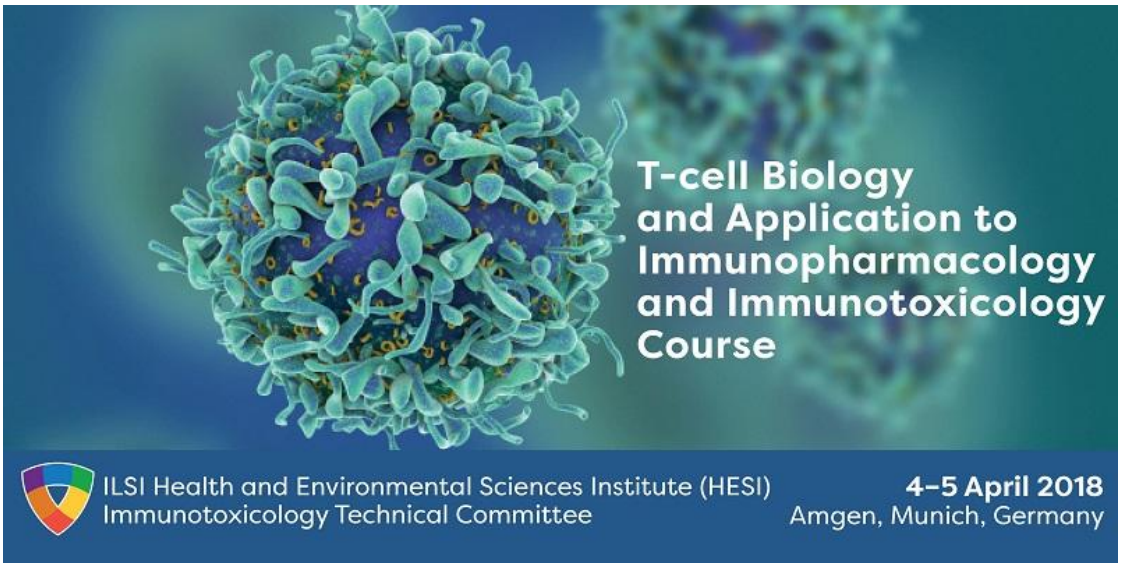
Several CT-TRACS members recently attended the Phacilitate Cell & Gene Therapy World Meeting in Miami, Florida, on 22–25 January 2018. The meeting aimed to promote networking, educate emerging biotechs to select their preferred suppliers, support industry and academic convergence, and provide a port of call for new arrivals in the cell and gene therapy space seeking solutions. Lucilia Mouriès presented the CT-TRACS poster during the meeting and received positive feedback.

The CT-TRACS committee also co-hosted the workshop “Safety Assessment of Cell Therapy Products: Current Advances and Challenges” with the Cell & Gene Therapy Catapult group on 14 February 2018 in London, England. Speakers detailed challenges, gaps, and needs to assess the safety of cell therapy products through a “Tumorigenicity” session and a “Biodistribution and Imaging” session. Meeting topics included

future needs in patient safety of cell-based therapies, evolving safety tools and applied safety techniques, and the role of collaboration in cell therapy development and use.

UPCOMING EVENTS

Register Today for the T-cell Biology and Application to Immunopharmacology and Immunotoxicology Course



The Immunotoxicology Technical Committee (ITC) welcomes you to register for the training course on "**T-cell Biology and Application to Immunopharmacology and Immunotoxicology"** that will be held **4–5 April 2018** at the Amgen site in Munich, Germany. The field of immunotoxicology is a dynamic one in which changing public health concerns, novel biomedical research advances, and innovative technological developments constantly change the landscape and the way in which work is carried out and utilized. Because this field requires combined expertise in both immunology and toxicology, the need for continued training and interdisciplinary interactions is essential both for those with an immunology background who seek to apply this expertise to drug development and safety, as well as those who wish to enhance their current drug safety expertise with a deeper understanding of immunology. For additional information, visit the training course website or contact Dr. Stan Parish.

Save The Date: Gut Microbiome Workshop

The HESI Microbiome Subcommittee is proud to announce **"The Gut Microbiome: Markers of Human Health, Drug Efficacy and Xenobiotic Toxicity Workshop**," which will be held in Alexandria, Virginia, on **25–26 June 2018**. The workshop will focus on:

- current science on the gut microbiome and identification of areas of interest regarding its role in human health
- our understanding of how xenobiotic toxicity affects the microbiome
- discussion of biomarkers of disease or organ damage due to alterations of microbiome structure or endogenous microbial metabolites

HESI Sessions at SOT 2018

Wednesday, 14 March 2018

11:00 AM to 12:20 PM
Genomics Committee Scientific Session: "Unlocking the 'Omics Archive: Enabling Toxicogenomic/Proteomic Investigation From Archival Samples"

- *Session Chairs:* Deidre Dalmas (GlaxoSmithKline, King of Prussia, PA) and Susan Hester (US EPA, Research Triangle Park, NC)

Thursday, 15 March 2018

8:30 AM to 11:30 AM
DART Committee Session: "Late-Breaking 11: Kidney and Liver; Reproductive and Developmental Toxicology"

- Abstract Number/Poster Board Number: 3634/ P428
- Abstract Title: "Evaluating Zebrafish Developmental Assays for Predicting a Drug's Teratogenic Plasma Level Using an Exposure-Based Validation Compound List"
- Presentation Location: Convention Center Hall 1

8:30 to 11:15 AM
HESI Translational Biomarkers of Neurotoxicity Committee Workshop Session: "A Search for Biomarkers of Neurotoxicity: A Practical Approach"

HESI 2018 Annual Meeting

Save the date! The **HESI 2018 Annual Meeting** will be held **12–14 June 2018** in Washington, DC. This year's meeting will feature sessions on "Implementing Risk Assessment for Health" and "Big Data From Small Sources" as well as presentations from the HESI THRIVE Awardees. Speakers will include:

- Rose Omari, PhD, Science and Technology Policy Research Institute
- Puspo Edi Giriwono, PhD, Southeast Asia Food and Agricultural Science and Technology (SEAFAST) Center
- John Parker, MBA, Springhood Impact Ventures
- Dr. Lukasz Piwek, University of Bath School of Management
- Taxiarchis Botsis, MS, PhD, Food and Drug Administration

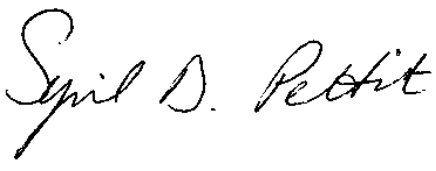
Learn more here.

RECENT PUBLICATIONS

Scialli AR, Daston G, Chen C, Coder PS, Euling SY, Foreman J, Hoberman AM, Hui J, Knudsen T, Makis SL, Morford L, Piersma AH, Stanislaus D, Thompson KE (2018) Rethinking developmental toxicity testing: evolution or revolution? *Birth Defects Research* (accepted).

FROM THE EXECUTIVE DIRECTOR

This month, I'd like to recognize the hard work and thoughtful deliberations of our HESI Board of Trustees. This public-private advisory body is responsible for the scientific, strategic, and fiscal oversight of our organization. At their in-person meeting in January 2018, they tackled a number of challenging governance and programmatic issues. Their decisions and insights will help further strengthen HESI's value to its stakeholders and its impact on improving environmental and human health.



Syril D. Pettit, MEM

HESI Executive Director

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