

Welcome to January *Insights*. Inside this edition: Genomics Committee submits new biomarker, Trustee receives award, and more!



## January Insights

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### HESI Trustee Receives Award

Dr. Sam Cohen, HESI Trustee, will receive the Society of Toxicology (SOT) Merit Award at the SOT Annual Meeting in March 2017. Dr. Cohen also received the Lifetime Achievement Award from the Society of Toxicologic Pathology in October 2015, the Ambassador Award from the Mid-Atlantic Society of Toxicology in October 2016, and the Distinguished Scientist Award from the American College of Toxicology in November 2016.

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### HESI Genomics Committee Submits Transcriptomic Biomarker via US FDA Biomarker Qualification Process

The HESI Genomics Committee recently submitted a qualification package to the US FDA to consider a transcriptomic biomarker for regulatory qualification. The committee developed an *in vitro* transcriptomic biomarker-based approach that provides mechanistic context to positive *in vitro* chromosome damage assays and proposes its application for assessing carcinogenic risk. The transcriptomic biomarker distinguishes DNA damage-inducing (DDI) agents from non-DDI agents. This intensive effort by the committee to develop the biomarker approach and prepare the qualification package will enhance understanding and utilization of signature-based biomarkers for risk assessment. For additional information, please contact [Dr. Raegan O'Lone](#).

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### Call for Protocols

The HESI Developmental and Reproductive Toxicology (DART) Committee recently launched a project to address the lack of a single, agreed-upon SOP that allows for the evaluation of two male reproductive endpoints, anogenital distance and nipple retention endpoints, in male rats. If you evaluate these endpoints and are willing to share your protocol or have questions about this project, please contact [Dr. Connie Chen](#).

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### HESI as a Platform for Creating New Solutions, Building Confidence in Data for Decision Making

The first edition of the COMPARE allergen database  
(**COMPREHENSIVE PROTEIN ALLERGEN RESOURCE**)

is about to be unveiled and available to the public in late January 2017, at [www.comparedatabase.org](http://www.comparedatabase.org).

COMPARE is a comprehensive list of protein allergen sequences provided as a resource to multiple stakeholders to meet the needs for allergy risk assessment in order to support public safety. The project involves public-private partners from the HESI Protein and Allergenicity Technical Committee (PATC) and the [Joint Institute for Food Safety and Nutrition](#) (JIFSAN), established between the US FDA and the University of Maryland, who provides programmatic support.



In its first year of operation, the COMPARE scientific advisory team has validated its initial allergen identification process, identified new allergens selected through a bioinformatics screening of all proteins entered into NCBI between May 2015 and May 2016, and completed the independent review, provided by an external panel of public sector allergy experts.

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## Upcoming Events

### Registration Now Open: T-cell Biology and Application to Immunopharmacology and Immunotoxicology Course

The HESI Immunotoxicology Technical Committee (ITC) is launching this training course to be held in Gaithersburg, Maryland, on 18–19 April 2017. The course highlights the foundational science and application to drug development. For more information and to register, please visit [here](#) or contact [Dr. Stan Parish](#).

### Register Today for the Rethinking Developmental Toxicity: Evolution or Revolution Workshop



Registration is now open for this workshop, which will be held on 19–20 April 2017 in Washington, DC. This workshop is being organized by the HESI DART Committee and will consider new strategies to identify developmental hazard alternatives or improvements to the current Segment 2 design. These considerations could include the use of new technology to overcome some of the limitations in predicting human response with current animal models or a completely new radical approach to developmental toxicity hazard identification. They may range from having a critical paradigm to decide when nonclinical studies are needed to using biotechnology and computational models or hazard characterization. Working groups can consider either strategy or combinations of the two. For additional information, visit the workshop's [website](#) or contact [Dr. Connie Chen](#). (This event is eligible for the HESI Future Leaders Travel Award [FLT]. Read more about the award and complete the application [here](#) by 21 February 2017.)

### Registration Is Now Open! Workshop on Advances and Roadblocks for Use of Genomics Data in Cancer Risk Assessment for Drugs and Chemicals

This 2-day workshop will be held on 25–26 May 2017 in Montreal, Canada, and is organized by Health Canada, McGill University, and the HESI Application of Genomics to Mechanism-Based Risk Assessment

Committee. The workshop will feature multisector and international perspectives on current and potential applications of genomics in cancer risk assessment. Registration details, including lodging information, are available [here](#). Additional information, including the workshop flyer and draft program, are available on our workshop website [here](#). For more information, please contact [Dr. Raegan O'Lone](#).


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## Recent Publications

Smith A, Calley J, Mathur S, Qian HR, Wu H, Farmen M, Caiment F, Bushel PR, Li J, Fisher C, Kirby P, Koenig E, Hall DG, and Watson DE (2016) The rat microRNA body atlas; evaluation of the microRNA content of rat organs through deep sequencing and characterization of pancreas enriched miRNAs as biomarkers of pancreatic toxicity in the rat and dog. *BMC Genomics*. 17:694. doi: 10.1186/s12864-016-2956-z [Read more](#).

Thompson KL, Boitier E, Chen T, Couttet P, Ellinger-Ziegelbauer H, Goetschy M, Guillemain G, Kanki M, Kelsall J, Mariet C, de La Moureyre-Spire C, Mouritzen P, Nassirpour R, O'Lone R, Pine PS, Rosenzweig BA, Sharapova T, Smith A, Uchiyama H, Yan J, Yuen PS, and Wolfinger R (2016) Absolute measurement of cardiac injury-induced microRNAs in biofluids across multiple test sites. *Toxicological Sciences* 154(1):115–125. doi: 10.1093/toxsci/kfw143. [Read more](#).

## FROM THE CHAIR



The success of HESI is in large measure directly attributable to its staff and volunteers. The staff may be small in number, but they are individually and collectively enormously impactful in their contribution. HESI, however, could not function, let alone be successful, without the support of its members and the dedicated work of its volunteers who populate the Technical Committees, the Emerging Issues Committee, as well as the Board of Trustees (BoT) and its Governance Committees. The BoT meets face-to-face just twice a year and will assemble a few days from now (at the ILSI Annual Meeting) for the first of the 2017 meetings. It is always a pleasure to meet with this enthusiastic, talented, and committed group of people, who are willing to take time out from their busy schedules to provide strategic oversight and guidance to HESI. The nexus of talented staff and dedicated volunteers comes together in the extensive planning that is essential to ensure that our time together is as productive as possible, so we have been busy over the holiday period. As avid readers of *HESI Insights* will know from the December 2016 issue, the past year has seen many highlights. At the BoT in January 2017, staff and volunteers aim to bring creative focus to planning—such as implementation of the various thematic elements of the 2016–2020 strategic plan. No doubt you will read in this newsletter about new activities and outputs during the course of 2017. I wish you all a productive and fulfilling 2017.



Dr. Ernie Harpur, HESI Chair

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