



March Insights

CT-TRACS Workshops

The CT-TRACS committee successfully co-hosted the “**Safety Assessment of Cell Therapy Products: Current Advances and Challenges**” workshop with the Cell & Gene Therapy Catapult group on **14 February 2018** in London, England. Presenters spoke about 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. Video recordings of presentations will be available on the CT-TRACS webpage shortly.



Please save the date for two upcoming meetings at which members of the CT-TRACS committee will be active participants: [ISCT 2018 \(2–5 May 2018\)](#) and [IABS/CIRM Symposium and CT-TRACS satellite workshop \(5–6 June 2018\)](#).

2018 HESI Annual Meeting



The **2018 HESI Annual Meeting** will be held **12–13 June 2018** in Washington, DC. This year’s meeting will feature exciting new science on risk assessment and big data, and we will hear from the HESI THRIVE awardees. The draft agenda is now available on the website [here](#). Check the [meeting website](#) to learn more!

Cardiac Safety Meetings

Cardiac Safety Committee Meeting

The Cardiac Safety Committee will host a face-to-face meeting on **15–17 May 2018** at the Langham Hotel in Boston, Massachusetts.



Registration is required for this event and will be free to all committee members. Members should e-mail Alex Feitel (afeitel@hesiglobal.org) for more details. Please complete your registration online [here](#) by **1 May 2018**. The room block is also now open for reservations. Please click [this link](#) to reserve your room. The deadline to reserve your room is **Friday, 20 April 2018**. Additional meeting details will be posted on the [event page](#) when available.

CSRC CiPA Meeting

CSRC, HESI, and FDA will host a 2-day meeting titled “**The Future of the Assessment of Drug-Induced Arrhythmias and the Comprehensive *In Vitro* Proarrhythmia Assay (CiPA)**” on **21–22 May 2018** in Washington, DC. Discussion topics will include:

- New approaches to evaluating the propensity of drugs to cause arrhythmias
- Potential revisions to ICH E14 and ICH S7B regulatory guidances
- Evolving data, ramifications, and potential regulatory implications from the Comprehensive *In Vitro* Proarrhythmia Assay ([CiPA](#))
- The use of statistical methodologies in lieu of a positive control for QT studies
- Updates from the FDA QT Interdisciplinary Review Team

Registration information will be available on the [CSRC website](#) in the coming weeks.



Cardiac Safety Research Consortium

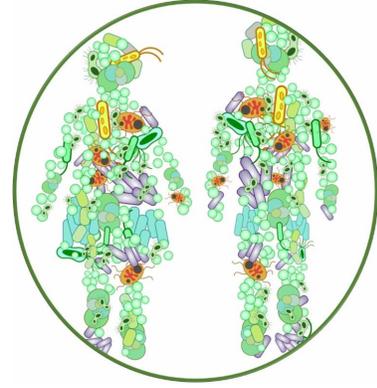


Save the Date: Gut Microbiome Workshop

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



Recent Publications

Chiang A, Guth B, Pugsley M, Foley M, Doyle J, Engwall M, Koerner J, Parish S, Sarazan RD (2018) The evaluation of endpoint variability and implications for study statistical power and sample size in conscious instrumented dogs. *Journal of Pharmacological and Toxicological Methods* (accepted).

From the President



HESI's New Future

During the January 2018 meeting of ILSI and HESI in Bermuda, the HESI Board of Trustees unanimously voted to conclude our charter agreement with ILSI as of the end of 2018. Prior to the January meeting, this move was carefully considered with thorough exploration of options and ramifications and included many teleconferences and meetings with HESI members, elected leaders, as well as ILSI staff and leadership. What does this really mean for HESI and its membership? In a nutshell: self-determination. Although HESI has been operating as a distinctly independent ILSI branch for decades, this move will greatly enhance HESI's ability to fully realize our own operating, financial, programmatic, and communications strategies and standards. What does not change? Collaboration. Collaboration is the center point in how HESI meets its vision of serving as a leading resource in protecting human and environmental health by generating purposeful and rigorous science. In addition to our work with a broad array of public and private partners, we look forward to continued collaboration with ILSI on regional projects of common interest and will continue to share space and services in the Washington, DC office. For most of you, this transition will have no evident impact on your engagement with HESI. We will continue to operate as we have, with HESI to convening, translating, and protecting well into its bright new future.

A handwritten signature in black ink, appearing to read 'TPastoor'.

Dr. Tim Pastoor
HESI President

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