

## GTA 2017 Annual Meeting Schedule: Wednesday, May 10th

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**Workshop:** *Mode of Action Approaches that Identify Genotoxic Mechanisms in Mammalian Cell Systems*

**Sponsored by:** *HESI GTTC*

**12:30 – 6:30 p.m.** Chairs: Jennifer Sasaki, Genentech & Maik Schuler, Pfizer Worldwide Research and Development

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### Abstract:

Standard genetic toxicology assays are intended for hazard identification only and provide very little mechanistic information. Without proper mode of action information, it is often very difficult to establish clear structure activity relationships and to design appropriate in vivo follow-up studies. This often leads to the discontinuation of valuable compounds that pose little to no risk to exposed humans. Recent developments in new assay platforms allow for the collection of mode of action information concurrently or as follow-up to the assays to positive responses in the standard genetic toxicology battery. However, most of these technologies have not been evaluated in the context of their use to establish a cellular genotoxic mode of action.

The first part of the workshop aims to discuss technologies like toxicogenomics, flow cytometric biomarker assays and other mechanistic platforms that could help to establish a genotoxic mode of action. For each of these technologies, the basic platforms will be described and specific examples of each application will be shown. In addition, technologies will be evaluated for favorable and unfavorable properties using a SWOT (**S**trengths, **W**eaknesses, **O**pportunities, **T**hreats) analysis.

The second part of the workshop is intended to establish key cellular and genetic events for defined molecular initiating events like tubulin poisons, alkylating agents and topoisomerase inhibitors. Similar to adverse outcome pathways (AOPs), the sequence of events will be summarized in a pathway map and possible ways to detect key cellular events will be proposed and discussed. The outcome of the workshop will be presented on the 2<sup>nd</sup> day of the GTA meeting.

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## **GTA 2017 Annual Meeting Schedule: Thursday, May 11th**

### ***Breakfast and Registration***

**7:30 – 8:30 a.m.**

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### ***Welcome and Introduction***

**8:30 – 8:40 a.m.** Kyle Glover, Defense Threat Reduction Agency, GTA Chair

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### ***Keynote Speaker***

**Sponsored by:** ***Pfizer Worldwide Research and Development***

**8:40 – 9:40 a.m.** **Precision Medicine: Lung Biomarkers**  
Curtis Harris, National Cancer Institute; Editor-in-Chief for Carcinogenesis

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**Symposium I:** ***Future of Genetic Toxicology: Impact of Extrinsic vs Intrinsic Risk Factors on Mutation and Carcinogenicity***

**Sponsored by:** ***Society of Toxicology***

**9:40 – 10:40 a.m.** Chairs: Rosalie Elespuru, US FDA and Miriam Poirier NIH/NCI

**9:40 – 10:10 a.m.** **Stem Cell Divisions, Somatic Mutations, and Cancer Etiology**  
Cristian Tomasetti, Johns Hopkins University

**10:10 – 10:40 a.m.** **Evaluating Intrinsic and Extrinsic Cancer Risk**  
Song Wu, Stony Brook University

**10:40 – 11:10 a.m.** **Coffee Break**

**Sponsored by:** ***Environmental Mutagenesis and Genomics Society***

**11:10 – 11:20 a.m.** **Introduction to Panel Discussion**  
Rosalie Elespuru, US FDA and Miriam Poirier NIH/NCI

**11:20 - 11:50 a.m.** **Panel Discussion**  
Leaders: Rosalie Elespuru and Miriam Poirier  
Discussants: Curt Harris, Cristian Tomasetti, Song Wu

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### ***GTA 2017 Business Meeting***

**11:50 – 12:10 p.m.**

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**12:10 – 1:10 p.m. *Networking Lunch***

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***Symposium II: Case Studies/Key Problems in Genetic Toxicology***  
***Sponsored by: BioReliance***

**1:10 – 2:20 p.m.** Chairs: Jennifer Sasaki, Genentech and Megan Fuller, Eli Lilly

**1:10 – 1:25 p.m. *De-risking an MLA Positive Test Result for a Pharmaceutical Agent***  
Aparajita Dutta, BioReliance

**1:25 – 1:40 p.m. *Trend or No Trend, That is the Question***  
Abby Myhre and Stephanie Kellum  
DuPont Haskell Global Centers for Health and Environmental Sciences

**1:40 – 2:00 p.m. *Worker Safety Limbo: How Low Should I Go?***  
Zhanna Sobol, Pfizer Worldwide Research and Development

**2:00 – 2:20 p.m. *Mechanistic Biomarkers Using Imaging Technologies Improve the Risk Assessment of Drug Development Candidates***  
Elizabeth Rubitski, Pfizer Worldwide Research and Development

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**2:20 – 2:50 p.m. *Coffee Break***  
***Sponsored by: DuPont***

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***Symposium III: Understanding Comets, without Using a Telescope***  
***Sponsored by: Bristol-Myers Squibb***

**2:50 – 3:50 p.m.** Chair: Dan Roberts, iuvo BioScience

**2:50 – 3:20 p.m. *Elucidating Mechanisms of DNA Damage and Repair with the Comet Assay***  
Andrew Richard Collins, Oslo University (Retired)

**3:20 – 3:50 p.m. *HESI Genetic Toxicology Committee evaluation of Compounds Tested in Both Comet and Transgenic Rodent Mutation Assays***  
Dan Levy, HESI Genetic Toxicology Technical Committee (GTTC)

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***Speed Session of Poster Presentations***

**3:50 – 4:30 p.m.** Chairs: Maria Engel and Randy Spellman, Pfizer Worldwide Research and Development

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**Poster Session and Cocktails**

**Sponsored by: BioReliance**

**5:00 – 7:00 p.m.** *Presenters will be at their posters as follows:  
Odd numbers from 5:00 to 6:00 p.m.  
Even numbers from 6:00 to 7:00 p.m.*

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**7:00 – 8:30 p.m.** *Dinner (included in the 2-day registration fee)*

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## GTA 2017 Annual Meeting Schedule: Friday, May 12th

### *Breakfast and Registration*

7:00 – 8:15 a.m.

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**Workshop:** *Novel Application of CometChip: DNA Damage Analysis of Cellular Subtypes*

**Sponsored by:** *Trevigen, Inc.*

7:15 – 8:15 a.m. Dr. Jay George, Trevigen Inc.

The presentation will demonstrate how the CometChip is used to isolate cellular subtypes from complex mixtures of cells before DNA damage analysis.

Grab your breakfast and take it next door to Room C120 for the workshop (beverage service will be provided there).

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### *Welcome to Day 2*

8:15 – 8:30 a.m. Michelle Kenyon, Pfizer Worldwide R&D, GTA Chair-Elect

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**Symposium IV:** *Future Approaches in Applied Genetic Toxicology*

**Sponsored by:** *Charles River Laboratories*

8:30 – 10:00 a.m. Chairs: Kyle Glover, Defense Threat Reduction Agency and Krista Dobo, Pfizer Worldwide Research and Development

8:30 – 8:55 a.m. **A Mechanism Based Testing Strategy to Identify Non-genotoxic Carcinogens**

Mirjam Luijten, RIVM

8:55 – 9:10 a.m. **MoA Workshop Read-out**

Maik Schuler, Pfizer Worldwide Research and Development

9:10 – 9:35 a.m. **Interpretation of Genetic Toxicity Benchmark Dose (BMD) Values – Comparisons Across Covariates, Determination of Endpoint-Specific BMRs (Benchmark Response), and Estimation of Human Exposure Levels**

Paul White, Health Canada

9:35 – 10:00 a.m. **Advances in Assessing Genetic Hazards in Germ Cells**

Francesco Marchetti, Health Canada

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**10:00 – 10:30 a.m. *Coffee Break***  
***Sponsored by: ILSI-HESI Genetic Toxicology Technical Committee***

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**10:30 – 11:15 a.m. *Award Presentations***

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***Symposium V: Case Studies/Key Problems in Genetic Toxicology II***  
***Sponsored by: Pfizer Worldwide Research and Development***

**11:15 – 12:15 p.m.** Chairs: Marilyn Aardema, Marilyn Aardema Consulting LLC and Michelle Kenyon, Pfizer Worldwide Research and Development

11:15 – 11:35 a.m. **Use of Expert Knowledge in Review of (Q)SAR Mutagenicity Predictions for Impurities: Case Examples from Industry**  
Michelle Kenyon, Pfizer

11:35 – 11:55 a.m. **(Q)SAR Evaluation of Potentially Mutagenic Impurities: Regulatory Experience with Out of Domain Results**  
Mark Powley, US Food and Drug Administration/CDER/OND

11:55 – 12:15 p.m. **Safety Assessment of Potentially Genotoxic Impurities: Case Study from Regulatory Perspective**  
Andrew Goodwin, US Food and Drug Administration

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**12:15 – 1:15 p.m. Lunch**

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***Symposium VI: Application of New Cell Culture Systems: The Role for 3D Organ Models in Genetic Toxicology***  
***Sponsored by: Society of Toxicology***

**1:15 - 2:45 p.m.** Chairs: Jeff Bemis, Litron Laboratories and Abby Myhre, DuPont

1:15 - 1:45 p.m. **Role and Status of 3D Tissue Models in Genetic Toxicology: Skin and Beyond**  
Stefan Pfuhler, Procter and Gamble

1:45 - 2:15 p.m. **Application of New Cell Culture Systems: The Role of 3D Organ Models in Genetic Toxicology**  
Steven Ferguson, NIH/NIEHS

2:15 - 2:45 p.m. **MIMETAS' Organ-on-a-Chip Platform for Predictive Toxicology**  
Anthony Saleh, Mimetas

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2:45 – 3:00 p.m.

***Concluding Remarks***

Michelle Kenyon, *Pfizer Worldwide Research and Development*