



The Annual Meeting of the GTA

April 10-12, 2024

John M. Clayton Hall Conference Center
University of Delaware, Newark, DE

GTA 2024 Annual Meeting Schedule: Wednesday, April 10

12:30 – 5:30 PM

Conference Registration

1:00 – 3:00 PM

Workshop 1

The Future of Genotoxicity Assessment: Interplay between NAMs, Data Visualization, and High Dimensional Analysis

1:00 – 1:05 PM

Welcome and Overview of Workshop

Co-chairs: *Alexandra Long (Health Canada) & Steve Bryce (Litron Laboratories)*

1:05 – 1:30 PM

Visualization strategies to aid interpretation of high-dimensional genotoxicity data
Erica Briggs (Litron Laboratories)

1:30 – 1:55 PM

An investigation on the mutagenicity of compounds using Benchmark Dose and Dose-Response data for research in genetic toxicology
Yusuf Hussien (Swansea University)

1:55 – 2:20 PM

Exploring high-dimensional data visualization and reduction methods with genotoxicity data in R
Andrew Williams (Health Canada)

2:20 – 2:45 PM

High throughput in vitro-in vivo extrapolation of genetic toxicity data
Marc Beal (Health Canada)

2:45 – 3:00 PM

Panel Discussion Q&A

3:00 – 3:30 PM

Coffee Break

3:30 – 5:30 PM

Workshop 2

Experimental Design Considerations, and Appropriate Use of Historical Negative Controls

3:30 – 3:35 PM

Welcome and Overview of Workshop

Co-chairs: *Dan Roberts (Toxys Inc.) & Carol Beevers (Corteva Agriscience)*

3:35 – 4:20 PM

Experimental design and analysis considerations
David Lovell (Emeritus Reader in Medical Statistics, University of London)

4:20 – 4:45 PM

Historical control database analysis and modeling
Stephen Dertinger (Litron Laboratories)

4:45 – 5:10 PM

Applying IWGT Guidance to In Vitro and NAM Data
Dan Roberts (Toxys, Inc.)

5:10 – 5:30 PM

Panel Discussion

GTA 2024 Annual Meeting Schedule: Thursday, April 11

7:30 – 8:30 AM	Breakfast and Registration
8:30 – 8:40 AM	Welcome and Introduction Penny Leavitt (<i>Bristol Myers Squibb</i>) 2023-2024 GTA Chair
8:40 – 9:40 AM	KEYNOTE ADDRESS
8:40 – 8:45 AM	Introduction Wen Sun (<i>Pfizer</i>), 2023-2024 GTA Chair Elect
8:45 – 9:40 AM	Microengineered models of human physiological systems for a variety of biomedical applications Dr. Dan Huh, <i>Department of Bioengineering, University of Pennsylvania</i>
9:40 – 10:10 AM	Coffee Break
10:10 – 11:45 AM	Symposium I Genetic Toxicity of Genome Editing
10:10 – 10:15 AM	Introduction Co-chairs: Steven Nicotra (<i>Johnson & Johnson</i>), Parimal Pande (<i>Johnson & Johnson</i>)
10:15 – 10:45 AM	Allogeneic cell therapy: manufacturing and genomic safety considerations Parimal Pande (<i>Johnson & Johnson</i>)
10:45 – 11:15 AM	Comparative analysis of off-target analysis methods Samantha Maragh (<i>NIST</i>)
11:15 – 11:45 AM	Applications of off-target analysis tools in development of allogeneic cell therapy Jennifer Dashnau (<i>Century Therapeutics</i>)
11:45 – 1:00 PM	Networking Lunch
1:00 – 3:00 PM	Symposium II Nitrosamines: Risk Assessment, Regulatory Challenges, and Case Studies
1:00 – 1:05 PM	Introduction Co-chairs: Tetyana Cheairs (<i>NYMC</i>), Krista Dobo (<i>Pfizer</i>), Penny Leavitt (<i>BMS</i>)
1:05 – 1:25 PM	Experimental testing of N-nitrosamines in the MUTAMIND project Kevin Cross (<i>Instem</i>)
1:25 – 1:45 PM	Updates from the HESI Nitrosamine MGRA Project Joel Bercu (<i>Gilead</i>)
1:45 – 2:05 PM	Applicability of ICH M7 approach for Less-than-Lifetime Assessments for Nitrosamines: Key Learnings from a HESI Working Group Susan Felter (<i>P&G</i>)

2:05 – 2:30 PM Setting Limits for NDSRIs
Raphael Nudelman (TEVA)

2:30 – 3:00 PM Panel Discussion Q&A

3:00 – 3:30 PM

Coffee Break

3:30 – 5:00 PM

Symposium III
Advancing the Genotoxicity Testing of Pharmaceutical Impurities

3:30 – 3:35 PM Introduction
Co-chairs: *Joel Bercu (Gilead), Alisa Vespa (Health Canada)*

3:35 – 3:50 PM Evaluation of common solvents in the in vitro micronucleus assay
Jessica Noteboom (Eli Lilly)

3:50 – 4:05 PM Use of the In Vivo Comet Assay as a Follow-up for Genotoxic Impurities
Maik Schuler (Pfizer)

4:05 – 4:20 PM All systems go: Replacing the transgenic rodent mutation assay with Duplex Sequencing
Carole Yauk (University of Ottawa)

4:20 – 4:35 PM Case Studies of Genotoxicity Qualification of Impurities
Alyssa Musso (Pfizer)

4:35 – 5:00 PM Panel Discussion Q&A

5:00 – 5:30 PM

Poster Presentation

5:00 – 5:05 PM Introduction
Co-chairs: *Elizabeth Rubitski (Pfizer) and James Kath (AbbVie)*

5:05 – 5:30 PM Speed Talks

5:30 – 7:30 PM

Poster Session and Cocktails

7:30 – 9:00 PM

Dinner (included in the 2-day registration fee)

GTA 2024 Annual Meeting Schedule: Friday, April 12

7:30 – 8:30 AM Breakfast and Registration

8:30 – 8:45 AM **Welcome to Day 3**
Wen Sun (Pfizer)
2023-2024 GTA Chair-Elect

8:45 – 10:30 AM

Symposium IV
Next-level NAMs: Exploring the Transition of In Vitro Genetic Toxicology to More Complex Models

8:45 – 8:55 AM	Introduction Co-chairs: <i>Wen Sun (Pfizer), Carole Yauk (Univeristy of Ottawa)</i>
8:55 – 9:15 AM	Application of 3D HepaRG spheroids in genotoxicity testing <i>Xiaoqing Guo (NCTR, US FDA)</i>
9:15 – 9:35 AM	Micronucleus and error-corrected sequencing in HepaRG <i>Les Recio (Scitovation)</i>
9:35 – 9:55 AM	Transcriptomic biomarkers in HepaRG and liver spheroid models <i>Alexandra Long (Health Canada)</i>
9:55 – 10:15 AM	Bone marrow models and more: developing predictive advanced cell-based systems for in vivo genotoxicity. <i>Jo Elloway (Astrazeneca)</i>
10:15 – 10:30 AM	Panel Discussion Q&A

10:30 – 11:00 AM

Coffee Break

11:00 – 12:30 PM

Business Meeting, Awards Ceremony and Presentation

12:30 – 1:30 PM

Networking Lunch

1:30 – 3:30 PM

Symposium V
Genetox Across Sectors - Testing Strategies, Unique Perspectives and Regulatory Challenges

1:30 – 1:35 PM	Introduction Co-chairs: <i>Ashley Allemang (P&G) & Abby Myhre (Corteva Agriscience)</i>
1:35 – 2:00 PM	Pharmaceutical Sector <i>Laura Custer (Bristol Myers Squibb)</i>

2:00 – 2:25 PM	Cosmetic Sector <i>Stefan Pfuhler (Procter & Gamble)</i>
2:25 – 2:50 PM	Industrial Chemical Sector <i>Matthew LeBaron (Dow Chemicals)</i>
2:50 – 3:15 PM	Agrochemical Sector <i>Abby Myhre (Corteva Agriscience)</i>
3:15 – 3:30 PM	Panel Discussion Q&A

3:30 – 3:45 PM **Concluding Remarks**
Wen Sun (Pfizer)
2023-2024 GTA Chair-Elect
