

Program Overview

Day 1 – Wednesday May 7 th	
12:00 – 1:30 PM	Conference Registration
Workshop 1 - Next Generation Genotoxicity Risk Assessments: AOPs as the foundation of NAM-based risk assessments for genotoxicity Co-chairs: Giel Hendriks (Toxys) & Susanne Stalford (Lhasa)	
1:30 – 1:40 PM	Workshop introduction
1:40 – 1:55 PM	Building weight of evidence to support indirect clastogenic effects within an AOP framework Dan Roberts (Toxys)
1:55 – 2:10 PM	Assessing genotoxicity in multiple cell culture models for quantitative Adverse Outcome Pathway (qAOP) development Caitlin Maggs (University of Swansea)
2:10 – 2:25 PM	Impact of ToxTracker Assay Inclusion in a Genotoxicity Adverse Outcome Pathway Weight of Evidence Assessment Tasha Jones (Lhasa)
2:25 – 2:40 PM	Human hepatic HepaRG cells - a new workhorse in your genetox NAM toolbox? Ashley Allemang (Procter & Gamble)
2:40 – 2:55 PM	What's in the wiki (or coming soon)? International, multi-sector efforts to build genotoxicity Adverse Outcome Pathway networks Carole Yauk (University of Ottawa)
2:55 – 3:30 PM	Moderated panel discussion, Q&A and closing statements
3:30 – 4:00 PM	Coffee Break
Workshop 2 - The Last Mile: Opportunities to Bridge Research and Increase Impact in Human and Environmental Health Science. What is the Last Mile and Why Should You Care? Co-chairs: Connie L. Chen & Raechel Puglisi (HESI)	
4:00 – 4:20 PM	Defining the Last Mile: The Bridge Between Research and Impact Raechel Puglisi (HESI)
4:20 – 4:40 PM	Advancing Genetic Toxicology: The Role of AOPs and/or in vitro NAMs in HESI GTTC Wen Sun (Pfizer)
4:40 – 5:00 PM	HESI eSTAR OASIS: Leveraging 'Omics Data for Next Gen Safety Assessment Srijit Seal (Merck)
5:00 – 5:20 PM	HESI Botanical Safety Consortium: Towards a Global Genotoxicity Testing Strategy for Botanicals Stefan Pfuhler (Procter & Gamble)

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John M. Clayton Hall Conference Center

University of Delaware, Newark, DE

May 7-9th, 2025

5:20 – 5:40 PM	From Discovery, to Validation and Implementation: The Journey of the TGx-DDI Biomarker Carole Yauk (University of Ottawa)
5:40 – 6:00 PM	Moderated panel discussion

Day 2 – Thursday, May 8th

7:30 – 8:30 AM	Conference Registration
7:30 – 8:30 AM	Breakfast
8:30 – 8:35 AM	Welcome Wen Sun (Pfizer), GTA Chair
8:35 – 9:35 AM	Keynote - Dr Silvia Balbo Professor, Division of Environmental Health Sciences at the University of Minnesota
9:35 – 10:00 AM	Coffee Break

Symposium I - Regulatory Acceptance of New Approach Methodologies (NAMs)

Co-Chairs: James Kath (AbbVie) & Stephanie Smith-Roe (NIH/NIEHS)

10:00 – 10:25 AM	Innovating the human health assessment portfolio using transcriptomics at the EPA's Office of Research and Development Alison Harrill (EPA)
10:25 – 10:50 AM	New Approach Methodologies Used in the Safety Assessment of Food Contact Substances. Laura C. Markley (HFP/FDA)
10:50 – 11:15 AM	Development of an OECD test guideline for the ToxTracker assay Giel Hendriks (Toxys)
11:15 – 11:30 AM	Panel Q&A
11:30 – 12:30 PM	Excellence in Science & Service Awards Sheroy Minocherhomji (Lilly) & Penny Leavitt (BMS)
12:30 – 1:45 PM	Lunch

Symposium II - Current State-of-the-art for Genotoxicity and Carcinogenicity Strategies for Novel Modalities

Co-Chairs: Yi Yang (AbbVie) & Sheroy Minocherhomji (Lilly)

1:45 – 2:05 PM	Peptides Yi Yang (AbbVie)
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The Genetic Toxicology Association (GTA) is a tax-exempt 501c3 educational and scientific organization that was founded in 1975 and incorporated in 1981 under the laws of the state of Delaware. Its primary purpose is to promote the development of the science of genetic toxicology and to foster the exchange and dissemination of information concerning the field.

Find up-to-date information on the GTA at <https://gta-us.org/>

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2:05 – 2:25 PM	Genetox Approaches for Oligonucleotide Therapeutics (ONT): Results of an Industry Survey Natalie Holman (Lilly)
2:25 – 2:45 PM	Cell and Gene Therapies Silvana Libertini (Novartis)
2:45 – 3:05 PM	CRISPR gene editing therapies Jonathan Phillips (Intellia)
3:05 – 3:15 PM	Panel Q&A
3:15 – 3:45 PM	Coffee Break
Symposium III - ecNGS techniques and their applicability to genotoxicity and carcinogenicity testing Co-Chairs: Carole Yauk (University of Ottawa) and Alper James Alcaez (University of Ottawa)	
3:45 – 4:10 PM	Closing the gap: IWGT recommendations on the adoption of ecNGS for regulatory mutagenicity testing Francesco Marchetti (Health Canada) and Anthony Lynch (GSK). <i>Anthony Lynch speaking</i>
4:10 – 4:35 PM	MADD-seq: Co-detection of DNA damage and mutations Marc Vermulst (University of Southern California)
4:35 – 4:55 PM	What happens to mutation frequency over prolonged exposure: mutagenesis after 28, 90 and 180 day exposures to benzo[b]fluoranthene David Schuster (University of Ottawa, Health Canada)
4:55 – 5:20 PM	Toward more predictive and human relevant carcinogenicity testing: Establishing study design and approach for detecting cancer driver gene mutations using Duplex Sequencing Alper James Alcaez (University of Ottawa on behalf of HESI committee)
5:10 – 5:30 PM	Panel Discussion: Given the improvement of ecNGS over the transgenic rodent mutation assay, and its demonstrated superior performance, what challenges do you anticipate encountering in OECD endorsement process (for integration with other 28-day tests)? What are the best approaches to overcome these challenges? Moderated by Carole Yauk
5:30 – 7:30 PM	Poster Session & Cocktails 5:30 – 6:30 PM Odd numbered posters attended 6:30 – 7:30 PM Even numbered posters attended
7:30 – 9:00 PM	Banquet Dinner (Included in 2-day registration)

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Day 3 – Friday, May 9th

7:30 – 8:30 AM	Conference Registration
7:30 – 8:30 AM	Breakfast
8:30 – 8:35 AM	Welcome Ashley Allemang (Procter & Gamble), GTA Chair-elect
Symposium IV - Metabolism as a Potentiator of Genetox Risk Assessment Co-Chairs: Stefan Pfuhler (Procter & Gamble) & Tetyana Chairs (NYMC)	
8:35 – 9:05 AM	The Role of Metabolism in Evaluating Fragrance Genotoxicity Yax Thakkar (RIFM)
9:05 – 9:35 AM	Modification of the co-factor mix for S9 treatments to improve genotoxicity predictions Stefan Pfuhler (Procter & Gamble)
9:35 – 10:05 AM	Tentative: Impact of metabolism on the genotoxicity potential of nitrosamines Speaker To be confirmed
10:05 – 10:35 AM	Coffee Break
Symposium V - Best Practices for Genetox Testing of Excipients, Impurities Co-Chairs: Laura Markley (FDA) & Penny Leavitt (BMS)	
10:35 – 11:05 AM	Regulatory Framework and Case Studies for Evaluating Genotoxic Potential of Impurities in Food Contact Substances Leighna Holt (Human Foods Program, US FDA)
11:05 – 11:35 AM	Special considerations for genotoxicity testing of particles David Kirkland (Kirkland Consulting)
11:35 – 11:50 AM	Genotoxicity testing of impurities in adjuvants Sandy Weiner (Johnson & Johnson)
11:50 – 12:05 PM	Considerations and Case study for genotoxicity testing of medical devices Steven Nicotra (Johnson & Johnson)
12:05 – 1:15 PM	Lunch
1:15 – 1:25 PM	Business meeting
1:25 – 2:00 PM	Student and Early- Stage Investigator Awards

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Symposium VI - Nitrosamines - Current Updates, Regulatory Experience

Co-Chairs: Kevin Cross (Instem) & Leon Stankowski (CRL)

2:00 – 2:20 PM	TBD
2:20 – 2:40 PM	The Enhanced Ames Test – One CRO's Perspectives and Experiences Leon Stankowski (CRL)
2:40 – 3:00 PM	In Vivo Mutation Frequency of NNK as determined in the Big Blue Rat and using error-corrected Next Generation Sequencing (ecNGS) Jessica Noteboom (Eli Lilly)
3:00 – 3:20 PM	(Q)SAR of nitrosamines and the CPCA. Where do we go from here? Kevin Cross (Instem)
3:20 – 3:30 PM	Panel Q&A
3:30 – 3:40 PM	Closing remarks