2025 Annual Meeting of the Genetic Toxicology Association

John M. Clayton Hall Conference Center
University of Delaware, Newark, DE
May 7-9th, 2025

Program Overview

Day 1 – Wednesday May 7th	
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 PhD (Toxys) & Susanne Stalford PhD (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 MS (Toxys)
1:55 – 2:10 PM	**Assessing genotoxicity in multiple cell culture models for quantitative Adverse Outcome Pathway (qAOP) development** Caitlin Maggs MSc (University of Swansea)
2:10 – 2:25 PM	**Contextualising Data from New Approach Methods Using Adverse Outcome Pathways: A Recipe for Better Genotoxicity Decision Making** Tasha Jones BSc (Lhasa)
2:25 – 2:40 PM	**Human hepatic HepaRG cells - a new workhorse in your genetox NAM toolbox?** Ashley Allemang MS (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 PhD (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 PhD, MPH (HESI) & Raechel Puglisi MPH (HESI)	
4:00 – 4:20 PM	**Defining the Last Mile: The Bridge Between Research and Impact** Raechel Puglisi MPH (HESI)
4:20 – 4:40 PM	**Advancing Genetic Toxicology: The Role of AOPs and/or in vitro NAMs in HESI GTTC** Wen Sun PhD (Pfizer)
4:40 – 5:00 PM	**HESI eSTAR OASIS: Leveraging 'Omics Data for Next Gen Safety Assessment** Srijit Seal PhD (Merck)
5:00 – 5:20 PM	**HESI Botanical Safety Consortium: Towards a Global Genotoxicity Testing Strategy for Botanicals** Stefan Pfuhler PhD (Procter & Gamble)

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5:20 – 5:40 PM	**From Discovery to Validation and Implementation: The Journey of the TGx-DDI Biomarker** Carole Yauk PhD (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 PhD (Pfizer), GTA Chair
8:35 – 9:35 AM	**Keynote - Integrating -omics approaches to improve genotoxicity analysis** **Silvia Balbo PhD** 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 PhD (AbbVie) & Stephanie Smith-Roe PhD (NIH/NIEHS)	
10:00 – 10:25 AM	**Roadmap to Regulatory Acceptance: Challenges and Solutions Facilitating Use of Non-Animal Approaches in the Global Arena** Hans Raabe MS (Institute for In Vitro Sciences)
10:25 – 10:50 AM	**New Approach Methodologies Used in the Safety Assessment of Food Contact Substances** Laura C. Markley PhD (Human Foods Program, US FDA)
10:50 – 11:15 AM	**Validation and Implementation of the ToxTracker Assay for Mechanistic Genotoxicity Assessment** Giel Hendriks PhD (Toxys)
11:15 – 11:30 AM	**Panel Q&A**
11:30 – 12:30 PM	**Excellence in Science & Service Awards** Sheroy Minocherhomji PhD, ERT, FRSB (Lilly) & Penny Leavitt MS, DABT (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 PhD, DABT (AbbVie) & Sheroy Minocherhomji PhD, ERT, FRSB (Lilly)	
1:45 – 2:05 PM	**Genetox Approaches for Therapeutic Peptides: Results of an Industry Survey** Yi Yang PhD, DABT (AbbVie)

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2:05 – 2:25 PM	**A Move Towards Tailored Genetic Toxicity Approaches for Oligonucleotide Therapeutics: Results of an Industry Survey** Natalie Holman PhD, DABT (Lilly)
2:25 – 2:45 PM	**Genotoxicity Evaluation of Gene Therapy Products** Silvana Libertini PhD (Novartis)
2:45 – 3:05 PM	**Mapping CRISPR within the atlas of genotoxic risk** Jonathan Phillips PhD (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 PhD (University of Ottawa) and Patricia Escobar PhD (Merck & Co., Inc.)

3:45 – 4:10 PM	**Closing the gap: IWGT recommendations on the adoption of ecNGS for regulatory mutagenicity testing** Stephanie L. Smith-Roe (NIEHS)
4:10 – 4:35 PM	**Characterization of Mutational Load Using Single-molecule Mutation (SMM) Sequencing Assay** Alex Maslov PhD (Mutagentech)
4:35 – 4:55 PM	**Duplex Sequencing after Prolonged Benzo[b]fluoranthene Exposure Reveals Tissue-Specific Differences in Mutagenic Response, Chemical Potency, and Clonal Expansion of Mutations.** David Schuster MS (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** Patricia Escobar (Merck Co & Inc.) and Alper James Alcarez (University of Ottawa) *Patricia Escobar speaking*
5:20 – 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 PhD
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 MS (Procter & Gamble), GTA Chair-elect
Symposium IV - Metabolism as a Potentiator of Genetox Risk Assessment Co-Chairs: Stefan Pfuhler PhD (Procter & Gamble) & Tetyana Cheairs MD., MSPH. (NYMC)	
8:35 – 9:05 AM	**The Role of Metabolism in Evaluating Fragrance Genotoxicity** Yax Thakkar PhD (RIFM)
9:05 – 9:35 AM	**Modification of the co-factor mix for S9 treatments to improve genotoxicity predictions** Stefan Pfuhler PhD (Procter & Gamble)
9:35 – 10:05 AM	**Optimizing the in vitro metabolization protocol for the genotoxicity assessment of N-Nitrosamines in mammalian cell assays** Inger Brandsma PhD (Toxys)
10:05 – 10:35 AM	**Coffee Break**
Symposium V - Best Practices for Genetox Testing of Excipients, Impurities Co-Chairs: Laura Markley PhD (Human Foods Program, US FDA), John Nicolette (Johnson & Johnson) & Penny Leavitt MS, DABT (BMS)	
10:35 – 11:05 AM	**Regulatory Framework and Case Studies for Evaluating Genotoxic Potential of Impurities in Food Contact Substances** Leighna Holt BS (Human Foods Program, US FDA)
11:05 – 11:35 AM	**Special considerations for genotoxicity testing of particles** David Kirkland BSc, PhD (Kirkland Consulting)
11:35 – 11:50 AM	**Novel Excipients and Genetic Tox Qualification** Sandy Weiner MS (Johnson & Johnson)
11:50 – 12:05 PM	**Considerations and Case study for genotoxicity testing of medical devices** Steven Nicotra BS, MBA (Johnson & Johnson)
12:05 – 1:05 PM	**Lunch**
1:05 – 1:15 PM	**Business meeting**
1:15 – 1:40 PM	**Student and Early- Stage Investigator Awards**

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Symposium VI - Nitrosamines - Current Updates, Regulatory Experience Co-Chairs: Kevin Cross PhD (Instem) & Leon Stankowski Jr. PhD (CRL)	
1:40 – 2:00 PM	**Current Regulatory Considerations on the Safety Assessment of Nitrosamine Impurities** Tim McGovern, PhD (White Oak Regulatory Tox, LLC)
2:00 – 2:20 PM	**Comparative Potency of N-Nitrosomorpholine and N-Nitroso Reboxetine** Shaofei Zhang PhD (Pfizer)
2:20 – 2:40 PM	**The Enhanced Ames Test – One CRO's Perspectives and Experiences** Leon Stankowski Jr. PhD (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 BS (Eli Lilly)
3:00 – 3:20 PM	**(Q)SAR of nitrosamines and the CPCA. Where do we go from here?** Kevin Cross PhD (Instem)
3:20 – 3:30 PM	**Panel Q&A**
3:30 – 3:40 PM	**Closing remarks**