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 (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 (P&G)
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** Caitlin Maggs (University of Swansea)
5:00 – 5:20 PM	**HESI Botanical Safety Consortium: Towards a Global Genotoxicity Testing Strategy for Botanicals** Stefan Pfuhler (P&G)

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/

2025 Annual Meeting of the Genetic Toxicology Association

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** Dan Roberts (Toxys)
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)

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/

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 Barbara Parsons (US FDA/NCTR)

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)
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 Alcarez (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)

2025 Annual Meeting of the Genetic Toxicology Association

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

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 (P&G), GTA Chair-elect
Symposium IV - Metabolism as a Potentiator of Genetox Risk Assessment Co-Chairs: Stefan Pfuhler (P&G) & 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 (P&G)
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	**Special considerations for genotoxicity testing of particles** David Kirkland (Kirkland Consulting)
11:05 – 11:35 AM	**Regulatory Framework and Case Studies for Evaluating Genotoxic Potential of Impurities in Food Contact Substances** Leighna Holt (Human Foods Program, US FDA)
11:35 – 11:50 AM	**Considerations and Case study for genotoxicity testing of medical devices** Steven Nicotra (Johnson & Johnson)
11:50 – 12:05 PM	**Genotoxicity testing of impurities in adjuvants** Sandy Weiner (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**

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/

Symposium VI - Nitrosamines - Current Updates, Regulatory Experience Co-Chairs: Kevin Cross (Instem) & Leon Stankowski (CRL)	
2:00 – 2:20 PM	**FDA Review of N-Nitrosamine Drug Submissions** Tim McGovern (FDA)
2:20 – 2:40 PM	**Positive Controls for Nitrosamines** Leon Stankowski (CRL)
2:40 – 3:00 PM	**HESI QM analysis of Nitrosamines** Bob Jolly (Eli Lilly)
3:00 – 3:20 PM	**Measuring Nitrosamines levels (ecNGS)** Kevin Cross (Instem)
3:20 – 3:30 PM	**Panel Q&A**
3:30 – 3:40 PM	**Closing remarks**