

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

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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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 8 th		
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	TBD	
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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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	Mapping CRISPR within the atlas of genotoxic risk 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 Alcarez (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). Anthony Lynch speaking	
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)	



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	Day 3 – Friday, May 9 th
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
Sym	posium 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	Optimizing the in vitro metabolization protocol for the genotoxicity assessment of N-Nitrosamines in mammalian cell assays Inger Brandsma (Toxys)
10:05 – 10:35 AM	Coffee Break
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Sym	Dosium V - Best Practices for Genetox Testing of Excipients, Impurities Co-Chairs: Laura Markley (FDA) & Penny Leavitt (BMS)
Sym1 0:35 – 11:05 AM	
	Co-Chairs: Laura Markley (FDA) & Penny Leavitt (BMS) Regulatory Framework and Case Studies for Evaluating Genotoxic Potential of Impurities in Food Contact Substances
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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	