

# 2023 Annual Meeting of the GTA

May 3-5, 2023

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

## 2023 GTA Meeting Registration

<https://gta-us.org/annualmeeting/>

Refreshments and meals included in registration. Come Join Us!

### Key Dates

- **Early Bird Registration: Expires April 3<sup>rd</sup>, 2023**
- **Poster Abstract Submissions: Deadline: March 20<sup>th</sup>, 2023**
  - Up to 6 poster awards (\$1,000 each)
  - 1 EMGS travel award (\$500)

### Keynote Address

**Prof. Carol Yauk, PhD**  
*University of Ottawa, Ottawa, Canada*

### Scientific Program

#### Workshop 1

*Navigating the Genetic Toxicology Testing Battery – Strategies & Case Studies*

#### Workshop 2

*Genetic Toxicology & Carcinogenicity Testing – Regulatory Updates*

#### Symposium I

*New Technologies for Genetic Toxicology Testing*

#### Symposium II

*Artificial Intelligence, Machine Learning and Modeling Advances in Genetic Toxicology Testing*

#### Symposium III

*Genetic Mechanisms in Metals Carcinogenesis*

#### Symposium IV

*Titanium Dioxide Risk Assessment and Updates*

#### Symposium V

*Nitrosamine Risk Assessment, Part 1 – In silico and In vitro Approaches*

#### Symposium VI

*Nitrosamine Risk Assessment Part 2 – In vivo Approaches*



2022 – 2023  
GTA Board of Directors

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*Sheroy Minocherhomji PhD; MSc; DIC  
Eli Lilly and Company*

#### Chair-Elect

*Penny Leavitt MS, DABT  
Bristol Myers Squibb*

#### Scientific Program Co-Chairs

*Yi Yang PhD, DABT – AbbVie Inc.  
Wen Sun PhD – Pfizer  
Laura Markley PhD – US FDA*

#### Secretary, Web Liaison

*Ashley Allemang MS  
Procter & Gamble*

#### Student Outreach

*Zhiying (Zane) Ji PhD  
Incyte Corporation*

*Maria Engel MS – Pfizer*

*Melisa Masuda-Herrera MS, DABT – Gilead*

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##### Newsletter Editors

*Paula van Rossum MSc – Toxys Inc.  
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##### Photographer

*Robert Preston  
Janssen Research & Development, LLC*

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**May 3-5, 2023**  
**John M. Clayton Hall Conference Center**  
**University of Delaware,**  
**Newark, DE**

Dear Colleagues,

The 2023 GTA meeting takes place once again at the University of Delaware in Newark, DE and marks our return to an in-person meeting of the GTA following the successful completion of 3 virtual meetings during the COVID-19 pandemic.

This year's Scientific Program Committee and Session co-chairs have put together an exciting program that includes 2 workshops, a Keynote Address by Prof. Carol Yauk PhD (University of Toronto, Canada) and 6 Symposia, including 25 invited speakers. Additionally, our Poster Presentation session will include 2 minute speed talks from each of our poster presenters.

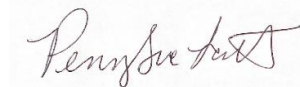
We are pleased to note that the majority of speakers at this year's meeting will be attending in person, which will once again foster in-person discussions, networking and meetings. Meals and refreshments will be served as indicated in the program. As always speaker presentations will be made available in the Scientific Meeting Presentations section of the Members portal on GTA website.

Following the successful completion of 3 virtual meetings, we are excited to be returning to an in-person meeting in 2023. We hope that you can join us in Newark, DE for our 2023 Annual Meeting of the Genetic Toxicology Association.

Sincerely,



**Sheroy Minocherhomji PhD; MSc; DIC**  
2022-2023 GTA Chair



**Penny Leavitt MS, DABT**  
2022-2023 GTA Chair Elect



2022 – 2023  
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*Jennifer Sasaki PhD, DABT – Seagen*

**Photographer**

*Robert Preston*  
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## 2023 Annual Meeting of the GTA

May 3-5, 2023

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

### 2023 Annual GTA Meeting: Wednesday, May 3<sup>rd</sup>

12:45 – 5:00 PM		Lobby A / Registration Desk
1:00 – 3:00 PM		Auditorium 125
<b>Workshop 1</b>		
<b>Navigating the Genetic Toxicology Battery – Strategies and Case Studies</b>		
Co-chairs: Yi Yang PhD, DABT, AbbVie Inc. & Dan Levy PhD, US FDA (retired)		
Panelists: Dan Roberts MS, Toxys, John Nicolette MS, J&J, Tim McGovern PhD, US FDA, Maria Donner PhD, Consultant		
In this workshop, speakers will bring their tough and intriguing cases to a group of panelists for assessment and recommendations. A variety of topics will be discussed, including:		
<ul style="list-style-type: none"><li>• Genetic toxicology data interpretations</li><li>• Design of a repeat genetic toxicology test</li><li>• Follow up characterization within genetic toxicology batteries</li><li>• Follow up characterization outside genetic toxicology batteries</li></ul>		
<i>Bring your questions, take the challenges, and be ready for an interactive discussion in a fun and entertaining format!</i>		
3:00 – 3:15 PM		Lobby A
<b>Coffee Break</b>		
3:15 – 4:15 PM		Auditorium 125
<b>Workshop 2 – Part 1</b>		
<b>Genetic Toxicology &amp; Carcinogenicity Testing – Regulatory Updates</b>		
Co-chairs: Maria Engel MS, Pfizer & Rosie Elespuru PhD, Discovery Life Sciences		
3:15 – 3:20 PM	<b>Pig-a Assay Introduction: Welcome and Overview of Workshop Part 1</b> Maria Engel MS, Pfizer	
3:20 – 3:40 PM	Sources of variability in the Pig-a assay and how to control them <i>Vasily Dobrovolsky PhD, FDA</i>	
3:40 – 4:00 PM	Approaches for evaluating the quality of historical negative control data: <i>Pig-a</i> examples <i>Stephen D. Dertinger PhD, Litron Laboratories</i>	
4:00 – 4:15 PM	Pig-a Assay Discussion / Q+A Period	

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4:15 – 5:25 PM

Auditorium 125

**Workshop 2 – Part 2**

**Genetic Toxicology & Carcinogenicity Testing – Regulatory Updates**

Co-chairs: Maria Engel MS, Pfizer & Rosie Elespuru PhD, Discovery Life Sciences

4:15 – 4:20 PM

**ICH S1B updates: Welcome and Overview of Workshop Part 2**

Rosie Elespuru PhD, Discovery Life Sciences

4:20 – 4:35 PM

Title TBD

*Tim McGovern PhD, US FDA*

4:35 – 4:55 PM

Using Adverse Outcome Pathways as a Framework for Carcinogenicity Assessment in ICH S1B(R1)"

*Susanne Stalford PhD, Lhasa Limited UK*

4:55 – 5:10 PM

Developing a Pragmatic Consensus Procedure Supporting the ICH S1B WoE Carcinogenicity Assessment

*Arianna Bassan PhD, Innovatune, Italy*

5:10 – 5:25 PM

ICH S1B update Discussion / Q+A Period

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# 2023 Annual GTA Meeting: Thursday, May 4<sup>th</sup>

<b>7:30 – 8:30 AM</b>	<b>Conference Registration</b>	<b>Lobby A / Registration Desk</b>
<b>7:30 – 8:30 AM</b>	<b>Breakfast</b>	<b>Room 101 A</b>
<b>8:30 – 8:40 AM</b>	<b>Welcome and Introduction</b> <i>Sheroy Minocherhomji PhD, Eli Lilly and Company</i> <i>2022-2023 GTA Chair</i>	<b>Auditorium 128</b>
<b>8:40 – 9:45 AM</b>	<b>KEYNOTE ADDRESS</b>	<b>Auditorium 128</b>
8:40 – 8:45 AM	<b>Introduction</b> <i>Co-chairs: Sheroy Minocherhomji PhD, Eli Lilly &amp; Penny Leavitt MS, DABT, Bristol Myers Squibb</i>	
8:45 – 9:45 AM	I didn't catch your NAM: Advancing genotoxicity testing strategies through multi-sector collaborations. <i>Prof. Carol Yauk PhD, University of Ottawa, Canada</i>	
<b>9:45 – 10:00 AM</b>	<b>Coffee Break</b>	<b>Lobby A</b>
<b>10:00 – 11:30 AM</b>	<b>Symposium I</b> <b>New Technologies for Genetic Toxicology Testing</b>	<b>Auditorium 128</b>
10:00 – 10:10 AM	<b>Introduction</b> <i>Co-chairs: Dan Roberts MS, Toxys &amp; Wen Sun PhD, Pfizer</i>	
10:10 – 10:30 AM	Duplex Sequencing studies to characterize chemical mutagenic mechanisms in mouse somatic tissues and germ cells <i>Francesco Marchetti PhD, Health Canada, Canada</i>	
10:30 – 10:50 AM	The reconstructed skin MN (RSMN) assay – next steps to improve use and aid implementation <i>Ashley Allemang MS, Procter &amp; Gamble, USA</i>	
10:50 – 11:10 AM	A novel DNA repair assay to investigate the mode-of-action of genotoxic compounds <i>Giel Hendriks PhD, Toxys Inc., Netherlands</i>	
11:10 – 11:30 AM	Detecting DNA reactivity using avian models <i>Yax Thakur MS, New York Medical College, USA</i>	
<b>11:30 – 12:00 PM</b>	<b>Awards Ceremony and Presentation – Part I</b>	<b>Auditorium 128</b>
11:30 – 11:40 PM	<b>ESA Introduction</b> <i>Chair: Dan Roberts MS, Toxys</i>	
11:40 – 12:00 PM	<b>Excellence in Service Award Presentation</b>	

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12:00 – 1:00 PM

Room 101 A

Networking Lunch

1:00 – 2:30 PM

Auditorium 128

Symposium II

Artificial Intelligence, Machine Learning and Modeling Advances in Genetic Toxicology Testing

1:00 – 1:05 PM

**Introduction**

*Co-chairs: Wen Sun PhD, Pfizer & Penny Leavitt MS, DABT, Bristol Myers Squibb*

1:05 – 1:30 PM

Role of DNA Repair in Modulating Susceptibility to Mutations and Cancer induced by N-Nitrosodimethylamine (NDMA)

*Prof. Bevin P. Engelward, ScD. Massachusetts Institute of Technology, USA*

1:30 – 1:55 PM

Tox-GAN: An Artificial Intelligence Approach Alternative to Animal Studies-A Case Study with Toxicogenomics

*Xi Chen, Ph.D. National Center for Toxicological Research US FDA, USA*

1:55 – 2:20 PM

Genotoxicity Predictions for Rapid Compound Screening: A Case Study for Accurate Classification using Machine Learning

*Seda Arat, Ph.D., Pfizer, USA*

2:20 – 2:30 PM

Panel Discussion Q&A

2:30 – 2:45 PM

Lobby A

Coffee Break

2:45 – 4:20 PM

Auditorium 128

Symposium III

Genetic Mechanisms in Metals Carcinogenesis

2:45 – 2:50 PM

**Introduction**

*Co-chairs: Laura Markley PhD, US FDA & Jamie Young PhD, University of Louisville*

2:50 – 3:10 PM

Mechanisms of Genomic Rearrangements: How Hexavalent Chromium, a Major Environmental Concern, Induces Chromosome Instability

*Prof. John P. Wise, Department of Pharmacology and Toxicology, University of Louisville, USA*

3:10 – 3:30 PM

Topic TBD

*Prof. Ke Jian "Jim" Liu, Stony Brook Cancer Center, Stony Brook University, USA*

3:30 – 3:50 PM

Potential mechanisms of tungsten-induced carcinogenesis

*Prof. Koren Mann, Lady Davis Institute for Medical Research, McGill University, Canada*

3:50 – 4:10 PM

Utilizing a stem cell based GFP reporter assay to demonstrate the mechanism of transition metal induced genotoxicity.

*Dan Roberts, MS, Toxys Inc, USA.*

4:10 – 4:20 PM

Panel Discussion Q&A

4:20 – 4:30 PM

Lobby A

Coffee Break

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<b>4:30 – 5:00 PM</b>		<b>Auditorium 128</b>
<b>Poster Presentation</b>		
4:30 – 4:35 PM	<b>Introduction</b> <i>Co-chairs: Ashley Allemang MS, Procter &amp; Gamble &amp; Yi Yang PhD, DABT, AbbVie Inc.</i>	
4:35 – 5:00 PM	2-minute Speed Talks (chronological order)	
<b>5:00 – 7:00 PM</b>		<b>Lobby A</b>
<b>Poster Session and Cocktails</b>		
5:00 – 6:00 PM	<b>Odd numbered posters</b> <i>Presenters available at their posters</i>	
6:00 – 7:00 PM	<b>Even numbered posters</b> <i>Presenters available at their posters</i>	
<b>7:00 – 8:30 PM</b>		<b>Room 101 A</b>
<b>Dinner (included in the 2-day registration)</b>		

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# 2023 Annual GTA Meeting: Friday, May 5<sup>th</sup>

Lobby A / Registration Desk

7:00 – 8:15 AM Conference Registration

7:00 – 8:15 AM Breakfast

Room 101 A

8:15 – 8:30 AM **Welcome to Day 3**  
*Penny Leavitt MS, DABT, Bristol Myers Squibb*  
*2022-2023 GTA Chair-Elect*

Auditorium 128

8:30 – 10:00 AM

Auditorium 128

## Symposium IV Titanium Dioxide Risk Assessment and Updates

*Co-chairs: David Kirkland PhD, Kirkland Consulting & Leon Stankowski PhD, CRL*

8:30 – 8:45 AM Introduction and Updates on the genotoxicity of TiO<sub>2</sub>: Part 1, data gaps and new data  
*David Kirkland PhD, Kirkland Consulting, Tadcaster, UK*

8:45 – 9:15 AM New *in vivo* gene mutation and comet studies  
*Carol Beevers, PhD, Corteva Agriscience, Abingdon, UK*

9:15 – 9:45 AM Fate of Titanium Dioxide after oral dosing  
*John W Wills, PhD, Department of Veterinary Medicine, University of Cambridge UK*

9:45 – 10:00 AM Updates on the genotoxicity of TiO<sub>2</sub>: Part 2, Regulatory opinions, industrial approaches to alternatives to TiO<sub>2</sub>, and new initiatives  
*David Kirkland PhD, Kirkland Consulting, Tadcaster, UK*

10:00 – 10:15 AM

Lobby A

Coffee Break

10:15 – 11:30 AM

Auditorium 128

## Symposium V Nitrosamine Risk Assessment, Part 1 – *In silico* and *In vitro* Approaches

10:15 – 10:20 AM **Introduction**  
*Co-chairs: Melisa Masuda-Herrera MS, DABT, Gilead & Kevin Cross PhD, Instem*

10:20 – 10:40 AM Framework for Establishing Acceptable Intakes for Drug Substance Related Nitrosamines  
*Krista Dobo PhD, Pfizer*

10:40 – 11:00 AM From Theory to Practice: Use of Computational Methods for Nitrosamine Assessments  
*Suman Chakravarti PhD, MultiCASE, USA*

11:00 – 11:20 AM Extension of the CADRE Platform: A Quantum-Mechanical Tool for Predicting the Carcinogenic Potency of N Nitroso Impurities in Pharmaceuticals  
*Jakub Kostal, PhD, ToxFix USA*

11:20 – 11:30 AM Panel Discussion Q&A

11:30 – 12:30 PM

Room 101 A

Networking Lunch

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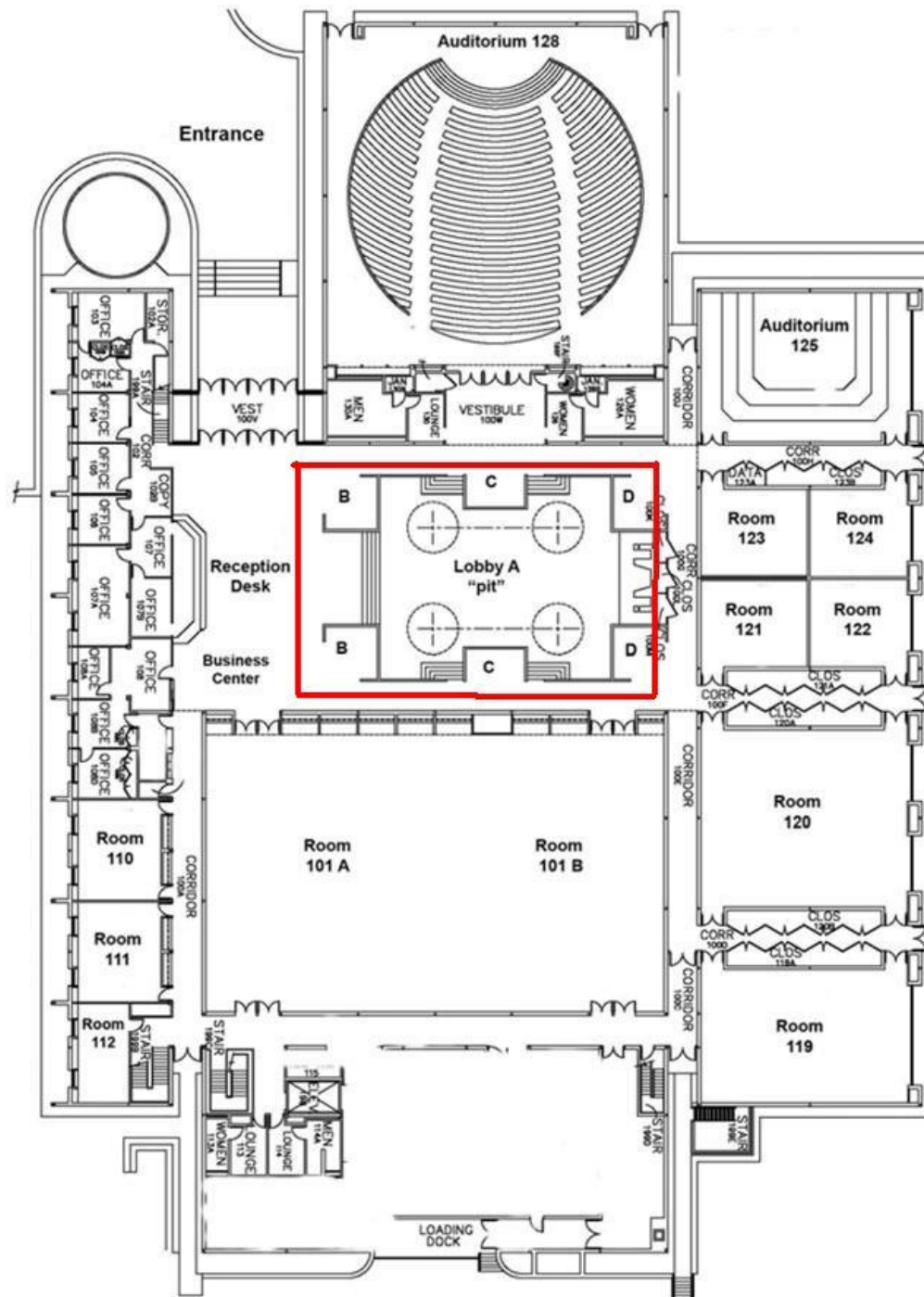


<b>12:30 – 1:00 PM</b>	<b>GTA 2023 Business Meeting</b>	<b>Auditorium 128</b>
<b>1:00 – 1:45 PM</b>	<b>Awards Ceremony and Presentation – Part II</b>	<b>Auditorium 128</b>
1:00 – 1:15 PM	<b>Abstract and Travel Awards</b> <i>Co-chairs: Sheroy Minocherhomji PhD, Eli Lilly &amp; Penny Leavitt MS,DABT, Bristol Myers Squibb</i>	
1:15 – 1:25 PM	<b>ESA Introduction</b> <i>Chair: Dan Roberts MS, Toxys</i>	
1:25 – 1:45 PM	<b>Excellence in Science Award Presentation</b>	
<b>1:45 – 2:00 PM</b>	<b>Coffee Break</b>	<b>Lobby A</b>
<b>2:00 – 3:15 PM</b>	<b>Symposium VI Nitrosamine Risk Assessment Part 2 – In vivo Approaches</b>	<b>Auditorium 128</b>
2:00 – 2:05 PM	<b>Introduction</b> <i>Co-chairs: Joel Bercu PhD, DABT, Gilead Sciences &amp; Jennifer Cheung BS, Pfizer</i>	
2:05 – 2:25 PM	EMA-Mutamind Analysis of Drug Substance Related Nitrosamines <i>Kevin Cross PhD, Vice President, Insteam, USA</i>	
2:25 – 2:45 PM	Mutation induction in Muta™Mouse following exposure to N-Nitrosodimethylamine (NDMA) with evidence for sub-linear mutation accumulation following repeat dosing <i>Anthony Lynch PhD, GSK Plc, UK</i>	
2:45 – 3:05 PM	<i>In vivo</i> genotoxicity assessment of N-nitrosodiethylamine with Error-Corrected Next-Generation Sequencing <i>Shaofei Zhang PhD, Pfizer, USA</i>	
3:05 – 3:15 PM	Panel Discussion Q&A	
<b>3:15 – 3:30 PM</b>	<b>Concluding Remarks</b> <i>Penny Leavitt MS, DABT, Bristol Myers Squibb 2022-2023 GTA Chair-Elect</i>	<b>Auditorium 128</b>

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