

2023 Annual Meeting of the GTA



## Workshop 1

# Navigating Genetic Toxicology Testing Batteries

## Strategies & Case Studies

Co-chairs

Yi Yang, PhD DABT, AbbVie Inc  
Dan Levy, PhD, US FDA (CFSAN, retired)

# Navigating Genetic Toxicology Testing Batteries

## Workshop Format

- 6 case studies with open end questions
- 4 experienced panelists with cumulative 60 years experience in genetic toxicology
  - Maria Donner, Maria Donner Consulting
  - Tim McGovern, US FDA (CDER)
  - John Nicolette, Janssen R&D
  - Dan Roberts, Toxys
- Audience engagement



The hosts and panelists of "Wait Wait ... Don't Tell Me!," from left: Carl Kasell, Roxanne Roberts, Peter Sagal, Adam Felber and P. J. O'Rourke. "We're all happily hams," said Mr. Sagal.  
William Zbaren for The New York Times

**Let's be Happily Hams in the Genetic Toxicology Fashion!**

# Navigating Genetic Toxicology Testing Batteries Strategies and Case Studies

	Case Contributor	Key Issue	Points of Discussion
Case 1a	Anonymous (Presented by Levy D)	<ul style="list-style-type: none"> <li>Ames: Apparent negative result</li> </ul>	<ul style="list-style-type: none"> <li>What follow-up, if any, is needed?</li> </ul>
Case 1b	IWGT (presented by Levy D)	<ul style="list-style-type: none"> <li>Ames: equivocal result for a toxic compound</li> </ul>	<ul style="list-style-type: none"> <li>Data interpretation and follow up</li> </ul>
Case 2	Nicolette J	<ul style="list-style-type: none"> <li>Ames: weakly positive at the highest concentration in one strain.</li> </ul>	<ul style="list-style-type: none"> <li>Data interpretation and follow up</li> </ul>
Case 3	Kellum S	<ul style="list-style-type: none"> <li>In vitro MN: cytotoxicity</li> </ul>	<ul style="list-style-type: none"> <li>Dose selection for in vitro MN</li> </ul>
Case 4	Anonymous (Presented by Yang Y)	<ul style="list-style-type: none"> <li>In vitro MN: Is this positive result indicative of genotoxicity or secondary to cytotoxicity?</li> </ul>	<ul style="list-style-type: none"> <li>Do you agree with the conclusion? Additional weigh of evidence?</li> </ul>
Case 5	Vasquez M	<ul style="list-style-type: none"> <li>In vivo Comet: Conflicting results from different labs</li> </ul>	<ul style="list-style-type: none"> <li>Data interpretation</li> </ul>
Case 6	Baracani R	<ul style="list-style-type: none"> <li>Strategy: Characterization of novel excipients</li> </ul>	<ul style="list-style-type: none"> <li>Should the sponsor conduct further genetox studies?</li> </ul>