NTP
National Toxicology Program

Genetic Toxicology: Opportunities to Integrate New Approaches

Session 3: New technologies and approaches

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ILSI Health and Environmental Sciences Institute
Silver Spring, MD
April 23-24, 2012

Rationale for the topics in Session 3

- **Cutting edge technologies with unrealized potential**
  - Opportunity to apply these in innovative ways to answer long-standing questions that previously could not be addressed as well as to tackle new areas of genetic toxicology such as epigenetic alterations and individual susceptibility
- **Ability to rapidly test thousands of compounds simultaneously and multiple endpoints in parallel**
  - Opportunity to produce comprehensive toxicity profiles for many compounds, and design class studies that might be extrapolated to even larger groups of compounds
- **Enhanced understanding of compound activity; linking *in vitro* data with *in vivo* observations and gene expression – elucidating mechanisms**

Presentations for Session 3

- **Imaging as an approach to safety assessment**
  - Dr. William Slikker, *US Food and Drug Administration, NCTR*
- **The Tox21 strategy for detecting genotoxicants**
  - Dr. Raymond Tice, *National Institute of Environmental Health Sciences, National Toxicology Program*
- **The behavior of genomic signatures of genotoxicity: Effect of dose level and exposure duration**
  - Dr. Scott Auerbach, *National Institute of Environmental Health Sciences, National Toxicology Program*

Questions for discussion in Session 3

- Think about novel applications for these new technologies – unexplored potential
- Might these new technologies reveal new and better biomarkers of genotoxcity?
- Will these new technologies supplement or supplant traditional tests for genotoxicity?
- For high-throughput cell-based assays, what constitutes an informative “genotoxicity pathway” or endpoint for screening?
- How do we extrapolate from *in vitro* concentrations to *in vivo* exposure levels in humans? What approaches or models should we explore?
- What is the specificity of genomic signatures for events directly related to genotoxicity?

Questions for discussion in Session 3

- What level of validation will be necessary for acceptance of data generated using these new technologies in the regulatory arena?
  - How do we anchor the results from these new technologies?
  - Will these data improve risk assessment?