

# NTP Associate Director's Report

Brian R. Berridge, DVM, PhD, DACVP  
NTP Associate Director  
Scientific Director, Division of NTP  
National Institute of Environmental Health Sciences

NTP Board of Scientific Counselors Meeting  
20 June 2018



# Staff Changes – New Roles



**John Bucher, PhD**  
Deputy Division  
Director for Analysis



**Nigel Walker, PhD**  
Acting Chief,  
Toxicology Branch



# Staff Changes – New Faces



**Troy Hubbard, PhD**  
Toxicology Branch  
postdoctoral fellow



**Atlee Watson, PhD**  
Toxicology Branch  
postdoctoral fellow



**Takeshi Izawa, DVM, PhD**  
Cellular & Molecular  
Pathology Branch  
visiting scientist - Japan



**Natalie Bell**  
Biomolecular Screening  
Branch  
summer intern



**Gabrielle Scales**  
Cellular & Molecular  
Pathology Branch  
summer intern



**Xian Wu, PhD**  
NTP Laboratory  
visiting scientist - China



# Staff Changes – Said Goodbye



Grace Kissling, PhD  
NTP Statistics  
(retired)



Peggy Mooring  
Toxicology Branch  
(retired)



Andy Shapiro, MS  
Program Operations Branch  
(left NIEHS)



# Awards and Recognition



**Linda Birnbaum, PhD, NIEHS and NTP Director**  
**Arnold J. Lehman Award at SOT, AAI Foundation**  
**and Dr. William W. and Judith H. Busse Lectureship**



**Alison Harrill, PhD, Biomolecular Screening Branch**  
**SOT Mentor Award for Molecular & Systems Biology**  
**Specialty Section**



**Sreenivasa Ramaiahgari, PhD, Biomolecular Screening**  
**Branch**  
**SOT Best Postdoctoral Publication Award for**  
Three-dimensional (3D) HepaRG Spheroid Model with  
Physiologically-Relevant Xenobiotic Metabolism Competence  
and Hepatocyte Functionality for Liver Toxicity Screening”.  
2017. *Toxicol. Sci.*, 159(1): 124-136.



**Cynthia Rider, PhD**, Toxicology Branch

Elected Vice President-elect of NC SOT Chapter



**Scott Auerbach, PhD**, Biomolecular Screening Branch

Invited to serve on the Editorial Board of *Toxicological Sciences*



**Erik Tokar, PhD**, NTP Laboratory

Invited to serve as Associate Editor for *Toxicology and Applied Pharmacology*

President of Metals Specialty Section, SOT



**Arun Pandiri, BVSc & AH, PhD**, Cellular & Molecular Pathology Branch

Invited to be keynote speaker at 1<sup>st</sup> Bilateral Joint NIEHS-Nanjing Medical University Symposium *Emerging Topics in Environmental Sciences*, September 8-9, 2018



## Need for Refinement of Strategic Plan

Where Have We Been?



Where Are We Going?



How Do We Get There?

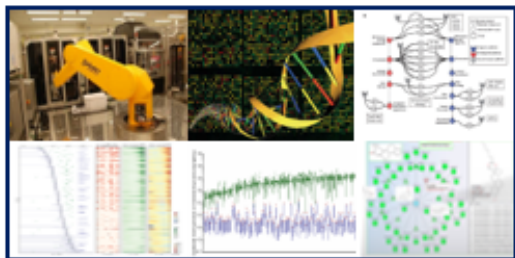
- Tox21 has been a very productive interagency collaboration
  - Thousands of chemicals tested in over 50 relevant pathways; public release of millions of data points
  - Over 200 joint publications
  - Data now being used for regulatory decisions
- Decision was made to broaden the focus beyond developing and applying high throughput screening to toxicology to developing toxicology approaches for the 21<sup>st</sup> century
- Reality is that the different partners have different missions
  - No single framework or one-size-fits-all approach
- New strategic plan needs to focus on:
  - Key challenges in toxicology in the 21<sup>st</sup> century
  - Common goals with substantial benefit in each organization regardless of mission.



# Primary Goals for Tox21 in Next 5 Years

## Tox21 Collaboration

### A Strategic Plan for Continued Leadership



Internal Use Only - Do Not Cite or Quote

ALTEX. March 8, 2018  
doi: 10.14573/altex.1803011

1. Develop and deploy alternative test systems that are predictive of human toxicity and dose response
2. Address key technical limitations of current *in vitro* test systems
3. Consolidate chemical compound library management
4. Curate and characterize legacy *in vivo* toxicity studies to serve as a resource for interpreting Tox21 data
5. Develop framework for efficient validation of Tox21 approaches
6. Refine and deploy *in vitro* methods for characterizing pharmacokinetics to increase predictivity and reduce uncertainty





# Implementation of New Strategic Plan

## Progress to Date



- Official roll-out at the SOT Annual Meeting, San Antonio, March 2018
- 3 teams formed and active
  - Communications (new unified website: <https://tox21.gov>)
  - Chemical Selection & Library
  - Assay Evaluation & Screening
- Cross-partner projects – initiated & active
  - Cross-partner projects are limited to 3-year terms
  - Driven by specific aims that match primary goals
  - Partner resource driven
  - Proposed time-line with benchmarks for “Go – No Go” decisions
  - Cross Partner Project members can recommend “No Go” based on science or resource priorities





- Tox21 Spring Face-To-Face General Meeting, May 15-16, at NIEHS
  - Tox21 federal partners from NTP, NCATS, EPA, and FDA attended
- ICCVAM Public Forum – May 24, at NIH
  - Slides and videocast recording available at <https://ntp.niehs.nih.gov/go/iccvamforum-201>
- Satellite Symposium Pathology Potpourri at Society of Toxicologic Pathology – June 16, Indianapolis, IN



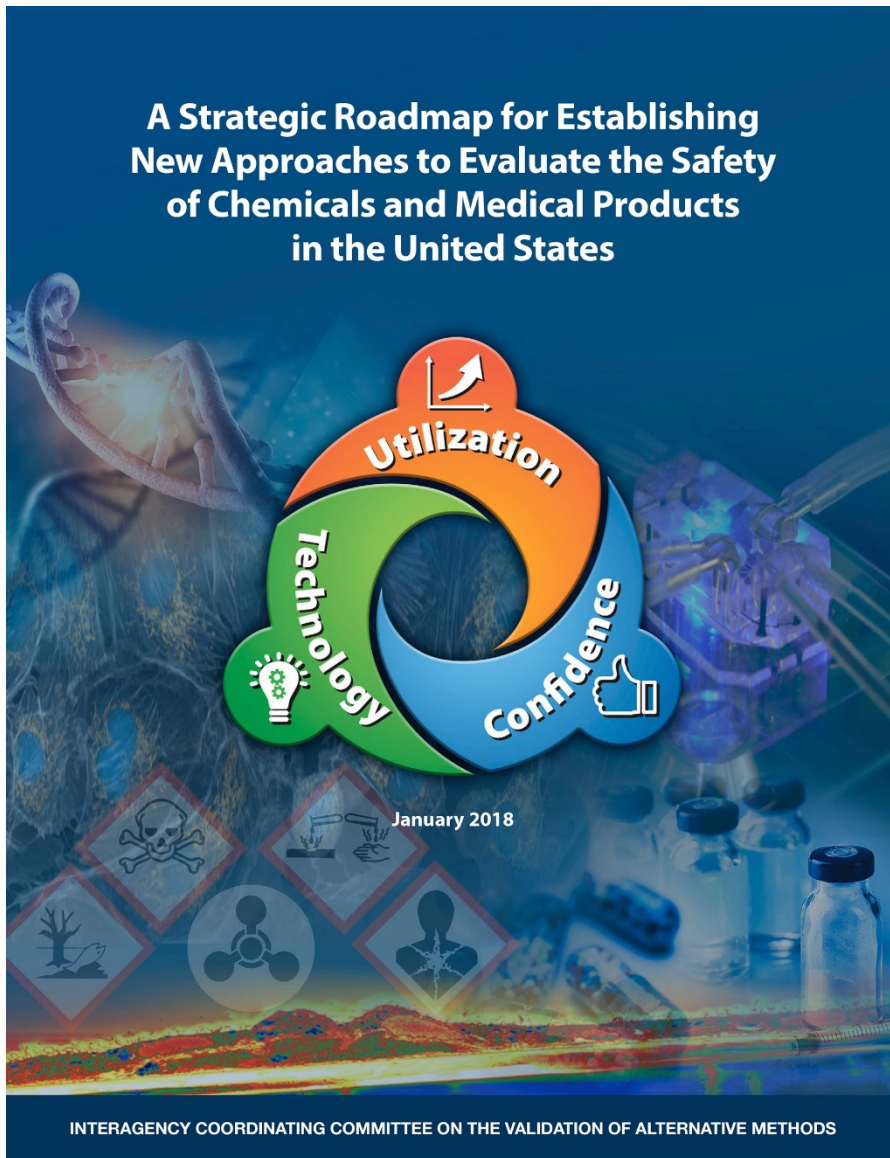


# Society of Toxicology Annual Meeting

## NIEHS/NTP staff participation

- 44 staff
- 5 talks at continuing education courses
- 3 symposium/workshop chairpersons
- 13 platform/symposium/workshop/information sessions
- 60 posters
- 5 poster-session chairpersons
- 1 exhibitor-hosted session: Implementing New Approaches to Evaluate the Safety of Chemicals and Medical Products in United States
- ToxExpo exhibit with staff-hosted tutoring sessions on BMDEExpress 2.0 and the Tox21 toolbox





## Integrate Processes that:



**Ensure adoption and use of new methods by both regulators and industry**



**Establish new validation approaches that are more flexible and efficient**



**Connect end users with the developers of alternative methods**



# US Strategic Roadmap Implementation

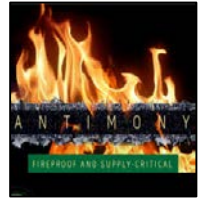
- FDA's Predictive Toxicology Roadmap (published Dec 2017)
  - <https://www.fda.gov/downloads/scienceresearch/specialtopics/regulatoryscience/ucm587831.pdf>
- EPA's Draft Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within TSCA (publication June 22, 2018)
  - <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>
- International collaboration of ICCVAM with ICATM and OECD to develop defined approaches (DA) for skin sensitization testing, based on analysis provided by NICEATM
  - DAs describe specific approaches for integrating data from multiple in vitro assays
  - US EPA is first agency world-wide to adopt a DA for skin sensitization, using data from 2 in vitro methods
  - NTP is currently testing agency-nominated mixtures and formulations in 2 in vitro methods to expand the applicability domain of the EPA-adopted DA





# NTP Reports – Peer Reviews

- Report on Carcinogens Monograph on Antimony Trioxide, Jan 24, 2018 (panel)
- NTP Technical Reports, March 26-28, 2018 (panel)
  - Cell Phone Radiofrequency Radiation Exposure in Rats
  - Cell Phone Radiofrequency Radiation Exposure in Mice
- NTP Research Report on CLARITY-BPA Core Study, April 26, 2018 (panel)
- NTP Monograph on Occupational Exposure to Cancer Chemotherapy Agents and Adverse Health Outcomes spring (letter)
  - Systematic review of published literature





**Thank You!**

