



Coordinating Activities and Promoting Adoption

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Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

NRC Toxicity Testing in the 21st Century: A Vision and A Strategy



- “Develop the infrastructure for **data sharing** and management, assay standardization, and reporting to enable broad data-sharing across academic, government, industry, and nongovernment-organization sectors and institutions.”
- “The realization of the vision will entail considerable interdisciplinary research (and substantial funding)....research will need **high-level coordination** to tackle the challenges presented in the vision efficiently.”
- “The committee sees the research institute funded and coordinated **primarily by the federal government**.... **participation by industry and public-interest groups should be ensured.**”

Combining Resources

- Collaboration, communication, and data sharing are key
- Engagement early and often from relevant stakeholder sectors (Academic, Government, NGO, Industry, Public)
- Data from alternatives (& paired in vivo data) provided from industry
 - Pilot projects (e.g., EPA AMCP; CropLife America)



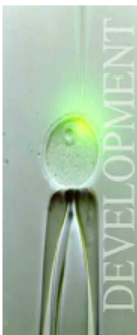
Funding Innovation and Implementation

- Need to ensure a sufficient alternative method research and development pipeline
- Funding sources are an important driver (e.g., NIEHS SBIR Phase 2B)



PHASE I Feasibility Study

- Budget Guide: \$225K (SBIR); \$225K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)



PHASE II Full Research/R&D

- \$1.5M (STTR), \$1.5M (SBIR) over two years

PHASE IIB Competing Renewal/R&D

- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~\$1M/year for 3 years

International Collaboration and Harmonization

- OECD Test Guidelines program provides a mechanism for the international evaluation and adoption of alternative methods by its 34 member countries.
- The International Cooperation on Alternative Test Methods (ICATM):
 - Promote international cooperation in the critical areas of validation studies, independent peer review, and development of harmonized test methods



Acute Toxicity “6 Pack”

- OPP has formed Acute Toxicity Workgroup with stakeholders
- Stakeholder group is meeting regularly to discuss progress, goals, & opportunities for collaboration
- Docket: EPA-HQ-OPP-2016-0093

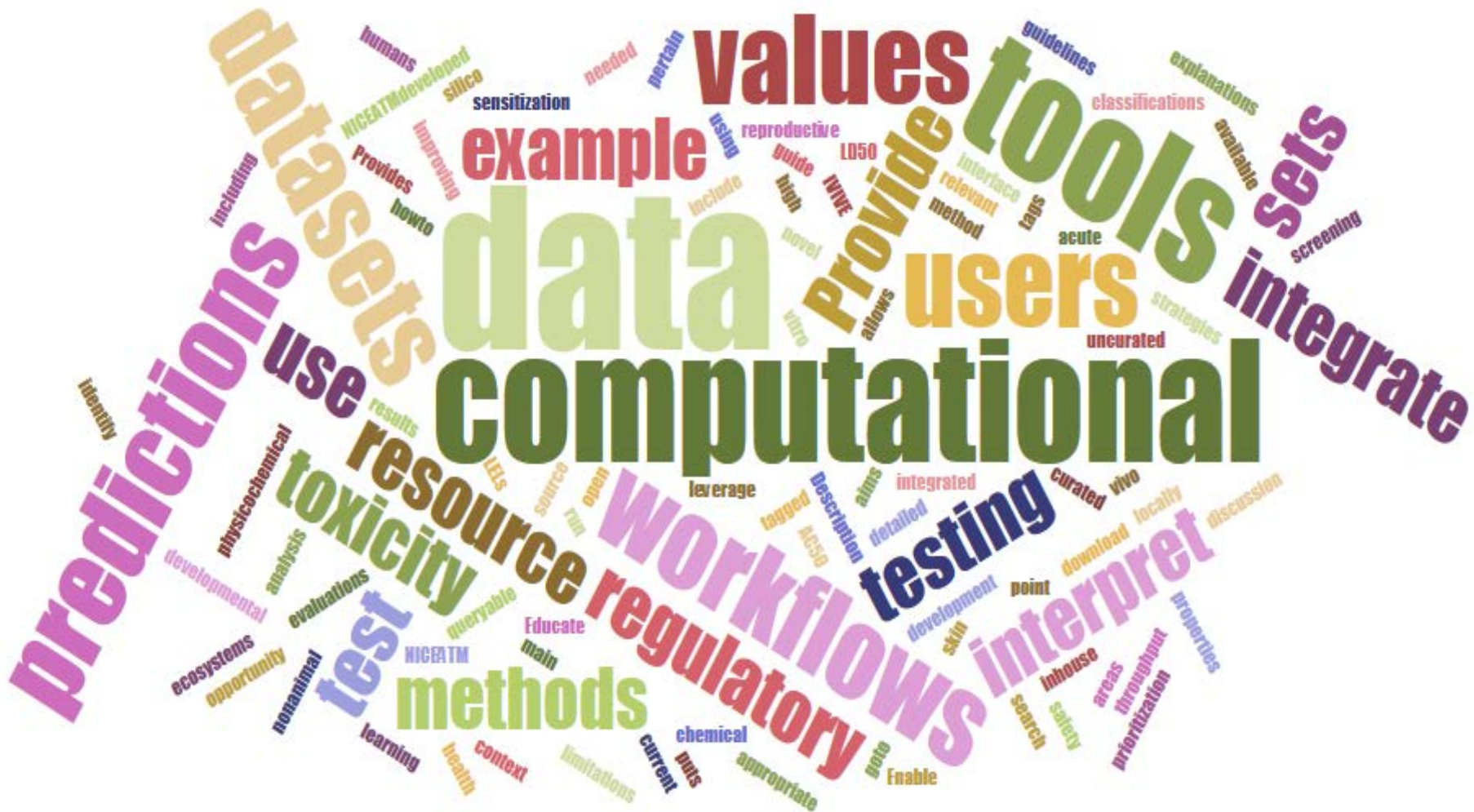
Outreach, Courses, and Workshops

- IIVS Practical Methods for In Vitro Toxicology
 - 5th Workshop and Training of Alternative Methods (Shanghai, China, Dec 2015)
- CAAT Academy Hands-On Training in Toxicology
 - Kidney Toxicity Testing & Best Practices (Sep 2016)
 - Upcoming topics: In vitro tools & models for: skin, lung, organs-on-a-chip, hepatotoxicity, pyrogenicity, endocrine disruption, ADME
- SOT 2017 Education Course on AOPs
- U.S. EPA ORD/NCCT Training on ToxCast/Chemistry Dashboards (<https://comptox.epa.gov/dashboard/>)
- AltTox: <http://alttox.org/resource-center/education-and-training/>

Promoting Adoption of Alternative Test Methods

- Education and training programs
 - In vitro assay transferability & commercialization
 - Modeling approaches and applications
- Clear guidance from regulatory authorities on acceptance of alternative methods
- Understanding impediments to adoption and addressing them
- Coordination with OECD, ICATM and other international partners

NICEATM web resource



ICE: Coming spring of 2017.....

Stakeholders (including international partners) would improve scientific and fiscal efficiency, providing greater return on investments while expediting the development and utilization of new technologies.

What strategies and mechanisms could be employed to increase communication and coordination of activities amongst and between the federal government and key stakeholders?