



Report of Scientific Advisory Committee on Alternative Toxicological Methods' Discussions on US Strategic Roadmap

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ICCVAM SACATM 2017

- Sep. 18-19
- NIH Campus, Bethesda, MD
- Attendees: SACATM members, ICCVAM representatives, ICATM representatives, NIEHS staff, ILS staff, public (n= 21)



- Acknowledges the decade of great effort following on the NRC report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*
- Recognizes that uptake and impact of the vision and strategy have not kept pace with the rapid development of technology and capability
- Suggests ‘institutional practices’ to be a limitation
- Roadmap offered as a resource and guide

- Advocates a few fundamental shifts in the approach
 - Driven by federal agencies
 - Includes both chemicals and medical products
 - Protecting human health and improving human relevance are key drivers
 - Implementation plans will be tracked and publicly reported

Salient discussion points

- Good support for the Roadmap from all stakeholders and alignment on the need for a shift in strategy
- Consistent points
 - Early engagement with end-users and stakeholders
 - Importance in articulating the problem we're trying to solve- with particular reference to patient/public health concerns
 - Clearly identifying context of use
 - Developing a framework for building confidence in new methods
 - Clear messaging (advocacy and acceptance) from regulatory stakeholders

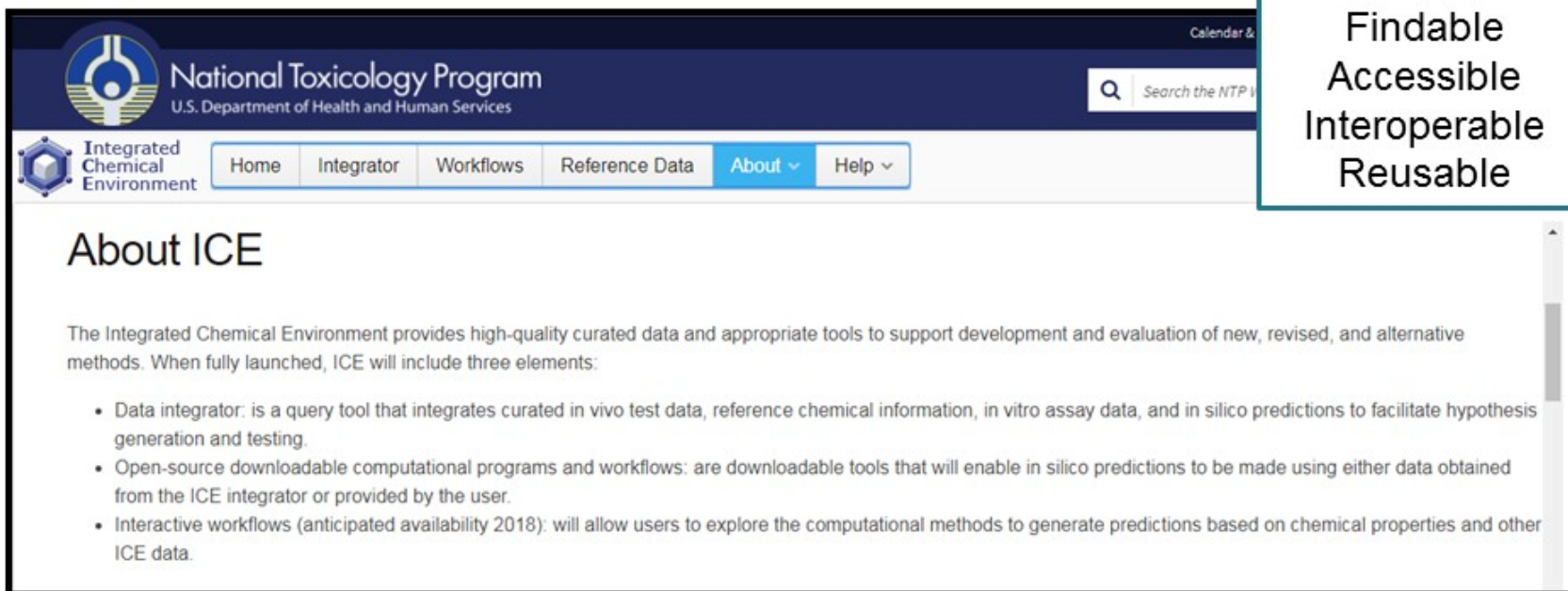
Salient discussion points (cont.)

- Challenges
 - Benchmarking against animal vs. human outcomes
 - Importance of international partnerships and acceptance
 - Alignment on risk assessment vs. hazard identification
 - Alignment on assessment of toxicity vs. safety
 - Metrics
 - animal numbers
 - # validated assays
 - testing waivers

Databases

'FAIR Principles'

Findable
Accessible
Interoperable
Reusable



The screenshot shows the National Toxicology Program website. The header includes the NTP logo and the text 'National Toxicology Program U.S. Department of Health and Human Services'. A search bar is visible with the text 'Search the NTP'. Below the header is a navigation menu with links for 'Home', 'Integrator', 'Workflows', 'Reference Data', 'About', and 'Help'. The main content area is titled 'About ICE' and contains the following text:

The Integrated Chemical Environment provides high-quality curated data and appropriate tools to support development and evaluation of new, revised, and alternative methods. When fully launched, ICE will include three elements:

- Data integrator: is a query tool that integrates curated in vivo test data, reference chemical information, in vitro assay data, and in silico predictions to facilitate hypothesis generation and testing.
- Open-source downloadable computational programs and workflows: are downloadable tools that will enable in silico predictions to be made using either data obtained from the ICE integrator or provided by the user.
- Interactive workflows (anticipated availability 2018): will allow users to explore the computational methods to generate predictions based on chemical properties and other ICE data.

Access to data supporting the use of an alternative approach



Summary

- Broad support for the need and content of the Roadmap
- Should integrate well with and support ongoing efforts
- Potential for a significant turning point in the application and impact of alternatives