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

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• 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
Reuable

About ICE

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: 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: 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