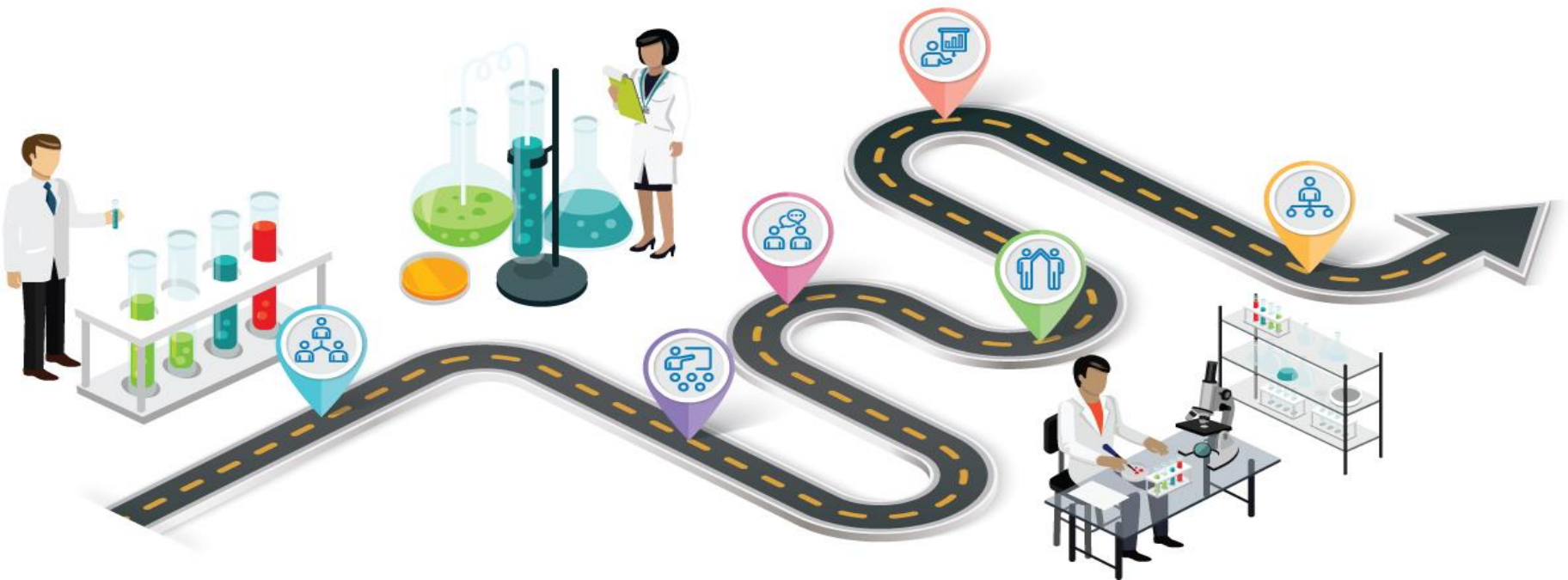


FDA Predictive Toxicology Road Map

National Toxicology Program,
Board of Scientific Councilors
February 15, 2019



FDA Senior Level Toxicology Working Group



- Foster enhanced communication among FDA product centers and researchers
- Leverage FDA resources to advance the integration of emerging predictive toxicology methods and new technologies into regulatory safety and risk assessments.



Formation of a Roadmap Committee



- Commissioner tasked the FDA Toxicology Working Group with development of a roadmap for integrating emerging predictive toxicology methods and new technologies into regulatory risk assessments
- Each of FDA's product centers has very different legal authorities for evaluation of product safety
- Nevertheless, greater cross-center collaboration can help accelerate the use of emerging predictive toxicology methods

Roadmap Emphasizes Qualification and Context of Use

- Qualification is a conclusion that the results of an assessment using the model or assay can be relied on to have a specific interpretation and application in product development and regulatory decision-making
- Context of use refers to a clearly articulated description delineating the manner and purpose of use for the tool



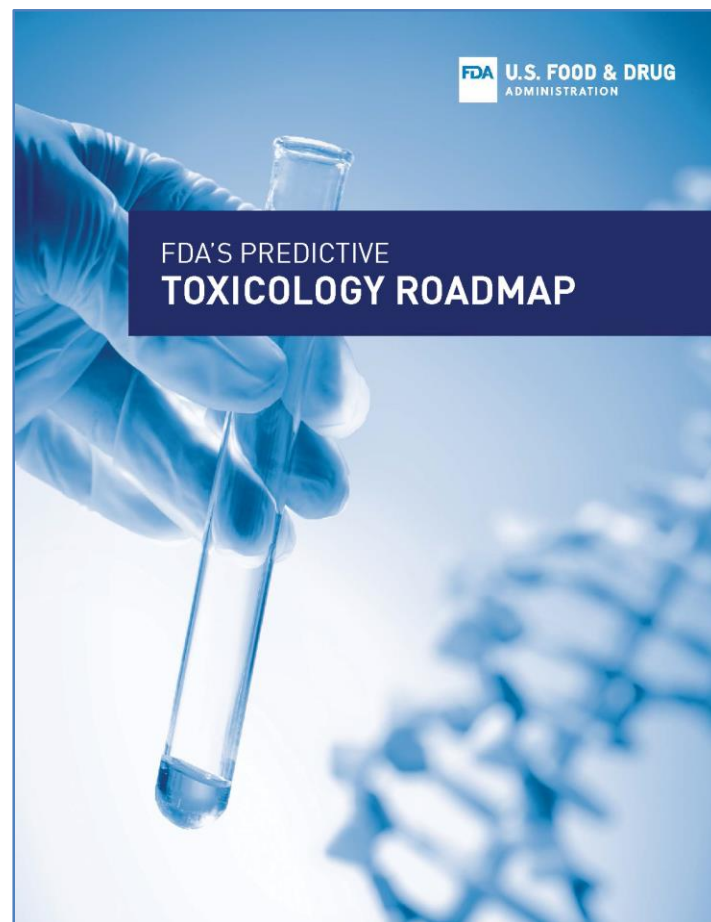


Roadmap Emphasizes the Importance of Partnerships for Accepting New Technologies

- Fostering collaborations between government researchers and regulators and between government regulators, industry , stakeholders and academia to ensure the most promising technologies are identified, developed, validated and integrated into regulatory risk assessment.

FDA Predictive Toxicology Roadmap Announced December 6, 2017

- <https://blogs.fda.gov/fda/voice/index.php/2017/12/fda-launches-predictive-toxicology-roadmap-to-enable-advances-in-toxicity-testing/>



Training of FDA regulators and researchers



- Continuing ongoing education in new predictive toxicology methods is essential for FDA regulators.
- Established an Agency-wide education calendar of events and a Toxicology Seminar Series to introduce concepts of new toxicology methodologies and updates in toxicology-related topics.



Continued Communication



- Reaffirm FDA's commitment to incorporate data from newly qualified toxicology methods into regulatory missions
- Encourages discussions with stakeholders as part of the regulatory submission process.
- Encourage sponsors to submit a scientifically valid approach for using a new method early in the regulatory process



Collaborations with Stakeholders



- Foster collaborations across sectors and disciplines nationally and internationally.
- Pivotal to identifying the needs, maintaining momentum, and establishing a community to support delivery of new predictive toxicology methods.

Oversight by Office of the Commissioner



- Track the progress of these recommendations and report to the Chief Scientist annually.
- Ensure transparency, fostering opportunities to share ideas and knowledge, showcase technologies, and highlight collaborations on developing and testing new methods

RoadMap Goals



- Roadmap identifies the critical priority activities for energizing new or enhanced FDA engagement in transforming the development, qualification, and integration of new toxicology methodologies and technologies into regulatory application
- Implementing the roadmap and engaging with diverse stakeholders will enable FDA to fulfill its regulatory mission today while preparing for the challenges of tomorrow.

FDA Public Meeting on the Roadmap

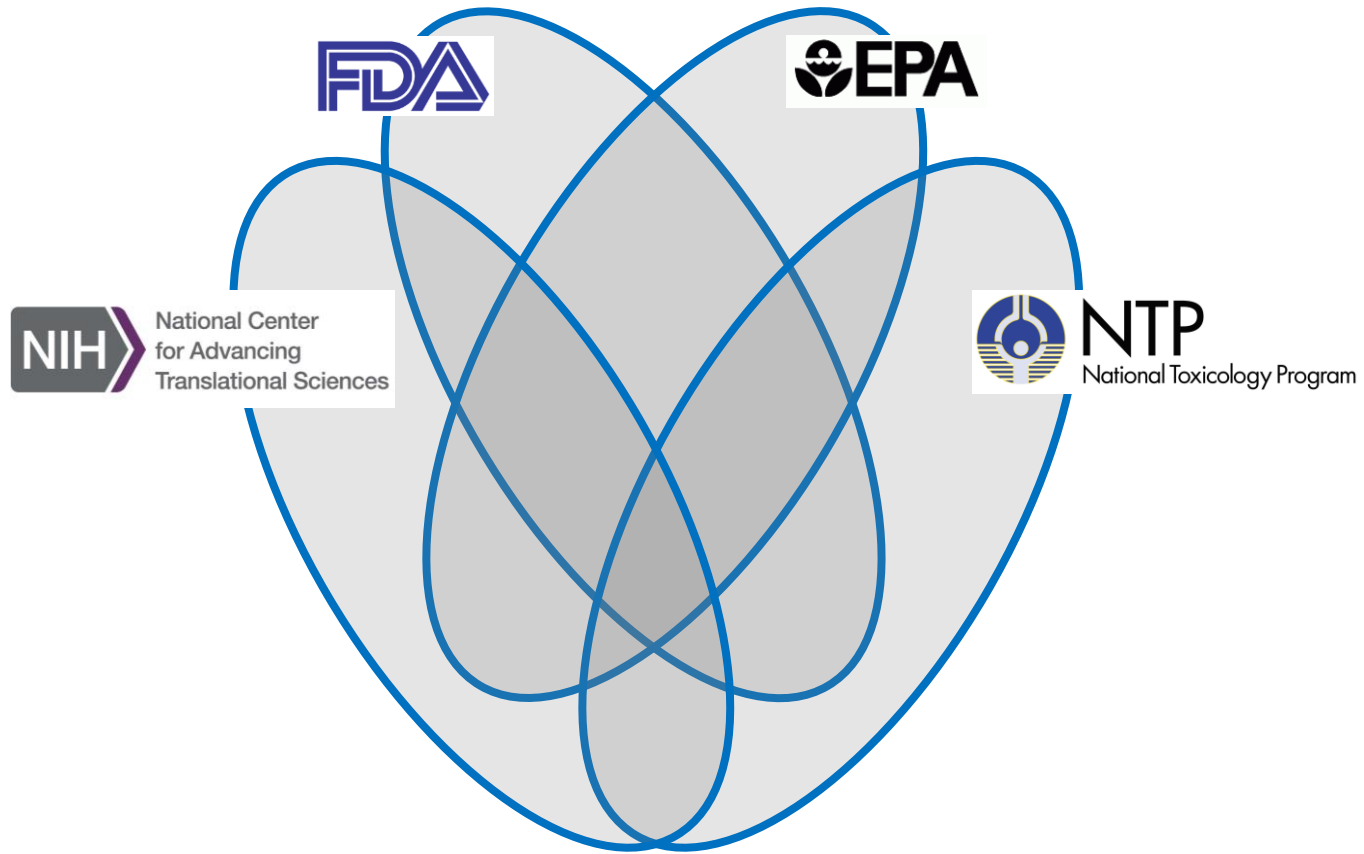
FDA

FDA held a public hearing on Wednesday, September 12, 2018 from 9 a.m. to 4 p.m. to solicit comments on its Predictive Toxicology Roadmap.

The Agency requested comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate them into regulatory review, as applicable.



The Challenge and Opportunity



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