Implementing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States- FDA Activities

Suzanne C. Fitzpatrick, PhD, DABT, ERT

US Food and Drug Administration

2019 SOT Meeting
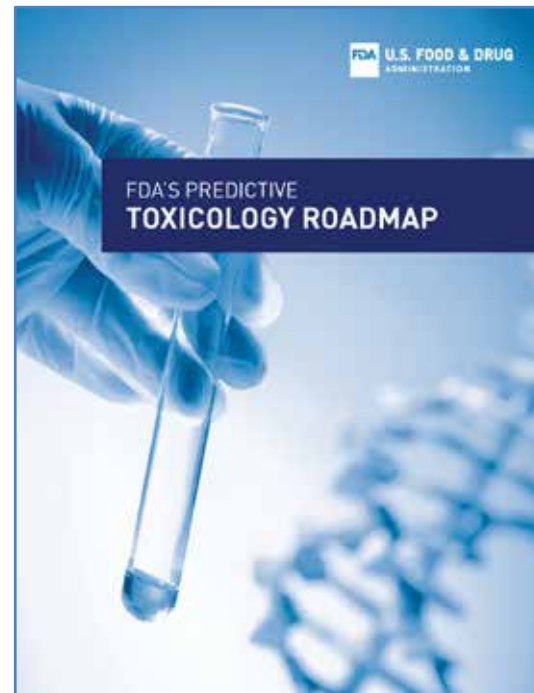
Partnerships: FDA NIH DARPA

- To jointly develop new tools that can be used in therapeutic development.
- Create a collaboration of government, academic and industry scientists working together on new toxicology tools.
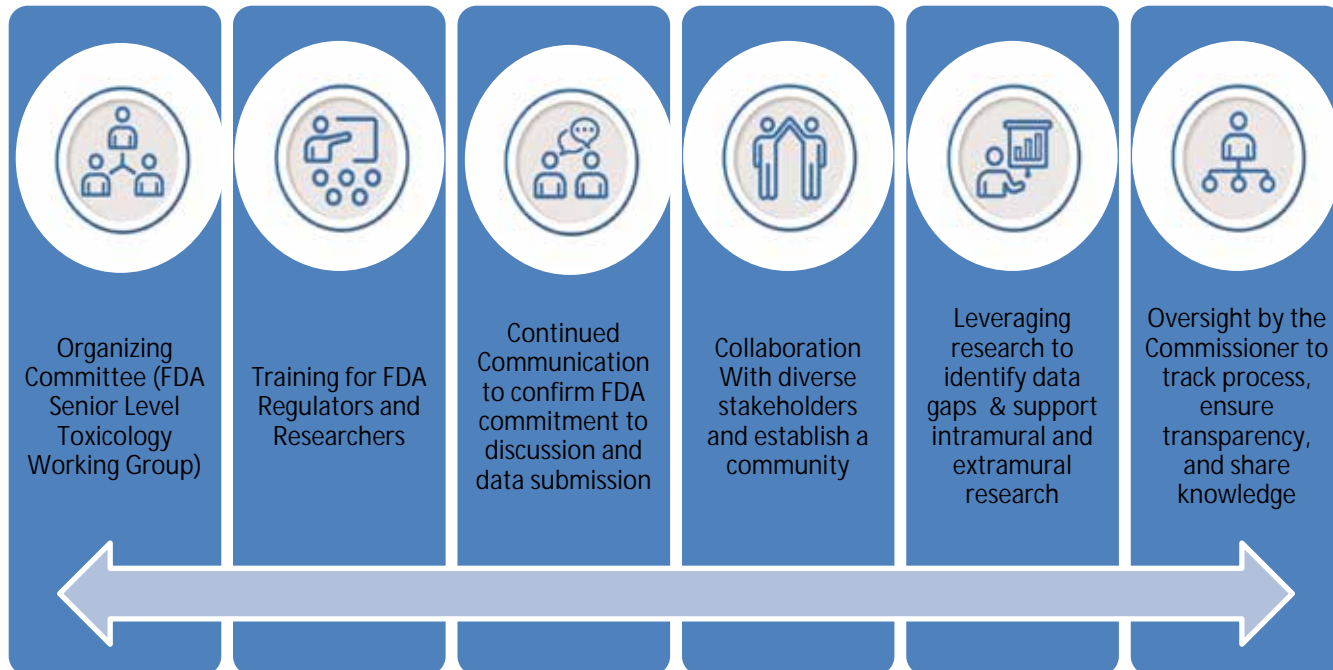
FDA Predictive Toxicology Roadmap
Announced December 6, 2017

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

FDA's Roadmap: Framework for Incorporating Emerging Predictive Toxicology Methods in Regulatory Reviews

Organizing Committee (FDA Senior Level Toxicology Working Group)

Training for FDA Regulators and Researchers

Continued Communication to confirm FDA commitment to discussion and data submission

Collaboration With diverse stakeholders and establish a community

Leveraging research to identify data gaps & support intramural and extramural research

Oversight by the Commissioner to track process, ensure transparency, and share knowledge

FDA held a public hearing on Wednesday, September 12, 2018. to solicit comments on its Predictive Toxicology Roadmap.
The Agency sought comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate them into regulatory review, as applicable.
https://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm601090.htm

Roadmap-Responsive Activities

- Each center developed its own plan to meet roadmap goals.
- Two goals for updating our toxicology toolboxes:
  - Revaluate Existing Tools For Regulatory Use
    - Use of Dog for Chronic Testing
    - Use of Chronic Rodent Bioassays
  - Evaluate New Tools for Regulatory Use
    - C.Elegans
    - Organs on Chips
    - Read Across

FDA U.S. FOOD & DRUG
ADMINISTRATION

Questions

Suzanne C. Fitzpatrick, PhD, DABT

suzanne.Fitzpatrick@fda.hhs.gov