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SACATM Meeting, September 27, 2016
Research Triangle Park, NC
• Ethics

• Efficiency

• Public Health (Human Relevance)
We must....

• Clearly define the objective and maintain focus

• Frame the discussion in a manner that can lead to a productive outcome
This is not:

• An indictment of existing methods, practice, or policy
• An attempt to replace animal-based tests in the absence of suitable alternatives
• A discreditation of animal models used for biomedical research
In Francis Collins’ recent testimony to the congressional subcommittee with NIH budget oversight responsibility, he offered that:

“Animal safety testing for environmental chemicals and drugs will largely be replaced by tissue chips and iPS cells in 10 years.”

“…..giving results that are more accurate, at lower cost and higher throughput.”
2004: A National Toxicology Program for the 21st Century

2007: Toxicity Testing in the 21st Century

2012: A Vision and a Strategy

2014: A 21st century roadmap for human health risk assessment

2016: Incorporating 21st Century Approaches into Risk Based-Science
It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology.
Technology is not self-implementing, obstacles are not self-resolving
• Animal Models as Gold Standard

• Institutional Resistance

• Harmonization
Developing a US Strategy and Roadmap

• ICCVAM is developing a short-term strategy to replace six commonly used animal toxicity tests (“EPA 6-pack”) within three years

• Implementing a more holistic, human-relevant, approach for toxicity testing in the 21st Century will require significant changes in policy, practice, and regulation; a challenge so complex and broad in scope that it cannot adequately be addressed by any single agency or existing government entity