FDA Interests in Regulatory Science

Regulatory Science

- Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of products regulated by the Food and Drug Administration (FDA).
- Products:
  - Medical devices: Center for Devices and Radiological Health (CDRH)
  - Drugs: Center for Drug Evaluation and Research (CDER)
  - Biologics: Center for Biologics Evaluation and Research (CBER)
  - Combination products
  - Veterinary medicine: Center for Veterinary Medicine (CVM)
  - Food and dietary supplements: Center for Food Safety and Applied Nutrition (CFSAN)
  - Tobacco products: Center for Tobacco Products (CTP)
- 2022 Update to the Focus Areas of Regulatory Science (RaS) Report

Goal and Agenda

- Goal: To familiarize faculty with FDA outcomes of interest for regulatory science research projects
- Regulatory Science
- Office of Regulatory Science and Innovation (ORSI)
  - University of Maryland Center for Excellence in Regulatory Science and Innovation (CERSI)
  - Outcomes of Interest for Regulatory Science Research Projects

When does FDA apply regulatory science?

- Some examples of employing tools, standards, and approaches:
  - Investigational New Drug (IND) application assessment
  - Premarket Approval (PMA) application assessment
  - Biological License Application (BLA) assessment
  - Risk Evaluation and Mitigation Strategy (REMS) program
  - Post-market surveillance
  - Designing product manufacture (including manufacturing changes over product lifecycle)
  - Safety, efficacy, quality, and performance
- Drug label: https://labels.fda.gov/
- FDA Guidance: https://www.fda.gov/regulatory-information/search-for-guidance-documents
- Consumer Updates: https://www.fda.gov/consumer/consumer-updates

Office of Regulatory Science and Innovation (ORSI)

- Located within Office of the Chief Scientist, within Office of the Commissioner
- Mission: FDA continues to have a strong regulatory science foundation
- Centers of Excellence in Regulatory Science and Innovation (CERSIs)
  - M-CERSI (https://cersi.umd.edu/)

Office of Regulatory Science and Innovation (ORSI)

- FDA-regulated products
- Cross-cutting areas to transform how FDA-regulated products are developed, evaluated, surveilled and used
  - e.g. digital health, artificial intelligence, data science, alternative methods, One Health, patient-centered outcomes, and behavior change/social science
- Health of the demographic groups and populations with clinical characteristics which may frequently preclude their participation in clinical research
  - e.g. racial and ethnic minorities; sex and gender minorities; persons who are immunocompromised; persons who are pregnant and lactating
Regulatory Science Framework and Examples

- Modernize development and evaluation of FDA-regulated products
  - Alternative methods to animal studies; advanced manufacturing approaches; biomarkers tools; novel clinical trial designs
- Strengthen post-market surveillance and labeling of FDA-regulated products
  - Approaches for assessing stability, reliability (fit-for-purpose), and relevance of real-world data (RWD); artificial intelligence approaches
- Invigorate public health preparedness and response of the FDA, patients and consumers
  - Mitigate antimicrobial resistance; strengthen patient and consumer engagement and communication; medical product shortages

Outcomes of Interest for Regulatory Science Research Projects

- Disseminate scientific knowledge
- Catalyze action among relevant stakeholders
  - Industry uses regulatory science outcome in premarket submission
  - Inclusion into clinical practice
- Inform regulatory decision making
  - FDA utilizes relevant methods/outcomes in regulatory submission
  - FDA guidance
  - Change in consensus standard
  - FDA surveillance strategy
  - Change in labeling
  - https://www.fda.gov/science-research/advancing-regulatory-science/outcomes-interest-regulatory-science-research-projects

Thank you!