

FDA Interests in Regulatory Science



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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 (M-CERSI)
- Outcomes of Interest for Regulatory Science Research Projects



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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 cosmetics - Center for Food Safety and Applied Nutrition (CFSAN)
 - Dietary supplements
 - Tobacco products - Center for Tobacco Products (CTP)
- 2022 Update to the Focus Areas of Regulatory Science (FARS) Report
 - <https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science-report>



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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
 - Biologics License Application (BLA) assessment
 - Risk Evaluation and Mitigation Strategy (REMS) program
 - Post-market surveillance
 - Ongoing 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-fda-guidance-documents>
 - Consumer Updates: <https://www.fda.gov/consumers/consumer-updates>



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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)
 - <https://www.fda.gov/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis>
 - M-CERSI (<https://cersi.umd.edu/>)



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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



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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 viability, 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



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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>



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Thank you !



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