FDA Center/Office Regulatory Science Research Priority Areas

February 5, 2018

FDA has identified the following priority areas for Centers of Excellence in Regulatory Science and Innovation (CERSIs) research, based on the Agency's current unmet regulatory science needs. This list will be updated periodically as FDA's needs change.

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1. **High-priority topics, with needs across product lifecycle and relevant subpopulations (sex, gender, age, race/ethnicity):**
    a. Tobacco, including, but not limited to toxicity, addiction, health effects, behavior, and communications. See link on CTP research priorities for more information.
    b. Reducing healthcare-associated infection:
        i. Better understanding of the effectiveness of sterilization and reprocessing of medical devices
        ii. Further development of pathogen-reduction technologies for whole blood and blood components
        iii. Promote development of innovative antimicrobial approaches
    c. Issues related to opioid use, misuse, and dependence
2. **Develop and evaluate methods to improve quality and safety of FDA-regulated products for use by patients and consumers, including methods to improve predictive value of nonclinical evaluation**
    a. Methodologies for development, manufacturing/quality control of complex generic drugs, biosimilars, biological products, and medical devices
    b. Biocompatibility and biological risk evaluation of medical devices and their component materials
    c. Evaluation of innovative methods such as:
        i. Microphysiological systems (MPS) (organs on a chip)
        ii. Computer modeling and simulation (e.g., in silico clinical trials and biocompatibility modeling)
        iii. Discovery and validation of minimally invasive biomarkers particularly for diseases and medical states where few markers exist (such as traumatic brain injury), including predictive microbiome biomarkers and use of current methods such as EEG and bio-imaging.
3. **Develop methods and tools to improve and streamline clinical and postmarket evaluation of FDA-regulated products, including**
    a. Scientifically valid approaches to incorporating patient input (e.g., patient preference, patient reported outcomes) into regulatory decision-making
    b. Complex adaptive, Bayesian, and other novel clinical trial designs
    c. Approaches to leveraging large, complex data to inform regulatory decision-making, including use of “real world” data sources and mobile technologies
    d. Evaluation of product safety and efficacy in special populations, such as maternal, pregnant, and lactating women, perinatal, pediatric, and geriatric individuals
    e. Subpopulation evaluations based on age, sex, gender, race and ethnicity, including evaluation of:
        i. Safety and efficacy
        ii. Effective comprehension and usability of FDA communications

    See links on Office of Women’s Health (OWH) Research Roadmap and Office of Minority Health (OMH) Research and Collaboration Program for more information.