CDRH Broad Agency Announcement: Highlighted Research Areas of Interest

Michele Lee, PhD

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Division of All Hazards Response, Science, and Strategic Partnerships

Partnerships to Advance Innovation and Regulatory Science

CDRH Research Areas of Interest: Highlights

- Health Equity
- Communication to Patients & Consumers
- Patient Science and Engagement
- Real-World Data, Real-World Evidence, and Clinical Investigation Design
- Digital Health
- In Vitro Diagnostics
- Advanced Manufacturing and Quality
- Medical Countermeasures (MCMs), Resilient Supply Chain

Health Equity

- Evaluate the effectiveness of interventions designed to **enroll diverse populations** in device clinical trials such as digital health technologies and decentralized clinical trials
- Understand the impact of **remote assessments and decentralized procedures** on underrepresented subgroups
- Improve clinical study design & conduct to better **identify and evaluate possible differences** related to racial & ethnic minority and pediatric populations
- Develop **methods to evaluate the magnitude of impact** of morbidity and mortality on pediatric populations (especially younger subpopulations), and on resource utilization within the healthcare system due to the relative lack of devices designed, evaluated, and labeled for pediatric populations and the associated need for “off-label” or physician-directed care

Communication to Patients & Consumers

- Assess awareness and understanding of FDA communications, especially among diverse audiences and populations, and identify **methods to improve the comprehension of content**
- Identify methods to improve the comprehension and usability of FDA communications, including **assessing health literacy, different formats, and amounts of numerical information** in FDA communications among those with low health literacy, low digital literacy, limited English proficiency, and cultural and language differences
- Identify and evaluate **best practices for user-centered recall communications**
- Evaluate timing of release of recall or warning messages, how and when these messages can enhance impact, and how to communicate recall updates and the end of a recall or warning

Patient Science and Engagement

- Develop and validate methods for collecting patient experience data
- Perform patient preference studies in preference sensitive areas for use in regulatory decision making (e.g., understanding benefit-risk tradeoffs, improving clinical trial designs, or prioritizing treatment outcomes)
- **Modify or adapt existing Clinical Outcome Assessment instruments** for a new subpopulation (e.g. pediatric subpopulations), regulatory use, intended use or context of use and collect evidence to support the modification or adaptation
- Foster and assess the development of **culturally and linguistically appropriate clinical outcome assessments and biomarkers** to better understand health inequities and develop improved medical products
- Improve upon patient science tools through targeted incorporation of diverse patient perspectives & integration of data from diverse patients
- Conduct **studies among racial and ethnic minority communities & underserved populations** (e.g., rural, elderly, pediatric populations and their parents/ caregivers) that investigate patient preferences in benefit-risk assessments to advance understanding and aid regulatory decisions

Real-World Data (RWD), Real-World Evidence (RWE) and Clinical Trial Design

- Leverage existing and future data to develop new tools and methodologies to harness big data and RWD to support regulatory decision-making
- Develop and validate tools and models that assess the **quality, interoperability, and utility of RWD** to support regulatory decision making
- Incorporate RWD sources in **innovative clinical trial designs**
- Develop and demonstrate tools for **assessing uncertainty around data elements** and drives for RWE study findings
- Develop **standards for data quality** and data sources that increase the quality, interoperability, and utility of RWD
- Design and optimize data infrastructure to **facilitate information exchange and data extraction**
- Medical device studies incorporating use of telemedicine and/or **decentralized approaches for patient assessments** to facilitate clinical trial enrollment
- Develop methods to harness clinical evidence and enhance evidence synthesis to **leverage RWD from multiple domains**

Digital Health

- Methods to evaluate the capture, transmission, aggregation, analysis, and use of digital health technologies (DHTs) to support medical product development and assessment
- Promote **user-centered transparency of digital health medical devices** (e.g., artificial intelligence/machine learning-enabled devices, virtual reality devices)
- Develop and validate methods to assess algorithm performance, including techniques to **manage bias for artificial intelligence**/machine learning-enabled medical devices
- Develop tools or methodologies to evaluate the **performance of large language models/generative AI** as they are applied to devices including methodologies that would enable robust post-market monitoring to ensure continued high-quality performance of LLM-enabled devices, including identifying and preventing data drift, and ensuring ongoing model accuracy

Digital Health

- Develop methods to leverage RWD in support of evaluation of DHTs relating to **opioid use disorder (OUD)** and substance use disorder SUD
- **Engage academic and community medical centers**, patients, and other stakeholders in the evidence development needed for digital health technologies for OUD and SUD
- Understand the **impact of remote assessments and decentralized procedures** (e.g., e- consent, telemedicine, collecting laboratory and/or imaging data from local facilities) on underrepresented subgroups (e.g., rural, pediatric, elderly, or tribal populations) participating in device clinical trials
- Develop **methods to incorporate data from DHTs** not in EHRs into patient care beyond clinical trials

In Vitro Diagnostics

- Support the **capture, harmonization, transmission, aggregation, analysis, and use of high-quality, interoperable diagnostic data** from real-world settings to aid in pre-market submissions, post-market review and/or surveillance
- Investigate precision medicine and biomarkers for predicting medical device performance, disease diagnosis and progression
- Demonstrate how terminology for encoding biomarkers in RWD can integrate with patient care data encoding standards (SNOMED, LOINC, and RxNorm)
- Improve existing or develop new approaches to **enhance agility, quality and consistency** of regulatory submission data, and to **harmonize standards for data synthesized across multiple sources**, including data captured from IVDs
- Develop methods to better **encode physiologic and social determinants of health data elements** that pertain to safety & efficacy of diagnostics & therapeutics targeting women

Advanced Manufacturing and Quality

- Facilitate development and evaluation of **automated or semi-automated in-process monitoring and control systems** and methods
- Investigate the effect of advanced manufacturing on product quality. Examine specific **novel material and manufacturing technologies** to determine how they impact product failure rates
- Investigate the **effects in supply chain** of implementing advanced manufacturing for specific types of medical products
- Develop standardized methods for devices to **dynamically update** their data dictionary and related embedded software to respond to new data needs
- Develop improved methods and tools for the validation and lifecycle maintenance of digital technologies supporting Industry 4.0 for device manufacturing including **data capture and storage, adaptive process control, digital twins, and internet of things**

Medical Countermeasures (MCMs), Resilient Supply Chain

- Advance the development of novel materials for manufacturing of respirators and other personal protective equipment including the development of integrated virocidal or other infection control blocking capabilities
- Support **enhanced data agility of data collection** using medical devices and through the use of enhanced data collection methods associated with medical products that could be harnessed during public health emergencies
- Explore novel approaches, technologies, platforms, and frameworks to increase the ability of suppliers' flexibility and **ability to respond to supply disruptions** and streamline supply chains.
- Advance the development of tools to enable the **rapid development and availability of investigational MCMs**
- Evaluate methods for facilitating and incentivizing the production and development of MCMs or MCM supply chain within the U.S
- Develop analytical models to **assess the risk of device recalls and shortages on small and special populations**, especially pediatric populations


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