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# CDRH Broad Agency Announcement: Highlighted Research Areas of Interest


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*Partnerships to Advance Innovation and Regulatory Science*

# Research Areas of Interest: Highlights

- Health equity
- Patient science and engagement
- Digital health
- Real-world data, real-world evidence and clinical investigation design
- In vitro diagnostics
- Advanced manufacturing
- Resilient supply chain, medical countermeasures, and sterilization


# Advance Health Equity

"CDRH can advance the development of knowledge and safe and effective technologies to meet the needs of *all patients and consumers*"

https://www.fda.gov/media/155888/download

# Health Equity

- **Culturally and linguistically appropriate** clinical outcome assessments and biomarkers to better understand health inequities and develop improved medical products
- **Patient preference studies among racial and ethnic minorities and underserved groups** (e.g., rural, elderly) to investigate benefit-risk assessments to advance understanding and aid regulatory decisions
- **Impact of remote assessments and decentralized procedures** (e.g., e- consent, telemedicine, collecting laboratory and/or imaging data from local facilities) on underrepresented subgroups participating in device clinical investigations
- Develop framework for **assessing clinical site readiness** to achieve adequate enrollment of participants from **historically under-represented racial/ethnic subgroups** in medical device clinical investigations
- Utilize **large, pooled clinical trial datasets** to identify potential biomarkers and trial endpoints, explore **differences in specific populations and subpopulations**
- Identify and develop interfaces to **access large medical databases** (e.g., EHR, claims, registries) to improve safety and effectiveness evaluations in patient subpopulations

# Patient Science & Engagement

- Approaches to streamlined **adaptation or modification** of existing validated **PRO instruments** to other sub-populations or regulatory uses
- Methods for collecting patient experience data
- **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)
- **User-centered transparency** of 1) digital health technologies, including artificial intelligence/machine learning (AI/ML)-enabled devices), 2) recall communication
- Strategies to improve the **comprehension of CDRH communications**, including appropriate level of detail for patients, timing of communication, understanding in diverse audiences including accounting for differences in literacy and health literacy

# Digital Health

- Explore the **role of digital health technologies (DHTs)** in the evaluation of new medical devices
- Methods to support **analytical and clinical validation** of biomarkers
- Advance methods to assess **digitally-derived endpoints**
- Interventions designed to **enroll diverse populations** in device clinical trials such as digital health technologies, decentralized clinical trials, patient/community/language navigators
- Methods to evaluate the **capture, transmission, aggregation, and analysis of data from DHTs** to support medical product development and assessment
- Develop and validate methods to **assess algorithm performance**, including techniques to **manage bias** for artificial intelligence/machine learning-enabled medical devices
- Methods to **leverage RWD and other forms of evidence** in support of evaluating DHTs relating to **opioid use disorder and substance use disorder**

# RWD/RWE and Clinical Investigation Design

- **Novel clinical investigation designs** using telemedicine and/or decentralized approaches to facilitate clinical trial enrollment of underserved populations, improved data collection, and evidence generation tools
- Identify develop and **evaluate data sources and efficient techniques for data mining, data linkage, and large data set analysis** to assess the safety and effectiveness of devices in underserved populations
- New tools and methodologies to **harness big data and RWD** to support regulatory decision-making
- Advance methodologies to **generate clinical evidence from RWD** sufficient to support regulatory use
- Develop and demonstrate tools for **assessing uncertainty around data elements** and drivers for RWE study findings
- Develop **standards for data quality** and data sources that increase the quality, interoperability, and usability of RWD
- Design and optimize data infrastructure to **facilitate information exchange and data extraction**
- Approaches to enhance quality and consistency of regulatory submission data, and to harmonize **standards for data synthesized across multiple sources**, including data captured from in vitro diagnostic devices

# In Vitro Diagnostics

- Support the **capture, harmonization, transmission, aggregation, analysis, and use of high-quality, interoperable diagnostic data** from real-world settings to evaluate in vitro diagnostic devices and other medical product performance during clinical trial development, premarket review, post-market review and/or surveillance of safety and performance of IVDs and other medical products
- Explore how RWD obtained from **in vitro diagnostic devices** can be used to **inform public health decision-making** in the premarket and post-market settings
- Develop standardized methods for devices to **dynamically update their data dictionary and related embedded software** to respond to new data needs, such as those driven by public health response to emerging threats
- 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

# Advanced Manufacturing and Quality

- Develop and validate methods to create **digital twins**
- Facilitate development and evaluation of 1) test and validation metrics for **advanced manufacturing processes**, and 2) how **implementation of digital technologie**s in product design, development, and life cycle risk management impacts the control, responsiveness, and product quality
- Develop and evaluate the use of **model-based digitally integrated systems**, **artificial intelligence**, **machine learning**, and **simulation** in production or quality system activities
- Advance the study of **quality management maturity**, **capability maturity**, and **organizational excellence**

# Resilient Supply Chain, MCM, Sterilization

- Develop **predictive models** that **identify risks** across the supply chain regardless of the product or its origin
- Approaches to better **aggregate and analyze multiple sources of information** to fully identify supply chain risks and emerging trends
- **Filter and analyze external indicators/signals/environmental vulnerabilities** in the supply chain to proactively identify the need for appropriate FDA interventions
- Modernize tools to evaluate **medical countermeasure (MCM) products** and secure the MCM **supply chain**
- Evaluate the use of **computational modeling and simulation** to improve or optimize device sterilization processes
- Develop approaches for collecting data on **mortality and reuse** among patients exposed to **capital and reusable devices**

# Resources

- MDUFA V Commitment
- CDRH 2022 – 2025 Strategic Priorities
- AI/ML-Based Software as a Medical Device (SaMD) Action
- Spotlight:  Digital Health Regulatory Science Research Opportunities
- Advancing Digital Health Medical Devices for Opioid Use Disorder
- Food and Drug Administration Overdose Prevention Framework