CDRH Broad Agency Announcement: Highlighted Research Areas of Interest

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Highlighting CDRH Research Areas of Interest

- Patient-Centered Development
- Digital Health Technologies
- Medical Device Innovation & Total Product Life Cycle Advisory Program (TAP)
- Advancing Health Equity

Patient-Centered Development

Charge I. Modernize development and evaluation of FDA-regulated products
Section E. Clinical Outcome Assessment (COA):

- **Modify or adapt** existing COA 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.
- Explore combined use and retrospective performance of **COAs and Patient-Generated Health Data (PGHD) in clinical datasets and/or artificial intelligence** (AI) studies.
- Identify and if possible, quantify, **known biases** (e.g., open-label bias, placebo effect, sex/gender bias) for Patient-Reported Outcomes (PROs).
- Investigate patient preferences in benefit-risk assessments and clinical trial design (including endpoints) **in racial and ethnic minority communities and underserved populations** (e.g., rural, elderly, pediatric populations and their parents/ caregivers).

Patient-Centered Development

Charge I. Modernize development and evaluation of FDA-regulated products
Section I. Approaches to Incorporate Patient and Consumer Input:

- Perform **patient preference studies** in preference sensitive areas for use in regulatory decision making for benefit-risk and beyond
- Investigate the aggregation of multiple patient preference studies for the assessment of new medical devices. Specifically, estimate and characterize the distribution of patients' **maximum acceptable risk** of harms or **minimum acceptable benefits** based on *publicly available* information for a broad spectrum of patients
- Investigate thematic elements of patient perspectives across *publicly available* device-related workshops and meetings to **understand key factors that influence patient and consumer decision-making** including but not limited to benefit/risk, outcomes of interest, and clinical study designs

Digital Health Technologies

Charge I. Modernize development and evaluation of FDA-regulated products
Section J. Methods to Assess Real-World Data (RWD) to serve as Real-World Evidence (RWE):

Charge II. Strengthen post-market surveillance and labeling of FDA-regulated products
Section A. Methods to Assess Real-World Data to Support Regulatory Decision Making:

- Advance tools and methodologies to **monitor & evaluate real-world performance of artificial intelligence (AI)** enabled technologies.

Digital Health Technologies

Charge II. Strengthen post-market surveillance and labeling of FDA-regulated products
Section B. Using and Validating Artificial Intelligence Approaches:

- 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.

Total Product Life Cycle Advisory Program (TAP)

Charge III. Invigorate public health preparedness & response of FDA, patients and consumers
Section G. Emerging Technologies

- Explore the value of innovators incorporating evidence generation **targeting requirements of downstream stakeholders** in the MedTech innovation space, for example, physician professional societies, payers, and patients into pivotal trial protocols to support commercialization and widespread availability of medical devices.

Advancing Health Equity

Charge I. Modernize development and evaluation of FDA-regulated products
Section F. Complex and Novel Clinical Trial Design

- Develop roadmaps and frameworks to **move from clinical sites to decentralized trials**. Explore what aspects are best suited for decentralized vs centralized clinical sites.
- Develop readiness models for both decentralized and clinical site studies in the areas of informed consent, **enrollment of underrepresented populations**, data collection, and post-trial communication.

Advancing Health Equity

Charge I. Modernize development and evaluation of FDA-regulated products
Section H. Methods for Assessing Behavioral, Economic, or Human Factors

- Explore the combined use of human factors engineering principles, patient science methods and patient engagement in device product design to **improve user experience of devices for all populations** (especially underrepresented, pediatric, elderly, rural, or tribal populations).
- Develop methods to identify and mitigate usability challenges related to sex- and gender-based differences. Support innovation in sex- and gender-conscious engineering design and development of medical devices.


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