U.S. FOOD & DRUG ADMINISTRATION

CDRH FY26

BAA Research Areas of Interest

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Highlighted Research Areas of Interest

1. New Approach Methodologies (NAMs)
2. Cybersecurity of Medical Devices
3. Artificial Intelligence (AI)
4. Patient-Centered Innovation
5. Future of Healthcare

NAMs & Cybersecurity

Charge I, Section A. New Approach Methodologies (NAMs)

- Develop and use NAMs approaches such as MPS, CIVM, and computational modeling to improve the predictability of nonclinical testing and support the regulatory assessment of medical products, potentially address the 3Rs **(replace, reduce, and refine) of animal use** in product testing and scientific research and support implementation of the Roadmap to Reduce Animal Testing in Preclinical Safety Studies.

Charge III, Section E. Emerging Technologies, Cybersecurity

- Investigate solutions to provide further clarity on **industry cybersecurity challenges** (e.g., legacy landscape and solutions, patient impact of vulnerabilities, etc.) to address emerging new technologies and their cybersecurity risks.

Artificial Intelligence (AI)

Charge II, Section A. Methods to Assess Real-World Data

- Advance methodologies to **monitor and evaluate real-world performance of AI** enabled medical devices.

Charge II, Section B. Using and Validating Artificial Intelligence Approaches

- Develop and validate methods to **assess algorithm performance**, including technologies to manage methodological or statistical bias for AI/ML-enabled devices.
- Develop tools or methodologies to **evaluate the performance of LLMs/ 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.

AI in Patient-Centered Innovation

Charge I, Section E. Clinical Outcome Assessment (COA)

- Explore combined use and retrospective performance of **COAs and Patient-Generated Health Data** in clinical datasets and/or artificial intelligence studies.

Charge I, Section J. Approaches to Incorporate Patient & Consumer Input

- Investigate the use of AI/ML to **identify patient perspectives** and/ or confirm patient perspectives from curated sources (i.e., patient support groups, registries, etc.) to understand patient and consumer decision-making including but not limited to benefit/ risk, meaningful outcomes, and clinical study designs.

Future of Healthcare

Charge III, Section E. Emerging Technologies

- **Human-Centered Design and Usability**: Evaluate and establish best practices for device and software design that account for the varied cognitive, physical and environmental realities of home use by lay-users and their caregivers, including factors like caregiver burden and multi-generational household dynamics.

- **System-Level Interoperability and Safety**: Develop methodologies to assess the safety and performance of multi-vendor medical device ecosystems within the home. This includes integration with non-medical consumer platforms (e.g., home automation standards) and creating frameworks for system-level risk assessment.

Future of Healthcare

Charge I, Section H. Methods for Assessing Behavioral, Economic, or HF

- Develop and evaluate options to improve financing and reimbursement, and **de-risk business investment early** in the development process, to increase breakthrough medical device development and innovation.

Charge III, Section E. Emerging Technologies

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


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Additional Areas of Interest

Charge I, Section J. Approaches to Incorporate Patient & Consumer Input

- Explore the use of patient and consumer input to de-risk the development of medical devices (for example, the use of **patient preference information early in development** to determine endpoint prioritization, or to lower clinical trial barriers to participation, or to increase post-market uptake, or as input in content generation for COAs to facilitate the endpoint definition, measurement, reporting and evaluation).

Charge I, Section K. Methods to Assess Data Source Interoperability

- Develop methods to **incorporate data from Digital Health Technologies (DHTs)** not in EHRs into patient care beyond clinical trials.