ConnectedHealthInitiative

May 2, 2024

International Medical Device Regulators Forum
United States Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland 20993-0002

RE: ***Connected Health Initiative Comments on the International Medical Device Regulators Forum's Proposed Document, 'Medical Device Software: Considerations for Device and Risk Characterization'***

The Connected Health Initiative (CHI) writes to provide input to the International Medical Device Regulators Forum (IMDRF) on its Proposed Document, Medical Device Software: Considerations for Device and Risk Characterization.[1]

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all patients benefit from an information and communications technology-enabled healthcare ecosystem. For more information, see www.connectedhi.com.

Medical device software has radically improved, and continues to radically improve, healthcare systems around the world. Mobile-app enabled telehealth and remote monitoring of patient-generated health data continues to represent the most promising avenue for improved care quality at lower cost. Further, as IMDRF notes, medical device software also includes artificial intelligence (AI) tools which, powered by streams of data and advanced algorithms, have incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and improve patient engagement.

We support the IMDRF's work to promote and inform clear and accurate characterizations of medical device software (including intended use/intended purpose statements) and introduce a general strategy for characterizing software-specific risks that leverages the key features of a comprehensive medical device software characterization. CHI generally supports the IMDRF's medical device software framework utilizing risk-based approaches that align the use of AI with recognized standards of safety, efficacy, and equity. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. The IMDRF's medical device software framework should ensure that those in the value

[1] https://www.imdrf.org/consultations/principles-and-practices-cybersecurity-legacy-medical-devices

chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. CHI also supports the IMDRF's medical device software framework providing that:

- Medical device software is safe, efficacious, and equitable;
- Developers tie medical device software systems to clinical outcomes research;
- The medical device software framework is based on a standardized nomenclature and terminology;
- Medical device software algorithms, datasets, and decisions are auditable and when applied to medical care (such as screening, diagnosis, or treatment) are clinically validated and explainable;
- Medical device software developers consistently utilize rigorous procedures, documenting their methods and results;
- Those developing, offering, or testing medical device software provide truthful and easy to understand representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the medical device software solution; and
- Adverse events are timely reported to relevant oversight bodies for appropriate investigation and action.

CHI also supports for the IMDRF's medical device software framework including the concept of thoughtful design. The IMDRF's framework should support the design of medical device software systems being informed by real-world workflow, human-centered design and usability principles, and end-user needs. Also, medical device software should help patients, providers, and other care team members overcome the current fragmentation and dysfunctions of the healthcare system. Medical device software solutions should facilitate a transition to changes in care delivery that advance the Quadruple Aim. The design, development, and success of medical device software should leverage collaboration and dialogue between caregivers, technology developers, and other healthcare stakeholders to have all perspectives reflected in medical device software solutions.

CHI notes that the IMDRF's risk framework for SaMD does not entirely account for issues unique to AI. For example, the IMDRF SaMD risk tables do not account for the added dimensions of autonomy level and whether a system is "locked" or "continuous," which have significant impacts on the design and validation to ensure safe, effective, and equitable AI systems. Therefore, in its medical device software framework, we urge IMDRF to consider aligning its approach to AI software with the following CHI resources:

- CHI's *Health AI Policy Principles*, a set of recommendations on the wide range of areas that should be addressed by policymakers examining AI's use in healthcare (available at https://bit.ly/3m9ZBLv);

- CHI's *Health AI Roles and Interdependencies Framework*, which describes the health AI value chain, defining actors and describing roles for ensuring safety and efficacy as well as the interdependencies between these actors (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf);
- CHI's *Good Machine Learning Practices for FDA-Regulated AI*, a proposed risk-based approach to benefit the Food and Drug Administration (FDA) as it addresses both locked and continuously-learning AI systems that meet the definition of a medical device (https://bit.ly/2YaYljk); and
- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5).

CHI appreciates the opportunity to submit its comments to IMDRF and urges consideration of the above input.

Sincerely,

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