SPECIAL ARTICLE

MAYO CLINIC PROCEEDINGS: DIGITAL HEALTH

MAYO CLINIC

Embedding Internal Accountability Into Health Care Institutions for Safe, Effective, and Ethical Implementation of Artificial Intelligence Into Medical Practice: A Mayo Clinic Case Study

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Abstract

Health care organizations are building, deploying, and self-governing digital health technologies (DHTs), including artificial intelligence, at an increasing rate. This scope necessitates expertise and quality infrastructure to ensure that the technology impacting patient care is safe, effective, and ethical throughout its lifecycle. The objective of this article is to describe Mayo Clinic's approach for embedding internal accountability as a case study for other health care institutions seeking modalities for responsible implementation of artificial intelligence–enabled DHTs. Mayo Clinic aims to enable and empower innovators by (1) building internal skills and expertise, (2) establishing a centralized review board, and (3) aligning development and deployment processes with regulations, standards, and best practices. In 2022, Mayo Clinic established the Software as a Medical Device Review Board (The Board), an independent body of physicians and domain experts to represent the organization in providing innovators regulatory and risk mitigation recommendations for DHTs. Hundreds of digital health product teams have since benefited from this function, intended to enable responsible innovation in alignment with regulation and state-of-the-art quality management practices. Other health care institutions can adopt similar internal accountability bodies using this framework. Opportunity remains to iterate on Mayo Clinic's approach in alignment with advancing best practices and enhance representation on The Board as part of standard continuous improvement practices.

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In safety-critical industries, a common pattern tends to emerge when technology iterates and evolves: innovations trigger rapid change, which in turn, results in a reaction by regulatory agencies seeking to promulgate standardized methodologies to protect the public. When novel technology introduces concepts or features that cannot be evaluated under existing laws or regulations, lawmakers and regulatory agencies respond to ensure continuity of public protection and safety.[1,2]

This pattern is frequently observed in the health care industry, wherein research and discoveries drive modifications to the standard of care that may improve diagnostic accuracy, clinical workflows, therapeutic options, and, ultimately, patient outcomes. The rate at which innovations have been introduced into health care has grown remarkably since the wide-scale adoption and application of artificial intelligence (AI). Many of these innovations are led by health care professionals who identify a problem or opportunity in practice and develop AI-enabled digital health technologies (DHTs) to address the problem or opportunity.[3]

To enable the next frontier of implementing AI-enabled DHTs at scale in practice,

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health care institutions must prioritize embedding enterprise accountability into their organizations to centralize monitoring, interpreting, and applying relevant laws, regulations, and best practices for these technologies. This article describes the approach taken by Mayo Clinic to establish internal accountability mechanisms that promote safe, effective, and ethical deployment of AI. With this approach, Mayo Clinic aims to enable and empower innovators by (1) building internal skills and expertise, (2) establishing a centralized review board, and (3) aligning development and deployment processes with regulations, standards, and best practices.

EMBEDDING INTERNAL ACCOUNTABILITY FOR AI

With known (and unknown) risks affiliated with the use of AI in medicine, federal regulations are evolving to apply more oversight to this emerging technology. These regulations include the White House Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence[4] and agency regulation and proposed rules from the Food and Drug Administration (FDA),[5] the Office of the National Coordinator for Health Information Technology,[6] and the Office for Civil Rights.[7]

Although regulatory rigor is intended to promote controls to further the safety, efficacy, and equity of these AI-enabled DHTs, it can also pose challenges for entities attempting to keep up with the evolving regulatory landscape. These challenges can be particularly daunting for health care institutions, which often do not have embedded expertise on staff, nor do they have infrastructures primed for quality management system regulations required for products that meet the definition of a medical device.[8]

Presently, health care institutions have numerous well-established governance functions that contribute to the internal accountability for AI-enabled DHTs, including institutional review boards (IRBs) and adherence to frameworks related to information security, data protection, and privacy. These governance functions operate effectively within the scope of their purpose. For example, IRBs are intended to review and monitor research involving human patients for the protection of their rights and welfare.[9] These existing accountability functions typically support (1) enterprise privacy and security infrastructure, (2) products deployed under research, and/or (3) vended solutions deployed into practice. Although existing functions remain in effect, a governance gap remains for the product lifecycle of AI-enabled DHTs that are locally developed and deployed within health care institutions.

In response to this gap, Mayo Clinic established the Software as a Medical Device[5] (SaMD) Review Board (hereafter referred to as The Board) as an independent body that assesses risk and regulatory applicability for DHTs and provides recommendations for mitigation activities to be applied during the development and deployment process. This novel Board was intentionally scoped to integrate with existing internal governance functions and augment external oversight bodies, adhering to the FDA regulations and international standards. The Board integrates with internal governance functions (eg, legal, privacy, and IRB) by including membership from each domain and delivering a sharable report with details of the regulatory analysis. Integrating rather than replacing existing governance functions was done to leverage existing frameworks with augmented support for AI and avoid the pitfalls of redoing all frameworks for each new technology.

Pragmatically, standing up The Board to enable safe, effective, and ethical translation of AI-enabled DHTs from research into clinical practice necessitated the following: (1) hiring skilled professionals in the medical technology (medtech) field and (2) operationalizing an enterprise-wide multidisciplinary team to assess and provide regulatory and risk mitigation recommendations for AI-enabled DHTs.

BUILDING INTERNAL SKILLS AND EXPERTISE

Federal regulations and international standards related to the development and deployment of DHTs are rapidly picking up pace. This acceleration has led to increased complexity and uncertainty for innovators attempting to manage risks and implement appropriate quality and regulatory controls. Further, the evolving regulatory landscape

instills apprehension/unease in individual innovators who, without assurance that risks have been fully vetted, hesitate to make decisions on behalf of their institution. Assessing regulatory and patient risks of applying specific DHT solutions in clinical care often requires multidisciplinary subject matter expertise that would be infeasible to embed on every product team.

To encourage safe and compliant innovation at scale, Mayo Clinic leadership identified the need to hire experts with medtech industry experience to comprehensively assess and manage risks, including regulatory affairs/quality assurance and engineering experts from safety-critical industries. These functions are essential for creating institutional processes and applying risk mitigation-based practices that align with US FDA regulations and International Organization for Standardization (ISO) standards, irrespective of the software policies applicable to AI-enabled DHTs (ie, medical device, nonmedical device, and enforcement discretion).[10]

Beyond hiring personnel with skills that mirror those in the medtech industry, health care organizations are generally well-positioned to leverage existing clinical expertise and knowledge to review AI-enabled DHTs before, during, and after deployment. Given the volume and diversity of DHTs at Mayo Clinic, leadership determined that a centralized board to review targeted content (eg, regulated status of product and known risks) was necessary to apply rigor to the translation process and to streamline standardized reviews of these technologies.

ESTABLISHING CENTRALIZED REVIEW BOARD

Mayo Clinic established a risk-based framework for all DHTs, including those with AI functionality, to promote innovation while mitigating the potential harm to patients and the organization. This framework is led by The Board, an independent group of voting and nonvoting physicians and domain experts that assess applicable regulations and risk of harm for DHTs developed at Mayo Clinic.

Established in 2022, The Board's purpose is to support Mayo Clinic Enterprise in the development and deployment of DHTs, enabling innovation by alleviating the uncertainty associated with evolving regulatory standards. The Board ensures adherence to regulatory standards and best practices by proactively evaluating the risks posed by DHTs and making recommendations to minimize those risks. The mission of The Board is to ensure the safe, effective, and ethical use of DHTs across the practice.

The Board is a cross-functional group with representation from clinical, legal, business operations, research, and engineering. Decisions made by The Board are on the basis of FDA regulations, guidance documents, and other relevant publications that inform the development, testing, and deployment of DHTs.

To make informed decisions, an internal accountability body should be diverse, equitable, and inclusive and ensure adherence to the broader regulatory and ethical standards guiding health care practices. Additionally, Mayo Clinic is a physician-led organization.[11] Consistent with that model, most voting members are practicing physicians at Mayo Clinic representing diverse clinical domains, including gastroenterology, radiology, cardiology, pulmonology, neurology, and laboratory medicine/pathology.

All Board members maintain experience or proficiency in various facets of AI-enabled DHTs. Members skilled in regulatory and risk management provide The Board with the appropriate training and expertise to continuously update regulatory and risk-based recommendations to advance safe, effective, and ethical innovation within the enterprise.

The Board does the following:

1) categorizes the regulatory risk classification of the digital health solution, on the basis of precedent and FDA's current thinking represented by regulation, guidance, and international consensus standards;
2) provides a recommendation on whether the software is subject to FDA notification and review by using current law, FDA guidance, and industry knowledge; and
3) advises on the applicable controls necessary to comply with the latest regulations, international standards, and internally defined best practice.

The analysis conducted by The Board is on the basis of the same analysis recommended by the FDA in their Digital Health Policy Navigator.[12] FDA's determination on what is and is not subject to quality systems regulation is a determination made in part not only based off of interpreting laws and regulations but also on the basis of a risk analysis—the higher the risk, the higher the likelihood of falling under FDA's jurisdiction. The Board both interprets regulation as well as assesses specific product-level risks as a means to determine the applicability of regulation as well as provide recommendations back to the innovators on how to manage and control product risks.

The outputs of The Board aim to accelerate translation of digital technology, offset risks, and ensure Mayo Clinic's values are inherent to digital innovation. Digital health innovators across Mayo Clinic have leveraged The Board to receive assistance from the multidisciplinary team knowledgeable and skilled in the most current regulations, standards, and best practices. In addition, the output of The Board informs decision-making for numerous other departments across the organization, including governance and oversight committees, information technology, legal, and executive leaders seeking to learn more about the digital health landscape at Mayo Clinic.

THE BOARD'S PROCESS

Initial Intake and Triage

With the high demand for The Board services, an intake and triage process was created to allow The Board to prioritize those innovations that require a deeper review by the multidisciplinary team. Figure 1 highlights the evaluation process which has been applied to thousands of digital health solutions at Mayo Clinic. This process is also intended to align with the FDA's Digital Health Policy Navigator and the guidance documents that drive the interpretation of software functionalities.[12]

Abbreviated Review

Most of the proposed DHTs built internally do not meet the definition of a medical device or fall into a software function exempt from the definition of a medical device per the 21st Century Cures Act and FDA's interpretation of the Act.[13] In accordance with The Board's risk-based approach, these teams are provided with a fast-track recommendation from a regulatory expert without full Board review. Typically, this fast-track recommendation requires a few hours of time for the team to articulate the specific scope of their DHT and gather evidence of quality controls followed by a 30-

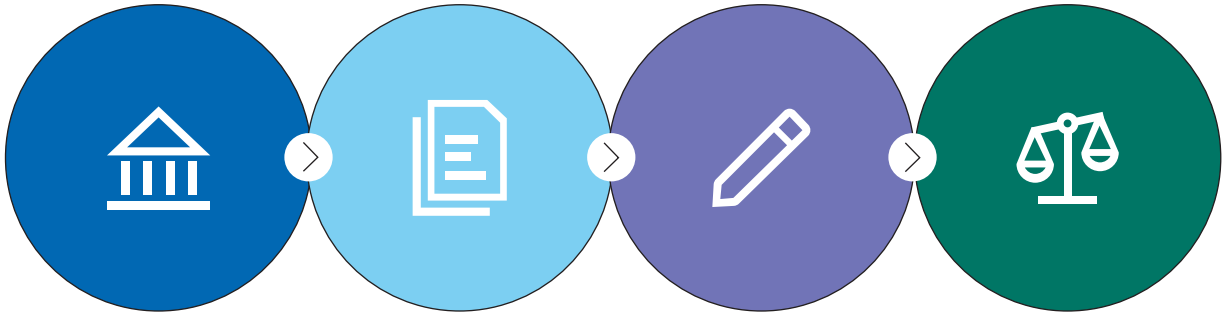

FIGURE 1. A visual representation of the Software as a Medical Device Review Board's process for evaluating the regulated status of a clinical decision support tool. FDA, Food and Drug Administration.

minute review by regulatory experts. This determination is provided to The Board in an offline review. However, a fast-track recommendation exempting innovation teams from deeper regulatory review and guidance on applicable controls does not exempt teams from the standards and best practices expected for software and AI solutions to ensure risks are appropriately mitigated.

In addition to The Board, Mayo Clinic has a robust review and assessment process available for AI, which includes empowering teams with guidance derived from regulatory bodies such as the FDA and Office of the National Coordinator for Health Information Technology.[6,14,15] These best practices are intended to ensure safety, efficacy, and ethics, including mitigation of bias, for all DHTs, irrespective of the regulated status. These recommendations can mitigate the risk of harm and introduce sufficient rigor in the design and development process to ensure agility within an evolving regulatory landscape for AI-based DHTs.

Furthermore, to ensure appropriate safety guardrails for AI-based DHTs not currently subject to regulation, recommendations are provided to maintain evidence of software development lifecycle best practices. This approach enables product development while supporting future modifications and enhancements. These activities may include the following:

- requirements and traceability
- change and configuration management
- verification and validation
- cybersecurity assessments
- data management

These recommendations are derived from policies and best practices represented as state-of-the-art in international standards.[16–19] In addition to the specific AI and software development lifecycle best practices informed by regulatory bodies, The Board also recommends that a risk-based framework be integrated into product development that considers potential patient harm and/or safety concerns before deployment. Product teams can work with regulatory experts to determine the rigor of the risk-based framework so that it is proportional to the functionality, pervasiveness, and dependency of the product in use.[8]

To maintain alignment with the predetermined software policy for nonmedical devices, product teams may also wish to collaborate with internal regulatory experts associated with The Board to appropriately scope communications in accordance with regulatory policies, including product instructions marketing materials, published articles, conferences, and presentations.

Full Review

DHTs that may be subject to FDA quality systems regulations necessitate further Board review. A more detailed analysis of the intended functionality and risks is conducted to consider the applicability of the software functionality to the exempt categories of administrative support, general wellness, or medical device data systems following FDA guidance.[13,20] The full review often spans approximately 2 weeks, involving iterative communication with the product team, followed by at least 1 convening of The Board to analyze and, in many cases, request further information before finalizing recommendations. The Board has received over (300?) requests for assessment, of which over (150?) have received a review with approximately (15%?) receiving a full review. When standing up The Board, we found the need to increase the number of dedicated subject matter experts to handle the expected volume and avoid the pitfall of becoming an organizational bottleneck.

Clinical decision support (CDS) software typically necessitates that The Board applies additional regulatory and risk analysis to determine whether the software functionality qualifies as a nonmedical device or medical device CDS. Per the established process, regulatory and domain experts first collect detailed information about the product and then apply a multistep process to validate the regulated status of that product, including comparison with existing devices and/or products (Figure 1). For these products, The Board begins by analyzing the proposed software function against the 4 criteria provided in the 21st Century Cures Act to qualify as "nonmedical device CDS" (Figures 2-5), which are not subject to FDA's jurisdiction.[13,21]

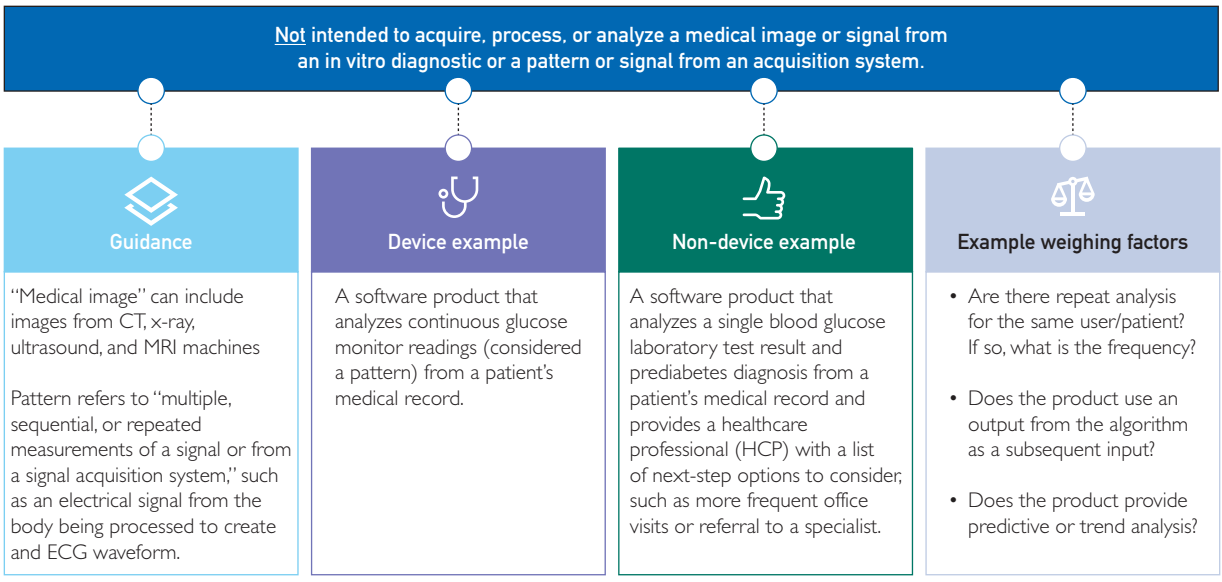

FIGURE 2. A summary of criterion 1 for nonmedical device clinical decision support software, including targeted language and examples from Food and Drug Administration's guidance document and weighing factors used by Mayo Clinic's Software as a Medical Device Review Board.[21] ECG, echocardiogram; CT, computed tomography; MRI, magnetic resonance imaging.

The Board relies on the FDA's current interpretation of the 21st Century Cures Act to assess risk and evaluate CDS tools. Generally, the FDA's CDS guidance document prompts The Board to rigorously identify whether the solution creates a higher-risk scenario through automation bias, such as providing a singular, specific disease output

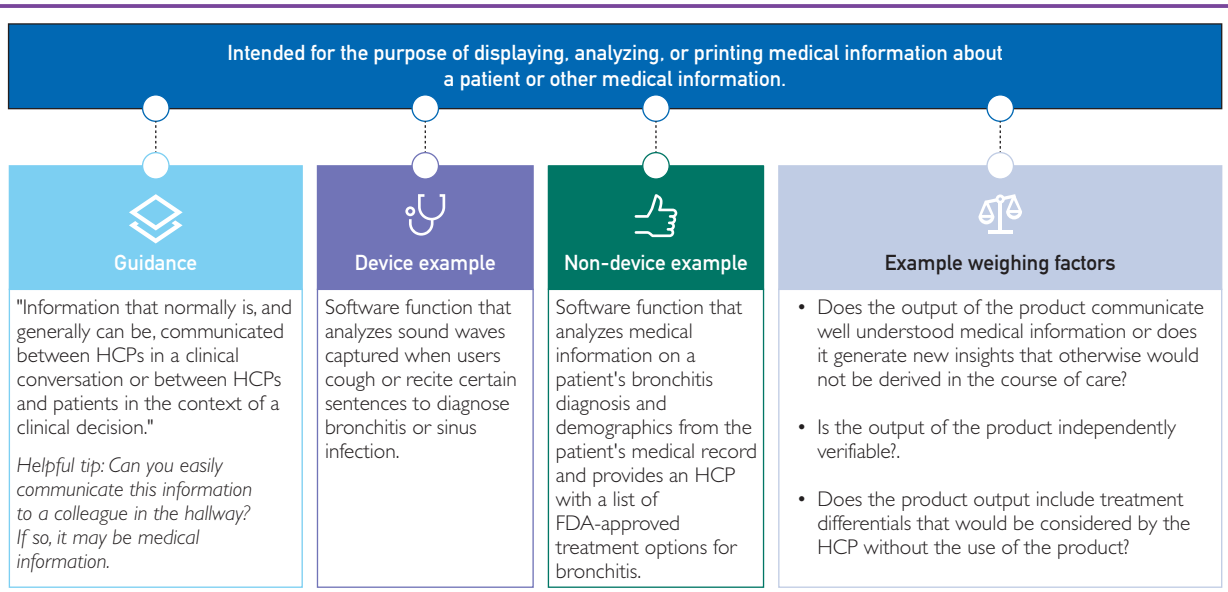

FIGURE 3. A summary of criterion 2 for nonmedical device clinical decision support software, including targeted language and examples from FDA's guidance document and weighing factors used by Mayo Clinic's Software as a Medical Device Review Board.[21] FDA, Food and Drug Administration; HCP, health care professional.

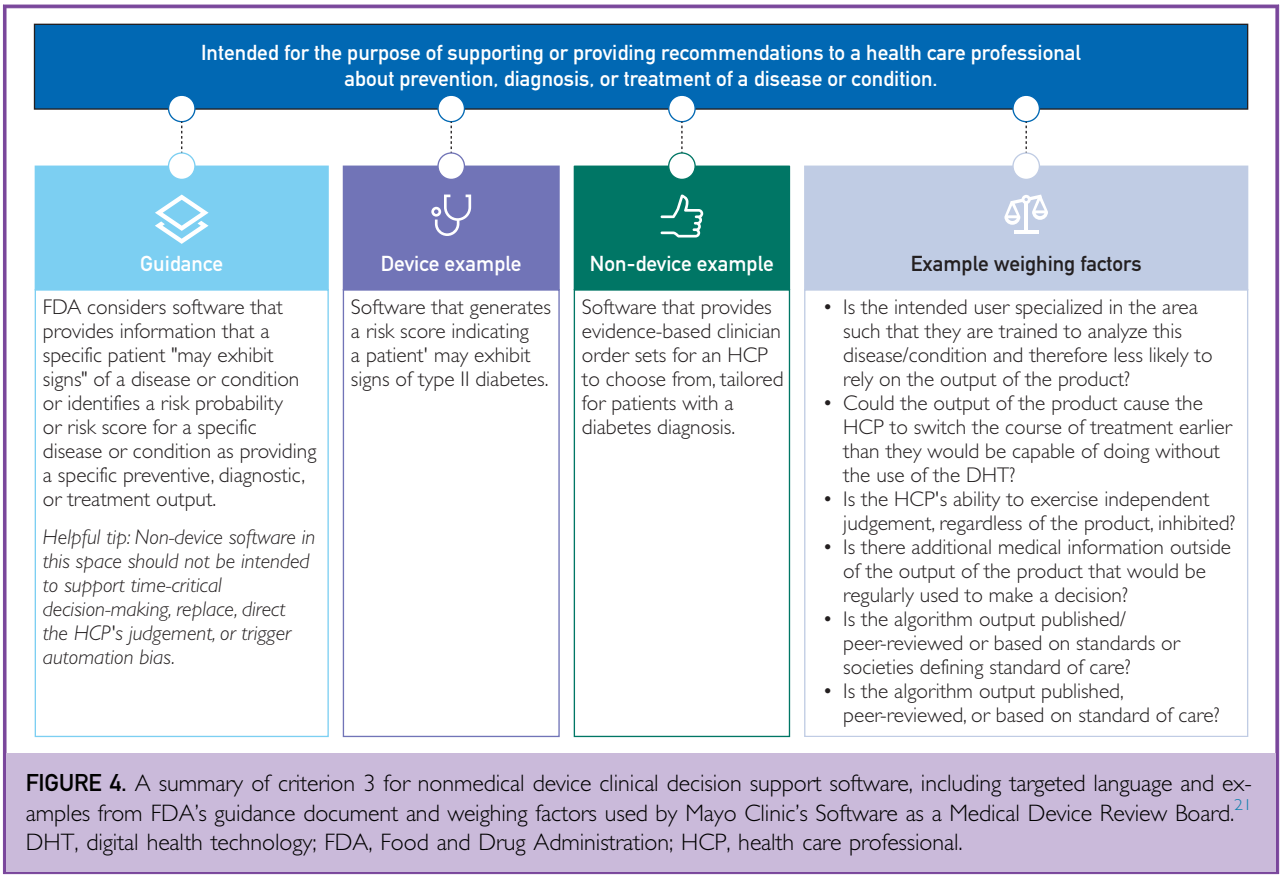

FIGURE 4. A summary of criterion 3 for nonmedical device clinical decision support software, including targeted language and examples from FDA's guidance document and weighing factors used by Mayo Clinic's Software as a Medical Device Review Board.[21] DHT, digital health technology; FDA, Food and Drug Administration; HCP, health care professional.

or being used in a time-critical scenario that offers little time for a health care professional user to consider alternative approaches.

Using examples from FDA guidance documents and previous evaluations from The Board, a consensus-based conclusion can often be reached by analogizing to established precedent. The Board also refers to its risk-based precedent, providing a methodology to continue building on the examples and set a more robust precedent for the organization. There are specific circumstances where FDA guidance is unclear, and The Board applies "weighing factors" that influence the satisfaction of the 4 criteria. These weighing factors also contribute to Board precedent, helping to streamline subsequent reviews and to consistently balance risk in making a final recommendation. Reference Figures 2 to 5 for the weighing factors applied for each criterion.

The review conducted by The Board results in a recommendation of regulatory applicability while simultaneously informing initial risk considerations as an input into Mayo Clinic SaMD quality management system. The Board recommends FDA controls for DHTs that are subject to quality systems regulations. These controls are defined in 21 CFR 820 quality systems regulation and informed by international standards recognized by FDA, including ISO 13485: Quality Management Systems, IEC 62304: Software Lifecycle Process, ISO 14971: Application of Risk Management, and ISO 62366: Application of Usability Engineering.

Limitations

Although strong patient representation exists at Mayo Clinic, the proprietary nature of the products under review and the consideration of business risks within The Board process currently impede The Board from establishing a direct link to patient review. Future opportunities include incorporating patient and societal perspectives in considering risks. Other

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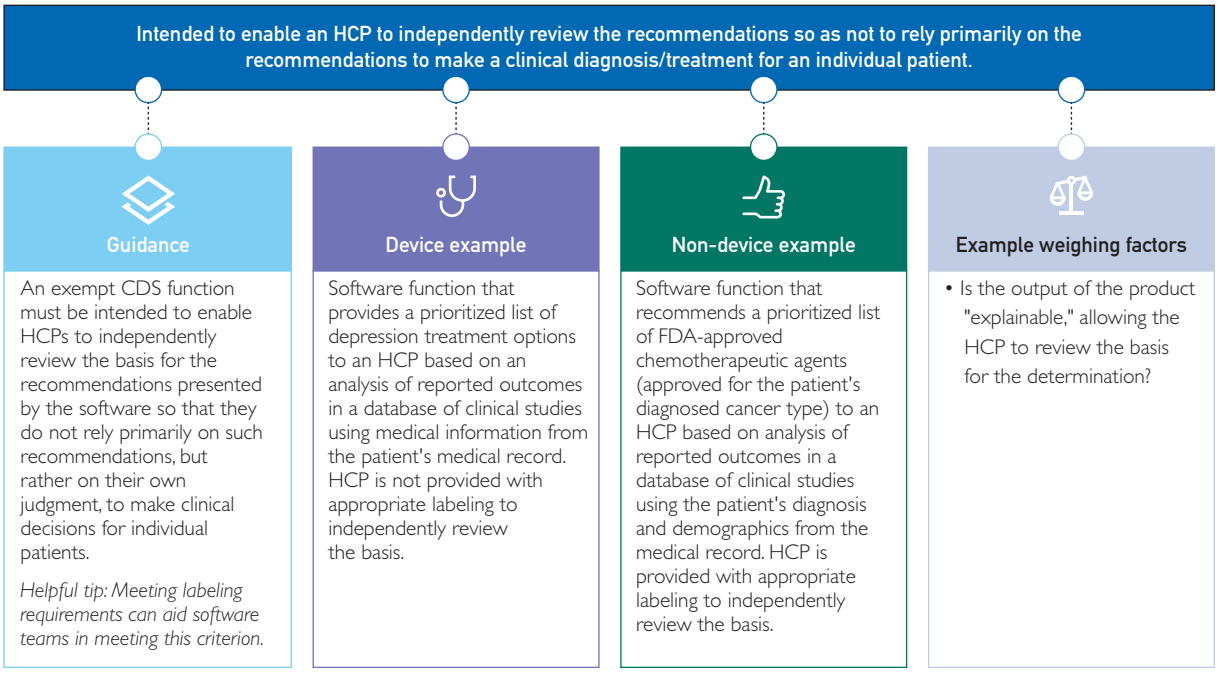

FIGURE 5. A summary of criterion 4 for nonmedical device clinical decision support software (CDS), including targeted language and examples from FDA's guidance document and weighing factors used by Mayo Clinic's Software as a Medical Device Review Board.[21] FDA, Food and Drug Administration; HCP, health care professional.

opportunities include diversifying the perspective of The Board, including representation from nursing allied health staff, other nonrepresented medical specialties, and operations.

Moreover, The Board necessitates industry regulatory and risk expertise to help inform the voting members and help follow through on recommended regulatory controls. Many health care organizations do not have such in-house resources, nor may they have the budgetary capacity to retain such expertise. Therefore, the creation of a similar internal accountability body within health care institutions may be hindered on the basis of the ability to hire or train staff to fill the roles needed to provide the requisite level of expertise on The Board.

We hope that by sharing the processes used at Mayo Clinic, we may help other health care organizations target practices that will work for their circumstances. FDA enforcement discretion on applicable policies for software functionality of digital health technologies is evolving. Interpretation of regulation and FDA guidance is consequently changing with little publicly available precedent. The authors recommend that health care organizations remain current on cleared FDA tools and precedent set by regulators to inform internal policies and best practices.

CONCLUSION

With access to extensive patient data, health care organizations are positioned to develop AI-enabled DHTs in-house, some of which are subject to regulatory requirements. These organizations likely lack robust regulation and governance to support safe, effective, and ethical implementation at scale over the product lifespan. Mayo Clinic established internal accountability for DHTs by creating a multidisciplinary Board to assess regulatory applicability and risks associated with the growing number of AI-enabled innovations emerging from our employees.

The Board enables internal innovators by providing an enterprise-level risk management process in alignment with applicable

regulations. The Board necessitates internal experts to inform health care professionals and optimize processes to review DHTs at scale. With hundreds of DHTs already benefiting from guidance and Board review, this regulatory and risk mitigation function at Mayo Clinic is a critical enterprise function enabling safe, effective, and ethical application of DHTs and AI into the health care setting.

POTENTIAL COMPETING INTEREST

Given her role as Guest Editor, Dr Overgaard had no involvement in the peer-review of this article and has no access to information regarding its peer-review. The authors report no competing interests.

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Abbreviations and Acronyms: **AI,** artificial intelligence; **CDS,** clinical decision support; **DHT,** digital health technology; **FDA,** Food and Drug Administration; **IRB,** institutional review board; **ISO,** International Standards Organization; **SaMD,** software as a medical device

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