



Digital Technology-Enabled Care Models for Diabetes:

A Framework for Developing Quality
Standards and Measures



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Contents

	EXECUTIVE SUMMARY	4
	A PRACTICAL FRAMEWORK TO GUIDE DEVELOPMENT OF QUALITY STANDARDS FOR DIABETES DIGITAL TECHNOLOGIES IS NEEDED	6
	Engaging Stakeholders in Developing a DDT Assessment Framework	7
	A Novel Approach to Categorizing DDTs	7
	Identifying a DDT Assessment Framework	9
	The Effectiveness of DDT-Enabled Care Models Will Drive Development of Quality Standards and Related Measures	10
	Looking to the Future	12
	CONCLUSION	13
	ACKNOWLEDGMENTS	14



Executive Summary

Diabetes is a highly prevalent, chronic health condition that has a profound impact on the lives of patients and caregivers. It is also exceptionally costly for public and private insurers, and places considerable demands on the health care delivery system. Patient behaviors (e.g., self-monitoring blood glucose, regular exercise) can improve diabetes outcomes, as can access to health care professionals who manage medications, coordinate care with specialists, and support patients with dietary and behavioral coaching and other services.

Given the persistent challenges of diabetes management for health systems, providers, patients, and caregivers, innovators have developed a variety of digital health tools specifically for diabetes, hereafter referred to as diabetes digital technologies (DDT). Although DDTs have proliferated in recent years, there are limited data supporting their efficacy, and many software products are not regulated by the Food and Drug Administration. These circumstances create challenges for stakeholders who want to make informed decisions about which technologies are best suited to their needs, or if they will use these technologies at all.

To address these challenges, the National Committee for Quality Assurance (NCQA) and the American Diabetes Association (ADA) hosted a roundtable discussion to set the stage for developing quality standards and measures for DDTs. A panel of experts with diverse perspectives and expertise was charged with three goals:

1. Refine and finalize a categorization scheme for DDTs that is suited to a structured assessment of these technologies.
2. Identify and prioritize criteria for assessing DDT categories.
3. Define next steps to facilitate mapping of DDT assessment criteria to future standards and/or accreditation programs.

The roundtable achieved all three goals, and identified additional considerations that will need to be addressed as work on DDT quality standards and measures proceeds. The panel's key recommendations and observations were:

- DDTs should be assessed on their ability to support care models (digital technology-enabled) that deliver high-quality care, and on the technologies' discrete properties.
- A diabetes-focused approach to quality standards and measures for digital technology-enabled care models could also be applied to other health conditions and environments.
- Design DDT quality standards and measures that address their effectiveness for diverse individuals, populations, and care environments, and other factors that drive equitable outcomes.
- Focus on developing DDT quality standards and measures that capitalize on information that can be gathered with relative ease.
- Incorporate enough flexibility to accommodate changes in the regulatory environment, reimbursement policy, care delivery mechanisms, and technology evolution.
- Preliminary DDT assessment criteria need additional prioritization.

Insights from the roundtable discussion center on the need to develop a roadmap that defines standards and quality measures for DDTs, and the feasibility of doing so. NCCQA and the ADA consider the time to be opportune for translating these insights into programs designed to identify DDT-enabled care models that will best meet the needs of people living with diabetes.





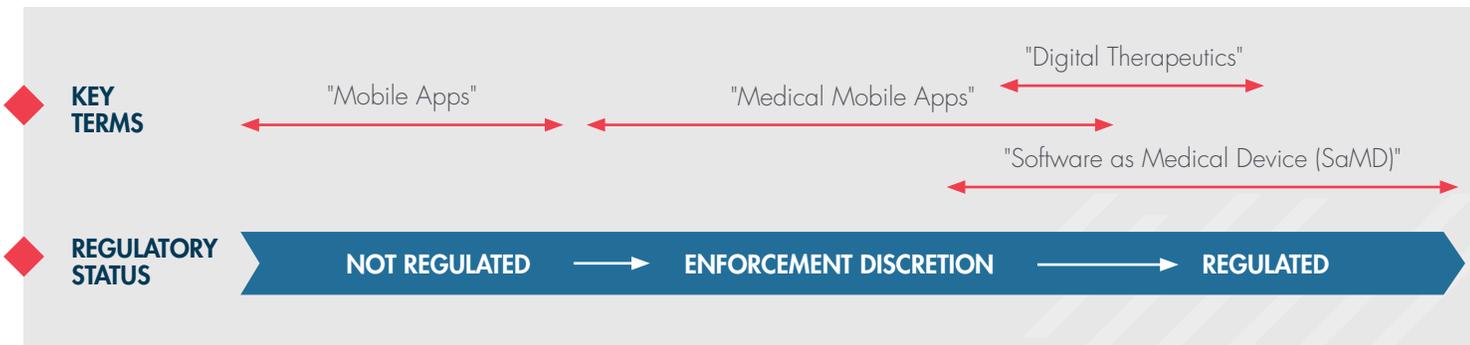
A Practical Framework to Guide Development of Quality Standards for Diabetes Digital Technologies Is Needed

In 2021, 537 million people aged 20–79 were living with diabetes. This condition is expected to impact 643 million people worldwide by 2030.¹ The growth in diabetes prevalence has incentivized innovators to develop digital health technologies that support diabetes care delivery and self-management. Interest in these technologies continues to grow in parallel with the increasing public health demands of this condition. In 2021, the global market for digital diabetes management was valued at \$17.5 billion, and it is projected to increase to \$86.2 billion by 2030.²

Digital health technologies are distinct from computer and information technology hardware, and may involve computing platforms, connectivity, software, and/or sensors with an array of intended uses. As a result of this heterogeneity, some products meet the Food and Drug Administration’s (FDA) definition of medical devices or software as a medical device (SaMD) and are therefore subject to regulation while others are not.^{3,4,5} For example, software that powers insulin pumps and allows them to integrate with a continuous glucose monitor is FDA regulated; a patient-facing, smartphone-based app that helps patients track their glucose monitoring and exercise is not.

Roundtable panelist Juan Espinoza, MD, developed a summary of relationships among health technology categories and degree of FDA regulation (Figure 1).

+ FIGURE 1: Key Definitions and Regulatory Concepts in Digital Health



Persistent challenges to diabetes management for health systems, providers, patients, and caregivers have led innovators to develop a variety of diabetes digital technologies (DDT), digital health tools specific to diabetes. These include products that facilitate virtual care delivery, patient education, information exchange, risk factor monitoring and feedback, and other patient self-monitoring and support tasks. DDTs are marketed to improve an array of diabetes-related outcomes, and have already achieved significant market penetration.

Despite the proliferation of DDTs, there is a lack of high-quality clinical trial evidence on the efficacy of many of these products, especially those that are not subject to FDA regulatory oversight. Moreover, there is no universally accepted infrastructure that defines quality standards and measures for DDT performance or effectiveness, and no comprehensive framework for assessing these products in practice or for ascertaining if they meet minimal performance or other standards. These gaps create challenges for payers, employers, patients, and clinicians, who are unable to make informed decisions about which DDTs are most effective and best suited to their needs. To address these gaps, stakeholders identified the need to establish a DDT assessment framework that sets the stage for developing quality standards and measures for these digital technologies.

ENGAGING STAKEHOLDERS IN DEVELOPING A DDT ASSESSMENT FRAMEWORK

Recognizing the need to engage stakeholders in developing DDT quality standards and measures, in March 2023, the National Committee for Quality Assurance (NCQA) and the American Diabetes Association (ADA) invited a panel of experts to a roundtable discussion to explore this complex topic. The roundtable had three goals:

1. Refine and finalize a categorization scheme for DDTs that is suited to a structured assessment of the technologies.
2. Identify and prioritize criteria for assessing DDT categories.
3. Define next steps to facilitate mapping DDT assessment criteria to future standards and/or accreditation programs.

The 18-member roundtable panel included federal and state government officials, clinicians, digital therapeutics experts, academics, policy makers, and technology innovators (Box 1).

Box 1: Perspectives Represented in the March 2023 Roundtable on Diabetes Digital Technologies (DDT)

- The Food and Drug Administration
- The Department of Veterans Affairs
- Commercial and public payers
- Digital therapeutics advocacy
- Patient advocacy
- Behavioral health
- Endocrinology and diabetology
- Primary care
- Psychiatry
- Pediatrics
- Pharmacy
- Informatics
- Health policy
- Rural health
- Diabetes care delivery
- Quality assurance

A NOVEL APPROACH TO CATEGORIZING DDTs

The roundtable's first goal was to finalize a DDT categorization scheme that could be used to assess the technologies for future quality standards and measures. Considerable work has been done in technology categorization, including a five-level, diabetes-specific scheme based on health care provider personnel resources,⁶ and a strategy, proposed by the World Health Organization, for discrete functionality of individual technologies.⁷ For developing DDT quality standards and measures, the roundtable panel suggested an approach that emphasizes how well these technologies support digital technology-enabled care models. This approach is more relevant to the task of evaluating quality than technology-focused assessments that evaluate functionality, but do not evaluate the capacity to improve self-management by people with diabetes or by clinicians.

Under this approach, DDTs are categorized according to one of three general digital technology-enabled care models (Table 1): patient-facing apps and tools, virtual self-management and support, and virtual diabetes care.

+ TABLE 1: Digital technology enabled care models—proposed taxonomy

CARE MODEL CATEGORY	EXAMPLE	KEY CONCEPT
Patient-facing diabetes apps and tools	<ul style="list-style-type: none"> Algorithm-driven health coach 	Patients receive feedback and self-management support based on data they enter into connected devices; no interaction with a professional or clinician
Virtual diabetes self-management and support	<ul style="list-style-type: none"> Live coaching from a diabetes educator Support from a dietitian using data patients enter into an app 	Patients connect virtually with non-prescribing professionals who support them using apps, coaching, and other strategies
Virtual diabetes care	<ul style="list-style-type: none"> Medication management Care coordination 	Patients connect with prescribing professionals who support high-level aspects of care planning and management

“Patient-facing apps and tools” includes technologies (some driven by artificial intelligence) that provide patients with interactive feedback and support and have the potential to improve outcomes through better self-management. Although clinicians may be involved in the design or refinement of patient-facing apps and tools, these DDTs are marketed primarily to patients, and the information they provide is delivered independently of health care professionals and does not involve their direct interaction.

Digital technology-enabled care models seek to improve diabetes outcomes by facilitating connections between patients and non-prescribing health care professionals like dietitians and diabetes educators. In the second category, online platforms facilitate data sharing with these professionals (or with other clinical team members), who use the information to support patients through coaching, behavior modification, meal planning, and other efforts that target diabetes-related behaviors and risk factors.

In the third category, DDTs connect patients with prescribing professionals and allow patients to share data that facilitate high-level services such as medication management, care coordination, and other supports that typically require oversight by a physician or nurse practitioner.

A key advantage of the DDT categorization scheme in Table 1 is that it allows for variation within care model categories in the way technologies and delivery protocols operate. This is important because there are many ways to incorporate DDTs into care streams. Care model categories not only integrate the flexibility needed to accommodate future advances in technology and health care delivery, they also create a framework that allows each category to be assessed in a manner that is relevant to patients, providers, payers, regulators, technology manufacturers, and other stakeholders.

IDENTIFYING A DDT ASSESSMENT FRAMEWORK

Once DDTs are categorized according to the relevant care model, an approach is needed to assess how well they support the model. Proposed health technology assessment strategies include approaches supported by the International Medical Device Regulators Forum and the National Institutes of Health (NIH).^{8,9} Although the rapidly advancing health technology market creates practical challenges for adopting a DDT assessment framework that will be relevant in the long term, the NIH assessment framework was selected because it is straightforward, widely used, and incorporates the flexibility needed to evaluate DDTs in the context of their impact on technology-enabled care models, now and in the future.

Panelists suggested that DDTs should be evaluated using the five classes of properties and impacts defined in the NIH's health technology assessment framework (Table 2): technical properties; safety; efficacy and/or effectiveness; economic attributes or impacts; and social, legal, ethical, and/or political impacts.¹⁰ An appealing feature of the NIH framework is that its flexibility facilitates prioritizing DDT assessment criteria in future efforts to develop relevant quality standards and measures, whereas for some technologies, certain properties/impacts are less relevant than others, or not sufficiently relevant to warrant assessment.

+ TABLE 2: Properties and impacts in the NIH health technology assessment framework

HEALTH TECHNOLOGY ASSESSMENT CATEGORY	CONCEPTS OR ELEMENTS THAT CAN BE ASSESSED
Technical properties	Performance characteristics and conformity with specifications for design, composition, manufacturing, tolerances, reliability, ease of use, and maintenance
Safety	Acceptability of risk associated with using a technology in a given situation
Efficacy and/or effectiveness	How well a technology accomplishes its intended purpose, usually based on changes in one or more specified health outcomes
Economic attributes or impacts	<ul style="list-style-type: none"> • Microeconomic: Costs, prices, charges, and payment levels associated with individual technologies • Macroeconomic: National and global patterns of investment, innovation, competitiveness, technology transfer; employment, regulation, third-party payment, and other policy change
Social, legal, ethical, political, and/or equity impacts	How and when to use technologies; research and the advancement of knowledge; resource allocation; and the integrity of health care technology processes

THE EFFECTIVENESS OF DDT-ENABLED CARE MODELS WILL DRIVE DEVELOPMENT OF QUALITY STANDARDS AND RELATED MEASURES

The roundtable’s second goal was to identify and prioritize criteria that can be used to develop DDT quality standards and measures. As noted above, criteria should focus on how well a DDT supports a specified care model, and should be defined and prioritized by its unique contribution to the care model’s impact on the quality of care and health outcomes.

Panelists moved this process forward by using the NIH technology assessment framework (Table 2) to identify potential assessment criteria for each category of DDT-enabled care models. Panelists noted that care model categories can include multiple models; for example, a patient-facing app might offer a care tracking model, a dietary coaching care model, or a cognitive behavioral therapy care model. All areas of impact on quality and health outcomes were considered: clinical outcomes; patient empowerment and self-management; adherence to care plans; patient experience; information exchange/data sharing; and improved access to care.

Table 3 summarized panelist insights into potential DDT assessment criteria, presented as a crosswalk between DDT-enabled care models and NIH technology assessment categories. The boxes include assessment criteria that can be used for future DDT standards and/or quality measures for a care model category.

+ TABLE 3: Quality assessment considerations and criteria that could be applied to digital technologies that aim to improve diabetes care

CONSIDERATIONS		PATIENT FACING APPS/ TOOLS	VIRTUAL SELF-MANAGEMENT SUPPORT	VIRTUAL DIABETES CARE AND MEDICAL MANAGEMENT
Technical	Data	Interoperability, accessibility, transportability, ownership	Device data and usage	Connectivity/linkage
	Privacy and security	Privacy / Cybersecurity	Privacy	Privacy
	Member/ patient experience	Usability and support	Usability and support	Patient navigation Self-management capabilities/components
Safety		Community management (preventing and managing misinformation) Escalation tactics/process	Community management (preventing and managing misinformation) Escalation tactics/process	Community management (preventing and managing misinformation)
Efficacy and/or effectiveness	Outcomes	Patient reported outcomes Patient satisfaction/ experience	Patient satisfaction/ experience Achieving goals/measures	Population outcomes
	Patient engagement	Platform usage/frequency and engagement Retention	Platform usage/frequency and engagement Retention	Platform usage/frequency and engagement Retention

+ **TABLE 3: Quality assessment considerations and criteria that could be applied to digital technologies that aim to improve diabetes care (cont.)**

CONSIDERATIONS		PATIENT FACING APPS/ TOOLS	VIRTUAL SELF-MANAGEMENT SUPPORT	VIRTUAL DIABETES CARE AND MEDICAL MANAGEMENT
Economic		Financial Coverage/responsibility Cost savings/ROI	Financial Coverage/responsibility Cost savings/ROI	Financial Coverage/responsibility
Social, legal, ethical and/or political impacts	Equity-related	Access Social determinants of health Cultural awareness and competency	Access Social determinants of health Cultural awareness and competency	Access Social determinants of health Cultural awareness and competency
	Data-related	Transparency and usage		Transparency and usage

Although there was some heterogeneity in the proposed assessment criteria for the DDT care models, proposed criteria generally indicated common themes across the three care models. For example, when considering future quality standards and measures for a DDT’s technical properties, assessment criteria related to data, privacy and security and member/patient experience were recommended for all care models. However, in some cases, specific features of a broad criterion differed across models. For example, privacy and security recommendations called for privacy policies for all care models, but cybersecurity considerations were highlighted only for patient-facing apps and tools.

For the “efficacy and/or effectiveness assessment” category, clinical outcomes and patient engagement were recommended across all care models. However, population-level clinical outcomes were recommended for virtual diabetes care and medical management, while patient-reported outcomes and patient satisfaction were recommended for patient-facing apps and tools and virtual self-management support. Potential criteria for the other NIH assessment categories often followed a similar pattern, with broad assessment criteria recommended across DDT-enabled care models, but more granular criteria recommended on a model-specific basis.

These results suggest that a core set of standards and measures that apply across care models could be developed. Continued exploration of potential DDT assessment criteria may lead to insights on model-specific distinctions that have implications for how criteria can be used, or should be used, to develop DDT quality standards and measures.

LOOKING TO THE FUTURE

Successful achievement of the first two roundtable goals—identify a DDT categorization framework and preliminary assessment criteria—allowed the panel to begin working on the third goal: Define next steps to facilitate mapping of assessment criteria to future quality standards and measures. Achieving this goal will require a thoughtful, targeted, and nimble long-term plan that continues to solicit and consider stakeholder input. Several key points emerged from the roundtable’s work on this goal:

DDTs should be assessed on their ability to support digital technology-enabled care models that deliver high-quality care in addition to evaluating the technologies’ discrete properties. Keeping care models and their impact on quality and health outcomes at the center of ongoing discussions about DDT quality standards and measures is critical to ensuring that advances in technology, evolving stakeholder expectations, and research developments guide the design and use of technologies. Notably, many criteria in Table 3 are suitable targets for future work to map criteria to robust quality standards and measures for diabetes care in the context of these care models.

Design DDT quality standards and measures that address DDT effectiveness for diverse individuals, populations, and care environments, and other factors that drive equitable outcomes. As work on DDT quality standards and measures evolves, it is important to consider factors that influence how these technologies interact with diabetes care streams (Box 2). Some factors hint at the breadth of issues that will need to be tackled in the future. A realistic approach to developing quality standards and measures will also require prioritizing assessment criteria further and pursuing only those that are most relevant, practical, and feasible. Additional work is needed to identify how these determinations will be made.

These challenges are only a preliminary list. As work on DDT quality standards and measures continues, additional considerations will arise that will need to be incorporated into ongoing discussions and measure development.

Focus on developing DDT quality standards and measures that capitalize on information that can be gathered with relative ease. Although many criteria could inform DDT quality standards and measures, it will be necessary to focus on those that can be assessed using data that are easily collected. This may include incorporating data collection into digital technologies as part of their deployment. This practical consideration has implications for technology developers, clinicians, patients, and other stakeholders who are involved in product development and use. Quality standards, measures, and related accreditation or certification programs will have limited uptake if stakeholders are unable to overcome data-related barriers.

Box 2: Challenges that need to be addressed in developing DDT quality standards and measures

- The ability of patients to customize DDTs to focus on relevant tasks or goals.
- How well DDTs promote long-term engagement for diverse individuals and populations.
- How DDTs address access gaps by increasing service and support options.
- How well DDTs decrease the impact of geographic distance on access to care.
- How easily DDTs can overcome regulatory and legal hurdles.
- How well DDTs can adapt to populations that differ by culture, life stage, literacy, or trust of the healthcare system and/or technology.

Incorporate flexibility to accommodate changes in the regulatory environment, reimbursement policy, care delivery mechanisms, and technology evolution. The practical application and impact of DDT quality standards and measures implies availability of a broad and receptive landscape in which these standards are relevant and feasible, and for which appropriate incentives are in place. It is therefore critical that development of standards and measures assumes and anticipates meaningful changes to the health care policy and payment environment, to ensure measures' relevance in the long term.

A diabetes-focused approach to quality standards and measures for digital technology-enabled care models could also be applied to other health conditions and environments. The digital health technologies developed for diabetes management and care target an array of behaviors and risk factors that are relevant to other chronic and acute health conditions. For this reason, the quality standards framework described in this paper—based on assessing how well DDTs support technology-enabled care models—could be extended to other health conditions. For example, a technology that aims to improve self-monitoring behaviors for blood glucose, blood pressure, and weight could apply this framework, and its diabetes-focused quality standards and measures, to conditions like hypertension, chronic kidney disease, asthma, and obesity. DDTs may also be applicable to behavioral health conditions where digital technologies are also proliferating. This approach could be extended to assessing how technology-enabled care models support public health emergencies, natural disasters, or other non-routine circumstances.



Conclusion

We propose a framework and preliminary assessment criteria for DDTs that rely on how well they support technology-enabled care models—patient-facing apps and tools, virtual self-management support, virtual diabetes care, and medical management—that differ in important ways, including the level and nature of clinician involvement, the type and extent of information sharing, and the goals of use. Yet, all models of care have the potential to benefit from DDTs that meet widely recognized quality standards. This report offers a path toward developing quality standards and measures that could provide a foundation for future DDT accreditation, certification, or recognition programs. Such programs would allow stakeholders to make informed decisions about which DDTs are best suited to their needs, and assess the value they contribute to both existing and innovative care models.

Some considerations should be kept in mind as this work progresses:

- DDTs should be assessed on their ability to support care models (digital technology-enabled) that deliver high-quality care, and on the technologies' discrete properties.
- A diabetes-focused approach to quality standards and measures for digital technology-enabled care models could also be applied to other health conditions and environments.
- Design DDT quality standards and measures that address their effectiveness for diverse individuals, populations, and care environments, and other factors that drive equitable outcomes.
- Focus on developing DDT quality standards and measures that capitalize on information that can be gathered with relative ease.
- Incorporate enough flexibility to accommodate changes in the regulatory environment, reimbursement policy, care delivery mechanisms, and technology evolution.
- Preliminary DDT assessment criteria need additional prioritization.

Development of DDT quality standards and measures holds great promise to improve the quality of, and access to, diabetes care and support. This report's findings are an important step to making them a reality.

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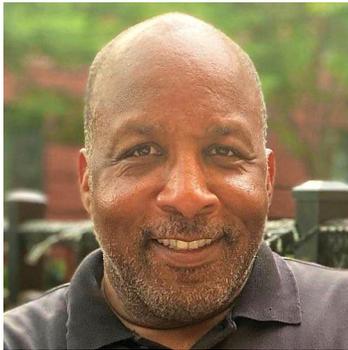
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- 1 International Diabetes Federation. IDF Diabetes Atlas—Diabetes Around the World in 2021. Available at: <https://diabetesatlas.org/>. Accessed January 11, 2023.

- 2 Stratix Research. Digital Diabetes Management Market Size is projected to reach USD 86.19 Billion by 2030, growing at a CAGR of 19.2%: Straits Research. Available at: <https://www.globenewswire.com/en/news-release/2022/10/06/2529821/0/en/Digital-Diabetes-Management-Market-Size-is-projected-to-reach-USD-86-19-Billion-by-2030-growing-at-a-CAGR-of-19-2-Straits-Research.html>. Accessed January 11, 2023.

- 3 U.S. Food and Drug Administration. Focus Area: Digital Health Technologies. Available at: <https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-digital-health-technologies>. Accessed May 12, 2023.

- 4 U.S. Food and Drug Administration. Digital Health Policy Navigator. Available at: <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator>. Accessed May 12, 2023.

- 5 U.S. Food and Drug Administration. How to Determine if Your Product is a Medical Device. Available at: <https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device>. Accessed May 12, 2023.

- 6 Levine BJ, Close KL, Gabbay RA. A care team-based classification and population management schema for connected diabetes care. *NPJ Digit Med.* 2020;3:104. Published 2020 Aug 7. doi:10.1038/s41746-020-00313-3.

- 7 World Health Organization. Classification of digital health interventions. Geneva: World Health Organization; 2018(WHO/RHR/18.06). License: CC BY-NC-SA 3.0 IGO. Available at: <https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf>. Accessed May 19, 2023.

- 8 International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Clinical Evaluation. Available at: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf. Accessed May 19, 2023.

- 9 National Institutes of Health, National Library of Medicine. National Information Center on Health Services Research & Health Care Technology (NICHSR). Available at: <https://www.nlm.nih.gov/hsrph.html>. Accessed May 15, 2023.

- 10 National Library of Medicine. National Information Center on Health Services Research and Health Care Technology (NICHSR). HTA 101: II. Fundamental Concepts. Available at: <https://www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading5>. Accessed May 15, 2023.



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