Integrated
Evidence Plans
for Digital Health Technologies

High-Quality Evidence for DHTs

A Checklist

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DIGITAL MEDICINE SOCIETY

Building trust & driving adoption of DHTs with robust evidence base

The High-Quality Evidence Checklist categorizes evidence requirements for DHTs across practical checklists that encode patient-centric outcomes, cost-effectiveness, and user-focused impact. Use this tool to drive the successful adoption of DHTs within health care to improve patient outcomes.

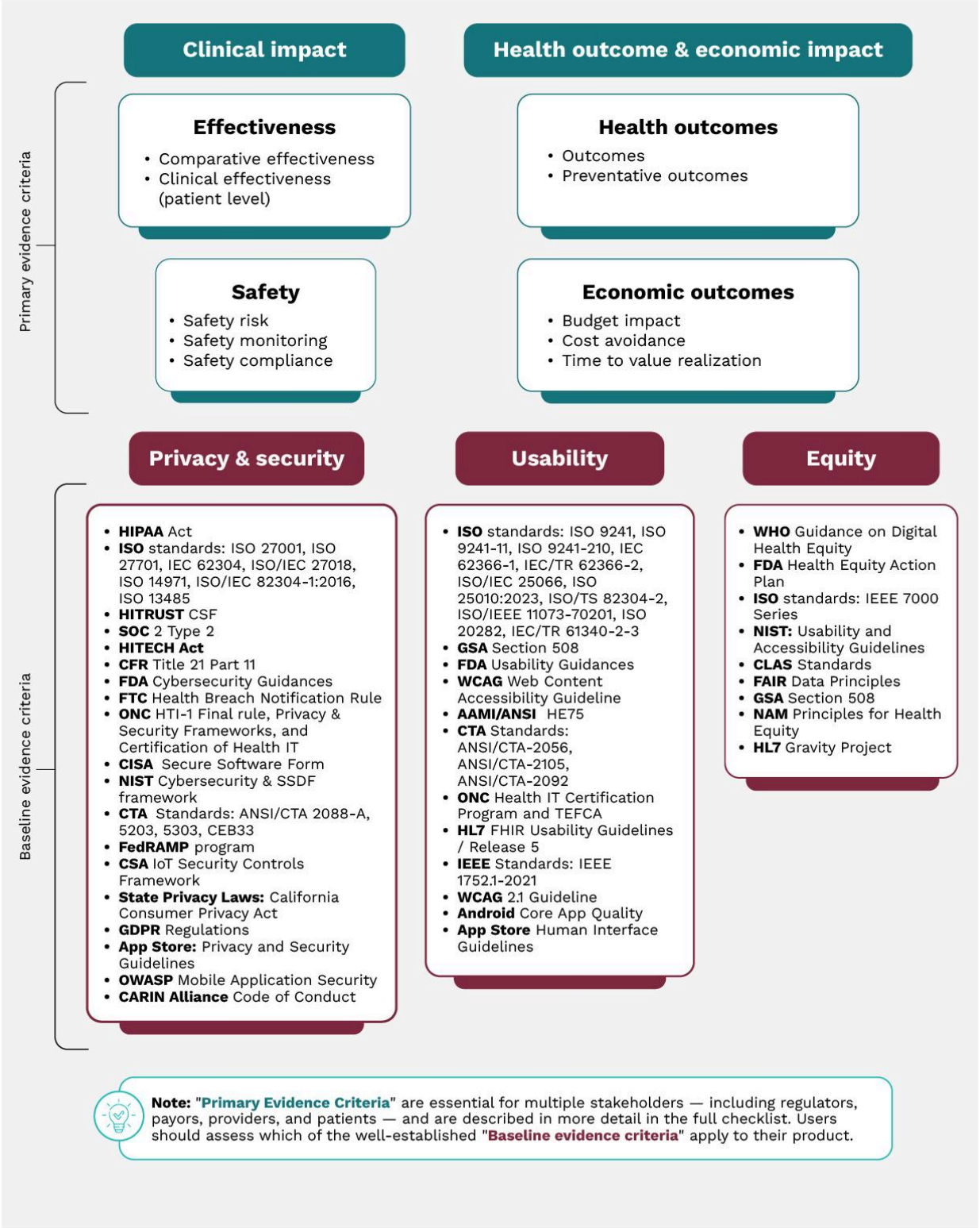
The High-Quality Evidence Checklist is intended for:

Developers
who seek to clarify evidence requirements to inform product development to ensure market adoption and credibility.

Adopters
who seek validated, patient-centered, and cost-effective digital health solutions with proven clinical and real-world impact for seamless integration into healthcare workflows.

Industry, academics & associations
who advocate for a more streamlined approach to establishing best practices and align evidence expectations across regulatory, payor, and research landscapes.

High-Quality Evidence for DHTs: An Overview



Clinical impact

Clinical impact is a core pillar for assessing the value of a DHT by addressing clinical effectiveness, risk mitigation, safety, and patient/user well-being. It is divided into evidentiary criteria for effectiveness and safety.

Effectiveness 

Clinical effectiveness

Clinical effectiveness evaluates the ability of a DHT to produce the intended clinical outcome.

Evidence criteria	Key considerations
☐ **Clinical validation**	✔ What type of clinical studies (e.g., observational, randomized clinical trial) are required to validate the DHT's claims and support its intended use? ✔ Has the DHT been tested across diverse patient populations to ensure generalizability and inclusivity? ✔ Was the accuracy of algorithmic outputs validated against established clinical workflows or reference standards? Note that conducting clinical validation assumes that analytical validation of algorithm performance was successfully completed [Check out V3 and VNDMC resources]. ✔ Is the quality of data sufficient to meet regulatory requirements and align with patient safety standards? ✔ Is adherence and engagement among patients using the DHT high enough, and how is it intended to be monitored over time?
☐ **Clinical utility**	✔ Does the DHT improve health outcomes effectively or provide actionable insights for diagnosis, treatment, or disease prevention? ✔ Can mechanisms (e.g., reminders, incentives,

	personalized feedback) support sustained patient adherence? ✔ How easily can the DHT integrate into existing clinical workflows without increasing the burden on clinicians or staff? ✔ Does the DHT demonstrate scalability across different healthcare settings (e.g., hospital systems, brick-and-mortar clinics, virtual care clinics)?
☐ **Time to effectiveness**	✔ Does the DHT reduce time to diagnosis or recovery time, enhance time to self-management, or expedite time to treatment compared to traditional interventions? ✔ How quickly does the DHT deliver meaningful clinical improvements?

Comparative effectiveness

Comparative effectiveness evaluates and contrasts multiple healthcare interventions, treatments, or strategies to determine which option provides better clinical outcomes for a given patient population and/or context of use.

Evidence criteria	Key considerations
☐ **Interventions & comparators**	✔ Do one or more comparators exist (e.g., standard of care, a different DHT, or no intervention)? ✔ Would the DHT replace existing standard of care, or augment existing protocols? ✔ Does the chosen comparator reflect current best practices in the relevant disease area and/or context of use? ✔ How do the outcomes achieved with the DHT compare to those of the chosen comparator (e.g., standard of care of a predicate device?)
☐ **Pragmatic trial design & generalizability**	✔ Has the DHT been tested in real-world clinical settings with diverse patient populations? ✔ Does the evidence reflect effectiveness in daily clinical practice beyond controlled trial environments? ✔ How does the DHT perform across various demographic groups, comorbidities, and healthcare settings? ✔ Does the study design allow for head-to-head comparisons between interventions, avoiding reliance on indirect comparisons?

☐ **Indirect benefits & shared decision-making**	✔ Does the comparative effectiveness strategy include measuring shared decision-making between patients and healthcare providers? ✔ Are patient preferences incorporated into clinical decision-making where appropriate? ✔ Does the evidence demonstrate that DHT adoption is likely to result in meaningful changes to clinical practice protocols and workflows?

Safety

Safety Risk

Identifying, mitigating, and minimizing risks associated with misuse, user error, or unintended use of DHTs is critical to ensuring patient safety. You should develop surveillance activities that are appropriate for the risks associated with using the product.

Evidence criteria	Key considerations
☐ **Risk of misuse or user error**	✔ Are there safeguards to prevent critical mistakes (e.g., confirmation steps, error detection mechanisms)? ✔ What educational resources or user training are provided? ✔ Is the user interface intuitive, and does it reduce the likelihood of errors?
☐ **Identification of adverse events**	✔ Are there mechanisms to detect, report, and address adverse events in real time? ✔ Are thresholds defined for triggering safety interventions when risks are identified?
☐ **Population-specific risk assessment**	✔ Are safety risks evaluated for vulnerable populations (e.g., children, elderly, pregnant individuals)? ✔ Does the DHT address risks for unintended usage by non-targeted populations?
☐ **Risk mitigation plan**	✔ Are risks, adverse effects, and safety profiles clearly identified and minimized? ✔ What fail-safe mechanisms and redundancies are built into the DHT to address operational failures? ✔ Has a structured risk analysis been conducted? ✔ Are there contingency plans for unexpected events, such as power outages or system errors?

Safety monitoring

Monitoring for potential safety events during and after DHT deployment to mitigate existing and new risks and continuously improve the product's safety profile.

Evidence criteria	Key considerations
☐ **Continuous monitoring**	✔ Does the DHT include real-time monitoring and alert systems for potential safety risks? ✔ How will healthcare providers/DHT implementors monitor device performance and safety issues?
☐ **Post-market surveillance monitoring**	✔ Is there a plan to collect real-world data for ongoing safety evaluation? ✔ Are patient-reported outcomes and feedback integrated into post-market safety monitoring?

Safety compliance

Compliance with established regulatory and industry standards to ensure safe and reliable DHT operations.

Evidence criteria	Key considerations
☐ **Regulatory adherence**	✔ Does the DHT comply with relevant regulatory standards?

Note: The interplay between effectiveness, safety, and certain baseline criteria such as usability and data security needs to be carefully considered. Poor usability or weak data protection can negatively impact clinical effectiveness and patient safety. For instance, a DHT with an unintuitive interface may lead to reduced engagement, with the potential to compromise its clinical impact.

Health outcomes & economic (HEOR) impact

Economic evaluation is critical for purchasers (e.g., health plans, employers, health systems) to determine whether the introduction of a technology reduces overall healthcare spending and/or improves health outcomes. Economic evaluations must consider direct costs, budget neutrality, and long-term savings, as well as the scalability and sustainability of the DHT across all intended patient populations. We propose assessing HEOR across two categories of evidentiary criteria: health outcomes and economic outcomes.

Health outcomes 

Outcomes

Outcomes focus on the specific clinical, functional, and/or quality-of-life improvements a DHT aims to achieve for its intended population. This is a critical consideration at the **population level**, as payors often seek outcomes that reflect the specific demographics of their covered groups. For instance, Medicare may prioritize outcomes demonstrated in populations aged 65 and older.

Evidence criteria	Key considerations
☐ **Primary outcomes**	✔ What are the primary clinical outcomes (e.g., the main clinical outcomes directly measuring the intended effect of the DHT? ✔ Does the evidence demonstrate that the primary outcome(s) align with patient-reported priorities? ✔ Are the clinical outcomes measured using validated tools or standards?
☐ **Secondary & additional outcomes**	✔ What secondary outcomes are relevant to the overall effectiveness of the solution (e.g., hospitalizations, mental health improvements, medication adherence)? ✔ Are these improvements informed by patient input; are the outcomes relevant to patients (e.g., quality of life), clinicians (e.g., reduced hospitalization rates), and payors (e.g., cost savings)? ✔ *Functional, Psychological & Social outcomes (if not a*

	primary outcome) ○ Are functional outcomes (Quality of life outcomes like a patient's ability to perform activities of daily living, participate in social activities, or engage in work or leisure activities) measured? ○ Are social outcomes (changes in patients' social relationships, support networks, overall well-being, and quality of life) measured? ○ Are psychological outcomes (changes in a patient's mental health, emotional well-being, and cognitive functioning) measured?
☐ **Population-level effect**	✔ Does the DHT demonstrate measurable impact across the intended population?

Preventative outcomes

Preventive outcomes focus on the ability of a DHT to prevent the onset, progression, or recurrence of a condition through early detection, lifestyle modifications, or proactive interventions.

Evidence criteria	Key considerations
☐ **Early detection**	✔ Does the DHT provide evidence of effectiveness in identifying risks or conditions at an early, clinically relevant stage? ✔ Do validated metrics for the clinical utility (e.g., sensitivity, specificity) of early detection exist, and does the DHT meet or exceed them?
☐ **Risk stratification**	✔ Can the DHT stratify patients by risk level to target preventive interventions appropriately?
☐ **Behavioral interventions**	✔ Does the DHT support evidence-based behavior change strategies (e.g., physical activity, dietary modifications)? ✔ Does evidence exist that demonstrates sustained behavioral changes driven by the DHT?
☐ **Preventing recurrence**	✔ Does the DHT demonstrate the ability to prevent relapse or recurrence of the targeted condition? Are those preventive measures grounded in clinical guidelines or evidence-based practices? ✔ Is long-term adherence to preventive strategies supported and measured?

Long-term impact

Long-term impact focuses on the ability of a DHT to impact the long-term clinical management of patients, especially those with chronic conditions.

Evidence criteria	Key considerations
☐ **Supporting patient education & self-management**	✔ Does the DHT provide ongoing patient education and support strategies for self-management to empower patients to take an active role in managing their health and well-being? ✔ Does the DHT provide resources (e.g., tutorials, reminders) to encourage sustained engagement? ✔ How does the DHT empower patients to manage their health independently?
☐ **Sustained clinical benefits**	✔ Does the evidence suggest that health benefits are maintained after discontinuation of active therapy provided by the DHT? ✔ Are there strategies for maintaining benefits without continued use of the DHT?
☐ **Adoption**	✔ How do real-world data and evidence (RWD/RWE) contribute to the adoption and deployment of the DHT? ✔ Is RWD/RWE used to support and improve clinical practice guidelines, treatment recommendations, and healthcare policy development?

Note: Demonstrating sustained clinical benefits post-intervention is critical. For example, if a six-month diabetes management tool shows improvements, long-term studies should verify that benefits are sustained without subsequent adverse outcomes like increased hospitalizations.

Economic outcomes 

Budget impact

The budget impact approach assesses the financial implications of adopting a DHT compared to alternative strategies (including no strategy) or standard of care. This helps you understand the short- and long-term cost impact of DHT adoption, including reimbursement considerations, payor budget planning, and potential return on investment.

Evidence criteria	Key considerations
☐ **Price**	✔ What is the price of the DHT under various reimbursement models (e.g., per patient per month, capitated agreements)? ✔ How do these costs compare to traditional treatment options? ✔ Do costs vary with patient population, usage, or monitoring levels?
☐ **Cost-effectiveness**	✔ How does the DHT's cost-effectiveness compare to standard-of-care interventions? ✔ Does the DHT demonstrate better value for money compared to other solutions? ✔ Are validated economic models (e.g., decision tree, Markov models) used to assess the cost-effectiveness of DHTs? ✔ Does evidence of downstream cost savings exist (e.g., reduced complications, hospitalizations, or long-term care needs)? ✔ Do indirect cost savings exist (e.g., productivity gains, caregiver burden reduction)?

Cost avoidance

DHTs should demonstrate the ability to avoid costly complications, hospitalizations, or high-cost interventions, thereby reducing the overall cost of care. Cost avoidance should include both direct and indirect savings, such as reductions in emergency room visits, disease progression, or costly procedures.

Evidence criteria	Key considerations
☐ **Cost avoidance & preventative savings**	✔ How much future healthcare cost is avoided by adopting the technology?

	✔ What is the long-term impact on reducing prevention or disease progression? ✔ Does the DHT reduce the need for high-cost treatments, such as surgeries or advanced imaging?

Time to value realization

The DHT's economic impact should be scalable across different population sizes, geographic regions, and health systems. Economic models should account for both small-scale (e.g., local clinics) and large-scale (e.g., national healthcare systems) deployments. The DHT should demonstrate financial sustainability over time, accounting for ongoing costs of maintenance, updates, and scaling as the technology matures. Sustainability ensures that the economic benefits continue to outweigh the costs.

Evidence criteria	Key considerations
☐ **Scalability of economic benefits**	✔ Can the DHT scale effectively across different healthcare settings (e.g., urban vs. rural, large hospitals vs. smaller practices)? ✔ What resources are required for scaling across different healthcare settings, and how do associated costs vary? ✔ How is the economic benefit impacted by increased adoption across broader patient populations? ✔ Is cost-effectiveness affected by usage in higher-risk vs lower-risk populations?
☐ **Long-term financial viability**	✔ Is the DHT financially sustainable beyond the initial implementation phase? ✔ How are ongoing costs (e.g., software updates, training, maintenance) managed over time? ✔ What is the potential for decreasing costs as the technology scales or improves?

Note: Adoption of DHTs hinges on seamless integration into provider workflows and alignment of reimbursement rates with clinical efforts. Providers may resist technologies if reimbursement rates are insufficient or workflows are overly burdensome. For instance, the rapid adoption of cardiovascular monitoring devices was seen when reimbursement aligned with provider workflows.

Similarly, cost-effectiveness must be able to accommodate different population sizes and healthcare settings. For instance, a remote cardiac monitoring system that shows significant benefits in early trials may face adoption challenges in rural clinics that lack the infrastructure to support its implementation.

Addendum

Baseline evidence criteria
Baseline evidence criteria are well-established foundational criteria supported by widely adopted industry best practices and regulatory standards. We provide an overview for Privacy & security, Usability, and Equity.

Privacy & security

Organization/entity	Standard/guidelines	Description
HIPAA (Health Insurance Portability and Accountability Act)	Health Insurance Portability and Accountability Act	Protects patient health information within the U.S. healthcare system.
ISO (The International Organization for Standardization	ISO 27001	International standard for information security management systems (ISMS).
	ISO 27701	Privacy Information Management Systems (PIMS), expanding on ISO 27001.
	IEC 62304	Focused on the medical device software and software life cycle processes

	ISO/IEC 27018	Provides guidelines for data protection in cloud computing environments.
	ISO 14971	Risk management framework for medical devices, including digital health solutions.
	ISO/IEC 82304-1:2016	Focuses on health software quality and reliability for healthcare applications.
	ISO 13485	Quality management system requirements for medical devices, ensuring product consistency and regulatory compliance.
HITRUST (Health Information Trust Alliance)	HITRUST CSF	Framework to safeguard sensitive healthcare information and manage compliance risks.
SOC (System and Organization Controls)	SOC 2 Type 2	Certification ensuring security, availability, and confidentiality for cloud-based systems.
HITECH Act (Health Information Technology for Economic and Clinical Health Act)	Health Information Technology for Economic and Clinical Health Act	Encourages secure adoption of electronic health records.
CFR (Code of Federal Regulations)	Title 21 Part 11	Ensures security and reliability of electronic records and signatures.
FDA (Food and Drug Administration)	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	Guidance regarding cybersecurity device design, labeling, and the documentation that FDA recommends be included in premarket submissions for devices with cybersecurity risk
	Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act	Guidance on updated recommendations to industry on cybersecurity considerations for cyber devices and for documentation in device premarket submissions.
	Postmarket Management of Cybersecurity in Medical Devices	Guidance for structured and comprehensive management of postmarket cybersecurity vulnerabilities for marketed and

		distributed medical devices throughout the product lifecycle.
	Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software	Guidance clarifies how existing regulations, including the Quality System (QS) Regulation, apply to such cybersecurity maintenance activities.
FTC (Federal Trade Commission)	Health Breach Notification Rule	Mandates notification of data breaches affecting personal health records.
ONC (Office of the National Coordinator for Health Information Technology)	Privacy and Security Framework for PCOR	Promotes privacy and security best practices for patient-centered outcomes research.
	Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule (ONC HTI-1)	Updates certification requirements for health IT, focusing on algorithm transparency and data sharing.
	ONC Certification of Health IT	Promotes interoperability while addressing data security concerns.
CISA (Cybersecurity and Infrastructure Security Agency)	Secure Software Development Attestation Form	Supports best practices for secure software development.
NIST (National Institute of Standards and Technology)	Cybersecurity Framework	Outlines best practices for managing cybersecurity risks across industries, including healthcare.
	Secure Software Development Framework (SSDF)	Establishes guidelines for secure software development.
CTA (Consumer Technology Association)	ANSI/CTA 2088-A, 5203, 5303, CEB33	Consumer technology standards for improving IoT device security.
FedRAMP (Federal Risk and Authorization Management Program)	FedRAMP®	Ensures standardized security for cloud services in federal applications.

CSA (Cloud Security Alliance)	IoT Security Controls Framework	Provides guidelines for securing IoT devices.
State Privacy Laws	California Consumer Privacy Act (CCPA)	Ensures privacy rights for California residents, setting a model for state-specific laws.
GDPR (General Data Protection Regulation)	General Data Protection Regulation	Protects personal data for individuals in the EU, emphasizing transparency and consent.
App store	Privacy Guidelines and Security Guidelines	Ensures apps comply with data security and privacy requirements for mobile health tools.
OWASP (Open Web Application Security Project)	OWASP Mobile Application Security	Provides best practices for securing mobile health applications.
CARIN Alliance	CARIN Code of Conduct	Establishes a framework for consumer-directed exchange of health information.

Usability

Organization/entity	Standard/guidelines	Description
ISO (The International Organization for Standardization	ISO 9241	Provides ergonomic principles for interactive systems to enhance usability.
	ISO 9241-11	Focuses on usability definitions and concepts for user-centered design.
	ISO 9241-210	Addresses human-centered design for interactive systems.
	IEC 62366-1	Specifies requirements for usability engineering of medical devices.
	IEC/TR 62366-2	Guidance for usability engineering implementation in medical devices.
	ISO/IEC 25066	Defines usability testing practices to ensure user satisfaction and

		minimize errors.
	ISO 25010:2023	Specifies quality attributes for usability, including functional suitability and performance efficiency.
	ISO/TS 82304-2	Covers usability standards for health software applications.
	ISO/IEEE 11073-70201	Defines communication between medical devices and external systems.
	ISO 20282	Provides guidelines for user operation of consumer products.
	IEC/TR 61340-2-3	Focuses on electrostatic compatibility for safe operation in healthcare settings.
GSA (General Services Administration)	Section 508	Mandates federal systems comply with accessibility standards for users with disabilities.
FDA (Food and Drug Administration)	Applying Human Factors and Usability Engineering to Medical Devices	Applies human factors engineering to reduce user errors and enhance safety in software as a medical device.
WCAG (Web Content Accessibility Guidelines)	Web Content Accessibility Guidelines	Standards for web-based healthcare tools to ensure accessibility for users with disabilities.
AAMI/ANSI (Association for the Advancement of Medical Instrumentation/American National Standards Institute)	HE75	Guidance for optimizing usability of medical devices through design and testing best practices.
CTA (Consumer Technology Association)	ANSI/CTA-2056, ANSI/CTA-2105, ANSI/CTA-2092	Consumer technology guidelines for usability and interoperability.
ONC (Office of the National Coordinator for Health Information Technology)	Health IT Certification Program API Resource Guide	Ensures usability of health IT systems, emphasizing intuitive design and reducing user burden.

	Trusted Exchange Framework and Common Agreement (TEFCA)	Promotes data sharing and interoperability in health IT.
HL7 (Health Level Seven International)	FHIR Usability Guidelines / Release 5	Establishes standards for data exchange and usability in electronic health records.
IEEE (Institute of Electrical and Electronics Engineers)	IEEE 1752.1-2021	Provides guidelines for improving functionality and usability in wearable health devices.
WCAG (Web Content Accessibility Guidelines)	WCAG 2.1	Ensures web-based health tools meet accessibility standards.
Android	Core App Quality	Defines usability and quality benchmarks for mobile health applications.
App store	Human Interface Guidelines	Ensures mobile apps meet usability, accessibility, and safety standards.

Note: Incorporating patient preference into the design and evaluation of DHTs is essential for adoption. The FDA guidance on integrating patient preference into regulatory decision-making highlights its importance, especially for technologies addressing stigma or reducing the logistical burdens of care. However, patient preferences must align with provider and payor priorities, potentially including reimbursement structures. For instance, even if patients prefer a digital mental health tool for convenience and to reduce in-person interactions that could be considered stigmatizing, if it is not covered/or reimbursed, access may be limited.

Equity

Organization/entity	Standard/guidelines	Description
WHO (World Health Organization)	Guidance on Digital Health Equity	Promotes equitable access to digital health solutions globally.

FDA (Food and Drug Administration)	Health Equity Action Plan	Guidance for incorporating diversity in clinical trials and ensuring AI/ML in DHTs does not exacerbate health disparities.
ISO (The International Organization for Standardization)	IEEE 7000 Series	Ensures ethical consideration in AI and digital health systems.
NIST (National Institute of Standards and Technology)	Usability and Accessibility Guidelines	Focuses on equitable access and inclusive design for all users, including those with disabilities.
CLAS (Culturally and Linguistically Appropriate Services)	Standards for Culturally and Linguistically Appropriate Services	Ensures culturally competent and linguistically relevant services in healthcare.
FAIR (Findable, Accessible, Interoperable, Reusable)	FAIR Data Principles	Promotes accessibility and usability of healthcare data through the Findable, Accessible, Interoperable, Reusable (FAIR) framework.
GSA (General Services Administration)	Section 508	Ensures federal systems comply with accessibility standards for users with disabilities.
NAM (National Academy of Medicine)	Principles for Health Equity	National Academy of Medicine principles to ensure fairness and inclusivity in healthcare systems.
HL7 (Health Level Seven International)	HL7 Gravity Project	Focuses on improving health equity through data standards and social determinants of health integration.