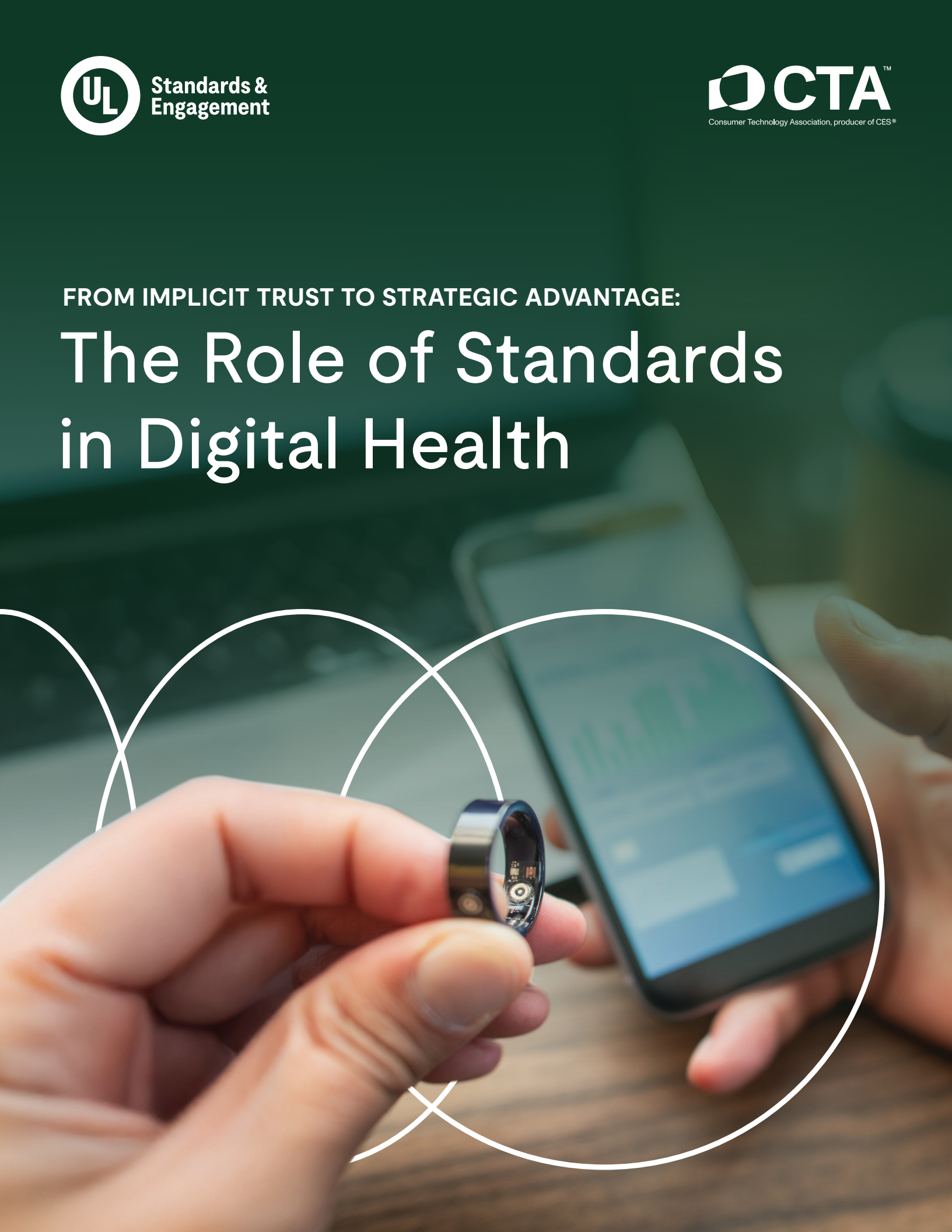
UL Standards & Engagement

CTA™
Consumer Technology Association, producer of CES®

FROM IMPLICIT TRUST TO STRATEGIC ADVANTAGE:

The Role of Standards in Digital Health



INTRODUCTION:

Adoption is Woven in, but Trust is Rooted in Proven Standards

Digital health is no longer a novelty; it is embedded into daily life. Nearly half of consumers (48%) now or have used smartwatches or fitness trackers in the past year. Another 31% rely on apps to monitor physical activity and 23% to track or guide nutrition. Adoption is extending beyond wellness into territory once reserved for clinical settings: 20% of consumers report using connected blood pressure monitors, pulse oximeters, or home testing kits. Nearly one in five consumers are using app-based services such as telehealth, virtual care, and mental health platforms.

Yet beneath this seamless adoption lies a subtle tension around trust. As digital tools become more embedded in everyday routines, consumer trust remains anchored in expectations shaped by traditional safety frameworks — and specifically the recommendation of healthcare providers. Consumers may move quickly to adopt new technologies, but their continued and comprehensive usage ultimately depends on giving them the validation to trust the technology.

Widespread adoption often outpaces consumer awareness regarding the necessary regulatory and safety infrastructure that governs these devices. In an unaided context, a staggering 78% of consumers admit they are not aware of any certifications or industry standards for digital health products. They are also not proactively seeking this information, with only 40% saying they make an effort to learn about standards and certifications during their product research journey.

While consumers may not have high awareness of specific standards and certifications, recognition of oversight markers remains strong: 79% recognize FDA authorization, and nearly half recognize the UL (46%) and CE (45%) certification marks, indicating that trust can be triggered by familiar signals, even if the underlying standards and certifications are not fully understood.

For digital health executives, standards and certifications are no longer just a checkbox; they have evolved into a foundational framework that substantively informs the design process. Nearly seven in ten (68%) executives indicate taking this strategic direction, building standards deeply into their product development lifecycle or embedding them in quality management systems. Executives are moving away from the days of standards conformance as an afterthought: only five percent of digital health organizations report ad hoc processes where they are considered late in development.

Instead, standards and certifications are the critical determinant of strategic direction. A combined 68% of digital health organizations have standards built deeply into their lifecycle, either integrated into the development cycle (36%) or fully embedded with automation and digital quality management systems (32%). For leaders in these organizations, standards are not just about compliance, they are also critical for market readiness. This commitment is rooted in strategy: around 68% executives cite that standards and certifications are primary drivers or strong influencers of their organization's R&D priorities and investments. They recognize that these standards and certifications facilitate market access, enable crucial business partnerships, and are a key factor in increasing consumer trust.

These findings emerge from a comprehensive study combining surveys conducted in November 2025 of 1,000 U.S. consumers and 84 digital health industry leaders.

Key Takeaways

The Implicit Trust Contract

While consumers are rapidly adopting digital health tools, they are not scrutinizing the safety mechanisms behind them. Nearly 80% of consumers can’t name a certification or industry standard for digital health, yet most assume that if a product is on the market, someone has already ensured it is safe and reliable. This creates an “implicit trust” contract — one that places real responsibility on manufacturers. For executives, maintaining this trust requires an investment of time and resources. Independent certification to safety standards serves as the essential bridge between consumer assumption and manufacturer accountability.

Bridging the AI and Data Sensitivity Gap

Consumer comfort is high when tracking metrics like daily steps but erodes quickly as data becomes more sensitive or when Artificial Intelligence (AI) is making decisions. Only about one in five consumers say they are very comfortable with AI-driven health insights, citing concerns about accuracy, consent, and the absence of human accountability. Executives echo this confidence gap, identifying AI governance and machine learning assurance as the highest priority for future standards development. To scale advanced digital health solutions, the industry must move beyond basic connectivity and rigorously validate the "black box" of AI to earn user confidence.

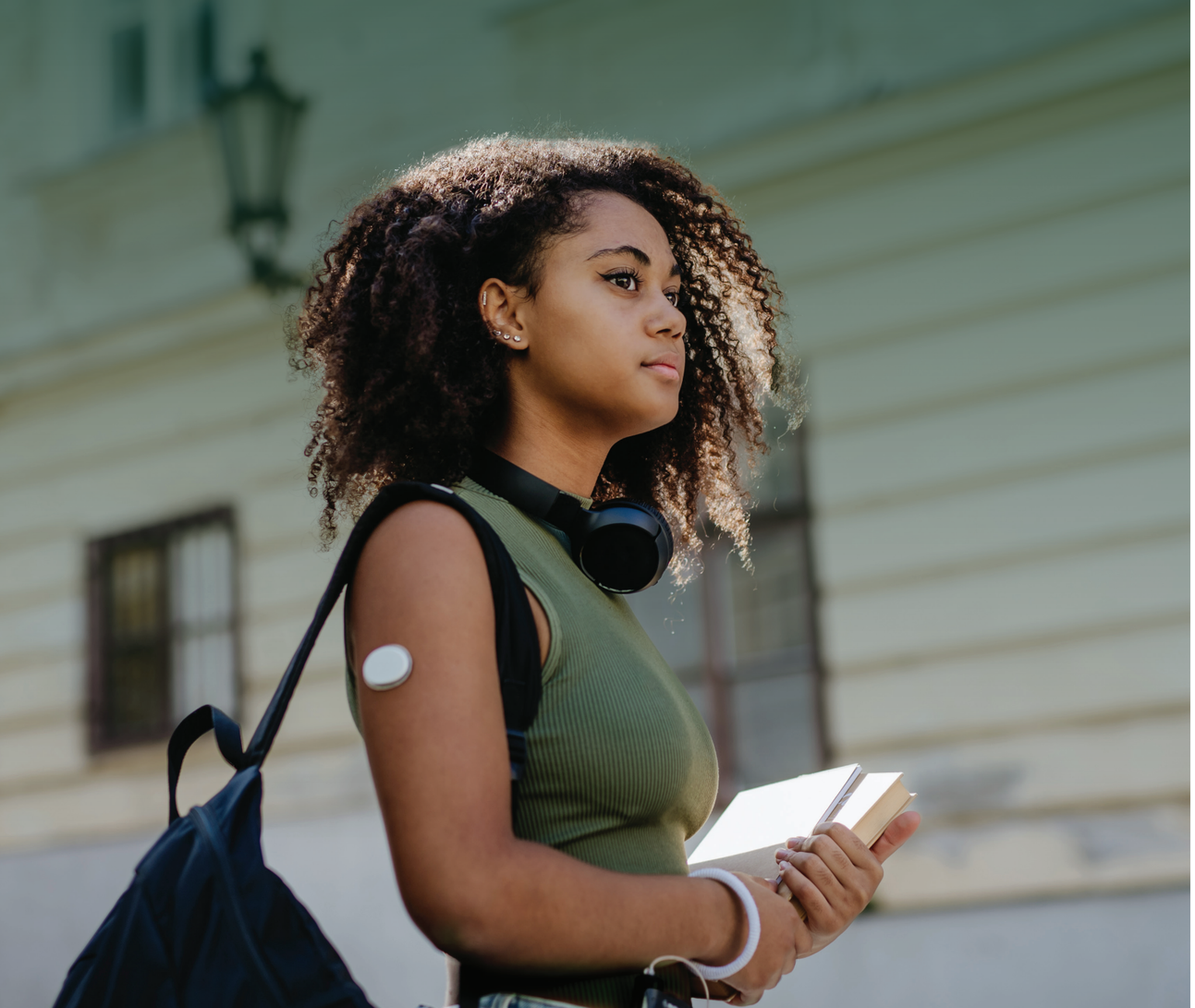
Standards Conformance as a Competitive Strategy

Organizations view standards and certifications not as a hurdle but as a strategic asset. Nearly seven in ten (68%) executives say they now build standards and certification directly into product development and R&D strategy, recognizing conformance as essential to market readiness, partnerships, and consumer trust. By actively measuring the ROI of certification and integrating it into the brand story, companies can justify the necessary resources and lean on the substantial consumer base who are willing to prioritize certified products. Success in the next era of digital health will belong to those who champion visible data stewardship and lead the development of standards, rather than reacting to industry change.

THE IMPLICIT TRUST CONTRACT:

Consumers Delegate Safety to Device Makers

There is a critical trust bridge to be crossed, where consumer assumptions meet executive responsibility. Consumers operate under an implicit trust contract, where they delegate safety to the manufacturer or retailer, assuming that if a device is on the market, it is safe for use. In fact, across critical risk areas, the data suggests that only about half of consumers who express a high concern of potential risks ultimately feel they are personally vulnerable. Digital health executives who understand this profound responsibility treat compliance to standards as a core strategic mandate. This commitment, despite requiring an investment of time and resources, is deemed a necessary undertaking to ensure the long-term viability of the consumer's trust.



Delegated Responsibility: Why Users Feel Less Personal Risk

Consumers are demonstrably secure in their use of digital health technologies, seemingly unburdened by intense, everyday worry about inherent risks. While a notable portion (an average of 43%) of the total market expresses high concern regarding foundational risks like physical safety, data privacy, and hacking, only about half of those concerned feel they are very much personally at risk (an average of 26% among users) across these same critical categories. This substantial gap between general market concern and the user's self-assessed risk suggests a strong implicit trust in the manufacturer: consumers know the risks exist externally, but they expect the company to have already managed these baseline safety and security measures through robust design, standards conformance, and certification, effectively offloading the burden of vigilance from the user to the manufacturer.

This lack of concern is not negligence — it is delegation. Consumers implicitly believe that safety is the manufacturer's responsibility. This reliance is fragile and requires continuous work from different players in the digital health ecosystem.

	Very Concerned About Risk	Very Much Feel Personally at Risk
Physical Safety	42%	25%
Data Privacy	45%	27%
Hacking	42%	26%

The Executive Burden: Managing the Investment Behind Implicit Trust

Executives are managing the operational demands associated with providing this assurance. They are strategically committed to standards conformance, recognizing its role in building trust, while acknowledging the time and resources this requires.

When asked about certifications and standards, 58% describe it as a major time and resource investment. The challenges are structural or procedural in nature. More than half (55%) cite navigating complex or changing regulations as a top challenge, followed closely by the cost of testing (46%) and the time required to move through the many stages of the certification process (43%).

70%

of consumers trust labels that show a product meets certain standards.

48%

consider independent certification "very important" when buying.

59%

rate government/regulatory approval as "very important."

Converting Cost to Asset: The ROI of Certification

Despite the time and resources involved, standards, certifications, and approvals are recognized by both consumers and executives as a primary vehicle for generating trust.

For executives, the ROI is clear; 55% of executives strongly agree that certifications increase customer trust and accelerate adoption. They are viewed as a primary lever for market performance.

For consumers, compliance to standards is a powerful differentiator. While they may not check for them initially, once they begin moving through the buying journey, standards become impactful.

Crucially, this trust translates to value. Sixty-eight percent of consumers indicate they would switch brands to a certified product, and 72% said they would prefer a certified product even if that certification was not required. This willingness to prioritize certified products creates a path for executives to recoup the investments required to meet standards.

BRIDGING THE AI AND DATA TRUST GAP:

An Executive Opportunity to Earn Consumer Confidence

As digital health technologies are evolving from simple step-trackers to more complex and personalized AI-driven diagnostics, the trust stakes get higher. Data is becoming more sensitive, and the algorithms processing it are often difficult for consumers to understand, compounding skepticism and concerns about accountability.

Trust Erosion: The Sensitivity and Source of Data

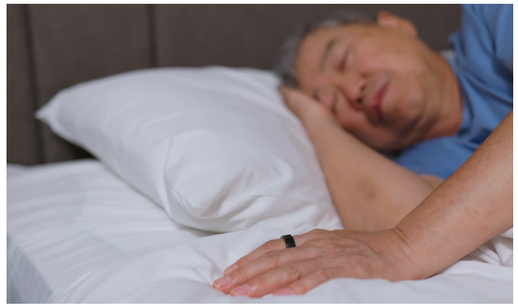
Trust in digital health is shaped by context, not treated the same across all sectors. Consumers tend to feel comfortable sharing data with companies they believe have a duty to keep it secure.

> 84% feel confident that doctors will use personal health data responsibly.

> 76% echo this sentiment for telehealth providers.

However, as soon as data leaves the clinical sphere, trust erodes. Confidence drops to 69% for fitness tracker companies, 60% for app store platforms, and 58% for government agencies.

Furthermore, not all data is treated equally. While 78% of consumers are comfortable sharing fitness data, comfort dips significantly as the data becomes more personal, dropping to 65% for mental health data and just 57% for reproductive or sexual health information. This sensitivity threshold suggests that the more sensitive the data, the harder companies must work to earn consumer trust.



The AI Confidence Gap: Accuracy and Accountability Skepticism

Artificial intelligence represents the new frontier of trust. Currently, consumer sentiment is best described as "cautiously open," with only 22% saying they are "very comfortable" with the role AI plays in digital health.

Their hesitation is rooted in specific factors. Consumers express high levels of concern regarding:

> AI providing inaccurate diagnoses (82%)

> Their personal health data being shared without consent (81%)

> The lack of accountability if something goes wrong (80%)

Executives are acutely aware of these skepticisms. They have identified AI and machine learning as the absolute highest priority for new standards over the next 3 to 5 years (52%), far outpacing other categories like cybersecurity (21%) and data governance (5%). They understand that to sell AI innovations to a skeptical public, they need the stamp of approval that standards and certifications provide.

Strategic Recommendations for Executives

The data presents a clear mandate: standards and certifications are a strategic asset that unlocks consumer trust and confidence.

Champion Data Stewardship

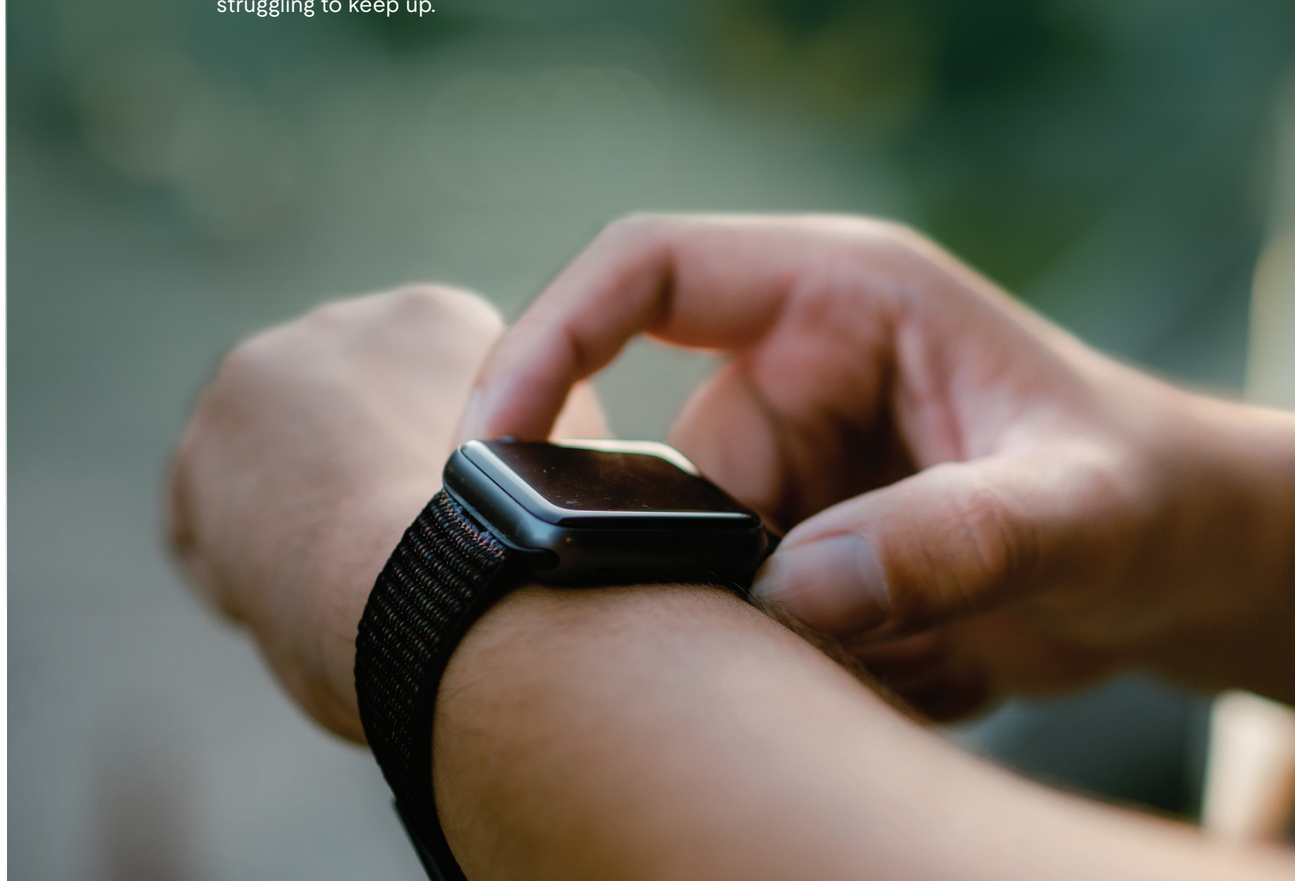
Trust declines when data moves away from health clinicians. To counter this reduction, digital health companies must act more like doctors and less like tech platforms. Implement clear, accessible data policies, especially for sensitive data (mental/reproductive health) and make stewardship visible.

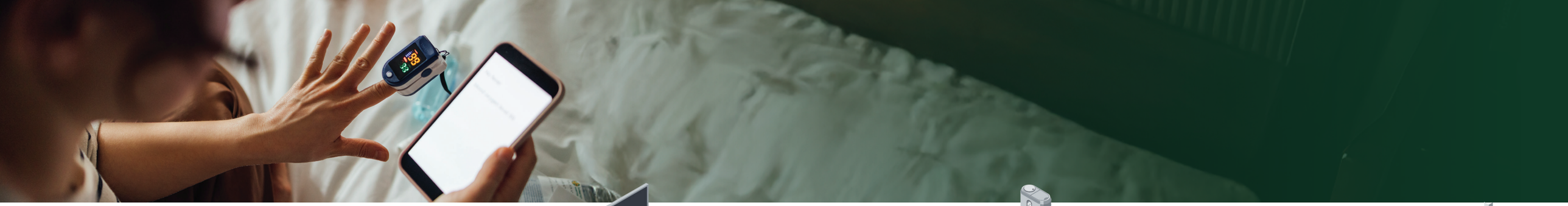
Prioritize AI Governance and Transparency

The AI confidence gap is the single biggest barrier to the next wave of innovation. Proactively seek third-party certification for AI and machine learning models to validate accuracy and fairness. Executives identified AI as the number one priority for standards. Now they must execute on this priority by adopting frameworks that prove their algorithms are safe, unbiased, and accountable.

Engage in Standards Development Leadership

Waiting for regulations to change — or exist — is a risk; shaping them is a strategy. While the vast majority of standards are adopted voluntarily, those who help develop them influence how safety is defined and how any future regulation may take shape. Active participation allows companies to position themselves as leaders defining safety and not followers struggling to keep up.





Advancing Innovation Through Standards

1. **Alert Devices**
   UL 1637 Ed.5, Home Health Care Signaling Equipment

2. **Blood Pressure Cuff**
   UL 60601-1, Medical Electrical Equipment

3. **Mobile Health App**
   ANSI/CTA-2135, Performance Verification and Validation for Predictive Health AI Solutions

   ANSI/CTA-2107-A, The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data

4. **Fitness Band**
   ANSI/CTA-2056-A, Physical Activity Monitoring for Step Counting

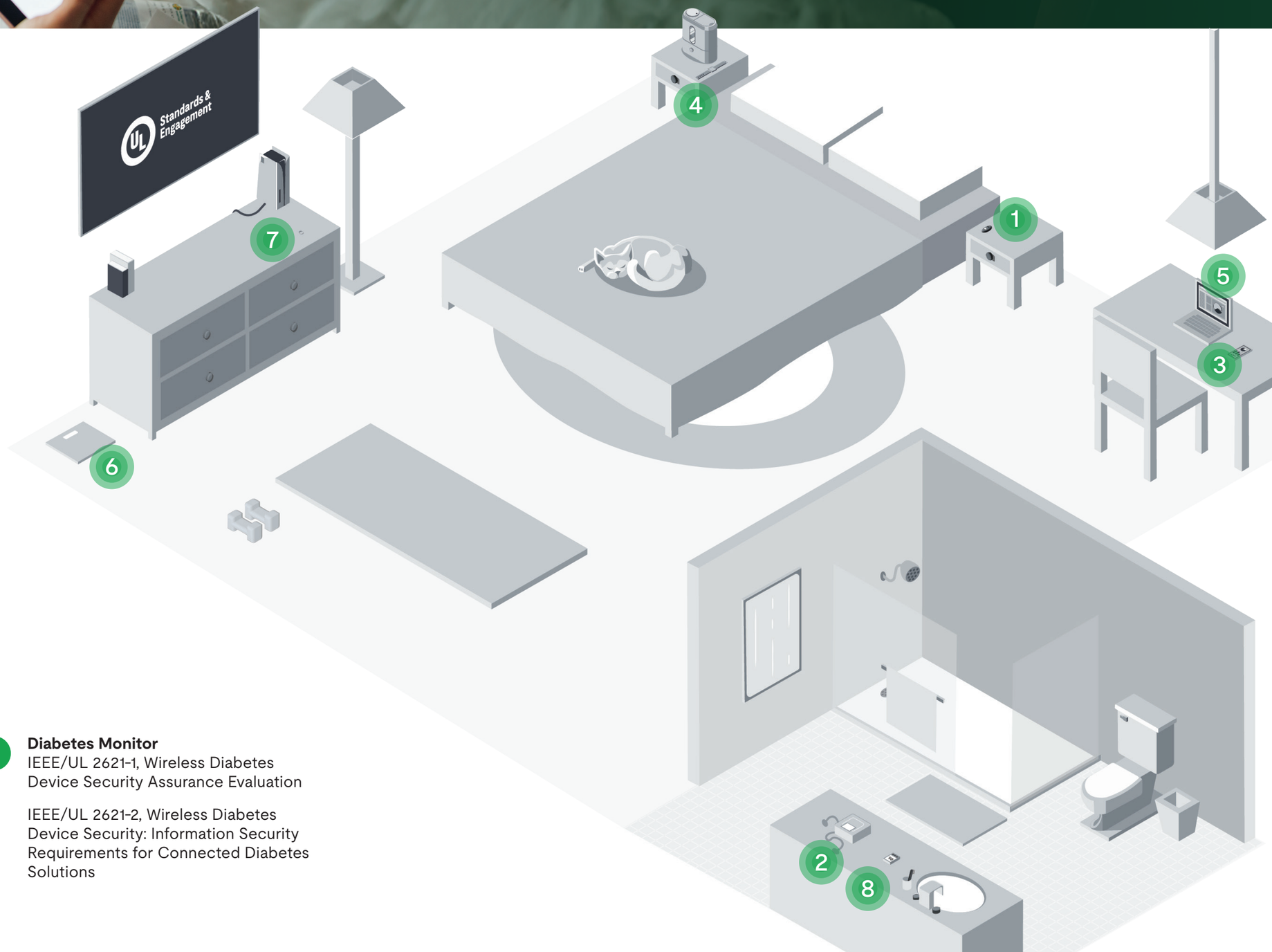
5. **Patient Portal**
   UL 2900-2-1, Software Cybersecurity for Network-Connectable Products

6. **Smart Scale**
   ANSI/CTA-2073-A, Guiding Principles of Practice and Transparency for Mobile Health Solutions

7. **Smart Ring**
   ANSI/CTA/NSF-2110, Recommendations and Best Practices of Sleep Quality Determination in Consumer Sleep Solutions

8. **Diabetes Monitor**
   IEEE/UL 2621-1, Wireless Diabetes Device Security Assurance Evaluation

   IEEE/UL 2621-2, Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions



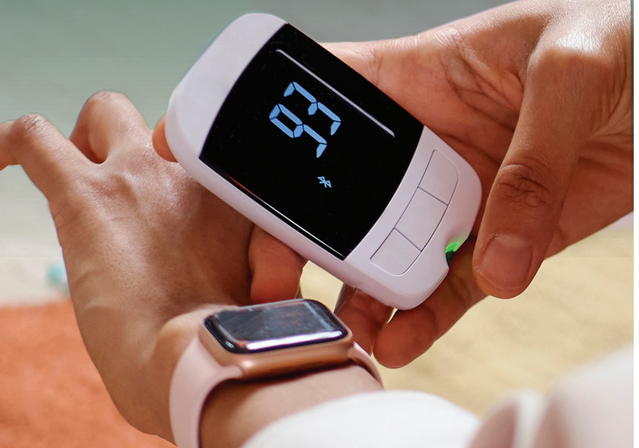
Advancing Innovation Through Standards

UL Standards & Engagement and the Consumer Technology Association® develop standards that guide technological progress across smart homes, artificial intelligence, cybersecurity, sustainable energy, and more.

The development of voluntary consensus safety standards represents a collaborative effort across industries, bringing together diverse expertise to establish trusted guidelines. These standards emerge through a transparent process where manufacturers, testing laboratories, academic researchers, government agencies, and consumer advocates work together to define best practices. What makes these standards particularly robust is their foundation in consensus-building – each standard must achieve substantial agreement among participating stakeholders before publication. This rigorous approach ensures standards reflect both current technical capabilities and market needs, while incorporating critical safety considerations from multiple perspectives.

From medical devices to consumer electronics, these standards enable manufacturers to create safer products while building trust and instilling confidence in consumers' technology choices. Taken together, standards form a framework that protects public safety and fosters innovation everywhere — from connected health devices to climate resilience.

Learn more about a selection of ULSE and CTA standards that, along with many others, are shaping the future of digital health.



Foundational Safety, Reliability, & Performance Accuracy Standards

- UL 416 Ed.4, Refrigerated Medical Equipment
- UL 1069 Ed.8, Hospital Signaling and Nurse Call Equipment
- UL 1637 Ed.5, Home Health Care Signaling Equipment
- UL 2560, Emergency Call Systems for Assisted Living and, Independent Living Facilities
- UL 60601 / IEC 60601 Series, Medical Electrical Equipment
- UL 60601-1 Ed.1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- UL 61010-2-101 Ed.3, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
- ANSI/CTA-2051-B, Wearable Sound Amplifier Performance Criteria
- ANSI/CTA/NSF-2052.3-A, Performance Criteria for Features in Sleep Tracking Consumer Technology Devices and Applications
- ANSI/CTA-2056-A, Physical Activity Monitoring for Step Counting
- ANSI/CTA-2065-A, Physical Activity Monitoring for Heart Rate
- ANSI/CTA-2068 R-2025, Definitions and Characteristics of Consumer Technologies for Monitoring Physical and Psychosocial Stress
- ANSI/CTA-2068.1, Definitions and Characteristics of Consumer Technologies for Monitoring Physical and Psychosocial Stress - Heart Rate and Related Measures
- ANSI/CTA-2074 R-2025, Intensity Metrics: Physical Activity Monitoring
- ANSI/CTA/NSF-2092, Performance Requirements for Sleep Solutions Detecting Snoring
- ANSI/CTA-2102, Performance Criteria and Testing Protocols for Breathing Parameters
- ANSI/CTA-2105, Best Practices for Consumer Cardiovascular Technology Solutions
- ANSI/CTA-2106, Characteristics & Requirements for Chronic Stress Technology Solutions
- ANSI/CTA-2109, Evidence Based Performance Criteria for Digital Therapeutics
- ANSI/CTA/NSF-2110, Recommendations and Best Practices of Sleep Quality Determination in Consumer Sleep Solutions
- ANSI/CTA-2112, Best Practices for Consumer Cardiovascular Technology Solutions: Screening and Diagnosis
- ANSI/CTA-2118, Four Frequency Pure Tone Average Testing Methodology and Reporting for Consumer Facing Hearing Solutions
- ANSI/CTA-2124, Characteristics and Requirements for Integrated Continuous Glucose Monitoring (iCGM) Solutions for Consumer Use Cases
- ANSI/CTA-2127, Performance Characteristics and Requirements for Consumer Pulse Oximetry Monitoring Solutions
- ANSI/CTA-2128, Physical Activity Monitoring for Human Gait Biomechanics
- ANSI/CTA-2135, Performance Verification and Validation for Predictive Health AI Solutions

Privacy & Cybersecurity

- UL 2900 Series / UL 2933, Standard for Clinical Internet of Things (CIoT) Data and Device Interoperability with TIPPSS (Trust, Identity, Privacy, Protection, Safety, and Security).
- UL 2900-2-1 Ed.1, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
- UL 5500, Standard for Safety for Remote Software Updates; establishes safety requirements for software updates delivered remotely to devices
- CTA-2073-A, Guiding Principles of Practice and Transparency for Mobile Health Solutions

AI & Algorithmic Transparency

- ANSI/CTA-2090, The Use Of Artificial Intelligence in Health Care: Trustworthiness
- ANSI/CTA-2107-A, The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data
- ANSI/CTA-2116, Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias
- ANSI/CTA-2135, Performance Verification and Validation for Predictive Health AI Solutions

Interoperability

- UL 1376, UL 1389, UL 8400 Series, IoT and Smart Systems Safety, cover data integrity, interoperability, and risk analysis for connected devices.
- UL 2800-1 Ed.2, Medical Device Interoperability

Broader Standards Influencing Digital Health

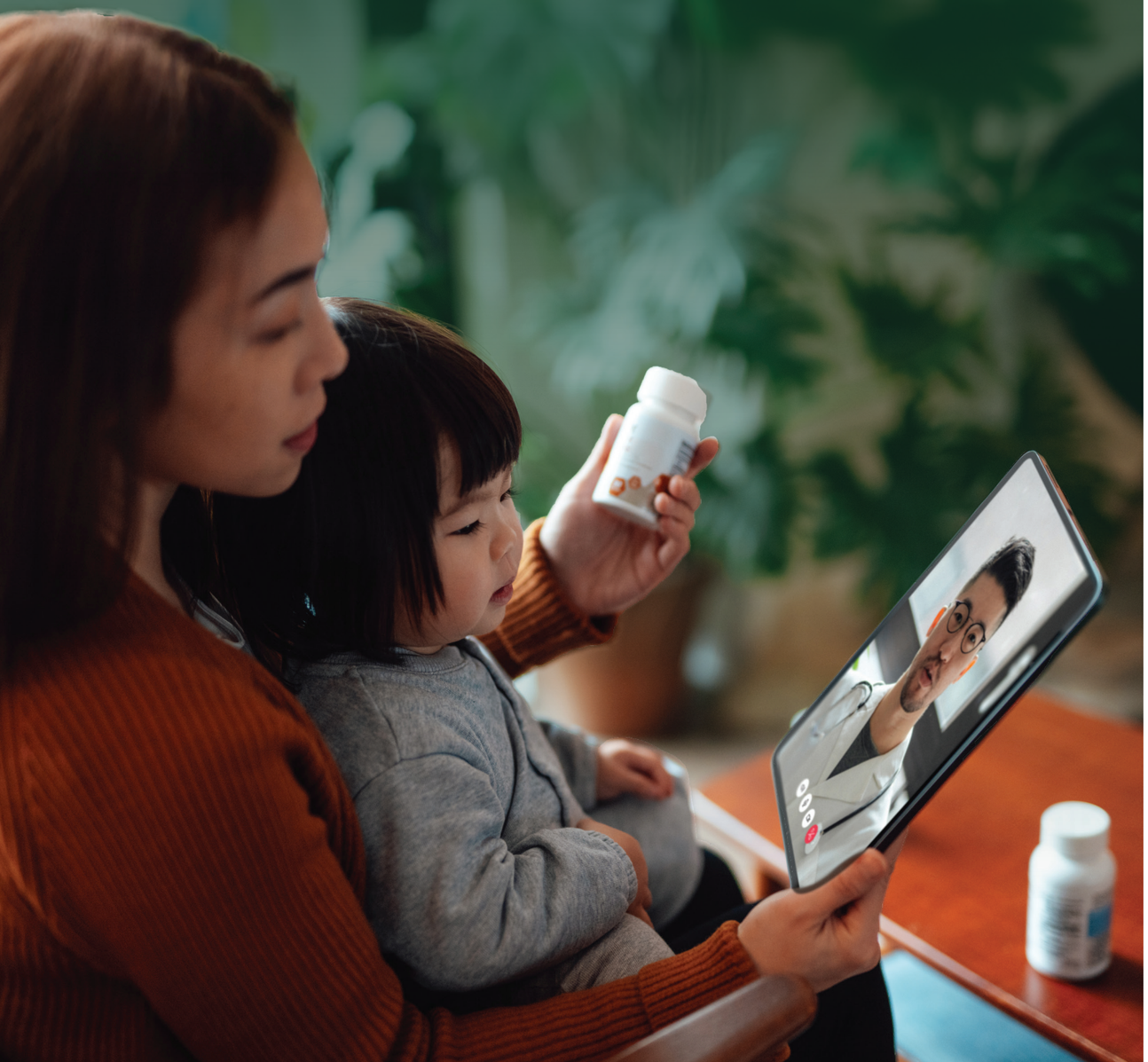
- IEEE/UL 2621-1, Wireless Diabetes Device Security Assurance Evaluation: Connected Electronic Product Security Evaluation Programs
- IEEE/UL 2621-2, Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions
- UL 2941, Cybersecurity for Inverter-Based Resources
- UL 3600, Circular Economy and Sustainability

Supporting Ecosystem Standards

- UL 1998, Software in Programmable Components
- UL 8820 Series, Energy Systems Equipment and Battery Management
- UL 62368-1 Ed.4, Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements

Research Methodology

These results were taken from two separate UL Standards & Engagement Insights surveys to provide a comprehensive view of how safety standards influence both consumer behavior and business innovation in the digital health sector. All studies were designed and formulated by UL Standards & Engagement. Surveys were administered online by NewtonX.



Consumer Study

- n=1,000 U.S. adults, conducted in November 2025
- The sampling allowed for natural fallout across digital health users and non-users
- 79% wellness digital health users, 70% medical digital health users
- 30% Early Adopter (i.e., “I am usually one of the first people to try new technologies”)

The margin of sampling error for the consumer study, at 95% confidence for aggregate results, is +/- 3%. Sampling error is larger for subgroups of the data.

Business Executive Study

- n=84 Senior decision-makers at companies that design, build, or operate digital health technologies (devices, apps, platforms/services) for wellness and/or medical use, conducted in November 2025
- 19% Leadership or Executive Management
- Primary industry: 23% Health IT/Care-Delivery Platforms (non-device), 23% Software as a Medical Device, 20% Wellness & Consumers Health Products, 20% Medical Device Hardware (non-IVD)
- Business Segment Classification: 29% Devices (including IVD), 23% Telehealth/Care-Delivery Platforms, 23% Digital Therapeutics & Software as a Medical Device
- 30% Less than 50 employees, 35% 50-500 employees, 36% More than 500 employees
- 61% always consulted or directly involved in decisions regarding product certifications

The margin of sampling error for the business executive study, at 95% confidence for aggregate results, is +/- 9%. Sampling error is larger for subgroups of the data.

As with any survey, sampling error is only one source of possible error. While non-sampling error cannot be accurately calculated, precautionary steps were taken in all phases of the survey design and the collection and processing of the data to minimize its influence.

Note: All numbers are percentages unless otherwise noted. Figures may not total 100% due to rounding.

ABOUT US

UL Standards & Engagement

UL Standards & Engagement is a nonprofit standards development and advocacy organization that translates safety science into practical, action-oriented standards, from toasters to life jackets, and lithium-ion batteries to solar power.

The organization also serves as a vital resource for policymakers and shares knowledge, advances partnerships, and advocates for standards and policies to create a safer, more sustainable world.

Learn more at **ULSE.org**.

Fast Facts:

- 1,700+ standards and documents in use today
- 4,000+ individuals serve on ULSE Technical Committees
- 40+ countries are represented through our Technical Committees
- 80+ MOUs with agreements in several countries and regions
- ULSE is the only organization accredited in the U.S. and Canada, and authorized in Mexico

ABOUT US

Consumer Technology Association (CTA)®:

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world.

The mission of CTA is to help innovators of all sizes grow their businesses. Through targeted advocacy, collaborative standard setting and cutting-edge insights, we provide the tools and support that businesses and individuals need to shape the future of technology and drive meaningful progress.

Our Advocacy
Through policy work on Capitol Hill, we protect the innovation economy from laws and regulations that delay, restrict or ban the development of technologies.

Our Research
Get exclusive research from CTA industry experts to help you predict market conditions and plan for the future. Whether it's evaluating technology trends or forecasting industry sales, you'll understand the opportunities and barriers to get products to market.

Our Standards
Market-shaping decisions start here. Influence the standards-setting process by becoming an early player in market-shaping decisions. ANSI accredited, CTA standards have shaped industry as we know it today.

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