Health data in the light of FDA's 2026 update

Collecting. Guiding. Deciding.
What digital health product teams need to know.

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Foreword

Przemek Jaworski
CTO & co-founder
of Shen AI

Digital health has reached a point where generating data is no longer the challenge. Today, we can capture physiological and behavioral signals continuously, across a wide range of devices and contexts. Wearables track sleep and activity, optical methods extract vital signs from a simple camera, and clinical systems add further layers of structured data. From a technical perspective, the foundations for continuous, personalized health monitoring are already in place.

What remains unresolved is how this data is actually used in practice.

For many product teams, the reality is still fragmented. Signals come from different sources, in different formats, with varying levels of reliability. Integrating them into a coherent product experience requires significant effort. At the same time, regulatory considerations are often addressed later than they should be, once the product is already taking shape. The boundary between general wellness and medical functionality is not always clear, and navigating that ambiguity can slow down both development and adoption.

The FDA's January 2026 update to its General Wellness guidance brings an important shift in this context. It acknowledges a class of technologies that until recently sat in a grey area. It also clarifies expectations around how physiological values are presented and communicated to users. For teams building digital health products, this is less about new restrictions and more about a clearer map of where the boundaries are.

This report brings together perspectives from people working directly in this space: across data infrastructure, product strategy, and regulatory interpretation. Rather than approaching the topic in isolation, it looks at how these layers interact in real-world product development. The goal is to better understand how the current health data ecosystem operates, what the latest regulatory changes actually mean in practice, and how teams can move forward with more confidence within this evolving framework.

We have more health data than ever, and it's still underutilized

These days, we track nearly everything about ourselves. With rings, watches, and sensors, we gather more data on a single morning's heart rate than our grandparents accumulated across years of doctor visits. Every step, every hour of sleep, every heartbeat is recorded somewhere, forming a dense digital map of our daily lives.

Despite this growth in data volume, comprehensive health insight remains difficult to achieve. Data is distributed across disconnected platforms, integration standards vary, and many organizations lack the infrastructure to convert raw signals into actionable outputs. Research indicates that approximately 47% of available clinical and operational health data remains underutilized in decision-making[1] – not due to lack of value, but due to fragmentation and workflow misalignment.

47%

of clinical and operational health data still left untapped in decision-making.

This structural disconnect defines the current digital health landscape. Resolving it requires not only technical interoperability, but also regulatory clarity. As health technologies evolve toward continuous, remote monitoring, policy frameworks must address how data can be presented, interpreted, and positioned within the boundaries of general wellness.

The sections that follow examine how these technical and regulatory dynamics intersect and what they mean for teams building digital health products today.

[1] The current state of healthcare analytics platforms, Arcadia and HIMSS

How health data is collected today

Not all health data is equivalent. Before discussing integration or regulatory positioning, it is essential to understand how data is collected. The collection modality directly influences signal type, measurement reliability, contextual depth, user adherence, and, in some cases, regulatory classification.

Camera-based monitoring

Camera-based health monitoring is a contactless measurement method that uses any kind of camera to extract physiological signs from a video. In a recording as short as 30 to 60 seconds, it can derive a meaningful set of health metrics from what essentially is a brief, structured health check-in.

Two core modalities play a role in this: remote photoplethysmography (rPPG) and remote ballistocardiography (rBCG), both of which analyze subtle visual signals to derive physiological parameters. rPPG detects micro-variations in skin coloration associated with blood flow, while rBCG analyzes small, pulse-induced head movements. Together, they support estimation of metrics such as heart rate, heart rate variability (HRV), breathing rate, and other cardiovascular indicators without requiring wearable hardware or physical contact.

In many use cases, camera-based monitoring functions as a health snapshot, at a defined moment in time. A user opens an app, completes a short scan, and receives a health report. This model fits naturally into daily check-ins, onboarding flows, or pre-session assessments.

The technology is not limited to these snapshots, though. In settings where continuous measurement is required, e.g. remote patient monitoring, extended wellness sessions, or background capture during a defined activity, camera-based

monitoring can also serve as an ongoing data stream - the use case defines the cadence.

Continuous monitoring with wearables

Wearable devices enable continuous physiological tracking. Platforms such as WHOOP, Oura Ring, Garmin, and Apple Watch monitor heart rate, heart rate variability (HRV), sleep patterns, and activity levels throughout the day.

Their primary advantage is contextual continuity. Measurements are captured during daily life rather than in structured clinical environments. This reduces the likelihood of situational artifacts that can occur in clinical settings.

The distinction between clinical and home-based measurement environments is well documented. Blood pressure readings obtained in medical offices are often elevated compared to home measurements – a phenomenon commonly referred to as white-coat hypertension. Similarly,

Jonas Dücker
COO & CMO, **ROOK**

When teams rely primarily on wearable data, which health signals are most likely to be missing?

Blood pressure and non-invasive glucose measurement remain two of the most technically challenging areas for wearables. While progress is ongoing, both are still evolving in terms of accessibility and clinical robustness.

Beyond hardware limitations, user adherence is a significant variable. Wearables must be worn consistently and correctly to generate reliable data. If a device is removed, runs out of battery, or is worn improperly, gaps or signal inconsistencies can occur.

In aggregated datasets, these issues often appear as anomalies – values that do not correlate with adjacent signals. In many cases, such outliers reflect usage variability rather than physiological change. Identifying and accounting for these patterns adds complexity to interpretation, particularly for teams aiming to build reliable, decision-supporting systems on top of wearable inputs.

laboratory-based sleep studies frequently produce results that differ from natural at-home sleep patterns. Continuous wearable monitoring mitigates some of these contextual distortions by design.

However, wearables also have limitations. Two areas that remain technically challenging are cuffless clinical-grade blood pressure measurement and fully non-invasive glucose monitoring. While innovation continues in both domains, solutions are still evolving in terms of accuracy, accessibility, and user convenience.

Beyond hardware constraints, user adherence introduces variability. Devices may be removed, worn incorrectly, or left uncharged, leading to data gaps or inconsistent signal quality.

Traditional data streams

The health data ecosystem encompasses a wide range of structured sources: laboratory diagnostics, electronic health records (EHRs), continuous glucose monitors (CGMs), genetic data, microbiome analysis, and medication histories. These form the clinical backbone of health data, generated within or adjacent to formal healthcare settings, and carrying a high degree of institutional trust and standardisation.

Each of these sources contributes something meaningful. But they all share a common limitation: they tend to capture health at specific moments in time, usually in the context of a clinical visit or a formal test. What happens between those moments - how someone's blood pressure behaves across a normal Tuesday, how their sleep shifts over a stressful week, how their body responds to a change in medication day by day - largely goes unrecorded. For most people, health data only exists when something has already prompted them to seek care.

That gap is where newer collection methods come in. Both camera-based monitoring and wearable devices make it possible to capture health signals continuously, in the context of everyday life, extending the picture beyond what clinical systems alone can see.

The integration challenge

The digital health ecosystem does not lack data overall. But for many patients, the reality is the opposite: there is not nearly enough of it, and what exists often arrives too late.

For a large share of the population, meaningful health monitoring only begins after a clinical encounter: a diagnosis, a referral, a concerning result at a routine check-up. Until that moment, there is often no baseline, no trend data, and no early signal. The entry threshold into regular monitoring is, in practice, a doctor's appointment. That creates a significant access barrier, and it means that the people who most need longitudinal health data - those managing chronic conditions, or those at risk of developing them - are frequently the least likely to have it.

This matters most in chronic disease management, where regularity of measurement is not a nice-to-have but a clinical necessity. Blood pressure, glucose levels, heart rate variability, breathing rate - these are not static readings. They shift with behavior, stress, medication, and time. A single measurement taken once every few months at a clinic captures almost none of that variation. Yet for many patients, that remains the standard cadence.

The challenge, then, is twofold. First, making health monitoring accessible enough that it happens before and beyond the clinical encounter, not just reactively, but as a continuous part of daily life. Second, making the data that results from that monitoring actually usable when it reaches the hands of clinicians, product teams, or the patients themselves.

For a large share of the population, meaningful health monitoring only begins after a clinical encounter.

That second challenge is where fragmentation bites. At the system level, medical records are distributed across

heterogeneous EHR platforms with limited interoperability. In the United States, initiatives such as Qualified Health Information Networks (QHINs) aim to enable broader health data exchange, but implementation remains uneven. Across Europe, interoperability challenges are further complicated by national variation in data governance, infrastructure, and health system architecture.

At the device level, data standardization remains inconsistent. Major wearable platforms, including Whoop, Oura, Garmin, Fitbit, and Apple Watch, collect similar physiological signals but structure and transmit them differently. Sampling frequencies vary, naming conventions differ, and even commonly referenced metrics such as “active minutes” are defined using distinct methodologies. When additional inputs such as CGM data, episodic optical

Jonas Dücker
COO & CMO, **ROOK**

Beyond collecting more data, what should product teams prioritize?

Quality must take precedence over volume. The focus should be on what can be described as intervention-ready or AI-ready data. Reaching that level requires progression through four distinct layers.

The first is access – establishing reliable connections to source systems and devices. The second is harmonization – standardizing inputs so that equivalent metrics are structured consistently, regardless of origin. The third is quality control – identifying anomalies, cleaning inconsistencies, and validating signal integrity.

Only after these foundational layers are in place does the fourth layer become meaningful: insight generation. This is where pattern shifts and clinically or behaviorally relevant deviations become visible.

Without the underlying infrastructure, insight generation lacks stability. Teams that attempt to extract conclusions without standardized, validated inputs risk producing outputs that are difficult to trust or operationalize.

measurements, and laboratory diagnostics are introduced, integration complexity increases further.

This fragmentation is not solely a technical limitation. It reflects a combination of architectural design choices, evolving standards, and market dynamics. Historically, device ecosystems have optimized for vertical integration rather than portability across platforms. As a result, even organizations with access to substantial data streams may struggle to synthesize them into coherent, decision-supporting systems.

The hierarchy Jonas outlines – Access, Harmonization, Quality Control, and Insight – provides a practical framework for product teams working across multiple health data sources. It shifts the strategic focus from increasing data volume to increasing data usability.

The intelligence layer, including AI models designed to identify pattern shifts and surface relevant signals, depends on the integrity of the layers beneath it. Without standardized inputs and validated signal quality, downstream analytics become unstable or misleading. Data alone does not create value. Value emerges when inputs are structured, harmonized, and quality-assured in a way that supports reliable interpretation and action.

Even organizations with access to substantial data streams may struggle to synthesize them into coherent, decision-supporting systems.

When insight becomes a product: The regulatory inflection point

As digital health products evolve, data shifts from backend infrastructure to user-facing experience. Signals are translated into displayed values, trend visualizations, notifications, and recommendations. At this stage, regulatory classification becomes a central design consideration.

The FDA regulates medical devices, including certain software functions. Historically, the boundary between general wellness functionality and regulated medical device software has not always been intuitive for product teams. The distinction carries substantial implications for development timelines, evidence requirements, and go-to-market strategy.

The 2026 update to the FDA's General Wellness guidance provides additional clarity on this boundary. For digital health teams, the practical importance lies not only in the text of the update, but in how it influences product design decisions, user messaging, and feature scope.

Rebecca Gwilt of Elevare Law frames regulatory positioning through three core FDA guidance documents applied sequentially:

1. **Device Software Functions Guidance** – the threshold question: does the software function meet the statutory definition of a medical device?
2. **General Wellness Guidance** – which outlines conditions under which low-risk wellness products may fall within enforcement discretion.
3. **Clinical Decision Support Guidance** –which addresses software that analyzes or interprets data for clinical purposes.

Together, these documents provide a structured pathway for evaluating where a digital health product sits. Many teams focus primarily on the General Wellness guidance, but a comprehensive assessment requires understanding how all three intersect.

What the FDA's 2026 update clarifies

The January 2026 update to the FDA's General Wellness guidance does not alter the foundational definition of a medical device. Instead, it provides additional clarification on how contemporary sensing technologies and software-driven experiences may fit within the existing regulatory framework. For product teams, the update primarily reduces ambiguity rather than expanding statutory scope.

The two-category framework

The guidance continues to define two categories of general wellness intended use.

Category 1

applies to claims related solely to general health improvement, without reference to specific diseases or medical conditions. Examples include weight management, physical fitness, stress management, sleep quality, relaxation, mental acuity, or sexual function. Applications that track sleep trends or display recovery scores without referencing disease risk typically fall within this category.

Category 2

permits limited references to diseases or chronic conditions, provided claims are framed in terms of supporting a healthy lifestyle that may help reduce the risk of or may help live well with a condition. Such claims must be supported by well-established scientific evidence in peer-reviewed literature or recognized by authoritative health organizations. Category 2 claims require careful documentation and disciplined framing.

Clarification around physiological sensing

One of the more consequential clarifications in the 2026 update concerns non-invasive physiological sensing technologies.

The guidance acknowledges that certain non-invasive optical or sensor-based technologies may output physiological parameters, such as heart rate, heart rate variability, oxygen saturation, or blood pressure estimates, and still qualify under general wellness enforcement discretion, provided specific criteria are satisfied.

These criteria include:

- The product must be non-invasive and non-implanted.
- The technology must not pose safety risks that would require active regulatory controls.
- The product must not be intended for diagnosis, cure, mitigation, treatment, or prevention of disease.
- It must not position itself as a substitute for an FDA-cleared medical device.
- It must not prompt specific clinical actions.
- It must avoid presenting values in a manner that implies clinical diagnostic use unless supported by appropriate validation.

The guidance further clarifies that qualifying products may display values, ranges, trends, baselines, and longitudinal summaries, and may contextualize those outputs within wellness domains such as activity, sleep, stress, or recovery.

> **The update primarily reduces ambiguity rather than expanding statutory scope.**

Refined expectations for notifications

The 2026 update also provides more nuanced guidance regarding user notifications.

Under prior interpretations, alerts encouraging users to consult healthcare professionals were often viewed as potentially shifting a product toward medical device classification. The revised guidance clarifies that a general recommendation to consider professional evaluation may fall within wellness bounds, provided the notification:

- Does not reference a specific disease,
- Does not characterize a value as diagnostic or clinically abnormal,
- Does not cite clinical thresholds,
- Does not include treatment recommendations, and
- Does not constitute ongoing disease management monitoring.

In practical terms, language that encourages general health follow-up may remain within the wellness category. Explicit statements linking a specific reading to a named condition or clinical threshold would not.

Rebecca Gwilt
Co-founder & Managing Partner
Elevare Law

Can you provide a concrete example of a product that clearly qualifies as general wellness, and one that would likely fall into regulated device territory?

Blood pressure provides a useful illustration. Displaying blood pressure trends alongside activity or recovery data, framed within a broader wellness context, can fall within the general wellness category.

However, the framing is critical. If the product states that a specific reading may indicate hypertension, or links the output directly to a named medical condition, the intended use shifts toward diagnosis. At that point, the product would likely be considered a regulated medical device.

The guidance makes clear that classification does not depend solely on the measurement itself, but on how the output is interpreted, presented, and positioned within the user experience. Intended use, as conveyed through labeling, claims, and instructions, is the determining factor.

It is also important to remember that FDA guidance documents represent the agency's interpretation of existing statutory authority. They are not statutes themselves. Companies may challenge or seek alternative interpretations, but doing so typically requires substantial regulatory resources and tolerance for legal risk, factors that many early-stage companies may not be prepared to assume.

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Boundaries that remain firm

While the clarification is meaningful, the underlying boundaries are unchanged. A product moves into medical device territory if it:

- Claims to diagnose, treat, cure, mitigate, or prevent a disease;
- Frames outputs as clinical determinations or abnormal findings;
- Provides alerts requiring specific medical action;
- Claims equivalence to or substitution for an FDA-cleared device; or
- Uses labeling, marketing, or interface design that establishes a diagnostic intended use.

Language that encourages general health follow-up may remain within the wellness category

The Whoop case is illustrative. In July 2025, the FDA sent a warning letter stating that Whoop's blood pressure insights feature made the product a regulated device, because the company was marketing it as a tool to measure blood pressure – a measurement the agency views as inherently associated with the diagnosis of hypertension and hypotension. The technology itself was not the problem, but the framing was.

Practical considerations for product teams

Understanding the regulatory guidance conceptually is one step. Embedding it into product development workflows is another. Organizations that manage this successfully tend to treat regulatory positioning as a design input from the outset, rather than a downstream legal review.

Begin with the intended use

A clearly articulated intended use statement is foundational. This does not need to be a legal memorandum or marketing language. It should be a concise, plain-English description of what the product is designed to do and explicitly what it is not designed to do.

Ideally, this statement is defined early in development and used as a reference point across product, engineering, marketing, and compliance functions. It serves as a decision filter: new features, claims, and interface elements are evaluated against whether they remain consistent with the stated intended use.

For organizations operating within the general wellness category, this often means maintaining a wellness-oriented framing that emphasizes self-awareness, trend visibility, and lifestyle context rather than diagnosis or clinical determination.

Claims and UX review

Regulatory risk frequently emerges not from the underlying technology, but from how outputs are described and contextualized. Language used in landing pages, in-app copy, notifications, and onboarding flows can materially influence

classification. For example, framing a feature as “detecting early signs of cardiovascular disease” introduces diagnostic intent, even if the underlying functionality has not changed.

Systematic review of claims, thresholds, visualizations, and notification logic is therefore essential. Regulatory alignment should extend beyond engineering decisions into product messaging and user interface design.

In practice, general wellness positioning often follows a few consistent principles:

- Emphasize trends, baselines, and longitudinal patterns rather than single-point clinical interpretation.
- Avoid explicit disease terminology or diagnostic framing.
- Design notifications to encourage reflection or follow-up, rather than direct specific medical action.

A common misconception is that a disclaimer alone determines classification. In reality, the FDA evaluates the totality of a product’s labeling, user interface, marketing materials, and claims. A disclaimer cannot offset language elsewhere in the product experience that implies diagnostic intent.

Validation as a foundational requirement

The 2026 guidance underscores that when products display values resembling clinical measurements, such as blood pressure readings, oxygen saturation percentages, or glucose estimates, those outputs should be supported by appropriate validation.

Validation may include manufacturer-led testing, peer-reviewed literature, or formal clinical evaluation, depending on the context and claims. Absent credible validation, presenting clinical-style values increases regulatory risk, particularly if the outputs resemble diagnostic measurements.

For camera-based monitoring and other emerging sensing modalities, maintaining clear documentation of validation methodology for each surfaced parameter is an important

component of a defensible compliance posture. Beyond regulatory considerations, validation increasingly influences enterprise procurement decisions and healthcare partnerships.

Cross-functional alignment

Regulatory positioning is not solely a legal function. Product design, engineering implementation, marketing language, and user experience all contribute to intended use.

In many organizations, these functions operate in parallel rather than in coordination. Establishing structured review processes – where claims, feature releases, and notification logic are evaluated collectively – reduces the likelihood of misalignment. Cross-functional governance becomes particularly important in early-stage companies, where rapid iteration can outpace regulatory review if clear checkpoints are not in place.

In practice, cross-functional alignment often translates into structured governance mechanisms:

- A centralized, approved language framework defining terminology that is in scope and out of scope;
- A user experience review checklist applied consistently before feature release;
- A formal escalation process for claims or outputs that approach clinical positioning.

These controls reduce ambiguity and create institutional consistency across teams.

AI systems and emerging compliance complexity

As product teams integrate generative AI and large language models into digital health products, including AI-driven health coaches, conversational interfaces, and personalized recommendation engines, regulatory considerations become more dynamic.

Unlike static user interface copy, AI-generated outputs evolve with model refinement. As models improve in pattern detection and personalization, their responses may become increasingly specific. Greater specificity, however, can inadvertently resemble clinical interpretation or advice, even if disease terminology is not explicitly used.

A product may launch with messaging clearly positioned within general wellness parameters, yet over time produce outputs that edge toward diagnostic framing through model optimization alone. Regulatory guidance does not yet address all aspects of this dynamic explicitly, and additional clarity in this area is anticipated as agencies continue evaluating AI-enabled health software.

Rebecca Gwilt
Co-founder & Managing Partner
Elevare Law

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What does effective cross-team alignment look like in practice and what are the risks when it breaks down?

When alignment breaks down, it often reflects organizational silos. Marketing messaging may be developed independently from regulatory review, or product features may be released without evaluating how they affect intended use. In many cases, the underlying technology remains unchanged but claims language or interface design inadvertently shifts the regulatory posture.

When alignment works well, intended use is treated as a shared operating constraint rather than a legal afterthought. Marketing, product, engineering, and legal functions all understand the regulatory boundaries and incorporate them into their decision-making processes.

In practical terms, this can involve structured review workflows, predefined claims guidelines, and clear escalation pathways. If a proposed feature or marketing statement extends beyond the defined intended use, that decision is elevated for deliberate review rather than implemented by default.

Effective alignment does not require every team member to become a regulatory specialist. It requires embedding regulatory awareness into the product development process, so that intended use informs decisions consistently across functions.

From a practical standpoint, mitigation strategies include embedding the intended use statement directly into model constraints, implementing output monitoring, and establishing review mechanisms for edge-case responses. While such controls do not eliminate regulatory risk entirely, they demonstrate proactive governance and strengthen a defensible compliance posture.

A function-by-function regulatory lens

The 2026 guidance reinforces an important principle: regulatory classification applies to individual software functions rather than entire platforms by default.

A single product ecosystem may contain features that qualify as general wellness and others that meet the definition of a regulated medical device. These can coexist, provided the functions are clearly delineated and positioned appropriately.

For product strategy, this creates optionality. Teams may elect to commercialize wellness-positioned functionality while pursuing separate regulatory pathways for device-classified features in parallel. Such an approach allows continued market engagement and iteration while more formal regulatory processes proceed independently.

Anna Szopa
Chief Quality & Regulatory Officer,
Shen AI

How does Shen AI approach the boundary between wellness and medical device classification in day-to-day product development and how do you maintain alignment without slowing execution?

We approach regulation as a design constraint from the outset rather than a downstream review step. In practice, this begins with three foundational elements.

First, we define the intended use in clear, plain language, positioned within a wellness context and centered on self-awareness rather than diagnosis.

Second, we conduct a structured review of claims language. Terminology associated with diagnosis, treatment, clinical monitoring, or remote patient management is evaluated carefully to ensure alignment with the defined intended use.

Third, we design user experience elements around trends, baselines, and contextual interpretation over time. We avoid framing outputs in terms of clinical thresholds or labeling values as normal versus abnormal.

To operationalize this consistently, we maintain shared governance tools, including an approved terminology framework and a standardized UX review checklist, that are accessible across teams. These mechanisms allow product, engineering, marketing, and regulatory stakeholders to work from the same reference points.

Clear regulatory boundaries do not slow development; they reduce uncertainty. When the intended use is well defined and internalized, teams can make decisions more efficiently and build with confidence within established parameters.

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Recommendations and next steps

The 2026 guidance provides greater clarity for teams operating in the wellness and preventive health space. Organizations that interpret and operationalize it early can reduce regulatory ambiguity and strengthen product confidence.

The following steps provide a practical starting point.

1. Conduct a structured claims and UX review

Before major releases, review user interfaces, notifications, onboarding flows, and marketing materials collectively. Evaluate whether language remains aligned with wellness positioning and avoids unintended diagnostic framing. Pay particular attention to disease references, clinical thresholds, and phrasing that could imply treatment or monitoring intent. A structured review process often yields significant risk reduction with minimal operational disruption.

2. Define and maintain a clear Intended Use Statement

If no formal intended use statement exists, develop one. If one is in place, reassess whether it accurately reflects current product functionality. The statement should be concise, written in plain language, and clearly describe both what the product is intended to do and what it is not intended to do. Cross-functional teams, including product, engineering, marketing, and leadership, should be familiar with and aligned around this definition.

3. Map product functions against the FDA Framework

Evaluate features individually rather than at the platform level. For each function, determine whether it aligns with:

- Category 1 general wellness claims,
- Category 2 wellness claims involving disease references, or
- Potential medical device functionality.
- Documenting this reasoning strengthens internal clarity and supports defensible decision-making.

4. Establish shared terminology governance

Create a centralized language framework that defines approved positioning and terminology guidelines. Rather than relying on informal word bans, implement review checkpoints to ensure that claims, feature descriptions, and notifications remain consistent with intended use. Consistency across product and marketing communications reduces classification ambiguity.

Evaluate whether language remains aligned with wellness positioning and avoids unintended diagnostic framing.

5. Validate physiological outputs appropriately

If the product displays physiological values that resemble clinical measurements, such as blood pressure readings or oxygen saturation percentages, ensure appropriate validation supports those outputs. Validation approaches may include internal testing, external benchmarking, or peer-reviewed research, depending on the context. Clear documentation strengthens both regulatory posture and enterprise credibility.

6. Apply governance controls to AI-generated outputs

For products incorporating generative AI or automated interpretation layers, embed intended use constraints into model

configuration and output review processes. Monitoring output behavior over time is essential, as model refinement may alter response specificity. Proactive oversight helps prevent unintentional drift toward diagnostic positioning.

7. Consider a parallel regulatory strategy where appropriate

If long-term product strategy includes medical device functionality, begin evidence planning and regulatory pathway assessment early. Wellness-positioned and device-classified functions can coexist within a broader ecosystem, provided they are clearly delineated. Early planning reduces timeline risk and supports strategic flexibility.

The opportunity within regulatory boundaries

Regulatory ambiguity is often viewed as a constraint. In digital health, it can also serve as a catalyst for disciplined product design.

The FDA's 2026 General Wellness guidance provides additional clarity around non-invasive sensing technologies, including optical modalities, within the wellness framework. It outlines conditions under which physiological values, such as blood pressure estimates, oxygen saturation, or HRV, may be presented in a wellness context, provided appropriate validation and framing are in place. It also refines how user notifications can encourage general health follow-up without implying diagnosis.

For teams that understand and operationalize these boundaries, the framework reduces uncertainty and enables more confident product development.

At the same time, areas of ongoing evolution remain. AI-driven health insights – particularly those that generate personalized interpretations based on continuous data streams – are developing faster than regulatory guidance. The FDA has indicated that further clarification regarding patient-facing software recommendations is forthcoming. In this interim period, the most resilient organizations are those that document their reasoning, define intended use precisely, and embed regulatory considerations directly into product architecture.

Competitive advantage in digital health is not determined solely by the volume of data collected. It depends on the ability to transform heterogeneous inputs into coherent, interpretable outputs while maintaining regulatory defensibility.

Product rigor and regulatory discipline are not opposing forces. When aligned, they reinforce each other. Clear positioning, validated measurement, and careful claim design build user trust and support sustainable growth within an evolving regulatory landscape.

Contributors

Rebecca Gwilt

Co-founder & Managing Partner, Elevare Law

Rebecca works with digital health, AI, and virtual care companies navigating innovation at the edge of regulation. She helps founders and growth-stage teams translate complex healthcare rules into a strategic advantage rather than a bottleneck.

Jonas Dücker

CMO, COO, ROOK

With an MBA as well as degrees in both international business and entrepreneurship, Jonas is fascinated by projects rooted in creating change. His years of experience in scaling fitness-tech startups and in social impact companies provide him with the organization, dedication, and out-of-the-box thinking that power innovation.

Anna Szopa

Chief Quality and Regulatory Officer, Shen AI

Anna leads medical certification and compliance efforts here at Shen AI across multiple markets, navigating global certification pathways (FDA,CE Mark and MDR) and translating innovative medical AI into safe, auditable, market-ready products.

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