Digital Health Industry Regulatory Needs Assessment

Opportunities and strategies to advance successful digital health product development and adoption through regulatory policy

August 2023

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) is committed to a vision of ensuring that patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

In pursuit of this vision, FDA's CDRH has released 24 guidance documents with digital health content to date. But the pace of digital health innovation is relentless and accelerating.

The rapid pace of digital health innovation offers enormous promise to address pressing and persistent challenges to access, equity, affordability, and outcomes that characterize modern healthcare systems around the world. But, to realize this promise, the regulation of digital health products must keep pace with industry advancements.

Predictable, consistent, transparent, and efficient regulatory pathways can incentivize high-value, high-quality innovation, providing industry with sufficient certainty to support investment, portfolio, R&D, and commercial strategies that drive the development of digital health products that transform the way we care for people.

To advance the development of regulatory science, strategy, and policy that supports this goal, the Digital Medicine Society (DiMe) conducted a digital health industry needs assessment to identify 1) the drivers of successful digital health product development and adoption, and 2) the regulatory policy needed to facilitate these drivers.
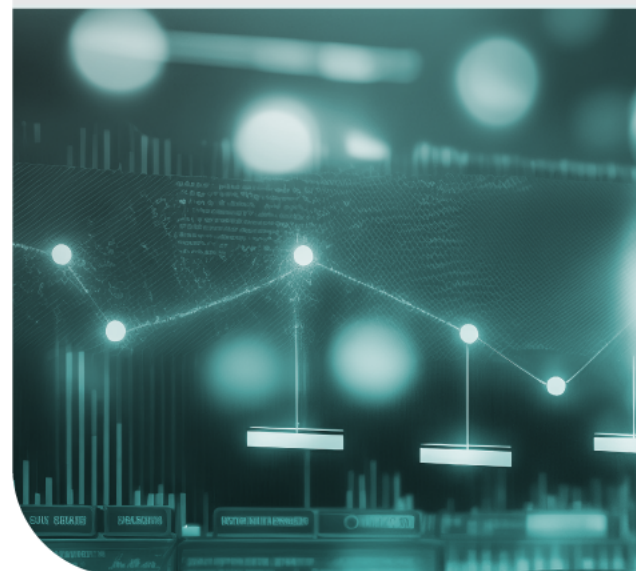
> "**Rapid digital innovation should transform healthcare.** Regulations should be a facilitator for innovation, not a barrier. And they should be compatible with the business pressures that digital health product developers face today."
>
> **Troy Tazbaz**
>
> *Director, Digital Health Center of Excellence, U.S. Food and Drug Administration*

The digital health industry regulatory needs assessment was conducted between May and July 2023. DiMe convened 86 individuals from across 66 organizations in a series of three workshops, followed by a follow-up survey to probe and quantify key themes and findings.

The needs assessment identified ten opportunities for the FDA to advance regulatory science and policy to support the product, portfolio, and organizational goals of the digital health industry.

Industry experts ranked these opportunities in order of urgency, impact, and relevance to advancing the field of digital health, identifying the **top three industry needs** as:

1 FDA alignment with downstream payer decision-makers

2 Clear alternate pathways to market, especially for truly novel digital health products

3 Better communication and coordination between FDA divisions, increased cross-center clarity, and improved consistency in interpretations

Proposed approaches to capture these opportunities fell into **six broad categories**:

1 Harmonize and optimize policy and practice with downstream decision-makers impacting the broad adoption of digital health products across U.S. government agencies and international regulatory agencies and within different centers, review divisions, and individuals within the FDA

2 Advance a multi-prong approach to optimizing the regulation of novel digital health products, including new legislative and regulatory pathways that contemplate iterative approaches to software development, total product lifecycle, and data captured in both the pre-and post-market

3 Articulate core requirements and best practices that are common and foundational to all digital health product types

4 Categorize and make available routinely captured data from the FDA and other agencies to support staff education, industry decision-making, and evidence-generation

5 Embrace industry expertise to address the gaps in regulatory science pertaining to digital health products and advance the knowledge base of regulators and policymakers

6 Support the commoditization of components of today's digital health tech stack, from third-party models to cloud infrastructure

This needs assessment highlights the substantial opportunity for regulatory policy and practice to support the **digital health innovation economy** in the U.S.

Digital health industry experts are committed to **innovation that improves lives**. The industry is highly supportive of regulatory innovation that is fit for purpose for the digital era of healthcare, drives alignment with multiple stakeholders, and is based on a foundation of clear scientific and practice principles to guide innovation in regulatory white space.

COMMERCIAL SUCCESS IS PARAMOUNT

The industry underscores the importance of regulatory approaches that support commercial success for digital health products. Such approaches are clear, support translation of best practices across different product types, endure over time and product life cycles, and provide appropriate flexibilities for dynamic, iterative approaches to digital health product development and advancement. Commercially viable regulatory policy for digital health must also align with the needs and requirements of downstream payer decision-makers, as well as regulators in other key global markets.

CONSISTENCY IS KEY

In addition to regulatory policies, the industry requires consistency in practice and supportive resources in order to optimize digital health innovation. Specifically, the industry is seeking consistency in opinions, approaches, and decision-making across the FDA. Digital health innovators identify the opportunity for the FDA's Digital Health Center of Excellence to provide clear leadership for the Agency, driving improved communication and the dissemination of existing knowledge and experience through data sharing and education.

DATA WILL DRIVE VALUE

Innovators want to learn from data on prior and pending FDA decisions relevant to digital health, but first require access to appropriately labeled databases of these decisions. Industry experts also recommend that FDA provide standardized data sets

> "In order for us to realize the promise of digital innovation for the patients our industry exists to serve, **we must create a regulatory environment that incentivizes** high-value innovation, ensures the safety and efficacy of new digital products, and does so in a way that is commercially viable."
>
> **Jennifer Goldsack**
>
> *Chief Executive Officer, Digital Medicine Society (DiMe)*

for testing algorithms in order to increase efficiency, reduce industry's data collection burden, set clear expectations of data quality, and speed the development of new AI-enabled digital health products.

As policymakers and regulatory agencies around the world grapple with the rapid pace of digital innovation in healthcare, digital health industry experts recognize the opportunity for the FDA to differentiate the U.S. market and bring the best of global digital health innovation to patients in the U.S.

A complete accounting of the ten opportunities for the FDA to advance regulatory science and policy to support the product, portfolio, and organizational goals of the digital health industry are presented below and detailed in the following pages.

LET'S STAY FOCUSED ON WHAT MATTERS

The relative importance that the digital health industry places on the key themes and opportunities identified during the workshop series varied substantially. We recommend that regulators, regulatory scientists, and policymakers accessing this report focus on the most urgent, impactful, and relevant opportunities.

Figure 1. Digital health industry needs for regulatory innovation, science, and policy
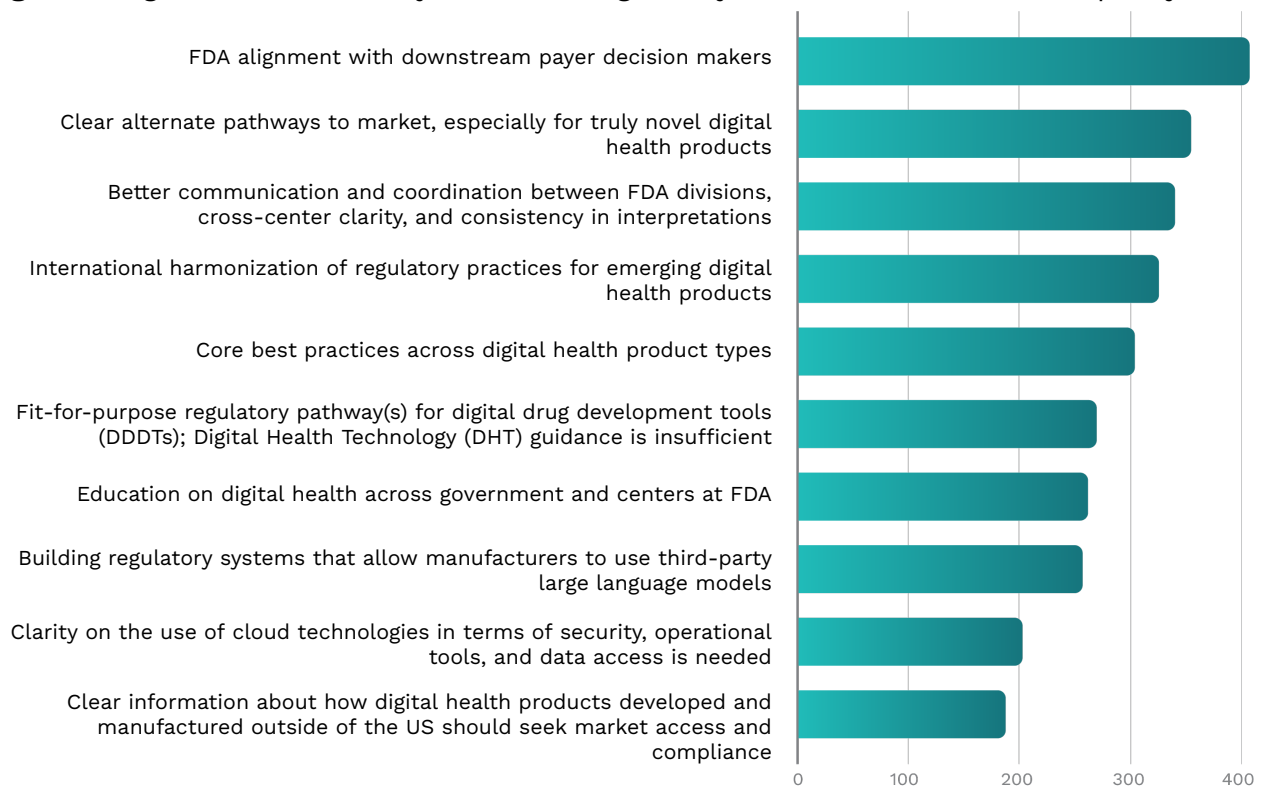
Industry leaders ranked these opportunities in order of urgency, impact, and relevance to advancing the field of digital health through regulatory action:

1 FDA alignment with downstream payer decision makers

2 Clear alternate pathways to market, especially for truly novel digital health products

3 Better communication and coordination between FDA divisions, increased cross-center clarity, and improved consistency in interpretations

4 International harmonization of regulatory practices for emerging digital health products

5 Core best practices across digital health product types

6 Fit-for-purpose regulatory pathway(s) for digital drug development tools (DDDTs); Digital Health Technology (DHT) guidance is insufficient

7 Education on digital health across government and FDA centers

8 Creation of regulatory systems that allow manufacturers to use third-party large language models

9 Clarity on the use of cloud technologies in terms of security, operational tools, and data access

10 Clear information about how digital health products developed and manufactured outside of the U.S. should seek market access and compliance

Click on on one of these ten priorities to jump to its section.

97% of digital health industry experts report that FDA alignment with downstream payer decision-makers would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts believe that while regulatory requirements for market access are generally reasonable, the 'burden of proof' across multiple decision-makers is currently too high to successfully commercialize digital health products in the U.S. Specifically, they report that the absence of aligned evidentiary requirements between regulators and payers is disincentivizing innovation and inhibiting the innovation economy.

Industry representatives are enthusiastic about proposed policies such as CMS' Transitional Coverage for Emerging Technologies (TCET) pathway. Such policies, however, would need to be rapidly scaled in size and across product types in order to be impactful.

The industry is keen to provide the necessary evidence that digital health products are safe, effective, reasonable, and necessary. However, the evidentiary requirements to support these claims across multiple stakeholders are not currently clear or harmonized. To support commercial success and sustained investment in digital health innovation, timelines for policy reform and stakeholder alignment in support of feasible pathways to commercialization must be substantially accelerated.

The alignment of regulatory and payer evidentiary requirements would incentivize innovation to expand the intended use and/or indications of consumer products, increasing the impact of digital health innovation on health and public health.

> "This is critical to surviving the 'valley of death', the gap between FDA authorization and payment/revenue generation."

> "Since both approvals are necessary for any innovation to succeed, alignment would simplify and streamline the process of getting innovations to market."

> "All too often we as manufacturers are left with eager doctors/surgeons/patients who are unable to use our technology due to the lack of reimbursement. All of the speed and support of the FDA is useless if the technology cannot be adopted."

Figure 2. Digital health industry support for strategies to align evidentiary requirements for FDA and downstream payer decision-makers
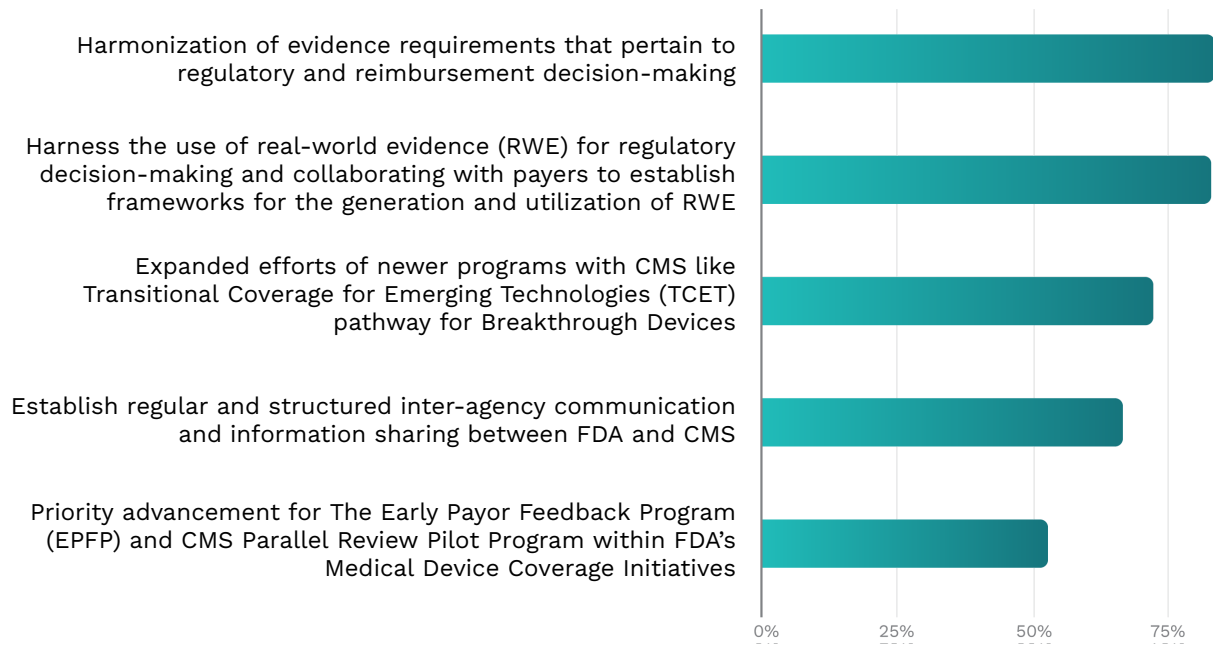
100% of digital health industry experts report that clear alternate pathways to market, especially for truly novel digital health products, would be valuable

Industry-reported needs, insights, and opinions

Digital health industry innovators find the De Novo pathway requirements to be too vague, intimidating innovators and investors alike when attempting to launch a truly novel product. Industry reports that exciting new digital innovations are often stripped down to the bare bones to avoid FDA oversight (and the associated business risk of an unclear regulatory pathway), limiting the benefits to patients.

Specific needs highlighted by the industry include clear alternate pathways for 'AI-light' products, such as those that rely on rules-based algorithms, as these are not contemplated under the current predetermined change control plan guidance. Such pathways are also necessary for digital diagnostics, where industry leaders report trying to extrapolate regulatory approaches for in vitro devices (IVDs) and computer-aided detection (CAD) to formulate their regulatory strategy, but ultimately need more clarity.

In addition to, and separately from, alternate pathways to address current gaps, the industry also highlighted a need to modify existing pathways to be fit-for-purpose. For example, digital therapeutics are held to evaluation frameworks that cascade from drug approvals, which does not support the development of these novel therapies. And most product definitions are so narrow that they fail to contemplate the needs of platform solutions, embrace opportunities for rapid translation of digital products to cover new indications, or provide viable opportunities to improve digital products following market access without triggering reclassification and review.

> "Right now the De Novo process is too uncertain, is too expensive, and takes too much time. We need a more efficient and more predictable pathway for novel digital products that don't fit squarely into a prior product code or classification."

> Better pathways to market access would increase the number and quality of new technologies coming to market, increase investment in novel technologies, and create opportunities to collect RWE and develop value models."

The industry recognizes the legislative constraints that the FDA faces in regulating novel digital health products, and identified a need for legislative reform while remaining optimistic about opportunities for creative regulatory approaches in the short term. Such creative approaches could include an embrace of real-world data and evidence, especially for AI/ML-enabled devices that are not amenable to RCTs, and leaning heavily on the internal expertise at the FDA that has facilitated the broad embrace of AI in radiology products.

Finally, the industry recognizes that AI regulation in the U.S. already leads policies in Europe and has identified the opportunity for FDA to leverage innovative, fit-for-purpose regulatory approaches to differentiate the U.S. market as the home for leading AI-driven digital health innovation in the world.

> We have a truly novel product that can be effective in the treatment of multiple conditions. Once a device has been proven safe & effective for a specific condition, expansion to other similar conditions should have a reduced burden."

Figure 3. Digital health industry support for FDA pursuing the following solutions for clear alternate pathways to market, especially for truly novel digital health products
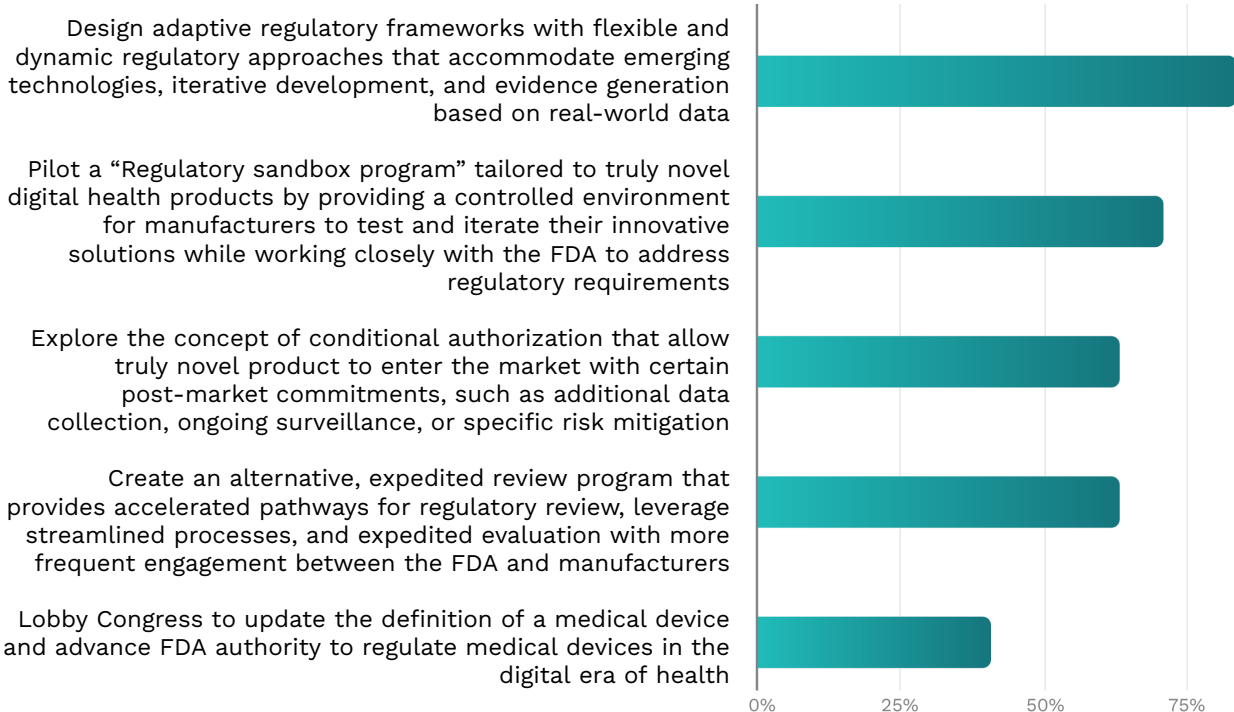
100% of digital health industry experts report that better communication and coordination between FDA divisions, increased cross-center clarity, and improved consistency in interpretations would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts described their experiences with the inconsistency of opinions across individuals, review divisions, and centers at the FDA. Reflecting on these inconsistencies, industry representatives underscored that streamlined, consistent, and coherent feedback is necessary to reduce risk and promote innovation for both digital devices seeking market access and digital drug development tools (DDDTs).

Industry leaders identified the absence of a mechanism to identify whose opinions take priority and precedence during decision-making as a root cause of substantial inefficiency, including frequent 'hand-offs' between internal teams at FDA as well as lengthy delays. The industry is increasingly relying upon informational meetings to establish relevant stakeholders and decision-makers, which they describe as sub-optimal and unnecessarily burdensome.

Inconsistency of opinions is not limited to scientific and evidentiary requirements, the industry reports. Substantial variation in openness to digital and methodological innovation is impacting the industry's appetite to innovate in certain therapeutic areas whose review divisions are perceived to be more or less open to innovation.

> "There are horizontal issues related to digital health that span FDA divisions, such as software development, machine learning best practices, or the use of real-world data for clinical validation. While guidance on these topics is provided at the Agency level, interpretation of that guidance is often inconsistent between review teams, divisions, and centers. Improving consistency would reduce the resourcing necessary to bring new technology to market to help patients."

> "Overall this has gotten better at FDA, but there are still cases where the right hand is not aware of what the left hand has done. It would be helpful to point to analog products, such as if you are developing a device for digital pathology and you can reference relevant analogs in digital radiology."

Industry leaders noted the opportunity for improved cross-Agency communication to include the diffusion of the substantial digital health knowledge and experience that already exists among FDA staff experts. Knowledge silos pose risks of inconsistency both across the Agency and over time when turnover of FDA staff with digital experience occurs. The industry is enthusiastic about the opportunity to create a master file repository of core functions that have already been through regulatory decision-making to support both cross-Agency consistency and to serve as a valuable resource for the industry, should it be made available for open access.

> "
> Software/AI/etc. is a growing component of all medical products, not just devices. We need all the centers to be competent when it comes to cutting-edge technologies that involve those technologies."

Figure 4. Digital health industry support for FDA pursuing the following solutions to improve communication and coordination between FDA divisions, cross-center clarity, and consistency in interpretations
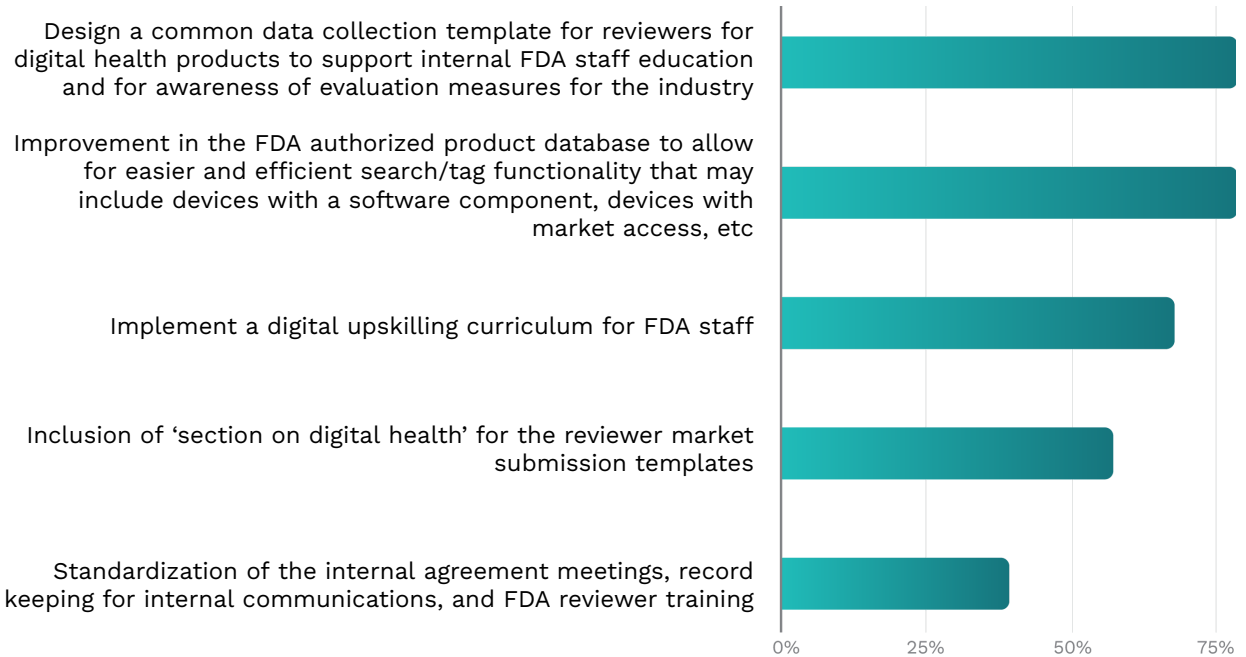
100% of digital health industry experts report that international harmonization of regulatory practices for emerging digital health products would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts identified substantial opportunities for international harmonization, or convergence, of digital health regulation to support commercial success in today's global market. The industry recognizes that regulatory authorities will maintain autonomy in their decision-making, but notes that IMDRF documents are dated and there is substantial opportunity for a leading regulatory authority to implement global regulatory best practices that drive a new era of regulatory science that is fit-for-purpose for the digital era.

Opportunities for international harmonization fall into two broad categories. First, the FDA can draw on global best practices to support CDRH's mission for patients in the U.S. to have access to high-quality, safe, and effective medical devices of public health importance first in the world. Second, the FDA can promote alignment on different digital health product types and risk profiles internationally to support global go-to-market strategies for companies of all sizes.

Industry leaders noted that the FDA is in a position to implement the substantial lessons learned from the global digital health regulatory community to date, specifically related to the regulation of: 1) digital therapeutics, where pathways are relatively advanced in other regulatory regions and strengths can be adopted and limitations minimized; and 2) AI/ML products where product and risk categorizations are largely still emerging and are sub-optimal in regions where definitive categorizations have been made.

> "This would assist in enabling scalability across jurisdictions, enabling greater patient access globally, while also enabling companies to survive with the reimbursement rates that governments are currently comfortable with."

> "When using digital health technologies in clinical trials or drug development would allow us to have the same approach globally and run multiregional clinical trials more seamlessly."

Representatives from industry whose companies develop digital drug development tools (DDDTs) noted the particular importance of international harmonization for these products in order to support global drug trials.

" International harmonization would 1) streamline the approval process for digital health products across different countries and regions, 2) facilitate cross-border collaborations and partnerships between digital health companies, which can accelerate innovation, and 3) promote interoperability and data sharing between digital health products and systems, improving patient outcomes."

Figure 5. Digital health industry support for FDA pursuing the following solutions for international harmonization of regulatory practices for emerging digital health products
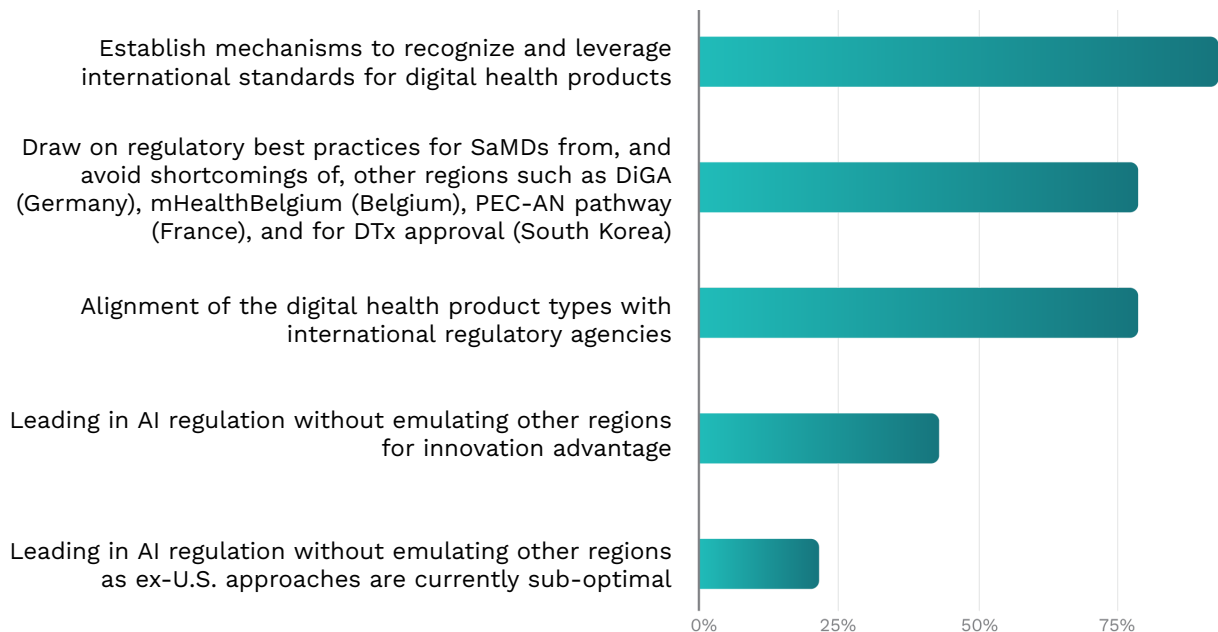
100% of digital health industry experts report that core best practices across digital health product types would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts reported that "horizontal guidance" would be a powerful strategy to illuminate key requirements that transcend guidances for individual digital product types. The industry cited short- and long-term value propositions associated with such core best practices.

In the short term, the articulation of preferred methodological practices will help reduce risk and uncertainty for developers pursuing market access for truly novel digital health products without clear regulatory pathways. It will also reduce the pressure on regulators to immediately define new product and risk categories for digital health innovations, allowing time to optimize these decisions while still providing the necessary certainty to the industry.

In the long term, such horizontal guidance will drive the development of skills, practices, and experience that can be translated across multiple different product categories to optimize evidence-generation practices. This shift will speed high-quality product development and support fit-for-purpose portfolio strategies across the industry as well as consistency in practices across the Agency.

The need to establish preferred methodologies and common evidentiary requirements for practices at the heart of digital health innovation is also fundamental to the success

" Establishment of common/core practices would reduce the barrier to bringing new technologies to market by following best practices of existing products."

" The need is for horizontal guidance that applies to generic functionality without being tied to a specific intended use. So, developing guidance on large language model validation that is not tied to a specific medical use would be extremely valuable for all those who are incorporating LLM's in their products."

of aligning approaches to decision-making across multiple stakeholders, according to the industry. In addition to the long and short-term benefits described above, several industry experts identified that establishing core best practices is fundamental to aligning regulatory decision-making with downstream payer decision-makers.

> " Horizontal guidance would give better clarity/certainty and enable us to pursue more robust evidence-generation activities with confidence that they are targeted at the right metrics."

Figure 6. Digital health industry support for FDA pursuing the following solutions to implement common/core best practices across digital health product types

100%
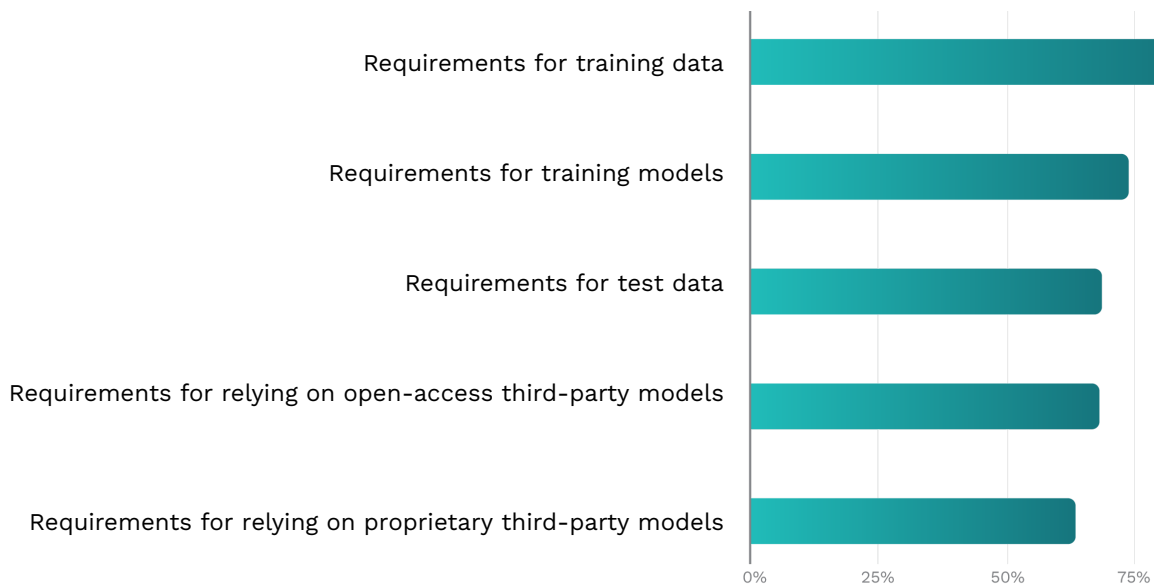
of digital health industry experts report that fit-for-purpose regulatory pathways for digital drug development tools (DDDTs) would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts who develop digital drug development tools reported that while the FDA guidance document, "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations," clearly states that digital health technologies (DHTs) would typically be exempt from device requirements, their customers across the life sciences demand some kind of regulatory endorsement of their products before considering them as DDDTs.

The biomarker and clinical outcome assessment (COA) qualification pathways for DDDTs cannot effectively satisfy this demand because the process is murky for digital tools, the evidentiary bar is prohibitively and unnecessarily high, the process is too long to be commercially viable, and there are no business incentives for an individual developer to pursue this pathway, according to the industry.

In the current state, the only alternative for DDDT developers wishing to meet the needs of their customers and drive broad adoption of their products is to pursue clearance of their product as a medical device even when they do not intend to market their product with a medical claim. The industry reports frustration that the 510(k) pathway is the only option they have to gain trust and traction for their products in their target market.

Recognizing that decision-makers across the clinical trials enterprise expect some FDA evaluation of the safety and data integrity of

> "A fit-for-purpose regulatory pathway would allow us to: 1) Better understand the experience and unmet needs of patients as DDDTs may offer a more efficient way of measuring certain concepts, which may reduce patient burden in terms of ease of data collection, 2) More efficiently develop or leverage novel COAs to support drug development and potentially improve the body of evidence to support regulatory approval and payer decision-making post-approval, and 3) Reduce the cost of conducting clinical trials as a smaller sample size may be able to support meaningful change due to reduced error."

DDDTs before considering them, even though it is not formally required, digital health industry experts recommend streamlined pathways focused on clinical trial use cases (rather than medical use cases) to speed the adoption of these digital products and, in turn, speed the development of new treatments and therapies.

The industry has identified two potential pathways for digital drug development tools. First, an accelerated, alternative regulatory pathway for DDDTs would allow developers to demonstrate FDA recognition of their safety and data quality. Of note, the industry underscored the importance of aligning such a regulatory pathway with the existing 510(k) pathway to allow developers and/or their customers to bring these products to market as medical devices in the future if desired. Second, a revamp of the biomarker and COA qualification programs for DDDTs is recommended. This update should focus on flexibility (specifically, a path to expand indications for use for DDDTs) and clarity around where FDA would commit to accepting qualified DDDTs as trial endpoints.

> " The absence of fit-for-purpose regulatory pathways for DDDTs makes it difficult to convince customers of the value of our products to their regulatory pathways."
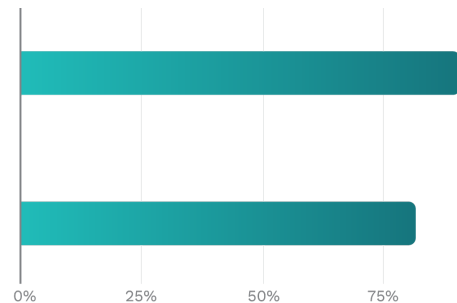
> " It is critical that fit-for-purpose regulatory pathways exist for digital drug development and such pathways would be extremely valuable to <deidentified>, our customers, and the industry."

Figure 7. Digital health industry support for FDA pursuing the following solutions to advance fit-for-purpose regulatory pathways for DDDTs

100% of digital health industry experts report that education on digital health across government and FDA centers would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts identified that policymakers across the government, including the FDA, are facing an exacerbation of the skills and knowledge gaps being experienced across the industry.

Inconsistent interpretation and application of existing regulations to digital health products undermines industry certainty. This lack of confidence is likely the result of high variability in digital health expertise and experience across the government. Similarly, delays in advancing fit-for-purpose and durable new regulatory policies are stifling innovation. The industry perceives that this situation is driven in part by insufficient digital innovation knowledge and skills across the government.

The industry supports broad and rapid digital upskilling of all government experts to support digital health innovation. First, the education of FDA experts is needed to reduce the uncertainty surrounding pathways to market for digital health products in the U.S. Second, educating policymakers and staff across all relevant legislative bodies and regulatory agencies is necessary to promote alignment and consistency in the development and implementation of all of the policies and practices necessary for the broad adoption of high-quality digital health products.

The industry strongly advocates for a data-driven approach to education; prioritizing

> "Government agencies and centers should be using the same digital health terms and definitions in order to drive forward with an aligned policy that does not interfere or contradict other government initiatives and activities."

> "Education across government is essential for myth busting and advancing understanding of capabilities that are quickly advancing so as to enable informed decision making on policy establishment that has some degree of future-proofing with the right controls in place."

learning from case examples; promoting inter-division, inter-center, and inter-agency data sharing; and leveraging the full catalog of digital health products authorized – and those that failed to be authorized – for market access. There is also enthusiasm for making these data available to the industry for shared learning.

Of note, industry experts are enthusiastic about engaging in these educational activities and have an appetite for bi-directional learning between industry and government.

> "
> More efficient regulatory review and alignment of policies and initiatives to advance digital health products requires education of policymakers and regulators."

Figure 8. Digital health industry support for FDA pursuing the following solutions for education on digital health across government and centers at FDA

86% of digital health industry experts report that building regulatory systems that allow manufacturers to use third-party large language models would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts are bullish about the efficiencies that can be captured when generative AI is used to power the foundation of stacked models. However, they note that the current draft guidance, "Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-enabled Device Software Functions," rules out the use of third-party models as part of the product stack.

Industry leaders report that this exclusion serves as a substantial disincentive for the industry to define claims and intended uses that put products with LLMs at the foundation of stacked models into regulated pathways. Industry experts believe that it is possible to have a testing approach where open models are used in digital health product stacks and we can still guarantee that products are safe and effective.

Industry leaders emphasized the need for a regulatory approach that recognizes the dynamism of the full product stack when generative AI is powering the foundation model. Requirements for such regulatory approaches include 1) testing approaches that reasonably allow developers to make well-substantiated claims of safety and effectiveness, and 2) some level of control over time. As an analogy, industry experts pointed to the challenges that would arise if a new regulatory application for market access for SaMD products was required every time there was an update to the Android or Apple OS.

> "Regulatory systems that allow manufacturers to use third-party large language models for product development would be extremely vital to expanding and growing cloud infrastructure solutions and services that speed digital health product development.

> Regulatory acceptance of LLMs within digital health product development would expedite timelines for developing protocols, conducting literature research, and developing regulatory submission documents."

Finally, industry recommended that the FDA consider three components to review when evaluating digital health products that include generative AI:

- The foundation LLMs.
- The analytic applications that are built on those models.
- The proprietary healthcare data on top of the LLMs used to fine-tune the model and differentiate each analytic application.

While industry experts recognize foundation LLMs may be certified as 'regulatory grade' in the future, they advocate for ad hoc reviews for the second and third components of this proposed review framework.

> "
> Creating a language model from scratch is time-consuming and costly. Pre-trained language models save time and resources."

Figure 9. Digital health industry support for FDA pursuing the following solutions for utilization of third-party large language models

100%
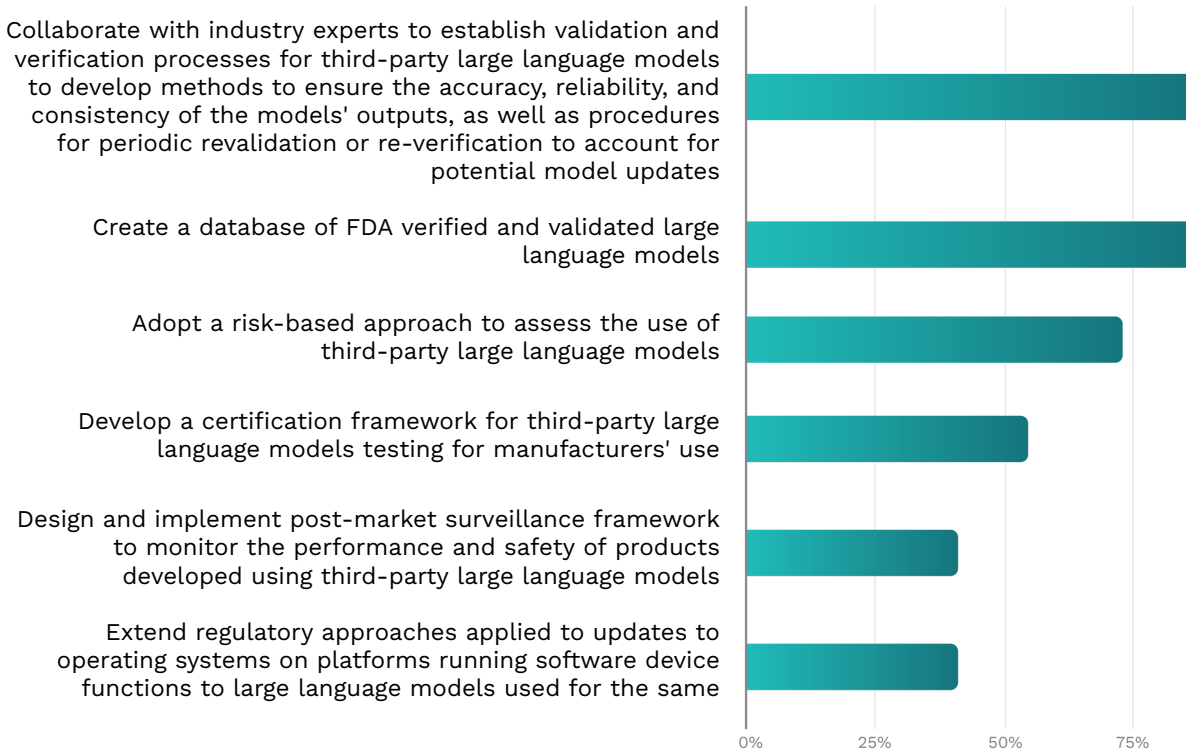
of digital health industry experts report that clarity on the use of cloud technologies in terms of security, operational tools, and data access would be valuable

Industry-reported needs, insights, and opinions

Digital health industry experts recognize that the cloud is not homogenous. Within each cloud service provider, both digital health product developers and pharma sponsors can select and vary the different services they use. This heterogeneity can shift the responsibility of different aspects of compliance. However, industry experts note that to embrace the benefits of these flexibilities, the industry requires more clarity on the FDA's interpretation of regulatory requirements, including what counts as a medical device vs. a non-medical device.

The industry reports substantial value promised by the increased use of cloud technologies, including secure data storage and management, opportunities to advance a learning health system, and substantial scope to scale digital health product adoption. To harness this value and to streamline the approvals process, more clarity on the use of cloud technologies is needed to more efficiently develop digital health products that are safe, secure, and effective.

More clarity on the use of cloud technologies would be helpful to the industry in the context of cybersecurity; specifically, understanding the responsibilities of key stakeholders, including cloud service providers, digital health product manufacturers, and end-users. Cloud service providers also report that clarity would help their customers know that they can rely on their products for key regulatory functions.

"
Digital health products use cloud technologies for key functionality within solutions. Delineating where the line is between a device function and a non-device function is left to the company to decide. Guidance from FDA would assist in this decision."

"
Many companies are early or evolving journeys in their transition to the cloud. Some folks still have some apprehension due to privacy and security largely, but as this is the way of the future for many reasons, any support and guidance would be helpful."

Figure 10. Digital health industry support for FDA pursuing the following solutions to clarify the use of cloud technologies
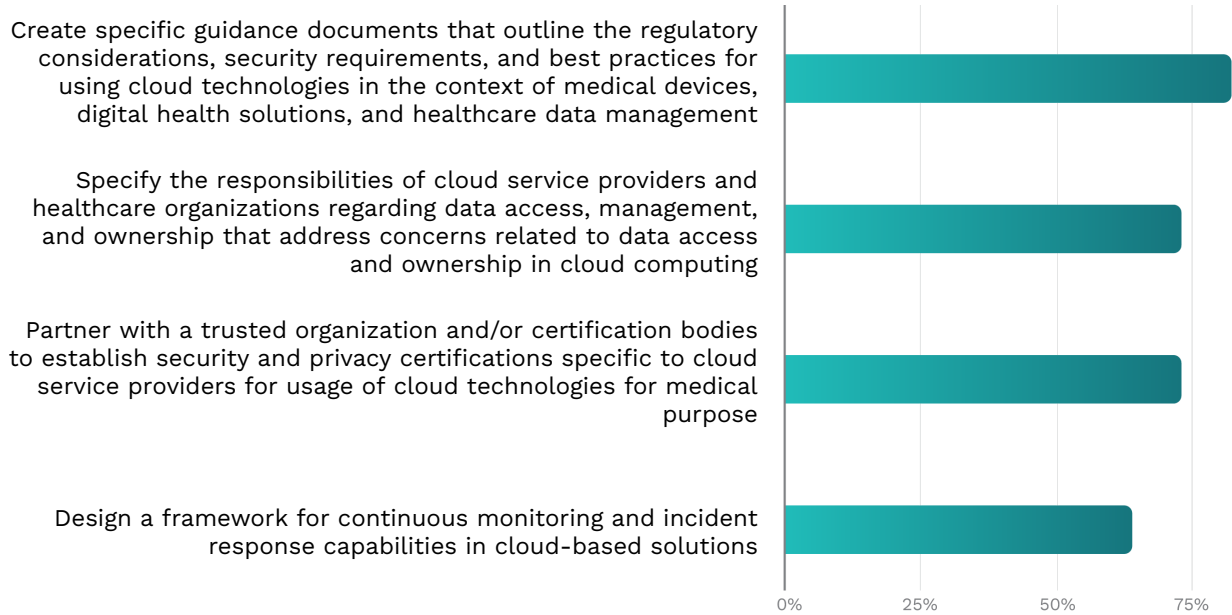
"We have experienced inconsistent perspectives from inspectors and reviewers related to the use of the cloud. Affirmation for the industry is needed."

88% of digital health industry experts report that clear information about how digital health products developed and manufactured outside of the U.S. should seek market access and compliance would be valuable

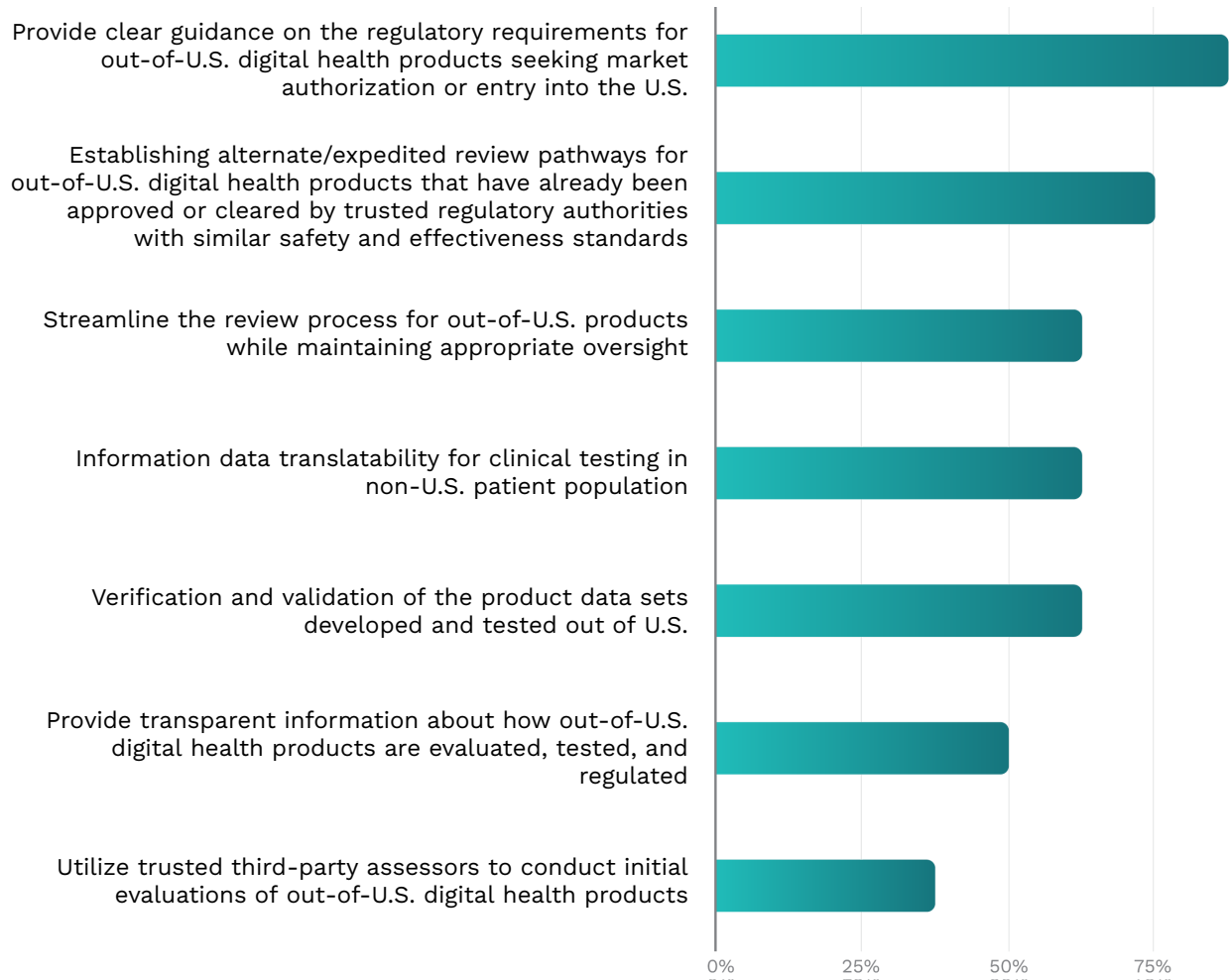**Industry-reported needs, insights, and opinions**

Digital health industry expert discussion on this topic was limited. However, the topic was raised multiple times during the workshop series with specific references to the importance of making the U.S. market accessible to digital health innovators around the world to ensure that U.S. patients can derive the greatest benefit from the global innovation economy.

> "Country-specific data rights and health regulation simplification would save companies a ton of time and resources."

> "As a digital health company based outside of the U.S., this would help us significantly."

> "This would drive optimization of resource use and ensure the best innovations make it to the U.S. market."

Figure 11. Digital health industry support for FDA pursuing the following solutions in order to provide clear information about how digital health products developed and manufactured outside of the U.S. should seek market access and compliance

Appendix 1: Needs assessment participant list

Actigraph

AdvaMed

Aetion

Amalgam Rx

Amazon

Amazon Web Services
(AWS)

Apple

AppliedVR

Astarte Medical

Atos

BehaVR

Big Health

Bill and Melinda Gates
Foundation

Boston Consulting Group
(BCG)

Byteflies

Caption Health

Cardio Signal

Consumer Technology
Association (CTA)

Cumulus Neuro

Datavant

Dexcom

Digital Therapeutics
Alliance (DTA)

Embecta

Empatica

Emteq labs

Epstein Becker Green (EBG)

Eversana

Evidation

Freespira

Glooko

Google

Gradient Health

Greenleaf Health

Harvard Business School
(HBS)

Harvard Medical
School/Massachusetts
General Hospital

Health Advances

Huma

Intel

Johnson & Johnson

Ki-elements

Limbix

Lunit

Mindmaze

Modality.ai

NewPage

Novo Nordisk

Oracle

Osso VR

Oura

Propeller Health

Proximie

Qure.ai

Real Chemistry

Rock Health

Samsung

Sidekick Health

Siemens Healthineers

Silicon Labs

Tempus

U.S. Department of
Veterans Affairs (VA)

Validic

Verisense Health

Verizon

VivoSense

Viz.ai

ZimVie

Appendix 2: Relevant resources for industry

- [FDA guidances with digital health content](#)

- [FDA Digital Health Policy Navigator](#)

- [DiMe Digital Health Regulatory Pathways resources](#)

- [Digitial Medicine Academy course, "Unlocking Regulatory Success for Digital Health Product Developers"](#)