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OMED24
Osteopathic Medical Education Conference

System + Product Implementation Opportunities The DiMe Seal Overview

Disclosures

- The Digital Medicine Society (DiMe) pays me
- AOIA has supported the development of this program

Objectives

Learn about the ways in which standardized evaluation frameworks can enable trust in the digital health software ecosystem

Learn about how the DiMe Seal can be used by physicians and patients to evaluate digital health software

Understand the current state of software evaluation and the complexities of software development for healthcare

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DiMe convenes stakeholders to take action to fix the problems in our complex field

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OUR MISSION:

To advance the safe, effective, and equitable use of digital approaches to **redefine healthcare** and **improve lives**

OUR VISION:

Better health powered by digital innovation

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How we do it

DiMe Approach

Convene & Collaborate

DiMe's superpower is convening stakeholders to drive action – not just admire – the problems in our complex field.

Build & Lead

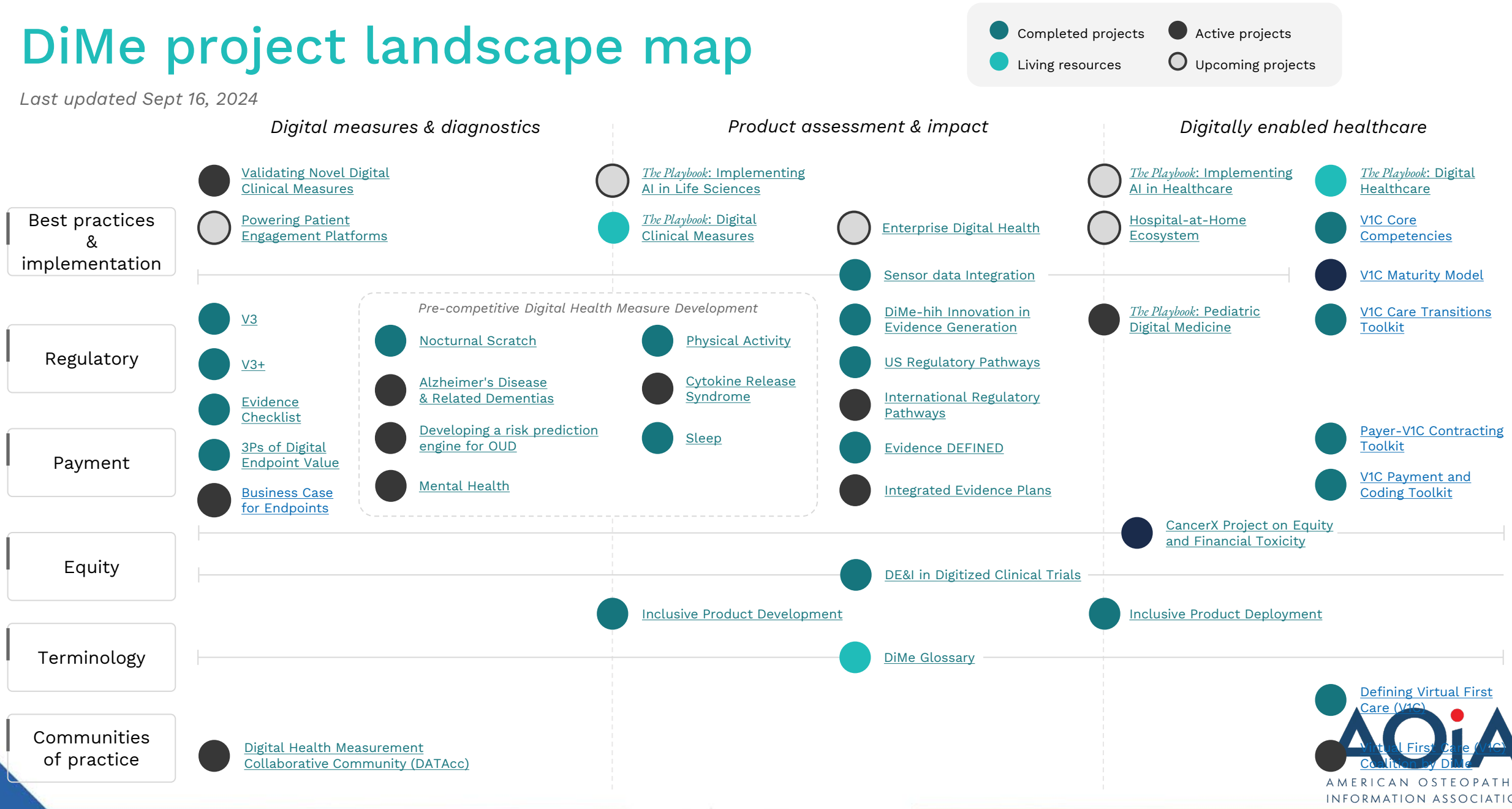
Harnessing the power of many, we create solutions to reduce the activation energy of digital innovation in healthcare.

Educate & Advise

Combining insights from our diverse community with best practices from our research, DiMe offers an unparalleled perspective on the digitization of healthcare.

DiMe project landscape map

Last updated Sept 16, 2024



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Integrated Evidence Plans for Digital Health Products

Join Integrated Evidence Plans and help streamline the **path to regulatory and commercial success** to optimize health outcomes for the greatest number of patients

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The Playbook

Pediatric Digital Medicine

Join *The Playbook* to define the unmet **need and market opportunity** for pediatric digital medicine products, **best practices for their development and deployment**, and address the unique ethical considerations accompanying the use of digital medicine products by children.

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DiMe Seal

A symbol of digital health software products built for quality and trust

Summer 2024

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Buyers and end-users are looking for easier ways to evaluate digital health software

"We're still trying to figure out how to discern signal from noise with these digital tools."

-SVP at a top U.S. insurance provider

"This process is so hard for everyone that we're pushing developers to overpromise and underdeliver."

-Head of Digital Innovation at a top health system

"Our doctors want two things: A way to see what technologies are trustworthy and how to use them."

-CMO at a national health advocacy organization

30,000+ Digital Health Software Products (DHSPs) on the market

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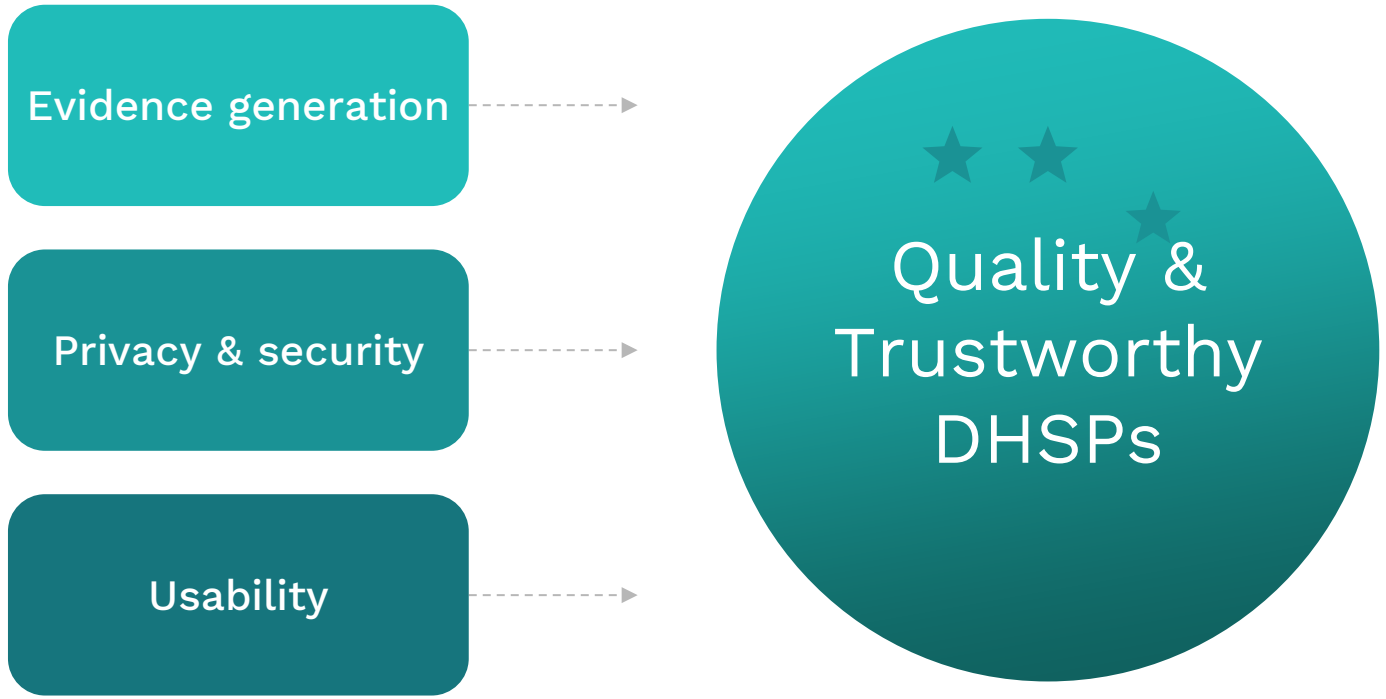
Developing high-quality, trustworthy products requires a holistic approach

Informed by leading experts

DiMe has **identified 3 key domains** critical for developing and evaluating DHSPs.

DiMe has been asked by a large number of buyers, end-users, and developers to **define and help implement best practices in these identified domains**, which will become the standard for "what good looks like" for product developers.



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Confusion in the digital health software product marketplace

We've done our homework...

DiMe has identified 100+ guidelines, standards, and certifications for digital health software products (DHSPs), **but no single tool exists to establish that a product is built against these best practices**.

The absence of such a tool **slows down the adoption of valuable digital health technologies and erodes trust** by patients and care providers alike.

1,000+ **Scientific articles** reviewed

47 **Regulatory guidances** examined

112 **Standards and quality programs** assessed

150+ **Industry experts** engaged

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Our goal

To develop an evidence-based evaluation framework that **cuts across multiple domains of trust and value**, harmonizes best practices, and eases the effective adoption of high-quality, trustworthy digital health software products.

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Introducing DiMe Seal

The DiMe Seal features:

- **A developer-friendly program** providing an easy way for product developers to attest to the criteria that matters most to **buyers** and **end users**.
- **Dynamic criteria** based on the intended users of the DHSP.
- **No duplication of efforts** with an Evaluation Framework designed to accept industry-standard audits and certifications covering relevant criteria.

Usability	Privacy & security	Evidence generation
✓ *Accessibility*	✓ *Access Controls*	✓ *Study Diversity*
✓ *Workflow Integration*	✓ *HIPAA Compliance*	✓ *Comparative Safety*
✓ *Patient-Centric Design*	✓ *Data Portability*	✓ *Data Analysis*

Addressing the needs of **both** product developers and adopters alike

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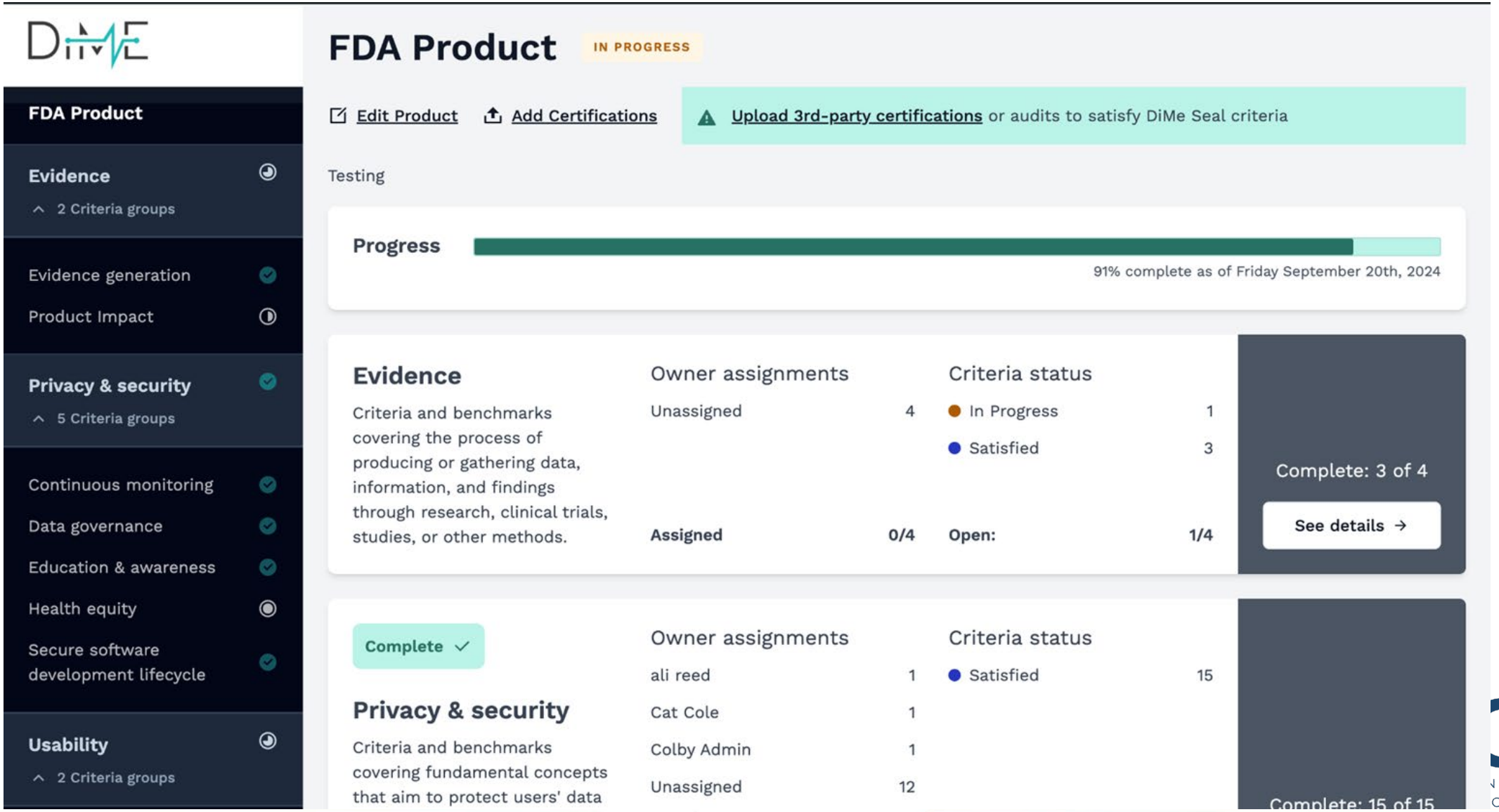
The DiMe Seal platform



Examples from our evaluation protocol

	Criteria	Example benchmarks*
Usability	**Task Efficiency:** The ability of users to achieve key application functionality in an efficient manner	Content can be presented without loss of information or functionality across all common web + mobile resolutions
Privacy & Security	**Risk Management:** Identifying, prioritizing, managing, and monitoring risks to information systems	NIST Cybersecurity Framework level 4 or above
Evidence generation	**Study Design:** Set of methods and procedures used to collect and analyze data is appropriate for product claims	Study populations are sufficiently diverse and/or representative of the patients for which the product intends to improve outcomes

**Example benchmarks are derived from key SME interviews and an extensive literature review of 100's publications, standards, guidance documents, and other certifications. Click here to view the full Evaluation Framework Criteria.*

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Defining DHSPs: Which products are eligible?

1. Software applications **built for a general-purpose computing platform** (i.e. not specialized hardware)

2. **Packaged and sold as a standalone product**, an extension to another standalone product, or as a companion to a hardware sensor

3. Intended to be **used for managing, maintaining, or improving health** of individual persons, or the delivery of care

Patient-facing	Both	Clinician-facing
Health + Wellness *Ex: WeightWatchers*	Digital Therapeutics *Ex: Daylight*	Diagnostic Support *Ex: STATdx*
Symptom Tracking *Ex: Bearable*	Disease Management *Ex: Lark Health*	Patient Analytics *Ex: Clarify Health*
Hardware Companions *Ex: Fitbit App*	RPM *Ex: Optimize Health*	Ambient Scribes *Ex: Abridge*

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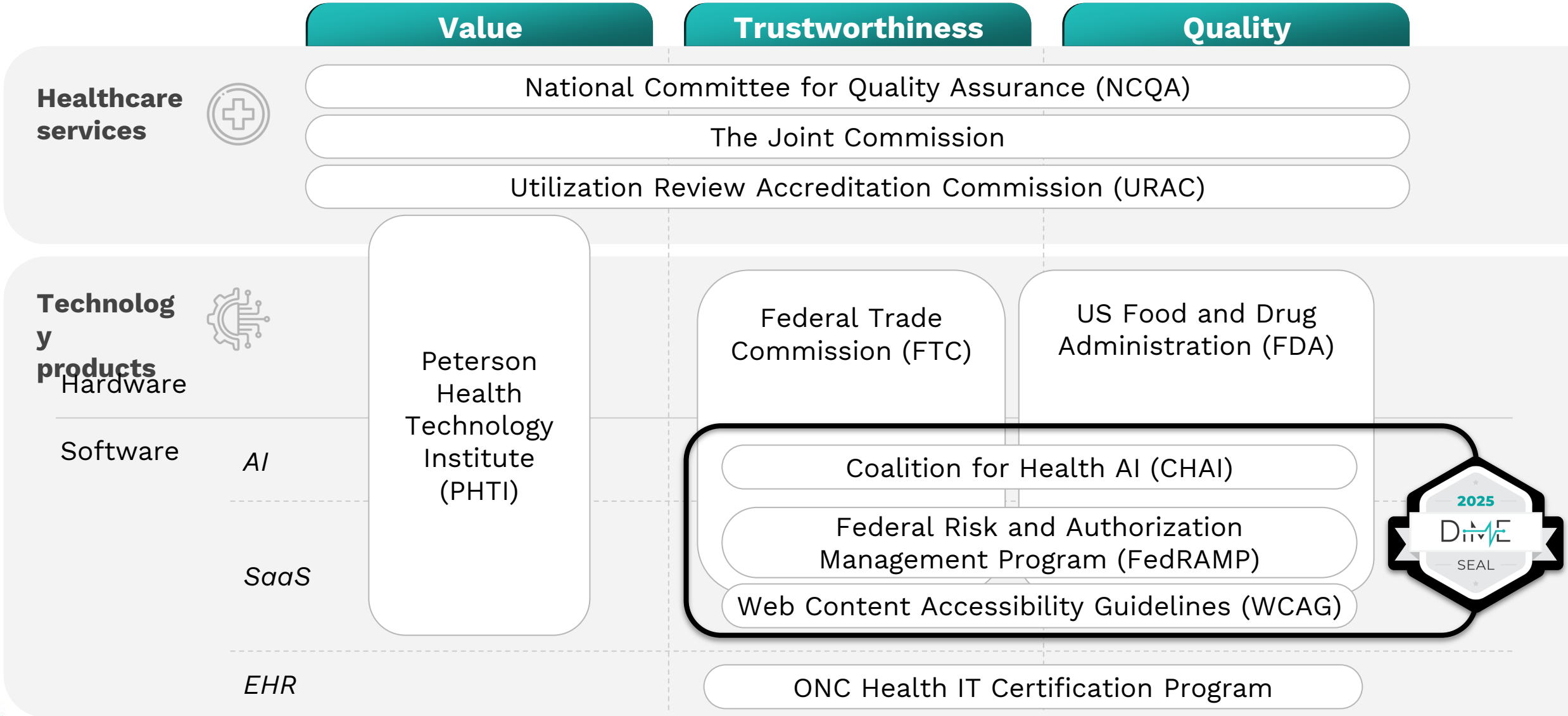
Third party certification landscape



Why DiMe Seal matters to patients, care providers, and patient advocates

By choosing digital health software products with the DiMe Seal, you are using tools that have been rigorously evaluated for quality, safety, and adherence to industry standards. DiMe Seal benefits you by:

Empowering informed decisions

DiMe Seal helps you choose tools that are safe, reliable, and trustworthy.

Fostering trust and reliability

The Dime Seal is a symbol of credibility, demonstrating that the product performs against a comprehensive framework of standards and best practices.

Enhancing healthcare outcomes

The DiMe Seal ensures that the tools you choose will align with recognized standards and best practices.

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Long-term impact and growth in patient-centered care

DiMe Seal is more than a mark of quality; it's a commitment to ongoing excellence in patient care. By choosing products with the DiMe Seal, you benefit from:

Expanding access to trusted tools

Products with the DiMe Seal are recognized by healthcare systems and stakeholders as reliable, trustworthy and effective.

Strengthening the healthcare ecosystem

DiMe Seal fosters the broad adoption of foundational best practices to set a bar of what "good" looks like across the digital health industry.

Continuous improvement and innovation

The annual renewal requirement ensures that products you rely on stay up-to-date with the latest best practices, and improvements that directly benefit your care.

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Timeline to launch

July:
Soft launch

October:
Public launch

2024

Feb **March** **April** **May** **June** **July** **Aug** **Sept** **Oct**

We are here

Feb-June: Gather KOL and SME feedback for Evaluation Framework

Mar-Apr: Platform development

April-Sept: User testing

July-Oct: Soft launch

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Thank you.

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DIGITAL MEDICINE SOCIETY

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www.linkedin.com/company/dime-society

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Questions