The problem and the solution

What is the DiMe Seal?

The DiMe Seal is a **symbol of quality and trust** awarded to digital health software products that demonstrate performance against a comprehensive framework of standards and best practices in evidence, privacy, and security. The DiMe Seal process guides software developers through a self-attestation workflow to assess their software product against specific criteria. Software products that meet the evidence-based criteria will be awarded the DiMe Seal.

Simply put, there is no broadly accepted definition of "good" digital health software. With its new software evaluation process, DiMe seeks to level set a **baseline definition of "good".**

DHSPs eligible for the DiMe Seal are...

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

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

- Intended to be **used for managing, maintaining, or improving the health** of individuals, or the delivery of care

- Seeking, or have, **market access in the U.S**.

(i) Telehealth services, EHR/EMR platforms, billing software, and products sold exclusively outside of the U.S. are **not** eligible to receive the DiMe Seal.

Who benefits from the DiMe Seal?

Expand the (+) below to learn more about each group.

Developers —

Developers are builders of DHSPs.

End-users   —

End-users are patients, physicians, and various clinical and non-clinical roles within hospital systems, health insurance companies, and biopharma organizations.

Industry Associations   —

Industry Associations are organizations that promote and benefit from the safe and ethical use of DHSPs in the industry.

Regulators   —

Regulators are agencies who supervise the activities of the healthcare industry with respect to DHSPs

Current challenges in an uncertain market of DHSPs

The digital health software market is rapidly expanding, reflecting a significant shift towards integrating technology with healthcare. IQVIA estimates as many as 90,000 new health apps

are created each year. As of 2023, the global digital health market was valued at approximately $309.93 billion and is expected to grow to over $1 trillion by 2033.

Overall, the market is becoming increasingly crowded, with more companies entering the space each year, driven by the ongoing digital transformation of healthcare and the growing need for accessible, cost-effective healthcare solutions.

These challenges call for **well-defined benchmarks** to help developers differentiate themselves and help end-users assess quality.

The DiMe Seal sets the baseline of quality

The DiMe Seal process helps to build trust in the market, accelerate the adoption of digital health tools to improve health outcomes, and invite a continuous cycle of rigorous evaluation to elevate digital medicine practices.

The DiMe Seal is more than just a symbol of quality and trust; it's a **call to action** for the entire digital health community.