Integrated evidence plans (IEP): Streamlining evidence for commercial success to drive broad acceptance of digital health technologies

DIGITAL MEDICINE SOCIETY

WEBINAR

Tuesday, March 18

11 am - 12 pm ET

RECORDINGS POSTED HERE

Agenda

- Welcome and introduction
- Opening remarks
- Project resource overview
- Fireside chat - A well-kept secret: Cracking the code for digital health technology (DHT) adoption with integrated evidence plans
- Panel discussion - Don’t stop believin’ In the power of the right evidence
- Panel discussion - Clinically proven, but is it commercially viable? The evidence - commercialization link
- Closing remarks

But first...

- **Today's session is being recorded.**
  - Slides and recording will be available on DiMe's webinar page after the session.
- **Type your question** into the chat box to the panelists.

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

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

Integrated Evidence Plans for Digital Health Technologies

Streamlining evidence for commercial success to drive broad acceptance of digital health technologies (DHTs)

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Opening remarks from our Chief Executive Officer

Jennifer Goldsack
Chief Executive Officer
Digital Medicine Society (DiMe)

DIGITAL MEDICINE SOCIETY

Unboxing the IEP treasure chest

Smit Patel
Director, Digital Health and AI
Digital Medicine Society (DiMe)

Integrated Evidence Plans for Digital Health Technologies

Integrated Evidence Plans for Digital Health Technologies

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Without a structured approach to evidence generation, many promising technologies risk **delayed adoption**, **high costs**, and **commercial failure**.

DiMe's recent Digital Health Industry Regulatory Needs Assessment reaffirmed the top priority from industry leaders: aligning FDA regulatory requirements with downstream payor and purchaser decision-making is critical to success. To address this, DiMe, in partnership with Peterson Health Technology Institute (PHTI), ZS Associates, and other industry leaders, developed the Integrated Evidence Plans (IEP) for Digital Health Technologies (DHTs) toolkit. This resource creates a clear, cost-effective evidence pathway to support your DHTs' commercial success by **meeting the needs of all decision-makers**.

Use this framework to build an integrated evidence plan

We have identified the core components of an integrated evidence plan you can follow to streamline the collection of necessary evidence for all decision-makers on your path to market success. The toolkit walks you through three key stages:

Stage A

If you are in the early stages of product development, start here. This stage helps you identify your **target markets**, create your **target product profile**, and build an aligned **regulatory and reimbursement strategy**.

VIEW THE RESOURCE

Stage B

If you've already identified your market and built a clinical strategy for your product, start here. This stage guides you through building comprehensive **evidence packages** while **engaging key stakeholders**.

VIEW THE RESOURCE

Stage C

If you are ready to develop and execute a strong **commercial strategy** to ensure market adoption and long-term success, start here.

VIEW THE RESOURCE

IEP Toolkit

Stage A
Market need & product benchmarking

Stage B
Evidence strategy & planning

Stage C
Commercial strategy & market access

- Market need evaluation
- Product benchmarking and target product profile (TPP)
- Competitor analysis
- Stakeholder mapping, value proposition, and needs assessment
- Develop an initial business model and explore GTM strategies
- Early engagement plan with downstream decision makers

Your work in Stage A should allow you to answer the following questions:

Regulatory strategy

- What are the target markets and regulatory jurisdictions for this product or service?
- How can we build a regulatory strategy that aligns with classification, pathway, and evidence requirements?

Reimbursement pathways

- What does the purchasers' landscape look like and what are the applicable reimbursement pathways?
- Which stakeholders to engage with and when to explore potential reimbursement opportunities?

Business priorities

- What are the current market trends, policy influencers, and business drivers relevant to this effort?

IEP Toolkit

Stage A
Market need & product benchmarking

Stage B
Evidence strategy & planning

Stage C
Commercial strategy & market access

Stage B is all about planning, testing, and executing.

Develop the plan

- Define purpose and strategic objectives
- Plan evidence roadmap development
- Determine evidence requirements
- Develop evidence generation strategy

Test & implement the plan

- Test evidence plan and conduct gap analysis with target stakeholders
- Implement the evidence plan and strategy

Execute the plan

- Generate robust evidence, monitor risks, and optimize outcomes

IEP Toolkit

Stage A
Market need & product benchmarking

Stage B
Evidence strategy & planning

Stage C
Commercial strategy & market access

Your work in Stage C should allow you to answer the following questions:

Regulatory strategy

- Have you obtained the necessary regulatory authorization for market entry?
- Is a post-market compliance plan in place to meet evolving regulatory requirements?

Reimbursement pathways

- Have viable reimbursement models and payment pathways been identified for the DHT?
- Is sufficient real-world evidence available to support additional reimbursement decisions?

Business priorities

- Is the go-to-market strategy optimized for maximum adoption and market penetration?
- Have strategic partnerships been established to accelerate commercialization?
- Is the business model structured for long-term sustainability and scalability?

Integrated Evidence Plans (IEP) Toolkit for DHTs

Stage A
Market need & product benchmarking

Stage B
Evidence strategy & planning

Stage C
Commercial strategy & market access

- Market need evaluation
- Product benchmarking and target product profile (TPP)
- Competitor analysis
- Stakeholder mapping, value proposition, and needs assessment
- Develop an initial business model and explore GTM strategies
- Early engagement plan with downstream decision makers

If your results are not confirming your strategy, you may need to go back to Stage A to refine your value proposition and assess market needs.

- Define purpose and strategic objectives
- Plan evidence roadmap development
- Determine evidence requirements
- Develop evidence generation strategy
- Test evidence plan and conduct gap analysis with target stakeholders
- Implement the evidence plan and strategy
- Generate robust evidence, monitor risks, and optimize outcomes

If your results are not confirming your strategy or you need additional confirmatory evidence, you may need to go back to Stage B to refine/expand your evidence and regulatory strategy.

- Assess the landscape of reimbursement for DHTs
- Refine target customer and needs
- Craft targeted value story
- Analyze successful DHT commercialization strategies
- Revise business model
- Implement a go-to-market and awareness plan

Long term

- Secure long-term market access and reimbursement
- Foster adoption through education, advocacy, and evidence dissemination

If you add new product features, make major product modifications, plan label expansion, or any other activities that require a (re)evaluation of the value proposition and evidence generation strategy.

Real world case studies

Case study

Integrated Evidence Plans
for Digital Health Technologies
Stage B

Expanding access to cardiac ultrasound through AI-guided digital technology

About Caption Health's Caption Guidance™

Caption Health, now part of GE HealthCare, revolutionized the diagnostic imaging landscape by developing the first FDA-authorized AI software for cardiac ultrasound, Caption Guidance™. It enables healthcare providers without prior ultrasound experience to perform diagnostic-quality echocardiograms, addressing the national shortage of cardiac sonographers. By achieving FDA De Novo clearance and securing New Technology Add-on Payment (NTAP) status from CMS, Caption Health expanded access to life-saving diagnostics for Medicare patients. This case highlights Caption Health's strategic approach to regulatory authorization, clinical validation, and commercialization, demonstrating how effective regulatory navigation and rigorous clinical validation by Caption Guidance drive the broader adoption of AI in medical imaging.

Let's explore Caption Health's journey through the lens of the Integrated Evidence Plan for digital health technologies toolkit - Stage B, highlighting the process, key decisions, and concepts that shaped their success.

Stage B: Market need & product benchmarking

- **Purpose and strategic objectives:** Caption Health demonstrated that Caption Guidance™ enables novice users to obtain diagnostic-quality cardiac ultrasound images, ensuring clinical efficacy, safety, and economic value.
- **Evidence roadmap development:** The team worked backward from opportunity cost and the standard of care, ensuring Caption Guidance™ demonstrated clear, measurable benefits over traditional methods. Engaged cross-functional teams (clinical, commercial, and technical) to align evidence planning with regulatory and market goals and key user groups. Determined required data robustness, deciding the right strategy for clinical validation and real-world studies.
- **Evidence requirements:** Caption Health aligned with FDA De Novo pathway requirements, focusing on usability, diagnostic accuracy, and durability across diverse patient populations. Conducted pre-submission meetings to refine study designs and address potential gaps. Adjusted clinical protocols based on feedback from regulators and payors, ensuring alignment with their expectations.
- **Develop and implement the evidence plan and strategy:** *Pivotal study design (for FDA review process)*: Two independent studies evaluated Caption Guidance's performance by the FDA as a part of the De Novo process:

Integrated Evidence Plans (IEP) in action

- ✓ Product roadmap, stakeholder engagements, and value proposition
- ✓ Evidence studies for regulatory and business success
- ✓ Insights for commercial pathways and reimbursement strategies

Caption Health

Explore Caption Health's success in Stage B where they gained evidence for clinical efficacy, safety, and economic value.

Download the Caption Health IEP case example

AppliedVR

Learn how AppliedVR secured De Novo market authorization and aligned with Medicare reimbursement in Stage B.

Download the AppliedVR IEP case example

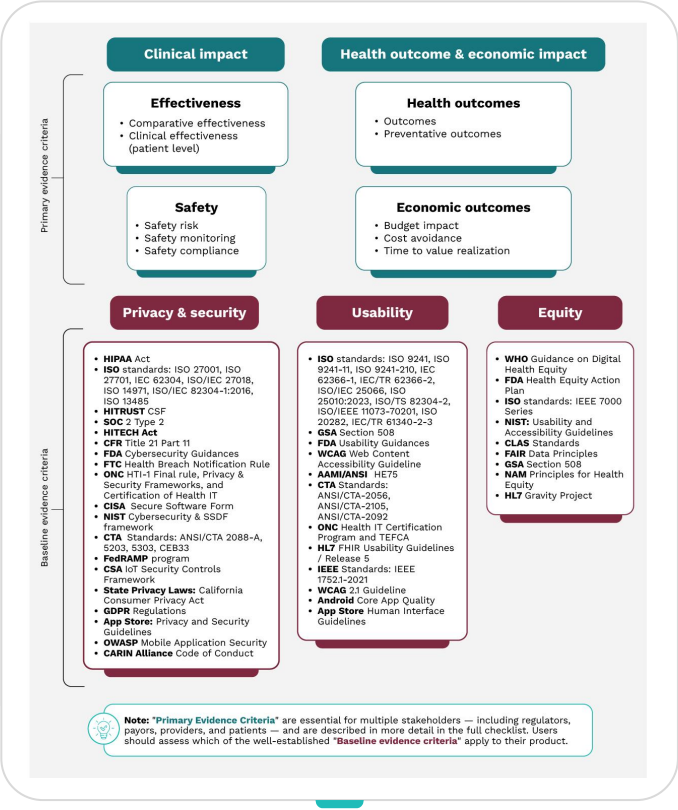
Stakeholder map: Key decision-makers influencing the adoption of DHTs

	Funders	Developers	Policymakers	Healthcare provider organizations	Payors	Patient	Research institutions & academia	Standards-setting organizations	Advocacy groups	Industry association
Examples of decision-makers	• Venture Capital (VC) • Angel investors • Private equity funds	• Tech companies • Life science organizations • MedTech (small- large)	• Congress • HHS agencies like FDA, CMS, ONC, CISA, etc. • State level jurisdictional bodies	• Hospital systems • Clinics (outpatient, LTC, etc) • Physician offices • FQHCs • Retail pharmacy	• Government Payors • Private Payors • GPOs • Health Plans, Employers, etc	• End user/patient • Caregivers	• Tufts CEVR • Brown-Lifespan Center Of Digital Health • Stanford Center for Digital Health • Mayo Clinic's Center for Digital Health	• ISO (International Organization for Standardization), • USP (United States Pharmacopeia), • Health Level Seven International (HL7)	• American Telemedicine, Association (ATA) • Patient-Centered Outcomes Research Institute (PCORI) • Connected Health Initiative	• Peterson Health Technology Institute (PHTI) • AdvaMed • Digital Therapeutics Alliance (DTA) • Consumer Technology Association (CTA) • Medical Device Innovation Consortium (MDIC)
Types of decision-making they are responsible for	Decision making responsibilities by funders determine allocation of financial resources for DHT development, research, and implementation projects.	Developers influence the design and development of DHTs by determining product features, user interface design, and integration with existing systems.	Influence policies, regulations, and standards governing the use, safety, quality, and effectiveness of DHTs.	Assess the feasibility, integration, and implementation of DHTs into existing healthcare workflows and systems.	Evaluate the cost-effectiveness, reimbursement, and coverage policies for DHTs within healthcare systems.	Adoption decisions based on factors such as perceived benefits, usability, privacy concerns, and personal preferences.	Conduct research, clinical trials, and validation studies to evaluate the effectiveness, safety, and real-world impact of DHTs.	Develop technical standards, protocols, and interoperability frameworks to ensure compatibility and seamless integration of DHTs with existing healthcare infrastructure and systems.	Advocate for the adoption of DHTs to address specific healthcare challenges or patient needs.	Develop industry standards, guidelines, and best practices for the development, implementation, and use of DHTs.
Potential adoption impact	The level of funding provided directly influences the pace and scale of DHT adoption by facilitating research, development, and accessibility.	The quality, functionality, and usability of DHTs developed by product developers directly influence their acceptance and adoption by end-users and other healthcare stakeholders.	Regulatory frameworks determine the legal and operational boundaries for DHTs, shaping their market entry, acceptance, and overall adoption rate.	Healthcare provider organizations (including clinicians) play an imp. role in determining the successful deployment of DHTs into clinical practice. Their decisions influence workflow efficiency, training requirements, and patient outcomes.	Decisions made by payor organization on coverage, pricing, and reimbursement policies, which significantly influence market access of DHTs.	Patient acceptance and utilization of DHTs are pivotal for widespread adoption. Factors influencing patient decisions include ease of use, trust in technology, perceived health benefits, and affordability.	Research institutions generate evidence-based insights, validate DHT technologies, and contribute to the knowledge base that informs policy-making, clinical practice, and investment decisions related to DHT adoption.	Standards-setting organizations promote interoperability, data exchange, and system compatibility, which are critical for the widespread adoption and effectiveness of DHTs across diverse healthcare environments.	Advocacy groups raise awareness, mobilize support, and lobby for resources to accelerate the adoption of DHTs in areas of need, support patient empowerment, and foster healthcare equity.	Industry associations facilitate collaboration among stakeholders, promote innovation, and establish benchmarks that contribute to the successful development and deployment of DHTs across various healthcare settings.

Must have // "Essential"
Essential decision-makers wield significant influence on DHT adoption; without their acceptance, it becomes challenging for DHTs to thrive, expand, or enter the market successfully.

Nice to have // "Important but not essential"
Desirable decision-makers can contribute to DHT adoption, but their acceptance is not indispensable for the survival, scalability, or market entry of DHTs.

High-quality evidence checklist for DHTs



What does high-quality evidence for DHTs look like?

Ensure your DHT meets the highest standards for regulatory authorization, payor acceptance, and seamless integration into healthcare systems.

IEP's Checklist provides a clear roadmap for DHT success

Download High Quality Evidence Overview

Download Full Checklist

Our partners thoughts about IEP

Malcolm Brown

Early-Stage Medical Affairs Head, Global Specialty TA

Astellas Pharma

It was great to be part of this excellent IEP project team. I had previous experience of adapting an existing pharma IEP model to a digital medicine solution. This was quite easily achieved by adopting a cross-functional approach with early identification of key stakeholders and timelines. This helped us address evidence needs optimally. These are only some of the learnings that have helped guide the development of resources which will now be available for other teams. In my view it is essential to have a clear plan for evidence generation in the development of digital health solutions.

Shilpa Patel

Managing Director, Innovation & Product Strategy

American College of Cardiology (ACC)

In digital health, evidence isn't just about proving a product works—it's about demonstrating clinical impact, improving patient outcomes, and integrating seamlessly into healthcare workflows. It's collaborations like these that push digital health forward, ensuring that innovation is backed by strong, clinically relevant evidence. The IEP resources—including toolkits, checklists, and case studies—ensures that innovators have the guidance they need to build strong, adaptive evidence plans.

Sean Tunis

Senior Fellow, Tufts Center for the Evaluation of Value and Risk in Health (CEVR) and Principal, Rubix Health

With a well-crafted IEP, digital health innovators can efficiently generate the evidence needed to demonstrate patient benefits, support market access and reduce risk of failure. The IEP resources will support companies in building smarter, efficient and more strategic evidence plans over the entire product lifecycle—turning great ideas into evidence based digital health products that provide value to patients and the health care system.

Terri Kim

Head of Strategy and Corporate Development

Lunit

This initiative is an important step toward bringing rigor and structure to evidence generation for digital health tools. By providing a strategic framework, IEP is enabling internal stakeholders to align on immediate evidence needs while keeping long-term financial viability in mind. It ensures efficient resource use, prevents redundant investments, and maximizes impact. Such a well-structured approach to evidence generation builds trust, supports scalability, and ultimately drives better patient outcomes.

Fireside chat

A well-kept secret: Cracking the code for digital health technology adoption with integrated evidence plans

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Maurice Solomon
Principal, Digital Health Strategy & Innovation
ZS Associates

Meg Barron
Managing Director, Engagement & Outreach
Peterson Health Technology Institute (PHTI)

Moderator:
Smit Patel
Director, Digital Health and AI
Digital Medicine Society (DiMe)

Panel 1 discussion

Don’t stop believin’ in the power of the right evidence

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Kirsten Langdon
Associate Director, Brown-Lifespan Center for Digital Health
Brown-Lifespan Center for Digital Health

Nesrine Lajmi
Global Evidence Generation Lead, Clinical Insights
Roche

Moderator:
Ben Vandendriessche
Chief Delivery Officer
Digital Medicine Society (DiMe)

Panel 2 discussion

Clinically proven, but is it commercially viable? The evidence - commercialization link

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Arun Bhatia
Commercial Strategy Lead, Digital Health, Rx+ Business Accelerator
Astellas Pharma

Sean Glynn
Lead Outcomes Researcher, Medical & Evidence
ZS Associates

Sharon Kaplow
Vice President of Clinical Operations
Feel Therapeutics

Moderator:
Smit Patel
Director, Digital Health and AI
Digital Medicine Society (DiMe)

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Genentech A Member of the Roche Group
Google
Lunit
Lura health
Mika
NeuraLight
Otsuka
Point32Health
Screenpoint Medical
Takeda
Tufts Medicine Tufts Medical Center CEVR
VA U.S. Department of Veterans Affairs
verily a precision health company
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New resources launch on March 26!

DATACC by DiME

Building the **Business Case** *for* Digital Endpoints

Join us to explore new resources designed to support the adoption of digital endpoints by demonstrating their value to decision-makers, digital health technologies (DHTs) developers, and clinical trial sponsors.

DiMe webinar
Wednesday
March 26
11 a.m. ET
Scan to register

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Aging in Place of Choice *with*
Connected Health Technologies

Creating a sustainable, connected ecosystem that empowers aging in place of choice

Join the project

ASSESSING MENTAL HEALTH TREATMENT EFFECTS

Digital Measures Development

DATACC by DiMe

Developing high-resolution, sensor-generated core digital measures that provide objective, scalable endpoints for common mental health disorders

Join us in transforming mental health research and care

Visit the project page

DATACC by DiME

Optimizing Treatment *of* **Type 2 Diabetes** using Sensor Data

Unlocking market access for diabetes management with sensor-based health data solutions

Join us

Visit the project page