Integrated Evidence Plans for Digital Health Technologies

IEP Project Resources

DIGITAL MEDICINE SOCIETY

Stage B:

Evidence strategy & planning

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

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.

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 B should allow you to answer the following questions:

Regulatory strategy

- Did you engage with the FDA for pre-submission meetings to validate study designs?
- Have you built evidentiary packets for regulatory submissions?

Reimbursement pathways

- Are you prioritizing the development of a reimbursement dossier that includes economic models and outcomes data?
- Have you initiated discussions with payors to explore provisional coverage pathways?

Business priorities

- Are you assessing and validating business model fit through stakeholder feedback and early partnerships?
- Have you evaluated technology scalability and planned for its integration into clinical workflows?

Define purpose and strategic objectives

Objective

Establish a clear **purpose** for the evidence strategy, aligning it with overarching goals for DHT development and intended adoption.

There are ~350,000+ digital health products in today's market with 200+ new ones added daily.

Strong evidence differentiates your product in the market.

What is the primary goal for your DHT evidence strategy (i.e., determining whether the DHT can tackle your identified unmet need)?

What evidence do key stakeholders (payors, providers, patients, regulators) need to support adoption, i.e., who is your target purchaser?

Can you generate evidence to quantify the clinical, economic, or operational burden of inaction?

How much de novo evidence will you need to support a reimbursement, procurement, or investment strategy?

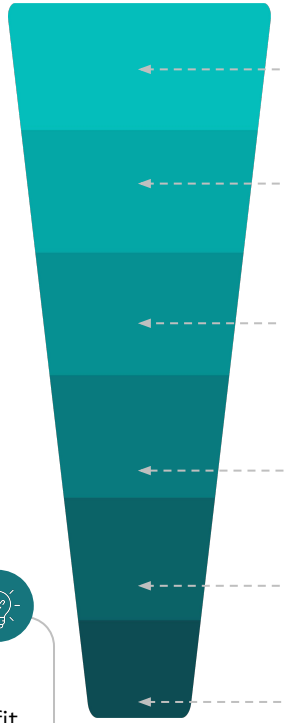
Plan evidence roadmap development

Objective

Develop a cohesive strategy that integrates clinical, real-world, economic, and patient-centric data to address stakeholder needs across the DHT lifecycle.

Pro tip: Work backwards from opportunity cost and standard of care — compare the new solution to usual care and ensure it demonstrates a clear, new net benefit to justify the DHT's value.

There is no one-size-fits-all evidence roadmap, so imagine an evidence funnel



Refine priorities	Align evidence generation with regulatory, payor, provider, and patient priorities.
Assess opportunity cost	Compare the new solution to usual care and ensure it demonstrates a clear, new net benefit to justify the DHT's value.
Determine data requirements	Define the type and depth of data needed (e.g., clinical, real-world, economic, or patient-reported outcomes) to meet key stakeholder evidence needs.
Develop draft hypotheses	Outline functional evidence requirements across clinical, economic, and real-world settings. Define endpoints and key hypotheses to test in early-stage studies.
Prioritize & finalize evidence gaps	Seek joint scientific advice from regulators and payors. Identify additional evidence sources.
Test, implement, & optimize	Conduct studies, adapt evidence models for different markets and reimbursement structures, and refine the roadmap based on new data and insights.

Plan evidence roadmap development

Template

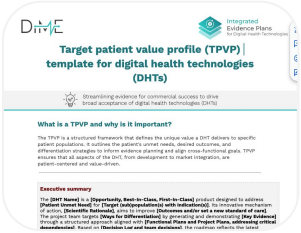
Develop a **TPVP** to define the unique value your DHT delivers to specific patient populations.

What is a target patient value profile (TPVP)?

The TPVP is a structured framework that defines the unique value a DHT delivers to specific patient populations. It measures differentiation and real-world usability to drive adoption and value.

Why is the TPVP important?

- ✔ **Addressing unmet patient needs:** It identifies gaps in current care
- ✔ **Strategic evidence planning:** IIt guides the generation of data that demonstrates value to stakeholders, including payors, providers, and regulators.
- ✔ **Differentiation:** It highlights unique outcomes, enhancing competitive positioning and market readiness.
- ✔ **Alignment:** It integrates cross-functional priorities, aligning R&D, medical affairs, and commercialization efforts toward shared goals.



Download the template

Connecting Your TPVP with the target patient profile (TPP) built in Stage A

The TPVP builds upon the TPP, adapting its structure to meet the unique needs of DHTs. By integrating insights from clinical, regulatory, and market objectives outlined in the TPP, the TPVP ensures a patient-centric focus while maintaining strategic alignment across evidence planning. This connection creates a cohesive roadmap for achieving differentiation, stakeholder engagement, and impactful outcomes.

Review the TPP section of Stage A

Determine evidence requirements

Objective

Identify **evidence requirements** that satisfy the needs for key downstream decision-makers, informed by insights from stakeholders and market analysis.

Resource

- ✔ Evidence checklist

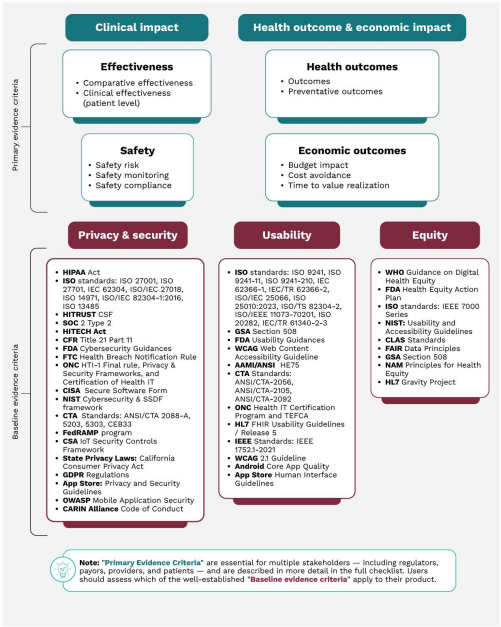
What does high-quality evidence for DHTs look like?

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

Our High-Quality Evidence Checklist provides a clear roadmap for success.

Download High Quality Evidence Overview

Download Full Checklist

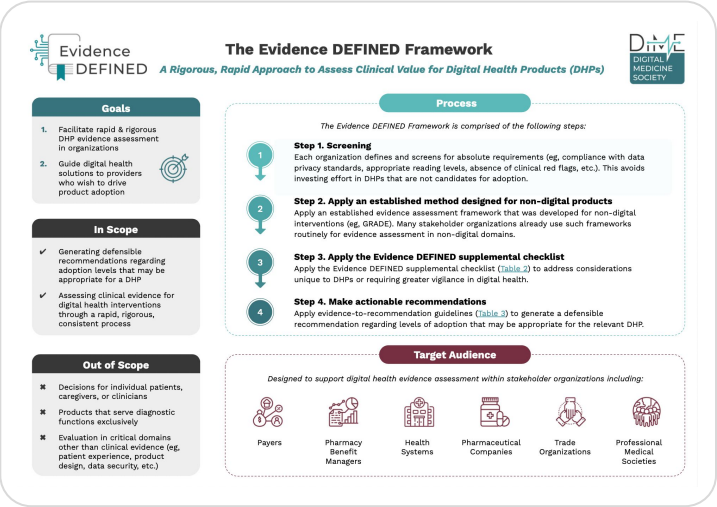


Determine evidence requirements

Resource

- ✔ Evidence DEFINED Framework

Leverage the Evidence DEFINED framework to access clinical value for your DHT



Payors, employers, health systems, and other key stakeholders rely on this **harmonized, rigorous, and rapid framework** as the standard of excellence for clinical assessment of DHTs.

Download Evidence DEFINED framework

Determine evidence requirements

Example

When DHTs lack rigorous evidence and safeguards, they could pose patient safety risks, hinder adoption, and undermine trust.

Read these case studies of clinical and health economic outcomes impact

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 Stage B case example

AppliedVR

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

Download the AppliedVR IEP Stage B case example

Review IEP case studies

Our philanthropic sponsor, Peterson Health Technology Institute (PHTI), has released insightful reports assessing innovative DHTs to improve health and lower costs.

- Review the Digital Hypertension Management report
- Review the Digital Diabetes Management report
- Review the Virtual Musculoskeletal (MSK) report

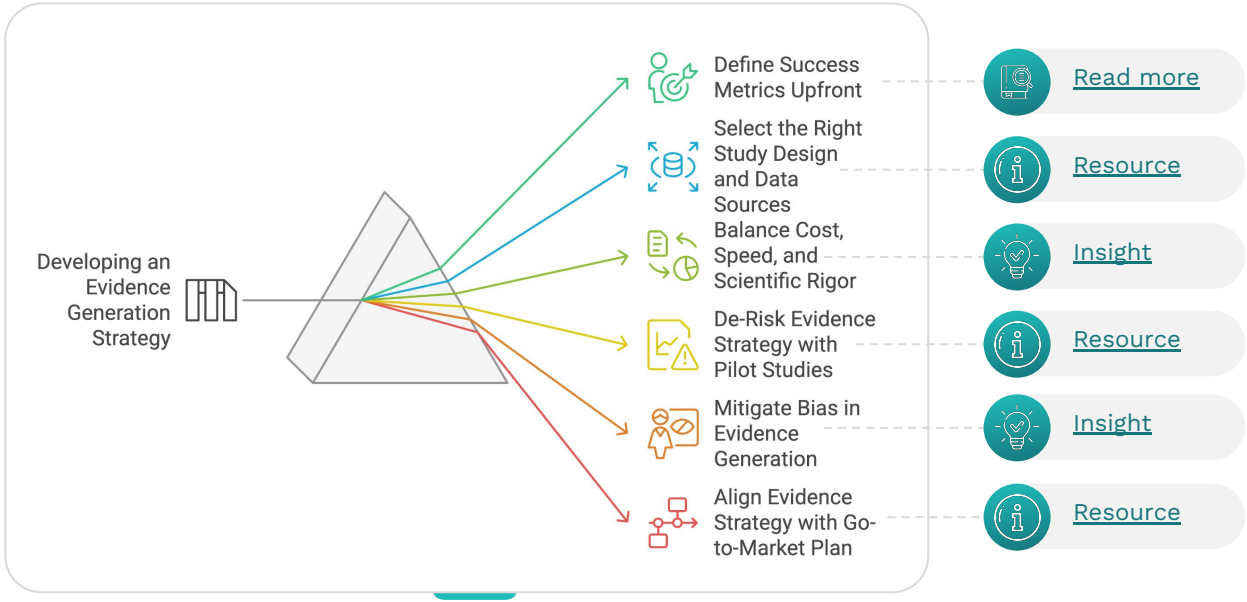
Develop evidence generation strategy

Objective

Build a robust strategy for evidence collection across different stages of the DHT lifecycle.

Considerations for your evidence generation strategy

Selecting the right evidence modalities is about **balancing speed, cost, and data quality**—paving the way for faster and broader market adoption.



Develop Evidence Generation Strategy

Resource

The selection or development of study endpoints is a critical part of your evidence generation strategy.

Developing study endpoints requires weighing ideal measures against practical considerations

Endpoint types are categorized by how outcomes are captured and by their position in the statistical hierarchy. Leverage the roadmap by Mercon, K et al. to develop DHT study endpoints that are practical and optimized for real world impact.

	ENDPOINT TYPE	DEFINITION
Outcomes Captured	Single-measure	Single variable that reflects a single outcome of interest
	Composite	Combination of "clinical outcomes into a single variable"[8]
	Multi-component	Combination of components or domains to create a single score according to specified rules[8]
	Intermediate	"Clinical outcome that can be measured earlier than an effect on irreversible morbidity or mortality (IMM) and that is considered reasonably likely to predict the medical product's effect on IMM or other clinical benefit"[7]
	Surrogate	"Substitute for a direct measure of how a patient feels, functions, or survives"[7]
	ENDPOINT POSITIONING	**DEFINITION**
Statistical Hierarchy	Primary	"Establish the effectiveness, and/or safety features, of the drug in order to support regulatory action"[8]
	Secondary	"To demonstrate additional effects after success on the primary endpoint"[8]
	Exploratory	"Include clinically important events that are expected to occur too infrequently to show a treatment effect or endpoints that for other reasons are thought to be less likely to show an effect but are included to explore new hypotheses"[8]

Download the full roadmap

Souce: Mercon, K et al. (2020, August 28). A roadmap for developing study endpoints in real-world settings. Duke-Margolis Center for Health Policy.

Develop Evidence Generation Strategy

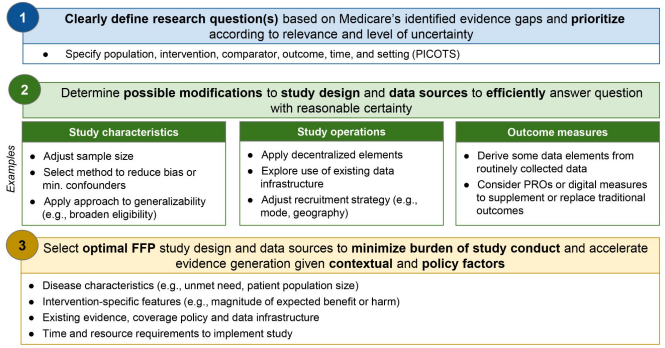
Resource

Conceptual framework for ‘fit-for-purpose’ Medicare studies.

Conceptual framework for creating ‘fit-for-purpose’ Medicare studies

The framework by Caroline Marra et al. will guide you in answering the following questions:

- ✔ What will be the utility of the evidence generated for informing coverage decisions and, ultimately, the care of Medicare beneficiaries?
- ✔ What will be the burden of conducting the study?
- ✔ How will the evidence development affect patient access to the technology?



Download Conceptual Framework to Build Evidence for Medicare

Souce: "Medicare ‘Fit-For-Purpose’ Studies For Coverage Of Emerging Medical Products, Part 1: A Framework,” Health Affairs Forefront, October 24, 2024.

Test your evidence plan and conduct a gap analysis

Objective

Choose the most suitable methodologies to balance your scientific evidence and commercial claims.

Choosing the right evidence generation modalities

Evidence design is used to generate and evaluate the evidence for your product. A fit-for-purpose evidence design means that you select the most suitable and feasible methods, tools, and data sources for your product and context.

For instance, you may use randomized controlled trials, observational studies, real-world data, patient-reported outcomes, or digital biomarkers, depending on the type, level, and scope of evidence you need. A fit-for-purpose evidence design will help you optimize your resources, reduce your risks, and increase your credibility.

Scientific evidence

Led by the R&D, medical, and data science teams

- ✔ Generates clinical and scientific evidence
- ✔ informs and validates commercial claims

Clinical study and evidence should guide commercial claims, ensuring accuracy and credibility.

Commercial claims

Managed by the commercial and market access teams

- ✔ Must be supported by robust scientific evidence
- ✔ Aligns with regulatory and market requirements

Test Evidence Plan and Conduct Gap Analysis

Objective

Define your desired state and trace back to the evidence you have to determine existing gaps.

Steps to conducting a gap analysis

Current state	Desired state	Identified gap	Gap due to knowledge/ skill/practice	Methods used to identify gaps
What evidence currently exists for the DHT?	What evidence is needed to meet regulatory, payor, provider, and patient expectations?	Difference between available evidence and required evidence.	Why does this gap exist? (E.g., lack of clinical trials, insufficient real-world evidence, missing economic evaluations.)	What data or stakeholder feedback validates this gap?
What are the existing real-world data sources?	What additional real-world evidence is necessary?	Difference between current and required real-world data.	Limited patient-reported outcomes, insufficient post-market surveillance, or missing longitudinal data.	Comparative analysis with regulatory and market access requirements.
What are the known safety and efficacy outcomes?	What further validation is required?	Difference between available and expected safety/efficacy data.	Lack of diverse population studies, insufficient follow-up duration.	Regulatory feedback, peer-reviewed studies, competitor benchmarking.

Implement the evidence plan and strategy

Objective

Ensure effective execution of the evidence plan by considering important success factors.

Implementation success factors

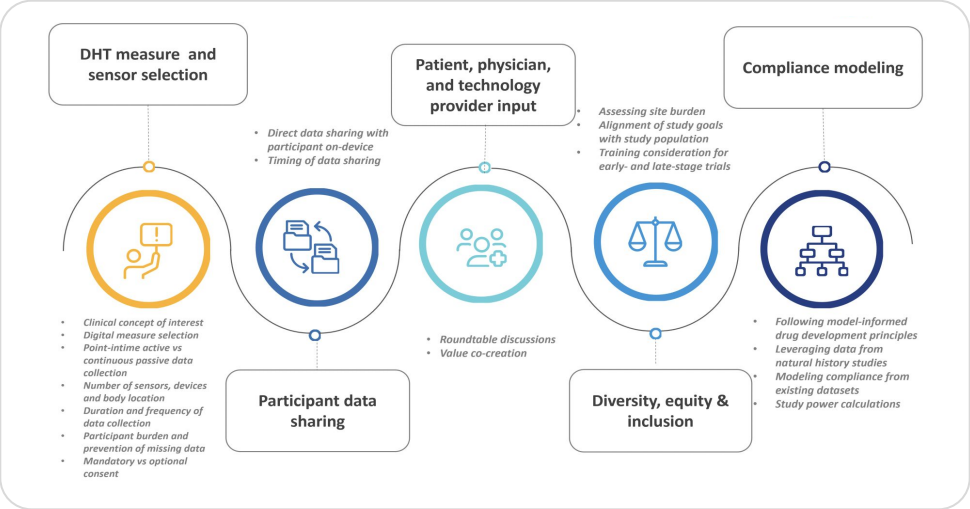
Clear study design	Robust data collection	Stakeholder alignment	Compliance risk
Conduct high-quality clinical and real-world studies to generate impactful evidence. Use validated endpoints to demonstrate safety, effectiveness, and health and economic outcomes. *The Playbook:* Digital Clinical Measures, sections on clinical research and clinical trials V3+ Framework Study design FAQ landscape	Establish a structured framework for aggregating diverse data sources (including RCTs, RWE, and digital biomarkers, as applicable). Running effective analytical validation studies *The Playbook:* Digital Clinical Measures, section on clinical research CTTI: Strategies for optimizing data quality	Align evidence generation with regulatory and reimbursement expectations early and implement necessary steps to ensure evidence generated meets their targeted requirements. U.S. Payor and Provider Landscape Map Engagement toolkit to communicate with US regulators	Difference between available evidence and required evidence. ✔ Comparative effectiveness key consideration ✔ Monitor and mitigate risk Risk assessment model: DHT lifecycle

Implement the evidence plan and strategy

Resource

Follow these key considerations when implementing your evidence plan to ensure effective execution.

Key considerations for implementing a sensor-based DHT in clinical trials



Souce: Izmailova, E. S. et al (2024). Implementing sensor-based digital health technologies in clinical trials: Key considerations from the eCOA Consortium. Clinical and translational science, 17(11), e70054.

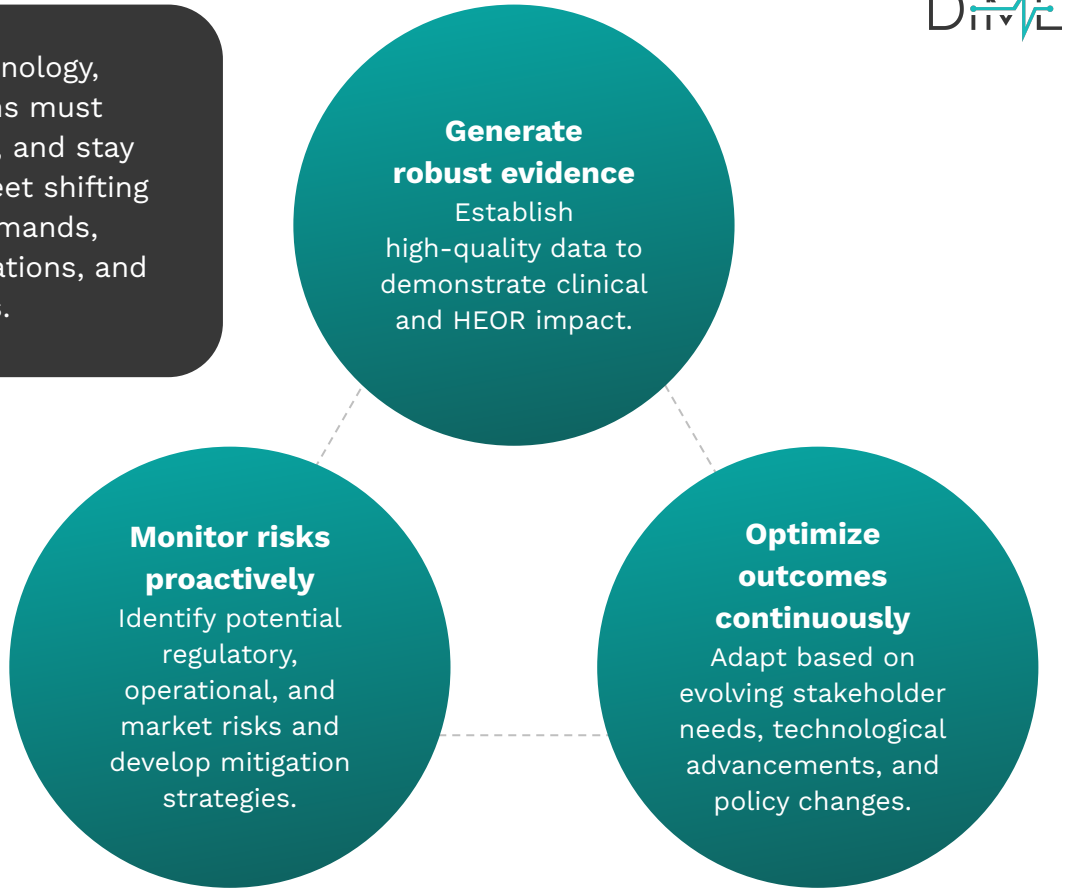
Download the implementation approach

Generate robust evidence, monitor risks, and optimize outcomes

Objective

Ensure the continuous generation of high-quality evidence.

Just like technology, evidence plans must evolve, adapt, and stay current to meet shifting regulatory demands, payor expectations, and patient needs.



Generate robust evidence, monitor risks, and optimize outcomes

Insight

Ensure the continuous generation of high-quality evidence.

Generate robust evidence

Monitor risks proactively

Optimize outcomes continuously

Demonstrate clinical and health economic and outcomes impact by aligning evidence generation timelines with product development and market-entry goals.

Considerations

- Define short-term (6-12 months) and long-term (24+ months) goals.
- Set clear evidence checkpoints (e.g., pilot studies, pivotal trials).
- Integrate budget and resource allocation with timelines.

Milestone categories

- Completion of feasibility studies.
- Key regulatory submissions (510(k), De Novo, etc.).
- Payor and HTA submission deadlines.
- Market launch and post-market surveillance initiation.

Best practices

- ✔ Incorporate buffer time for regulatory feedback.
- ✔ Align milestones with critical investment decisions.
- ✔ Regularly review and adjust timelines based on emerging data.

Generate robust evidence, monitor risks, and optimize outcomes

Insight

Generate high-quality evidence to support regulatory submission and reimbursement dossiers.

Generate robust evidence

Monitor risks proactively

Optimize outcomes continuously

Identify, assess, and mitigate potential threats to evidence credibility, regulatory compliance, and market adoption.

Considerations

- Identify key risks related to patient recruitment, data integrity, regulatory changes, and technological reliability.
- Implement a risk-based monitoring approach to detect potential issues early.
- Ensure compliance with evolving data privacy and security regulations.

Risk categories

- **Regulatory & Compliance Risks**: Changes in authorization requirements, evolving payor expectations.
- **Operational Risks**: Delays in trial execution, interoperability issues with digital health tools.
- **Data Integrity Risks:** Incomplete datasets, biases in real-world evidence, inconsistent data capture.
- **Market & Adoption Risks**: Payor hesitancy due to insufficient cost-effectiveness data, lack of provider buy-in.

Best practices

- ✔ Establish **real-time risk dashboards** for early detection and intervention.
- ✔ Conduct **frequent cross-functional risk assessments** involving regulatory, clinical, and commercial teams.
- ✔ Develop **contingency plans** to address potential trial delays, data gaps, and regulatory shifts.

Generate robust evidence, monitor risks, and optimize outcomes

Insight

Continuously refine evidence strategies to maximize impact and accelerate market readiness.

Generate robust evidence

Monitor risks proactively

Optimize outcomes continuously

Leverage adaptive strategies to refine evidence plans, enhance market readiness, and maximize patient and stakeholder impact.

Considerations

- Define **clear success metrics** for anticipated future outcomes.
- Continuously refine evidence based on **new market insights, stakeholder feedback, and real-world data**.
- Adapt trial designs and study endpoints to ensure relevance across diverse healthcare settings.

Outcome optimization strategies

- **Dynamic evidence updates:** Regularly update analyses based on real-world performance data.
- **Stakeholder-driven refinements:** Align with evolving payor, provider, and regulatory expectations.
- **Market access adaptability:** Optimize evidence communication to facilitate market access across target market.

Best practices

- ✔ Implement **rolling evidence reviews** to ensure timely adjustments in study design.
- ✔ Foster **collaborative partnerships** with payors and providers to generate real-world validation.
- ✔ **Collect data and success stories** to continuously assess the impact.

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

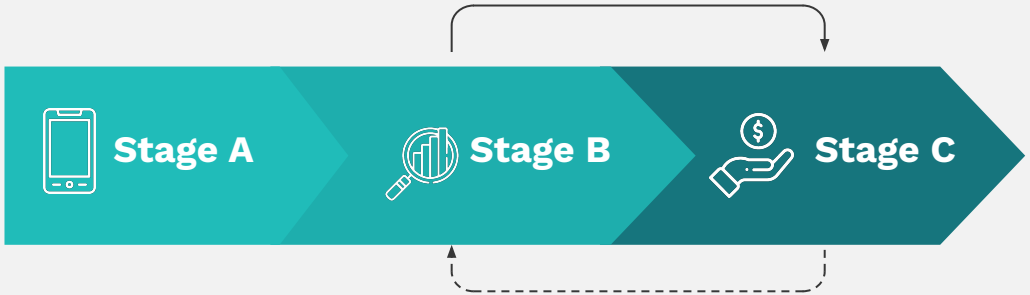
Regulatory strategy	Reimbursement pathways	Business priorities
• Did you engage with the FDA for pre-submission meetings to validate study designs? • Have you built evidentiary packets for regulatory submissions?	• Are you prioritizing the development of a reimbursement dossier that includes economic models and outcomes data? • Have you initiated discussions with payors to explore provisional coverage pathways?	• Are you assessing and validating business model fit through stakeholder feedback and early partnerships? • Have you evaluated technology scalability and planned for its integration into clinical workflows?

We encourage you to leverage the tools provided in this section at your own pace.
Think of this process as an evolving journey rather than a one-time task.

Ready for Stage C? Double-check your work

As a reminder, before you move to **Stage C (Commercial strategy & market access)**, your team should have answered all the questions for Stage B: Evidence Strategy & Planning.

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.



To move to Stage C, you should have already determined your evidence strategy, developed robust evidence, created a reimbursement dossier with economic and outcomes data, and validated commercial claims fit through stakeholder engagement.