Integrated
Evidence Plans
for Digital Health Technologies
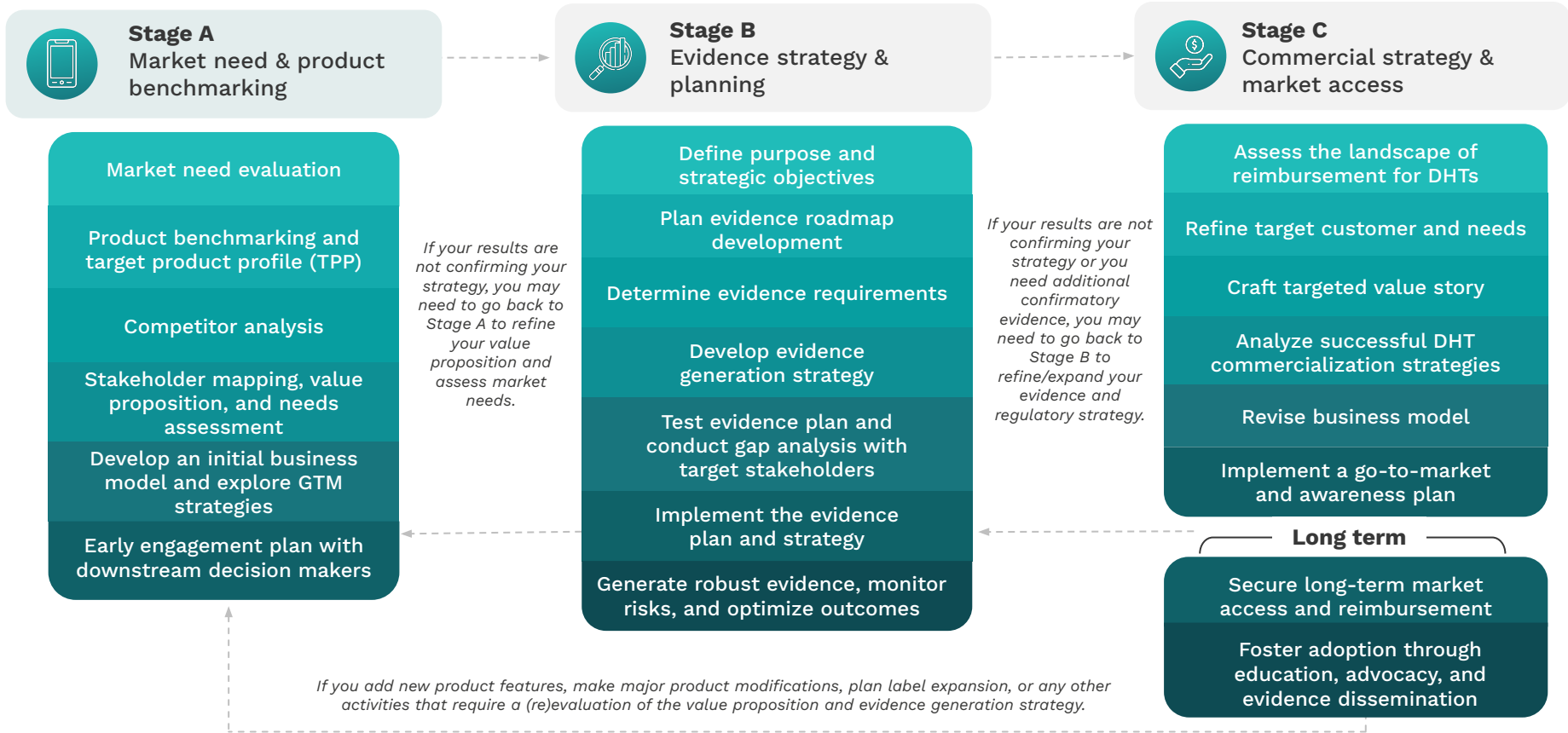
IEP Project Resources

Stage A:

Market need & product benchmarking

DIGITAL
MEDICINE
SOCIETY

IEP Toolkit

DiME

Stage A
Market need & product benchmarking

→

Stage B
Evidence strategy & planning

→

Stage C
Commercial strategy & market access

Stage A Items
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.

Stage B Items
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.

Stage C Items
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

Long term Items
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	

- 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?

Market need evaluation

Objective

To thoroughly understand and validate the market need by **identifying unmet clinical needs** for both patients, health professionals, and the healthcare market.

1. Define the unmet need

- Is there a clear unmet need in the market for your solution?

- How urgent is this need in the market? (Quantify it)

- Why is this unmet need a problem in the first place?

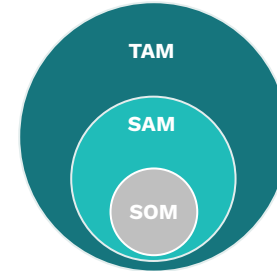- Is a digital health technology the best approach to address this need?

- What is the market size for addressing this need?

- Who would be willing to pay for this solution, and at what price?

2. Quantify the unmet need

TAM: Total addressable market
TAM = Total # of potential customers x average annual revenue per customer

SAM: Serviceable addressable market
SAM = TAM x Percentage of customers you can serve

SOM: Serviceable obtainable market
SOM = SAM x Percentage of market you can capture (based on your business model)

Market need evaluation

Example

A health-tech startup in Boston developing a virtual reality (VR) therapy program designed to reduce chronic lower back pain: the program offers daily 30-minute VR sessions for 6 weeks. This service is targeted at adults aged 18 and older experiencing chronic pain, focusing on Massachusetts as the initial launch market.

VR-based digital health therapy (DHT) for chronic pain

TAM

TAM: The total potential market for VR pain therapy globally.
TAM = 60 million individuals experiencing chronic pain x $1200 annual therapy cost per user = **$72 billion (global)**

SAM

SAM: The subset of people with chronic lower back pain who are actively seeking solutions.
SAM = $72 billion (global) x 8% (% of individuals with chronic pain experiencing chronic low back pain) x 10% (US market share) x 1.5% (Massachusetts market share) = **$ 8.64 million**

SOM

SOM: The share of SAM that the startup can realistically capture (Assumption: 5% adoption).
SOM = $8.64 million x 5% = **$432,000**

Realistic initial market capture based on competition and resources is $432,000 annually

Product benchmarking and TPP

Objective

Clearly define the **DHT's characteristics**, its target disease, patient population, clinical setting, and comparison benchmarks

What is a target product profile (TPP) and why is it important?

A **target product profile (TPP) is a vital planning tool introduced by the FDA to streamline the drug development process**. A TPP serves as a strategic roadmap aligning stakeholders by providing a comprehensive vision for the final product and ensuring unified efforts toward a clear goal.

For drugs, a TPP streamlines clinical, regulatory, and commercial objectives for efficient development. **For DHTs**, it navigates the complexities of development, usability, and cybersecurity—ensuring readiness for reimbursement while driving innovation.

Strategic guidance
Ensures alignment of product development with clinical and market needs.

Regulatory planning
Defines the pathway for FDA, CE, and global approvals, minimizing delays.

Benefits of a TPP for digital health technologies

Stakeholder engagement
Ensures alignment of product development with clinical and market needs.

Market differentiation
Provides a roadmap to achieve competitive advantages through unique features.

Product benchmarking and TPP

Resources

✔ Regulatory strategy

✔ Intended use and indication for use statement

✔ DHT TPP template

Determine your regulatory strategy

Defining a regulatory strategy early ensures that evidence collection aligns with FDA expectations, avoiding unnecessary hurdles later in development.

Visit the FDA's Digital Health Policy Navigator

Visit DiMe's Digital Health Regulatory Pathways resources

Define your intended use and your indication for use

Building a TPP requires an intended use and indications for use statement for the DHT.

Review DiMe's Quick guide on intended use and indication for use

Target Product Profile (TPP) template for digital health technologies (DHTs)

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

What is a TPP and why is it important?

A **Target Product Profile (TPP) is a vital planning tool introduced by the FDA to streamline the "drug development process".** A TPP serves as a strategic roadmap aligning stakeholders by providing a comprehensive vision for the final product and ensuring unified efforts toward a clear goal.

Key sections of the TPP

Attribute	Minimum acceptable result	Ideal result
Indications/use	Monitor [specific health metric] or facilitate [specific service].	Real-time, multi-functional health monitoring or services.
Target population	Adults with [specific condition] in urban settings.	Broad population across all demographics globally.
Efficacy	Accuracy of 80% for key	Accuracy of ≥95% with

Use the TPP template to craft your strategic product roadmap for your DHT.

Product benchmarking and TPP

Best Practice

When collating information for your TPP, ask yourself the following questions to start defining product requirements.

Who is the target population (age group, demographics, patient type)?

What healthcare setting will this product be used in (hospital, home, clinic)?

What product features or functionalities are necessary to meet the unmet need?

Are there other technologies or products that this solution will need to integrate or connect with (e.g., apps, sensors)?

Will the product require a prescription, or will it be available as a non-prescription or over-the-counter solution?

Competitor analysis

Objective

Identify **competitors**, assess market trends, and **benchmark products** to position yourself in the market effectively.

To stay competitive, it's essential to analyze how other players in the market operate, engage with their audience, and differentiate their products. Competitor insights reveal market trends, customer preferences, and potential gaps your product can fill. By identifying what makes competitors successful—or where they fall short—you can refine your strategy, enhance your value proposition, and position your product more effectively.

What makes competitors' products unique?

Who are their target customers, and how well are they meeting their needs?

How are they building trust with their end users?

What existing solutions are available, and how is your product different or better?

If similar products are already reimbursed, will your solution be sufficiently differentiated and/or better at the same cost?

Competitor analysis

Resources

Methods to assist in a competitive analysis

✔ SWOT
✔ Porter's Five Forces
✔ Perceptual mapping
✔ Growth Share Matrix (BCG)
✔ Competitive pricing
✔ Analog analysis
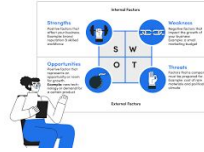
SWOT analysis
Analyze strengths, weaknesses, opportunities, and threats.

Porter's Five Forces analysis
Identify the five main factors that influence a company's competitive position in an industry.
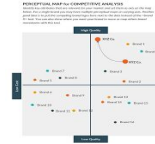
Perceptual mapping
Evaluate how consumers perceive competing products or services in the marketplace.
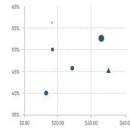
Growth Share Matrix (BCG)
A framework that helps companies decide how to prioritize their different businesses.

Competitive pricing analysis
Analyze competitor's product pricing model and strategies.

Analog analysis
broadens the perspective by studying products or companies in adjacent industries that solve similar problems.

Select the method that aligns with your business goals, product focus, and competitive landscape.

Stakeholder mapping, value proposition, and needs assessment

Objective
Map out and identify various downstream **decision-makers** who will influence the DHT's development, adoption, and market success.

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

Use these [stakeholder maps](#) to help you identify relevant decision-makers and key influencing factors such as:

- Types of decision-making stakeholders are responsible for

- Examples of key decision-makers

- Potential impact to adoption
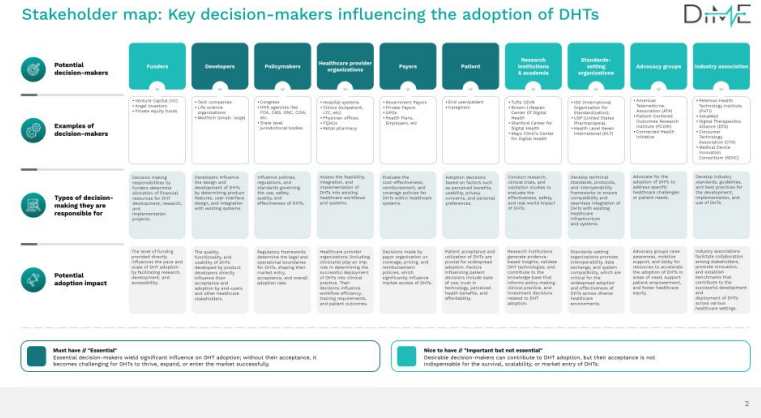
Stakeholder mapping, value proposition, and needs assessment

Resources

✔ Stakeholder mapping template
✔ Stakeholder needs assessment template
✔ Value proposition template

Stakeholder needs assessment template

For each stakeholder group, identify: wants, needs, and fears.

Stakeholder	Wants	Needs	Fears
	Specify what your target customers aspire to achieve with your DHT.	Outline the essential requirements/problems your DHT addresses	Identify potential concerns or hesitations your customers might have
	•	•	•

Stakeholder mapping template

| Keep completely informed | Manage most thoroughly |
| Regular minimal contact | Anticipate and meet needs |

Interest of stakeholder / Influence of stakeholder

Value proposition template

Based on your stakeholder needs assessment, identify the value proposition your DHT provides.

BENEFITS	EXPERIENCE	SUBSTITUTES
Identify and list the key advantages your DHT offers to patients, healthcare providers, or other stakeholders	Describe the overall experience users (e.g., patients, clinicians) will have when interacting with your DHT, focusing on the value it adds to their healthcare	List alternatives: Detail existing options customers might consider instead of your DHT, including traditional care methods, competitor
UNIQUE FEATURES		

Download the templates here
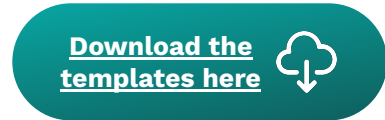
Develop initial business model and explore GTM strategies

Objective

Establish an early sustainable **business model** and identify effective **go-to-market (GTM) strategies** to drive adoption, commercialization, and market success.

Once you've defined and articulated your value proposition, a critical next step is selecting the right business model for your DHT.

Companies have experimented with a range of strategies to bring their products to market and drive revenue. **Consider exploring both traditional and emerging payment models** to find the best fit for your business. We will explore business models in more detail in <u>Stage C - Commercial strategy & market access</u>.

Business models that rely on reimbursement	Business models that rely on consumers (as payors)	B2B-like business models
Fee-for-service	Direct to Consumer	Licensing model
Time-limited add-on reimbursements	B2C2B/Bottom-up sales models	Channel partnerships
Risk-based contracting	Subscription-based model	Two-sided network

Develop initial business model and explore GTM strategies

Resource

✔ Nine key areas to define your **business model**.

Define your business model:
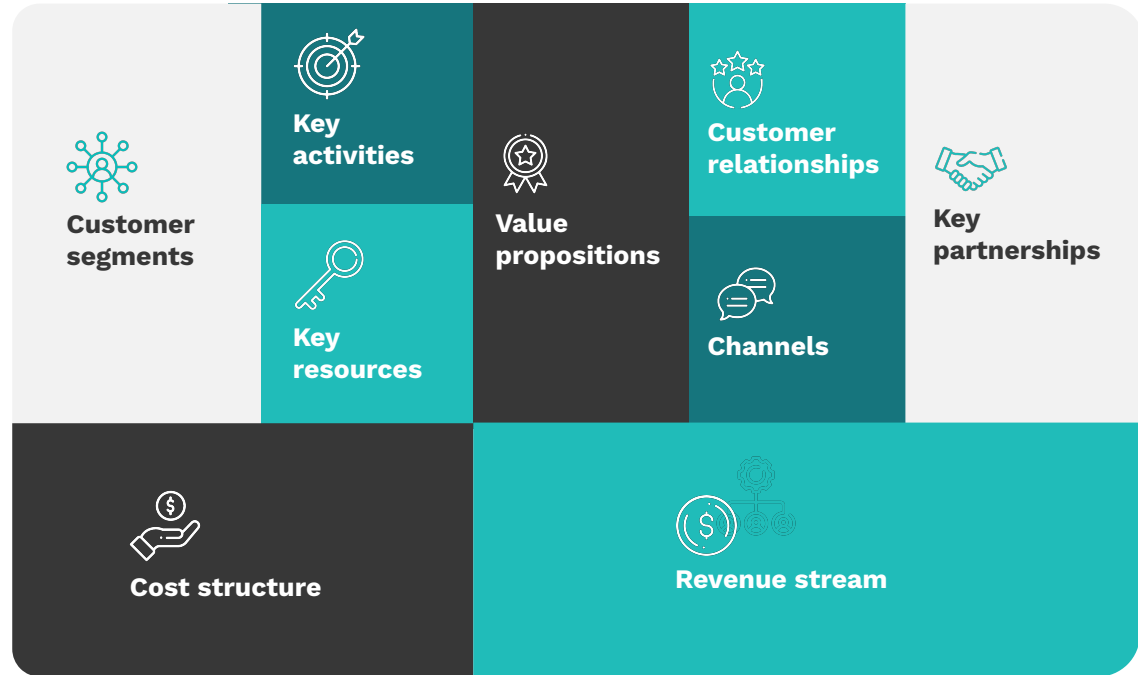
Within the template, you will find key questions to ask regarding each of the nine areas to help guide the development of your business model.

Download the business model template

Develop initial business model and explore GTM strategies

Resource

✔ 5 W's approach to designing your go-to-market strategy

Market need evaluation

Product benchmarking

Competitor & analog analysis

Stakeholder value assessment

Business model & strategies

Who? Led by **market research teams**, financial analysts, commercial strategists, founders.

What? Design GTM plan for execution **tailored to current market needs**, including target identification, pricing models, and distribution channels.

When? In the **early** stages of **product development** and **pilot testing**. Refine the plan through evidence generation and commercialization.

Where? Engage through **industry conferences**, digital channels, and direct B2B partnerships.

Why? To ensure a **competitive advantage**, drive **commercialization**, and **adoption**.

Use the 5 W's approach to design your GTM strategies

Early engagement plan with downstream decision makers

Objective

Establish early relationships and communication channels with **downstream decision-makers**.

Early engagement with key decision-makers ensures your DHT aligns with their top priorities. For example, engaging purchasers early in Stage A helps align your product with decision-makers' key needs, maximizing adoption and reducing the risk of being replaced due to unmet need. Learn more in the PHTI 2024 State of Digital Health Purchasing Survey results.

1. Define engagement success metrics: Set goals for engagement (initial buy-in, critical feedback gathered, or co-development opportunities) that support identifying and addressing early bottlenecks. E.g., Setting early **buy-in goals with payors** ensures reimbursement pathways are addressed before market entry, reducing financial adoption barriers.

2. Establish regular communication and feedback loops: Set up structured communication channels with your target stakeholder to gather insights and address pain points. E.g., Feedback loops with patients can refine usability and engagement, ensuring the DHT is tailored to their real-world needs and improving long-term adherence.

3. Integrate early feedback into development: Proactively incorporate insights from decision-makers and SMEs into the DHT's design and evidence strategy. E.g., Early discussions with regulators help shape evidence-generation strategies that meet approval requirements, preventing costly redesigns later.

4. Build long-term relationships for advocacy: Cultivate connections with key stakeholders and SMEs who can become advocates, helping to remove barriers and drive the DHT's acceptance into clinical pathways and formularies.

Early engagement plan with downstream decision makers

Resource

Meet at least three key downstream decision makers as a part of your product and market benchmarking.

Regulators

Engaging early ensures you align with expectations, minimizing delays and streamlining authorization. By addressing classification, pathway, and evidence needs proactively, you can build credibility and accelerate compliance.

Check out channels for US regulatory engagement within FDA

Payors

By engaging early, you can understand reimbursement needs & pathways, align your value proposition, and shape pricing and coverage strategies, ensuring market access and adoption.

Take a look at the US payor landscape map to identify who to engage with

Healthcare Providers/ Organizations

Engaging providers early helps you align with their workflows, build trust, demonstrate value, and foster advocacy to drive adoption.

View the US Provider Organization landscape map to identify who to engage with

Case study

Examples

🔍 **Caption Health:** Expanding access to cardiac ultrasound

🔍 **AppliedVR**: Virtual reality (VR)-based home therapy

Explore these retrospective case studies, developed through a review of publicly available data and existing sources to provide an analysis of the companies' approaches to Stage A - Market need and product benchmarking.

Caption Health

Explore Caption Health's journey through Stage A highlighting the process, key decisions, and concepts that shaped their success.

Download the Caption Health IEP Stage A case example ☁️⬇️

AppliedVR®

Explore how AppliedVR identified key graphic regions, held pre-submission meetings with the FDA and prioritized payer discussions to build a reimbursement strategy.

Download the AppliedVR IEP Stage A case example ☁️⬇️

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?

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 B? Double-check your work

As a reminder, before you move to **Stage B (Evidence strategy and planning)**, your team should be able to answer all the questions for Stage A: Market Need and Product Benchmarking.

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.

Stage A   **Stage B**   **Stage C**
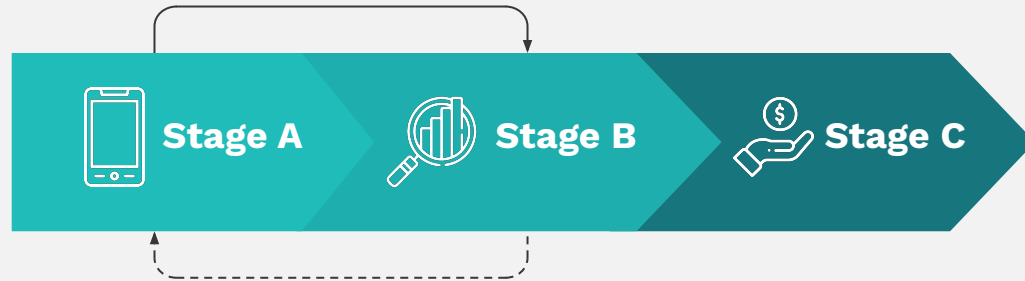
Remember: The goal is to understand the unmet needs, define benchmarks, and identify opportunities for differentiation. Don't get lost in analysis — stay focused on what will directly impact your product's market success.