

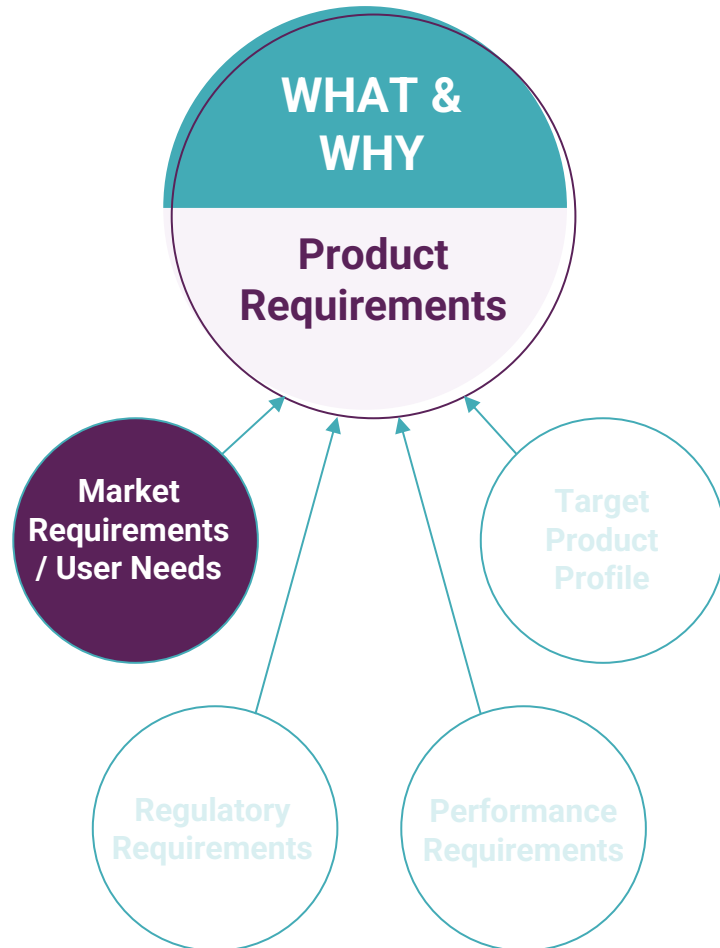


DEFINING PRODUCT NEEDS: MARKET REQUIREMENTS

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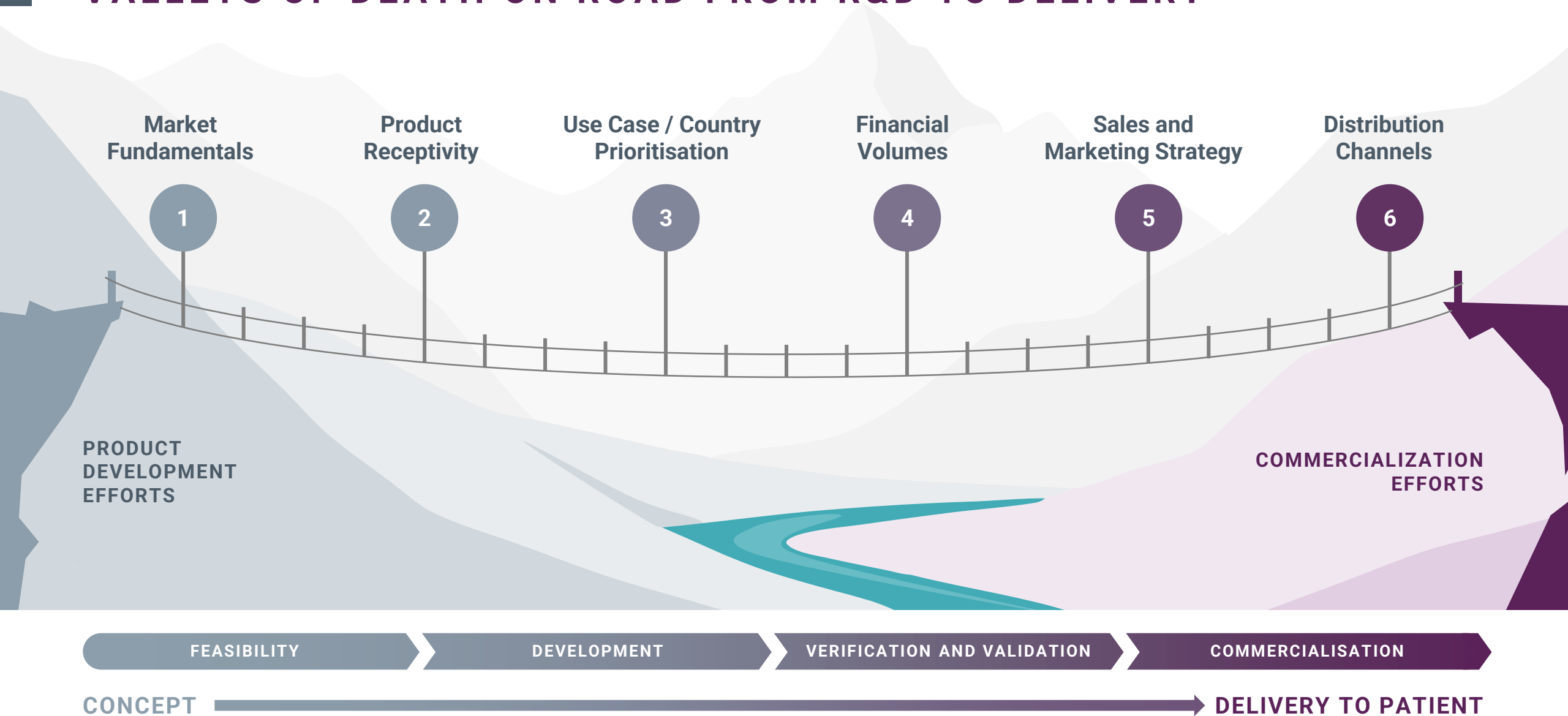
MARKET REQUIREMENTS



Examples of relevant categories/aspects for product requirements consideration:

Market Need Why is the product needed?	Intended Use Purpose of your device What the test does / how it works	Indications for Use Circumstances under which the test will be used
Target Markets Where is the test going to be sold?	Procurement Who will buy the product?	Target Settings Where the test will be used?
Target Analyte Which analyte to test?	Specimen Type (e.g. swap, urine, blood...)	Analytical & Clinical Performance (e.g. LoD, sen., spe.)
Operational Characteristics (e.g. shelf life, stability)	Test Format (e.g. LFT, strip, ELISA)	Target COGs What is the target cost?
Device Classification Based on Risk associated with Intended Use of test	Waste Management Test disposal after use	Digital / Connectivity Data storage, sharing...

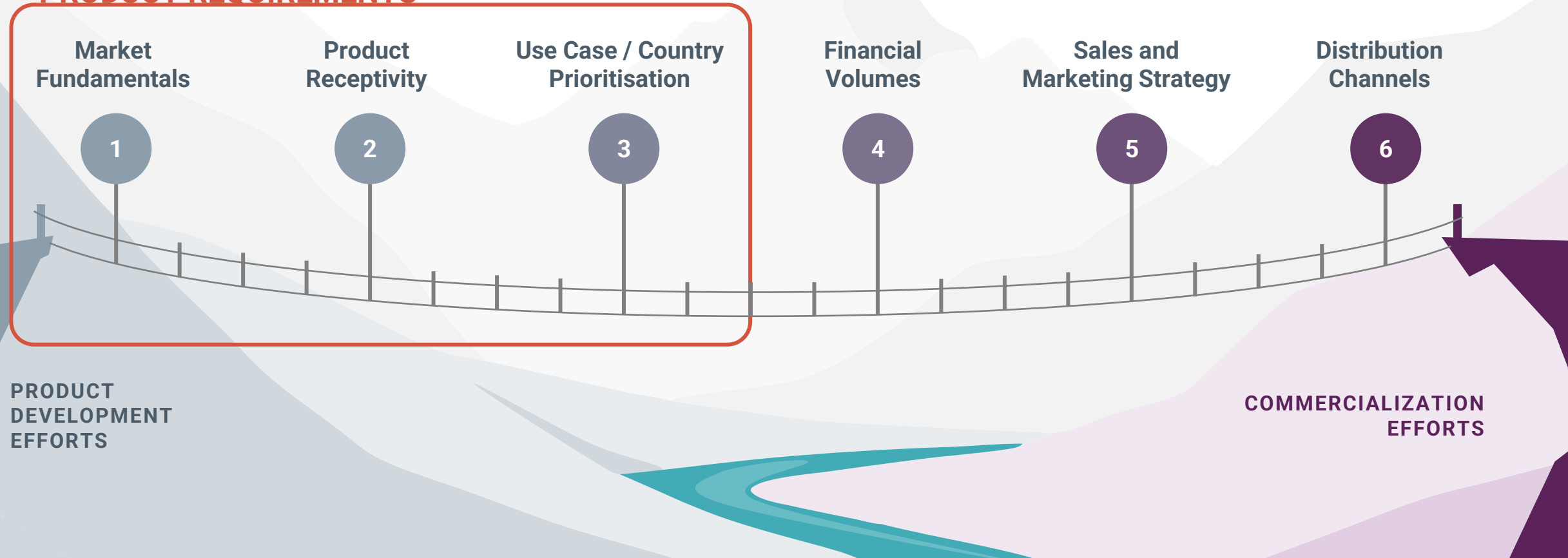
MARKET RESEARCH STARTS EARLY AND HELPS OVERCOME VALLEYS OF DEATH ON ROAD FROM R&D TO DELIVERY



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PRODUCT REQUIREMENTS



FEASIBILITY

DEVELOPMENT

VERIFICATION AND VALIDATION

COMMERCIALISATION

CONCEPT

DELIVERY TO PATIENT

DEFINITIONS

Market Fundamentals

Factors shaping the specific diagnostic market, including diagnostic practices and algorithm, key stakeholders, market size, growth potential, competitive dynamics, and regulatory pathways essential for strategic planning.

Product Receptivity

Degree to which diagnostic products are embraced by target audiences, considering factors like technological compatibility, willingness to pay, clinical relevance, and user acceptance.

Country / Use case Prioritization

Strategically assessing and ranking markets or use-cases based on criteria such as healthcare infrastructure, disease prevalence, competition, regulatory environment, and potential for collaboration.

For example

Understand if a lateral flow test to detect pathogen antigen is enough or if algorithms and guidelines requires molecular tests

A highly accurate Continuous Glucose Monitoring device, but with a complex and unintuitive user interface, is likely to experience decreased usage, user frustration, and negative word-of-mouth, ultimately resulting in a decline in market share.

Defining priority countries for launch of product early on is important to understand quality and data requirements for validation and verification.

UNDERSTANDING MARKET FUNDAMENTALS



Acts as a phase gate to go from feasibility to development

KEY RESEARCH QUESTIONS

1. What is the testing need? What are the gaps in health insurance coverage that need to be identified?
2. What is the unmet diagnostic need – what are the discrepancies between national health guidelines and actual patient experiences, and what barriers and challenges that hinder correct testing and treatment?
3. What is the competitive landscape and end user affordability?
4. How can the diagnostic market's accurate size (SOM) be estimated through a comprehensive market sizing assessment?
5. What is existing regulatory framework for diagnostics?

ACTIVITIES

1. Diagnostic needs and Insurance analysis
2. Nation health guideline implementation gap
3. Competitive landscape + Pricing
4. Market sizing Assessment
5. Regulatory Pathway Mapping

OUTPUT

Comprehensive overview of the current landscape, challenges, and opportunities related to diagnostics in the specific country, aiding in strategic decision-making and planning.

UNDERSTANDING PRODUCT RECEPTIVITY



Acts as a phase gate to continue product development

KEY RESEARCH QUESTIONS

1. Map the needs and key purchasing criteria of decision makers/ Payers (example, price, time-to-result, assay specificity, assay sensitivity, etc.)
2. What product attributes contribute the most to Willingness to Pay?
3. Assess your product against key purchasing criteria and competitor pricing.
4. What are the specific expectations users have regarding diagnostic features, usability, and convenience?

ACTIVITIES

1. Target audience persona creation
2. Pricing sensitivity analysis
3. Diagnostics fit assessment
4. User experience expectations
5. Communication channel preference

OUTPUT

Actionable insights into how well the potential diagnostics align with the target audience's needs, preferences, and decision-making dynamics.

UNDERSTANDING STAKEHOLDER/USE CASE PRIORTISATION



Needed to understand regulatory requirements for V&V

KEY RESEARCH QUESTIONS

1. What valuable insights can be gathered from the KOLs and key stakeholders? Can we identify critical challenges and opportunities through these interviews?
2. Which other countries / geographies need to be prioritized for the pilots/ diagnostic product launch?
3. Who are the key decision-making bodies and stakeholders in the country?

ACTIVITIES

1. Country selection - based on epidemiological factors, market opportunity factors, policy and advocacy factors
2. Stakeholder analysis

OUTPUT

1. **Target launch countries identified**
2. **Target stakeholders/key decision makers identified**

FIND 

QUESTIONS &
FEEDBACK

