FIND

DEFINING PRODUCT NEEDS: PRODUCT REQUIREMENTS

Olga Ordeig

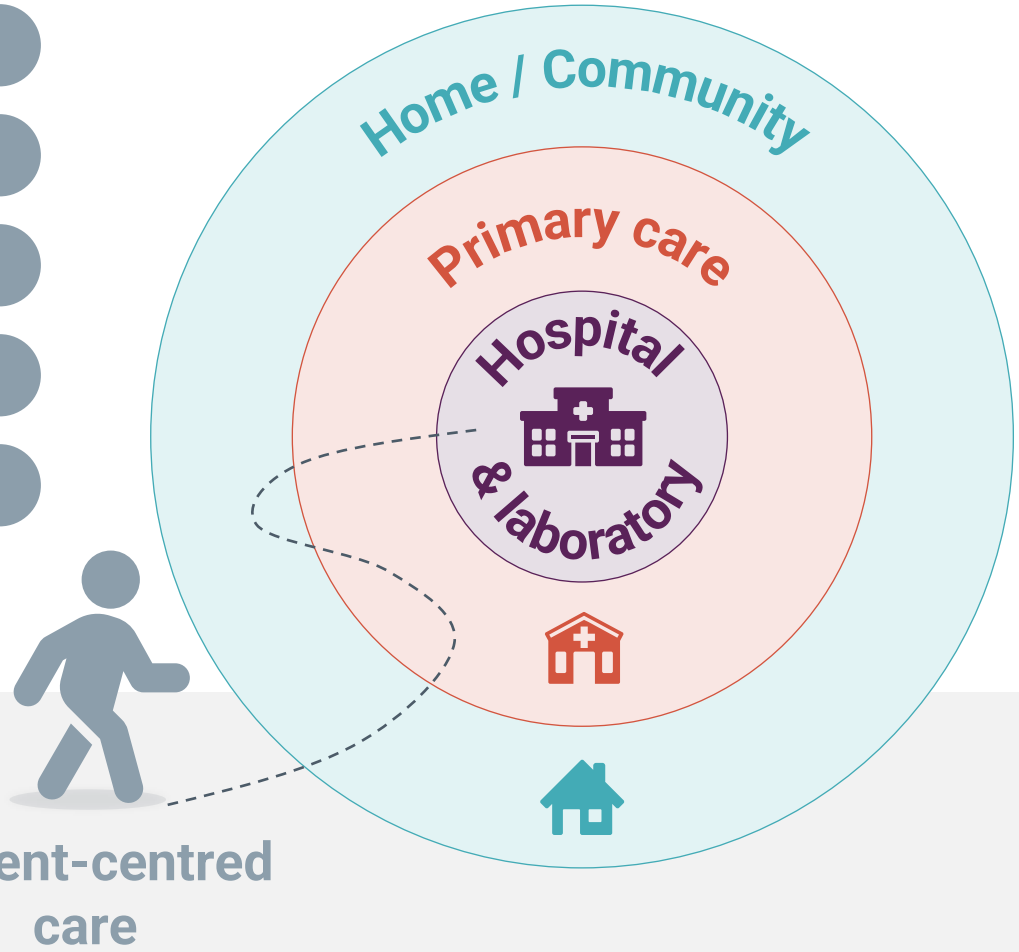
TOPICS

1. The importance of fit-for-purpose diagnostics
2. Product Requirements vs Design Inputs
3. Requirements from Target Use Settings

DIAGNOSTIC SOLUTIONS MUST BE ADAPTED FOR THE PEOPLE WHO NEED IT

AND THE CONTEXT IN WHICH THEY WILL USE IT

- Screening
- Severity assessment
- Clinical diagnosis
- Treatment monitoring
- Disease surveillance



- FIT-FOR-PURPOSE DIAGNOSTICS
- INTERCONNECTED DATA SYSTEMS

DIAGNOSTIC SOLUTIONS MUST BE ADAPTED FOR THE PEOPLE WHO NEED IT

FIT FOR PURPOSE DIAGNOSTICS

At home /Community

Primary care

District hospital

Testing infrastructure

- No mains power
- No water
- No lab equipment
- No temperature control

- No mains power (unreliable)
- Minimal lab equipment (may not support cold chain)
- BSL-1 containment

- Mains power (may be intermittent)
- Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge)
- BSL-2/1 containment

Suitable IVD technologies

Instrument free
True POC

Instrument free
True POC
Near POC

Near POC
Laboratory IVD

PRODUCT REQUIREMENTS VS DESIGN INPUTS

WHAT & WHY	HOW
Product Requirements	**Design Inputs**

Product Requirements Document:
provides an overview of the product's purpose, intended use, and high-level requirements (minimal and optimal) to ensure it meets user needs and regulatory standards.

EXAMPLE

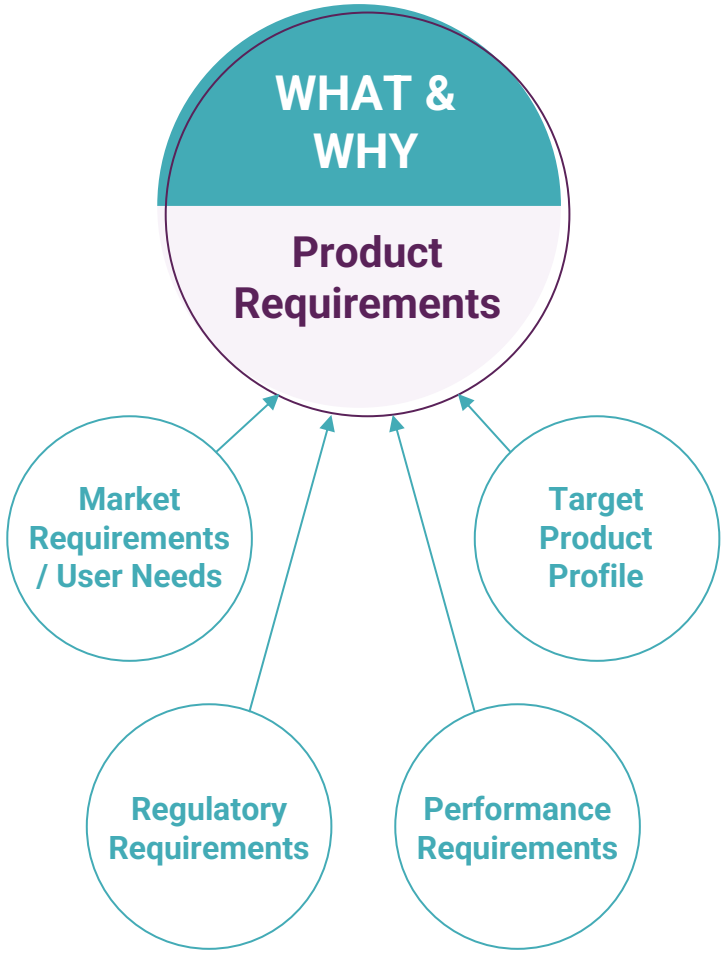
Hemoglobin content should not interfere with the test result.

Design Input Document:
details the precise technical and performance criteria the product must meet, including accuracy, sensitivity, stability, and environmental conditions.

EXAMPLE

Test signal can vary +/- 10% with hemoglobin levels <20 g/dL.

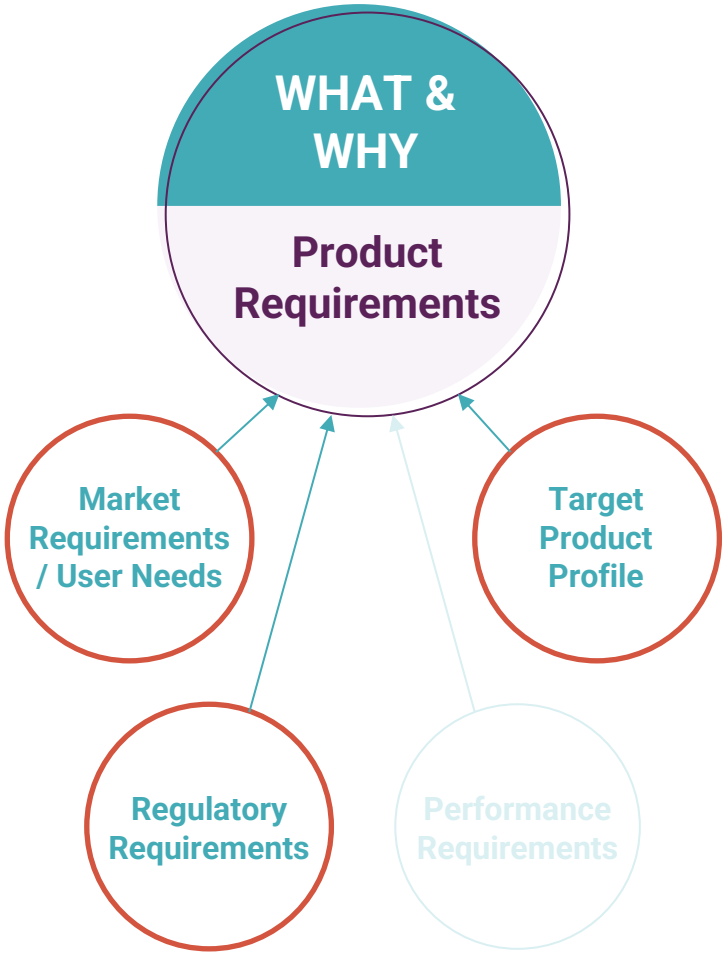
PRODUCT REQUIREMENTS



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…

PRODUCT REQUIREMENTS



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REQUIREMENTS FROM TARGET USE SETTINGS

	Self-Testing	Level 0 (L0) Community	Level 1 (L1) Primary Care	Level 2 (L2) District Hospital Lab	Level 3 (L3) Regional/Provincial Lab	Level 4 (L4) Reference/National Lab
Use setting	• Home testing	• Community outreach • Home testing	• Primary care facility	• Near-patient laboratory • Referral hospital laboratory • Emergency Department testing	• Near-patient laboratory • Referral hospital laboratory • Emergency Department testing	• Reference laboratory
Infrastructure	• No mains power • No water • No lab equipment • No environmental control (e.g., temp, dust, humidity)	• No mains power • No water • No lab equipment • No environmental control (e.g., temp, dust, humidity)	• No mains power (unreliable) • Minimal lab equipment (may not support cold chain) • BSL-1 containment • No environmental control (e.g., temp, dust, humidity)	• Mains power (may be intermittent) • Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge) • -20 freezers (some) • BSL-2/1 containment (some) • Environmental control	• Mains power (may be intermittent) • Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge) • -20 freezers • BSL-2/1 containment • Environmental control	• Mains power (reliable) • High infrastructure facility • -20 freezers • -80 freezers (some) • BSL-2/3 containment • Environmental control (e.g., temp, dust, humidity)
Operator skill	• Self-testing ➢ Simple reagent/sample transfer	• Nurse/pharmacist • Community health workers ➢ Simple reagent/sample transfer	• Nurse • Trained laboratory worker ➢ Minimal sample processing (≤ 3 steps)	• Laboratory technician (1-2 year certif) ➢ Sample processing with calibrated volumes (≤ 3 steps)	• Laboratory technician (1-2 year certif) ➢ Sample processing with calibrated volumes (≤ 3 steps)	• Science research specialists • Laboratory technician (1-2 year certif)
Specimen capacity	• Can process minimally invasive samples: fingerstick blood, nasal swabs, saliva, urine	• Can process minimally invasive samples: fingerstick blood, nasal swabs, saliva, urine	• Can process upper respiratory specimens; clinic may not have capacity for lower respiratory, venipuncture, plasma	• Can process most BSL-2 specimens; depends on clinic sample capacity	• Can process most BSL-2 specimens; depends on clinic sample capacity	• Can process most BSL2/3 specimens
Test capacity	• True-POC MDx (some) • RDT	• True-POC MDx (some) • RDT	• True-POC MDx • Basic microscopy • RDT	• Near-POC MDx • ELISA with simple reader • Microscopy • RDT • Clinical chemistry (some)	• Blood culture and microbiology capacity • Near-POC MDx • ELISA with simple reader • Microscopy • RDT • Clinical chemistry	• Blood culture and microbiology capacity • Lab MDx / PCR / LDT • ELISA/EIA/CLIA/PRNT • Clinical chemistry • Sequencing (some) • Mass spectrometry (some)

EXAMPLES

DESIGN FOR THE ENVIRONMENT WHERE THE TEST ARE USED

Example for an instrumented diagnostic in LMIC settings:

TARGET USE SETTINGS	INSTRUMENT DESIGN	REAGENT and ASSAY
Healthcare level	Size	Kits & Bundle
Electricity outage	Weight	Specimen
No climate control	Throughput	Sample volume
High dust	Operating range	Sample preparation
Limited lab equipment	Biosafety	Time to result
Staff with no or limited training	Maintenance & calibration	Controls
	Data display	Transportation
	Connectivity	Stability
	Data export	Low COGS
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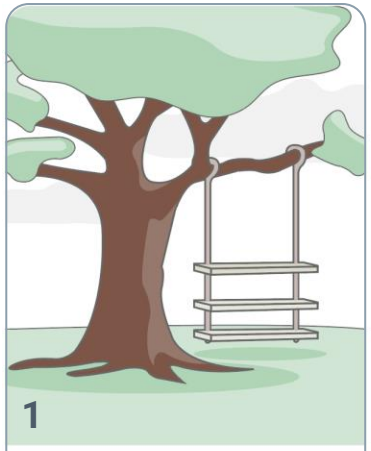
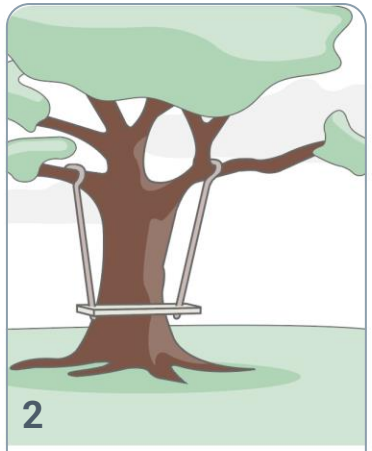
FIND

THE TREE SWING STORY

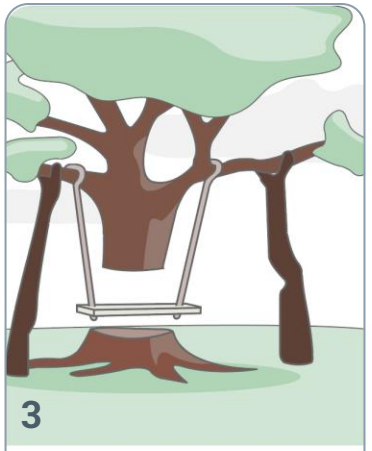
A LESSON IN COMMUNICATION AND COLLABORATION



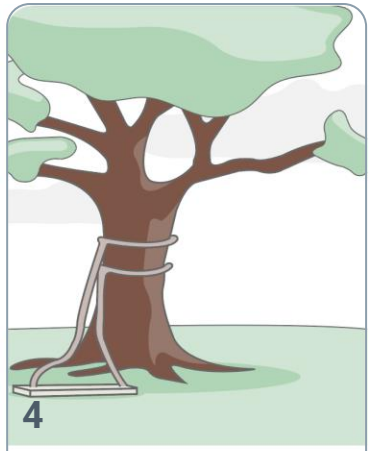
How the customer explained it



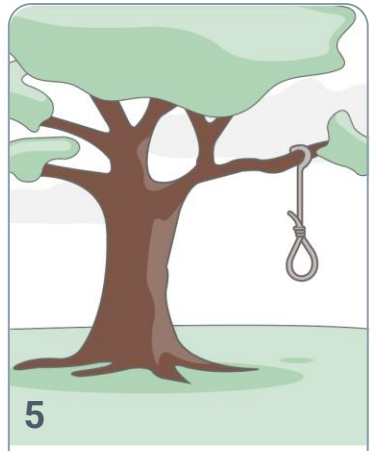
How the project leader understood it



How the analyst designed it

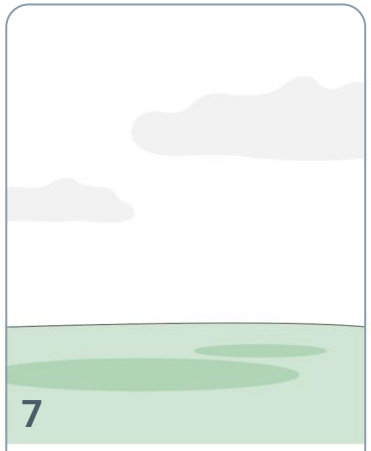


How the programmer wrote it

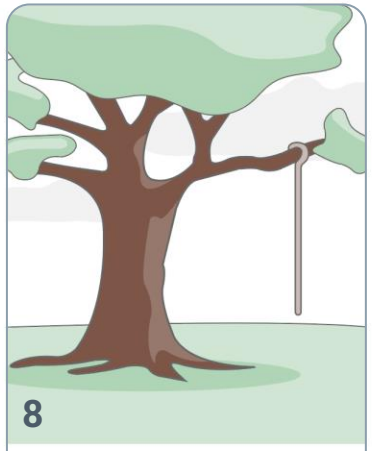


What the beta testers received

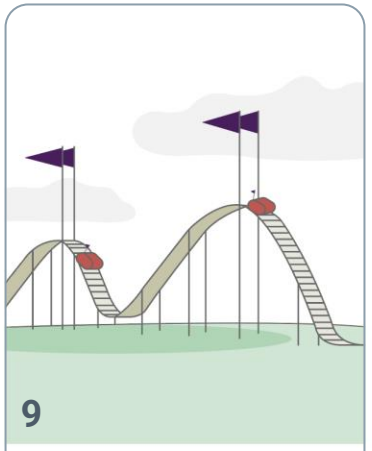
How the business consultant described it



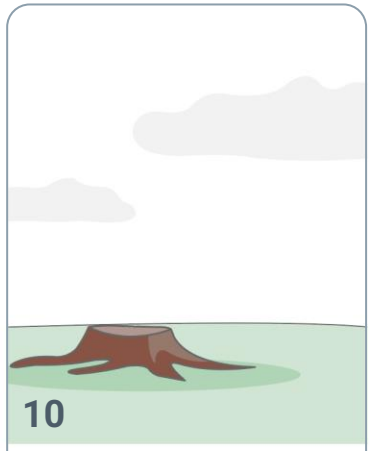
How the project was documented



What operations installed

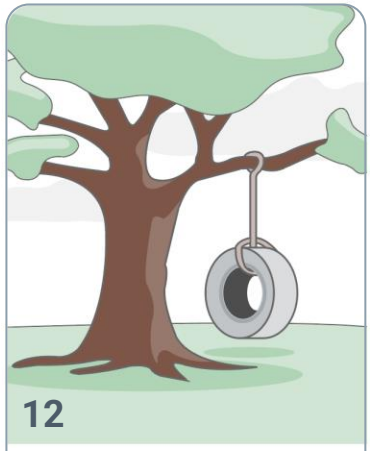


How the customer was billed



How it was supported

What marketing advertised



What the customer really needed

KEY TAKEAWAYS

1

If you're working on a new product, take the time to create a PRD. It will save you time and money in the long run and increase the chances of success for your product.

2

Benefits to having a well-written PRD are:

- Clarifying the product vision and goals.
- Defining the target market and user requirements.
- Facilitate alignment among stakeholders.
- Improve changes of success for the product.
- Reduce the risk of scope creep.

FIND

QUESTIONS & FEEDBACK