

BASED ON THE BOOK

Inside the Clinical Diagnostics Industry

Constraints Shaping Strategy — Towards Health Intelligence

PRESENTATION · DEBATE

Diagnostics is changing. Where is the industry going?

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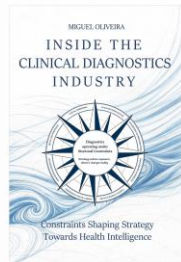
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“Inside the Clinical Diagnostics Industry” historical narrative *

Across decades, the IVD industry made biological measurement increasingly reliable, scalable, insightful and accessible.



Inside the Clinical Diagnostics Industry

Constraints Shaping Strategy —
Towards Health Intelligence
2026

PART I Analytical systematisation

Biological measurement became
reliable and reproducible.

Technical and product mastery

PART II Systems integration and automation

Reliability scaled through
automation, workflow, informatics
and service.

Workflow, systems, service and
organisational expertise

PART III Diagnostics Specialisation

Diagnostics addressed deeper
biological and disease-specific
questions.

Scientific, clinical, regulatory and
domain expertise

PART IV Interdependence

Diagnostic value increasingly
depended on coordination across
multiple actors.

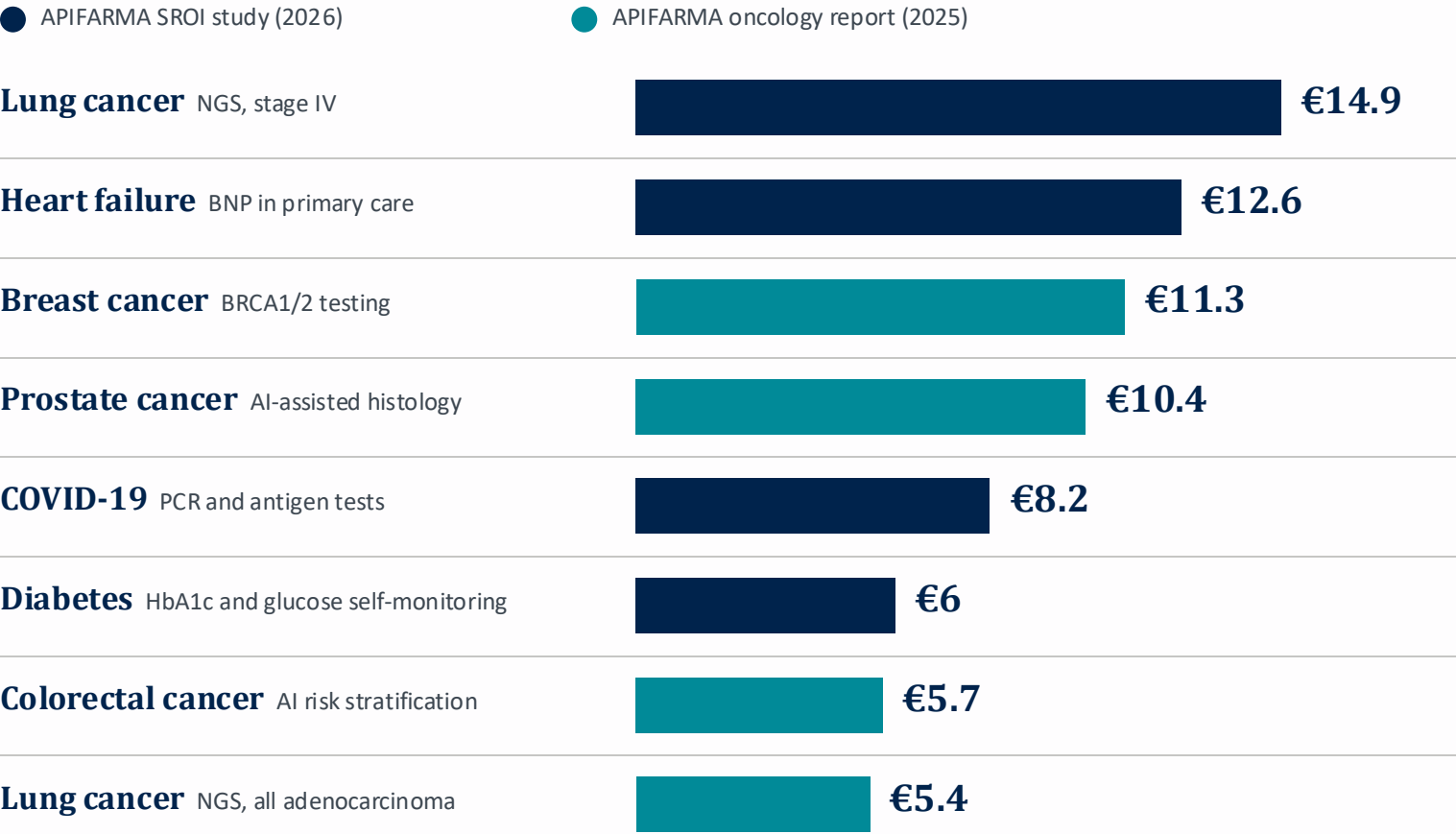
Cross-functional coordination,
partnerships and institutional fluency

EPILOGUE

Health Intelligence — dependable, decision-ready insight over time, built on accumulated capabilities.

Diagnostics creates value far beyond its cost

Eight Portuguese cases from two APIFARMA studies: social return for every €1 invested in IVD testing



THE ACHIEVEMENT

€5–15

returned for every €1 invested in IVD testing

Patients, the health system and the economy all gain — in chronic disease, infection, cardiology and cancer.

Lung cancer NGS appears twice: the two studies measure different scopes.

Sources: (1) Rodrigues et al. (APIFARMA), Front. Public Health 2026;14:1715491; (2) APIFARMA, Quando o tempo é essencial: Valor dos Testes DIV nas Doenças Oncológicas (2025). Social return per €1 invested; scopes and reference years differ by case.

Thirty-six years changed the scale and shape of the IVD market

Scale increased dramatically; the market also became broader, more specialized and structurally more complex

SCALE · GLOBAL IVD MARKET

~US\$18bn

1990



~US\$147bn

2025E · Overall market perimeter (inc. CGM and other)

THE STRUCTURE CHANGED · 1990 → 2025

Genetic / molecular diagnostics <2% → 22%



Point-of-care 3% → 14%



Patient devices* 2% → 15%



grey 1990 · teal 2025

THE MARKET TODAY · GIMI 2025E

3,150

analytical manufacturer groups*

132

product markets across the GIMI taxonomy

Larger, and structurally broader, more specialized and more fragmented than the market of 1990.

Success also created a paradox. Diagnostics became so reliable that people assume it always works, inexpensive enough to be managed as a cost line, and specialist enough to stay largely out of public view.

5 pressures that determine demand

Five pressures act simultaneously — and together they broaden the demand placed on diagnostic capability

DEMOGRAPHIC & DISEASE



Ageing, chronic disease & cancer

More people living longer with complex disease, requiring repeated assessment, stratification and monitoring over time.

SCIENTIFIC & THERAPEUTIC



New therapeutic possibilities

Treatment decisions increasingly depend on biological subgroups, biomarkers, response patterns and resistance mechanisms.

PREVENTIVE & PERSONAL



Preventive medicine

Society and healthcare professionals understand the benefit of identifying risk, disease or deterioration early, while intervention can still change the trajectory.

SOCIETY & AUTONOMY



Citizen autonomy

A sociological shift toward self-service: people increasingly want to, and can, take charge of their own health.

SYSTEM & RESOURCES



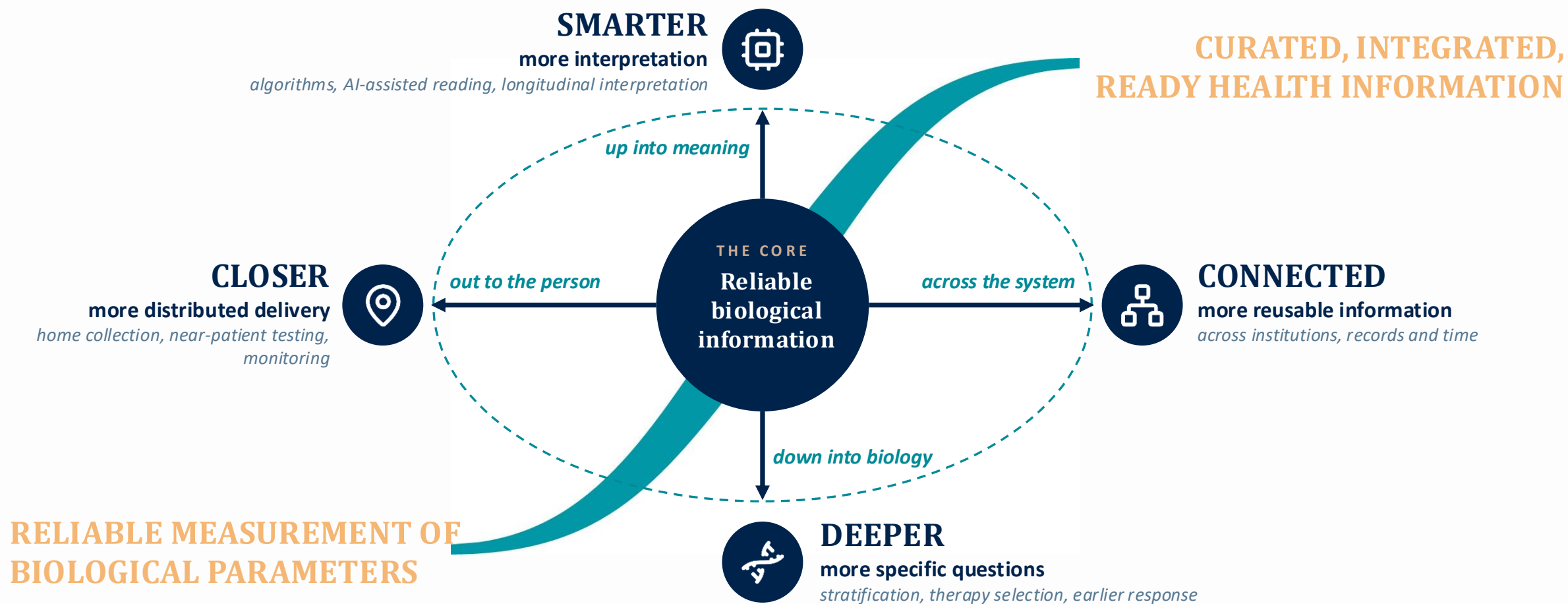
Resources & sustainability

Healthcare must manage more demand with constrained people, time and budgets, while improving allocation and avoiding unnecessary use of scarce resources.

These pressures broaden the role of diagnostics. Demand now spans many decision types, care settings and business models — creating opportunity across multiple specialised fields of the industry.

Four development directions, towards Health Intelligence

Across the full range of demand and opportunity, diagnostics is evolving along four axes



DEEPER – diagnostics follow science by industrialising the meaning of fine biology

Two sources of deeper diagnostics — and a clinical role moving from baseline selection to serial treatment decisions

FROM BIO-PHARMA R&D

Biomarkers developed in parallel with therapies



CURRENT



POTENTIAL EXPANSION INTO ROUTINE USE TOWARDS 2031



FROM BIO ANALYTICAL INNOVATION

New analytical technology crossing into diagnostics



CURRENT



POTENTIAL EXPANSION INTO ROUTINE USE TOWARDS 2031



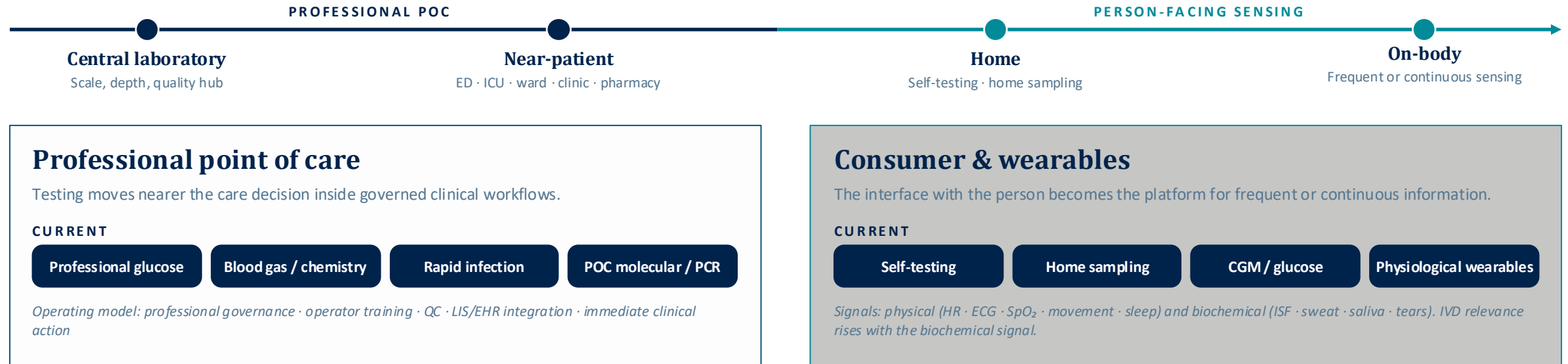
BOTH ROUTES may converge to a standardised IVD when evidence, volume, technology maturity and economics support it — increasingly delivering interpreted, longitudinal diagnostic information.

Diagnostics as a Product

Diagnostics as a Service

CLOSER – the trend to decentralise continues, now with new technologies

Two operating models move diagnostic information closer to the person: governed professional decentralisation and person-facing sensing



Progress continue rapidly

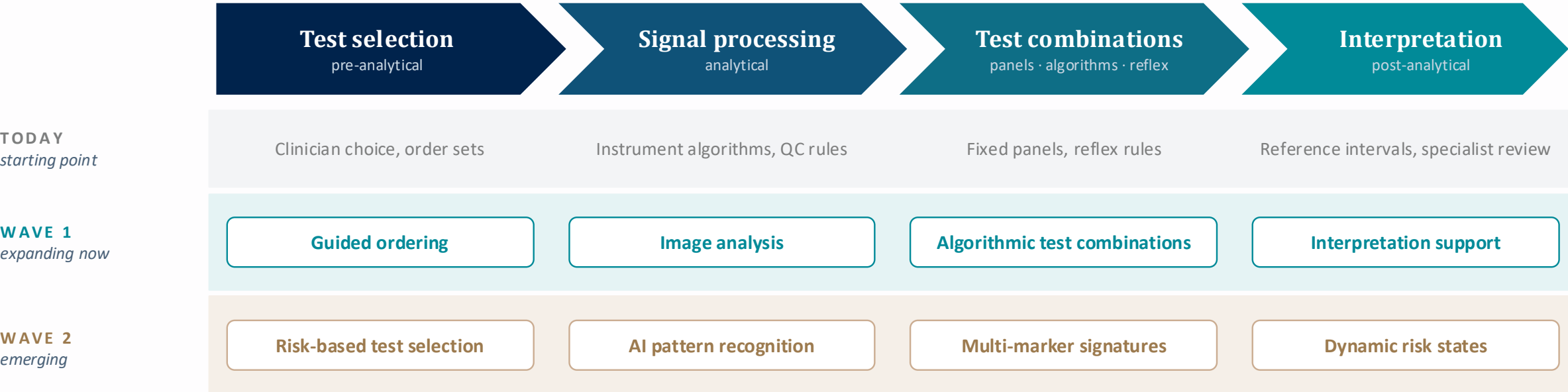
Wearables are revolutionizing health information

THE STRATEGIC QUESTION

Some wearables are already on the market – registered as medical devices – is this a new industry ?

SMARTER: computation strengthens every diagnostic process step

Test selection, signal processing, test combinations and interpretation gain computational power — with clinical expertise at the centre throughout



THE SHIFT

Diagnostic information becomes a validated health intelligence asset

Measurement

 +

Analytical context

 +

Computation

 +

Clinical context

Where these create more value together, the capability moves into the diagnostic product. IFCC anticipates “AI-as-an-assay” certification.

CONNECTED diagnostics make laboratory data reusable — once curated

From curated laboratory data to connected applications — built on EHDS infrastructure, launched indication by indication

1 CURATE

Curated IVD data from the laboratories and other DX feeds

Structured, coded diagnostic information that keeps its meaning when reused.

method

units

timing

biological context

provenance

reference framework

Other contexto data

2 CONNECT

Interoperability and EHDS as data infrastructure

HL7 FHIR exchange in a federated space: information stays with responsible systems, reached through governed routes.



Apifarma organized a dedicated session on this topic few days ago.

3 COMPUTE

Applications running on the data

Computational diagnostics and decision support working on qualified, longitudinal information.

Longitudinal baselines

Clinicians: each patient's own trend over time

Real-world evidence and post-market

Manufacturers: performance and lifecycle data in use

Interpretation at the point of decision

Clinicians: interpreted information inside the EHR

Public-health and AMR surveillance

Public health: outbreaks and resistance seen early

Risk and triage algorithms

Health systems: earlier action on deterioration

Trial feasibility and patient identification

Pharma: the right patients found faster

OTHER EXAMPLES

Reference ranges and normality definition

Acute kidney injury recognised during admission

Project Santa Fe · Northwell

Chronic kidney disease, diabetes and liver-fibrosis risk

Project Santa Fe demonstrations

Pregnancy care gaps found in a Medicaid population

Project Santa Fe · TriCore

Laboratory signals that were not acted on, flagged

Project Santa Fe · Kaiser Permanente

Real-world evidence, AMR surveillance, trial patients

EHDS secondary use, from 2029–2031

REGULATION AROUND THE APPLICATIONS

Software with an intended medical purpose may qualify under MDR or IVDR, depending on its function and intended use.

AI Act obligations where applicable · GDPR and EHDS rules for data use

These innovations can expand the value of diagnostics

However, the diagnostics business runs under structural constraints.

THE 8 STRUCTURAL CONSTRAINS DESCRIBED IN “INSIDE CLINICAL DIAGNOSTICS INDUSTRY”

1 OPERATIONAL ARCHITECTURE

physical, technical, capital lock-in

Infrastructure irreversibility

Installed systems create high switching costs

Capital embedding

Capital locked into long-lifecycle assets

2 COMPANY ARCHITECTURE

portfolio, structure, scale

Regulated portfolio inertia

Portfolios accumulate regulatory burden

Scale reconfiguration

Growth forces structural resets

3 MARKET INTERFACE

channels, partners, execution

Downstream mediation

Intermediaries control workflow and access

Partnership asymmetry

Partners hold unequal power

4 SYSTEM ENVIRONMENT

validation, reimbursement, legitimacy

Market access gatekeeping

Reimbursement decides adoption

Evidence escape

Validation sits with external institutions

TODAY · 1

Developing products

Large companies carry installed bases, embedded capital and heavy portfolios. Startups carry the idea — and run short of time and capital.

TODAY · 2

Delivering the value

Adoption is decided by intermediaries, gatekeepers and evidence held by external institutions.

Product development is hard for incumbents and startups alike

From practice: partnership scouting at Abbott, and many conversations with startups at recent entrepreneurship forums

LARGE COMPANIES

RESOURCES AND SYSTEMS

- Heavy but resourceful
- Consequent but expensive.
- Own commercial resources.

Many projects are not adopted due to lack of funding

STARTUPS

TECHNOLOGY AND AMBITION

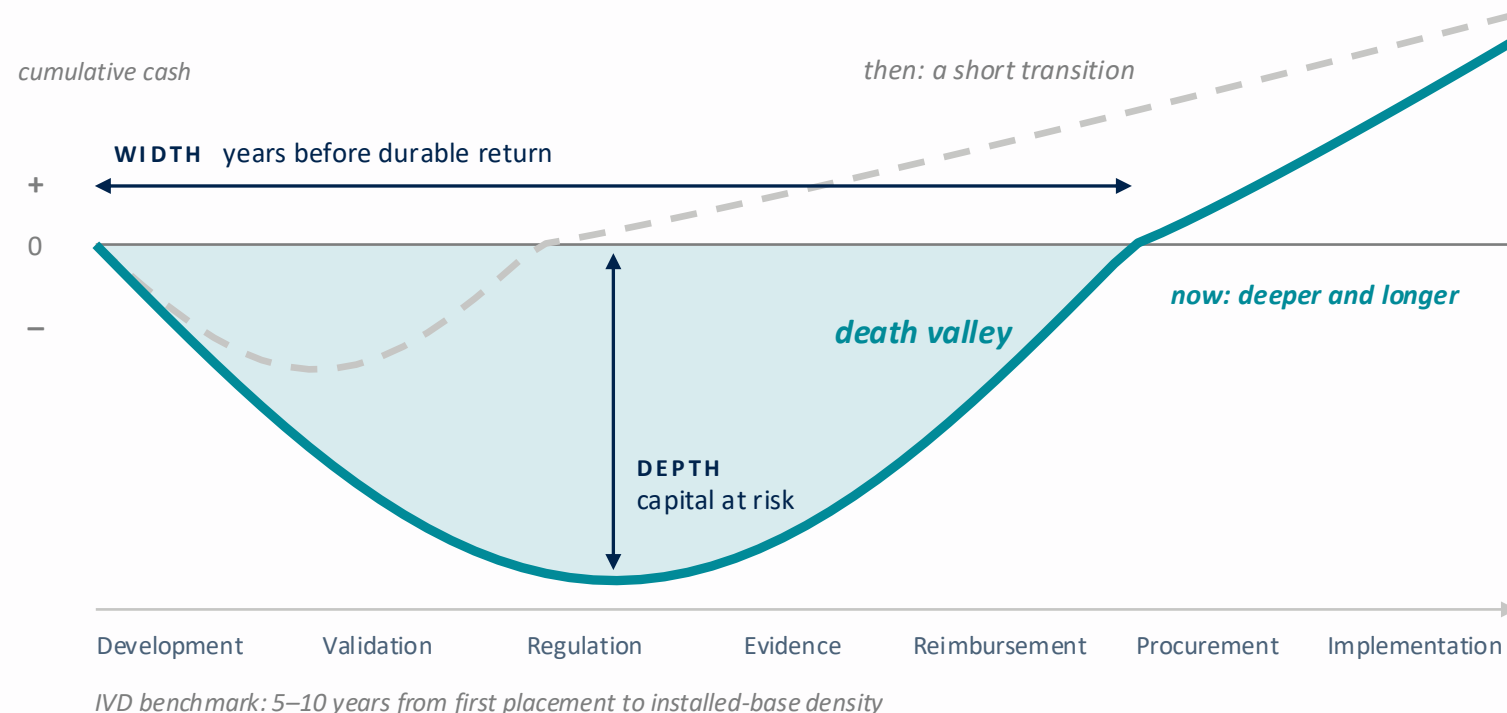
- Technology addressing customer needs
- Difficulties in industrialization.
- Finite structures to support the crossing

Many projects are managed from milestone to milestone

Both meet the same valley: years of time and capital before a durable return.

SPEED is becoming decisive for diagnostic innovation economics

Financial every year adds cash burn and delays payback | **Competitive** competitors gain time; the technology can age before it scales



WHAT MAKES THE VALLEY DEEP AND BROAD

FRAGMENTED markets and adoption gates

EVIDENCE held by external institutions

ACCESS reimbursement decides adoption

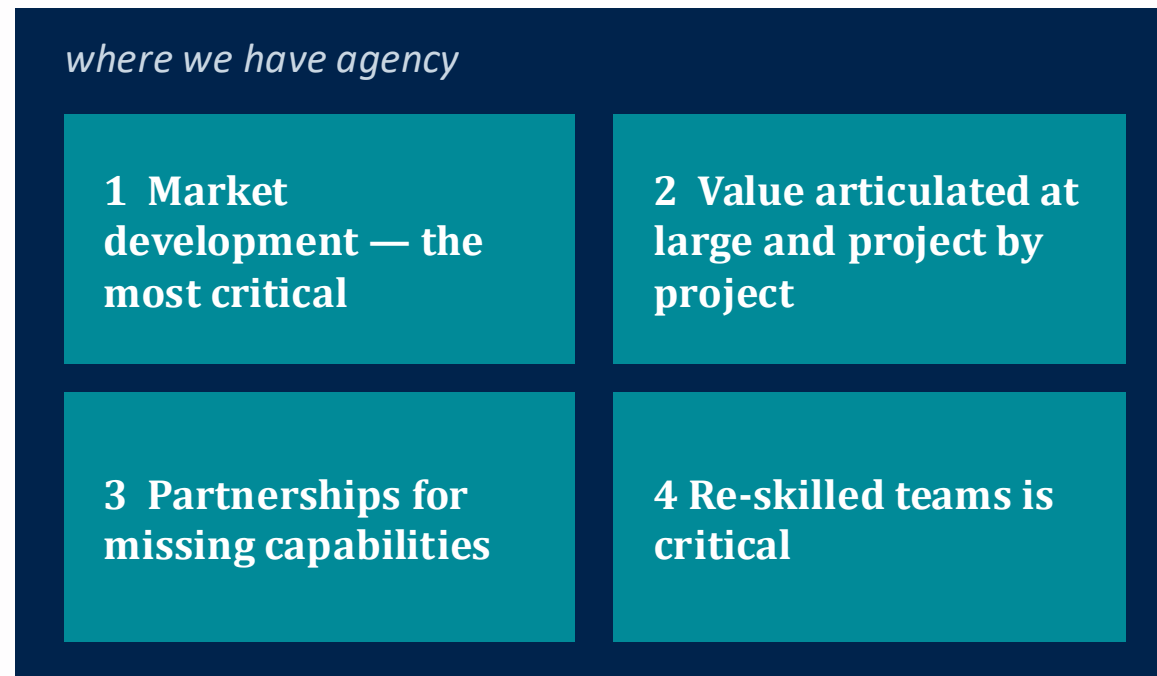
FAST Market development narrows the valley to a feasible width

Many factors, in many fragmented markets — each demanding local resources

SYSTEMIC STAKEHOLDERS



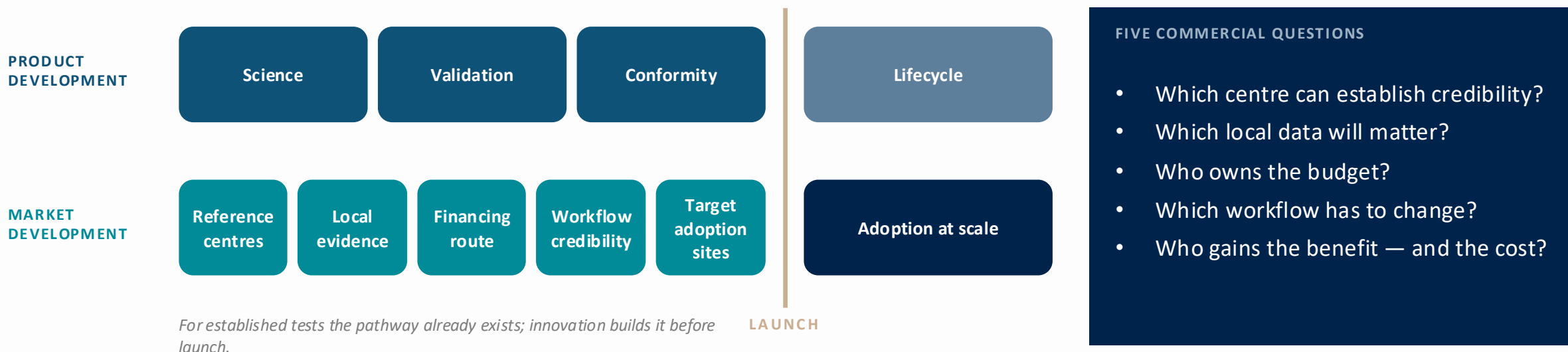
INDUSTRY



The industry shapes a large part of the crossing — and it can start before launch.

Market development shortens the time to break-even

Product and market development run in parallel — affiliates and country teams create the conditions for adoption



AFFILIATES AND COUNTRY TEAMS BECOME MARKET-BUILDERS

They create adoption conditions before launch, alongside the product team.

PHARMA ANALOGY Commercial capability moves upstream and becomes more scientific.

Value has to be articulated at two levels — both are necessary

Collective action improves the conditions for access. Application-specific evidence supports adoption and funding.

COLLECTIVELY

Make diagnostic value count in system decisions

WHAT COLLECTIVE ACTION CAN CHANGE

Shared evidence and public understanding

Diagnostic access and capacity in health plans

Evaluation of benefits across care pathways

Procurement and funding that recognise value

WHO

Associations and companies, with professional, patient and health-system organisations

APPLICATION BY APPLICATION

Demonstrate the value of a defined use

WHAT EACH APPLICATION MUST ESTABLISH

Clinical utility and relevant comparators

Fit with local workflows and implementation

Health economics and budget impact

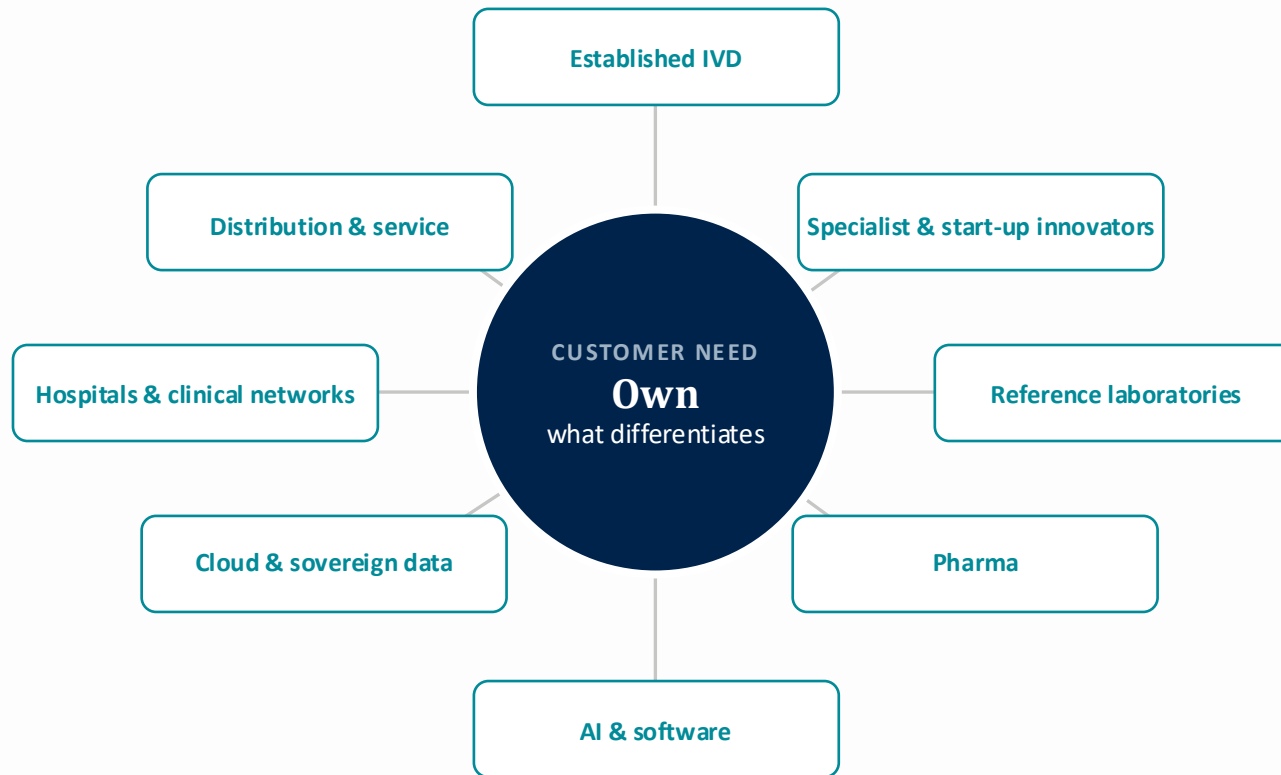
Adoption, funding and monitoring of results

WHO

Companies, laboratories, clinicians, providers, patients and decision-makers

Interdependence is turning partnership into an operating model

Frequently, meeting customers' needs evolve providing a solution – partnerships join forces to deliver what can't be done alone economically.



HOW PARTNERSHIP EVOLVED

Supplier consortium

Tactical partnership

Strategic alliance

Customer-centred ecosystem

**If you want to go fast go alone
If you want to go far go together.**

Crossing the valley faster requires re-skilled teams

When value moves beyond the product, the activities change — and the skills of country teams must change with them

THEN · ROCHE PORTUGAL, 2000–2003

Value moved from the analyser to the laboratory system.

New activities: middleware, information management, workflow and interfaces, people and organisation.

The answer was a new capability: a laboratory consultancy team of five, built from the start, working inside customers' laboratories.

The same principle now applies one level higher.

NOW · ACTIVITIES THAT CROSS THE VALLEY → CAPABILITY THE TEAM NEEDS

Evidence generation and real-world data



Medical and scientific affairs; study design

KOLs and scientific societies



Scientific credibility; clinical networks

HTA and health economics



Economic modelling; value dossiers

Market access and reimbursement



Access strategy; payer dialogue

Procurement and specifications



Tender intelligence; pre-tender market dialogue

Data, connectivity and digital



Data fluency; integration; EHDS readiness

Patient associations and consumers



Patient engagement; public communication

Partnerships



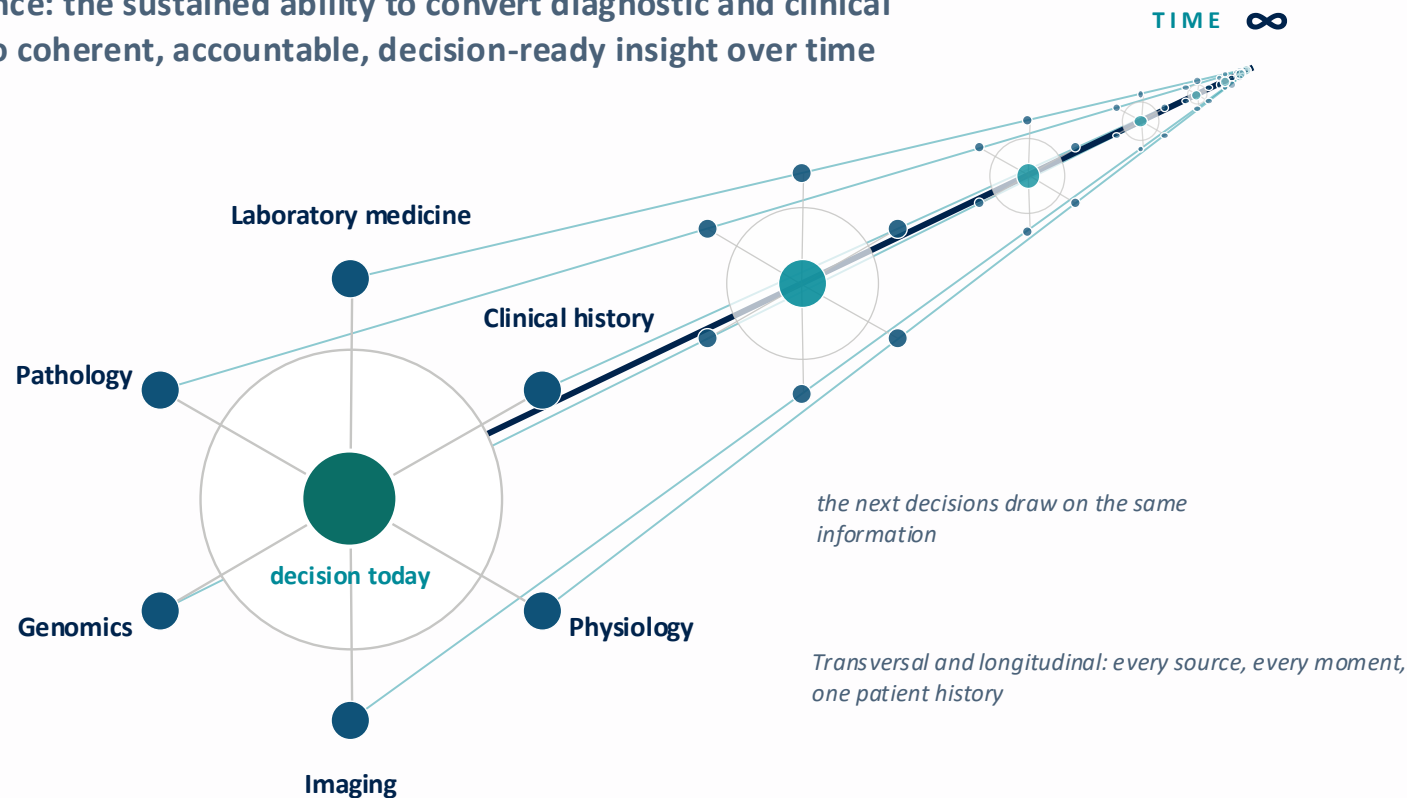
Partner scouting, deal design and management

Requirement: country teams able to run these activities — through re-skilling, hiring or partners.

The IVD industry keeps delivering more insight into healthcare

The innovation ahead may be an opportunity to elevate diagnostics to the level it deserves – Diagnostics must be “at the table” – is it ?

Health Intelligence: the sustained ability to convert diagnostic and clinical information into coherent, accountable, decision-ready insight over time



WHAT THE IVD INDUSTRY BRINGS

Reliable

Reproducible

Traceable

Lifecycle-controlled

Contextualised

Clinically usable

**Biology based
health intelligence**

CONCLUSIONS

- **Diagnostics delivers real value, at scale and affordably.**
- **Innovation is needed, and it is possible.**
- **Strategy means handling the constraints.**
- **Market development is decisive.**
- **New skills are needed to promote value and to partner.**

Selected references and source basis

Selected sources supporting the presentation. Teal reference numbers link to publications or official resources.

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Additional basis: author’s professional experience and synthesis; Project Santa Fe demonstrations (cl2lab.org).

Selection focuses on the presentation’s evidence, conceptual framework and regulatory context; background reading is not exhaustive.