

Building the future of molecular diagnostics

From PCR to NGS: ecosystem, market opportunities,
and strategic prospects

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Executive Overview

Why this White Paper.

Helyx Industries S.p.A. has completed a significant industrial transition: from a company focused on individual technology lines to an integrated group, structured into three divisions with clear boundaries and a common platform logic. This White Paper was created to provide a clear and verifiable overview of this transition, reducing the information asymmetry typical of biotech contexts: what the Group does, how it is organized, where it is positioned in the supply chain (from distributed qPCR to NGS), and why this architecture was designed to reduce operational risk, adoption times, and interface fragility between products, processes, and data. It is neither an informative document nor a scientific paper: it is an institutional asset designed to support high-impact conversations with investors and partners, including in the context of international meetings.

Scope of analysis.

The document is divided into three chapters, each with a distinct and complementary function. The first defines the "One Group – Three Divisions" industrial architecture, the logic of vertical integration, and the operational synergies that bring together hardware, reagents, software, and quality and data governance. The second outlines the opportunity: structural trends in molecular diagnostics, demand drivers, regulatory dynamics, and scalability logic, including a market sizing (TAM/SAM/SOM) presented in a prudent and readable manner, with a dedicated box and an appendix for tables and graphs. The third clarifies the direction: continuous innovation, R&D priorities, and a 2030 vision anchored to operational trajectories (hybrid networks, data governance, standardization, industrialization of innovation). At the end of the document, a cross-cutting Q&A section allows for quick "meeting" reading and anticipates the main due diligence questions.

Who it is intended for.

The White Paper is intended for three categories of readers who, although using different languages, are looking for the same thing: predictability of execution. For institutional investors, it is a tool for assessing architecture, risks, evolutionary consistency, and growth levers. For industrial and technological partners, it clarifies where there are real opportunities for collaboration (platforms, channels, co-development, programs) and which areas are covered by direct responsibility. For institutional stakeholders and decision-makers in clinical and territorial ecosystems, it makes it clear how the Group integrates quality, traceability, and operability into scalable models, avoiding generic promises and focusing on measurable processes and results.

How to read it.

The recommended reading order is linear, but the document is also designed for selective consultation.

Chapter 1

Read to understand the industrial architecture, the operational boundaries of the Divisions (Hyris, Vytro, Mytho), and the logic of vertical integration as risk reduction.

Chapter 2

Read to place Helyx in the market context and understand where scale is created (recurrence, menu, deployment, services), with a focus on sizing and growth model.

Chapter 3

Read to assess the credibility of the technological and organizational direction, and how the Group intends to industrialize innovation in the medium term.

The appendices

These are useful for those who want quicker access or greater detail without weighing down the main body of the text.

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Chapter 1

Ecosystem overview: industrial architecture and integration logic

This chapter describes the industrial architecture of Helyx Industries S.p.A. and the 'One Group – Three Divisions' logic that underpins it. The aim is to explain how the Group has organised its skills, technologies and processes along a complete molecular biology supply chain: from distributed qPCR to next-generation sequencing (NGS). The structure is not intended as a communication exercise; it is an operational choice. Clear boundaries, dedicated roadmaps, metrics consistent with different markets and a shared platform for quality, production and data. In a context where the speed of innovation can amplify execution risks, this architecture has a specific function: to reduce ambiguity and make complexity manageable.

1.1 Identity of Helyx Industries and Group Manifesto

Helyx Industries was born from the evolution of an industrial journey that brought together under a single identity capabilities that had originally grown with different timelines and priorities. The transition from Ulisse Biomed to Helyx is not a nominal operation. It is the formalisation of a structure that is more transparent to the outside world and more disciplined internally: what the Group does, for which contexts of use, with which operational responsibilities. In molecular biology, the gap between technological "promise" and industrial adoption is often the main risk multiplier. The choice was to make the boundaries explicit and, at the same time, make the underlying consistency more evident.

The Group's manifesto is summarised in a formula that links purpose and method: "Life to knowledge. Knowledge to life." It is a concrete direction. It means transforming biological data into usable knowledge and designing tools, reagents, software and services so that the knowledge produced is traceable, replicable and integrable into decision-making flows. From an industrial perspective, the value is not in the data itself; it is in the ability to govern the entire cycle that makes that data reliable: test design, variability control, document management, continuity of supply, quality of results and interpretation.

This approach is consistent with systemic evidence: the availability of reliable in vitro diagnostics is considered a key factor in strengthening access to care and the ability to respond to health crises, as well as improving outcomes and the sustainability of clinical pathways [3]. For an integrated biotech group, the issue is not simply a matter of "increasing volumes" in the abstract. It is about reducing the gap between need and response, without compromising quality and without creating unmanageable complexity for those working in the field or in the laboratory.

Helyx's vision translates into three recurring industrial principles.

Reliability

The first is reliability. In molecular testing, a test is not just an idea: it is a chain of responsibility that goes from design to validation, from production to logistics, from use to result management. Reliability is the product of processes and controls that make performance predictable over time.

Functional integration

The second is functional integration. The applied genetics supply chain consists of components that must communicate with each other: reagents, instruments, software, algorithms, interpretation. Integration means reducing friction between these parts, especially in critical steps (sample → data → result) where costs, time and operational risk are concentrated.

Operational accessibility

The third is operational accessibility. This includes the ability to take molecular biology out of large hubs into distributed contexts with logistical constraints. It also includes the accessibility of results: data that cannot be interpreted or integrated into systems becomes a cost and a risk.

The Group's structure is based on these principles. Helyx Industries is organised into three divisions with distinct identities and markets, but with a common trajectory: Hyris for distributed qPCR, Vytro for clinical PCR in laboratories with IVD solutions, and Mytho for customised NGS and advanced bioinformatics [1]. The logic is clear: do not force different technologies and customers into a single container and do not confuse needs that, in practice, require different metrics and decision-making cycles.

1.2 One Group, Three Divisions: operational architecture and synergies

At Helyx, “vertical integration” does not mean total control of the upstream supply chain. It means control and coordination of the technology stack that makes genetics usable in real-world contexts: reagent chemistry and multiplexing logic, instrument miniaturisation, connectivity, traceability and data transformation into insights. In this supply chain, the division of perimeters serves to maintain focus and accountability. Integration serves to reduce time, friction and interface risks, i.e. those points where different systems do not communicate and variability becomes costly.

The model is therefore twofold. On the one hand, each division has its own roadmap and addresses a market with specific languages and constraints. On the other hand, the divisions share assets and skills that only make sense if governed by a Group-wide approach: quality, methods, intellectual property, software platforms, production capacity, regulatory know-how and data governance. For an investor, this structure clarifies the drivers of development for each area and makes the risks more readable, because it places them within defined operational boundaries.

1.2.1 Hyris — distributed molecular diagnostics and qPCR

Hyris is the division focused on distributed qPCR: bringing reliable genetic analysis to places where a centralised laboratory is not available, is not cost-effective or is not compatible with the required turnaround times. At its operational core is the Hyris System™ ecosystem: miniaturised qPCR instruments (bCUBE™ and bGATE™), the bAPP™ cloud software platform for management, analysis and traceability, and proprietary reagents designed for robustness in non-ideal environments, including ambient-stable reagents such as Sagitta™ [1].

From an industrial point of view, Hyris should be seen as a platform. The unit of value is not the individual component, but the ability to offer a repeatable workflow: test configuration, field execution, results management, remote control and updatability. This approach is relevant in two ways. The first is direct application in sectors where speed and logistics are crucial (agri-food, nutraceuticals, environment, local services). The second is supply to industrial partners with specific needs, according to co-development and OEM models.

The key point is deployment scalability. A system designed for distributed contexts must work with different levels of user expertise, must be remotely manageable, and must minimise logistical dependencies. The integration of hardware, software and reagents meets this constraint with an industrial objective: to reduce adoption friction and make implementation replicable across multiple geographies and use cases, without multiplying the operational effort.

1.2.2 Vytro — comprehensive PCR and IVD solutions for the modern laboratory

Vytro is the division that operates in molecular diagnostics in laboratories, focusing on clinical PCR and standardised workflows for hospitals, laboratories and diagnostic centres. In this area, the dominant requirement changes: it is not portability, but process robustness within a regulated, high-volume context. Traceability, compliance and reliability of results are structural elements.

The Vytro portfolio is designed as a comprehensive PCR offering: panels and kits for clinically relevant areas (molecular microbiology, genetics, oncohaematology, pharmacogenetics), proprietary reagents for deep multiplexing, and optimised DNA/RNA extraction systems [1]. The industrial aspect is not the breadth of the catalogue. It is the ability to manage performance and stability throughout the product life cycle, with a close link between R&D, validation, production and post-market management.

In Europe, the regulatory framework for IVDs has been strengthened by the entry into force of Regulation (EU) 2017/746 (IVDR), which increases requirements for risk classification, performance evaluation, transparency and post-market surveillance [4]. For a group such as Helyx, this context is a constraint, but also a selective factor. The ability to operate credibly in regulated markets depends on the maturity of processes, documentation and quality discipline. Vytro is the part of the group most directly exposed to this discipline, with an industrial approach that favours standardisation and controllability.

Customer Reference

Johns Hopkins University
and Gates Foundation Active malaria surveillance

The second phase of an international malaria project places Helyx in a “stress test” operational context for distributed diagnostics: remote areas, complex logistics, and the need for timely and traceable data. The project is being carried out in collaboration with Johns Hopkins University and funded by the Gates Foundation. It involves the field implementation of technology for active transmission surveillance, with real-time data collection to optimise control campaigns and anticipate epidemics.

From an industrial point of view, the interest is not only epidemiological. It is about execution: putting in place a replicable workflow that can be managed across multiple sites and sustained over a period of several years. In practice, this means validating the integration of the tool, data management and operational control in the field, in conditions where environmental variability and infrastructural limitations highlight any weaknesses in the process.

Snapshot

- Three-year timeframe;
- Implementation in 30 health districts in Cameroon, with plans to extend to another 170 districts;
- Context of need: estimated 263 million cases and 597,000 deaths worldwide in 2023.

Customer Reference

Vytro: SYNLAB Italy
Test menu for personalised medicine

In the clinical laboratory market, industrial credibility is based on three factors: depth of the test menu, operational standardisation, and continuity of supply and documentation. In this context, the renewal of the distribution agreement with Biomol Laboratories for IVD devices in areas of personalised medicine (genetics, pharmacogenetics, oncohaematology) is a concrete example of how the Group manages the extension of its application portfolio without disrupting workflow consistency. The relevant point, from an investor's perspective, is the “translatability” of the offer to large-scale operators: the agreement is presented as a lever to maintain a distinctive depth of the catalogue, integrating the Hyris System™ platform with highly innovative tests and supporting a wide-ranging dialogue with customers and users. In the press release, SYNLAB Italia is cited as an example of a customer and user of these tests on Hyris System™: a reference that signals interoperability and acceptance in contexts where process governance and quality are non-negotiable.

Snapshot

- agreement signed in January 2023 and renewed in January 2024;
- areas of application: Genetics, Oncohaematology, Pharmacogenetics;

Customer Reference

Mytho: Revvity Italia
NGS for neonatal genomic screening
(Puglia Genome Project)

The supply agreement with Revvity Italia links the Group's entry into NGS to a public use case with defined technical requirements: neonatal genomic screening in the Puglia region ('Progetto Genoma Puglia'), awarded to Revvity through a public tender. The scope of the agreement is clear: Helyx will develop, produce and supply customised NGS screening kits based on Revvity's requirements to analyse the DNA of newborns and detect more than 400 relevant and treatable metabolic disorders and rare diseases at an early stage. For an investor, this is an example of delivery-oriented "NGS industrialisation": not only technical capability, but also production and supply capability in a context where quality standards, compliance and operational continuity are an integral part of value. The published economic data also introduces an element of short-term readability.

Snapshot

- clinical setting: neonatal genomic screening;
- panel targeting >400 relevant and treatable conditions;
- context: regional programme with public tender awarded to Revvity Italia.

1.2.3 Mytho — Customised NGS and bioinformatics for advanced insights

Mytho is the Group's NGS centre. It operates exclusively in next-generation sequencing and in transforming genomic data into interpretable insights. Its model is not a catalogue product: it is custom-designed, compatible with the main instrumental platforms and bioinformatic infrastructure oriented towards quality, transparency and replicability [1].

This scope stems from a reality: generating data is not the same as generating information. In NGS, complexity shifts to panel design and analytical strategy, quality control throughout the workflow, and interpretation of results in a way that makes them usable. The industrial output is not a file, but information that must enter a clinical pathway, a study, or a decision-making process without multiplying time and ambiguity.

Mytho therefore targets specialist contexts (oncology, rare diseases, precision medicine, screening) where a "one-size-fits-all" approach tends to generate inefficiencies. The consultative approach reduces two risks typical of NGS adoption: the proliferation of ungoverned pipelines and the production of data that does not reach an adequate level of interpretability.

For the Group, Mytho completes the supply chain towards advanced genomics without confusing PCR boundaries with different delivery and validation logics.

HYRIS

Distributed qPCR: platforms and services to bring genetics out of the laboratory, with replicable workflows and centralised data management.

VYTRO

Clinical IVD PCR: kits, panels and reagents for laboratories and hospitals, with a focus on standardisation, compliance and reliability.

MYTHO

Tailor-made NGS: panel design and bioinformatics to transform complex genomic data into actionable insights.

1.2.4 Group synergies and integrated advantage

The choice of distinct perimeters reduces ambiguity and improves market readability, but only creates value if synergies are real and managed. At Helyx, the most significant synergies are concentrated on four levels.

Shared technology base

The first is the shared technological base. Hyris and Vytro operate on different PCR workflows, but share structural elements: reagent design, multiplexing expertise, quality control logic. This allows for the transfer of learning between contexts without duplicating investments and without multiplying parallel lines of development.

Quality and compliance system

The second is the quality and compliance system. An integrated group reduces friction when development, production and deployment are not silos. Quality is not a final step; it is an architecture that defines from the outset what is traceable, what is auditable, what can be scaled. This reduces execution risk because it makes the transition from prototype to product and from product to portfolio more predictable.

Data management

The third is data management as an industrial asset. Molecular biology generates value only if the results become manageable information. Hyris, with its cloud component, enables centralised management even in distributed contexts. Mytho brings advanced analysis and interpretation skills. The combination reduces the distance between data generation and data use, reducing decision times, operational errors and integration complexity.

Risk allocation

The fourth is risk allocation across different portfolios. Divisions are not just product lines; they are also exposures to markets with different cycles and constraints. Distributed qPCR has adoption and partnership dynamics typical of platforms. Clinical IVD PCR exists in a regulated and procurement context. Tailor-made NGS follows project logic and specialist collaboration. Keeping these boundaries distinct reduces the risk of confusing commercial strategies and allows the Group to manage growth with different tools, without losing consistency.

1.3 Origins and milestones: from lab to global market

The current structure is the result of a trajectory in which expertise in reagents and multiplexing, PCR workflows, miniaturisation and data management has been progressively transferred from the laboratory to industrial processes and, finally, organised within the Group.

Some milestones help to understand this trajectory: launch of Hyris as an initiative focused on miniaturised qPCR and connectivity; the reverse takeover in 2023 that enabled the creation of the integrated Group; completion of operational integration in 2024; announcement of entry into the NGS market and rebranding as Helyx Industries in 2025, with the formalisation of the three divisions [5].

The first step is the development of proprietary skills and their validation in the field. This is where methods, protocols and quality control are established, along with a culture of replicability.

The second aspect is industrialisation: production stability, documentation, technical support and the ability to support adoption in regulated or logistically complex environments.

The third aspect is the organisation of complexity: the integration between Hyris and Ulisse Biomed and the definition of the Hyris-Vytro-Mytho perimeters make the offer more readable and the execution more manageable, without diluting responsibilities and KPIs [1], [2].

Across the board, consistency in this evolution is as important as technology. A clear structure reduces information asymmetry, makes roadmaps measurable and separates risks: distributed platform, IVD catalogue, NGS projects. It provides a more solid basis for allocating capital and evaluating performance over time.

Management Perspective

The 'one Group, three divisions' structure responds to an industrial need: managing complexity without losing control. In molecular biology, markets and technologies evolve rapidly, but at different speeds and with different constraints. Separating the perimeters allows each division to operate with metrics and timelines consistent with its own context, without sacrificing the efficiency of a common infrastructure.

This architecture has three practical implications. First, it increases transparency by making objectives and risks clear for each operational area. Second, it reduces friction because quality, production and data management are designed as shared platforms, not as replicated functions. Third, it preserves strategic optionality. The Group can grow on different models — platform, IVD catalogue, NGS projects — while maintaining a single trajectory: transforming genetics and data into operational value.

— Leadership Team, Helyx Industries S.p.A.

Sources

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Chapter 2

Opportunities, growth and investment

Growth in molecular diagnostics is not automatic. It depends on the ability to transform a clinical need into a repeatable operational process: sample, test, report, decision. Today, this ability is worth more than individual analytical performance. In many cases, the constraint is not “whether” a test works, but “where” it can be performed, with what continuity, and with what regulatory evidence. It is an industrial interpretation: the market rewards those who reduce friction and variability along the supply chain.

The macroeconomic picture reinforces this selection. In OECD countries, healthcare expenditure rose from 8.8% of GDP in 2019 to 9.7% in 2021 and, according to estimates for 2022, to 9.2% during the post-pandemic normalisation phase. In the same context, ageing, chronic conditions and staff shortages continue to squeeze delivery capacity.[1] For diagnostics, this means structural demand, but also pressure to standardise, integrate and measure. For an investor, the issue is not only the size of the need, but also the ability to convert it into recurring revenues under constraints of quality, cost and continuity.

Within this scenario, the industrial architecture of Helyx Industries S.p.A. (a group with three operating divisions, each with different roles along the value chain) is consistent with demand trajectories: decentralisation of molecular testing, regulatory consolidation, and growth in clinical genomics. The three trajectories do not add up: they feed off each other. This is why it is useful to read trends, sizing and business models as a single design.

2.1 Industry trends and new diagnostic requirements

Decentralisation

Diagnostics is shifting from the laboratory to the community. The market is internalising an operational lesson: when logistics become dominant, centralisation leads to delays and loss of coverage. This applies to infectious disease emergencies, screening in underserved areas, and recurring monitoring. The industrial driver is simple: reduce time-to-result and increase access density without losing controllability.

The clearest institutional impetus comes from public health and emergency preparedness. The WHO strategy on genomic surveillance for pathogens with pandemic and epidemic potential sets out a metric for success: by 2032, all 194 Member States must have, or have access to, timely genomic sequencing for these pathogens. [3] This is not an “NGS-only” goal. It requires an end-to-end supply chain: sampling, molecular testing, traceability, data quality, sharing and the ability to scale up in a crisis. In practice, it creates demand for platforms and operational flows that lie between the sample and the data, and not just for the sequencing “machine”.

Point-of-care NAAT

The frontier is the pre-analytical phase. Taking nucleic acid amplification tests (NAATs) out of the laboratory is not a problem of principle; it is a problem of execution. Recent literature highlights that the bottleneck is often sample preparation: extraction, stabilisation, lysis, inhibitor management. In a 2024 peer-reviewed review of iNAAT (isothermal nucleic acid amplification tests) in point-of-care settings, the authors point to the limitations of sample preparation as a significant technical barrier to deployment and propose an “extraction-free” approach to reduce time, infrastructure and dependence on highly specialised personnel. [8] This is an industrial point: if sample preparation becomes simpler and more robust, the market shifts value towards platforms, consumables and scalable processes.

Oncology

More cases, more complexity, more clinically usable testing. Oncology is not only a clinical driver; it is an economic driver. According to the WHO, new cancer cases are estimated at around 20 million in 2022 and are expected to exceed 35 million in 2050 (+77%). [5] The population eligible for diagnosis and treatment is growing, and the pressure to stratify is increasing. For molecular diagnostics, this translates into an expansion of the scope: from confirmatory testing to characterisation and therapeutic selection, with direct impacts on costs and outcomes.

The guidelines are accelerating this expansion. In its 2024 update, ESMO recommends the use of tumour NGS in various cancers and also recommends NGS to identify “tumour-agnostic” alterations where access to combination therapies exists. [7] For an industrial model, this is a clear signal: genomics becomes a permanent part of the clinical workflow when it produces a decision, not when it remains “descriptive” data.

Prevention and women's health

Long-term volumes and programmes. A second driver, often underestimated, is prevention based on molecular testing. The cervix is a case in point. The WHO reports approximately 660,000 new cases and 350,000 deaths in 2022 and refers to the global 90–70–90 targets, including 70% screening coverage for women between the ages of 35 and 45.[4]

Regulation

This drives demand towards high-performance testing and traceable laboratory processes. Here, growth is not a spike: it is a programme. Efficient screening programmes generate recurring volumes, quality standards and data integration needs, i.e. conditions typical of industrialisable demand.

The cost curve enables access, but does not eliminate complexity. Another underlying force is the decline in sequencing costs. NHGRI data, based on cost accounting of “production sequencing” activities, show a decline from ~\$95 million per genome in 2001 to ~\$525 in the May 2022 dataset. [6] It is an enabler, but it must be read correctly: these metrics do not include the complete chain of downstream analysis and interpretation. [6] Industrial value, therefore, is shifting: it is not just about generating data, but managing samples, pipelines, quality, interpretation and reporting with sustainable times and costs.

The market is becoming more selective and rewards industrial discipline. In Europe, the evolution of the IVD regulatory framework is increasing the barrier to entry and the demand for evidence. The European Commission, in its amendment through Regulation (EU) 2024/1860, explicitly states the objective of mitigating the risk of IVD device shortages without lowering quality and safety requirements, granting additional time to complete IVDR compliance. [2] This is an industry signal: continuity of supply and quality system maturity are becoming competitive factors. It is not a “regulatory” issue in the abstract sense. It is a market selection issue because it influences access times, compliance costs and reliability throughout the product life cycle.

2.2 Market size and growth potential (TAM/SAM/SOM)

For institutional investors, sizing makes sense if it is based on robust drivers. In diagnostics, commercial estimates vary greatly in scope and criteria; here, the reading is based on institutional and clinical proxies: disease burden, programme targets, adoption trajectories codified by strategies and guidelines. [3][4][5][7] It is a more “defensible” approach, useful in the industrial positioning phase.

TAM

Total demand can be addressed as the sum of three domains. Overall demand is distributed across three adjacent domains that converge on the industrial level:

1. *Decentralised molecular diagnostics and surveillance.*

The driver is territorial coverage and emergency preparedness. The WHO goal of universal access to timely sequencing for high-risk pathogens by 2032 implies ongoing, rather than episodic, investment and operational capacity. [3] In this domain, the scale is not just the “number of tests”, but the number of active sites, speed of activation, and continuity of the sample-to-data flow.

2. *Regulated clinical molecular diagnostics.*

The driver is laboratory standardization in a context of capacity under stress. With high healthcare costs and pressure on staff and throughput, the value of robust operational flows that reduce variability and timeframes without compromising quality is growing. [1] Here, sizing is linked to recurring volumes and a mix of panels in high-demand areas (infectious diseases, genetics, oncohematology).

3. *Clinical genomics and NGS.*

The driver is precision medicine in oncology and, in part, in prevention. The expected increase in the global cancer burden by 2050, combined with clinical recommendations that expand the use of NGS and the need for interpretation and reporting, points to a trajectory of increasing adoption where the result is clinically usable. [5][7] The decline in the cost component of sequencing is an accelerator, although it does not coincide with the overall cost of a pathway. [6]

A useful proxy for reading ‘scale and duration’ is HPV screening. The WHO figures (660,000 cases and 350,000 deaths in 2022) and the 90–70–90 targets describe a need that generates programmes repeated over time, not just campaigns. [4]

From an industrial perspective, this translates into demand for reliable testing and processes that manage quality, traceability, and follow-up. Even with equal pricing, it is programme continuity that generates scale.

SAM

Servable market as a function of regulation, channels and service capacity. The servable market does not coincide with the total market. It depends on practical constraints: regulatory requirements, access to tenders and distribution channels, ability to provide support and continuity of supply. In Europe, the evolution of IVDR tends to make the "serviceable" perimeter more defined for those who operate with industrial discipline and adequate documentation; and more complex access for fragmented or unsustainable solutions over time.[2]

For an investor, this is relevant: regulation does not reduce demand, it "filters" it and shifts value towards those who can sustain compliance and quality.

SOM

Quota achievable as a function of execution and recurrence. The quota realistically achievable in the short to medium term depends on four drivers:

1. installed base and utilisation rate;
2. breadth and depth of the menu;
3. reliability of supply continuity and support;
4. regulatory credibility.

In diagnostics, many customers change platforms for test lines and steps, rather than migrating entirely. This makes SOM less dependent on "single competitions" and more dependent on the ability to build recurring consumption.

Market sizing

TAM / SAM / SOM

Scope and reading notes.

The values below are third-party market estimates useful for providing an order of magnitude of the industrial potential of the Group's three operating divisions (molecular diagnostics, decentralised molecular diagnostics, clinical NGS). The definitions of 'market' are not perfectly uniform across sources (inclusion/exclusion of instruments, reagents, software, services). For this reason, they should be read as comparable references, not as 'accounting' figures. The actual scope of the Group depends on product mix, geographies, channels and time-to-market.

External references (TAM)

Global and, where available, European values.

Molecular Diagnostics (global)

\$20,3 billion (2024) → \$42,6 billion (2030), CAGR 13,1% [A].

Industrial relevance: core for the Division focused on PCR-based IVD testing and laboratory workflows.

Point-of-Care Molecular Diagnostics (global)

\$4.30 billion (2025) → \$709 billion (2030), CAGR 10,5% [B].

Industrial relevance: primary reference for the 'distributed qPCR' Division, with a focus on decentralisation, speed and usability in near-patient/near-field contexts.

Clinical Next-Generation Sequencing / NGS (global)

\$13.95 billion (2024) → \$29.53 billion (2030), CAGR 14,6% (2025-2030) [C].
NGS Europe: \$4.11 billion (2024) → \$8.88 billion (2030), CAGR 15,0% (2025-2030) [C].

Industrial relevance: reference for the 'customised NGS' Division in clinical applications (oncology, rare diseases, reproductive health, infectious diseases).

Note on how to read SAM and SOM

Here, the above values are external 'TAM'. The SAM (serviceable addressable market) and SOM (realistically obtainable market share) depend on deliberately managed perimeter choices: geographies (e.g. Europe, MENA, selection of markets with regulatory and infrastructural capacity), priority applications, commercial mode (direct vs. partner), and production/operational capacity. A practical example, with conservative assumptions, is provided in the Appendix.

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[C] MarketsandMarkets — "Clinical Next-Generation Sequencing (NGS) Market" (report search page; dati globali e Europa, pubblicazione indicata in pagina).
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In summary, the economic unity of the three domains is different, but comparable:

- In decentralised diagnostics, the scale derives from active sites and consumables/year.
- In regulated clinical diagnostics, it derives from volumes and mixes of panels under quality requirements.
- In NGS, it derives from profiled cases and interpretative capacity, in a context of adoption guided by guidelines. [2][7][8]

2.3 Value proposition and business model for growth

In a diagnostic industrial group, the value proposition to the market largely coincides with that to investors: transforming scientific capabilities into replicable, certifiable and distributable output. Growth is not linear. It becomes predictable when there is an operating asset that generates recurring revenues: tools and operating flows that drive consumables, application menus and services.

The three-division structure allows value to be captured at three different points in the same supply chain.

HYRIS

In the logic of distributed testing, Hyris oversees a platform model through Hyris System™ (with bCUBE™ as a miniaturised qPCR tool and bAPP™ as a management software layer), in which the installed base and usage are decisive for recurrence.

VYTRO

In the field of regulated clinical diagnostics, Vytro operates on PCR/IVD catalogues and workflow components, where demand favours standardisation, robustness and continuity.

MYTHO

In the NGS domain, Mytho works on customised projects and panels, where industrial value is focused on design, validation, interpretation and the ability to transform specific requirements into solutions that can be repeated over time, including as a basis for subsequent productisation.

This architecture enables a specific industrial mechanism: industrialising knowledge. Much innovation begins as a project (a panel, a protocol, a local need). Scale comes when that project becomes a "catalogue": kit, process, documentation, quality control, replicability.

The European regulatory trajectory makes this transition even more relevant, because evidence and QMS discipline is part of the competition, not an additional cost. [2]

Risk reduction, here, is functional. In this context, it does not mean "more markets" in a generic sense; it means three different ways of capturing value in the same macro-supply chain (instrument/consumption; kit/operational flow; service/panel), with imperfect correlations.

In practical terms: demand for emergency preparedness and surveillance supports the expansion of networks and sites.[3] Regulated clinical demand is consolidated when laboratories seek continuity and standardisation under stringent requirements.[2] NGS grows where the result becomes part of the decision-making process, as indicated by the guidelines. [7] This diversification reduces dependence on a single product cycle and makes uncertainty about adoption timelines across different segments more manageable.

The critical point remains execution. The market demands continuity and quality precisely because it fears discontinuity. It is no coincidence that recent regulatory interventions also refer to the risk of IVD shortages and the need to maintain safety and quality requirements. [2]

This leads to an industrial interpretation of growth: real scalability lies in repeated consumption and the reduction of operational flow friction (especially in the pre-analytical phase when it comes to decentralised NAAT). [8]

For NGS, economic sustainability is also linked to the separation between the cost of data generation and the complexity of interpretation: the decline in “production sequencing” costs is gradually shifting value towards pipelines and interpretation, i.e. towards processes that can be organised and scaled.[6]

Investor Lens

Implicit question: where is scale created today in molecular diagnostics – and how can execution risk be reduced?

The scale arises when diagnostics becomes infrastructure. Three signals are already “institutionalised”: emergency preparedness and genomic surveillance with measurable global targets; increase in cancer burden towards 2050; extension of clinical indications for NGS in advanced practice. [3][5][7] Growth is captured through industrial processes: continuity of supply, quality and documentation become competitive criteria, as shown by European interventions that aim to avoid shortages without reducing requirements. [2] Execution risk is reduced when the model does not depend on a single product cycle, but on recurrence and functional diversification along the supply chain: sites and consumables for distributed testing; kits and operational flows for regulated laboratories; panels and services for genomics, with complexity managed in a scalable manner.[6][8]

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Chapter 3

Vision and Future Prospects

Hyris

Strategic roadmap

- Simplification and automation of the pre-analytical phase
- More tolerant and stable chemicals
- Evolution of the digital platform for workflow simplification and distributed network management

Vytro

Strategic roadmap

- IVDR compliance
- Addition of new products related to both central laboratories and distributed laboratories

Mytho

Strategic roadmap

- Development of proprietary software for bioinformatics and sequencing data analysis
- Standardization of development and production processes to improve margins
- Identification of meaningful non-custom panels

In molecular diagnostics, competitive positioning does not derive from a single product. It depends on the ability to innovate continuously and industrialise innovation: making results reproducible, manageable and scalable as clinical needs, regulatory requirements and digital infrastructures change. In this chapter, the perspective is pragmatic: which R&D choices make the project credible in the medium term, and which 2030 scenario justifies an investment in integrated capabilities today?

3.1 Continuous innovation: technology roadmap and R&D

A credible R&D roadmap is not a wish list. It is a sequence of choices aligned with the real bottlenecks in the sector and the ability to transform them into industrial outputs. In diagnostics, the barrier is rarely analytical sensitivity alone. More often than not, it is pre-analytical factors, sample quality, reproducibility between sites, data management and integration into operational processes. In other words, competitive advantage is built on workflow, not on individual tests.

The group's roadmap reads like a path of consolidation and expansion along three lines consistent with the Divisions: Hyris (distributed qPCR), Vytro (clinical PCR in the laboratory with IVD solutions and deep multiplexing), Mytho (customised NGS and consultative bioinformatics). The integrated architecture reduces the duplication typical of single-line players: cross-cutting investments in automation, data integrity, validation and IT security can generate value across multiple lines, with tighter end-to-end quality control.

Within the Hyris framework, the Hyris System™ platform (bCUBE™ and bAPP™) requires a “complex systems” approach: even incremental improvements in robustness, user experience, reagent stability and connectivity management have a multiplier effect on adoption in non-laboratory settings. Molecular diagnostics in the field is conditioned by a variable that cannot be controlled with a good primer set: the sample. The literature on the sample-to-answer paradigm highlights that sample preparation and nucleic acid extraction remain among the main technical barriers to bringing nucleic acid amplification tests (NAATs) truly to the point-of-care, and influence the design of the entire system [6]. In terms of roadmaps, this directs priorities towards: simplification of pre-analytics, more tolerant and stable chemistries, and a digital layer that ensures traceability and quality control in distributed networks.

Within the Vytro framework, R&D has a different industrial objective: to transform PCR into a scalable IVD product, with a menu that grows over time without increasing complexity in an unsustainable way. Deep multiplexing is a response to two converging pressures: the demand for faster clinical decisions and the need to make better use of instrumental capacity and laboratory resources. Menu growth requires development discipline: performance evaluation, design controls, industrialisation and lifecycle management. Here, the institutional context is an accelerator: the WHO Model List of Essential In Vitro Diagnostics (EDL) is designed to support countries in defining national lists of essential diagnostics and strengthening diagnostic capacity at different levels of the healthcare system [2]. The practical consequence is that “useful” innovation must also be affordable, implementable and sustainable in routine practice.

Within the Mytho framework, the roadmap is part of a trajectory towards the normalisation of NGS in precision medicine. The ESMO recommendations on sequencing in advanced tumours represent an operational reference point: they set expectations on where NGS should be part of the diagnostic-therapeutic pathway [4]. This shifts the competition from access to sequencing to the quality of interpretation and data management. The cost trend is consistent with this transition: the NHGRI historical series shows a dramatic decline in cost accounting per genome in NHGRI-funded centres, down to a few hundred dollars in 2022 [5]. In a context where data production is becoming less and less exclusive, R&D must focus on robust bioinformatics pipelines, automation, data quality control and advisory capabilities to transform complex results into actionable decisions.

The cross-cutting dimension common to all three divisions is data. In an increasingly connected diagnostic environment, data is both an asset and a risk: it only generates value if it is reliable, interoperable and governed. It is also a prerequisite for applying AI responsibly. The 2025 WHO publication on the ethics and governance of large multi-modal models indicates that the adoption of AI in healthcare is entering a phase of formalisation: no longer generic enthusiasm, but requirements for security, transparency and accountability [3]. For an integrated group, this means incorporating “non-negotiable” elements into the roadmap: audit trails, validation, performance drift control, cybersecurity and human oversight. These are not accessories. They are part of the product.

A second cross-cutting theme is surveillance. The boundary between clinical diagnostics and public health diagnostics has become blurred, and the WHO strategy on genomic surveillance for pathogens with pandemic and epidemic potential sets an explicit goal: by 2032, all 194 Member States should have, or have access to, timely sequencing capabilities [1]. This goal requires end-to-end infrastructure: sampling, testing, sequencing, data sharing, and analysis. The industry interpretation is that networks are built by integrating detection nodes (rapid, distributed) and in-depth nodes (high resolution), with sufficient standardization to make the data comparable.

A credible roadmap must therefore have two properties: modularity (adaptability to contexts) and standards (comparability and governance).

Finally, there is a portfolio discipline that addresses risk directly. Innovation means choosing where to invest capital and time, and what not to do. An effective industrial roadmap balances incremental continuity (reducing adoption friction, increasing productivity and quality) and development options (opening up new applications where there is a structural advantage). The metric that guides this logic is simple: increase information density per sample and the replicability of results, without exploding complexity and support costs. This is where the integrated structure helps: innovation is distributed across platforms, not fragmented into isolated projects.

3.2 Vision 2030: the evolution of diagnostics according to Helyx

A vision for 2030 must be an operational hypothesis. It does not describe “how the world will be,” but rather what capabilities will have structural value if certain trajectories—already documented—continue to consolidate. Two signals are particularly clear: the infrastructure of genomic surveillance as a permanent public health function [1] and the construction of digital health foundations as a multi-year program, extended until 2027 in the WHO strategy [7]. This leads to a guiding idea: by 2030, technology itself will matter less than the architecture with which it is made operational.

Diagnostic networks

The first element of the scenario is the growth of hybrid diagnostic networks. Healthcare systems do not converge on a single model; they combine. Peripheral nodes perform rapid molecular tests for triage, screening, and immediate decisions; central hubs perform high-resolution analysis, including genomics, for confirmation and characterization. The WHO strategy on genomic surveillance emphasizes that genomics has an impact when it is part of end-to-end capabilities, including data sharing and analysis [1]. In a hybrid system, the “information chain” is the product: from the signal in the field to high-resolution reading and the return of information to operational decisions.

Information density

The second element is the increase in information density in the laboratory. Multiplex panels and high-information-content workflows are becoming the natural response to diagnostic complexity, especially in the field of infectious diseases and screening. At the same time, genomics is becoming the norm in precision medicine, with oncology as the most immediate reference point. ESMO recommendations make it clear that, in many advanced cancers, NGS is no longer an “extra” but an expected component of the pathway [4]. Convergence, here, does not necessarily mean “one machine for everything.” It means orchestrating the right test at the right time: speed where needed, depth where needed.

Data chain

The third element is the maturation of the data chain. The reduction in sequencing costs makes data generation more accessible [5], but amplifies the burden of interpretation and governance. For this reason, by 2030, competitiveness will be increasingly linked to digital infrastructure and accountability models. The WHO’s 2020–2027 digital health strategy emphasizes robust foundations and the integration of financial, organizational, human, and technological resources [7]. The 2025 WHO guidance on large multi-modal models clarifies that AI in healthcare will require rules on security, transparency, and accountability [3]. A group that wants to remain relevant must therefore design, starting now, solutions in which the software component is verifiable, manageable, and integrable into real systems.

Standard

The fourth element is the definition of diagnostics as an essential and standardizable asset. The WHO EDL—updated and maintained as a reference for national lists—is a policy signal: diagnostic capacity becomes the subject of planning and procurement, not just episodic clinical choice [2].

In 2030, this will tend to favor solutions that combine performance with operational sustainability: reliable tools, manageable reagents, replicable technical support, and governance that can withstand multi-site implementations.

Within this framework, Helyx's vision cannot be summed up as simply "doing more tests." It can be summed up as helping to transform molecular diagnostics from a product to an infrastructure, with an industrial structure that separates and specialises: accessibility and replicability of testing in the territory (Hyris), industrialisation of clinical diagnostics in multiplex menus and IVD (Vytro), NGS and bioinformatics capabilities to transform data into usable results (Mytho).

For investors, risk reduction lies in a combination of factors: monitoring the rapid decision-making cycle while building the capacity for in-depth analysis and interpretation that is central to precision medicine and surveillance.

In a context that is moving towards hybrid and digitized networks, this combination is a form of structural resilience.

R&D Lens

Direction and principles

The group's R&D is structured as platform engineering. The aim is to increase the density of information per sample and the reproducibility of results across different contexts, reducing operational friction.

There are five key principles:

- | | | |
|---------------------------|--|--|
| 1. workflow-first | | <i>pre-analytical and variability as priorities</i> |
| 2. modularity | | <i>adaptability to hybrid networks</i> |
| 3. quality by design | | <i>integrated validation and traceability</i> |
| 4. data governance | | <i>auditability, security, responsible use of AI</i> |
| 5. industrial scalability | | <i>replication, supply chain, and support</i> |

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Appendix A

Q&A

Q1. What is the operational scope of each Division and what remains outside its scope?

Hyris oversees qPCR distributed as an operating platform (instrumentation, software, and workflow) geared toward decentralized contexts and multi-site networks. Vytro is the clinical division: PCR solutions for laboratories and hospitals with IVD logic and a quality and documentation system consistent with regulated markets. Mytho operates exclusively in NGS: tailor-made panels, workflow, and bioinformatics with a consultative approach. Outside the scope, by choice: Mytho does not perform PCR or offer "ready-made" IVD catalogs; Hyris and Vytro do not shift their focus to NGS. This separation avoids ambiguity and dilution of responsibilities.

Q2. What does vertical integration mean in practice in your model?

Here, "integration" means control of the technology stack that makes diagnostics usable: test and chemistry design, workflow robustness, quality and traceability, industrialization, data management, and operational support. It is not a generic statement about the upstream supply chain. The deliberately modular part is what increases flexibility and reduces lock-in: compatibility with different environments and tools where it makes sense (typically in NGS), commercial and distribution partnerships, and delivery configurations that depend on the context. The industrial goal is to reduce friction between components and make execution manageable.

Q3. What "hard" synergies exist between divisions and how do you manage them?

There are four key synergies: quality and documentation (a common system of methods, controls, and change management), development skills (chemistry, multiplexing, and validation as shared assets), operations (industrialization, batch release, supply, and technical support), and data management (traceability, quality control, digital workflows). Governance is central: what is "core to the Group" has cross-functional owners and KPIs; what is "division-specific" has separate roadmaps, budgets, and objectives. It is a balance: synergies where costs and risk are reduced, autonomy where speed and focus are increased.

Q4. Which demand drivers do you consider structural and which cyclical? How do you reduce dependence on a single cycle?

Structural: decentralization of molecular testing, growth of diagnostics as infrastructure (screening and routine procedures), expansion of precision medicine, and consolidation of quality requirements in regulated markets. Cyclical: peaks linked to emergencies, seasonality in certain test categories, waves of extraordinary procurement. Mitigation does not come from "doing everything," but from overseeing three different ways of capturing value in the same supply chain: distributed platforms and networks, regulated clinical portfolios, and highly specialized NGS projects. At the same time, recurrence is built on consumables, menus, and repeated services, not on one-off events.

Q5. What is the revenue model for each Division and where is the recurring component concentrated?

The economic logic is consistent with the three areas. Hyris typically works on a combination of installed base and usage: tools and workflows enable recurring consumption (reagents/consumables) and management/operational services. Vytro works on continuity of supply and repetition of routine tests: kits, panels, and reagents in laboratory and procurement logic. Mytho works on projects and services: panel design, workflow, bioinformatics, and interpretive support; recurrence derives from pipelines, reorders, and progressive standardization of deliverables. The key is to avoid "hardware-only" revenues and favor consumption and continuity.

Q6. Which leading KPIs would you use to measure execution over the next 12-24 months?

A few indicators related to workflow. For Hyris: active installed base, utilization rate (consumption per tool), uptime, operational quality, and multi-site management capabilities. For Vytro: menu mix and depth, production stability (batches), delivery punctuality, quality and complaint indicators, validation progression, and lifecycle. For Mytho: turnaround times, success rate/QC, project backlog and pipeline, repurchase rate, and pipeline standardization. At the Group level: quality metrics, industrialization capacity, and support cost per customer/site.

Q7. Go to market: which channels are a priority and how do you choose your markets?

The criterion is not “geographical coverage” per se. It is consistency between channel and type of offering. Distributed diagnostics often requires scalable models across networks (partnerships, qualified indirect channels, institutional or industrial projects) and replicable deployment capabilities. Clinical diagnostics requires channels with regulatory expertise, access to laboratories/hospitals, and robust document management. Customized NGS requires a consultative relationship and service capabilities. Market selection favors: regulatory clarity, sustainability of after-sales support, logistical stability, and the possibility of building recurrence (not just first sale).

Q8. Regulatory and quality: what is your approach to IVD compliance and what timeline risks do you see?

The approach is “quality-by-design”: requirements, evidence, and traceability are set during development and not added at the end. In regulated markets, commercial sustainability depends on the discipline with which performance evaluation, documentation, and post-market management are handled. The main risk is not the standard itself; it is the ability to maintain continuity and control of change as the portfolio grows. This is why we separate scopes and responsibilities: Vytro oversees the IVD domain with consistent processes and languages, while Hyris and Mytho operate in contexts with different constraints, without forcing overlaps.

Q9. Industrialization and supply: how do you manage scalability and resilience in the supply chain?

With a “process-first” approach: supplier qualification, incoming inspections, batch release with stable criteria, traceability, and deviation management. Real scalability comes from standardization and reducing unnecessary variations. At the same time, product and consumable design must limit logistical dependencies where possible (e.g., by reducing complexity in storage and distribution). For a multi-divisional group, resilience is also organizational: operations and quality must have service capabilities consistent with commercial expansion, otherwise growth creates instability and cost.

Q10. Defensibility: What are the competitive barriers, and where are you most difficult to replicate?

In diagnostics, defensibility is rarely a single “magic” patent. It is a combination of: integrated and replicable workflow, expertise in chemistry and multiplexing, industrialization and quality, and a digital layer that enables traceability and multi-site management. The difficulty of replication increases when these components are designed to work together and when the organization is structured to maintain them over time (change control, production, support). In NGS, defensibility focuses on the ability to transform complex requests into repeatable deliverables: pipelines, QC, interpretation, and reliable timelines. It is disciplined execution, not rhetoric.

Q11. Data, cloud, and cybersecurity: how do you guarantee data integrity, and what do you mean by “governance” when AI comes into play?

Data integrity means: traceability of operations, access control, audit trails, data quality, and lifecycle management (versioning, change management, logging). Cybersecurity is not an add-on: it must be designed alongside processes and infrastructure. As for AI, governance is an operational constraint: avoiding opacity, managing validation, monitoring performance stability over time, defining responsibilities and limits of use. For an investor, the point is simple: AI only creates value if it can be managed as an industrial component, with controls and responsibilities comparable to those of a quality system.

Q12. R&D roadmap: what industrial priorities do you see in the next 24–36 months and what deliverables are aimed at scalability?

Priorities are focused on real bottlenecks: workflow robustness, reduction of pre-analytical friction, multi-site quality and reproducibility, menu expansion where there is repeated demand, and “responsible” automation of analysis and data. A deliverable is “scalable” when it is not a one-off project: it has specifications, quality criteria, a validation process, documentation, and a sustainable support model. In PCR, this means industrialized panels and consumables. In NGS, it means standardized pipelines and interpretation based on case classes, maintaining flexibility where needed. In all cases, the roadmap must reduce variability and operating costs per test, not increase them.

Appendix B

Market sizing: definitions,
scope, and conservative
conversion scenario
TAM → SAM → SOM

A. Operational definitions used in the White Paper

TAM (Total Addressable Market)

Estimate of the total value of the reference “market,” as defined by the external source. This value is useful for understanding scale and trajectory, but does not automatically correspond to the Group’s economic opportunity.

SAM (Serviceable Available Market)

Share of TAM that becomes truly “serviceable” given a concrete scope:

1. priority geographies and regulatory contexts;
2. application segments within scope (e.g., respiratory, STI, HPV; oncology, rare diseases);
3. serviceable channels (e.g., clinical laboratories, hospitals, regional networks, public programs);
4. industrial requirements (supply, quality, post-market, support).

SOM (Serviceable Obtainable Market)

Share of SAM that can reasonably be captured within a defined timeframe, based on conservative assumptions regarding:

- commercial conversion rates and time-to-revenue;
- production capacity and scalability (tools/consumables/services);
- access times to reimbursement and procurement;
- competition and switching costs.

In practice, SAM and SOM are “management” metrics: they do not exist as unique public data. They make sense if constructed using transparent and conservative criteria.

B. Summary table: three segments, three operational guidelines

	Molecular diagnostics <i>(PCR/NAAT, IVD and laboratory setting)</i>	Decentralized molecular diagnostics <i>(POC molecular)</i>	Clinical NGS <i>(including the “NGS market” perimeter in the clinical field)</i>
2024	\$20.3 billion		\$13.95 billion
2025		\$4.30 billion	\$14.94 billion
2030	\$42.6 billion	\$7.09 billion	\$29.53 billion
CAGR	13.1% (2024-2030) [1]	10.5% (2025-2030) [2]	14.6% (2025-2030) [3]
			Europe <i>(useful proxy for SAM in regulated markets)</i> 2024 \$4.11 billion → 2030 \$8.88 billion [3]

Technical note: there are areas of conceptual overlap in these segments (for example: part of molecular POC is, by definition, also “molecular diagnostics”). For this reason, the figures should be read by industry sector (division) and not added together mechanically as if they were additive.

C. Conservative conversion scenario TAM → SAM → SOM (replicable example)

C.1 — Case study: Clinical NGS in Europe (proxy SAM) and prudent SOM

1. External TAM (global NGS): \$13.95 billion (2024) → \$29.53 billion (2030) [3].
2. SAM proxy (Europe NGS): \$4.11 billion (2024) → \$8.88 billion (2030) [3].

This value is useful because it represents a market with: established clinical standards, infrastructure and “structural” demand linked to oncology/rare diseases, and procurement/reimbursement mechanisms that are relatively more transparent than in other contexts.

3. Conservative SOM (illustrative, not predictive):

To provide investors and stakeholders with an “understandable” scale, a conservative penetration rate can be applied to SAM Europe (horizon and assumptions to be declared). For illustrative purposes only:

SOM = 0.10% of SAM Europe (2030):	~\$8.9 million/year
SOM = 0.20% of SAM Europe (2030):	~\$17.8 million/year
SOM = 0.30% of SAM Europe (2030):	~\$26.6 million/year

This is not a communicated target or guidance. It is a transparent way of showing that, in double-digit growth markets, even very small market shares generate economies of scale consistent with industrial models based on platforms, quality, and repeatability.

C.2 — How to replicate the scheme on PCR IVD and POC molecular

For the other two segments (molecular diagnostics and POC molecular), the method is identical:

- Define SAM as a combination of: priority geographies + applications “in scope” + serviceable channels + regulatory/operational requirements;
- Define SOM as a conservative share of SAM, consistent with: commercial pipeline, production capacity, and average adoption times.

Where available (in the complete report datasets), the “estimated” SAM can be replaced with the “measured” SAM (e.g., Europe, MENA, etc.), avoiding the use of arbitrary percentages.

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Appendix C

Glossary

The following definitions are operational: they serve to standardise the reading of the White Paper and to clarify recurring terms used with a specific industrial meaning.

Audit trail

Verifiable record of operations performed on a system or data (who did what, when, and with what result). In diagnostics and digital healthcare, it is a key element for quality, compliance, and accountability.

Installed base

Set of tools/systems already installed at customers' premises and operational sites. It is a key metric in 'platform' models because it enables recurrence on consumables, menus and services.

Bioinformatics

A set of methods and software tools that transform raw data (e.g. sequencing data) into interpretable results. In the NGS context, it is the part that makes the data "usable", not just "produced".

CAGR (Compound Annual Growth Rate)

Compound annual growth rate. Expresses the average annual growth over a period, assuming a 'compound' (non-linear) trend. It is useful for comparing market trajectories over different time horizons.

Cloud (in diagnostics)

Software and data infrastructure accessible via the network, used for remote management, analysis, traceability and updating. In a distributed model, it enables multi-site control and operational standardisation, but requires governance and cybersecurity.

Compliance

Ability to operate in compliance with applicable requirements (regulatory, quality, contractual, safety). In WP, compliance is not treated as 'fulfilment' but as an industrial component that enables scalability and continuity.

Consumables

Materials used in each test or operating cycle (reagents, kits, cartridges, etc.). In diagnostic models, economic recurrence often depends on repeated consumption, not just on the sale of the instrument.

Cybersecurity

Protection of systems, data and infrastructure from unauthorised access, tampering and interruptions. In connected diagnostics, it is part of the product: it affects reliability, continuity and risk.

Data governance

Set of rules and responsibilities regarding data quality, access, use and storage. Includes versioning, logging, controls, roles and processes. It is a prerequisite for using data as an industrial asset without turning it into a risk.

Data integrity

A property whereby data remains complete, consistent, unaltered, and traceable throughout its lifecycle. In a regulated environment, it is a requirement for trust and verifiability.

Deep multiplexing

Ability to simultaneously detect a large number of targets in a single test, maintaining performance and controllability. Industrially, it serves to increase information density and laboratory productivity.

Deployment (grounding scalability)

The ability to install and operate a system across multiple sites and contexts while maintaining performance, quality, and support. In distributed testing, this is a more concrete metric than 'technological scalability' alone.

Drift (performance drift)

Variation over time in the performance of a model or system compared to what was initially validated (due to changes in data, context or operating conditions). This must be monitored because it impacts safety and reliability.

EDL (WHO Model List of Essential In Vitro Diagnostics)

WHO list of essential diagnostics, designed as a reference to strengthen diagnostic capacity and support procurement decisions in health systems.

End-to-end (end-to-end supply chain)

Complete process from sample collection to usable results, including process, quality, traceability and data management. In the WP, the key is to interpret 'vertical integration' as workflow integration, not just supply chain integration.

Extraction-free (non-extraction approach)

A strategy that reduces or eliminates complex sample extraction/preparation steps prior to amplification. This is important because pre-analytics is often the bottleneck at the point of care.

Human oversight

Human supervision of decisions or outputs from automated systems (particularly when AI is involved). This is part of accountability: it defines who controls, when to intervene, and with what responsibilities.

IVD (In Vitro Diagnostic)

In vitro diagnostic device: reagents, kits, instruments or software used for analysis on biological samples outside the body. In the WP, it is treated as a "regulated" area, where evidence and quality standards are part of the market.

IVDR (EU Regulation 2017/746)

European Regulation on in vitro diagnostic devices. It is mentioned in the WP for its industrial impact: it increases market requirements and selectivity, making QMS maturity, documentation and post-market more important.

KPI (Key Performance Indicator)

Key performance indicator. In WP, KPIs are understood as execution metrics (utilisation, quality, stability, turnaround time, pipeline), not as slogans.

Lifecycle management

Product lifecycle management: development, validation, production, updates, post-market surveillance, change management. This is what makes an offering sustainable in regulated, large-scale markets.

Menu (test menu)

Set of tests/panels available on a platform or offer. Industrially, 'menu depth' is a driver of adoption and recurrence in laboratories.

Multiplexing

Performing multiple measurements in a single reaction/test. This reduces the time and cost of obtaining information, but requires robust chemicals and controls.

NAAT (Nucleic Acid Amplification Test)

Tests based on nucleic acid amplification (DNA/RNA). In molecular diagnostics, this is a broad category that includes PCR and various isothermal approaches.

NGS (Next-Generation Sequencing)

Next-generation sequencing techniques that produce large amounts of genomic data. In the WP, NGS is interpreted as a supply chain:
real value = panel design + quality + pipeline + interpretation.

OEM (Original Equipment Manufacturer)

A model in which a company develops/manufactures components or solutions sold under its own brand or through a partner's channels. In diagnostics, this is often a lever for commercial scalability and market access.

Pipeline

In WP, it has two meanings: bioinformatics pipeline:

- software flow that transforms raw data into results;
- commercial pipeline: set of opportunities in development with customers/partners.

In both cases, the word indicates a governed flow, not a "potential" list.

POC (Point-of-Care)

Testing can be performed close to the patient or close to the point of decision, reducing time and dependence on centralized laboratories. The industrial focus is on workflow reproducibility, not just speed.

Post-market (post-market surveillance)

Activities after market launch: performance monitoring, reports, complaints, corrective actions. In IVD markets, this is part of product sustainability and regulatory credibility.

Pre-analytical

Phase prior to the actual analysis: collection, transport, stabilization, and preparation of the sample. This is often the point at which variability and therefore operational risk arise.

Procurement

Purchasing process (typically institutional or large networks) that includes tendering, evaluation, contracts, and supplier management. For IVD, it is a driver of sales cycles and barriers to entry.

Quality by design

An approach in which quality, traceability and verification requirements are incorporated at the design stage, rather than added retrospectively. It reduces execution risk and accelerates industrialisation in regulated environments.

QMS (Quality Management System)

Quality management system: processes, procedures, controls, responsibilities and documentation that make development and production repeatable and auditable. It is central to scaling up in regulated markets.

Reimbursement

Reimbursement mechanisms and financial recognition of tests (healthcare systems, insurance companies, etc.). Influence of adoption, test mix, and revenue predictability in clinical segments.

Sample-to-answer

An end-to-end workflow that brings a sample to a final result with minimal manual steps and variability, integrating preparation, amplification/sequencing, quality controls and reporting.

Switching cost

Cost (financial and operational) for a customer to change platform/supplier: training, validation, IT integration, procedures, contracts. In diagnostics, this can slow down migrations and encourage step-by-step adoption.

TAM / SAM / SOM

Sizing metrics: total market, addressable market, achievable share. These are defined in detail in Appendix B of the White Paper.

Technology stack

Integrated set of components (reagents, instruments, software, connectivity, data) necessary to make a workflow truly operational. In the WP, 'vertical integration' is understood primarily as control of the technology stack.

Time-to-result / Turnaround time

The time between the start of the process (or arrival of the sample) and the availability of the result. It is an industrial metric because it impacts decisions, throughput, and operational value.

Workflow

Operational sequence that makes a test repeatable: procedures, tools, software, controls, and output. In WP, competitive advantage 'accumulates on the workflow,' because that is where replicability and scalability come into play.

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