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IVD Industry Monograph - No. 4

Beyond the Data Feed: Diagnostics Contribution in Health Intelligence

Health Intelligence is expanding the reuse of diagnostic information across healthcare. This monograph examines how Diagnostics can contribute more visibly as information supports wider forms of care, research and analysis.

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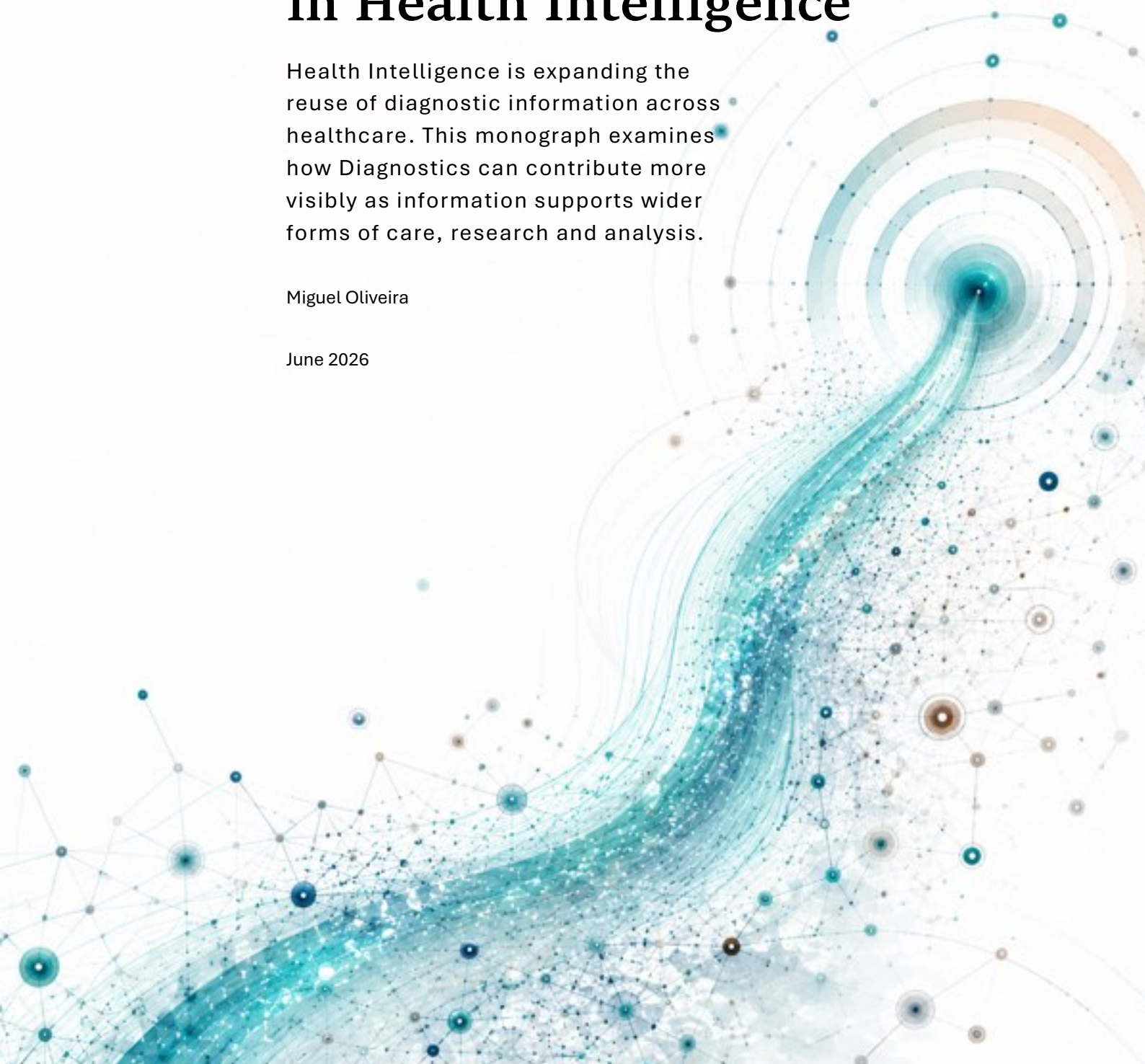

IVD Industry Monograph Series

The IVD Industry Monograph Series is the primary analytical output of Persodia Research. Each volume examines a defined strategic question at the intersection of Diagnostics industry structure, clinical deployment, health-system transformation, evidence and value creation.

The series applies the structural framework developed in *Inside the Clinical Diagnostics Industry: Constraints Shaping Strategy — Towards Health Intelligence* (Oliveira, 2026) to contemporary questions. The volumes are not summaries or updates of the book. They are focused applications of its underlying industry logic.

Each volume combines structural analysis with selected public evidence, field observation and professional dialogue. The series is analytical and observational rather than prescriptive. Its purpose is to clarify the conditions within which operators, institutions and industry participants make decisions; it does not claim to determine those decisions.

Each monograph stands alone as a complete analytical unit. Its length and editorial form follow the question under examination: some require extended structural analysis, while others call for concise, evidence-disciplined treatment of a live strategic signal. Together, the series develops a cumulative account of how the IVD industry is changing in relation to clinical practice, health-system architecture, evidence, technology and value creation.

Where a question requires deeper empirical, economic, technical or sector-specific analysis than one volume can carry, that work may become a later stage of the Persodia Research programme. Relevant professional perspectives, evidence and substantive dialogue are welcomed.

Previous Monographs in This Series

Monograph No. 1 — Crossing from Analytical to Diagnostics: The Difficulty is the Moat
Examines the structural distance between analytical technologies and clinical diagnostics: why superior measurement capability does not automatically establish a diagnostic market position, and the conditions required to cross that distance.

Monograph No. 2 — Earning Position: How Evidence Becomes Authority
Examines the evidence architecture required to convert market entry into clinical adoption, and the structural conditions that determine whether evidence achieves durable practical authority.

Monograph No. 3 — Beyond Market Access: Foundations for Sustaining Europe's IVD Leadership
Examines the foundations on which a financially viable, strategically capable and publicly consequential European Diagnostics sector depends, and the industrial conditions shaping their continuity.

Previous volumes are available through the Persodia Research repository at persodia.org.

This Volume

Monograph No. 4 — Beyond the Data Feed: Diagnostics Contribution in Health Intelligence

This volume examines an emerging strategic question for Diagnostics: as health intelligence expands the authorised reuse of diagnostic information across care, research, public health and analytical environments, what new operating requirements arise for the systems and organisations that generate, manage and support that information?

It takes a focused, evidence-disciplined form appropriate to a live strategic signal. The monograph considers how analytical quality, report discipline, method knowledge, provenance, lifecycle information, structured representation, connectivity, maintenance and access to relevant expertise may need to remain available as diagnostic information is retrieved, exchanged or reused beyond its original reporting workflow.

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Executive Signal

Health Intelligence is a new operating concept for healthcare. It seeks to use information more broadly across care, prevention, research, public health, operations and AI-enabled analysis. Its promise is not only better connectivity between systems, and eventually people. It is the possibility that information can remain usable across institutions, over time and, increasingly, for people themselves as they engage with their own health and care.

Europe provides a leading practical model through the European Health Data Space (EHDS). Its direction is clear: defined categories of health information, including laboratory results, are scheduled to become electronically exchangeable through interoperable and governed architectures. EHDS is not the whole global story, but it makes a wider international direction visible in law, implementation planning and technical work.[2,3]

Diagnostics is moving from being a producer of results to becoming part of the operating infrastructure of health intelligence.

For Diagnostics, this introduces an additional operating requirement. The task is no longer only to generate and issue a validated report. Relevant information must also be available, on demand and through authorised routes, to support the uses and data architectures in scope. Reports remain formal records. The underlying information stays with the responsible systems and is queried, returned and reused under the relevant governance conditions; EHDS is not a single central database.

That requires work: data structures, better-organised information elements, standards conformance, connectivity, maintenance, curation, provenance, change management and, where relevant, routes to supporting documentation or expertise. This does not mean every report contains every possible detail. It means that systems can provide the information conditions required by the architecture and the uses they support.

This work will often be expected as part of normal health-system participation, rather than as a separately funded diagnostic service. Whether it becomes routine depends on implementation design, incentives, accountability and collaboration.

The future of Diagnostics is not only about what and how can be measured. It is about how diagnostic information can remain enhanced, reusable and usable for institutions and for people themselves.

Contents

1. Health Intelligence Is Taking Shape

From the book's epilogue to Amsterdam

Inside the Clinical Diagnostics Industry: Constraints Shaping Strategy—Towards Health Intelligence closed with an open question. After successive transformations in systematisation, integration and specialisation, might the next phase of Diagnostics be shaped not only by new tests and platforms, but by the way diagnostic information contributes to wider systems of health intelligence?[1]

HLTH Europe Amsterdam 2026 provided a useful setting in which to revisit that question. Across artificial intelligence, data infrastructure, workflow redesign, prevention and governance, health intelligence appeared less as a finished category than as a direction of travel. Biomarkers, genomics, longitudinal monitoring and clinical decision support appeared repeatedly as inputs into wider digital-health environments.

The signal was not that Diagnostics had become a separate digital-health sector. It was that diagnostic information was increasingly assumed to be available within systems designed to connect, retrieve and use health information across time, settings and institutions.

This observation is not empirical proof of an industry-wide trend. It frames the question examined in this monograph:

As health intelligence becomes operational, how can Diagnostics contribute to the information conditions on which it depends?

Health intelligence is not one system replacing others; it is the growing capacity to connect what has previously remained separate.

What health intelligence means

Health intelligence is used here as an emerging operating concept for healthcare. It is not a single platform, product, legal category or technical stack. It describes an environment in which information generated in different settings can increasingly be connected and used, through authorised routes, to support decisions beyond one clinical episode or institution.

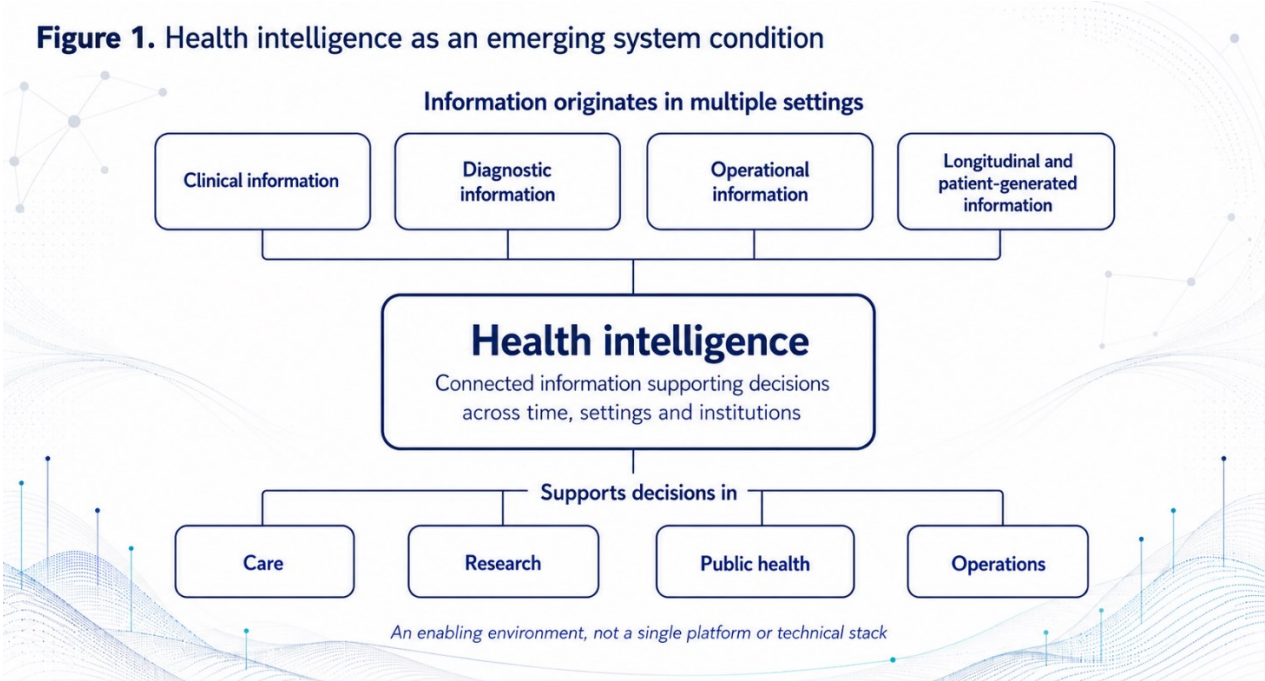

Figure 1. Health intelligence as an emerging system condition

The figure shows information originating in clinical, diagnostic, operational, and longitudinal or patient-generated settings. Health intelligence connects these information types to support decisions in care, research, public health and operations.

Its purpose is not simply to accumulate more data. It is to make relevant information more usable across time, settings and institutions.

Diagnostic information is central to this environment. Laboratory results, biomarkers, microbiology, pathology and molecular findings provide biological evidence for diagnosis, risk assessment, treatment selection and monitoring.

Why it matters

Health intelligence may improve continuity for people and healthcare systems, but its value depends on information being governed, usable and reliable; for Diagnostics, it expands the settings in which analytically qualified, professionally supported information can contribute beyond the originating laboratory and clinical workflow, a direction Europe is now translating into legal, technical and operational practice through EHDS..

Health intelligence does not replace diagnostic reporting or turn Diagnostics into a generic data sector.

It expands the settings in which diagnostic information may be used.

2. Europe Makes Health Intelligence Operational

Europe is used here as a practical model for a global concern. The underlying direction is wider than Europe, but the European Health Data Space provides one of the clearest current examples of a political decision to move beyond largely voluntary exchange arrangements toward a regulated health-information framework.

Regulation (EU) 2025/327 establishes the European Health Data Space (EHDS) through common rules, standards, infrastructures and governance. It addresses primary use of electronic health data, secondary use for research, innovation, policy and regulatory purposes, and a harmonised framework for electronic health record systems.[2,3]

The implementation timetable is phased. Patient summaries and ePrescriptions/eDispensations form the first priority group. Medical images, laboratory results and hospital discharge reports form the second priority group, for which cross-border primary-use exchange is scheduled to be operational across Member States from March 2031. The exact legal and operational duties differ by role, system type, data category, national law and implementing acts. The direction, however, is not voluntary: actors and systems in scope will need to comply with the applicable requirements as they enter into application. [2,3]

Policy becomes operational when information can move through agreed routes, under defined rules, toward authorised use.

What EHDS changes

EHDS does not create a central European database containing all health information. It establishes a federated environment in which health information remains within responsible systems and is made available through governed routes. For Diagnostics, this matters because information previously designed mainly for local reporting must increasingly be queryable, retrievable or exchangeable in agreed forms where the applicable architecture and authorised use require it.

The framework is being translated into technical and operational detail through the European EHR Exchange Format, MyHealth@EU, HealthData@EU and implementation initiatives such as Xt-EHR. HL7 FHIR offers a general exchange model; the HL7 Europe Laboratory Report Implementation Guide illustrates how laboratory reports, observations, requests, specimens, organisations, devices and provenance may be represented in related structures. These documents indicate direction and implementation work; not all are final legal specifications.[4,5,6]

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Table 1. Europe is assembling legal, technical and operating layers through which defined health information can become available across settings.

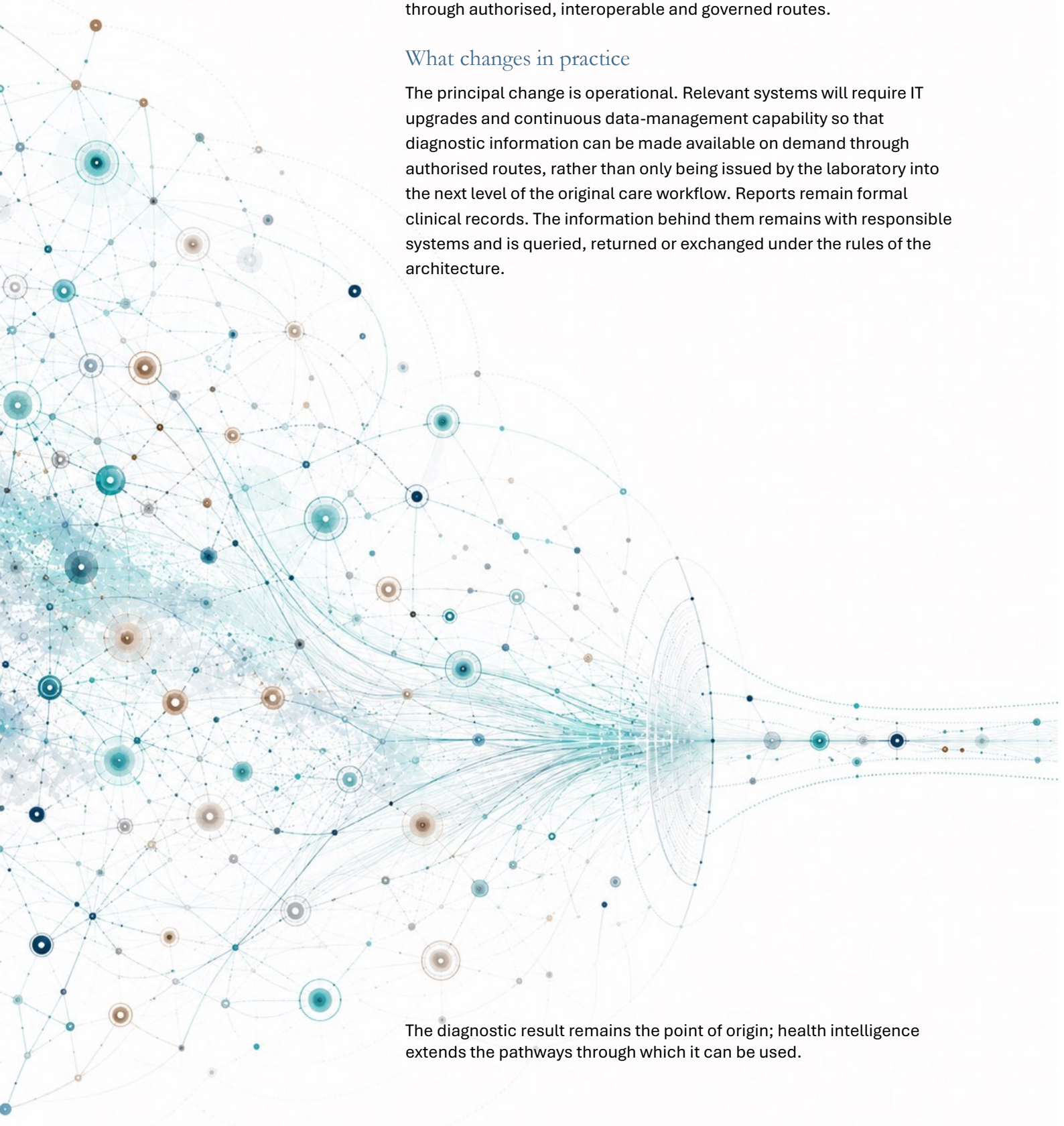
Policy, architecture and operating layer	What it provides
EHDS Regulation	Common legal framework, rights, obligations, governance and phased application.
European / national specifications	Detailed formats, common specifications and national implementation choices.
EHR, LIS and middleware implementation	Systems able to create, retain, retrieve and exchange information in the required forms.
Authorised access and reuse	Use through defined primary- and secondary-use routes, not unrestricted data circulation.
Access and processing conditions	For individuals, access to their own electronic health data is intended to be free. For permitted secondary use, data-access bodies may charge transparent cost-recovery fees for processing applications, preparing datasets and secure access; this is not a market price for the data itself.

3. A New Operating Concept for Diagnostics

Diagnostic systems have long been designed to produce, validate and issue results in support of a defined clinical transaction. That core function remains unchanged and essential. The operating shift is architectural: alongside validated reporting, relevant systems will increasingly need to make specified diagnostic information available through authorised, interoperable and governed routes.

What changes in practice

The principal change is operational. Relevant systems will require IT upgrades and continuous data-management capability so that diagnostic information can be made available on demand through authorised routes, rather than only being issued by the laboratory into the next level of the original care workflow. Reports remain formal clinical records. The information behind them remains with responsible systems and is queried, returned or exchanged under the rules of the architecture.



The diagnostic result remains the point of origin; health intelligence extends the pathways through which it can be used.

This creates three additional demands: new or upgraded information-system capability; continuous management of structured diagnostic data and links; and authorised availability on demand. Availability requires more than transport. Relevant information must be findable, retrievable and interpretable within its intended scope, with an appropriate access route to supporting context when needed.

Table 1. From validated reporting to health-intelligence participation: the shift adds architecture participation; it does not replace diagnostic reporting.

What remains	What is added
A validated report remains the formal record of what was measured, reported and interpreted at the moment of issue.	Relevant information must be made available through the architectures and routes required for authorised access and reuse.
Laboratory quality, report control and local accountability remain core responsibilities.	Data-architecture conformance, structured representation, connectivity, retrievability and maintenance become additional operating requirements.
Information remains held by responsible systems and actors.	Information can be queried or returned on demand where authorised users and the governing architecture require it.
A report is valid at the point of issue, within the conditions that applied at that moment.	Corrections, amendments, addenda, supersession and later interpretive updates must be visible in controlled and traceable ways where relevant.

Historical integrity and change visibility

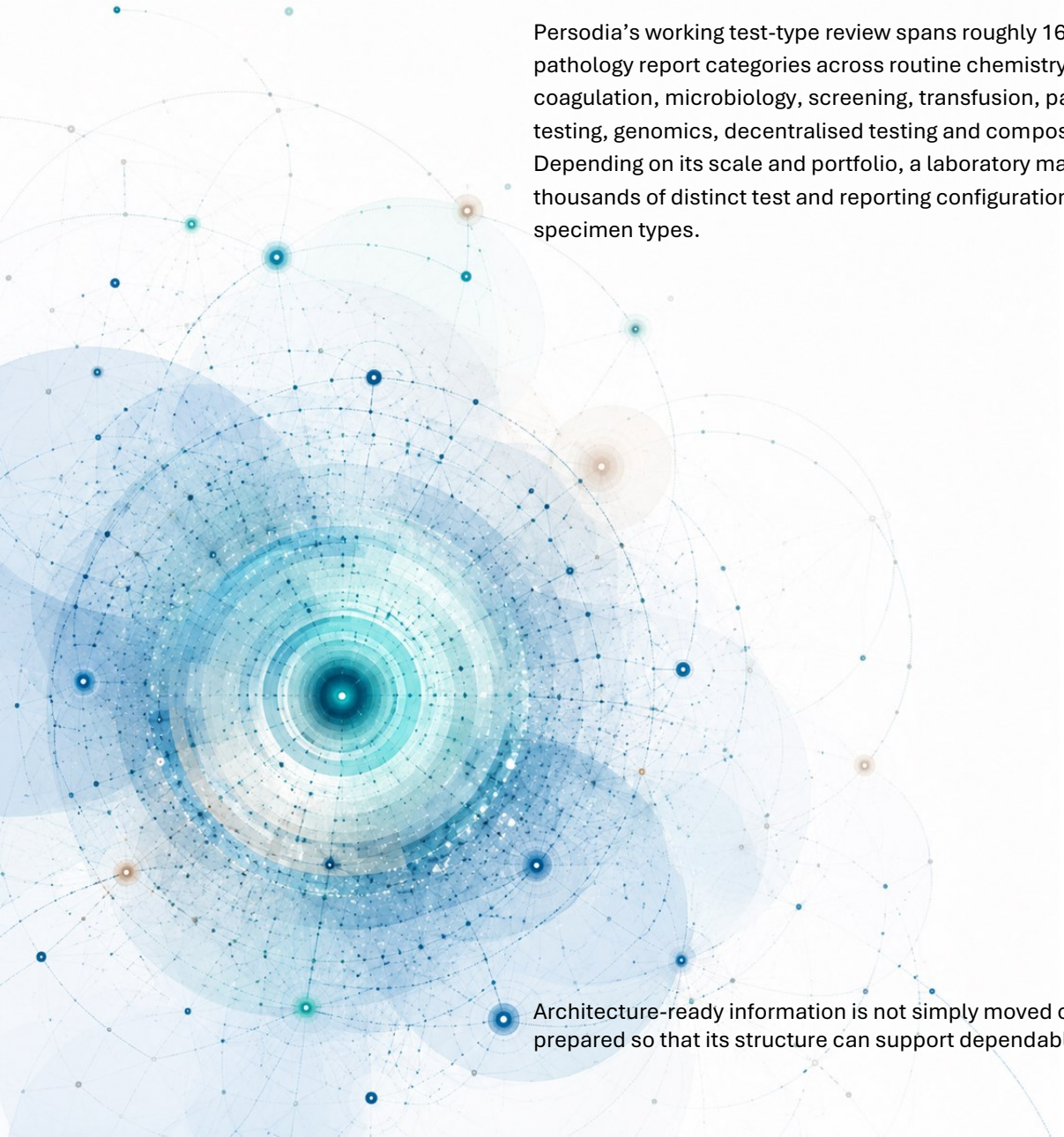
Architecture-ready systems do not retrospectively rewrite formal reports. They preserve report status and historical integrity while making corrections, amendments, appended information, supersession and later interpretive updates visible in a controlled way. This distinction is particularly relevant where method changes, corrected reports or later genomic interpretation matter to an authorised use.[4,5,6,11,]

4. Making Diagnostic Information Architecture-Ready

Architecture-ready diagnostic information meets the requirements of a relevant health-data architecture and its intended use. It is not a universal package that every result must carry. It is the combination of data elements, structure, identifiers, links, status and maintenance arrangements needed for information to be made available in a dependable form.

Much of the underlying capability already exists within laboratory, manufacturer and informatics practice. The additional requirement is to make relevant elements available in the structures, formats and routes required by the architecture. Information is also not static: manufacturers update products and technical documentation; laboratories change methods, platforms, reference conditions and reporting practice; science changes evidence and interpretation. Architecture readiness therefore requires continuous care, not a one-time conversion.

Persodia's working test-type review spans roughly 160 laboratory and pathology report categories across routine chemistry, haematology, coagulation, microbiology, screening, transfusion, pathology, molecular testing, genomics, decentralised testing and composite outputs. Depending on its scale and portfolio, a laboratory may manage thousands of distinct test and reporting configurations across analytes, specimen types.



Architecture-ready information is not simply moved outward; it is prepared so that its structure can support dependable reuse.

Table 2: *Architecture readiness extends existing diagnostic-information practices into the structures required by wider architectures.*

Information layer	Existing diagnostic information	Architecture-ready requirement
Patient and episode	Identity, request, clinical setting, timing.	Persistent identifiers, structured links and elements usable across authorised systems.
Test and specimen	Test name, panel, specimen, collection details.	Standardised representation of the test, specimen and relevant relationships.
Measurement and report	Result, unit, range, comments, interpretation, status.	Coded observations, structured report context, status and provenance.
Method and device	Local method knowledge; device and assay documentation.	Assay, method or device identification where material to intended use.
Report history	Final report, correction, amendment or addendum.	Preserved status, version and amendment visibility.
Lifecycle information	Laboratory and manufacturer documentation and change records.	Supporting documentation accessible where a later use requires it.
Connectivity	Local interfaces, portals and local retention.	Interoperable retrieval and authorised exchange through the architecture.
Continuous change and curation	Method, reagent, platform, reference, coding, product and evidence changes.	Ongoing data governance, traceable updates and maintenance so that architecture-ready information remains current.

What architecture readiness requires

Architecture readiness is not achieved by exporting a single result field. It requires a clear inventory of what each information type needs to remain identifiable, structured, retrievable and maintainable in the relevant architecture. Across a laboratory portfolio this can include identifiers, test and specimen relationships, result structure, units and reference conditions, report status, source provenance, method or device information where material, and controlled access to supporting documentation or expertise.

The work is continuous. Data models, mappings, interfaces, data-quality controls, product information and access routes must evolve as test menus, clinical practice, scientific evidence and technical architectures change. The required depth differs by information type and use, but the need for ongoing informatics and data-management capability is common.

The essential principle is not universal enrichment. It is disciplined preparation and maintenance of highly varied diagnostic information for the architectures and authorised uses it is expected to support.

Diagnostic information types are diverse. The implementation task is therefore not one generic data exercise, but a large and continuing programme of informatics upgrades, curation and data management across a complex portfolio.

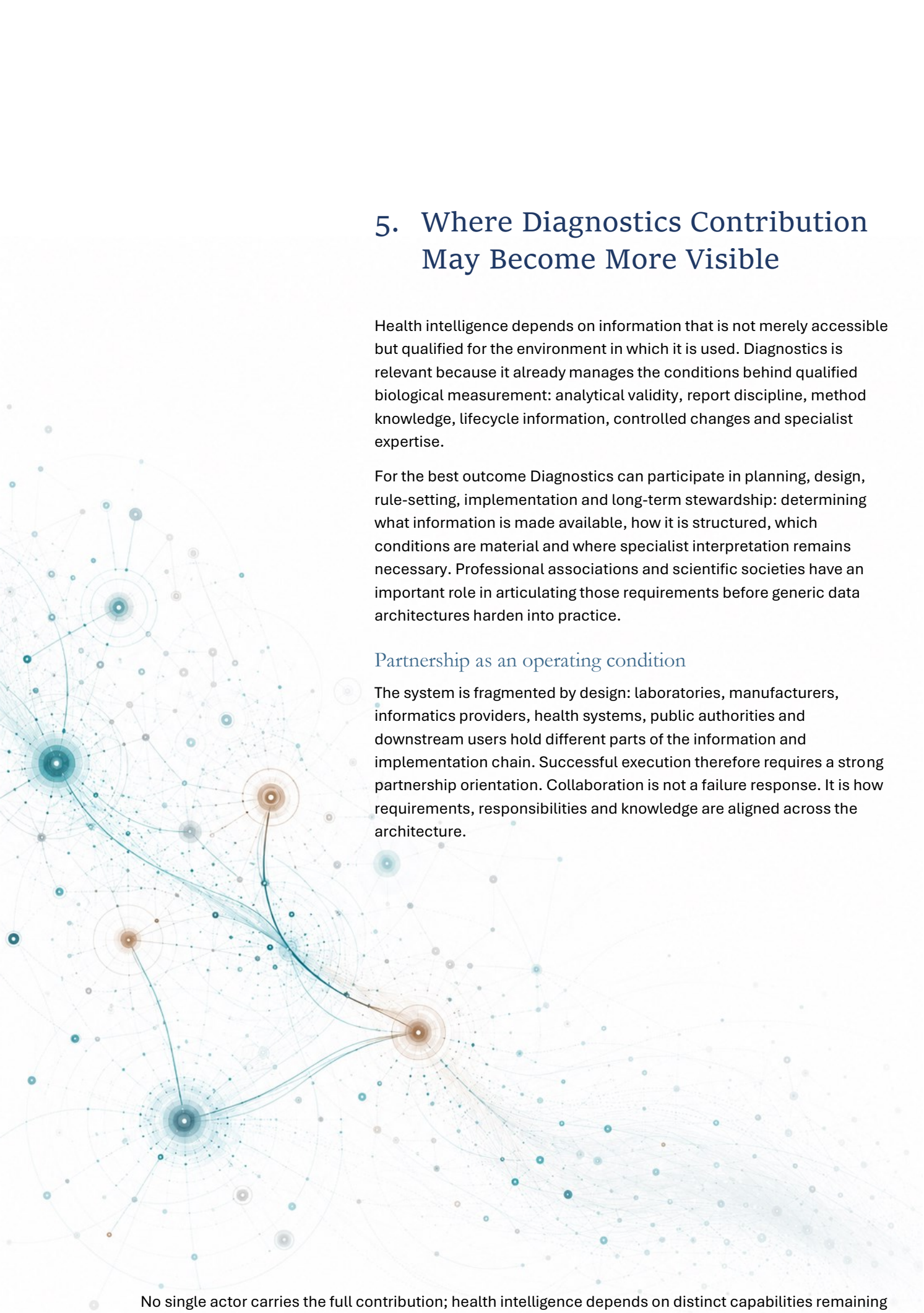
5. Where Diagnostics Contribution May Become More Visible

Health intelligence depends on information that is not merely accessible but qualified for the environment in which it is used. Diagnostics is relevant because it already manages the conditions behind qualified biological measurement: analytical validity, report discipline, method knowledge, lifecycle information, controlled changes and specialist expertise.

For the best outcome Diagnostics can participate in planning, design, rule-setting, implementation and long-term stewardship: determining what information is made available, how it is structured, which conditions are material and where specialist interpretation remains necessary. Professional associations and scientific societies have an important role in articulating those requirements before generic data architectures harden into practice.

Partnership as an operating condition

The system is fragmented by design: laboratories, manufacturers, informatics providers, health systems, public authorities and downstream users hold different parts of the information and implementation chain. Successful execution therefore requires a strong partnership orientation. Collaboration is not a failure response. It is how requirements, responsibilities and knowledge are aligned across the architecture.



No single actor carries the full contribution; health intelligence depends on distinct capabilities remaining connected where they matter.

Table 3. Diagnostics Contribution spans design, implementation and stewardship; it is not confined to data supply.

Stakeholder	Role in design, implementation and stewardship	Why it matters to the stakeholder
Laboratories and laboratory medicine	Source completeness, validation, report quality, local quality control, change control and practical advice on which data elements matter.	Protects the integrity of laboratory practice as information is reused; makes laboratory capability visible in wider care and data-system design.
IVD manufacturers	Assay identity, intended-use conditions, performance knowledge, lifecycle and technical documentation.	Keeps product, performance and lifecycle knowledge connected to the environments in which results are used, rather than leaving it isolated in product files. Able to get RWE for reference ranges.
Diagnostic-informatics providers	Data structures, interfaces, interoperability, persistence, retrieval, maintenance and implementation tools.	Creates a larger strategic role in translating diagnostic knowledge into durable, usable information architecture and maintaining it over time.
Health systems and data holders	System adoption, architecture design, governance, access, procurement and workflow integration.	Determines whether health intelligence becomes dependable practice rather than a technical aspiration, and whether implementation conditions match real workflows.
Professional bodies and scientific societies	Shared conventions, rule-setting input and articulation of diagnostic quality conditions.	Helps ensure that architecture design reflects diagnostic requirements rather than generic data assumptions, and provides a shared voice for stewardship needs.

The most important interfaces are between laboratory and informatics environments, where report content becomes structured and exchangeable information; between manufacturer and laboratory or platform environments, where assay, device and lifecycle facts can be made accessible in forms that support appropriate use; and between health systems, data holders and downstream users, where governance determines what is available, to whom, for which purpose and with what evidence of provenance.

When diagnostic requirements are not specified

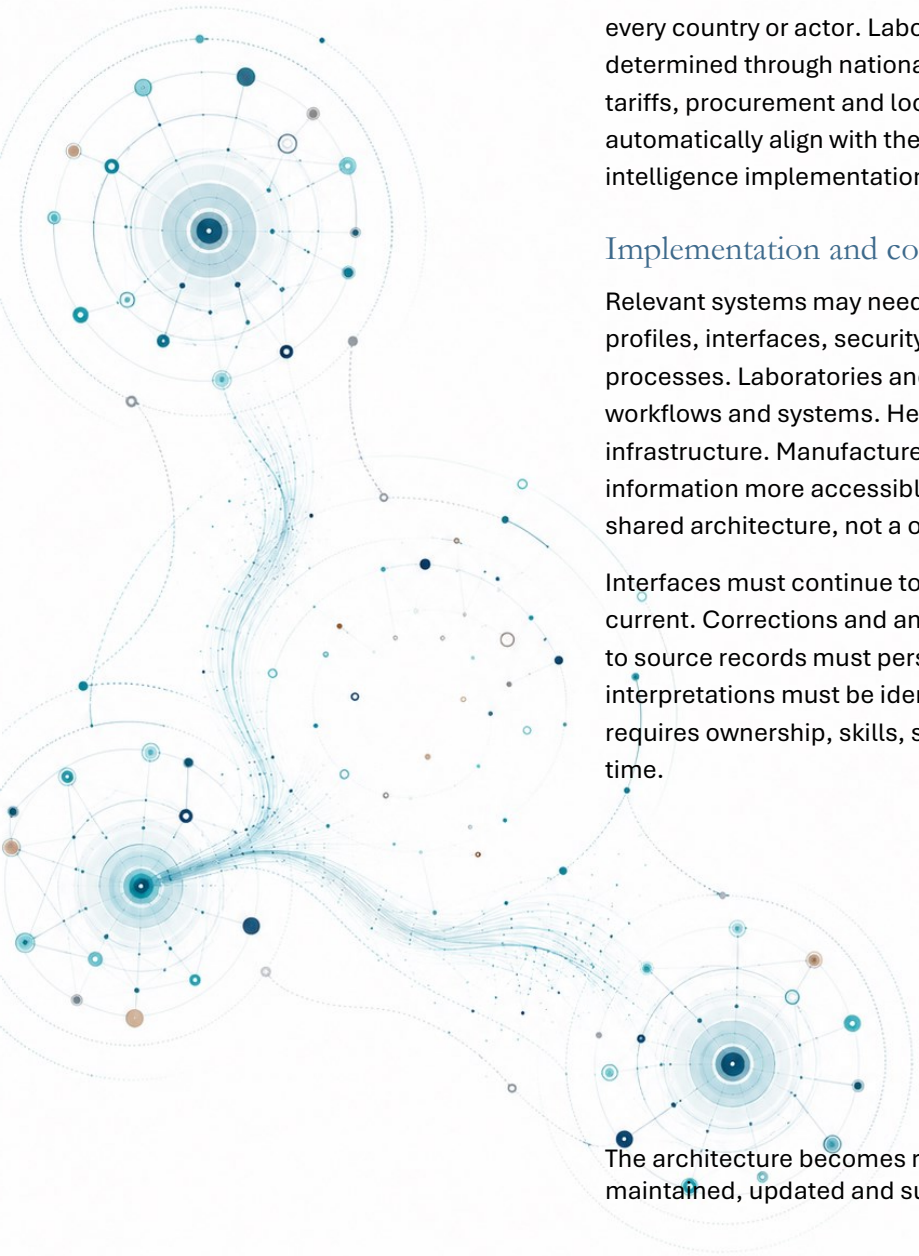
A health-information architecture can exchange a laboratory result successfully while still leaving relevant diagnostic implementation requirements unspecified. Where this occurs, later users may need clarification, additional curation or further validation before the information supports a new purpose. The issue is not that meaning has eroded in transit. It is that the required diagnostic conditions were not defined or carried through when the information entered the architecture.

6. Making Health Intelligence Work

The previous chapter addressed who needs to shape health intelligence. This chapter addresses what makes its implementation durable at scale: continuing technical work, operational ownership, reimbursement and contracting realities, accountability, maintenance and feedback.

Health intelligence creates new work for Diagnostics. Systems must be adapted. Information must be structured. Interfaces maintained. Changes recorded. Data made available through governed routes. Expertise must remain accessible where it matters. Laboratories, manufacturers and informatics providers are already carrying expanding regulatory, evidence, software, cybersecurity, quality and lifecycle obligations. Architecture readiness adds further pressure to those existing responsibilities.

This is a Persodia structural inference, not a quantified claim about every country or actor. Laboratory-service reimbursement will remain determined through national health systems, insurance arrangements, tariffs, procurement and local contracts. Those mechanisms do not automatically align with the location of the new work required by health-intelligence implementation.



Implementation and continuing work

Relevant systems may need data fields, terminology, identifiers, profiles, interfaces, security controls, access rules and conformance processes. Laboratories and informatics suppliers may need to adapt workflows and systems. Health systems may need to adopt or upgrade infrastructure. Manufacturers may need to make assay and lifecycle information more accessible in structured forms. This is participation in shared architecture, not a one-off data export project.

Interfaces must continue to function. Codes and mappings must remain current. Corrections and amendments must remain visible. References to source records must persist. Changes in methods, products or interpretations must be identifiable where they matter. This work requires ownership, skills, service capacity and sustained attention over time.

The architecture becomes real only when its connections can be maintained, updated and supported over time.

Implementation quality, reimbursement and accountability

In many organisations, architecture readiness will initially be absorbed within existing budgets, contracts and operating models. A laboratory may be asked to supply additional structured information through its current information-system programme. A manufacturer may provide lifecycle facts through existing technical documentation or connectivity work. An informatics supplier may include new profiles and interfaces within product development and service obligations. A health system may expect the capability to emerge through procurement and implementation of EHR infrastructure.

None of these arrangements is inherently inappropriate. The issue is that the work is real even when it is not separately priced. Where system design does not recognise the location of work, maintenance and accountability, implementation quality may be uneven. That can delay participation and weaken the health-intelligence aims that the architecture was intended to support.

Table 4. Added architecture work may be absorbed across existing budgets, contracts and service arrangements; reimbursement and service models remain country- and institution-specific.

Work required	Typical location	How it may be absorbed initially
Data fields, terminology and profiles	LIS, middleware, EHR, laboratory workflow	IT and implementation programmes
Interfaces and retrieval	Informatics suppliers and health systems	Product development, service and infrastructure budgets
Lifecycle and technical information	Manufacturers and laboratories	Quality, regulatory and technical-documentation functions
Maintenance and change visibility	Laboratories, suppliers and data holders	Ongoing operations and service arrangements
Feedback and clarification	Distributed participants	Governance, support and partnership mechanisms

Feedback and collaboration

Health intelligence should not be one-way extraction from diagnostic systems. Later users may encounter a limitation, a method change, a missing field or a new evidence requirement. More dependable environments create routes by which questions, corrections and requirements travel back toward laboratories, manufacturers, informatics suppliers and health-system teams able to address them. A wider architecture needs feedback loops, not only data flows.

The question is not whether every contributor should be paid separately for every data element. It is whether long-term availability, maintenance and feedback can be assumed to appear automatically once an exchange standard exists. They cannot.

Conclusion
The Contribution of Diagnostics in Health Intelligence

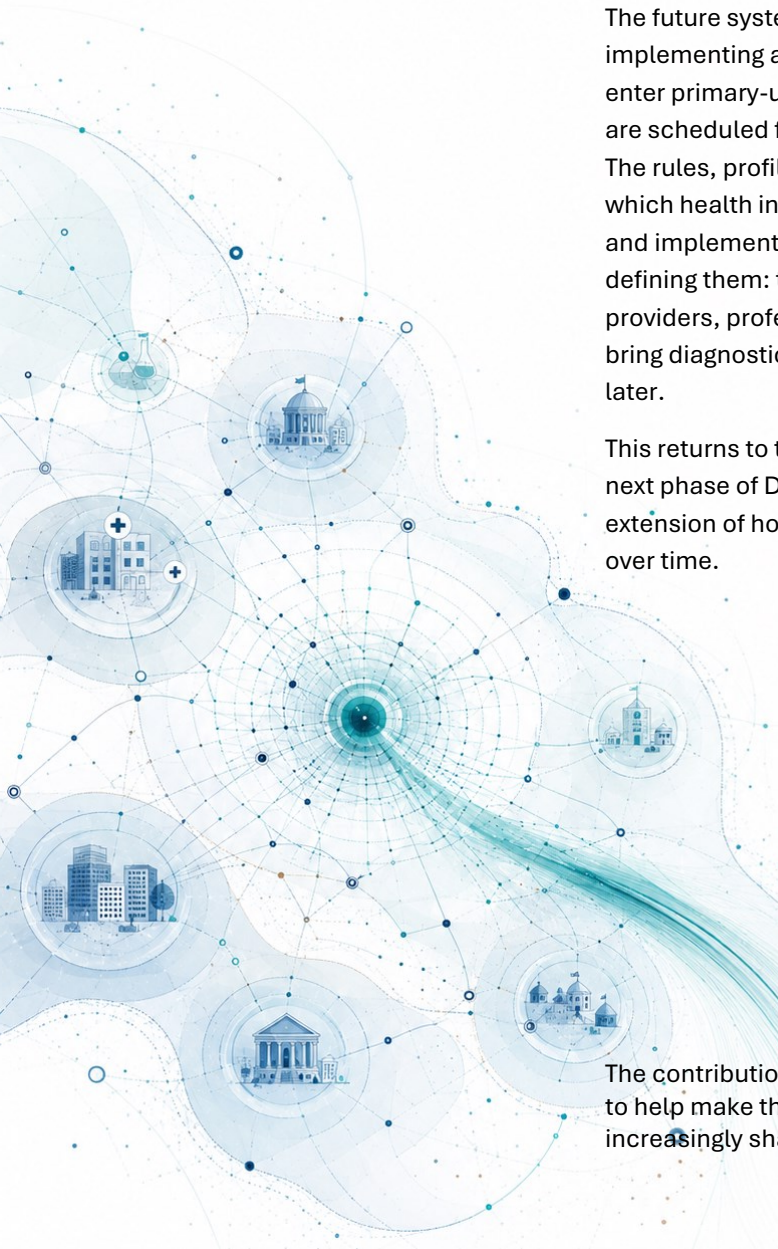
The strategic question is not whether health intelligence has merit. It is whether the conditions for its implementation can be created effectively, durably and at scale.

Health intelligence is coming into view as the next operating concept for connected healthcare. Europe is giving that direction legal and technical form through EHDS. Implementation will be phased, role-specific and demanding, but the general movement is clear: health information will increasingly be made available through governed architectures for wider authorised use.

Diagnostics is a key component of this future. It provides much of the biological evidence on which care, prevention, research, public health and analytical systems depend. Its contribution is not exhausted by the issue of a result. It includes the disciplined work that makes diagnostic information qualified, structured, maintainable and usable when architectures require it.

The future system is not yet fixed. The Commission is due to adopt key implementing acts by March 2027. The first priority group is scheduled to enter primary-use application from March 2029, and laboratory results are scheduled for operational cross-border exchange from March 2031. The rules, profiles, operating models and information conditions through which health intelligence will function are therefore still being designed and implemented. Diagnostics has an open opportunity to participate in defining them: through laboratories, manufacturers, informatics providers, professional bodies, health systems and partnerships that bring diagnostic capability into architecture design rather than adding it later.

This returns to the book's proposition. Health intelligence may be the next phase of Diagnostics: not a departure from measurement, but an extension of how diagnostic information serves institutions and people over time.



Diagnostics is moving from being a producer of results to becoming part of the operating infrastructure of health intelligence.

The contribution of Diagnostics is not only to generate information, but to help make that information usable across the wider systems that increasingly shape health.

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Annexes

Key Terms Used in This Monograph

Health intelligence
A trendy concept describing an emerging healthcare environment in which clinical, diagnostic, operational and longitudinal information can increasingly be connected and used across institutions, time and professional settings. It is not a technology, company or single platform. Rather, it describes the growing capacity to make relevant information available through governed routes for care, prevention, research, public health, operational planning and analysis. Health intelligence does not assume that all information should be used in the same way; reliable use depends on the information remaining appropriate to the purpose for which it is accessed.

Health-intelligence architecture
The combination of data structures, systems, workflows, institutions, governance arrangements and access routes through which health information is made available and used for care, research, public health, operations or analysis. It includes both technical components, such as information systems, interfaces, standards and repositories, and institutional components, such as access rules, responsibilities, professional roles and implementation arrangements. In this monograph, the term refers to the wider environment into which diagnostic information may increasingly need to participate.

Diagnostic information
Results and related observations produced through diagnostic processes, including laboratory, molecular, microbiology, pathology and other clinically relevant measurements. It may be numerical, categorical, textual or image-based, and may include associated information on the patient, specimen, timing, method, report status, interpretation and relevant source conditions. Its usefulness in a later setting depends not only on the result itself, but also on the purpose, context and degree of continuity required for the intended use.

Architecture-ready diagnostic information
Diagnostic information structured, maintained and made available in the forms required by a relevant health-data architecture and authorised use. It is not a universal data package; requirements differ by information type, setting and purpose. Depending on the use, architecture readiness may involve structured representation, identifiers, report status, provenance, controlled change visibility, connectivity, retrievability and routes to supporting documentation or expertise. It represents an additional operating requirement alongside validated diagnostic reporting, not a replacement for it.

Diagnostics contribution
The value Diagnostics brings beyond producing a result: analytical quality, report discipline, method knowledge, lifecycle information, structured representation, continuity and access to relevant expertise where needed. This contribution is distributed across laboratories, manufacturers, diagnostic-informatics providers, professional bodies and health-system partners. Its relevance may become more visible when diagnostic information is reused across care settings, over time, or for research, public-health and analytical purposes.

Diagnostic stewardship
The practices through which diagnostic information is generated, qualified, maintained, interpreted and supported within defined settings. These practices already exist in laboratories, manufacturers, information systems and professional governance through quality assurance, validation, reporting, lifecycle management, change control, technical documentation and consultation. Health intelligence may make their connection across wider architectures more important, particularly where information must remain available, traceable and usable beyond the original reporting workflow..

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Analytical Grounding

This monograph forms part of Persodia Research's continuing work on structural change in Diagnostics. It builds on the framework developed in *Inside the Clinical Diagnostics Industry: Constraints Shaping Strategy—Towards Health Intelligence* and the preceding IVD Industry Monographs.

It is a documented analytical synthesis drawing on selected public regulatory, policy, standards, clinical and implementation sources. These sources are organised through retained Persodia research dossiers on diagnostic-information reuse, FHIR/EHDS capability and EHDS use cases.

HLTH Europe Amsterdam 2026 informed the framing through field observations on artificial intelligence, interoperability, data infrastructure, clinical pathways and health-system transformation. These observations are treated as contextual input rather than formal evidence unless independently supported by the public source base cited in this publication.

The analysis combines those sources with the author's professional pattern recognition across Diagnostics commercialisation, workflow, systems integration, market development and strategic partnerships.

It does not treat Diagnostics as a unified actor, portray health intelligence as inherently harmful, or argue that any one participant should control emerging information environments. It proposes no universal technical standard, implementation blueprint, reimbursement model or business model.

Its purpose is narrower: to examine how diagnostic information can remain sufficiently qualified, continuous and usable when accessed across care, research, public health and analytical environments, and how the contribution of Diagnostics may remain visible within that wider health-intelligence context.

About the Author

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Colophon

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