Case Study

Building a Digital-First Cancer Diagnostic Laboratory with Sapio Sciences

Navignostics collaborated with Sapio Sciences to establish a digital-first cancer diagnostics lab, aiming for rapid, treatment-guiding reports. The outcome is a highly efficient, automated, and scalable diagnostic environment, allowing fast turnaround times and complete data traceability for advanced cancer care.

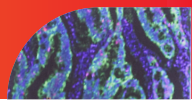
About the customer

Founded in
2022

Location
Horgen, Switzerland

Focus
Cancer diagnostics

Website
navignostics.com



The customer

Navignostics, emerging from the University of Zurich, was founded with the precise objective of transforming cancer diagnostics through spatial single-cell proteomics. Their ambitious aim was to deliver treatment-guiding diagnostic reports within 48 hours, a timeframe significantly shorter than current oncology standards. Achieving this necessitated a departure from conventional methodologies.

Navignostics adopted a digital-first strategy from its inception. This commitment precluded the use of paper binders, disparate spreadsheets, or the integration of legacy systems. As Federico Lionetti, Software Systems Lead and the company's first employee, articulated, "We didn't transition from paper to digital—we started digital from day one." This approach required a complete re-evaluation of laboratory construction and operation, encompassing everything from sample movement to clinician interaction with the final diagnostic report.

The challenge

Navignostics operates at the forefront of cancer diagnostics. This domain is characterized by exceptionally high data complexity and stringent regulatory requirements. Their diagnostic workflows involve diverse sample types, including FFPE tissue sections, tissue microarrays, and patient-derived samples, alongside advanced imaging and bioinformatics pipelines. From the outset, the team recognized that traditional laboratory tools, commonly found in academic settings—such as manual logs, disconnected software, and static PDF or Excel files—would be inadequate for scaling up to commercial ambitions. A robust system was required to:

- Track a diverse range of biospecimens and reagents through intricate workflows

- Seamlessly integrate real-time data into downstream bioinformatics and machine learning pipelines
- Support comprehensive audit trails and regulatory compliance (CLIA, 21 CFR Part 820, ISO 13485, ISO 15189)
- Facilitate clear collaboration across wet lab, software, QA, and healthcare professionals

The team recognized that fragmented systems would impede progress. A unified foundation with robust integration capabilities and regulatory readiness was essential.

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Federico Lionetti
Software Systems Lead,
Navignostics

The solution: Choosing a platform designed for diagnostics

After evaluating multiple vendors, Navignostics selected Sapio Sciences, valuing both its technology and underlying philosophy. Sapio provided a fully integrated platform encompassing LIMS, ELN, and a physician-facing portal within a single ecosystem. This platform's architecture was designed to accommodate Navignostics' growth without encountering infrastructure or compliance limitations. Lionetti explained, "Thanks to the flexibility of the Sapio platform, integrating the processes went hand in hand with development—without having to make compromises that would undermine the processes."

Crucially, the Sapio platform was not merely configurable but also API-first. This characteristic enabled seamless integration with laboratory instruments, data pipelines, and diagnostic algorithms. Whether retrieving QC data from an instrument, printing sample labels, or transmitting data to machine learning models, Sapio's system integrated effectively into the workflow. Moreover, the platform was specifically developed for diagnostics. With integrated support for electronic signatures, version control, and audit trails, Sapio met regulatory expectations inherently. It offered a reliable system capable of supporting Navignostics as it transitioned into clinical operations.

Implementation: From vision to execution

Implementing a LIMS solution in a startup, particularly one operating rapidly and building for regulatory compliance, presents a significant undertaking. Navignostics addressed this by treating the implementation as a distinct product. All teams—laboratory operators, scientists, QA personnel, and software engineers—participated in structured workshops, open feedback loops, and rigorous testing. This comprehensive involvement ensured that all stakeholders operated from a shared understanding. Lionetti emphasized, "The LIMS is the foundation of our lab, not just another tool."

Integration with laboratory instruments proceeded smoothly due to Sapio's APIs. Navignostics transformed their laboratory into what Lionetti described as a "relay race" by automating data capture and transfers, with each station seamlessly transitioning to the next. Onboarding and configuration required approximately six months. Lionetti noted that this timeline could have been shorter had early documentation been more robust. Nevertheless, collaborative support from Sapio facilitated their progress, and today, enhanced documentation and a mature support portal benefit new clients.

Regulatory validation without consultants

Establishing a diagnostic laboratory necessitates building for audits. Navignostics embedded compliance from the outset. The Sapio platform facilitated accelerated validation by providing:

- A pre-validated core platform
- Templates to guide the validation of custom workflows
- Integrated audit trails, version control, and digital signatures at every step

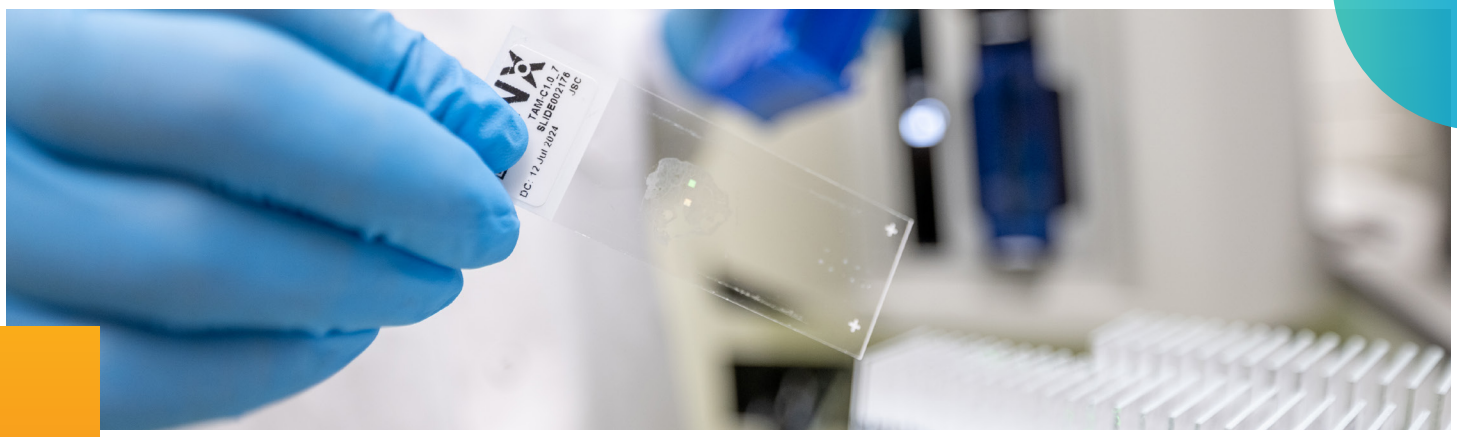
This approach yielded substantial time and cost savings for the team. When the QA manager requested documentation or audit readiness checks, the system contained most of the necessary information. No panic, no reliance on paper records, and no uncertainty.

hCRM: Connecting laboratory and clinic

Diagnostics extends beyond the laboratory, culminating with the clinician. As Navignostics approaches commercial readiness, a notable feature of the Sapio implementation is the hCRM (healthcare Customer Relationship Management) physician portal. The portal:

- Integrates seamlessly with LIMS workflows, tracking samples from receipt through imaging and report generation
- Provides healthcare professionals with direct, secure access to diagnostic reports and dashboards
- Supports API-based integration with AI pipelines, enabling rapid, automated data analysis and feedback loops

Built on the same architecture and API layer as the LIMS, the hCRM integrated smoothly into existing workflows. It is currently being piloted with early clinical partners as Navignostics prepares for market launch.



The results: A seamless, scalable system

Presently, Navignostics operates one of Europe's most comprehensively integrated diagnostic laboratory environments. Every sample, reagent, and result is traceable, auditable, and automated. Data flows in real-time, from sample intake through imaging and AI to the final clinical report. This has resulted in a laboratory that is faster, more intelligent, and prepared for scale. Key outcomes of the Sapio Platform implementation include:

- Robust, end-to-end data traceability
- Real-time integration with data pipelines and reporting tools for enhanced laboratory efficiency
- Regulatory compliance embedded within daily operations
- Improved turnaround times and reduced manual errors
- Strong cross-functional alignment among laboratory operations, data science, and clinical reporting teams

As Lionetti remarked, "We've built the kind of lab that big pharma is still trying to digitize. Starting fresh and starting digital made that possible."

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> Software Systems Lead,
> Navignostics

Lessons for laboratory leaders

Navignostics' journey offers critical insights for any laboratory seeking to transform its operations:

- **Involve all stakeholders, particularly end users, early.** Engaging all parties from the outset ensured the system met diverse needs and fostered adoption.
- **Prioritize documentation.** Early and thorough documentation was crucial for regulatory compliance and future scalability.
- **Treat your LIMS software as a core product.** Positioning the LIMS as central to operations, rather than merely a support tool, accelerated digital transformation.
- **Foster cross-functional alignment.** Regular workshops and feedback loops facilitated alignment among wet lab, data science, and clinical teams, streamlining both implementation and ongoing usage.

Furthermore, for Navignostics, as a startup, a key lesson was:

- **Initiate and maintain a digital approach.** Implementing digital systems from the outset prevented the entrenchment of inefficiencies and manual processes.

While challenges will inevitably arise—such as documentation gaps, evolving needs, and cross-functional alignment—a configurable platform and a collaborative vendor can convert these challenges into opportunities for growth.

Future directions

Navignostics is currently advancing its automation efforts. They are expanding the utilization of the Sapio Platform to encompass:

- Temperature monitoring
- Supplier management and issue tracking
- Full workflow traceability, establishing a single platform as the definitive source of truth

With a robust digital foundation, Navignostics is positioned for scalability, not only as a diagnostics company but also as a paradigm for modern laboratories.

Conclusion

Navignostics' collaboration with Sapio Sciences represents more than a software success story; it serves as a blueprint for digital transformation within precision medicine. Together, they have established a laboratory that is intelligent, efficient, and prepared for the future of cancer care. Their experience underscores that the future is not merely approaching; it is already attainable through deliberate design.