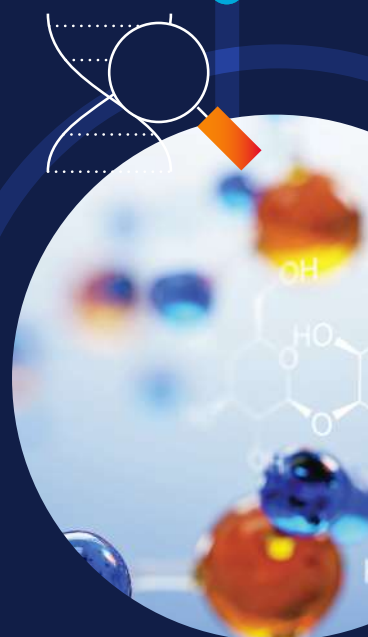




Accelerating Digital Transformation in Biopharma R&D:

Complex Science Needs Agile IT



Introduction

Adopting digitization and automation within biopharmaceutical research and discovery (R&D) holds immense promise for enhancing drug discovery. But outdated, legacy informatics systems—often fragmented and incompatible with modern laboratory technologies—can create bottlenecks that inhibit innovation. A unified, configurable, and AI-powered laboratory informatics platform that incorporates the principles and features of biopharma 4.0 enables IT to streamline laboratory operations and accelerate biopharmaceutical drug discovery.

Biopharma 4.0 represents the convergence of Industry 4.0 principles with the digitization of the biopharmaceutical sector. Key elements of biopharma 4.0 include automation, advanced data analytics, and artificial intelligence (AI). Collectively, these technologies help streamline complex processes, minimize human error, increase overall efficiency, and extract meaningful insights from complex datasets.¹ Agility in biopharma R&D “combines a stable backbone of core processes and capabilities with a high degree of flexibility for rapid response to change.”² Agile IT, characterized by adaptability and responsiveness, is a critical aspect of R&D agility.

The Sapio Laboratory Informatics Platform unifies Sapio ELN®, Sapio LIMS®, and Sapio Jarvis® SDMS on a common architectural foundation to ensure seamless functionality and unified data across all R&D laboratory operations. This white paper describes specific features of the Sapio Platform that enable IT agility to meet the rapidly evolving needs of the modern, digital biopharmaceutical R&D lab.



The Sapio Laboratory Informatics Platform incorporates features that enable agile IT



Agile Workflows

Meeting the Dynamic Demands of Modern R&D

Workflows in automated, digital labs must accommodate the way scientists work, meet the highly specialized nature of today's advanced scientific discovery, and provide the flexibility to address rapidly changing R&D requirements in the future. The Sapio platform provides a comprehensive suite of pre-built, specialized workflows that can be rapidly deployed to meet many research needs. Additionally, the Sapio platform's no/low-code configuration capabilities empower scientists to easily define unique data concepts, design custom experiments, and orchestrate complex workflows without writing a single line of code.

The Innovation Labs of the Ellison Institute of Technology (EIT) exemplify the benefits of Sapio's approach. EIT conducts innovative research across various health and medical sciences, including developing new therapeutic compounds for cancer treatment. Roi Bagsic, a quality control analyst responsible for laboratory operations at EIT, played a pivotal role in selecting the Sapio Platform and states that,

"The easy customization and quick adaptability of the platform for the different projects and scenarios we undertake gave me confidence that it could do whatever we needed."



Automation

Driving Efficiency and Improving User Satisfaction

The automation of routine and repetitive laboratory tasks, historically performed manually, is a powerful means of increasing efficiency, reducing human error, and improving user satisfaction. The Sapio Informatics Platform (including ELN and LIMS) is designed for out-of-the-box integration with various laboratory instruments and robots. Because of its cloud-based architecture, Sapio ensures that new instrument integrations and workflows are continuously added and existing ones updated automatically. Beyond instrument integration, the Sapio platform can also automate critical operational activities such as inventory management, sample tracking, and data tracking.

The Human Genome Sequencing Center (HGSC) at the Baylor College of Medicine, known for its cutting-edge research, successfully implemented Sapio to streamline instrument integration, optimize robotics workflows, and improve inventory, sample, and data management. HGSC was able to rapidly integrate the Sapio platform with their robotics and reporting systems and successfully deploy the entire solution over a single weekend. Harshavardhana Doddapaneni, Director of the HGSC Research Laboratory, summarized the impact of the platform:

“Sapio software was a game-changer for our lab operations, streamlining our processes and reducing wastage.”




Unified Multimodal Data

Providing a Single Source of Truth

Traditional biopharmaceutical R&D has typically relied on separate workflows and registration systems for small-molecule and large-molecule research. The emergence of new modalities, such as recombinant proteins, peptides, and engineered antibodies, is redefining that paradigm. Over the past few years, revenues from new-modality products increased by \$60 billion, with the percentage value of new modalities in the five-year forward pipeline projected to increase from 41% to a staggering 56%.³ The future of biopharmaceutical R&D is clearly multimodal.

The foundation of the Sapio Laboratory Informatics Platform is a single materials management system that does not distinguish between small-molecule, large-molecule, or multimodal entities—rather they are all collected and managed as molecular materials. As a result, chemists and biologists work together on a single, unified multimodal discovery platform that automatically tracks the complete lineage of every entity and its component parts to integrate and harmonize collective scientific data across the entire laboratory informatics enterprise.

This unified data foundation serves as a “single source of truth” for every R&D scientist, fostering a collaborative and efficient environment. By eliminating information silos and allowing teams controlled access, the Sapio platform minimizes miscommunication and accelerates the discovery of insight. Oxford BioMedica (OXB), a pioneering gene and cell therapy company and a leading contract development and manufacturing organization (CDMO), has recognized the value of this unified approach. The company collaborates with some of the world’s most innovative biopharmaceutical companies, emphasizing the importance of seamless data access and utilization.



Prashant Vaidyanathan, Director of Data Science and Software Development at OXB, is responsible for ensuring that all users have access to data that meets their specific needs and enables them to extract maximum value from their research. He aptly summarized the challenges of a multimodal lab: “One of the most challenging and complex approaches to [digitizing your data] is to have one platform that caters to the needs of all your departments.” He emphasized the success of the Sapio platform across departments, stating,

“It was really great to see end users who have been using Sapio giving it glowing recommendations.”



Built-in AI and Advanced Tools Unlocking Scientific Potential

Artificial intelligence (AI) is rapidly transforming the scientific landscape. While the 2010s experienced a boom in the development of machine-learning algorithms for analyzing complex scientific data sets, the 2020s ushered in the era of generative AI, offering unprecedented potential for accelerating drug discovery.⁴ The McKinsey Global Institute (MGI) estimates that generative AI in biopharmaceutical research could generate \$60 billion to \$100 billion a year in economic value by accelerating the process of identifying and developing novel drug candidates.⁵

Sapio ELaiN (Electronic Laboratory Artificial Intelligence Notebook) exemplifies the power of AI within the Sapio platform. By integrating with multiple scientific applications and data sources, ELaiN provides a unified interface for designing experiments, analyzing data, and generating actionable insights. Through a simple natural language chat interface, a scientist can leverage large language models (LLMs) to rapidly create experiments, search and visualize data, and generate code to create an experiment, simply by describing what they want to do.

In addition to AI, Sapio’s Molecular Biology Toolkit incorporates advanced tools to visualize, analyze, and utilize scientific data—from CRISPR design and plasmid construction to PCR primer and compound design. Collectively, built-in AI and other advanced tools enable scientists to conduct research easier and faster and to develop new approaches that outperform existing methods.

Interoperability Connecting the R&D Ecosystem

The modern R&D lab doesn't operate in a vacuum but rather within a dynamic ecosystem that extends beyond the informatics platform. Seamless integration with external systems and applications is essential for synchronizing data, automating processes, and achieving smooth cross-platform interoperability.

During the evaluation of the Sapio platform for the Ellison Institute of Technology, Frank Callari, director of IT, was particularly impressed with Sapio's API-first architecture because it enabled him to programmatically streamline and automate many lab operations. Additionally, the platform's Webhook functionality allowed the Institute to extend the product as they desired. Mr. Callari especially appreciated the uniqueness of Sapio's unified lab informatics platform, "Most competitors offered products, but Sapio offered more — it offered a complete platform."

Designed with interoperability in mind, the Sapio Platform offers multiple integration options, including:

- **A RESTful API (application programming interface)—the de facto standard for life sciences software, facilitating easy data exchange and integration with other systems.**
- **Webhooks to enable real-time communications with web applications for dynamic and responsive data exchange.**
- **Pre-built plugins that streamline common integration tasks and enhance connectivity capabilities with a wide range of third-party systems.**





Data Security and Compliance

Establishing a Foundation of Trust

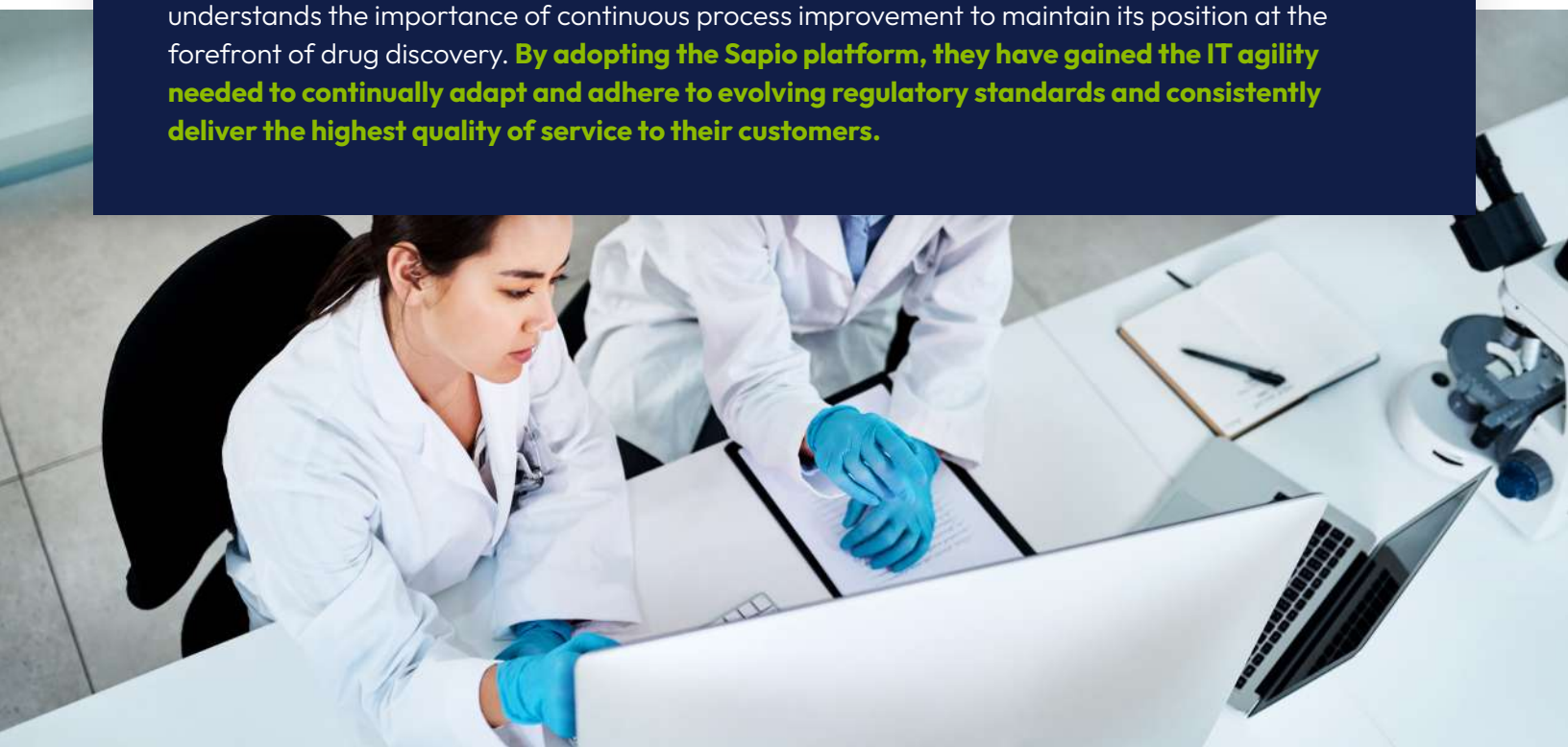
In today's interconnected world, data security and regulatory compliance are paramount. The Sapio Platform includes robust safeguards to ensure the confidentiality, integrity, and availability of all research data. The platform adheres to the highest industry standards, including:

- **SOC 2 Type II certification, demonstrating strong controls over security, availability, processing integrity, confidentiality, and privacy.**
- **ISO 27001, adhering to international best practices for information security management.**
- **Compliance with major regulations, including HIPAA, EU-US Data Privacy Framework (DPF), and EU General Data Protection Regulation (GDPR).**







Furthermore, the Sapio platform is certified for Good Laboratory Practices (GLP) to ensure the highest quality of data generation and adherence to stringent regulatory requirements. Global GLP certifications include:

- **ISO/IEC 17025, a globally recognized standard for testing and calibration laboratories.**
- **FDA GLP compliance to meet the rigorous standards of the US Food and Drug Administration (FDA).**
- **OECD principles of GLP compliance, adhering to the guidelines of the Organization for Economic Cooperation and Development.**
- **Compliance with other global regulatory bodies, including the Environmental Protection Agency (EPA), the Medicines and Healthcare products Regulatory Agency (MHRA), the China Food and Drug Administration (CFDA), and the Therapeutic Goods Administration (TGA).**

A US-headquartered leader in biopharmaceutical discovery laboratory services with over 150 facilities across more than 20 countries uses the Sapio Informatics Platform (including Electronic Lab Notebook and Laboratory Information Management System) to connect scientists worldwide, ensure compliance with global GLP standards, and safeguard the privacy and integrity of all research data. The organization, known for its decades of excellence in laboratory services, understands the importance of continuous process improvement to maintain its position at the forefront of drug discovery. **By adopting the Sapio platform, they have gained the IT agility needed to continually adapt and adhere to evolving regulatory standards and consistently deliver the highest quality of service to their customers.**



Features and Benefits of IT Agility in a Biopharmaceutical R&D Lab

 Built-in AI and Advanced Tools	<ul style="list-style-type: none">• Generative AI accessed through a simple, natural language chat interface leverages large language models (LLM) to rapidly create experiments, search and visualize data, and even generate code.• Advanced molecular tools — such as CRISPR, plasmid, and PCR design — enable scientists to quickly and easily visualize, analyze, and utilize scientific data.
 Agile Workflows	<ul style="list-style-type: none">• A comprehensive suite of pre-built, specialized workflows for rapid deployment.• No/low-code configuration capabilities enable lab scientists to quickly modify workflows without writing code.
 Automation	<ul style="list-style-type: none">• Integration with a broad range of laboratory instruments and robots.• Automation of critical operational activities such as inventory, sample, and data management.• Cloud-based architecture for continual, automated software updates.
 Unified Multimodal Data	<ul style="list-style-type: none">• A single, unified multimodal discovery platform tracks the complete lineage of every molecular entity and its component parts to integrate and harmonize collective scientific data across the entire laboratory.• A single, unified view of all information by every scientist in the lab, regardless of discipline, improves collaboration, reduces miscommunication, and accelerates delivery of complete, accurate results.
 Interoperability	<ul style="list-style-type: none">• Multiple interface and communications options — including API, Webhooks, and pre-built plugins — provide seamless integration with external systems and applications to synchronize data and automate processes across platforms.
 Security and Compliance	<ul style="list-style-type: none">• Built-in protection in accordance with comprehensive global information security and data privacy standards to assure data confidentiality, integrity, and availability.• Global compliance certifications to ensure that data generated is of the highest quality leading to better, more effective research outcomes.

Conclusion

Scientists innovate. This has been true since the 19th century, when the primary tools to conduct and document experiments in early pharmaceutical labs were glass beakers, Bunsen burners, and paper notebooks.

Today, the digitization and automation of the modern biopharmaceutical laboratory is enabling the discovery and development of new, complex modalities for innovative drug therapies. Simultaneously, AI technologies, such as machine learning, generative AI, and large language models are helping scientists rapidly search large, complex datasets, analyze and visualize selected data, and create experiments—simply by asking.

Deploying, maintaining, and extending these technologies throughout the lab requires agile IT. The Sapio Laboratory Informatics Platform incorporates features such as built-in AI, no-code configuration, open APIs/webhooks, unified multimodal data, agile workflows, and more. These features enable the platform to adapt and respond as needed to keep pace with the rapidly evolving technologies in biopharmaceutical R&D labs and accelerate the discovery of new, innovative drugs.

[Learn More](#)



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3. <https://www.bcg.com/publications/2023/benefits-and-risks-of-new-drug-modalities>
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