sapio sciences

Enhancing Drug Candidate Evaluation and Clinical Trial Progression:

The Benefits of AI-Powered, Integrated Laboratory Systems and Digital Transformation

Benefits of Digital Transformation

In biopharmaceutical development, clinical trials generate vast amounts of data from various experimental sources and methods. The ability to effectively collect, integrate, and interpret this data in a meaningful way can be a powerful tool for steering research efforts and expediting the regulatory approval process, ultimately reducing costs.

Considerations for Successful Digital Transformation in R&D

Given the volume and complexity of data generated in modern biopharmaceutical research, there is an urgent need for integrated and adaptable platforms for data handling. These solutions must effectively address critical challenges bridging data access, data privacy and analysis, collaborative research, and operational flexibility. Here, we explore the key principles that are a catalyst to accelerate complex scientific endeavors:

Data Unification

Consolidating data from various sources, including laboratory information management systems (LIMS) and electronic laboratory notebooks (ELNs), into a unified research environment. This also encompasses implementing robust data curation and stewardship practices aligned with FAIR principles to ensure data quality and accessibility.

User Access Control

Establishing rigorous user access controls and role-based permissions across all research platforms to safeguard data, ensure its integrity, and maintain regulatory compliance (e.g., with 21 CFR Part 11 on Electronic Records and Signatures). The most effective platforms implement advanced access control mechanisms that exceed basic requirements to ensure secure and controlled data access throughout the drug development pipeline, helping to protect intellectual property.

Expedited Experimental Direction

Leveraging AI-powered analytics and automated workflows to rapidly analyze experimental data, identify promising therapeutic candidates, and optimize research pathways. This significantly reduces time to market by accelerating decision-making and streamlining the drug development process.

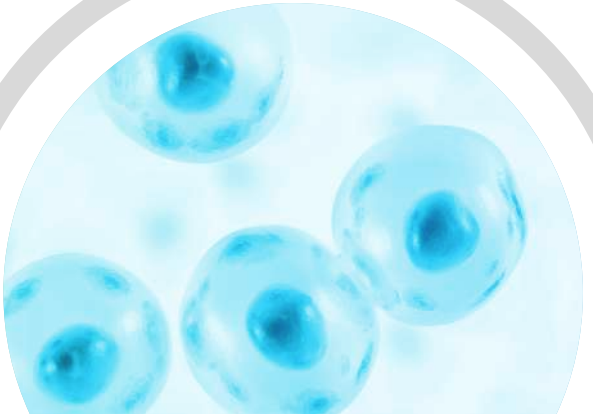
Stronger Interdisciplinary Collaboration

Promoting seamless information sharing and communication between research teams through integrated platforms and natural language processing (NLP) tools helps to break down communication barriers and foster interdisciplinary synergy to accelerate scientific discovery.

Operational Flexibility

Using highly configurable platforms enables quick adaptation to meet the evolving needs of diverse research projects and therapeutic areas, substantially enhancing research productivity by enabling rapid response to new scientific challenges and opportunities.

A seamless research platform (i.e. one environment, rather than several integrated products) is required to fully realize the potential of these advancements. Such a platform should seamlessly combine AI/LLMs, user-friendly interfaces, no-code configuration ability, and a comprehensive suite of integrated informatics tools to empower researchers with the necessary capabilities for efficient and impactful scientific discovery.



What Requirements Define a Configurable Solution?

A configurable, unified R&D workflow platform underpins this new paradigm, built on the following foundational elements:

01

AI/LLMs

Enhance research efficiency by integrating a scientific assistant that can automate repetitive experimental tasks and accelerate the analysis of scientific data.

02

Natural Language Interfaces

Simplify data exploration and interpretation by enabling researchers to interact with data using natural language queries.

03

Instrument and Software Integration

Facilitate the continuous data flow by seamlessly connecting laboratory instruments and software applications.

04

No-Code Configuration Capabilities

Facilitate the continuous data flow by seamlessly connecting laboratory instruments and software applications.

05

Centralized Informatics Platforms

Leverage unified seamless informatics platforms, combining ELN and LIMS, as the core of the electronic research environment to connect people, processes, and technology.

06

Dedicated Scientific Expertise

To successfully implement an initial minimally viable product (MVP) workflow, organizations will require the support of a dedicated team of scientific business analysts (BAs) and solution architects (SAs) to effectively define, design, and deploy the chosen solution.

Traditional ELN Limitations Hindering Effective Digital Transformation

Traditional laboratory informatics systems, such as ELNs, LIMS, laboratory execution systems (LES), manufacturing execution systems (MES), and quality management systems (QMS) frequently operate as data silos that hinder workflow efficiency and analytical throughput. These fragmented systems are ill-equipped to support the high-throughput demands of modern drug discovery, limiting real-time data integration and impeding the rapid advancement of therapeutic candidates.

Sapio Sciences believes that the pace of therapeutic development can be significantly accelerated through the implementation of a unified solution. By addressing the limitations of legacy systems, Sapio aims to help clients achieve a 2x acceleration in research progress.

Key challenges that a configurable, unified solution effectively addresses include:

Data Silos and Limited Data Integration

Traditional ELNs often operate as isolated systems, hindering seamless data flow between instruments, databases, and software applications. This data fragmentation impedes detailed data analysis and the generation of meaningful insights creating obstacles for researchers who need real-time access to unified information. The integration of additional tools, such as LIMS or QMS, can further exacerbate these data silos, making data access and retrieval more difficult.

Inability to Leverage Modern AI and AI Agents

Conventional ELNs typically lack the built-in AI capabilities necessary for effectively harmonizing and analyzing large datasets. This limitation precludes the use of AI-driven insights and deploying intelligent agents to:

Create complex search queries.

Automate repetitive tasks.

Generate hypotheses.

Optimize experimental designs.

Access a wide array of applications through a single AI-powered science assistant.

Insufficient Adaptability to Evolving Scientific Needs

Modern scientific research evolves rapidly, demanding tools that can adapt to new data types and methodologies. Traditional ELNs, with their rigid templates and workflows, often fail to keep pace with the evolving requirements of interdisciplinary research. Furthermore, integrating new instruments into these legacy systems can be a complex and time-consuming process, requiring significant involvement of the ELN vendor.

Delays in Translating Data into Actionable Insights

Legacy ELNs frequently struggle to support novel experimentation, flexible data capture, and rigorous data analysis. The absence of advanced visualization and analysis tools can significantly delay:

Extracting actionable insights.

Maintaining compliance with regulatory standards.

Achieving the high-quality clarity necessary for successful therapeutic development and FDA submissions.

Hindrance to Collaborative Research

Traditional ELNs primarily focus on static record keeping and offer limited real-time collaboration features. This limitation impedes the efficient resolution of research challenges and leads to wasted time searching for information. Consequently, collaborative efforts to address complex problems are slowed, hindering the pace of scientific discovery and innovation.

The Future:

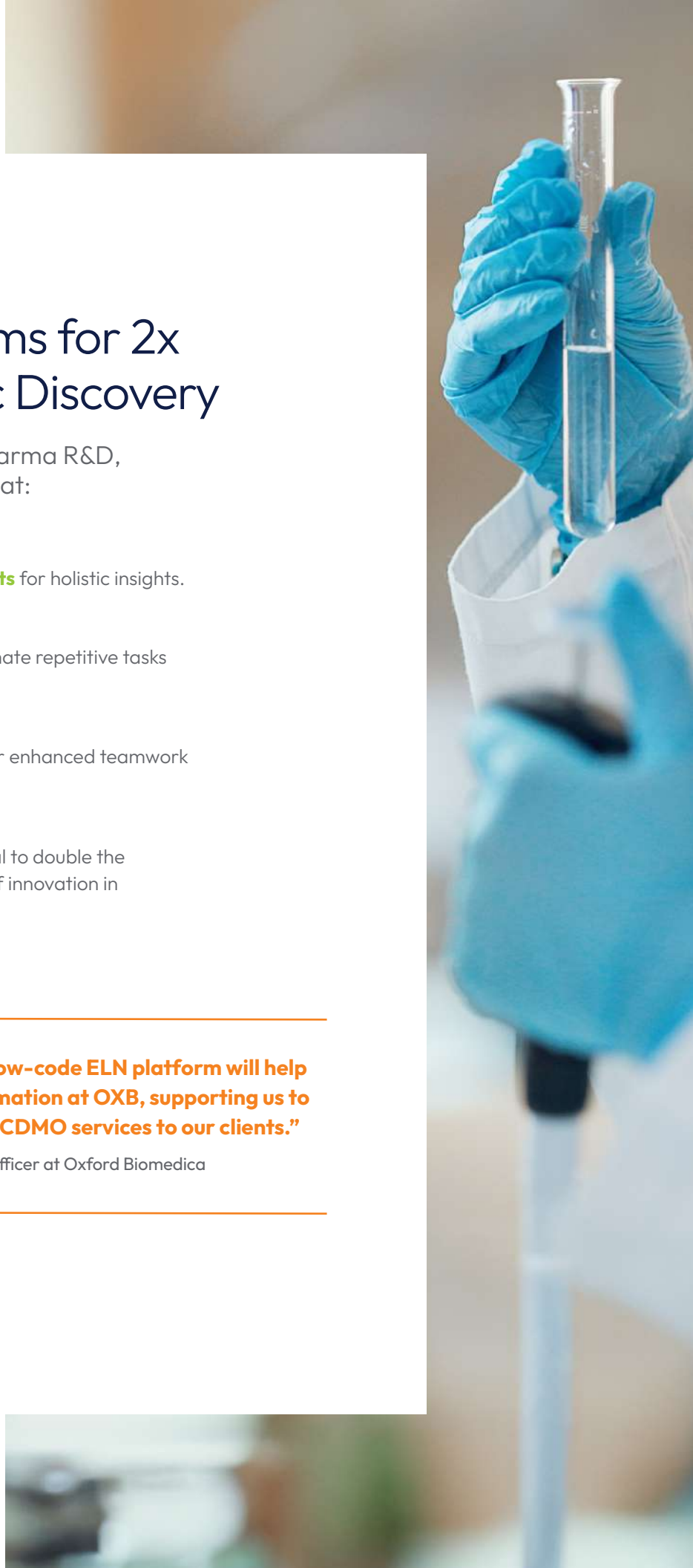
AI-Enhanced Platforms for 2x Accelerated Scientific Discovery

To meet the demands of modern biopharma R&D, researchers need dynamic platforms that:

1. **Unify data sources and instruments** for holistic insights.
2. **Leverage AI-driven tools** to automate repetitive tasks and generate actionable insights.
3. **Enable real-time collaboration** for enhanced teamwork and faster decision-making.

These next-generation platforms have the potential to double the pace of scientific discovery, ushering in a new era of innovation in biopharmaceutical research.

> **"Sapio's configurable no-code/low-code ELN platform will help to facilitate our digital transformation at OXB, supporting us to deliver high-quality viral vector CDMO services to our clients."**
>
> **– Matthew Treagus,** Chief Information Officer at Oxford Biomedica



Unified and Configurable Informatics Solutions:

Building a Future-Ready R&D Workflow

Integrated and Dynamic Scientific Tools

Dynamic, science-aware platforms must seamlessly integrate a complete suite of scientific tools, enabling:

- **Real-time access to experimental results.**
- **The creation of searchable, structured data repositories.**
- **The use of built-in analytics tailored to specific research domains, such as Preclinical Studies, Antibody Discovery, and Bioanalysis.**

Customizable and Scalable Scientific Data Management

Three core challenges significantly impede scientific progress:

01

Data Silos

The isolation of instrument and assay data within disconnected systems hinders thorough cross-experiment analysis.

02

Manual Data Processing Inefficiencies

Transcription errors and time-consuming manual data entry processes reduce research productivity.

03

Lack of Real-Time Insights

Delayed access to experimental data slows down critical decision-making processes. Moreover, relying on outdated information can lead scientists to make suboptimal research decisions and waste resources.

Modern platforms effectively address these challenges through:

No-SQL databases to accommodate unstructured and semi-structured data.

Customizable data models that align with the specific requirements of diverse experimental workflows.

Scalable architectures capable of managing large and complex datasets across Preclinical and Bioanalytical studies.

Automated data capture directly from instruments, minimizing errors and increasing the efficiency of data acquisition, thereby saving time.

Centralized, real-time data access to facilitate unified analysis and rapid data-driven decision making.

Streamlined and Efficient Scientific Workflows

Automated workflows enhance operational efficiency, allowing researchers to dedicate more time to core scientific pursuits. Key benefits include:

- **Ability to allocate tasks to the right individuals at the right time.**
- **Ability to make real-time, agile workflow updates without disruption.**
- **Assurance of compliance with role-based data access and security protocols.**

AI-Powered Innovation in Scientific Research

The integration of AI-driven tools simplifies complex tasks, empowering scientists to:

- **Automate sample tracking and data harmonization processes.**
- **Generate predictive insights for faster decision making.**
- **Detect anomalies within bioanalytical processes.**
- **Identify critical trends with real-time anomaly detection and pattern recognition algorithms.**

Accelerating R&D:

From Obsolete ELNs to Unified R&D Platforms

The shift from traditional ELNs to AI-enhanced R&D platforms is not just an upgrade; it's a paradigm shift.

By embracing unified, configurable solutions, biopharma researchers can:

- **Break down data silos.**
- **Leverage AI to transform workflows.**
- **Collaborate seamlessly across disciplines.**

This transformation is essential for accelerating science, ensuring compliance, and driving innovations that bring therapies to market faster.

Case Study 1

Global CDMO Accelerates Global Operations with Sapio Sciences

A global leader in contract research and development, operating 150 facilities across 20 countries, partnered with Sapio Sciences to modernize and unify their informatics network. Facing the critical need to ensure compliance with dynamic global Good Laboratory Practice (GLP) standards while simultaneously safeguarding data privacy and security, the organization adopted Sapio ELN to digitize workflows and seamlessly integrate sample management range of platforms. Sapio provided a highly configurable and adaptable ELN solution capable of supporting thousands of scientists in a secure, paperless environment, and enabling them to adhere to rigorous FDA, EMA, and OECD regulations. The system was specifically designed to accommodate the diverse workflow needs of the organization, encompassing a wide range of research areas, including bioanalysis and genomics.

In collaboration with Sapio Sciences' team of scientific experts, the client employed a tailored "hybrid agile" methodology to successfully implement the ELN across 17 sites with varying operational requirements. This phased approach ensured minimal disruption to ongoing research activities while meeting the stringent validation requirements for cloud hosting, robust sample management capabilities, and inventory modules. This collaboration not only successfully digitized the organization's operations but also improved efficiency and adaptability. By leveraging the power of the Sapio ELN platform, the client has sustained their leadership position in delivering rapid, reliable, and high-quality R&D services, ultimately accelerating the journey from scientific discovery to marketable therapeutics.

Read the full case study here.

The Challenge

Ensuring GLP compliance while unifying global informatics.

The Solution

Hybrid agile ELN implementation with secure, configurable workflows.

Case Study 2

Leading Neuroscience BioTech Accelerates R&D Beyond Terabytes of Data with Sapio Sciences

The Challenge

Managing exponential growth of multi-omics and histology data.

The Solution

Unified LIMS, ELN, and SDMS with automated, scalable workflows.

A biotechnology company specializing in personalized cell therapies encountered significant challenges stemming from the exponential growth of their research data. As the company evolved from a startup to a mid-size clinical entity, their R&D capabilities began to generate a deluge of data, encompassing whole genome sequencing, multi-omics, and histology. This data explosion necessitated a robust, scalable solution for effective management and analysis. The company partnered with Sapio Sciences to implement the Sapio Platform, a unified system that seamlessly integrates LIMS, ELNs, and scientific data management systems (SDMS). The company launched a three-phase project to transform data management practices within the organization. Phase 1 focused on automating workflows and improving sample tracking accuracy. By replacing labor-intensive, manual processes with dynamic, barcode-driven sample management, the company reduced the incidence of errors and inefficiencies, enabling their research scientists to devote more time to critical research activities.

The comprehensive data integration capabilities and no-code configurability of the Sapio Platform allowed the biotech company to seamlessly adapt workflows to its unique research needs. The platform leveraged the integrated data analysis capabilities to facilitate more informed decision making, empowering the scientists to delve deeper into experimental results to extract valuable insights that would have remained obscured within vast datasets. Looking ahead, Phase 2 of the project will expand data tracking to include histology and translational research, while Phase 3 will integrate legacy and real-time datasets into a single, accessible platform. Through this strategic implementation of the Sapio Platform, the company is not only optimizing current processes but also proactively preparing for the future of data management in scientific research, ensuring scalability and readiness to effectively manage the volumes of data to be generated in the post-terabyte era.

Read the full case study here.

Case Study 3

Schrödinger Accelerates Drug Discovery with Sapio Sciences

Schrödinger, a global leader in computational chemistry and drug discovery, revolutionized its wet lab operations with Sapio Sciences' integrated informatics platform. Transitioning from reliance on external contract research organizations (CROs) to in-house lab work, the company needed a robust, integrated informatics solution to digitize operations, manage massive datasets, and enhance traceability. By selecting the Sapio platform, which unifies LIMS and ELN functionalities, Schrödinger addressed critical challenges such as creating end-to-end audit trails, automating resource tracking, and tailoring workflows for specialized processes such as plasmid expression and protein purification. Sapio's advanced search capabilities and flexible customization ensured seamless integration into existing workflows while providing the flexibility to support future innovation.

The results were transformative. Research teams gained unprecedented visibility across the entire drug discovery process, from plasmid design to characterization of target structure, with cost tracking and resource allocation insights. Automated data capture simplified audit processes, supporting regulatory compliance and providing leadership with a clear and concise view of laboratory performance. The platform's robust data retention capabilities ensure that Schrödinger's scientists can access and use decades of historical experimental data, enabling continuous improvement and driving innovation. By implementing Sapio's platform, Schrödinger has accelerated drug discovery, improved efficiency, and established a scalable foundation for future advancements in life sciences and materials science research.

Read the full case study here.

The Challenge

Managing in-house lab operations with complex datasets and workflows.

The Solution

Unified LIMS and ELN for end-to-end traceability and automation.

Schrödinger

> **"Working with Sapio Sciences marks a significant step forward in our workflow and data management capabilities. The highly flexible Sapio solution nicely captures our existing workflows, streamlining data capture and processing, requiring only limited retooling of our processes or retraining for our employees. It also provides a platform for future growth and optimization, and we are confident that this integration will enhance our ability to serve our global client base with even greater efficiency and precision."**
>
> **– Stefan Schmidt,** CEO of evitria

Conclusion

Biopharma R&D is at a turning point. Traditional ELNs have proven inadequate to meet the demands of modern, complex science. Unified informatics platforms offer a transformative approach to accelerating complex scientific research and development.

These advanced platforms enable:

- **Comprehensive data integration** and a single point of data access.
- **AI-powered acceleration of scientific processes,** including experiments, data analysis, and decisions.
- **No-code configurability** for enhanced agility to connect people, processes, and technology
- **Seamless collaboration** and adaptability.

By adopting these advanced informatics platforms, biopharmaceutical organizations can double the pace of discovery, ensuring that biopharma innovation keeps pace with the challenges of the future.

Find out more about Sapio ELN

Learn More

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