BIOVIA

3DEXPERIENCE®

ACCELERATING DISCOVERY WITH IMPROVED IP MANAGEMENT

STREAMLINING LAB EXECUTION WITH BIOVIA

Use Case

DASSAULT SYSTEMES

Challenge:
Increasing pipeline to mitigate the risk of failure in clinical stage; decreasing time-to-market to keep pace with competitors; enabling collaboration while avoiding IP loss; complex and inflexible IT landscape; risk of losing innovation culture during business transformation.

Solution:
BIOVIA Workbook, BIOVIA Chemical Registration.

Results:
- Data-driven innovation
- Single source of data across chemistry and biology
- Enhanced oversight/decision support
- Faster project cycle times
- Improved IP retention/protection
- Elimination of redundant work
- Enhanced internal/external collaborations
- Faster time to market

CUSTOMER: A LEADING, CLINICAL-STAGE BIOTECHNOLOGY COMPANY

This biotechnology company specializes in the discovery and development of small molecule medicines with novel modes of action. Their pipeline comprises Phase 1-3 studies, pre-clinical studies and discovery programs in inflammation, fibrosis, osteoarthritis, metabolic diseases and other indications. The company's workforce includes more than 300 R&D specialists engaged in the discovery of breakthrough therapies for the treatment of unmet medical needs.

CHALLENGE: EXPANDING PIPELINE, MANAGING IP WITH PARTNERS

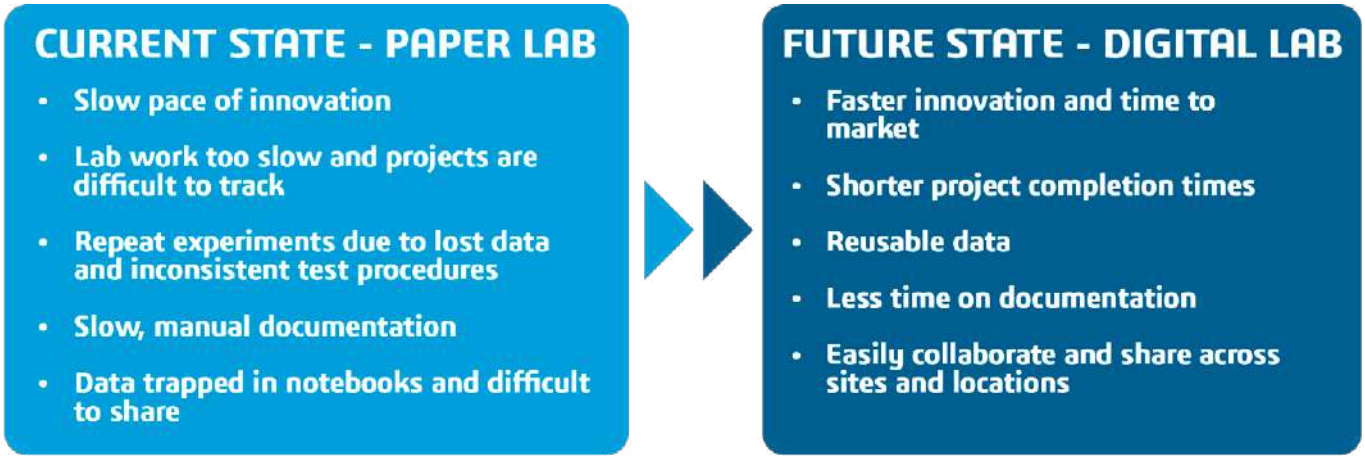
IResearch and Development is this company's innovation engine. For this reason, they require a robust lab informatics infrastructure with all processes supporting a healthy product pipeline. Inefficient lab workflows and poor visibility across research data was threatening to jeopardize clinical programs, from discovery to registration and beyond. The company wanted to improve data and process standardization, automate routine activities and avoid duplicating experiments. They also wanted to secure their intellectual property (IP) and minimize the risk of confidentiality breaches, while also supporting long-term, risk-sharing collaborative partnerships with top pharma companies. To address these challenges, they needed to replace their legacy, paper-based processes with an entirely digitalized lab environment that supported the innovation lifecycle from target identification to compound discovery and process development.

SOLUTION: MOVING FROM AD HOC, OPPORTUNISTIC PRACTICES TO REPEATABLE, OPTIMIZED PROCESSES

This company's new integrated R&D environment features the BIOVIA Workbook electronic laboratory notebook (ELN) as the main access point for workflow execution and scientific information, allowing scientists to retrieve and share information through a single software interface. They have also implemented BIOVIA Chemical Registration, a flexible, fully featured, web-based solution for building, managing and searching corporate substance and batch databases. BIOVIA Workbook consolidates experimental data from multiple domains into fully versioned, shareable and searchable documents controlled by document workflows with secure versioning, electronic signatures and audit trails. The integration of BIOVIA Workbook with other laboratory systems eliminates time-wasting, error-prone manual data transfer and streamlines data sharing across systems. Chemistry and biology experiments are stored in the same Workbook repository but have different folders and use different templates within the system.

> "Our move to a paperless lab has been very successful with early and rapid adoption of BIOVIA Workbook. This was largely due to thorough acceptance testing and an extensive e-learning program, both of which were developed in close coordination with BIOVIA."
>
> — Director, Screening & Operations
> Leading Biotechnology Company

Both chemistry and biology ELN deployments utilize a phased approach in which Phase 1 focuses on the transition from paper-based to electronic notebooks. For example, Phase 1 of the biology ELN kept the ELN setup as simple and straightforward as possible with one generic experiment template and limited integrations between the ELN and other lab systems. Phase 2 of the biology ELN will embed two additional templates in the system, one for in vitro experiments and one for in vivo experiments. Phase 2 templates will contain more structured fields, allowing more options for structured searches in the Workbook. In addition, the company will set up a web service integration between Workbook and their LIMS to retrieve information on plate content and new substances. They are also planning to integrate Workbook with their Biobank system, so that scientists can link experiments to Biobank samples.



With regard to Workbook user roles, the company has identified an administrative role for business users and two scientific roles. Regular scientific users can create experiments, query experiments, send experiments through the review workflow, collaborate with colleagues in their experiments and create experiment reports. Advanced ELN users receive additional training, allowing them to assist regular users with questions on functionality. Advanced users can create subfolders in the ELN and customize the master template, e.g., by prepopulating some fields or sections in the template and saving it as a new template. They can also save an imported Excel file as a new section template, so that users do not need to reimport the same Excel file repeatedly.

The company has validated its Workbook system as non-GxP compliant because they use it exclusively in R&D. With this in mind, they have adopted a lean validation approach that documents all testing and training requirements using System Development Life Cycle (SDLC) best practices. BIOVIA provides deliverables related to system testing and deployment, while the company provides deliverables related to acceptance testing. Training is a combined effort between BIOVIA and the customer. BIOVIA handles the training for third-party acceptance testing contractors. The customer is responsible for training their ELN users.

RESULTS: STREAMLINING LAB EXECUTION AS A FORCE MULTIPLIER FOR R&D PRODUCTIVITY

BIOVIA Workbook offers tools for leveraging data across all R&D functions at this company, while also helping to establish data standards supporting data accuracy required for actionable data analysis. The digital continuum provided by BIOVIA supports a single source of data across chemistry and biology, enhancing oversight and decision support, reducing the number of repeated experiments, accelerating project cycle times and improving IP retention/protection for more effective pipeline innovation. Centralized IP protection and retention makes it much easier for this customer to establish provenance in cases of dispute.

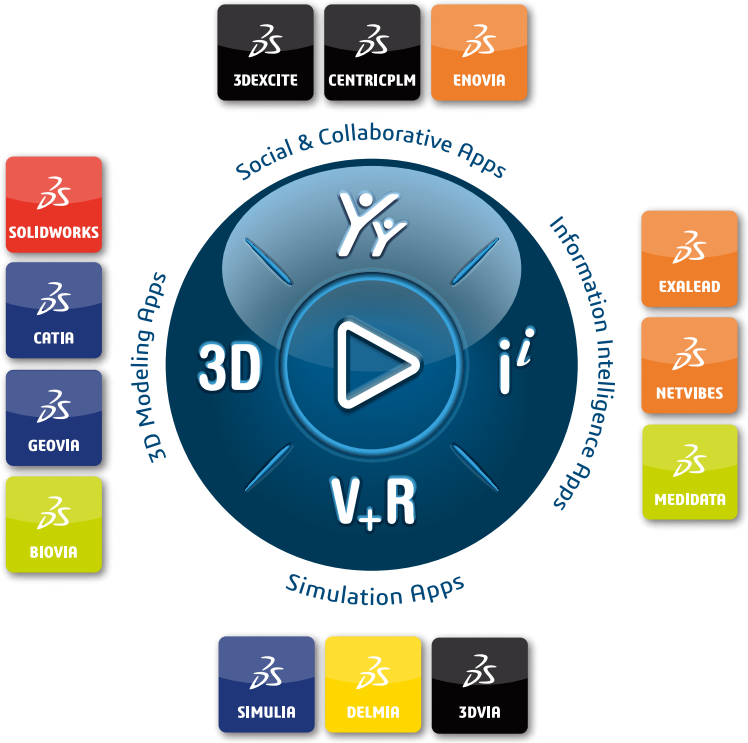
The ability to transfer lead compounds successfully to the clinical stage depends largely upon internal and external collaborations involving teams. BIOVIA Workbook allows this company to fine-tune data visibility across projects and partners in different geographic regions and disciplines. This makes it possible for them to manage data and information in an agile workflow environment with disparate confidentiality demands.

The company attributes their successful initial deployment of BIOVIA Workbook to three critical factors:

- **Excellent preliminary workshops** with BIOVIA solution architects and specialists, allowing the customer to understand BIOVIA Workbook's functionality while also educating BIOVIA about the customer's needs
- **Efficient and thorough User Acceptance Testing** involving ten business users from different sites and departments, all of whom were encouraged to look beyond the test scripts and conduct exploratory testing as required
- **Early and high user adoption** with most users switching from paper to digital within two weeks and all users transitioning within one month

This company's R&D group is now poised to realize significant value from adopting the combined BIOVIA Workbook and BIOVIA Chemical Registration solution, which accelerates innovation, increases efficiency and extends a digital continuum across all collaborators within this company's drug discovery and development process.

LEARN MORE



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