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## CASE STUDY

Selecting an R&D Data Management Platform to Support the Development of Novel Antibody-Based Therapeutics



ProPharma has supported the selection of an R&D data management platform for a commercial-stage Biotech based near Munich, whose focus is on the development of monoclonal antibody-based therapeutics.

The company was reliant on paper-based processes, but laboratory staff were very busy with day-to-day project work, so it was difficult to find the time needed to dedicate to look for a new electronic solution.

Representatives from this company spoke with colleagues at another biotech in the local area who recommended they contact ProPharma.

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From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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#### What Process was Followed?

ProPharma used our established, proven Digital Blueprint methodology, which leverages our extensive experience delivering similar projects. This highly effective methodology is designed to reduce the time required by scientists, enabling them to focus on delivering R&D projects.

Through a series of interviews with subject matter experts and key stakeholders from across the R&D and IT organizations, ProPharma was able to rapidly develop a thorough understanding of the 'as is' situation, the resulting business implications and identify and prioritize key areas to address to improve the flow of data through the organization, increase data integrity and traceability and improve the degree to which data could be reused.

#### What were the Key Findings?

Following the stakeholder interviews, ProPharma generated a comprehensive set of findings and recommendations.

The R&D teams were reliant on Excel-based processes for data capture and analysis, with heavy use of fragile macros. Documenting experiments involved many hours of 'arts and crafts', printing instrument output files and spreadsheets and sticking them into paper notebooks. Scientists also relied on a legacy freezer inventory system that did not meet their needs and was completely disconnected from the other aspects of the data management process.

Data was difficult to find as it was stored in data silos and managed inconsistently. There was no easy way to perform data analytics and trending as data was unstructured and often inaccessible. There was also a lack of traceability from experiment execution to data analysis and documenting results.

Consequently, researchers were spending a significant proportion of their time away from the bench.

#### What Were the Immediate Priorities?

ProPharma provided clear, actionable advice on where the company should focus its resources to embark on an efficient and impactful digital journey. This included a digital roadmap and systems landscape which made it simple to visualize how different capability would fit into the wider R&D informatics ecosystem and easily identify where technology investments could be directed to have the highest impact. Each of the R&D processes was visually mapped to highlight bottlenecks. 'To be' maps were also created to illustrate how the data would flow once improvements had been implemented.

Based on the highest priorities, ProPharma documented detailed requirements, linked to business use cases, and provided independent advice and support through a technology selection process. Using our proprietary database of lab informatics technologies, we compiled an initial list of those candidates with the best match to the requirements and co-ordinated initial demonstrations. The most promising suppliers were shortlisted to proceed to a Request for Proposal and in-depth, use-case driven, workshops from which a preferred solution was identified.

We also developed a tangible, quantifiable Return on Investment (RoI) analysis which formed the basis of a robust business case.

While this biotech company is at the start of the digital transformation, we are proud to have supported their first steps of their digital journey and are looking forward to continuing our fruitful collaboration.

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