

CASE STUDY:

Informatics Roadmap for a Global Biotechnology Company

OVERVIEW: A global biotechnology company focused on discovering and developing treatments for people living with rare metabolic diseases maintained R&D facilities around the world and had plans to develop manufacturing facilities in the near future. The organization engaged in collaborations with Universities and worked with clinical research organizations (CROs) in the testing and analysis of samples.

The company had been managing its scientific data with an ELN and a variety of paper/Excel based processes and recognized the need for long-term R&D informatics Strategy and Roadmap aligned with the needs of their R&D activities. Due to our expertise with strategic planning, the customer

engaged Astrix Technology Group to help create a comprehensive global informatics roadmap that encompassed an enterprise-wide program supporting all functions from early research through commercial operations.



BUSINESS CHALLENGE: As a consequence of utilizing paper-based processes and a lack of an integrated informatics roadmap, the customer was experiencing a number of business challenges:

- Multiple approaches to sample accessioning, which prevented understanding of sample provenance.
- Multiple materials registration processes dependent upon type, which prevented understanding of material provenance.
- Multiple sample lifecycle management and inventory tracking systems, resulting in no consistent sample chain of custody data available from accession to disposition.
- Multiple approaches to and archiving raw and intermediate data files, presenting challenges for find-ability.
- No uniform traceability among data or referencing of source data, which inhibited timely action and decisions based on experimental data.
- Lack of authoritative repository of project work, inhibiting the ability of project leads and steering committees to find available information when working with external collaborators and submissions.
- Lack of structured experimental results data storage, which did not support direct access to experiment results data in a form suitable for analytics.
- Lack of an overall request tracking mechanism, preventing the systematic tracking of work in progress (either internally or at external partners).
- Inefficient data consolidation from experimental work performed by external partners, generally requiring manual effort on the part of company scientists to record in current systems.

The Astrix Team developed a global Informatics Roadmap that provided guidance on the order and priority of implementation to achieve the desired future state environment.

In order to address these challenges, Astrix was contracted to develop a strategic plan that recommended:

- An informatics strategy aligned with the company's R&D strategy, effectively providing a scalable, integrated platform to foster collaboration and access to data.
- A robust and scalable overarching R&D information/data architecture.
- Set candidate system architectures and a recommended Roadmap with estimated timelines and resource requirements.

SERVICES PROVIDED

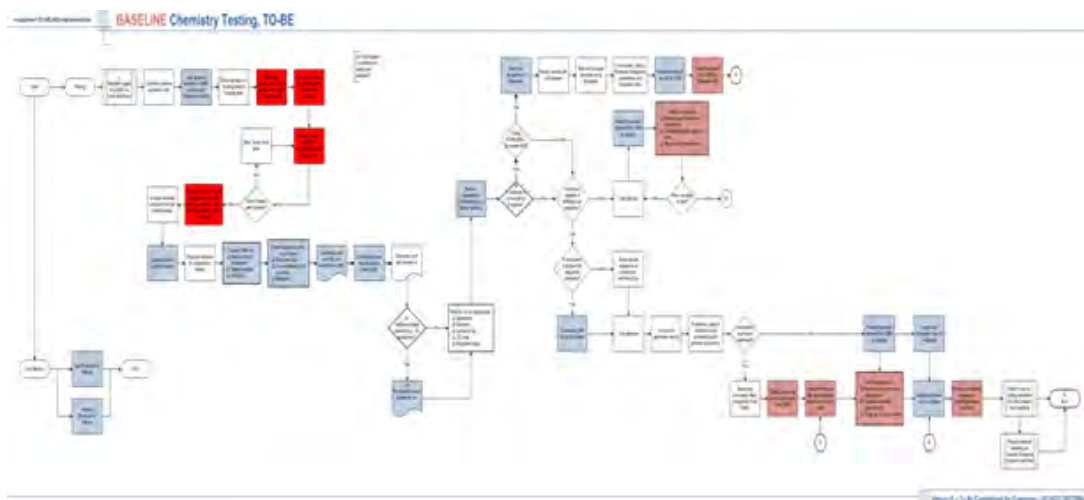
There were a number of steps involved in the production of a comprehensive, global Informatics Strategy and Roadmap. Astrix provided the following services to the customer:

Project Initiation and Kickoff Meeting – Prior to any site visits, the Astrix team reviewed available information about the customer's laboratory environment, processes and procedures in an effort to become familiar with the customer's operations. The kickoff meeting served to introduce Astrix team members and the customer's project team staff. In addition, the project scope and approach were reviewed and finalized with input from the customer to establish a shared project vision and focus. The end result of this phase was a finalized Project Plan that was delivered to the customer.



Current and Future State Assessment – These assessments established the foundation for the Informatics Roadmap. The Astrix team met with over 10 different stakeholder groups to conduct interviews that were used to develop the current state or "As-Is" work process maps. These As-Is process maps served to identify inefficiencies and wait states and thus helped guide development of the optimized future (To-Be) state work processes that detailed process improvements. The To-Be maps were also used to define critical system requirements that factored into candidate system architectures and the IT systems Roadmap. Both As-Is and To-Be process maps were provided to the customer's project team members for review and discussion before being finalized.

Example To-Be Process Map



Business Needs Assessment. In order to develop a robust candidate solution architecture, the Astrix Team collected information on the customer’s overall business drivers and specific strategic R&D initiatives during stakeholder interviews. Key areas addressed included:

- Current R&D and enterprise systems inventory
- Management of master and reference data
- Transactional data structures and inter-system data flow
- Analytical and reporting requirements

All information gathered was summarized in a Business Needs Assessment Report for the customer.

Informatics Roadmap. Leveraging the process maps and the Business Needs Assessment, the Astrix Team presented candidate architectures to the customer that included target systems, scope use, deployment models, approaches to supporting future workflow/processes, and high-level assessments of cost-benefit tradeoffs as well as potential technical and business risks. Following an agreed-upon direction from the options presented, the Astrix Team developed a global Informatics Roadmap that provided guidance on the order and priority of implementation to achieve the desired future state environment.

Factors that contributed to development of the Roadmap included:

- Direct and Indirect project costs
- The rate of return on project investments
- Business priority of the capability to be delivered
- The potential for organizational disruption from the project
- Cost-benefit and technical dependencies in system integrations

The roadmap included the following:

- A recommended 3 to 5-year R&D informatics strategy
- Candidate high level architectures with recommendations
- Structure for projects to reach the recommended architecture
- Potential project approaches and high-level timelines
- High-level internal and external resource requirements



In addition , the Astrix Team delivered an on-site presentation based on the final report to management and key stakeholders.

RESULTS DELIVERED: The Astrix Team provided a comprehensive global informatics roadmap across the enterprise that resulted in the elimination of manual and paper-based processes, established authoritative and structured data repositories, and uniform traceability protocols. The optimized informatics structure significantly improved all R&D functions across the global organization from early research through commercial operations, enabling material provenance, chain of custody tracking, and improved searchability of data and project files. The new robust informatics strategy provides a scalable, integrated data architecture capable of fostering seamless collaboration within the company’s R&D divisions.

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ABOUT US:

Astrix Technology Group Astrix Technology Group has over 25 years' experience helping scientific organizations architect, select, implement, integrate and validate laboratory informatics technologies. Our experienced professionals have the skills necessary to help your laboratory turn data into knowledge, increase workflow efficiency, improve quality and facilitate regulatory compliance.

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