Business Sector: **CLINICAL**

CASE STUDY:

LIMS Biobanking Roadmap for Clinical Trials Sample Management

OVERVIEW: A prominent biotechnology institute managed biospecimens using a vendor supplied system, paper-based processes and homegrown informatics platforms to generate, process and store information. To support the growth of the business, the institute recognized the need for a more robust and automated biospecimen management system as well as LIMS to support GxP in laboratories under development.

The institute engaged Astrix to create a comprehensive strategic plan for the future state of the informatics platform that encompasses an enterprise-wide program supporting all functions of the business including the management of samples for clinical trials.

BUSINESS CHALLENGE: The institute required a fully automated biorepository for the collection, processing and distribution of biospecimens to support clinical trials at cancer centers worldwide. The workflow needed to include the ability to:

- Identify which samples from their bank of biological specimens to include in each clinical study based upon specific criteria
- Manage the location and data for clinical samples, following GxP regulations
- Track the shipment of clinical samples to and from various cancer centers worldwide
- Maintain the associated consent and HIPAA forms

To support the growth of the business, the institute recognized the need for a more robust and automated biospecimen management system as well as LIMS to support GxP in laboratories under development.

SERVICES PROVIDED: Astrix's approach and methodology for satisfying the objectives of the project were comprised of four primary workstreams within the Research Operations group:

Project Initiation and Kickoff Meeting. Astrix reviewed all available documentation covering the institute's environment, process, and procedures to become familiar with the current operations. A conference call was held with the institute's staff to request relevant information, review the existing environment, plan the upcoming Kickoff Meeting, and coordinate with any other initiatives as needed. The Kickoff Meeting was fundamental in confirming project direction, and was scheduled ahead of any substantive project activities.

At the conclusion of the Kickoff Meeting, a finalized project plan was completed, the team was formed and chartered, initial relevant material was collected and reviewed, and any concerns about the plan were addressed.

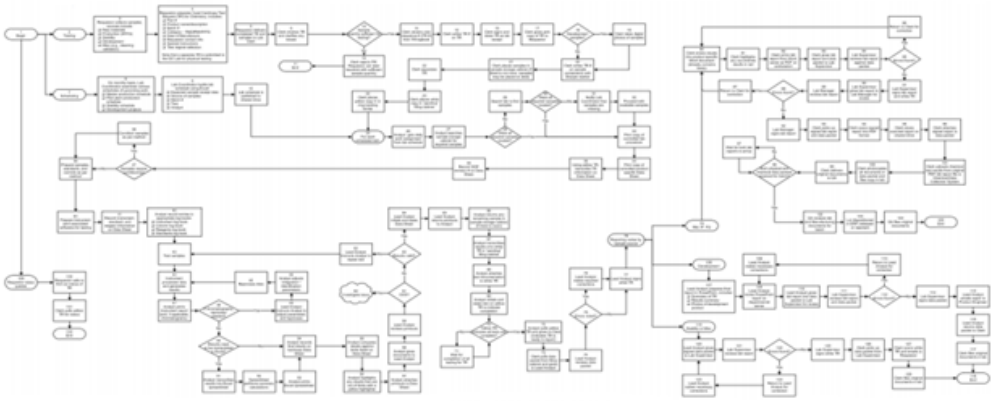
Business Process Analysis. The Business Process Analysis allowed Astrix to understand the institute's current processes and procedures. The objectives of this task were to develop the current state or "As-Is" process maps and begin to develop the future "To Be" processes. This was accomplished in group workshops and individual interviews. This was a critical phase of the project, as it established the foundation for assessing the benefits that may be achieved in a future state. The current state (As-Is) process maps were used to identify inefficiencies and wait states and served as the underpinnings for process improvements. The To-Be state maps will also define critical system requirements that factor into candidate system architectures and the IT systems Roadmap.

Astrix met with all of the stakeholder groups to understand each individual step in the process to develop a complete map that identified and detailed even the smallest parts of the process. To extract the most accurate picture of the current state, these are sessions were designed to "spend a day in their shoes". The stakeholder groups included:

- Management and Executives
- Clinical Operations
- Cell Therapy
- Information Technology
- Translational Medicine
- Bioinformatics
- Research Operations

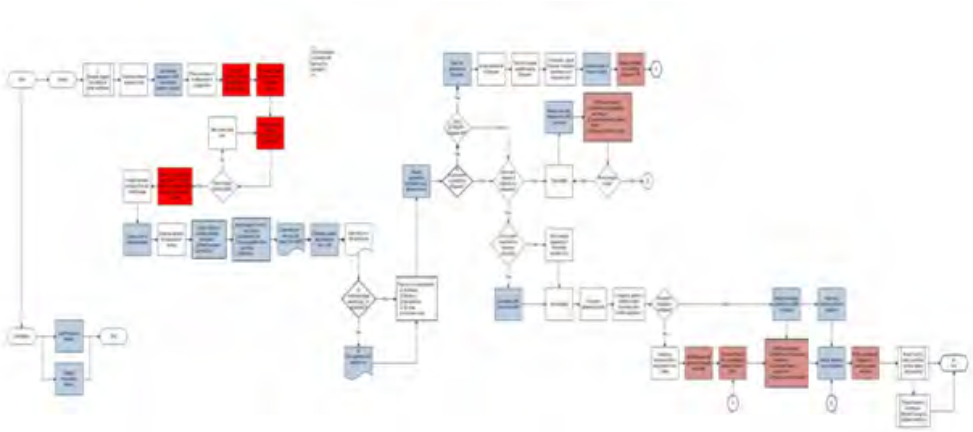
A representative As-Is Process Map is provided in Figure 1.1.

Figure 1.1 Representative As-Is Process Map



After the completion of the As-Is portion of the assessment, Astrix used its experience in process analysis and optimization, informatics systems implementations and operations, and industry best practices to construct potential To-Be process maps. The maps were provided to the institute for review and discussion before they were finalized. A representative To-Be Process Map is provided in Figure 1.2.

Figure 1.2 Representative To-Be Process Map



Business Needs Assessment. To obtain the goal of developing a robust solution architecture for the institute, it was important to understand the business drivers for the institute overall as well as specific strategic initiatives. The Business Needs Assessment gathered key information regarding this to support the critical requirements of the informatics ecosystem. This part of the assessment included meetings and interviews with the stakeholders and were performed in conjunction with the Business Process Analysis meetings. Key areas included:

- **Functional area review**
  - Business/system processes
  - Integrations and data flow
  - Data integrity aspects
  - Roadmap priorities
- **Architecture topics for growth**
  - Developing master data management
  - Evolving additional value from data
  - Addressing records retention and data archival
  - Mitigation of external data risk
- **Overall informatics platforms analysis**
  - Authoritative data systems
  - Strategy and roadmap against plan/build/run model
  - Governance
- **Transactional data structures and inter-system data flow**
- **Analytical and reporting requirements**

After gathering this information, Astrix produced a Business Needs Assessment that summarized key findings and observations. This assessment along with the process analysis formed the building blocks to the subsequent task of developing a biobanking informatics roadmap.

Biobanking Informatics Roadmap. Leveraging the Process Maps and Business Needs Assessment, Astrix considered high-level candidate architectures to satisfy the project objectives. These candidate architectures 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 a discussion of the candidate architectures and an agreed-upon direction from the options, Astrix formulated a recommended Biobanking Informatics Roadmap that provided guidance on the order and priority of implementation to achieve the desired future state environment.

The primary factors that contributed to establishing the biobanking roadmap were:

- 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

Astrix weighed these factors, in discussion with the institute's stakeholders, and leveraged industry best practices to develop a roadmap that most efficiently met the needs identified in the Business Needs Assessment.

The final Roadmap included:

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

Astrix delivered a draft of the Roadmap for discussion with the institute. Using feedback from the review, Astrix revised the document and delivered an on-site presentation based upon the final report to management and key stakeholders.

RESULTS DELIVERED: Biomedical research provides the basis for the prevention and treatment of disease in humans. This important area of research is supported by clinical trials, which are phased studies using human volunteers, and are designed to study the safety and efficacy of new biological therapies, medical devices or potential new treatments. The successful clinical trial is reliant upon the quality management of biological samples throughout the entire biomedical research lifecycle. The ability to effectively collect, store, classify, ship and track these samples, all within GxP guidelines, is paramount to managing an efficient biobanking repository.

The biotechnology institute recognized that their manual processes, homegrown systems and not 'fit for purpose' informatics technologies were unable to sustain the effective operation of a best-in-class biobanking organization. The Astrix team was able to provide an automated, integrated informatics strategy that was aligned with the institute's business goals. Through the design of a robust and scalable overarching data architecture design, Astrix delivered:

- An optimized future state biobanking informatics roadmap
- A set of candidate system architectures to support the roadmap
- Estimated project and delivery timelines
- Resource requirements for the timely completion of project

Astrix's extensive experience in process analysis and optimization, informatics systems implementations and operations, and industry best practices were essential in constructing a comprehensive strategic plan for the future state of an enterprise-wide informatics platform to support all functions of the institute's growing biobanking operations.

ABOUT US:

Astrix has been an industry leader for over 25 years in helping scientific organizations implement and integrate new informatics systems in the laboratory. Our experienced team of expert informatics consultants bring together technical, strategic, regulatory and content knowledge to provide the most effective solutions to problems faced by scientific organizations. Our domain experts have helped hundreds of companies globally effectively navigate their digital transformation journey.
Visit astrixinc.com for more information.

CORPORATE HEADQUARTERS
125 Half Mile Rd, Suite 200
Red Bank, NJ 07701
732-661-0400