

Informatics for the Laboratory

Laboratory managers and information technology professionals are under increasing pressure to improve efficiency, reduce costs, shorten the time to market for new compounds, and improve regulatory compliance and data quality. Through the assistance of software technology, organizations feel they can accomplish many of these objectives. However, with the plethora of software solutions available, it is common to see these companies struggling with the development of an informatics strategy. *Where does one begin?*

Every week a new category of scientific software seems to be emerging. Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELN), Scientific Data Management Systems (SDMS), Enterprise Content Management (ECM), Laboratory Process Management (LPM), instrument automation, and other software solutions all help to improve some aspect of laboratory effectiveness. Unfortunately, the current state of available solutions demands that the modern laboratory deploy multiple solutions requiring integration. This further complicates strategy development. *What will my system architecture look like? How will my data flow?*

Based on several decades of industry experience with LIMS, instrument automation, ELN, CDS, SDMS, cheminformatics, and ECM combined with our market research reviewing industry best practices, Atrium Research has developed a systematic process for the development of an informatics strategy. Our Clarity, Vision, Enlightenment™ (“CVE”) process helps guide organizations through the minefield of conflicting technologies and vendor claims.

Our method looks at organizational objectives, the creation of an articulated vision, and the development of a strategy with measurable goals and objectives. This strategy provides the foundation for the analysis and streamlining of processes prior to decisions regarding technology and suppliers. We realize that organizational and operational changes are required *before* the implementation of technology. Only through a

detailed understanding of where the organization is now and where it needs to be can an informatics strategy be effectively developed.

Vision Drives Strategy - Strategy Drives Process

Over 60% of laboratory informatics projects fail to meet initial system expectations. Why is this? Well, this is primarily due to:

- Lack of strategic alignment
- “One-off” departmental solutions
- Poor requirements analysis and definition
- Poor project planning and management
- Insufficient resources and funding
- “Scope creep” or out of control requirements
- “Committee-itis”
- Lack of internal communication
- Lack of management support
- Over commitment and poor expectation setting
- Software that does not tie to organizational objectives
- Lack of change management and resistance to change

These problems are avoidable with the proper strategy, planning, process analysis, and change management. Our gate-based method is designed to avoid spending large sums of money until information data flows are well understood, processes are simplified, resources are allocated, and a business case is signed off with all stakeholders. We work with organizations to implement the process, help guide it, or actively manage it depending on the needs of the client.

As shown in Figure 1, we start by helping to formulate a *Vision Statement*. The Vision Statement outlines the organization’s strategy, what the laboratory has to do to meet that strategy, the definition of the informatics problem, and a vision for the solution. Current practices are compared to industry best practices and technology trends. A gap analysis determines what needs to be addressed in the strategy.

Once the Vision Statement is signed off, a small, manageable, and decisive project team representing stakeholders is created. This team, working in conjunction with an executive sponsor and/or steering committee, is lead by an overall project manager. This team is comprised of the best talent in the organization – projects often fail due to improper attention to the make-up of the project team.

What follow is the development of a *Strategy*. Based on the foundation of the Atrium Research modified SEI Capability Maturity Model (CMM), this strategy outlines the requirements to meet the vision, scope, stakeholder's needs, business expectations, financial objectives, priorities, and estimates of resources to move forward. The strategy is a realizable set of tangible goals with achievable objectives. These goals and objectives are consolidated into a project planning document with assigned resources.

The strategy addresses much more than just technology. Legal, regulatory, and record management requirements are defined. The overall process and structure governance for scientific data management is addressed (an example of a governance structure is shown in Figure 2.) Information Lifecycle Management (ILM) and infrastructure needs of the organization are evaluated. Gaps in infrastructure are identified goals with specific objectives to attend to.

As part of the scientific data management strategy, laboratory processes and data flows are typically documented. Understanding workflow starts at a high level with special attention to those processes that link to strategic objectives. These are analyzed for opportunities for process optimization. The benefit of this approach is to guide the client toward how the processes *should* work, rather than how they currently exist. Implementing software to duplicate what is currently done is rarely successful.

Through the analysis and benchmarking of current operations, a formal *Business Case* is developed to address the financial goals of the strategy. The Business Case describes the organizational impact of a solution and process changes, outlines the

financial impact (i.e. return on investment), the required resources (money, personnel, time), risks and dependencies, and the impact of the projects on the organization. This document is routed for approval and a *go or no-go* decision is reached with management before the strategy proceeds. This creates a foundation for an informatics strategy that is fact-based and agreed and understood by all impacted parties.

If a "go" decision is reached, functional and non-functional requirements are developed within the scope of specific projects. Based on the processes that will be used and a clear description of the project scope, these requirements are defined in a clear and unambiguous fashion. *Use Cases* are used to bring life to a requirement. Use Cases describe a real life scenario, how the processes are used and the steps, who are affected, and who plays a role in the requirement. Requirements are reviewed for technical feasibility, prioritized and measurement criteria are established. A "laundry list" of requirements is avoided to ensure the successful facilitation of process change.

Suppliers are engaged to determine their fit to requirements of the specific projects. Our supplier selection process narrows the list of available technologies to a limited set for further investigation. Evaluations are based on facts, rather than on emotional preferences.

Change is often difficult to accept, especially in research. That's why our change management process, based on our adaptation of GE's Change Acceleration Process (CAP) helps to overcome emotional barriers to transformations in work practices. Basic and applied research are areas where change management is often recommended.

Atrium Research does not perform installation or implementation services to maintain our supplier neutrality. However, we pass onto our clients the latest best practices from pilot to system roll-out, with special attention to communication, building consensus, and peer-based demand creation.

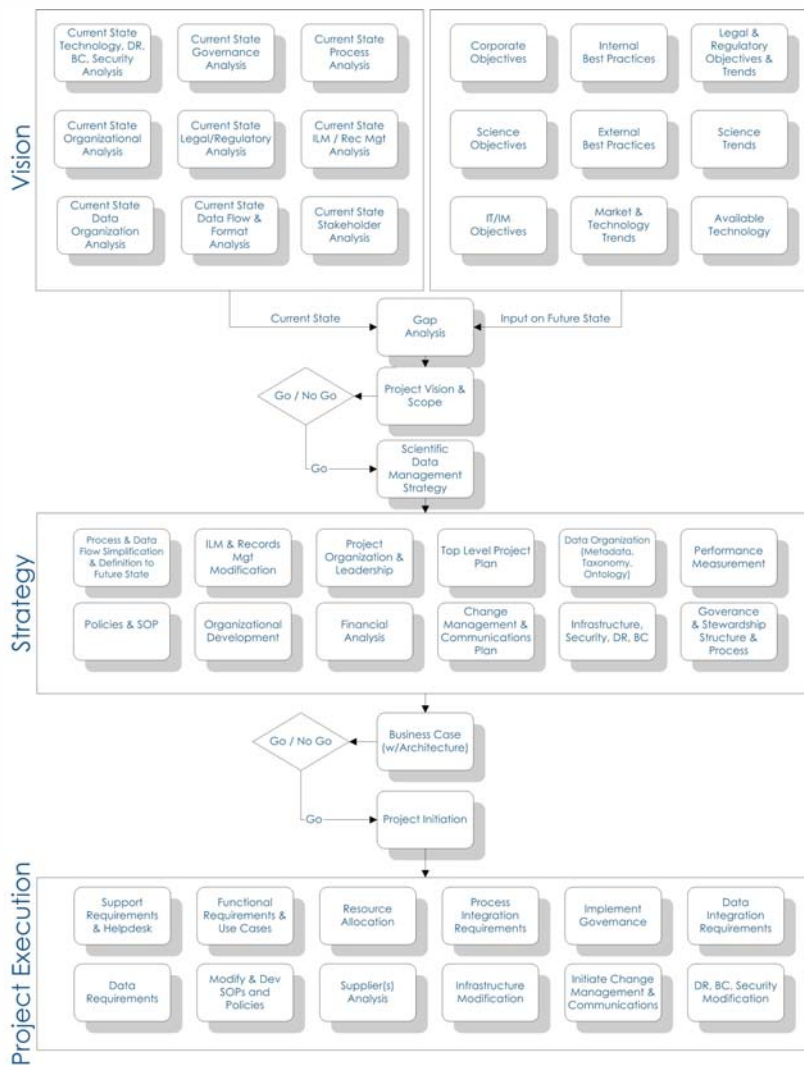


Figure 1 – Process for Vision and Strategy Creation

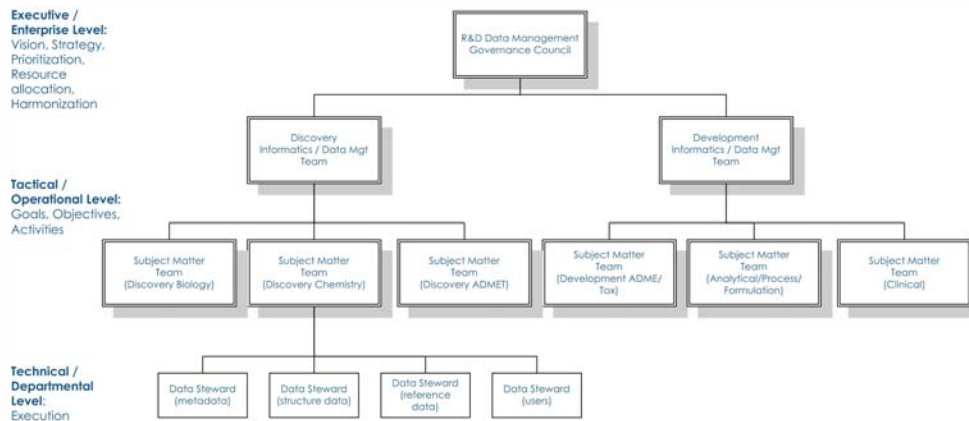


Figure 2 – Example Governance Structure

Why Atrium Research?

Atrium Research is the only market research and consulting organization dedicated to laboratory informatics. This makes us uniquely positioned to provide the services needed to help successfully achieve project objectives.

- **Experience:** We have seasoned professionals who have been in laboratory informatics over 25 years. This provides our clients a unique insight unparalleled in the industry. Not confined just to technology know-how, we have the business management and laboratory expertise to provide a proper balance and perspective.
- **Supplier-Neutral:** We do not perform implementation services of vendor products. These services are best provided by companies who are closely aligned with a supplier and this tight linkage affects impartiality.
- **Knowledge:** Through our market research efforts, we spend significant time reviewing vendor software, examining best practices, learning from market failure and success, and exploring industry trends. We pass this knowledge on to our clients. Our connections in the industry offer a market insight found nowhere else.
- **Not limited to LIMS:** There are many LIMS consulting organizations. However, there are very few that have experience with ELNs, data acquisition, SDMS, ECM, cheminformatics, and other laboratory software technology. We bring a broad perspective about finding the *right* solution to requirements, not just what the company knows.
- **Affordable:** Versus the big consulting organizations, we focus on quickly and affordably achieving project success

Our Benefits

Atrium Research provides considerable benefits to our client companies. By partnering with our clients, we strive to find the clarity they need in a maze of competing technologies. We help to:

- **Conserve money.** By working with recognized industry experts, an organization can avoid the costs associated with trial and error. Companies gain from the experience and knowledge of why some organizations have succeeded and why others have failed. We minimize the possibility of selecting technology which will have a high total cost of ownership due to deficiencies which are not clearly identified by the manufacturer.
- **Conserve time.** Through our independence and leadership, we provide the data and analysis that permit projects to stay on-track and on budget.
- **Conserve energy.** Many professionals are doing the equivalent of two or three jobs already within their organizations. We offer facts and analysis to expedite project decision-making.
- **Protect your long-term investment.** Through our experience and process, we can help select the right solutions for the long term from the uncertainty of vendor offerings.
- **Manage suppliers.** We streamline the interaction with technology suppliers, permitting internal resources to be focused on project resource requirements.
- **Objective viewpoint.** We have an objective viewpoint, separate from individual preferences of potential solution candidates.