

Transformations

QUARTERLY NEWSLETTER

VOLUME 11, ISSUE 1

OF SPECIAL INTEREST:

- **Creating Foundational Data Quality**
- **A strategy roadmap provides a vehicle to link business objectives to a well defined set of projects.**
- **Partnership announced with Arcondis Group**
- **Bio-IT Best of Show Poster Award goes to ResultWorks**

KNOWLEDGE MANAGEMENT STARTS WITH HIGH QUALITY DATA

For many Biopharmaceutical companies knowledge management has been a keen interest for many years. Many programs have come and gone leaving a sour taste for knowledge management programs in general. Technology has often been the main focus of these initiatives. Significant energy has been expended in building data warehouses and seeking ever better search engines to pull together disparate data that is dispersed throughout the organization.

The trouble is that in some organizations the state of the operational systems and the underlying data “takes a village” to piece together even routine searches for data. Instead of focusing on the top level knowledge management, greater effort needs to be spent on shoring up the foundational data and systems on which the business depends.

Data standards are often non-existent. Linkage of data and

systems is dependent on people. The business is typically focused

There is a cost associated with patch-work data management in terms of productivity, throughput, quality, & compliance.

on the day-to-day efforts to move compounds through the pipeline in the most expeditious manner. This usually involves

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BUILDING A BUSINESS & IT STRATEGY ROADMAP FROM THE GROUND UP

Over the last several years, ResultWorks has been involved in developing numerous strategy roadmaps for diverse groups in Life Sciences from research to pre-clinical and clinical development to manufacturing for traditional pharmaceutical, biopharmaceutical, and vaccines businesses. While the objectives and the environments vary widely across companies, our approach to developing a business and IT strategy roadmap has been applied consistently. That approach is framed in ten steps as follows:

1. Establish business objectives
2. Scope the effort
3. Build the right team
4. Define the current environment

5. Agree on the future environment
6. Develop a gap analysis
7. Draft a roadmap
8. Refine & align the roadmap
9. Formalize the roadmap
10. Revisit the roadmap periodically.

The strategy, the supporting roadmap, and the investment will be very different depending on the breadth and depth of the objectives the business is trying to achieve.

Business Objectives

Businesses function best when they can stay focused on the big-picture of the organization.

What are the goals: throughput, compliance, doubling productivity, or perhaps end-to-end information flow? Asking an organization to double productivity elicits a much different response than merely asking for a 10% increase in productivity. Another recent goal from some groups has been “versatility” since it is not uncommon to hear strategies to outsource almost any element of a pharmaceutical company’s operation. The strategy, the supporting roadmap, and the investment will be very different depending on the breadth and depth of the demands on the business.

Scope the Effort

The goal of getting a laboratory up and running is quite different

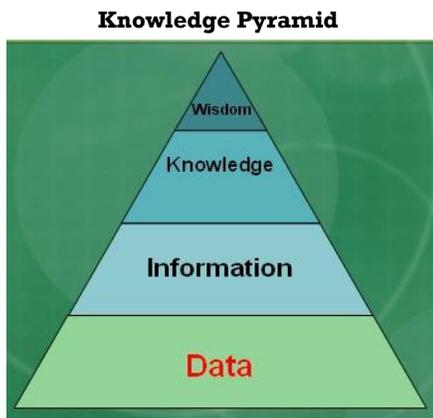
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DATA QUALITY (CONTINUED FROM PAGE 1)

working around, not through, well-deployed systems with strong data governance. There is a cost associated with this patch-work approach to data management in terms of productivity, efficiency, throughput, overall quality, and even compliance.



How big of a problem is it? Often the business is so heads down that they do not have a good sense of data quality issues. In fact, they may think their data is just fine. An objective data quality assessment may be useful to illuminate problem areas and to develop an effective strategy for improving data quality.

Reality Pyramid



A five step approach for a data quality assessment includes:

1. Define the data
2. Determine data quality criteria
3. Analyze data in selected operational systems (e.g., lab data systems)
4. Assess root cause of problems
5. Develop recommendations and a strategy forward.

Data Definition

At the risk of stating the obvious, data quality starts with the data. A solid definition of master data and key meta data is critical to the

assessment. Master data is typically controlled and used across a variety of departments and systems. Compound identifier is a good example of master data in life sciences. Meta data describes key attributes of

master data and other data generated in the business. It is preferred that master data be controlled within one system and referenced from other systems. Automated references or links to master data is desirable, but often this data is manually entered into an operational system like LIMS (Laboratory Information Management System) or ELN (electronic lab notebooks) via research spreadsheets.

Once identified, it is also critical that the primary source of the data be identified. There should be one source of data that everyone references and that source should be controlled by the business. That source is where the data is accessed by researchers and other applications for security, performance, and other reasons.

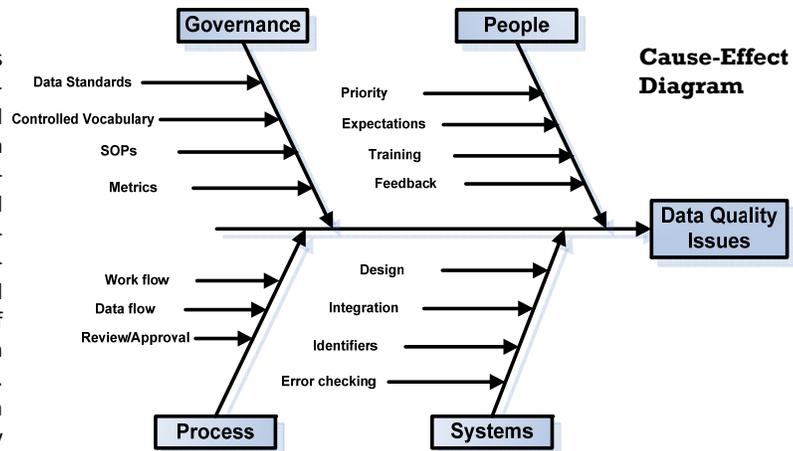
Data Quality Criteria

Once the key data has been defined, the criteria for data quality must be determined. Criteria may already be established in SOPs, in data entry procedures/business rules, or in other data/system governance documents.

In some cases, determining the business rules around data entry may be the most difficult step. Quite often, the business rules are either inferred, assumed to be commonly understood, or left up to the discretion of the scientist. Relying on individual discipline to follow business rules is not likely to result in strong compliance. Without more system-oriented data entry checking, it is often difficult to establish and enforce business rules.

Analyze the Data

Once the data criteria are documented, analysis of the data in selected systems can readily proceed. Database tools can be used to construct, refine, and execute queries. Results can be captured and profiled to deter-



mine where issues exist and the severity of those issues. In some cases, profiling the data may allow for reverse engineering of business rules as they are being followed.

Assess Root Cause

After the data has been analyzed, problem areas stand out. The root cause of those issues must be determined in order to correct the problems with the data as uncovered as well as the issue that is causing the problem in the first place.

As the cause-effect diagram shows, the root cause of problems in this area stem broadly from data governance, business process challenges, systems, and people or organizational issues.

Recommendations

The root cause analysis highlights the most critical issues for the short-term. These deal with direct quality issues that need to be rectified immediately. Next, data standards and governance need to be addressed so that more formal business rules are applied, training can be conducted, and metrics can be put in place to set a baseline for performance. Longer-term, greater investments in automation can be made which will ultimately free people from spending an inordinate amount of time in maintaining data quality manually.

Conclusions

High quality data is a requirement for an information strategy in R&D organizations. As a starting point, it may be useful to conduct a data quality assessment of key systems. The results of the assessment might be surprising, but they can be the driving force for business and informatics investments that will strengthen the foundation before making larger investments in a broader information management infrastructure.



STRATEGY ROADMAP (CONTINUED FROM PAGE 1)

than integrating that laboratory into the end-to-end workflow of an entire R&D organization. Taking too narrow a vision likely ensures that decisions and investments are made for the short-term and these will have to be revisited as the needs of the broader organization are considered. Thinking big but starting small has great advantages especially when constructing a strategy roadmap that plans several years out while implementing the highest priority needs first.

The Right Team

Engaging the right members and building a collaborative team is critical to the success of strategic projects. Senior leadership, commitment, and communication is the cornerstone of that team. They set the tone for the importance of the strategy and clear the obstacles to success so that the objectives can be achieved. The team needs to be cross-functional to speak for and make decisions throughout the project as trade-offs arise. The best team members are often the busiest and most involved people, so the right level of participation needs to be struck so that “day jobs” can still be performed. A solid project management approach will facilitate this need.

Thinking big but starting small has great advantages especially when constructing a strategy roadmap that plans several years out while implementing the highest priority needs first.

Current Environment

Understanding and documenting the current environment is almost always required. There are some organizations where there really is no process but rather work efforts are open to individual preference. This is more often the case in smaller, growing organizations. Typically though, there are some processes and technology that are working well. Other work flows and systems may be suspect or even hindrances to meeting newly defined goals. Analyzing the current environment establishes a baseline while uncovering issues in need of better solutions that will propel the organization forward.

Future Environment

Determining the desired future state requires some vision and creativity. End-to-end processes should be considered.

“What-if” challenges to the team should be routine. Benchmarks against other best-in-class organizations should be weighed. This is the “think big” part of the project that stretches the organization to reach beyond the current state.

Gap Analysis

The gap analysis defines the delta between current and future environments. It accounts for the work effort and the investment needed to change from the current processes, technology, and organization to the desired future end-to-end processes, integrated technology, and a high performing organization. The outcome of the gap analysis is a list of projects needed to “close the gap” between the “as-is” and “to-be” states of the organization.

Draft Roadmap

The projects defined by the gap analysis must then be prioritized and categorized. It is best if the business participates in the activity by prioritizing (A, B, C...) and also by stack ranking the projects (A1, A2, A3...) so that not everything winds up as a priority “A1” project. The draft roadmap emerges out of this exercise.

Refine and Align

Organizational buy-in to the roadmap is as important as the roadmap itself. The functional business organizations deserve an opportunity to provide input to the roadmap. Informatics/IT organizations need to weigh in on implications and impacts. In the end, it is important that all stakeholders are aligned with the recommendations.

Formalize the Roadmap

Once the stakeholders are aligned around the roadmap, the leadership team must confirm that the roadmap supports the business objectives. Assuming all the right work has been done, the roadmap should be formalized through organization-wide communication. This should include commitment to first year projects reflected in the roadmap.

The effort to develop a strategy roadmap will provide a vehicle to link business objectives to a well defined set of projects.

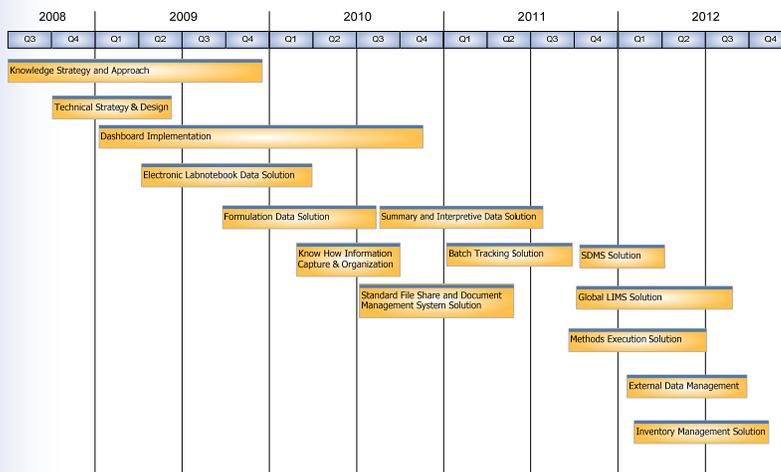
Revisit the Roadmap

As the business changes and adapts, objectives will change, and the roadmap must be revised to support the business. At least once a year, typically in the planning cycle, the organization should revisit the roadmap and make adjustments as necessary.

Conclusions

If done well, the effort to develop a strategy roadmap will provide a vehicle to link business objectives and business strategies to a well defined set of projects. By engaging stakeholders from across the business, it will also facilitate collaboration among the functional areas of the organization as they build and align around the roadmap from the ground up. Downstream, the strategy roadmap will provide a common reference for on-going decision-making around projects as it supports evolving business objectives.

Strategy Roadmap (Top Level Example)



Strategy roadmap reflects the company's business priorities and projects to achieve the business objectives



RESULTWORKS

Transforming Strategy. Delivering Success.

PAPERLESS LAB BECOMING REALITY

The paperless lab concept has been around at least since the thought of the paperless office. As long as paper scientific notebooks were the industry norm for experiment and laboratory work, paperless was not going to happen. With the rapid progress of electronic lab notebooks over the last five years, the concept of the paperless laboratory is now becoming a reality.

ResultWorks has been engaged by clients to help them dramatically increase efficiencies in their global QC laboratories. Sandwiched between the enterprise resource planning (ERP) system and a diverse array of instruments in the lab, is the space where a significant amount of data is captured, analyzed, and used to make critical decisions in the manufacturing process. It is a terribly inefficient space that is heavily reliant on manual data reviews, manual analysis, and manual data re-entry into systems at each level. The QC analyst is the primary integration point for all of this data collection, analysis, and reporting.

To realize the strategy, a mix of systems may be required from traditional LIMS, to Scientific Data Management, to a QC Electronic Lab Notebook. Taken together we consider these the QC Lab Execution System (LES).

For more on this topic, contact ResultWorks and stay tuned for more detail in future newsletters and independent articles. 

NUDGING BIOPHARMA

In a New York Times best selling book, *Nudge* by Richard Thaler and Cass Sunstein they argue that people need to be given choices that will self-consciously move them in a direction that will make their lives easier. They need to be “nudged.” In the book they present numerous examples of “nudges” that would help people from prescription drugs to healthcare to retirement.

In our Life Sciences domain, how might we nudge scientists to make choices that would result in better data management or more efficient end-to-end business processes.? Generally people do want to do the right thing in the right way. Most of the time, it just takes someone to ask or to lead people in a purposeful direction. Leaving too much up to individual scientist choice often results in organizational ineffectiveness that takes a lot of extra effort to resolve downstream.

One concrete thought is to make data more transparent across the organization by putting it on internal display. By determining the key data at different gates in the business process and displaying that data, people would be “nudged” to improve the timing and quality of their data. 

RESULTWORKS NEWS



Bio-IT World Poster Award

ResultWorks was pleased to accept the poster award for Best of Show. The poster entitled “Knowledge Management Starts with High Quality Data” outlines an approach to assessing data quality in laboratory systems and defining a strategy for foundational data management.

Recent and Upcoming Appearances:

- DIA Conference on Electronic Document Management
- IQPC Laboratory Informatics Conference
- LRIG—Philly LIMS/Lab Informatics Meeting, April 2011
- Bio-IT World in Boston, April 2011
- IMACS in Boston, May 2011

Sample Client Initiatives:

- R&D Data Quality Assessment
- Vaccines & Biologics IT Strategy
- Biologics Formulation Business Process & Data Flow Assessment
- Manufacturing QC Lab Systems Strategy
- QC ELN/Lab Execution System Definition & Vendor Selection

RESULTWORKS & ARCONDIS GROUP PARTNER TO BETTER SERVE GLOBAL CLIENTS

ResultWorks and Arcondis Group, a European based life science consulting company, announced a strategic partnership to better serve the needs of our global customers in the Life Sciences Industry. Arcondis and ResultWorks both have proven track records of success in their respective geographies. Under this agreement clients can profit from the shared service portfolio and consultant capabilities as well as from a transparent delivery model to facilitate client project successes. [Click here for the complete press release.](#)

ABOUT RESULTWORKS

ResultWorks is a management and business process consulting company which transforms strategies for Life Science companies into successful technology and process optimization initiatives. Results are achieved through skilled facilitation and exceptional management leadership. To request additional information, send us an email or visit our website at www.resultworkslc.com.

1060 First Avenue, Suite 400
King of Prussia, PA 19406
610-688-5870
marketing@resultworkslc.com