

Transformations

RESULTWORKS NEWSLETTER

VOLUME 14 ISSUE 2

OF SPECIAL INTEREST:

- **Strategies for Scientific Systems**
- **Enabling Clinical Sample Management**
- **Change management requires that people shift mindset and focus**
- **Technology solutions should complement business process changes**
- **The FDA's focus on metrics, performance and quality**

ASSESS SCIENTIFIC SYSTEMS AND SET A STRATEGY TO OPTIMIZE BUSINESS & IT INVESTMENT

Face facts: scientific systems were rarely implemented in a way that considered the big picture. They were often purchased and installed with great expediency to add some level of coordination across laboratories or other scientific areas. Certainly these systems added more structure than what existed. Though as one wise old woman once said of her seven sons: "When all else fails, lower your expectations." Until recently, our expectations of scientific systems have been remarkably low.

As investments in systems have been more closely scrutinized, most mid to large sized biopharma companies have looked for broader outcomes from their IT investments. At the same time, decision-makers want and need to access and ana-

lyze information about a compound, a product, or a study more readily than ever before. Often they are disap-

An assessment sets a baseline which considers the present while planning for the future.

pointed that it is just not as easy as their experiences in accessing information in personal, non-work environments. This is now driving expectations higher and along with it a willingness to look more critically at today's environments and to invest in a more thoughtful way.

Scientific processes, information and systems need to be viewed more broadly as shown in Figure 1, since in-

formation is now consumed increasingly for secondary and tertiary purposes. An assessment in the context of a vision for the organization, offers an excellent start towards developing a scientific systems strategy.

Assessing Scientific Systems

Most scientific automation and IT people understand the many causes of today's scientific systems dilemma including (but not limited to):

- Systems implemented in silos
- Little or poor integration
- Significant manual data entry
- Too little attention to data management (e.g., authoritative sources, master data management, meta data, controlled vocabularies)

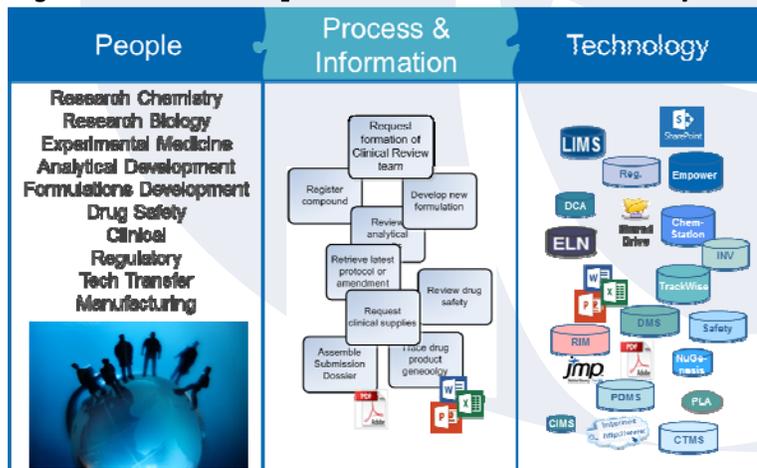
- Inconsistent business processes and use of systems

People can and do spend a lot of time debating the issues and potential solutions. Without raising the thinking up a level, systems and information are bound to become more divergent rather

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Fig 1: Broader Landscape for Scientific Information and Systems



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SCIENTIFIC SYSTEMS ASSESSMENT (CONT. FROM PAGE 1)

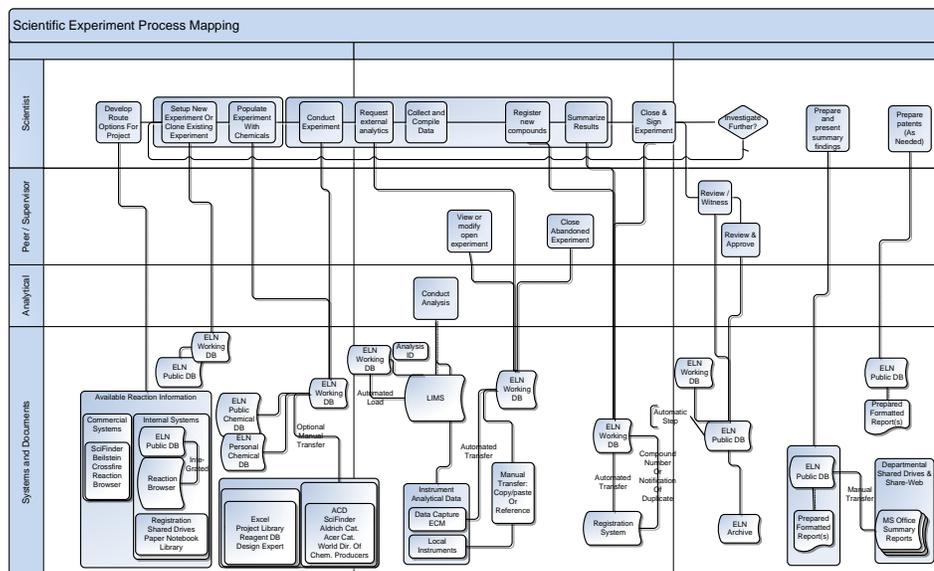


Figure 2: Example mapping for scientific experiment process including roles, processes, information content, and systems

than more integrated. Conducting an assessment of the scientific systems environment is an excellent way to set a common baseline for the organization which considers the present while planning for the future.

An assessment might be focused narrowly on a function or more broadly on a department or the enterprise. It should consider the following:

- Business processes / workflows
- Information content and flow
- Roles and responsibilities
- Systems

An example process map for a typical experimental process is shown in Figure 2. While the process is rather simple, the information and system interactions are complex.

Quite often, conducting this effort is the first time that people will have seen and considered end-to-end processes and all the interactions along the way. Many managers perceive that they are ex-

cuting a single, well-understood business process, when in reality, people are getting the job done any way they can. This also means that people may be using systems differently or even executing the same process using different systems.

Conducting an assessment allows people to see the differences more clearly, understand the challenges better, and ultimately move toward a common vision for how to best conduct their scientific work.

The assessment ultimately identifies “pain points” or “productivity barriers” which must be addressed from the work group to the enterprise depending on the scope of the assessment.

Information Supply Chain

Solutions to productivity barriers could be simple communications improvements, to process changes, to well-placed technology solutions. It is key though to think more broadly about solutions. Information can and should be considered as a supply chain from

data creation to how it is consumed and all the transformations and storage along the way, as shown in the Data Process Stream in Figure 3.

The implications of this concept for scientific systems is that a LIMS (Laboratory Information Management System) or ELN (Electronic Lab Notebook) project should be implemented (or improved, upgraded, enlarged) with the bigger picture in mind. These systems and projects need to be evaluated in terms of enterprise needs and enterprise tools and technologies that will better support the information supply chain.

Define the Strategy—Pain to Gain

At this point in the effort, the organization is in a solid position to make trade-offs between process improvements that the business can undertake directly to areas where technology is warranted to propel the business forward. Both process and systems projects factor into a multi-year planning cycle which could be assimilated in a roadmap. The roadmap should consider not only the scientific systems themselves, but also technology building blocks (e.g., IT architecture, data federation, controlled vocabularies, etc.), process changes perhaps managed via a business process management (BPM) tool, as well as tools for presenting the data via dashboard capabilities.

In most organizations today, technology building blocks may already be available or in progress by the IT groups. It becomes a matter of taking the extra time to design and incorporate the tools into the implementation of scientific systems in order to drive significant gains for the organization.

An example strategy roadmap is offered in Figure 4. Keep in mind that the strategy roadmap is not a once and done exercise—technologies change; needs change; and priorities shift. The strategy roadmap for any given group should be

Figure 3: Data Process Stream



SCIENTIFIC SYSTEMS ASSESSMENT (CONTINUED FROM PAGE 2)

revisited every year in the planning cycle and mapped to the roadmap so that the organization can leverage other work in progress.

Conclusions

A scientific systems assessment can surface barriers to productivity in the organization that are often caused by legacy scientific processes, applications, and even technology infrastructure. Having the business and IT organizations participate in an assessment can lead to better understanding of issues and needs while making people more receptive to change.

With information being important more broadly to the enterprise than ever before, it is important to consider the end-to-end information supply chain.

The organization can then align around not only the issues and potential solutions, but also the long-term

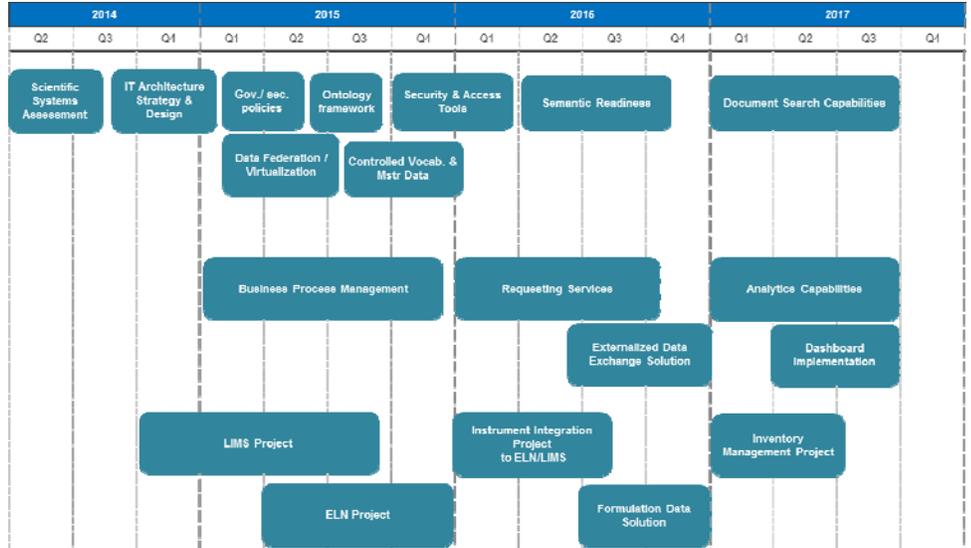


Figure 4: Example Strategy Roadmap for Scientific Process and Systems

strategy and the roadmap for implementation. The strategy roadmap becomes the guiding document for investment of time, talent and funding by both the business and IT. By aligning with and executing the roadmap, the organization should

have confidence that people are working on and investing in the right programs. They are more likely to work in a concerted way and in so doing, they will be optimizing business outcomes as well.

RESULTWORKS POSTER HITS THE MARK

Earlier this year at the Bio-IT conference ResultWorks contributed a poster that captured the attention of many conference attendees.

Pictured in Figure 6 is the poster entitled “Business Process Analysis Enables Clinical Sample Management Collaboration.” It explores the challenges of clinical sample management in increasingly complex collaborative environments. It addresses the need for and the benefits of end-to-end business process analysis which can yield rapid, high-value improvements that the business can undertake in addition to technology solutions for a comprehensive approach to the entire clinical sample lifecycle.

Some of the conclusions include:

- Sample management has become more complex with increasingly collaborative environments
- End-to-end business process analysis can yield rapid, high value improvements that the business can undertake to improve sample management, schedule of events, and informed consent form tracking

- Root cause analysis can identify “pain points” to guide priorities and investments
- Supplier partnerships, services, and performance measurements must be revisited in light of revised business processes
- Sample uses and needs must be considered well beyond the immediate clinical trials
- Technology solutions should complement business process changes for a comprehensive approach to managing the entire clinical sample lifecycle

For an electronic copy of the poster please contact Bob O’Hara via our marketing email link.

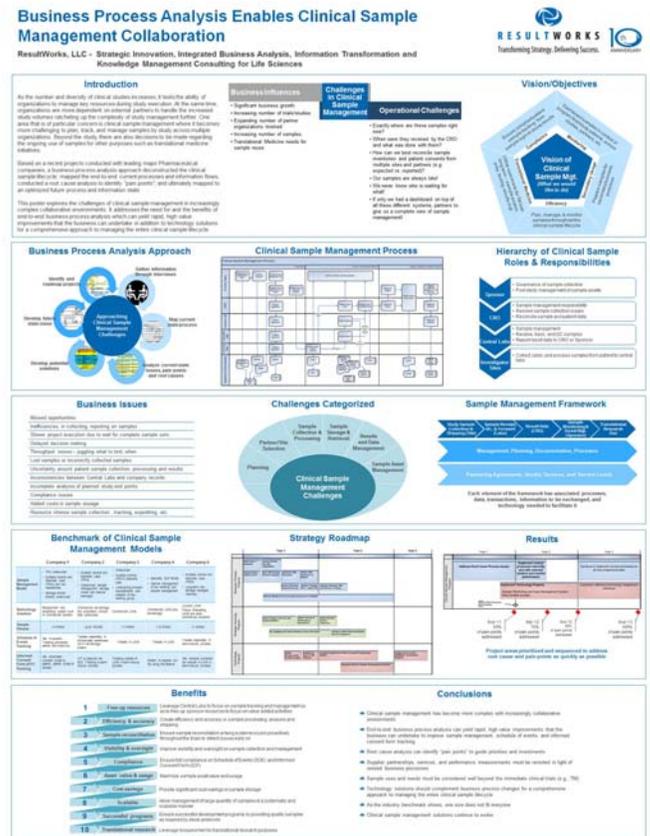


Fig 6: Clinical Sample Management Poster



RESULTWORKS

Transforming Strategy. Delivering Success.

DELIVERING SUCCESS

Several new ResultStories, ResultWorks' project briefs based on real world successes, have been added recently to our website.

One such ResultStory describes the creation of a **Competitive Intelligence IT Strategy**. The project undertook the analysis of capabilities in the competitive intelligence arena to monitor, filter, evaluate, disseminate and integrate relevant competitive intelligence information from both external and internal sources. ResultWorks identified the key competitive intelligence gathering needs and priorities, reviewed technology solution options, and developed a strategy to enable these needs.

A roadmap was developed to lay out construction of the IT architecture and acquisition of COTS solutions that delivered highest priority needs first.

MANAGING CULTURE IS CRITICAL TO CHANGE

There are many factors to consider for successful change. When planning for and implementing change, consider what should the change involve, how will the change impact workflow and technology, who will be impacted by the change, how fast should/can the change occur, what are the costs of change, how will the success of the change be measured, etc. These factors are all important to the process. However, none is more critical than those factors that surround the cultural and organizational change - those changes that impact each and every employee on a personal basis.

Ensure that people make the required changes in mindset and focus.

It is critical to the success of any transformational project to ensure that people make the required changes in mindset and focus. Those involved in projects tend to forget that for the change around them to be successful they must change as well.

Similarly, those managing projects tend to overlook personal change factors and focus on the more technical and tangible aspects of the project.

See the full article on [Managing Culture](#).

FDA FOCUS ON METRICS, QUALITY

As we see a push in the industry toward improved data quality, the FDA is also shifting its attention in the same direction. Some of our clients tell us that the FDA these days actually seems to have better data than some of the suppliers.

In the Pharmaceutical Online article "[The FDA's Focus On Metrics, Performance, And Quality](#)" by Ellen Leinfuss, she recaps FDA CDER Director Janet Woodcock's goals to shift the FDA toward performance and away from compliance. That emphasis targets establishment of metrics for key process steps. With that comes the need for better data collection and quality.

(To read the full article, click on the link in the title above.)

RESULTWORKS NEWS

Recent Events & Activities:

- Greater Philadelphia and the Biotech Industry - a Panel Discussion led by ResultWorks with diverse Philadelphia Life Sciences Business Executives
- Completed an Industry Benchmark Analysis on Statistical Controlled Environments
- Presented a poster entitled "Data Quality Framework: A Path to Trusted Data for Better Decision Making"

Current / Recent Client Initiatives:

- Statistical Controlled Environment Strategy and Roadmap
- Compound Management Work Flow, User Requirements, and Functional Requirements
- Business Process Analysis for Regulatory Information
- Electronic Document Storage & Retrieval Strategy & Requirements
- Data Quality Assessment for Regulatory Information

ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

Contact Us:

1060 First Avenue, Suite 400, King of Prussia, PA, USA 19406

Phone: 610-688-5870

Email: marketing@resultworksllc.com

Website: www.resultworksllc.com