RESULTWORKS
Transforming Strategy. Delivering Success.

Transformations

INFORMATICS - LINCHPIN OR AFTERTHOUGHT OF BUSINESS EXTERNALIZATION STRATEGY

Many large BioPharmaceutical companies are anxiously expanding partnerships with a variety of contract research and specialty organizations in order to cut costs, share risk, and streamline the business. This is not really a new approach. Companies have been using partners (e.g., central labs, CRO's, specialty labs, CMO's) for many years in a wide variety of study/trial situations. However, as large Pharmaceutical companies transition to a new paradigm for drug development, one that is focused on creating a flexible environment that allows easy movement between use of internal and external resources, the use of and the dependency on external partners is accelerating and broadening.

So what happens with the information associated with externalized work? Who needs it? Who owns it? Where is it stored? How accessible is it for immediate and for long-term use to inform future investments? These questions need to be spotlighted upfront in considering externalization strategies.

Development On-Demand

When the original video-on-demand service was started many years ago, hotel customers would request the video they wanted to see. The request would go to a technician in a room who would find and insert the video into a VCR and hit play. This was a crawl before you run approach that worked as long as there were not too many requests at once and as long as no two people ordered the same video. Of course technology has come a long way and that industry has exploded since then.

Early adopter Pharma companies moving toward externalization are finding that too much of the process is reliant on manual interactions and data movement. In planning for and executing a body of work (e.g., a study or trial), organizations self-optimize based on their business objectives using their own processes and systems. CRO's and CMO's strive to be more cost effective in leveraging economies of scale by performing similar functions and providing similar deliverables using the same processes and systems for all of their customers. These efficiencies are the reason big Pharma see them as attractive partners in the first place. So while manual processes and interactions with partners may suffice for the short term, like video-on-demand, manual approaches in product development do not scale long term.

This problem is compounded by the fact that each Pharma has multiple partners some who are large and sophisticated; others who are small, specialized, and not technologically savvy. Each of the partners may also be working with multiple other Pharma customers. All of these organizations have their own processes, systems, nomenclature, and business practices creating the conundrum depicted in the graphic below.
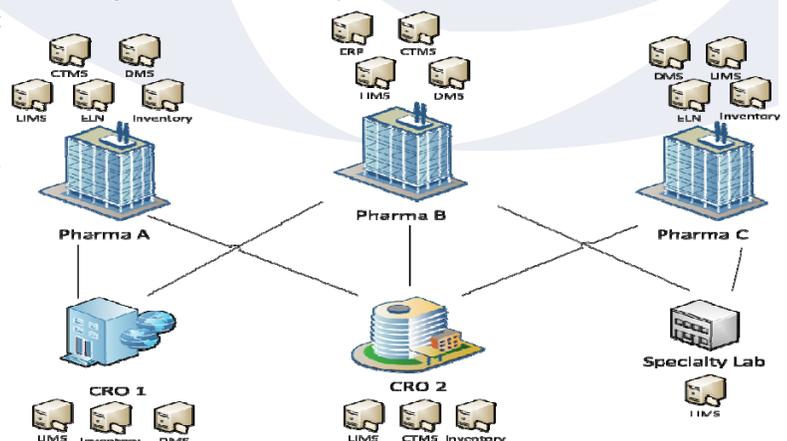
INFORMATICS LINCHPIN (CONTINUED FROM PAGE 1)

Informatics Scope

It is easy to get overwhelmed with the challenges of building an IT infrastructure to handle every possible mix of business relationships. A key factor is to have a broad, well-conceived technical framework based on strategic needs and then test the framework in a more focused area to ensure that it works and that it can scale. The framework has to think "big" and focus on methods for integrating information that are versatile for either non-technical or technologically advanced external partners. The diagram below outlines an approach to this challenge.

Work Flow & Information Flow

What information is needed end-to-end to manage the process and what information is generated as a result of the process? Who uses that information? When is it needed for decision making in the work flow? What data is needed retrospectively to support completed work (e.g., for audits, etc.)? Who needs the data and how does it need to be accessed? These questions need to be clearly addressed so that the range of potential solutions becomes more straightforward.

End-to-end processes can be divided into

Other information needs to be retained, metadata needs to be added, and there needs to be a clear strategy for storage and access to that information across the virtual enterprise. The approach also needs to balance opportunities to leave information in situ with external partners versus the need to bring information in house. In the ideal world a federated approach to data access would simplify the framework but achieving this presents many technical challenges in the areas of data security, use of common ontologies for data normalization, partner technical capabilities and maturity, intellectual property rights, long term retention and preservation of data.

Technical solutions need to address both machine to machine interchange of information as well as more human visible information exchanges. Collaboration tools, data virtualization, semantic web linked data concepts, traditional data warehouses, portal technologies, and cloud-based solutions are some of the tools and technologies that are being employed to address integration issues. The mix depends on the nature of the data (how persistent it needs to be) and the degree of data integration that may be required.

Assimilating data from diverse sources requires transformation of data to standard vocabularies to facilitate unambiguous meaning and comparison. This is typically one of the more difficult areas to address and where information governance becomes essential.

Assess Current Landscape

Before looking outside, consider the landscape and capabilities within the company. What are the strengths of the organization which are not easily replaced by external organizations? What areas are cost effective and what areas are resource drains? Likewise, what areas could be better managed by outside organizations dedicated to specific work activities? This approach applies not only to the organization but also to processes, systems, and information management.
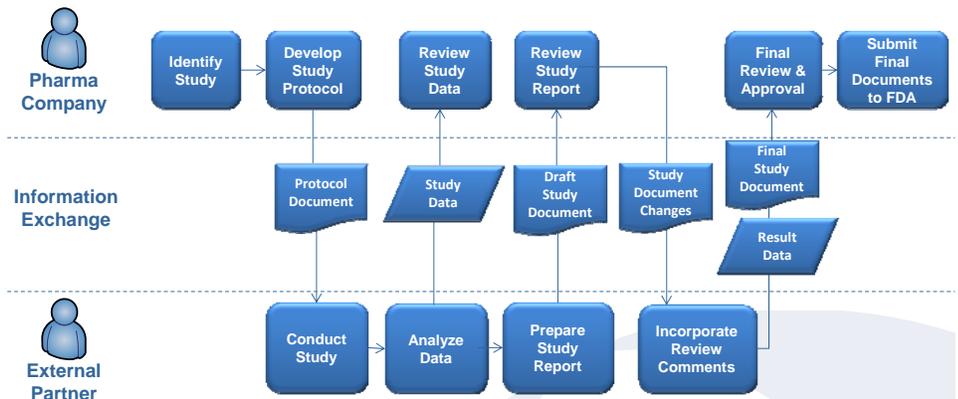
Define High Level Business Needs

Having a clear understanding of the business objectives and the strategy to attain them is a critical starting point. A streamlined business process which takes advantage of each partners' competencies is very different than maintaining versatility to interchange resources and partners with very different capabilities. Will partners be performing certain functions exclusively or will decisions be left to each project/study team to decide resources? Allowing for too much flexibility adds complexity to the process and to the technology to support it. Planning for too little flexibility may hamstring the business from using the right partner when needed. It may also unnecessarily constrain the information architecture too early in the process.

discrete work stages and transactions, and the information content associated with them as depicted in the simplified study process in the graphic below. The overall process (made up of multiple work flows and transactions) needs to be defined discretely enough, (i.e., modularized) so that you could plug and play "work" from multiple partners or inter-

nal company resources. That work is bounded by transactions with specific information deliverables that should be essentially the same (or convertible to the same) regardless of who performs the work.

Technical Approach

The technical approach should support how information will be used today and in the future. Some information has a limited lifetime as part of immediate decision making.

Information Governance

The foundation of a solution with clean, consistent, and integrated transfers of information among organizations is to establish governance to control vocabularies, manage master data, monitor data quality, and track metrics. Unfortunately, this area has been plagued by a lack of comprehensive or accepted standards in some areas and historically poor levels of compliance by partners when

MAKING THE PAPERLESS LAB A REALITY

The paperless lab concept has been around at least since the notion of the paperless office came into being. However, 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 manufacturing 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 as shown in the figure below. The QC analyst is the primary integration point for data collection, analysis, and reporting. Depending on the environment and past investments, there could be a mix of systems including chromatography data systems, scientific data management systems, LIMS,

manufacturing execution systems (MES), document management systems, and ERP systems. Today, QC leads want to integrate and automate the QC lab operation reducing their paperwork and increasing their overall efficiency.

The approach offered by ResultWorks is outlined as follows:

- Assess current QC lab environment

- Develop strategy for paperless lab

- Construct a gap analysis

- Build business justification
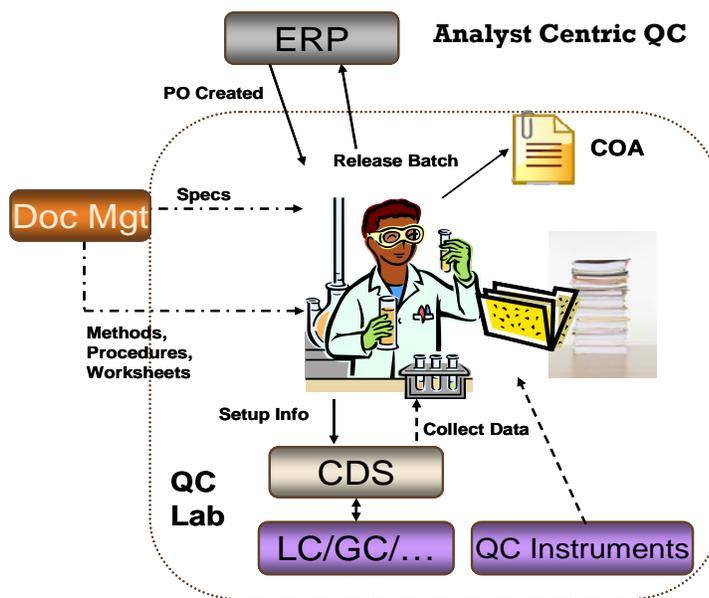
tion management, test requesting, procedure execution, and long-term data management to name a few. To realize the strategy, a mix of systems may be required from traditional LIMS, to Scientific Data Management, to a QC Electronic Lab Notebook (ELN). Taken together we refer to these as a lab execution system (LES). The diagram on the next page depicts the LES concept. LES becomes central to the QC lab function.

Gap Analysis

The next step is the gap analysis to define the delta between the current state and what is required to achieve the desired future state. This effort can delve down to specific work flows in order to determine where efficiencies might be realized with an LES solution.

Business Justification

The gap analysis provides the basis for the business justification. The returns on investment are primarily cost savings resulting from more efficient operations in the QC labs. Some examples of typical savings include:

Analyst Centric QC

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standards have been agreed. But that doesn't mean you should not try. The more diverse the partner organizations involved, the more reliant everyone will be on clear standards, performance metrics, and ongoing commitment to information governance.

Conclusions

In the haste to use external partners, the industry is in effect in a shell game with informatics. Information integration challenges seen within pharmaceutical companies are even more complex when externalized across multiple partner companies. Information management should really be one of the leading considerations of an externalization strategy. If done poorly, information management will be a burden on the collective organization. If done properly, information management could really be the linchpin of success in a business externalization initiative.

QC Lab Assessment

The assessment of the current environment consists of a review of documentation of each site QC lab, and interviews of key stakeholders from senior managers to QC scientists. This groundwork helps to establish the key work flows, primary systems in use, pain points in the process, and needs of the organization. The consistent theme that emerges from organizations looking to move ahead is a paperless or integrated electronic laboratory operation. The baseline information collected during the assessment phase is the foundation for developing the strategy.

Paperless Lab Strategy

Once the needs and desires of the organization are assimilated, a strawman strategy can be developed considering the business and IT constraints. Some systems may already be in place (ERP, LIMS, CDS). Needs may span multiple systems - method management, specifica-

- Elimination of paper documents and handling

- Reduced time performing data transcription and manual calculations.

- Reduction in data review/checking

- Reduction in peer and supervisory review time

- Reduced deviations/investigations

It is not uncommon to see analyst and supervisor efficiencies of 25% or more by implementation of an LES solution.

The investment side of the business justification will depend on the starting point and the vendor selected. Some vendors will provide budgetary estimates incorporating licensing costs and full implementation costs inclusive of training, metrics around methods development, and integration. The full

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PAPERLESS LAB (CONTINUED FROM PAGE 3)

cost of the implementation effort needs to be developed based on a complete project plan considering organizational resource availability, external resources, the number of methods/procedures that need to be automated, and validation requirements. The business justification exercise requires a lot of detailed work, but the returns on the effort are worth the time invested.


Conclusions

The paperless lab is no longer just a gleam in the eye of QC leadership. With the latest technologies and the merging of traditional data management and lab management systems, it is a real possibility these days. However, there is no easy "one size fits all" solution.

A structured approach must be undertaken to assess the current QC lab operations. Ground work must also be done to define a strategy for a paperless lab based on organizational objectives. While the return on investment is typically much shorter, the strategy should reach out 3-4 years to give the organization adequate time to invest in new technologies and new business processes; time to assimilate the new technology; and time to achieve credible results.

The gap analysis and the business justification are critical to getting approval for the investment. They are also key for establishing metrics to track the success of the project and the return on investment.

Of course there is a significant project at this point to implement the system, but if these steps are taken to start, the paperless lab can be a reality for your organization.
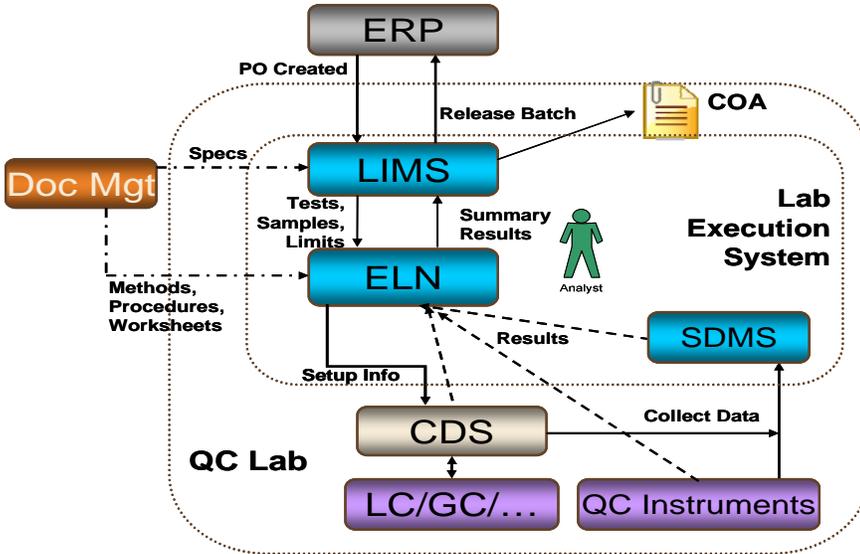
RESULTWORKS NEWS

Recent and Upcoming Appearances:
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Sample Client Initiatives:
Discovery Medicine Change Management Initiative
Clinical Sample Management Strategy
Clinical Supply Chain IT Strategy
Externalization Information Exchange
Data Quality Analysis
Manufacturing QC Lab Systems Strategy
Lab Execution System / ELN Implementations

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: call us, send us an email, or visit our website.

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INVENTING THE FUTURE

What Steve Jobs Taught Me About Growth -
Blog by Nilofer Merchant, Harvard Business Review

In this Harvard Business Review blog, Merchant recounts Jobs' harsh direction to her years ago forcing her to unlearn lessons from dramatic successes and create even more innovative approaches which played a role in shaping Apple's long-term growth. In Life Sciences we are saddled with legacy processes, systems, and structures which are no longer adequate for our evolving industry. Consider what a Life Sciences

"Our job as innovative leaders is to manage the present while inventing the future."

company would look like if Steve Jobs were leading it today? This blog offers five key leanings for effective business leaders which are readily applicable to the innovation required in our industry. To read the blog click here . (Please pardon the language as quoted from Jobs.)

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