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 vid-

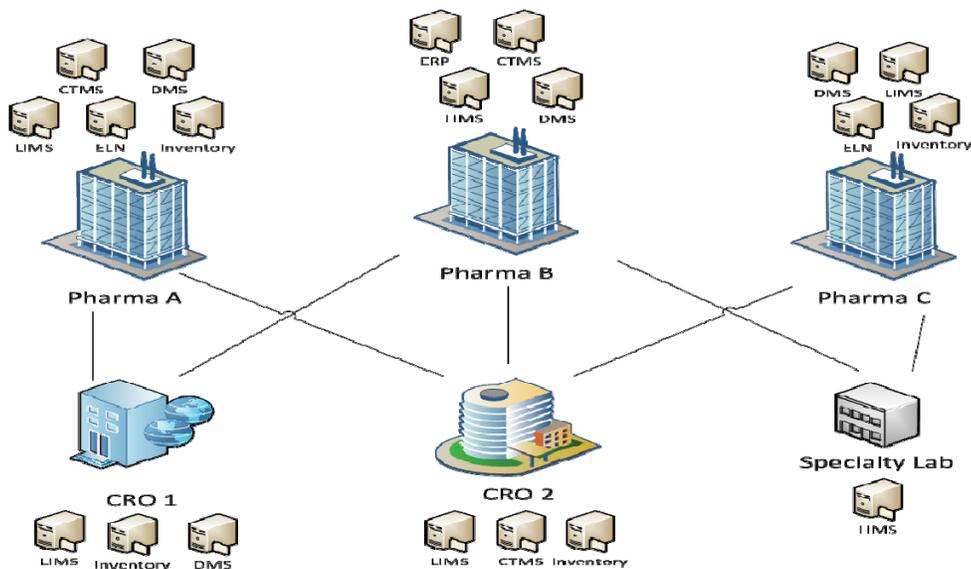eo. Of course technology has come a long way and that industry has exploded since then.

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 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 at the top of the next page outlines an approach to tackling this challenge.

Apply Information Governance

Develop Technical Approach

Develop Detailed Business Work & Information Flows

Externalization Information Management Approach

Assess Current Landscape & Capabilities

Define High Level Business Requirements

Identify Information Needs & Access (who, what, when, how...)

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.

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.
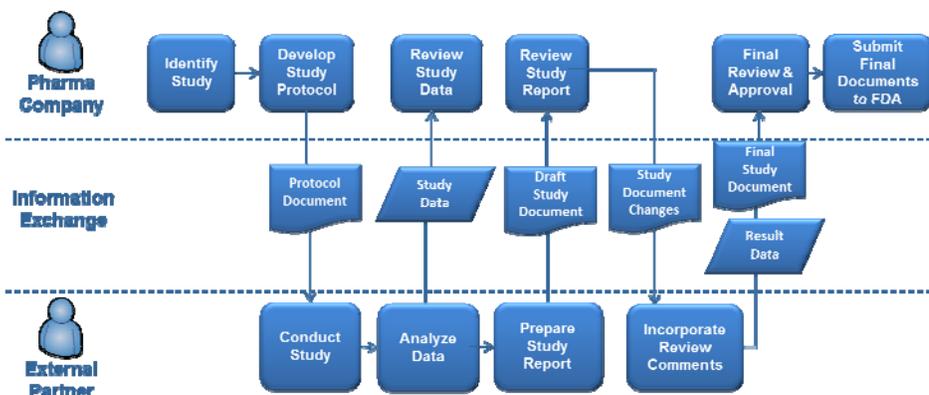
End-to-end processes can be divided into discrete work stages and transactions, and the information content associated with them as depicted in the simplified study process in the graphic be-

low. 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 internal 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. 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.

Pharma Company: Identify Study → Develop Study Protocol → Review Study Data → Review Study Report → Final Review & Approval → Submit Final Documents to FDA

Information Exchange: Protocol Document, Study Data, Draft Study Document, Study Document Changes, Final Study Document, Result Data

External Partner: Conduct Study → Analyze Data → Prepare Study Report → Incorporate Review Comments

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.

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 standards (external or internal) have been agreed. But that doesn't mean you shouldn't try. The more diverse the partner organizations involved, the more reliant everyone will be on clear standards, performance metrics, and on-going 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.

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