

An Approach to Externalizing R&D Information Management

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INTRODUCTION

Externalization is rapidly evolving in Life Sciences well beyond the old outsourcing models. Although the need to innovate has never been greater in R&D, today's environment is growing in emphasis on effectiveness at each step of the process. External organizations are emerging which are more specialized and therefore better prepared for the volume and quality of work that is needed today. Not so long ago if you associated "service" with any one R&D organization, it was a dirty word and people were put-off. Today, if you are in an R&D group and you are not behaving as a service provider, there are outside organizations willing to provide those services faster, better, and cheaper.

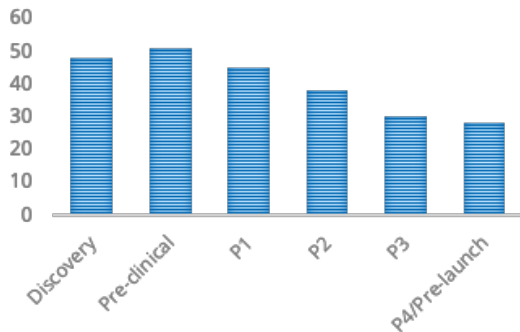
One stumbling block in the shift toward externalization has been information management. Information management is inherently more complex than the old Pharma model when businesses were relatively self-contained. Today, better strategies are required when contemplating who needs what data at what point in the process and who is providing data at each

step and in what form. You also need the right tools to acquire, organize, and access data from different sources for a variety of purposes. This article outlines an approach to establishing an information management strategy in organizations that are increasingly trending towards externalization.

WHO'S YOUR PARTNER?

As some Pharma organizations cling to the traditional business models, others are strategically weighing broader partner strategies. Although partner organizations used by one company today may be relatively limited, it may be best to plan on a spectrum of partners. Certainly, the trend is toward an increasingly diverse set of interchangeable partners. The figure below shows the results of a survey conducted by Nice Insight and published in Life Sciences Leader magazine indicating outsourcing at high rates throughout the product lifecycle.

Survey of Life Sciences companies engaged in outsourcing



Source: Nice Insight published in Life Sciences Leader – March Edition

Partners can also be differentiated by size, types of relationship, sophistication, and volume of work activities. Added to that is the fact that most projects involve multiple partners. In another recent survey, respondents indicated that 74% of projects involved two or more partners while 17% involved more than four partners.

Given this accelerating trend, organizations need to think differently about how they work with partners from the scope of their activities to the onboarding process to the information flow at each stage of the process.

FRAMEWORK FOR EXTERNALIZATION

Regardless of the drug development stage, once a determination has been made to externalize that service, there are some key elements needed to facilitate the end-to-end process. The partner framework shown below highlights building blocks for

consideration in contracting an external partner for a range of activities.

In each of the stages defined, consideration must be given to the information and business processes that drive the work before considering technologies to support it.

Partner Framework

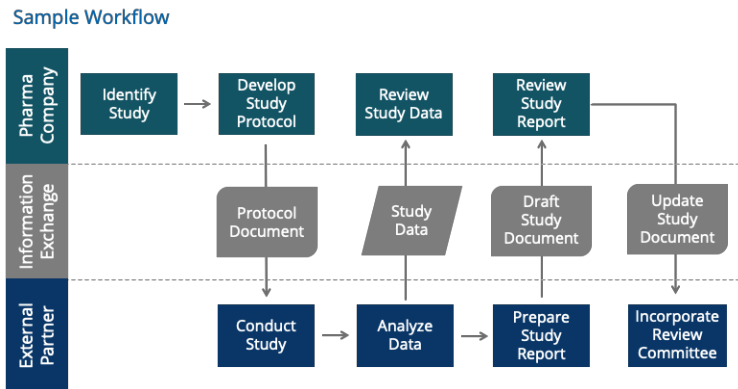


Analyze the business process

Focusing on the business process for “execute the study”, a sample work flow is shown on the next page. Bi-directional documents and data are routinely exchanged on a transaction basis. A majority of this data transfer today still occurs via email and file exchanges. However, these manual business processes will not scale as the business grows in volume and complexity. In order to understand what information is needed in what form and for what purpose, the

information needs to be better defined and categorized.

Define the Information



There are numerous data sets in Pharma R&D that are specialized for a particular science or process. Generally, the data might be segmented as operational data, result data, or study and experiment reports. Information can be categorized as follows:

- Traditional scientific data based on studies and experiments
- Detailed result data including multi-parametric data, instrument data, images, etc.
- Summarized result data in tables and spreadsheets
- Documents and reports which likely include some or all of the data described above
- Operational data about programs, projects, or studies regarding status, tracking, reporting, etc.

Unfortunately, this data is rarely well standardized making it difficult to bring

together data from the same company-internal groups let alone data from different parts of the product lifecycle, from different partners, and from different stages in the partner framework. Clearly, the details are critical as organizations attempt to employ technologies to scale the process.

Harmonize Information

Knowing that data will be used and integrated in a variety of ways over time, it is important to harmonize information at some point in the process. As information is created, it is critical that harmonized vocabularies and metadata are injected applying the same nomenclature that will be used throughout the extended enterprise. Preferably standards will be employed to facilitate the broadest use across partner organizations. Certainly, SEND and SDTM standards from CDISC for non-clinical and clinical data respectively is a great starting point. Company and metadata standards are also required so that master data items are consistently used and referenced with a common nomenclature. This said, CRO's are adopting at a much faster rate than Pharma

according to a CDISC survey. So, Pharma companies need to step it up.

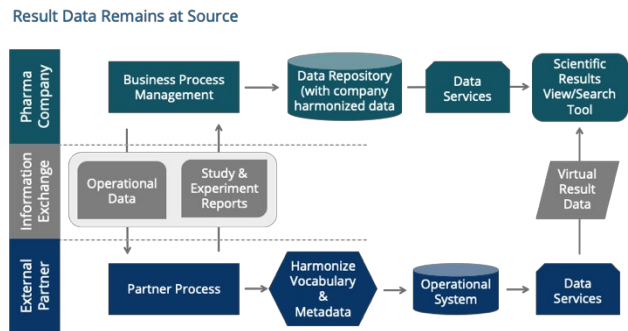
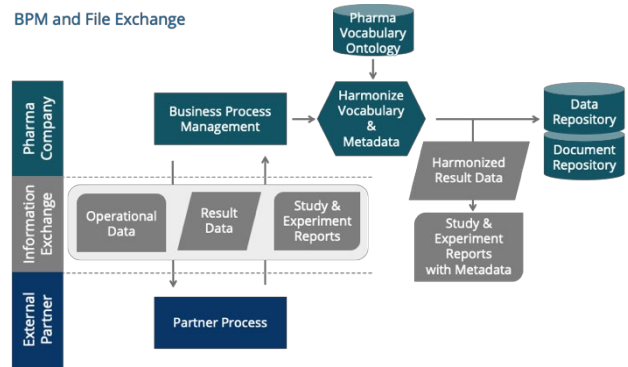
Point of Attack for Harmonization

Business rules associated with the exchange of information and the technologies for the exchange need to be designed in a versatile way for multiple, diverse partners. Developing use cases helps to draw out the issues and challenges of each scenario with participating organizations. Where harmonization occurs is a big consideration which also ties to the method of data exchange. In a traditional ETL (extract, transform, load) model, harmonization would occur once external files (e.g., documents, spreadsheets) are brought into the company and loaded into company systems.

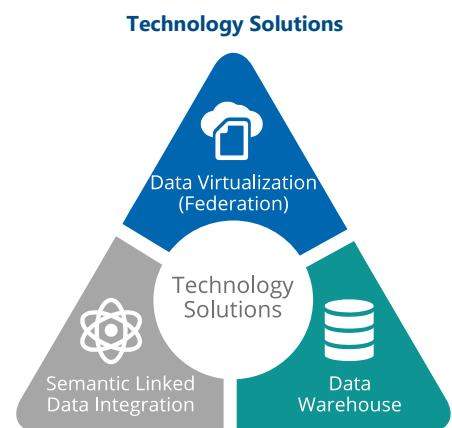
Another approach would be to use business process management (BPM) tools to facilitate external partner data entry and upload, see BPM and File Exchange figure. Again, in this scenario the harmonization would occur within the company requiring some manual effort as well as technology tools to make the data accessible.

A third approach as shown in the Result Data Remains at Source figure puts the onus on the partner organization to harmonize data and documents and to facilitate leaving the data at the source.

In the final approach shown in the Technology Solutions figure, third party tools are used to conduct the harmonization



and the data exchange in the cloud via a third-party service. Data could then be left in the cloud application and accessed as needed via other data services.



Information Integration

Once information has been “exchanged”, the next challenge is integration with required company applications.

Unfortunately, there is no single tool solution that solves all integration needs. Data warehouses, semantic technologies, and data virtualization solutions all have their places. Different approaches solve different challenges. At the end of the day, combining various approaches yields the best results. Assuming various heterogeneous repositories, data access should be federated to make data available throughout the extended enterprise. This environment should be constructed using a building block approach enabling the company to take advantage of the best technology available at any one point in time without a top-heavy investment that will make it hard to swap out as better technologies come along.

CONCLUSIONS

Developing an externalized information management solution can be overwhelming because it is inherently complicated on many levels. While the challenge must be addressed holistically, the problems need to be dissected and then tackled in stages.

Where at all possible, rely on industry standards as the foundation of vocabulary and metadata harmonization, and distribute the harmonization work among participants. Preferably that occurs at the source when data is created. Likewise, leave the data at the source when possible. In order to do this, decisions need to be made regarding what data and documents need to be

brought in-house, and which can be managed by trusted partners. Minimizing the physical transfer of data will minimize backend work required to manage information and the infrastructure to support it.

As the numbers of partners grow, recognize that not all partners are created equal, and they will change over time. In order to maintain a versatile information management environment for the business, a range of solutions of varying complexity are needed that can accommodate different partners, processes, and information.

Finally, one size technologies do not fit all situations. There are excellent tools today so leverage the best-in-class technology building blocks for an optimal solution in the evolving externalized information environment.

For more information, visit our website www.resultworkslc.com or contact us at marketing@resultworkslc.com.