RESULTWORKS
Transforming Strategy. Delivering Success.

Clinical Sample Monitoring in a Collaborative Study Environment

by Susan Butler and Bob O'Hara, Managing Partners and Co-Founders,
and Michael Smart, Senior Consultant

INTRODUCTION

As the number and diversity of clinical studies increases, it tests the ability of organizations to manage key resources during study execution. At the same time, organizations are more dependent on external partners to handle the increased study volumes which ratchets up the complexity of study management further. One area that is of particular concern is clinical sample management where it becomes more challenging to plan, track, and manage samples by study across multiple organizations. Beyond the study, there are also decisions to be made regarding the ongoing use of samples for other purposes such as translational medicine initiatives.

This article explores the challenges of clinical sample management in increasingly complex collaborative environments. Based on work with several large pharmaceutical companies, it addresses both business and technology issues along with the business benefits of a comprehensive approach to managing the entire clinical sample lifecycle.

Figure 1: Clinical Sample Management Challenges

SAMPLE MANAGEMENT OBJECTIVES

As business directions evolve, so too do the objectives for clinical sample management. At the core of any program is an objective to manage patient samples in a compliant manner. With that as a given, there various other considerations that may or may not be important to the business. For example:

- Ensure compliant sample tracking throughout the sample lifecycle—begins

and ends with sample login to assay results

- Monitor samples—think dashboard of samples in context of program/trial/ study, patient related, ability to link across studies, partners, etc.
- Utilize specimens for Translational Medicine purposes over long term—begs long-term issue over sample access, secondary sample prep, testing, results management
- Business Efficiencies—managing, monitoring, samples throughout lifecycle can be manually intensive
- Secondary business efficiency—preparing samples for secondary purposes

Thinking through the end-to-end needs of the organization are critical to making the best decisions for each organization.

CURRENT LANDSCAPE

Keeping clinical samples synchronized has long been a challenge in managing a study. There are numerous systems involved in managing the study—eCRF, CDM, CTMS, LIMS, etc. Then there are numerous departments cooperating to conceive, plan, and execute the study. There are also an increasing number of collaboration partners involved from specialty labs, to central labs, to CRO's.

Some of the questions to that arise are: who needs what samples; where are the samples now; which organization is handling which samples; were they processed; who is waiting for what samples; etc. If these questions cannot be answered quickly and accurately, this can lead to: slower project execution, delayed decision making, reduced throughput, lost samples,

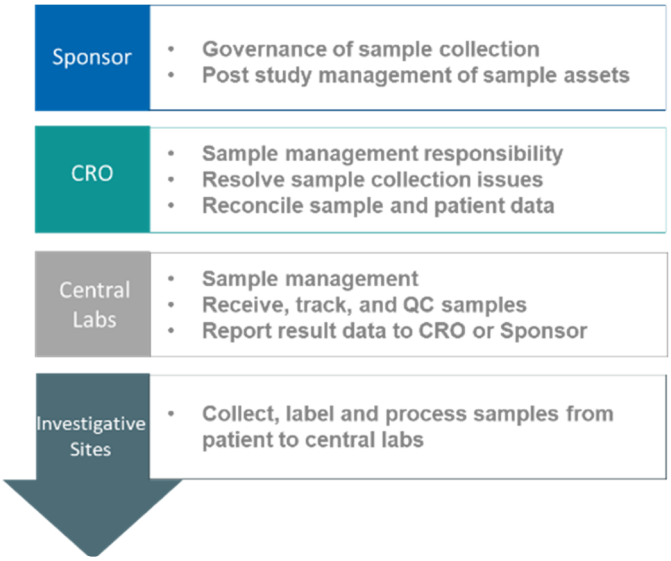

Figure 2: Hierarchy of Clinical Sample Roles and Responsibilities

uncertainty around patient sample collection, inability to complete the analysis and answer key endpoint questions, increased costs for repeat sample series, and compliance issues.

While LIMS (Laboratory Information Management Systems) are used for sample tracking within central labs and analytical

departments, the broader challenge is tracking and managing samples across collaborating organizations at any point in the study lifecycle.

Based on assessments conducted for several Life Sciences clients, the graphic on clinical sample management (pain points) categorizes the issues from planning of a new trial through storage and access to samples throughout their lifecycle.

These assessments of clinical sample management practices identified process, data management, and system gaps and opportunities in all of these pain point areas.

SAMPLE MANAGEMENT FRAMEWORK

One of the temptations in this space is to throw technology solutions at the initial problem. This has been one of the downfalls of many unsuccessful sample tracking projects over the last 25 years. Breaking down the sample lifecycle into components enables the business to tease apart the problem. This is shown in the Sample Management Framework figure. This approach identified of process issues and opportunities to address the first wave of challenges. One example of this is the gap in sample collection between a problem arising at the site and corrective action being taken by the lab. The cause of this is the distributed nature of sample management where each party has owned and managed its own samples. The end-to-end process chain then was only as strong as the weakest link.

Figure 3: Sample Management Framework

Another issue that emerged was the lack of consistent standards applied to instructions for sample collection, standard vocabulary, approval processes, roles, responsibilities, training. Consequently, the metrics around sample management were difficult to define, apply, and measure from study to study and partner to partner.

TECHNOLOGY SOLUTION

Sample management has traditionally been the domain of Laboratory Information Management Systems (LIMS). These systems have evolved to support traditional laboratory environments which could either be centralized or decentralized. The technical challenge in this case is that multiple companies are working together in a decentralized, contract related fashion. It is likely that most of these organizations have

their own, disparate LIMS technology, processes, and standards in place. The objectives of sponsors for clinical sample management involve establishing a view of clinical samples, status, etc. regardless of where the sample resides, and which company is performing the analysis. While a LIMS with significant modification and integration could be used to solve this problem, other solutions are also gaining traction in this space which should be explored.

Linked closely to the sample is management of patient informed consent forms (ICF). This is not something for which traditional LIMS have been built. Many businesses manage this external to the LIMS and link patients and samples through carefully managed manual processes.

Be clear on the objectives to be attained before starting down one technology road or another.

Beyond sample monitoring, there is also a question of secondary uses of the biospecimen. Storing samples beyond clinical trials opens a discussion about biospecimen inventory management which has been the realm of biobanking solutions. It also opens a discussion of biospecimen handling, rights, access, preparation for other uses, testing, and results management beyond any original contract with an external laboratory company.

The bottom line is to be clear on the objectives to be attained before starting down one technology road or another.

BUSINESS BENEFITS

Regardless of the system or the collection of solutions employed to satisfy objectives, there are clear benefits to defining and deploying a clinical sample monitoring solution:

1. Leverage Central Labs to focus on sample tracking and management to free up sponsor resources to focus on value added activities
2. Create efficiency and accuracy in sample processing, analysis and shipping
3. Ensure sample reconciliation among systems occurs proactively throughout the trials to detect issues early on
4. Improve visibility and oversight on sample collection and management
5. Ensure full compliance on SOE and ICF
6. Maximize sample asset value and usage
7. Provide significant cost-savings in sample storage

8. Allow management of large quantity of samples in a systematic and scalable manner
9. Ensure successful development programs by providing quality samples as required by study protocols
10. Leverage biospecimen for translational research purposes

CONCLUSIONS

Clinical trial approaches are evolving as collaboration becomes the order of the industry. This is exposing challenges we face in how we plan, collect, store, test, and report on clinical samples. The challenges encompass not only the physical management of the sample, but also the information associated with the sample regarding logistics and scientific properties.

In order to solve the challenges effectively, consideration must be given to the complete and end-to-end needs for the samples, the use of the samples within and post-trial, and the access to the associated sample data throughout its lifecycle.

Today, a combination of technologies is needed to address these challenges. As the industry starts to see these needs more pervasively, this is a problem that will be solved.

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