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Accurate Sample Tracking at the Heart of Timely, Quality Clinical Study Results

by Bob O'Hara, Managing Partner and Co-Founder, Michael Smart, Senior Consultant and Dan Joyce, Consultant

INTRODUCTION

As the number, diversity, and complexity of clinical studies increase, sponsor organizations are challenged to coordinate and track key resources during study execution. Sponsors are also reliant on an array of external partners from investigative sites to specialty labs to central lab operations, which are likely to be different organizations across a portfolio of studies. One area of particular concern is clinical sample management where it is challenging to plan and track samples and assays of various types in a consistent manner across numerous studies while relying on external organizations that all have their own processes and systems.

Based on several initiatives conducted with leading Pharmaceutical companies, a business process analysis approach teased apart the clinical study and sample lifecycle. This enabled stakeholders to delve into issues and challenges in study and sample planning, sample kits and logistics, site sample collection, sample shipping, receiving and tracking, and coordinated results management across service providers. Processes and information were mapped and analyzed in each of these areas to establish baseline needs.

This article explores the challenges of clinical sample management by segmenting the major stages of the lifecycle, identifying key issues at each stage, and identifying components required for a well architected, versatile solution to improve the accuracy and timeliness of sample tracking and results.

CHALLENGES OF SAMPLE MANAGEMENT

There are numerous challenges in managing clinical trial samples. Quite literally, hundreds of pain points associated with the process were identified across several different client initiatives. In an attempt to define specific areas of focus, the following five areas were defined:

1. Trial Design
2. Subject Status & Group Assignment
3. Subject Visit & Sample Collection
4. Sample Tracking

5. Results Management

These challenges are called out in Figure 1 below.

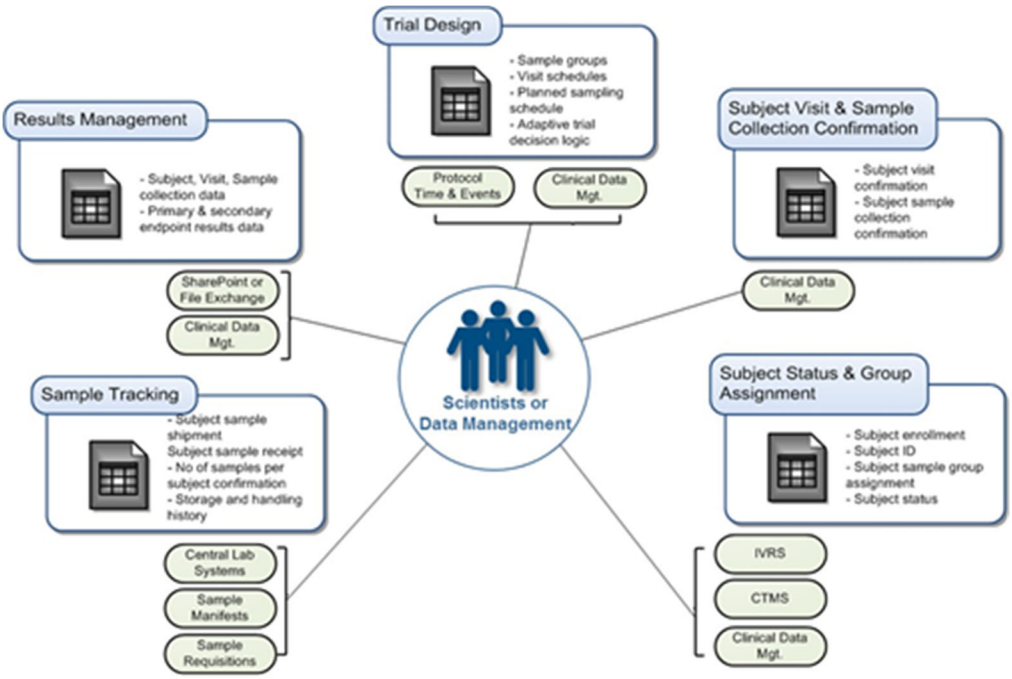

Figure 1: Sample Management Challenges

Trial Design - The initial trial and sample planning information is typically captured in the protocol and not readily accessible to downstream systems. As a result, managing sample information and keeping it up to date presents a challenge right from the start of the trial. In order to answer baseline questions (What is the visit schedule for each arm/cohort?; What samples are planned?) or changes in sample requirements (e.g., protocol amendments), team members must refer back to the protocol or associated amendment.

Subject enrollment and status throughout the study is another layer of complexity. Study teams need visibility of new subjects, subjects that withdraw or transfer sites, and the arm/cohort to which they are assigned.

As the study proceeds, subject visits and samples collected need to be reported and confirmed near real-time. Teams need to address "What subject visits occurred and what samples are recorded for each subject visit?"

Tracking the actual patient sample throughout its lifecycle is required. Visibility of where that sample is at any point in the process is needed.

- When did the sample get collected?
- Did the sample get shipped from the site?

- Was the sample received by the central lab or specialty lab?

> Time and event data is replicated in many different systems and documents which drive various processes

- Has the central lab shipped samples to the next step in the process?
- How has the sample been stored at each location and to what processes has it been subjected?

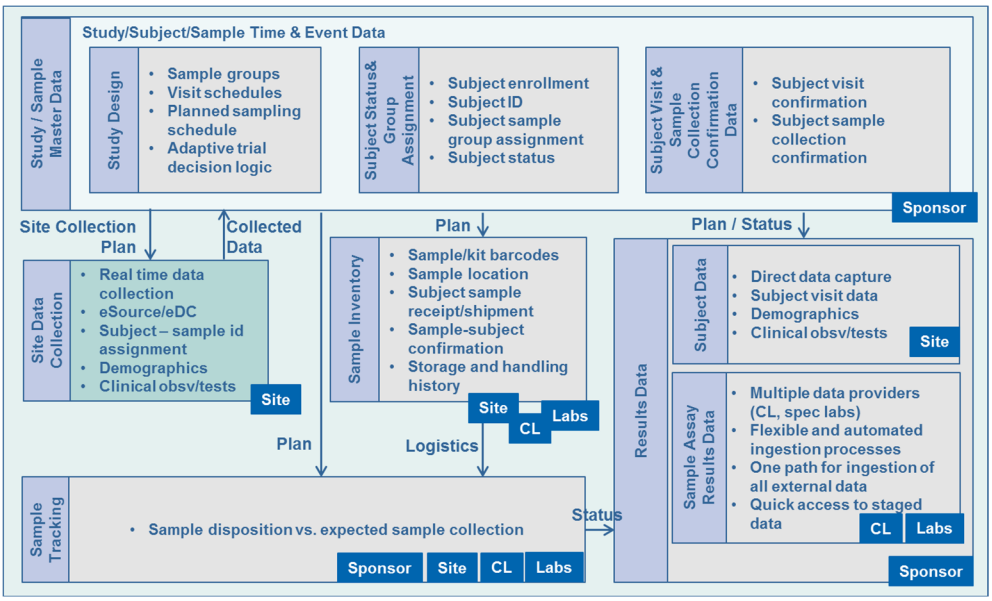

Figure 2: Study & Sample Master Data

Results Management - Once the sample is received at the right lab, study personnel need to know if the sample has been analyzed. Streamlined mechanisms need to be in place to accept the result data and integrate it into the clinical results repository. The ability to positively confirm that results have been received for the sample is required.

MASTER THE STUDY DATA

Time and event data for studies, subjects, and sample collection are initially captured in the protocol. In many organizations this data gets replicated in many different point solutions and documents to drive different sub-processes.

In order to be more useful, this information needs to be managed as study master data as shown in Figure 2. This master would capture study design data, subject enrollment, and subject visit and sample collection. It establishes a base-line plan of expected samples. While it would need to be managed in conjunction with the protocol and subsequent amendments, it becomes a better vehicle to drive information management associated with sample tracking.

Site data collection could then reference that master data with samples collected and tracked against the plan. Sample inventory information would also key into the master data and feed into the sample tracking information.

FUTURE OF CLINICAL SAMPLE MANAGEMENT

With the present-day complexity of clinical trials, there are so many partners with so many different systems that all need to talk. It becomes a many (sponsors) to many (sites) to many (central, safety, and specialty labs) information management problem. A preferred solution is one where information is captured one time in one place for access by all study participants.

This vision is portrayed in Figure 3 as a cloud-based system and services solution combination. For all the study participants, this environment needs to answer the following key questions:

- Are we collecting the right samples for enrolled subjects?
- Are we collecting a full set of planned samples?
- Are the samples getting shipped in a timely manner to the right places?

> A centralized repository for sample information represents a dramatic improvement since much of this data is still tracked in spreadsheets.

BENEFITS

Having a centralized repository for sample information represents a dramatic improvement over current environments where much of this data is still tracked in spreadsheets. Some of the potential benefits include:

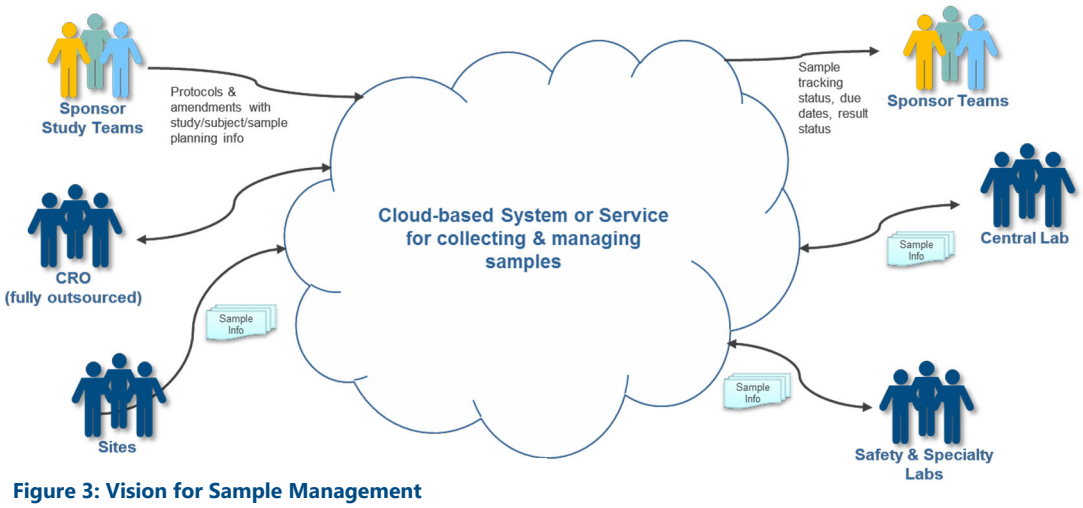

Figure 3: Vision for Sample Management

- A single authoritative source for study timing and events including sample information
- Better forecasting of expected samples and corresponding assay results
- More accurate, complete and timely tracking of samples facilitating closer to real-time reconciliation
- Comprehensive view of trial data allowing better tracking of samples and results.

CONCLUSIONS

While various solution strategies were explored for the key stages in the lifecycle presented, solutions are not a one-size-fits-all, but they are evolving.

Broadly speaking, several key takeaways were identified:

- Site sample handling and processing remains a critical success factor for real-time data collection in studies
- Driving common site processes and technology requires coordination with other sponsors or industry groups
- Harmonization of specialty lab sample and results management requires industry guidance, standards and leadership
- Independent commercial services and systems solutions would benefit all parties
- Industry groups, such as TransCelerate BioPharma, could play a helpful role to drive collaborative solutions
- Although the uptake is slow, there is a strong potential for eSource initiatives to make a difference at sites and specialty labs, especially with continued support from the FDA
- Ultimately the ability to interface with electronic health records systems would be ideal to minimizing site burdens, duplicate data and systems

At the end of the day, solutions need to be versatile enough to handle the range of partner capabilities while still giving sponsors timely, accurate, and consistent sample information with which to monitor and conduct studies. Solutions need to be architected and layered in order to meet today's needs, while investing toward more advanced capabilities in the future.

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