RESULTWORKS
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Transformations

RESULTWORKS NEWSLETTER VOLUME 15 ISSUE 2

SAMPLE TRACKING - KEY TO TIMELY AND PREDICABLE CLINICAL STUDIES

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 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/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.

Business process analysis teased apart the study and sample lifecycle.

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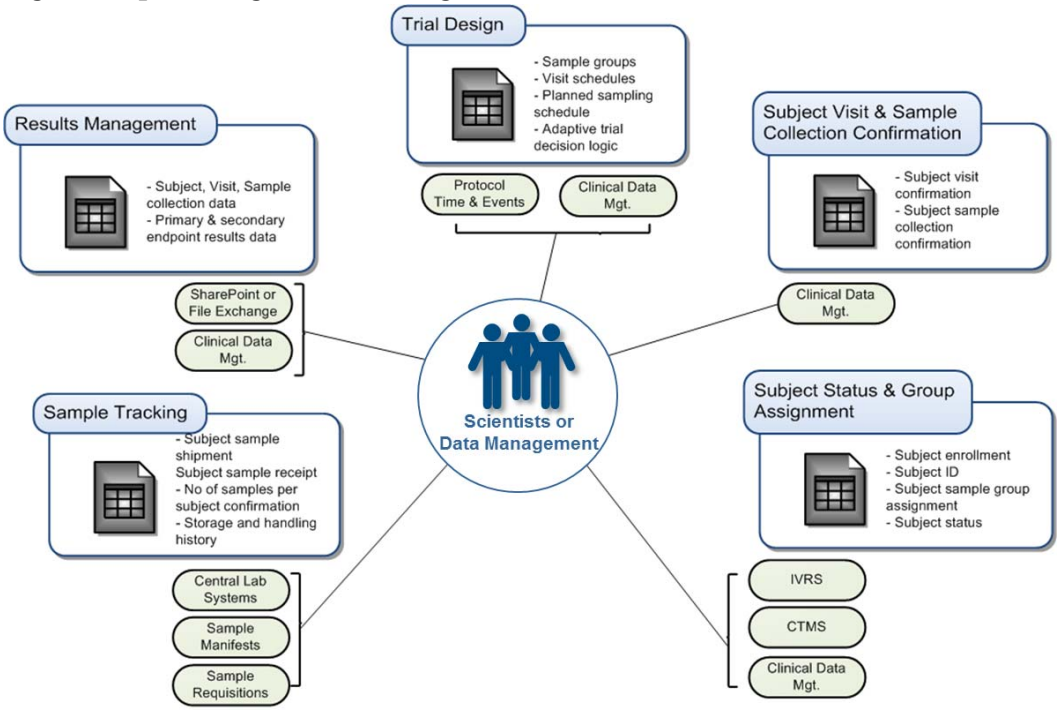
Fig. 1: Sample Management Challenges



OF SPECIAL INTEREST:

- ***Centralized repository for clinical sample planning and tracking data***
- ***Why HealthCare may finally be ready for big data***
- ***Systems Strategy Prioritizes Investments for Biologics Development***
- ***Integration with electronic health record systems would reduce site burdens, duplicate data and redundant systems***

INSIDE THIS ISSUE:

CLINICAL SAMPLES (CONT. FROM PAGE 1)

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. 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.

Trial Design—The initial trial planning and sample collection schedule information is typically captured in the protocol and is 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

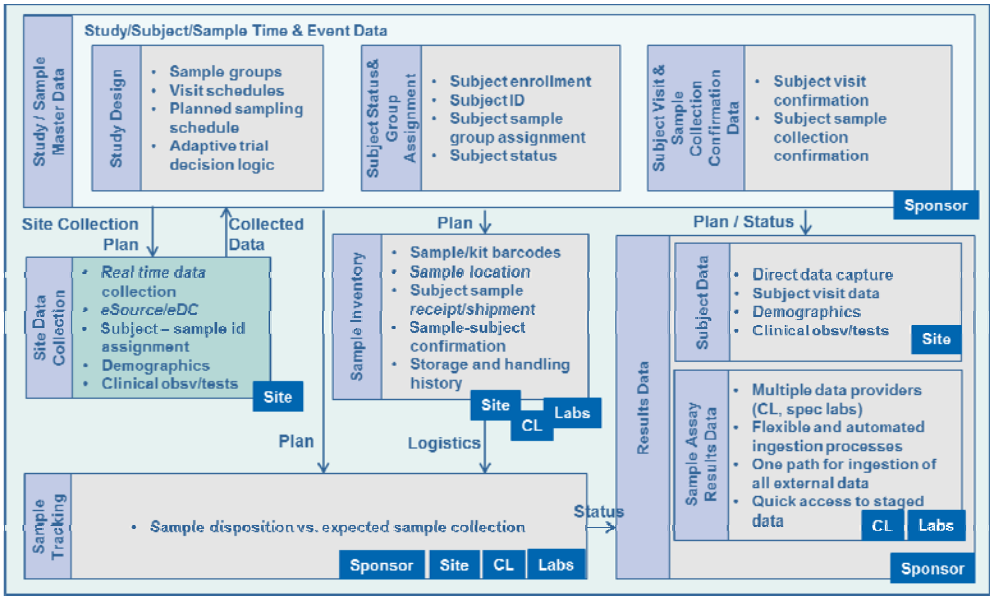


Figure 2: Study and Sample Master Data

point in the process is needed. Questions to be addressed include:

- 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?
- 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?

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 been received for the sample is required.

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

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 baseline 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 Sample Management

With the present day complexity of clinical trials, there are so many partners with so many different systems that all need to link. 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 of the study

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CLINICAL SAMPLES *(CONTINUED FROM PAGE 2)*

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 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:

- 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

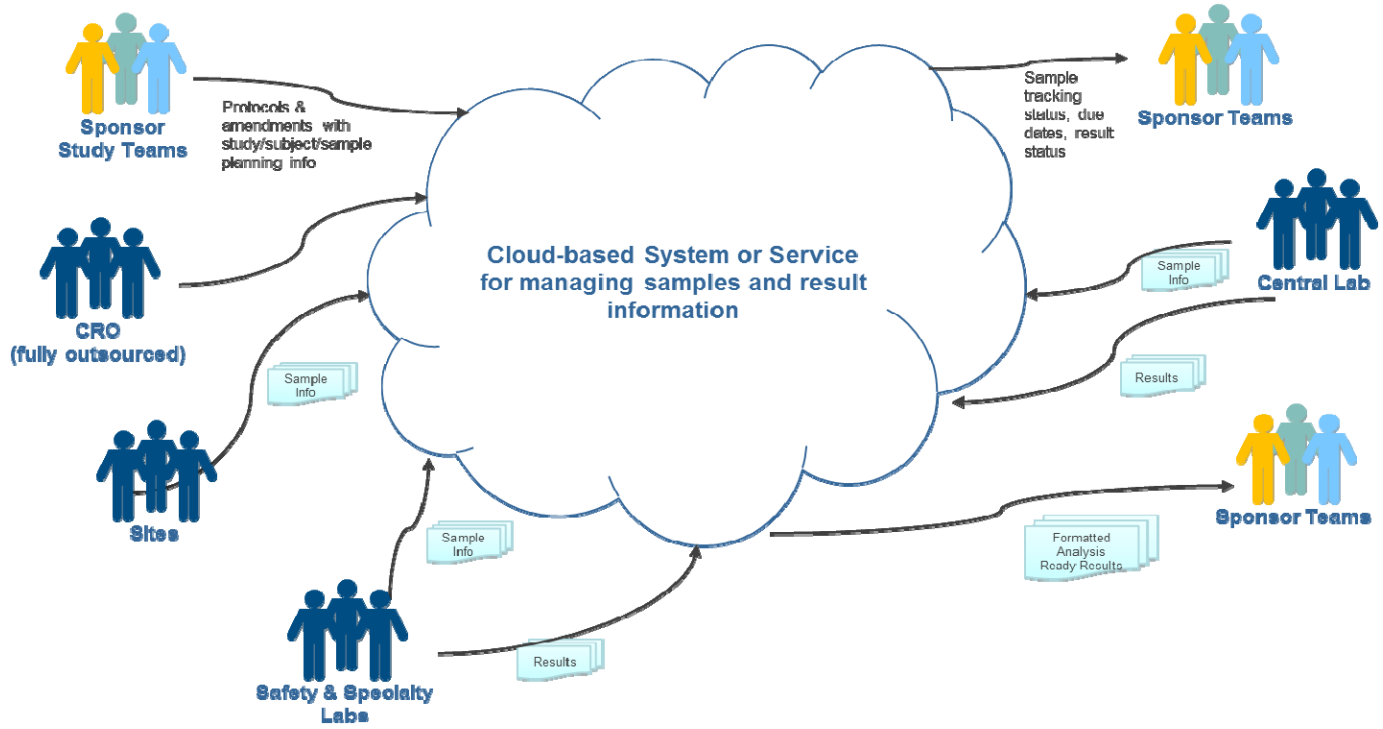
While various solution strategies were explored for the key stages in the lifecycle presented, solutions are not a one-size-fits-all, but they are evolving.

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.

Figure 3: Vision for Sample Management



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DELIVERING SUCCESS

Several new ResultStories have been added recently to our website. These are project briefs based on real world successes.

One such ResultStory describes how a ***Scientific Systems Strategy Prioritizes Investments for Biologics Development.*** The Biologics Development organization within a global pharmaceutical company was challenged to significantly increase their development of new biological entities. To meet the established goals, the business and IT organizations sought a deeper understanding of the company's current work practices, barriers to efficient operations and evolving business needs. The IT organization aspired to provide industry leading capabilities for the business but their position versus industry peers was unclear. Working together, they defined a shared vision for achieving their goals along with a multi-year strategic roadmap to get there.

"ResultWorks' investigation techniques were both rapid and thorough and your IT strategy opened our thinking to new opportunities for leveraging our siloed information assets."

BIO-IT POSTERS OFFER INSIGHTS TO STATISTICAL ENVIRONMENTS AND SAMPLE MANAGEMENT

Earlier this year at Bio-IT, ResultWorks presented two posters which garnered significant attention. The first poster was entitled *Enabling the Next Generation Statistical Computing Environment.* This poster described a business process analysis of current statistical environments identifying common issues and opportunities. An industry benchmark explored trends and challenges experienced by various companies. It also addressed how various companies are solving their own SCE needs.

The second poster, *Accurate Clinical Sample Tracking at the Heart of Timely, Quality Results Data,* ties to the feature article in this issue. The poster delves into the issues and strategies that were considered to optimize sample management in support of clinical studies.

For copies of either of these posters, please contact us at marketing@resultworksllc.com.

LEVERAGING DATA IN HEALTHCARE

As we know, Life Sciences companies are in the business of generating and managing information. We are challenged by huge volumes of data, the lack of data standardization as well as the broad organizational collaborations it takes to bring drug products to market. In a recent HBR article, "*Why HealthCare May Finally Be Ready for Big Data*", the authors N. Shah and J. Pathak argue that across the healthcare industry, teams are increasingly leveraging available data to challenge traditional approaches. Data-driven approaches are being used to accelerate randomized clinical trials for example. This is also being reflected back into the protocols and on a daily basis into the treatment of patients.

(To read the full article, click on the link in the title above.)

RESULTWORKS NEWS

Recent Events & Appearances:

- Greater Philadelphia Senior Executive Group Event hosted Dr. Fredric Abramson who presented Personalizing Personalized Medicine
- Bio-IT 2015—Presented two posters on Statistical Computing Environments and Clinical Sample Management
- CBI eSource Conference
- Life Science Knowledge Management Summit

Current / Recent Client Initiatives:

- Managing Clinical Content
- Clinical Sample and Results Data Management
- Streamlining Data Curation
- Strategy to Bridge Pharmaceutical Development and Manufacturing Information Management
- Early Phase Clinical Trial Data Flow and Management
- Improving Data Quality for the Clinical Trial Registry

ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

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