RESULTWORKS
Transforming Strategy. Delivering Success.

# Transformations

*RESULTWORKS NEWSLETTER*
*10 YEAR ANNIVERSARY ISSUE*

*VOLUME 13 ISSUE 1*

## *Of Special Interest:*

- ***10 Years of Results!***
- ***Collaboration can be facilitated by technology, but be clear on objectives***
- ***Current state and future outlook for Compound Management***
- ***Harnessing the power of modeling and simulation for more effective clinical trial designs***
- ***Close the chasm between strategy and execution***

## *Inside this issue:*



## *10 YEAR MILESTONE FOR RESULTWORKS*

How can we make more of our life sciences colleagues business and IT projects successful? That was the overwhelming desire and direction we set for ourselves 10 years ago when we started ResultWorks. We felt at that time that we had a breadth of experience across many projects in the course of our careers to really make a difference in the success rate of life sciences projects.

In one of our first meetings with a marketing consultant, we discussed some of our early projects in which we developed a strategy, laid out a plan, and delivered rapid results. This led to our company tagline "*Transforming Strategy. Delivering Success.*" which felt like just the right fit for us. Today, it still does!

Over the course of 10 years ResultWorks has helped many life sciences clients through hundreds of projects, deliver the results that they needed. In one of our favorite client quotes, a senior vice president wrote simply: *"ResultWorks certainly have helped us deliver results!"*

Results have been delivered in the form of visions created, strategies developed, business processes optimized, requirements defined, technologies implemented and change managed across numerous life sciences enterprises.

With great appreciation to our clients, employees, partners and our families, we look forward to delivering success to the life sciences industry for another 10 years to come.

Gratefully,

Susan & Bob

## *CLINICAL SAMPLE MONITORING IN A COLLABORATIVE STUDY ENVIRONMENT*

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.

**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 are various other considerations that may be important to the business. For example:

- Ensure compliant sample tracking throughout the sample lifecycle from sample login to assay results
- Monitor samples—view a dashboard of samples in the context of program/trial/study, patient connection, ability to link across studies, partners, etc.
- Utilize specimens for Translational Medicine purposes beyond the current study—begs long-term issue over

*(Continued on page 2)*

## *CLINICAL SAMPLES (CONTINUED FROM PAGE 1)*


**Figure 1: Clinical Sample Management Challenges**

sample access, secondary sample prep, testing, results management

- Business Efficiencies—managing and monitoring samples throughout the lifecycle can be manually intensive
- Secondary business efficiency—preparing samples for secondary purposes beyond the original study

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—eDC, 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 that arise are: who needs what samples; where are the samples now; which organization is handling which samples; were are 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, 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 challenges (Figure 1) categorizes the issues from planning of a new trial through storage and access to samples throughout their lifecycle.

These assessments of the clinical sample management practices identified process, data management, and systems gaps and opportunities in all of these challenged 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 2. This approach identified 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.

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

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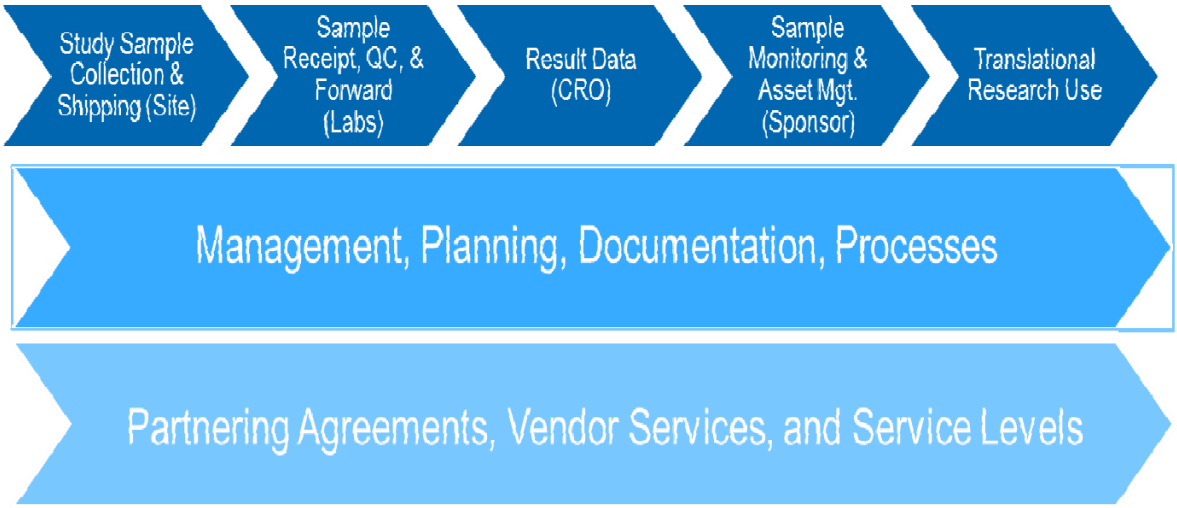
**Figure 2: Sample Management Framework**



## CLINICAL SAMPLES (CONTINUED FROM PAGE 2)

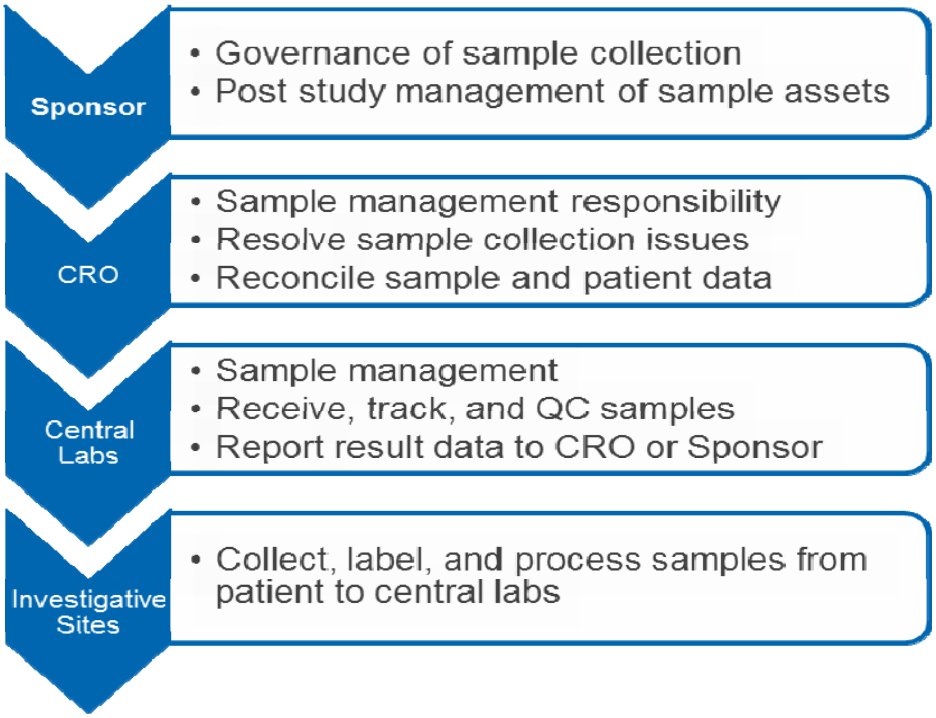



**Figure 3: Hierarchy of Clinical Sample Roles and Responsibilities**

**Solution Strategy**

Recognizing that the challenges involved in sample management encompass organizational, process, logistical, and technical issues, solutions must also address each of these areas.

As Figure 3 conveys, roles and responsibilities need to be well defined, along with optimized business processes, information definition and flow leading to selection of technologies which best support the collective business needs.

**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 be either 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 function external to the LIMS and link patients and samples through carefully managed manual processes.

Beyond sample monitoring, there is also a question of secondary uses of 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 collaborating CRO.

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 so as 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 Schedule of Events (SOE) and ICF

6. Maximize sample asset value and usage

7. Provide significant cost-savings in sample storage

8. Allow management of large quantities 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.

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

**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 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 are needed to address these challenges. As the industry starts to see these needs more holistically, clinical sample management problems will attract more comprehensive solutions.

# TRENDS IN COMPOUND MANAGEMENT

ResultWorks recently completed a survey on "The Current State and Future Outlook for Compound Management." The survey was administered to compound management practitioners and those providing automation hardware and software services to the industry. The survey was sponsored by a ResultWorks client in May 2013. The objective of the survey was to solicit perspectives from across different industries and from different roles of those associated with compound management. Figure 4 shows the business sectors and roles of the survey participants. Highlights of the blinded survey results are presented herein.

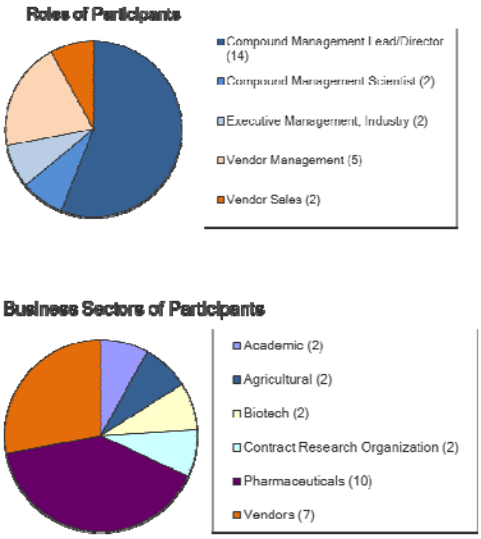



**Fig. 4: Survey Roles & Business Sectors**

## Survey Questions

Participants were asked a wide range of questions from organization to technology to strategy. Categories of questions posed include:

- Structure of the compound management group (centralized, decentralized, hybrid, outsourced)
- Potential for future growth envisioned in compound or sample management
- Challenges in compound management operations
- Approaches to use of collaboration partners (e.g., CRO's)
- Compound acquisition channels and library integration
- Capabilities required by customers supported by compound management
- Staffing issues and plans
- Strategies for managing inventory and evaluating compound collection
- Technological areas of interest applicable to compound management
- Major drivers behind investments in compound management technologies

## Business Challenges

Most of the respondents indicated that overall changes to the business at large are impacting compound management. Some of the challenges and issues expressed include:

1. Cost, budget constraints (unanimous)
2. More focused screening of targeted library subsets instead of HTS
3. Consolidation of libraries from mergers/acquisitions (centralizing to one area)
4. Increased use of outsourcing practices (to save fixed costs)
5. Need to improve operational efficiencies (faster, more reliable cycle time)
6. Need to reduce staffing/resources
7. Need for increased quality (inspection of compounds and solutions)
8. Increased support for biologics
9. Concerns over future uncertainty and obsolescence of current systems
10. Need to change business processes without changing integrated automation

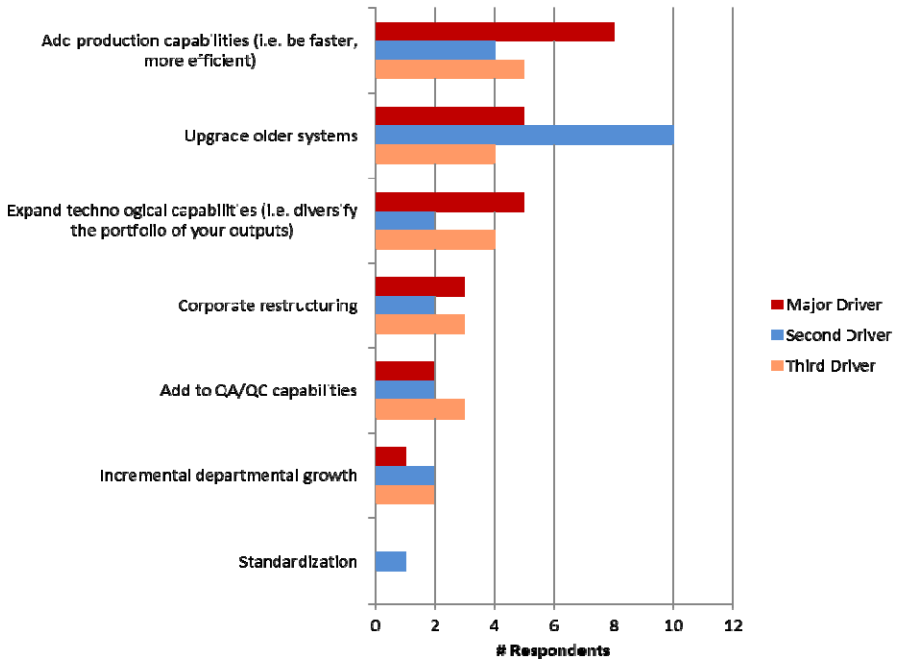
As a result of these business drivers, the primary compound management investments are shown in Figure 5.

The majority of the groups surveyed do not use CRO's for compound management at present. The groups that do leverage partner resources are still working to find the best way to balance CRO's with internal resources. Concerns over quality, costs, turnaround time and IP protection are the most likely reasons that CRO's are not used by more of the respondents.

On the other hand, those surveyed who are using CRO's do seem to be satisfied with their services since many of them are looking to expand the role of CRO's, especially to offload more routine tasks, archival storage or to meet expanding business needs by buying capacity.

For a copy of "The Current State and Future Outlook for Compound Management" survey results document, please contact us at marketing@resultworksllc.com.

**Figure 5: Primary Compound Management Investments**



# CLINICAL TRIAL MATURITY MODEL

ResultWorks recently completed a whitepaper entitled "A Maturity Model for Clinical Trial Design—Harnessing the Power of Modeling and Simulation." This white paper was developed in conjunction with ***Tessella***, combining their experiences with adaptive clinical trials, and ResultWorks experience with change management in this environment. An abstract for the whitepaper is offered below.

**Abstract**

The challenges faced by the life sciences industry are well documented – fall-off in NDA's, more complex clinical trial programs, and overall increasing costs with diminishing successes. With such widely-published, consistent depictions of these challenges, one would expect the industry to look for more opportunities to change their approach to drug development. Instead, the industry sticks to the same ground-losing game with reliance on traditional drug development processes and organization – using human-intensive work without applying more advanced integrated information technology. Perhaps Einstein was thinking of the pharmaceutical industry when he defined insanity as "doing the same thing over and over again and expecting different results."

Over the last five to ten years, pockets of change have emerged in advances in simulating clinical trials and clinical trial programs, and organizations willing to utilize them. For those who have persevered and evolved with the technologies, the returns have been significant, including reductions in time and cost, and improved decision-making based on scientific data.

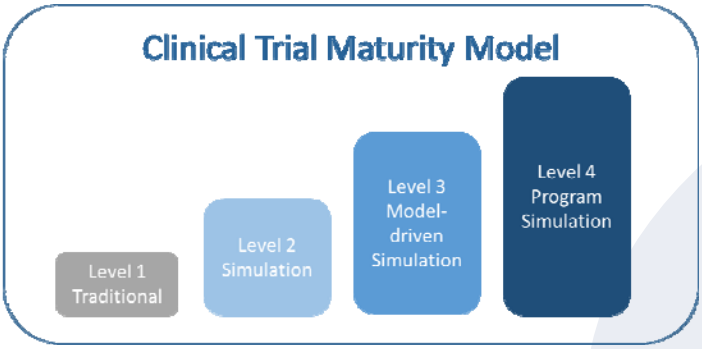



**Figure 6: Clinical Trial Maturity Model**

This paper proposes a progressive approach to addressing drug development challenges. It is couched in a proposed clinical trial design maturity model which allows for incremental use of effective simulation technologies. Key to the success of the technologies is the organizational commitment to shifting from the current state to increasingly mature methods which affect culture, organization, people, and process. Over time these technologies are incorporated into individual trials and ultimately into entire clinical trial programs where the returns can be impressive.

For a copy of the full whitepaper, contact us at marketing@resultworksllc.com.



# STRATEGY VS. EXECUTION

ResultWorks is involved in many strategy development projects as well as the required execution projects to realize business objectives. In a recent blog in *Harvard Business Review* entitled "Closing the Chasm Between Strategy and Execution" by Doug Sundheim, he argues that "execution is a minefield. The clean and elegant logic of strategy gets dirty in the real world. Agendas compete. Priorities clash. Decisions stall. Communication breaks down. Timelines get blown. It's never a question of if these problems will happen; it's a question of when and to what degree."

We see these minefields on many fronts in life sciences projects. As Sundheim goes on to say, "The easy solutions for this divide are the process solutions: better project management, clearer rules of engagement, and tighter operating policies. The tougher (and more powerful) solutions are the cultural solutions: getting each side to actually care about what the other side is doing."

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

# RESULTWORKS NEWS:

## Recent & Upcoming Appearances:

- Society of Laboratory Automation & Screening (SLAS) Conference—presented "An Approach to an Information Management Framework to Support External Collaboration"
- Bio-IT 2013 Conference
- DIA 2013
- Compound Management & Integrity Summit 2013

## Current / Recent Client Initiatives:

- R&D Information Management Strategy encompassing Externalization
- Pharmaceutical Development Transaction Mapping
- Compound Management Strategy and Workflow Analysis
- Lab Operations Assessment and Strategy
- Data Quality Assessment
- Data Quality Framework
- PMO Governance

# ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy, business process, and information management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of client engagements is generally on optimizing life sciences efficiency, throughput, and compliance across research, development, and manufacturing.

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