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BPM-enabled solutions for collaboration between Sponsor and CROs

White Paper

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Introduction

Is there a standard algorithm for flawless execution of clinical trials? On the face of it, the question should not even have to be posed. However, many clinical operations professionals will agree on a certain number of considerations. First, alignment is needed among different departments around the overall strategy for product development: it starts with a commercial strategy, under which fit successively, a regulatory strategy and a clinical strategy. The planning of clinical trials is a way to give input in the clinical strategy, and, most importantly, assess feasibility and affordability of the different studies that will be necessary to reach a successful filing with Regulatory Agencies.

Outsourcing the execution of trials to Contract Research Organizations (CROs) continues to be widespread in our industry. In fact, very few companies, from start-up biotech companies to “top 10 pharmas” will keep all activities in-house. Anticipation of the potential issues around implementation of the trials will allow the teams to develop contingency plans and evaluate solutions for commonly encountered problems, especially when the majority of the responsibilities have been delegated to third party service providers.

The goal of this article is to present common challenges faced by Sponsors of clinical trials when they outsource. How can Sponsors develop better processes around the management of trial operations information, particularly when the work is done by CROs? After all, the FDA and other regulatory agencies are focusing their audits more and more around the collaboration and partnership with CROs.

The Challenge

Even when an entire development program is outsourced to CROs, everyone agrees that the Sponsor is still ultimately accountable for the quality of the filing. Imagine the following scenario where a biotech company is filing a New Drug Application with the FDA. Phase 3 pivotal trials have been outsourced to a well respected CRO. During the review of the application, FDA decides to audit a few sites. They are concerned with some observations around GCP compliance at the sites and the fact that these have not been addressed diligently by the monitors. They then decide to audit the CRO and find that the sites have not been monitored with the expected frequency and that monitors were weak in documenting and resolving data integrity issues. They also criticize the Sponsor for not taking a collaborative role in their interactions with the CRO during the conduct of the trial. The ultimate outcome becomes disastrous for the Sponsor: based on their concerns, FDA issues an “approvable letter” and requires that more monitoring be done before accepting the data. Delays in time to market will cost the Sponsor millions of dollars.

Although the FDA acknowledges and expects that a lot of trial management activities are conducted by CROs, the FDA still holds the Sponsor ultimately accountable for the study outcome. Therefore, during regulatory inspections, they may ask what systems and processes have been put in place to ensure the quality of the CRO work meets expectations.

As we can see in the case study above, Sponsor companies, who have transferred regulatory obligations to their service providers, are unfortunately at the mercy of information systems used by their partners. Even if the CRO is already collecting, tracking and monitoring the progress of the trial, this information does not always meet all the Sponsor needs. Therefore, Sponsors will have a tendency to create redundant systems or tracking tools to follow the different milestones of the project.

Even when a trial is managed internally, multiple functions are collaborating to achieve the ultimate goal of producing a Final Study Report. The challenge, from a project management perspective, is to identify deliverables from the different contributors and how the “co-dependencies” may become an obstacle to meet the pre-defined milestones.

Validated computer systems to collect and analyze trial management information are not a requirement for the approval of new products. The challenge is for trial managers to know the exact status of projects and identify solutions needed to get back on track if studies are delayed or if more issues than anticipated are arising.

Finally, another type of issue seems to arise more and more in CRO/Sponsor relationships: the increasing popularity of “Adaptive Design Trials”. These types of trials use accumulating data to decide in a well-defined manner how to modify aspects of the study without compromising the integrity of the results. Few CROs (and few Sponsors) have experience in the execution of adaptive trials and know how to avoid operational bias. In the next few years, success will be defined by companies who can perform effective scenario planning, define ahead of time the decision criteria and demonstrate the most flexibility in the use of resources to monitor the trial, as well as collect and analyze the data.

The Solution

In today’s economic climate, life sciences companies need better cost control, risk management and collaboration tools, as well as greater strategic and tactical flexibility to cope with frequent regulatory changes and surrounding competitive pressure. They need to constantly monitor and continuously increase their operational efficiency.

In any organization processes are the core elements of operations. As such, operational excellence cannot be achieved without focusing on processes. Some of those processes are captured and automated by packaged applications in various segments of the life sciences industry, such as CTMS or IVRS in the Clinical Trials space.

However, in traditional applications the underlying processes are hardwired and offer no flexibility and opportunity for process improvements.

The newly emerging BPM (Business Process Management) enabled solutions provide, out-of-the-box, the required agility along with real time visibility within a process context that Six Sigma and other business process improvement methodologies require. The explicit and direct access to underlying processes not only facilitates continuous process improvement cycles, but also helps capture the best practices and retain knowledge within organizations.

Savvion’s Life Sciences Foundation provides a platform to model, simulate, optimize and execute various collaborative processes, as well as an integration framework that allows tying disparate systems into end-to-end processes. It provides an easy way to define performance metrics and monitor them in real-time through user dashboards, with unprecedented visibility into concurrently running processes.

Companies can leverage the Life Sciences Foundation to quickly customize and deploy BPM-enabled solutions for managing clinical operations (also known as Clinical OMS).

The Clinical OMS is precisely the correct solution for meeting Sponsors/CROs operational challenges. The System helps manage, optimize and automate the clinical trial processes across the following stages:

- Study Start-Up
- Study Conduct
- Study Close-out

The Savvion Clinical OMS facilitates collaboration between participants from Sponsor, CRO, CMO and Sites and provides visibility required to:

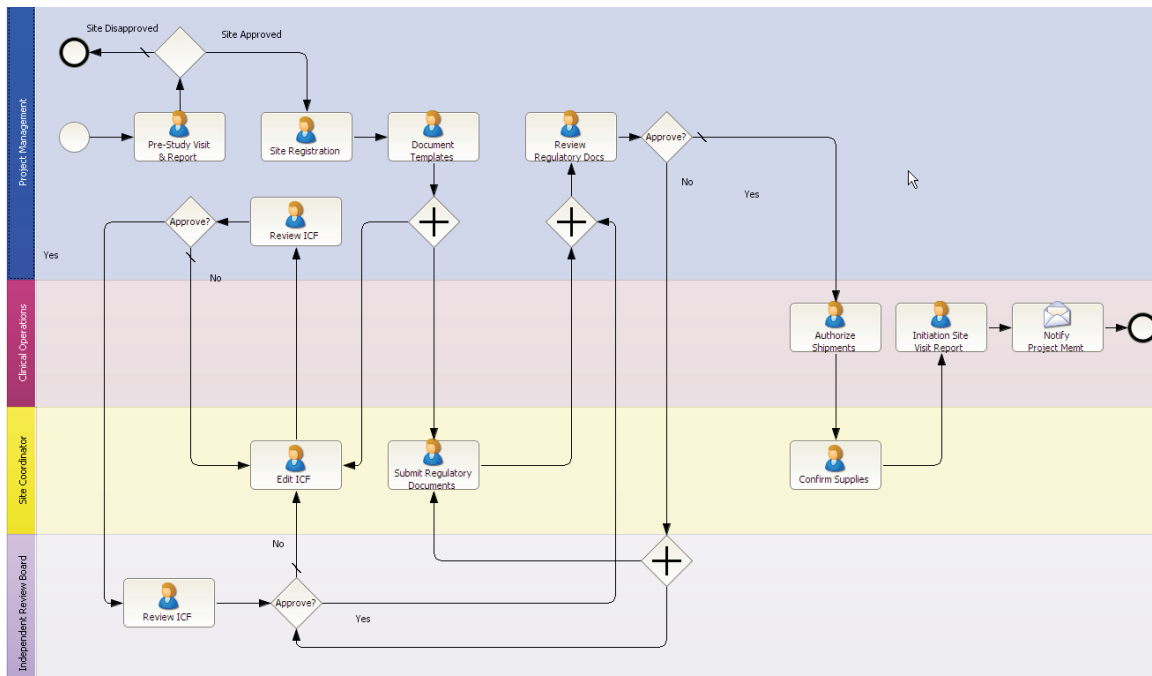
- Monitor the progress of trials
- Expedite the time to market of drugs
- Increase the ROI on clinical research
- Allow for business process improvements
- Communicate, verify and enforce business and regulatory processes



The system also allows Sponsors/CROs to leverage and complement their existing clinical trial systems to control the end-to-end process. And since access to the data is centralized, there is no need for creating redundant tracking tools to follow the progress of the trials.

This is a value added tool for trial managers to know the exact status of projects and identify solutions needed to get back on track when studies are delayed or if more issues than anticipated are arising. By making quicker decisions sooner rather than later, this allows the Sponsor (in collaboration with the CRO) to minimize delays in the clinical trial phases and save millions of dollars throughout the project lifecycle.

An integrated business rule and event correlation system allows for automated reactions and timely escalations when a study faces an issue or meets the threshold for changes. For example, if you reach a certain pre-defined point in the enrollment of certain patient groups, an automatic notification can trigger clinical supply chain management to ship new doses of investigational products through a seamless integration with an IVR system.



The backbone for clinical trial process is essentially the same from study to study; however every study is conducted differently with variations to the clinical trial process template. In a BPM-enabled solution any part of the process template can be easily modified to fit the needs for new studies.

Adaptive trials, which allow changing the operational plan while it is being carried out, require appropriate IT infrastructure to deliver agility and flexibility to trial processes. A BPM-enabled solution will provide this effectively to obtain study results faster by quickly adapting to the regulatory conditions and changing business needs by using data-mining and simulation to identify opportunities for optimization and in-flight process updates. The changes that needed months can now be delivered in days, while meeting the regulatory requirements at the user and system level.

Conclusion:

The systems currently available on the market to track clinical trials and manage CRO relationships do not meet the needs of sponsor companies. In almost all cases, there is a lack of consideration for the multiple external collaborators who also use systems to collect trial metrics. This makes the process cumbersome and highly inefficient.

The specific requirements for the tracking of clinical trials are generally not well defined. For example, what is considered a critical issue by a given trial manager may not even appear on the radar screen for another manager in the same department. Issue escalation criteria are rarely standardized within sponsor companies. This makes it difficult to pool data across several trials and also does not allow for easy sharing of resources (each clinical research associate can only work on one project at a time due to the unique nature of the activities being managed for their trial).

A BPM approach for the planning and execution of clinical trials and collaboration between the parties is needed to gain visibility, agility, and efficiency throughout the clinical development phases.

What Benefits does the Savvion Solution Provide?

The Clinical OMS, built on BPM, provides the following key values that ensure successful clinical trials with quick time to market:

- **VISIBILITY.** This is an ability to gain insight into fast-changing business challenges in order to develop responsive processes. It's critical to have visibility into your business processes and monitor what is going on in the business. Timely notifications are critical for steering clear of disastrous situations or avoiding huge fines and liabilities if your system drifts out of regulatory compliance.
- **AGILITY.** This is an ability to respond to business changes quickly. In today's dynamic environment, companies need to deal with continuous change and adapt quickly to an ever-shifting business environment. Organizations don't have the luxury of 12 to 18 month software upgrade cycles. Circumstances can change in a matter of weeks or a couple of months, and the processes that govern businesses need to adapt just as quickly. A BPM solution must provide the change management functionality to accomplish this.
- **EFFICIENCY.** This is an ability to obtain the greatest productivity from business operations. To maximize efficiencies, your business processes need to be "lean and mean" - devoid of wasted time and effort. That means knowing your processes thoroughly: where the redundant steps and where the bottlenecks are. Understanding the processes and deploying process solutions removes wasteful business activities and eliminates shadow processes that create systemic inefficiencies. The result: humans and systems that work together across departmental boundaries—a well-oiled machine that maximizes your results with minimal effort.
- **BUSINESS EMPOWERMENT.** This is an ability to empower business user to describe, analyze and optimize the business processes and take quick and informed decisions. People closest to the process are the most knowledgeable about it. It is critical, therefore, that business users are engaged in all process management and improvement activities. The tools they employ to describe their processes and document requirements must be suited for their use. Business empowerment is all about giving business users the capability to make decisions quickly on their own.
- **ECONOMY.** This is an ability to achieve the highest ROI for the lowest total cost of ownership (TCO) on company's investment in improving their business. Companies must be mindful of their investments as never before. As a business executive, you need to know what business efficiencies your investment in BPM will bring and how quickly you will realize ROI.

Authors

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Bruno Gagnon is an opinion leader with over 15 years of experience in the field of Clinical Operations. He is the Senior Director of Clinical Operations at Roche Molecular Systems, Inc., located in Pleasanton, CA. Bruno oversees operational activities for Medical Affairs as well as functional areas such as Medical Writing and Clinical Systems. Prior to his current position, Bruno was heading up the Clinical Operations group at FibroGen, Inc., a privately owned biotechnology company in South San Francisco. Prior to that, he worked for 6 years at Chiron Corporation (now Novartis), where he had leadership responsibility for various global functional areas. He also worked as a Clinical Outsourcing consultant as well as a manager in the CRO and big pharma sectors.

Bruno holds a bachelor in pharmacy from Laval University and a Masters in Pharmaceutical Sciences from University of Montreal, in Quebec, Canada. He is on the faculty at San Francisco State University, College of Extended Learning where he teaches a Clinical Trial Design class.

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Pejman is a Silicon Valley technology veteran and serial entrepreneur with more than fifteen years of progressive experience in providing software expertise and best practices to technology investors, business enterprises and forward-thinking startups.

Widely known as a leader in the field of Business Process Management and Knowledge Modeling, Pejman has been a key architect of multiple high-profile products, including Savvion's award-winning BPM platform.

Today, Pejman is the VP of Solutions at Savvion where he combines his decade of BPM experience with his expertise as a PMP & Lean Six Sigma Black Belt to incorporate continuous process improvement into next generation of business solutions.

Pejman holds a B.S./M.S. degree in Computer Science from Dortmund University in Germany and has authored multiple Patents and Standards.

About Savvion

The world's top-performing companies, including 22 of the Fortune 100, choose Savvion to operate more productively and profitably. As the business process trailblazer, Savvion moves enterprises beyond ordinary BPM with groundbreaking business-critical software, solutions and services that make them more competitive, agile and cost-efficient. Headquartered in Santa Clara, California, Savvion can be reached at www.savvion.com or 888-544-5511.

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