

# PROGRESS<sup>®</sup> SAVVION<sup>™</sup> LIFE SCIENCES FOUNDATION

## LIFE SCIENCES OPPORTUNITY

In today's difficult market, the life sciences industry is focusing on a number of challenging business drivers. The challenges range from the expiration of patents, escalating cost of global clinical trials and increasingly stringent regulatory guidelines. Due to these factors, the pharmaceutical and medical device companies and their contract research organizations (CROs) must re-evaluate their clinical trials processes and look for efficiencies, enabling them to adapt more quickly while reducing costs. They are being asked to do this in a climate of decreasing budgets and with less people.

## HIGHLIGHTS

> Built on the Progress<sup>®</sup> Savvion<sup>™</sup> industry-leading Business Process Management (BPM) system, the Savvion Clinical Operations Framework provides out-of-the-box agility along with real-time visibility to help optimize, automate, and manage clinical trial operations



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Clinical trials are a particularly costly and time-consuming part of the R&D process, frequently accounting for over 40% of total R&D spending. Inefficient trial management causes 70% of missed clinical trial deadlines, costing sponsors and CROs up to \$100,000 per day.

## CHALLENGES

Some of the key problems and critical challenges in clinical operations today are:

### ***Lack of Control***

- > Manual gaps in the clinical operations process make it difficult to track, manage and control.

### ***Poor Integration***

- > Multiple systems are not integrated for a complete end-to-end solution.
- > Data that resides in the clinical trial management (CTMS) system, also resides in the electronic data capture (EDC), safety, regulatory affairs, interactive voice response (IVRS), grant management, SAS, procurement, and contract management systems.
- > Data redundancies cause regulatory risk, and increase reconciliation time required for reporting and data evaluation.

### ***Lack of Visibility***

- > The visibility is very limited into each necessary step of the clinical trial.
- > Global roll-up of the trial status information delays trial completion by weeks or even months.

The core elements of a business operation are its business processes, or the ways in which it organizes and uses resources to achieve its desired results. 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 trial space. However, in traditional point solutions the underlying processes are limited and, as such, offer less flexibility and opportunity for interdepartmental process optimizations.

## SOLUTIONS FOR CLINICAL OPERATIONS

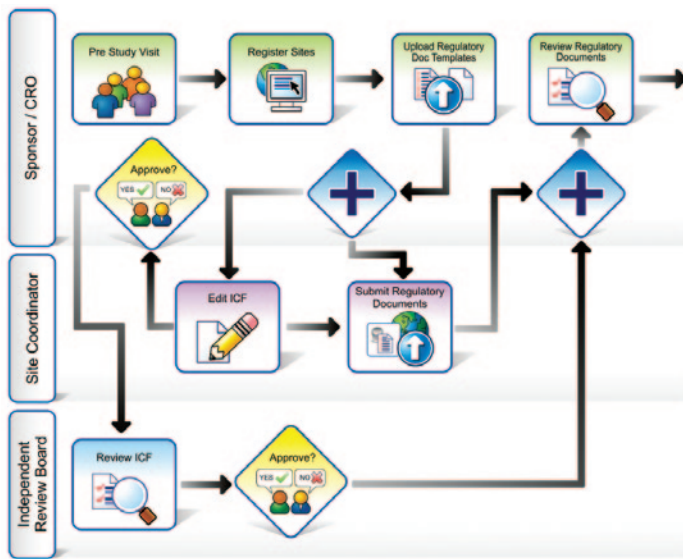
With Business Process Management (BPM), an organization can cooperatively define its business processes, integrate them with its existing software systems, and deploy them as applications accessible via the Web. Managers and their teams can monitor, analyze, control and improve the execution of those processes in real time. Built on the industry-leading Progress® Savvion™ Business Process Management (BPM) system, the Savvion Clinical Operations Framework provides out-of-the box agility along with real-time visibility to help optimize, automate, and manage clinical trial operations.

The Clinical Operations Framework is made up of a collection of “BPM-enabled” applications in key clinical operational processes such as:

- > Study start-up
- > Site set-up and activation
- > Ethics and informed consent process
- > Site monitoring, close-out visits
- > Site status tracking
- > Adverse event monitoring and reporting
- > Managing good clinical practices (GCP) non-compliance at sites
- > Patient enrollment
- > Development of study protocols
- > Sponsor and CRO collaboration

The Savvion “BPM-enabled” application allows you to **model**, **simulate**, **optimize** and **execute** various collaborative clinical operational

processes. These applications can complement existing clinical trial systems (such as IVRS, CTMS, EDC, etc.) to control the end-to-end process. And since control of human resources, systems, processes, and data can be centralized by a BPM-enabled application, there is no need for creating redundant tracking tools to follow the progress of the trials. The Clinical Operations Framework provides an easy way to define performance metrics and monitor them in real-time through user dashboards, with unprecedented visibility into concurrently running clinical operational processes.



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## BENEFITS

### ***Visibility***

- > Timeliness of critical information such as site activation, case report form (CRF) data, enrollment metrics, and monitoring time allows for more informed decision making
- > Provides real-time visibility into all global trial sites to get red, yellow, green status
- > Easy-to-understand dashboards that can collect the data entered into your other enterprise systems and compile it into graphs, charts and plots
- > Immediate access to trial results as the trials progress for everyone from sponsor to CRO
- > Value-added tool for trial managers to know the exact status of projects and identify where fixes are needed to get back on track when studies are delayed or if more issues than anticipated are arising
- > Rapid, accurate decisions sooner rather than later, resulting in better resource usage
- > Allows sponsors and CROs to minimize delays in the clinical trial phases and potentially save millions of dollars throughout the project lifecycle

### ***Agility***

- > Provides you the ability to quickly adapt clinical operational processes and respond to FDA inquiries, regulatory, and business changes
- > In a typical cross-functional environment of a clinical trial, the downstream functions can react quickly to changes that occur earlier in the upstream part of the process
- > In a “BPM-enabled” application, any part of the process template can be easily modeled to fit the needs for new or existing studies
- > Leverages your existing systems or quickly build new process templates to fill the process gaps

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### **Efficiency**

- > Allows maximum productivity in sponsor/CRO relationships by reducing duplication of effort and redundancies
- > Provides out-of-the-box functionality for continuous process improvement in clinical operational processes
- > Improves resource management and management decisions to effectively increase your usable resource pool by optimizing and automating workflow processes across multiple sites, studies, teams, and trials
- > Allows for clinical drug supplies delivery to each trial site on a “just-in-time” basis

### **FEATURES AND FUNCTIONS**

- > Solution templates—out-of-the-box, configurable solution templates and process models help jump start a quick deployment of clinical operational processes
- > Configurable R&D dashboards—provide real-time results into your entire clinical operations
- > Support for standard operating procedures (SOPs)—allows you to make changes to SOPs, and deploy instantly to a distributed clinical operations team
- > Integration with existing business systems (Documentum, SAP, Oracle, Siebel, etc.)
- > Support for HIPAA and 21 CFR Part 11 requirements
- > Alerts and exception and resolution management—triggered alerts, issue resolution, delegation, and intelligent rerouting of work assignment
- > Drag-and-drop process changes, UI modifications—optimize for process improvement, and then quickly deploy the application
- > Clinical operational processes—evolve without software changes as your environment, policy and regulations change
- > Electronic binder to store, manage, and control versions of regulatory documents

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## PROGRESS SOFTWARE

Progress Software Corporation (NASDAQ: PRGS) is a global software company that enables enterprises to be operationally responsive to changing conditions and customer interactions as they occur. Our goal is to enable our customers to capitalize on new opportunities, drive greater efficiencies, and reduce risk. Progress offers a comprehensive portfolio of best-in-class infrastructure software spanning event-driven visibility and real-time response, open integration, data access and integration, and application development and management—all supporting on-premises and SaaS/cloud deployments. Progress maximizes the benefits of operational responsiveness while minimizing IT complexity and total cost of ownership.

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