



# BPM-Based Case Management Approach To Optimizing Clinical Trial Efficiency

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# BPM-Based Case Management Approach To Optimizing Clinical Trial Efficiency

Over the past decade, clinical trials have become notoriously inefficient undertakings plagued by problematic protocols, missed enrollment targets, and an unsettling level of redundancy and rework. Only about a third of drugs that enter clinical testing ever progress to large-scale phase III studies and the success rate could decline further if health care reform ratchets up the standard for proving value over therapeutic and generic alternatives. Even the most promising new medicines set regulators on vigil for undiscovered safety issues. Life sciences companies, forced to abandon their traditional “blockbuster” approach to drug development, suddenly find themselves on a quest for a forward-looking operating model predicated on cutting waste and managing risk.

They need look no further than their own manufacturing and marketing divisions, streamlined years ago by the principles of Business Process Management (BPM). And look they must. The sour economy, coupled with looming patent cliffs and a risk-averse and increasingly complex regulatory environment, is making obvious that delays in study startup and the expense of complying with adverse event (AE) reporting mandates are as much BPM problems as bottlenecks in product assembly lines and customer call centers.

Steering a turnaround requires unifying and automating the business rules driving corporate policies and procedures and navigating people, information, and systems down the most direct and suitable path to their desired goal. Directional

shifts happen in response to a string of if-then scenarios, detouring only when necessary to avoid any unexpected potholes. Interested study subjects — be they reaching out by telephone, email, or the Web — might thereby be whisked to an automated pre-screening tool of a geographically appropriate and enrolling clinical trial for which they are suited by virtue of age, gender, and diagnosis. Adverse event reports might also get accurately processed in compliance with an assortment of worldwide guidelines with a minimum of human intervention, while producing dashboard views of local safety metrics.

As a discipline, BPM’s goal is to optimize the performance and transparency of business processes so they remain in sync with business execution. Although first developed to automate mechanistic processes, the focus of BPM today also encompasses people-driven processes requiring human judgment and interactions. The BPM approach anticipates frequent process change inherent to clinical trials and provides an enlarging role for business users to alter process specifications ad hoc in response to exceptional triggering events.

At the macro level, BPM eliminates all the needless repetition spawned by multiple clinical trial information systems used to manage data and documents. BPM software knits these disparate information systems together so companies can leverage existing applications and utilize each of their best features. Additionally, BPM serves the information technology (IT) needs of companies that never had the wherewithal to invest in expen-



sive clinical trial software in the first place. A robust, BPM-based clinical application can be constructed incrementally to cover all the vital and interconnected tasks from protocol development onward.

To date, BPM has been enthusiastically embraced by the healthcare and financial service industries in search of efficiencies and the process agility to meet productivity and effectiveness goals. But life sciences companies that have applied BPM solutions to clinical trial tasks have also seen impressive results. In addition to improved workflow, the positive effects include increased productivity, fewer errors and rework, heightened confidence in regulatory compliance, improved communications with investigators and study subjects, and decreased reliance on the IT department during process-changing events.

In short, BPM has demonstrated the ability to help companies apply the right resources in the right combination at the right time in support of critical work tasks. Over the long term, this provides the nimbleness to meet changing market and user needs as well as mounting regulatory demands. In the clinical trials arena, these attributes are as much competitive necessities as they are competitive advantages.

## Parallels with case management

Process management has a great deal in common with case management, whereby people collaborate and dynamically take action to meet a specific business objective. Managing a “case” — be it the care of a patient, an insurance claim, a clinical trial, or even a blockbuster product — means contending with one huge process problem within which any number of sub-cases, tasks, steps, events, processes, prior related cases, and supporting content nest. The tasks that get accomplished along the way likewise have processes associated with them, which invariably include routine as well as knowledge-based work. Procedures for inputting data on case report forms or issuing investigator grant payments can probably be distilled into discrete and repeatable steps. But coping with unexpected events, such as customs-related drug shipment de-

lays or mid-study regulatory changes, necessitates the flexibility to respond in ad hoc fashion within a looser set of parameters. Intelligent clinical trial case management, like intelligent BPM, thus accommodates both dynamic and structured processes.

Management of a case and management of a process is a one-to-many relationship. Managing a clinical trial as a case brings control and visibility to previously manual processes, providing a granular view of content and actions so customers — be they patients, clinical investigators, or regulators — get better served. Because overlaps become transparent they’re avoidable. Subtasks can also be more readily recognized and get reassigned, as appropriate, to lower skilled workers.

Clinical research is a far more knowledge-based business activity than the production of a pill or device. BPM, though itself a structured process, makes an ideal “home base” for the dynamic, collaborative, and highly contextual nature of clinical trial case management. Pegasystems is mindful of the need for this synergy. With its SmartBPM technology, powered by an industry-leading business rules engine, routine tasks get mapped out in traditional BPM fashion. Intended changes to the process can be simulated and compared to determine the optimal improvement. Knowledge-based work gets automated in customary case management style, where an informed user picks and chooses from a broader menu of step options to achieve an objective. But no one leaves the BPM environment, regardless of work type, so activity gets tracked and monitored even as problems get creatively resolved.

## An embarrassment of inefficiencies

It is widely accepted that the current approach to planning and managing clinical trials is outdated. Protocols have become challenging to design because clinicians and regulatory agencies require more data from trials than ever before. The added complexity, often in the form of higher procedural volume(1), in turn makes an already limited pool of qualified study volunteers more difficult to attract. The clinical enrollment process has yet to be

standardized within some companies, let alone across the industry, and continues to limit the means if not the hours that would-be subjects and investigators can make inquiries. Investigators overall are overused and poorly managed. Clinical trial budgets get negotiated based on assumptions of low site performance(2). And alternatives to traditional and largely inefficient site-based monitoring remain in the piloting stage(3).

Global study teams operate in silos because they have difficulty collaborating. Safety reporting is likewise decentralized, despite more stringent requirements for the consolidation and reporting of safety data(4). Potential problems aren't anticipated, so corrective action happens in rescue mode, compounding the inefficiencies and redundancies. Since operational plans typically reside on spreadsheets, they are in any case difficult to adjust when things go awry.

Given this scenario, it is unsurprising that clinical trials consume an estimated 60% of total R&D budgets(5) and have become a focal point for belt-tightening. There is waste literally at every juncture. Timelines reflect this. Between 1999 and 2005, the length of time required to conduct a clinical trial increased a whopping 70%, to roughly 26 months, and the situation shows few signs of improvement. Study startup may be one of the biggest clogs in the pipeline. The Center for the Information & Study on Clinical Research Participation reports that nearly three-quarters of studies are delayed more than a month. Half of all sites under-enroll, with 20% failing to enroll a single patient(6). Regulatory approval submissions get delayed at incalculable expense to companies, shareholders, and patients amidst all the inactivity and confusion.

A now vast number of IT tools have emerged to create order out of the chaos. These include interactive voice and web response systems to automate patient randomization and drug supply management, electronic data capture to speed the transfer and cleaning of case report forms, electronic patient-reported outcomes to improve the integrity of functional outcome data, clinical trial management systems to deal with copious amounts of operational data, trial simulation systems to expedite protocol design, and electronic systems for the submission of clinical trial documents and the report-

ing of AEs. An enterprise-wide solution has not been a viable option for most life sciences companies, so IT applications are not truly integrated. The problems compound in the aftermath of a merger, with some companies finding themselves in the untenable position of running several of each IT "solution" simultaneously. The industry as a whole finds itself ill situated to manage risks and potentially variable margins that a recent Deloitte study suggests will be the requisite operating model of the future.(7)

Efficiencies achievable by consolidation, outsourcing, and process efficiency initiatives are insufficient for this Brave New World. Companies must not only streamline clinical trial timelines, but develop meaningful relationships early in the drug development process with patients, health-care payers, clinicians, and regulatory agencies. They also require the wherewithal to continually evolve and adapt.

Information is the balm that cures all that ails clinical trials only if it is organized to be found, tracked, and managed based on the task and case at hand. As senior business leaders across industries can attest, SmartBPM can be that Holy Grail, allowing business users to orchestrate data from multiple applications to accomplish clinical trial goals and fill the "execution gaps" between business objectives and the underlying IT systems that attempt to meet them. From a customer service perspective, these gaps might include the inability to waive repetitive Good Clinical Practice (GCP) training for veteran investigators or recognize, reward, and retain high-performing investigative sites with better payment terms.

## Bridging the gaps

Life sciences companies have systems in place to address specific processes. The difficulty is integrating them in a manner that allows for the free exchange of information and economically keeping them up-to-date with regulatory requirements. Legacy systems and processes make adapting to a changing global environment, reducing operating costs, and expediting New Drug Applications titanic undertakings.

The enormity of BPM's savings potential is sug-



gested by the experience of one multi-national biopharmaceutical company that utilized Pegasystems' SmartBPM technology to rapidly adapt to new dispensing guidelines shortening from 14 to 7 days the window female patients had to retrieve certain prescription drugs after taking a blood test guaranteeing non-pregnancy. The company expected it would cost \$100,000 to re-code and manually change the timeframe rule for these drugs across thousands of applications. Instead, it reaped \$1.5 million annually in operational efficiencies by creating an easily amendable central repository for all of its business rules with an end-to-end solution combining SmartBPM with an interactive voice response application and contact center management software.

In addition to allowing for more judicious allocation of resources, BPM eliminates duplicative efforts. Life sciences companies have used SmartBPM to capture AE/safety information once and automatically create and transmit reports to multiple stakeholders in the required format and timeframe — e.g. within days to the Food and Drug Administration (FDA) for AEs serious enough to result in death versus for those considered serious and reportable but not life threatening.

BPM enhances customer relations across the board by serving up the right information to the right people at the right time. Those may be physicians and patients communicating through a company's web portal or would-be study subjects engaged in guided, rule-based interactions with call center representatives to confirm eligibility.

On an enterprise level, BPM can provide important IT linkages between clinical trial work and other functional areas to allow an even broader array of improvements ranging from pre-clinical study design and drug production procedures to grants management and post-approval safety monitoring and reporting. Pegasystems provides a central repository for shared SmartBPM application building blocks (processes, business rules, user interfaces, and integration), so IT can easily reuse existing assets and create a layer of specialization for specific customers, geographical locations, new lines of business, or new functions. Pegasystems SmartBPM Suite also serves to empower customers' existing enterprise resource planning solutions

with the ability to intelligently route work, easily encode change policies and business rules, contribute to BPM reports and key performance indicators, leverage a repertoire of solution frameworks to meet larger corporate objectives, and seamlessly interact with each other to foster continuous improvement.

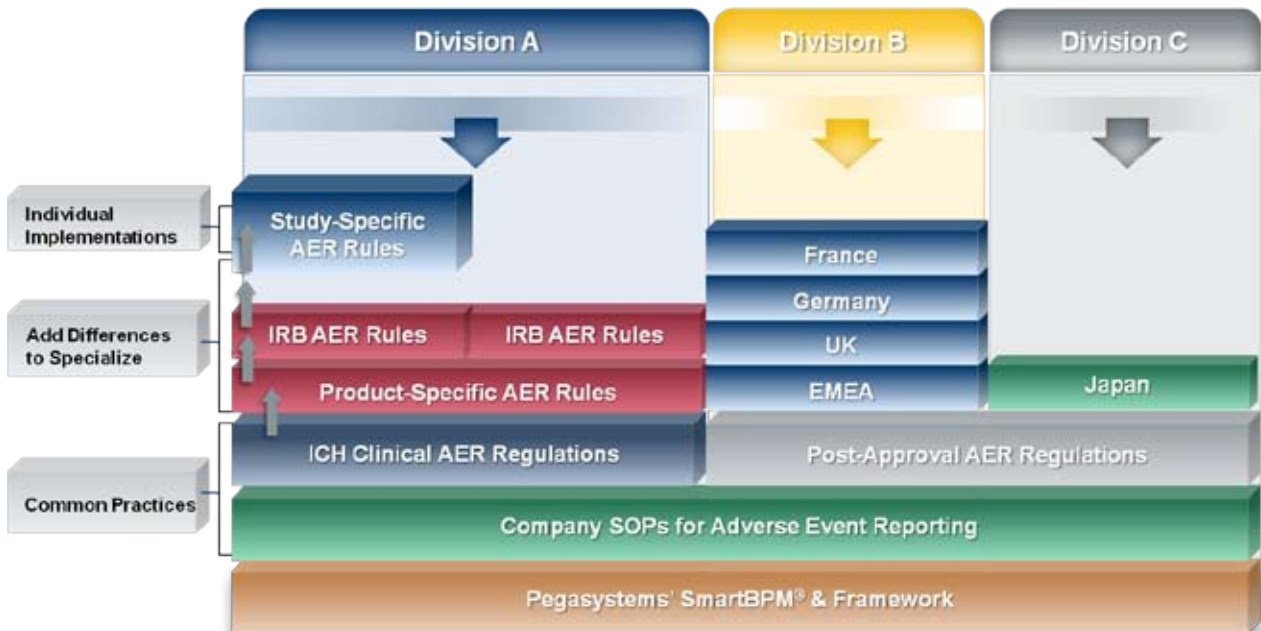
## Competitive advantages of SmartBPM

Pegasystems offers life sciences companies a web-based design environment in which to manage all elements of its multi-faceted SmartBPM solution, including Smart Case Management. Applications in the SmartBPM Suite are based on service-oriented architecture to allow disparate applications to integrate as well as entirely new ones to be created as needed. The company's patented Build for Change™ technology has several distinctive features that have made Pegasystems the worldwide BPM market leader.

For starters, properly permitted business users or analysts can directly capture their business requirements with SmartBPM. Because the Java-based platform automates the coding, they can program in needed changes to the protocol review process or new triggers for site payments without having to consult the IT department. Requirements get documented in the system using a browser and familiar Microsoft tools. Once a flow, user interface, or business rule has been created, it's immediately executable. SmartBPM updates documentation when operational changes are introduced and tracks previous versions. It also ensures that changes apply only where they should (pediatric antidepressant drugs, for example). All needed downstream changes to business rules, processes, interfaces, integration points, and data elements happen automatically.

Importantly, SmartBPM unifies policies and procedures in a single repository that allows users to declaratively state the goal of a clinical trial process using the full breadth of business rules. Whenever the goal is not being met — e.g. database lock is three months behind schedule — the process dynamically adapts to get the trial back on track, perhaps by sending out appropriate alerts and

## Use Adaptive and Specialized Rules to Manage Complex Clinical Processes — Adverse Event Reporting



prompting investigation into the delay before it worsens.

Since Pegasystems doesn't believe in hard coding the user interface, SmartBPM can be tailored according to the role and information needs of each end user. This "situational layer cake," as the company terms it, accommodates both foundational and specialized rules and processes. That is, it allows the reuse of common elements (such as harmonized global regulations and a company's standard operating procedures or SOPs) while quickly isolating differences across requirements (country- and product-specific variations).

Flexible, scalable deployment is another key advantage of SmartBPM. Common policies and procedures can run across multiple platforms and channels simultaneously. When change is warranted, the improvements can be installed instantly to the necessary systems.

The application intelligently decides how transactions are best handled by matching the intents of customers (e.g. to learn about a trial) and business (e.g. to recruit eligible subjects) at the point of contact. When it comes to work automation, Smart-

BPM has set the bar at a new height by including researching, resolving, and responding to requests — not merely receiving, routing, and reporting on them, as with traditional clinical trial management applications. In the clinical trials business, this might automate the search for investigators in a new therapeutic area, help locate the nearest enrolling trial for a type 1 diabetic over age 50, or guide referrals to specific sites and institutional review boards.

In 2007, Forrester Research declared Pegasystems SmartBPM "head and shoulders above" its competitors based on the capabilities of its simple but powerful business rules engine. It was also recognized as a particularly good fit for businesses that require the ability to change frequently, want to simplify administration in a complex global environment, and require a highly integrated platform. Additional kudos came in a February 2009 report in which Gartner placed SmartBPM ahead of all other multi-regional, cross-industry BPM suites in terms of its "ability to execute" and "completeness of vision."

In addition to the highly adaptable on-premise



version of its SmartBPM Suite, Pegasystems introduced a cloud-based service in 2009 known as SmartPaaS. The benefits of cloud computing, notably resource savings and ease of technology adoption across organizational boundaries and lines of business, has not escaped the notice of growing numbers of clinical trial sponsors. With SmartPaaS, the BPM implementation process can be completed in half the time and at half the cost of traditional on-premise solutions with no sacrifice to security or reliability. With over 1,000 cloud environments provisioned, SmartPaaS is already the most popular way customers are developing and testing their BPM solutions.

## Gaining control of clinical trial processes

Pegasystems' Smart Case Management capabilities utilize the strengths of SmartBPM in support of clinical trials by tapping whatever specified SOPs, GCPs, and protocol rules are applicable to the occasion. Project managers can utilize personalized event notifications to stay abreast of what work colleagues have done on a clinical trial, such as complete a site initiation visit or host a patient recruitment fair. Multiple parties can work collaboratively or in parallel without fear of redundancy or conflicts because case views are offered in the context of timelines, content, correspondence, and the status of work done. A My Cases Portal keeps individuals apprised of their caseload and most pressing tasks, in addition to offering a graphical status report inclusive of all subcases, tasks, and processes relevant to the trial. Additions and modifications to the clinical trial case — mid-study abandonment of a problematic e-PRO system, for example — can be made in impromptu fashion and leave an audit trail.

As with all SmartBPM applications, Smart Case Management supports multi-channel collaboration for defining and managing processes in lieu of e-mail, stand-alone instant messaging, and other disconnected communication means that increase workloads and slow the pace of change. Every interaction, question, and exception becomes part of a fully documented collaborative process, providing transparency for compliance in a validated en-

vironment.

Smart Case Management on the enterprise level ensures the clinical trial process happens consistently over phases and across multiple therapeutic areas and product cycles. It can also capture associations between past and current studies that can improve protocols, provide an early warning of potential safety issues, and identify operational bottlenecks.

## Integration gains

Case studies of SmartBPM implementations reveal efficiency gains greater than what IT systems can accomplish independent of one another, and exponentially better than archaic manual processes by which some critical clinical trial tasks get done. One international biotechnology company successfully utilized SmartBPM to establish paperless adverse event reporting across 23 countries, resulting in upwards of a 100% increase in productivity and a nearly 50% reduction in costs. Today, the system is used in 14 offices by 28 teams and three external companies in 24 different countries, processing 35,000 AE reports per month. Two-thirds of them require no human intervention.

Another multinational pharmaceutical company is employing SmartBPM to automate grant tracking from inception to final disbursement, improving the user experience on both sides of the encounter while reducing correction and maintenance costs. A global clinical research organization has found SmartBPM particularly useful in automating the site selection process, allowing sites to fill in and transmit documents online. Notable features include event-based email notifications to personnel involved in the process and automated follow-up and tracking of regulatory information required by the FDA.

For companies managing complex clinical trials, SmartBPM provides all the necessary components for automating critical clinical trial processes ranging from protocol development and patient enrollment to site management and investigator payments. Whether leveraging Pega's solution Frameworks or built to fit, SmartBPM serves as the vital informational link permitting individual tools to collectively optimize performance.



The return on investment is potentially stunning on several levels. The ability to directly execute business requirements, rather than communicate changes via an IT group, has been shown to speed application development time by a minimum of 50%. SmartBPM has also demonstrated it can improve customer retention and reduce training time by 50% across a variety of industries, suggestive of its enticing potential to enhance relationships with investigators, subjects, and regulators and bring momentum to the technology-impaired study startup phase. The overall time and dollar savings, while inestimable, would likely be staggering wherever there is corporate recognition of BPM as a wide-ranging solution to most of what ails the planning and management of clinical trials today.

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