

## Services thinking: A services thinking approach to clinical trial start ups



The clinical trials process is a lengthy one that involves multiple parties, including contract research organizations (CRO's), site management organizations, study sponsors and clinicians. While pharmaceutical companies incur significant costs bringing a drug to market, about two-thirds of research and development costs are incurred in Phase III trials. Longer clinical trials cycles result from an inability to perform rapid drug safety and efficacy analyses on patient populations; and increasingly, many life sciences companies experience significant delays due to trial startup and clinician enrollment. Key challenges include recruiting appropriate trial sites, patients and CRO's; developing relationships with new sites and clinicians, and trial site startup (i.e., training, systems setup and access, regulatory process and documentation). Efficiency has also been hampered by a lack of necessary communication and relationship-building between involved parties.

Achieving rapid initiation for clinical partners has become more complicated throughout the years. While the trial process has grown more reliant on IT systems, many organizations retain manual and heavily paper-based processes that make initiation even more daunting. Research groups have become more reliant on outside research support and heightened security concerns and sensitivity have lengthened time to systems access - resulting in companies investing to create digitally secure and regulatory-compliant models. To exacerbate existing security concerns, current workarounds (email, shared workspaces, etc.) have introduced new risks.

The dynamic nature of relationships with clinical partners can widen the gap between business and IT solutions, challenging technology to provide support to core processes. Relationship management with partners requires sustainable and repeatable processes to build brand, scientific mind-share and brand loyalty.

To meet this challenge of closing the gap, we provide here a case study utilizing Deloitte's Services Thinking approach. Services Thinking leverages time-tested components and tools that have come before: Service Oriented Architecture (SOA), Business Process Management (BPM), Enterprise Architecture, Change Management, Process Reengineering, Business Function and Process Deconstruction. Typically, results with any one of these components is not always enough - they are usually a piece of the answer, but often cannot stand alone. Services Thinking requires the marriage of SOA concepts with Business Value Mapping, Process Engineering, Enterprise Architecture, and human capital. In other words, this integration requires more than a change in technology, processes, or organizational structures. It requires an evolution in thinking. Services Thinking is designed to help companies in their efforts to bridge the complex boundaries between organizations, processes, and technologies and achieve the power to turn complexity into advantage. We believe the changing landscape of clinical research and development requires this kind of multi-pronged business and technology solution to begin addressing unnecessary complexity and manual steps plaguing trial startup and execution.

This paper will discuss ways Services Thinking can help companies transform multiple stand-alone systems into a fluid business process. We have developed this approach for rapid initiation and access for clinical partners by evaluating the major processes that involve clinicians, and focusing on the key on-boarding processes where growth opportunities exist. This paper will also cover tools currently available and how they have been leveraged to help companies in their efforts to change and improve operational data systems.

### Approach

Achieving success in adopting our Services Thinking approach depends considerably upon the following set of principles that easily adapt to changes in technology.

### Principles

- Adopt common data formats and utilize information exchange standards whenever possible
- Drive workflow through business processes— not applications
- Build common components within a business
- Process a framework that allows for plug 'n play flexibility —customize the partner experience
- Build extensions to include partner common components —provide ease of working together
- Proactively manage semantic interoperability (i.e., build checks and balances for a common data language and vocabulary)

We have adapted our Services Thinking approach for life sciences companies beginning with an overarching framework based upon our ValueMap for life sciences and our industry experience.

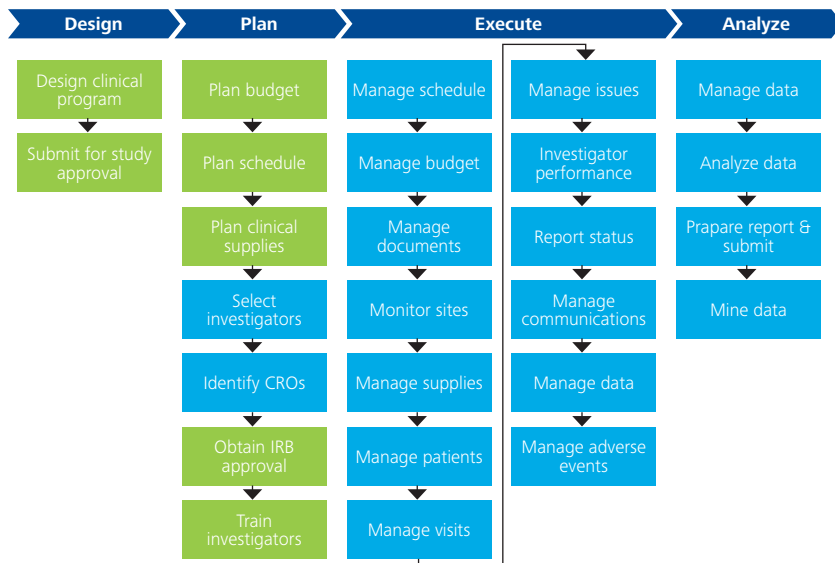
### Begin with high ROI business processes

As previously mentioned, the clinical trials process involves multiple parties - addressing the systems that interact with clinicians should assist in managing the clinician relationship and their "on-boarding."

At many life sciences companies, trial start-up processes are tightly linked to the specific process operations and systems that have been implemented over time. As a result, processes are often constrained due to dependencies on the specific systems currently in place. Alternatively, a more abstract set of steps could be followed if the trial start-up wasn't burdened with all of the steps, people or systems currently in place. Often, the application of our Services Thinking approach results in the elimination of unnecessary or redundant steps, more streamlined activities, increased transparency of the process, and a reduction of excess communications. Ultimately, each activity becomes carefully structured to meet a specific, prioritized requirement.

## Key on-boarding business processes

**Figure 1: High ROI areas based on our experiences in the life sciences industry**  
Clinical Trial Phases and Major Business Processes



Source: Deloitte's Industry Practices Reference Guide/ Deloitte Industry Print  
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The highlighted areas in Figure 1 are the typical areas of differentiation for a life sciences company in the highly competitive investigator market. In the Planning and Execution phases, they include the investigator selection process (including CROs), and management of the execution of the trial (in particular, study start-up).

Many vendors in the clinical trials space have developed solutions that address different steps in the clinical trials process such as data capture, patient/physician recruiting, patient monitoring, data analysis, financial management and relationship management. However, we have not seen an end-to-end solution that addresses each step of the process.

The goal should be to develop a well-rounded solution that encompasses both business and technology components. Systems have become a key part of the clinician relationship, yet as the number of clinician relationships has increased, often, organizational support

has been reduced and system functionality has not followed. A properly implemented on-boarding solution can provide limited access to systems earlier in the clinician relationship and can manage access to systems based on the type of relationship and the stage in the relationship cycle (i.e., through an Identity and Access Management (IAM) component). Eventually, as the relationship grows, access to systems should expand and organizational trust should increase. The ideal goal is to accept complexity and control clinical expectations while simplifying their management.

By creating a logical separation between the business processes and the specific activities and systems necessary to support those processes, opportunities to improve the actual execution of a business process can become apparent. This separation allows process models to be built using key performance indicators associated with them, and it is this knowledge, coupled with effective practices, that is fed into the core of a Business Process Management (BPM) tool set. A BPM tool manages and orchestrates the business process in real-time. The power of this approach depends on a simple principle: service levels must be set for each node, and each node needs to reflect the realities of the operational capability of that piece of the startup process.

The key performance indicators associated with this process include:

- Increased patient and investigator recruitment rates and effectiveness
- Increased acceptance rates and reduced attrition of investigators
- Reduced time spent in trial setup and execution processes
- Improved speed to trial data (in terms of access and quality)
- Improved early documentation and protocol compliance
- Streamlined administration processes such as agreements, scheduling and protocol development
- Improved ability to monitor regulatory compliance of site (e.g., informed consent and IRB approvals)

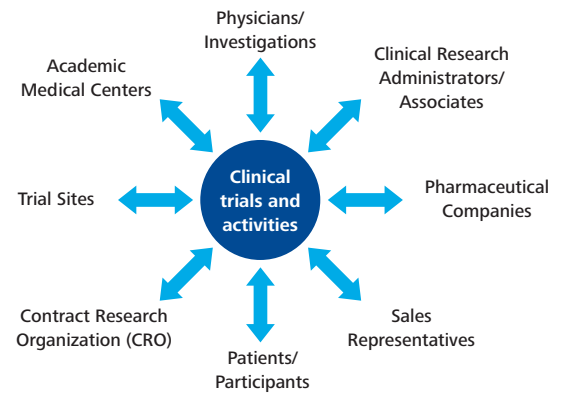
**Standardize relationship management processes**

Currently, clinicians typically work with investigators in a fragmented environment that utilizes various security models. Creating a seamless, standardized relationship between entities will require the willingness of each of the parties to collaborate and adopt a compliant, standards-based system that mediates information exchange safely. Benefit opportunities for the stakeholders in the process include:

**Clinical Trial Activities and Actors**

- Clear identification of methods to introduce new clinical partners
- Clear methods to negotiate with new clinical partners
- Clear exposure of expectations to new clinical partners early in the process
- Clear method for granting access to systems for new partners
- Clear definition of what systems to grant access to for each type of clinical partner

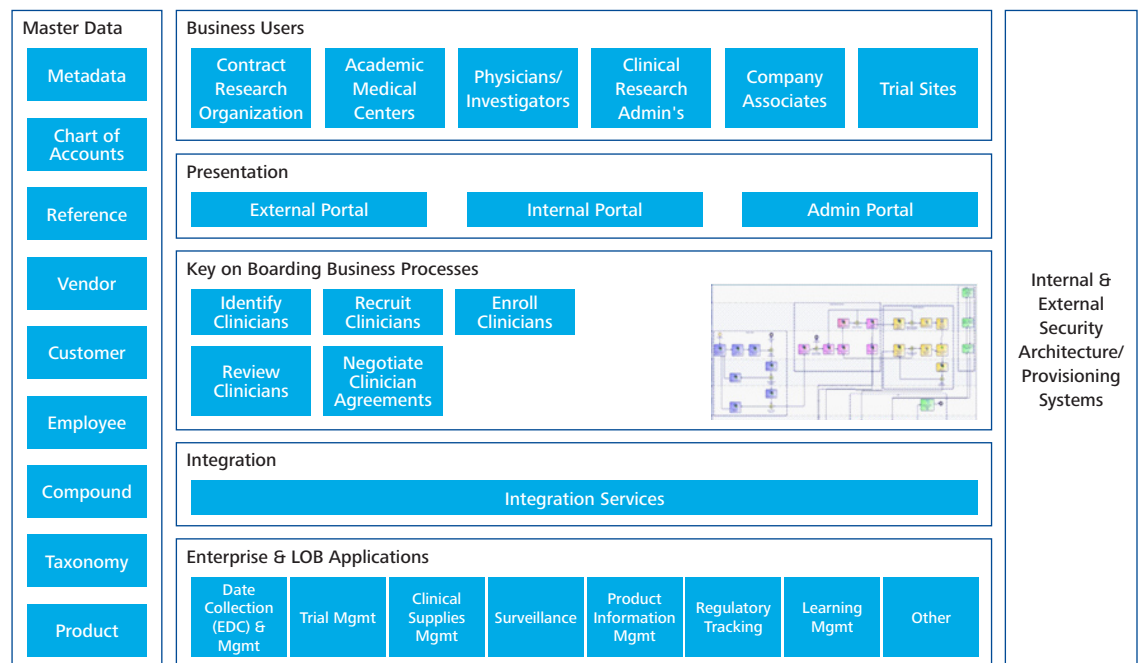
**Figure 2: Actors engaged in clinical trials and processes**



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A viable solution should reduce the IT complexity that is present throughout most systems. Clinician on-site systems are becoming more inconvenient and IT stability can be hindered by multiple systems with a lack of interoperability. The conceptual architecture below provides an end-to-end depiction of components required to select and onboard clinical partners.

**Figure 3: Conceptual architecture model for clinical trials onboarding**



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### Business users and presentation

Business users will include clinicians, clinical research administrators, trial sites, contract research organizations and other colleagues within the pharma company - all part of the clinical trials startup, management and study closing processes.

A critical element to the achievement of adaptability and flexibility is the concept of building systems from components where each component provides one or more services. This approach will help separate the business logic from the technology components, so that, as requirements change and new functionality is needed, the technology components remain stable or can be incrementally augmented with new technical components. The technology components will provide the integration and interoperability services for the business components through the use of open standards within a services oriented architecture (SOA).

In the conceptual services model shown above, a SOA framework has been applied to the required components in order to plan, specify, and enable simplistic more efficient CRO and participant systems access and start-up. It also provides a single face to the CRO and reduces fragmentation and complexity. It is the goal of using an SOA framework to help simplify application connectivity in order to reduce manual steps. Each application should be able to be modified whenever necessary to support flexible business processes.

### Connecting to existing systems infrastructure

The solution should be based on the concept of services that are used as building blocks. Individual services will be exposed through one or more interfaces where each interface uses one or more standard communication protocols. Messaging via queuing or publish/subscribe mechanisms (JMS), protocols (RMI/IIOP, SOAP), web access (HTTP, RMI/HTTP) and Java API, represent some of the mechanisms used within the integration services layer. The resultant architecture should loosely couple services via a BPM/orchestration layer to provide business task

flexibility, as well as process flexibility. Service adapters and agents are connected to each system that performs a function or executes an activity. These may include EDC, CTM, PIM, and Clinical Supplies Management systems. These agents are integrated to the BPM execution engine which monitors events and individual actions, orchestrates process activities and displays progress in real time.

### Providing visibility into the business process

A critical aspect of an orchestrated process is visibility. BPM tools can provide visibility into a business process, both in real-time and historically, by displaying: the events and actions that have occurred; who executed them; how long they took; where the process is and who owns the particular action at the current moment; how long this and future steps are expected to take, based on past metrics; and where it will head next, based on various deciding criteria.

### Maintaining security in a SOA implementation

In 2004, Pharmaceutical Research and Manufacturers of America (PhRMA) reported that approximately 40% of Research and Development costs were attributed to paper-based business processes (\$9 billion in the U.S. alone)<sup>1</sup>. Today, the pharmaceutical industry spends a considerable amount on various models that aim to provide independent validation of digital signatures and other credentials. In order to reduce cycle time and resources, IT solutions must embrace shared credentialing, such as SAFE-Biopharma for new partners. A SAFE credential will allow companies to reduce the complexity of managing multiple identity credentials as well as provide security through a centralized identity.

The goal of SAFE is to deliver unique and globally valid electronic identity credentials for legally enforceable and regulatory-compliant digital signatures.

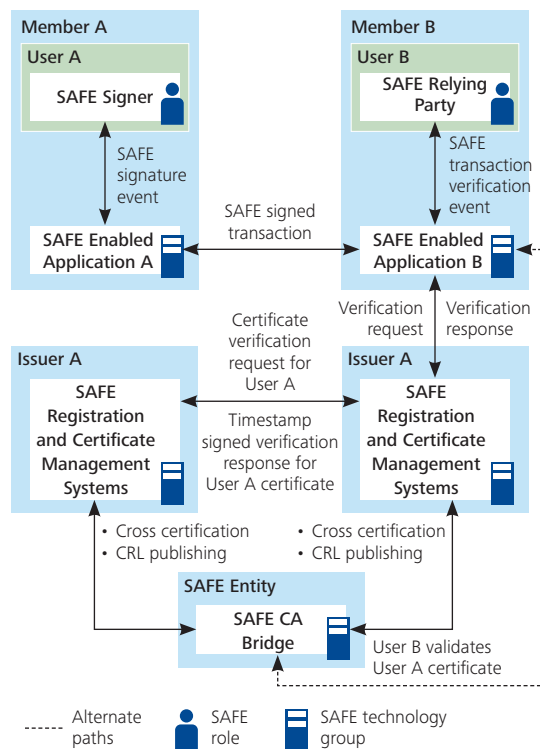
The life sciences and pharmaceutical industries spend a significant amount on systems dedicated to security of data. The SAFE framework serves as a cost effective way to leverage the Internet for authentication and electronic

<sup>1</sup> McBee, 2005

records processing, and SAFE members reap the benefits of short and long-term infrastructure cost savings. SAFE benefits are also scalable: as more processes are converted from paper to electronic using SAFE, the more a company eliminates paper, saves time, and reduces expenses.

Lastly, life sciences information exchanged electronically must be compliant with international regulatory requirements, contain strong security features, and be legally enforceable across borders.

**Figure 4: SAFE implementation example (Illustrative)**



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As Figure 4 shows, SAFE framework can enhance electronic relationships through a reduction in the number of multiple password-based authentications used to gain access to corporate networks, while at the same time, making certain proper levels of security for users and groups are maintained.

### Other security considerations

Initial access to partners may be limited to basic tools and can be expanded upon as the relationship grows in maturity and trust. For example, some shared workspaces may provide access to only certain areas based on the level of trust and negotiated business agreements.

The growth path for the relationship should be predefined and may be leveraged as a point of negotiation. The relationships should include roles and responsibilities with respect to data, process and electronic usage for:

- Limited joint working relationships
- Trial business agreements
- Investigators

Lastly, agreements should include language and instructions for closeout and an evaluation of the results regardless of the completion status of the study.

### Moving forward

Beginning the journey starts with three key activities with a properly defined scope and set of boundaries. These three activities include:

- Orchestrate the business process to engage business partners
  - Internal clinicians
  - Internal IT for systems access and security
  - External investigator/CRO agreements and IT for systems access
- Collaborate to execute the business process
  - Reduce manual steps and provide human interface capabilities
  - Enable closed loop communications and expedite information sharing
- Improve the business process
  - Enable more efficient investigator/CRO and participant systems access and start-up
  - Provide a single face to the investigator/CRO and a less fragmented approach

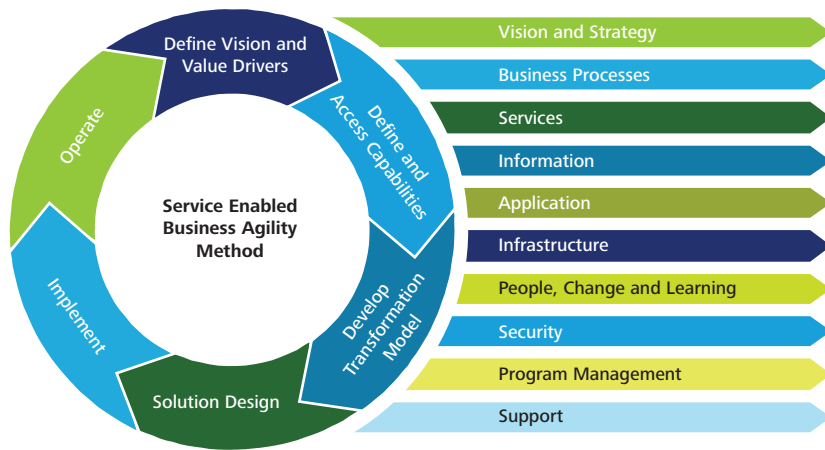
**Service Enabled Business Agility (SEBA) methodology**

SEBA is the Deloitte methodology that enables the use of our Services Thinking with a repeatable approach to a broad service transformation, while also considering the security needs for an SOA implementation. SEBA can also be used to help integrate our Services Thinking approach with components of other Deloitte methodologies, including BPM/Integration project design and execution through the use of effective practices, architectural patterns and frameworks, vendor product insight, and design/configuration templates.

**Conclusion**

We believe the concept of Services Thinking applied to clinician on-boarding can yield significant improvements in the overall clinical trials process. In its current state, many trials start-up processes are characterized by multiple process owners, unmanaged hand-offs, and frequent, unproductive communications with little or no visibility into the various nodes of the process. A Services Thinking approach can help an organization develop a managed process, which is designed with the KPIs in mind, and that leverages tools such as Business Process Management (BPM). BPM can facilitate the consistent orchestration of the components involved in the start-up process, and provide linkages to third party identity and access management/provisioning systems. In addition, it can also provide visibility into the what, who and when of the various business processes being managed. As the current business archetype evolves from a complex, inefficient process, to one that is standardized and unites multiple parties and simplifies the management of relationships, it is evident to us that a Services Thinking approach is necessary in achieving the goal of an efficient clinical trial start-up process.

Figure 5: Service Enabled Business Agility – Deloitte Methods™



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ServicesPrint is a proprietary accelerator we use to help organizations in their efforts to define software services used during BPM implementations. ServicesPrint provides a common rationale to define the correct granularity of service naming, use, and reuse throughout the enterprise. ServicesPrint is used in concert with our proprietary bottom up process accelerators such as IndustryPrint™ and ValueMap, in order to help organizations focus on key value-added services to support the solution. In addition to project needs, ServicesPrint can be used by enterprise architects and project leads to help them in their efforts to determine the level of reuse, domain ownership, quality of services, availability, and security needs each service must meet.

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