



Leveraging Service Management to Improve Clinical Development Operations

Executive Summary

The challenges within the R&D function of pharmaceutical companies are well understood. The total cost for developing a new drug exceeds \$1 billion due to the stringent requirements for large clinical trials. At the same time, the pipeline for new “blockbusters” (defined as drugs with market potential of more than \$1 billion in annual sales) targeting the general population has pretty much dried up, and pharmaceutical companies are increasingly developing drugs that address the needs of specific smaller populations, a trend called personalized medicine.

The impact on R&D departments has been staggering: Not only do they have to find ways to do more with less, but at the same time, they also have to become much more flexible, conducting research on larger numbers of specialty compounds. They also have to operate in a much more connected environment, wherein they collaborate with other companies, usually smaller biotech firms, university research centers, etc., to discover and develop these compounds.

While in the past clinical development was primarily performed in-house, leading pharma companies now rely on a host of external vendors, such as clinical research organizations (CROs), global services companies and other development partners. The decision to source particular activities is usually made on a trial-by-trial basis,

which increases complexity even further. Most pharma R&D units are not set up in a way to take full advantage of these new ways of operating and thus struggle to find one-off approaches and solutions to the challenges they face.

There is general agreement that the pharma R&D model has to be completely reinvented to successfully address these challenges, adjust to the industry's new realities and continue to produce new products efficiently and cost-effectively. To improve R&D “yield” in generating high-value, patient-centered and regulatory-approved treatments, R&D organizations must find a way to more quickly and effectively move from data to decisions by focusing on activities such as:

- **Adopting predictive capabilities** through adaptive trials, signal detection or predictive clinical trial planning.
- **Providing data and insights at the point of need** through R&D mobility solutions, adaptive monitoring or portals.
- **Bringing market insights to R&D** more consistently through market-aligned R&D and clinical trial feasibility.

In sum, the pressure on R&D organizations to deliver break-through molecules has never been greater. As a result, they must become much more efficient; open; standardized; innovative; continuously improving; and flexible and adaptive.

With these objectives in mind, R&D organizations have been asking difficult questions, such as:

- How will I be able to effectively serve the different therapeutic units that rely on my services?
- What activities should I keep in-house vs. outsource? On the basis of what criteria will I make these decisions?
- Do I have to continue investing in new technologies, or is it more cost-effective to leverage external providers, for example, through cloud computing?
- What operating model will I put in place for the activities I keep in-house to achieve my objectives?
- How will I ensure that the vendors I employ are successfully aligned with the business objectives I have to meet?

This white paper explores the concept of service management and how it can be applied not only as a framework to answer these key questions but also to inform the development of a new operating model that improves clinical development operations of large pharmaceutical companies. We will touch on what service management entails, its benefits and how it can be applied to clinical development. We will also introduce a framework describing two options for how to introduce service management, as well as provide guidelines for how to choose between these two options.

Further, we will suggest some elements that we view as critical success factors for how to implement this new model. Finally, we will provide two case studies of bio-pharmaceutical companies that recently have adopted this model, each choosing different paths to do so.

Service Management: Definition & Benefits

Service management is the practice of transferring day-to-day management responsibility of operations to an internal or external provider as a strategic method for improving effectiveness and efficiency. The organization that has direct responsibility for defining and agreeing to service level targets for the services rendered is referred to as the customer. The organization that accepts service level targets and meets requirements to provide service at the negotiated level is regarded as the service provider.

The service provider can be internal – typically another group within the same company – or external to the company. With an internal provider, the company must decide whether the customer will pay for the services, typically in the form of a cost chargeback. In the case of an external provider, the customer will, of course, pay for the services provided. Providing services through a service management model requires the establishment of service agreements, which are contracts stipulating to a great level of detail the expectations from both the customer and service provider of the other party.

The use of service management originated in the information technology (IT) space, with the objective of enabling better strategic alignment between the business and IT departments. ITIL (Information Technology Infrastructure Library) has been used by IT organizations as a best-practices framework for IT service management, and it has grown to become the most widely accepted approach to IT service management in the world. The ITIL framework and its best practices can provide significant value for the implementation of service management operating models.

Based on our experience, we believe that the service management concepts described by ITIL can be applied very well to the world of pharmaceutical clinical development, which we will demonstrate with two case studies detailed at the end of this white paper. The reasons that a service model can be applied so well to clinical development include:

- **The customer-provider relationships** that have emerged in many pharmaceutical companies, with the therapeutic areas as customers, to be serviced by the clinical organization as their key provider for clinical trials execution.
- **The integration of IT capabilities into clinical development business processes** to enable enhanced electronic data capture (EDC), data analysis, trial management and monitoring, etc.
- **The increasing use of external vendors**, which highlights the need for trial sponsors to think and act in a service management mode when they set up contractual agreements with these vendors.

There are significant benefits that the use of a service management model can bring to a clinical

development organization. The main benefits include the following:

- **Improved communications with customers:** Introducing a service management model requires the service provider to work with its customer(s) in terms of understanding their needs and requirements and corresponding service levels. This generates more frequent, streamlined and effective conversations, in which both the customer and service provider start using the same language and increase their alignment.
- **More clarity around roles and responsibilities:** The service model requires the customer and service provider to clearly articulate expectations and roles and responsibilities in order for the services to be provided, consumed and supported in an effective and efficient fashion. This, in turn, leads to better and more meaningful interactions, in which both parties operate in a more collaborative manner.
- **Better marketing of services to customers:** Services are introduced to customers through a service catalog, which lists available services and their key features. Generating and maintaining the service catalog drives service providers to better articulate and define the services to be offered, using phrasing that resonates well with customers.
- **Increased focus on business outcomes:** By documenting services in terminology familiar to the business, and by describing their value and benefits in a language easily understood by customers, the provider shifts the focus from functionality, to business outcomes.
- **Streamlining service activities:** Through the activity of services definition and the service supply chain (i.e., how the services will be fulfilled), the service provider typically identifies elements that are common across services, which in turn enables the provider to generate efficiencies and lower costs by eliminating duplication.
- **Setting the stage for continuous improvement:** Putting in place a service model is not an endpoint but rather a starting point for customers and providers to continuously work on improving their services, such as the way they are introduced and the way they are delivered to the customer. Continuous improvement usually includes identifying and eliminating gaps and overlaps in services.

Service Management Framework for Clinical Development

Based on our experience, we have developed a framework that shows two key options for clinical development organizations that want to adopt a service management model (see Figure 1, below).

Characteristics of Functional and Capability Service Models

	Functional Model	Capability Model
Service Definition	Services are defined to closely follow the existing working activities of the service provider. These activities are usually functionally aligned with the business processes of the customer.	Services are defined based on the underlying capabilities needed to deliver business outcomes, in order to increase re-use and streamline operations.
Use of SLAs	Service-level information is used as an indication of the availability and supportability of services offered by the provider, but it is not captured in binding agreements.	Detailed SLAs are introduced with different levels of service available for customers and spanning various levels of service availability, supportability and cost. Customers choose among service levels based on their needs/requirements and available budget (e.g., bronze-silver-gold).
Starting Focus	The starting point is to turn the current offerings into a structured, marketable catalog of capabilities aligned with R&D activities and evolve them into streamlined services at a later stage.	The starting point is to transform current distributed capabilities into a service-centric organization, ensuring introduction of services from the top-down in a controlled fashion.
Service Support	The initial goal is understanding customer needs, defining them and then releasing a catalog of services that addresses these needs. Support of the services is viewed as a secondary priority.	The service support approach and back-end processes are developed at the onset of the initiative, to provide the basis upon which the services can be introduced and managed.
Speed of Adoption	Adoption rate is intentionally kept low to enable all parties to adjust and learn from the new model.	Adoption rate is generally high, but it can vary depending on business readiness and the customer's and provider's capacity and capabilities.
Driver of Initiative	The driver is the business or a mixed business/IT group.	The driver is typically the IT organization.

Figure 1

Advantages, Disadvantages of Functional and Capability Service Models

Functional / Activity Model		Capability Model	
<p>Pros</p> <ul style="list-style-type: none"> • Services are easily recognizable by customers, leading to lower resistance. • Services align well with the customer's business process activities, making it easy to see how they fit in. • Lower resource requirements to implement. 	<p>Cons</p> <ul style="list-style-type: none"> • Limited to no shared services benefits. • Limited improvement against current state. • Lays foundation only for services definition to align with functionality and will require more work in later phases to build true service management on this foundation. 	<p>Pros</p> <ul style="list-style-type: none"> • Development of services focused on capability, resulting in shared, re-usable and scalable services to support new or changing requirements. • Faster to realize increased efficiencies and cost savings. • Stronger fit with ITIL framework used for managing services and support. 	<p>Cons</p> <ul style="list-style-type: none"> • More difficult to implement, and with a larger impact on the organization, typically generating more organizational resistance. • More resource intensive and requires more work upfront before services can be released into production.

Figure 2

The pros and cons of each model are compared in Figure 2, above.

Introducing service management can result in multiple benefits, as indicated in the previous section. To achieve these, it is important to choose the model that fits best with your organizational capabilities and maturity. It is certainly possible for a company to start with the functional model and evolve into the shared capability model. However, it is important to choose the model that presents the best fit, both with the current situation and with the short- and long-term strategic objectives of the business.

While there is no right or wrong model, choosing one that is not aligned with your organization will detract from the success of the service management initiative. To help in making that choice, we have provided some decision criteria (see Figure 3, below).

Critical Success Factors for Implementation

To achieve the intended benefits, it is important for the service management model to be fully embraced by all parties. Based on our experience, we have identified critical success factors that will greatly enhance the probability of a successful

Determining the Right Service Management Model

Criteria	Questions to Consider
Relationship with Customers	<ul style="list-style-type: none"> • How established are the communication processes and channels to understand, prioritize and address customer needs? • How close is the alignment between the service provider activities and customer needs? • Is there clarity and agreement on who "owns" the customer relationship?
Operational Maturity	<ul style="list-style-type: none"> • Is there a clear understanding of which activities are core vs. non-core? • How well are processes documented and followed? • What is the level of comfort with continuous process improvement?
Organizational Clarity	<ul style="list-style-type: none"> • Are different roles and responsibilities within the organization clearly defined? • Are the leadership teams within the different supplier organizations aligned on the priorities relating to service fulfillment?
Provider Complexity and Alignment	<ul style="list-style-type: none"> • How much of the service supply chain does the main provider control? • How well aligned around customer priorities and needs are the different suppliers that need to collaborate to provide and support the services? • What is the level of experience with managing different suppliers (including vendors) in servicing customers?

Figure 3

implementation. In this section, we will address two very important critical enablers of success.

Leveraging the ITIL Methodology

As indicated previously, the ITIL methodology is the most widely accepted approach to IT service management in the world. ITIL has enjoyed widespread adoption since its publication two decades ago. Indeed, because of its success, ITIL has become synonymous with IT Service Management (ITSM), of which it is one of the best practices.

Pharmaceutical R&D organizations can leverage the ITIL methodology, as it offers a consistent, repeatable, controlled and measurable process for delivering services. It does so while managing operational costs and capital investments to meet business requirements. With the introduction of its latest version, ITIL introduces a lifecycle approach to managing services, allowing for more robust management of demand and its changes. This paves the way to a more efficient way of prioritizing activities to achieve business objectives.

Leveraging ITIL to define services, and using ITIL processes to support and manage the defined services, can help clinical development organizations realize significant benefits and even competitive advantage. The journey begins with defining the service portfolio, which encompasses documenting the provider's offering and capabilities. The service portfolio management process emphasizes strategic thinking to assess the present situation, defining goals to improve existing services or introducing new services to support current and future business activities.

The definition of a service portfolio by the clinical development organization will drive the development of the business and technical service catalogs, which is managed by the service catalog management process of ITIL. Analogous to direct marketing catalogs of online merchants and mailed catalogs, business and technical service catalogs serve as a tiered and structured presentation of services to customers, with varying business requirements and price points. The identification, negotiation and institutionalization of services and service levels to align with the customer's requirements and price points encourages the adoption of other ITIL processes to effectively and efficiently deliver on service commitments.

Using the ITIL methodology as the de facto standard of ITSM allows clinical development organizations to:

- Define and differentiate service levels to meet requirements and price.
- Optimize services through standardization.
- Drive cost reduction through service-centric delivery of capabilities.
- Shift away from organizational reactivity.
- Transform the IT organization into a true partner with the business.

Treating the Implementation as Transformation

Implementing a service management approach will have a major impact on the organization. Not only will your team have to start thinking and communicating in terms of services, but they will also have to change their mindset about what they do on a daily basis and how they deliver value to customers. As a result, the implementation must be treated as a real transformation, focused on establishing a new operating model with new roles, processes and tools.

One other reason to treat the implementation as a transformation is that this will be a gradual process, typically taking several years to transition through the different maturity levels. Therefore, it will be essential to take the necessary steps to keep the momentum going until the initiative's completion and the achievement of its objectives.

Some of the key elements needed to enable this transformation and ensure its success include:

- **Leadership:** High levels of leadership involvement will be required to implement the new

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service management model. One key enabler is to create alignment among the key leaders to ensure they lead by example and set the pace for the program by maintaining urgency, focus and excitement. Leaders are also expected to allocate adequate levels of investment (dollars and resource time) for executing the transformation. They will be expected to make trade-off and prioritization decisions in a timely manner throughout the implementation. Finally, the organization's leaders will be needed in terms of marketing the initiative and the new approach to other parts of the extended enterprise (including customers and suppliers).

Overall, the team will have to balance the goal of achieving financial/operational benefits with a strong focus on and measurement of behavioral and cultural change to ensure that the changes “stick.”

- **Organization design:** Introducing and operating a service management model will require the establishment of new roles (for example, “service owners”) and responsibilities in the organization. Additionally, as the services are defined and organized into logical groupings, many will see the value of aligning the organization accordingly to ensure that the internal provider group is set up in the best possible way to deliver the services.

- **People change management:** Implementing a service management model is challenging and time-consuming, making it a necessity to place a strong focus on people change management throughout the effort. Many transformations fail to achieve their stated objectives, so in order to beat the odds and deliver successfully against increasingly higher expectations, it is imperative from the get-go to devote sufficient amounts of time and resources to the change management aspects of the transformation.

Having a fully dedicated team for the transformation is typically a pre-requisite for successful

implementation. These team members will also have to act as change agents to make sure they bring along their peers in the organization. It will also be important to identify quick wins wherever possible and celebrate these with the broader organization. Overall, the team will have to balance the goal of achieving financial/operational benefits with a strong focus on and measurement of behavioral and cultural change to ensure that the changes “stick.”

- **Communications and training:** Introducing a service management model will introduce many new concepts, as well as new ways of interacting with customers and suppliers. Because of this, it will be important to devote sufficient attention to communications and training.

A good starting point is to identify different stakeholder types and their needs from a communications and training perspective. After that, a plan can be developed, outlining the communication and training activities that target all impacted stakeholder groups. It will be important to also communicate with leaders in other impacted organizations to ensure they are aware of the initiative and get their buy-in to contribute to service development and delivery. Communications with customers should be a two-way street, including marketing of the services, as well as gathering feedback based on their usage.

Based on experience, we know that 100% of transformation programs will show signs of failure at some point in time. The key to successful execution is to anticipate and expect these challenges and be prepared to address them with appropriate counter-measures, in a timely fashion. The guidelines provided above will help ensure this happens in the right way and at the right time.

Service Management in Action

In the next section, we will describe two case studies based on recent engagements we completed in the R&D units of key pharmaceutical clients.

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Case Study >>

Deploying Service Management for a Large Pharma Company's Clinical Operations

Business situation

The client is a Top-10 global pharmaceutical company that had embarked on a corporate-wide service management initiative in IT. The clinical development organization launched its own service strategy and initiative to implement a service management model as part of its ongoing journey to become a world-leading research organization. Lacking the necessary expertise, the client engaged us to provide service management (including ITIL), transformation and change management expertise to define the strategy and drive the implementation for the new service model.

Objectives

The goals for the clinical development organization's service initiative included the following:

- Providing its business partners and customers with high-quality business services, essential for supporting clinical trial operations.
- Ensuring quality on-demand responses to customer needs through a service catalog.
- Reducing cost and increasing flexibility and efficiency of service delivery and support.

Approach

- **Strategy:** We conducted interviews and surveys to gather and analyze information related to applications, customers, future needs, etc. and to build a baseline document assessing the organization's current state. We also facilitated a large executive workshop to decide on the future services and implementation approach. Recommendations were generated on how to deploy the services and adopt the service management framework using the functional option, as well as the type of transformation effort needed to put the new operating model in place.
- **Design:** We analyzed current-state activities and processes and made recommendations for the overall approach of the implementation, as

well as identification of priority services and ITIL processes for deployment. Following this, we developed the template for service design and facilitated sessions with service owners and service managers to populate templates with high-impact and customer-focused descriptions of services. We provided best-practice ITIL/process guidance and drove the completion of gap identification and analysis, as well as documentation of process flows, process-process relationships, metrics and governance. Lastly, stakeholder assessments were conducted, and a change management and communication plan was developed for use during the implementation.

- **Implementation:** We assisted the client with developing the first release of its service catalog and helped drive implementation. We also provided advice to the client to execute a reorganization aimed at aligning the organization with the major service categories. Materials were developed for key communications, including sponsor updates, presentations to the client staff, customer introductions, etc. We also conducted workshops and provided training to the team resources, which greatly enhanced their knowledge of service management and how to make sure the different components work well together.

Outcome

The client organization is well on its way to implementing the new service management model and has already achieved the following:

- Implementation of the new organization.
- Release of Version 1 of the service catalog, which is now being used as a template by other groups in the clinical development organization.
- Increased service management knowledge throughout the organization.
- Implementation of key support processes throughout the R&D organization.

Case Study >>

Creating a Service Portfolio and Catalog for a Major Biotech's R&D Arm

Business Situation

This client is among the world's largest multinational biotechnology companies and a global leader in genetic disorders drug research. The company is engaged in a corporate-wide service management initiative to develop and implement IT service management processes. Its research and development organization is leveraging the global IT service management program and has launched its own initiative to define and implement services, including a supporting architecture. The client engaged us to provide service management expertise to architect services to better support clinical research customers and leverage vendors more effectively.

Objectives

The objectives for the service management initiative included the following:

- Map existing business functions, processes and applications.
- Define a service portfolio and service catalog structure.
- Define services and document a service maturity roadmap.

Approach

- **Strategy:** We conducted a series of workshops and interviews to validate business architecture, as well as gather and analyze information related to business processes, customers, business applications and projected needs. We also generated a service model, implementation and maturity model to transform the unit into a service-centric organization using the shared capability option.
- **Design:** We analyzed the existing business process and support structure and supporting applications and validated that the existing IT applications, processes and activities supported R&D needs. Recommendations for service architecture, service portfolio,

catalog design and the service maturity model were made to align with the organization's propensity for change. The design of services was conducted with identified service owners and service managers before negotiating with customers on the warranted service levels. We also populated the service portfolio and catalog to support the negotiated service levels and allow for seamless visibility for supporting ITIL processes.

- **Implementation:** We led the development of the service portfolio and catalog structure and assisted the client with the development and negotiation of the first release of services. All supporting materials to create and implement the services, along with a maturity model for the services, were implemented. We developed communications material for the executive staff, promotional material and sponsor updates. Training for key team resources was also performed to ease the transition from a vendor-led initiative.

Outcome

The client is currently using ITIL processes and supporting an application implemented by the IT department to support the services, which were designed and implemented within the R&D department to reduce the cost of IT. Specific achievements include:

- Implementation of Version 1 of the service portfolio and catalog.
- Implementation of the service maturity model.
- Implementation of a service-centric organization model.
- Leveraging vendors to fulfill service support and reduce cost.
- A more robust operating model, enabling a higher level of outsourcing of non-core activities.

Looking Ahead

Clinical development organizations in the pharmaceutical industry are feeling relentless pressure to increase productivity and reduce costs. This paper has introduced the concept of service management and how it can be applied to achieving these objectives. As has been dem-

onstrated by the companies highlighted in the case studies above, this approach is setting them on the path to improving relations with their customers and suppliers, while at the same time increasing the effectiveness and efficiencies of their operations.

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About Cognizant

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