



Reader ROI

- Achieving clinical excellence requires a careful blend of well-defined business processes, seamless information flows, and technology tools that enable the efforts of well-trained clinical professionals.
- Applying enterprise architecture practices to define secure, consistent, and robust information and solution architectures is a key enabler of clinical excellence
- Enterprise architecture is a discipline that provides the strategy and framework for defining and evolving an organization's processes, information management, and technology environment.
- A rationalized enterprise architecture enables the breakthroughs a clinical organization needs in order to maximize the value of information in supporting business objectives, ensure information security, and minimize the cost of capturing, managing, and using information.

Enterprise Architecture in Clinical Development

A key enabler of clinical excellence

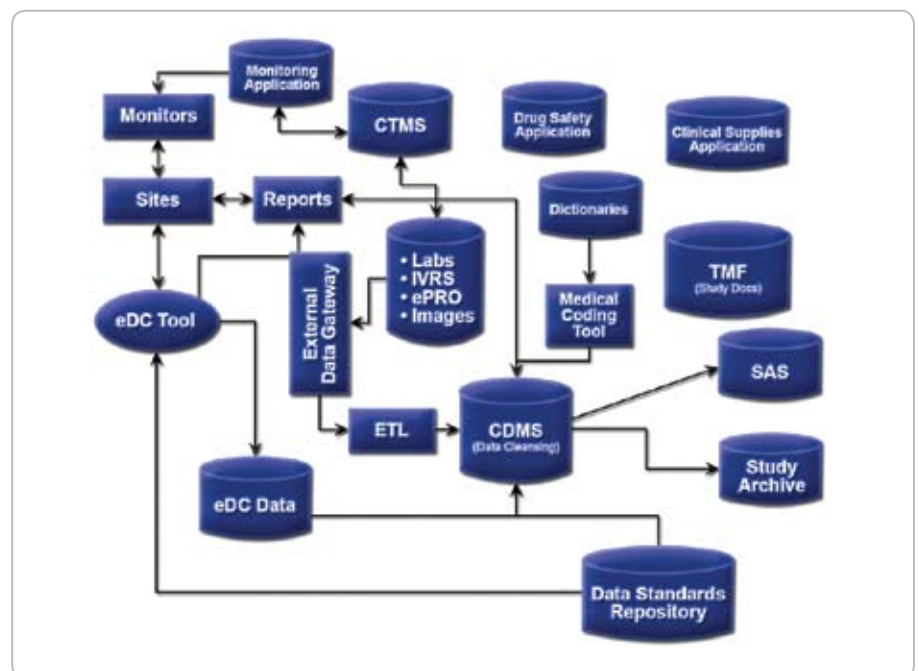
The pharmaceutical industry is facing a crisis in productivity that threatens to delay the delivery of much-needed medications to the market place and ultimately damage the financial stability and growth of the industry. The U.S. Food and Drug Administration (FDA) in 2004 issued an alarming paper that described a general slow down in the development of new medicinal products and laid down a challenge to the industry, academia, and the government itself, that they should do something in order to turn the situation around. Although there have been some improvements in regulatory filings for new medicines since then, clinical development productivity remains a considerable concern.

Clinical development is a costly and time-consuming activity that lays on the critical path to introducing new medications into the marketplace. The efficiency and effectiveness of clinical processes are critically impacted by the quality of information and technology management within clinical organizations. Unfortunately though, many of these organizations suffer from fragmented information management processes and technology silos that impede the seamless flows of information that are so critical to efficient execution of clinical processes. **Developing and adhering to architecture is a key way to ensure that clinical technologies actually enable clinical process excellence.**

Fragmentation in the status quo

Although life sciences companies have invested heavily in clinical information technologies, fragmentation of information management limits return on many technology investments. The typical clinical technology landscape (see Figure 1) is a loose amalgamation of legacy systems designed to address specific parts of the overall clinical domain.

Figure 1: Legacy Clinical Technology Environment



The legacy systems in most clinical organizations were not designed to communicate with one another effectively and are typically integrated via point-to-point links that are expensive to build and maintain. Disparate groups often duplicate information on multiple systems, so there is no single, authoritative source or owner of key information assets. Information exchanges among groups are too often accomplished via manual transfers of data that must then be reentered and reconciled in the destination system.

The simple fact is that the fragmentation of information and technology in clinical development is a critical contributor to the inefficiency so often seen in this essential business process.

The role of architecture

The essence of an enterprise architecture is to define the four key architectural views. The **business architecture** defines the business processes that must be executed to achieve the organization's business objectives. The **information architecture** defines the logical organization of information in domains and the flow of information among domains required to support key business processes. The **solution architecture** defines the applications and details of integration required to enable seamless flow of information among domains. Finally, the **technology architecture** defines the infrastructure platform, which needs to include an integration framework to enable interaction among solution components. Such an enterprise architecture addresses the issues of functional and information fragmentation by applying, in a rigorous way, clear definitions of business processes, information domains, information flows, technology tools, and integration points.

With these architectural views defined, initiatives can be undertaken to move from the undisciplined and fragmented legacy environment to a future state based on standards, integration, and interoperability.

The future-state vision

In a future state based on a rationalized enterprise architecture, the clinical business processes are well-designed and fully documented, and are tightly aligned with SOPs and regulatory guidelines. Information objects are grouped into logical domains and each domain is assigned an "owner," so that information users and solution designers know where to go for the "one version of the truth." The information domains are abstracted from specific processes, groups, or systems, because in the clinical domain, information tends to be more stable than organizations, processes, or technology. By abstracting the information domains, changes to the other layers of the architecture will not impact the information architecture. With the information domains established, the information flows among domains can be examined and effectively managed.

Solutions and integrations needed to support the information flows are defined in the solution architecture. Extensive integration among key applications allows seamless flow of information among domains within the clinical organization to minimize duplication of effort and maximize re-use of valuable information assets. The architectural principle at work here is to capture information once—as close as possible to the source—and then move it downstream for use by other groups as well as for other purposes.

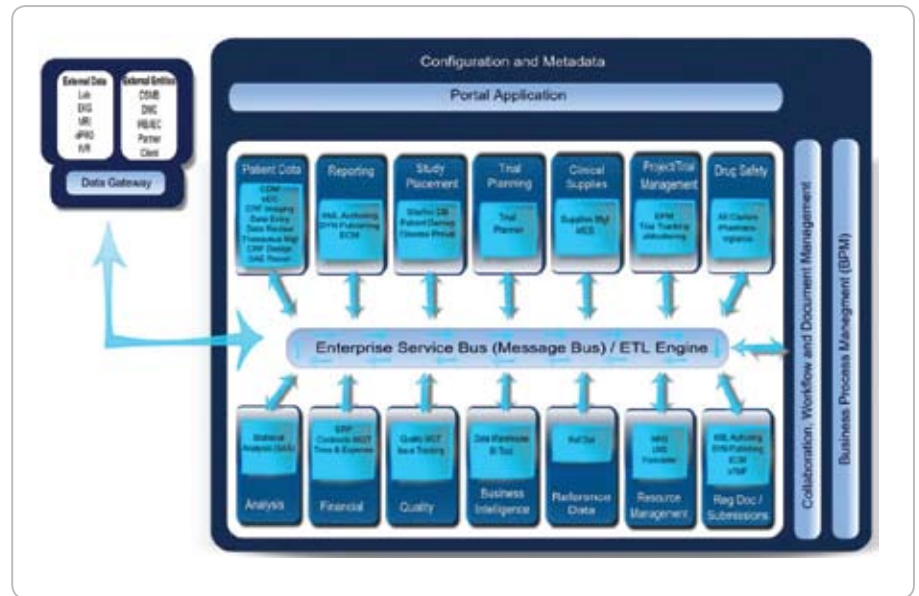
The technology architecture defines the infrastructure components and an integration framework that facilitates application integration and seamless information flows within the enterprise. The integration framework of a well-defined architecture also supports flexible and efficient exchange of information with external partners, vendors, and customers.

The future-state vision of a clinical architecture is illustrated in Figure 2.

In this illustration, the information domains are the light blue boxes. The systems and tools that provide primary support to each domain are shown within them. Internal integration among systems is provided by the combination of: 1) an enterprise service bus (ESB), a middleware component based on messaging technology that facilitates incremental communication of information from one domain to another; 2) For batch transfers of large data sets, an extract, transform, and load (ETL) tool. Standardized external integration is provided by a data gateway.

Two other important features are the collaboration and process automation platform shown on the right and the clinical portal platform at the top. The future state assumes that a collaboration, workflow, and document management platform is readily available to support the automation of key business processes throughout the organization. Business process automation and workflows based on business rules help to ensure that processes are executed consistently and in accordance with standard operating procedures (SOPs).

Figure 2: Legacy Clinical Technology Environment



The portal platform can be used to create both internally and externally facing portals to enable collaboration and information sharing. For example:

- An internal clinical management dashboard with metrics
- An investigator portal
- A portal to enhance collaboration with regulatory bodies, health authorities, IRBs/IECs, and third-party vendors.

Configuration and metadata

As clinical organizations become more sophisticated in their adoption of enterprise architecture, they will also benefit from formally managing their technology environment as a “platform.” The “platform” is the holistic view of all of the technology applications and integrations. Supporting the “platform” is an information domain called configuration and metadata. Configuration defines how the systems that makeup the platform will function to support a particular clinical trial. Ultimately, the configuration domain would be supported by an application that facilitates and automates the configuration of the platform to introduce an unparalleled level of flexibility and speed in responding to changing business demands or clinical assumptions.

The metadata domain is a repository of data about other information domains—especially what types of information live in each domain and identification of the owner or steward of that type of information. Metadata is a key to allowing people to find the “one version of the truth” for all types of information. Using this approach eliminates the problem of asking a questions and getting answers which depend on which system is used to answer the question. Enterprise architecture provides logical organization and consistency of management of an organization’s most valuable information assets.

Business benefits of architecture

There are many benefits for companies that use the practices of enterprise architecture to design and evolve their clinical information management landscapes. First and foremost, the architecture provides a framework in order to **ensure that IT initiatives are directly aligned with business objectives** and that IT projects are based on solid planning rather than reaction to crises.

Second, abstracting the information architecture from specific groups, processes, or systems **ensures that changes in an organization or introduction of new technologies do not impact the logical organization and flow of information** in support of process execution.

Third, the integration framework facilitates retirement of obsolete technologies and the introduction of new technologies with minimum impact on other applications. **The integration framework also enables seamless information flows** among information domains to maximize the value of information assets.

The remaining elements of the future state architecture facilitate interaction among stakeholders, as well as enable process execution excellence and effective collaboration. The data gateway offers a powerful mechanism for importing information from external entities and exporting data to those entities. The use of a collaboration, workflow, and document management platform enable business process automation and help to ensure consistent process execution in accordance with SOPs. Finally, the use of portal technology enables one-stop shopping for clinical management metrics and the possibility of streamlined collaborations among both internal and external stakeholders.



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