Enterprise Architecture - Fundamental to the Overall Transformation of a Pharmaceutical Company

Today’s pharmaceutical industry particularly within the clinical R&D domain faces enormous challenges from growing market competition, increasingly stringent regulatory environments, rising cost and a collaborative environment. Partners are leading organizations to embark on a transformation journey impacting people, processes and IT. This process involves huge investments and challenges in terms of budget, time and resource constraints and as a result the focus is often lost without a clear definition of guiding Enterprise Architecture (EA).

For enterprise architecture definition, various industry standard methodologies and frameworks such as TOGAF ADM, IMPACT, ZACHMAN etc. offer a generic approach to various phases and deliverables.

The aim of this paper is to demonstrate how an industry standard methodology was adopted, tailored and extended to create enterprise and specific architecture artifacts. The paper is based on a real life example in defining enterprise architecture for a clinical R&D unit of a leading pharmaceutical company undergoing a large transformation. The approach and artifacts described in this paper are intended to aid in EA definition for large transformation programs with a proven, effective, reusable and result oriented set of architecture views that can be adapted across industries.
About the Authors

Suyog Shah
Suyog Shah has nearly a decade of experience in providing IT solutions for customers and specializes in enterprise architecture definition and review. He further helps organizations design and implement roadmaps that help align IT to the business. Suyog has been working across multiple consulting engagements as an Engagement Manager for TCS’ IT Architecture Consulting Practice. He has worked predominantly across banking, financial services, pharmaceutical and insurance industries. Suyog is a certified TOGAF 8 practitioner and IBM SOA Architect and has received multiple awards for architecture solutions and consulting services to large multinational companies. Academically Suyog has a Bachelor of Engineering in electronics from Mumbai University.

Ninad Rajadhyaksha
Ninad Rajadhyaksha is a part of TCS’ Global Consulting Practice in UK. With over 14 years of experience, he has spent 10 years in the architecture domain primarily practicing in financial services (trading system architectures for capital & derivatives market). A certified TOGAF architect, Ninad has a Masters degree in structural engineering.
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Introduction
Clinical R&D business units within pharmaceutical companies today are facing enormous challenges leading them to overhaul and transform operation affecting overall business organization and IT processes. Some of the key drivers leading to such transformations include:

- Cost pressures in the R&D space
- Stringent rules and regulations
- Growing consolidation in pharmaceutical companies
- Outsourcing in R&D
- Compliance with industry standards

Apart from the challenges mentioned above, information security, data integrity and quality are some of the other issues that persist in many large pharmaceutical organizations.

All these industry trends and challenges impose huge constraints on the business. Business depends on IT to remediate such issues and enable business transformation - a drive to move away from conventional business manner to a more flexible, agile and integrated extended enterprise.

Given these challenges, drivers and business expectations, a leading pharmaceutical company embarked on a multiyear (3+), multimillion (£60M+) transformation programme covering 25+ projects spanning initiatives such as:

- Process optimization of clinical R&D core business to double its productivity within 3 years
- Evaluation and migration to next generation electronic data capture systems to improve clinical trial data setup and capture process
- Migration from multiple home grown data management systems to an industry standard product
- Creation of a portal to facilitate collaboration within study teams, investigators, business partners and regulators
- Data standards management solution aligning clinical trials to industry standards such as BRIDGE & SDTM thus enabling cross trial analysis
- Creation of a clinical and operational data repository for analysis and regulatory reporting
- BI and analytics for strategic and tactical decision making
- Elimination of point to point interfaces through the adoption of service based integration via existing web sphere message broker platform
- Migration to next generation statistical analysis and graphical tools
- Automation of study planning and protocol authoring using industry standard tools

Some of the key challenges faced by the pharmaceutical company can, in fact, be applied to any large transformation effort. Here are some of them:

- Ability to deliver within deadlines and budget
- Managing change within organization, processes and systems
- Aligning project implementations towards a common objective
- Defining the scope of transformation and that of individual implementation projects
- Planning and clustering implementation projects for identification of necessary transition states in a multiyear transformation programme
- Management of various business and IT stakeholders
- Ability to make timely and informed decisions
- Keeping the light on during the transformation
As the pharmaceutical company did not define EA holistically, the focus remained primarily on specific implementation projects. As a result, it struggled to cater to the high level challenges mentioned above.

**Need for Enterprise Architecture**

Enterprise Architecture (EA) is defined as a bridge between strategy and implementation by aligning implementation projects with the IT strategy to achieve business objectives and change scenarios. The figure below depicts how EA definition enables the translation from strategy to implementation:

![Figure 1. Role of EA](image-url)
Organizations tend to ignore the definition of enterprise architecture and are tempted to embark on implementation projects in an attempt to demonstrate immediate value to sponsors. However, following such an approach leads to major roadblocks in the long term.

Absence of a clear enterprise architecture definition impacted business and IT stakeholders of the pharmaceutical company by presenting them with the following specific challenges:

**Business units** –
- **BU1** Unable to identify solutions to specific challenges and problems leading to gaps in traceability and overall success of the transformation programme
- **BU2** Unable to understand the impact of changes in the business organization and thereby unable to use the implementation solutions to meet business requirements
- **BU3** Unable to appreciate the value of IT in enabling business transformation

**Program and change managers** –
- **PC1** Unable to scope and estimate size of transformation leading to budget overrun and unrealistic timelines
- **PC2** Unable to define boundaries of projects and transition states leading to ambiguity in responsibility and ownership of a project especially in areas like data migration
- **PC3** Inability to monitor and guide project implementations leading to a reactive rather than proactive approach
- **PC4** Inability to plan and impart training to business units, thus risking the existing studies
- **PC5** Incomplete impact analysis of changes, lead to deficiencies in planning critical activities such as training and rollouts, which may have an adverse impact on the schedule and budget of a release

**Project Managers and IT leads** –
- **PI1** Ambiguities in the scope of individual projects leading to gaps/deviations from expected outcomes
- **PI2** Unable to understand dependencies initially and interfaces with other projects thereby leading to excess cost and timelines
- **PI3** Unable to make objective design decisions and hence deviate from the expected end solution outcome
- **PI4** Unable to make any specific technology and infrastructural considerations due to absence of non functional requirements thereby affecting the usability of implementation systems

**Chief Architect** –
- **Ca1** Unable to demonstrate value and benefits of IT systems to business units leading to suggestions for a ‘future proof’ roadmap due to a lack of traceability between business drivers, objectives, business functions, implementations and benefits

**Architects** –
- **A1** Unable to make decisions and govern implementation projects due to the absence of a target state architecture definition, policies and principles leading to diverse implementations without realizing the overall benefits from transformation
- **A2** Unable to create a flexible and agile IT environment leading to point-to-point integration between systems
- **A3** Unable to analyze impact on systems due to factors such as degree of standardization, change in business operating models and the need for information integration resulting in misaligned IT to business.
- **A4** Unable to communicate a single consistent picture of EA to the stakeholders resulting in gaps and inconsistencies in solutions
- **A5** Unable to identify existing solutions for reusability
- **A6** Unable to create canonical models that derive the requisite flexibility in architecture
It was therefore necessary to invest in the definition of enterprise architecture to guide implementation projects and various stakeholders throughout the transformation journey.

**Enterprise Architecture definition**

**High Level Approach**
The table below provides the tailored high level approach adopted for EA definition in the current programme:

<table>
<thead>
<tr>
<th>TOGAF ADM Steps</th>
<th>Tailoring details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frameworks and Principles</td>
<td><strong>Adopted.</strong> Existing principles and policies were analyzed and extended where required based on business drivers and existing challenges to guide the target architecture definition using TOGAF 8 taxonomy.</td>
</tr>
<tr>
<td>Architecture Vision</td>
<td><strong>Adopted.</strong> The scope of architecture work, architecture artifacts, definition plan and benefits were defined and communicated to various stakeholders so that they could get on board with the solution.</td>
</tr>
<tr>
<td>Business Architecture</td>
<td><strong>Tailored.</strong> Business architecture was limited to defining business processes. The initial set of TO-BE business architecture artifacts were defined and later tailored to meet the needs of predominantly packaged solutions identified in the TO-BE application architecture.</td>
</tr>
<tr>
<td>Information Architecture</td>
<td><strong>Tailored.</strong> A green field approach was adapted for information architecture with a top down definition for TO-BE architecture. Detail in TO-BE architecture was restricted to the creation of conceptual data model, logical data model, CRUD matrix of entities vs. business functions and mastering matrix to map entities mastered in systems once the draft application architecture was available</td>
</tr>
<tr>
<td>Application Architecture</td>
<td><strong>Tailored.</strong> AS-IS application architecture views were created for analysis and further referenced in transition state definitions. TO-BE application architecture views were limited to the creation of catalogues and mapping applications to business processes.</td>
</tr>
<tr>
<td>Technology Architecture</td>
<td><strong>Tailored.</strong> The application landscape comprised predominantly COTS products as determined by the TO-BE application architecture. The technology architecture was limited to the identification of TO-BE technologies catalogue based on selected products. AS-IS technology catalogue was also created to identify new technologies that will need investment and administration.</td>
</tr>
<tr>
<td>Integration Architecture</td>
<td><strong>Introduced.</strong> A new phase for integration architecture was introduced to define the TO-BE interaction views. AS-IS interaction views were also created to define transition states and identify needs of tactical solutions during transformation. The TO-BE interaction views along with other artifacts were extended to identify business and application interaction services and solutions for integration.</td>
</tr>
<tr>
<td>Opportunities &amp; Solutions</td>
<td><strong>Tailored.</strong> The implementation initiatives were identified prior to EA definition. Clustering the implementation projects into releases was executed as part of the EA definition. This was conducted through top down planning and analyzing the business benefits and challenges addressed through those implementations.</td>
</tr>
</tbody>
</table>
Migration Planning

**Tailored.** Transition views comprising AS-IS and TO-BE architecture components were defined for each release to identify tactical solutions to ‘keep the lights on’ during the transformation.

Implementation Governance

Architecture governance framework is currently under construction.

Architecture Change Management

**Adopted.** All architecture artifacts were maintained in a single architecture repository using an EA tool. Necessary changes were executed during impact analysis across artifacts through controlled releases.

**Detailed Approach**

**AS-IS Analysis and TO-BE Definition**

**AS-IS Analysis**
- Analyze AS-IS Business Processes
- Define AS-IS Application Architecture
- Define AS-IS Interaction Views

**TO-BE Architecture Definition**
- Define TO-BE Business Processes
- Define TO-BE Information Architecture
- Define TO-BE Application Architecture

**Figure 2. AS-IS analysis and TO-BE architecture definition**

**AS-IS Analysis**

Key Highlights –

AS-IS functional architecture views, applications inventory, business processes to applications mappings, Interaction diagrams and technologies catalogue were defined.

Challenges Addressed - BU2, BU3, PC1, PI1
Principles, Policies and Governance Framework

Key Highlights –
Existing principles, policies, processes and governance frameworks were analyzed and customized with respect to business requirements and challenges. New principles, policies and processes were defined as required to meet business and IT objectives and ensure existing pain areas were addressed by TO-BE architecture definitions. Various solution patterns were defined to aid decision making during the creation of TO-BE architecture.
Challenges Addressed – A1, A2

TO-BE Architecture Definition

TO-BE Business Process Definition

Key Highlights –
The definition of the optimized TO-BE business process covered inputs, outputs for business functions, trigger events, exceptions, user roles and information requirements. Processes were further tailored using the definition of application architecture based on identified COTS products.
Challenges Addressed – BU1, CA1, A3, PC4

TO-BE Application Architecture Definition

Key Highlights –
TO-BE application catalogue was created with brief descriptions of each application along key IT and business contacts. Various views were created to demonstrate application landscape mapped to functional areas. Architecture views were also created mapping TO-BE applications to functions identified in business processes.
Challenges Addressed – BU1, BU2, BU3, CA1, A4, PC1, PC2, PC4, PI1, PI2, PI3, PI4

TO-BE Information Architecture Definition

Key Highlights –
Conceptual and logical data models with defined entities and relationships. A defined CRUD matrix mapped each entity against business processes while the mastering matrix aligned it with corresponding systems.
Challenges Addressed – A1, PC2, PI2, PI3

TO-BE Technology Architecture definition

Key Highlights –
TO-BE application technologies catalogue was created based on technologies of the COTS products identified. AS-IS and TO-BE technologies were compared to identify new technologies.
Challenges Addressed – PI4

Gap Analysis

Key Highlights –
Gaps were identified in TO-BE application capabilities that were provisioned by AS-IS systems but were not addressed.
Challenges Addressed – BU2, A1, PC1, PC5, PI1

Integration Architecture - TO-BE Interaction Views
Key Highlights –
TO-BE business process, application architecture and information architecture were analyzed to identify interactions. Based on the processes, application functionalities and mastering matrix was created which identified TO-BE interactions between systems and users. End to end TO-BE interaction views enabled the creation of program and release plans through the identification of systems, functionalities and dependencies. Application environment views were created for all major TO-BE applications demonstrating functionalities, interactions with other systems and user interactions to aid the creation of application specific project plans.
Challenges Addressed - A1, A3, PC1, PI1, PI2, PI3

Transition State Definitions
Key Highlights –
Initiatives were classified into quick wins, medium term and long term value by analyzing them against business benefits. Implementation projects were classified into the clusters and release plans were created for each one.
TO-BE application systems and functionalities were identified for each release. These applications and interactions were then superimposed on AS-IS interaction diagrams to define transition views for each release. Data migration requirements, technology and infrastructure changes were identified for each transition state.

Challenges Addressed - A1, A3, PC1, PC2, PC3, PC5, PI1, PI2, PI3

Integration Architecture - Service Definitions

**Figure 5. TO-BE Service Identification and Integration Specifications**

**TO-BE Services Catalogue**

Key Highlights –

TO-BE business processes specific to releases were identified in a top-down manner to categorize task services. TO-BE application architecture was also analyzed to identify bottom-up application services based on system functionalities. Task services were then mapped to corresponding application services to classify business and system services with appropriate granularity. The primary focus was on the identification of services that were involved in system-to-system interactions based on business processes and capabilities.

Challenges Addressed - A1, A2, PC5, PI1
- **Service Design and Specifications**
  Key Highlights –
  System use cases were analyzed to identify affected services from the catalogue. TO-BE interaction diagrams were analyzed to identify services involved in interactions across systems. Service specifications were defined by identifying corresponding operations and underlying implementation details in terms of systems and system functionalities. Input entities required for performing the operations were identified and corresponding output entities were defined. TO-BE interaction diagrams and system use cases were further analyzed to identify service orchestrations.

- **Message Models**
  Key Highlights –
  Service orchestrations were analyzed and corresponding information entities were identified. TO-BE information architecture was used to define canonical message flows covering detailed attributes for all logical entities that were affected.
  Challenges Addressed - A2, A5, A6, PI1

- **Integration Specifications**
  Key Highlights –
  Service orchestrations and message flows were analyzed to identify relevant integration patterns. Based on business and system requirements and integration patterns, corresponding integration specifications were defined. Integration specifications covered various aspects of high level solutions using integration technologies, exchanged messages, frequency, synchronous/ asynchronous etc.
  Challenges Addressed - A2, A5, PI1, PI2

**Challenges in EA definition for large transformations**

Some of the key challenges experienced during definition of enterprise architecture were as follows:

- **Alignment of stakeholders to a common objective** – Various stakeholders have different perspectives and emphasis on respective focus areas. The challenge was aligning all of them to a common objective and enables a shift to programme from project thinking.

- **Agreement on details for various architecture views** – The challenge in this case was to identify details when documenting AS-IS architecture and defining TO-BE architecture. Different stakeholders have different expectations of details in the architecture views and artefacts.

- **Obtaining consistent and complete business requirements** – Business requirements keep changing and pose huge challenges to ongoing architecture work in terms of adapting changing requirements consistently across all views.

- **Availability of key stakeholders** – Availability of key business stakeholders, application SMEs and IT leads was a big challenge.

- **Varied perspectives of architects** – Depth of architecture artefacts and prioritization was a key challenge.

- **Scope of EA definition** – Scoping of enterprise architecture definition thereby identifying the architecture artefacts was a key challenge.

- **Timely review of deliverables** – Lack of rigor in various stakeholders to review architecture artefacts was a big challenge to signoff architecture artefacts.

- **Gaps in the to-be architecture definition** – Progressing with architecture artefacts including gaps and later including the solutions while acting on key deliverables was a challenge.
Actively engaging the stakeholders in the discussion – Getting the required inputs from various stakeholders in planned meetings was a challenge as there was reluctance to commit on inputs. Also inputs were not definite and subjective or conditional leading to gaps in the architecture at later stages.

Buy-in from the stakeholders – Despite meeting expectations of stakeholders, there was reluctance for signoff from many key stakeholders as they had a tendency to accommodate changing requirements and documented architecture views.

Availability of accurate AS-IS business process documentation – AS-IS business processes were either not always documented or if documented were out of date leading to gaps in AS-IS analysis. Knowledge was either scattered across documents or resided with various stakeholders and getting them together for workshops was a challenge.

Mitigation to the above challenges varied depending on the organization culture and stakeholder management.

Conclusion
Investing in EA definition addressed challenges during transformation, brought value, improved clarity in terms of scope and dependencies and ensured that the IT implementations justified the investments.

The following benefits were perceived by various stakeholders from definition of EA:
- Brought in a common understanding of end to end target state amid stakeholders
- Ensured IT implementations were aligned towards meeting business objectives
- Helped to identify gaps in the solution and target state
- Enabled identification and planning for implementation releases
- Enabled creation of training plans and change management
- Enabled effective and timely decisions
- Enabled programme managers to define an end-to-end plan with clear dependencies
- Enabled transition plans and creation of specific release test cases
- Enabled identification of services and creation of an agile service oriented enterprise
- Helped identify systems for decommissioning and reduced operational costs
- Enabled creation of architecture governance framework to oversee implementation
- Helped in definition of migration strategy and plans

With this paper we aimed to communicate the following to the readers:
- Importance of enterprise architecture definition in large transformations
- Demonstrate how an industry standard methodology can be tailored to meet the specific needs of transformation and organizational environment
- Provide a reference set of architecture artefacts and detailed approach that can be adapted and further tailored to define enterprise architecture for transformations in an industry or organization.
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