

Chapter 8

Architecture of an Integrated Regulatory Information Management Platform for Clinical Trials:

A Case Study in Regulatory Information Management System Implementation

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ABSTRACT

The pharmaceutical and medical manufacturing sectors have entered a period of disruptive transformation in the way regulatory affairs are conducted globally. The global clinical and regulatory landscape is evolving more quickly in this decade than ever before. The advent of adaptive trial designs, rolling submissions for indications, as well as the impact of regulatory policies in emerging markets, are influencing Pharma's ability to secure approvals efficiently and effectively and with required emphasis on safety and compliance. The impact of these changes on Regulatory Information Management can be significant over the next 5-7 years. Companies are rightfully asking what the transformation in business processes and technology might look like and what types of innovations they can adopt now to prepare them for the future state. The case study below introduces the need for an integrated Regulatory Information Management (RIM) platform, addressing key functionality of such an environment and describes the architecture & design consideration to industrialize such a platform.

INTRODUCTION

According to industry sources and publications, the pharmaceutical and medical manufacturing sectors have entered a period of disruptive transformation in the way regulatory affairs are conducted globally and the global clinical and regulatory landscape is evolving more quickly in this decade than ever before. The advent of adaptive trial designs, rolling submissions for indications including oncology and HIV/

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HCV, as well as the impact of regulatory policies in emerging markets and the BRIC countries, are influencing Pharma's ability to secure approvals efficiently and effectively and with the required emphasis on safety and compliance. The impact of these changes on Regulatory Information Management can be significant now and over the next 5-7 years. Companies are rightfully asking what the transformation in business processes and technology might look like and what types of innovations they can adopt now to prepare them for the future state.

The case study below introduces the need for an integrated Regulatory Information Management (RIM) platform, addressing key functionality of such an environment and describes the architecture & design consideration to industrialize such a platform. The intended audiences of this case study are the architects & designers of similar systems

The desired transformation objectives of a Regulatory Information Management (RIM) transformation initiative are:

- Move from a present state architecture which is highly distributed (with a slew of point solutions) to a fully integrated Regulatory system
- Optimize and drive business transformation by leveraging the best practices and approaches that will create a strong regulatory affairs value proposition among key stakeholders - Pharma, CRO and health authorities
- Demonstrate effective methods for incorporating health authority and industry standards
- Deliver a high quality, timely and reliable business integrated environment
- Develop an approach and solution for Pharma, device and diagnostic combined and separately
- Gain advantage through cloud to synergize the processes across geographies and increase collaboration internally and externally

In the Drug development life cycle multiple Regulatory roles/users play a pivotal role in planning and tracking information related to one or more submissions, authoring primary labeling document and other regulatory activities associated with a product.

In this case study we will first review the various *business drivers* that drive the need for an integrated regulatory platform to enable and orchestrate the activities of the different regulatory roles and subsequently look at the possible architecture options to realize the following business requirement scenarios.

- Transform Product and Life Cycle Registration Management
 - Consolidate multitude of central systems and hundreds of local systems
 - End to end product lifecycle management
 - Regulatory information shared throughout cycle
- Augment Publishing Capability
 - Replace end-of-life eCTD system in short term
 - Long term solution to include comprehensive publishing capabilities: via eCTD with seamless exchange of documents and workflows
- Improve Regulatory Data Quality
 - Data standards and data governance
 - Regulatory Information Foundation establishment: Master Data
 - Build and enforce standardized policies across LOCs and systems with clear roles and responsibilities

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