

# Chapter 7

## Architecture of an Integrated Collaboration Portal for Clinical Trial A Case Study

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### ABSTRACT

*Collaboration is defined as the actions for individuals and teams to work together for a common goal. There are several bottlenecks to an efficient and effective collaborative model of clinical trial including: the lack of a centralized, consistent, globally accessible platform to manage and store essential study related documentation; inconsistent or incomplete work assignments; inefficient notification of key events requiring follow-on action; and incomplete, missing, expired, or redundant documentation and training activities and need to maintain multiple credential to access various system, Removing these barriers is an important part of establishing an environment that fosters collaboration among all constituencies involved in managing clinical trial keeping them connected, informed, and on task by providing access to everyone at any time, from anywhere. The case study below introduces need of an integrated clinical collaboration platform, addressing key functionality of such an platform and describes the architecture & design consideration to industrialize such a platform. The intended audience of this case study is the architects & designers of similar systems. The clinical trial activity for a drug in research is approximately 70% of the overall drug development cost. It is estimated that 4% of the cost of a trial is in 'rework' involving communication, regulatory issues, patient enrollment, document review and replacement of patients. The integrated clinical collaboration platform has potential to eliminate significant amount of cost of re-work, which is in order of \$3.5M per trial.*

### 1. INTRODUCTION

In the Clinical trial process an Investigator plays a pivotal role in the documentation, compliance and procedures involved in a trial. To run a successful trial an investigator is anticipated to:

DOI: 10.4018/978-1-4666-8726-4.ch007

- Collaborate with various stakeholders and team in effective and efficient manner .
- Access multiple discrete applications like clinical trial management system (CTMS), procurement systems, Enterprise resource planning (ERP) systems, Electronic data capture (EDC) systems, learning management systems, patient recruitment information and Document management system (DMS)- to track, trace and update information
- Fill battery of time consuming forms like FDA forms 1572 and equivalent, financial disclosure forms, investigator agreement form, confidential disclosure form and facilities description form- to be compliant
- Communicate and coordinate to numerous stakeholders like Clinical Research associate, multiple stakeholders within sponsor organization like business sponsor of the trial, Regulatory affairs personnel, physicians, IT personnel etc.
- Manage grants and payments to site co-coordinators, patients etc. The process is time intensive and involves lots of stakeholders for auditing, receipt acknowledgement, records management etc. Keep a tab of trial master file (TMF) - contains every piece of essential information associated with a trial under Good Clinical Practices (GcP). Management of a paper TMF is resource intensive; documents are handled by multiple people from collection at the investigational site to placement in regulatory binders. TMF documents are tracked manually using spreadsheets or checklists that provide little visibility, often, causing duplication of effort. This causes decreased operational efficiency, higher costs, and the risk of non-compliance, and possibly approval delays
- Keep oneself updated and compliant with the trainings and certifications as well as the profiles and resumes

Due to wide array of activities and diverse spectrum of work, often plagued redundant or missing information causing rework, escalating the time and cost of the Clinical trial. Research found that large and mid size Pharmaceutical companies may have more than 15,000 investigators engaged at a given point in time. With the activities listed above and the associated challenges, the reduction in rework cost per trial is a good enough business case for Pharmaceutical companies to implement an integrated solution. Furthermore, shrinking pipelines, pharmaceutical companies are increasingly recognizing the value of timely communication, simplified process and strong and lasting relationships with investigators and site personnel to improve clinical trial execution, reduce rework cost and to ensure the ongoing success of clinical programs.

## **2. INTEGRATED CLINICAL COLLABORATION PLATFORM**

An integrated clinical collaboration platform is one of the key solutions to combat the challenges/costs listed above. Such a portal solution must have following components:

- *Self registration* of the external collaborators and access to multiple applications through a single sign on platform are one of the key features. In past one decade, globalization, specialization, and outsourcing have changed the way clinical trials are conducted. In order to support this transformation, corporate IT is being asked to provision collaboration with individuals outside the organization. Automating the user account provisioning process eliminates the need for corporate

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