

Rashedul Hasan¹, PhD, Sviglin Helena², MPH, Mitra Rocca¹, Dipl. Inform. Med.
¹Office of Translational Science | ²Office of Computational Science | Center for Drug Evaluation and Research

Introduction

Clinical trials submissions generate a huge amount of data at FDA , that are not currently well visualized. In the Information Age, there are many needs to assemble a picture of what happened to a subject during a clinical trial. Currently, FDA reviewers have few capabilities for automated visualization for decision-making. Even with tools available to reviewers, for example SAS and R, data has to be processed in a manual and stepwise fashion. As a result, the review process is time-consuming and labor intensive. Moreover, reviewers are under increasing demand to make timely and accurate decisions. To address these challenges, the “Subject Glance” application has been developed.

Limitations of State of the Art

The figure below (Figure 1) illustrates limitations and lack of scalability to manually analyze SDTM Data sets by FDA reviewers:

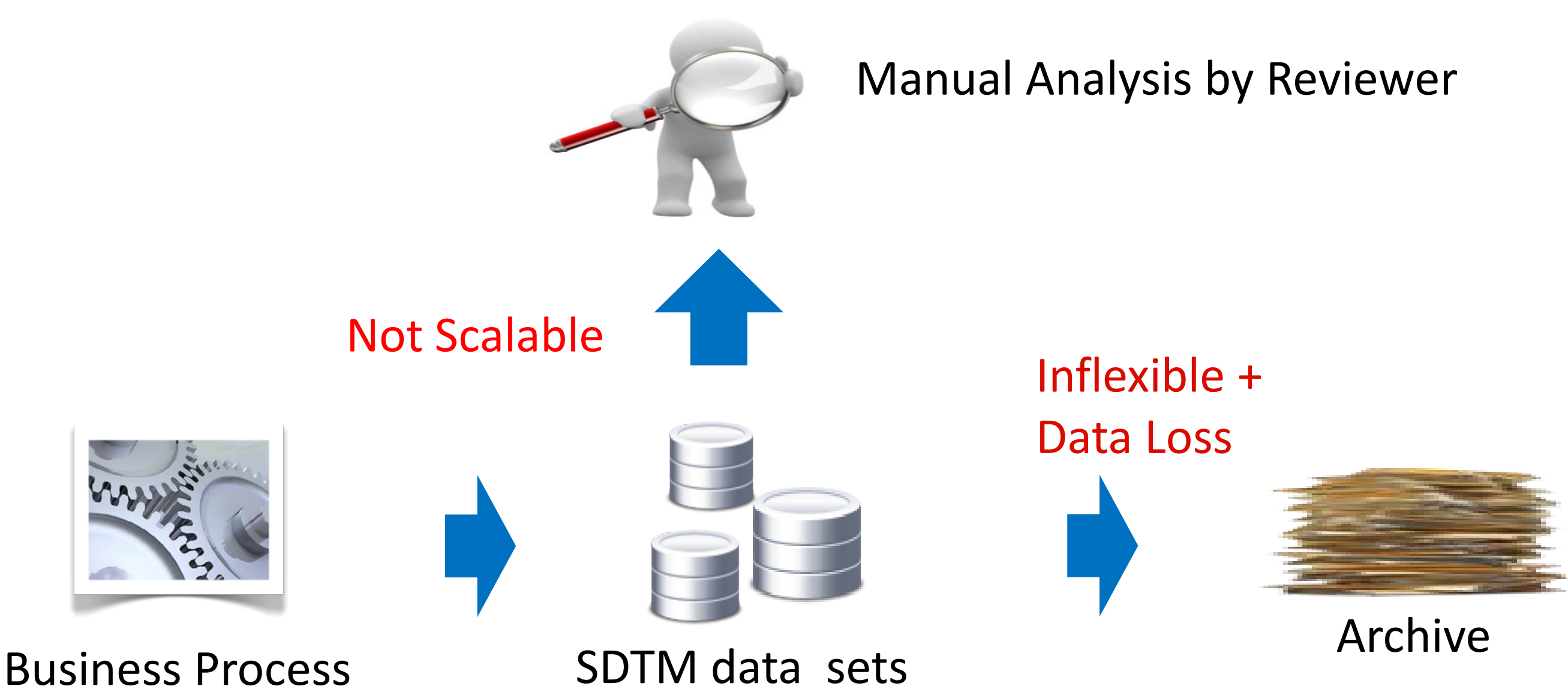


Figure 1: Manual analysis of SDTM datasets

Desire step for the implementation

Subject Glance is a web-based visualization tool that provides reviewers with the top 25 key pieces of information about any subject participating in a clinical trial and represents this information in a single image. The Subject Glance application also provides a mechanism to manage information and knowledge that will make systems semantically interoperable. Following are steps for the implementation:

- Step 1: Data Warehouses (relational Databases)
- Step 2: Data Warehouses + Ruby on Rails (ROR)
- Step 3: Data Warehouses + Ruby on Rails + XML (Standards)
- Step 4: Business Process + Analytics + Exchange + Real-Time + Visualization

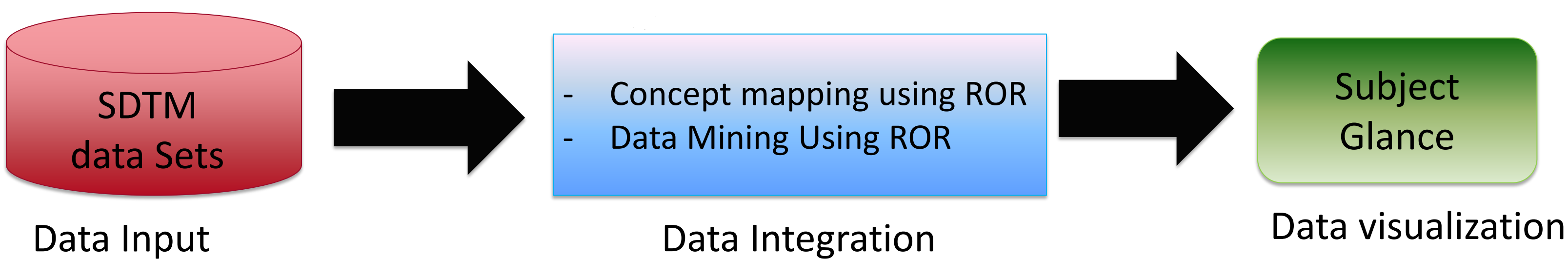


Figure 2: Automated Approach

System Architecture

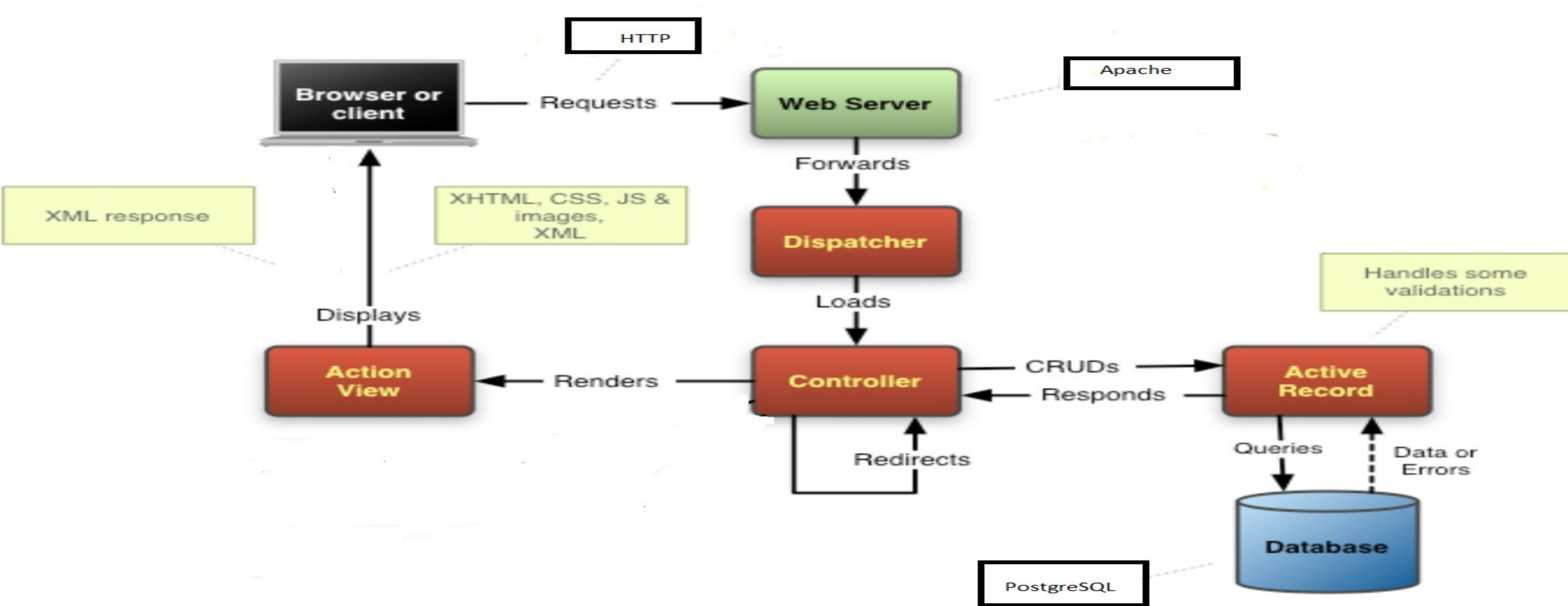


Figure 3: Subject Glance Schematic Diagram

Environmental Challenges



Slow development due to organizational barriers such as firewall restriction, hardware (scientific workstation acquisition), software acquisition (Passenger, ROR and Web server) and slow internal approval process.

Use of multiple development tools

Results: Subject Glance User Interface (UI)



Figure 4: Subject Glance User interface

Conclusion:

When deciding server architecture to use for our Subject Glance environment, there are many factors to consider, such as performance, scalability, availability, security, reliability, ownership, and ease of management. To address these challenges, our next step is to improve the performance of our developed system and implement the remaining questions for the visualization application.