

## Achieving Efficiency in CDISC SDTM Data Conversion and it's Challenges - Case Study

Ilango Ramanujam, TAKE Solutions Inc, Princeton, NJ

### Abstract

The standardization of raw data into CDISC SDTM data involves multiple challenges such as sponsor-vendor collaboration, raw data governance, decision making on the logical interpretation of SDTM concepts, collecting study related documents, meeting the timeline etc. This is even more challenging if the conversion activities are for submission purpose with large number of studies and multiple vendors participation. This paper will demonstrate a case study of SDTM conversion of over 35 clinical trials and preparation of integrated database. The challenges involved in the conversion and how we achieved efficiency through processes, tools and methodologies are described in this paper.

### Introduction

The Overview of the project chosen for a Case Study

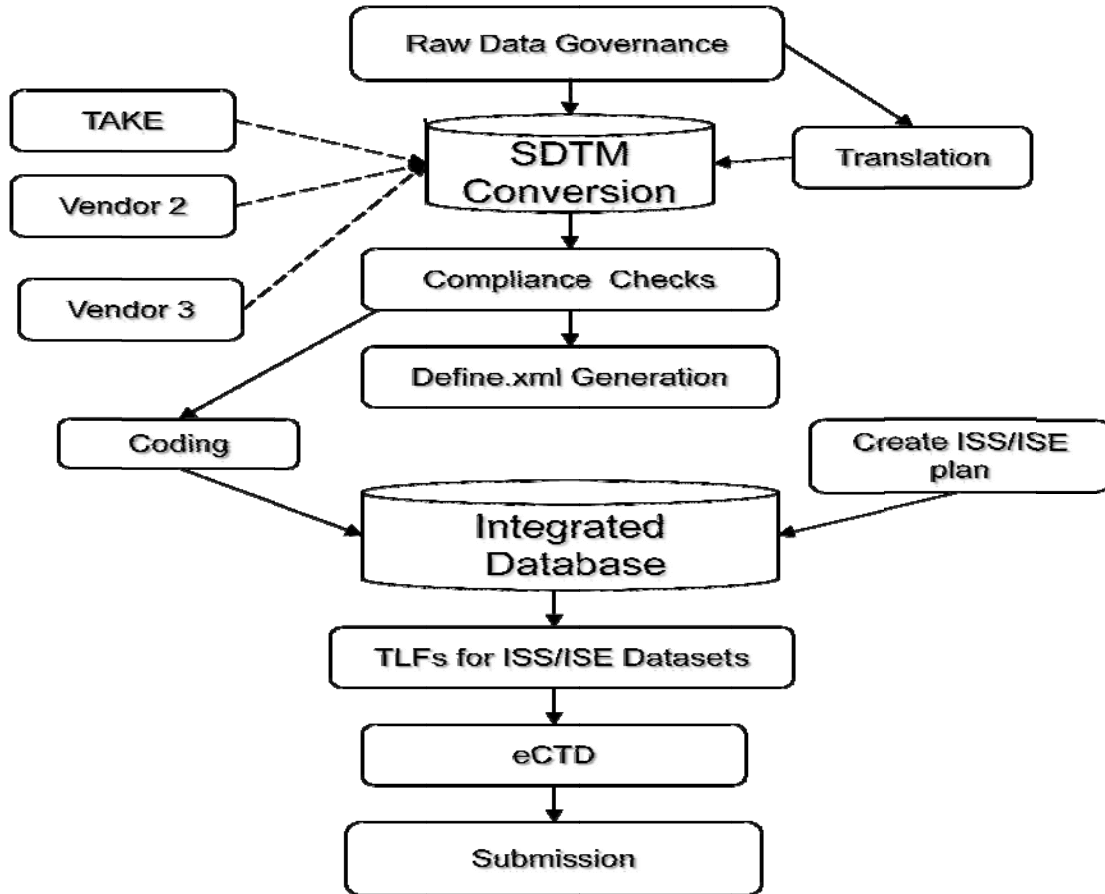


Figure 1: Case Study

The above project involves conversion of the raw data into CDISC SDTM v3.1.1 for over 35 studies from various phases of the trial (Phase I, Phase II and Phase III), integration of all studies to facilitate programming for ISS/ISE Tables/listings and Figures. There were multiple vendors involved in these activities.

## **Implementation Approach:**

The agreed upon implementation strategy was as follows to meet the timeline and quality for submission.

The completed studies were to be handled by us for conversion. In order to achieve consistent interpretation of logical mapping and over all consistency across studies, the mapping of all the studies were given to us and the ongoing studies programming of the mapping were to be handled by the other two vendors who were performing the data management of those trails. The other activities are generating definition files as part of the CRT and up coding of adverse events, Medications and Medical History is part of the integrated database. Sponsor agreed to review the CRF annotations in SDTM and parts of mapping specification, Spot checks on the SDTM data, and complete review of compliance validation report. Review and approve all documents related to the plans (PM, Communication, Validation, Change Control, Define.xml ). Sponsor involved in providing inputs on certain critical decision like identifying the appropriate Reference Start Date (RFSTDTC), Reference End Date (RFENDTC), bad data, Inclusion of Screen Failures and standardization of --TESTs & --TESTCDs and DS,AE, DM domain control terminology.

## **Challenges**

The challenges of this project were collaboration between sponsor and the vendors, collaboration between multiple vendors, decision making on the logical mapping, the studies were conducted in several geographical locations over a period of 12 years with different standards of the CRF or no standard at all, studies with no CRF books, CRFs with no source annotations, several extension studies, Some of the cross over studies had subjects who went through different arms were not properly identified and instead collected as a new subject, External Vendor files for LAB, ECG,PK were not available for many studies and Identified later during conversion.

## **Achieving Efficiency**

The project was completed successfully in 8 months for all the activities. The resources for conversion activities were divided into 3 groups as SDTM analysts, Programmers, and Project managers. The roles and responsibilities were clearly defined and communicated to the internal teams and the entire team.

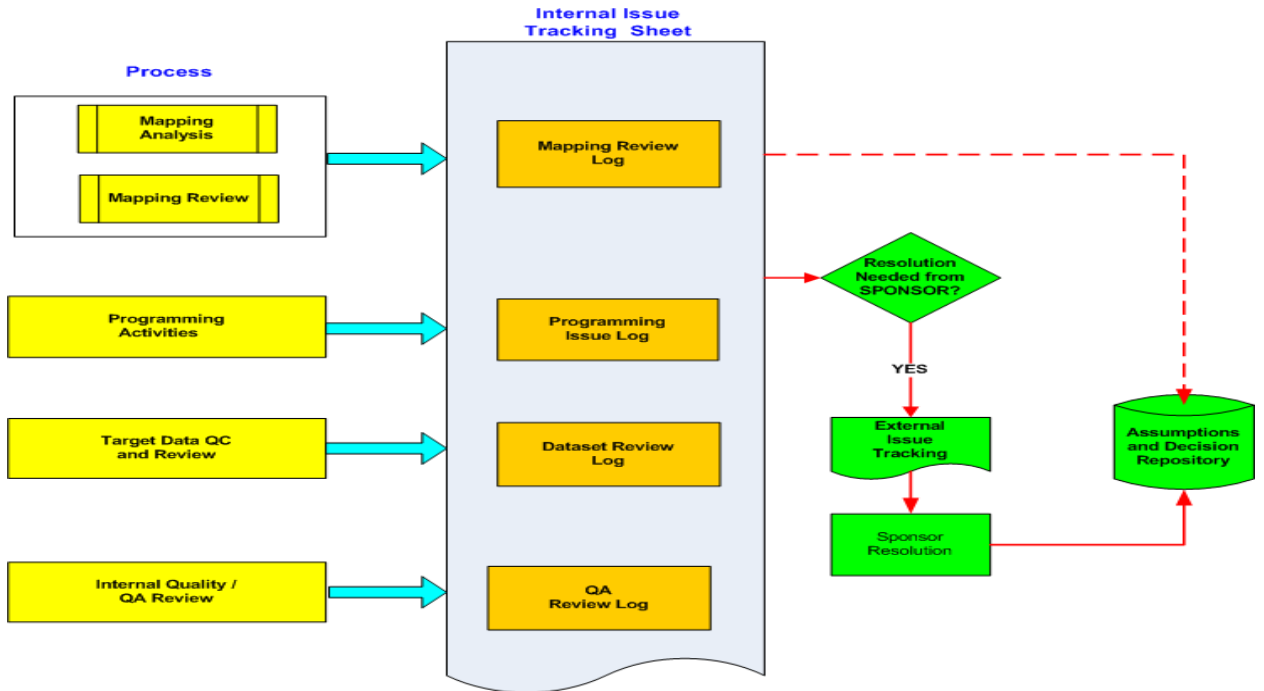
The implementation strategy includes the following,

- 1. Communication Plan**
- 2. Project Management Plan**
- 3. Conversion Methodology**
- 4. Process/tools improvement through metrics**
- 5. Sponsor involvement**

### **1. Communication Plan**

Communication Plan was created between TAKE and the Sponsor which includes the plan for communicating with other vendors, Roles and Responsibilities of personnel on both sides including other Vendors, and Periodic meetings between the review teams. Project lead of TAKE will communicate with Manager of CDM who is responsible for SDTM conversions at the sponsor on technical issues. TAKE Project Manager Conversion activities will communicate with the sponsor's overall program PM and the concerned review team at the sponsor. Project leaders (SMEs) were assigned to work with internal team, sponsor's technical team, and other Vendors. The issue tracking repository was created and it helped the SDTM analyst to make consistent interpretation of the logical mapping and reusability of annotation & mapping.

## ISSUE TRACKING AND RESOLUTION REPOSITORY MANAGEMENT



**Figure 2: Issue tracking Mechanism**

### 2. Project management

The project management is one of key function to meet the timeline. The Project Manager identified resources for Data and related documents Inventory, prior to the conversion activities. Sponsor was notified in advance to obtain missing information and project plan was updated accordingly. The Inventory resources performed the macro analysis to ensure that the source data is as per the CRF and Protocol. The team will also ensure that all external Lab data are available. The conversion activities were performed after the notification from the Inventory team. Triggers and alerts were set when new versions of the deliverables are posted to the secure shared environment. The other vendors, sponsor were notified timely to download the correct version for further processing.

### 3. Conversion methodology

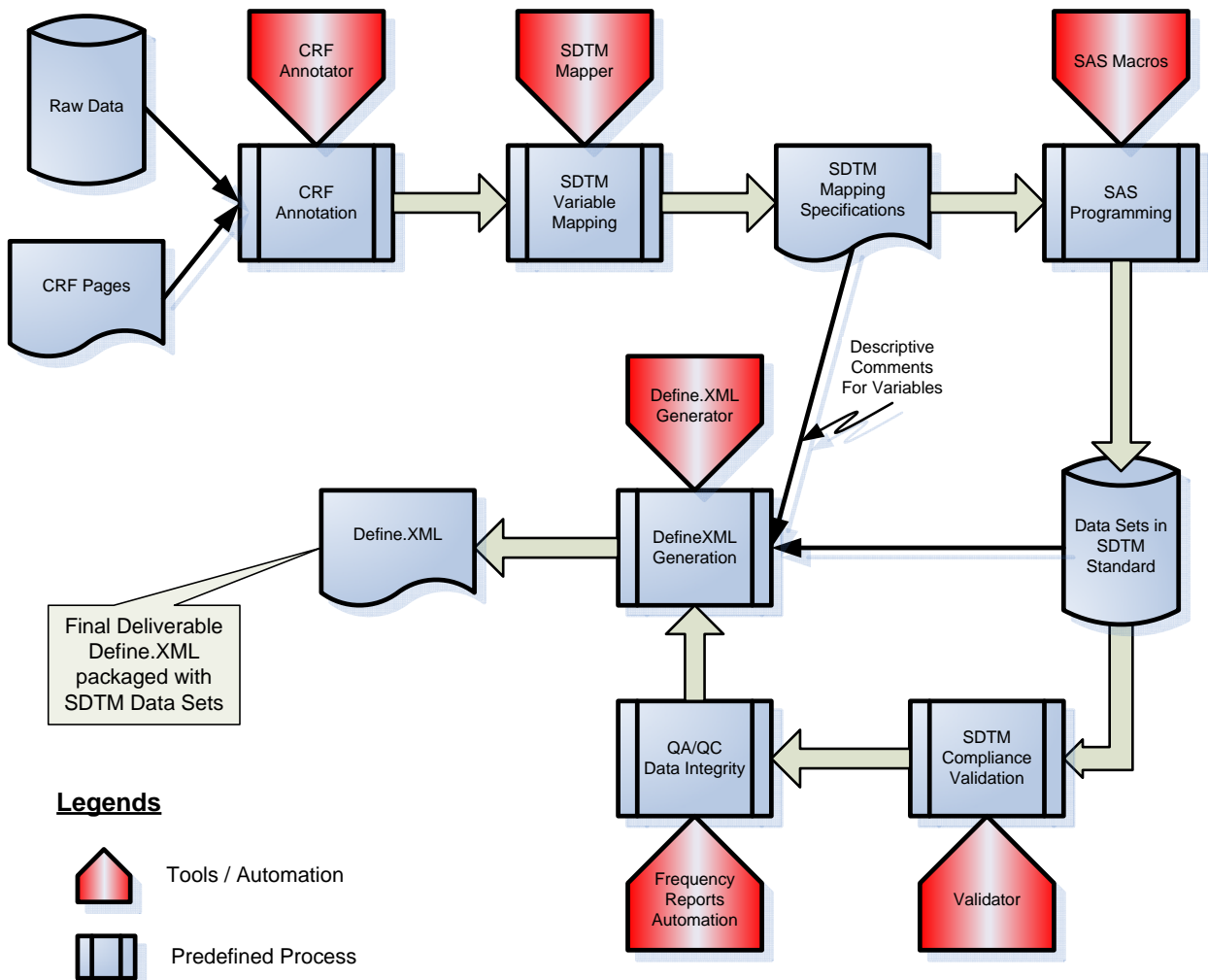


Figure 3: Conversion Methodology

### 4. Metrics

#### Phase 1

The first phase of the project with 5 studies has taken the following efforts without all the tools and process in place.

Activity	Effort in Hours
CRF Annotation	80
Mapping Specification	120
Generate datasets	150
Compliance Checks & Review	40
Trial design Review	8
<b>Total</b>	<b>398</b>

**Phase 2:** The second phase of the project has taken the following with processes and tools in place as mentioned in conversion methodology.

Activity	Effort in Hours
CRF Annotation (with Reusability & Annotator)	24
Mapping Specification (with tools in SAS)	64
Generate datasets	72
Compliance Checks & Review	16
Trial design Review	8
<b>Total</b>	<b>184</b>

## 5. Sponsor involvement with Deliverables

Sponsor review and approval on the aCRF as a first step. Mapping Specification was finalized after the approval of aCRF. Sponsor Approval of Standards documents after the ISS/ISE Plan was created. Review of mapping specifications for few studies. Mapping issues identified during programming were documented and sent to the sponsor and vendor who performs the programming activities for few studies. Spot Checks on SDTM datasets. Several Decisions were made after reviewing first few studies to go back and change the logical mapping which was identified easily through impact analysis.

## **Conclusion**

Including the Conversion Vendor to be part of the overall strategy would save cost & help to meet the timeline. Having the logical mapping and programming activities separate and modular approach to automate large part of programming helped us to achieve efficiency.

By having a strategic plan of sponsor involvement in the conversion process at each stage of the project, would help both sponsor and vendor in achieving the project goals. It is important for sponsor to make the necessary data and documents available in time and for vendor to produce the deliverables according to the timelines and agreed upon formats. Communication, Collaboration and Planning are the keys for successful SDTM conversion.

## **CONTACT INFORMATION**

**Ilango Ramanujam**

**TAKE Solutions Inc**

**201 Carnegie Center**

**Princeton, NJ 08540**

**[Ilango.ramanujam@takesolutions.com](mailto:Ilango.ramanujam@takesolutions.com)**