EVIDENTIQ

Successful SDTM Implementation

Transforming Data for Regulatory Success with Marvin EDC.

marvin
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Details

This case study showcases how Marvin EDC allowed our customer to successfully build regulatory-compliant datasets for an academic study, paving the way for regulatory submission and potential market approval.

Why CDISC SDTM is essential for your Studies

Regulatory authorities like the FDA, EMA, and PMDA require clinical trial data in standardized formats like CDISC SDTM. Harmonizing data collection to SDTM ensures compliance, which is crucial for the approval of new drugs and therapies. Harmonizing data collection to CDISC SDTM ensures compliance with evolving regulatory requirements and industry standards. This future-proofing maintains the long-term viability and relevance of the data collected.

Background

Our customer collaborated with the study sponsor (an European academic institution) to prepare the data for regulatory submission. To meet these regulatory submission requirements, we needed to transform the data collected in Marvin into SDTM format (Study Data Tabulation Model). This required significant data restructuring efforts to ensure compliance with SDTM and regulatory submission standards.

Marvin EDC

Marvin by EvidentIQ is a powerful EDC solution that simplifies clinical trial data management by providing advanced tools including the Marvin **Tabulator for ODM to SDTM conversion**, Medical Coder supporting MedDRA and WHODrug coding for data consistency, and Automated Data Transformation **ensuring real-time updates in SDTM datasets.**

Requirements and Challenges

KEY CHALLENGES INCLUDED:

- The study design was not optimally aligned with SDTM dataset creation.
- Managing over 3,000,000 observations (9,000,000 data points).
- Data privacy constraints restricted processing outside the EU. Patients had to reconsent, and the list of eligible patients changed throughout the project.
- Evolving project requirements during execution.
- Ongoing data review activities during SDTM generation - hence **frequent data changes.**
- Data tabulation could not be executed in the live environment due to necessary eCRF modifications **to meet certain requirements.**

Solution Overview

KEY ASPECTS OF THE IMPLEMENTATION:

- Direct conversion from ODM to SDTM using **Marvin's Tabulator tool.**
- Implementation of Data Base Views in Marvin to **resolve limitations** of tabulator tool.
- Creation of SAS XPT files was generated using direct data base connection with SAS ->no data export and import to SAS required.
- Usage of the Marvin Coder tool for **MedDRA and WHODrug** coding.
- Specialized SQL checks were implemented to **simplify validation processe**s for frequently changing data.
- Usage of clone instance with frequent data update from the live instance.

> *Executing this project was complex, demanding meticulous planning and close collaboration across teams. Leveraging CDISC SDTM standards helps maintain high data quality with clear guidelines for data collection, entry, and validation. This reduces errors, ensures accurate data capture, and deliver reliable datasets for regulatory submission*

Kalaivani Durai
Project Data Manager, EvidentIQ Germany

Process

Over a span of four months, EvidentIQ Germany was required to generate SDTM datasets on a weekly basis. With each delivery, our client conducted a **thorough review of the dataset to ensure continuous data validation.** Following each review cycle, queries were generated for the sites to facilitate data cleaning. Additionally, SDTM rules were subject to ongoing modifications.

Our long-term partner, CRO Sanaclis, has used Marvin since 2016 and has extensive experience with our Marvin Tabulator Tool. Their data management team collaborated closely with our client to map Marvin data to SDTM and executed the technical mapping using the Tabulator. They also created all submission-related documents, including aCRF, define.xml, and the Clinical Study Data Reviewer's Guide.

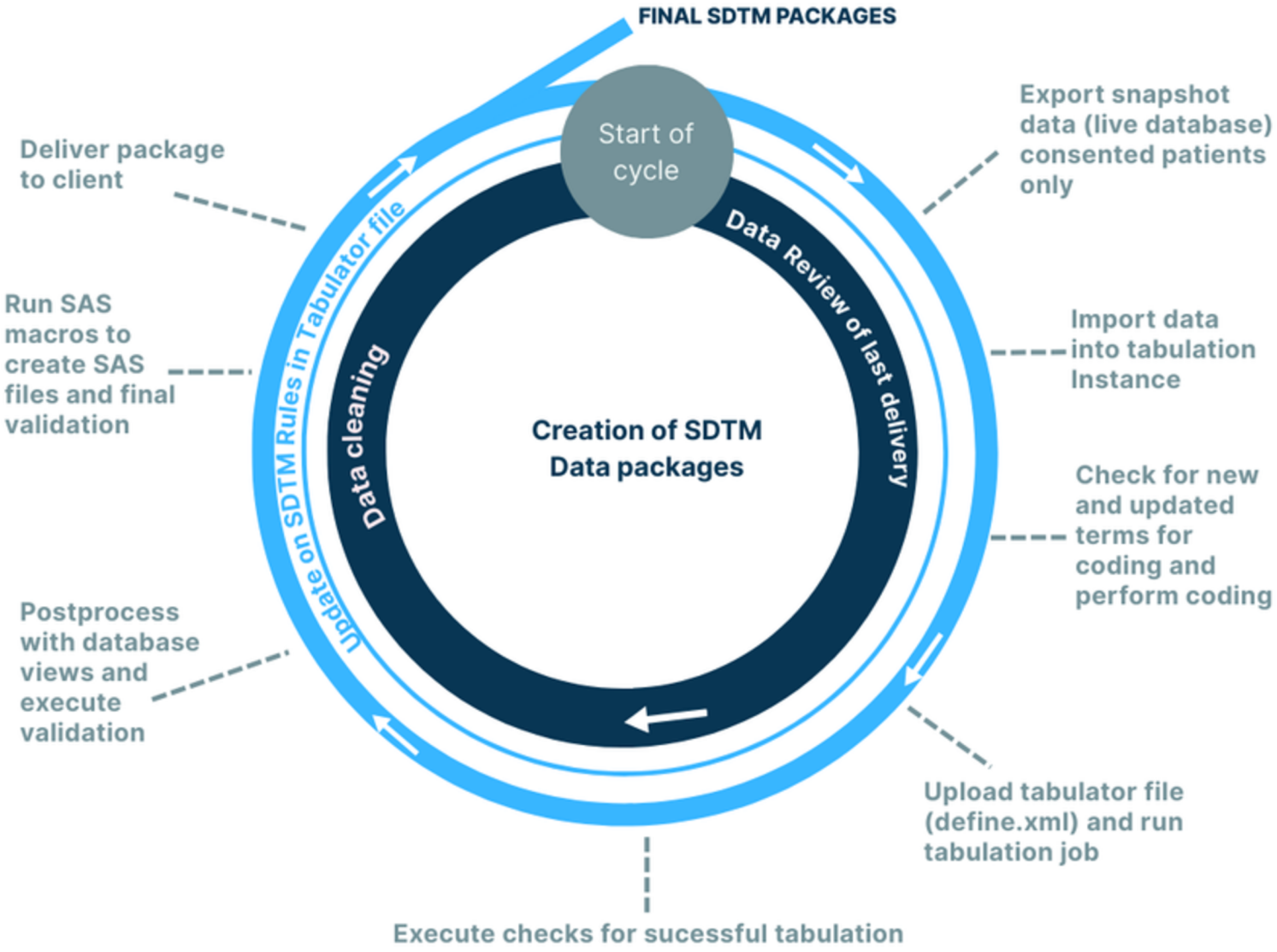
Before generating the datasets for each delivery cycle, the clone instance had to be prepared by refreshing the database with the latest data and establishing a connection to the coder instance. Any newly added or updated AE (Adverse Events), CM (Concomitant Medication), PR and MH (Procedures and Medical History) data resulting from the refresh process had to be coded (or recoded) within two days. Once the refresh and coding were completed, the SDTM tabulator was executed, incorporating any concurrent changes to tabulation rules.

Our longstanding CRO partner, Zifo (Chennai, India), supported coding activities using the Marvin Coder tool. They coded new and updated terms within two days after each refresh cycle, ensuring seamless continuation of tabulation activities.

After tabulation, SAS scripts were run to directly access the database and generate SAS and XPT files containing the tabulated SDTM datasets.

Our partner, Cliniva, specializes in SDTM and SAS programming. They integrated SAS macros into our Marvin workflow, established robust validation procedures, and assisted with SDTM submission-related questions.

SDTM Generation Process



The light blue circle represents EvidentIQ work streams and tasks

The dark blue circle stands for the client work streams and tasks

Close coordination between the client, Sanaclis, Zifo, Cliniva and EvidentIQ's Marvin team was essential to maintaining compliance with SDTM standards and meeting regulatory submission requirements.

Benefits

Creation of regulatory-compliant SDTM datasets for research presented significant data management challenges. Implementing a comprehensive data transformation strategy delivered multiple benefits.

The team maintained operational efficiency despite working with constantly changing data, adjusting mapping rules, **perform adhoc coding** for 8 years of data and being unable to access the live environment. As a Marvin EDC user, the Tabulator enables creation and access of SDTM datasets directly within the database, no data export or import to other tools is required.

A special thank you to our trusted partners, Zifo, Sanaclis, and Cliniva for their support and commitment to excellence.

Are you struggling with the complexities of CDISC SDTM standards? We understand how time-consuming and complex they can be, especially when balancing your day-to-day operations.

Our SDTM experts make the process seamless:

- Free consultation: We'll review your study needs in detail.
- Tailored solution: You'll receive a customized proposal designed just for your project.

Get started today: sdtm@evidentiq.com

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EvidentIQ is a leading provider of modern eClinical solutions designed specifically for experts in clinical research.

Our eClinical software, Marvin, is an effective **CDISC-certified** EDC system that includes numerous modules such as randomization, patient-reported outcomes (ePRO), IWRS, CDISC tabulation, reporting, medical coding, and more.