

# Statistical Reporting Metadata Manager: Web Application to streamline and centralize Global & Study Metadata preparation and management

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## ABSTRACT

**SRMM (Statistical Reporting Metadata Manager)** is a web-based application built to streamline and centralize Global & Study Metadata (MD) preparation and management.

Harnessing the power of graph database technology, SRMM connects metadata end to end from data collection (SDS) to statistical reporting (TLF). The Python backend is connected to the database and handles requests from users who interact with the application through a Vue.js interface. The User Interface is ergonomic, and enables the user to browse Global Metadata, Study Metadata and inspect connections between different metadata types.

The goal of SRMM is to help standardization teams, biostatistician and programmers by saving critical time spent on manual, error-prone work. It empowers them to focus on their area of expertise, thereby accelerating the analysis and reporting of clinical data. In the future, these can be further enriched by connecting to protocol & SAP to drive automation.

## INTRODUCTION

In the ever-evolving landscape of clinical research and data management, the efficient preparation and standardization of metadata plays a pivotal role in ensuring the seamless creation of Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) datasets. SRMM is a comprehensive solution designed to streamline the intricate process of metadata management, preparation, and mapping.

Our approach extends beyond mere compliance, incorporating cutting-edge mapping and automation techniques to generate preliminary SAS/R scripts, thereby reducing manual workload and expediting the programming phase. By automating the script creation process, we will take care of the boilerplate code which will empower statisticians and programmers to focus on critical analysis tasks, fostering a more efficient and error-resistant environment.

Furthermore, SRMM goes beyond data preparation, integrating with tools that facilitate the design and generation of Tables, Listings, and Figures (TLF). Through this integrated approach, we not only ensure the consistency and accuracy of data but also enhance the overall efficiency of the reporting process.

## BUSINESS STRATEGY AND VALUE

In the dynamic landscape of Metadata Assisted Programming Services (MAPS), Strategic Metadata Mapping Management (SRMM) emerges as an integral component, seamlessly integrating with the overarching MAPS framework. Rooted in innovative graph technologies, MAPS provides a sophisticated platform for the harmonious integration and linking of diverse Clinical Data Interchange Standards Consortium (CDISC) metadata types, including CDASH, SDTM, ADaM, and CT.

Within this comprehensive ecosystem, SRMM takes center stage, serving as the orchestrator for all metadata transformations and mappings. As illustrated in the accompanying diagram, SDS, denoting Sanofi's adaptation of CDASH metadata, and CG Metadata, representing Code Generator Metadata, coalesce under the auspices of SRMM.

Noteworthy is the pivotal role of SRMM in managing and governing all aspects of metadata transformations and mappings. This centralized control mechanism ensures a streamlined and efficient process, allowing for the seamless translation and linkage between various CDISC metadata types. By leveraging graph technologies, SRMM not only facilitates the integration of disparate metadata elements but also provides a dynamic framework that adapts to the evolving needs of the MAPS ecosystem.

In essence, SRMM stands as the linchpin in the MAPS architecture, embodying the commitment to precision, efficiency, and adaptability in metadata transformations within the realm of CDISC standards. As MAPS continues to

evolve, SRMM remains at the forefront, empowering the seamless integration and linkage of diverse metadata types, contributing to the overall efficacy of Metadata Assisted Programming Services.

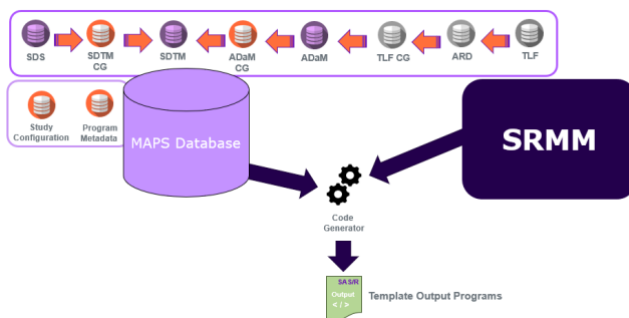


Figure 1: SRMM Ecosystem

## ACCESSING THE APPLICATION

Elevating accessibility and user convenience, SRMM is thoughtfully designed as a web application, ensuring users can seamlessly engage with its robust functionalities through standard web browsers. This user-friendly interface provides a straightforward and intuitive experience, enabling efficient navigation and interaction with the SRMM platform.

By adopting a web-based architecture, SRMM can be integrated with Single-Sign On, facilitating user access control and collaboration from virtually anywhere. This approach aligns with contemporary technological trends, offering flexibility and ease of use for stakeholders involved in metadata transformations and mappings.

## APPLICATION SNIPPETS

Global Standard Metadata - ADaM

| Class | SubClass | Relative Order | Dataset Name | Dataset Description | Dataset Description (Long) | Split Parent | Split Parent Dataset Label | Dataset Structure | Purpose | Key Variables | Repeating | IsReferenceData | Need for Comm |
|-------|----------|----------------|--------------|---------------------|----------------------------|--------------|----------------------------|-------------------|---------|---------------|-----------|-----------------|---------------|
| ▼     | S...     | 1              | ADSL         | Subject-Level...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | No        | No              |               |
| ▼     | B...     | 2              | ADADA        | Analysis Anti...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 3              | ADEG         | Analysis ECG...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 4              | ADES         | Analysis Exp...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 5              | ADIS         | Analysis Imm...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 6              | ADLB         | Analysis Labo...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 7              | ADLBUS       | Analysis Lab ...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 8              | ADPC         | Analysis Phar...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 9              | ADPP         | Analysis Phar...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |
| ▼     | B...     | 10             | ADTR         | Analysis Tum...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y             |

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Figure 2: Global Metadata ADaM

**Analyses**

Q Global search Clear All

| Analysis Code | Name                    | Analysis Description     | Compound code | Study code | Main Global Standard ADaM Version | Main Global Standard CT Version | Created                          | Creator | Edited                           | Editor |
|---------------|-------------------------|--------------------------|---------------|------------|-----------------------------------|---------------------------------|----------------------------------|---------|----------------------------------|--------|
| ^ CSR_MAPS    | Standard Parallel Study | Analysis for Pilot Phase | SAR231893     | EFC16720   | 1.9                               | 3.1                             | 2023-12-14T11:01:38.773725+00:00 | admin   | 2023-12-14T12:51:19.011518+00:00 | admin  |
| ^ CSR_MAPS    | Basket Trial            | Analysis for Pilot Phase | SAR444245     | ACT16845   | 1.9                               | 3.1                             | 2023-12-14T11:02:31.088560+00:00 | admin   | 2023-12-14T12:53:24.987398+00:00 | admin  |
| ^ CSR_MAPS    | Early Phase study       | Analysis for Pilot Phase | SAR444559     | SAD17442   | 2.1                               | 4.0                             | 2023-12-14T10:59:22.511273+00:00 | admin   | 2023-12-14T10:59:22.511273+00:00 | admin  |

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Figure 3: List of Analysis

**Study Metadata - ADaM**

SAR231893 > EFC16720 > CSR\_MAPS (reading)

EXPORT TO WISE

Based on global standard: 1.9  
Last edited on: 2023-12-14T12:51:19.011518+00:00

READING MODE

Dataset Metadata Variable Metadata ComplMethod WhereClauses Shared Comments External Dictionary Study Info SuppDocs Variable Category Descriptions

Q Global search Clear All

| Class  | Relative Order | Dataset Name | Dataset Description | Dataset Description (Long) | Split Parent | Split Parent Dataset Label | Dataset Structure | Purpose | Key Variables | Repeating | IsReferenceData | Need for Common Variables from ADSL | Require |
|--------|----------------|--------------|---------------------|----------------------------|--------------|----------------------------|-------------------|---------|---------------|-----------|-----------------|-------------------------------------|---------|
| ^ O... | 12             | ADMH         | Analysis Medi...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ B... | 17             | ADED         | Analysis E-Di...    | Analysis E-Diary Fin...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ B... | 5              | ADLB         | Analysis Labo...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ A... | 20             | ADIVRS       | Randomizatio...     | Randomization and ...      |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ B... | 2              | ADEG         | Analysis ECG...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ O... | 10             | ADCM         | Analysis Con...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ S... | 1              | ADSL         | Subject-Level...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | No        | No              |                                     |         |
| ^ B... | 5              | ADIS         | Analysis Imm...     | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ B... | 6              | ADPC         | Analysis Phar...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |
| ^ O... | 9              | ADAE         | Analysis Adve...    | Contains key informa...    |              |                            | One record ...    | An...   | STUDY...      | Yes       | No              | Y                                   |         |

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Figure 4: Study Metadata Management

Note: The application is under active development.

## CONCLUSION

Strategic Metadata Mapping Management (SRMM) is not just a tool; it's a catalyst for transformative achievements in metadata management. By aligning with key organizational goals, SRMM propels efficiency and innovation in the realm of data preparation. Here's how SRMM facilitates the realization of crucial objectives:

- Efficiency Enhancement:** SRMM stands as a cornerstone in making working with metadata more efficient. It introduces streamlined processes and centralized controls that significantly reduce the complexities associated with metadata management. This efficiency boost ensures that teams can focus on core tasks, optimizing their productivity.
- Enhanced Access to Mapping and Derivations:** SRMM provides a comprehensive solution for achieving better access to existing mapping and derivations. Whether sourced globally or at the study level, SRMM acts as a repository, allowing users to retrieve vital information swiftly. This centralized access ensures consistency and accuracy in metadata usage throughout the organization.
- Elimination of Repetitive Tasks:** Repetitive work becomes a thing of the past with SRMM. The tool is engineered to automate mundane tasks and retrieve information automatically. This not only minimizes the

chances of errors but also liberates valuable human resources from monotonous endeavors, allowing them to contribute to more strategic and impactful activities.

4. **Acceleration of Data Preparation:** SRMM is designed to be a time-saving powerhouse. Its features and functionalities accelerate the data preparation phase, ensuring that timelines are met without compromising on quality. By automating intricate processes, SRMM becomes an invaluable asset in expediting the overall data preparation journey.

In essence, SRMM transcends the conventional boundaries of metadata management, aligning seamlessly with organizational aspirations. It is a dynamic solution that not only meets but exceeds goals, fostering a data preparation environment characterized by efficiency, accessibility, automation, and accelerated performance. With SRMM, organizations can confidently embrace a future where metadata management is not just a task but a strategic advantage.

## REFERENCES

References go at the end of your paper. This section is not required.

## ACKNOWLEDGMENTS

The successful development and realization of SRMM and MAPS stand as a testament to the collaborative spirit and dedication of numerous individuals. The journey from conceptualization to product fruition would not have been possible without the invaluable contributions of my esteemed colleagues at Sanofi.

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## CONTACT INFORMATION (HEADER 1)

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