Paper SD03

Turbocharge Your Trials: Transform CRF Creation and the CDISC standardization process with Xbiom's Smart Metadata Repository and AI/ML Integrations

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ABSTRACT

In clinical trials, managing and standardizing vast amounts of data efficiently is critical. As the volume and variety of data collected across therapeutic areas continues to grow, Sponsor organizations rely on a growing number of CROs, central labs, and non-EDC data sources. Efforts to consolidate and narrow the analysis focus through Risk Based Monitoring and "endpoint-centric" data review, can be at the expense of a holistic, patient stratified, and harmonized collection of trial data (especially non-EDC data) for both analysis and submission datasets.

Non-EDC data, namely a wide array of multi-omic biomarker data, presents challenges to the Sponsor data management and standards community who often have to consult biomarker leads for clarification, gating definition, or assay validation documentation.

This demonstration showcases a Smart Metadata Repository (MDR) that streamlines Case Report Form (CRF) creation in Electronic Data Capture (EDC) systems and ensures consistency in Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) datasets. The MDR serves as a centralized platform, enabling teams to reuse metadata, reduce redundancy, and ensure compliance with Company & CDISC standards.

By automating CRF creation and data standardization processes, the MDR minimizes manual work, cuts down on setup time, and improves data quality. The demonstration will highlight how the MDR simplifies data mapping to SDTM and ADaM, accelerates study setup, and supports efficient regulatory submissions. Attendees will learn how integrating an MDR into their workflow can lead to faster, more cost-effective trials with reliable, high-quality data that drives better decision-making.

INTRODUCTION

As the complexity of clinical trials continues to grow, organizations face significant challenges in managing metadata, ensuring data consistency, and maintaining regulatory compliance. Traditional approaches to Case Report Form (CRF) design, data standardization, and study setup are often fragmented, requiring extensive manual effort and increasing the risk of inconsistencies across studies. This not only slows down trial execution but also impacts regulatory submissions, data quality, and overall operational efficiency.

To address these challenges, **PointCross introduces the Xbiom Metadata Repository (MDR)**—a smart, centralized platform designed to transform clinical data management and Biostatistics & Statistical Programming (B&SP) by automating metadata-driven workflows. Xbiom MDR enables organizations to seamlessly create CRFs within Electronic Data Capture (EDC) systems, standardize datasets in alignment with CDISC standards, and efficiently map data to Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) formats. By eliminating redundancy and enabling metadata reuse, the MDR ensures consistency across studies, accelerates setup timelines, and reduces manual errors.

At its core, **Xbiom MDR** acts as an intelligent metadata hub, allowing clinical teams to:

- Automate CRF design within EDC systems to maintain uniformity and compliance.
- Standardize study data efficiently by integrating predefined templates aligned with CDISC requirements.
- Minimize redundancy by enabling seamless metadata reuse across multiple studies.
- Ensure regulatory compliance by providing an audit trail of metadata-driven transformations.
- Improve data quality by reducing manual intervention and ensuring consistency across datasets.

By integrating **Xbiom MDR** into clinical data workflows, sponsors and CROs can achieve greater efficiency, reduced setup time, and higher-quality submissions to regulatory agencies. The platform not only enhances data standardization but also enables faster, more informed decision-making, ultimately leading to cost-effective and reliable clinical trials.

This demonstration will showcase how **PointCross Xbiom MDR** is revolutionizing metadata management, highlighting its role in accelerating study setup, ensuring compliance, and supporting efficient regulatory submissions. Attendees will gain insights into how this innovative solution optimizes clinical trial data workflows, reduces operational burden, and enables organizations to focus on scientific outcomes rather than manual data processing.

The XBIOM MDR

Xbiom Metadata Repository (MDR) is an intelligent, centralized metadata management platform developed by PointCross Life Sciences to streamline clinical trial data management, standardization, and regulatory compliance. It serves as a single source of truth for study metadata, enabling standards managers across pharmaceutical companies, CROs, and regulatory teams to efficiently manage metadata-driven workflows throughout the clinical data lifecycle.

Xbiom MDR is designed to eliminate redundancies, enhance data quality, and accelerate study setup by automating the creation of Case Report Forms (CRFs) in Electronic Data Capture (EDC) systems, standardizing study data in compliance with CDISC standards (SDTM, ADaM, Define-XML), and ensuring seamless regulatory submissions.

Core Capabilities of Xbiom MDR

a) **Centralized Metadata Management**
- Stores all clinical trial metadata in a structured repository, ensuring consistency across studies.
- Provides a single, controlled environment for metadata reuse, eliminating redundancy and improving data quality.
- Allows teams to manage CDISC-compliant templates, ensuring adherence to evolving regulatory standards.

b) **Automated CRF Creation in EDC Systems**
- Automates the design and population of CRFs directly in major EDC systems.
- Reduces manual effort by enabling metadata-driven CRF reuse, ensuring standardization across multiple studies.
- Supports version control and audit trails, tracking changes in CRF designs over time.

c) **Seamless SDTM and ADaM Mapping**
- Ensures efficient data transformation and standardization by automatically mapping raw datasets to Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) formats.
- Reduces manual errors and inconsistencies by applying predefined metadata rules.
- Supports Define-XML generation, ensuring datasets are submission-ready for regulatory agencies.

d) **Regulatory Compliance and Traceability**
- Ensures CDISC compliance (SDTM, ADaM, SEND) with automated validation and quality checks.
- Maintains a complete audit trail of metadata changes for regulatory transparency.
- Supports regulatory submission requirements for FDA, EMA, and PMDA, ensuring faster approvals.

Point Cross's Xbiom: Life Sciences Digital Transformation

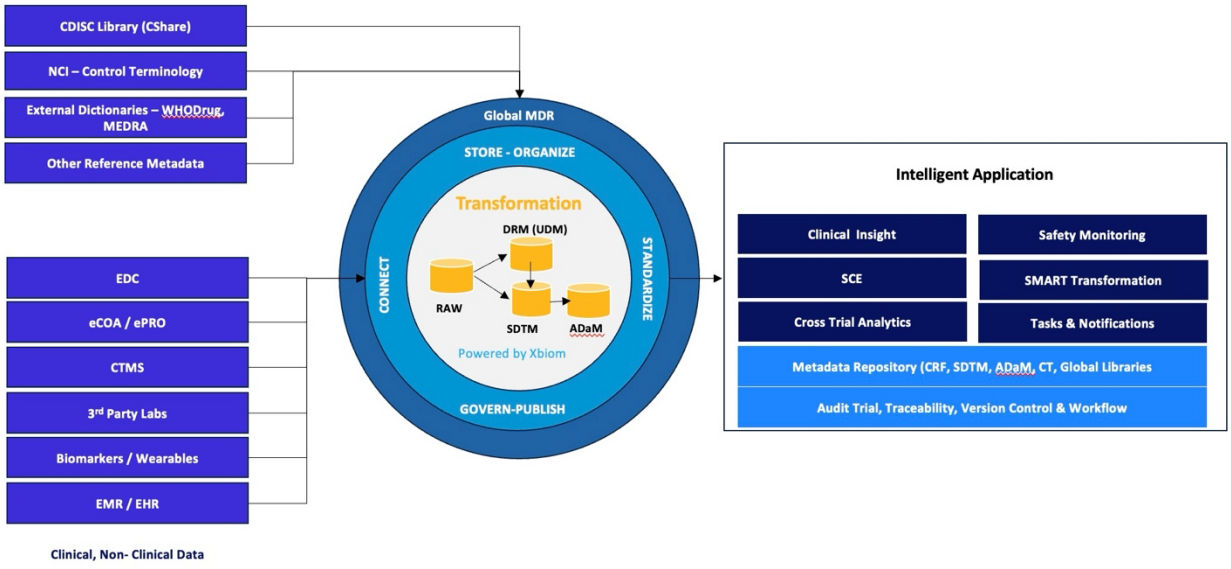

Figure 1: Xbiom Life Sciences Digital Transformation platform

1. Xbiom MDR: A Software-as-a-Service (SaaS) Solution for Clinical Data Management, B&SP

Xbiom Metadata Repository (MDR) is a **Software-as-a-Service (SaaS)** solution designed to transform clinical data management by automating metadata handling, streamlining Case Report Form (CRF) creation, and ensuring seamless CDISC-compliant data standardization. Developed by PointCross Life Sciences, Xbiom MDR provides a cloud-based, scalable, and secure platform for sponsors, CROs, and regulatory teams to efficiently manage metadata and optimize clinical trial workflows.

Unlike traditional on-premise metadata repositories that require extensive infrastructure management and manual updates, Xbiom MDR as a SaaS offering provides on-demand accessibility, automatic updates, comprehensive current and legacy terminologies lists with built-in version controls, and enhanced scalability, allowing organizations to standardize and streamline their data workflows across global clinical studies.

Key Features of Xbiom MDR as a SaaS Solution

a) Cloud-Based Accessibility and Scalability

- Hosted on a secure cloud environment, enabling global teams to access, manage, and reuse metadata from anywhere.
- Offers scalable infrastructure, accommodating studies of varying complexity and volume without IT overhead.
- Provides multi-tenant and private cloud deployment options to suit different organizational needs.

b) Secure and Regulatory-Compliant SaaS Infrastructure

- Built with enterprise-grade security including role-based access control (RBAC), encryption, and audit logging.
- Ensures data integrity through version control, traceability, and automated backups.
- Meets compliance standards such as 21 CFR Part 11, GxP, and GDPR, ensuring data protection and regulatory readiness.

c) Cost-Effective and Low-Maintenance

- Eliminates the need for on-premise infrastructure and IT maintenance, reducing operational costs.
- Provides automated or scheduled software updates to accommodate varying Sponsor-defined SOPs, while offering continuous feature enhancements without disruption of ongoing studies.
- Flexible subscription-based pricing model, making it cost-efficient for both large and small organizations.

2. Xbiom MDR: Integration and Advanced Features

Seamless Integration with Clinical Data Ecosystem

One of the key strengths of Xbiom Metadata Repository (MDR) is its ability to integrate seamlessly with existing clinical trial systems, enabling a connected and automated data management workflow. Xbiom MDR is designed to interact with a wide variety of Electronic Data Capture (EDC) systems, clinical data warehouses, regulatory submission platforms, and statistical computing environments, ensuring a smooth flow of standardized metadata and clinical trial data.

a) Integration with EDC Systems for CRF Creation

- Xbiom MDR automates CRF creation and metadata population in leading EDC platforms
- Ensures metadata consistency across EDC platforms, reducing manual errors and enforcing CDISC-compliant CRFs.
- Enables bidirectional integration, allowing metadata updates to be synchronized between MDR and EDC systems.

b) SDTM and ADaM Data Mapping and Transformation

- Directly integrates with clinical data transformation engines to automate mapping from raw datasets to SDTM and ADaM formats.
- Provides predefined SDTM and ADaM templates, ensuring compliance with CDISC standards.
- Supports Define-XML, aCRF & SDRG generation to streamline submission to regulatory agencies like FDA, EMA, and PMDA.

c) Integration with Statistical Computing and Reporting Environments

- Xbiom MDR connects with SAS, R, Python, and other statistical analysis platforms, ensuring that analysis-ready datasets (ADaM) are generated efficiently.
- Supports automated data standardization and validation, ensuring consistency in statistical outputs.

d) Regulatory Submission and Compliance Integration

- Ensures seamless data flow to regulatory submission platforms
- FDA Study Data Reviewer's Guide (SDRG) and Define-XML compliance tools
- eCTD submission tools for regulatory dossier preparation
- Maintains an audit trail of metadata changes, ensuring transparency and compliance with regulatory expectations.
- Enables real-time validation against CDISC rules, reducing errors before submission.

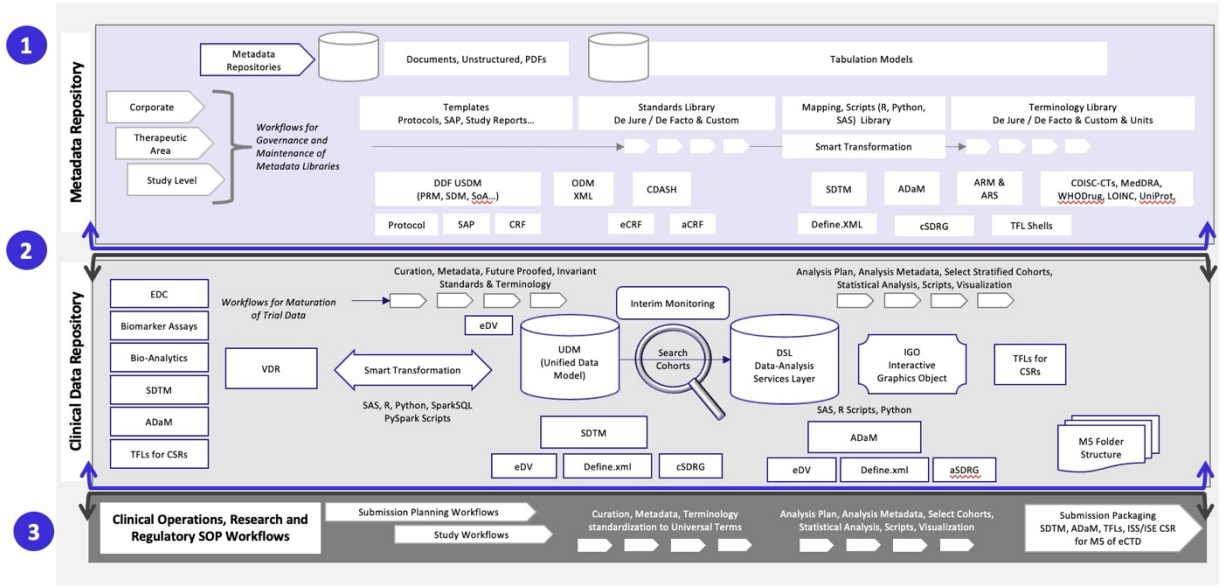

Figure 2: Xbiom Clinical Metadata & Data Repository

3. Advanced Features of Xbiom MDR

In addition to seamless integration, **Xbiom MDR** offers several advanced features that enhance efficiency, compliance, and data quality in clinical trials.

a) Intelligent Metadata Reuse
- Enables the reuse of standardized metadata across multiple studies, reducing setup time and ensuring consistency in CRFs and datasets.
- Helps sponsors and CROs enforce company-wide metadata standards, ensuring harmonization across studies.

b) Automated Version Control and Change Management
- Tracks metadata versions over time, ensuring that all changes are documented and traceable.
- Provides an automated rollback mechanism, allowing study teams to revert to previous metadata configurations if needed.
- Supports impact analysis, showing how changes in metadata affect downstream datasets and compliance.

c) Real-Time Quality Checks and Validation (eDV)
- Built-in data validation engine (eDV) ensures compliance with CDISC standards, FDA rules, PMDA rules, and internal metadata policies.
- Generates real-time alerts and reports for data inconsistencies, ensuring high-quality datasets before submission.
- Allows custom validation rules based on study-specific requirements.

d) Role-Based Access Control (RBAC) and Security
- Provides granular access control, ensuring that only authorized personnel can edit, approve, or view metadata.
- Ensures data integrity through audit logs, encryption, and secure cloud storage.
- Compliant with 21 CFR Part 11, GDPR, and other global data security standards.

e) Cloud-Based Collaboration and Multi-Tenant Support
- Enables real-time collaboration among global study teams, allowing multiple users to work on metadata simultaneously.
- Supports multi-tenant deployment, enabling organizations to maintain separate metadata environments for different business units or therapeutic areas.

Point Cross's Xbiom Platform

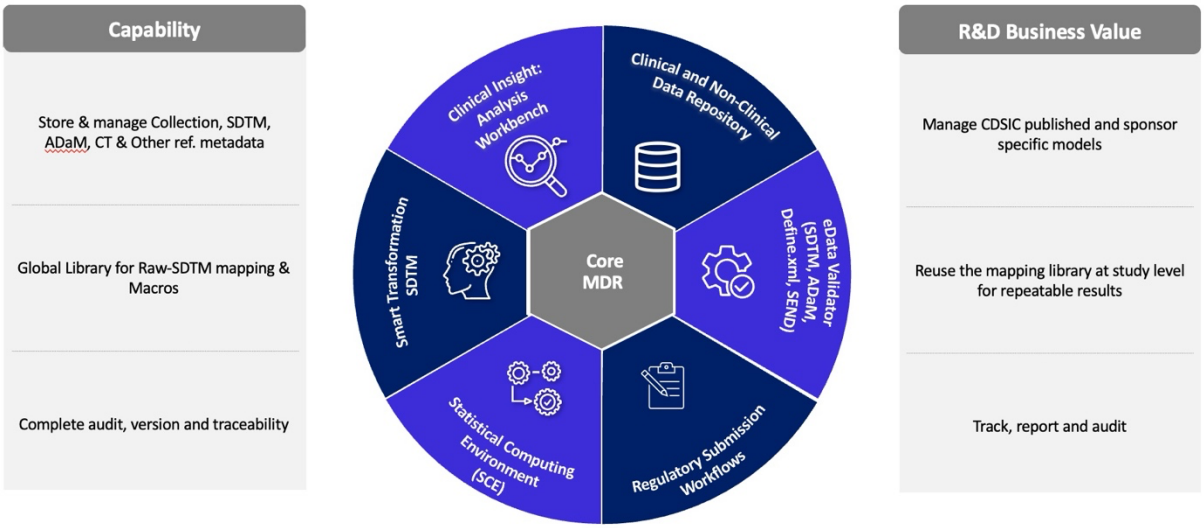

Figure 3: Xbiom Platform

Xbiom: CRF Metadata Management

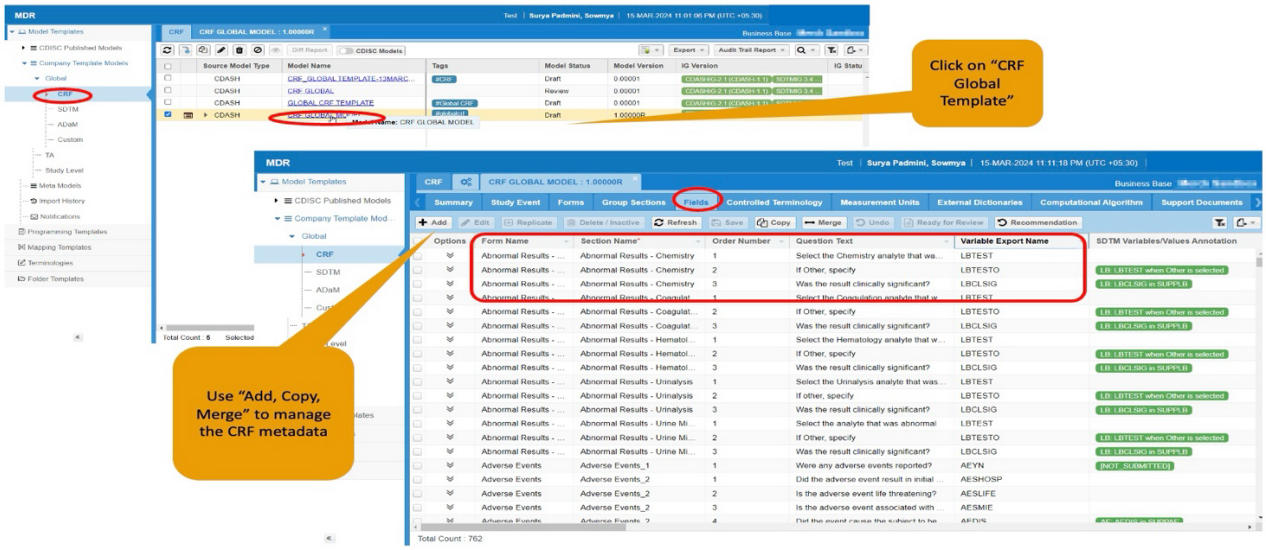

Figure 4: Xbiom CRF Metadata Management

4. Xbiom MDR CRF Metadata Management

Xbiom MDR streamlines CRF metadata management by automating CRF creation, standardization, and compliance across clinical trials. It enables metadata reuse, ensuring consistency and reducing redundancy across studies. The platform integrates seamlessly with major EDC systems, automating CDISC-compliant CRF design and validation. With version control, audit trails, and regulatory compliance checks, Xbiom MDR ensures traceability from CRF metadata to SDTM datasets, enhancing study setup efficiency, data quality, and regulatory readiness.

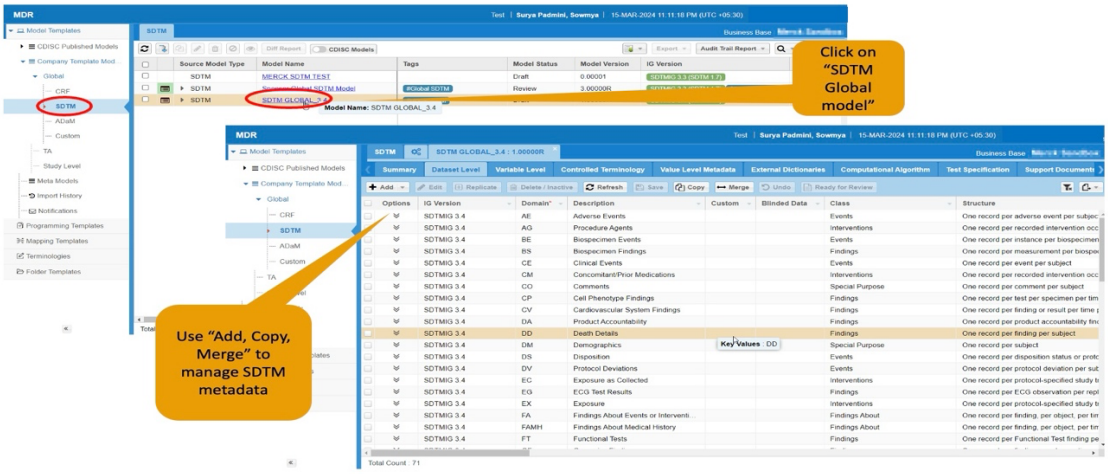

Figure 5: Xbiom CDISC SDTM & ADaM Metadata Management

5. Xbiom MDR CDISC SDTM & ADaM Metadata Management

Xbiom MDR provides a centralized and automated solution for managing CDISC SDTM and ADaM metadata, ensuring compliance, consistency, and efficiency in clinical trial data standardization.

Key Capabilities:

a) **Automated SDTM Metadata Management**
- Standardizes study data tabulation (SDTM) datasets using predefined CDISC-compliant templates.
- Automates data mapping from raw datasets to SDTM domains, reducing manual transformation efforts.
- Ensures Define-XML generation, supporting submission-ready datasets for FDA, EMA, and PMDA.

b) **Efficient ADaM Metadata Handling**
- Enables structured metadata for analysis datasets (ADaM), ensuring traceability from SDTM.
- Supports ADaM dataset creation aligned with SAP (Statistical Analysis Plan).
- Integrates with SAS, R, and other statistical platforms for streamlined analysis.

c) **Regulatory Compliance and Validation**
- Conducts real-time validation against CDISC SDTM and ADaM compliance rules.
- Maintains audit trails and version control, ensuring traceability and transparency.
- Supports Define-XML, SDRG, and ADRG generation for regulatory submissions.

d) **Seamless Integration with Clinical Data Workflows**
- Links CRF metadata, SDTM, and ADaM datasets for an end-to-end metadata-driven workflow.
- Allows bidirectional updates, ensuring metadata consistency across EDC, MDR, and statistical analysis platforms.

By automating metadata management for SDTM and ADaM, Xbiom MDR enhances data quality, regulatory compliance, and operational efficiency, making clinical trials faster, more accurate, and submission ready.

Xbiom: Mapping & Library Management

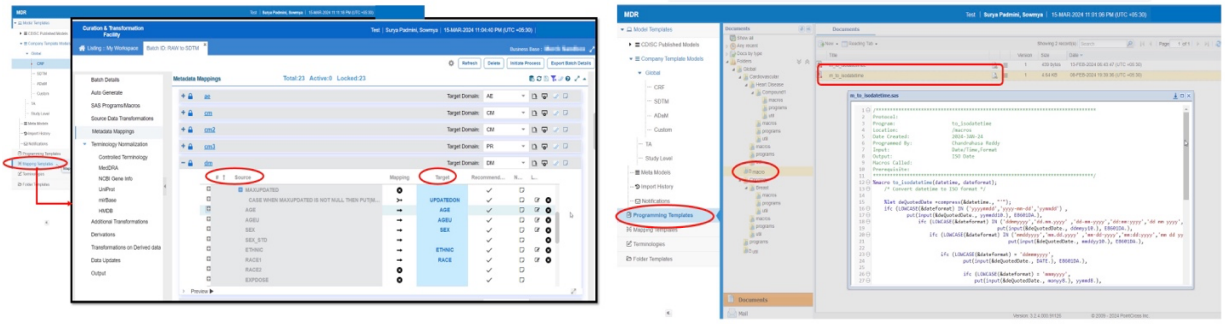

Figure 6: Xbiom Mapping & Library Management

Xbiom: In-built compliance and validation engine (eDV)

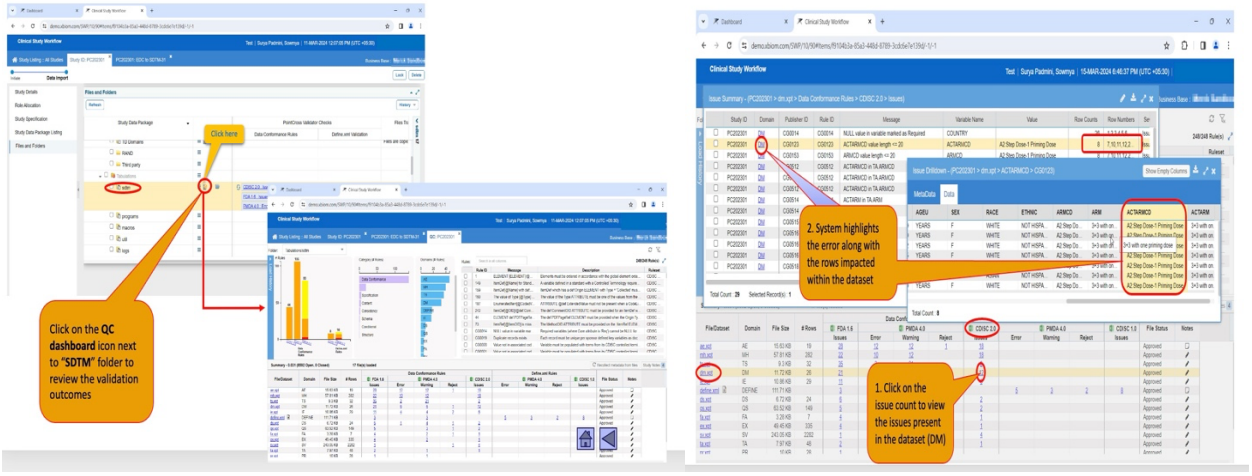

Figure 7: Xbiom eData Validator (eDV)

6. Xbiom's In-Built Compliance and Validation Engine (eDV)

Xbiom MDR features an advanced in-built compliance and validation engine, known as **eDV (Electronic Data Validator)**, designed to ensure metadata accuracy, CDISC compliance, and regulatory submission readiness. By automating real-time validation checks, eDV significantly reduces errors, improves data integrity, and accelerates study timelines. eDataValidator is entirely custodial, allowing the Sponsor user to validate and re-run quality checks any number of times in order to support a quality dataset build. With over 10,000 studies run on eDV by Sponsors, CROs, and regulatory agencies, eDV is a trusted and widely used validation tool.

Key Capabilities of Xbiom eDV:

a) **Automated Metadata Compliance Validation**
- Runs compliance checks against metadata standards, ensuring CRFs, controlled terminologies, and datasets follow sponsor-defined and industry standards.
- Detects inconsistencies and missing metadata elements, preventing downstream errors.
- Supports version-controlled metadata validation, ensuring alignment with evolving standards.

b) **CDISC SDTM and ADaM Validation**
- Automated checks for SDTM and ADaM datasets, ensuring compliance with CDISC standards.
- Validates domain structures, controlled terminology usage, and dataset relationships.
- Ensures traceability from raw data to SDTM and ADaM, supporting seamless data standardization.

c) **Define-XML and Submission Readiness**
- Validates Define-XML against CDISC and regulatory submission standards.
- Ensures proper dataset metadata definitions, annotations, and controlled vocabulary adherence.
- Identifies potential FDA and PMDA submission errors before finalizing datasets.

d) **Regulatory Compliance & Real-Time Auditing**
   - Runs regulatory validation rules required for FDA, PMDA, and global submissions.
   - Provides detailed compliance reports with error classifications, enabling quick issue resolution.
   - Maintains audit trails for all validation results, ensuring full regulatory traceability.

e) **Integrated with Data Workflows**
   - Seamlessly integrates with Xbiom MDR's metadata, SDTM mappings, and study datasets.
   - Real-time validation execution ensures continuous compliance monitoring throughout the study lifecycle.
   - Supports custom rule configurations, allowing sponsors to define study-specific validation rules.

Business and Operational Benefits of eDV:

* **Ensures Submission-Ready Datasets** – Identifies and resolves compliance issues before regulatory submission.
* **Reduces Manual Validation Efforts** – Automates metadata, SDTM, and Define-XML compliance checks.
* **Improves Data Integrity** – Ensures consistent, high-quality datasets, reducing risks of submission rejection.
* **Accelerates Study Timelines** – Early compliance detection prevents last-minute delays in regulatory approvals.

With eDV, Xbiom MDR provides a robust, automated, and intelligent validation framework, ensuring that clinical trial data is accurate, compliant, and regulatory-ready.

CONCLUSION

Xbiom MDR is a comprehensive, metadata-driven solution designed to transform clinical data management by automating CRF creation, data standardization, and regulatory compliance. By providing a centralized metadata repository, Xbiom MDR ensures consistency, traceability, and compliance across clinical trials while reducing manual efforts and operational inefficiencies.

With seamless integrations into EDC systems, SDTM and ADaM workflows, and statistical computing environments, Xbiom MDR simplifies study setup and metadata management. Its in-built compliance engine, eDV, further enhances data integrity by automating CDISC, Define-XML, and regulatory validation checks, ensuring submission-ready datasets for FDA, EMA, and PMDA.

By automating metadata workflows, enabling real-time validation, and supporting global regulatory standards, Xbiom MDR accelerates study timelines, reduces costs, and enhances data quality. As clinical trials become increasingly complex, Xbiom MDR provides a scalable, secure, and intelligent solution that empowers sponsors and CROs to achieve faster, more efficient, and compliant clinical trials.

CONTACT INFORMATION

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