

Enhancing Clinical Trial Management with Automated Data Integration and Real-Time Analytics

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- **Background and Rationale**
- **Project Goal**
- **Use Case Identification**
- **Key Stakeholder Needs & Impact**
- **Data Ingestion**
- **Mapping in SAS LSAF**
- **SAS LSAF Process Flow**
- **Examples**
- **Ongoing Challenges in Data Integration**
- **Next Steps**

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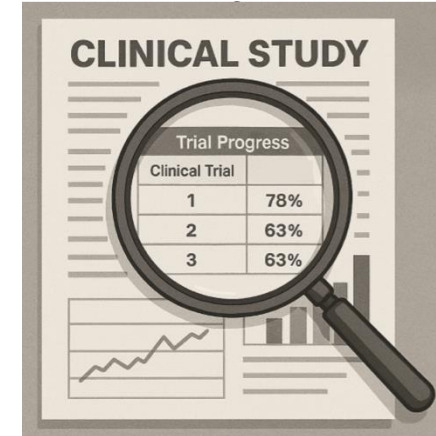


Argenx manages multiple compounds across various development phases, collaborating with several CROs

Key challenge:

Achieving unified, timely oversight of operational performance and trial progress across portfolios

Traditional oversight via CRO Clinical Trial Management Systems (CTMS) resulted in data latency, inconsistencies, and limited interoperability



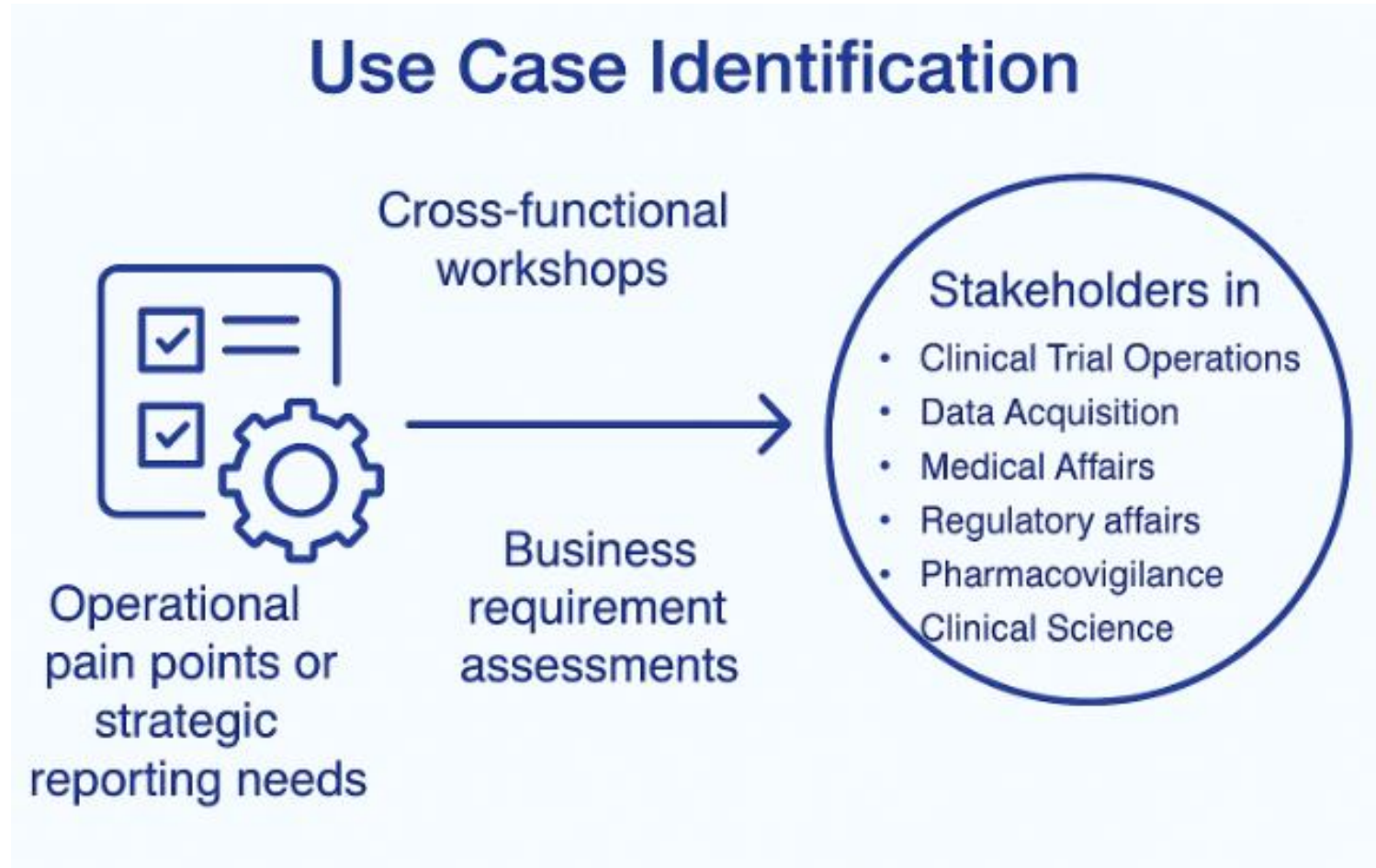
Provide near real-time access to key operational metrics

- study progress
- site activation
- enrollment

Create a standardized, automated data integration pipeline across multiple vendor systems

Automate ingestion of clinical operations data from external vendors





- **Clinical Trial Managers**

- Site activation & milestone tracking
→ Manage risks proactively instead of reactively

- **Medical Monitors**

- Patient safety & deviation alerts
→ Instant visibility into protocol deviations → better patient safety

- **Upper Management**

- Portfolio trends & performance dashboards
→ Real-time portfolio insights for strategic decisions

- **Regulatory Liaisons**

- Use automated reports to ensure compliance with regulatory requirements
→ Automated compliance reporting saves time and reduces risk





Across Study Dashboard

- Provides a cross-trial view of key operational metrics such as site activation, enrollment status, and study milestones
- Data sources. CRO CTMS, SDTM, and manually created Excel files



Recruitment Rate Dashboard

- Visualizes recruitment performance at study, country, and site level
- Compares planned vs. actual enrollment, highlights underperforming regions



Delta PI Report

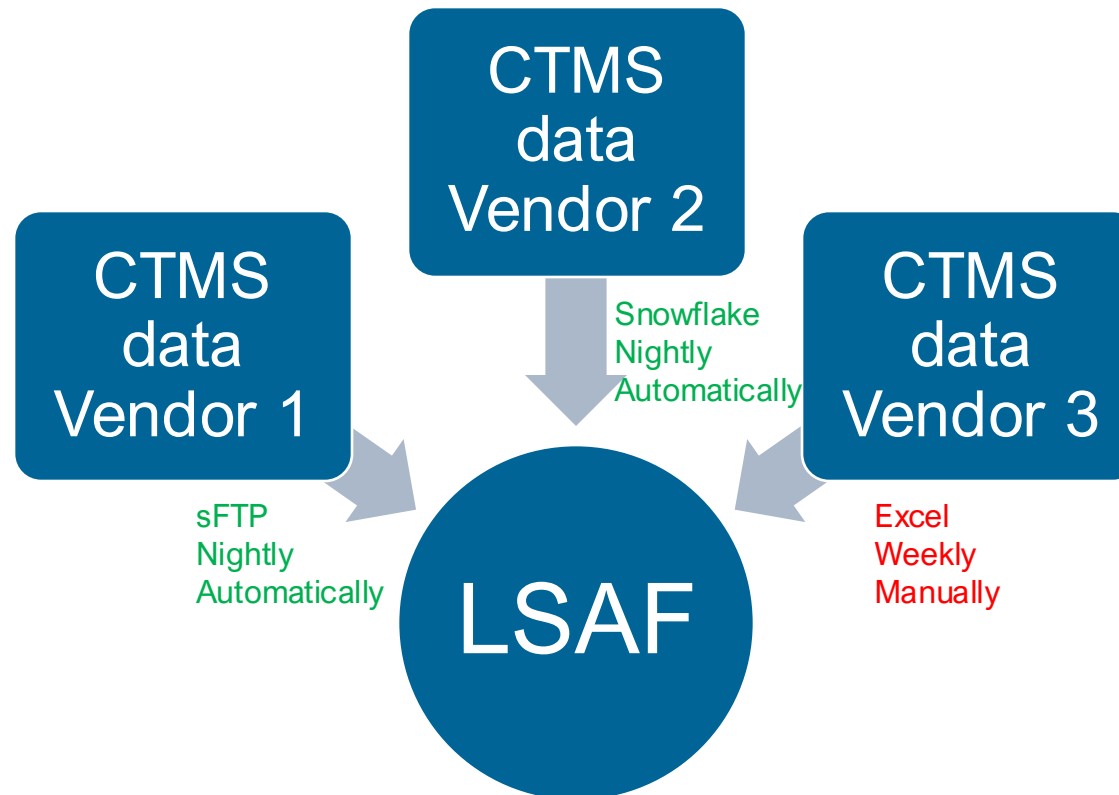
- Supports regulatory compliance with 21 CFR 312 (FDA notification within 30 days of adding new investigators)
- Ensures timely publication of activated sites on ClinicalTrials.gov



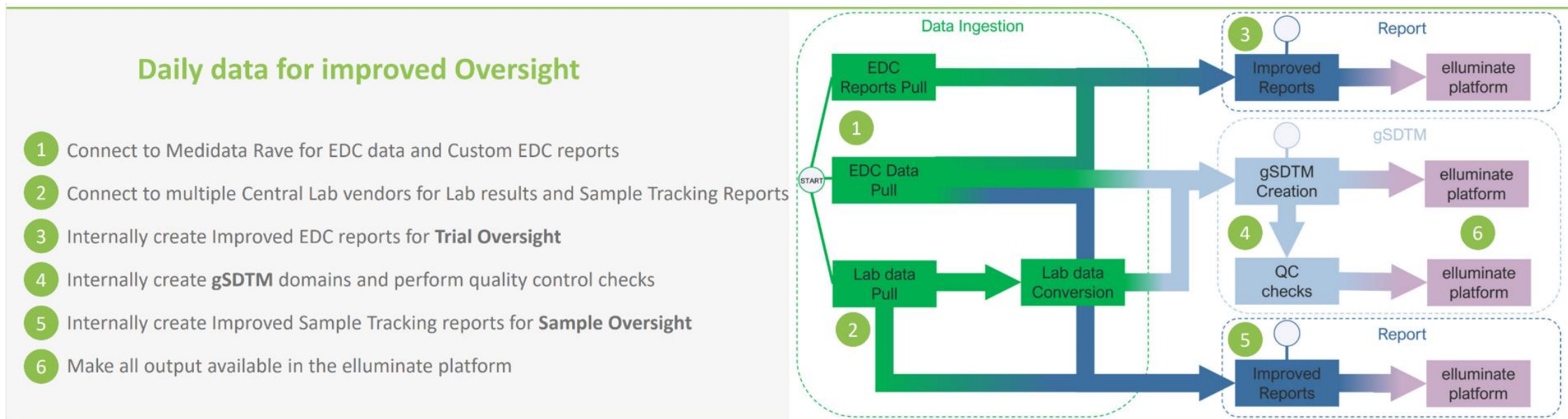
Protocol Deviation Dashboard

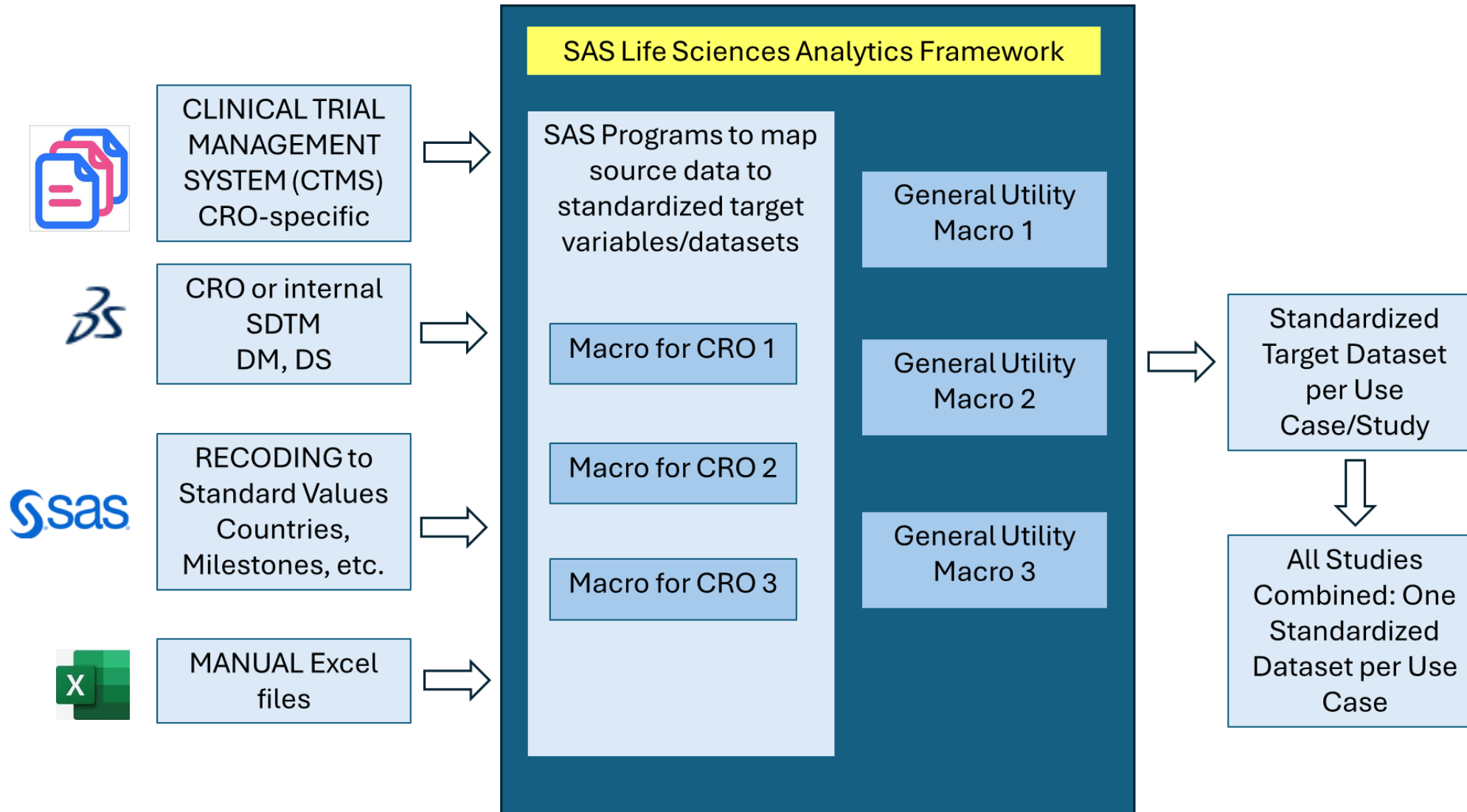
- Visual interface for monitoring subject-level protocol deviations across clinical trials

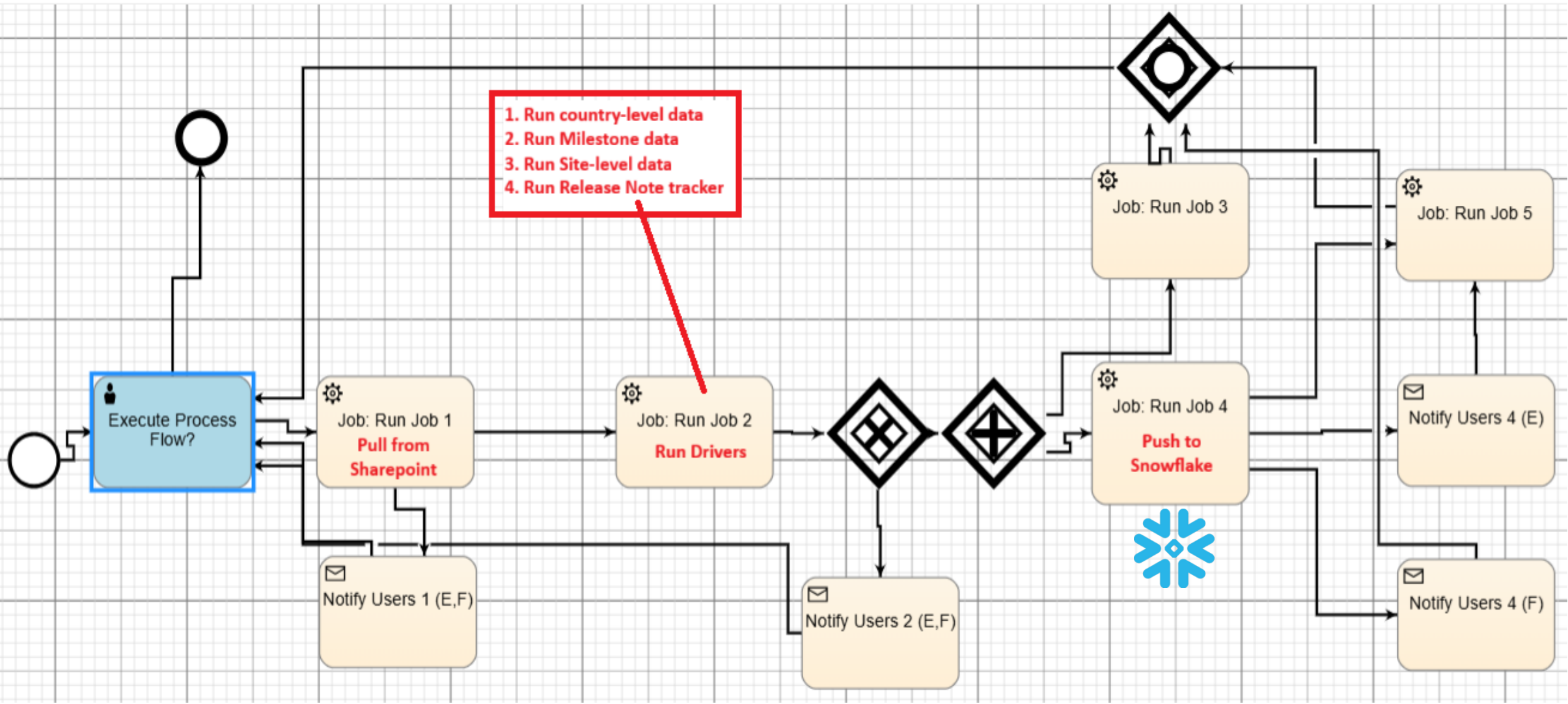
- Each vendor has its own CTMS system
- Developed standardized data mapping framework within the SAS Life Science Analytics Framework (LSAF)
- Automated daily data sharing via sFTP or snowflake



- Near Real-Time Data Flow
- Pulling in nightly RAVE EDC (eCRF) data
- Includes Central Lab Partners
- Automated jobs to create SDTM datasets







Clinical Operations
Across Study Dashboard

Study

(All)

Study Product

All

Compound

All

Indication

(All)

Study Status

(All)

Study Phase

(All)

Masking

(All)

Country

(All)

Principal Investigator

(All)

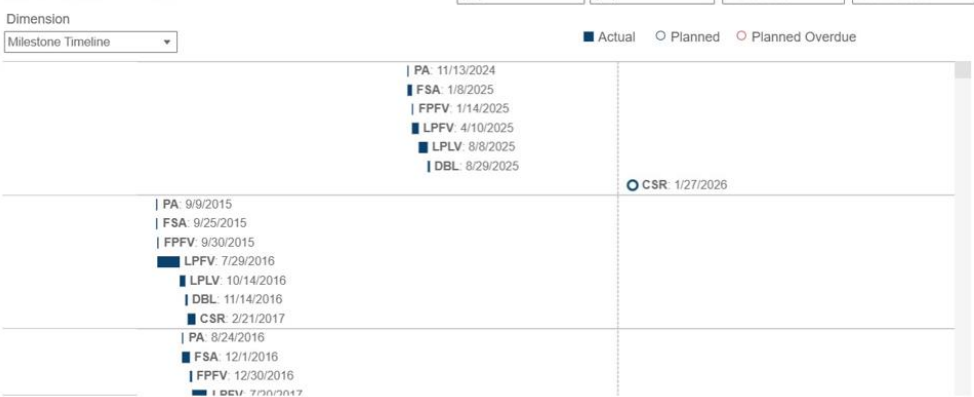
Reset filters

Study: All | Study Product: All | Compound: All | Indication: All | Study Status: All | Study Phase: All | Masking: All | Country: All | Principal Investigator: All

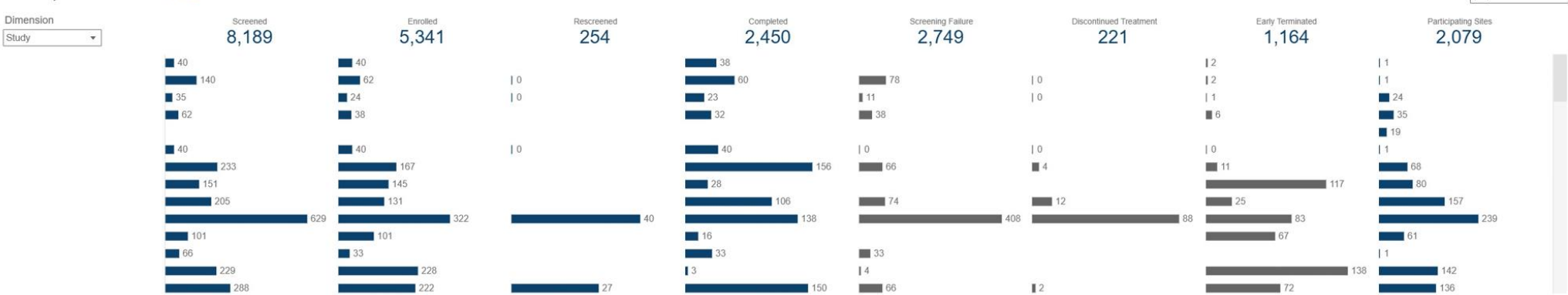
Study Information

Compound	Indication	Study Phase	Study Status	Masking	Enrolment (A/P)	Enrolment %	Last Achieved Milestone
Generalized Myasthenia Gravis (gMG)	Phase III	Completed	Double-blind				CSR
Generalized Myasthenia Gravis (gMG)	Phase II/III	Conduct	Open Label	13/26	50%		FPFV
Generalized Myasthenia Gravis (gMG)	Phase III	Conduct	Open Label	7/18	39%		FPFV
Generalized Myasthenia Gravis (gMG)	Phase II/III	Conduct	Open Label	13/24	54%		FPFV
Generalized Myasthenia Gravis (gMG)	Phase II/III	Conduct	Open Label	69/72	96%		LPLV
Ocular Myasthenia Gravis (Ocular MG)	Phase III	Conduct	Double-blind	93/133	70%		FPFV
Generalized Myasthenia Gravis (gMG)	Phase III	Completed	Open Label	110/76	145%		CSR

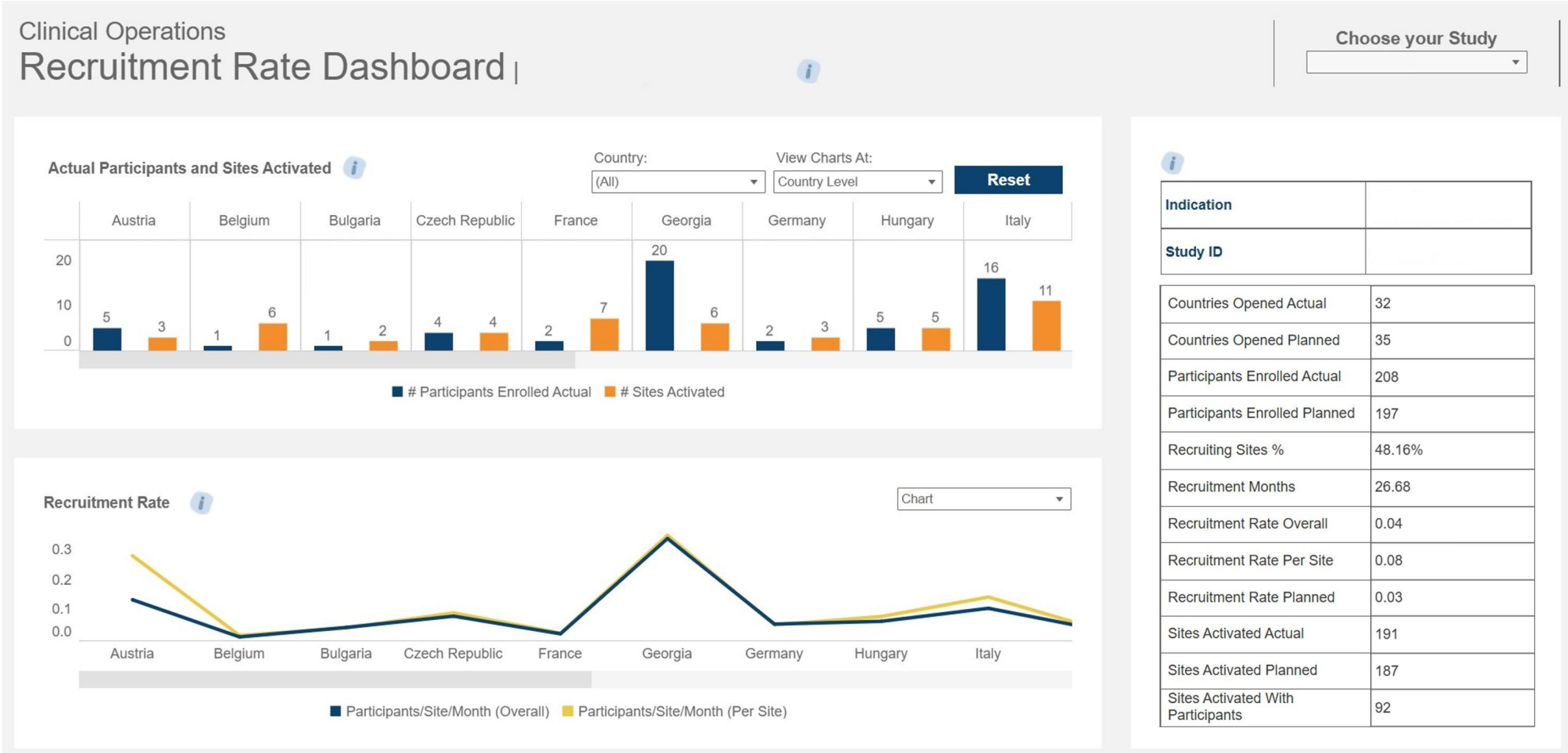
Milestones



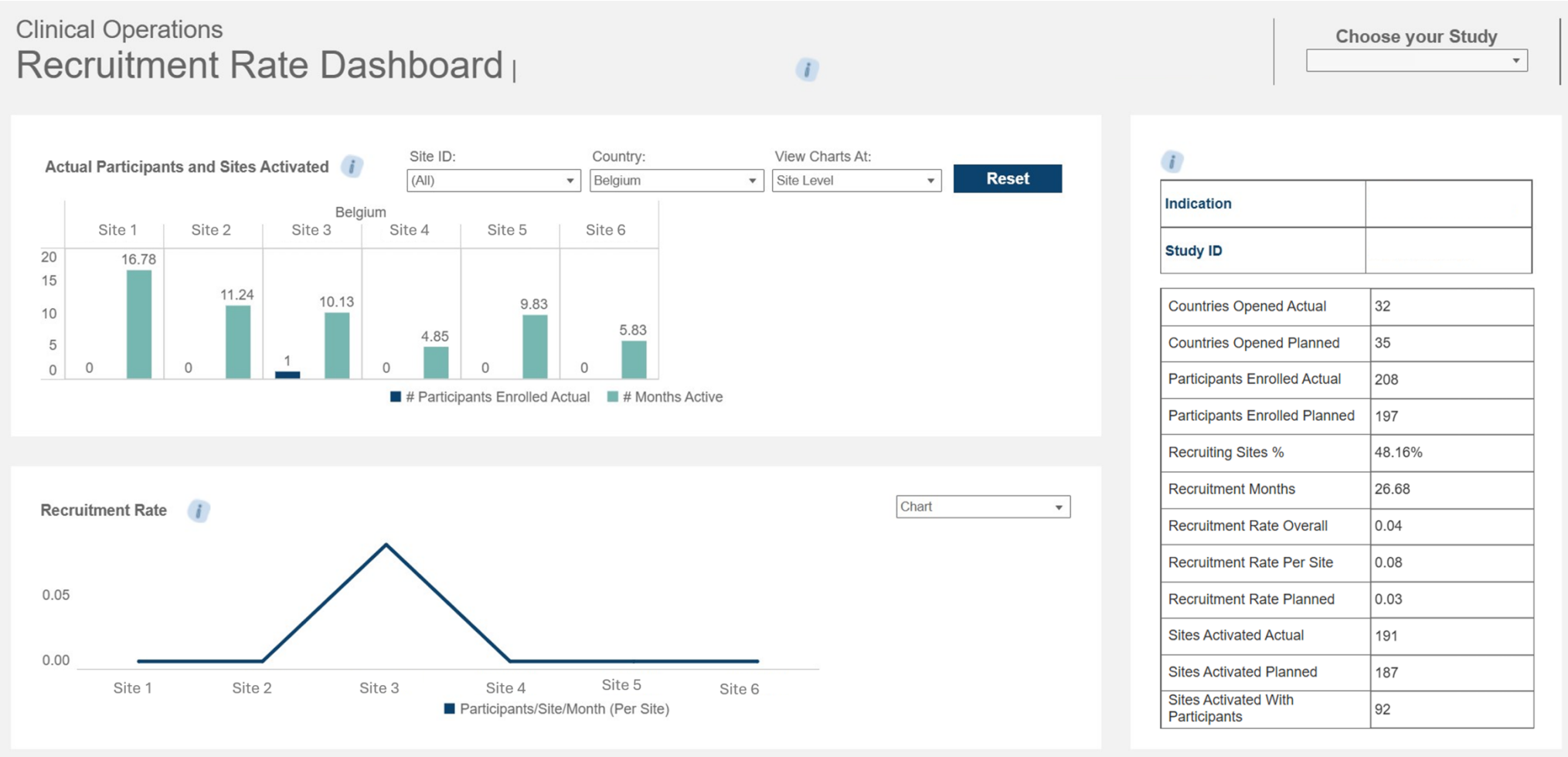
Participant Metrics



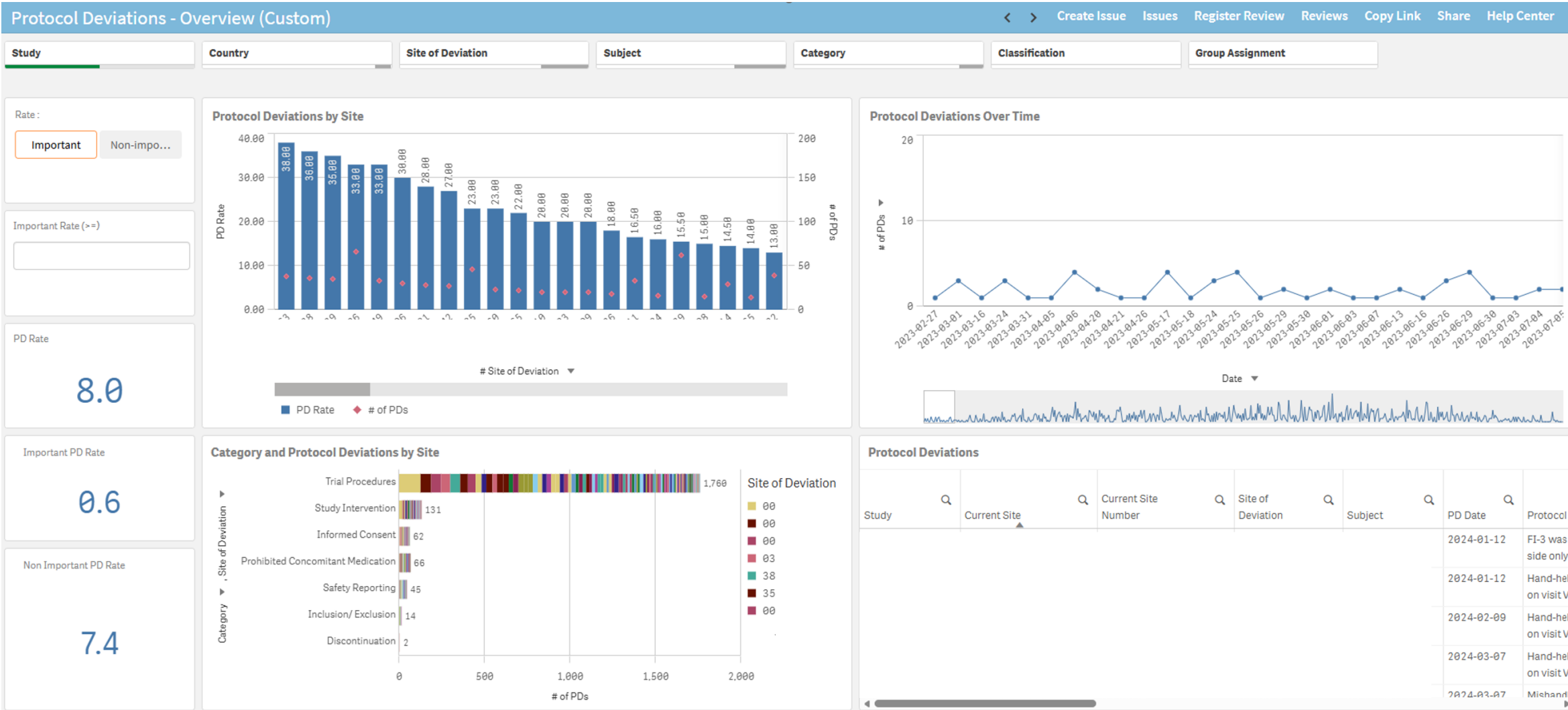
• VISUALIZATION COUNTRY LEVEL



- VISUALIZATION SITE LEVEL



CLINICAL TRIAL OPERATIONAL ANALYTICS MODULE OF ELLUMINATE



- **Vendor Data Variability**

- CROs differ in data formats, naming conventions, update frequency
- Requires study-specific mapping and continuous vendor engagement

- **Legacy Studies**

- No automated CTMS feeds → reliance on CRO SDTM datasets
- Inconsistencies in Disposition (DS) domain across studies

- **Early Startup Phase**

- Sites activated but participant-level data missing
- Leads to incomplete dashboards and delayed insights

- SUBJ_ID
- SUBJID
- USUBJID
- SUBJECT_ID
- SUBJECTID
- PATIENT_ID
- PATIENTID
- PATIENTIDENTIFIER
- PT_ID
- PTNUM
- PTNUMBER
- PATNUM
- PATIENTNUMBER
- SUBJNUM
- SUBJECTNUMBER

- **Strengthen CRO Collaboration**

- Align on data standards and structured CTMS feeds.
- Reduce reliance on manual Excel submissions.

- **New Use Cases**

- Scope and develop future dashboards within Operational Insights.

- **Collaborate on industry-wide standards?**





- **Operational Insights = Modernization**

- Automation, standardization, and real-time analytics.

- **Unified Analytics Framework**

- Integrated data from diverse vendor systems.

- **Impact**

- Scalable, near real-time visibility across 70+ studies.
- Faster, data-driven decisions → improved efficiency, quality, and compliance.

Questions?

