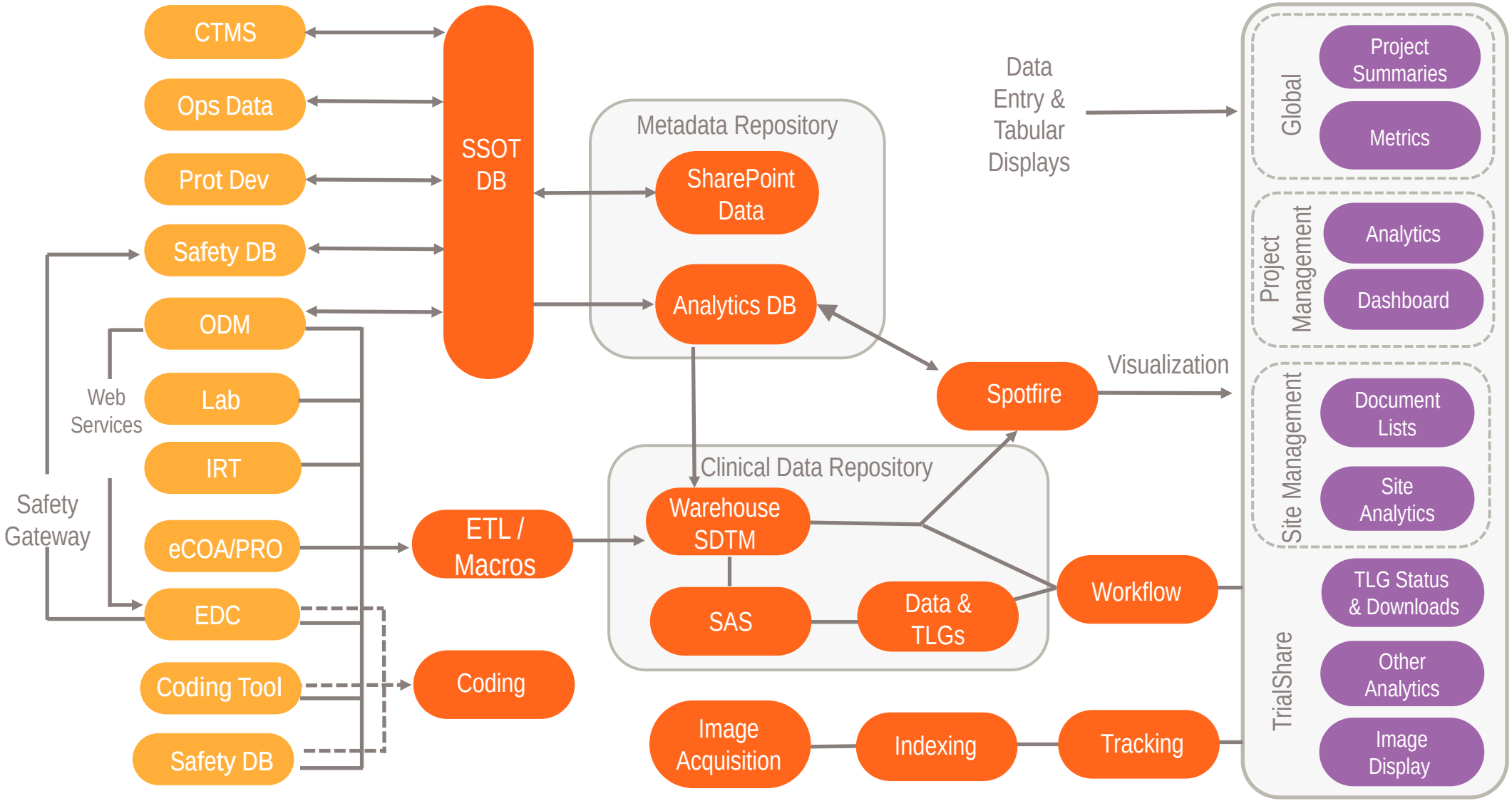
Strategies for Managing Your Data to Support RBM Workflow

PhUSE Single Day Event
Deerfield, IL
July 21, 2016

Discussion Items

- Managing through different requirements from functional areas
- Tracking status of the data for data monitoring
- Dealing with anomalies
- Determining Key Risk Indicators (KRI) based on risks or the availability of data
- Methods of stacking multiple studies to allow for risk detection across a study portfolio

Data Flow Map



What's the Status of My Data?

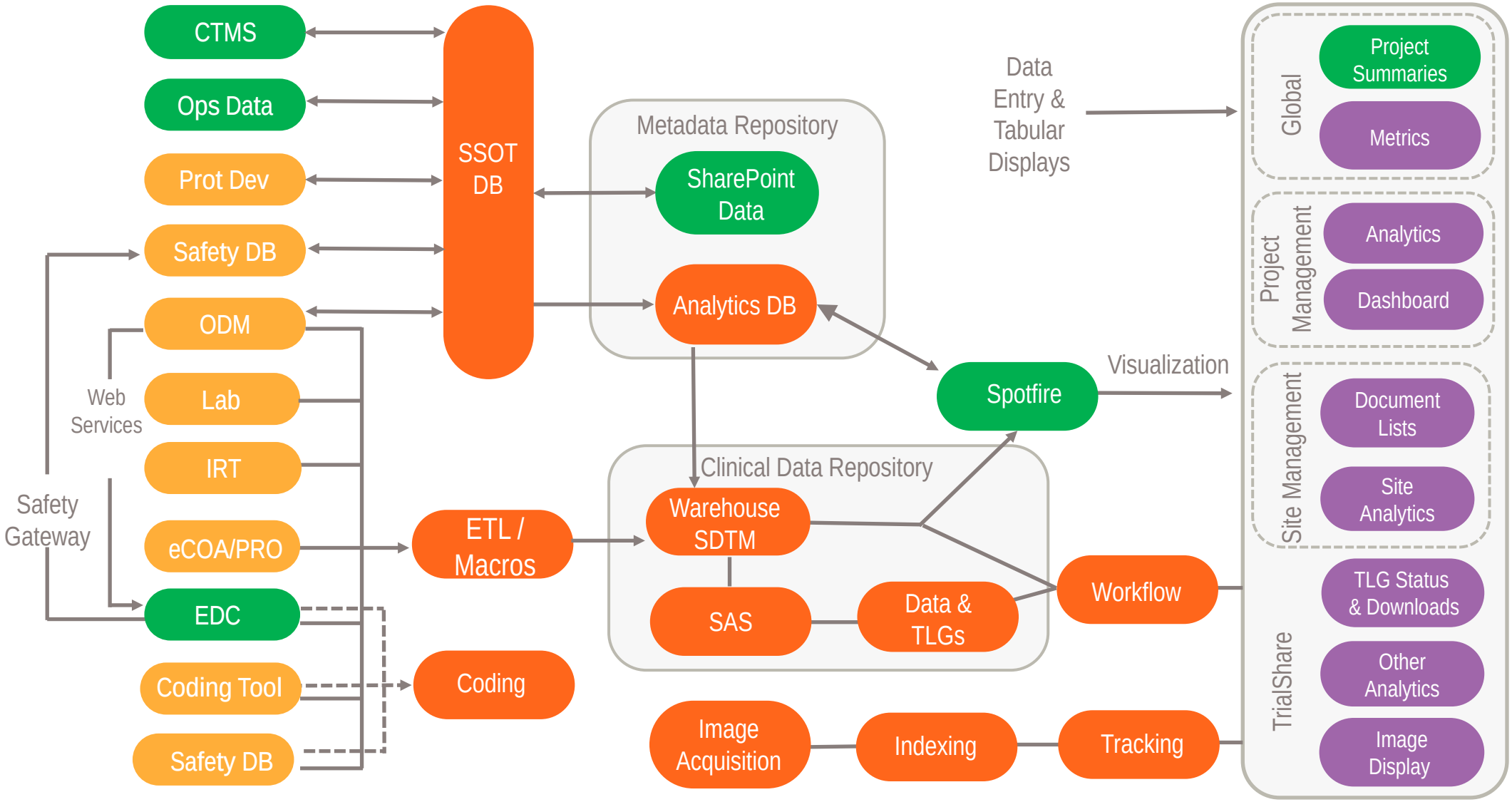
Considerations

- Measuring site performance on partial reviewed data
- Medical and statistical monitoring on unprocessed data
  - Coding
  - Non-EDC captured data
  - Missing data

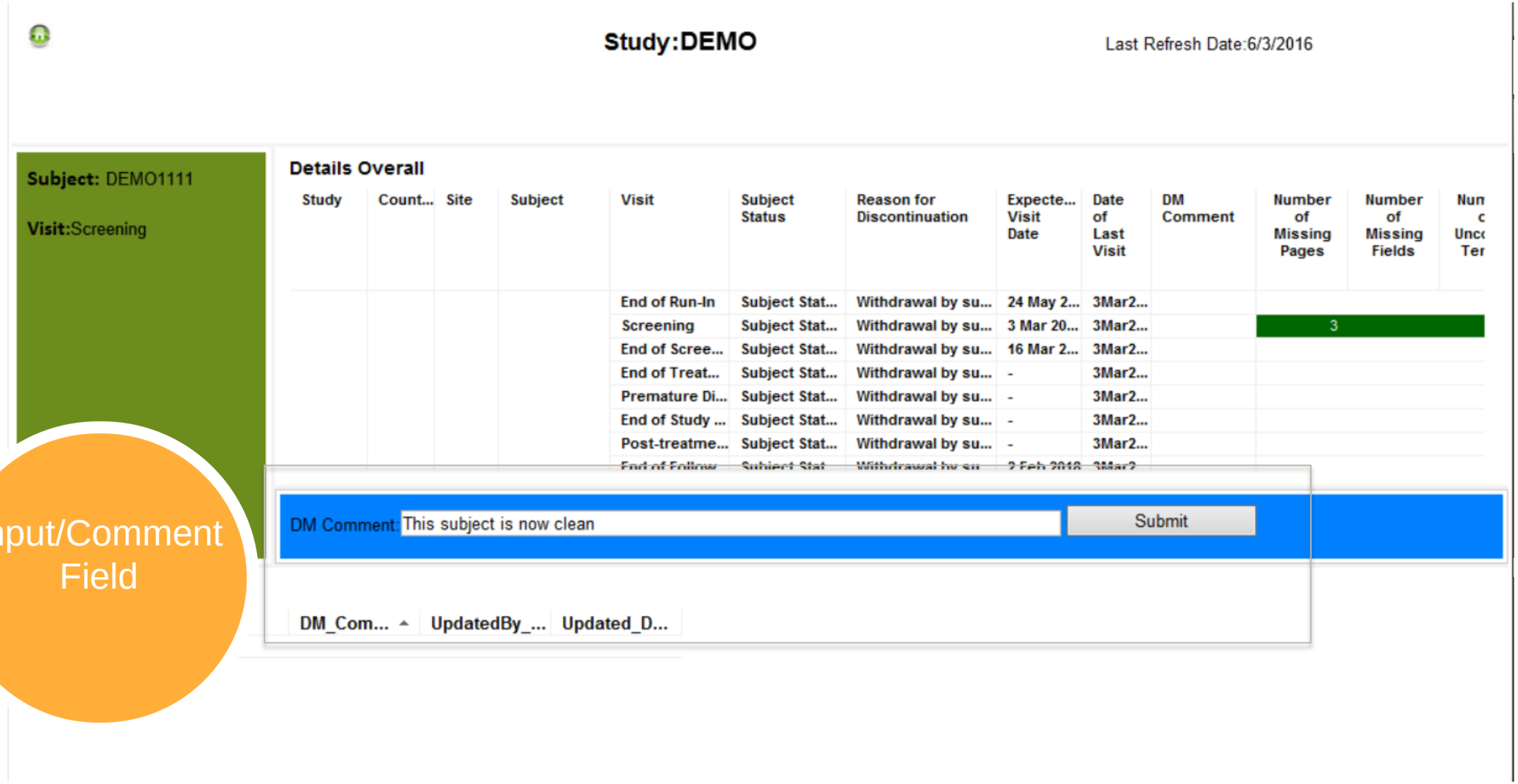
Status tracking requirements

- Data acquisition
- Data management processing
- Workflow status
- Relational structure

Data Flow Map: Data Status

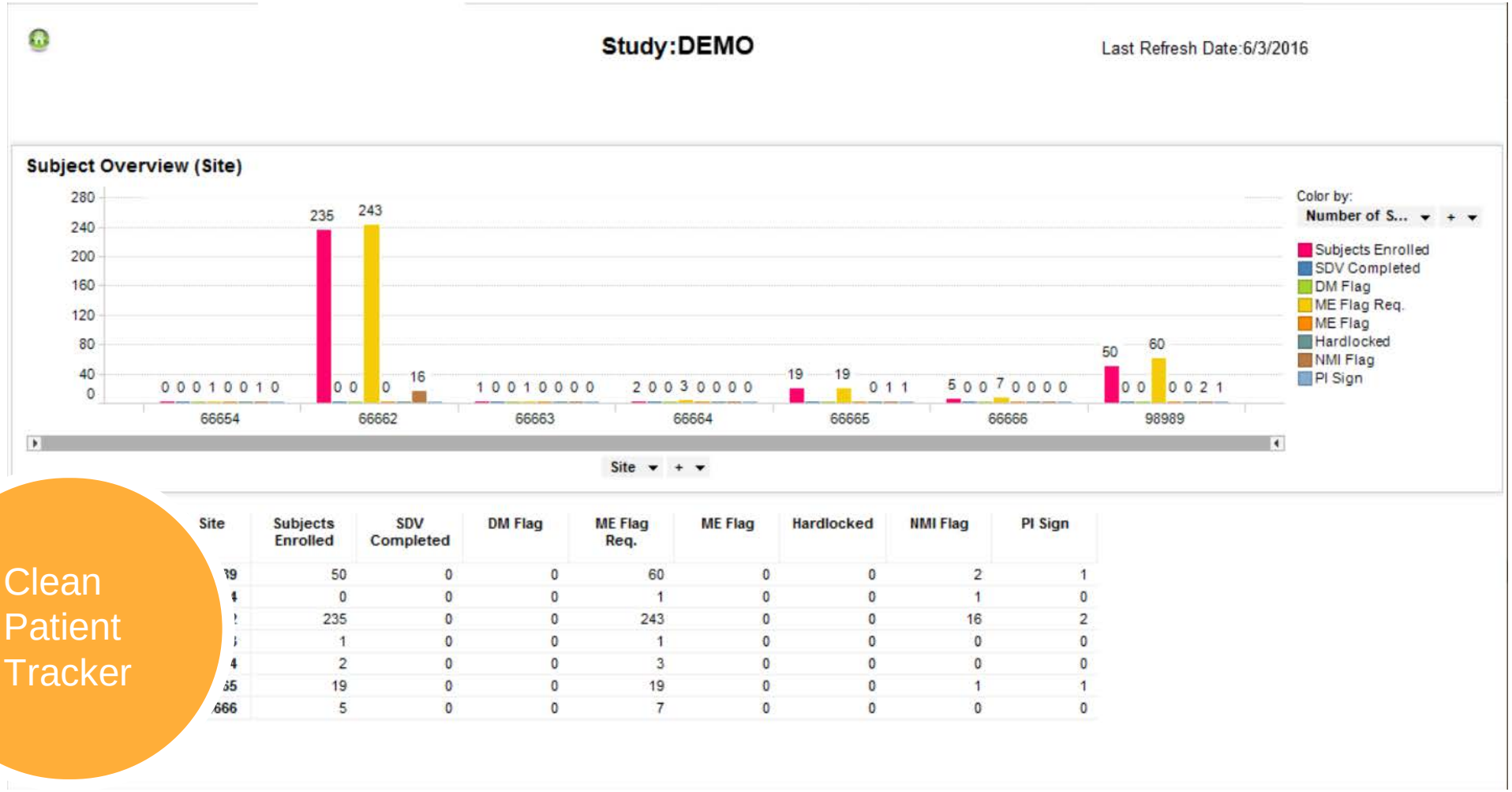


Data Review Status and Issue Management



Input/Comment Field

Visual Analytics of Patient Status



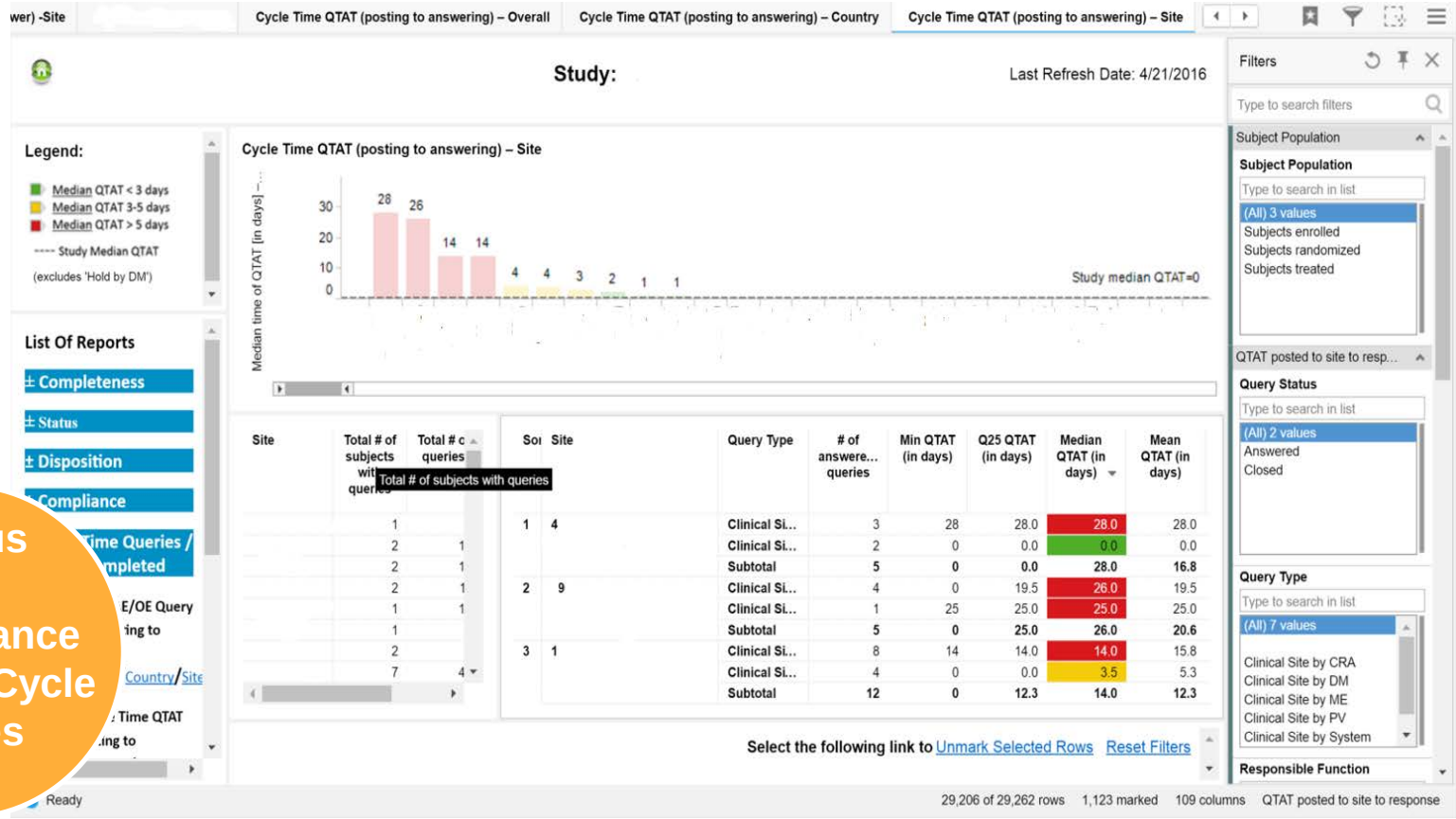
Site	Subjects Enrolled	SDV Completed	DM Flag	ME Flag Req.	ME Flag	Hardlocked	NMI Flag	PI Sign
19	50	0	0	60	0	0	2	1
4	0	0	0	1	0	0	1	0
!	235	0	0	243	0	0	16	2
)	1	0	0	1	0	0	0	0
4	2	0	0	3	0	0	0	0
65	19	0	0	19	0	0	1	1
666	5	0	0	7	0	0	0	0

Clean Patient Tracker

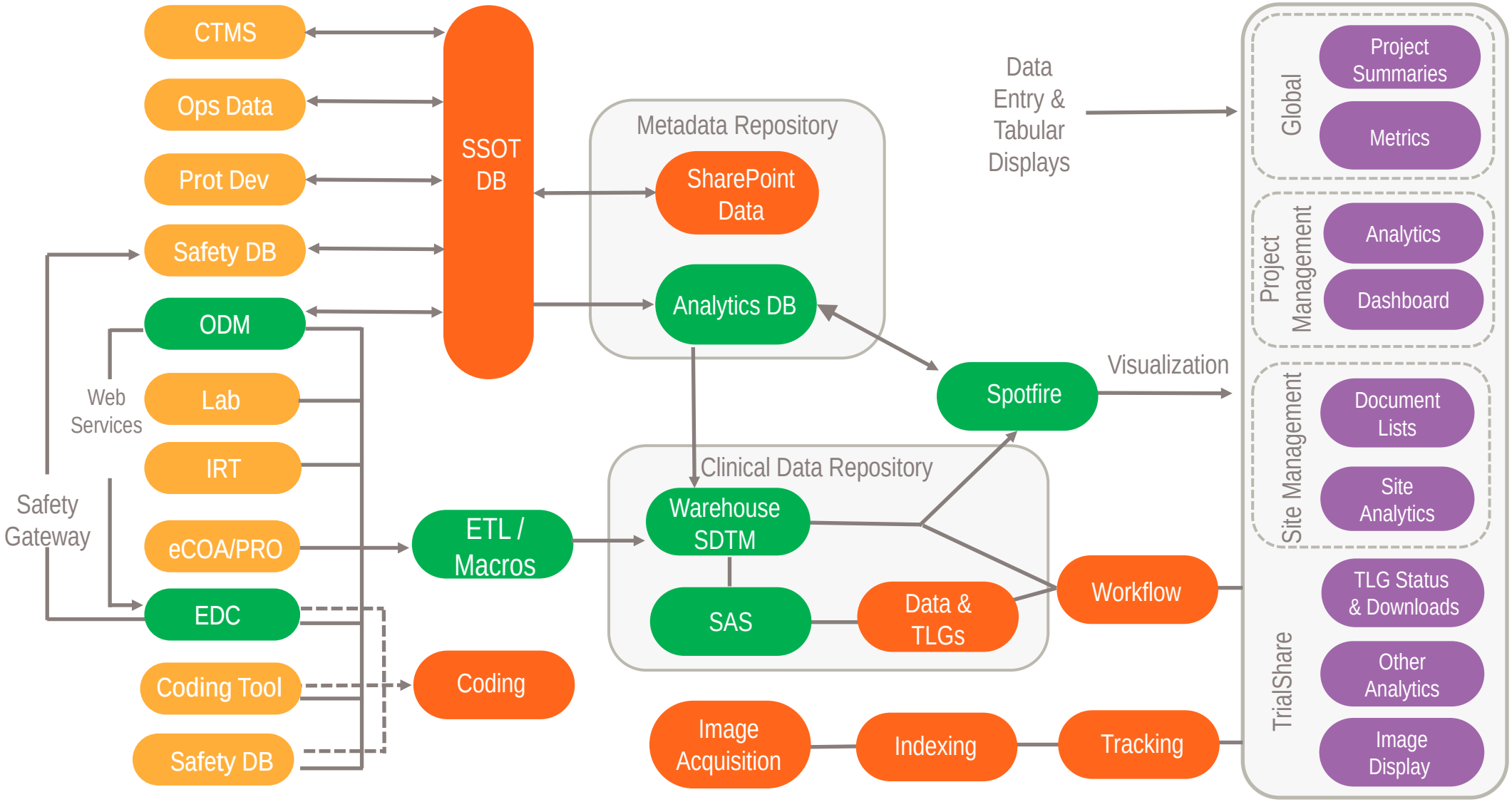
Anomalies in the Data

- Metadata scenarios that skew the data
  - Re-queries
  - Activating & re-activating pages
- Skillsets to resolve the issue
  - Business Analyst
  - Data Scientist
- How to manage
  - Build into data marts
  - Program hard code
  - UI to analytics database
  - Leave it as is

Status and Compliance - Query Cycle Times

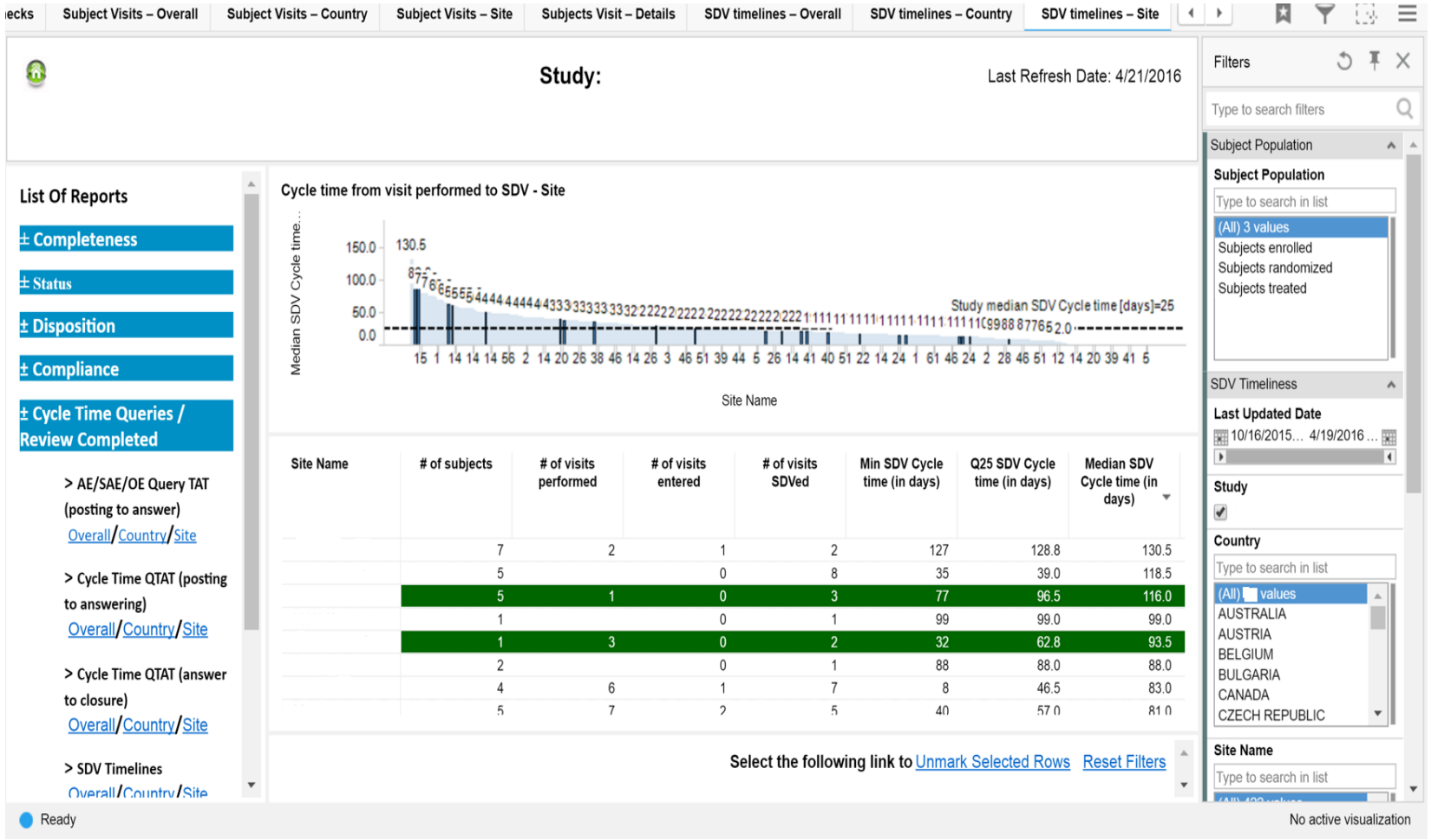


Data Flow Map: Anomalies

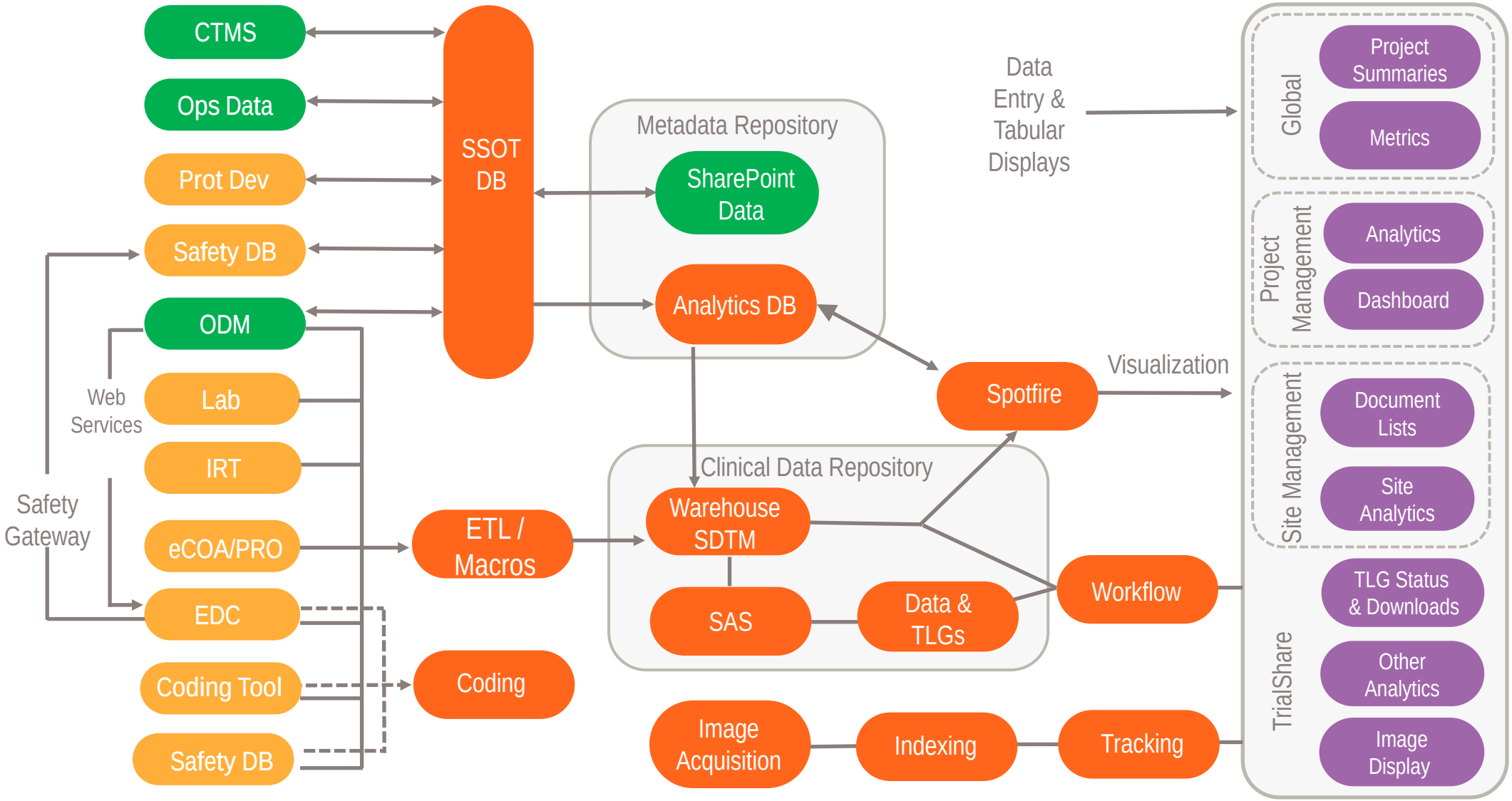


Reporting on Key Risk Indicators

- Highest Risk vs Measureable Data Availability?
- Case Example:
  - Source Document Verification (SDV) vs. Source Document Review (SDR)
- What is the best indicator of site backlog when SDV is reduced?
- Where do you collect and manage SDR requirements?

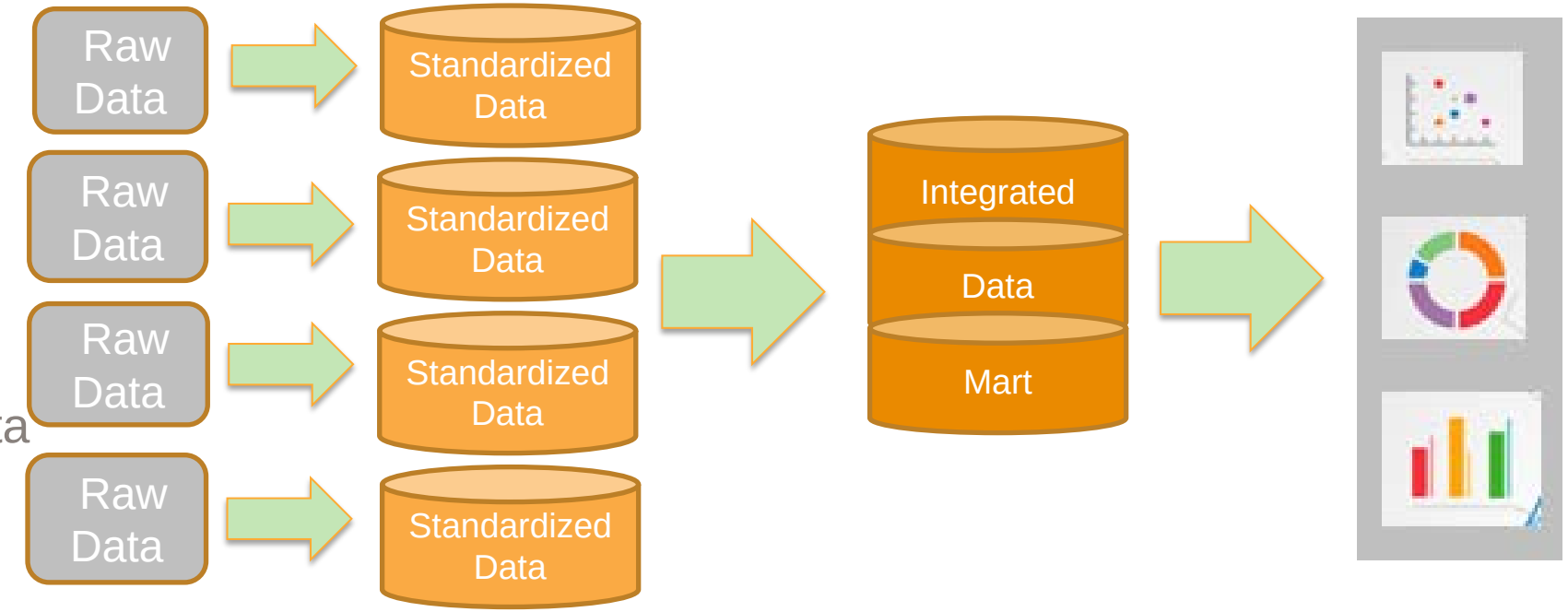


Data Flow Map: Key Risk Indicator Data Availability

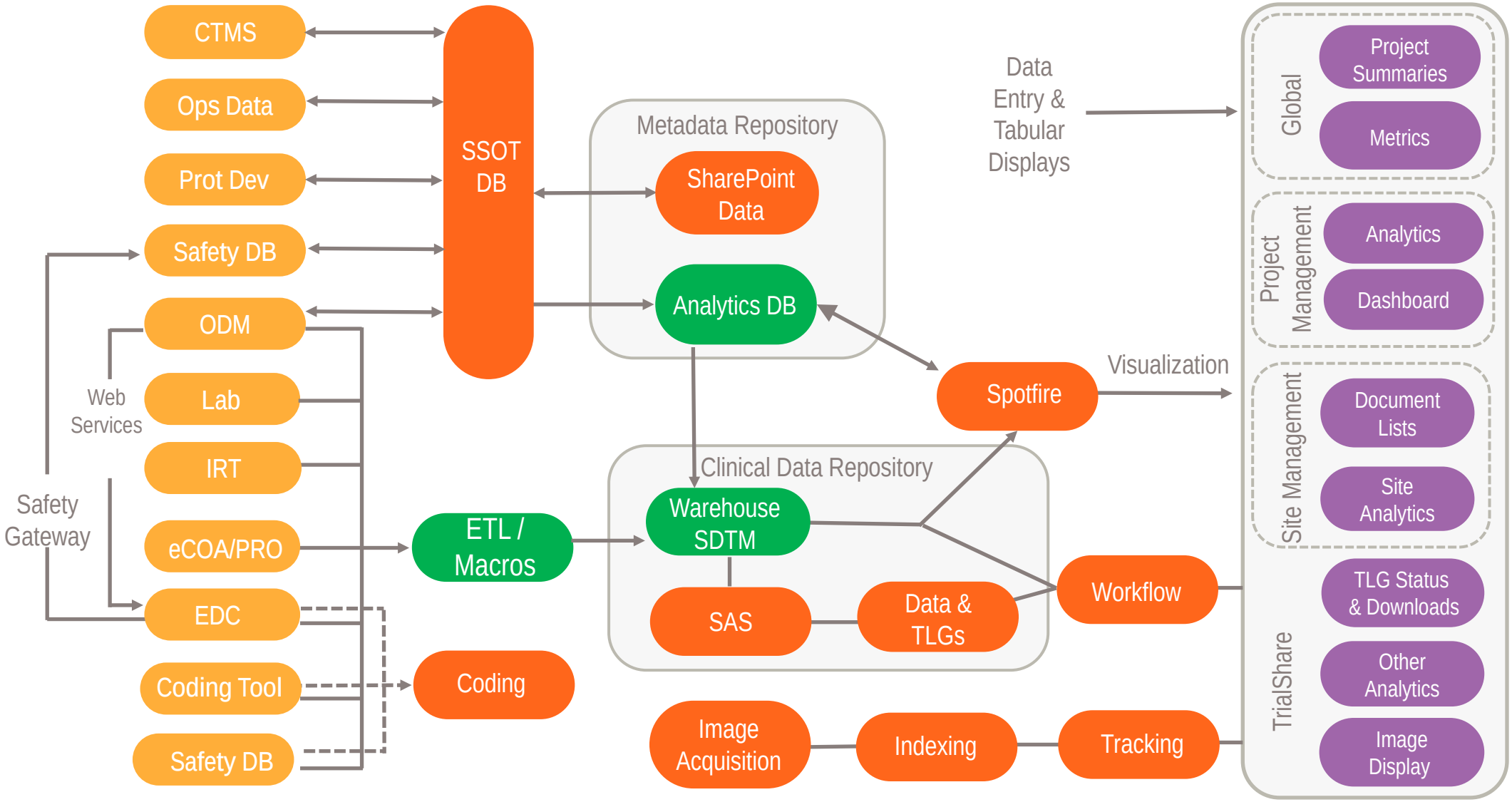


Data Mart Implementation

- Multi-Study Data Monitoring
  - Signal Detection
  - Historical Metadata Analysis
- Standardized Data
  - SDTM or Custom
  - Linking operational data



Data Flow Map: Portfolio Building



Conclusions

- Centralized monitoring requires the status of the data to be in a relational structure
- Access to technology and availability of data factor in data strategy decisions
- Scalable solutions will evolve as the process matures