



THE CHALLENGE

A client was suffering from the use of inconsistent terminology, definitions, and operational terms across functions and systems within Clinical Operations. To make matters worse, clear sources of truth had not been established for all data points. Thus, compiling and reporting on operational data was a manual, error-prone and time-consuming process due to the need to reconcile data from multiple sources.

HOW PHARMICA HELPED

Pharmica knows that data definition, quality, and consistency are foundational to process optimization and system usage. As part of the project, Pharmica established standard operational terminology, definitions, and business rules, and identified the client's official "sources of truth". Pharmica also created an operational study data governance model, including data stewardship facilitating higher data quality, consistency, and common vernacular within the client organization. Lastly, Pharmica developed the implementation plan for an MDM solution to master site and investigator records across clinical systems.

LASTING RESULTS & RELATIONSHIPS

The client now has a clear and concise picture of its organization, with no more "language barrier" between systems or functions. Terminology, definitions, and use of operational terms are woven into key documents such as SOPs. Now dashboards and reports can be created without a laborious manual process, saving the client hundreds of thousands of dollars each year going forward.

Approach

Reference Data and Operational Terms/Definitions

- Built Inventory of LOVs & identified system interdependencies
- Consulted business SMEs to standardize reference and definitions across systems and business areas
- Engaged management to manage stakeholders impacted by definition change

Master Data Management

- Identify key domains based on business pain points and opportunities
- Performed CRUD (Create, Read, Update, Delete) analysis to identify conflicts across in-scope systems
- Identified and selected MDM option (solutions and technologies)
- Integrated MDM solution (Analyze, Design, Conceptualize)

Data Governance

- Defined, approved and communicated data strategies, policies, standards, architecture, procedures, and metrics
- Tracked and enforced conformance to data policies, standards, architecture, and procedures