

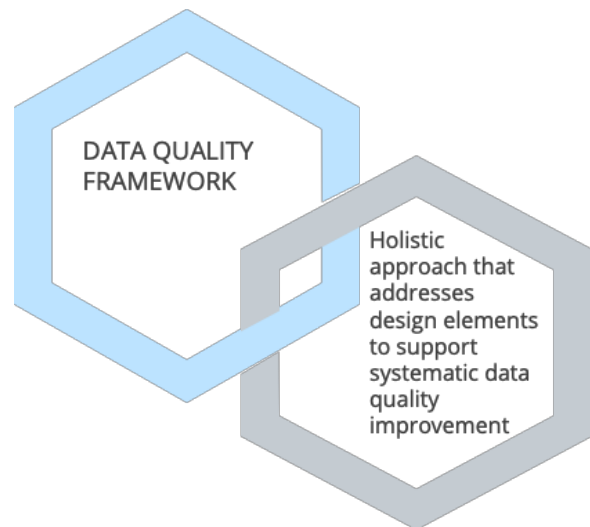
A Data Quality Framework: Path to Trusted Data for Optimal Decision-Making

INTRODUCTION

Pharmaceutical companies face challenges as the pace, volume and complexity of R&D increases. Correspondingly, data volumes grow, data quality challenges become more acute, and the ability to make timely and informed decisions is compromised. Critical business questions such as “which studies have met their enrollment targets within the past month?” and “what is the genealogy of this drug product?” often require substantial staff effort to answer.

Manually identifying, gathering, interpreting, cleansing, verifying and integrating data requires significant time and labor investments. Compounding this, those efforts must often be repeated each time these questions are asked.

The flow of data through an R&D organization is complex and involves many internal and external data producers and information consumers. Data traverses many functional areas, disparate systems, enrichments, and transformations before being used by the ultimate information consumer.



Situations exist where data among systems are not in agreement, leading to questions about data integrity. Lack of authoritative sources, master data, and common business vocabularies results in different interpretations of the data creating additional uncertainty.

What can an organization do to meet these challenges, have higher quality data and make better decisions? Implement a Data Quality Framework. It offers a holistic approach that addresses the multiple organizational design elements required to support the goal of systematic data quality improvement across the organization.

A Data Quality Framework has the following five elements: Process, Organization, Governance, Technology, and Culture.



PROCESS

The process component provides a consistent, repeatable, best practice approach for data quality projects. The approach consists of: Assess, Plan, Design and Implement, and Measure and Control activities as shown in the figure below.

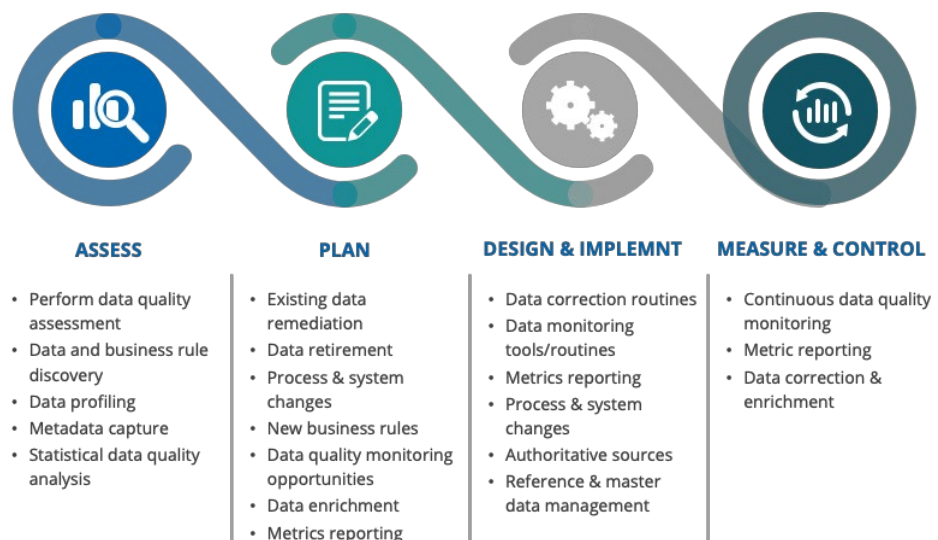
Assess is focused on a data quality analysis, data and business rule discovery, data profiling, metadata capture and statistical data quality analysis.

Plan activities include the

following: remediation of existing data, planning for retirement of data no longer needed, identification of required process and system changes, creation of new business rules, identification of data quality monitoring opportunities, data enrichment needs, and metrics definition.

Design and Implement takes outputs from the Plan activity and puts them into action. The emphasis here is on data correction routines, data monitoring routines, specifying metrics reporting, developing process and system changes, authoritative sources and reference and master data management.

Measure and Control activities put the necessary foundations in place to ensure the Data Quality Framework delivers benefit and can be sustained over time. It establishes continuous data quality monitoring, periodic



metric reporting and data correction and enrichment sustaining activities.

ORGANIZATION

The Organization element focuses on organizational design and roles within the Data Quality Framework. Structure, team membership, team charters, and roles and responsibilities need to be defined for those involved in data quality activities. Data quality teams are formed, and data quality subject matter experts are identified in key technical areas to address data quality, master data management, metadata management, and controlled vocabularies.

GOVERNANCE

Governance evaluates the structures needed to guide the Framework development, implementation and maintenance. Governance structures need to be established to a) enforce business ownership and accountability for data quality, b) set strategic direction, c) set priorities for data quality projects, and d) arbitrate cross-functional data issues that project teams are unable to resolve.

TECHNOLOGY

Technology is selected and standardized to facilitate productivity, repeatability and automation. Tools are needed for a) data discovery and profiling, b) metadata capture and management, c) business and data rule definition, d) data quality monitoring,

e) data correction and enrichment, f) master data management; and g) metrics collection and trending.

CULTURE

Culture is a key component for the success of a Data Quality Framework. Successful data quality initiatives need to be accompanied by an effective change management program aimed at changing the organization's culture to recognize the value of information assets, appreciate the impact of data quality on downstream decision-making and instill business ownership of data and data quality. Implementing a Framework successfully requires a long-term mindset with culture change being a key area of focus.

Successful data quality initiatives need to be accompanied by an effective change management program.

BENEFITS

The overarching goal of an R&D data quality program and the implementation of a Data Quality Framework is to improve data quality such that the organization can implicitly trust its information, allowing it to:

- Reduce the labor burden associated with making data-based decisions by making

it easier to aggregate and reuse data and information for different purposes

- Increase the accuracy of those decisions
- Implement automated processing to support decision making

CONCLUSIONS

A Data Quality Framework is not a “once-and-done” effort. It requires establishing a Framework and then implementing it incrementally. Certain strategic projects should be undertaken to address key areas, such as master data management. Tactical projects are undertaken to address specific areas based on need. Not all of the data and information in a given area of focus can be successfully addressed at the same time – it requires focusing on the critical data and information elements. Similarly, not all business areas and domains can be tackled at the same time. Priorities need to be established and projects should be undertaken as a progression. Successfully implementing a Data Quality Framework is a long-term commitment that will pay significant dividends over time.

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