RESULTWORKS
Transforming Strategy. Delivering Success.

10th ANNIVERSARY

Transformations

RESULTWORKS NEWSLETTER VOLUME 14 ISSUE 1

BUILD A DATA QUALITY FRAMEWORK TO SUPPORT DATA-DRIVEN DECISION-MAKING

Global pharmaceutical companies face challenges as the pace, volume and complexity of R&D increases. Correspondingly, data volumes grow, data quality challenges becomes 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. As shown in Figure 1, the Framework has the following five elements: Process, Organization, Governance, Technology, and Culture.

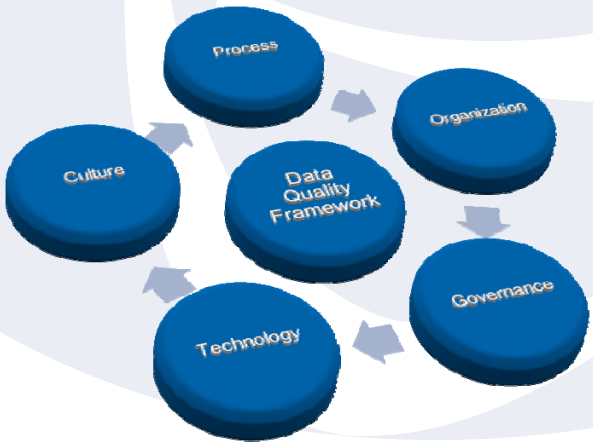
A Data Quality Framework offers a holistic approach to support systematic data quality improvement.

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

(Continued on page 2)

Figure 1: Data Quality Framework



OF SPECIAL INTEREST:

- ***Companies are wrestling with information that comes in varieties and volumes never encountered before***
- ***Successful data quality initiatives need to be accompanied by effective change management***
- ***Develop a strategic vision for an ELN to optimize R&D workflow***
- ***A layered technical architecture enables information exchange***

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DATA QUALITY FRAMEWORK (CONTINUED FROM PAGE 1)

and Control activities as shown in Figure 2. 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 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.

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

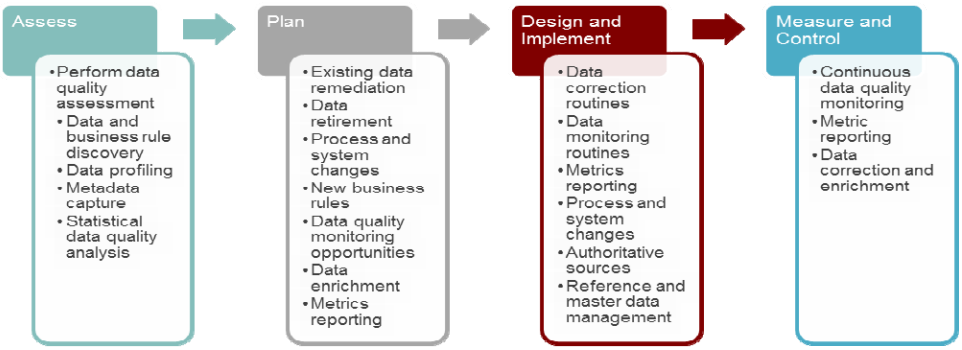
Governance

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.

Figure 2: Process Element of Data Quality Framework



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.

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.

DATA SCIENTISTS ARE ALREADY AT WORK

In a recent Harvard Business Review (HBR) article entitled *"Data Scientist: The Sexiest Job of the 21st Century"*, Tom Davenport and D.J. Patil describe new roles in business as companies learn to appreciate the wealth of information in their data.

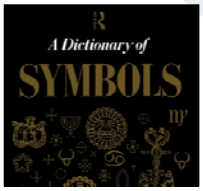
"Data scientists are already working at both start-ups and well-established companies. ...this reflects the fact that companies are now wrestling with information that comes in varieties and volumes never encountered before."
- Davenport & Patil

The article presents a brief case study on the evolution of LinkedIn based on the relationships among people that were derived only as "data scientists" dug into systems. While the thrust of this article leads to "big data" analysis, we certainly see evidence of similar trends at a grass-roots level in Life Sciences.

Life Sciences data and sources of that data continue to expand. The need for integrating and analyzing data continues to accelerate. There should be and in general there is more emphasis on improving data definition, controlled vocabularies, metadata, information structure and architecture, data quality, and governance.

These improvements don't come without emphasis on roles to drive them. Data stewards are emerging more frequently as roles within the business to manage and improve the quality and value of data. Data quality teams are being pulled together on a project-basis to address specific areas of concern or need. Information architects are addressing the structural information issues for long-term success. These "scientific data" roles are all becoming increasingly critical to enabling the knowledge we need from our life sciences data.

"Nothing is meaningless or neutral: everything is significant."



J.E. Cirlot
A Dictionary of Symbols

DEFINING AND SELECTING AN ELN

Many laboratory organizations today are planning their first Electronic Laboratory Notebook (ELN) implementation or an upgrade to an earlier system. Solutions are expected to replace existing departmental systems and in most cases will replace paper notebooks with a searchable repository of R&D information and corporate intellectual property. The ELN promises to save information in legible, searchable form while eliminating the collection, scanning and storage of paper notebooks. Some organizations even eliminate the witnessing process since the ELN system can keep legally defensible records and audit trails showing exactly when information was known and reduced to practice.

Develop a strategic vision of the ELN, how it fits with other informatics systems, and how to use it to optimize R&D workflows.

Whether you are considering a new system or a replacement, this compilation of articles addresses some best practices and pitfalls often encountered by organizations throughout the lifecycle of an ELN implementation.

See full article Best Practices for ELN Implementation.

DELIVERING SUCCESS

Several new ResultStories, ResultWorks' project briefs based on real world successes, have been added recently to our website.

The first of these describes the creation of a Clinical Development IT Strategy for a mid-sized pharmaceutical company. They had expanded rapidly from several hundred to several thousand employees over the course of a few years. They were likewise experiencing a growth in the number and duration of clinical trials being executed. Point informatics solutions and manual processes were proving unscalable for executive management to monitor, control, and effectively manage the portfolio of programs. ResultWorks help was enlisted to design an integrated information management strategy to support the new scale of the business and to deliver the needed management information.

The layered technical architecture design enables information exchange with many different partner types and information integration across R&D.

The second featured ResultStory involves a Technical Architecture for Externalization. As the industry has moved to externalize more functional areas of R&D, one leading pharmaceutical company decided to rethink its associated information management strategy. Processes and information flows that were once second nature were now very different depending on the collaborating external partner and the agreed roles, processes, and information movement required for a contracted work effort. With increasing volume and variety of work – experiments, studies, trials, programs – being externalized, and the number of partners with varying technical capabilities, the increasingly complex information flow was overwhelming. Older systems and infrastructure no longer supported the way the business had evolved, and a new strategy was required. ResultWorks was engaged to develop a new technical architecture strategy bridging the in-house needs with the needs of enterprise collaboration partners.

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NEW SERVICES OFFERINGS

ResultWorks is refocusing our offerings with four key services for Life Sciences as shown in our new graphic in Figure 3. The key value proposition for each service is:

Strategic Innovation - Collaborative strategy development to address emerging trends with an executable path forward.

Integrated Business Analysis - Bridge people, process and technology needs for modernizing operations.

Information Transformation - Versatile information architectures and technologies to accelerate decision making and adaptability .

Knowledge Management - Maximize knowledge assets to assure integrity and to surface intelligent, valuable information.

(See our new website for more information.)

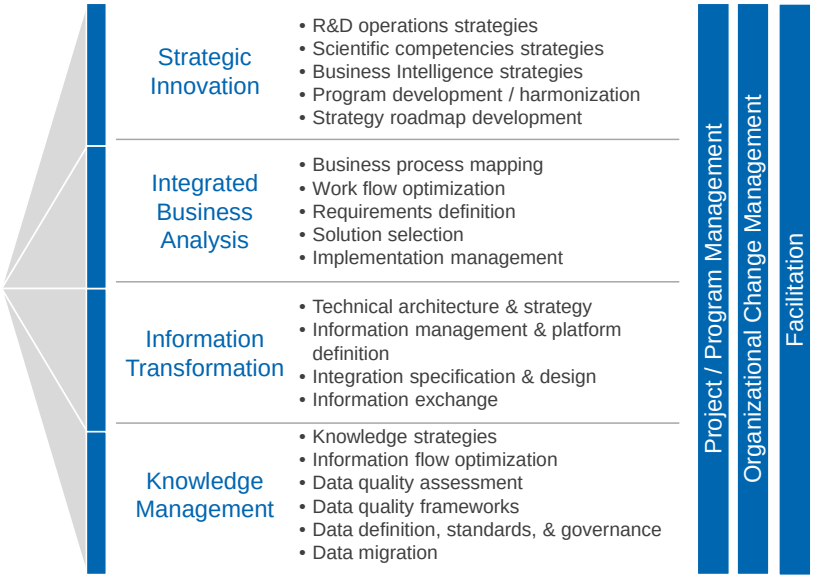

Figure 3: Expertise for R&D, Clinical, Regulatory & Manufacturing

RESULTWORKS NEWS

New ResultWorks Logos:

Three new ResultWorks logos have been introduced. Our traditional logo shows a subtle difference highlighting **RESULT** in blue. The three boomerangs within the oval continue to represent people, process, and technology that are integral to every project we undertake.

Leveraging our traditional logo is the 10 year anniversary logo which is on the front of this issue and which we have been using in our email for several months.

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We have also introduced a new logo for our ResultSessions. Similar to our company logo, the infinity symbol conveys the importance of the current environment while considering the future, and gaining alignment in the organization to make the future happen.

RESULTSESSIONS

New Website:

After 10 years it's time for a makeover. Visit our new website at www.resultworksllc.com.

Follow Us on New LinkedIn Company Page:

http://www.linkedin.com/company/resultworks-llc.

Recent & Upcoming Appearances:

- Society of Laboratory Automation & Screening (SLAS)
- BMS IT Conference in Princeton, NJ
- Bio-IT 2014 Conference in Boston April 29 - May 1—ResultWorks will be delivering two posters at the conference. Be sure to visit.
  - Business Process Analysis enables Clinical Sample Management Collaboration
  - Data Quality Framework: A Path to Trusted Data for Better Decision Making

Current / Recent Client Initiatives:

- Business Analysis for Regulatory Information Management
- Compound Management Strategy
- Biologics Development Scientific Systems Assessment
- Data Quality Assessment for Regulatory
- Pilot of Data Quality Framework in Clinical

ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

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