

Change Management & Model Based Drug Development

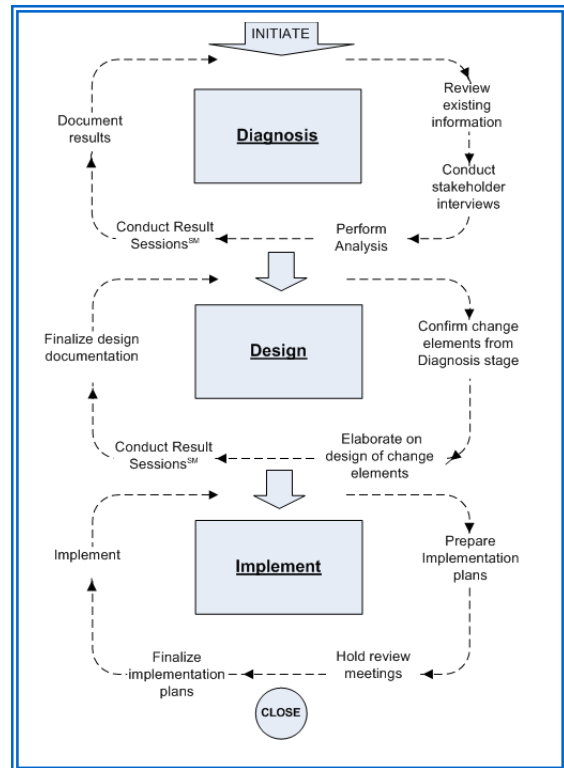
The Situation: The discovery medicine organization of a global pharmaceutical company sought to change their current working practices to embrace a model based drug development (MBDD) paradigm that would encourage quantitative data analysis and use of that analysis to provide support for early go/no-go decisions and future trial design. The organization was functionally siloed both in terms of business process and data integration. In order to achieve the necessary paradigm shift the organization recognized that change would be required across many fronts including changes in mindset and culture, changes to organizational structure and business processes, as well as the development of technical tools and infrastructure to better support access to and analysis of disparate data.

The Solution: ResultWorks followed a Diagnosis . Design . Implement methodology with each phase centered around a series of ResultSessions to focus client stakeholders on the deliverables for that specific segment. Executive buy-in was fostered throughout the process.

In the **Diagnosis** phase of the project ResultWorks senior consultants facilitated the definition of the new vision and the identification of components to address what needs to change and why.

In the **Design** phase ResultWorks managed several work streams through the design of the change elements including:

- Organization: design of new matrix team organization and governance models
- Process: design and agreement of new business processes and business rules (especially in the area of shared data access and changes to who and how data were accessed)
- Culture: development of stakeholder maps, stakeholder communication, change management plans to facilitate organizational buy-in
- Technology: identification of technology projects to support data access, data integration, and visualization activities
- Training: development of a training curriculum and identification of suitable training courses



A comprehensive **Implementation** plan was developed to manage the rollout of the new MBDD approach first to pilot teams and then to full scale production.

Key Benefits of this Project:

Shared Vision: Developed a shared vision regarding why the change was necessary and goals of the changes; successfully communicated the vision; and attained buy-in to the vision

Business Alignment: Achieved alignment on key data access and process issues

Strategy Implementation: ResultWorks facilitation and disciplined methodology delivered well constructed implementation plans resulting in pilot completion within 8 months

For more information, visit our website www.resultworksllc.com or contact us at marketing@resultworksllc.com.