

Clinical Solution Implementation

The Situation: Over the last few years, this global pharmaceutical company has been faced with constrained resources with an increased demand on resources in both the Drug Metabolism and Safety Assessment groups. At the same time, the volume and complexity of assembling data from multiple systems and from multiple departments for initial analysis, let alone cross study analysis was a daunting task for the scientists. So the Company decided to integrate study data from the laboratory information management system (LIMS) and the clinical data management system to form study data repositories for two departments. The Company decided to deploy a commercial software application for both Drug Metabolism and Safety Assessment.

The Solution: ResultWorks led the implementation effort for the software application on behalf of the solution provider, working with the solution provider's product experts and the Company's project team. Using ResultWorks' methodology, the team organized the project, held initial meetings with the Company's project team and conducted a kickoff meeting with the Company and the solution provider within weeks after agreements were signed.

Through strategically planned stakeholder interviews, ResultWorks laid the foundation for defining a working solution for the Company. ResultWorks' consultants evaluated the Company's clinical and safety assessment data management process and the technical environment. The technology landscape included a custom clinical data management system, LIMS, SAS and various point software applications that were integral to a complete solution.

ResultWorks mapped current processes and proposed workflows with the new integrated system. They then led stakeholders from clinical and pre-clinical functional areas (i.e., Drug Metabolism, Safety Assessment, Statistics, and Informatics) through a Result SessionSM, a facilitated decision-making workshop. Processes were analyzed; study data was mapped to the new repository; and system configurations and integration were defined to support the project objectives in an expedited timeframe. The Result SessionSM also promoted cross department teamwork, laying the foundation for adoption of the solution by scientists.

Within four months, ResultWorks completed and achieved approval of the solution definition, process documentation, configuration specifications, and technical specifications for the systems. By six months, implementation was complete including development of custom integration, system configuration, installation, installation qualification, operational qualification, training and system acceptance. Within eight months, the system was authorized and the project successfully concluded.

Key Benefits:

1. **Thorough and Timely Solution:** In the space of eight months, defined an integrated solution, optimized processes, configured the system, transferred data and performed scientific analysis as envisioned.
2. **Balanced Approach:** ResultWorks' methodology and project skills blended with the solution provider's product expertise allowed the Company to assimilate the application, to anticipate the required process and technology changes and to achieve rapid implementation and acceptance of the new application.



"ResultWorks' Project Manager did an amazing job of managing everything and keeping the project moving forward." (Client's Manager of Informatics)