

Clinical Study Process Assessment

The Situation: Higher throughput in any business challenges a process that has evolved over time. So it was not surprising that this major biotech company was experiencing growth pains in several areas of its clinical and pre-clinical study process. With an increasing appetite for studies and less tolerance for missing key milestones, it was time to look across the study process to determine bottlenecks and inefficiencies encumbering the business.

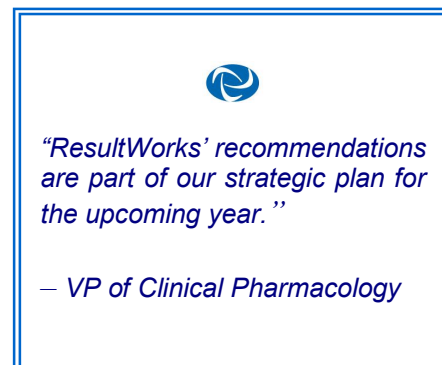
The Solution: Based on its experience and methodology, ResultWorks was contracted to assess the clinical and pre-clinical study process with a focus on the clinical pharmacology area. ResultWorks interviewed representatives from a cross-section of the organization including: study management, clinical pharmacology, toxicology, sample handling, sample analysis, clinical programming, data management, biostatistics, medical writing, and research IT. Based on these interviews and supporting documentation, ResultWorks constructed current process workflows from protocol creation through study reporting. Based on an understanding of the current process flow, ResultWorks identified process opportunities and created a strawman future process that touched all areas of the organization.

A cross-functional core team convened for a three-day Result SessionSM to explore the current and future process. In the course of discussion, it was clear that while people understood the process within their work group, there were misconceptions about the process inputs from internal suppliers and there were also misunderstandings about how work products would be used by internal customers. Terminology issues also came to light. For example, the meaning and implications of database lock meant different things to different work groups which impacted workflow, timing, and mutual expectations. System and data transfer issues also highlighted compliance issues.

The outcome of the Result SessionSM was a process assessment document. This document captured the current process, issues with the process, systems, and data, and the proposed future process. An implementation plan was also constructed to tackle priority issues in a timely way. An executive summary was prepared by ResultWorks and jointly presented with the core team to a Steering Committee of senior managers for their consideration and action.

Key Benefits:

1. **Common Understanding:** The team benefited from having a comprehensive understanding of the full process which led to natural improvements among work groups.
2. **Compliance Issue Resolution:** Details of the process assessment uncovered compliance issues which led to planned solutions.
3. **Process Improvements:** Organizational, system, and workflow changes were identified that would lead to improved study throughput and quality.



About ResultWorks, LLC

ResultWorks, LLC, a professional services company, specializes in transforming the business strategies of Life Sciences companies into successful technology and process harmonization initiatives. Remarkable results are achieved through skilled facilitation and exceptional management leadership. Consistent quality is delivered across a broad variety of challenging engagements through ResultWorks signature methodology. The Result SessionSM is the cornerstone of that methodology yielding collaboration and rapid decision-making while balancing process, user and technical requirements.

For more information about ResultWorks, please contact us at Marketing@ResultWorksLLC.com.