

ResultWorks Completes Global Clinical Process Harmonization

The Situation: Significant growth in the number of clinical trials resulted in increased volumes of clinical pharmacology data and added complexity to processing the data, analyzing it and reporting study results. At the same time this major pharmaceutical company was challenged with compliance issues in managing pharmacokinetic and pharmacodynamic data. So the company decided to implement a global pharmacology data repository to improve data access. They also recognized that current workflows would not support the new enterprise system and launched a process harmonization initiative to improve consistency in data capture, analysis, and reporting of clinical pharmacology studies from protocol creation through study reporting.

The Solution: After thorough consideration of commercial products and internal development, the team chose the Pharsight PKS product. Pharsight introduced ResultWorks to provide process management expertise.

ResultWorks interviewed over 30 stakeholders across Company sites worldwide. They talked to representatives from clinical data management, pharmacology, biostatistics, informatics, drug safety, regulatory and quality. Discussions covered the entire process from protocol development to clinical data management to pharmacology across all study phases. Existing systems such as Oracle Clinical, Watson LIMS, SAS and Documentum were integral to the process discussions.

Current processes were mapped and then refined to take advantage of the new systems and global best practices. Within two months, process maps were drafted and ResultWorks led 20 stakeholders from the Company through a Result SessionSM, a facilitated decision-making workshop. In three days, the team refined clinical study processes and made decisions on system configurations. The Result SessionSM fostered global teamwork and commitment while laying the foundation for the process change program. The program results laid the foundation for process, technical, and organizational changes that still continue as the business evolves.

Key Benefits to the Client:

1. **Global Agreement:** Data definition, handling, transfer, and ownership.
2. **Processes Mapped:** Key business processes were mapped and change plans were agreed.
3. **Project Complete:** In just three months – done!

Key Benefits to the Solution Provider:

1. **Rapid Deployment:** Accelerated system deployment and acceptance
2. **Leveraged Resources:** Product specialists were used more effectively and where they were most needed by the client

In the words of the
Client's Project Leader



“Of all the efforts we undertook this year, this is the only one that delivered what and when we promised.”

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.