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Transforming Strategy. Delivering Success.

Improving Timeliness & Accuracy of Clinical Study Data Flow

THE SITUATION

Clinical studies remain a bastion of manual data management in the pharmaceutical industry. For the volume of studies managed and the amount of data processed, it takes a great deal of human capital to conduct studies in traditional ways. One global pharmaceutical company facing these business challenges was looking for a transformation of their study data flow that would bring about more timely and accurate access to clinical data. This required an assessment of what data was needed, who needed the data, how the data flowed, and where the data resided as a precursor to determining how to streamline the data flow, the workflow, and the information systems to optimize clinical study efficiency.

THE SOLUTION

The company enlisted ResultWorks to lead an assessment and to develop a strategy to improve the clinical study data flow. The clinical study process was divided into the four areas shown in the graphic below: Study Planning and Design, Study Execution, Results Capture and Data Analysis, and Study Reporting. For each area, the current process was mapped, data flows were diagramed, and specific pain points were identified. In most cases the existing business processes were optimized around manual data handling, where "manual" was the rate-limiting issue.

The design of the future clinical study data flow environment emphasized the capture of data electronically at the source. Capture of study design data such as the schedule of events is critical to driving the design and setup of downstream systems (i.e., the eDC for the electronic

case report form and central lab vendor sample management systems). Collecting site data on subjects and samples electronically improves the speed, accuracy and visibility of study progression by the study team. At every stage of the study process, similar improvements were identified with sufficient detail to define a three-year strategy roadmap with projects encompassing both business and IT activities.

KEY BENEFITS

Common Understanding of Current Processes: Due the breadth of stakeholders and partners involved in the clinical study process, key pain points and critical bottlenecks were not commonly understood or appreciated. By mapping the clinical study process and data flow, it enabled the team to identify necessary improvement areas.

Shared Data Flow Vision: The adopted vision for clinical study data flow embraced: the design and capture of study data electronically, broader use of data standards, an integrated information management architecture, and more accurate, timely data for making clinical study decisions.

Strategy Roadmap to Realize the Vision: A three-year strategy roadmap of business and IT projects was developed and aligned, supporting the clinical development business direction and leveraging key information management platforms.

> "ResultWorks did a great job of quickly grasping our clinical study process and pulling the information together for decision making."
>
> –Director Clinical Data Management

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