

ResultWorks Orchestrates CTMS Definition, Selection, & Implementation Planning

The Situation: Initiatives that begin with a product focus often fail. Yet, this happens time and again in the life sciences industry. The clinical operations group of a life sciences company initiated a clinical trial management system (CTMS) project without the participation of several key stakeholder groups. They engaged a CTMS vendor to write their requirements and then selected a solution based on each vendor's standard demonstrations in which the vendor controlled the environment and the demo content. Shortly thereafter, senior management stopped the project due to insufficient due diligence, limited adherence to IT standards, and lack of confidence in the approach. ResultWorks was asked to assess the project and to create a new strategy for the CTMS effort.

The Solution: ResultWorks formalized a strategy for defining CTMS requirements based on defined future workflow. With this in mind the team mapped out future business processes supported by the CTMS, and applied its methodology to a requirements definition and vendor selection. Because there were no formalized standard processes in place within the client's Clinical Operations group, the decision was taken to forgo study of the current process in favor of looking forward to a well designed future process. The future process design drove requirements which were then built into a request for proposal (RFP). A facilitated Result SessionSM was conducted to confirm and refine processes and requirements. Key processes included: study planning, study setup, investigator setup, study management, clinical monitoring, financial management, study reporting, and management reporting. A cross-functional team was included in the Result SessionSM to enable end-to-end process definition and to assist with buy-in of the solution across stakeholder organizations.

ResultWorks managed the bid process sending the RFP to six CTMS vendors. Three vendor responses were considered further. In order to evaluate the vendors, there were three key activities. The vendor proposals were analyzed and compared. Vendor references were interviewed and analyzed. Finally the vendor was requested to demonstrate the company requirements by following a script, prepared by ResultWorks, which was based on the future workflow. By enforcing a scripted demo, the company stakeholders could more readily compare all the vendors based on their stated requirements. This also kept the vendor from showing off their own bells and whistles which were not necessarily important in meeting company needs.

Selection criteria were developed ahead of time so that assessments at each step of the process could be tabulated. Ultimately a single vendor emerged who could meet not only today's needs, but also the needs defined for the future. The decision taken at the end of this process had a broad base of support across the organization.

ResultWorks also assisted procurement with preparations for vendor negotiations considering not only software costs, but also services, configuration, customization, integration, and validation. Considerations in the implementation planning included: a small scale pilot, confirmation of the selected vendor solution, configuration decisions, and refinement of the future workflow based on the selected CTMS solution.

Key Benefits:

Establish a Vision: Focusing on the future business processes laid the foundation for requirements and the RFP.

Broad Solution Support: Determining end-to-end processes by including cross-functional groups who would depend on the CTMS enabled broad support for the solution - a key success factor.

Focus on Needs: By focusing the vendor demos on company needs, rather than vendor features allowed the stakeholders to better envision their use of one system over others.



ResultWorks' approach forced us to identify the best product to support our business process and is a model for future projects of this nature."
- Asst. Director IT