

SELECTING A CLINICAL TRIAL MANAGEMENT SYSTEM —RE-ENGINEER YOUR BUSINESS PROCESS FIRST!

Selecting a new Clinical Trial Management System (CTMS) for an organization holds the promise of better and timelier information sharing, more informed forecasting and planning, and better partner relationships. However, before you leap in it is a good idea to re-examine and re-engineer your current business processes.

Many organizations do not have an existing CTMS, and business processes have evolved around non-shared personal spreadsheets of data and informal communications. Those organizations who were early adopters of CTMS' have often customized their systems heavily, potentially embedding business processes that may no longer be best practice.

Invest time upfront in business process analysis and modeling to determine how people will work more effectively with the new solution in place.

Invest time upfront in business process analysis and process workflow modeling. Analysis of the impacted business functions and interactions with customer groups provides the following benefits:

- Agree 'best practice' workflow for your organization
- Identify and eliminate redundant processes and supporting systems
- Get buy-in for implementation from all stakeholder groups

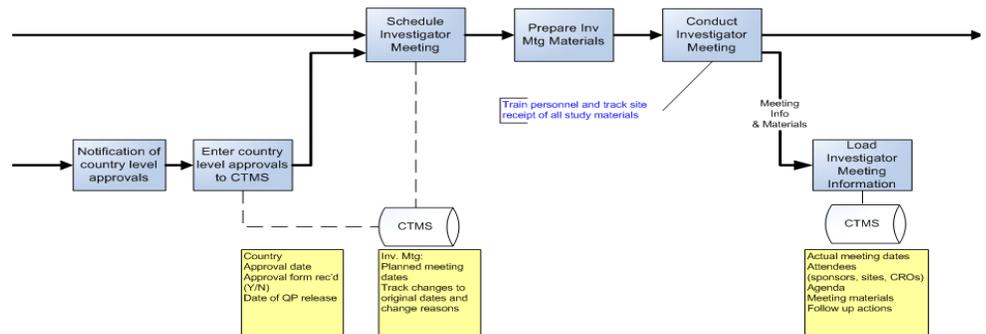


Figure 1: Example Process Flow

- Understand data flow, eliminate data duplication and optimize data sharing
- Define the scope of operations that the CTMS will need to support
- Agreed process workflows directly feed the development of User Requirements for the selection process

Process re-engineering need not be a lengthy exercise. A typical evaluation, from zero to agreed new processes, may only need 8 – 9 weeks if a disciplined methodology is followed. ResultWorks' proven methodology includes the following steps:

- Identify the project team and conduct a formal kick off meeting
- Conduct short teleconference or face to face interviews with key stakeholders to understand how the current process works, identify issues and gaps, and get input for future process improvements
- Develop end to end strawman 'to-be' processes (for situations where an existing CTMS is in place then 'as-is' processes may be developed as well so that before and after can be contrasted)

- Conduct a ResultSession with the project team to review the and adjust the new processes
- Document the new processes and conduct final review

ResultWorks experience of CTMS selection has demonstrated the effectiveness and value of investing time in business process analysis and re-engineering as a first step in a CTMS selection process. By undertaking this upfront effort the downstream user requirements and vendor request for proposal (RFP) package truly reflect the system requirements for an optimized process. This minimizes scope creep and unexpected requirements during implementation.

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