Giving Clinical Trial Start-Up a Project Management Make-Over: Reducing Cycle Times Through Critical Path Focus

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Problem Statement
- Site activation is on the critical path in trial conduct and is commonly cited as a cause of delay, having an often unrecoverable impact on patient recruitment and database lock
- The activation process involves many stakeholders and offers multiple opportunities for improvement. The interface between sponsor and CRO during this phase presents further opportunities for improvement

Objectives
- To reduce site activation timelines through proactively examining and optimizing critical path processes prior to initiating any activities
- To establish site management processes and communication pathways that reduce lag in the activation process at the site level

Projected Benefits
- Reduced site activation timelines leading to overall timeline reduction and cost saving
- Improved reliability in site activation allowing for more efficient resource planning and management

Factors Examined that Impact Timelines
- Site identification process
- Site selection process
- Contract and budget development and negotiation
- ICF development and customization
- Delegation and review cycle timelines
- Training in study specific processes
- Site management strategies
- Team stability

Methodology

Site Identification
- Early development of the golden site profile
- Taking potential impact of country affiliates, KOLs off the critical path
- Application of streamlined site identification and SIV methodology

Site Contracts
- Six Sigma Kaizen event conducted between Covance and Sponsor
- Use of grant plan tool to develop acceptable and credible budget
- Early engagement strategy (contract and budget available for PSV)
- Clear negotiation windows and minimal review cycles
- Review and agreement of contract execution timelines as part of site selection
- Focused action plan for non-responsive sites

Site Management Strategies
- Establishing and agreeing critical milestones with sites as part of site selection
- Managing sites to milestones through PI engagement
- CRO sponsor collaboration and leveraging site relationships

Results

Impact of Process Improvements on Contract Cycle Times
- Elimination of >75% of contract escalations
- 32-day mean reduction in contract execution timelines
- Early identification and deselection of sites with activation challenges

Impact of Optimization on Critical Path
- 8-month reduction in time to 80% sites activated by proactive identification and streamlining of key process and active site management and engagement strategies

Summary of Requirements to Optimize Start-Up Timelines
- This poster shows that start-up timelines are far from fixed, but are dependent upon the processes we follow
- Working together, it is possible to significantly reduce timelines by:
  - Taking a flexible and proactive approach to process requirements
  - Planning and implementing process changes prior to starting the activation process, rather than part way through or in response to crisis
  - Challenging and controlling internal stakeholders on their requirements as typically greater efficiency can be obtained
  - Challenging the status quo—do we have to do it this way?
  - Using leverage and project management methodology over external stakeholders that is typically discarded or implemented only as a last resort

Disclosures
The author of this presentation has the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
- Benjamin Quartley: Nothing to disclose

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