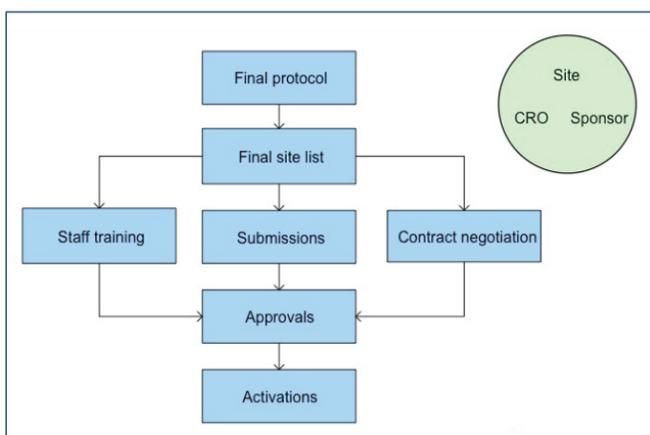


Giving Clinical Trial Start-Up a Project Management Make-Over: Reducing Cycle Times Through Critical Path Focus

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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



Start-Up Critical Path

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

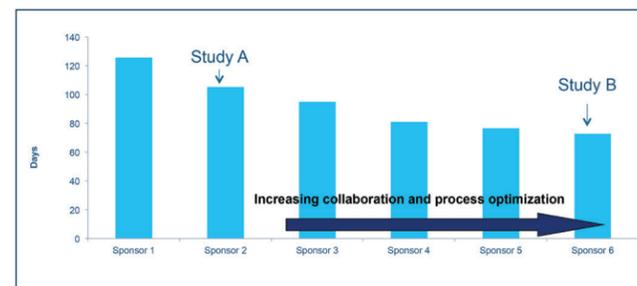
Site Contracts

- ▶ 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

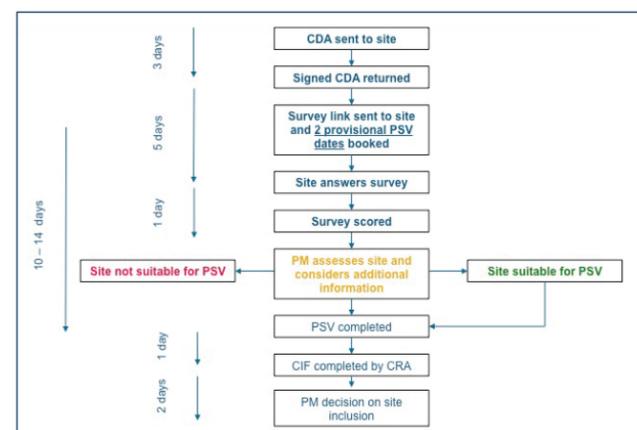
- ▶ Establishing and agreeing critical milestones with sites as part of site selection
- ▶ Managing sites to milestones through PI engagement
- ▶ CRO sponsor collaboration and leveraging site relationships

Results



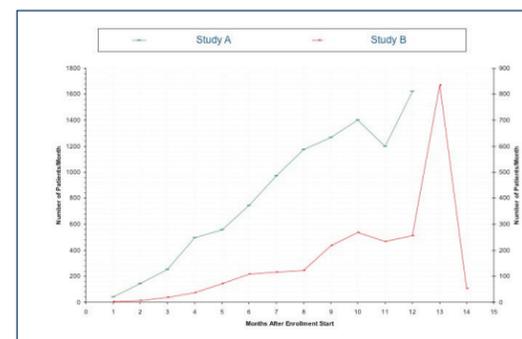
Impact of Process Improvements on Contract Cycle Times

- ▶ Elimination of >75% of contract escalations
- ▶ 32-day mean reduction in contract execution timelines
- ▶ Early identification and deselection of sites with activation challenges



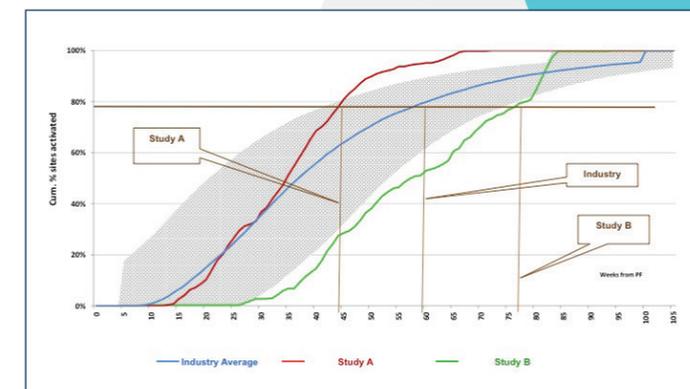
Optimized Site Identification Process

- ▶ Site identification cycles reduced by 40%
- ▶ SIV cycle times reduced by 50%



Comparison of Recruitment Rates Study A and Study B

- ▶ Study B experienced back ended recruitment compared to Study A applying significant pressure to monitoring and data management



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