Rapid Path to Recruiting

Taking a close look at site initiation and defining what is required to make this process successful.

Disclaimer: Speaker is participating in an individual capacity and not representing the views or opinions of current or previous employers.
Agenda

- Rethinking the site initiation process
- Defining key processes
- Understanding and measuring interdependent processes and outputs
- Analyzing the key internal and external performance indicators that have the biggest impact on site initiation
- Identifying and implementing solutions where improvements are needed
- Developing long-term plans to monitor and maintain continuous improvement and control performance slippage
The Case for Change

Increasing development costs

Governmental Mandates

Change fatigue

“Do more with less”

Decentralization

Outsourcing

investigator agreements

Increased trial complexity

Fiscal cliff

cost of lost opportunity

Trial Subject Education

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Investigator Agreements: Stumbling Block or Launch Pad on the Critical Path?

- The Process takes **too long**
  - Industry benchmarks between 90-120 days (blended range is based on data published by Cornell, CenterWatch, and Quintiles)
  - Variables: Phase, Therapy, Site/IRB Type
- Process is getting more **complex**
  - Outsourcing
  - Decentralized decision-making
  - Unclear roles and responsibilities
  - Relationships
  - Access to historical information
  - Staff turn-over
- Complex legal language
- Trial complexity increases budget complexity

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Define the “As Is” Process

USSC – Outsourced U.S. Contracts Process

**CASE STUDY**
Measure, Test, Analyze

- Understand and measure interdependent processes and outputs
- Open regular communication channels with key partners and stakeholders
- Align on “as is” processes and “pain points”
- Share available tools and job aids
- Identify gaps and needs
- Later, use these forums to “pressure test” and implement
Scope and Goal

- **Problem/Scope:** CRA and CDA process for site contracts needs to be accelerated and simplified to get studies up and running faster; emphasis on time critical study-start up

- **“Game Changing” Goals:**
  - Reduce contracting cycle time to 50 days
  - Reduce the number of touch points/hand-offs to optimize resources

- **Key Concepts:**
  - To achieve better overall cycle times, we need to focus our efforts on engaging the right sites; difficult sites are a reality, but by acknowledging this and proactively planning, we can better utilize resources
  - Key partners are aligned on goals, but not roles, responsibilities and decision-making

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You may need professional help!
Workshop Debrief

- Partners listened and learned a lot from each other
- Innovation was encouraged/no ideas off the table
- Exhaustive mapping and analysis of process with facilitator
- Established a partnership- jointly accountable for solutions and implementation
- RACI and process clarified decision-making
- Focus on highest impact changes - study start-up and negotiations
- Developed pro-active solutions and actionable plans
Implement Improvement Solutions

- Leverage the momentum and partnership as a forum for implementation
- Project roles – sponsor, project leader, process leads
- Accountability check ins
- Communication plans – “if you build it...”
So...What’s the Plan?

- Improvement #1 - Simplified CDA Process
  - Centralized, one-stop shop for all CDAs
  - Leverage over 1,300 master CDAs
  - Clear plan and roles for remaining CDAs

CASE STUDY

Reduced PAIN

Increased stakeholder satisfaction

Save 3 Days!
So...What’s the Plan?

- Improvement #2 – Strategy!
  - Contracts kick off strategy
  - Robust “Site Contracting Toolkit”
  - Escalation plan template outlines RACI
  - Smart site selection and prioritization
  - Leverage historical data and masters
  - Faster decision making “in the moment”

Help more patients sooner

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...And how are we doing?

Control and Monitor

- Develop a long-term plan to monitor and maintain continuous improvement
- Must know what the priorities are to monitor and measure them
- Control performance slippage
- Plan for “disruptions”
Measuring and Monitoring

- **Qualitative**
  - Survey - Ease of contracting process?
  - Level of support?
  - Trial outcome - were timelines met?
  - Did we prioritize the correct sites?

- **Quantitative**
  - Turn around time metrics (draft sent to site to contract executed)
  - Number of touch points/negotiation rounds
  - Resource demand

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Recap

- Imagine the possible and have no fear of legacy process paralysis
- A picture is worth a thousand words – take the time to document the “as is” process
- Aim for “game changing,” tempered with serenity
- Prioritize improvements based on effort and results
- Quick “wins” build momentum
- Look around the corner for inspiration/trends
Questions?

Comments or feedback?
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