CluePoints

TIP SHEET

6 Tips for Maximizing Success with Adaptive Site Monitoring

On-site monitoring has long been resource-intensive, consuming 25–30% of clinical trial costs. At the same time, evolving regulatory expectations are compelling Sponsors and CROs to modernize their approaches. As a result, adaptive site monitoring is rapidly gaining traction as the preferred solution to address both operational challenges and compliance requirements.

How do you transition from a traditional monitoring model to an adaptive one while maintaining speed, quality, and accuracy? Our Site Profile & Oversight Tool (SPOT) implementation process is designed to ensure a seamless, confident transition. Beyond technical deployment, we focus on fully integrating SPOT into your operations for maximum impact. Our partnership begins well before the first site visit—**here's how we guide you through every step of the journey.**

1 Begin with Tailored Assessment Workshops

- Evaluate current site monitoring processes, tools, and challenges
- Align on intended goals and expected outcomes from implementation stakeholders
- Ensure compatibility of existing systems (e.g., CTMS, EDC, IRT) with SPOT
- Identify opportunities for SPOT to address challenges and enhance efficiency
- Define KPIs, such as visit reduction rates or query resolution times
- Engage CRAs, site managers, data teams, and other relevant cross-functional stakeholders early to align goals and expectations

2 Launch a Meticulous Pilot Program

- Select a pilot trial with diverse site and data scenario conditions to ensure comprehensive testing
- Configure SPOT's initial settings, dashboards, and action templates tailored to trial needs
- Gather feedback from direct end users and stakeholders to assess usability and improvement opportunities
- Validate all software components, data integrations, and configurations

3 Transition to Full Deployment

- Expand implementation across multiple trials, applying insights from the pilot phase
- Coordinate knowledge transfer training to equip teams with proficiency in using SPOT's features
- Communicate program success and the reason for expansion to a broader organization

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SPOT Implementation Continued...

CluePoints is there every step of the way.

4 Maximize Efficiency with Customization

- Create tailored SPOT dashboards to centralize site data for clear risk and workload insights
- Standardize automated and user-triggered responses to address risks and performance needs
- Incorporate anticipated workload and central data review risks into decision-making processes
- Develop and replicate effective recruitment strategies, CRA assignments, and training plans

5 Collaborate for Ongoing Support

- Partner with CluePoints for periodic performance reviews and ongoing consultation, ensuring success measures and outcomes are continually met, evaluated, or modified
- Leverage continuous training and updates to refine SPOT utilization as trials progress, requirements change, or organizational objectives change

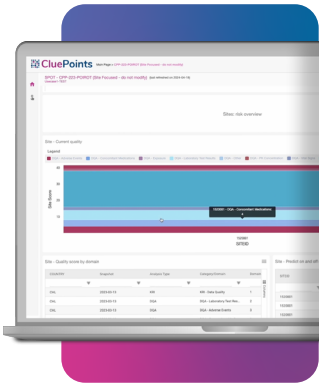
6 Drive Long-Term Success

- Incorporate SPOT insights into a comprehensive Risk-Based Quality Management (RBQM) strategy connecting centralized data oversight with actionable site-level management
- Regularly review SPOT outputs to stay aligned with success metrics and adapt to evolving trial needs

Results of Effective Implementation & Continuous Optimization

The future of clinical trial oversight isn't just about adopting technology—it's making innovation work for you. With SPOT, we don't just introduce a platform; we redefine how you approach site monitoring, providing the expertise, tools, and confidence to excel. **Here's how SPOT delivers.**

- Accelerate the move from traditional on-site monitoring to adaptive practices.
- Adjust site visits in line with workload and risk, saving resources and tackling risks head-on.
- Automate performance assessments to save time and adjust underperforming sites faster.
- Tap into data insights to replicate recruitment wins and supercharge study efficiency.
- Customize SDV and SDR for each study, cutting wasted effort and sharpening resource use.
- Use real-time data to boost CRA effectiveness, refining assignments and training.
- Contribute to corporate sustainability goals through reduced on-site travel required.



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