A Data-Driven Approach to Clinical Trial Site Selection

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Introduction

Data quality and integrity are fundamental to clinical trial success. While sponsors invest heavily in post-site-selection quality measures like rater training and data quality monitoring, opportunities to enhance data quality exist much earlier in the process - particularly during site selection. By leveraging historical performance data analytics at this crucial stage, sponsors can further optimize opportunities for trial success from the very beginning.

Site selection and site verification in clinical trials

Selecting the right research sites is one of the most critical decisions sponsors make when planning a clinical trial. Site selection involves evaluating and choosing research centers that will conduct the trial, while site verification provides detailed quality assessment of pre-selected sites. These processes directly impact patient recruitment, data quality, and ultimately, trial success.

Common challenges with clinical trial site selection

The industry has historically relied on familiar sites with proven recruitment capabilities and extensive trial experience. However, research shows that even experienced sites can present unexpected data quality issues (Signant will present a poster at ISCTM's 21st Annual Scientific Meeting related to this subject). Poor site selection can lead to enrollment delays, protocol deviations, and compromised data integrity - issues that become extremely costly to address once a trial is underway. Furthermore, this traditional approach can limit participant diversity and potentially impact treatment efficacy assessment across broader populations.

Our solution: evidence-based site selection/verification with PureSignal Analytics

PureSignal Analytics, Signant's blinded data analytics solution, enables sponsors and CROs to harness advanced data science capabilities to transform the site selection process. It can analyze historical performance data across multiple dimensions while maintaining data privacy and trial integrity. By analyzing patterns in anonymized historical data, the system provides sponsors and CROs with evidence-based insights to optimize site selection.

How it works

Our Digital Health Science team employs PureSignal Analytics to identify sites and raters with demonstrated excellence in data quality. The platform evaluates performance across multiple parameters:

- Historical data quality metrics
- Cross-indication experience
- Geographic performance patterns
- Patient recruitment efficiency
- Protocol compliance rates
- Assessment consistency
- Data completion rates

The system generates intuitive, ranked site lists based on customizable quality metrics designed by clinical and scientific experts. This enables sponsors to:

- Identify sites requiring specific training interventions
- Detect potential eligibility or placebo response concerns
- Target areas for enhanced monitoring
- Make evidence-based site selection decisions
- Optimize resource allocation

For sponsors with predetermined sites of interest, our verification reviews provide detailed quality assessments to inform training and monitoring strategies. This targeted approach helps sponsors maximize the return on their site management investments.

Conclusion

Evidence-based site selection and verification represent powerful opportunities to enhance clinical trial quality before the first patient is enrolled. Powered by PureSignal Analytics, our comprehensive site performance analysis helps sponsors identify and select sites with proven track records of generating high-quality data. This data-driven approach enables sponsors to optimize their site networks, enhance protocol compliance, and improve data integrity from study start. When sponsors make evidence-based decisions in selecting the best-performing sites for their trials, they build stronger foundations for study success and accelerate the development of new treatments.

EXPLORE OUR BLINDED DATA ANALYTICS SOLUTION FURTHER OR GET IN TOUCH WITH OUR EXPERTS ABOUT YOUR SITE SELECTION/VERIFICATION QUESTIONS.

About the Authors

Martina Micaletto is a Clinical Scientist at Signant Health, with extensive experience in the pharmaceuticals industry. She specializes in computerized cognitive batteries, scale administration and scoring, rater training and certification, and endpoint assessments. Martina is skilled in statistics, research, negotiation, psychology, and customer care. She holds an MSc in Social and Cultural Psychology from The London School of Economics and Political Science (LSE) and an MSc in Development and Psychopathology from The University of Reading.

Dr. Alan Kott is the Practice Leader for Data Analytics at Signant Health, with both academic and industry experience in clinical trials. He has led the development of Signant's Data Analytics Program, overseeing data analytics in over 200 clinical trials across multiple indications. Prior to joining Signant, Dr. Kott was an Assistant Professor at Charles University and a house officer in psychiatry at General Teaching Hospital in Prague. He holds a Medicinae Universae Doctor (MUDr.) from Charles University.

Dr. Petra Reksoprodjo, MD, is Director of Clinical Science, Data Analytics at Signant, where she leverages over 20 years of expertise in the clinical trials industry, with a particular focus on CNS clinical trials. Holding a medical degree from Charles University in Prague, she oversees clinical project delivery and maintains quality assurance across a large portfolio. Petra collaborates closely with Signant's data analytics team to prepare and deliver clinical data analyses for clients and is a frequent presenter at international investigator meetings. Based in Signant's Prague office, she also contributes to internal training programs and fosters clinical excellence through mentoring and leadership.