

The Signal

Analytics Approaches to Assessing Clinical Endpoint Data Consistency

Clinical research sponsors collect more data on more endpoints than ever before, especially since the proliferation of remote/decentralized clinical trials. From electronic data capture systems to digital health technologies and biological data, data sets in clinical research continue to grow exponentially every year. Yet, with so many data points, quality issues and data inconsistencies that result from errors, non-adherence, or fraud often remain hidden until the end of a study.

How can study teams leverage these data to monitor endpoint quality throughout the course of a study and program?

An in-study data quality monitoring and analytics strategy, such as [Signant's Blinded Data Analytics](#), can help sponsors proactively monitor data as they flow in, providing opportunities to mitigate consistency, accuracy, and other quality issues before they can compromise a study.

Study teams can leverage Signant's analytics tools and expertise to compare data beyond the individual study; when these data are compared with site-, rater-, country-, and region-level data, analysts and biostatisticians can identify anomalies and outliers that may indicate areas of quality concern. For example, in CNS studies which rely on subjective clinician-reported outcome assessments, data analytics services can identify variations in inter- and intra-rater scoring that can compromise endpoint data reliability.

This strategy, coupled with remediation approaches such as rater training programs or independent central reviews of assessments, detects and mitigates common challenges that endanger study success including:

- Participant eligibility issues
- Variability in raters' scoring and administration of assessments
- Protocol non-adherence
- Errors
- Fraud

Monitoring data quality in these ways improves endpoint reliability and prevents costly trial failures, but it is equally important to have experienced data scientists, analysts, and clinicians interpret the data to ensure conclusions are correct.

Learn more about [Signant's analytics solutions and services](#), and subscribe to our blog to stay apprised of important trends and topics.



Alan Kott, MUDr.

Clinical Vice President and Practice Lead, Data Analytics