SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

試験を成功に導くデータアナリティクス

PROOF
AT THE
SPEED OF LIFE

SIGNANT SMARTSIGNALS® SOLUTIONS

EVIDENCE GENERATION

- eCOA
- Electronic Clinician Ratings
- EDC/DDC
- Rater Training & Qualification
- Central Rating & Consulting
- CDR System®
- Sensors & Wearables
- Analytics

IP MANAGEMENT

- RTSM
- Supplies

ENABLING SOLUTIONS

- Patient Engagement
- eConsent
- Telemedicine

UNIFIED PLATFORM

- EDC/DDC
- eCOA
- eConsent
- RTSM
- TeleVisit
- Participant Tracker

SHARED COMPONENTS

- Data Aggregation & Intelligence Platform
- Marketplace (eClinical Integration)

PARTNER SERVICES

- Home Health
- Courier Logistics

SIGNANT HEALTH SERVICES

- Scientific and Clinical consulting
- Scale Management
- Translations
- Logistics
- Helpdesk

The failure rate of clinical programs continues to be staggering

Over 90% of all drugs entering clinical development do not succeed.

Even when they reach Phase 3, the risk of failure is significant.

For example, 49% of Phase 3 CNS trials fail, many due to lack of separation between active and placebo treatments.

Source: Bio | Informa | QLS, Clinical Development Success Rates and Contributing Factors 2011–2020, 2021
Wong, Chi Heem, Kien Wei Siah, and Andrew W Lo. "Estimation of Clinical Trial Success Rates and Related Parameters." Biostatistics 20, no. 2 (April 1, 2019): 273–86

Common reasons for failure to show treatment group separation in CNS trials

1.  High placebo response
2.  Eligibility / Baseline score inflation
3.  Rater variability and quality

Signant's Lines of Defence

HIGH QUALITY DATA = **GOOD DATA COLLECTION** + **COLLECTING GOOD DATA**

INTELLIGENT eCOA

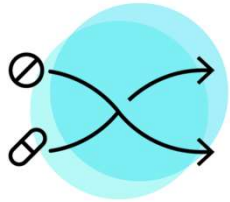
- Training modules and reminders
- Edit checks and restricted fields
- Navigation/branching logic

RATER TRAINING

- Expert trainers
- Certification examinations
- Centralized review
- Rater standardization
- Mitigation

BLINDED DATA ANALYTICS

- In-study Analytics
- Signal Review
- Site Selection / Verification
- Screening Optimization
- Fraud Detection
- Cross-Study Analytics

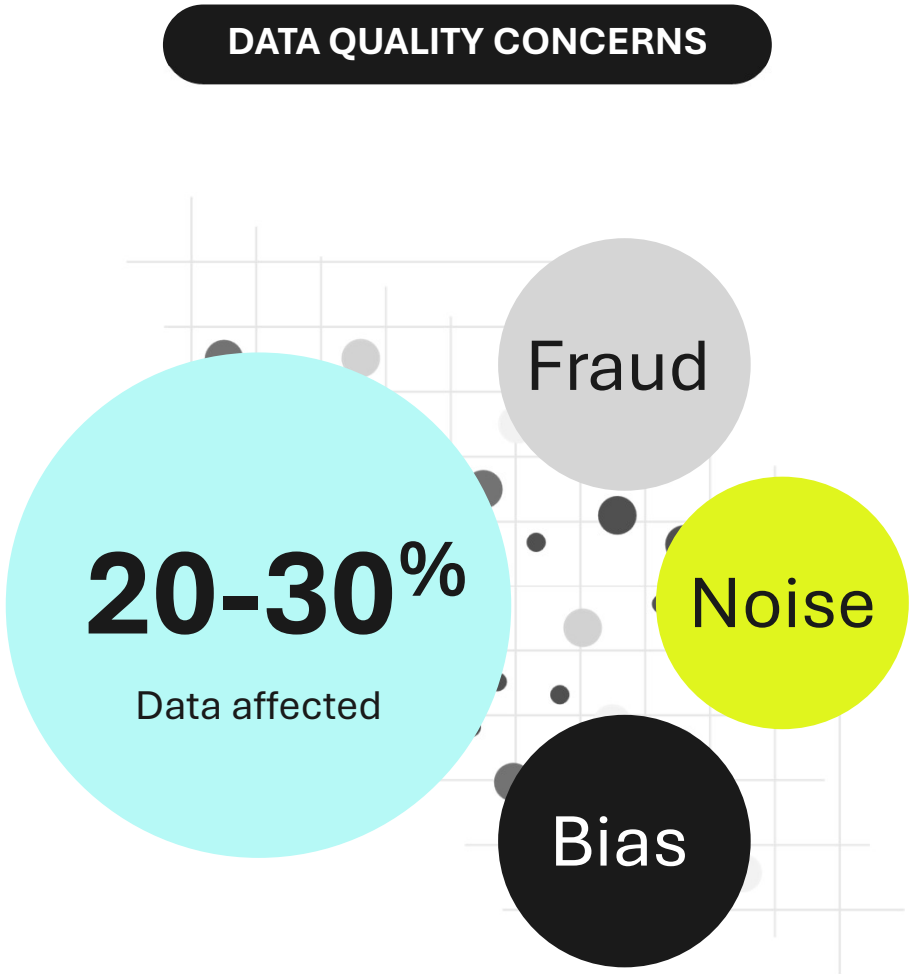


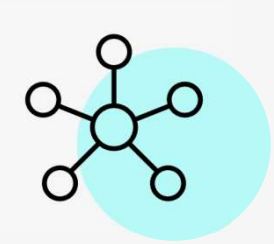
PLACEBO RESPONSE MITIGATION

- Training provided to investigators, site personnel, and patients
- Reduces augmentation of the placebo response

The Problem

- Questionable data integrity
- Detrimental effect on study outcomes
- Degradation of signal
- Impact on patient safety





Endpoint Data Concerns

DIVERSE QUALITY ISSUES

We encounter a variety of endpoint data quality issues. Left unaddressed, they pose serious risks for sponsors, ultimately jeopardizing the trial's very ability to demonstrate its real therapeutic value.

1. **Inappropriate inclusion**
2. **Administration / scoring errors**
3. **Variability**
4. **Discordances**
5. **Fraud**

Signant's Data Analytics Solution

Analysis

- Clinically driven central statistical & algorithmic monitoring
- Tailored to study and critical endpoints

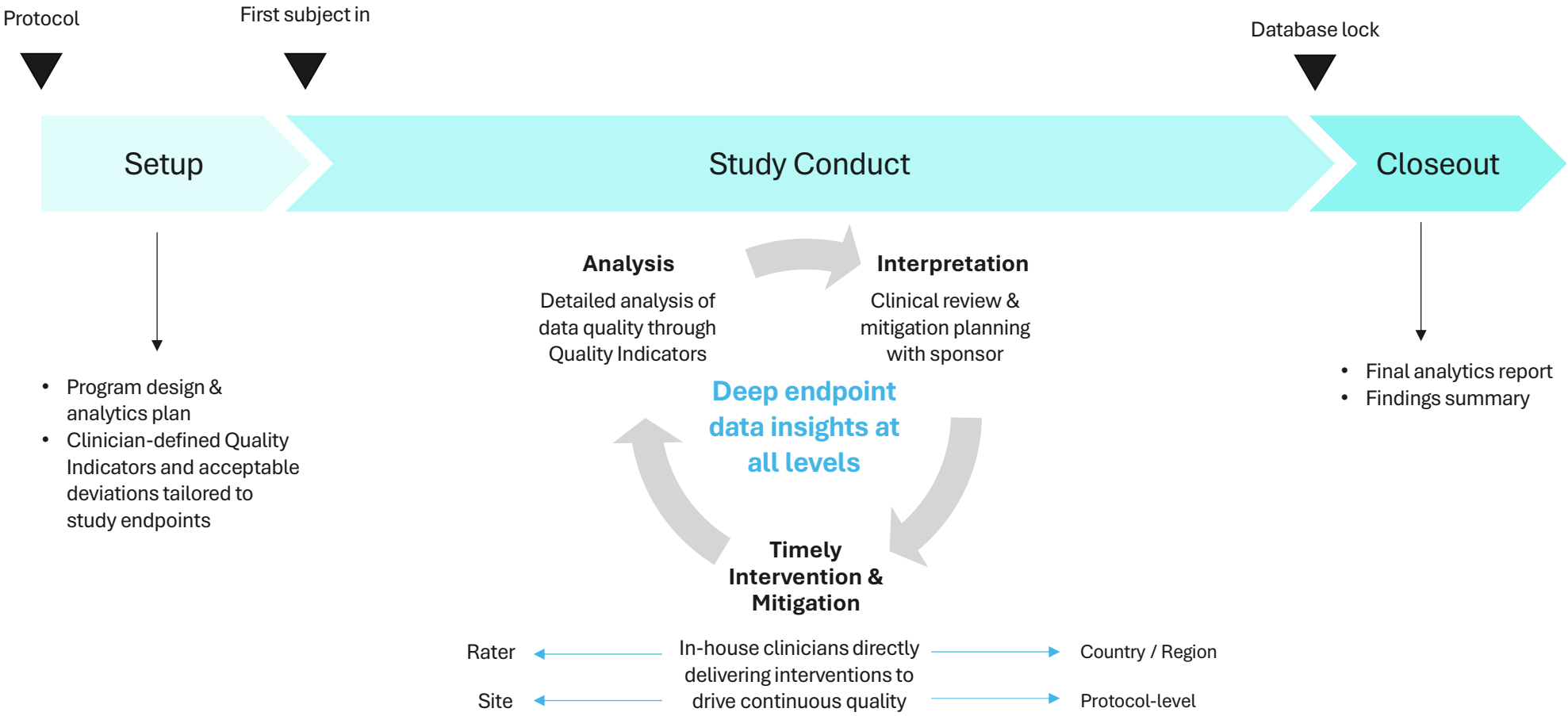
Interpretation

- Dedicated team of specialized BDA Clinicians and Data Scientists
- Interactive visualizations
- Ability to analyze data across all levels
- Study level ← → Visit level

Intervention

- Timely and targeted intervention by Signant's Clinical Team
- Post intervention follow-up
- Collaborative approach

In-study Analytics Process



CASE STUDY

In-study analytics

Signant helped a pharmaceutical company to optimize signal detection potential in a study requiring a high number of clinician raters

Study Phase	**Phase II**
Therapeutic Area	**Dermatology**
Patient Population	**Adults**
Number of Patients	**250+**
Number of Sites	**90**
Instruments	**11**
Countries	**10**

Challenges

The multicenter, placebo-controlled clinical trial involved a high number of sites and relatively small number of patients randomized at each site.

Due to the high number of sites and raters, driving low rater variability to achieve standardized and consistent scoring was a priority for ensuring quality endpoint data.

Solutions

Signant's analytics solution was deployed to the study in addition to CRO's statistical monitoring and other surveillance methodologies.

Results

Our solution proactively identified a problematic site with 3 randomized patients before CRO data review could begin. Detailed analysis revealed highly divergent data pattern across all ClinRO and PRO instruments, including suspected data fabrication.

Upon Signant's recommendation, the Sponsor agreed to halt recruitment at the site immediately, preventing further propagation of flawed endpoint data, and driving overall study data quality.

CASE STUDY

Post-hoc Signal Review

Signant assisted a pharmaceutical company perform a post-hoc analysis to help determine optimal go/go-no decision due to inconsistent signal patterns.

Study Phase	**Phase II**
Therapeutic Area	**Neurology**
Patient Population	**Adults**
Number of Patients	**95**
Number of Sites	**22**
Instruments	**8**
Countries	**1**

Challenges

The study had detected signal; however, it contained inconsistent results whereby site raters showed drug-placebo separation, but central raters did not show separation.

Solutions

A post-hoc analysis was performed using our proven methodology to identify the potential cause of the discrepancy between site vs. central raters and provide evidence-based decision support for the sponsor.

Results

In-depth analysis uncovered one investigative site with highly problematic data. When data from this particular site was removed from the dataset, the site raters' results no longer showed separation.

Signant Health concluded that the original signal that was observed was likely driven by error and recommended a no-go decision to the sponsor.

CASE STUDY

Recruitment Strategy Optimization

Signant helped a pharmaceutical company to improve signal detection by optimizing patient recruitment to sites providing the highest quality clinician rating data

Study Phase	**Phase III**
Therapeutic Area	**Psychiatry**
Patient Population	**Adults**
Number of Patients	**500+**
Number of Sites	**47**
Instruments	**8**
Countries	**2**

Challenges

Improve signal detection by ensuring that highest quality data is maintained at all times by driving patient recruitment to sites providing the best quality data.

Solutions

Our data analytics solution was deployed to the study to assess clinician rating quality. This was combined with a gated recruitment process to ensure that patient recruitment was prioritized to the sites providing the highest data quality.

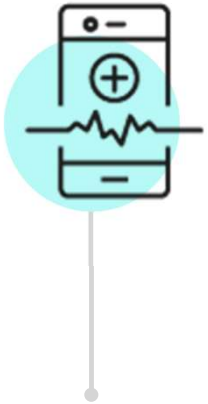
Results

The solution identified high-performing sites for quality endpoint data, allowing the sponsor to utilize a data-driven recruitment allocation to optimize recruitment at those sites.

Comprehensive Utility

Optimizes endpoint data quality across different therapeutic areas

- CNS, Dermatology, Immunology, Rheumatology and more
- Clinically driven evaluation of endpoint data quality



Value and utility for both ClinRO and PRO

- ClinRO diverse types of data quality concerns
- PRO data quality issues and fraudulent behavior

Complements RBQM/RBM

RBQM

- Broad coverage
- Site monitoring efficiency
- Protocol compliance
- Monitoring resource optimization
- General risk management

Signant Analytics Solution

- Deep and specialized focus
- Clinically relevant endpoint quality
- Scientific validity
- Direct intervention independent of CRO/Sponsor

Confidence in Endpoint

VALUE FOR STUDY TEAMS

Sponsors must safeguard the quality and integrity of trial endpoints. The specialized solution blends advanced analytics with relevant clinical context to enable proactive mitigation of quality challenges before they impact signal detection.

- **Clean, quality data**
- **Optimized signal detection**
- **Evidence-based go/no-go decisions**

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THANK YOU

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