

COA DATA ANALYTICS & RATER TRAINING SOLUTIONS STRENGTHEN ENDPOINT RELIABILITY IN DERMATOLOGY TRIAL



OVERVIEW

A biotechnology company engaged Signant to implement PureSignal Analytics, a clinical outcome assessment (COA) data analytics solution, in a multinational Phase 2b atopic dermatitis trial. PureSignal Analytics provided real-time monitoring of data quality, proactively identifying potential risks to data integrity.

As the trial progressed and data patterns emerged, the sponsor expanded the partnership to include Signant's Rater Training & Qualification solution, to ensure consistent, accurate endpoint assessments across all high-recruiting sites.

TRIAL SUMMARY

Study Phase: 2b

Therapeutic Area: Dermatology

Indication: Atopic Dermatitis/Eczema

Patient Population: Adults

Geographic Scope: 10+ Countries

Number of Sites: 110+

Number of Patients: 350+

Number of COAs: 10

Languages: 10+

CHALLENGES

- ① **Traditional Rater Training:** The prior rater training vendor delivered training via remote slide decks, which did not adequately ensure raters understood scoring conventions and relationships between scales
- ② **Maintaining Data Quality:** Continuous monitoring revealed anomalous data patterns and potentially problematic sites, requiring timely remediation
- ③ **Need for Refresher Training:** Emerging data issues demanded more than a review of original materials, training needed to be interactive, relevant, and at the level expected of key opinion leaders
- ④ **Tight Timelines:** High-quality training content had to be developed and deployed quickly to influence ongoing collection of trial data
- ⑤ **Limited Accessibility:** Some sites could not attend investigator meetings, requiring flexible delivery methods to achieve full rater coverage

SOLUTIONS

- ① **Targeted Training Program:** Signant designed and delivered a training program specifically targeted at the most common data issues identified through our data quality monitoring, moving beyond the generic slide-based approach
 - ② **Holistic Data Review:** PureSignal Analytics enabled both a macro-level overview of trial data, coupled with a detailed clinical review of specific findings - ensuring a truly holistic approach. The solution's frequent, systematic monitoring allowed for the timely identification of data quality issues as they emerged. This near real-time detection capability enabled immediate remediation discussions conducted collaboratively. It was specifically tailored to address the needs of individual sites or raters before issues could compound or impact broader study outcomes.
 - ③ **Engaging, Evidence-Based Training:** Training developed by Signant's clinical experts emphasized differences and relationships between scales, incorporated real-life examples of discordant data, and highlighted the impact of accurate scoring on study outcomes
 - ④ **Sponsor Collaboration:** Training development was closely coordinated with the sponsor, ensuring their priorities, needs, and any specific concerns were fully addressed in the training content and delivery
 - ⑤ **Expanded Training Access:** Signant offered additional refresher training opportunities. Over 20 online training sessions were conducted, allowing a greater number of sites and raters to participate and benefit from the training
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RESULTS

The combination of PureSignal Analytics and Rater Training Solutions enabled proactive identification and resolution of data quality risks while strengthening inter-rater reliability across sites.

- Improved consistency and accuracy in COA scoring
- Sponsor successfully met primary and key secondary endpoints, advancing the drug candidate to Phase 3
- Based on the trial's success, the sponsor is considering expanding their collaboration with Signant for future development phases

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