SMi Trial™

Situation

Conduct phase III global clinical trial

- Multi-arm study for a CNS investigational product
- 2 pivotal efficacy protocols, 1 long-term efficacy/safety study
- 142 sites, 40 CRAs
- Investigational product with the potential to change the practice of medicine as the first preventative treatment option for this disease

Mandate

Complete study 6 months sooner

- Speed site activations and enrollment
- Reduce cost per subject
- Important protocol deviations
- Ensure overall trial quality

"This program is our company's future!"

—Chief Science Officer

Challenges

Eliminate issues found in the Phase II study

- High placebo rates requiring hands-on site training that would be impossible to implement globally
- Misdiagnoses of disease subtypes leading to errors in subject enrollment into each study arm
- Mistakes in dosing, timing of interventions, and measurements as they varied by visit

SMi Trial™

Solution

SMi Trial™ was employed to improve study quality, eliminate important protocol deviations, reduce study risk and remonitoring, and ultimately accelerate study completion.

Feature	Critical Fix
Interactive, multimedia eLearning content that reinforces critical elements of the trial	Provided a modern, engaging format for protocol education
Focused narrative on the key risks of the clinical trial	Delivered consistent training to reduce placebo rates and prevent major mistakes during study execution
Mobile-friendly delivery with always-on accessibility	Fought the "forgetting curve" by allowing site staff to look up required activities prior to patient visits
Modular approach that facilitates knowledge retention and allows role-based assignments	Trained the entire study team while tailoring information to each study member's role and education
Integrated assessment questions and inspection-ready audit reports	Identified misunderstandings that led to focused interventions by CRAs during site visits
English, Japanese, and Russian localizations	Ensured clear communication by avoiding language and cultural barriers

Results

FDA and EMA approvals ahead of schedule

- Trial completion 7 months early
- Deviation rates in top 10% of all studies conducted in the clinical organization's history
- Hundreds of thousands of dollars in remonitoring savings and additional time-to-market opportunity costs
- Significantly lower placebo rates
- No adverse findings in audits of training, protocol compliance, and patient protection
- No regulatory issues after multiple site and sponsor inspections
- SMi Trial recognized for driving adoption and "Changing the Practice of Medicine"

About ScienceMedia and SMi Trial

For over 25 years, **ScienceMedia** has delivered innovative learning solutions to improve clinical competency throughout life science R&D, clinical operations, medical affairs, and commercial organizations worldwide.

SMi Trial is a cutting-edge solution proven to reduce risk, remonitoring, and protocol deviations, which ultimately improves the quality of study data in clinical trials through effective, protocol-specific education.