



SMi  
Trial™

*“By decreasing protocol deviations, SMi Trial improved data quality and reduced the overall number of patients required for trial completion.”*

EVP & Chief Scientific Officer | CRO

# Phase III Clinical Trial Accelerates Time to Market

## A Case Study of SMi Trial Implementation Success

- 🎯 Clinical trial completed 7 months early
- 🎯 \$250M+ potential additional peak revenue
- 🎯 \$100,000+ saved in monitoring
- 🎯 20% fewer screen failures

## Background

A large, global pharmaceutical organization identified one of its investigational CNS drug programs as “the future of the company.” The program’s multi-arm, Phase II trial was jeopardized by enrollment errors and protocol deviations despite the deployment of hands-on site training. ***In order to mitigate risks and to scale the trial globally, the sponsor selected a leading CRO who implemented SMi Trial™ and exceeded the sponsor’s expectations.***

## Phase II Challenges

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

## Phase III Expectations

- Complete study 6 months sooner
- Streamline enrollment
- Reduce subject costs
- Prevent protocol deviations
- Standardize compliance across 142 global sites and 40 CRAs
- Ensure clinical data quality

## Solution

*“SMi Trial allowed study teams and site staff to learn on their own time and at their own level, which greatly facilitated the understanding of the therapeutic area and the protocol. This training improved comprehension and the consistency of messaging, and ultimately led to better study conduct.”*

- Senior Medical Director, CRO

### SMi Trial Feature

### Critical Fix



# Complete Results

FDA and EMA approvals ahead of schedule



Trial completed 7 months early



Deviation rates among the lowest of all studies in the CRO's history



\$250M+ potential additional peak revenue



\$100,000s saved in monitoring



Significantly lower placebo rates



ZERO audit findings across training, compliance, and patient protection

## About ScienceMedia

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