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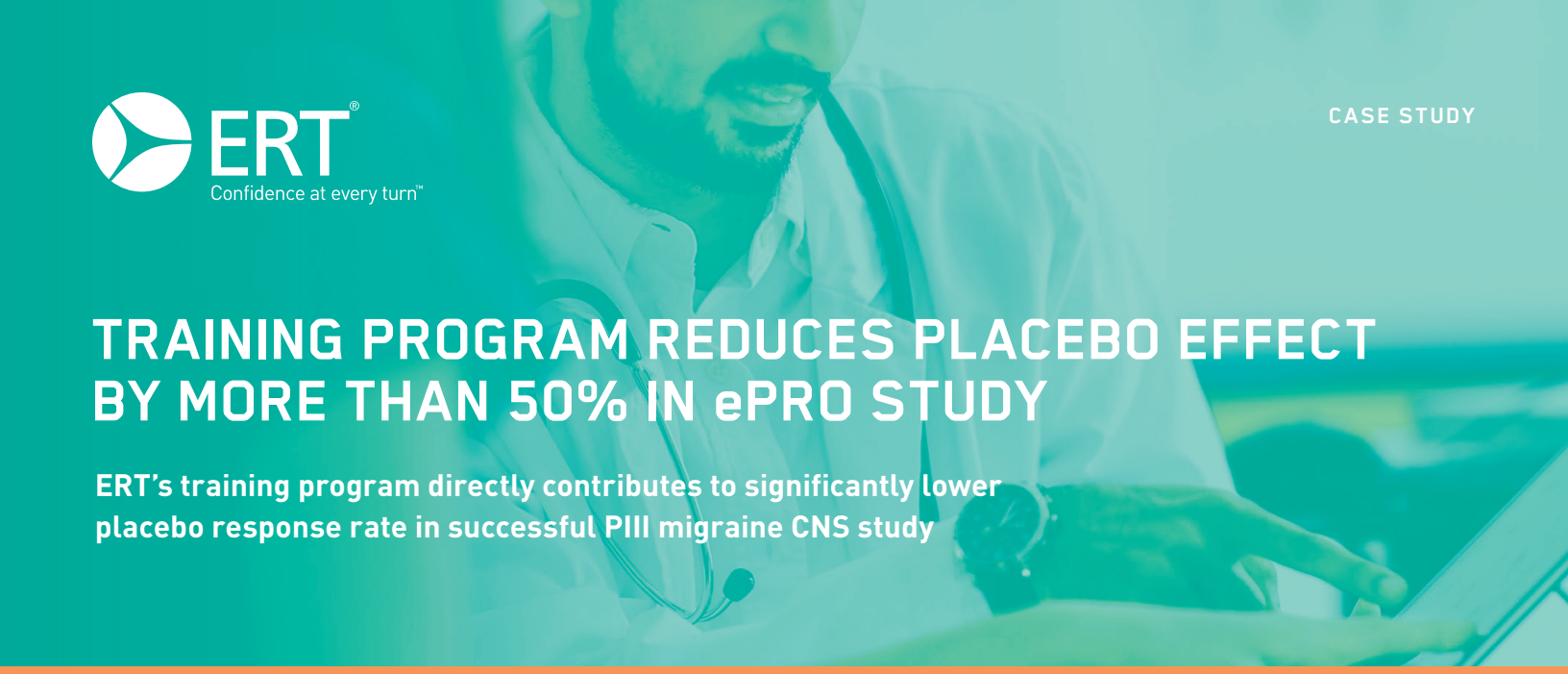
CASE STUDY



TRAINING PROGRAM REDUCES PLACEBO EFFECT BY MORE THAN 50% IN ePRO STUDY

ERT's training program directly contributes to significantly lower placebo response rate in successful PIII migraine CNS study

SITUATION

Migraine is a common and debilitating neurological disease, affecting 39 million people in the United States alone. It has a considerable impact on patients' lives, with 90% of people unable to work or function normally during an attack*. Current treatments, such as triptans, are not effective as headaches can reoccur within 24 hours after taking migraine medication — and also produce cardiovascular contraindications and warnings. High placebo response rates, averaging 29% in migraine studies, can mask the true therapeutic effect of a drug**.

In this phase III CNS migraine study, a biopharmaceutical company sought to evaluate the efficacy and safety of its drug for the acute treatment of migraines. The trial needed to demonstrate that the treatment was statistically differentiated from a placebo on two co-primary endpoints.

It was therefore vital for the sponsor to minimize the placebo response rate to ensure the trial results were as accurate as possible.

The eight month long trial took place in the US, involving 1,400 patients who suffered from acute migraines.

SUMMARY

- 8 month PIII CNS migraine study
- Patient training included in eCOA solution
- Placebo response rate cut in half

IMPACT

- Patient training significantly reduced placebo response rate
- Data showed drug statistically differentiated from placebo
- Training contributed to successful trial

*https://migraineresearchfoundation.org/about-migraine/migraine-facts/
**https://link.springer.com/article/10.1007/s00228-005-0088-5 trial

SOLUTION

ERT's eCOA Clinical Science team created a tailored online training program specific to the requirements of the sponsor's migraine study. Patients were required to undertake the training, which was delivered via an interactive multimedia program with a comprehension quiz in both English and Spanish, and covered:

- Patients' roles and responsibilities as study participants
- How to use the handheld devices to complete the electronic Patient-Reported Outcome Assessments (ePROs)
- What is meant by the placebo effect and how to answer questions about their symptoms accurately to minimize the placebo effect

ERT's eCOA handheld solution was then used to deliver both the Migraine Quality of Life (MQOL) and the Profile of Moods (POMs) questionnaires as well as alarm reminders.

IMPACT

ERT's patient training program cut the placebo response rate in half from that typically seen in migraine studies. This significant reduction delivered more accurate trial data and supported the successful outcome of the biopharma's PIII trial.

"*This study clearly shows the vital role patient and rater training plays in delivering higher-quality data in clinical trials*," comments Ken Faulkner, Vice President, eCOA Science, ERT. "*ERT's training enabled the sponsor to demonstrate that their drug was statistically differentiated from the placebo on the two co-primary endpoints.*"

The trial also delivered high compliance rates. Investigative sites received email alerts when patients reported migraines, which allowed them to track when patients completed an assessment and follow-up when necessary.

PATIENT TRAINING REDUCES PLACEBO RESPONSE RATE BY OVER 50%

Improve clinical trial data quality with ERT eCOA.
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