Case Study

Outcome Trials

DESCRIPTION

- Evaluating efficacy and safety of study drug added to standard therapy in reducing incidence of atherothrombotic events
- A phase III, randomized, double-blind, placebo-controlled study of a platelet PAR-1 receptor inhibitor in atherosclerosis (2007–2012)
- Patients: Adults with a history of MI, ischemic stroke, or PAD
- 26,499 randomized to 2 treatment arms

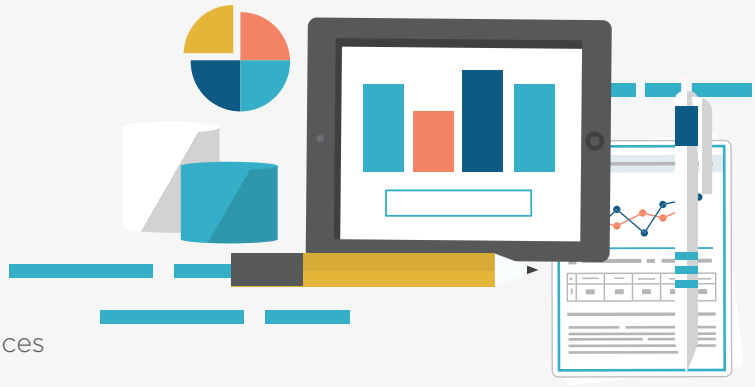
CHALLENGE

- To evaluate the efficacy and safety of the study drug when added to standard therapy, in reducing incidence of atherothrombotic events relative to the study therapy alone
- Numerous cultures and time zones to navigate: 1032 sites in 32 countries, including Asia-Pacific, South Africa, Western and Eastern European Union and North and South America
- Retaining subjects for the study duration (4-5 years)

SOLUTION

Our expert team collaborated with the TIMI Study Group to provide:

- Project and site management (with the exception of North America)
- Global CTMS
- IVRS
- Statistical programming
- Drug supply and investigator payment services
- Clinical monitoring for UK sites (48)
- Solutions were available from the offset due to a Project Operating Procedure Manual already created by our expert team



OUTCOMES

Integration of Worldwide services, efficient coordination of vendors, and immediate contact and tracking of patients after only one missed visit, were some of many solutions that resulted in:

THE IDENTIFICATION OF

4,074 ENDPOINTS

99.9% FOLLOW-UP RATE

(2% of patients withdrew consent for follow-up)

TRIAL WAS CITED AS A 'MODEL OF RIGOR' FOR EXECUTION AND DATA INTEGRITY BY FDA CV ADVISORY PANEL

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