



CASE STUDY

PRAHEALTHSCIENCES

CHALLENGING STUDY TIMELINE GOALS ACHIEVED IN GLOBAL POST-AUTHORIZATION SAFETY STUDY (PASS)

Cutting-Edge Analytics Transform Global Cardiovascular Post-Marketing Commitment





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STUDY DESCRIPTION

A global real world safety study program, mandated by various regulatory bodies, to confirm risk/benefit profile for a novel oral anticoagulant. The first study was designed to generate data on the effectiveness of the study drug to reduce the risk of stroke in patients with atrial fibrillation. The second study was designed to collate data from patients treated for an acute deep vein thrombosis with either the study drug or Standard of Care. Both studies investigated the bleeding risk associated with the study drug.

STUDY DURATION

72
MONTHS

NO. OF CLINICAL SITES

888

PATIENT POPULATION

16,676

TREATMENT PERIOD

12+
MONTHS

PRIMARY ENDPOINT

Post-marketing safety of novel treatment

PRIMARY SERVICES

Analysis & Reporting
Data Management
(including multilingual EDC)
Direct-to-Patient Management
Drug Safety-SAE Reporting
Medical Writing
Project Management
Quality Review Visits
Vendor Management

INDICATION

Stroke Prevention
Treatment of DVT

DRUG CLASS

Chemical Entity

STUDY PHASE

Phase IV

BUSINESS SEGMENT

Late Phase Services

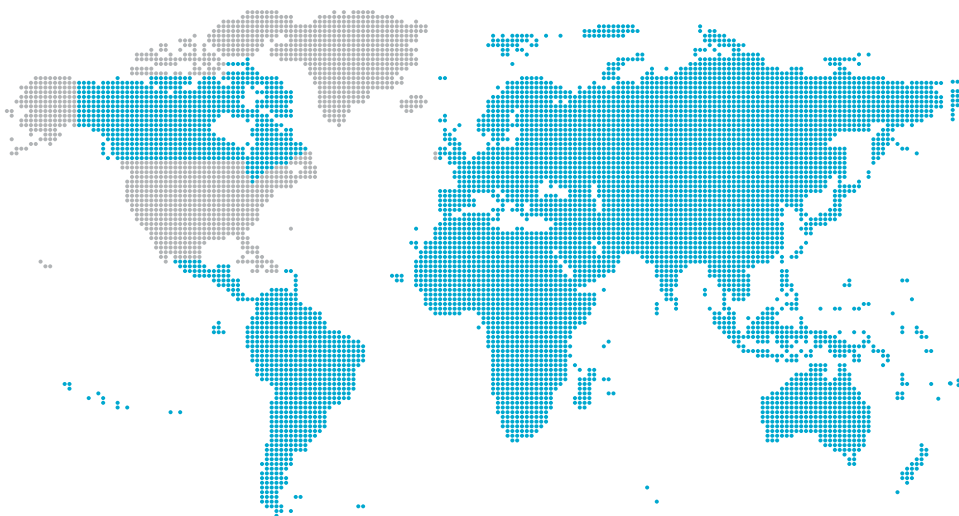
REGIONS

North America (Canada)
Eastern and Central Europe

Latin America
Middle East

Western Europe
Africa

Asia Pacific





SITUATION

A leading pharmaceutical company selected PRA's Late Phase Services (LPS) division to conduct 2 Post-Authorization Safety Studies (PASS) to evaluate the risk/effectiveness profile of a highly innovative blockbuster oral anticoagulant drug throughout global markets. The LPS team contended with each study challenge through our superior operational design aligned with product approval and uptake, use of innovative analytics to identify trends and risk, and commitment to global transparency.



CHALLENGES

- The sponsor's previous use of individual local CROs and separate protocols by country compromised efficient global study roll out due to their lack of operational oversight and parallel strategies.
- More than 50 countries with research-naïve sites were slated for start-up, including several non-English speaking sites, which risked accurate completion of the required data collection.
- Due to the drug's novel compound class and treatment approach, evaluating the drug's risk/effectiveness profile required high-quality data and location-specific regulatory standards.
- The size of the studies generated a high volume of safety events with complex reporting requirements varying by country.
- Without concise oversight and established communication channels between the global team, the sites, and the sponsor's local affiliates, many sites' data entries/signatures were backlogged, threatening on-time database lock and our sponsor's regulatory compliance.



SOLUTIONS

- The LPS team overcame each of these challenges by devising a plan that accomplished several key processes in tandem, mitigating the risk for timeline delays.
- The team developed a multilingual (6 languages) electronic data capture (EDC) database that included:
 - Intuitive data collection screens.
 - System configurations to minimize site burden.
 - Programmed edit checks to align with Standard of Care.
- Multilingual central monitoring teams supported manual queries in the local languages.
- Site training was completed in local languages directly within the EDC system via eLearning.
- Optimized site management was supported through analytics, complemented by on-site quality review visits based on pre-identified triggers.
- Subject data medical review through data visualization tools eliminated the likelihood of data inconsistencies.
- Safety cases were processed through different drug safety hubs to manage volume and provide timely data reporting.
- Our multilingual Patient Management Associates (PMAs) conducted direct-to-patient follow-up to increase subject retention and maintain high quality study data.



- The team eliminated data entry/signature backlog and achieved on-time database lock through state-of-the-art analytics.
- By combining our analytics with key performance indicators, our team introduced programmed site status letters to ensure each site maintained consistent data entry and on-time database lock (Figure 1).

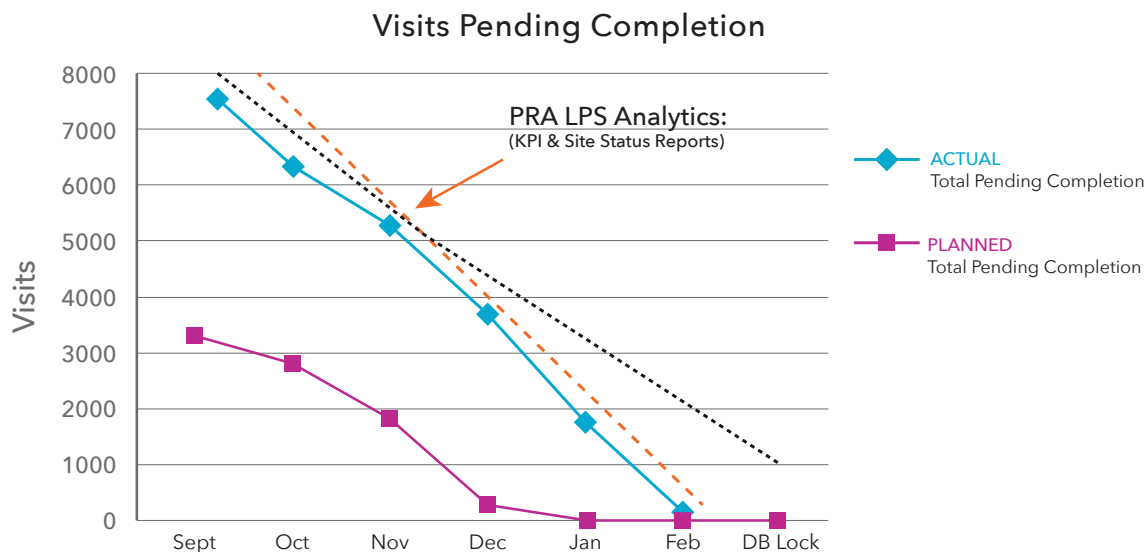


Figure 1: Data Collection Before and After PRA's Analytics Site Status Letter Launch



RESULTS

Our ability to provide global operational oversight and efficiencies, ensure consistent communication with sites, and keep our patients engaged resulted in the successful review of 858,600 pages, in which over 482,574 queries have been fired, many requiring data management review. Our team also created over 1,557 tables, figures, and listings (TFL) to support various internal and external stakeholder needs. By working closely with the client to establish achievable goals and maintain open communication regarding project risks, the LPS team has become the client's CRO of choice and is currently rolling out regulatory-mandated studies in several other countries globally.

"A very big 'thank you!' to the PRA team! Thank you for proactively suggesting that we use your tailored report and for providing it to us in a timely and cost effective manner."

"I would like to personally congratulate the (Sponsor's) team in cooperation with the PRA team for performing this remarkable progress for the sites! This is great and wonderful teamwork! Thank you."

-Large Pharma, Global Project Manager, Non-Interventional Studies

PRA Health Sciences conducts comprehensive Phase I-IV biopharmaceutical drug development.

To learn more about our solutions, please visit us at prahs.com
or email us at prahealthsciences@prahs.com.