



CASE STUDY

PRAHEALTHSCIENCES

PRA SUCCESSFULLY RESCUES PHASE II HEMATOLOGY STUDY

Effective Project Plan Identifies Risks, Enables Timely Transition





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STUDY DESCRIPTION

A Phase II, single-blind, randomized, placebo-controlled trial to study the efficacy and safety of Study Drug administered as adjunctive treatment to patients with acquired thrombotic thrombocytopenic purpura

STUDY DURATION

37
MONTHS

NO. OF CLINICAL SITES

45

PATIENT POPULATION

110

TREATMENT PERIOD

90
DAYS

PRIMARY ENDPOINT

Time-to-response

PRA SERVICES

Full Service

INDICATION

Thrombocytopenia

DRUG CLASS

Antibody

STUDY PHASE

Phase II

REGIONS

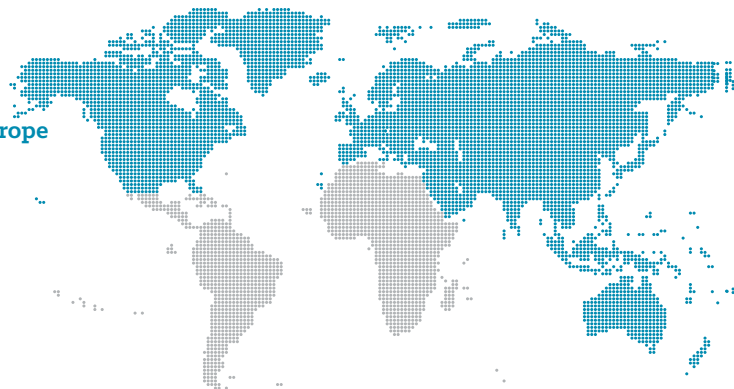
North America

Western Europe

Central & Eastern Europe

Middle East

Asia Pacific



SITUATION

PRA was selected to take over a Phase II hematology study from another CRO. The project had missed start-up milestones, and the client was dissatisfied with the previous CRO's site management.



CHALLENGES

Certain challenges are inherent to rescue studies, particularly at the beginning of the trial process. A timely transition is critical to recover from start-up delays that were incurred prior to rescue, as well as to reduce duplicate payments for the client. In this case, obtaining the necessary information and start-up documentation from the previous CRO was particularly challenging. PRA needed to implement and update our systems quickly to be able to fully assess the project's status. Finally, recruiting patients for a rare disease with relatively few patients requires carefully planned enrollment strategies.



SOLUTIONS

PRA developed a comprehensive plan to guide all aspects of the transition. The plan included risk mitigation measures, transition pathways for each functional area and a detailed schedule of meetings. These meetings covered each applicable functional area to ensure that specialists from each group were involved in discussions. For example, the assigned PRA clinical team members organized calls with CRAs from the previous CRO in all study countries and in some cases conducted co-monitoring visits.

PRA established a transition team immediately upon takeover. The team included core, permanent staff assignments as well as other roles needed for a timely changeover. PRA's clinical team manager and regulatory staff were able to initiate work on the transition plan right away. A central PRA contact was assigned to track incoming documents from the previous CRO, so that missing information could be addressed at weekly transition calls.

A clear regulatory strategy was essential to position PRA for project takeover. This global study involved wide-ranging regulatory authorities with differing requirements. The PRA regulatory team planned conference calls with every regulatory agency involved in the project and notified them of the changes and submitted amendments where necessary, allowing PRA to take over responsibilities in each country as quickly as possible.

PRA had successfully collaborated with this client before and leveraged the existing partnership throughout the transition. Strong senior management relationships and our knowledge of the client's working practices contributed to effective communication and project planning.



RESULTS

With an organized approach, PRA achieved the agreed-upon transition milestone. We gained control of the study effectively, enabling a smooth transition and allowing for accurate project status evaluation. Working with the client, PRA developed renewed enrollment goals for the study and has begun making strategic recommendations accordingly. Due to PRA's ability to manage a complex transition, the study is now positioned for future success.

The client selected PRA to take over a challenging study based on a history of success. PRA delivered results and guided the client's study back on track.

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