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CASE STUDY

PRAHEALTHSCIENCES

PRA DELIVERS STUDY START-UP SUCCESS

Contingency Plan Leads to Timely FPI





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STUDY DESCRIPTION

A Phase IIa randomized double-blind, placebo-controlled, multi-center study to evaluate the efficacy, safety, and tolerability of Study Drug when given Methotrexate (MTX) to subjects with active rheumatoid arthritis (RA) who have had an inadequate response to conventional disease-modifying anti-rheumatic drug therapy (DMARD).

STUDY DURATION

24
MONTHS

No. OF CLINICAL SITES

28

PATIENT POPULATION

150
adults with active
rheumatoid arthritis

TREATMENT PERIOD

3
MONTHS

PRIMARY ENDPOINT

To evaluate the clinical efficacy of the Study Drug with MTX in subjects with active RA who have had an inadequate response to DMARD therapy

PRA SERVICES

Full Service

INDICATION

Rheumatoid Arthritis

DRUG CLASS

Small Molecule

STUDY PHASE

Phase IIa

BUSINESS SEGMENT

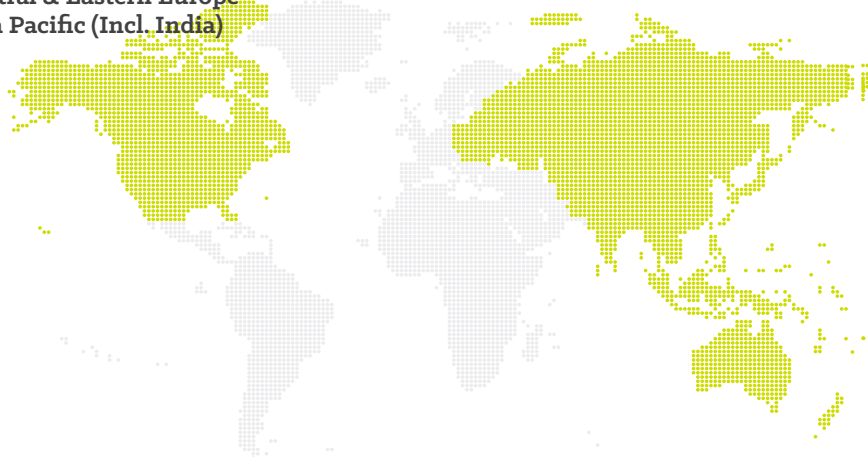
Product Registration

REGIONS

North America

Central & Eastern Europe

Asia Pacific (Incl. India)



SITUATION

After an impressive bid defense, a major PRA client awarded a rheumatoid arthritis study contract based on our strategy for achieving first-patient-in (FPI) by the end of the calendar year. PRA's plan depended on a closely managed project with clear timelines and responsibilities, as well as selecting key sites that could support our goal.



CHALLENGES

During the ethics committee (EC) submission process, last-minute revisions to the subject questionnaire and a protocol amendment caused PRA to miss the established EC milestone. In addition, PRA would have to screen patients during the December holiday season, and there were delays with the investigational product/supply shipments.



SOLUTIONS

PRA and the client recognized the need to address study start-up delays. The PRA team collaborated to develop an innovative and efficient contingency plan, which involved activating 4 new central institutional review board (IRB) sites in Canada and targeting Ministry of Health (MoH) approval in November. Although the FPI goal was escalated to “at risk” status in November, we continued to proactively identify and manage all risks while maintaining continual communication with the client through weekly project start-up summary reports.



RESULTS

Despite numerous study start-up delays and challenges, PRA reduced the project’s cost by approximately 15% through our ability to enroll the targeted number of patients with fewer sites and in a shorter time period. In addition, we met the client’s corporate FPI goal, randomizing the first subject on the fifth month. PRA and this client are now in a successful strategic partnership with a relationship focused on absolute transparency, frequent communication, and clear responsibilities and expectations.

MONTH 1	MONTH 2	MONTH 3	MONTH 4	MONTH 5
• Letter of Intent Signed • Initial Protocol/Final Investigators • Brochure	• Final Feasability Report • Client/PRA Kick-off Meeting • Selection of 2 FPI Countries (AUS & CAN) • Submission of Protocol Version 2 in Australia	• Protocol Version 3 • EC/MoH Review (AUS & CAN) • MoH Approval (CAN) • EC Approvals (AUS & CAN)	• First Site Activated • MoH Approval (AUS)	• SIVs (AUS & CAN) • First Patient Screened • First Patient Randomized

Despite unexpected study delays and challenges, PRA met the client’s FPI goal by:

- Developing an effective contingency plan.
- Proactively identifying and managing risks to the client’s goal.
- Maintaining excellent communication with the client’s project team.

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.