



CASE STUDY

PRAHEALTHSCIENCES

PRA'S STRATEGIES IMPRESS CLIENT

Tight Timelines, Last-Minute Changes — No Problem



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STUDY DESCRIPTION

A randomized, double-blind, placebo-controlled study of the safety and tolerability of Study Drug and its effects on biomarkers in subjects with coronary artery disease

STUDY DURATION

48
MONTHS

NO. OF CLINICAL SITES

136

PATIENT POPULATION

700

TREATMENT PERIOD

20
WEEKS

PRIMARY ENDPOINT

Safety & tolerability

PRA SERVICES

Full Service

INDICATION

Stable Angina

DRUG CLASS

Antibody

STUDY PHASE

IIb

BUSINESS SEGMENT

Product Registration

REGIONS

North America

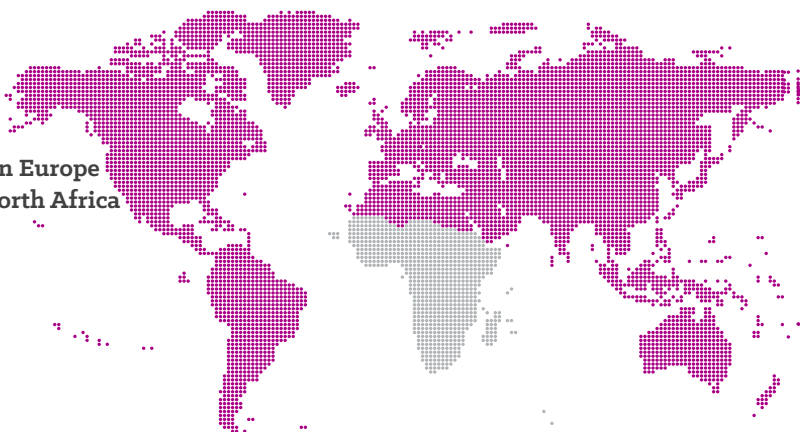
Latin America

Western Europe

Central & Eastern Europe

Middle East & North Africa

Asia Pacific



SITUATION

PRA was awarded a global Phase II safety and tolerability study of a drug with a novel action for the treatment of coronary artery disease. The study, which involved more than 130 sites and 700 patients, encountered many challenges due to last-minute design and operational changes and tight timelines. Regardless, PRA completed the study successfully, thanks to our project team's determination and innovation.

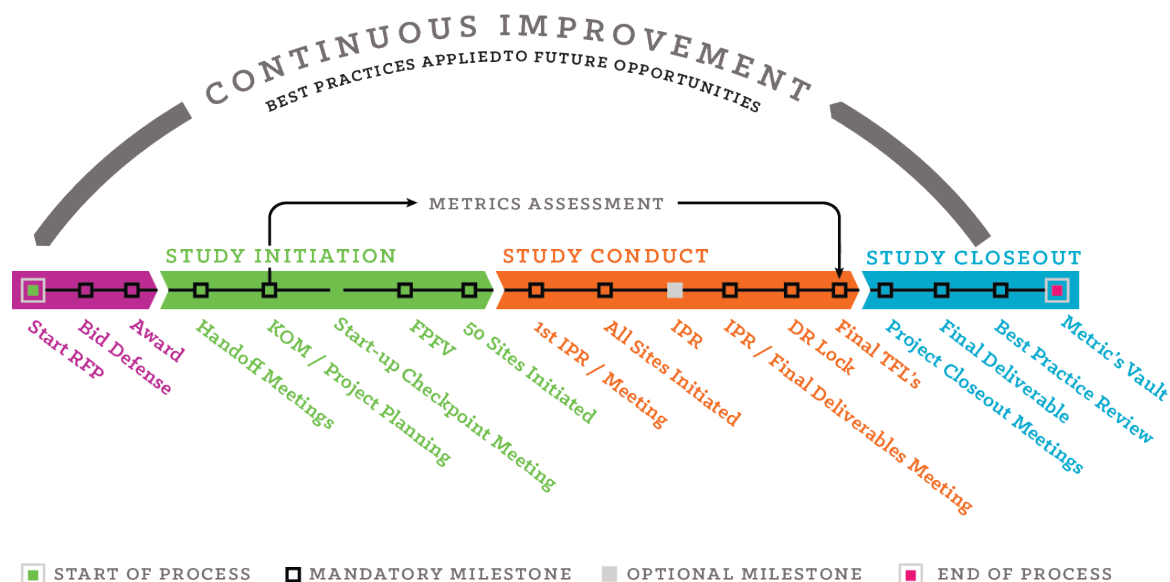


CHALLENGES

This study required PRA to achieve milestones under extremely challenging timelines and operational logistics. For example, the team had to execute a late requirement to fully lock 90% of the subjects 5 months earlier than originally planned. This initiative required fast implementation of a patient profile review process, which also had not been previously required, and reconciliation across 6 vendors. The revised schedule put extra pressure on team members, who had to work nights and weekends for months. Site relationships were strained, and there were difficulties with reviewing profile data that was still being monitored, collected, and cleaned. In addition, profile review cohorts



overlapped, and each cohort required specific data collection/query cycles in conjunction with case adjudications. This mandated a complex orchestration of resourcing, CRF/query/profile tracking, vendor reconciliation, and both internal and site communications. As a result, changes in the timing of any step required numerous communication and planning adjustments to mitigate risks that would otherwise jeopardize the aggressive timelines that had been introduced mid-study.



PRA PROJECT MANAGEMENT



SOLUTIONS

PRA recognized the need for different strategies in Europe and North America due to language and equipment limitations. For example, the call center concept did not translate well in Europe, even though this was implemented promptly and successfully with a dedicated sub-team in North America to facilitate the support of sites in query resolution and prioritization of work. In Europe, in-house CRAs were utilized for key site communication in support of the CRAs who were traveling extensively to meet the monitoring demands. PRA also programmed a number of customized tools to provide the team with tracking mechanisms that distilled complex information so the team and sites could respond with decisive action and efficient status communication. Interim monitoring visits (IMVs) were pre-scheduled at difficult or high-volume sites during precise days per the cohort review timelines when queries were to be issued, which greatly improved turnaround. These visits also required very close coordination with PRA's Data Management group. PRA escalated issues of non-responsive sites promptly to enable the client to support actions toward resolving the problems. In addition, PRA worked with the vendors extensively to obtain status on their data cleaning and coordinated the cleaning and reconciliation of the clinical database.



RESULTS

Thanks to PRA's leadership, tenacity, and big-picture vision, we achieved a quality clinical database lock on time. A pre-lock database audit confirmed all data met quality standards despite over 16,000 queries having been sent, retrieved, and processed in under 5 months. Our experiences on this study generated many lessons learned that the project team has shared throughout the company, which will be beneficial to our clients in the future (see Key Points & Brief below). The way PRA overcame the study's challenges also strengthened our partnership with the client, as demonstrated by the client's quotes on page 3.

PRA remained flexible and determined to reach our goals during this study, which strengthened our client part-



nership. We delivered quality results in a study that featured unrealistic timelines, communication problems, and unresponsive sites. In addition, this study's success is owed in part to the following lessons learned:

- Utilize in-house CRAs in addition to CRAs for following up on query responses
- Pre-schedule IMVs at difficult or high-volume sites during key query-cycle time points, and avoid altering the individual cohort review timelines
- If required, plan for the patient profile process at study start
- When case adjudications are required, plan to implement a re-adjudication cycle between freeze/lock
- In situations where complex timelines must be carried out with the orchestration of many functional groups, design and utilize communication tools that clearly convey status and requirements to ensure everyone is working in sync toward the same daily priorities
- Ensure every team member is managing from one set of timelines

“Congratulations, we have now received and delivered the datasets to biostats and are considered officially LOCKED! My most sincere gratitude and appreciation for your endless efforts and support in achieving this critical milestone! Your hard work, long hours, and perseverance are much appreciated by the entire team!..”

– CLIENT DIRECTOR, OPERATIONS

“In my 20+ years in the industry, you are the BEST project manager I have ever had the pleasure to work with. Your leadership, tenacity, attention to detail, and big picture vision helped turn our screaming, gut-wrenching, roller-coaster study around to a much nicer and smoother roller-coaster ride.”

– CLIENT ASSOCIATE DIRECTOR, OPERATIONS

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