



CASE STUDY

PRAHEALTHSCIENCES

PRA EXCEEDS TOUGH ENROLLMENT GOALS

Service Delivery Model Drives Positive Results





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STUDY DESCRIPTION

A Phase IIb, double-blind, randomized, parallel-group, placebo-controlled study to evaluate the safety, tolerability and efficacy of Study Drug in adults with chronic hepatitis C virus infection

STUDY DURATION

22
MONTHS

Nº OF CLINICAL SITES

130

PATIENT POPULATION

240

TREATMENT PERIOD

6.5
MONTHS

PRIMARY ENDPOINT

Safety, tolerability, and efficacy of study drug

PRA SERVICES

Full Service

INDICATION

Hepatitis C

DRUG CLASS

Caspase Inhibitor

STUDY PHASE

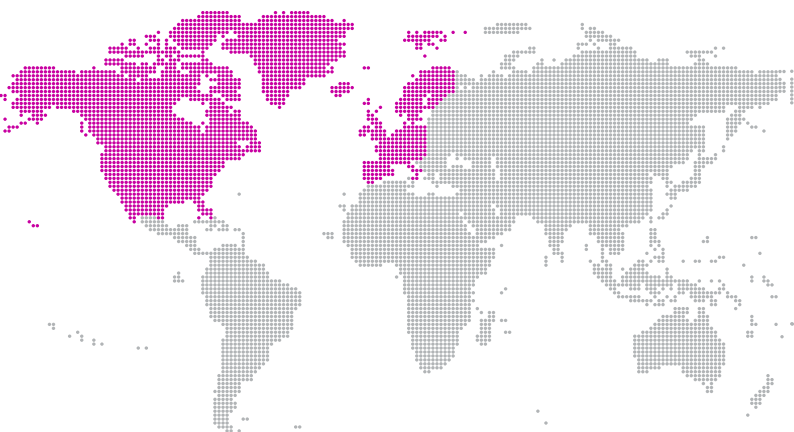
IIb

BUSINESS SEGMENT

Product Registration

REGIONS

North America
Western Europe
Central Europe



SITUATION

A large biotech client awarded PRA a full-service contract to perform a Phase IIb study of hepatitis C drugs with a target to enroll 240 subjects in 130 global sites.



CHALLENGES

Changes in resources for both the client and PRA teams led to significant challenges with the start-up and enrollment activities in Europe and North America. Because the study's enrollment criteria and endpoint involved invasive procedures, project team members questioned whether sites would be interested, and if the subjects could be enrolled in a reasonable time or at all. The client expected PRA to overcome these obstacles and follow the contracted timelines.



SOLUTIONS

Relying on its innovative Service Delivery Model, PRA escalated concerns and took the following actions:



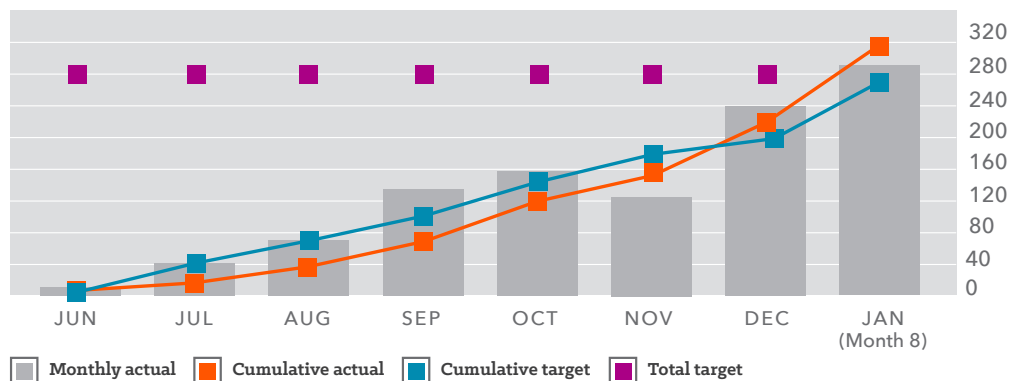
- Replaced the Director of Project Delivery (DPD) and project managers in both Europe and North America to better align with the client's project needs
- Arranged a meeting between PRA's executive vice president of Clinical Operations in Europe, the DPD, and the client to discuss strategies for improving start-up timelines in Europe
- With oversight from the new DPD and project director (PD), developed an activation and enrollment plan that addressed concerns specific to regions and study design
- Established monthly status meetings between PRA's and the client's management teams to discuss potential concerns and focus areas
- Scheduled ongoing meetings between the DPD and the PD to discuss areas of risk and mitigation plans

Several months into the project, PRA and the client distributed a feasibility questionnaire to investigators to address ongoing concerns regarding the invasive procedures. Investigators agreed recruitment would be challenging, but thought subjects could be enrolled. Based on the questionnaire responses, PRA and the client generated an activation and enrollment plan. To expedite enrollment, the PRA team:

- Used sites that relied more on subject databases than advertising
- Initiated a Phase I strategy
- Monitored site-aging and screen-to-enroll ratios, and included metrics in newsletters and email blasts
- Provided focused and consistent support to the sites to discuss subjects and enrollment criteria

The project teams realized that to successfully complete the trial, they would have to ensure that the subjects finished the treatment period and returned for the on-treatment invasive test. The teams established tracking mechanisms and communication plans that kept both sites and subjects informed about testing and appointment times.

Subject Enrollment - Number of Subjects Enrolled By Month (12-Month Window)



RESULTS

PRA overcame the challenges that the resource changes presented, completing both screening and enrollment a month earlier than scheduled (see figure above). Pleased with PRA's work and the relationships the project teams have built, we are now a preferred provider for this client.

Client satisfaction was a result of PRA exceeding expectations. By working closely with the client to establish achievable goals and maintain open communication regarding project risks, PRA was able to develop and maintain a true partnership, which has led to the establishment of trust and new opportunities with the client.

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