



CASE STUDY

PRAHEALTHSCIENCES

DIAGNOSTIC RESEARCH PROGRAM SUCCESS

PRA's Planning and Innovation Reduce Costs



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STUDY DESCRIPTION

Non-invasive screening for fetal aneuploidy: a new maternal plasma marker

PRIMARY ENDPOINT

Develop a prenatal aneuploidy test

PRA SERVICES

Analysis & Reporting
Clinical Operations
Data Management
Project Management
Scientific Leadership/
Consulting

INDICATION

Fetal Diagnostic

STUDY PHASE

IV

BUSINESS SEGMENT

Clinical Diagnostic Services

STUDY DURATION

30
MONTHS

NO. OF CLINICAL SITES

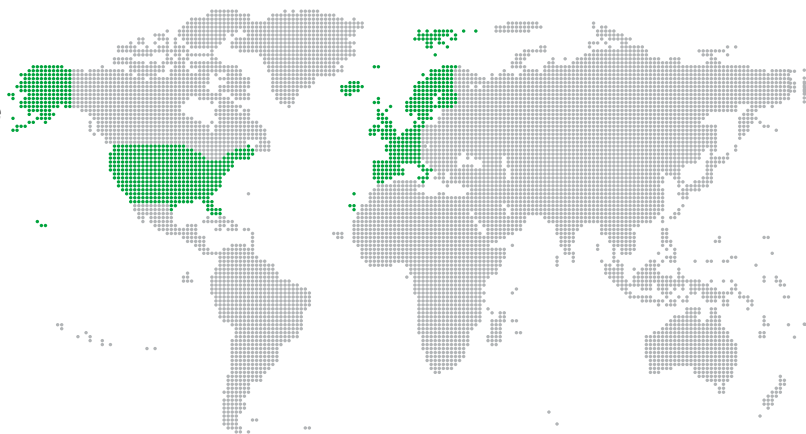
37

PATIENT POPULATION

6,600

REGIONS

United States
Western Europe



SITUATION

A biotechnology company selected PRA's Clinical Diagnostic Services (CDS) group to conduct a global diagnostic study, which involved validating innovative, non-invasive blood sample test results collected from high-risk pregnant women against the "gold standard" results from amniocentesis or chorionic villus sampling.

To successfully complete the program, the PRA team had to ensure the study tested only high-quality maternal blood samples. Therefore, the study would need to over-enroll for any damaged samples, which would require additional funds.



CHALLENGES

The study required PRA to deliver milestones under extremely challenging timelines and operational logistics. For example, the team had to fully lock 90% of the subjects 5 months earlier than originally planned. This ramped-up schedule required the accelerated implementation of a new patient profile review process and reconciliation across 6 vendors. The schedule also put extra pressure on our team members, who had to work nights and weekends for months. Site relationships were strained, and there were difficulties with reviewing profile data that were 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. To manage the cohorts, PRA developed a complex orchestration of resourcing, case report form (CRF)/query/profile tracking, vendor reconciliation, and 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.



SOLUTIONS

The PRA project team understood that developing a comprehensive sampling and logistics plan would be critical in meeting many of the study's challenges. Our CDS director of Scientific Affairs, project manager, and operational team lead worked together to create the plan, while the project team members successfully executed its implementation. This strategic planning and teamwork ensured the timely delivery of viable samples in a highly efficient and coordinated manner.

Our team also assisted with protocol development to clearly define the steps involved in the specimen processing. PRA developed and conducted extensive training with each site's participating staff members. We also implemented a robust vendor management and courier strategy to facilitate timely specimen processing.

In addition, PRA created a non-interventional study design to limit patient risks and introduce new efficiencies into the study.



RESULTS

PRA's strategic planning and teamwork ensured the timely delivery of viable samples in a highly efficient and coordinated manner.

PRA's approach led to successful specimen processing in both in both the US and France, which yielded an overall success rate of approximately 98% in delivering viable samples on time for processing and inventory. Roughly 1,380 samples have been collected by study sites, and only 35 samples could not be processed.

Furthermore, PRA's non-interventional study design provided financial value to the client. PRA achieved minimal patient risk by only requiring a simple blood draw, enabling the study to be categorized and approved by the Institutional Review Board (IRB) as qualified minimal risk. This design also enabled rapid study start-up and reduced operational burden on the sites. These factors reduced investigator grant costs, as well as client costs associated with PRA's overall study management. Cumulatively, the streamlining of processes and resulting efficiencies maximized the client's return on investment without compromising quality or control.

Key Points & Brief

- Client management and partnership are essential, particularly when collaborating with a research-naïve client on a logistically complex study design.
- PRA gained knowledge on how best to manage, mitigate, and prevent financial risk and exposure while working with biotech companies.
- Clearly defined objectives and a mutual understanding of assumptions are crucial to success in studies with dynamic client needs.

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