

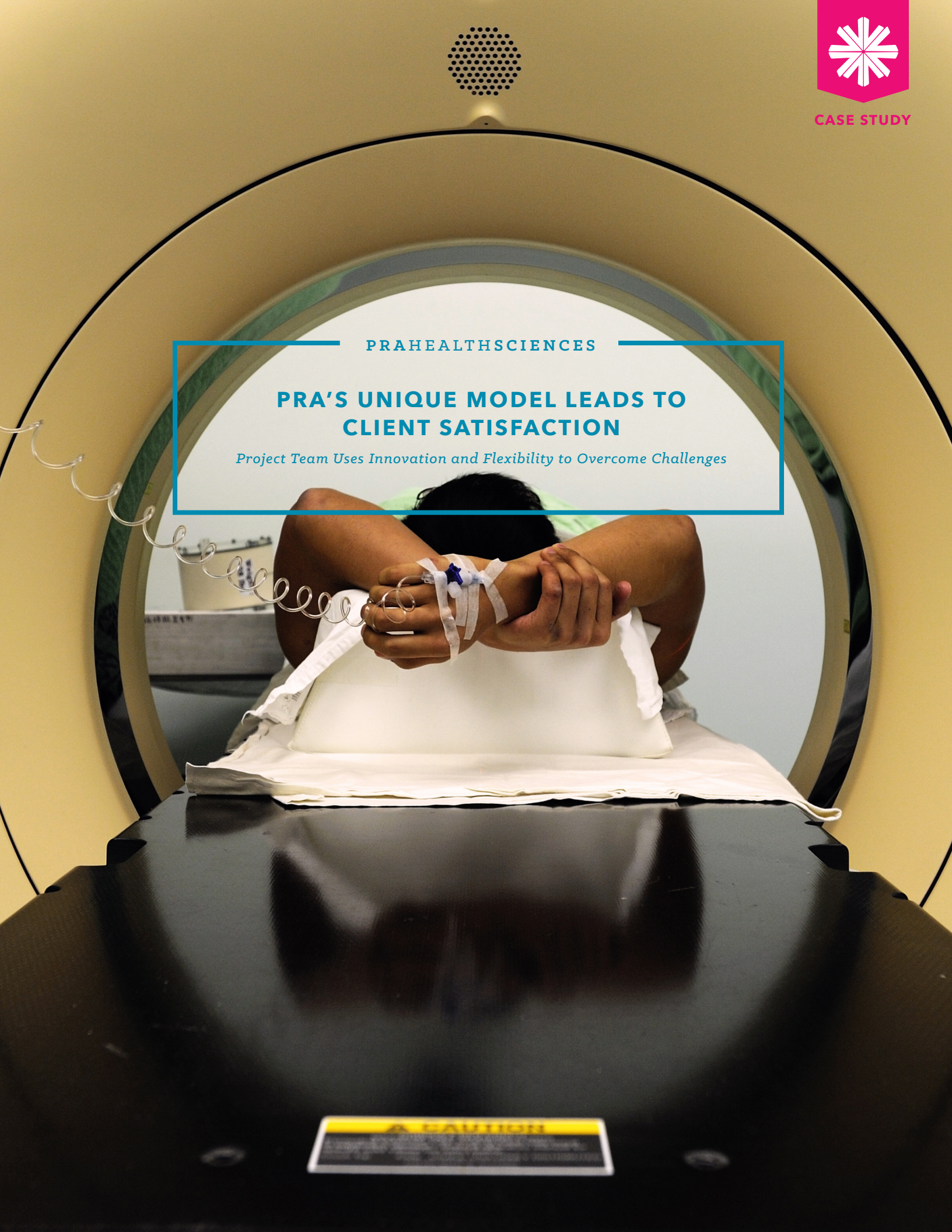


CASE STUDY

PRAHEALTHSCIENCES

PRA'S UNIQUE MODEL LEADS TO CLIENT SATISFACTION

Project Team Uses Innovation and Flexibility to Overcome Challenges





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STUDY DESCRIPTION

A randomized, double-blind, placebo-controlled, Phase II study evaluating the efficacy and safety of Study Drug A in combination with Study Drug B administered as first-line treatment to subjects with unresectable, locally advanced, or metastatic pancreatic adenocarcinoma

STUDY DURATION

31
MONTHS

No. OF CLINICAL SITES

65

PATIENT POPULATION

168

TREATMENT PERIOD

6
MONTHS

PRIMARY ENDPOINT

Overall Survival

PRA SERVICES

Full Service

INDICATION

Pancreatic Cancer

DRUG CLASS

Nucleoside Analog

STUDY PHASE

II

BUSINESS SEGMENT

Product Registration

REGIONS

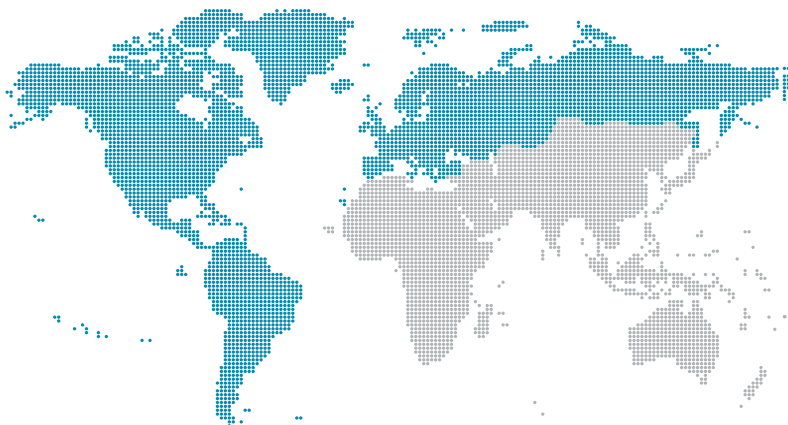
North America

Latin America

Western Europe

Central and

Eastern Europe



SITUATION

PRA was awarded a global, full-service Phase II pancreatic cancer trial by a biotech client. The project was originally launched by a different company that PRA's client had acquired. The first sites were opened in October, with first-patient-in occurring in January.



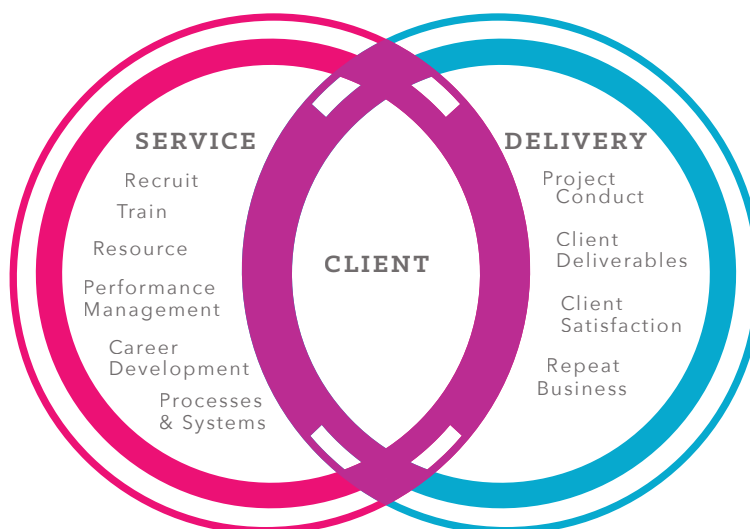
CHALLENGES

PRA's key challenges include study start-up delays and client communication issues.



SOLUTIONS

We improved the situation through our Service Delivery Model—by developing an effective communication plan that involved daily and weekly calls between PRA project managers and the client. The calls gave both parties opportunities to review questions and PRA's performance. This process was successful in building the solid and trusting relationship that continues today.



PRA's Service Delivery Model

PRA collaborated with the client on its financial constraints, which it shared with PRA in July following the start of the study. With only 6 months left in the year, the client requested that PRA make an accrual impact of \$430k USD. The accrual impact was achieved by reviewing all tasks with the client and internally discussing which activities could be reduced or postponed, assessing the impact on the quality of the deliverable, and finally agreeing on a change order. The change order enabled the client to continue the study within its financial constraints and with new expectations for data quality.



RESULTS

Overcoming these challenges resulted in many successes for both companies, including client satisfaction and financial management. The last site was initiated in February, with last-patient-in occurring in March (originally contracted patients enrolled 1 month ahead of schedule). Last-patient-out took place in November, and a successful database lock occurred in January.

PRA's successes are the result of quality work, dedication, and effective communication. Our Service Delivery Model combined with the project team's collaborative approach allowed a Europe-based project manager to successfully manage the US-based 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.