



CASE STUDY

PRAHEALTHSCIENCES

PERSISTENCE LEADS TO HIGH ENROLLMENT

PRA Convinces Client to Stick with Recruitment Strategies



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STUDY DESCRIPTION

A Phase IV, randomized, single-blind, placebo-controlled, multi-center study to evaluate the immunogenicity of pneumococcal and influenza vaccines in adult subjects with rheumatoid arthritis receiving Study Drug or placebo

PRIMARY ENDPOINT

Immunogenicity of pneumococcal and influenza vaccines

PRA SERVICES

Medical Affairs
Project Management
Site Management
Site Monitoring
Site Recruitment
Vendor Management

INDICATION

Rheumatoid Arthritis

DRUG CLASS

Biologic

STUDY PHASE

IV

BUSINESS SEGMENT

Late Phase Services

STUDY DURATION

18
MONTHS

NO OF CLINICAL SITES

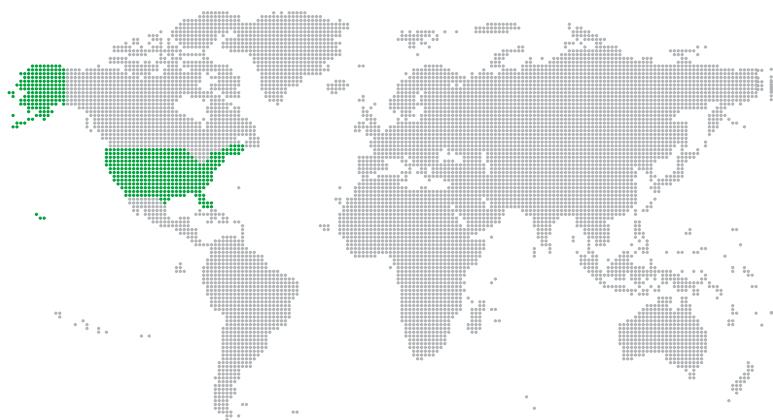
50

PATIENT POPULATION

220

REGION

United States



SITUATION

PRA was contracted by a large biotech client to evaluate the immunogenicity of a flu vaccine in adult subjects with rheumatoid arthritis. Early on, PRA realized the potentials for study delays and so began discussing recruitment planning strategies with the client.



CHALLENGES

From the start, the PRA study team faced a shortened enrollment period and other timeline challenges, including the protocol's late delivery, as well as problems with the vaccine's availability. The study team realized that the shortened enrollment period would limit the number of patients eligible for recruitment because many would have had already received their seasonal flu and/or H1N1 vaccinations. In addition, the client resisted PRA's initial attempts to discuss and implement recruitment planning strategies.

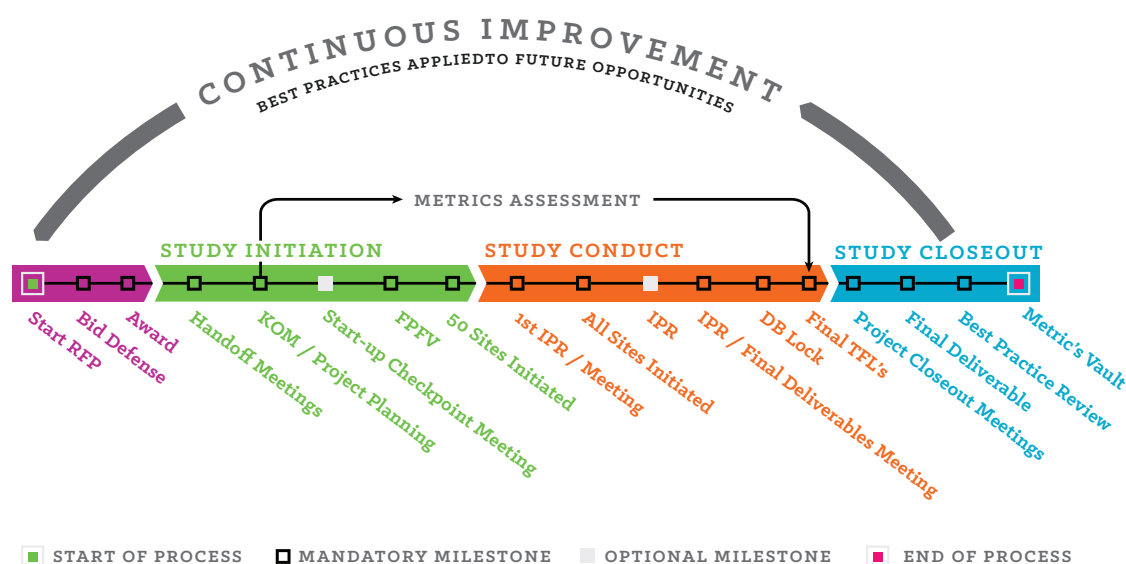


SOLUTIONS

The project team utilized PRA's Project Management Methodology (see graphic below), which supports project teams in every project-related objective, and our Service Delivery Model, with its focus on delivery and service, to



ensure the successful execution of this project. PRA held weekly recruitment planning discussions with the client, presenting graphs that demonstrated how October and November could produce solid screening results. At the end of October, PRA implemented a weekly e-mail blast to sites providing updates on enrollment and other hot topics. By November, PRA convinced the client to allow us to request sites to forecast their screening activity for the next four weeks. This effort proved that the sites were not hitting their goals. Therefore, we used that information to get the client to approve additional strategies to help sustain recruitment.



PRA PROJECT MANAGEMENT

Overall, PRA's recruitment strategies involved:

- Informing sites through emails, teleconferences, and bulletins that the flu season hadn't peaked, the H1N1 vaccine doesn't protect against seasonal flu, and the flu vaccine could be given at anytime and still provide benefits
- Communicating to sites that we still needed them to screen, recruitment was still open, and it was an important study per FDA request for the client to complete
- Ensuring clinical team managers, clinical research associates, and medical monitors stayed in frequent contact with sites



RESULTS

The PRA team screened and randomized the first patients 10 days ahead of schedule.

PRA overcame recruitment challenges and exceeded deadline expectations thanks to our dedicated team's knowledge of recruitment strategies, excellent communication with the client, and commitment to success in the face of daunting challenges. It also proved crucial that PRA stressed this study's importance to the sites, so they would never give up on recruitment efforts.

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