OVERCOMING DIFFICULT RECRUITMENT CHALLENGES TO MEET VACCINE STUDY ENROLLMENT GOALS
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STUDY DESCRIPTION
A randomized, observer-blind, placebo-controlled, multi-center, multi-national, Phase III trial evaluating the efficacy, immunogenicity, and safety of a clostridium difficile (C difficile) toxoid vaccine in subjects at risk for C difficile infection (CDI).

PATIENT POPULATION
15,000 adult subjects—aged 50 years or older—at risk for CDI

TREATMENT PERIOD
The vaccine or placebo was administered in a 3-dose schedule on days 0, 7, and 30.

DRUG CLASS
Antibody

STUDY PHASE
Phase III

BUSINESS SEGMENT
Strategic Solutions (Embedded ™) Vaccine Solutions

REGIONs
North America
Latin America
Western Europe
Central Europe
Eastern Europe
Asia Pacific

STUDY DURATION 48 MONTHS
No. OF CLINICAL SITES 300
PATIENT POPULATION AT RISK FOR C DIFFICILE INFECTION 15,000
TREATMENT PERIOD 30 DAYS
PRA Health Sciences enrolled patients according to 1 of 2 risk strata (detailed below) across the treatment groups, which created several key challenges causing delayed enrollment.

- Patients in risk stratum 1:
  - Underwent at least 2 hospital stays (each lasting at least 24 hours) during the 12-month period before enrollment.
  - Received systemic (not topical) antibiotics in the 12 months prior to enrollment.

- Patients in risk stratum 2:
  - Were hospitalized for a planned, in-patient surgical procedure within 60 days of enrollment; hospital stay must be at least 72 hours.

The key enrollment challenges were:

- General unawareness of the disease
- Lack of referral networks for sites not affiliated with the hospitals
- Long-term patient commitments, including multiple surveillance follow-ups
- Lack of site commitment

Within the first few months of enrollment, PRA provided the client with an enrollment enhancement plan, detailing several strategies that addressed the study challenges. In response, the client increased marketing support and site tools, and PRA’s Strategic Solutions group worked closely with the client to identify and mitigate further enrollment challenges.

Key solutions:

- PRA’s Feasibility group identified new sites in the countries initially targeted by the client, as well as in sites that were not, as these sites/countries had a higher potential to enroll eligible patients.
- We applied lessons learned from existing, high-enrolling sites to aid low-performing ones on a country-, regional-, and local-level.
- Our Site Communication Champions group contacted numerous sites to further assess enrollment and assist when needed.
RESULTS

PRA’s strategies helped the client to not only meet challenging enrollment goals, but also helped to foster the client’s ability to recruit for future projects. Once implemented, these strategies contributed to a significant and continued improvement in monthly study enrollment, which ultimately was critical to achieving the study recruitment milestones.

“We could not reach this challenging milestone without PRA’s support. Not only did we achieve our target, but we were also able to reach a much higher confidence level in our ability to project recruitment timelines in the future, which is also a big success.”

-CLIENT’S GLOBAL HEAD OF STUDY MANAGEMENT AND LOGISTICS