CASE STUDY

PRAHEALTHSCIENCES

OVERCOMING 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).

STUDY DURATION
48 MONTHS

No. OF CLINICAL SITES
300

PATIENT POPULATION
AT RISK FOR C DIFFICILE INFECTION
15,000

TREATMENT PERIOD
30 DAYS

PATIENT POPULATION
15,000 adult patients—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

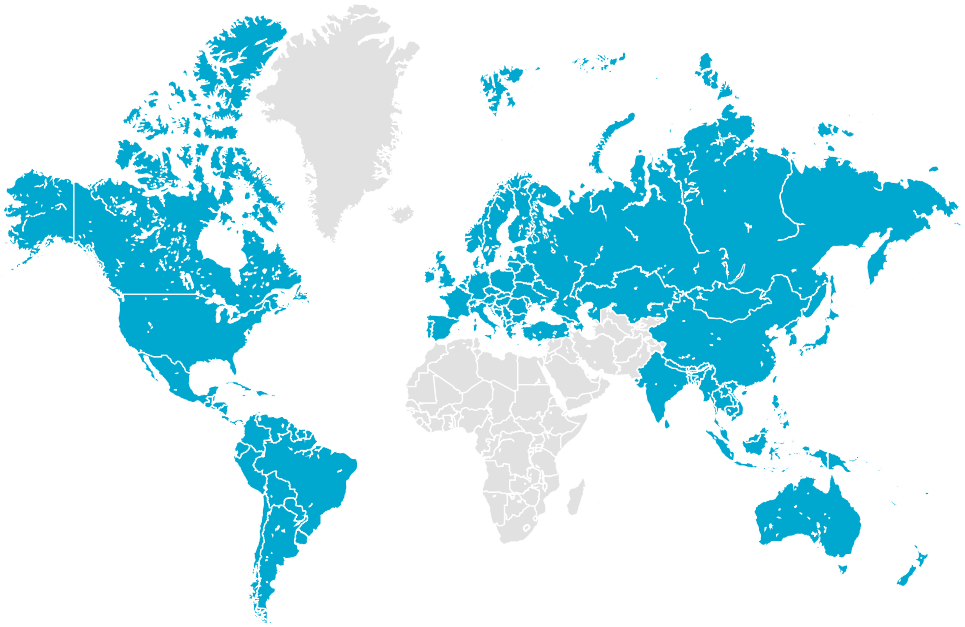
STUDY PHASE
Phase III

BUSINESS SEGMENT
Strategic Solutions embedded services

Vaccine Solutions

REGIONS

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



SITUATION

Protocol dictated that patients be enrolled according to 1 of 2 risk strata (detailed below) across the treatment groups; this created several key challenges in the process, causing the sponsor to face much slower enrollment than projected.

- Patients in Risk Stratum 1:
  - Underwent at least 2 hospital stays (each for 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, inpatient surgical procedure within 60 days of enrollment; hospital stay was at least 72 hours.

CHALLENGES

The key enrollment challenges were:

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

SOLUTIONS

Within the first few months of enrollment, PRA provided the client with an enrollment enhancement plan, which detailed several strategies to address challenges. In response, the client increased marketing support and site tools, and PRA's Strategic Solutions group worked 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 sites in countries 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 help lower-performing ones on the country, region, and local levels.
- Our Site Engagement group (dubbed "champions" by the client) contacted numerous sites to assess enrollment and assist when needed.

RESULTS

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

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.