CASE STUDY

PRAHEALTHSCIENCES

STRONG SITE SELECTION LEADS TO SUCCESS

PRA Screens 5 Months Ahead of Schedule

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STUDY DESCRIPTION

A randomized, double-blind, placebo-controlled Phase III study of Study Drug versus placebo for patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatments

STUDY DURATION
33 MONTHS

No. OF CLINICAL SITES
85

PATIENT POPULATION
170

TREATMENT PERIOD
6 MONTHS

PRIMARY ENDPOINT
Progression

PRA SERVICES
Full Service

INDICATION
GIST

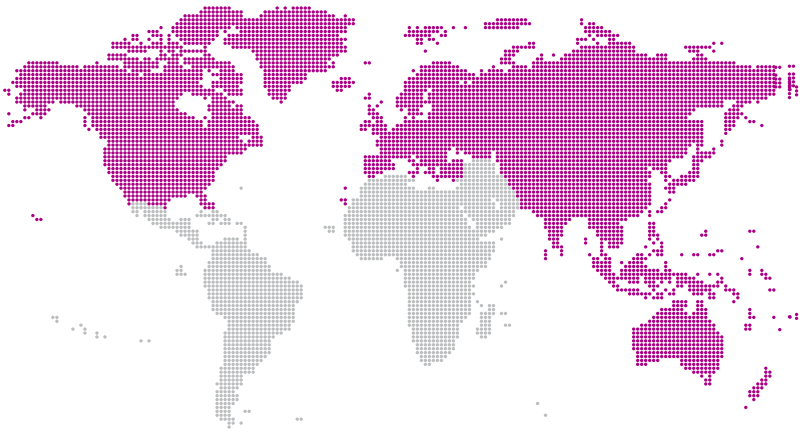
DRUG CLASS
Multikinase Inhibitor

STUDY PHASE
III

BUSINESS SEGMENT
Product Registration

REGIONS

North America
Western Europe
Central and
Eastern Europe
Asia-Pacific



SITUATION

PRA was selected to conduct a global Phase III gastrointestinal stromal tumors (GIST) study for a top 20 large pharmaceutical client.

CHALLENGES

GIST is less specialized in the United States (US) compared to other global locations, and PRA required a large number of US sites to satisfy the regulatory recruitment target. Site identification was also challenging in Europe, as selection occurred during the summer months. While the study's fixed-price contract included a buffer with extra sites, start-up delays effectively reduced this buffer.

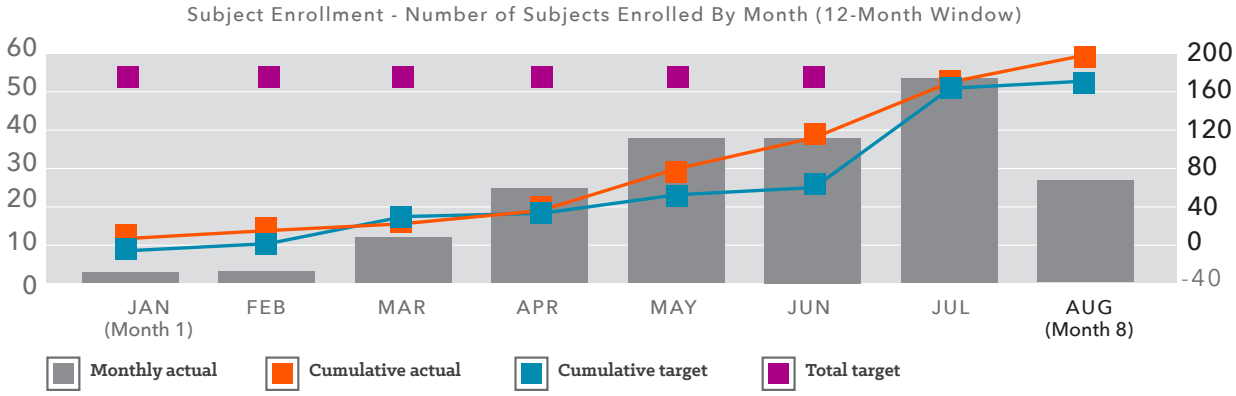
Client communication was particularly complex due to local affiliate involvement in many key decisions. Lack of communication surrounding the client's expectations for key opinion leaders presented another hurdle for PRA. The client's training schedule threatened timely site activations.

SOLUTIONS

PRA developed a plan for detailed involvement and close communication from our oncology therapeutic experts. The experts developed tailored site selection strategies based on their knowledge of regional considerations and in-depth understanding of the indication. PRA then collaborated with the client's steering committee to identify key sites.

RESULTS

PRA's approach allowed us to screen 5 months ahead of schedule and put the study on track to complete enrollment ahead of initial timelines. The client has since selected PRA as a strategic partner for Product Registration services.



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