



CASE STUDY

PRAHEALTHSCIENCES

PRA'S OPTIMAL RECRUITMENT STRATEGIES REDUCE ENROLLMENT TIMELINES

A Focus on Emerging Markets for Recruitment Success in Breast Cancer Studies



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STUDY DESCRIPTION

A Phase III trial comparing drug treatments in patients with advanced breast cancer previously treated with or resistant to an anthracycline and who are taxane resistant

STUDY DURATION

62
MONTHS

No. OF CLINICAL SITES

25

PATIENT POPULATION

381

TREATMENT PERIOD

24
MONTHS

PRIMARY ENDPOINT

Time-to-Response

PRIMARY SERVICES

Regulatory Submission
Document Management
Project Management
Drug Safety Reporting
Site Management,
Monitoring & Recruitment
Feasibility
Medical Monitoring
Vendor Management
Trial Logistics

INDICATION

Thrombocytopenia

DRUG CLASS

Chemical Entity

STUDY PHASE

Phase III

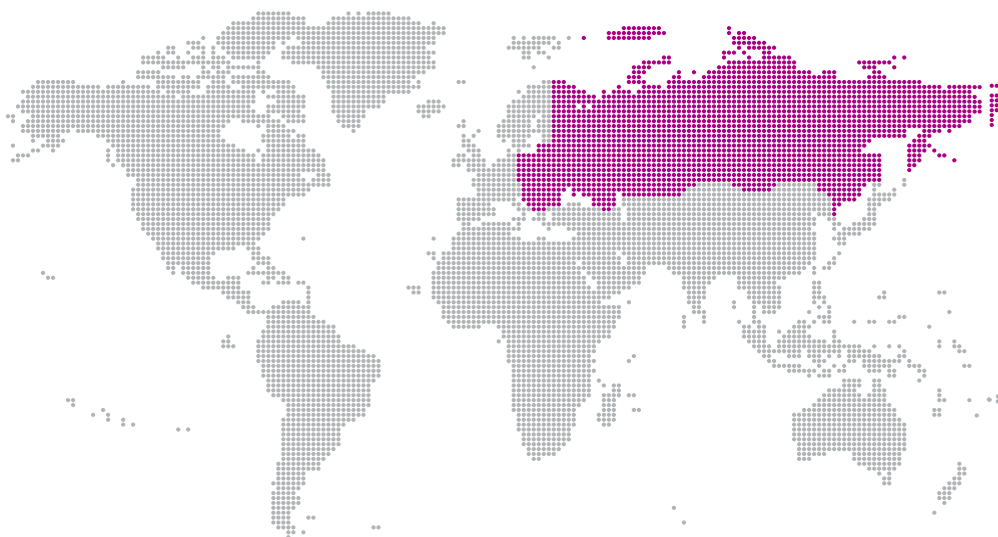
BUSINESS SEGMENT

Product Registration

REGIONS

Eastern Europe

Russia



PRA has significant experience conducting oncology trials within Central and Eastern Europe, including Russia, the Ukraine, Belarus, and the Baltic States. Our recent experience includes 12 Phase II–III oncology trials for which we have recruited more than 1,200 patients.



SITUATION

A mid-size, top 5 European pharmaceutical company was conducting a global Phase III study in 770 patients with advanced breast cancer previously treated with or resistant to airmaximus an anthracycline and who are taxane resistant (Figure 1). The study was to be conducted in more than 20 countries, and the sponsor proactively included emerging markets in the global study plans to avoid the need for a rescue phase later.

STUDY AT A GLANCE		
Phase: III	Indication: Breast Cancer	Number of Countries: 22
PRA Planned Enrollment: 300		PRA Actual Enrollment: 318
PRA Targeted Sites: 22		PRA Actual Sites: 25

Figure 1: PRA Site & Patient Enrollment in Russia & Eastern Europe (Phase III Breast Cancer)



CHALLENGES

PRA recommended the sponsor conduct the study in Russia, Ukraine, Belarus, and Estonia. We also expeditiously handled the regulatory submissions and ethics committee (EC) and customs approvals for these countries in only 3 months following feasibility and site identification completion (Figure 2). Ultimately, PRA recruited 318 patients at 25 sites, compared to 450+ patients at 150 sites in Rest of World (ROW).



Figure 2: Study Timelines



SOLUTIONS

At 0.53 patients/site/month, PRA's recruitment rate outpaced the average ROW recruitment rate of 0.13 patients/site/month. In addition, PRA reduced the sponsor's enrollment timeline from 41 months to 24 months by recruiting subjects in Russia, Ukraine, Belarus, and Estonia.

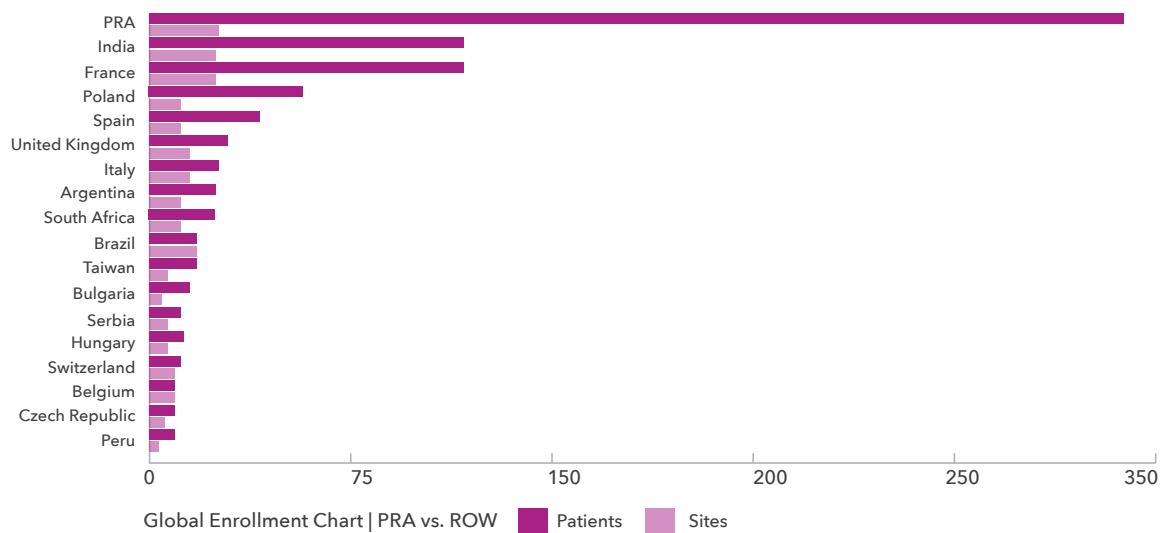


Figure 3: Global Enrollment Chart - PRA vs. ROW



RESULTS

Through a complimentary detailed assessment by one of our therapeutic experts, PRA can assess the likelihood for successful study recruitment in a Russia and Eastern Europe. Over the past 12 years, PRA has participated in more than 130 clinical trials and built an investigator network of over 700 qualified sites in this region.

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.