



CASE STUDY

PRAHEALTHSCIENCES

MEETING ENROLLMENT GOALS

Problem-Solving Leads to Early Completion of Breast Cancer Study



STUDY DESCRIPTION

An open-label, randomized, multi-center study to evaluate the use of Study Drug in the prevention of cancer treatment-related bone loss in post-menopausal women with ER+ and/or PR+ breast cancer receiving letrozole as adjuvant therapy

PRA SERVICES

Full Service

INDICATION

Breast Cancer

DRUG CLASS

Chemical Entity

STUDY PHASE

Phase IIIb

BUSINESS SEGMENT

Late Phase Services

STUDY DURATION

87
MONTHS

No. OF CLINICAL SITES

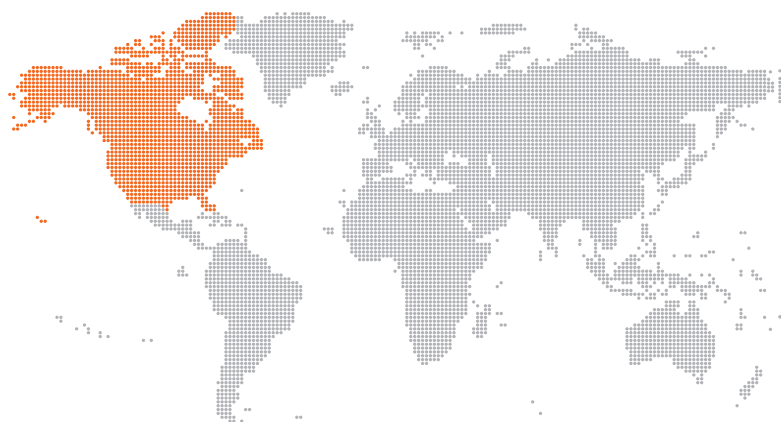
115

PATIENT POPULATION

600
oncology out-patient
adult females

REGION

North America



SITUATION

A long-standing top 20 pharmaceutical client awarded PRA a Phase IIIb study involving treatment of cancer-related bone loss in post-menopausal women with breast cancer. The study was to be conducted in 600 patients at 115 sites in Canada and the United States.

Although the sites were activated on schedule, patient recruitment fell behind by 5 weeks.



SOLUTIONS

PRA and the client worked together to interview the investigational sites to identify the causes of delay. In response, PRA took the following actions to address the causes:

- Amended the protocol to increase the randomization window
- Involved the client more closely with HIPAA issues
- Resolved delays caused by the central radiology group



- Identified patient recruitment tools for each site
- Provided enrollment incentives



RESULTS

These decisive, early actions led to the recruitment of 600 patients 2 weeks ahead of schedule.

PRA is now a preferred provider for this client.

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