



case study:

i3 ONCOLOGY LEADS PATIENT REGISTRY TO GATHER KEY POST-APPROVAL DATA

Challenge: Maintain site relationships, efficiency, and flexibility during registry study.

The sponsor needed post-marketing data about its treatment for metastatic breast cancer: safety data to augment the product profile, data to support meeting abstracts, and information about the treatment context and regimens in which the sponsor's drug was being used. i3 worked with the sponsor to launch a disease registry study for metastatic breast cancer patients. The nature of the registry study required i3 to motivate sites to complete regulatory documents in a timely manner, search their medical databases for eligible patients, and respond to the changing data needs of the sponsor throughout the study, while creating a "value-added" environment for investigator and study coordinators via immediate availability of data.

Solution: Ease the burden, create incentives.

i3 knew it would be a challenge to recruit and retain sites because registry studies typically have low investigator grants. i3 reviewed its extensive site network to find the right sites, and applied an in-depth knowledge of site workflow to make study participation as easy as possible. That meant working with the sponsor to pare down regulatory documents and use computer-based templates for emailing to sites, attempting to work in a virtually paperless environment. It also meant thinking outside the box to provide Web-based training

and support for hundreds of investigators and sites. i3 managed investigator recruitment through a secure Web site, and handled the high call volume (including protocol and electronic data capture support) via phone "help desk" in order to facilitate rapid response to questions. i3 also created value for the investigators by providing up-to-date trial information via Web site and newsletters.

Result: Gather the needed data, faster.

Because of their strong working relationships with the sites (357 clinical sites and more than 1,000 patients) and flexible processes, i3 could adapt to changing sponsor needs, capturing different data at different times. The patient enrollment rate was much greater than expected, and the sponsor was able to gather the data needed to support its product in the market.