



case study:

i3 ONCOLOGY MANAGES CHANGE IN EXPANDED ACCESS PROGRAM

Challenge: Expanded access program with changing requirements. i3 worked with a sponsor who was conducting an expanded access program in mesothelioma cancer that included more than 400 sites and more than 1,000 patients, as well as a call center to handle the large volume of patients and investigator inquiries. During the course of the program, which was otherwise proceeding well, the sponsor and i3 were following the evolving regulatory discussion surrounding expanded access programs. The sponsor determined it would be prudent to work to collect survival data. This decision by the sponsor was finalized late in the program and i3 worked closely with the sponsor to develop a process to retrospectively collect survival data for patients previously treated and prospectively gather survival data for new patients. i3 developed a process and implemented a system that could collect data from a large number of patients without creating an additional burden on the sites. This was very important because the sites did not receive financial support for data collection due to the nature of an expanded access program.

Solution: Sensitivity, flexibility i3's positive relationships with investigative sites contributed to the initial success of the study, helping to find sites and draft a CRF that would be most efficient for the sites and still gather critical data for the sponsor. Once the data requirements changed, i3's site understanding was even more important. Using crisp communication and sensitivity, i3 staff returned to the sites to collect survival data after the sites or patients had been closed out. i3 also maintained close contact with the sponsor's medical director to allow for ongoing data review, in order to meet the sponsor's goals.

Result: Critical data captured to provide clinical support for the product. By applying an understanding of the needs of the site and adapting to changing FDA requirements, i3 was able to prospectively capture 80% of critical variables. This supported submission of key abstracts to peer-reviewed associations such as ASCO.