



## case study:

### i3 TAKES ON ENTIRE ONCOLOGY DEVELOPMENT PROGRAM

**Challenge: Go from recovering a failing study to managing an entire program.** Initially, i3 Oncology was asked to take over two supportive care studies with flagging enrollment from another CRO. Despite the suspension of the studies, i3's experienced oncology clinical team was able to step in and get the sites re-initiated and back on track. i3 completed enrollment in the same amount of time it had taken the previous CRO to enroll only one-fifth of the patients, and the study goals were met. The success of those studies led the sponsor to engage i3 on subsequent trials within the same drug development program, looking for even more efficiency and expertise.

**Solution: Apply lessons learned, shared knowledge.** Working across different indications within oncology, the i3 team reviewed all the information from the previous trials and applied their shared knowledge of the sites, the protocol, the data management challenges to develop an integrated approach to developing the new studies. They considered start-up plans, contracting idiosyncrasies of the large academic institutions, case report form designs, data plans, validation checks, statistical analyses methods, tables, files, listing, and the clinical study reports and more.

**Result: Smarter work, higher quality.** The experience generated from the previous oncology studies in the program, the team's proactive management of applying "lessons learned" to the new programs, and the integration of teams across functions yielded great efficiencies and better quality for the sponsor. These included reduced time to set up, increased depth of knowledge for monitoring, streamlined data plans, and reduced queries, and also ensured that experience from previous programs was tied into the final deliverable of the analysis, as well as into the clinical study report. In-depth understanding of the client's product and development program enabled the team to continually manage and deliver high-quality results.