



case study:

i3 ONCOLOGY NEGOTIATES INSTITUTIONAL COMPLEXITIES IN PHASE I HEMATOLOGY STUDY

Challenge: Phase I hematology study at a large academic site.

A sponsor engaged i3 Oncology for a Phase I study in patients with relapsed or refractory hematologic malignancies. The open-label study was conducted at a large academic institution, which meant i3 had to interact with the complex systems unique to an academic site. Additional challenges included an aggressive timeline and frequent protocol revisions throughout the study.

Solution: Know the institution, know the population.

i3 has a working knowledge of academic institutions, ties to key oncology opinion leaders, and a strong existing relationship with this particular investigative site, a premier oncology research center. These connections created more seamless interaction with the many systems involved in the study — contract negotiations, grants administration, institutional review board, and scientific review board — and fostered a strong working relationship with the principal investigator. i3's understanding of this unique patient population enabled them to better support the needs of the site, as well as respond to the protocol amendments.

Result: Meet enrollment, despite the

challenges. Despite an aggressive timeline and frequent changes, the study successfully enrolled the first group of patients, then the remaining group after approval from a data monitoring committee at 180 days. i3's understanding of the academic site, the investigator, and the patient population was pivotal to helping the sponsor meet the enrollment goals.