

The unique patient populations, study design challenges, and special endpoints associated with oncology trials demand specialized knowledge. i3 Oncology, which is staffed by experts who are dedicated to oncology research, is uniquely qualified to manage that complexity. Our experience spans many indications, interventions, and phases of oncology drug development. We apply our therapeutic expertise to address the unique challenges of oncology research—and help get critical products to market faster.

Therapeutic expertise

Our team includes board-certified oncologists and hematologists. Medical oversight is closely integrated into all project teams so that therapeutic understanding enhances every aspect of a trial. Our therapeutically focused CRAs and project managers average five or more years of experience, and their therapeutic alignment gives them unique oncology knowledge.

Global programs

We have the global capabilities to facilitate study start-up and execution around the world, with access to more than 300 oncology professionals worldwide. Our flexible services can accommodate both highly specialized Phase I studies in oncology patients and large-scale, global Phase III trials. From international regulatory submissions to patient recruitment, we understand the clinical and geographic aspects of global oncology research.

Category experience

i3 has experience that spans the spectrum of oncology indications. This includes working on studies in all research phases, focusing on targeted therapies (alone or in combination with chemotherapy), chemotherapy, radiopharmaceuticals, *in vivo* diagnostics, and supportive care.

Our oncology work includes clinical monitoring for full-service oncology trials across all investigative phases (I–IV) at more than 3,000 sites globally, targeting the enrollment of more than 18,000 oncology patients since January 2002. This broad experience gives

us a better view of the entire clinical trial process, which means we can provide insights into the overall development program.

In addition, we have experience in specialized areas such as tumor assessment and NCI Common Toxicity Criteria, as well as a detailed understanding of hematological malignancies. We can also assist companies when a compound is ready for the transition from the preclinical lab to its first Phase I study in humans.

Indications include:

- Solid tumors, including breast, colorectal, endometrial, glioblastoma, melanoma, mesothelioma, non-small cell lung, ovarian, pancreatic, prostate, renal cell, small cell lung, and urothelial
- Hematological malignancies, including non-Hodgkin's lymphoma, multiple myeloma, myelodysplastic syndrome (MDS), and a range of leukemias, including AML and CML
- Supportive care, including analgesia and anemia in cancer patients

Ties to oncology community

Through years of experience in oncology, we have formed close ties with oncology opinion leaders, professional organizations, and other stakeholders. This enables our clients to benefit from even greater insights on study strategies and gain access to a wider network of investigators and patient populations.

Experienced with oncology data

i3 understands the critical role that data issues play in the success of oncology studies. We have oncology-trained biostatisticians who consult on study design and stay involved throughout a project. Our data managers design CRFs and databases that support important study deliverables. Our therapeutic expertise and oncology site relationships improve data collection at the site level. All this means that data are cleaner, studies run more efficiently, and sponsors can make better decisions based on sound data.

Expanded access, patient registries

In addition to managing Phase I–III programs, we also have experience with late phase trials, including oncology expanded access and patient registry studies. Our in-depth understanding of what's involved in these programs enables us to plan, launch, and run them efficiently. We work to balance the needs of the investigative sites with the needs of the sponsor.

Specialized oncology services include:

- Protocol and program development
- Feasibility assessment
- Statistical planning and design
- Therapeutically focused project management and clinical monitoring
- Data Safety Monitoring Board set-up and management
- Interim analysis support
- Expanded access studies
- Patient registries

Find out what i3's specialized approach can do for your next oncology study.

Contact us

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