

## Oncology

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At INC Research, we understand that cancer is not one disease, but a category of widely varying diseases, each with its own specialized scientific complexities, patient populations and range of treatment options. Our Oncology Practice is dedicated to advancing scientific knowledge and helping customers through the focused, thoughtful management of critical oncology trials. Through our Trusted Process® methodology for delivering dependable trial outcomes, we have the resources, clinical expertise and development know-how to help our clients with every facet of cancer research.

### Wide-ranging expertise

The oncology research community is engaged in an intense quest for new and better therapeutic options. We are passionately committed to this quest. We have mobilized global, multidisciplinary teams to develop and implement a broad variety of oncology research programs.

- Our Oncology Practice is led by well-experienced oncology drug developers with a thorough understanding of clinical oncology trials.
- All of our project managers and CRAs have had substantial experience in the unique complexities of cancer research.
- We have managed Phase I-IV trials spanning a full spectrum of therapies, endpoints and cancer indications, from protocol development through data analysis and completion of the final study report.
- Our proven, proactive recruitment methods speed enrollment and aid retention.
- We provide agency-experienced regulatory consultation for oncology research in a variety of regulatory climates.

### Robust investigator relationships

Because oncology is such a rapidly-moving and competitive field, we know that gaining access to the right investigators for an oncology study involves much more than simply keeping a database. INC Research has strong relationships with key opinion leaders, providing access to an extensive global network of leading oncologists. We've also developed good partnerships with cooperative groups such as the Eastern Oncology Group in the United States, the Clinical Oncological Society of Australia and the Grupo Oncologico Cooperativo del Sur in Latin America, and use them as excellent sources of expertise for our studies. These relationships ensure we get the very best and most up-to-date advice from the outset of any study, helping to save you resources in the long term.

Our ability to build strong investigator relationships to drive study enrollment has been consistently recognized. We are the only CRO to have been ranked among the top three providers in five consecutive years by CenterWatch surveys of U.S. and European investigative sites.<sup>1</sup>

### Global reach, individualized solutions

Our expertise in oncology is spread strategically throughout key countries, with critical knowledge of regional regulatory, medical and cultural nuances.

- In Asia/Pacific, we have offices in India, where there are 800,000 new cancer cases every year and oncology is the most researched therapeutic area.<sup>2</sup>
- In Australia we have expert oncology staff. This is a desirable location for conducting Phase I-IV oncology trials, particularly in the areas of breast cancer and melanoma.
- In Latin America, we have significant experience in gastric and hepatic cancers as well as cervical cancer, which is less prevalent in developed countries due to high rates of screening.

### Our Phase I capabilities

Although most oncology/hematology Phase I trials share the same challenges and follow familiar designs, the conduct of each and every study may bear pitfalls, complex issues, First-in-Human curiosity and/or relatively new targets. These all require intensive yet clear communication and careful consideration for all stakeholders (sponsor, investigators). At INC Research, setting clear expectations, managing teams and partners and using real-time data are all ingredients of our data-driven operational mindset. With our extensive global reach, we can deliver the services clients need, even at the Phase I stage, regardless of sponsor and investigational site locations.

## Our oncology expertise

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- Actinic keratoses
  - Acute lymphoblastic leukemia
  - Acute myelocytic leukemia
  - Anaplastic large cell lymphoma
  - Astrocytoma
  - B-cell lymphoma
  - Basal cell carcinoma
  - Bladder cancer
  - Bone cancer
  - Bowen's disease
  - Brain cancer
  - Breast cancer
  - Cancer-induced cachexia
  - Cancer pain
  - Carcinoid syndrome
  - Cervical cancer
  - Chronic lymphocytic leukemia
  - Chronic myelogenous leukemia
  - Chemotherapy-induced:
    - Anemia
    - Diarrhea
    - Mucositis
    - Nausea and vomiting
    - Neuropathy
    - Neutropenia
  - Colorectal cancer
  - Familial adenomatous polyposis
  - Gastrointestinal cancer
  - Glioblastoma
  - Glioma
  - Head and neck cancer
  - Hepatocellular cancer
  - Hodgkin's lymphoma
  - Leukemia
  - Lymphoma
  - Mantel cell lymphoma
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## Case study

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### From preferred provider to strategic partner

When a pharmaceutical company recently needed to conduct two full-service studies as part of their large oncology program, INC Research's global site relationships, therapeutic know-how and regulatory expertise made us an ideal partner.

In fact, the customer was so pleased with our capabilities, that shortly after awarding us the studies it made INC Research a preferred provider and expanded our remit to include five prostate cancer studies, involving around 800 patients across 165 sites in 14 countries.

As our relationship matured from preferred provider to strategic partner, training was provided to project leaders within INC Research and the customer's organization to harmonize communication, preferences and expectations and ensure that everyone was working toward the same goals.

In addition, steering and governance committees were established to guide the teams. Through this relationship, we have been able to deliver a number of value-added benefits for this customer, including task and time efficiencies, faster study start-up procedures, consistent project staffing, rollover of teams from one project to the next and significant cost savings.

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## Case study

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### Turning around a large combination oncology study

INC Research delivered the largest trial ever conducted of combination therapies for the treatment of oncology patients with severe chemotherapy-induced nausea and vomiting. The trial, for a privately owned European healthcare company, comprised five multinational full-service Phase III studies. The goal was to recruit more than 2,800 patients at more than 350 sites worldwide, but it was a complex undertaking and site recruitment initially was slow.

INC Research's solution was to provide executive oversight and enhanced project leadership to ensure all expectations were met or exceeded. We used our experience to speed site and patient recruitment by adding countries and regions rich in qualified investigative sites and patient populations that met the study criteria (e.g., Mexico and Russia). Additionally, our Regulatory Affairs group provided support in the assembly and filing of the New Drug Application (NDA) in the United States. The New Chemical Entity (NCE) gained FDA approval in 297 days, the fastest out of 12 products undergoing a standard review procedure in that year – a true measure of our ability to turn around a slow study start up.

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## Case study

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### Prostate cancer study

In a prostate cancer study, INC Research's Oncology team was able to complete recruitment of 140 patients within 3 months versus 5 months. Through proactive project management and the use of a variety of creative recruitment strategies during the ProgramAccelerate phase of our Trusted Process, our project team shaved two months off the recruitment timeline, despite two protocol amendments and over one-third of the sites used being academic in nature.

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- Medulloblastoma
- Melanoma
- Multiple myeloma
- Myelodysplastic syndrome
- Non-Hodgkin's lymphoma
- Non-small cell lung cancer
- Oral cancers
- Osteosarcoma
- Ovarian cancer
- Pancreatic cancer
- Prostate cancer
- Radiation-induced:
  - Esophagitis
  - Mucositis
  - Nausea and vomiting
  - Pneumonitis
- Renal cell carcinoma
- Sarcoma

- Skin cancer prevention
- Small cell lung cancer
- Soft tissue sarcoma
- Solid tumors
- Sporadic adenomatous polyposis
- Testicular cancer
- Thrombocytopenia
- Thyroid cancer
- Tumorlysis syndrome
- Uterine cancer
- Vulva carcinoma

## Case study

### Innovation in Phase I oncology studies

INC Research was asked to deliver a full-service Phase I study to determine the maximum tolerated dose of a biological compound for solid tumors, including renal cell cancer. The compound under investigation was a variant of one already on the market, which had significant toxicity. The new compound had been designed specifically to target tumors more efficiently, thus improving the safety profile.

INC Research utilized two sites to deliver this study, including a dedicated unit at the European Centre for Oncology in Milan. We appointed a local Project Manager and Lead Monitor in Milan to ensure effective communication among all key contacts during the year-long study, which included medical monitoring, project management, data management, statistical services and medical writing.

One of our investigators for the study, a radiologist, was keen to use Positron Emission Tomography (PET) scanning for assessments, an unusual request for a Phase I study. We were able to obtain a protocol amendment on PET scanning as this was not yet established by the regulatory authorities.

The result? We completed our recruitment objective of the target 22 patients and delivered the study on time.

## Case study

### Phase IIIb global study

INC Research performed project management and data management services for a Phase IIIb study conducted in 52 countries, with study sites recruiting 8,000 patients. The challenge in this study was to blend client-driven clinical monitoring with INC Research services, thus operating as service provider for client's headquarters, as well as the dedicated liaison for all 40 involved international affiliates and partners. INC Research successfully maintained relationships with all stakeholders in a "lean-and-mean" Phase IIIb operational setting. Notably, during conduct of this study and its QualityFinish, the accrued data has served scientific needs while also increasing marketing information both from the client's headquarters' point of view and from a local affiliate perspective.

## Case study

### Phase II hematology study

A Phase II study that initially started as a pilot AML/MDS study with a few dozen patients, evolved from a 2nd tier supportive study into a pivotal Phase II study. Through the ProgramAccelerate phase of our Trusted Process, we recruited over 160 patients across sites in North America and Europe. INC Research was flexible to the client's needs and provided proactive study management that helped drive study evolution while providing the continuous study updates required by the client.

## For more information

about INC Research's capabilities in oncology, please contact us at [info@incresearch.com](mailto:info@incresearch.com) or at one of the telephone numbers below:

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### Reference

1. CenterWatch Investigative Site Surveys, 2007-2010.
2. Cherian Varghese, Cancer Prevention and Control in India. Available at: [www.whoindia.org/linkfiles/cancer\\_resource\\_pg56to67.pdf](http://www.whoindia.org/linkfiles/cancer_resource_pg56to67.pdf) [accessed: 29/04/10]

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