inVentiv Health Clinical is uniquely qualified to tackle the most demanding challenges in oncology research anywhere in the world. In the last five years, we have conducted over 200 full-service oncology programs in more than 65 countries. We provide the expertise to:

- Manage Phase I to IV oncology trials, including expanded access and patient registry studies
- Utilize extremely complex trial designs, including adaptive designs
- Acquire data on not just drug activity and safety but also on the most efficient use of biomarkers and imaging to measure endpoints
- Enroll hard-to-recruit patient populations

**ALIGNED TO MEET ONCOLOGY CHALLENGES**

Oncology is one of the most complex and fast-changing therapeutic areas. inVentiv Health Clinical meets the challenges of oncology research through therapeutic alignment. We provide:

- Actionable insight through our established relationships with KOLs
- Oncology project managers with an average of more than 10 years of experience
- Deep understanding of disease states, patient populations, and complex protocols
- The highest levels of personalized service and the “feel” of a much smaller organization

**ORGANIZED FOR GLOBAL CAPABILITY**

inVentiv Health Clinical has the global capabilities to facilitate study startup and execution worldwide. Our flexible oncology services can accommodate both highly specialized Phase I studies and large-scale, global Phase III trials. From patient recruitment to international regulatory submissions, we understand the clinical, geographic, and cultural aspects of global oncology research.

**EXPERIENCED WITH NOVEL MECHANISMS OF ACTION**

inVentiv Health Clinical’s experience includes:

- Therapeutic radiopharmaceuticals
- iRNA gene silencing technology
- First-in-class new pathway inhibitors
- Nucleic acid vaccine
- Antibody-peptide fusion proteins
- Antibody-drug conjugates
- Autologous activated cell therapy

**HEMATOLOGY EXPERIENCE**
- Last Five Years - 67 Studies

- Leukemias 25%
- Lymphoma 22%
- Myeloma 12%
- Multiple Myeloproliferative Disorders 6%
- Other Hematologic Disorders 12%
- Anemia 23%

**TOP FIVE SOLID TUMORS**
- Last Five Years

- Breast
- Colorectal
- Lung
- Melanoma
- Prostate

A LEADER IN IMMUNOTHERAPY ONCOLOGY RESEARCH

We understand the enormous potential of novel agents that target immune mechanisms to address unmet medical needs in cancer therapy. With our experience in using immunotherapy to treat more than 10,000 cancer patients, we fully appreciate the unique requirements of this new modality with regard to assessment criteria, training of sites, safety profiles and kinetics of response. Our services in immunotherapy include:

- Phase I to IV studies, including:
  - Complex Phase I dose-escalation studies using single agents and experimental combination therapies
  - Phase III pivotal trials
  - Large, global expanded-access programs

Our experience and breadth of services enable us to bring unique patient, prescriber, and payor insights into the development of your immuno-oncology portfolio.
Marty Birkhofer, MD  
Chief Medical Officer, inVentiv Health Clinical

Dr. Birkhofer brings a wealth of experience to inVentiv Health Clinical, with extensive leadership experience in all facets of clinical development, medical affairs and business development. A 20-year veteran of Bristol-Myers Squibb, Dr. Birkhofer most recently served as Vice President, Business Development, leading global search, evaluation, and diligence for the company’s worldwide business development interests. Previously, he managed global medical affairs for oncology. Notably, Dr. Birkhofer led the development, launch and life cycle management of Erbitux® in colorectal cancer as well as head and neck tumors.

Dawn Sauro  
Senior Vice President and General Manager, Hematology & Oncology  
inVentiv Health Clinical

Ms. Sauro provides senior level global oversight to all hematology and oncology projects managed at inVentiv Health Clinical. Ms. Sauro has over 20 years industry experience, with a specific focus in the execution of hematology and oncology registration programs. Her global experience includes management of trials in more than 60 countries and she has successfully lead several successful registration programs in solid tumors, hematologic malignancies as well as supportive care. Her experience in maximizing timelines and developing robust operational plans translates to success for early phase studies and helping clients reach the critical “go/no-go” decision quickly.

Alanna Fox, PhD  
Vice President, Hematology & Oncology, inVentiv Health Clinical

Dr. Fox leads the Europe/ROW operational team and provides oversight to projects with clients based in Europe, Asia-Pacific and the Middle East. Dr. Fox managed several international oncology programs in Head and Neck Cancer, Multiple Myeloma and Melanoma. Dr. Fox worked for Sterling Drug monitoring breast cancer studies and Schwarz Pharma managing international development programs in various indications.

Dawn East, R.N., B.S.N.  
Executive Director, Hematology & Oncology, inVentiv Health Clinical

Ms. East provides leadership to the North American operational team and provides oversight to projects with clients based in the Americas. Prior to joining inVentiv Health Clinical in 2006, Ms. East worked at IVAX/Baker Norton Pharmaceutical as a Project Manager and Senior Clinical Research Associate. Overall, Ms. East has over 30 years of clinical research experience, 20 years of Project Management experience and 8 years of Site Monitoring experience. She has conducted oncology clinical research on Phase I – IV projects for both North America and global clinical trials.

EVOLVED FOR OPTIMAL PRODUCT DEVELOPMENT

inVentiv Health Clinical is a next-generation CRO. We take a patient-centric approach and apply smarter, fresher thinking to go beyond traditional outsourcing services. We offer therapeutically specialized capabilities for Phase I to IV clinical development, bioanalytical services, and strategic resourcing.

As part of inVentiv Health, we can leverage our vast commercial organization to bring insight into your development plan and help you think beyond clinical trials. We are the only company in the world that can both develop and fully commercialize a product for the life sciences industry.

inVentiv Health, with its unique ability to both develop and commercialize oncology products, has supported more than 78% of all oncology products approved by the FDA over the last five years.