

OVERVIEW

In the demanding oncology clinical research arena, the Worldwide Clinical Trials' commitment to sound science and innovative medicine, supported by a global network of experienced sites, represents the basis for reaching your study objectives and overcoming operational challenges.

AT THE EDGE OF ONCOLOGY RESEARCH
- TRANSLATIONAL MEDICINE

Worldwide Clinical Trials differentiators in oncology include activities in Translational Clinical Research, for example; facilitating gene expression profiling in exploratory studies that are designed to explore pharmacodynamic biomarkers for molecularly targeted cancer therapies. Our ability to create a platform for continued basic research in clinical development reflects an appreciation of how clinical data can be integrated with drug discovery activities. Worldwide Clinical Trials' contributions as a partner are recognized in this Sponsor's testimonials prior to trial initiation and following study completion.

"...This is a challenging project in a number of respects, not least of which is the timeline. We were impressed with [Worldwide Clinical Trials'] approach to problem-solving...we'll continue to partner closely."

*- Senior Director, Experimental Medicine,
Gene Expression Profiling, Oncology*

"...On a personal note, I would work with Worldwide Clinical Trials again in a heartbeat. The staff that supported the project were all fantastic and I felt, as an outsourcing experience, it was exactly what we should be striving for. My effort was significantly less for this study because they took ownership of the protocol responsibilities so well. A truly great experience..."

- Director, Clinical Operations, Oncology

DEFINING THE VALUE PROPOSITION

Successful formulary placement and reimbursement decisions following health technology assessments require informed clinical development programs in which the perspective of multiple stakeholders are considered. Competing on value, rather than novelty, requires that the CRO present design options for clinical development that resonate with payer's demands for actionable data. These include assessments of outcomes, rather than measures, changes in quality of life and productivity, and reductions in both direct and indirect costs. Studies in patients and practice settings representative of the population likely to receive treatment are mandatory.

At Worldwide Clinical Trials, access to key opinion leaders within this domain includes partnership with Thomas Jefferson University, School of Population Health who provide a unique unbiased perspective on issues relevant to researchers and administrators in the payer environment.

ONCOLOGY PORTFOLIO

Solid Tumor Malignancies

- Brain
- Breast
- Cervix Uteri
- Colon
- Lung
- Ovary
- Pancreas
- Prostate
- Kidney
- Small Intestine
- Stomach
- Thyroid

Hematological Malignancies

- Multiple Myeloma and Malignant Plasma Cell Neoplasms
- Myelodysplastic Syndromes
- Non-Hodgkin's Lymphoma
- Chronic Lymphocytic Leukemia
- Chronic Myelogenous Leukemia

Our Medical & Scientific team have discussed the methodological expertise which can be applied during product development in various publications - most recently:



Murphy M.
'When novelty is not enough.'
American Health & Drug Benefits.
2008; 1(2):29-33:

Continued on Back >



BEATING THE COMPETITION – THE REGIONS

As oncology drug development has gathered pace, competition for investigators and patients has intensified, impacting timelines and inflating the cost of trials. Worldwide Clinical Trials' clients benefit from our operational capability in emerging regions where competition is low or absent and patient access unencumbered; examples include Lebanon, Saudi Arabia, Jordan and the United Arab Emirates.

We understand that in-depth knowledge of local care standards and regional variation in oncology practice, can materially impact a site's ability to participate in a proposed program. Our extensive experience with local cultural, medical, and regulatory environments translates into reliable metrics and the delivery of impeccable data vital to successful oncology clinical research.

Worldwide Clinical Trials operational capabilities also includes regions such as Russia, and Central/Eastern Europe where a centralized healthcare system of patient referral promotes efficiencies in study execution by establishing large referral networks for recognised centers of excellence.

DELIVERING EXPERIENCE

Since 2006 Worldwide Clinical Trials has participated in the design, execution or analysis of more than 70 Oncology studies.

We have study experience across phases I-IV in solid tumors and hematological malignancies. Participating sites have numbered more than 250 with over 3300 patients randomized and our portfolio of therapeutic interventions includes the following drug classes:

- Hormone therapy
- Antimetabolites
- Mitotic inhibitors
- Anti-tumor antibiotics
- Alkylating agents and platinum compounds
- Immunotherapy (e.g., cancer vaccine)
- Targeted therapies
 - Biologic agents (e.g. monoclonal antibodies)
 - Small molecule inhibitors (e.g. protein kinase inhibitors)
 - Antisense compounds (e.g. antisense DNA)

DESIGN & ANALYSIS OF EARLY PHASE ONCOLOGY TRIALS

Our scientific and biostatistical teams have the training and experience to provide expert design and analysis of your Phase I oncology study. This experience encompasses the following;

- Traditional algorithm-based design (with or without dose re-escalation)
- Sequential trial design that delivers innovation and efficiencies
- Employing pharmacodynamic endpoints to evaluate target engagement.
- Working with compounds with innovative biological properties

Our work with adaptive design is also reflected in 'An adaptive first in man dose escalation study of NGX267: Statistical, clinical and operational considerations.' Ivanova A., Murphy M.; *J Biopharm Stat.* 2009; 19(2):247-55)

CASE STUDY

Phase III program in ErbB-2-positive locally recurrent or metastatic breast cancer

Patients: 714

Sites: 121

Key Challenges: Sensitivity around mandatory contraception and pregnancy testing in the MENA region

Actions & outcomes: A rigorous feasibility assessment coupled with experience in cultural and standard of care requirements informed site procedures, allowing successful initiation of 3 concurrent studies

SUPPORTING SERVICES

Study design, "proof of concept" synopses

Protocol development

Feasibility and site selection

Regulatory affairs (including regulatory and consultancy)

Scientific consultancy and advice meetings

Clinical monitoring

Medical writing services

IVRS/IVRS for Study Supply Management

Global project management

Data Management (paper and EDC)

Biostatistical services

Work with third parties for specialized assessments (eg. molecular imaging)

