

Fully Integrated, Specialized
Solutions in *the New Health*
Targeting Oncology



An Ally in Meeting the Challenge

In the search to improve cancer outcomes, each promising advance across the biopharmaceutical frontier comes with challenges as unique as the specific molecular pathway and individual genetic profile it targets. Because oncology is not a one-size-fits-all discipline, Quintiles provides fully integrated clinical, commercial, consulting and capital solutions at every stage of a product's lifecycle so customers can stay focused without missing opportunities.

Despite dramatic advances — *today, two-thirds of patients survive 5 years after diagnosis compared to just half of patients 40 years ago, and mortality rates have dropped 15% since 1990* — the WHO predicts new cancer cases will soar by 50% globally between 2000 and 2010.¹ Against the complex backdrop of escalating risk, spiraling development costs averaging \$1 billion dollars,² and success rates as low as 5% moving from Phase 1 to NDA,^{2,3} we share your sense of urgency to develop new and better therapies.

Agility and Access at Every Stage

We also share the renewed sense of optimism emerging among our customers, because we're seizing more opportunities for success than ever before in *the New Health*. We're part of the patient-centric progress being made in oncology treatments.

Like you, we understand that oncology drug development demands both a deeper level of scientific expertise and a broader, more holistic approach to global regulatory approvals and market access. From portfolio strategy to trial design and execution; to regulatory submission and post-marketing requirements, you need an ally with the know-how to navigate every stage of oncology product development to help you minimize risk and seize opportunity. We're here to help.

Invested in Your Success from Early Development and Study Design to Lifecycle Management

The commercial success of a therapy hinges upon more than developing and executing the clinical trial. At Quintiles, our approach incorporates not just clinical, but also commercial, consulting and capital solutions. We're the only biopharmaceutical services company that can offer this integrated approach to oncology drug development and commercialization, providing data-driven insights that spur action, overcome complexities and streamline processes, and help drive better outcomes.

Expertise throughout the Development-Commercialization Continuum

As the industry leader, we helped develop or commercialize 48 of the top 50 best-selling oncology products in 2008.⁴ Our unparalleled oncology expertise includes a global network of:

- > 16 board certified oncologists
- > 60+ oncology global project managers
- > More than 500 CRA with experience in monitoring oncology clinical trials
- > 1000+ sites in 42 countries with access to local investigators

Our specialists can work with your scientific team in developing trials using biomarkers, imaging, assay development, telepathology, and regulatory strategy and translational medicine. We've done leading work in monoclonal antibodies, recombinant proteins, targeted small molecules (TKIs), cancer vaccines and other advanced oncology therapies. Our experts can also advise you on the most appropriate market access strategies, commercial launch plans, medical communications, product and brand solutions, and scientific services to optimize the success of your oncology product.

Global Access Streamlines Success

Quintiles' global market access capabilities leverage our commercial experience in 65 oncology markets and strong relationships with centers of excellence and key opinion leaders worldwide. Our extensive commercial resources include:

- > 10,500 medical sales representatives around the world
- > 250+ in-country regulatory experts
- > Built 20+ medical science liaison teams and 14+ multi-country sales teams
- > Relationships with 6,500+ oncologists and 1,700+ hematologists worldwide
- > Experts in reimbursement strategy and formulary access

Since 2005, we've deployed 68 oncology teams globally, involving more than 500 medical sales reps and 100 nurses.

Deep Capabilities, Broad Expertise

With a shift toward more specialized oncology indications and targeted treatments, pharmaceutical companies are looking for partners that have an extremely high level of scientific and therapeutic expertise coupled with global knowledge of patient pathways and standards of care.

Building on a Holistic Knowledge Base

At Quintiles, our "big picture" business model provides a holistic knowledge base that informs every step of the oncology product development and commercialization process. In addition to board certified oncologists, our team of experts includes those in: clinical monitoring, data management, biostatistics, medical writing, regulatory, pharmacovigilance; biomarker and assay clinical development; and product and brand solutions.

The Regulatory Support Needed to Gain Approval

In the face of rising scrutiny, our regulatory team — which includes former FDA, European and other regulatory officials — can advise customers regarding the types of metrics and evidence needed to gain approval.

Broad Therapeutic Experience

Quintiles' unmatched oncology experience includes a full spectrum of therapies, protocol design / development endpoints and a wide range of cancer indications. They include the following:

Tumor Types

- > Most solid tumors (primary, advanced, metastatic)
- > Leukemia and Pre-Leukemia (myelodysplastic syndrome, myeloproliferative disease)
- > Lymphoproliferative disease (Hodgkin's, Non-Hodgkin's, multiple myeloma)

Therapy Types

- > Cytotoxic therapy
- > Targeted therapy (protein and small molecule)
- > Gene therapy
- > Growth factor therapy
- > Supportive care therapy
- > Alternative medicines (botanical, etc.)
- > Device evaluation
- > Diagnostic evaluation
- > Hormonal therapy
- > Immune therapy (cytokine, MAB, T-cells)
- > Stem cell therapy
- > Photodynamic therapy

Non-Traditional Partnerships: A New Approach to Risk Sharing and Oncology Drug Development

Quintiles is pioneering new risk-sharing models that help ease our customers' upfront investment. For instance, in 2009, Eisai Co., Ltd., a global pharmaceutical company based in Tokyo, turned to Quintiles to help develop six potential oncology products in its R&D pipeline. The goal was to determine the efficacy of the products in the shortest amount of time in order to bring the products to market as quickly as possible.

The alliance formed between Quintiles and Eisai distributes the risk. Quintiles will contribute to the funding of the design and execution of the clinical trials in exchange for success milestone payments. Eisai benefits through the extension of its oncology program, increasing the number of indications investigated for the six potential products.

"I am pleased that Quintiles and Eisai share the same goals and our incentives are aligned for speed, quality and efficiency."

— Mr. Hideki Hayashi, Senior VP and Chief Product Creation Officer for Eisai Co., Ltd.

Contact Quintiles to see how we can help you optimize your oncology programs.

- 1 The WHO.
- 2 Kola I and Landis J. Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery*. 2004;3:711-715.
- 3 DiMasi JA, et al. Economics of new oncology drug development. *JCO*. 2007; 25:209-216.
- 4 Evaluate Pharma, 2008.

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Navigating the new health