iTrials CASE STUDY

THERAPEUTIC AREA: Cancer

INDUSTRY: Pharmaceutical

iTRIALS PRODUCTS: Site Locator

CLIENT PROFILE: Lilly

Eli Lilly (Indianapolis, IN) is the world's 10th largest pharmaceutical company and a leader in thoracic cancer treatment. Because no two cancer patients are alike, Lilly Oncology is committed to developing treatment approaches tailored to the individual.

PILOT STUDY:

Lung cancer is the leading cause of cancer death in African-Americans, with 21,550 new cases diagnosed and 16,700 deaths expected annually. Equally devastating, lung cancer is the leading cause of cancer death in Hispanic men, and the second leading cause in Hispanic women. Lilly's researchers are actively investigating the efficacy and safety of lung cancer treatments ALIMTA® (pemetrexed for injection) and GEMZAR® (gemcitabine HCl for injection) in treating African-Americans, Hispanics and other diverse populations for non-small cell lung cancer (NSCLC). NSCLC is the largest oncology market.

ALIMTA® was evaluated as NSCLC maintenance therapy, a new treatment modality providing additional treatment immediately after first line chemotherapy. Traditionally, patients are treated with second line therapy only if the disease progresses or recurs. Lilly's study offers hope that additional treatment (even before disease progression) could benefit some (if not most) patients.

Lilly's Phase III multi-year study of 1,000 patients is one of the largest, most diverse NSCLC studies to date. iTrials supported Lilly's efforts in recruiting minority patients including 200 African Americans, 200 Asians, 200 Hispanics and 400 Caucasians. iTrials was challenged to find sites with lung cancer populations featuring a 60+% ethnic minority population within the practice.

iTRIALS IMPACT:

The study was underway for three months when iTrials became involved. Site Locator identified 40 pre-qualified sites. From these, iTrials contacted, vetted and enrolled 6 new sites within only 2 weeks (10 within 10 weeks, and 13 within 15 weeks). All 13 iTrials-enrolled sites continue to deliver medically qualified ethnically relevant patients to this important study.

"Scientific reasoning tells us that because of genetic differences, patients with similar tumors may respond differently to specific treatment regimens. Ultimately, our goal is to ensure that we offer the optimal outcome to each and every patient."

- Richard Gaynor, M.D., *Vice President, cancer research and global oncology platform leader at Lilly*

CLIENT SUCCESS:

In 2008, ALIMTA (in combination with cisplatin) was approved as a first-line treatment for locally advanced or metastatic non-squamous NSCLC. FDA simultaneously approved ALIMTA as a second-line indication, used after chemotherapy for locally advanced or metastatic, nonsquamous NSCLC. Lilly's efforts have shifted the paradigm for NSCLC treatment, offering a maintenance therapy option to prolong survival in non-squamous NSCLC patients.

ABOUT:

iTrials services are offered by Nashville-based Provisio, Inc., a steward for leveraging health care data and proprietary information technologies to drive innovation in clinical trial protocol design, site selection and patient recruitment.

iTrials leverages its unique-to-industry data warehouse (comprehensive longitudinal health histories on over 80 million patients), combining patient level data with proprietary analytical instruments. Our valuable insight into patient populations and ability to identify success factors produces high patient enrollment rates into productive investigative sites.

Provisio, Inc. | 615-279-3425 | 3212 West End Avenue | Suite 500 | Nashville, TN 37203 | www.iTrials.com