

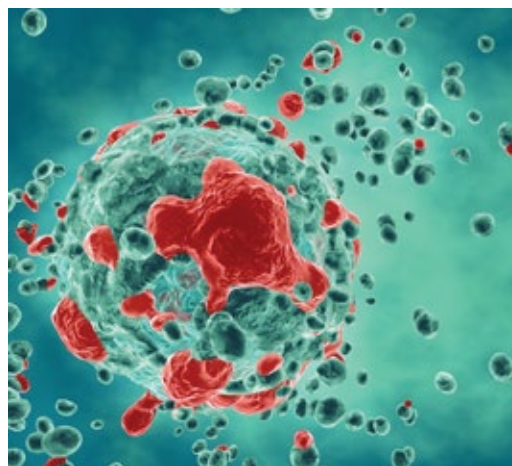
Gaining Ground In the War on Cancer



In the complex battle against cancer, scientist John Cobb ensures that clinical trials around the world are using consistently high-quality drugs that are safe for patients

Cancer is a formidable enemy, but new drugs are joining the battle. The National Cancer Institute and private pharmaceutical companies are on the front lines, consistently developing and testing new medicines to push back the disease and increase life spans.

Working with NCI and commercial companies, MRIGlobal supplies a piece of the complex puzzle in the war against cancer. MRIGlobal's customized, flexible analytical chemistry support provides faster bench-to-bedside processes for delivering therapeutic drugs to clinics for efficacy testing.



Support for Government Cancer Research

NCI, the federal government's principal agency for cancer research, coordinates and supports all phases of clinical trials across 2,500 sites nationwide. University researchers may submit compounds they have developed to NCI's Division of Cancer Treatment and Diagnosis. If NCI determines the agent shows promise in fighting cancer, it takes on much of the early regulatory work, including testing the drug and distributing it for clinical trials.

MRIGlobal's contract with NCI spans over 17 years and focuses on early-clinical-stage cancer research. John Cobb, staff chemist and group leader in MRIGlobal's Pharmaceutical Analysis group, oversees research on investigational and new NCI medications aimed at many types of cancer – including breast cancer, colon cancer, and lymphoma.

MRIGlobal's "piece of the puzzle" involves method development, method transfer and drug stability and potency testing, which the company achieves using its own stability chambers, designed to assess the effects of environmental stresses on medications. Cobb and his staff store NCI compounds in MRIGlobal's in-house repository, exposing them to various conditions. The team might, for example, subject a medication to elevated humidity or heat. After exposure to these high-stress conditions, Cobb and his team rigorously evaluate the drugs to determine whether they have remained stable and maintained their potency. If they have, NCI can be confident the medications will be stable and potent

throughout clinical trials. If not, the process allows for the trial to be stopped while problems are identified and corrected to ensure participants receive only the highest quality medication.

This highly regulated work establishes the shelf-life stability of cancer drugs, documents the storage conditions under which they maintain their potency with no adverse impurities and ensures that clinical trials around the world are using consistent, high quality drugs that are safe for patients.



Fighting on the Commercial Front

For commercial pharmaceutical companies, bringing a medication to market typically requires a multi-million-dollar investment and a decade of research and testing. Cobb and his team facilitate multiple parts of the process, from method evaluation to coordinating outsource tests with other contractors to handling repository management and distribution.

Some commercial clients are large pharmaceutical firms that outsource segments of testing; others are virtual companies that may have spun out of academia after its teams discovered promising compounds. These smaller companies, for whom building proprietary lab facilities and repositories is cost prohibitive, typically outsource all of the testing work to MRIGlobal.

Cobb's work encompasses any chemical support commercial companies may need for their pharmaceutical products. The full suite of services often begins in the synthesis of new drugs, with MRIGlobal's skilled analytical team investigating the compounds to ensure they are properly made and have high purity. Cobb handles method development and method validation to confirm that the methodology used to evaluate each new drug meets required regulations and is scientifically sound and reproducible.

Because Cobb works with new compounds no one has tested before and because funding often is contingent upon a drug advancing to the next phase of testing, time is a crucial resource. MRIGlobal excels in this area, with a nimble group that can accommodate tight client schedules. With Cobb as a single point of contact, MRIGlobal provides a big-picture perspective to attack complicated issues and supports quick and efficient investigation of new testing methodologies that can be completed on time and on budget.

The work is critical. The role of clinical cancer trials is to determine whether people get better taking the drug being tested. But Cobb points to well-publicized examples of scientific research conducted using the wrong drug, requiring results to be retracted. MRIGlobal's work ensures that quality, purity and dosages are correct, supporting the scientific validity of clinical trials.

MRIGlobal bridges the gap between drug discovery and commercialization in the complex fight for public health and the battle against cancer. Its critical role ensures that investigational medications receive rigorous method validation and stability testing, continue through the complex new-drug application process and, ultimately, help patients heal.

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About MRIGlobal

Celebrating its 75th year of business, MRIGlobal addresses some of the world's greatest threats and challenges. Founded in 1944 as an independent, non-profit organization, we perform contract research for government, industry, and academia. Our customized solutions in national security and defense and health include research and development capabilities in clinical research support, infectious disease and biological threat agent detection, global biological engagement, *in vitro* diagnostics, and laboratory management and operations.