MRIGlobal

2023

IMPACT REPORT

Innovative Solutions to Important Challenges

2023

LETTER FROM OUR CEO

Today's rapidly changing global landscape demands transformative technological advances that help strengthen national security and improve the public's health. For nearly eight decades, MRIGlobal's work has been critical in successfully developing and deploying such measures.

This year, our research scientists, engineers, and support staff continued providing innovative solutions to the world's most important challenges. Our work has included serving as the repository for the National Cancer Institute's clinical investigation of chemopreventative materials, psupporting preclinical advancement of an inflammatory disease therapy through the FDA, and even development, validation, enhancement, and evaluation of technologies aimed at ensuring the safety of those responsible for responding to overdose scenes.

Through these programs and many others across the institute, we resolve each day to achieve our mission of improving the lives of people through innovative scientific and engineering research.

Dr Ian Colrain

Dr. Ian M. Colrain
President & CEO

TRANSLATIONAL DEVELOPMENT

SECURING FDA APPROVAL FOR INFLAMMATORY DISEASE THERAPY

In patients around the world, the COVID-19 pandemic caused lung complications like acute respiratory distress syndrome (ARDS) and ventilator-induced lung injury (VILI), conditions that are accompanied by high mortality rates.

Lung injury may also result from inflammatory diseases, which are common side effects following radiation treatment for cancer. As there are no FDA-approved therapies to prevent the cascading and damaging effects of these types of inflammatory diseases, which can also lead to fibrosis, there is a significant clinical need for safe and effective medical treatments. In response, our customer Aqualung developed the novel therapeutic ALT-100 mAb and chose the interdisciplinary team at MRIGlobal to support its advancement through the preclinical space for the Food and Drug Administration (FDA) authorization to conduct human trials.

Before performing this work, we first imported the drug from its overseas manufacturer through our foreign-trade zone. We then initiated a series of studies with the goal of obtaining authorization from the FDA to administer the drug to humans in Phase I clinical trials. Using Sprague-Dawley rats and Göttingen minipigs as our animal models, we performed work ranging from pharmacokinetic studies to Investigational New Drug Application-enabling GLP toxicology studies. This work provided Aqualung with the necessary safety data to gain approval for Phase 1 clinical studies, which were successfully performed with FDA approval to initiate a Phase 2 clinical trial in patients with moderate/severe ARDS.

PROVIDING SAFETY DATA TO GAIN APPROVAL FOR CLINICAL STUDIES

HEALTH SURVEILLANCE & DIAGNOSTICS

BRINGING TO MARKET A FIELD DIAGNOSTIC SYSTEM TO DETECT CHEMICAL EXPOSURE FROM A DROP OF BLOOD

As part of MRIGlobal's mission, we defend this country's warfighters and civilians against exposure to harmful chemicals.

To accomplish this goal, we are developing the ChemDx Acetylcholinesterase Test System as an ultra-portable, easy-to-use, In Vitro Diagnostic (IVD) device to provide early warning of suspected chemical warfare nerve agent (CWA) exposure on the battlefield or pesticide exposure in agriculture. Using a single drop of blood from an exposed individual, this handheld device is being designed to provide acetylcholinesterase activity assessment in less than five minutes. Our work is intended to lead to premarket clearance of the IVD system by the U.S. Food and Drug Administration (FDA).

MRIGlobal has an agreement with the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) Joint Project Manager (JPM) CBRN Medical to serve as the ChemDx Acetylcholinesterase Test System program lead to coordinate analytical and clinical performance assessments and successive prototyping with Conductive Technologies Inc. In this role, we provide multidisciplinary technical expertise, programmatic management, chemical agent testing for verification and validation studies, and ensure compliance to regulatory development processes to support an FDA premarket submission.

The team recently manufactured and tested a beta-prototype. In the next stage, a preclinical prototype for formal analytical studies will be produced by early 2024. Clinical trials with a device version under cGMP, or formal regulatory controls, for medical device manufacturing are planned for late 2024, and a 510(k) premarket submission to the FDA is planned for early 2025.

FAST-TRACKING DEVELOPMENT, COMMERCIALIZATION, AND IMPLEMENTATION OF DIAGNOSTICS

The COVID-19 pandemic caught the world by surprise, infecting populations around the globe within a few short months.

In response, the National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx®) initiative to fast-track the development, commercialization, and implementation of novel diagnostic tests for SARS-CoV-2, the virus that causes COVID-19.

2020

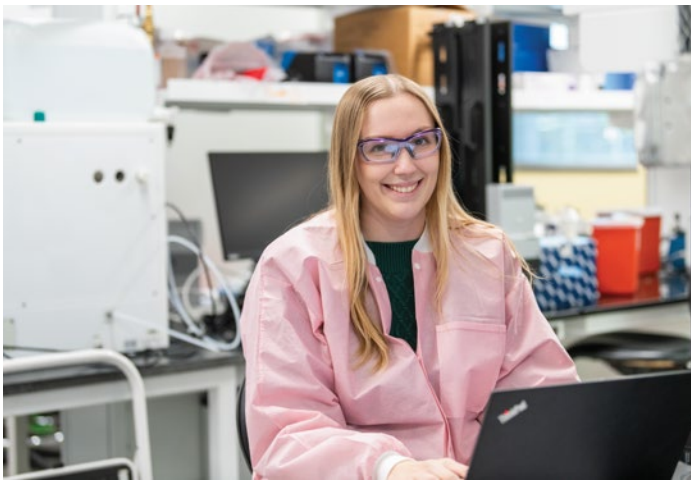
In Fall 2020, MRIGlobal was contracted as part of the NIH RADx Tech program (administered by the National Institute of Biomedical Imaging and Bioengineering (NIBIB)) to perform analytical studies for companies seeking Emergency Use Authorization (EUA) of their COVID-19 at-home test devices from the U.S. Food and Drug Administration. This work provided test manufacturers with the data needed to support their EUA submissions or make improvements to their devices.

2021

When demand for these diagnostic tests rose in late 2021, our scientists completed studies for three device manufacturers in record time which enabled their tests to reach the market in time for the anticipated holiday COVID-19 surge. To date, MRIGlobal has performed analytical studies for more than 30 test manufacturers that enabled many of these companies to receive an EUA.

2023

The success of the RADx Tech program has led NIBIB to expand the program to support other diagnostic tests for infectious diseases that include mpox, hepatitis C virus, multiplex tests for influenza A & B, and SARS-CoV-2. MRIGlobal has completed or is contracted to perform some of these studies.



This project has been funded in part with Federal funds from the National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institutes of Health, Department of Health and Human Services, under Contract Nos. 75N92022D00013, 75N92022C00027, 75N92022P00030, 75N92021P00129, and 75N92020P00171.

PHARMACEUTICAL SCIENCES

PHARMACEUTICAL REPOSITORY SUPPORTS HIV/AIDS VACCINE DEVELOPMENT

First discovered in 1959 and declared an epidemic in 1981, HIV (human immunodeficiency virus) is a virus that attacks cells that help the body fight infection, making a person more vulnerable to other infections and diseases.

The development of a safe and efficacious preventive vaccine to combat HIV-1, the most common strain of HIV, is one of the highest priorities of the National Institute of Allergy and Infectious Diseases (NIAID). In partnership with their Division of AIDS (DAIDS), MRIGlobal is supporting the study of novel vaccines at various stages of development.

BEING MISSION-DRIVEN, WE ARE PERSONALLY INVESTED IN WHAT NIAID AND DAIDS ARE STRIVING TO ACHIEVE.

By working as a collaborative and experienced partner, we are dedicated to their success.

DRUG DEVELOPMENT SERVICES

Our team is providing a broad and flexible range of integrated drug development services that enable preclinical and clinical studies of these vaccines. We utilize our pharmaceutical repository to receive, store, package, and distribute preclinical and clinical vaccines from research sites worldwide.

COLD CHAIN MANAGEMENT

We leverage decades of expertise and experience in cold chain management and supply chain logistics to maintain the integrity and quality of the vaccines, and to ensure timely and efficient delivery.

PROGRAM MANAGEMENT

MRIGlobal's exceptional program management, responsiveness, and problem-solving ensure that the DAIDS team is fully supported in their overall efforts to make an impact in the HIV/AIDS global research portfolio.

+ INNOVATIVE SOLUTIONS

TO SUPPORT CANCER PREVENTION STUDIES

A CENTRALIZED PROGRAM FOR PREVENTING CANCER

Cancer is the second most common cause of death in this country, and one that has impacted nearly all of us.

With the goal of preventing or reducing rates of cancer, the Division of Cancer Prevention (DCP) at the National Cancer Institute (NCI) promotes chemo/immunoprevention studies for effective medical interventions.

To support this effort, MRIGlobal operates a centralized repository program that provides important logistical operations for the acquisition, tracking, storage, maintenance, testing, and quality control of agents that are being investigated in the fight to prevent cancer. Our team offers an array of integrated services such as manufacturing, analytical testing, and clinical trial materials management to holistically support the program, which studies agents at various stages of preclinical and clinical development. The program is operated in compliance with Federal and National Institutes of Health (NIH) regulations and guidelines, including Good Laboratory Practices and Good Manufacturing Practices.

With our world-class and centralized facilities, our team provides innovative solutions to support cancer prevention studies and trials across the country, advancing the efforts to prevent cancer and improve the health of all people.

DEFENSE SOLUTIONS

CBRNE TECH INDEX TO COUNTER FUTURE THREATS

Chemical, biological, nuclear, and radiological threats are an ever-present danger to warfighters and civilians.

To effectively counter these threats, first responders, government agencies, and others must be prepared with proven equipment, processes, and intelligence.

Since it was founded nine years ago, CBRNE Tech Index has become the most comprehensive database of CBRNE equipment in the world. Our team performs testing and evaluation of CBRNE detection, collection, decontamination, and personal protection equipment, which we share at www.cbrnetechindex.com. Its user-friendly database enables scientists and first responders to search, filter, and compare more than 2,100 CBRNE-related products to find the right ones for them and their job.

CBRNE Tech Index also provides MRIGlobal researchers with a growing and sustainable pipeline of commercial and government programs, while serving as a launch point for partnerships with leading-edge tech companies. As a result, our engineers and scientists help our partners develop sensors, design and integrate software, operate and maintain field-forward laboratories, and train end users to prepare for and mitigate future threats.

THE CBRNE TECH INDEX PLATFORM PROVIDES INDUSTRY AND GOVERNMENT PARTNERS WITH CRITICAL METRICS TO EFFECTIVELY COUNTER THREATS, while sharing our best-in-class capabilities and talents to drive internal and external innovation for a safer, healthier world.

KEEPING FIRST RESPONDERS SAFE FROM DRUG EXPOSURE

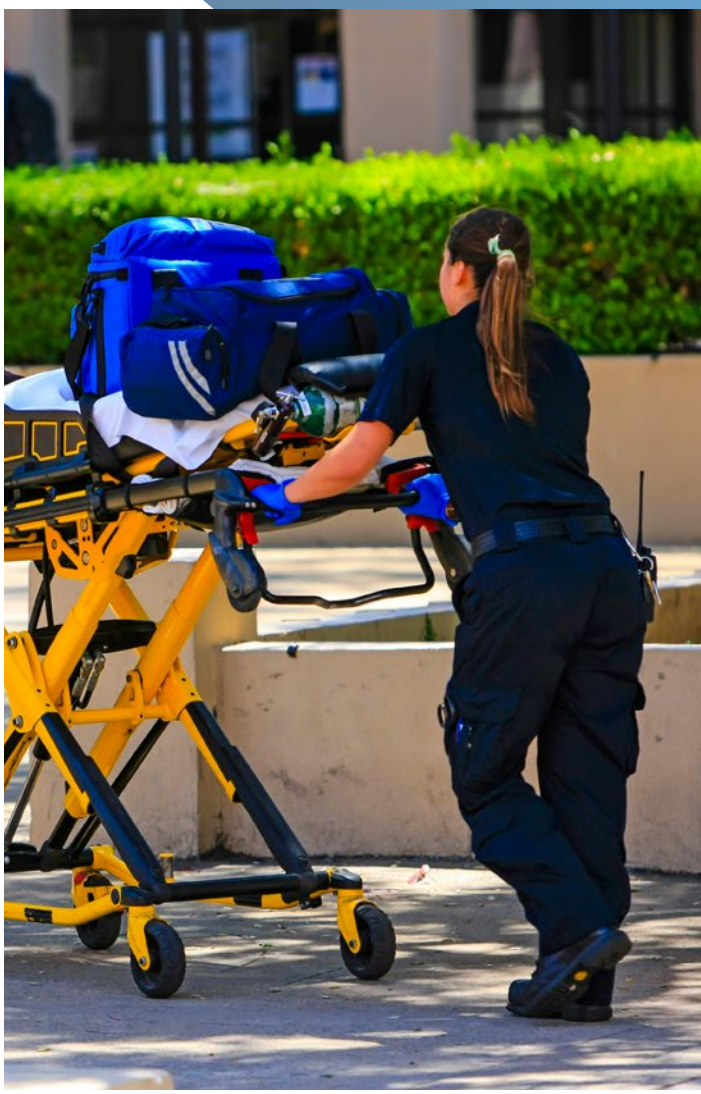
Drug overdose deaths have increased by more than six times since 1999. In 2022, more than 75 percent of those 110,000 overdose deaths involved an opioid, including fentanyl and heroin.

Unfortunately, providing emergency services to individuals impacted by an overdose can also put first responders at risk of exposure to those same substances. As a result, it has never been more important to equip them with effective and reliable tools to ensure their safety.

MRIGlobal's chemists frequently partner with industry to develop, validate, enhance, and evaluate technologies aimed at ensuring the safety of these first responders. In this role, our scientists determine the best experimental design and test methods to ensure our customer partners are provided the irrefutable supporting data they need to claim product efficacy.

We then evaluate the efficacy of various decontamination products on a variety of chemical threats, often focused on opioids and other drugs of abuse. We also help develop sensors, build reference libraries, and evaluate product performance against extreme conditions to ensure that devices operate without fail when it matters most.

Each of these activities helps safeguard those responding to incidents involving these drugs, while helping those possibly impacted by an overdose.



OUR TEAM

OUR LEADERSHIP

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