

TEXAS A&M CENTER FOR INNOVATION

IN ADVANCED DEVELOPMENT AND MANUFACTURING

FACT SHEET

The Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM) will accelerate the research and development of vaccines and therapeutics and rapidly produce these products in cases of pandemics or other national emergencies.

The Texas A&M CIADM will supply preventive vaccines for pandemic influenza; once fully operational, the Center will have the capability to supply fifty million vaccine doses within four months of receipt of a pandemic influenza strain, with first doses available in twelve weeks. The Center will also develop and manufacture vaccines and treatments for chemical, biological, nuclear, and radiologic threats, and also be a national response platform for new naturally emerging diseases like SARS and West Nile Virus.

The Center is founded on an initial \$285.6 million investment, including a \$176.6 million contribution from the US Department of Health and Human Services, with the remainder cost-shared by commercial and academic proposal partners. The contract includes options for continued readiness and task orders, as well as delivery of pandemic influenza vaccines, with a total potential value in excess of \$2 billion over a 25-year duration.

ADDRESSING A CRITICAL NEED

The Texas A&M location is one of three Centers established as public-private partnerships with the U.S. Department of Health and Human Services. Each of the three Centers is structured as a public-private partnership that leverages the training expertise of academic institutions, the innovation of small biotech firms, and the development and manufacturing capabilities of large pharmaceutical companies.

The Centers represent a long-term, strategic initiative to assure preparedness and will deliver on several critical objectives:

- Ensure the US can develop and produce life-saving vaccines and therapies quickly and nimbly
- Improve the ability to protect the health of Americans in emergency situations
- Fill recognized gaps in preparedness and response to known and unknown threats

The Centers are overseen by the Biomedical Advanced Research and Development Authority (BARDA) within the HHS Office of the Assistant Secretary for Preparedness and Response. The need for this advanced public health and biosecurity capability was identified following a comprehensive review of federal public health emergency medical countermeasures.

In addition to accelerating research and development, and ensuring domestic manufacturing capacity, the Centers will mentor the next generation of public health professionals through extensive workforce training.

LEVERAGING EXPERTISE

As an integral part of the Texas A&M Center will be the development and manufacture of GSK's cell-based influenza vaccine to protect the nation against global pandemics and annual outbreaks. Operations at the CIADM will complement and support GSK's existing influenza vaccines operations, based in Quebec and Dresden, Germany. GSK Vaccines U.S. operations hub is based in Marietta, PA.

GSK is the world's largest and most successful vaccine developer with 30+ vaccines currently marketed worldwide, with eleven licensed by the FDA. GSK distributes 1.4 billion vaccine doses annually.

Among the resources to be leveraged by the CIADM is the National Center for Therapeutics Manufacturing (NCTM). Located on the Texas A&M University campus, the NCTM facility has over 150,000 square feet of space for biopharmaceutical manufacturing, advanced development and training. The NCTM offers modular, flexible technologies for process development, pilot and commercial manufacturing, and emergency surge production. In addition to meeting the nation's biosecurity needs, this program can also be utilized by academic and commercial scientists to facilitate development of new vaccines and biological drugs for diseases such as cancer and diabetes, as well as for globally significant infectious diseases like tuberculosis and HIV/AIDS.

INVESTING IN THE FUTURE

To sustain this national capability, The Texas A&M Center for Innovation will train the next generation of scientific, engineering, medical and policy professionals who will in the future be responsible for sustaining and growing our nation's capabilities and eventually assuming national leadership roles.

Workforce training will focus on:

- Therapeutics manufacturing to directly support biomanufacturing and related jobs, including process development, production systems, assay development, quality assurance, quality control and regulatory science.
- Advanced development to directly support professions related to animal model development, characterization, validation, extrapolation to human efficacy, regulatory science and compliance.

LEADERSHIP

Brett P. Giroir, M.D. – Principal Investigator (PI)

Dr. Brett P. Giroir is Vice Chancellor for Strategic Initiatives for The Texas A&M University System and is responsible for leading the Center for Innovation. Dr. Giroir is a former director of the Defense Sciences Office at DARPA and chair of the Chemical and Biological Defense Panel for the Threat Reduction Advisory Committee (TRAC) for the U.S. Department of Defense. Giroir received his undergraduate education at Harvard University and his medical training at the University of Texas Southwestern Medical Center. He is a frequently published basic science and clinical investigator. Giroir currently holds professor appointments at the Texas A&M Colleges of Medicine and Engineering and an adjunct professor appointment at the Texas A&M University Bush School of Government and Public Service. He is the recipient of the Texas A&M System Award for Innovation and the U.S. Secretary of Defense Medal for Outstanding Public Service. Dr. Giroir was a 2012 finalist for the Dallas Morning News "Texan of the Year."

Scott Lillibridge, M.D. – Deputy Principal Investigator and Chief Scientific Officer

Dr. Scott Lillibridge is professor of epidemiology and biostatistics at the Texas A&M Health Science Center School of Rural Public Health and also serves as clinical professor at the TAMHSC College of Medicine, Department of Family and Community Medicine. Dr. Lillibridge has more than 30 years of experience in the field of medical and public health preparedness in domestic and international settings. He was the founding director of the CDC Bioterrorism Preparedness and Response Program in 1999 and has worked throughout the world in various emergency response roles related to biodefense and biotechnology. While serving in the U.S. Public Health Service he was assigned to the CDC Epidemic Intelligence Service and also was assigned as special assistant to the secretary of the Department of Health and Human Services during the anthrax attacks of 2001.