EXAMPLE 1 EXAMPLE 1 EXAMP

Pharmaceutical clinical trials in **TEXAS**

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Executive

This report shows how biopharmaceutical research companies continue to be vitally important to the economy and patient health in Texas.

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 17,000 clinical trials of new medicines in Texas in collaboration with clinical research centers, hospitals and local research institutions. These clinical trials have investigated or are investigating some of Texas' biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and gastrointestinal diseases.

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CLINICAL TRIALS IN TEXAS ARE A VITAL PART OF THE FDA DRUG APPROVAL PROCESS

In the development of new medicines, clinical trials are conducted to establish therapeutic effectiveness and safety and compile the evidence needed for the U.S. Food and Drug Administration (FDA) to approve new treatments.

Clinical trials of new medicines are typically conducted in three phases and, on average, account for nearly seven of the more than 10 years it takes to bring a new medicine from development to patients. Clinical trials are responsible for more than half of the \$2.6 billion average cost of developing one new innovative medicine.

Institutional Review Boards (IRBs), independent committees of physicians, statisticians, local community advocates and others, review and approve clinical trials in advance to ensure trials are ethically conducted and patient rights are protected.

TEXAS

Executive Summary (cont.)

CLINICAL TRIALS MAY OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

For patients, clinical trials may offer the potential for another therapeutic option, or provide for a treatment where no FDA-approved treatments exist. Clinical trials may provide a new avenue of care for some chronic disease sufferers who are still searching for the medicines that are best for them.

Additionally, some clinical trials are conducted to compare existing treatments and some are done to explore whether a medicine is appropriate for a different patient population, such as children or the elderly. Still others are conducted to find ways to make existing approved treatments more effective and easier to use with fewer side effects.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN TEXAS

Biopharmaceutical research companies have been and continue to be a good source of jobs, tax revenue and research spending in Texas.

A study by TEConomy Partners¹ found that in 2020, the industry supported more than 249,800 jobs throughout Texas. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in \$3.4 billion in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$76.5 billion in economic activity in the state, including the direct economic output of the sector itself, the output of the sector's vendors and suppliers and the output generated by the buying power of its workforce. Company employees in Texas include life science researchers, management executives, office and administrative support workers, production workers, engineers, architects, computer and math experts, and sales representatives. Biopharmaceutical companies also supported the jobs of their vendors and suppliers, including construction and IT firms. And the employees of biopharmaceutical companies help to support local restaurants, day care centers and other community businesses.

ECONOMIC IMPACT OF CLINICAL TRIALS IN TEXAS

A separate study by TEConomy Partners² found that in 2017 alone, there were 1,989 active industry-sponsored clinical trials in Texas, with an estimated enrollment of 91,696 Texas residents. Oncology was the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was more than \$1.5 billion and the estimated total economic impact was more than \$4.6 billion.

"The Texas biopharmaceutical sector is creating tens of thousands of good paying jobs, investing in research and development of new cures and treatments for patients. By helping us live healthier lives, the industry provides hope for individuals and families across our state and country"

> Kent Hance, Chair, We Work for Health Texas

¹ The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, TEConomy Partners, https://www.phrma.org/-/media/Project/PhRMA/PhRMA/Org/PhRMA-Org/PDF/Economic-Impact-States-2022/US--Puerto-RicoEco-Impact-One-Pager-FINAL.pdf

² Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies, TEConomy Partners, http://phrma-docs.phrma.org/files/dmfile/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf "Biopharmaceutical research and manufacturing create jobs, drive investment and contribute to local, state and the larger national economy. Since 2004, this vibrant and critical industry has hosted more than 17,000 clinical trials right here in Texas, which benefits local patients but also powers jobs and the economy. It is critical that Texas continues to embrace public and legislative policies that drive research and innovation here at home."

> Tony Bennett, President and CEO, Texas Association of Manufacturers

Open Clinical Trials in Texas by Disease	
Disease	Number of Trials
Allergy	4
Alzheimer's Disease and Dementia	29
Arthritis/Musculoskeletal Disorders	55
Autoimmune Diseases	49
Blood Disorders	18
Cancer	1,325
Cardiovascular Diseases	82
Diabetes	24
Eye Disorders	81
Gastrointestinal/Esophageal Disorders	77
Genetic Disorders	45
Infectious Diseases	156
Kidney Diseases	59
Liver Diseases	70
Mental Disorders	78
Neurological Diseases	125
Respiratory Diseases	52
Skin Diseases	102
Transplantation	17
Other Diseases	61
Total	2,509

Source: www.clinicaltrials.gov. Search criteria: Texas, United States; Phase: early 1, 1, 2, 3: Industry only, first posted on or after 1/1/2004. Search performed 3/3/2022. Open clinical trials are recruiting not yet recruiting, or are expanded access available.

Clinical Trial Policy Resources

THE BIOPHARMACEUTICAL SECTOR'S ROLE IN THE ECONOMY

America's biopharmaceutical research companies serve as the foundation for one of the country's most dynamic innovation and business ecosystems. The biopharmaceutical industry is among the most research and development (R&D) intensive industries in the United States. In fact, the sector accounts for the single largest share of all U.S. business R&D, accounting for approximately 17% of all R&D spending by U.S. businesses.¹ The industry and its large-scale research and manufacturing supply chain support high-quality jobs across the U.S. economy.

Biopharmaceutical companies invest 12 times more in R&D per employee than manufacturing industries overall.

The biopharmaceutical industry supported more than 4.4 million jobs across the U.S. economy in 2020, according to a study by TEConomy Partners.¹

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested nearly \$1 trillion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN TEXAS

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Texas. A TEConomy Partners study¹ found that the biopharmaceutical sector:

- Supported more than 249,800 jobs throughout Texas in 2020.
- Supported the generation of \$76.5 billion in economic activity in the state.
- Resulted in \$3.4 billion in federal and state taxes through jobs supported by the biopharmaceutical sector.

For more information on the **economic** impact of the biopharmaceutical industry in Texas, see page 2.

¹ The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, TEConomy Partners,

PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

The following are just a few of the prominent institutions that biopharmaceutical research companies are collaborating with on clinical trials for new medicines:

AARA Research Center, Dallas

Acclaim Bone & Joint Institute and Plastic Surgery, Fort Worth Advanced Clinical Research, Cedar Park Austin Neuromuscular Center, Austin Baylor Charles A. Simmons Cancer Center, Dallas Baylor College of Medicine, Houston Baylor Scott and White Health, Dallas Baylor St. Luke's Medical Center, Houston Brooke Army Medical Center, Fort Sam Houston Central Texas Clinical Research. Austin Children's Medical Center, Dallas **Clinical Associates of Research Therapeutics of** America, San Antonio Clinical Trial Network, Houston Cook Children's Medical Center, Fort Worth Corsicana Medical Research, Corsicana Covance Clinical Research Unit, Dallas Crofoot Research Center, Houston Dallas VA Medical Center, Dallas DM Clinical Research, Tomball Driscoll Children's Hospital, Corpus Christi El Paso Children's Hospital, El Paso Element Research Group, San Antonio Endeavor Clinical Trials, San Antonio Excel Diagnostics and Nuclear Oncology Center, Houston First Surgical Hospital, Houston HD Research, Bellaire

Houston Methodist Hospital, Houston, Sugar Land

ICON Early Phase Services, San Antonio

Jennie Sealy Hospital, Galveston

JP Smith Hospital, Fort Worth

Juno Research, Houston, Katy

Keystone Research, Austin

Las Palmas Medical Center, El Paso

Mary Crowley Cancer Research Center, Dallas

McLane Children's Specialty Clinic, Temple

Memorial Hermann Memorial City Medical Center, Houston

Metroplex Clinical Research Center, Dallas

Metroplex Pulmonary and Sleep Center, McKinney

Michael E. DeBakey Veterans Affairs Medical Center, Houston

Mission Research Institute, New Braunfels

Next Oncology, Austin, San Antonio

Pharmatex Research, Amarillo

Pinnacle Clinical Research, San Antonio

Plano Surgical Hospital, Plano

PnP Research, Amarillo

PPD Clinical Research, Austin

PRX Research, Dallas Regional Medical Center, Mesquite

Renovatio Clinical Consultants, Spring

Retina Foundation of the Southwest, Dallas

Retina Research Institute of Texas. Abilene

Sherman Clinical Research, Sherman

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, Dallas

South Texas Accelerated Research Therapeutic, San Antonio

PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION CONTINUED

South Texas Veterans Health Care System, Audie L. Murphy Veterans Hospital, San Antonio

St. David's Medical Center, Austin

START (South Texas Accelerated Research Therapeutics), San Antonio

Texas A&M University, College Station, Kingsville

Texas A&M University College of Dentistry, Dallas

Texas Children's Hospital, Houston

Texas Clinical Research Institute, Arlington

Texas Liver Institute, American Research Corporation, San Antonio

Texas Oncology, Austin, Dallas, Denton, McKinney, Sherman, Tyler

Texas Tech University Health Sciences Center, El Paso

The Methodist Hospital, Houston

TTS Research, Boerne

University of Houston College of Medicine, Houston

University of North Texas Health Science Center, Fort Worth

University of Texas at Austin, Austin

University of Texas Health Science Center, Houston, San Antonio

University of Texas MD Anderson Cancer Center, Houston

University of Texas Medical Branch, Galveston

University of Texas Rio Grande Valley, Edinburg

University of Texas Southwestern, Dallas

US Oncology, The Woodlands

Worldwide Clinical Trials, San Antonio

TEXAS UNIVERSITIES PLAY A KEY ROLE IN RESEARCH

Collaborations between the biopharmaceutical research industry and universities play an important role in the development of new medicines. In the United States, there are more than 8,500 open clinical trials¹ being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined.

These trials represent studies being funded by industry, research collaboration studies, and research the other groups are undertaking on their own.

In Texas, of the 2,509 open clinical trials involving the biopharmaceutical research industry, the campuses of the University of Texas are collaborating on more than 500 clinical trials¹ and Baylor College of Medicine on approximately $300.^{1}$ Texas Tech University has completed more than 200 clinical trials in the last 15 years, averaging more than 13 per year.² Texas A&M

University, the University of Houston and the University of North Texas are also collaborating on multiple clinical trials.

In addition to the research medical schools in Texas, the Texas Tech Jerry H. Hodge School of Pharmacy has research interests and expertise in many areas of study. These include expertise in the blood-brain barrier and neurovascular studies, pharmacokinetics, medicinal chemistry, drug delivery and formulations, stroke and brain ischemia, pulmonary embolism and hypertension, brain vascular effects of emerging tobacco products, cancer biology, cancer immunology and immunotherapy, nanoparticle drug delivery, tumor microenvironment, metastatic brain cancer, drug resistance, and molecular cancer therapy.

¹ Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase early 1, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 4/16/2021. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

² Texas Tech University

THE STATE OF DISEASE IN TEXAS

More than 29.1 million people live in Texas,¹ and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics i	n Texas
Disease	Health Statistic
Alzheimer's Deaths 2015 ²	8,892
Asthma Prevalence-Children 2021 ²	479,712
Cancer New Cases 2021 ³	133,730
Cancer Deaths 2021 ³	42,840
Chronic Lower Respiratory Dis. Deaths 2015 ²	10,216
Diabetes Prevalence-Adults 2019 ⁴	12.2%
Diabetes Deaths 2015 ²	5,503
Heart Disease Deaths 2015 ²	43,133
HIV Deaths 2015 ²	634
HIV-Number Living with a Diagnosis ⁴	91,764
Influenza/Pneumonia Deaths 2015 ²	3,208
Kidney Disease Deaths 2015 ²	4.048
Liver Disease Deaths 2015 ²	3,841
Mental Illness-Adults 2018-2019 ⁴	3,602,000
Parkinson's Deaths 2015 ²	1,982
Septicemia Deaths 2015 ²	4,370
Stroke Deaths 2015 ²	10,470

Sources: 1. U.S. Census Bureau 🛛 2. Texas Health and Human Services 🖪 American Cancer Society 👍 Kaiser Family Foundation, State Health Facts

TEXAS CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up 25.5%¹ of the population in Texas. Pediatric clinical trials are being conducted in the state for asthma, atopic dermatitis, Crohn's disease, cystic fibrosis, diabetes, epilepsy, Lennox-Gastaut syndrome, leukemia, neuroblastoma and sickle cell disease, among others.²
- Texans aged 65 and older account for 12.9%¹ of the states' population. In Texas, clinical trials are recruiting older people to study potential treatments for diseases such as breast cancer, chronic obstructive pulmonary disease,

Crohn's disease, diabetic kidney disease, glaucoma, heart failure, leukemia, lymphoma, prostate cancer and rheumatoid arthritis, among others.²

• Women and girls make up 50.3%¹ of the population in Texas. Clinical trials are recruiting women for studies on medicines for breast cancer, cervical cancer, endometriosis, osteoporosis, postpartum depression, respiratory syncytial virus, rheumatoid arthritis, urinary tract infections, among others.²

Population	Number of Trials
Children (birth-17)	383
Seniors (66 and older)	2,206
Women (only)	74

"With continued research, development and manufacturing in Texas and beyond, the biopharmaceutical industry has, since 2000, brought more than 500 new medicines to patients in the U.S. As a result, many patients, like me, are seeing better quality of life and improved medical outcomes as we face some of the costliest and most challenging diseases, including cancer and diabetes. Our leaders must recognize the value that research, clinical trials, medical innovation and manufacturing bring to patients right here at home, and support policies that encourage this industry to continue to invest in Texas."

¹ U.S. Census Bureau, ² www.clinicaltrials.gov

SCIENCE AND CLINICAL TRIALS

Some of the medicines in clinical testing in Texas feature cutting-edge medical technologies. For example:

- A synthetic analogue of human parathyroid hormone-related protein (hPTHrP) is in development for the treatment of male osteoporosis. The protein hPTHrP is thought to be a critical cytokine for promoting new bone formation. The medicine is designed to build bone rapidly without inducing hypercalcemia (too much calcium in the blood) or significant bone resorption. The medicine is in clinical trials in **Houston** and **McAllen**.
- An approved monoclonal antibody is in development for first-line treatment of nonsmall cell lung cancer (NSCLC). The antibody inhibits PD-L1 interactions and is thought to enable the activation of T-cells and the adaptive immune system. The monoclonal antibody may potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity. It's being studied at **Coastal Bend** Cancer Center in Corpus Christi and Oncology Consultants in Houston. Additional combination studies are underway at the University of Texas Southwestern Medical Center in Dallas, the UT Southwestern Simmons Comprehensive Cancer Center in Dallas and the University of Texas MD Anderson Cancer Center in Houston.
- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It was studied in clinicals at the Arlington Cancer Center in Arlington, the Urology Clinic of North Texas in Dallas, the Texas Cancer Center in Fort Worth and Weatherford, the Mary Crowley Cancer Research Center in Dallas, the Central Texas Veterans Health Care System in Temple and at Scott and White Memorial Hospital in Temple.
- A novel treatment being testing for ischemic stroke may be able to reverse brain damage suffered from a stroke. The treatment, a combination of a variant of human activated protein C and human stem cells, is administered to patients within a few hours of having had an ischemic stroke. The transplanted stem cells mature into neurons and other brain cells, helping to reverse brain damage from the stroke. The treatment was studied in a clinical trial in **Dallas**.

- An ex vivo gene-edited cell therapy uses a new technology called CRISPR (clustered regularly interspaced short palindromic repeats) to replace stem cells with those engineered to produce high levels of fetal hemoglobin in red blood cells, replacing the damaged hemoglobin. The increase in fetal hemoglobin has the potential to reduce or eliminate painful and debilitating crises in sickle cell disease. It is being studied at Methodist Children's Hospital/Texas Transplant Institute in San Antonio.
- A broad-spectrum antiviral medicine approved to treat COVID-19 infections in adults, is being studied in children, adolescents and young adults at the **Children's Medical Center** in Dallas and the **Texas Children's Hospital** in Houston. The medicine blocks the RNA polymerase (an enzyme that is responsible for duplicating the virus's RNA) of the virus and prevents its replication.
- A potential first-in-class oral medicine in development provides a new way for addressing type 1 and type 2 diabetes by acting on two different targets in the body. It is a dual inhibitor of both sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2), which are molecules that also help move glucose in and out of the body's cells, independent of insulin. This movement is important for the absorption of glucose in the body, one by the intestine, with glucose absorption from food and the other by the kidney, which determines how much glucose leaves the body via urine. The medicine was tested in clinical trials at locations in Austin, Beaumont, Dallas, Fort Worth, Houston, Hurst, Katy, McAllen, North Richland Hills, San Antonio, Schertz, Shavano Park and Sugar Land.
- An oral fixed-dose combination of two therapeutics which target distinct receptors in the central nervous system is in development for the treatment of treatment-resistant major depressive disorder. The medicine offers a novel mechanism of action with one therapeutic increasing the therapeutic effect of the second, offering hope to the millions of patients who do not respond to standard antidepressant therapies. The medicine was tested at research sites in Austin, Dallas, Fort Worth, Houston, San Antonio and Wichita Falls.

Patient Resources & Directory

WHAT IS THE CLINICAL TRIAL EXPERIENCE?

Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety and effectiveness of drugs, vaccines and other therapies, or new ways of using existing treatments. Clinical trials can generate data to support FDA approval of a new medicine or a new indication for an existing medication. They may also grant participants early access to new medicines. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Texas, 17,087 clinical trials since 2004 have targeted diseases and conditions like asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

PHASES OF CLINICAL TRIALS

There are typically three phases of clinical testing used to evaluate potential new medicines:

PHASE I—Researchers test the medicine in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range and identify potential side effects.

PHASE II—The medicine is given to volunteer patients, usually between 100 and 500 people, to study its efficacy, identify an optimal dose and to further evaluate its short-term safety.

PHASE III—The medicine is provided to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. They are the longest studies and usually take place in multiple sites around the world.

LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials in several ways. Health care providers may be aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. Patients can also use hospital and university websites to find the trials being conducted in their area.

For instance, clinical trials being conducted at Texas universities and hospitals can be found at:

Baylor College of Medicine, www.bcm.edu/healthcare/clinical-trials

Baylor Scott and White Health, *britrials.bswsites.com/Participate*

Texas Tech University, www.ttuhsc.edu/research/clinical-trial.aspx

University of Texas (UT) Health Science Center Houston, *www.uth.edu/ctrc/trials-today.htm* UT MD Anderson Cancer Center, www.mdanderson.org/patients-family/diagnosistreatment/clinical-trials.html

UT Medical Branch Galveston, www.utmbhealth.com/support-pages/trials

UT Southwestern, www.utsouthwestern.edu/ research/translational-medicine/participateclinical-trial/how-to-participate/search-clinicalresearch.html.

For more information about clinical trials in Texas and how to participate in a clinical trial, visit *www.centerwatch.com*, or *www.clinicaltrials.gov*.

WHAT TO EXPECT

Since clinical trials are often conducted in a doctor's office, patients may need to devote more time to physician visits and physical examinations. They may also have additional responsibilities, like keeping a daily log of their health. Generally, prospective participants will receive information about the potential risks and benefits of participating in the trial and must sign an informed consent document saying, among other things, they understand that the clinical trial is research, and that they can leave the trial at any time. Patients can volunteer to participate, leading to a pre-screening interview. If they fit the criteria and requirements of the test, they may be enrolled.

PATIENT EXPENSES

As part of the informed consent process, clinical trial sponsors must disclose any additional costs to the subject that may result from participating in the research. During pre-screening discussions with the clinical trial investigator, the patient can also ask about associated costs to participate in the trial. Clinical trial sponsors usually pay for all research-related expenses and additional testing or physician visits required by the trial. Patients or their health insurance plan may be asked to pay for any routine treatments for their disease. However, it is important for the patient to know whether their health plans will pay for clinical trial participation or whether there will be out-of-pocket costs at the patient's expense.

Patients should learn whether they or their health insurance plan will be assessed any fees, and they should determine if their insurance will cover the expense of routine examinations. Patients who live a distance from the trial site should inquire whether the clinic has a policy for covering travel costs and living expenses. The National Cancer Institute, for example, makes patients cover for their own travel costs for the initial screening visits. Once a patient is enrolled in the trial, the Institute pays for transportation costs for all subsequent trial-related visits. These patients may also receive a small per diem for food and lodging.

EXPANDED ACCESS

For patients with a serious or life-threatening disease who are ineligible or unable to participate in a clinical trial, use of an unapproved investigational medicine through an expanded access program may be an option. Expanded access is the use of an unapproved investigational medicine outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition, when there are no other comparable or satisfactory alternative treatment options. Expanded access programs are part of many biopharmaceutical companies' commitment to patients.

For more information about the drug development and approval process in the United States, see page 15.

LOCAL PATIENT ADVOCACY GROUPS

Patient advocacy groups in Texas serve as an exceptional resource for patients, offering opportunities to connect and learn more about their condition and what treatment options are available locally. These groups also provide an important voice on behalf of patients to protect access to medicines and treatments.

The following are just a few major groups that work on behalf of patients in Texas and may provide more information to patients with further questions.

Alzheimer's Association

CAPITAL OF TEXAS CHAPTER 5508 Highway 290 West, Suite 206 Austin, TX 78735 (512) 592–0990

Alzheimer's Association

Dallas & Northeast Texas Chapter 3001 Knox Street, Suite 200 Dallas, TX 75205 (800) 272–3900

Alzheimer's Association

Houston & Southeast Texas Chapter 6055 S. Loop East Freeway Houston, TX 77087 (713) 314–1313

Alzheimer's Association

North Central Texas Chapter 2630 West Freeway, Suite 100 Fort Worth, TX 76102 (817) 336–4949

Alzheimer's Association

SAN ANTONIO & SOUTH TEXAS CHAPTER 10223 McAllister Freeway, Suite 100 San Antonio, TX 78216 (210) 822–6449

American Cancer Society

Texas Chapter 11000 North MoPac Expressway, Suite 100 Austin, TX 78759 (800) 227–2345

American Diabetes Association

P.O Box 7023 Merrifield, VA 22116–7023 (713) 977–7706 adacstx@diabetes.org

American Heart Association

Houston Chapter 10060 Buffalo Speedway Houston, TX 77054 (832) 918–4000

American Heart Association

Irving (Dallas) Chapter 105 Decker Court, Suite 200 Irving, TX 75062 (214) 441–4200

American Heart Association

San Antonio Chapter 8415 Wurzbach Road San Antonio, TX 78229 (210) 810–3100

American Liver Foundation

Texas State Resource Center (800) 465–4837 info@liverfoundation.org

American Lung Association

Dallas Chapter 8140 Walnut Hill Lane, Suite 410 Dallas, TX 75231 (214) 631–5864 txinfo@lungs.org

American Lung Association

Houston Chapter 2550 North Loop West, Suite 265 Houston, TX 77092 (713) 629–5864 txinfo@lungs.org

Arthritis Foundation

NATIONAL OFFICE 1355 Peachtree Street, NE, Suite 600 Atlanta, GA 30309 (800) 283–7800

Coalition of Texans with Disabilities 1716 San Antonio St.

Austin, TX 78701 (512) 478-3366 info@txdisabilities.org

Epilepsy Foundation of Texas

Dallas Office 8390 Lyndon B. Johnson Freeway, Suite 930 Dallas, TX 75243 (214) 420–2737

Epilepsy Foundation of Texas

HOUSTON OFFICE 2401 Fountain View Drive, Suite 900 Houston, TX 77057 (713) 789–2737

LUNGevity

6917 Arlington Rd., Suite 352 Bethesda, MD 20814 (817) 501-9313

NAMI Texas

National Alliance on Mental Illness P.O. Box 300817 Austin, TX 78703 (512) 693–2000

Texas Kidney Foundation

4204 Gardendale, Suite 106 San Antonio, TX 78229 (210) 396-8440

Texas Rare Alliance

Austin, TX 78759 (512) 688-1914 Khrystal@txrare.org

OTHER PATIENT RESOURCES

MEDICINE ASSISTANCE TOOL (MAT): The Medicine Assistance Tool is a PhRMA-sponsored search engine designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs. MAT is available to those who need financial support due to their lack of insurance or inadequate prescription medicine coverage. MAT is not its own patient assistance program, but rather, a search engine for many of the support programs and resources that the biopharmaceutical industry has offered for decades. The online process takes about 15 minutes, and patients can find out instantly if they are eligible for assistance. Patients can visit *www.mat.org* for more information.

HEALTHCARE READY: Healthcare Ready is a tool activated to help keep emergency responders informed on the status of the biopharmaceutical supply chain in the event of a natural disaster or emergency. Healthcare Ready's Rx Open tool has been deployed in 11 states and the District of Columbia and helps victims and evacuees who needed to fill or re-fill their prescriptions find open pharmacies. Healthcare Ready also helps emergency responders with critical information on the challenges facing supply chain partners relating to electricity, fuel and transportation issues. Patients can visit *www.healthcareready.org* for more information.



The Texas bioscience industry supports more than 249,800 jobs throughout Texas with wages and benefits supported by the sector, resulting in \$3.4 billion in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of \$76.5 billion in direct and indirect economic activity in Texas.

Texans are also positively impacted by the presence of a strong biopharmaceutical sector and clinical trials in the state. Innovative treatments developed today are helping to expand the frontiers of science and could lead to more and better treatments for patients in the future.

In Texas, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions. And the sector's growth and strength in Texas are driving our economy and communities forward.

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of \$2.6 billion.^{*} Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine and US FDA Infographic, "Drug Approval Process," http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf (accessed Jan. 20, 2015).

Pharmaceutical Research and Manufacturers of America 950 F Street, NW, Washington, DC 20004

www.phrma.org