



RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
NEW MEXICO

Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting **more than 2,200 clinical trials** of new medicines in New Mexico in collaboration with clinical research centers, hospitals and local research institutions. These clinical trials have investigated or are investigating some of New Mexico's biggest health care challenges, including asthma, arthritis, cancer, cardiovascular disease and infectious diseases.

Summary

Clinical trials in **NEW MEXICO**

CLINICAL TRIALS IN NEW MEXICO 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.

Clinical Trials in New Mexico since 2004 — Completed and Open

All Clinical Trials

2,221

Open Clinical Trials

193

Source: www.clinicaltrials.gov. Search criteria: New Mexico, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2004. Search performed 5/8/2024. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

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.

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 NEW MEXICO

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

A study by TEconomy Partners¹ found that in 2022, the industry supported **more than 8,500 jobs** throughout New Mexico. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in **\$122.9 million in state and federal taxes paid**.

Biopharmaceutical research companies supported the generation of **\$2.7 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 New Mexico 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 NEW MEXICO

A separate study by TEconomy Partners² found that in 2017 alone, there were **232 active industry-sponsored clinical trials** in New Mexico, with an estimated enrollment of **3,536 New Mexico 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 **\$53.4 million** and the estimated total economic impact was more than **\$126 million**.

¹ TEconomy Partners, LLC. *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates*. February 2024. Report prepared for PhRMA.

² TEconomy Partners, LLC. *Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies*, April 2019. Report prepared for PhRMA. https://www.phrma.org/-/media/TEconomy_PhRMA-Clinical-Trials-Impacts.pdf

“New Mexico BIO’s mission to build, advance, and grow New Mexico’s life sciences industry is largely driven by the large economic impact that this industry has on our state, with biopharma being a crucially important contributor. Our goal is to continually generate new breakthrough solutions catalyzed by research efforts that support the development of new drugs and vital clinical trials that can extend life, enhance quality of life, and relieve suffering for patients everywhere. We are grateful for the impactful partnerships between industry, researchers, healthcare organizations, and patient advocates that energize and fuel our missions.”

Rick VanNess
President, NMBio

Open Clinical Trials in New Mexico by Disease	
Disease	Number of Trials
Alzheimer’s Disease/Dementia	2
Arthritis/Musculoskeletal Diseases	9
Autoimmune Disorders	12
Cancer	80
Cardiovascular Diseases	9
Diabetes	4
Eye Diseases	12
Gastrointestinal/Esophageal Disorders	4
Infectious Diseases	11
Kidney Diseases	4
Liver Diseases	6
Mental Disorders	8
Neurologic Disorders	8
Respiratory Diseases	13
Skin Disorders	4
Other Diseases	7
Total	193

Source: www.clinicaltrials.gov. Search criteria: New Mexico, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 5/8/2024. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

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, 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 New Mexico, **2,221** 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 more information about clinical trials in New Mexico 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 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.

"Clinical trials are essential for discovery and development of novel treatments and strategies. Our motto at UNM is 'research means hope, and it saves lives.' We are dedicated to broadening clinical trial accessibility in New Mexico as we address research disparities by enrolling participants from our diverse population."

Hengameh Raissy, PharmD
Research Professor and Interim Vice President for Research
HSC School of Medicine, Health Sciences Center
University of New Mexico

For more information about **the drug development and approval process in the United States**, see page 17.

LOCAL PATIENT ADVOCACY GROUPS

Patient advocacy groups in New Mexico 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 New Mexico and may provide more information to patients with further questions.

Alzheimer's Association

NEW MEXICO CHAPTER
6731 Academy Road, NE
Albuquerque, NM 87109
(505) 266-4473

Alzheimer's Association

NE REGIONAL OFFICE
1409 Luisa Street, Suite F
Santa Fe, NM 87505
(505) 473-1297

Alzheimer's Association

SW REGIONAL OFFICE
141 Roadrunner Parkway, Suite 133
Las Cruces, NM 88011
(575) 647-3868

Alzheimer's Association

SE REGIONAL OFFICE
Sunwest Centre Office Complex
500 N. Main, Suite 501
Roswell, NM 88201
(575) 624-1552

American Cancer Society

NEW MEXICO CHAPTER
P.O. Box 36240
Albuquerque, NM 87176
(800) 227-2345

American Diabetes Association

SERVING ARIZONA AND NEW MEXICO
P.O. Box 7023
Merrifield, VA 22116-7023
(602) 861-4731
adunn@diabetes.org

American Heart Association

NEW MEXICO CHAPTER
2201 San Pedro, NE
Building 2, Suite 102
Albuquerque, NM 87110
(800) 242-8721

American Liver Foundation

NEW MEXICO STATE RESOURCE CENTER
(800) 465-4837
info@liverfoundation.org

American Lung Association

NATIONAL OFFICE
55 W. Wacker Drive, Suite 1150
Chicago, IL 60601
(800) 586-4872

Arthritis Foundation

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

Brain Injury Alliance of New Mexico

(505) 292-7414
(888) 292-7415
info@braininjurynm.org

Epilepsy Foundation New Mexico

500 4th Street NW, Suite 102
PMB 1652
Albuquerque, NM 87102
(844) 557-1380
newmexico@efa.org

NAMI New Mexico

NATIONAL ALLIANCE ON MENTAL ILLNESS
3900 Osuna Road NE
Albuquerque, NM 87109
(505) 260-0154

National Kidney Foundation

*SERVING COLORADO, NEW MEXICO,
MONTANA AND WYOMING*
2000 S. Colorado Blvd.
Tower One Suite 2000-420
Denver, CO 80222
(800) 596-7943
nkfconm@kidney.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 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 several 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.

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 percent of all R&D spending by U.S. businesses. 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 4.9 million jobs across the U.S. economy in 2022, according to a study by TEconomy Partners.³

Over the last decade, biopharmaceutical companies that are members of the Pharmaceutical

Research and Manufacturers of America (PhRMA) have more than doubled their annual investment in the search for new treatments and cures, including \$101 billion in 2022 alone.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN NEW MEXICO

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in New Mexico. A TEconomy Partners study³ found that the biopharmaceutical sector:

- Supported more than 8,500 jobs throughout New Mexico in 2022.
- Supported the generation of \$2.7 billion in economic activity in the state.
- Resulted in \$122.9 million in federal and state taxes through jobs supported by the biopharmaceutical sector.

³ TEconomy Partners, LLC. *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. February 2024. Report prepared for PhRMA.*

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

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:

- **AccumetRx Clinical Research**, Albuquerque
- **Albuquerque Center for Rheumatology**, Albuquerque
- **Albuquerque Clinical Trials**, Albuquerque
- **Albuquerque Neuroscience**, Albuquerque
- **Arthritis and Osteoporosis Associates of New Mexico**, Las Cruces
- **AXCES Research Group**, Albuquerque, Santa Fe
- **Bosque Women's Care**, Albuquerque
- **Christus St. Vincent Regional Cancer Center**, Santa Fe
- **Eye Associates of New Mexico**, Albuquerque
- **IMA Clinical Research**, Albuquerque
- **Lovelace Scientific Resources**, Albuquerque
- **MedPharmics**, Albuquerque
- **Memorial Medical Center**, Las Cruces
- **New Mexico Cancer Care Alliance**, Albuquerque
- **New Mexico Cancer Center**, Albuquerque
- **New Mexico Clinical Research**, Albuquerque
- **New Mexico VA Healthcare System**, Albuquerque
- **Optimum Clinical Research Group**, Albuquerque
- **Presbyterian Rust Medical Center/Jorgensen Cancer Center**, Rio Rancho
- **Quantum Santa Fe**, Santa Fe
- **Renal Medicine Associates**, Albuquerque
- **San Juan Oncology Associates**, Farmington
- **The Nene and Jamie Koch Comprehensive Movement Disorders Center**, Albuquerque
- **University of New Mexico**, Albuquerque
- **Velocity Clinical Research**, Albuquerque
- **Vision Research Center Eye Associates of New Mexico**, Albuquerque
- **Xcancer/NM Oncology**, Albuquerque

NEW MEXICO 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 8,200 open clinical trials⁴ being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies, and research undertaken by other groups on their own.

In New Mexico, of the 193 open clinical trials involving the biopharmaceutical research industry, the University of New Mexico is collaborating on more than 57 of the clinical trials.

⁴ 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 5/4/2024. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

THE STATE OF DISEASE IN NEW MEXICO

More than 2.1 million people live in New Mexico¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in New Mexico	
Disease	Health Statistic
Alzheimer's Disease Deaths 2020 ²	728
Asthma Adult Prevalence 2021 ²	175,000
Asthma Children Prevalence 2021 ²	30,000
Cancer News Cases 2024 ³	11,220
Cancer Deaths 2024 ³	3,890
Chronic Liver Disease and Cirrhosis Deaths, 2020 ²	754
Chronic Lower Respiratory Deaths 2020 ²	1,164
COVID-19 Deaths 2020 ²	2,847
Diabetes Deaths 2020 ²	795
Heart Disease Deaths 2020 ²	4,226
HIV-Number Living with a Diagnosis 2021 ⁴	4,017
Influenza and Pneumonia Deaths 2020 ²	370
Kidney Disease (Nephritis) Deaths 2019 ²	340
Mental Illness – Adults 2018–2019 ⁴	338,000
Stroke Deaths 2020 ²	935

Source: 1. U.S. Census Bureau 2. New Mexico Department of Health 3. American Cancer Society 4. Kaiser Family Foundation, State Health Facts

NEW MEXICO CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up 21.7%⁵ of the population in New Mexico. Pediatric clinical trials are being conducted in the state for asthma, epilepsy, leukemia and migraine among others.⁶
- New Mexicans aged 65 and older account for 19.1%⁵ of the states’ population. In New Mexico, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer’s disease, osteoporosis, Parkinson’s disease, prostate cancer and pulmonary arterial hypertension among others.⁶
- Women and girls make up 50.2%⁵ of the population in New Mexico. Clinical trials are recruiting women for studies on medicines for cytomegalovirus infections, incontinence, ovarian cancer and uterine cancer, among others.⁶

⁵U.S. Census Bureau, ⁶ www.clinicaltrials.gov

Open Clinical Trials in New Mexico for Special Populations	
Population	Number of Trials
Children (birth–17)	22
Seniors (65 and older)	175
Women (only)	11

Source: www.clinicaltrials.gov. Search criteria: New Mexico, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2007. Search performed 5/8/2027. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in New Mexico by Sex, 2020

Disease	Male	Female
Heart Disease	2,389	1,837
Cancer	1,923	1,729
SARS Coronavirus Disease (COVID-19)	1,600	1,247
Unintentional Injuries	1,257	617
Chronic Lower Respiratory Disease	584	580
Stroke	406	529
Diabetes Mellitus	428	367
Chronic Liver Disease/Cirrhosis	448	306
Alzheimer's Disease	218	510
Suicide	412	108

Source: New Mexico Death Data; Bureau of Vital Records and Health Statistics, Epidemiology and Response Division, New Mexico Department of Health, 2020

10 Leading Disease Causes of Death in New Mexico by Race/Ethnicity, 2018–2020

Disease	American Indian/Alaska Native	Asian/Pacific Islander	Black	Hispanic	White
Heart Disease	604	93	262	3,969	7,432
Cancer	628	88	196	3,790	6,207
SARS Coronavirus Disease (COVID-19)	821	16	33	1,201	771
Unintentional Injuries	719	30	104	2,234	1,974
Chronic Lower Respiratory Diseases	70	14	55	802	2,478
Stroke	165	35	55	980	1,418
Diabetes Mellitus	359	18	50	969	749
Chronic Liver Disease/Cirrhosis	543	10	20	885	481
Alzheimer's Disease	41	11	32	585	1,208
Suicide	189	25	32	529	784

Source: New Mexico Death Data: Bureau of Vital Records and Health Statistics, Epidemiology and Response Division, New Mexico Department of Health, 2020

INDUSTRY COMMITMENT TO CLINICAL TRIAL DIVERSITY

As a nation, we are in a new era of medicine where breakthrough science is transforming patient care, but these innovations are meaningless if they don't reach all patients. It is critical that patients from traditionally underserved communities have access to innovative medicines. Achieving health equity is essential in creating a health care system that truly works.

Systemic racism that exacerbates health inequities has contributed to long-standing disparities in prevalence and severity of disease across racial and ethnic groups. These disparities can reflect in how often a disease occurs in a certain patient population, how serious the disease manifests itself in patients or how often a disease results in death.

Health disparities have many causes, including limited access to quality health care, health screenings, living and working conditions, experiences with the health care system/patient confidence, racism, bias in the treatment setting, underrepresentation of minority health care providers, and other social determinants of health, clinical trial participation, language barriers, and economics and insurance coverage.

The research-based biopharmaceutical industry recognizes the importance of including diverse patients in clinical trials for new medicines so that

the clinical trial population reflects the intended treatment population. Addressing the systemic issues that deter Black and Hispanic communities from participating in clinical trials is critical to enhancing clinical trial diversity so that those who want to participate, can.

In an effort to address this long-standing mistrust and other issues, PhRMA and its member companies recently issued the first-ever industry-wide principles on clinical trials diversity, adding a new chapter to the already existing *Principles on Conduct Clinical Trials & Communication of Clinical Trial Results*. The new clinical trial diversity principles address:

- Building Trust and Acknowledging Past Wrongs
- Reducing Barriers to Clinical Trial Access
- Using Real-World Data to Enhance Information on Diverse Populations Beyond Product Approval
- Enhancing Information About Diversity and Inclusion in Clinical Trial Participation

SCIENCE AND CLINICAL TRIALS⁷

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

- A next-generation GABA-A receptor modulator is in development to treat major depressive disorder. The GABA system contributes significantly to regulating brain function, helping to reduce fear, anxiety, and stress. Low levels of GABA have been linked to increased risk of anxiety and depression and next generation GABA-A modulators are being developed to activate the GABA receptor pathway. Clinical trials were conducted in **Albuquerque**.
- A once weekly fixed-dose combination medicine in development for type II diabetes is comprised of a long-acting basal insulin analog and an approved GLP-1 (glucagon-like peptide-1) agonist. The long-acting basal insulin has the potential to reduce the number of annual insulin injections from daily to weekly. Research has found that the GLP-1 agonist has the potential to lower blood glucose by stimulating the release of insulin and also lowers body weight. Clinical trials are being conducted at **Albuquerque Clinical Trials in Albuquerque**.
- A disease-modifying treatment in development for relapsing multiple sclerosis is an inhibitor of Bruton's tyrosine kinase (BTK) and targets the source of multiple sclerosis damage in the brain (lesions). The BTK inhibitor not only inhibits the peripheral immune system, but also crosses the blood-brain barrier to suppress immune cells that have migrated into the brain, while also modulating microglia cells that are responsible for removing damaged neurons that have been implicated in multiple sclerosis progression. The medicine shows promise for reducing neuroinflammation and neurodegeneration, both implicated in disease progression. Clinical trials are being conducted at the **University of New Mexico in Albuquerque**.
- A monoclonal antibody in development for the prevention of migraine binds to and inhibits the activity of a peptide expressed in the nervous system where it plays a role in controlling the widening of blood vessels and the transmission of nociceptive pain (pain arising from nerve cells) information. By inhibiting CGRP activity, anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. Clinical trials are ongoing at **Albuquerque Clinical Trials in Albuquerque**.
- A long-acting injectable capsid inhibitor is being developed as an anti-retroviral (ARV) treatment for HIV infections. The medicine inhibits HIV-1 replication in human peripheral blood cells by inhibiting capsid protein formation (the capsid protein is the shell around the virus containing genetic material). It is being studied in both heavily treatment-experienced patients with multi-drug resistance and treatment-naïve patients living with HIV. Clinical trials are ongoing at **AXCES Research Group in Albuquerque**.
- A novel bacterial topoisomerase II inhibitor is being developed to treat Neisseria gonorrhoeae infections and uncomplicated urinary tract infections. The drug has a dual mechanism of action and works by selectively inhibiting two bacterial enzymes – DNA gyrase and topoisomerase IV – that play a role in bacterial replication. The drug may have activity against most target pathogens resistant to established antibiotics. A clinical trial has been completed in **Albuquerque**.

The innovative treatments that are being developed today are helping to expand the frontiers of science and could lead to more and better treatments for patients in the future. In New Mexico, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions.

⁷ PhRMA Medicines in Development reports, <https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development>

Conclusion

The New Mexico bioscience industry supports more than 8,500 jobs throughout New Mexico with wages and benefits supported by the sector, resulting in \$122.9 million 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 \$2.7 billion in direct and indirect economic activity in New Mexico.

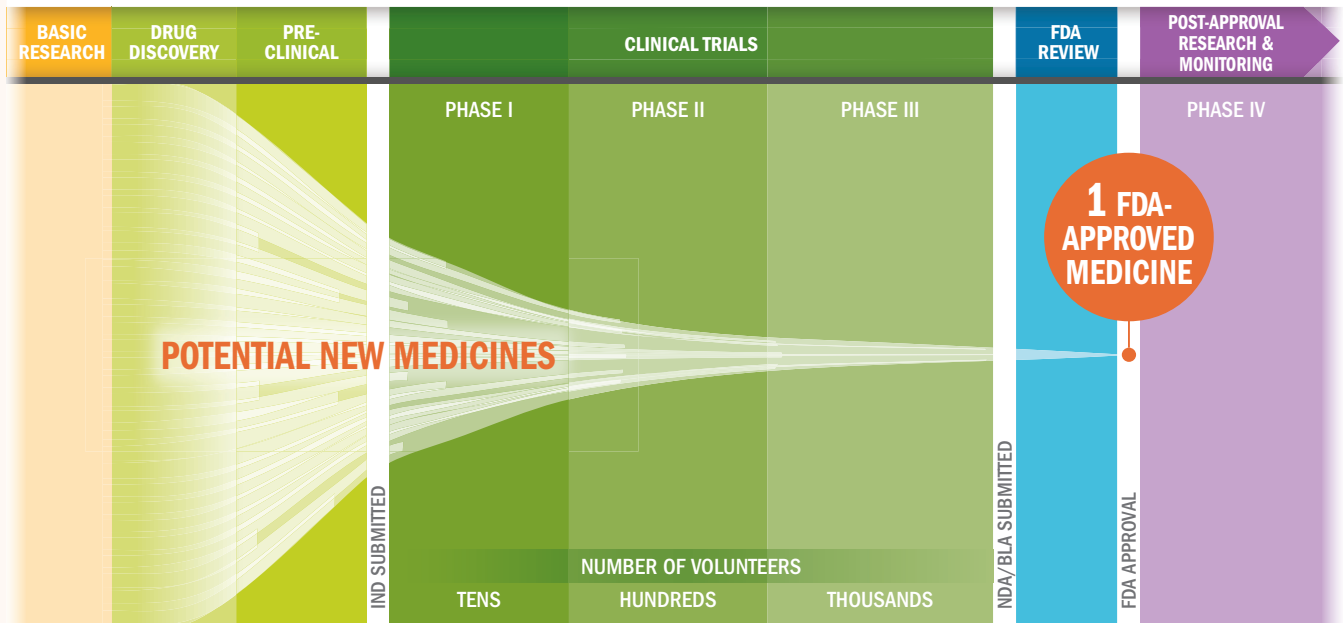
New Mexicans are also positively impacted by the presence of a strong biopharmaceutical sector

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 New Mexico, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions. And the sector's growth and strength in New Mexico are driving the 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

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