RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

NEVADA

Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting **more than 3,700 clinical trials** of new medicines in Nevada in collaboration with clinical research centers, hospitals and local research institutions. These clinical trials have investigated or are investigating some of Nevada's biggest health care challenges, including Alzheimer's disease, cancer, heart disease, arthritis, asthma and diabetes.

Summary

Clinical trials in
NEVADA

CLINICAL TRIALS IN NEVADA 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 Nevada since 2004 — Completed and Open	
All Clinical Trials	**Open Clinical Trials**
3,714	335

Source: www.clinicaltrials.gov Search criteria: Nevada, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 5/4/2024. 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 NEVADA

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

A study by TEConomy Partners[1] found that in 2022, the industry supported **more than 19,000 jobs** throughout Nevada. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in **more than $334 million in state and federal taxes paid**.

Biopharmaceutical research companies supported the generation of **$5.5 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 Nevada 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 NEVADA

A separate study by TEConomy Partners[2] found that in 2017 alone, there were **418 active industry-sponsored clinical trials** in Nevada, with an estimated enrollment of **8,189 Nevada residents**. Conditions of the central nervous system and the brain were the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was **more than $138 million** and the estimated total economic impact was **more than $357 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*

"Clinical trials are crucial to the development of innovative new treatments for diseases like cancer, obesity, and Alzheimer's disease. These trials also allow patients access to try new therapies, offering a potential lifeline for patients whose conditions may not be treatable by existing FDA-approved options. Cardiovascular conditions like heart disease, which rank as one of the leading causes of death in Nevada, are among the hundreds of clinical trials currently underway. We should all be proud to be home to the innovation responsible for tomorrow's cures."

Jeffrey L. Cummings, MD, ScD (HC),
Joy Chambers-Grundy Professor of Brain Science,
Director, Chambers-Grundy Center for Transformative Neuroscience,
Department of Brain Health, School of Integrated Health Sciences
University of Nevada Las Vegas (UNLV)

Open Clinical Trials in Nevada by Disease

Disease	Number of Trials
Alzheimer's Disease/Dementia	8
Arthritis/Musculoskeletal Diseases	8
Autoimmune Disorders	9
Blood Disorders	3
Cancer	105
Cardiovascular Diseases	16
Diabetes	11
Eye Diseases	24
Gastrointestinal/Esophageal Disorders	18
Genetic Diseases	5
Infectious Diseases	19
Kidney Diseases	9
Liver Diseases	12
Mental/Developmental Disorders	17
Neurologic Disorders	7
Obesity	10
Respiratory Diseases	23
Skin Disorders	17
Other Diseases	14
Total	**335**

Source: www.clinicaltrials.gov. Search criteria: Nevada, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1 1 2004. Search performed 5 4 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 Nevada, **3,714** 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 Nevada 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.

"At the Latin Chamber of Commerce, we support the work of clinical researchers to develop the next generation of treatments here in Nevada. These efforts bring hundreds of millions of dollars into the state and supports local businesses of all kinds. We should all be very supportive and proud of these trials' presence in Nevada and pursue policies that keep these studies here."

Peter Guzman
President
Latin Chamber of Commerce, Nevada

*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 Nevada 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 Nevada and may provide more information to patients with further questions.

Alzheimer's Association
Southern Nevada Office
7220 S. Cimarron Road, Suite 210
Las Vegas, NV 89113
(702) 248–2770

Alzheimer's Association
Northern Nevada Office
639 Isbell Road, Suite 240
Reno, NV 89509
(775) 786–8061

American Cancer Society
Nevada Chapter
P.O. Box 231359
Las Vegas, NV 89105
(800) 227–2345

American Diabetes Association
Serving Southern California and Nevada
P.O. Box 7023
Merrifield, VA 22116–7023
(317) 352–9226
ADASOCAL@diabetes.org

American Heart Association
Nevada Chapter
4445 S. Jones Blvd., Suite B1
Las Vegas, NV 89103
(702) 789–4379

American Liver Foundation
Nevada State Resource Center
(800) 465–4837
info@liverfoundation.org

American Lung Association
Nevada Office
3552 W. Cheyenne Ave., Suite 130
North Las Vegas, NV 89032
(702) 431–6333
NVInfo@lung.org

Arthritis Foundation
National Office
1355 Peachtree St. NE, Suite 600
Atlanta, GA 30309
(800) 283–7800
rangeles@arthritis.org

Cancer Community Clubhouse
1344 Disc Drive, Suite 220
Sparks, NV 89436
(940) 231–6209
natalie@cancercommunityclubhouse.org
www.cancercommunityclubhouse.org

Center for Healthy Aging
11 Fillmore Way
Reno, NV, 85919
(775) 376–3210
www.addinglifetoyears.com

Children's Advocacy Alliance
2310 Paseo del Prado, Suite A–209
Las Vegas, NV 89102–4330
(702) 228–1869
www.caanv.org

Chronic Care Collaborative
10580 N. McCarran Blvd., #115–368
Reno, NV 89503
(775) 232.0194
tommccoy@nvchroniccare.org

Cure 4 the Kids
1 Breakthrough Way
Las Vegas, NV 89135
(702) 732–1493
info@cure4thekids.org
www.cure4thekids.org

Epilepsy Foundation of Nevada
3540 West Sahara Ave., Suite 126
Las Vegas, NV 89102
877–467–3496
nvepilepsy@efa.org

Friends of Parkinsons
2400 N. Tenaya Wy,
Las Vegas, NV 89128
(702) 381–4141
www.friendsofparkinsons.org

NAMI Northern Nevada
National Alliance on Mental Illness
3100 Mill Street, Suite 210–B
Reno, NV 89502
(775) 433–1470

NAMI Southern Nevada
National Alliance on Mental Illness
2820 W. Charleston Blvd., Unit 19
Las Vegas, NV 89102
(702) 890–9729

NAMI Western Nevada
National Alliance on Mental Illness
3094 Research Way, Suite 61
Carson City, NV 89706
(775) 350–7977

National Bleeding Disorders
Nevada Chapter
222 S. Rainbow Blvd., Suite 203
Las Vegas, NV 89145
(702) 564–4368
www.hfnv.org

National Kidney Foundation
Serving Southern California and Nevada
20929 Ventura Blvd., Suite 47–216
Woodland Hills, CA 91364
(800) 747–5527

Nevada Cancer Coalition
5250 Neil Road
Reno, NV 89502
(775)451–1670
www.nevadacancercoalition.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 NEVADA

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Nevada. A TEConomy Partners study[3] found that the biopharmaceutical sector:

- Supported more than 19,000 jobs throughout Nevada in 2022.
- Supported the generation of $5.5 billion in economic activity in the state.
- Resulted in more than $334 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 Nevada**, 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:

- **AB Clinical Trials,** Las Vegas
- **Accent Clinical Trials,** Las Vegas
- **Advanced Biomedical Research of America,** Las Vegas
- **Advanced Research Institute,** Reno
- **Alliance for Childhood Diseases, Cure 4 the Kids Foundation,** Las Vegas
- **Alliance for Multispecialty Research,** Las Vegas
- **Carson Tahoe Regional Medical Center,** Carson City
- **Center for Psychiatry & Behavioral Medicine,** Las Vegas
- **Center of Hope,** Reno
- **Childrens Lung Specialists,** Las Vegas
- **Cleveland Clinic Lou Ruvo Center for Brain Health,** Las Vegas
- **Clinical Research of South Nevada,** Las Vegas
- **Comprehensive Cancer Care of Nevada,** Las Vegas
- **Comprehensive Cancer Centers of Nevada,** Las Vegas
- **Coram CVS/Specialty Infusion Services,** Henderson
- **DaVita Clinical Research,** Las Vegas
- **Excel Clinical Research,** Las Vegas
- **Healor Primary Care,** Las Vegas
- **Hope Research Institute,** Las Vegas
- **James Del Rosso Dermatology Research,** Las Vegas
- **Jubilee Clinical Research,** Las Vegas
- **Kaplan Medical Research,** Las Vegas
- **Kidney Specialists of Southern Nevada,** Las Vegas
- **Las Vegas Clinical Research Unit – PPD,** Las Vegas
- **Las Vegas Clinical Trials,** North Las Vegas
- **Las Vegas Medical Research,** Las Vegas
- **Las Vegas Research Center,** Las Vegas
- **M3 Wake Research,** Las Vegas
- **Machuca Family Medicine,** Las Vegas
- **Nevada Kidney Disease & Hypertension Center,** Las Vegas
- **Northern Nevada Endocrinology,** Reno
- **Option Care,** Las Vegas
- **OptumCare Cancer Care,** Henderson, Las Vegas
- **Palm Research Center,** Las Vegas
- **PAS Research,** Henderson, Las Vegas
- **Renown Institute for Cancer,** Reno
- **Renown Institute for Heart and Vascular Health,** Reno
- **Renown Regional Medical Center,** Reno
- **Renown South Meadows Medical Center,** Reno
- **Retina Consultants of Nevada,** Las Vegas
- **Saint Mary's Regional Medical Center,** Reno
- **Santa Rosa Medical Centers of Nevada,** Las Vegas
- **Sierra Clinical Research,** Las Vegas
- **Sierra Eye Associates,** Reno
- **Skin Cancer and Dermatology Institute,** Reno
- **University of Nevada School of Medicine,** Reno
- **VA Sierra Nevada Health Care System,** Reno
- **Vivida Dermatology,** Las Vegas
- **Wake Research - CRCN,** Las Vegas
- **Women's Cancer Center of Nevada,** Las Vegas

NEVADA 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 trials[4] 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.

[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 Nevada Chronic Care Collaborative represents a wide range of chronic diseases advocates seeking to improve access to quality, affordable, and integrated healthcare. According to a recent report, nearly one third of Nevadans currently live with chronic diseases like asthma, diabetes, and mental illness. Clinical trials provide the scientific findings that will lead to new treatments for these conditions. The enrollment of more than eight thousand Nevadans in clinical trials since 2017 illustrates our communities' commitment to the progress of medical science these trials represent."

Tom McCoy, JD
Executive Director - State Government Affairs
Nevada Chronic Care Collaborative

THE STATE OF DISEASE IN NEVADA

More than 3.1 million people live in Nevada[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Nevada	
Disease	**Health Statistic**
Alzheimer's Disease Deaths 2021[2]	804
Asthma Adult Prevalence 2021[3]	223,954
Asthma Deaths 2021[3]	28
Cancer News Cases 2024[4]	18,250
Cancer Deaths 2024[4]	5,440
Chronic Liver Disease and Cirrhosis Deaths, 2021[2]	632
Chronic Lower Respiratory Deaths 2021[2]	1,426
COVID-19 Deaths 2021[2]	5,145
Diabetes Deaths 2021[2]	866
Diabetes Prevalence 2021[3]	269,800
Heart Disease Deaths 2021[2]	7,345
HIV-Number Living with a Diagnosis 2021[5]	11,416
Influenza and Pneumonia Deaths 2021[2]	459
Kidney Disease (Nephritis) Deaths 2021[2]	309
Mental Illness-Adults 2018-2019[5]	512,000
Stroke Deaths 2021[2]	1,442

Source: 1. U.S. Census Bureau 2. Nevada Department of Health and Human Services 3. Centers for Disease Control and Prevention (CDC) 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts

NEVADA 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 Nevada. Pediatric clinical trials are being conducted in the state for acute myeloid leukemia, anemia, atopic dermatitis, diabetes, migraine and seizures, among others.[6]

- Nevadans aged 65 and older account for 16.9%[5] of the states' population. In Nevada, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, atrial fibrillation, breast cancer, depression, Parkinson's disease and prostate cancer, among others.[6]

- Women and girls make up 49.5%[5] of the population in Nevada. Clinical trials are recruiting women for studies on medicines for interstitial cystitis (bladder pain syndrome), ovarian cancer, triple negative breast cancer, urinary tract infections and uterine fibroids, among others.[6]

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

Open Clinical Trials in Nevada for Special Populations	
Population	**Number of Trials**
Children (birth–17)	45
Seniors (65 and older)	305
Women (only)	15

Source: www.clinicaltrials.gov. Search criteria: Nevada, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 4/5/2024. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Nevada by Sex, 2021		
Disease	**Male**	**Female**
Heart Disease	4,438	2,907
Cancer	2,840	2,471
COVID-19	3,192	1,953
Accidents (non-transport)	1,043	552
Stroke	686	756
Chronic Lower Respiratory Disease	649	777
Diabetes	520	346
Alzheimer's Disease	283	521
Suicide	520	163
Chronic Liver Disease and Cirrhosis	389	243

Source: Nevada Department of Health and Human Services, Office of Analytics, 2021.

10 Leading Disease Causes of Death in Nevada by Race/Ethnicity, 2021					
Disease	**American Indian/Alaska Native**	**Asian/ Pacific Islander**	**Black**	**Hispanic**	**White**
Heart Disease	62	486	827	76	5,306
Cancer	32	412	479	73	3,882
COVID-19	67	576	510	101	2,956
Accidents	22	68	113	60	1,060
Stroke	5	166	175	5	959
Chronic Lower Respiratory Diseases	9	43	93	26	1,222
Diabetes	11	71	109	5	541
Alzheimer's Disease	0	47	57	22	628
Suicide	7	34	49	16	490
Chronic Liver Disease and Cirrhosis	26	20	44	1	435

Source: Nevada Department of Health and Human Services, Office of Analytics, Office of Minority Health and Equity, 2021

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 TRIALS[7]

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

- A medicine in development to treat triple negative breast cancer binds to and inhibits AKT proteins. AKT helps to regulate cellular processes, such as cell division, cell death, and glucose and fatty acid metabolism. Mutations in the PI3K/AKT/mTOR signaling pathway can promote several types of cancer, including breast cancer, because normal cellular processes are disrupted. The medicine works by inhibiting AKT in cancer cells and is being tested in combination with paclitaxel, an approved chemotherapy treatment. Clinical trials are underway in **Las Vegas**.
- A therapy in development for hereditary thrombotic thrombocytopenic purpura (hTTP) is a bio-engineered version of the naturally occurring protein ADAMTS13 that plays a critical role in blood coagulation. A deficiency of the protein can lead to the formation of blood clots in the small blood vessels throughout the body, leading to TTP. Acquired TTP is often due to antibodies directed against ADAMTS13, while hTTP is caused by mutations of the ADAMTS13 gene, resulting in a severe deficiency of the protein. The therapy is also being studied as a treatment of vaso-crisis related to sickle cell disease. About 4,000 people have hTTP worldwide. Clinical trials are being conducted at the Alliance for Childhood Diseases, Cure 4 the Kids Foundation in **Las Vegas**.

[7] *PhRMA Medicines in Development reports, https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development*

- 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 locations in **Las Vegas**.
- A medicine approved to treat type II diabetes is in clinical trials for the treatment of obesity. The medicine binds to and activates the GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) receptors in the body. GIP and GLP-1 are hormones involved in blood sugar control. In preclinical models, GIP has been shown to decrease food intake and increase energy expenditure resulting in weight reductions. When combined with a GLP-1 receptor agonist, the treatment may result in greater effects on body weight, glucose and lipids. The medicine was recently approved in the U.S. as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus. In clinical trials, the medicine helped 63% of trial participants achieve at least a 20% reduction in body weight. Clinical trials are underway at the **Las Vegas Clinical Research Unit** in **Las Vegas**, **Jubilee Clinical Research** in **Las Vegas**, **Excel Clinical Research** in **Las Vegas**, **DaVita Clinical Research** in **Las Vegas**, **Palm Research Centers** in **Las Vegas** and the **Advanced Research Institute** in **Reno**.
- 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. A clinical trial is being conducted at the **Lou Ruvo Center for Brain Health** in **Las Vegas**.
- A disease-modifying gene therapy is being tested as a single-dose treatment for patients with GBA1-mutated Parkinson's disease. The GBA gene contains instructions for making glucocerebrosidase (GCase), which is needed for the removal and recycling of the glycolipids. Glycolipids are a cellular component that accumulates with age, causing lysosomal dysfunction and aggregation of alpha synuclein in the cells, which is thought to lead to inflammation and neurodegeneration. The gene therapy delivers a non-mutated GBA1 gene to the brain. Another DMT being tested against Parkinson's disease is a monoclonal antibody that targets alpha-synuclein and is designed to block cell-to-cell transmission of aggregated alpha-synuclein found in Parkinson's. A clinical trial is being conducted at the **Wake Research – Clinical Research Center of Nevada** in **Las Vegas**.
- 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 being conducted at the **Huntridge Family Clinic** in **Las Vegas**.
- An antibacterial targeting Clostridioides difficile for the treatment of Clostridum difficile (C. difficile) infections is an orally administered, narrow-spectrum antibacterial to specifically target C. difficile at the infection site, without causing damage to the healthy gut flora, to reduce the risk of recurrent infection. A clinical trial was conducted at **AB Clinical Trials** in **Las Vegas**.
- 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. Clinical trials were conducted in **Las Vegas**.

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 Nevada, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions.

Conclusion

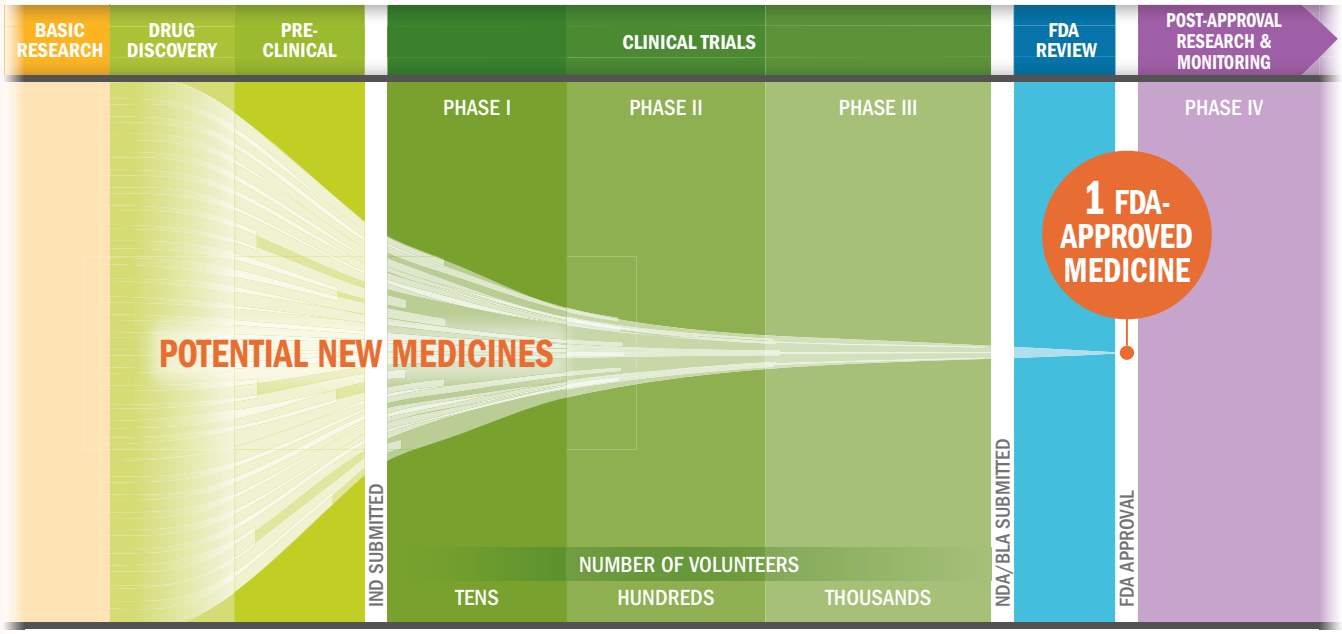
The Nevada bioscience industry supports more than 19,000 jobs throughout Nevada with wages and benefits supported by the sector, resulting in more than $334 million in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $5.5 billion in direct and indirect economic activity in Nevada.

Nevadans 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 Nevada, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions. And the sector's growth and strength in Nevada 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).

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