RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

COLORADO

Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting **more than 7,500 clinical trials** of new medicines in Colorado in collaboration with clinical research centers, hospitals, and local research institutions. These clinical trials have investigated or are investigating some of Colorado's biggest health care challenges, including Alzheimer's disease, asthma, arthritis, cancer, diabetes, cardiovascular disease and infectious diseases.

Summary

Clinical trials in
COLORADO

CLINICAL TRIALS IN COLORADO 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 Colorado since 2004 — Completed and Open

All Clinical Trials	Open Clinical Trials
7,581	853

Source: www.clinicaltrials.gov. Search criteria: Colorado, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 2/6/2024. 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 COLORADO

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

A study by TEConomy Partners[1] found that in 2022, the industry supported more than 79,000 jobs throughout Colorado. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in $1.6 billion in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $23.4 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 Colorado 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 COLORADO

A separate study by TEConomy Partners[2] found that in 2017 alone, there were 847 active industry-sponsored clinical trials in Colorado, with an estimated enrollment of 14,947 Colorado residents. Oncology/cancer was the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was more than $237 million and the estimated total economic impact was more than $706 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] *Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies, TEConomy Partners, https://www.phrma.org/-/media/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf*

"My life was saved in 2009 when my acute leukemia was cured by a bone marrow transplant from a perfectly matched donor. There are still many blood cancer and sickle cell patients who do not have a perfect match on the NMDP registry. Clinical trials are making it possible for many of those patients to receive life saving treatment from slightly mismatched donors on the registry while achieving the same results. Clinical trials are critical to advancement of new treatments and producing better outcomes for more patients."

Bob Falkenberg, Fort Collins, CO

Open Clinical Trials in Colorado by Disease

Disease	Number of Trials
Allergy	4
Alzheimer's Disease/Dementia	12
Arthritis/Musculoskeletal Diseases	10
Autoimmune Disorders	30
Blood Disorders	18
Cancer	411
Cardiovascular Diseases	32
Diabetes	11
Eye Disorders	34
Gastrointestinal Disorders	18
Genetic Diseases	30
Infectious Diseases	20
Kidney Diseases	21
Liver Diseases	21
Mental Illnesses	14
Neurologic Disorders	56
Obesity	9
Respiratory Diseases	67
Skin Disorders	18
Transplantation-Related	2
Other Diseases	15
Total	**853**

Source: www.clinicaltrials.gov. Search criteria: Colorado, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 2/6/2024. 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 Colorado, **7,581** 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 information on clinical trials being conducted at the University of Colorado visit www.uchealth.org/clinical-trials/

For more information about clinical trials in Colorado 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 in Colorado provide significant scientific and economic value to our communities. Above all else, we would not have any of the breakthrough treatments we rely on without the willingness of everyday Coloradans to participate in these trials. A recent report showed that almost 15,000 Coloradans elected to be part of clinical trials in 2017, generating a total economic impact of $706 million. We at the Fruita Area Chamber of Commerce support this vital work and give our thanks to those making tomorrow's life-saving medicines possible."

Kayla Bowers
Executive Director
Fruita Area Chamber of Commerce

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

Alzheimer's Association
Boulder and Mountain Region
5353 Manhattan Circle, Suite 100
Boulder, CO 80303
(303) 813-1669

Alzheimer's Association
Greater Denver Region
455 N. Sherman Street, Suite 500
Denver, CO 80203
(303) 813-1669

Alzheimer's Association
Northern and Northeastern Colorado Region
2695 Rocky Mountain Avene, Suite 265
Loveland, CO 80538
(303) 813-1669

Alzheimer's Association
Southern and Central Colorado Region
1520 N. Union Blvd., Suite 103
Colorado Springs, CO 80909
(303) 813-1669

Alzheimer's Association
Western Colorado Region
2232 N. 7th Avenue, Suite B1
Grand Junction, CO 81501
(303) 813-1669

American Cancer Society
Colorado Chapter
P.O. Box 370207
Denver, CO 80237
(800) 227-2345

American Diabetes Association
Rocky Mountain Area
P.O. Box 7023
Merrifield, VA 22116-7023
(720) 855-1102
ADARockyMtn@diabetes.org

American Heart Association
Denver Chapter
1777 S. Harrison Street, Suite 500
Denver, CO 80210
(303) 801-4630

American Heart Association
Colorado Springs Chapter
1586 S. 21st Street, Suite 10
Colorado Springs, CO 80904
(303) 801-4630

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

American Lung Association
Colorado Office
5600 Greenwood Plaza Blvd., Suite 300
Greenwood Village, CO 80111
(303) 388-4327

Arthritis Foundation
National Office
1355 Peachtree Street NE, Suite 600
Atlanta, GA 30309
(800) 283-7800

Epilepsy Foundation of Colorado & Wyoming
6025 S. Quebec Street, Suite 150
Englewood, CO 80111
(303) 377-9774

NAMI Colorado
National Alliance on Mental Illness
3333 S. Bannock Street, Suite 430
Englewood, CO 80110
(303) 321-3104
info@namicolorado.org

National Kidney Foundation
Serving Colorado, New Mexico, Montana & Wyoming
2000 S. Colorado Blvd.
Tower One Suite 2000-420
Denver, CO 80222
(720) 748-9991
(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.

"Health innovations from Colorado save and change lives around the world. We are proud Colorado's life sciences ecosystem is an important driver of the state's economy, providing more than 38,000 Coloradans with purpose-driven, high-paying jobs representing more than $4.4 billion in annual payroll. This is an exciting time of unprecedented growth and momentum for our life sciences ecosystem."

Elyse Blazevich
President & CEO
Colorado BioScience Association

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.

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN COLORADO

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

- Supported more than 79,000 jobs throughout Colorado in 2020.
- Supported the generation of $1.6 billion in economic activity in the state.
- Resulted in $23.4 billion 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.*

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:

- **Advanced Neurosciences Research**, Fort Collins
- **Advanced Women's Health Institute,** Greenwood Village
- **Alpine Clinical Research Center,** Boulder
- **Asthma and Allergy Associates,** Colorado Springs
- **Aurora Denver Cardiology Associates**, Denver
- **Banner MD Anderson Cancer Center at McKee Medical Center,** Loveland
- **Banner MD Anderson Cancer Center at North Colorado Medical Center,** Greeley
- **Boeson Research,** Grand Junction
- **Cancer Care & Hematology,** Fort Collins
- **Cancer Centers of Colorado,** Denver
- **CenExel Rocky Mountain Clinical Research,** Englewood
- **Childrens Hospital Colorado,** Aurora
- **Clinical and Translational Research Center,** Aurora
- **Colorado Blood Cancer Institute,** Denver
- **Colorado Center for Reproductive Medicine,** Lone Tree
- **Colorado Clinical Research,** Lakewood
- **Colorado Eye Consultants,** Littleton
- **Colorado Research Center,** Aurora
- **Colorado Retina Associates,** Lakewood
- **Colorado Springs Neurological Associates,** Colorado Springs
- **Colorado Springs Pulmonary Consultants,** Colorado Springs
- **Corneal Consultants of Colorado,** Littleton
- **Delta Waves,** Colorado Springs
- **Denver Health and Hospital Authority,** Denver
- **Denver VA Hospital,** Denver
- **Dinosaur Pediatrics,** Grand Junction
- **Downtown Women's Health Care,** Denver
- **Eye Care Center of Northern Colorado,** Longmont
- **Front Range Endoscopy Center,** Colorado Springs
- **Highlands Ranch Hospital,** Highlands Ranch
- **Innovative Clinical Research,** Lafayette
- **Kidney Associates of Colorado,** Denver
- **Lynn Institute of Denver,** Aurora
- **MCB Clinical Research Center,** Colorado Springs
- **Medical Center of the Rockies,** Loveland
- **Memorial Health Central,** Colorado Springs
- **Memorial Hospital North,** Colorado Springs
- **Mile High Research Center,** Denver
- **Mountain Mind,** Denver
- **National Jewish Health,** Denver
- **New West Physicians Clinical Research,** Golden
- **Optum-Southwestern,** Colorado Springs
- **Paradigm Clinical Research Centers,** Wheat Ridge
- **Peak Gastroenterology Associates,** Colorado Springs
- **Poudre Valley Health System,** Fort Collins
- **Red Rocks OB/GYN,** Lakewood
- **Retina Consultants of Southern Colorado,** Colorado Springs
- **Rocky Mountain Cancer Centers,** Aurora, Boulder, Centennial, Colorado Springs, Denver, Lakewood, Littleton, Lone Tree, Longmont, Pueblo, Thornton
- **Rocky Mountain Internal Medicine**, Aurora
- **Sarah Cannon Research Institute at HealthONE,** Denver
- **Intermountain Health-Saint Joseph Hospital Cancer Center,** Denver
- **Intermountain Health-Good Samaritan Medical Center Cancer Centers of Colorado,** Broomfield
- **Southwest Retina Consultants,** Durango
- **St. Mary's Hospital & Regional Medical Center,** Grand Junction
- **Swedish Medical Center,** Englewood
- **Tekton Research,** Fort Collins, Longmont
- **The Wright Eye Center,** Colorado Springs
- **UCHealth Memorial Hospital,** Colorado Springs
- **UCHealth Metro Denver,** Aurora
- **University of Colorado Health Memorial Hospital,** Colorado Springs
- **University of Colorado Health,** Fort Collins
- **University of Colorado School of Medicine,** Anschutz Medical Campus, Aurora
- **Velocity Clinical Research,** Denver
- **Vision Institute,** Colorado Springs

COLORADO 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 8,300 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.

In Colorado, of the 853 open clinical trials involving the biopharmaceutical research industry, the University of Colorado is collaborating on more than 261 of the clinical trials.

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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 2/6/2024. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

"I'm proud of Colorado's life science rich history, our talented workforce and our premier higher education institutions. At this crucial juncture, when the state is focused on creating jobs, attracting new businesses and rebuilding the economy, supporting clinical research and the biopharmaceutical industry is pivotal to our success. I am encouraged to see the industry's academic research partnerships growing throughout Colorado. We must all work together to grow a supportive infrastructure for the conduct of clinical and translational research."

Rep. Lindsey Daugherty
Arvada, CO

THE STATE OF DISEASE IN COLORADO

More than 5.8 million people live in Colorado[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease

Selected Disease Statistics in Colorado	
Disease	**Health Statistic**
Alzheimer's Disease Deaths 2022[2]	1,870
Asthma Prevalence Adults 2021[3]	476,932
Asthma Deaths 2022[2]	61
Cancer New Cases 2024[4]	29,430
Cancer Deaths 2024[4]	8,480
Chronic Lower Respiratory Deaths 2022[2]	2,461
COVID-19 Deaths 2022[2]	2,261
Diabetes Deaths 2022[2]	1,210
Diabetes Prevalence 2021[3]	345,800
Heart Disease Deaths 2022[2]	8,371
HIV Deaths 2022[2]	40
HIV-Number Living with a Diagnosis 2021[5]	13,442
Influenza/Pneumonia Deaths 2022[2]	468
Kidney Disease (Nephritis) Deaths 2022[2]	555
Chronic Liver Disease Deaths 2022[2]	1,208
Mental Illness-Adults 2018–2019[5]	1,014,000
Parkinson's Disease Deaths 2022[2]	664
Stroke Deaths 2022[2]	2,093

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

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

- Children under the age of 18 make up 20.8%[5] of the population in Colorado. Pediatric clinical trials are being conducted in the state for asthma, atopic dermatitis, cystic fibrosis, diabetes, epilepsy, migraine and leukemia, among others.[6]

- Coloradans aged 65 and older account for 15.7%[5] of the states' population. In Colorado, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, breast cancer, osteoarthritis of the knee, age-related macular degeneration, Parkinson's disease, prostate cancer and respiratory syncytial virus, among others.[6]

- Women and girls make up 49.2%[5] of the population in Colorado. Clinical trials are recruiting women for studies on medicines for Alzheimer's disease, breast cancer, endometrial cancer, ovarian cancer, rheumatoid arthritis and stress incontinence, among others.[6]

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

Open Clinical Trials in Colorado for Special Populations

Population	Number of Trials
Children (birth-17)	189
Seniors (65 and older)	715
Women (only)	19

Source: www.clinicaltrials.gov. Search criteria: Colorado, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 2/6/2024. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Colorado by Sex, 2022		
Disease	**Male**	**Female**
Heart Disease	4,658	3,713
Cancer	4,334	3,987
Chronic Lower Respiratory Diseases	1,199	1,262
COVID-19	1,295	966
Stroke	893	1,200
Alzheimer's Disease	569	1,301
Diabetes	770	440
Chronic Liver Disease, Cirrhosis	728	480
Nephritis, Nephrosis, Nephrotic Syndrome	296	259
Influenza and Pneumonia	228	240

Source: 2022 Vital Statistics Program, Colorado Department of Public Health and Environment

10 Leading Disease Causes of Death in Colorado by Race/Ethnicity, 2022

Disease	American Indian/ Native Alaskan	Asian	Black/ African American	Hispanic	Native Hawaiian/ Other Pacific Islander	White
Heart Disease	37	132	320	885	5	6,715
Cancer	34	156	279	1,043	11	6,578
Chronic Lower Respiratory Diseases	9	24	81	191	*	2,083
COVID-19	21	35	83	470	*	1,588
Stroke	12	50	83	253	7	1,635
Alzheimer's Disease	4	29	38	168	0	1,588
Diabetes	16	21	83	260	4	796
Chronic Liver Disease, Cirrhosis	22	8	29	347	0	758
Nephritis, Nephrosis, Nephrotic Syndrome	3	9	24	107	3	401
Influenza and Pneumonia	3	13	19	71	*	340

Source: 2022 Vital Statistics Program, Colorado Department of Public Health and Environment (note: not including those categorized as two or more races)
** Indicates one or two events in the category.*

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 Colorado feature cutting-edge medical technologies. For example:

- An anti-TIGIT monoclonal antibody (mAb) is in development for non-small cell lung cancer and esophageal cancer. The medicine works as an immune amplifier, by potentially enhancing the body's immune response. It blocks the interaction of TIGIT with a poliovirus receptor that can suppress the body's immune response. It is being studied as a monotherapy and in combination with an approved anti-PD-L1 mAb. The combination of the TIGIT mAb and the PD-L1 mAb offers a dual blockade that has the potential to increase anti-tumor activity. A clinical trial is being conducted at the **Rocky Mountain Cancer Center** in **Denver**.

- An estrogen receptor protein degrader is in development for estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer. The estrogen receptor is a primary driver of hormone receptor positive (HR+) breast cancer, the most common subtype of breast cancer. The potential treatment is designed to specifically target and degrade the estrogen receptor. It is being developed as a monotherapy and in combination with other therapies. Clinical trials are underway at **UCHealth Poudre Valley Hospital** and **UCHealth Harmony** in **Fort Collins**, **UCHealth Greeley Hospital** in **Greeley** and **UCHealth Medical Center of the Rockies** in **Loveland.**

- An oral kappa opioid receptor (KOR) antagonist is in development as an adjunctive treatment for major depressive disorder. KOR antagonists play an important role in helping regulate stress and mood. Kappa opioid receptors are involved in anxiety-like, dysphoric, aversive and drug-seeking behavioral responses. KOR antagonists block kappa-opioid receptors and reduce these responses, producing antidepressant and anti-addictive effects. A clinical trial is being conducted at the **MCB Clinical Research Center** in **Colorado Springs.**

- A medicine in development for post-traumatic stress disorder (PTSD) is an inhibitor of the transient receptor potential (TRP) channels 4 and 5. TRP channels are expressed in the brain and implicated in the innate fear function (innate fear helps humans avoid or escape dangerous situations). TRP channels are involved in anxiety-like behavior. For example, TRPC5 increases the activity of the hormone CCK (cholecystokinin), which increases neuronal anxiety. By inhibiting the activity of TRPC4/5 and therefore reducing CCK activity, depressive and anxiety behaviors are suppressed. The medicine is also in development for major depressive disorder and borderline personality disorder. A clinical is being conducted at **Mountain Mind** in **Denver.**

- A gene therapy is in development that uses AAV vectors to deliver a high-activity Factor IX gene to the liver for the treatment of hemophilia B. Hemophilia B is caused by a mutation in Factor IX, which leads to deficient blood coagulation and an increased risk of bleeding or hemorrhaging. Hemophilia B is four times less common than hemophilia A. A clinical trial is being conducted at the **University of Colorado Anschutz Medical Campus** in **Aurora.**

- 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 being conducted at the **University of Colorado** in **Aurora, Optum-Southwestern** in **Colorado Springs, Kidney Associates of Colorado** in **Denver** and **New West Physicians Clinical Research** in **Golden.**

- 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 Colorado** in **Aurora** and **Advanced Neurosciences Research** in **Fort Collins.**

- 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. The medicine is being studied in pediatric patients at **Children's Hospital Colorado** in **Aurora.**

- 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. A clinical trial is being conducted at the **University of Colorado** in **Aurora.**

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 Colorado, 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

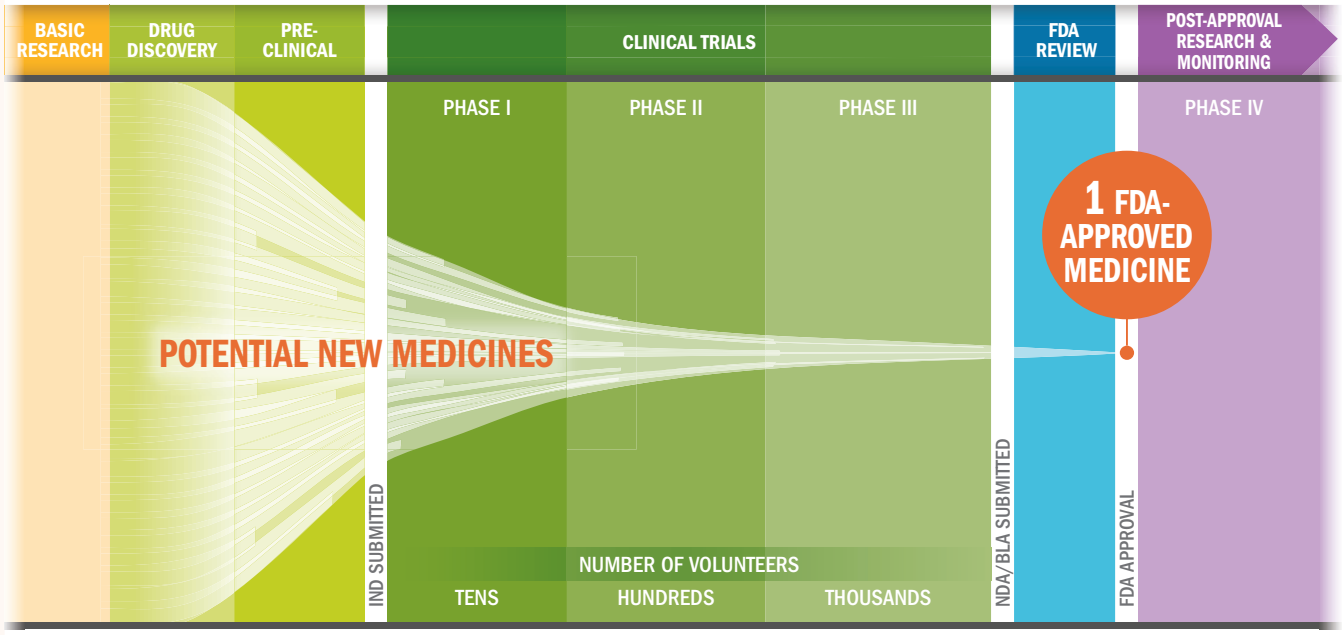
The Colorado bioscience industry supports more than 79,000 jobs throughout Colorado with wages and benefits supported by the sector, resulting in $1.6 billion in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $23.4 billion in direct and indirect economic activity in Colorado.

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