RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

NEBRASKA

Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 3,400 clinical trials of new medicines in Nebraska in collaboration with clinical research centers, hospitals and local research institutions. These clinical trials have investigated or are investigating some of Nebraska's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and gastrointestinal diseases.

Summary

Clinical trials in
NEBRASKA

CLINICAL TRIALS IN NEBRASKA 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 Nebraska since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
3,407	394

Source: www.clinicaltrials.gov. Search criteria: Nebraska, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 9/28/2021. 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.

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN NEBRASKA

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

A study by TEConomy Partners[1] found that in 2017, the industry supported more than 14,600 jobs throughout Nebraska. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in $187 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $4.2 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 Nebraska 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 NEBRASKA

A separate study by TEConomy Partners[2] found that in 2017 alone, there were 403 active industry-sponsored clinical trials in Nebraska, with an estimated enrollment of 8,403 Nebraska residents. Infectious diseases/virology was the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was more than $153 million and the estimated total economic impact was more than $394 million.

[1] *The Economic Impact of the U.S. Biopharmaceutical Industry: 2017 National and State Estimates, TEConomy Partners, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf*

[2] *Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies, TEConomy Partners, http://phrma-docs.phrma.org/files/dmfile/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf*

"Clinical trials offer cancer patients a chance to receive the most up-to-date and promising care available, with the prospects of improved health outcomes and the benefit of advancing medical research."

Megan Word, Nebraska Government Relations Director, American Cancer Society Cancer Action Network

Open Clinical Trials in Nebraska by Disease	
Disease	**Number of Trials**
Alzheimer's Disease and Dementia	4
Arthritis/Musculoskeletal Disorders	16
Autoimmune Diseases	7
Blood Disorders	2
Cancer	179
Cardiovascular Diseases	24
Diabetes	6
Eye Disorders	2
Gastrointestinal/Esophageal Disorders	11
Genetic Disorders	3
Infectious Diseases	57
Kidney Diseases	4
Liver Diseases	4
Mental Disorders	8
Neurological Diseases	17
Obesity	3
Respiratory Diseases	15
Skin Diseases	15
Transplantation	4
Other Diseases	13
Total	**394**

Source: www.clinicaltrials.gov. Search criteria: Nebraska, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2004. Search performed 9/28/2021. 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 Nebraska, 3,407 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. Information about clinical trials being conducted at the University of Nebraska Medical Center can be found at *https://www.unmc.edu/research/clinical-trials/index.html.*

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

WHAT TO EXPECT

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

PATIENT EXPENSES

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

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

EXPANDED ACCESS

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

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

LOCAL PATIENT ADVOCACY GROUPS

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

Alzheimer's Association
Nebraska Chapter
11711 Arbor Street, Suite 110
Omaha, NE 68144
(402) 502-4300

American Cancer Society
Nebraska Chapter
P.O. Box 24168
Omaha, NE 68124
(800) 227-2345

American Diabetes Association
Serving Iowa, Nebraska and South Dakota
P.O Box 7023
Merrifield, VA 22116-7023
(317) 352-9226
adain@diabetes.org

American Heart Association
Lincoln Chapter
1540 S. 70th Street, Suite 100
Lincoln, NE 68506
(402) 875-7382

American Heart Association
Omaha Chapter
900 Nicholas Street, Suite 200
Omaha, NE 68114
(402) 810-6870

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

American Lung Association
Nebraska Chapter
11225 Davenport Street, Suite 101
Omaha, NE 68154
(402) 502-4950

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

Epilepsy Foundation of Nebraska
108 N. 49th Street, Suite 210
Omaha, NE 68132-3147
(402) 715-9416

NAMI Nebraska
National Alliance on Mental Illness
University of Nebraska Omaha
6001 Dodge Street, CEC219
Omaha, NE 68182-0305
(402) 345-8101

Nebraska Kidney Foundation
Serving Iowa and Nebraska
6165 Northwest 86th Street
Johnston, IA 50131
(800) 596-7943
iana@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 available to those who need financial support due to their lack of insurance or inadequate prescription medicine coverage. MAT is not its own patient assistance program, but rather, a search engine for many of the support programs and resources that the biopharmaceutical industry has offered for decades. The online process takes about 15 minutes, and patients can find out instantly if they are eligible for assistance. Patients can visit *www.mat.org* for more information.

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

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 17.7% of all R&D spending by U.S. businesses.[1] The industry and its large-scale research and manufacturing supply chain support high-quality jobs across the U.S. economy.

Biopharmaceutical companies invest on average six times more in R&D as a percentage of sales than all other manufacturing industries.

The biopharmaceutical industry supported more than 4 million jobs across the U.S. economy in 2017, according to a study by TEConomy Partners.[1]

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested more than $1 trillion in the search for new treatments and cures, including an estimated $91.1 billion in 2020 alone.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN NEBRASKA

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Nebraska. A TEConomy Partners study[1] found that the biopharmaceutical sector:

- Supported more than 14,600 jobs throughout Nebraska in 2017.
- Supported the generation of $4.2 billion in economic activity in the state.
- Resulted in $187 million in federal and state taxes through jobs supported by the biopharmaceutical sector.

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

[1] *The Economic Impact of the U.S. Biopharmaceutical Industry: 2017 National and State Estimates, TEConomy Partners, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf*

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 Dermatology of the Midlands, Omaha

Alegent Health Bergan Mercy Medical Center, Omaha

Alegent Health Immanuel Medical Center, Omaha

Alegent Health Lakeside Hospital, Omaha

Alivation Research, Lincoln

Barrett Clinic, La Vista

Bryan Health, Lincoln

Bryan Women's Care Physicians, Lincoln

Celerion, Lincoln

CHI Health Good Samaritan, Kearney

CHI Health Research Center, Omaha

CHI Health Saint Elizabeth, Lincoln

CHI Health St. Francis, Grand Island

Children's Hospital & Medical Center, Omaha

Children's Physicians Clinic, Omaha

Creighton University Medical Center, Omaha

Faith Regional Health Services Carson Cancer Center, Norfolk

Fred and Pamela Buffett Cancer Center, Omaha

Great Plains Health Callahan Cancer Center, North Platte

GU Research Network, Omaha

Heartland Clinical Research, Omaha

Heartland Hematology and Oncology, Kearney

Meridian Clinical Research, Norfolk, Omaha, Hastings

Methodist Physicians Clinic, Fremont

Midlands Community Hospital, Papillion

Midwest Children's Health Research Institute, Lincoln

Missouri Valley Cancer Consortium, Omaha

Nebraska Cancer Research Center, Lincoln

Nebraska Cancer Specialists, Omaha, Papillion

Nebraska Heart Institute, Grand Island, Lincoln

Nebraska Methodist Hospital, Omaha

Omaha OB-GYN Associates, Omaha

Physician Research Collaboration, Lincoln

Pioneer Clinical Research, Bellevue

Prairie Fields Family Medicine, Fremont

Quality Clinical Research, Omaha

Regional West Medical Center, Scottsbluff

Southeast Nebraska Cancer Center, Lincoln

Synexus Clinical Research US, Omaha

University of Nebraska Medical Center, Omaha

Upstate Clinical Research Associates, Omaha

VA Nebraska-Western Iowa Health Care System, Omaha

NEBRASKA 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 8,800 open clinical trials[1] being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies, and research the other groups are undertaking on their own.

In Nebraska, of the 394 open clinical trials involving the biopharmaceutical research industry, the University of Nebraska is collaborating on more than 80 clinical trials.[1] Creighton University is also collaborating on multiple clinical trials.

[1] Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase early 1, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 9/28/2021. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

"Clinical trials are an essential component of today's healthcare system. This report illustrates that not only are clinical trials important to improving patient care and the lives of Nebraskans and citizens across the world, but have a significant impact on Nebraska's economy with a total economic impact of $394 million. With more than 3,400 clinical trials being held in Nebraska since 2004, we should be proud of Nebraska's contribution to providing cutting-edge care to patients."

Rob Owen, Executive Director,
Bio Nebraska

THE STATE OF DISEASE IN NEBRASKA

More than 1.9 million people live in Nebraska[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Nebraska	
Disease	**Health Statistic**
Alzheimer's Deaths 2016[2]	634
Asthma Deaths 2016[2]	28
Cancer New Cases 2021[3]	11,180
Cancer Deaths 2021[3]	3,560
Chronic Lung Disease Deaths 2016[2]	1,032
Diabetes Prevalence—Adults 2016[2]	8.8%
Diabetes Deaths 2016[2]	501
Heart Disease Deaths 2016[2]	3,318
HIV Deaths 2016[2]	17
HIV—Number Living with a Diagnosis 2018[4]	2,174
Influenza/Pneumonia Deaths 2016[2]	338
Kidney Disease Deaths 2016[2]	220
Mental Illness—Adults 2018–2019[4]	290,000
Parkinson's Deaths 2016[2]	201
Septicemia Deaths 2016[2]	162
Stroke Deaths 2016[2]	784

Source: 1. U.S. Census Bureau 2. Nebraska Department of Health and Human Services 3. American Cancer Society 4. Kaiser Family Foundation, State Health Facts

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

- Children under the age of 18 make up 24.6%[1] of the population in Nebraska. Pediatric clinical trials are being conducted in the state for asthma, atopic dermatitis, diabetes, epilepsy, leukemia, melanoma, pneumococcal disease, respiratory syncytial virus infections and sickle cell disease, among others.[2]

- Nebraskans aged 65 and older account for 16.2%[1] of the states' population. In Nebraska, clinical trials are recruiting older people to study potential treatments for diseases such as colorectal cancer, chronic obstructive pulmonary disease, Crohn's disease, chronic kidney disease, glaucoma, heart failure, leukemia, lymphoma, prostate cancer, type 2 diabetes and rheumatoid arthritis, among others.[2]

- Women and girls make up 50%[1] of the population in Nebraska. Clinical trials are recruiting women for studies on medicines for breast cancer, cervical dysplasia, endometriosis, ovarian cancer, osteoporosis, respiratory syncytial virus infections, rheumatoid arthritis and vasomotor symptoms of menopause, among others.[2]

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

Open Clinical Trials in Nebraska for Special Populations

Population	Number of Trials
Children (birth–17)	60
Seniors (65 and older)	335
Women (only)	11

Source: www.clinicaltrials.gov. Search criteria: Nebraska, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 9/28/2021. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

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

- An antisense treatment in development for amyotrophic lateral sclerosis (ALS) is thought to reduce the production of mutated superoxide dismutase (SOD1) protein and potentially the fatal progression of SOD1-ALS. This mutated protein has been associated with the degeneration of motor neurons in ALS. SOD1-ALS is a rare form of the disease that accounts for 20% of inherited or familial ALS and 2% of all ALS cases. Studies were conducted at sites in **Lincoln**.

- A second-generation CAR-T cell therapy comprised of genetically-modified T cells is designed to target B-cell maturation antigen (BCMA) and to redirect the T-cells to recognize and kill malignant myeloma cells. BCMA is a surface protein that is absent in most normal tissues but found in normal plasma cells and the majority of multiple myeloma cells. A clinical is underway at the **University of Nebraska** in **Omaha**.

- A potential treatment for bladder cancer, renal cell carcinoma and melanoma, among others, is designed to stimulate cancer killing cells in the body by targeting CD122 on the surface of the immune cells. This experimental immune-therapy is being studied in combination with an approved immune checkpoint inhibitor which works by unleashing the body's own powerful immune system to target and kill cancer cells. The treatment works by increasing the number of tumor-infiltrating lymphocytes (TILs) which generate an immune response leading to increased therapeutic activity of the checkpoint inhibitor to attack cancer cells while leaving normal cells alone. Clinical trials are recruiting at **Nebraska Cancer Specialists**, **Nebraska Methodist Hospital** and the **University of Nebraska Medical Center** in **Omaha**.

- A first-in-class treatment in development for higher-risk myelodysplastic syndromes (HR-MDS) targets the NEDD-8 activating enzyme (NAE). Inhibiting the NAE enzyme blocks the modification of select proteins, resulting in disruption of the cell cycle progression and cell survival, leading to cancer cell death. In clinical trials, the medicine used in combination with other anticancer therapies demonstrated promising clinical activity. If approved, it would be the first new treatment for HR-MDS in more than a decade. A clinical trial is being conducted at **Nebraska Cancer Specialists** in **Omaha**.

- 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. A clinical trial is underway for children age 6 to 17 at **Meridian Clinical Research** in **Hastings**.

- A broad-spectrum antiviral medicine, with in vitro activity against Ebola, Middle Eastern respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), is being studied as a treatment for the COVID-19 infections. The medicine blocks the RNA polymerase (an enzyme that is responsible for duplicating the virus's RNA) of the virus and prevents its replication. A clinical trial for children from birth to 18 is recruiting at **Children's Hospital & Medical Center** in **Omaha**.

- A potential first-in-class medicine in development for asthma, blocks TSLP, an immune system messenger protein that is critical in the development and persistence of inflammation of the airways. It is believed that by blocking TSLP, the release of pro-inflammatory proteins by immune cells will be stopped, resulting in the prevention of asthma exacerbations and improved asthma control. Clinical trials took place at sites in **Lincoln** and **Omaha**.

- A vaccine for the prevention of respiratory syncytial virus (RSV) infections in adults over the age of 60 acts different than traditional vaccines that "mimic" viruses and activate the natural immune system to fight the infection. The vaccine is genetically-engineered to elicit immune responses, which may be more effective than naturally-occurring immunity. Clinical trials are recruiting at **Meridian Clinical Research** in **Norfolk** and **Omaha** and at **Synexus Clinical Research US** in **Omaha**.

- A CAR-T (genetically modified chimeric antigen receptor T-cell) therapy is in development for leukemia and lymphoma. CAR-T therapy utilizes a patient's own T-cells to uniquely recognize and kill cancerous tumor cells. To make the therapy, a patient's blood is filtered to remove T-cells, which are then altered in the lab by inserting a gene that codes for a receptor that targets a protein unique to cancer cells. The T-cells are then returned to the patient intravenously, where they can then bind to and kill the cancer cells. Clinical trials are recruiting at the **University of Nebraska Medical Center** in **Omaha**.

- A monoclonal antibody (large protein molecules produced by white blood cells that seek out and destroy harmful foreign substances) is being studies in a clinical trial for the treatment of pancreatic cancer at the **University of Nebraska Medical Center** in **Omaha**.

- A long-acting version of an oral integrase inhibitor is in development for HIV pre-exposure prophylaxis (PrEP). PrEP is the use of antiviral medicines in uninfected people who have not been exposed to the virus to prevent infection. Long-acting, injectable medicines help with patient adherence to treatment for chronic illnesses. Integrase inhibitors block the action of integrase, a viral enzyme that inserts the viral genome into the DNA of the host cell. This is a vital step in retroviral replication and it's believed that blocking it can halt further spread of the virus. Clinical trials are underway at sites in **Omaha**.

Conclusion

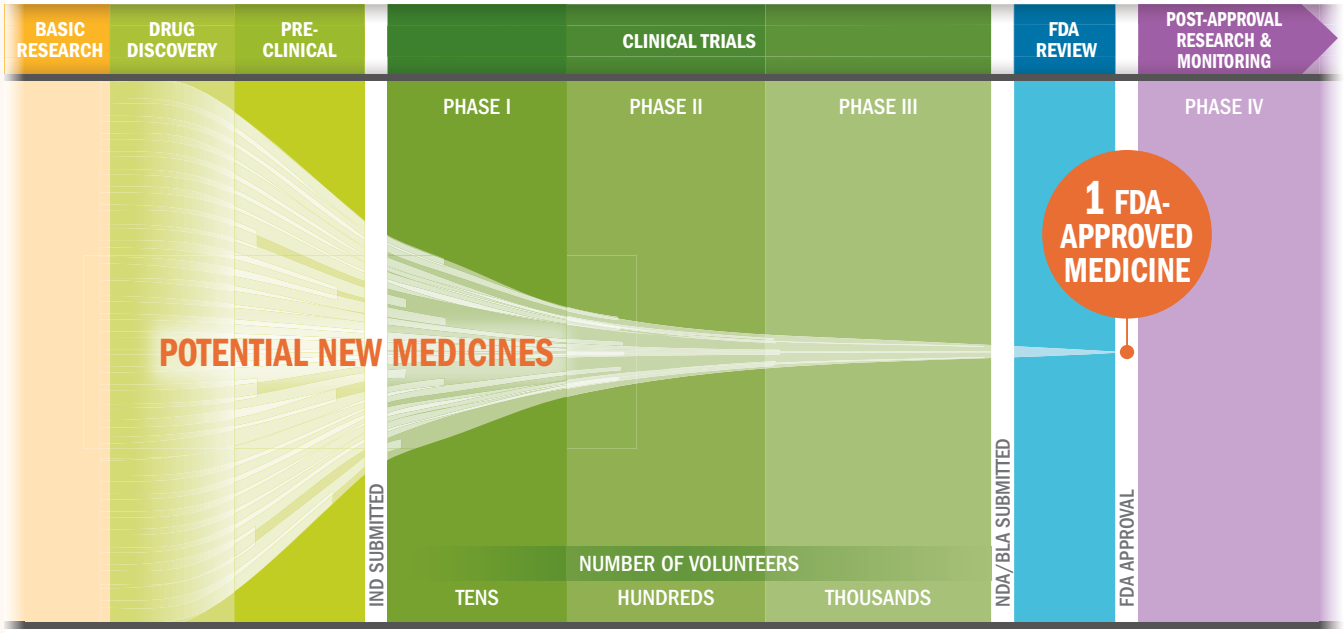
The Nebraska bioscience industry supports more than 14,600 jobs throughout Nebraska with wages and benefits supported by the sector, resulting in $187 million in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $4.2 billion in direct and indirect economic activity in Nebraska.

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

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

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



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

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

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

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

www.phrma.org