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 nearly 3,000 clinical trials of new medicines in Nebraska in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Nebraska's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

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 prove therapeutic safety and effectiveness and compile the evidence needed for the U.S. Food and Drug Administration (FDA) to approve new treatments.

Clinical tests of new drugs are conducted in three phases and, on average, account for nearly seven of the more than 10 years it takes to bring a new drug 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.

All clinical trials must be reviewed and approved by an Institutional Review Board (IRB) in advance; an independent committee of physicians, statisticians, local community advocates and others to ensure a trial is ethically conducted and patient rights are protected.

Clinical Trials in Nebraska since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
2,978	326

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 10/1/2019. Open clinical trials are recruiting, not yet recruiting or expanded access available.

Executive Summary (cont.)

CLINICAL TRIALS OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

For patients, clinical trials offer the potential for another therapeutic option. Clinical tests 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 drug is appropriate for a different patient population, such as children or the elderly. Still others are conducted to find ways to make existing approved drugs 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 found that in 2015, the industry supported more than 17,900 jobs throughout Nebraska. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than $233 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $5.4 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 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 found that in 2017 alone, there were 403 active industry-sponsored, site-based clinical trials in Nebraska, with an estimated enrollment of 8,403 Nebraska residents. Infectious diseases and virology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than $153 million and the estimated total economic impact was more than $394 million.

"This report illustrates one segment of life sciences—clinical trials—and gives us yet another opportunity to publicize the impact this industry makes on our state's economy and, more importantly, the role this industry has to impact patient care. The clinical trials ongoing in our state—further our knowledge about disease and help to improve lives of Nebraskans."

Rob Owen,
Executive Director,
Bio Nebraska Life Sciences Association

"Clinical research is critical to the mission of our academic medical center, because it is critical to the development of cutting edge care for our patients. Through clinical research we strive to improve the health of individuals throughout Nebraska, and throughout the World."

Christopher J. Kratochvil, M.D.
Associate Vice Chancellor for Clinical Research, University of Nebraska Medical Center
Vice President for Research, Nebraska Medicine
Executive Director of Clinical Research, Global Center for Health Security
Chief Medical Officer, UNeHealth

Open Clinical Trials in Nebraska by Disease

Disease	Number of Trials
Alzheimer's Disease	3
Arthritis/Musculoskeletal Disorders	10
Autoimmune Diseases	3
Bladder Conditions	2
Cancer	141
Cardiovascular Diseases	22
Diabetes	5
Gastrointestinal/Esophageal Diseases	19
Genetic Disorders	5
Infectious Diseases	35
Kidney Diseases	5
Liver Diseases	5
Mental Disorders	8
Neurological Disorders	9
Respiratory Diseases	10
Skin Diseases	27
Transplantation-Related	3
Other Diseases	14
Total	**326**

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 10/1/2019. 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 research studies that generate data to support FDA approval of a new medicine or a new indication for an existing medication. They also grant participants early access to new medicines, which are being developed to help combat chronic and serious diseases. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Nebraska, 2,978 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 three phases of clinical testing used to evaluate potential new medicines:

PHASE I—Researchers test the drug 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 drug 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 drug 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 are aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. Patients can also use hospital and university websites to find the trials being conducted in their area. For instance, for clinical trials at the University of Nebraska Medical Center visit *www.unmc.edu/cctr/for-public/clinical-trials/index.html*.

More information about clinical trials in Nebraska and how to volunteer for one can be found at *www.centerwatch.com*, a PhRMA-recommended website.

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. All prospective participants must sign an informed consent document saying they understand that the clinical trial is research, and that they can leave the trial at any time. After consulting with their health care providers, patients can volunteer to participate, leading to a pre-screening interview. If they fit the criteria and requirements of the test, they can be enrolled.

PATIENT EXPENSES

Patients should ask during pre-screening interviews what it will cost them to participate in a clinical trial. Clinical trial sponsors usually pay for all research-related expenses and additional testing or physician visits required by the trial. Patients or their insurance companies may be asked to pay for any routine treatments of their disease. And it's important to know some health plans do not pay for clinical trials.

Patients should make it a point to learn if they or their insurance company will be assessed any fees and should determine if their insurance company will cover the expense of routine examinations. Patients who live a distance from the trial site should learn the clinic's policy for covering travel costs and living expenses.

The National Cancer Institute, for example, makes patients responsible for their own travel costs for the initial screening visits. Once a patient is enrolled, the Institute will pay for transportation costs for all subsequent trial-related visits. These patients will receive a small per diem for food and lodging.

EXPANDED ACCESS

Successful completion of the clinical trials is required to demonstrate to the FDA that an investigational drug is safe and effective, so that it can be approved and made available to a broad patient population. Clinical trials are the primary route by which patients can participate in the drug development process, receive access to unapproved investigational drugs and contribute to the collection of safety and efficacy data necessary for FDA approval.

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 drug through an expanded access program may be an option. The current FDA process for a patient to gain access to an investigational drug through expanded access was established in 2009 in close consultation with patients, physicians and the biopharmaceutical industry. 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 13.*

LOCAL PATIENT ADVOCACY GROUPS

Patient advocacy groups in Nebraska provide an exceptional resource for patients to connect and learn more about their condition and what treatment options are available in the state. These groups also provide an important voice on behalf of patients to protect their access to medicine and treatment.

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
Kearney Office
4009 6th Avenue, Suite 11
Kearney, NE 68845
(402) 502–4300

Alzheimer's Association
Lincoln Office
1500 South 70th Street, Suite 201
Lincoln, NE 68506
(402) 502–4300

Alzheimer's Association
Omaha Office
11711 Arbor Street, Suite 110
Omaha, NE 68144
(402) 502–4300

American Cancer Society
Kearney Office
3808 28th Avenue, Suite E
Kearney, NE 68845
(308) 237–7481

American Cancer Society
Lincoln Office
5733 S. 34th Street, Suite 500
Lincoln, NE 68516
(402) 423–4888

American Cancer Society
Omaha Office
9850 Nicholas Street, Suite 200
Omaha, NE 68114
(402) 393–5800

American Diabetes Association
Iowa, Nebraska & South Dakota Office
7285 W. 132nd Street, Suite 160
Overland Park, KS 66213
(913) 383–8210

American Heart Association
Lincoln Office
1540 South 70th Street, Suite 100
Lincoln, NE 68506
(402) 875–7382

American Heart Association
Omaha Office
9900 Nicholas Street, Suite 200
Omaha, NE 68114
(402) 810–6870

American Liver Foundation
Mid-America Division
1110 Highlands Plaza Drive East
Suite 100
St. Louis, MO 63110
(314) 352–7377

American Lung Association
Nebraska Chapter
11225 Davenport Street, Suite 101
Omaha, NE 68154
(401) 502–4950

Arthritis Foundation
Nebraska Chapter
11414 W. Center Road, Suite 348
Omaha, NE 68144
(402) 262–0144

Epilepsy Foundation of Nebraska
108 North 49th Street, Suite 210
Omaha, NE 68132
(402) 660–6193

NAMI Nebraska
National Alliance on Mental Illness
415 S. 25th Avenue
Omaha, NE 68131
(402) 345–8101

OTHER PATIENT RESOURCES

MEDICINE ASSISTANCE TOOL (MAT): The Medicine Assistance Tool, a PhRMA-sponsored web platform designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs offered 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 been offering for decades. Patients should go to *www.mat.org* for more information. The on-line process takes about 15 minutes, and you'll find out instantly if you're likely to be eligible for help.

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 helped victims and evacuees who needed to fill or re-fill their prescriptions find open pharmacies. Healthcare Ready also helped emergency responders with critical information on the challenges facing supply chain partners relating to electricity, fuel and transportation issues. See more at *www.healthcareready.org*.

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 supports 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 4.7 million jobs across the U.S. economy in 2015, according to a study by TEConomy Partners.

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested more than $800 billion in R&D in the search for new treatments and cures.

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 found that the biopharmaceutical sector:

- Supported more than 17,900 jobs throughout Nebraska in 2015.
- Supported the generation of $5.4 billion in economic activity in the state.
- Resulted in more than $233 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.*

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:

Adult & Pediatric Urology, Omaha

Advanced Dermatology of the Midlands, Omaha

Alegent Health Bergan Mercy Hospital, Omaha

Alegent Health Bergan Mercy Medical Center, Omaha

Alegent Health Immanuel Medical Center, Omaha

Alegent Health Lakeside Hospital, Omaha

Alivation Research, Lincoln

Allergy, Asthma & Immunology Associates, Lincoln

Barrett Clinic, La Vista

Boys Town National Research Hospital, Boys Town

Bryan Health, Lincoln

Bryan Women's Care Physicians, Lincoln

Celerion, Lincoln

CHI Health Good Samaritan, Kearney

CHI Health Midlands, Papillion

CHI Health Research Center, Omaha

CHI Health Saint Elizabeth, Lincoln

CHI Health St. Francis, Grand Island

Children's Physicians Embassy Park, Omaha

Creighton University Medical Center, Omaha

Diabetes and Endocrine Associates, 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

Hematology and Oncology Consultants, Omaha

Meridian Clinical Research, Norfolk, Omaha

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 Hematology and Oncology, Lincoln

Nebraska Medical Research Institute, Bellevue

Nebraska Methodist Hospital, Omaha

Omaha OB-GYN Associates, Omaha

Physician Research Collaboration, Lincoln

Prairie Fields Family Medicine, Fremont

Quality Clinical Research, Omaha

Regional West Medical Center, Scottsbluff

Skin Specialists, Omaha

Southeast Nebraska Cancer Center, Lincoln

Synexus Clinical Research US, Elkhorn, Omaha

University of Nebraska Medical Center, Omaha

VA Nebraska-Western Iowa Health Care System, Omaha

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 7,600 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 319 open clinical trials involving the biopharmaceutical research industry, the **University of Nebraska Medical Center** is collaborating on more than 68 clinical trials and **Creighton University Medical Center** on more than 10.

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
Asthma Prevalence [Adults], 2017[3]	118,181
Cancer New Cases, 2019[3]	9,780
Cancer Deaths, 2019[3]	3,520
Chronic Lung Disease Deaths, 2016[2]	1,032
Diabetes Prevalence-Adults, 2016[4]	8.8 percent
Diabetes Deaths, 2016[2]	501
Essential Hypertension/Hypertensive renal Disease Deaths, 2016[2]	266
Heart Disease Deaths, 2016[2]	3,318
HIV Deaths, 2016[2]	17
HIV-Number Living with a Diagnosis, 2016[5]	2,086
Influenza/Pneumonia Deaths, 2016[2]	338
Kidney Disease Deaths, 2016[2]	220
Liver Disease Deaths, 2016[2]	199
Mental Illness-Adults, 2016–2017[5]	424,000
Parkinson's Death, 2016[2]	201
Septicemia Deaths, 2016[2]	162
Stroke Deaths, 2016[2]	784

Source: 1. U.S. Census Bureau 2. Nebraska Health Authority 3. U.S. Centers for Disease Control and Prevention 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts

[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 9/23/2019. Open clinical trials are recruiting, not yet recruiting or are expanded access available.*

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

- Children under the age of 18 make up 24.7 percent of the population in Nebraska. Pediatric clinical trials are being conducted in the state for ADHD, asthma, Crohn's disease, cystic fibrosis, atopic dermatitis, ulcerative colitis, acne, leukemia, pediatric heart failure and depression, among others.

- Nebraskans aged 65 and older account for 15.7 percent of the states' population. In Nebraska, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, Crohn's disease, diabetic macular edema, melanoma, prostate cancer, heart failure and rheumatoid arthritis, among others.

- Women and girls make up 50.1 percent of the population in Nebraska. Clinical trials are recruiting women for studies on medicines for breast cancer, endometriosis, candidiasis, cervical cancer, respiratory tract infections and osteoporosis, among others.

Clinical Trials in Nebraska for Special Populations

Population	Number of Trials
Children (birth–17)	62
Seniors (65 and older)	292
Women (only)	13

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 10/1/2019. 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 revolutionary medical technologies. For example:

- A monoclonal antibody in development to treat head and neck cancer and non-small cell lung cancer, inhibits PD-L1 interactions, and is thought to enable the activation of T-cells and the adaptive immune system. The monoclonal antibody may potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity. The antibody is in clinical trials at **Nebraska Cancer Specialists** in Omaha.

- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It was studied in clinical trials at **GU Research Network** and at the **University of Nebraska Medical Center** in Omaha.

- A monoclonal antibody in development for Huntington's disease binds to and blocks the activity of Semaphorin 4D (SEMA4D), a protein that plays a key role in the neuro-inflammatory processes that can cause inflammation in the brain of people with the disease. By blocking the activity of SEMA4D, it may slow or prevent the neurodegeneration in Huntington's disease, a fatal disorder that causes the breakdown of nerve cells in the brain. The antibody is being studied in a clinical trial in **Omaha**.

- Antibody-drug conjugates (ADC) utilize a monoclonal antibody to deliver a therapeutic drug to cancer cells, staying stable in the bloodstream and only releasing the therapeutic once inside the cancer cells. An ADC in development specifically targets epidermal growth factor receptors (EGFR), a growth factor that stimulates the proliferation of cell growth. The medicine is being tested in patients with EGFR-amplified **glioblastoma**. The ADC is in clinical trials at **Nebraska Methodist Hospita**l and the **University of Nebraska Medical Center** in Omaha.

- A potential first-in-class oral medicine in development provides a new way for addressing type 1 and type 2 diabetes by acting on two different targets in the body. It is a dual inhibitor of both sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2), which are molecules that also help move glucose in and out of the body's cells, independent of insulin. This movement is important for the absorption of glucose in the body, one by the intestine, with glucose absorption from food and the other by the kidney, which determines how much glucose leaves the body via urine. The medicine has been and is being studied at locations in **Norfolk**, **Omaha** and **Papillion**.

- An oral version of an already approved glucagon-like peptide (GLP-1) receptor agonist is in development for type 2 diabetes. The approved subcutaneous medicine is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It lowers blood glucose levels and reduces body weight. The oral version is being developed as a once-daily treatment offering patients the option of an injection-free option to manage their diabetes. The oral medicine was studied at clinical trial sites in **Elkhorn** and **Omaha**.

- Both type 1 and type 2 diabetes can affect nerves throughout the body, including the vagus nerve, which controls how quickly the stomach empties after eating or drinking. When the nerve is damaged, digestion slows down and food stays in the body longer than it should, causing diabetic gastroparesis. A medicine in development for diabetic gastroparesis, and derived from natural ghrelin, has been enhanced to stimulate gastrointestinal motility with greater potency and enhanced stability and pharmacokinetics (absorption, distribution, metabolism and excretion). The medicine is recruiting patients for clinical trials at **Diabetic & Endocrine Associates** and **Heartland Clinical Research** 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. The medicine is in clinical trials at locations in **Lincoln** and **Omaha**.

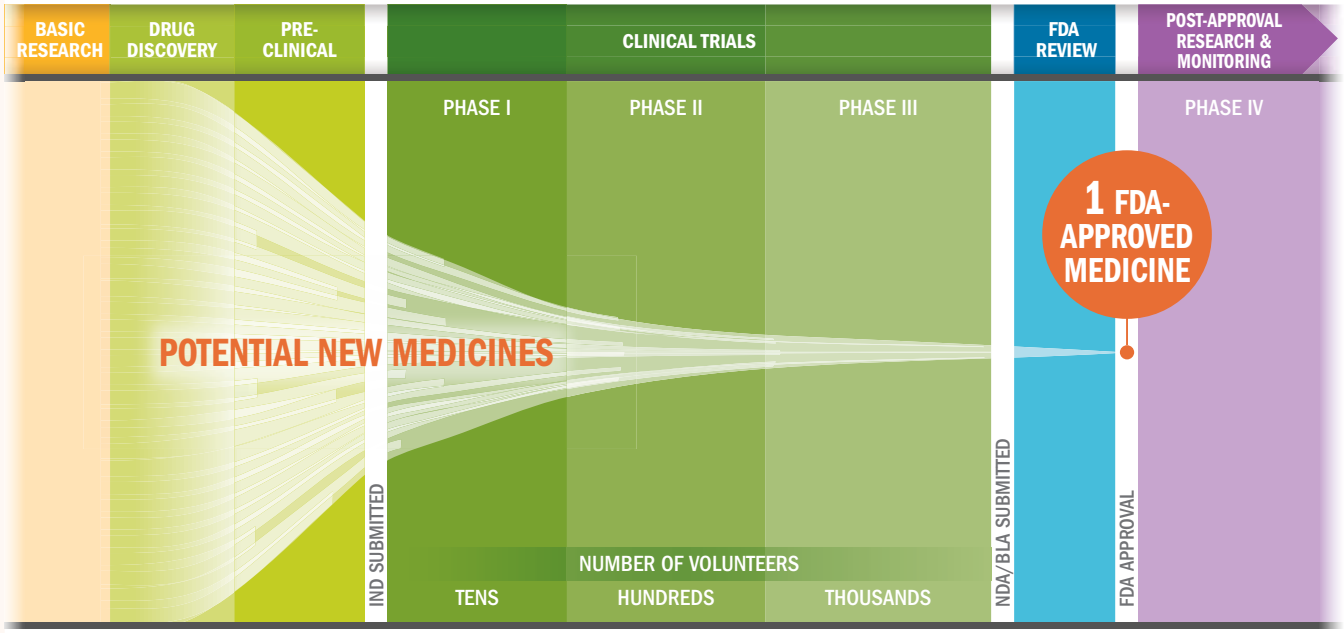
- A vaccine for the prevention of respiratory syncytial virus (RSV) infections in adults over the age of 60 acts different than traditional vaccines that "mimic" viruses and activate the natural immune system to fight the infection. The vaccine is genetically-engineered to elicit immune responses, which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

- A dopamine/norepinephrine reuptake inhibitor in development for attention-deficit/hyperactivity disorder (ADHD) with an extended treatment window, showed significant improvement in both inattentive and hyperactivity/impulsivity ADHD symptoms in clinical trials. The medicine has also shown to have low potential for abuse. The medicine was studied in a clinical trial at **Alivation Research** in **Lincoln**.
- An oral fixed-dose combination of two therapeutics which target distinct receptors in the central nervous system is in development for the treatment of treatment-resistant major depressive disorder. The medicine offers a novel mechanism of action with one therapeutic increasing the therapeutic effect of the second offering hope to the millions of patients who do not respond to standard antidepressant therapies. The combination medicine is being studied at a clinical trial site in **Lincoln**.

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

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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