RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
MINNESOTA

Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting **more than 6,500 clinical trials** of new medicines in Minnesota in collaboration with clinical research centers, hospitals, and local research institutions. These clinical trials have investigated or are investigating some of Minnesota's biggest health care challenges, including cancer, autoimmune diseases, cardiovascular disease, respiratory diseases and genetic diseases.

Summary

Clinical trials in
MINNESOTA

CLINICAL TRIALS IN MINNESOTA 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 Minnesota since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
6,569	721

Source: www.clinicaltrials.gov. Search criteria: Minnesota, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 10/23/2025. 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 MINNESOTA

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

A study by TEConomy Partners[1] found that in 2022, the industry supported more than 66,900 jobs throughout Minnesota. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in $1.4 billion in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $20.2 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 Minnesota 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 MINNESOTA

A separate study by TEConomy Partners[2] found that in 2023 alone, there were 695 active industry-sponsored clinical trials in Minnesota, with an estimated enrollment of 8,525 Minnesota residents.

The investment at clinical trial sites was more than $362 million and the estimated total economic impact was more than $758 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. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf*

[2] *TEConomy Partners, LLC. Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies, March 2025. Report prepared for PhRMA. https://phrma.org/resources/state-map/clinical-trials*

"In Minnesota, clinical research is more than a profession, it's a legacy. From the heart of the Twin Cities to the quiet corners of greater Minnesota, our researchers embody integrity, innovation, and impact. We turn questions into cures with the same precision and pride that built our medical heritage. Every trial here is a reflection of our commitment to ethical science, community health, and the future of medicine."

Lindsay DesLaurier, Associate Director of Recruitment, Nucleus Network

Open Clinical Trials in Minnesota by Disease

Disease	Number of Trials
Allergy	3
Alzheimer's Disease/Dementia	3
Arthritis/Musculoskeletal Diseases	6
Autoimmune Disorders	45
Blood Disorders	18
Cancer	346
Cardiovascular Diseases	46
Diabetes	8
Eye Diseases	29
Gastrointestinal/Esophageal Disorders	19
Genetic Diseases	40
Infectious Diseases	19
Kidney Diseases	26
Liver Diseases	14
Mental Illnesses	4
Neurologic Disorders	19
Obesity	5
Respiratory Diseases	36
Skin Disorders	16
Transplantation-Related	4
Other Diseases	15
Total	**721**

Source: www.clinicaltrials.gov. Search criteria: Minnesota, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 10/23/2025. 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 Minnesota, **6,569** 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 Mayo Clinic School of Medicine visit www.mayo.edu/research/clinical-trials and at the University of Minnesota visit www.med.umn.edu/research/clinical-trials.

For more information about clinical trials in Minnesota 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.

"Research is how new therapies like cancer drugs and heart valves become available to patients. We need it, we support it, we take good care of our research patients and teams because it impacts our families, too."

Sarah Moeller, President and CEO of The Greenlight Group

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

Aliveness Project
3808 Nicollet Avenue
Minneapolis, MN 55409
(612) 822–7946
info@aliveness.org

ALS Association
Minnesota Chapter
(612) 672–0484
infoMN@als.org

Alzheimer's Association
Minnesota — North Dakota Chapter
12701 Whitewater Drive,
Suite 290
Minnetonka, MN 55343
(952) 830–0512
(800) 272–3900
mnnd-info@alz.org

Alzheimer's Association
Duluth Office
4960 Miller Trunk Highway,
Suite 700
Hermantown, MN 55811
(218) 733–2560

Alzheimer's Association
Rochester Office
3261 19th Street, NW, Suite 201
Rochester, MN 55901
(952) 767–7570

Alzheimer's Association
St. Cloud Office
Cooper Collective, Unit 350
Mailing Address:
12701 Whitewater Drive,
Suite 290
Minnetonka, MN 55343
St. Cloud, MN 56301
(320) 257–0699

American Cancer Society
Minnesota Office
P.O. Box 21600
Saint Paul, MN 55121
(800) 227–2345

American Diabetes Association
Minnesota Chapter
P.O. Box 7023
Merrifield, VA 22116–7023
(763) 593–5333
adamn_nd@diabetes.org

American Heart Association
Minnesota Office
2750 Blue Water Road,
Suite 250
Eagen, MN 55121
(952) 278–7900

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

American Lung Association
Minnesota Chapter
P.O. Box 4037
Saint Paul, MN 55103
(651) 646–5443
(800) 732–9339
jill.heins@lung.org

American Parkinson Disease Association
Minnesota Chapter
P.O. Box 4425
Saint Paul, MN 55104
(651) 241–8297
apdamn@apdaparkinson.org

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

Crohn's & Colitis Foundation
Minnesota/Dakotas Chapter
2277 Hwy 36 West, Suite 170
Roseville, MN 55113
(651) 917–2424
(888) 422–3266

Epilepsy Foundation of Minnesota
7760 France Avenue S, Suite 210
Bloomington, MN 55435
(651) 287–2338
customerservice@efmn.org

Family Voices of Minnesota
(612) 440–1609
connected@familyvoicesmn.org

Gilda's Club Minnesota
10560 Wayzata Blvd.
Minnetonka, MN 55305
(612) 227–2147

Huntington's Disease Society of America
Minnesota Chapter
P.O. Box 16103
Minneapolis, MN 55416-6103
(800) 345–4372
HDSAinfo@HDSA.org

Lupus Foundation of America
Midwest Regional Office
2121 K Street, NW, Suite 200
Washington, DC 20037
(312) 459–6271
pendleton@lupus.org

Minnesota Spina Bifida Association
P.O. Box 29323
Brooklyn Center, MN 55429
(651) 222–6395
sbamn@hotmail.com

NAMI Minnesota
National Alliance on Mental Illness
1919 University Avenue, W,
Suite 400
Saint Paul, MN 55104–3455
(651) 645–2948
namihelps@namimn.org

National Kidney Foundation of Minnesota
1970 Oakcrest Avenue,
Suite 208
Saint Paul, MN 55113
(651) 636–7300
(800) 596–7943
nkfmn@kidney.org

National Multiple Sclerosis Society
Upper Midwest Chapter
P.O. Box 88540
Carol Stream, IL 60188
(800) 344–4867

National Psoriasis Foundation
Midwest Regional Office
(503) 546–5558
jhamel@psoriasis.org

Sickle Cell Foundation of Minnesota
P.O. Box 22306
Minneapolis, MN 55422
www.sicklecellmn.org

Tourette Association of America
Minnesota Chapter
P.O. 4266
Mankato, MN 56001
(651) 212–4711
tsaofmn@gmail.com

OTHER PATIENT RESOURCES

MEDICINE ASSISTANCE TOOL (MAT): The Medicine Assistance Tool is a PhRMA-sponsored search engine designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs. MAT is not its own patient assistance program, but rather, a search engine for many of the support programs and resources that the biopharmaceutical industry has offered for decades. The online process takes about 15 minutes, and patients can find out instantly if they are eligible for assistance. Patients can visit *www.mat.org* for more information.

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

Clinical Trial Policy Resources

THE BIOPHARMACEUTICAL SECTOR'S ROLE IN THE ECONOMY

America's biopharmaceutical research companies serve as the foundation for one of the country's most dynamic innovation and business ecosystems. The biopharmaceutical industry is among the most research and development (R&D) intensive industries in the United States. In fact, the sector accounts for the single largest share of all U.S. business R&D, accounting for approximately 17 percent of all R&D spending by U.S. businesses. The industry and its large-scale research and manufacturing supply chain support high-quality jobs across the U.S. economy.

Biopharmaceutical companies invest 12 times more in R&D per employee than manufacturing industries overall.

The biopharmaceutical industry supported more than 4.9 million jobs across the U.S. economy in 2022, according to a study by TEConomy Partners.[3]

PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN MINNESOTA

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

- Supported more than 66,900 jobs throughout Minnesota in 2022.
- Supported the generation of $20.2 billion in economic activity in the state.
- Resulted in $1.4 billion in federal and state taxes through jobs supported by the biopharmaceutical sector.

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

[3] *TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. February 2024. Report prepared for PhRMA. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.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:

- **Abbott Northwestern Hospital**, Minneapolis
- **CentraCare Heart and Vascular Center**, St. Cloud
- **CentraCare St. Cloud Hospital**, St. Cloud
- **Children's Hospitals and Clinics of Minnesota**, Saint Paul
- **Clinical Research Center**, Plymouth
- **Clinical Research Institute**, Minneapolis, Plymouth
- **DaVita Clinical Research**, Minneapolis
- **Fairview Ridges Hospital**, Burnsville
- **Fairview Southdale Hospital**, Edina
- **Hennepin County Medical Center,** Minneapolis
- **Hutchinson Area Health Care**, Hutchinson
- **Lakeview Hospital**, Stillwater
- **MAPS Applied Research Center (MARC)**, Edina
- **Mayo Clinic**, Rochester
- **Mercy Hospital**, Coon Rapids
- **Methodist Hospital**, St. Louis Park
- **Metro Urology**, Woodbury
- **Midwest Immunology Clinic and Infusion Center**, Plymouth
- **Minneapolis Clinic of Neurology**, Golden Valley, Robbinsdale
- **Minneapolis Heart Institute Foundation**, Minneapolis
- **Minneapolis VA Health Care System**, Minneapolis
- **Minnesota Colon & Rectal Surgery Associates**, Minneapolis
- **Minnesota Epilepsy Group**, Saint Paul
- **Minnesota Eye Consultants**, Bloomington
- **Minnesota Gastroenterology (MNGASTRO)**, Plymouth
- **Minnesota Lung Center**, Minneapolis
- **Minnesota Oncology Hematology**, Edina, Maplewood, Minneapolis, Woodbury
- **New Ulm Medical Center**, New Ulm
- **North Memorial Hubert H. Humphrey Cancer Center**, Robbinsdale
- **Prism Clinical Research DBA Nucleus Network**, Saint Paul
- **Radiant Research**, Edina
- **Regions Hospital**, Saint Paul
- **Rice Memorial Hospital**, Willmar
- **Ridgeview Medical Center**, Waconia
- **Sanford Clinic North**, Bemidji
- **St. John's Hospital**, Maplewood
- **St. Joseph's Hospital**, Saint Paul
- **St. Luke's Hospital Whiteside Institute for Clinical Research**, Duluth
- **St. Mary's Hospital**, Mayo Clinic, Rochester
- **St. Mary's Medical Center**, Duluth
- **United Heart and Vascular Center**, Saint Paul
- **Unity Hospital**, Fridley
- **University of Minnesota Masonic Children's Hospital**, Minneapolis
- **University of Minnesota**, Minneapolis
- **Virginia Piper Cancer Institute-Abbott Northwestern Hospital**, Minneapolis
- **Woodbury Clinic-CornerStone Medical Specialty Centre**, Woodbury

MINNESOTA 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 9,102 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 Minnesota, of the 721 open clinical trials involving the biopharmaceutical research industry, the Mayo Clinic is collaborating on more than 328 of the clinical trials and the University of Minnesota is collaborating on more than 125.

[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 10/23/2025. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

"Minnesota is a clinical research "diamond" — our many clinical research teams are trained and educated to collect human data ethically and appropriately. Figuratively, Minnesota is home to 10,000 lakes and 10,000 points of light we call clinical research professionals. Proud to design and run clinical trials on drug, device, food and "other" products, we support detailed technical data analysis, medical writing, and truth telling."

Dr. Joy Frestedt, President & CEO of Frestedt Inc.

THE STATE OF DISEASE IN MINNESOTA

More than 5.7 million people live in Minnesota[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Minnesota	
Disease	**Health Statistic**
Alzheimer's Disease Deaths 2023[2]	2,357
Asthma Prevalence 2022[2]	516,200
Asthma Deaths 2022[2]	53
Cancer News Cases 2025[3]	37,650
Cancer Deaths 2025[3]	10,490
Chronic Liver Disease 2023[2]	845
Chronic Obstructive Pulmonary Disease 2023[2]	2,131
COVID-19 Deaths 2023[2]	888
Diabetes Deaths 2023[2]	1,452
Diabetes Prevalence—Adults 2024[2]	470,000
Essential Hypertension Deaths 2023[2]	911
Heart Disease Deaths 2023[2]	8,830
HIV-Number Living with a Diagnosis 2022[4]	9,467
Influenza and Pneumonia Deaths 2023[2]	462
Kidney Disease Deaths (Nephritis) 2023[2]	527
Mental Illness—Adults 2022–2023[4]	1,038,000
Parkinson's Disease Deaths 2023[2]	779
Septicemia Deaths 2023[2]	534
Stroke Deaths 2023[2]	2,368

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

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

- Children under the age of 18 make up 22.6%[5] of the population in Minnesota. Pediatric clinical trials are being conducted in the state for aplastic anemia, asthma, chronic kidney disease, Crohn's disease, cystic fibrosis, epilepsy, glioma, leukemia and migraine, among others.[6]

- Minnesotans aged 65 and older account for 17.4%[5] of the states' population. In Minnesota, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, heart failure, chronic kidney disease, Crohn's disease, lymphoma, macular degeneration, melanoma and prostate cancer, among others.[6]

- Women and girls make up 49.8%[5] of the population in Minnesota. Clinical trials are recruiting women for studies on medicines for breast cancer, chronic kidney disease, contraception, heart failure, ovarian cancer, stroke, systemic lupus erythematosus, uterine cancer, among others.[6]

[5] U.S. Census Bureau (2023), [6] www.clinicaltrials.gov

Open Clinical Trials in Minnesota for Special Populations

Population	Number of Trials
Children (birth–17)	130
Seniors (65 and older)	640
Women (only)	26

Source: www.clinicaltrials.gov. Search criteria: Minnesota, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 10/23/2025. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Minnesota by Sex, 2023		
Disease	**Female**	**Male**
Cancer	4,769	5,594
Heart Disease	4,050	4,780
Accidents (Unintentional Injury)	1,530	2,190
Stroke	1,311	1,057
Alzheimer's Disease	1,576	781
Chronic Obstructive Pulmonary Disease	1,131	1,000
Diabetes	606	846
Essential Hypertension	472	439
COVID-19	462	426
Chronic Liver Disease	331	514

Source: Minnesota Health Authority

10 Leading Causes of Death in Minnesota by Race/Ethnicity, 2023						
Disease	**White**	**Black**	**Hispanic**	**American Indian/ Alaska Native**	**Asian/ Pacific Islander**	**Multiple Races**
Cancer	9,254	383	168	137	209	28
Heart Disease	7,994	273	86	119	138	24
Accidents	2,755	394	139	191	79	46
Stroke	2,077	101	29	18	72	*
Alzheimer's Disease	2,267	29	14	*	22	*
Chronic Obstructive Pulmonary Disease	1,950	64	*	36	28	*
Diabetes	1,226	80	41	43	46	*
Essential Hypertension	802	52	19	*	22	*
COVID-19	795	29	12	*	20	*
Chronic Liver Disease	683	34	36	41	11	*

*Source: Minnesota Department of Health (Note: fewer than 10 deaths are represented with an *)*

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

"The clinical research community in Minnesota consists of a dynamic mix of well-educated and reliable research professionals coupled with a diverse and remarkably compliant population of study volunteers. This dynamic combination results in quality data, delivered on time, to drive development of novel medicines."

Jarrod Midboe, VP Clinical Operations USA, Nucleus Network

SCIENCE AND CLINICAL TRIALS[7]

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

- A monoclonal antibody (mAb) is in development for the reduction of asthma attacks in severe asthma with type 2 inflammation (a condition that elevates white blood cell levels, which increase asthma symptoms). Type 2 inflammation is responsible for more than 80% of severe asthma cases and can lead to exacerbations of the disease (increased coughing, shortness of breath or wheezing). The mAb in development targets the action of interleukin-5 (IL-5), a protein known to play a key role in the growth, activity and survival of eosinophils associated with type 2 inflammation in severe asthma. In clinical trials, the medicine has shown significant reductions in exacerbations over 52 weeks versus placebo. Clinical trials are underway in **Rochester** and **Minneapolis**.

- Post-approval research of an amyloid-beta protein inhibitor for the treatment of mild Alzheimer's disease is being studied as a treatment for preclinical Alzheimer's disease (the disease stage when changes in the brain are occurring but before any symptoms are seen). The medicine works by targeting the build-up of amyloid beta plaques in the brain, a key element in the development of Alzheimer's disease. Amyloid plaques appear between nerve cells in the brain and disrupt cell function. It is being studied to determine its ability to reduce brain amyloid accumulation and possibly prevent the disease from progressing. A clinical trial is ongoing in **Rochester**.

- An oral PCSK9 inhibitor is in development for the reduction of low-density lipoprotein (LDL) cholesterol, or "bad cholesterol." Currently, approved PCSK9 inhibitors are all injectable medicines. PCSK9 plays a key role in cholesterol by lowering levels of LDL receptors, which are responsible for removing LDL cholesterol from the blood. Inhibiting the interaction of PCSK9 and LDL receptors results in a greater number of LDL receptors to remove LDL cholesterol. Elevated LDL cholesterol is a major risk factor for atherosclerotic cardiovascular disease, which can lead to heart attacks and strokes. Clinical trials are underway at **Fairview Health Services** in **Maplewood** and at **Abbott Northwestern Hospital** and the **University of Minnesota** in **Minneapolis**.

- A factor XIa (FXIa) inhibitor is being developed for the prevention of secondary ischemic stroke in patients who have had a stroke or who are at high-risk for transient ischemic attack (TIA). Many patients are untreated or undertreated for the risk of blood clots (thrombosis) due to the risk of bleeding. Factor XIa is a key factor in the process promoting clot formation but with reduced risk of bleeding compared to other factors. FXIa inhibitors may reduce clot formations while maintaining the body's ability to respond to bleeding events. Clinical trials are ongoing at the **Minneapolis Clinic of Neurology** in **Golden Valley** and the **Mayo Clinic** in **Rochester**.

- Ananti-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 Tecentriq® (atezolizumab), 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. Clinical trials are underway in **Minneapolis**, **Rochester** and **St. Louis Park**.

- 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. A clinical trial was conducted at **Prism Clinical Research DBA Nucleus Network** in **Saint Paul**.

[7] *PhRMA Medicines in Development reports, https://phrma.org/policy-issues/innovative-medicines*

- A medicine in development to treat prostate cancer binds to and inhibits AKT proteins. AKT helps to regulate cellular processes, such as cell division, cell death, and glucose and fatty acid metabolism. Mutations in the PI3K/AKT/ mTOR signaling pathway can promote several types of cancer, including prostate cancer, because normal cellular processes are disrupted. The medicine works by inhibiting AKT in cancer cells. Clinical trials are ongoing in **Minneapolis**.

- A once weekly fixed-dose combination medicine in development for type II diabetes is comprised of a long-acting basal insulin analog and an approved GLP-1 (glucagon-like peptide-1) agonist. The long-acting basal insulin has the potential to reduce the number of annual insulin injections from daily to weekly. Research has found that the GLP-1 agonist has the potential to lower blood glucose by stimulating the release of insulin and also lowers body weight. A clinical trial was conducted at the **International Diabetes Center** in **Minneapolis**.

- 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 **Mayo Clinic** in **Rochester** and the **Minneapolis Clinic of Neurology** in **Golden Valley**.

- A monoclonal antibody in development for the prevention of migraine binds to and inhibits the activity of a peptide expressed in the nervous system where it plays a role in controlling the widening of blood vessels and the transmission of nociceptive pain (pain arising from nerve cells) information. By inhibiting CGRP activity, anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. Clinical trials were conducted at the **Clinical Research Institute** in **Minneapolis**.

- 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 **Hennepin Healthcare HCMC** in **New Brighton**.

- A cell therapy in clinical trials for amyotrophic lateral sclerosis (ALS) uses transplanted mesenchymal stromal cells (MSCs) derived from the patient's own bone marrow which are then enriched outside the body and re-transplanted into the patient. MSCs are potent cells that can differentiate into a variety of cells, such as bone cells, muscle cells, or fat cells. In this case, the cells have been customized to treat neurodegenerative diseases by secreting a variety of neurotrophic factors. Neurotrophic factors are known to support the survival of neurons in a variety of conditions, including neurodegenerative diseases, such as ALS. A clinical trial is scheduled to begin at the **Mayo Clinic** in **Rochester**.

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

Conclusion

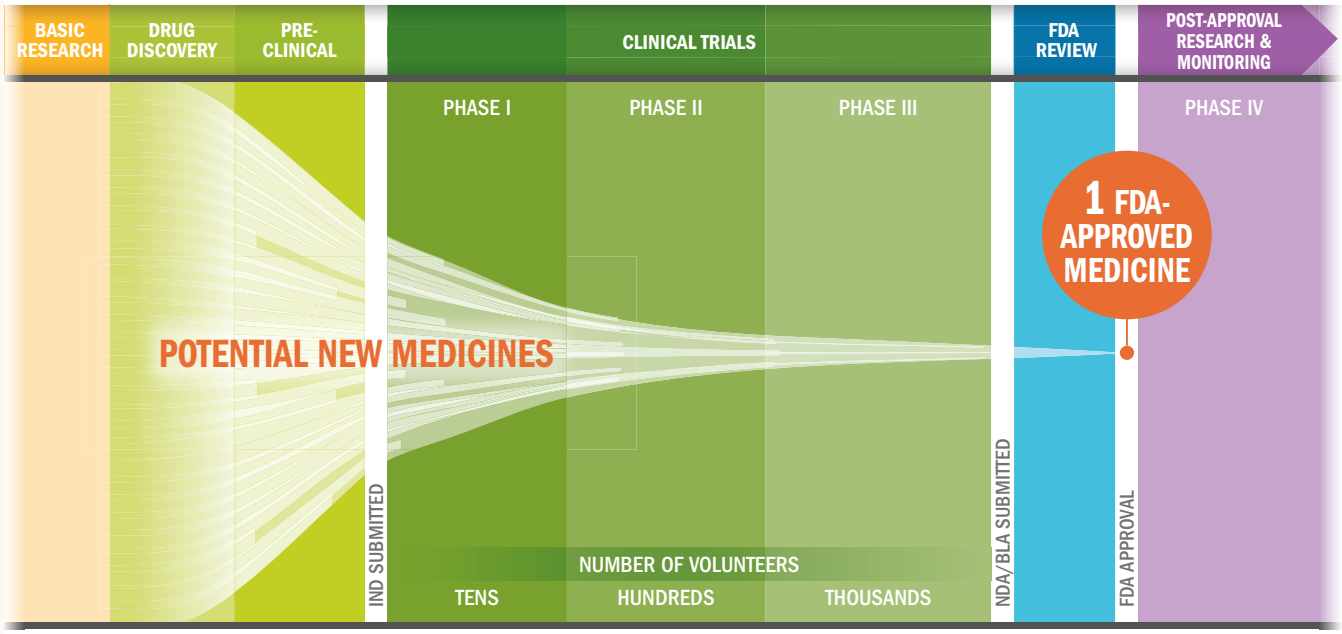
The Minnesota bioscience industry supports more than 66,900 jobs throughout Minnesota with wages and benefits supported by the sector, resulting in $1.4 billion in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $20.2 billion in direct and indirect economic activity in Minnesota.

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