RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

IOWA

Executive

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

Since 2004, **over 2,500 clinical trials** of new medicines have been conducted or are being conducted in collaboration with clinical research centers, hospitals, and local research institutions across Iowa. These clinical trials investigate some of Iowa's biggest health care challenges, including Alzheimer's disease, asthma, arthritis, cancer, diabetes, cardiovascular disease and infectious diseases.

Summary

Clinical trials in
IOWA

CLINICAL TRIALS IN IOWA 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 Iowa since 2004 — Completed and Open	
All Clinical Trials	**Open Clinical Trials**
2,536	327

Source: www.clinicaltrials.gov. Search criteria: Iowa, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 8/26/2023. 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 currently exist. Clinical trials may provide a new avenue of care for some chronic disease patients 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. 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 IOWA

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

A study by TEConomy Partners[1] found that in 2020, the industry supported more than **22,000 jobs** throughout Iowa. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in **$327.9 million in state and federal taxes paid**.

Biopharmaceutical research companies supported the generation of **$6.7 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 Iowa 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 IOWA

A separate study by TEConomy Partners[2] found that in 2017 alone, there were **293 active industry-sponsored clinical trials in Iowa**, with an estimated enrollment of **5,650 Iowa residents**. Oncology/cancer was the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was more than **$77 million** and the estimated total economic impact was more than **$187 million**.[2]

[1] *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, TEConomy Partners, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Economic-Impact-States-2022/US--Puerto-RicoEco-Impact-One-Pager-FINAL.pdf*

[2] *Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies, TEConomy Partners, https://www.phrma.org/-/media/TEConomy_PhRMA-Clinical-Trials-Impacts.pdf%EF%BB%BF*

"It is known that biological differences exist in how people respond to certain therapies. The staff and physicians at ICTS understand that various people may experience the same disease processes and treatments differently. This is why increasing diversity in clinical trials participants is critical and we are very happy to be a part of the ICCR in order to help create a stronger voice for this need in Iowa."

Kristine Majors, Co-owner of Integrated Clinical Trial Services

Open Clinical Trials in Iowa by Disease

Disease	Number of Trials
Alzheimer's Disease	3
Arthritis/Musculoskeletal Diseases	3
Autoimmune Disorders	10
Blood Disorders	4
Cancer	147
Cardiovascular Diseases	25
Diabetes	5
Eye Disorders	7
Gastrointestinal Disorders	11
Genetic Diseases	14
Infectious Diseases	18
Kidney Diseases	9
Liver Diseases	9
Neurologic Disorders	27
Respiratory Diseases	20
Skin Disorders	3
Transplantation-Related	4
Other Diseases	8
Total	**327**

Source: www.clinicaltrials.gov. Search criteria: Iowa, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 8/26/2023. 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 Iowa, **2,536** clinical trials since 2004 have targeted diseases and conditions including asthma, arthritis, cancer, diabetes, cardiovascular disease, infectious diseases and Alzheimer's disease.

PHASES OF CLINICAL TRIALS

There are typically three phases of clinical trial testing used to evaluate potential new medicines:

PHASE I — Researchers test the medicine in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range and identify potential side effects.

PHASE II — The medicine is given to volunteer patients, usually between 100 and 500 people, to study its efficacy, identify an optimal dose and to further evaluate its short-term safety.

PHASE III — The medicine is provided to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. They are the longest studies and usually take place in multiple sites around the world.

LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials in several ways. Health care providers may be aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. Patients can also use hospital and university websites to find the trials being conducted in their area.

For information on clinical trials being conducted at the University of Iowa Carver College visit www.medicine.uiowa.edu/research/clinical-trials.

For more information about clinical trials in Iowa 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, such as 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 inquire about 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.

"Beyond the benefits to patients, clinical research plays a major role in our local economy. While many people may not naturally think of drug development when they think of our state economy, Iowa has been growing and diversifying, and the innovative research sector—which includes clinical trials—is a significant part of that. The research being done in our state has impacts on people everywhere."

Jessica Hyland,
Iowa Biotechnology Association
(Iowa Bio)

*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 Iowa serve as exceptional resources for patients, offering opportunities to connect and learn more about various health conditions 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 some of the prominent groups that work on behalf of patients in Iowa and may provide more information to patients with further questions.

Alzheimer's Association
Des Moines/Central Iowa Area Office
1415 28th Street, Suite 430
West Des Moines, IA 50266
(515) 440-2722

Alzheimer's Association
Burlington Area Mobile Office
1225 E. River Road, Suite 130
Davenport, IA 52803
(319) 237-4900

Alzheimer's Association
Cedar Rapids Area Office
317 17th Avenue SE, Suite 402
Cedar Rapids, IA 52401
(319) 294-9699

Alzheimer's Association
Council Bluffs Area Mobile Office
1415 28th Street, Suite 430
West Des Moines, IA 50266
(712) 454-5035, ext. 8223

Alzheimer's Association
Davenport Area Office
1225 E. River Road, Suite 130
Davenport, IA 52803
(563) 293-8056

Alzheimer's Association
Dubuque Area Mobile Office
1415 28th Street, Suite 430
West Des Moines, IA 50266
(319) 238-7783

Alzheimer's Association
Fort Dodge Area Mobile Office
1415 28th Street, Suite 430
West Des Moines, IA 50266
(515) 414-8124

Alzheimer's Association
Sioux City Area Office
3535 Southern Hills Drive, Bldg. D
Sioux City, IA 51106
(712) 454-5035, ext. 8223

Alzheimer's Association
Waterloo Area Mobile Office
1415 28th Street, Suite 430
West Des Moines, IA 50266
(319) 238-7783

American Cancer Society
Iowa Chapter
P.O. Box 715
Des Moines, IA 50303
(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
Des Moines Chapter
8805 Chambery Blvd., Suite 300
PMB 126
Johnston, IA 50131
(515) 414-3200

American Heart Association
Eastern Iowa Chapter
1035 N. Center Point Road, Suite B
Hiawatha, IA 50131
(319) 536-3900

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

American Lung Association
Iowa Office
2530 73rd Street
Urbandale, IA 50322
(515) 309-9507

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

Epilepsy Foundation of Iowa
1111 19th Street, Suite 370
Des Moines, IA 50314
(515) 259-8528
rcogil@efa.org

NAMI Iowa
National Alliance on Mental Illness
3839 Merle Hay Road, Suite 229
Des Moines, IA 50310
(515) 254-0417

National Kidney Foundation
Serving Iowa and Nebraska
6165 Northwest 86th Street
Johnston, IA 50311
(515) 440-0402, ext. 463
(800) 596-7943

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.[1] 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 4.4 million jobs across the U.S. economy in 2020, according to a study by TEConomy Partners.[1]

Over the last decade, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America (PhRMA) have more than doubled their annual investment in the search for new treatments and cures, including $101 billion in 2022 alone.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN IOWA

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

- Supported more than 22,000 jobs throughout Iowa in 2020.
- Supported the generation of $6.7 billion in economic activity in the state.
- Resulted in $327.9 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 Iowa**, see page 2.*

[1] *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, TEConomy Partners, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Economic-Impact-States-2022/US--Puerto-RicoEco-Impact-One-Pager-FINAL.pdf*

PUBLIC–PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

The following are just some of the prominent institutions that biopharmaceutical research companies are collaborating with on clinical trials for new medicines:

- **Acellacare US**, Ames
- **Alegent Health Mercy Hospital,** Council Bluffs
- **Blank Children's Hospital**, Des Moines
- **Broadlawns Medical Center**, Des Moines
- **Department of Veterans Affairs**, Iowa City
- **Des Moines Oncology Research Association**, Des Moines
- **Genesis Cancer Care Institute**, Davenport
- **Genesis Medical Center**, Davenport
- **Greater Regional Medical Center**, Creston
- **Heartland Medical Research, Inc.**, Clive
- **Hematology-Oncology Associates of the Quad Cities**, Bettendorf
- **Holden Comprehensive Cancer Center**, University of Iowa, Iowa City
- **Integrated Clinical Trial Services**, West Des Moines
- **Iowa Diabetes and Endocrinology Research Center**, West Des Moines
- **Iowa Diabetes Research**, West Des Moines
- **Iowa Digestive Disease Center**, Clive
- **Iowa Methodist Medical Center**, Des Moines
- **Mary Greeley Medical Center**, Ames
- **Mcfarland Clinic**, Ames, Boone, Fort Dodge, Jefferson, Marshalltown
- **Mercy Cancer Center**, Clive, Des Moines, Fort Dodge
- **Mercy Hospital**, Cedar Rapids
- **Mercy Medical Center**, Des Moines
- **Mercy Medical Center**, Mason City
- **Mercy Medical Center**, Sioux City
- **MercyOne Waterloo Medical Center**, Waterloo
- **Meridian Clinical Research**, Sioux City
- **Methodist West Hospital**, West Des Moines
- **Northeast Iowa Medical Education Foundation**, Waterloo
- **Oncology Association of Cedar Rapids—Iowa Cancer Care**, Cedar Rapids
- **Quality Cancer Care Alliance — Mission Blood & Cancer**, Des Moines
- **Saint Anthony Regional Hospital**, Carroll
- **Saint Luke's Regional Medical Center**, Sioux City
- **Stead Family Children's Hospital**, University of Iowa, Iowa City
- **The Iowa Clinic,** Ankeny, West Des Moines
- **Trinity Regional Medical Center**, Fort Dodge
- **UnityPoint Clinic**, Des Moines
- **UnityPoint Health (Nassif Community Cancer Center)**, Cedar Rapids
- **University of Iowa Hospitals and Clinics**, Iowa City
- **Wolfe Eye Clinic**, West Des Moines

IOWA 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 9,800 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 undertaken by other groups on their own.

In Iowa, of the 327 open clinical trials involving the biopharmaceutical research industry, the University of Iowa is collaborating on more than 190 of the clinical trials.

[1] D1 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 8/24/2023. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

THE STATE OF DISEASE IN IOWA

More than 3.2 million people live in Iowa[1], and many of whom are dealing with disease and disability from asthma to cancer or from diabetes to heart disease.

Selected Disease Statistics in Iowa	
Disease	**Health Statistic**
Alzheimer's Disease Deaths 2021[2]	1,179
Asthma Prevalence Adults 2021[3]	224,466
Asthma Deaths 2021[2]	39
Cancer New Cases 2023[4]	20,460
Cancer Deaths 2023[4]	6,310
Chronic Lower Respiratory Deaths 2021[2]	1,669
COVID-19 Deaths 2021[2]	3,055
Diabetes Deaths 2021[2]	1,022
Diabetes Prevalence 2021[3]	248,300
Heart Disease Deaths 2021[2]	7,654
HIV-Number Living with a Diagnosis 2020[5]	2,940
Influenza/Pneumonia Deaths 2021[2]	361
Kidney Disease (Nephritis) Deaths 2021[2]	411
Chronic Liver Disease Deaths 2021[2]	504
Mental Illness-Adults 2018–2019[5]	441,000
Stroke Deaths 2021[2]	1,395

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

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

- Children under the age of 18 make up 22.6% of the population in Iowa. Pediatric clinical trials are being conducted in the state for asthma, diabetes, migraine, leukemia and hemophilia, among others.

- Iowans aged 65 and older account for 18.3% of the states' population. In Iowa, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, breast cancer, osteoarthritis, prostate cancer and pulmonary arterial hypertension, among others.

- Women and girls make up 49.8% of the population in Iowa. Clinical trials are recruiting women for studies on medicines for Alzheimer's disease, breast cancer, cytomegalovirus infections, endometrial cancer and rheumatoid arthritis, among others.

Open Clinical Trials in Iowa for Special Populations

Population	Number of Trials
Children (birth–17)	66
Seniors (66 and older)	291
Women (only)	5

Source: www.clinicaltrials.gov. Search criteria: Iowa, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 8/26/2023. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Iowa by Sex, 2021 *(As a Percent of All Deaths)*		
Disease	**Male**	**Female**
Heart Disease	23.7%	20.9%
Cancer	18.6%	17.8%
COVID-19	9.7%	8.1%
Unintentional Injuries	5.8%	4.2%
Chronic Lower Respiratory Diseases	4.7%	5.0%
Stroke	3.3%	4.9%
Alzheimer's Disease	2.1%	5.0%
Diabetes	3.4%	2.6%
Infectious/Parasitic Diseases	1.6%	1.7%
Essential Hypertension and Hypertensive Renal Disease	1.3%	1.9%

Source: 2021 Vital Statistics of Iowa, Iowa Department of Health and Human Services

10 Leading Causes of Death in Iowa by Race/Ethnicity, 2021						
Disease	**American Indian/Alaska Native**	**Asian**	**Black or African American**	**Hispanic**	**Native Hawaiian/ Other Pacific Islander**	**White**
Heart Disease	10	40	164	76	4	7,374
Cancer	14	51	137	73	4	5,981
COVID-19	18	26	97	101	2	2,857
Unintentional Injuries	2	14	95	60	4	1,562
Chronic Lower Respiratory Diseases	3	2	32	5	0	1,629
Stroke	3	16	31	26	2	1,327
Alzheimer's Disease	2	6	6	5	0	1,159
Diabetes	5	4	44	22	2	953
Suicide	5	6	16	16	1	503
Influenza and Pneumonia	0	0	8	1	0	352

Source: Iowa Department of Health & Human Services, Division of Public Health, Office of Health Disparities & Health Equity, 2021
(note: not including those categorized as two or more races or other/unknown race)

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.

Underrepresentation of racial and ethnic groups in clinical trials for new medicines has a long history. In an effort to address this long-standing mistrust and other issues, PhRMA and its member companies recently issued the first-ever industry-wide principles on clinical trials diversity, adding a new chapter to the already existing *Principles on Conduct Clinical Trials & Communication of Clinical Trial Results*. The new clinical trial diversity principles address:

- Building Trust and Acknowledging Past Wrongs
- Reducing Barriers to Clinical Trial Access
- Using Real-World Data to Enhance Information on Diverse Populations Beyond Product Approval
- Enhancing Information About Diversity and Inclusion in Clinical Trial Participation

SCIENCE AND CLINICAL TRIALS[1]

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

- A medicine in development to treat triple negative breast cancer binds to and inhibits AKT proteins. AKT helps to regulate cellular processes, such as cell division, cell death, and glucose and fatty acid metabolism. Mutations in the PI3K/AKT/mTOR signaling pathway can promote several types of cancer, including breast cancer, because normal cellular processes are disrupted. The medicine works by inhibiting AKT in cancer cells and is being tested in combination with paclitaxel, an approved chemotherapy treatment. A clinical trial is being conducted in **Iowa City**.

- 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 is being conducted in **West Des Moines**.

- A medicine approved to treat type II diabetes is in clinical trials for the treatment of obesity. The medicine binds to and activates the GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) receptors in the body. GIP and GLP-1 are hormones involved in blood sugar control. In preclinical models, GIP has been shown to decrease food intake and increase energy expenditure resulting in weight reductions. When combined with a GLP-1 receptor agonist, the treatment may result in greater effects on body weight, glucose and lipids. The medicine was recently approved in the U.S. as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus. In clinical trials, the medicine helped 63% of trial participants achieve at least a 20% reduction in body weight. A clinical trial is being conducted at the **Iowa Diabetes and Endocrinology Research Center** in **West Des Moines**.

- 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 brains of individuals 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. A clinical trial has been completed at the **University of Iowa** in **Iowa City**.

- A gene therapy uses a recombinant AAV9 capsid to deliver a shortened version of human dystrophin (mini-dystrophin) to treat Duchenne muscular dystrophy (DMD). DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. In the absence of dystrophin, muscle cells deteriorate. A clinical trial is underway at the **University of Iowa** in **Iowa City**.

- A monoclonal antibody for the treatment of pancreatic cancer, Duchenne muscular dystrophy and idiopathic pulmonary fibrosis. Clinical trials are underway at the **University of Iowa** in **Iowa City**.

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

Conclusion

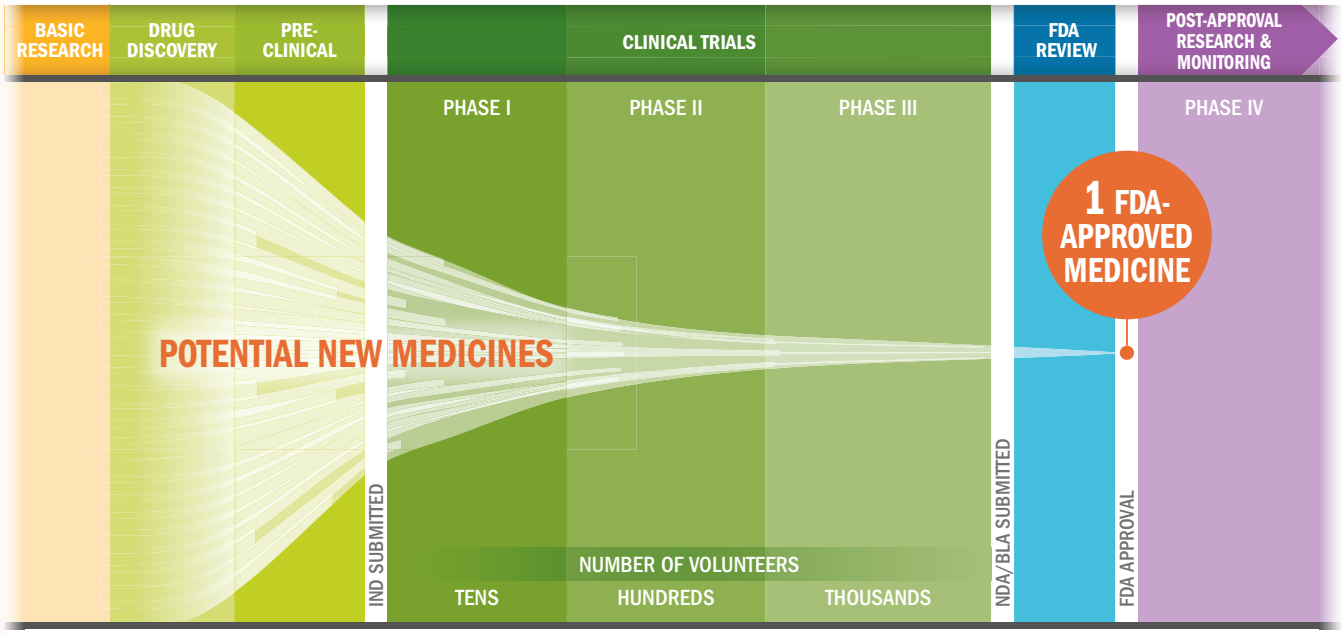
The Iowa bioscience industry supports 22,000 jobs throughout Iowa with wages and benefits supported by the sector, resulting in $327.9 million in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $6.7 billion in direct and indirect economic activity in Iowa.

Iowans 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. Additionally, Iowa residents benefit from the pharmaceutical industry's commitment to clinical trial diversity and efforts to address health equity.

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