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Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

ILLINOIS

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PhRMA RESEARCH • PROGRESS • HOPE

Executive

Summary

Clinical trials in ILLINOIS

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

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 6,800 clinical trials of new medicines in Illinois in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Illinois's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

CLINICAL TRIALS IN ILLINOIS 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 Illinois since 2004— Completed and Open	
All Clinical Trials	**Open Clinical Trials**
6,808	945

Source: www.clinicaltrials.gov. Search criteria: Illinois, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 10/11/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

Executive Summary (cont.)

"The opportunities that exist for Illinoisans to participate in the research and development of new and improved therapies have never been greater. The clinical trials being conducted in Illinois are focusing on some of the most challenging diseases, including asthma, arthritis, cancer, COPD, diabetes, cardiovascular disease, lung cancer and Alzheimer's disease."

Joel Africk, President and Chief Executive Officer
Respiratory Health Association

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 ILLINOIS

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

A study by TEConomy Partners found that in 2014, the industry supported more than 293,000 jobs throughout Illinois. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than $4 billion in federal taxation and $634.4 million in state taxes.

Biopharmaceutical research companies supported the generation of $81.1 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 Illinois 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 ILLINOIS

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,701 active industry-sponsored, site-based clinical trials in Illinois, with an estimated enrollment of 29,294 Illinois residents. Oncology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was nearly $250 million and the estimated total economic impact was more than $678 million.

Open Clinical Trials in Illinois by Disease

Disease	Number of Trials
Allergy	7
Alzheimer's Disease	16
Arthritis/Musculoskeletal Disorders	23
Autoimmune Diseases	38
Bladder Disorders	5
Blood Disorders	17
Cancer	449
Cardiovascular Diseases	53
Diabetes	21
Eye Disorders	21
Gastrointestinal/Esophageal Diseases	42
Genetic Disorders	35
Infectious Diseases	40
Kidney Diseases	17
Liver Diseases	14
Mental Disorders	46
Neurological Disorders	48
Respiratory Diseases	13
Skin Diseases	21
Transplantation-Related	9
Other Diseases	10
Total	**945**

Source: www.clinicaltrials.gov. Search criteria: Illinois, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 10/11/2017. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

"Illinois is home to renowned academic institutions, a steady supply of skilled labor, world-class biopharmaceutical companies, and some of the country's best research hospitals and academic medical centers. Add in one of the most diverse patient populations in the world and you have all the ingredients for the epicenter of clinical research."

Joseph Gaspero
President and Co-founder
Center for Healthcare Innovation

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 Illinois, 6,808 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, the links below will find clinical trials at several universities in Illinois:

- **Loyola University Stritch School of Medicine,** *www.loyolamedicine.org/clinicalresearch*
- **Northwestern University Feinberg School of Medicine,** *www.feinberg.northwestern.edu/Research/clinical-trials/index.html*
- **Robert H. Lurie Comprehensive Cancer Center at Northwestern University,** *cancer.northwestern.edu/clinicaltrials/index.cfm*

- **Rush University Medical School,** *www.rush.edu/clinical-trials-rush-university-medical-center*
- **Southern Illinois University-Springfield,** *www.siumed.edu/ccr/enroll-clinical-trial.html*
- **University of Chicago,** *www.uchospitals.edu/clinical-trials/index.html*

More information about clinical trials in Illinois 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 Illinois 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 Illinois, and may provide more information to patients with further questions.

Alzheimer's Association
Bloomington Office
207 S. Prospect, Suite 1
Bloomington, IL 61704
(309) 664-0495

Alzheimer's Association
Carbondale Office
320 E. Walnut, Suite A
Carbondale, IL 62901
(618) 985-1095

Alzheimer's Association
Champaign Office
207 S. Prospect, Suite 1
Bloomington, IL 61704
(217) 351-1726

Alzheimer's Association
Greater Illinois Chapter
8430 West Bryn Mawr
Suite 800
Chicago, IL 60631
(847) 933-2413

Alzheimer's Association
Joliet Office
850 Essington Road, Suite 200
Joliet, IL 60435
(815) 744-0804

Alzheimer's Association
Peoria Office
612 West Glen Avenue
Peoria, IL 61614
(309) 681-1100

Alzheimer's Association
Quincy Office
639 York Street, Room. 200
Quincy, IL 62301
(217) 228-1111

Alzheimer's Association
Rockford Office
1111 South Alpine, Suite 307
Rockford, IL 61108
(815) 484-1300

Alzheimer's Association
Springfield Office
2309 W. White Oaks Drive
Suite E
Springfield, IL 62704
(217) 726-5184

American Cancer Society
Chicago Regional Office
225 N Michigan Avenue
Suite 1200
Chicago, IL 60601
(312) 372-0471

American Cancer Society
Lake Regional Office
100 Tri-State International
Suite 125
Lincolnshire, IL 60069
(847) 317-0025

American Cancer Society
Southern Regional Office
4503 W. DeYoung Street
Suite 200 C
Marion, IL 62959
(618) 998-9898

American Cancer Society
Metro East Regional Office
5 Schiber Court, Building A
Maryville, IL 62062
(618) 288-2320

American Cancer Society
DuPage Regional Office
1801 Meyers Road, Suite 100
Oakbrook Terrace, IL 60181
(630) 932-1141

American Cancer Society
West Central Regional Office
4234 N. Knoxville, Suite B
Peoria, IL 61614
(309) 688-3488

American Cancer Society
Western Regional Office
675 E. Linton Avenue
Springfield, IL 62703-5902
(217) 523-4503

American Cancer Society
Prairie Land Regional Office
17060 Oak Park Avenue
Tinley Park, IL 60477
(708) 633-7770

American Diabetes Association
Chicago Office
55 E. Monroe Street, Suite 3420
Chicago, IL 60603
(312) 346-1805

American Diabetes Association
Springfield Office
2501 Chatham Road, Suite 210
Springfield, IL 62704
(217) 875-9011

American Heart Association
Greater Chicago Regional Office
208 S. LaSalle Street, Suite 1500
Chicago, IL 60604
(312) 346-4675

American Heart Association
Greater Illinois Regional Office
2141 W. White Oaks Drive, Suite A
Springfield, IL 62704
(217) 331-6773

American Lung Association
Greater Chicago Chapter
55 West Wacker Drive
Suite 800
Chicago, IL 60601
(312) 781-1100

American Lung Association
Springfield Chapter
3000 Kelly Lane
Springfield, IL 62711
(217) 787-5864

Arthritis Foundation
Greater Chicago Office
35 E. Wacker Drive, Suite 2260
Chicago, IL 60601
(312) 372-2080

Arthritis Foundation
Central Illinois Office
615 N. Alabama Street
Suite 430
Indianapolis, IN 46204
(317) 879-0321

NAMI Illinois
National Alliance on Mental Illness
218 West Lawrence
Springfield, IL 62704
(217) 522-1403

NAMI Northern Illinois
National Alliance on Mental Illness
P.O. Box 6971
Rockford, IL 61125
(815) 963-2470

NAMI Chicago
National Alliance on Mental Illness
1801 W. Warner, Suite 202
Chicago, IL 60613
(312) 563-0445

Illinois Asthma Partnership
The Partnership is dedicated to improving the health status and quality of life of Illinois residents affected by asthma. *http://www.dph.illinois.gov/topics-services/diseases-and-conditions/asthma/il-asthma-partnership*.

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 205,000 Illinois patients access free or nearly free prescription medicines for residents who are underinsured or uninsured within the state. Patients should go to *www.pparx.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 was deployed in 11 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 4.4 million jobs across the U.S. economy in 2014, 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 $600 billion in R&D in the search for new treatments and cures.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN ILLINOIS

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

- Supported more than 293,000 jobs throughout Illinois in 2014.
- Supported the generation of $81.1 billion in economic activity in the state.
- Resulted in more than $4 billion in federal taxation and $634.4 million in state taxes through jobs supported by the biopharmaceutical sector.

*For more information on the **economic impact of the biopharmaceutical industry in Illinois**, 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:

- **Adventist Midwest Health,** Hinsdale
- **Advocate Christ Medical Center,** Oak Lawn
- **Advocate Health and Hospital Corporation,** Downers Grove, Elmhurst
- **Advocate Illinois Masonic Medical Center/ Creticos Cancer Center,** Chicago
- **Ann and Robert H. Lurie Children's Hospital of Chicago,** Chicago
- **Cadence Health,** Geneva
- **Cancer Treatment Centers of America,** Zion
- **Carle Cancer Center**, Urbana
- **Central DuPage Hospital,** Winfield
- **Community Cancer Center Foundation,** Normal
- **Crossroads Cancer Center,** Effingham
- **Decatur Memorial Hospital,** Decatur
- **Delnor Community Hospital,** Geneva
- **Dr. William M. Scholl College of Podiatric Medicine,** North Chicago
- **Edward Hospital,** Naperville
- **Edward J Hines, Jr. VA Hospital,** Hines
- **Holy Family Medical Center,** Monmouth
- **Ingalls Memorial Hospital,** Harvey
- **James A. Lovell Federal Health Care Center,** North Chicago
- **John H. Stroger Jr. Hospital of Cook County**, Chicago
- **Loyola University Stritch School of Medicine,** Maywood
- **Memorial Medical Center,** Springfield
- **Mercy Hospital and Medical Center,** Chicago
- **Midwestern Regional Medical Center,** Zion
- **Midwestern University,** Downers Grove
- **North Chicago VA Medical Center,** North Chicago
- **North Shore University Health System-Kellogg Cancer Center,** Evanston
- **Northwestern Memorial Hospital,** Chicago
- **Northwestern University Feinberg School of Medicine,** Chicago
- **OSF St. Francis Medical Center,** Peoria
- **Ottawa Regional Hospital and Health Care Center,** Ottawa
- **Pekin Cancer Treatment Center,** Pekin
- **Proctor Hospital,** Peoria
- **Robert H. Lurie Comprehensive Cancer Center of Northwestern University,** Chicago
- **Rosalind Franklin University of Medicine and Science,** North Chicago
- **Rush University Medical Center,** Chicago
- **Southern Illinois University School of Medicine,** Springfield
- **St. Joseph Medical Center,** Bloomington
- **Swedish American Regional Cancer Center,** Rockford
- **University of Chicago Pritzker School of Medicine**, Chicago
- **University of Illinois,** Chicago
- **Vanguard Health Chicago,** Chicago
- **Weiss Memorial Hospital,** Chicago

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 7,100 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.

[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 10/11/2017. Open clinical trials are recruiting, not yet recruiting, or are expanded access.*

In Illinois, of the 955 open clinical trials involving the biopharmaceutical research industry, the **University of Chicago** is collaborating on more than 228 of the trials, **Northwestern University** on more than 156 clinical trials, **Rush University** on more than 90 clinical trials, **Loyola University Chicago** on more than 54, the **University of Illinois** on more than 39, and **Southern Illinois University** on more than 19.

THE STATE OF DISEASE IN ILLINOIS

More than 12.8 million people live in Illinois[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Illinois	
Disease	**Health Statistic**
Alzheimer's Deaths, 2015[2]	3,687
Asthma Prevalence, 2012[2]	850,000
Cancer New Cases, 2017[3]	64,720
Cancer Deaths, 2017[3]	24,040
Chronic Lower Respiratory Diseases, 2015[2]	5,544
Diabetes Prevalence-Adults, 2015[4]	9.9 percent
Diabetes Deaths, 2015[2]	2,818
Heart Disease Deaths, 2015[2]	25,653
HIV-Number Living with a Diagnosis, 2014[4]	34,843
HIV Deaths, 2015[2]	224
Influenza / Pneumonia Deaths, 2015[2]	2,343
Liver Disease/Cirrhosis Deaths, 2015[2]	1,290
Mental Illness-Adults, 2013-2014[4]	1,587,000
Nephritis Deaths, 2015[2]	2,543
Parkinson's Death, 2015[2]	1,079
Septicemia Deaths, 2015[2]	1,819
Stroke Deaths, 2015[2]	5,709

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

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

- Children under the age of 18 make up 22.9 percent of the population in Illinois. Pediatric clinical trials are being conducted in the state for Crohn's disease, cystic fibrosis, diabetes, epilepsy, glioblastoma, sickle cell anemia, juvenile arthritis, leukemia and neuroblastoma, among others.
- Illinoisans aged 65 and older account for 14.6 percent of the states' population. In Illinois, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, Crohn's disease, depression, glaucoma, prostate cancer, heart failure and osteoarthritis, among others.
- Women and girls make up 50.9 percent of the population in Illinois. Clinical trials are recruiting women for studies on medicines for breast cancer, endometriosis, interstitial cystitis, ovarian cancer and vaginal infections, among others.

Clinical Trials in Illinois for Special Populations

Population	Number of Trials
Children (birth–17)	187
Seniors (66 and older)	768
Women (only)	43

Source: www.clinicaltrials.gov. Search criteria: Illinois, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 10/11/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

SCIENCE AND CLINICAL TRIALS

Some of the medicines in clinical testing in Illinois feature revolutionary medical technologies. For example:

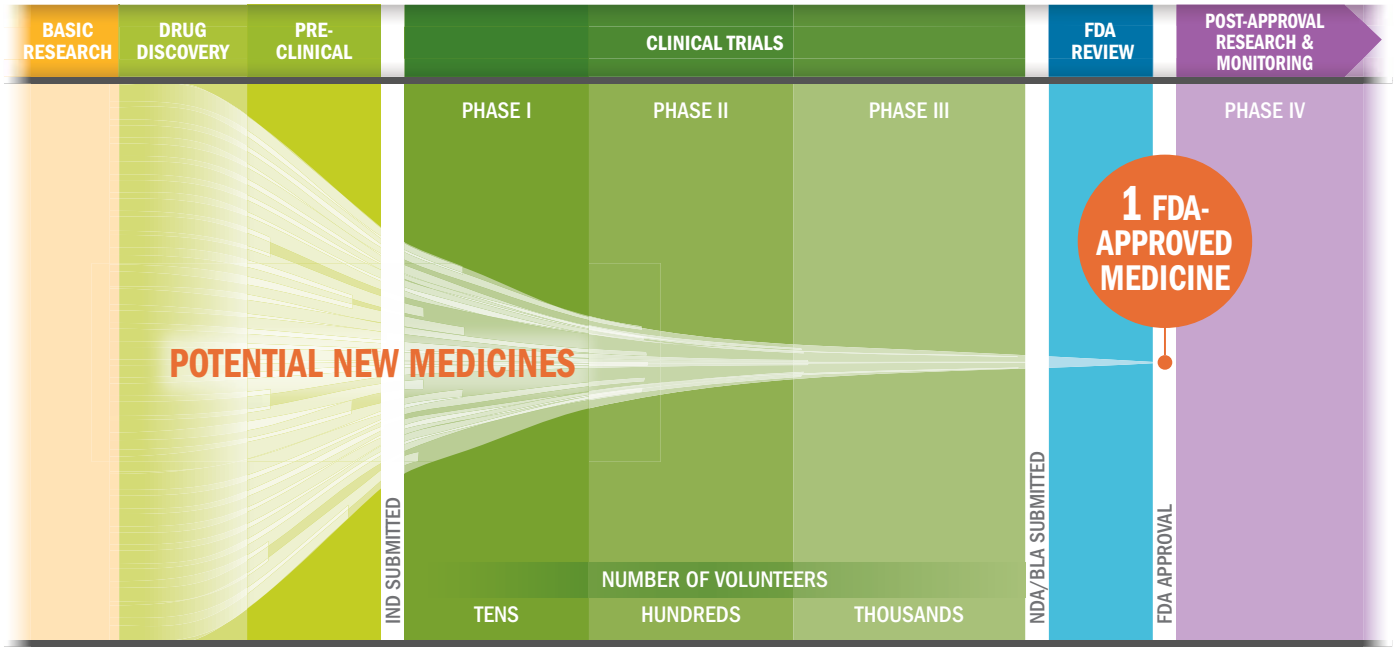
- A monoclonal antibody for the treatment of idiopathic pulmonary fibrosis is being studied in a clinical trial at **Northwestern University** in Chicago.
- A second-generation medicine for leukemia that blocks the activation of a receptor which is mutated in about one-third of all patients with acute myeloid leukemia is being tested in patients at **University of Chicago Medical Center** and **Rush University Medical Center** in Chicago.
- A medicine for advanced acute myeloid leukemia that inhibits a mutated form of a gene that can lead to increased production of an oncometabolite that prevents immature white cells from developing into healthy infection-fighting cells is in clinical trials at **Northwestern University Medical Center**, **Rush University Medical Center, University of Chicago Medical Center** and **Northshore University Health System Research Institute** in Evanston.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process is being studied in clinical trials in **Chicago**.
- A potential first-in-class medicine for mixed lineage leukemia, a devastating genetically-defined type of acute myeloid leukemia was studied in a clinical trial at **Northwestern University** in Chicago.
- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied to treat mutation-positive malignancies at **Rush University Medical Center** and the **University of Chicago Medical Center**.
- A monoclonal antibody is in development for the prevention of migraine by inhibiting calcitonin gene-related peptide (CGRP) activity. Anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. The antibody completed a late-stage clinical study in **Gurnee**.
- A medicine in development to treat peripheral artery disease is a non-viral gene therapy that targets a tissue repair and regeneration pathway in the body. This pathway promotes cardiac function, cell survival and the repair of injured heart tissue. It is being studied in clinical trials at **Northwestern University Medical Center** and **Rush University Medical Center.**
- An anti-inflammatory medicine in development for acute coronary syndrome inhibits the activity of p38 mitogen activated protein (MAP) kinase, an enzyme associated with the acute inflammation that occurs in the blood vessels during and immediately following an acute coronary syndrome event. The medicine was studied in clinical trials in **Aurora** and **Elmhurst**.
- A monoclonal antibody in development for osteoporosis binds to and inhibits the action of sclerostin, a protein encoded by the SOST gene. Mutations in sclerostin have been associated with abnormal bone growth. It was studied in clinical trials in **Maywood** and **Quincy**.
- A monoclonal antibody in development to treat head and neck cancer, ovarian cancer and gastric cancer inhibits PD-L1 interactions, and is thought to enable the activation of T-cells and the adaptive immune system. The antibody is in clinical trials at locations in **Elk Grove Village, Flossmoor, Harvey, Hoffman Estates, Joliet, Niles, Park Ridge, Rolling Estates, Tinley Park** and **Urbana.**

- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It completed a clinical trial at the **Jesse Brown Veterans Affairs Medical Center** in Chicago.
- An investigational therapeutic using RNAi (RNA interference) is targeting the protein transthyretin (TTR) for the treatment of familial amyloid cardiomyopathy (FAC). RNAi is a biological process that can be used to silence a gene and, in turn, prevent production of the protein it encodes. The therapeutic was studied in clinical trials at locations in **Chicago**.

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 Illinois, 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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