



RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
MARYLAND



Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting nearly 6,000 clinical trials of new medicines in Maryland in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Maryland's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

Summary

Clinical trials in **MARYLAND**

CLINICAL TRIALS IN MARYLAND 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 Maryland since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
5,982	856

Source: www.clinicaltrials.gov. Search criteria: Maryland, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 11/20/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

Executive Summary (cont.)

CLINICAL TRIALS OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

For patients, clinical trials offer the potential for another therapeutic option. Clinical tests may provide a new avenue of care for some chronic disease sufferers who are still searching for the medicines that are best for them.

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN MARYLAND

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

A study by TEconomy Partners found that in 2015, the industry supported more than 111,700 jobs throughout Maryland. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than \$1.9 billion in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$27.5 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 Maryland 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 MARYLAND

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,405 active industry-sponsored, site-based clinical trials in Maryland, with an estimated enrollment of 25,291 Maryland residents. Oncology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than \$222 million and the estimated total economic impact was more than \$527 million.

"Securing and protecting funding for urologic research is a pivotal part of the AUA's mission and advocacy efforts. We see great value for patients and physicians when innovative treatment therapies are derived from successful clinical trials. New therapies offer hope and improved quality of life for individuals living with urologic conditions."

Jessica Bateman
Senior Manager, Patient and Research Advocacy
American Urological Association

“Clinical trials have been conducted in every corner of Maryland, not only in Baltimore and Bethesda, the home of NIH and Walter Reed National Military Medical Center, but also in Hagerstown, Frederick, Annapolis, Rockville, Salisbury, Cumberland and several other communities. Patients and local economies from all over the state have benefited from the strong partnership and collaboration between the nation’s biopharmaceutical research companies, government and academic research institutions.”

**Martin Rosendale, CEO
Maryland Technology Council**

Open Clinical Trials in Maryland by Disease	
Disease	Number of Trials
Allergy	7
Alzheimer’s Disease	11
Arthritis/Musculoskeletal Disorders	18
Autoimmune Diseases	27
Bladder Disorders	4
Blood Disorders	7
Cancer	390
Cardiovascular Diseases	40
Diabetes	11
Eye Disorders	28
Gastrointestinal/Esophageal Diseases	54
Genetic Disorders	30
Infectious Diseases	33
Kidney Diseases	14
Liver Diseases	23
Mental Disorders	52
Neurological Disorders	43
Respiratory Diseases	22
Skin Diseases	12
Transplantation-Related	7
Other Diseases	23
Total	856

Source: www.clinicaltrials.gov. Search criteria: Maryland, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 11/20/2018. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

Patient Resources & Directory

WHAT IS THE CLINICAL TRIAL EXPERIENCE?

Clinical trials are research studies that generate data to support FDA approval of a new medicine or a new indication for an existing medication. They also grant participants early access to new medicines, which are being developed to help combat chronic and serious diseases. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Maryland, 5,982 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, to find clinical trials at the University of Maryland Medical Center go to <https://www.umms.org/ummc/health-services/research-clinical-trials> and for trials at Johns Hopkins University go to <http://trials.johnshopkins.edu/>.

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

AIDS Action Baltimore

10 East Eager Street
Baltimore, MD 21202
(410) 837-2437

Alzheimer's Association

GREATER MARYLAND CHAPTER
1850 York Road, Suite D
Timonium, MD 21093
(800) 272-3900 or (410) 561-9099

Alzheimer's Association

NATIONAL CAPITAL AREA CHAPTER
8180 Greensboro Drive, Suite 400
McLean, VA 22102
(703) 359-4440

American Cancer Society

BALTIMORE OFFICE
405 Williams Court, Suite 120
Baltimore, MD 21220
(410) 931-6850

American Cancer Society

CUMBERLAND OFFICE
1050 East Industrial Blvd., Unit 3
Cumberland, MD 21502
(301) 772-2145

American Cancer Society

ELDERSBURG OFFICE
1393 Progress Way, Suite 908
Eldersburg, MD 21784
(410) 781-4316

American Cancer Society

GREENBELT OFFICE
7500 Greenway Center Drive
Suite 300
Greenbelt, MD 20770
(301) 982-2161

American Cancer Society

SALISBURY OFFICE
1315 Mt. Hermon Road, Suite D
Salisbury, MD 21904
(410) 749-1624

American Diabetes Association

BALTIMORE OFFICE
2002 Clipper Park Road, Suite 110
Baltimore, MD 21211
(410) 265-0075

American Diabetes Association

WASHINGTON, DC OFFICE
2451 Crystal Drive, Suite 900
Arlington, VA 22202
(202) 331-8303

American Heart Association

MARYLAND OFFICE
217 E. Redwood Street, 11th Floor
Baltimore, MD 21202
(410) 685-7074

American Lung Association

MARYLAND CHAPTER
211 East Lombard Street, Suite 260
Baltimore, MD 21202
(302) 565-2073

American Urological Association

1000 Corporate Boulevard
Linthicum, MD 21090
(410) 689-3700

Arthritis Foundation

MARYLAND OFFICE
9891 Broken Land Parkway
Suite 101
Columbia, MD 21046
(443) 274-7480

Epilepsy Foundation of Maryland

1340 Smith Avenue, Suite 200
Baltimore, MD 21209
(301) 918-2100

Lupus Foundation of America

DC/MARYLAND/VIRGINIA CHAPTER
2121 K Street, NW, Suite 200
Washington, DC 20037
(202) 349-1155

NAMI Maryland

NATIONAL ALLIANCE ON MENTAL ILLNESS
Century Plaza East
10630 Little Patuxent Parkway
Suite 475
Columbia, MD 21044
(410) 884-8691

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA):

The Partnership for Prescription Assistance has helped more than 88,000 Maryland 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 has been 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 MARYLAND

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

- Supported more than 111,700 jobs throughout Maryland in 2015.
- Supported the generation of \$27.5 billion in economic activity in the state.
- Resulted in more than \$1.9 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 Maryland, 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:

Anne Arundel Health System Research Institute, Annapolis

Anne Arundel Medical Center, Annapolis

**Anne Arundel Medical Group Orthopedics and Sports
Medicine Specialists**, Annapolis, Bowie, Odenton, Pasadena

Arthritis Treatment Center, Frederick

Auerbach Hematology Oncology Associates, Baltimore

Baltimore Suburban Health, Pikesville

Baltimore VA Medical Center, Baltimore

Bay Hematology Oncology, Easton

Centennial Medical Group, Elkridge

Certified Research Consultants, Silver Spring

Charlotte R. Bloomberg Children's Center, Baltimore

Charm City Research Group, Towson

Chesapeake Clinical Research, Baltimore

Chesapeake Research Group, Pasadena

Chesapeake Center for Urologic Specialties, Baltimore

Chevy Chase Clinical Research, Chevy Chase

Chevy Chase Health Care Center, Chevy Chase

Chevy Chase Regional Cancer Care Associates, Chevy
Chase

Continental Clinical Solutions, Towson

Cumberland Valley Retina Center, Hagerstown

Delmarva Heart Research Foundation, Salisbury

FAAR Institute, Gaithersburg

Frederick Memorial Hospital, Frederick

Gastro Center of Maryland, Columbia

Good Samaritan Hospital, Baltimore

Greater Baltimore Medical Center, Baltimore

**Greenebaum Comprehensive Cancer Center, University of
Maryland**, Baltimore

Holy Cross Hospital, Silver Spring

Hugo W. Moser Research Institute at Kennedy Krieger,
Baltimore

Institute for Asthma & Allergy, Chevy Chase

James M. Stockman Cancer Institute, Frederick

Johns Hopkins Bayview Medical Center, Baltimore

Johns Hopkins University Medical Center, Baltimore

Klein and Associates, Cumberland, Hagerstown

Maryland Brain and Spine, Annapolis

Maryland Medical Research, Oxon Hill

Maryland Oncology Hematology, Bethesda, Brandywine,
Clinton, Columbia, Rockville, Silver Spring

Mercy Medical Center, Baltimore

Meritus Center for Clinical Research, Hagerstown

Metropolitan Cardiovascular Consultants, Beltsville

Mid-Atlantic Retina Specialists, Hagerstown

Mid-Atlantic Pulmonary & Research Center, Westminster

MODEL Clinical Research, Baltimore

National Cancer Institute, Bethesda

National Institute of Allergy and Infectious Disease,
Bethesda

National Institute of Mental Health, Bethesda

National Institutes of Health Clinical Center, Bethesda

NIH Hatfield Clinical Research Center, Bethesda

Optimal Research, Rockville

**Parexel Early Phase Clinical Unit at Medstar Harbor
Hospital**, Baltimore

Peninsula Regional Medical Center, Salisbury

Pharmaron, Baltimore

PharmaSite Research, Baltimore

Sheppard Pratt Health System, Baltimore

Shore Regional Cancer Center, Easton

**Sidney Kimmel Comprehensive Cancer Center at Johns
Hopkins**, Baltimore

Sinai Hospital of Baltimore, Baltimore

Spectrum Clinical Research, Towson

St. Joseph Medical Center, Towson

Suburban Hospital, Bethesda

The Center for Cancer and Blood Disorders, Bethesda

The Center for Rheumatology and Bone Research, Wheaton

The National Retina Institute, Towson

The Retina Care Center, Baltimore

The Retina Group of Washington, Chevy Chase

Union Memorial Hospital (Medstar), Baltimore

University of Maryland Medical Center, Baltimore

Walter Reed National Military Medical Center, Bethesda

Weinberg Cancer Institute at Franklin Square, Baltimore

Wilmer Eye Institute, Baltimore

Woodholme Gastroenterology Associates, Pikesville

Collaborations between the biopharmaceutical research industry and universities play an important role in the development of new medicines. In the United States, there are more than 7,600 open clinical trials¹ being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies,

and research the other groups are undertaking on their own.

In Maryland, of the 856 open clinical trials involving the biopharmaceutical research industry, the **University of Maryland** is collaborating on more than 125 clinical trials and **Johns Hopkins University** is collaborating on more than 119.

THE STATE OF DISEASE IN MARYLAND

More than 6 million people live in Maryland¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Maryland	
Disease	Health Statistic
Alzheimer's Deaths, 2016 ²	1,178
Arthritis Prevalence ³	1.1 million
Asthma Prevalence, 2012 ²	838,600
Cancer New Cases, 2018 ⁴	33,810
Cancer Deaths, 2018 ⁴	10,780
Chronic Lower Respiratory Diseases, 2016 ²	2,073
Diabetes Prevalence—Adults, 2017 ⁵	10.4 percent
Diabetes Deaths, 2016 ²	1,357
Heart Disease Deaths, 2016 ²	11,408
HIV—Number Living with a Diagnosis, 2015 ⁵	33,072
Influenza/Pneumonia Deaths, 2016 ²	1,025
Liver Disease/Cirrhosis Deaths, 2016 ²	464
Mental Illness—Adults, 2015-2016 ⁵	758,000
Nephritis Deaths, 2016 ²	824
Parkinson's Death, 2016 ²	499
Septicemia Deaths, 2016 ²	878
Stroke Deaths, 2016 ²	2,706

Source: 1. U.S. Census Bureau 2. Maryland Department of Health 3. Arthritis Foundation 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts

¹ Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase early 1, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 11/20/2018. Open clinical trials are recruiting, not yet recruiting, expanded access available.

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

- Children under the age of 18 make up 22.3 percent of the population in Maryland. 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.
- Marylanders aged 65 and older account for 14.9 percent of the states’ population. In Maryland, 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 51.5 percent of the population in Maryland. 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 Maryland for Special Populations

Population	Number of Trials
Children (birth-17)	162
Seniors (65 and older)	735
Women (only)	33

Source: www.clinicaltrials.gov. Search criteria: Maryland, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2007. Search performed 11/20/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

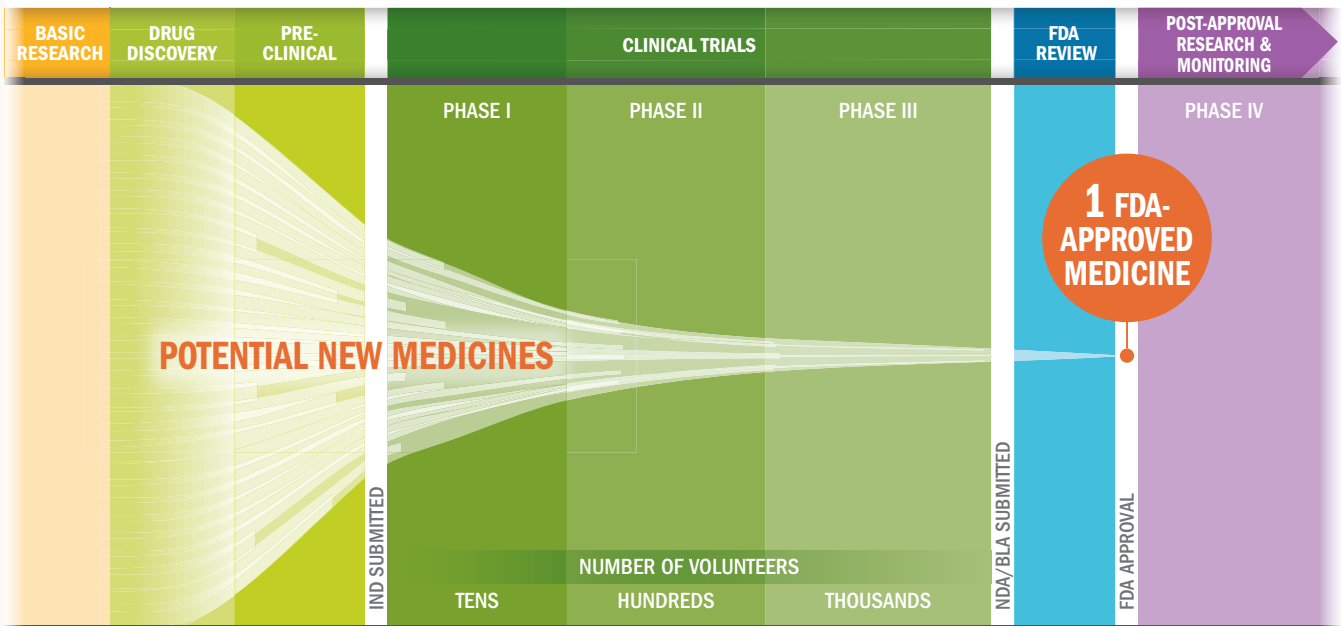
Some of the medicines in clinical testing in Maryland feature revolutionary medical technologies. For example:

- 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 **Johns Hopkins University** in Baltimore.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process is being studied in clinical trials in **Cumberland, Frederick, Hagerstown** and **Wheaton**.
- 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. The medicine is being studied at **Johns Hopkins University** in Baltimore.
- A monoclonal antibody in development for relapsing multiple sclerosis targets LINGO, a protein that is involved in the development of myelin, a protective sheath covering the nerve fibers. It is believed that LINGO may inhibit myelin growth and, by blocking LINGO's production, the medicine could support the growth of myelin and restore nerve communication in multiple sclerosis patients. The monoclonal antibody was studied in a clinical trial at **Johns Hopkins University** in Baltimore.
- A monoclonal antibody in development for the prevention of migraine binds to and inhibits the activity of a calcitonin gene-related peptide (CGRP) 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. The antibody completed a late-stage clinical study in **Baltimore**.
- Acute coronary syndrome (ACS) refers to cardiovascular events, including heart attack, where there is an abrupt reduction of blood flow to the heart through the coronary arteries. An anti-inflammatory medicine in development for the 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 **Baltimore**.
- 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. Inhibiting sclerostin may play a critical role in increasing bone formation and decreasing bone breakdown. It was studied in clinical trials in **Bethesda**.
- 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 monoclonal antibody may potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity. The antibody is in clinical trials at **Maryland Oncology Hematology** locations in Bethesda, Columbia, and Silver Spring; the **Maryland Proton Treatment Center** in Baltimore, the **National Cancer Institute** in Bethesda, the **University of Maryland** in Baltimore, the **Sidney Kimmel Comprehensive Cancer Center** in Baltimore and **Holy Cross Hospital** in Silver Spring.
- 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 **Maryland Prostate Center** in Baltimore, the **Greater Baltimore Medical Center, Union Memorial Hospital** in Baltimore, and the **National Cancer Institute** and the **Walter Reed Army Medical Center** in Bethesda.

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 Maryland, 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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