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Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
GEORGIA

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Executive

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

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

Summary

Clinical trials in
GEORGIA

CLINICAL TRIALS IN GEORGIA 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 Georgia since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
6,851	945

Source: www.clinicaltrials.gov. Search criteria: Georgia, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 2/27/2019. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

Executive Summary (cont.)

CLINICAL TRIALS OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

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

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN GEORGIA

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

A study by TEConomy Partners found that in 2015, the industry supported more than 61,800 jobs throughout Georgia. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than $782 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $14.3 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 Georgia 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 GEORGIA

A separate study by TEConomy Partners found that in 2017 alone, there were 1,024 active industry-sponsored, site-based clinical trials in Georgia, with an estimated enrollment of 23,479 Georgia residents. Cardiovascular and circulatory diseases had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than $385 million and the estimated total economic impact was more than $1.1 billion.

"Clinical trials in mental health care lead the way for important breakthroughs in treatments that can mean the difference between just getting by and being able to thrive."

Kim Jones,
NAMI Georgia

"Georgia Bio's mission to build, advance, and grow the life sciences industry in Georgia is heavily driven by the incredible economic impact this industry has on the peach state, as the fastest growing segment of our innovation economy—with biopharma being a crucially important contributor. Beyond the stunning economic impact, the ultimate goal is to continually generate new breakthrough solutions catalyzed by research efforts, that support new drug development and vital clinical trials that can extend life, enhance quality of life, and relieve suffering for patients everywhere. We are immensely grateful for dynamic partnerships between industry, researchers, health care organizations, and associations like PhRMA and Georgia Bio that energize and fuel these compelling missions—that ultimately impact each of us and our loved ones at the most personal level."

Maria Thacker
President & CEO, Georgia Bio

Open Clinical Trials in Georgia by Disease

Disease	Number of Trials
Allergy	3
Alzheimer's Disease	24
Arthritis/Musculoskeletal Disorders	20
Autoimmune Diseases	39
Blood Disorders	27
Cancer	362
Cardiovascular Diseases	49
Diabetes	29
Eye Disorders	32
Gastrointestinal/Esophageal Diseases	58
Genetic Disorders	32
Infectious Diseases	50
Kidney Diseases	15
Liver Diseases	20
Mental Disorders	64
Neurological Disorders	52
Respiratory Diseases	18
Skin Diseases	22
Transplantation-Related	8
Other Diseases	21
Total	**945**

Source: www.clinicaltrials.gov. Search criteria: Georgia, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 2/27/2019. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

Patient Resources & Directory

WHAT IS THE CLINICAL TRIAL EXPERIENCE?

Clinical trials are research studies that generate data to support FDA approval of a new medicine or a new indication for an existing medication. They also grant participants early access to new medicines, which are being developed to help combat chronic and serious diseases. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Georgia, 6,851 clinical trials since 2004 have targeted diseases and conditions like asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

PHASES OF CLINICAL TRIALS

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

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

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

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

LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials in several ways. Health care providers are aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. Patients can also use hospital and university websites to find the trials being conducted in their area. For instance, for clinical trials at the Medical College of Georgia at Augusta University visit *www.augusta.edu/research/studies/* and for Emory University visit *clinicaltrials.emory.edu/*. For information about research at Mercer University visit *medicine.mercer.edu/research/* and at Morehouse School of Medicine visit *www.msm.edu/Research/research-centers-institutes/index.php#.*

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

Alzheimer's Association
State and Metro Atlanta Office
41 Perimeter Center East
Suite 550
Atlanta, GA 30346
(404) 728-1181

Alzheimer's Association
Chattahoochee Valley Regional Office
5156 River Road, Suite M
Columbus, GA 31904
(706) 327-6838

Alzheimer's Association
North Georgia Regional Office
922 East Morris Street
Dalton, GA 30721
(706) 275-0819

Alzheimer's Association
Augusta Regional Office
106 SRP Drive, Suite A
Evans, GA 30809
(706) 860-4599

Alzheimer's Association
Central Georgia Regional Office
886 Mulberry Street
Macon, GA 31201
(478) 746-7050

Alzheimer's Association
Coastal Georgia Regional Office
4849 Paulsen Street, Suite 103
Savannah, GA 31406
(912) 920-2231

Alzheimer's Association
South Georgia Regional Office
225 East 2nd Street
Tifton, GA 31794
(229) 388-8219

American Cancer Society
Athens Office
105 Westpark Drive, Suite C
Athens, GA 30606
(706) 549-4893

American Cancer Society
Atlanta Office
250 Williams Street NW
Atlanta, GA 30303
(404) 816-7800

American Cancer Society
Augusta Office
901 Greene Street
Augusta, GA 30901
(706) 731-9900

American Cancer Society
Columbus Office
233 12th Street, Suite 710
Columbus, GA 31901
(706) 324-4573

American Cancer Society
Cobb County Office
3380 Chastain Meadows
Parkway, NW
Suite 200
Kennesaw, GA 30144
(770) 429-0089

American Cancer Society
Gainesville Office
2565 Thompson Bridge Road
Suite 114
Gainesville, GA 30501
(770) 297-1176

American Cancer Society
Gwinnett County Office
6500 Sugarloaf Parkway, Suite 260
Duluth, GA 30097
(770) 814-0123

American Cancer Society
Macon Office
804 Cherry Street, Suite A
Macon, GA 31201
(478) 743-6391

American Cancer Society
Savannah Office
4849 Paulsen Street, Suite 102
Savannah, GA 31405
(912) 355-5196

American Diabetes Association
Atlanta Office
233 Peachtree Street, Harris Tower
Suite 2225
Atlanta, GA 30303
(404) 320-7100

American Heart Association
Atlanta Office
10 Glenlake Parkway, South Tower
Suite 400
Atlanta, GA 30328
(678) 224-2000

American Heart Association
Athens Office
1720 Epps Bridge Parkway
Suite 108-383
Athens, GA 30606
(800) 257-6941, ext. 6160

American Heart Association
Columbus Office
1639 Bradley Park Drive
Suite 500, PMB 379
Columbus, GA 31904
(800) 257-6941, ext. 6162

American Heart Association
Hall County Office
821 Dawsonville Highway
Suite 250-323
Gainesville, GA 30501
(800) 257-6941, ext. 6161

American Heart Association
Macon Office
5962 Zebulon Road, PMB 359
Macon, GA 31210
(800) 257-6941, ext. 6164

American Liver Foundation
Southeast Division
9100 South Dadeland Blvd.
Suite 5157
Miami, FL 33156
(786) 834-1100

American Lung Association
Georgia Chapter
2452 Spring Road SE
Smyrna, GA 30080
(770) 434-5864

Arthritis Foundation
Southeast Regional Chapter
P.O. Box 78423
Atlanta, GA 30357
(404) 965-7611

Epilepsy Foundation of Georgia
6065 Roswell Road, Suite 715
Atlanta, GA 30328-4030
(404) 527-7155

NAMI Georgia
National Alliance on Mental Illness
4120 Presidential Parkway
Suite 200
Atlanta, GA 30340
(770) 234-0855

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 274,000 Georgia 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 4.7 million jobs across the U.S. economy in 2015, according to a study by TEConomy Partners.

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested more than $600 billion in R&D in the search for new treatments and cures.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN GEORGIA

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

- Supported more than 61,800 jobs throughout Georgia in 2015.
- Supported the generation of $14.3 billion in economic activity in the state.
- Resulted in more than $782 million in federal and state taxes paid through jobs supported by the biopharmaceutical sector.

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

Atlanta VA Medical Center, Atlanta

Cancer Center at DeKalb Medical, Decatur

Center for Cancer Care/Gwinnett Hospital System, Duluth, Lawrenceville, Snellville

Children's Healthcare of Atlanta, Atlanta

Children's Hospital of Atlanta, Atlanta

Columbus Regional Research Institute, Columbus

Eisenhower Army Medical Center, Fort Gordon

Emory Clinic, Atlanta

Emory Clinic-Crawford Long Hospital, Atlanta

Emory Healthcare Heart Center, Johns Creek

Emory University Hospital Midtown, Atlanta

Emory University School of Medicine, Atlanta

Georgia Regents University, Augusta

Glynn Brunswick Memorial Authority, Brunswick

Grady Health System, Atlanta

Gwinnett Medical Center, Duluth

John B. Amos Cancer Center, Columbus

John D. Archbold Memorial Hospital, Thomasville

Lewis Hall Singletary Oncology Center at John D. Archbold Memorial Hospital, Thomasville

Medical Center of Central Georgia, Macon

Medical College of Georgia at Augusta University, Augusta

Memorial Health University Medical Center, Savannah

Mercer University School of Medicine, Macon

Morehouse School of Medicine, Atlanta

Nancy N. & J.C. Lewis Cancer Center at St. Joseph/Candler, Savannah

Newton Medical Center, Conyers

Northeast Georgia Cancer Care, Athens

Northeast Georgia Heart Center, Gainesville

Northeast Georgia Medical Center, Gainesville

Northside Hospital, Atlanta

Northside/Alpharetta Medical Campus, Alpharetta

Phoebe Putney Memorial Hospital Cancer Center, Albany

Piedmont Atlanta Hospital, Atlanta

Redmond Regional Medical Center, Rome

Shepherd Center, Atlanta

Southeastern Regional Medical Center, Newnan

St. Joseph's Hospital, Atlanta

St. Joseph's/Chandler Health System, Savannah

University of Georgia, Athens

Winship Cancer Institute at Emory University School of Medicine, Atlanta

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 7,700 open clinical trials[1] being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies, and research the other groups are undertaking on their own.

In Georgia, of the 945 open clinical trials involving the biopharmaceutical research industry, **Emory University** is collaborating on more than 242 clinical trials, the **Medical College of Georgia at Augusta University** on more than four, **Mercer University** on more than three and **Morehouse School of Medicine** on more than two of the clinical trials.

THE STATE OF DISEASE IN GEORGIA

More than 10.5 million people live in Georgia[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Georgia	
Disease	**Health Statistic**
Alzheimer's Deaths, 2017[2]	4,289
Asthma Prevalence, 2014[2]	Children 10.2% / Adults 8.4%
Cancer New Cases, 2018[3]	56,920
Cancer Deaths, 2018[3]	17,730
Chronic Lower Respiratory Diseases Deaths, 2017[2]	4,867
Diabetes Prevalence—Adults[4]	880,495
Diabetes Deaths, 2017[2]	2,348
Heart Disease Deaths, 2017[2]	20,170
HIV Deaths, 2017[2]	336
HIV—Number Living with a Diagnosis, 2015[5]	49,463
Influenza/Pneumonia Deaths, 2017[2]	1,401
Kidney Disease Deaths, 2017[2]	1,943
Liver Disease Deaths, 2017[2]	1,146
Mental Illness—Adults, 2015–2016[5]	1.3 million
Parkinson's Death, 2017[2]	844
Stroke Deaths, 2017[2]	4,393

Source: 1. U.S. Census Bureau 2. Georgia Health Authority 3. American Cancer Society 4. American Diabetes Association 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 2/27/2019. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

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

- Children under the age of 18 make up 24.1 percent of the population in Georgia. Pediatric clinical trials are being conducted in the state for Crohn's disease, cystic fibrosis, type 1 diabetes, epilepsy, atopic dermatitis, glaucoma, pediatric heart failure, juvenile arthritis, peanut allergy, leukemia and neuroblastoma, among others.

- Georgians aged 65 and older account for 13.5 percent of the states' population. In Georgia, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, Crohn's disease, age-related macular degeneration, prostate cancer, heart failure and rheumatoid arthritis, among others.

- Women and girls make up 51.3 percent of the population in Georgia. Clinical trials are recruiting women for studies on medicines for breast cancer, endometriosis, irritable bowel syndrome, menopause symptoms, ovarian cancer, depression and uterine fibroids, among others.

Clinical Trials in Georgia for Special Populations

Population	Number of Trials
Children (birth–17)	224
Seniors (66 and older)	766
Women (only)	43

Source: www.clinicaltrials.gov. Search criteria: Georgia, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 2/27/2019. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

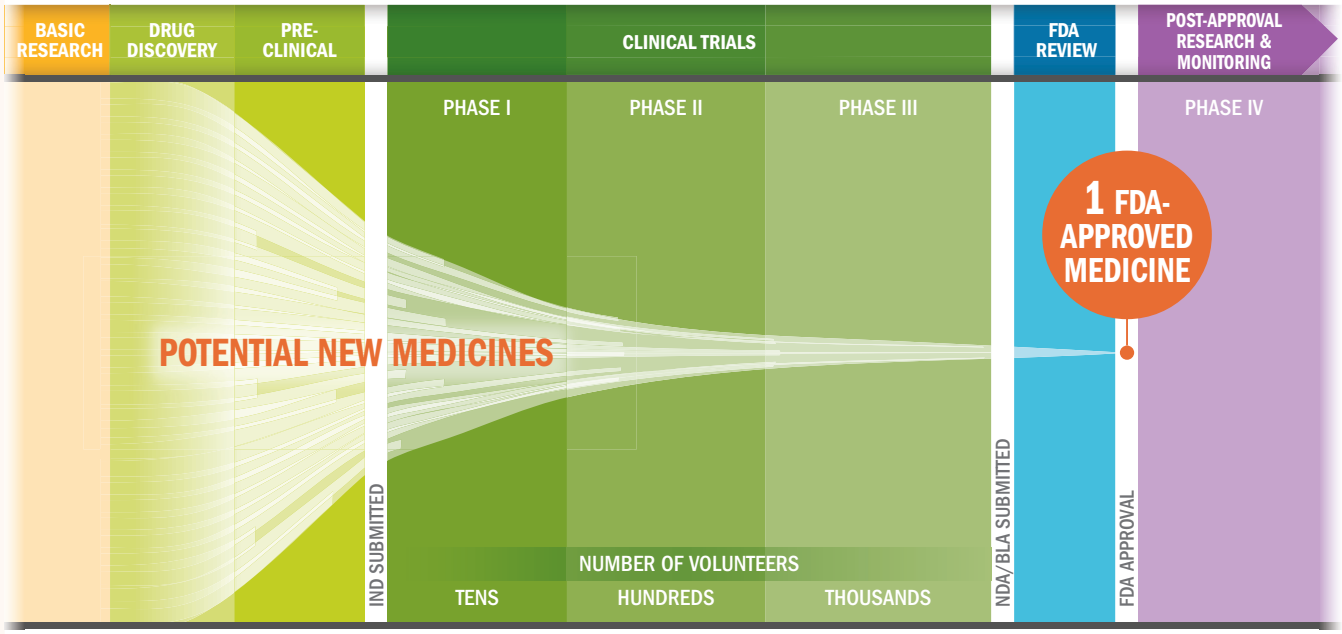
Some of the medicines in clinical testing in Georgia feature revolutionary medical technologies. For example:

- A monoclonal antibody for the treatment of Duchenne muscular dystrophy and idiopathic pulmonary fibrosis completed clinical trials at Rare Disease Research and Emory University in **Atlanta**.
- A potential first-in-class medicine for mixed lineage leukemia, a devastating genetically-defined type of acute leukemia was studied in a clinical trial at **Emory Children's Healthcare of Atlanta**.
- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied as a combination treatment for BRAF-mutant solid tumors is being studied in a clinical trial at **University Cancer & Blood Center** in Athens, **Northeast Georgia Medical Center** in Gainesville and **Southeastern Regional Medical Center** in Newnan.
- 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. The medicine is currently in a pediatric clinical trial in **Atlanta**.
- 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. It is currently in a clinical trial in **Atlanta**.
- 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. Clinical trials were conducted in **Atlanta** and **Gainesville**.
- A synthetic analogue of human parathyroid hormone-related protein (hPTHrP) is in development for the treatment of postmenopausal osteoporosis. The protein hPTHrP is thought to be a critical cytokine for promoting new bone formation. The medicine is designed to build bone rapidly without inducing hypercalcemia (too much calcium in the blood) or significant bone resorption. It is currently in a clinical trial at the **Center for Advanced Research & Education** in Gainesville and **Meridian Clinical Research** in Savannah.
- A monoclonal antibody in development to treat BRCA or ATM-mutant solid tumors and ovarian cancer, lung cancer, urothelial 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 **Atlanta Cancer Care** in Alpharetta, Atlanta, Cumming, Decatur, Jonesboro; **Northside Hospital** in Athens, Atlanta, Canton, Macon and Marietta; **Emory University** in Atlanta and **Winship Cancer Institute** in Atlanta.
- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It was studied in a clinical trial at **Midtown Urology** in Atlanta.
- A monoclonal antibody in development for Huntington's disease binds to and blocks the activity of Semaphorin 4D (SEMA4D), a protein that plays a key role in the neuro-inflammatory processes that can cause inflammation in the brain of people with the disease. By blocking the activity of SEMA4D, it may slow or prevent the neurodegeneration in Huntington's disease, a fatal disorder that causes the breakdown of nerve cells in the brain. The antibody is in a clinical trial at **Emory University School of Medicine** in Atlanta.
- Antibody-drug conjugates (ADC) utilize a monoclonal antibody to deliver a therapeutic drug to cancer cells, staying stable in the bloodstream and only releasing the therapeutic once inside the cancer cells. An ADC in development specifically targets epidermal growth factor receptors (EGFR), a growth factor that stimulates the proliferation of cell growth. The medicine is being tested in patients with EGFR-amplified glioblastoma. The ADC is in a clinical trial at **Piedmont Hospital** and **Emory University Hospital** in Atlanta.

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 Georgia, 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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