



RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
SOUTH CAROLINA



Executive

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

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 4,700 clinical trials of new medicines in South Carolina in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of South Carolina's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

Summary

Clinical trials in **SOUTH CAROLINA**

CLINICAL TRIALS IN SOUTH CAROLINA 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 South Carolina since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
4,757	572

Source: www.clinicaltrials.gov. Search criteria: South Carolina, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2004. Search performed 8/14/2018. 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 SOUTH CAROLINA

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

A study by TEconomy Partners found that in 2015, the industry supported more than 29,500 jobs throughout South Carolina. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than \$319 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$7.9 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 South Carolina 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 SOUTH CAROLINA

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,097 active industry-sponsored, site-based clinical trials in South Carolina, with an estimated enrollment of 36,104 South Carolina residents. Cardiovascular and circulatory disorders had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than \$238 million and the estimated total economic impact was more than \$540 million.

"Being diagnosed with a rare adrenal cancer usually means a shortened life span, but clinical trials change the way we view cancer, and one day we will view cancer as a disease that once killed people, and that is a result I can live with."

Greg McDuffie
Clinical Trial Patient

“SCBIO’s mission to build, advance, and grow the life sciences industry in South Carolina is heavily driven by the incredible \$11.4 billion economic impact this industry has on the palmetto 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 SCBIO that energize and fuel these compelling missions—that ultimately impact each of us and our loved ones at the most personal level.”

Sam Konduros
President & CEO, SCBIO

Open Clinical Trials in South Carolina by Disease

Disease	Number of Trials
Allergy	3
Alzheimer’s Disease	11
Arthritis/Musculoskeletal Disorders	15
Autoimmune Diseases	30
Bladder Disorders	8
Blood Disorders	9
Cancer	215
Cardiovascular Diseases	35
Diabetes	21
Eye Disorders	21
Gastrointestinal/Esophageal Diseases	34
Genetic Disorders	22
Infectious Diseases	26
Kidney Diseases	8
Liver Diseases	6
Mental Disorders	32
Neurological Disorders	16
Respiratory Diseases	28
Skin Diseases	16
Transplantation-Related	4
Other Diseases	12
Total	572

Source: www.clinicaltrials.gov. Search criteria: South Carolina, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 8/14/2018. 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 South Carolina, 4,757 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 Medical University of South Carolina go to www.muschealth.org/clinical-trials/index.htm and for clinical trials in neurologic disorders at the University of South Carolina go to, www.phuscmg.org/specialties/neuroscience/neurology/clinical-trials.

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

Alzheimer's Association

SOUTH CAROLINA OFFICE
4124 Clemson Blvd., Suite L
Anderson, SC 29621
(864) 224-3045

American Cancer Society

CHARLESTON OFFICE
5900 Core Avenue, Suite 504
North Charleston, SC 29406
(843) 744-1922

American Heart Association

CHARLESTON AND COASTAL OFFICE
174 East Bay Street, Suite 300 A-B
Charleston, SC 29401
(843) 480-4900

Alzheimer's Association

GREENVILLE OFFICE
301 University Ridge, Suite 5850
Greenville, SC 29601
(864) 250-0029

American Cancer Society

COLUMBIA OFFICE
200 Center Point Circle, Suite 100
Columbia, SC 29210-1790
(803) 750-1693

American Heart Association

COLUMBIA OFFICE
190 Knox Abbott Drive, Suite 301
Columbia, SC 29033
(803) 806-3008

Alzheimer's Association

LOW COUNTRY OFFICE
2090 Executive Hall Road
Suite 130
Charleston, SC 29407
(843) 571-2641

American Cancer Society

GREENVILLE OFFICE
154 Milestone Way
Greenville, SC 29615
(864) 627-1903

American Heart Association

FLORENCE OFFICE
181 E. Evans Street, BTC-009
Suite 200
Florence, SC 29506
(843) 665-0985

Alzheimer's Association

MIDLANDS OFFICE
140 Stoneridge Drive, Suite 210
Columbia, SC 29210
(803) 791-3430

American Cancer Society

GREENWOOD OFFICE
P.O. Box 1741
Greenwood, SC 29648
(864) 321-1166

American Heart Association

HILTON HEAD OFFICE
P.O. Box 1410
Bluffton, SC 29910
(843) 540-6338

Alzheimer's Association

MYRTLE BEACH OFFICE
1105 48th Avenue North, Suite 109
Myrtle Beach, SC 29577
(843) 213-1516

American Cancer Society

MYRTLE BEACH OFFICE
950 48th Avenue, North, Suite 101
Myrtle Beach, SC 29577
(843) 213-0333

American Heart Association

MYRTLE BEACH OFFICE
1113 44th Avenue, Suite 200
Myrtle Beach, SC 29577
(843) 282-2901

Alzheimer's Association

SPARTANBURG OFFICE
901 South Pine Street, Lower Level
Spartanburg, SC 29302
(864) 542-9998

American Diabetes Association

CAROLINA OFFICE (NORTH AND SOUTH)
1300 Baxter Street, Suite 150
Charlotte, NC 28204
(704) 373-9111

American Heart Association

UPSTATE SC AND WESTERN NC OFFICE
156 Milestone Way, Suite A
Greenville, SC 29615
(864) 627-4158

American Heart Association

AUGUSTA OFFICE
516 West Avenue
North Augusta, SC 29841
(803) 341-9592

American Lung Association

SOUTH CAROLINA CHAPTER
44-A Markfield Drive
Charleston, SC 29407
(843) 556-8451

Arthritis Foundation

CAROLINA OFFICE (NORTH AND SOUTH)
4530 Park Road, Suite 230
Charlotte, NC 28209
(704) 912-1365

NAMI South Carolina

NATIONAL ALLIANCE ON MENTAL ILLNESS
1735 St. Julian Place, Suite 300
Columbia, SC 29204
(800) 788-5131 or (803) 733-9591

South Carolina Asthma Alliance

P.O. Box 4484
Greenville, SC 29608
(864) 347-0031

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA):

The Partnership for Prescription Assistance has helped more than 135,700 South Carolina 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 SOUTH CAROLINA

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

- Supported more than 29,500 jobs throughout South Carolina in 2015.
- Supported the generation of \$7.9 billion in economic activity in the state.
- Resulted in more than \$319 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 South Carolina, 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:

ACME Research, Orangeburg
Allergic Disease & Asthma Center, Greenville
Anderson Pharmaceutical Research, Anderson
AnMed Health Clinical Research, Anderson
Atlantic Urology Clinics, Myrtle Beach
BG Neurology, Spartanburg
Bogan Sleep Consultants, Columbia
Bon Secours Saint Francis Hospital and Cancer Center, Greenville
Cancer Center of the Carolinas, Greenville
Carolina Blood and Cancer Care of South Carolina, Rock Hill
Carolina Clinical Trials, Charleston
Carolina Heart Specialists, Lancaster
Carolina Urologic Research Center, Myrtle Beach
Carolinas Center for Advanced Management of Pain, Spartanburg
Charleston Cancer Center, Charleston
Charleston Neuroscience Institute, Ladson
Clinical Research Center of the Carolinas, Charleston
Clinical Research of Rock Hill, Rock Hill
Clinical Trials of South Carolina, Charleston
Coastal Carolina Research Center, Mount Pleasant, North Charleston
Coastal Neurology, Port Royal
Coastal Pediatric Associates, Mount Pleasant
Coastal Pediatric Research, Charleston
Columbia Arthritis Center, Columbia
Columbia Heart Clinic, Columbia
DeGarmo Institute of Medical Research, Greer
Dermatology and Laser Center of Charleston, Charleston
Family Medicine of SayeBrook, Myrtle Beach
Fellows Research Alliance, Bluffton
Fusion Clinical Research of Spartanburg, Spartanburg
Gastroenterology Associates of Orangeburg, Orangeburg
Gibbs Cancer Center & Research Institute, Spartanburg
Greenville Endoscopy Center, Greenville
Greenville Health System, Clinton, Easley, Greenville, Greer, Seneca, Spartanburg
Greenville Pharmaceutical Research, Greenville
Hematology and Oncology Associates, Greenville
Hillcrest Clinical Research, Simpsonville
Hollings Cancer Center at the Medical University of South Carolina, Charleston
Innovative Clinical Research, Greenville
Institute for Translational Oncology Research, Greenville Hospital System, Greenville
Invocare Clinical Research Center, West Columbia
Low Country Research Center, North Charleston
Low Country Rheumatology, Charleston, North Charleston
Lowcountry Lung & Critical Care, Charleston
Magnolia OB/GYN Research Center, Myrtle Beach
Main Street Physician's Care—Waterway, Little River
McLeod Regional Medical Center, Florence
Medical Research South, Charleston
Medical University of South Carolina, Charleston
MedTrial, Columbia
Metrolina Neurological Associates, Indian Land
Mountain View Clinical Research, Greer
National Allergy and Asthma Research, North Charleston
Palmetto Clinical Research, Charleston, Summerville
Palmetto Health, Columbia
Palmetto Institute of Clinical Research, Pelzer
Palmetto Pediatrics, North Charleston
Palmetto Retina Center, Florence
Parkside Pediatrics, Greenville
Pharmacorp Clinical Trials, Charleston
Piedmont Comprehensive Pain Management Group, Greenville
Piedmont Research Partners, Fort Mill, Indian Land
PMG Research of Charleston, Moncks Corner, Mount Pleasant
Radiant Research, Anderson, Greer
Rainbow Research, Barnwell
Ralph H. Johnson Veterans Affairs Medical Center, Charleston
Retina Consultants of Charleston, Charleston
Roper St. Francis Hospital, Charleston
Self Regional Hospital Research Center, Greenwood
SleepMed Of South Carolina, Columbia
South Carolina Cancer Specialists, Hilton Head Island
South Carolina Nephrology & Hypertension Center, Orangeburg
Spartanburg Regional Medical Center, Spartanburg
Spectrum Medical Research, Gaffney
University Medical Group, Greenville
University of South Carolina Medical School, Columbia, Greenville
Vista Clinical Research, Columbia
VitaLink Research, Greenville, Spartanburg
Wm. Jennings Bryan Dorn Veterans Affairs Medical Center, Columbia

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 7,400 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 South Carolina, of the 572 open clinical trials involving the biopharmaceutical research industry, the **University of South Carolina Medial School** is collaborating on more than 143 clinical trials and the **Medical University of South Carolina** is collaborating on more than 142.

THE STATE OF DISEASE IN SOUTH CAROLINA

More than 12.8 million people live in South Carolina¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in South Carolina	
Disease	Health Statistic
Alzheimer's Deaths, 2016 ²	2,481
Arthritis Prevalence ³	1,110,000
Asthma Prevalence, 2013 ²	413,979
Cancer New Cases, 2018 ⁴	30,450
Cancer Deaths, 2018 ⁴	10,630
Chronic Lower Respiratory Diseases, 2016 ²	2,873
Diabetes Prevalence-Adults, 2015 ⁵	13 percent
Diabetes Deaths, 2016 ²	1,369
Heart Disease Deaths, 2016 ²	10,183
HIV-Number Living with a Diagnosis, 2015 ⁵	16,224
HIV Deaths, 2016 ²	152
Influenza/Pneumonia Deaths, 2016 ²	686
Liver Disease/Cirrhosis Deaths, 2016 ²	752
Mental Illness-Adults, 2015-2016 ⁵	677,000
Nephritis Deaths, 2016 ²	902
Parkinson's Death, 2016 ²	432
Septicemia Deaths, 2016 ²	871
Stroke Deaths, 2016 ²	2,627

Source: 1. U.S. Census Bureau 2. South Carolina Department of Health and Environmental Control 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 8/14/2018. Open clinical trials are recruiting, not yet recruiting, expanded access available.

SOUTH CAROLINA CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up 22 percent of the population in South Carolina. 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.
- South Carolinians aged 65 and older account for 17.2 percent of the states’ population. In South Carolina, 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 South Carolina. 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 South Carolina for Special Populations

Population	Number of Trials
Children (birth-17)	188
Seniors (65 and older)	503
Women (only)	28

Source: www.clinicaltrials.gov. Search criteria: South Carolina, United States; Phase: early 1, 1, 2, 3; Industry only; first received on or after 1/1/2007. Search performed 8/17/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

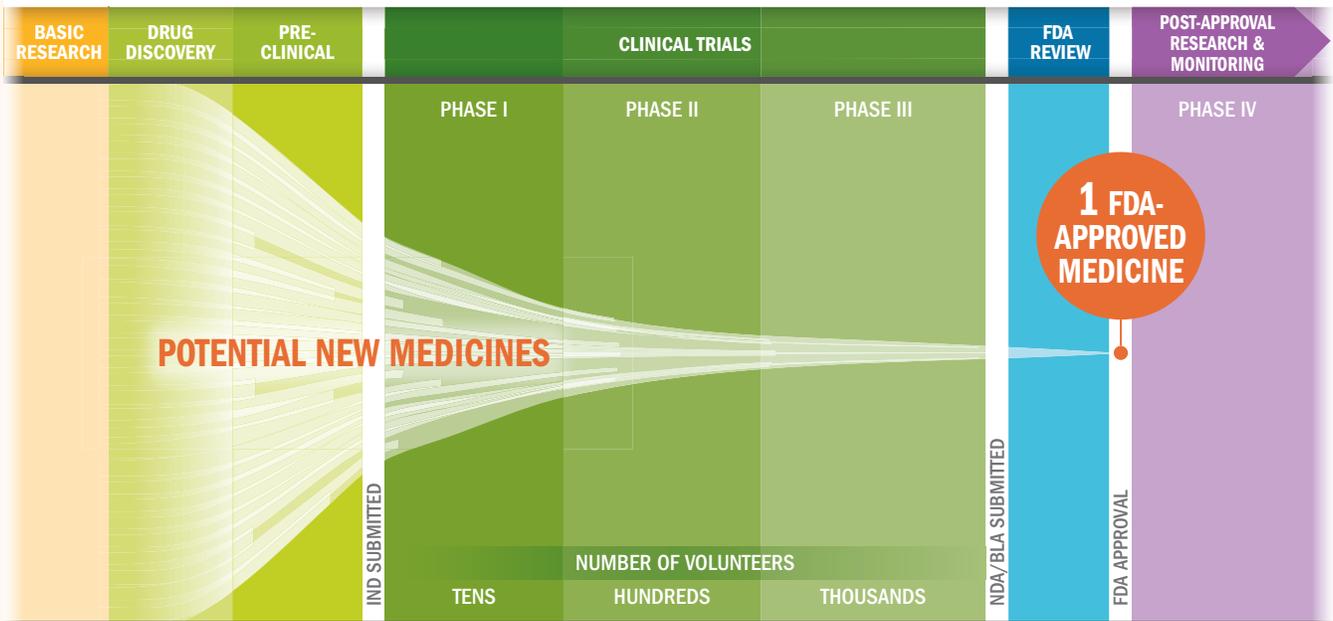
Some of the medicines in clinical testing in South Carolina feature revolutionary medical technologies. For example:

- Antibody-drug conjugates (ADC) utilize a monoclonal antibody to deliver a chemotherapy drug to cancer cells, releasing the drug once in contact with the cancer cells. One ADC in development specifically targets epidermal growth factor receptors (EGFR), a growth factor that stimulates the proliferation of cell growth. This approach has the potential to provide more targeted therapy to the cancer and thus limit side effects. The medicine is being tested in patients with EGFR-amplified glioblastoma. The medicine is in clinical trials at the **Medical University of South Carolina** in Charleston.
- 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 the **Cancer Center of the Carolinas** in Greenville.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process is being studied in clinical trials in **Columbia** and **North Charleston**.
- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied to treat mutation-positive malignancies at the **Hollings Cancer Center at the Medical University of South Carolina**.
- 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 late-stage clinical studies in **Mount Pleasant** and **Port Royal**.
- 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 **Anderson**.
- 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 **Charleston, Orangeburg** and **Spartanburg**.
- 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 the **Medical University of South Carolina, Greenville Health System** locations in **Easley, Greenville, Greer, Seneca** and **Spartanburg**; the **University of South Carolina School of Medicine** Greenville campus and **Saint Francis Hospital** in Greenville.
- 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 **Ralph H. Johnson Veterans Affairs Medical Center** in Charleston, the **Wm. Jennings Bryan Dorn Veterans Affairs Medical Center** in Columbia, the **Greenville Health System**, the **Charleston Cancer Center** and the **Carolina Urologic Research Center** in Myrtle Beach.

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 South Carolina, 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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