RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

NORTH CAROLINA

PhRMA

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Executive

Summary

Clinical trials in NORTH CAROLINA

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

Since 2004, biopharmaceutical research companies are conducting or have conducted more than 7,200 clinical trials of new medicines in North Carolina in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of North Carolina's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

CLINICAL TRIALS IN NORTH 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 North Carolina since 2004—Completed and Open	
All Clinical Trials	**Open Clinical Trials**
7,279	1,035

Source: www.clinicaltrials.gov. Search criteria: North Carolina, United States; Phase 0, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 5/1/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

Executive Summary (cont.)

"In North Carolina, life science companies benefit from a vibrant academic research environment, a deep labor pool, and an unparalleled level of public private partnership. The North Carolina Biotechnology Center, funded with more than $3.6 million in state funds, offers a robust portfolio of loan and grant programs that support start-up companies and promising innovations within our university system. A $75 million array of worker training facilities supplies associate, undergraduate and graduate level education and training for new and incumbent workers. In short, what life science companies need to succeed can be found in North Carolina"

- **Sam Taylor, President of NCBIO**

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 NORTH CAROLINA

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

A study by TEConomy Partners found that in 2014, the industry supported more than 259,000 jobs throughout North Carolina. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than $2.7 billion in federal taxation and $407.2 million in state taxes.

Biopharmaceutical research companies supported the generation of $77.6 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 North 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 NORTH CAROLINA

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,779 active industry-sponsored, site-based clinical trials in North Carolina, with an estimated enrollment of 45,524 North Carolina residents. Oncology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than $400 million and the estimated total economic impact was more than $1 billion.

Open Clinical Trials in North Carolina by Disease

Disease	Number of Trials
Allergy	4
Alzheimer's Disease	25
Arthritis/Musculoskeletal Disorders	40
Autoimmune Diseases	51
Bladder Disorders	9
Blood Disorders	35
Cancer	392
Cardiovascular Diseases	70
Diabetes	32
Eye Disorders	36
Gastrointestinal/Esophageal Diseases	57
Genetic Disorders	12
Infectious Diseases	47
Kidney Diseases	24
Liver Diseases	22
Mental Disorders	33
Neurological Disorders	62
Respiratory Diseases	29
Skin Diseases	25
Transplantation-Related	6
Other Diseases	24
Total	**1,035**

Source: www.clinicaltrials.gov. Search criteria: North Carolina, United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 5/1/2017. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

"My aspiration is to use my scientific training to positively impact the lives of patients, their families and physicians. At Biogen, I lead a skilled team of scientists focused on developing tools to support the discovery and development of innovative medicines for patients living with serious diseases. My approach to this stems from something Marie Curie said, which I hold dear to my heart, "Nothing in life is to be feared, it is only to be understood." Our group strives to understand Alzheimer's disease and develop tools (biomarkers) that allow us to diagnose this disease early with better accuracy, and develop appropriate treatments for individual patients living with this debilitating progressive disease."

Meena Subramanyam, Ph.D.
Vice President, Translational Sciences, Biogen

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 North Carolina, 7,279 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 information on clinical trials at institutions in North Carolina, visit:

- Duke University has information on clinical trials at *https://www.dukehealth.org/clinical-trials.*
- University of North Carolina's Translational & Clinical Sciences Institute lists clinical trial information at *https://tracs.unc.edu/.*
- Wake Forest University School of Medicine can be found at *www.wakehealth.edu/BeInvolved.*
- East Carolina University clinical trial information can be accessed at *http://www.ecu.edu/cs-dhs/ecuphysicians/clinicalTrials.cfm.*

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

Alzheimer's Association
Western North Carolina Chapter
4600 Park Road, Suite 250
Charlotte, NC 28209
(980) 498-7760

Alzheimer's Association
Eastern North Carolina Chapter
The Cumberland Building
3739 National Drive, Suite 110
Raleigh, NC 27612
(919) 803-8285

Alzheimer's Association
Asheville Office
31 College Place, Suite D-103
Asheville, NC 28801
(828) 254-7363

Alzheimer's Association
Greensboro Office
4615 Dundas Drive, Suite 103
Greensboro, NC 27407
(336) 285-5920

Alzheimer's Association
Hickory Office
228 2nd Street, NW
Hickory, NC 28601
(828) 514-3124

American Cancer Society
McConnell-Raab Hope Lodge
930-A Wellness Drive
Greenville, NC 27834
(252) 695-6143

American Cancer Society
Charlotte Office
1901 Brunswick Avenue,
Suite 100
Charlotte, NC 28207
(704) 552-6147

American Cancer Society
Greensboro Office
4-A Oak Branch Drive
Greensboro, NC 27407-2145
(336) 834-0844

American Cancer Society
Greenville Office
930 Wellness Drive, Suite B
Greenville, NC 27834
(252) 695-9028

American Cancer Society
Raleigh Office
8300 Health Park, Suite 10
Raleigh, NC 27615
(919) 334-5218

American Cancer Society
Wilmington Office
2202 Wrightsville Avenue,
Suite 111
Wilmington, NC 28403
(910) 254-4870

American Diabetes Association
Charlotte Office
1300 Baxter Street, Suite 150
Charlotte, NC 28204
(704) 373-9111

American Diabetes Association
Raleigh Office
2418 Blue Ridge Road, Suite 206
Raleigh, NC 27607
(919) 743-5400

American Heart Association
Eastern North Carolina Office
3131 RDU Center Drive,
Suite 100
Morrisville, NC 27560
(919) 463-8300

American Heart Association
Greater Charlotte Office
128 South Tryon Street,
Suite 1588
Charlotte, NC 28202
(704) 417-5751

American Heart Association
Triad Area Office
7029 Albert Pick Road, Suite 200
Greensboro, NC 27409
(336) 542-4825

American Lung Association
Charlotte Chapter
401 Hawthorne Lane, Suite 110
Charlotte, NC 28204
(980) 237-6611

American Lung Association
Raleigh Chapter
514 Daniels Street, Suite 109
Raleigh, NC 27605
(919) 792-1641

Arthritis Foundation
North Carolina Office
4530 Park Road, Suite 230
Charlotte, NC 28209
(704) 705-1808

Epilepsy Foundation of North Carolina
Piedmont One
1920 W. First Street, Suite 554-A
Winston-Salem, NC 27104
(336) 716-2320

NAMI North Carolina
National Alliance on Mental Illness
309 W. Millbrook Road, Suite 121
Raleigh, NC 27609
(919) 788-0801

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 336,000 North 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 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 NORTH CAROLINA

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

- Supported more than 259,000 jobs throughout North Carolina in 2014.
- Supported the generation of $77.6 billion in economic activity in the state.
- Resulted in more than $2.7 billion in federal taxation and $407.2 million in state taxes through jobs supported by the biopharmaceutical sector.

*For more information on the **economic impact of the biopharmaceutical industry in North Carolina**, see page 2.*

PUBLIC–PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

The following are just a few of the prominent institutions in North Carolina that biopharmaceutical research companies are collaborating with on clinical trials for new medicines.

- **Carolina BioOncology Institute,** Huntersville
- **Carolinas Medical Center,** Charlotte
- **Carolinas Pain Institute,** Winston-Salem
- **Center for Clinical Research,** Winston-Salem
- **Cumberland Research Associates,** Fayetteville
- **Duke University School of Medicine,** Durham
- East Carolina University, Greenville
- **FirstHealth Outpatient Cancer Center,** Pinehurst
- **Forsyth Medical Center,** Winston-Salem
- **High Point Clinical Trails Center,** High Point
- **LaBauer Cardiovascular Research Foundation,** Greensboro
- **Levine Cancer Institute,** Charlotte
- **Levine Cancer Institute-Concord,** Concord
- **Lucas Research,** Morehead City
- **Moses H. Cone Memorial Hospital,** Greensboro
- **Pharmaceutical Product Development LLC,** Wilmington
- **Piedmont Healthcare,** Statesville
- **Piedmont Respiratory Research Foundation,** Greensboro
- **PMG Research,** Wilmington
- **Preston Robert Tisch Brain Tumor Center at Duke University,** Durham
- **UNC Lineberger Comprehensive Cancer Center,** Chapel Hill
- **Wake Forest Baptist Health,** Winston-Salem
- **Wake Forest University Health Services,** Winston-Salem

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.

In North Carolina, of the 1,035 open clinical trials involving the biopharmaceutical research industry, **Duke University** is collaborating on more than 184 clinical trials, **East Carolina University** on more than 16, the **University of North Carolina-Chapel Hill** on more than 87, and **Wake Forest University** on more than 45 of the clinical trials.

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[1] Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase 0, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 5/1/2017. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

THE STATE OF DISEASE IN NORTH CAROLINA

More than 10 million people live in North Carolina[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in North Carolina	
Disease	**Health Statistic**
Alzheimer's Deaths, 2015[2]	3,803
Asthma Prevalence-Adults, 2015[3]	8.2 percent
Cancer New Cases, 2017[4]	56,900
Cancer Deaths, 2017[4]	20,020
Chronic Lower Respiratory Diseases, 2015[2]	5,221
Diabetes Prevalence-Adults, 2015[3]	10.7 percent
Diabetes Deaths, 2015[2]	2,743
Heart Disease Deaths, 2015[2]	18,467
HIV-Number Living with a Diagnosis, 2015[3]	28,897
Mental Illness-Adults, 2015[3]	1,429,000
Influenza / Pneumonia Deaths, 2015[2]	2,113
Stroke Deaths, 2015[2]	5,028

Source: 1. U.S. Census Bureau 2. North Carolina Center for Health Statistics 3. Kaiser Family Foundation, State Health Facts 4. American Cancer Society

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

- Children under the age of 18 make up nearly 23 percent of the population in North Carolina. Pediatric clinical trials are being conducted in the state for solid tumors, leukemia, diabetes, Duchenne muscular dystrophy, epilepsy, cystic fibrosis and hemophilia A, among others.

- North Carolinians aged 65 and older account for 15.1 percent of the states' population. In North Carolina, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, lung cancer, heart failure, macular degeneration, epilepsy and osteoarthritis.

- Women and girls make up 51.3 percent of the population in North Carolina. Clinical trials are recruiting women for studies on medicines for cervical cancer, ovarian cancer, vaginal infections and postpartum depression, among others.

Clinical Trials in North Carolina for Special Populations

Population	Number of Trials
Children (birth–17)	170
Seniors (66 and older)	857
Women (only)	48

Source: www.clinicaltrials.gov. Search criteria: North Carolina, United States; Phase 0, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 5/1/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

SCIENCE AND CLINICAL TRIALS

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

- A monoclonal antibody for the treatment of **idiopathic pulmonary fibrosis** is being studied in a clinical trial in Greensboro.

- 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 the University of North Carolina at Chapel Hill.

- 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 Duke University Medical Center in Durham.

- A monoclonal antibody for **rheumatoid arthritis** that may block the inflammatory process is being studied in a clinical trial in Wilmington.

- A novel targeted therapy that combines recombinant interleukin-3 with truncated diphtheria toxin is in development for **acute myeloid leukemia** and **blastic plasmacytoid dendritic cell neoplasm**, a rare hematological disorder with high unmet medical need and no standard treatment in clinical trials at Duke University Medical Center in Durham.

- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied to treat **melanoma** in Durham.

- 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 antibody is being studied in clinical trials in Durham, Greensboro and Raleigh.

- A medicine in development for **Huntington's disease** targets the PDE10A enzyme, which is present in the neurons most damaged in Huntington's and was studied in a clinical trial at Wake Forest Baptist Medical Center in Winston-Salem.

- 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 at the University of North Carolina in Chapel Hill and NC Heart and Vascular Research in Raleigh.

- 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. It is in a clinical trial in Durham.

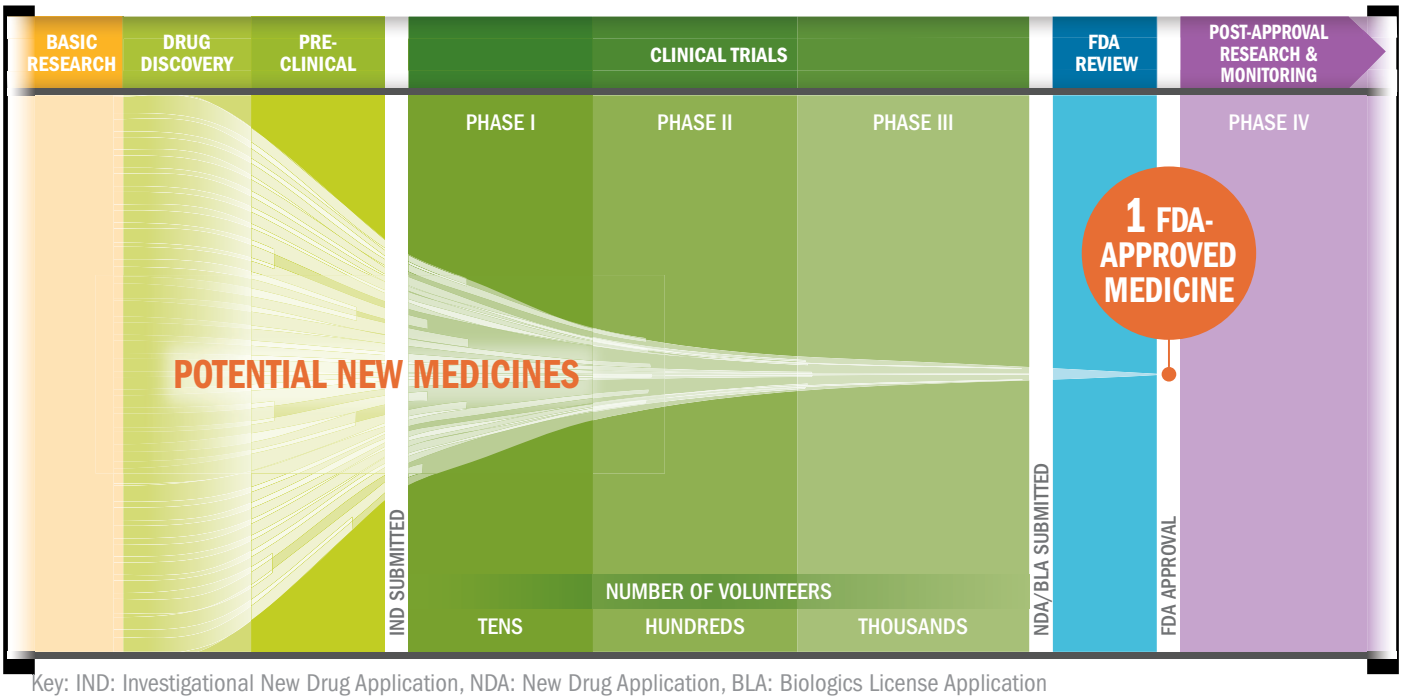
- **Acute coronary syndrome** (ACS) refers to cardiovascular events, including heart attack, where there is an abrupt reduction of blood flow to the heart through the coronary arteries. An anti-inflammatory medicine in development for the syndrome inhibits the activity of p38 mitogen activated protein (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 Chapel Hill, Charlotte, Greensboro and Raleigh.

- A monoclonal antibody in development for **osteoporosis** bind to and inhibit 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. The antibody was studied in a clinical trial in Asheville.

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 North 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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