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Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

SOUTHEASTERN NORTH CAROLINA

PhRMA

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Executive

Dots show locations of clinical trials in Southeastern North Carolina

Summary

Clinical trials in SOUTHEASTERN NORTH CAROLINA

ABOUT CLINICAL TRIALS

- In the development of new medicines, clinical trials are conducted to prove therapeutic safety and effectiveness and compile the evidence needed for the Food and Drug Administration (FDA) to approve treatments.
- Clinical tests of new drugs are conducted in three phases and account for an average of seven of the 10 to 15 years it takes to bring a new drug from development to patients.
- Clinical trials for a given drug or treatment involve thousands of volunteer patient participants, and the generation of tens of thousands of pages of technical and scientific data.
- Clinical trials are responsible for about half of the $1.2 billion average cost of developing one new cutting-edge biotechnology medicine.
- For patients, the trials offer another potential 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 trials are also conducted to compare existing treatments while others are done to learn if a drug is appropriate for a particular patient population, such as children. Still others are conducted to find ways to make existing approved drugs more effective and easier to use with fewer side effects.
- All clinical trials must be reviewed and approved by an Institutional Review Board (IRB), an independent committee of physicians, statisticians, local community advocates and others to ensure a trial is ethically conducted and patient rights are protected.
- Clinical trial progress reports must be submitted at least annually to the FDA and IRB.
- All facilities that conduct or support biomedical research involving patients must comply with federal regulations and have an IRB.
- Earlier this year, PhRMA and the National Minority Quality Forum launched **I'm In**, a national campaign to raise awareness about

Executive Summary (cont.)

"Along with food processing, defense, advanced textile development, building products, aviation and seafood, our region's industry clusters include local research institutions that have conducted hundreds of clinical trials of new medicines in collaboration with the nation's biopharmaceutical companies. The Southeast North Carolina region has a strong biomedical research infrastructure, and that has led to biopharmaceutical companies conducting about 500 clinical trials with our local research institutions over the last 15 years. The companies and their collaborators have targeted disease wisely, with 203 of the trials aimed at the six most debilitating chronic diseases—cancer, diabetes, heart disease, stroke, asthma and mental illnesses."

Randall Johnson
Executive Director, Southeastern Office of the North Carolina Biotechnology Center

and encourage greater diversity in clinical trials through strategic outreach and partnerships. Increased diversity in clinical trials can help ensure that the process used to test safety and effectiveness of potential new medicines accurately reflects patient populations that will take the medications if they are approved.

- Inclusion of individuals of varied races, ethnicities, ages, gender and sexual orientation in clinical trials can help to prevent disparities in the evaluation of potential new medicines. However, groups including African Americans, Asian Americans and Hispanics are significantly underrepresented in clinical studies. For example, Hispanics make up 16 percent of the U.S. population, but only 1 percent of all clinical trial volunteers and African Americans are 12 percent of the population, but only 5 percent of clinical research participants.

- Research shows biological differences can influence how people process their medicines. For example, differences in genetic coding can make cancer treatments, antidepressants and blood pressure medications less effective in some races and ethnicities.

- **I'm In** will support the build-up of the National Minority Quality Forum's Clinical Trial Engagement Network, which allows patients to connect to clinical trials while giving industry, physicians, researchers and academic institutions access to key data. This information identifies different populations by disease status and validates where recruitment efforts should occur.

CLINICAL TRIALS IN SOUTHEASTERN NORTH CAROLINA

- Biopharmaceutical research companies are conducting or have conducted nearly 500 clinical trials of new medicines in Southeastern North Carolina since 1999 in collaboration with clinical research centers and hospitals. Southeastern North Carolina consists of nine counties, including: Bladen, Brunswick, Columbus, Cumberland, New Hanover, Onslow, Pender, Robeson and Sampson.

- Of the nearly 500 clinical trials, 203 have targeted the nation's six most debilitating chronic diseases—**asthma, cancer, diabetes, heart disease, mental illness** and **stroke**.

Clinical Trials in Southeastern North Carolina since 1999—Completed and Active	
All Clinical Trials	**Six Major Chronic Diseases**
497	203

Source: www.clinicaltrials.gov Note: Search criteria - Southeastern North Carolina cities; North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 4/7/2014.

ECONOMIC BENEFITS OF CLINICAL TRIALS IN NORTH CAROLINA

- Biopharmaceutical research companies have been a source of jobs, tax revenue and research spending in North Carolina, including Southeastern North Carolina.
- A study by Battelle Technology Partnership Practice found that in 2011 the industry supported more than 226,000 jobs throughout the state, some of them in Southeastern North Carolina.
- Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in about $787 million in federal taxation and $137 million in state taxes.
- Biopharmaceutical research companies supported the generation of $50.3 billion in economic activity in the state two years ago, 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 sciences 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.
- According to the U.S. Bureau for Labor Statistics, there are 3,950 life science jobs in Southeast North Carolina, up 24.4 percent since 2006.
- In Southeastern North Carolina, Pharmaceutical Product Development, LLC (PPD)—with its global headquarters in Wilmington—is one of the largest contract research organizations (CROs) in the world, collaborating with biopharmaceutical industry clients to deliver life-changing medicines to patients in need more efficiently and with the highest possible quality. With more than 13,000 employees globally and offices in 46 countries, PPD leverages its Wilmington headquarters, which

"Though I recognize the positive impact clinical research has on our economy, I am focused more on patients. And it's important biopharmaceutical companies alone have conducted 500 trials in Southeast North Carolina, with more to come, giving chronic disease sufferers and others who want to participate in trials ample opportunities. For some patients, a trial of a new medicine can be a good therapeutic alternative to discuss with health care providers and clinicians conducting trials. Patients participating in clinical research take an active role in managing their health care, and are contributing to scientific knowledge that could ultimately help treat many other patients."

Kay Castillo
Director of Advocacy, Policy, and Legislation, National Association of Social Workers of North Carolina

employs approximately 1,600 professionals, to conduct clinical trials on a global scale. The resulting medical advances have positively impacted untold numbers of North Carolina residents, including in Wilmington and across southeastern North Carolina. PPD believes it is our responsibility as a good corporate citizen to help strengthen the communities where we live and work. PPD encourages employees and leaders to play active roles in their communities through charitable giving and volunteerism.

CLINICAL TRIALS AND CHRONIC DISEASES

- Chronic diseases pose the greatest threats to our nation's health and our ability to treat and prevent medical conditions.
- According to the U.S. Centers for Disease Control and Prevention (CDC), today, in the United States:
  - > Patients with chronic diseases account for **75 cents of every dollar** spent on health care.
  - > Chronic diseases are the **leading cause of death and disability**.

Clinical Trials in Southeastern North Carolina

Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Calabash	—	—	1	1	—	1
Fayetteville	—	1	—	—	—	—
Hope Mills	—	—	—	—	1	—
Whiteville	—	—	3	—	—	—
Wilmington	3	1	8	2	2	2

Source: www.clinicaltrials.gov Note: Search criteria – Southeastern North Carolina cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 4/7/2014. See Appendix for detailed information about these clinical trials. Disease columns will not match totals in the Appendix because some clinical trials are recruiting in more than one city.

  - > Chronic diseases are a **leading driver of rising health care costs** with expenses totaling billions of dollars every year.

- Biopharmaceutical research companies are developing new medicines to help treat those conditions that are taking an unprecedented toll on American lives, and many of these medicines are being tested today in clinical trials in Southeastern North Carolina.
- Since 1999, biopharmaceutical research companies are sponsoring or have sponsored 203 clinical trials of potential new medicines in Southeastern North Carolina alone for **asthma, cancer, heart disease, stroke, diabetes** and **mental illness**. Of these trials, 25 are either not yet recruiting or are just now seeking patients.
- Biopharmaceutical companies are collaborating on the tests with such prominent institutions as **PPD** and **PMG Research** in Wilmington, and **Inquest Clinical Group** in Hope Mills.
- Some of the medicines being clinically tested in Southeastern North Carolina are new-generation biotechnology treatments.

Clinical Trials for Top Chronic Diseases in Southeastern North Carolina

Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	6	3
Cancer	53	2
Diabetes	89	11
Heart Disease	22	3
Mental Illness	24	3
Stroke	9	3
Total	203	25

Source: www.clinicaltrials.gov Note: Search criteria – Southeastern North Carolina cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 4/7 2014. Some clinical trials appear in more than one disease category.

Clinical Trials in Southeastern North Carolina

Clinical tests of new medicines are a vitally important part of the drug development and approval process—they account for about half of the $1.2 billion average cost of developing a new drug and are conducted to determine the safety and effectiveness of that treatment in patients.

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

It's essential that trials be conducted properly so that clinicians and drug reviewers can develop accurate assessments of the efficacy and safety of medicines when used by patients. The FDA is a vigilant regulatory agency and its pharmaceutical review officers are effective in detecting flawed information.

Questionable or confusing data can lead to lengthy delays in product approval or outright FDA rejection of a new drug. Biopharmaceutical research companies are looking for the best physicians and research institutions to help design and conduct their clinical trials to determine whether a medicine is safe and effective. Side effects must be carefully documented and a determination made as to whether they occur too often and are dangerous.

Clinical tests involve three phases, thousands of volunteer patients, and are often conducted at multiple sites around the country. In Southeastern North Carolina, biopharmaceutical companies are providing funds to have trials conducted at the region's well-respected hospitals and clinical research organizations.

ASTHMA is a debilitating condition for more than 25 million Americans, including 7.1 million children under the age of 18, according to the American Lung Association. In North Carolina, 901,000 adults and 383,000 children have been diagnosed with asthma, according to the State Center for Health Statistics (NCSCHS). In 2009, nine counties in Southeastern North Carolina were responsible for 14.6 percent of all emergency room visits due to asthma in North Carolina.

Currently, three clinical trials of new asthma medicines are recruiting patients in Southeastern North Carolina. The trials are being conducted in **Wilmington**.

CANCER, the second leading cause of death in the United States, now afflicts nearly 14 million Americans, according to the National Cancer Institute. In North Carolina, more than 52,000 new cancer cases will be diagnosed this year and 18,980 victims in the state will die, according to the American Cancer

Society. Southeastern North Carolina accounts for about 11 percent of new cancer cases and cancer deaths in North Carolina, according to NCSCHS.

Currently, two clinical trials of new cancer medicines are recruiting patients in Southeastern North Carolina. Biopharmaceutical companies are collaborating on the tests with institutions at locations in **Wilmington**.

DIABETES affects more than 25 million Americans—8.3 percent of the U.S. population—including 7 million people who are unaware they have the disease, according to the current National Diabetes Fact Sheet. In North Carolina, 9.8 percent of the population has been diagnosed with diabetes, according to the U.S. Centers for Disease Control and Prevention (CDC). In 2012, Southeastern North Carolina counties accounted for 15.5 percent of diabetes deaths in North Carolina, according to NCSCHS.

Currently, 11 diabetes clinical tests are seeking patients in Southeastern North Carolina. The trials are being conducted at **PMG Research** in Wilmington and at sites in **Calabash** and **Whiteville**.

HEART DISEASE AND STROKE are the first and fourth leading disease causes of death in the United States and in North Carolina. According to the American Heart Association, more than 83 million Americans are affected by these diseases. In 2012, more than 21,000 residents of North Carolina died from these diseases and more than 2,500 of them were from Southeastern North Carolina, according to NCSCHS.

Currently, three heart disease and three stroke clinical tests are seeking patients in Southeastern North Carolina. The trials are being conducted at sites in **Calabash** and **Wilmington**.

MENTAL ILLNESS affects about 61.5 million Americans who suffer from some form of the disease—from anxiety to depression to addiction to Alzheimer's disease. In North Carolina, about 335,000 adults and 99,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness. In 2012, 408 residents from Southeastern North Carolina died from suicide and Alzheimer's disease, according to NCSCHS.

Currently, three clinical trials for mental health conditions are recruiting patients in Southeastern North Carolina. The trials are being conducted at **Inquest Clinical Group/Global Research Associates** in Hope Mills and at **PMG Research** in Wilmington.

*Physicians and patients can find out about clinical trials being conducted all over the state in collaboration with local institutions by accessing **www.clinicaltrials.gov**, a database sponsored by the National Institutes of Health. Information on clinical trials and medicines in development is also available on **www.phrma.org/innovation/research-in-your-backyard**, the website of the Pharmaceutical Research and Manufacturers of America (PhRMA).*

What is the Clinical Trial Experience?

Clinical trials are research studies that 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 healthcare by helping researchers test new treatments. In Southeastern North Carolina alone, 203 clinical trials have targeted chronic conditions like asthma, cancer, diabetes, heart disease, mental illness and stroke.

PHASES OF CLINICAL TRIALS

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

PHASE I—This phase is designed to test the safety of a new medicine. Researchers test the drug on a small group of people (20-80) and evaluate safety aspects of the drug, such as safe dosage range, the best way of administering the treatment (pill form vs. a shot, for example) and identifying what, if any, side effects there may be.

PHASE II—This phase is designed to test effectiveness and safety. The treatment is given to 100 to 300 people to assess efficacy and try to identify less common side effects, which may appear when more people are tested. This phase is usually placebo-controlled and double-blinded—neither patients nor doctors know if the patient is getting placebo or the medicine.

PHASE III—This phase is designed to confirm effectiveness and safety, monitor side effects and compare the unapproved drug being tested to commonly used medications from the market to determine which is more effective. A large group (1,000-3,000) receives this treatment, and like Phase II, it is usually placebo-controlled and double-blinded.

LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials several ways. Healthcare providers are aware of clinical trials being conducted at hospitals, universities and other leading healthcare 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. More information about clinical trials in Southeastern North Carolina and how to volunteer for one can be found at *http://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 healthcare 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.

New Generation Medicines in Development

Some of the medicines that have been tested in Southeastern North Carolina are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of new medicines and vaccines today. And Southeastern North Carolina is one place where this research and development work is being done.

Through biotechnology, new ways are being developed to not only more effectively treat disease, but also to predict and even prevent it.

Biotechnology medicines are developed through biological processes using living cells or organisms, rather than traditional chemical synthesis, the mainstay of pharmaceutical development for decades.

Such novel treatments use a variety of new approaches to treat disease. For example, a monoclonal antibody is a laboratory-made version of the naturally occurring immune system protein that binds to and neutralizes foreign invaders. Interferons are proteins that interfere with the ability of a cell to reproduce.

Antisense drugs, meanwhile, are medicines that interfere with the communication process that tells a cell to produce an unwanted protein. In addition, nanotechnology is being used in biotechnology research to provide drug-delivery systems, new treatments and diagnostics.

Some of the medicines in clinical testing in Southeastern North Carolina feature these technologies.

For example:

- A monoclonal antibody in the pipeline that targets lupus is being studied in **Wilmington**.
- An engineered human antibody to reduce inflammation in psoriasis is in clinical trials in **Wilmington**.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process is in clinical trials in **Wilmington**.

The biotechnology medicines and vaccines that are being developed today are helping to expand the frontiers of science and that could lead to more and better treatments for patients. In Southeastern North Carolina, as in other locations, this innovation is the result of a successful collaboration of biopharmaceutical companies and local research institutions.

I'm In – Encouraging Greater Diversity in Clinical Trials

PhRMA and the National Minority Quality Forum have teamed up to launch **I'm In**, a campaign to raise awareness of clinical trials, and encourage greater diversity in clinical research, through strategic outreach and partnerships.

I'm In will support the build up of the National Minority Quality Forum's Clinical Trial Engagement Network, which will accelerate the inclusion of underrepresented patient populations in trials by utilizing zip code-level mapping of disease clusters, points of care, clinical research sites and community resources.

THE ISSUE

Clinical trials are used to evaluate safety and effectiveness of medicines by monitoring their effects in patients who volunteer to participate in the research. The process should accurately reflect the patient populations that will take the medications if they are approved.

Ethnically and racially diverse groups are currently underrepresented in clinical research. For example, despite comprising 12 percent of the U.S. population, African Americans make up only 5 percent of clinical trial participants. Hispanics represent 16 percent of the population, but only 1 percent of clinical trial participation.

WHY IT MATTERS

Research has demonstrated that biological differences can influence how people process medicines. For example, differences in genetic coding can make cancer treatments, antidepressants and blood pressure medications less effective in some races and ethnicities.

According to the Food and Drug Administration, increased diversity in clinical trials could help researchers find better ways to fight diseases that disproportionately impact certain populations, and may be important for the safe and effective use of new treatments. Here are some examples of patient populations that are underrepresented in clinical research:

- African American men are twice as likely to die from prostate cancer as Caucasians, but represent only four percent of prostate cancer clinical trial participants.
- Suicide is one of the top three causes of death for Asian American women ages 15-45, but only two percent of trial participants targeting major depression have been Asian American.
- Mexican Americans and Puerto Ricans have more than double the prevalence of diabetes than Caucasians, but represented only four percent of participation in trials targeting the disease from 1998-2001.

Participation in a clinical trial not only could benefit the patient, it may also benefit future patients by helping researchers develop medical innovations that are effective in various ethnic and racial groups. The development of these treatments is not possible without the patients who volunteer to participate in clinical research.

Conclusion

Biopharmaceutical research companies' close collaboration with clinicians and research institutions in Southeastern North Carolina benefits patients, the local economy, and the advancement of science and patient care. Clinical trials provide stimulating biopharmaceutical research work and a reliable source of revenue for hospitals and local contract research organizations, and the medicines being tested are sometimes cutting-edge cell and protein treatments with the potential to be safer and more effective than older chemical compound drugs.

What's more, patients in Southeastern North Carolina considering participation in clinical trials have a wide range of choices, including 25 tests of new medicines for the six most debilitating chronic diseases.

THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

It takes 10-15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

	Discovery/ Preclinical Testing		Clinical Trials				FDA	Phase IV
			Phase I	Phase II	Phase III			
Years	**6.5**		**1.5**	**2**	**3.5**		**1.5**	
Test Population	Laboratory and animal studies	File IND at FDA	20 to 80 healthy volunteers	100 to 300 patient volunteers	1,000 to 3,000 patient volunteers	File NDA/BLA at FDA	Review process/ approval	Additional post-marketing testing required by FDA
Purpose	Assess safety, biological activity and formulations		Determine safety and dosage	Evaluate effective-ness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use			
Success Rate	5,000 compounds evaluated			5 enter trials			1 approved	

THE DRUG DEVELOPMENT AND APPROVAL PROCESS

The U.S. system of new drug approvals is perhaps the most rigorous in the world.

It takes 10-15 years, on average, for an experimental drug to travel from lab to U.S. patients, according to the Tufts Center for the Study of Drug Development. Only five in 5,000 compounds that enter preclinical testing make it to human testing. And only one of those five is approved for sale.

On average, it costs a company $1.2 billion, including the cost of failures, to get one new medicine from the laboratory to U.S. patients, according to a 2007 study by the Tufts Center for the Study of Drug Development.

Once a new compound has been identified in the laboratory, medicines are usually developed as follows:

Preclinical Testing. A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety.

Investigational New Drug Application (IND). After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. All clinical trials must be reviewed and approved by the Institutional Review Board (IRB) where the trials will be conducted. Progress reports on clinical trials must be submitted at least annually to FDA and the IRB.

Clinical Trials, Phase I—Researchers test the drug in a small group of people, usually between 20 and 80 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Clinical Trials, Phase II—The drug is given to volunteer patients, usually between 100 and 300, to see if it is effective, identify an optimal dose, and further evaluate its short-term safety.

Clinical Trials, Phase III—The drug is given to a larger, more diverse patient population, often involving between 1,000 and 3,000 patients (but sometime 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.

New Drug Application (NDA)/Biologic License Application (BLA). Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more.

Approval. Once FDA approves an NDA or BLA, the new medicine becomes available for physicians to prescribe. A company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional trials (Phase IV) to evaluate long-term effects.

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. PhRMA member companies invested an estimated $51.1 billion in research and development in 2013.

The Good News — Many Clinical Trials are Still Recruiting

There are 25 clinical trials of new chronic disease drugs recruiting patients in Southeastern North Carolina. These trials target the most debilitating chronic conditions—cancer, heart disease, stroke, asthma, diabetes and mental illness.

Clinical Trials in Southeastern North Carolina

Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Calabash	—	—	1	1	—	1
Fayetteville	—	1	—	—	—	—
Hope Mills	—	—	—	—	1	—
Whiteville	—	—	3	—	—	—
Wilmington	3	1	8	2	2	2

Source: www.clinicaltrials.gov Note: Search criteria – Southeastern North Carolina cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 4/7/2014. See Appendix for detailed information about these clinical trials. Disease columns will not match totals in the Appendix because some clinical trials are recruiting in more than one city.

LEADING INSTITUTIONS CONDUCTING/CONDUCTED CLINICAL TRIALS

- **Cape Fear Valley Cancer Center,** Fayetteville
- **Highlands Oncology Group,** Fayetteville
- **Inquest Clinical Group/Global Research Associates,** Hope Mills
- **Pharmaceutical Product Development LLC (PPD),** Wilmington
- **PMG Research of Wilmington,** Wilmington

Appendix

The clinical trials listed here involve tests that have not yet started recruiting patients or are just now seeking volunteers to participate. This information is potentially valuable to patients still seeking effective treatments for their chronic diseases. These trials provide a new therapeutic option to discuss with physicians.

Those interested in obtaining more information about certain trials can use the URL code listed for each test to log onto *www.clinicaltrials.gov*, the clinical tests database of the National Institutes of Health.

ASTHMA

(3 CLINICAL TRIALS RECRUITING)

STUDY 1:

Efficacy and Safety Study of Benralizumab Added to Medium-dose Inhaled Corticosteroid Plus LABA in Patients With Uncontrolled Asthma

http://ClinicalTrials.gov/show/NCT01947946

STUDY 2:

Efficacy and Safety Study of Benralizumab Added to High-dose Inhaled Corticosteroid Plus LABA in Patients With Uncontrolled Asthma

http://ClinicalTrials.gov/show/NCT01914757

STUDY 3:

A Study of Lebrikizumab in Patients With Uncontrolled Asthma Who Are on Inhaled Corticosteroids and a Second Controller Medication

http://ClinicalTrials.gov/show/NCT01867125

CANCER

(2 CLINICAL TRIALS RECRUITING)

STUDY 1:

TRINOVA-3: A Study of AMG 386 or AMG 386 Placebo in Combination With Paclitaxel and Carboplatin to Treat Ovarian Cancer

http://ClinicalTrials.gov/show/NCT01493505

STUDY 2:

Video Impact on Neulasta Education

http://ClinicalTrials.gov/show/NCT01752907

DIABETES

(11 CLINICAL TRIALS RECRUITING)

STUDY 1:

A Trial Comparing Cardiovascular Safety of Insulin Degludec Versus Insulin Glargine in Subjects With Type 2 Diabetes at High Risk of Cardiovascular Events

http://ClinicalTrials.gov/show/NCT01959529

STUDY 2:

Efficacy and Safety of Semaglutide Once-weekly Versus Placebo in Drug-naïve Subjects With Type 2 Diabetes

http://ClinicalTrials.gov/show/NCT02054897

STUDY 3:

Efficacy and Safety of Semaglutide Once-weekly Versus Exenatide ER 2.0 mg Once-weekly as add-on to 1-2 Oral Antidiabetic Drugs (OADs) in Subjects With Type 2 Diabetes

http://ClinicalTrials.gov/show/NCT01885208

STUDY 4:

Efficacy and Safety of FIAsp Compared to Insulin Aspart in Combination With Insulin Glargine and Metformin in Adults With Type 2 Diabetes

http://ClinicalTrials.gov/show/NCT01819129

STUDY 5:

A Trial Comparing the Efficacy and Safety of Insulin Degludec/Liraglutide Versus Insulin Glargine in Subjects With Type 2 Diabetes Mellitus

http://ClinicalTrials.gov/show/NCT01952145

STUDY 6:

Addition of MK-3102 to Participants With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Combination Therapy With Glimepiride and Metformin (MK-3102-022 AM4)

http://ClinicalTrials.gov/show/NCT01704261

STUDY 7:

Efficacy and Safety of the Insulin Glargine/ Lixisenatide Fixed Ratio Combination Versus Insulin Glargine in Patients With Type 2 Diabetes

http://ClinicalTrials.gov/show/NCT02058160

STUDY 8:

Efficacy and Safety of Insulin Glargine/ Lixisenatide Fixed Ratio Combination Compared to Insulin Glargine Alone and Lixisenatide Alone on Top of Metformin in Patients With T2DM

http://ClinicalTrials.gov/show/NCT02058147

STUDY 9:

Phase III Study to Evaluate Efficacy and Safety of DSC127 in Diabetic Foot Ulcers

http://ClinicalTrials.gov/show/NCT01830348

STUDY 10:

Study Of Diabetic Nephropathy With Atrasentan

http://ClinicalTrials.gov/show/NCT01858532

STUDY 11:

Open-Label Study in Diabetic Foot Ulcers (DFU), to Evaluate Safety of 0.03% DSC127 Topical Gel in Chronic Use

http://ClinicalTrials.gov/show/NCT01840085

HEART DISEASE

(3 CLINICAL TRIALS RECRUITING)

STUDY 1:

Cardiovascular Risk Reduction Study (Reduction in Recurrent Major CV Disease Events)

http://ClinicalTrials.gov/show/NCT01327846

STUDY 2:

ODYSSEY Outcomes: Evaluation of Cardiovascular Outcomes After an Acute Coronary Syndrome During Treatment With Alirocumab SAR236553 (REGN727)

http://ClinicalTrials.gov/show/NCT01663402

STUDY 3:

Cardiovascular Safety of Febuxostat and Allopurinol in Patients With Gout and Cardiovascular Comorbidities

http://ClinicalTrials.gov/show/NCT01101035

MENTAL ILLNESS

(3 CLINICAL TRIALS RECRUITING)

STUDY 1:

A Study of Mifepristone vs. Placebo in the Treatment of Patients With Major Depression With Psychotic Features

http://ClinicalTrials.gov/show/NCT00637494

STUDY 2:

Safety and Efficacy Study of IPX159 in Restless Legs Syndrome (RLS)

http://ClinicalTrials.gov/show/NCT01521663

STUDY 3:

Efficacy and Safety Study of ELND005 as a Treatment for Agitation and Aggression in Alzheimer's Disease

http://ClinicalTrials.gov/show/NCT01735630

STROKE

(3 CLINICAL TRIALS RECRUITING)

STUDY 1:

Cardiovascular Risk Reduction Study (Reduction in Recurrent Major CV Disease Events)

http://ClinicalTrials.gov/show/NCT01327846

STUDY 2:

Cardiovascular Safety of Febuxostat and Allopurinol in Patients With Gout and Cardiovascular Comorbidities

http://ClinicalTrials.gov/show/NCT01101035

STUDY 3:

The Evaluation Of PF-04950615 (RN316), In Reducing The Occurrence Of Major Cardiovascular Events In High Risk Subjects

http://ClinicalTrials.gov/show/NCT01975376

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