

Research in Your Backyard

Developing Cures, Creating Jobs



**PHARMACEUTICAL
CLINICAL TRIALS IN THE
PIEDMONT TRIAD REGION**

Dots show locations of clinical trials in the region.

Executive Summary

Clinical Trials in the Piedmont Triad

- Biopharmaceutical research companies are conducting or have conducted more than 2,000 clinical trials of new medicines in the Piedmont Triad in collaboration with Wake Forest University School of Medicine, clinical research centers and hospitals (1999 to present). The Piedmont Triad consists of 12 North Carolina counties, including: Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Montgomery, Randolph, Rockingham, Stokes, Surry and Yadkin.
- Of the more than 2,000 clinical trials, 902 have targeted the nation's six most debilitating chronic diseases—**asthma, cancer, diabetes, heart disease, mental illnesses and stroke.**

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 the Piedmont Triad.
- 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 the Piedmont Triad.
- 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.

“The fact that we have top-notch university medical schools, hospitals and specialty treatment centers in the 12-county Piedmont Triad has made our region a center of clinical research. And that distinction should cause more than a few ripples of excitement, considering the resulting benefits to patients and the regional economy. Since 1999, institutions like Wake Forest University and Forsyth Medical Center in Winston-Salem, Alamance Regional Cancer Center in Burlington and Moses H. Cone Regional Cancer Center in Greensboro have conducted 2,007 clinical trials of potential new medicines. Over 900 of those trials have targeted our most devastating chronic diseases—heart disease, stroke, cancer, diabetes, mental illnesses and asthma.”

— Dr. Johnny L. Williams, MD
President, Old North State Medical Society

- 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

“It is gratifying that biopharmaceutical companies and local research institutions have included mental illnesses as a target in their clinical trials of new therapies in the Piedmont Triad. Over 100 trials just in the Piedmont region alone have been aimed at mental health conditions and that gives many of our patients renewed hope that effective new medications are being developed. There is an acute need for improved treatment throughout North Carolina and in the Piedmont Triad. Statewide, about 335,000 adults and almost 100,000 children live with serious mental illnesses and in the Triad area, 743 residents died from suicide and Alzheimer’s disease in 2012. We urge pharmaceutical sector researchers in our state to continue their efforts to develop new medicines.”

— Sally Cameron
Executive Director, NC Psychological Association

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.

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.

Clinical Trials in Piedmont Triad since 1999—Completed and Active

All Clinical Trials	Six Major Chronic Diseases
2,007	902

Source: www.clinicaltrials.gov
Note: Search criteria = Piedmont Triad cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 2/15/2014.

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**.

> 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 the Piedmont Triad.
- Since 1999, biopharmaceutical research companies are sponsoring or have sponsored 902 clinical trials of potential new medicines in the Piedmont Triad alone for **asthma, cancer, heart disease,**

Clinical Trials in the Piedmont Triad						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Asheboro	—	2	5	2	—	2
Burlington	—	4	4	1	—	1
Greensboro	1	11	7	4	1	4
High Point	3	4	1	3	—	2
Lexington	—	—	1	—	—	—
Winston-Salem	9	37	12	12	7	9

Source: www.clinicaltrials.gov

Note: Search criteria = Piedmont Triad cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 2/15/2014. 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.**

stroke, diabetes and mental illnesses. Of these trials, 117 are either not yet recruiting or are just now seeking patients. The 117 trials are being conducted at 158 sites in the Piedmont Triad.

- Biopharmaceutical companies are collaborating on the tests with such prominent institutions as Wake Forest University and Forsyth Medical Center in Winston-Salem, Alamance Regional Cancer Center in Burlington and the Moses H. Cone Regional Cancer Center in Greensboro.
- Some of the medicines being clinically tested in the Piedmont Triad are new-generation biotechnology treatments.

“Much of the clinical research conducted in and around Winston-Salem in recent years has involved the development of cutting-edge treatments. Many of these are listed in the new Research in Your Backyard report. Here at Targacept, we are hard at work on treatments for overactive bladder, Alzheimer’s disease and diabetic gastroparesis. Our overactive bladder treatment has completed recruitment into a Phase II clinical trial. We are collaborating with Wake Forest University in connection with our gastroparesis project, which has already been evaluated for safety in earlier trials associated with other indications. Our work at Targacept, and the important work in our region, reflects a nationwide trend: biopharmaceutical companies are using biotechnology to develop hundreds of new medicines and vaccines as we seek to improve our treatment of disease and ability to predict and prevent it.”

— Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S.
President and Chief Executive Officer, Targacept

Clinical Trials in the Piedmont Triad

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.

Clinical Trials for Top Chronic Diseases in the Piedmont Triad

Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	57	10
Cancer	359	53
Diabetes	220	22
Heart Disease	114	14
Mental Illness	112	7
Stroke	40	11
Total	902	117

Source: www.clinicaltrials.gov

Note: Search criteria = Piedmont Triad cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 2/15/2014. **Some clinical trials appear in more than one disease category.**

In the Piedmont Triad, biopharmaceutical companies are providing funds to have trials conducted at the city's well-respected medical school, hospitals and clinical research organizations. According to *U.S. News and World Report*, **Wake Forest University School of Medicine** ranked 46th among last year's top 100 research-oriented medical schools in the United States.

Asthma is a debilitating condition for more than 25 million Americans, including 7.1 million children under the age of 18. 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, the 12 Piedmont Triad counties were responsible for 15.8 percent of all emergency room visits due to asthma in North Carolina.

Currently, 10 clinical trials of new asthma medicines are recruiting patients in the Piedmont Triad. Trials are being conducted in **Greensboro, High Point,** and at **Wake Forest University School of Medicine** in Winston-Salem.

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 19,980 victims in the state will die, according to the American Cancer Society. Piedmont Triad accounts for about 19 percent of new cancer cases and cancer deaths in North Carolina, according to NCSCHS.

Currently, 53 clinical trials of new cancer medicines are recruiting patients in the Triad region. Biopharmaceutical companies are collaborating on the tests with such prominent institutions as the **Moses H. Cone Regional Cancer Center** in Greensboro, the **Alamance Regional Cancer Center** in Burlington and the **Wake Forest University Comprehensive Cancer Center** in Winston-Salem.

Diabetes affects more than 25 million Americans—more than 8 percent of the U.S. population—including 7 million people who are unaware they have the disease. 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, Piedmont Triad counties accounted for nearly 17 percent of diabetes deaths in North Carolina, according to NCSCHS.

Currently, 22 diabetes clinical tests are seeking patients in the Piedmont Triad. The trials are being conducted

at **Triad Clinical Trials** in Greensboro, and **Clinical Research of Winston-Salem and Guilford Neurologic Associates** in Winston-Salem.

Heart disease and stroke are the first and fourth leading disease causes of death in the United States and the second and fourth in Forsyth County. 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 nearly 4,000 of them were from the Piedmont Triad, according to NCSCHS.

Currently, 14 heart disease and 11 stroke clinical tests are seeking patients in the Piedmont Triad. The trials are being conducted at the **LaBauer Cardiovascular Research Foundation** in Greensboro and **Forsyth Medical Center** and **Wake Forest Baptist Medical Center** in Winston-Salem.

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, 743 residents from the Piedmont Triad died from suicide and Alzheimer’s disease, according to NCSCHS.

Currently, seven clinical trials for mental health conditions are recruiting patients in the Piedmont Triad. Among the trials, a smoking cessation trial is being conducted at the **Duke Center for Smoking Cessation-Winston-Salem Office**.

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 the Piedmont Triad alone, 902 clinical trials have targeted chronic conditions like asthma/allergy, 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. Wake Forest University School of Medicine lists clinical trials taking place at their facilities on their website, www.wakehealth.edu/BeInvolved. More information about clinical trials in the Piedmont Triad 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 the Piedmont Triad are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of new medicines and vaccines today. And the Piedmont Triad 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 the Piedmont Triad feature these technologies. For example:

- A genetically-modified virus-based vaccine to treat melanoma is being studied at **Wake Forest University School of Medicine** in Winston-Salem.
- A recombinant fusion protein to treat diabetic macular edema is being studied at the **Wake Forest University Eye Center** in Winston-Salem.
- A therapeutic vaccine designed to jump-start the immune system to fight disease is in development for melanoma in **Winston-Salem**.
- An engineered human antibody to reduce inflammation in psoriasis and psoriatic arthritis is in clinical trials in **Greensboro, High Point** and **Winston-Salem**.

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 the Piedmont Triad, as in other locations, this innovation is the result of a successful collaboration of biopharmaceutical companies and local research institutions.

Conclusion

Biopharmaceutical research companies' close collaboration with clinicians and research institutions in the Piedmont Triad 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 the Wake Forest School of Medicine, hospitals and local contract research organizations, and the medicines be-

ing 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 the Piedmont Triad considering participation in clinical trials have a wide range of choices, including 117 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.

Clinical Trials						
	Discovery/ Preclinical Testing	Phase I	Phase II	Phase III	FDA	Phase IV
Years	6.5	1.5	2	3.5	1.5	
Test Population	Laboratory and animal studies	20 to 80 healthy volunteers	100 to 300 patient volunteers	1,000 to 3,000 patient volunteers	Review process/ approval	Additional post-marketing testing required by FDA
Purpose	Assess safety, biological activity and formulations	Determine safety and dosage	Evaluate effectiveness, 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 \$48.5 billion in research and development in 2012.

The Good News— Many Clinical Trials are Still Recruiting

There are 117 clinical trials of new chronic disease drugs recruiting patients in the Piedmont Triad. These trials target the most debilitating chronic conditions—cancer, heart disease, stroke, asthma, diabetes and mental illness.

Clinical Trials in the Piedmont Triad						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Asheboro	—	2	5	2	—	2
Burlington	—	4	4	1	—	1
Greensboro	1	11	7	4	1	4
High Point	3	4	1	3	—	2
Lexington	—	—	1	—	—	—
Winston-Salem	9	37	12	12	7	9

Source: www.clinicaltrials.gov

Note: Search criteria = Piedmont Triad cities, North Carolina, United States; Phase 0, 1, 2, 3; industry only. Search performed 2/15/2014. 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.**

The Good News—Many Clinical Trials are Still Recruiting

(continued)

Asthma—Leading Institutions Conducting Clinical Trials

Wake Forest University School of Medicine,
Winston-Salem

Cancer—Leading Institutions Conducting Clinical Trials

Alamance Regional Cancer Center, Burlington
Cornerstone Hematology/Oncology, High Point
Moses H. Cone Regional Cancer Center, Greensboro
Piedmont Hematology Oncology Associates, PLC,
Winston-Salem
Wake Forest Baptist Medical Center, Winston-Salem
Wake Forest University School of Medicine,
Winston-Salem

Diabetes—Leading Institutions Conducting Clinical Trials

Clinical Research of Winston-Salem, Winston-Salem
Guilford Neurologic Associates, Winston-Salem
Triad Clinical Trials LLC, Greensboro

Heart Disease—Leading Institutions Conducting Clinical Trials

Clinical Research of Winston-Salem, Winston-Salem
Forsyth Medical Center, Winston-Salem
Guilford Neurologic Associates, Winston-Salem
LeBauer Cardiovascular Research Foundation,
Greensboro
Wake Forest Baptist Medical Center, Winston-Salem
Wake Forest University School of Medicine,
Winston-Salem

Mental Illness—Leading Institution Conducting Clinical Trials

Duke Center for Smoking Cessation-Winston-Salem
Office, Winston-Salem

Stroke—Leading Institutions Conducting Clinical Trials

Clinical Research of Winston-Salem, Winston-Salem
Guilford Neurologic Associates, Winston-Salem

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 (10 clinical trials recruiting)

Study 1:

A 6 Month Safety Study Comparing Symbicort With Inhaled Corticosteroid Only in Asthmatic Adults and Adolescents

<http://ClinicalTrials.gov/show/NCT01444430>

Study 2:

Study of Efficacy and Safety of Brodalumab Compared With Placebo in Inadequately Controlled Asthma Subjects With High Bronchodilator Reversibility

<http://ClinicalTrials.gov/show/NCT01902290>

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>

Study 4:

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

<http://ClinicalTrials.gov/show/NCT01928771>

Study 5:

A Study to Establish the Efficacy of QBX258 in Patients With Moderate to Severe Asthma

<http://ClinicalTrials.gov/show/NCT01479595>

Study 6:

A Safety and Efficacy Study of Beclomethasone Dipropionate Delivered Via Breath-Actuated Inhaler (BAI) or Metered-Dose Inhaler (MDI) in Participants Ages 5-11 Years Old With Persistent Asthma

<http://ClinicalTrials.gov/show/NCT02040766>

Study 7:

A Study to Determine Long-term Safety of Mepolizumab in Asthmatic Subjects

<http://ClinicalTrials.gov/show/NCT01842607>

Study 8:

A Study of JNJ-38518168 in Symptomatic Adult Participants With Uncontrolled, Persistent Asthma

<http://ClinicalTrials.gov/show/NCT01823016>

Study 9:

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

<http://ClinicalTrials.gov/show/NCT01875003>

Study 10:

Long-Term Efficacy and Safety Study of SCH 900237/MK-8237 in Children and Adults With House Dust Mite-Induced Allergic Rhinitis/Rhinoconjunctivitis (P05607)

<http://ClinicalTrials.gov/show/NCT01700192>

Cancer

(53 clinical trials recruiting)

Study 1:

Anemia Treatment for Advanced Non-Small Cell Lung Cancer (NSCLC) Patients Receiving Chemotherapy

<http://ClinicalTrials.gov/show/NCT00858364>

Study 2:

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 3:

Regorafenib+FOLFIRI Versus Placebo+FOLFIRI as 2nd Line Tx in Metastatic Colorectal Cancer

<http://ClinicalTrials.gov/show/NCT01298570>

Study 4:

VTX-2337 and Pegylated Liposomal Doxorubicin (PLD) in Patients With Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer

<http://ClinicalTrials.gov/show/NCT01666444>

Study 5:

A Study Comparing the Combination of Trabectedin (YONDELIS) and DOXIL/CAELYX With DOXIL/CAELYX for the Treatment of Advanced-Relapsed Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer

<http://ClinicalTrials.gov/show/NCT01846611>

Study 6:

First-Line Treatment for Locally Advanced or Metastatic Mesenchymal Epithelial Transition Factor (MET)—Positive Gastric, Lower Esophageal, or Gastroesophageal Junction (GEJ) Adenocarcinoma

<http://ClinicalTrials.gov/show/NCT01697072>

Study 7:

Evaluate Risk/Benefit of Nab-paclitaxel in Combination With Either Gemcitabine or Carboplatin to the Combination of Gemcitabine and Carboplatin in First Line Treatment of Triple Negative Metastatic Breast Cancer (TNMBC)

<http://ClinicalTrials.gov/show/NCT01881230>

Study 8:

Denosumab Compared to Zoledronic Acid in the Treatment of Bone Disease in Subjects With Multiple Myeloma

<http://ClinicalTrials.gov/show/NCT01345019>

Study 9:

Safety and Efficacy Study of Enzalutamide Versus Bicalutamide in Men With Prostate Cancer

<http://ClinicalTrials.gov/show/NCT01664923>

Study 10:

A Study of AT13387 in Patients With Non-Small Cell Lung Cancer (NSCLC) Alone and in Combination With Crizotinib

<http://ClinicalTrials.gov/show/NCT01712217>

Study 11:

Safety and Efficacy Study of Enzalutamide in Patients With Advanced, Androgen Receptor-Positive, Triple Negative Breast Cancer

<http://ClinicalTrials.gov/show/NCT01889238>

Study 12:

Open-label, Phase II, Study of Everolimus Plus Letrozole in Postmenopausal Women With ER+, HER2- Metastatic or Locally Advanced Breast Cancer

<http://ClinicalTrials.gov/show/NCT01698918>

Study 13:

A Study of Necitumumab and Chemotherapy in Participants With Stage IV Squamous Non-Small Cell Lung Cancer

<http://ClinicalTrials.gov/show/NCT01769391>

Study 14:

A Study of Kadcyla (Trastuzumab Emtansine) Plus Perjeta (Pertuzumab) Following Anthracyclines in Comparison With Herceptin (Trastuzumab) Plus Perjeta and a Taxane Following Anthracyclines as Adjuvant Therapy in Patients With Operable HER2-positive Primary Breast Cancer

<http://ClinicalTrials.gov/show/NCT01966471>

Study 15:

Video Impact on Neulasta Education

<http://ClinicalTrials.gov/show/NCT01752907>

Study 16:

Tesetaxel as First-line Therapy for Metastatic Breast Cancer

<http://ClinicalTrials.gov/show/NCT01221870>

Study 17:

A Maintenance Study With Niraparib Versus Placebo in Patients With Platinum Sensitive Ovarian Cancer

<http://ClinicalTrials.gov/show/NCT01847274>

Study 18:

Long Term Safety of Sativex® Oromucosal Spray (Sativex®; Nabiximols) as Adjunctive Therapy in Patients With Uncontrolled Persistent Chronic Cancer Related Pain

<http://ClinicalTrials.gov/show/NCT01337089>

Study 19:

Phase III Study of BKM120/Placebo With Fulvestrant in Postmenopausal Patients With Hormone Receptor Positive HER2-negative Locally Advanced or Metastatic Breast Cancer Refractory to Aromatase Inhibitor

<http://ClinicalTrials.gov/show/NCT01610284>

Study 20:

A Study of CH5424802/RO5424802 in Patients With ALK-Rearranged Non-Small Cell Lung Cancer

<http://ClinicalTrials.gov/show/NCT01871805>

Study 21:

Study Evaluating the Safety and Efficacy of Carboplatin/Paclitaxel and Carboplatin/Paclitaxel/Bevacizumab With and Without GDC-0941 in Patients With Previously Untreated Advanced or Recurrent Non-small Cell Lung Cancer

<http://ClinicalTrials.gov/show/NCT01493843>

Study 22:

Trial in Squamous Non Small Cell Lung Cancer Subjects Comparing Ipilimumab Plus Paclitaxel and Carboplatin Versus Placebo Plus Paclitaxel and Carboplatin

<http://ClinicalTrials.gov/show/NCT01285609>

Study 23:

Study Of Dacomitinib (PF-00299804) In Advanced NSCLC Patients (Post Chemo Or Select First Line) To Evaluate Prophylactic Intervention On Derm And GI AEs And PRO

<http://ClinicalTrials.gov/show/NCT01465802>

Study 24:

A Study to Evaluate the Safety and Efficacy of Inactivated Varicella-zoster Vaccine (VZV) as a Preventative Treatment for Herpes Zoster (HZ) and HZ-related Complications in Adult Participants With Solid Tumor or Hematologic Malignancy (V212-011)

<http://ClinicalTrials.gov/show/NCT01254630>

Study 25:

Neoadjuvant Chemoradiotherapy With CRLX-101 and Capecitabine for Rectal Cancer

<http://ClinicalTrials.gov/show/NCT02010567>

Study 26:

Phase 3 Study of Bavituximab Plus Docetaxel Versus Docetaxel Alone in Patients With Late-stage Non-squamous Non-small-cell Lung Cancer

<http://ClinicalTrials.gov/show/NCT01999673>

Study 27:

Phase II Randomized Trial Evaluating Neoadjuvant Therapy With Neratinib and/or Trastuzumab Followed by Postoperative Trastuzumab in Women With Locally Advanced HER2-positive Breast Cancer

<http://ClinicalTrials.gov/show/NCT01008150>

Study 28:

A Multinational, Randomized, Open-Label Study of Custirsén In Patients With Advanced or Metastatic (Stage IV) Non-Small Cell Lung Cancer

<http://ClinicalTrials.gov/show/NCT01630733>

Study 29:

A Study of ARN-509 in Men With Non-Metastatic Castration-Resistant Prostate Cancer

<http://ClinicalTrials.gov/show/NCT01946204>

Study 30:

Mibefradil Dihydrochloride and Temozolomide in Treating Patients With Recurrent Glioma

<http://ClinicalTrials.gov/show/NCT01480050>

Study 31:

Vaccine Therapy With Bevacizumab Versus Bevacizumab Alone in Treating Patients With Recurrent Glioblastoma Multiforme That Can Be Removed by Surgery

<http://ClinicalTrials.gov/show/NCT01814813>

Study 32:

A Study of Sativex® for Relieving Persistent Pain in Patients With Advanced Cancer

<http://ClinicalTrials.gov/show/NCT01262651>

Study 33:

A Study of Rindopepimut/GM-CSF in Patients With Relapsed EGFRvIII-Positive Glioblastoma

<http://ClinicalTrials.gov/show/NCT01498328>

Study 34:

Phase III Study of Rindopepimut/GM-CSF in Patients With Newly Diagnosed Glioblastoma

<http://ClinicalTrials.gov/show/NCT01480479>

Study 35:

MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma

<http://ClinicalTrials.gov/show/NCT01850524>

Study 36:

Phase III Study of Lenalidomide and Dexamethasone With or Without Elotuzumab to Treat Newly Diagnosed, Previously Untreated Multiple Myeloma

<http://ClinicalTrials.gov/show/NCT01335399>

Study 37:

Nilotinib Treatment-free Remission Study in CML (Chronic Myeloid Leukemia) Patients

<http://ClinicalTrials.gov/show/NCT01784068>

Study 38:

Phase 3 Study With Carfilzomib and Dexamethasone Versus Velcade and Dexamethasone for Relapsed Multiple Myeloma Patients

<http://ClinicalTrials.gov/show/NCT01568866>

Study 39:

Phase 3 Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (RCC)

<http://ClinicalTrials.gov/show/NCT01582672>

Study 40:

Randomized Trial of Lenalidomide, Bortezomib, Dexamethasone vs High-Dose Treatment With SCT in MM Patients up to Age 65

<http://ClinicalTrials.gov/show/NCT01208662>

Study 41:

Everolimus and Pasireotide (SOM230) in Patients With Advanced or Metastatic Hepatocellular Carcinoma

<http://ClinicalTrials.gov/show/NCT01488487>

Study 42:

coBRIM: A Phase 3 Study Comparing GDC-0973 (Cobimetinib), a MEK Inhibitor, in Combination With Vemurafenib vs Vemurafenib Alone in Patients With Metastatic Melanoma

<http://ClinicalTrials.gov/show/NCT01689519>

Study 43:

A Study of the BRAF Inhibitor Dabrafenib in Combination With the MEK Inhibitor Trametinib in the Adjuvant Treatment of High-risk BRAF V600 Mutation-positive Melanoma After Surgical Resection

<http://ClinicalTrials.gov/show/NCT01682083>

Study 44:

A Study of Two Vismodegib Regimens in Patients With Multiple Basal Cell Carcinomas

<http://ClinicalTrials.gov/show/NCT01815840>

Study 45:

Safety and Efficacy in Premenopausal Women With Heavy Menstrual Bleeding (HMB) Associated With Uterine Fibroids (UF)

<http://ClinicalTrials.gov/show/NCT01817530>

Study 46:

A Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination With Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas

<http://ClinicalTrials.gov/show/NCT01732913>

Study 47:

A Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination With Bendamustine and Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas

<http://ClinicalTrials.gov/show/NCT01732926>

Study 48:

Single Agent Ofatumumab Vs. Single Agent Rituximab in Follicular Lymphoma Relapsed After Rituximab-Containing Therapy

<http://ClinicalTrials.gov/show/NCT01200589>

Study 49:

Phase III Study of RAD001 Adjuvant Therapy in Poor Risk Patients With Diffuse Large B-Cell Lymphoma (DLBCL) of RAD001 Versus Matching Placebo After Patients Have Achieved Complete Response With First-line Rituximab-chemotherapy

<http://ClinicalTrials.gov/show/NCT00790036>

Study 50:

Safety and Efficacy of CML Patients Who Switch to Nilotinib and Stop Treatment After Achieving and Sustaining MR4.5

<http://ClinicalTrials.gov/show/NCT01744665>

Study 51:

A Study Of Inotuzumab Ozogamicin Versus Investigator's Choice Of Chemotherapy In Patients With Relapsed Or Refractory Acute Lymphoblastic Leukemia

<http://ClinicalTrials.gov/show/NCT01564784>

Study 52:

Phase III Study of CPX-351 Versus 7+3 in Patients 60-75 Years Old With Untreated High Risk (Secondary) Acute Myeloid Leukemia

<http://ClinicalTrials.gov/show/NCT01696084>

Study 53:

A Trial of TH-302 in Combination With Doxorubicin Versus Doxorubicin Alone to Treat Patients With Locally Advanced Unresectable or Metastatic Soft Tissue Sarcoma

<http://ClinicalTrials.gov/show/NCT01440088>

Diabetes

(22 clinical trials recruiting)

Study 1:

Safety and Efficacy of the Combination of Empagliflozin and Linagliptin Compared to Linagliptin Alone Over 24 Weeks in Patients With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01734785>

Study 2:

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 3:

A Study to Evaluate ITCA 650 for the Treatment of Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01455857>

Study 4:

Safety and Efficacy of Combination Saxagliptin & Dapagliflozin Added to Metformin to Treat Subjects With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01606007>

Study 5:

Safety and Efficacy Study of Empagliflozin and Metformin for 24 Weeks in Treatment Naive Patients With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01719003>

Study 6:

A Study of the Safety and Efficacy of MK-3102 in ≥18 and <45 Year-Old Subjects With Type 2 Diabetes Mellitus and Inadequate Glycemic Control (MK-3102-028 AM1)

<http://ClinicalTrials.gov/show/NCT01814748>

Study 7:

Dose-finding Study of LIK066 Compared With Placebo or Sitagliptin to Evaluate Change in HbA1c in Patients With Diabetes

<http://ClinicalTrials.gov/show/NCT01824264>

Study 8:

Multicenter Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Cardiovascular Events

<http://ClinicalTrials.gov/show/NCT01730534>

Study 9:

Insulin Resistance Intervention After Stroke Trial

<http://ClinicalTrials.gov/show/NCT00091949>

Study 10:

Efficacy and Safety of FIAsp in a Basal-bolus Regimen Versus Basal Insulin Therapy, Both in Combination With Metformin in Adult Subjects With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01850615>

Study 11:

MARLINA - T2DM : Efficacy, Safety & Modification of Albuminuria in Type 2 Diabetes Subjects With Renal Disease With LINagliptin

<http://ClinicalTrials.gov/show/NCT01792518>

Study 12:

The Efficacy and Safety of Liraglutide as Adjunct Therapy to Insulin in the Treatment of Type 1 Diabetes

<http://ClinicalTrials.gov/show/NCT01836523>

Study 13:

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 14:

Study Of Two Dosing Regimens Of PF-04937319 Compared To An Approved Agent (Sitagliptin) In Patients With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01933672>

Study 15:

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 16:

A Study to Assess Cardiovascular Outcomes Following Treatment With MK-3102 in Participants With Type 2 Diabetes Mellitus (MK-3102-018 AM5)

<http://ClinicalTrials.gov/show/NCT01703208>

Study 17:

A Study to Evaluate ITCA 650 Compared to Sitagliptin as add-on Therapy for the Treatment of Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01455870>

Study 18:

A Study to Evaluate Cardiovascular Outcomes in Patients With Type 2 Diabetes Treated With ITCA 650

<http://ClinicalTrials.gov/show/NCT01455896>

Study 19:

A Phase 2 Multi-Center Study To Evaluate The Efficacy And Safety Of A Chemokine CCR2/5 Receptor Antagonist In Adults With Type 2 Diabetes And Overt Nephropathy

<http://ClinicalTrials.gov/show/NCT01712061>

Study 20:

A Trial Comparing the Safety and Efficacy of Insulin Degludec and Insulin Glargine, Both in Combination With Metformin in Subjects With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT02030600>

Study 21:

Study Of Diabetic Nephropathy With Atrasentan

<http://ClinicalTrials.gov/show/NCT01858532>

Study 22:

A Study to Test Safety and Efficacy of Baricitinib in Participants With Diabetic Kidney Disease

<http://ClinicalTrials.gov/show/NCT01683409>

Heart Disease (14 clinical trials recruiting)

Study 1:

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

<http://ClinicalTrials.gov/show/NCT01327846>

Study 2:

A Study Comparing Cardiovascular Effects of Ticagrelor and Clopidogrel in Patients With Peripheral Artery Disease

<http://ClinicalTrials.gov/show/NCT01732822>

Study 3:

A Study to Assess the Effectiveness and Safety of Rivaroxaban in Reducing the Risk of Death, Myocardial Infarction or Stroke in Participants With Heart Failure and Coronary Artery Disease Following Hospitalization for Heart Failure

<http://ClinicalTrials.gov/show/NCT01877915>

Study 4:

ST Monitoring to Detect Acute Coronary Syndrome Events in Implantable Cardioverter Defibrillator Patients

<http://ClinicalTrials.gov/show/NCT01424722>

Study 5:

Multicenter Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Cardiovascular Events

<http://ClinicalTrials.gov/show/NCT01730534>

Study 6:

Insulin Resistance Intervention After Stroke Trial

<http://ClinicalTrials.gov/show/NCT00091949>

Study 7:

Safety and Efficacy Continued Access Study of the Medtronic CoreValve® System in the Treatment of Symptomatic Severe Aortic Stenosis in Very High Risk Subjects and High Risk Subjects Who Need Aortic Valve Replacement

<http://ClinicalTrials.gov/show/NCT01531374>

Study 8:

A Study of Genetically Targeted Enzyme Replacement Therapy for Advanced Heart Failure

<http://ClinicalTrials.gov/show/NCT01643330>

Study 9:

BIOHELIX-I Bare Metal Stent Study

<http://ClinicalTrials.gov/show/NCT01612767>

Study 10:

Efficacy and Safety of Ularitide for the Treatment of Acute Decompensated Heart Failure

<http://ClinicalTrials.gov/show/NCT01661634>

Study 11:

Clinical Trial of the SonRtip Lead and Automatic AV-VV Optimization Algorithm in the PARADYM RF SonR CRT-D

<http://ClinicalTrials.gov/show/NCT01534234>

Study 12:

Efficacy, Safety and Tolerability of Serelaxin When Added to Standard Therapy in AHF

<http://ClinicalTrials.gov/show/NCT01870778>

Study 13:

Vest Prevention of Early Sudden Death Trial and VEST Registry

<http://ClinicalTrials.gov/show/NCT01446965>

Study 14:

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

<http://ClinicalTrials.gov/show/NCT01101035>

Mental Illness

(7 clinical trials recruiting)

Study 1:

Progress of Mild Alzheimer's Disease in Participants on Solanezumab Versus Placebo

<http://ClinicalTrials.gov/show/NCT01900665>

Study 2:

The Safety and Efficacy of AF-219 in Female Subjects With Interstitial Cystitis /Bladder Pain Syndrome

<http://ClinicalTrials.gov/show/NCT01569438>

Study 3:

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

<http://ClinicalTrials.gov/show/NCT01735630>

Study 4:

Safety and Efficacy Study Evaluating TRx0237 in Subjects With Mild Alzheimer's Disease

<http://ClinicalTrials.gov/show/NCT01689233>

Study 5:

Clinical Trial of Solanezumab for Older Individuals Who May be at Risk for Memory Loss

<http://ClinicalTrials.gov/show/NCT02008357>

Study 6:

A Phase 2, to Evaluating the Safety and Efficacy of Pridopidine Versus Placebo for Symptomatic Treatment in Patients With Huntington's Disease

<http://ClinicalTrials.gov/show/NCT02006472>

Study 7:

Evaluation of Moclobemide, a Reversible MAO-A Inhibitor, as an Adjunct to Nicotine Replacement Therapy in Female Smokers

<http://ClinicalTrials.gov/show/NCT01926626>

Stroke

(11 clinical trials recruiting)

Study 1:

Efficacy and Safety Study of Desmoteplase to Treat Acute Ischemic Stroke (DIAS-4)

<http://ClinicalTrials.gov/show/NCT00856661>

Study 2:

Insulin Resistance Intervention After Stroke Trial

<http://ClinicalTrials.gov/show/NCT00091949>

Study 3:

A Study to Assess the Effectiveness and Safety of Rivaroxaban in Reducing the Risk of Death, Myocardial Infarction or Stroke in Participants With Heart Failure and Coronary Artery Disease Following Hospitalization for Heart Failure

<http://ClinicalTrials.gov/show/NCT01877915>

Study 4:

Efficacy and Safety Study of Botulinum Toxin Type A Against Placebo to Treat Spasticity in the Leg After a Stroke

<http://ClinicalTrials.gov/show/NCT01464307>

Study 5:

A Study Comparing Cardiovascular Effects of Ticagrelor and Clopidogrel in Patients With Peripheral Artery Disease

<http://ClinicalTrials.gov/show/NCT01732822>

Study 6:

[SOCRATES-Acute Stroke Or Transient Ischaemic Attack Treated With Aspirin or Ticagrelor and Patient Outcomes]

<http://ClinicalTrials.gov/show/NCT01994720>

Study 7:

Multicenter Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Cardiovascular Events

<http://ClinicalTrials.gov/show/NCT01730534>

Study 8:

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

<http://ClinicalTrials.gov/show/NCT01327846>

Study 9:

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

<http://ClinicalTrials.gov/show/NCT01101035>

Study 10:

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

<http://ClinicalTrials.gov/show/NCT01975376>

Study 11:

A Randomized Controlled Trial of Aliskiren in the Prevention of Major Cardiovascular Events in Elderly People

<http://ClinicalTrials.gov/show/NCT01259297>