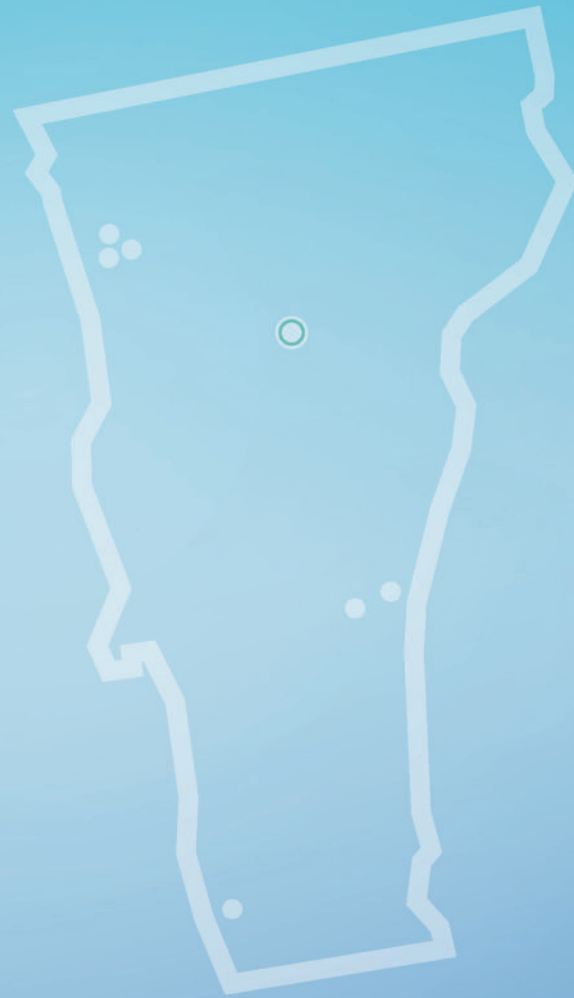


# Research in Your Backyard

Developing Cures, Creating Jobs



Dots show locations of clinical trials in the state.

**PHARMACEUTICAL  
CLINICAL TRIALS IN  
VERMONT**

# Executive Summary

## Clinical Trials in Vermont

- Biopharmaceutical research companies are conducting or have conducted more than 560 clinical trials of new medicines in collaboration with the state's university medical school, clinical research centers and hospitals (1999 to present).
- Of the more than 560 clinical trials, 365 target the nation's six most debilitating chronic diseases—**asthma, cancer, diabetes, heart disease, mental illnesses and stroke.**

## Economic Benefits of Clinical Trials in Vermont

- Biopharmaceutical research companies have been a source of jobs, tax revenue and research spending in Vermont.
- A study by Battelle Technology Partnership Practice found that in 2011 the industry supported nearly 1,500 jobs throughout the state.
- Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in about \$11 million in federal taxation and \$2 million in state and local taxes.
- Biopharmaceutical research companies supported the generation of \$267 million in economic activity

*“Vermont is committed to good health for people, our environment, and our institutions including our schools, colleges and universities, our businesses and our cities and communities. One significant health care effort that doesn’t receive the attention it deserves is the active research activity of local research institutions—from Chittenden County to White River Junction, from Brattleboro to Bennington. Many of these institutions are members of the Vermont Biosciences Alliance. Working often in partnership with NIH and most major pharmaceutical companies, our research efforts are contributing to the development of life saving drugs, devices, and treatments. No one researcher or institution can single handedly develop a drug or a medical device. It requires capital, talent, drive, initiative and teamwork. Some of the things for which Vermont is known.”*

—Bill Church, President of Green Mountain Antibodies;  
Chair, Vermont Biosciences Alliance (VBSA)

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.

*“Biopharmaceutical companies have targeted disease wisely in Vermont—well over half of the medications that have been clinically tested in the state have targeted the nation’s most debilitating chronic diseases, including cancer, diabetes, heart disease, stroke and asthma. Nearly 50 of those trials are still active and recruiting patients. We are pleased that in Burlington, these collaborations have been with researchers at the University of Vermont and Fletcher Allen Health Care Medical Center.”*

—Susan Fayette, Administrator,  
Vermont Biosciences Alliance (VBSA)

- Company employees in Vermont 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.

## 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 45 to 75 percent 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 Vermont since 1999— Completed and Active

All Clinical Trials	Six Major Chronic Diseases
566	365

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Note: Search criteria = Vermont, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/19/2013.

## 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 more than 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.

Clinical Trials in Vermont Communities						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Bennington	—	—	2	1	8	1
Burlington	1	16	2	9	1	2
Colchester	—	1	—	—	—	—
S. Burlington	—	—	1	—	—	—
White River Junction	—	3	—	—	—	—
Woodstock	—	—	—	—	1	—

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Note: Search criteria = Vermont, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/19/2013. 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.**

- 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 throughout Vermont.
- Since 1999, biopharmaceutical research companies have sponsored 365 clinical trials of potential new medicines in Vermont alone for **asthma, cancer, heart disease, stroke, diabetes and mental illnesses**. Of these trials, 48 are either not yet recruiting or are just now seeking Vermont patients. The 48 trials are being conducted at 49 sites in Vermont.
- Biopharmaceutical companies are collaborating on the tests with such prominent institutions as the **University of Vermont and Fletcher Allen Health Care**.
- Some of the medicines being clinically tested in Vermont are new-generation biotechnology treatments.

Clinical Trials for Top Chronic Diseases		
Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	22	1
Cancer	106	20
Diabetes	52	5
Heart Disease	34	10
Mental Illness	141	9
Stroke	10	3
<b>Total</b>	<b>365</b>	<b>48</b>

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Note: Search criteria = Vermont, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/19/2013. **Some clinical trials appear in more than one disease category.**

*“The broad availability of clinical trials in Vermont results from a very productive relationship between the Academic Medical Center and industry. This has insured that promising novel treatments are locally available and that our community benefits from these emerging therapeutic opportunities.”*

—Ira M. Bernstein M.D.,  
 John Van Sicklen Maeck Professor and Chair,  
 Department of Obstetrics, Gynecology and Reproductive  
 Sciences, Senior Associate Dean for Research,  
 University of Vermont College of Medicine

# Clinical Trials in Vermont

Clinical tests of new medicines are a vitally important part of the drug development and approval process—they account for 45 to 75 percent 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 Trials for Top Chronic Diseases

Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	22	1
Cancer	106	20
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<b>Total</b>	<b>365</b>	<b>48</b>

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Note: Search criteria = Vermont, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/19/2013. **Some clinical trials appear in more than one disease category.**

Clinical tests involve three phases, thousands of volunteer patients, and are often conducted at multiple sites around the country. In Vermont, biopharmaceutical companies are providing funds to have trials conducted at the state's well-respected medical school and hospitals. According to *U.S. News and World Report*, the **University of Vermont** ranked 59th 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. The toll is also severe in Vermont, where 67,000 residents suffer from asthma and nearly 13,000 of them are children, according to the Vermont Department of Health.

Currently, one clinical trial of a new asthma medicine is recruiting patients in **Burlington**.

**Cancer**, the second leading cause of death in the United States, now afflicts nearly 14 million Americans, according to the National Cancer Institute. In Vermont, about 4,200 new cancer cases will be diagnosed this year and 1,300 victims in the state will die, according to the American Cancer Society.

Currently, 20 clinical trials of new cancer medicines are recruiting patients in Vermont. Biopharmaceutical companies are collaborating on the tests with such institutions as the **Fletcher Allen Health Care Medical Center** and the **University of Vermont** in Burlington, and the **Veteran's Hospital VA Medical Center** in White River Junction. Clinical trials are also being conducted in **White River Junction** and **Colchester**.

**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 Vermont, diabetes affects more than 55,000 residents, according to the Vermont Department of Health.

Currently, five diabetes clinical tests are seeking patients in Vermont. The trials are being conducted at the **University of Vermont** in Burlington and at locations in **Bennington** and **South Burlington**.

**Heart disease and stroke** are the first and fourth leading disease causes of death in the United States and the second and fifth in Vermont. According to the American Heart Association, more than 82 million Americans are affected by these diseases. In Vermont, in 2009, nearly 1,200 residents died from some form of heart disease and 219 died from a stroke, according to the Vermont Department of Health.

Currently, 10 heart disease and three stroke clinical tests are seeking patients in Vermont. The trials are being conducted at the **Fletcher Allen Health Care Medical Center** and the **University of Vermont** in Burlington.

**Mental illness** affects nearly 60 million Americans who suffer from some form of the disease—from anxiety to depression to schizophrenia to eating disorders. In Vermont, about 187,000 adults live with serious mental illness and about 51,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness.

Currently, nine clinical trials for mental illness are recruiting patients in Vermont. The trials are taking place at the **Neuropsychiatric Associates** in Woodstock and **The Pharmacy** in Bennington.

*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](http://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](http://www.phrma.org), the website of the Pharmaceutical Research and Manufacturers of America (PhRMA). Click on Innovation, Clinical Trials and then Research in Your Backyard.*

# 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 Vermont alone, hundreds of clinical trials have been conducted to target 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 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 Vermont are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of new medicines and vaccines today. And Vermont is one of the states 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 at Vermont hospitals and research centers feature these technologies. For example:

- A monoclonal antibody for the treatment of idiopathic pulmonary fibrosis is being tested in **Colchester**.
- A recombinant fusion protein to treat age-related macular degeneration was studied in **Burlington**.
- A monoclonal antibody that targets lymphoma is in clinical trials at **Mountainview Medical** in Berlin and **Fletcher Allen Health Care Medical Center** in Burlington.

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 Vermont, as in other states, 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 Vermont benefits patients, the state's economy and the advancement of science and patient care. Clinical trials provide stimulating biopharmaceutical research work and a reliable source of revenue for the states' medical schools, hospitals and 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, Vermonters considering participation in clinical trials have a wide range of choices, including 48 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
<b>Years</b>	6.5	1.5	2	3.5	1.5	
<b>Test Population</b>	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
<b>Purpose</b>	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		
<b>Success Rate</b>	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 48 clinical trials of new chronic disease drugs recruiting patients in Vermont. These trials target the most debilitating chronic conditions—cancer, heart disease, stroke, asthma, diabetes and mental illness.

Clinical Trials in Vermont Communities						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Bennington	—	—	2	1	8	1
Burlington	1	16	2	9	1	2
Colchester	—	1	—	—	—	—
S. Burlington	—	—	1	—	—	—
White River Junction	—	3	—	—	—	—
Woodstock	—	—	—	—	1	—

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Note: Search criteria = Vermont, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/19/2013. 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)

## **Cancer—Leading Institutions Conducting Clinical Trials**

Fletcher Allen Health Care Medical Center, Burlington

University of Vermont, Burlington

Veteran’s Hospital VA Medical Center, White River  
Junction

## **Diabetes—Leading Institutions Conducting Clinical Trials**

University of Vermont, Burlington

## **Heart Disease—Leading Institutions Conducting Clinical Trials**

Fletcher Allen Health Care Medical Center, Burlington

University of Vermont, Burlington

## **Mental Illness—Leading Institutions Conducting Clinical Trials**

Neuropsychiatric Associates, Woodstock

The Pharmacy, Inc., Bennington

## **Stroke—Leading Institutions Conducting Clinical Trials**

University of Vermont, Burlington

# 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. It provides 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

(1 clinical trial recruiting)

### Study 1:

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

(20 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:

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

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

### Study 3:

A Randomized, Double-blind, Phase 3 Efficacy Trial of PROSTVAC-V/F +/- GM-CSF in Men With Asymptomatic or Minimally Symptomatic Metastatic Castrate-Resistant Prostate Cancer

<http://ClinicalTrials.gov/show/NCT01322490>

### Study 4:

Olaparib Monotherapy in Patients With BRCA Mutated Ovarian Cancer Following First Line Platinum Based Chemotherapy

<http://ClinicalTrials.gov/show/NCT01844986>

### **Study 5:**

**FOLFOX6m Plus SIR-Spheres Microspheres vs. FOLFOX6m Alone in Patients With Liver Mets From Primary Colorectal Cancer**

<http://ClinicalTrials.gov/show/NCT01721954>

### **Study 6:**

**Study Of Dacomitinib 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 7:**

**Elesclomol Sodium and Paclitaxel in Treating Patients With Recurrent or Persistent Ovarian Epithelial Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer**

<http://ClinicalTrials.gov/show/NCT00888615>

### **Study 8:**

**First-in-Human Dose Escalation Trial in Subjects With Advanced Malignancies**

<http://ClinicalTrials.gov/show/NCT01971515>

### **Study 9:**

**LUX-Lung 8: A Phase III Trial of Afatinib (BIBW 2992) Versus Erlotinib for the Treatment of Squamous Cell Lung Cancer After at Least One Prior Platinum Based Chemotherapy**

<http://ClinicalTrials.gov/show/NCT01523587>

### **Study 10:**

**Study Comparing Combination of LGX818 Plus MEK162 and LGX818 Monotherapy Versus Vemurafenib in BRAF Mutant Melanoma**

<http://ClinicalTrials.gov/show/NCT01909453>

### **Study 11:**

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

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

### **Study 12:**

**Safety Study of Adenovirus Vector Engineered to Express hIL-12 (Human Interleukin 12) in Combination With Activator Ligand to Treat Melanoma**

<http://ClinicalTrials.gov/show/NCT01397708>

### **Study 13:**

**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>

### **Study 14:**

**Docetaxel, Gemcitabine and Pazopanib as Treatment for Soft Tissue Sarcoma**

<http://ClinicalTrials.gov/show/NCT01719302>

### **Study 15:**

**A Study of the Bruton's Tyrosine Kinase Inhibitor Ibrutinib Given in Combination With Bendamustine and Rituximab in Patients With Newly Diagnosed Mantle Cell Lymphoma**

<http://ClinicalTrials.gov/show/NCT01776840>

### **Study 16:**

**A Study of the Bruton's Tyrosine Kinase Inhibitor, PCI-32765 (Ibrutinib), in Combination With Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone in Patients With Newly Diagnosed Non-Germinal Center B-Cell Subtype of Diffuse Large B-Cell Lymphoma**

<http://ClinicalTrials.gov/show/NCT01855750>

### **Study 17:**

**A Study of PCI-32765 (Ibrutinib) in Patients With Refractory Follicular Lymphoma**

<http://ClinicalTrials.gov/show/NCT01779791>



### Study 18:

**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 19:

**Alisertib (MLN8237) or Investigator's Choice in Patients With Relapsed/Refractory Peripheral T-Cell Lymphoma**

<http://ClinicalTrials.gov/show/NCT01482962>

### Study 20:

**Myelodysplastic Syndromes (MDS) Event Free Survival With Iron Chelation Therapy Study**

<http://ClinicalTrials.gov/show/NCT00940602>

## Diabetes

(5 clinical trials recruiting)

### Study 1:

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

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

### Study 2:

**Trial to Evaluate Cardiovascular and Other Long-term Outcomes With Semaglutide in Subjects With Type 2 Diabetes**

<http://ClinicalTrials.gov/show/NCT01720446>

### Study 3:

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

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

### Study 4:

**Safety and Efficacy of Different Oral Doses of BAY94-8862 in Subjects With Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Nephropathy**

<http://ClinicalTrials.gov/show/NCT01874431>

### Study 5:

**Insulin Resistance Intervention After Stroke Trial**

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

## Heart Disease

(10 clinical trials recruiting)

### Study 1:

**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 2:

**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 3:

**Cangrelor to Clopidogrel or Prasugrel Transition Study**

<http://ClinicalTrials.gov/show/NCT01979445>

### Study 4:

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

<http://ClinicalTrials.gov/show/NCT01663402>

### Study 5:

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

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

### Study 6:

**Phase IIb Safety and Efficacy Study of Four Dose Regimens of BAY1021189 in Patients With Heart Failure With Reduced Ejection Fraction Suffering From Worsening Chronic Heart Failure (SOCRATES-REDUCED)**

<http://ClinicalTrials.gov/show/NCT01951625>

### Study 7:

**Phase IIb Safety and Efficacy Study of Four Dose Regimens of BAY1021189 in Patients With Heart Failure and Preserved Ejection Fraction Suffering From Worsening Chronic Heart Failure (SOCRATES-PRESERVED)**

<http://ClinicalTrials.gov/show/NCT01951638>

### Study 8:

**Determining the Feasibility of Spinal Cord Neuromodulation for the Treatment of Chronic Heart Failure**

<http://ClinicalTrials.gov/show/NCT01112579>

### Study 9:

**Insulin Resistance Intervention After Stroke Trial**

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

### Study 10:

**A Study to Evaluate the Safety and Efficacy of AC607 for the Treatment of Kidney Injury in Cardiac Surgery Subjects**

<http://ClinicalTrials.gov/show/NCT01602328>

## Mental Illness (9 clinical trials recruiting)

### Study 1:

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

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

### Study 2:

**A Study of Gantenerumab in Patients With Prodromal Alzheimer's Disease**

<http://ClinicalTrials.gov/show/NCT01224106>

### Study 3:

**A Study to Evaluate Safety, Tolerability, and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease**

<http://ClinicalTrials.gov/show/NCT01767311>

### Study 4:

**Open Label Extension in Adults With Binge Eating Disorder (BED)**

<http://ClinicalTrials.gov/show/NCT01657019>

### Study 5:

**A Long-Term Safety Extension Study of Studies ABE4869g And ABE4955g in Patients With Mild To Moderate Alzheimer's Disease Treated With Crenezumab**

<http://ClinicalTrials.gov/show/NCT01723826>

### Study 6:

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

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

### Study 7:

**Efficacy, Safety and Tolerability Study of AVP-923 (Dextromethorphan/Quinidine) for Treatment of Symptoms of Agitation in Alzheimer's Patients**

<http://ClinicalTrials.gov/show/NCT01584440>

### Study 8:

**Study Evaluating The Safety And Efficacy Of PF-05212377 Or Placebo In Subjects With Alzheimer's Disease With Existing Neuropsychiatric Symptoms On Donepezil**

<http://ClinicalTrials.gov/show/NCT01712074>

### Study 9:

**Safety and Efficacy Study Evaluating TRx0237 in Subjects With Behavioral Variant Frontotemporal Dementia (bvFTD)**

<http://ClinicalTrials.gov/show/NCT01626378>

## Stroke

(3 clinical trials recruiting)

### Study 1:

**Insulin Resistance Intervention After Stroke Trial**

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

### Study 2:

**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 3:

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

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



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