

Research in Your Backyard

Developing Cures, Creating Jobs



**PHARMACEUTICAL
CLINICAL TRIALS IN
MAINE**

Stars show locations of clinical trials in the state.

Executive Summary

Clinical Trials in Maine

- Biopharmaceutical research companies are conducting or have conducted more than 550 clinical trials of new medicines in collaboration with the state's clinical research centers, university medical schools and hospitals (1999 to present).
- Of the more than 550 clinical trials, more than 300 target the nation's six most debilitating chronic diseases—**asthma, cancer, diabetes, heart disease, mental illnesses and stroke.**

Economic Benefits of Clinical Trials in Maine

- Biopharmaceutical research companies have been an important source of jobs, tax revenue and research spending in Maine.
- A study by Archstone Consulting found that in 2008 the industry supported nearly 12,000 jobs throughout the state.
- Employees working directly for the companies were paid \$119.4 million, leading to more than \$25 million in federal taxation and \$4.1 million in state taxation.
- Biopharmaceutical research firms that year also invested \$54.2 million in research and development and supported \$2.4 billion in products and services.

“This new report illustrates just how important it is to patients and our state’s economy to have had 568 industry-funded clinical trials of new medicines conducted in the state over the last 13 years. This cutting-edge research has helped to sustain jobs at research centers and hospitals in Portland, Biddeford, Brunswick, Sanford, Scarborough, Rockport, Bangor and other Maine communities. The clinical research collaboration with biopharmaceutical companies has benefited researchers and clinicians at the Maine Medical Center and Mercy Hospital in Portland, the University of New England in Biddeford, Penobscot Bay Neurology in Rockport, Eastern Maine Medical Center in Bangor, the facilities of the Maine Center for Cancer Medicine all over the state and other institutions.”

—Dana Connors
President
Maine Chamber of Commerce

- Company employees in Maine include life sciences researchers, management executives, office and administrative support workers, production workers, engineers, architects, computer and math experts and sales representatives.

“Biopharmaceutical research is a significant economic force in the Portland region. We host 28 active clinical trials, many conducted at our leading medical facilities. That’s more than one-third of the total trials ongoing today in Maine, and the work produces thousands of good paying jobs and tens of millions of dollars in payroll. Our region is stronger because of biopharmaceutical research, and we’re here today to support its continuance and expansion in Maine.”

—Christopher Hall
Chief Executive Officer
Portland Regional Chamber

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 and some are done to learn if 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.
- 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 Maine since 1999— Completed and Active

All Clinical Trials	Six Major Chronic Diseases
568	323

Source: www.clinicaltrials.gov

Note: Search criteria = Maine, Phase I, II, III; industry only. Search performed 4/5/2013.

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 Centers for Disease Control and Prevention, 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.

“There is no cure for cancer yet. The only way a cure can be found is through clinical research. We want Maine to be a part of finding the cure, and we want our patients to have the opportunity to participate.”

—Betsy Chase
 Research Director
 Maine Center for Cancer Medicine

Active Clinical Trials in Maine Communities

Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Auburn	—	1	3	5	—	2
Bangor	5	4	4	4	—	2
Biddeford	—	1	—	2	—	2
Lewiston	—	2	—	—	—	—
Portland	—	2	5	4	—	2
Rockport	—	—	3	2	—	2
Scarborough	—	11	—	—	1	—

Source: www.clinicaltrials.gov

Note: Search criteria = Maine, Phase I, II, III; industry only. Search performed 4/5/2013. See Appendix for detailed information about these clinical trials. The numbers in these disease columns are not the same as the 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 Maine.
- Since 1999, biopharmaceutical research companies are sponsoring or have sponsored 323 clinical trials of potential new medicines in Maine alone for **asthma, cancer, heart disease, stroke, diabetes** and **mental illnesses**. Of these trials, 57 are either not yet recruiting or are just now seeking Maine patients.
- Many of the state’s clinical tests involve collaborations with such respected local institutions as the **Mercy Hospital, the Maine Medical Center, the Penobscot Bay Medical Center** and **Maine Center for Cancer Medicine**.
- Some of the medicines being clinically tested here are new-generation biotechnology treatments.

“From a patient’s perspective, it was comforting and an aid in my healing process to be able to participate in a clinical trial focused on my specific form of Acute Myeloid Leukemia (AML) without having to travel a significant distance from home. Proximity to treatment also eases the burden on the family.”

—Tom Sotir
Harold Alfond Center for Cancer Care
MaineGeneral Health patient

Clinical Trials for Top Chronic Diseases		
Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	19	5
Cancer	123	22
Diabetes	60	14
Heart Disease	95	10
Mental Illness	13	1
Stroke	13	5
Total	323	57

Source: www.clinicaltrials.gov

Note: Search criteria = Maine, Phase I, II, III; industry only. Search performed 4/5/2013. Some clinical trials appear in more than one disease category.

Clinical Trials in Maine

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 learn if 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 meticulously help design and conduct their clinical trials to determine whether a medicine is safe and effective. Side effects must be painstakingly documented and a determination made as to whether they occur too often and are dangerous.

Clinical Trials for Top Chronic Diseases

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Cancer	123	22
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Mental Illness	13	1
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Source: www.clinicaltrials.gov

Note: Search criteria = Maine, Phase I, II, III; industry only. Search performed 4/5/2013. Some clinical trials appear in more than one disease category.

Clinical tests involve three phases and thousands of volunteer patients and are often conducted at multiple sites around the country. In Maine, biopharmaceutical companies are providing funds to have trials conducted at the state's hospitals, clinical research organizations and the University of New England in Biddeford. According to *U.S. News and World Report*, the **University of New England** was listed among this year's top research-oriented medical schools in the United States.

Asthma is a debilitating condition for more than 24 million Americans, including 7.1 million children under the age of 18. The toll is also severe in Maine—in 2008, about 14.9 percent of adults and 14.6 percent of children suffered from asthma, according to the Maine Department of Health and Human Services.

Currently, five clinical trials of new asthma medicines are recruiting patients in Bangor.

Cancer, the second leading cause of death in the United States, now afflicts nearly 14 million Americans, according to the National Cancer Institute. In Maine, nearly 9,200 new cancer cases will be diagnosed this year and 3,240 victims in the state will die, according to the American Cancer Society.

Currently, 22 clinical trials of new cancer medicines are recruiting patients in Maine. Biopharmaceutical companies are collaborating on the tests with such prominent institutions as the **Maine Center for Cancer Medicine** with several locations in the state, **Eastern Maine Medical Center Cancer Care** in Bangor, **Mercy Hospital** in Portland and the **Maine Medical Center** in Scarborough.

Diabetes affects more than 25 million Americans—about 8 percent of the U.S. population—including 7 million people who are unaware they have the disease. About 120,000 Maine adults have diabetes, including more than 32,000 who have not been diagnosed, according to the Maine Department of Health and Human Services.

Currently, 14 diabetes clinical tests are seeking patients in Maine. The trials are being conducted at **Penobscot Bay Neurology** and **Penobscot Bay Medical Center** in Rockport, **Maine Research Associates** in Auburn and **Northeast Cardiology Associates** in Auburn.

Heart disease and stroke are the first and fourth leading disease causes of death in the United States and in Maine. According to the American Heart Association, more than 82 million Americans are affected by these

diseases. In Maine, in 2009, nearly 2,700 residents died from some form of heart disease and 647 died from a stroke, according to the U.S. Centers for Disease Control and Prevention.

Currently, 10 heart disease and five stroke clinical tests are seeking patients in Maine. The trials are being conducted at **Maine Research Associates** in Auburn, the **Maine Medical Center** in Portland, **Northeast Cardiology Associates** in Bangor, and **Penobscot Bay Neurology** in Rockport.

Mental illness affects nearly 60 million Americans suffering from some form of the disease—from anxiety to depression to schizophrenia to eating disorders. In Maine, more than 51,000 adults live with serious mental illness and about 13,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness.

Currently, one clinical trial is recruiting patients in Scarborough.

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 medicines in development is also available on www.phrma.org, the web site of the Pharmaceutical Research and Manufacturers of America (PhRMA), under “Related Content” in the “Innovation” section.

“Clinical trials are at the heart of medical advances. Participating in research allows people with arthritis to help researchers find better treatments for others in the future.”

—Margaret Duffy
Public Health and Advocacy
Arthritis Foundation
New England Region

New Generation Medicines in Development

Some of the medicines being tested in Maine are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of medicines and vaccines today. And Maine is one of the states where new-generation 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 it and eventually 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.

Many of the medicines in clinical testing at Maine's medical school and research centers feature these technologies.

For example:

- A recombinant fusion protein to treat diabetic macular edema.
- A monoclonal antibody in the pipeline targets lupus and various types of cancer.

These are only a portion of the examples of new ways the nation's biopharmaceutical companies and Maine research institutions are working together to attack disease. The biotechnology medicines and vaccines in development are helping to expand the frontiers of science and potentially bring more and better treatments to patients.

“Our center sponsors more than 40 clinical trials for adults with cancer and 30 clinical trials for children with cancer. We believe Maine citizens should have access to the most important new cancer treatments that are being developed. The best way to do this is to bring clinical trials to patients in Maine, rather than referring patients out of state. We are working to make these important new treatments available to all patients across the state of Maine.”

—Thomas Openshaw, M.D.
Head, Oncology Research
Eastern Maine Medical Center Cancer Care

Conclusion

Biopharmaceutical companies' close collaboration with clinicians and research institutions in Maine 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 University of New England's medical school, the state's 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, Mainers considering participation in clinical trials have a wide range of choices, including 57 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 57 clinical trials of new chronic disease drugs recruiting patients in Maine. These trials target the top most debilitating chronic conditions—cancer, heart disease, stroke, asthma, diabetes and mental illnesses.

Active Clinical Trials in Maine Communities						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Auburn	—	1	3	5	—	2
Bangor	5	4	4	4	—	2
Biddeford	—	1	—	2	—	2
Lewiston	—	2	—	—	—	—
Portland	—	2	5	4	—	2
Rockport	—	—	3	2	—	2
Scarborough	—	11	—	—	1	—

Source: www.clinicaltrials.gov

Note: Search criteria = Maine, Phase I, II; industry only. Search performed 4/5/2013. See Appendix for detailed information about these clinical trials. The numbers in these disease columns are not the same as the 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

Eastern Maine Healthcare Systems, Brewer
Eastern Maine Medical Center Cancer Care, Bangor
Maine Center for Cancer Medicine, Biddeford,
Brunswick, Sanford, Scarborough
MaineGeneral Health, Harold Alfond Center for
Cancer Care, Augusta
Maine Medical Center, Scarborough
Mercy Hospital, Portland

Diabetes—Leading Institutions Conducting Clinical Trials

Acadia Clinical Research LLC, Bangor
Maine Research Associates, Auburn
Northeast Cardiology Associates, Bangor
Penobscot Bay Medical Center, Clinical Research,
Rockport
Penobscot Bay Neurology, Rockport

Heart Disease and Stroke—Leading Institutions Conducting Clinical Trials

Acadia Clinical Research LLC, Bangor
Maine Medical Center, Portland
Maine Research Associates, Auburn
Northeast Cardiology Associates, Bangor
Penobscot Bay Neurology, Rockport

Stroke—Leading Institutions Conducting Clinical Trials

Penobscot Bay Neurology, Rockport

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

(5 clinical trials recruiting)

Study 1:

A Study of the Effectiveness and Safety of Different Doses of Fluticasone Propionate Taken From a Dry Powder Inhaler in Adolescents and Adults Who Have Asthma That is Not Controlled by Asthma Medications Not Containing Steroids

<http://ClinicalTrials.gov/show/NCT01479621>

Study 2:

A Study of the Effectiveness and Safety of Different Doses of Fluticasone Propionate Taken From a Dry Powder Inhaler (Puffer) in Adolescents and Adults Who Have Asthma That is Not Controlled by High Dose Inhaled Corticosteroid Asthma Medications

<http://ClinicalTrials.gov/show/NCT01576718>

Study 3:

A Study to Evaluate the Efficacy and Safety of Reslizumab (3.0 mg/kg) in the Reduction of Clinical Asthma Exacerbations in Patients (12-75 Years of Age) With Eosinophilic Asthma

<http://ClinicalTrials.gov/show/NCT01285323>

Study 4:

Efficacy of Inhaled Albuterol Spiromax® in Subjects With Persistent Asthma

<http://ClinicalTrials.gov/show/NCT01747629>

Study 5:

Dose Finding Study for QAW039 in Asthma

<http://ClinicalTrials.gov/show/NCT01437735>

Cancer

(22 clinical trials recruiting)

Study 1:

A Study of Pertuzumab in Addition to Chemotherapy and Herceptin (Trastuzumab) as Adjuvant Therapy in Patients With HER2-Positive Primary Breast Cancer

<http://ClinicalTrials.gov/show/NCT01358877>

Study 2:

A Clinical Trial Testing The Efficacy Of Crizotinib Versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin In Patients With ALK Positive Non Squamous Cancer Of The Lung

<http://ClinicalTrials.gov/show/NCT01154140>

Study 3:

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

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

Study 4:

A Study in Second Line Metastatic Colorectal Cancer

<http://ClinicalTrials.gov/show/NCT01183780>

Study 5:

Study of MEDI-573 Plus Standard Endocrine Therapy for Women With Hormone-sensitive Metastatic Breast Cancer

<http://ClinicalTrials.gov/show/NCT01446159>

Study 6:

Study of Bevacizumab/mFOLFOX6 Versus Bevacizumab/Folfiri With Biomarker Stratification in Patients With Previously Untreated Metastatic Colorectal Cancer

<http://ClinicalTrials.gov/show/NCT01374425>

Study 7:

A Study of Avastin (Bevacizumab) in Combination With Standard of Care Treatment in Patients With Lung Cancer

<http://ClinicalTrials.gov/show/NCT01351415>

Study 8:

A Study of Paclitaxel With GDC-0941 Versus Paclitaxel With Placebo in Patients With Locally Recurrent or Metastatic Breast Cancer

<http://ClinicalTrials.gov/show/NCT01740336>

Study 9:

A Study of Trastuzumab-MCC-DM1 in Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer

<http://ClinicalTrials.gov/show/NCT01120561>

Study 10:

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 AM2)

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

Study 11:

Trial of Eribulin/Cyclophosphamide or Docetaxel/Cyclophosphamide as Neoadjuvant Therapy in Locally Advanced HER2-Negative Breast Cancer

<http://ClinicalTrials.gov/show/NCT01527487>

Study 12:

Trial of Eribulin in Patients Who Do Not Achieve Pathologic Complete Response (pCR) Following Neoadjuvant Chemotherapy

<http://ClinicalTrials.gov/show/NCT01401959>

Study 13:

Effect of NovoTTF-100A Together With Temozolomide in Newly Diagnosed Glioblastoma Multiforme (GBM)

<http://ClinicalTrials.gov/show/NCT00916409>

Study 14:

A Study to Investigate the Efficacy and Safety of Bendamustine Compared With Bendamustine+RO5072759 (GA101) in Patients With Rituximab-Refractory, Indolent Non-Hodgkin's Lymphoma (GADOLIN)

<http://ClinicalTrials.gov/show/NCT01059630>

Study 15:

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

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

Study 16:

Bendamustine and Rituximab Followed by 90-yttrium (Y) Ibritumomab Tiuxetan for Untreated Follicular Lymphoma

<http://ClinicalTrials.gov/show/NCT01234766>

Study 17:

Study of Cabozantinib (XL184) Versus Prednisone in Men With Metastatic Castration-resistant Prostate Cancer Previously Treated With Docetaxel and Abiraterone or MDV3100 (COMET-1)

<http://ClinicalTrials.gov/show/NCT01605227>

Study 18:

A Study of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy in Patients With HER2-Positive Breast Cancer Who Have Residual Tumor in the Breast or Axillary Lymph Nodes Following Preoperative Therapy (KATHERINE)

<http://ClinicalTrials.gov/show/NCT01772472>

Study 19:

A Global Study to Compare the Effects of Fulvestrant and Arimidex in a Subset of Patients With Breast Cancer (FALCON)

<http://ClinicalTrials.gov/show/NCT01602380>

Study 20:

A Phase II Study of Everolimus in Combination With Exemestane Versus Everolimus Alone Versus Capecitabine in Advance Breast Cancer (BOLERO-6)

<http://ClinicalTrials.gov/show/NCT01783444>

Study 21:

Phase 2 Study of Maintenance OSI-906 Plus Erlotinib (Tarceva®), or Placebo Plus Erlotinib in Patients With Nonprogression Following 4 Cycles of Platinum-based Chemotherapy

<http://ClinicalTrials.gov/show/NCT01186861>

Study 22:

Study Comparing the Efficacy of MEK162 Versus Dacarbazine in Unresectable or Metastatic NRAS Mutation-positive Melanoma

<http://ClinicalTrials.gov/show/NCT01763164>

Diabetes

(14 clinical trials recruiting)

Study 1:

A Study of BMS-512148 (Dapagliflozin) in Patients With Type 2 Diabetes With Inadequately Controlled Hypertension on an ACEI or ARB and an Additional Antihypertensive Medication

<http://ClinicalTrials.gov/show/NCT01195662>

Study 2:

Study to Assess Safety & Efficacy of Sitagliptin as Initial Monotherapy for Treatment of Type 2 Diabetes Mellitus in Pediatric Participants (MK-0431-083)

<http://ClinicalTrials.gov/show/NCT01485614>

Study 3:

A Study of BMS-512148 (Dapagliflozin) in Patients With Type 2 Diabetes With Inadequately Controlled Hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB)

<http://ClinicalTrials.gov/show/NCT01137474>

Study 4:

BI 10773 Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus Patients

<http://ClinicalTrials.gov/show/NCT01131676>

Study 5:

Exenatide Study of Cardiovascular Event Lowering Trial (EXSCEL): A Trial To Evaluate Cardiovascular Outcomes After Treatment With Exenatide Once Weekly In Patients With Type 2 Diabetes Mellitus

<http://ClinicalTrials.gov/show/NCT01144338>

Study 6:

Study of TAK-875 in Adults With Type 2 Diabetes and Cardiovascular Disease or Risk Factors for Cardiovascular Disease

<http://ClinicalTrials.gov/show/NCT01609582>

Study 7:

A Study Comparing Dulaglutide With Insulin Glargine on Glycemic Control in Participants With Type 2 Diabetes (T2D) and Moderate or Severe Chronic Kidney Disease (CKD)

<http://ClinicalTrials.gov/show/NCT01621178>

Study 8:

A Study of the Safety and Efficacy of MK-0431A in Pediatric Participants With Type 2 Diabetes Mellitus (MK-0431A-170 AM1)

<http://ClinicalTrials.gov/show/NCT01472367>

Study 9:

A Study to Evaluate Safety and Efficacy of TTP054 for 12 Weeks in Subjects With Type 2 Diabetes

<http://ClinicalTrials.gov/show/NCT01665352>

Study 10:

A 16 Weeks Study on Efficacy and Safety of Two Doses of Empagliflozin (BI 10773) (Once Daily Versus Twice Daily) in Patients With Type 2 Diabetes Mellitus and Preexisting Metformin Therapy

<http://ClinicalTrials.gov/show/NCT01649297>

Study 11:

A Study on The Potential of Alogliptazir to Reduce Cardiovascular Risk in Patients With Stable Cardiovascular Disease and Glucose Abnormalities

<http://ClinicalTrials.gov/show/NCT01715818>

Study 12:

Insulin Resistance Intervention After Stroke Trial

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

Study 13:

Acthar for Treatment of Proteinuria in Diabetic Nephropathy Patients

<http://ClinicalTrials.gov/show/NCT01601236>

Study 14:

A Study of the Safety and Efficacy of MK-3102 Compared With Glimperiride in Participants With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin (MK-3102-016 AM1)

<http://ClinicalTrials.gov/show/NCT01682759>

Heart Disease (10 clinical trials recruiting)

Study 1:

Prevention of Cardiovascular Events (eg, Death From Heart or Vascular Disease, Heart Attack, or Stroke) in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin

<http://ClinicalTrials.gov/show/NCT01225562>

Study 2:

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

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

Study 3:

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

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

Study 4:

A Phase 3 Multi-center Study to Assess PET Imaging of Flurpiridaz F 18 Injection in Patients With CAD

<http://ClinicalTrials.gov/show/NCT01347710>

Study 5:

Ranolazine for Incomplete Vessel Revascularization Post-Percutaneous Coronary Intervention (PCI)

<http://ClinicalTrials.gov/show/NCT01442038>

Study 6:

Clinical Outcomes Assessment of the MitraClip Therapy Percutaneous Therapy for High Surgical Risk Patients

<http://ClinicalTrials.gov/show/NCT01626079>

Study 7:

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

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

Study 8:

Insulin Resistance Intervention After Stroke Trial

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

Study 9:

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>

Study 10:

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

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

Mental Illness

(1 clinical trial recruiting)

Study 1:

A Study of the Safety and Tolerability of Pimavanserin (ACP-103) in Patients With Parkinson's Disease Psychosis

<http://ClinicalTrials.gov/show/NCT00550238>

Stroke

(5 clinical trials recruiting)

Study 1:

Prevention of Cardiovascular Events (eg, Death From Heart or Vascular Disease, Heart Attack, or Stroke) in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin

<http://ClinicalTrials.gov/show/NCT01225562>

Study 2:

Insulin Resistance Intervention After Stroke Trial

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

Study 3:

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

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

Study 4:

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

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

Study 5:

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

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



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