

# Research in Your Backyard

Developing Cures, Creating Jobs



**PHARMACEUTICAL  
CLINICAL TRIALS IN  
MONTANA**

Dots show locations of clinical trials in the state.

# Executive Summary

## Clinical Trials in Montana

- Biopharmaceutical research companies are conducting or have conducted more than 800 clinical trials of new medicines in collaboration with the state's clinical research centers and hospitals (1999 to present).
- Of the more than 800 clinical trials, 469 target the nation's six most debilitating chronic diseases — **asthma, cancer, diabetes, heart disease, mental illnesses and stroke.**

## Economic Benefits of Clinical Trials in Montana

- Biopharmaceutical research companies have been a source of jobs, tax revenue and research spending in Montana.
- Governor Bullock's Office of Economic Development estimates that as of 2011 the bioscience industry generated 7,000 jobs in the state—1,700 direct jobs and 5,300 indirect jobs.
- Further, a study by Battelle Technology Partnership Practice found wages and benefits for employees working directly for the biopharmaceutical sector resulted in about \$15 million in federal taxation and \$2 million in state and local taxes in 2011.
- Battelle also found the biopharmaceutical research

*“The future of disease treatment depends entirely on the clinical trials process. Their aim is to get faster, better, more effective therapies to patients. As a patient advocate, I know these trials have the potential to mitigate and eventually eradicate the devastating impact of diseases like Alzheimer's, cancer, and heart disease. Patients and their families can hope to live longer and healthier lives because of research being conducted in Montana and around the world.”*

—Suzanne Belser  
Executive Director  
Alzheimer's Association Montana Chapter

companies generated \$451 million in goods and services in the state, including the direct economic output of the sector itself, the output of the sector's vendors and suppliers and the output generated by the buying power of its workforce.

- Company employees in Montana 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 support the jobs of their vendors

*“Clinical trials in Montana allow patients access to cutting edge research, treatment and quality care. In addition to the human impact, they also have a significant economic impact that benefits all Montanans. As of 2011, the biotechnology industry created 1,700 direct and 5,300 indirect jobs in Montana with an average salary of \$49,500. These numbers reflect the fact that the clinical research not only shapes the future of disease treatment, but also employs Montanans and stimulates our economy.”*

—Sharon Peterson  
Executive Director  
Montana Bioscience Alliance

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 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 Montana since 1999— Completed and Active

| All Clinical Trials | Six Major Chronic Diseases |
|---------------------|----------------------------|
| 818                 | 469                        |

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
Note: Search criteria = Montana, United States; Phase 0, 1, 2, 3; industry only.  
Search performed 8/14/2013.

## 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 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 throughout Montana.

| Clinical Trials in Montana Communities |        |        |          |               |                |        |
|--|--------|--------|----------|---------------|----------------|--------|
| Location                               | Asthma | Cancer | Diabetes | Heart Disease | Mental Illness | Stroke |
| Billings                               | 1      | 29     | 9        | 3             | 1              | 3      |
| Bozeman                                | 1      | 4      | —        | —             | —              | —      |
| Butte                                  | —      | 2      | 2        | 1             | —              | 1      |
| Great Falls                            | —      | 5      | 2        | 2             | —              | 2      |
| Helena                                 | —      | 2      | —        | —             | —              | —      |
| Kalispell                              | —      | 5      | 3        | 5             | —              | 2      |
| Missoula                               | 2      | 9      | 1        | 1             | 1              | —      |

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

Note: Search criteria = Montana, United States; Phase 0, 1, 2, 3; industry only. Search performed 8/14/2013. 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.**

- Since 1999, biopharmaceutical research companies are sponsoring or have sponsored 469 clinical trials of potential new medicines in Montana alone for **asthma, cancer, heart disease, stroke, diabetes and mental illnesses**. Of these trials, 61 are either not yet recruiting or are just now seeking Montana patients. The 61 trials are being conducted at several sites in Montana.
- Biopharmaceutical companies are collaborating on the tests with prominent institutions like the **Frontier Cancer Center and Blood Institute**, the

**Billings Clinic** and the **Montana Health Research Institute** in Billings, the **Bozeman Deaconess Hospital Cancer Center** in Bozeman, **Glacier View Research Institute** in Kalispell, **Saint James Community Hospital Cancer Treatment Center** in Butte, **Saint Peter’s Community Hospital** in Helena and **Saint Patrick Hospital** in Missoula.

- Some of the medicines being clinically tested in Montana are new-generation biotechnology treatments.

| Clinical Trials for Top Chronic Diseases |                     |                                  |
|--|---------------------|----------------------------------|
| Chronic Disease                          | All Clinical Trials | Clinical Trials Still Recruiting |
| Asthma                                   | 37                  | 4                                |
| Cancer                                   | 218                 | 31                               |
| Diabetes                                 | 125                 | 12                               |
| Heart Disease                            | 45                  | 8                                |
| Mental Illness                           | 22                  | 2                                |
| Stroke                                   | 22                  | 4                                |
| <b>Total</b>                             | <b>469</b>          | <b>61</b>                        |

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

Note: Search criteria = Montana, United States; Phase 0, 1, 2, 3; industry only. Search performed 8/14/2013. **Some clinical trials appear in more than one disease category.**

# Clinical Trials in Montana

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 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 is 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.

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Note: Search criteria = Montana, United States; Phase 0, 1, 2, 3; industry only. Search performed 8/14/2013. **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.

**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 Montana, with more than 9 percent of adults and nearly 7 percent of children suffering from asthma, according to the Montana Department of Public Health and Human Services.

Currently, four clinical trials of new asthma medicines are recruiting patients in Montana. Trials are being conducted in **Billings, Bozeman** and **Missoula**.

**Cancer**, the second leading cause of death in the United States, now afflicts nearly 14 million Americans, according to the National Cancer Institute. In Montana, nearly 5,500 new cancer cases will be diagnosed this year and 2,000 victims in the state will die, according to the American Cancer Society.

Currently, 31 clinical trials of new cancer medicines are recruiting patients in Montana. Biopharmaceutical companies are collaborating on the tests with such prominent institutions as the **Frontier Cancer Center and Blood Institute** and the **Billings Clinic Cancer Center** in Billings, the **Bozeman Deaconess Hospital Cancer Center** in Bozeman, **Glacier View Research Institute** in Kalispell, **Saint James Community Hospital Cancer Treatment Center** in Butte, **Saint Peter's Community Hospital** in Helena and **Saint Patrick Hospital** in Missoula.

**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 Montana, an estimated 33,000 residents have been diagnosed with diabetes, according to the Montana Department of Public Health and Human Services. In 2011, 246 Montanans died from diabetes.

Currently, 12 diabetes clinical tests are seeking patients in Montana. The trials are being conducted at the **Billings Clinical Research Center** in Billings, **Advanced Neu-**

**rology Specialists** in Great Falls and at locations in **Butte** and **Kalispell**.

**Heart disease and stroke** are the first and fourth leading disease causes of death in the United States and the second and fourth in Montana. According to the American Heart Association, more than 82 million Americans are affected by these diseases. In Montana, in 2011, more than 1,900 residents died from some form of heart disease and 451 died from a stroke, according to the Montana Department of Public Health and Human Services.

Currently, eight heart disease and four stroke clinical tests are seeking patients in Montana. The trials are being conducted at the **Billings Clinic** in Billings, **Advanced Neurology Specialists** in Great Falls and at locations in **Butte, Kalispell** and **Missoula**.

**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 Montana, about 39,000 adults live with serious mental illness and about 10,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness.

Currently, two clinical trials for mental illness are recruiting patients in Montana. The trials are taking place at the **Montana Health Research Institute** in Billings and at locations in **Missoula**.

*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 and find better ways of using existing treatments. In Montana 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 doctors' offices, 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 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 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 the 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 Montana are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of new medicines and vaccines today. And Montana 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 it 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 which 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, and those that have already been tested at Montana hospitals and research centers, feature these technologies. For example:

- A recombinant fusion protein to treat diabetic macular edema and other types of macular edema with trials conducted in **Billings, Bozeman, Butte, Great Falls, Helena, Kalispell** and **Missoula**.
- A monoclonal antibody in the pipeline targets various types of cancer with trials being conducted at the **Billings Clinic**, the **Oncology Center of the Northern Rockies** and **St. Vincent Healthcare** in Billings, **Bozeman Deaconess Cancer Center** in Bozeman, the **Great Falls Clinic and Sletten Cancer Institute** in Great Falls, **St. Peter's Hospital** in Helena, **Kalispell Regional Medical Center** and **Glacier Oncology** in Kalispell, and the **Montana Cancer Center** in Missoula.

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 Montana, 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 Montana 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' hospitals and local contract research organizations, and the medicines being tested are sometimes cutting-edge cell and protein treat-

ments with the potential to be safer and more effective than older chemical compound drugs.

What's more, Montanans considering participation in clinical trials have a wide range of choices, including 61 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/<br>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 61 clinical trials of new chronic disease drugs recruiting patients in Montana. These trials target the most debilitating chronic conditions—cancer, heart disease, stroke, asthma, diabetes and mental illness.

| Clinical Trials in Montana Communities |        |        |          |               |                |        |
|--|--------|--------|----------|---------------|----------------|--------|
| Location                               | Asthma | Cancer | Diabetes | Heart Disease | Mental Illness | Stroke |
| Billings                               | 1      | 29     | 9        | 3             | 1              | 3      |
| Bozeman                                | 1      | 4      | —        | —             | —              | —      |
| Butte                                  | —      | 2      | 2        | 1             | —              | 1      |
| Great Falls                            | —      | 5      | 2        | 2             | —              | 2      |
| Helena                                 | —      | 2      | —        | —             | —              | —      |
| Kalispell                              | —      | 5      | 3        | 5             | —              | 2      |
| Missoula                               | 2      | 9      | 1        | 1             | 1              | —      |

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

Note: Search criteria = Montana, United States; Phase 0, 1, 2, 3; industry only. Search performed 8/14/2013. 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

Billings Clinical Cancer Center, Billings

Bozeman Deaconess Hospital Cancer Center,  
Bozeman

Five Valleys Urology, Missoula

Frontier Cancer Center and Blood Institute, Billings

Glacier View Research Institute, Kalispell

Hematology-Oncology Centers of the Northern  
Rockies, Billings

Kalispell Regional Medical Center, Kalispell

Montana Cancer Consortium, Billings

Montana Cancer Specialists, Missoula

Saint James Community Hospital and Cancer  
Treatment Center, Butte

Saint Patrick Hospital-Community Hospital, Missoula

Saint Peter's Community Hospital, Helena

Saint Vincent Healthcare, Billings

Sletten Cancer Institute-Benefits Healthcare, Great Falls

## Diabetes—Leading Institutions Conducting Clinical Trials

Advanced Neurology Specialists, Great Falls

Billings Clinic Research Center, Billings

## Heart Disease—Leading Institutions Conducting Clinical Trials

Advanced Neurology Specialists, Great Falls

Billings Clinic Research Center, Billings

## Mental Illness—Leading Institutions Conducting Clinical Trials

Montana Health Research Institute, Billings

## Stroke—Leading Institutions Conducting Clinical Trials

Advanced Neurology Specialists, Great Falls

Billings Clinic Research Center, Billings

# 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](http://www.clinicaltrials.gov), the clinical tests database of the National Institutes of Health.

## Asthma

(4 clinical trials recruiting)

### Study 1:

**An Evaluation of Dupilumab in Patients With Moderate to Severe Uncontrolled Asthma**

<http://ClinicalTrials.gov/show/NCT01854047>

### Study 2:

**Efficacy and Safety of QGE031 versus Placebo and Omalizumab in Patients Aged 18-75 Years With Asthma**

<http://ClinicalTrials.gov/show/NCT01716754>

### Study 3:

**Efficacy and Safety Comparison of Albuterol Spiromax<sup>®</sup> and ProAir<sup>®</sup> Hydrofluoroalkane (HFA) in Pediatric Patients**

<http://ClinicalTrials.gov/show/NCT01899144>

### Study 4:

**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

(31 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:

**Comparison of Cabazitaxel/Prednisone Alone or in Combination With Custirsen for 2nd Line Chemotherapy in Prostate Cancer**

<http://ClinicalTrials.gov/show/NCT01578655>

### Study 4:

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

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

### Study 5:

**A Study of MEK162 vs. Physician's Choice Chemotherapy in Patients With Low-grade Serous Ovarian, Fallopian Tube or Peritoneal Cancer**

<http://ClinicalTrials.gov/show/NCT01849874>

### Study 6:

**A Study in Second Line Metastatic Colorectal Cancer**

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

### Study 7:

**Study for Women With Platinum Resistant Ovarian Cancer Evaluating EC145 in Combination With Doxil® (PROCEED)**

<http://ClinicalTrials.gov/show/NCT01170650>

### Study 8:

**Sativex® for Relieving Persistent Pain in Patients With Advanced Cancer**

<http://ClinicalTrials.gov/show/NCT01361607>

### Study 9:

**A Phase II Study of Everolimus in Combination With Exemestane Versus Everolimus Alone Versus Capecitabine in Advanced Breast Cancer**

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

### Study 10:

**Study of the Effect of GTx-758 on Serum PSA and Testosterone in Men With Prostate Cancer**

<http://ClinicalTrials.gov/show/NCT01615120>

### Study 11:

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

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

### Study 12:

**A Study of MPDL3280A Compared With Docetaxel in Patients With Non-Small Cell Lung Cancer After Platinum Failure**

<http://ClinicalTrials.gov/show/NCT01903993>

### Study 13:

**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 AM3)**

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

### Study 14:

**NOLAN: Naproxen or Loratadine and Neulasta**

<http://ClinicalTrials.gov/show/NCT01712009>

### Study 15:

**A Study of VGX-3100 DNA Vaccine With Electroporation in Patients With Cervical Intraepithelial Neoplasia Grade 2/3 or 3**

<http://ClinicalTrials.gov/show/NCT01304524>

### Study 16:

**Gemcitabine and ON 01910.Na in Previously Untreated Metastatic Pancreatic Cancer**

<http://ClinicalTrials.gov/show/NCT01360853>

### Study 17:

#### Continued HER2 Suppression With Lapatinib Plus Trastuzumab Versus Trastuzumab Alone

<http://ClinicalTrials.gov/show/NCT00968968>

### Study 18:

#### S0820, Adenoma and Second Primary Prevention Trial

<http://ClinicalTrials.gov/show/NCT01349881>

### Study 19:

#### 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 20:

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

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

### Study 21:

#### Recombinant Vaccinia Virus Administered Intravenously in Patients With Metastatic, Refractory Colorectal Carcinoma

<http://ClinicalTrials.gov/show/NCT01394939>

### Study 22:

#### A Study of LY2875358 in Non Small Cell Lung Cancer (NSCLC) Participants

<http://ClinicalTrials.gov/show/NCT01900652>

### Study 23:

#### 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 24:

#### Safety and Efficacy of Pomalidomide, Bortezomib and Low-dose Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma

<http://ClinicalTrials.gov/show/NCT01734928>

### Study 25:

#### Phase 3 Study of Carfilzomib, Melphalan, Prednisone vs. Bortezomib, Melphalan, Prednisone in Newly Diagnosed Multiple Myeloma (CLARION)

<http://ClinicalTrials.gov/show/NCT01818752>

### Study 26:

#### A Phase 3 Study Comparing Dinaciclib Versus Ofatumumab in Patients With Refractory Chronic Lymphocytic Leukemia (P07714 AM2)

<http://ClinicalTrials.gov/show/NCT01580228>

### Study 27:

#### A Study Being Conducted at Multiple Locations to Compare the Safety and Effectiveness of Three Different Treatment Regimens: 1) Lenalidomide, 2) Lenalidomide + Azacitidine, or 3) Azacitidine Alone in Newly Diagnosed Acute Myeloid Leukemia in Elderly Subjects ≥ 65 Years of Age

<http://ClinicalTrials.gov/show/NCT01358734>

### Study 28:

#### Phase II Phosphatidylinositol 3-Kinase (PI3K) Inhibitor in Relapsed, Indolent or Aggressive Non-Hodgkin's Lymphomas (NHL)

<http://ClinicalTrials.gov/show/NCT01660451>

### Study 29:

#### 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 30:

**A Study of Obinutuzumab (RO5072759) Plus Chemotherapy in Comparison With MabThera/Rituxan (Rituximab) Plus Chemotherapy Followed by GA101 or MabThera/Rituxan Maintenance in Patients With Untreated Advanced Indolent Non-Hodgkin's Lymphoma (GALLIUM)**

<http://ClinicalTrials.gov/show/NCT01332968>

### Study 31:

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

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

## Diabetes

(12 clinical trials recruiting)

### Study 1:

**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 2:

**Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of Saxagliptin as Monotherapy in Pediatric Patients With Type 2 Diabetes**

<http://ClinicalTrials.gov/show/NCT01204775>

### Study 3:

**Researching Cardiovascular Events With a Weekly Incretin in Diabetes (REWIND)**

<http://ClinicalTrials.gov/show/NCT01394952>

### Study 4:

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

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

### Study 5:

**A Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) in Combination With Metformin IR or Metformin XR in Pediatric Patients With Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Alone**

<http://ClinicalTrials.gov/show/NCT01434186>

### Study 6:

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

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

### Study 7:

**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 8:

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

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

### Study 9:

**Safety and Efficacy of CBX129801 in Patients With Type 1 Diabetes**

<http://ClinicalTrials.gov/show/NCT01681290>

### Study 10:

**Insulin Resistance Intervention After Stroke Trial**

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

### Study 11:

**Evaluation of Cardiovascular Outcomes in Patients With Type 2 Diabetes After Acute Coronary Syndrome During Treatment With AVE0010 (Lixisenatide)**

<http://ClinicalTrials.gov/show/NCT01147250>

### Study 12:

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

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

## **Heart Disease** (8 clinical trials recruiting)

### Study 1:

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

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

### Study 2:

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

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

### Study 3:

#### **Evaluation of Cardiovascular Outcomes in Patients With Type 2 Diabetes After Acute Coronary Syndrome During Treatment With AVE0010 (Lixisenatide)**

<http://ClinicalTrials.gov/show/NCT01147250>

### Study 4:

#### **A Study Exploring Two Strategies of Rivaroxaban and One of Oral Vitamin K Antagonist in Patients With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention**

<http://ClinicalTrials.gov/show/NCT01830543>

### Study 5:

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

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

### Study 6:

#### **Insulin Resistance Intervention After Stroke Trial**

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

### Study 7:

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

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

### Study 8:

#### **GLobal Assessment of Plaque reGression With a PCSK9 antibOdy as Measured by intraVascular Ultrasound**

<http://ClinicalTrials.gov/show/NCT01813422>

## **Mental Illness** (2 clinical trials 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>

### Study 2:

#### **Efficacy and Safety of TBS-2 Testosterone Gel in Women With Acquired Female Orgasmic Disorder**

<http://ClinicalTrials.gov/show/NCT01607658>

## **Stroke** (4 clinical trials recruiting)

### Study 1:

#### **Insulin Resistance Intervention After Stroke Trial**

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

### **Study 2:**

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

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

### **Study 3:**

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

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

### **Study 4:**

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

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



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