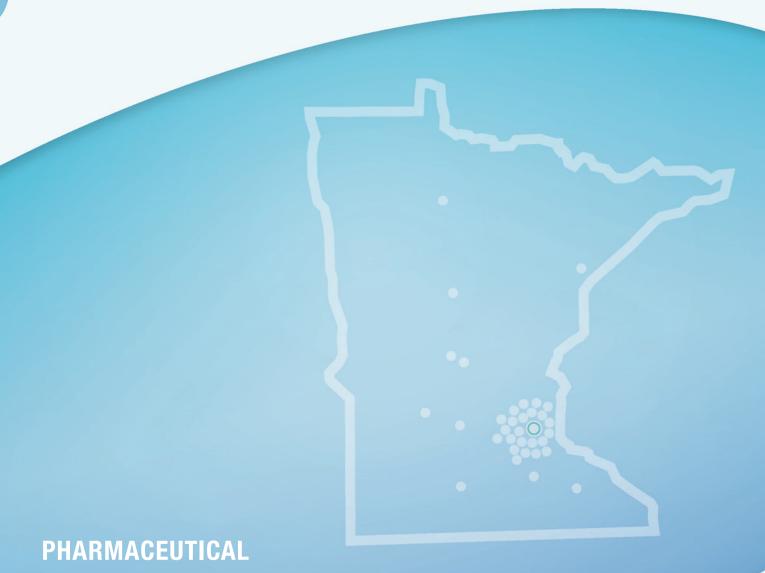
## Research in Your Backyard

**Developing Cures, Creating Jobs** 



PHARMACEUTICAL
CLINICAL TRIALS IN
MINNESOTA

Dots show locations of clinical trials in the state.



## **Executive Summary**

#### Clinical Trials in Minnesota

- Biopharmaceutical research companies have conducted more than 2,900 clinical trials of new medicines since 1999 in collaboration with the state's local research institutions, including the Clinical Research Institute in Minneapolis and Plymouth, Twin Cities Clinical Research/
   Prism Clinical Research in Brooklyn Center,
   Prism Clinical Research in St. Paul, MAPS
   Applied Research Center in Edina, Minnesota Diet Research Center/Frestedt Inc. in St. Louis Park, Mercy Hospital in Coon Rapids, St. Mary's Duluth Clinic in Duluth, St. Cloud Hospital in St. Cloud, St. Paul's Heart Clinic in St. Paul, the University of Minnesota School of Medicine in Minneapolis and the Mayo Clinic in Rochester.
- The trials have been aimed at a wide array of diseases and medical conditions, ranging from the most debilitating chronic diseases, including cancer, pain, heart disease, obesity and diabetes, to bothersome allergies, sinusitis, chronic obstructive pulmonary disease (COPD), migraine headaches, pneumonia and rare diseases affecting small patient populations.
- With so much clinical trial activity in the state, widespread public awareness of trials is a challenge which led to the formation of a unique coalition—the Minnesota Clinical Research Alliance (MCRA).

"Advancements in medicine would not be possible without individuals willing to volunteer their time to participate in clinical studies. The Minnesota Clinical Research Association (MCRA) is a collaboration of Minnesota based research institutions and professionals who are committed to objectively informing the general public to the benefits and risks involved in clinical research far beyond international and domestic regulations. MCRA members believe that a fully informed participant is critical to successful clinical research outcomes."

—Jeff Cosgrove, President Prism Clinical Research

- MCRA provides important clinical research education at a time when it is a challenge for biopharmaceutical and device companies and local research collaborators to recruit volunteers, and patients often don't know about trials of new drugs.
- Clinical trials in Minnesota have not only been good for patients, but also the state's economy and the advancement of science and overall patient health care.

"Clinical research brings together teams of hundreds of healthcare professionals, patients, suppliers, statisticians, monitors and other partners to carefully review how potential new treatments work in real people. MCRA makes sure we stay focused on the patient while creating awareness of the unique research environment Minnesota has to offer. We bring new clinical trials to patients every day, and we love what we do, because it makes a difference."

—Sarah Moeller, M.S., President The Greenlight Group, LLC

## MCRA—Making Patients Aware of Clinical Trials and Their Importance

- The MCRA was launched two years ago to educate the public, elected officials and the media about the importance of clinical research to patients and the health care system and the state's economy.
- A collaborative effort of key elements of the Minnesota medical research community, MCRA is dedicated to explaining research all over the state "in understandable terms."
- Alliance presentations, media meetings, opinion
  pieces and materials stress the patient safety
  protections built into the clinical trial system and
  how trials of new drugs and medical devices are
  helping to advance science and, ultimately, overall
  patient health care.
- MCRA also stresses the economic impact of clinical research on a state that, in 2010, had 11 percent of all of the clinical trials conducted in the United States. Minnesota also boasts the second highest number of medical technology jobs in the nation.

- In the words of Dr. Gary Berman of the Clinical Research Institute, an Alliance partner, the MCRA has chosen "to put collaboration above competition in the best interests of patients. We can all accomplish more by working together to promote the strength of research in Minnesota."
- Many of the partners in the MCRA are heavily involved in the clinical testing of new products in the state for a range of diseases, including infectious and respiratory conditions, cancer, asthma, migraine headaches, allergies and others.
- Some of the partners provide clinical research expertise and sophisticated equipment that enable biopharmaceutical companies and their local collaborators to conduct trials.
- To learn about the companies that make up the Alliance, visit the website www.mnclinicalresearch.org.
- The website address of each partner is provided and at each site, explanations in easy-to-read language are provided about the important work of each organization. On some sites, information is provided on trials recruiting patients, making them potentially important to some disease sufferers and their health care providers.
- MCRA partners include Agility Research,
   Courante Oncology, the Clinical Research Institute,
   Frestedt Inc., MAPS Applied Research Center
   (MARC), MEDTOX Laboratories, the Minnesota
   Center for Obesity, Metabolism & Endocrinology
   (MNCOME), Minnesota Diet Research Center
   (MDRC), Minnesota Gastroenterology, Prism
   Clinical Research, The Greenlight Group, LLC,
   and Twin Cities Clinical Research/Prism Clinical
   Research.
- The BioBusiness Alliance of Minnesota and LifeScience Alley, another bioscience support organization, collaborate with the Alliance as affiliates.

## About Clinical Trials and Why the MCRA Mission is Important

- According to a 2007 survey by CenterWatch, a company that publishes information on clinical trials, patient enrollment problems delay more than 70 percent of clinical trials from one to six months. Fewer than five percent of cancer patients participate in clinical trials. The educational efforts of the MCRA help to create more awareness and understanding of trials of new drugs, devices and food that gives Minnesota patients the opportunity to discuss becoming trial volunteers with their doctors.
- Delays in clinical trials mean drug development takes longer, costs more and patients have to wait for treatments they may desperately need.
- Clinical trials are conducted to help evaluate the safety and effectiveness of new products and generate the data the Food and Drug Administration needs to approve new treatments.
- Clinical tests of new drugs are conducted in three pre-approval phases and account for an average of seven of the 10 to 15 years required today to research and develop a new treatment. Trials involve thousands of volunteer patients and the generation of large volumes—sometimes tens of thousands of pages—of technical and scientific data.
- Clinical trials account for 45 to 75 percent of the average \$1.2 billion cost of developing one new

- biotechnology medicine and that's an important statistic considering that biopharmaceutical companies frequently hire local research institutions, such as members of the MCRA and the University of Minnesota School of Medicine, to conduct the tests.
- For some patients who are still seeking treatments that are best for them, clinical trials can be a potential therapeutic option to discuss with health care providers.
- Many medicines, devices and other products that have been clinically tested in Minnesota and other states are cutting-edge technologies with a strong potential to advance science and patient health care.
- Biotech medicines may be derived from novel biological processes that feature cells, genes and other living organisms. With biotechnology, we have the strong potential to develop safer and more effective treatments and we are improving our ability to predict and prevent diseases.
- From the standpoint of patient safety, clinical trials are rigorously reviewed and approved by an Institutional Review Board (IRB)—an independent committee of health care providers, social workers, statisticians, local patient advocates and others—to ensure trials protect patient rights, and safety and are ethically conducted. Many IRBs exist right here in the state of Minnesota.

## The Importance of Clinical Trials

Since 1999, more than 2,900 clinical trials have been conducted or are being conducted in Minnesota. The clinical trials have addressed many of the leading causes of death in the United States and in Minnesota, such as cancer, heart disease and diabetes. And they've targeted debilitating diseases that cause severe pain, such as psoriasis, rheumatoid arthritis, and epilepsy. Of these trials, 419 are either not yet recruiting or are just now seeking Minnesota patients. The 419 trials are being conducted at more than 550 sites in Minnesota.

All of these conditions contribute to health care spending in Minnesota.

- In 2010, health care spending in Minnesota was \$37.7 billion—for hospital care, physician services, long-term care, prescription drugs, dental services and other health care costs.
- Per capita spending on health care in Minnesota was \$7,090 in 2010, compared to the national average of \$7,900.
- In 2010, Minnesota was home to 11 percent of all clinical trials in the United States

Clinical Trials in Minnesota								
All Clinical Trials	Clinical Trials Still Recruiting							
2,945	419							

Source: www.clinicaltrials.gov

Note: Search criteria = Minnesota, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/27/2013.

#### Economic Benefits of Clinical Trials in Minnesota

- Biopharmaceutical research companies have been a source of jobs, tax revenue and research spending in Minnesota.
- A study by Battelle Technology Partnership Practice found that in 2011 the industry supported more than 31,000 jobs throughout the state.
- Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in about \$127 million in federal taxation and \$23 million in state and local taxes.
- Biopharmaceutical research companies supported the generation of \$7.4 billion in economic activity in the state two years ago, including the direct economic output of the sector itself, the output of

- the sector's vendors and suppliers and the output generated by the buying power of its workforce.
- Company employees in Minnesota include life sciences researchers, management executives, office and administrative support workers, production workers, engineers, architects, computer and math

experts and sales representatives. Biopharmaceutical companies, in 2011, 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.

Clinical Trials in Minnesota Communities												
Location	Arth	Ca	Crd	Crohn's	Dia	Ер	ID	K/L	Mental	Psor	Resp	Other
Brooklyn Ctr	_	_	1	_	_	_	_	_	_	_	_	_
Chaska	2	_	2	1	_	_	_	_	_	_	_	1
Duluth	1	3	6	_	2	_	2	1	_	_	_	_
Eagan	10	_	_	_	1	_	_	_	_	_	1	1
Edina	3	6	5	_	1	_	2	_	_	1	5	5
Fridley	_	2	1	_	_	_	_	_	_	10	6	1
Golden Valley	_	_		_	_	4	_	_	_	_	_	_
Minneapolis	_	62	42	5	5	6	20	14	2	1	31	8
Plymouth	_	_	_	7	_	1	1	1	_	_	6	1
Rochester	2	77	15	16	_	4	2	14	1	_	12	5
St. Louis Park	_	21	3	_	_	1	_	_	_	_	_	_
St. Cloud	_	3	10	_	2	_	1	_	_	_	_	_
St. Paul	_	4	8	3	4	6	4	5	1	_	_	1

Source: www.clinicaltrials.gov

Note: Search criteria = Minnesota, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/27/2013. 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. This list of cities and towns is representative and not a complete list of where clinical trials are taking place in Minnesota.

## Clinical Trials in Minnesota

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 research provides access to new and promising treatments for patients while connecting them with first rate care. At CRI, we are committed to helping patients today and in the future through cutting-edge research. We are passionate about the work we do and participating in MCRA allows us to draw attention to researchers across Minnesota who wake up every day with the goal of improving the lives of other Minnesotans."

—Gary D. Berman, M.D.
Clinical Research Institute

Clinical tests involve three phases, thousands of volunteer patients, and are often conducted at multiple sites around the country.

In Minnesota, biopharmaceutical companies are providing funds to have trials conducted at the state's well-respected medical schools, hospitals and clinical research organizations. According to *U.S. News and World Report*, Mayo Medical School ranked 27th and the University of Minnesota Medical School ranked 38th among this year's top 100 research-oriented medical schools in the United States.

Clinical Trials in Minnesota	
Disease	Clinical Trials Still Recruiting
Arthritis	15
Cancer	154
Cardiovascular Disease	58
Crohn's Disease/Ulcerative Colitis/ Gastrointestinal	24
Diabetes	10
Epilepsy/Neurological Disorders	21
Infectious Diseases	31
Kidney and Liver Disorders	32
Mental Illnesses	4
Psoriasis/Skin Disorders	11
Respiratory Disorders	35
Other Diseases	26

Source: www.clinicaltrials.gov

Note: Search criteria = Minnesota, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/27/2013. See Appendix for detailed information about these clinical trials. Some clinical trials appear in more than one disease category.

**Arthritis**, the most common cause of disability in the United States, affects about 50 million adults and 300,000 children, according to the Arthritis Foundation. In Minnesota, according to the Minnesota Department of Health (MDH), approximately 995,000 adults or 26 percent of Minnesota adults have arthritis. Arthritis consists of more than 100 different diseases or conditions affecting the joints, bones, muscles and other connective tissues.

There are 15 clinical trials recruiting patients in Minnesota for arthritis, specifically rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Trials are being conducted at **St. Paul Rheumatology** in **St. Paul and the Mayo Clinic** in Rochester, among others.

**Cancer**, the second leading cause of death in the United States, now afflicts nearly 14 million Americans, according to the National Cancer Institute. In Minnesota, more than 28,000 new cancer cases will be diagnosed this year and 9,610 victims in the state will die, according to the American Cancer Society.

Currently, 154 clinical trials of new cancer medicines are recruiting patients in Minnesota. Biopharmaceutical companies are collaborating on the tests with such institutions as the Mayo Clinical Cancer Center in Rochester, the Virginia Piper Cancer Institute at Abbott Northwestern Hospital and the Masonic Cancer Center at the University of Minnesota in Minneapolis, the Park Nicollet Fravenshuh Cancer Center in St. Louis Park, St. Luke's Hospital Association in Duluth, and the Regions Hospital Cancer Care Center in St. Paul.

**Cardiovascular Disease** is the leading cause of death in the United States and in Minnesota. According to the American Heart Association, more than 82 million Americans are affected by these diseases. In Minnesota, in 2011, more than 10,000 residents died from some form of cardiovascular disease, according to the Minnesota Department of Health.

Currently, 58 cardiovascular disease clinical tests are seeking patients in Minnesota. The trials are being conducted at the University of Minnesota and the Minneapolis Heart Institute at Abbott Northwestern Hospital in Minneapolis, MAPS Applied Research Center (MARC) in Edina, Minnesota Center for Obesity, Metabolism and Endocrinology (MNCOME) in Eagan, Prism Clinical Research and the St. Joseph Hospital in St. Paul, CentraCare Heart and Vascular Center in St. Cloud and the Park Nicollet Institute in St. Louis Park.

**Crohn's Disease and Ulcerative Colitis** (inflammatory bowel disease) affect 1.4 million Americans and are evenly split between the two, according to the Crohn's and Colitis Foundation of America. Other gastrointestinal disease medicine trials that are still recruiting patients in Minnesota are targeting GERD, chronic idiopathic constipation, celiac disease, irritable bowel syndrome and erosive esophagitis.

Currently, 24 clinical tests are seeking patients in Minnesota for Crohn's disease, ulcerative colitis, irritable bowel syndrome and other gastrointestinal disorders. The trials are being conducted at Minnesota Gastroenterology (MNGASTRO) in Plymouth, the Mayo Clinic in Rochester and Minnesota Colon & Rectal Surgery Associates in Minneapolis.

**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. About 290,000 adults have been diagnosed with diabetes and as many as 1.4 million adults have prediabetes in Minnesota, according to the Minnesota Department of Health.

Currently, 10 diabetes clinical tests are seeking patients in Minnesota. The trials are being conducted at the Twin Cities Clinical Research/Prism Clinical Research in Brooklyn Center, the International Diabetes Center/Maya Clinic in Minneapolis, Prism Clinical Research in St. Paul, Minnesota Center for Obesity, Metabolism and Endocrinology (MNCOME) in Eagan, and Radiant Research in Edina.

**Epilepsy** affects nearly 3 million Americans, according to the Epilepsy Foundation. The Epilepsy Foundation Minnesota estimates that one in 26 people will develop the disease at some point in their life. Other neurologic disorders targeted by clinical trials that are still recruiting include migraine, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, spinal cord injury and muscular dystrophies.

Currently, there are 21 clinical trials recruiting patients in Minnesota for neurologic disorders. The trials are underway at the Mayo Clinic in Rochester, the University of Minnesota in Minneapolis, MAPS Applied Research Center (MARC) in Edina, Prism Clinical Research and Gilette Children's Specialty Healthcare in St. Paul and the Minneapolis Clinic of Neurology in Golden Valley.

**Infectious Diseases**, both newly emerging and reemerging, caused more than 62,000 deaths in the United States in 2010, according to the U.S. Centers for Disease Control and Prevention. In 2011, 708 Minnesota residents died from infectious and parasitic diseases, according to the Minnesota Department of Health.

There are 31 clinical trials recruiting patients in Minnesota for infectious diseases, including, aspergillosis, herpes zoster, influenza, meningococcal disease, onychomycosis, candidiasis, HIV infection, urinary tract infections, intraabdominal infections, Hepatitis B, Hepatitis C, *Clostridium difficle* infections, and athlete's foot (tinea pedis). Trials are being conducted at Minnesota Gastroenterology (MNGASTRO) in St. Paul, the University of Minnesota and the Hennepin County Medical Center in Minneapolis, and the Mayo Clinic in Rochester.

**Kidney and Liver Diseases** are among the 15 leading causes of death in the United States and Minnesota. Clinical trials recruiting patients in Minnesota are aimed at polycystic kidney disease, end stage renal disease, liver failure, hepatic veno-occlusive disease, cirrhosis, chronic kidney disease, liver fibrosis, among others.

There are 32 clinical trials for kidney and liver diseases recruiting patients in Minnesota. Trials are underway at DaVita Clinical Research and the University of Minnesota in Minneapolis, Children's Hospitals and Clinics of Minnesota in St. Paul, the Mayo Clinic in Rochester, and Minnesota Gastroenterology (MNGASTRO) in Plymouth and St. Paul.

**Mental Illness** affects nearly 60 million Americans suffering from some form of the disease—from anxiety to depression to schizophrenia to eating disorders. In Minnesota, about 168,000 adults live with serious mental illness and about 56,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness.

Currently, four clinical trials are recruiting patients in Minnesota. The trials are being conducted at the University of Minnesota in Minneapolis and at locations in Rochester.

**Psoriasis** and other skin disorders affect about 7.5 million Americans. In Minnesota and estimated 140,000 residents suffer from psoriasis, according to the Psoriasis Foundation.

Currently, 11 clinical trials are recruiting patients in Minnesota for skin disorders such as plaque psoriasis, atopic dermatitis and acne. The trials are being conducted at the University of Minnesota in Minneapolis, Radiant Research in Edina and the Minnesota Clinical Study Center in Fridley.

Respiratory Disorders, such as asthma and chronic obstructive pulmonary disease (COPD), are the third leading cause of death in the United States and the fourth in Minnesota. Asthma affects more than 25 million Americans, including 7.1 million children under the age of 18. The toll is also severe in Minnesota—about 390,000 adults and children suffer from asthma, according to the Minnesota Department of Health. COPD, which includes chronic bronchitis and emphysema, affects more than 12.7 million Americans and in Minnesota 70,600 adults over the age of 45 have COPD.

Currently, 35 clinical trials of new respiratory disease medicines are recruiting patients in Minnesota. Trials are being conducted at the University of Minnesota and the Minnesota Lung Center in Minneapolis, the Clinical Research Institute in Plymouth, and the Mayo Clinic in Rochester.

**Other diseases and medical conditions** that are being targeted in Minnesota include:

- amyloidosis
- androgenic alopecia
- cataracts
- cervical dystonia
- endometriosis
- growth disorders
- hemophilia
- overactive bladder
- pigmented villonodular synovitis
- primary immunodeficiency diseases
- sarcopenia
- uveitis

Currently, there are 26 clinical trials recruiting patients for these diseases. The trials are underway at the Mayo Clinic in Rochester, the Abbott Northwestern Hospital and the University of Minnesota in Minneapolis, Radiant Research in Edina, Prism Clinical Research in St. Paul, and Midwest Immunology Clinical and Infusion Center in Plymouth.

Physicians and patients can find out about clinical trials being conducted all over the state in collaboration with local institutions by accessing www.clinicaltrials.gov, a database sponsored by the National Institutes of Health. Information on clinical trials and medicines in development is also available on www.phrma.org, the website of the Pharmaceutical Research and Manufacturers of America (PhRMA). Click on Innovation, Clinical Trials and then Research in Your Backyard.

## New Generation Medicines in Development

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

America's biopharmaceutical research companies are using biotechnology to develop hundreds of new medicines and vaccines today. And Minnesota 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 Minnesota hospitals and research centers feature these technologies.

#### For example:

- A genetically-modified virus-based vaccine to treat melanoma with clinical trials conducted at the Hubert H. Humphrey Cancer Center in Robbinsdale.
- A recombinant fusion protein to treat diabetic macular edema is being studied at the Retina Center in Minneapolis and the Mayo Clinic in Rochester.
- A therapeutic vaccine, designed to jump-start the immune system to fight disease, is in development for lung cancer and melanoma with clinical trials ongoing in Fridley, Maplewood, Minneapolis, Rochester and St. Louis Park.
- A monoclonal antibody in the pipeline that targets non-Hodgkin's lymphoma is in trials at the Mayo Clinic in Rochester

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 Minnesota, 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 Minnesota 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, Minnesotans considering participation in clinical trials have a wide range of choices, including 419 tests of new medicines for the most chronic and most debilitating 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		Phase III		FDA		Phase IV		
Years	6.5		1.5	2	3.5		1.5				
Test Population	animal studies	ND at FDA	20 to 80 healthy volunteers	100 to 300 patient volunteers	1,000 to 3,000 patient volunteers	/BLA at FD/	Review		Additional post-		
Purpose		File IN		Determine safety and dosage	Evaluate effective- ness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use	File NDA/	process/ approval		marketing testing required by FDA	
Success Rate	5,000 compounds evaluated				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 419 clinical trials of new medicines recruiting in Minnesota. These trials target many of the chronic and debilitating diseases affecting Americans and Minnesotans.

Clinical Trials in Minnesota Communities												
Location	Arth	Ca	Crd	Crohn's	Dia	Ер	ID	K/L	Mental	Psor	Resp	Other
Brooklyn Ctr	_	_	1	_	_	_	_	_	_	_	_	_
Chaska	2	_	2	1	_		_	_	_	_	_	1
Duluth	1	3	6	_	2	_	2	1	_	_	_	_
Eagan	10	_	_	_	1	_	_	_	_	_	1	1
Edina	3	6	5	_	1	_	2	_	_	1	5	5
Fridley	_	2	1	_	_	_	_	_	_	10	6	1
Golden Valley	_	_	_	_	_	4	_	_	_	_	_	_
Minneapolis	_	62	42	5	5	6	20	14	2	1	31	8
Plymouth		_	_	7	_	1	1	1	_	_	6	1
Rochester	2	77	15	16	_	4	2	14	1	_	12	5
St. Louis Park		21	3	_	_	1	_	_	_	_	_	_
St. Cloud		3	10	_	2	_	1	_	_	_	_	_
St. Paul	_	4	8	3	4	6	4	5	1	_	_	1

Source: www.clinicaltrials.gov

Note: Search criteria = Minnesota, United States; Phase 0, 1, 2, 3; industry only. Search performed 11/27/2013. 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. This list of cities and towns is representative and not a complete list of where clinical trials are taking place in Minnesota.

#### The Good News-Many Clinical Trials are Still Recruiting

(continued)

## Arthritis—Institutions Conducting Clinical Trials

Mayo Clinic, Rochester St. Paul Rheumatology, St. Paul

## Cancer—Institutions Conducting Clinical Trials

Abbott Northwestern Hospital, Minneapolis

CentraCare St. Cloud Hospital, St. Cloud

Children's Hospital & Clinics of Minnesota, Minneapolis

Fairview Ridges Hospital, Burnsville

Fairview Southdale Hospital, Edina

Hennepin County Medical Center, Minneapolis

Hutchinson Area Health Care, Hutchinson

John Nasseff Neuroscience Institute, Minneapolis

Lakeview Hospital, Stillwater

Mayo Clinic, Rochester

Mercy Hospital, Coon Rapids

Minnesota Oncology Associates, Coon Rapids, St. Paul

Minnesota Oncology Hematology, Edina, Maplewood,

Minneapolis, Woodbury

Minnesota VA Medical Center, Minneapolis

New Ulm Medical Center, New Ulm

North Memorial Hubert H. Humphrey Cancer

Center, Robbinsdale

Park Nicollet Fravenshuh Cancer Center, St. Louis Park

Regions Hospital-Healtheast, St. Paul

Rice Memorial Hospital, Willmar

Ridgeview Medical Center, Waconia

Sanford Clinic North, Bemidgi

St. Francis Regional Medical Center, Shakopee

St. John's Hospital, Maplewood

St. Luke's Hospital Whiteside Institute for Clinical Research. Duluth

St. Mary's Hospital-Mayo Clinic, Rochester

Unity Hospital, Fridley

University of Minnesota, Minneapolis

University of Minnesota Children's Hospital, Minneapolis Virginia Piper Cancer Institute-Abbott Northwestern Hospital, Minneapolis

Woodbury Clinic-CornerStone Medical Specialty Centre, Woodbury

## Cardiovascular Disease—Institutions Conducting Clinical Trials

Abbott Northwestern Hospital, Minneapolis

CentraCare Heart and Vascular Center, St. Cloud

Cub Pharmacy, Rosemont

Goodrich Pharmacy, Fridley, St. Francis

Hennepin County Medical Center, Minneapolis

Kemper Drug, Elk River

MAPS Applied Research Center (MARC), Edina

Mayo Clinic, Rochester

Minneapolis Clinic of Neurology, Robbinsdale

Minneapolis Heart Institute Foundation, Minneapolis

Minneapolis VA Health Care System, Minneapolis

Minnesota Center for Obesity, Metabolism and

Endocrinology (MNCOME), Eagan

Northfield Pharmacy, Northfield

Park Nicollet Institute/Methodist Hospital,

St. Louis Park

Prism Clinical Research, St. Paul

Radiant Research, Edina

St. Joseph's Hospital-Healtheast, St. Paul

St. Mary's Hospital, Mayo Clinic, Rochester

United Heart and Vascular Center, St. Paul

University of Minnesota, Minneapolis

## Crohn's Disease/Ulcerative Colitis—Institutions Conducting Clinical Trials

Mayo Clinic, Rochester

Minnesota Colon & Rectal Surgery Associates, Minneapolis

Minnesota Gastroenterology (MNGASTRO),

Plymouth

University of Minnesota, Minneapolis

#### The Good News-Many Clinical Trials are Still Recruiting

(continued)

## Diabetes—Institutions Conducting Clinical Trials

Children's Hospitals and Clinics of Minnesota, St. Paul Mayo Clinic International Diabetes Center, Minneapolis

Minnesota Center for Obesity, Metabolism and
Endocrinology (MNCOME), Eagan
Prism Clinical Research, St. Paul
Twin Cities Clinical Research/Prism Clinical
Research, Brooklyn Center

## **Epilepsy/Neurologic Disorders—Institutions Conducting Clinical Trials**

Clinical Research Institute, Minneapolis, Plymouth
Gilette Children's Specialty Healthcare, St. Paul
Hennepin County Medical Center/Berman Center
for Research, Minneapolis
MAPS Applied Research Center (MARC), Edina
Mayo Clinic, Rochester
Minneapolis Clinic of Neurology, Golden Valley
Minnesota Epilepsy Group, St. Paul
Prism Clinical Research, St. Paul
University of Minnesota, Minneapolis

## Infectious Diseases—Institutions Conducting Clinical Trials

Abbott Northwestern Hospital, Minneapolis
Hennepin County Medical Center, Minneapolis
Mayo Clinic, Rochester
Minnesota Gastroenterology (MNGASTRO), St. Paul
Minnesota VA Health Care System, Minneapolis
Prism Clinical Research, St. Paul
Radiant Research, Edina
University of Minnesota, Minneapolis

## Kidney and Liver Disorders—Institutions Conducting Clinical Trials

Children's Hospitals and Clinics of Minnesota, St. Paul DaVita Clinical Research, Minneapolis Mayo Clinic, Rochester

Minnesota Gastroenterology (MNGASTRO),
Plymouth, St. Paul

Prism Clinical Research, St. Paul

St. Mary's Medical Center, Duluth

Twin Cities Clinical Research/Prism Clinical
Research, Brooklyn Center

University of Minnesota, Minneapolis

## Mental Illness—Institutions Conducting Clinical Trials

University of Minnesota Medical Center, Minneapolis

## Respiratory Diseases—Institutions Conducting Clinical Trials

Clinical Research Institute, Minneapolis, Plymouth Mayo Clinic, Rochester Minnesota Lung Center, Minneapolis University of Minnesota, Minneapolis University of Minnesota Children's Hospital, Minneapolis

## Other Diseases—Institutions Conducting Clinical Trials

Abbott Northwestern Hospital, Minneapolis

Clinical Research Center, Plymouth
Frestedt Inc., Edina
Mayo Clinic, Rochester
Metro Urology, Woodbury
Midwest Immunology Clinic and Infusion Center,
Plymouth
Minnesota Center for Obesity, Metabolism and
Endocrinology (MNCOME), Eagan
Minnesota Diet Research Center (MDRC), Edina
Minnesota Eye Consultants, Bloomington
Prism Clinical Research, St. Paul
Radiant Research, Edina

Rehabilitation Consultants, Eagan University of Minnesota, Minneapolis

## **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**

(15 clinical trial recruiting)

#### Study 1:

Secukinumab Efficacy and Safety Study in Patients With Active Rheumatoid Arthritis (RA) and an Inadequate Response to Anti-TNF $\alpha$  Agents.

http://ClinicalTrials.gov/show/NCT01770379

#### Study 2:

A Study of CNTO 136 (Sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Patients With Active Rheumatoid Arthritis Despite Anti-TNF-Alpha Therapy

http://ClinicalTrials.gov/show/NCT01606761

#### Study 3:

Efficacy at 16 Weeks and Long Term Efficacy, Safety and Tolerability up to 5 Years of Secukinumab in Patients With Active Ankylosing Spondylitis

http://ClinicalTrials.gov/show/NCT01649375

#### Study 4:

A Study on the Impact of Methotrexate Discontinuation on the Efficacy of Subcutaneous RoActemra/Actemra (Tocilizumab) With Methotrexate in Patients With Moderate to Severe Active Rheumatoid Arthritis

http://ClinicalTrials.gov/show/NCT01855789

#### Study 5:

Long-Term Effectiveness And Safety Of CP-690,550 For The Treatment Of Rheumatoid Arthritis

http://ClinicalTrials.gov/show/NCT00413699

#### Study 6:

Safety and Efficacy of Extended Treatment With Secukinumab in Anti-TNF Inadequate Responders in RA

#### Study 7:

Efficacy at 24 Weeks and Safety, Tolerability and Long Term Efficacy up to 1 Year of Secukinumab (AIN457) in Patients With Active Rheumatoid Arthritis (RA) and an Inadequate Response to Anti-Tumor Necrosis Factor  $\alpha$  (Anti-TNF $\alpha$ ) Agents.

http://ClinicalTrials.gov/show/NCT01350804

#### Study 8:

Efficacy at 24 Weeks and Safety, Tolerability and Long Term Efficacy up to 2 Years of Secukinumab (AIN457) in Patients With Active Rheumatoid Arthritis and an Inadequate Response to Anti-TNFα Agents

http://ClinicalTrials.gov/show/NCT01377012

#### Study 9:

Efficacy at 24 Weeks With Long Term Safety, Tolerability and Efficacy up to 5 Years of Secukinumab (AIN457) in Patients of Active Psoriatic Arthritis (PsA)

http://ClinicalTrials.gov/show/NCT01752634

#### **Study 10:**

Extension Study up to 3 Years for Secukinumab in Psoriatic Arthritis

http://ClinicalTrials.gov/show/NCT01892436

#### **Study 11:**

Study to Evaluate the Long Term Efficacy, Safety and Tolerability of Secukinumab in Patients With Rheumatoid Arthritis

http://ClinicalTrials.gov/show/NCT01640938

#### **Study 12:**

Tofacitinib In Psoriatic Arthritis Subjects With Inadequate Response to TNF Inhibitors

http://ClinicalTrials.gov/show/NCT01882439

#### **Study 13:**

A Study of CNTO 136 (Sirukumab), Administered Subcutaneously, in Patients With Active Rheumatoid Arthritis Despite Disease-Modifying Antirheumatic Drug (DMARD) Therapy

http://ClinicalTrials.gov/show/NCT01604343

#### Study 14:

Dose-finding Study of GLPG0634 as add-on to Methotrexate in Active Rheumatoid Arthritis Patients (DARWIN1)

http://ClinicalTrials.gov/show/NCT01888874

#### **Study 15:**

Efficacy and Safety of Subcutaneous Abatacept in Adults With Active Psoriatic Arthritis

http://ClinicalTrials.gov/show/NCT01860976

#### Cancer

(154 clinical trials recruiting)

#### Study 1:

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

http://ClinicalTrials.gov/show/NCT01666444

#### Study 2:

Comparison of Pixantrone + Rituximab With Gemcitabine + Rituximab in Patients With Aggressive B-cell Non-Hodgkin Lymphoma or Follicular Grade 3 Lymphoma Who Have Relapsed After Therapy and Are Not Eligible for Stem Cell Transplant

http://ClinicalTrials.gov/show/NCT01321541

#### Study 3:

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

#### Study 4:

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

http://ClinicalTrials.gov/show/NCT00940602

#### Study 5:

Study of Efficacy and Safety of LEE011 in Postmenopausal Women With Advanced Breast Cancer

http://ClinicalTrials.gov/show/NCT01958021

#### Study 6:

DN24-02 as Adjuvant Therapy in Subjects With High Risk HER2+ Urothelial Carcinoma

http://ClinicalTrials.gov/show/NCT01353222

#### Study 7:

Efficacy Evaluation of TheraSphere Following Failed First Line Chemotherapy in Metastatic Colorectal Cancer

http://ClinicalTrials.gov/show/NCT01483027

#### Study 8:

A Study of Obinutuzumab (RO5072759) in Combination With CHOP Chemotherapy Versus MabThera/Rituxan (Rituximab) With CHOP in Patients With CD20-Positive Diffuse Large B-Cell Lymphoma (GOYA)

http://ClinicalTrials.gov/show/NCT01287741

#### Study 9:

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

http://ClinicalTrials.gov/show/NCT01763164

#### **Study 10:**

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

http://ClinicalTrials.gov/show/NCT01966471

#### Study 11:

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

http://ClinicalTrials.gov/show/NCT01582672

#### **Study 12:**

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

http://ClinicalTrials.gov/show/NCT01610284

#### **Study 13:**

PEGPH20 Plus Nab-Paclitaxel Plus Gemcitabine Compared With Nab-Paclitaxel Plus Gemcitabine in Subjects With Stage IV Untreated Pancreatic Cancer

http://ClinicalTrials.gov/show/NCT01839487

#### **Study 14:**

Phase 1/2, Open-label, Dose-escalation Study of ISIS-STAT3Rx, Administered to Patients With Advanced Cancers

http://ClinicalTrials.gov/show/NCT01563302

#### **Study 15:**

A Study of LY2090314 and Chemotherapy in Participants With Metastatic Pancreatic Cancer

http://ClinicalTrials.gov/show/NCT01632306

#### **Study 16:**

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

http://ClinicalTrials.gov/show/NCT01712217

#### **Study 17:**

Safety and Tolerability Study of SNS01-T in Relapsed or Refractory Multiple Myeloma, Mantle Cell Lymphoma, or Diffuse Large B Cell Lymphoma

#### **Study 18:**

Safety Study of Human Myeloid Progenitor Cells (CLT-008) After Chemotherapy for Leukemia

http://ClinicalTrials.gov/show/NCT01297543

#### Study 19:

ch14.18 Pharmacokinetic Study in High-risk Neuroblastoma

http://ClinicalTrials.gov/show/NCT01592045

#### Study 20:

Multiple Ascending Dose of BMS-911543

http://ClinicalTrials.gov/show/NCT01236352

#### **Study 21:**

Study of Brentuximab Vedotin Combined With Bendamustine in Patients With Hodgkin Lymphoma

http://ClinicalTrials.gov/show/NCT01874054

#### **Study 22:**

CNDO-109-AANK for AML in First Complete Remission (CR1)

http://ClinicalTrials.gov/show/NCT01520558

#### **Study 23:**

Safety and Tolerability of HSC835 in Patients Undergoing Single Umbilical Cord Blood Transplant

http://ClinicalTrials.gov/show/NCT01930162

#### **Study 24:**

Study of Veltuzumab and 90Y-Epratuzumab in Relapsed/Refractory, Aggressive NHL

http://ClinicalTrials.gov/show/NCT01101581

#### **Study 25:**

Safety and Tolerability of HSC835 in Patients With Hematological Malignancies

http://ClinicalTrials.gov/show/NCT01474681

#### Study 26:

Phase I/II Study of De-immunized DI-Leu16-IL2 Immunocytokine Administered Subcutaneously in Patients With B-cell NHL

http://ClinicalTrials.gov/show/NCT01874288

#### **Study 27:**

Study of US-ATG-F to Prevent Chronic Graft Versus Host Disease (GVHD)

http://ClinicalTrials.gov/show/NCT01295710

#### Study 28:

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

http://ClinicalTrials.gov/show/NCT01846611

#### Study 29:

A Phase I Study Evaluating ABT-199 in Subjects With Relapsed or Refractory Multiple Myeloma

http://ClinicalTrials.gov/show/NCT01794520

#### Study 30:

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

http://ClinicalTrials.gov/show/NCT01664923

#### Study 31:

Regorafenib as Adjuvant Therapy for Colorectal Cancer (CRC) With Resected Liver Metastases

http://ClinicalTrials.gov/show/NCT01939223

#### **Study 32:**

A Study Comparing Treatment With 177Lu-DOTA0-Tyr3-Octreotate to Octreotide LAR in Patients With Inoperable, Progressive, Somatostatin Receptor Positive Midgut Carcinoid Tumours

#### **Study 33:**

Study of Bortezomib and Dexamethasone With or Without Elotuzumab to Treat Relapsed or Refractory Multiple Myeloma

http://ClinicalTrials.gov/show/NCT01478048

#### **Study 34:**

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

http://ClinicalTrials.gov/show/NCT01262651

#### **Study 35:**

ECHELON-2: A Comparison of Brentuximab Vedotin and CHP With Standard-of-care CHOP in the Treatment of Patients With CD30-positive Mature T-cell Lymphomas

http://ClinicalTrials.gov/show/NCT01777152

#### **Study 36:**

A Study Evaluating BMN 673, a PARP Inhibitor, in Advanced and/or Metastatic Breast Cancer Patients With BRCA Mutation

http://ClinicalTrials.gov/show/NCT01945775

#### **Study 37:**

Phase 3 Frontline Therapy Trial in Patients With Advanced Classical Hodgkin Lymphoma

http://ClinicalTrials.gov/show/NCT01712490

#### **Study 38:**

A Study to Evaluate New or Worsening Lens Opacifications in Subjects With Non-metastatic Prostate Cancer Receiving Denosumab for Bone Loss Due to Androgen-Deprivation Therapy

http://ClinicalTrials.gov/show/NCT00925600

#### **Study 39:**

Safety and Efficacy Study of Bruton's Tyrosine Kinase Inhibitor in Subjects With Relapsed or Refractory Diffuse Large B-cell Lymphoma

http://ClinicalTrials.gov/show/NCT01325701

#### Study 40:

Efficacy and Safety of a Sunscreen Against Porfimer Sodium-induced Phototoxicity to Visible Light

http://ClinicalTrials.gov/show/NCT01256203

#### **Study 41:**

Safety and Efficacy Study of PRI-724 in Subjects With Advanced Solid Tumors

http://ClinicalTrials.gov/show/NCT01302405

#### Study 42:

A Phase 2, Multicenter, Randomized, Open-label Study of MEDI-551 in Adults With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

http://ClinicalTrials.gov/show/NCT01453205

#### Study 43:

Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)

http://ClinicalTrials.gov/show/NCT01844505

#### **Study 44:**

A Study of RO5424802 in Patients With Non-Small Cell Lung Cancer Who Have ALK Mutation and Failed Crizotinib Treatment

http://ClinicalTrials.gov/show/NCT01801111

#### **Study 45:**

Study of Brentuximab Vedotin Combined With RCHOP in Front-line Treatment of Patients With Diffuse Large B-cell Lymphoma (DLBCL)

http://ClinicalTrials.gov/show/NCT01925612

#### **Study 46:**

Study of INCB040093 in Subjects With Previously Treated B-Cell Malignancies

#### **Study 47:**

A Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients With Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer

http://ClinicalTrials.gov/show/NCT01968213

#### **Study 48:**

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

http://ClinicalTrials.gov/show/NCT01351415

#### **Study 49:**

Efficacy and Safety Study of Etodolac and Propranolol in Patients With Clinically Progressive Prostate Cancer

http://ClinicalTrials.gov/show/NCT01857817

#### **Study 50:**

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

http://ClinicalTrials.gov/show/NCT01689519

#### **Study 51:**

A Phase 1B Dose-escalation Study of TRC105 in Combination With Pazopanib in Patients With Advanced Soft Tissue Sarcoma

http://ClinicalTrials.gov/show/NCT01975519

#### **Study 52:**

MORAb-004 in Treating Young Patients With Recurrent or Refractory Solid Tumors or Lymphoma

http://ClinicalTrials.gov/show/NCT01748721

#### **Study 53:**

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

http://ClinicalTrials.gov/show/NCT01850524

#### Study 54:

Study of Imprime PGG® in Combination With Cetuximab in Subjects With Recurrent or Progressive KRAS Wild Type Colorectal Cancer

http://ClinicalTrials.gov/show/NCT01309126

#### Study 55:

Study of Cabozantinib (XL184) vs. Placebo in Subjects With Hepatocellular Carcinoma Who Have Received Prior Sorafenib

http://ClinicalTrials.gov/show/NCT01908426

#### Study 56:

Study of MK-3475 in Participants With Progressive Locally Advanced or Metastatic Carcinoma, Melanoma, or Non-small Cell Lung Carcinoma (P07990/ MK-3475-001)

http://ClinicalTrials.gov/show/NCT01295827

#### **Study 57:**

A Study of PD-0332991 + Letrozole vs. Letrozole For 1st Line Treatment Of Postmenopausal Women With ER+/HER2- Advanced Breast Cancer (PALOMA-2)

http://ClinicalTrials.gov/show/NCT01740427

#### Study 58:

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

http://ClinicalTrials.gov/show/NCT01498328

#### Study 59:

Treatment Extension Study for Patients Who Have Previously Participated and Have Benefited From Iniparib in a Clinical Trial

http://ClinicalTrials.gov/show/NCT01593228

#### Study 60:

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

#### Study 61:

Efficacy and Safety of Oral Rigosertib in Transfusion-dependent, Low or Int-1 or Trisomy 8 Int-2 Myelodysplastic Syndrome

http://ClinicalTrials.gov/show/NCT01584531

#### **Study 62:**

Immunotherapy Study in Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer

http://ClinicalTrials.gov/show/NCT01836432

#### Study 63:

Study is Designed to Assess the Safety and Tolerability of AZD4547 at Increasing Doses in Patients With Advanced Tumours

http://ClinicalTrials.gov/show/NCT00979134

#### Study 64:

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 65:**

A Phase II Study of the Selective BRAF Kinase Inhibitor GSK2118436 in Subjects With Advanced Non-small Cell Lung Cancer and BRAF Mutations

http://ClinicalTrials.gov/show/NCT01336634

#### **Study 66:**

A Study of CDX-1127 in Patients With Select Solid Tumor Types or Hematologic Cancers

http://ClinicalTrials.gov/show/NCT01460134

#### **Study 67:**

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 68:

Safety Study of Human Myeloid Progenitor Cells (CLT-008) After Cord Blood Transplant for Hematologic Malignancy

http://ClinicalTrials.gov/show/NCT00891137

#### Study 69:

Phase 1 Study of PI3 (Phosphatidylinositol-3)-Kinase Inhibitor BAY80-6946 With Gemcitabine or Cisplatin Plus Gemcitabine in Patients With Advanced Cancer

http://ClinicalTrials.gov/show/NCT01460537

#### **Study 70:**

Study of MK-8242 Alone and in Combination With Cytarabine in Participants With Acute Myelogenous Leukemia (P07649)

http://ClinicalTrials.gov/show/NCT01451437

#### **Study 71:**

A Phase 3 Study Comparing Oral MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Relapsed and/or Refractory Multiple Myeloma

http://ClinicalTrials.gov/show/NCT01564537

#### **Study 72:**

Efficacy and Safety of IV Rigosertib in MDS Patients With Excess Blasts Progressing After Azacitidine or Decitabine

#### **Study 73:**

Brentuximab Vedotin in Patients With CD30-positive Non-lymphomatous Malignancies

http://ClinicalTrials.gov/show/NCT01461538

#### **Study 74:**

A Study in Cancer Patients to Evaluate the Effect of a Single Dose of NKTR-102 (Etirinotecan Pegol) on the QTc Interval and to Assess Pharmacokinetics and Safety

http://ClinicalTrials.gov/show/NCT01976143

#### **Study 75:**

A Study of Pemetrexed & Carboplatin/Cisplatin or Gemcitabine & Carboplatin/Cisplatin With or Without IMC-1121B in Patients Previously Untreated With Recurrent or Advanced Non-small Cell Lung Cancer (NSCLC)

http://ClinicalTrials.gov/show/NCT01160744

#### **Study 76:**

Trial of Eflornithine Plus Sulindac in Patients With Familial Adenomatous Polyposis (FAP)

http://ClinicalTrials.gov/show/NCT01483144

#### **Study 77:**

Intravesical Administration of INSTILADRIN (rAd-IFN With Syn3) in Patients With Bladder Cancer

http://ClinicalTrials.gov/show/NCT01687244

#### **Study 78:**

A Study of PSMA ADC in Subjects With Metastatic Castration-resistant Prostate Cancer (mCRPC)

http://ClinicalTrials.gov/show/NCT01695044

#### **Study 79:**

Study of Regorafenib After Sorafenib in Patients With Hepatocellular Carcinoma

http://ClinicalTrials.gov/show/NCT01774344

#### Study 80:

A Study of Rucaparib in Patients With Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (ARIEL2)

http://ClinicalTrials.gov/show/NCT01891344

#### Study 81:

Phase 2 Study of Ipilimumab in Children and Adolescents (12 to < 18 Years) With Previously Treated or Untreated, Unresectable Stage III or Stage IV Malignant Melanoma

http://ClinicalTrials.gov/show/NCT01696045

#### **Study 82:**

A Study of LY2875358 in Patients With Advanced Cancer

http://ClinicalTrials.gov/show/NCT01287546

#### **Study 83:**

A Study to Compare BMS-936558 to the Physician's Choice of Either Dacarbazine or Carboplatin and Paclitaxel in Advanced Melanoma Patients That Have Progressed Following Anti-CTLA-4 Therapy (CheckMate 037)

http://ClinicalTrials.gov/show/NCT01721746

#### Study 84:

A Study of Cabozantinib (XL184) vs. Everolimus in Subjects With Metastatic Renal Cell Carcinoma

http://ClinicalTrials.gov/show/NCT01865747

#### **Study 85:**

Dose Escalation Study of Safety and Tolerability of AT-406 in Patients With Advanced Solid Tumors and Lymphomas

#### **Study 86:**

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

http://ClinicalTrials.gov/show/NCT01170650

#### **Study 87:**

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

http://ClinicalTrials.gov/show/NCT01660451

#### **Study 88:**

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

http://ClinicalTrials.gov/show/NCT01900652

#### **Study 89:**

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

http://ClinicalTrials.gov/show/NCT01909453

#### **Study 90:**

Phase IIb Study of Dasatinib Versus Imatinib in Patients With CML-CP Who Have Not Achieved an Early Optimal Response to Imatinib

http://ClinicalTrials.gov/show/NCT01593254

#### **Study 91:**

A Study Using MABp1 To Increase Overall Survival In Patients With Colorectal Cancer And Weight Loss

http://ClinicalTrials.gov/show/NCT01767857

#### **Study 92:**

Panitumumab Pediatric Study

http://ClinicalTrials.gov/show/NCT00658658

#### Study 93:

Pediatric Philadelphia Positive Acute Lymphoblastic Leukemia

http://ClinicalTrials.gov/show/NCT01460160

#### Study 94:

Phase I Clinical Study of CWP232291 in Acute Myeloid Leukemia Patients

http://ClinicalTrials.gov/show/NCT01398462

#### Study 95:

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

http://ClinicalTrials.gov/show/NCT01482962

#### Study 96:

Standard of Care +/- Midostaurin to Prevent Relapse Post Stem Cell Transplant in Patients With FLT3-ITD Mutated AML

http://ClinicalTrials.gov/show/NCT01883362

#### **Study 97:**

Study of Ramucirumab or IMC-18F1 With Docetaxel or Docetaxel Alone as Second-Line Therapy in Participants With Bladder, Urethra, Ureter, or Renal Pelvis Carcinoma

http://ClinicalTrials.gov/show/NCT01282463

#### **Study 98:**

Clinical Study of BYM338 for the Treatment of Unintentional Weight Loss in Patients With Cancer of the Lung or the Pancreas

http://ClinicalTrials.gov/show/NCT01433263

#### **Study 99:**

Safety and Efficacy of VB-111 in Subjects With Advanced Differentiated Thyroid Cancer

#### **Study 100:**

Study of Minnelide<sup>TM</sup> in Patients With Advanced GI Tumors

http://ClinicalTrials.gov/show/NCT01927965

#### **Study 101:**

Phase Ib, Dose Escalation Study of Oral LDE225 in Combination With BKM120 in Patients With Advanced Solid Tumors

http://ClinicalTrials.gov/show/NCT01576666

#### **Study 102:**

A Study of Brentuximab Vedotin in Relapsed or Refractory Non-Hodgkin Lymphoma

http://ClinicalTrials.gov/show/NCT01421667

#### **Study 103:**

Study of a Drug [DCVax®-L] to Treat Newly Diagnosed GBM Brain Cancer

http://ClinicalTrials.gov/show/NCT00045968

#### **Study 104:**

BKM120 for Patients With PI3K-activated Tumors

http://ClinicalTrials.gov/show/NCT01833169

#### **Study 105:**

Safety Study of Anti-Programmed Death-1 in Hematologic Malignancy

http://ClinicalTrials.gov/show/NCT01592370

#### **Study 106:**

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

http://ClinicalTrials.gov/show/NCT01697072

#### **Study 107:**

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 108:**

Randomized, Double-blind Study Comparing Tremelimumab to Placebo in Subjects With Unresectable Malignant Mesothelioma

http://ClinicalTrials.gov/show/NCT01843374

#### **Study 109:**

Volasertib in Combination With Low-dose Cytarabine in Patients Aged 65 Years and Above With Previously Untreated Acute Myeloid Leukaemia, Who Are Ineligible for Intensive Remission Induction Therapy (POLO-AML-2)

http://ClinicalTrials.gov/show/NCT01721876

#### **Study 110:**

An Open-Label Study to Assess the Pharmacokinetics and Safety of HALAVENTM in Subjects With Cancer Who Also Have Impaired Renal Function

http://ClinicalTrials.gov/show/NCT01418677

#### **Study 111:**

Safety and Efficacy Study of PRI-724 Plus Gemcitabine in Subjects With Advanced or Metastatic Pancreatic Adenocarcinoma

http://ClinicalTrials.gov/show/NCT01764477

#### **Study 112:**

A Study in Cancer Patients With Hepatic Impairment to Evaluate the Pharmacokinetics and Safety of NKTR-102 (Etirinotecan Pegol)

#### **Study 113:**

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

http://ClinicalTrials.gov/show/NCT01480479

#### **Study 114:**

Cabazitaxel at 20 mg/m<sup>2</sup> Compared to 25 mg/m<sup>2</sup> With Prednisone for the Treatment of Metastatic Castration Resistant Prostate Cancer

http://ClinicalTrials.gov/show/NCT01308580

#### **Study 115:**

Safety Study of BMS-986015 (Anti-KIR) in Combination With Ipilimumab in Subjects With Selected Advanced Tumor

http://ClinicalTrials.gov/show/NCT01750580

#### **Study 116:**

Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma

http://ClinicalTrials.gov/show/NCT01948180

#### **Study 117:**

Study With SAR302503 in Patients With Polycythemia Vera or Essential Thrombocythemia

http://ClinicalTrials.gov/show/NCT01420783

#### **Study 118:**

Study of Zevalin Versus Observation in Patients at Least 60 Yrs Old With Newly Diagnosed Diffuse Large B-cell Lymphoma in PET-negative Complete Remission After R-CHOP or R-CHOP-like Therapy

http://ClinicalTrials.gov/show/NCT01510184

#### **Study 119:**

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

http://ClinicalTrials.gov/show/NCT01696084

#### **Study 120:**

Ph 3 ADI-PEG 20 Versus Placebo in Subjects With Advanced Hepatocellular Carcinoma Who Have Failed Prior Systemic Therapy

http://ClinicalTrials.gov/show/NCT01287585

#### **Study 121:**

A Study of Perjeta (Pertuzumab) in Combination With Herceptin (Trastuzumab) and Chemotherapy in Patients With HER2-Positive Metastatic Gastroesophageal Junction or Gastric Cancer

http://ClinicalTrials.gov/show/NCT01774786

#### **Study 122:**

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

http://ClinicalTrials.gov/show/NCT01844986

#### **Study 123:**

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 124:**

A Study of Oral LGH447 in Patients With Relapsed and/or Refractory Multiple Myeloma

http://ClinicalTrials.gov/show/NCT01456689

#### **Study 125:**

A Phase 2 of GS-9973 in Subjects With Relapsed or Refractory Hematologic Malignancies

http://ClinicalTrials.gov/show/NCT01799889

#### **Study 126:**

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

#### **Study 127:**

Efficacy Evaluation of TheraSphere in Patients With Inoperable Liver Cancer

http://ClinicalTrials.gov/show/NCT01556490

#### **Study 128:**

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

http://ClinicalTrials.gov/show/NCT01769391

#### **Study 129:**

Study of Denosumab in Subjects With Giant Cell Tumor of Bone

http://ClinicalTrials.gov/show/NCT00680992

#### **Study 130:**

A Study of DMOT4039A in Patients With Unresectable Pancreatic or Platinum-Resistant Ovarian Cancer

http://ClinicalTrials.gov/show/NCT01469793

#### **Study 131:**

A Randomized, Double-Blind and Placebo-Controlled Study of Idelalisib in Combination With Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukemia (CLL)

http://ClinicalTrials.gov/show/NCT01569295

#### **Study 132:**

The Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Placebo and Best Supportive Care in Subjects With Red Blood Cell (RBC) Transfusion-Dependent Anemia and Thrombocytopenia Due to International Prognostic Scoring System (IPSS) Low Risk Myelodysplastic Syndrome (MDS)

http://ClinicalTrials.gov/show/NCT01566695

#### **Study 133:**

A Study of Oral Sapacitabine in Elderly Patients With Newly Diagnosed Acute Myeloid Leukemia

http://ClinicalTrials.gov/show/NCT01303796

#### **Study 134:**

A Study of Vismodegib With Surgery in Patients With Previously Untreated Basal Cell Carcinoma

http://ClinicalTrials.gov/show/NCT01898598

#### **Study 135:**

Clinical Study of PM01183 in Patients With Acute Leukemia

http://ClinicalTrials.gov/show/NCT01314599

#### **Study 136:**

Lenalidomide and Low-Dose Dexamethasone in Patients With Previously Treated Multiple Myeloma and Kidney Dysfunction

http://ClinicalTrials.gov/show/NCT00790842

#### **Study 137:**

Trial of Nelarabine, Etoposide and Cyclophosphamide in Relapsed T-cell ALL and T-cell LL

http://ClinicalTrials.gov/show/NCT00981799

#### **Study 138:**

A Phase II Study Evaluating the Safety and Efficacy of Subcutaneous Plerixafor

http://ClinicalTrials.gov/show/NCT01696461

#### **Study 139:**

S0820, Adenoma and Second Primary Prevention Trial

http://ClinicalTrials.gov/show/NCT01349881

#### **Study 140:**

S1216, Phase III ADT+TAK-700 vs. ADT+Bicalutamide for Metastatic Prostate Cancer

http://ClinicalTrials.gov/show/NCT01809691

#### **Study 141:**

A Phase II Study of Tivozanib in Patients With Metastatic and Non-resectable Soft Tissue Sarcomas

#### **Study 142:**

A Study Of Panobinostat In Children With Refractory Hematologic Malignancies

http://ClinicalTrials.gov/show/NCT01321346

#### **Study 143:**

Sorafenib Tosylate and Hypoxia-Activated Prodrug TH-302 in Treating Patients With Advanced Kidney Cancer or Liver Cancer That Cannot Be Removed By Surgery

http://ClinicalTrials.gov/show/NCT01497444

#### **Study 144:**

Ruxolitinib Phosphate (Oral JAK Inhibitor INCB18424) in Treating Patients With Relapsed or Refractory Diffuse Large B-Cell or Peripheral T-Cell Non-Hodgkin Lymphoma

http://ClinicalTrials.gov/show/NCT01431209

#### **Study 145:**

Study of Fulvestrant +/- Everolimus in Post-Menopausal, Hormone-Receptor + Metastatic Breast Ca Resistant to AI

http://ClinicalTrials.gov/show/NCT01797120

#### **Study 146:**

Rituximab, Bendamustine Hydrochloride, and Lenalidomide in Treating Patients With Refractory or Relapsed Indolent Non-Hodgkin Lymphoma

http://ClinicalTrials.gov/show/NCT01429025

#### **Study 147:**

OGX-427 in Metastatic Castrate-Resistant Prostate Cancer With Prostate-Specific Antigen Progression While Receiving Abiraterone

http://ClinicalTrials.gov/show/NCT01681433

#### **Study 148:**

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

http://ClinicalTrials.gov/show/NCT01008150

#### **Study 149:**

Accelerating Gastrointestinal Recovery

http://ClinicalTrials.gov/show/NCT01704651

#### **Study 150:**

Treosulfan/Fludarabine/Low Dose TBI as a Preparative Regimen for Children With AML/MDS Undergoing Allo HCT

http://ClinicalTrials.gov/show/NCT01772953

#### **Study 151:**

CD3/CD19 Depleted or CD3 Depleted/CD56 Selected Haploid Donor Natural Killer Cell Treatment in Older AML in First Complete Remission

http://ClinicalTrials.gov/show/NCT01639456

#### **Study 152:**

Everolimus Versus Placebo in Head and Neck Cancer

http://ClinicalTrials.gov/show/NCT01111058

#### **Study 153:**

Study of Pazopanib in the Treatment of Surgically Unresectable or Metastatic Chondrosarcoma

http://ClinicalTrials.gov/show/NCT01330966

#### **Study 154:**

Study of Pazopanib in the Treatment of Surgically Unresectable or Metastatic Liposarcoma

#### **Cardiovascular Disease**

(58 clinical trials recruiting)

#### Study 1:

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

http://ClinicalTrials.gov/show/NCT01663402

#### Study 2:

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

http://ClinicalTrials.gov/show/NCT01661634

#### Study 3:

Efficacy and Safety of LCZ696 Compared to Valsartan, on Morbidity and Mortality in Heart Failure Patients With Preserved Ejection Fraction

http://ClinicalTrials.gov/show/NCT01920711

#### Study 4:

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

http://ClinicalTrials.gov/show/NCT01101035

#### Study 5:

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

http://ClinicalTrials.gov/show/NCT01327846

#### Study 6:

INcrease Of VAgal TonE in CHF

http://ClinicalTrials.gov/show/NCT01303718

#### Study 7:

Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk

http://ClinicalTrials.gov/show/NCT01764633

#### Study 8:

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

http://ClinicalTrials.gov/show/NCT01732822

#### Study 9:

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 10:

A Study of Evacetrapib in High-Risk Vascular Disease

http://ClinicalTrials.gov/show/NCT01687998

#### Study 11:

Efficacy and Safety of Targeted Intramyocardial Delivery of Auto CD34+ Stem Cells for Improving Exercise Capacity in Subjects With Refractory Angina

http://ClinicalTrials.gov/show/NCT01508910

#### **Study 12:**

The PARTNER II Trial: Placement of AoRTic TraNscathetER Valves

http://ClinicalTrials.gov/show/NCT01314313

#### **Study 13:**

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

http://ClinicalTrials.gov/show/NCT01813422

#### **Study 14:**

Intracardiac CrYoablation for AtrioVentricular Nodal Reentrant Tachycardia

http://ClinicalTrials.gov/show/NCT01426425

#### **Study 15:**

Actual Use Trial of Atorvastatin Calcium 10 mg

#### **Study 16:**

AMR-001 Versus Placebo Post ST Segment Elevation Myocardial Infarction

http://ClinicalTrials.gov/show/NCT01495364

#### **Study 17:**

Efficacy and Safety of LCZ696 Compared to Olmesartan in Essential Hypertensive Patients Not Responsive to Olmesartan

http://ClinicalTrials.gov/show/NCT01876368

#### **Study 18:**

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

http://ClinicalTrials.gov/show/NCT01112579

#### **Study 19:**

Inhaled Nitric Oxide/INOpulse DS for Pulmonary Arterial Hypertension (PAH)

http://ClinicalTrials.gov/show/NCT01457781

#### **Study 20:**

An Efficacy, Safety and Tolerability Study of Ixmyelocel-T Administered Via Transendocardial Catheter-based Injections to Subjects With Heart Failure Due to Ischemic Dilated Cardiomyopathy (IDCM)

http://ClinicalTrials.gov/show/NCT01670981

#### **Study 21:**

THERMOCOOL® SMARTTOUCH<sup>TM</sup> Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation CONTINUED ACCESS

http://ClinicalTrials.gov/show/NCT01639495

#### **Study 22:**

Gene Therapy for the Treatment of Chronic Stable Angina

http://ClinicalTrials.gov/show/NCT01002495

#### **Study 23:**

Allogeneic Heart Stem Cells to Achieve Myocardial Regeneration

http://ClinicalTrials.gov/show/NCT01458405

#### **Study 24:**

A Randomized, Concurrent Controlled Trial to Assess the Safety and Effectiveness of the Separator 3D as a Component of the Penumbra System in the Revascularization of Large Vessel Occlusion in Acute Ischemic Stroke

http://ClinicalTrials.gov/show/NCT01584609

#### **Study 25:**

Safety Study of Allogeneic Mesenchymal Precursor Cells (MPCs) in Subjects With Recent Acute Myocardial Infarction

http://ClinicalTrials.gov/show/NCT00555828

#### Study 26:

Study to Assess the Effects of Intravenous Bendavia in Patients Undergoing Percutaneous Transluminal Angioplasty of the Renal Artery (PTRA)

http://ClinicalTrials.gov/show/NCT01755858

#### **Study 27:**

The eMESH 1 Feasibility Study

http://ClinicalTrials.gov/show/NCT01676376

#### **Study 28:**

COSMIC-HF—Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure

http://ClinicalTrials.gov/show/NCT01786512

#### **Study 29:**

The Medtronic CoreValve<sup>TM</sup> Evolut R<sup>TM</sup> Clinical Study

#### **Study 30:**

Oral Rivaroxaban in Children With Venous Thrombosis

http://ClinicalTrials.gov/show/NCT01684423

#### **Study 31:**

Study to Evaluate the Efficacy and Safety of an Every Four Weeks Treatment Regimen of Alirocumab (REGN727/SAR236553) in Patients With Primary Hypercholesterolemia (ODYSSEY CHOICE 1)

http://ClinicalTrials.gov/show/NCT01926782

#### **Study 32:**

Study to Examine the Effects of MultiStem in Ischemic Stroke

http://ClinicalTrials.gov/show/NCT01436487

#### **Study 33:**

VIVID—Valvular and Ventricular Improvement Via iCoapsys Delivery—Feasibility Study

http://ClinicalTrials.gov/show/NCT00512005

#### **Study 34:**

The Efficacy and Safety of PRC-4016 in Hypertriglyceridemic Subjects

http://ClinicalTrials.gov/show/NCT01893515

#### **Study 35:**

Acute Medically Ill VTE Prevention With Extended Duration Betrixaban Study (The APEX Study)

http://ClinicalTrials.gov/show/NCT01583218

#### **Study 36:**

Open Label Study of Long Term Evaluation Against LDL-C Trial-2

http://ClinicalTrials.gov/show/NCT01854918

#### **Study 37:**

Gadobutrol/Gadavist-enhanced Cardiac Magnetic Resonance Imaging (CMRI) to Detect Coronary Artery Disease (CAD)

http://ClinicalTrials.gov/show/NCT01890421

#### **Study 38:**

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

http://ClinicalTrials.gov/show/NCT01424722

#### **Study 39:**

Safety and Feasibility Trial of Adipose-Derived Regenerative Cells in the Treatment of Chronic Myocardial Ischemia

http://ClinicalTrials.gov/show/NCT01556022

#### Study 40:

A Study of the Safety and Efficacy of Two Different Regimens of Mipomersen in Patients With Familial Hypercholesterolemia and Inadequately Controlled Low-Density Lipoprotein Cholesterol

http://ClinicalTrials.gov/show/NCT01475825

#### Study 41:

Study of ALD-401 Via Intracarotid Infusion in Ischemic Stroke Subjects

http://ClinicalTrials.gov/show/NCT01273337

#### Study 42:

A Study to Assess Regadenoson Administration Following an Inadequate Exercise Stress Test as Compared to Regadenoson Alone for Myocardial Perfusion Imaging (MPI) Using Single Photon Emission Computed Tomography (SPECT)

#### **Study 43:**

A Study Exploring Two Treatment Strategies in Patients With Atrial Fibrillation Who Undergo Catheter Ablation Therapy

http://ClinicalTrials.gov/show/NCT01729871

#### **Study 44:**

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

http://ClinicalTrials.gov/show/NCT01870778

#### **Study 45:**

Safety and Tolerability of Initiating LCZ696 in Heart Failure Patients

http://ClinicalTrials.gov/show/NCT01922089

#### **Study 46:**

Study to Evaluate the Safety and Activity of BB3 to Treat Heart Attack

http://ClinicalTrials.gov/show/NCT01539590

#### **Study 47:**

Safety and Efficacy of Allogeneic Cells for the Treatment of Intermittent Claudication (IC)

http://ClinicalTrials.gov/show/NCT01679990

#### **Study 48:**

nMARQ<sup>™</sup> Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation

http://ClinicalTrials.gov/show/NCT01824394

#### **Study 49:**

C-Pulse® System: A Heart Assist Device Clinical Study

http://ClinicalTrials.gov/show/NCT01740596

#### Study 50:

Acute Venous Thrombosis: Thrombus Removal With Adjunctive Catheter-Directed Thrombolysis

http://ClinicalTrials.gov/show/NCT00790335

#### Study 51:

The Evaluation of VAD InterVEntion Before Inotropic Therapy

http://ClinicalTrials.gov/show/NCT01369407

#### Study 52:

Lp-PLA2, Progenitor Cells and Coronary Atherosclerosis in Humans AIM III

http://ClinicalTrials.gov/show/NCT01067339

#### Study 53:

Insulin Resistance Intervention After Stroke Trial

http://ClinicalTrials.gov/show/NCT00091949

#### Study 54:

A Study Examining the Effects of Nebivolol Compared to Atenolol on Endothelial Function

http://ClinicalTrials.gov/show/NCT01522950

#### Study 55:

Patients With Intermittent Claudication Injected With ALDH Bright Cells

http://ClinicalTrials.gov/show/NCT01774097

#### Study 56:

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

http://ClinicalTrials.gov/show/NCT01626079

#### **Study 57:**

A Study of RoActemra/Actemra (Tocilizumab) in Patients With Giant Cell Arteritis

http://ClinicalTrials.gov/show/NCT01791153

#### Study 58:

Study of GSK1278863 to Reduce Ischemic Events in Patients Undergoing Thoracic Aortic Aneurysm Repair

## Crohn's Disease/Ulcerative Colitis/Gastrointestinal Diseases (24 clinical trials recruiting)

#### Study 1:

Study To Test Whether PF-00547659 Is Safe And Improves Disease Symptoms In Patients With Crohn's Disease

http://ClinicalTrials.gov/show/NCT01276509

#### Study 2:

A Study Of PF-00547659 In Patients With Moderate To Severe Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01620255

#### Study 3:

A Study To Monitor Long-Term Treatment With PF-00547659

http://ClinicalTrials.gov/show/NCT01298492

#### Study 4:

Safety Study of Entocort for Children With Crohn's Disease

http://ClinicalTrials.gov/show/NCT01444092

#### Study 5:

Effect of TU-100 in Patients With Irritable Bowel Syndrome (IBS)

http://ClinicalTrials.gov/show/NCT01890837

#### Study 6:

Safety and Efficacy of Dexlansoprazole Delayed-Release Capsules in Treating Symptomatic Non-Erosive Gastroesophageal Reflux Disease in Adolescents

http://ClinicalTrials.gov/show/NCT01642602

#### Study 7:

Phase 2 Study to Evaluate Safety and Efficacy of RM-131 Administered to Patients With Chronic Constipation

http://ClinicalTrials.gov/show/NCT01781104

#### Study 8:

Prospective, Multicenter Trial to Investigate the Safety and Efficacy of Percutaneous Tibial Nerve Stimulation for the Treatment of Fecal Incontinence

http://ClinicalTrials.gov/show/NCT01666405

#### Study 9:

Induction and Maintenance Study of BMS-936557 Patients With Moderate to Severe Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01294410

#### Study 10:

Long-Term Study Of CP-690,550 In Subjects With Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01470612

#### Study 11:

OBS in Adolescent and Adults With EOE: A Phase II, Randomized, Double-Blind, Placebo Controlled, Study With an Open Label Extension

http://ClinicalTrials.gov/show/NCT01642212

#### **Study 12:**

Safety and Efficacy of Dexlansoprazole Delayed-Release Capsules for Healing of Erosive Esophagitis and Maintenance of Healed Erosive Esophagitis and Relief of Heartburn in Adolescents

http://ClinicalTrials.gov/show/NCT01642615

#### **Study 13:**

The Plecanatide Irritable Bowel Syndrome With Constipation Study (IBS-C)

http://ClinicalTrials.gov/show/NCT01722318

#### **Study 14:**

Evaluation of the Efficacy and Safety of ALV003 in Symptomatic in Celiac Disease Patients

#### **Study 15:**

A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Patients With Moderately to Severely Active Crohn's Disease (UNITI-2)

http://ClinicalTrials.gov/show/NCT01369342

#### **Study 16:**

Safety and Maintenance Study of Entocort for Children With Crohn's Disease

http://ClinicalTrials.gov/show/NCT01453946

#### **Study 17:**

A Study To Evaluate Both The Efficacy and Safety Profile of CP-690,550 In Patients With Moderately to Severely Active Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01458951

#### **Study 18:**

Intra-patient Dose Escalation Study Evaluating Efficacy, Safety and Pharmacokinetics of Pasireotide (SOM230) Subcutaneous (s.c.) Followed by Pasireotide LAR in Patients With Dumping Syndrome

http://ClinicalTrials.gov/show/NCT01637272

#### **Study 19:**

A Study Of Oral CP-690550 As A Maintenance Therapy For Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01458574

#### **Study 20:**

A Study to Assess the Safety and Pharmacokinetics of Subcutaneously Administered Golimumab, a Human Anti-TNF $\alpha$  Antibody, in Pediatric Patients With Moderate to Severe Active Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01900574

#### **Study 21:**

A Phase 2 Study to Evaluate Pharmacodynamics of YKP10811 in Patients With Chronic or Functional Constipation

http://ClinicalTrials.gov/show/NCT01523184

#### Study 22:

Trial of Montelukast in Eosinophilic Esophagitis

http://ClinicalTrials.gov/show/NCT00511316

#### **Study 23:**

Trichuris Suis Ova Treatment in Left-sided Ulcerative Colitis

http://ClinicalTrials.gov/show/NCT01953354

#### Study 24:

A Placebo-Controlled Trial of Pregabalin (Lyrica) for Irritable Bowel Syndrome

http://ClinicalTrials.gov/show/NCT00977197

#### **Diabetes**

(10 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:

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 3:

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 4:

Efficacy and Safety of FIAsp Compared to Insulin Aspart Both in Combination With Insulin Detemir in Adults With Type 1 Diabetes

#### 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:

Effect of Renal Impairment on the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Ertugliflozin in Participants With Type 2 Diabetes Mellitus (MK-8835-009)

http://ClinicalTrials.gov/show/NCT01948986

#### Study 7:

Phase 1 Multicenter, Single Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Response of PE0139 Injection in Adult Subjects With Type 2 Diabetes Mellitus

http://ClinicalTrials.gov/show/NCT01835730

#### Study 8:

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

http://ClinicalTrials.gov/show/NCT01824264

#### Study 9:

A Comparative Effectiveness Study of Major Glycemia-lowering Medications for Treatment of Type 2 Diabetes

http://ClinicalTrials.gov/show/NCT01794143

#### **Study 10:**

Effectiveness and Safety of Intranasal Glucagon for Treatment of Hypoglycemia in Adults

http://ClinicalTrials.gov/show/NCT01994746

### **Epilepsy/Neurological Disorders**

(21 clinical trials recruiting)

#### Study 1:

Study to Evaluate the Safety and Efficacy of USL261 (Intranasal Midazolam) in Patients With Seizure Clusters

http://ClinicalTrials.gov/show/NCT01390220

#### Study 2:

Exploring the Efficacy and Safety of Siponimod in Patients With Secondary Progressive Multiple Sclerosis (EXPAND)

http://ClinicalTrials.gov/show/NCT01665144

#### Study 3:

A Phase 2a, Proof-of-Concept Study of GIC-1001 in the Management of Visceral Pain During Sedation-Free, Full Colonoscopy

http://ClinicalTrials.gov/show/NCT01926444

#### Study 4:

A 12-week Randomized Study to Evaluate Oral Istradefylline in Subjects With Moderate to Severe Parkinson's Disease

http://ClinicalTrials.gov/show/NCT01968031

#### Study 5:

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

http://ClinicalTrials.gov/show/NCT01262651

#### Study 6:

Efficacy and Safety of ISIS-TTRRx in Familial Amyloid Polyneuropathy

http://ClinicalTrials.gov/show/NCT01737398

#### Study 7:

Phase 2 Study of Adjunctive Ganaxolone in Adults With Drug-resistant Partial Onset Seizures, With Long-term Open-label Extension

### Study 8:

Dysport® Pediatric Lower Limb Spasticity Study

http://ClinicalTrials.gov/show/NCT01249417

#### Study 9:

Brivaracetam Efficacy and Safety Study in Subjects With Partial Onset Seizures

http://ClinicalTrials.gov/show/NCT01261325

### **Study 10:**

A Multicenter, Open-Label Study To Investigate The Safety And Pharmacokinetics Of Lacosamide In Children With Partial Seizures

http://ClinicalTrials.gov/show/NCT00938431

### Study 11:

Study to Evaluate the Long-term Safety and Tolerability of USL261 in Patients With Seizure Clusters

http://ClinicalTrials.gov/show/NCT01529034

### **Study 12:**

A Efficacy and Safety Study of Adjunctive Perampanel in Primary Generalized Tonic Clonic Seizures

http://ClinicalTrials.gov/show/NCT01393743

#### **Study 13:**

Safety Study of 3 mg/mL Baclofen Injection (Intrathecal) Using A Programmable Pump

http://ClinicalTrials.gov/show/NCT01520545

#### **Study 14:**

A Placebo-controlled Study of Efficacy & Safety of 2 Trough-ranges of Everolimus as Adjunctive Therapy in Patients With Tuberous Sclerosis Complex (TSC) & Refractory Partial-onset Seizures

http://ClinicalTrials.gov/show/NCT01713946

### Study 15:

Study of Safety, Tolerability & Efficacy of CK-2017357 in Amyotrophic Lateral Sclerosis (ALS)

http://ClinicalTrials.gov/show/NCT01709149

### Study 16:

A Study to Explore the Safety and Tolerability of Acthar in Patients With Amyotrophic Lateral Sclerosis

http://ClinicalTrials.gov/show/NCT01906658

### **Study 17:**

A Phase 2 Study to Evaluate the Efficacy and Safety of AMG 334 in Migraine Prevention

http://ClinicalTrials.gov/show/NCT01952574

### **Study 18:**

Phase 3 Study of Ataluren in Patients With Nonsense Mutation Duchenne Muscular Dystrophy

http://ClinicalTrials.gov/show/NCT01826487

### **Study 19:**

Riluzole in Spinal Cord Injury Study

http://ClinicalTrials.gov/show/NCT01597518

#### **Study 20:**

Safety and Efficacy of Gabapentin for Neuropathic Pain in Fabry Disease

http://ClinicalTrials.gov/show/NCT01588314

#### Study 21:

ACTH in Progressive Forms of MS

## **Infectious Diseases**

(31 clinical trials recruiting)

### Study 1:

Ceftazidime-Avibactam Compared With Doripenem Followed by Oral Therapy for Hospitalized Adults With Complicated UTIs (Urinary Tract Infections)

http://ClinicalTrials.gov/show/NCT01595438

### Study 2:

Evaluation of Ceftaroline Fosamil Versus Vancomycin Plus Aztreonam in the Treatment of Patients With Skin Infections

http://ClinicalTrials.gov/show/NCT01499277

### Study 3:

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 4:

A Study of CB-183,315 in Patients With Clostridium Difficile Associated Diarrhea

http://ClinicalTrials.gov/show/NCT01598311

#### Study 5:

Sofosbuvir/Ledipasvir Fixed-Dose Combination + Ribavirin in Subjects With Chronic HCV With Advanced Liver Disease or Post-Liver Transplant

http://ClinicalTrials.gov/show/NCT01938430

### Study 6:

Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Positive, Antiretroviral Treatment-Naïve Adults

http://ClinicalTrials.gov/show/NCT01797445

### Study 7:

Isavuconazole (BAL8557) in the Treatment of Candidemia and Other Invasive Candida Infections

http://ClinicalTrials.gov/show/NCT00413218

### Study 8:

Safety and Efficacy of Merlin (Ethanol and Glycolic Acid Mixture) for the Treatment of Cold Sores

http://ClinicalTrials.gov/show/NCT01985321

#### Study 9:

A Study Comparing Ceftazidime-Avibactam+ Metronidazole Versus Meropenem in Adults With Complicated Intra-abdominal Infections

http://ClinicalTrials.gov/show/NCT01500239

### Study 10:

Study of CB-183,315 in Patients With Clostridium Difficile Associated Diarrhea

http://ClinicalTrials.gov/show/NCT01597505

#### **Study 11:**

A Pharmacokinetic/Pharmacodynamic Study of Tamiflu (Oseltamivir) in Immunocompromised Children With Confirmed Influenza Infection

http://ClinicalTrials.gov/show/NCT01715909

### Study 12:

Study to Evaluate Efficacy, Safety, and Immunogenicity of GlaxoSmithKline (GSK) Biologicals' Herpes Zoster Vaccine GSK1437173A

http://ClinicalTrials.gov/show/NCT01610414

#### **Study 13:**

Microbiota Restoration Therapy for Recurrent Clostridium Difficile-associated Diarrhea

### Study 14:

Safety and Immunogenicity Study of Prophylactic Streptococcus Pneumoniae Vaccine

http://ClinicalTrials.gov/show/NCT01995617

### **Study 15:**

Study of the Safety, Tolerability, and Efficacy of MK-7655 + Imipenem/Cilastatin Versus Imipenem/Cilastatin Alone for the Treatment of Complicated Urinary Tract Infection (cUTI) (MK-7655-003 AM4)

http://ClinicalTrials.gov/show/NCT01505634

#### **Study 16:**

Open-Label Study to Evaluate Switching From a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects

http://ClinicalTrials.gov/show/NCT01815736

### **Study 17:**

Open-Label Study of Sofusbuvir+Ribavirin With or Without Peginterferon Alfa-2a in Subjects With Chronic HCV Infection Who Participated in Prior Gilead HCV Studies

http://ClinicalTrials.gov/show/NCT01625338

### **Study 18:**

Efficacy of Tenofovir Alafenamide Versus Placebo Added to a Failing Regimen Followed by Treatment With Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide in HIV-1 Positive, Antiretroviral Treatment-Experienced Adults

http://ClinicalTrials.gov/show/NCT01967940

### **Study 19:**

Sofosbuvir+RBV for 16 or 24 Weeks and Sofosbuvir+PEG+RBV for 12 Weeks in Subjects With Genotype 2 or 3 Chronic HCV Infection

http://ClinicalTrials.gov/show/NCT01962441

### Study 20:

Safety and Efficacy of Fidaxomicin Versus Placebo for Prophylaxis Against Clostridium Difficile-Associated Diarrhea in Adults Undergoing Hematopoietic Stem Cell Transplantation

http://ClinicalTrials.gov/show/NCT01691248

#### Study 21:

Phase 3 Open-Label Study to Evaluate Switching From Optimized Stable Antiretroviral Regimens Containing Darunavir to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) Plus Darunavir (DRV) in Treatment Experienced HIV-1 Positive Adults

http://ClinicalTrials.gov/show/NCT01968551

### **Study 22:**

A Trial to Assess the Lot Consistency, Safety, Tolerability and Immunogenicity of Bivalent rLP2086 Vaccine When Given to Healthy Subjects Aged ≥10 to <19 Years

http://ClinicalTrials.gov/show/NCT01830855

### Study 23:

Study to Evaluate the Pharmacokinetics and Safety of GSK2336805 in Subjects With Hepatic Impairment and Healthy Matched Control Subjects

http://ClinicalTrials.gov/show/NCT01827657

### **Study 24:**

Study of the Safety, Tolerability, and Efficacy of MK-7655 + Imipenem/Cilastatin Versus Imipenem/Cilastatin Alone to Treat Complicated Intra-Abdominal Infection [cIAI] (MK-7655-004 AM2)

http://ClinicalTrials.gov/show/NCT01506271

### **Study 25:**

Maribavir for Treatment of Resistant or Refractory CMV Infections in Transplant Recipients

#### **Study 26:**

Assessment of Efficacy of CR8020 and CR6261, Monoclonal Antibodies, Against Influenza Infection

http://ClinicalTrials.gov/show/NCT01992276

### **Study 27:**

Study of Intravenous Ceftolozane/Tazobactam vs. Piperacillin/Tazobactam in Ventilator Associated Pneumonia

http://ClinicalTrials.gov/show/NCT01853982

### **Study 28:**

Safety and Immunogenicity of Three Influenza Vaccines Adults Ages 18 and Older

http://ClinicalTrials.gov/show/NCT01992094

### **Study 29:**

Open-label Safety Study of Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Alafenamide Single-Tablet Regimen in HIV-1 Positive Patients With Mild to Moderate Renal Impairment

http://ClinicalTrials.gov/show/NCT01818596

#### **Study 30:**

A Pilot Trial of Safety and Efficacy of Telaprevir +Peginterferon +Ribavirin +Vitamin D3 v. Telaprevir +Peginterferon +Ribavirin Among Treatment-naive Veterans With Genotype 1 Hepatitis C Virus

http://ClinicalTrials.gov/show/NCT01890772

#### **Study 31:**

Reversing Tissue Fibrosis to Improve Immune Reconstitution in HIV

http://ClinicalTrials.gov/show/NCT01852942

# **Kidney and Liver Disorders**

(32 clinical trials recruiting)

#### Study 1:

Defibrotide for Patients With Hepatic Veno-occlusive Disease: A Treatment IND Study

http://ClinicalTrials.gov/show/NCT00628498

#### Study 2:

Phase 2 Study to Evaluate LUM001 in Combination With Ursodeoxycholic Acid in Patients With Primary Biliary Cirrhosis

http://ClinicalTrials.gov/show/NCT01904058

### Study 3:

A Safety, Pharmacokinetic and Dose-Escalation Study of KD019 in Subjects With Autosomal Dominant Polycystic Kidney Disease (ADPKD)

http://ClinicalTrials.gov/show/NCT01559363

### Study 4:

Effects of PINTA 745 in End Stage Renal Disease (ESRD) Patients Who Require Hemodialysis and Have Protein Energy Wasting

http://ClinicalTrials.gov/show/NCT01958970

#### Study 5:

A Phase 2A Trial of FMX-8 Treatment for Anemia in Patients With ESRD on Hemodialysis HD

http://ClinicalTrials.gov/show/NCT01873534

#### Study 6:

Pharmacodynamic Study of AZD1722 in End-stage Renal Disease Patients on Hemodialysis

http://ClinicalTrials.gov/show/NCT01764854

#### Study 7:

Study of IDN-6556 in Patients With Severe AH and Contradictions to Steroid Therapy

### Study 8:

Phase 2 Study on Effects of Obeticholic Acid (OCA) on Lipoprotein Metabolism in Subjects With Primary Biliary Cirrhosis

http://ClinicalTrials.gov/show/NCT01865812

#### Study 9:

Study Assessing the Behavior of Delayed-Release Metformin in Subjects With Kidney Dysfunction

http://ClinicalTrials.gov/show/NCT01658514

### **Study 10:**

Contrast Media Reduction and Removal in Patients With CKD (PRESERV)

http://ClinicalTrials.gov/show/NCT01168024

#### **Study 11:**

Assess Safety and Efficacy of ELAD (Extracorporeal Liver Assist System) in Subjects With Alcohol-Induced Liver Failure

http://ClinicalTrials.gov/show/NCT01471028

### **Study 12:**

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 13:**

Efficacy and Safety of Everolimus in Liver Transplant Recipients of Living Donor Liver Transplants

http://ClinicalTrials.gov/show/NCT01888432

#### **Study 14:**

Simtuzumab (GS-6624) in the Prevention of Progression of Liver Fibrosis in Subjects With Primary Sclerosing Cholangitis (PSC)

http://ClinicalTrials.gov/show/NCT01672853

### **Study 15:**

Anti-Tweak in Lupus Nephritis Patients

http://ClinicalTrials.gov/show/NCT01499355

### **Study 16:**

Safety, Tolerability, PK & PD Study of JTZ-951 in Anemic Subjects With End-stage Renal Disease

http://ClinicalTrials.gov/show/NCT01971164

#### **Study 17:**

A Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery

http://ClinicalTrials.gov/show/NCT01777165

#### **Study 18:**

Simtuzumab (GS-6624) in the Treatment of Cirrhosis Due to NASH

http://ClinicalTrials.gov/show/NCT01672879

#### **Study 19:**

A Study of LY2928057 in Hemodialysis Participants

http://ClinicalTrials.gov/show/NCT01991483

#### **Study 20:**

Efficacy, Safety and Tolerability of Everolimus in Combination With Reduced Exposure Cyclosporine or Tacrolimus in Paediatric Liver Transplant Recipients

http://ClinicalTrials.gov/show/NCT01598987

#### **Study 21:**

Effect of Hemodialysis on the PK of JTZ-951 in Subjects With End-stage Renal Disease

http://ClinicalTrials.gov/show/NCT01978587

#### **Study 22:**

BIIB023 Long-Term Extension Study in Subjects With Lupus Nephritis

#### **Study 23:**

Calcineurin Inhibitor Sparing After Kidney Transplantation

http://ClinicalTrials.gov/show/NCT01062555

### **Study 24:**

Dosing Regimen of Eculizumab Added to Conventional Treatment in Positive Crossmatch Deceased Donor Kidney Transplant

http://ClinicalTrials.gov/show/NCT01106027

#### **Study 25:**

Eculizumab Added to Conventional Treatment in the Prevention of Antibody-mediated Rejection in ABO Blood Group Incompatible Living Donor Kidney Transplantation

http://ClinicalTrials.gov/show/NCT01095887

#### Study 26:

Xolair (Omalizumab) for Treatment of Drug-induced Acute Tubulointerstitial Nephritis (AIN)

http://ClinicalTrials.gov/show/NCT01893658

#### **Study 27:**

Safety and Efficacy of IMM 124-E for Patients With Severe Alcoholic Hepatitis

http://ClinicalTrials.gov/show/NCT01968382

#### **Study 28:**

Study to Evaluate Pharmacokinetics of Pomalidomide in Hepatically Impaired Males

http://ClinicalTrials.gov/show/NCT01835561

#### **Study 29:**

A Study of Fresolimumab in Patients With Steroid-Resistant Primary Focal Segmental Glomerulosclerosis (FSGS)

http://ClinicalTrials.gov/show/NCT01665391

### Study 30:

Safety & Efficacy of Eculizumab to Prevent AMR in Living Donor Kidney Transplant Recipients Requiring Desensitization

http://ClinicalTrials.gov/show/NCT01399593

#### **Study 31:**

Erlotinib for Chemoprevention in Trisomy 7 Positive Primary Sclerosing Cholangitis (PSC)

http://ClinicalTrials.gov/show/NCT00955149

#### **Study 32:**

Assessment of the Pharmacokinetics of GSK1278863 and Metabolites in Normal Subjects and Subjects With Renal Impairment

http://ClinicalTrials.gov/show/NCT01406340

### **Mental Illnesses**

(4 clinical trials recruiting)

### Study 1:

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

http://ClinicalTrials.gov/show/NCT01735630

#### Study 2:

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

http://ClinicalTrials.gov/show/NCT01657019

#### Study 3:

A Study of Bitopertin (RO4917838) in Combination With Selective Serotonin Reuptake Inhibitors in Patients With Obsessive-Compulsive Disorder

### Study 4:

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

http://ClinicalTrials.gov/show/NCT01626378

## **Psoriasis/Skin Disorders**

(11 clinical trials recruiting)

### Study 1:

Study to Evaluate the Efficacy and Safety of M518101 in Subjects With Plaque Psoriasis

http://ClinicalTrials.gov/show/NCT01873677

### Study 2:

A Comparison of 000-0551 Lotion Versus Vehicle Lotion in Subjects With Plaque Psoriasis

http://ClinicalTrials.gov/show/NCT01871402

### Study 3:

Study of Efficacy and Safety of Brodalumab Compared With Placebo and Ustekinumab in Moderate to Severe Plaque Psoriasis Subjects

http://ClinicalTrials.gov/show/NCT01708603

#### Study 4:

A Study to Evaluate the Efficacy and Safety of Subcutaneous MK-3222, Followed by an Optional Long-Term Safety Extension Study, in Participants With Moderate-to-Severe Chronic Plaque Psoriasis (MK-3222-010)

http://ClinicalTrials.gov/show/NCT01722331

#### Study 5:

Study Comparing Clindamycin Phosphate and Benzoyl Peroxide Gel to Acanya<sup>®</sup> Gel and Both to a Vehicle Control in the Treatment of Acne Vulgaris

http://ClinicalTrials.gov/show/NCT01769235

### Study 6:

A Long Term Study To Evaluate The Safety And Tolerability Of CP-690,550 For Patients With Moderate To Severe Chronic Plaque Psoriasis

http://ClinicalTrials.gov/show/NCT01163253

#### Study 7:

An Evaluation of PDI-192 0.1% in Comparison to PDI-192 0.15% in the Treatment of Mild to Moderate Atopic Dermatitis

http://ClinicalTrials.gov/show/NCT01826461

### Study 8:

Phase 2 Study of HL-009 Liposomal Gel to Treat Mild to Moderate Atopic Dermatitis

http://ClinicalTrials.gov/show/NCT01568489

### Study 9:

Long Term Study to Evaluate Safety and Efficacy of M518101 in Subjects With Plaque Psoriasis

http://ClinicalTrials.gov/show/NCT01908595

#### Study 10:

Study Comparing AM001 Cream to Vehicle in the Treatment of Plaque Psoriasis

http://ClinicalTrials.gov/show/NCT01938599

### Study 11:

Use of Botulinum Toxin to Treat Psoriasis

## **Respiratory Disorders**

(35 clinical trials recruiting)

### Study 1:

Study to Evaluate the Effect of Fluticasone Furoate/ Vilanterol on Survival in Subjects With Chronic Obstructive Pulmonary Disease

http://ClinicalTrials.gov/show/NCT01313676

### Study 2:

A 12 Week Treatment, Multi-center, Randomized, Double-blind, Parallel-group, Placebo and Active Controlled Study to Assess the Efficacy, Safety, and Tolerability of Indacaterol Maleate/Glycopyrronium Bromide in COPD Patients With Moderate to Severe Airflow Limitation

http://ClinicalTrials.gov/show/NCT01727141

### Study 3:

Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe COPD (PINNACLE 1)

http://ClinicalTrials.gov/show/NCT01854645

### Study 4:

Extension Study to Evaluate the Safety and Efficacy of PT003, PT001, and PT005 in Subjects With Moderate to Very Severe COPD, With Spiriva® Handihaler® (PINNACLE 3)

http://ClinicalTrials.gov/show/NCT01970878

#### Study 5:

Long Term Safety Study of NVA237 vs. QAB149 in COPD Patients

http://ClinicalTrials.gov/show/NCT01697696

#### Study 6:

A Phase 2 Study to See if Simtuzumab (GS-6624) is Safe and Works in Idiopathic Pulmonary Fibrosis (IPF)

http://ClinicalTrials.gov/show/NCT01769196

### Study 7:

Nintedanib Twice Daily vs. Placebo in Patients Diagnosed With Idiopathic Pulmonary Fibrosis (IPF)

http://ClinicalTrials.gov/show/NCT01979952

### Study 8:

Multi-Center Study to Assess the Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe COPD (PINNACLE 2)

http://ClinicalTrials.gov/show/NCT01854658

### Study 9:

A Multi-centre Randomized Double Blind 52-week Study to Assess the Safety of QVA149 Compared to QAB in Patients With COPD Who Have Moderate to Severe Airflow Limitation

http://ClinicalTrials.gov/show/NCT01682863

#### Study 10:

NVA237 BID Versus Placebo Twelve-week Efficacy Study

http://ClinicalTrials.gov/show/NCT01715298

#### **Study 11:**

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

http://ClinicalTrials.gov/show/NCT01854047

### **Study 12:**

Apnex Clinical Study of the Hypoglossal Nerve Stimulation (HGNS®) System to Treat Obstructive Sleep Apnea

http://ClinicalTrials.gov/show/NCT01446601

#### **Study 13:**

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

### Study 14:

Evaluate Safety of T/I on Diabetic Subjects With Mild Obstructive Pulmonary Disease

http://ClinicalTrials.gov/show/NCT00642616

### Study 15:

Safety and Efficacy of a Lysophosphatidic Acid Receptor Antagonist in Idiopathic Pulmonary Fibrosis

http://ClinicalTrials.gov/show/NCT01766817

### **Study 16:**

A Study to Evaluate Efficacy and Safety of ADC3680 in Subjects With Inadequately-Controlled Asthma

http://ClinicalTrials.gov/show/NCT01730027

### **Study 17:**

An Efficacy and Safety Study of Fluticasone Furoate/ Vilanterol (FF/VI) 200/25 Microgram (Mcg), FF/VI 100/25 Mcg, and FF 100 Mcg in Adults and Adolescents With Persistent Asthma

http://ClinicalTrials.gov/show/NCT01686633

#### **Study 18:**

International Randomized Study of the TransMedics Organ Care System (OCS Lung) for Lung Preservation and Transplantation (INSPIRE)

http://ClinicalTrials.gov/show/NCT01630434

#### **Study 19:**

Arikace® for Nontuberculous Mycobacteria

http://ClinicalTrials.gov/show/NCT01315236

#### **Study 20:**

Study to Evaluate the Effect of KB001-A on Time-to-Need for Antibiotic Treatment

http://ClinicalTrials.gov/show/NCT01695343

### Study 21:

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

http://ClinicalTrials.gov/show/NCT01716754

#### **Study 22:**

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

http://ClinicalTrials.gov/show/NCT01868061

### Study 23:

A Phase 2, Randomized Dose-ranging Study to Evaluate the Efficacy of Tralokinumab in Adults With Idiopathic Pulmonary Fibrosis

http://ClinicalTrials.gov/show/NCT01629667

### Study 24:

A Study of Mometasone Furoate Metered Dose Inhaler in Children With Persistent Asthma (P04223)

http://ClinicalTrials.gov/show/NCT01502371

#### **Study 25:**

A Study to Assess the Effect of QAW039 in Non-atopic Asthmatic Patients

http://ClinicalTrials.gov/show/NCT01836471

### **Study 26:**

Safety and Pharmacokinetic Study of N6022 in Subjects With Cystic Fibrosis Homozygous for the F508del-CFTR Mutation

http://ClinicalTrials.gov/show/NCT01746784

#### **Study 27:**

A Study of Lebrikizumab in Patients With Idiopathic Pulmonary Fibrosis

#### **Study 28:**

Lung Volume Reduction Coil Treatment in Patients With Emphysema (RENEW) Study

http://ClinicalTrials.gov/show/NCT01608490

#### **Study 29:**

Rollover Study of Ivacaftor in Subjects With Cystic Fibrosis and a Non G551D CFTR Mutation

http://ClinicalTrials.gov/show/NCT01707290

### Study 30:

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

http://ClinicalTrials.gov/show/NCT01902290

### **Study 31:**

Testing the Feasibility of Patient Controlled Sedation for Ventilated ICU Patients

http://ClinicalTrials.gov/show/NCT01606852

#### **Study 32:**

Effects of an Antioxidant-Enriched Multivitamin Supplement on Inflammation and Oxidative Stress in Cystic Fibrosis

http://ClinicalTrials.gov/show/NCT01859390

### **Study 33:**

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

#### **Study 34:**

Safety and Efficacy Trial of Dymista Nasal Spray in Children Ages 4 to 11 With Seasonal Allergic Rhinitis (SAR)

http://ClinicalTrials.gov/show/NCT01915823

### Study 35:

Phase III Cat-PAD Study

http://ClinicalTrials.gov/show/NCT01620762

### **Other Diseases**

(26 clinical trials recruiting)

#### Study 1:

Study Evaluating the Safety, Tolerability, and Efficacy of Dexmecamylamine (TC-5214) for Treatment of Overactive Bladder

http://ClinicalTrials.gov/show/NCT01868516

### Study 2:

Phase 2/3 Study of IGSC, 20% in Primary Immunodeficiency Diseases (PIDD)

http://ClinicalTrials.gov/show/NCT01218438

### Study 3:

Versartis Trial in Children to Assess Long-Acting Growth Hormone

http://ClinicalTrials.gov/show/NCT01718041

### Study 4:

Study of the Safety and Efficacy of REGN1033 (SAR391786) in Patients With Sarcopenia

http://ClinicalTrials.gov/show/NCT01963598

#### Study 5:

Efficacy and Safety of Odanacatib in Postmenopausal Women Previously Treated With Oral Bisphosphonate (MK-0822-076 AM1)

http://ClinicalTrials.gov/show/NCT01803607

#### Study 6:

A Randomised Placebo-Controlled Study Evaluating the Efficacy and Safety of DYSPORT Using 2mL Dilution in Adults With Cervical Dystonia (CD)

### Study 7:

A Safety and Efficacy Study of Bimatoprost in Men With Androgenic Alopecia (AGA)

http://ClinicalTrials.gov/show/NCT01904721

### Study 8:

A Clinical Study to Evaluate the Safety and Efficacy of Elagolix in Subjects With Moderate to Severe Endometriosis-Associated Pain

http://ClinicalTrials.gov/show/NCT01620528

#### Study 9:

Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) During Soft Tissue Open Surgeries

http://ClinicalTrials.gov/show/NCT01731938

### **Study 10:**

MCS110 in Patients With Pigmented Villonodular Synovitis (PVNS)

http://ClinicalTrials.gov/show/NCT01643850

### **Study 11:**

Human Heterologous Liver Cells for Infusion in Children With Urea Cycle Disorders

http://ClinicalTrials.gov/show/NCT01195753

#### **Study 12:**

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

http://ClinicalTrials.gov/show/NCT01607658

#### **Study 13:**

Study of Dexamethasone Plus MLN9708 or Physician's Choice of Treatment in Relapsed or Refractory Systemic Light Chain (AL) Amyloidosis

http://ClinicalTrials.gov/show/NCT01659658

#### **Study 14:**

Phase I, Open Label, Dose Escalation Study of NEOD001 in Subjects With Light Chain (AL) Amyloidosis

http://ClinicalTrials.gov/show/NCT01707264

### Study 15:

Pivotal Study of the LVIS (Low Profile Visualized Intraluminal Support)

http://ClinicalTrials.gov/show/NCT01793792

### Study 16:

Open Label Dose Escalation Phase I Study to Investigate the Safety and Pharmacokinetics of T121E01F in Healthy Postmenopausal Women

http://ClinicalTrials.gov/show/NCT01721993

### **Study 17:**

Compassionate Use of Mepolizumab in Subjects With Hypereosinophilic Syndrome (HES)

http://ClinicalTrials.gov/show/NCT00244686

### **Study 18:**

Open-Label Single Ascending Dose of Adeno-associated Virus Serotype 8 Factor IX Gene Therapy in Adults With Hemophilia B

http://ClinicalTrials.gov/show/NCT01687608

#### **Study 19:**

A Multinational, Open-Label, Non-Controlled Trial on Safety, Efficacy and Pharmacokinetics of NNC 0129-0000-1003 in Previously Treated Paediatric Patients With Severe Haemophilia A

http://ClinicalTrials.gov/show/NCT01731600

#### Study 20:

Wilate in Subjects With Von Willebrand Disease Who Undergo Surgery

### Study 21:

Safety and Efficacy of Polymyxin B Hemoperfusion (PMX) for Septic Shock

http://ClinicalTrials.gov/show/NCT01046669

### **Study 22:**

Safety and Effectiveness of the CustomFlex Artificial Iris Prosthesis for the Treatment of Iris Defects

http://ClinicalTrials.gov/show/NCT01860612

### Study 23:

Study to Evaluate Eye Function in Patients Taking Linezolid for Six Weeks or Greater

http://ClinicalTrials.gov/show/NCT00359632

### **Study 24:**

Study Assessing Double-masked Uveitis Treatment

http://ClinicalTrials.gov/show/NCT01358266

### **Study 25:**

Multicenter Study Using Glaukos® Trabecular Micro-Bypass Stent Model GTS400 Using the G2-M-IS Injector System in Conjunction With Cataract Surgery

http://ClinicalTrials.gov/show/NCT01461291

### Study 26:

Safety and Effectiveness of Wavefront-guided LASIK for the Correction of Mixed Astigmatism

