

Research in Your Backyard

Developing Cures, Creating Jobs



**PHARMACEUTICAL
CLINICAL TRIALS IN
OREGON**

Dots show locations of clinical trials in the state.

PhRMA

Executive Summary

This report shows that biopharmaceutical research companies continue to be vitally important to the economy and patient health in Oregon, despite the recession.

At a time when the state still faces significant economic challenges, biopharmaceutical research companies are conducting or have conducted more than 2,300 clinical trials of new medicines in collaboration with the state's clinical research centers, university medical schools and hospitals. Of the more than 2,300 clinical trials; 1,252 target or have targeted the nation's six most debilitating chronic diseases—**asthma, cancer, diabetes, heart disease, mental illnesses and stroke.**

What are Clinical Trials?

In the development of new medicines, clinical trials are conducted to prove therapeutic safety and effectiveness and compile the evidence needed for the Food and Drug Administration to approve treatments. Clinical tests of new drugs are conducted in three phases and account for seven of the 10 to 15 years required for drug development and approval.

Clinical trials involve thousands of volunteer patient participants, the generation of tens of thousands of pages of technical and scientific data and are responsible for 45 to 75 percent of the \$1.2 billion average cost of developing one new cutting-edge biotechnology medicine.

Quite often, biopharmaceutical companies hire local research institutions to conduct the tests and in Oregon, they help to bolster local economies in communities all over the state, including Eugene, Bend and Portland.

“At Oregon’s only Academic Health Center, OHSU Physicians and Researchers work closely with the Pharmaceutical Industry through Clinical Trials. These studies make cutting edge treatments available to our patients suffering from a wide range of diseases. They also attracted nearly \$43 million to Oregon supporting numerous jobs and stimulating the economy.”

—Oregon Health & Science University

For patients, the trials offer another potential therapeutic option. Clinical tests may provide a new avenue of care for some chronic disease sufferers who are still searching for the medicines that are best for them. More than 230 of the trials underway in Oregon are still recruiting patients.

Participants in clinical trials can:

- Play an active role in their health care.
- Gain access to new research treatments before they are widely available.

- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

Patient Safety in Clinical Trials

- All tests must be reviewed and approved by an Institutional Review Board (IRB), an independent committee of physicians, statisticians, local community advocates and others to ensure a trial is ethically conducted and patient rights are protected.
- Clinical trial progress reports must be submitted at least annually to the Food and Drug Administration and the IRB.
- All facilities that conduct or support biomedical research involving patients must comply with federal regulations and have an IRB.

Many different entities and individuals contribute to the safe and appropriate conduct of clinical research, including not only sponsoring companies but also regulatory agencies; investigative site staff and medical professionals who serve as clinical investigators; hospitals and other institutions where research is conducted; and institutional review boards and ethics committees.

Clinical Trials in Oregon since 1999— Completed and Active

All Clinical Trials	Six Major Chronic Diseases
2,388	1,252

Source: www.clinicaltrials.gov

Note: Search criteria = Oregon, Phase I, II, III; industry only.
Search performed 1/4/2012.

Local Involvement

Oregon institutions involved in clinical tests of treatments include medical schools, research centers and hospitals, such as:

- Oregon Health & Science University (OHSU) in Portland
- Clinical Research Institute of Southern Oregon in Medford
- North Bend Medical Center in Coos Bay
- Willamette Valley Cancer Institute & Research Center in Eugene and Springfield
- Legacy Meridian Park Medical Center in Tualatin
- Oregon Center for Clinical Investigations in Portland and Salem
- Willamette Valley Clinical Studies in Eugene
- Sacred Heart Medical Center in Springfield
- Providence St.Vincent Medical Center in Portland

The biopharmaceutical research companies working with these institutions have targeted disease wisely—more than half of Oregon’s new medicine clinical trials are aimed at chronic conditions that plague patients all over the state, including cancer, diabetes, heart disease and stroke.

There are 235 clinical trials recruiting patients all over the state. These trials target the top six chronic diseases—**asthma, cancer, diabetes, heart disease, mental illness and stroke.**

Equally as important is the fact that many of the medicines being clinically tested here are new-generation biotechnology treatments. With biotechnology, we have the potential to develop safer and more effective therapies and we can improve our ability to predict, preempt or even prevent disease.

“Bioscience growth in Oregon continued between 2007 and 2009 despite a regional and national economic downturn. As a whole, clinical trials, drug development and medical device manufacturing boosted Oregon’s bioscience industry with an additional 585 jobs added between 2007 and 2009. In 2010, the local biosciences industry supported 36,800 jobs and \$1.9 billion in personal income. The sector generated \$273.9 million in local and state tax revenues, and with the strong economic multiplier effect, the industry has a \$7 billion footprint here.”

—Oregon Bioscience Association

Economic Impact of Biopharmaceutical Companies

Earlier reports show biopharmaceutical research companies have been an important source of jobs, tax revenue and research spending:

- A study by Archstone Consulting found that in 2008 biopharmaceutical firms invested \$84.4 million in research and development and provided \$4 billion in products and services.
- Company employees in Oregon include life sciences researchers, management executives, office and administrative support workers, engineers, architects, computer and math experts and sales representatives.

Clinical Trials in Oregon Communities

Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Ashland	2	0	0	1	2	1
Beaverton	0	4	0	0	0	0
Bend	1	11	3	5	0	2
Corvallis	1	3	2	1	0	1
Eugene	4	14	6	1	8	1
Gresham	0	3	1	0	0	0
Hillsboro	0	0	1	2	0	1
Lake Oswego	8	0	0	0	0	0
Medford	12	0	2	0	2	0
Portland	12	115	13	15	32	11
Springfield	0	19	1	1	0	0
Tualatin	0	15	0	0	0	1

Source: www.clinicaltrials.gov

Note: Search criteria = Oregon, Phase I, II, III; industry only. Search performed 1/4/2012. See Appendix for detailed information about these clinical trials. Disease columns will not add to totals in Appendix because some clinical trials are recruiting in more than one city.

“Research conducted through clinical trials drives the development of new evidence that will deliver the next generation of innovations to improve care and patient quality of life. However, while nearly 20% of cancer patients are eligible for participation in cancer clinical trials, enrollment among adults consistently ranges between 3-5%. Clearly, more has to be done to unlock the incredible potential of clinical trials in solving the cancer problem.”

—American Cancer Society Cancer Action Network

The Need for New Chronic Disease Medicines

Chronic diseases pose the greatest threats to our nation’s health and our ability to treat and prevent medical conditions. According to the Centers for Disease Control and Prevention, today, in the United States:

- Patients with chronic diseases account for 75 cents of every dollar spent on health care.
- Chronic diseases are the leading cause of death and disability.
- Chronic diseases are a leading driver of rising health care costs with expenses totaling billions of dollars every year.

With the stakes so high, America’s biopharmaceutical research companies are developing new medicines to help treat those conditions that are taking an unprecedented toll on American lives.

Many of these medicines are being tested today in clinical trials throughout Oregon.

At a time when tens of thousands of state residents are suffering from one or more chronic diseases, America’s biopharmaceutical research companies are sponsoring or have sponsored 1,252 clinical trials of potential new medicines in the Beaver State alone for **asthma, cancer, heart disease, stroke, diabetes and mental illnesses**. Of the 1,252 trials, 235 are either not yet recruiting or are just now seeking Oregon patients, giving those still searching for effective treatments potential new options and new hope.

Many of the state’s clinical tests involve collaborations with such respected local institutions as the **Oregon Health & Science University** in Portland, the **Willamette Valley Cancer Institute and Research Center** in Eugene, Florence and Springfield, the **Providence Portland Medical Center** in Portland, the **Knight Cancer Institute at OHSU** in Portland, the **St. Charles Medical Center** in Bend, and the **VA Medical Center** in Portland.

Clinical Trials for Top Chronic Diseases

Chronic Disease	All Clinical Trials	Clinical Trials Still Recruiting
Asthma	97	16
Cancer	559	130
Diabetes	212	21
Heart Disease	91	16
Mental Illness	258	39
Stroke	35	13
Total	1,252	235

Source: www.clinicaltrials.gov

Note: Search criteria = Oregon, Phase I, II, III; industry only. Search performed 1/4/2012.

Clinical Trials in Oregon

Clinical tests of new medicines are a vitally important part of the drug development and approval process—they account for 45 to 75 percent of the \$1.2 billion average cost of developing a new drug and are conducted to determine the safety and effectiveness of that treatment in patients.

Some trials are also conducted to compare existing treatments and some are done to learn if a drug is appropriate for a different patient population, such as children. Still others are conducted to find ways to make existing approved drugs more effective and easier to use with fewer side effects.

It's essential that trials be conducted properly so that clinicians and drug reviewers can develop accurate assessments of the efficacy and safety of medicines when used by patients. The Food and Drug Administration (FDA) is a vigilant regulatory agency and its pharmaceutical review officers are effective in detecting flawed information.

Questionable or confusing data can lead to lengthy delays in product approval or outright FDA rejection of a new drug.

Biopharmaceutical research companies are looking for the best physicians and research institutions to meticulously help design and conduct their clinical trials to determine whether a medicine is safe and effective. Side effects must be painstakingly documented and a determination made as to whether they occur too often and are dangerous.

Clinical Trials for Top Chronic Diseases

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Search performed 1/4/2012

Clinical tests involve three phases and thousands of volunteer patients and are often conducted at multiple sites around the country. In Oregon, biopharmaceutical companies have the luxury of having trials conducted at the states' well-respected university medical schools, comprehensive cancer centers and clinical trial research centers. According to *U.S. News and World Report*, **Oregon Health & Science University** ranked 36th among this year's top 100 research-oriented medical schools in the United States.

Asthma is a debilitating condition for more than 24 million Americans, including 7 million children under the age of 18. The toll is also severe in Oregon—more than 300,000 adults and 83,000 children have asthma, according to the Public Health Division of the Oregon Health Authority.

Currently, 16 clinical trials of new asthma medicines are recruiting patients in Oregon. Trials are being conducted at the **Clinical Research Institute of Southern Oregon** in Medford, **Allergy Associates Research Center** in Portland, **Integrated Medical Research** in Ashland, and **Baker Allergy, Asthma and Dermatology Research Center** in Lake Oswego.

Cancer, the second leading cause of death in the United States, now afflicts nearly 12 million Americans, according to the National Cancer Institute. In Oregon, more than 21,000 new cancer cases will be diagnosed this year and 7,790 victims in the state will die, according to the American Cancer Society.

Currently, 130 clinical trials of new cancer medicines are recruiting patients in Oregon. Biopharmaceutical companies are collaborating on the tests with such prominent institutions as the **Knight Cancer Institute at Oregon Health & Science University** in Portland, the **Willamette Valley Cancer Institute and Research Center** in Eugene, **Cancer Care of the Cascades** and **St. Charles Medical Center** in Bend, and **Doernbecher Children's Hospital** in Portland.

Diabetes affects more than 25 million Americans—about 8 percent of the U.S. population—and nearly one-third are unaware they have the disease. In Oregon, an estimated 186,000 have diabetes and another 76,000 are undiagnosed in Oregon, according to the Public Health Division of the Oregon Health Authority.

Currently, more than 20 diabetes clinical tests are seeking patients in Oregon. The trials are being conducted at **Willamette Valley Clinical Studies** in Eugene, the

Harold Schnitzer Diabetes Health Center at OHSU and **Cyn3rgy Research** in Gresham.

Heart disease and stroke are the first and fourth leading disease causes of death in the United States and in Oregon. According to the American Heart Association, more than 82 million Americans are affected by these diseases. In Oregon, in 2009, more than 6,200 residents died from some form of heart disease and 1,900 died from a stroke, according to the Public Health Division of the Oregon Health Authority.

Currently, 16 heart disease and 13 stroke clinical tests are seeking patients in Oregon. The trials are being conducted at the **Oregon Health & Science University** and **Providence St. Vincent Medical Center** in Portland, the **Sacred Heart Medical Center** in Springfield, **Legacy Meridian Park Medical Center** in Tualatin, and the **Oregon Stroke Center at OHSU** in Portland.

Mental illness affects nearly 60 million Americans suffering from some form of the disease—from anxiety to depression to schizophrenia to eating disorders. In Oregon, about 137,000 adults live with serious mental illness and about 39,000 children live with serious mental health conditions, according to the National Alliance on Mental Illness.

Currently, more than 30 clinical trials are recruiting patients in Oregon. The trials are taking place at the **Oregon Center for Clinical Investigations** in Salem, the **Oregon Health & Science University** in Portland, and **Sunstone Medical Research** in Medford.

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

New Generation Medicines in Development

Many of the medicines being tested in Oregon are cutting-edge biotechnology drugs.

America's biopharmaceutical research companies are using biotechnology to develop hundreds of medicines and vaccines today. And Oregon is one of the states where new-generation research and development work is being done.

Through biotechnology, new ways are being developed to not only more effectively treat disease, but also to predict, preempt and prevent it.

Biotechnology medicines are developed through biological processes using living cells or organisms, rather than traditional chemical synthesis, the mainstay of pharmaceutical development for decades.

Such novel treatments use a variety of new approaches to treat disease. For example, a monoclonal antibody is a laboratory-made version of the naturally occurring immune system protein that binds to and neutralizes foreign invaders. Interferons are proteins that interfere with the ability of a cell to reproduce.

Antisense drugs, meanwhile, are medicines that interfere with the communication process that tells a cell to produce an unwanted protein. In addition, nanotechnology is being used in biotechnology research to provide drug-delivery systems, new treatments and diagnostics.

Many of the medicines in clinical testing at Oregon medical schools and research centers feature these technologies. For example:

- A genetically-modified virus-based vaccine to treat melanoma.
- An antisense medicine for the treatment of cancer.
- A recombinant fusion protein to treat diabetic macular edema.
- A monoclonal antibody in the pipeline targets lupus and various types of cancer.
- A therapeutic vaccine, designed to jump-start the immune system to fight disease, is in development for lung cancer and melanoma.

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

Conclusion

Biopharmaceutical companies' close collaboration with clinicians and research institutions in Oregon benefits patients, the state's economy and the advancement of science and patient care. Clinical trial business is good business for the state's medical schools and clinical research centers and the medicines being tested are often cutting-edge cell and protein treatments with the potential to be safer and more effective than older chemical compound drugs.

What's more, Oregonians contemplating participation in clinical trials have a wide range of choices—235 tests of new medicines for the six most debilitating chronic diseases in America are underway in communities large and small all over the state and they need patient volunteers. Additional clinical trials recruiting patients target other diseases such as rheumatoid arthritis, chronic obstructive pulmonary disease, traumatic brain injury, cystic fibrosis, influenza, lupus, and psoriasis.

The Drug Discovery, Development and Approval Process

It takes 10-15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

Clinical Trials							
Discovery/ Preclinical Testing		Phase I	Phase II	Phase III	FDA	Phase IV	
Years	6.5	1.5	2	3.5	1.5		
Test Population	Laboratory and animal studies	20 to 100 healthy volunteers	100 to 500 patient volunteers	1,000 to 5,000 patient volunteers	Review process/ approval	Additional post-marketing testing required by FDA	
Purpose	Assess safety, biological activity and formulations	Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use			
Success Rate	5,000 compounds evaluated	5 enter trials			1 approved		

The Drug Development and Approval Process

The U.S. system of new drug approvals is perhaps the most rigorous in the world.

It takes 10-15 years, on average, for an experimental drug to travel from lab to U.S. patients, according to the Tufts Center for the Study of Drug Development, based on drugs approved from 1994 through 1998. 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 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. These tests usually involve about 20 to 100 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized, and excreted as well as the duration of its action.

Clinical Trials, Phase II. In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug's effectiveness and determine the early side effect profile.

Clinical Trials, Phase III. This phase usually involves 1,000 to 5,000 patients in clinics and

hospitals. Physicians monitor patients closely to confirm efficacy and identify adverse events.

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. The average review time for the 21 new therapeutics approved by the FDA in 2010 was 14.8 months.

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. Pharmaceutical companies invested an estimated \$67.4 billion in research and development in 2010.

The Good News – Many Clinical Trials are Still Recruiting

There are 235 clinical trials recruiting in Oregon. These trials target the top six chronic diseases and other debilitating diseases affecting Americans and Oregonians.

Clinical Trials in Oregon Communities						
Location	Asthma	Cancer	Diabetes	Heart Disease	Mental Illness	Stroke
Ashland	2	0	0	1	2	1
Beaverton	0	4	0	0	0	0
Bend	1	11	3	5	0	2
Corvallis	1	3	2	1	0	1
Eugene	4	14	6	1	8	1
Gresham	0	3	1	0	0	0
Hillsboro	0	0	1	2	0	1
Lake Oswego	9	0	0	0	0	0
Medford	12	0	2	0	2	0
Portland	12	115	13	15	32	11
Salem	0	0	0	0	9	0
Springfield	0	19	1	1	0	0
Tualatin	0	15	0	0	0	1

Source: www.clinicaltrials.gov

Note: Search criteria = Oregon, Phase I, II; industry only. Search performed 1/4/2012. See Appendix for detailed information about these clinical trials. Disease columns will not add to totals in Appendix because some clinical trials are recruiting in more than one city.

The Good News—Many Clinical Trials are Still Recruiting

(continued)

Asthma—Leading Institutions Conducting Clinical Trials

Allergy and Asthma Research Group, Eugene
Allergy Associates Research Center, Portland
Baker Allergy, Asthma and Dermatology Research
Center, Lake Oswego
Integrated Medical Research, Ashland
The Clinical Research Institute of Southern Oregon,
Medford
Transitional Clinical Research, Portland

Cancer—Leading Institutions Conducting Clinical Trials

Bend Memorial Clinic, Bend
Cancer Care of the Cascades, Bend
Celilo Center for Cancer Care, The Dalles Center for
Hematologic Malignancies, Oregon Health &
Science University, Portland
Doernbecher Children's Hospital, Portland
Kaiser Permanente Northwest, Portland
Legacy Health System, Portland
North Bend Medical Center, Coos Bay
Northwest Cancer Specialists, Tualatin, Portland,
Rose Quarter, St. Vincent
Knight Cancer Center, Beaverton, Gresham, Portland,
Tualatin
Oregon Health & Science University Cancer Center,
Portland
Oregon Health & Science University,
Portland
Pain Research of Oregon, Eugene
Providence Oncology & Hematology Care, Portland
Providence Portland Cancer Center, Portland
Providence Portland Medical Center, Portland
Providence St. Vincent Medical Center, Portland
St. Charles Medical Center, Bend
VA Medical Center, Portland
Willamette Valley Cancer Center, Eugene, Springfield

Willamette Valley Cancer Institute and Research
Center, Eugene, Springfield

Diabetes—Leading Institutions Conducting Clinical Trials

Cyn3rgy Research, Gresham
Diabetes Research Center, Oregon Health & Science
University, Portland
Legacy Clinical Research & Technology Center,
Portland
North West Renal Clinic, Portland
Portland Hypertension & Nephrology Clinic, Portland
Willamette Valley Clinical Studies, Eugene

Heart Disease—Leading Institutions Conducting Clinical Trials

Oregon Health & Science University, Portland
Providence St. Vincent Medical Center, Portland
Sacred Heart Medical Center, Springfield

Mental Illness—Leading Institutions Conducting Clinical Trials

CODA, Portland
Columbia Research Group, Portland
Integrated Medical Research, Ashland
Oregon Center for Clinical Investigations, Portland,
Salem
Oregon Health & Science University, Portland
Summit Research Network, Portland
Sunstone Medical Research, Medford

Stroke—Leading Institutions Conducting Clinical Trials

Oregon Health & Science University, Portland
Oregon Stroke Center, Oregon Health & Science
University, Portland
Providence St. Vincent's Medical Center, Portland
Legacy Meridian Park Medical Center, Tualatin



Pharmaceutical Research and Manufacturers of America
950 F Street, NW, Washington, DC 20004

www.phrma.org