

RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
OREGON

PhRMA
RESEARCH • PROGRESS • HOPE

Executive

This report shows how biopharmaceutical research companies continue to be vitally important to the economy and patient health in **Oregon**.

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 4,000 clinical trials of new medicines in Oregon in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Oregon's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

Summary

Clinical trials in **OREGON**

CLINICAL TRIALS IN OREGON ARE A VITAL PART OF THE FDA DRUG APPROVAL PROCESS

In the development of new medicines, clinical trials are conducted to prove therapeutic safety and effectiveness and compile the evidence needed for the U.S. Food and Drug Administration (FDA) to approve new treatments.

Clinical tests of new drugs are conducted in three phases and, on average, account for nearly seven of the more than 10 years it takes to bring a new drug from development to patients. Clinical trials are responsible for more than half of the \$2.6 billion average cost of developing one new innovative medicine.

All clinical trials must be reviewed and approved by an Institutional Review Board (IRB) in advance; an independent committee of physicians, statisticians, local community advocates and others to ensure a trial is ethically conducted and patient rights are protected.

Clinical Trials in Oregon since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
4,067	523

Source: www.clinicaltrials.gov. Search criteria: Oregon, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 10/26/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

Executive Summary (cont.)

CLINICAL TRIALS OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

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

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN OREGON

Biopharmaceutical research companies have been and continue to be a good source of jobs, tax revenue and research spending in Oregon.

A study by TEconomy Partners found that in 2015, the industry supported more than 18,500 jobs throughout Oregon. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than \$252 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$4.1 billion in economic activity in the state, including the direct economic output of the sector itself, the output of the sector's vendors and suppliers and the output generated by the buying power of its workforce.

Company employees in Oregon include life science researchers, management executives, office and administrative support workers, production workers, engineers, architects, computer and math experts, and sales representatives. Biopharmaceutical companies also supported the jobs of their vendors and suppliers, including construction and IT firms. And the employees of biopharmaceutical companies help to support local restaurants, day care centers and other community businesses.

ECONOMIC IMPACT OF CLINICAL TRIALS IN OREGON

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 904 active industry-sponsored, site-based clinical trials in Oregon, with an estimated enrollment of 10,620 Oregon residents. Oncology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was \$107.5 million and the estimated total economic impact was more than \$264 million.

Open Clinical Trials in Oregon by Disease

Disease	Number of Trials
Allergy	3
Alzheimer's Disease	15
Arthritis/Musculoskeletal Disorders	10
Autoimmune Diseases	25
Bladder Disorders	2
Blood Disorders	8
Cancer	262
Cardiovascular Diseases	28
Diabetes	8
Eye Disorders	24
Gastrointestinal/Esophageal Diseases	14
Genetic Disorders	11
Infectious Diseases	13
Kidney Diseases	3
Liver Diseases	3
Mental Disorders	20
Psychiatric Conditions	21
Respiratory Diseases	22
Skin Diseases	20
Transplantation-Related	3
Other Diseases	8
Total	523

Source: www.clinicaltrials.gov. Search criteria: Oregon, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2007. Search performed 10/26/2018. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

Patient Resources & Directory

WHAT IS THE CLINICAL TRIAL EXPERIENCE?

Clinical trials are research studies that generate data to support FDA approval of a new medicine or a new indication for an existing medication. They also grant participants early access to new medicines, which are being developed to help combat chronic and serious diseases. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Oregon, 4,067 clinical trials since 2004 have targeted diseases and conditions like asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

PHASES OF CLINICAL TRIALS

There are three phases of clinical testing used to evaluate potential new medicines:

PHASE I—Researchers test the drug in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range and identify potential side effects.

PHASE II—The drug is given to volunteer patients, usually between 100 and 500 people, to study its efficacy, identify an optimal dose and to further evaluate its short-term safety.

PHASE III—The drug is provided to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes 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.

LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials in several ways. Health care providers are aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. In addition to the National Institutes of Health's website www.clinicaltrials.gov, patients can also use hospital and university websites to find the trials being conducted in their area. For instance, for clinical trials at Oregon Health and Science University go to www.ohsu.edu/xd/health/clinical-trials.

More information about clinical trials in Oregon and how to volunteer for one can be found at www.centerwatch.com, a PhRMA-recommended website.

WHAT TO EXPECT

Since clinical trials are often conducted in a doctor's office, patients may need to devote more time to physician visits and physical examinations. They may also have additional responsibilities, like keeping a daily log of their health. All prospective participants must sign an informed consent document saying they understand that the clinical trial is research, and that they can leave the trial at any time. After consulting with their health care providers, patients can volunteer to participate, leading to a pre-screening interview. If they fit the criteria and requirements of the test, they can be enrolled.

PATIENT EXPENSES

Patients should ask during pre-screening interviews what it will cost them to participate in a clinical trial. Clinical trial sponsors usually pay for all research-related expenses and additional testing or physician visits required by the trial. Patients or their insurance companies may be asked to pay for any routine treatments of their disease. And it's important to know some health plans do not pay for clinical trials.

Patients should make it a point to learn if they or their insurance company will be assessed any fees and should determine if their insurance company will cover the expense of routine examinations. Patients who live a distance from the trial site should learn the clinic's policy for covering travel costs and living expenses.

The National Cancer Institute, for example, makes patients responsible for their own travel costs for the initial screening visits. Once a patient is enrolled, the Institute will pay for transportation costs for all subsequent trial-related visits. These patients will receive a small per diem for food and lodging.

EXPANDED ACCESS

Successful completion of the clinical trials is required to demonstrate to the FDA that an investigational drug is safe and effective, so that it can be approved and made available to a broad patient population. Clinical trials are the primary route by which patients can participate in the drug development process, receive access to unapproved investigational drugs and contribute to the collection of safety and efficacy data necessary for FDA approval.

For patients with a serious or life-threatening disease who are ineligible or unable to participate in a clinical trial, use of an unapproved investigational drug through an expanded access program may be an option. The current FDA process for a patient to gain access to an investigational drug through expanded access was established in 2009 in close consultation with patients, physicians and the biopharmaceutical industry. Expanded access programs are part of many biopharmaceutical companies' commitment to patients.

For more information about the drug development and approval process in the United States, see page 13.

LOCAL PATIENT ADVOCACY GROUPS

Patient advocacy groups in Oregon provide an exceptional resource for patients to connect and learn more about their condition and what treatment options are available in the state. These groups also provide an important voice on behalf of patients to protect their access to medicine and treatment.

The following are just a few major groups that work on behalf of patients in Oregon, and may provide more information to patients with further questions.

Alzheimer's Association

PORTLAND OFFICE

1650 NW Naito Parkway, Suite 190
Portland, OR 97209
(800) 272-3900

American Cancer Society

MEDFORD OFFICE

31 W. 6th Street
Medford, OR 97501
(541) 779-6091

Epilepsy Foundation Northwest

OREGON AND WASHINGTON OFFICE

2311 N. 45th Street, Suite 134
Seattle, WA 98103
(206) 547-4551

Alzheimer's Association

CASCADE COAST REGIONAL OFFICE

1000 Willagillespie Road, Suite 100
Eugene, OR 97401
(541) 345-8392

American Cancer Society

PORTLAND OFFICE

0330 SW Curry Street
Portland, OR 97239
(503) 295-6422

HIV Alliance

1195a City View Street
Eugene, OR 97402
(541) 342-5088

Alzheimer's Association

CENTRAL OREGON REGIONAL OFFICE

777 NW Wall Street, Suite 104
Bend, OR 97701
(541) 317-3977

American Diabetes Association

OREGON OFFICE

4380 SW Macadam Avenue
Suite 270
Portland, OR 97239
(503) 736-2770

Lupus Foundation of America

PACIFIC NORTHWEST REGIONAL OFFICE

1605 5th Avenue, Suite 1100
Seattle, WA 98101
(425) 336-2309

Alzheimer's Association

MID-WILLAMETTE VALLEY OFFICE

Center 50+
2615 Portland Road NE, Suite 2
Salem, OR 97301
(800) 272-3900

American Heart Association

OREGON OFFICE

4380 SW Macadam Avenue
Suite 480
Portland, OR 97239
(503) 820-5300

NAMI Oregon

NATIONAL ALLIANCE ON MENTAL ILLNESS

4701 SW 24th Avenue, Suite E
Portland, OR 97202
(503) 230-8009

Alzheimer's Association

SOUTHERN OREGON REGIONAL OFFICE

1245 N. Riverside Avenue, Suite 23
Medford, OR 97501
(800) 272-3900

American Lung Association

OREGON OFFICE

16037 SW Upper Boones Ferry
Road, Suite 165
Tigard, OR 97224
(503) 924-4094

National Psoriasis Foundation

6600 SW 92nd Avenue, Suite 300
Portland, OR 97223
(503) 244-7404

Alzheimer's Network of Oregon

2673 12th Street, SE
Salem, OR 97302
(503) 364-8100

Arthritis Foundation

OREGON OFFICE

4145 SW Watson Avenue
Suite 350
Beaverton, OR 97007
(503) 946-6715

American Cancer Society

EUGENE OFFICE

2350 Oakmont Way, Suite 200
Eugene, OR 97401
(541) 484-2211

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA):

The Partnership for Prescription Assistance has helped more than 83,900 Oregon patients access free or nearly free prescription medicines for residents who are underinsured or uninsured within the state. Patients should go to www.pparx.org for more information. The on-line process takes about 15 minutes, and you'll find out instantly if you're likely to be eligible for help.

HEALTHCARE READY: Healthcare Ready is a tool activated to help keep emergency responders informed on the status of the biopharmaceutical supply chain in the event of a natural disaster or emergency. Healthcare Ready's Rx Open tool was deployed in 11 states and the District of Columbia, and helped victims and evacuees who needed to fill or re-fill their prescriptions find open pharmacies. Healthcare Ready also helped emergency responders with critical information on the challenges facing supply chain partners relating to electricity, fuel and transportation issues. See more at www.healthcareready.org.

Clinical Trial Policy Resources

THE BIOPHARMACEUTICAL SECTOR'S ROLE IN THE ECONOMY

America's biopharmaceutical research companies serve as the foundation for one of the country's most dynamic innovation and business ecosystems. The biopharmaceutical industry is among the most research and development (R&D) intensive industries in the United States. In fact, the sector accounts for the single largest share of all U.S. business R&D, accounting for approximately 17 percent of all R&D spending by U.S. businesses. The industry and its large-scale research and manufacturing supply chain supports high-quality jobs across the U.S. economy.

Biopharmaceutical companies invest 12 times more in R&D per employee than manufacturing industries overall.

The biopharmaceutical industry supported more than 4.4 million jobs across the U.S. economy in 2014, according to a study by TEconomy Partners.

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested more than \$600 billion in R&D in the search for new treatments and cures.

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN OREGON

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Oregon. A TEconomy Partners study found that the biopharmaceutical sector:

- Supported more than 18,500 jobs throughout Oregon in 2014.
- Supported the generation of \$4.1 billion in economic activity in the state.
- Resulted in more than \$252 million in federal and state taxes paid through jobs supported by the biopharmaceutical sector.

For more information on the economic impact of the biopharmaceutical industry in Oregon, see page 2.

PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

The following are just a few of the prominent institutions that biopharmaceutical research companies are collaborating with on clinical trials for new medicines:

Allergy & Asthma Center of Southern Oregon, Medford

Allergy Associates Research Center, Portland

Baker Allergy, Asthma & Dermatology, Portland

Bay Area Hospital, Coos Bay

Bend Memorial Clinic, Bend

Center for Cognitive Health, Portland

Clackamas Radiation Oncology Center, Clackamas

Clinical Research Institute of Southern Oregon, Medford

Columbia Research Group, Portland

Crisor, Medford

Cyn3rgy Research Center, Gresham

Devers Eye Institute, Portland

Doernbecher Children's Hospital, Portland

Good Samaritan Regional Medical Center, Corvallis

Kaiser Permanente Center for Health Research, Portland

Legacy Devers Eye Institute, Portland

Legacy Emanuel Hospital and Health Center, Portland

Legacy Good Samaritan Hospital and Medical Center,
Portland

Legacy Meridian Park Hospital, Tualatin

Legacy Mount Hood Medical Center, Gresham

Legacy Research Institute, Portland

Memory Health Center at Summit Research Network,
Portland

Northwest Gastroenterology Clinic, Portland

OHSU Casey Eye Institute, Portland

OHSU Center for Health and Healing, Portland

OHSU Knight Cancer Institute, Portland

OHSU Layton Aging and Alzheimer's Disease Center,
Portland

Oregon Center for Clinical Investigations, Portland, Salem

Oregon Clinical & Translational Research Institute, Portland

Oregon Dermatology and Research Center, Portland

Oregon Health and Science University (OHSU), Portland

Oregon Medical Research Center, Portland

Oregon Retina Institute, Medford

Oregon Retina, Eugene

Oregon Stroke Center, Portland

Oregon Urology Institute, Springfield

Pacific Clear Vision Institute, Eugene

PeaceHealth Medical Group, Eugene

Portland VA Research Foundation, Portland

Providence Brain and Spine Institute ALS Center, Portland

**Providence Cancer Center Oncology and Hematology Care
Clinic**, Portland

**Providence Cancer Center, Earle A. Chiles Research
Institute**, Portland

Providence Heart and Vascular Institute, Portland

Providence Medical Center, Portland

Providence Multiple Sclerosis Center, Portland

Providence Newberg Medical Center, New Berg

Providence Oncology and Hematology Care Eastside,
Portland

Providence Oncology and Hematology Care Southeast,
Clackamas

Providence Saint Vincent Medical Center, Portland

Providence Willamette Falls Medical Center, Oregon City

Randall Children's Hospital at Legacy Emanuel, Portland

Retina Northwest, Portland

Robert W. Franz Cancer Research Center, Portland

Saint Alphonsus Medical Center, Baker City, Ontario

Samaritan Pastega Regional Cancer Center, Corvallis

Shriners Hospital for Children, Portland

St. Charles Medical Center, Bend

Summit Research Network, Portland

The Center for Men's & Women's Urology, Gresham

The Corvallis Clinic, Corvallis

The Oregon Clinic, Portland

VA Portland Healthcare System, Portland

Willamette Valley Cancer Institute and Research Center,
Eugene, Springfield

Collaborations between the biopharmaceutical research industry and universities play an important role in the development of new medicines. In the United States, there are more than 7,600 open clinical trials¹ being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies,

and research the other groups are undertaking on their own.

In Oregon, of the 523 open clinical trials involving the biopharmaceutical research industry, **Oregon Health and Science University** is collaborating on more than 91 of the trials.

THE STATE OF DISEASE IN OREGON

More than 4.1 million people live in Oregon¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Oregon	
Disease	Health Statistic
Alzheimer's Deaths, 2016 ²	1,786
Alzheimer's Prevalence, 2018 ³	65,000
Cancer New Cases, 2018 ⁴	21,520
Cancer Deaths, 2018 ⁴	8,310
Chronic Lower Respiratory Diseases Deaths, 2016 ⁴	2,081
Diabetes Prevalence—Adults, 2015 ²	287,000
Diabetes Deaths, 2016 ²	1,240
Heart Disease Deaths, 2016 ²	6,972
Hepatitis, Viral Deaths, 2016 ²	159
HIV-Number Living with a Diagnosis, 2014 ⁵	6,598
Hypertensive Renal Disease Deaths, 2016 ⁵	557
Influenza/Pneumonia Deaths, 2016 ²	452
Nephritis Deaths, 2016 ²	399
Parkinson's Death, 2016 ²	452
Parkinson's Prevalence, 2013 ⁶	22,500
Septicemia Deaths, 2016 ²	265
Stroke Deaths, 2016 ²	1,944

Source: 1. U.S. Census Bureau 2. Oregon Health Authority 3. Alzheimer's Association 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts 6. Oregon Health & Sciences University

¹ Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase early 1, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 10/26/2018. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

OREGON CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up 21.1 percent of the population in Oregon. Pediatric clinical trials are being conducted in the state for Crohn’s disease, cystic fibrosis, type 1 diabetes, epilepsy, atopic dermatitis, genetic eye diseases, juvenile arthritis, leukemia and neuroblastoma, among others.
- Oregonians aged 65 and older account for 17.1 percent of the states’ population. In Oregon, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer’s disease, chronic obstructive pulmonary disease, Crohn’s disease, age-related macular degeneration, prostate cancer, heart failure and rheumatoid arthritis, among others.
- Women and girls make up 50.4 percent of the population in Oregon. Clinical trials are recruiting women for studies on medicines for breast cancer, endometriosis, ovarian cancer and overactive bladder, among others.

Clinical Trials in Oregon for Special Populations

Population	Number of Trials
Children (birth-17)	105
Seniors (66 and older)	453
Women (only)	17

Source: www.clinicaltrials.gov. Search criteria: Oregon, United States; Phase: early 1, 1, 2, 3; Industry only; first received on or after 1/1/2007. Search performed 10/26/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

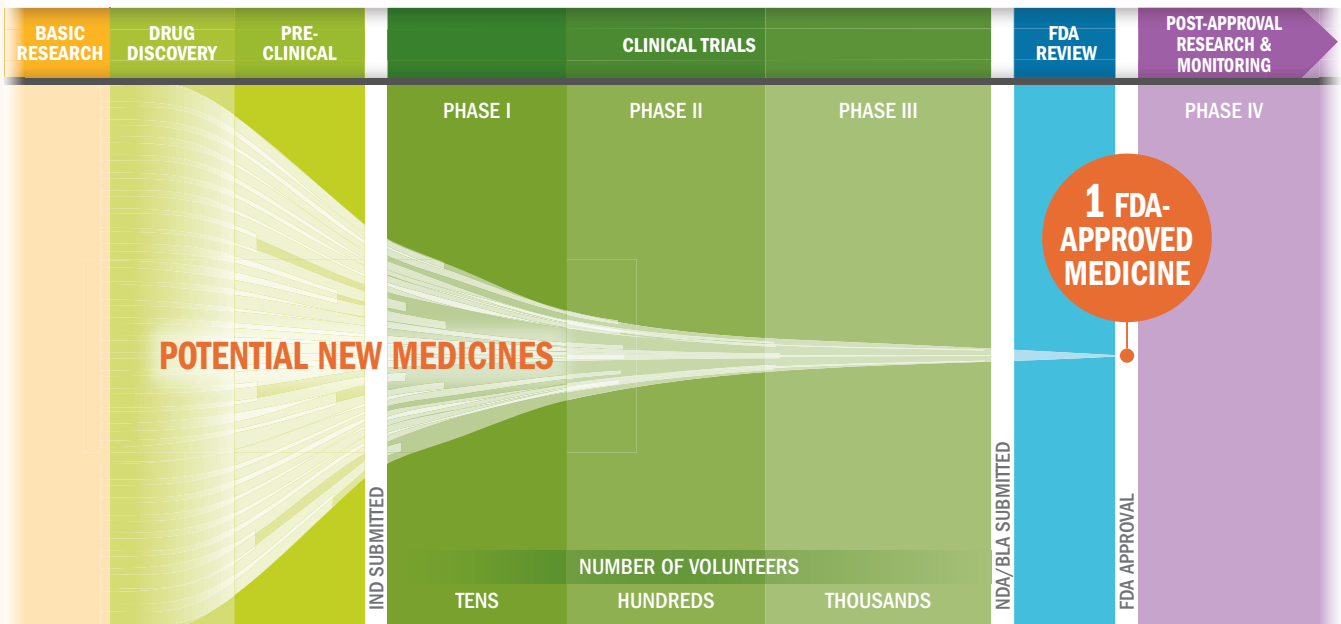
Some of the medicines in clinical testing in Oregon feature revolutionary medical technologies. For example:

- A monoclonal antibody for the treatment of Duchenne muscular dystrophy is being studied in a clinical trial at **Shriner's Hospital for Children** in Portland and for idiopathic pulmonary fibrosis at **Legacy Research Institute** in Portland.
- A second-generation tyrosine kinase inhibitor in clinical trials for leukemia blocks the activation of a receptor that is mutated in about one-third of all patients with acute myeloid leukemia. It is in a clinical trial at **Kaiser Permanente Northwest** in Clackamas.
- A medicine for advanced acute myeloid leukemia inhibits a mutated form of a gene that can lead to increased production of an oncometabolite that prevents immature white cells from developing into healthy infection fighting cells. It is in clinical trials at the **Oregon Health and Science University** in Portland.
- A novel targeted therapy that combines recombinant interleukin-3 with truncated diphtheria toxin is in development for relapsed or refractory multiple myeloma is in a clinical trial at the **Oregon Health and Science University** in Portland.
- A monoclonal antibody in development for the prevention of migraine binds to and inhibits the activity of a peptide expressed in the nervous system where it plays a role in controlling the widening of blood vessels and the transmission of nociceptive pain (pain arising from nerve cells) information. By inhibiting CGRP activity, anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. The antibody completed trials in **Portland**.
- A monoclonal antibody in development for relapsing multiple sclerosis targets LINGO, a protein that is involved in the development of myelin, a protective sheath covering the nerve fibers. It is believed that LINGO may inhibit myelin growth and, by blocking LINGO's production, the medicine could support the growth of myelin and restore nerve communication in multiple sclerosis patients. The monoclonal antibody is being studied in a clinical trial in **Portland**.
- A monoclonal antibody in development to treat lung cancer, ovarian cancer and gastric cancer inhibits PD-L1 interactions, and is thought to enable the activation of T-cells and the adaptive immune system. The monoclonal antibody may potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity. The antibody is in clinical trials at the **Willamette Valley Cancer Institute and Research Center** in Eugene, **Hematology Oncology Associates** in Grants Pass and Medford, **Asante** in Medford, and **Northwest Cancer Specialists, Kaiser Permanente Northwest** and **Oregon Health and Science University** in Portland.
- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It completed clinical trials at the **Willamette Valley Cancer Center** in Springfield.

The innovative treatments that are being developed today are helping to expand the frontiers of science and could lead to more and better treatments for patients in the future. In Oregon, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions.

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of \$2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).



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