

RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
OREGON



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 5,000 clinical trials of new medicines in Oregon in collaboration with clinical research centers, hospitals, and local research institutions. These clinical trials have investigated or are investigating some of Oregon's biggest health care challenges, including asthma, arthritis, cancer, infectious diseases, cardiovascular disease and gastrointestinal diseases.

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 establish therapeutic effectiveness and safety and compile the evidence needed for the U.S. Food and Drug Administration (FDA) to approve new treatments.

Clinical trials of new medicines are typically conducted in three phases and, on average, account for nearly seven of the more than 10 years it takes to bring a new medicine 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.

Clinical Trials in Oregon since 2004— Completed and Open

All Clinical Trials

5,082

Open Clinical Trials

668

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 4/18/2022. Open clinical trials are recruiting, not yet recruiting or expanded access available.

Executive Summary (cont.)

Institutional Review Boards (IRBs), independent committees of physicians, statisticians, local community advocates and others, review and approve clinical trials in advance to ensure trials are ethically conducted and patient rights are protected.

CLINICAL TRIALS MAY OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

For patients, clinical trials may offer the potential for another therapeutic option, or provide for a treatment where no FDA-approved treatments exist. Clinical trials may provide a new avenue of care for some chronic disease sufferers who are still searching for the medicines that are best for them.

Additionally, some clinical trials are conducted to compare existing treatments and some are done to explore whether a medicine is appropriate for a different patient population, such as children or the elderly. Still others are conducted to find ways to make existing approved treatments 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 Partners¹ found that in 2020, the industry supported more than 24,900 jobs throughout Oregon. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in \$401.5 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$6.7 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 TEconomy Partners² found that in 2017 alone, there were 577 active industry-sponsored clinical trials in Oregon, with an estimated enrollment of 8,675 Oregon residents. Oncology/cancer was the largest clinical trial disease area by total estimated enrollment in the state.

The investment at clinical trial sites was more than \$171 million and the estimated total economic impact was more than \$450 million.

¹ *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates*, TEconomy Partners, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Economic-Impact-States-2022/US--Puerto-RicoEco-Impact-One-Page-FINAL.pdf>

² *Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies*, TEconomy Partners, http://phrma-docs.phrma.org/files/dmfile/TEconomy_PhRMA-Clinical-Trials-Impacts.pdf

"Biopharmaceutical research companies have been and continue to be a good source of high-paying jobs, tax revenue and research spending in Oregon. These companies also support the jobs of their vendors, construction, local restaurants, day care centers and other community businesses. But first and foremost, we're here for our patients. Helping patients and ensuring their safety is our profession's top priority. There is no doubt that all Oregonians benefit from this industry and its innovations."

Curt A. Heiting, B.B.A, President of Cyn3rgy Research and Development and member of the Oregon Alliance of Clinical Researchers

Open Clinical Trials in Oregon by Disease	
Disease	Number of Trials
Allergy	3
Alzheimer's Disease/Dementia	14
Arthritis/Musculoskeletal Disorders	11
Autoimmune Diseases	7
Blood Disorders	7
Cancer	381
Cardiovascular Diseases	32
Eye Disorders	37
Gastrointestinal/Esophageal Diseases	6
Genetic Disorders	21
Infectious Diseases	27
Kidney Diseases	5
Mental Illnesses	10
Neurological Disorders	33
Respiratory Diseases	26
Skin Diseases	33
Transplantation Related	6
Other Diseases	9
Total	668

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 7/18/2022. 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 voluntary research studies conducted in people and designed to answer specific questions about the safety and effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments. Clinical trials can generate data to support FDA approval of a new medicine or a new indication for an existing medication. They may also grant participants early access to new medicines. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Oregon, 5,082 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 typically three phases of clinical testing used to evaluate potential new medicines:

PHASE I—Researchers test the medicine 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 medicine 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 medicine 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 may be 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. Patients can also use hospital and university websites to find the trials being conducted in their area.

For information on clinical trials being conducted at Oregon Health and Science University visit www.ohsu.edu/health/clinical-trials.

For more information about clinical trials in Oregon and how to participate in a clinical trial, visit: www.orclinicalresearch.com/clinical-trials-search-tool/, www.centerwatch.com or www.clinicaltrials.gov.

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. Generally, prospective participants will receive information about the potential risks and benefits of participating in the trial and must sign an informed consent document saying, among other things, they understand that the clinical trial is research, and that they can leave the trial at any time. Patients can volunteer to participate, leading to a pre-screening interview. If they fit the criteria and requirements of the test, they may be enrolled.

PATIENT EXPENSES

As part of the informed consent process, clinical trial sponsors must disclose any additional costs to the subject that may result from participating in the research. During pre-screening discussions with the clinical trial investigator, the patient can also ask about associated costs to participate in the trial. Clinical trial sponsors usually pay for all research-related expenses and additional testing or physician visits required by the trial. Patients or their health insurance plan may be asked to pay for any routine treatments for their disease. However, it is important for the patient to know whether their health plans will pay for clinical trial participation or whether there will be out-of-pocket costs at the patient's expense.

Patients should learn whether they or their health insurance plan will be assessed any fees, and they should determine if their insurance will cover the expense of routine examinations. Patients who live a distance from the trial site should inquire whether the clinic has a policy for covering travel costs and living expenses. The National Cancer Institute, for example, makes patients cover for their own travel costs for the initial screening visits. Once a patient is enrolled in the trial, the Institute pays for transportation costs for all subsequent trial-related visits. These patients may also receive a small per diem for food and lodging.

EXPANDED ACCESS

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 medicine through an expanded access program may be an option. Expanded access is the use of an unapproved investigational medicine outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition, when there are no other comparable or satisfactory alternative treatment options. Expanded access programs are part of many biopharmaceutical companies' commitment to patients.

"I've participated in a clinical trial to help manage my chronic pain and it was so worth the time and effort. And as someone with lupus, which currently doesn't have a cure, I encourage all patients to never give up hope that progress can be made to find cures and treatments and improve our lives through clinical trials. Not only is participating beneficial for the individual person but also for the community as a whole and for the advancement of medicine. I am proud to have participated and can't encourage individuals enough to do the same. If we don't try, how will we ever see improvement in our lives and the lives of others?"

Searcy Craighead Oregon patient with lupus, fibromyalgia and interstitial lung disease, Kaleidoscope Fighting Lupus

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 serve as an exceptional resource for patients, offering opportunities to connect and learn more about their condition and what treatment options are available locally. These groups also provide an important voice on behalf of patients to protect access to medicines and treatments.

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.

ALS Association Oregon and SW Washington

700 NW Multnomah St., Suite 210
Portland, OR 97232
(503) 616-8533
www.als.org/oregon-sw-washington

Alzheimer's Association

PORTLAND METRO OFFICE
5285 Meadow Road, Suite 451
Lake Oswego, OR 97035
(800) 272-3900
www.alz.org

American Cancer Society

OREGON OFFICE
P.O. Box 22770
Portland, OR 97269
(800) 227-2345
www.cancer.org

American Diabetes Association

OREGON OFFICE
P.O. Box 7023
Merrifield, VA 22116-7023
(503) 820-5300
www.diabetes.org

American Lung Association

PACIFIC WEST OFFICE
16037 SW Upper Boones Ferry Road, Suite 165
Tigard, OR 97224
(800) 732-9339
www.lung.org

Answer2Cancer

7299 SW Linette Way
Beaverton, OR 97007-5099
(503) 201-7019
www.answer2cancer.org

Caring Ambassadors

OREGON OFFICE
PO Box 1748
Oregon City, OR 97045
(503) 632-9032
www.caringambassadors.org

Epilepsy Foundation of Oregon

9340 SW Barnes Road, Suite 102
Portland, OR 97225
(503) 205-1404
www.epilepsy.com/oregon

HIV Alliance

SALEM OFFICE
3886 Beverly Avenue NE
Bldg. I, Suite 6
Salem, OR 97305
(541) 342-5088
(866) 470-3419

Kaleidoscope Fighting Lupus

2705 SE Milwaukie Avenue
Portland, OR 97202
(503) 936-0187
www.kaleidoscopefightinglupus.org

Lupus Foundation of America

PACIFIC NORTHWEST REGIONAL OFFICE
1417 NW 54th Street, Suite 476
Seattle, WA 98107
(877) 774-2992
www.lupus.org

NAMI Oregon

NATIONAL ALLIANCE ON MENTAL ILLNESS
4701 SW 24th Avenue, Suite E
Portland, OR 97202
(503) 230-8009
(800) 353-6264
www.namior.org

National Psoriasis Foundation

660 SW 92nd Avenue, Suite 300
Portland, OR 97223
(503) 244-7404
(800) 723-9166
www.psoriasis.org

Pacific Northwest Bleeding Disorders

456 SW Monroe Ave., Suite 102
Corvallis, OR 97333
(541) 753-0730
www.pnwbd.org

OREGON ALLIANCE OF CLINICAL RESEARCHERS: MAKING PATIENTS AWARE OF CLINICAL TRIALS AND THEIR IMPORTANCE

The Oregon Alliance of Clinical Researchers (OACR) provides clinical research expertise and sophisticated technology that enables biopharmaceutical companies and their local collaborators to conduct trials of new medicines that are easily accessible to patients throughout Oregon. Members conduct clinical testing of new medicines in the state for a range of diseases, including Alzheimer's disease, dementia, depression, macular edema, macular degeneration, psoriasis, eczema, atopic dermatitis, adult and pediatric cancers, prostate cancer, coronavirus, and others.

The OACR focuses on defining clinical research in easily understandable terms that educate all about the instrumental role that the industry plays in healthcare and the state's economy. The OACR is focused on providing clinical research education and support for the public, elected officials, the media, manufacturers, vendors, service providers and academic partners. The safety of Oregon's patients is the profession's top priority.

Alliance members include: Center for Cognitive Health, Cyn3rgy, Legacy Health, Oregon Health & Science University, Oregon Medical Research Center, Oregon Urology Institute and Summit Research Network.

To learn about the Oregon Alliance of Clinical Researchers or to find clinical trials taking place in Oregon, visit www.orclinicalresearch.com.

OTHER PATIENT RESOURCES

MEDICINE ASSISTANCE TOOL (MAT): The Medicine Assistance Tool is a PhRMA-sponsored search engine designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs. MAT is available to those who need financial support due to their lack of insurance or inadequate prescription medicine coverage. MAT is not its own patient assistance program, but rather, a search engine for many of the support programs and resources that the biopharmaceutical industry has offered for decades. The online process takes about 15 minutes, and patients can find out instantly if they are eligible for assistance. Patients can visit www.mat.org for more information.

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 has been deployed in 11 states and the District of Columbia and helps victims and evacuees who needed to fill or re-fill their prescriptions find open pharmacies. Healthcare Ready also helps emergency responders with critical information on the challenges facing supply chain partners relating to electricity, fuel and transportation issues. Patients can visit www.healthcareready.org for more information.

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.¹ The industry and its large-scale research and manufacturing supply chain support 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 2020, according to the study by TEconomy Partners.

Since 2000, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America have invested more than \$1 trillion in the search for new treatments and cures, including \$91.1 billion in 2020 alone.

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 Partners¹ study found that the biopharmaceutical sector:

- Supported more than 24,900 jobs throughout Oregon in 2020.
- Supported the generation of \$6.7 billion in economic activity in the state.
- Resulted in \$401.5 million in federal and state taxes through jobs supported by the biopharmaceutical sector.

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

¹ *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, TEconomy Partners, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Economic-Impact-States-2022/US--Puerto-RicoEco-Impact-One-Pager-FINAL.pdf>*

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:

Adventist Health Portland, Portland

Bay Area Hospital, Coos Bay

Cascade Medical Research Institute, Eugene

Cascade View Medical, Corvallis

Center for Cognitive Health, Portland

Clinical Research Institute of Southern Oregon, Medford

Crisor, Medford

Doernbecher Children's Hospital, Portland

Good Samaritan Hospital, Corvallis

Kaiser Sunnyside Medical Center, Clackamas

Kaiser Westside Medical Center, Hillsboro

Legacy Devers Eye Institute, Portland

Legacy Emanuel Medical 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

Neural Net Research, Portland

Northwest Cancer Specialists, 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 Dermatology and Research Center, Portland

Oregon Health and Science University (OHSU), Portland

Oregon Medical Research Center, Portland

Oregon Retina, Eugene

Oregon Urology Institute, Springfield

Providence Brain and Spine Institute, Portland

Providence Cancer Institute, Clackamas, Newburg, Portland

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

Providence Medical Center, Portland

Providence Neurological Specialties West, Portland

Providence Newberg Medical Center, Newberg

Providence Oncology and Hematology Care Clinics, Portland

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

Shriners Hospital for Children, Portland

St. Charles Health System, Bend, Redmond

Summit Research Network, Portland

The Oregon Clinic, Portland

Tuality Healthcare, Hillsboro

VA Portland Healthcare System, Portland

Willamette Valley Cancer Institute and Research Center, Eugene

OREGON UNIVERSITIES PLAY A KEY ROLE IN RESEARCH

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 8,800 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 undertaken by other groups on their own.

In Oregon, of the 668 open clinical trials involving the biopharmaceutical research industry, the Oregon Health & Science University is collaborating on more than 230 of the clinical trials.

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 1/1/2007. Search performed 4/18/2022. Open clinical trials are recruiting, not yet recruiting or are expanded access available.

THE STATE OF DISEASE IN OREGON

More than 4.2 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, 2020 ²	2,009
Alzheimer's Prevalence (65+), 2020 ³	69,000
Cancer New Cases, 2022 ⁴	25,130
Cancer Deaths, 2022 ⁴	8,460
Chronic Liver Disease/Cirrhosis Deaths, 2020 ²	832
COVID-19 Deaths, 2020 ²	1,436
Diabetes Deaths, 2020 ²	1,359
Diabetes Prevalence—Adults, 2015 ²	287,000
Heart Disease Deaths, 2020 ²	7,369
HIV-Number Living with a Diagnosis, 2019 ⁵	7,280
Hypertensive Renal Disease Deaths, 2020 ²	674
Influenza/Pneumonia Deaths, 2020 ²	390
Nephritis Deaths, 2020 ²	374
Parkinson's Deaths, 2020 ²	539
Parkinson's Prevalence, 2016 ⁶	10,500
Septicemia Deaths, 2020 ²	267
Stroke Deaths, 2020 ²	2,236

Sources: 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. Parkinson's Foundation

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

- Children under the age of 18 make up 20.5%¹ of the population in Oregon. Pediatric clinical trials are being conducted in the state for asthma, cystic fibrosis, epilepsy, leukemia, migraine, muscular dystrophy and respiratory syncytial virus infections, among others.²
- Oregonians aged 65 and older account for 18.2%¹ of the states' population. In Oregon, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, heart failure, chronic kidney disease, lymphoma, macular degeneration, Parkinson's disease, prostate cancer and respiratory syncytial virus infections, among others.²
- Women and girls make up 50.4%¹ of the population in Oregon. Clinical trials are recruiting women for studies on medicines for breast cancer, cervical cancer, fibromyalgia, ovarian cancer, symptoms of menopause and urinary tract infections, among others.¹

¹ U.S. Census Bureau, ² www.clinicaltrials.gov

Open Clinical Trials in Oregon for Special Populations

Population	Number of Trials
Children (birth-17)	132
Seniors (66 and older)	592
Women (only)	30

Source: www.clinicaltrials.gov. Search criteria: Oregon, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 4/18/2022. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

"Biomedical startups dream of reaching the clinical trial phase with their ideas. Support from our state, whether that be investments or policies, make it so more innovators can thrive in Oregon and see their dreams come true. Making a difference in the lives of patients and their families is a great return on investment."

Heather Ellis Executive Director, Oregon Translational Research and Development Institute (OTRADI) and Oregon Bioscience Incubator (OBI)

SCIENCE AND CLINICAL TRIALS¹

Some of the medicines in clinical testing in Oregon feature cutting-edge medical technologies. For example:

- Several medicines in development for Alzheimer's disease are disease-modifying treatments that may stop or slow disease progression by targeting one or more of the changes in the brain associated with the disease. One monoclonal antibody medicine in development is a Tau protein inhibitor designed to block and reduce the spread of Tau from neuron to neuron and potentially from forming damaging Tau tangles. A clinical is underway at sites in **Portland**.
- A second-generation CAR-T cell therapy comprised of genetically-modified T cells is designed to target B-cell maturation antigen (BCMA) and to redirect the T-cells to recognize and kill **malignant myeloma** cells. BCMA is a surface protein that is absent in most normal tissues but found in normal plasma cells and the majority of multiple myeloma cells. A clinical trial is underway at **Oregon Health & Science University in Portland**.
- An antisense treatment in development for amyotrophic lateral sclerosis (ALS) is thought to reduce the production of mutated superoxide dismutase (SOD1) protein and potentially the fatal progression of SOD1-ALS. This mutated protein has been associated with the degeneration of motor neurons in ALS. SOD1-ALS is a rare form of the disease that accounts for 20% of inherited or familial ALS and 2% of all ALS cases. A clinical trial is ongoing in **Portland**.
- A disease-modifying treatment in development for relapsing multiple sclerosis is an inhibitor of Bruton's tyrosine kinase (BTK) and targets the source of multiple sclerosis damage in the brain (lesions). The BTK inhibitor not only inhibits the peripheral immune system, but also crosses the blood-brain barrier to suppress immune cells that have migrated into the brain, while also modulating microglia cells that are responsible for removing damaged neurons that have been implicated in multiple sclerosis progression. The medicine shows promise for reducing neuroinflammation and neurodegeneration, both implicated in disease progression. A clinical trial is recruiting patients in **Portland**.
- A potential treatment for bladder cancer, renal cell carcinoma and melanoma, among others, is designed to stimulate cancer killing cells in the body by targeting CD122 on the surface of the immune cells. This experimental immune-therapy is being studied in combination with an approved immune checkpoint inhibitor which works by unleashing the body's own powerful immune system to target and kill cancer cells. The treatment works by increasing the number of tumor-infiltrating lymphocytes (TILs) which generate an immune response leading to increased therapeutic activity of the checkpoint inhibitor to attack cancer cells while leaving normal cells alone. Clinical trials are being conducted at **Portland Providence Medical Center and Oregon Health & Science University in Portland**.
- A disease-modifying gene therapy is being tested as a single-dose treatment for patients with GBA1-mutated Parkinson's disease. The GBA gene contains instructions for making glucocerebrosidase (GCase), which is needed for the removal and recycling of the glycolipids. Glycolipids are a cellular component that accumulates with age, causing lysosomal dysfunction and aggregation of alpha synuclein in the cells, which is thought to lead to inflammation and neurodegeneration. The gene therapy delivers a non-mutated GBA1 gene to the brain. Another DMT being tested against Parkinson's disease is a monoclonal antibody that targets alpha-synuclein and is designed to block cell-to-cell transmission of aggregated alpha-synuclein found in Parkinson's. A clinical trial is underway at **Oregon Health & Science University in Portland**.
- A monoclonal antibody is in development for the treatment of pancreatic cancer, Duchenne muscular dystrophy and idiopathic pulmonary fibrosis. Clinical trials are ongoing at **Shriners Hospital for Children in Portland**.
- A medicine in development to treat breast cancer binds to and inhibits AKT proteins. AKT helps to regulate cellular processes, such as cell division, cell death, and glucose and fatty acid metabolism. Mutations in the PI3K/AKT/mTOR signaling pathway can promote several types of cancer, including breast cancer, because normal cellular processes are disrupted. The medicine works by inhibiting AKT in cancer cells and is being tested in combination with paclitaxel, an approved chemotherapy treatment. Clinical trials are underway in **Portland**.

¹ PhRMA Medicines in Development reports, <https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development>

Conclusion

The Oregon bioscience industry supports more than 24,900 jobs throughout Oregon with wages and benefits supported by the sector, resulting in \$401.5 million in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of \$6.7 billion in direct and indirect economic activity in Oregon.

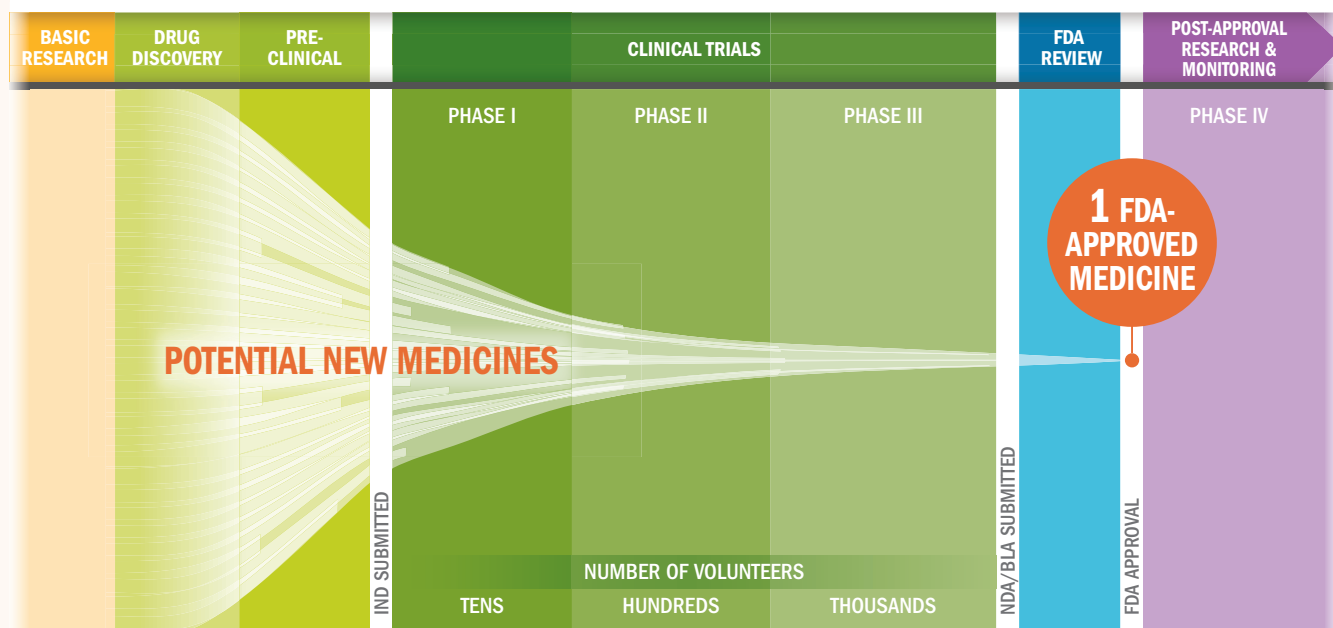
Oregonians are also positively impacted by the presence of a strong biopharmaceutical sector and clinical trials in the state. Innovative treatments

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. And the sector's growth and strength in Oregon are driving our economy and communities forward.

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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