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 5,600** 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.

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 in Oregon since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
5,665	572

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 7/18/2024. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

Executive Summary (cont.)

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.

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 Partners[1] found that in 2022, the industry supported **more than 28,600 jobs** throughout Oregon. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in **$580.5 million in state and federal taxes paid**.

Biopharmaceutical research companies supported the generation of **$8.2 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 Partners[2] 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 **$171 .7 million** and the estimated total economic impact was more than **$450 million**.

[1] *TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. February 2024. Report prepared for PhRMA. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf*

[2] *TEConomy Partners, LLC. Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies, April 2019. Report prepared for PhRMA. https://www.phrma.org/-/media/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, President of Cyn3rgy Research and Development

Open Clinical Trials in Oregon by Disease

Disease	Number of Trials
Alzheimer's Disease/Dementia	8
Arthritis/Musculoskeletal Diseases	5
Autoimmune Disorders	17
Blood Disorders	4
Cancer	333
Cardiovascular Diseases	24
Diabetes	2
Eye Diseases	32
Gastrointestinal/Esophageal Disorders	3
Genetic Diseases	9
Infectious Diseases	12
Kidney Diseases	9
Mental Illnesses	7
Neurologic Disorders	32
Obesity	5
Respiratory Diseases	37
Skin Disorders	20
Transplantation-Related	3
Other Diseases	10
Total	**572**

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 7/18/2024. 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, **5,665** 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 & Science University visit https://www.ohsu.edu/health/clinical-trials.

For more information about clinical trials in Oregon and how to participate in a clinical trial, visit: 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 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.

"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)

*For more information about **the drug development and approval process** in the United States, see page 17.*

LOCAL PATIENT ADVOCACY GROUPS

Patient advocacy groups in Oregon serves 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

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 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 several 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.

"The biopharmaceutical industry supports more than 28,600 Oregon jobs. Many are skilled union labor helping build manufacturing and research facilities. In the last several years, Oregon's union construction industry have helped build pharmaceutical and biotech and manufacturing projects. These investments have supported craftworkers and apprentices learning a trade for career opportunities and helped grow the Oregon economy."

John Mohlis, Pharmaceutical Industry Labor-Management Association

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 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 4.9 million jobs across the U.S. economy in 2022, according to a study by TEConomy Partners.[3]

Over the last decade, biopharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America (PhRMA) have more than doubled their annual investment in the search for new treatments and cures, including $101 billion in 2022 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 Partners study[3] found that the biopharmaceutical sector:

- Supported more than 28,600 jobs throughout Oregon in 2022.
- Supported the generation of $8.2 billion in economic activity in the state.
- Resulted in $580.5 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.*

[3] *TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. February 2024. Report prepared for PhRMA. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf*

PUBLIC–PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION[4]

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
- **Cyn3rgy Research and Development**, Gresham
- **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 & 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

[4] *www.clinicaltrials.gov. Retrieved 7/18/2024.*

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 9,400 open clinical trials[5] 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 572 open clinical trials involving the biopharmaceutical research industry, Oregon Health & Science University is collaborating on more than 150 of the clinical trials.

[5] 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 7/18/2024. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

"The biopharmaceutical industry — from the small startups like those at OTRADI to the larger clinical research institutions and manufacturers — bring profound value to patients through new treatments and cures for society's most devastating and costly diseases and conditions providing patients with the treatment options they wouldn't otherwise have. Their efforts help develop cures and treatments that are improving the lives of Oregon patients.

Rep. Daniel Nguyen

THE STATE OF DISEASE IN OREGON

More than 4.2 million people live in Oregon[1], 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 Disease Deaths 2022[2]	2,028
Asthma Adult Prevalence 2021[2]	11.2%
Cancer News Cases 2024[3]	26,200
Cancer Deaths 2024[3]	8,670
Chronic Lower Respiratory Deaths 2022[2]	2,013
COVID-19 Deaths 2022[2]	1,894
Diabetes Deaths 2022[2]	1,451
Diabetes Prevalence 2022[4]	322,300
Heart Disease Deaths 2022[2]	8,116
HIV-Number Living with a Diagnosis 2021[5]	7,484
Hypertension/Hypertensive Renal Disease Deaths 2022[2]	710
Influenza and Pneumonia Deaths 2022[2]	367
Kidney Disease Deaths 2022[2]	489
Liver Disease Deaths 2022[2]	891
Mental Illness—Adults 2018-2029[5]	783,000
Parkinson's Disease Deaths 2022[2]	627
Septicemia Deaths 2022[2]	320
Stroke Deaths 2022[2]	2,626

Source: 1. U.S. Census Bureau 2. Oregon Health Authority 3. American Cancer Society 4. Centers for Disease Control and Prevention 5. Kaiser Family Foundation, State Health Facts

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

- Children under the age of 18 make up 19.7%[6] of the population in Oregon. Pediatric clinical trials are being conducted in the state for asthma, atopic dermatitis, epilepsy, juvenile arthritis, leukemia, migraine, muscular dystrophy and respiratory syncytial virus infections, among others.[7]

- Oregonians aged 65 and older account for 19.2%[6] of the states' population. In Oregon, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, breast cancer, chronic obstructive pulmonary disease, lymphoma, macular degeneration, Parkinson's disease, prostate cancer and respiratory syncytial virus infections, among others.[7]

- Women and girls make up 50.1%[6] of the population in Oregon. Clinical trials are recruiting women for studies on medicines for Alzheimer's disease, breast cancer, cervical cancer, migraine, ovarian cancer and psoriatic arthritis, among others.[7]

[6] U.S. Census Bureau, [7] www.clinicaltrials.gov

Open Clinical Trials in Oregonfor Special Populations

Population	Number of Trials
Children (birth–17)	96
Seniors (65 and older)	517
Women (only)	13

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 7/18/2024. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Oregon by Sex, 2022		
Disease	**Male**	**Female**
Cancer	4,477	3,961
Heart Disease	4,563	3,553
Unintended Injuries	2,045	1,143
Stroke	1,153	1,463
Alzheimer's Disease	672	1,356
Chronic Lower Respiratory Disease	1,011	1,002
COVID-19	1,075	819
Diabetes	880	571
Chronic Liver Disease/Cirrhosis	525	366
Suicide	686	191

10 Leading Causes of Death in Oregon by Race/Ethnicity, 2022						
Disease	**White**	**African American/ Black**	**Hispanic**	**Asian**	**American Indian/ Alaska Native**	**Native Hawaiian/ Pacific Islander**
Cancer	7,655	126	309	187	53	20
Heart Disease	7,462	146	186	139	63	25
Unintended Injuries	2,647	88	232	37	74	6
Stroke	2,351	42	97	77	18	7
Alzheimer's Disease	1,902	14	50	37	8	2
Chronic Lower Respiratory Disease	1,902	18	29	17	17	3
COVID-19	1,678	21	92	48	31	7
Diabetes	1,239	36	76	38	25	15
Chronic Liver Disease/Cirrhosis	767	6	64	7	25	2
Suicide	743	13	57	22	16	4

Source: Oregon Health Authority

INDUSTRY COMMITMENT TO CLINICAL TRIAL DIVERSITY

As a nation, we are in a new era of medicine where breakthrough science is transforming patient care, but these innovations are meaningless if they don't reach all patients. It is critical that patients from traditionally underserved communities have access to innovative medicines. Achieving health equity is essential in creating a health care system that truly works.

Systemic racism that exacerbates health inequities has contributed to long-standing disparities in prevalence and severity of disease across racial and ethnic groups. These disparities can reflect in how often a disease occurs in a certain patient population, how serious the disease manifests itself in patients or how often a disease results in death.

Health disparities have many causes, including limited access to quality health care, health screenings, living and working conditions, experiences with the health care system/patient confidence, racism, bias in the treatment setting, underrepresentation of minority health care providers, and other social determinants of health, clinical trial participation, language barriers, and economics and insurance coverage.

The research-based biopharmaceutical industry recognizes the importance of including diverse patients in clinical trials for new medicines so that the clinical trial population reflects the intended treatment population. Addressing the systemic issues that deter Black and Hispanic communities from participating in clinical trials is critical to enhancing clinical trial diversity so that those who want to participate, can.

In an effort to address this long-standing mistrust and other issues, PhRMA and its member companies recently issued the first-ever industry-wide principles on clinical trials diversity, adding a new chapter to the already existing Principles on Conduct Clinical Trials & Communication of Clinical Trial Results. The new clinical trial diversity principles address:

- Building Trust and Acknowledging Past Wrongs
- Reducing Barriers to Clinical Trial Access
- Using Real-World Data to Enhance Information on Diverse Populations Beyond Product Approval
- Enhancing Information About Diversity and Inclusion in Clinical Trial Participation

SCIENCE AND CLINICAL TRIALS[8]

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

- An anti-TIGIT monoclonal antibody (mAb) is in development for non-small cell lung cancer and esophageal cancer. The medicine works as an immune amplifier, by potentially enhancing the body's immune response. It blocks the interaction of TIGIT with a poliovirus receptor that can suppress the body's immune response. It is being studied as a monotherapy and in combination with an approved anti-PD-L1 mAb. The combination of the TIGIT mAb and the PD-L1 mAb offers a dual blockade that has the potential to increase anti-tumor activity. Clinical trials are being conducted in **Eugene**.

- An estrogen receptor protein degrader is in development for estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer. The estrogen receptor is a primary driver of hormone receptor positive (HR+) breast cancer, the most common subtype of breast cancer. The potential treatment is designed to specifically target and degrade the estrogen receptor. It is being developed as a monotherapy and in combination with other therapies. Clinical trials are being conducted at the **Providence Cancer Institute Franz Clinic** and **Providence Portland Medical Center** in **Portland**.

- An oral small molecule treatment is in development for head and neck squamous cell carcinoma. It is designed to promote apoptosis (programmed cell death) in tumor cells by blocking the activity of at least three inhibitors of apoptosis proteins (IAPs). IAPs are key inhibitors of the process that activates enzymes called caspases that contribute to the breakdown of cancer cells. The potential treatment binds to the IAP and prevents it from inhibiting caspase activation leading to cancer cell destruction. A clinical trial is being conducted at the **Providence Portland Medical Center**.

- A medicine in development to treat triple negative 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 being conducted in **Eugene**.

- A bio-engineered adeno-associated virus (AAV) vector-based gene therapy is being developed to treat hemophilia A, or factor VIII deficiency. Hemophilia is a rare, serious inherited bleeding disorder, characterized by mutations in the F8 gene. The mutation leads to deficient blood coagulation and an increased risk of bleeding or hemorrhaging. A clinical trial was conducted at **Oregon Health & Science University** 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**.

[8] *PhRMA Medicines in Development reports, https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development*

- 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**.

- An approved monoclonal antibody for the prevention of migraine in adults 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. A clinical trials studying the drug in pediatric patients is recruiting patient at **Oregon Health and Science University** in **Portland**.

- A novel bacterial topoisomerase II inhibitor is being developed to treat Neisseria gonorrhoeae infections and uncomplicated urinary tract infections. The drug has a dual mechanism of action and works by selectively inhibiting two bacterial enzymes — DNA gyrase and topoisomerase IV — that play a role in bacterial replication. The drug may have activity against most target pathogens resistant to established antibiotics. A clinical trial was conducted in **Eugene**.

Conclusion

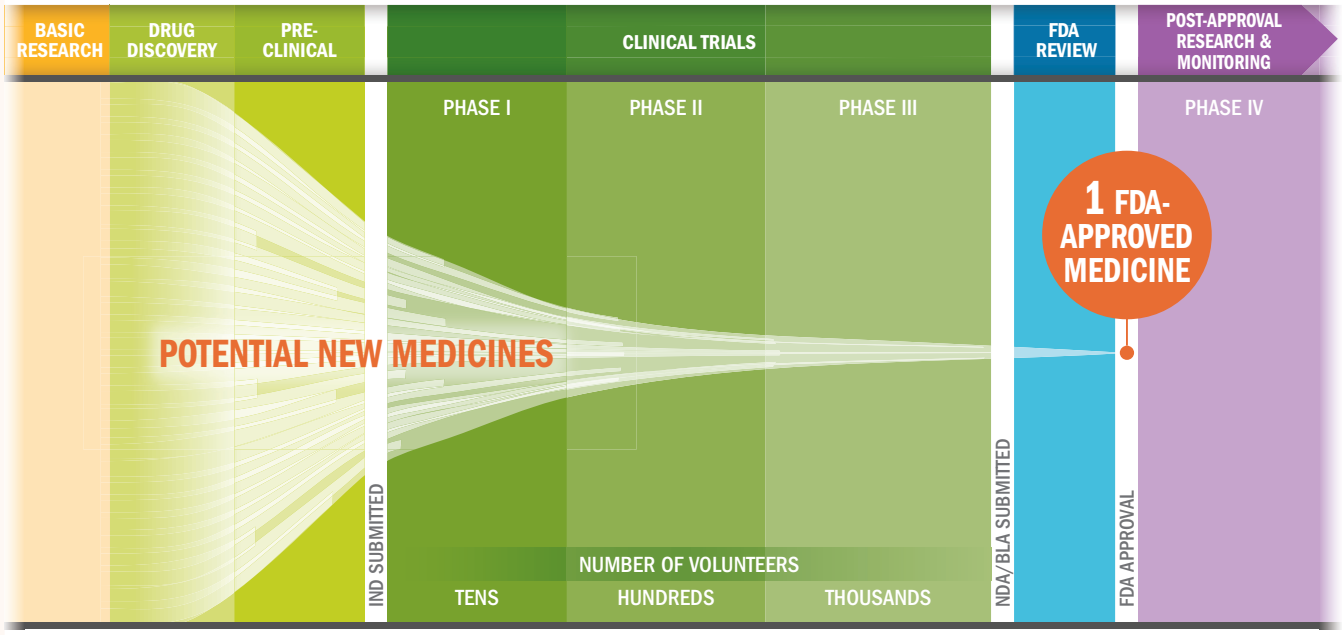
The Oregon bioscience industry supports more than 28,600 jobs throughout Oregon with wages and benefits supported by the sector, resulting in $580.5 million in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $8.2 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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