Research in Your Backyard

Developing Cures, Creating Jobs

Pharmaceutical Clinical Trials in **Washington**

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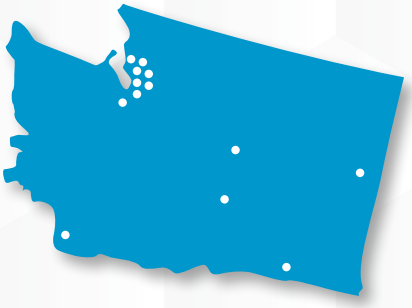
Executive Summary

Clinical trials in Washington

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



Since 2004, biopharmaceutical research companies have conducted or are conducting more than 8,500 clinical trials of new medicines in Washington in collaboration with clinical research centers, hospitals, and local research institutions. These clinical trials have investigated or are investigating some of Washington's biggest health care challenges, including cancer, infectious diseases, cardiovascular disease, respiratory diseases and gastrointestinal diseases.

Clinical Trials in **Washington** 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 Washington since 2004—Completed and Open

All Clinical Trials

8,555

Open Clinical Trials

862

Source: www.clinicaltrials.gov. Search criteria: Washington, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 9/5/2025. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

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.

"From pioneering startups to major clinical research institutions and manufacturers, Washington's biopharmaceutical industry delivers life-changing treatments for patients. Our labor partners play a critical, and often unseen, role in advancing new treatments and cures for society's most serious and costly diseases. They make innovation possible for patients. Their work is transforming lives and improving health outcomes across the state."

— **Mike Chapman**, Washington State Senator – 24th Legislative District

Economic Impact of the Biopharmaceutical Sector in Washington

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

A study by TEConomy Partners[1] found that in 2022, the industry supported more than 81,000 jobs throughout Washington. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in $1.9 billion in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of $26.7 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 Washington 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.

"Washington's biopharmaceutical sector has benefited from over 1.5 million union craft hours in just the last few years alone. In recent years, local union labor partners have powered the construction of research and manufacturing facilities and played a vital role in developing pharmaceutical, biotech, and advanced manufacturing projects. These investments not only expand opportunities for skilled trades and apprenticeships but also fuel lasting growth for Washington's economy."

— **Lee Newgent**, Pharmaceutical Industry Labor-Management Association (PILMA)

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

Economic Impact of Clinical Trials in Washington

A separate study by TEConomy Partners[2] found that in 2023 alone, there were 838 active industry-sponsored clinical trials in Washington, with an estimated enrollment of 13,459 Washington residents.

The investment at clinical trial sites was $369 million and the estimated total economic impact was more than $715 million.

2 TEConomy Partners, LLC. Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies, March 2025. Report prepared for PhRMA. https://phrma.org/resources/state-map/clinical-trials

Open Clinical Trials in Washington by Disease	
Disease	**Number of Trials**
Alzheimer's Disease/Dementia	14
Arthritis/Musculoskeletal Diseases	10
Autoimmune Disorders	46
Blood Disorders	22
Cancer	451
Cardiovascular Diseases	29
Diabetes	9
Eye Diseases	27
Gastrointestinal/Esophageal Disorders	29
Genetic Diseases	17
Infectious Diseases	20
Kidney Diseases	12
Liver Diseases	20
Mental Illnesses	35
Neurologic Disorders	35
Obesity	7
Respiratory Diseases	20
Skin Disorders	30
Transplantation-Related	11
Other Diseases	18
Total	**862**

Source: www.clinicaltrials.gov. Search criteria: Washington, United States; Phase: early 1, 1, 2, 3; Industry only, first posted on or after 1/1/2004. Search performed 9/5/2025. 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 Washington, 8,555 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 the University of Washington visit **www.iths.org/participate/**, for trials at Washington State University-Spokane visit www.spokane.wsu.edu/research/participate-in-research/ and for trials at Pacific Northwest University of Health Sciences visit www.pnwu.edu/research-at-pnwu/participate-in-research/.

For more information about clinical trials in Washington 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.

*For more information about the **drug development** and **approval process** in the United States, see page 16.*

Local Patient Advocacy Groups

Patient advocacy groups in Washington 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 Washington and may provide more information to patients with further questions.

Alzheimer's Association
Washington State Chapter
10700 Meridian Avenue N, Suite 503
Seattle, WA 98133
(206) 363-5500

Alzheimer's Association
Oregon & S.W. Washington Chapter
5285 Meadows Road, Suite 451
Lake Oswego, OR 97035
(503) 416-0201
(800) 272-3900

American Cancer Society
Washington Office
P.O. Box 3682
Seattle, WA 98124
(800) 227-2345

American Diabetes Association
Pacific Northwest Chapter
P.O Box 7023
Merrifield, VA 22116-7023
(206) 282-4616
ADApnw@diabetes.org

American Heart Association
Washington Office
601 Union Street, Suite 2420
Seattle, WA 98101
(206) 336-7200
puget.sound@heart.org

American Liver Foundation
Washington State Resource Center
(800) 465-4837
info@liverfoundation.org

American Lung Association
Washington Chapter
5601 6th Avenue S, Suite 460
Seattle, WA 98108
(206) 512-3293

(800) 732-9339
Carrie Nyssen
Senior Director of Advocacy
Carrie.Nyssen@lung.org
(360) 921-1484

Arthritis Foundation
National Office
1355 Peachtree Street, Suite 600
Atlanta, GA 30309
(800) 283-7800
mwiesbrock@arthritis.org

Seattle Office
155 NE 100th Street, Suite 303
Seattle, Washington 98125
(206) 489-4610
Washington@arthritis.org

Bellingham Office
1329 North State Street, 304
Bellingham, Washington 98225
(360) 939-3543
Bellingham@arthritis.org

Center for Chronic Illness
P.O. Box 31193
Seattle, WA 98103
(425) 296-2705
info@thecenterforchronicillness.org

Epilepsy Foundation of Washington
2311 N. 45th Street, Suite 134
Seattle, WA 98103
(301) 276-2348
washington@efa.org

Lupus Foundation of America
Pacific Northwest Regional Office
1417 NW 54th Street, Suite 368
Seattle, WA 9810
(206) 875-4422
InfoPNW@lupus.org

National Kidney Foundation
Serving the Pacific Northwest
220 Montgomery Street, Suite 1041
San Francisco, CA 94104
(253) 201-0881
eventsnca@kidney.org

NAMI Washington
National Alliance on Mental Illness
1107 NE 45th Street, Suite 330
Seattle, WA 98015
(206) 783-4288
office@namiwa.org

National Psoriasis Foundation
Northwest Regional Office
(503) 546-8402
getinfo@psoriasis.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.

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]

PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

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

Economic Impact of the Biopharmaceutical Sector in **Washington**

Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Washington. A TEConomy Partners study[3] found that the biopharmaceutical sector:

81,000

Supported more than 81,000 jobs throughout Washington in 2022.

$26.7B

Supported the generation of $26.7 billion in economic activity in the state.

$1.9B

Resulted in $1.9 billion in federal and state taxes through jobs supported by the biopharmaceutical sector.

For more information on the ***economic impact of the biopharmaceutical industry in Washington***, see page 3.

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

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

- Advanced Clinical Research, Spokane
- Bellingham Asthma & Allergy Clinic, Bellingham
- Bloodworks Northwest Research Institute, Seattle
- Cancer Care Northwest, Spokane
- Capital Clinical Research Center, Olympia
- CHI Franciscan Research Center, Tacoma
- Compass Oncology, Vancouver
- Core Clinical Research, Everett
- Evergreen Hospital Medical Center, Kirkland
- Fred Hutchinson Cancer Research Center, Seattle
- Harborview Medical Center, Seattle
- Harrison Medical Center, Bremerton
- Highline Medical Center, Burien
- Jefferson Healthcare, Port Townsend
- Kadlec Regional Medical Center, Kennewick
- Legacy Salmon Creek Hospital, Vancouver
- Madigan Army Medical Center, Tacoma
- MultiCare Allenmore Hospital, Tacoma
- MultiCare Auburn Medical Center, Auburn
- MultiCare Deaconess Hospital, Spokane
- MultiCare Good Samaritan Hospital, Puyallup
- MultiCare Health System Mary Bridge Children's Hospital and Health Center, Tacoma
- MultiCare Institute for Research & Innovation, Tacoma
- MultiCare Regional Cancer Center, Auburn, Gig Harbor
- MultiCare Women's Center, Covington
- North Spokane Women's Health, Spokane
- Northwest Clinical Research Center, Bellevue, Seattle
- Overlake Medical Center and Clinics, Bellevue
- Pacific Institute of Medical Sciences, Bothell
- PeaceHealth Southwest Medical Center, Vancouver
- PeaceHealth St. John Medical Center, Longview
- PeaceHealth St. Joseph Medical Center, Bellingham
- PeaceHealth United General Medical Center, Sedro-Woolley
- Peninsula Cancer Center, Poulsbo
- Premier Clinical Research, Spokane
- Principle Research Solutions, Spokane
- Providence Regional Cancer System, Aberdeen, Centralia, Everett, Lacey, Shelton, Yelm
- Providence Sacred Heart Medical Center & Children's Hospital, Spokane
- Providence St. Mary Regional Cancer Center, Walla Walla
- Providence St. Peter Hospital, Olympia
- Rainier Clinical Research Center, Renton
- Rockwood Clinic, Spokane
- Seattle Cancer Care Alliance, Seattle
- Seattle Children's Hospital, Seattle
- Seattle Children's Research Institute, Seattle
- Seattle Institute for Biomedical & Clinical Research, Seattle
- Skagit Valley Hospital, Mount Vernon
- Spokane Valley Cancer Center, Spokane
- St. Clare Hospital, Lakewood

- St. Elizabeth Hospital, Enumclaw
- St. Francis Hospital, Federal Way
- St. Joseph Medical Center, Tacoma
- Stonesifer Clinical Research, Federal Way
- Summit Cancer Center, Spokane
- Swedish Cancer Institute, Edmonds, Issaquah, Seattle
- Swedish Medical Center, Seattle
- The Polyclinic, Seattle
- University of Washington Medical Center/School of Medicine, Seattle
- VA Puget Sound Health Care System, Seattle
- Valley Medical Center, Renton
- Vancouver Clinic, Vancouver
- Virginia Mason Bainbridge Island Medical Center, Bainbridge Island
- Virginia Mason Federal Way Medical Center, Federal Way
- Virginia Mason Lynnwood Medical Center, Lynnwood
- Virginia Mason Medical Center, Seattle
- Walla Walla Clinic, Walla Walla
- Wenatchee Valley Hospital & Clinics, Wenatchee
- Yakima Valley Memorial Hospital, Yakima
- Zain Research, Richland

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 9,165 open clinical trials[4] 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 Washington, of the 862 open clinical trials involving the biopharmaceutical research industry, the University of Washington is collaborating on more than 148 of the clinical trials.

4 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 9/5/2025. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

The State of Disease in Washington

More than 8.1 million people live in Washington[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Washington

Disease	Number of Trials
Alzheimer's Disease Deaths 2023[2]	3,313
Asthma Prevalence 2021[3]	641,131
Asthma Deaths 2021[3]	85
Cancer News Cases 2025[4]	46,500
Cancer Deaths 2025[4]	13,870
Chronic Liver Disease & Cirrhosis Deaths 2023[2]	1,204
Chronic Lower Respiratory Deaths 2023[2]	2,739
COVID-19 Deaths 2023[2]	966
Diabetes Deaths 2023[2]	1,986
Diabetes Prevalence 2022[3]	595,825
Heart Disease Deaths 2023[2]	12,425
HIV-Number Living with a Diagnosis 2022[5]	14,928
Influenza and Pneumonia Deaths 2023[5]	741
Kidney Disease Deaths 2023[3]	528
Mental Illness-Adults 2022-2023[5]	1,695,000
Parkinson's Disease Deaths 2023[3]	943
Stroke Deaths 2023[2]	3,143

Source: 1. Washington State Office of Financial Management 2. Washington State Department of Health, Center for Health Statistics 3. U.S. Center for Disease Control and Prevention 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts

Washington Clinical Trials And Special Populations: Children, Older Americans And Women

- Children under the age of 18 make up 21.1%[5] of the population in Washington. Pediatric clinical trials are being conducted in the state for aplastic anemia, asthma, chronic kidney disease, epilepsy, glioma, leukemia, migraine, muscular dystrophy and plaque psoriasis, among others.[6]

- Washingtonians aged 65 and older account for 16.8%[5] of the states' population. In Washington, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, atrial fibrillation, heart failure, chronic kidney disease, lymphoma, macular degeneration, Parkinson's disease and prostate cancer, among others.[6]

- Women and girls make up 49.5%[5] of the population in Washington. Clinical trials are recruiting women for studies on medicines for breast cancer, contraception, endometriosis, heart failure, ovarian cancer, postmenopausal osteoporosis, Sjogren's syndrome and urinary tract infections, among others.[6]

5 U.S. Census Bureau (2023), 6 www.clinicaltrials.gov

Open Clinical Trials in Washington for Special Populations	
Population	**Number of Trials**
Children (birth-17)	127
Seniors (65 and older)	782
Women (only)	26

Source: www.clinicaltrials.gov. Search criteria: Washington, United States; Phase: early 1, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 9/5/2025. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

10 Leading Causes of Death in Washington by Sex, 2023		
Disease	**Male**	**Female**
Cancer	7,203	6,497
Heart Disease	7,062	5,362
Accidents	4,215	1,979
Alzheimer's Disease	1,109	2,204
Stroke	1,391	1,752
Chronic Lower Respiratory Diseases	1,359	1,380
Diabetes	1,176	810
Intentional Self Harm (Suicide)	1,007	269
Chronic Liver Disease & Cirrhosis	766	437
COVID-19	511	455

Source: Washington State Department of Health, Center for Health Statistics, Death Certificate Data, 2011-2023, March 2025

10 Leading Causes of Death in Washington by Race/Ethnicity, 2023							
Disease	White	Black	Hispanic	Asian	American Indian/ Alaska Native	Pacific Islander	Multiple Races
Cancer	11,510	420	515	732	157	106	156
Heart Disease	10,615	383	409	457	150	91	164
Accidents	4,363	471	584	201	197	40	210
Alzheimer's Disease	2,965	54	81	151	18	0	21
Stroke	2,602	137	106	195	29	15	36
Chronic Lower Respiratory Diseases	2,488	71	44	45	28	0	41
Diabetes	1,511	106	136	133	29	27	31
Intentional Self Harm (Suicide)	978	35	103	57	25	13	44
Chronic Liver Disease & Cirrhosis	915	25	123	33	57	0	30
COVID-19	833	19	28	47	13	0	0

Source: Washington State Department of Health, Center for Health Statistics, Death Certificate Data, 2011-2023, March 2025

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[7]

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

- A mRNA-based therapeutic vaccine is in clinical trials for high-risk (stage IIb-IV) melanoma. Melanoma is the most serious form of skin cancer with 100,640 new cases and 8,290 deaths expected in 2024.xv The personalized therapeutic vaccine is a synthetic mRNA that can code up to 34 neoantigens that is designed and constructed based on the unique mutations of the patients' tumor. The vaccine neoantigens train and activate an antitumor immune response by generating specific T-cell responses directed at the cancer cells expressing the neoantigens. Clinical trials are underway at the **Fred Hutchinson Cancer Center** and the **Swedish Cancer Institute in Seattle** and at **Virginia Mason Franciscan Health's St. Michael Cancer Center** in **Silverdale**.

- An mRNA-based therapeutic vaccine is being studied for the treatment of solid tumors. The personalized therapeutic vaccine is tailored to a specific patient's tumor and encodes up to 20 patient-specific neoantigens (proteins that are produced by cancer cells that differ from the proteins produced by healthy cells). The targeted delivery of the vaccine stimulates the immune system to target the specific cancer. A clinical trials are being conducted at the **Fred Hutchinson Cancer Center** and **Seattle Cancer Care Alliance** in **Seattle**.

- A monoclonal antibody (mAb) is in development for the reduction of asthma attacks in severe asthma with type 2 inflammation (a condition that elevates white blood cell levels, which increase asthma symptoms). Type 2 inflammation is responsible for more than 80% of severe asthma cases and can lead to exacerbations of the disease (increased coughing, shortness of breath or wheezing). The mAb in development targets the action of interleukin-5 (IL-5), a protein known to play a key role in the growth, activity and survival of eosinophils associated with type 2 inflammation in severe asthma. In clinical trials, the medicine has shown significant reductions in exacerbations over 52 weeks versus placebo. Clinical trials were conducted at locations in **Bellingham** and **Seattle**.

- Post-approval research of an amyloid-beta protein inhibitor for the treatment of mild Alzheimer's disease is being studied as a treatment for preclinical Alzheimer's disease (the disease stage when changes in the brain are occurring but before any symptoms are seen). The medicine works by targeting the build-up of amyloid beta plaques in the brain, a key element in the development of Alzheimer's disease. Amyloid plaques appear between nerve cells in the brain and disrupt cell function. It is being studied to determine its ability to reduce brain amyloid accumulation and possibly prevent the disease from progressing. Clinical trials are being conducted at the **University of Washington Memory and Brain Wellness Center** and the **Seattle Institute for Biomedical and Clinical Research** in **Seattle**, the **Kingfisher Cooperative** in **Spokane**.

- An oral PCSK9 inhibitor is in development for the reduction of low-density lipoprotein (LDL) cholesterol, or "bad cholesterol." Currently, approved PCSK9 inhibitors are all injectable medicines. PCSK9 plays a key role in cholesterol by lowering levels of LDL receptors, which are responsible for removing LDL cholesterol from the blood. Inhibiting the interaction of PCSK9 and LDL receptors results in a greater number of LDL receptors to remove LDL cholesterol. Elevated LDL cholesterol is a major risk factor for atherosclerotic cardiovascular disease, which can lead to heart attacks and strokes. Clinical trials are being conducted at the **Rainier Clinical Research Center** in **Renton**.

- A medicine approved to improve glycemic control in people with type 2 diabetes and obesity is continuing to be studied in adults with heart failure with preserved ejection fraction (HFpEF) and who are obese. HFpEF accounts for nearly half of all people with heart failure cases and 60% of those are also clinically obese. The medicine is a dual acting GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1), which are receptors found in areas of the brain that regulate appetite. In clinical trials, the medicine reduced the risk of heart failure events – urgent care visits, hospitalization, the

need for additional oral diuretics or cardiovascular death – by 38% compared to placebo. It also led to a 15.7% weight loss in clinical trial participants and a significant improvement in heart failure symptoms and physical limitations. It is also being studied for the reduction of morbidity and mortality associated with obesity and for the reduction of adverse cardiovascular outcomes in patients with type 2 diabetes. A clinical trials was conducted at the **MultiCare Good Samaritan Hospital** in **Puyallup**.

- 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 at the **Fred Hutchinson Cancer Center** and the **Seattle Cancer Care Alliance** in **Seattle**.

- 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 underway in **Seattle** and **Tacoma**.

- A fixed-dose combination treatment of two approved medicines is in development for metastatic castration resistant prostate cancer with BRCA mutations. The dual action medicine, in combination with prednisone, targets two drivers of prostate cancer – the androgen receptor and BRCA mutations. The medicine inhibits the production of androgens, which are necessary for prostate cancer growth, and inhibits PARP enzymes, which play a role in DNA repair (in this case specifically the BRCA mutation) that results in tumor cell death. BRCA1 and 2 are tumor suppressor genes and when they work normally, they help keep certain cancer cells from growing and dividing. Clinical trials were conducted at **VA Puget Sound Healthcare System** in **Seattle**, **Seattle Cancer Care Alliance** in **Seattle** and **MultiCare Health System** in **Tacoma**.

- A gene therapy is in development that uses AAV vectors to deliver a high-activity Factor IX gene to the liver for the treatment of hemophilia B. Hemophilia B is caused by a mutation in Factor IX, which leads to deficient blood coagulation and an increased risk of bleeding or hemorrhaging. Hemophilia B is four times less common than hemophilia A. A clinical trial is underway at the **Washington Institute for Coagulation** in **Seattle**.

- A potential first-in-class medicine is in development for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), a rare hematopoietic stem cell disorder (affecting .05-1.5 per million people worldwide)7 where red blood cells become defective and subsequently produce defective red blood cells. These defective red blood cells in PNH are highly susceptible to premature destruction by a part of the body's own immune system called the complement system. The medicine, a complement factor B inhibitor, targets the underlying cause of PNH through its action on the complement system's alternative pathway. A clinical trial was conducted at the **University of Washington Medical Center** in **Seattle**.

- A once weekly fixed-dose combination medicine in development for type II diabetes is comprised of a long-acting basal insulin analog and an approved GLP-1 (glucagon-like peptide-1) agonist. The long-acting basal insulin has the potential to reduce the number of annual insulin injections from daily to weekly. Research has found that the GLP-1 agonist has the potential to lower blood glucose by stimulating the release of insulin and also lowers body weight. A clinical trial was conducted at the **Rainier Clinical Research Center** in **Renton**.

- An oral kappa opioid receptor (KOR) antagonist is in development as an adjunctive treatment for major depressive disorder. KOR antagonists play an important role in helping regulate stress and mood. Kappa opioid receptors are involved in anxiety-like, dysphoric, aversive and drug-seeking behavioral responses. KOR antagonists block kappa-opioid receptors and reduce these responses, producing antidepressant and anti-addictive effects. Clinical trials are being conducted at **Northwest Clinical Research Center** in **Bellevue** and **Core Clinical Research** in **Everett**.

- A next-generation GABA-A receptor modulator is in development to treat postpartum depression and major depressive disorder. The GABA system contributes significantly to regulating brain function, helping to reduce fear, anxiety, and stress. Low levels of GABA have been linked to increased risk of anxiety and depression and next generation GABA-A modulators are being developed to activate the GABA receptor pathway. Clinical trials were conducted in **Bellevue**.

- A medicine in development for post-traumatic stress disorder (PTSD) is an inhibitor of the transient receptor potential (TRP) channels 4 and 5. TRP channels are expressed in the brain and implicated in the innate fear function (innate fear helps humans avoid or escape dangerous situations). TRP channels are involved in anxiety-like behavior. For example, TRPC5 increases the activity of the hormone CCK (cholecystokinin), which increases neuronal anxiety. By inhibiting the activity of TRPC4/5 and therefore reducing CCK activity, depressive and anxiety behaviors are suppressed. The medicine is also in development for major depressive disorder and borderline personality disorder. Clinical trials were conducted at **Core Clinical Research** in **Everett**.

- A gene therapy is in development that uses AAV vectors to deliver a high-activity Factor IX gene to the liver for the treatment of hemophilia B. Hemophilia B is caused by a mutation in Factor IX, which leads to deficient blood coagulation and an increased risk of bleeding or hemorrhaging. Hemophilia B is four times less common than hemophilia A. A clinical trial is planned at the **Washington Institute for Coagulation** in **Seattle**.

- A monoclonal antibody in development for Huntington's disease binds to and blocks the activity of Semaphorin 4D (SEMA4D), a protein that plays a key role in the neuro-inflammatory processes that can cause inflammation in the brains of individuals with the disease. By blocking the activity of SEMA4D, it may slow or prevent the neurodegeneration in Huntington's disease, a fatal disorder that causes the breakdown of nerve cells in the brain. Clinical trials were conducted at the **University of Washington** and **VA Puget Sound Health Care System** in **Seattle**.

- 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 was conducted at the **Multiple Sclerosis Center/Swedish Neuroscience Institute** in **Seattle**.

- 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. Clinical trials are ongoing at the **Evergreen Health Care Center** in **Kirkland** and **Inland Northwest Research** in **Spokane**.

- A long-acting injectable capsid inhibitor is being developed as an anti-retroviral (ARV) treatment for HIV infections. The medicine inhibits HIV-1 replication in human peripheral blood cells by inhibiting capsid protein formation (the capsid protein is the shell around the virus containing genetic material). It is being studied in both heavily treatment-experienced patients with multi-drug resistance and treatment-naïve patients living with HIV. Clinical trials are ongoing in **Seattle**, **Spokane** and **Tacoma**.

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 Washington, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions.

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

Conclusion

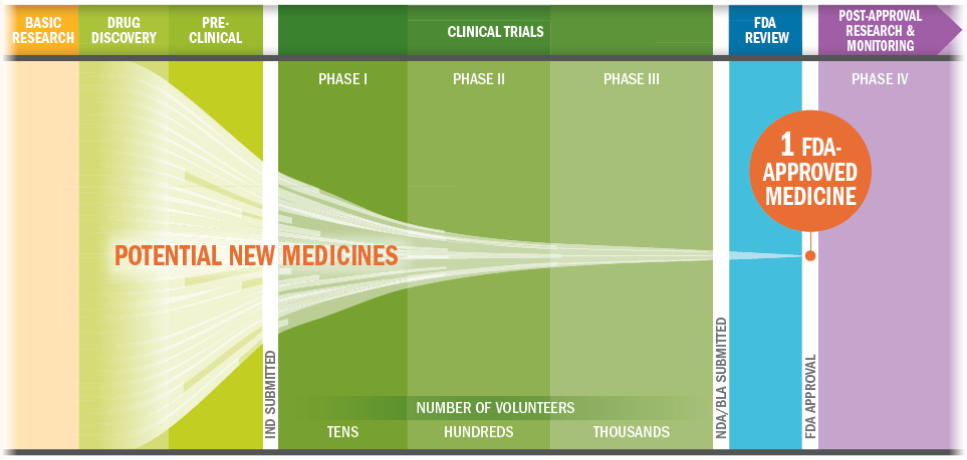
The Washington bioscience industry supports more than 81,000 jobs throughout Washington with wages and benefits supported by the sector, resulting in $1.9 billion in state and federal taxes paid. The industry is also driving innovation and additional economic activity in the state. Biopharmaceutical research companies supported the generation of $26.7 billion in direct and indirect economic activity in Washington.

Washingtonians 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 Washington, this innovation is the result of a successful collaboration between biopharmaceutical companies and local research institutions. And the sector's growth and strength in Washington 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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