



# RESEARCH *in* YOUR BACKYARD

*Developing Cures, Creating Jobs*

Pharmaceutical clinical trials in  
**IDAHO**

# *Executive*

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

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 1,700 clinical trials of new medicines in Idaho in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Idaho's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and gastrointestinal diseases.

# Summary

## Clinical trials in **IDAHO**

### **CLINICAL TRIALS IN IDAHO ARE A VITAL PART OF THE FDA DRUG APPROVAL PROCESS**

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

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

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

#### **Clinical Trials in Idaho since 2004— Completed and Open**

<b>All Clinical Trials</b>	<b>Open Clinical Trials</b>
1,797	185

*Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Search criteria: Idaho, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2004. Search performed 7/16/2021. Open clinical trials are recruiting, not yet recruiting, or expanded access available.*

# Executive Summary (cont.)

## CLINICAL TRIALS OFFER IMPORTANT THERAPEUTIC OPTIONS FOR PATIENTS

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

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

## ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN IDAHO

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

A study by TEconomy Partners found that in 2017, the industry supported more than 3,800 jobs throughout Idaho. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in \$47 million in state and federal taxes paid.

Biopharmaceutical research companies supported the generation of \$910 million 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 Idaho 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 IDAHO

A separate study by TEconomy Partners found that in 2017 alone, there were 217 active industry-sponsored clinical trials in Idaho, with an estimated enrollment of 4,139 Idaho residents. Infectious disease had the leading clinical trial enrollment in the state.

The investment at clinical trial sites was more than \$58 million and the estimated total economic impact was more than \$144 million.

*“Clinical trials in Idaho allow patients access to cutting edge research, treatment and quality care. In addition to the human impact, they also have a significant economic impact that benefits all Idahoans. Biopharmaceutical research companies support more than 3,800 jobs across Idaho, while generating \$910 million in economic activity in the state. These numbers reflect the fact that the clinical research not only shapes the future of disease treatment, but also, employs Idahoans and stimulates our economy.”*

**Jay Larsen**  
CEO & Founder  
Idaho Technology Council

*“For years, biopharmaceutical company-sponsored clinical trials of new medicines have been conducted by many hospitals, health systems and academic institutions. These clinical trials have helped advance our understanding of diseases and how best to treat them. These trials have led to the development and approval of innovative medications that have improved—and even saved—lives around the globe. Since 2004, there have been more than 1,700 clinical trials of new and innovative medicines in Idaho. They have afforded local researchers’ rich opportunities to be involved in cutting-edge science. In addition, hospitals that participate in research have been shown to provide better overall care and to achieve a higher degree of patient satisfaction. Clinical trials help save patient lives and pave the way for cures—leading our communities to a better, healthier future.”*

**Dr. James Loveless**  
**St. Luke’s Health System**

Open Clinical Trials in Idaho by Disease	
Disease	Number of Trials
Arthritis/Musculoskeletal Disorders	11
Autoimmune Diseases	7
Cancer	23
Cardiovascular Diseases	8
Diabetes	14
Eye Disorders	3
Gastrointestinal/Esophageal Diseases	22
Genetic Disorders	4
Infectious Diseases	40
Kidney Diseases	8
Mental Disorders	3
Neurological Disorders	14
Respiratory Diseases	5
Skin Diseases	10
Other Diseases	13
<b>Total</b>	<b>185</b>

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Search criteria: Idaho, United States; Phase: early 1, 1, 2, 3; Industry only; first posted on or after 1/1/2004. Search performed 7/16/2021. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

# Patient Resources & Directory

## WHAT IS THE CLINICAL TRIAL EXPERIENCE?

Clinical trials are research studies that generate data to support FDA approval of a new medicine or a new indication for an existing medication. They also grant participants early access to new medicines, which are being developed to help combat chronic and serious diseases. By volunteering for a clinical trial, patients take an active role in their health care by helping researchers test new treatments. In Idaho, 1,797 clinical trials since 2004 have targeted diseases and conditions like asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

## PHASES OF CLINICAL TRIALS

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

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

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

**PHASE III**—The drug is provided to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. They are the longest studies and usually take place in multiple sites around the world.

## LEARNING ABOUT AND ACCESSING CLINICAL TRIALS

Patients can learn about clinical trials in several ways. Health care providers are aware of clinical trials being conducted at hospitals, universities, and other leading health care facilities, and these institutions can be valuable sources of information for patients looking to participate. Patients can also use hospital and university websites to find the trials being conducted in their area. For instance, clinical trials being conducted at St. Luke's Health System can be found at [www.stlukesonline.org/health-services/service-groups/research-studies-and-clinical-trials-at-st-lukes](http://www.stlukesonline.org/health-services/service-groups/research-studies-and-clinical-trials-at-st-lukes).

More information about clinical trials in Idaho and how to volunteer for one can be found at [www.centerwatch.com](http://www.centerwatch.com), a PhRMA-recommended website.

## WHAT TO EXPECT

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

## PATIENT EXPENSES

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

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

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

## EXPANDED ACCESS

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

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

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

## LOCAL PATIENT ADVOCACY GROUPS

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

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

### **Alzheimer's Association**

*GREATER IDAHO CHAPTER*

2995 N. Cole Road, Suite 120  
Boise, ID 83704  
(208) 206-0041

### **American Heart Association**

*IDAHO CHAPTER*

350 N. 9th Street, Suite 404  
Boise, ID 83702  
(208) 501-7800

### **Arthritis Foundation**

*NATIONAL OFFICE*

1355 Peachtree Street, NE, Suite 600  
Atlanta, GA 30309  
(800) 283-7800

### **American Cancer Society**

P.O. Box 8449  
Boise, ID 83707  
(800) 227-2345

### **American Liver Foundation**

*IDAHO STATE RESOURCE CENTER*

(800) 465-4837  
[info@liverfoundation.org](mailto:info@liverfoundation.org)

### **Epilepsy Foundation of Idaho**

100 E. Warm Springs Avenue  
Boise, ID 83712  
(208) 344-4340

### **American Diabetes Association**

*OREGON & SW WASHINGTON OFFICE*

P.O. Box 7023  
Merrifield, VA 22116-7023  
(503) 736-2770  
[adaor\\_wa@diabetes.org](mailto:adaor_wa@diabetes.org)

### **American Lung Association**

*IDAHO CHAPTER*

1412 W. Idaho Street, Suite 100  
Boise, ID 83702  
(208) 345-5864

### **NAMI Idaho**

*(NATIONAL ALLIANCE ON MENTAL ILLNESS)*

1985 E. 25th Street  
Idaho Falls, ID 83404-6461  
(208) 520-4210  
[idahonami@gmail.com](mailto:idahonami@gmail.com)



## OTHER PATIENT RESOURCES

**MEDICINE ASSISTANCE TOOL (MAT):** The Medicine Assistance Tool, a PhRMA-sponsored web platform designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs offered 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 been offering for decades. Patients should go to [www.mat.org](http://www.mat.org) for more information. The on-line process takes about 15 minutes, and you'll find out instantly if you're likely to be eligible for help

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

# Clinical Trial Policy Resources

## THE BIOPHARMACEUTICAL SECTOR'S ROLE IN THE ECONOMY

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

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

The biopharmaceutical industry supported more than 4 million jobs across the U.S. economy in 2017, according to a study by TEconomy Partners.

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

## ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN IDAHO

- Biopharmaceutical research companies have been and continue to be a source of quality jobs, tax revenue and research spending in Idaho. A TEconomy Partners study found that the biopharmaceutical sector:
  - Supported the generation of \$910 million in economic activity in the state.
  - Resulted in \$47 million in federal and state taxes through jobs supported by the biopharmaceutical sector.
- Supported more than 3,800 jobs throughout Idaho in 2017.

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

# PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

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

**Advanced Clinical Research**, Meridian

**ASR**, Nampa

**Bingham Memorial Hospital**, Blackfoot

**Boise Kidney & Hypertension Institute**, Boise, Caldwell, Meridian

**Boise State University**, Boise

**Clinical Research Prime**, Idaho Falls

**Eastern Idaho Regional Medical Center**, Idaho Falls

**Elite Clinical Trials**, Blackfoot, Rexburg

**Family First Medical Center**, Idaho Falls

**Grand Teton Research Group**, Idaho Falls

**Grove Creek Medical Center**, Blackfoot

**Idaho Catalyst Clinical Research**, Idaho Falls

**Idaho Division of Veteran's Services**, Boise

**Idaho Falls Pediatrics**, Ammon, Idaho Falls

**Idaho State University**, Pocatello

**Idaho Urologic Institute**, Meridian

**Institute of Arthritis Research**, Idaho Falls

**Kootenai Medical Center**, Coeur d'Alene, Post Falls, Sandpoint

**Leavitt Women's Healthcare**, Idaho Falls

**Mountain View Hospital**, Idaho Falls

**Pocatello Women's Health Clinic**, Pocatello

**Portneuf Medical Center**, Pocatello

**Rocky Mountain Clinical Research**, Idaho Falls

**Rocky Mountain Diabetes and Osteoporosis Center**, Idaho Falls

**Saltzer Health**, Nampa

**Snake River Research**, Idaho Falls

**Solaris Clinical Research**, Meridian

**Sonora Clinical Research**, Meridian

**St. Alphonsus Cancer Care Center**, Boise, Caldwell, Nampa

**St. Alphonsus Medical Group**, Meridian

**St. Luke's Cancer Institute**, Boise, Fruitland, Meridian, Nampa, Twin Falls

**St. Luke's Children's Endocrinology**, Boise

**St. Luke's Cystic Fibrosis Center of Idaho**, Boise

**St. Luke's Health System**, locations across Idaho

**St. Luke's Humphreys Diabetes Center**, Boise

**St. Luke's Idaho Cardiology Associates, Heart Failure Clinic**, Meridian

**St. Luke's Idaho Cardiology Associates, Heart Rhythm Center**, Boise

**St. Luke's Intermountain Research Center**, Boise

**The Pediatric Center**, Idaho Falls

**Treasure Valley Medical Research**, Boise

**University of Idaho**, Moscow

**Velocity Clinical Research**, Meridian

**Walter Knox Memorial Hospital**, Emmett

**Women's Healthcare Association**, Idaho Falls

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 8,500 open clinical trials<sup>1</sup> being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies, and research the other groups are undertaking on their own.

**Health System** collaborating on more than 70 of the trials. In addition to those collaborations, St. Luke's has 290 active clinical trials targeting, cancer, cardiovascular diseases, pulmonary diseases, such as cystic fibrosis; COVID-19, orthopedic indications, nursing trials and the SPARC (Suicide Prevention Among Recipients of Care) Trial. St. Luke's treats about 1.3 million patients in the state out of 1.8 million total population and employs tens of thousands of employees, including 1,000 health care providers.

In Idaho, there are 185 open clinical trials involving the biopharmaceutical research industry, with **St. Luke's**

## THE STATE OF DISEASE IN IDAHO

More than 1.7 million people live in Idaho<sup>1</sup>, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Idaho	
Disease	Health Statistic
Alzheimer's Deaths, 2017 <sup>2</sup>	672
Asthma Prevalence, 2018 <sup>2</sup>	111,954
Cancer New Cases, 2021 <sup>3</sup>	10,240
Cancer Deaths, 2021 <sup>3</sup>	3,230
Chronic Lower Respiratory Dis. Deaths, 2017 <sup>2</sup>	925
Diabetes Prevalence, 2019 <sup>4</sup>	10.3% of adults
Diabetes Deaths, 2017 <sup>2</sup>	394
Heart Disease Deaths, 2017 <sup>2</sup>	3,084
HIV-Number Living with a Diagnosis, 2018 <sup>4</sup>	1,176
Influenza/Pneumonia Deaths, 2017 <sup>2</sup>	255
Mental Illness-Adults, 2018-2019 <sup>4</sup>	293,000
Parkinson's Death, 2017 <sup>2</sup>	206
Stroke Deaths, 2017 <sup>2</sup>	726

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

<sup>1</sup> Data collected from [www.clinicaltrials.gov](http://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 4/16/2021. Open clinical trials are recruiting, not yet recruiting, or are expanded access available.

# IDAHO CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up 25.1% of the population in Idaho. Pediatric clinical trials are being conducted in the state for asthma, atopic dermatitis, Crohn’s disease, type 1 diabetes, Lennox-Gastaut Syndrome, leukemia, neuroblastoma and respiratory syncytial virus, among others.
- Idahoans aged 65 and older account for 16.3% of the states’ population. In Idaho, clinical trials are recruiting older people to study potential

treatments for diseases such as breast cancer, Crohn’s disease, glaucoma, heart failure, leukemia, lymphoma, prostate cancer and rheumatoid arthritis, among others.

- Women and girls make up 49.9% of the population in Idaho. Clinical trials are recruiting women for studies on medicines for breast cancer, cervical cancer, endometriosis, respiratory syncytial virus, urinary tract infections, among others.

## Open Clinical Trials in Idaho for Special Populations

Population	Number of Trials
Children (birth–17)	61
Seniors (66 and older)	146
Women (only)	11

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Search criteria: Idaho, United States; Phase: early 1, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 4/16/2021. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

## SCIENCE AND CLINICAL TRIALS

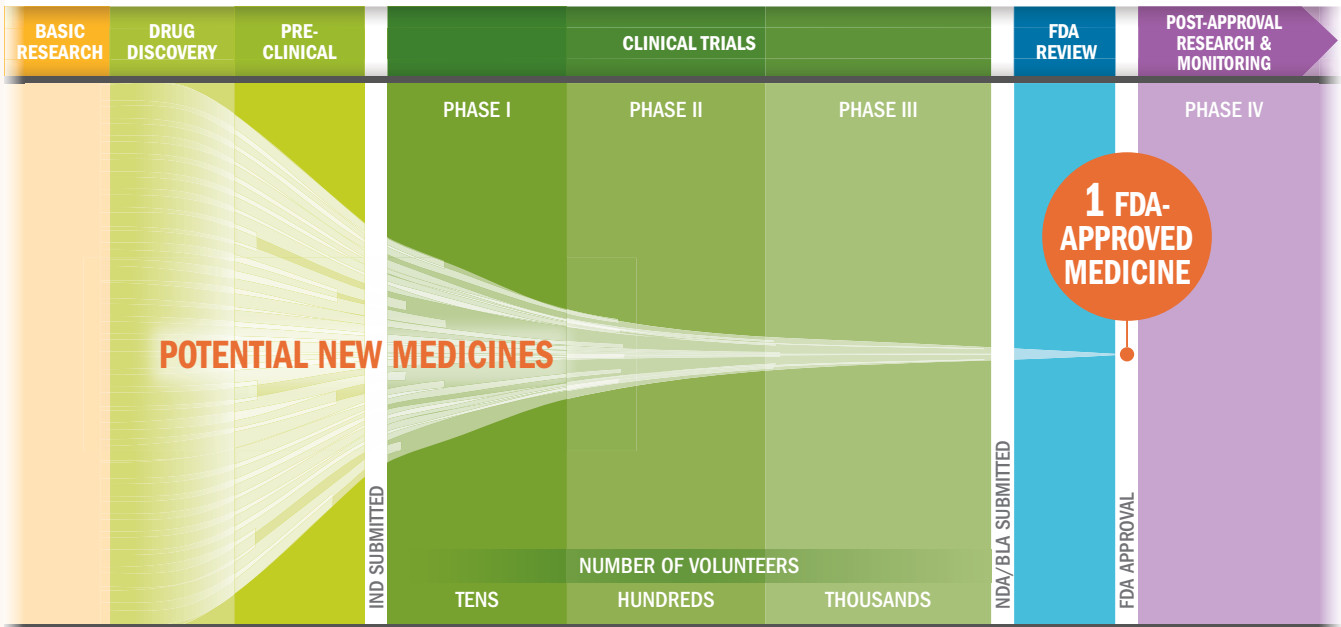
Some of the medicines in clinical testing in Idaho feature revolutionary medical technologies. For example:

- Recent novel treatments in the world of cystic fibrosis (CF) have been a “game-changer” for those living with CF. One medication targets the defective CFTR protein made by a gene mutation to work more effectively. It has been shown to significantly improve outcomes and helps to treat 90% of cystic fibrosis patients. Previous treatments helped only 6% of Americans with CF. In the 1950s, a child with CF succumbed to lung disease before they were old enough to attend elementary school. In the 1980s, few CF patients lived beyond their teens. Now, with the advances in research, the life expectancy of CF patients is almost 50 years, with some living well into their sixties and seventies. **St. Luke’s Health System** took part in these important clinical trials.
- A broad-spectrum antiviral medicine, with in vitro activity against Ebola, Middle Eastern respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), is being studied as a treatment for the COVID-19 infections at **Family Care Research** in **Boise**. The medicine blocks the RNA polymerase (an enzyme that is responsible for duplicating the virus’s RNA) of the virus and prevents its replication.
- A first-in-class treatment in development for higher-risk myelodysplastic syndromes (HR-MDS) targets the NEDD-8 activating enzyme (NAE). Inhibiting the NAE enzyme blocks the modification of select proteins, resulting in disruption of the cell cycle progression and cell survival, leading to cancer cell death. In clinical trials, the medicine used in combination with other anticancer therapies demonstrated promising clinical activity. If approved, it would be the first new treatment for HR-MDS in more than a decade. The medicine is in clinical trials at **Saint Alphonsus Medical Center locations** in **Boise, Caldwell** and **Nampa**.
- A potential first-in-class oral medicine in development provides a new way for addressing type 1 and type 2 diabetes by acting on two different targets in the body. It is a dual inhibitor of both sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2), which are molecules that also help move glucose in and out of the body’s cells, independent of insulin. This movement is important for the absorption of glucose in the body, one by the intestine, with glucose absorption from food and the other by the kidney, which determines how much glucose leaves the body via urine. The medicine was tested in clinical trials at locations in **Blackfoot** and **Nampa**.
- An oral fixed-dose combination of two therapeutics which target distinct receptors in the central nervous system is in development for the treatment of treatment-resistant major depressive disorder. The medicine offers a novel mechanism of action with one therapeutic increasing the therapeutic effect of the second, offering hope to the millions of patients who do not respond to standard antidepressant therapies. The medicine was tested at research sites in **Boise**.
- Research in pediatric leukemia began in the late 1940s. At that time, the median survival for patients was 8 months. By the mid-1950s, it had increased to 22 months. Due to advances through clinical research, event free survival rates for patients with standard risk leukemia are about 95%. **St. Luke’s Cancer Institute** (formerly Mountain States Tumor Institute or MSTI) has been involved in this type of cancer research for over 50 years. Currently, SLCI has 43 pediatric and 64 adult cancer trials.

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

# THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

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



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

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

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



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