RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in

TENNESSEE

PhRMA

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Executive

Summary

Clinical trials in TENNESSEE

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

Since 2004, biopharmaceutical research companies have conducted or are conducting more than 6,100 clinical trials of new medicines in Tennessee in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Tennessee's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

CLINICAL TRIALS IN TENNESSEE 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 Tennessee since 2004—Completed and Open	
All Clinical Trials	**Open Clinical Trials**
6,147	945

Source: www.clinicaltrials.gov. Search criteria: Tennessee, United States; Phase: early 1, 1, 2, 3; Industry only, First received on or after 1/1/2004. Search performed 1/5/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

Executive Summary (cont.)

"It is absolutely critical that we build on the major advances in understanding of human disease to develop new breakthrough treatments for patients. This can only be accomplished by highly collaborative teamwork to leverage the major investments made by federal and state governments, research universities and hospitals, and the pharmaceutical and biotech industries. At the Vanderbilt Center for Neuroscience Drug Discovery, our mission is to work across these major institutions to develop new treatments for the most devastating brain disorders, including Alzheimer's disease, schizophrenia, major depression, addictive disorders, and others. It is so exciting to see new potential treatments that are being advanced into clinical testing and have the potential to fundamentally change the standard of care for these illnesses."

Dr. Jeffrey Conn,
Director, Vanderbilt Center for Neuroscience Drug, Discovery and Professor of Pharmacology

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 TENNESSEE

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

A study by TEConomy Partners found that in 2014, the industry supported more than 52,000 jobs throughout Tennessee. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than $535 million in federal taxation and more than $19 million in state taxes.

Biopharmaceutical research companies supported the generation of $11.7 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 Tennessee 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 TENNESSEE

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,578 active industry-sponsored, site-based clinical trials in Tennessee, with an estimated enrollment of 42,895 Tennessee residents. Respiratory diseases had the leading clinical trial enrollment in the state. The investment of these site-based clinical trials was nearly $283 million and the estimated total economic impact was more than $705 million.

Open Clinical Trials in Tennessee by Disease

Disease	Number of Trials
Allergy	2
Alzheimer's Disease	15
Arthritis/Musculoskeletal Disorders	22
Autoimmune Diseases	31
Bladder Disorders	3
Blood Disorders	15
Cancer	521
Cardiovascular Diseases	48
Diabetes	16
Eye Disorders	17
Gastrointestinal/Esophageal Diseases	51
Genetic Disorders	15
Infectious Diseases	39
Kidney Diseases	13
Liver Diseases	23
Mental Disorders	31
Neurological Disorders	22
Respiratory Diseases	16
Skin Diseases	13
Transplantation-Related	10
Other Diseases	22
Total	**945**

Source: www.clinicaltrials.gov. Search criteria: Tennessee, United States; Phase: early 1, 1, 2, 3; Industry only, First received on or after 1/1/2004. Search performed 1/5/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

"After my husband was diagnosed with Alzheimer's disease, my family and I really wanted to know what we could do. Luckily, he qualified for a clinical trial. For four years, he received personalized care from two physicians along with a team of nurses and dietitians, who worked with us in hopes of halting the progression of his condition. They also helped me with caregiver-related issues, like making sure that I was taking care of myself ... not just always worrying about him. Although there is still no cure, ultimately the trial gave us something we were struggling to find after his diagnosis: hope."

Josi Felts, wife of Alzheimer's disease patient and recent clinical trial participant in Nashville, Tennessee

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 Tennessee, 6,147 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. Information about clinical trials being conducted at the University of Tennessee can be found at *www.uthsc.edu/prevmed/curr_research_studies.php,* for clinical trials at Vanderbilt, go to *www.vanderbilthealth.com/clinicaltrials/*, and for trials at Meharry Medical College, visit, *www.mmc.edu/research/office-for-research/clinical-research/irb/clinical-trials.html.*

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

WHAT TO EXPECT

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

PATIENT EXPENSES

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

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

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

EXPANDED ACCESS

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

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

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

LOCAL PATIENT ADVOCACY GROUPS

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

Alzheimer's Association
Southeast Tennessee Office
7625 Hamilton Park Drive, Suite 6
Chattanooga, TN 37421
(423) 265-3600

Alzheimer's Association
North Alabama Office
117A Longwood Drive, SE
Huntsville, AL 35801
(256) 880-1575

Alzheimer's Association
Northeast Tennessee Office
2020 Meadowview Parkway,
Suite 100
Kingsport, TN 37660
(423) 928-4080

Alzheimer's Association
Knoxville Office
9050 Executive Park Drive,
Suite A-106
Knoxville, TN 37923
(865) 200-6668

Alzheimer's Association
West Tennessee Office
713 S. Mendenhall Road
Memphis, TN 38117
(901) 565-0011

Alzheimer's Association
Tennessee Chapter/
Middle Tennessee Office
478 Craighead Street, Suite 200
Nashville, TN 37204
(615) 315-5880

American Cancer Society
Chattanooga Office
6221 Shallowford Road, Suite 102
Chattanooga, TN 37421
(423) 267-8613

American Cancer Society
Jackson Office
2935 U.S. Highway 45 Bypass
Jackson, TN 38305
(731) 664-4663

American Cancer Society
Knoxville Office
871 Weisgarber Road
Knoxville, TN 37909
(865) 584-1668

American Cancer Society
Memphis Office
1378 Union Avenue
Memphis, TN 38104
(901) 278-2000

American Cancer Society
Nashville Office
2000 Charlotte Avenue
Nashville, TN 37203
(615) 327-0991

American Diabetes Association
Knoxville/Nashville Chapter
220 Great Circle Road, Suite 134
Nashville, TN 37228
(865) 524-7868 (Knoxville)
(615) 298-3066 (Nashville)

American Diabetes Association
Memphis Chapter
1779 Kirby Parkway, Suite 1-317
Memphis, TN 38138
(901) 682-8232, ext. 3121

American Heart Association
Chattanooga Office
519 E. Fourth Street
Chattanooga, TN 37403
(800) 257-4400

American Heart Association
Johnson City Office
3101 Browns Mill Road,
Suite 6, PMB 321
Johnson City, TN 37604
(423) 763-4400

American Heart Association
Knoxville Office
4708 Papermill Drive
Knoxville, TN 37909
(865) 293-5100

American Heart Association
Memphis Office
5384 Poplar Avenue, Suite 100
Memphis, TN 38119
(901) 248-7950

American Heart Association
Nashville Office
1818 Patterson Street
Nashville, TN 37203
(615) 340-4100

American Lung Association
Chattanooga Chapter
1466 Riverside Drive, Suite D
Chattanooga, TN 37406
(423) 629-1098

American Lung Association
Nashville Chapter
One Vantage Way, Suite C120
Nashville, TN 37228
(615) 329-1151

Arthritis Foundation
Tennessee Chapter
209 10th Avenue South, Suite 123
Nashville, TN 37203
(615) 806-8541

Mental Health America
of Middle Tennessee
446 Metroplex Drive, Suite A-224
Nashville, TN 37211
(615) 269-5355

NAMI Tennessee
National Alliance on Mental Illness
1101 Kermit Drive, Suite 605
Nashville, TN 37217
(800) 467-3589

Clinical Trial Policy Resources

THE BIOPHARMACEUTICAL SECTOR'S ROLE IN THE ECONOMY

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

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

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

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

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR IN TENNESSEE

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

- Supported more than 52,000 jobs throughout Tennessee in 2014.
- Supported the generation of $11.7 billion in economic activity in the state.
- Resulted in more than $535 million in federal taxation and more than $19 million in state taxes through jobs supported by the biopharmaceutical sector.

*For more information on the **economic impact of the biopharmaceutical industry in Tennessee**, 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:

- **Accelerated Community Oncology Research Network (ACORN),** Memphis
- **AM Diabetes & Endocrinology Center,** Bartlett
- **Apex Cardiology,** Jackson
- **Baptist Hospital,** Nashville
- **Baptist Memorial Hospital,** Memphis
- **Blue Ridge Medical Specialists,** Bristol
- **Boston Baskin Cancer Foundation,** Memphis
- **Cardiovascular Research of Knoxville,** Knoxville
- **Centennial Heart Cardiovascular Consultants,** Nashville
- **Center for Biomedical Research,** Knoxville
- **Charles Retina Institution,** Germantown
- **Chattanooga Center for Neurologic Research,** Chattanooga
- **Chattanooga Heart Institute,** Chattanooga
- **Chattanooga Medical Research,** Chattanooga
- **Chattanooga Oncology and Hematology Associates,** Chattanooga
- **Chattanooga Research & Medicine,** Chattanooga
- **Chattanooga's Program in Women's Oncology,** Chattanooga
- **Clinical Neuroscience Solutions,** Memphis
- **Clinical Research Associates,** Nashville
- **ClinSearch,** Chattanooga
- **Complete Family Care of Knoxville,** Knoxville
- **Cookeville Regional Medical Center,** Cookeville
- **East Tennessee Children's Hospital,** Knoxville
- **Erlanger Cancer Center,** Chattanooga
- **Family Cancer Center,** Collierville, Memphis
- **Gastro One,** Germantown
- **Henry-Joyce Cancer Clinic and Clinical Research Center,** Nashville
- **Holston Medical Group,** Kingsport
- **Jackson-Madison County General Hospital,** Jackson
- **James H. Quillen VA Medical Center,** Mountain Home
- **Kore Cardiovascular Research,** Jackson
- **McLeod Cancer and Blood Center,** Johnson City
- **Meharry Medical College,** Nashville
- **Memorial GYN Plus,** Ooltewah
- **Memorial Hospital,** Chattanooga
- **Memphis Research Associates,** Memphis
- **Methodist Medical Center,** Oak Ridge
- **Methodist University Hospital,** Memphis
- **Monroe Carell Jr. Children's Hospital at Vanderbilt,** Nashville
- **Mountain States Health Alliance,** Johnson City
- **New Orleans Center for Clinical Research,** Knoxville
- **New Phase Research & Development,** Knoxville
- **PMG Research of Bristol,** Bristol
- **Pulmonary Medical Center of Chattanooga,** Hixson
- **Research Associates of Jackson,** Jackson
- **Research Strategies of Memphis,** Memphis
- **Saint Thomas Health,** Nashville
- **Sarah Cannon Research Institute,** Nashville

- **Southeast Renal Research Institute,** Chattanooga
- **St. Jude Children's Research Hospital,** Memphis
- **Stern Cardiovascular Foundation,** Germantown, Memphis
- **Tennessee Cancer Specialists,** Harrogate, Knoxville, Morristown, Newport
- **Tennessee Clinical Research Center,** Nashville
- **Tennessee Oncology,** Dickson, Franklin, Gallatin, Hermitage, Lebanon, Murfreesboro, Nashville, Shelbyville, Smyrna
- **Tennessee Retina,** Nashville
- **Tennessee Valley VA Healthcare System,** Nashville
- **Tennova Healthcare Turkey Creek Medical Center,** Knoxville
- **The Asthma Institute,** Chattanooga
- **The Jones Clinic,** Germantown
- **Thompson Cancer Survival Center,** Knoxville
- **University of Tennessee Medical Center,** Knoxville
- **Vanderbilt University Medical Center,** Nashville
- **Vanderbilt-Ingram Cancer Center Cool Springs,** Franklin
- **Volunteer Research Group,** Knoxville
- **Wellmont Bristol Regional Medical Center,** Bristol
- **Wellmont CVA Heart Institute,** Kingsport
- **Wellmont Holston Valley Medical Center,** Kingsport
- **West Cancer Center,** Germantown, Memphis

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 191,000 Tennessee patients access free or nearly free prescription medicines for residents who are underinsured or uninsured within the state. Patients should go to *www.pparx.org* for more information. The on-line process takes about 15 minutes, and you'll find out instantly if you're likely to be eligible for help.

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

Collaborations between the biopharmaceutical research industry and universities play an important role in the development of new medicines. In the United States, there are more than 7,000 open clinical trials[1] being sponsored by the biopharmaceutical industry, universities, individuals, and organizations combined. These trials represent studies being funded by industry, research collaboration studies, and research the other groups are undertaking on their own.

In Tennessee, of the 945 open clinical trials involving the biopharmaceutical research industry, **Vanderbilt University** is collaborating on more than 245 and the **University of Tennessee** on more than 34.

THE STATE OF DISEASE IN TENNESSEE

More than 6.6 million people live in Tennessee[1], and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Tennessee	
Disease	**Health Statistic**
Alzheimer's Deaths, 2015[2]	3,122
Asthma Adult Prevalence, 2010[3]	6 percent
Asthma Child Prevalence, 2010[3]	9.5 percent
Cancer New Cases, 2017[4]	37,080
Cancer Deaths, 2017[4]	14,830
Chronic Lower Respiratory Disease, Deaths, 2015[2]	4,239
Diabetes Prevalence-Adults, 2015[2]	11.4 percent
Diabetes Deaths, 2015[2]	1,798
Heart Disease Deaths, 2015[2]	15,730
HIV-Number Living with a Diagnosis, 2014[5]	16,163
HIV Deaths, 2016[2]	5.4 percent per 100,000
Influenza / Pneumonia Deaths, 2015[2]	1,723
Kidney Disease Death, 2015[2]	1,090
Mental Illness-Adults, 2014-2015[5]	988,000
Stroke Deaths, 2015[2]	3,447

Source: 1. U.S. Census Bureau 2. Centers for Disease Control and Prevention (CDC) 3. Tennessee Department of Health 4. American Cancer Society 5. Kaiser Family Foundation, State Health Facts

[1] *Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase early 1, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 1/5/2018. Open clinical trials are recruiting, not yet recruiting, or are expanded access.*

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

- Children under the age of 18 make up 22.6 percent of the population in Tennessee. Pediatric clinical trials are being conducted in the state for asthma, Crohn's disease, cystic fibrosis, diabetes, epilepsy, glioblastoma, sickle cell anemia, juvenile arthritis, leukemia and neuroblastoma, among others.
- Tennesseans aged 65 and older account for 15.7 percent of the states' population. In Tennessee, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, Crohn's disease, depression, glaucoma, prostate cancer, heart failure and osteoarthritis, among others.
- Women and girls make up 51.2 percent of the population in Tennessee. Clinical trials are recruiting women for studies on medicines for breast cancer, endometriosis, preterm birth, endometrial cancer, ovarian cancer and vaginal infections, among others.

Clinical Trials in Tennessee for Special Populations

Population	Number of Trials
Children (birth-17)	156
Seniors (66 and older)	798
Women (only)	55

Source: www.clinicaltrials.gov. Search criteria: Tennessee, United States; Phase: early 1, 1, 2, 3; Industry only, First received on or after 1/1/2004. Search performed 1/5/2018. Open clinical trials are recruiting, not yet recruiting, or expanded access available.

SCIENCE AND CLINICAL TRIALS

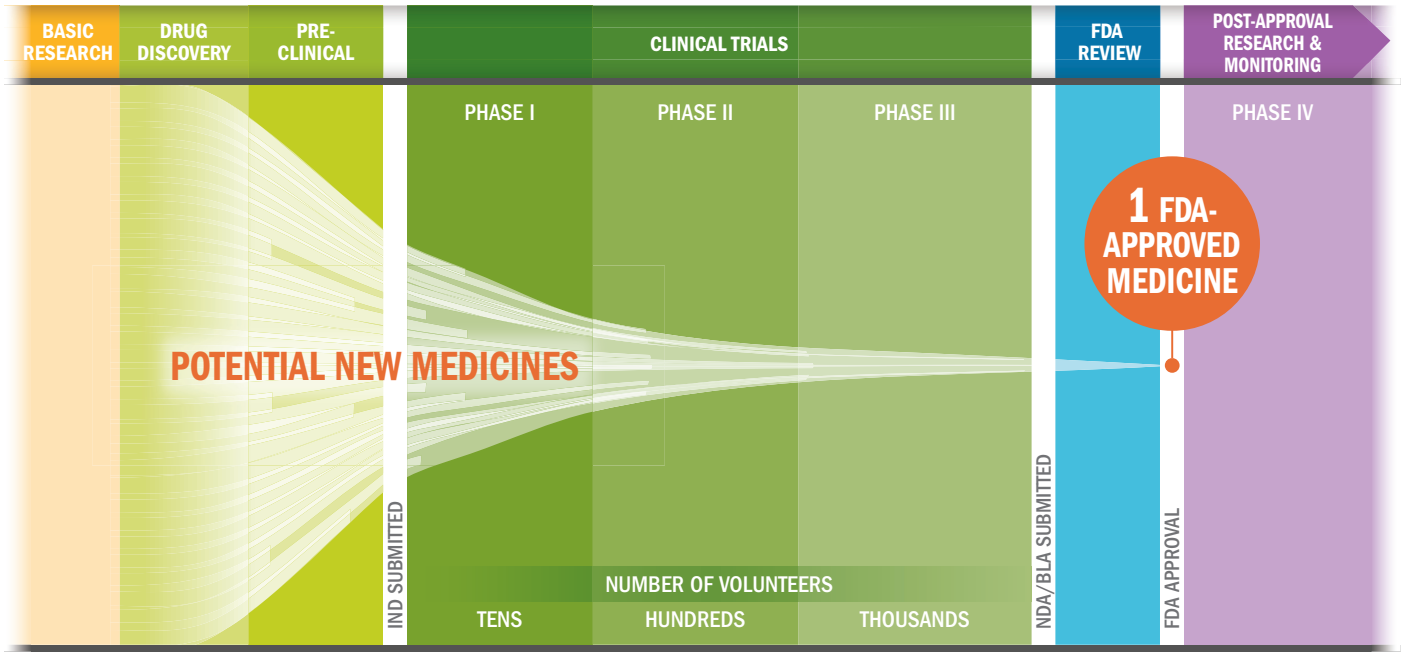
Some of the medicines in clinical testing in Tennessee feature revolutionary medical technologies. For example:

- A monoclonal antibody for the treatment of idiopathic pulmonary fibrosis is being studied in a clinical trial at **Vanderbilt University** in Nashville.
- A second-generation medicine for leukemia that blocks the activation of a receptor which is mutated in about one-third of all patients with acute myeloid leukemia is being tested in patients at **Vanderbilt University** and **Tennessee Oncology** with the **Sarah Cannon Research Institute** in Nashville.
- A medicine for advanced acute myeloid leukemia that inhibits a mutated form of a gene that can lead to increased production of an oncometabolite that prevents immature white cells from developing into healthy infection-fighting cells is in clinical trials at **Tennessee Oncology** with the **Sarah Cannon Research Institute** in Nashville.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process was studied in clinical trials at locations in **Jackson** and **Memphis**.
- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied to treat melanoma at the **West Cancer Center** in Germantown, **Vanderbilt University** and **Tennessee Oncology** with the **Sarah Cannon Research Institute** in Nashville.
- A monoclonal antibody in development for the prevention of migraine binds to and inhibits the activity of a calcitonin gene-related peptide (CGRP) expressed in the nervous system where it plays a role in controlling the widening of blood vessels and the transmission of nociceptive pain (pain arising from nerve cells) information. By inhibiting CGRP activity, anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. The antibody completed a late-stage clinical trial in **Nashville**.
- A monoclonal antibody in development to treat cancer, inhibits PD-L1 interactions, and is thought to enable the activation of T-cells and the adaptive immune system. The monoclonal antibody may potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity. The antibody is being studied in clinical trials at **Vanderbilt University** and **Tennessee Oncology** with the **Sarah Cannon Research Institute** in Nashville and the **Center for Biomedical Research** in Knoxville. Additional trials are underway in **Cookeville, Dickson, Franklin, Harrogate, Gallatin, Hermitage, Lebanon, Morristown, Murfreesboro, Newport, Shelbyville,** and **Smyrna**.
- A therapeutic recombinant pox virus vaccine that encodes the prostate-specific antigen (PSA) is being studied for the treatment of prostate cancer. It is in clinical trials at the **University of Tennessee** in Knoxville, the **West Cancer Center** in Memphis, and the **James H. Quillen Veterans Affairs Medical Center** in Mountain Home.

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.

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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