



RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs



Pharmaceutical clinical trials in
FLORIDA

Executive



Summary

Clinical trials in FLORIDA

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

Since 2004, biopharmaceutical research companies are conducting or have conducted more than 9,700 clinical trials of new medicines in Florida in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of Florida's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

CLINICAL TRIALS IN FLORIDA 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.

"Florida has built an impressive and diverse life sciences ecosystem that has considerable potential for continued innovation and growth. Since 2004, biopharmaceutical research companies are conducting or have conducted more than 9,700 clinical trials of new medicines in Florida in collaboration with clinical research centers and hospitals. The biopharmaceutical sector of the life sciences industry supported more than 148,000 direct and indirect jobs throughout Florida to address some of our state's biggest health care challenges."

**Nancy Bryan, President & CEO,
BioFlorida**

Clinical Trials in Florida since 2004— Completed and Open

All Clinical Trials	Open Clinical Trials
9,784	1,396

Source: www.clinicaltrials.gov. Search criteria: Florida, United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 8/22/2016. Open clinical trials are recruiting, not yet recruiting, or expanded access.

Executive Summary (cont.)

“Biopharmaceutical research companies drive a large portion of Florida’s jobs, tax revenue and research spending, supporting the generation of \$31.2 billion in economic activity in the state supporting Florida as a research destination. Clinical trials not only draw top scientists and researchers working on cutting-edge advancements, but employ vendors and suppliers, including construction and IT firms to support not only the direct economic output of the sector itself, but the output generated by the buying power of its workforce as well.”

**Julio Fuentes, President,
Florida State Hispanic
Chamber of Commerce**

“For patients, clinical trials offer the potential for another option or a new avenue of care for some chronic disease sufferers who are still searching for the medicines that are best for them. One of the most debilitating diseases in Florida is cancer. For cancer alone, there are 505 trials of new medicines active and recruiting patients in Florida.”

**Heather Youmans,
Senior Director,
Government Relations,
American Cancer Society
Cancer Action Network**

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 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 FLORIDA

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

A study by TEconomy Partners found that in 2014, the industry supported more than 148,000 jobs throughout Florida. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in about \$1.6 billion in federal taxation and \$57.4 million in state taxes.

Biopharmaceutical research companies supported the generation of \$31.2 billion in economic activity in the state, including the direct economic output of the sector itself, the output of the sector’s vendors and suppliers and the output generated by the buying power of its workforce.

Company employees in Florida 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 FLORIDA

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 2,571 active industry-sponsored, site-based clinical trials in Florida, with an estimated enrollment of 119,256 Florida residents. Infectious diseases had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than \$963 million and the estimated total economic impact was more than \$2.6 billion.

Open Clinical Trials in Florida by Disease	
Disease	Number of Trials
Alzheimer's Disease	37
Arthritis/Musculoskeletal Disorders	52
Autoimmune Diseases	36
Blood Disorders	26
Cancer	505
Cardiovascular Diseases	90
Diabetes	55
Eye Disorders	53
Gastrointestinal/Esophageal Diseases	59
Genetic Disorders	17
Infectious Diseases	72
Kidney Diseases	26
Liver Diseases	31
Mental Disorders	56
Neurological Disorders	98
Respiratory Diseases	47
Skin Diseases	51
Other Diseases	85
Total	1,396

Source: www.clinicaltrials.gov. Search criteria: Florida, United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 8/22/2016. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

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 Florida, 9,784 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 information on clinical trials at institutions in Florida, visit:

- University of Florida, www.ctsi.ufl.edu/community/become-a-research-participant/
- University of Miami, www.uhealthsystem.com/clinical-trials
- Cleveland Clinic, my.clevelandclinic.org/florida/medical_professionals/clinical_research
- Mayo Clinic, www.mayo.edu/research/clinical-trials/search-results?locations=FL

- H. Lee Moffitt Cancer Center at the University of South Florida, www.moffitt.org/clinical-trials-research/
- Baptist M.D. Anderson Cancer Clinic, www.baptistjax.com/patient-info/baptist-research-institute
- Mount Sinai Medical Center, www.msmc.com/clinical-trials/
- University of South Florida, health.usf.edu/medicine/psychiatry/clinicaltrials/

More information about clinical trials in Florida 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 15.

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION

ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 433,000 Florida 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.

LOCAL PATIENT ADVOCACY GROUPS

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

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
9220 Bonita Beach Road,
Suite 223
Bonita Springs, FL 34135
(239) 405-7008

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
309 North Parsons Avenue
Brandon, FL 33510
(813) 684-1296

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
14010 Roosevelt Blvd., Suite 709
Clearwater, FL 33762
(727) 578-2558

Alzheimer's Association

SOUTHEAST FLORIDA CHAPTER
3323 West Commercial Blvd.,
Suite 260
Fort Lauderdale, FL 33309
(954) 786-1533

Alzheimer's Association

CENTRAL AND NORTH FLORIDA CHAPTER
2727 NW 43rd Street, Suite 5B
Gainesville, FL 32606
(352) 372-6266

Alzheimer's Association

CENTRAL AND NORTH FLORIDA CHAPTER
4237 Salisbury Road, Suite 406
Jacksonville, FL 32216
(904) 281-9077

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
601 S. Florida Avenue, Suite 3
Lakeland, FL 33801
(863) 292-9210

Alzheimer's Association

CENTRAL AND NORTH FLORIDA CHAPTER
2180 West State Road 434,
Suite 1100
Longwood, FL 32779
(407) 951-7992

Alzheimer's Association

SOUTHEAST FLORIDA CHAPTER
1475 NW 14th Avenue
Miami, FL 33125
(305) 835-2451

Alzheimer's Association

ALABAMA FLORIDA PANHANDLE CHAPTER
223 W. Gregory Street
Pensacola, FL 32501
(850) 462-5410

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
227 Sullivan Street, Suite 125
Punta Gorda, FL 33950
(941) 235-7470

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
3277A Fruitville Road, Suite 1
Sarasota, FL 34237
(941) 365-8883

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
134 N. Ridgewood Drive, Suite 17
Sebring, FL 33870
(863) 385-3444

Alzheimer's Association

FLORIDA GULF COAST CHAPTER
4108 Lamson Avenue
Spring Hill, FL 34608
(352) 688-4537

Alzheimer's Association

SOUTHEAST FLORIDA CHAPTER
850 NW Federal Hwy.,
Suite 185/186
Stuart, FL 34994
(772) 564-1619

Alzheimer's Association

CENTRAL AND NORTH FLORIDA CHAPTER
2000 Apalachee Parkway,
Suite 200
Tallahassee, FL 32312-1231
(850) 408-9984

Alzheimer's Association

SOUTHEAST FLORIDA CHAPTER
3333 Forest Hill Blvd.
West Palm Beach, FL 33406
(561) 967-0047

American Cancer Society

FORT LAUDERDALE OFFICE
3363 West Commercial Blvd.,
Suite 100
Fort Lauderdale, FL 33309
(954) 564-0880

American Cancer Society

FORT MYERS OFFICE
4575 Via Royale, Suite 110
Fort Myers, FL 33919
(239) 936-1113

American Cancer Society

GAINESVILLE OFFICE
2119 SW 19th Street
Gainesville, FL 32608
(352) 376-6866

American Cancer Society

JACKSONVILLE OFFICE
1430 Prudential Drive
Jacksonville, FL 32207
(904) 398-0537

American Cancer Society

KEY WEST OFFICE
1010 Kennedy Drive, Suite 303
Key West, FL 33040
(305) 292-2333

American Cancer Society

LAKELAND OFFICE
1920 South Florida Avenue
Lakeland, FL 33803
(863) 688-2326

American Cancer Society

LUTZ OFFICE
21754 SR54, Suite 101
Lutz, FL 33549
(813) 949-0291

American Cancer Society

MELBOURNE OFFICE
5545 N. Wickman Road, Suite 107
Melbourne, FL 32940
(321) 253-0361

American Cancer Society

MIAMI OFFICE
8095 NW 12th Street, Suite 200
Doral, FL 33126
(305) 594-4363

American Cancer Society

PENSACOLA OFFICE
5401 Corporate Woods Drive,
Suite 100
Pensacola, FL 32504
(850) 475-0850

American Cancer Society

PINELLAS OFFICE
4801 86th Avenue North
Pinellas Park, FL 33782
(727) 546-9822

American Cancer Society

SARASOTA OFFICE
2970 University Pkwy., Suite 104
Sarasota, FL 34243
(941) 365-2858

American Cancer Society

TALLAHASSEE OFFICE
2619 Centennial Blvd., Suite 101
Tallahassee, FL 32308
(850) 297-0588

American Cancer Society

TAMPA OFFICE
3709 West Jetton Avenue
Tampa, FL 33629
(813) 253-0541

American Cancer Society

VERO BEACH OFFICE
3375 20th Street, Suite 100
Vero Beach, FL 32960
(772) 562-2272

American Cancer Society

WEST PALM BEACH OFFICE
621 Clearwater Park Road
West Palm Beach, FL 33401
(561) 366-0013

American Diabetes Association

FORT LAUDERDALE OFFICE
6400 North Andrews Avenue,
Suite 480
Fort Lauderdale, FL 33309
(954) 772-8040

American Diabetes Association

JACKSONVILLE OFFICE
7825 Baymeadows Way, Suite 104A
Jacksonville, FL 32256
(904) 730-7200

American Diabetes Association

ORLANDO-MAITLAND OFFICE
2290 Lucien Way, Suite 230
Maitland, FL 32751
(407) 660-1926

American Diabetes Association*PENSACOLA OFFICE*

12385 Sorrento Road, Suite A2
Pensacola, FL 32507
(850) 492-6100

American Diabetes Association*TAMPA AND SOUTHWEST FLORIDA OFFICE*

1511 North Westshore Blvd.,
Suite 980
Tampa, FL 33607
(813) 885-5007

American Heart Association*BONITA SPRINGS OFFICE*

28441 Bonita Crossings Blvd.
Bonita Springs, FL 34135
(239) 495-4900

American Heart Association*GREATER MIAMI/FORT LAUDERDALE OFFICE*

4000 Hollywood Blvd., Suite 170-N
Hollywood, FL 33021
(954) 364-5000

American Heart Association*JACKSONVILLE REGIONAL OFFICE*

5851 St. Augustine Road
Jacksonville, FL 32207
(904) 256-5700

American Heart Association*ORLANDO OFFICE*

237 East Marks Street
Orlando, FL 32803
(407) 481-6300

American Heart Association*ST. PETERSBURG OFFICE*

11207 Blue Heron Blvd. N
St. Petersburg, FL 33716
(727) 563-8000

American Heart Association*TALLAHASSEE OFFICE*

2851 Remington Green Circle,
Suite C
Tallahassee, FL 32308
(850) 878-3885

American Heart Association*WEST PALM BEACH OFFICE*

2300 Centrepark West Drive
West Palm Beach, FL 33409
(561) 697-6600

American Lung Association*FORT LAUDERDALE CHAPTER*

2020 South Andrews Avenue
Fort Lauderdale, FL 33316
(954) 524-4657

American Lung Association*FORT MYERS CHAPTER*

P.O. Box 07142
Fort Myers, FL 33919
(239) 908-2680

American Lung Association*JACKSONVILLE CHAPTER*

6852 Belfort Oaks Place
Jacksonville, FL 32216
(904) 743-2933

American Lung Association*ORLANDO CHAPTER*

851 Outer Road
Orlando, FL 32814
(407) 425-5864

American Lung Association*TALLAHASSEE CHAPTER*

539 Silver Slipper Lane, Suite A
Tallahassee, FL 32303
(850) 386-2065

American Lung Association*TAMPA CHAPTER*

100 South Ashley Drive, Suite 275
Tampa, FL 33612
(813) 712-2307

American Lung Association*WEST PALM BEACH CHAPTER*

2701 N. Australian Avenue, Suite 100
West Palm Beach, FL 33407
(561) 659-7644

Arthritis Foundation*FLORIDA CHAPTER*

14499 N. Dale Mabry Hwy., Suite 139
Tampa, FL 33618
(813) 968-7000

NAMI Florida*NATIONAL ALLIANCE ON MENTAL ILLNESS*

3333 W. Pensacola Street, Suite 250
Tallahassee, FL 32304
(850) 671-4445

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 FLORIDA

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

- Supported more than 148,000 jobs throughout Florida in 2014.
- Supported the generation of \$31.2 billion in economic activity in the state.
- Resulted in about \$1.6 billion in federal taxation and \$57.4 million in state taxes through jobs supported by the biopharmaceutical sector.

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

PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

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

- **Arnold Palmer Hospital for Children**, Orlando
- **Baptist Hospital of Miami**, Miami
- **Baptist M.D. Anderson Cancer Center**, Orlando
- **Baptist Medical Center South**, Jacksonville
- **Barry University School of Podiatric Medicine**, Hialeah
- **Bay Pines VA Healthcare System**, Bay Pines
- **Bethesda Memorial Hospital**, Boynton Beach
- **Boca Raton Regional Hospital**, Boca Raton
- **Cancer Institute of Florida**, Orlando
- **Cleveland Clinic Florida**, Weston
- **Florida Hospital Cancer Institute**, Orlando
- **Florida Hospital Memorial Medical Center**, Daytona Beach
- **Florida Hospital Pepin Heart Institute**, Tampa
- **H. Lee Moffitt Cancer Center**, Tampa
- **Halifax Health Medical Center**, Daytona Beach
- **Holy Cross Hospital**, Fort Lauderdale
- **Jackson Memorial Hospital**, Miami
- **Johns Hopkins All Children's Hospital**, St. Petersburg
- **Lakeland Regional Medical Center**, Lakeland
- **Lee Memorial Health System**, Fort Myers
- **Martin Health System**, Stuart
- **Mayo Clinic Florida**, Jacksonville
- **Memorial Cancer Center**, Hollywood
- **Miami Cardiac and Vascular Institute**, Miami
- **Miami Jewish Health System**, Miami
- **Morton Plant Hospital**, Clearwater
- **Mount Sinai Medical Center Comprehensive Cancer Center**, Miami Beach
- **Munroe Regional Medical Center**, Ocala
- **Nemours Children's Hospital**, Orlando
- **Nicklaus Children's Hospital**, Miami
- **North Florida/South Georgia Health System**, Gainesville
- **Nova Southeastern University**, Fort Lauderdale
- **Orlando Health Medical Center**, Orlando
- **Osceola Regional Medical Center**, Kissimmee
- **Sarasota Memorial Hospital**, Sarasota
- **Shands Cancer Center at University of Florida**, Gainesville
- **South Florida VA Foundation for Research and Education**, Miami
- **St. Joseph's Children's Hospital**, Tampa
- **Sylvester Comprehensive Cancer Center**, Miami
- **Tampa General Hospital**, Tampa
- **The Roskamp Institute**, Sarasota
- **Translational Research Institute for Metabolism and Diabetes**, Orlando
- **University of Florida, Gainesville**, Jacksonville
- **University of Miami Miller School of Medicine**, Miami
- **University of South Florida**, Tampa
- **VA Medical Center**, Miami
- **Winter Park Memorial Hospital**, Winter Park

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 6,900 open clinical trials¹ being sponsored by the biopharmaceutical industry, universities, individuals and organizations combined. These trials represent studies being funded by industry, research collaboration studies and research the other groups are undertaking on their own.

In Florida, of the 1,396 open clinical trials involving the biopharmaceutical research industry, **Mayo Clinic** is collaborating on more than 123 clinical trials, the **University of Miami** on more than 98, the **University of Florida** on more than 95, the **Mount Sinai Medical Center of Florida** on more than 90, the **H. Lee Moffitt Cancer Center and Research Institute** on more than 63, the **Baptist M.D. Anderson Cancer Clinic** on more than 15, and the **University of South Florida** on more than 29 of the clinical trials. Other institutions collaborating with industry include **Florida Atlantic University**, **Nova Southeastern University** and the **University of Central Florida**.

¹ Data collected from www.clinicaltrials.gov. Search criteria: United States, Phase 0, 1, 2, 3; Industry and Other, first received on or after 1/1/2004. Search performed 7/20/2016. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

THE STATE OF DISEASE IN FLORIDA

More than 20 million people live in Florida¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in Florida	
Disease	Health Statistic
Alzheimer's Deaths, 2014 ²	5,814
Asthma Prevalence, 2012 ³	1.6 million
Cancer New Cases, 2016 ⁴	121,240
Cancer Deaths, 2016 ⁴	43,600
Chronic Liver Disease Deaths, 2014 ²	2,996
Chronic Lower Respiratory Diseases, 2014 ²	11,089
Diabetes Prevalence—Adults, 2013 ⁵	1.7 million
Diabetes Deaths, 2014 ²	5,324
Heart Disease Deaths, 2014 ²	43,747
HIV—Number Living with a Diagnosis, 2013 ⁵	101,452
Influenza and Pneumonia Deaths, 2014 ²	2,663
Mental Illness—Reported by Adults, 2013–2014 ⁵	16 percent
Nephritis Deaths, 2014 ²	3,026
Parkinson's Deaths, 2014 ²	2,031
Stroke Deaths, 2014 ²	9,605

Source: 1. U.S. Census Bureau. 2. Florida Bureau of Vital Statistics. 3. Florida Department of Health. 4. American Cancer Society. 5. Kaiser Family Foundation, State Health Facts.

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

- Children under the age of 18 make up more than 20 percent of the population in Florida. Pediatric clinical trials are being conducted in the state for asthma, diabetes, epilepsy, cancer and cystic fibrosis, among others.
- Floridians aged 65 and older account for more than 19.4 percent of the states' population. In Florida, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, colorectal cancer, heart failure, macular degeneration and osteoarthritis.
- Women and girls make up 51.1 percent of the population in Florida. Clinical trials are recruiting women for studies on medicines for arthritis, breast cancer, endometriosis and ovarian cancer, among others.

Clinical Trials in Florida for Special Populations	
Population	Number of Trials
Children (birth–17)	214
Seniors (66 and older)	1,148
Women (only)	72

Source: www.clinicaltrials.gov. Search criteria: Florida, United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 8/22/2016. Open clinical trials are recruiting, not yet recruiting, or expanded access.

SCIENCE AND CLINICAL TRIALS

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

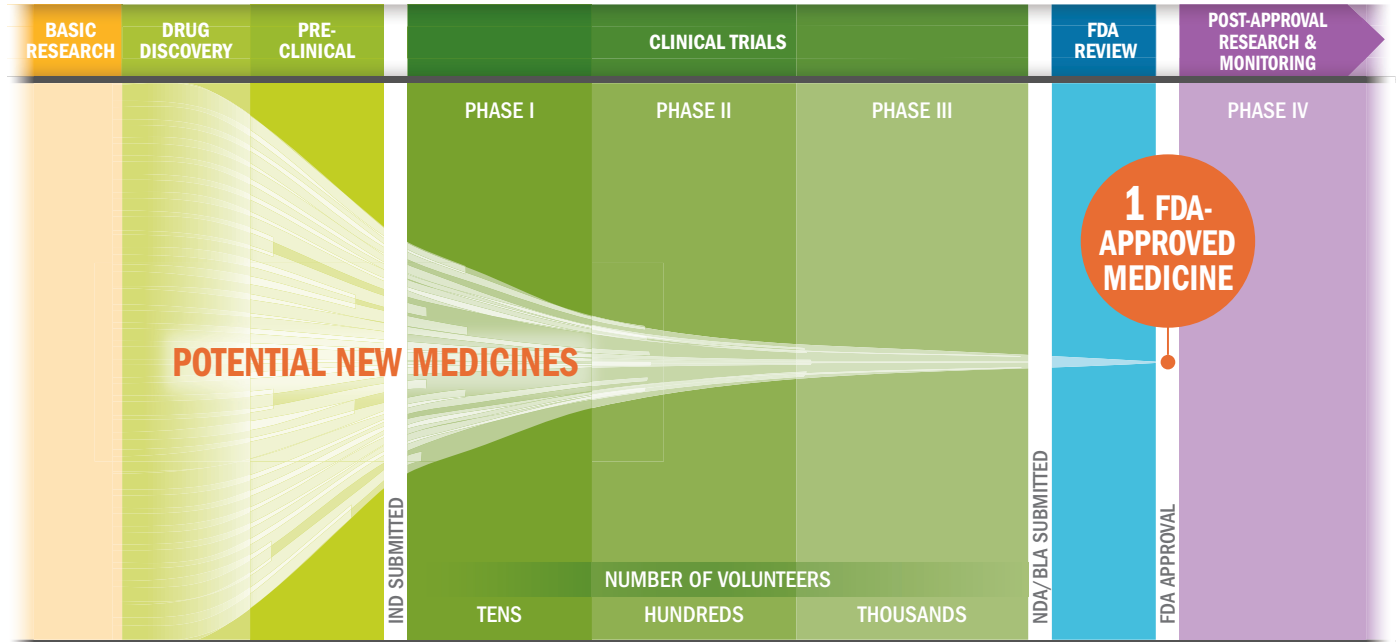
- A second generation medicine for leukemia that blocks the activation of a receptor which is mutated in about one-third of all patients with acute myeloid leukemia is being tested at the H. Lee Moffitt Cancer Center in Tampa, the University of Florida Shands Cancer Center in Gainesville, Memorial Cancer Institute at Memorial Regional Hospital in Hollywood, the Baptist Cancer Institute in Jacksonville and the Florida Hospital Cancer Institute in Orlando.
- A medicine for advanced hematological malignancies that inhibits a mutated gene that prevents immature white cells from developing into healthy infection-fighting cells is being studied at the University of Florida Shands Cancer Center in Gainesville, the University of Miami Sylvester Cancer Research Center in Miami and the University of Florida Health Cancer Center in Orlando.
- A monoclonal antibody for the prevention of migraine binds to and inhibits the activity of a peptide expressed in the central nervous system to help inhibit the transmission of pain signals associated with migraines is being studied in Bradenton, Hollywood, Jacksonville, Leesburg, Melbourne, Miami, Ocala, Orlando, Oviedo, Palm Beach Gardens, Sunrise and West Palm Beach.
- An investigational therapeutic using RNAi (RNA interference) a biological process that can be used to silence a gene and, in turn, prevent production of the protein it encodes. The therapeutic targets the protein transthyretin for the treatment of familial amyloid and is being studied in clinical trials in Tampa.
- An anti-inflammatory medicine in development for acute coronary syndrome that inhibits the activity of an enzyme associated with inflammation in the blood vessels during and following an acute coronary event was studied in trials in Daytona Beach, Jacksonville, Ocala, Pensacola, Tallahassee, Tampa and Vero Beach.
- A monoclonal antibody that binds to and inhibits the action of the protein sclerostin, which plays a role in increasing bone formation and decreasing bone breakdown in osteoporosis is being studied in trials in Fort Lauderdale, Leesburg, Miami, Palm Harbor, Plantation, Stuart, Tampa and West Palm Beach.
- A monoclonal antibody for rheumatoid arthritis that may block the inflammatory process associated with arthritis is being studied in clinical trials in Aventura, Dunedin, Fort Lauderdale, Jacksonville, Jupiter, Miami, Naples, Orlando, Ormond Beach, Palm Harbor, Sarasota, Tampa and Vero Beach.

- A medicine in development for Huntington's disease targets the PDE10A enzyme, which is present in the neurons most damaged by the disease. The medicine is in clinical trials at the University of Florida Center for Movement Disorders & Neurorestoration in Gainesville.
- A synthetic analogue of human parathyroid hormone-related protein (hPTHrP) is in development for the treatment of postmenopausal osteoporosis. The protein hPTHrP is thought to be a critical cytokine for promoting new bone formation. The medicine is designed to build bone rapidly without inducing hypercalcemia (too much calcium in the blood) or significant bone resorption and is being studied in Miami and North Miami.

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 Florida, 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).

