



RESEARCH *in* YOUR BACKYARD

Developing Cures, Creating Jobs

Pharmaceutical clinical trials in
NEW JERSEY

Executive



Summary

Clinical trials in NEW JERSEY

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

Since 2004, biopharmaceutical research companies are conducting or have conducted more than 4,900 clinical trials of new medicines in New Jersey in collaboration with clinical research centers and hospitals. These clinical trials have investigated or are investigating some of New Jersey's biggest health care challenges, including asthma, arthritis, cancer, diabetes, cardiovascular disease and Alzheimer's disease.

CLINICAL TRIALS IN NEW JERSEY 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.

"New Jersey continues to lead the way in medical innovation with clinical trials activity in the State above the national average in oncology, infection and inflammatory diseases. With a dynamic life sciences ecosystem, featuring leading research institutions, cutting-edge biopharma companies (small and large) and the industry's top talent pool, New Jersey has led more than 4,900 clinical trials of new medicines since 2004, with 675 active trials today. The investment in clinical trials and research confers economic benefits to New Jersey's economy and gives patients access to innovative technologies and treatments they would otherwise not have – providing hope to those in need of therapies and cures around the globe."

Debbie Hart,
President & CEO, BioNJ

Clinical Trials in New Jersey since 2004—Completed and Open

All Clinical Trials	Open Clinical Trials
4,967	675

Source: www.clinicaltrials.gov. Search criteria: New Jersey; United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 6/1/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

Executive Summary (cont.)

"Today, New Jersey is home to more than 3,000 life sciences companies, including 13 of the world's top 20 research-based biopharmaceutical companies that have a headquarters or significant presence in the state. The industry has a long history of collaborating with local academic and health care institutions on cutting-edge research and developing new cures and therapies. In addition to improving patient care and outcomes, the life sciences continue to be a strong source of support for these institutions and a pillar of the New Jersey economy."

**Dean Paranicas, President & CEO,
HealthCare Institute of New Jersey**

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 NEW JERSEY

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

A study by TEconomy Partners found that in 2014, the industry supported more than 378,000 jobs throughout New Jersey. Wages and benefits for employees whose jobs were supported by the biopharmaceutical sector resulted in more than \$6.5 billion in federal taxation and \$799.9 million in state taxes.

Biopharmaceutical research companies supported the generation of \$108.7 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 New Jersey 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 NEW JERSEY

A separate study by Battelle Technology Partnership Practice found that in 2013 alone, there were 1,234 active industry-sponsored, site-based clinical trials in New Jersey, with an estimated enrollment of 25,127 New Jersey residents. Oncology had the leading clinical trial enrollment in the state.

The investment of these site-based clinical trials was more than \$245 million and the estimated total economic impact was more than \$617 million.

Selected Disease Statistics in New Jersey	
Disease	Number of Trials
Allergy	3
Alzheimer's Disease	30
Arthritis/Musculoskeletal Disorders	34
Autoimmune Diseases	21
Bladder Disorders	3
Blood Disorders	8
Cancer	314
Cardiovascular Diseases	33
Diabetes	13
Eye Disorders	19
Gastrointestinal/Esophageal Diseases	29
Genetic Disorders	3
Infectious Diseases	31
Kidney Diseases	17
Liver Diseases	16
Mental Disorders	31
Neurological Disorders	27
Respiratory Diseases	14
Skin Diseases	14
Transplantation-Related	3
Other Diseases	12
Total	675

"I'm proud of New Jersey's life science rich history, our talented workforce and our premier higher education institutions. At this crucial juncture, when the state is focused on creating jobs, attracting new businesses and rebuilding the economy, supporting clinical research and the biopharmaceutical industry is pivotal to our success. I am encouraged to see the industry-academic research partnerships growing throughout our state and I will continue to sponsor and support legislation that builds on existing partnerships and incentivizes further collaboration. We must all work together to grow a supportive infrastructure for the conduct of clinical and translational research."

**Assemblyman Gary Schaefer,
Chair, Assembly Budget Committee,
D-NJ-36**

Source: www.clinicaltrials.gov. Search criteria: New Jersey, United States; Phase 0, 1, 2, 3; Industry only; first received on or after 1/1/2004. Search performed 6/1/2017. 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 New Jersey, 4,967 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 Rutgers New Jersey Medical School, go to rbhs.rutgers.edu/trials.shtml and for trials at Robert Wood Johnson Medical School go to www.rwjms.rutgers.edu/patient_care/clinical_research/index.html. For clinical trials at Rowan University-Stratford, go to

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

www.rowan.edu/som/research/clinicalTrials.html. For clinical trials targeting cancer at Rutgers Cancer Institute of New Jersey, go to <http://www.cinj.org/clinicaltrials>. And, for clinical trials targeting cancer at Hackensack University Medical Center, go to <http://www.jtcancercenter.org/research/clinical-trials/> and at MD Anderson Cancer Center at Cooper University call (856) 735-6237.

More information about clinical trials in New Jersey 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.

LOCAL PATIENT ADVOCACY GROUPS

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

Action CF

66 Nottingham Road
Fair Lawn, NJ 07410
(201) 523-2257

Alzheimer's Association

ATLANTIC CITY BRANCH OFFICE
25 Dolphin Avenue
Building D, Ground Floor
Northfield, NJ 08225
(800) 272-3900

Alzheimer's Association

DELAWARE VALLEY CHAPTER
399 Market Street, Suite 102
Philadelphia, PA 19106
(800) 272-3900

Alzheimer's Association

SOUTH JERSEY REGIONAL OFFICE
3 Eves Drive, Suite 310
Marlton, NJ 08053
(973) 866-8143

American Cancer Society

NORTHWEST NEW JERSEY REGION
7 Ridgedale Avenue, Suite 103
Cedar Knolls, NJ 07927
(973) 285-8010

American Cancer Society

SOUTH JERSEY REGION
1851 Old Cuthbert Road
Cherry Hill, NJ 08034
(856) 616-1650

American Cancer Society

NORTHERN NEW JERSEY REGION
20 Mercer Street
Hackensack, NJ 07601
(201) 343-2222

American Cancer Society

JERSEY SHORE REGION
2310 Route 34, Suite 1D
Manasquan, NJ 08736
(732) 292-3112

American Cancer Society

CENTRAL NEW JERSEY REGION
2600 U.S. Highway 1
North Brunswick, NJ 08902
(732) 297-8000

American Cancer Society

METRO NEW JERSEY REGION
986 South Springfield Avenue
Springfield, NJ 07081
(973) 379-2830

American Diabetes Association

BRIDGEWATER OFFICE
1160 Route 22 East, Suite 103
Bridgewater, NJ 08807
(732) 469-7979

American Diabetes Association

PHILADELPHIA OFFICE
150 Monument Road, Suite 100
Bala Cynwyd, PA 19004
(610) 667-1761

American Heart Association

NEW JERSEY OFFICE
1 Union Street, Suite 301
Robbinsville, NJ 08691
(609) 208-0020

American Lung Association

NEW JERSEY CHAPTER
P.O. Box 10188, 37214
Newark, NJ 07101
(908) 685-8040

Arthritis Foundation

NEW JERSEY OFFICE
555 Route 1 South, Suite 220
Iselin, NJ 08830
(732) 283-4300

Epilepsy Foundation of New Jersey

SOUTHERN REGIONAL OFFICE
208 White Horse Pike, Suite 8
Barrington, NJ 08007
(856) 858-5900

Epilepsy Foundation of New Jersey

SHORE AREA OFFICE
Lions Head Office Park
35 Beaverson Blvd., Building 11
Brick, NJ 08723
(732) 262-8020

Epilepsy Foundation of New Jersey

NORTHERN REGIONAL OFFICE
322 U.S. Highway 46, Suite 290
Parsippany, NJ 07054
(973) 244-0850

NAMI New Jersey

NATIONAL ALLIANCE ON MENTAL ILLNESS
1562 Route 130
North Brunswick, NJ 08902
(732) 940-0991

New Jersey Association of Mental Health and Addiction Agencies (NJAMHAA)

3575 Quakerbridge Road
Suite 102
Trenton, NJ 08619
(609) 838-5488

OTHER PATIENT RESOURCES

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA): The Partnership for Prescription Assistance has helped more than 197,000 New Jersey 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.

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 NEW JERSEY

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

- Supported more than 378,000 jobs throughout New Jersey in 2014.
- Supported the generation of \$108.7 billion in economic activity in the state.
- Resulted in more than \$6.5 billion in federal taxation and \$799.9 million in state taxes through jobs supported by the biopharmaceutical sector.

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

PUBLIC-PRIVATE PARTNERSHIPS AND LOCAL COLLABORATION

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

- **Cancer Institute of New Jersey**, New Brunswick
- **Carol G. Simon Cancer Center**, Morristown
- **Christiana Care Health System**, Newark
- **Cooper University Hospital**, Camden, Voorhes
- **Deborah Heart and Lung Center**, Browns Mill
- **East Orange VA Medical Center**, East Orange
- **Englewood Hospital & Medical Center**, Englewood
- **Gagnon Cardiovascular Institute, Atlantic Health System**, Morristown
- **Global Medical Institute, Princeton Medical Institute**, Princeton
- **Goryeb Children's Hospital**, Morristown
- **Hackensack University Medical Center**, Hackensack
- **Holy Name Medical Center**, Teaneck
- **Jersey Shore University Medical Center**, Neptune City
- **JFK Medical Center**, Edison
- **JFK Neuroscience Institute**, Edison
- **John Theurer Cancer Center at Hackensack University**, Hackensack
- **Kessler Institute for Rehabilitation**, West Orange
- **Luckow Pavilion at Valley Hospital**, Paramus
- **MD Anderson Cancer Center at Cooper University**, Camden
- **Memorial Sloan Kettering at Basking Ridge**, Basking Ridge
- **Memorial Sloan Kettering Monmouth**, Middletown
- **Meridian Health Systems**, Brick
- **Monmouth Medical Center**, Long Branch
- **Morristown Medical Center**, Morristown
- **Newark Beth Israel Medical Center**, Newark
- **Our Lady of Lourdes Medical Center**, Camden
- **Overlook Medical Center**, Summit
- **Raritan Bay Medical Center**, Perth Amboy
- **Rowan University**, Stratford
- **Rutgers New Jersey Medical School**, Newark
- **Rutgers Robert Wood Johnson Medical School**, New Brunswick
- **Saint Barnabas Medical Center**, Livingston
- **St. Joseph's Regional Medical Center**, Paterson
- **St. Michael's Medical Center**, Newark
- **Trinitas Comprehensive Cancer Center**, Elizabeth
- **University Hospital Center**, Newark
- **Valley Hospital**, Ridgewood
- **Women's Cancer Center**, Morristown
- **Women's Health Research Center**, Plainsboro

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 7,200 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 New Jersey, of the 675 open clinical trials involving the biopharmaceutical research industry, **Hackensack University** is collaborating on more than 90 clinical trials, **Rutgers New Jersey Medical School** on more than 52, and the **Robert Wood Johnson Medical School** on more than 13 of the clinical trials.

THE STATE OF DISEASE IN NEW JERSEY

More than 8.9 million people live in New Jersey¹, and many are dealing with disease and disability from asthma to cancer and from diabetes to heart disease.

Selected Disease Statistics in New Jersey	
Disease	Health Statistic
Alzheimer's Deaths, 2014 ²	1,946
Asthma Prevalence-Adults, 2015 ³	7.2 percent
Cancer New Cases, 2017 ⁴	51,680
Cancer Deaths, 2017 ⁴	15,880
Chronic Lower Respiratory Diseases, 2014 ²	3,037
Diabetes Prevalence-Adults, 2015 ³	9 percent
Diabetes Deaths, 2014 ²	2,054
Heart Disease Deaths, 2014 ²	18,186
HIV-Number Living with a Diagnosis, 2014 ³	35,682
Kidney Disease Deaths, 2014 ²	1,492
Mental Illness-Adults, 2013-2014 ³	1,106,000
Influenza / Pneumonia Deaths, 2014 ²	1,229
Stroke Deaths, 2014 ²	3,391

Source: 1. U.S. Census Bureau 2. New Jersey Center for Health Statistics and Informatics 3. Kaiser Family Foundation, State Health Facts 4. American Cancer Society

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 6/1/2017. Open clinical trials are recruiting, not yet recruiting, or are expanded access.

NEW JERSEY CLINICAL TRIALS AND SPECIAL POPULATIONS: CHILDREN, OLDER AMERICANS AND WOMEN

- Children under the age of 18 make up nearly 22.3 percent of the population in New Jersey. Pediatric clinical trials are being conducted in the state for juvenile arthritis, glioma, leukemia, diabetes, epilepsy, cystic fibrosis and hemophilia A, among others.
- New Jerseyans aged 65 and older account for 15 percent of the states' population. In New Jersey, clinical trials are recruiting older people to study potential treatments for diseases such as Alzheimer's disease, chronic obstructive pulmonary disease, prostate cancer, heart failure, glaucoma, Parkinson's dementia and osteoarthritis.
- Women and girls make up 51.2 percent of the population in New Jersey. Clinical trials are recruiting women for studies on medicines for breast cancer, ovarian cancer, UTI infections, uterine fibroids and postpartum depression, among others.

Clinical Trials in New Jersey for Special Populations	
Population	Number of Trials
Children (birth-17)	90
Seniors (66 and older)	586
Women (only)	42

Source: www.clinicaltrials.gov. Search criteria: New Jersey, United States; Phase 0, 1, 2, 3; Industry only, first received on or after 1/1/2004. Search performed 6/1/2017. Open clinical trials are recruiting, not yet recruiting, or expanded access.

SCIENCE AND CLINICAL TRIALS

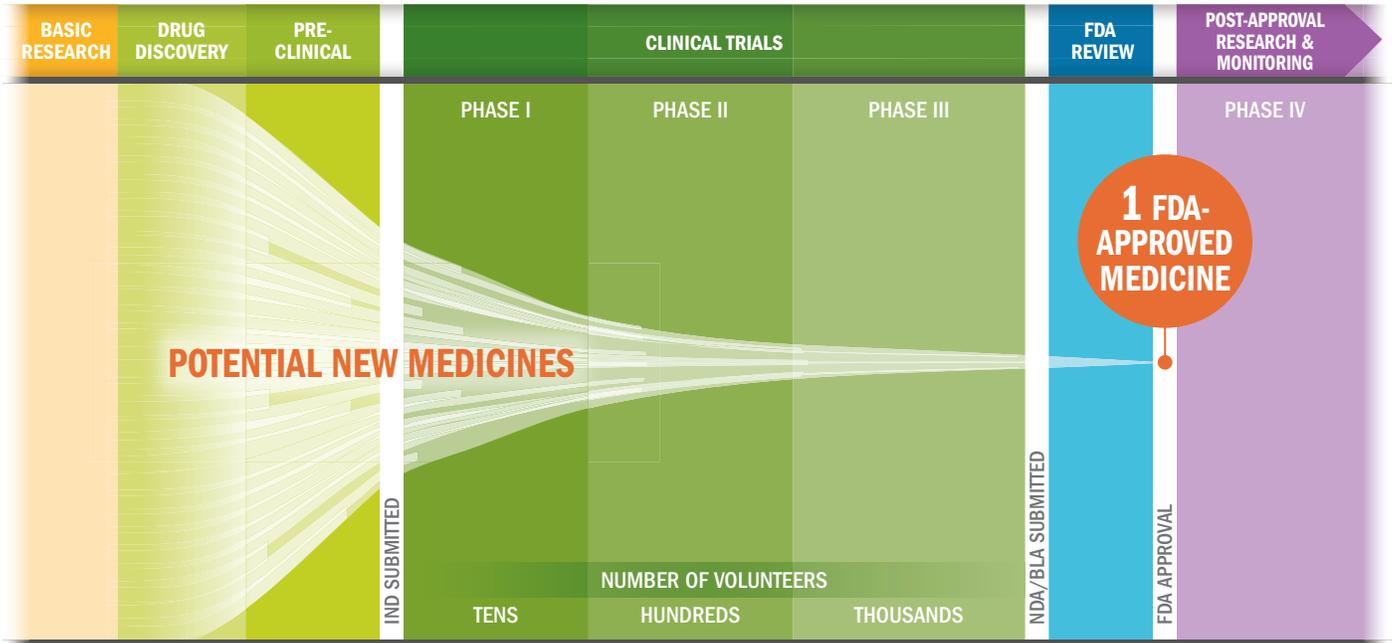
Some of the medicines in clinical testing in New Jersey feature revolutionary medical technologies. For example:

- A monoclonal antibody for the treatment of **idiopathic pulmonary fibrosis** is being studied in a clinical trial at Rutgers–Robert Wood Johnson Medical School in New Brunswick.
- 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 Hackensack University Medical Center in Hackensack.
- 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 The John Theurer Cancer Center at Hackensack University Medical Center in Hackensack.
- A monoclonal antibody for **rheumatoid arthritis** that may block the inflammatory process was studied in clinical trials in Freehold.
- A novel targeted therapy that combines recombinant interleukin-3 with truncated diphtheria toxin is in development for **acute myeloid leukemia** and is in clinical trials at Hackensack University Medical Center in Hackensack.
- A medicine that targets a mutation in the gene that encodes BRAF kinase is being studied to treat **melanoma** at MD Anderson Cancer Center at Cooper in Camden, Morristown Medical Center in Morristown and Overlook Hospital in Summit.
- A monoclonal antibody in development for the prevention of **migraine** binds to and inhibits the activity of a peptide expressed in the nervous system where it plays a role in controlling the widening of blood vessels and the transmission of nociceptive pain (pain arising from nerve cells) information. By inhibiting CGRP activity, anti-CGRP antibodies are thought to help inhibit the transmission of pain signals associated with migraines. The antibody is being studied in a clinical trial in Princeton.
- A medicine in development to treat **peripheral artery disease** is a non-viral gene therapy that targets a tissue repair and regeneration pathway in the body. This pathway promotes cardiac function, cell survival and the repair of injured heart tissue. It is being studied at Holy Name Medical Center in Teaneck.
- An investigational therapeutic using RNAi (RNA interference) is targeting the protein transthyretin (TTR) for the treatment of **familial amyloid cardiomyopathy (FAC)**. RNAi is a biological process that can be used to silence a gene and, in turn, prevent production of the protein it encodes. It is in a clinical trial in Newark.
- **Acute coronary syndrome (ACS)** refers to cardiovascular events, including heart attack, where there is an abrupt reduction of blood flow to the heart through the coronary arteries. An anti-inflammatory medicine in development for the syndrome inhibits the activity of p38 mitogen activated protein (MAP) kinase, an enzyme associated with the acute inflammation that occurs in the blood vessels during and immediately following an acute coronary syndrome event. The medicine was studied in clinical trials in Flemington, Ridgewood, Teaneck and Voorhes.

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 New Jersey, 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).

