



Chronic Diseases

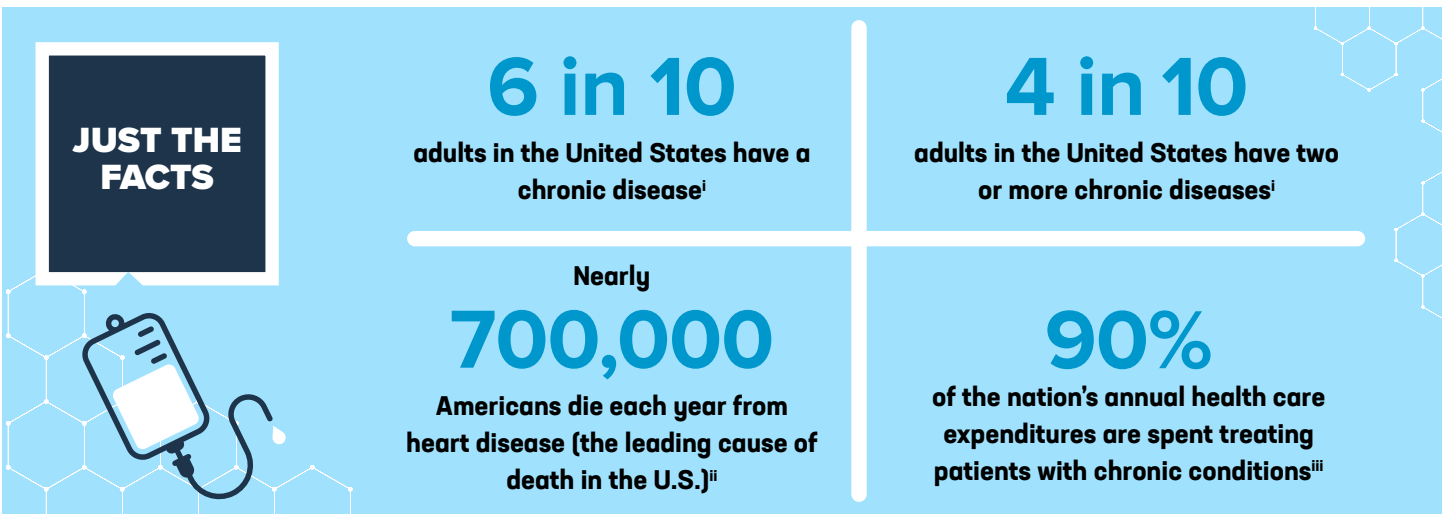
Nearly **800** Medicines in Development for Leading Chronic Diseases

Chronic diseases impose a substantial clinical and economic burden that affect millions of patients, families and communities across the United States each day. Differing from acute diseases, which usually demand short-term care, chronic diseases often require extended and, in some cases, life-long treatment. As such, chronic diseases are a significant driver of health care spending and can have a detrimental impact on a patient's quality of life.

Chronic diseases are defined broadly as conditions lasting one year or more and require ongoing medical attention or limit activities of daily living or both.ⁱ In the United States, chronic conditions – including heart disease, cancer, stroke, respiratory diseases, Alzheimer's disease and diabetes – are highly prevalent and make up a majority of the nation's leading causes of death.ⁱⁱ According to the Centers for Disease Control and Prevention (CDC), six out of 10 adults in the United States have at least one chronic condition and four in 10 have two or more chronic conditions.ⁱ All combined, it is estimated that 90% of the United States' \$4.1 trillion annual health care expenditures are spent treating those with chronic health conditions.ⁱⁱⁱ

It is expected chronic conditions will continue to remain a leading driver of health care costs over the coming years. By 2030, it is estimated that 80% of the U.S. population will experience one or more chronic conditions, costing society more than \$42 trillion in health care spending and losses in employment productivity. But with better prevention and treatment of chronic diseases, 1.1 million lives could be saved annually, leading to as much as \$534 billion in savings each year.^{iv}

In response to the projected burden chronic diseases will continue to impose on the health care system, biopharmaceutical researchers have made tremendous efforts over the past 30 years to develop novel treatments that target leading chronic conditions.



The Chronic Disease Drug Development Pipeline

Whether targeting underlying mechanisms of disease to prevent or slow disease progression or providing a new approach to better control and manage disease symptoms, medicines play a critical role in the treatment of chronic disease. This report focuses on medicines in development for chronic conditions – some of which are leading causes of death in the U.S.– including various forms of cancer, cardiovascular diseases, Alzheimer’s disease, type I and II diabetes, arthritis, chronic respiratory diseases, gastrointestinal diseases, obesity and kidney disease. These diseases represent a wide range of chronic conditions with different origins, symptoms and treatments.

To address the need for various new treatments to help manage chronic diseases, America’s biopharmaceutical research companies are currently developing **799** medicines.^v These medicines are either in clinical trials or under review by the U.S. Food and Drug Administration (FDA). The medicines in development include:

- **322** for chronic forms of **cancer**, including breast cancer, ovarian cancer, prostate cancer, pediatric cancer and chronic forms of leukemia and lymphoma.
- **102** for **cardiovascular diseases**, including congestive heart failure, coronary artery disease, high cholesterol, hypertension and stroke. Heart disease and stroke together cause more than 850,000 deaths each year in the U.S.ⁱⁱ
- **83** medicines in development for **Alzheimer’s disease**, the most common form of dementia. Alzheimer’s affects more than six million Americans and, along with other dementias, was projected to cost the American economy an estimated \$355 billion in 2021.^{vi}
- **71** for type I and type II **diabetes**, which affects 37.3 million people in the U.S., including 28.7 million diagnosed and an estimated 8.5 million undiagnosed.^{vii}
- **70** for **arthritis**, including osteoarthritis, psoriatic arthritis, rheumatoid arthritis and gout. In the U.S., nearly one out of four adults have been diagnosed with some form of arthritis.^{viii}
- **67** for chronic **respiratory diseases**, including asthma, chronic obstructive pulmonary disease (COPD) and pulmonary fibrosis. Asthma affects nearly 8% of the U.S. population,^{ix} while more than 16.4 million people in the U.S. have been diagnosed with COPD.^x
- **65** for chronic **gastrointestinal diseases**, such as Crohn’s disease, ulcerative colitis and irritable bowel disease. Crohn’s disease and ulcerative colitis affect more than 1.6 million^{xi} Americans, while between 25 to 45 million people in the U.S. are affected by irritable bowel syndrome.^{xii}
- **32** for obesity, defined as having a body mass index (BMI) of more than 30^{xiii}, which affects approximately two in five adults in the U.S.^{xiv}
- **26** for chronic **kidney disease**, which affects about 37 million U.S. adults; most of which are undiagnosed.^{xv}

With expanded scientific knowledge, new technologies, and the commitment of America’s biopharmaceutical research companies, we can work to uncover new targets for earlier detection, treatments and, ultimately, cures for patients with chronic diseases.

Innovative Medicines in the Chronic Disease Pipeline

The **799** medicines in development for chronic diseases represent innovative new ways to target chronic conditions, including:

- Several medicines in development for **Alzheimer's disease** are disease-modifying treatments that may stop or slow disease progression by targeting one or more of the changes in the brain associated with the disease. These targets include beta-amyloid plaques that appear between nerve cells and disrupt cell function, Tau protein tangles that damage and kill brain cells, and a receptor that decreases a neurotransmitter necessary for the brain to function normally. Other areas of research target neuroinflammation, immune response and metabolic changes. One monoclonal antibody medicine in development is a Tau protein inhibitor designed to block and reduce the spread of Tau from neuron to neuron and potentially from forming damaging Tau tangles.
- A once weekly fixed-dose combination medicine in development for **type II diabetes** is comprised of a long-acting basal insulin analog and an approved GLP-1 (glucagon-like peptide-1) agonist. The long-acting basal insulin has the potential to reduce the number of annual insulin injections from daily to weekly. Research has found that the GLP-1 agonist has the potential to lower blood glucose by stimulating the release of insulin and may also lower body weight.
- A potential first-in class myeloperoxidase (MPO) inhibitor is in clinical trials for the treatment of **heart failure** with preserved ejection fraction - an advanced form of congestive heart failure - caused by microvascular inflammation. The investigational medicine inhibits MPO, which is known to cause the formation of hypochlorous acid and other free radicals that interfere with microvascular function (the tiny blood vessels in the heart). In preclinical models, MPO inhibitors have been found to reduce inflammation and fibrosis and improve microvascular function.
- A medicine approved to treat type II diabetes is in clinical trials for the treatment of **obesity**. The medicine binds to and activates the GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) receptors in the body. GIP and GLP-1 are hormones involved in blood sugar control. In preclinical models, GIP has been shown to decrease food intake and increase energy expenditure resulting in weight reductions. When combined with a GLP-1 receptor agonist, the treatment may result in greater effects on body weight, glucose and lipids. The medicine was recently approved in the U.S. as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus.
- A monoclonal antibody in development targets **rheumatoid arthritis**, a chronic inflammatory condition characterized by pain, swollen joints, stiffness and joint destruction. The monoclonal antibody inhibits granulocyte-macrophage colony-stimulating factor (GM-CSF), a protein that plays a key role in the inflammatory process, leading to inflammation, joint damage and pain associated with immune-mediated disease, including rheumatoid arthritis. The medicine neutralizes the biological function of the protein that causes inflammation, GM-CSF, by blocking its interaction with its receptor on the surface of the cell.





Patient perspective

The near 800 medicines in development for chronic conditions today seek to employ the latest in scientific treatment advances to the benefit of patients for years to come. Hear what patients are saying:

“Having managed my type I diabetes since I was 12 years old, I have seen vast improvements in the technology and medications I depend on daily for my chronic condition. I am hopeful that with continued pharmaceutical research and development, I, along with other diabetics, may be able to manage our symptoms easier or even see a cure for diabetes in our lifetime.”

– Lauren M. (Pennsylvania)

“I suffer from asthma, and for years, I went undiagnosed. While I have been fortunate to have now found the right solution to manage my condition, I know that asthma affects each patient differently. It is imperative that new medications continue to be [developed] because asthma treatment plans can’t take a one-size fits all approach.”

– Petra V. (West Virginia)



Preventing chronic diseases

By making healthy choices, some people may be able to reduce their likelihood of acquiring a chronic disease and improve their quality of life as a result. Unfortunately, social determinants of health—meaning conditions in which we live, learn, work and play—can have a significant impact on the ability to practice healthy behaviors and contribute to disparities in incidence and severity of chronic disease. Healthy behaviors that can reduce the likelihood of chronic diseases include:

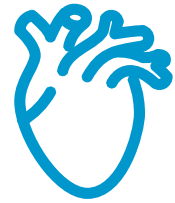
Cessation of tobacco use: Regular tobacco use is known to be associated with several chronic conditions, including type II diabetes, respiratory diseases and coronary heart disease, and can accelerate disease progression, worsen health outcomes and negatively impact treatment adherence.^{xvi, xvii} Stopping smoking, or never starting in the first place, lowers the risk of chronic disease.



Tobacco use causes nearly half a million deaths each year in the United States.^{xviii}

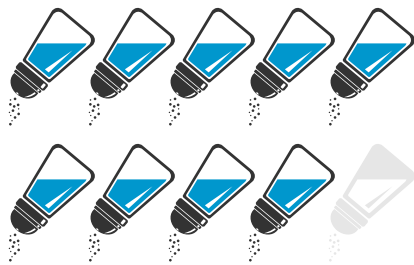


Tobacco use causes about 80% of all deaths from COPD.^{vii}



Tobacco use increases the risk of coronary heart disease by two to four times, stroke by two to four times and lung cancer in men by 25 times.^{viii}

Maintaining a healthy diet: Good nutrition is essential in helping children develop properly and can increase the lifespan of adults. People who maintain healthy eating habits are often at a lower risk of being diagnosed with obesity, which often leads to comorbidities, such as heart disease, type II diabetes and some cancers. However, when healthy options are unavailable, people may have no choice but to settle for foods that have higher calorific levels and lack nutritional value.^{v, xix, xx}



Nine out of 10 adults in the United States consume too much sodium.^{viii}



20% of young people living in the United States aged two to 19 years have obesity.^{viii}

Being physically active: Exercise and staying active helps prevent and manage chronic conditions by promoting heart health, increasing endurance and aiding in weight loss. Aerobic exercises and high-intensity interval training can lower the risk or progression of heart disease in people with high blood pressure and helps insulin more effectively lower blood sugar levels.^{xxi} Additionally, strength training helps improve endurance and provides stability in the joints.



About half of all adults in the United States do not get the appropriate amount of physical activity needed to prevent chronic disease.^{xxii}

\$117B

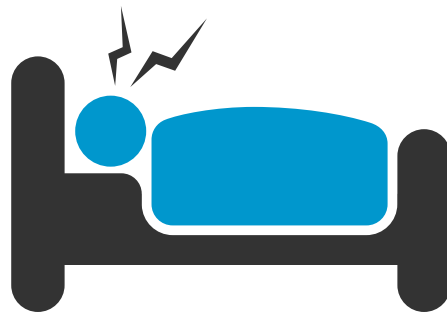
\$117B in annual health care costs can be associated with physical inactivity.^{xix}

Reduce excessive alcohol consumption: Over time, excessive alcohol consumption can increase a person's risk of developing chronic conditions associated with high blood pressure, including heart disease and liver disease.^{xxiii}



Excessive drinking is estimated to cost the U.S. economy nearly \$250B each year in lost work productivity, health care expenditures and criminal justice expenses.^{xxiv}

Healthy sleeping habits: Sleep allows the body to recover and helps the heart rest. Insufficient sleep is associated with the development of multiple chronic conditions, including type II diabetes, cardiovascular disease, obesity and depression.^{xxv}



Adults who habitually sleep less than seven hours during a 24-hour period are more likely to develop a chronic condition later on in life.^{xxvi}

Preventative screenings: Earlier detection and intervention can help identify individuals who are at risk of developing a chronic disease or can help identify those who are in the early stages of a disease and lessen the severity of symptoms. Clinical tests for risk factors, such as high cholesterol and high blood pressure, and for specific conditions, like cancer, have been developed to identify high-risk individuals early on. However, like the availability of healthy food options, certain communities may have disproportionately less access to screening services due to being uninsured, living in rural areas and having low-income levels.^{xxvii}



Effective Disease Management

Effectively managing chronic conditions can help improve the quality of life for patients and bring about a substantial reduction in health care costs by avoiding unnecessary care. Examples of effective chronic disease management include having regular checkups with a provider once a disease has been diagnosed, seeking coordinated care delivery for patients with multiple or complex health conditions, improving patient education, comprehensive medication management and access to approved medicines.

*For patients with **type II diabetes**, effective disease management entails: understanding the condition, taking correct doses of insulin, healthy eating and regularly checking blood sugar levels.^{xxviii}*

*For patients with **COPD**, effective disease management entails: incorporating better breathing and relaxation techniques.^{xxix}*



Health Equity and Chronic Diseases

Health equity can be achieved when no one person is prevented from attaining their health potential because of social position or socially determined circumstances. Social determinants of health include a range of factors from socioeconomic status, education, neighborhood and physical environment, employment, and social support networks, as well as access to health care.

Health disparities are seen in particular among those with chronic conditions—due to varying rates of disease, severity of disease and access to treatment among certain disadvantaged communities. Differences in chronic disease among certain racial, ethnic and socioeconomic groups can be driven by limitations on healthy behaviors that can prevent these diseases and environmental factors that influence development.



Environmental Factors influence Health Disparities

Certain chronic diseases are linked to environmental factors including poor nutrition, air pollution, and exposure to other toxins. Furthermore, the availability of resources in a community, such as grocery stores, public transportation, walkable environments and health clinics, impacts key risk factors related to chronic diseases. In under-resourced communities, such as rural areas and urban regions with high numbers of low-income individuals, environmental factors can be a key driver of health inequities and disparities. Recognizing the link between environmental factors and chronic conditions is key to understanding and addressing health disparities among people of differing races, ethnicities, income levels and geographic locations.^{xxx}

Adopting more sustainable practices can aid in promoting a healthier planet and population, while also advancing health equity initiatives. That's why PhRMA has joined with the National Academy of Medicine (NAM) as a member of the Action Collaborative on Decarbonizing the U.S. Health Sector, a public-private partnership of leaders from across the health care system committed to addressing environmental impacts.

- **Climate change:** It has been well documented that climate change can adversely impact human health. Better understanding of climate change and its impacts on chronic diseases, particularly for those in under-resourced communities, is critical to developing solutions to manage climate change related health risks such as poor air quality, flooding and extreme weather events.^{xxxii}
- **Air quality (indoor and outdoor):** Experiencing unhealthy levels of particle pollution increases a person's risk of developing a chronic condition, particularly those affecting the lungs like asthma. Unfortunately, the burden of poor air quality is not shared, and low-income and minority communities are disproportionately affected. As a result, those living in these communities often experience higher cases of chronic conditions related to air pollution exposure and poorer health outcomes.

People of color are 3.6 times more likely than white people to live in the most polluted counties.^{xxxii}

- **Water quality:** Drinking water with unsafe levels of contaminants can have detrimental health effects and increase one's risk of gastrointestinal illness and other chronic conditions like cancer. While most waterborne diseases that are caused by microbes, such as cholera and typhoid fever, are rare in the United States, diseases caused by exposure to harmful chemicals, such as lead, are still common.^{xxxiii, xxxiv} Areas that face higher exposure to contaminated water tend to be those living in low-income housing communities with outdated water delivery systems.
- **Lead exposure:** Exposure to lead, even in small amounts, can have detrimental impacts on a person's health. In children particularly, exposure to lead has been shown to have a negative impact on a child's mental development and can lead to learning and behavioral problems.^{xxxv} Furthermore, exposure to lead in adults can lead to chronic symptoms like high blood pressure and joint pain. Common sources of lead exposure include paint in older housing units, water pipes and imported canned goods.^{xxxvi}
- **Built environment not conducive to walking or cycling:** The neighborhoods people live in can have a major impact on a person's well-being and health. Creating infrastructure that promotes healthy behaviors, such as sidewalks or bike lanes, provides more opportunities for people to be more active in their everyday commute and increase safety.^{xxxvii}



Clinical Trial Diversity and Health Equity

As companies across the biopharmaceutical ecosystem continue to develop new medicines for the treatment of chronic conditions, it is essential to take meaningful action to help ensure underserved and historically marginalized communities are included in every step of the way. One such effort is to continue to increase diversity in clinical trials in a way that helps underrepresented patient populations become more involved in the research and development of potentially lifesaving treatments. Diverse clinical trials provide researchers with critical information on a patient's experience with a new treatment and potentially identify different responses among individuals. As a result, clinical trial diversity will help better inform the safety and effectiveness profiles of new medicines.^{xxxviii}

In 2021, PhRMA and the Deloitte Center for Health Solutions (CHS) released a report that outlines five critical strategies for enhancing diversity in clinical trials during the research and development of new medicines. The report, titled "Enhancing Clinical Trial Diversity: Stakeholder Perspectives on Advancing Research Through Representative Clinical Trials," is based on a year-long stakeholder engagement effort that included research and feedback from more than 500 stakeholders across 150+ organizations, including community stakeholders, experts in clinical trials and in racial justice, patient advocates, health care practitioners, pharmaceutical companies, academia and more.^{xxxix}

Five key strategies to enhance clinical trial diversity:



i.

Create a network of clinical trial sites in underserved communities. Establishing research sites in locations where potential participants already receive care, including non-traditional locations such as community health centers and pharmacies, can help improve clinical trial diversity.

ii.

Develop a diverse pool of investigators and staff. Racially and ethnically diverse investigators and staff who reflect the communities they serve are key community ambassadors for clinical trials and can help ensure trials are culturally competent and mindful of unconscious/implicit bias.

iii.

Establish long-term relationships and invest in the community. Stakeholders of a community-based clinical-trial infrastructure should prioritize long-term and sustainable community building efforts, like investing in health education or supporting the next generation of diverse health practitioners and investigators.

iv.

Engage the community in conversations. Sponsors should communicate and work toward shared understanding with the community about the importance of volunteer participation in trials. They should also commit to transparent engagement throughout the process, including design of the trial, desired endpoints and the results of the trial. They should also seek input into the elements of design that might impact community members' ability to participate.

v.

Provide sustainable support and standardized platforms. Building a data infrastructure that leverages real world data could facilitate investigators identifying and engaging with patients appropriate for clinical trials and should include baseline measurements to improve data on race and ethnicity.



Better understanding of social determinants of health will be a guiding star as companies and researchers within the industry continue to engage in broader health equity efforts. Consideration of these factors plays a critical role in improving access to care, including medicines and preventative services. There are myriad of intersecting social determinants of health that create disparities in health outcomes related to chronic conditions. This includes health insurance coverage, income, living in a medically underserved area, transportation, accessibility of health care providers and discrimination.



Digital Health

Chronic disease management is a comprehensive process and demands a great level of coordination between providers, communities and patients in order to improve health outcomes. As lifestyle habits play a large factor in preventing and managing chronic conditions, digital health tools, when used appropriately, can be leveraged to improve access to health care services, track disease progression and monitor biomarkers, like high blood pressure and heart rate, associated with chronic conditions.

The types of products and processes that make up digital health vary widely and can include examples of tools that have potential applicability to treating chronic conditions in addition to new medicines.^{xi}

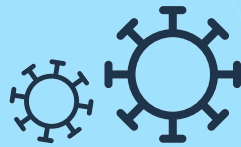
- **Disease management tools:** Tools used to help patients and providers manage their disease, such as platforms that engage individuals with type II diabetes, hypertension, and obesity—and their providers—to improve self-management and outcomes.
- **Electronic clinical outcomes assessments:** Digital measures used to capture how patients feel, function, or survive, such as tools that apply AI algorithms to data captured from sensors to predict disease onset/progression and identify key intervention points.
- **Digital diagnostics:** Software-driven connected technologies that are used to detect or confirm the presence of a disease or condition of interest to identify individuals with a subtype of the disease, such as an ML software system used to diagnose diabetic retinopathy.

Impact of Leading Chronic Diseases



Arthritis

Nearly **60 million adults** are diagnosed with arthritis, 300,000 children have juvenile arthritis.¹



Cancer

1,918,030 estimated new cancer cases in 2022, 609,360 estimated cancer deaths in 2022.²

Cardiovascular Diseases (CVD)

In 2019 in the United States, **coronary heart disease (CHD) was the leading cause (41.3%) of deaths** attributable to CVD in the United States, followed by other CVD (17.3%), stroke (17.2%), high blood pressure (11.7%), heart failure (9.9%), and diseases of the **arteries** (2.8%).³



Diabetes

More than 37 million Americans have type II diabetes. Another 1.9 million Americans have type I diabetes, including about 244,000 children and adolescents. 96 million American adults—more than one in three—have prediabetes.⁴



Gastrointestinal Diseases

An estimated three million Americans have inflammatory bowel disease - Crohn's disease and ulcerative colitis.⁵



Kidney Disease

Chronic kidney disease affects an estimated 37 million people in the U.S. (15% of the adult population; more than 1 in 7 adults).⁶



Lung Diseases

About 25 million people in the U.S. have asthma⁷ and 16.4 million have been diagnosed with COPD.⁸

Obesity

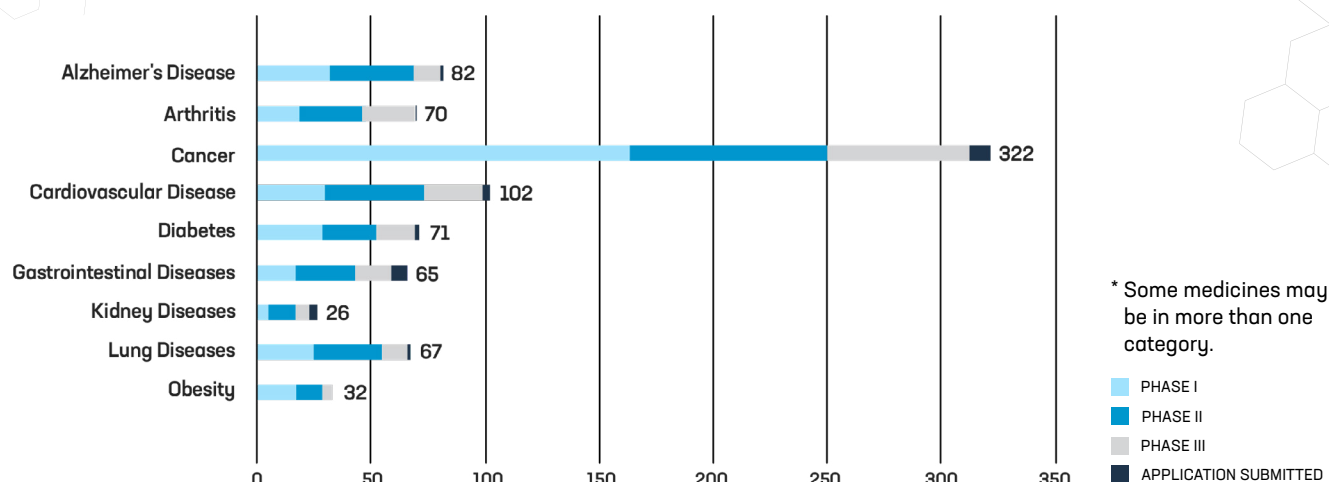
About two in five American adults and one in five American children are considered obese.⁹



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Medicines in Development for Chronic Diseases



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