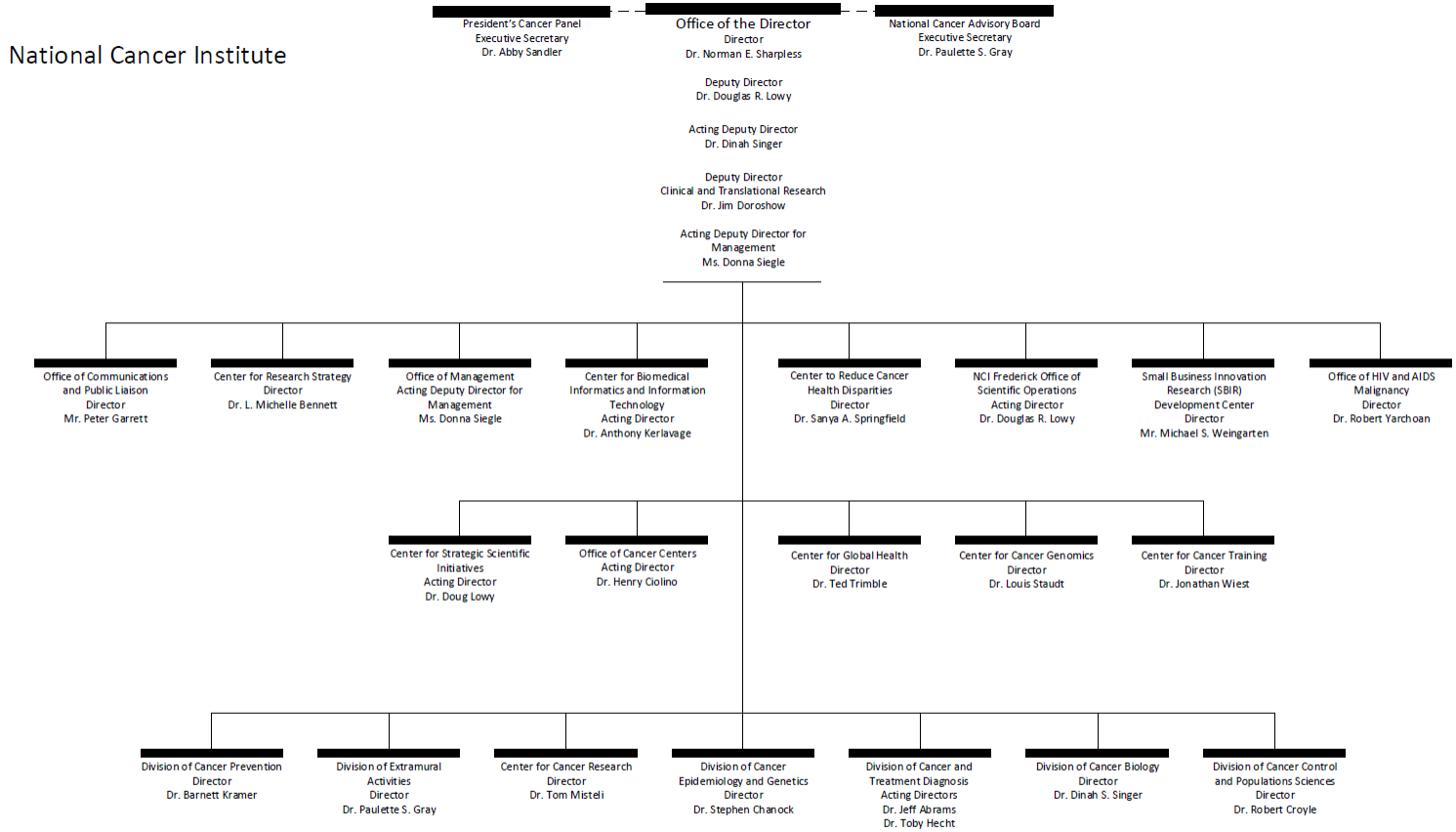
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute (NCI)

FY 2019 Budget — Page No.

National Cancer Institute



NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, $5,226,312,000 of which up to $20,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NIH INNOVATION CURES ACT

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the National Institutes of Health in this Act, $711,000,000, to remain available until expended: Provided, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act and are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act: Provided further, That of the amount appropriated under this heading, $400,000,000 shall be transferred to the "National Cancer Institute" for the purposes described in section 1001(b)(4)(C) of such Act, $57,500,000 shall be transferred to the "National Institute of Neurological Disorders and Stroke" for the purposes described in section 1001(b)(4)(B) of such Act, and $57,500,000 shall be transferred to the "National Institute of Mental Health" for the purposes described in section 1001(b)(4)(B) of such Act: Provided further, That remaining amounts may be transferred by the Director of the National Institutes of Health to any accounts of the National Institutes of Health: Provided further, That upon a determination by the Director that funds transferred pursuant to any of the previous provisos are not necessary for the purposes provided, such amounts may be transferred back to this account: Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Amounts Available for Obligation[1,2]

(Dollars in Thousands)

Source of Funding	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget[3]
Appropriation	$5,689,329	$5,689,329	$5,626,312
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	-38,636	0
Sequestration	0	0	0
Secretary's Transfer	-11,971		
Subtotal, adjusted appropriation	$5,677,358	$5,650,693	$5,626,312
OAR HIV/AIDS Transfers	-17,403	0	0
Subtotal, adjusted budget authority	$5,659,955	$5,650,693	$5,626,312
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year[4]	-23,315	0	0
Subtotal, adjusted budget authority	$5,636,640	$5,650,693	$5,626,312
Unobligated balance lapsing	-247	0	0
Total obligations	$5,636,393	$5,650,693	$5,626,312

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2017 - $20,490 FY 2018 - $20,351 FY 2019 - $18,316

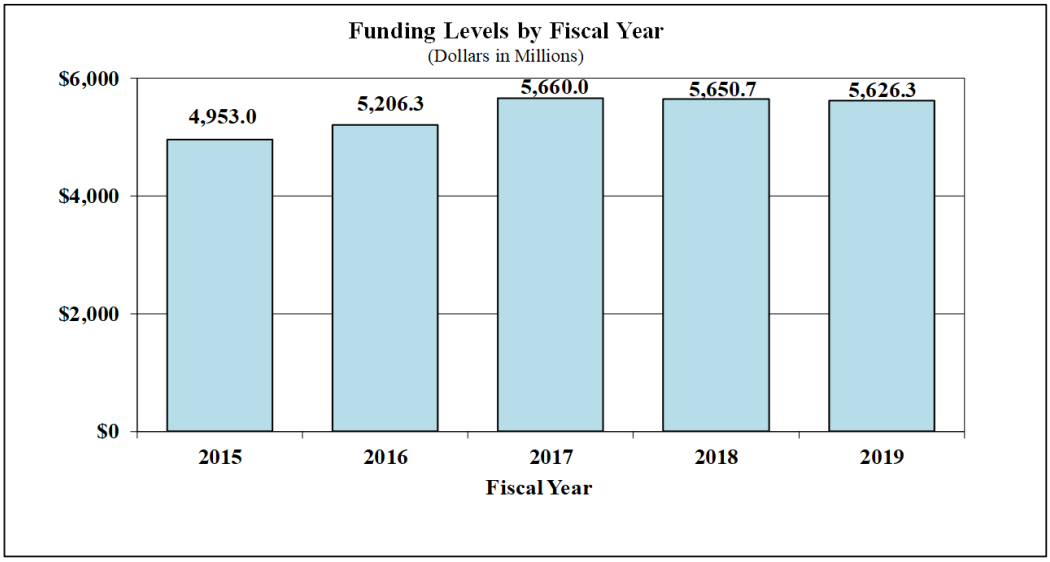
[2] Of which $300,000 in FY 2017, $297,963 in FY 2018, and $400,000 in FY 2019 is derived by transfer from the NIH Innovation Fund, Cures Act Account

[3] Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019

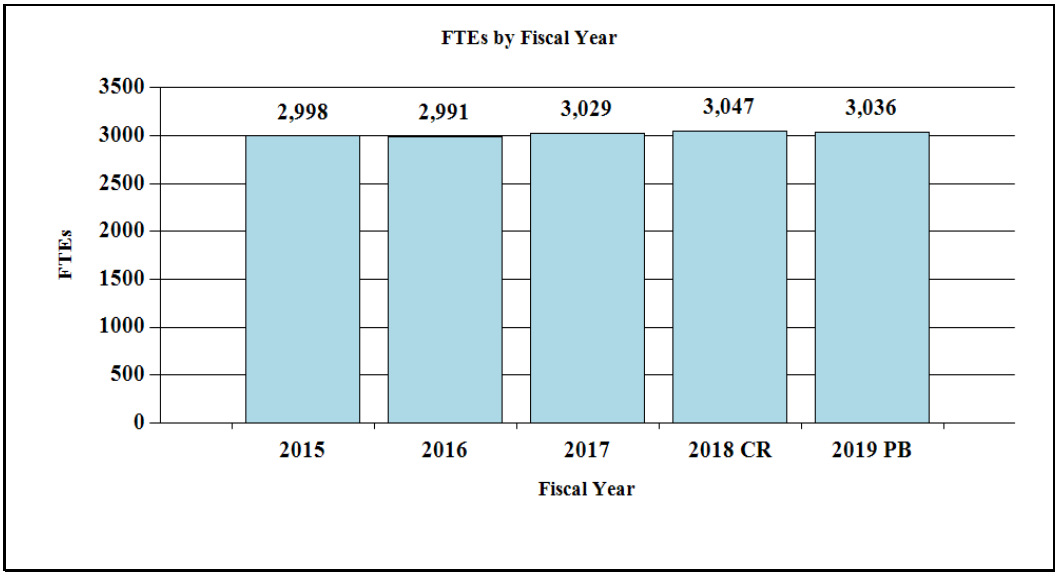
[4] NIH Innovation Fund, Cures Act Account carryover that is available for obligation in FY 2018

Fiscal Year 2019 Budget Graphs

History of Budget Authority and FTEs:



Of which $300.0 in FY 2017, $298.0 in FY 2018, and $400.0 in FY 2019 is derived by transfer from the NIH Innovation Fund, Cures Act Account



Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Authorizing Legislation[1]

	PHS Act/ Other Citation	U.S. Code Citation	2018 Amount Authorized	FY 2018 Annualized CR	2019 Amount Authorized	FY 2019 President's Budget[2]
Research and Investigation	Section 301	42§241	Indefinite	$5,650,692,767	Indefinite	$5,626,312,000
National Cancer Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$5,650,692,767		$5,626,312,000

[1] Of which $298 million in FY 2018 and $400 million in FY 2019 is derived by transfer from the NIH Innovation Fund, Cures Act Account

[2] Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Appropriations History

Fiscal Year	Budget Estimate to Congress[1]	House Allowance	Senate Allowance	Appropriation
2009	$4,809,819,000	$4,975,039,000	$4,958,594,000	$4,968,973,000
Rescission				$0
2010	$5,150,170,000	$5,150,170,000	$5,054,099,000	$5,103,388,000
Rescission				$0
2011	$5,264,643,000		$5,256,409,000	$5,103,388,000
Rescission				$44,810,787
2012	$5,196,136,000	$5,196,136,000	$5,001,623,000	$5,081,788,000
Rescission				$9,604,579
2013	$5,068,864,000		$5,084,227,000	$5,072,183,421
Rescission				$10,144,367
Sequestration				($254,588,730)
2014	$5,125,951,000		$5,091,885,000	$4,923,238,000
Rescission				$0
2015	$4,930,715,000			$4,950,396,000
Rescission				$0
2016	$5,098,479,000	$5,081,812,000	$5,204,058,000	$5,214,701,000
Rescission				$0
2017[2]	$5,893,509,000	$5,388,444,000	$5,429,769,000	$5,689,329,000
Rescission				$0
2018[3]	$4,474,222,000	$5,771,181,000	$5,858,270,000	$5,689,329,000
Rescission				$38,636,233
2019[4, 5]	$5,626,312,000			

[1] Budget Estimate to Congress includes mandatory financing in FY 2017

[2] Of which $300 million in the FY 2017 Appropriation is derived by transfer from the NIH Innovation Fund, Cures Act Account

[3] Of which $300 million in FY 2018 is derived by transfer from the NIH Innovation Fund, Cures Act Account

[4] Of which $400 million in the FY 2019 Budget Estimate to Congress is derived by transfer from the NIH Innovation Fund, Cures Act Account

[5] Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019

FY 2019 Justification of Budget Request

National Cancer Institute

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.
Budget Authority (BA):

	FY 2017 Actual	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
BA	$5,659,955,000	$5,650,692,767	$5,626,312,000	-$24,380,767
FTE	3,029	3,047	3,036	-11

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The budget of the National Cancer Institute (NCI) supports a broad array of biomedical research to advance scientific discovery, reduce the burden of cancer, and help all people live longer, healthier lives. This overview and the pages that follow offer highlights of NCI research and strategies to achieve these goals.

NCI Progress under the 21st Century Cures Act

FY 2017 was the first year of NCI funding under the 21st Century Cures Act. In the Cures Act, Congress authorized $1.8 billion across seven fiscal years for the Cancer Moonshot. NCI received the first installment of $300 million during FY 2017 to supplement the larger annual appropriation NCI receives for cancer research. Guided by the recommendations of a Blue Ribbon Panel convened to identify research priorities, NCI awarded funds to a wide range of promising cancer research.

During FY 2017, NCI allocated Cures Act funding to nearly all the priority areas identified by the Blue Ribbon Panel, and NCI will fund additional priorities in FY 2018. However, one example of NCI's commitment to the progress envisioned in the Cures Act is the promising area of immunotherapy – activating a patient's immune system to attack cancer cells.

To accelerate the development of immunotherapy strategies for cancer patients, in the fall of 2017, NCI launched a public-private partnership with NIH and 11 pharmaceutical companies, known as the Partnership for Accelerating Cancer Therapies, or PACT. The Foundation for the National Institutes of Health will manage and coordinate PACT, and the Food and Drug Administration will play an essential advisory role.

A centerpiece of PACT is NCI's $54 million investment across five fiscal years of Cures Act funds to establish four Cancer Immune Monitoring and Analysis Centers and a Cancer Immunologic Data Commons. Together, the centers and data commons will operate as a network to identify

mechanisms of response and resistance to cancer therapy and to support adult and pediatric immunotherapy trials.

NCI created the immunotherapy network to speed discovery of molecular signatures associated with immune response and to predict whether immunotherapy will benefit individual patients. The network will identify biological markers of disease and response to treatment that researchers and clinicians can use to design optimum treatment strategies for cancer patients. The entire cancer research community can access data from analysis conducted by the four centers and use this resource to further their own research on cancer cures. Other priorities of the NCI immunotherapy network and the 11 PACT partners include establishing a set of standardized biomarkers for testing in research studies, harmonizing assays to strengthen data reproducibility, fostering the comparability of data across clinical trials, and reducing duplication of effort, thereby allowing the research community to conduct more high-quality clinical trials.

In addition to support for PACT, NCI also awarded Cures Act funding to other promising research to harness the immune system to attack cancer. The goal of this research is to expand the initial successes in immunotherapy to a much wider range of cancers, to a broader range of patients experiencing the same form of cancer, and to cancers that have been most resistant to cure.

Appropriations for Other Cancer Research Priorities

The 21st Century Cures Act deserves prominence in any discussion of NCI's current cancer research priorities. However, as a component of our total budget, FY 2017 Cures Act funding represented about five percent of NCI's cancer research portfolio. It is therefore important to emphasize the breadth of other research that NCI conducts.

As the detailed narrative for this budget request demonstrates, sustained progress that will benefit cancer patients relies on many forms of research, including:

- basic research, such as genetics, cell biology, immunology, and cancer pathogenesis
- translational and clinical sciences to prevent, screen, and diagnose cancer, and to develop and test drugs, biomarkers, imaging technologies, diagnostics, and radiotherapies
- population sciences, including epidemiological, environmental, and behavioral studies.

These areas constitute the bedrock of NCI cancer research. Continued funding across all these disciplines is essential to understanding the causes and mechanisms of cancer, preventing cancer, strengthening cancer screening, developing, and refining cancer therapies, and improving cancer survivorship. Many of these disciplines will experience profound changes based on the new understanding of cancer that is driving precision oncology. Others will continue to depend on more traditional approaches to research.

Just as NCI's portfolio reflects many forms of research, we rely on many mechanisms to conduct cancer research and advance scientific priorities. The most prominent of these include NCI funding for research project grants, research centers, NCI intramural research, cooperative clinical research, Small Business Innovation Research, research contracts, and research training. The research resources that NCI makes available to the cancer research community is another mechanism of growing importance to cancer science. Examples of NCI research resources include:

- The Biopharmaceutical Development Program (BDP), which produces novel antibodies and proteins when industry is not prepared to do so. For example, researchers turned to the BDP to manufacture a monoclonal antibody (ch14.18) necessary for a clinical trial to proceed. The antibody is now the standard of care for children with certain types of neuroblastoma.

- NCI's Experimental Therapeutics (NExT) program advances breakthroughs in new cancer therapies by shortening the timeline for drug discovery, development, and approval. Researchers with promising cancer drug development projects can apply to NExT for assistance to overcome the challenges they face along the path to drug approval.

- NCI's RAS Initiative supports the development of therapies for tumors that contain mutations in the RAS family of oncogenes. One-third of all cancers involve RAS gene mutations. Through the RAS Initiative, NCI generates standardized reagents, assays, and datasets and provides them to scientists worldwide to support research on RAS oncogenes.

- NCI's cryo-electron microscopy program, or Cryo-EM, provides researchers access to a breakthrough technology to advance their research. Cryo-EM has the potential to revolutionize the field of structural biology, and has many applications for cancer research and drug discovery.

- The Cancer Genome Atlas (TCGA) – a collaboration between NCI and the National Human Genome Research Institute – is a resource of comprehensive, multi-dimensional maps of key genomic changes in 33 types of cancer. The publicly-available TCGA dataset – containing 2.5 petabytes of data – has contributed to more than a thousand cancer studies.

- Launched in June of 2016, NCI's Genomic Data Commons (GDC) is a unified data system for sharing genomic and clinical data. The GDC centralizes, standardizes, and makes data from large-scale NCI programs more accessible and useful to scientists and clinicians. One measure of the importance of this resource is that non-profit and for-profit organizations are now offering their data sets for sharing through the GDC.

Thanks to support from Congress over many years, NCI research in these and other areas has yielded important results that have contributed to steady decreases in cancer mortality. Sustained Congressional support for NCI and the national cancer program has led to new diagnostics, treatments, and prevention strategies, improved our ability to manage the symptoms of cancer and the side effects of cancer treatments, and allowed us to more effectively monitor the prevalence of cancers and the factors associated with cancer risk.

NCI-led cancer research on prevention and treatment is paying off: translating into a more than 25 percent reduction in cancer death rates since 1991. Yet despite steady progress, too many Americans face a cancer diagnosis, and far too many still die from the disease. There will be more than 1.6 million new cases of cancer in the United States in the coming year and more than 600,000 will die from cancer. Thus, much work remains to meet the needs of those suffering from cancer, those at risk of cancer, and the growing population of cancer survivors. The resources in this budget will allow NCI to continue to conduct our cancer research mission in ways that deliver important results for the patients we serve.

Overall Budget Policy

The FY 2019 President's Budget request is $5,626.312 million, a decrease of $24.381 million compared to the FY 2018 Annualized CR level. For FY 2019, NCI made strategic choices that prioritize how it allocates funding to NCI research programs. For example, NCI will prioritize research project grants and research training programs during FY 2019.

Included in the FY 2019 budget request is the transfer of the Dermatology Branch within NCI's Center for Cancer Research to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This transfer will decrease NCI's appropriation by $4.093 million and decrease NCI's Full-Time Equivalent count by 11.

FY 2019 Program Descriptions and Accomplishments

NCI conducts basic and applied research that advances five broad scientific goals:

- Understanding How Cancer Develops
- Understanding the Causes of Cancer
- Advancing Early Detection and Diagnosis
- Developing and Improving Treatments and Improving Cancer Survivorship
- Improving Cancer Prevention and Control

To pursue these goals, NCI issues grants to support investigator-initiated research, conducts clinical trials, and finances a range of other cancer research programs. NCI selects and provides support to NCI-designated Cancer Centers; conducts basic, clinical, and population research through its intramural programs; issues and manages research contracts, including a Federally Funded Research and Development Center (FFRDC) supporting the operations of the Frederick National Laboratory for Cancer Research; and operates research facilities to support NCI intramural and FFRDC activities.

NCI uses these and other mechanisms to support cancer research and advance NCI's scientific goals. Investigator-initiated research project grants constitute a large portion of the research investment for all five goals. During FY 2017, NCI issued 5,622 new and non-competing grant awards across all grant mechanisms, including 2,927 traditional research project grant (R01) and 369 exploratory (R21) grants. These grant awards include 65 grants funded with appropriations that NCI received following the enactment of the 21st Century Cures Act.

The FY 2017 total for new grants also includes 29 Outstanding Investigator (R35) Awards (OIA), which provide seven years of funding to investigators with outstanding records of productivity in cancer research. OIA grants are an opportunity for researchers to test high-risk hypotheses supported by a higher award level and for more years than is possible under a traditional research project grant (R01). In the three years since NCI began the OIA program, NCI has issued 107 competing OIAs.

In addition to its five scientific goals, NCI supports more than 100 specialized centers for cancer research, including 69 NCI-designated Cancer Centers and NCI community research partners. NCI designated Cancer Centers provide training and career development to maintain a strong workforce of cancer researchers, and to support essential management, administration, infrastructure, and facilities that advance the NCI cancer research mission.

During FY 2017, nearly 30,000 new patients enrolled in clinical trials that NCI sponsored or supported. Two-thirds of these patients enrolled in trials supported by NCI through the National Clinical Trials Network.

The narratives that follow highlight some of NCI's programs and identify recent progress as well as ongoing and future activities in each scientific area. However, it is important to appreciate that virtually all NCI research under one scientific goal influences the approaches used to advance goals in the other scientific areas.

The breadth and complexity of NCI research precludes a complete review of all NCI programs in this budget document. The examples that follow offer a meaningful overview of NCI operations, but understate the vast amount of valuable NCI work to advance the national cancer program.

I. Understanding How Cancer Develops

Cancer is driven by alterations of a cell's genome (DNA) and the proteins that its DNA encodes. During this process, abnormal types and amounts of proteins emerge that lead to a variety of molecular abnormalities. These abnormalities cause a normal cell to transform into a tumor cell and lead to a diminished ability to control growth and other hallmarks of cancer. Precision medicine, in all its forms, depends on a deeper understanding of the genetic and functional changes that occur in cancer cells and the tumor microenvironment.

To better understand how cancer develops, NCI supports large-scale, high-throughput studies of the genes, proteins, and pathways altered in cancer. In addition, NCI funds studies of basic cell biology, cell interactions, angiogenesis (the formation of blood vessels supporting a tumor), immune responses, and other essential research to understand the mechanisms of cancer development. NCI also supports laboratory studies in a variety of model systems, including animal and computational models, to investigate the functions of these systems and their relationship to cancer. Examples of initiatives under this NCI research goal include:

Identifying Molecular Changes That Drive Cancer: NCI is committed to increasing fundamental knowledge of the inner workings of cancer cells. Such research supports discoveries that identify molecular targets and the ability to translate discoveries into therapies that benefit cancer patients. This commitment includes research on understanding mechanisms that cause cancer cells to develop resistance to therapies and finding ways to overcome resistance. In addition to supporting investigator-initiated grants and other extramural research in this area, NCI provides resources to the extramural community to support their research on the molecular changes that drive cancer. One example is NCI's The Cancer Genome Atlas (TCGA), which contains the genomes of more than 30 types of cancer and thousands of genetic alterations in cancer cells that could be targets for existing or new therapies. NCI plans to use FY 2018 funding from the Cures Act to launch the Human Tumor Atlas Network (HTAN), a resource for cellular, morphological, and molecular mapping of human cancers that will include longitudinal studies of pre-cancers, metastasis, and drug resistance.

Understanding Tumor Heterogeneity: As our ability to detect heterogeneity within a tumor improves, this knowledge presents new challenges for accurately diagnosing and treating tumors. Cell diversity within tumors may occur due to genetic alterations, epigenetic and phenotypic switching (biological or environmental influences that switch a gene on or off), changes in the

microenvironment surrounding the tumor, and differentiation among cancer stem cells. To better understand the processes that lead to heterogeneity, NCI is supporting research to gain a more comprehensive understanding of cellular plasticity and how tumors evolve. Such knowledge is essential for developing new and more targeted cancer therapies.

The Tumor Microenvironment: The tumor microenvironment includes cancer cells, normal connective tissue (stroma), blood, immune, nerve, and in some cases, bacterial cells. These components interact and influence tumor development, tumor progression, and resistance to therapy. Research supported by NCI through investigator-initiated projects and collaborative networks, such as the Tumor Microenvironment Network and the Molecular and Cellular Characterization of Screen Detected Lesions Consortium, are identifying key features of the tumor microenvironment.

Recent success with immunotherapies has focused attention on the role of immune cell interactions with cancer cells in the microenvironment. Another priority is better understanding how tumor cell and host metabolism can modulate the immune system's response to tumor development and immunotherapy. Pediatric immunotherapy, in particular, will benefit from a greater understanding of the tumor microenvironment in children and adolescents.

Sequencing HPV 16 Reveals New Criterion for Carcinogenicity: Human papilloma virus (HPV) type 16 causes about half of all cervical cancers worldwide. A large genomic analysis of HPV revealed that whether HPV16 leads to cancer hinges on whether a protein – known as E7 – remains intact. Although most HPV 16 infections resolve on their own, some that persist can eventually lead to cancer. The puzzling question was why these common and typically benign HPV 16 infections only sometimes cause cancer. NCI researchers compared the genome sequences of HPV16 in cancer patients and healthy subjects. The researchers discovered that the HPV 16 sequences in individuals who experienced benign infections had significantly more changes in the HPV protein. In contrast, samples taken from cervical cancer cases did not have changes in the E7 gene. This insight may lead to refinements in HPV-DNA screening to identify women more effectively who would benefit from prevention and early intervention strategies.

II. Understanding the Causes of Cancer

Cancer develops through a complex interplay of genetics, lifestyle decisions, environmental factors, and the normal changes that occur through aging. These factors probably influence the likelihood of developing almost all cancers. In some cases, however, cancer risk is more strongly influenced by inheriting a mutation (or a variant) of a single gene or a combination of genes. In other cases, cancer risk is determined principally by external factors, such as exposure to tobacco or infectious agents.

Understanding the interactions among genetic background, environmental, and lifestyle factors will improve the ability of scientists to prevent as well as detect, diagnose, and treat cancers at the earliest possible time. NCI-funded studies on the causes of cancer range from small-scale laboratory-based research to large-scale studies that use population cohorts or case-controlled comparisons of subpopulations. The studies may also involve modeling to determine cancer risk within an individual or population. Through these types of studies, NCI research strives to identify the causes of cancer. Examples of initiatives under this NCI research goal include:

Reducing Cancer Disparities: The disproportionate burden of cancer among some population

groups is an NCI priority. NCI programs to address this concern include the Early Onset Malignancies Initiative (EOMI), a study to understand factors that contribute to the early onset of cancer among four demographic groups. Through EOMI, NCI is studying breast, colorectal, liver, renal, and prostate cancers, as well as multiple myeloma. There are significant disparities associated with these cancers for some groups, such as an earlier age of onset, a higher incidence rate, and a more aggressive course of disease. Through another NCI program, the African-American Breast Cancer Consortium, NCI is supporting a study of 40,000 African American women – 20,000 who have breast cancer and 20,000 who do not – to understand the genetic and biological factors that contribute to breast cancer risk. African American women are almost 40 percent more likely to die from breast cancer compared to non-Hispanic white women.

Cancer Risk from Medical Radiation: Radiation exposure from medical sources in the United States has increased six-fold since 1980. Research on cancer risks from historical, contemporary, and emerging sources of radiation used in diagnosis, screening, and treatment can improve our understanding of radiation-induced carcinogenesis, reduce cancer risks, and address public health and clinical concerns. NCI researchers are currently assessing cancer risks associated with newer diagnostic technologies, the risk of childhood cancer associated with CT scans, and the incidence of second cancers occurring in cancer survivors treated with radiation. As an example of progress in this area, a recent genome-wide association study of female childhood cancer survivors identified a common genetic variant linked to a higher risk of developing breast cancer for those who received radiotherapy to their chest as children.

Establishing a Gynecologic Cancers Tissue Bank: Developing a gynecologic tissue specimen bank will support research to improve our understanding of the causes of high-grade ovarian cancer, how ovarian cancer develops, and strategies to prevent high-grade ovarian cancer. To advance this proposal, NCI is leading studies to survey the pathologic methods used to characterize gynecologic tissues and to determine the proportion of pre-cancerous lesions in gynecologic tissues. Completing these studies will allow researchers to determine the feasibility and optimum approach for establishing a specimen bank.

Dietary Intake and Cancer: Diet is one of the most fundamental and complex exposures relevant to human health. However, diet is often inadequately measured using current dietary assessment tools that rely primarily on self-reporting, such as questionnaires or 24-hour dietary recalls – approaches known to contain bias and measurement error. Evaluating and overcoming these challenges will strengthen the rigor and reproducibility of nutrition science. To address this need, NCI is developing a funding opportunity announcement for further research that will improve our ability to identify relationships between diet and cancer.

III. Advancing Early Detection and Diagnosis

Many deaths occur because cancers are diagnosed at late stages when treatment is often less effective. NCI-supported researchers are working on techniques to image tumors earlier and to identify molecules – nucleic acids, proteins, metabolites, and other substances – that may improve early detection and diagnosis. This often involves uncovering the distinct molecular signatures of cancers and developing and refining molecular tests to detect cancer.

NCI has an array of programs to advance all aspects of early cancer detection and diagnosis. Examples include –

- developing new technologies and improving existing methods of noninvasive imaging to support cancer diagnosis, to identify disease subsets in patients, to determine the stage of disease, and to monitor the progress of cancer treatment
- coordinating efforts to obtain high-quality tissue specimens and associated data for the research community, and developing databases of molecularly characterized specimens
- maintaining infrastructure and programs such as the Genomic Data Commons, the Cancer Genome Characterization Initiative, and The Cancer Genome Atlas (a collaboration with the National Human Genome Research Institute) to improve cancer detection and diagnosis.

Investigator-initiated research project grants are one mechanism that NCI relies on to support and improve early detection and diagnosis of cancer. However, other larger research programs also play important roles, as the examples listed above illustrate. Other initiatives under this NCI research goal include:

Cancer Biomarker Data Commons: To accelerate the pace of cancer biomarker discovery, data from NCI initiatives must be integrated with data from private collections and information in public literature and databases. With this need in mind, NCI is launching a Cancer Biomarker Data Commons (CBDC) to serve as a cornerstone of a national cancer data ecosystem. The CBDC will be a resource to accelerate the pace of cancer biomarker discovery and development. The CBDC will also improve research reproducibility and deepen our understanding of the genetic causes of cancer health disparities in ways that offer unique opportunities to advance discovery and research collaboration.

PET Imaging Agents: The NCI Small Business Innovation Research (SBIR) program is funding the development of new diagnostic probes used in positron emission tomography (PET). PET is a nuclear medicine imaging technology commonly used in cancer research and clinical practice. Clinicians use PET agents to diagnose and stage cancers and to identify cancer metastasis – cancer that has spread from the site where it first occurred. PET technology is also used to guide cancer therapies and monitor response in cancers such as lung, breast, head and neck, and lymphoma. With support from the NCI SBIR program, CellSight Technologies is developing novel PET agents that can predict response to new treatment strategies such as immunotherapy and reduce the time required to produce PET reagents. Another SBIR-funded company, Sofie Biosciences, is also advancing technology used to synthesize PET agents and thereby allow more researchers to develop new diagnostic agents for a broader range of cancers.

Tomosynthesis Mammographic Imaging Screening Trial: NCI is supporting a large nationwide clinical trial to determine whether tomosynthesis technology should routinely be added to digital mammography (DM) for breast cancer screening. DM is 2-D mammography, while tomosynthesis (TM) is an FDA-approved technology that is often referred to as 3-D mammography. The clinical trial – known as TMIST – began recruiting participants in September 2017 and plans to enroll 165,000 women between the ages of 45 and 74. TMIST will provide evidence on the ability of these technologies to detect breast cancer and reduce the incidence of advanced cancers.

Detecting Breast Cancer Earlier: Beginning in 2004, the NCI SBIR program funded the development of LumaGEM, a dedicated molecular breast imaging (MBI) system that, when compared to mammography, has been shown in clinical studies to improve cancer detection in women with dense breasts. In a recent breast screening study of 1,696 women, 13 cancers were

detected that were not identified using mammography. LumaGEM is intended to complement mammography, and more than 20 instruments have been installed across the country. Based in part on these results, in 2017 the American College of Radiology Practice Parameters identified MBI as a potential option for additional screening for women with dense breasts.

New Onset Diabetes and Pancreatic Cancer Risk: Individuals with new-onset diabetes at age 50 or greater face an elevated risk of developing pancreatic ductal adenocarcinoma (PDAC). To better understand why, NCI is supporting a prospective cohort study involving 10,000 individuals over age 50 with newly diagnosed diabetes. The New Onset Diabetes Cohort is a joint project of NCI and the National Institute of Diabetes and Digestive and Kidney Diseases. The objectives of the study are to estimate the probability of PDAC, establish a biobank of clinically annotated biospecimens for research, and support validation of diagnostic tests to identify individuals at high risk for PDAC.

Precancer Atlas (PCA): The PCA program will be a resource for the research community to systematically collect, catalogue, and analyze large numbers of precancerous growths and early cancers to understand how cancers arise and progress. In October 2017, NCI requested applications to establish PCA Research Centers. The PCA will serve as a comprehensive source of high-resolution, multidimensional, and multi-parametric atlases of pre-cancerous lesions and their surrounding microenvironment. PCA data will allow the research community to better understand what drives the transition from a pre-malignant to a malignant state over time. The atlas will also be a resource to identify molecular markers of cancer risk and early detection, to identify targets for intercepting and preventing cancer, and to model and predict the trajectory of tumor development and progression. The research community will have access to the PCA to support precision medicine for cancer patients and to identify molecular targets for prevention strategies.

Traceback Testing to Identify BRCA1/2 Mutation Carriers: Some ovarian cancers are associated with mutations in the BRCA1/2 gene. BRCA1/2 germline mutations are present in 15 percent of women with high-grade serous ovarian cancer. Current guidelines recommend that women diagnosed with high-grade serous ovarian cancer be referred for genetic testing, yet only about 10 percent of these women are tested. To address this concern, NCI is examining the feasibility of identifying previously diagnosed but un-referred ovarian cancer patients, performing gene testing of their surgical samples, and communicating results to relevant family members. This could serve as a framework to better identify BRCA1/2 mutation carriers and to disseminate risk information to family members. Traceback also will provide an opportunity to gain much-needed information related to genetic risk in under-studied populations.

IV. Developing and Improving Treatments and Improving Cancer Survivorship

Research on cancer therapy has many facets that go beyond developing and testing drugs, radiotherapy, immunotherapy, and surgery. These include controlling symptoms, improving palliative care, and enhancing long-term survivorship and quality of life. Still, developing new therapies and the means to monitor cancers before and during treatment are central to successfully treating cancer. Increasingly, progress is linked to new knowledge about the molecular fingerprints of tumors, the structure of cancer-associated molecules and how to target them with new drugs, how cancer cells interact with the host environment and the immune system, and the altered behaviors of cancer cells.

To develop and improve cancer treatments, NCI invests in basic, translational, and clinical research.

These investments identify therapeutic targets and strategies, and commercial interests frequently validate many of these targets and develop interventions against them. NCI supports clinical research to develop and test interventions at many sites across the country and at the NIH Clinical Center, often through clinical research networks. Examples of initiatives under this NCI research goal include:

Precision Medicine in Oncology Trials: The NCI Molecular Analysis for Therapy Choice (NCI-MATCH) Trial and the Pediatric MATCH Trial are cornerstones of NCI's Precision Medicine Initiative[SM]. Rather than selecting therapies based on where a tumor originated in the body, these trials focus on evaluating the effectiveness of treating cancer based on specific genetic changes. In 2017, the adult NCI-MATCH Trial achieved its enrollment goal, nearly two years ahead of schedule. The trial involves more than 6,000 patients from all 50 states. NCI also successfully opened enrollment for the Pediatric MATCH Trial. Other NCI precision medicine trials include the Lung Cancer Master Protocol (Lung-MAP) Trial, the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials (ALCHEMIST), and Molecular Profiling-Based Assignment of Cancer Therapy (NCI-MPACT) Trial.

NCI Drug Formulary: In January 2017, NCI launched an initiative to speed access to approved drugs and investigational agents for research conducted at NCI-designated Cancer Centers. Based on a public-private partnership with pharmaceutical and biotechnology companies, the NCI Formulary will streamline access to pharmaceutical agents and help researchers avoid lengthy, separate agreement negotiations often required to obtain cancer compounds for research. To speed access, NCI negotiated blanket Cooperative Research and Development Agreements – known as CRADAs – with pharmaceutical collaborators to make approved drugs and research agents available. With the CRADAs in place, cancer center researchers can more promptly obtain agents for their research from the NCI Formulary and test them in new preclinical or clinical cancer studies. The NCI Formulary launched with 15 research agents from 6 pharmaceutical companies. During its first year, the formulary expanded to 27 research agents from 9 companies.

Precision Immunotherapy for Adults and Children: Immunotherapy is rapidly becoming a standard therapeutic option for some cancers. However, more research is needed to identify biomarkers of response and resistance so we can better understand why some patients benefit while others do not. NCI supports a range of immunotherapy research, including investigator-initiated research as well as immunotherapy research networks. In 2017, NCI announced the formation of a new network of laboratories, known as Cancer Immune Monitoring Analysis Centers, to analyze tumors from patients participating in immunotherapy clinical trials. Through the network, NCI expects to identify biomarkers and targets for patient selection and treatment. In addition, with FY 2017 appropriations that NCI received following the enactment of the 21st Century Cures Act, NCI established two networks to accelerate the translation of immunotherapy research discoveries to clinical applications for adult and pediatric cancers.

Integrated Proteogenomics for Precision Oncology: NCI is advancing precision oncology by comprehensively characterizing and analyzing the proteomic (protein) and genomic profiles of tumors across an array of cancers. The goal is to identify signatures that will improve our ability to determine the grade and stage of cancers, predict patient prognosis, understand therapeutic resistance, and predict treatment response. Through the Clinical Proteomic Tumor Analysis Consortium (CPTAC), NCI is integrating proteogenomic data with medical and pathological imaging and clinical information. NCI will initially focus on five cancer types, selected based on

their clinical importance and the need to close significant gaps in knowledge about these cancers. The first tranche of data from this initiative will be available in FY 2019. CPTAC has also begun pre-clinical studies on three additional types of cancer (breast cancer, epithelial ovarian cancer, and acute myeloid leukemia). Data and analysis from this effort, available through NCI's Cancer Research Data Commons, are critical to precision oncology and to discovering how to treat each patient for their specific disease.

Cancer-Related Cardiovascular Symptoms and Toxicities: Cancer and its treatments significantly increase the risk of cardiovascular symptoms and toxicities. These adverse effects can confound the choice and duration of cancer treatments, decrease quality of life, and reduce overall survival. To address these concerns, NCI and the National Heart, Lung, and Blood Institute (NHLBI) support research to understand, prevent, and treat adverse cardiovascular effects. Investigators are pursuing these goals by identifying at-risk patients to better mitigate cardiotoxicities and by studying cancer interventions to identify strategies to address toxicities. Through the Consortium Linking Oncology with Thrombosis (CLOT), NHLBI and NCI are translating research on harmful, cancer-associated blood clots into therapeutic approaches and risk assessment models. This research collaboration is addressing a major source of cancer-related morbidity.

NCI Patient-Derived Models Repository: In May of 2017, NCI launched a national repository of Patient-Derived Models (PDMs) to advance precision oncology. PDMs may be more predictive research models compared to traditional cancer cell lines because they closely reflect human tissue biology. More than 100 PDMs are currently available, and NCI anticipates that cancer researchers will have access to 300 models by the end of FY 2018. NCI plans to expand the repository to more than 1,000 patient-derived models produced from tissues and blood obtained from NCI programs. The PDM repository will support important new cancer research opportunities, especially for investigators that do not currently have access to patient tumor material because they perform research at universities not affiliated with a medical school. Researchers will also have access to data files containing complete PDM molecular characterization information, regardless of whether they obtain PDM biological material from NCI. In addition, through a new collaboration with the Department of Energy (DOE) and five national laboratories on high-performance computing, NCI and DOE are analyzing the vast data generated from the PDM repository and from other NCI programs to build sophisticated predictive models to better understand the biological processes in cancer and to predict which drugs will be most effective against specific cancers.

New Treatments for Children with Cancer: NCI conducts and supports research that is essential to progress against childhood cancers. Because childhood cancers are rare, they are difficult to study and difficult to attract pharmaceutical investment. With support from NCI, the Children's Oncology Group (COG) tests new therapies for children with cancer. In one recent accomplishment, COG successfully tested a technique known as tandem autologous transplant treatment in children with neuroblastoma, a cancer of the adrenal glands. Autologous transplant involves collecting a patient's bone marrow stem cells before starting high-dose chemotherapy. After chemotherapy, the healthy stem cells that were not damaged by chemotherapy are restored to the patient, allowing them to more quickly rebuild blood and cells of the immune system. COG studies showed that two autologous transplants improved response and survival compared to a single transplant. Children who receive tandem transplants generally live longer with better quality of life. Based on this research, the tandem transplant protocol is now standard of care.

Another important new treatment is FDA's August 2017 approval of the first cell-based immunotherapy (Kymriah™) for pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL) who no longer respond to traditional treatments. ALL progresses quickly and is the most common childhood cancer in the United States. The FDA approval follows decades of investment in immunology research by NCI and other research organizations.

Survivorship: Today, there are an estimated 15.5 million cancer survivors in the United States, a population that is expected to grow to more than 20 million during the coming decade. These numbers demonstrate the need to understand the physical, psychological, social, and financial challenges that cancer survivors and their loved ones' face. The challenges can be multi-faceted, and often include late-emerging effects of cancer treatment and the need for interventions to prevent or mitigate them. NCI-supported research has demonstrated that evidence-based post-treatment care can improve health outcomes and quality of life for cancer survivors and their caregivers.

NCI's portfolio of survivorship research includes the Detroit Research on Cancer Survivors (ROCS) study, the largest study to date of African American cancer survivors in the United States. ROCS is examining factors affecting cancer progression, recurrence, mortality, and quality of life among African American cancer survivors, a population that continues to experience disproportionately higher cancer incidence and mortality for most cancer types. The ROCS study also includes family members, which will allow researchers to understand how a cancer diagnosis affects those who care for a family member with cancer. An estimated 2.8 million adults in the United States currently provide care for someone with cancer. Given the importance of caregivers to the well-being of cancer patients, cancer caregiving is an important focus of survivorship research.

NCI also focuses on pediatric cancer survivors. Thanks to treatment advances, more than 80 percent of children with cancer are alive five years after diagnosis. Ongoing pediatric survivorship research includes the Childhood Cancer Survivor Study, the St. Jude Lifetime Cohort Study, and survivorship research conducted through NCI's Pediatric Provocative Questions initiative.

V . Improving Cancer Prevention and Control

Cancer prevention research focuses on actions that individuals can take to lower their risk of getting cancer. Such actions include maintaining a healthy lifestyle, avoiding exposure to known cancer-causing substances, and taking medicines or vaccines that can prevent cancer from developing. Prevention measures should ideally be tailored to an individual's underlying risk of developing cancer.

Cancer prevention draws on our growing knowledge of the mechanisms and causes of cancer. Prevention also relies on population-based surveys to obtain epidemiological information, such as the incidence of specific types of cancers and factors that may cause a specific cancer. Through education, behavior modification, vaccination or preventive medications, and policies that limit exposures to known carcinogens, it is estimated that the overall risk of cancer can be reduced by one-third to one-half.

Cancer control science relies on basic and applied research in behavioral, social, and population sciences to enhance interventions that reduce cancer risk, incidence, morbidity and mortality, and improve quality of life. Cancer control seeks to understand the causes and distribution of cancer throughout the population, identify and implement effective healthcare practices to reduce cancer

incidence, and monitor and explain cancer trends and health disparities in the population. Cancer control research aims to generate basic knowledge about how to monitor and change individual and collective behavior, and translate that knowledge into practice.

To improve cancer prevention and control, NCI supports research to understand the factors that influence cancer outcomes, quality of care, and quality of life. NCI also promotes studies in underserved communities in the United States and globally to advance the goal of controlling cancer more effectively for all populations. Examples of initiatives under this NCI research goal include:

Immunoprevention: With FY 2018 Cures Act funding, NCI will support Cancer Immunoprevention Research Projects through a new Immuno-Oncology Translation Network. In October 2017, NCI announced funding opportunities for an integrated network of multi-disciplinary teams to accelerate translational research on immune mechanisms that contribute to tumor initiation and progression, and to evaluate new or improved immune-preventive and immune-therapeutic strategies. The prevention component of this effort seeks to identify actionable targets in pre-cancerous lesions and develop and validate early intervention vaccines for these targets. The immune-prevention projects will focus on cancers in high-risk cohorts, such as individuals with Lynch Syndrome (colon and endometrium), BRCA1/2 (ovary and breast), DCIS (breast), Barrett's esophagus, and Monoclonal gammopathy of undetermined significance, also known as MGUS (a precursor of multiple myeloma).

Cancer Vaccines: Vaccines that prevent infections known to cause cancer – such as HPV vaccines to prevent infection that may lead to cervical cancer – have gained widespread acceptance. NCI also supports research to develop vaccines to prevent cancers that are not associated with viral infection, such as vaccines that target cancer-driving mutations or target overexpressed proteins found in precancerous lesions. These experimental vaccines offer the potential to delay or stop cancer cell growth, to shrink tumors, to prevent cancer from recurring, and to eliminate cancer cells that remain after other treatments.

Through the Consortia for Early Phase Prevention Trials, NCI is supporting research on vaccines to treat breast cancer (NeuVAX and WOKVAC). NCI is also supporting a clinical trial for a vaccine to target the abnormal MUC1 protein found in advanced colorectal adenomas (polyps). In this trial, healthy individuals who face a risk of colorectal adenomas becoming malignant receive an experimental vaccine to boost the ability of their immune system to keep abnormal cells from becoming cancerous. Another NCI program, the PREVENT Cancer Preclinical Drug Development Program, is pursuing other immuno-prevention opportunities. This includes a vaccine to address the mutations that characterize Lynch syndrome, which can lead to cancers of the colon, rectum, stomach, small bowel, pancreas, ovary, and endometrium. Such vaccines may be a next generation approach for cancer immuno-intervention.

Human Papillomavirus (HPV) Vaccine Trials: Results from the Costa Rica Vaccine Trial that NCI commenced in 2004 suggested that women who received one, two, and three doses of the HPV16/18 vaccine had similar protection against HPV infection, and achieved stable, high antibody levels over a seven-year period. Because the vaccine recipients were not randomly assigned to receive one or two doses, a study of the minimum number of doses needed to confer durable protection could provide seminal evidence to justify changing the current vaccine recommendations from two doses to one dose for adolescents. To address this question, NCI commenced a new trial in Costa Rica to formally compare one- versus two-dose HPV vaccination, and to determine the

benefit of one- and two-dose schedules. Enrollment in the trial is planned for the next two years, and participants will be followed for four years. If effective, a single-dose vaccine could increase vaccine uptake in the United States and abroad and establish a new standard of care, thereby improving prevention for HPV-related cancers.

Improving Cervical Cancer Screening: In 2014, the FDA approved the first HPV DNA test for primary cervical cancer screening in the United States. In response to this important development, screening programs worldwide are transitioning to primary HPV-based screening from cytology (examining cervical cells via microscope). Since most HPV-positive women clear their infections after a few months, it is important to identify women with the highest risk of progressing to cancer among all HPV-positive women. NCI is conducting research on different strategies for triaging HPV-positive women. This includes developing machine-learning approaches for cytological and visual triage strategies, identifying biomarkers, translating biomarkers into clinical assays, and evaluating these approaches on a large-scale in different settings in the United States and globally. NCI is also focusing on ways to disseminate and implement these new technologies, and to develop new risk-based precision prevention screening and management guidelines to screen for cervical cancer.

Population Studies Support Cancer Screening and Prevention: NCI advances precision cancer prevention by integrating biological, behavioral, socioeconomic, and other risk factor data to develop comprehensive risk prediction and risk management tools. These tools can lead to practical and cost-effective screening principles. For example, in 2017, NCI experts presented evidence for phasing out cytology-based (Pap Test) screening for cervical cancer in favor of the more sensitive HPV testing. Based on the findings from NCI research, the American Society for Colposcopy and Cervical Pathology released recommendations on new standards of practice for colposcopy, a cervical cancer prevention technique in which the cervix is inspected for signs of cancer or precancer.

Reducing Tobacco Use: Lung cancer claims more lives in the United States than any other cancer, and at least 20 types of cancer are linked to tobacco use. NCI is conducting and supporting research on ways to further reduce tobacco use to prevent more cancers and improve the survivorship of cancer patients who use tobacco. To cite one example, NCI is funding programs at NCI-designated Cancer Centers to develop and implement tobacco cessation interventions for their patients. Use of tobacco products after a cancer diagnosis increases the risk of recurrence and second cancers, and such patients experience a greater treatment-related side effects.

MRI to Monitor Prostate Cancer Patients on Active Surveillance: Many men with prostate cancer can be closely followed with active surveillance (AS) in lieu of undergoing immediate surgery or radiation. However, the U.S. population of men on AS experience frequent need for biopsies to identify whether their cancer has progressed and whether surgery or radiation is appropriate. Over the past 10 years, improvements in magnetic resonance imaging (MRI) as well as in image-guided biopsy techniques permit the sampling of suspicious areas of the prostate with high precision. An NCI research team at the NIH Clinical Center is working to reduce the risks of prostate biopsies using an enhanced, targeted biopsy technique guided by MRI. Reducing the risk of prostate biopsies can lead to safer monitoring of patients on active surveillance.

VI. Cancer Centers

The NCI Cancer Centers program is a key component of the nation's cancer research efforts. Together with their community partners, the 69 NCI-designated Cancer Centers, located in 35 states and the District of Columbia form the backbone of NCI's extramural programs for studying and controlling cancer.

The NCI-designated Cancer Centers are the nation's single most important source of new insights into the causes of cancer and into strategies to prevent, diagnose, and treat cancer. Research proposals from cancer center investigators account for about three-quarters of the successful investigator-initiated grants that NCI awards.

At any given time, hundreds of research studies are under way at NCI Cancer Centers, ranging from basic laboratory research to clinical assessments of new treatments. Many studies are collaborative, involving several research centers and other partners in industry and the cancer research community. In addition to conducting basic and applied research, Cancer Centers deliver quality cancer care to patients and their families, and serve communities with underserved and understudied populations. A sample of important research developments at NCI Cancer Centers include:

- At Memorial Sloan Kettering Cancer Center in New York, researchers are working with Cornell Dots – nanoparticles that adhere to and light up cancer cells – to enhance cancer detection and monitor treatment response in melanoma and brain tumors.

- At the Lineberger Cancer Center in North Carolina, researchers are using data from The Cancer Genome Atlas to unravel the differences in germline genetic variations between African American and white women with breast cancer. This is the first ancestry-based comprehensive analysis of genomic and proteomic data.

- At the University of Maryland Greenebaum Cancer Center, researchers developed inhibitors that block the synthesis of the male hormone androgen, which fuels the growth of prostate cancer cells. These inhibitors are now being tested in clinical studies of prostate cancer patients.

- At the Case Western Cancer Center in Ohio, researchers performed the first genome-scale study identifying genetic changes that place African Americans at greater risk for worse colon cancer outcomes. Ongoing studies will identify opportunities to improve therapeutic approaches and target genetic changes to reduce African American colorectal cancer deaths.

- At the Masonic Cancer Center in Minnesota, researchers are using dogs that develop spontaneous glioblastoma multiforme (GBM, a form of brain cancer) as a preclinical platform to test the safety and efficacy of novel immunotherapies for this incurable primary brain tumor. Although the focus of this research is developing new drugs for humans, the dogs will be receiving the new treatments for GBM that researchers develop.

- At the Simon Cancer Center in Indiana, researchers received the first pediatric-focused Specialized Program of Research Excellence grant. Under this grant, research will not

focus on a particular cancer, but on treatments for pediatric tumors that develop in different tissues.

- At the University of Chicago Cancer Center, researchers launched the NCI Genomic Data Commons (GDC). The GDC is a next-generation research platform of the Open Cloud Consortium (Google, Amazon, Broad) that enables unprecedented access to standardized data and analytical tools for research. This platform will enable all research institutions to share genetic information to advance cancer discovery.

- At the Markey Cancer Center in Kentucky, researchers are conducting a "bioprospecting" initiative with the Kentucky Geological Survey and the University of Kentucky Center for Applied Energy Research to develop new anti-cancer drugs from natural compounds found in the richly diverse natural resources of Appalachian Kentucky.

In addition to the 69 NCI-designated Cancer Centers, NCI supports research at more than 100 other specialized centers for cancer research.

VII. Research Workforce Development

NCI has a long-standing commitment to training and developing a strong workforce of cancer researchers that spans the career continuum. NCI's investment in early-stage investigators helps attract strong talent and ensure the strength of future cancer research. In addition to NCI's direct support for training, our support for established investigators – scientists that have proven their ability to conduct robust science – also fosters mentoring for the next generation of cancer researchers.

NCI supports opportunities for training in basic, clinical, and behavioral research through formal training programs, individual fellowships, and career development awards. NCI training occurs at universities and other institutions across the country. In addition, NCI supports research experiences for high school, college, graduate and medical school students, and domestic and foreign post-doctoral fellows working in NCI intramural research programs. Recipients of training and career development grants span the career continuum and include pre-doctoral candidates, postdoctoral fellows, new faculty in independent research positions, and established midcareer investigators.

NCI is committed to supporting a well-defined career path to research independence for scientists. During FY 2017, NCI funded the second round of a new mechanism, the F99/K00, which supports the transition from graduate research to postdoctoral training. The new mechanism is designed to position awardees to be competitive for a second NCI transition mechanism to support their independence, the K99/R00, which facilitates the transition from postdoctoral training to serving as a tenure track investigator. These mechanisms will provide awardees with resources and a meaningful pathway to smoothly make these difficult transitions. Several F99 awardees have already successfully transitioned to the K00 phase.

NCI also merged two other career development mechanisms, the K08 and K23, to allow more physician scientists to compete for support based on their best scientific ideas. This approach will avoid creating an artificial boundary that forces applicants into specific research disciplines.

During FY 2018, NCI plans to increase the level of salary support available per award under the K08

mechanism to the maximum salary allowed for principal investigators. NCI will also increase the research funding that K08 investigators receive. These changes should increase the number and quality of applicants by physician-scientists pursuing cancer research.

Finally, NCI is also exploring new approaches to attract and support physician-scientists to research during residency training. NCI has opened its K12 programs, which typically support junior faculty and clinical fellows, to residents interested in research. Furthermore, NCI is one of four NIH institutes participating in the R38 Stimulating Access to Research in Residency (StARR) program. StARR is designed to recruit and retain outstanding postdoctoral-level health professionals who have demonstrated potential and interest in pursuing careers as clinician-investigators.

NCI is committed to developing a cancer research workforce that reflects the nation that we serve. The NCI Center to Reduce Cancer Health Disparities (CRCHD) collaborates with NCI's Center for Cancer Training in this effort. Examples of CRCHD programs include:

Partnerships to Advance Cancer Health Equity (PACHE): The PACHE program aims to address cancer health disparities in underserved populations, a major public health concern in the United States and globally. PACHE creates stable, comprehensive, long-term partnerships between institutions serving underserved populations and NCI-designated cancer centers to develop cancer programs and build capacity in cancer research, education, and outreach. In FY 2017, PACHE supported 25 partnerships, funded 77 research projects – 45 of which focused on cancer health disparities – and published 272 peer review publications. Furthermore, PACHE supported the training of 65 underrepresented early stage investigators. Next steps include strengthening the program's growth and sustainability through increased research, training, education, and outreach.

Continuing Umbrella of Research Experiences (CURE): The CURE program trains underrepresented individuals for independent cancer research careers. In FY 2017, NCI expanded the CURE program to support middle school students, in addition to high school students through early stage investigators. CURE includes individualized program navigation, professional development workshops and mock peer review of grants, and has been successful in increasing the participation of underrepresented individuals in cancer and cancer health disparities research. In FY 2017, CURE supported 174 new and 517 continuing students and investigators. In response to a one-time funding opportunity, four NCI-designated Cancer Centers received funding to establish training programs focusing on increasing the number of American Indian and Alaska Native students interested in pursuing cancer research. In addition to the extramural program, an Intramural CURE (iCURE) Program was developed in partnership with NCI's Center for Cancer Research (CCR) in FY 2017. The iCURE parallels the design and philosophy of the CURE, and provides mentored research experience in the NCI Intramural Research Program.

VIII. Research Management and Support

NCI research management and support personnel serve an indispensable role by supporting and enabling the success of all NCI-funded programs.

IX. Repairs and Improvements

Established in 1971 under the National Cancer Act, the NCI Frederick National Laboratory for Cancer Research (FNLCR) is the only Federally Funded Research and Development Center

(FFRDC) dedicated to biomedical research. Located at Fort Detrick in Frederick, Maryland, this NCI enterprise is a national asset and a unique resource. It brings public and private partners together to address some of the most difficult cancer research challenges.

Funding for the Repairs and Improvements account allows NCI to operate FNLCR laboratories as a modern research enterprise and to maintain core infrastructure that is essential to the NCI-Frederick research campus. The repairs and improvements allow NCI to perform world-class research at the Frederick campus to support NCI's national cancer mission.

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2017 Final			FY 2018 Annualized CR			FY 2019 President's Budget[1]		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Cancer Research									
Direct:	1,327	15	1,342	1,299	15	1,314	1,288	15	1,303
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	1,328	15	1,343	1,300	15	1,315	1,289	15	1,304
Division of Cancer Biology									
Direct:	52	-	52	53	-	53	53	-	53
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	52	-	52	53	-	53	53	-	53
Division of Cancer Control and Population Sciences									
Direct:	168	2	170	177	2	179	177	2	179
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	168	2	170	177	2	179	177	2	179
Division of Cancer Epidemiology and Genetics									
Direct:	162	3	165	156	3	159	156	3	159
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	162	3	165	156	3	159	156	3	159
Division of Cancer Prevention									
Direct:	102	2	104	109	3	112	109	3	112
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	102	2	103	109	3	112	109	3	112
Division of Cancer Treatment and Diagnosis									
Direct:	226	3	229	230	3	233	230	3	233
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	226	3	229	230	3	233	230	3	233
Division of Extramural Activities									
Direct:	105	-	105	106	-	106	106	-	106
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	105	-	105	106	-	106	106	-	106
Office of the Director									
Direct:	857	3	861	886	3	889	886	3	889
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	858	3	862	887	3	890	887	3	890
Total	3,001	28	3,029	3,018	29	3,047	3,007	29	3,036
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	**Average GS Grade**								
2015	12.3								
2016	12.4								
2017	12.4								
2018	12.5								
2019	12.5								

[1] Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Detail of Positions[1]

GRADE	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget[2]
Total, ES Positions	1	3	3
Total, ES Salary	187,000	568,800	571,530
GM/GS-15	286	338	338
GM/GS-14	486	519	519
GM/GS-13	471	503	503
GS-12	465	487	487
GS-11	180	179	179
GS-10	10	10	10
GS-9	115	114	114
GS-8	72	72	72
GS-7	54	54	54
GS-6	17	16	16
GS-5	7	8	8
GS-4	9	12	12
GS-3	4	4	4
GS-2	1	1	1
GS-1	4	6	6
Subtotal	2,181	2,323	2,323
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	15	15	15
Senior Grade	5	5	5
Full Grade	6	6	6
Senior Assistant Grade	2	3	3
Assistant Grade	0	0	0
Subtotal	28	29	29
Ungraded	944	980	980
Total permanent positions	2,163	2,186	2,175
Total positions, end of year	3,153	3,332	3,332
Total full-time equivalent (FTE) employment, end of year	3,029	3,047	3,036
Average ES salary	187,000	189,600	190,510
Average GM/GS grade	12.4	12.5	12.5
Average GM/GS salary	108,918	110,470	111,000

1 Includes FTEs whose payroll obligations are supported by the NIH Common Fund

2 Reflects the transfer of the Dermatology Branch from NCI to NIAMS in FY 2019