

NCI Director's Update

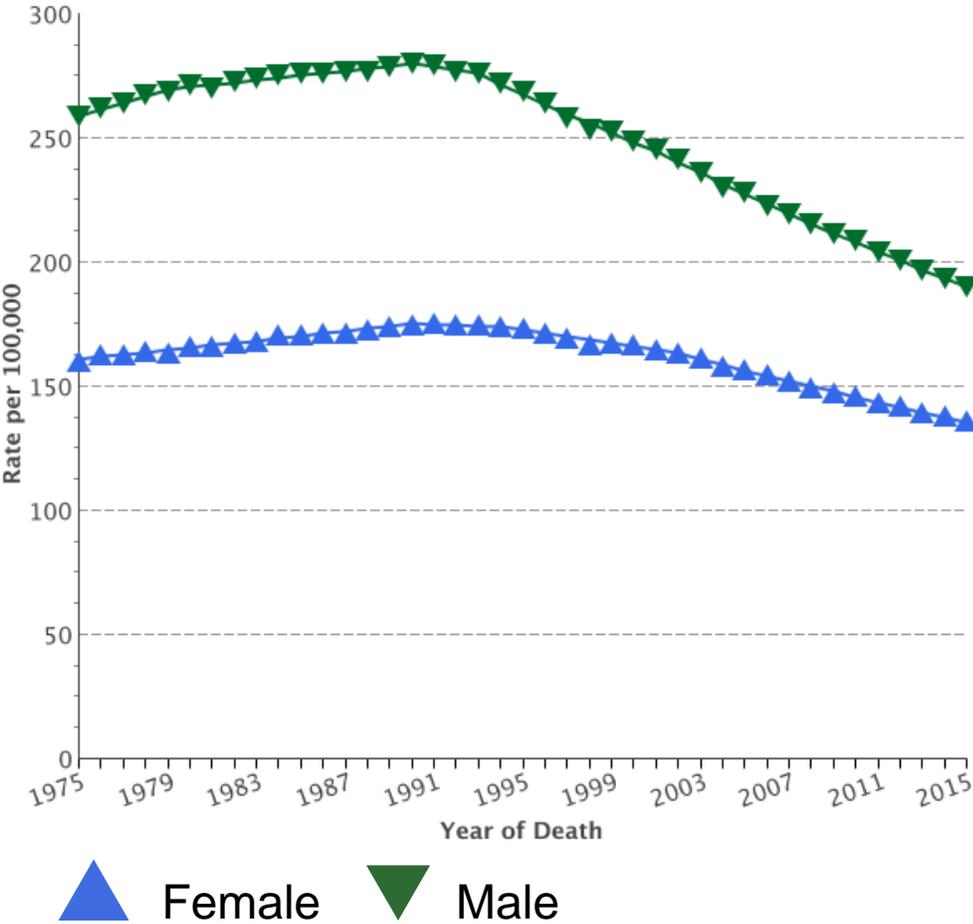
Board of Scientific Advisors

Norman E. Sharpless, M.D.
Douglas R. Lowy, M.D.

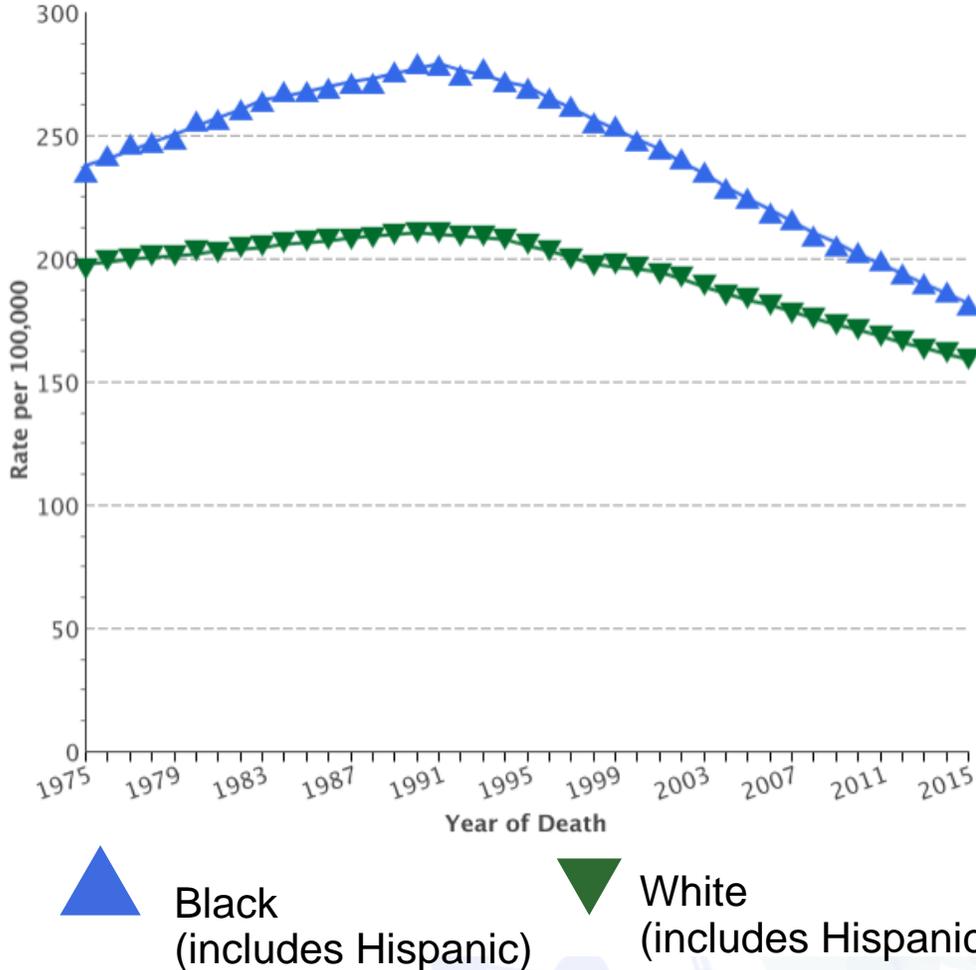
March 25, 2019

Long-Term Trends in U.S. Mortality Rates - All Cancer Sites Combined

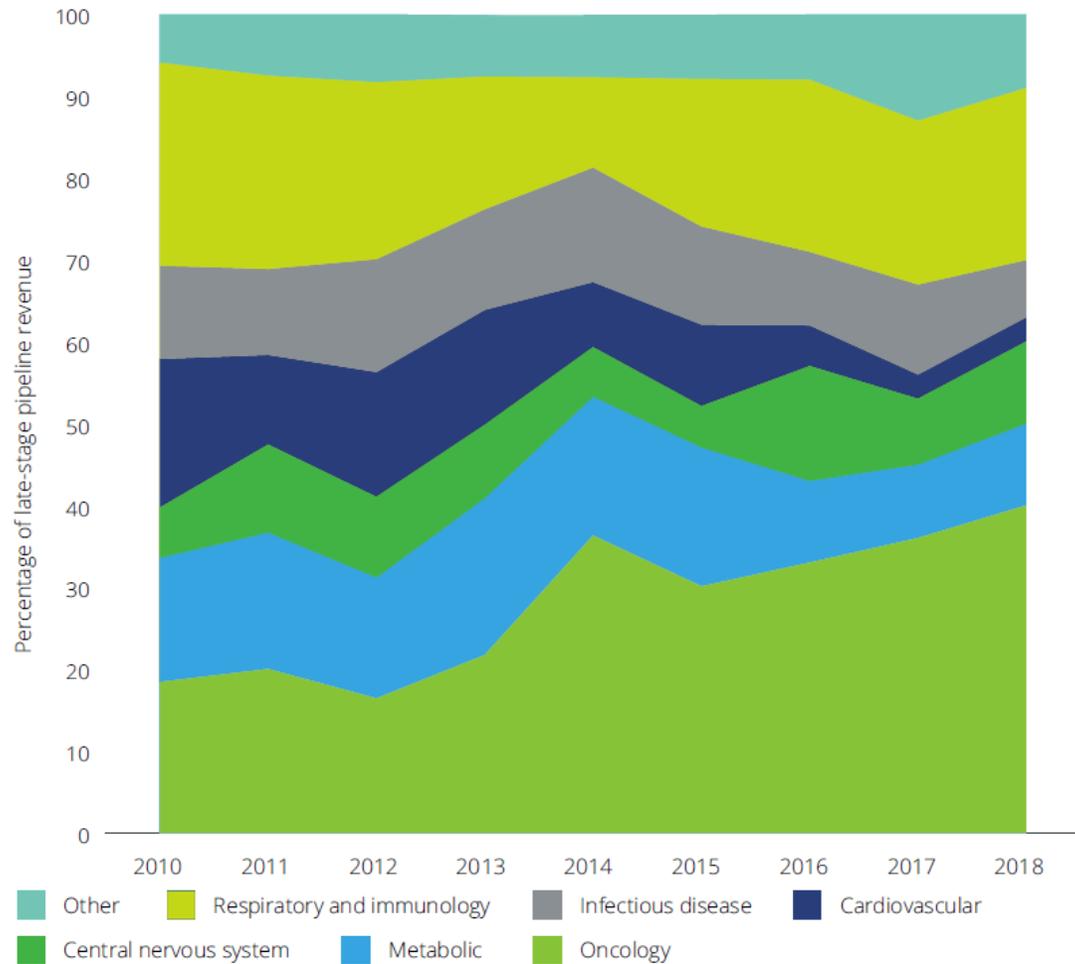
By Sex
All Races (includes Hispanic), All Ages



By Race/Ethnicity
Both Sexes, All Ages

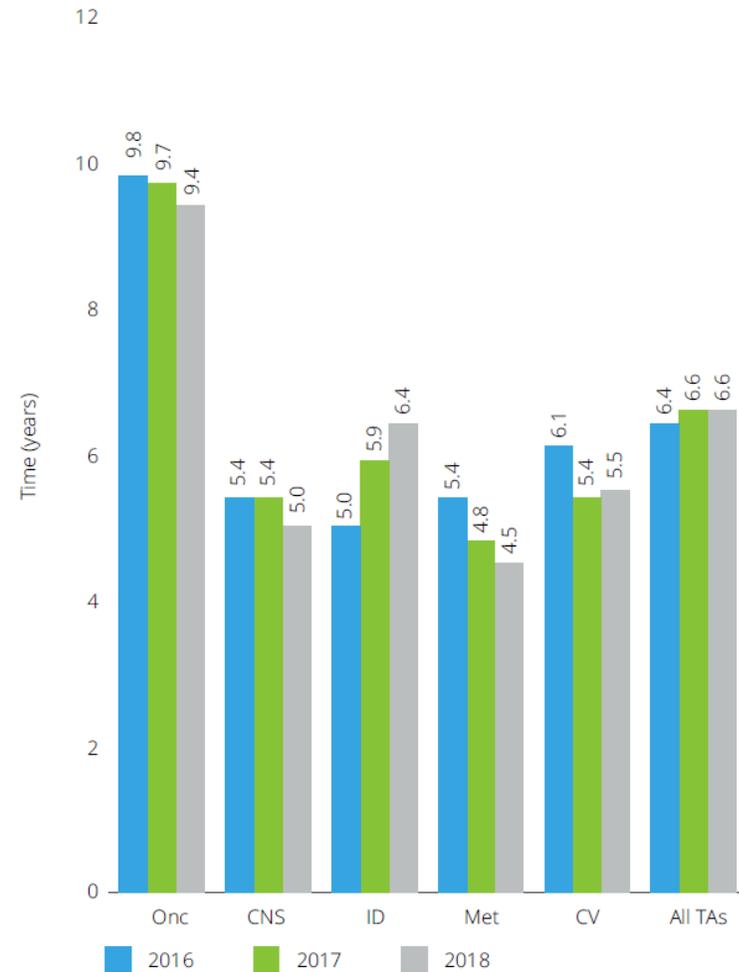


Late-stage pipeline composition by therapeutic area, 2010-18 – original cohort



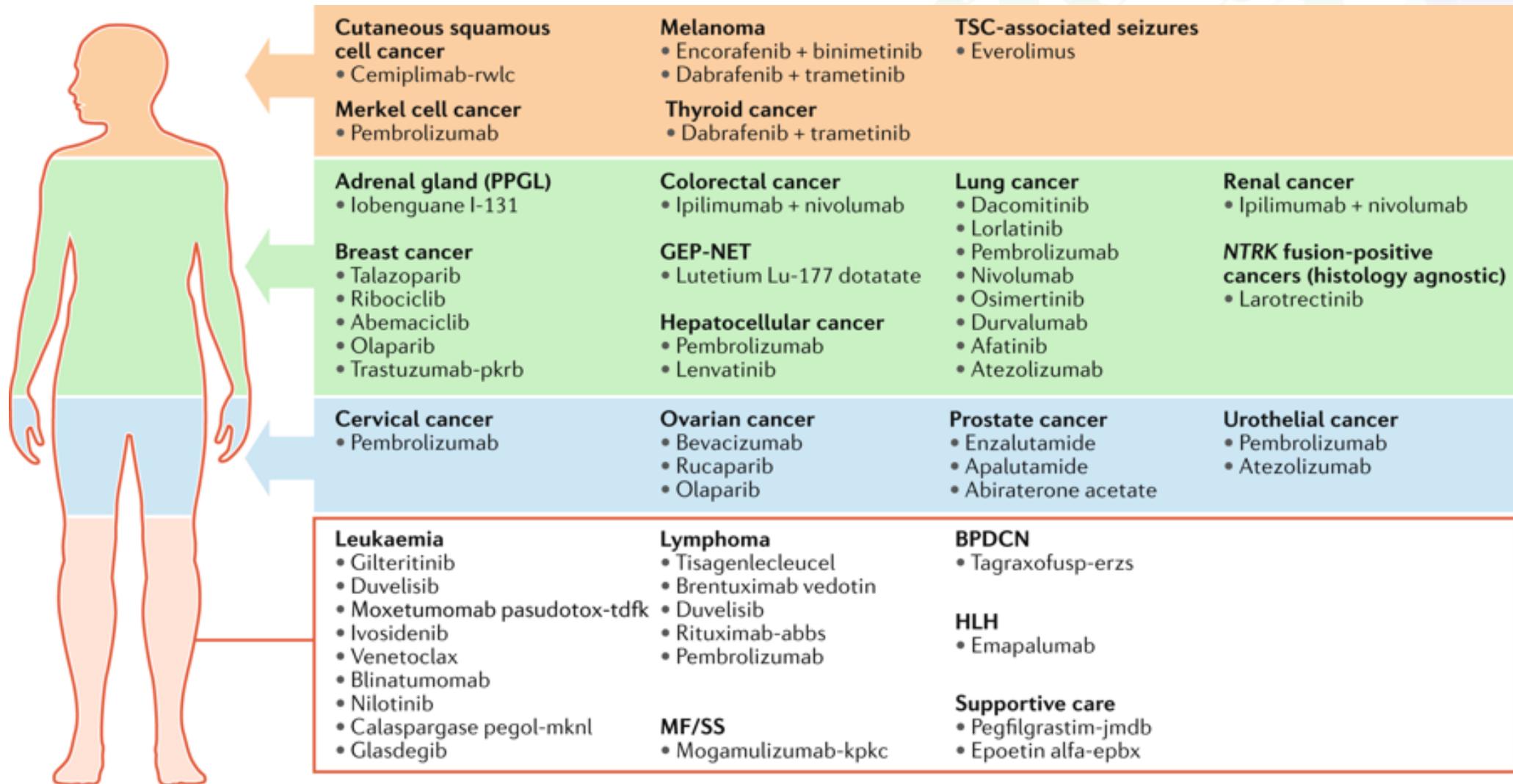
Source: Deloitte LLP, 2018

Clinical cycle time by therapy area (selected therapy areas only), 2016-18



Source: GlobalData and Deloitte LLP, 2018

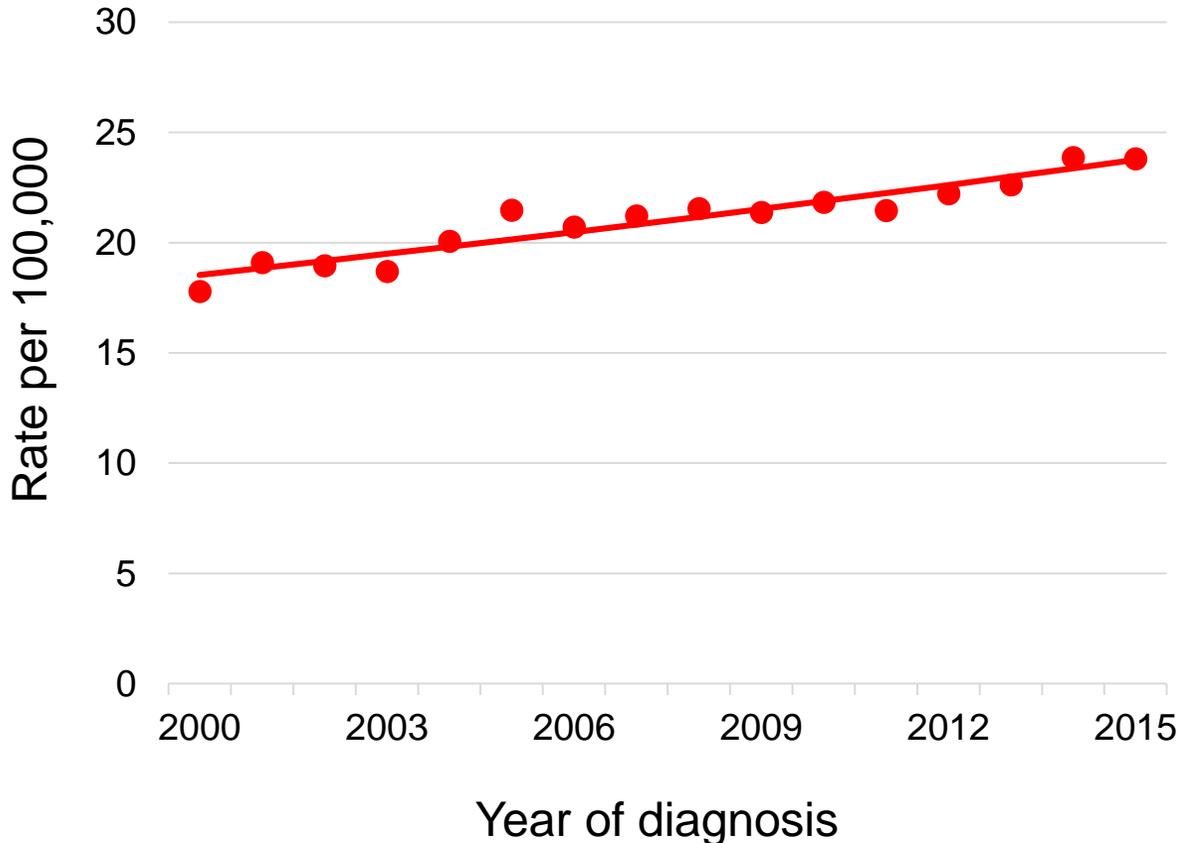
Cancer drug approvals in 2018



Melanoma incidence & mortality

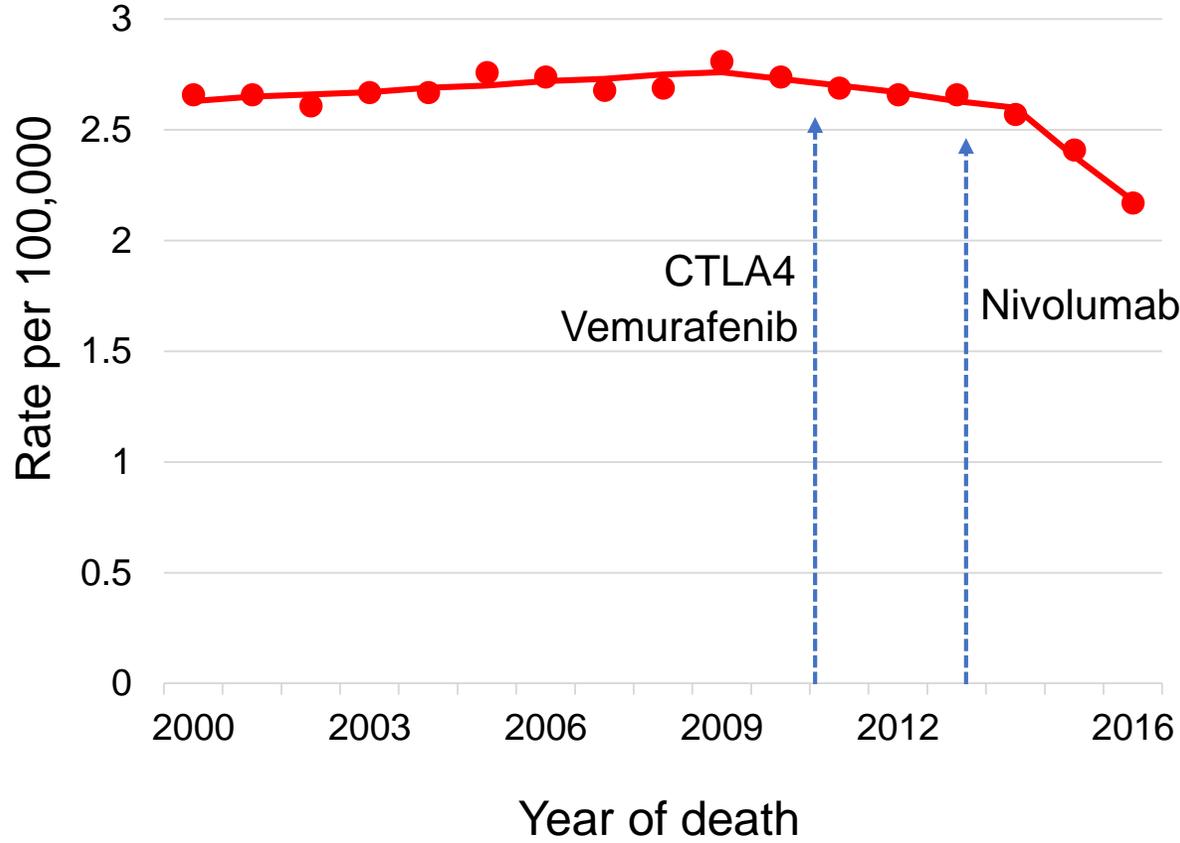
**Incidence has increased by ~2% per year
2000-2015**

Melanoma of the skin
SEER incidence rates



**Mortality has decreased by ~5% per year
2012-2016**

Melanoma of the skin
US mortality rates



Key Focus Areas

WORKFORCE DEVELOPMENT

Support the cancer research enterprise by focusing on the workforce of cancer investigators

BASIC SCIENCE

Reaffirm our commitment to basic science to drive novel approaches and technologies

BIG DATA

Increase data aggregation and interpretation to speed our work across the cancer enterprise

CLINICAL TRIALS

Fully realize the power of clinical trials through innovative design, administration, and analyses

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Workforce Development



Method to Extend
Research in Time

ESI
PAYLINE



14th
PERCENTILE

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**FY 2018
RPG POOL**



**+ \$170M over
FY 2017**

*Largest increase
since FY 2003*

**FY 2019
RPG POOL**



**>\$100
MILLION**

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Modernizing Clinical Trials

To Promote the Science and Art of Medicine and the Betterment of the Public Health

JAMA[®]

January 23, 2019

VIEWPOINT

EVOLVING ISSUES IN ONCOLOGY

Modernizing Clinical Trials for Patients With Cancer

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MD

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MD

Division of Cancer
Treatment and
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Cancer Institute,
National Institutes of
Health, Bethesda,
Maryland; and Center
for Cancer Research,
National Cancer
Institute, National
Institutes of Health,
Bethesda, Maryland.

Clinical trials involve evaluating and validating new therapies in humans and represent the fundamental means of making progress in cancer care. The oncology community has made significant improvements in treating most cancers and, in some cases, has developed cures, such as for testicular cancer, Hodgkin disease, and acute lymphocytic leukemia. In an even larger number of cancers, researchers and clinicians have succeeded in making cancer a chronic disease that people die *with* rather than *of*. Each of these therapeutic discoveries represents the results of clinical trials.

Many of these advances were made possible in large part through the Clinical Trials Program at the National Cancer Institute (NCI). This program began in 1955,¹ and since then has changed substantially in its approach to the design, coordination, and implementation of clinical trials. The past 10 years, in particular, have seen a transformational reworking of the NCI's clinical trials infrastructure.² The NCI National Clinical Trials Network (NCTN) now includes more than 3000 study sites

trials are then passed on to patients in drug prices.

The NCI is therefore focused on "r to answer essential questions about th treatments with fewer patients. For e trials of highly active agents, it may be traditional control group interventions annotated "synthetic" controls create previous trials. The NCI is also exploring end points that reflect the mechanism drug under study through "pragmatic tr ducted in clinical practice settings a mented annotation and aggregation c ing trials data to answer relevant cl without additional enrollment.

Conduct Trials That Complement Those
The emergence of industry as the major cer clinical trials has led to redundanc lio of novel agents in development

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March 7, 2019, by P. Ivy, A. Denicoff, G. Mishkin & F. Arnaldez

The authors are from NCI's [Division of Cancer Treatment and Diagnosis](#). Percy Ivy, M.D., and Fernanda Arnaldez, M.D., help manage NCI's [Experimental Therapeutics Clinical Trials Network](#). Andrea Denicoff, R.N., M.S., and Grace Mishkin, M.P.H., help manage NCI's [National Clinical Trials Network](#). Ivy, Arnaldez, and Denicoff are members of working groups assembled by the American Society of Clinical Oncology and Friends of Cancer Research to develop new recommendations for expanding trial eligibility criteria.

With so many new and promising cancer treatments being developed, the need for clinical trials to efficiently and effectively test them has never been greater.

Maximizing the number of patients who are eligible for clinical trials, while still maintaining an appropriate level of safety, is a top priority for NCI leadership, given the challenges of enrolling enough patients in clinical trials. Eligibility criteria—the requirements that must be met before a person can enroll in a trial—have not kept pace with the modernization of clinical trials. Restrictive criteria have not only been a significant hurdle for many patients who have wanted to participate in trials, but they have also limited the generalizability of study findings.



NCI is expanding eligibility criteria for its cancer clinical trials in the hope that more patients will enroll.
Credit: iStock

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Childhood Cancer Data Initiative

- Data infrastructure and inter-operability
- Data acquisition
- Extramural grants



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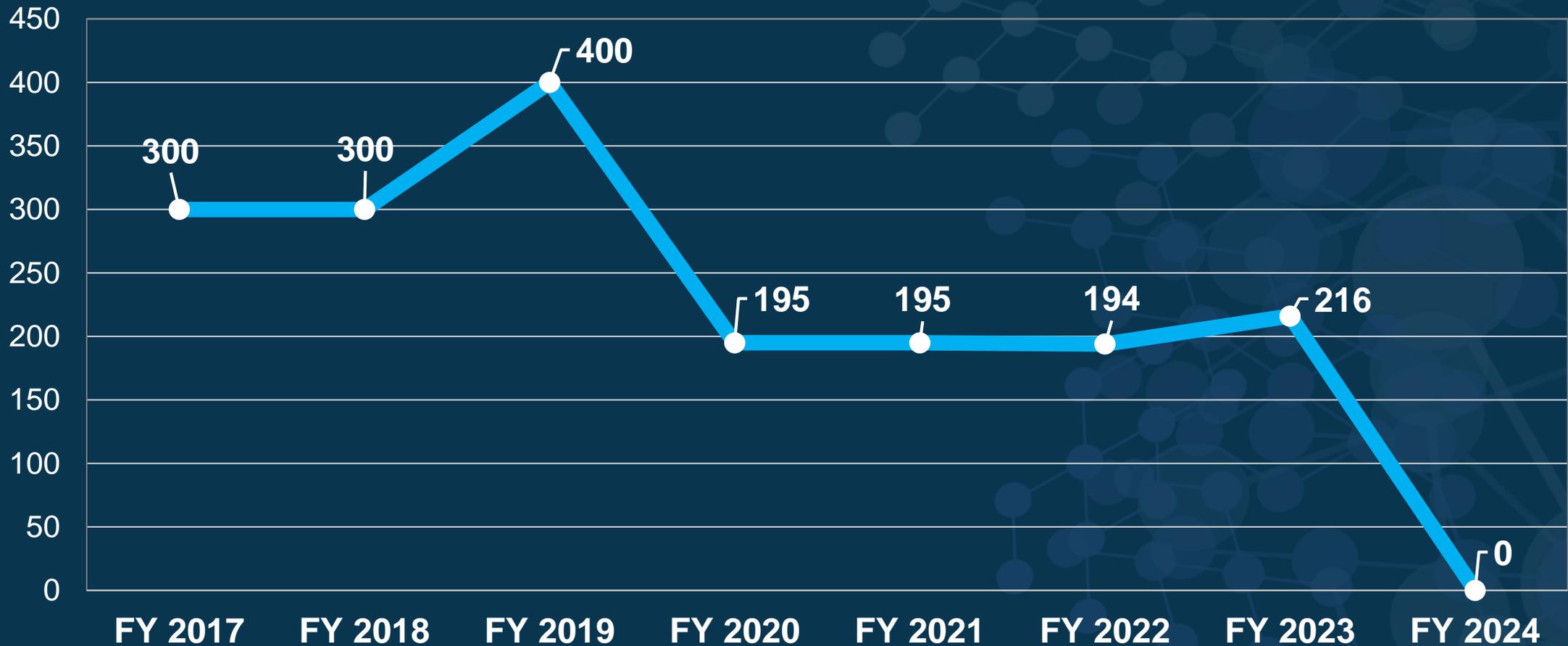
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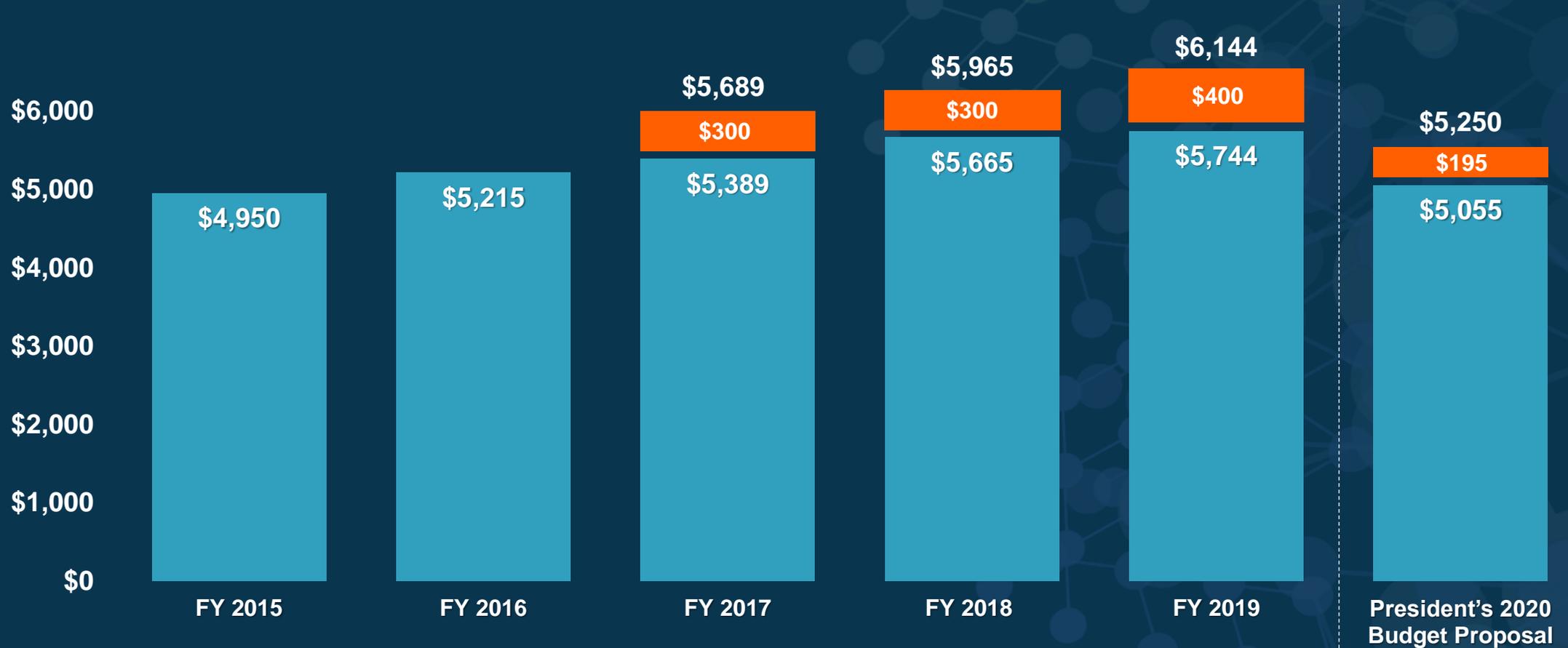
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Cancer Moonshot Funding Authorized Under the 21st Century Cures Act (dollars in millions)



NCI Appropriations FY 2013 - 2019 (in millions)

21st Century Cures Act
funding shown in orange





NCI/NIH BUDGET PROCESS FOR REGULAR APPROPRIATION

STEP 1



White House OMB coordinates with federal agencies to formulate the President's budget proposal

FY 2020

STEP 2



Congressional appropriations committees consider President's proposal & prepare legislation

STEP 3



Congress reconciles & finalizes appropriations legislation & sends to the President

STEP 4



President signs the appropriations bill into law making funds available for NIH & NCI

FY 2019

Leadership transitions

- Director, Center for Global Health (CGH)
- Director, Center for Bioinformatics and Information Technology (CBIIT)
- Director, Cancer Therapy Evaluation Program (CTEP)
- Director, Division of Cancer Prevention (DCP)

Associate Director, NCI at Frederick

- Cancer Research Technology Program, Frederick National Laboratory for Cancer Research
- NCI's Office of Cancer Nanotechnology Research
- Research Associate, University of Virginia Health Sciences Center, Department of Biochemistry and Molecular Genetics
- Post-doctoral Fellowship, Fred Hutchinson Cancer Research Center, Division of Basic Sciences
- Ph.D. in Pharmacology, Duke University Medical Center in 1999



Sara Hook, Ph.D.

NCI @ AACR 2019



**Opening
Ceremony
Sunday, March 31
9:00 AM**



- 15 NCI-sponsored sessions
- > 25 additional presentations by NCI staff
- 40 Meet-the-Experts sessions at the NCI Exhibit
- 80 poster sessions



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CANCER
INSTITUTE**

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