

Accelerating Progress in Cancer Research

*Douglas R. Lowy
Acting Director, National Cancer Institute,
National Institutes of Health*

Outline of Presentation

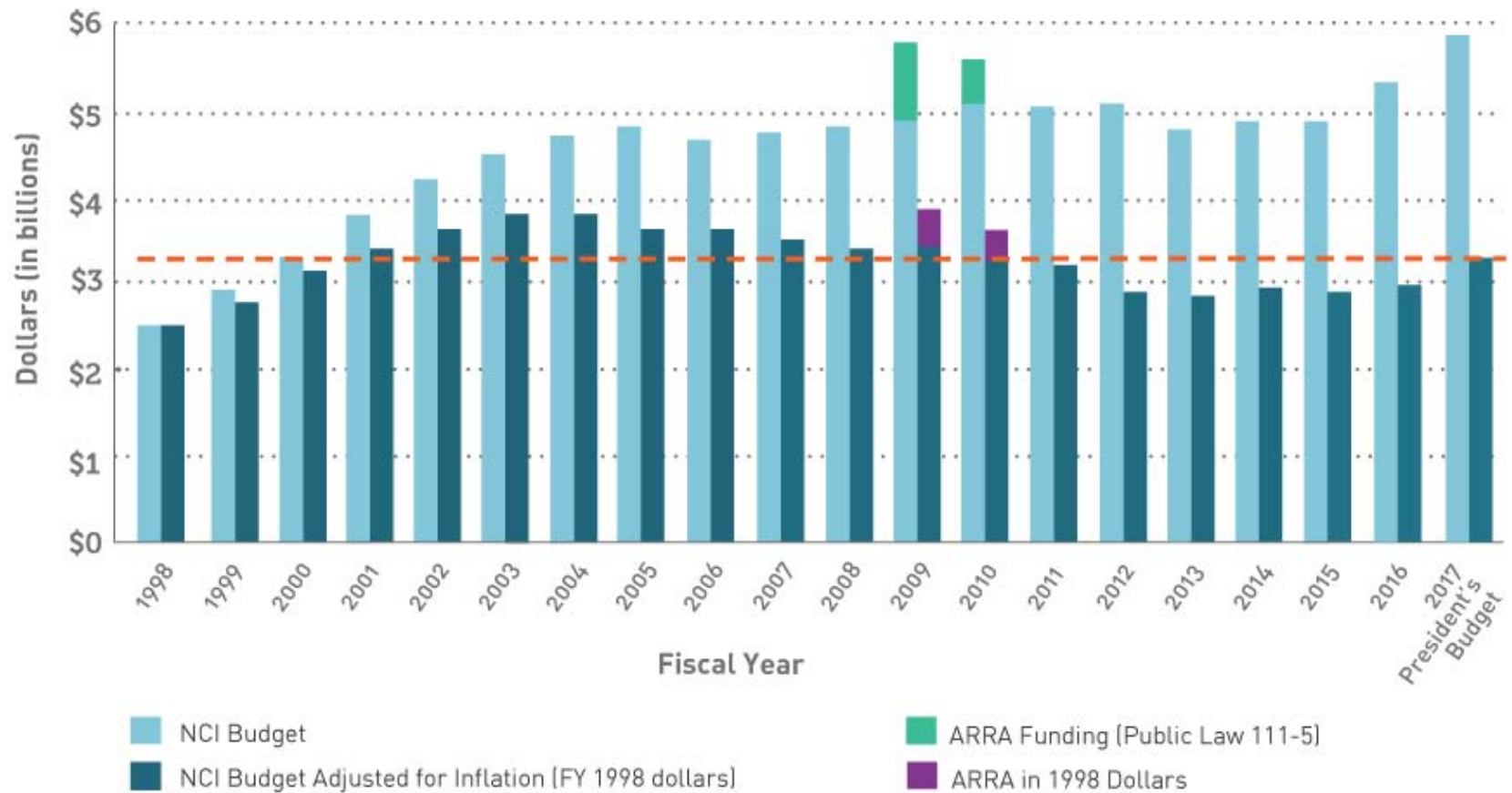
- FY17 budget
- Investigator-initiated research
- Cancer health disparities
- Precision Medicine Initiative in Oncology
- The Vice President's Cancer Moonshot (Dr. Singer)

A Positive Outlook for Cancer Research Funding

- Strong bipartisan support for NCI/NIH
 - Key role of advocacy
 - Faster progress for patients
- Potential for continuing increases in Federal cancer research funding
- Coordination with private funding efforts

NCI BUDGET 2005 – 2015: A PERIOD OF LEVEL BUDGETS & PROGRESSIVELY DECREASING PURCHASING POWER

FY 2016 & 2017: AN ENCOURAGING TREND



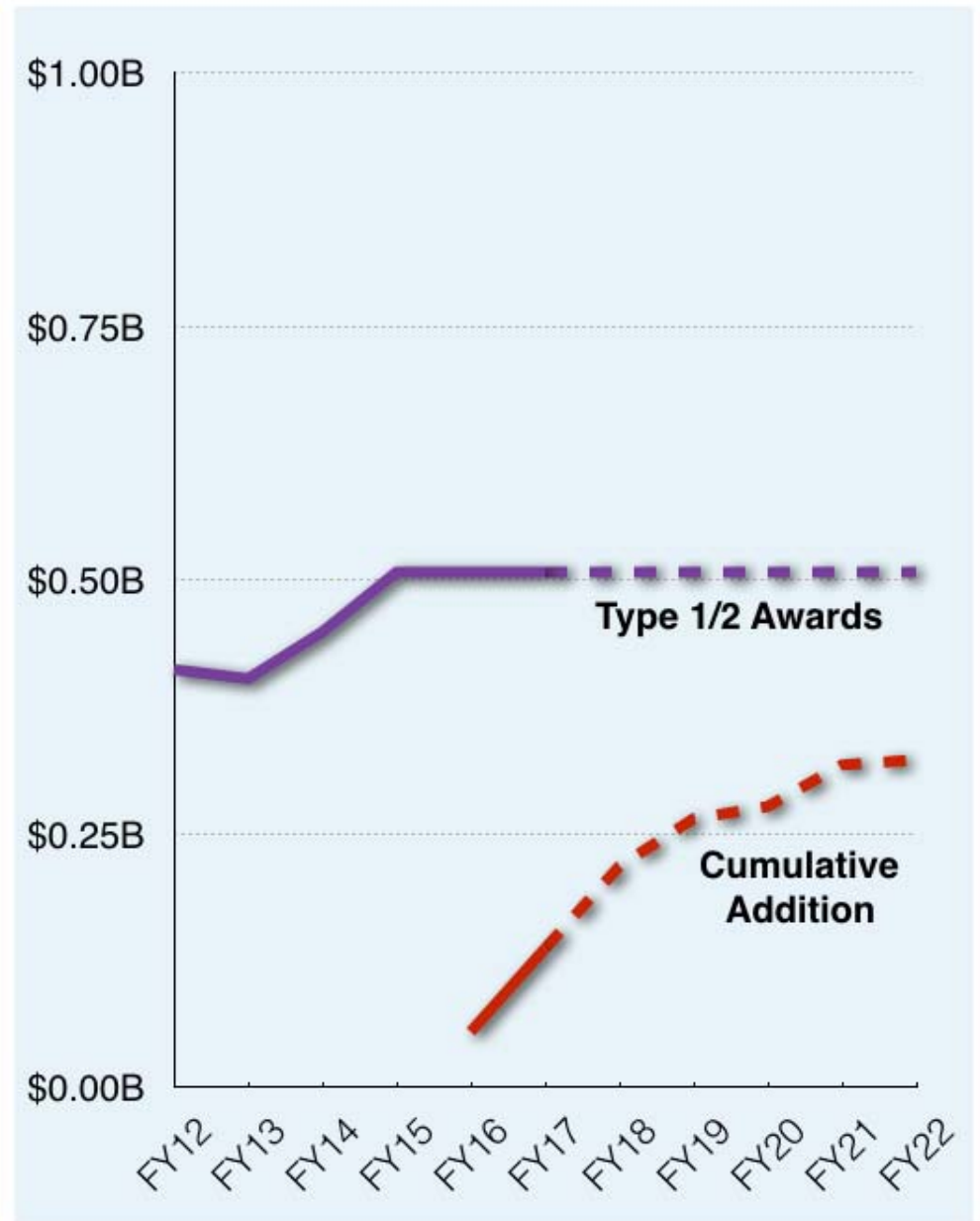
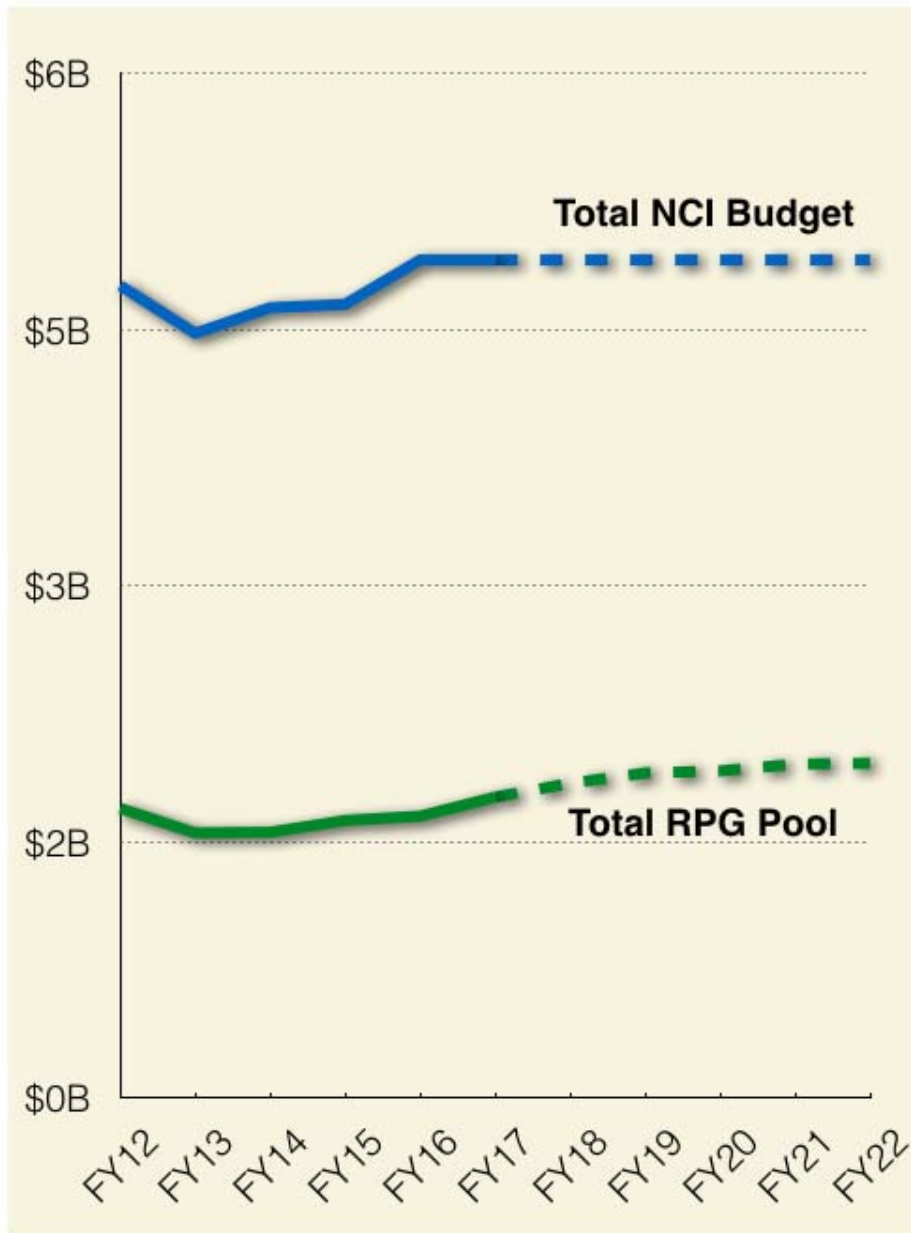
----- The dashed line at approximately \$3.3 billion indicates that the inflation-adjusted FY 2017 proposed budget is similar to the FY 2000 budget

***Continuing to
strongly support
investigator-initiated
research***

Investigator-initiated research

- ***Basic***
- Prevention
- Screening/early diagnosis
- Treatment
- Survivorship

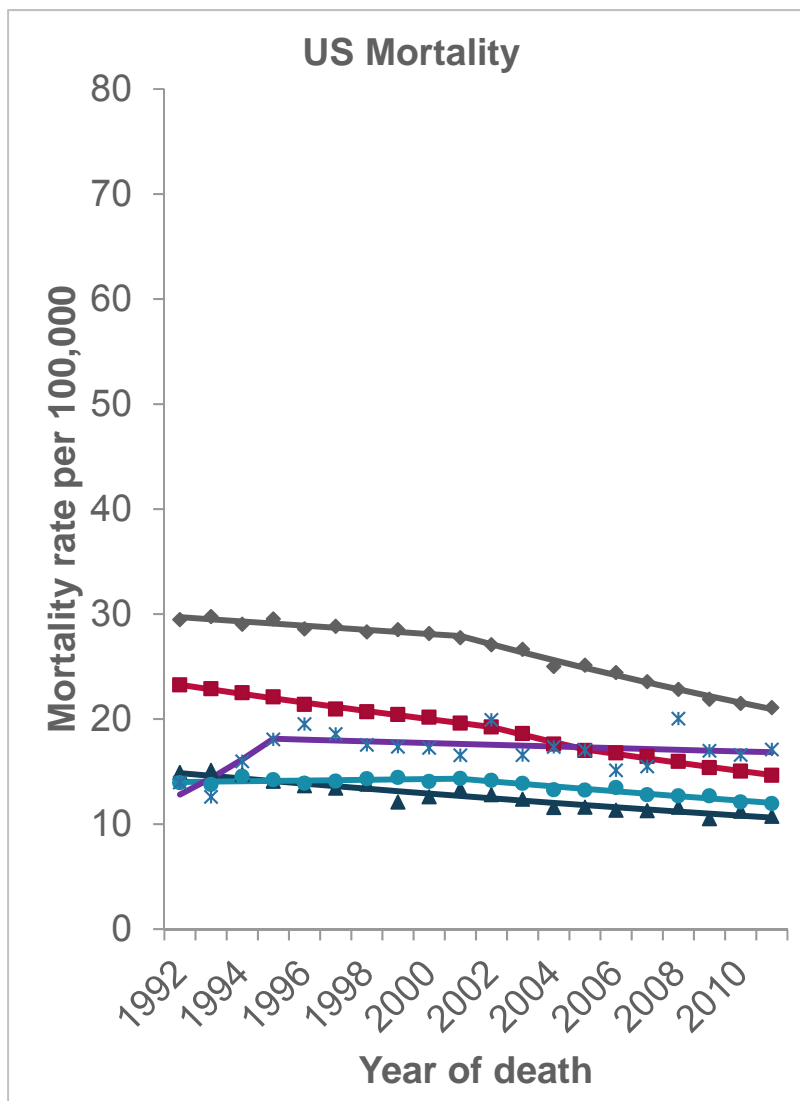
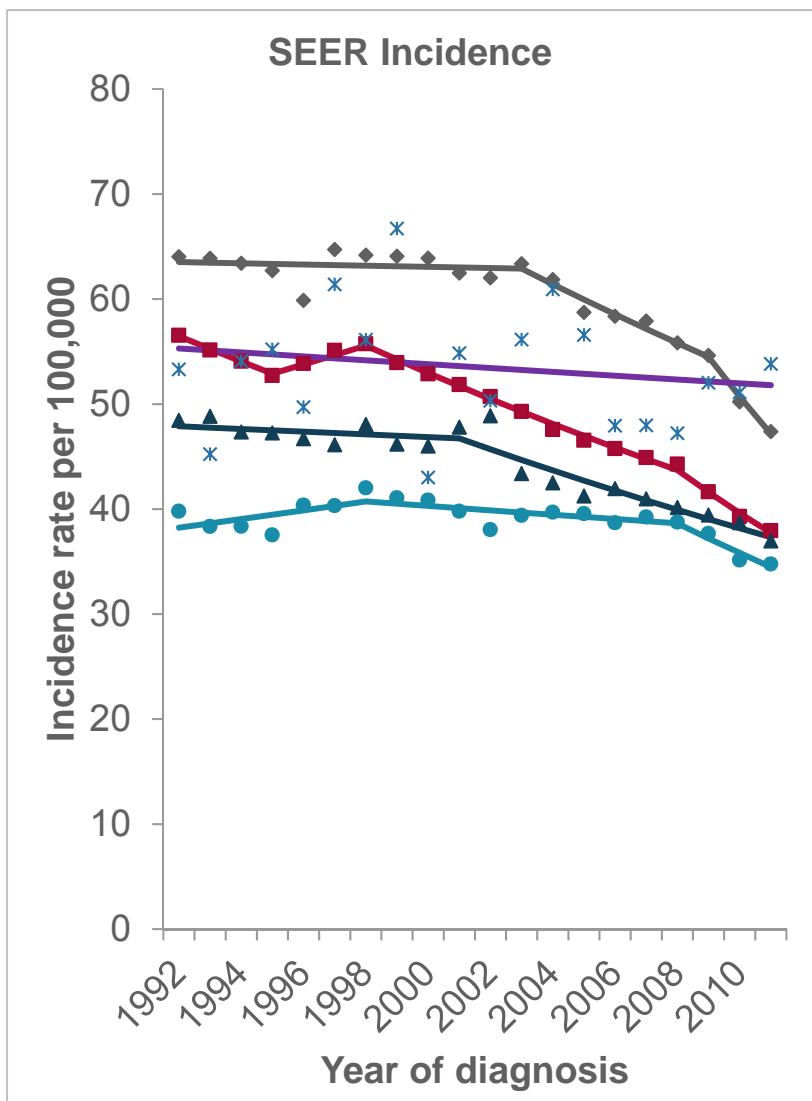
Changes in RPG pool: FY12-FY16 and beyond



Focus on specific cancers with health disparities

- Some examples: lung cancer, colorectal cancer, liver cancer, breast cancer, prostate cancer, multiple myeloma
- Identify the risk factors and their relative contribution to the disparities: **biologic factors, life-style factors, health care access/utilization**
- Explore efforts to mitigate the risk factors

Colon & Rectum



- White
- ◆ Black
- ▲ API
- * AI/AN
- Hispanic*

*Hispanic is not mutually exclusive from other groups
 Incidence data from SEER 13 1992–2011, Mortality data from NCHS

Some Principles to Follow

- Develop better genomic, biologic, environmental, and treatment response information about cancer in minority populations
- Minority populations represented in clinical trials & preclinical cancer models
- Ensure from the beginning that appropriate minority representation will be included

Two new NCI research initiatives

- Early onset malignancy initiative: the first minority-based cancer tissue bank; early onset tumors; collect information on treatment, response, and outcome
- Detailed molecular characterization of fully annotated tumors
- Organized through NCORP (NCI Community Oncology Research Program)
- Develop new cancer models from tumors of minority patients

Two White House Initiatives in Cancer

- The President's Precision Medicine Initiative in Oncology: announced 2015
 - To advance cancer treatment through genomics
- The Vice President's Cancer Moonshot: announced 2016
 - To accelerate progress, from cutting edge research to wider dissemination of standard of care
- PMI-O is related to some of the Moonshot

The President's Precision Medicine Initiative in Oncology

- Foundational clinical trials (MATCH—Adult and Pediatric)
- Preclinical models to advance predictive oncology: the right drugs for the right patient at the right time
- A large annotated database of cancer patients: for researchers, health care providers, and patients; the Genomic Data Commons (GDC)

The President's Precision Medicine Initiative in Oncology

- FY16: A group of administrative supplements
- RFA concepts approved by BSA:
 - enhance preclinical drug development and preclinical clinical trials utilizing patient derived xenograft (PDX) models
 - Approaches to identify and overcome (primary or acquired) resistance to cancer therapy
 - canine immunotherapy trials and correlative studies
 - Translational implications of the microenvironment in pancreatic ductal adenocarcinoma (immunotherapy)
 - biomarker development and correlative studies associated with immunotherapy clinical trials

The MATCH trials

- For cancer patients with progressive disease and no standard of care treatment.
- Each patient is treated according to molecular abnormalities of his/her tumor, rather than according to the tumor site of origin
- Adult MATCH trial: Initial goal of screening 3,000 patients; now increased to 5,000 patients
- Pediatric MATCH trial: to open in 2017

- MATCH = Molecular Analysis for Therapy CHoice

Adult MATCH trial

- Opened August 2015 with 10 treatment arms; has 23 arms since May 2016; increase to 29 arms expected in near future
- >1000 approved sites throughout the USA
- Accruing ~500 patients/month for screening with biopsy and tumor sequence analysis
 - Initial accrual estimate had been ~50 patients/month
- Results of first tumor biopsy: 85% success rate for initial 750 patients in 2015; 94% success rate since June 2016
- ~24% of screened tumors have molecular abnormalities that make the patient eligible for at least one treatment arm

The Vice President's Cancer Moonshot

Vice President's Office



**Cancer Moonshot
Federal Task Force**



NCI/NIH



NCAB



"Blue Ribbon Panel"



Working Groups



Goals of the Cancer Moonshot

- Accelerate progress in cancer, including prevention & screening
 - From cutting edge basic research to wider uptake of standard of care
- Encourage greater cooperation and collaboration
 - Within and between academia, government, and private sector
- Enhance data sharing

(Presidential Memo 2016)

NCI Virtual Drug Formulary

- Goal: To greatly shorten the time needed to start multidrug cancer treatment trials when the drugs come from more than one pharmaceutical company
- Would overcome a major roadblock to precision medicine clinical trials
- For trials not funded by NCI in academic centers
- Agents will be provided for both clinical and pre-clinical studies
- Pharmaceutical company will have 8 weeks for review
- 40 drugs now pledged by 10 companies; early 2017 anticipated start date

Cancer Moonshot: Why now?

- The need has been present for decades; it is now matched by the opportunity to be able to benefit from a major infusion of additional resources
- Many opportunities for bold, but feasible, initiatives that could have important implications for understanding cancer and for patients through improved prevention, screening, treatment, and survivorship
- Immunotherapy has come of age

Blue Ribbon Panel Goals

- Identify major scientific opportunities that are poised to be accelerated by additional emphasis and funding
- Identify major scientific and regulatory hurdles that can be overcome with additional emphasis and funding
- *Develop ~10 recommendations of opportunities that would be pursued through the Vice President's Cancer Moonshot*

The NCI Genomic Data Commons opens at the University of Chicago



Genomic Data Commons: a repository for publicly available annotated cancers

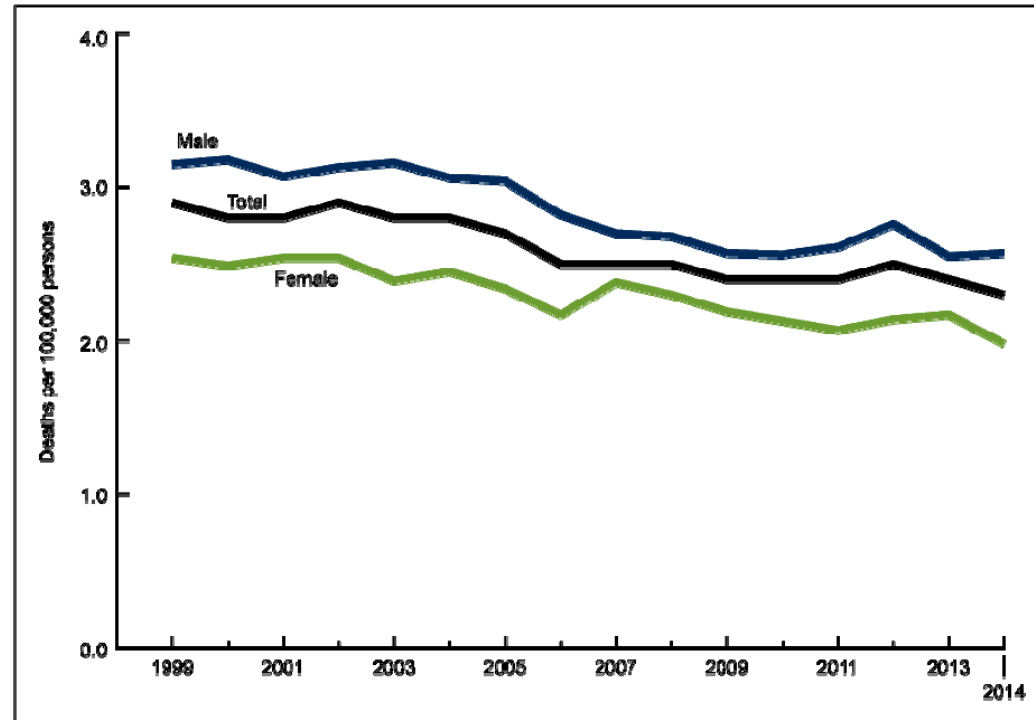
- Start with ~14,000 cancers from TCGA and TARGET (pediatric TCGA)
- Will house data from NCI-supported clinical trials
- Opportunity for others to add their annotated cancers
- Foundation Medicine is adding ~18,000 cancers with analysis of ~350 genes
- Anticipate adding an additional ~20,000 cancers in the next year

The BRP recommendations: a few highlights

- Develop immunological approaches to prevent cancers not attributable to infectious agents
- Tumor cell atlas: goes beyond TCGA in at least two important ways: 1) includes 3D organization of microenvironment in addition to the tumor; 2) includes pre-malignant lesions
- Pediatric cancer: immunotherapy and fusion oncoproteins

A 20% decline in childhood cancer mortality rates 1999-2014

Figure 1. Cancer death rates for children and adolescents aged 1–19 years, by sex: United States, 1999–2014



NOTE: Decline in rates from 1999 through 2014 was statistically significant for all groups ($p < 0.05$). Access data table for Figure 1 at: http://www.cdc.gov/data/data/briefs/257_table.pdf.

SOURCE: NC-19, National Vital Statistics System, Mortality, ICD-10 underlying cause-of-death codes malignant neoplasms (C00-C97)

Cancer research leading to improved cancer treatment accounts for most of the improvement in childhood cancer

Implementation research and increased dissemination of standard of care

- Cancer health disparities: racial, socio-economic, demographic
- Linking proposed implementation research to a sustainable dissemination plan
- Blue Ribbon Panel recommendations:
 - Colorectal cancer screening
 - Tobacco cessation
 - HPV vaccination

Where we need to go

- Improve prevention, screening, and treatment to continue to bring down cancer mortality rates, including those cancers for which there has been limited progress
- Redouble our efforts to understand and overcome cancer health disparities
- Take full advantage of the opportunity to accelerate progress by working together on a wide range of projects, from the most basic to the most applied



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol