NCI Overview and Priorities

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ONS Capitol Hill Day
September 6, 2017
NIH Clinical Center

- Largest research hospital in the world
- Approximately 1600 clinical research studies in progress
- Over 600 nurses
- Recently featured in *First in Human*, a Discovery channel documentary
NCI Mission

NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.
Presentation Outline

• Organization and Budget
• Identifying Research Opportunities
• Priorities
• Special Initiatives
  • Cancer Moonshot
  • Precision Medicine
• The Future of Data
NCI Appropriations: 2013-2018 (in billions)

+$300 million for Cancer Moonshot*

*21 Century Cures Act authorized $1.8 billion over 7 years for the Beau Biden Cancer MoonshotSM Initiative
NCI is the Largest Funder of Cancer Research in the World

Approximately 75% of the NCI budget is distributed in extramural research grants & contracts

- **RPGs**
- **Contracts**
- **Centers & SPOREs**
- **Other**

*Includes training, resource, and conference grants*

*Such as cancer center grants*

Data from FY 2016 NCI Fact Book
Research and Funding

• Extramural Divisions
  • Division of Cancer Biology
  • Division of Cancer Control and Population Sciences
  • Division of Cancer Diagnosis and Treatment
  • Division of Cancer Prevention

• Intramural Research Program
  • Center for Cancer Research
  • Division of Cancer Epidemiology and Genetics

Identifying Research Opportunities

• Investigator Initiated Research

• NCI-wide Planning
  • The Annual Plan and Budget Proposal

• Division Planning and Priority Setting

• NCI Advisory Boards

• President’s Cancer Panel
NCI Annual Plan & Budget Proposal

• Communicates NCI’s best professional judgment on the optimum funding needed to make the most rapid progress against cancer

• Enabled by the National Cancer Act of 1971

“The time has come in America when the same kind of concentrated effort that split the atom and took a man to the moon should be turned toward conquering this dread disease.”

State of the Union Address, 1971

President Nixon signing the National Cancer Act of 1971

https://www.cancer.gov/about-nci/budget/annual-plan
FY 2019 NCI Annual Plan & Budget Proposal

Available now

https://www.cancer.gov/about-nci/budget/annual-plan

Available September 12th
FY 2019 NCI Annual Plan & Budget Proposal

- Vision for the future and research approaches
- Scientific areas for which additional support will enable more progress
FY 2019 NCI Annual Plan & Budget Proposal

Stories of Impact
Treating Cancer: Precision Immunotherapies

• **Progress**
  - 6 immune checkpoint inhibitors
  - Other immunotherapies also available (e.g., CAR-T)
  - Hundreds of new agents in development

• **More research needed**
  - Clinical response and resistance
  - Biomarkers
  - Combination therapies

“Without further research, we will never know why I am living and so many others have not benefited.”

T.J. Sharpe
Melanoma Survivor
FY 2019 NCI Annual Plan & Budget Proposal

Advancing Public Health: Body Weight & Physical Activity

• Progress
  • Survivor outcomes and quality of life
  • Risk of more than 12 types of cancer
  • Physical activity may benefit cancer survivors

• More research needed
  • Biological mechanisms
  • Effective interventions
  • Accurate measures

“It has led to a better, healthier life.”

Sue Wharfe
Breast Cancer Survivor
Research Priorities and Special Initiatives

• Priorities
  • Basic Research
  • Precision Medicine in Oncology
  • Cancer Research Health Disparities

• Cancer Moonshot

• Precision Medicine in Oncology
Goals:

• To investigate why certain populations are at increased risk of developing cancer at an early age, through the collection and characterization of malignancies
• To obtain genomic data from underrepresented populations
• To obtain information about treatment and response
• To generate data that can be used for future study
The Cancer Moonshot℠ Initiative

At the 2016 State of the Union Address the President called on the Vice President to lead a new, national “Moonshot” initiative to eliminate cancer as we know it

• Goals
  • Accelerate progress in cancer, including prevention & screening
    • From cutting-edge basic research to wider uptake of standard care
  • Encourage greater cooperation and collaboration
    • Break down silos within and between academia, government, and private sector
  • Enhance data sharing
    • Genomic Data Commons
    • Annotated patient-level clinical data and -omics
The Role of the NCI

• Established in April 2016
• Charged with recommending a limited number of initiatives poised to accelerate progress in cancer
• Formed Working Groups of scientists, clinicians, advocates

Identify and implement exceptional scientific opportunities that could be accelerated through the Moonshot Initiative
Blue Ribbon Panel Report

• The Final Report summarizes the recommendations of exceptional research opportunities that could lead to powerful advances in our understanding of cancer

• The online Report includes all recommendations in their entirety at www.cancer.gov/brp
Blue Ribbon Panel Recommendations

A. Establish a network for **direct patient involvement**
B. Create a translational science network devoted to **immunotherapy**
C. Develop ways to overcome **resistance to therapy**
D. Build a national cancer **data ecosystem**
E. Intensify research of the major drivers of **childhood cancer**
F. Minimize cancer treatment’s debilitating **side effects**
G. Expand use of proven **prevention and early detection** strategies
H. Mine past patient data to predict future **patient outcomes**
I. Develop a 3D **cancer atlas**
J. Develop new cancer **technologies**
Cancer Funding in 21st Century Cures Act

- The cancer research portion is named the Beau Biden Cancer Moonshot Initiative
- $1.8 billion over 7 years, with $300 million for FY17
- “To support cancer research, such as the development of cancer vaccines, the development of more sensitive diagnostic tests for cancer, immunotherapy and the development of combination therapies, research that has the potential to transform the scientific field that has inherently higher risk, and that seeks to address major challenges associated with cancer.”
Network for Direct Patient Engagement

- Enlist patients in federated network that includes patient tumor profiling data and “pre-registers” patients for clinical trials

- Develop a simple mechanism to provide comprehensive tumor profiling (genomics, immune cells, and microenvironment) for all high-risk and advanced stage cancer patients for a 5 year period

- Patients could be contacted for “smart-therapy” options

- Link to a novel, simple, and straightforward national consent to allow patients to “donate their data” on clinical outcomes so that profiling and clinical characteristics could be linked
Prevention and Early Detection
Implementation of Evidence-Based Approaches

• Implementation research to accelerate the adoption and deployment of evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings

• Recommendation would significantly impact cancer outcomes in the general population and among populations that experience persistent cancer disparities (e.g., low income, minority, rural, and other underserved populations)

• Coming Soon: ACCSIS FOA
  • Acceleration Colorectal Cancer Screening and Follow Up Through Implementation Science
Symptom Management Research

• Accelerate research that can identify approaches to monitor and manage patient reported symptoms, and integrate information to revise and update national guidelines for symptom control and support

• Recommendation would accelerate development of systems that collect patient self-reported symptoms to track patient outcomes to aid in revision of evidence-based guidelines and identification of gaps and new scientific questions in this area of research

• Coming Soon: PRO-CTCAE and IMPACT FOAs
  • Patient Reported Outcomes-Common Terminology Criteria for Adverse Events
  • Improving Management of Symptoms Across Cancer Treatments
Cross-Cutting Themes

• Health disparities research
• National network of patient biological and clinical data
• Prevention
• Data sharing, analytics, and predictive computational modeling
• Biomarkers
• Development of technology and preclinical models
• Collaboration; public-private partnerships
Stay Informed

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding
The Precision Medicine Initiative®

- Announced by the president at the 2015 State of the Union

“To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care.”

The right treatment for the right person at the right time
The All of Us℠ Research Program (formerly the PMI Cohort)

- One million or more volunteers, reflecting the broad diversity of the U.S.
- Opportunities for volunteers to provide data on an ongoing basis
- Data shared freely and quickly to inform a broad variety of research studies

Goal: Improve our ability to prevent and treat disease based on individual differences

https://allofus.nih.gov/
PMI in Oncology

• NCI-MATCH Trial
  • Molecular Analysis for Therapy Choice Trial

• Pediatric MATCH Trial

• Genomic Data Commons
NCI-MATCH Trial

- Largest Precision Medicine Trial to date
  - Nation-wide trial that matches the characteristics of an individual’s cancer with treatment
- Phase II basket trial run by ECOG ACRIN
  - Seeks to determine whether targeted therapies for people whose tumors have specific gene mutations will be effective regardless of their cancer type
- Enrollment closed, with the exception of the rare variants initiative
  - ~ 6400 patients screened in less than 2 years
  - 2/3 of accrual from NCORP sites
  - 25 treatment arms
NCI-MATCH Trial Goals

• Determine the percentage of patients whose tumors have a complete or partial response
  • Objective response rate
  • Treatments will be considered promising if 16% of patients in an arm have tumor shrinkage
• Determine the percentage of patients whose disease does not worsen for at least 6 months
  • Progression-free survival
• Will also determine time to progression and evaluate side effects
Bringing PMI to the People

NCI-MATCH* Has Enrolled Patients From All 50 States

U.S. Enrollment Per One Million People:

- 7 or less
- 8-30
- 30-65

*NCI-Molecular Analysis for Therapy Choice trial
NCI-Children’s Oncology Group Pediatric MATCH Trial

Pediatric MATCH is for patients ages 1 to 21 who have both:
- Solid tumors, including lymphomas and brain tumors, or histiocytoses
- Tumors that no longer respond to standard treatment or that have come back after treatment

Tumor tissue will undergo testing for changes in more than 160 genes.

If a patient’s tumor has a genetic change that matches one targeted by a drug used in the trial, the patient may be eligible to join the treatment arm targeting that genetic change.

Opened July 2017

About 200-300 pediatric patients are expected to be screened each year.

The trial is offered in the U.S. at about 200 children’s oncology group sites.

Call NCI’s Contact Center (formerly known as the Cancer Information Service) to learn more about the trial or trial locations at 1-800-4-CANCER (1-800-422-6237) for assistance in English and Spanish.

*The Pediatric Molecular Analysis for Therapy Choice (MATCH) trial is being led jointly by NCI and the Children’s Oncology Group (COG), part of the NCI-sponsored National Clinical Trials Network (NCTN).

cancer.gov/pediatricmatch

*Germline sequencing will accompany tumor sequencing.
NCI Genomic Data Commons (GDC)

• An expanding knowledge base for cancer that stores genomic and clinical data
  • Promotes and facilitates data sharing
  • Promotes strategies for tissue collection that ensure adequate quantity and high quality
  • Offer cutting edge bioinformatics tools
    • Researchers will be able to compare their data with other data using cloud computing capabilities
    • Will enable data sharing while assuring ownership is respected
PMI in Oncology

• Necessitates changes in clinical trials
  • Infrastructure, organization and design
• Large numbers of patients needs to be screen
  • Need to identify a group with a distinct molecular target to test a therapy
• Trial participants need to reflect real-world diversity
• Cancer Research Data Ecosystem
  • Evidence-based knowledge system
The Future of **DATA**

- Data access and data sharing are critical
  - Generating more data than ever before
  - More will be generated in the future
- Need strategies to collect additional data types
- Engage patients in research more directly
  - Donate data
  - Interact with data
  - Receive benefits

Expanding access to genomic and clinical data will accelerate cancer research and help improve the diagnosis and treatment of each cancer patient.

www.cancer.gov
SEER – Turning Cancer Data into Discovery

- Facilitates the collection and analysis of cancer statistics at the population level
- Authoritative source of information on cancer incidence and survival in the United States
- Used extensively to support research at NCI and beyond
  - Researchers use SEER to track trends in cancer at the national, state, and local levels; understand factors that influence these trends; and describe cancer disparities among different populations
NCI's comprehensive source of cancer information. It contains cancer information summaries on a wide range of cancer topics; drug information summaries on many cancer-related drugs and drug combinations; and dictionaries of general cancer terms, drug terms, and genetics terms.
Finding Clinical Trials

Coming Soon:
- Advanced search form on trials.cancer.gov
- Greater precision
- Facilitate the identification of relevant cancer clinical trials

Continued improvements planned
- Allow patients and providers to more readily find trials at the point of need
- Goal: to increase accrual to trials and accelerate the pace of cancer research
The Power of Interdisciplinary Health Care Teams

Together we can seize the opportunities before us and harness the commitment and determination of the entire cancer community to improve patient outcomes and reduce the burden of cancer.
Thank-you

LMBennett@nih.gov

Clinical Trials New Reforms and Initiatives

• All Research Involving Human Participants
  • New forms to collect human subjects information
  • Use of a single Institutional Review Board (IRB) for domestic multi-site studies

• Research that Meets the NIH Definition of a Clinical Trial
  • Training in Good Clinical Practice (GCP)
  • Clinical trial-specific Funding Opportunity Announcements (FOAs)
  • New review criteria
  • Expanded registration and results reporting in ClinicalTrials.gov
NIH Definition of a Clinical Trial

• A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

• Learn more at https://grants.nih.gov/policy/clinical-trials/definition.htm

• As of January 25th, 2018, if your study is a clinical trial you must apply to the clinical trials specific FOA
Determining if a Study is an NIH-Defined Clinical Trial

Does your study…

✓ Involve one or more human subjects?

✓ Involve one or more interventions?

✓ Prospectively assign human subject(s) to intervention(s)?

✓ Have a health-related biomedical or behavioral outcome?

If “yes” to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm
Interdisciplinary Health Care Teams

• Critical in health care today
• Demand for professionals knowledgeable about medicine, psychology, genetics, survivorship, data sharing, and technology who can work closely with patients is increasing
• There will be power in integrated interdisciplinary teams that work iteratively with patients to help them make informed decisions about their lifestyle, care, and follow-up

Together we can seize the opportunities before us and harness the commitment and determination of the entire cancer community to improve patient outcomes and reduce the burden of cancer
Divisional Planning and Priority Setting

Program Director (PD) develops an idea

Gathers information from:
- Workshops
- Conversations with the community
- RFIs
- Portfolio Analyses
- Literature Searches

PD obtains Division approval to develop a concept

Concept is presented to NCI Scientific Program Leadership Committee (SPL) for approval

Concept presented to Board of Scientific Advisors (BSA)

Approved concepts become Funding Opportunity Announcements (grants.nih.gov)
BRP Working Groups

- Cancer Immunology
- Clinical Trials
- Enhanced Data Sharing
- Implementation Science
- Pediatric Cancers
- Precision Prevention and Early Detection
- Tumor Evolution and Progression
Brushing the Airway to Detect Lung Cancer Earlier

“Percepta® is now a product because of NCI’s support.”

Avrum Spira, MD, MSc
Boston University

- More people die from lung cancer than any other cancer type
- CT screening can lead to false positives and invasive follow up tests
- NCI supported the basic science and small business commercialization of a less invasive, more accurate diagnostic test for lung cancer available to patients today