NCI Director’s Report

Clinical Trials and Translational Research Advisory Committee (CTAC)

Norman E. Sharpless, M.D.
November 10, 2021
Commemoration across the Community

Cancer Centers

- Commemoration of the 50th anniversary of the National Cancer Act of 1971.
- Highlighting 50 important innovations, people, and stories from our 50-year history.
- #WeSetTheMode #NothingWillStopUs

Cancer Organizations

- Lasker Foundation
  - Commenorates 50th anniversary of the National Cancer Act, which created the National Cancer Act program led by @DrLasker.

Govt. Organizations

- Remarks by President Joe Biden:
  - "On Nov. 20, 1971, President Richard Nixon signed the National Cancer Act, a landmark piece of legislation that set the stage for today’s advances."
NCI PROFESSIONAL JUDGMENT BUDGET PROPOSAL FOR FISCAL YEAR 2023
(DOLLARS IN MILLIONS)

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount (Millions)</th>
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<tbody>
<tr>
<td><strong>FISCAL YEAR 2021 NCI BASE APPROPRIATION</strong></td>
<td>$6,365*</td>
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<tr>
<td><strong>TOTAL BUDGET INCREASE (Proposed Allocation)</strong></td>
<td>$1,185†</td>
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<td>$277 Inflation Adjustment††</td>
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<tr>
<td>$165 Cancer Biology Research</td>
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<tr>
<td>$185 Cancer Prevention Research</td>
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<tr>
<td>$150 Cancer Detection &amp; Diagnosis Research</td>
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<tr>
<td>$205 Cancer Treatment Research</td>
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<tr>
<td>$125 Public Health &amp; Cancer Control Research</td>
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<tr>
<td>$78 Training &amp; Infrastructure</td>
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<tr>
<td><strong>FY 2023 BUDGET RECOMMENDATION</strong></td>
<td>$7,550</td>
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<tr>
<td><strong>FY 2023 CANCER MOONSHOT™ FUNDING</strong></td>
<td>$216</td>
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<tr>
<td><strong>FY 2023 TOTAL</strong></td>
<td>$7,766</td>
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National costs for cancer care were estimated to be

- $190.2 billion in 2015
- $208.9 billion in 2020

Modeled annual productivity cost from cancer mortality

- $147.6 billion for 2020

If you think research is expensive, try disease!

Mary Lasker

# NCI Appropriations

**FY 2015 – 2022 (in millions)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Appropriations (in millions)</th>
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<tbody>
<tr>
<td>FY 2015</td>
<td>$4,950</td>
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<tr>
<td>FY 2016</td>
<td>$5,215</td>
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<tr>
<td>FY 2017</td>
<td>$5,689</td>
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<tr>
<td>FY 2018</td>
<td>$5,965</td>
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<tr>
<td>FY 2019</td>
<td>$6,144</td>
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<tr>
<td>FY 2020</td>
<td>$6,440</td>
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<tr>
<td>FY 2021</td>
<td>$6,559</td>
</tr>
<tr>
<td>FY 2022</td>
<td>$6,733</td>
</tr>
<tr>
<td>FY 2023</td>
<td>$6,994</td>
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</tbody>
</table>

## 21st Century Cures Act - orange

Childhood Cancer Initiative - green

- + $306M COVID-19 serology (April 2020)

**FY 22 Continuing Resolution expires December 3.**
How does NCI spend its money?

Based on FY 2020 Actuals and excludes Cancer Moonshot funding.
FY 2020 Research Project Grants

Based on FY 2020 Actuals and excludes Cancer Moonshot funding.

R01 Traditional

R01 RFA

P01 Program Projects (Excludes RFA)

R21 (Excludes RFA)

R35

R37

U01, U19, U43, UM1, UH2, UH3, UG3 (Excludes RFA)

DP1, DP2, DP5, R15 (Excludes RFA)

RFA (Excludes R01 RFA)

Other (R33, R00, R03, R50, R56)

SBIR/STTR
• 163 trials
• N=108,102 patients
  → 30.9% (163/528) of estimated trials conducted
• Most common: Breast (33), gynecologic (28), lung (15), prostate (12)
• Trials cited 166,771 times
• 128 trials showed overall survival favoring the experimental arm

These trials were estimated to have generated gains of 14.0 million life-years to cancer patients.
NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible, faster, simpler, less expensive, high-impact** clinical trials that seamlessly integrate with clinical practice

Streamline processes for trial design and execution

Decrease regulatory hurdles and broaden trial access

Focus on essential endpoints

Increase efficiency of data collection
NCI Clinical Trials and Translational Research Advisory Committee Strategic Planning Working Group Overview

**Themes:**
- Trial Complexity and Cost
- Decentralized Trial Activities
- Promoting Accrual and Access
- New Data Collection Approaches
- PRO Data for Clinical Trials
- Operational Burden
- Statistical Issues
- Workforce Outreach and Training

**Actions:**
1. Re-assess strategic vision for clinical trials system for 2030 and beyond
2. Review and address necessary clinical trials infrastructure
3. Developed recommendations and initiatives - 15
   - 3 operational initiatives
Childhood Cancers

Childhood Cancer Data Initiative
Annual Symposium
November 9, 2021

Cancer Currents: An NCI Cancer Research Blog
Seeing a Promising Future for Progress against Childhood Cancer
September 16, 2021, by Norman E. Sharpless, M.D.

NCI Director Dr. Ned Sharpless discusses progress against childhood cancers, like CAR T-cell therapy and collecting more comprehensive data on children and adolescents with cancer, and the need to better address disparities in childhood cancer.
Cancer Moonshot℠

Cancer Cell July 12, 2021
Progress and Potential: The Cancer Moonshot
Norman E. Sharpless
Dinah S. Singer

DART: Dual Anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors
Recent results in angiosarcoma

DART | SWOG 1609
- Launched in 2017
- 53 cohorts based on condition
- Recruitment for some cohorts ongoing
Ibrutinib improves survival for younger people with diffuse large B-cell lymphoma

NCI Press Release: November 4, 2021

“People thought the trial didn’t work, but...if you just considered younger patients under the age of 60, they had a real benefit from ibrutinib.”

Louis M. Staudt, M.D., Ph.D., Chief Lymphoid Malignancies Branch, NCI

Highlights of NCI’s SARS-CoV-2 Serology Activities

Antibody test performance evaluation with FDA
• ~ 350 tests received; 130 evaluations completed

Work with All of Us showing timeline of early seroconversion in US

COVID-19 Seroprevalence Studies Hub (SeroHub)
https://covid19serohub.nih.gov/

Standard reference serum
• Standard shipped to >31 requestors; now shipping to more requestors referred by WHO (depleted supply)

First demonstration that antibody status correlates with reduced risk of infection

NCI COVID-19 in Cancer Patients Study (NCCAPS)
• >1200 adult and >75 pediatric COVID-19 patients enrolled
• >800 trial sites (all 50 States, DC, PR, Canada)
Repeated Cross-Sectional Sero-Monitoring of SARS-CoV-2 in New York City

Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals

Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants
Edara, et al. NEJM, August 12, 2021

Humoral signatures of protective and pathological SARS-CoV-2 infection in children

Durable Humoral and Cellular Immune Responses 8 Months after Ad26.COVID2.S Vaccination

• 8 U54 Centers of Excellence
• 13 U01 Research Projects
• 4 Capacity Building Centers (contracts)
• FNL Serology Lab & Network Coordinating Center
• >90 publications; >30 preprints
CUSP2CT Connecting Underrepresented Populations to Clinical Trials

PURPOSE
To implement and evaluate multi-level and culturally tailored outreach and education interventions with the primary goal to increase referral of racial/ethnic minority populations to NCI-supported clinical trials.

CUSP2CT Network FY 22-26
• Data, Evaluation, and Coordinating Center 1 U24: RFA-CA-21-057
• Resource-Related Research Projects Up to 4 U01s: RFA-CA-21-058

Due November 19, 2021
# NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Initiative</th>
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<tbody>
<tr>
<td>Morehouse School of Medicine</td>
<td>FIRST Coordination and Evaluation Center to promote inclusive excellence (U24)</td>
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<tr>
<td>Cornell University</td>
<td>Cornell FIRST</td>
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<tr>
<td>Icahn School of Medicine at Mount Sinai</td>
<td>NIH FIRST Cohort Cluster Hiring Initiative at Icahn School of Medicine at Mount Sinai</td>
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<tr>
<td>Drexel University</td>
<td>Catalyzing Systemic Change at Drexel University to Support Diverse Faculty in Health Disparities Research</td>
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<tr>
<td>University of Alabama at Birmingham</td>
<td>UAB/Tuskegee Faculty Institutional Recruitment for Sustainable Transformation (UAB/TU FIRST) Partnership</td>
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<tr>
<td>Florida State University</td>
<td>Fostering Institutional Resources for Science Transformation: The FLORIDA-FIRST Health-Science Brigade</td>
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<tr>
<td>San Diego State University</td>
<td>SDSU FUERTE: Faculty United towards Excellence in Research and Transformational Engagement</td>
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Cancer Diagnostic Devices (CD2) Interagency Task Force

The CD2 Task Force will
- Coordinate scientific and programmatic collaborations
- Discuss areas of regulatory and technical challenges to translation and implementation of cancer screening and diagnostic devices for near patient use
- Efforts will emphasize challenges of rural and medically underserved communities

VIRTUAL SIGNING CEREMONY
FRIDAY, SEPTEMBER 17, 2021

NIH NATIONAL CANCER INSTITUTE
FDA U.S. FOOD & DRUG ADMINISTRATION
HRSA
U.S.-U.K. Bilateral Cancer Summit

“We will bring together researchers, patients, and other stakeholders to share ideas and identify opportunities for collaboration to accelerate advances in lifesaving approaches to cancer, which remains a leading cause of death worldwide.”

Joint statement, June 10, 2021

- Scientific Summit – November 2021
- Leadership Summit – Spring 2022
Updates to NCI Training Programs

• Increased flexibility for surgeon-scientists under the K08 career development program

• Changes to stimulate greater inclusion and innovation within the T32 grant program for institutional research training

• Details of a new Early-Stage Surgeon-Scientist Program, to encourage surgeon-scientists to pursue careers in cancer science.
Division of Cancer Control and Population Sciences Leadership

Robert T. Croyle, Ph.D.
Director
NCI Division of Cancer Control and Population Sciences
Retiring December 2021

Katrina Goddard, Ph.D.
Kaiser Permanente Center for Health Research
Incoming DCCPS Director pending final reviews
Discussion