

NCI Director's Report: Opportunities and realities for clinical cancer research

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53rd Meeting of the Clinical Trials and Translational Research Committee

March 13, 2024

@NCIDirector
@TheNCI

Today's Topics:

1. Brief introduction
2. Budget outlook
3. Research highlights
4. Q&A

A little about me

Background in brief:

- Scientist
- Clinician, oncologist
- Educator/mentor
- Health care management and administration
- Leader
- Advocacy
- Basketball player (and aficionado)

Principles I value



Listening, openness



Teamwork, collaboration



Solving complex problems

Patient story



A story about science, collaboration, and impact



Meeting and
treating “Paul”



Connecting with
advocates through
social media



Think tank
meeting



Creating RMC Alliance



IMPACT:
Improved health outcomes,
clinical trials, information,
visibility, education, grants

Budget outlook

Where we are today (for FY24)



Potential lapses in appropriation averted:

September 30, 2023
November 17, 2023
February 2, 2024
March 8



Current Continuing Resolution expires March 22
(halfway through the fiscal year).



Interim grant policies have been set.
Final adjustments will be made when NCI receives a full-year appropriation.

NCI's budget is determined within the federal budget ecosystem

alongside many other
national priorities

Appropriations bills for FY24

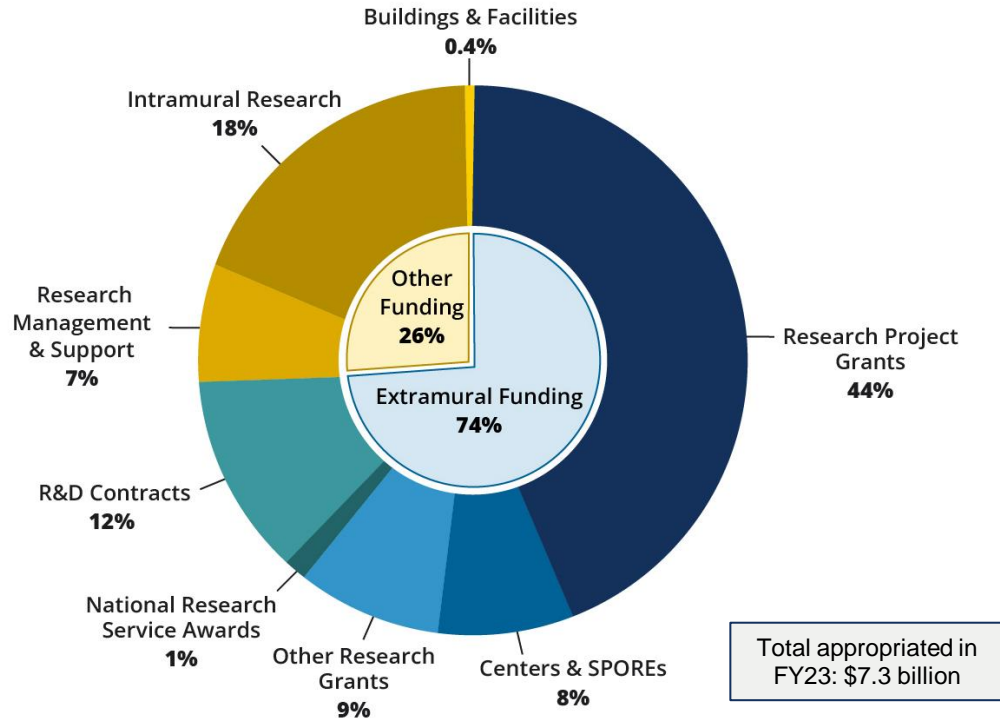
Completed on March 9

- Agriculture, Rural Development, FDA, and Related Agencies
- Commerce, Justice, Science, and Related Agencies
- Energy and Water Development
- Interior, Environment, and Related Agencies
- Military Construction, Veterans Affairs, and Related Agencies
- Transportation, Housing and Urban Development, and Related Agencies

Pending (continuing resolution through March 22)

- Defense
- Financial Services and General Government
- Homeland Security
- ***Labor, Health and Human Services, Education, and Related Agencies***
- Legislative Branch
- State, Foreign Operations, and Related Programs

How NCI spends its budget



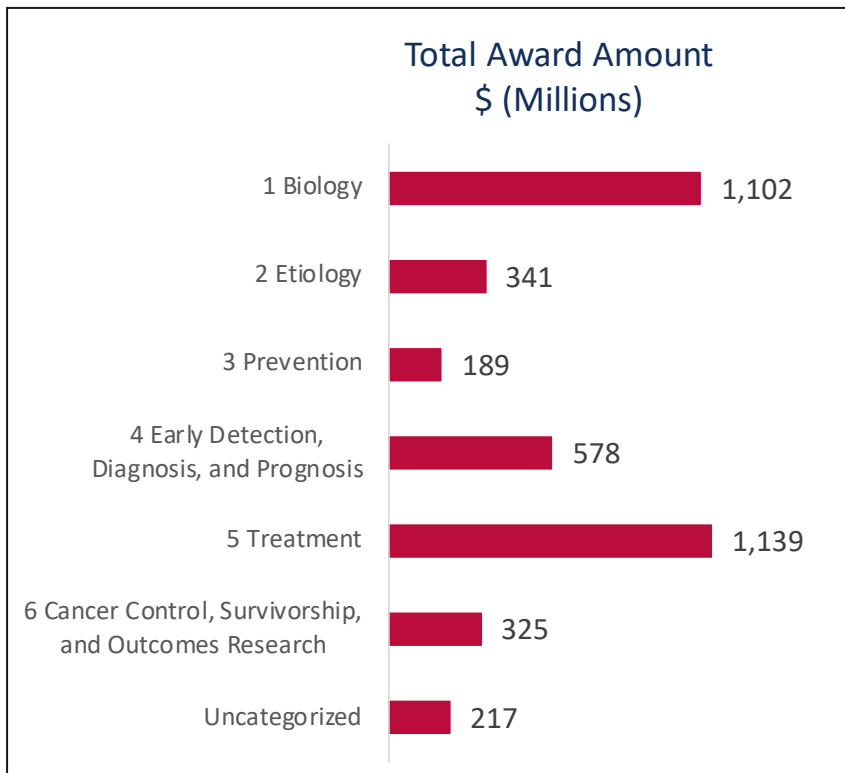
Major areas of NCI's work span more than one of the categories in the chart:

- Clinical trials
- Training & career development
- Basic science

These efforts are funded through multiple mechanisms and approaches, including:

- Intramural research
- Extramural research
- National networks
- Research project grants

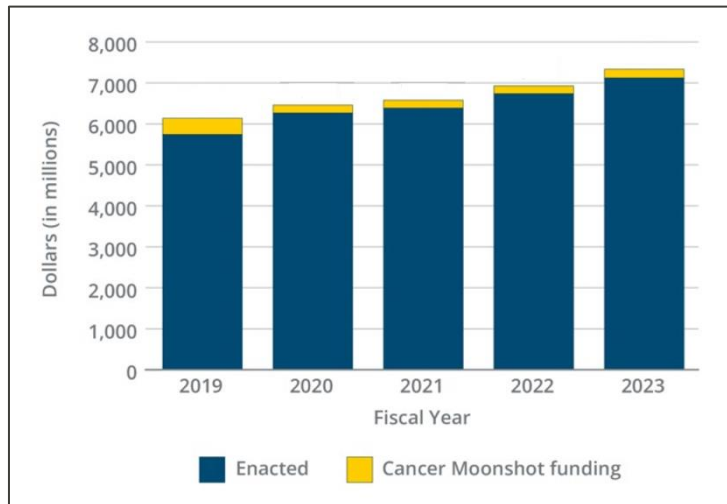
FY22 Total Award Amount for RPGs by Category



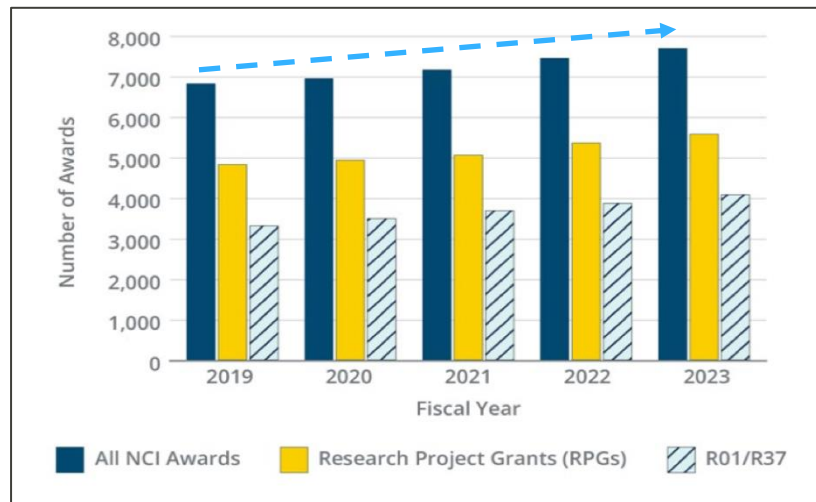
CSO category of Treatment is the largest total category followed closely by Biology

NCI has been funding more awards year over year

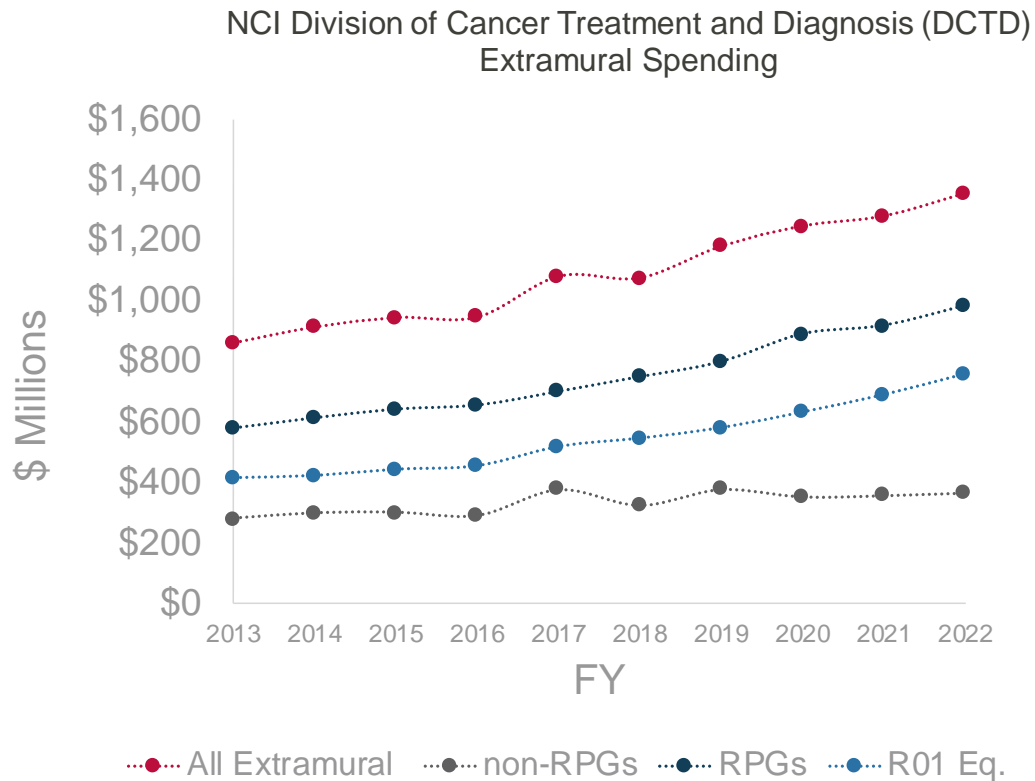
NCI Budget History (appropriations)
FY19 – FY23



NCI Grant Awards (competing and non-competing)
FY19 – FY23



DCTD Extramural Grant Award Amounts: FY13-FY22



Example: Opportunities for Collaborative Research at the NIH Clinical Center (U01 Program)

Opportunities for Collaborative Research at the NIH Clinical Center (U01 Program)

Purpose of U01 funding opportunity:

- Support **collaboration between intramural and extramural** investigators
- **Allow extramural investigators to take advantage of the NIH Clinical Center** – unique resources and patient populations

FY13-FY24	No. of Applications Received	No. of Awards Granted	% Accepted
NIH	302	63	21%
NCI	134	25	19%

NCI administers:

- 44% of all U01 applications
- 40% of all U01 competing awards

The number of NCI U01 applications has remained consistent since 2014.

U01 Program: Examples that tap the Clinical Center

- Unique biospecimen resources
- State of the art imaging and testing facilities
- Rare disease populations
- U01 is an important mechanism for collaboration between the intramural and extramural community



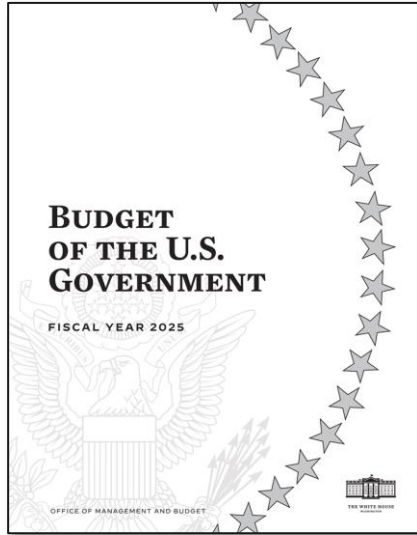
NIH Clinical Center

What it would cost to do what we expect for cancer

	NCI's Professional Judgment Budget Proposal	Actual NCI Budget
FY 2024	\$9.988B	?
FY 2025	\$11.466B	?

- *FY 2023 total appropriation: \$7.3 billion*

FY 2025 President's Budget Proposal released this week



FY 2025 President's
Budget Proposal

\$7.839B (discretionary)
+ \$1.448B (mandatory)
= \$9.287B total

- Proposes \$716M of discretionary funding for Cancer Moonshot
- Proposes \$1.448B of mandatory funding for Cancer Moonshot

NCI Fiscal Year 2025 Professional Judgment Budget Proposal

NIH NATIONAL CANCER INSTITUTE



Leading Progress against Cancer
NCI Fiscal Year 2025 Professional Judgment Budget Proposal

View the budget proposal and the Director's Message:
www.cancer.gov/research/leading-progress

Highlighted Scientific Opportunities

- Improving patients' lives through symptom science research
- Revolutionizing cancer clinical trials
- Clarifying the impact of the environment on cancer risk
- Harnessing the power of cancer data
- Unraveling the complexity of cancer metastasis

A “flat” budget is not truly flat – it is a reduction

Why?

- End of 21st Century Cures Act funding for the Cancer MoonshotSM
- Research costs and salaries increase (COLA)
- Non-negotiable expenses for NCI increase each year by \$75M to \$100M
- RPG cost increases \$250M annually to fully fund at current levels

Available levers to manage constrained budget:

Research Project Grants (RPGs)

- Decrease the “payline” for new awards
- Fund non-competing awards < 100%

Cancer Center Support Grants (CCSGs)

- Forgo increases for competing renewals
- Decreases to non-competing CCSGs

Cancer Training Awards

- Fewer new awards (F’s, K’s, T’s)

Specialized Programs of Research Excellence (SPORE) Grants

- Fewer new awards
- Decreases to non-competing awards

Intramural Research Program

- Planned budget reductions
- Reduced hiring
- Decreased contractor utilization
- Trim programs

Resources about NCI budget and appropriations



Sept. 6, 2023 NCAB meeting: NCI budget overview
www.videocast.nih.gov/watch=52268&start=3723

NCI's Fiscal Year 2024 Budget Challenges and Interim Paylines Explained

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November 15, 2023, by NCI Acting Director, Dr. Douglas R. Lowy

UPDATE: Since this blog was posted on November 15, Congress passed another short-term continuing resolution that extends funding for the National Institutes of Health at last fiscal year's budget levels through February 2, 2024. In this post, NCI Acting Director Dr. Lowy describes key challenges that this "flat" budget presents to NCI and its effects on NCI's ability to support cancer research. He also discusses newly announced interim paylines for competing grants.



NCI *Bottom Line* blog post on FY24 budget outlook:
www.cancer.gov/grants-training/nci-bottom-line-blog/



Updated budget and appropriations page:
www.cancer.gov/about-nci/budget



NCI Fiscal Year 2025
Professional Judgment Budget Proposal:
www.cancer.gov/research/leading-progress

National Cancer Plan

Everyone has a role.

8 goals:

Prevent Cancer

Detect Cancers Early

Develop Effective Treatments

Deliver Optimal Care

Maximize Data Utility

Eliminate Inequities

Optimize the Workforce

Engage Every Person



THE PRESIDENT AND FIRST LADY'S

CANCER MOONSHOT

ENDING CANCER AS WE KNOW IT

Goals of the reignited Cancer Moonshot

- Reduce U.S. cancer mortality rate by 50% by 2047
- Improve the experience of people and their families living with and surviving cancer

Recent wins – some examples

Recent wins and accomplishments in cancer research

- ✓ First FDA approval of **cell therapy in solid tumors** (tumor-infiltrating lymphocytes, TILs, for advanced melanoma)
- ✓ New “SHIP” Trial Network announced: **Self-collection for HPV testing** to Improve Cervical Cancer Prevention
- ✓ New **Cancer Screening Research Network** launched
- ✓ New **NCI Virtual Clinical Trials Office** launched
- ✓ Announcement of new **Cancer Grand Challenges** teams and challenges

(More details in following slides.)

*More at NCI Cancer Currents blog:
www.cancer.gov/blog*

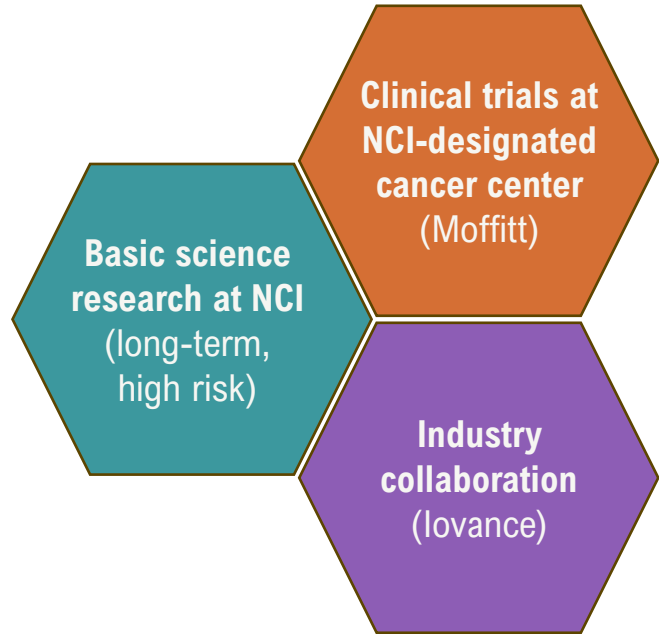
Breakthrough in cellular therapy for solid tumors – pioneered by decades of NCI research

Tumor-infiltrating lymphocytes (TILs) for advanced melanoma

- **First-ever FDA approval of cellular therapy for solid tumors**
- Marks a new era of cancer treatment

Exemplary model of collaboration and translational science:
basic science > clinical research > treatment development

Considerations: Scaling; application to other cancers; access



Contributes to National Cancer Plan goals:



Pioneered by Dr. Steven A. Rosenberg
NCI Center for Cancer Research

- ~40 years of basic science research

Breakthrough in cellular therapy for solid tumors – pioneered by decades of NCI research

First Cancer TIL Therapy Gets FDA Approval for Advanced Melanoma

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March 5, 2024, by Carmen Phillips

In an event more than three decades in the making, the Food and Drug Administration (FDA) has approved lifileucel (Amtagvi), the first treatment for cancer that uses immune cells called tumor-infiltrating lymphocytes, or TILs. Announced on February 16, the agency's decision also makes lifileucel the first cellular therapy to be approved for a solid tumor, the skin cancer melanoma.

The agency's accelerated approval covers the use of lifileucel for people with advanced melanoma that has gotten worse after treatment with certain immunotherapy drugs or targeted therapies.



FDA has approved the first treatment for cancer that uses tumor-infiltrating lymphocytes, or TILs.

Credit: National Cancer Institute



Cancer Currents: An NCI Cancer Research Blog

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Read full story at:
www.cancer.gov/blog

New “SHIP” trial network on self-sampling for cervical cancer prevention announced at White House (January 25, 2024)



JANUARY 31, 2024

Readout of White House Cervical Cancer Forum

Last week, the Biden Cancer Moonshot hosted the White House Cervical Cancer Forum to recognize Cervical Cancer Awareness Month and spur action on education, prevention, early detection, and treatment.

As part of the Forum, National Cancer Institute (NCI) Director Kimryn Rathmell announced a new NCI-supported trial to drive progress on cervical cancer prevention. The brand new ‘Last Mile’ Initiative, Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) Trial Network aims to test the performance of multiple self-collection devices for HPV, the leading driver of cervical cancer, so that cervical cancer screening can be brought closer to the people in the communities that are behind on screening.



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www.whitehouse.gov/briefing-room

Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) Trial Network

- Great example of:
 - ✓ **Broad collaboration** – within research and beyond, including federal and private sector
 - ✓ **Addressing disparities**
 - ✓ **Engaging with the community**, beneficiaries of research

Contributes to National Cancer Plan goals:



First large scale network on cancer screening launched

NCI Press Release

NIH launches research network to evaluate emerging cancer screening technologies

February 21, 2024



Goal: To evaluate emerging cancer screening technologies (e.g., multi-cancer detection blood tests) – with the ultimate aim to save lives.

CSRN is the first large scale network to focus on cancer screening.



Contributes to National Cancer Plan goals

New NCI Virtual Clinical Trials Office pilot program

NCI Media Advisory

NIH to address dwindling clinical trial patient enrollment with centralized staffing support

February 29, 2024



Image: iStock

What:

- Centralized, remote staff support for NCI-supported clinical trials activities

Aims:

- **Improve accrual and retention rate** to trials – by addressing staffing challenges and burdens of clinical research

Status:

- 6 sites selected for initial pilot phase

Contributes to National Cancer Plan goals:



Childhood Cancer Data Initiative (CCDI) continues to make progress toward National Cancer Plan goals

- Recent progress
 - **Molecular Characterization Initiative (MCI) expands enrollment** to children newly diagnosed with **advanced stage neuroblastoma**
 - Includes **Renal Medullary Carcinoma (RMC)**
- Upcoming events
 - **March CCDI Community Forum (3/18)** – interactive Q&A for community input



CCDI continues to make important contributions to National Cancer Plan goals

WHAT IS THE CCDI MOLECULAR CHARACTERIZATION INITIATIVE?

- Provides state-of-the-art **molecular characterization at time of diagnosis** to inform optimal treatment decisions.
- A **national collaboration** between:
 - ✓ Childhood cancer community (including COG)
 - ✓ Advocates
 - ✓ Pediatric oncologists
 - ✓ Researchers
 - ✓ Data scientists
 - ✓ Children, adolescents, and young adults with cancer
 - ✓ Families

Cancer Grand Challenges

New teams announced

CANCER
GRAND
CHALLENGES



Five teams, four challenges:

Reducing **cancer inequities**

Understanding mechanisms of **early-onset cancers**

Developing drugs for **solid tumors in children**

Broadening knowledge about how **T cells** recognize cancer cells

About Cancer Grand Challenges

- Global funding initiative to advance **bold cancer research**
- Co-founded by NCI and Cancer Research UK (CRUK) in 2020
- Each team receives up to \$25M over five years
- New awardees:
 - Span 12 countries
 - Represent 45 institutions
 - Include ~70 investigators and researchers

What I need from CTAC...

Guidance on the clinical research portfolio

- NCTN/NCORP
- ETCTN
- CSRN
- NCI Clinical Center
- Funded clinical research portfolio, SPOREs, CCSG
- Training in clinical research (T32, K12, others)
- Community engagement in clinical research priority setting

Simply...

- Are there areas we are missing?
- Are we in spaces that are better served by foundations or industry?
- Are we resourcing programs so that they can be successful?

Closing thoughts

Given the budget realities...

We must work together – creatively, collaboratively, and efficiently – to make the best decisions given the tough reality.

Our work is ultimately for the benefit of people, patients and families touched by cancer.

We will use the National Cancer Plan as our roadmap toward ending cancer as we know it.



*Working together to assemble puzzle.
Image generated by AI.*

Thank You!

www.cancer.gov

www.cancer.gov/espanol

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