Cancer Moonshot Accomplishments and New Opportunities

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June 8, 2023

126th Meeting of the Advisory Committee to the Director (ACD), NIH





About the Cancer Moonshot

- Initial launch in 2016 to:
 - Accelerate cancer research
 - Foster greater collaboration
 - Enhance data sharing
- Major progress made in implementing recommendations of the Blue Ribbon Panel
- Reignition by President Biden in February 2022
- New goals announced:
 - Reduce the cancer death rate by 50% in the next
 25 years (in the U.S.)
 - Improve the experience of people and their families living with and surviving cancer

GG

For the lives we can save and for the lives we have lost, let this be a truly American moment that rallies the country and the world together and proves that we can still do big things.

Let's end cancer as we know it and cure some cancers once and for all.



President Biden February 7, 2023

President's NCI Budget for Fiscal Year 2024

\$7.8B
TOTAL

President's budget proposal for NCI for FY 2024

+ \$500M

Cancer Moonshot increase (relative to FY 2023 enacted)

+ \$216M

Included for "Year 8" of 21st Century

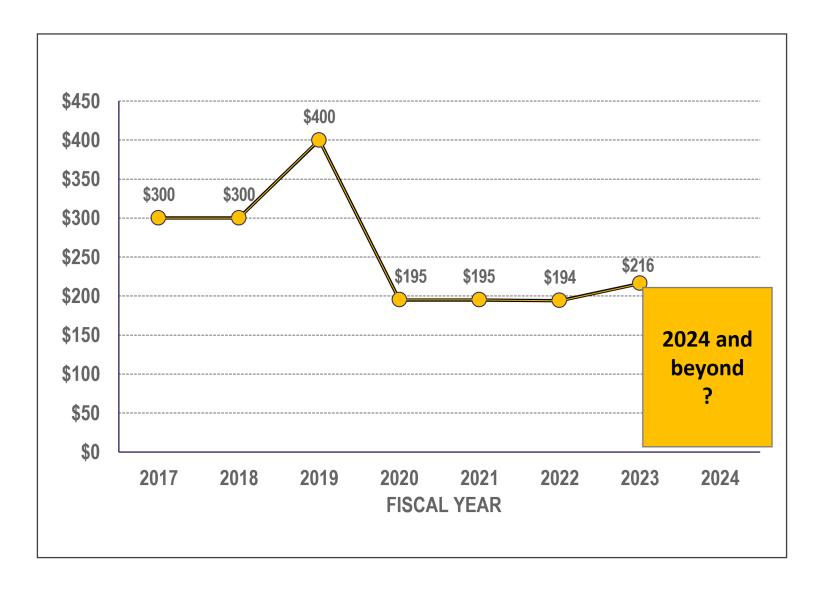
Cures Act (to prevent funding gap/"cliff")

= \$716M

As discretionary resources for Cancer Moonshot (no-year funds)

The Biden Administration is proposing a further increase of \$1.45 billion in mandatory budget authority for both FY25 and FY26.

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



Examples of Progress Made Through the Initial Cancer Moonshot

Initial Cancer Moonshot

Blue Ribbon Panel Recommendations

- 1. Establish a network for direct patient involvement
- 2. Create a translational science network devoted exclusively to immunotherapy
- 3. Develop ways to overcome cancer's resistance to therapy
- 4. Build a National Cancer Data Ecosystem
- 5. Intensify research on the major drivers of childhood cancers
- 6. Minimize cancer treatment's debilitating side effects
- 7. Expand use of proven cancer prevention and early detection strategies
- 8. Mine past patient data to predict future patient outcomes
- 9. Develop a 3-D cancer atlas
- 10. Develop new cancer technologies

In the first four years (2017–2022):



~3,000 publications



61 clinical trials

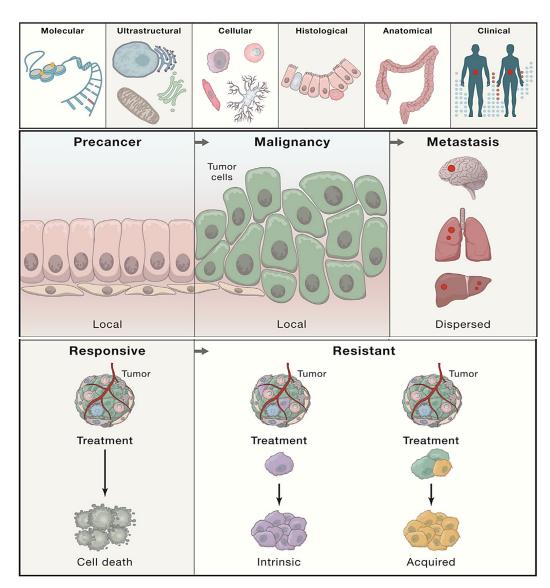


52 patent filings

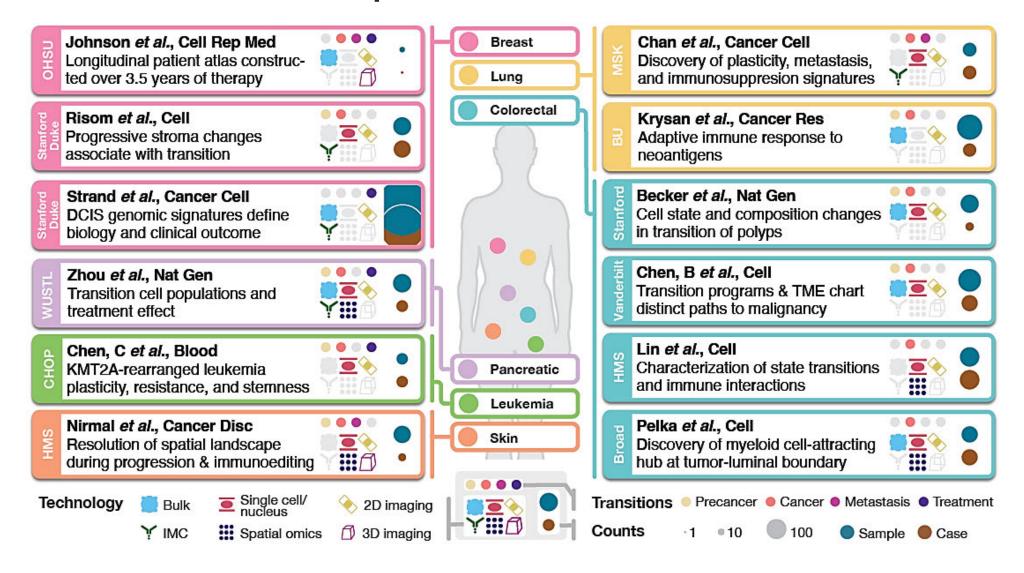
The NCI Human Tumor Atlas Network (HTAN)

Program goal: Construct dynamic 3D atlases of human cancers

- Integrate molecular, cellular, and tumor tissue composition and architecture, including the microenvironment and immune milieu
- Describe transitions during cancer: pre-malignant lesions to malignancy, locally invasive to metastatic cancer, response to therapy and development of resistance
- Enable predictive modeling to discover biomarkers, understand basic cancer mechanisms, (eventually) refine therapeutic choices for patients
- Represent a diverse patient population, including underrepresented and underserved patients



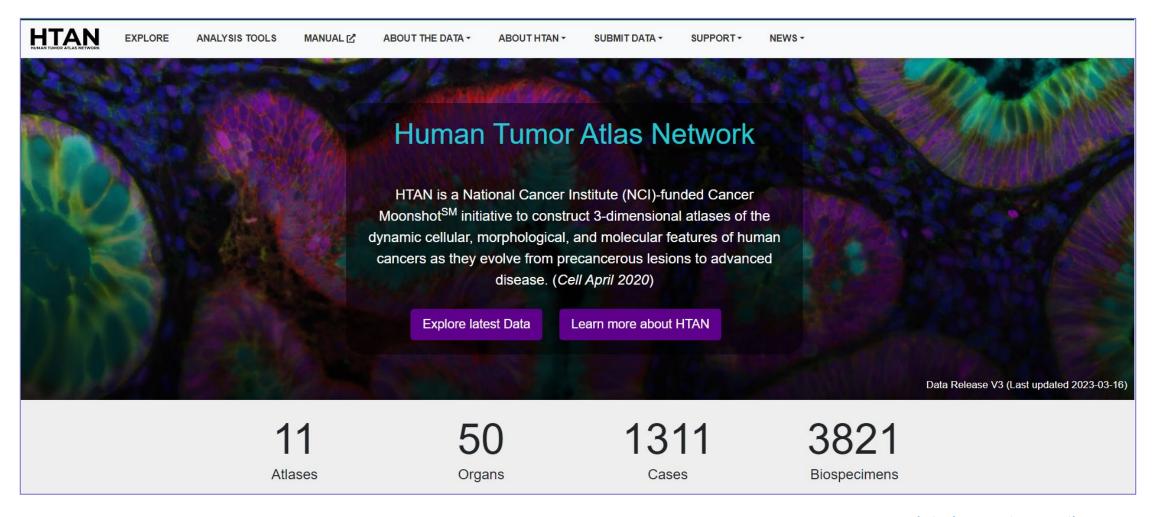
HTAN Atlases as of April 2023



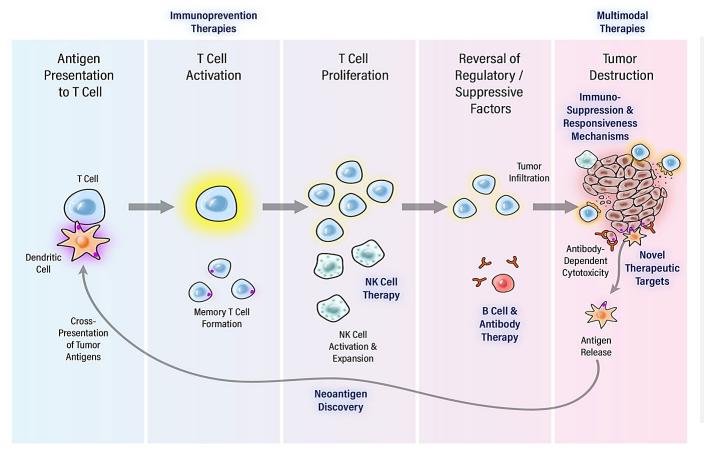
Key scientific accomplishments of the HTAN pilot phase

- Discovery of tumor architecture and recurrent cellular neighborhoods as biomarkers of recurrence, progression, and response to therapy.
- Description of the dynamics of stromal and immune organization in precancer.
- Identification of rare cell states that that predict tumor metastasis or response to therapy.
- Spatial mapping of tumor and microenvironment co-evolution.
- Development of analysis and visualization tools for HTAN-like data.

HTAN data and resources available for the cancer research community



Immuno-Oncology Translational Network (IOTN) Scientific Goals The IOTN is addressing critical control of the IOTN is addressing control of the IOTN is addressed to the IOTN is



The IOTN is addressing critical steps toward achieving effective anti-tumor immunity

- Neoantigen Discovery: Alternative splicing, TCR approaches with IEDB
- NK Cell Therapy: Engineering iNKTs
- B Cell and Antibody Approaches: Targeting tertiary lymphoid structures
- Immunosuppression and Responsiveness: Immune profiling and murine models
- Novel Therapeutic Targets: Gly-TR, MUC-1
- Multimodal Therapies: Combined immunoRx with other drug therapy, radiotherapy

IOTN Key Accomplishments

- Established a translational science network collaboratively addressing immunotherapy, immunoprevention, immunoengineering and mitigating immune related adverse events (irAEs) research
- Created publicly available data and resource sharing catalogs, including data, pre-clinical mammalian models, software, clinical trials and educational resources
- Published 410 manuscripts in high impact journals
- The IOTN Clinical Trials Task Force (CTTF) has collaborated with Accelerating Anticancer Agent Development and Validation (AAADV, https://aaadv.org/) to bridge the gap in clinical development of immuno-oncology platforms

Fusion Oncoproteins in Childhood Cancer (FusOnC2) Consortium

Intensify research on the major drivers of childhood cancers

Goal: To learn more about the molecular mechanisms of transformation driven by fusion oncoproteins and apply this knowledge to target identification, small molecule inhibition, and pre-clinical testing.

Multidisciplinary team science approach:

- proteomics
- structural biology
- genomics/epigenomics
- medicinal chemistry
- experimental therapeutics
- cancer biology

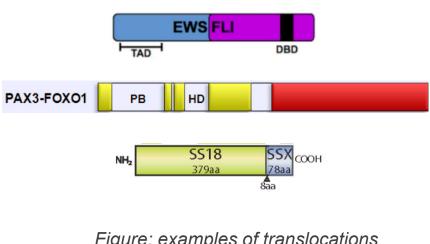
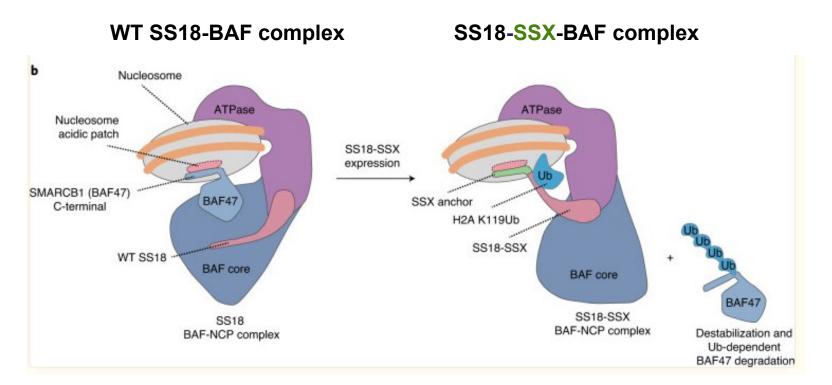


Figure: examples of translocations currently being studied

Shared Mechanism of Fusion-Driven Oncogenesis: Co-opting the Transcriptional Regulation Machinery

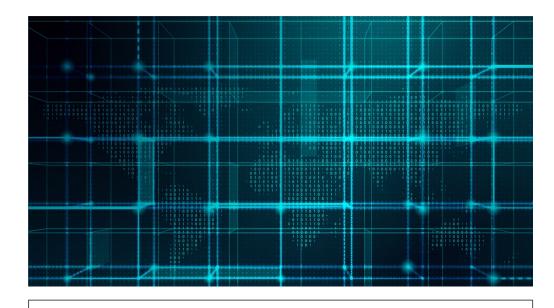


- SS18-SSX
- NUP98-rearrangements
- ZTFA-RELA

Data Sharing is Critical to Achieving our Goals

Available to the global scientific community via the Cancer Research Data Commons:

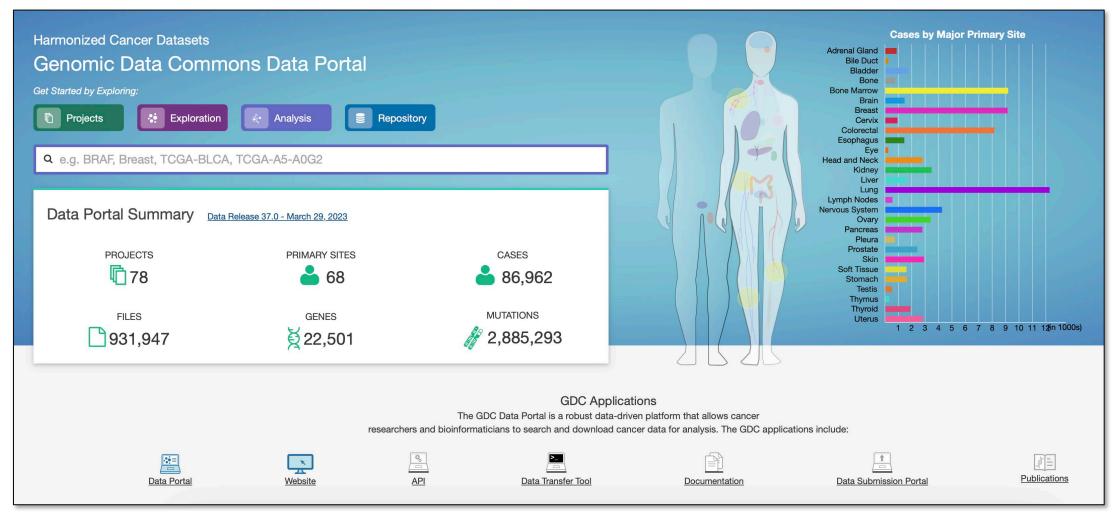
- Repositories (Genomic Data Commons, Imaging Data Commons, etc.)
- Infrastructure
- Cloud Resources



Fueled by the Cancer

Moonshot
and in service of the National
Cancer Plan's goals

Genomic Data Commons





Actions laid out by the White House to drive us toward ending cancer as we know it today:

- Diagnose cancer sooner
- Prevent cancer
- Address inequities
- Target the right treatments to the right patients
- Seed progress against the most deadly and rare cancers, including childhood cancers
- Support patients, caregivers, and survivors
- Learn from all patients

Cancer Cabinet



The first Cancer Cabinet Meeting, at the White House on March 16, 2022.

"[The Cancer Cabinet will] drive a whole-of-government effort to unleash every possibility within our power, within their jurisdictions."

-President Joe Biden



Fact Sheet: White House Announces Initial Steps for Reignited Cancer Moonshot

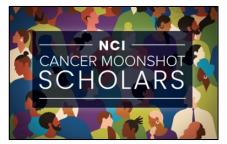
MARCH 17, 2022

PRESS RELEASES

Reignited Cancer Moonshot Activities



Telehealth Research Centers of Excellence (TRACE)



Cancer Moonshot Scholars



Multi-Cancer Detection (Vanguard Study)

Achieving the Cancer Moonshot Goals

REDUCE CANCER
MORTALITY BY AT LEAST

50%
over the next 25 years

and improve the experience of people and their families living with and surviving cancer.



SOURCE: Shiels M, et al. Cancer Discovery. 2023

National Cancer Plan

NationalCancerPlan.cancer.gov

Cancer Plan



Everyone has a role.

April 3, 2023

U.S. Department of Health & Human Services | National Institutes of Health | National Cancer Institute





Describes goals, strategies, and actions needed to end cancer as we know it

- Long-term vision for ending cancer as we know it
- A framework for collaboration
- All-of-government approach
- All-of-society approach
- Inclusive of everyone (organizations and individuals)

- Not a medium-term strategic/action plan
- Not confined to research includes care, advocacy, policy, individual behaviors

Learn more: NationalCancerPlan.cancer.gov

Prevent Cancer

All people and society adopt proven strategies that reduce the risk of cancer

Deliver Optimal Care

The health care system delivers to all people evidence-based, patient-centered care that prioritizes prevention, reduces cancer morbidity and mortality, and improves the lives of cancer survivors, including people living with cancer

Detect Cancers Early

Cancers are detected and treated at early stages, enabling more effective treatment and reducing morbidity and mortality

Engage Every Person

Every person with cancer or at risk for cancer has an opportunity to participate in research or otherwise contribute to the collective knowledge base, and barriers to their participation are eliminated.

Develop Effective Treatments

Effective treatment, with minimal side effects, is accessible to all people with all cancers, including those with rare cancers, metastatic cancers, and treatment-resistant disease

Maximize Data Utility

Secure sharing of privacy-protected health data is standard practice throughout research, and researchers share and use available data to achieve rapid progress against cancer

Eliminate Inequities

Disparities in cancer risk factors, incidence, treatment side effects, and mortality are eliminated through equitable access to prevention, screening, treatment, and survivorship care

Optimize The Workforce

The cancer care and research workforce is diverse, reflects the communities served, and meets the needs of all people with cancer and those at risk for cancer, ensuring they live longer and healthier lives

Examples of NCI's Contributions to Our Shared Goals



- Pragmatica-Lung Study (S2302)
- Clinical Trials
 Innovation Unit (CTIU)



- Connecting
 Underrepresented
 Populations to Clinical Trials
 (CUSP2CT)
- Telehealth Research Centers of Excellence (TRACE)



- Childhood Cancer–Data Integration for Research, Education, Care, and Clinical Trials (CC-DIRECT)
- NCI Community Oncology Research Program (NCORP)

CC-DIRECT: Childhood Cancer Data Integration for Research, Education, Care and Clinical Trials program

Major components

- Standardized electronic health record
- Patient navigation services

Status

- Currently in planning stages
- As the project evolves, there will be opportunities for provider and advocacy communities to be involved

Stay informed: <u>nciadvocacy@nih.gov</u>



- **National Cancer Institute**
- Centers for Medicare and Medicaid Services
- Office of the National Coordinator for Health Information Technology
- Alliance for Clinical Trials in Oncology
- American Cancer Society
- American Society of Clinical Oncology
- Children's Oncology Group
- MITRE Corporation

Clinical Trials Innovation Unit (CTIU)



The CTIU will:

- Select a few high-priority studies for new study designs and operational procedures
- Help speed clinical testing to deliver new approaches for diagnosis, treatment, and prevention of cancer
- Accept inputs from the extramural research community
 - ✓ First proposal submission deadline: June 12

CTIU leadership includes representatives from NCI, FDA, NCTN, and NCORP

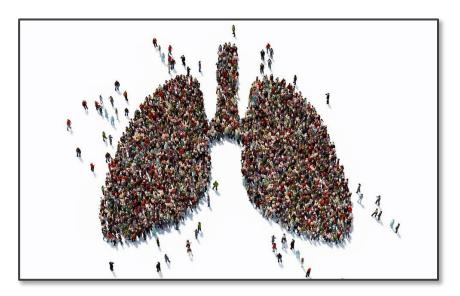
Pragmatica-Lung Study (S2302)

A streamlined model for future cancer clinical trials

Designed to:

- Eliminate potential barriers to enrollment
- Increase diversity and enrollment in clinical trials
- Streamline processes for trial design and execution
- Use focused endpoints and efficient data collection
- Complete enrollment of 700 participants, by 2025

Led by SWOG Cancer Research Network, in collaboration with the Alliance for Clinical Trials in Oncology





Purpose: Evaluate whether ramucirumab + pembrolizumab combination therapy improves overall survival over standard treatment in people with advanced NSCLC.

Public Engagement

- Read the National Cancer Plan: nationalcancerplan.cancer.gov
- Follow @theNCI & @NCIDirector
 on social media and use
 #Every1HasARole and
 #NationalCancerPlan
- Subscribe for email updates to learn about ways to engage with the plan





theNCI @theNCI

Imagine a where most cancers can be prevented. #Every1HasARole in the #NationalCancerPlan to make that world a reality. Read the plan to learn what you can do to end cancer as we know it today.

http://bit.ly/40MAsJt #Can



National Plan



Everyone has a role.

Thank you!

www.cancer.gov/gdc

www.cancer.gov/espanol

1-800-4-CANCER

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@NCIDirector

@TheNCI