Clinical Trials Informatics Updates: CTAC Working Group and Other Activities

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Director, Center for Biomedical Informatics and Information Technology, NCI

NIH NATIONAL CANCER INSTITUTE

July 13, 2016

NCI CTAC Clinical Trials Informatics Working Group

- Purpose: To provide extramural expertise and advice on the implementation of clinical trial informatics initiatives. The goals are to:
  - Minimize the burden of cancer clinical trial data management
  - Improve the value of cancer clinical trial data
  - Increase the impact of clinical trials, by streamlining initiation, conduct, data analysis and reporting as originally envisioned in the 2005 Clinical Trials Working Group (CTWG) Report
    - Co-chairs: Louis Weiner, M.D., Warren Kibbe, Ph.D.
- Initial Focus: NCI's Clinical Trials Reporting Program, a comprehensive registry of interventional cancer clinical trials supported by NCI,
  - Scope of trials reported
  - Reporting requirements
  - Data access

NCI CTAC Clinical Trials Informatics Working Group: Membership

Louis Weiner, M.D., Co-Chair **Director, Georgetown-Lombardi Cancer Center**	**Warren Kibbe, Ph.D., Co-Chair** **Acting Deputy Director, NCI** **Director, Center for Bioinformatics and Information Technology, NCI**
Rhoda Azoomanian, RN, MSM Associate Director, Yale Center for Clinical Investigation, Yale Cancer Center	Lynn Matrisian, Ph.D. Vice President, Scientific & Medical Affairs, Pancreatic Cancer Action Network
Kevin J Cullen, M.D. Director, Marlene and Stewart Greenebaum Cancer Center	Robert Miller, M.D., FACP, FASCO Medical Director, Institute for Quality, ASCO
Walter J Curran Jr., M.D. Executive Director, Winship Cancer Institute	Mary McCabe, RN, MN Director, Cancer Survivorship Initiative
Stanton Gerson, M.D. Director, Case Comprehensive Cancer Center	Sorena Nadaf, MS, MMI Senior Vice President and Chief Informatics Officer, City of Hope
Michael LeBlanc, Ph.D. Research Professor of Biostatistics, University of Washington	George W. Sledge, Jr., M.D. Professor of Medicine, Stanford University
Mia Levy, M.D., Ph.D. Director, Cancer Clinical Informatics, Vanderbilt-Ingram Cancer Center	Richard Zellars, M.D. Associate Professor of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins Kimmel Cancer Center
Gisele A. Sarosy, M.D. – Executive Secretary Coordinating Center for Clinical Trials, NCI	

NCI CTAC Clinical Trials Informatics Working Group: NCI Liaisons

Jeffrey Abrams, M.D. Associate Director, Cancer Therapy Evaluation Program	Lori Minasian, M.D., FACP Deputy Director, Division of Cancer Prevention
Henry Ciolino, Ph.D. Acting Director, Office of Cancer Centers	Sheila Prindiville, M.D., M.P.H. Director, Coordinating Center for Clinical Trials
Peter Garrett Director, Office of Communications and Public Liaison	Julia Rowland, Ph.D. Director, Office of Cancer Survivorship
James Gulley, M.D., Ph.D., FACP Director, Medical Oncology Service, Center for Cancer Research	

NCI CTAC Clinical Trials Informatics Working Group: Progress to Date

- Several meetings have taken place via webinar, most recently in April, 2016
- Agenda items included:
  - Review of CTRP reporting requirements
  - Type and scope of information contained in CTRP
  - Feedback from CTRP users
- The group concurred that it would be most efficient to address the topics emerging during these webinars in subgroups

NCI CTAC Clinical Trials Informatics Working Group: Subgroups

Subgroup 1: Enhancing the Usability and Accessibility of CTRP data for Patients, Treating Physicians, and the Public. This subgroup will be asked to provide input regarding improving clinical trial search capabilities in coordination with the Vice-President's Cancer Moonshot initiative and provide additional recommendations as needed for improving the usability and accessibility of CTRP data.

NCI CTAC Clinical Trials Working Group: Subgroups

Subgroup 2: Enhancing the Value of CTRP Data for the Cancer Research Community (Enhancing CTRP Data). This subgroup will be asked to consider the following:

1) Resolving inconsistencies and definitional ambiguities in current data;
2) Assessing the value and burden of collecting patient–level demographic data;
3) Assessing the value and burden of expansion of CTRP to include data on observational/correlative studies, outcomes, and toxicities;
4) Providing extramural access to CTRP information for researching the NCI-supported clinical trials landscape.

NCI CTAC Clinical Trials Working Group: Subgroups

Subgroup 3: CTRP Data as the Source for Cancer Center Support Grant (CCSG) Clinical Trials Reporting (CCSG Data Tables). This subgroup will be asked to consider the following:

1) Identify issues and benefits of using CTRP data as a source for reporting interventional clinical trials activity;
2) Assess the issues, approaches and value of using CTRP as a data source for observational/ancillary/correlative studies activity if these data were reported;
3) Recommend approaches for facilitating implementation of CTRP data as source of CCSG reporting.

NCI CTAC Clinical Trials Informatics Working Group: Next Steps

- The three subgroups are being formed, and will start meeting in the near future.
- We will continue to update CTAC with the working group's progress.

NCI Clinical Trials Informatics Updates

Warren Kibbe, Ph.D.

Acting Deputy Director, NCI

Director, Center for Biomedical Informatics and Information Technology, NCI

Outline

- Genomic Data Commons
- Rethinking Clinical Trial Search
  - Development of Application Programming Interface (API) to NCI's Clinical Trials Reporting Program, for use by:
    - NCI's Cancer.gov website
    - Third party innovators providing clinical trial content to their communities
- Recent Initiatives
  - Changes to the NCI's Cancer.gov Search Form in June
  - Twitter Feed and Gov Delivery Service
- Vice President's Moonshot Summit – June 29, 2016
- Next Steps and Involvement of NCI's CTAC Clinical Trials Informatics Working Group

Genomic Data Commons

- Unified knowledge base that promotes sharing of genomic and clinical data between researchers and facilitates precision medicine in oncology
- Contains standardized data from approximately 14,500 patients, derived from NCI programs, including:
  - The Cancer Genome Atlas (TCGA)
  - Therapeutically Applicable Research to Generate Effective Treatment (TARGET)
  - Cancer Genome Characterization Initiative (CGCI)
  - The Cancer Line Encyclopedia (CCLE)

Genomic Data Commons

Went live at ASCO June 6, 2016

The NCI and VP Communication teams showed their mettle! Special thanks to Shannon Hatch!

The New York Times

Biden Unveiling Public Database for Clinical Data on Cancer

The Washington Post

Biden unveils launch of major, open-access database to advance cancer research

CHICAGO SUN-TIMES

VP Joe Biden in Chicago to promote Moonshot Initiative vs. cancer

FOX NEWS Health

Biden unveiling public database for clinical data on cancer

THE CANCER LETTER

Biden Designates NCI's Genomic Data Commons As Foundation of Cancer Moonshot

HealthData Management

NCI launches open access resource to spur cancer research

Daily Mail

New US data system to centralize cancer information

HOUSTON CHRONICLE

Biden unveils searchable government cancer database

genomeweb

NCI Launches Genomic Data Commons for Cancer Data Sharing

SCIENTIFIC AMERICAN · REUTERS PUBLIC HEALTH

Biden Unveils Major Database to Advance Cancer Research

HealthITAnalytics

NIH Launches Genomic Data Commons Supporting Cancer Moonshot

THE HUFFINGTON POST

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Biden Announces Crucial Piece Of His Cancer Moonshot Initiative

FORTUNE

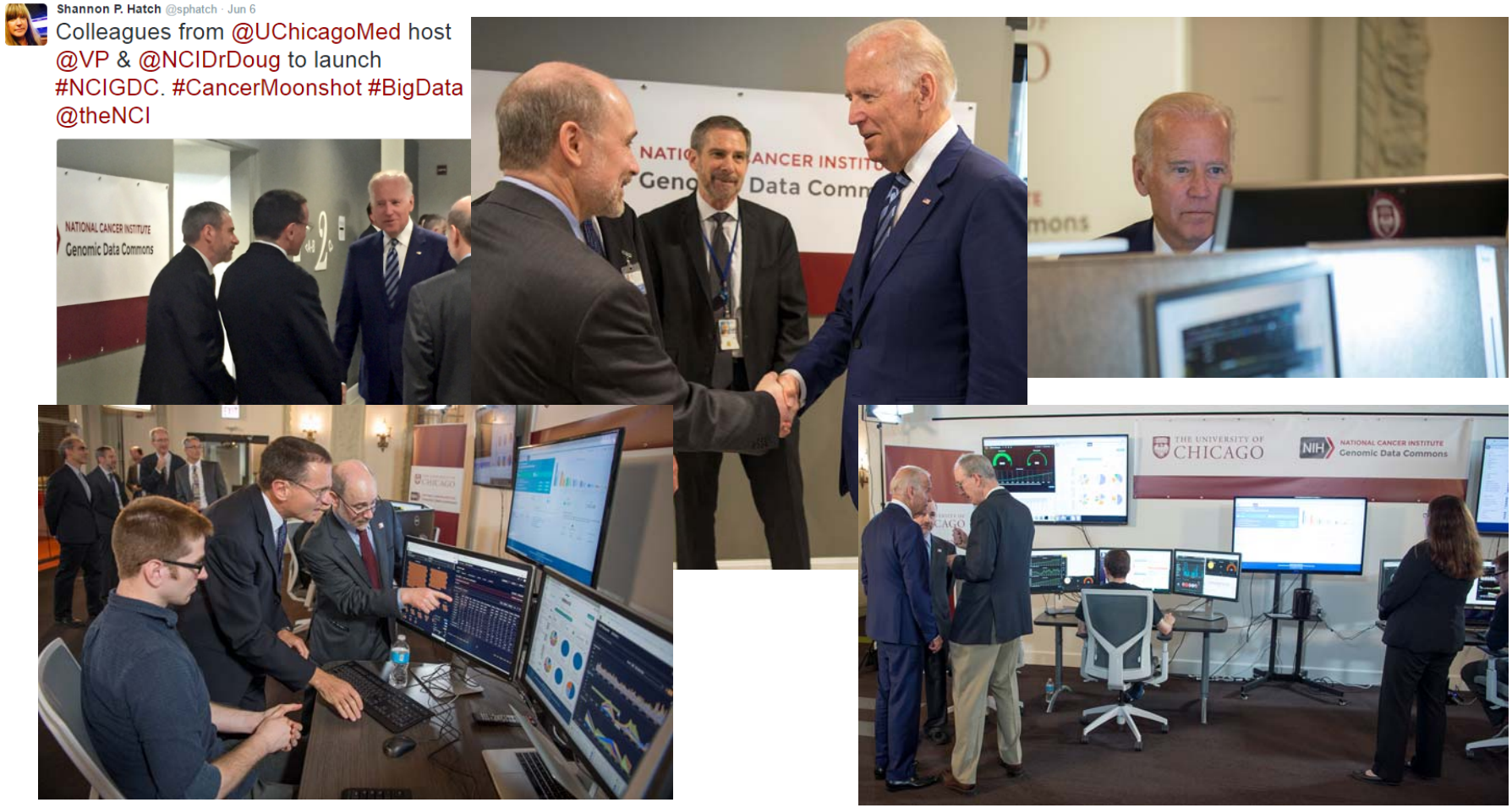
Joe Biden Just Announced a Huge New National Cancer Database

REUTERS

Biden announces U.S. project to promote cancer data sharing

fedscoop

Biden launches data portal to back Cancer Moonshot


Shannon P. Hatch @sphatch · Jun 6
Colleagues from @UChicagoMed host @VP & @NCIDrDoug to launch #NCIGDC. #CancerMoonshot #BigData @theNCI
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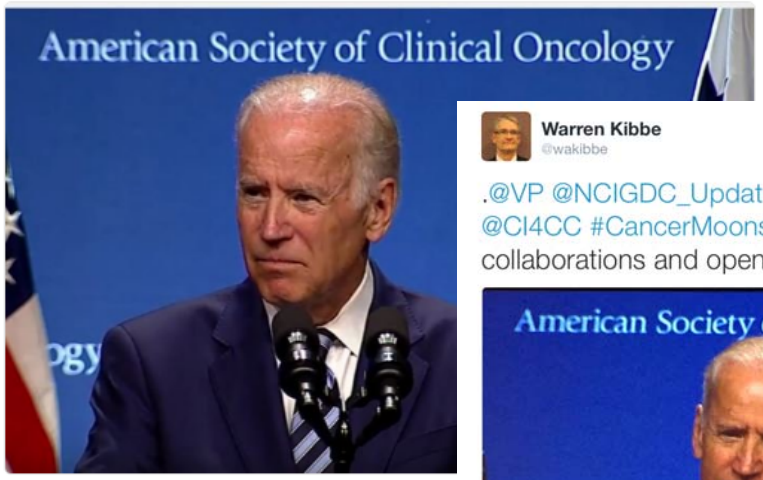
See @VP speak today at #ASCO2016 on the #CancerMoonshot youtube.com/watch?v=s44YVo… #NCIGDC



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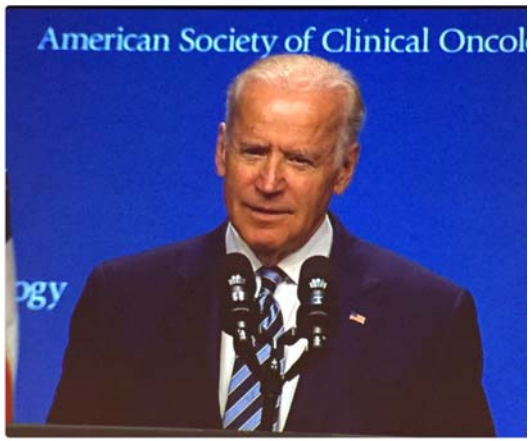
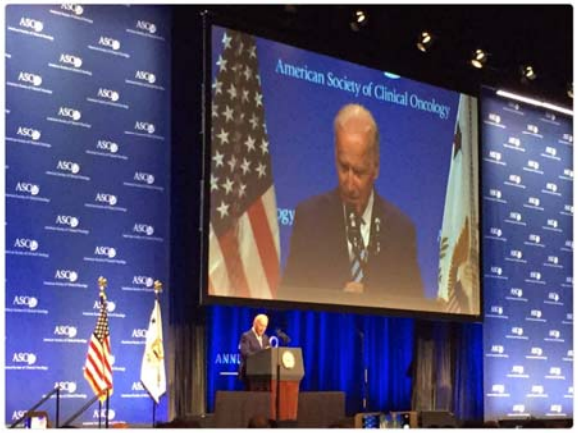
Warren Kibbe
@wakibbe

.@VP @NCIGDC_Updates #asco2016 @theNCI @CI4CC #CancerMoonshot Need more collaborations and open data sharing

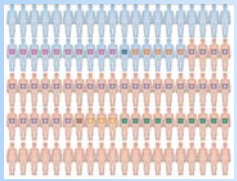


Warren Kibbe
@wakibbe

@VP @NCIGDC_Updates @theNCI @CI4CC #CancerMoonshot #asco2016 genomic data commons @NCIDrDoug



Cancer Data Ecosystem

Discovery	Patient engaged Research	Surveillance Big Data Implementation research
Genomic research Clinical trials with genomic data	Clinical Research Observational studies	EHR, lab data, PROs, smart devices, decision support
Well characterized genomic data sets	Cancer cohorts	Patient data
		 SEER
Genomic information donor	Active research participation	Learning from every cancer patient

Rethinking Clinical Trials Search

- Engage Presidential Innovation Fellows
- Create an Application Programming Interface (API) for Clinical Trials
- Create an example search interface based on the API
- Incorporate these innovations into NCI's website, Cancer.gov
- Thanks to OCPL and Li Gwatkin in particular

Our Presidential Innovation Fellow Team

Alex Pelletier
Product Manager

Product development and management, business strategy, healthcare experience

Michael Balint
Software Architect

Full-stack engineering, data science

Kate McCall-Kiley
Design Strategy

Service and experience design, social change

Luke Keller
Product Designer

User experience, frontend web development

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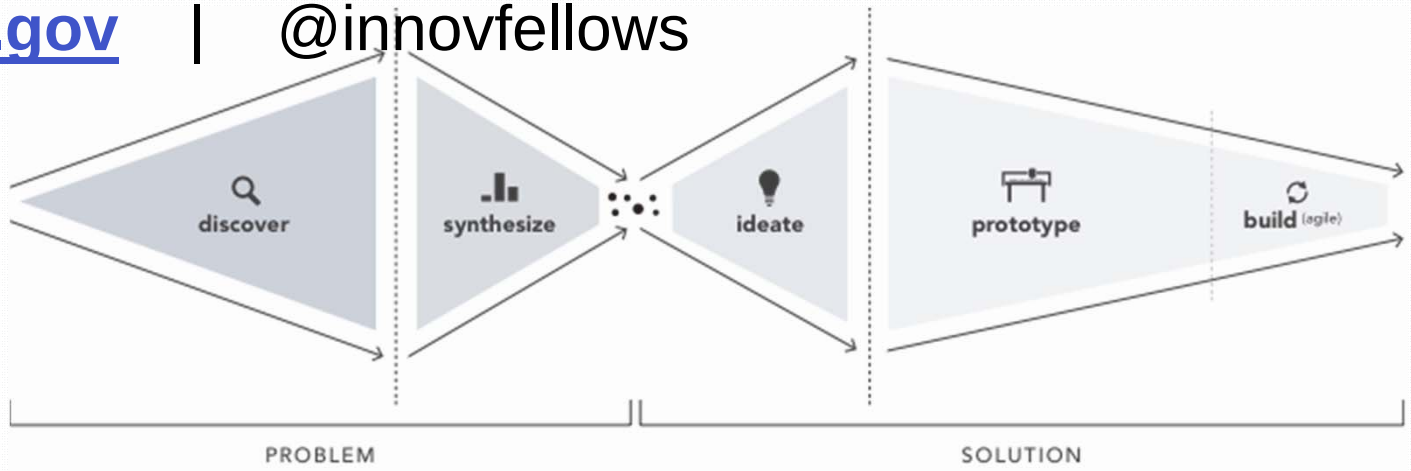

DISCOVER

Goal: Discover what the user's & system's needs are.

SYNTHESIZE

Goal: Synthesize discovery into themes and prioritize.

IDEATE

Goal: Develop hypotheses and validate them through iterative solutions.

PROTOTYPE

Goal: Iterate on successful solutions to create a higher fidelity prototype.

BUILD/AGILE

Goal: Build & Launch the solution
Evaluation & iteration

PROPOSED TIMELINE:

1. Discovery Sprint & Synthesis (week 1-4)
2. Develop Prototypes & Iterate (week 3-9)
3. Outreach/Communication- Launch Planning (week 6-12)

Rethinking and Enhancing Clinical Trial Search: June, 2016

- Initial Release of an API (Application Programming Interface) (API)[1], developed by the Presidential Innovation Fellows, for testing. This tool, found at https://clinicaltrialsapi.cancer.gov, makes publicly available trial registration information from the CTRP database, currently found on cancer.gov, assessable to third-party innovators so that they can build new digital tools tailored to the clinical trial search needs of their users

- Launch of @NCICancerTrials on Twitter and dissemination of clinical trial information via GovDelivery: https://public.govdelivery.com/accounts/USNIHNCI/subscriber/new

- Changes the Cancer.gov Website to enhance clinical trial searching

[1]A set of protocols designed to provide communication between a software application and a computer operating system or between applications.

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ABOUT CANCER | CANCER TYPES | RESEARCH | GRANTS & TRAINING | NEWS & EVENTS | ABOUT NCI | search

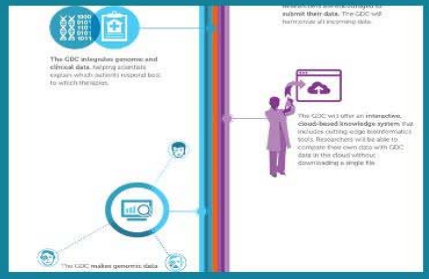
Find a Clinical Trial

Cancer Moonshot Milestones

Stay up to date on the latest activities and other progress from the Cancer Moonshot.

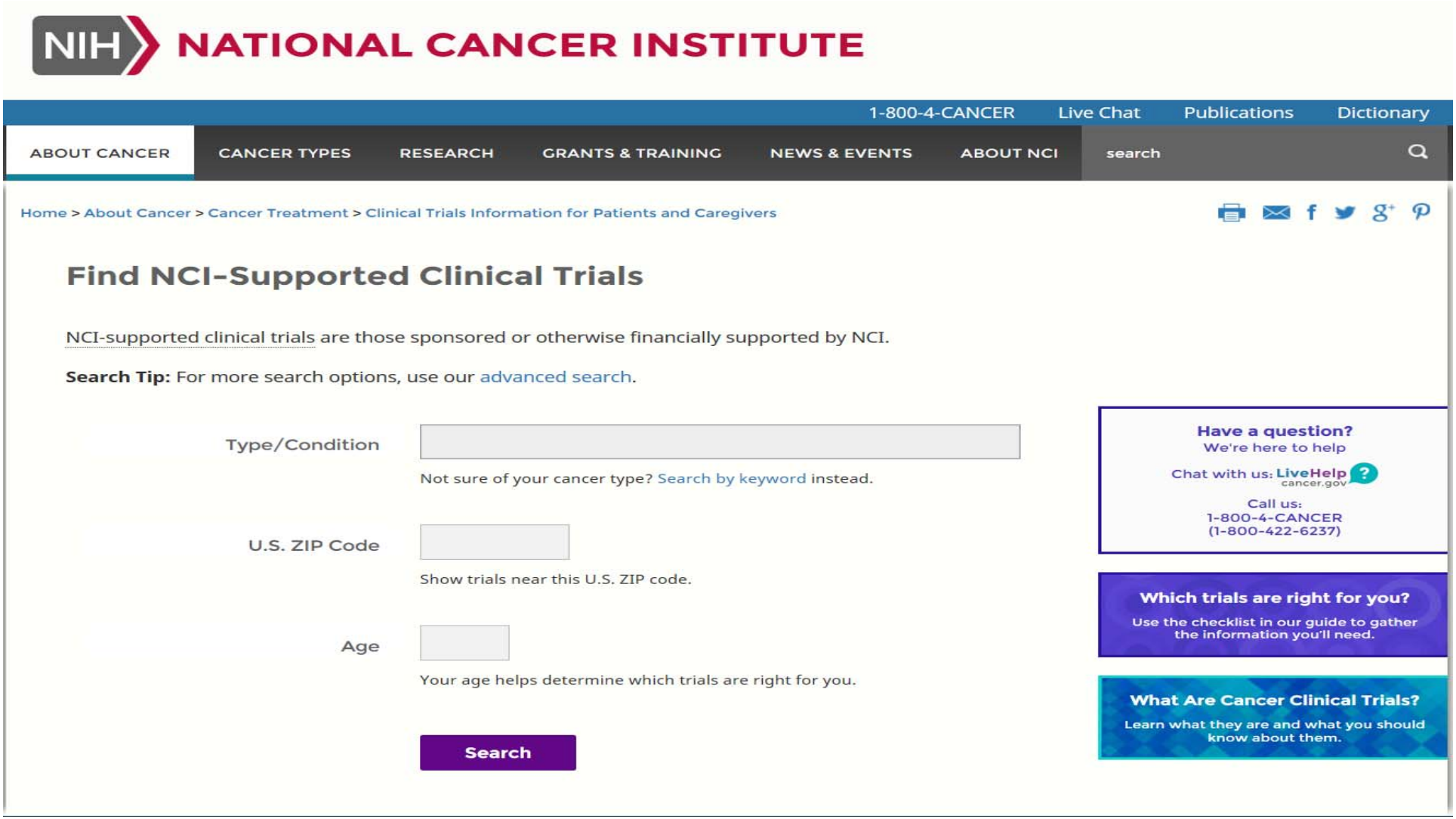
Looking for a Clinical Trial?

With our new basic search form, you can find a trial or contact the NCI for help via phone, email, or online chat.



Genomic Data Commons

Stores, analyzes, and distributes cancer genomics data generated by NCI and other research organizations.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Find NCI-Supported Clinical Trials
NCI-supported clinical trials are those sponsored or otherwise financially supported by NCI.
Search Tip: For more search options, use our advanced search.
Type/Condition
Not sure of your cancer type? Search by keyword instead.
U.S. ZIP Code
Show trials near this U.S. ZIP code.
Age
Your age helps determine which trials are right for you.
Search
Have a question?
We're here to help
Chat with us: LiveHelp cancer.gov
Call us:
1-800-4-CANCER
(1-800-422-6237)
Which trials are right for you?
Use the checklist in our guide to gather the information you'll need.
What Are Cancer Clinical Trials?
Learn what they are and what you should know about them.

Cancer Moonshot Summit - Announcements on June 29th

- NCI-pharma & Biotech Formulary
- Applied Proteogenomics OrganizationaL Learning and Outcomes (APOLLO) NCI-DoD-VA
- NCI – DOE partnership to incorporate computational science into cancer research
- NIH Partnership for Accelerating Cancer Therapies (PACT) – collaboration with 12 biopharmaceutical companies
- NCI, DOE, and GlaxoSmithKline public-private-partnership for using high performance computing in drug development

Cancer Moonshot Summit – Announcements on June 29th

- Genomic Data Commons (https://gdc.nci.nih.gov) went live June 6th and is a data sharing point for clinical and basic science data generating genomic information

- CTRP data:
  - NCI Clinical Trials Search https://trials.cancer.gov
  - NCI Clinical Trials API https://clinicaltrialsapi.cancer.gov

The White House
Office of the Press Secretary

For Immediate Release June 28, 2016

FACT SHEET: At Cancer Moonshot Summit, Vice President Biden Announces New Actions to Accelerate Progress Toward Ending Cancer As We Know It

WASHINGTON, D.C. – Today, the Cancer Moonshot is hosting a summit at Howard University, in Washington, D.C. as part of a national day of action that also includes more than 270 events in communities across the United States. Vice President Joe Biden will join over 350 researchers, oncologists and other care providers,

Making Clinical Research Trials More Accessible to Cancer Patients: Today, the National Cancer Institute (NCI), in partnership with the White House Presidential Innovation Fellows, is announcing its plan for re-designing how patients and oncologists learn about and find information about cancer clinical trials. The goal is to ensure that patients and their care teams have access to the information they need at the right time, as well as strengthen participation in cancer research studies to help accelerate medical discoveries and treatments for cancer. The first phase will make cancer clinical data hosted on cancer.gov available through an application programming interface (API) for advocacy groups, academia, and others in the cancer ecosystem to access directly. The API will enable third-party innovators, including Smart Patients, Syapse, Cure Forward, and Trial Reach, to use the new cancer clinical trial API to build applications, integrations, search tools, and digital platforms tailored to individual communities that bring clinical trial information to more providers, patients, and their family members.

Rethinking Clinical Trial Search – Next Steps

- Cancer.gov
  - Work with the CTAC Clinical Trials Informatics Working Group (CTIWG) on the design on a “front end” to the API for use on the Cancer.gov website
    - This will allow search and retrieval of information that is currently available on Cancer.gov directly from NCI’s Clinical Trials Reporting Program
  - The CTIWG will provide input regarding design and usability of the Cancer.gov website, as well as:
    - Prioritization of requested enhancements (e.g., structured eligibility criteria)
- Other websites and/or providers of clinical trial search
  - Test API and use publicly assessable CTRP data for use in their systems
- Obtain input via Ideascale

https://cancerresearchideas.cancer.gov/

ideascale

register log in

CLINICAL trials ideas

About

Ideas

How To

NCI is redesigning the way patients and oncologists learn about and find information about cancer clinical trials.

How can we make cancer clinical trials information more accessible to you? Submit your ideas by August 30.

Patients, Caregivers, Advocates

Health Professionals

Technical Partners

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www.cancer.gov **www.cancer.gov/espanol**