

NCI's Clinical Trials Reporting Program (CTRP)



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What is NCI's Clinical Trials Reporting Program (CTRP)?

- Comprehensive database containing regularly updated information, including accrual, on interventional trials and observational studies either directly or indirectly funded by NCI
- Supports NCI clinical trials portfolio management
 - Identify gaps in portfolio
 - Prioritize clinical research opportunities
- Supports registration and results reporting to ClinicalTrials.gov for NCI sponsored trials consistent with NIH policies and FDAAA (and 42 CFR Part 11)

CTRP: Key Attributes

- Consistent terminology and standardized data elements to optimize search and retrieval of cancer clinical trials information
- Inclusion of structured biomarker and disease information
- Standard representation of persons and organizations
- Identification of associated NCI awards and contracts
- Regular updates to reflect protocol amendments, as well as participating site and status changes
 - Automated NCI system data feeds update participating site information on trials directly funded and managed by NCI nightly
- Quarterly reporting of accrual, including participant-level demography

Scope of CTRP – Trial Registration

- Trials taking place in at least one NCI-Designated Cancer Center, including industrial trials
 - Interventional* clinical trials open to accrual on or after 1/1/2009
 - Observational studies open to accrual on or after 1/1/2020
- Trials sponsored by NCI, as well as trials sponsored by other entities
- More than 85% of interventional cancer clinical trials open to patient accrual in the United States found in ClinicalTrials.gov are also in CTRP (as of September 2022)

*Studies in human beings in which individuals are assigned by an investigator, based on a protocol, to receive specific interventions. Subjects may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The individuals are followed and biomedical and/or health outcomes are assessed. (Source: <http://prsinfo.clinicaltrials.gov/definitions.html> and <http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf>)

CTRP – Source and Management

- Source
 - Internal NCI programs, including CCR¹, CTEP², DCP³, e.g., NCORP⁴, NCTN⁵ trials
 - NCI Awardees, e.g., trials ongoing in NCI-Designated Cancer Centers
- Management
 - Protocol document required for registration (except for industrial trials)
 - Trial abstract prepared by professional scientific abstractors
 - Coding with cancer specific terminology adds structure to disease, biomarkers, and interventions
 - Regularly updated to reflect protocol amendments, as well as participating site and status changes
 - Data abstraction harmonized with ClinicalTrials.gov
 - Supports registration with CTRP content in ClinicalTrials.gov by trial sponsors, including NCI

¹CCR = Center for Cancer Research; ²CTEP = Cancer Therapy Evaluation Program; ³DCP = Division of Cancer Prevention; ⁴NCORP = NCI Community Oncology Research Program; ⁵NCTN = National Clinical Trials Network

CTRP – Data Distribution

- **Clinical Trials Search API (CTS API)**
 - NCI Cancer.gov website for clinical trial searching (trials.cancer.gov)
 - More than 150 academic, advocacy, and industry groups
- **Reporting**
 - CTRP-Generated Cancer Center Support Grant Data Table 4*
 - Competing applications – interventional trials
 - Non-Competing applications – interventional trials and observational studies
- **ClinicalTrials.gov**
 - Source of Registration Records for NCI-Sponsored Trials
 - PRS Upload from CTRP – facilitates use of CTRP record for use by other sponsors for registration in ClinicalTrials.gov.

*Data Table 4 serves as a report of the cancer-related hypothesis-driven clinical research studies open at the Cancer Center during a center-defined 12-month reporting period.

<https://cancercenters.cancer.gov/GrantsFunding/DataGuide>

The screenshot shows the National Cancer Institute's website with the header "NIH NATIONAL CANCER INSTITUTE". The navigation bar includes links for "ABOUT CANCER", "CANCER TYPES", "RESEARCH", "GRANTS & TRAINING", "NEWS & EVENTS", "ABOUT NCI", and a search bar. The main content area is titled "Find NCI-Supported Clinical Trials" and includes a "Search Tip" box with a lightbulb icon. Below this are three search filters: "Cancer Type/Keyword", "Age", and "U.S. Zip Code", each with a text input field and a help icon. A "Find Trials" button is at the bottom. On the right side, there are two circular icons: one with a person icon labeled "HAVE A QUESTION? WE'RE HERE TO HELP" and another with a question mark icon labeled "WHAT ARE CANCER CLINICAL TRIALS?".



CTRP and ClinicalTrials.gov

Trial Registration

CTRP Supports ClinicalTrials.gov Registration

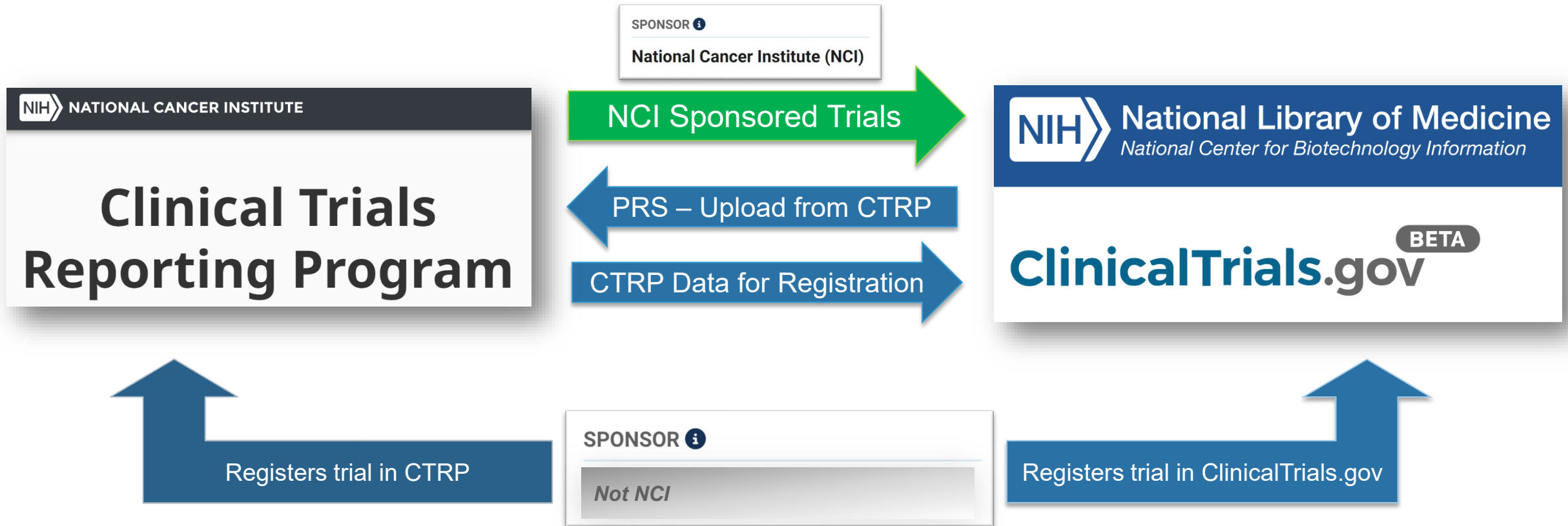
- When NCI is the sponsor (per FDAAA¹):
 - NCI registers and updates the trial in ClinicalTrials.gov
- When another entity, e.g., grantee is the sponsor (per FDAAA)
 - The grantee can use the CTRP protocol abstract for ClinicalTrials.gov registration and updates using PRS Upload from CTRP²

¹ Food and Drug Administration Amendments Act of 2007 (FDAAA) <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007>

² Upload from CTRP <https://prsinfo.clinicaltrials.gov/prs-users-guide.html#section9>

CTRP and ClinicalTrials.gov: Registration

Information provided by National Cancer Institute (NCI) (Responsible Party)



Registration of NCI Sponsored Trials in ClinicalTrials.gov

Use of CTRP Record for Non-NCI Sponsors for ClinicalTrials.gov Registration

ClinicalTrials.gov: Upload from CTRP

ClinicalTrials.gov PRS Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

Organization:

One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:

[Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS account

See [PRS Guided Tutorials](#) for assistance with entering registration and results information in

[Send email to ClinicalTrials.gov PRS Administration](#).

A Sponsor's PRS Admin/User logs into their Sponsor PRS account and with appropriate CTRP access can use the PRS Upload from CTRP feature

ClinicalTrials.gov PRS Protocol Registration and Results System

Upload Protocol Information from CTRP

Only for trials that have been registered with CTRP, the US National Cancer Institute's Clinical Trial Registration Program.
[About Upload from CTRP...](#)

[CTRP Announcement on FDAAA Final Rule](#)

Fill in the requested information and click Analyze to confirm authorization to upload from CTRP.

NCI Record ID:

Example: NCI-2011-01234

Unique Protocol ID:

Must match CTRP Lead Organization Trial Identifier.

Upload Option:

- ☐ Create new PRS record.
☐ Overwrite protocol in existing PRS record.
☐ Overwrite locations in existing PRS record.

CTRP Username:

Enter the username and password that you use to access CTRP.

CTRP Password:

CTRP User Account

The screenshot shows the login interface for the Clinical Trials Reporting Program. At the top, the NIH logo and 'NATIONAL CANCER INSTITUTE' are displayed. The main heading is 'Clinical Trials Reporting Program Login'. Below this, there is a section for 'Clinical Trials Reporting Program' with an 'NIH Login' button. A horizontal line with 'OR' separates this from the login fields. The 'Username' field is a text input, and the 'Password' field is a password input. Below the password field is a 'Remember me' checkbox. A blue 'SIGN IN' button is positioned below the password field. At the bottom left, there is a link for 'Need help signing in?' and another link for 'Don't have an account? Sign up'. On the right side of the login form, there is a disclaimer: 'You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following:'. Below this, another disclaimer states: 'You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system.' At the bottom right, a final disclaimer reads: 'Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.'

A CTRP user account is required to use the PRS Upload from CTRP feature – available to NCI-designated Cancer Centers and NCI grantees

The screenshot shows the registration interface for the Clinical Trials Reporting Program. At the top, the NIH logo and 'NATIONAL CANCER INSTITUTE' are displayed. The main heading is 'Clinical Trials Reporting Program Registration'. Below this, there is a 'Sign Up' button. A text box prompts the user: 'To request a CTRP user account, enter the email address you plan to use and click Next.' Below this, another text box prompts the user: 'Then follow the onscreen instructions.' An 'Email Address' input field is provided, followed by a 'Next' button with a right arrow. On the right side of the registration form, there is a 'Warning Notice' section. It states: 'This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.' Below this, it says: 'This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring. By using this system, you understand and consent to the following:'. A bulleted list follows: '• The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system.' and '• Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.' Below the registration form, there is a section titled 'This site enables you to' with two icons: a plus sign for 'Register clinical trials' and a magnifying glass for 'Search registered trials by Title, Phase, Trial Identifiers and Organizations'. At the bottom, there is a link for 'Want to learn more about the Reporting Program? Visit the NCI Clinical Trials Reporting Program website. If you have questions or want to report any issues, send an email to ctrp_support@nih.gov'.

Note – Each NCI-Designated Cancer Center has a CTRP Administrator who approves new CTRP accounts for their Center

Challenges of Trial Registration: Master Protocol Research Program (MPRP)¹

- May involve testing multiple interventions against multiple targets
- Single MPRP may increase efficiency, e.g., shared infrastructure for screening patients for eligibility
- Clinical trial repositories, e.g., CTRP and ClinicalTrials.gov were designed for traditional clinical trials and pose challenges for the registration and reporting of MPRPs

¹ Williams RJ, Dobbins JD, Tse T, et al. Approach for Reporting Master Protocol Study Designs on ClinicalTrials.gov: Qualitative Analysis. *BMJ* 2022; 377: e067745

NCI-MATCH Trial (Molecular Analysis for Therapy Choice) EAY171 NCT02465060

- Patients assigned to treatment with a single drug based on the genetic changes found during screening of their tumors
- Several treatment arms are open at any given time, each enrolling participants whose tumors have a specific genetic change
- Initially registered in CTRP and ClinicalTrials.gov as one trial
- Challenges with one record:
 - Does not display status changes of individual arms opening and closing to accrual
 - Does not support results reporting until all arms with all interventions are closed
 - Includes all eligible disease sites, biomarkers, and interventions studied in all arms

NCI-MATCH Trial (Molecular Analysis for Therapy Choice) EAY171 NCT02465060

- When a treatment arm closes, the primary outcome of that arm has been reached
- MATCH has 39 treatment arms; waiting until the primary completion date of the last arm would have delayed reporting for many years
- To support results reporting, NCI, the sponsor:
 - Modified the original record to become the “screening” record
 - Registered each treatment arm in a separate record
 - Has been reporting primary outcomes as the primary completion dates for each of the treatment arms/records is reached

Pediatric MATCH

- Screening and treatment are registered in separate records in CTRP and ClinicalTrials.gov at initiation
- Screening record and the treatment record reference each other in the title

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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[Home](#) > [Search Results](#) > Study Record Detail ☐ Save this study

Trial record **4 of 643** for: pediatric match

[Previous Study](#) | [Return to List](#) | [Next Study](#)

Targeted Therapy Directed by Genetic Testing in Treating Pediatric Patients With Relapsed or Refractory Advanced Solid Tumors, Non-Hodgkin Lymphomas, or Histiocytic Disorders (The Pediatric MATCH Screening Trial)

Screening Record

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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[Home](#) > [Search Results](#) > Study Record Detail ☐ Save this study

Trial record **1 of 643** for: pediatric match

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Tipifarnib for the Treatment of Advanced Solid Tumors, Lymphoma, or Histiocytic Disorders With HRAS Gene Alterations, a Pediatric MATCH Treatment Trial

One of Several
Treatment Records

CTRP and ClinicalTrials.gov

- CTRP includes all trials directly or indirectly funded by NCI
- Upon receipt of a protocol document, CTRP abstracts a file with data suitable for registration in ClinicalTrials.gov
- Use of Upload from CTRP in PRS provides the sponsor, when not NCI, access to the record for ClinicalTrials.gov registration
- Master Protocol Research Program (MPRP) trials pose challenges for registration and results reporting
 - Separate registration records for screening and treatment may help simplify registration and results reporting
 - Referencing the other parts of the clinical trial, e.g., in the title or body of the registration record, can be helpful.
 - Coordination needed when different sponsors manage separate components of the MPRP

Resources & Contact Information

- Search CTRP content on NCI Website: trials.cancer.gov
- NCI's Clinical Trials Search API: clinicaltrialsapi.cancer.gov
- How to obtain a CTRP User Account (required for Upload from CTRP): trials.nci.nih.gov/registry/registerUser.action
- Contact CTRP: ctrp_support@mail.nih.gov



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