



# Cracking the Code to Clinical Trial Enrollment

How to Start | Who Can Help

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- The American College of Surgeons Clinical Research Program (ACS CRP) received feedback that surgeon participation in clinical trials is challenging due to administrative barriers
- The ACS CRP held an all day, open-house style session during ACS Clinical Congress 2019 to help surgeons overcome these barriers
- ACS CRP staff provided in-person support and guidance for Investigators interested in enrolling to clinical trials

- Information and resources on the following trainings and requirements was available during the session:
  - Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) ID
  - NCI Registrations and Credential Repository (RCR)
  - Enhanced training requirements, including Good Clinical Practice (GCP)
  - Regulatory requirements, including NCI Biosketch, Financial Disclosure Form and Agent Shipment Form

# Summary of Requirements

In order to begin enrolling in clinical trials, the NIH requires the documents below. Please refer to subsequent slides for additional detail:

- A Personal Statement for your Biosketch: 3-4 sentences explaining why you are interested in becoming an Investigator, be sure to mention any relevant research experience
- A Current CV with your current position, including Start Date for your current position
- Medical Board Information, including Effective Date and Expiration Date (if applicable)
- Your Date of Birth (For research CV and Electronic 1572)
- Required Research Training (CITI Training through HealthPartners Institute)  
<https://www.citiprogram.org> *\*Note that most institutions will accept Good Clinical Practice (GCP) from outside organizations if current*

**Step 1:** [Determine your Registration Type](#)

**Step 2:** [Understand the registration process](#) and [information required from you](#)

**Step 3:** Obtain your [CTEP-IAM account](#) and access the RCR system

- If you are beginning the registration process, your first step is to obtain an CTEP-IAM account, this will provide you access to the RCR system and other NCI applications
- All CTEP-IAM account holders must annually renew their CTEP-IAM account registration and maintain an active password
- Persons assigned to the Investigator and Non-Physician Investigator Registration Types must submit their annual NCI registration documents through the RCR system

**Step 4:** Gain knowledge about the RCR [system layout](#) and [common features](#)

**Step 5:** You're ready to begin! Go to the RCR Home Page and select an option from the [Would you like to](#) field to start your registration.

# Registration and Credential Repository (RCR) (1/2)

- Access the RCR: <https://ctepcore.nci.nih.gov/rcr>
- 5 Registration Types:
  - **Investigator (IVR):** MD, DO, or international equivalent
  - **Non-Physician Investigator (NPIVR):** Advanced practice provider (e.g., NP or PA) or graduate level researcher (e.g., PhD)
  - **Associate Plus (AP):** Clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD)
  - **Associate (A):** Other clinical site staff involved in the conduct of NCI-supported research
  - **Associate Basic (AB):** Individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems
- All registration types are required to have a CTEP Identity and Access Management (CTEP-IAM) account

# Registration and Credential Repository (RCR) (2/2)

Documentation Required	Investigator	Non-physician Investigator
FDA Form 1572	X	X
Financial Disclosure Form	X	X
NCI Biosketch (education, training, employment, certification, license)	X	X
HSP/GCP training	X	X
Agent Shipment Form (if applicable)	X	
CV (optional)	X	X



If you need to **obtain** your CTEP-IAM Account:

- Access CTEP-IAM <https://ctepcore.nci.nih.gov/iam/>; Select “Request New Account”
- Answer the “Have you ever registered with CTEP?” question by selecting “Yes” and “Proceed”
- Enter your CTEP Person ID, First Name and Last Name (check your registration notification email) and select “Continue”
- Answer the “Does the above information identify you?” question by selecting “Yes” and “Proceed”.
- Answer the “Would you like to request for an IAM Account?” question by selecting “Yes” and “Continue”
- Complete the new account request and select “Continue”

If you need to **edit** an existing CTEP-IAM Account:

- Access CTEP-IAM <https://ctepcore.nci.nih.gov/iam/>
- Select “Request New Account”
- Answer the “Have you ever registered with CTEP?” question by selecting “Yes” and “Proceed”
- Enter your CTEP Person ID, First Name and Last Name (check your registration notification email) and select “Continue”
- Answer the “Does the above information identify you?” question by selecting “Yes” and “Proceed”
- Answer the “Would you like to update your CTEP-IAM Account?” question by selecting “Yes” and “Continue”
- Update your account accordingly

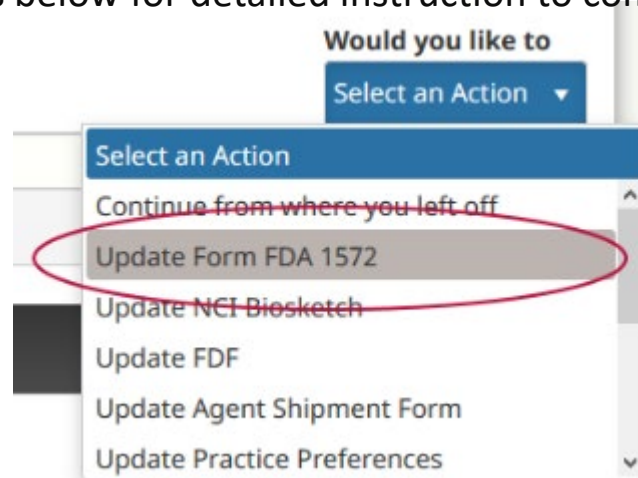
## How to complete FDA Form 1572/NCI Biosketch

1. Select 'Update Form FDA 1572' as illustrated in below screenshot  
<br>
2. Click the 'Update Form FDA 1572' button from the [Draft NCI Profile](#) Form FDA 1572 tab.  
When the Form FDA 1572 [document workflow](#) 'Welcome' page displays, click Next to begin the workflow. Click from the links below for detailed instruction to complete the Form FDA 1572 sub-sections.

[Practice Sites](#)

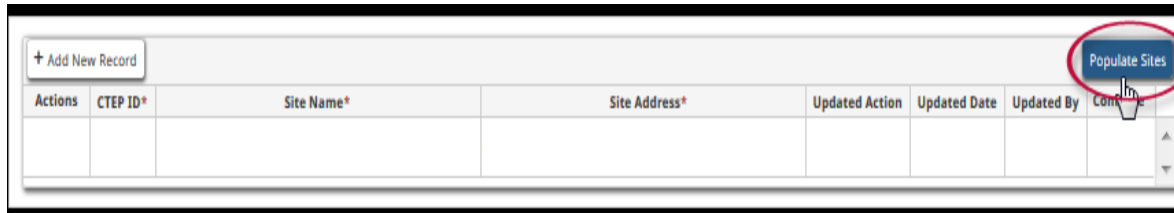
[Labs](#)

[IRBs](#)



## How to add Practice Sites to your 1572

1. Click “Populate Sites” to automatically add sites that you are rostered to and sites at which you are the Site-Protocol PI



Actions	CTEP ID*	Site Name*	Site Address*	Updated Action	Updated Date	Updated By	Completed

2. Click “Add New Record” to search for and manually add sites

3. Note that the **Practice Sites** screen displays when any of your selected practice sites are associated to a Lead Academic Participating Site (LAPS) or the NCI Community Oncology Research Program (NCORP). In some cases, this list may be rather long, but it offers an easy method to review and select sites that may be otherwise overlooked

4. Selecting sites from this table is optional. Click the column headings or use the filter fields from each column to sort the search results

## How to add Labs to your 1572

*This subsection must include at least one practice lab, but all labs that support NCI-sponsored clinical trials on which you participate must also be entered.*

*The list of labs from which you select is extensive. It may be beneficial to ask study personnel or the lab's point of contact to obtain the lab's Provider Number, CLIA, or CAP identification number prior to and for use when conducting a search for labs.*

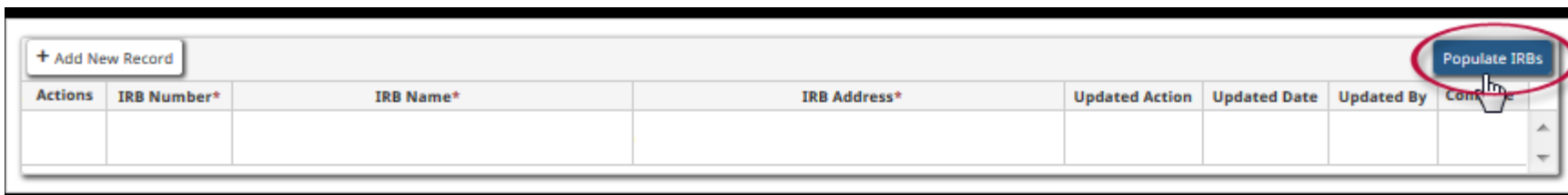
1. Click the **Add New Record** button; the **Labs** Advance Search screen displays.
2. Enter criteria to search for the lab, then click **Search**. Entering the lab's Provider Number, CLIA, or CAP identification number within the **Provider Number** field provides the most direct method to locate the lab.
3. The labs that match the search criteria display in the table at the lower portion of the screen. Click the checkbox(es) from the **Select** column, then click **Add**. The screen will close and your selection(s) will populate the **Labs** table on the workflow page.

## How to add IRBs to your 1572

*This subsection must include at least one IRB, but all IRBs that support NCI-sponsored clinical trials on which you participate must also be entered. The IRBs available for selection are those associated to your practice site(s) and may be either a local IRB or a NCI Central IRB (CIRB). Each CIRB consists of four separate IRBs, which will populate as a "package" in the IRB subsection upon selection. In addition, if one of the four IRBs are deleted from the **IRBs** subsection, then the remaining three IRBs will also be deleted.*

To enter IRBs:

1. Access the Form FDA 1572 IRBs subsection.
2. Click the **Populate IRBs** button. The IRBs associated to the sites selected in the **Practice Sites** subsection and/or the sites at which you are the IRB PI of Record are automatically populated in the **IRBs** table.
3. Review the IRBs displayed in the **IRBs** table. Click the **Delete** button if a site was entered erroneously or click the **Add New Record** button to manually search and select IRBs.
4. Click "Save and Continue"



Actions	IRB Number*	IRB Name*	IRB Address*	Updated Action	Updated Date	Updated By	Com

## A surgeon's NCI Biosketch is their representation to the NCI and the FDA

- The registering individual will populate their NCI Biosketch with:
  - Education, Professional Training, Employment
  - Professional License/Certifications
  - Board Certifications
  - **Good Clinical Practice (GCP) training**, including a scanned copy of the certificates
  - Electronic signature and date
- The attachment of a CV is optional, however completion of the NCI Biosketch is required to ensure standardized collection

- The Cancer Therapy Evaluation Program (CTEP) recognizes the diverse experience of Investigators and has created a “Not applicable” selection for those NCI Biosketch sections that may not apply to the requestor
- If this selection is used inappropriately, the NCI will have no information to evaluate the qualifications of the requestor and will either return the Biosketch to the requestor or outright deny the registration request
- Thus, please ensure the requestor completes the NCI Biosketch as fully as possible



## Human Subjects Protection (HSP) Training Information

As of February 14, 2019, the Human Subjects Protection (HSP) training is **no longer collected** for NCI registration. If you have successfully submitted registration packets prior to that date, you will need to delete your HSP information the next time you update your information. You will still be able to access HSP certificates from your NCI Profile History.

Approved NCI Profile Switch to Draft NCI Profile

You are viewing currently approved NCI Profile (read-only).

PRIMARY CONTACT INFORMATION | **NCI BIOSKETCH** | FDF | PRACTICE PREFERENCES | SUBMITTED DOCUMENTS

▼ Personal Information \*

▼ Education \*

▼ Professional Training \*

▼ Employment \*

▼ Professional Certification \*

▼ Professional License \*

▼ ABMS Board Certification \*

▲ NCI Required Training \*

Country*	Course Type*	Course Title*	Training Provider*	Completion Date*	Expiration Date*	Upload Certificate*
USA (US)	Good Clinical Practice	Good Clinical Practice	CITI	JAN-2016	JAN-2019	CITI GCP exp. 1.26.19.pdf
USA (US)	Human Subject Protection	Basic Refresher	CITI	JAN-2016	JAN-2020	CITI Refresher exp. 1.13.20.pdf

History

## How to complete Good Clinical Practice (GCP) Training

- Required **at least every three years** for all Investigators and Non-Physician Investigators
- The Training Provider, Course Title, Completion Date, Expiration Date (if applicable) and provider's training certificate must be uploaded in the NCI Required Training subsection of the NCI Biosketch
- The GCP Expiration Date can be set by the course provider **or** three years from course completion date, whichever occurs first
- The NCI recommends the ***TransCelerate GCP Mutual Recognition Program*** for GCP training. Any training included from this website is considered acceptable by NCI standards. This includes:  
<http://www.transceleratebiopharmainc.com/gcp-training-attestation/>  
  
[http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/03/GCP-MR-Minimum-Criteria-R2\\_FINAL.pdf](http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/03/GCP-MR-Minimum-Criteria-R2_FINAL.pdf)
- See next slide for other acceptable GCP training options

## Additional Good Clinical Practice (GCP) Training options

- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus) < <https://about.citiprogram.org/en/series/good-clinical-practice-gcp/> > and < <https://about.citiprogram.org/en/course/good-clinical-practice-basic-fda/> > (charges apply, CITI completion and expiration dates apply)
- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) < <https://about.citiprogram.org/en/series/good-clinical-practice-gcp/> > and < <https://about.citiprogram.org/en/course/good-clinical-practice-basic-ich/> > (charges apply, CITI completion and expiration dates apply)
- National Institute of Allergy and Infectious Diseases (NIAID) Good Clinical Practices course (free of charge, NIAID completion date applies, default three year expiration date applies): <https://gcplearningcenter.niaid.nih.gov/>
- National Institute on Drug Abuse (NIDA) Good Clinical Practice Course (free of charge, NIDA completion and expiration dates apply): <https://gcp.nidatrainng.org/>

## Unacceptable Good Clinical Practice (GCP) Training options include:

- CITI - Responsible Conduct of Research
- CITI - Health Canada Division 5 - Drugs for Clinical Trials Involving Human Subjects
- CITI - Data Security and HIPAA Training
- CITI - Conflict of Interest
- CITI - Health Information Privacy and Security (HIPS)

For more information, please refer to the Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

# Financial Disclosure Form (1/2)

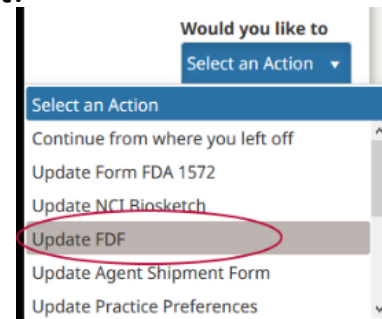
## How to complete the Financial Disclosure Form

1. Click 'Update FDF' from the drop-down menu as illustrated in the screenshot:

2. Click the radio button to indicate *Yes* or *No* for each of the four questions included on the FDF

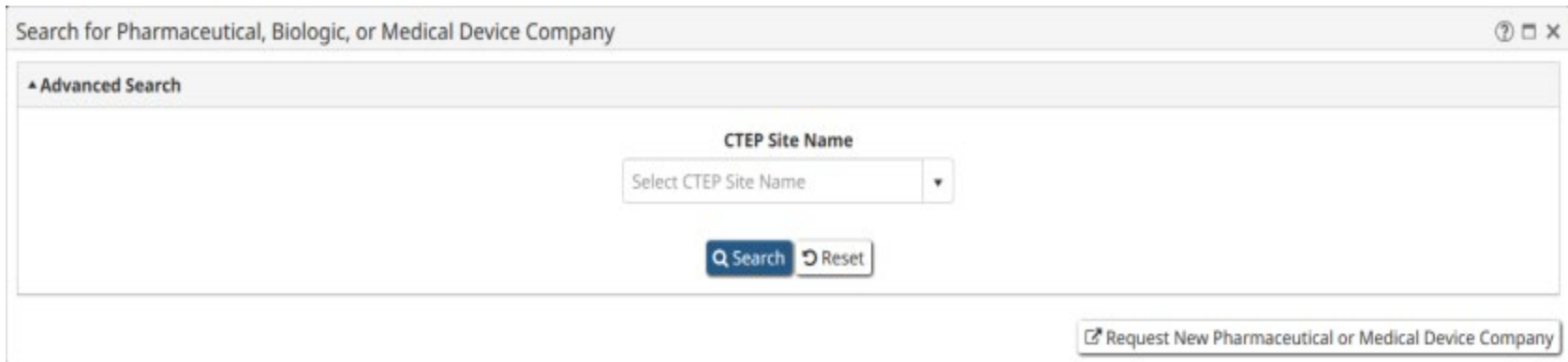
3. If *Yes* is answered to at least one question, the Search for Pharmaceutical, Biologic, or Medical Device Company information box displays for completion:

- Click the **Add New Record** button.
- The **Search for Pharmaceutical, Biologic, or Medical Device Company** screen displays.
- Enter the name of the company in the **CTEP Site Name** field. The system will provide an [auto-complete](#) list of companies that match the name entered in the field. You can also click **Search** to see a complete list of results in the grid.



## How to complete the Financial Disclosure Form

4. Click the checkbox from the Select column to choose the pharmaceutical company, then click Add.
5. Click Save and Continue.



Search for Pharmaceutical, Biologic, or Medical Device Company

Advanced Search

CTEP Site Name

Select CTEP Site Name

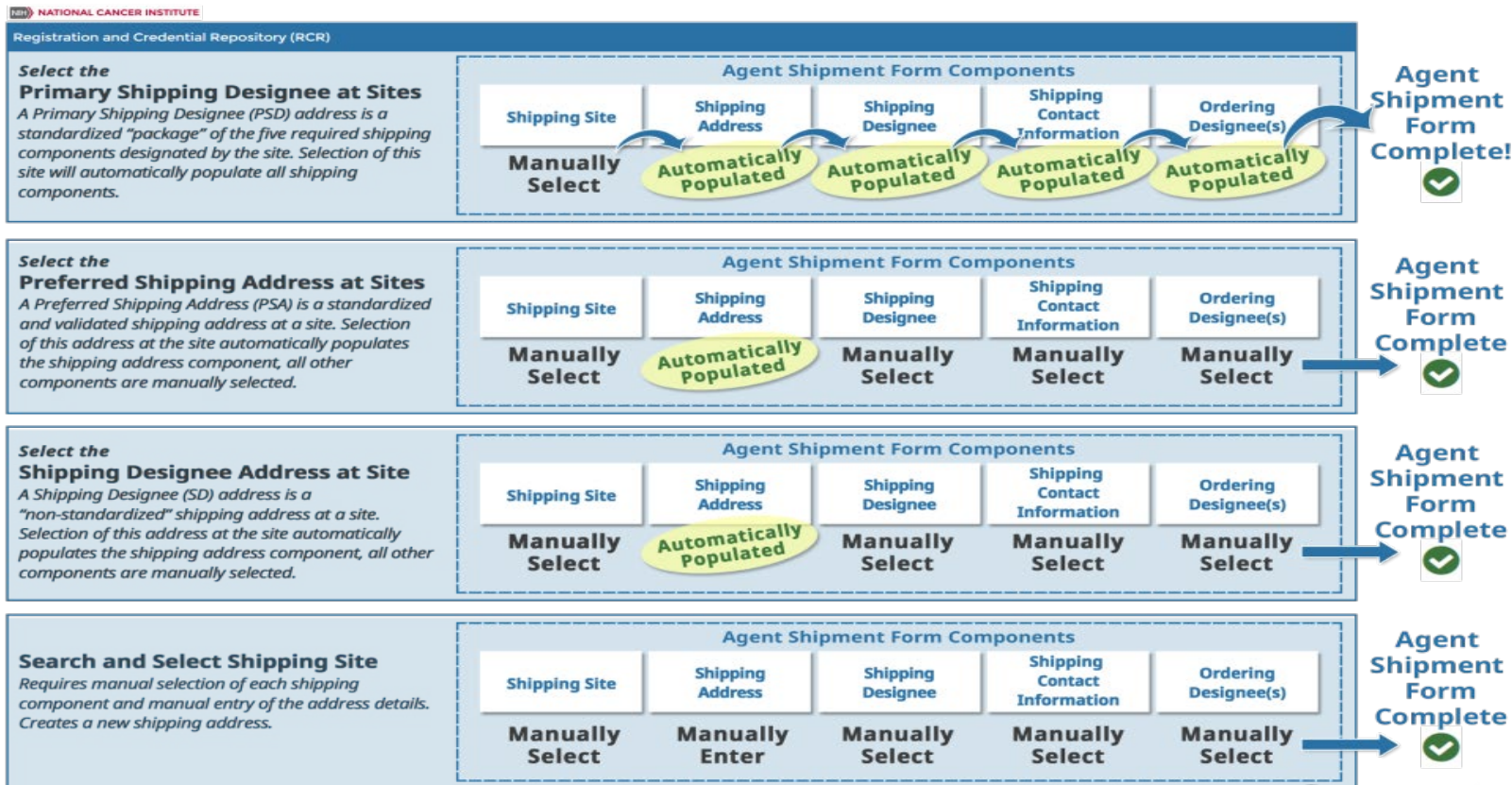
Search Reset

[Request New Pharmaceutical or Medical Device Company](#)

## How to complete the Agent Shipment Form

- To request agents from CTEP, eligible persons under the Investigator Registration Type must identify a practice site to serve as their shipment location for all drug orders. Along with the location and address, a responsible person, preferably a pharmacist, and their contact information must also be identified at the site to serve as the shipping designee to oversee receipt and proper handling of the agent. One or more ordering designees must be selected as well to accurately order drug through the Online Agent Order Processing (OAOP) system.
- Note, the Agent Shipment Form is **only available to Investigators** and is only required for those Investigators requesting shipment of investigational agent(s) from the Pharmaceutical Management Branch (PMB)
- The RCR system will first display the **List of Primary Shipping Designees (PSD)** associated with any of the practice sites entered on your 1572 form.
- Selecting a site with a **Primary Shipping Designees** will automatically insert all the details necessary to complete the shipment summary. The RCR system provides the option to modify the components, if needed, but the Agent Shipment Form is essentially finished with just a couple clicks of the mouse!

# Agent Shipment Form (2/2)





# Find NCI-Supported Clinical Trials (1/3)

NCI-supported clinical trials are those sponsored or otherwise financially supported by NCI. Follow the link to access a customizable search tool of all active NCI-supported clinical trials: <https://www.cancer.gov/about-cancer/treatment/clinical-trials/search>.

See below and the next slide for descriptions of some of the major clinical **Treatment** trials that NCI supports:

## Treatment Trials

### [NCI-COG Pediatric MATCH](#)

In this precision medicine clinical trial, children and adolescents with advanced cancers whose tumors have particular genetic mutations are being treated with drugs designed to target those mutations.

### [NCI-MATCH Trial \(Molecular Analysis for Therapy Choice\)](#)

Information about the NCI-MATCH precision medicine trial, in which researchers will examine tumor tissue from patients with advanced solid tumors and lymphomas that have stopped responding to treatment and assign patients to treatment arms based on the molecular profiles of their disease.

### [The ALCHEMIST Lung Cancer Trials](#)

A collection of material about the ALCHEMIST lung cancer trials that will examine tumor tissue from patients with certain types of early-stage, completely resected non-small cell lung cancer for gene mutations in the EGFR and ALK genes, and assign patients with these gene mutations to treatment trials testing post-surgical use of drugs targeted against these mutations.

# Find NCI-Supported Clinical Trials (2/3)

Additional major clinical **Treatment** trials that NCI supports:

## Treatment Trials

### [Lung-MAP: Master Protocol for Lung Cancer](#)

The Lung Cancer Master Protocol, or Lung-MAP, is a precision medicine research study for people with advanced non-small cell lung cancer that has continued to grow after treatment. Patients are assigned to different study drug combinations based on the results of genomic profiling of their tumors.

### [The ALTTO Breast Cancer Trial](#)

A collection of material about the Adjuvant Lapatinib And/Or Trastuzumab Treatment Optimisation, or ALTTO, study that will compare the targeted agents lapatinib and trastuzumab alone, in sequence, or in combination as adjuvant therapy for HER2-positive breast cancer.

### [The TAILORx Breast Cancer Trial](#)

A collection of material about the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, which will examine whether a molecular test can assign women with early-stage breast cancer to the most appropriate and effective treatment.

# Find NCI-Supported Clinical Trials (3/3)

See below for descriptions of some of the major **Testing and Screening** clinical trials that NCI supports:

## Testing and Screening Trials

### [TMIST \(Tomosynthesis Mammographic Imaging Screening Trial\)](#)

TMIST is a randomized breast screening trial that compares two Food and Drug Administration (FDA)-approved types of digital mammography, standard digital mammography (2-D) with a newer technology called tomosynthesis mammography (3-D).

### [National Lung Screening Trial](#)

Information about the National Lung Screening Trial (NLST), a research study sponsored by the National Cancer Institute that used low-dose helical CT scans or chest X-ray to screen men and women at risk for lung cancer.

### [Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial](#)

A large-scale clinical trial to determine whether certain cancer screening tests reduce deaths from prostate, lung, colorectal, and ovarian cancer. In addition, there are numerous epidemiologic and ancillary studies going on that will answer other crucial questions about these cancers and these screening tests.

### [NCI-MATCH Trial \(Molecular Analysis for Therapy Choice\)](#)

Information about the NCI-MATCH precision medicine trial, in which researchers will examine tumor tissue from patients with advanced solid tumors and lymphomas that have stopped responding to treatment and assign patients to treatment arms based on the molecular profiles of their disease.

# Find Cooperative Group Surgical Cancer Trials (1/2)

Follow the links below to learn more about major **surgical** clinical trials that the NCI supports through their cooperative group network:

## Alliance for Clinical Trials in Oncology

- Alliance A221505: <https://ozarkscancerresearch.org/wp-content/uploads/2019/04/Alliance-A221505.pdf>
- Alliance A011106: <https://clinicaltrials.gov/ct2/show/NCT01953588>
- Alliance AFT-25:  
<https://www.allianceforclinicaltrialsinoncology.org/main/cmsfile?cmsPath=/Public/Annual%20Meeting/files/AFT%2025-May2019.pdf>
- Alliance A021502: <https://clinicaltrials.gov/ct2/show/NCT02912559>

## Find Cooperative Group Surgical Cancer Trials (2/2)

Follow the links below to learn more about major **surgical** clinical trials that the NCI supports through their cooperative group network:

### NRG Oncology

- NRG BR005: <https://clinicaltrials.gov/ct2/show/NCT03188393>
- NRG 9353: [https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15\\_suppl.TPS589](https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.TPS589)

### SWOG *\*formerly Southwest Oncology Group, now goes by acronym only*

- SWOG S1316: <https://www.swog.org/swog-study-s1316-page>

# Additional Resources

- Additional resources for RCR Assistance:
  - CTEP Identity and Access Management (IAM): <https://ctepcore.nci.nih.gov/iam>
  - CTEP Registration and Credential Repository (RCR): <https://ctepcore.nci.nih.gov/rcr>
  - CTEP Registration Help Desk: [CTEPRegHelp@nih.gov](mailto:CTEPRegHelp@nih.gov)
  - RCR Help Desk: [RCRHelpDesk@nih.gov](mailto:RCRHelpDesk@nih.gov)
- Questions? Contact the Clinical Research Program at [clinicalresearchprogram@facs.org](mailto:clinicalresearchprogram@facs.org) or 312-202-5685