NCI's National Clinical Trials Network (NCTN) Brief Overview and Resources

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NIH NATIONAL CANCER INSTITUTE

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Objectives

- Provide a brief overview of NCI's National Clinical Trials Network (NCTN)

- Briefly describe NCTN Navigator, a clinical trials biospecimen resource

Brief NCTN Overview

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NCI National Clinical Trials Network (NCTN) Structure

Selected Major NCTN Trials

- **Precision Medicine Trials: Screening & Assignment to Multiple Interventions Requiring a National Patient Catchment Area**

  ADULT MATCH & PEDIATRIC MATCH (Target Therapies Across Histologies)

  DART (Dual Immunotherapy in Rare Cancers)

  LUNG MAP, ALCHEMIST (Target Therapies in Advanced & Early Stage Lung Ca)

- **Multimodality & Non-Drug Trials**

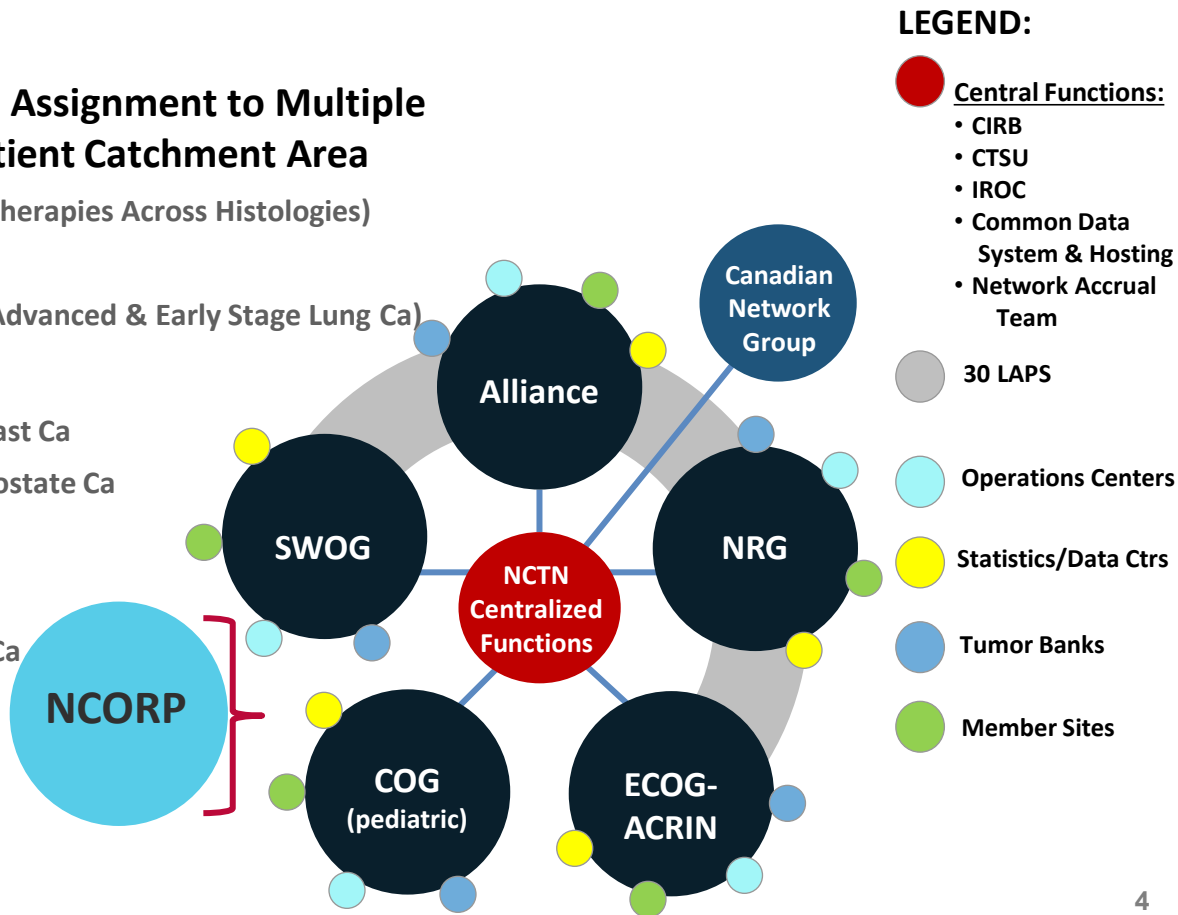 Role of Weight Loss in Treatment of Early Breast Ca

  Dose-Escalated RT +/- ADT in Intermediate Prostate Ca

- **Combination Therapy Trials**

  Cediranib & Olaparib in Recurrent Ovarian Ca

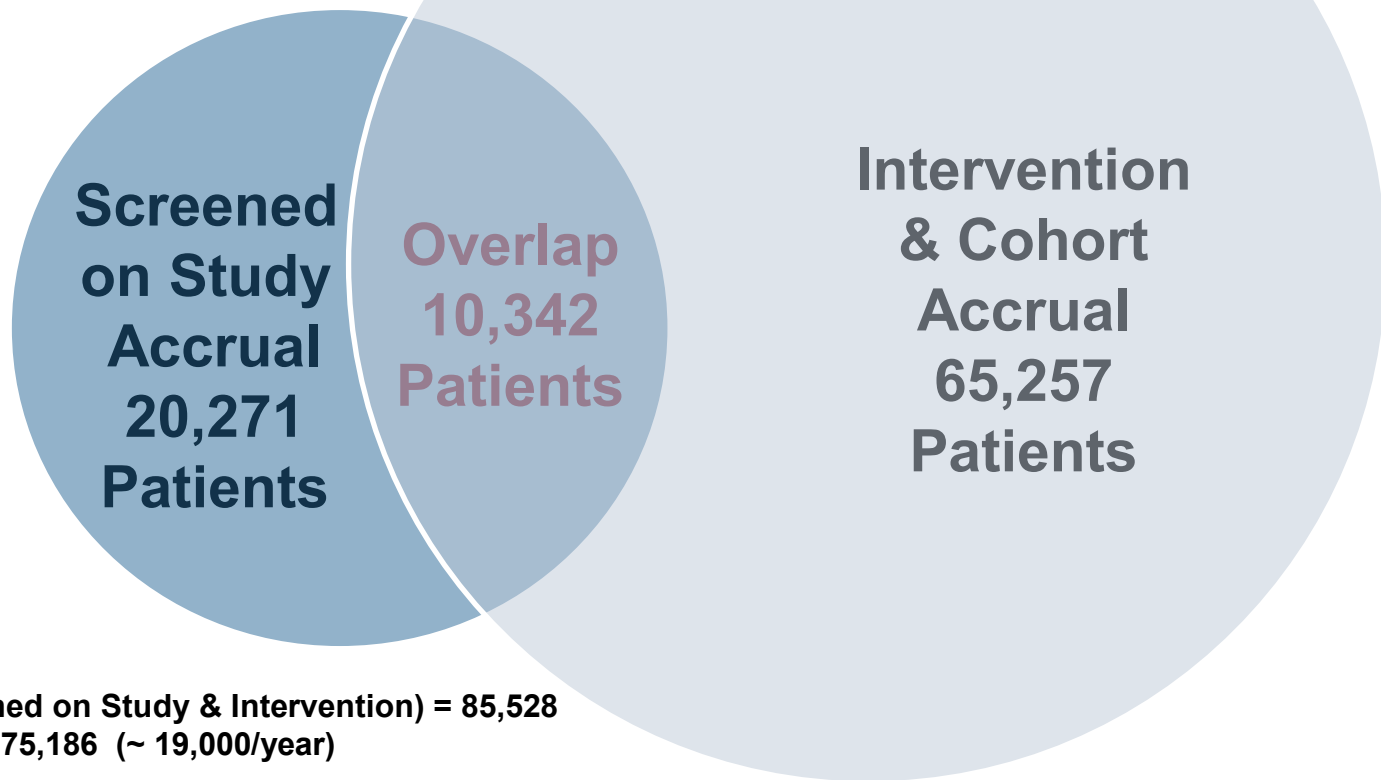 Chemo + Immunotx in Resected Stage III Colon Ca and Deficient DNA Mismatch Repair

 Brentuximab Vedotin or Crizotinib with Chemotx for Newly Diagnosed ALCL

LEGEND:

🔴 **Central Functions:**
- CIRB
- CTSU
- IROC
- Common Data System & Hosting
- Network Accrual Team

⚪ **30 LAPS**

🔵 **Operations Centers**

🟡 **Statistics/Data Ctrs**

🔵 **Tumor Banks**

🟢 **Member Sites**

Sites with at Least 1 Enrollment to NCTN studies - Mar 1, 2014 to Feb 28, 2018
(First 4 Years of the NCTN Program)

NCTN LAPS sites   NCORP sites   NCTN US Member Sites
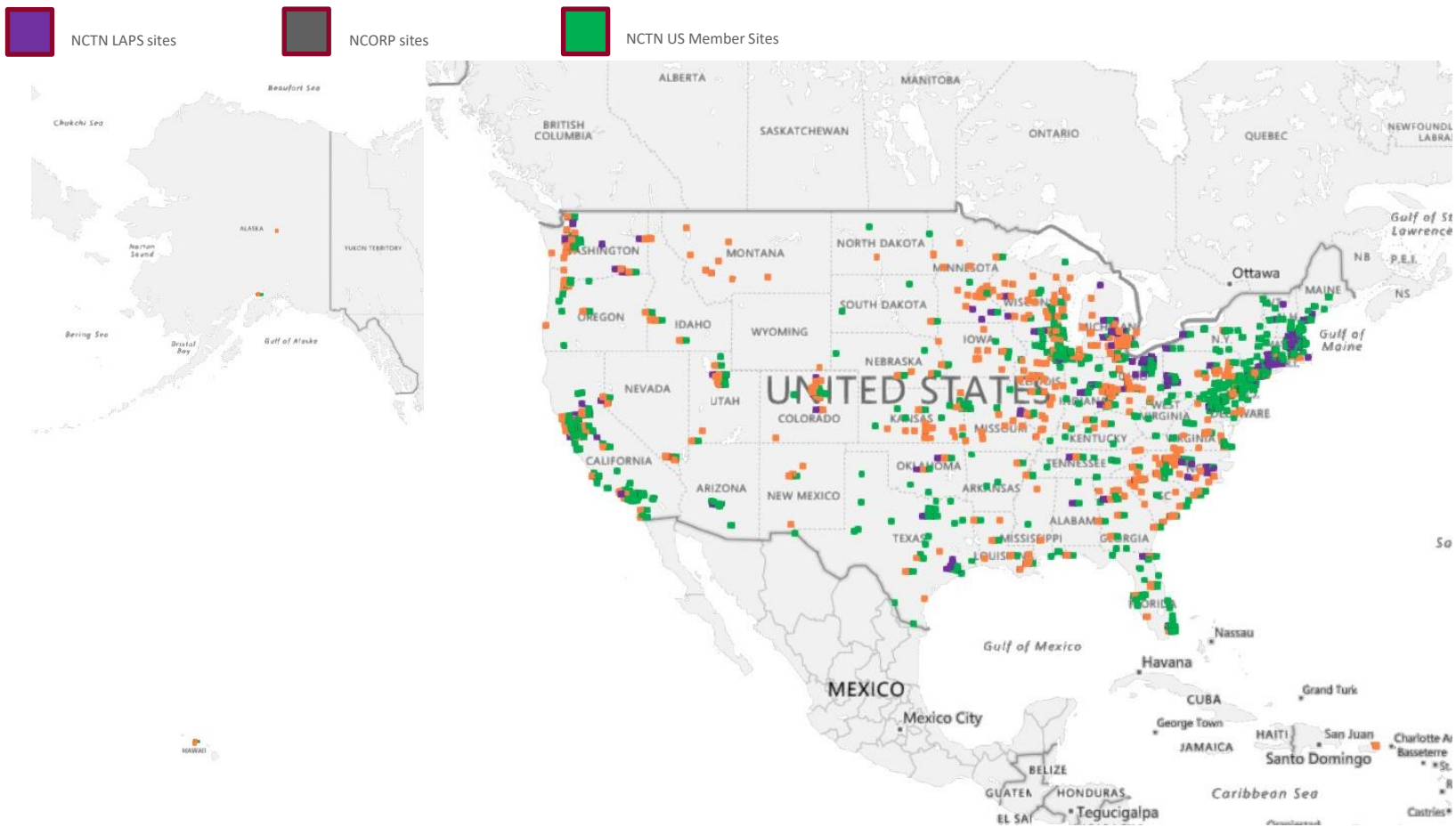
NCTN Program Accrual
3/1/14 to 2/28/2018

Screened on Study Accrual 20,271 Patients

Overlap 10,342 Patients

Intervention & Cohort Accrual 65,257 Patients

Total Enrollments (Screened on Study & Intervention) = 85,528
Total # Unique Patients = 75,186 (~ 19,000/year)

6
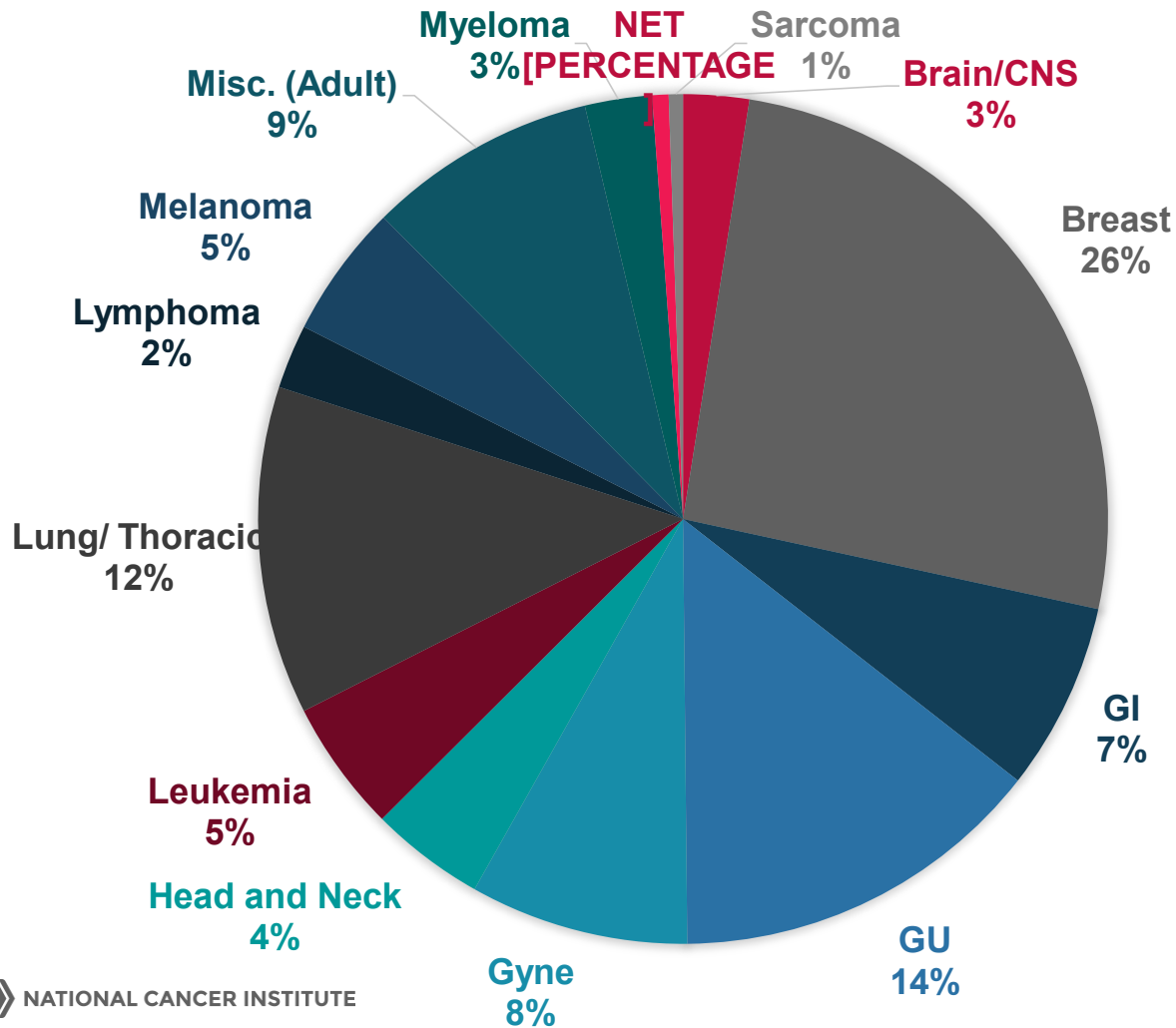
Intervention & Cohort Accrual on **ADULT** NCTN Studies by Major Disease Area

3/1/2014 through 2/28/2018

Pie chart: Intervention & Cohort Accrual on ADULT NCTN Studies by Major Disease Area

- Breast 26%
- Brain/CNS 3%
- Sarcoma 1%
- NET [PERCENTAGE]
- Myeloma 3%
- Misc. (Adult) 9%
- Melanoma 5%
- Lymphoma 2%
- Lung/ Thoracic 12%
- Leukemia 5%
- Head and Neck 4%
- Gyne 8%
- GU 14%
- GI 7%

NCTN Group Websites

- Alliance for Clinical Trials in Oncology

  - https://www.allianceforclinicaltrialsinoncology.org/main/public/index.xhtml

- ECOG-ACRIN Cancer Research Group

  - http://ecog-acrin.org/

- NRG Oncology

  - https://www.nrgoncology.org/

- SWOG

  - https://www.swog.org/

- Children's Oncology Group (COG) https://childrensoncologygroup.org/

    https://www.cancer.gov/research/areas/clinical-trials/nctn/

NCTN Clinical Trial Resources

Grace Mishkin, MPH

NCTN Navigator

NCTN Navigator | A Clinical Trials Specimen Resource

✉ Contact FDS   ⓘ FAQ

NCI's National Clinical Trials Network (NCTN) ↗ Navigator is a resource for investigators who have typically conducted exploratory correlative analysis and are now seeking specimens to validate their hypotheses. Click the "Explore Specimens" button to the right to explore the inventory.

CTEP-IAM Log-In should only be used when you are ready to submit a LOI. If you have questions, please review the FAQs and if your question is not answered there, contact the Front Door Service ✉ for assistance.

Navigator Process Flow

The Navigator inventory is currently limited to select adult treatment trials that were conducted by NCI's NCTN clinical trials Groups, Phase 3 or large biospecimen collection protocols with clinical data, and completed, with the primary outcome reported. For additional information on the process workflow, refer to the Steps for Researchers ↗ document.

To Search Specimens Only

🔓 Explore Specimens

To Submit a LOI

🔒 CTEP-IAM Login

— OR —

ⓘ Provisional Account Login or New Request

Current NCTN Navigator Inventory – July 2018

99
Trials

61653
Patients

857981
Specimens

NCTN Navigator Specimens by Disease Category

Pie chart categories: Breast, Gynecologic, Gastrointestinal, Prostate, Lung, Hematologic, Head and Neck, Other
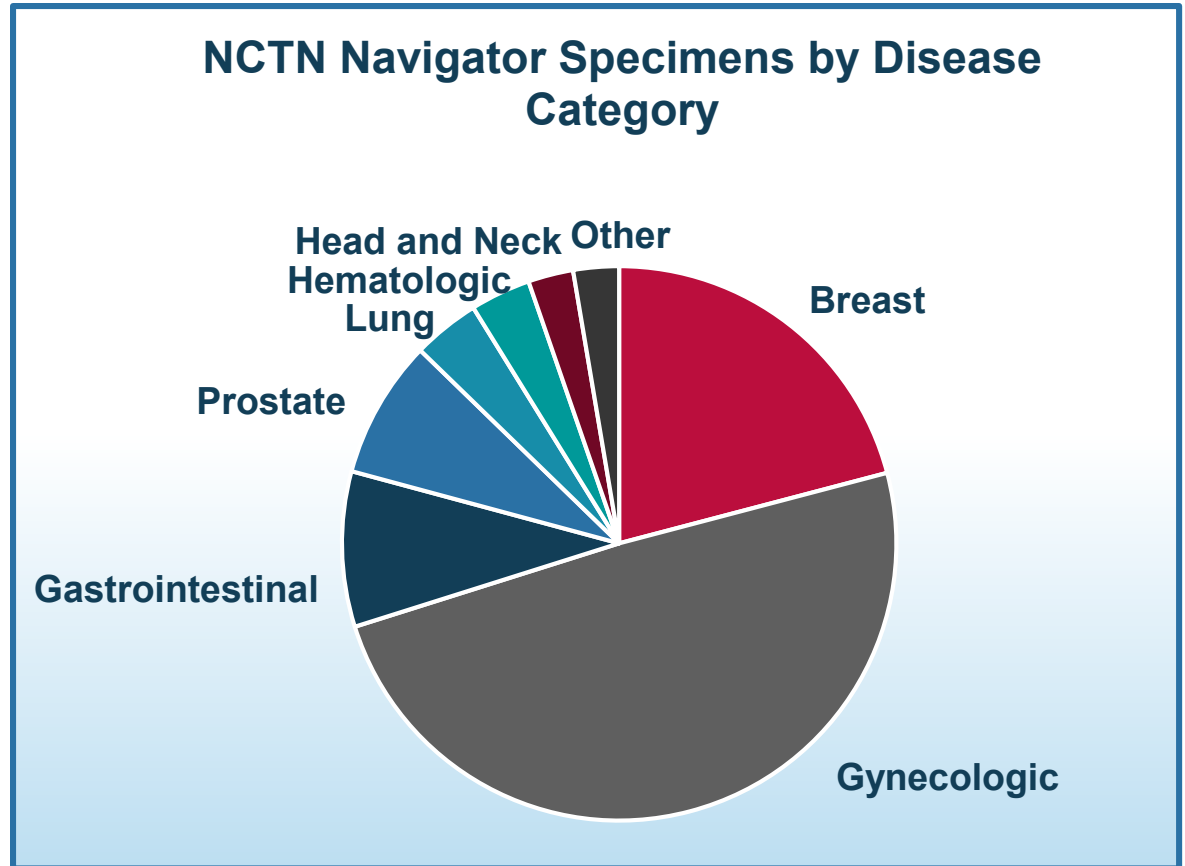
NCTN Navigator

STEPS FOR RESEARCHERS

1 — EXPLORE THE NAVIGATOR WEBSITE
Read about what Navigator offers, including the overall process, available specimens, expected timelines, and potential costs for approved proposals.

2 — SEARCH FOR SPECIMENS USING GUEST ACCESS
Enter Navigator as a guest and search for specimens. Download a report for more details. Contact the Front Door Service if you have questions.

3 — REVIEW THE SPECIMENS AND TRIALS
Review published data from the trials to learn more about the specimen collections, completed projects, and available clinical data.

4 — CONSIDER YOUR SCIENTIFIC QUESTION
Are these specimens appropriate for your question? Is your question an appropriate use of this finite specimen resource and clinical data?

5 — CREATE AN ACCOUNT
Create a CTEP-IAM account. Log in with your provisional account to move forward.

6 — SUBMIT AN LOI
Fill out and submit an LOI with your project title, hypothesis, requested specimens and clinical data, and proposed assays.

7 — REVIEW THE FEASIBILITY REPORT
The LOI will be reviewed for feasibility based on your requested specimens and data. If your LOI is feasible, you can submit a proposal.

8 — SUBMIT A PROPOSAL
Fill out the scientific proposal form and upload it in Navigator. You will need letters of support from all collaborators.

9 — FUNDING, IRB APPROVAL, & USE AGREEMENTS
If your proposal is approved, document your funding, IRB approval, and data and material use agreements before specimens and data can be released to you.

10 — COMPLETE THE PROPOSED PROJECT
Use the specimens and data as outlined in your approved proposal. Publish your results and comply with data sharing requirements.

Types of Searches

Key Navigator Resources

- NCTN Navigator FAQs:
  https://www.ctsu.org/navigator/resources/documents/NCTN_Navigator_FAQ.pdf

- NCTN Navigator User Guide: https://www.ctsu.org/navigator/resources/guides/

- NCTN Core Correlative Sciences Committee (CCSC) Website: https://ctep-test.cancer.gov/initiativesPrograms/nctn_ccsc_overview.htm

- The Front Door Service, or FDS, is a help desk available to investigators using Navigator
  - You can contact the FDS at navigatorcontact@imsweb.com

Additional NCTN Information

NCTN/NCORP Data Archive

NATIONAL CANCER INSTITUTE
NCTN/NCORP Data Archive

https://nctn-data-archive.nci.nih.gov/

Main Menu
- Home
- Search Trial Data
- How to Make a Request [PDF]

Login

Username *

Password *

- Create new account
- Request new password

Math question *
10 + 6 =
Solve this simple math problem and enter the result. E.g. for 1+3, enter 4.

Log in

Request Research Data

NCI has created a centralized, controlled-access database, called the NCTN/NCORP Data Archive, for storing and sharing datasets generated from clinical trials of the National Clinical Trials Network (NCTN) to make these datasets available in a timely manner, on appropriate terms and conditions, to researchers who wish to analyze the data in secondary studies to enhance the public health benefit of the original work.

Contact:
For questions about the NCTN/NCORP Data Archive, please contact NCINCTNDataArchive@mail.nih.gov✉.

Internet Explorer users: This site is not currently optimized for IE, please consider using another browser.

Search the NCTN/NCORP Data Archive

Data requesters must sign a Data Use Agreement (DUA) before being able to download data for a given data request. A DUA is also required for initial account creation. When you request data, a DUA will automatically be generated that contains the details of your request. The DUA contains certain key points to which each data user must agree.

- Sample Data Use Agreement template for Trials with No Collaborative Agreement (PDF - 144KB)
- Sample Data Use Agreement template for Trials with Collaborative Agreements (PDF - 144KB)

Accessibility | Disclaimer | FOIA | Privacy & Security
U.S. Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov

New Trial Portfolios by Disease

NCTN trials: https://ctep.cancer.gov/initiativesPrograms/nctn_trials_by_disease.htm

ETCTN trials: https://ctep.cancer.gov/initiativesPrograms/docs/ETCTN_trials_by_diseaseFiles.pdf

NCTN Trial Portfolios by Disease

(For full functionality, download the PDF file, and read it in PDF reader)

- Adolescent and Young Adult (AYA) (pdf)
- Brain (pdf)
- Breast (pdf)
- Gastrointestinal (pdf)
- Genitourinary (pdf)
- Gynecologic (pdf)
- Lung (pdf)
- Lymphoma (pdf)
- Skin (pdf)

ETCTN Trials

NCI's Experimental Therapeutics Clinical Trials Network (ETCTN) is conducting early-stage trials of cancer treatment therapies in the areas listed below. To see trials that are **in review**, **approved**, and **active** for a specific disease area, please click that disease area from the following list.

Note: For full functionality, it is recommended that users download the PDF file, and open with a PDF reader.

Cancer trials by disease area:

Brain	Lymphoma
Breast	Myeloma
Gastrointestinal	Sarcoma
Genitourinary	Skin and Other Melanoma
Gynecological	Solid Tumors
Head and neck	Solid Tumor Expansion Cohorts
Leukemia	**Printable Listing**
Lung	

New NCTN Trial Portfolios by Disease: Breast Cancer

NCTN Breast Cancer Trials Portfolio (Open as of 5/15/2018) Click Trial Number to go to the associated ClinicalTrials.gov webpage.

Neoadjuvant	Post-Neoadjuvant	Adjuvant	Metastatic
A011106 (ALTERNATE) HR+/HER2-	**NRG-BR005** Any HR/HER2 status	**NRG-BR003** TNBC	**E2112** HR+/HER2- ≤1 prior chemotherapy

Surgery (Intra-Operative)
- **NSABP-B-51** Any HR/HER2 status
- **A011202** Any HR/HER2 status

Residual Disease
- **EA1131** TNBC Stage II/III
- **S1418** TNBC Stage II/III

- **S1207** HR+/HER2- High Risk Stage II/III
- **A011401 (BWEL)** HER2- Stage II/III
- **A011502 (ABC)** HER2- Stage II/III
- **NSABP-B-55** BRCA 1/2 mutations

- **RTOG-1119** HER2+ Patients with brain mets
- **S14|16** TNBC and/or|BRCA1/2 ≤1 Prior Che|motherapy
- **NRG-BR002** Any HR/HER2 status Female only; No brain mets
- **EAY131 (MATCH)**
- **S1609 (DART)**

Legend by Subtype Status

White = Any HR/HER2 status	Green = TNBC	Blue = HER2- (Any HR status)	Purple = HR+ and HER2-	Orange = HER2+ (Any HR status)	Yellow = BRCA1/2 mutations	Pink = Cross-disease trials

CTEP Twitter Account: @NCICTEP_ClinRes

Account Target Audience:

- Clinical cancer grantees, sites, researchers, and research staff involved in CTEP-supported trials including the NCTN and ETCTN (Experimental Therapeutics Clinical Trials Network) trials.

Account Goals:

- Provide another way for our audience to learn about CTEP initiatives, trials, and trial requirements

CTEP Twitter Account: [@NCICTEP_ClinRes](https://twitter.com/NCICTEP_ClinRes)

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