

**Biospecimen Banks to Support
NCI National Clinical Trials Network (NCTN),
NCI Community Oncology Research Program (NCORP)
and CTEP-Supported Early Trials/Studies**

Re-issue RFA/Cooperative Agreement/Limited Competition

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Biospecimen Banks to Support NCI Clinical Trials

Goal: to collect, process, store and distribute well-annotated NCI Clinical Trials biospecimens for research

- NCTN Banking RFA CA14-501 (2015-2020) supports 5 U24 Banking Grants: **ALLIANCE, SWOG, ECOG-ACRIN, NRG Oncology, COG**
- Grant PIs: pathologists specialized in biospecimen banking
- Specimens collected for NCTN phase III, phase II and other trials (on protocols) are well-annotated with clinical and outcome data
- Specimens initially used by NCTN trial Group Investigators for **integral** and **integrated biomarker** studies/assays (prognosis/prediction)
- Specimens remaining in excess after clinical trial requirements have been met become **“legacy”** specimens and are available to investigators for **secondary correlative studies** following a defined NCTN biospecimen access process and approval by NCTN Core Correlative Science Committee (NCTN CCSC)

NCTN Biospecimen Distribution (2013-2017)

ALL Organ Sites; Adult & Pediatric Cancer

Total Samples* Distributed		440,114
- Solid Tumor Samples		410,248
- Leukemia Samples		29,866
NCTN Investigators Served (Integral/integrated)		223
ALL Investigators Served (Legacy Specimens)		348
- NCTN Group Investigators	220	
- Non-Group Investigators	128	
▪ Publications (based on specimens used for research)		572

**Sample” is defined as one processed piece of a biospecimen, regardless of the sample size or type of initial processing: FFPE block/frozen tissue/vial/aliquot.*

Solid Tumors DISTRIBUTED by NCTN Banks (2013-2017)

		SELECTED MAJOR SAMPLE TYPE				
5 NCTN Groups	Samples	FFPE	Frozen	Plasma	Serum	# of Trials OVER ENTIRE 2013 – 2017 PERIOD
2013	106,902	41,025	2,042	27,235	18,682	316
2014	74,163	24,990	1,526	22,155	14,342	
2015	50,615	34,018	4,404	5,270	7,411	
2016	78,353	50,746	11,174	2,564	3,103	
2017	100,215	70,947	9,543	5,831	5,191	
TOTAL	410,248	221,726	28,689	63,055	48,729	

Leukemia Specimens DISTRIBUTED by NCTN Banks (2013-2017)

		SELECTED MAJOR SAMPLE TYPE				
4 NCTN Groups	Samples	Bone Marrow	Blood WBC	DNA	RNA	# of Trials OVER ENTIRE 2013 – 2017 PERIOD
2013	6,823	2,251	265	1,393	1,233	83
2014	7,410	2,863	794	996	1,100	
2015	6,373	3,614	284	1,037	714	
2016	4,924	1,279	401	988	558	
2017	4,336	1,475	612	527	341	
TOTAL	29,866	11,482	2356	4,941	3,946	

“# of Trials Over Entire 2013-2017 Period” - number of unique trials involved across all 5 years, as number of trials with active sample distributions will vary from year to year.

NCTN “Legacy” Biospecimens-Access

<https://navigator.ctsu.org/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](#)



Explore specimens in Navigator using a Guest Account

Explore related trial publications & develop a question

Create a CTEP-IAM account & submit a LOI

The LOI will be reviewed for feasibility

Submit a proposal, if the LOI was feasible

The proposal will be scientifically reviewed

Obtain regulatory approvals & funding, receive specimens, complete project.

1. Consolidate inventory of biospecimens

2. Connect biospecimens and clinical data

3. Provide biospecimen access to research community

4. Track applications

Published Data Load Status as of May 29, 2019



119

Trials



72363

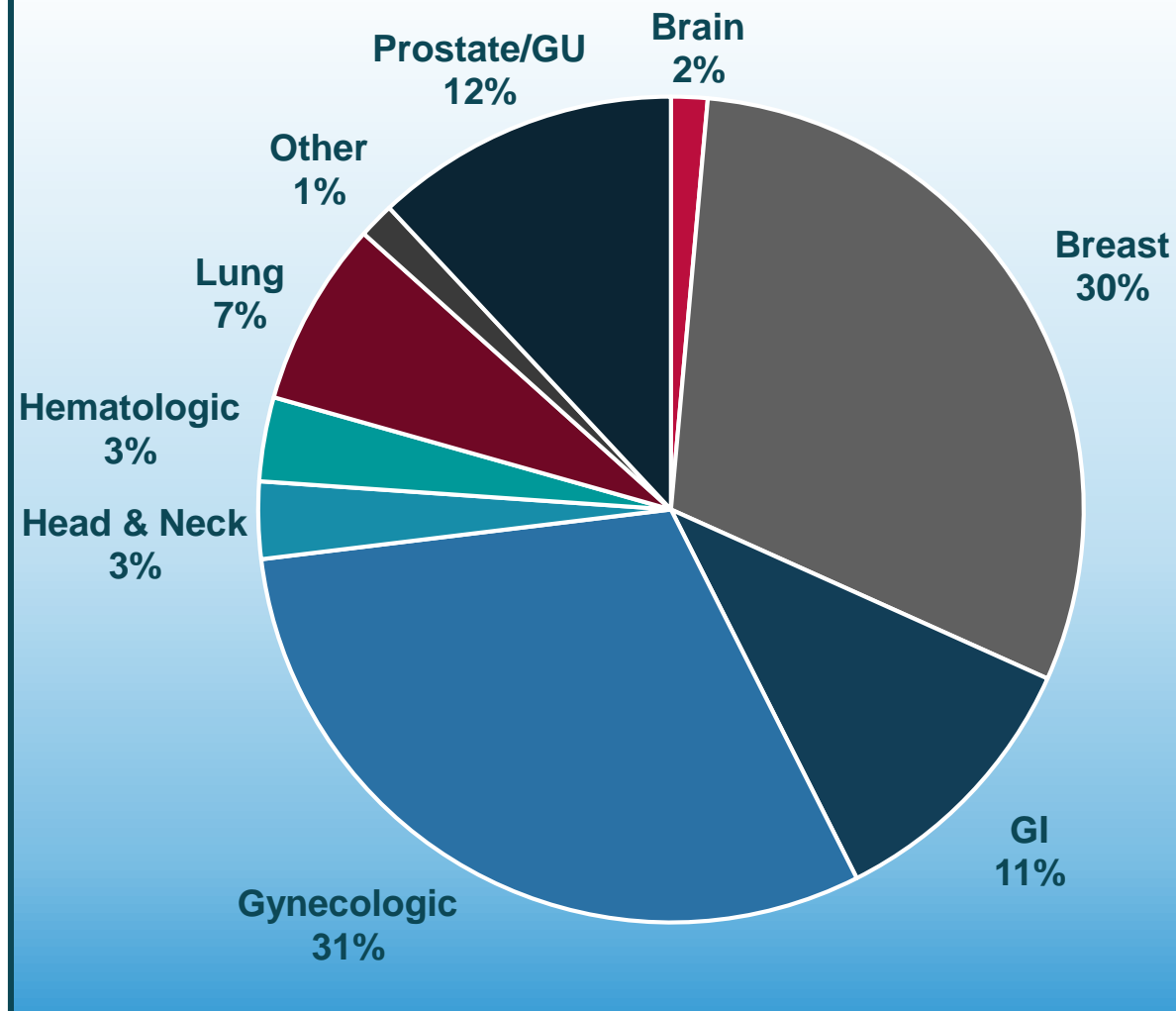
Patients



852946

Specimens

NCTN Navigator Specimens by Disease Category



Biospecimen Banks: U24-Cooperative Agreement (2020-2026)

Current funding:

5 NCTN banks (11.1 M/year) and ETCTN bank pilot (650K/year)

5 Awards for NCTN Biospecimen Banks

\$15.2M

- Infrastructure and operations
- NCTN Biospecimen IT Navigator & Front Door Service curation
- “Legacy” specimens retrieval, processing, QA/QC
- Specimens for CIMAC (specialized processing/handling)
- Specialized kits and tubes for collection sites & processing
- Digital whole slide images storage/scanning
- NCORP cancer prevention trials biospecimens (restricted)
- * New PEP-CTN Biospecimen Banking in COG NCTN Bank

\$1.8M

\$0.23M

1 Award for Early Clinical Trials Bank (ETCTN, CITN, & CIMAC) **\$2.5M**

Total cost for 6 Banks per year

\$19.73M

BSA Subcommittee Reviewers' Question

- *To further understand the Navigator program, which is only in its first year, what are the demand metrics?*

Navigator: Investigator Requests as of May 29, 2019

61 Letters of Intent (LOIs) submitted

- 45 feasible (specific specimens & associated data are available)
- 15 not feasible (specific specimens are not available)
- 1 in review

Of the 45 feasible LOIs, 28 full proposals have been submitted

- 6 approved
- 2 pending
- 8 disapproved
- 12 scheduled for review in coming months
- 17 not yet submitted by investigators to CCSC

BSA Subcommittee Reviewers' Question

➤ *Is the data ever linked back to the original specimen? If yes, indicate if the data are easily available to other researchers and how one can access the data.*

- NIH policies include requirements for data sharing and public access to publications from NCTN clinical trials
- De-identified patient-level data from all NCTN phase III and phase II/II trials must now be submitted to the NCTN/NCORP Data Archive (<https://nctn-data-archive.nci.nih.gov/>) after publication of the trial's primary results (which may also include results from any integral biomarker included in the trial)
- Data submission to the Archive includes the dataset, data dictionary, and relevant metadata, along with a de-identified code for each patient that can be used for future linkage to genomic, imaging, or other specimen data contained in other databases
- For example, research proposals for use of “legacy” specimens from NCTN Navigator approved by the NCTN-CCSC may be submitted to NIH's dbGAP/NCI Genomic Data Commons (<https://gdc.cancer.gov/>). If the trial data also exists in the NCTN/NCORP Data Archive, linked patient IDs can be provided to approved investigators to facilitate linkage between the patients' specimens data and the their trial data.

BSA Subcommittee Reviewers' Question

➤ *Has consideration been given to developing standards and common data elements to support and address the scalability of data?*

- Each NCTN trial/study protocol is different and includes 100s or 1000s of data elements.
- NCTN uses the CDEs listed in the CDE Browser to facilitate cross study comparisons. There is a set of NCI Standard Modules and CDEs in the caDSR that have been vetted across the larger user community.
- There are ~1800 released NCI Standard CDEs on the list (another ~1000 are in draft status).

CDE Browser:

<https://cdebrowser.nci.nih.gov/cdebrowserClient/cdeBrowser.html#/search>

NCI CDE Project:

<https://wiki.nci.nih.gov/display/cadsr/ctep+common+data+elements#CTEPCommonDataElements-StandardsLeveragedbytheCDEProject>