

National Cancer Institute Biospecimen Resource Landscape

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On behalf of the

Pathology Investigations & Resources Branch

CDP, DCTD, NCI

Board of Scientific Advisors Meeting

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Main Messages

- **Biospecimen resources (BSRs) are historically diverse i.e. organized at different times and for different purposes.**
- **BSRs may serve basic, translational and clinical researchers, depending on the scientific goals of the Program**
- **BSRs are supported by individual grants, cooperative agreements, contracts or intramural funds.**
- **Each resource is developed for the grant mechanism it supports**
- **Resources developed for Cancer Centers, SPOREs, Clinical trials (NCTN), Population Science (DCCPS) and High Risk (DCEG) cohorts**

Main Messages (2)

- **Each BSR follows resource-specific SOPs to collect specimens for distribution to researchers.**
- **BSRs include completed and ongoing biospecimen collections.**
- **Specimens types vary by resource e.g. cell lines, blood and body fluids, FFPE and/or frozen tissue.**
- **'Specimen' definitions vary among resources**
- **Survey includes specimens collected and distributed in 2017 only; several resources had a higher specimen distribution in other years**

Main Messages (3)

- **Resource IT systems track specimen collection, storage and distribution and cater to specific resource goals/investigator needs**
- **IT systems are funded by different resource grants/contracts**
- **Specimen information is kept within resource IT systems**
- **Review and re-assessment of resources occurs every cycle to re-issue the infrastructure resource grants**

NCI Biospecimen Resources Questionnaire

***NOTE:** If multiple institutions are in your biospecimen resource (e.g. Cancer Centers, SPOREs, CHTN) please answer questions for the ENTIRE resource collectively and not for each institution.*

1. Name of NCI Division/Program:

2. Name of Biospecimen Resource/Number of Institutions Funded/Year when established:

3. Purpose of Biospecimen Resource:

4. Tumor/Disease Type:

5. Type of Investigator Served: (Select all that apply)

Basic Translational Clinical

6. Biospecimen Access for Research (*Please also provide the BIOREPOSITORY ACCESS POLICY on a separate page – 1-page limit):

Institution/Network Investigator Only Outside of Network Investigator Both

a) What information is required in the application for specimens? (Select all that apply)

Abstract LOI Study description Full study proposal

b) What entity approves a specimen request application based on scientific rationale?

The biorepository Standing Scientific Committee NCI

Other, specify:

7. Please provide a URL(s) for a resource website:

8. Is the resource a procurement service or a specimen bank/biorepository?

2018 NCI Biospecimen Resources Survey Questions

- ***Name of NCI Division/Program***
- ***Name of Biospecimen Resource/Number of Institutions Funded/ Year When Established***
- ***Purpose of Biospecimen Resource***
- ***URL(s) for Resource Website***
- ***Type of Investigator Served: Basic, Translational, Clinical***
- ***Tumor/Disease Type***
- ***Types of Biospecimens Collected: (e.g. Tumor, Normal tissue, Blood, Other Fluids, Organ-specific, Other)***

2018 NCI Biospecimen Resources Survey Questions (2)

- ***Is the Resource a Procurement Service or a Specimen Bank/Biorepository?***
- ***Biospecimen Access for Research - Access Policy: (Institution/Network Investigator Only, Outside of Network Investigator, Both)***
- ***What Information is Required in the Application for Specimens? (Abstract, Letter of Intent, Study Description, Full Proposal)***
- ***What Entity Approves a Specimen Request Application Based on Scientific Rationale? (Biorepository, Standing Scientific Committee, NCI)***

2018 NCI Biospecimen Resources Survey Questions (3)

Specimen Distribution

- *Fee for Specimen*
- *Fee for Service*
- *Collaboration*
- *Collaboration and Fee for Service*

Metrics of success

- *Number/Impact of Publications/Number of Patents*
- *Number of Fulfilled Investigator Requests*
- *Investigator Feedback*
- *Number of NCI Grants Served*

2018 NCI Biospecimen Resources Survey Questions (4)

- ***How Are the Specimens Annotated? (Demographic, Pathology Report, Disease Stage, Treatment, Outcome)***
- ***What Is the Source of the Specimen Annotation? (Clinical Trial, Tumor Registry, Chart Review, Other)***
- ***Informatics (IT) System for Biospecimen Tracking Used by the Resource/Network***
- ***Does the Repository Link Its Data to Public or Controlled Access Databases?***

RESULTS

NCI-Supported Biospecimen Resources (44)

- Office of the NCI Director (3)
- Division of Cancer Treatment & Diagnosis (5)
- Division of Cancer Biology (4)
- Division of Cancer Control & Population Sciences (18)
- Division of Cancer Epidemiology & Genetics (4)
- Division of Cancer Prevention (6) and (1) with DCEG
- Center for Cancer Research (Intramural) (3)

Biospecimen Access: Public; Controlled; Collaboration

- **Public:** CHTN-Cooperative Human Tissue Network (academia, industry)
- **Members of a scientific network:** Cancer Centers; SPOREs
- Specific ongoing **research project investigators** first. When the project is completed the specimens become available for sharing with **other investigators (collaborators):** DCCPS; DCEG
- **NCI intramural investigators and collaborators:**
CCR (intramural); DCEG (intramural) PI collections;
OD Proteomics (CPTAC Breast Cancer plasma samples)

DCTD: NCI BIOSPECIMEN RESOURCES

Division of Cancer Treatment and Diagnosis	Name of Biospecimen Resource/Funding Mechanism	Specimens Collected in 2017	Specimens Distributed in 2017
DCTD/Cancer Diagnosis Program	Cooperative Human Tissue Network (CHTN) (UM1CA Grants)	50,000	44,259
DCTD/Cancer Diagnosis Program	National Clinical Trials Network Biospecimen Banks (NCTN Banks; U24CA Grants)	351,177	104,551
DCTD/Cancer Diagnosis Program	Experimental Therapeutics Clinical Trials Network (ETCTN) Biorepository (U24CA Grant)	20	0
DCTD/ Translational Research Program	53 SPORE Biospecimen Cores (P50 Grants)	169,484	22,962
DCTD/Cancer Diagnosis Program	GTEx (Genotype-Tissue Expression) Biorepository (NIH Common Fund)	0	8,775

DCCPS and DCEG: NCI BIOSPECIMEN RESOURCES

NCI Division/ Program	Name of Biospecimen Resource/Funding Mechanism	Specimens Collected in 2017	Specimens Distributed in 2017	
Division of Cancer Control & Population Sciences (DCCPS)	18 Biospecimen NCI Epidemiology Cohorts (U01 & UM1 grants)	>1,250	>11,000	
DCEG (Intramural) & Division of Cancer Prevention	PLCO Biorepository (Contract)	11,450	88,454	
Division of Cancer Epidemiology & Genetics (DCEG) (Intramural)	DCEG Principal Investigator Collections (Contract)	189,831	144,992	
DCEG (Intramural)	U.S. Radiologic Technologists Study (Contract)	0	0	
DCEG (Intramural)	Alpha-Tocopherol, Beta- Carotene Prevention Study (Contract)	0	2,624	
DCEG (Intramural)	Agricultural Health Study- (Contract)	0	2,841	

CENTER FOR CANCER RESEARCH (CCR): NCI BIOSPECIMEN RESOURCES

NCI Division/ Program	Name of Biospecimen Resource/Funding	Specimens Collected in	Specimens Distributed in	
<p style="text-align: center;">CCR/OD/Clinical Pharmacology Program (Intramural)</p>	<p style="text-align: center;">Blood Processing Core (Intramural Funds)</p>	<p style="text-align: center;">29,008</p>	<p style="text-align: center;">7,817</p>	
<p style="text-align: center;">CCR/Lab of Pathology (Intramural)</p>	<p style="text-align: center;">Clinical Pathology Archives/ Anatomic Pathology (Intramural Funds)</p>	<p style="text-align: center;">19,626</p>	<p style="text-align: center;">16,491</p>	
<p style="text-align: center;">CCR/Lab of Pathology (Intramural)</p>	<p style="text-align: center;">Clinical Pathology Archives/ Tissue Procurement & Processing Facility (Intramural Funds)</p>	<p style="text-align: center;">310</p>	<p style="text-align: center;">15</p>	

NCI-Supported Biospecimen Resources: Examples

□ U Cooperative Agreement Grants:

Support Biospecimen Resource Infrastructure: specimen collection, processing, storage and distribution for research

U24 (Resource-related Research Project):

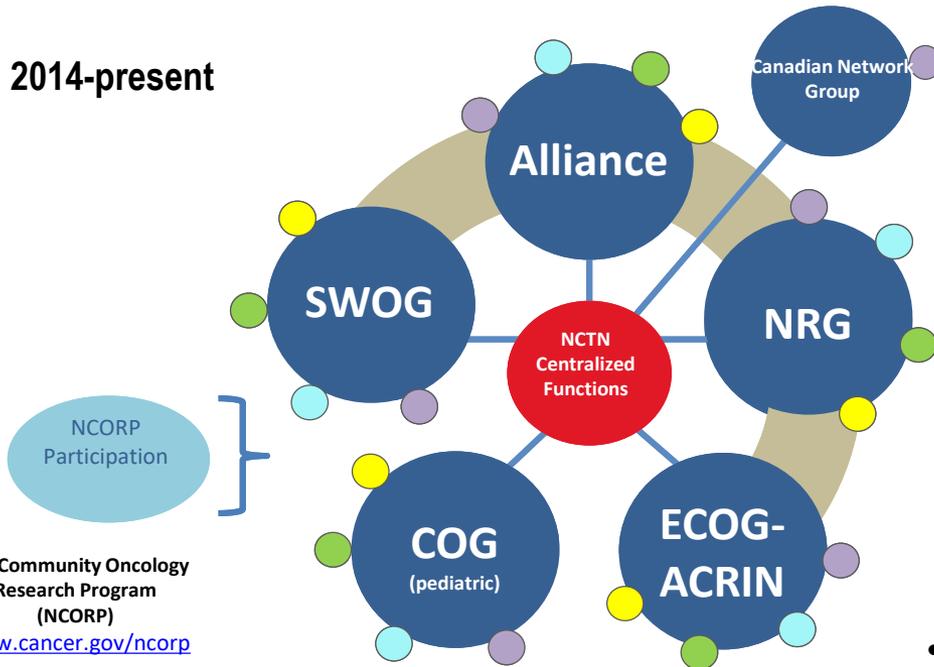
NCI National Clinical Trials Network Biospecimen Banks (NCTN Banks)

UM1 (Large-scale Research Activities with Complicated Structures):
Cooperative Human Tissue Network (CHTN)

NCI National Clinical Trials Network (NCTN)

<http://www.cancer.gov/clinicaltrials/nctn>

2014-present



NCI Community Oncology
Research Program
(NCORP)
www.cancer.gov/ncorp

LEGEND

- Centralized Functions
 - Cancer Trials Support Unit (CTSU)
 - Centralized Institutional Review Board (CIRB)
 - Imaging and Radiation Oncology Core (IROC)
- 30 NCTN Lead Academic Participating Sites (LAPS)
- Network Group Operations
- Network Group Statistics & Data Management
- *NCTN Biospecimen Banks*
- NCTN Member Sites

- 2,000+ enrolling sites across North America (plus international sites)
- 22,000+ patients enrolled in 2017
- 175+ trials active in 2017

NCTN Biospecimen Banks (NCTN Banks)- Five U24-CA grants

- **Unique Resource:** Store and provide researchers with well-annotated specimens and clinical data from NCTN phase III, phase II and other trials
- **Biospecimens** are collected on NCTN trial protocols and used for integral and integrated biomarker studies/assays (prognosis/prediction)
- **Biospecimens** that remain in excess after clinical trial requirements have been met become **“legacy” specimens** and are distributed to investigators following a defined NCTN biospecimen access process and approval of the correlative study by expert review (NCTN Core Correlative Science Committee - NCTN CCSC)
- **2013-2017 Impact**

Total # Specimens Distributed:	440,114
Solid Tumor Specimens	410,248
Leukemia Specimens	29,866
Total # Tumor Specimens Collected:	1,755,886
Publications (specimens used for research)	572

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

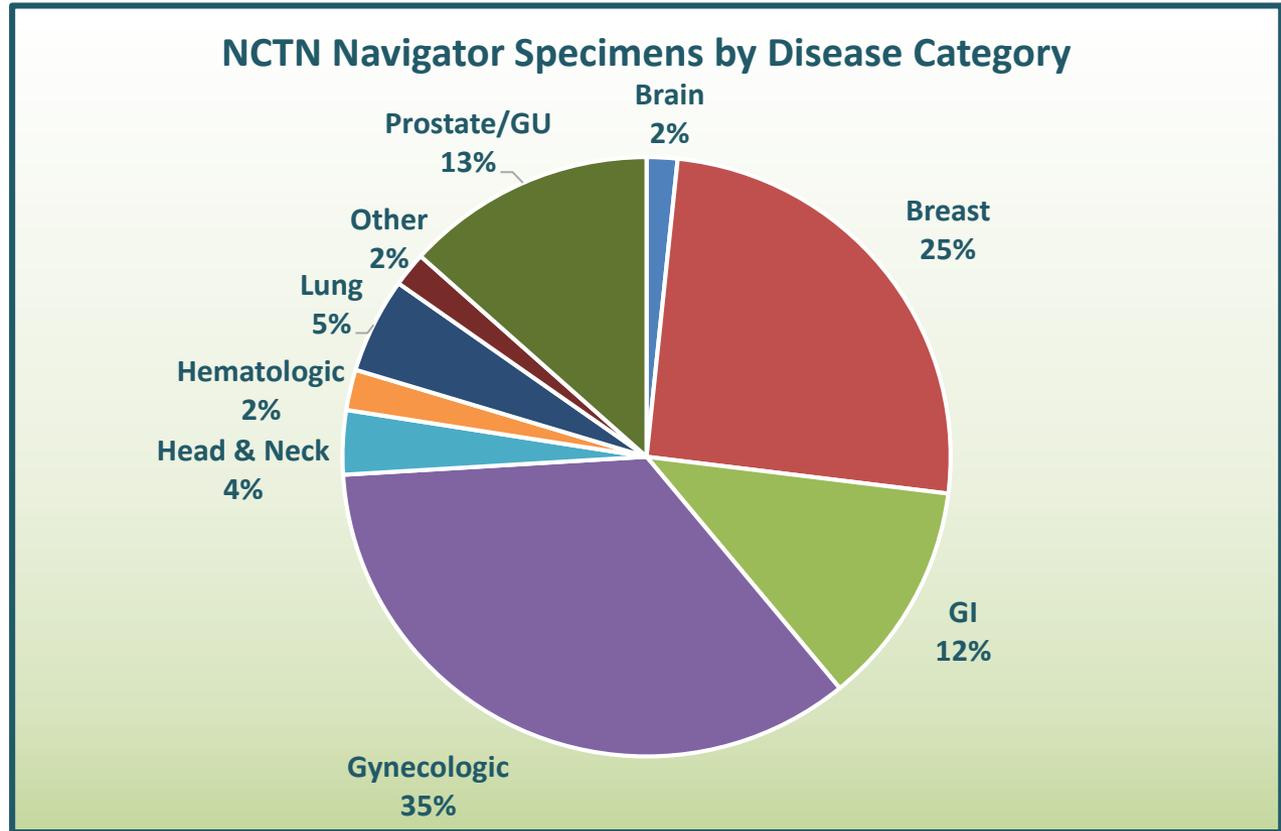
CTEP-IAM Login

OR

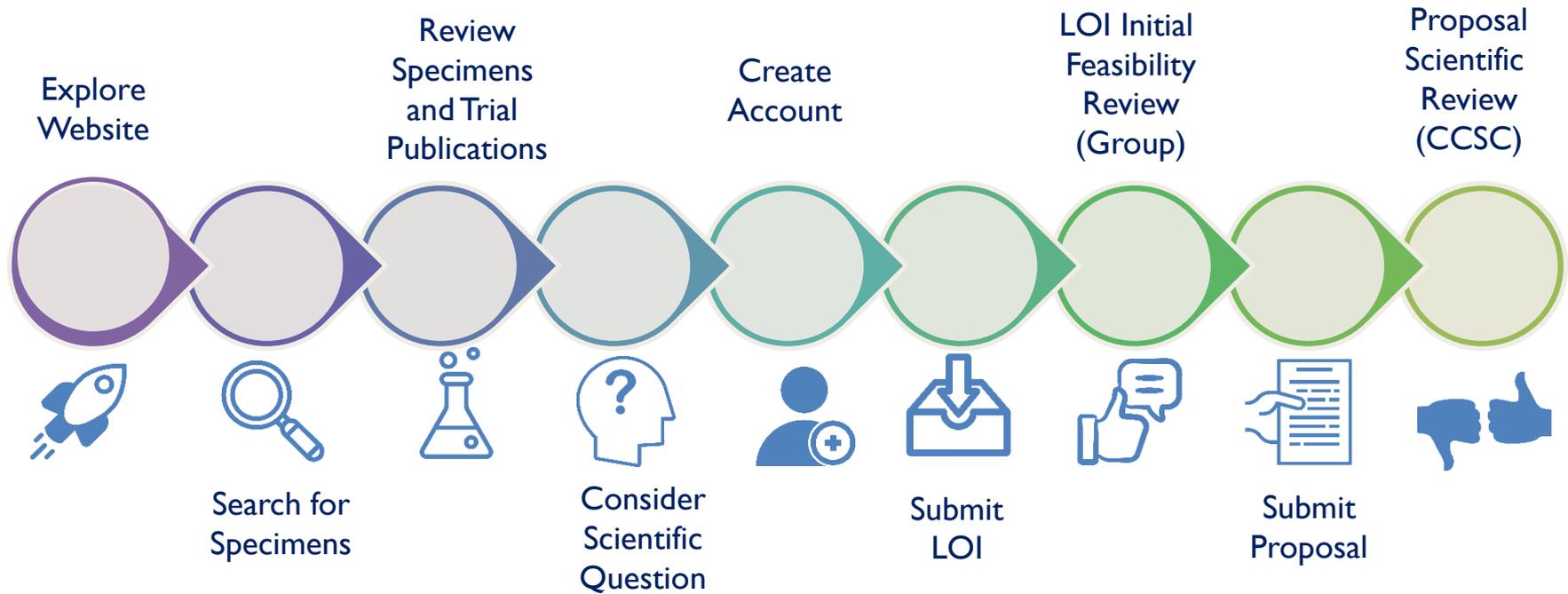
Provisional Account Login or New Request



Published Data Load Status as of October 30, 2018



How Does NCTN Navigator Work?



Post-Approval (outside of Navigator Website)



NCI Biospecimen Resources and Communication Efforts

- **NCI Research Resources Website:** <https://www.cancer.gov/research/resources>
- **Specimen Resource Locator** <https://specimens.cancer.gov>
- **DCTD and CDP Websites:**
<https://dctd.cancer.gov/ResearchResources/ResearchResources-humantissue.htm>

Communication Efforts:

- **Meeting Exhibits, Presentations & Flyers: AACR, ISBER, ASCO, NCI Programs**
- **NCI CDP E-mail push to NIH grantees**
- **govDelivery: NCI email platform for public subscribers; LinkedIn; Twitter**

Conclusions

- *NCI has 44 Biospecimen Resources funded by grants, contracts cooperative agreements and intramural funds*
- *Each resource is designed to serve the needs of a different group of investigators for a different purpose.*
- *Distribution of specimens varies each year and is dependent on resource needs of investigators for specific projects.*

Conclusions

- *Harmonization of resources may be best achieved by ongoing efforts to publicize available BSRs to the community through various websites and communication vehicles.*
- *A single IT system for all NCI resources is unlikely to be feasible based on the great diversity of efforts and purposes.*
- *Resource sharing requirements for all BSRs could be stipulated to ensure optimal utilization.*

Additional slides

OFFICE OF NCI DIRECTOR: NCI BIOSPECIMEN RESOURCES SURVEY SUMMARY

NCI Division/ Program	Name of Biospecimen Resource/Funding Mechanism	Specimens Collected in 2017	Specimens Distributed in 2017	Annual Total Cost to NCI
OD/Office of Cancer Centers	54 Cancer Centers with Shared Biospecimen Resources (P30 Grants)	NA	NA	\$ 8 M
OD/Office of HIV & AIDS Malignancy	AIDS & Cancer Specimen Resource (ACSR) (UM1CA Grants)	6,233	4,032	\$ 4.1 M
OD/CSSI/Clinical Proteomic Tumor Analysis Consortium	CPTAC Breast Cancer Plasma Samples (Contract)	0	0	\$ 30 K

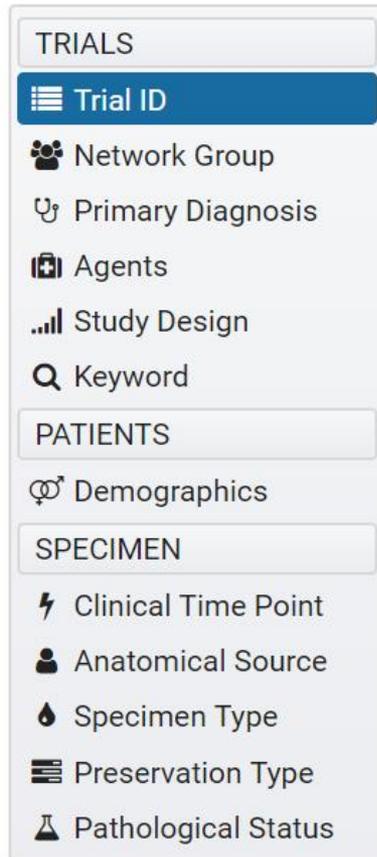
DIVISION OF CANCER BIOLOGY: NCI BIOSPECIMEN RESOURCES SURVEY SUMMARY

NCI Division/ Program	Name of Biospecimen Resource/Funding Mechanism	Specimens Collected in 2017	Specimens Distributed in 2017	
Division of Cancer Biology	Chernobyl Tissue Bank (U24 Grant)	674	1258	
Division of Cancer Biology	International Registry of Werner Syndrome (R01 Grant)	24	119	
Division of Cancer Biology	Barrett's Esophagus BETRNet Virtual Biorepository/Coordinating Center (U24 Grant)	NA	NA	
Division of Cancer Biology	Physical Sciences-Oncology Network Bioresource Core Facility (PBCF) (Contract)	0	209	

DIVISION OF CANCER PREVENTION: NCI BIOSPECIMEN RESOURCES

NCI Division/ Program	Name of Biospecimen Resource/Funding Mechanism	Specimens Collected in 2017	Specimens Distributed in 2017	Annual Total Cost to NCI
DCP	Breast Cancer Prevention Trial (BCPT) Cohort Specimens (Contract)	0	0	\$ 25.5 K
DCP	Early Detection Research Network (EDRN) Reference sets (Contract)	0	1,696	\$ 113 K
DCP	Interactive Diet and Activity Tracking in AARP (iDATA) (Contract)	0	0	\$ 12 K
DCP	Prostate Cancer Prevention Trial Cohort Specimens (Contract)	0	0	\$ 22.6 K
DCP	Selenium and Vitamin E Cancer Prevention Trial (SELECT) Biorepository (Contract)	0	0	\$ 22.6 K
DCP	Study of Tamoxifen and Raloxifene (STAR) cohort Specimens (Contract)	0	0	\$ 25.5 K

Searching the Navigator



- You can search for specimens in Navigator by creating queries with three general categories of information:
 - information about the **Trials** the specimens were collected on
 - information about the demographics of the **Patients**
 - information about the **Specimens**