

This *issue* is the *tissue*!

**The NCTN Core Correlative Sciences
Committee updates and recommendations**

I have no conflicts/disclosures.

Correlative studies and biospecimen collection

The NCI appreciates the importance of biospecimen collection for correlative analyses on all trial phase studies.

Opportunities for execution of unspecified future research are built into trials. This involves use of specimens remaining after protocol-defined integral and integrated endpoints are completed.

Resources for biospecimen access

- Biospecimens from phase 1/2 studies can be requested from NCI via proposal submission to CTEP PRC via PIO
- Remaining biospecimens from phase 2/3 and 3 studies, and large annotated biospecimen collection studies, can be found in

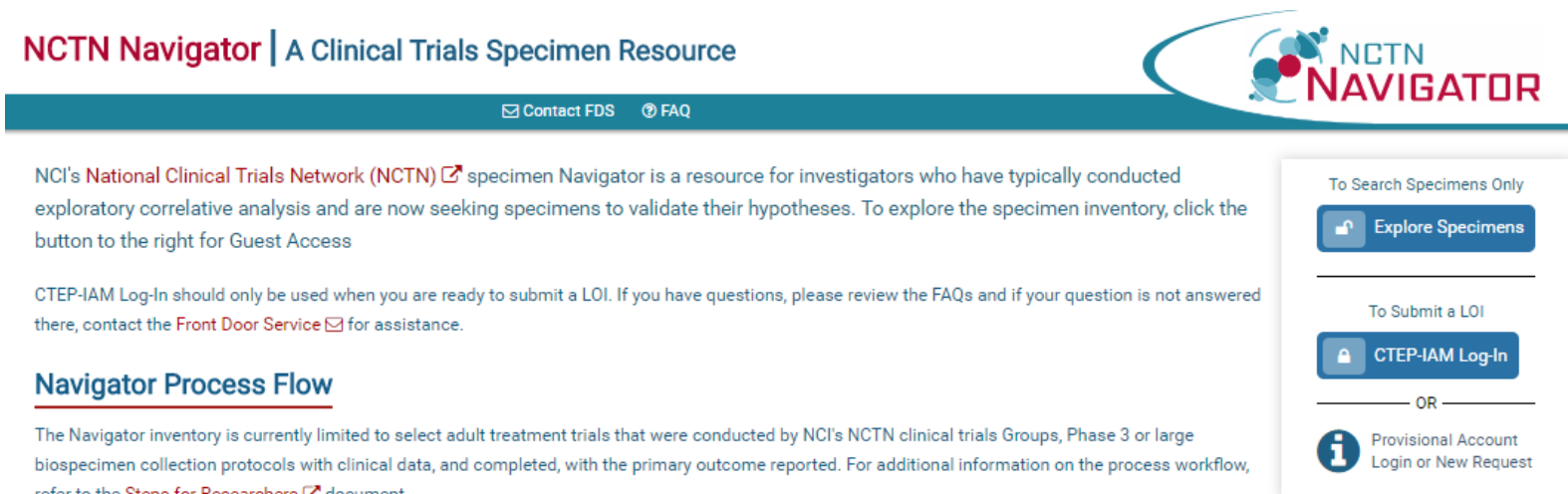
NCI NAVIGATOR

<https://navigator.ctsu.org/>

- Navigator is an inventory resource
- Navigator specimens are clinically-annotated specimens

What is NCTN Navigator?


- **NCTN Navigator website:** Inventory resource for external investigators to identify specimens of interest
- **NCTN Navigator associated processes:** Processes through which investigators can submit queries, LOIs, and proposals and carry out approved proposals for specimens and data of interest




The screenshot shows the NCTN Navigator website. At the top, the header reads "NCTN Navigator | A Clinical Trials Specimen Resource" with a logo on the right. Below the header is a teal navigation bar with links for "Contact FDS" and "FAQ". The main content area on the left contains text about the NCTN specimen Navigator, a link for "Guest Access", and a section titled "Navigator Process Flow" which explains the current limitations of the inventory and refers to a "Steps for Researchers" document. On the right side, there is a white sidebar with three main sections: "To Search Specimens Only" with an "Explore Specimens" button, "To Submit a LOI" with a "CTEP-IAM Log-In" button, and "OR" followed by a "Provisional Account Login or New Request" button with an information icon.


NCTN Navigator | A Clinical Trials Specimen Resource

Contact FDS FAQ


NCI's **National Clinical Trials Network (NCTN)**  specimen Navigator is a resource for investigators who have typically conducted exploratory correlative analysis and are now seeking specimens to validate their hypotheses. To explore the specimen inventory, click the button to the right for Guest Access

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 Log-In**

OR

 **Provisional Account Login or New Request**

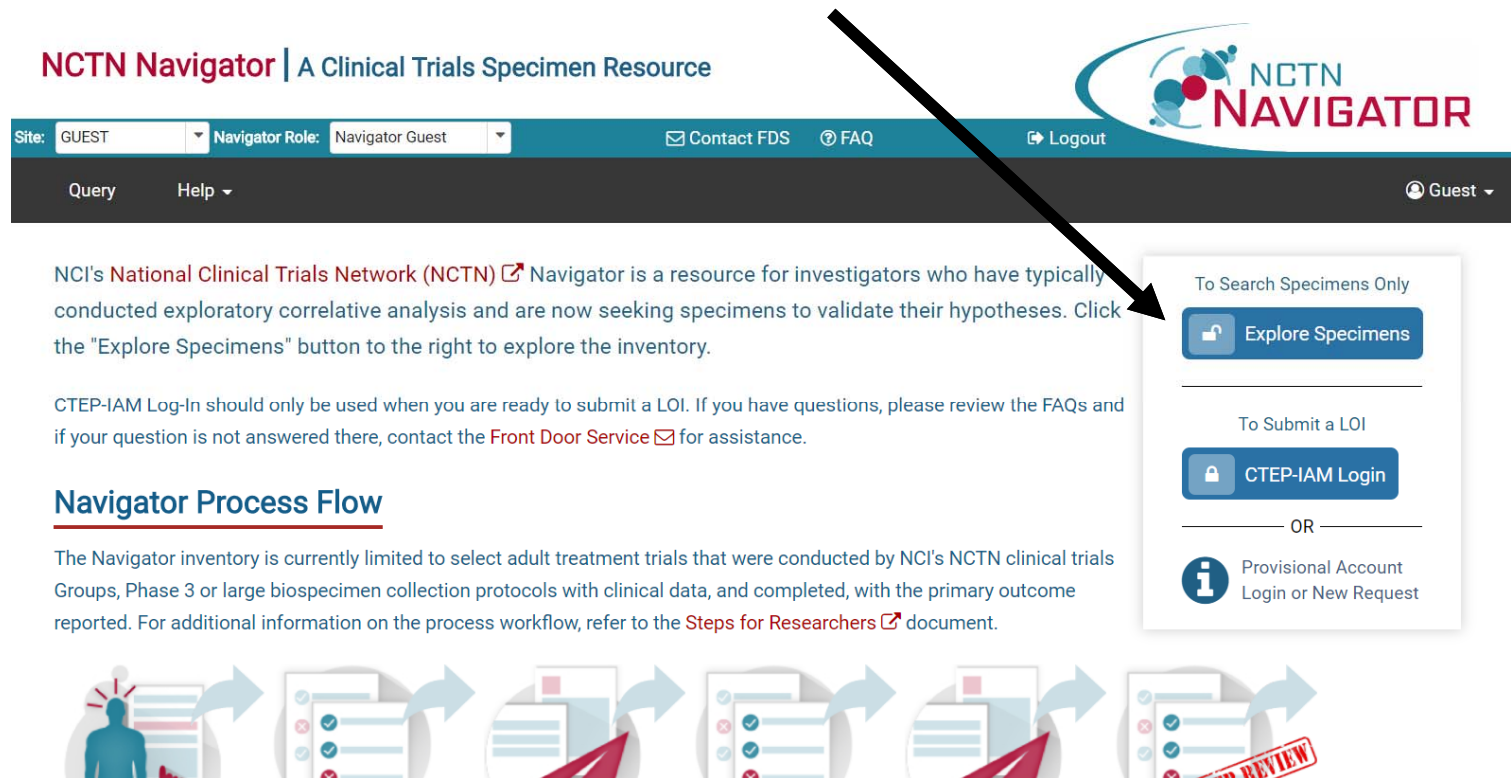
How Does NCTN Navigator Work?



Post-Approval (outside of Navigator Website)



How do I Explore Specimens in Navigator?



NCTN Navigator | A Clinical Trials Specimen Resource

Site: Navigator Role: [Contact FDS](#) [FAQ](#) [Logout](#)

Query Help Guest

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.

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To Search Specimens Only
[Explore Specimens](#)

To Submit a LOI
[CTEP-IAM Login](#)

OR

[Provisional Account Login or New Request](#)



How do I Explore Specimens in Navigator?

Use multiple parameters in search to target specific elements of interest

The screenshot displays the NCTN Navigator interface. At the top, the header includes the NCTN Navigator logo and navigation links like 'Contact FDS', 'FAQ', and 'Logout'. Below the header, a navigation bar shows '8 Trial(s)', '3954 Patient(s)', and '33417 Specimen(s)'. On the left, a sidebar menu lists categories: TRIALS (Trial ID, Network Group, Primary Diagnosis, Agents, Study Design, Keyword), PATIENTS (Demographics), and SPECIMEN (Clinical Time Point, Anatomical Source, Specimen Type, Preservation Type, Pathological Status). The 'Primary Diagnosis' filter is selected. The main content area shows a search for 'lung' with results: 'Lung adenocarcinoma (10025032)', 'Small cell lung cancer (10041071)', and 'Squamous cell lung carcinoma (10025126)'. To the right, a 'Query' panel shows a note about incomplete query information and a filter for 'Primary Diagnosis' with the value 'Non-small cell lung cancer, NOS (10029514)'. Arrows numbered 1 through 4 point to the 'Primary Diagnosis' filter in the sidebar, the search input field, the 'Primary Diagnosis' filter in the query panel, and the 'View Query Results' button, respectively.

Finding Out More About Clinical Data from Navigator Trials

The screenshot shows the NCI National Clinical Trials Network interface. At the top, a 'Search Results' section displays a table of trials. A black arrow points to the 'CALGB-9633' trial in the table. Below the table, a 'Create LOI' button is visible. The bottom section, titled 'At-a-Glance for Trial ACOSOG-Z0030', provides detailed protocol information for that trial. A black arrow points to the 'NCT Number' field, which contains 'NCT00003831' and a link icon.

Search Results

NOTE: These numbers are based on the best information available at this time. Final numbers for available patients and specimens cannot be confirmed until a proposal is approved.

Trials				
	Trial	Network Group	Patients	Specimens
<input type="checkbox"/>	CALGB-9633	ALLIANCE	212	318
<input checked="" type="checkbox"/>	CALGB-9761	ALLIANCE	338	1867
<input checked="" type="checkbox"/>	CALGB-30801	ALLIANCE	84	84
<input type="checkbox"/>	ACOSOG-Z0030	ALLIANCE	280	565
<input type="checkbox"/>	CALGB-140202	ALLIANCE	392	479

Create LOI Save Query Download

At-a-Glance for Trial ACOSOG-Z0030

Protocol Information for ACOSOG-Z0030

Trial: ACOSOG-Z0030

Title: Randomized Trial of Mediastinal Lymph Node Sampling Versus Complete Lymphadenectomy During Primary Resection in the Patient with N0 or N1 (Less Than 4 cm) Non-Small Cell Carcinoma

Phase: III

NCT Number: NCT00003831 [Link](#)

Lead Organization: ALLIANCE

Primary Study Type: Treatment

Secondary Study Type:

Study PI Name: Mark Allen

Study Diseases

NCI National Clinical Trials Network

- Trials with specimens shown in Navigator are completed and reported
- Trial publications are linked on the trial page on www.clinicaltrials.gov
- Navigator has a link to the trial page on www.clinicaltrials.gov → click the information button next to the trial number
- This will open the “At-a-Glance” information for the trial
- In the “At-a-Glance” screen, click the link next to the NCT number to go to the www.clinicaltrials.gov trial page

How Do I Submit an LOI?

- The LOI is an online form submitted through the Navigator website and requires a CTEP IAM account
- The LOI is a basic form that **is not reviewed on scientific merit**; it serves as a brief feasibility check to assess the initial availability of the specimens and data
- Specimen and data availability will be confirmed after a proposal is approved
- The Front Door Service coordinates for Navigator submissions
- Feasible LOIs receive a prompt for proposal submission



Proposals are reviewed by the NCTN-CCSC

- **NCTN Core Correlative Science Committees (CCSCs) are charged with scientific review & prioritization of proposals requesting use of banked, non-reserved biospecimens collected from NCTN trials for use in correlative science studies.**
- **There are two active NCTN CCSCs:**
 - **CCSC-A primarily reviews proposals in adult tumors**
 - **CCSC-B primarily reviews proposals in hematology and sarcoma and will review pediatric proposals**

https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_overview.htm

Proposals are reviewed by the NCI CCSC

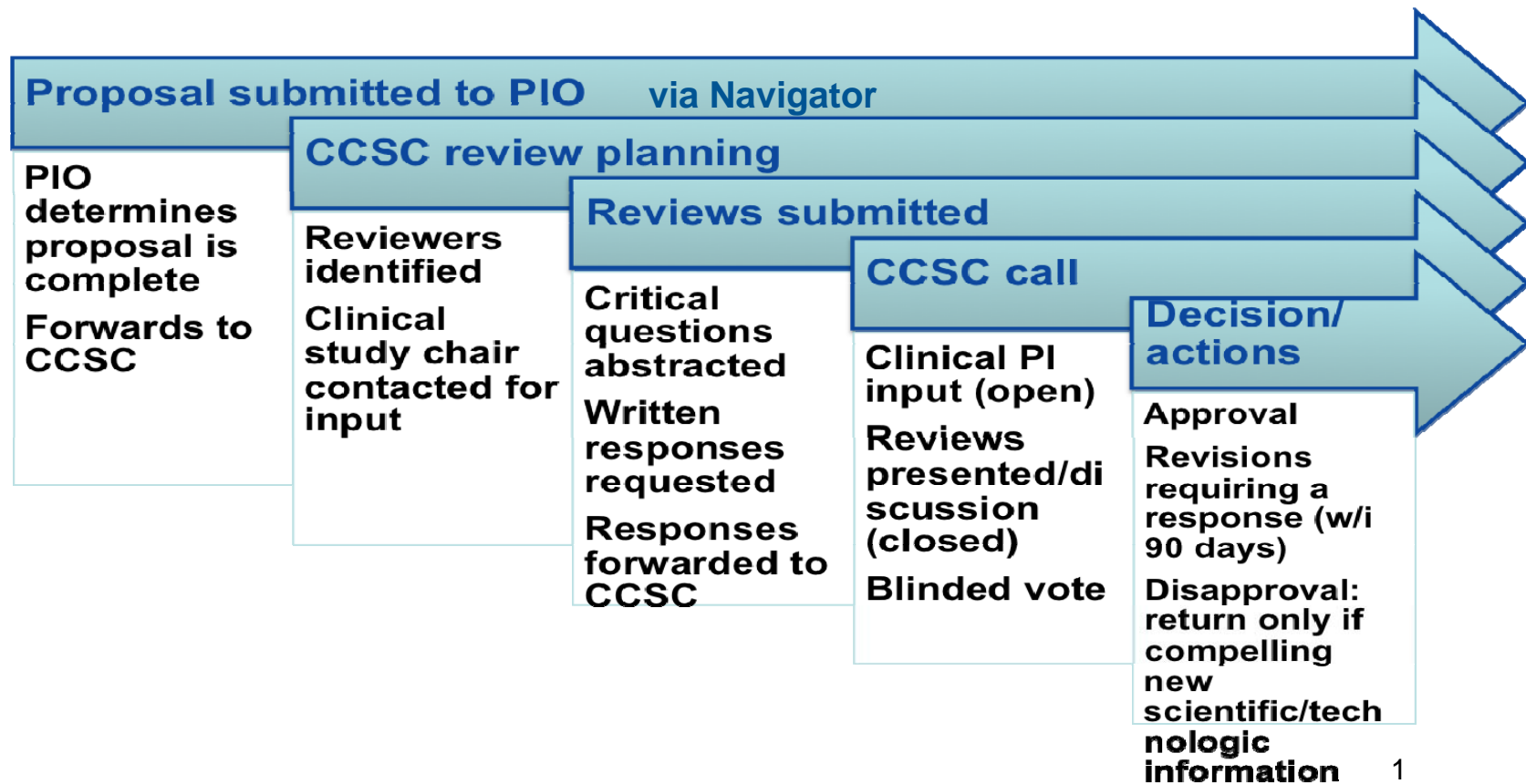
NCTN-CCSCs prioritization helps ensure optimal use of these irreplaceable clinical trial biospecimens.

The CCSCs consists of representatives from each NCTN group, translational scientists, pathologists, the Banks, and statisticians.

- **Primary use is for *validation of locked down optimized predictive assays*.**
- **Criteria for exploratory use can be found on the CCSC website.**

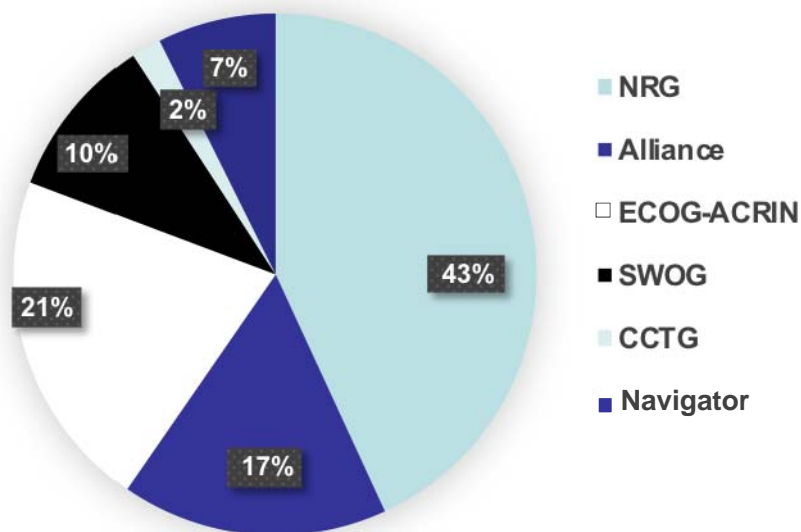
https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_overview.htm

NCTN-CCSC Workflow

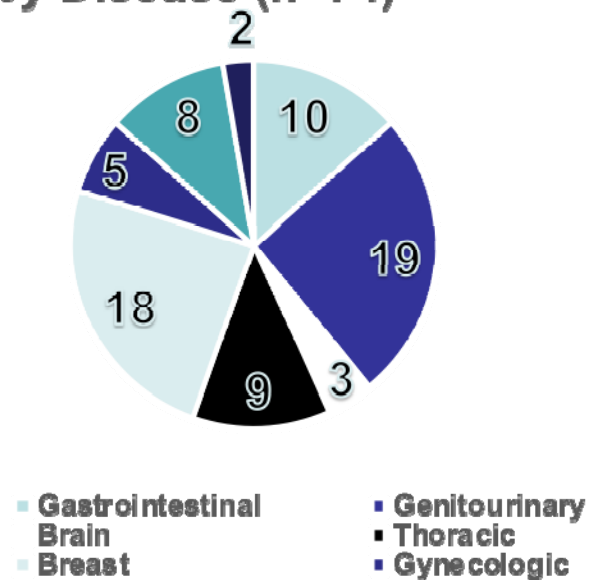


NCTN-CCSC first 4 years: submissions

Proposals submitted to
CCSC
by Group (n=109)



Proposals reviewed by
CCSC
by Disease (n=74)

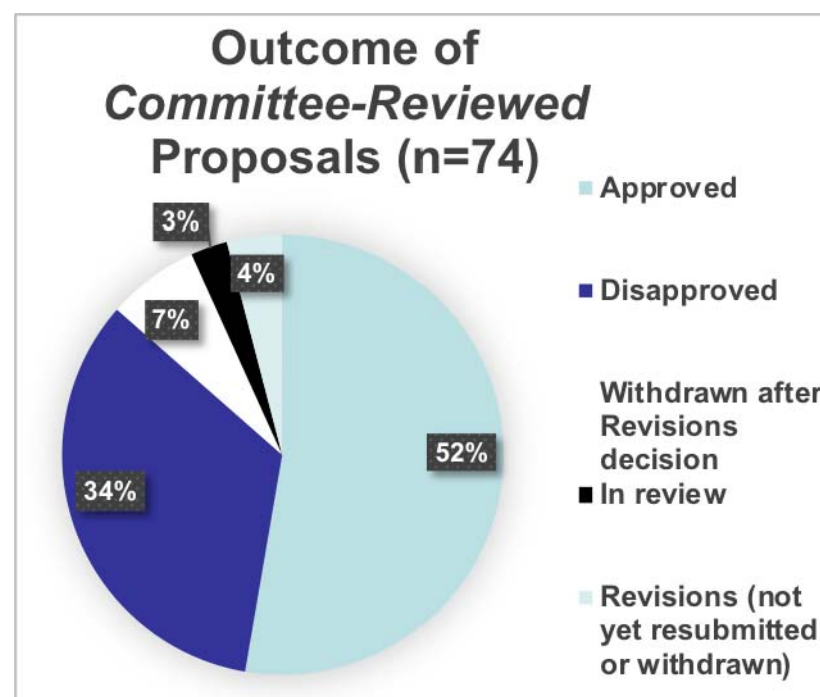


https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_overview.htm

Quarterly update: list of approved proposals

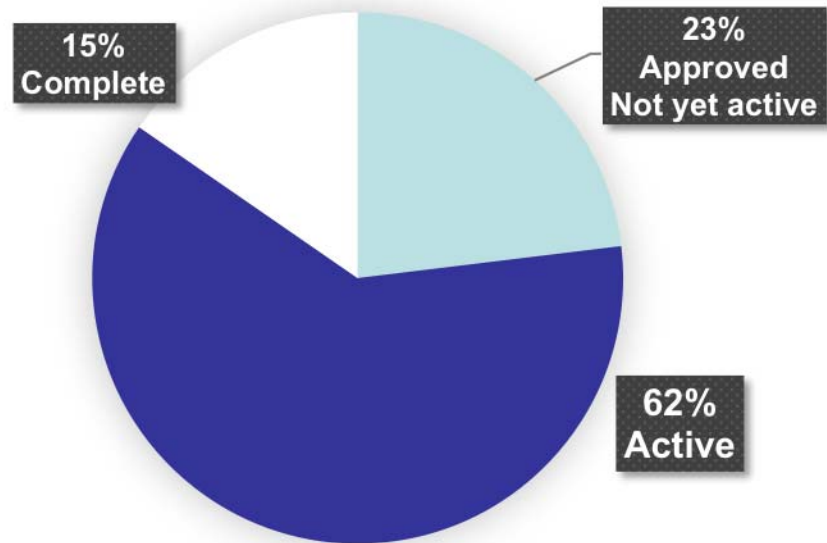
NCTN-CCSC first 4 years: outcomes

Final Outcome	N
Approved	39
Disapproved	25
Withdrawn after Revisions decision	5
Withdrawn prior to Committee review	4
Not forwarded for review	31
In review	2
Revisions (not yet resubmitted or withdrawn)	3
Total	109



NCTN-CCSC first 4 years: approved proposals status

Status of approved proposals 1-year progress reports (n=26/36)



To date:

- 3 publications
- 4 abstracts presented
- 5 abstracts submitted to NCI

NCTN-CCSC proposal pitfalls: an informal analysis

- **Statistical section:**
 - Incomplete
 - Plan can not be recapitulated
 - Inadequate power for defined objective
- **Assay details:**
 - Inadequate description
 - Lack of validation
 - lack of QC parameters
 - Not locked down
- **Objectives:**
 - Not feasible by hypothesis, number of cases
 - Planning exploratory endpoints from a positive study

Questions?

Thank you!

CCSC Administrative Coordinator: Courteney McCoppin

CCSC CTEP Lead: Elise Kohn

NCINCTN-CCSC@mail.nih.gov