



NCTN Navigator User FAQs

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General Questions

1. How is Navigator different from other specimen resources?

Most specimens listed in Navigator were collected as part of the large cancer clinical trials done by NCI's National Clinical Trials Network (NCTN) or their legacy groups. As a result, unlike most specimen collections, the specimens in Navigator are associated with extensive clinical treatment and outcomes data. Investigators can see what treatment and outcomes data are available for a given set of specimens by reviewing the primary publication from the associated clinical trial.

Navigator is also a unique resource because information is included in the electronic inventory at a specimen level and investigators can search for specimens by trial, patient demographics, or specimen characteristics. However, specimen and data availability will not be confirmed until after a proposal is approved. All investigators should be aware that the Navigator inventory shown is not a guarantee of specimen availability.

All proposals for use of specimens listed in Navigator will be reviewed for scientific strength. See FAQ #6 for information about the types of hypothesis-driven proposals that are more likely to be approved and situations in which exploratory proposals may be approvable.

2. Who can I contact for help?

The Front Door Service, or FDS, is a help desk available to investigators using Navigator. All questions related to Navigator and the specimen collections that are not answered in these FAQs or on the Navigator website should be directed to the FDS. If they are unable to answer the question, they will help find the appropriate person to help. You can contact the FDS at navigatorcontact@imsweb.com.

3. What types of trials are in Navigator?

The Navigator inventory is limited to trials that were:

- Conducted by NCI's National Clinical Trials Network (NCTN) clinical trials Groups;
- Phase 3 or large biospecimen collection protocols with clinical data; and
- Completed with the primary outcome reported.

Closed trials that meet these characteristics are being added on a rolling basis. Specimens from trials that are not yet completed with the primary outcome reported cannot be requested through Navigator. Trials with no remaining available specimens will not be shown in Navigator.

See FAQ #16 for additional information about trials not in Navigator. If you have questions about the availability of specimens from trials not listed in Navigator, please contact the Front Door Service (FDS) for assistance at navigatorcontact@imsweb.com.

For smaller or older studies that are outside the scope of the current Navigator inventory, your request will be forwarded for consideration by the NCTN Group that led the trial. Investigators can also contact the NCTN Groups directly for more information about specimens outside of the scope of Navigator. The Group contact information is available at <https://nctnbanks.cancer.gov/contacts.html>.

Please note that proposals requesting specimens from **any** trials included in Navigator **must** be submitted through Navigator, even if some of the requested trials are outside of the scope of Navigator.

4. What specimen resources could I use for more exploratory proposals?

Information about several alternative specimen collections that are not part of the Navigator inventory can be found via the NCI Cancer Diagnosis Program website:

https://cdp.cancer.gov/resources/human_specimen/finding_human_tissue.htm

One of the resources on that page is the Specimen Resource Locator, which provides information about a number of resources that may be appropriate for more exploratory proposals: <https://www.specimens.cancer.gov/>

5. What kind of scientific review will be done for proposals in Navigator?

Most proposals submitted through Navigator will be reviewed by NCI's National Clinical Trials Network (NCTN) Core Correlative Sciences Committee (NCTN-CCSC), a committee made up of NCI and extramural experts. The NCTN-CCSC is charged with scientific review and prioritization of proposals to ensure optimal use of these irreplaceable clinical trial biospecimens. More information about the NCTN-CCSC can be found on their page via the NCI CTEP website:

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

Note: Some small, exploratory proposals requesting specimens solely from pediatric trials may be eligible for a pediatric expedited proposal review process. Eligible requests will be identified at the Letter of Intent (LOI) stage (see note for FAQ #22). These pediatric expedited proposals will be reviewed by NCI instead of the NCTN-CCSC. For more information, see:

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

6. What types of proposals are likely to be approved through Navigator?

Strong proposals asking questions that require depth of annotated clinical information and validate or advance a clinically applicable finding are most likely to be approved. For example,

specimens could be used to validate predictive biomarker hypotheses based on the trial treatments and outcomes. Successful Navigator proposals will generally utilize the unique clinical data and trial design to test a question with potential clinical implications.

Some specimens in Navigator are appropriate for more exploratory studies. The NCTN-CCSC has developed **Expanded Evaluation Guidelines** which include conditions in which proposals for exploratory studies may be appropriate. Before submitting an exploratory proposal through Navigator, investigators should confirm that all trials from which they are requesting specimens meet these conditions:

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

Note: Because of the rarity of childhood cancers and the scarcity of resources for pediatric cancer biospecimens, specimens from pediatric trials in Navigator may also be appropriate for small, exploratory proposals to facilitate developmental research. For more information, see: https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_pediatric_expedited_review.htm

7. What costs are involved in using specimens from Navigator?

Significant costs are involved in obtaining specimens for approved proposals. There may also be costs associated with obtaining the clinical data. Before seeking grant funding, investigators should have an approved proposal with the approval documented in the Navigator system. After proposal approval, investigators will need to document their funding covering all costs before any specimens or data will be processed or distributed to the investigator.

Investigators considering seeking NIH grant funding for their proposals should not submit a grant request to NIH for this funding until **after** their proposal is approved through the Navigator system. Grant applications for funding and proposals for use of Navigator specimens are reviewed based on different criteria. Approval of a grant application **does not** constitute approval of use of the Navigator specimens. A proposal approval recognizes that time may be required to ascertain funding and is in place for a year with potential for extensions pending funding status.

Investigators will receive a working budget from the biospecimen bank(s) currently storing their requested specimens and from the statistical center(s) storing the associated data after their proposal is approved. This working budget is typically available within two months after Group receipt of the approved proposal. The figures estimated in the working budget may increase as the investigator requirements are clarified. At least half of the costs will need to be paid upfront before specimens or data can be distributed.

Here is some more information about the specimen fees and data fees that may be involved in an approved Navigator proposal:

Specimen Fees

- **Processing Fees:** Investigators will incur processing fees for biospecimens distributed by the biospecimen banks for an approved Navigator proposal. Such fees are for procedures such as sectioning of tissues and aliquotting bodily fluids. Fees may also apply for special and/or additional biospecimen processing by the bank, such as pathology review, tumor microarray (TMA) production, and isolating nucleic acids from whole blood, plasma, and formalin-fixed paraffin-embedded (FFPE) or frozen tissue.
- **Shipping Fees:** Investigators are also responsible for the cost of shipping biospecimens from the biospecimen bank to their laboratory.

Data Fees

- **Data Element Costs:** Investigators are responsible for costs incurred by the trial statistical center(s) in preparing, processing, and transferring the trial data if their approved proposal includes any data elements that are not included in the trial primary outcome publication.
- **Collaboration Costs:** If investigators are interested in collaborating with the statistical center(s) for statistical assistance completing their proposed project, they may see if the statistical center(s) are available to collaborate. If the statistical center(s) agree to a collaboration, the investigators should typically expect to obtain funding to cover costs incurred by the statistical center(s) during the collaboration.
- **Contract Support Costs:** If investigators are interested in the statistical center(s) providing support in understanding and using the trial data, they may see if the statistical center(s) are willing to provide this support through a contract.

8. How long will it take to get specimens from Navigator?

There are several steps involved before specimens from Navigator will be distributed for an approved proposal:

- Investigator searches Navigator, reviews trials, develops hypothesis-driven research question, and is ready to submit an LOI: **time will vary**; see FAQs #9-17 for more details.
- Investigator creates a CTEP-IAM account and submits an LOI form: **typically 1-2 weeks**, see FAQs #18-21 for more details.
- LOI is reviewed for feasibility: **typically two months or less**, see FAQs #22-26 for more details.
- If LOI is feasible, investigator develops and submits a complete proposal for scientific review: **proposals should be submitted within six months**, see FAQs #27-28 for more details.

- Proposal is scientifically reviewed by the NCTN Core Correlative Sciences Committee: proposal will be scheduled for the **next available committee meeting that is at least 6 weeks out** from the time of proposal submission, see FAQs #29-31 for more details. (Note: pediatric expedited proposals will generally be reviewed by NCI within 4 weeks.)
- If proposal is approved, investigator has one year to obtain funding, complete required Material Transfer and Data Use Agreements, and document IRB approval or exemption before specimens and data are distributed (extensions may be requested): **time will vary**, see FAQs #32-36 for more details.
- Groups begin distribution of specimens and data: **typically two months** after confirmation that all post-approval steps have been completed, see FAQ #36 for more details.

Using Navigator to Search for Specimens

9. What's the difference between Guest Access and CTEP-IAM Log-in?

All Navigator website users should start by using Guest Access. Guest Access allows you to search and see all available information about the specimens and trials.

CTEP-IAM access is only required when users have developed a project idea and are ready to submit an LOI. Users should explore the specimen inventory, identify specimens they are interested in, read the publications from the associated trials, and have an idea for a project they would like to complete before requesting a CTEP-IAM account and submitting an LOI. See FAQs #20-21 for more information about requesting a CTEP-IAM account.

10. What types of searches can I do to find specimens in 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**, and information about the **Specimens**. You can build queries by combining search elements from different categories. When you have compiled your query, click "View Query Results" to see the numbers of trials, patients with specimens, and specimens available for that query. The parameters of your query will be shown on the left. The search results will be shown on the right.

Items you can search on within the Trials category include:

- **Trial ID:** the NCTN trial identifier number associated with a given trial. This allows you to search for specimens that are associated with a given trial.
- **Network Group:** the NCTN Group that led the trial. The Group system was consolidated in 2014. This allows you to search by the current lead Groups. The predecessor Group(s) for each current Group are listed in parentheses.
- **Primary Diagnosis:** the lead disease being studied in the trial. This is coded using the CTEP Simplified Disease Classification, which is available at: https://ctep.cancer.gov/protocoldevelopment/codes_values.htm#disease
- **Intervention:** the agents being studied in the trial. Please note that this search function does not include non-agent interventions such as surgery and radiation.
- **Study Design:** the study phase and study types. Most trials will be Phase 3. Some trials may have a phase listed as "Other" if they are large biospecimen collection trials. Most trials will have a study type of "treatment."
- **Keyword:** this allows you to search for words in the study title or by the name of the study Principal Investigator.

Demographics you can search on within the **Patients** category include:

- **Gender:** Male or Female.
- **Age:** by 10-year age grouping for ages 0 to 60 and then 61 or older.
- **Race:** American Indian or Alaska Native, Asian, Black or African American, Native Hispanic or other Pacific Islander, Not Reported, Unknown, or White.
- **Ethnicity:** Hispanic or Latino, Not Hispanic or Latino, Not Reported, or Unknown.

For more information about what can be searched on in the Specimens category, see FAQ #11.

11. What information may be available about specimens in Navigator?

Information about the specimens that you can search on in Navigator includes:

- **Clinical Time Point:** the time point when the specimen was collected. *Please note that this information is not available in the electronic inventory for most specimens, so a search in this category may eliminate specimens of interest.*
- **Anatomical Source:** the area of the body where the specimen was collected. Choose from the “Other” category for specimens such as blood and bone marrow.
- **Specimen Type:** the type of specimen. Some of the most common specimen types are tissue and tissue slides, plasma, serum, and DNA.
- **Preservation Type:** the type of preservation used on the specimen. *Please note that this information is not available in the electronic inventory for a subset of the specimens, so a search in this category may eliminate specimens of interest.*
- **Pathological Status:** whether the specimen was malignant, non-malignant, metastatic, or pre-malignant. *Please note that this information is not available in the electronic inventory for most specimens, so a search in this category may eliminate specimens of interest.*

12. What information is included in the Specimen Report?

Once you have developed your query and viewed the query results, you can download a PDF Specimen Report. The first page of the Specimen Report shows the parameters of your query. Then, the report lists the trials included in your query results. Finally, the report shows a table with the number of patients with specimens and the number of specimens by Trial and Specimen Type within your query.

13. Is the same information available for all specimens in Navigator?

No. Information about the clinical time point, preservation type, and pathological status is not available for all specimens in the electronic inventory. As a result, a search in these categories may eliminate specimens of interest.

14. What are some of the limitations of the specimen information in Navigator?

Navigator is a unique resource because information is included in the electronic inventory at a per specimen level, which allows for detailed searches. However, specimen and data availability will not be confirmed until after a proposal is approved. All investigators should be aware that **the Navigator inventory shown for a query is not a guarantee of specimen availability**. This is especially true because the Navigator inventory does not include patient-level consent information.

15. How often are trials with specimens added to Navigator?

Specimens from completed trials are being added after their primary publication on a rolling basis. Each of the Groups add specimen inventory to Navigator on a regular basis throughout the year depending on what is newly available. Groups upload updated information quarterly or more frequently.

16. How do I know if there are other trials with specimens that are not listed in Navigator?

Many trials may have not collected specimens or have exhausted the banked specimens. If you have a question about a trial that is not in the Navigator inventory, please contact the Front Door Service at navigatorcontact@imsweb.com.

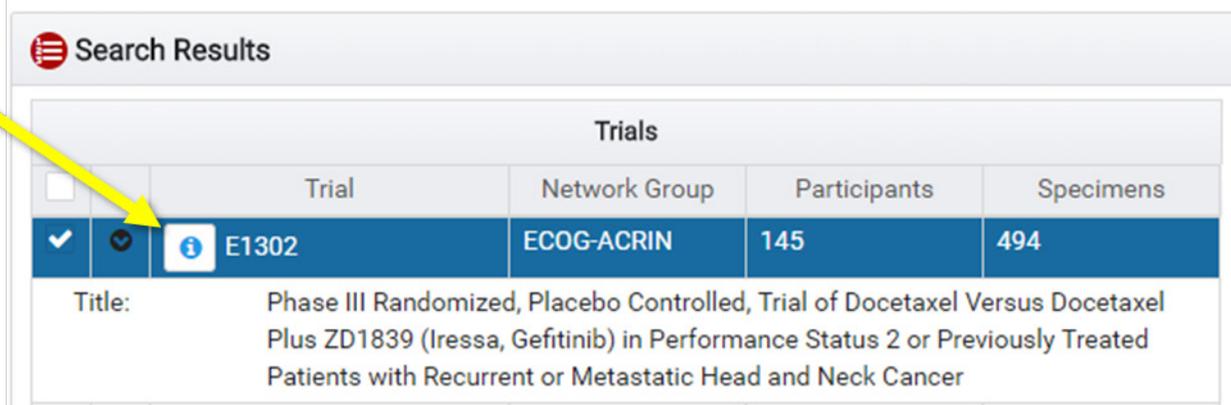
For smaller or older studies that are outside the scope of the current Navigator inventory, investigators can also contact the NCTN Groups directly for more information about available specimens. The Group contact information is available at:

<https://nctnbanks.cancer.gov/contacts.html>

17. How can I find out more about the clinical data from the trials in Navigator?

Trials with specimens shown in Navigator have been completed and reported results in either abstract or manuscript form. Strong proposals requesting use of specimens in Navigator will be hypothesis-driven and will take advantage of the unique level of clinical annotation available for these specimens.

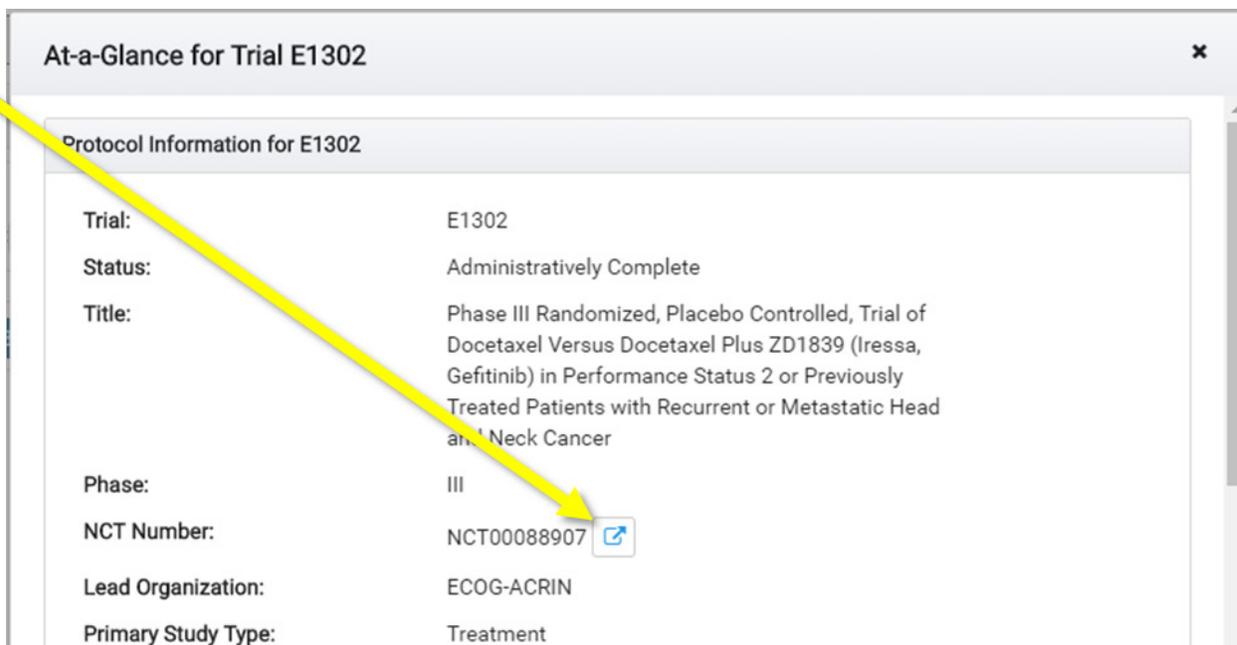
You can easily find publications linked to a specific trial on the trials page at www.clinicaltrials.gov. Navigator provides a link to the trial page on www.clinicaltrials.gov when you click the information button next to the trial number in your search results. Clicking this button will open the “At-a-Glance” information for the trial.



Search Results

Trials				
<input type="checkbox"/>	Trial	Network Group	Participants	Specimens
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>  E1302	ECOG-ACRIN	145	494
Title:		Phase III Randomized, Placebo Controlled, Trial of Docetaxel Versus Docetaxel Plus ZD1839 (Iressa, Gefitinib) in Performance Status 2 or Previously Treated Patients with Recurrent or Metastatic Head and Neck Cancer		

In the *At-a-Glance* screen, click the link next to the NCT number to be taken to the clinicaltrials.gov page for the trial. You can also search for the trial by NCT number.



At-a-Glance for Trial E1302

Protocol Information for E1302

Trial:	E1302
Status:	Administratively Complete
Title:	Phase III Randomized, Placebo Controlled, Trial of Docetaxel Versus Docetaxel Plus ZD1839 (Iressa, Gefitinib) in Performance Status 2 or Previously Treated Patients with Recurrent or Metastatic Head and Neck Cancer
Phase:	III
NCT Number:	NCT00088907 
Lead Organization:	ECOG-ACRIN
Primary Study Type:	Treatment

Review the publications that came out of the study to get a better understanding of the interventions and clinical outcomes. There may also be other publications describing correlative science results. However, remember that the data in the primary outcome publication are the data you are most likely to be able to obtain.

Navigator Letters of Intent (LOIs)

18. When should I submit an LOI?

Navigator users should explore the specimen inventory, identify specimens they are interested in, read the publications from the associated trials, and know the general parameters of their project of interest before requesting a CTEP-IAM account (FAQ #20) and submitting an LOI.

Most successful projects will build on prior exploratory research and be hypothesis-driven. If your project is more exploratory, please review FAQ #6 and confirm that all trials from which you are requesting specimens meet the NCTN-CCSC Expanded Evaluation Guidelines, available at https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_expanded_evaluation.htm.

The LOI will be reviewed for feasibility and if it is considered feasible, Navigator will direct you to move forward with a proposal based on the biospecimens and clinical data identified in your LOI. You will have six months after your LOI has been deemed feasible to submit your proposal (see FAQ #27).

If you decide at a later point that you are interested in other biospecimens or data, you will need to submit a new LOI and wait for it to be reviewed for feasibility. As a result, you should ensure that the information in your LOI is as accurate as possible to avoid delays at a later stage.

19. What is required to submit an LOI?

The LOI is a basic form that is not reviewed on scientific merit. Instead, it serves as a brief feasibility check to assess the availability of the specimens and data that you requested. The LOI requires the following information:

- **Project Title.** This must include the protocol number(s) of the trial(s) from which you are requesting specimens and should be as descriptive as possible.
- **Project Hypothesis.** This should be a brief description of your planned hypothesis.
- **Are you interested in potentially collaborating with the NCTN Group(s) that led the clinical trial(s) from which you are requesting biospecimens?** Yes/No question. If yes, please describe the type of collaboration that is of interest to you in the LOI comments box.
- **Biospecimen Request.** Biospecimens needed for your proposed project, including the trial number, clinical time point, pathological status, specimen type, and quantity/units/cases. Please note that all biospecimens requested in the LOI should be biospecimens that were identified in the query used to generate the LOI. The only exception is for LOIs that also request specimens from trials not in the scope of

Navigator. In that case, detail the additional trials and specimens requested in the Biospecimen Request comments box.

- **Clinical Data.** Clinical data points needed for your proposed project with any special requests described in the *Other Specify* field.
- **Planned assays.** Select from the list of assays or describe in the *Other Specify* field.
- **Comments.** In this field you can provide additional detail or clarifications. This information is especially helpful if there is any flexibility in your requested specimens and/or clinical data. If you had submitted a previous LOI that was not feasible, please include that LOI reference number in the Comments box to help facilitate the next review. Please also include details about any potential for collaboration with the NCTN Group(s).

20. When I'm ready to submit an LOI, how do I create a CTEP-IAM account?

If you already have a CTEP-IAM account, you can log in to Navigator via the login page with your account information.

Please note that the Principal Investigator should use their own CTEP-IAM account to submit their LOI and proposal. The submitter's CTEP-IAM credentials are used to electronically sign the completed proposal before proposal submission and the Principal Investigator's signature is what is required on the proposal form.

21. How long will it take for my CTEP-IAM account to be approved?

CTEP-IAM account requests are manually reviewed during NCI's business hours, so the account creation process is not immediate.

22. How are LOIs reviewed?

After LOIs are submitted, they are reviewed by the Front Door Service (FDS) for completeness. If the LOI appears to be complete, it will be routed to representatives from the NCTN Group(s) that ran the trials from which you are requesting specimens, who are called Group Concierges. If specimens from multiple Groups are requested, each Group will perform a feasibility review for their respective trial(s).

The Group Concierges will coordinate the Group feasibility review. This will include an assessment of the requested specimens against the current specimen bank inventory, an assessment of the availability of the requested data, an evaluation of the trial consent, and a collaborative review to compile the feasibility information and see if there are concerns about the feasibility of the requests. In many cases, more detailed specimen information (beyond what is electronically available in the Navigator inventory) will be reviewed, for instance, to

confirm whether paired specimens for patients are available. Group(s) will also provide a minimum preliminary cost estimate and respond if the investigator expressed interest in collaboration. The details of the feasibility review will depend on the details of the individual LOI.

If any part of the LOI is not feasible, the entire LOI will be deemed not feasible. If all parts of the LOI are feasible, it will be deemed feasible and the investigator will be able to move forward with submitting a proposal.

The feasibility report will also provide an estimation of whether the specimen request would exhaust the supply of available specimens. This information will be considered when a proposal is reviewed.

Keep in mind that the initial feasibility review does not guarantee that specimens and data are available. Specimen and data availability will not be confirmed until after a proposal is approved.

Note: Some LOIs requesting a small number of specimens from pediatric trials may be eligible for a pediatric expedited proposal review process. As part of the Group feasibility review process, the pediatric NCTN Group (the Children’s Oncology Group) will determine if a request for pediatric trial specimens meets the criteria for the expedited review process. If the LOI is eligible for the pediatric expedited proposal review process, the investigators will be prompted to complete an abridged “Expedited Proposal for the use of NCTN Pediatric Clinical Trial Specimens” which will be reviewed by NCI instead of the NCTN-CCSC. For more information about the pediatric expedited proposal review process, see:

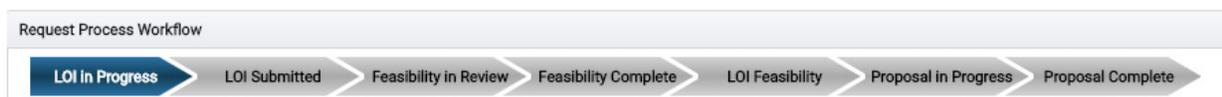
https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_pediatric_expedited_review.htm

23. How long does it take for LOIs to be reviewed?

LOIs are expected to be reviewed for feasibility within **two months** after submission of a complete LOI, due to the collaborative work at multiple institutions required to perform the feasibility assessment (see FAQ #22). This timeline may be extended depending on workload. However, many LOI feasibility reviews are completed in less than two months. If delays are expected, you will be notified.

24. How can I track where my LOI is in the review process?

When you create a CTEP-IAM account and begin a request, you will be able to see a Request Process Workflow that shows where your request is in the workflow. An example of this workflow is shown below.



25. What does it mean if my LOI is not feasible?

If your LOI is deemed not feasible, it indicates that your requested biospecimens, requested data, or both were not available. It may mean that the biospecimens you requested were not collected at the clinical time points you were interested in, or if they were collected, they may have been exhausted or there may not be sufficient numbers of paired samples from patients. It may mean that you requested a clinical data point that was not collected.

The Group will provide basic information about why the LOI was deemed not feasible in the feasibility report.

If you would like to submit a new LOI with a revised request, please include your prior request number in the Comments box to help link the requests. This may help facilitate the next feasibility review.

26. If my LOI is feasible, what happens next?

If your LOI is feasible, you may move forward with submitting a proposal for scientific review. For more information, see FAQs #27-36.

However, keep in mind that this initial feasibility review does not guarantee that specimens and data are available; it merely provides an initial review. Specimen and data availability will not be confirmed until after a proposal is approved.

Navigator Proposals

27. When should I submit a proposal?

You can submit a proposal for the specimens and data that were requested in your LOI after that LOI has been reviewed and deemed feasible. You should submit your proposal within six months of your LOI being deemed feasible. After six months, there is a greater risk that the specimen availability information may have changed. If you are not ready to submit your proposal within six months, you can email the Front Door Service at navigatorcontact@imsweb.com to request an extension.

28. What is required to submit a proposal?

You must complete the Word proposal form and submit it with all required attachments. The proposal form is much more extensive than the LOI form. You can download a copy of the proposal form, using the Proposal Submission Form link, at the following location: https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_proposal_submission.htm

Proposal form sections include:

- **Objectives and Hypotheses.**
- **Background and Significance.** Justification for why the specimens from the specific trials requested are needed to answer the proposed hypothesis. Preliminary data justifying the need for the proposed study, including the expected clinical utility.
- **Research Design and Methods.** Explanation of what specimens are requested and whether the proposal would exhaust any specimens. Detailed information about the laboratory methods. Descriptions of the facilities and personnel.
- **Statistical Considerations.** A detailed description of important statistical concerns, including the endpoints, case selection, analysis plan, and sample size justification.
- **Required Attachments.** Letters of collaboration from each co-investigator. The completed feasibility report confirming availability of the specimens and data requested in the proposal will be attached by the Navigator system.

Successful proposals will fully address all prompts found in the proposal form and will be developed in collaboration with a biostatistician(s).

All parts of the proposal packet should be saved as a single PDF and uploaded in Navigator for submission.

Note: LOIs that are deemed eligible for the pediatric expedited proposal review process (FAQ #22) will be prompted to complete an abridged “Expedited Proposal for the use of NCTN Pediatric Clinical Trial Specimens” which is also available for download at:

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

29. How are proposals reviewed?

The proposals are reviewed by NCI’s National Clinical Trials Network (NCTN) Core Correlative Sciences Committee (NCTN-CCSC), a committee made up of NCI and extramural experts. The NCTN-CCSC is charged with scientific review and prioritization of proposals to ensure optimal use of these irreplaceable clinical trial biospecimens. More information about the NCTN-CCSC can be found at their website on the NCI CTEP website:

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

One to three weeks prior to the scheduled committee review date, the proposal Principal Investigator will receive key questions raised by reviewers and a request for written responses. Responses received by the deadline noted in the message accompanying the questions will be provided to the Committee. NCTN-CCSC members, alternates, and ad hoc reviewers are under Confidential Disclosure Agreements.

Note: Proposals submitted through the pediatric expedited proposal review process will be reviewed by NCI instead of the NCTN-CCSC. For more information about the pediatric expedited proposal review process, see:

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

30. How long does it take for proposals to be reviewed?

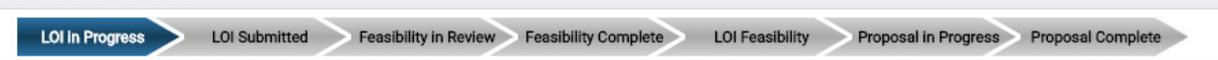
Proposals will be scheduled for review at the first available NCTN-CCSC monthly review date that is ≥ 6 weeks after the proposal is received and accepted by the NCTN-CCSC coordinator.

Note: Proposals submitted through the pediatric expedited proposal review process will generally be reviewed by NCI within 4 weeks. For more information about the pediatric expedited proposal review process, see:

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

31. How can I track the progress of my proposal review?

When you create a CTEP-IAM account and begin a request, you will be able to see a Request Process Workflow that shows where your request is in the workflow. An example of this workflow is shown below. Your proposal will move from “Proposal in Progress” to “Proposal Complete” when a decision has been made.



32. Where can I get funding for a proposal approved in Navigator?

Significant costs are involved in obtaining specimens for approved proposals. There may also be costs associated with the clinical data. Investigators will need funding to cover these costs, and this funding must be documented before any specimens or data can be processed or distributed.

In some cases, NIH grant mechanisms may be appropriate places to apply for funding for an approved Navigator proposal. (See FAQ #33 for more information about when you should apply for funding.) In addition to unsolicited or investigator-initiated applications, other funding opportunities that may be relevant are listed on the Cancer Diagnosis Program website: https://cdp.cancer.gov/funding_opportunities/current_funding_opportunities.htm

33. When should I try to get funding for a proposal in Navigator?

Samples for approved proposals will be held up to one year while investigators seek funding and complete the other post-approval requirements (see FAQ #35). If there are challenges in obtaining funding within that time frame, you can request an extension from NCI when you submit your one-year progress report or contact the CCSC.

Investigators should not submit a grant request to NIH for the funding until **after** their proposal is approved through the Navigator system. Grant applications for funding and proposals for use of Navigator specimens are reviewed based on different criteria. Approval of a grant application **does not** constitute approval of use of the Navigator specimens.

It is not required that funding to support your proposal come from NCI or NIH.

34. What type of consent was obtained for the specimens in Navigator?

Specimens are shown in Navigator for patients who consented to the specimen collections and to their specimens being banked for future research. The wording in the consent forms varies some from trial to trial. Some consents allowed banked specimens to be used for future unspecified cancer research. This is generally the broadest consent wording that was used in these trials. Some consents have more restrictive wording. Because the trials in Navigator are generally older, consent for sequencing was typically not explicitly obtained.

35. What will I have to do before specimens and data for an approved proposal are released to me?

There are a number of steps that the investigator must complete before the specimens and data may be distributed. It is up to the investigator to track their progress through these steps.

Before any specimens or data will be released, you must:

- Complete required **Materials Transfer Agreements** and **Data Use Agreements** with the banks and statistical centers providing specimens and data for the approved proposal.
- Document **IRB approval or exemption** of the proposal.
- Obtain and document **funding** to cover all costs associated with your proposal and begin payments for the processing and shipment of specimens and data by the Group. At least half of the funding will need to be paid upfront before specimens or data can be distributed.

Material Transfer and Data Use Agreement language has been harmonized as much as possible across the Groups. As a result, investigators should not expect to make significant changes to the Agreements. One of the most common reasons for delays in the past is finalizing the Agreements due to changes requested by the investigator's institution. The investigator is expected to remain engaged throughout this process and will need to work with their institution to ensure the harmonized language is acceptable.

You must submit **annual progress reports** for your approved proposals. If there are delays in obtaining funding, you can explain the delay and request an extension in this progress report.

36. How long will it take to get specimens from Navigator for an approved proposal?

The Groups are typically expected to provide a working budget within two months after receipt of the approved proposal. This working budget can be used when submitting funding requests. However, the figures estimated in the working budget may increase as the investigator requirements are clarified.

The Groups will also perform an initial identification and review of the requested data and specimens at the time of proposal approval. This is intended to confirm the availability information from the feasibility review. At this point, a sample of the requested specimens will typically be examined physically. Investigators will be notified if there are any concerns about the data or specimens that arise during this more thorough review. The findings of this review will typically be available within two months of Group receipt of the approved proposal, with larger requests taking longer.

As discussed in FAQ #35, there are a number of steps that the investigator must complete before the specimens and data may be distributed. The timing of these steps will be driven by the investigator and the investigator's institution. Groups will work with the investigators to complete the required Material Transfer Agreements and Data Use Agreements but changes from the harmonized text will delay the process and are strongly discouraged. It is up to the investigator to track their progress through these steps.

When all required steps have been completed, including payment of at least half of the funding, the Groups will begin distribution of the specimens and data. Distribution will typically begin within two months of confirmation of the completion of these steps and payment. The distribution process will take longer for larger requests.