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| Department of Health & Human Services USA picture | **PHASE 1, 2, or 1/2 — LETTER OF INTENT Submission Form v9.3** |
| **NIH Logo** | **National Cancer Institute****Division of Cancer Treatment and Diagnosis****Cancer Therapy Evaluation Program** |

#  New LOI

**To** **complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter information for each text field.**

## Administrative Information

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| Lead LAO/Group/Institution1: | Enter Lead LAO/Group; use Institution for non-ETCTN/non-Group trials |
| Lead LAO/Group/Institution Code1,2: | Enter Lead LAO/Group Code; use Institution Code for non-ETCTN/non-Group trials ONLY |
| Other LAOs or Trial Team Sites1,2: | Enter other LAOs, other Groups, and any non-LAO/non-Group Clinical Site/Institution Codes. List sites outside USA separately by country. If trial will involve all ETCTN LAOs, write "All ETCTN LAOs" (no codes needed.) |
| Title of LOI: | Enter title |
| LOI Version Submission Date: | Enter Date of Submission to PIO |

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|  Agent Information2: | *(Select a field and click the The "plus" button to add a row to table. button at the bottom right of the row to add rows as needed. ETCTN trials must include at least one “Investigational” drug.)* |  |
|   | Name | NSC # | Investigational/Commercial |  |
| Agent: | Enter Agent Name | Enter NSC# | Select Investigational or Commercial |  |

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| **IND Holder:** | Specify IND Holder | If “Other, specify,” provide details |  |

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| Tumor Type:(Click the appropriate check boxes.) | [ ]  Solid Tumor |
| [ ]  Hematologic Malignancy (NOS) |
| [ ]  Disease-Specific |
| Disease-Specific2: | *(Specify the Name and Code of the Study Disease. Select a field and click the The "plus" button to add a row to table. button at the bottom right of the row to add rows as needed.)* |
| Disease: | Enter Disease Name | Enter Disease Code |

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| Phase of Study: | Enter Study Phase |
| Estimated Monthly Accrual: | Enter Accrual |
|  | (**Note**: Projected accrual rates should be realistic. Actual accrual will be monitored and measured against this accrual estimate, and failure to meet accrual goals may result in study closure.) |
| Proposed Sample Size: | Minimum: Enter size.  | Maximum: Enter size  |
| Earliest Date the Study can Begin: | Enter earliest study start date |
| Projected Accrual Dates: | Enter projected accrual start date **to** Enter projected accrual end date |

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| Is this study as a whole partof an NIH Grant, Cooperative Agreement or Contract? | Select Yes or No |
| If yes, provide the Award Number (*e.g.*, UM1 or U10 Number): | Enter Award Number |

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| Provide any other relevant NIH Grant/Award Number(s) (*e.g.* SPORE): | Enter Award Number |

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| Will this study receive support from non-NCI sources(i.e., industry, foundations)? | Select Yes or No |
| If yes, indicate the source of the funding: | Enter source of non-NCI funding |
| If no, will non-NCI funding be sought?: | Select Yes or No |

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| Is this a Career Development LOI (CrDL)? | Select Yes or No |
|  | Further information and instructions regarding the submission of a Career Development LOI (CrDL) may be found at [*https://ctep.cancer.gov/protocolDevelopment/letter\_of\_intent.htm*](https://ctep.cancer.gov/protocolDevelopment/letter_of_intent.htm) **Note**: If “Yes,” provide the mentor’s name below.The CrDL PI and mentor must schedule a call with the IDB agent monitor(s) prior to LOI submission. |
| **If yes**, please attach andcheck off the following: | [ ]  PI Curriculum Vitae |
| [ ]  Institutional Letter of Commitment |
| [ ]  Mentor Letter of Commitment |

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| CrDL Mentor Name: | **Enter your full name to certify the submission** | Date: Enter date |
| CrDL Mentor Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| CrDL Mentor Phone: | Enter Phone Number |
| CrDL Mentor Fax: | Enter Fax Number |
| CrDL Mentor Email: | Enter E-mail Address |

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| The **Investigational Drug Steering Committee (IDSC)** is designed to provide NCI with broad external scientific and clinical input for the design and prioritization of phase 1 and phase 2 trials with agents for which CTEP holds an IND. Membership of the IDSC includes the Principal Investigators of early phase drug development grants and contracts, representatives from the NCI National Clinical Trials Network (NCTN), NCI staff members, and additional representatives with expertise in biostatistics, correlative science technologies, radiation oncology, etc., as well as patient advocates and community oncologists, as needed. Individuals with special expertise will be included as ad hoc members for consideration of specific agents. The current membership list may be found at <https://www.cancer.gov/about-nci/organization/ccct/steering-committees/investigational-drug>.**Note:** If the LOI is disapproved by CTEP, the Principal Investigator may appeal the decision by requesting a review by the IDSC. |

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| Principal Investigator (PI) Name: | **Enter your full name to certify the submission** | Date: Enter date |
| PI Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| PI Phone: | Enter Phone Number |
| PI Fax: | Enter Fax Number |
| PI Email: | Enter E-mail Address |

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| Co-PI Name (if applicable): | **Enter your full name to certify the submission** | Date: Enter date |
| Co-PI Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| Co-PI Phone: | Enter Phone Number |
| Co-PI Fax: | Enter Fax Number |
| Co-PI Email: | Enter E-mail Address |

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| Translational PI Name: | **Enter your full name to certify the submission** | Date: Enter date |
| Translational PI Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| Translational PI Phone: | Enter Phone Number |
| Translational PI Fax: | Enter Fax Number |
| Translational PI Email: | Enter E-mail Address |

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| Study Statistician Name: | **Enter your full name to certify the submission** | Date: Enter date |
| Statistician Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| Statistician Phone: | Enter Phone Number |
| Statistician Fax: | Enter Fax Number |
| Statistician Email: | Enter E-mail Address |

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| Grant PI Name: | **Enter your full name to certify the submission** | Date: Enter date |
| Grant PI Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| Grant PI Phone: | Enter Phone Number |
| Grant PI Fax: | Enter Fax Number |
| Grant PI Email: | Enter E-mail Address |

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| Group Chair-PI (GC-PI) Name: | **Enter your full name to certify the submission** | Date: Enter date |
| GC-PI Address: | Enter Room/Suite/DepartmentEnter Street AddressEnter City, State and Postal Code |
| GC-PI Phone: | Enter Phone Number |
| GC-PI Fax: | Enter Fax Number |
| GC-PI Email: | Enter E-mail Address |

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| The **Principal Investigator** agrees to accept Confidential Information, such as the Investigator Brochure and any other shared information and employ all reasonable efforts to maintain the Confidential Information secret and confidential, such efforts to be no less than the degree of care employed by the Principal Investigator/Institution (the receiving Party) to preserve and safeguard its own confidential information. The Confidential Information of the NCI (the disclosing Party) shall not be disclosed, revealed, or given to anyone by the receiving Party except individuals working on behalf of the receiving Party who are under an obligation of confidentiality to the receiving Party and who have a need to review the Confidential Information in connection with the receiving Party's evaluation. Such individuals shall be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly. By submission of this Letter of Intent Submission Form, the Principal Investigator agrees to this statement.**Please submit LOIs as a Word document to the Protocol Information Office (PIO) via e-mail at:** **pio@ctep.nci.nih.gov****, Attention: LOI Coordinator****Notes:** * LOIs from a NCTN Group must be submitted through the Group Operations.
* Proposals for trials to be conducted under a Cooperative Agreement must include complete contact information for the Principal Investigator and Protocol Chair.
* **CrDL investigators/mentors must schedule a call with the IDB** agent monitor(s) prior to LOI submission. All other investigators are encouraged to schedule a call before LOI submission.
* **Questions?** Please e-mail the LOI Coordinator at pio@ctep.nci.nih.gov.
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## Study Information

Rationale and Background

Provide the study rationale and supporting preclinical and/or clinical data and address the following:

* what is the unmet need?
* why the patient population was chosen?
* why the drug or drug combination was chosen and any potential safety concerns with the drugs or drug combination? and
* how the study results might impact future trials/practice?

**Preclinical data supporting the proposed study should be presented, and not merely referenced.** The background information should be limited to what is relevant to the proposed study and should be presented succinctly but with sufficient detail to enable evaluation by the reviewers. Avoid indiscriminate cutting-and-pasting from investigator brochures, trial solicitations, or other CTEP communications.

**Click and enter Rationale and Background.**

Hypotheses:

**Succinctly state the hypothesis for each primary and secondary objective.**

**Click and enter** **Hypotheses.**

Objectives:

**List primary and secondary objectives.** Note that each objective, whether primary or secondary, must have an endpoint that is measurable. Ensure that the study design allows for these objectives to be met and that the statistical plan provides an adequate plan to analyze or describe the data for each objective.

**Click and enter Objectives.**

Abbreviated Eligibility Criteria:

**Provide key inclusion criteria.** These should include patient age, performance status, whether abnormal organ function is permitted (if Yes, list only abnormal organ function parameters), permissible and required prior therapy, tumor type, and integral markers, if applicable. NCI has adopted ASCO/Friends guidelines for broadened eligibility criteria, which will be used in clinical trials when applicable. Please refer to [CTEP’s Broadened Eligibility Criteria Guidance](https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Broadened_Eligibility_Criteria_Guidance.pdf).

**Click and enter Eligibility Criteria.**

Study Design:

**Succinctly describe the general study design.** If applicable, describe randomization and/or stratification. A schema or flow diagram may be used, if appropriate. If the trial involves biomarker studies, the Biomarkers Tables below **must** be filled out according to the instructions. Appendices detailing the biomarker assays may be required as well. Please read the instructions carefully.

**Click and enter Study Design.**

Treatment Plan:

**State and provide a tabular/graphic presentation (both) of the dose, method of administration, and schedule of each drug. If phase 1, provide the dose escalation scheme, and definitions of DLTs. State the duration of treatment, the duration of the study, and the duration of follow-up.**

**Click and enter Treatment Plan.**

Biomarker Correlates:

For **all** correlates complete the **Biomarkers and Specimen Collection Tables** below.

In the Biomarker table, please list all biomarker assays proposed for the study and provide all requested information.

* In the column labeled “Assay (CLIA: Y/N)”:
	+ Please briefly identify the method used (e.g., IHC, NGS, Flow Cytometry, etc.).
	+ If the assay result will be reported to the patient or the patient’s physician at any time, on or off study, the assay must be performed at a CLIA-approved laboratory and CLIA should be “Yes”.
* Definitions of integral and integrated biomarkers are provided below. All other biomarker tests are considered exploratory.
* In the column labeled “Assay Laboratory and Lab PI”, please provide the laboratory that will perform the assay (including the institution), the name of the laboratory PI and his/her site and email address.
* In the column labeled “Funding”, please identify funding which will support the biomarker.
	+ Note, if institutional or grant funding will support **integral** assays, please provide a letter confirming the funding.
	+ If CRADA support is requested, please indicate “CRADA requested”. **Note, a budget is required for any CRADA request**.

**Integral studies** are defined as assays/tests that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the outset and must be performed in real time for the conduct of the trial. Examples include tests to determine eligibility, tests to assign treatment or stratify randomization, and tests whose results serve as the primary endpoint of the trial. Integral biomarkers may require a CLIA-certified laboratory, which will be needed if the test results will be returned to the patient or their physician.

An integral assay that will be used to determine eligibility or treatment may need to be performed under an Investigational Device Exemption (IDE) from the FDA.

**Integrated studies** are defined as assays/tests that are clearly identified as part of the clinical trial from the outset and are intended to address the highest priority scientific question in the trial. Integrated studies in general should be performed on all the trial participants or on a pre-defined subset such as an expansion cohort. Plans for specimen collection, laboratory measurements, use of cutpoints, and statistical analysis should be pre-specified and should be based on sufficient preliminary data to ensure scientifically valid results from the trial.

In the Specimen Collection table, provide details about the type and quantity of the specimen(s) to be collected for the correlative studies outlined in the Biomarker table. **All specimens listed in the Specimen Collection Tables should have a corresponding biomarker in the Biomarker Table.**

**Biomarker Review Committee (BRC) Requirements:** With the current emphasis on biomarker-driven drug development, it is necessary to ensure that fit-for-purpose assays of these biomarkers are incorporated in CTEP-sponsored protocols. To that end, the NCI Division of Cancer Treatment and Diagnosis (DCTD) has formed the Biomarker Review Committee (BRC), which is now responsible for reviewing the biomarker components of CTEP-sponsored clinical trials. Specifically, LOIs for trials that are not reviewed by an NCI disease-specific steering committee will require BRC review and approval if they meet **any** of the following criteria:

* Integral or integrated biomarkers
* Requires biopsies obtained specifically for the purpose of a biomarker assay, whether mandatory or optional.
* Procedure is burdensome on the patient (invasiveness, schedule, etc.)

The BRC may also, at its discretion, review any assay judged to be of particular importance to the trial or for which ETCTN or CRADA funding is requested to support sample collection and/or performance of the assay. To expedite biomarker review, please complete Appendix B.

***(Note: For LOI review, each biomarker assay intended for inclusion in the study must be entered into the Biomarkers and Specimen Collection tables below, and all fields must be completed.)***

Biomarkers Table

Select a field and click the  button at the bottom right of the row to add rows as needed.

| **Priority** | **Biomarker Name a** | **Assay and CLIA: Y/N** | **Use in the Trial (Integral, Integrated, or Exploratory) and Purpose b** | **Specimens****Tested** | **Collection Time Points** | **Mandatory orOptional** | **Assay Laboratory, Lab PI, and Lab PI Email c** | **Funding Source(s) d** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Tissue-based** |
| EnterPriority# | Enter Biomarker Name | Enter Assay Type Enter CLIA: Yes orCLIA: No  | Enter Use in TrialEnter Purpose | Enter Specimens Tested | Enter Collection Time Points | EnterM or O | Enter Assay Laboratory, Lab PI, and Lab PI Email | Enter Funding Source(s) |
| **Blood-based** |
| EnterPriority# | Enter Biomarker Name | Enter Assay TypeEnter CLIA: Yes orCLIA: No  | Enter Use in TrialEnter Purpose | Enter Specimens Tested | Enter Collection Time Points | EnterM or O | Enter Assay Laboratory, Lab PI, and Lab PI Email | Enter Funding Source(s) |

**a There should be only one biomarker listed per row. However, panels (e.g., WES, RPPA, RNAseq, mIHC, multiplex ELISA) may be listed in a single row** if they are performed using the same assay in the same laboratory by the same investigator with the same intended use (integral, integrated, exploratory). Individual markers in the panel may be listed in Appendix B.

**b Briefly specify the role of the biomarker in the study** (e.g., eligibility criterion, assignment to treatment, stratification factor, response assessment, prospective research, hypothesis generation, etc.). If a hypothesis will be tested, please succinctly state it (e.g., “to identify biomarkers of response”).

**c If an outside company will be contracted to perform the assay**, please enter the company name under Assay Lab.

**d Indicate all funding sources.** Specify whether company funding (either through CTEP CRADA or directly from the company) is requested for the sample (tissue/fluid) collection, for the assay, or both. If CTEP CRADA funding is requested, please provide a budget.

Specimen Collection Table

* **This table must identify how each individual specimen to be collected in this study will be used.** Insert additional rows or columns as needed. Grouping frequent time points with the same collection quantity (e.g., blood for pharmacokinetic assays) is permitted.
* **Notes:**
	+ **Cores 1 & 2** are obtainable in most circumstances and settings based on safety and risk assessment, including lesion size and location.
	+ **Cores 3 & 4** are obtainable in some circumstances based on safety and risk assessment
	+ **More than 4 cores** are RARELY obtainable and should not be the basis for planned biomarker assays
	+ N/A = Not Applicable

Select a field and click the  button at the bottom right of the row to add rows as needed.

| **Specimen Type** | **Intended Biomarker(s)** | **Archival** | **Baseline** | **Click and enter Time Point** | **Click and enter Time Point** | **Click and enter Time Point** | **Click and enter Time Point** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Archival Specimens** |
| Enter Specimen Type (e.g., Tumor, FFPE) | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | Enter quantity.EnterMandatory or Optional | N/A | N/A | N/A | N/A | N/A |
| **Core Biopsy Specimens a** |
| Enter Specimen Type and post-biopsy specimen processing, e.g., Tumor/Formalin, Bone Marrow Core/Frozen | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional |
| Enter Specimen Type, e.g., Bone Marrow Aspirate  | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter quantity (e.g., 1 x 3 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 3 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 3 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 3 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 3 mL.)EnterMandatory or Optional |
| Enter Specimen Type and specimen processing, e.g., Skin Punch/Formalin | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional | Enter core biopsy priority (e.g., Core Biopsy #1)EnterMandatory or Optional |
| **Blood Specimens** |
| Enter Specimen Type (e.g., Blood/Streck cell-free DNA tube) | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter quantity (e.g., 1 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 1 x 10 mL.)EnterMandatory or Optional |
| Enter Specimen Type (e.g., Blood/green-top tube) | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter quantity (e.g., 3 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 3 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 3 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 3 x 10 mL.)EnterMandatory or Optional | Enter quantity (e.g., 3 x 10 mL.)EnterMandatory or Optional |
| **Other Specimens** |
| Enter Specimen(s), e.g. saliva, stool, urine | 1. Enter assay(s) that will use this specimen.If >1 list priority.
 | N/A | Enter quantityEnterMandatory or Optional | Enter quantityEnterMandatory or Optional | Enter quantityEnterMandatory or Optional | Enter quantityEnterMandatory or Optional | Enter quantityEnterMandatory or Optional |

**a Core biopsy priority (1-4) should be entered under relevant time point.** The biopsy requirement and order of core biopsy importance could be different at different time points. If no core biopsies are to be collected at a time point, add “N/A”.

**An Interventional Radiologist (defined as a Radiologist responsible for acquisition of biopsy specimens) should be consulted** during the initial preparation of the LOI involving any core biopsy procedures and to assure that a system is in place for patient assessment and consultation prior to undergoing a procedure to obtain tissue specimens.

Imaging Correlates Table

Select a field and click the  button at the bottom right of the row to add rows as needed.

| **Correlative Objective(Name of Correlate and Lead PI & Site)** | **Imaging Technique** | **Organ(s) Scanned andTiming of Scans** | **Mandatory orOptional** |
| --- | --- | --- | --- |
| Enter information | Enter information | Enter information | Select Mandatory or Optional |

Endpoints/Statistical Considerations:

State explicitly the null and alternative hypothesis(es) for the primary objective(s). Also state the sample size and associated type I and type II errors. Provide an analysis plan for both primary and secondary objectives, including correlatives, and assume that each objective has a measurable endpoint. Include information about which statistical tests will be applied. State the projected accrual rate and ensure that the accrual goals are realistic and achievable with current resources. **If the trial will be an ETCTN trial involving 3 or fewer LAOs, please justify the projected accrual rate by completing Appendix A.**

**Click and enter Endpoints.**

References:

Provide references for cited data and key background/concepts. **Verify all references.**

**Click and enter References.**

**Appendix A – Projected Accrual & Competing Trials**

**Instructions:**

**If the proposed trial will involve 3 or fewer ETCTN LAOs, the “Competing Trials Table” below must be provided.**

*Please note that after LOI review, a list of ETCTN site investigators (at least 3 for phase 1 and 12 for phase 2 trials) who commit to opening this study at their institution must be submitted to CTEP before LOI approval will be granted.*

If the study fails to achieve at least 50% of its planned accrual rate by the second quarter, CTEP may, at its discretion, issue a request for a Corrective Action Plan (CAP) and/or open the trial across the ETCTN. For more details, please see the most recent Early Phase Trial Slow Accrual Guidelines at <https://ctep.cancer.gov/protocolDevelopment/cde_data_policies.htm> .

Competing Trials Table

* **If this trial will involve 3 or fewer ETCTN LAOs,** list all Active, Approved, or In Review studies at the Lead (coordinating) LAO for which this patient population will be eligible (active trials should also be listed under documented accrual). To provide data on additional trials, insert additional rows as needed.
* If this study will involve more than 3 ETCTN LAOs or is a Group (e.g., Alliance, ECOG-ACRIN) trial, please write “Not applicable” below.

Select a field and click the  button at the bottom right of the row to add rows.

| **Protocol Number, Title, and Sponsor of Relevant Site Only***(Include NCI Number if NCI-Sponsored)* | **TrialActivation Date** | **AnticipatedCompletion Date** | **Number of Patients Enrolled to Date, Duration of Patient Enrollment, and Total Planned Enrollment***(Only include patients enrolled at site(s) relevant to LOI proposal)* |
| --- | --- | --- | --- |
| * Enter Protocol Number
* Enter Title
* Enter Sponsor of Relevant Site
 | Enter date | Enter date | * Enter Number of Patients Enrolled to Date
* Enter Duration of Patient Enrollment
* Enter Total Planned Enrollment
 |

**Appendix B –** **Biomarker Assay Description(s)**

**Details of biomarker assays may be provided here.**

For all non-NCLN integral and integrated biomarkers and for any non-NCLN exploratory biomarkers for which CTEP support is requested for sample collection or performance of the assay, state experience with the assay and assay methods, performance, operating characteristics, and whether the assay will be performed in a CLIA-approved laboratory.

For any biomarker(s) that would require BRC Review, please complete the Study Checklist for CTEP-Supported Early Phase Trials with CTEP-Supported Biomarker Assays at: <http://ctep.cancer.gov/protocolDevelopment/docs/Study_Checklist_Early_Phase_Trials_Biomarker_Assays.docx> and submit your LOI.

**Click and enter Biomarker Assay Description.**