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|  | **PHASE 2, 2/3 and 3 TRIAL  CONCEPT SUBMISSION, Version 4.3** | CLINICAL INVESTIGATIONS BRANCH |
| **National Cancer Institute**  **Division of Cancer Treatment and Diagnosis**  **Cancer Therapy Evaluation Program**  **April 4, 2024** | |

*NOTES: Concepts must be submitted in electronic format (tables or schema may be converted to .pdf format to assure accurate transfer). To complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter text for each text field (the Insert key must be set to Off) or follow instruction when given. Submit by e-mail to PIO@CTEP.NCI.NIH.GOV.*

*If this is a Phase 2/3 or a Phase 3 study that involves an IND agent or IDE biomarker, then the concept will be forwarded to the FDA to receive regulatory comments to assist with completion of the protocol.  For Phase 2/3 and Phase 3 drug studies which do not fit this category, we will also send the concept to the FDA, but for purely informational purposes****.***

***Each of the scientific sections should be sufficient to briefly describe the major elements of the study. Within these principles as a guide, there are no specific requirements or limitations on length; however, concept proposals should be concise (recommended maximum length 8 to 10 pages). The concept proposal is NOT meant to be a draft of the protocol document and the sections below should NOT be excessive or encyclopedic.***

# I. ADMINISTRATIVE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title of Concept: |  | | | |
| Sponsoring Organization’s Local Protocol Number: |  | | | |
| Concept Version Date: | | [Click here to enter a date] | | |
| Study Chair Name (printed): |  | | | |
| Study Chair Signature (optional): | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Date: | [Click here to enter a date] |
| Study Chair Address: |  | | | |
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|  |  | | | |
| Study Chair Phone: |  | | | |
| Study Chair Fax: |  | | | |
| Study Chair e-mail: |  | | | |
| Name(s) of co-chairs or discipline chairs, if any: |  | | | |
| Group Chair/Cooperative Agreement Name: |  | | | |
| Group Chair Signature (optional): | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Date: | [Click here to enter a date] |
| Group Chair Address: |  | | | |
|  |  | | | |
|  |  | | | |
| Group Chair Phone: |  | | | |
| Group Chair Fax: |  | | | |
| Group Chair e-mail: |  | | | |
| NIH Grant Number: |  | | | |
| Study Statistician Name: |  | | | |
| Study Statistician E-mail: |  | | | |

# II. PHASE OF STUDY

Specify what type of phase this study will be conducted under (2 or 3).

**2 ☐ 3 ☐ 2/3 ☐**

# III. DISEASE AND INTEGRAL MARKER SPECIFIC SECTION

Specify the Name and Code of all the Study Diseases below (MeDRA Code Disease list available on CTEP Web site, <http://ctep.cancer.gov/protocolDevelopment/codes_values.htm>.

1. If study involves multiple diseases, please provide Disease Name and Disease Code for each disease.

2. If this disease is under a Steering Committee, please indicate if this Concept version has already been reviewed by the Task Force? **Yes ☐ No ☐ Not Known ☐**

3. Does the study involve any investigational (non-standard of care) integral marker(s) (e.g., laboratory test, imaging test) defined as test(s) that must be performed in order for the trial to proceed or for the trial data to be analyzed with respect to the primary endpoint?

**Yes ☐ No ☐ Not Known ☐**

If yes, please describe briefly below (not to exceed 1 page) the integral purpose for the marker (e.g., eligibility criterion, assignment to treatment, stratification variable, risk classification or score, etc.) and how the marker will be funded for the study. Also provide the main supporting background information on the characteristics, performance, and validation of the investigational integral marker and whether an IDE will be required.

**Information on investigational integral marker:**

Purpose:

Description:

Does this investigational device require an IDE?

If the above requires an IDE, please provide what entity will hold the IDE:

4. For Network Groups of the NCTN Program Only: BIQSFP STUDY APPLICATION

a) Is a BIQSFP application being submitted in conjunction with this concept for an **integral study(ies)**?If a BIQSFP application is being submitted with the concept, the information on the investigational integral study(ies) should be provided in the application and not in this concept form.

**Yes ☐ No ☐**

**b)** Will an **INTEGRATED** BIQSFP application be submitted in conjunction with this concept?

**Yes ☐ No ☐**

If so, please identify each proposed integrated study assay/test/assessment/instrument \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The completed BIQSFP integrated study application packet must be received by the respective PIO **within 3 months of official notification of parent concept approval.**

**If this is an NCTN IND Exempt study, it will be expected to follow the streamlining data initiative.**

<https://ctep.cancer.gov/protocolDevelopment/docs/NCTN_Streamlined_Data_Standard_Practices.docx>

IV. PHARMACEUTICAL SECTION

1. Specify the agent(s) to be used in the study:1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Agent Name | Request for CTEP/PMB-distribution? | Is the agent Investiga-tional? | Who is the IND Holder?2 | NSC  Number[[1]](#footnote-1) | Placebo  Controlled? |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |
|  | ☐Yes ☐No | ☐Yes ☐No | ☐Company ☐Consortium ☐CTEP  ☐Group ☐Investigator ☐Other (Specify): |  | ☐Yes ☐No |

*1. For treatment protocols, include only anti-cancer agents.*

*2. An Investigator Brochure must be submitted for any investigational agent used in the study that is not under a CTEP IND.*

1. If CTEP is being requested to distribute any agents not under a CTEP IND, provide the reason for the request for each agent.

# V. ACCRUAL SECTION

Provide the following accrual information:

**Accrual Rate**: pts/month.

**Total Expected Accrual**: **Minimum** [Click here and enter] **Maximum** [Click here and enter]

**Projected Accrual Dates**: **Start** [Enter Month] / [Enter Year] **End**: [Enter Month] / [Enter Year]

(Please provide the justification for this accrual rate estimate.)

# VI. SCIENCE SECTION

*To enter text, click on the blank line under each question and type or paste text.*

## Specific hypotheses:

## Objective(s) (it is preferable to specify one primary objective and secondary objectives):

2.1 Primary objective:

2.2 Major Secondary objective(s):

## Background Information. This section should include a BRIEF description of the following:

3.1 Rationale for selected approach and trial design.

3.2 Discuss why this trial is important (include summary of clinical issues and competing study questions relevant to the trial setting) and potential impact on, for example, overall survival, quality of life or advances in proof of biologic principles. Also, how would research strategy or future clinical practice be altered by either positive or negative results?

3.3 All pertinent data (include phase 1-3 trial results, and any pilot or confidential data from companies that justify the use of the control and experimental arms).

(For publications cited, include either the NLM/Medline ID number or the URL address to permit retrieval of the full text or abstract by reviewers)

## Eligibility (include rationales for selecting or excluding particular cohorts):

## Arms/Regimens (include schema):

* 1. Schema

5.2 Arms/Regimens

## Statistical design:

6.1 Endpoint(s).

6.1.1 Primary Endpoint

6.1.2 Secondary Endpoint (if any)

6.2 Include any stratification to be used in the randomization.

6.3 Provide sample size with power justification.

6.4 Provide analysis plan including plans for formal interim analysis.

## Feasibility (Discuss, as appropriate, size of eligible population, anticipated acceptance of trial by patients and referring physicians and experience with accrual to similar trials). Investigators must include:

7.1 Competing phase 3 trials in your Group.

7.2 Competing trials in other U.S. or international Groups.

7.3 Competing company studies of which you are aware.

# VII. POTENTIAL EMBEDDED INTEGRATED CORRELATIVE STUDY SECTION

Please provide below a **BRIEF description (no more than a brief paragraph of 5 to 6 sentences)** to indicate any primary integrated laboratory, imaging, or quality of life (QOL) embedded sub-study that the study team is planning should this concept be approved. Integrated studies are defined as tests/sub-studies that are clearly identified as part of the clinical trial from the beginning and are intended to identify or validate assays/markers or imaging tests that are planned for use in future trials or QOL studies that are intended to inform on treatment options and side effects and/or validation of biological and functional clinical correlates of patient–reported outcome (PRO) data. Integrated studies must be designed to test a hypothesis, not simply to generate hypotheses.

**This information is NOT part of the review of the concept proposal and will only be used should the concept be approved to provide subsequent submission and review of the potential integrated embedded sub-study prior to final protocol submission.**

## **LABORATORY CORRELATIVE SCIENCE STUDY**

**Yes ☐ No ☐**

Brief Description:

## **IMAGING CORRELATIVE SCIENCE STUDY**

**Yes ☐ No ☐**

Brief Description:

## **QOL CORRELATIVE SCIENCE STUDY**

**Yes ☐ No ☐**

Brief Description:

# VIII. PERSON COMPLETING CONCEPT SUBMISSION

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| --- | --- | --- | --- |
| Name of Person Completing Form: |  | Date: |  |
| Person Completing Form Address: |  | | |
|  |  | | |
|  |  | | |
| Person Completing Form Phone: |  | | |
| Person Completing Form Fax: |  | | |
| Person Completing Form E-mail: |  | | |
| NOTE: Concepts must be submitted in electronic format by e-mail to [PIO@CTEP.NCI.NIH.GOV](mailto:PIO@CTEP.NCI.NIH.GOV).  Questions? Please contact the Protocol Information Office (PIO) at: [pio@ctep.nci.nih.gov](mailto:pio@ctep.nci.nih.gov) | | | |

1. The NSC Number must be provided if the agent is investigational. See <http://ctep.cancer.gov/protocolDevelopment/codes_values.htm#agent> for a complete list of Organization (Group, Consortium and Institution), IND and NSC Numbers and Disease Names and Codes. [↑](#footnote-ref-1)