**NExT Application Template for Multiple Agents for NCI-Sponsored Clinical Development in NCI’s Experimental Therapeutics Clinical Trials Network (ETCTN)**

**Please Read before Proceeding:**

*Applicants who are requesting NCI-sponsorship of ETCTN clinical trials for a portfolio of agents should outline the scientific nature and rationale of the proposed project. The introduction to the application should be two pages or less. The application should include Background, Hypothesis, Research Strategy, Justification and Uniqueness sections completed for each agent. The required information should be summarized in no more than 3 pages per agent. Therefore, if proposing the evaluation of 2 agents, a maximum 8 page Concept is allowable; for 3 agents, a maximum 11 page Concept is allowable; etc. For additional information, please refer to the* ***NExT Proposal Instructions****. Additional material can be uploaded as an appendix.*

***For resubmissions:***  *In addition to the required* ***Resubmission Summary Template*** *(max 2 pages), applicants should submit an amended version of the original concept application. As with the original application, the resubmission is limited to not more than 3 pages per agent. Substantial changes must be clearly marked with underlining or italic formatting. However, if the changes are substantial enough that would cause more than 50% of the text to be marked, please clearly indicate this in the beginning of the Resubmission Summary.*

*Any work completed since the original application was submitted can be included as an appendix. Appendices should be limited to papers in press and preliminary data. Do not include entire RO1 grant applications.*

*For additional information, please refer to the* ***NExT Proposal Instructions****.*

**Remove this page and text instructions from the Concepts submission.**

**Please complete Header and enter Concepts in the designated boxes.**

**Do not modify margin size.**

**Name:**

**Institution:**

**Address:**

**E-mail:**

**Title:**

**Background**

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| ***Replace text with the requested information.*** *Provide a summary of the field sufficient to allow an appropriate understanding of the scientific and medical context from which the opportunity emerges. Describe the target, targeted cellular pathways, and molecular mechanism of action, if known. Please be concise and specific; it is not necessary to address cancer incidence.* |

**Hypothesis**

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| ***Replace text with the requested information.***  *Include a clear statement of the hypothesis(es) to be tested and define the objectives of the proposal for each agent. Specifically, address the scientific merit of your proposal by evaluating whether your hypothesis is supported by the field. Provide evidence to validate the target and/or the approach for pharmacological intervention based on in vitro, in vivo, or clinical studies from your research or the literature. Provide a summary of the key experiments you have conducted to date; manuscripts and supporting material can be uploaded as an appendix. Include an assessment of safety and therapeutic index. When available, include information on the competitive landscape and comparator efficacy studies.* |

**Research Strategy**

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| ***Replace text with the requested information.*** *Clearly describe the intended research strategy, defining the specific activities requested from the NCI with the proposal; if the research activities necessary to move the concept forward to the clinic are not established or clear, please indicate this. Include specific details as necessary to demonstrate that the project has been well thought out (for example, if requesting assistance in the development of a pharmacodynamic assay, include a description of the analyte to be measured, strategy for biospecimen acquisition, assay platform, etc.). Address the feasibility of the proposed research strategy.*  *Please also indicate whether you are submitting the application with support from the Cancer Therapy Evaluation Program (CTEP) and whether you have met with the FDA.*  ***For clinical drug development projects (Phase 0/I/II),*** *provide a summary of all pertinent preclinical and clinical efficacy, toxicology, pharmacokinetic, and pharmacodynamic data, including studies of agent combinations for each agent. Describe the company’s sponsored development plan for each agent, and the proposed NCI-sponsored development plans for each agent, including the number and types of trials proposed, the clinical trial designs and objectives of the proposed trials. Describe how the proposed NCI collaboration will complement and not overlap the company’s agent development plans. For combination trials, include details about the originator of the agents (investigational/marketed) and rationale for conducting the study, indicating possible advantages over single agents/current therapies. If available, please upload the Investigator’s Brochures as an appendix.* |

**Justification**

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| ***Replace text with requested information.*** *For each agent, provide a statement to indicate whether your proposal adequately addresses unmet needs in oncology, including orphan or rare malignancies, pediatric cancers, “incurable” cancers, or cancers not commonly addressed by the pharmaceutical industry. Specify how the proposed collaboration will advance clinical practice and improve current therapy. For imaging agents, provide an explanation of why the imaging represents a particularly innovative or promising approach to the prevention, detection, diagnosis, or treatment of cancer.* |

**Uniqueness**

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| ***Replace text with requested information.*** *Include a statement**about how the proposed collaborations differ from standard therapies in practice or under clinical evaluation. If available, provide comparator efficacy and safety data for your investigational agent (biologic, vaccine, or new molecular entity) or cell therapy approach. Address the novelty of the concept with respect to the target and approach and indicate the likelihood of the concept advancing into the clinic without the assistance of the NExT Program.* |