**NExT Application Template for Discovery, Development or Clinical Trial Evaluation of an Investigational Agent (single or combination) Clinical Study**

*The* ***5-page******NExT Concept*** *document should outline the scientific nature and rationale of the proposed project. For additional information, please refer to the* [***NExT Proposal Instructions***](https://next.cancer.gov/content/docs/NExT_Application_Instructions.pdf)*. Additional material can be uploaded as an appendix.*

***Please Note:*** *Applicants who are requesting early discovery resources should be aware that such resourcing is done via the NCI's Chemical Biology Consortium (CBC). Applicants whose projects are approved will be invited to join the CBC and are expected to become signatories to the* [*CBC Participant’s Agreement*](http://dctd.cancer.gov/CurrentResearch/CBC_Agreement.pdf)*. If you are submitting an early discovery NExT Program application, you are expected to have read and understand the referenced agreement and to have contacted your institution's or company's Technology Transfer Office to make certain that your organization is willing to accept the terms of this agreement.*

***For resubmissions:***  *In addition to the required Resubmission Summary Template (2-page max), applicants should submit an amended version of the original concept application. As with the original, the resubmission is limited to* ***5 pages****. Substantial scientific changes must be clearly marked with underlining or italics.* *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.*

*If the original application was submitted prior to the restructuring of proposals in April 2010, please add any sections that are now required for the application.*

*For additional information, please refer to the* [*NExT Proposal Instructions*](https://next.cancer.gov/content/docs/NExT_Application_Instructions.pdf)*.*

**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. 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.*  ***For early-stage drug discovery projects****: describe the proposed screening strategy, readiness of the primary assay, and any supporting secondary assays available, including structure-based, virtual, and selectivity assays. Supporting data can be uploaded as an appendix. For new molecular entities, describe the development status of the compound and optimization strategy (for guidance, please refer to the* [*NExT Stage Gates*](http://nexttest.cancer.gov/pipelineManagement/stageGate.htm)*). Indicate whether the compound has undergone medicinal chemistry optimization; if not, describe the proposed strategy. Describe available enzymatic, cell-based, and ADME assays, and where appropriate, access to a structure-based drug design platform; include a description of validated disease animal models (e.g., GEMMs). Specify the expected resources or expertise required from NCI to facilitate advancement of the agent into first-in-human studies.*  ***For late-stage drug discovery/development projects:*** *describe the current compound optimization status and strategy for further development (refer to the* [*NExT Stage Gates*](http://nexttest.cancer.gov/pipelineManagement/stageGate.htm) *for guidance). Indicate whether the compound has undergone medicinal chemistry optimization. Indicate whether any formulation work has been performed or describe the proposed formulation strategy. Describe available PK/PD assays and clinical readiness of assays. Include an evaluation of functional activity, potency, and pharmacokinetic/pharmacodynamic relationship, with an emphasis on therapeutic index if available; supporting data can be uploaded as an appendix.*  *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. Describe the development plans for the agent, including the clinical trial design and objectives if known (e.g., primary and secondary study objectives, endpoints, patient population, eligibility criteria, estimated sample size, treatment arms/regimens, statistical endpoints, correlative studies, and patient samples required to perform correlative studies). 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 Brochure as an appendix.* |

**Justification**

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| ***Replace text with requested information****. 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 compound or approach 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 agent or therapy differs 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.* |