Guide for Applicant

The call for proposal and the application form are available at http://www.euncl.eu/working-with-us/submission-procedure/

The call is open to anyone, academic, industry or any stakeholder and does not require any funding.

Data and information will be covered through a NDA to be signed prior to application. The NDA model is available at http://www.euncl.eu/working-with-us/submission-procedure/

The **submission** will be separated **in two steps.** The proposals should be sent to

EU-NCL
c/o CEA/Clinatec
17, rue des Martyrs
38054 Grenoble cedex France
Email: tna@euncl.eu

STEP 1: Light proposal

This proposal should include an abstract and a background description, the strategy or concept of action, synthesis data, a description of innovation, clinical impact and scale-up compatibility, and any preexisting data relating to characterisation, *in vitro* and *in vivo* testing, (note that prequalification requires at least supporting *in vitro* data).

Submission should include the following criteria

> The application should describe all applicable data on a *single lead candidate* nanotechnology strategy. The primary evaluation criterion for Light Proposal in Step I is the strategy's previously demonstrated efficacy in a biological system relevant to cancer research. The EU-NCL appreciates that biologically relevant data for proposed nanotechnology strategies may be preliminary and limited because of the novelty of this field. However Light Proposal that address only the "material sciences" aspects of nanotechnology are not desired. If *in vivo* and/or *in vitro* experiments were not conducted, detailed scientific justification explaining why a given nanomaterials is advantageous in cancer diagnosis and/or therapy should be provided. Another important evaluation criterion for the Step I application is that the concept described in the application actually involves nanoscale components. Data demonstrating this (e.g. size measurements) is most appropriately included in the section titled "Physical/Chemical Characterization"

The light proposal is intended to give EU-NCL reviewers an overview of the strategy, without requiring investigators to prepare costly, time-consuming proposals.

The proposal template is available at http://www.euncl.eu/working-with-us/submission-procedure/

A Peer-Review Committee composed of international experts and the EUNCL Experts will review this short application. They will nominate the selected proposal for step 2.

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STEP 2: Full proposal dossier/interview

The second step demands the development of either a more detailed 10-page written proposal or a 45-minutes oral presentation, which should include in addition to **STEP 1** further detail on the following areas:

- Anticipated impact of strategy on clinical cancer (disease) therapeutics and/or diagnosis
- Previous characterization of the NP
- Detailed manufacturing process description
- Inherent toxicity of the NP
- Plan or strategy of transfer the concept to the clinical use

Evaluation criteria

- **Demonstrated Efficacy in a Biological System (In Vitro or In Vivo)**

Give a detailed overview of the nanotechnology strategy: what it is, what it does, how it works. Provide detailed descriptions of the nanomaterial's physical properties, chemical structure, and stability. Present and discuss preliminary data and the materials and methods used. Address the inherent strengths and limitations of the strategy (e.g., anticipated in vivo half-life of the material, toxicity, potential to elicit an immune response, etc.).

- **Anticipated Impact of Strategy on Clinical Therapeutics and/or Diagnostics**

Describe the projected clinical use of the material and the basic biological mechanisms of action. What is the strategy's "value added" when compared to existing/reference therapeutics and diagnostics? If the strategy has benefits due to targeting and/or specificity, discuss the specific underlying mechanisms and include data to support these claims. Describe any measured ADME/Tox, pharmacokinetic parameters, and any analyses comparing the results to current therapeutics or devices.

- **Previous Characterization of Material**

The material providers need to supply detailed information on assays previously used to characterize the material and the reproducibility of those assays. As part of its assay cascade, the EU-NCL will provide an initial screening to determine the variability of basic physical and chemical parameters of the material provided. If the variability is so large that further physical and biological assays will not provide meaningful data, the assay cascade will be discontinued for that strategy. The demonstrated ability to control the physical parameters of the material will therefore be a weighted evaluation criterion.

- **Manufacturing Process; Compatibility with Scale-Up**

Briefly describe the manufacturing process and steps used during purification. Discuss impurities that may be present in the final product. Provide information on the cumulative amount of nanomaterial (e.g., milligram, gram, or kilogram) produced to date, and the batch-to-batch variability. Discuss potential obstacles associated with producing enough material for preliminary pharmacology and toxicology studies. Is a reference standard for the nanomaterial available?

- **Inherent Toxicity of Nanotechnology Concept**

Include information on relevant safety and/or environmental issues related to the production, purification, and/or handling of the nanomaterial. For example, if the nanomaterial contains a known toxic compound, discuss how the strategy overcomes or mitigates potential adverse health effects. If known, discuss supporting reagents/reactants/solvents that may be used in scale-up production, as well as waste streams that might be generated in the manufacturing process.

- **Plan or Strategy To Transition the Concept to Clinical Use**

Information related to teaming with industry, academic, or other government partners in the translation effort is of interest to the NCL. If applicable, describe steps previously taken toward translation of the strategy/nanomaterial to clinical use. Discuss possible sponsors for future studies or trials and/or arrangements with commercial production firms. Discuss intellectual property issues related to the material, especially if the material utilizes licenses or represents an improvement or modification of an existing material or production process. If applicable, a brief summary of similar or closely related antecedents or approaches to the submitted strategy/nanomaterial should be described.

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