INNOVATE 2 REQUEST FOR PROPOSAL (RFP):

CABOTEGRAVIR LONG ACTING FOR PREVENTION

Concept Submission Template

*Concept pages should have 1-inch margins & Normal style (10-point Arial font, single spaced) and should be no more than 4 pages in length. Concepts must include the Level 1 Heading sections identified below. If section is “not applicable to the type of study, enter “N/A” under the heading. Level 1 Headings should not be modified. Level 2 headings can be added as appropriate.*

*Don´t forget to save your document with your name to help us to link the document to the specific Study Proposal*.

All concepts submitted must include the sections below

Title of Research Project

Provide a descriptive title for the topic your study addresses. Note: This title should align with the title entered on the ISR portal

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| Enter Response in this area |

Study Background and Rationale

Explain the significance of the proposed study and how it will support one or more of the RFP’s priority areas. The rationale should also include relevant background information to support the proposed study and a brief review of any other studies completed or being conducted that address the priority area. This section should be no longer than 150 words.

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Purpose Statement

Please state the research question, what the study is expected to demonstrate, and how this study will address the Priority Area(s) you selected. This section should be no longer than 50 words.

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| Enter Response in this area |

Objectives and Endpoints

Please specify key objectives and corresponding endpoints. Please specify how each endpoint will be measured and at what timepoint(s) (e.g., for a health outcomes objective, specify the patient reported outcome instrument that will be used to measure the endpoint). Please delineate clinical versus implementation objectives/endpoints, as appropriate

Primary

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| *Primary Objective 1* | *Endpoint 1* |
| Enter Response in this area | Enter Response in this area |
| *Primary Objective 2 (if essential)* | *Endpoint 2* |
| Enter Response in this area | Enter Response in this area |

Secondary

|  |  |
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| *Secondary Objective 1* | *Endpoint 1* |
| Enter Response in this area | Enter Response in this area |
| *Secondary Objective 2* | *Endpoint 2* |
| Enter Response in this area | Enter Response in this area |
| *Additional Objective* | *Additional Endpoint* |
| Enter Response in this area | Enter Response in this area |

Methods

a. Type of Study (select more than one category if hybrid study)

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| --- | --- | --- | --- |
| \_\_\_\_ | Interventional Study | |  |
| \_\_\_\_ | Retrospective Observational Study | |  |
| \_\_\_\_ | Prospective Observational Study | |  |
| \_\_\_\_ | Implementation Science/Dissemination Research Study | |  |
| \_\_\_\_ | Other | Provide Description of Other | |

b. Study Design

Describe and justify the type of study you are proposing. For example, state type of design, comparison groups, main tests, or procedures, primary and secondary, outcome variables, study duration, and study outline. State whether the design is case-control, cohort, case-cohort, case-crossover, systematic review, meta-analysis, etc. and whether the participants are followed retrospectively or prospectively. Any comparison groups should also be described. This should be no longer than 250 words

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c. Study Population

A brief description of the participant population to be studied including a brief discussion of any specific inclusion/exclusion criteria that may affect enrollment.

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| Enter Response in this area |

Inclusion Criteria

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| Enter Response in this area |

Exclusion Criteria

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Data Source

If applicable, please describe the source of data that will be used for this study (e.g. databases, etc.).

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| Enter Response in this area |

*Interventions*

Outline the interventions planned which may include study-administered medications, patient reported outcome measures, other surveys, implementation science frameworks & strategies, etc. This should be no longer than 150 words

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| Enter Response in this area |

Statistical Plan

a. Sample Size

Provide the target sample size for the primary objective. Justify the total sample size based on the study design and research question. For a single-arm study, please quantify precision by providing the 95% confidence around the estimated treatment effect for the primary endpoint. For a study with a comparator arm, please provide the expected effect size between the two groups in the primary endpoint and the desired power.

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b. Statistical Analyses

Outline the statistical analyses planned for the primary endpoints and key secondary endpoints

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Reporting Timeframes

Please provide estimated timings for achievement of key milestones in study (e.g. enrollment duration, completion of primary analyses, etc.).

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| Enter Response in this area |

References

Please list up to 5 key references

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| Enter Response in this area |