|  |
| --- |
| **Study Title:** |
| **Principal Investigator:**   * Name: * Institute: * E-mail: * Primary degree: * Medical specialty:   **Sub- Investigator (if applicable):**   * Name: * Institute: * E-mail: * Primary degree: * Medical specialty:   **\*Please attached CV** |
| **Type of Study:** Clinical or Non-clinical |
| **Type of Request:** Drug Product, Financial, or Both (Drug Product and Financial)  **Budget Request Summary:**  **Drug Request Summary:** |
| **Study Rationale:** |
| **Study Design: (e.g. control, number of treatment arms, product doses, treatment duration, numbers of animals)** |
| **Figure1. Study Schema:** |
| **Primary Objective:**  **Secondary Objectives:**  **Exploratory Objectives:** |
| **Key Inclusion Criteria:**  **Key Exclusion Criteria:** |
| **Study Population/Indication:** |
| **Study Endpoints:** |
| **Planned Sample Size and Statistical Powering Justification:** |
| **Planned number of subjects and sites/site locations (country only):** |
| **Study Visit Schedule of Events:** |
| **Planned Timeline and Study Duration:**   * Study start date: * Study end date: * Last patient out date:   **If enrolling patients, the following are required:**  • Planned FPFV (First Patient First Visit) date:  • Planned LPFV (Last Patient First Visit) date:  • Planned LPLV (Last Patient Last Visit)date:  • Planned FSR (Final Study Report\*) date:  \*FSR; : Clinical Study Report etc   * Submission for publication:   **Publication plan:** |

**References**

1. XX