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| --- |
| **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