**Investigator Initiated Study – IIS**

**Abbreviated Study Outline**

**Substance (INN) / Product:**

**Indication:**

|  |  |
| --- | --- |
| Principal Sponsor-Investigator |  |
| Address |  |
| Phone/Fax |  |
| E-mail |  |
| Planned number of study sitesOnly for multi-center studies |  |
| **Study Title** |  |
| KeywordsUp to seven study specific keywords should be listed |  |
| **Study Type*** interventional study or
* non-interventional study or
* pre-clinical study
 |  |
| **Medical Study Rationale**Description of evidence and medical needDefinition of study hypothesis |  |
| **Study Design*** single-center // multi-center
* prospective // retrospective
* controlled // non-controlled
* open // single-blind or double-blind
* randomized // non-randomized
* *n* arm parallel // *n* arm cross-over
* interventional // observational
* confirmatory // exploratory pilot
* *other*
 |  |
| **Primary Objective**Major goal of the study |  |
| **Secondary Objectives**Most important to be listed |  |
| **Evaluation Criteria*** Primary analysis variable/endpoint
* Most important secondary analysis variables/endpoints
* Safety variables
* Quality of life (*if applicable*)
* Health economics (*if applicable*)
 |  |
| Treatments and Visits* Treatment plan and therapeutic goals
* Schedule of visits displayed in a graph
* Dosage and dosing regimen for all study periods
* Formulation and strength(s) for study products
* Route of administration for study products
* Blinding techniques (*if applicable*)
 | *Please describe the study design and display a graph including study treatment arms and visit schedule* |
| **Study Population**Brief description of major inclusion criteriaand major exclusion criteria | **Inclusion criteria*** nn

**Exclusion criteria*** nn
 |
| **Sample Size** | Plan is to recruit up to n = xxx subjects*For hypothesis generating exploratory clinical studies the sample size calculation and justification should refer to the primary objective/primary endpoint solely* |
| Safety ReportingClassification requested | ❑ Solicited reporting *Safety data reporting should be performed in  accordance with BI pharmacovigilance requests*❑ Spontaneous stimulated reporting |
| Required Support | ❑ Financial Support❑ Study medicinal product originated by BI: - Compound 1 (in total n = x pills) - Compound 2 (in total n = y pills)❑ Other (*please specify*): ............................ |
| **Additional information** on the study concept to support IIS application | *Please add additional information if applicable* |