**IIT Full Proposal Submission Form**

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| --- | --- |
| Principal Sponsor-Investigator, Title, Specialty |  |
| Institution |  |
| **Address** |  |
| **Phone/Fax** |  |
| **E-mail** |  |
| *Only for multi-center IIT*:Principal Investigator of**Collaborating Trial Center No. *n*** |  |
| **Address** |  |
| **Phone/Fax** |  |
| **E-mail** |  |
| **Trial Title** |  |
| **Trial Short Title** |  |
| **Trial Drug Trade Name ®,**  |  |
| **Trial Drug INN**International Non-proprietary Name |  |
| **Comparator Drug(s) INN if applicable**International Non-proprietary Name |  |
| **Indication** |  |
| **Trial Type and Design*** interventional trial non-interventional
* prospective
* retrospective
* single-centre
* multi-center
 |  |
| **Trial Rationale**Description of evidence and medical needDefinition of study hypothesis |  |
|  |  |
| Treatments and Visits* Treatment plan and therapeutic goals
* Dosage and dosing regimen for all trial periods
* Formulation and strength(s) for trial products
* Route of administration for trial products
* Blinding techniques (*if applicable*)
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| **Primary Objective**Major goal of the trial  |  |
| **Key Secondary Objectives**Additional important aspects to be evaluated |  |
| * **Evaluation Criteria**Primary analysis variable/endpoint
* Key secondary analysis variables/endpoints
* Safety variables
* Quality of life variables (*if applicable*)
* Health economics variables (*if applicable*)
 |  |
| **Trial Population**Brief description of subjects to be recruited by addressing the major inclusion and exclusion criteria**Background medication should be clearly defined** | **Inclusion Criteria:****Exclusion Criteria:** |
| Statistics |  |
| Safety ReportingClassification requested | ❑ Solicited reporting *Safety data reporting should be performed in  accordance with pharmacovigilance requests*❑ Spontaneous stimulated reporting |
| Required Trial Drug Support (Drug, strength, quantity) |  |
| Required Financial Support (if applicable) |  |
| Required Xellia drug product information (if applicable) |  |
| **Trial Duration and Timelines**Best case scenario based on feasibility | **Recruitment pool of eligible subjects:** **Estimated duration or recruitment period:** **Major Trial Periods**Trial set up (signed IIT contract to FPI): First Patient In (FPI) to Last Patient In (LPI): LPI to Last Patient Out (LPO): LPO to Data Base Lock (DBL): DBL to First Results available: DBL to final Clinical Trial Report: **Estimated total duration or trial conduct:**  |
| **Publication Plan** | **Submission Date**Abstract: Oral presentation: Full paper: Poster:  |
| Dedicated Ethical Review Board / Institutional Review BoardName and address |  |

Signature of the principal sponsor-investigator

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[*Please insert place and date*] [*Please insert name of sponsor-investigator*]
Principal Sponsor-Investigator

**Enclosure:**

1. **Clinical Trial Protocol**
2. **Curriculum Vitae of Sponsor-Investigator**