**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 need Definition 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*) |  |
| **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 Reporting Classification 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 Board Name 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**