Clinical Research Proposal: investigator Initiated Studies

Please complete all sections of this form. This will help us to process your Research Proposal efficiently. Additional sheets can be attached as required (Please list these in Section 3 below). Following a review, you will receive a response and comments from Groupe Lépine within 28 Business Days.

Please contact the Clinical Affairs Department if any further information or details are required.

**Groupe Lépine**

**175 Rue Jacquard, 69730 Genay**

**Clément Tran, Head of Clinical Affairs**

**clinical-affairs@groupe-lepine.com**

In order to process your application in a timely manner, please provide the following information as clearly and accurately as possible:

* Research proposal/protocol
* Description and quantity of Groupe Lépine product requested
* Resume for each Investigator, with a certificate of training in Good Clinical Practice (GCP), if available

**Content:**

Section 1: Contact Details

Section 2: Research Proposal Information

Section 3: Declaration

Section 1

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| --- |
| Contact and Site Details |
| Principal investigator’s name: |  |
| Telephone: |  |
| Email address: |  |
| Site / Hospital Address: |  |

Section 2

|  |  |
| --- | --- |
|  Study Title: |  |
| Study main objective: |  |
| Study secondary objectives: |  |
| Primary evaluation criterion (primary endpoint): |  |
| Secondary evaluation criteria : |  |
| Study design (*Retro or prospective? Mono or multicentric?*) |  |
| Proposed duration of study per patientFirst Patient Included (FPI)  | Study duration: FPI: |
| Follow-Up duration: |  |
| Inclusion criteria:  |  |
| Non-inclusion criteria: |  |
| Product(s) evaluated: |  |
| Comparison considered in the study (e.g. against literature, standard of care): |  |
| Study sample size (taking account of lost to follow-up): |  |
| Number of centers and associated investigators |  |

Section 3

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| [ ]  I have attached a signed copy of my resume  |
| Please List any additional documents attached to this proposal (Including any Budget templates): :

|  |  |  |
| --- | --- | --- |
| Document type  | Document name | Number of pages |
|  |  |  |
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[ ]  The Clinical Investigation will be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and in compliance with the Clinical Research Proposal, Good Clinical Practice and the applicable regulatory requirement(s).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date and signature of the principal investigator |
| Please return your application to the Clinical Affairs department of Groupe Lepine:**Groupe Lépine** **Service des Affaires Cliniques****Clément Tran, Head of Clinical Affairs****clinical-affairs@groupe-lepine.com**  |