Proposal for study: XXX – Laboratory XXX

For the attention of

NS-PARK
CIC de Toulouse (Toulouse Clinical Investigation Centre)- Purpan CHU (Purpan Hospital)
Hôpital Pierre Paul Riquet
Hall D – 2ème étage
Place du Dr Baylac - TSA 40031
31059 Toulouse Cedex 9
+33 (0)5 61 77 24 07 / +33 (0)5 61 77 25 24
www.parkinson.network
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1. Reference

Protocol XXX

2. Background

The XXXX Laboratory wishes to collaborate with the NS-Park/F-CRIN network to carry out the following clinical trial:

"FULL TITLE."

*Insert name of sponsor* is the trial sponsor, and the principal clinical investigator is Professor XXXX

The laboratory has approached the NS-Park/F-CRIN network for support in the coordination of the feasibility study for this trial. It wants to identify the investigation centres in the network with an interest in carrying out this research and evaluate the feasibility of the protocols at their sites. All 24 centres in the network will be approached. The network's coordinating team will also provide expertise to establish and monitor the trial. The centres will be responsible for the recruitment of patients and for the management of the study at their own sites.

This collective approach, combined with the coordinating activities of the NS-Park/F-CRIN network, will facilitate the effective running of the project.

3. Presentation of the NS-Park network, F-CRIN certified in 2013

The NS-Park/F-CRIN network is a national group of clinical research centres for Parkinson's disease and other movement disorders which brings together researchers and clinical experts in the field. The network is coordinated by Professors Corvol (Pitié Salpêtrière Hospital, Paris), Durif (CHU de Clermont-Ferrand [Clermont Ferrand Hospital]) and Rascol (CHU de Toulouse [Toulouse Hospital]). The NS-Park network comprises 24 expert centres specialising in Parkinson's disease created by the DGOS (Direction Generale de l'Offre de Soins: a directorate of the French Department of Health with responsibility for the quality and organisation of health care in France) in 2012, 16 of which have clinical investigation centres.

Its objective is to promote clinical research in order to understand the brain mechanisms involved in the control of movement (physiology) and the pathological phenomena that affect them (physiopathology), and to participate in the development of innovative therapies that improve patient care.

The NS-Park/F-CRIN network has expertise in clinical trial methodologies, pharmacogenetics and genetic biomarkers, medical devices and deep-brain stimulation, as well as in rare pathologies of movement disorders. The network is made up of professionals who work together regularly, each of whom have several years of experience in carrying out clinical research projects in this field.

Since 2010, the NS-Park/F-CRIN network has aimed to develop privileged partnerships with commercial partners, who can thus benefit from the expertise of a network that offers combined scientific and methodological know-how, underpinned by a strong investigatory capacity. NS-Park/F-CRIN can offer these commercial partners the methodological, administrative and logistical support required to establish and conduct research studies.
A single point of contact has been established to facilitate access to all 24 centres in the network and the dissemination of information to them. As a result, sponsors benefit from an efficient and effective channel of communication. An operational contact person (a clinical research associate) has also been identified at each centre. Monthly phone calls with them allow regular monitoring of the progress of studies and the recruitment of patients.

NS-Park was awarded F-CRIN certification in 2013. F-CRIN, the French Clinical Research Infrastructure Network (http://www.fcrin.org), is a national clinical research network, and winner of the tender for the National Infrastructures in Biology and Health projects, launched in 2010 by the ANR (the French National Research Agency), within the Investissements d’Avenir (Future Investments) framework for research and innovation. Its mission is to increase the profile and competitiveness of French clinical research, whether academic or industrial, especially at European and international levels. To build on existing strengths, F-CRIN has instigated a process to identify and select networks of excellence in clinical research that have proven scientific and methodological expertise and a strong investigatory capacity. In their fields of research, these networks have a strength of expertise, and set of investigatory skills, which are unparalleled at national level.

Since 2010, the NS-Park/F-CRIN network has been involved in more than 50 academic and industrial clinical trials on Parkinson's disease and movement disorders (half of which were international studies) and in almost 50 publications published in international, peer-reviewed journals.

The NS-Park/F-CRIN network has conducted projects whose operational scope was similar to the requirements of the XXXX Laboratory: the coordination of feasibility studies, management of investigation centres, development of collaborative tools (brochures, newsletters, etc.), recruitment monitoring, and development of harmonised cost schedules for additional care costs.

### 4. Proposal for support by the NS-Park/F-CRIN network

The services identified, and the advantages the NS-Park/F-CRIN network brings to the facilitation and effective management of the XXX study, are the following:

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<thead>
<tr>
<th>Tasks</th>
<th>Time required (hours)</th>
<th>Cost (based on €90/h)</th>
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<tbody>
<tr>
<td>Administrative costs</td>
<td></td>
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<td>Establishment of the agreement; management of invoicing.</td>
<td>15% of total cost</td>
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<tr>
<td>Feasibility</td>
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<tr>
<td>1 – Single point of contact: sponsor/network interface. Progress-monitoring calls with the sponsor (feasibility and network support).</td>
<td>5</td>
<td>450</td>
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<tr>
<td>2 - Centralisation and management of documents: centralisation, following up of progress with the centres, and return of documents to the sponsor. Compilation of participation agreements, confidentiality agreements, and the management of feasibility questionnaires (3 hours per centre, x centres).</td>
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<tr>
<td>Setting up the trial</td>
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<tr>
<td>3- Single point of contact: sponsor/network interface - Progress-monitoring telephone calls with the sponsor throughout the preparatory</td>
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Proposal for NS-Park support

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<th>Period</th>
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<td>- Centralisation and standardisation of requests from centres, prior to the start of the study. This will result in time savings for the sponsor, who will no longer have to answer questions from each centre in an individual and repetitive manner.</td>
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4 - Proofreading and centralisation of regulatory documents (*proofreading of documents for submissions, such as informed consent or French summaries*).

5 - Support for the scheduling of preliminary site visits (1h per centre, x centres).

6 - Participation in the preliminary visit with the coordinating centre.  

7 - Central evaluation of the costs of the investigation, in agreement with the coordinating centre:
   - Preparation of a budget breakdown by the network project manager, which will be approved by the centres before being sent to the sponsor.
   - Support during negotiations between the centres and the sponsor.

8 - Registration of the study on the Fox Trial Finder website.

9 - Support to the sponsor to facilitate the signing of contracts with each centre (1h per centre, x centres).

10 - Establishment of a recruitment strategy adapted to the objectives and constraints of the study:
   - Writing of the documents that will support the recruitment and the carrying out of the study at the centres (worksheets, leaflets presenting the study, posters, etc.).
   - Adaptation and customisation of tools for each centre, depending on the targets (patients, investigators, General Practitioners, etc.).

**Recruitment and trial-monitoring phase**

11 - Single point of contact: sponsor/network interface
   Regular progress meetings with the sponsor throughout the study: 1h per month over X months.

12 - Planning, preparation, chairing, and writing of the minutes for monthly telephone meetings with the clinical research associate at each centre, in order to monitor recruitment, discuss any issues blocking progress, share experiences and optimise operational networks: 1h per month over X months.

13 - Planning, preparation, chairing, and writing of the minutes for meetings with the investigators at each centre, ensuring that centres remain engaged and can meet recruitment targets and deadlines. (4 meetings per year): 2h per year.

Total in Euros (excl. VAT).

If you find this proposal acceptable, please return a signed copy to us, adding the words: "Read and approved", before the signature.

Date:   
Signature: