**Submission Date (Scientific Board date DD/MM/YYY):**

**Name of the Study/project:**

**project Title in English:**

**Sponsor:  Academic  pharma Industry**

**Name and location:**

|  |  |
| --- | --- |
| **Project Coordinator** | |
| Title | Ph. D Dr. Mr. Mrs. |
| Name |  |
| First Name |  |
| Address |  |
| E-mail |  |
| Phone number |  |
| Fax |  |
| Host research laboratory |  |

|  |  |
| --- | --- |
| **Expected start date** |  |
| **Expected End date** |  |

|  |  |
| --- | --- |
| **Type of study  :** |  |
| **Observational** | **Interventional** |

**keywords (5):**

**Type of requested data (please complete in appendix2 the list of OFSEP available data)**

**Clinical data  MRI data  Biological samples**

**Does the project require data from multiple centres**

**YES  NO  ?**

**has the project been submitted to regulatory Authorities in place?**

**YES  NO  N/A**

**If yes, which one:**

**Project summary (20 lines)**

**Context**

**Objectives**

**Methodology**

**Statistical analysis**

**Expected results**

**Protocol (10 pages maximum) – Please, complete each of following sections**

**1. context (1 page maximum)**

**2. objectives (primary and secondary objectives)**

**3. Methods**

**3.1 Study design**

**3.2 Study population**

**3.2.1 Inclusion criteria**

**3.2.2 exclusion criteria**

**3.2.3 period/duration of follow-up**

**3.3 Primary outcomes**

**3.4 Secondary outcomes**

**3.5 Study conduct**

**3.5.1 Clinical parameters to be collected**

**3.5.2 mri parameters**

**3.5.3 number and characteristics of requested biological samples (if needed)**

**3.5.4 collection of missing data, management of lost to follow up patients**

**3.6 additional data required (not included in the minimum sheet)**

**4. data process**

**4.1 in case of extraction (5 lines minimum)**

**4.2 In case of collection of additional data (20 lines minimum)**

**4.2.1 who collects, what and how (field aspect)?**

**4.2.2 SET UP AND MANAGEMENT THE DATABASE TO BE IMPLEMENTED (data aspect)**

**5. Statistical analysis (10 lines minimum)**

**5.1 statistical method**

**5.2 calculation of the required subjects number**

**5.3 missing data management**

**6. Expected results (10 lines minimum)**

**Please provide other useful documents, for example:**

**✓ CRF (Case report Forms)**

**✓ User’s guides**

**✓ Endorsement letters**

**✓ etc.**

**Will other organizations participate to this project?**

**YES  NO**

**If yes, name of other organizations and investigators:**

**project budget:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **name of partner 1** |  |  |
| **Status of personnel and time allocated** |  |  |  |
| **Equipment** |  |  |  |
| **consumables** |  |  |  |
| **Travels** |  |  |  |
| **Other** |  |  |  |

**Do you need support from the OFSEP National Coordination Center?**

**Data Management**

**Statistical Analysis**

**Project Management**

**Other**

**………………………………**

**Appendix 1**

|  |  |
| --- | --- |
| **For OFSEP usage only (do not fill):** |  |
| **Date de prise en compte du dossier :** | |\_\_\_| |\_\_\_| |\_\_\_\_\_\_\_\_\_| |
| **Approbation par le Comité Scientifique :** | **Oui  Non  NA** |
| **Approbation par le Centre de Coordination :** | **Oui  Non  NA** |
| **Approbation par le Comité de Pilotage :** | **Oui  Non  NA** |
| **Autorisation CNIL :** | **Oui  Non  NA** |
|  | **Date :** |
| **Approbation comité d’éthique (CPP, autre)** | **Oui  Non  NA** |
| **Nom :** | **Date :** |

|  |  |  |
| --- | --- | --- |
| **For OFSEP usage only, do not fill :**  **Statut de l’étude :** | | |
| **A venir** | **Inclusions terminées** | **OU :** |
| **Inclusions en cours** | **Etude clôturée** | **Cohorte Ouverte** |

**Appendix 2** – **List of requested variables and biological sample from OFSEP database and biological collection**

**Clinical data**

|  |  |  |  |
| --- | --- | --- | --- |
| Tables | Description | Data from the minimal form | Put« 1 » if data requested |
| perso | Basic personnel data (center, sex, birth date, date of first exam in the service, Devic disease, stating date of disease, age at start of the disease, date of death) | x |  |
| perso | Department of country birthplace | x |  |
| perso | Department and country of residence | x |  |
| socioeco | Education level and domestic situation | x |  |
| perso | Number of children | x |  |
| sbshpchild | Sex and birth date of children |  |  |
| perso | History of cancer | x |  |
| perso | Family history of MS | x |  |
| sbshpchild | Siblings sex and birth date |  |  |
| episod | Neurological episodes: basic data (date and type) | x |  |
| episod | Neurological episodes semiology | x |  |
| episod | Corticosteroid treatment during neurological episodes | x |  |
| perso | Permanent disability | x |  |
| clinic | Clinical evaluations (date, form, disability score) | x |  |
| csf | Paraclinical evaluations: CSF (ig G index, oligoclonal bands) | x |  |
| csf | Paraclinical evaluations: CSF(date, presence of blood, numeration, cytology, biochemistry) |  |  |
| mri | Paraclinical evaluations: MRI (T1/Gado, T2/PD/FLAIR, number of lesions, comparison with previous MRI, diagnostic criteria) | x |  |
| mri | Paraclinical evaluations: MRI (Hyposignal T1) |  |  |
| diag | Diagnostic : basic data (Poser and McDonald 2010 criteria, disease form, disease start date, date of progression) | x |  |
| diag | Diagnostic : details of dissemination criteria in time and space | x |  |
| tdm | Background therapies : basic data (synthetic dates, treatments, reason for stopping) | x |  |
| posology | Background therapies: additional data (dates, dosage) | x |  |
| protocols | Therapeutic protocols |  |  |
| trtother | Relapses treatment |  |  |
| trtother | Symptomatic treatments |  |  |
| trtother | Other diseases treatments |  |  |
| patientdss | Patient diseases (description, starting date, evolution) |  |  |
| ae | Adverse events (description, starting date, evolution) |  |  |
| aedetails | Adverse events (details of events) |  |  |
| familydss | Family members diseases(description) |  |  |
| exams | Exams (blood count, infection, inflammation, etc.) |  |  |
| cardiacm | Cardiac monitoring |  |  |
| studies | Inclusion in studies |  |  |
| Please list other variables required for the project | | | |

**Biological samples**

|  |  |  |
| --- | --- | --- |
| Description | Write1 if a sample is requested | Quantity |
| Serum |  |  |
| Plasma EDTA |  |  |
| DNA |  |  |
| Peripheral blood mononuclear cells (PBMC) |  |  |
| Urine |  |  |
| Liquid Cerebrospinal Fluid (LCS) |  |  |
| Cells from Liquid Cerebrospinal Fluid |  |  |
| Stools |  |  |

**Imaging**

|  |  |
| --- | --- |
| Description | Write« 1 » if a sequence is requested |
| Sequences selection  according to the MRI machine characteristics | |
| **Machine characteristics** | |
| Manufacturer |  |
| Model |  |
| Magnetic field : | □1,5T □ 3T |
| Antenna |  |
| **Brain RMI** | |
| 3D unenhanced T1 |  |
| Axial DWI with ADC map |  |
| Axial 2D TSE T2/PD or 3DT2 |  |
| 3D FLAIR |  |
| 3D T1 with gadolinium injection |  |
| DT1 ≥15 directions \* |  |
| 2D gradient echo T2\* |  |
| **Spinal MRI** | |
| Sagittal T2 |  |
| Sagittal T1 with gadolinium injection |  |
| Axial T2 gradient echo \* |  |
| Axial T1\* |  |
| Sagittal STIR \* |  |
| *\* Optional sequences :their number depends on centers ability to acquire optional sequences* |  |
| Sequences selection  regardless of the MRI machine characteristics | |
| **Brain MRI** | |
| 3D unenhanced T1 |  |
| Axial DWI with ADC map |  |
| Axial 2D TSE T2/PD or 3DT2 |  |
| 3D FLAIR |  |
| 3D T1 with gadolinium injection |  |
| DT1 ≥15 directions \* |  |
| 2D gradient echo T2\* |  |
| **Spinal MRI** | |
| Sagittal T2 |  |
| Sagittal T1 with gadolinium injection |  |
| Axial T2 gradient echo \* |  |
| Axial T1\* |  |
| Sagittal STIR \* |  |
| *\* Optional sequences: their number depends on centers ability to acquire optional sequences* |  |

**Please return all documents to the OFSEP national coordination Center:**

**projects@ofsep.org ;** Fax : +33 (0)4 72 12 97 14