

## CALL FOR PROPOSALS : GREAT JOINT PROJECT 2020

### 1. FONDATION PARALYSIE CEREBRALE

La Fondation Paralysie Cérébrale, a recognized public interest foundation was founded by APETREIMC-Envoludia, SESEP, CDI and PASSE-R'AILE.

Its missions are:

- To promote and support research and innovation in the field of the prevention, management of cerebral palsy (CP), and the improvement of the situation and quality of life of people with CP and their relatives. The fields in this research are including medical and biomedical sciences, social sciences and humanities, educational sciences, health economics, technology and engineering research.
- To work for the improvement of the quality of care and support, the quality of the education, the dissemination of best practices and development of knowledge.

Since more than ten years, la Fondation Paralysie Cérébrale has been committed to support research in the field of CP, particularly through its annual calls for projects focusing on CP in general but also on pain, motor rehabilitation or development of other disabilities associated to CP.

### 2. CONTEXT OF THE CALL

Neurodevelopmental disorders associated with cerebral palsy affect motor, cognitive functions, language, behavioural and learning outcomes with lifelong consequences. Early identification of children at risk of developing such disorders in the first months or years of life can be achieved through:

- clinical evaluation (developmental tests, neuro-sensory and neuro-motor examinations, observation of spontaneous movements, etc.)
- specific technical tools such as neuro-imaging (e.g. ultrasound, MRI), neurophysiological tests (e.g. EEG and evoked potentials) and biological or genetic biomarkers, validation of which remains to be confirmed.

This early identification is an important prerequisite for screening the patients who are most able to benefit from the implementation of early intervention programmes, the objectives of which are to prevent or minimize the motor consequences, cognitive and emotional impairment related to the damages on the developing brain and thus promote their autonomy and participation.

Progress has been made in screening for perinatal and neonatal brain lesions but validation of certain diagnostic or biomarker methods remains low, variable or missing. Thus, it remains difficult to predict with sufficient precision which infants, in an at-risk population will develop CP and/or its associated disorders and which patients in a population affected by CP will develop complications.

The search for early markers of the onset of CP and/or its associated disorders is crucial for determining a target population on which a neuroprotection strategy, as well as an adequate follow-up, could be targeted.

Similarly, clinical validation of tools to measure the impact of an intervention on the onset of cerebral palsy and/or its associated disorders seems necessary to guide the accompaniment and monitoring of this population.

The optimization of current resources (Organization of care, perinatal networks) could help prevent the failure to follow-up on some children and thus improve the diagnosis and identification of subjects at risk of cerebral palsy or of complications in people with PC.

Finally the quality of the human environment - in particular the family environment - can also have an influence on the evolution of CP as well as on the impact of deficiencies on the development.

In this context, la Fondation Paralysie Cérébrale decided to pursue its support for research on CP by launching a call for a great joint project in 2020.

This call for proposals will evaluate:

- **Projects with a total budget between € 500 K to € 1.5 million maximum over a period of 3 to 5 years**
- **Projects aiming to improve diagnostic capacities and/or early detection of CP, and its associated disorders from the prenatal period up to the end of adolescence.**

Furthermore, la Fondation Paralysie Cérébrale wishes to encourage :

- collaborative projects, including multidisciplinary research teams,
- projects with high scientific impact, likely to improve / significantly change the evaluation and the management of at-risk patients,
- projects with reasonable modalities of applicability in the management of patients,
- projects that will take into account the impact of screening methods on children and their families.

### **3. SCOPE OF THE CALL**

This call concerns projects aimed at improving diagnostic capacities and/or early detection of cerebral palsy and/or its associated disorders (motor functions, superior functions, epilepsy, sensory disorders, secondary orthopedic disorders, etc.). This call will involve large scale projects in the field of clinical or translational research projects, public health, or humanities and social sciences aimed at validating, for example, one of the following themes:

- validation of a diagnostic marker (biological, genetic, imaging, clinical or other) for a substantial improvement in the current care of children at-risk of CP or children with CP,
- validation of a marker of the effectiveness of an intervention,
- innovative means of early functional assessment and its validation,
- innovative modalities for the organization of care or follow-up of at-risk children or children with CP,
- innovative modalities of work and collaboration with relatives and particularly with parents.

The proposed projects will generally be able to answer the question posed over a period of 3 to 5 years. To carry out the projects, investigators could rely on existing cohorts, databases or biological resource centres. For example, they may use the development of services or registers, but these tools should only be a support to their research.

Close collaboration with patients, their relatives and their representatives is encouraged in the implementation and realization of the project. Special attention to the human environment of the person (family situation of parents, siblings, socio-economic situation, etc.) is desired. The consideration and analysis of social, cultural and psychological data in the project is encouraged.

### **4. BENEFICIARIES OF THE CALL -- COMPOSITION OF THE TEAMS**

This call for research proposals addresses any certified research team situated in the European countries such as defined in the program Horizon 2020 of the European Union (member states of the European Union or countries associated in Europe, as defined in Appendix 1). Projects will be based on a consortium whose coordinator will be a leader working in Europe. The presence in the consortium of at

least two French teams involved in the care of patients is mandatory. It is also requested that there be a francophone spokesperson within the consortium.

International cooperation will be welcomed. Only the teams of the countries listed in Appendix 1 can be financed by la Fondation Paralysie Cérébrale. The non European teams will have to justify their own financing to be a member of the project.

### **Project Leader**

The project leader (or coordinator) must be a principal investigator (PI) of a public research or higher education institution located in Europe: university, university hospital, scientific and technical public institution (EPST), public industrial and commercial (EPIC). He/she will devote a substantial part of his/her time (at least 20%) to the realization of the project.

In addition to its scientific and technical role, the project leader will be responsible for establishing working arrangements between the participating teams, the production of the required documents (scientific and financial reports), promotion and communication of results.

The project leader may participate in only one project in this call.

### **Project partners**

Partners teams within the consortium will be French, European or even international (see above) and from different disciplines. Particular attention will be paid to the complementarity of the teams involved in the proposed project and to the multidisciplinary aspect. Moreover the presence of concerned persons as well as relatives or representatives of family associations is encouraged at each stage of the project.

The tasks performed by any person involved in the project must be clearly identified and explained in the application for funding. Each person involved in the project must be responsible for at least one task and devote at least 10% of his/her time.

Partner teams may participate in several separate projects to be submitted for this call.

## **5. FUNDING and FINANCING AGREEMENT**

Projects must be sized for funding between **€ 500 K and € 1.5 million maximum over a period of 3 to 5 years**. The relevance of the project to the characteristics of the call as described in paragraphs 2 and 3 and the scientific excellence of the project and of the consortium will be the main criteria for the selection of the project (s). La Fondation Paralysie Cérébrale reserves the right not to award funding if the quality of the submitted files is deemed insufficient by the scientific committee.

A financing agreement will be signed between la Fondation Paralysie Cérébrale and the organizations or institutions managing the funding.

## **6. FUNDING MODALITIES**

**A detailed budget broken down by expenditure heading must be presented.** The funds may cover:

- Operating costs (consumables),
- Staff costs (Personnel) recruited specifically for the project (technicians, research engineers, PhD students, statisticians, etc.),
- Purchase of equipments necessary to the research (if the amount exceeds **10% of the total amount requested, it must be justified**),
- Mission expenses (travels) and publication (maximum **5% of the total amount requested**).

La Fondation Paralysie Cérébrale usually requests the cancellation of the management fees (overheads) taken by the institutions and organizations from its grant. In case of strict impossibility, the rate of management costs attributable to the project will be capped at 4% of the total amount requested. On this point, an agreement of the institution or organization is required in the application file.

Institutional or industrial co-financing are possible since conflicts of interests are considered, but the part of the financing paid by la Fondation Paralysie Cérébrale will have to remain the majority.

As far as possible, the project leader will manage the funds allocated in connection with its supervision, including the distribution of the funds to the partner teams involved in the project and belonging to different organizations. Should the opposite occur, every participating team benefiting from a part of the allocated funds will have to indicate its managing organization in charge of receiving the funds. Each managing organization will then have to sign an agreement with la Fondation Paralysie Cérébrale.

The granted budget will be paid in several terms according to the duration and the organization of the project.

The first payment will be made after the signature of the financing agreement, subject to receipt by la Fondation Paralysie Cérébrale of the administrative documents authorizing the start of the project (in particular for clinical projects: ethics committee, drug regulatory agencies). The documents needed to start the project have to be obtained and provided within the 12 months following the signature of the agreement. If this period is exceeded, la Fondation Paralysie Cérébrale reserves the right to cancel the financing of the project.

The payments will be made according to the following timetable:

- 10 to 20% to initiate the project after the signature of the financial agreement with the Foundation,
- several terms according to the duration and the amount of the financed project, after receipt by la Fondation Paralysie Cérébrale of a scientific report showing the progress of the project and a report justifying the use of the already paid funds. These terms correspond to 75 to 85 % of the total allocated amount,
- 5% at the end of the project, after receiving a full report and a public summary.

## **7. EVALUATION OF THE PROJECTS**

The selection of the proposals will be conducted by 3 bodies:

- A panel of independent, international experts, who will judge the scientific quality and the methodology of the projects,
- The scientific committee of la Fondation Paralysie Cérébrale (list of members in Appendix 2) whose members will be the rapporteurs of the projects submitted. They will propose a list of one or more projects which may be financed on the basis of the expertise carried out by the external evaluators,
- The executive Board of la Fondation Paralysie Cérébrale who will choose one or several project(s) to be financed based on the proposal of the scientific committee.

The external evaluators as well as the members of the scientific committee must declare their direct or indirect links with each project, with the project leader or any other member of the project team.

The main steps in the selection process are as follows:

- Verification of admissibility and eligibility criteria: la Fondation Paralysie Cérébrale and the scientific committee verify that the projects meet the eligibility criteria indicated in the text of the call.
- External evaluation: external evaluators are requested to provide an evaluation report of the submitted projects (at least 4 evaluators including one methodologist).
- Evaluation by the scientific committee
  - the members of the scientific committee evaluate the projects (two rapporteurs per project), on the basis of external evaluations,
  - the scientific committee selects one or more projects and proceeds to the hearing of the project team. This hearing will be carried out in French or English by the project leader and the team of the pre-selected project (s); It will include:
    - an oral presentation of the project,

- an exchange of questions/answers based on the expertise of the files (which will previously have been communicated to each project leader),
- the scientific committee proposes to the Board of la Fondation Paralysie Cérébrale a list of one or several project(s) susceptible to be financed.
- Results : the Board of la Fondation Paralysie Cérébrale chooses one or several project(s) and validate the funding.

## **8. CRITERIA FOR ADMISSIBILITY OF PROJECTS**

In order to be admissible, the files must be submitted on time, in the requested format and in their entirety.

- On time :
  - electronic submission: after the date and the time limit of deposit on the submission site, no file will be accepted (cf. 12. Calendar).
  - submission by post: with authentic postmark, within the time indicated (cf. 12. Calendar).
- In the requested format :

The application shall be written in English and must follow the plan given in the application form. A public summary must also be written both in French and in English.

- Electronic submission : the application form includes two documents:
  - first, a scientific document in Word format and
  - second, a financial document in Excel format.

Any ancillary documents must be included in the Word document in the "Annex" section.
- Submission by post: the paper document includes the originals and signatures required.
- In their entirety :
 

The application form (scientific part in Word and financial part in Excel) must be submitted completely filled out. Incomplete applications will not be handled.

## **9. PROJECT ELIGIBILITY CRITERIA**

To be eligible, the project must meet the following conditions:

- the project must meet the objectives of this call and the identified topics
- the project must have a duration of 3-5 years
- the grant requested from la Fondation Paralysie Cérébrale may not be less than 500 000 € or more than 1 500 000 €
- a tentative timetable for the key milestones should be presented
- the Consortium and the team must meet the criteria described in paragraph 4
- the project leader cannot be a member of the Evaluation Committee of this call (independent expert, scientific committee)
- the project leader undertakes to devote at least 20% of his time to the project.

Files not satisfying the eligibility criteria will not be subject to evaluation. Projects considered outside of the scope of the call for projects will not be assessed.

## **10. CRITERIA FOR EVALUATION AND SELECTION OF THE PROJECTS**

Particular attention will be paid to the relevance of the research project and the question asked in regard of the current state of the art, the quality of the used methodology, and the potential impact on the management and quality of life of CP patients and their relatives.

The evaluation of the project by the Scientific Committee of la Fondation Paralysie Cérébrale will cover:

- adequacy to the call,
- relevance and innovation in regards to Cerebral Palsy,

- potential benefits for the concerned people and their families and benefits in terms of public health,
- ethical aspects,
- project leader qualities (training, publications, national and international fame, ability to federate and coordinate the consortium, communication ...). Particular attention will be paid to the recognition of the PI in the field of cerebral palsy.
- quality of the involved teams and laboratory (ies) (scientific, publications, fame),
- adequacy of financial resources to the scale of the proposed project in order to ensure its feasibility. Any project of an amount upper to that asked to la Fondation Paralysie Cérébrale will have to justify current, on-going or future co-financing(s). Co-financing(s) must be entirely declared in the application form. The part of the project corresponding to the financing of la Fondation Paralysie Cérébrale must be clearly documented.

*PARTICULAR POINT:* Projects should specify the used strategies "From the protocol to the publication" to apply the principles of "free access" and of "open data" and consider communication to the public.

## 11. PROPOSAL SUBMISSION – TIMELINES

**Between September 1<sup>st</sup> and November 1<sup>st</sup>, 2019**, the project leader will have the opportunity to address to the Scientific Committee of la Fondation Paralysie Cérébrale any question relating to the call (exclusively via e-mail at the following address: [directionscientifique@fondationparalysiecerebrale.org](mailto:directionscientifique@fondationparalysiecerebrale.org)).

**Before sending the application file**, it will be asked to send by e-mail **before December 15<sup>th</sup>, 2019** a **project synopsis** indicating the project title, the teams involved as well as the project leader, the discipline and the main theme of the project, 5 keywords as well as the names of potential reviewers. **Although not entering the selection process, this project synopsis is mandatory and only the projects whose synopsis has been received will be evaluated.**

**The application file, dated and signed, must be sent before February 15<sup>th</sup>, 2020.** Its content will have to follow the plan and the specifications of the form. The project (Excluding administrative data, bibliographic references, budget presentations and CV's which will be provided in appendices) should not exceed 20 pages (single-spaced, Arial 11 minimum). Only complete applications will be evaluated.

The project synopsis and the application forms can be downloaded on the website of the foundation: <http://www.fondationparalysiecerebrale.org/appel-projets>.

In case of download difficulties, the Foundation may be contacted by e-mail at the following address [directionscientifique@fondationparalysiecerebrale.org](mailto:directionscientifique@fondationparalysiecerebrale.org)

The whole project (scientific document of 20 pages and appendices) must be sent in 2 copies:

- One copy, PDF format signed and dated by e-mail to [directionscientifique@fondationparalysiecerebrale.org](mailto:directionscientifique@fondationparalysiecerebrale.org) (Before February 15<sup>th</sup>, 2020. 1 pm, Paris Time)
- One hard copy with original signatures by mail out to: FONDATION PARALYSIE CEREBRALE Appel d'offre Grand Projet 2020, 67 rue Vergniaud, 75013 Paris, France (Before February 25<sup>th</sup>, 2020; sending date will be attested by postmark date).

### Summary of the timelines

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|---|---|
| <b>Launch of the call</b>   | <b>May 23<sup>rd</sup>, 2019</b>  |
| <b>Candidates' questions to the Foundation and the Scientific Committee</b>   | <b>September 1<sup>st</sup>, 2019 – November 1<sup>st</sup>, 2019</b>   |
| <b>Project synopsis : Deadline for submission</b>   | <b>December 15<sup>th</sup>, 2019 (1 pm, Paris time)</b>  |
| <b>Application files : Deadline for submission</b>  | <b>Electronic version: February 15<sup>th</sup>, 2020 (1 pm, Paris time)<br/>Hard copy : February 25<sup>th</sup>, 2020</b> |
| <b>Expected date for information on the pre-selected projects for the oral hearing</b>  | <b>June 30<sup>th</sup>, 2020</b>   |
| <b>Expected date for the hearing of the pre-selected projects</b>   | <b>September 2020</b>   |
| <b>Expected date for information on the Project (s) selected for funding after the decision of the Scientific Committee and the Board of Administrators</b> | <b>October 2020</b>   |
| <b>Establishment of Financing Agreements</b>  | <b>November-December 2020</b>   |

The notification of acceptance or refusal of funding will be sent by e-mail to the Project leader (address of follow-up indicated in the file). If la Fondation Paralysie Cérébrale/Fondation Motrice decided to support a project, the mail of notification will specify the amount of the grant. This notification letter will mark the beginning of a negotiation period (definition of milestones and evaluation points, justification of expenditure) which will end with the signature of the financial agreement (s).

## **12. SCIENTIFIC AND FINANCIAL FOLLOW-UP- VALUATION OF THE RESEARCH**

Accurate, scientific and financial interim reports have to be produced by the project leader according to the timetable agreed in the agreement of funding. The satisfactory progress of the project (compared to the steps outlined in the grant application form) and the respect of the planned budget will condition the payment of the following funding. The final payment will be made after the main results have been disseminated in the form of reports and publications.

- A final research report and a public summary in English and French of the results must be produced by the project leader respectively 6 months and 3 months after the end of the project.
- According to the duration of the project, works related to the project (s) funded (s) will have to be the object of at least 3 to 5 international scientific publications of high quality. Publications relative to the intermediate stages of the project and to its terminal realization are encouraged.

The financed teams are deeply encouraged to propose scientific communications in national and international congresses. Project leader(s) could be invited to present their final results during a dedicated scientific day and will be asked once a year to present the project in connection with the foundation for information of the general public and donors of the foundation.

The team(s) of researchers will commit to mention the support of la Fondation Paralysie Cérébrale in all the publications and communications in connection with the funded project.

### **CONTACT :**

[directionscientifique@fondationparalysiecerebrale.org](mailto:directionscientifique@fondationparalysiecerebrale.org) or [ngenes@fondationparalysiecerebrale.org](mailto:ngenes@fondationparalysiecerebrale.org)

## **Appendix 1: Countries eligible for funding by la Fondation Paralysie Cérébrale**

**Countries members of the European Union** : Austria, Belgium, Bulgaria, Cyprus, Croatia, Denmark, Spain, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Latvia, Luxembourg, Malta, the Netherlands, Poland, Portugal, the Czech Republic, Romania, Slovakia, Slovenia, Sweden and United Kingdom

**Countries non members of the European Union:** Albania, Bosnia and Herzegovina, Faroe Islands, Former Yugoslav Republic of Macedonia, Georgia, Iceland, Israel, Moldavia, Montenegro, Norway, Serbia, Switzerland, Tunisia, Turkey and Ukraine



## **Appendix 2: List of the members of the Scientific Committee as 2019, January 1<sup>st</sup>**

Pr Olivier Baud (Genève, Suisse), Chairman  
Mme Gaëlle Drewnowski (Lyon, France), Expert patient  
Mr Jean Claude Graindorge (Saint Brieuc, France), Family representative  
Dr Stéphane Armand (Genève, Suisse)  
Pr Bernard Dan (Bruxelles, Belgique)  
Dr Javier De la Cruz (Madrid, Espagne)  
Dr Jessica Dubois (Saclay, France)  
Mme Audrey Fontaine (Paris, France)  
Pr Patricia Limousin (Londres, UK)  
Pr Régine Scelles (Nanterre, France)  
Pr Anita Truttmann (Lausanne, Suisse)  
Dr Carole Vuillerot (Lyon, France)