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2016 Call for Projects on ALS Research

2016 AriSLA Call for Research Projects: PROMOTING RESEARCH EXCELLENCE IN THE FIGHT AGAINST ALS

Deadline: at 1.00 pm, March 17th 2016

1. Aims of the *"2016 AriSLA Call for Research Projects"*

AriSLA, Italian Foundation for Research on ALS – Amyotrophic Lateral Sclerosis, opens the "2016 AriSLA Call for Research Projects". The Call aims to significantly advance knowledge of ALS to efficiently translate research outcomes from bench to bedside in order to improve ALS patients' care, quality of life and survival. Further, the Call intends to promote networking among nationwide ALS researchers as stated in the mission of the Foundation. In addition, the implementation of nation-based clinical research has been deemed as priority by AriSLA Board of Directors.

2. Call for Projects themes

"2016 AriSLA Call for Research Projects" funds two distinct types of research projects: **Full Grants and Pilot Grants**.

FULL GRANTS, i.e. research projects with a solid background and consistent preliminary data, proposing multi-disciplinary and innovative approaches, can be submitted in the following areas:

A. **Basic and Translational research**.
Applications to Basic and Translational Full Grant must comply with the followings topics:
- Markers of disease onset and progression;
- Novel disease models;
- Pathological pathways and mechanisms translationally oriented;
- Genetics;
- Innovative imaging approaches.

B. **Interventional Clinical Trial**.
Applications to Interventional Clinical Trial Full Grant must investigate novel, high-potential treatments in Amyotrophic Lateral Sclerosis.

PILOT GRANTS, i.e. research projects with high innovative and original hypotheses, with preliminary data to be consolidated or not available. Applications are intended to collect or strengthen preliminary data for subsequent larger scale funding. Pilot Grants can be submitted in the following areas:

- **Basic and Translational research**.
Applications to Pilot Grants must comply with the followings topics:
  - Drug discovery and design;

- Markers of disease onset and progression;
- Novel disease models characterization;
- Novel pathological pathways and mechanisms;
- Innovative imaging approaches.

Common features required for Full and Pilot research projects are **innovation** and **priority over the state-of-the-art science**. To be financed, Applications must be deemed of significant scientific interest and with a strong potential to impact on disease understanding, diagnosis and treatment.

2.1 Full Grant Application: Basic and Translational Research

Applications must have a maximum duration of **36 months**. It is allowed a maximum request of **€ 300,000** as contribution from AriSLA.

It is encouraged to apply for Basic and Translational research Grants in scientific collaboration with other Italian or foreign partners.

Project partners based in host Institutions out of Italy will however not be beneficiary of grant contribution by AriSLA. They are allowed to participate in the project partnership by co-funding their research activities.

The Principal Investigator (PI), as recipient of AriSLA funding, is the scientific coordinator of the project both in case of a single-centre project and in a multi-centre project. Partners should coherently contribute to the achievement of the project objectives (see paragraph 3).

2.1.1 Full Grant Application: Interventional Clinical Trial

Clinical trials must include therapeutic interventions that have:

- a biomarker that can measure whether pathway of interest has been affected, and
- a plan to collect samples for biomarker studies.
  The samples collection procedure must be performed according with the **SOPHIA Standard Operating Procedure** for acquisition, collection, processing, storage (and shipment) of biological samples (http://www.sophiaproject.eu/library/publications.html).

It is mandatory to apply for Interventional Clinical Trials in scientific collaboration with other Italian or foreign partners.

Project partners based in host Institutions out of Italy will however not be beneficiary of grant contribution by AriSLA. They are allowed to participate in the project partnership by co-funding their research activities.

Partnerships with Industry for co-funding are encouraged. For-profit partners will however not be beneficiary of grant contribution by AriSLA.

The Principal Investigator, as scientific coordinator of the project and recipient of AriSLA funding, must be affiliated to a non-profit Institution (Sponsor). Other non-profit and profit Partners should coherently contribute to the achievement of the project objectives (see paragraph 3).

Applications must have a maximum duration of **36 months**. It is recommended not to exceed the request of **€ 400,000** as contribution from AriSLA. Consortia including more than 8 Partners are allowed to request a maximum contribution of **€ 700,000.** Higher budget requests, if justified, will be evaluated.

The budget requested in the Letter of Intent is considered indicative and can be modified and re-evaluated in the Full Proposal following the indication received by reviewers and, if applicable, by the methodological support.

Methodological support for Interventional Clinical Trial Applications

It is mandatory for Interventional Clinical Trial Applications to submit a request for methodological support once the Applicant has been invited to present a Full Proposal.

This support offers to PIs assistance on methodological aspects related to clinical protocols: as an example, appropriateness of the study design, compliance with the Italian regulation on clinical trials, sample size calculation and study feasibility. The requests will be evaluated by experts in biomedical statistics and epidemiology. **The methodological support form can be downloaded at the AriSLA website and must be filled out in Italian.** For the submission of the Methodological support request, please see paragraph 4.

2.2 Pilot Grant Application

Pilot Grant Applications are allowed to request a contribution up to **€ 60,000** over maximum **12 months.**

This fund may cover the whole or part of the remuneration of the Principal Investigator, if, at the moment of the contract signature with AriSLA, he does not hold any employment contract and has not reached 40 years of age.

This type of research projects has to be managed by a single proponent.

3. Eligible subjects

Subjects eligible to participate as Principal Investigator in the "2016 AriSLA Call for Research Projects" are researchers of **Italian non-profit Universities and Research Institutes, either public or private**, performing clinical and research activities consistent with the statutory purposes of the Foundation. The Principal Investigator and all partners must be scientists with demonstrated scientific competence and independence, able to self-manage the proposed project.

It is expected that the Principal Investigator of a Full Grant, as Coordinator of a potential Consortium, will be the leader of the project design and implementation.

Researchers are allowed to apply for a maximum of 2 Grants, and in any case, can be the Principal Investigator of only 1 Application in this Call.

Principal Investigators of an ongoing AriSLA grants, not yet ended at the date of November 30th, 2016, are not eligible to submit new Project Application[1] as PI, but can apply as a Partner in a consortium.

Partners in a consortium of ongoing projects financed by AriSLA in previous Calls can apply for a new Grant either as a Principal Investigator or as a Partner.

Researchers who have submitted a new research Application to the "2015 AriSLA Ice Bucket Calls", which has not been funded, may participate in this Call by submitting a revised Application, modified in accordance with the

[1] *Principal Investigators of ongoing projects are allowed to participate only if the contract with AriSLA is going to be concluded within November 30th, 2016. The signature of the new contract is contingent upon the end of the scientific, economical and administrative procedure concerning the previous Grant.*

comments received during the evaluation process. In this case, special attention should be given to the issues raised by the reviewers.

Projects that have already been fully funded by other Agencies are not eligible to be financed.

Full Grants

Principal Investigators of a Full Grant Application must hold a **track record of proven international profile** in the area of the submitted research and **a permanent position for the whole duration of the project** in their affiliation Institute. Alternatively, if the investigator does not hold a permanent position, the Host Institution is required to declare that it will provide a salary for the duration of the entire project.

When submitting the Application, a formal partnership agreement among participating institutions is not required. This document will be compiled once the Project has been granted.

AriSLA funds researchers affiliated to nation-based Institutions only. The participation of foreign research groups in project partnerships led by an organization located in Italy is allowed, if it is proved that competences/skills/equipment are not available on the national territory. Project partners based in host Institutions out of Italy will however not be beneficiary of grant contribution by AriSLA. They are allowed to participate in the project partnership by co-funding their research activities.

Please note that for-profit Partners are allowed to participate in the research partnerships although will not be beneficiary of grant contribution by AriSLA.

Pilot Grants

Principal Investigators of a Pilot Grant Application **must hold proven scientific competences, with at least 3-years experience in a research laboratory**. AriSLA Foundation encourages applications from junior investigators and investigators who are new to the ALS field.

3.1 Sub-contractors

Full Grant and Pilot Grant Applications may be assisted by sub-contractors.

The sub-contractor is intended to be who provides external services or supplies which are necessary for the execution of the project. **Total budget request for subcontracting must not exceed 20% of the funding requested to AriSLA.**

4. Submitting the Application

Applications have two-steps submitting process:

1. LETTER OF INTENT (LOI)

Letter of Intent must be submitted by the Principal Investigator by filling up **Full Grant** or **Pilot Grant forms** available on the AriSLA website http://proposals.arisla.org, starting from **February 17th 2016**. Applications must be

compiled following the specific guidelines for the two types of grant (see "**Guidelines for the submission of the *Letter of Intent***" for Full and Pilot Grants).

The LOI has to be only electronically submitted in English by **March 17th, 2016 at 1.00 pm**.

The hard copy of the online application does not need to be sent.

2. FULL PROPOSALS

Full Proposals have to be submitted by the PI exclusively **after the receipt of an AriSLA "invitation letter to submit a Full Proposal"** (see paragraph 5), which will include the guidelines for the Full Proposal submission.

It is mandatory for Interventional Clinical Trial Applications to submit a request for methodological support, once the Applicant had been invited to present a Full Proposals (see paragraph 2.1.1).

The methodological support form can be downloaded at the AriSLA website and **must be filled out in Italian**.

In order to be allowed to submit the Full Proposal for Interventional Clinical Trial, the methodological support form must be sent to bandi@arisla.org within two weeks after receiving the AriSLA "invitation to submit a Full Proposal". Requests for methodological support submitted after the deadline will not be considered eligible for Full Proposal application. Written feedback by the consultants will be sent to the Investigator by July 5th, 2016.

5. Applications evaluation and selection criteria

Each Application will be evaluated by an International Scientific Committee appointed by AriSLA, in order to guarantee meritocracy, transparency and impartiality of the selection process.

5.1 Methodology

Applications will be screened by means of a three-step process:

In the **first step**, the International Scientific Committee will perform a remote evaluation of the submitted *Letters of Intent*. Each LOI will be independently evaluated by three reviewers of proven expertise in the field of the topic of the research Application. Reviewers will provide a written report. During this step AriSLA may directly contact the Applicant in order to gather further elements for the evaluation. The best LOIs will be admitted to the second phase based on a ranking list. The results of the first-step will be communicated to the PI and the report will include the reviewers' comments.

In the **second step**, Full Proposals presented following AriSLA invitation will be assigned to three independent reviewers of the AriSLA International Scientific Committee, who agreed to take part to the Consensus Meeting (see third step).

In the **third step**, the panel of reviewers involved in the second step will provide an overall assessment and a comparative evaluation of the Full Proposals during a Consensus Meeting. The outcome of the evaluation process will be a final merit-based list.

The conclusion of the evaluation process is expected to end within December 2016. AriSLA will take care to inform all PIs about the Scientific Committee comments.

AriSLA claims the right to not allocate any fund if the proposed Applications will be considered not worthy of contribution according to the evaluation process, even in presence of availability of funds.

5.2 Evaluation criteria

Applications that are incomplete or not conform to the rules indicated in the "2016 AriSLA Call for Research Projects" and the specific guidelines will not be processed for evaluation.

Basic and Translational Research Full Grants

The evaluation and the assessment of the overall quality of the Applications, formulated by the AriSLA International Scientific Committee, will be carried out according to the following criteria:

1. Strength of the **background** and **rationale**: availability of solid preliminary data to support the research program; consistency of the research project with the AriSLA Call aims;
2. **Objectives** and **methodologies**: adequateness of methods and analyses development, integration and appropriateness with respect to the aims of the study; description of potential critical issues and consideration of alternative approaches;
3. **Innovation** and **priority** of the proposed project with regards to the current science;
4. **Impact on ALS**: promising exploitation of the expected results for diagnosis or treatment of the disease or significant improvement of the knowledge of the disease; results eligible for intellectual property protection;
5. **Investigators** and **collaborative potential**: competence and experience of PI/partners in the field of the proposal and complementarity within the Consortium, if present;
6. Suitability of requested **budget** in relation to the activity time schedule.

Interventional Clinical Trial Full Grants

The evaluation and the assessment of the overall quality of the Applications, formulated by the AriSLA International Scientific Committee, will be carried out according to the following criteria:

1. Strength of the **background** and **rationale**: availability of sufficient preclinical data to support the conduction of the proposed trial; consistency of the research project with the AriSLA Call aims and requirements;
2. **Objectives** and **methodologies**: adequateness of the conceptual framework, clinical design, methods and statistical analyses; appropriateness with respect to the aims of the study; description of potential critical issues and consideration of alternative approaches;
3. **Innovation** and **priority** of the proposed project with regards to the current science;
4. **Impact on ALS**: potentiality to adequately address the clinical needs of ALS patients; likelihood of the clinical trial to be initiated in a reasonable time-frame; results eligible for intellectual property protection;
5. **Investigators and collaborative potential:** competence and experience of PI/partners in the field of the proposal and complementarity within the Consortium;
6. Suitability of requested **budget** and reasonability of activity time schedule**.**

Pilot Grants

The evaluation and assessment of the overall quality of the Applications, formulated by the AriSLA International Scientific Committee, will be performed according to the following criteria:

1. Consistency of the research project, specifically **objectives** and **rationale**, with the AriSLA Call aims;
2. **Methodologies**: adequateness of methods and analyses development, integration and appropriateness with respect to the aims of the study;
3. **Originality** and **advancement** of the proposed project with regards to the current science;
4. **Impact on ALS**: promising exploitation of the expected results for diagnosis or treatment of the disease or improvement of the knowledge of the disease; results eligible for intellectual property protection;
5. **Capacity to deliver**: ability of the PI to finalize the proposed research program according to the project duration and budget;
6. **Potentiality** of the expected results **to be attractive for larger scale funding**.

5.3 Ineligible Applications

Applications with the following characteristics will be considered ineligible:

- Applications merely covering management cost of research centers;
- Applications aimed to finance the construction/creation of facilities, laboratories, research centers or coordination centers;
- Applications submitted by a Principal Investigator holder of an AriSLA ongoing funding at the date of 30th November 2016 (see paragraph 3 and note);
- Projects that are already fully funded by other Agencies;
- Applications not fully or correctly completed;
- Applications not written in English;
- Applications not electronically submitted by the AriSLA online submission platform;
- Applications lacking the authorization to process personal data (see Privacy Statement section).

6. Dissemination of results of funded projects

AriSLA ensures that new knowledge generated by its research funding will be widely disseminated and readily made available for the benefit of ALS patients. In particular, the Foundation reminds the Principal Investigator:

- **the obligation to inform in advance about any publication** and to acknowledge AriSLA Foundation of all publications arisen from the project;
- to adhere to the Open access Policy.

For further details please refer to AriSLA "Dissemination Policy".

7. Intellectual property

AriSLA mission is to translate research results into therapies and to make them available to patients. To achieve this goal, the Foundation requests the Principal Investigator to undertake any necessary steps to ensure adequate valorization and exploitation of the research outcomes.

AriSLA offers support and assistance to the PI and his host Institution with regards to intellectual property.

For further information please refer to AriSLA "Intellectual Property Rights Policy".

8. AriSLA project adoption

AriSLA claims the right to promote the "adoption" by third party institutions of the funded projects; therefore it is recommended to consult the document "Projects Adoption Policy" of AriSLA.

9. "Direct management" of the granted contribution

The administrative management of the granted contribution of the winner projects will be performed directly by AriSLA, according to the "direct management" protocol. In accordance with the approved Integrated Economic Plan, the obtained funds will not be remitted to the PI's Institution. The Principal Investigator will take advantage of AriSLA Administrative Office for their management. This is a free service offered by AriSLA Foundation.

10. AriSLA Animal Facility

AriSLA, since 2011, offers an Animal Facility service to research groups needing to perform preclinical and translational studies on ALS transgenic murine models.

The access to the Animal Facility is guaranteed to the winners of AriSLA Calls once cleared by the AriSLA Ethical-Scientific Commission, in charge to verify project's ethics and workplan. AriSLA will help the PI in the fulfilment of all procedures required by the Italian Ministry of Health animal experiments authorization process (see Italian Law decree n.116/92).

The catalogue of available services can be downloaded here: Animal Facility Technical sheet.

11. Privacy

According to the Italian Law n.196/2003 regulating the protection of persons and other subjects with regard to the treatment of personal data, AriSLA, with head office located in Viale Ortles 22/4 – 20139 Milan, *"holder"* of the information and responsible for the data processing, is legally bound to obtain the consent of the *"Applicant"* regarding the use of the personal data included in the Project Application (*Letter of Intent* and *Full Proposal)*. It is recommended in this regard to consult the document "AriSLA Privacy Policy" for further clarification.