

“2015 AriSLA Ice Bucket Call for Clinical Projects”

Deadline: at 1.00 pm, May 12th, 2015

1. Background

AriSLA, Italian Foundation for research on ALS – Amyotrophic Lateral Sclerosis, opens its 2015 Call for Clinical Research Proposals. The Call is aimed to bring advancements to improve ALS patients’ care and quality of life and to develop novel preventive, diagnostic, therapeutic and rehabilitative therapies for ALS.

2. Call for Project objectives and themes

The 2015 AriSLA “Ice Bucket Call for Clinical Projects” has been conceived to specifically fund Clinical Research within the following areas:

1. **Experimental clinical research (ie new therapies, palliative care);**
2. **Observational clinical research (ie biomarkers, diagnostic and prognostic studies);**
3. **Epidemiologic studies;**
4. **National registries set-up.**

The Grant Proposals must have a maximum duration of 36 months. It is expected a budget request range between euro 300,000 and 500,000 as contribution from AriSLA. Nonetheless, if properly justified, different budget requests will be evaluated. AriSLA strongly encourages investigators to apply for projects in collaboration with other partners.

3. Eligible subjects

Subjects eligible to apply to the 2015 AriSLA “Ice Bucket Call for Clinical Projects” are researchers of Italian non-profit Universities and public or private Research Institutes, fitting within the statutory purposes of the Foundation.

The Principal Investigator (PI) is the recipient of AriSLA funding, being the scientific coordinator of the project. It is expected the Principal Investigator, as Coordinator of a Consortium, to be the leader of the project coordination and implementation. Partners should contribute to the achievement of the project objectives and should be themselves eligible as stated in the AriSLA Call. The Principal Investigator and partners must be scientists with demonstrated scientific competence and independence, able to self-manage the proposed project.

Principal Investigators of a Proposal must, in addition to their scientific expertise, hold a track record of proven international profile in the area of application and a permanent position in their affiliation Institute for the whole duration of the project. Alternatively, if the investigator does not hold a permanent position, the Host Institution is required to state that the investigator’s salary will be covered for the duration of the entire project. For the

submission of a Project Proposal it is not required a formal partnership agreement between the participating Institution which will be necessary drawn up and signed in case of the Grant assignment.

It's allowed to apply for a maximum of 2 Proposals and, in any case, to apply as Principal Investigator of 1 project proposal only.

Investigators of an ongoing project financed by AriSLA can apply for a new Grant either as a Principal Investigator or as a Partner.

Proposals with co-funding are encouraged, specifying the overlap with the project proposed to AriSLA.

Partners based out of Italy are not eligible subjects.

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

3.1 Sub-contractors

Clinical Proposals may be assisted by sub-contractors.

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

4. Guidelines for Project presentation

4.1 How to submit Project Proposals

Project Proposals must be submitted by Principal Investigators by filling up the proposal format. Applications must be submitted according to the specific guidelines of the Call (see the form "Guidelines for the submission of Project Proposals").

The proposals must be only submitted electronically and drawn up in English on the e-forms downloadable from AriSLA website (<http://www.arisla.org/>) after registration. The completed Proposal has to be sent to the following e-mail address: bandi@arisla.org. A receipt with the notification of the transmission will follow.

4.2 Methodological support for Clinical Trial

AriSLA is pleased to offer to Investigators assistance on methodological aspects related to clinical protocols. The Investigators may take advantage of this service if he/she deems it necessary.

Those Investigators wishing to explore, as an example, the appropriateness of the study design, its compliance with the Italian regulation on clinical trials, sample size calculation, may send a "Pre-Submission inquiry". The requests will be evaluated by AriSLA experts. In order to receive the above mentioned assistance, the Pre-Submission inquiry form (available on AriSLA website) must be filled out in Italian specifying the type of consultancy requested and submitted by email to the AriSLA Scientific Office (maddalena.ravasi@arisla.org) no later than **March, 10th**. Requests submitted after this date will not be considered (although this has no bearing with the submission of the final version of the proposal).

A written feedback will be sent to the Investigators within 30 days from receipt. Please note that the received support does not guarantee the success of the application.

4.3 Grant Proposals deadline

The deadline for the submission of the Proposals is **Thursday May 12th, 2015 at 1:00 pm.**

5. Project evaluation and selection criteria

Each proposal will be evaluated by an International Scientific Committee appointed by AriSLA, guaranteeing transparency and impartiality of the evaluation process.

5.1 Methodology

The Proposals will be evaluated by means of a two-steps process.

In the first step, the International Scientific Committee will perform a remote evaluation of the submitted Grant Proposals. Each Proposals will be independently evaluated by at least three reviewers of proven expertise in the field of the topic of the research project. Reviewers will provide a written report. During this step AriSLA may directly contact the proponents in order to gather further elements for the evaluation. This step will end up with a merit-based ranking list.

In the second step, a subpanel of reviewers involved in the first step will provide an overall assessment and comparative evaluation of the projects during a **Consensus Meeting**. The outcome of the evaluation process will be a final comparative list.

The conclusion of the evaluation phase is expected within **December 15th 2015**. At the end of the revision process, AriSLA will take care to inform all Principal Investigators about the Scientific Committee recommendation for funding together with the reviewers' comments.

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

5.2 Evaluation criteria

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

- consistency of the research project, specifically objectives and background, with the 2015 AriSLA "Ice Bucket Call for Clinical Projects" aims;
- innovation, relevance and priority of the proposed project with regards to the current science;
- availability of solid preliminary data;
- advancement beyond the state-of-the-art;
- impact on ALS;
- results eligible for intellectual property protection;

- ability of the PI (and Partners) to finalize the proposed research program;
- CV of Principal Investigator/Partners;
- composition of the network.

5.3 Ineligible projects

Project Proposals with the following characteristics will be considered ineligible:

- projects merely covering management cost of research centers;
- applications aimed to finance the construction/creation of facilities, laboratories, research centers or coordination centers;
- projects that are already fully funded by other agencies;
- projects not fully or correctly completed;
- projects not written in English;
- projects not electronically submitted;
- projects lacking of the required attachments: pdf images of the General Information and Privacy Statement sections, signed by the Principal Investigator and bearing signature and stamp of the Legal Representative of the Research Institute.

6. Dissemination of results of funded projects

AriSLA will take charge that any new knowledge generated by funded projects will be widely disseminated and readily made available to ALS scientific and patients community. In particular, the Foundation reminds the applicants:

- the obligation to acknowledge AriSLA Foundation in advance about any publications or scientific report arising from the funded project (please refer to AriSLA "**Dissemination Policy**");
- to adhere to the Open access Policy (please refer to AriSLA "**Dissemination Policy**").

7. Intellectual property and Technology Transfer Office

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

AriSLA offers support and assistance to applicants and their Institutions with regards to the intellectual property with the AriSLA TT Office (link).

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 the funded projects. It is recommended in this regard to consult the "**Projects Adoption Policy**" of AriSLA.

9. “Direct management” of the granted contribution

The administrative management of the granted contribution of the funded projects, will be performed directly by AriSLA offices, according to the "direct management" protocol. In accordance with the approved Integrated Economic Plan, the allocated funds will then not be remitted to the PI's Institution, but entirely managed by AriSLA's Administrative Offices. This service is free of charge.

10. Privacy

According to the Italian Law 196/2003 regulating the protection of persons and other subjects with regard to the treatment of personal data, AriSLA, as holder of information and responsible for data processing, is legally bound to obtain the consent of the “Applicant” regarding the use of the personal data included in the Project Proposal. It is recommended in this regard to consult the document "**AriSLA Privacy Policy**" for further clarification.