**“2015 AriSLA Ice Bucket Call for Assistive Technology Projects”**

**Deadline: at 1.00 pm, September 15th, 2015**

1. **Introduction**

AriSLA - Italian Foundation for Research on Amyotrophic Lateral Sclerosis (ALS) - (“AriSLA” or the “Foundation”) has been investing in Italy since 2009 in the best research to find a cure for ALS. ALS is a fatal motor neuron disease characterized by degenerative loss of upper and lower motor neurons. Patients present signs and symptoms of progressive muscle atrophy and weakness, increased fatigue and problems with swallowing, which typically lead to respiratory failure and death. Progressive functional deficits lead to an overall loss of patient independence. Sensory, sexual, and sphincter functions, and, in most cases, cognitive functions remain intact. ALS affects in Italy about 3 out of 100,000 people every year. Although recent pivotal improvements in the knowledge of disease pathogenesis, no crucial successes have been achieved up to now in ALS diagnosis and treatment.

In the absence of a cure, palliative measures remain an integral part of individual and family therapy: technology solutions (products or services) helping patients and their families to adapt to worsened life conditions are essential, in order to maintain patients’ and caregivers’ Quality of Life (QoL) as high as possible.

The Ice Bucket Challenge 2014 campaign, promoted in Italy by AISLA, the Italian Patient Association for Amyotrophic Lateral Sclerosis, has made available to AriSLA additional funds to bring novel assistive technology to patients. The “2015 AriSLA Ice Bucket Call for Assistive Technology Projects” is specifically intended to endorse the translation of technological research into clinically important products (the “Call”).

The Call aims to create new collaborations and synergies between technology solutions and clinical need to advance the development of new tools and services with high impact on ALS patients Quality of Life.

Specifically, the Call has been conceived to cover the “last mile” of the entire life-cycle of a technology, product or service, through its implementation, customization and validation for ALS patient usability. The flexible funding model presented in the Call, creating new partnership with crossing stakeholder (public and private sector, profit, non-profit, patient associations, grouping of enterprises, etc.), will not only accelerate access of crucial technologies to patients but also increase the probability of commercialization.

2. **Scope**

To explore the unmet needs of available assistive technology in a large population of ALS patients and related caregivers, AriSLA has previously investigated the level of satisfaction on existing devices and their usefulness in improving their Quality of Life. The survey involved an equal number of ALS patients and caregivers. Results showed
that more than 50% of Italian patients and caregivers are dissatisfied about available devices for communication and motor disability.

Accordingly, the overall scope of “2015 AriSLA Ice Bucket Call for Assistive Technology Projects” is to finance project proposals capable to facilitate the translation (through implementation, customization and validation) of an existing technology, product or service to ALS patient needs (the “Proposal”). The AriSLA funding will then be addressed to a product or service with an immediate usability on ALS community. An entry level of maturity for a starting technological solution is then required.

Required entry level of maturity of a starting technology (product or service) admitted to the Call:

- technologies with an established proof-of-concept which has been successfully validated in an operational and relevant environment;
- advanced engineering systems that thanks to AriSLA funding could be immediately ready to use by ALS patients.

According to the Technology Readiness Level (TRL, see also TRL Scale Description 1 and TRL Scale Description 2) scale, the indicative minimum maturity level of admitted technology is between TRL 3 and 5.

Project proposals must also ensure the creation of a product or service ready for marketing. The subject, as further defined in article 6 (the “Subject”), must indicate in the Proposal the Business Model demonstrating the product or service sustainability in the Italian ALS market.

3. Specific Challenge

Basing on the results of our questionnaire, an urgent need of amelioration of mobility and communication for ALS patients has emerged. To match these expectations, an improvement of usability and handiness of existing products or services implemented on specific ALS patient’s features is advisable.

Areas of intervention:

1. Devices that improve maintaining mobility and patient independence. As an example:
   - Devices that improve motricity (i.e. standing, walking, brace for upper/lower limbs, ...);
   - Devices for personal hygiene and dressing;

2. Devices that improve communication and social activities. As an example:
   - New technological strategies that support patients communication throughout the progression of the disease;
   - Improved augmentative communication devices;
   - Domotic solutions for enhanced environmental control.

Regulatory aspects and biomedical certification of the proposed assistive technology should be specified as appropriate.
4. Expected Impact

The Call is an “acceleration program” intended to cover a comprehensive plan for the exploitation of a given technology (tools, services, platforms, ...) enabling ALS community access to innovative solutions to improve Quality of Life, motricity, communication and surveillance.

The new product or service must be able to increase patients and the caregivers QoL. The expected outcome is an implemented and customized technology, product or service with an indicative TRL 7-8 as validated in the ALS clinical setting.

The clinical validation must be accomplished both in patients and caregivers in order to generate a proof-of-concept of the proposed technology, product or service impact on ALS.

In submitting the project, Subject shall indicate a developmental plan correlated with an adequate budget allowing to accurately assess whether the funding requested is consistent for the clinical implementation of a validated and certified technology, product or service.

5. Duration and Budget

It is admitted a project duration between 12 and 24 months.

It is expected a budget request range between euro 30,000 and 300,000, nonetheless, if properly justified, different budget requests will be evaluated. Awards are contingent upon the availability of funds.

AriSLA reminds that funds are raised through donations from the “Ice Bucket Challenge”, therefore recognizes its own responsibility to oversee an appropriate allocation of funds.

Proposals with co-funding are encouraged, specifying the overlap with the project proposed to AriSLA: overlapping with other national and international projects and initiatives should be explored in order to avoid duplication of efforts.

6. Eligible Subject

Subject eligible to participate to the Call are:

(i) partnerships composed by Italian-based non-profit (i.e. non-profit Universities and public or private Research Institutes, social enterprises, social cooperatives, etc.) and profit entities (the “Partnership”). The applicant of the Proposal should be the non-profit entity;

(ii) innovative startup with social purpose (Law no. 221/2012).
In any case, the involvement in the Partnership or in the innovative startups with social purpose - as a partner, shareholder, member - of a “PRESIDIO ACCREDITATO PER LA DIAGNOSI, LA CERTIFICAZIONE E LE DEFINIZIONI TERAPEUTICHE PER LA SLA” (DM no. 279/2001) is mandatory.

Should the project is submitted by a Partnership, the participants undertakes to enter into a cooperation contract, in the legal forms provided by the law, within 30 days from the acceptance of the financing methods proposed by the Foundation for the specific project.

The Foundation reserves the right to evaluate the compliance with the mission and purpose of the Call of the Subject mentioned above during the admission process.

7. Eligible Costs

AriSLA funds expenses consistent with the proposed activities and strictly concerning the implementation, customization and validation of the proposed assistive technology according to the project aims. Any other cost related to the generation and validation of a prototype in its original operational environment are not admitted.

Hereby the categories classifying the project costs:

- Personnel: costs for non-tenure /not permanent staff are admitted to the extent of 50% of the grant, following rules of the committing Institution.
- Material, supplies and equipment: these costs are considered eligible considering necessities and consistency to the project. Scientific and technological equipment costs are admitted limited to depreciation charged on the project.
- Sub-contracting (services): provision of external services or supplies are eligible costs depending on the need for the execution of the project and are admitted to the extent of 20% of the grant.
- Other expenses: this category includes different costs such as expenses for scientific publications, trips or visits to project collaborators, expenses related to participation in Congresses, etc.
- Overheads: general expenses incurred by the Host Institution, including administrative and maintenance costs for any machinery. These costs are calculated as a lump sum and allowed to a maximum of 5% of incurred direct costs.

8. Financing and funding methods

Given the nature of this Call, besides granting the project, AriSLA may consider other funding opportunities, for instance by the participation in the corporate capital of the financed Subject (i.e through equity) or by other forms established on a case by case basis, according to the specific needs and evaluations.

AriSLA Board of Directors will identify and evaluate the more suitable and adequate funding during the decision making process. Once the outcome of the evaluation concerning the to-be-founded projects is established, the funding allocation, other than granting the project, will be submitted to the selected Subject for approval.
9. Intellectual Property

The Subject acknowledges that for any Intellectual Property rights deriving or arising from the projects funded by AriSLA (the “IP”), the Foundation will provide assistance and support to ensure adequate legal protection to potential invention, in accordance with the policy of AriSLA on the protection of Intellectual Property.

Without prejudice to any other written agreement between the Foundation and the Subject, the management of any IP shall be assigned to the Subject.

In submitting the Proposal, the Subject shall indicate:

- their respective obligations and responsibilities concerning the protection and the exploitation of the IP;
- the terms and conditions of the distribution of any revenue deriving from the exploitation of the IP.

The ownership and management of IP shall be then formalized through an agreement within and no later than 30 (thirty) days from the formalization of the grant.

In managing the IP, the Subject shall consider all the guarantees of ethical management in compliance with the “Convenzione per la salvaguardia dei diritti dell’Uomo e delle libertà fondamentali” (Law no. 848 /1955).

It is understood that any expense, fee and cost concerning the management and the exploitation of the IP shall be borne by the Subject.

Should the Subject decide not to exploit the IP, they shall promptly communicate to the Foundation their decision, who shall have the right to replace the Subject in the exploitation of the IP, within 60 (sixty) days from the receipt of the communication by the Subject. AriSLA shall evaluate its decision in line with its mission of supporting research and in order not to leave out any chance to improve the quality of life for ALS patients and their caregivers, by proposing possible opportunities for development of the products or services also through the involvement of any third party.

In case of replacement by AriSLA, without prejudice to the ownership rights in favor of the inventors and to any other written agreement, the Subject shall have the right to a consideration, which amount shall be agreed in writing with the Foundation before the replacement.

In any case, regardless of the ownership of the IP, the Foundation shall have the right to a percentage of the revenues deriving from the exploitation, transfer or assignment of the inventions deriving from the project, as set forth under the AriSLA "Intellectual Property Rights Policy".

10. Dissemination of Funded Project Results

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 Subject shall:

- communicate to AriSLA in advance about any publications or scientific report arising from the funded project;
- adhere to the Open access Policy; and
11. Guidelines for Project Presentation

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

The Proposal must be submitted only electronically and drawn up in English on the e-forms downloadable from AriSLA website (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.

The deadline for the submission of the Proposal is Tuesday September 15th, 2015 at 1:00 pm.

12. Project Evaluation

12.1 Methodology

The Proposal 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 Proposal. Each Proposal will be independently evaluated by at least three reviewers and eventually other expert of proven expertise in the field of the topic of the research project guaranteeing transparency and impartiality of the evaluation process. Reviewers will provide a written report. During this step AriSLA may directly contact the Subject 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 panel of reviewers 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 31, 2015. At the end of the revision process, AriSLA will take care to inform all Subject about the Scientific Committee recommendation for funding along 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.

12.2 Evaluation criteria

The evaluation and the assessment of the overall quality of the Proposal, formulated by the AriSLA International Scientific Committee and eventually other experts in the field selected ad hoc, will be performed according to the following criteria:
1) Impact on ALS:
- satisfaction of a clinical need/social necessity;
- improvement on patient and caregiver Quality of Life;
- ethical dimension (e.g. human rights and protection of human beings, data protection and privacy, environmental protection, malevolent use of research results, dual use).

2) Feasibility and priority of the development project:
- innovation, relevance and consistency of the proposed project with regards to the priority of the Call;
- availability of a mature starting technology;
- technical and economic feasibility;
- scalability/replicability of a new or improved technology, product or service;
- creation and exploitation of market potential and gain of a competitive technology advantage.

3) Team composition:
- competence of the Subject to finalize the proposed research program;
- composition of the network/quality and Subject skills;
- communication, dissemination of project results, management of IPR.

12.3 Ineligible projects

Project Proposal with the following characteristics will be considered ineligible:
- projects not matching the Scope of the Call;
- projects merely covering management cost or aimed at development of prototype;
- project lacking the clinical center involvement;
- projects 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 Subject and bearing signature and stamp of the Legal Representative.
13. Privacy

According to the Italian Law 196/2003 regulating the protection of persons and other subject 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 Subject 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.