

2020 Call for Applications for ALS research projects

Deadline: June 11th, 2020 at 1.00 pm

General features

With this Call, AriSLA, the Italian Foundation for Research on ALS - Amyotrophic Lateral Sclerosis (in brief "AriSLA" or "the Foundation") aims at selecting excellent research to promote knowledge on ALS and fight the disease.

The Call admits both Pilot and Full Grant Applications for projects on ALS research.

PILOT GRANTS concern research projects with highly innovative and original hypotheses, where preliminary data are either not available or to be consolidated. As such, they are intended to collect or strengthen preliminary data for subsequent larger scale funding. Addressed topics may concern **basic or preclinical research areas or clinical observational studies**. Applications based on clinical interventional studies are not admitted.

Particularly for this type of Application, AriSLA Foundation encourages Applications from junior investigators and investigators who are new to the ALS field.

Only Single-centre Applications are admitted.

The duration of the proposed project is 1 year.

FULL GRANTS concern research projects with a solid background and consistent preliminary data. Addressed topics may concern **preclinical research or clinical observational studies only**. Applications addressing basic mechanisms or based on clinical interventional studies are not admitted.

Applications can either be Single-centre or Multi-centre. The Principal Investigator (PI) is the scientific coordinator of the project, either in case of a Single-centre or a Multi-centre project. In case of a Multi-centre project, the synergy derived from Partners' contribution to the achievement of the project objectives should be evident.

The duration of the proposed project can range from 1 to 3 years.

In order to be fundable, either type of Applications should be original and ground-breaking with respect to current science and of high scientific quality. Projects should demonstrate a strong potential to impact on disease understanding, diagnosis or treatment of ALS.

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

Awards are contingent upon availability of funds.



Eligibility Criteria

Eligible Host Institutions

Only research Applications submitted by investigators working in **Italian non-profit Universities and Research Institutes, either public or private**, performing research activities consistent with the statutory purposes of the Foundation, are eligible. In case of Multi-centre studies, this applies to both the PI and the Partners, generally defined as Applicant.

The Host Institution declares that the Applicant is authorised to submit the Application on its behalf. By signing the *General Information* page (which must be attached to the Application by the PI, also on behalf of Partners, if any) the Host Institution shall undertake to respect any and all conditions under this Call for Applications and discharges AriSLA from any liability related to any breach of said conditions by the Applicant and/or by the Host Institution itself.

The Legal Representative of the Host Institution has to declare that the Host Institution will provide the necessary facilities and personnel to carry out the submitted research project. If the Applicant is not holder of a permanent position, her/his salary needs to be provided through other means.

Investigators working in Host Institutions outside Italy or in **for-profit organisations** can participate as Collaborators only, upon presentation of a **collaboration letter**, explaining the type of support to the research project.

Eligible Applicants

Applicants must demonstrate proven scientific competence, independence, and capability to self-manage the proposed project and must operate in the Host Institution for the entire duration of the Grant.

If the Applicant does not hold a permanent position, the Host Institution should be aware that the salary of the Investigator cannot be requested in the budget of the Application.

If the Application is successful, but the scientific independence of the Applicant is not clearly evident to the International Scientific Committee (ISC), the Committee may recommend funding, pending a statement by the Applicant's Director (e.g. head of laboratory/department) stating that the results of the funded project will belong to the Applicant in the form of adequate authorship in any ensuing publications (last name/corresponding author).

Investigators are allowed to apply for a maximum of 2 Grants, and can be PI of 1 Application only, in response to this Call.

For Applicants of ongoing AriSLA projects that are not expected to end by December 31st, 2020, the following rules apply:

- a PI is not eligible to submit a new Application as PI, but can apply as Partner in one Multi-centre Application;
- a Partner of one ongoing project can apply for one new Grant, either as PI or Partner;
- a Partner of two ongoing projects is not eligible for the current Call.



The Host Institution declares that the Principal Investigator is authorized to submit the Application on its behalf. By signing the Host Institution Agreement (which will be uploaded within the Application) the Host Institution shall undertake to respect any and all conditions under this Call for Application and discharges AriSLA from any liability related to any breach of said conditions by the Applicant and/or by the Host Institution itself.

New application or Renewal Application by a former grantee

The holder of a previously funded AriSLA project that will end by December 31st, 2020 may submit a New or a Renewal Application.

A "Renewal Application" is a new funding request based on data from a previously funded AriSLA Grant, while a "New Application" is a new funding request dealing with a different research topic.

Renewal Applications of previously funded Grants are encouraged, and the effective exploitation of the results obtained with the previous Grant will be matter of evaluation.

The "Renewal Application" of a previously funded Pilot Grant can only be submitted as Full Grant Application.

The holder of a previously funded Pilot Grant may apply for another Pilot Grant as a "New Application" specifying the reasons of changing the research topic.

Revised Applications

Applicants who have submitted an Application to a previous AriSLA Call for Research Projects that was not funded may participate in this Call by submitting a "Revised Application", modified in accordance with the comments received during the evaluation process. In this case, a reply to the issues raised by the reviewers should be reported in the box "Changes from previous revision".

Only up to two resubmissions of a previously unsuccessful Application, not necessarily in consecutive years, are allowed.

Budget

Pilot Grant Applications are allowed to request a contribution up to € 60,000.

Full Grant Applications are allowed to request a contribution up to a maximum of 80,000 €/year for a maximum of 3 years.

The budget description must be accurate and every item must be justified.

AriSLA reminds all Applicants and their Institutions that funds are raised through many small individual donations and therefore AriSLA feels a special responsibility to oversee an appropriate allocation of funds.



Evaluation steps

Submitting the Application

Applications must be written in English and compiled following the specific guidelines (see "Application Guidelines 2020") which are an integral part of this Call.

Applications that are incomplete, lack any of the mandatory documents or do not comply with the requirements stated in this Call for Applications and pertinent Guidelines will not be accepted.

Applications have one-steps submission process and will be evaluated through two consecutive phases: Triage and Full Proposal Evaluation.

The Application has to be electronically submitted by **June 11th**, **2020 at 1.00 pm** by the PI, by filling out **all forms** of the **Pilot Grant** or **Full Grant Application**. Forms are available on the AriSLA <u>website</u>, starting from **April 21st**, **2020**.

No hard copy of the online Application needs to be sent via email.

Triage and Full Proposal Evaluation

Each accepted Application will be evaluated by the AriSLA ISC, in order to guarantee meritocracy, transparency and impartiality of the selection process.

The list of members of last year's AriSLA ISC is reported on the AriSLA website (<u>Comitato Scientifico Internazionale 2019</u>). Additional experts may be involved if considered necessary.

Procedure

AriSLA staff and reviewers involved in the evaluation process are bound by strict confidentiality and conflict of interest rules defined by the Foundation. Grants will be awarded on a competitive basis.

Applications will be assessed by a two-step peer-review:

1) Triage

The AriSLA ISC will perform a remote evaluation of the following sections of the Application:

- Section I General Information
- Section II Project Information
- Section V Applicant

During the Triage phase each Application will be independently evaluated by three reviewers of proven expertise in the field of the topic of the project, who will provide a brief written comment and a score. All Applications will be ranked based on the evaluation criteria reported below. The results of the Triage phase will be communicated to all PIs. In addition, the PIs of the excluded Applications will receive a report with the reviewers' comments. It is anticipated that approximately up to the top-ranking 40 Applications will proceed to the second step.



2) Full Proposal Evaluation

The Applications selected for the Full Evaluation will be assigned to three independent reviewers of the AriSLA ISC, available to take part in the Consensus Meeting in Milan. During this phase, all Sections of the Application will be evaluated.

In addition to remote individual evaluations, the panel of reviewers involved in the second step will proceed to a comparative evaluation of the top-scoring Full Proposals during the Consensus Meeting in Milan, and all reviewers will score each Application. The outcome of the Consensus Meeting will be a final merit-based list.

Information on the evaluation process and outcomes of the Full Proposals will be provided to the interested PIs by the end of December 2020.

Reviewers' AriSLA Guidelines for Triage and Full Proposal Evaluations are available online.

Evaluation criteria

Pilot Grants

<u>Triage evaluation</u> will be based on the following criteria.

- 1. Innovation and originality of the proposed project with regards to the current knowledge
- 2. Quality and feasibility of the scientific approach. The following parameters will be evaluated:
 - Relevance and significance for ALS
 - Rationale
 - Appropriateness of design and methods
 - Overall feasibility of the study.

<u>Full proposal evaluation</u> will be based on the following criteria.

- Innovation of the proposed project with regards to the current knowledge
- **Expected impact** of the results **on the disease** knowledge and treatment or any other influence on clinical management of patients; proximity to therapeutic development or to any other potential impact on patients of the proposed study; potential admissibility of results for intellectual property protection
- **Objectives** and **methodologies**: appropriateness of methods and analyses with respect to the aims of the study
- Capability to successfully carry out the project: ability of the Applicant to finalize the proposed research program according to the project duration and budget
- Potential of the expected results to be attractive for larger scale funding.

Full Grants

<u>Triage evaluation</u> will be based on the following criteria:

- 1. Innovation and originality of the proposed project with regards to the current knowledge
- **2. Quality and feasibility** of the scientific approach; the following parameters will be evaluated:
 - Relevance and significance for ALS
 - Soundness of background and rationale



- Robustness of the preliminary data
- Appropriateness of design and methods
- Experience of the Applicants in the field
- Overall feasibility of the study

<u>Full proposal evaluation</u> will be based on the following criteria:

- Strength of the background and rationale
- Availability of solid preliminary data to support the research program and relevance of the project for ALS
- Clarity of the objectives and appropriateness of design and methods proposed to achieve them
- **Expected impact** of the results **on the disease** knowledge and treatment or any other influence on clinical management of patients; proximity to therapeutic development or to any other potential impact on patients of the proposed study; potential admissibility of results for intellectual property protection
- Investigator experience and synergy with Partners (if any): competence and scientific independence of the Applicants; complementarity and synergy among PI and Partners of Multi-centre studies
- Sound and effective exploitation of the results derived from previously funded AriSLA Pilot/Full Grants.

The ISC will also review the budget, which may be reduced with respect to the original request.

In particular, care will be taken to avoid overlapping funding of scientific activities already supported by other Applicant's grants, which must be accurately described in the appropriate section of the online Application.

Awarding of research funds

Awarded funds must be spent to accomplish the research for which they have been approved. AriSLA requires that the funds be used effectively and economically, and that the expenses be essential for the research for which the funds were awarded.

No funds will be awarded by AriSLA to any Host Institution until both parties have signed a specific agreement according to art. 3 of the D.P.R. 20th March 2003, n. 135.

AriSLA reserves the right to ask for a copy of the statute of the Host Institution and of the latest available balance sheet, as well as the acknowledgement of the legal status for all the investigators working for non-profit private organisations. AriSLA reserves the right to evaluate the compatibility of the statutory guidelines of the private Institutions on a case by case basis, with the aim of ensuring social benefit and of the financial reliability in order, if necessary, to dictate the conditions for the assignment/payment of the contribution.

AriSLA reserves the right to site visit the Host Institution before releasing any funds and/or at any time afterwards, during the grant period.

The release of funds is subject to the submission of all required documentation, as specified in the respective "Application Guidelines_2020" for Full and Pilot Grants and as requested by the AriSLA Offices.

All costs allocated will be reimbursed upon administrative report of the expenses.



In case of two- or three-year awards, recipients must provide a detailed a periodic administrative report in order to obtain the subsequent payment.

AriSLA reserves the right to cancel payments whenever a conflict arises regarding the stipulations contained in this Call for Applications, or stipulations specifically made by AriSLA to the Host Institution and/or to the Investigator.

Code of Conduct for research integrity

AriSLA adheres to the principles for a responsible conduct of research (RCR) reported by the European Code of Conduct for Research namely: reliability, honesty, respect, accountability (https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf).

As such, the Foundation expects Applicants, Grantees and all research personnel involved at any level with the AriSLA research Applications or approved grants to strictly adhere to the highest standards of research conduct therein reported.

Dissemination of results of funded projects

AriSLA wants to ensure 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 that the funded investigators have the obligation to:

- **inform in advance about any publication** and to acknowledge AriSLA for all publications arisen from the project;
- adhere to the Open Access Policy;
- be compliant with the European General Data Protection Regulation no. 679/2016 as well as with any other applicable local law;
- submit Final Scientific Reports at the end of the project.

For further details please refer to AriSLA Dissemination Policy, "Policy sulla Comunicazione e Disseminazione della Ricerca".

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 funded investigators to undertake any necessary steps to ensure adequate valorisation and exploitation of the research outcomes.

For further information please refer to AriSLA Intellectual Property Rights Policy, "Policy sulla Proprieta' Intellettuale"



Adoption of an AriSLA funded project

AriSLA claims the right to promote the "adoption" by third party Institutions of the funded projects; therefore, it is recommended to consult the AriSLA Projects Adoption Policy, "Policy per l'Adozione dei Progetti di AriSLA".

Privacy of personal data

According to the Current Law, General Data Protection Regulation (EU) 2016/679 (GDPR) and D.Lgs 196/2003, regulating the protection of natural persons in relation to the processing of personal data, AriSLA and the Host Institution will be considered as being autonomous data controllers of the personal data to be processed under the Application.

The Host Institution is allowed to indicate the personal data of the Applicant as well as of any other researcher involved in the Application (Key Personnel and Collaborators not actively involved in the research project), on the condition that the Host Institution: (i) has provided the involved researchers with the attached information (INFORMATIVA SUL TRATTAMENTO DEI DATI PERSONALI E CONSENSO) (ii) has thereby gathered the relevant consents; and (iii) has undersigned the *General Information* page of the Application ensuring that the above conditions have been respected. AriSLA shall, at any time, have the right to examine such documents (information to data subjects and declaration of consent) at the Host Institution location. The Host Institution shall deliver any document, according to AriSLA's request.

Assistance

For any information about the Call or about the Application Form compilation please contact:

E-mail Help Desk: bandi@arisla.org

Phone Help Desk: at the phone number +39 02.20.24.23.90 from 9.00 am to 5.00 pm (Mon-Fri).



INFORMATIVA SUL TRATTAMENTO DEI DATI PERSONALI E CONSENSO

ex artt. 13 e 14 del Regolamento UE 2016/679

Ai sensi degli artt. 13 e 14 del Regolamento UE 2016/679 (GDPR) e a tutela del Suo diritto alla protezione dei Dati personali la Fondazione Italiana di ricerca per la SLA - Sclerosi Laterale Amiotrofica (AriSLA) intende fornirle le seguenti informazioni.

TITOLARE DEL TRATTAMENTO

TITOLARE del trattamento dei Suoi Dati personali è la Fondazione Italiana di ricerca per la SLA - Sclerosi Laterale Amiotrofica (AriSLA), con sede in Via Poerio, 14 - 20129 Milano (C.F.: 97511040152), in persona del legale rappresentante pro tempore, avente i seguenti dati di contatto:

- email: privacy@arisla.org
- Tel. 02.20242390

FINALITÀ DEL TRATTAMENTO

Il Trattamento dei Dati personali da parte del Titolare avrà ad oggetto esclusivamente Dati comuni (a titolo meramente esemplificativo: dati anagrafici, dati di contatto, esperienze professionali, istruzione, formazione, titoli, pubblicazioni, la sua immagine in formato digitale) e sarà specificamente destinato alle seguenti finalità:

- A) gestione della procedura concorsuale o selettiva, per l'eventuale erogazione di contributi per il finanziamento di progetti di ricerca scientifica, per la gestione delle graduatorie (ove previste nel bando) e correlata attività amministrativa, incluso l'invio di informazioni relative al predetto bando di concorso agli indirizzi e-mail e/o numeri telefonici da Lei indicati;
- B) in caso di aggiudicazione, gestione del progetto di ricerca e correlata attività amministrativa per l'avvio del progetto anche con riferimento ai dati del Responsabile del progetto (Principal Investigator, PI), dei Partner e del personale medico, scientifico, tecnico ed amministrativo coinvolto nel progetto;
- **C)** in caso di aggiudicazione, diffusione (sia mezzo stampa sia a mezzo web) di divulgazione laica del progetto anche con riferimento ai dati del Responsabile del progetto (Principal Investigator, PI) e dei Partner.

BASE GIURIDICA DEL TRATTAMENTO

La base giuridica dei trattamenti operati dal Titolare del trattamento è la seguente:

- per le finalità di cui alla lettera A), l'esecuzione di misure precontrattuali e l'adempimento di obblighi legali;
- per le finalità di cui alla lettera B), l'esecuzione del contratto e l'adempimento di obblighi legali;
- per le finalità di cui alla lettera C), il perseguimento del legittimo interesse del Titolare del trattamento.

NATURA OBBLIGATORIA O FACOLTATIVA DEL CONFERIMENTO E CONSENSO

Il conferimento dei Suoi Dati personali è indispensabile affinché il Titolare possa compiere le attività necessarie per le finalità di cui alle predette lettere A), B) e C) e pertanto, in tal senso, tale conferimento è da considerarsi obbligatorio.



CONSEGUENZE DEL MANCATO CONFERIMENTO E CONSENSO

Il mancato conferimento dei Suoi Dati per le finalità di cui alle predette lettere A), B) e C) non consentirà la Sua partecipazione al bando di concorso organizzato dal Titolare del trattamento.

MODALITÀ DEL TRATTAMENTO

Il trattamento dei Suoi Dati personali sarà effettuato con le modalità manuali ed informatizzate, anche con l'ausilio di mezzi elettronici o comunque automatizzati, nei modi e nei limiti necessari per perseguire le predette finalità e con l'adozione delle misure tecniche previste dall'art. 32 del GDPR - Regolamento UE 2016/679.

Il Trattamento sarà svolto direttamente dall'organizzazione del Titolare, con la collaborazione degli incaricati all'uopo autorizzati e degli eventuali responsabili esterni, nominati, ove necessario, per specifiche operazioni.

I Suoi Dati personali sono protetti da misure di sicurezza che puntano a limitarne l'accesso ai soli professionisti autorizzati ed agli incaricati del Titolare e per le sole funzioni che ad essi competono. Altre misure di sicurezza sono applicate a tutti i Suoi Dati personali per garantire l'integrità dei dati, il loro salvataggio quotidiano e il recupero in caso di incidenti o guasti ai sistemi di elaborazione anche a tutela della continuità operativa dell'organizzazione del Titolare del Titolare del trattamento.

DESTINATARI DEI DATI PERSONALI

Il Titolare del trattamento non diffonderà i Suoi Dati personali di natura particolare (artt. 9 e 10 GDPR).

I Dati comuni identificativi dell'interessato potranno essere pubblicati sul sito internet del Titolare del trattamento e potranno essere riprodotte nel materiale informativo predisposto da AriSLA.

Il personale amministrativo operante all'interno della struttura può, in qualità di incaricato del trattamento, consultare solo le informazioni necessarie per assolvere alle funzioni amministrative cui è preposto e strettamente correlate alle proprie mansioni; l'accesso ai Dati deve essere circoscritto al periodo di tempo indispensabile per espletare le operazioni per le quali è abilitato il soggetto che accede.

I Suoi Dati personali potranno altresì essere comunicati a:

- Revisori / Esperti valutatori o Consulenti di AriSLA;
- soggetti terzi che si occupano dello sviluppo e manutenzione degli strumenti informatici o che forniscono
 prestazioni o servizi legati alle finalità sopra indicate. Tali soggetti terzi opereranno nell'ambito di
 specifiche nomine a Responsabile Esterno al trattamento dei dati personali e per finalità specificatamente
 indicate;
- Enti pubblici e privati, esclusivamente per attività strettamente legate alle finalità di cui sopra.

LUOGO DI TRATTAMENTO E TRASFERIMENTO DEI DATI

I trattamenti hanno luogo presso la predetta sede del Titolare del trattamento e presso i soggetti terzi individuati.

I Dati personali potranno essere trasferiti in Paesi extra - UE, in particolare nel caso di servizi che siano ubicati al di fuori del territorio dell'Unione Europea (es. cloud storage). In tal caso, il Titolare assicura sin d'ora che il trasferimento dei Dati extra-UE avverrà in conformità alle disposizioni di legge applicabili, ad esempio previa stipula delle clausole contrattuali standard adottate dall'Unione Europea.



PERIODO DI CONSERVAZIONE DEI DATI PERSONALI:

I Suoi Dati personali saranno conservati per il tempo necessario alla conclusione di tutta l'attività relativa alla gestione della procedura concorsuale o selettiva e del progetto ed esaurito il progetto, per tutto tempo strettamente necessario al perseguimento delle finalità di cui sopra, fatti salvi gli eventuali termini di conservazione previsti da norme di legge o regolamenti.

DIRITTO DI ACCESSO AI DATI PERSONALI ED ALTRI DIRITTI

Lei potrà far valere i propri diritti come espressi dall'art. 15, 16, 17, 18, 20 e 21 del Regolamento UE 2016/679 (GDPR), rivolgendosi al Titolare ai Dati di contatto sopra indicati.

In particolare il Titolare La informa dell'esistenza dei seguenti diritti:

- chiedere al Titolare l'accesso ai Dati, la loro cancellazione, la rettifica dei Dati inesatti, l'integrazione dei Dati incompleti, nonché la limitazione del trattamento nei casi previsti dall'art. 18 del GDPR;
- opporsi, in qualsiasi momento, in tutto od in parte, al trattamento dei Dati necessario per il perseguimento legittimo dell'interesse del Titolare;
- nel caso in cui siano presenti le condizioni per l'esercizio del diritto alla portabilità di cui all'art. 20 del GDPR, ricevere in un formato strutturato, di uso comune e leggibile da dispositivo automatico i Dati forniti al Titolare, nonché, se tecnicamente fattibile, trasmetterli ad altro Titolare senza impedimenti;
- revocare il consenso prestato in qualsiasi momento;
- proporre reclamo all'Autorità di controllo competente.

Il Titolare del trattamento