Fondazione per la Ricerca
sulla Fibrosi Cistica - Onlus
italian cystic fibrosis research foundation

ITALIAN CYSTIC FIBROSIS RESEARCH FOUNDATION (FFC Ricerca)
CALL FOR THE FIRST
"GIANNI MASTELLA STARTING GRANT"

08 February 2022

The Italian Cystic Fibrosis Research Foundation (FFC Ricerca) funds research projects that have the ultimate aim to improve the health status of persons with cystic fibrosis (CF) and to providing a breakthrough in understanding the molecular basis of the disease.

This call is in the memory of prof. Gianni Mastella, pediatrician and key scientist in CF research and co-founder of FFC Ricerca.
The "Gianni Mastella Starting Grant - GMSG" is addressed at young investigators operating in the field of CF to continue their scientific career in the study of the basic defect of the disease or in the development of therapeutic approaches to improve the life of people with CF.

What are the relevant features of this call?

- only **monocentric projects** are allowed;
- the duration of the projects is set at **36 months**;
- the maximum budget allowed is set at 60,000 euros per year for a total of **180,000 euros for the entire project**;
- a **training period** in an External Research Institution (ERI) is encouraged (see Project duration and training period below);
- the candidate must be **35 years old or younger** (see Eligibility criteria below);
- the candidate must produce a document certifying the willingness of the host institution and, if applicable, of the external research center to conduct the research;
- deadline for submitting applications: **15 March 2022**;
- the funding grant starts on **1 September 2022**.

1. Priority areas

The GMSG aims to fund projects focused on the following 5 priority areas in CF research:

1.1.Innovative therapies to correct the basic defect: designing of new approaches to correct defective CFTR or to compensate for its deficient function with the following particular indications:

- novel mutation-specific therapies;
- ancillary supports to modulator therapy;
- targeting alternative chloride channels;
- development of therapies based on gene or RNA editing.

Piazzale Stefani 1 | c/o Azienda Ospedaliera Universitaria Integrata | 37126 Verona
Codice fiscale 93100600233 | fondazione.ricercafc@aovr.veneto.it | Tel 045 812 3438
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1.1.Personalized therapies: identification and validation of new and appropriate *in vivo* and *ex vivo* models and assays, such as *theratyping*, to predict and monitor the potential efficacy of new therapies aimed to correct the CFTR defect.
1.2.Airway infection in CF: development of innovative diagnostic and antimicrobial strategies with special indication for the rapid and accurate diagnosis of infections and the treatment of difficult-to-treat microorganisms.
1.3.Inflammation in CF: innovative strategies of containing the inflammation pathology.
1.4.Clinical applications and epidemiological studies: clinical trials, with special regard to phase IV clinical studies (post-marketing studies in real life) and those to improve the outcomes of lung transplantation in CF; revision and update of traditional therapies which place a heavy burden on the sick innovative diagnostic approaches to predict and monitor the evolution of the disease also in the context of new therapies; epidemiological studies (with reference also to the database of the Italian CF Registry) and systematic reviews.

General notes and recommendations

- Applicants can submit only one project for this call.
- Priority will be given to research proposals where translational objectives are clearly evident.
- Accordingly, research projects involving clinical studies or pre-clinical studies exploiting animal models of CF are encouraged.
- Projects involving international collaborators are encouraged. Collaborators can ask budget to cover their costs. Please see Eligibility criteria and Budget session below.
- FFC Ricerca also encourages projects focused on studies on therapeutic perspectives on rare mutations and/or mutations not susceptible to currently available modulators.
- In vitro studies dealing with non-CF cell lines are strongly discouraged, unless required for preliminary experiments or used to reinforce data obtained with primary cells.
- Researchers should consider the facilities offered by FFC Ricerca in the design of the projects presented:
    - **Servizio Colture Primarie (SCP)** which collects primary cell cultures obtained from bronchial epithelium of CF and non-CF patients. For more details please visit the dedicated web page and contact the service coordinator.
    - **Cystic Fibrosis animal Core Facility (CFaCore)** which develop and provides mouse models for research applications in the field of CF. For more details please visit the dedicated web page and contact the service coordinator.
    - **Cystic Fibrosis Data Base (CFDB),** the data base of clinical interventions in CF. For more details please visit the dedicated web page and write at info@cfdb.eu.

- **FFC Ricerca facilities** (SCP, CFaCore, CFDB) must be considered as a service, therefore the coordinator of the facility must not be indicated as a collaborator. Please see guidelines at *Outside Collaborations/Services* section to fill in Form 9.
- Studies aimed at identifying **new therapeutic compounds** will also be considered, provided they suggest new strategies for influencing the mutated CFTR function and/or CFTR-dependent mechanisms of cellular pathology, including modification of DNA and RNA.
- **FFC Ricerca will not fund formal preclinical studies**, except those that address the effects of the drug/compound on animal models of CF disease, when existing and

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available, and only provide proof of concept that they work in the animal models without toxic effects. Lack of toxicity should also be documented in projects included in other priority areas.

- Studies to identify **novel antimicrobial strategies** will only be considered if original strategies are proposed, along with sufficient preliminary data, to support a potential advantage over conventional treatment protocols. FFC Ricerca will not consider studies aimed at the identification or preliminary characterization of active hit compounds against multidrug-resistant pathogens unless a clear advantage is expected over current agents (including the pre-clinical stage) for treating CF infections.
- Collaboration and the transfer of knowledge and expertise from basic to clinical research is particularly recommended. To this end, the advice of a clinical consultant for basic research projects is conceivable and her/his role must be clearly highlighted in the application cover letter.
- By "translational research" this call does not only mean "bench-to-bedside" studies. Research projects considering translating clinical study results into daily clinical practice and healthcare decision-making are also welcome. Topics to be considered include clinical epidemiology, communication, behavioral sciences, organizational theory, quality monitoring and quality improvement research.

2. Eligibility criteria

- **Applicant**
  - Must not be more than **35 years** (born within 31 December 1987);
  - **not having a permanent position** in the host institution (see Budget for details);
  - the **PhD** is welcome but not mandatory;

- **Host Institution (HI) and External Research Institution (ERI)**
  - The **Host Institution** is the research center where the applicant carries out the research activity described in the application.
    - It must be an **Italian research institute**;
    - it can be **profit or no-profit, private or public**. Pharmaceutical and biotech companies are not eligible.
    - a declaration, undersigned by the HI head/responsible, must be provided by the applicant (see *Additional documents*).
  - The **External Research Institution (ERI)** is the center where the applicant carries out his/her training period.
    - It can be an **Italian or an international** research center;
    - it can be **profit or no-profit, private or public**. Pharmaceutical and biotech companies are not eligible.
    - it must provide the spaces and equipment necessary to carry out the training period;
    - if applicable, the applicant can provide a **letter of intent** of the head/responsible of the ERI where the training period will be carried out;
    - a **declaration**, undersigned by the ERI head/responsible, must be provided by the applicant by the beginning of the project (see *Additional documents*).

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3. Research team

- Only monocentric projects are admitted; no partners are admitted for this call.
- If required, only **collaborators are admitted**;
- Collaborators are researchers with limited roles and functions in the project, they can be internal or external:
    - **internal collaborators** are part of the PI's research group belonging to his/her research institute;
    - **external collaborators** are researchers of external research institutions (Italian or foreign).
- External collaborators can request a cost recovery for a specific task (technical service, research or clinical consultancy – see Budget section).

4. Project duration and training period

- Only projects lasting **36 months** are admitted for this call;
- a **training period** is encouraged at an ERI (Italian or foreign), and the related costs are allowed (see *Budget* section);
- the maximum duration of the training period is **6 months**;
- the applicant must provide a declaration from the host institution where the research project will be conducted (see "**Acceptance of the HI**" in *Additional documents – Upload area* (**Form 13**);
- if already available, the applicant can provide a **letter of intent** in which the head/responsible of the ERI certifies his/her willingness to host the applicant for his/her training period. Please upload this document in "*Additional documents – Upload area* (**Form 13**);
- the "**Acceptance of the ERI**" is the agreement with the external research center. This document must be signed by the head/responsible of the ERI and must be provided by the start of the project. The head/responsible of the institute must report his/her willingness to host the applicant for his/her training period and must provide him/her with the necessary spaces and equipment to conduct the training period.

5. Budget

The budget description (**Form 10**) must be accurate and each item must be motivated and detailed per each research unit and per each year of the funding period. **An inadequate budget description will lead to the exclusion of the project**. As a general rule, the maximum budget request cannot exceed 60,000 euros per year for a total of 180,000 euros for the whole project. Any exceptions can be discussed on a case-by-case basis. The part of the budget dedicated to the salary can reach up to 31,000 euros.
If the researcher has a permanent position from his host institution during the GMSG project, the contribution of the FFC Ricerca will no longer cover the costs of the salary. In this case the researcher is requested to contact FFC Ricerca's administration.

5.1.Eligible costs (all must be clearly related to the project):

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- Salary for the PI. FFC Ricerca will cover the cost of the research contract of the PI (fellowship) for the duration of the project. In case the applicant already has a contract with his/her host institution, FFC Ricerca can integrate it up to a maximum of 31,000 euros per year for the duration of the project. If needed, please use the box in the *Additional notes* section (**Form 12**) to describe contract details.
- Small research equipment or accessories and software (justified and related to the current project).
- Consumables and animals.
- Participation in trip and scientific meeting (international conferences on CF)
- Costs to cover the training period (travel, accommodation, health/travel insurance).
- Publication costs, with clear reference to the project funded by this call.
- Costs for patients participating in clinical trials such as insurance coverage and travel costs.
- Overheads (general expenses not foreseen in the previous items, but in any case compatible with the admitted expenses): they cannot exceed 5% of the total budget.
- Collaborators cost recovery, such as external and occasional professional or technical services, costs for clinical consultancy or patentability analysis. The applicant can ask to use part of the budget to finance research activities carried out by one or more collaborators;

5.2.Ineligible costs:

- Salary for internal or external collaborators.
- Furniture and stationery.
- Software not specifically related to the project.
- Basic laboratory or clinical equipment.
- Equipment repair or technical assistance costs.
- Office materials.
- Laboratory or clinical equipment for the ERI in which the researcher intends to carry out her/his training period.

6. Guidelines to fill in the forms

The research project must contain all the following information, which must be followed very carefully.

- **General information (Form 1).**
    - Application details: Project title; Application (Type of Applicant and Type of Application); Number of researchers involved (including internal and external collaborators); Research area; Animals or human subjects involved in the project.
    - Applicant information and contract details; internal and external collaborators possibly involved in the project, the details of their host institution and their specific roles in the project. The acceptance of collaboration must be corroborated by personal declaration (see also point 7, *Additional documents*).
    - Enter here whether the training period is foreseen. If already available, the letter of intent can be uploaded in form *13 - Administrative documentation - Upload Area*.

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- **Project overview (Form 2).** It must include: background/rationale, hypothesis and objectives, preliminary results relevant to the project, experimental plan and methods description, timing, anticipated output, relevance for FFC Ricerca mission.
- **Research Plan: Background, specific aims and rationale (Form 3).** The originality of the project must be clear from these items. The **bibliography cited** must be reported in this section.
- **Preliminary results (Form 4).** They must be proved and convincing and refer to the results obtained by the applicant in preliminary investigations that bring the motivation and the justification of the proposal. The preliminary results will serve to demonstrate that the candidate has the capacity to carry out the proposed project. This part will be considered as absolutely necessary and decisive for the evaluation of the project. Images and graphs relating to preliminary results must be uploaded in this section as a single PDF document (max 25 Mb).
- **Experimental plan and methods (Form 5).** In this part the following must be specified in detail: the experimental plan or clinical protocol, the methodology and materials intended to use, the justified number of the samples (whether patients or animals) to be examined and the statistical methods that will be required for the evaluation of the results. A description of the development phases of the project is also requested, including temporal ones (also with a Gantt chart), quality controls, and all pertinent references. In addition, the organization and management must be described to ensure the quality and feasibility of the project. It would be interesting if the critical points of the experimental plan and any "B plans" indicated in case of problems are detailed. The Gantt chart and, if available, other images must be uploaded here as part of a single PDF document (max 25 Mb). Indicate in this form if it is a clinical project/trial.
- **Curriculum vitae (Form 6).** Education and training, previous job and research experiences, significant publications in last five years (in peer-reviewed journals only).
- **Role and contribution of the applicant in the project (Form 7).** Please describe the applicant's contribution to the project and how to coordinate the activities of the collaborators.
- **Features and facilities (Form 8).** Applicant position title (if applicable); Main research fields; name of laboratory or clinical department and his/her responsible/chief and number of staff members; description of facilities (spaces, clinical resources, IT equipment, major equipment, facilities and services available). The technologies and services available for the implementation of the project must be detailed, indicating their specific relevance to each phase of the experimental plan.
- **Outside Collaborations/Services (Form 9).** Describe the collaborators contribution to the project. External technical services or consultancy / professional services are to be considered. External collaborators must be supported by specific letters (*Letter of commitment*) to be uploaded in the form *13 - Administrative documentation – Upload Area*. If required, facilities of FFC Ricerca must be reported in this section.
- **Budget (Form 10).** Specify overall expenses and for each year (see Budget section). Any other financial supports must be indicated in this section, reporting the related details (description, amount, project title, granting agency).
- **Lay summary (Form 11).** This must be written both in English and Italian (including Italian title), in a popular and well understood style. This summary is meant to serve as a succinct and accurate description of the proposed work; if the application is funded, this summary will be published in the "Notiziario FFC Ricerca" and in other media. The summary must state clearly the relevance of the proposed study to the FFC Ricerca mission (to promote innovative treatment and care for CF).

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- **Additional notes (Form 12).** If needed, please use this box to describe contract details.
- **Additional documents – Upload area (Form 13).** Documents to be uploaded: Cover letter, Acceptance of Host Institution, Acceptance of collaboration/Consent to Personal Data Processing, Acceptance of External Research Institution (ERI) for the training period (if applicable), Letter of commitment/Consent to Personal Data Processing - External collaborators.
- **Validate and Download PDF.** This section lists all empty fields which are highlighted in red. By clicking on the empty fields, the system opens the section to be filled out. Download the application by clicking on the appropriate button (at the top of the page), then click on "Validate and send" to complete the submission.

7. Additional documents

7.1. Cover Letter

The application must be accompanied by a cover letter summarizing:

- the general plan of the project;
- the reasons why it falls within the priorities indicated in the call for applications, in line with the objectives of the Foundation's mission;
- why it is believed that FFC Ricerca should consider the project worthy of funding.

If applicable, the applicants can also report in the cover letter:

- any **suggested or excluded reviewers**, indicating their name, surname and affiliation;
- any **patent registration**, completed or in progress if related to the proposed project, specifying available the details.

The **Cover letter** must be uploaded in the **Form 13 Additional documents – Upload area.**

7.2. Host Institution (HI) and External Research Institution (ERI) documents.

- "Acceptance of the HI": an agreement with the host institution, signed by the head/responsible of the HI must be provided; the head/responsible of the HI must indicate his/her willingness to host the applicant and must provide him/her with the necessary spaces and equipment to necessary to carrying out the research activity;
- Consent for use of personal data, according to the Italian Law 196/2003.
- Declaration of commitment signed by each internal and/or external collaborator involved in the project listed in the application.
- PI declaration of adherence to provisions governing laboratory animal care, if applicable.
- If applicable, the applicant can provide a letter of intent of the head/responsible of the ERI where the training period will be carried out;

7.3. Letter of commitment/Consent to Personal Data Processing - External collaborators

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The letter must include the contribution of collaborator to the project. Each External collaborator will have to upload its own Letter of Commitment written on the headed paper of department or institution.

7.4.Clinical project

Projects that fall within this intervention area must be clearly patient-oriented. They must include, even if only in part, diagnostic, therapeutic or rehabilitative interventions on humans, not foreseen by common standards or by the personal plan of diagnosis, care and rehabilitation.

7.4.1.Documentation

A clinical project must **provide the following documentation**, in accordance with the provisions of the Italian Ministero della Salute (D.M. 15/07/1997, D.M. 18/03/1998, D.M. 19/03/1998, DL 26/05/2000 and DL 24/06/2003):

- Ethical Committee Approval to be sent to FFC Ricerca after award of the grant and not later than 31st October 2022;
- "Parere Unico", released by the Ethical Committee of the PI's centre, if applicable (not later than 31 October 2022 if the project will be funded);
- Informed consent form (for interventions and for use of personal data, anonymously, for research purpose, released by patients or people involved in the study) plus information sheet for the patient;
- Declaration of Good Clinical Practice by the applicant.

7.4.2.Methods and data management

For the preparation of a clinical application, FFC Ricerca suggests following the procedures provided by the main international checklists, such as:

- CONSORT (for randomized studies)
- STROBE for observational studies)
- STARD (for diagnostic studies)
- PRISMA (for systematic reviews)

Further information is also available at the link of the Equator Network Initiative.

Clinical studies are advised to use a web-based Case Report Form (CRF). Data management and monitoring could be more appropriately provided by a Contract Research Organization (CRO). Given the relevant cost of CROs, FFC Ricerca could propose one which has been assessed as reliable and cost-effective. The costs and agreement with the CRO have to be reported in the budget.

7.4.3.Projects including use of animal models

Any project involving animals testing must be accompanied by a specific authorization of the Ethics/Technical Committee of the Institute hosting the animal facility to be presented only after the grant has been awarded, and not later than 31 October 2022.
Furthermore, the PI must declare that the procedures relating to these experiments will follow the indication contained in the legislative decree 2014, n. 26, "Attuazione della

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direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici (14G00036) (GU n. 61 del 14- 3-2014)".

NOTE: *If the approval of Ethic Committee (for clinical trials) or Ethic / Technical Committee (for animals) and "Parere Unico" are not available by 31 October 2022, a follow-up report on the ongoing application either to the Italian Ministero della Salute or the Local Ethical Committee must be sent to this Foundation by email. Providing this information to FFC Ricerca is crucial for the correct management of the grant.*

8. Evaluation of applications

Incomplete or late applications will not be processed for evaluation.

Procedures

Grants will be awarded on a priority basis. Specific factors that will play a major role in determining a successful application are:

- relevance to the FFC Ricerca's mission and to the priority areas (see point 1);
- soundness, solidity and originality of the study;
- relevance of the preliminary results;
- the potential value to improving the clinical and care strategies;
- the potential value to stimulating further studies, mainly on a translational basis;
- the adequacy of the study design;
- the scientific record of the participants;
- reliability of the methods;
- feasibility within the duration of the project;
- adequacy of the host structures.

All accepted applications will be subjected to a preliminary examination by the FFC Ricerca Scientific Direction with the possible support from its Scientific Committee on the basis of their relevance for the mission of the Foundation and the overall quality. A maximum 3 applications selected in this preliminary phase will undergo a full peer-review by international experts. In the final phase, the applications will be discussed by the Scientific Committee during a consensus meeting, taking into due consideration the comments of the external reviewers. The Scientific Committee will also review the budget, and the PI may be asked to reduce the original request and to reshape the budget accordingly. The evaluation of the Committee is final, with the approval of the Board of Governors.

Due to the competitive nature of project selection, projects that have received a positive evaluation by the external reviewers may be denied funding.

The co-funding of projects must be declared and accurately described in the specific section of the application (see Form 10).

9. Research grants

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9.1. FFC Ricerca also reminds that the project must be carried out mainly with the direct involvement of PI and internal and/or external collaborators as indicated in the application.

9.2. FFC Ricerca will directly manage the research grant. Exceptionally, other modes of managing the grant and research collaborators must be discussed with the FFC Ricerca. Upon awarding the grant, FFC Ricerca will provide the PI with detailed information on the procedure to follow.

9.3. Principal Investigator must participate at the Annual Convention of the Italian CF Researchers as guests of FFC Ricerca. Participation in the entire Convention is mandatory because it is a working time on research funded by FFC Ricerca and not just a general updating conference.

10. Awarding and management of research funds

The allocation of funds will be formally decided by the Board of Governors of the FFC Ricerca, and communicated at the time of award. As a rule, funds are disbursed to the PI and not to the Institution where he/she intends to carry out the funded project.
FFC Ricerca will manage directly the funds according to the PI's indications. Approved PI must maintain an accurate and up-to-date administrative account, parallel to FFC Ricerca. With reference to budget indications, expenses will be administered per year.
Award recipients will be required to provide a detailed annual administrative report by the end of the first and by the end of the second year to obtain subsequent payments.
Any changes of the original destination of budget formalized at the time of assignment, occurring during the completion of the project, must be exceptional and formally requested and agreed with FFC Ricerca.
FFC Ricerca will not pay any expenses made after the date of conclusion of the project or in excess of the assigned budget. It is not possible to issue expense orders in the last month of the project. Any costs exceeding the budget will be charged personally to the PI.

11. Scientific and administrative reports, publications

At the end of the first and the second year the PI must provide a detailed scientific and administrative progress report, which is necessary to decide the continuation of the funding. At the end of the project, the investigators are invited to submit, together with the administrative report, a final scientific report including any publications and congress presentation abstract referring to the project. Papers or abstracts reporting the project results need to be forwarded to the Foundation when submitted for publication. No publication or dissemination of the results of ongoing research should jeopardize the future patenting of any research results as a form of pre-dissemination.
The Fondazione per la Ricerca sulla Fibrosi Cistica must be acknowledged in all publications deriving from the funded project (congress abstracts, book chapters, scientific articles, congress slides, press releases, etc) specifying the code of the relative grant and by inserting the FFC Ricerca logo both on the slides and the posters of the congress. Furthermore, the adopters of a project, as indicated by FFC Ricerca, have to be mentioned (see Progetti di ricerca on FFC Ricerca website).
FFC Ricerca may ask investigators to collaborate to public commitment and dissemination of the results of their research in order to support the fundraising of FFC Ricerca. To this end, it is up to FFC Ricerca to contact the investigators.

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12. Research results, intellectual property and patents

One of the main goals of FFC Ricerca is to translate research findings into clinical applications available to CF patients. Sometimes, this can be achieved by partnering with the industry, so that the most promising research results can be fully developed into therapies, devices and diagnostics.
FFC Ricerca requires that all scientific results derived from projects finances by FFC Ricerca, which are of importance for a possible development, are evaluated for the purposes of patent protection and/or commercial valorization.
Funded scientists must promptly notify FFC Ricerca in writing of the intention to file any patent and the execution of agreements with for-profit entities relating to the results of research funded by FFC Ricerca.
The patent application relating to results from projects funded by FFC Ricerca must first be discussed and authorized by FFC Ricerca. The dedicated institutional offices of the founded investigators (TTOs - Technology Transfer Offices) can provide support and assistance on intellectual property matters and technology transfer activities.
In any case, the intention to file a patent application must be previously communicated to FFC Ricerca, in time to allow negotiations between TTOs of the PI's/Collaborators Institutions and FFC Ricerca regarding evaluation of the expenses incurred by each of them and the percentage of ownership of the patent of each of the parties, both in term of expenses to sustain it and in terms of possible future revenues. The relevant agreement with the funded scientists' institutions shall be negotiate by the parties in good faith.
FFC Ricerca reserves the right to participate in the ownership of any know how, intellectual property and inventions derived from funded projects, proportionally to its investments.
FFC Ricerca is confident that FFC Ricerca funded researchers will operate with clarity and honesty regarding the attribution of relative merit to any work, invention or discovery. FFC Ricerca researchers must always remember that all funds supporting CF research are raised through voluntary donations.

13. Writing and submitting applications

Applications must be written in English and must be as detailed as possible. Applications must be submitted through the dedicated online platform https://forms.fibrosicisticaricerca.it/en/; no other submission options are available. For first time access a registration is required to create a personal account and allow submission of applications. Care must be taken not to exceed the indicated number of characters in each form. Any images (photos, graphs, tables) must be low-resolution version, and uploaded as part of one single PDF document (max 25Mb) in section where figures are expected (Preliminary Results, Experimental Plan and Methods).

Applications must be submitted through this platform **by midnight of 15 March 2022.**

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