

FONDAZIONE



Telethon and Monzino Together for The Heart

Introduction

Fondazione Telethon (FT) is an Italian non-profit organization with the mission of advancing biomedical research toward the treatment of rare genetic diseases. FT, thanks to fundraising activities, guarantees the necessary resources for research projects through several funding schemes (for more information <https://www.telethon.it/en/>).

Centro Cardiologico Monzino (CCM) is the first hospital in Europe entirely and exclusively devoted to cardiovascular diseases. Since 1992, CCM provides an intellectual home and a critical mass of researchers who pursue translational research. The research model foresees the constant interaction between basic and clinical research to provide data and results that can tangibly be applied to patients (for more information <https://www.cardiologicomonzino.it/en/>).

FT and CCM are collaborating to solicit **cutting-edge projects in the field of genetic cardiovascular diseases, conducted by outstanding postdocs**. Research will be supported with dedicated funds by CCM and conducted at the CCM for a 3-year period; the applicant will carry on her/his project independently, within the CCM Research Programs and Units, and will be mentored by the Scientific Director. FT will be in charge of the evaluation process. During the project development the selected researcher will be evaluated for future possible recruitment within the CCM research staff after the 3-years period.

SUBMISSION DEADLINES

Call available on FT website on **December 3rd, 2021**.

Online Application and guidelines available on the FT [grants portal](#) and on FT [website](#) by **December 10th, 2021**.

Full Application Submission deadline: **January 31st, 2022**.

Evaluation will conclude by **end of March, 2022**.

Eligibility criteria

Eligible diseases

This call is in support of research projects focusing on **genetic cardiovascular diseases**.

Eligible Projects

Cardiovascular disease burden has greatly decreased thanks to recent pharmacological and surgical advances. However, the employment of advanced therapies, as defined by EMA (<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview>) is still limited in the field, while having the potential of providing an additional therapeutic option where conventional treatment is ineffective, or for specific genetic diseases with no known cure. On the other hand, genetic diseases often represent a forerunner for the development of key knowledge and for research on novel advanced therapies which could be then applied to more frequent diseases. The present call aims at funding translational research projects targeting genetic cardiovascular diseases with a specific focus on advanced therapies. Projects aiming at validating a proof of concept (PoC) for a translatable gene therapy approach will be prioritized.

Eligible Applicants

This Call for applications is intended for Italian and foreign applicants who have completed at least one postdoctoral training showing extraordinary promise and who are ready for a transition to an independent research position. Generally, the most recent doctoral degree (PhD, MD, or equivalent) will have been received at least 3 years before the application is submitted and the candidate will not have reached 40 years of age at the time of call closing. A background in advanced therapies is preferred. Two (2) reference letters assessing the scientific abilities and potential of the applicant must be provided. At the time of submission, applicants can be affiliated with any Host Institution including affiliation within Telethon's Research Institutes (TIGEM, SR-TIGET, and DTI). Applicants with active projects funded by FT can apply.

Budget and duration

Budget up to **350,000 Euros** for 3 years can be requested. This includes a salary up to 150,000 Euros for 3 years based on relevant postdoctoral experiences. Salary support for additional staff is not allowed. The applicant will have free access to all the internal facilities (consumables only will be charged). Please note that a list of all the facilities will be available on this [link](#).

Application details and requirements

Applications must be prepared according to the specific guidelines (Application Guidelines), which are an integral part of this Call.

Guidelines and a sample.pdf of the Application will be available by December 10th, 2021 on the grants portal and on FT website.

Specific Requirements for the Application:

- All studies using biological material of human origin and/or involving human subjects must comply with the relevant Italian laws
- All studies employing vertebrate animals must comply with the relevant Italian laws.

THE EVALUATION PROCESS

Applications that are incomplete, do not comply with the requirements stated in this Call for Applications and pertinent Guidelines will not be accepted.

Procedure

All Telethon staff and reviewers involved in the evaluation of Applications are bound by strict confidentiality and conflict of interest rules defined by Telethon.

All Applications will be reviewed by the Telethon Scientific Committee: an international panel of experts (the panel composition, once defined, will be available in the dedicated section at the link: <https://www.telethon.it/en/what-we-do/research/research-calls/telethon-and-monzino-together-for-the-heart-2%20>). Grants will be awarded on a competitive basis.

The Peer Review process entails two separate and consecutive phases: Remote evaluation and Interviews.

Phase I – Remote Evaluation

Applications will be evaluated by the Telethon Scientific Committee members according to the following criteria:

Scientific merit (is the proposed research excellent?)

- Significance and Innovation
- Appropriateness of design and methods
- Preliminary results (if available) or data supporting the hypothesis and the feasibility
- Feasibility and appropriateness of the budget
- Potential impact on patients

Research Experience (Is the applicant qualified to conduct the proposed research?)

- Qualification and research experience of the Applicant in the cardiovascular and/or advanced therapies field
- Reference letters
- Publications, prior research training and career plans.

After the remote evaluation, a shortlist of the top ranking projects and candidates will be prepared.

Phase II – Interviews

Shortlisted Candidates will be invited to an interview with the Telethon Scientific Committee within the plenary review session that will take place by the **end of March, 2022**.

Award notification

The candidates will be notified of the evaluation outcome by **mid-April, 2022** and will have access to their online Review Summary by **end of April, 2022**.

Administrative details will follow by CCM within 2 weeks after FT notification.

Privacy of personal data

Telethon Foundation informs that the Data controller of the Applicant's data, as well as of any Collaborator involved in the application, is identified in the CCM - with operational headquarters in Via Carlo Parea 4, 20138 Milan - in the person of the Chief Executive Officer, Mauro Melis. CCM, as required by law on the processing of personal data, provides appropriate Privacy Notice within this call (Appendix 1). FT, based on art. 28 of the European Union Regulation 2016/679, has therefore been appointed Data Processor by the Data Controller.

It should be noted that this Privacy Notice cancels and replaces any other that the Applicant and Collaborators may receive through the platform.

The Applicant is responsible to provide the Collaborators with the attached Privacy Notice and to thereby gather the relevant consents.

December 3rd, 2021

FONDAZIONE TELETHON

INFORMATION ON DATA PROCESSING

In the contest of medical and scientific research activities aimed at the treatment of cardiovascular diseases, and specifically, to select researchers and projects in the area of genetic cardiovascular diseases, Centro Cardiologico Monzino (CCM) signed a collaboration agreement with Fondazione Telethon, which will conduct the phases of the funding process described below through the “Tetra” Platform (hereinafter the “Platform”):

a) Application – Participation to calls

The purpose of the Platform is to allow the Organizations/Institutions interested, who wish to request financial contributions (hereinafter “**Contributions**”), to present their projects, through the researchers affiliated to them (these researchers are defined “**Applicants**”), according to the specifications contained in the pertinent research calls and the guidelines published by Fondazione Telethon. Within the projects, the Applicants may indicate the personal details of other researchers **involved** in various capacities **in the project presented** (these researchers are defined “**Researchers**”).

b) Review process

The presentation of the projects by the Applicants allows the activation of the review and selection process of such projects by the researchers chosen by Fondazione Telethon as members of the Scientific Committee or identified ad hoc because of the specific nature of the project (these researchers are defined “**Reviewers**”). The review process will be carried out on the Platform, through which the Reviewers will have direct access to the projects presented to the Call.

The aim of the selection and review process carried out by the Reviewers is to select from a scientific point of view those projects most deserving of Contributions.

c) Payment of Contributions

The Contribution will be assigned by CCM, up to the amount of available funds.

In view of the foregoing, it follows that CCM in the process of assigning the Contribution, will process, *inter alia*, the personal data of the following subjects:

- **Applicants**
- **Researchers**

Hereinafter jointly referred to as the “**Users**”.

To guarantee proper, transparent processing of the Users’ personal data, CCM provides the following information, under the provisions of art. 13 of European Regulation no. 679/2016.

A) Identity and contact data of the Data Controller and Data Protection Officer

Users' personal data will be processed by the Data Controller, identified as Centro Cardiologico Monzino, with headquarters in Via C. Parea 4, 20138 Milan (hereinafter the "Data Controller").

The DPO of CCM is Dr. Massimo Monturano, who can be contacted at: privacy@cardiologicomonzino.it or direzione.sanitariaccm@legalmail.it

B) Personal data processed

For this activity, the Data Controller will mainly process Users' data that can be described as personal and identifying data.

C) Purposes and legal bases for processing

The Data Controller has identified the following as legal bases on which data processing and the purposes thereof are deemed lawful:

- 1. Purposes for fulfilling a legal obligation (art. 6 para. 1 lett. (c) of Regulation (EU) no. 2016/679):**
 - the management of preliminary activities for the carrying out of the institutional activity of the Data Controller, and specifically, the formal assessment and assessment of the merits of the projects submitted for the research call;
 - the communication of data for fulfilling general transparency obligations.
- 2. Purposes necessary for the execution of a contract or pre-contractual activities with the data subject (art. 6 para. 1 lett. (b) of Regulation (EU) no. 2016/679):**
 - to allow the Data Controller to have the research project to be funded assessed by the Reviewers, in implementation of the research call;
 - to allow the management of operational activities aimed at guaranteeing payment of any contributions, in implementation of the research call;
 - allow the management of administrative, accounting and fiscal processes, in implementation of the agreement for the assigning of Contributions in the event that a Contribution is to be paid for the project presented by the Applicants;
 - to allow the Data Controller to assess the administrative and scientific report, in implementation of the contract for the assigning of Contributions in the event that a Contribution is to be paid for the project presented by the Applicants.
- 3. Purposes pursued based on a legitimate interest on the part of the Data Controller (art. 6 para. 1 lett. (f) of Regulation (EU) no. 2016/679):**
 - to file the data strictly necessary for monitoring, analysis and research activities, including records and statistics.
 - communication and promotional activities regarding institutional activity.
- 4. Purposes pursued based on consent (art. 6 para. 1 lett. a of Regulation (EU) no. 679/2016):**
 - to allow the Data Controller to transmit the personal data of the Applicants whose projects have received a Contribution, through institutional channels, mass media and on the occasion of scientific events, to (i) allow the carrying out of the analysis, research and monitoring activities aimed at further study and improvement of the scientific research funding activity of the Data Controller, through institutional channels, mass media and on the occasion of scientific events, and (ii) facilitate the transmission of the scientific content promoted by the Data Controller.

Users' personal data will be processed in digital format and will be held on the Platform. The Data Controller will have the right to export some data or reports and file them on their database.

D) Recipients or categories of recipients and areas in which personal data may be transmitted.

Users' personal data may be transmitted to:

- i) personnel of the Data Controller, in particular to employees and workers dealing with the specific activities for which the data are processed, authorised for processing under the direct authority of the Data Controller pursuant to article 2-*quaterdecies* of Legislative Decree no. 101/2018;
- ii) third parties who deal with the development and maintenance of IT tools, or who provide services instrumental to the purposes specifically indicated (merely by way of example, companies that manage and/or take part in the management and/or maintenance of the Platform), who will operate based on specific confidentiality clauses, or, where necessary, specific appointments as data processors, with the possibility to appoint another

processor on a case-by-case basis in compliance with the aforementioned regulation to protect the confidentiality of the data acquired by the Data Controller; in this specific case, Fondazione Telethon acts as Data Processor in the name and on behalf of CCM, which acts as the Data Controller.

- iii) third parties, for the fulfilment of publicity obligations established by regulatory measures, or when necessary for reporting the institutional activity carried out or representing the Data Controller, or connected to the operating procedures adopted for the pursuit of their institutional purposes;
- iv) third parties entrusted with carrying out fiscal/legal consulting or account auditing activity, for which they will acquire the data as independent data controllers;
- v) the competent authorities and/or public bodies and supervisory and control bodies, for the fulfilment, where necessary, of legal obligations; research centres, agencies and communication companies, and other subjects working in any capacity with the Data Controller for the achievement of their institutional purposes;
- vi) Reviewers identified, for their scientific skills, as suitable to assess the research projects presented for the research call and appointed as subjects authorised to process personal data. The data will be transmitted through the Platform on which the assessment process is carried out.

E) Duration of processing and period of processing

Users' personal data will be stored for the time necessary for the execution of the project, and then for a period no longer than 10 years from the end of the project. The personal data may be stored further for filing processes, based on the continual, lasting nature of the scientific research that is part of the institutional purposes of the Data Controller, as a result of which it may be necessary to access the project data again for monitoring, analysis and research, in compliance with the principle of data minimisation.

F) Rights of Users

Concerning the aforementioned data processing, Users may exercise the rights referred to in art. 13 of **REG.EU no. 679/2016** and expressed in more detail in arts. 15-16-17-18-20-21 and 22 of **REG.EU n. 679/2016**. Specifically, they shall have the right to:

- 1) obtain confirmation as to whether or not personal data concerning them are being processed;
- 2) ask the Data Controller for access to their personal data, as well as the right to data portability;
- 3) have their data updated, rectified, or if in their interest, completed;
- 4) object, in whole or in part, for legitimate reasons, to the processing of personal data that regard them, even if pertinent to the purpose for which they were collected;
- 5) obtain the deletion and anonymisation or block of data processed in breach of the law, including those it is not necessary to store with the purposes for which the data were collected or subsequently processed;
- 6) withdraw consent (solely for processing on which a legal basis for consent is required) at any time, without prejudice to the lawfulness of processing based on consent given before withdrawal;
- 7) make a complaint with a supervisory authority.

G) Nature of the communication of personal data and consequences of refusal to provide them

Refusal to provide data and/or the provision of inaccurate and/or incomplete information regarding personal data processed on a legal basis other than consent will make it impossible to pursue the corresponding purposes, i.e. the carrying out of contractual and pre-contractual activities.

The provision of data about processing for which consent is required is optional, and if said consent is refused, it will not be possible to use the data for the transmission and communication purposes specified above.

H) Transfer of data

The personal data processed through the Platform managed by Fondazione Telethon in its capacity as Data Processor are stored in data centres located in the United Kingdom. Transfer of data to the United Kingdom is currently considered lawful by the Italian Data Protection Authority, based on the commercial and cooperation agreement signed on 30 December 2020 between the United Kingdom and the European Union.

In addition, Users' personal data present on the Platform will also be processed by Reviewers who may occasionally be located in countries outside of the European Union for which the European Commission has not issued an adequacy decision for the processing of personal data, for the sole purpose of the assessment of the projects in implementation of the call, and therefore because it is necessary for the execution of the contract to which the data subject is a party. In this case, personal data will be transferred under art. 49, para. 1 lett. b) of Regulation (EU) no. 2016/679, and the Data Processor will endeavour to guarantee the maximum security of the data received, in compliance with the regulations in force, establishing that the entire selection and review process shall be carried out by Reviewers with adequate guarantees.

Milan, December 3rd, 2021

The Data Controller
 Centro Cardiologico Monzino

Consent for the transmission of the personal data of the Applicants whose projects have received the Contribution (Applicants Funded)

I, the undersigned _____, born in _____, on _____, in reference to the Project " _____",

declare

- that I have read and understood the content of the information provided by Centro Cardiologico Monzino, in its capacity as Data Controller, and that I am aware that if the project presented for the call is a recipient of the Contribution, my personal data may be transmitted to (i) allow for the carrying out of analysis, research and monitoring activities aimed at the further study and improvement of the scientific research finding activity of the Data Controller through institutional channels, the mass media and during scientific events, and (ii) facilitate the transmission of the scientific content promoted by the Data Controller.

I agree

I do not agree

Date and signature
