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

15th December 2022

ITALIAN CYSTIC FIBROSIS RESEARCH FOUNDATION (FFC Ricerca)
CALL FOR GRANT APPLICATIONS YEAR 2023

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 provide a breakthrough in the understanding of the molecular basis of the disease.

Relevant features of the call

- Applicants can submit only one project for this call.
- Principal Investigator (PI) or Coordinator and Partner must have a permanent position; their salary coverage is not provided.
- Applicants can submit projects **lasting 12, 24 or 36 months**.
- Total budget for three options are:
  - **12-months** project: **70.000 euros**
  - **24-months** project: **130.000 euros**
  - **36-months** project: **200.000 euros**.
- For clinical research projects only, the cost for salary coverage can exceed 40% of the entire budget.
- **Deadline** for submitting applications: **15th February 2023**.

FFC Ricerca anticipates to finance between 15 and 20 projects, depending on the type and quality of the applications and the availability of funds.

1. Priority areas

This Call for grant applications aims at funding projects focused on the following 5 priority areas in the field of CF research:

1.1. Understanding and treating CFTR basic defects: design of new approaches to correct defective CFTR or to compensate for its deficient function with the following particular indications:

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

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1.2. **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 finalized to correct the CFTR defect.
1.3. **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.
1.4. **Inflammation in CF**: innovative strategies to contain the inflammation-based pathology.
1.5. **Clinical applications and epidemiological studies**: clinical trials, with special regard to phase IV clinical studies (post-marketing studies in the real life) and those to improve the outcomes of lung transplantation in CF; review and update of traditional therapies that involve a heavy burden on sick people; innovative diagnostic approaches to predict and monitor the evolution of the disease also in the context of new therapies; epidemiological studies and systematic reviews with reference also to the database of the Italian CF Registry; studies on the correlation between climate changes, environment and the health of persons with CF.

General notes and recommendations

- Research proposals in which **translational objectives** are clearly evident will be prioritized.
- Accordingly, research projects dealing with either **clinical studies or pre-clinical** studies exploiting animal models of CF or performed on primary CF cells culture are encouraged.
- Multicentre projects involving **international partners** and collaborators are encouraged. Please note that researchers working in foreign research centers are admitted to the call and can manage their own project budget, see *2.Eligibility criteria* and *3.Budget* session below.
- FFC Ricerca also encourages projects focused on studies on **rare mutations and/or mutations not susceptible to current 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 CF cells.
- The study must be supported by preliminary data already acquired; **this call does not fund proof of concepts (PoC)**.
- Researchers should consider the **facilities offered by FFC Ricerca** in the design of the projects presented (see also Appendix 1):
  - **Servizio Colture Primarie (SCP)** which collects primary cell cultures obtained from bronchial epithelium of CF and non-CF patients. For further details please visit the dedicated webpage and contact the service coordinator. At this link is available the SCP ppt slides showed during the 2022 webinar.
  - **Cystic Fibrosis animal Core Facility (CFaCore)** which develop and provides mouse models for research applications in CF field. For further details please visit the dedicated webpage and contact the service coordinator.
  - **Cystic Fibrosis Data Base (CFDB),** the data base of clinical interventions in CF: http://www.cfdb.eu. For further details please visit the dedicated webpage and write at info@cfdb.eu. At this link is available the CFDB ppt slides showed during the 2022 webinar.
- **FFC Ricerca facilities** (SCP, CFaCore, CFDB) must be considered as a service, therefore the facility coordinators must not be indicated as partners or collaborators. Please see guidelines at point 4 (Outside Collaborations/Services) to fill in the Form 9.

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- FFC Ricerca encourages **repurposing** studies if there is a strong rationale that demonstrates the validity of the approach in the context of CF pathology.
- Studies aimed at identifying **new therapeutic compounds** will also be taken into consideration, provided that they suggest new strategies to affect mutated CFTR function and/or CFTR-dependent mechanisms of cell pathology, also including modification of DNA and RNA. Both types of studies may exploit *in vitro* or *ex vivo* primary cell models.
- **FFC Ricerca will not fund formal preclinical studies**, with the exception of those addressing the drug/compound effects on animal models of CF pathology, when existing and available, and limited to provide the 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 aimed at identifying **new antimicrobial strategies** will only be considered if original strategies are proposed, along with enough preliminary data, to support a potential advantage vs. conventional treatment protocols. FFC Ricerca will not consider studies aimed at the identification or preliminary characterization of hit compounds active against multidrug-resistant pathogens unless a clear advantage over current agents (even at the pre-clinical stage) is expected for treating CF infections.
- Collaboration and transferring of knowledge and expertise from basic to clinical research is particularly recommended. To this aim 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 means not only "bench-to-bedside" studies. Research projects considering the translation of results from clinical studies into everyday clinical practice and health decision making are also welcome. Topics to be considered include clinical epidemiology, communication, behavioral science, organizational theory, quality monitoring and quality improvement research.

2. Eligibility criteria

- **Scientists with scientific track record** of at least 3 experimental/clinical papers as first/last/corresponding author in the last 5 years (these papers have to be highlighted with an asterisk in the P.I./Coordinator's curriculum vitae in **Form 6**) are eligible to apply as PI or Coordinator of a multicenter project.
- **The PI or Coordinator must have a permanent position.** FFC Ricerca will also consider applications from RTD researchers ("fixed research contract", as stated in the Italian Law 240/2010, article 24, clause 3, for the University system): this type of applicants must meet the criterion of scientific independence providing that their contract **completely** covers the duration of the funding period (a copy of the contract must be submitted).
- The role of **Coordinator** of a **multicentre project** can also be assumed by researchers who live and work in another country of the European Community, provided that the project includes at least one partner who lives and works in Italy. Partners of a multicentre project may be co-opted by an Italian coordinator even among scientists living and working in any country outside of Italy. In case of funding of a foreign research institution, the budget could be transferred to such institution only upon written agreement with FFC Ricerca.
- **Partners** are those scientists providing an autonomous (though coordinated), active and substantial contribution to a specific part of the project. The FFC Ricerca does not

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consider Partners those who work as collaborators in the PI or Coordinator's group or in their laboratory or hospital ward. Individuals involved in supplying biological materials, or clinical and biological data are not eligible as Partners and should rather be enlisted as internal or external Collaborators.

- **Partners** must have a permanent position. Also RTD researchers (with "fixed research contract" as stated by the Italian Law 240/2010, article 24, clause 3, for the University system) are eligible: in that case they must attach a copy of their contract with a declaration of the legal representative of the host institution, as specified above for PI (see also point 5).
- **PI (or Coordinator)** cannot be Partner or PI or Coordinator in other FFC Ricerca projects simultaneously, including projects funded by FFC Ricerca which are in progress, unless they will be concluded on 31st August 2023. A researcher can be a simultaneous partner in no more than two FFC Ricerca projects as long as he/she is not a PI/Coordinator in another project.
- The **position and function of partner** should not be confused with that of **external collaborator**. External collaborators are usually researchers with limited roles and functions in the specific project, functions that are not to be confused with "provision of external services", which have their own specific position and specific treatment in the identification of costs. An external collaborator cannot be involved in more than two FFC Ricerca projects.

3. Budget

The budget description (**Form 10**) must be accurate and every item must be justified and detailed per each research unit and per each year of the funding period. **Inadequate budget description will lead to rejection of the project**. The maximum budget request cannot exceed:

- € 70.000 for one-year projects,
- € 130.000,00 for 2-years projects,
- € 200.000,00 for 3-years projects.

Please note that for clinical research projects, the salary coverage can exceed 40% of the entire budget.

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

- Small research equipment or accessories and software (justified and related to the current project): not more than 7% of the total budget.
- Consumables and animals.
- Fellowships or research contracts (for graduates and technicians). See also point 9 of the Call and also take into account the exception for clinical research projects.
- Travel and scientific meeting participation (international conferences on CF), training sessions: no more than 4% of the total budget.
- Publication expenses, with clear reference to the project funded by this call (max 2,5% of the budget).
- Costs for patients participating in clinical trials such as insurance coverage and travel costs.
- Overheads (general expenses not provided for in the previous items, but in any case compatible with the admitted expenses): cannot exceed 3% of the total budget.
- External and occasional professional or technical services for no more than 20% of the total budget). Expenses for clinical consultancy or patentability analysis.

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3.2. Ineligible costs:

- Salary and wages for PI, Coordinators, Partners and internal or external collaborators (with the exclusion of personnel above mentioned for FFC Ricerca fellowship or research contract).
- Furniture and stationery articles.
- PC and other hardware.
- Software not specifically related to the project.
- Basic lab or clinical equipment.
- Equipment repairing or technical assistance fees.
- Office materials.

4. Guidelines to fill in the forms

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

General note for filling in the forms: please **avoid past/copy of formatted text** (such those from PDF files) which could create technical problems in downloading the final PDF of the application. We suggest you copy the text in a .txt file and, then, copy it in the application forms.

- **Form 1 - General information**. Project title, name of the principal investigator, or coordinator for multicentre studies, host institution, project duration (1 to 2 years); type of application (new, resubmitted, renewal of a project both concluded or in progress); research area; name of the partner/s, their host institutions, names of collaborators (internal and external) really involved in the project (in the case of multicentre study specify the collaborators for each research team) and their host institution and specific roles in the project. For each collaborator, please provide a brief biosketch. The acceptance of collaboration must be supported by personal declaration (see also point 5, *Additional documents*). Also, the main personal data have to be included in the form, both for PI and Partner/s.
- **Form 2 - Project overview.** 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.
- **Form 3 - Research Plan: Background, Specific Aims & Rationale.** The originality of the project must be clear from these items. The cited bibliography must be reported in this section.
- **Form 4 - Preliminary Results.** They must be proved and convincing and refer to the results obtained by the applicant in preliminary investigations bearing the rationale 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 regarded 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.
- **Form 5 - Experimental Plan and Methods.** In this part it must be specified in detail: the research plan or clinical protocol, methodology and materials intended

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to use, justified numerousness of the samples (whether patients or animals) which are going to be examined and the statistical methods that are going to be applied for results evaluation. Moreover, it is requested a description of the development phases of the project, even temporal (timeline), quality controls, and whole pertinent references. Also, the organization and the management to assure quality and feasibility of the project have to be described. It would be interesting if the critical points of the experimental plan are detailed, and the eventual "B plans" indicated in case problems are found. If applicable, please describe in this section a realistic way to valorize the project results in terms of translational research. Gantt chart must be uploaded in this section.

- **Form 6 - Curriculum vitae.** Education and training, previous job and research experiences, significant publications **in the last 5 years** (only in peer-reviewed journals). Please indicate with an asterisk the publications in which you are first/last or corresponding author. For multicentre study enclose also Partners' CV and publications of the **last 5 years.**
- **Form 7 - Roles and Contribution of Coordinator and Partner(s) in the project**. The coordinator has to fill in this part with a detailed description of the specific contribution of each partner in the project. Description of the coordinator's strategies to monitor each team activities, to facilitate communication among one another, to promote exchanges of ideas and methods, to integrate research phases and results.
- **Form 8 - Features and facilities of the unit.** Laboratory spaces; clinical, IT, laboratory equipment; technologies and services available for the realization of the project must be detailed, indicating their specific relevance to each phase of the experimental plan.
- **Form 9 - Outside Expertises/Services.** They have to be considered as external technical services or professional consulting/performances. If required, facilities of FFC Ricerca must be reported in this section.
- **Form 10 - Budget.** Specify the expenses both overall and per each year; in case of multicentre study, also per each partner (see point 3). Any other financial supports must be indicated in this section, reporting the related details (description, amount, project title, granting agency).
- **Form 11 - Lay Summary.** This must be written both in English and Italian (including Italian title), in a popular and well comprehensible 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). In the Appendix 2 you can find some tips to help you write the lay summary.
- **Form 12 - Cover letter and scientific report.** Upload the Cover letter and the scientific report (if applicable) in this form. The scientific report is required in the case you are asking for the renewal of a project that has already been completed or is about to be completed.
- **Form 13 - Additional documents – Upload area.** Use the dedicated optional box "**Referees**" in this form to provide any name of reviewers to suggest or to exclude, please indicate name, surname, affiliation and email. Upload all required documents in this form.

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- **Form 14 - Validate and Download PDF.** This section reports any empty fields or errors that are highlighted in red. By clicking on the empty fields, the system opens the section that needs to be filled out. Download the application in PDF format by clicking on the "Download/print this project" button (at the left of the page). You can download the PDF at any stage. Once the application is competed (no errors are highlighted), click on "Validate and send" to complete the submission and send the application to FFC Ricerca's Scientific Direction.

5. Additional documents (See Forms 12 and 13 in the application platform)

5.1.Cover Letter

Each project must be accompanied by a cover letter that summarizes the overall project plan and the reasons why it falls within the priorities indicated in the call for applications, in line with the Foundation's mission objectives and why it is believed that FFC Ricerca should consider the project worthy of funding. If applicable, in the cover letter the applicant must declare (specifying the details) any **patent registration**, completed or in progress, for an invention referring to the proposed project.
Resubmitted projects (previously submitted to FFC Ricerca and not approved) require extensive explanation (see point 6), and cannot be resubmitted with only minor tweaks. Resubmissions must include in the cover letter point-by-point answers to the reviewers' critiques.
For **Renewal projects** the scientific report must be included (by attaching it in the appropriate box in Form 12). The scientific report must include the details of the project's achievements, the contribution of each Partner (for multicentre projects) and a list of the resulting publications and congress presentations (abstracts).

Cover letter and scientific report (applicable only for Renewal projects) must be uploaded in the **Form 12.**

5.2.Individual project

- Acceptance by the host Institution of the PI.
- Copy of the contract and its duration (see point 2), in case the PI or Partner has no permanent position.
- Consent for use of personal data, according to the Italian Law 196/2003.
- Declaration of commitment (signed, scanned copy) by each internal and external collaborator involved in the project and listed in the application.
- PI declaration of adherence to provisions governing laboratory animal care, if applicable.

5.3.Multicentre Project

The coordinator of a multicentre project is the only responsible for both the accuracy and the completeness of all the documentation submitted to the Italian CF Research Foundation (including those of partners' centres). Researchers (coordinator or partner) working in foreign institutions can manage their own project budget in accordance with specific agreement with FFC Ricerca issued after the possible funding (see *2. Eligibility criteria* and *3. Budget*).
Coordinator: see documents required for individual project.

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Partners: each partner has to transmit to the coordinator (who will send them to FFC Ricerca) the following documents:

- Acceptance of partnership (along with personal data and consent to use them, address, telephone and fax number, e-mail and fiscal code)
- Copy (just scanned copy) of the time contract, in case of not permanent position
- Declaration of acceptance by the host institution
- Partner's declaration of adherence to provisions governing laboratory animal care, if required
- Declaration of commitment (signed, scanned copies) by each internal and external collaborator involved in the project and listed in the application. A single pre-compiled form to fill in with the names and signatures of all collaborators is available in the "Administrative documentation - Upload Area" of the platform.

5.4.Clinical project

Projects that fall into this area of intervention must be clearly patient oriented. They must include, even just in part, diagnostic, therapeutic or rehabilitative interventions on humans, not provided for in common standard or from the personal plan of diagnosis, care and rehabilitation.

5.4.1.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 (for each partner/centre, if multicentre study) to be sent to FFC Ricerca after award of the grant and not later than 31st October 2023;
- "Parere Unico", released by the Ethical Committee of the Principal Investigator/Coordinator/Partner's centre (if applicable) (not later than 31st October 2023 if the project will be funded);
- Informed consent form (for interventions and for use of personal data, in anonymous form, for research purpose, released by patients or people involved in the study) plus patient information leaflet;
- Good Clinical Practice declaration by the applicant.

5.4.2.Methods and data management

For the preparation of a clinical application, FFC Ricerca suggests to follow 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 are also available at the link of the Equator Network Initiative.

Multicenter clinical studies are advised to use a web-based Case Report Form (CRF). Data management and monitoring could be more appropriately supplied 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-efficient. Costs and agreement with the CRO have to be reported in the budget.

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5.4.3. Projects including use of animal models

Any project which includes experiments on animals must be accompanied by a specific authorization of the Ethical/Technical Committee of the Institute hosting the animal facility to be submitted only after award of the grant and not later than 31st October 2023. Moreover, the PI or coordinator must declare that the procedures concerning those experiments will follow the instructions included in the legislative decree 2014, n. 26, "Attuazione della 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 Ethical Committee (for clinical trials) or Ethical / Technical Committee (for animals) and "Parere Unico" are not available by 31st October 2023, 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 the FFC Ricerca Foundation is crucial for the correct management of the grant.*

6. Resubmitted projects

Researchers who are going to resubmit a project previously not funded by FFC Ricerca, even with a different title and improvements, must follow these recommendations:

- The **cover letter** must highlight the year of the previous submission and the relevant modifications of the revised one.
- If the previous application underwent full review, the cover letter must also include detailed, point by point, reply to the critiques of the referees and FFC Ricerca Scientific Board.
- In case the revised application is submitted by a different PI, an explanation must be provided in the cover letter.
- **The same research project can be resubmitted only once, even if substantially modified.**

7. Submission of applications by former FFC Ricerca grant recipients

A former FFC Ricerca grant holder may submit a new project or a proposal of development of a project already funded by FFC Ricerca ("Renewal project"). In both cases all of the following must apply:

- The previous project has been completed and its final scientific report has been already submitted to FFC Ricerca. The scientific report must include details of the project's achievements, the contribution of each Partner (for multicentre projects) and a list of the resulting publications and congress presentations (abstracts).
- Coordinators or partners in a multicentre project financed by FFC Ricerca may submit a new research proposal as PI or Coordinator (see the conditions in 2.) provided their previous projects were completed or that the ongoing project expires on 31st August 2023, and that they are not involved in other FFC Ricerca projects in accordance with the provisions of point 2.

8. Evaluation of applications

Incomplete or behind schedule 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 outcome of the application are:

- relevance to the Italian CF Research Foundation's mission and to the priority areas (see point 1);
- soundness 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 translational basis;
- the appropriateness of the design of the study;
- the scientific record of the participants;
- methods reliability;
- feasibility within the duration of the project;
- facilities appropriateness;
- clarity and quality of lay summary.

All accepted applications will undergo a preliminary review by the Scientific Committee of the Italian CF Research Foundation on the basis of their relevance to the Foundation's mission and overall quality. Projects selected in this triage step will undergo full peer-review by an international panel of experts. In the final step, the projects will undergo evaluation by the Scientific Committee, taking in due consideration the independent referees' comments. The Scientific Committee will also review the research activities related to the required budget and the project duration. **If the proposed activities and the budget are not considered consistent with the duration, the project will be rejected. 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. Co-funding of projects must be declared and accurately described in the appropriate section of the application (see Form 10).

9. Fellowship and research grants

9.1. Cost for salaries cannot exceed 40% of the total amount of the grant, with the exception for clinical research projects (see below, point 9.2).
9.2. Clinical research projects can apply for more than one contract per year for the entire duration of the project and the related costs can exceed 40% of the required budget. Please consider a maximum cap of 31.000 euro per year for graduated personnel.
9.3. FFC Ricerca also recalls that the project must be conducted mainly with the direct involvement of PI/Coordinator, partners and internal and/or external collaborators as indicated in the application.
9.4. The life of the research grant (including the part concerning scholarships and contracts) cannot exceed the duration of the project and will expire at its end date.
9.5. FFC Ricerca will directly manage the research grant (including scholarship or contract). Exceptionally, other modes of administration of the grant and research collaborators must be discussed with the FFC Ricerca. On assignment of the grant, FFC Ricerca will provide to the PIs or Coordinators detailed information about the procedure to follow.
9.6. Fellows or contract holders have to be mentioned in any documents or publications as "Italian CF Research Foundation fellow/contract holder". The FFC Ricerca reserves

the right to have direct contacts with the fellows or contract holders and to ask for periodical progress reports on their work in the project.

9.7. Principal Investigators/Coordinator, Partners and fellows or contract holders must participate at the annual Convention of the Italian CF Researchers as FFC Ricerca guests. The attendance to the whole Convention is mandatory because it is a working time on research funded by FFC Ricerca and not just a general update conference.

10. Awarding and management of research funds

The awarding of funds will be formally decided by the FFC Ricerca Board of Governors and communicated on assignment. As a rule, funds are given to the PI and not to the Institution where he/she intends to carry out the funded project.
The FFC Ricerca will manage directly the funds according to the PI's or Coordinator's indications. Approved PI/Coordinators and Partners have to keep an accurate and update account, in parallel to CF Foundation. With reference to budget indications, expenses will be administered per year and per each partner centre.
In case of 2-year or 3-years projects, award recipients will be expected to provide a detailed yearly administrative report by the end of September to obtain subsequent payments.
Any changes of the original destination of budget formalized on assignment, occurring during the fulfillment of the project, must be exceptional and formally asked and agreed with FFC Ricerca.
FFC Ricerca will not pay any expenses made after the date of conclusion of the project or exceeding the budget assigned. No expense orders can be issued in the last month of the project. Any costs in excess of the budget will be charged personally to the PI or Coordinator.

11. Scientific and administrative reports, publications

At the end of each year of activity 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. Any publication or congress abstract relevant to the project must be forwarded to the Foundation before such reports to be published.
No publication or dissemination of the results of ongoing research should jeopardise 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.

12. Research results, intellectual property and patents

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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 negotiated by the parties in good faith.
The FFC reserves the right to participate in the ownership of any know how, intellectual property and inventions derived from funded projects, proportionally to its investments.
The funded researchers must promptly inform FFC in writing of the intention to file any patent and of any proposal by for-profit entities related to FFC funded research results.
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 detail and submitted only through the dedicated online platform https://forms.fibrosicisticaricerca.it/en/, other options are not available. For first time access a registration is required to create a personal account and allow applications submission. Attention must be paid to not exceed the indicated number of characters in each form. Any images (photos, graphs, table
s) must be low-resolution version and inserted in the text near the point to which they refer. Applications must be submitted through this platform **by midnight of 15th February 2023.**

Appendix 1 - The FFC Ricerca facilities

- **SCP – Primary Cell Facility (Servizio Colture Primarie)**

Established in 2012 the primary cell facility, born from the collaboration between the FFC Ricerca and the Medical Genetics laboratory of the Giannina Gaslini Institute in Genoa, provides a collection of **cell cultures obtained from bronchial epithelium of both CF patients and non-CF** control subjects to CF researchers. The bronchi, from which the

cells are isolated, come from the transplant center in Milan (Thoracic Surgery Unit, Polyclinic of Milan).

The **aims** of the facility are:

- the study of the pathophysiology of cystic fibrosis.
- the evaluation of therapeutic strategies.

The **cells and available services** are:

- collection of primary bronchial cultures isolated from bronchi of explanted lungs from individuals undergoing lung transplantation (CF patients or subjects transplanted for other pathologies)
- protocol for the correct cultivation of the submitted cells;
- training in SCP's laboratories.
- advanced tests depending on researchers requests and the expertise acquired by the lab.

The following is a list of cells **genotypes** available in the facility:

F508del/F508del	F508dl/G85E
F508del/G542X	F508del/2184insA
F508del/R1162X	F508del/1259insA
G542X/711+5G->A	F508del/3878delG
del Ex 22-23-24/UK	F508del/1874insT+Y577F
F508del/1717-1 G->A	1525-1G->A/G458R
F508del/R553X	F508del/L927P
F508del/delE 17A-18	N1303K/711+5G->A
R1162X/3849+10KbC->T	F508del/L1077P
F508del /3849+10KbC->T	F508del/C276X
F508del/R1066H	R1162X/2789+5G->A
F508del/N1303K	R1006C/M1V
F508del/621+1G>T	N1088D/G542X
	2789+5G>A/R1070Q

For further information, please write to: direzionescientifica@fibrosicisticaricerca.it.

- **CFaCore - Cystic Fibrosis animal Core Facility**

Established in 2009, the CFaCore is an infrastructure, a stabulary with Biosafety Level 2 (BSL2), with an expertise in animal models for CF that provides different kind of services to CF researchers. CFaCore maintains CF mice colony and provides pre-clinical research to accelerate new strategies for the treatment of CF. Is located at the San Raffaele Hospital in in Milan and is running since 2009. Mice colonies are managed and C57Bl/6 wt and FC mice are used to establish infection and inflammation models. CF-related pathogens such as *Pseudomonas aeruginosa*, *Burkholderia cenocepacia* and *Staphylococcus aureus* and related virulence factors (LPS) are used to create infection and inflammation models. Chronic lung infection is established by the inclusion of pathogens in agar beads and intratracheal administration.
Three levels of services are available to CF researchers:

- Level 1 - distribution of CF mice, such as:
  - CF transgenic mice;
  - Lung infection mouse models;
  - Inflammation mouse models.

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- Level 2 - specialized animal treatments and services, such as:
    - Request to the ethics committee;
    - Acute or chronic infection/inflammation model;
    - Pharmacological treatments;
    - Animal welfare monitoring;
    - Sacrifice and collection of biological samples.
- Level 3 - research project execution:
    - Processing and analysis of biological samples;
    - Statistical analyses.

For further information, please contact CFaCore coordinator Dr.ssa Alessandra Bragonzi, Infections and Cystic Fibrosis Unit, San Raffaele Scientific Institute. bragonzi.alessandra@hsr.it

- **CFDB - Cystic Fibrosis DataBase - www.cfdb.eu**

Established in 2011, the CFDB is a web-based, free access tool for health care professionals, researchers and students to evaluate in real time what are the current evidences about clinical efficacy of interventions in CF.
The CFDB collects more than **1,300 studies divided in 8 sections**, including Cochrane reviews, Cochrane protocols, DARE, HTA and Economic reviews, published RCT, published non-RCT, congress abstracts and ongoing trials. In addition, CFDB collects **50 thematic worksheets**, named *Topics*, on relevant clinical subjects in CF that critically summarize the state of the art of available evidences.

The objective of CFDB is to classify clinical studies to get answers to specific questions:

- which interventions are effective, in which groups of CF patients and for which outcomes?
- to what extent do the results of the literature allow to make decisions for specific clinical issues? What issues need to be studied further?

This tool may help clinicians, researchers, students to have a faster updated view of clinical research in CF by using queries on the main topics in CF care. It could also be helpful to anyone going to design new studies, as it provides a concise description of what is currently known and what issues, on the contrast, need additional research.

What can you do with CFDB?

- You can build a query, selecting terms from search menus;
- You can also select one or more citations and read the details of the studies;
- You can read updated summaries (Related topics) on the state of the art of the most relevant topics in CF.

For further information, please contact CFDB coordinator Roberto Buzzetti at robuzze@gmail.com.

Appendix 2 - How to write a lay summary

What is a lay summary?

A lay summary is a **brief paragraph about your research project**. It explains complex ideas and technical terms to people who do not know about the subject, or a **lay audience**. The audience of FFC Ricerca includes everyone from non-specialists in your field to volunteers, patients, caregivers and the general public.

The lay summary scheme

The lay summary should be no longer than 3500 characters with spaces included, and should consist all of the following sections and questions to answer:

- *Title*
- *Lay Title* [pleas avoid acronyms, e.g. cystic fibrosis not CF]
- *Authors*
- *Affiliations* [University/Institute, Department, City, State]
- *What is your research question?* [max 300 characters with spaces included]
- *Why is this important?* [max 700 characters with spaces included]
  (Explain the impact of the work, what is going to change)
- *How will you do the research?* [max 700 characters with spaces included]
  (Methodological information of how you will carry out your research project)
- *What do you hope to achieve?* [max 700 characters with spaces included]
  (Summary of the most important anticipated results)
- *What are the implications of your research for persons with cystic fibrosis? Reasons for caution?* [max 700 characters with spaces included]
- *Future perspectives* [max 400 characters with spaces included]

Instructions to authors:

- Make the summary easy to read and interesting. Don't Oversimplify. While trying to make it simple, ensure that the crux of your research is not missed out. The reader must clearly understand what the research is about and how it will affect the society.
- Attempt to keep the 'reading age' of your summary at high school level.
- Use first person and active voice ("we agreed" rather than "it was agreed").
- Use positives not negative sentences.
- Keep sentences short, clear and focused.
- Do not overstate the importance/relevance of your study. Place it honestly within the existing literature and how the study adds to current knowledge.
- Avoid jargon and scientific abbreviations (e.g. FEV1) unless absolutely necessary. Technical terms and complex mechanisms/measurements need to be thoroughly explained using basic terminology. Acronyms should be used sparingly and must be spelled out on first reference.

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