



CALL FOR APPLICATIONS 2019

Roche > *per la* < *Ricerca*

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Foreword

Research and innovation should be the driver of development in this country and, in the healthcare field, they represent the key to improve people's quality of life.

For the past 120 years, Roche has made research its core business: we believe that being alongside Italians has always meant striving to find new treatments that could make a tangible contribution to improve patient's lives.

The road that leads to this ambitious objective is a long one that requires a great deal of work, commitment and resources. It is a road that cannot be undertaken alone. This is why we have decided to fund research, and not just our own. Indeed, the main aims of the newly-established Fondazione Roche include promoting independent research, in order to support those researchers who every day have the courage to follow new paths, overcome failures with tenacity, dedication and creativity and carry forward, often in the silence of a laboratory, something great: the progress of health.

This is why Fondazione Roche has decided to sponsor a call for applications to support research projects promoted by public or private organisations working in the scientific/healthcare sector and that are inspired by the courage to take innovative pathways in precision medicine and to develop a new approach in the doctor-patient relation.

1. Purposes of the Call for applications

Fondazione Roche, whose registered offices are in via in Lucina 17, Rome, is publishing this annual call for applications, with the title "**Roche per la Ricerca 2019**" (hereinafter "Call for applications"), in order to fund research projects for personalised pharmacological approaches. With this Call for applications, Fondazione Roche intends to sponsor 12 (twelve) research projects, to be selected – as described under article 8 below – by **Springer Nature Limited** (hereinafter "Springer Nature"), a world leading research, educational and professional publisher.

2. Resources available

- 2.1 The resources that have been set aside for this Call for applications amount to a total of € 600,000.00 [six hundred thousand].
- 2.2 Each of the 12 winning projects will be sponsored by Fondazione Roche with a fixed grant of € 50,000.00 (fifty thousand), according to the criteria settled in section 8.

3. Addressees

- 3.1 With this Call for applications, Fondazione Roche intends to sponsor research projects promoted by public or private Organisations with registered and operational offices in Italy or by public or private research hospitals that meet the criteria set forth in this Call for applications and applicable regulations. Natural persons may not take part in this Call for applications. The lead researcher (PI – Principal Investigator) that submit the grant project on behalf and for the account of the Organisation must be employed by a University, Research Institute or Hospital, and hold a professional degree (PhD, MD, PharmD). The Call is open to researchers holding Italian citizenship.

- 3.2 In order to guarantee the absence of any potential conflict of interest in the assessment of the research projects promoted by the Organisations indicated in point 3.1, research projects on Roche's medicinal or diagnostic products, and research projects conducted jointly by Roche and external partners, in which Roche obtains information, data, intellectual rights or other benefits in exchange for funding, are excluded from this Call for applications.
- 3.3 The payment of the grants by Fondazione Roche does not involve any commercial consideration and shall never be made available in order to induce or encourage the prescription, use or purchase of Roche products.
- 3.4 Each organisation that is awarded a research grant, must be the actual beneficiary, i.e. the recipient and direct user of the grant.
- 3.5 Each Organisation taking part in the Call for applications shall maintain full ownership over any invention or right generated by the research project, without Fondazione Roche or any other Roche Group company being entitled to any interest, right or faculty in the same.
- 3.6 Organisations and other legal entities to which any directors of Fondazione Roche, Roche S.p.A. or other Roche Group companies and their spouses and family or first- or second-degree relations may belong may not take part in this Call for applications.
- 3.7 Subjects and organisations that have taken part in and/or benefitted from contributions in previous editions of "Bando Roche per la Ricerca" may take part in this Call for applications, without any kind of restriction.
- 3.8 Participation in this Call for applications is free of charge.

4. Type of projects eligible

4.1 Given the growing interest in and the need to develop increasingly in-depth and up-to-date scientific knowledge regarding an individualised approach to treatment based on the evaluation and determination of biomolecular factors involved in the development of the diseases (personalised healthcare – PHC), research projects concerning the evaluation and determination of biomolecular factors involved in the development of the diseases which fall within the following areas are eligible for submission for the Call for applications:

- **ONCOLOGY AREA**

TOPICS:

- Biological heterogeneity of cancer
- Prediction of molecular and/or biological response to cancer treatment
- Study of immune escape
- Cancer stem cell maintenance mechanisms
- Study of cell microenvironment processes and the dynamics of immune suppression/stimulation
- Role of the microbiota in cancer development
- Characterisation of neoantigens in solid tumors

- **HAEMATO-ONCOLOGY AREA**

TOPICS:

- Biological heterogeneity of blood malignancies
- Prediction of molecular and/or biological response to cancer treatment
- Study of cell microenvironment processes and the dynamics of immune suppression/stimulation
- Mechanisms of haematopoietic stem cell maintenance
- Characterisation of neoantigens in blood malignancies

- **RESPIRATORY DISEASES AREA**

TOPICS:

- Identification of the role of molecular, functional and clinical-radiological markers as predictors of clinical evolution and prognosis in the restrictive lung disease sector

- **RHEUMATOLOGY AREA**

TOPICS:

- Population studies on rheumatological diseases (rheumatoid arthritis, giant cell arteritis, vasculitis, Systemic Lupus Erythematosus), in which biomarkers are assessed as prognostic response factors
- New preclinical strategies for the development of novel immunotherapy approaches for diseases with an immunomediated component

- **NEUROSCIENCES AREA**

TOPICS:

- Epidemiology, pathophysiology and the role of biomarkers in neurological, neuroinflammatory and neurodevelopment diseases, especially Multiple Sclerosis, Alzheimer's Disease, Spinal Muscular Atrophy, Duchenne Muscular Dystrophy, Parkinson's Diseases and Autism Spectrum Disorders
- Biomarkers in PET: tracers for activated microglia and amyloid tracers
- Cognitive rehabilitations in Multiple Sclerosis
- Updated incidence and prevalence for Spinal Muscular Atrophy, Duchenne Muscular Dystrophy and Huntington disease

- **HEREDITARY CLOTTING DISEASES**

TOPICS:

- Studies regarding molecular or genetic diagnostic techniques for congenital clotting diseases
- Translational research regarding the development of inhibitors or the identification of other associated risk factors
- Population and Real World Evidence (RWE) studies regarding the impact of comorbidities, exercise and bleeding on the Quality of Life (QoL) in congenital haemorrhagic disorders

- Characterization of molecular mechanisms underlying the micro-bleeding of joints in congenital haemorrhagic disorders

- **DOCTOR-PATIENT RELATIONS**

TOPICS:

- Neurophysiological assessment of the aspects of doctor-patient interaction from the standpoint of both the patient (trust and confidence in the treating doctor) and the clinician (empathic and compassionate behaviour in the treatment relationship)
- Relationship between doctor-patient interaction and the positive and negative results (e.g. placebo effect and nocebo effect).

5. Documentation required for submission

- 5.1 Any Organisation wishing to take part in this Call for applications must submit its application through the website www.rocheperlaricerca.it. Research projects may not be submitted using procedures other than those described in this article.
- 5.2 Any organisation applying for a grant must enter the following information through the website www.rocheperlaricerca.it:
- general particulars of the organisation;
 - general particulars of the principal investigator (PI), including the H-index and the Curriculum Vitae;
 - detailed description of the project and the purposes for which sponsorship is being sought, using the standard format that can be downloaded from www.rocheperlaricerca.it.
- 5.3 The project submitted for consideration must be accompanied by a timeline (GANTT charting) of a maximum of 12 months (extension may be granted upon request and after proper justification) using the standard format that can be downloaded from www.rocheperlaricerca.it.
- 5.4 Each project can be submitted for just one area. If the same project is submitted to two or more different areas, it will be excluded from the Call for applications.
- 5.5 Any fraudulent documents or untruthful declarations shall constitute the grounds for disqualification from the Call for applications, even once the selection phase is completed, potential disqualification from future payments and the application of the sanctions envisaged by applicable law.

6. Terms and procedures for application submission

- 6.1 In order to take part in this Call for applications, the Organisations applying for the grant must submit their application, complete with all the necessary information, between April 29th (from 15:00 GMT+1) – July 1st (until 23:59 GMT+1), using the website www.rocheperlaricerca.it.
- 6.2 Each Organisation may submit, in each area, more than one project without any restriction or numerical limit in relation to the areas listed under article 4, but each principal investigator (PI) can only submit one application.

6.3 Participants assume responsibility for the proprietorship of the research projects, their content and all other aspects imposed by applicable regulations. Consequently, Fondazione Roche and Springer Nature shall not be held responsible for breaches of rights by third parties.

6.4 Applications received after the deadline and/or submitted using procedures other than that described and/or not accompanied by all the necessary documentation shall not be taken into consideration. Fondazione Roche shall not accept responsibility for delayed receipt or failed delivery of applications due to electronic faults or other cases that cannot be attributed to it.

6.5 The projects and all attachments must be in the English language.

6.6 Projects must not contain information regarding the identity of the Organisation and/or researchers such as to make a blinded assessment impossible.

6.7 At the Call for applications deadline, the principal investigator (PI) must be under 40 years of age, without any limits with regard to the position of the PI or his/her relationship with the Organisation.

6.8 Any additional requests for clarification must be forwarded by email to the address: italy.ricerca@roche.com

7. Eligibility criteria

7.1 Applications shall be considered unacceptable if they:

- are submitted by Organisations that do not meet the requirements set forth under article 3;
- do not meet the criteria established for each type of project set forth under article 4;
- do not comply with the terms and/or requirements and/or submission procedures described in article 6.

8. Project assessment and selection process

8.1 The submitted projects will be assessed and selected by an independent panel of experts under the administration of Springer Nature Limited, a company incorporated in England and Wales (company number 00785998), whose registered office is at The Campus, 4 Crinan Street, London, United Kingdom, N1 9XW. This appointment guarantees the impartiality, detachment and transparency of the selection process. Roche shall not participate in any way in the choice of the reviewers, application review, or the selection of the grant-winning projects.

8.2 The project assessment and selection process shall involve the following phases:

Phase 1: Identification of the panel of experts

Springer Nature shall convene and appoint an international Panel of experts suitably qualified to evaluate the applications. The Panel shall operate independently of Fondazione Roche and Springer Nature.

Phase 2: Triage

Springer Nature shall exclude all projects that do not meet the eligibility criteria, and shall triage all applications based on key evaluation criteria in order to create a longlist.

Phase 3: Review of longlist

Each longlisted application shall be evaluated by at least two different panel members using a consistent set of evaluation criteria and a consistent scoring methodology.

The score assigned by each panelist to the individual project will be evaluated on the basis of the following criteria:

Innovation

Research funded under the programme must contribute to knowledge of the field. Research proposals should explain the originality of the proposed research. This may include novel insights into the field of study or the development of novel techniques.

Personalized HealthCare (PHC)

Research Proposals should contribute to this new model of practicing medicine by taking into account the progress driven by the recent technological advances and new revolutionary massive sequencing technologies in the area of personalized medicine and the prospective impact.

Potential impact

Research proposals should set out the importance of the contribution they will make. For example, the research may directly answer key questions, develop techniques to further probe crucial aspects of the field or address unmet challenges or opportunities. The ultimate aim of the scheme is to benefit society and patients through improved knowledge, tools and techniques to understand and address human health.

Scientific quality

Research Proposals must set out well-designed, robust studies using the most appropriate methodologies, equipment, data and analytical techniques to reach the stated objectives.

Quality of the applicant/team

The applicant (and other team members) must have the necessary skills and experience to carry out the research, both in terms of the science and the leadership of a research grant. This will be judged on the track record of the applicant(s) and the appropriateness of the host universities and institutes.

Value for money

The project budget must be clearly explained and will be judged on the appropriateness to deliver the proposed programme of research. This is not about costing the project as cheaply as possible,

it is about showing why the requested resources are necessary and reassuring the panel that everything is in place to conduct the research and deliver on the objectives. The panel will also consider how the project will be managed to ensure the resources are deployed effectively.

Phase 4: Meeting of Panel

Based on the combined scores of the panelists for each longlisted application, a shortlist of applications shall be created. Each of the panel members shall review all of the shortlisted applications, and shall meet to make final decisions of which applications to fund. Neither Roche nor Springer Nature shall influence the decisions of the Panel.

8.3 Springer Nature and the reviewers nevertheless have absolute discretion with regard to assessment of the satisfaction and/or relevance of the eligibility requirements and aforesaid criteria.

8.4 The opinion of Springer Nature and the Panel of experts is unchallengeable and, consequently, appeals, complaints, re-examination requests or any other form of objection shall not be permitted.

9. Announcement of the winning projects and award ceremony

9.1 Further to grant assessment, Springer Nature will inform Fondazione Roche of the grant-winning Organisations by 30 November 2019. This will be followed by the communication to the 12 winning PI and to all the applicants. Applicants will be allowed to access their own personal area on the website www.rocheperlaricerca.it to know the score assigned by Springer Nature and the position in the final ranking. On the website will be published all the details regarding the date, venue and time of the award ceremony.

9.2 Fondazione Roche shall cover the travel and hospitality costs for one representative of each winning Organisation.

9.3 Within 1 week of the receipt of the communication, the winning principal investigators (PI) must provide to Fondazione Roche the following information:

- declaration signed by the Legal Representative of the Organisation - or special attorney in accordance with an attached power of attorney document - certifying the undertaking to provide, at the end of the project, documentation confirming that the project for which sponsorship was sought was actually completed;
- if the Organisation is a private subject, the Articles of Association or, alternatively, the Articles of Organisation, must also be provided.

10. Awarding of the grant and payment procedure

10.1 The grant shall be paid by 31 December 2019 and the winners shall be notified of the details of payment directly from the email account: italy.ricerca@roche.com.

11. Documentation certifying the start and completion of the research project

11.1 The project must be started within 6 months of the date on which Fondazione Roche paid the grant.

11.2 Within 6 months of the time the grant was paid, each grant-winning Organisation is under obligation to send a declaration confirming that the research project has been started to the email address: italy.ricerca@roche.com, in order to allow Fondazione Roche to make the appropriate checks.

11.3 Within 36 months of the project start date, each grant-winning Organisation is under obligation to send to the email address: italy.ricerca@roche.com the documentation confirming that the grant received from Fondazione Roche was actually used to support the research project.

12. Publication of the Call for applications

12.1 This Call for applications and the corresponding documentation are published on the dedicated website: www.rocheperlaricerca.it.