

Proof-of-Concept Proposal SPARK PISA

DEFINITIONS AND GLOSSARY

Proof-of-Concept (PoC): A health-related product or service, including digital and computational solutions, addressing unmet medical needs and used to demonstrate to the organization stakeholders (current and potential financiers/partners, potential customers/users) the innovative capacity of a project/product, its technical feasibility, or its applicability; it is usually identified with an incomplete or final prototype of the innovative idea, but also, sometimes, with an environment of experimentation and support services for technology transfer and the commercialization of innovation.

Project: work submitted in response to this call for proposals.

Principal Investigator (PI): is the coordinator of the PoC project, is responsible for the use of funds that will be allocated to the project and will be responsible for signing the documents required during the performance of activities (deliverable), the final scientific report and the financial statement. A formal relationship with the University of Pisa is required until the end of the project.

Project team: is the group of people involved in the activities described in the submitted application for funding.

TRL: Technology Readiness Level according to the European Commission terminology (table in Annex A)

NDA: Non-Disclosure Agreement.

PA: Patent application submitted to the official authority (UIBM, EPO, WIPO, etc.).

SD: Start date of the project corresponding to the formal communication of grant allocation to the project from which the activities (and related costs) can begin.

Deliverable: description of the activities of the project and the results achieved for the implementation of the PoC. The deliverable can be either a document or a presentation to the project committee or a research product.

SPARK Mission: Turn 'good ideas into great projects and solutions' through education, mentorship and financial support of selected PIs and projects in academia to benefit patients and society

SPARK Vision: Become a recognized non-commercial participant in the global biomedical innovation system, overcoming barriers to innovation by driving patient benefit through improved projects, innovation-driven PIs and innovative financing and development instruments inside academia. Create a global community of like-minded translation-oriented scientists and clinicians ('Translational Scientists without Borders')



Art. 1 - GENERAL INFORMATION

1.1 AIMS

The Proof-of-Concept (PoC) SPARK PISA call funds innovative research projects developed by research teams at the University of Pisa with a TRL (Technology Readiness Level) strictly greater than 3, in the transition from the idea to the working prototype, and then to the transfer to corporations or the market.

SPARK PISA supports the development of new therapies/technologies (small molecules or biological), diagnostics and computational approaches for unmet medical needs in the fields of systems pharmacology, systems medicine, and systems nutrition.

SPARK PISA is part of an international network of scientists and physicians educated in translational research focused on advancing academic discoveries and products that benefit patients and society addressing new health challenges as they arise.

1.2 FUNDING

SPARK PISA will fund 2 projects up to € 17,000.00 each for at most 2 years. SPARK PISA will also provide mentorship from experts in all areas of development and training to the project team to address the needs that arise during project running.

The funding can cover the costs listed in art. 3 of this call for proposals, if preliminarily approved by the monitoring and mentoring group assigned to the project. There is no minimum or maximum budget limit for the project.

The funding is meant to be a co-funding of existing projects that have already shown their capability of addressing unmet medical needs and ready to move towards tangible IP generation or product development.

1.3 PROJECT TIME

Projects may have a maximum duration of 2 years from the Starting Date (SD) and should end on December 30, 2021.

Art. 2 - ADMISSION REQUIREMENTS

2.1 TOPICS

Areas of interest are (but not limited to):

- clinical analytics for precision medicine approaches in systems pharmacology and clinical pharmacology;
- immune-oncology;
- precision dosing;
- responder vs non-responder identification,
- metabolic disorders,
- neurodegeneration.

2.2 PROJECT REQUIREMENTS

Projects submitted by PI of the University of Pisa for the development of therapies/technologies and diagnostics with TRL (Technology Readiness Level) strictly greater than 3 are eligible.

2.3 PROJECT TEAM

The Project Teams are composed of a PI and members.

2.3.1 Principal Investigator

The PI must be a first or second level professor or role researcher appointed in accordance with the law before the entry into force of Law 240/2010, or work at the University of Pisa with a fixed-term researcher contract referred to in letter b) of paragraph 3, art. 24 of Law 240/2010 (so-called RTD type B), or be an extraordinary professor on a fixed-term basis pursuant to Law 230/2005, or be a Post-doc fellow. The requirement must remain for the entire duration of the project. For this purpose, it should be noted that any period of contractual extension will be considered.

2.3.2 Project Team Members

All affiliates to the University of Pisa can be project team members. Project Teams may include other subjects with useful skills for the planned activities that cannot be identified within the University of Pisa. Members affiliated with institutions other than the University of Pisa can only collaborate free of charge. All the IP generated by the project is owned by the University of Pisa.

All the members of the Project Team (as per art. 2.3) must sign a specific confidentiality agreement (ANNEX B: NDA) before submitting the project,

Art. 3 - ELIGIBILITY COSTS AND PROJECT REPORTING

3.1 DIRECT COSTS

The grant can only be used for expenses needed to further develop the product of the research through additional experiments and testing. The additional activities must be discussed beforehand with the mentorship team assigned to the project and the grant money will only be used to pay preliminary approved expenses. No personnel cost and general expenses can be covered by the grant.

3.2 FINANCIAL STATEMENT AND FINAL SCIENTIFIC REPORT

The financial statement must report the eligible costs incurred by the project. The final scientific report and the financial statement must be produced at latest one month after the end of the project.

Art. 4 - RIGHTS OF PROPERTY AND INDUSTRIAL EXPLOITATION, PUBLICITY OF RESULTS

Without prejudice to the inalienable right of inventors to be recognized as the authors of the invention, all the results, total or partial, resulting from the activities under this agreement (including any patents, copyrights or trademarks) will be owned by the University of Pisa. The consequent management and economic exploitation of the results will be regulated in specific additional agreements.

Art. 5 - METHODS OF PARTICIPATION AND DEADLINES

On pain of exclusion, the application form (Annex A) and NDA (Annex B) indicated in the Art. 13 must be sent only by email to protocollo@pec.unipi.it by **SEPTEMBER 10, 2019** and specify **SPARK PISA** in the subject line of the email.

All proposals must adhere to SPARK *mission* and *vision*.

Art. 6 - PROCESS OF EVALUATION

6.1 EVALUATION PROCESS

The evaluation process consists of the following steps

1. Formal check of the eligibility of proposals;
2. Evaluation of each proposal by the International Committee;
3. Interview with the International Committee;
4. Admission for funding.



6.2 FORMAL CHECK OF THE ELIGIBILITY OF PROPOSALS

A formal check will be performed to ensure that eligibility requirements set out in the call for proposals in art. 2 are met and all the documentation listed in art. 5 have been submitted. Projects not passing the formal check will be excluded from the selection process.

6.3 INTERNATIONAL COMMITTEE

The selection will be performed by an International Committee that may use telematic systems. The International Committee will be composed of representatives of SPARK PISA, the global SPARK network and representatives of sponsors and mentors. The committee will be formalized later.

6.4 CRITERIA

Short proposals will be evaluated on the basis of:

- a. **Scope of unmet clinical need (30 pts);**
- b. **Novelty of approach (10 pts);**
- c. **Feasibility (cost and time – 30 pts):**

Projects passing the first selection phase will be invited to an audit with the International Committee in accordance with a model to be provided to the project PI together with the communication of the results of the first evaluation phase.

Proposals that get at least 60 points are admitted to the audit phase. The date of the interview will be communicated by e-mail.

- d. **Audit with the International Committee (30 pts)**

Proposals that obtain at least 85 points are fundable.

6.5 TIMING

Communication of the project(s) eligible for funding will be given in the section of the University of Pisa website dedicated to technology transfer - Projects:

<https://www.unipi.it/index.php/trasferimento/itemlist/category/674-progetti>

Strict deadline for submission the short proposal: 10 September 2019.

Results of the first selection phase: 10 October 2019.

Interview with the International Committee: end of October 2019.

Project start: 1 December 2019.

The amount financed depends on the compliance to the deadlines and activities listed in the application form. The PI will have the opportunity to accept or reject the proposed budget.

6.6 MONITORING THE PROGRESS OF THE PROJECT

A representative of the project team will report quarterly to the mentor team through a 15 minutes presentation of the last developments and the expected results or activities of the next period.

6.7 EDUCATION

The project team must participate to the lecture and seminars organized by SPARK PISA to train the affiliated scientists towards translational research. The goal of the education aspect of the SPARK PISA is to help implementing the vision to create a global community of like-minded translation-oriented scientists and clinicians ('Translational Scientists without Borders'). This community building effort will help developing a critical mass of scientists within University of Pisa that will be confident in IP management and startup and spin-off creation.



UNIVERSITÀ DI PISA

Art. 7 - FINANCING GRANT

The resources allocated will be managed directly by the Department of the PI.

The Department will have autonomy in the management of the resources assigned, in accordance with the rules defined in this call for proposals, the relevant University Rules and national law.

The allocation will take place in a single solution. The unspent funds will be recovered by this administration and reallocated to the SPARK fund for the calls for proposals of the subsequent years.

Art. 8 - OBLIGATIONS FOR THE PI

The activities of the funded project can be carried out in the premises and offices of the University of Pisa. PI must also submit a final report within 30 days of the project final date. The PI must ensure participation of project team members to the education activities according to art. 6.7.

Art. 9 - CONTACTS

For legal and administrative clarifications send requests only by e-mail to: valorizzazionericerca@unipi.it

Art. 10 – PUBLIC ADMINISTRATOR

Mauro Bellandi, Director of the Research Services and Technology Transfer Office - University of Pisa - Lungarno Pacinotti, 44 - 56126 Pisa, e-mail valorizzazionericerca@unipi.it, has been appointed responsible for the procedure, pursuant to and for the purposes of Law 241/1990 as amended and supplemented.

Art. 11 - DATA PROCESSING AND CONFIDENTIALITY

University of Pisa shall provide for the processing, dissemination and communication of personal data relating to this agreement, as part of the pursuit of its institutional purposes and as provided for its regulations, in full compliance with all the provisions of current legislation.

SPARK Global, in turn, undertakes to process the personal data of University of Pisa, only for the purposes provided for by the Convention and in full compliance with current legislation.

Art. 12 - PUBLISHING PoC

This call and its attachments will be published on the website of the University of Pisa, on the home page of the website and in the section dedicated to Technology Transfer - <https://www.unipi.it/index.php/trasferimento>

This publication constitutes a communication pursuant to and for the purposes of Law 241/90 (Rules on the administrative procedure) and Legislative Decree 104/2010 (Code of the Administrative Process) and subsequent amendments and integrations.

Art. 13 - LIST OF ANNEXES

To be submitted the proposal:

Annex A - Application form and table TRL

Annex B – NDA, Non-Disclosure Agreement