



Agenzia Italiana del Farmaco

AIFA

Linee guida per valutazione dei protocolli di studio

Bando AIFA 2016

GUIDELINES FOR PROPOSALS EVALUATION

For full proposals, the following evaluation criteria apply.

CRITERIA	SCORE RANGE
Scientific quality, worth of the proposed research and feasibility of the objectives	1-9*
Novelty, originality and transferability	1-9*
Methodologies and development strategy of the project (detailed over the 3 years of the project), preliminary data and bibliographic references	1-9*
Merits of the applicant (general information and contact details), scientific activity (based on the curriculum vitae and publication track records presented by the applicant - 5 best articles, 5 articles related to the topic, taking into consideration the IF of the scientific journals the articles were published in, the number of citations from the publication to the request for funding, and the h-index) and the 5 latest publications. With reference to the projects involving Italian Researchers operating abroad, the data of the Italian researcher operating abroad are relevant too. Expertise of the group of researchers.	1-9*
Facilities, infrastructures and equipment available. Economic adequacy and detailed financial statement. Economic consistency of the project.	1-9*

ALLEGATO 2

Does this project relate to products or ideas already covered by an industrial patent by the co- financing company or otherwise subjected to the rights of a legal subject other than the corresponding Institutional Authority?	Yes/No
Overall evaluation (half page)	Text
Final score	Sum

*Maximum value=1; Minimum value=9. Scores are admitted in fractions of 0,5 points.

The scores indicate the following with respect to the criterion under examination:

SCORE

1	Outstanding. The proposal stands out for exceptional novelty, originality and renewal of science at a global level providing a cost-saving approach and/or establishing by references and presentation of material far superior capability.
1,5	Excellent plus.
2	Excellent. The proposal successfully addresses the criterion very well, although some minor improvements are still possible.
2,5	Excellent minus.
3	Very good to excellent. The proposal addresses the criterion very well, although some elements could be improved.
3,5	Very good plus.
4	Very good. The proposal addresses the criterion well, although certain improvements are still possible.
4,5	Good plus.
5	Good. The proposal addresses the criterion well, although improvements would be necessary.
5,5	Good minus.
6	Fair to Good. While the proposal broadly addresses the criterion, there are some weaknesses.
6,5	Fair plus.
7	Fair minus.
7,5	Fair minus.
8	Weak. The criterion is addressed in an inadequate manner or there are serious inherent weaknesses.
8,5	Poor to Weak.
9	Poor. The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information.

On the Scientific quality, worth of the proposed research and feasibility of the objectives

This topic considers if the project address important problems, with feasible outcomes, and potential relevant effects on scientific knowledge and/or methods, technologies, treatments, services or preventative interventions involved in clinical practice.

1-2: this score reflects an excellent application, which fulfills the following criteria:

- The proposed study is in line with the mission of the AIFA and has clear consequences on the national health system, with a great potential impact on human health and appropriateness of treatments.
- The research aim is a relevant issue to a research agenda, sufficiently focused and clearly stated.
- The project is of outstanding scientific quality; it is built on solid experimental evidence and is focused on a highly relevant scientific subject.
- The research plan is well written, realistic and highly feasible.
- The scientific/intellectual merits of the proposed research are clear, convincing and compelling.
- The general design, including time schedule, is optimal for implementing the project.
- The project is very well written and presented, and it is fully understandable.
- Problems, planned solutions and current state of the art are thoroughly examined.
- The project has high translational potential, with a potential broad impact on the health.

3-4: the application is very good, yet fails to fulfill important criteria listed in the previous paragraph. The proposal requires adjustments.

5-9: the application suffers from critical flaws.

On the Novelty, originality and transferability

1-2: this score reflects an excellent application, which fulfills the following criteria:

- The application includes a thorough review of the current scientific literature on the subject, providing an accurate analysis of the existing theories and concepts and demonstrating the importance of the proposed project to fill the gap in current knowledge.
- The project is highly innovative and original, with great potential for the creation of scientific knowledge, exciting new ideas and approaches, directions for research and understanding of health and illness.
- The project includes the use of novel technologies/methodologies, and/or innovative application of existing methodologies/technologies in new areas.
- The project can be regarded as unconventional, and it challenges prevalent opinion or practice.
- The project has obvious translational potential; for instance, upon its successful execution, it will provide essential information to unravel physiopathological processes important for therapy development, or will lay foundation to develop future therapeutic strategies, new diagnostic tools, or equipment to be used in healthcare.
- The project will certainly provide findings that can be translated into health gains and differences in score are only determined by the relevance of the outcome. For instance, results directly impacting healthcare should be seen more positively.

3-4: the project presents a good grade of novelty and originality. Despite some potential, translation is not easily achievable; amendments to the research plan and/or additional experimental evidence will successfully overcome weaknesses.

5-9: The project has low novelty and originality. It also shows no or low translational potential.

On the Methodology and development strategy of the project (detailed over the 3 years of the project), preliminary data and bibliographic references

1-2: this score reflects an extremely well designed and described experimental plan.

- The methodology is appropriate for the project objectives and fully consistent with the candidate's skills. The application is realistic and highly feasible within the proposed timeframe.
- Framework, methods, design and analyses are clearly described, adequately developed, thoroughly integrated, well-reasoned and appropriate.
- Milestones, timetable and outputs are clearly stated and suitable.

- Where applicable, the sampling is appropriate and adequate, with the indication of the approximate values regarding the size of the sample required and the assurance that enough subjects will be studied to provide sufficient information.
- Participants, events and similar study features are selected to maximize appropriate information.
- The strategy for data collection is clearly stated and suitable, representing the best with respect to the research plan. A rationale for methodological choices is provided. The framework is adequate, in view of the aims of the study.
- The project takes into consideration any potential problems that are likely to arise, and alternative strategies and benchmarks for success are considered with sufficient flexibility in the study' design and timeline in order to change course should a problem occur.
- A thorough investigation is presented, providing not only the potential findings but also an exhaustive analysis of the existing data.
- The project takes advantage of particularly powerful technical resources, for instance particular models, or unique samples repositories, or cutting edge technologies.

3-4: the section suffers from some flaws; for instance, the profile of the applicant might not be fully compatible with the proposed methodology, thus compromising feasibility of the project. Alternatively, the project might rely on sub-optimal models.

5-9: the project is unrealistic, or it is based on obsolete techniques and inappropriate models. Overall, the methodology is weak.

On the Merits of the applicant (general information and contact details), scientific activity (based on the curriculum vitae and publication records presented by the applicant – 5 best articles, 5 articles related to the topic, taking into consideration: the IF of the scientific journals where the articles were published, the number of citations from the year of publication to year of the request for funding, and the h-index) and the 5 most recent publications.

1-2: the applicant is internationally competitive and demonstrates scientific independence and thinking.

- The applicant is appropriately trained and sufficiently experienced to carry out the work, having sufficient expertise, level of independence and scientific network for the conduct and implementation of the proposed project, as reflected by
 1. his/her overall cv and bibliometric data.
 2. his/her role in obtaining the preliminary data included in the application
- Relevant experience in the field of interest representing the primary focus of the research project (e.g. a principal investigator with a degree in biology might not be suitable for the conduct of a project with one or more primary clinical aim/s).
- So far, the applicant has demonstrated adequate skills and abilities to make a significant contribution to research in the chosen field through his/her work and/or publications.

ALLEGATO 2

- Based on the above reported characteristics, the applicant has the potential to step forward a successful academic career.
- The applicant works in a suitable host institution and the each component of the research team adds complementarities and integrated expertise to the project.

3-4: the applicant has a very good record, but fails to fulfill essential requirements highlighted in the previous point.

5-9: the applicant profile needs substantial improvement and the candidate should dedicate particular attention to overcome prominent weaknesses in his/her CV.

On the Facilities, infrastructures and equipment available. Economic adequacy and detailed financial statement. Economic consistency of the project.

1-3: FEASIBLE AND ECONOMICALLY CONSISTENT

- The project includes the availability and accessibility of relevant personnel, skills, equipment, facilities/infrastructures and any other necessary resources. The request of one or more subcontractor/s in the economic plan should invite the reviewer to carefully evaluate the possibility of assigning a 1-3 score for the criterion under consideration. Indeed, such request somewhat underlies the lack, either partial or total, of adequate equipment and/or structural/functional limitations of the facilities/infrastructures for the host institution.
- The requested budget is highly appropriate.
- Potentials for successfully disseminating research findings.

4-5: PARTLY FEASIBLE – the availability and accessibility of personnel, skills, equipment and facilities/infrastructure are not completely adequate; the requested budget is appropriate.

6-7: HARDLY FEASIBLE – the proposed infrastructure, equipment and fieldwork are hardly sufficient; the requested budget is marginally appropriate.

8-9: NOT FEASIBLE – the proposed infrastructure, equipment and fieldwork are insufficient; the requested budget is inappropriate.

On the time requested for the results/benefits to be extended to the final patients

1-3: the results of the project will be immediately extended to the final patients.

4-7: the results of the project will be extended to the final patients within a year from the conclusion of the project.

8-9: the results of the project will be extended to the final patients after at least a year from the conclusion of the project.

On the integration and involvement of the National Health System in the territorial dimension

1: Outstanding capacity of integration and involvement of other structures.

- There is ability to successfully disseminate research findings.
- The application clearly states how the results will be disseminated to enhance scientific and technological understanding.

2: Excellent capacity of integration and involvement

3-4: Very good capacity of integration and involvement

5-6: Good capacity of integration and involvement

7: Fair capacity of integration and involvement **8:**

Weak capacity of integration and involvement **9:**

Poor capacity of integration and involvement