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#### SPECIAL ARTICLE

# How to prepare a research proposal in the health science?



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#### **KEYWORDS**

Research proposal; Protocol; Health sciences Abstract Knowing how to properly prepare a research proposal is a real challenge — and being able to prepare an excellent research proposal is increasingly a requirement to compete for funding with assurances of success. With this in mind, we aim to share with the reader our experience (in many cases, unsuccessful) as applicants on the most important aspects of preparing a research proposal and securing its approval and funding. This article aims not only to list theoretical recommendations but also to share some personal and eminently practical suggestions on the following elements of a research proposal: the title, the abstract, the introduction, the objectives, the methodology, the work plan or schedule, the proposal's consistency and coherence, its viability, its applicability, the importance of the principal investigator and the research team, the proposal's limitations and alternatives, its budget, its references, and, finally, the research proposal's form or wording. In summary, a research proposal is a carefully written plan that includes all the scientific, ethical and logistical aspects of the study to be conducted. Writing a good research proposal requires considerable effort and a great deal of time, but it's worth it.

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#### PALABRAS CLAVE

Proyecto de investigación; Protocolo; Ciencias de la salud

#### ¿Cómo elaborar un proyecto de investigación en ciencias de la salud?

**Resumen** Saber elaborar correctamente un proyecto de investigación supone un auténtico reto. Y ser capaz de preparar un buen -mejor, un excelente- proyecto de investigación se convierte en una exigencia para poder competir, con garantías de éxito, para obtener financiación. Con esta filosofía, en el presente manuscrito pretendemos compartir con el lector

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nuestra experiencia como solicitantes (fallidos en muchos casos) sobre los aspectos más importantes para elaborar un proyecto de investigación y que este sea premiado con su aprobación y financiación. La intención del presente artículo no es enumerar, sin más, una serie de recomendaciones teóricas, sino compartir algunas sugerencias personales y, por tanto, de índole eminentemente práctica, sobre los siguientes apartados o elementos del proyecto de investigación: el título, el resumen, la introducción, los objetivos, la metodología, el plan de trabajo o cronograma, la coherencia de la propuesta, su viabilidad, la aplicabilidad de la misma, la importancia del investigador principal y del equipo investigador, las limitaciones y alternativas del proyecto, su presupuesto, la bibliografía y, finalmente, el fondo y la forma del proyecto de investigación. En resumen, el proyecto de investigación es un plan escrito minuciosamente que contempla todos los aspectos, científicos, éticos y logísticos del estudio que nos proponemos llevar a cabo. Redactar un buen proyecto de investigación requiere un notable esfuerzo y una gran inversión de tiempo; pero merece la pena.

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#### Introduction

Research is an activity aimed at obtaining new knowledge and applying it to solve problems or questions. Scientific research, in particular, uses the steps of scientific method to study a certain aspect of reality, either theoretically or experimentally. The basis of the research process is the research proposal or protocol, a document that outlines in detail the organisation that has been put into this activity and the way in which it will be executed, and is thus a guide for the research team during the course of the research.

In research, proposal and protocol are often used synonymously. Strictly speaking, we should reserve the term protocol for the document that explains all the details about how to conduct a research study; that is, the scientific structure (objectives, design, stages of implementation and analysis) and instructions for the staff involved (operating manual). For its part, the research proposal includes, in addition to the study protocol itself, administrative and additional information required by the corresponding evaluating agency.<sup>2</sup> Therefore, throughout this article we will refer mainly to the latter.

The research proposal gives an overview of the aspects of the study before it starts, and should be described with sufficient clarity to enable another investigator to conduct the study, or to carry it out at another time.<sup>3</sup> Its objective is to present and describe in detail what is going to be investigated, the conceptual theoretical basis, the methodological components and the human, technical and financial resources that will be necessary to carry out the research. It describes what will be investigated, how, when and with what.<sup>4</sup>

A research protocol is in itself a scientific document, and constitutes the conventional means to formalise a scientific research proposal. It includes an ordered sequence of sections, a series of relevant information on the scientific, ethical and logistical aspects, and the guidelines that the research team must comply with.<sup>5</sup> In this way, the research protocol pursues the following objectives: to transform the

initial idea into an execution plan; facilitate the discussion and prior agreement among members of the research team; standardise the tasks, activities and actions undertaken by the members of the research team; serve as a roadmap for all those who will participate in the research; save time and resources; request permits and authorisation to carry out the study; and, ultimately, to convince the evaluating body of the importance of the project and of the need to finance it.  $^{2,6,7}$ 

#### The research project and the search for funding

One of the keys to achieving scientific progress is the correct allocation of resources for research, both public and private. Indeed, one of the main reasons for preparing and submitting a research proposal is to obtain such funding. In fact, research activity is usually linked to another that is not so pleasant and that often takes up much more time than expected: the search for funding.

Despite being the fourth largest economy in the European Union, Spain has a long and pitiful history of insufficient funding for research and development (R&D) plans. Never in the country's history has more than 1.5% of its GDP been allocated to research, well below the European Union average (2%) and placing our country as the fourth lowest investor in R&D in the Organisation for Economic Cooperation and Development (OECD).<sup>8</sup> Partly because of this, currently, competition to obtain research funding in Spain is fiercer than ever.<sup>9</sup>

The evaluation of research projects is an essential step in the process of prioritising those that will be funded in a call for proposals. Therefore, it is necessary to do the utmost to draw up a research proposal, so as to ensure it has the best chance of securing funding. Although funding bodies and agencies can define specific priorities in their calls for project proposals, there are some general criteria for scientific evaluation. The proposal must allow the evaluator to clearly understand what is to be investigated, in what way, in what time period, and in what circumstances.

### Rules and tips for drawing up a good research proposal

In view of the above, it seems clear that knowing how to properly prepare a research proposal is, especially in our setting, a real challenge. And being able to prepare a good – or better, an excellent – research proposal, becomes a requirement to be able to compete, with some guarantee of success, to obtain funding.

With this philosophy, in this manuscript we aim to share with the reader our experience in the most important aspects of drawing up and submitting a research proposal of excellence. We will usually refer to research in a broad sense, although, given our training, we always have a special focus on biomedical research. The aim of this article is not merely to list a series of theoretical recommendations, but to share some personal suggestions, based on our experience as applicants (failed in many cases) and as evaluators for various organisations or agencies, that are, thus, highly practical in nature. We trust that this article will be useful, both for professionals who are starting out in research, and for those with a more consolidated career.

#### Essential elements of a research proposal

Scientific research is a free and creative process. However, this does not mean that it should not be organised and systematic, especially when it comes to the planning stage, which is specified precisely in the research proposal. The content and structure of the sections in which a proposal is structured may vary according to the requirements of the different funding agencies or institutions, so it will always be necessary to know in detail and to scrupulously follow the instructions of the call for projects.

Generally speaking, a research project proposal should contain the following elements<sup>12</sup>: 1) a scientific presentation of the problem and some clearly defined objectives; 2) a transparent and realistic research design, particularly emphasising a suitable choice of scientific methods; and 3) a plan for the work and the use of resources. In particular, and in more detail, the usual sections of a research protocol are: title, project summary, background and current status of the subject, rationale of the study, references, objectives, hypothesis, methodology, work plan, experience of the research team in the subject, applicability and practical utility of the results, means available for carrying out the project, justification of the requested funds, budget and annexes. Our objective is not to review in detail each and every one of the sections mentioned, but to offer a series of tips about those that are frequently insufficiently - or poorly - complied with in research proposals. These aspects are usually precisely the most relevant and critical when it comes to obtaining the maximum score from the evaluators. In short, we aim to share with the reader a kind of recipe for drawing up a successful research proposal and for this to be rewarded with approval and funding.

#### The title

Although it only represents a small part of the research proposal, the title is a key part of it. It is like the project

business card: it is the first piece of information that the reader (the reviewer) obtains from the article, so it must be attractive enough to catch their attention. In addition, this is the part of the article that provides the most information in the smallest space. For this reason, it is worth investing the time needed to come up with a good title, although the time spent may seem disproportionately long for such a small section.

The title of the research to be carried out must be clear, concise, precise and, at the same time, complete. In other words, the title must clearly and concisely reflect the content of the project, without ambiguity. It should not be too general, but rather informative. Finally, it can, and should, be attractive.

Ideally, the title should not exceed approximately 15 words (or two lines). Sometimes, especially if the title is too long, it may be better to break it up and add a subtitle. Thus, the title would express what is going to be investigated, and the subtitle, the conditions under which it will be carried out. <sup>13</sup> The subtitle is thus especially useful for including aspects of the study design, which can make it possible, if necessary, to emphasise the methodological quality of the study; for example, adding the subtitle: Randomised, double-blind clinical trial: It should not contain acronyms or abbreviations. Although it may seem paradoxical, it is often when we are finishing writing the entire proposal that we will choose the final title, since that is the moment when we have the best perspective on the content.

#### The project summary

This is an essential part of the proposal, since, after the title, it is the first contact with the possible evaluators. It is the project's letter of presentation, including a structured outline that gives an overview of the project. It should summarise, following a logical sequence, the essential aspects of the research to be carried out, fundamentally including the aims and methodology of the project. Thus, it should clearly reflect its general objective and, schematically, the design, scope of the study, study subjects, instruments to be used and the most important measurements or variables.

If the project summary is of interest to the evaluator, they are likely to review the entire proposal with interest, but if the summary does not convince the reviewer, we can be almost certain that the rest of the proposal will be read with little chance of being approved or funded.

The bibliographical searches of scientific projects are based mainly on the information included in the summary, so the components that appear in it will be especially important. Therefore, in the summary, more than in any other part, extreme care should be taken in choosing the terms used, since an error in this will have greater significance, if possible, than in any other part of the protocol.

The maximum length of the project summary depends on the call, but in general it should not exceed 250 words. Therefore, although it is not always easy, a balance must be struck between thoroughness, clarity and brevity. In this sense, the summary should be able to be understood without having to read the entire project proposal. As with the title, abbreviations should not be used in the summary, except in exceptional cases. Despite its location, at the beginning of

the research proposal, the summary is usually written after the entire proposal has been drafted.

#### The introduction

The introduction section of any research proposal includes the background, the current state of the subject and the rationale for the study. This section, the importance of which is often underrated, serves an important function: it attracts the reviewer's attention to continue reading the proposal with interest. It would be a real shame if, having initially captured the attention of the evaluator sufficiently for them to begin diving into introduction of our proposal, they ended up not wanting to finish reading it. Therefore, the introduction should briefly explain the gaps that there are in the knowledge of the subject and the reasons that led us to carry out the study, explaining what hypotheses have led us to propose it.

The introduction section should have three essential objectives<sup>14</sup>: the first is to demonstrate the importance of the subject area; the second is to describe what research has been carried out on the subject, including the strengths and weaknesses of the previous studies; and the third is to indicate why the present project needs to be undertaken, and how it plans to resolve the previous limitations and contribute to scientific progress in this field, including the rationale of the methodology to be used.

A problem can be important, fundamentally, because of its frequency, its consequences in terms of morbidity and mortality, or its cost. Thus, providing the rationale for a research project is to explain the epidemiological, scientific, economic or social reasons for which it is aimed to be conducted. It should be explained why it is desirable to carry out the study in question and what will be the benefits deriving from the scientific results obtained.

The introduction should be relatively short. This section should not provide detailed information that can be found in any textbook of the speciality, including aspects well known to readers interested in the subject in question. But, at the same time, we should convince the evaluator that the literature has been reviewed in a detailed and critical way, with special emphasis on the most recent publications (last five years). Although it seems obvious, it is important to make it clear that we know well what has been published so far, and that, in this sense, our research is novel.

Although it is essential to carry out a thorough bibliographical review, it is not a requirement to carry out a prior systematic review and a formal meta-analysis.<sup>15</sup> The latter constitutes a research study in itself, with very strict methodological requirements, and which requires a considerable effort to be carried out. On the other hand, the fundamental function of meta-analyses is not to identify knowledge gaps; but rather to bring together or summarise information about a previously identified research question.<sup>16</sup>

The number of bibliographical citations used in the introduction should be moderate: only those strictly necessary and relevant should be used. A reference to a good and upto-date systematic review or meta-analysis of the literature may be the most appropriate and efficient way to support a certain claim, rather than citing the numerous individual studies included in that review.

Finally, it is important to remember that a project is more likely to be evaluated positively if the applicants give evidence of prior experience in the area, either through articles already published or with preliminary data on the proposed project. For this reason, if possible, it would be best for the researcher to show in the project proposal how their previous research – typically in the form of funded projects or publications, but also through preliminary results – contribute to achieving the objectives set out in the proposal. Thus, in the case, for example, of submitting a proposal to the Fondo de Investigación en Salud (FIS) [Health Research Fund], the introduction will be the right place to highlight the results achieved thanks to previous investment by the Instituto de Salud Carlos III (ISCIII) [Carlos III Health Institute] in our research group.

#### The hypothesis and objectives

As a preliminary reflection, it is evident that, in order to correctly present the objectives of our study, we must be clear what the hypothesis and the research question are. The qualities of an initial question should be: clarity, feasibility and relevance. Furthermore, research questions must be concrete and specific (novicestend to ask questions that are too broad). Although asking research questions seems like a relatively simple matter, in reality it is not. These questions are basic because they set the tone for the entire investigation and guide the search for answers throughout the process. It is not uncommon to find disoriented research project proposals that answer questions that have not really been asked or that, on the contrary, do not answer questions that should have been asked.

The objectives are one of the most important parts of a research proposal. They are goals that the researcher sets in relation to the aspects that they wish to investigate and learn about. They must be concrete, precise, evaluable (measurable), feasible (achievable) and relevant (of public health or scientific interest). Therefore, very general, speculative or unimportant objectives should be avoided.

Objectives can be classified into general (usually only one) and specific (generally no more than four). The general objective is a description of the overall goal that is expected to be achieved during the period defined for the execution of the project, which must be broken down into specific objectives. <sup>19</sup> Thus, the latter are a detailed development of the general objective - logical steps or groups of ordered activities that will be carried out to achieve it - and include actions that are not described in the general objective, trying not to duplicate what has already been stated there.

In biomedicine, and especially in clinical research projects, where there is more than one objective, a categorisation based on primaryand secondaryobjectives is usually used. In this case, all the objectives are independent (unlike in the previous classification into general and specific) and it must be clearly established what is the fundamental – main – objective, since this defines the overall design of the study and the sample size.

The objectives are usually written starting with a verb (in the infinitive) that denotes a search for knowledge. Among the most used are: to determine, identify, describe, establish, demonstrate, confirm, assess, evaluate, verify. More ambiguous verbs (such as learn, study, understand, among others) should not be used, since these are already implicit in the very act of investigating.<sup>20</sup>

It is in the formulation of the objectives where it is often detected whether the researcher is clear about what they want to do or needs to think through the research project more. For this reason, it is important to describe clearly, precisely and realistically (that is, suited to the expected duration of the project), the specific objectives that are being pursued. We must make it clear to the evaluator that we are not going on a fishing expedition but that we are very clear about what we are looking for. Another common mistake is to state objectives as methodology (the use of a certain technique), rather than as objectives per se that use a certain methodology to be achieved.

Finally, it is essential that the objectives of our research project are aligned with the values, mission and vision of the entity that awards the grants. For this reason, it is advisable that, after thoroughly reading the call for subsidies or grants, we identify their purpose and the priority lines of research. This is important, as the objective has to be formulated in such a way that it fits perfectly within the framework and strategic challenges of the funding institution. Thus, a project proposal may be formally or scientifically impeccable and be negatively evaluated for lacking applicability, originality, novelty or being outside the priorities of the call.

#### The methodology

The methodology section should describe in detail what will be done, how, when and where. But it should not consist of a mere enumeration of the techniques to be used, but rather we should establish a coherent relationship between the proposed objectives and the methodology presented.<sup>23</sup> Thus, the purpose of the methodology section in a research proposal is to explain the study design and the procedures that the researchers will carry out to respond to each of the proposed objectives. In this section, we will not only proceed to explain what is going to be done, but we should also convince the evaluator that the methods and procedures selected are the most suitable and, in addition, that we are familiar with them (an aspect that, as we discussed earlier, should already have been mentioned in the introduction section).<sup>24</sup> It would therefore be most desirable to include preliminary results (ideally with the same techniques included in the current proposal) that support the technical viability of the project if it receives funding.<sup>25</sup>

The detail with which we must describe the methodology should allow the study to be reproduced by other researchers. If the methods to be used in our study have already been used previously by the same authors, a brief description accompanied by the bibliographical reference of the previous study will suffice. However, if it is a new method, it should be described in detail. Sometimes, due to the limited space available, it is not possible to include in this section all the information that we would like. However, some calls allow some complementary documentation, such

as questionnaires, figures or informed consent forms, among others, to be included in annexes.

#### The work plan or schedule

The work plan or schedule specifies the tasks to be carried out in the project, some of which may overlap in time, indicating the start and end dates, as well as the people who will perform them.<sup>2</sup> The stages that are usually established in the schedule are: bibliographical review, study planning and project preparation, execution, processing and analysis of the information, analysis of the results, writing of the final report and dissemination of the results.

The work plan should be realistic and take into account possible delays in obtaining some documents, permits and additional funds. For example, in clinical trials it is advisable to include in the schedule a section specifically dedicated to the administrative tasks related to obtaining research project approval (Ethics Committee and Agencia Española de Medicamentos y Productos Sanitarios [Spanish Agency of Medicines and Medical Devices], among others), a process that can easily take one year.<sup>26</sup>

A frequent error consists in estimating an unrealistic amount of time to perform all the activities of the research project until its conclusion, and of the scope of the objectives, even beyond the maximum time established in the call for grants.<sup>27</sup> In projects lasting several years, it should be indicated at what point(s) the partial objectives are expected to be achieved. This is an important point for the periodic evaluations that almost every funded project is subject to.<sup>2</sup>

#### Coherence of the proposal

A basic condition of any research project proposal is that it must exhibit an adequate interrelation and coherence between all its parts, in such a way that each element of the project holds together on its own, but at the same time, all are logically related to each other. Thus, from reading the background section, the objectives and hypothesis of the study should be derived. The design and the other sections of the methodology should respond precisely to these objectives, and other sections, such as the schedule, the work plan or the budget, must also follow the same common thread. The project must therefore have a logical fluidity, without jumps, gaps, inconsistencies, contradictions, incomplete reasoning or unnecessary repetitions. <sup>28</sup>

#### The viability of the proposal

When we prepare a research proposal to apply for possible funding, two aspects must be very clear and well reflected in the proposal: its quality and scientific impact, on the one hand, and its viability, on the other. Both are key for the evaluators to give us their vote of confidence and maximum score. The viability must analyse the appropriateness of the objectives and methodology with respect to the work plan, distribution of tasks, available equipment and requested budget.

Ideally, we should present a proposal that is novel and ambitious but, at the same time, credible in terms of content and time frames. Otherwise, the evaluator may conclude that the researcher is exaggerating or even lying. In fact, the risk *per se* in the formulation of a proposal should not be viewed negatively, but quite the opposite, if it is supported by a viable, well-founded project, promoted by a research group with a solid scientific background and with the available material, financial and human resources.

#### Applicability of the proposal

Biomedicine and clinical medicine projects should try to give concrete answers to health problems, so an important aspect in their evaluation is that they focus on important pathologies, not only based on their frequency, but also on their public health and human impact. For any funding agency it is important that the results derived from the research produce some benefit in aspects related to health. This is why some funding agencies request, among the elements to be quantitatively analysed, a specific evaluation of the project's applicability. If this is the case, we must make it clear that the research proposed is easily applicable. For example, a FIS project should emphasise the benefits that the research will bring to the national health system, both in terms of generating knowledge and innovation, as well as incorporating talent and employability. Finally, in this section we should emphasise the potential of the project to obtain results transferable to the industrial diagnostic/therapeutic field or to generate patents.

#### The importance of the principal investigator

All research proposals, whatever their type, have a lead or principal investigator (PI). A frequent mistake is to magnify the importance of the research project in relation to that of the PI, considering as secondary the role of the researcher who will lead a good project.

The evaluation of the PI must cover a limited period of time, generally set by the funding agencies, but which, for example, the former Agencia Nacional de Evaluación y Prospectiva (ANEP) [National Evaluation and Prospective Agency] or the current Agencia Estatal de Investigación (AEI) [State Research Agency] consider to be around a maximum of 10 years, with special regard to the last five or six years.<sup>23</sup>

The evaluation of the PI will be carried out through the analysis both of their scientific productivity and their ability to develop research projects. In some calls (such as those of the ISCIII), the training or teaching capacity of the PI is also valued positively, including directing doctoral theses or obtaining funding in human resources activities (such as the calls for projects by Sara Borrell, Juan de la Cierva, Ramón y Cajal, Miguel Servet or Río Hortega, among others) in the last five years.

Regarding the scientific productivity of the PI, the evaluation is carried out through the analysis of their öriginalresearch articles, published in journals included in the standard international registries. Reviews are not considered original articles, unless they are systematic reviews and meta-analyses. Publications of project summaries, conference presentations, clinical cases or letters to the editor

are usually given minimal value, except in the case of emerging researchers.  $^{\rm 23}$ 

In the evaluation of publications, two aspects are fundamentally valued: the quality and the degree of participation in these. The quality is evaluated according to the bibliometric indices in use (Journal Citation Report, JCR), giving special relevance to those publications that are in the first quartile, and even more so, in the first decile, of their area of knowledge. More importance is still given to publications in which the PI appears as the main or lead author, that is, first, senior (last) or corresponding author. The fact of being named as a secondary author must be analysed based on the experience of the PI and the characteristics of the research work. According to the AEI, in general, a maximum score (100%) will be awarded to a researcher who publishes regularly in journals included in the JCR, appearing as the main author in publications of the first quartile (an average of one to two publications/year), some of these being within the first decile (an average of one publication/one to two vears).<sup>23</sup>

The main role of bibliometric indicators is not to replace experts, but to facilitate their decisions and provide objectivity and transparency to the evaluation processes. However, for example, a simple publication count of each researcher is an unreliable indicator to measure the contribution they have made to the progress of science. Using the number of citations that papers have received as a bibliometric indicator also has some limitations. Among the various impact indicators, the best known is the so-called impact factor(published by Thomson Scientific). However, despite the widespread use of this index, it has been repeatedly shown that it does not predict the quality of each of the published works. Therefore, publishing in a high-impact journal is not necessarily an indicator of the quality of the manuscript. Due to the significant limitations of the impact factor; it is progressively falling into disuse in scientific evaluations, and currently there is a tendency to consider that it should be, at least, complemented by other indices, such as the h (Hirsch) index. The h index has a number of advantages that make it very useful and attractive, including that it combines, in the same bibliometric index, the effect of quantity(number of publications) and quality(citation rate), in a balanced way, outperforming total document and citation counts.<sup>29</sup>

When evaluating the capacity of the PI to conduct research projects, it must be taken into account that more value is usually given to projects financed through competitive calls. Researchers who regularly obtain European funding, being project leaders, or those who obtain private funds that culminate in accredited knowledge transfer (patents, clinical guidelines) will be especially highly valued.<sup>23</sup>

Obviously, all the criteria mentioned above for evaluating the PI are indicative, and the experience of the evaluators or other additional criteria, such as the impact on the scientific community, may lead them to be modified. For example, for researchers with a short research trajectory, the assessment should be adapted to the period evaluated; or for researchers with a long research trajectory, but with few publications as the main author, the assessment should be lowered; or researchers who receive regular funding for their projects but with poor or low-quality sci-

Finally, it should be noted that the leadership transition from a senior PI to a junior co-investigator (co-PI) is often particularly well regarded. The combination of a PI with an excellent CV and a co-PI that meets emerging investigator criteria makes for an excellent dance partnership.

#### The importance of the research team

One of the fundamental sections within a research proposal is the evaluation of the research team or the participants who are going to carry out the research. In this section, we will refer to those researchers who accompany the PI in the project. Although the different calls for research project proposals have their own evaluation scale, in all of them the evaluation of the team constitutes a very relevant section, counting up to 30–50% of the final grade. For this reason, it is necessary to have an experienced research team and provide the CVs of its members in the format requested in the call.<sup>30</sup>

Although there is no clear and unique definition of what is considered a research group, it is important to distinguish it from a mere grouping of researchers in different organisational units or institutions. In fact, it is positively valued that there is a prior cohesion among the researchers participating in the study, that is, it is not simply a group of researchers who meet exceptionally to carry out a specific study, but rather the members of the research team have started their work as a group some time before applying for funding. The previous experience of the team in the subject to be investigated will support the feasibility of the project in question. There is no doubt that a consolidated team, with shared experience in studies on a subject related to that of the current project, will have a better chance of completing the research successfully.<sup>2,25,30</sup>

The evaluation of the research team should be based, on the one hand, on the productivity of the different researchers involved in the proposal and, on the other, on the suitability of the team for the tasks set. The evaluation of the different researchers participating in the project should be made according to the criteria previously set out for the PI, although it will not be so demanding and they will be considered as a whole (for example, in the case of students, residents or doctoral students, scientific production should be evaluated in the context of their professional trajectory, and in no case should the group be penalised for including staff in training).<sup>23</sup> In short, the suitability of the team should be based on its ability to carry out the objectives set out in the proposal.<sup>23</sup>

Membership in the research team of people trained in different disciplinary fields – that is, the multidisciplinary nature of the team – and linked to different institutions, is usually valued very positively by the evaluators, obviously when this is justified and explained in the project's funding application. Letters of support and of commitment of availability from collaborators can be added, which will help the reviewers to have confidence in the viability of the proposed interdisciplinary team. <sup>25</sup>

We should always choose the best collaborators, convincing them that our leadership is a guarantee of success

for joint projects. We should select the number of collaborators carefully (enough to achieve the objectives). As almost always, quality matters more than quantity. A frequent mistake is to incorporate (too) many members of our own service into the research team, and also other professionals who are not really going to work directly on the project. Another common mistake consists of not assigning specific tasks to the team members (according to their qualifications), in an attempt to hide the fact that we already have specific professionals to perform certain tasks, and therefore, funding should not be requested for hiring additional staff (for example, funding should not be requested for hiring a laboratory technician, when there is already such a person included among the members of the research team). <sup>27</sup>

Continuous selective pressure on researchers has spawned a symbiotic evolution that has enabled us to survive this ënvironmentalpressure. One of the most representative examples of this collaboration is that of the Centros de Investigación Biomédica en Red [Biomedical Research Network Centres] (and specifically the Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas, CIBEREHD [Biomedical Research Network Centre for Liver and Digestive Diseases]), of the ISCIII. Indeed, the growth in network collaboration is one of the most important strengths of biomedical research in our country. 8 If a conclusion can be drawn from the Spanish experience, it is that collaboration between institutions and networks of researchers is the most worthwhile strategy for improving the quantity and, more importantly, the quality of research. 8 There is no doubt that working as a team produces great results; unity is strength and, in research, this is especially evident.31

### The limitations and alternatives of the research project

Specifying the limitations of the project, as declared by the researchers themselves, is a sign of modesty and scientific honesty. In addition, anticipating possible criticism that we might receive from the reviewers who evaluate our proposal can be advantageous, allowing us to pre-empt it and justify some of these limitations. In this section, the authors should make their own critical review of the main limitations derived from the chosen methodology and also of the possible difficulties that may arise during the course of the project (for example, not being able to reach the required sample size or the appearance of unexpected biases). It is important not only to recognise these possible eventualities, but also, when possible, to provide solutions to minimise their negative effect (or at least justify that their influence will be minimal on the viability and quality of the study). 3,19,21 In other words, it is about pricking the balloon before it bursts:

The research proposal should include, whenever possible, a contingency plan in case some parts of the project go wrong or cannot be carried out.<sup>25</sup> Planning an alternative approach – a plan B – is particularly relevant when most of the objectives are interrelated and (unexpected) negative results from one may compromise the opportunity of developing other objectives.<sup>27</sup> These contingency plans, which would allow the investigation to continue and finally

achieve the proposed objectives, emphasise the maturity of the proposal and of the research team.<sup>25</sup>

#### The research project budget

In general, the budget requested must be broken down into expenses for staff, inventory material, consumables, and travel and per diets. The requested funding should be reasonable (well justified) and realistic (the budget allocated to each research project is regulated by the different calls, so the requested funding should be adjusted to the maximum amount (if any) established for each call).

The budget must specify what is and is not being requested. Thus, if funding is not requested for any device or service necessary to carry out the project, it should be explained that this is already available or that it can be obtained from the group's own funds (or from other calls).

In some calls (such as those of the ISCIII), the evaluators frequently proceed to cutthe budget requested by the researchers and even if the project is finally granted funding, it may end up receiving considerably less than the amount initially requested. This fact usually produces a bittersweetfeeling in the researcher, in which the euphoria at the project being accepted is tempered by the uncertainty of whether they will be able to carry it out with the budget finally granted. In the most drastic cutback situations, the research project investigators should consider whether it is not more appropriate to substantially modify the study design to make it feasible with the new budget granted, rather than simply try to cut staff and material costs, or planned time frames.

#### The bibliographical references

The references say a lot more about a research project than one might think. Although it is obvious, it is worth emphasising that only references to the authors who have actually been consulted should be included. Mentioning works and opinions that are known through third-party references, results in many authors being attributed things that they have never said.

It should again be remembered that, as almost always, what is truly important is the quality rather than the quantity of things, in this case of the bibliographical citations. The most relevant references should be commented on concisely, making a critical analysis of the studies on the subject. The bibliography should be as up-to-date as possible: a maximum of five to 10 years old, unless there is a fundamental reference on the subject that is older.<sup>3</sup> A frequent mistake by a novice is to include an excessive number of bibliographical references, perhaps in an attempt to show that they have mastered the subject in detail. However, someone knowledgeable in the subject in question will not fail to notice that many of the references used are superfluous, or even inappropriate. On the other hand, all the statements made in the text that require the support of references should include the corresponding citations. We can (and should, if possible) include citations from our own studies, but without overdoing it, referencing only those strictly necessary.

In general, references to original articles are preferred over references to reviews. However, sometimes it may be especially appropriate to include citations from reviews, especially if they are good systematic reviews or metaanalyses, since these can summarise, in a single citation. all the information that we wish to convey. In general, the use of citations from abstracts of communications presented to congresses should be avoided, especially if the study has since been published in its full form, or if the congress was held two or three years ago and the full article has not yet been published. The quantity and quality of the scientific information contained in these abstracts frequently leaves much to be desired, as they are preliminary data, not having followed the peer review process usual in full articles, or simply not having enough space to present all the details of the study. However, on occasions, in the case of very novel topics for which there has not yet been time for complete publications, this form of presentation - and therefore, of reference - may be the only one available.

#### The substance and form of the research proposal

A frequent mistake is to consider that the content, the substance, of a research proposal is the only thing that matters, and that the vessel, the form, is irrelevant. It is evident that scientific content constitutes the essential aspect of any proposal and will have the greatest role in the decision of whether it is accepted or rejected. However, great scientific work can be overshadowed by a flaw in the presentation of the proposal. A large number of research proposals that are submitted force their authors to compete fiercely for the approval of the evaluators. Given equal scientific quality, a correctly presented proposal will undoubtedly be more likely to be accepted than another with a poor presentation. This observation is also applicable to correctly following the rules or specific requirements of the funding institutions. <sup>32,33</sup>

Some researchers review the content and structure of a project at the same time as its style, but it is certainly more efficient to focus on the substance first and leave the form until last.<sup>34</sup> This is so, firstly, because it is possible that in the end we will eliminate or substantially change some parts of the project, so a previous stylistic correction would have been useless, and secondly, because it is really hard to focus on correcting content and style flaws at the same time and in the same sentence. In any case, starting by reviewing the stylistic aspects without first refining the content and structure of the article seems to us like putting the cart before the horse.

Before finalising the final version of a research proposal, we should consider whether the entire written text is really needed or if some part can be suppressed, or if information that is already given in one place is repeated somewhere else. The task of cutting or summarising a project proposal can be very painful for the researcher who has written it, who often interprets it as an amputation of some of the parts of the project that have been so difficult to develop. This is where the help of colleagues and friends, especially if they have not been directly involved in the writing of the proposal, can be of great help: their objectivity will make the use of scissors less traumatic.

#### **Table 1** Key points for writing a suitable research proposal.

Title: Clear, concise, precise and, at the same time, complete, informative and attractive.

Summary: Clearly reflects the general objective of the project and, schematically, the design, study scope, study subjects, instruments to be used and the most important outcomes or variables. Balance between thoroughness, clarity and brevity. Introduction: Briefly describe the gaps that there are in knowledge of the subject and the reasons that have led us to conduct the study, and what benefits will be derived from the results obtained. Review the literature in a detailed and critical way. Give details of our previous experience in the area.

**Objectives:** Concrete, precise, assessable, viable and relevant. Classify as generalor primary (usually just one) and specificor secondary (usually no more than four). Objectives aligned with the values, mission and vision of the funding body.

**Methodology:** Describe in detail what will be done, how, when and where. Show that the procedures selected are the most suitable and that we are familiar with them. Include any preliminary results that support the technical viability of the project.

**Work plan:** It should be realistic and take into account possible delays in obtaining some documents, permits and additional funds.

**Coherence:** The proposal must have logical fluency, without any jumps, gaps, inconsistencies, contradictions, incomplete reasoning or unnecessary repetitions.

**Viability:** Tailor the objectives and methodology to the work plan, distribution of tasks, available equipment and requested budget. Submit a proposal that is novel and ambitious, but at the same time, credible in terms of content and timelines.

Applicability: Explain that the results derived from the project will create some benefit in aspects relating to health and that they will be easily applicable. Emphasise the potential of the project to obtain results that are transferable to the industrial diagnostic/therapeutic setting or to generate patents.

**Principal investigator:** Highlight their scientific productivity (öriginalresearch articles published in journals) and ability to undertake research projects (especially those funded through competitive calls), primarily over the last five years.

**Research team:** Always choose the best collaborators. The team's previous experience in the subject to be investigated supports the feasibility of the project. Highlight the multidisciplinary nature of the team and its link to different institutions.

Limitations and alternatives: Conduct a critical review of the main limitations and potential difficulties that may arise and offer solutions to minimise their negative effect. Include a contingency plan (plan B) in case some parts of the proposal cannot be carried out.

**Budget:** It must be reasonable and realistic. Justify what is being sought and what is not (because it is already available or can be obtained from own funds or other grants).

**References:** What is important is the quality, not the quantity, of citations. Critically comment on the most relevant and recent literature (maximum of 5–10 years). It is a mistake to include an excessive number of references. We can (and should, if possible) include citations of our own studies.

**Substance and form:** Focus first on reviewing the content and leave the form of the proposal until the end. Critical review by people other than the author is essential. The five qualities of good prose are fluency, clarity, precision, sobriety and attractiveness.

An essential aspect in the final stage of preparing the research proposal is the critical review by people other than the author, whether they are co-researchers or other colleagues (not necessarily experts in our field), since our familiarity with the content of the project often detracts from our ability to review it. Once an error has slipped by us and we have not detected it in the first review(s), it is very possible that it will escape our attention definitively. This is where, once again, having the manuscript read by other colleagues can be of great help. They will read the work with a wider perspective and can identify, for example, paragraphs that are confusing or lacking in logic, or other questions that we had not even asked ourselves. It is worth emphasising that for the final review of the proposal we should ask people who we know will carry out a truly critical reading, work that requires from them an interest and an effort that only true friends or honest colleagues will be willing to make for us. On the contrary, we should not have recourse to colleagues who we suspect will pat us on the back and flatter us by saying how perfect our study is.

Finally, when the content and structure of the project have been thoroughly reviewed, it is time to carefully review the prose style. It is evident that, when faced with a project that investigates an exceptionally novel and important topic, and that has excellent methodological quality, a positive decision accepting it will not be substantially clouded by minor defects in the style of the application. However, rarely is the decision to fund a project so clear and if it is written in dense, tangled and confusing prose, it is likely that these seemingly inconsequential flaws in form could tip the evaluator's balance toward rejection.

Five qualities of good prose have been described: fluency, clarity, precision, sobriety and attractiveness. Fluency depends primarily on the connections between paragraphs and the sequence of ideas within each paragraph. The fundamental objective of clarity is to ensure that nothing stands between the reader and the message that the author is trying to convey. Precision implies that the words chosen are not only correct, but the best to express the meaning that is intended. Sobriety will help us choose a concise clear

style of prose that is not over elaborate and dense. Lastly, simplicity does not diminish a text's attractiveness. Attractive prose does not distract the reader from the message it conveys nor does it intend to impress them with stylistic flourishes. <sup>32,33</sup>

#### Final reflections

The research proposal is a carefully written plan that includes all the scientific, ethical and logistical aspects of the study that we propose to carry out. This proposal aims to present and describe in detail what is going to be investigated, the conceptual theoretical basis, the methodological components and the human, technical and financial resources necessary to carry out the research. The research proposal is the culmination of all the work carried out in the planning stage of the research, and therefore serves as a guide for the researchers during the study. It must also contain enough information to allow others to evaluate the real possibility of carrying it out with the established human, technical and financial budgets.

As in any work, to achieve excellent results, practice is essential. Guidance is required – especially at the beginning of a research career – on how to prepare proposals for funding agencies. In the midst of competition for the limited funds available for research, proposals must meet high demands for scientific quality, viability and consistency to successfully make it through the evaluation and selection processes.

A researcher's work is not always easy, nor is it always gratifying. This is why the researcher must learn to live with success, but above all, how to deal with failure. A positive attitude in the face of adversity, when, for example, a research proposal that has taken us so many hours to prepare is rejected, is something that, at least in part, can be learned. Developing tolerance for frustration is vital. In addition, a researcher must know how to be self-critical and be open to feedback. We have to learn not to take critical feedback from evaluators (too) personally and to adopt the philosophy that if we have learnt from our failures, we have not really failed. Thus, when a proposal is rejected in a competitive call, we should take the reviewers' criticisms positively and take advantage of the invaluable opportunity their comments give us to improve our current and, above all, future proposals.

Writing a good research proposal requires considerable effort and a great investment of time, but it's worth it. Writing a good proposal is the best guarantee that it will have a successful outcome. In any case, regardless of the final resolution (positive or negative), one of the definite benefits of preparing a research proposal is the experience gained from having planned and explained in a document the design of a research project and the work plan necessary for its execution.

In this manuscript we have shared with the reader a series of recommendations, the key points of which are summarised in Table 1, arising from our own experience, sometimes positive and many other times negative, which we consider essential for drawing up and submitting a successful research project proposal, and for it to win approval and funding. We sincerely hope that they are helpful.

#### Conflicts of interest

J.P. Gisbert has provided scientific advice and support for research and/or training activities for: MSD, AbbVie, Hospira, Pfizer, Kern Pharma, Biogen, Takeda, Janssen, Roche, Sandoz, Celgene, Ferring, Faes Farma, Shire Pharmaceuticals, Dr Falk Pharma, Tillotts Pharma, Chiesi, Casen Fleet, Gebro Pharma, Otsuka Pharmaceutical, Vifor Pharma, Mayoly, Allergan and Diasorin.

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