

Biostatistics Laboratory of Católica Medical School – LBFM-UCP

1. Recognition

The Consulting area, even at the internal level, requires the definition of performance parameters to regulate the activity of the Laboratory in order to protect the interests of all those involved. This area can then be expanded abroad through the creation of a business model that allows obtaining revenue for the CMS.

1.1 Acknowledgments

The service provided by the Laboratory must be recognized in publications, of any nature, whenever there is a contribution in terms of method of obtaining data, experimental design, analysis, generation of scientific content and / or interpretation of results, even in the context of informal requests (see below).

In all cases, from theses to publications and reports, and whenever there is no place for co-authorship, the contribution of the Laboratory must be mentioned in the "Acknowledgements". The "thank you" format will be standardized:

The Authors would like to thank for the support given by the Laboratory of Biostatistics of Católica Medical School, which provided assistance in [insert relevant themes].

The Laboratory also requires that a PDF version of the entire publication, thesis or report in which it has collaborated be sent.

The publication of any work in which the Laboratory is involved may only take place after the sharing and validation of the printing proofs with the Laboratory.

1.2 Co-authorship

In the absence of payment and whenever there is a *significant* contribution by the Laboratory to a scientific publication, the Laboratory reserves the right to ask the person in charge of the study to include the member(s) involved in the analysis as co-authors. This will have to be accepted by the person in charge of the study and should be defined, as far as possible, when accepting the formal request (see below).

The designation of "significant" will depend on what is negotiated with the person in charge of the study and will be in writing as part of a formal request for support. However, it is immediately stipulated that, in the following cases, the Laboratory will *always have* the right to co-authorship, which it may choose to exercise or not:

- Complete definition of the experimental study design;
- Execution of all statistical analyses used in the publication, in cases where these are central to the conclusions;
- Active participation in the writing and revision of the publication, with *non-standard text modules* written by members of the Laboratory.

1.3 Payments

Consulting services can be paid, and the Laboratory functions as a service provider in the traditional sense. This model will be preferred whenever there is room for the provision of services to entities external to UCP. There may be exceptions to the existence of a cash payment in the following cases, subject to the approval of the coordination of the Laboratory:

- Payment in kind;
- Possibility of using the trademark for advertising;
- Support for social, charitable, or similar institutions.

There may also be payment for intra UCP services, in particular:

- In relation to Organic Units other than the Medical School, there may be exceptions to the extent of mutual interest in recognition via joint scientific publication;
- In cases where the Laboratory needs to use resources external to it, through expenses;
- In cases of high complexity or specificity;
- When the request is associated with a funded project, with budget for contracting external biostatistics or similar services.

This will always be agreed at the beginning of the service and put in writing as detailed in the Procedures below. In these cases, there is no place for recognition by co-authorship.

The amount to be paid per study will have a reference value of €50/hour and can be negotiated on a case-by-case basis. Any initial budgeting can be revised to the extent of the uncertainties that may arise in terms of workload – these revisions are presented to those responsible and only implemented if they accept them. When the Laboratory is close to the agreed time limit, the proponents will be contacted and alternatives will be presented, not committing the Laboratory to carry out remunerable work without a prior agreement.

There will always be a deposit to be paid based on the budget, with a reference percentage of 30% of the estimated total. The work will only start after receipt of the deposit amount.

2. Procedures

2.1 Dedicated support – Master's Dissertations and PhD Theses

Any master's thesis or doctoral thesis of CMS may benefit from the support of the Laboratory, from the design of the study to the analysis and writing of the conclusions, within the scope of the "Informal Requests" below. In any case, students will receive statistical training in the process to ensure their autonomy.

However, there may be theses in which this support is integrated into the work plan itself, accompanying the Laboratory all the steps. Due to limited resources, the number of theses that may benefit from this full support will be reduced and limited to all that require a methodological weight that justifies the integration of a member of the Laboratory as co-supervisor.

This limitation depends on the available resources and will be stipulated annually, whenever the thesis proposals are defined.

For other theses, there can be no formal requests.

2.2 "Open Door" and Informal Requests

The Laboratory must follow an open-door policy at a time to be defined and to be communicated to the entire Faculty of Medicine. It is intended to create a space to answer in person statistical questions of a simple or just theoretical nature. All requests that require more time will imply the need for formal requests for support. It should be stressed, however, that these formal requests may benefit from this timetable to ensure a more detailed and/or supportive framework in the formatting of the data, for example.

Informal requests by email will *not* be analyzed, unless later framed in conversation with a member of the Laboratory. Therefore, any informal request, even if simple, must be accompanied by a request for a meeting, even if brief, thus ensuring that there are no answers that can lead to erroneous conclusions in the absence of the context, always relevant.

Whenever there is a succession of informal requests, on an open door, by email, or otherwise, always referring to the same study, the Laboratory reserves the right to request that a formal request be made, or to consider this succession as the basis of the formal request.

Informal requests are always free of charge.

2.3 Formal requests

The requests for greater expression will be the formal requests. The open door and informal requests can serve as a basis for constructing a formal request, which will entail defining, at a basic level:

- Type of study
- Objectives (primary and other)
- Fundamental question and hypotheses
- Definition of population and sample
- Identification of variables of interest
- Experimental design
- Relevant comments
- *Intended timings*

This type of request can be standardised using a standard form, available through the website. There will be cases where not all this information will be available. However, in order to be able to proceed with a forecast of the type of recognition desired and budgeting of time (and price, when applicable), depending on the type of intervention requested, this information is essential and can be worked on within the scope of informal requests. This process may be iterative and require several sessions before stabilizing a formal request with the necessary parameters requested by the Laboratory to submit a proposal.

Once the formal request has been delivered and accepted by the Laboratory as such, with written confirmation, the following steps are followed:

- The Laboratory will have a *period of 5 working days* to respond with the requested budgeting and suggested recognition model, to be discussed with the person responsible for the study. The Laboratory reserves the right to refuse requests due to lack of resources, or due to limitations of such requests, as described in the "Elimination Points";
- If the quotation is accepted in writing and the method of recognition or payment is agreed, the data must be submitted to the Laboratory in Excel or SPSS format as *soon as possible*, in an appropriate format;
- Once the data has been submitted, a meeting will be scheduled *within one week* for a first joint analysis with a view to:
 - Data verification to identify sampling issues, missing data and formatting issues;
 - Identification and definition of variables
 - Structuring of variables
 - Exploratory descriptive analysis
 - Consolidation of hypotheses and objectives
- The minimum deadline for delivery of results is always *at least 2 weeks* from this first meeting, and can be reduced only in very exceptional situations;
- The delivery and explanation of results will be made in person in a meeting with the proponents. Intermediate meetings may be required by the Laboratory whenever necessary;
- The Laboratory reserves the right to review the initial decision budgeting and recognition whenever the context and new information that arises justifies it.

2.4 Follow up of formal requests

- Depending on the type of request and study, there may be continued support after the delivery of results, negotiated on a case-by-case basis – however, where a fundamental revision of the study principles is required, or more statistical analysis work not foreseen in the initial budget, *this requires a new formal request*;
- In cases where co-authorship is agreed, the Laboratory undertakes to participate in the publication review process whenever necessary, even if in accordance with the limitations of the Laboratory – however, if this implies changing the structure of the study, and as in the previous point, a new formal request is required to manage the *pipeline* of requests and associated work.

2.5 Research projects

The Laboratory can also provide support for the writing of research projects, in particular at the level of study design and data sampling process. This must be done through a formal request, albeit with the following particularities:

- In research projects funded by external entities, the Laboratory should be included in a relevant heading and at least as "External Consultant" (or similar) in the absence of LBFM's human resources in the project structure;
- The continued support of the Laboratory requires its inclusion, or that of one of its members, in the project budget, at least as an "External Consultant" (or similar) in the absence of LBFM's human resources foreseen in the project structure – this inclusion implies a budget to be agreed with the Principal Investigator;

- In these cases, the recognition at the level of co-authorship in the *outputs* of the project, if any, should be agreed *in principle* and in accordance with the contribution of the LBFM foreseen in the budget and detailed in connection with the project plan – however, there are no co-authorships "by default" in any case;
- In the event that the Principal Investigator only needs support in the writing of the proposal and not in its eventual operationalization, then the Laboratory will provide a paid service that may be covered by the project in a service contracting rubric.

2.6 Courses

To the extent of the available resources and the needs of the CMS, the Laboratory will organize courses and seminars on Biostatistics and related topics on a regular basis. The calendar must be on the CMS/Laboratory's website, with links for registrations.

For CMS and related Research Centres, these courses will be free. For other structures, even if internal, a payment model will be considered and defined on a case-by-case basis. The payment model may be by individual registration (preferred for entities external to the UCP) or by organized course (in particular at the request of other UCP structures, with payment at the level of the involved units or centres).

The Laboratory may also receive requests for specific courses, structured with a target audience in mind (e.g. clinical staff). The structure of this type of course should be defined together with the proponents of the same. The Laboratory will present a structured proposal, which will include the program of the course together with the budgeting of time and prices that must be accepted in writing and upon payment of a deposit.

Due to limited resources, however, these courses will have to be limited to an overall maximum of 50 hours in a calendar year.

3. Elimination points

The Laboratory reserves the right to:

- Reject any application due to flaws in the experimental design and/or sampling process, as well as due to the absence of fundamental hypotheses or inadequacy of these in relation to the data collected. *It is highly recommended that the Laboratory be contacted when defining the experimental design;*
- Stop responding to a formal request if there is not the necessary collaboration on the part of those responsible, delivering all the analysis and prepared and detailed documentation in progress (and adjusting the amount to be charged/returned based on the budget and deposit paid, if applicable);
- Limit the number of formal requests to be accepted on the basis of available resources, in order to ensure the quality of the services provided.

4. Other Situations

Doubts and omissions that result from difficulties in the full application of this document will be the subject of deliberation by the competent body upon a reasoned proposal from the head of the Laboratory.