

APPENDIX B

GUIDELINES FOR DISTRIBUTION OF BUDGET EXPENDITURES

Call 2017

C1. Personnel

The personnel expenditures shall refer to subjects specifically enrolled for the project activity. Duration of the employment contracts shall not exceed duration of the research project. Please note that duration of contracts can also differ from duration of the project, but the cost of the contract shall exclusively be reimbursed for the period included within duration of the project.

Besides personnel recruited *ad hoc* for the project, it is possible to charge to funding a share of permanent or fixed-term staff of the institution to which the research unit belongs; the said staff shall be directly engaged in scientific and technical research activities as well as in scientific and technical management. However, funding cannot be used as incentive and/or remuneration of consultancies or in any way to integrate remuneration of permanent staff working for the institutions involved in the project. The relative cost shall be determined according to the required time commitment dedicated to the project (within the percentage limit prescribed in the budget annexed to the protocol).

The personnel cost shall be determined as follows:

- a) For each person involved in the project, the benchmark shall be the effective gross annual cost per employee (effective gross annual wage/employee, with separate indication of employer's contributions, to the exclusion of payments for extra work and daily allowances); gross monthly cost shall later be determined dividing gross annual cost by 12 annual working months;
- b) The cost to be charged to the project shall be calculated multiplying gross monthly cost by the number of person-months dedicated to the project, based on the percentage of time dedicated to the project itself compared to the total of the activities, as per *time-sheet* to be filled in the arrangement phase of the economic reports drafted in the course of the study.

The item "Personnel" shall also include costs of seconded staff currently working for the Institution to which the Research unit belongs, who can be reimbursed in the aforementioned way.

For each expert involved in the project, it is necessary to specify:

- Degree: qualification shall be indicated.
- Tasks: role and type of assignment, e.g. coordination, data analysis, monitoring, etc. (it is possible to indicate more than one assignment).

- Contract: type of employment contract; for permanent staff, the existing type of contract shall be indicated (e.g. permanent or temporary employment contract, project-based contract, PhD or equivalent, research fellowship, secondment, etc.).
- Participating centres: location(s) where activity shall be performed (Coordinating centre and/or participating centres).
- Duration (in months): duration of contract or collaboration (in months). As mentioned above, the cost of the contract shall exclusively be reimbursed for the period included within duration of the project.
- % of full time equivalent (FTE): percentage of commitment of the contract with relation to full time. Should a person be collaborating to the project with a partial commitment up to half of the overall time, "*% of full time equivalent*": 50% shall be indicated. For the statistical analysis of the project data, it shall be generally envisaged a part-time commitment.
- Salary: gross salary for the whole duration of the contract per unit of staff (Gross salary per employee), with a separate indication of any related charge (Charges: Related charges to be paid by institutions), independently of the full time equivalent dedicated to the study project. Please note that, in case a staff unit collaborates to the study project for a full-time equivalent lower than 100%, the remaining part of the indicated salary shall not be charged to the project, but shall be funded by other resources of the institution.
- Quantity: number of subjects with the same contract features in the same centre.
- Total: total shall be calculated as product of the items *% of full time equivalent*, *salary* (gross salary per employee plus related charges) and *quantity* and it shall indicate the exact cost of unit of staff to be charged to the project.

C2. Equipment and supplies

Expenditures for furniture (e.g. desks, chairs), telephones, mobiles and faxes are not allowed.

- Hardware and software: the overall expenditure allowed for the whole duration of the project (for all participating centres) shall not exceed € 40.000 (forty thousand). In any case, the share for any single centre shall not exceed € 10.000 (ten thousand).
- Labs Material: allowed exclusively if indispensable to carry out the research project.

- Stationery: an overall expenditure is allowed which does not exceed € 5.000 (five thousand) for the whole duration of the project and for all the participating centres.

Please note that purchase of equipment provides reimbursement of the purchase cost, provided that such purchase is consistent from both a technical and a temporal viewpoint with the objectives and aims of the projects.

C3. Services

- Monitoring: please indicate in this section if the monitoring activity is outsourced.
(Attention: do not include in this table eventual costs of staff already described in table C1).
- Data collection: expenditure for electronic Case Report Form (CRF) shall be consistent with complexity of the study, data collected and number of samples.
- Publication costs-reprints: specify estimated expenditure to purchase publications (if any).
- Insurance: as for insurance expenditures, reference should be made to the provisions of Ministerial Decree 14 July 2009 “Minimum insurance requirements to cover subjects participating in clinical trials of medicinal products”.

Possible consultancies and/or self-employment contracts can be entered under this cost item.

C4. Drug cost

Drug(s) cost for not approved indications. It is requested to enter the total drug cost, if used outside the approved indication, in case it is not provided for free by the pharmaceutical company or paid by others. Also indicate possible costs for blinding, placebo, primary and secondary repackaging, preparation of blind (or double blind) – in case they are not provided for free by the pharmaceutical company or paid by others.

- Please note the provision of AIFA Call 2017, section “General information on the call for proposals”, laying down that:

“co-financing by private companies is allowed only as follows:

- Medicines reimbursed by the NHS can be provided in case of a packaging modality for a “blind” administration.*
- Medicines for off-label uses may be provided.*
- Companies or public and private bodies may co-finance the individual thematic areas. The statement of availability to co-financing by the potential sponsor must be submitted within the deadline for submission of the protocols. This co-financing will be divided equally between all the selected protocols of the call for the thematic area covered by the co-financing.*

- Public bodies and non-profit organizations and/or associations may also co-finance individual studies; the statement of availability to co-financing must be submitted within the deadline for submission of the protocols”.

Should the pharmaceutical company provide the medicinal product for free, a formal commitment letter shall be sent to AIFA before signing the contract, in case funding is approved by AIFA. Should the abovementioned letter be not submitted, AIFA is entitled to not proceed with funding of the project.

C.5 Meetings – conferences – workshops

Participation and organisation of meetings, conferences, workshops, seminars: the overall expenditure allowed for the whole duration of the project (and for all the participating centres) cannot exceed € 50.000 (fifty thousand Euros).

C6. Overall expected costs for each of the items indicated below and for each year of the project)

Summary table of expenditure for extra costs spread over the years. It is possible to enter in this table the overhead share, which cannot exceed 10% of the total budget.

C7. Distribution of costs between coordinating and participating centres

Indicate the amounts, including the eventual drug cost, with the related distribution between the participating centres.