

APPENDIX B

GUIDELINES FOR ALLOCATION OF BUDGET EXPENDITURES

Call 2018

C1. Personnel

The personnel expenditures shall refer to subjects specifically enrolled for the project activity. Duration of the employment contracts must 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 will 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 workers of the institutions involved in the project. The relative costs will be determined according to the time spent by the worker in the project activities (within the percentage limit prescribed in the budget annexed to the protocol).

The share of funding for permanent or fixed-term staff of the institution shouldn't exceed 25% of the total budget for personnel stated in this section. If no personnel recruited *ad hoc* for the project is expected, the share of funding allocated to permanent or fixed-term staff of the institution shouldn't exceed 5% of the total budget of the project (tables C6 and C7).

The personnel cost will be determined as follows:

- a) For each person involved in the project, it refers to the annual cost per employee (effective gross annual wage/employee, with separate indication of employer's contributions, except for overtime work payments and daily allowances); gross monthly cost will 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 compared to the total of the activities, as per *time-sheet* to be filled in the economic reports required during 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 professional 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) shall be indicated.
- 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 will 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 (that is 0.5). For the statistical analysis of the project data, it shall be generally envisaged a part-time commitment.
- Personnel cost: cost expected for the whole duration of the contract per staff unit. The amount corresponds to the sum of the gross salary paid to the personnel unit (Gross: Gross salary for employees) and the related social charges paid by the institution employer (Charges: Related charges to be paid by institutions), except for overtime work payments/daily allowances and 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, mobile phones and faxes are not allowed.

Please note that for equipment purchase it is possible to reimburse the purchase cost, if it is technically and temporally consistent with the objectives and the aims of the project. .

- 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.

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, collected data and sample size.
- Other: in this section the following costs should be indicated:
 - ✓ 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”.

- ✓ CRO, costs deriving from contracts for professional services.
- ✓ Possible consultancies and/or self-employment contracts

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, blinding (or double blinding) – in case they are not provided for free by the pharmaceutical company or paid by others.

Please note the provision of AIFA Call 2018 on section **“Funding of projects: maximum ceiling and items eligible for funding - Co-funded projects”** regarding the possibility of co-financing by public or private companies or organizations that have an interest in supporting the independent research program of the AIFA.

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

- a) *Medicines reimbursed by the NHS can be provided in case of a packaging modality for a “blind” administration.*
- b) *Medicines for off-label uses may be provided.*
- c) *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 provides the medicinal product for free (point “a” and “b”), a formal commitment letter shall be provided. This availability must be included in the documentation attached to the application form ("budget" section) at the moment of the study protocol submission.

The co-financings obtained after the project submission must be promptly communicated to the Independent Research Office of AIFA which, before the possible stipulation of the contract, verifies its admissibility and proceeds to request an equal reduction of the initially proposed budget.

C.5 Meetings – conferences – workshops

Organisation and participation to 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). These expenditures must exclusively concern meetings aimed at carrying out the project and the dissemination of its results.

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

Summarize in the table all the estimated expenditures for each item and distribute them within the time frame of the project. In the table it is also possible to insert an amount of *overhead* that must not exceed 10% of the sub-total (given by the sum of all the items except for the cost of the drug and the *overhead* itself).

C7. Distribution of costs between coordinating and participating centres

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