



Instructions to Applicants on completing the EDCTP budget and annual financial reporting forms

I. General

The *form* serves two purposes, firstly as the budget form for up to 5 periods, and secondly as the periodic reporting form which should be returned to EDCTP by the Project Coordinator each year on the anniversary of signing the grant contract. **Only “eligible” costs should be entered in the budget or actual column.**

There are 2 types of forms in the spreadsheet; 8 yellow tab coloured sheets which should be completed for the EDCTP requested funding entitled “EDCTP Funding Coordinator/Collaborator”, one separate sheet should be completed for each coordinator and collaborator which is taking part in the clinical trial and 6 other blue tab sheets entitled “Member state/third party funder” which need to be completed for each separate member state, or third party which is contributing either “in kind” i.e. by the provision of resources towards the execution of the project, or by giving cash directly to the project or when using cash that the donor has firstly given through EDCTP to be used at the project.

Where a member state/third party is contributing either by direct cash contribution to the project or from cash funds first donated to EDCTP then only the amount of the contribution needs to be entered in the appropriate box at the top of the blue sheet (**cells L42 and L46**).

If the cash contribution is a direct one (the cash is not passing through EDCTP first) to the site only then the value of the funding given to each site should be indicated in **cell K49-R50** on the blue tab sheet of how much each site is receiving and indicate the site’s name by writing the institution name on top of it to replace the word “Site 1”– but please note that, as EDCTP will not be responsible for controlling or administering these types of donations, then the costs for which it is being used to cover should not be included within the main body (lines 62 to 225) of the site’s spreadsheet in the yellow tab sheet. A separate bank account from EDCTP should be ensured so that double dipping to both donors will be avoided.

Conversely where cash funding is being made from donor funds already held by EDCTP at its bank then the value of the funding shown in the blue sheet **cell L42** will be split across the sites where it is to be spent in **cell I43** on each yellow sheet and also included as costs in the main body of the spreadsheet (lines 62 to 241) so that EDCTP can review and administer the budget and use of funding for the sites concerned.

For “in kind” contributions the cost is calculated in the blue spreadsheet in **cell L44** and is simply the total of the amounts which you will enter as individual line items in the main body of the spreadsheet below it. “In kind” contributions should not be shown anywhere in the yellow sheets as again EDCTP is not responsible for controlling or administering it.

For all direct cash and “in kind” donations made direct to the institute, a supporting letter in a letter headed paper by the institution and signed by the head of institute or Institute legally authorised representative must be sent to EDCTP declaring that this will be the amount of cofunding provided to the project

Please see the EDCTP guidelines on financial requirements at www.edctp.org for what comprises eligible “in kind” contributions.

For the budget approval process, figures should be inserted only under the column “Budget” and all “Actual” columns should be left empty.

Once the budget has been approved by EDCTP the spreadsheet will be sent back to the Project Coordinator with the budget columns duly protected to prevent any amendments; it will then only be possible to enter figures under the actual column at the time of the periodic financial report. *Please note that EDCTP will not accept as eligible any cost items which were not included in the original budget. Therefore, no new cost lines should be added at the time of completing the annual financial reporting form, unless the grantee has written to EDCTP requesting and justifying such a change and it has been agreed by the DFA.*

Overheads are automatically calculated in the form at 10% on all eligible costs - **please note that overheads include all costs of freight, bench fees, office rental and all other internal recharges so these should not be included as separate line items on the budget form, as they will be disallowed. Most line item headings have been suggested but there are also spaces where you can add additional items not already included**

Applicants should ensure to complete all mandatory information required on the form fully where relevant for a required cost and not to leave boxes empty, which will result in the budget being rejected.

All costs are to be quoted in Euro on all of the forms – local currency costs should be converted into Euro following the instructions given in the financial guidelines.

Annual budget figures should be estimated on the basis of when the grantee expects to spend the money over the life of the grant i.e. in relation to necessary expenditure and in relation to the deliverables and milestones rather than just dividing the total into equal parts for each year. In practice it will normally be the case that more money is spent in the early years and especially the first year as the equipment is bought then.

Actual data periods other than the last will be completed on the basis of 12 month periods from the anniversaries of the date of signing the grant agreement. This means that for the annual reports the figures quoted will all be for 12 month periods except for the last period which will be to the end date of the trial, which will be a shorter period than 12 months or more if a no-cost extension is granted to the grant.

The annual financial and technical report should be sent to the relevant EDCTP project officer every year as per the conditions of the contract. The Project Coordinator is responsible for collecting the figures from each of the collaborators and sending those to EDCTP in one consolidated package. Please note that this is only for the yellow forms – the blue ones do not require annual updating as the budget figures are applicable only. All yellow tab sheets need to be signed before being submitted to EDCTP (a scanned copy sent to the Project officer will suffice.)

II. Applicant details

1. The role in project is selected from a drop down box and is either collaborator or Project Coordinator (there is only one Project Coordinator for each project).
2. A separate budget sheet should be completed for each different collaborator or Project Coordinator for which EDCTP funding is being requested.
3. Select the category of clinical trial grant award from a drop down box and note that the EDCTP cost centre will be filled in automatically.
4. Interest received on EDCTP funds should be completed **by the Project Coordinator site only** for periodic financial reports. Interest received on EDCTP funds held by the Project coordinator will be deducted from the next payment due under the grant where it exceeds 1% of the whole value of the overall grant to prevent making a profit from the grant.

III. Project Personnel – Wages & Salaries Cost

5. This section covers all the project personnel's wages and salaries cost per work packages. The purpose of providing this information is for EDCTP to be aware of the amount being spent on the project personnel's basic salaries and how much salary top-ups is required on top of these (basic salaries) from the public institution, the costs for which EDCTP

would be required to cover. The salary top-ups should be fixed for the entire life of the project which means yearly increment is not applicable on it. Please note that salary top ups cannot be paid to personnel working in a European institution. The cost centre in the second column is automatically displayed once the function (work packages) per person is selected from the dropdown box on the third column to recognise in which work package the person's salary is paid for. Please note that column B should be completed at the periodic reporting only.

6. The percentage of each project personnel's time over the term of the project must be entered in column E (percentage (%) of person's time spent on project), along with the gross monthly salary under cell N60 (inclusive of all employment taxes and social security) and the number of months under cell O60 (maximum 60) which the employees will be assigned to the project. The purpose of entering the percentage utilisation of each of the employees is to provide an audit trail (monthly timesheets should be kept as per EDCTP financial guidelines) and to ensure that no single employee is charged out at over 100% of their time across all the projects they may be working on.
7. The spreadsheet then automatically calculates the total salary cost per employee, which can be spread between the budget columns as required. If this has been done correctly the figures appearing in the check column (column R) will always be blank– if they are not; then adjust the sums allocated to each budget year so that the total equals the salary cost over the 5 periods accurately. Where personnel working on the project split their time between the sites then they should be entered in this section as a member of staff on each of the sites they are working at with the appropriate percentage of their time. Please note this does not mean for minor time such as site visits but only where the employee spends a significant time (i.e. over 5% of their annual time) at any particular site involved in the trial. For your reference, please find enclosed an example for the computations of the wages and salaries per year.
8. Where employees have not yet been recruited then the acronym "TBR" meaning "to be recruited" should be inserted in the name column. Otherwise, full details of the employee and position should be entered where they are already in situ.

Please note that all salaries and wages costs should be included in the box "Project Personnel – Wages and Salaries". The spreadsheet will automatically allocate them to the correct work package based on your selection from the drop down box of which function they are fulfilling.

III. Clinical Trial Costs (Overseas and local subsistence cost/Consumables/Subcontract/Capital Equipment

9. **The total value of the Clinical trials should not exceed 65% of the total EDCTP requested funding.** You may check the summary section by work packages to ensure that you did not exceed this amount.
10. For overseas travel you are required to enter the name of the traveller and purpose/destination of each single trip. If the same trip is repeated more than once by the same person then that number of trips over the full 5 periods should be entered in the column entitled "no. of individual trips over life of the project". Please ensure that the value you input on **overseas section does not exceed 5% of the total budget of the grant only.** You may check yourself at the summary per cost category at the bottom of the budget form. If column AB231 is red it means you have to adjust the values in the overseas travel section because they presently exceed 5% of the overall costs for the site.
11. For patient food, patient transport reimbursables and patient compensation, where there are patient costs to be paid by EDCTP, then the numbers of patients in the study by year must be entered in the box on consumables section. Only fill in the "Patients Budget" during the budgeting period and "Patients Actual" will be completed during periodic reporting.

12. For *subcontract*, the name of the subcontractor should be identified and the service to be rendered or performed should be described.
13. *Capital equipment* covers any single item inclusive of freight charges and import duties with an individual value over 10,000 Euro (this includes vehicles) and can include second hand equipment which is specifically for clinical trial laboratory machinery only. All other equipment of a general upgrade and for general use not restricted to the clinical trial only is to be included under the "capacity building site infrastructure upgrade".
14. All capital equipment items will be automatically allocated to the cost centre of the clinical trial.

IV .Project Management

15. **The total value of the Project management section should not exceed 15% of the total EDCTP requested funding.**
16. Cost details should be specified along with the itemized data and the total amount should be spread over the years of the project.

V. Capacity Building Activities

17. **The total value of the capacity building activities should not exceed 35% of the total EDCTP requested funding.** This includes short-term training, site infrastructure, baseline studies, MSc, PhD, CD/SR Fellowships and Post doctoral studies.
18. *Short term-training*, the type of training to be followed is to be selected from a drop down box and the cost centre will be displayed automatically. Costs that are associated to this training are itemised for budgeting as required and the totals should be spread over the years of the project as necessary.
19. *Site infrastructure upgrade*, eligible costs for EDCTP funding do not include the costs of erecting new buildings but can include costs of all building maintenance, and equipment upgrades or replenishment including new ward furniture or local area network and service upgrade or power supplies installation which will enhance the facilities in general and will be of continuing use after the trial. Please note this does not include trial specific equipment bought solely for use on the trial and with a value over € 10,000 which should be included in the "capital equipment" box above. **The total value for site infrastructure upgrade should not be below 2% of the total EDCTP requested funding.**
20. *Baseline Studies*, details of the study should be specified and all projected costs should be budgeted for over the life of the project.
21. *MSc, PhD, Senior Fellowship, Career development sections*, select from the dropdown box what type of study is being awarded and then the cost centre will be displayed automatically. Projected costs should be allocated over the life of the project.

VI. Networking

22. **The total value of the Networking should not exceed 5% of the total EDCTP requested funding.**
23. *Networking section*, select from the dropdown box the category of the activity and the cost centre will be displayed automatically. Please write the description of the meeting and its objectives of what will it achieve. Projected costs should be allocated over the life of the project.

VII. Summary Budget by cost category

24. If any items within column AB231-AB242 becomes red, it means you have exceeded the EDCTP limitation of the budget for each cost category, and then you have to adjust the

values accordingly by going through each section. Please note that this section excludes the 10% overhead rate.

VIII. Summary for work packages

25. If any items within column T249-T255 becomes red, it means you have exceeded the limitation of the budget for each work packages, and then you have to adjust the values per work packages accordingly by going through each section. The overhead cost is calculated automatically for each of the work packages.
26. When the budget has been accepted by the EDCTP Director Finance and Administration this will be communicated to the Grantee, and included as an annex to the grant agreement which will be signed by EDCTP and the hosting institution of the Project Coordinator.
27. The budget and annual financial returns should be signed by the head of finance and the collaborator of the individual institutes. A readable and clear PDF copy is acceptable to expedite the process.

For more detailed information on how to fill in the budget form, please refer to the table below. Please note that EDCTP has set the following budget limits per work package and on other category items to ensure a distribution of funds that is in accordance to our mandate:

Work Packages	Maximum limit
Project Management	15% of the total budget to be contracted with EDCTP
Clinical Trial	65% of the total budget to be contracted with EDCTP
Capacity Building	35% of the total budget to be contracted with EDCTP
Networking	5% of the total budget to be contracted with EDCTP
Category items	Maximum limit
Overseas Travel	5% of the total budget excluding the capacity building activities but should not exceed 10% of the overall budget value to be contracted with EDCTP.
Site Infrastructure	A minimum of 2% of the total budget to be contracted with EDCTP should be spent on this
Overhead	EDCTP automatically calculates 10% overhead on all costs.

Should you have any further queries about how to complete the budget or annual financial reporting forms please contact your relevant EDCTP Project Officer who will then contact the GFA at Finance department for assistance.

EDCTP Finance Department
08 December 2009