



EDCTP

European & Developing Countries
Clinical Trials Partnership

Financial Guidelines for Beneficiaries

EDCTP Association

October 2016

This document is prepared as a supplement to the Grant Agreement (GA), where majority of the information is extracted from. In the event of a conflict between this document and the GA, the GA takes precedence. Beneficiaries must therefore ensure that they are familiar with all the chapters, including the articles, of the GA. This document is meant purely to act as a documentation tool and therefore EDCTP management does not accept any liability for its contents.



Table of Contents

| | | |
|-------|---|----|
| 1 | Acronyms..... | 4 |
| 2 | Definitions..... | 5 |
| 3 | Introduction..... | 6 |
| 3.1 | Purpose of the financial guidelines..... | 6 |
| 3.2 | Content and structure..... | 6 |
| 3.3 | Application of the guidelines..... | 6 |
| 3.4 | Distribution responsibilities..... | 6 |
| 4 | Financial viability checks..... | 6 |
| 5 | Eligible and ineligible costs..... | 7 |
| 5.1 | Conditions for eligible costs..... | 7 |
| 5.1.1 | For actual costs:..... | 7 |
| 5.1.2 | For unit costs:..... | 8 |
| 5.1.3 | For indirect costs:..... | 8 |
| 5.2 | Eligible direct costs..... | 8 |
| 5.3 | Receipts and no-profit rule..... | 9 |
| 5.4 | Ineligible costs..... | 10 |
| 5.5 | VAT (sales tax)..... | 10 |
| 6 | Cost of Equipment, infrastructure or other assets..... | 11 |
| 6.1 | General..... | 11 |
| 6.2 | Types of equipment costs..... | 11 |
| 6.2.1 | Options for charging equipment costs as actual costs in the accounts..... | 11 |
| 6.2.2 | Costs of renting or leasing of equipment, infrastructure or other assets..... | 13 |
| 6.2.3 | The costs of equipment, infrastructure or other assets contributed in-kind against payment..... | 13 |
| 7 | Grant Amendments..... | 14 |
| 7.1 | Introduction..... | 14 |
| 7.2 | Procedure..... | 14 |
| 7.3 | Instances in which an amendment is required..... | 14 |
| 7.4 | Cases where an amendment is not necessary..... | 15 |
| 7.5 | No-cost extension (change in the duration – end date of the action)..... | 15 |
| 8 | Budgeting..... | 16 |
| 8.1 | Budget categories and forms of costs..... | 16 |
| 8.2 | Forms of costs..... | 16 |
| 8.3 | Budget form..... | 16 |
| 8.4 | Budget transfers and re-allocation..... | 16 |
| 8.5 | Reduction of the grant..... | 17 |
| 9 | Treasury management..... | 17 |
| 9.1 | Types of bank account to maintain – designated or pooled..... | 17 |
| 9.2 | The currency of the bank account..... | 18 |
| 9.3 | Currency for financial statements and conversion into euro..... | 18 |
| 9.4 | Payments to beneficiaries..... | 18 |
| 9.5 | Cost of payment transfers..... | 19 |
| 9.6 | Types of payments..... | 19 |

| | | |
|-------|--|----|
| 9.6.1 | Pre-financing (first) payment | 19 |
| 9.6.2 | Interim payments..... | 20 |
| 9.6.3 | Payment of balance | 21 |
| 9.7 | Notification of amounts due..... | 22 |
| 9.8 | Suspension of payments | 22 |
| 9.9 | Suspension of payment deadline | 22 |
| 9.10 | Rejection of ineligible costs | 23 |
| 9.11 | Recovery of unused funds | 23 |
| 10 | Subcontracting | 24 |
| 10.1 | Introduction..... | 24 |
| 10.2 | Special subcontracting rules..... | 24 |
| 10.3 | Distinction between contracts to purchase of goods, works or services and subcontracting | 24 |
| 10.4 | Subcontractor’s rights and obligations | 25 |
| 11 | Financial Reports | 25 |
| 11.1 | Financial reporting period | 25 |
| 11.2 | Introduction..... | 25 |
| 11.3 | Audit certificate | 26 |
| 11.4 | Audit certificate rules..... | 26 |
| 12 | Records and documentation to support the costs declared | 27 |

1 Acronyms

| | |
|-------|---|
| CFS | Certificate on the Financial Statements |
| DFA | Director of Finance and Administration |
| EDCTP | The European and Developing Countries Clinical Trials Partnership |
| FMAQC | Financial Management Assessment Questionnaire for Coordinators |
| GA | Grant Agreement |
| GFA | Grant Finance Assistant |
| GFO | Grant Finance Officer |
| IFAC | International Federation of Accountants |
| ISRS | International Standard on Related Services |
| OLAF | European Anti-Fraud Office |
| ToR | Terms of Reference |
| VAT | Value added tax |

2 Definitions

Set out below is the definition of the key terms used in this manual:

1. Annual workable hours

Annual workable hours is the period during which the personnel must be working at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

2. Beneficiaries

Beneficiaries refer to the legal entities which have signed the Grant Agreement (GA) or the Accession Form and include the Coordinator.

3. Coordinator

Coordinator is the beneficiary which is the central contact point for the project and represents the consortium towards EDCTP.

4. Actual costs

Costs actually incurred, identifiable and verifiable, recorded in the accounts.

5. Direct costs

Direct costs are the costs of a project that can be clearly identified and specifically related to a particular grant, as set out in the Grant Agreement.

6. Action/project

The term project and action are used interchangeably in these guidelines.

7. Indirect costs

Indirect costs are calculated by applying the 25% flat-rate to the eligible actual costs or unit costs after the deduction of eligible subcontracting costs. The formula for calculating indirect costs is: $(\text{total eligible costs} - \text{subcontracting costs}) \times 25\%$.

8. Estimated budget

It is the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category.

9. Subcontracting

A subcontract means the purchase of goods, works or services that are identified in Annex 1 of GA as action tasks.

10. Reporting periods

Each project is divided into reporting periods. The length and number of the reporting periods is set out in the Article 20.2 of the GA.

The financial reports must be drawn up using the forms and templates provided in Annex 4 of the GA (Model for the financial statements) and Annex 5 of the GA (Model for the certificate on the financial statements).

11. Duration and starting date of the action (project) duration

The duration of the action is fixed by the EDCTP in Article 3 of the GA. It is expressed as a number of months, running from the action start date until the end date of the action. Unless otherwise agreed, the default start date of the action is the first day of the month following the date when the last party signs it (the EDCTP signatories usually sign the GA last).

3 Introduction

3.1 Purpose of the financial guidelines

These guidelines have been prepared to supplement the GA by providing an explanation of the accounting policies, financial reporting and budgeting requirements. However, in the event a conflict arises between these guidelines and the Grant Agreement (GA), the GA takes precedence.

The main objectives of preparing this document are:

- To provide a quick reference and easy to follow guide to beneficiaries of EDCTP funding
- To act as a reference document for external auditors and other stakeholders in carrying out financial audits or other reviews of EDCTP funded projects
- To ensure consistency in the financial management of EDCTP grants.

3.2 Content and structure

These guidelines describe the policies and procedures for the financial management of grants.

3.3 Application of the guidelines

These guidelines are applicable in the financial management of grants funded by EDCTP. All beneficiaries of EDCTP grants are therefore required to follow these guidelines. Any questions a beneficiary may have regarding the interpretation of any section should be directed to the designated EDCTP contact person (Article 52.3 of the GA).

3.4 Distribution responsibilities

It is the responsibility of the Coordinator to distribute these guidelines to beneficiaries and to those responsible for financial management. To ensure that the EDCTP financial guidelines are distributed, read and understood by those responsible for the financial management and reporting of EDCTP grants, EDCTP requires each beneficiary to sign a declaration form (annex 1 of these guidelines) and return it to EDCTP.

4 Financial viability checks

Before signing the Grant Agreement, the EDCTP must assess the financial viability of a Coordinator if the requested EDCTP funding for the action is greater than or equal to EUR 500,000 unless the coordinator is:

- A public body
- A higher or secondary education establishment
- an international organisation or body whose participation is guaranteed by the government of an EU country or associated country, in accordance with the Grants Manual section on legal entity validation and the H2020 Annotated Model Grant Agreement
- A private individual in receipt of a scholarship.

For example, the EDCTP must assess the financial viability if the Coordinator is a private entity and is requesting funding of more than or equal EUR 500,000.

It is important to note that EDCTP reserves the right to verify the financial viability of the Coordinator or other beneficiaries (including public bodies) even if the requested funding is less €500,000.

5 Eligible and ineligible costs

5.1 Conditions for eligible costs

The main criteria for acceptance of costs as eligible by EDCTP are:

5.1.1 For actual costs:

- They must be actually incurred by the beneficiary, (i.e. real and not estimated, budgeted or imputed and definitively and genuinely borne by the beneficiary and not by any other entity);
- They must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.
- They must be indicated in the estimated budget set out in Annex 2 of GA. When the final amount of the grant is calculated, the eligible costs cannot include costs under budget categories that did not appear in the action estimated budget, unless the initial estimated budget was amended or if these additional costs were approved in accordance with Articles 11 to 13 of the GA.
- They must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;
- They must be incurred in the period set out in Article 3 of the GA, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report. The duration of the action is the period running from the starting date of the action to the end date of the action. The following special cases apply:
 - Costs related to drafting and submitting the periodic report for the last reporting period and the final report (including costs of certificates of financial statements required by the GA) are eligible even if they are incurred after the action duration
 - Costs actually incurred should normally also be paid during the action duration. In general, costs declared but not paid during the action duration (for instance because the beneficiary is waiting for the payment of the balance) are eligible only if the debt (and invoice) already existed during the action duration, and the final cost is known
 - Costs of services or equipment supplied to a beneficiary may be invoiced and paid after the action is completed, if the services or equipment were used by the beneficiary during the action duration
 - If there is a check or an audit after the action ends, beneficiaries will need to prove (with supporting documents) that the payments were actually made (except for depreciation costs)
 - Costs of services or equipment supplied after the end of the action or the GA termination are not eligible
 - Costs related to drafting the consortium agreement are not eligible because the consortium agreement should be signed before the action starts.
 - Depreciation costs for equipment used for the action but bought before the action's start — if the equipment has not yet been fully depreciated according to the beneficiary's usual cost accounting practices, the remaining depreciation costs may be eligible (only for the portion corresponding to the duration of the action and rate of actual use for the purposes of the action)
 - Costs related to preparing, submitting and negotiating the proposals cannot be declared as eligible for the action (they are incurred before the action starts)
 - Travel costs for the kick-off meeting — if the first leg of the journey takes place before the starting date of the action the costs may be eligible if the meeting is held during the action duration.
- They must comply with the applicable national law on taxes, labour and social security.

- They must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices.

The beneficiaries must be able to show (with records and supporting documents – see article 18 of the GA) the actual costs of the work, i.e. what was actually paid for the work (and for depreciation costs: what is actually recorded in the beneficiary's profit and loss accounts).

5.1.2 For unit costs:

The eligible costs are calculated by multiplying the number of actual units and the amounts per unit set out in the approved budget or calculated by the beneficiary in accordance with its usual cost accounting practices. The number of actual units must comply with the following conditions:

- The units must be actually used or produced in the duration of the grant
- The number of units must be necessary for the action; the beneficiaries must be able to show the link between the number of units declared and the work on the action
- The units must be necessary for implementing the action or produced by it, and
- The units must be identifiable and verifiable, in particular supported by records and documentation.

5.1.3 For indirect costs:

Indirect costs must be calculated by applying the 25% flat-rate to the eligible actual costs or unit costs, which must comply with the conditions for eligibility of actual or unit costs.

Indirect costs do not need supporting evidence because they are declared using a flat-rate.

5.2 Eligible direct costs

Direct costs are the costs of a project that can be clearly identified and specifically related to a particular grant, as set out in the GA. Eligible costs may include the following:

1) Direct personnel costs:

Personnel costs are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the project. They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Additional remuneration:

Beneficiaries that are non-profit legal entities may also declare as personnel costs additional remuneration for personnel assigned to the project if:

- It is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;
- The criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

- If the person works full time and exclusively on the grant during the full year: up to €8,000 per year
- If the person works exclusively on the grant but not full-time or not for the full year: up to the corresponding pro-rata amount of €8,000, or

- If the person does not work exclusively on the action: up to a pro-rata amount calculated as €8,000 divided by the number of annual productive hours multiplied by the number of hours that the person has worked on the grant during the year.

Calculation of personnel costs:

Personnel costs must be calculated by multiplying hourly rate and the number of actual hours worked on the project plus any additional remuneration, if applicable. The number of actual hours declared for a person working in EDCTP project must be identifiable and verifiable and cannot be higher than the annual productive hours used to calculate the hourly rate.

Timesheets

To support the declared personnel costs for employees who work part-time (working less than 100%) on an EDCTP funded project, beneficiaries must prepare timesheets for number of hours declared for each employee who did not work exclusively on a specific EDCTP funded project. The timesheets must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the EDCTP may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

There is no need for persons working exclusively on an individual EDCTP funded project to keep timesheets if the beneficiary signs a declaration confirming that the persons concerned have worked exclusively on the individual EDCTP funded project. A sample Declaration Form is attached as an annex (Annex 3) to these guidelines.

2) Direct costs of subcontracting:

These include related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary.

3) Other direct costs

- Travel and subsistence allowances for the staff taking part in the grant provided that they are in line with the beneficiary's standard policy on such costs for staff travelling
- Costs of consumables and supplies, provided that they are identifiable and assigned to the grant
- Costs entailed by subcontracts awarded by the Beneficiary for the purposes of carrying out the grant, provided they have been awarded to the bid offering best-value for money following a transparent procedure
- Costs of obtaining an audit certificate within 45 days of the end of the grant for any beneficiary which receives EDCTP funds in excess of €325,000 (indirect costs, costs based on lump sums, and unit costs - other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices - are not counted in determining the EUR325,000 threshold)
- Irrecoverable VAT (sales tax)
- Clinical trial indemnity, unless paid for by the clinical trial Sponsor, and clinical trials regulatory costs.

5.3 Receipts and no-profit rule

The grant must not produce a profit.

The action's total receipts are the consolidated total receipts generated during its duration. The following are considered receipts:

- Income generated by the action. These include income generated from selling equipment or other assets purchased under the Agreement

- Financial contributions given by third parties to the beneficiary specifically to be used for the action, and
- In-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

If there is a receipt, it will be deducted from the final grant amount.

The following are however not considered receipts:

- Income generated by exploiting the action's results;
- Financial contributions by third parties, if they may be used to cover costs other than the eligible costs; and
- Financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the final grant amount.

5.4 Ineligible costs

Costs are ineligible if they do not meet the general and specific eligibility conditions as set out in Articles 6.1 to 6.4 of the GA. The following costs shall be considered as ineligible:

- Debt and debt service charges
- Costs incurred by the Beneficiary before the effective date of the grant agreement, i.e. any backdated costs and/or costs incurred after the end date of the grant
- Provisions for future losses or debts
- Interest owed
- Doubtful debts
- Currency exchange losses
- Fiscal deductions from funding sent by EDCTP to the Beneficiary whether by the government of the country of the Beneficiary or any other body
- Costs declared by the Beneficiary within another grant or work programme receiving an EDCTP Grant
- Legal or financial compensation arising from accident or loss in respect of any travel paid for in an EDCTP grant
- Excessive or reckless expenditure
- Loans or salary advances
- Expenditures not included in the project budget
- Any costs which are proven to be fraudulent
- Deductible VAT (sales tax)
- Costs incurred during the suspension of the implementation of the action.

5.5 VAT (sales tax)

VAT (sales tax) which is recoverable is ineligible, even if it is not actually recovered. Irrecoverable VAT (sales tax) can be claimable as eligible costs.

6 Cost of Equipment, infrastructure or other assets

6.1 General

- Unless the EDCTP Association requests or agrees otherwise or unless it is impossible, any infrastructure or equipment purchased with EDCTP funds must:
 - Include the text that “This [equipment/infrastructure/other type of result] is part of the EDCTP2 programme supported by the European Union’s Horizon 2020 research and innovation programme”; and
 - Display the EU and EDCTP emblems. When displayed together with another logo, the EU and EDCTP emblems must have appropriate prominence.
- To be eligible, all forms of equipment costs must fulfil the general conditions for actual costs
- The capitalisation limit (the minimum amount equipment must cost for it to be recorded as an assets in the balance sheet) must be specified in the relevant policy documents.
- The beneficiaries must ensure the best value for money or, if appropriate, the lowest price, when making purchases of equipment

6.2 Types of equipment costs

EDCTP Beneficiaries may declare the following types of equipment costs as ‘other direct costs – equipment costs’:

- a) One of the following options of charging equipment costs as actual costs in the accounts:
 - Either depreciation costs of equipment, infrastructure or other assets, or
 - Full purchase costs of equipment, infrastructure or other assets (if option applies)
- b) Costs of renting or leasing of equipment, infrastructure or other assets
- c) Costs of equipment, infrastructure or other assets contributed in-kind against payment.

6.2.1 Options for charging equipment costs as actual costs in the accounts

6.2.1.1 Option 1- charging the depreciation cost of the equipment, infrastructure or other assets (this is the default option)

- This is the default option. It covers the depreciation charge of equipment, infrastructure or other assets used for the action
- The depreciation costs of equipment, infrastructure or other assets (new or second-hand) as recorded in the beneficiary’s accounts are eligible, if:
 - Necessary to implement the action,
 - The purchases of the items were made with due regard to value for money,
 - Conflict of interests were avoided through the entire procurement process, and
 - Written off in accordance with international accounting standards and the beneficiary’s usual accounting practices.

- They must be calculated according to the following principles:
 - The depreciable amount (purchase price) of an asset must be allocated on a systematic basis over its useful life (i.e. the period during which the asset is expected to be usable; see also 'cash-based accounting' below)
 - Depreciated equipment costs cannot exceed the equipment's purchase price
 - Depreciation cannot be spread over a period longer than the equipment's useful life.
- The depreciation costs must be calculated for each reporting period.

6.2.1.2 Points to note

- Equipment used only partly for the action

Only the part of the equipment's or asset's 'working time' for the action may be declared (i.e. the percentage of actual use and time used for the action). The amount of use (percentage and time used) must be auditable (i.e. the hours that the equipment has been used for the action must be recorded).

- Full price of an asset in one single year

Declaring the full price of an asset in one single year might be considered either as not compliant with the international accounting standards or as an 'excessive' cost, if the asset is expected to be used over more than one year. It may therefore be considered ineligible. If recording the equipment's total purchase cost as an expense (cash accounting basis) follows the beneficiary's usual accounting practices and national accounting law, the beneficiary may declare the part of the cost that corresponds to the use of the item for the action in each relevant reporting period or in a single reporting period. The amount declared can only be accepted if all of the following apply:

- The cost is economic and necessary;
- Only the portion of the equipment used for the action is declared (i.e. if the equipment is used for other projects and/or for other activities, part of the equipment cost must be charged to these other projects/activities);
- The amount of use (percentage used and time) must be auditable
- The percentage of the purchase cost charged to the action is calculated by dividing the amount of time during which the equipment was used for the action by equipment's total useful life. Useful life means the time during which the equipment is useful to the beneficiary. It may be defined according to the beneficiary's practices or be established per type of equipment in line with national tax regulations.

- Use of equipment bought before the action start

Depreciation charge up to the net book value of the asset (the remaining depreciation costs) at the start of the action may be eligible. The depreciation charge must relate to the duration of the action and rate of actual use for the purposes of the action.

6.2.1.3 Option 2: Full purchase costs of equipment, infrastructure or other assets (can only be used as an exception when explicitly foreseen in the EDCTP2 work plan and included in Article 6.2.D2 of the Grant Agreement)

- This option covers the full purchase costs of capitalised equipment, infrastructure or other assets used for the action (not only the depreciation costs for the relevant periodic report). Capitalised means recorded as assets in the beneficiary's balance sheet.

- The option of full purchase costs must be used as an exception, only if justified by the nature of the action and the context of the use of the equipment or assets, if provided for in the work plan.

6.2.2 Costs of renting or leasing of equipment, infrastructure or other assets

- The costs of renting or leasing equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.
- The costs must be calculated according the following principles:

Finance leasing with the option to buy the durable equipment

- The equipment leased by the beneficiary must be recorded as an asset of the beneficiary and the depreciation costs may be declared in accordance with the beneficiary's usual accounting practices.
- The costs declared cannot exceed the costs that would have been incurred if the equipment had been purchased and depreciated under normal accounting practices. This means that the finance charges included in the finance lease payments are not eligible.
- The costs declared can NOT include any interest on loans taken to finance the purchase, or any other type of financing fee.

Renting and operational leasing

The rental or lease costs payments are eligible if they follow the beneficiary's usual practices and do not exceed the costs of purchasing the equipment. The equipment rented or leased by beneficiary should not be recorded as an asset of the beneficiary

6.2.3 The costs of equipment, infrastructure or other assets contributed in-kind against payment

- This option covers the costs of equipment, infrastructure or other assets that were used for the action and contributed in-kind against payment.
- The costs of equipment, infrastructure or other assets contributed in-kind against payment are eligible if:
 - They do not exceed the depreciation costs of similar equipment, infrastructure or assets;
 - They do not include any financing fees; and
 - The conditions set out in the rules for the use of in-kind contributions against payment are met (Article 11).
- The costs must correspond to the amount paid by the beneficiary and must not exceed the depreciation cost of the third party.

7 Grant Amendments

7.1 Introduction

The Grant Agreement specific data and options can be added, removed or changed via an amendment, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

7.2 Procedure

Amendments may be requested by any of the parties. The coordinator submits requests for amendment on behalf of the beneficiaries. If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The amendment request must include:

- The reasons for the amendment
- The appropriate supporting documents; and
- For a change of coordinator without its agreement, the opinion of the coordinator (or proof that this opinion has been requested in writing).

After the amendment is made, all amended provisions become an integral part of the GA; and all other provisions remain unchanged and continue to have full effect.

7.3 Instances in which an amendment is required

An amendment is necessary whenever there is a need to change the GA.

Normally amendments are requested by the consortium via the Coordinator. EDCTP may also propose an amendment where errors need to be rectified or to modify Annex 1 following a review of the action. An amendment is necessary in the following cases:

- Removal of a beneficiary whose participation is terminated
- Adding a new beneficiary
- Changes to the status of a beneficiary. This happens for example if the change of address of a beneficiary implies that the beneficiary will no longer be eligible for EDCTP funding
- Change of coordinator
- If the new coordinator is not a beneficiary of the GA, it must first accede to the GA as a new beneficiary. The former coordinator may continue to participate in the action as a beneficiary or may terminate its participation
- Change of the coordinator's bank account for payments
- An amendment is necessary for all changes that imply a change to the account number/IBAN code
- Change of the action's title and/or acronym
- Amendment for resuming the action after a suspension of the action implementation
- Changes to Annex 1 of the GA (description of the action)
- Change concerning specific cost categories
- A budget transfer of amounts between beneficiaries or between budget categories (or both) which arises from a significant change that affects the action's work (i.e. Annex 1).

7.4 Cases where an amendment is not necessary

- Transfers of amounts between beneficiaries or between budget categories (or both) do not require an amendment provided that the action is implemented in line with Annex 1 of GA.
- Change of name or address of a beneficiary or coordinator - simple changes of name, legal form, official registration number, address, VAT number or persons authorised to represent it for the purposes of signing the GA do NOT require an amendment.

7.5 No-cost extension (change in the duration – end date of the action)

Changing the end date of the action requires an amendment to the GA. EDCTP expects Coordinators to complete projects by the end date stipulated in the Grant Agreement, but in exceptional cases, more time may be needed to complete the scope and objectives of the action. In such cases, an extension of the action must be requested before the action ends (preferably 6 months before the original action end date) and will only be accepted in exceptional cases.

It is important for Coordinators to know that extending the duration of the action is only granted under exceptional circumstances and at the sole discretion of the EDCTP's management.

The fact that cash surplus is projected at the end date of a grant is not, in itself, sufficient justification for a no-cost extension.

All requests for no-cost extension must be made in writing to the EDCTP address for communication indicated in Article 52.3 of the GA preferably at least 6 months before the end of the project to allow time for EDCTP's management to review and process the request before the end date of the project.

The Coordinator should provide the following information in the request for no-cost extension:

- The reasons for the request, including a clear description of specified activities in the approved work plan that remain to be completed
- Appropriate supporting documents
- The requested new end date
- The balance of funds that is projected to remain outstanding at the original end date of the project
- A revised estimated budget, which must be less than or equal to the maximum grant amount
- A revised work plan with clear indications and milestones to assure that outstanding objectives will be delivered during the no-cost extension period.

If the request is approved, the amendment must be signed by EDCTP within 45 days of receiving notification for no-cost extension (or any additional information the EDCTP Association has requested). If the request is not approved, EDCTP will formally notify the Coordinator of our disagreement within the 45 days of receiving notification. The deadline may be extended, if necessary for the assessment of the request. An amendment for no-cost extension enters into force on the day it is signed by EDCTP.

8 Budgeting

8.1 Budget categories and forms of costs

Eligible costs must be declared under the following budget categories and forms of costs:

| Budget category | Forms of costs |
|------------------------------------|-------------------------|
| Direct personnel costs | Actual costs/Unit costs |
| Subcontracting | Actual costs |
| Travel | Actual costs |
| Equipment | Actual costs |
| Other goods and services | Actual costs |
| Research infrastructure | Actual costs |
| Financial support to third parties | Actual costs |
| Indirect costs | Flat-rate costs |

8.2 Forms of costs

1. Actual costs

These are costs actually incurred, identifiable and verifiable, and recorded in the accounts. This can be used for all categories of costs, except for indirect costs.

2. Unit costs

It means a fixed amount per unit determined by EDCTP. Unit costs are used only for direct personnel costs and specific categories of costs.

3. Flat rate costs

Flat rate costs are calculated by applying a fixed percentage to other types of eligible costs – 25% flat rate for indirect costs.

8.3 Budget form

All grant applicants (project coordinator and other beneficiaries) on receipt of a conditional award letter from EDCTP must complete the EDCTP budget form. The budget form must only include estimated eligible costs broken down by beneficiary, forms of costs, and budget category.

These forms are available online in EDCTPgrants the web-based grant management system used by EDCTP. The steps that are involved are as follows:

- The project coordinator must log onto EDCTPgrants and complete a budget form. A separate budget form must be filled by each beneficiary
- The budget forms are then reviewed by the EDCTP Grant Finance Officers (GFO) or Grant Finance Assistants (GFA). During this review, applicants may be asked to provide additional information and/or explanations to adequately support the requested budget.

8.4 Budget transfers and re-allocation

EDCTP will make funds available to the beneficiary up to the maximum amount specified in the grant agreement- EDCTP will not provide any resources in excess of amount specified in the Grant Agreement. The budget in Annex 2 of the GA is an estimate, and therefore at the time of reporting, beneficiaries may declare costs that are different from the estimated eligible costs in the budget. The budget in Annex 2 may be adjusted by transfer of amounts

between beneficiaries or between budget categories (or both). These adjustments do not require an amendment of the Grant Agreement (GA) if the project is implemented as described in Annex 1 (description of the project) of the GA and payment to beneficiaries is made through the coordinating site. However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13 of the GA.

If the budget revision falls into one of the following categories, an amendment to the GA will be required for:

- Budget transfers between beneficiaries or between budget categories (or both) arising from a significant change that affects Annex 1 of the GA (re-allocation of annex 1 tasks),
- Budget transfers entailing a transfer to a form of cost (actual cost, unit costs and flat rate) that is not budgeted for (not foreseen) in the approved budget
- Additional costs relating to subcontracts not provided for in Annex 1 of the GA unless such additional subcontracts are approved. The EDCTP may approve subcontracts not set out in Annex 1 of GA without amendment, if:
 - They are specifically justified in the periodic technical report and
 - They do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

8.5 Reduction of the grant

The EDCTP may — at the payment of the balance or afterwards — reduce the maximum grant amount if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

9 Treasury management

9.1 Types of bank account to maintain – designated or pooled

Before signing the Grant Agreement, the Coordinator (or any beneficiary that EDCTP is going to make direct payments to) is required to complete a Financial Management Assessment Questionnaire for Coordinators (FMAQC). This questionnaire is divided into six sections:

1. Organisation of the finance department
2. Accounting system
3. Time recording system (Timesheets)
4. Fixed asset register
5. Bank accounts
6. Experience of managing donor funded projects.

The purpose of this questionnaire is to assist EDCTP Grant Finance Officers and Grant Finance Assistants to form an informed opinion of the relevant beneficiary's internal financial control systems with the objectives of:

- Deciding whether the control environment is strong enough for EDCTP funds to be paid into an existing bank account of the Coordinator (pooled bank account), an account into which funds from EDCTP and those from other donors may be paid into; or to request the Coordinator to open a new bank account (EDCTP designated project bank account), an account into which only funds for the particular EDCTP project under consideration may be paid into
- Getting an overview of the financial management systems and procedures, and to identify areas where improvements are required.

The following rules apply to the different types of bank accounts:

EDCTP designated project account

- This is the preferred option since the bank statements will effectively show all the receipts and payments of the project. Having a project-specific bank account will not only make the preparation of the periodic financial reports easier, but it will also reduce the time that will be spent by auditors in their audit work
- The name of the account should include the name of EDCTP and the project title in abbreviated form
- The details of the account must be submitted to EDCTP so that it can be included in the Grant Agreement
- Cheque signatories to a designated bank account should only be those people authorised to sign cheques under the coordinator or collaborator institutions' internal regulations
- The beneficiary must prepare a monthly bank reconciliation statement for this bank account.

Pooled bank account

EDCTP will only pay funds into a pooled account if the following conditions are fulfilled:

- The beneficiary has a sound financial management system with a chart of accounts structure that allows the generation of financial reports by project and type of expenditure
- The beneficiary has extensive experience in managing multi-donor projects.

9.2 The currency of the bank account

Opening of a Euro bank account, unless not allowed in the country participating in the action, is one of the conditions that must be fulfilled prior to the signing of the Grant Agreement. In a country where the opening of a foreign currency bank account is not allowed, EDCTP may agree for the beneficiary to open a local currency bank account. The beneficiary bears all risks associated with foreign currency fluctuations between the Euro and the local currency and also between the local currency/Euro and the currency or currencies of project expenditure.

9.3 Currency for financial statements and conversion into euro

- EDCTP funds received by beneficiaries in countries where the opening of a Euro account is not allowed should be translated at the spot rate (the quoted exchange rate by the bank where the account is held) on the day the income was received.
- For financial reporting purposes, all expenditures from bank accounts held in currencies other than Euros should be converted into Euros using the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.
- If no daily Euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website <https://ec.europa.eu/budget/graphs/inforeuro.html> calculated over the corresponding reporting period.
- Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

9.4 Payments to beneficiaries

The general rule is that EDCTP makes all its disbursements in Euro to the Coordinator, but in exceptional circumstances EDCTP may pay directly to beneficiaries.

Where disbursement is made to the Coordinator by EDCTP, the Coordinator must transfer the funds due to other beneficiaries within 3 months of the receipt of funds by the Coordinator from EDCTP. If disbursement to other beneficiaries is not made within three months, the Coordinator must write to EDCTP explaining the reasons for the delayed disbursement. However, a coordinator is not, under any circumstances, allowed to transfer funds to beneficiaries, who have not yet acceded to the action.

After disbursement of funds to other beneficiaries in the consortium, the Coordinator shall request the beneficiaries to submit a confirmation letter to EDCTP stating the amount of funds received from the Coordinator, using the letter template provided (annex 4 of these guidelines). EDCTP may request beneficiaries to provide additional evidence such as a scanned copy of bank statement showing the amount received.

9.5 Cost of payment transfers

All payments by EDCTP to beneficiaries will be made in euro. The cost of the payment transfer is borne as follows:

- The EDCTP bears the cost of transfers charged by its bank;
- The beneficiary bears the cost of transfers charged by its bank; and
- The party causing a repetition of a transfer bears all costs of the repeated transfer.

9.6 Types of payments

Payments to beneficiaries are made in accordance with the provisions of Grant Agreement, signed between EDCTP and Coordinators. There are three types of payments to beneficiaries:

- Pre-financing payment at the beginning of the action
- Interim payments to cover eligible costs incurred in the reporting periods
- Payment of balance after the end of the action.

9.6.1 Pre-financing (first) payment

The aim of the pre-financing payment is to provide beneficiaries with a float (sufficient funds to cover the expenditure of beneficiary from the start of the project or from the date of last interim payment date to the next interim payment or balance of funds payment date). Pre-financing will not be paid before:

- The GA is signed (even if the action starts prior to that)
- 10 days before the action starting date.

There is no standard amount (or percentage) for the pre-financing payment. The amount is specified in Article 21.2 of the GA.

Some of the conditions that must be fulfilled before the pre-financing payment include:

- Approval of project funding by the EDCTP General Assembly
- Entry into force of the Grant Agreement
- Completion of Financial Management Assessment Questionnaire by the Coordinator
- The opening of a designated bank account, if required
- Receipt of signed accession forms from all beneficiaries.

The EDCTP will — except if payment is suspended or terminated— make the pre-financing payment to the coordinator/directly to beneficiaries within 30 days of the latest of the following dates:

- For the coordinator, the entry into force of the Agreement and for other beneficiaries, the receipt of its signed Accession Form

- 10 days before the starting date of the action.

9.6.2 Interim payments

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods. The trigger for interim payment is the approval of the relevant periodic report (both financial and technical reports).

The total amount of pre-financing and interim payments will not exceed 90 percent of the maximum grant amount minus pre-financing and previous interim payment(s). However, in exceptional cases EDCTP may agree for the total pre-financing and interim payments to be more than 90%. This is usually the case where EDCTP Operations Department assesses that withholding 10% may undermine the successful completion of the project. The decision to reduce the withheld amount to below 10% must be based on a financial and technical risk assessment by EDCTP

The EDCTP Association will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report except in the event of a suspension or termination.

Before an interim payment is made, the following conditions must be satisfied:

- Approval of the periodic report (financial and technical report). The beneficiaries need to bear in mind that approval of the reports does not imply recognition of the compliance, authenticity, completeness or correctness of its content
- Evidence that all specified conditions in the Grant Agreement have been met
- The coordinator has submitted a periodic report within 60 days following the end of each reporting period. The periodic report must include a periodic technical report and a periodic financial report. These reports must include:

Periodic technical report must include:

- An explanation of the work carried out by the beneficiaries;
- An overview of the progress towards the objectives of the action, including milestones and deliverables identified in the description of the action (annex 1 of GA);
- Explanations justifying the differences between work expected to be carried out in accordance with Annex 1 of GA and that actually carried out;
- Details of the exploitation and dissemination of the results and - if required in Annex 1 of the GA - an updated plan for the exploitation and dissemination of the results;
- A summary for publication by the EDCTP;
- The answers to the questionnaire covering issues related to the action implementation and the economic and societal impact, notably in the context of the key performance indicators and monitoring requirements.

Periodic financial report must include:

- An individual financial statement from each beneficiary [and from each linked third party], for the reporting period concerned;
- Details of the eligible costs (actual costs, unit costs and flat-rate costs) for each budget category;
- A declaration of costs in the financial report by beneficiaries [and linked third parties]. Each beneficiary [and each linked third party] must declare that: the information provided is full, reliable and true; the costs declared are eligible; the costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations; and for the last reporting period that all the receipts have been declared. Amounts which are not declared in the individual financial statement will not be taken into account by EDCTP;

- An explanation of the use of resources and the information on subcontracting and in-kind contributions provided by third parties from each beneficiary [and from each linked third party], for the reporting period concerned;
 - A periodic summary financial statement , consolidating the individual financial statements for the reporting period concerned and including - except for the last reporting period - the request for interim payment.
- If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period
 - The individual financial statements of the last reporting period must also detail the receipts of the action.

9.6.3 Payment of balance

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action. Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content. The amount due as the balance is arrived at by the EDCTP by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount.

Depending on the total amount of eligible costs incurred, the payment of balance can be in the form of recovery or payment:

- Recovery: if the total amount of earlier payments to the beneficiary is greater than the final grant amount the payment of the balance takes the form of a recovery. In such cases an invoice will be sent to the beneficiary
- Payment: if the total amount of earlier payments is lower than the final grant amount, EDCTP will make a payment after all the conditions for payment are met. The amount to be paid may however be offset, without the beneficiary's consent, against any other amount owed by the beneficiary to the EDCTP, up to the maximum EDCTP contribution indicated, for that beneficiary, in the estimated budget for the action (annex 2 of the Grant Agreement)

Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period. The final report must include a final technical report and a final financial report. These reports must include:

- A final technical report with a summary for publication containing:
 - An overview of the results and their exploitation and dissemination;
 - The conclusions on the action, and
 - The socio-economic impact of the action;
- A final financial report containing:
 - Final summary financial statement (drawn up in accordance with Annex 4) consolidating the individual financial statements for all reporting periods and including the request for payment of the balance; and
 - A certificate on the financial statements' (drawn up in accordance with Annex 5) for each beneficiary [and for each linked third party], if the beneficiary requests a total contribution of EUR 325,000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices.

EDCTP may require the coordinator to submit additional information both during and after the duration of the action so that it can comply with its obligation to report on the programme to the European Commission and EDCTP Participating States.

9.7 Notification of amounts due

When making payments, the EDCTP will formally notify the coordinator of the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount of the action. In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by a 'pre-information letter' to the coordinator or beneficiary concerned:

- Informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- Inviting it to submit observations within 30 days of receiving notification.

If the EDCTP does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due).

9.8 Suspension of payments

EDCTP may at any moment suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement.

If EDCTP decides to suspend payment to a beneficiary, the beneficiary concerned will receive a letter from EDCTP explaining the reasons for suspension. The beneficiary will be invited to submit observations within 30 days of receiving the notification. If no observations have been submitted or if, despite the observations submitted, EDCTP decides to pursue suspension, the beneficiary will be notified by a suspension letter. Otherwise, the letter will formally notify that the suspension procedure is not continued.

The suspension takes effect the day the confirmation notification is sent by EDCTP. During the suspension, the periodic report(s) must not contain any individual financial statements from the beneficiary concerned [and its linked third parties]. When the EDCTP resumes payments, the coordinator must include them in the next periodic report.

9.9 Suspension of payment deadline

EDCTP2 may at any moment suspend the payment deadline if a request for payment cannot be approved because:

- It does not comply with the provisions of the Agreement (as set out in article 20 of the Grant Agreement);
- The technical reports or financial reports have not been submitted or are not complete or additional information is needed, or
- There is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

If EDCTP decides to suspend the payment deadline for a beneficiary, a letter will be issued to the beneficiary concerned, specifying the reasons for suspension and informing the beneficiary concerned of a revised payment deadline.

9.10 Rejection of ineligible costs

EDCTP will at the time of making a payment (at interim payment or payment of the balance) or even afterwards reject any costs which are ineligible, in particular following checks, reviews, audits or investigations. The ineligible costs will be rejected in full except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented.

- If costs are rejected at the time of an interim payment or the payment of the balance, EDCTP will calculate the interim payment or payment of the balance after deducting those costs from the total eligible costs declared in the periodic or final summary financial statement
- If costs are rejected after an interim payment but before the payment of the balance, and the ineligible costs were declared in a periodic summary financial statement, EDCTP will deduct these rejected costs from the total eligible costs declared in the next periodic summary financial statement
- If costs are rejected after the payment of the balance, EDCTP will deduct the amount rejected from the total eligible costs declared in the final summary financial statement. The revised final grant amount will be calculated by deducting the rejected costs from the original grant amount.

The coordinator will be notified by EDCTP of all the ineligible costs and be provided with an opportunity to respond to the notification within 30 days. Where the response fails to address the ineligible costs, EDCTP will either reduce the total grant funding by the sum of the ineligible expenses, and then include/consider this amount in the calculation of the next payment or, where applicable, recover the undue amounts from the Coordinator.

9.11 Recovery of unused funds

Unused funds will be recovered from the beneficiary in the following circumstances:

- During the course of the project, if a beneficiary's participation in the project is terminated. In such events, EDCTP will calculate, on the basis of the periodic reports, the termination report and the report on the distribution of payments, if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's final grant amount. Only costs incurred by the beneficiary until termination takes effect are eligible. Costs relating to contracts due for execution only after termination are not eligible. If the payments received exceed the amounts due, EDCTP will recover the undue amount from the beneficiary concerned by formally notifying it a debit note. This note will specify the amount to be covered, the terms and the date for payment.

If payment is not made by the date in the debit note, the amount to be recovered will be increased by the late-payment interest (see below). Partial payments will be first credited against expenses, charges and late payment interest and then against principal. All bank charges incurred in the recovery process will be borne by the beneficiary.

- At the end of the project, if the amount of funds paid is higher than the amount of eligible expenditure. A debit note with the terms and the date for payment will be issued to the beneficiary if payments were made directly to the beneficiary or to the coordinator if payments were made only to the coordinator.

10 Subcontracting

10.1 Introduction

A subcontract means the purchase of goods, works or services that are identified in Annex 1 of GA as action tasks.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests.

The tasks to be implemented by subcontractors and the estimated cost for each subcontract must be set out in Annex 1 of the GA and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2 of GA. The EDCTP may however approve subcontracts not set out in Annex 1 and 2 without amendment if:

- They are specifically justified in the periodic technical report and
- They do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

10.2 Special subcontracting rules

- Core project activities cannot be subcontracted
- Subcontracting between beneficiaries is not allowed in the same Grant Agreement. If one beneficiary needs the services of another in order to perform its part of the work it is the second beneficiary who should declare the costs for that work.
- Subcontracting to affiliates is not allowed, unless they have a framework contract or the affiliate is their usual provider, and the subcontract is priced at market conditions.
- Coordination tasks of the coordinator (as set out in article 41.2(b) of the GA) cannot be subcontracted. Other activities of the coordinator may in principle be subcontracted. These include:
 - Monitoring that the action is implemented properly
 - Acting as the intermediary for all communications between the beneficiaries and the EDCTP (in particular, providing the EDCTP with the information described in Article 17 of the GA), unless the Agreement specifies otherwise
 - Requesting and reviewing any documents or information required by the EDCTP and verifying their completeness and correctness before passing them on to the EDCTP
 - Submitting the deliverables and reports to the EDCTP
 - Ensuring that all payments are made to the other beneficiaries without unjustified delay;
 - Informing the EDCTP of the amounts paid to each beneficiary, when required under the Agreement or requested by the EDCTP.
- The name of the subcontractor should be indicated for existing framework contracts or subcontracts.
- To be eligible, costs for subcontracting must fulfil the general conditions for actual costs as defined in Article 6.1 of the GA. These include being incurred during the action duration, necessary, and linked to the action.

10.3 Distinction between contracts to purchase of goods, works or services and subcontracting

Subcontracts concern the implementation of action tasks that are described in Annex 1. The price for the subcontracts must be declared as 'direct costs of subcontracting'. The declared costs of subcontracting shall be excluded in the calculation of indirect costs. The formula for calculating indirect costs is: (total eligible costs – subcontracting costs) x 25%.

Purchase contract means ordinary contract for services, works or goods needed to carry out the action, including the purchase of consumables and supplies. Purchase contracts are not implementation of action tasks, but they are necessary to implement action tasks by beneficiaries. They do not have to be indicated in Annex 1. The price for contracts is declared as 'other direct costs' in the financial statement. They will be taken into account in the application of the flat-rate for indirect costs.

They are necessary to the project, but do not concern central action tasks.

10.4 Subcontractor’s rights and obligations

The subcontractor has no contractual relation with the EDCTP or other beneficiaries. However, the subcontractor can be audited by the EDCTP, the European Commission, the European Anti-Fraud Office (OLAF) and the Court of Auditors. It is the beneficiaries’ responsibility to ensure that the obligations under Article 22 and 23 of the GA are accepted by the subcontractor. If access is refused and EDCTP cannot verify the eligibility of costs, the costs will be rejected.

11 Financial Reports

11.1 Financial reporting period

The reporting periods are stated in Article 20.2 of the GA.

In addition to financial reports, beneficiaries must submit a summary of funds received from the Coordinator, detailing the date the payment is received and the cumulative amount received from the start of project to date in the following format:

| Date | Cumulative amount received from start to date (€) |
|------|---|
| | |
| | |
| | |

11.2 Introduction

Beneficiaries must submit:

- 1) A periodic financial report within 60 days following the end of each reporting period which contains:
 - An individual financial statement from each beneficiary detailing the eligible costs per budget category. The report should be prepared using EDCTP’s financial reporting template. Each beneficiary must provide a certification that the information provided is full, reliable and true; the costs declared are eligible, can be substantiated by adequate records and supporting documentation that will be produced upon request or in the reviews, checks and investigations performed by EDCTP or any agents of the European Commission.
 - An explanation of the use of funds and the information on subcontracting and in-kind contributions provided by third parties from each beneficiary for the reporting period concerned.
 - A periodic summary financial statement, consolidating the individual financial statements of beneficiaries and the request for interim payment.

- 2) A final financial report within 60 days of the end of the last reporting period which contains:

- A final summary financial statement consolidating the individual financial statements for all beneficiaries and for all reporting periods and including the request for payment of the balance
- An audit certificate on the financial statements for each beneficiary requesting a total contribution of €325,000 or more

3) All financial reports to EDCTP in the language of the GA, which is English.

11.3 Audit certificate

At the end of the grant, a beneficiary must submit an original audit certificate on the financial statements covering the period from start date of the grant to the end (whole life cycle of the grant) if the actual expenditure is greater than €325,000.

A final financial report containing:

A final summary financial statement (drawn up in accordance with Annex 4 of GA), consolidating the individual financial statements for all reporting periods and including the request for payment of the balance; and

A certificate on the financial statements (drawn up in accordance with Annex 5 of GA) for each beneficiary that claims a total EDCTP contribution of €325,000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (excluding flat rates).

11.4 Audit certificate rules

- Costs based on lump sums, flat-rates (e.g. indirect costs) or unit costs (other than those for personnel costs calculated according to the beneficiary's usual cost accounting practices) are not counted in determining the €325,000 threshold (and do not need to be covered by the certificate).
- If a certificate is required, all costs declared as actual costs or average personnel costs must be covered by the certificate. Incomplete certificates will be returned for correction.
- Certificates submitted before the €325 000 threshold is reached will be rejected by the EDCTP.
- Beneficiaries may submit either one certificate per reporting period or a single CFS for the whole action.
- The certificate must be issued by a qualified auditor, using the template in Annex 5 of GA.
- Only qualified auditors may issue a certificate. Qualified' means qualified in accordance with national legislation implementing Directive 2006/43 (or any EU legislation that replaces this Directive).
- The auditor must certify that the costs declared in the financial statement are accurately recorded in the beneficiary's accounting system and eligible and that all receipts have been declared. If the auditor cannot confirm (for any reason), s/he must explain this in detail in the certificate. The EDCTP will consider the explanation in light of the facts provided by the auditor, and decide on steps to take.
- Public bodies — for public bodies, the certificate may be issued by an independent public officer with formal competence to audit the beneficiary (instead of by an external auditor).
- International organisations — for international organisations, it can be an internal or external auditor that is appointed in accordance with the internal financial regulations and procedures of the organisation.
- Beneficiaries established in a third country must provide a certificate that complies with national regulations in the field. Auditors qualified in the EU may provide certificates for beneficiaries established in third countries, if they are familiar with the relevant national regulations (national accounting rules) and comply with them when preparing the certification.

12 Records and documentation to support the costs declared

The beneficiaries must — up to five years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible. They must make them available upon request or in the context of checks, reviews, audits or investigations.

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the GA, beneficiaries must keep the records and other supporting documentation until the end of these procedures. The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The EDCTP may accept non-original documents if it considers that they offer a comparable level of assurance.

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

- **For actual costs:** adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation.
- **For unit costs:** adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.
- For direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2 of GA.
- In addition, for personnel costs (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the EDCTP Association may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.
- **For flat-rate costs:** adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

As an exception, for persons working exclusively on the action, there is no need to keep time records, if the beneficiary signs a declaration confirming that the persons concerned have worked exclusively on the action.

Proper supporting documentation shall be maintained for a minimum period of five years after the payment of the balance; and to make such documents available to EDCTP staff and auditors. In addition, all financial records must be kept for at least five years after the payment of the balance. The EDCTP expects beneficiaries to maintain at least the following records:

- A file containing all correspondence relating to the project
- Payment vouchers file
- Monthly bank statements file
- Bank reconciliations file for filing bank reconciliation statements
- Financial reports' file for filing copies of all financial reports
- An administrative file for filing the following:
 - Appointment, redundancy, termination and dismissal letters
 - Leave letters
 - Administrative issues
 - Time sheets: for personnel costs declared as actual costs or on the basis of unit costs, the beneficiaries must keep time records for the number of hours declared for persons not working exclusively on the project.
 - Payroll file for filing payroll related reports.

If there are ongoing procedures such as audits or litigations, the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

**Annex 1: Declaration of reading and distributing the
EDCTP Financial Guidelines**

Beneficiary

As a beneficiary of the EDCTP funded project titled _____,

I am pleased to provide the declaration that I have received and distributed the latest version (version dated October 2016) of the EDCTP financial guidelines to the person(s) responsible for financial management and reporting of this grant.

Name: _____

Signature: _____

Date: _____

Head of Finance/Person responsible for financial management

I confirm that I have received, read and understood all the sections of the latest version (version dated October 2016) of the EDCTP financial guidelines.

Name: _____

Signature: _____

Date: _____

Please e-mail a scanned copy of this declaration to the EDCTP Grant Finance Officer/Assistant responsible for this project.

A copy of this declaration must be retained in the files of this project at your site.

Annex 2: Timesheet

| Timesheet | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|---------------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-------|
| Name of staff: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of supervisor: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Project Acronym | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Type of contract - FTor PT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Year | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Calender month | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| January | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of projects/day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | Total |
| Project 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| Project 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| Total | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Weekends | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Annual leave | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Public and EDCTP holidays | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Illness | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Other absence | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Total | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Total productive hrs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Total hours | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Signature of staff: _____ | | | | | | | | | | | | | | Signature of supervisor : _____ | | | | | | | | | | | | | | | | | | |
| Date | | | | | | | | | | | | | | Date | | | | | | | | | | | | | | | | | | |

For illustration purposes, only 2 projects are created. You can increase the number of

Timesheet - Annual Summary

| | | | | | | | | | | | | | |
|---|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|
| Name of staff member | | | | | | | | | | | | | |
| Name of supervisor | | | | | | | | | | | | | |
| Project Acronym | | | | | | | | | | | | | |
| Type of contract - Full-time or Part-time | | | | | | | | | | | | | |
| Year | | | | | | | | | | | | | |
| | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total |
| Projects/Days in month | 31 | 28 | 31 | 30 | 31 | 30 | 31 | 31 | 30 | 31 | 30 | 31 | 365 |
| Project 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Work Package 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Work Package 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Project 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Weekends | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Annual leave | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Public and EDCTP holidays | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Illness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other absence | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total productive hrs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total hours | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Signature of staff member: _____ | Signature of supervisor | | | | | | | | | | | | |
| Date | Date | | | | | | | | | | | | |

Annex 3: Declaration of staff working full time in the EDCTP funded project

| Action | | | |
|--|--|---------------------------------------|--|
| Title of the action (acronym) | | Grant Agreement number | |

| | |
|---|--|
| Beneficiary's/ linked third party's name | |
|---|--|

| Reporting period covered by this declaration ¹ | | |
|---|-------------|-----------|
| Reporting period number | from (date) | to (date) |
| | | |

This document certifies that [name of the person]..... has worked for the beneficiary/linked third party exclusively on the above-mentioned EDCTP funded action (project) during (chose one below)²:

- the whole reporting period
- from the start date of the reporting period until [insert date]/...../.....

SIGNATURES

For the beneficiary/linked third party
(supervisor)

Name:.....

Date:/...../.....

Signature:

For the person working exclusively on
the action

Date:/...../.....

Signature:

¹ Only one declaration can be made per reporting period for each person working in the action

² In all other cases the person must keep timesheets to show the actual hours worked for the action

Annex 4: Coordinator request for confirmation of funds received by beneficiaries

(Sent by coordinators to beneficiaries)

Name of Beneficiary

Address

Date

Subject: Request of financial information

Dear *Dr/Prof,*

In connection with the financial review of the *acronym of the project (project code)*, please send to EDCTP the cash receipts summary showing the amount of funds received from *name of the Coordinator* from the start of the project (*contract date*) to date as per the table below:

| Date | Amount received | Currency |
|------|-----------------|----------|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

The letter should be written in your own letterhead paper and should be sent through email to *name of GFO* at *email address of GFO*.

Your prompt attention to this request will be appreciated.

Yours sincerely,

Name of the Coordinator

Project Coordinator

Please insert the beneficiary's institution letterhead logo

(Sent by beneficiaries to EDCTP)

Confirmation of Funds Received

This letter is to confirm that the EDCTP *acronym of the project (project code)* project funds were received from *name of the Coordinator*. Details of the date the payment was received and the cumulative amount received from the start of the project (*contract date*) are shown below:

Date and amount of funds received:

| Date | Amount received | Currency |
|-------|-----------------|----------|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| Total | | |

Name of the beneficiary:

Signature of the beneficiary:

Date:

Annex 5: Fixed asset register

| Fixed Asset Register | | | | | | | | | | | |
|----------------------------------|--------------------------|---------------|-------------|------|------------|-----------------------|--------------|---------------|---------------|--|-------|
| Site's name: | | | | | | | | | | | |
| Unique Asset Identification Code | Description of the asset | Supplier name | Brand /Make | Site | Asset Type | Funding Source/ Donor | Project code | Purchase Date | Purchase Cost | Location of Asset on site/Employee using the asset | Notes |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

Prepared by: _____

Date: _____

**Annex 6: Certification of truth, accuracy and completeness
of the EDCTP project financial report**

As a beneficiary of the EDCTP funded project titled

I declare that for the submitted period financial report:

- the information provided is full, reliable and true;
- the costs declared are eligible;
- the costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the reviews, checks and investigations performed by EDCTP or any agents of the European Commission;
- that all the receipts have been declared (*only for the last reporting period*)

Name: _____

Signature: _____

Date: _____

Annex 7: Audit Terms of Reference (ToR)

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed from the EDCTP Programme with co-funding under the Horizon 2020 Research and Innovation Programme

This document sets out the 'Terms of Reference (ToR)' under which _____ (the Beneficiary) agrees to engage _____ (the 'Auditor') to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s) drawn up by the Beneficiary for the EDCTP Programme grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a 'Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement(s) has (have) been concluded between the Beneficiary and the European and Developing Countries Clinical Trials Partnership implementing 'EDCTP Programme' ('the EDCTP-IS').

The EDCTP-IS is mentioned as a signatory of the Agreement with the Beneficiary only. The European Union is not a party to this engagement.

1. Subject of the engagement

The coordinator must submit to the EDCTP-IS the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the [Beneficiary] [Linked Third Party] and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the EDCTP-IS, the European Commission, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

2. Responsibilities

The [Beneficiary] [Linked Third Party]:

- Must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according

to the [Beneficiary's] [Linked Third Party's] accounting and book-keeping system and the underlying accounts and records;

- Must send the Financial Statement(s) to the Auditor;
- Is responsible and liable for the accuracy of the Financial Statement(s);
- Is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- Accepts that the Auditor cannot carry out the Procedures unless it is given full access to the [Beneficiary's] [Linked Third Party's] staff and accounting as well as any other relevant records and documentation.

The Auditor:

- [Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].
- [Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].
- [Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].

The Auditor:

- must be independent from the Beneficiary [and the Linked Third Party], in particular, it must not have been involved in preparing the [Beneficiary's] [Linked Third Party's] Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the [Beneficiary] [Linked Third Party].

The EDCTP-IS sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

3. Applicable Standards

The Auditor must comply with these Terms of Reference and with:

- the International Standard on Related Services ('ISRS') 4400 Engagements to perform Agreed-upon Procedures regarding Financial Information as issued by the International Federation of Accountants (IFAC);
- the Code of Ethics for Professional Accountants issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [Commission] [Agency] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary [and the Linked Third Party], and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

4. Reporting

The Report must be written in English.

Under Article 22 of the Agreement, the EDCTP-IS, the European Commission, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from EDCTP- Programme with co-funding under the Horizon 2020 research and innovation programme. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the EDCTP-IS, the European Commission, the European Anti-Fraud Office or the European Court of Auditors requests them.

5. Timing

The Report must be provided by [dd Month yyyy].

6. Other terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]
[name & function of authorised representative]
[dd Month yyyy]
Signature of the Auditor

[legal name of the [Beneficiary][Linked Third Party]]
[name & function of authorised representative]
[dd Month yyyy]
Signature of the [Beneficiary][Linked Third Party]]