



E D C T P



**Horizon 2020
European Union Funding
for Research & Innovation**

**Mono-beneficiary
Model Grant Agreement
for
2nd European & Developing Countries
Clinical Trials Partnership Programme (EDCTP2)**

Version 1.0

10 July 2015

Disclaimer

This document is aimed at assisting applicants for Horizon 2020 funding. It shows the full range of provisions that may be applied to this type of grant agreement, and is provided for information purposes only. The legally binding grant agreement will be that which is signed by the parties for each action.

**GENERAL MONO-BENEFICIARY MODEL GRANT AGREEMENT FOR THE
SECOND EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS
PARTNERSHIP PROGRAMME¹ ('EDCTP2')**

- Footnotes blue will not appear in the grant agreement for signature since they are internal instructions only.
- Text in grey indicates that text which appears in the General MGA — Multi is not applicable in this grant agreement.
- For options [*in italics, in square brackets*]: the applicable option must be chosen before signature of the grant agreement. Options not chosen will either not appear or appear as 'not applicable'. Options chosen will appear *in italics* without brackets and without the Option title (to allow beneficiary to easily spot that a specific rule applies).
- For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the grant agreement.

¹ Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States (OJ L 169, 7.6.2014, p. 38).

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

EDCTP 2 Model Grant Agreements: EDCTP 2 General MGA — Mono: September 2015

GRANT AGREEMENT

NUMBER [insert number] — [insert acronym]

This **Agreement** (‘the Agreement’) is **between** the following parties:

on the one part,

the European and Developing Countries Clinical Trials Partnership Association implementing EDCTP2 (‘the EDCTP Association’) represented for the purposes of signature of this Agreement by [function, forename and surname],²

and

on the other part,

‘the beneficiary’:

[**full official name (short name)**][legal form], [official registration No], established in [official address in full], [VAT number], represented for the purposes of signing the Agreement by [function, forename and surname]

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement, the beneficiary accepts the grant and agrees to implement it under its responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Not applicable

[OPTION to be used if Article 14 applies and if joint and several liability has been requested by the EDCTP Association: 3a Declaration on joint and several liability of linked third parties]

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

² The person representing the EDCTP Association must be the legal representative authorised to sign legal acts, contracts for the EDCTP Association.

Annex 7 Model for technical reports

TERMS AND CONDITIONS

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiary for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED [— COMPLEMENTARY GRANT] [— JOINTLY FUNDED ACTION]

The grant is awarded for the action entitled [insert title of the action] — [insert acronym] ('**action**'), as described in Annex 1.

[OPTION for complementary grants if foreseen in the work plan: The grant is a 'complementary grant' to [the grant agreement(s) under the call(s) for proposals [call identifier(s)] [the following complementary grant agreement(s) No(s):

- [insert number] [insert acronym]
- [insert number] [insert acronym]].]

[OPTION for joint actions (joint call with a third country or an international organisation): The action is a 'jointly funded action' which must be coordinated with the 'joint action' called [insert the name of the third country or international organisation action], as described in Annex 1.]

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be [insert number] months as of [OPTION by default: the first day of the month following the date the Agreement enters into force (see Article 58)] [OPTION if needed for the action: [insert date]³ ('starting date of the action').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

³ This date must be the first day of a month and it must be later than the date of entry into force of the agreement, unless authorised otherwise by the EDCTP Association, if the applicant can demonstrate the need to start the action before the entry into force of the grant agreement or the need to start the action on another day than the first day of the month. In any case, the starting date should not be earlier than the date of the submission of the grant application (Article 130 FR).

The ‘**estimated budget**’ for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down [for the beneficiary (and linked third party) and] by budget category (see Articles 5, 6 [and 14]).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between budget categories. This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiary 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.

[OPTION if lump sum foreseen in Article 5.2: Lump sums set out in Annex 2 can never be adjusted.]

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The ‘**maximum grant amount**’ is EUR [insert amount (insert amount in words)].

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses *[OPTION for research and innovation actions (RIA): 100 % of the action’s eligible costs] [OPTION for innovation actions (IA)⁴, if the beneficiary and all linked third parties are non-profit legal entities⁵: 100% of the action’s eligible costs][OPTION for innovation actions (IA), if the beneficiary and all linked third parties are profit legal entities: 70% of the action’s eligible costs] [OPTION for innovation actions (IA), if either the beneficiary or some linked third parties are non-profit legal entities and some are profit legal entities: 100% of the eligible costs of [the beneficiary][and][the linked third parties] that [are non-profit legal entities][is a non-profit legal entity] and 70% of the eligible costs of [the beneficiary][and][the linked third parties] that [are profit legal entities][is a profit legal entity]] [OPTION for training and mobility actions (TMA): 100 % of the action’s eligible costs] [OPTION for exceptional cases*

⁴ For the definition, see Article 2.1(6) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in “Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)” (‘**Rules for Participation Regulation No 1290/2013**’) (OJ L 347, 20.12.2013 p.81): ‘**innovation action**’ means an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

⁵ For the definition, see Article 2.1(14) of the Rules for Participation Regulation (EU) No 1290/2013: ‘**non-profit legal entity**’ means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

if foreseen in the work plan: [...%] of the action's eligible costs] (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR [**insert amount** (insert amount in words)].

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**')

(a) for **direct personnel costs** [(excluding direct personnel costs covered by the unit cost[lump sum] under Point (f))]⁶:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel costs for SME owners or if the beneficiary is a natural person not receiving a salary (see Article 6.2 points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs of subcontracting** [(excluding subcontracting costs covered by the unit cost[lump sum] under Point (f))]⁷: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties** [(excluding costs of financial support covered by the unit cost[lump sum] under Point (f))]⁸: [**OPTION to be used if Article 15 applies: as actually incurred costs (actual costs);**][**OPTION: not applicable;**]

(d) for **other direct costs** [(excluding other costs covered by the unit cost[lump sum] under Point (f))]⁹: as actually incurred costs (**actual costs**);

(e) for **indirect costs** [(excluding indirect costs covered by the unit cost[lump sum] under Point (f))]¹⁰: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) [**OPTION for specific unit costs (if unit cost foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)]¹¹: on the basis of the amount(s) per unit set out in Annex 2¹² (unit costs).**]

[**OPTION for specific lump sum costs (if lump sum foreseen by Commission decision and applicable to the grant): for [insert name of specific cost category(ies)]: as the lump sum set out in Annex 2 ('lump sum costs').**]

⁶ To be used only if option in Point (f) is used.

⁷ To be used only if option in Point (f) is used.

⁸ To be used only if option in Point (f) is used.

⁹ To be used only if option in Point (f) is used.

¹⁰ To be used only if option in Point (f) is used

¹¹ Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump-sum). For example: 'access costs for providing trans-national access to research infrastructures', 'costs for clinical studies'; 'costs for energy efficiency measures in buildings'.

¹² Annex 2 must clearly show, for the beneficiary (and each linked third party) concerned, all the parameters for the unit cost (i.e. the unit(s), the amount(s) per unit, the research installation/infrastructure for which it is used, the clinical study for which it is used, etc).

[OPTION: specific cost category(ies): not applicable.]

5.3 Final grant amount — Calculation

The ‘**final grant amount**’ depends on the actual extent to which the action is implemented in accordance with the Agreement’s terms and conditions.

This amount is calculated by the EDCTP Association — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiary *[and linked third parties]* (see Article 20) and approved by the EDCTP Association (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

‘**Profit**’ means the surplus of the amount obtained following Steps 1 and 2 plus the action’s total receipts, over the action’s total eligible costs.

The ‘**action’s total eligible costs**’ are the consolidated total eligible costs approved by the EDCTP Association.

The ‘**action’s total receipts**’ are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

- (a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;
- (b) financial contributions given by third parties to the beneficiary *[or to a linked third party]* specifically to be used for the action, and

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- (c) 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.

The following are however not considered receipts:

- (a) income generated by exploiting the action's results (see Article 28);
- (b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);
- (c) 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 amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the EDCTP Association will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the EDCTP Association rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**'.

This amount is calculated by the EDCTP Association on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the EDCTP Association ;
- in case of **reduction of the grant**: in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

- (i) they must be actually incurred by the beneficiary;
- (ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);
- (iii) they must be indicated in the estimated budget set out in Annex 2;
- (iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;
- (v) 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;
- (vi) they must comply with the applicable national law on taxes, labour and social security, and
- (vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

- (i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

- (ii) the number of actual units must comply with the following conditions:
 - the units must be actually used or produced in the period set out in Article 3;
 - the units must be necessary for implementing the action or produced by it, and
 - the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

- (i) they must be calculated by applying the flat-rate set out in Annex 2, and
- (ii) the costs (actual costs or unit costs [*or lump-sum costs*]) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article[;]/[.]

(d) [*OPTION if lump sum foreseen in Article 5.2: for lump sum costs*]:

- (i) *the eligible amount is equal to the amount set out in Annex 2, and*
- (ii) *the corresponding tasks or parts of the action must have been properly implemented in accordance with Annex 1.]*

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

- A. direct personnel costs;
- B. direct costs of subcontracting;
- C. *[OPTION to be used if Article 15 applies: direct costs of providing financial support to third parties;] [OPTION: not applicable;]*
- D. other direct costs;
- E. indirect costs;
- F. *[OPTION for specific unit[lump sum] costs: [insert name(s) of specific cost category(ies)]¹³] [OPTION: not applicable].*

‘Direct costs’ are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

‘Indirect costs’ are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs [(not covered by Point F)]

Types of eligible personnel costs

A.1 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 action (**‘costs for employees (or equivalent)’**). 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).

If the beneficiary is a non-profit legal entity¹⁴, it may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

- (a) 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;

¹³ Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: ‘access costs for providing trans-national access to research infrastructure’, ‘costs for clinical studies’, ‘costs for energy efficiency measures in buildings’.

¹⁴ For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013’): ‘**non-profit legal entity**’ means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

- (b) 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:

- (a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;
- (b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or
- (c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

- (a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;
- (b) the result of the work carried out belongs to the beneficiary, and
- (c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs if the conditions in Article 11.1 are met.

A.4 If the beneficiary is a small and medium-sized enterprise ('SME'), the **costs of its owner** who is working on the action and who does not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 If the beneficiary is a **natural person not receiving a salary**, its **costs** are eligible personnel costs if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

[A.6[OPTION to be used for trans-national access to research infrastructure: Personnel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.] [OPTION to be used for virtual access to research infrastructure: Personnel costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.]]

Calculation

Personnel costs must be calculated by the beneficiary as follows:

{ hourly rate
multiplied by
the number of actual hours worked on the action },
plus
for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EDCTP2 grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{ number of annual productive hours for the year (see below)
minus
total number of hours declared by the beneficiary, for that person for that year, for other EDCTP2 grants }.

The ‘**hourly rate**’ is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{ actual annual personnel costs (excluding additional remuneration) for the person
divided by
number of annual productive hours }.

The beneficiary must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiary must use the hourly rate of the last closed financial year available.

For the ‘number of annual productive hours’, the beneficiary may choose one of the following:

- (i) ‘fixed number of hours’: 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);
- (ii) ‘individual annual productive hours’: the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{ annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

‘Annual workable hours’ means 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.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

- (iii) ‘standard annual productive hours’: the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the ‘standard annual workable hours’.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- (i) for an SME owner or beneficiary that is a natural person: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or
- (ii) for personnel costs declared on the basis of the beneficiary’s usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary’s accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting [(not covered by Point F)] (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

[OPTION to be used for trans-national access to research infrastructure: Subcontracting costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.]

[OPTION to be used for virtual access to research infrastructure: Subcontracting costs for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.]

C. Direct costs of providing financial support to third parties [(not covered by Point F)]
[OPTION to be used if Article 15 applies: are eligible if the conditions set out in Article 15.1.1 or 15.2.1 are met.]

[OPTION: Not applicable]

D. Other direct costs [(not covered by Point F)]

D.1 Travel costs and related subsistence allowances (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

[OPTION to be used for trans-national access to research infrastructure: Travel costs for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.]

D.2 [OPTION by default: The depreciation costs of equipment, infrastructure or other assets (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

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 also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

*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, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.]

[OPTION (alternative to option above) to be used if foreseen in the work plan¹⁵: The cost of purchasing equipment, infrastructure or other assets (new or second-hand) (as recorded in the

¹⁵ To 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.

beneficiary's accounts) are eligible if the equipment, infrastructure or other assets was purchased in accordance with Article 10.1.1.

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 also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

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, do not include any financing fees and if the conditions in Article 11.1 are met.]

[OPTION (in addition to one of the two options above) for trans-national and virtual access to research infrastructure: *As an exception, the beneficiary must not declare such costs (i.e. costs of renting, leasing, purchasing depreciable equipment, infrastructure and other assets) for providing trans-national or virtual access to research infrastructure (see Article 16).]*

D.3 Costs of other goods and services (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

- (a) purchased specifically for the action and in accordance with Article 10.1.1 or
- (b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

[OPTION to be used for trans-national access to research infrastructure: *Costs of other goods and services for providing trans-national access to research infrastructure are eligible only if also the conditions set out in Article 16.1.1 are met.]*

[OPTION to be used for virtual access to research infrastructure: *Costs of other goods and services for providing virtual access to research infrastructure are eligible only if also the conditions set out in Article 16.2 are met.]*

D.4 Capitalised and operating costs of 'large research infrastructure'¹⁶ **[OPTION by default:** *directly used for the action are eligible, if:*

- (a) *the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure¹⁷);*

¹⁶ 'Large research infrastructure' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

¹⁷ For the definition see Article 2(f) of the H2020 Framework Programme Regulation No 1291/2013 : 'Research infrastructure' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public

- (b) *the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('ex-ante assessment');*
- (c) *the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and*
- (d) *they comply with the conditions as further detailed in the annotated H2020 grant agreements.]*

[OPTION for all topics within calls under Part 'Research Infrastructure' (except for e-Infrastructure topics): Not applicable]

[OPTION to be used if foreseen in the work plan: Not applicable]

E. Indirect costs [(not covered by Point F)]

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Articles 5.2 and 6.2 A to D above), from which are excluded:

- (a) costs of subcontracting [and][;]
- (b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises [and][;]
- (c) **[OPTION to be used if Article 15 applies: costs of providing financial support to third parties [and][;]][OPTION: not applicable;]**
- (d) **[OPTION if Article 6.2 F applies and the specific unit/[lump sum] cost includes indirect costs: [unit costs under Article 5.2(f) and Point F below][lump sum costs under Articles 5.2(f) and 6.2 F below]][OPTION: not applicable].**

If the beneficiary receives an operating grant¹⁸ financed by the EU or Euratom budget, it cannot declare indirect costs for the period covered by the operating grant.

F. [OPTION: Insert name of specific cost category(ies)]¹⁹[OPTION if no specific cost categories applicable to the grant: Specific cost category(ies)]

services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

¹⁸ For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**') (OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

¹⁹ Insert precise name of the cost category (as in the Commission decision authorising the use of the unit cost/lump sum). For example: 'access costs for providing trans-national access to research infrastructure', 'costs for clinical studies', 'costs for energy efficiency measures in buildings'.

[OPTION for specific unit costs (unit cost foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category] are eligible, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual units [and if [insert eligibility conditions, if any]].]

[OPTION for specific lump sum costs (lump sum foreseen by Commission decision and applicable to the grant): [Insert name of specific cost category] are eligible, if they correspond to the lump sum set out in Annex 2 and the corresponding tasks or parts of the action have been properly implemented in accordance with Annex 1.]

[same for each specific cost category]

[OPTION: Not applicable]

6.3 Conditions for costs of linked third parties to be eligible

[OPTION to be used if Article 14 applies: Costs incurred by linked third parties are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.]

[OPTION: Not applicable]

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary [*or linked third party*]), if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

‘Ineligible costs’ are:

- (a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:
 - (i) costs related to return on capital;
 - (ii) debt and debt service charges;
 - (iii) provisions for future losses or debts;
 - (iv) interest owed;
 - (v) doubtful debts;
 - (vi) currency exchange losses;
 - (vii) bank costs charged by the beneficiary’s bank for transfers from the EDCTP Association ;
 - (viii) excessive or reckless expenditure;

- (ix) deductible VAT;
 - (x) costs incurred during suspension of the implementation of the action (see Article 49);
- (b) costs declared under another EU or Euratom grant (including other grants awarded by the EDCTP Association, a Member State and financed by the EU or Euratom budget and grants awarded by other bodies for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period[;][.]
- [(c) *OPTION for cost categories explicitly excluded in the work plan: [insert name of excluded cost category]*].

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiary must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiary must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiary may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);

- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiary retains sole responsibility towards the EDCTP Association for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY A BENEFICIARY NOT RECEIVING EDCTP2 FUNDING

[OPTION by default: Not applicable]

[OPTION to be used if there is a beneficiary not receiving EDCTP2 funding but with a linked third party that receives EDCTP2 funding: 9.1 Rules for the implementation of action tasks by a beneficiary not receiving EDCTP2 funding

A beneficiary not receiving EDCTP2 funding must implement the action tasks attributed to it in Annex 1 according to Article 7.1.

Its costs are estimated in Annex 2 but:

- *will not be reimbursed and*
- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 20.6, 23a and 40 do not apply to the beneficiary.

Articles 26.4, 27.2, 28.1 [OPTION: (with the exception of additional exploitation obligations)], 28.2, 30.3, 31.5 do not apply to results generated without EDCTP2 funds.

The beneficiary will not be subject to financial checks, reviews and audits under Article 22 for its own costs.

9.2 Consequences of non-compliance

If the beneficiary not receiving EDCTP2 funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.]

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiary may purchase goods, works or services.

The beneficiary must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION: In addition, if the value of the purchase exceeds EUR [...], the beneficiary must comply with the following rules: [...].²⁰]

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its contractors.

10.1.2 If the beneficiary is a ‘contracting authority’ within the meaning of Directive 2004/18/EC²¹ or a ‘contracting entity’ within the meaning of Directive 2004/17/EC²² it must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiary may use in-kind contributions provided by third parties against payment.

The beneficiary may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties’ costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

²⁰ If the EDCTP Association decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EDCTP2 contribution in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The EDCTP Association may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

²¹ Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

²² Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

The third parties and their contributions must be set out in Annex 1. The EDCTP Association may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does 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.

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiary may use in-kind contributions provided by third parties free of charge.

The beneficiary may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The EDCTP Association may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does 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.

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiary may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests (see Article 35).

[OPTION: In addition, if the value of the subcontract to be awarded exceeds EUR [...], the beneficiary must comply with the following rules: [...].²³]

[OPTION for actions involving PCP or PPI: In addition, for the pre-commercial procurement (PCP) or procurement of innovative solutions (PPI), the beneficiary must follow a transparent and non-discriminatory procedure, including at least the following:

- (a) an ‘open market consultation’ published in the Official Journal of the European Union via a ‘prior information notice (PIN)’ and promoted and advertised widely;*
- (b) a ‘contract notice’ allowing for a time-limit for receipt of tenders of at least 2 months, published in the Official Journal of the European Union and promoted and advertised widely;*
- (c) a ‘request for tenders’ based on functional or performance-based specifications (that take into account the outcome of the open market consultation) and describing the practical set-up for the implementation of the subcontract(s);*
- (d) an objective and non-discriminatory evaluation of the tenders and award of subcontract(s) to the tender(s) offering best value for money;*
- (e) a ‘contract award notice’ published in the Official Journal of the European Union.*

The beneficiary must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

“This procurement receives funding from the EDCTP2 Programme supported by the European Union. The EDCTP Association and the European Union are however not participating as a contracting authority in this procurement.”]

²³ If the EDCTP Association decides to set specific rules, they should have due regard for the principle of proportionality, taking into account the value of the contracts and the relative size of the EDCTP2 contributions in relation to the total cost of the action and the risk. Specific rules must be based on the rules contained in the Financial Regulation. Simply citing the FR without specifying the applicable provisions should be avoided. Specific rules may only be set for the award of contracts of a value higher than EUR 60 000. The EDCTP Association may set a threshold higher than EUR 60 000 on the basis of a risk assessment.

[OPTION only for actions involving PPI: *Participation in PPI tendering procedures must be open on equal terms to tenderers from EU Member States, associated countries and other countries with which the EU has an agreement in the field of public procurement. If the WTO Government Procurement Agreement applies, PPI subcontracts must also be open to tenderers from States that have ratified this agreement.*

*If the procurement of the innovative solution (PPI) consists (and is limited to) buying a set of prototypes and/or test products that were developed during a preceding PCP Cofund action, the beneficiary does not need to make an open market consultation, contract notice and contract award notice under Points (a), (b) and (e) above. In this case, it must make a **request for tenders** from at least **three providers** (including the providers that participated in the preceding PCP), in accordance with the negotiated procedure without publication under Directives 2004/18/EC and 2004/17/EC ²⁴.]*

[OPTION only for actions involving PCP: *Subcontracts for pre-commercial procurement must provide for the following:*

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*
- *the right of the buyer to access results — on a royalty-free basis — for its own use;*
- *the right of the buyer to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*
- *the obligation of the subcontractors to transfer to the buyer the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*
- *the right of the buyer to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiary must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').]

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting must be set out in Annex 2. The EDCTP Association may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

²⁴ See Articles 28 and 31(2)(a) of Directive 2004/18 and Article 40(3)(b) of Directive 2004/17/EC.

- 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.

[OPTION for classified results: Classified results may be subcontracted only after explicit approval (in writing) from the EDCTP Association (see Article 37).]

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its subcontractors.

13.1.2 The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

If the beneficiary is a ‘contracting authority’ within the meaning of Directive 2004/18/EC or a ‘contracting entity’ within the meaning of Directive 2004/17/EC it must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

[OPTION: 14.1 Rules for calling upon linked third parties to implement part of the action

*14.1.1 The following **affiliated entities**²⁵ and **third parties with a legal link to the beneficiary**²⁶ (‘**linked third parties**’) may implement the action tasks attributed to them in Annex 1:*

²⁵ For the definition see Article 2.1(2) of the Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that is:

- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:

- (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
- (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

- (a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
- (b) the legal entities concerned are owned or supervised by the same public body.

²⁶ ‘**Third party with a legal link to a beneficiary**’ is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

- [name of the entity (short name)], affiliated or linked to the beneficiary [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]
- [name of the entity (short name)], affiliated or linked to the beneficiary [**OPTION if joint and several liability has been requested:**, if it has accepted joint and several liability with the beneficiary (see Annex 3a)]
[same for more linked third parties]

The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards its linked third parties.

14.1.2 The beneficiary must ensure that its obligations under Articles 18, 20, 35, 36 and 38 also apply to its linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[**OPTION:** Not applicable]

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

[**OPTION to be used if foreseen in the work plan:** 15.1.1 The beneficiary must provide financial support in accordance with the conditions set out in Annex 1.

At a minimum, these conditions must include:

- (a) the maximum amount of financial support for each third party.

The maximum amount may not exceed EUR 60 000 for each third party, unless it is necessary to achieve the objectives of the action as described in Annex 1;

- (b) the criteria for calculating the exact amount of the financial support;

(c) the different types of activity that qualify for financial support, on the basis of a closed list;

(d) the persons or categories of persons that may receive financial support, and

(e) the criteria for giving financial support.

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving financial support.

15.1.2 The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving financial support.]

[OPTION: Not applicable]

15.2 Financial support in the form of prizes

[OPTION to be used if foreseen in the work plan: 15.2.1 The beneficiary must provide prizes in accordance with the conditions described in Annex 1.

At a minimum, these conditions must include:

- (a) the conditions for participation;*
- (b) the award criteria;*
- (c) the amount of the prize, and*
- (d) the payment arrangements.*

The beneficiary must ensure that the EDCTP Association, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties receiving a prize.

15.2.2 The beneficiary must ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the third parties receiving a prize.]

[OPTION: Not applicable]

15.3 Consequences of non-compliance

[OPTION to be used if 15.1 and/or 15.2 are applicable: If the beneficiary breaches any of its obligations under Articles 15.1.1 or 15.2.1, the costs related to the financial support or prize will be ineligible (see Article 6) and will be rejected (see Article 42).

If the beneficiary breaches any of its obligations under Articles 15.1.2 or 15.2.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION: Not applicable]

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

[OPTION trans-national access to research infrastructure: 16.1.1 ‘Access providers’²⁷ must provide access to research infrastructure or installations²⁸ in accordance with the following conditions:

(a) *access which must be provided:*

The access must be free of charge, trans-national access to research infrastructure or installations for selected user-groups.

This access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure.

(b) *categories of users that may have access:*

Trans-national access must be provided to selected ‘user-groups’, i.e. teams of one or more researchers (users) led by a ‘user group leader’.

The user group leader and the majority of the users must work in a country other than the country(ies) where the installation is located.

This rule does not apply:

- *if access is provided by an International organisation, the Joint Research Centre (JRC), an ERIC or similar legal entities;*
- *in case of remote access to a set of installations located in different countries offering the same type of service.*

Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access, unless the users are working for SMEs.

Access for user groups with a majority of users not working in a EU or associated country²⁹ is limited to 20% of the total amount of units of access provided under the grant, unless a higher percentage is foreseen in Annex I;

(c) *procedure and criteria for selecting user groups:*

The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

*The user groups must be selected by a **selection panel** set up by the access providers.*

²⁷ ‘**Access provider**’ means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructure or installations, or part of them, as described in Annex 1.

²⁸ ‘**Installation**’ means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

²⁹ For the definition, see 2.1(3) of the Rules for Participation Regulation No 1290/2013: ‘**associated country**’ means a ‘third country’ which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiary, unless otherwise specified in Annex 1.

The selection panel must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panel must base its selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- *have not previously used the installation and*
- *are working in countries where no equivalent research infrastructure exist.*

It will apply the principles of transparency, fairness and impartiality.

[OPTION: In addition, the beneficiary must comply with the following additional rules for the selection of user groups: [...]]³⁰.

(d) other conditions:

The access provider must request written approval from the EDCTP Association (see Article 52) for the selection of user groups requiring visits to the installation(s) exceeding 3 months, unless such visits are foreseen in Annex 1.

16.1.2 In addition, the access provider must:

- *advertise widely, including on a dedicated website, the access offered under the Agreement;*
- *promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users;*
- *ensure that users comply with the terms and conditions of the Agreement;*
- *ensure that its obligations under Articles 35, 36, 38 and 46 also apply to the users.]*

[OPTION: Not applicable]

16.2 Rules for providing virtual access to research infrastructure

[OPTION virtual access to research infrastructure: ‘Access providers’³¹ must provide access to research infrastructure or installations³² in accordance with the following conditions:

(a) access which must be provided:

³⁰ If the EDCTP Association considers necessary to give priority to certain categories of users.

³¹ ‘Access provider’ means a beneficiary or linked third party that is in charge of providing access to one or more research infrastructures or installations, or part of them, as described in Annex 1.

³² ‘Installation’ means a part or a service of a research infrastructure that could be used independently from the rest. A research infrastructure consists of one or more installations.

The access must be free of charge, virtual access to research infrastructure or installations.

‘Virtual access’ means open and free access through communication networks to resources needed for research, without selecting the researchers to whom access is provided;

(b) other conditions:

The access provider must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiary, unless otherwise specified in Annex 1.]

[OPTION: Not applicable]

16.3 Consequences of non-compliance

[OPTION to be used if 16.1 and/or 16.2 are applicable: *If the beneficiary breaches any of its obligations under Articles 16.1.1 and 16.2, the costs of access will be ineligible (see Article 6) and will be rejected (see Article 42).*

If the beneficiary breaches any of its obligations under Articles 16.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION: Not applicable]

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiary must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

The beneficiary must immediately inform the EDCTP Association of any of the following:

- (a) **any change related to its name, address, legal representatives, legal form and organisation type** *[or those of its linked third parties]* and to its legal, financial, technical, organisational or ownership situation *[or those of its linked third parties];*

- (b) **events** which are likely to affect significantly or delay the implementation of the action or the EDCTP Association's financial interests;
- (c) **circumstances** affecting:
 - (i) the decision to award the grant or
 - (ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiary must — for a period of [*OPTION by default: five*][*OPTION for low value grants*³³: *three*] 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 it declares as eligible.

It must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement, the beneficiary must keep the records and other supporting documentation until the end of these procedures.

The beneficiary must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The EDCTP Association may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiary must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

³³ For the definition, see Article 185 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1) ('**Rules of Application Regulation No 1268/2012**'): 'low value grants' are lower or equal to EUR 60 000.

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

- (a) 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 beneficiary' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in its accounts and the amounts stated in the supporting documentation;
- (b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. *[OPTION for trans-national access to research infrastructure: This documentation must include records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them.]* The beneficiary does 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.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiary must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiary *[and linked third parties]* may submit to the EDCTP Association, for approval by the Commission, a certificate (drawn up in accordance with Annex 6) stating that its usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiary has concealed information for the purpose of the approval.

- (c) 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 beneficiary does not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate[;][.]
- (d) *[OPTION if lump sum foreseen in Article 5.2: for lump sum costs: adequate records and other supporting documentation to prove that the corresponding tasks or part of the action as described in Annex 1 were implemented properly. The beneficiary does not need to identify the actual eligible costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared as a lump sum.]*

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiary 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.

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.

[OPTION to be added if Article 14 applies: For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.]

18.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit the ‘**deliverables**’ identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the EDCTP Association may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the EDCTP Association (see Article 52) the technical and financial reports set out in this Article. The financial reports must be drawn up using the forms and templates provided in Annex 4 and 5. These reports include the requests for payment. The technical reports must be drawn up using the forms and templates provided in Annex 7.

20.2 Reporting periods

The action is divided into the following ‘**reporting periods**’:

- RP1: from month 1 to month [X]
- [- RP2: from month [X+1] to month [Y]*
- RP3: from month [Y+1] to month [Z]*
- [same for other RPs]*
- RPN: from month [N+1] to [the last month of the project].]*

20.3 Periodic reports — Requests for interim payments

The beneficiary must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a **‘periodic technical report’** containing:

- (i) an **explanation of the work carried out** by the beneficiary;
- (ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated **‘plan for the exploitation and dissemination of the results’**;

[OPTION for providing access to trans-national access to research infrastructure: The report must detail the access activity, indicating the members of the selection panel, the selection procedure, the exact amount of access provided to the user groups, the description of their work, and information on the users (including names, nationality and home institutions);] [OPTION for providing access to virtual services: The reports must detail the access activity, with statistics on the virtual access provided in the period, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure;]

- (iii) a **summary** for publication by the EDCTP Association ;
- (iv) 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 of the Horizon 2020 and EDCTP2 Programmes;

(b) a **‘periodic financial report’** containing:

- (i) an **‘individual financial statement’** (see Annex 4) *[from the beneficiary and from each linked third party]*, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) for each budget category (see Annex 2).

The beneficiary *[and linked third parties]* must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the EDCTP Association.

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** (see Article 5.3.3).

The beneficiary *[and each linked third party]* must **certify** that:

- the information provided is full, reliable and true;
 - the costs declared are eligible (see Article 6);
 - the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
 - for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- (ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) *[from the beneficiary and from each linked third party]*, for the reporting period concerned;
- (iii) not applicable;
- (iv) a **‘periodic summary financial statement’** (see Annex 4), *[OPTION if Article 14 applies: consolidating the individual financial statements for the reporting period concerned and]* including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the beneficiary must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

- (a) a **‘final technical report’** with a **summary** for publication containing:
- (i) an overview of the results and their exploitation and dissemination;
 - (ii) the conclusions on the action, and
 - (iii) the socio-economic impact of the action;
- (b) a **‘final financial report’** containing:
- (i) a **‘final summary financial statement’** (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and
 - (ii) a **‘certificate on the financial statements’** (drawn up in accordance with Annex 5) *[for the beneficiary and for each linked third party]*, if it requests a total contribution

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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 5.2 and Article 6.2, A).

20.5 Information on cumulative expenditure incurred

[OPTION for big grants with reporting periods beyond 18 months³⁴: In addition to the reporting requirements set out above (Article 20.1 to 20.3), the beneficiary must inform the EDCTP Association by [31 December][30 November] each year of the cumulative expenditure incurred by the beneficiary from the start date of the action.

This information is required for the EDCTP2 Association's accounting purposes and will not be used to calculate the final grant amount.]

[OPTION: Not applicable]

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

If the beneficiary *[or linked third party]* has an accounting established in a currency other than the euro it must convert the costs recorded in their accounts into euro at 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, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

If the beneficiary *[or linked third party]* has an accounting established in euro it must convert costs incurred in another currency into euro according to its usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the EDCTP Association may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the beneficiary breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the EDCTP Association, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

³⁴ To be added in the case of grants of more than EUR 5 million for which a pre-financing is paid and the reporting periods for interim payments or payments of the balance exceed eighteen months.

21.1 Payments to be made

The following payments will be made to the beneficiary:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — [Pre-financing guarantees]

The aim of the pre-financing is to provide the beneficiary with a float.

It remains the property of the EDCTP Association until the payment of the balance.

The amount of the pre-financing payment will be EUR [insert amount (insert amount in words)].

The EDCTP Association will — except if Article 48 applies — make the pre-financing payment to the beneficiary within 30 days of the latest of the following dates:

- either from the entry into force of the Agreement (see Article 58) or
- from 10 days before the starting date of the action (see Article 3) [;] [.]
- **[OPTION to be used if the EDCTP Association³⁵ requires a pre-financing guarantee: the receipt of a financial guarantee of an amount equal to the pre-financing.**

This financial guarantee must fulfil the following conditions:

- a) it is provided by a bank or an approved financial institution or — if requested by the beneficiary and accepted by the EDCTP Association — by a third party;*
- b) the guarantor stands as first-call guarantor and does not require the EDCTP Association to first have recourse against the principal debtor (i.e. the beneficiary concerned), and*
- c) it explicitly remains in force until the payment of the balance and, if payment of the balance takes the form of recovery, until three months after the debit note is notified to the beneficiary.*

The EDCTP Association will release the guarantee within the following month.]

21.3 Interim payments — Amount — Calculation

The interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The EDCTP Association will pay to the beneficiary the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

³⁵ A pre-financing guarantee may be required by the EDCTP Association, if it considers it necessary (i.e. appropriate and proportionate), to limit the financial risks connected with the payment of pre-financing: pre-financing guarantees may not be requested for low-value grants (see Article 134 of the Financial Regulation).

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the EDCTP Association in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to *[OPTION by default: 90%]* *[OPTION to be used by the EDCTP Association in exceptional cases and following an assessment of the financial risk and the technical implementation of the action: [...] %]* of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs *[and lump sum costs]*; see Article 6) declared by the beneficiary *[and the linked third parties]* (see Article 20) and approved by the EDCTP Association (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to *[OPTION by default: 90%]* *[OPTION to be used by the EDCTP Association in exceptional cases and following an assessment of the financial risk and the technical implementation of the action: [...] %]* of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed *[OPTION by default: 90%]* *[OPTION to be used by the EDCTP Association in exceptional cases and following an assessment of the financial risk and the technical implementation of the action: [...] %]* of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{[OPTION by default: 90%] *[OPTION to be used by the EDCTP Association in exceptional cases and following an assessment of the financial risk and the technical implementation of the action: [...] %]* of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}.

21.4 Payment of the balance — Amount — Calculation

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiary for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the EDCTP Association will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

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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 calculated by the EDCTP Association by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

$$\begin{aligned} & \{ \text{final grant amount (see Article 5.3)} \\ & \text{minus} \\ & \{ \text{pre-financing and interim payments (if any) made} \} \}. \end{aligned}$$

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 Association, up to the maximum EDCTP2 contribution indicated, for the beneficiary, in the estimated budget (see Annex 2).

If the balance is negative, the amount unduly paid will be recovered from the beneficiary

21.5 Notification of amounts due

When making payments, the EDCTP Association will formally notify to the beneficiary 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.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The EDCTP Association will make all payments in euro.

21.7 Payments to the beneficiary

Payments will be made to the beneficiary.

Payments will discharge the EDCTP Association from its payment obligation.

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: [...]
Address of branch: [...]
Full name of the account holder: [...]
Full account number (including bank codes): [...]
[IBAN code: [...]]³⁶

³⁶ BIC or SWIFT code applies to for countries if the IBAN code does not apply.

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

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

21.10 Date of payment

Payments by the EDCTP Association are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the EDCTP Association does not pay within the payment deadlines (see above), the beneficiary is entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the Official Journal of the European Union.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the beneficiary only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if the beneficiary is an EU Member State (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 Not applicable

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the *[Agency and the]* Commission

22.1.1 Right to carry out checks

The EDCTP Association or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the EDCTP Association or the Commission may be assisted by external persons or bodies.

The EDCTP Association or the Commission may also request additional information in accordance with Article 17. The EDCTP Association or the Commission may request the beneficiary to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The EDCTP Association or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the beneficiary and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary must inform the third party.

The EDCTP Association or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the beneficiary of the identity of the external persons or bodies. It has the right to object to the appointment on grounds of commercial confidentiality.

The beneficiary must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The EDCTP Association or the Commission may request the beneficiary to provide such information to it directly.

The beneficiary may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiary must allow access to its sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a **‘review report’** will be drawn up.

The EDCTP Association or the Commission will formally notify the review report to the beneficiary, which has 30 days to formally notify observations (**‘contradictory review procedure’**).

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The EDCTP Association or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the beneficiary and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary must inform the third party.

The EDCTP Association or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the beneficiary of the identity of the external persons or bodies. It has the right to object to the appointment on grounds of commercial confidentiality.

The beneficiary must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The EDCTP Association or the Commission may request the beneficiary to provide such information to it directly.

For **on-the-spot** audits, the beneficiary must allow access to its sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The EDCTP Association or the Commission will formally notify the draft audit report to the beneficiary, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the EDCTP Association or the Commission in justified cases.

The '**final audit report**' will take into account observations by the beneficiary. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The EDCTP Association or the Commission may also access the beneficiary's statutory records for the periodical assessment of unit costs or flat-rate amounts [*or lump sums*].

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013³⁷ and No 2185/96³⁸ (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during

³⁷ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No

implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012³⁹, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

[OPTION for international organisations: In conformity with the EU financial regulations, the European Union, including the European Anti-Fraud Office (OLAF) and the European Court of Auditors (ECA), as well as the EDCTP Association, may undertake, including on the spot, checks, reviews audits and investigations.

This Article will be applied in accordance with any specific agreement concluded in this respect by the international organisation and the European Union or the EDCTP Association.]

[OPTION: Not applicable]

22.5 Consequences of findings in checks, reviews, audits and investigations

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

³⁸ Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

³⁹ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Not applicable

22.5.3 Procedure

Not applicable

22.6 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The EDCTP Association may carry out interim and final evaluations of the impact of the action measured against the objective of the EDCTP2 programme.

Evaluations may be started during implementation of the action and up to [*OPTION by default: five*][*OPTION for low value grants: three*] years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the beneficiary.

The EDCTP Association may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The beneficiary must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the EDCTP Association may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

If the beneficiary is a university or other public research organisation it must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the

Commission Recommendation on the management of intellectual property in knowledge transfer activities⁴⁰.

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the EDCTP Association may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

[OPTION if an option under Article 25.5 applies: 24.1 Agreement on background

The beneficiary must identify (in writing) the background for the action.

‘Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiary before its accession to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION: Not applicable]

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (**‘request for access’**).

‘Access rights’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

⁴⁰ Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

Not applicable

25.3 Access rights for other beneficiaries, for exploiting their own results

Not applicable

25.4 Access rights for affiliated entities

Not applicable

25.5 Access rights for third parties

[OPTION for trans-national access to research infrastructure: The access provider must — unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — give users royalty-free access to background needed to implement the action.

The access provider must inform the users as soon as possible of any restriction which might substantially affect the granting of access rights.]

[OPTION: Not applicable]

25.5a Access rights for the researcher

[OPTION mandatory for fellowships: The beneficiary must — on a royalty-free basis — give access to the recruited researcher to background necessary for their research training activities under the action.]

[OPTION: Not applicable]

25.6 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

The beneficiary owns the results it generates..

‘Results’ means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Not applicable

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 The EDCTP2 Association ownership, to protect results

26.4.1 The EDCTP2 Association may — with the consent of the beneficiary — assume ownership of results to protect them, if the beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

- (a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);
- (b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or
- (c) the beneficiary intends to transfer the results to a third party established in an EU Member State or associated country⁴¹, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the EDCTP Association and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the EDCTP Association decides to assume ownership, it will formally notify the beneficiary within 45 days of receiving notification.

⁴¹ For the definition, see Article 2.1(3) Rules for Participation Regulation No 1290/2013: ‘**associated country**’ means a third country which is party to an international agreement with the Union, as identified in Article 7 of the H2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

No dissemination relating to these results may take place before the end of this period or, if the EDCTP Association takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The EDCTP Association may — with the consent of the beneficiary — assume ownership of results to protect them, if the beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

- (a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;
- (b) an extension would not be justified given the circumstances.

The beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the EDCTP Association at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the EDCTP Association decides to assume ownership, it will formally notify the beneficiary within 45 days of receiving notification.

26.5 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EDCTP2 FUNDING

27.1 Obligation to protect the results

The beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

- (a) the results can reasonably be expected to be commercially or industrially exploited and
- (b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests.

27.2 The EDCTP Association ownership, to protect the results

If the beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the EDCTP2 Association may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of the beneficiary must — unless the EDCTP Association requests or agrees otherwise or unless it is impossible — include the following:

“The project leading to this application is part of the EDCTP2 programme supported by the European Union”.

27.4 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

The beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure ‘**exploitation**’ of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

- (a) using them in further research activities (outside the action);
- (b) developing, creating or marketing a product or process;
- (c) creating and providing a service, or
- (d) using them in standardisation activities.

[OPTION for additional exploitation obligations if foreseen in the work plan: In addition, the beneficiary must — up to four years after the period set out in Article 3 — comply with the additional exploitation obligations set out in Annex 1.]

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EDCTP2 funding

[OPTION for results that could contribute to standards if foreseen in the work plan: If results could reasonably be expected to contribute to European or international standards, the beneficiary must — up to four years after the period set out in Article 3 — inform the EDCTP Association.]

If results are incorporated in a standard, the beneficiary must — unless the EDCTP Association requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

“Results incorporated in this standard received funding from the EDCTP2 programme supported by the European Union”.

28.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EDCTP2 FUNDING

29.1 Obligation to disseminate results

Unless it goes against its legitimate interests, the beneficiary must — as soon as possible — ‘**disseminate**’ its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

[OPTION for additional dissemination obligations if foreseen in the work plan: In addition, the beneficiary must comply with the additional dissemination obligations set out in Annex 1.]

[OPTION for additional dissemination obligations for interoperability if foreseen in the work plan: Moreover, the beneficiary must — up to four years after the period set out in Article 3 — disseminate any technical specifications of the results that are needed for interoperability.]

[OPTION for additional dissemination obligations for cross-border interoperability if foreseen in the work plan: Moreover, the beneficiary must — up to four years after the period set out in Article 3 — disseminate the deliverables relating to cross-border interoperability (see Annex 1) and any results needed for cross-border interoperability (in particular common technical specifications and software components).]

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

If the beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the EDCTP Association before dissemination takes place.

29.2 Open access to scientific publications

The beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

- (a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

- (b) ensure open access to the deposited publication — via the repository — at the latest:

- (i) on publication, if an electronic version is available for free via the publisher, or
 - (ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.
- (c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “EDCTP2”, “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

[OPTION for actions participating in the open Research Data Pilot: *Regarding the digital research data generated in the action (‘data’), the beneficiary must:*

- (a) *deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:*
 - (i) *the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;*
 - (ii) *other data, including associated metadata, as specified and within the deadlines laid down in the ‘data management plan’ (see Annex 1);*
- (b) *provide information — via the repository — about tools and instruments at the disposal of the beneficiary and necessary for validating the results (and — where possible — provide the tools and instruments themselves).*

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiary does not have to ensure open access to specific parts of its research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.]

[OPTION: Not applicable]

29.4 Information on EDCTP2 funding — Obligation and right to use the EU and EDCTP emblems

Unless the EDCTP Association requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

- (a) display the EU and EDCTP emblems and
- (b) include the following text:

“This project is part of the EDCTP2 programme supported by the European Union”.

When displayed together with another logo, the EU and EDCTP emblems must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU emblem without first obtaining approval from the Commission and the EDCTP Association respectively.

This does not however give it the right to exclusive use.

Moreover, the beneficiary may not appropriate the EU and EDCTP emblems or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding the EDCTP Association responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the EDCTP Association is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

The beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

30.2 Granting licences

The beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

- (a) this does not impede the access rights under Article 31 and
- (b) *[OPTION if additional exploitation obligations in Annex 1: the beneficiary complies with its additional exploitation obligations (see Article 28.1 and Annex 1)] [OPTION: not applicable].*

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 The EDCTP Association right to object to transfers or licensing

[OPTION: The EDCTP Association may — up to four years after the period set out in Article 3 — object to a transfer of ownership or the exclusive licensing of results, if:

- (a) *it is to a third party established in a non-EU country not associated with Horizon 2020 and*
- (b) *the EDCTP Association considers that the transfer or licence is not in line with EU interests regarding competitiveness or is inconsistent with ethical principles or security considerations.*

The beneficiary that intends to transfer ownership or grant an exclusive licence must formally notify the EDCTP Association before the intended transfer or licensing takes place and:

- *identify the specific results concerned;*
- *describe in detail the new owner or licensee and the planned or potential exploitation of the results, and*
- *include a reasoned assessment of the likely impact of the transfer or licence on EU competitiveness and its consistency with ethical principles and security considerations.*

The EDCTP Association may request additional information.

If the EDCTP Association decides to object to a transfer or exclusive licence, it must formally notify the beneficiary within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- *pending the EDCTP Association decision, within the period set out above;*
- *if the EDCTP Association objects;*
- *until the conditions are complied with, if the EDCTP Association objection comes with conditions.]*

[OPTION: Not applicable]

30.4 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

Not applicable

31.3 Access rights for other beneficiaries, for exploiting their own results

Not applicable

31.4 Access rights of affiliated entities

Not applicable

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

The beneficiary must give access to its results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiary for communication and publicising activities (see Article 38.2).

31.6 Access rights for third parties

[OPTION for additional access rights for complementary grants if foreseen in the work plan: The beneficiary must give — under the conditions set out below — access to its results to complementary beneficiaries⁴², for the purposes of the complementary grant agreement(s) (see Article 2).

The beneficiary must give complementary beneficiaries access — on a royalty-free basis — to results needed for implementing their own tasks under the complementary grant.

⁴² ‘Complementary beneficiary’ means a beneficiary of a complementary grant agreement.

The beneficiary must give complementary beneficiaries — under fair and reasonable conditions — access to results needed for exploiting their own results.

‘Fair and reasonable conditions’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access for exploitation purposes may be made — unless agreed otherwise — up to one year after the period set out in Article 3.]

[OPTION for additional access rights for interoperability if foreseen in the work plan: The beneficiary must give third parties — up to four years after the period set out in Article 3 and [OPTION: under fair and reasonable conditions][OPTION: on a royalty-free basis] — access to its results needed for interoperability.

[OPTION if fair and reasonable conditions apply: ‘Fair and reasonable conditions’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.]

[OPTION for additional access rights for cross-border interoperability if foreseen in the work plan: The beneficiary must give third parties — up to four years after the period set out in Article 3 and on a royalty-free basis — access to its results needed for interoperability, in particular for implementing the results in EU Member States or associated countries that are not participating in the action.

The beneficiary must give access to software components under an EU public license (or compatible licenses) and must comply with any additional requirements set out in Annex 1.]

[OPTION for trans-national access to research infrastructure: The access provider must give the users royalty-free access to the results needed to implement the action.]

[OPTION: Not applicable]

31.7 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

[OPTION mandatory, except for fellowships: 32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiary must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers⁴³, in particular regarding:

- *working conditions;*
- *transparent recruitment processes based on merit, and*
- *career development.*

The beneficiary must ensure that researchers and third parties involved in the action are aware of them.]

[OPTION mandatory for fellowships: 32.1 Obligations towards the recruited researcher

The beneficiary must respect the following recruitment and working conditions for the researcher recruited under the action:

(a) take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers⁴⁴ and ensure that the researcher and third parties are aware of them;

(b) ensure that the researcher enjoys at the place of the implementation at least the same standards and working conditions as those applicable to local researchers holding a similar position;

(c) ensure that the employment contract, the letter of engagement, or other direct contract specifies:

(i) the name of the supervisor for the research training activities as indicated in Annex 1;

(ii) the starting date and duration of the research training activities under the action;

(iii) the obligation of the researcher to work exclusively for the action;

(iv) the obligation of the researcher to inform the beneficiary as soon as possible of any events or circumstances likely to affect the Agreement (see Article 17);

(v) the arrangements related to the intellectual property rights between the beneficiary and the researcher — during implementation of the action and afterwards;

(vi) the obligation of the researcher to maintain confidentiality (see Article 36);

(vii) the obligation of the researcher to ensure the visibility of EU and EDCTP 2 funding in communications or publications and in applications for the protection of results (see Articles 27, 28, 29 and 38);

⁴³ Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

⁴⁴ Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

*[(viii) **OPTION mandatory for EDCTP-TDR Clinical Research and Development Fellowships: the obligation of the researcher to carry out a mandatory return period of at least 24 months at the premises of the beneficiary;]***

(d) assist the researcher in the administrative procedures related to the recruitment;

(e) inform the researcher about:

- the description, conditions, location and the timetable for the implementation of the research training activities under the action and the name of the supervisor;

- the rights and obligations of the beneficiary toward the researcher under this Agreement;

- the obligation of the researcher to complete and submit — at the end of the research training activities — the evaluation questionnaire and — two years later — follow-up questionnaire provided by the EDCTP Association;

(f) host the researcher and provide training as well as the necessary means for implementing the action;

(g) ensure that the researcher is adequately supervised;

(h) ensure that — at the beginning of the research training activities — a training plan and/or a reintegration plan are established together with the supervisor and are implemented as set out in Annex I;

*[(i) **OPTION mandatory for EDCTP-TDR Clinical Research and Development Fellowships: support the placement of the researcher for a minimum period of [insert number of months] months in the host organisation as set out in Annex I;]***

*[(j) **OPTION mandatory for EDCTP-TDR Clinical Research and Development Fellowships: support the return of the researcher to its premises to carry out a mandatory reintegration period of [insert number of months] months, in compliance with the reintegration plan as set up in Annex I.]***

The beneficiary must ensure that the researcher and third parties involved in the action are aware of them.]

32.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the EDCTP Association may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiary must take all measures to promote equal opportunities between men and women in the implementation of the action. It must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the EDCTP Association may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiary must carry out the action in compliance with:

- (a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity⁴⁵ — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and
- (b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiary must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiary must ensure that the activities under the action do not:

- (a) aim at human cloning for reproductive purposes;
- (b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- (c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the ‘**ethics requirements**’ set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the beneficiary must submit (see Article 52) to the EDCTP Association copy of:

- (a) any ethics committee opinion required under national law and
- (b) any notification or authorisation for activities raising ethical issues required under national law.

⁴⁵ The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

If these documents are not in English, the beneficiary must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The beneficiary must submit a declaration that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the beneficiary has obtained explicit approval (in writing) from the EDCTP Association (see Article 52).

34.4 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiary must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (**'conflict of interests'**).

It must formally notify to the EDCTP Association without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The EDCTP Association may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (**'confidential information'**).

If the beneficiary requests, the EDCTP Association may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiary may disclose confidential information to its personnel or third parties involved in the action only if they:

- (a) need to know to implement the Agreement and
- (b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The EDCTP Association may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

- (a) this is necessary to implement the Agreement or safeguard the EU's financial interests and
- (b) the recipients of the information are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party;
- (b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;
- (c) the recipient proves that the information was developed without the use of confidential information;
- (d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or
- (e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

[OPTION: Not applicable]

37.2 Classified results

[OPTION if applicable to the grant: Activities related to ‘classified results’ (see Annex 1) must comply with the ‘security requirements’ (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the Commission. The request must be submitted to EDCTP Association for the approval by the Commission

The beneficiary must inform the EDCTP Association of any changes in the security context and — if necessary — request for Annex 1 to be amended (see Article 55).]

[OPTION: Not applicable]

37.3 Activities involving dual-use goods or dangerous materials and substances

[OPTION: Activities involving dual-use goods or dangerous materials and substances must comply with applicable EU, national and international law.

Before the beginning of the activity, the beneficiary must submit to the EDCTP Association for approval by the Commission (see Article 52) a copy of any export or transfer licences required under EU, national or international law.]

[OPTION: Not applicable]

37.4 Consequences of non-compliance

[OPTION to be used if 37.1, 37.2 and/or 37.3 are applicable: If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.]

[OPTION: Not applicable]

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EDCTP2 FUNDING

38.1 Communication activities by the beneficiary

38.1.1 General obligation to promote the action and its results

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The beneficiary must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiary must inform the EDCTP Association (see Article 52).

38.1.2 Information on EDCTP2 funding — Obligation and right to use the EU and EDCTP emblems

Unless the EDCTP Association requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

- (a) display the EU and EDCTP emblems and
- (b) include the following text:

For communication activities: *“This project has received funding from the EDCTP2 programme supported by the European Union”*

For infrastructure, equipment and major results: *“This [infrastructure][equipment][insert type of result] is part of the EDCTP2 programme supported by the European Union's Horizon 2020 research and innovation programme”.*

When displayed together with another logo, the EU and EDCTP emblems must have appropriate prominence.

For the purposes of its obligations under this Article, the beneficiary may use the EU and EDCTP emblems without first obtaining approval from the Commission and the EDCTP Association respectively.

This does not, however, give it the right to exclusive use.

Moreover, the beneficiary may not appropriate the EU or EDCTP emblems or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding EDCTP Association responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the EDCTP Association is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the EDCTP Association

38.2.1 Right to use the beneficiary's materials, documents or information

The EDCTP Association may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well

as any other material, such as pictures or audio-visual material that it receives from the beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the EDCTP2 Association's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary may request the EDCTP Association not to use it (see Article 52).

The right to use the beneficiary's materials, documents and information includes:

- (a) **use for its own purposes** (in particular, making them available to persons working for the EDCTP Association or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);
- (b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);
- (c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);
- (d) **translation**;
- (e) giving **access in response to individual requests** under Regulation No 1049/2001⁴⁶, without the right to reproduce or exploit;
- (f) **storage** in paper, electronic or other form;
- (g) **archiving**, in line with applicable document-management rules, and
- (h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the EDCTP Association .

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiary), the EDCTP Association will insert the following information:

⁴⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

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“© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the [European Union (EU)][Euratom][insert the name of the Agency] under conditions.”

38.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the EDCTP Association

Any personal data under the Agreement will be processed by the EDCTP Association in compliance with national law on data protection (including authorisations or notification requirements).

Such data will be processed by the ‘**data controller**’ of the EDCTP Association for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller of EDCTP Association.

39.1a Processing of personal data by the Commission

Any personal data under the Agreement will be processed by the Commission under Regulation No 45/2001⁴⁷ and according to the ‘notifications of the processing operations’ to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the ‘**data controller**’ of the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the ‘service specific privacy statement(s) (SSPS) ‘ that are published on the Commission’s websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiary

⁴⁷ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

The beneficiary must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiary may grant its personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiary must inform the personnel whose personal data are collected and processed by the EDCTP Association or by the Commission

39.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under Article 39.2, the EDCTP Association may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE EDCTP ASSOCIATION

The beneficiary may not assign any of its claims for payment against the EDCTP Association to any third party, except if approved by the EDCTP Association on the basis of a reasoned, written request.

If the EDCTP Association has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiary from its obligations towards the EDCTP Association.

CHAPTER 5 DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF THE BENEFICIARY'S ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Role and responsibility towards the EDCTP Association

The beneficiary has full responsibility for implementing the action and complying with the Agreement.

The beneficiary is itself responsible for:

- (a) monitoring that the action is implemented properly (see Article 7);
- (b) informing the EDCTP Association immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);
- (c) submit the deliverables and reports to the EDCTP Association (see Articles 19 and 20);

(d) submit to the EDCTP Association in good time any documents or information required by it

and may not subcontract these tasks to any third party.

41.2 Internal division of roles and responsibilities

Not applicable

41.3 Internal arrangements between beneficiaries — Consortium agreement

Not applicable

41.4 Relationship with complementary beneficiaries — Collaboration agreement

[OPTION for complementary grants if foreseen in the work plan: The beneficiary must conclude a written ‘collaboration agreement’ with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:

- *efficient decision making processes and*
- *settlement of disputes.*

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiary and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiary must give access to its results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

The beneficiary must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.]

[OPTION: Not applicable]

41.5 Relationship with partners of a joint action — Coordination agreement

[OPTION for joint actions (joint call with a third country or an international organisation): The beneficiary must conclude a ‘coordination agreement’ with the partners of the third country or international organisation action (see Article 2), covering for instance:

- *the internal organisation of the beneficiaries in both actions, including the decision making procedures;*
- *rules on intellectual property rights (for example regarding protection, dissemination, use and access rights);*

- *the settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries in both actions.*

The coordination agreement must not contain any provision contrary to the Agreement.]

[OPTION: Not applicable]

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The EDCTP Association will — at the time of an **interim payment, at the payment of the balance or afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 Not applicable

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full *[OPTION if lump sum foreseen in Article 5.2:; except for lump sum costs, which will be rejected proportionally to the tasks or parts of the action not implemented]*.

If the EDCTP Association rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the beneficiary the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The beneficiary may — within 30 days of receiving notification — formally notify the EDCTP Association of its disagreement and the reasons why.

If the EDCTP Association rejects costs **with reduction of the grant or recovery of undue amounts**, it will formally notify the rejection in the ‘**pre-information letter**’ on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the EDCTP Association rejects costs at the time of an **interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the EDCTP Association — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the EDCTP Association rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The EDCTP Association may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 Not applicable

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the EDCTP Association will formally notify a ‘**pre-information letter**’ to the beneficiary:

- 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 Association 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; see Article 21).

43.3 Effects

If the EDCTP Association reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the EDCTP Association reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the EDCTP Association will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

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The EDCTP Association will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

44.1.1 Recovery after termination of a beneficiary's participation

Not applicable

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the EDCTP Association will formally notify a '**pre-information letter**' to the beneficiary:

- informing it of its intention to recover, the amount due as the balance and the reasons why; and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the EDCTP Association decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5).

If payment is not made by the date specified in the debit note, the EDCTP Association will **recover** the amount:

- (a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the EDCTP2 Association;

In exceptional circumstances, to safeguard the EDCTP Association's financial interests, the EDCTP Association may offset before the payment date specified in the debit note;

- (b) *[OPTION to be used if the EDCTP Association requires a pre-financing guarantee: by drawing on the financial guarantee (see Article 21.2)]**[OPTION: not applicable;]*
- (c) *[OPTION if Article 14 applies and joint and several liability has been requested by the EDCTP Association : if a linked third party has accepted joint and several liability (see Article 14), by **holding the third party liable** up to the maximum EDCTP2 contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]**[OPTION: not applicable;]*
- (d) by **taking legal action** (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the EDCTP Association receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, the revised final grant amount (see Article 5.4) is lower than the final grant amount, the beneficiary must repay the difference to the EDCTP Association.

The EDCTP Association will formally notify a **pre-information letter** to the beneficiary:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the EDCTP Association decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the EDCTP Association will **recover** the amount:

- (a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the EDCTP Association.

In exceptional circumstances, to safeguard the EDCTP Association's financial interests, the EDCTP Association may offset before the payment date specified in the debit note;

- (b) *[OPTION to be used if the EDCTP Association requires a pre-financing guarantee: by drawing on the financial guarantee (see Article 21.2)]**[OPTION: not applicable;]*

- (c) *[OPTION if Article 14 applies and joint and several liability has been requested by the EDCTP Association: if a linked third party has accepted joint and several liability (see Article 14), by holding the third party liable up to the maximum EDCTP2 contribution indicated, for the linked third party, in the estimated budget (see Annex 2) and/or]* *[OPTION: not applicable;]*

- (d) by taking legal action (see Article 57)

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the EDCTP Association receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

Not applicable

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the EDCTP Association

The EDCTP Association cannot be held liable for any damage caused to the beneficiary (or to third parties) as a consequence of implementing the Agreement, including for gross negligence.

The EDCTP Association cannot be held liable for any damage caused by the beneficiary or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiary

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiary must compensate the EDCTP Association for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

46.2.2 Amount of damages — Calculation

The amount the EDCTP Association can claim from the beneficiary will correspond to the damage caused by it.

46.2.3 Procedure

Before claiming damages, the EDCTP Association will formally notify the beneficiary:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the EDCTP Association does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the EDCTP Association may **recover** the amount:

- (a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary by the EDCTP Association .

In exceptional circumstances, to safeguard the EDCTP Association's financial interests, the EDCTP Association may offset before the payment date in the debit note;

- (b) by **taking legal action** (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the EDCTP Association receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The EDCTP Association may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

- (a) it does not comply with the provisions of the Agreement (see Article 20);
- (b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or
- (c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The EDCTP Association will formally notify the beneficiary of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the EDCTP Association (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the beneficiary may request the EDCTP Association if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the EDCTP Association may also terminate the Agreement (see Article 50.3.1(I)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The EDCTP Association may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments or the payment of the balance, if the 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 or

48.2 Procedure

Before suspending payments, the EDCTP Association will formally notify the beneficiary:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the EDCTP Association does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the EDCTP Association.

If the conditions for resuming payments are met, the suspension will be **lifted**. The EDCTP Association will formally notify the beneficiary.

During the suspension, the beneficiary must not submit a periodic report(s) (see Article 20.3). When the EDCTP Association resumes payments, the beneficiary may include them in the next periodic report.

The beneficiary may suspend implementation of the action (see Article 49.1) or terminate the Agreement (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiary

49.1.1 Conditions

The beneficiary may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

[OPTION mandatory for fellowships: The beneficiary may request suspension of the action implementation (or any part of it) for professional, personal or family reasons (including parental leave) of the recruited researcher.]

49.1.2 Procedure

The beneficiary must immediately formally notify to the EDCTP Association the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the EDCTP Association.

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

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Once circumstances allow for implementation to resume, the beneficiary must immediately formally notify the EDCTP Association and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

*[OPTION mandatory for fellowships: For the purpose of a suspension of the action implementation (or any part of it) for professional, personal or family reasons (including parental leave), the beneficiary must formally notify a request for **amendment** (to make the necessary changes and to set the date of resumption) in accordance with Article 55. The suspension **will take effect** on the date set out in the amendment.]*

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the EDCTP Association

49.2.1 Conditions

The EDCTP Association may suspend implementation of the action or any part of it:

- (a) if the 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;
- (b) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the EDCTP Association will formally notify the beneficiary:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the EDCTP Association does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the beneficiary (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The beneficiary will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiary may not claim damages due to suspension by the EDCTP Association (see Article 46).

Suspension of the action implementation does not affect the EDCTP Association's right to terminate the Agreement (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT

50.1 Termination of the Agreement, by the beneficiary

50.1.1 Conditions and procedure

The beneficiary may terminate the Agreement.

The beneficiary must formally notify termination to the EDCTP Association (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the EDCTP Association considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The beneficiary must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the open reporting period until termination; see Article 20.3) and
- (ii) the final report (see Article 20.4).

If the EDCTP Association does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The EDCTP Association will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

Not applicable

50.3 Termination of the Agreement, by the EDCTP Association

50.3.1 Conditions

The EDCTP Association may terminate the Agreement if:

- (a) not applicable;
- (b) a change to the beneficiary's legal, financial, technical, organisational or ownership situation *[(or those of its linked third parties)]* is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;
- (c) not applicable;
- (d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the beneficiary (see Article 49.1) and either:
 - (i) resumption is impossible, or
 - (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;
- (e) the beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;
- (f) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;
- (g) the beneficiary does not comply with the applicable national law on taxes and social security;
- (h) the action has lost scientific or technological relevance;
- (i) ***[OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) has not started by the date specified in Annex 1][OPTION: not applicable];***
- (j) ***[OPTION for joint actions (joint call with a third country or an international organisation): the third country or international organisation action (see Article 2) is terminated or can no longer contribute to the action][OPTION: not applicable];***
- (k) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money

laundrying or any other illegal activity affecting the EDCTP Association's financial interests;

- (l) the beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:
- (i) substantial errors, irregularities, fraud or
 - (ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;
- (m) *[OPTION mandatory for fellowships: the researcher cannot continue implementing the research training activities, or has committed fraud, including submission of false information or failure to provide required information for the purpose of the action.] [OPTION: not applicable]*

50.3.2 Procedure

Before terminating the Agreement, the EDCTP Association will formally notify the beneficiary:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the EDCTP Association of the measures to ensure compliance with the obligations under the Agreement.

If the EDCTP Association does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the beneficiary **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the beneficiary.

50.3.3 Effects

The beneficiary must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the last open reporting period until termination; see Article 20.3) and
- (ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the beneficiary may not submit any reports after termination.

If the EDCTP Association does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The EDCTP Association will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the EDCTP Association's right to reduce the grant (see Article 43)

The beneficiary may not claim damages due to termination by the EDCTP Association (see Article 46).

After termination, the beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, ‘formal notifications’, etc.) must be made in writing, identify the number of the Agreement, the nature and details of the request or communication and be submitted to the addresses listed in Article 52.3.

Formal notifications must be made by registered mail with return receipt.

Electronic communications must be confirmed by an original signed paper version of that communication, if requested by any of the parties, provided that this request is submitted without unjustified delay. The sender shall send the original signed paper version without unjustified delay.

52.2 Date of communication

Any communication is deemed to have been made when it is received by the receiving party, unless the agreement refers to the date when the communication was sent.

Electronic communication is deemed to have been received by the receiving party on the day of successful dispatch of that communication, provided that it is sent to the addressees listed in Article 52.3. Dispatch must be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party must immediately send again such communication to any of the other addresses listed in Article 52.3. In case of unsuccessful dispatch, the sending party shall not be held in breach of its obligation to send such communication within a specified deadline.

Any communication is deemed to have been made when it is received by the receiving party, unless the agreement refers to the date when the communication was sent.

Formal notifications are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

52.3 Addresses for communication

For information or documents to be transferred by **email**, the following address must be used:

For EDCTP Association: _____

For the beneficiary: _____

Formal notifications addressed to the EDCTP Association must be sent to the following address:

The EDCTP Association

[insert name of the representative of EDCTP Association]

[Post code, town and country]

Formal notifications addressed to the beneficiary must be sent to the following address:

[insert legal name of the beneficiary]
[insert name of the representative of beneficiary]
[Post code, town and country]

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

[OPTION for all international organisations: Nothing in the Agreement may be interpreted as a waiver of any privileges or immunities accorded to the beneficiary by its constituent documents or international law.]

[OPTION: Not applicable]

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71⁴⁸, periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, 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.

Amendments may be requested by any of the parties.

[OPTION mandatory for fellowships: The beneficiary may, in particular, request a change of the time spent on the action (part-time employment) for personal or family reasons (including parental leave) of the recruited researcher.]

55.2 Procedure

Any party may request an amendment.

The request for amendment must include:

- the reasons why;

⁴⁸ Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

- the appropriate supporting documents, and

Any party may request additional information.

If the party receiving the request agrees, it must sign the amendment within 45 days of receiving notification (or any additional information the EDCTP Association has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

Not applicable

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

[OPTION by default: The Agreement is governed by the applicable EU law, supplemented, if necessary by the law of Belgium.]

[OPTION for international organisations that do not accept application of Union law: Not applicable.]

[OPTION for international organisations that accept application of Union law but not Belgium law: The Agreement is governed by the applicable EU law, supplemented if necessary by the law of [insert name of a Member State or an EFTA country] [and, where appropriate, by the general principles governing the law of international organisations and the rules of general international law].]

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the competent Belgian [OPTION: Dutch] national court has jurisdiction.

[OPTION if the beneficiary is an international organisation: Disputes between the beneficiary and the EDCTP Association relating to the Agreement must — if they cannot be settled amicably — will be referred to arbitration.

Each party must formally notify to the other party its intention of resorting to arbitration and the identity of the arbitrator.

The Permanent Court of Arbitration Optional Rules for Arbitration Involving International Organisations and States in force at the date of entry into force of the Agreement will apply.

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The appointing authority will be the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either party.

The arbitration proceedings must take place in Brussels and the language used in the arbitral proceedings will be English.

The arbitral award will be binding on all parties and will not be subject to appeal.]

If a dispute concerns offsetting, the beneficiary must bring action before the competent Dutch national court.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the EDCTP Association or the beneficiary, depending on which is later.

SIGNATURES

For the beneficiary

[function/forename/surname]
[signature]

For the EDCTP Association

[forename/surname]
[signature]

Done in English at [place], on [insert date]

Done in English at [place], on [insert date]

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

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ANNEX 2



EDCTP2_MGA mono
Annex 2.xls

DECLARATION ON JOINT AND SEVERAL LIABILITY OF LINKED THIRD PARTIES

(to be filled by the linked third party and submitted by the beneficiary if Article 14 applies and linked third party liability has been requested by the EDCTP Association)

[full official name of the entity affiliated or linked to the beneficiary], [short name of the entity], [legal form], [official registration No], established in [official address in full], [VAT number] ('the linked third party'), represented for the purpose of signing this Declaration on joint and several liability by its legal representative(s) [forename and surname, function of the legal representative(s) of the linked third party],

linked to the beneficiary [insert number] [full official name of the beneficiary], [short name], [legal form], [official registration No], established in [official address in full], [VAT number] ('the beneficiary'),

hereby accepts joint and several liability with the beneficiary

for any amount owed to the EDCTP Association by the beneficiary under Grant Agreement No [insert agreement number] [(insert acronym)], up to the maximum EDCTP2 contribution indicated, for the linked third party, in the estimated budget (see Annex 2).

The linked third party irrevocably and unconditionally agrees to pay amounts requested under this Declaration to the EDCTP Association, immediately and at first demand.

For the linked third party
[forename/surname/function]

signature

Done in English at [place], on [date]

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

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ANNEX 4



EDCTP2_ MGA mono
Annex 4.xls

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed from the EDCTP2 Programme supported by the Horizon 2020 Research and Innovation Framework Programme

This document sets out the ‘**Terms of Reference (ToR)**’ under which

[*OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)*] [*OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’)*]

agrees to engage

[**insert legal name of the auditor**] (‘the Auditor’)

to produce an independent report of factual findings (‘the Report’) concerning the Financial Statement(s)⁴⁹ drawn up by the [*Beneficiary*] [*Linked Third Party*] for the EDCTP2 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 has been concluded under the EDCTP2 Programme supported by the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and the EDCTP2 Association.

The EDCTP2 Association is mentioned as a signatory of the Agreement with the Beneficiary only. The EDCTP2 Association or the European Union is not a party to this engagement.

1.1 Subject of the engagement

The beneficiary must submit to the EDCTP Association the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for itself and for each of its linked third parties 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 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 EDCTP2 Association,

⁴⁹ By which costs under the Agreement are declared (see template ‘Model Financial Statements’ in Annex 4 to the Grant Agreement).

the 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.

1.2 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 EDCTP2 Association 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.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with⁵⁰:

- the International Standard on Related Services (‘ISRS’) 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the EDCTP Association 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.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the EDCTP Association, the 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 the EDCTP2 budget. 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 Association, the Commission, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

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

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

⁵⁰ Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services (‘ISRS’) 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under a grant agreement financed from the EDCTP2 Programme supported by the Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],

we

[name of the auditor] ('the Auditor'),
established at
[full address/city/state/province/country],
represented by
[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)⁵¹ of the [Beneficiary] [Linked Third Party] concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [Beneficiary's] [Linked Third Party's] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the [Beneficiary's] [Linked Third Party's] usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

⁵¹ By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

The Procedures were carried out solely to assist the EDCTP Association in evaluating whether the [Beneficiary's] [Linked Third Party's] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The EDCTP Association draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the EDCTP Association. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the [Beneficiary's] [Linked Third Party's] Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

If a Finding was not applicable, it must be marked as 'N.A.' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.

The reasons of the non-application of a certain Finding must be obvious i.e.

- i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;*
- ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.*

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

....

Exceptions

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- If the Auditor was not able to successfully complete a procedure requested, it must be marked as 'E' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as 'E' ('Exception') and, where possible, the reasons why the*

Finding was not fulfilled and its possible impact must be explained here below.

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

....

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on ... because*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: ...*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by ...*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because ...*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures:*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the [Beneficiary] [Linked Third Party] and the EDCTP2 Association and only to be submitted to the EDCTP Association in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the [Beneficiary] [Linked Third Party] or by the EDCTP Association for any other purpose, nor may it be distributed to any other parties. The EDCTP Association may only disclose the Report to authorised parties, in particular to the Commission, the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the [Commission] [Agency] by the [Beneficiary] [Linked Third Party] for the Agreement. Therefore, it does not extend to any other of the [Beneficiary's] [Linked Third Party's] Financial Statement(s).

There was no conflict of interest⁵² between the Auditor and the Beneficiary [and Linked Third Party] in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR _____ of deductible VAT).

⁵² A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

EDCTP2 Model Grant Agreements: H2020 General MGA — Mono: September 2015

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]

[name and function of an authorised representative]

[dd Month yyyy]

Signature of the Auditor

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The EDCTP Association reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to ‘the Beneficiary’ is to be considered as a reference to ‘the Linked Third Party’.

The ‘result’ column has three different options: ‘C’, ‘E’ and ‘N.A.’:

- ‘C’ stands for ‘confirmed’ and means that the auditor can confirm the ‘standard factual finding’ and, therefore, there is no exception to be reported.
- ‘E’ stands for ‘exception’ and means that the Auditor carried out the procedures but cannot confirm the ‘standard factual finding’, or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- ‘N.A.’ stands for ‘not applicable’ and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for ‘beneficiaries with accounts established in a currency other than the euro’ the Procedure related to ‘beneficiaries with accounts established in euro’ is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE		
	<p>The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A.</p> <p><i>(The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)</i></p>		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor sampled _____ people out of the total of _____ people.		
A.1	<p>PERSONNEL COSTS</p> <p><u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u></p> <p>To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; ○ the payslips of the employees included in the sample; ○ reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; ○ information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; ○ the Beneficiary’s usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); ○ applicable national law on taxes, labour and social security and ○ any other document that supports the personnel costs declared. <p>The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA)</p>	<p>1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary’s sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary’s usual practices.</p> <p>2) Personnel costs were recorded in the _____ Beneficiary's accounts/payroll system.</p> <p>3) Costs were adequately supported and reconciled with the accounts and payroll records.</p> <p>4) Personnel costs did not contain any ineligible elements.</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	and recalculated the personnel costs for employees included in the sample.	5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	<p><i>Further procedures if ‘additional remuneration’ is paid</i></p> <p>To confirm standard factual findings 6-9 listed in the next column, the Auditor:</p> <ul style="list-style-type: none"> ○ reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary’s usual policy on additional remuneration, criteria used for its calculation...); ○ recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 ‘Productive hours’ and A.4 ‘Time recording system’). <p><i>IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:</i></p> <p><i>(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;</i></p> <p><i>(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR</i></p>	6) The Beneficiary paying “additional remuneration” was a non-profit legal entity.	
		7) The amount of additional remuneration paid corresponded to the Beneficiary’s usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>(C) <i>IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.</i></p>	<p>per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).</p>	
	<p><i>Additional procedures in case “unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices” is applied:</i></p> <p>Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column:</p> <ul style="list-style-type: none"> ○ obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs; ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; ○ verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; 	<p>10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all EDCTP2 and H2020 actions.</p> <p>11) The employees were charged under the correct category.</p> <p>12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents. 	13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<p><u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u></p> <p>To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; ○ the employment conditions of staff in the same category to compare costs and; ○ any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.). 	14) The natural persons reported to the Beneficiary (worked under the Beneficiary’s instructions).	
		15) They worked on the Beneficiary’s premises (unless otherwise agreed with the Beneficiary).	
		16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<p><u>For personnel seconded by a third party and included in the sample (not subcontractors)</u></p>	19) Seconded personnel reported to	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; ○ if there is reimbursement by the Beneficiary to the third party for the resource made available_(in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; ○ if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; ○ any other document that supports the costs declared (e.g. invoices, etc.). 	<p>the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).</p> <p>20) The results of work carried out belong to the Beneficiary.</p> <p><i>If personnel is seconded against payment:</i></p> <p>21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.</p> <p><i>If personnel is seconded free of charge:</i></p> <p>22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.</p>	
A.2	<p>PRODUCTIVE HOURS</p> <p>To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time</p>	<p>23) The Beneficiary applied method [<i>choose one option and delete the others</i>]</p> <p>[A: 1720 hours]</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>records of the persons included in the sample, to verify that:</p> <ul style="list-style-type: none"> ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. <p>If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours.</p> <p>If the Beneficiary applied method C, the auditor verified that the ‘annual productive hours’ applied when calculating the hourly rate were equivalent to at least 90 % of the ‘standard annual workable hours’. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.</p> <p><i>BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:</i></p> <p><i>A. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)</i></p> <p><i>B. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS ‘TOTAL NUMBER OF HOURS WORKED’ IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).</i></p> <p><i>C. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS</i></p>	<p>[B: the ‘total number of hours worked’]</p> <p>[C: ‘annual productive hours’ used correspond to usual accounting practices]</p> <p>24) Productive hours were calculated annually.</p> <p>25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.</p> <p><i>If the Beneficiary applied method B.</i></p> <p>26) The calculation of the number of ‘annual workable hours’, overtime and absences was verifiable based on the documents provided by the Beneficiary.</p> <p><i>If the Beneficiary applied method C.</i></p> <p>27) The calculation of the number of ‘standard annual workable hours’ was verifiable based on the documents provided by the</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><i>ALSO REFERRED TO AS ‘TOTAL ANNUAL PRODUCTIVE HOURS’ IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.</i></p> <p><i>‘ANNUAL WORKABLE HOURS’ MEANS 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.</i></p>	Beneficiary.	
		28) The ‘annual productive hours’ used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the ‘annual workable hours’.	
A.3	<p>HOURLY PERSONNEL RATES</p> <p><u>D) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u></p> <p>If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission’s letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary.</p> <p>If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:</p> <ul style="list-style-type: none"> ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. 	<p>29) The Beneficiary applied [choose one option and delete the other]:</p> <p>[Option I: “Unit costs (hourly rates) were calculated in accordance with the Beneficiary’s usual cost accounting practices”]</p> <p>[Option II: Individual hourly rates were applied]</p>	
		<p><i>For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):</i></p> <p>30) The Beneficiary used the Commission-approved metho-</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><u>II) For individual hourly rates:</u></p> <p>The Auditor:</p> <ul style="list-style-type: none"> ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <p><i>“UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES”:</i></p> <p><i>IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.</i></p> <p><i>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</i></p> <p><i>IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.</i></p>	<p>dology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.</p> <p><i>For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:</i></p> <p>31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.</p> <p><i>For option II concerning individual hourly rates:</i></p> <p>32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.</p>	
A.4	<p>TIME RECORDING SYSTEM</p> <p>To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in</p>	<p>33) All persons recorded their time dedicated to the action on a daily/ weekly/ monthly basis using a paper/computer-based system. <i>(delete the</i></p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>the sample that declare time as worked for the action on the basis of time records:</p> <ul style="list-style-type: none"> ○ description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); ○ its actual implementation; ○ time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; ○ the hours declared were worked within the project period; ○ there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; ○ the hours charged to the action matched those in the time recording system. <p><i>ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).</i></p> <p><u>If the persons are working exclusively for the action and without time records</u></p> <p>For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.</p>	<p><i>answers that are not applicable)</i></p> <p>34) Their time-records were authorised at least monthly by the project manager or other superior.</p> <p>35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.</p> <p>36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.</p> <p>37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.</p>	
B	COSTS OF SUBCONTRACTING		
B.1	The Auditor obtained the detail/breakdown of subcontracting costs and sampled [redacted] cost items selected randomly (full coverage is required if there are fewer than 10 items,	38) The use of claimed subcontracting costs was	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><i>otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).</i></p> <p>To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample:</p> <ul style="list-style-type: none"> ○ the use of subcontractors was foreseen in Annex 1; ○ subcontracting costs were declared in the subcontracting category of the Financial Statement; ○ supporting documents on the selection and award procedure were followed; ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). <p>In particular,</p> <ol style="list-style-type: none"> i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. 	<p>foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.</p> <p>39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money.</p> <p><i>(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption “Exceptions” of the Report. The EDCTP Association will analyse this information to evaluate whether these costs might be accepted as eligible)</i></p> <p>40) Not Applicable</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>For the items included in the sample the Auditor also verified that:</p> <ul style="list-style-type: none"> ○ there were signed agreements between the Beneficiary and the subcontractor; ○ there was evidence that the services were provided by subcontractor; 	<p>41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.</p>	
		<p>42) There was evidence that the services were provided by the subcontractors.</p>	
C	COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES		
C.1	<p>The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled [] cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).</i></p> <p>The Auditor verified that the following minimum conditions were met:</p> <ul style="list-style-type: none"> a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected. 	<p>43) All minimum conditions were met</p>	
D	OTHER ACTUAL DIRECT COSTS		
D.1	<p>COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES</p> <p>The Auditor sampled [] cost items selected randomly <i>(full coverage is required if there</i></p>	<p>44) Costs were incurred, approved and reimbursed in line with the</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><i>are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).</i></p> <p>The Auditor inspected the sample and verified that:</p> <ul style="list-style-type: none"> ○ travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; ○ travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; ○ no ineligible costs or excessive or reckless expenditure was declared. 	<p>Beneficiary's usual policy for travels.</p> <p>45) There was a link between the trip and the action.</p> <p>46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.</p> <p>47) No ineligible costs or excessive or reckless expenditure was declared.</p>	
D.2	<p>DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS</p> <p>The Auditor sampled [] cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).</i></p> <p>For “equipment, infrastructure or other assets” [from now on called “asset(s)”] selected in the sample the Auditor verified that:</p> <ul style="list-style-type: none"> ○ the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; ○ they were correctly allocated to the action (with supporting documents such as delivery 	<p>48) Procurement rules, principles and guides were followed.</p> <p>49) There was a link between the grant agreement and the asset charged to the action.</p> <p>50) The asset charged to the action was traceable to the accounting records and the underlying documents.</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>note invoice or any other proof demonstrating the link to the action)</p> <ul style="list-style-type: none"> ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); <p>The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary’s country and with the Beneficiary’s usual accounting policy (e.g. depreciation calculated on the acquisition value).</p> <p>The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).</p>	<p>51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.</p> <p>52) The amount charged corresponded to the actual usage for the action.</p> <p>53) No ineligible costs or excessive or reckless expenditure were declared.</p>	
D.3	<p>COSTS OF OTHER GOODS AND SERVICES</p> <p>The Auditor sampled [redacted] cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).</i></p> <p>For the purchase of goods, works or services included in the sample the Auditor verified that:</p> <ul style="list-style-type: none"> ○ the contracts did not cover tasks described in Annex 1; ○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary’s usual 	<p>54) Contracts for works or services did not cover tasks described in Annex 1.</p> <p>55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.</p> <p>56) The costs were charged in line with the Beneficiary’s accounting policy and were adequately supported.</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>accounting practices;</p> <ul style="list-style-type: none"> ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). <p>In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:</p> <ul style="list-style-type: none"> ○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. <p>For the items included in the sample the Auditor also verified that:</p> <ul style="list-style-type: none"> ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); <p><i>SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.</i></p>	<p>57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.</p> <p>58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money.</p> <p><i>(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The EDCTP Association will analyse this information to evaluate whether these costs might be accepted as eligible)</i></p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.4	<p>AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE</p> <p>The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.</p> <p><i>In the cases that a positive ex-ante assessment has been issued (see the standard factual findings 59-60 on the next column),</i> The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment;</p> <p><i>In the cases that a positive ex-ante assessment has NOT been issued (see the standard factual findings 61 on the next column),</i> The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category;</p> <p><i>In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes (see the standard factual findings 61 on the next column),</i></p> <ul style="list-style-type: none"> The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large 	<p>59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.</p> <p>60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.</p> <p>61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.</p>	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Research Infrastructures or issued recommendations.		
E	USE OF EXCHANGE RATES		
E.1	<p>a) <u>For Beneficiaries with accounts established in a currency other than euros</u></p> <p>The Auditor sampled [] cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):</p> <p><i>COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.</i></p> <p><i>IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.</i></p>	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>b) <u>For Beneficiaries with accounts established in euros</u></p> <p>The Auditor sampled [] cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):</p> <p><i>COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.</i></p>	<p>63) The Beneficiary applied its usual accounting practices.</p>	

[legal name of the audit firm]

[name and function of an authorised representative]

[dd Month yyyy]

<Signature of the Auditor>

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data.

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TERMS OF REFERENCE FOR AN AUDIT ENGAGEMENT FOR A METHODOLOGY CERTIFICATE IN CONNECTION WITH ONE OR MORE GRANT AGREEMENTS FINANCED FROM THE EDCTP2 PROGRAMME SUPPORTED BY THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME..... 2

INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED FROM THE EDCTP2 PROGRAMME SUPPORTED BY THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME 5

Grant Agreement number(s): [insert numbers and acronyms]

EDCTP2 Model Grant Agreements: EDCTP2 General MGA — Mono: September 2015

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed from the EDCTP2 Programme supported by the Horizon 2020 Research and Innovation Framework Programme

This document sets out the ‘**Terms of Reference (ToR)**’ under which

[OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)] [OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’)]

agrees to engage

[insert legal name of the auditor] (‘the Auditor’)

to produce an independent report of factual findings (‘the Report’) concerning the [Beneficiary’s] [Linked Third Party’s] usual accounting practices for calculating and claiming direct personnel costs declared as unit costs (‘the Methodology’) in connection with grant agreements financed from the EDCTP2 Programme supported by the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] (‘the Agreement(s)’)

The Agreement(s) has(have) been concluded between the Beneficiary and the EDCTP2 Association. The EDCTP2 Association is mentioned as a signatory of the Agreement with the Beneficiary only. The EDCTP2 Association *or European Union* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, the beneficiary [and linked third parties] that declares direct personnel costs as unit costs calculated in accordance with its [their] usual cost accounting practices may submit to the EDCTP2 Association, for approval by the Commission, a certificate on the methodology (‘CoMUC’) stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which 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’) issued on the Auditor’s letterhead, dated, stamped and signed by the Auditor which includes; the standard statements (‘the Statements’) evaluated and signed by the [Beneficiary] [Linked Third Party], the agreed-upon procedures (‘the Procedures’) performed by the Auditor and the standard factual findings (‘the Findings’) assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the [Beneficiary’s] [Linked Third Party’s] usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary]* *[Linked Third Party]* and the Auditor.

The *[Beneficiary]* *[Linked Third Party]*:

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's]* *[Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary]* *[Linked Third Party]* providing full and free access to the *[Beneficiary's]* *[Linked Third Party's]* staff and to its accounting and other relevant records.

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 *[and 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 these 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 Commission sets out the Procedures to be carried out and the Findings to be endorsed 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.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with⁵³:

⁵³ Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI

Grant Agreement number(s): [insert numbers and acronyms]

EDCTP2 Model Grant Agreements: EDCTP2 General MGA — Mono: September 2015

- the International Standard on Related Services (‘ISRS’) 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code’s independence requirements.

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

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the EDCTP2 Association, the 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 claimed from the EDCTP2 Programme budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the EDCTP2 Association, the Commission, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

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

1.6 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 & title of authorised representative]
 [dd Month yyyy]
 Signature of the Auditor

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

instead of the International Standard on Related Services (‘ISRS’) 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Grant Agreement number(s): [insert numbers and acronyms]

EDCTP2 Model Grant Agreements: EDCTP2 General MGA — Mono: September 2015

**Independent report of factual findings on the methodology concerning grant agreements
financed from the EDCTP2 Programme supported by the Horizon 2020 Research and
Innovation Framework Programme**

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of
the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of
the beneficiary] ('the Beneficiary')],

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the [Beneficiary's] [Linked Third Party's] usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the [Beneficiary] [Linked Third Party], the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the [Beneficiary] [Linked Third Party].

Grant Agreement number(s): [insert numbers and acronyms]

[EDCTP2 Model Grant Agreements: EDCTP2 General MGA — Mono: September 2015](#)

The Report covers the methodology used from [dd Month yyyy]. In the event that the [Beneficiary] [Linked Third Party] changes this methodology, the Report will not be applicable to any Financial Statement⁵⁴ submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the [Beneficiary's] [Linked Third Party's] Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

.....

Explanation of possible exceptions in the form of examples (to be removed from the Report):

- i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number ... because...;*
- ii. the Auditor could not carry out the procedure ... established because (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);*
- iii. the Auditor could not confirm or corroborate the standard Finding number ... because*

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates ...

Regarding standard Finding 15 it has to be noted that ...

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner:

...

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the EDCTP2 Association for approval by the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;

⁵⁴ Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

Grant Agreement number(s): [insert numbers and acronyms]

[EDCTP2 Model Grant Agreements: EDCTP2 General MGA — Mono: September 2015](#)

3. An example of the time records used by the [Beneficiary] [Linked Third Party];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [Beneficiary] [Linked Third Party] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [Beneficiary] [Linked Third Party] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted by the [Beneficiary] [Linked Third Party] in connection with Article 18.1.2 of the Agreement to the EDCTP2 Association for the approval by the Commission;
- may not be used by the [Beneficiary] [Linked Third Party] or by the EDCTP2 Association for any other purpose, nor distributed to any other parties;
- may be disclosed by the EDCTP2 Association or by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [Beneficiary] [Linked Third Party].

No conflict of interest⁵⁵ exists between the Auditor and the Beneficiary [and the Linked Third Party] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR [] (including EUR [] of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

⁵⁵ A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party (‘the Statements’) and Procedures to be carried out by the Auditor (‘the Procedures’) and standard factual findings (‘the Findings’) to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party’s usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to ‘the Beneficiary’ is to be considered as a reference to ‘the Linked Third Party’.

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p>A. Use of the Methodology</p> <p>I. The cost accounting practice described below has been in use since [dd Month yyyy].</p> <p>II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy].</p>	<p>Procedure:</p> <p>✓ The Auditor checked these dates against the documentation the Beneficiary has provided.</p> <p>Factual finding:</p> <p>1. The dates provided by the Beneficiary were consistent with the documentation.</p>
<p>B. Description of the Methodology</p> <p>III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures.</p> <p><i>[Please describe the methodology your entity uses to calculate <u>personnel</u> costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]</i></p> <p><i>[If the statement of section “B. Description of the methodology” cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings: - ...]</i></p>	<p>Procedure:</p> <p>✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology.</p> <p>Factual finding:</p> <p>2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed.</p> <p>3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.</p>
<p>C. Personnel costs</p> <p><u>General</u></p>	<p>Procedure:</p> <p><i>The Auditor draws a sample of employees to carry out the procedures indicated in</i></p>

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p>IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act;</p> <p>V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility;</p> <p>VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary’s usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to EDCTP2, the European Union or Euratom, unless explicitly provided for in the grant agreement(s);</p> <p>VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice;</p> <p>VIII. Personnel costs are based on the payroll system and accounting system.</p> <p>IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. <i>[Please describe the ‘budgeted or estimated elements’ and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].</i></p> <p>X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary’s bank for transfers from the the EDCTP2 Association; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action.</p> <p>XI. Personnel costs were not declared under another EU or Euratom grant (including other grants awarded by a Member State and financed by the EU budget and grants awarded by bodies for the purpose of implementing the EU budget).</p> <p><u>If additional remuneration as referred to in the grant agreement(s) is paid</u></p>	<p><i>this section C and the following sections D to F.</i> <i>[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.].</i> For this sample:</p> <ul style="list-style-type: none"> ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: <ul style="list-style-type: none"> i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary’s usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary’s usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from EDCTP2 or the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p>XII. The Beneficiary is a non-profit legal entity;</p> <p>XIII. The additional remuneration is part of the beneficiary’s usual remuneration practices and paid consistently whenever the relevant work or expertise is required;</p> <p>XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding;</p> <p>XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action).</p> <p><i>[If certain statement(s) of section “C. Personnel costs” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings: - ...]</i></p>	<p>to objective and verifiable information;</p> <ul style="list-style-type: none"> ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. <p>Factual finding:</p> <ol style="list-style-type: none"> 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary’s usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month’s pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
	full-time during the year or did not work exclusively on the action).
<p>D. Productive hours</p> <p>XVI. The number of productive hours per full-time employee applied is <i>[delete as appropriate]</i>:</p> <p>A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time).</p> <p>B. the total number of hours worked in the year by a person for the Beneficiary</p> <p>C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours.</p> <p><u>If method B is applied</u></p> <p>XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave).</p> <p>XVIII. ‘Annual workable hours’ are hours 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.</p> <p>XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.</p> <p><u>If method C is applied</u></p> <p>XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately.</p> <p>XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary’s usual accounting practices; ii) is at least 90 %</p>	<p>Procedure (same sample basis as for Section C: Personnel costs):</p> <ul style="list-style-type: none"> ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. <p>Factual finding:</p> <p><u>General</u></p> <p>12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column.</p> <p>13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action.</p> <p><u>If method B is applied</u></p> <p>14. The number of ‘annual workable hours’, overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate.</p> <p>15. The contract specified the working time enabling to calculate the annual</p>

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p>of the standard number of workable (working) hours per year.</p> <p>XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary’s disposal performing the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence.</p> <p><i>[If certain statement(s) of section “D. Productive hours” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: - ...]</i></p>	<p>workable hours.</p> <p><u>If method C is applied</u></p> <p>16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary.</p> <p>17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary.</p> <p>18. The number of productive hours per year used for the calculation of the hourly rate was at least 90 % of the number of workable (working) hours per year.</p>
<p>E. Hourly rates</p> <p>The hourly rates are correct because:</p> <p>XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above.</p> <p><i>[If the statement of section ‘E. Hourly rates’ cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: - ...]</i></p>	<p>Procedure</p> <ul style="list-style-type: none"> ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. <p>For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs):</p> <ul style="list-style-type: none"> ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. <p>Factual finding:</p> <p>19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.</p>
<p>F. Time recording</p> <p>XXIV. Time recording is in place for all persons with no exclusive dedication to one EDCTP2 or Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a daily/weekly/monthly basis <i>[delete</i></p>	<p>Procedure</p> <ul style="list-style-type: none"> ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time.

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p><i>as appropriate</i>] using a paper/computer-based system <i>[delete as appropriate]</i>;</p> <p>XXV. For persons exclusively assigned to one EDCTP2 or Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time;</p> <p>XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly;</p> <p>XXVII. Measures are in place to prevent staff from:</p> <ol style="list-style-type: none"> i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. <p>XXVIII. No working time was recorded outside the action period;</p> <p>XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates.</p> <p><i>[Please provide a brief description of the <u>time recording system</u> in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate⁵⁶].</i></p>	<p>The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular:</p> <ul style="list-style-type: none"> ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a EDCTP2 or Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a EDCTP2 or Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for EDCTP2 or Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. ✓ <p>In addition, the Auditor has verified that no more hours were charged to</p>

⁵⁶ The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in EDCTP2 or H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Grant Agreement number(s): [insert numbers and acronyms]

<i>Please explain any discrepancies in the body of the Report.</i>	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p><i>[If certain statement(s) of section “F. Time recording” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: - ...]</i></p>	<p>EDCTP2 or Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action.</p> <p>Factual finding:</p> <ol style="list-style-type: none"> 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the [Beneficiary] [Linked Third Party]]
[name and title of authorised representative]
[dd Month yyyy]
 <Signature of the [Beneficiary] [Linked Third Party]>

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
 <Signature of the Auditor>

I. Periodic Technical report

I.1. Explanation of the work carried out by the beneficiary and Overview of the progress

Reports to be prepared online via [EDCTP grants](#)⁵⁸

Please include the following:

- Explanation of the work carried out during the reporting period in line with the Annex 1 to the Grant Agreement.
- Overview of the progress towards the objectives of the action in line with the structure of the Annex 1 to the Grant Agreement **including summary of deliverables and milestones**
- Summary of the results, outputs, achievements, and implications of the activities part of the action and how these will be taken forward, exploited and/or disseminated

Where applicable, the report should include:

- **Update of the plan for exploitation and dissemination of results**
- **Update of the data management plan**
- **Follow-up of recommendations and comments from previous review(s).**
- **Explain the reasons for deviations from Annex 1, the consequences and the proposed corrective actions**
- **Explanations for tasks not fully implemented**, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks on the available resources and the planning.
- Explanations on **deviations of the use of resources** between actual and planned use of resources in Annex 1 (Description of the Action), especially related to person-months **per work package**.
- ✓ **Unforeseen subcontracting**. Exceptionally, the EDCTP Association may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the Grant Agreement (GA) under the conditions set out in Article 13.1 of the GA, if the circumstances are explained and justified by the beneficiary in this section
 - The approval is at the discretion of the EDCTP Association, and there is no automatic entitlement to it. Therefore, the beneficiary that does not

⁵⁸ <https://www.edctpgrants.org/Login.aspx?ReturnUrl=%2f>

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amend the GA to include subcontracting assumes the risk of non-approval by the EDCTP Association and rejection of costs.

- If the subcontracting substantially changes the nature of the project (i.e. there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action) the costs will be rejected.

Please give details of:

- a) the work (the tasks) performed by a subcontractor which may cover only a limited part of the action;
- b) explanation of the circumstances which caused the need for a subcontract, taking into account the specific characteristics of the action;
- c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests.

✓ **Unforeseen use of in kind contribution from third party against payment or free of charge**

Exceptionally, the EDCTP Association may approve costs related to in-kind contributions not included in Annex 1 and 2 without formally amending the GA if the circumstances are explained and justified by the beneficiary in this section.

- The approval is at the discretion of the EDCTP Association, and there is no automatic entitlement to it. Therefore, the beneficiary that does not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assumes the risk of non-approval by the EDCTP Association and rejection of costs.
- Approval will not be granted if the in-kind contribution risks to substantially change the nature of the action (i.e. there is doubt whether the action is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

Please give details of:

- a) the identity of the third party;
- b) the resources made available by the third party respectively against payment or free of charges;
- c) explanation of the circumstances which caused the need for using these resources for carrying out the work.

I.2. Summary for publication

All EDCTP2 grants have a summary published on the EDCTP website.

The summary must be of suitable quality for publication on the EDCTP website. It should be easy to read i.e. written in a language easily understood by a broader public, thereby

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promoting the dissemination and supporting the exploitation of EDCTP2 funded results. The summary should not exceed two pages of text.

The summary must not contain any confidential data.

The summary for publication must be drafted as a "stand-alone" text. No references should be made to other parts of the report. References can be made only to publicly available information.

The summary for publication of each periodic report must cover all of the elements below:

- A summary description of the context and overall objectives of the action.
- **A description of the work performed from the beginning of the action to the end of the period covered by the report, and the main results achieved so far.**
- Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the action so far).
- The address (URL) of the action's public website.

For each periodic report, the previous summary must be updated.

I.3. Tables

I.3.1 Deliverables (This section should be in line with the list of deliverables from the Description of Action (DoA))

The deliverables due in this reporting period, as indicated in Annex I to the Grant Agreement have to be uploaded in *EDCTP grants*. They can be Reports (R: Document, report **excluding the periodic and final reports**), Demonstration (DEM: Reports on Demonstrator, pilot, prototype, plan designs, new or revised health policies, new or improved guidelines for clinical practice, submitted requests for market authorisation of new medical intervention, etc), Dissemination / Exploitation / Communication (DEC: Reports on Websites, patent filing, press & media actions, public engagement & community feedback activities, videos, etc) or OTHER (Reports on Software, technical diagram, etc).

Please provide a summary and justification for the following:

- Delays in submission of deliverables and a revised timeline
- Cancellation or regrouping of one deliverable with another.

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

Del. no. ⁵⁹	Deliverable title	Related WP no.	Type ⁶⁰	Dissemination level ⁶¹	Delivery date from Annex I (proj month) ⁶²	Actual delivery date dd/mm/yyyy	If deliverable not submitted on time : Forecast delivery date if appropriate	Comments ⁶³

⁵⁹ Deliverable numbers in order of delivery dates. Following the numbering convention <WP number>.<number of deliverable within that WP>, deliverable 4.2 for example would be the second deliverable from work package 4.

⁶⁰ **Type:** Use one of the following codes:

R: Document, report (excluding the periodic and final reports)

DEM: Demonstrator, pilot, prototype, plan designs, new or revised health policies, new or improved guidelines for clinical practice, submitted requests for market authorisation of new medical intervention, etc

DEC: Websites, patents filing, press & media actions, public engagement & community feedback activities, videos, etc.

OTHER: Software, technical diagram, etc.

⁶¹ Use one of the following codes:

PU = Public, fully open, e.g. web

CO = Confidential under conditions set out in Grant Agreement.

CI = Classified, information as referred to in Commission Decision 2001/844/EC.

⁶² Measured in months from the action start date (month 1)

⁶³ Mandatory if a due deliverable is not submitted at the moment of the submission of a periodic report

I.3.2 Milestones

Please complete this table if milestones are specified in Annex I to the Grant Agreement. Milestones will be assessed against the means of verification defined in Annex 1.

This table is cumulative, which means that it should always show all milestones from the beginning of the action.

Milestones							
Milestone (MS) no ⁶⁴	Milestone title	Related Work package(s) no	Due date from Annex I dd/mm/yyyy	Means of verification	Achieved Yes/No	If not achieved Forecast achievement date Dd/mm/yy	Comments

⁶⁴ Milestone numbers in order of delivery dates. Following the numbering convention <WP number>.<number of milestone within that WP>, milestone 4.2 for example would be the second milestone from work package 4.

I.3.3 Ethical issues (if applicable)

Please complete this table:

Ethical requirements	Due date of the compliance of the ethic requirement	Report of the independent ethics advisor/ advisory board if applicable	Comments ⁶⁵
1			
2			
3			
...n			

⁶⁵ Mandatory if a due ethical requirement is not cleared at the time of submission of a periodic report

I.3.4 Critical implementation risks and mitigation actions

Risk number	Description of risk	WP concerned	Proposed risk-mitigation measures	Current status ⁶⁶			
				Were the risk mitigation measures applied Y/N	Did the risk materialise Y/N	Comments	
1		WP1					
2		WP1					
x							
N1 ⁶⁷							

I.3.5. Dissemination and exploitation of results

I.3.5.1 Scientific publications

Please list the accepted (in press or published) peer-reviewed publications resulting from the action in the following table.

The beneficiary must ensure open access to all peer-reviewed publications⁶⁸ relating to its results generated by the action. The beneficiary may choose to deposit their peer-reviewed publications in those repositories which are most appropriate for their subject and publication.⁶⁹

⁶⁶ At each period the beneficiary should give an update on the current status and indicate new mitigation measures, where necessary.

⁶⁷ Newly identified risks may be added as applicable

⁶⁸ 'Peer-reviewed' publications refer to publications that have been evaluated by peers, i.e. other scholars. The dominant type of peer-reviewed scientific publication is the journal article, for which open access is mandatory in the EDCTP2 Programme. In addition, however, the beneficiaries are strongly encouraged to provide open access to

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

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All publications must include the statement set out in the GA that the results were generated with the assistance of financial support from the EDCTP2 programme supported by the European Union (see article 29.4 of the Grant Agreement).

Scientific publications													
Type of scientific publication ⁷⁰	Title publication	DOI ⁷¹	ISSN or eSSN	Authors	Journal name or equivalent	Number, date	Publisher	Place of publication	Year of publication	Page numbers	Public & private participation YES/NO	Peer-review ⁷² Yes / No	Is/Will open access ⁷³ provided to this publication?-
											YES/NO – To be selected by beneficiary	YES/NO – To be selected by beneficiary	* Yes Green OA / specify the length of embargo if any * Yes Gold/Specify the amount of processing charges if any in € * No -- To be selected by beneficiary

other types of scientific publications, some of which may, in some cases, not be peer-reviewed, including monographs, books, conference proceedings and grey literature (informally published written material not controlled by scientific publishers, e.g. reports).

⁶⁹ For instance a thematic repository or an institutional repository.

⁷⁰ Drop list: Article in peer-reviewed journal, Publication in conference proceeding/workshop, Books/Monographs, Chapters in books, Thesis/dissertation.

⁷¹ DOI: Digital Object Identifier – Permanent identifier which should be a persistent link to the published version full text or abstract (if article is pay per view) or to the final manuscript accepted for publication (link to article in repository).

⁷² 'Peer-reviewed' publications refer to publications that have been evaluated by peers, i.e. other scholars. The dominant type of peer-reviewed scientific publication is the journal article, for which open access is mandatory in the EDCTP2 Programme. In addition, however, beneficiaries are strongly encouraged to provide open access to other types of scientific publications, some of which may, in some cases, not be peer-reviewed, including monographs, books, conference proceedings and grey literature (informally published written material not controlled by scientific publishers, e.g. reports).

⁷³ Open Access is defined as free of charge access for anyone via Internet. Open access is **MANDATORY** for peer-reviewed publications under the GA. Green OA: Access is granted after an embargo period, Gold OA: Paid Open Access as processing charges. For non-peered review publications, answer "yes/Green OA' or 'Yes/ Gold OA'.

I.3.5.2 Dissemination and communication activities

Please give details of other dissemination and communication activities that took place during the reporting period. This should include, for example:

- Conferences and academic workshop presentations (oral/poster)
- Feedback activities to research participants and related communities
- Meetings with policy makers or health care professionals
- Media coverage or other related activities
- Research resources generated and made publicly available(e.g. website, software or database developments)

Please confirm that the EDCTP Association and the EU have been acknowledged as per Article 29 of the GA.

Type of activity ⁷⁴	Date(s)	Type of audience reached ⁷⁵	Number of persons reached	Details

⁷⁴ Please list only activities directly linked to the Action. A drop down of dissemination activity: organisation of conferences, organisation of workshops, press releases, policy document, other publications (non scientific and non-peer reviewed publications (popularised publications)), exhibitions, flyers, trainings, social media, websites, communication campaigns (e.g. radio, TV), participation in a conference, participation in a workshop, participation in a policy meeting, participation in other events, community feedback events, videos/films, brokerage events, pitch events, participation in activities organised jointly with other EDCTP2 or H2020 action(s), Other.

⁷⁵ A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, General Public, Policy makers, Medias, Investors, Other ('multiple choices' is possible).

1.3.5.3 Intellectual property rights resulting from the action

Applications for patents, trademarks, registered designs, etc. shall be listed according to the template provided hereafter.

The list should specify at least one unique identifier (ex: European Patent application reference).

REGISTERED INTELLECTUAL PROPERTY RIGHTS (IPR)

REGISTERED INTELLECTUAL PROPERTY RIGHTS (IPR)						
Type of IP Rights ⁷⁶ :	Application reference ⁷⁷	Date of the application (dd/mm/yy)	Official title of the application	Applicant(s)	Has the IPR protection been awarded? YES/NO/Not applicable	If available, official publication number of award of protection ⁷⁸
1						
2						

One IPR can have several IP organisations, identifiers, and even more applicants.

In the case of multiple applications covering the same IP (e.g the same invention), in different offices, the beneficiary should only indicate one. If an application is filed with the European Patent Office, only this application should be mentioned. If not, only the first application should be reported. The same principle applies to the publication number of award of protection.

⁷⁶ A drop down list allows choosing the type of registered IP rights: Patents, Trademarks, Registered designs, Utility models, Other.

⁷⁷ For patents, international applications are made up of a IP international organisation code (ex: EP for EPO) and a serial number, national applications are generally made up of a country code (two letters) and a serial number and. For other registered IPR, the application references given should be able to permit an easy identification of the IPR in question, including by identifying the country, organisation or office involved. The structure of the entering should be by "Country code or organisation code + alpha numeric identifier".

⁷⁸ Publication numbers are assigned to an awarded of protection when it is published. For, patents they are generally made up of a code (two letters referring to a country or organisation) and a serial number. An example of a publication number is: EP2743965.

1.3.5.4 Clinical trials or observational studies (applicable for RIA and TMA only)

How many clinical trials are supported under this action [Number]

Please complete and/ or update the information about each clinical trial or observational study supported under this action

Trial/study title and acronym:	
Trial registration	EDCTP requires that clinical trials are registered in a public trials registry at or before the time of first patient enrolment. The registry must be a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or ClinicalTrials.gov, which is a data provider to the WHO ICTRP. Please give details of where the trial is registered and provide the URL. The trial entry must be up to date at the time of submission of this report.
Clinical trial sponsor	
Sponsor’s representative	Provide Name and contact details
Trial Steering Committee (TSC) membership	List the members, their affiliations and Chair; indicate whether the member is independent of the trial investigators. Please provide details of all TSC meetings that have taken place during this reporting period and upload the minutes of the meetings.
Data Safety and Monitoring Board (DSMB)	List the members, their affiliations and Chair. Please provide details of all DSMB meetings that have taken place during this reporting period and upload the minutes (open session) of the meetings.
Purpose	
Primary objective(s)	
Secondary objective(s)	
Study type	
Study design	
Site Principal Investigator(s)	
Clinical Trial/Study site(s)	
Estimated and actual start date of recruitment per	Estimated: dd/mm/yyyy

site	Actual: dd/mm/yyyy										
Estimated study completion date											
Study population and target number of recruits per site	<p>Insert table showing planned recruitment versus actual recruitment; withdrawals; loss to follow-up.</p> <table border="1"> <thead> <tr> <th>Site</th> <th>Estimated/target recruitment at time of submission of report</th> <th>Actual recruitment (number screened)</th> <th>Number of withdrawals</th> <th>Number lost to follow up</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Site	Estimated/target recruitment at time of submission of report	Actual recruitment (number screened)	Number of withdrawals	Number lost to follow up					
Site	Estimated/target recruitment at time of submission of report	Actual recruitment (number screened)	Number of withdrawals	Number lost to follow up							
Investigational product(s)/Manufacturer/ Developer	Provide details of the product(s). Indicate whether the products are new chemical entities; improved/modified existing products; existing products										
Control product(s)	Provide details of the control product(s), including the provider(s) of the control product(s).										
Status	Not yet recruiting, recruitment ongoing, recruitment completed and in follow-up phase, trial completed										
Protocol Development <i>*Upload the approved, signed protocol or protocols. These should include a description of the changes made between protocol or versions. Also upload electronic copies of all ethical or regulatory approvals.</i>	<p>Current version of protocol:</p> <p>For each site, list</p> <p>The expected or actual date of approval:</p> <p>Name of independent ethics committee(s) that approve(d) the protocol</p> <p>Name of the national regulatory authority(ies) that approve(d) the protocol:</p> <p>Please upload electronic copies of all ethical and regulatory approvals received during the reporting period and copies of all reports sent to the ethics committees and regulatory authorities during this reporting period.</p>										

	<p>Confirmation that all required ethical and regulatory approval is in place for this study. YES/NO/comments</p> <hr/> <p>Serious Adverse Events: Give details of the SAEs that have occurred, how these have been managed and which authorities have been informed. .</p>
<p>Monitoring plan <i>*Upload the independent monitors 'reports during this period.</i></p>	<p>Give details of the trial monitors/CROs in the study; dates of monitoring visits; copies of the reports. Please indicate how the identified corrective actions have been addressed and/or the timeline for addressing these.</p>
<p>Recruitment/ enrolment</p>	<p>Deviation from time table? [YES/NO] If yes, please explain the reason(s) for this deviation and the impact on the completion of the trial. Please provide an updated recruitment plan per site for the remainder of the trial. If any reduction in sample size is proposed, please provide justification for the changes. These changes must be supported by the TSC and DSMB.</p>
<p>Summary of progress made during the reporting period. Give details of changes in objectives, timelines, setbacks and challenges that have occurred and how these are being addressed.</p>	

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

I.3.5.5 Capacity building (applicable for RIA, CSA, TMA)

Short-term training and workshops

Type of activity	Date(s)	Number of persons trained	Location and dates of training, details of the trainer(s), assessment of training objectives

Postgraduate training and career development

Name of trainee and type of training	% time working on the action	Nationality	Gender	Institution	Supervisor(s)	Title of study	Start & end date
Masters							
PhD							
Post-doc							
Senior staff							
Technical/nursing staff							
Other personnel							
	<p>Summarise the progress during the reporting period. Please highlight career development, promotions that have occurred during the reporting period.</p> <p>"[insert text here]"</p>						
	<p>Infrastructure improvements</p> <p>Give details of any site upgrade or improvement conducted during the reporting period in line with the objectives of the GA.</p>						

I.3.5.6 Is there anything else you wish to report about your EDCTP grant, e.g. awards or prizes, special recognitions, etc.?

"[insert text here]"

I.3.6 Impact on Small and Medium-sized Enterprises (SMEs)[For all actions with an SME]

The following table is cumulative and will be filled at the end of each reporting period.

SME Name	Turnover of the company at the beginning of the action/most recent accountability period from the beginning of the action	Number of employees at the beginning of the action/most recent accountability period from the beginning of the action	Turnover of the company at the most recent accountability period	Number of employees at the most recent accountability period

I.3.7 Open Research Data (Mandatory for the projects taking part in the ‘Open research data pilot’ – see article 29.3 of the GA- and optional for the other actions).

If the action will result in data of potential value as a resource for the wider research community, then a data management and sharing plan may be requested as part of the GA.

DOI (if available) if the dataset is linked to a publication	Title/Identifier (if no DOI available)	Is this dataset Openly accessible ⁷⁹ ? Drop list: YES/NO	Is this dataset re-usable ⁸⁰ Drop list: YES/NO	Please provide a summary to support the answers given in this table (including justification where NO is stated as the answer)
1				

⁷⁹ Accessible means Open Access defined as free of charge access for anyone via Internet. Answer "yes" if the open access to the data is already established or if it will be established after an embargo period.

⁸⁰ Re-usability has 2 aspects: 1) technical: the technical standards used are compatible 2) legal : the necessary rights are in place for other users to use the dataset.

2				
....n				

The Data Management Plan (DMP) should give details of what data the action will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is required for projects participating in the Open Research Data Pilot. Other projects are invited to submit a Data Management Plan if relevant for their planned research, although this is not an obligation. The purpose of the DMP is to support the data management life cycle for all data that will be collected, processed or generated by the action.

I.3.8 Gender

Gender of R&D participants⁸¹ involved in the action

Beneficiary	Number F including third parties (if appropriate)	Number M including third parties ((if appropriate)	Total Including third parties (if appropriate)

Gender dimension in the action

Does the action include a gender dimension in research⁸²? YES / NO
Please give details.

I.3.11 Infrastructures *(if options under Article 16 MGA apply)*

If access to research infrastructures has been provided under the grant please include in Section I.1. "Explanation of the work carried out during the reporting period in line with the Annex 1 to the Grant Agreement and overview of the results of the action, a specific Sub-section on access provision activities.

a. Trans-national Access Activities (TA)

For the set of TA Work Packages, the integrated information described below should be provided.

- **Description of the publicity concerning the new opportunities for access**

⁸¹ Participants in the context of this question are defined as people actively participating and paid by the EDCTP2 action. It does not refer to the participants (subjects) of the trial.

⁸² Gender dimension in research is a concept regrouping the various elements concerning biological characteristics and social/cultural factors of both women and men into the development of research policies, programmes and actions.

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In the first periodic report describe the measures taken to publicise to research teams throughout Europe the opportunities for access open to them under the Grant Agreement. In the following periodic reports indicate only additional measures and changes.

- **Description of the selection procedure**

In the first periodic report, describe the procedure used to select users: organisation of the Selection Panel, any additional selection criteria⁸³ employed by the Selection Panel, measures to promote equal opportunities, etc. Specify if feedback is given to rejected applicants and in which form. In the following periodic reports indicate only changes to the existing procedure.

The list of the Selection Panel members should be maintained and update when necessary in order to prove that the panel is composed following the conditions indicated in Article 16.1 of the GA⁸⁴. The EDCTP Association reserves the right to request this list at any time.

Indicate number, date and venue (if not carried out remotely) of the meetings of the Selection panel during the reporting period.

Provide integrated information on the selection of user projects and on the scientific output of supported users. In particular indicate the number of eligible User projects submitted in the reporting period and the number of the selected ones taking into account only calls for which the selection has been completed in the reporting period. Indicate also the number of user projects, started and supported in the reporting period, which have a majority of users not working in an EU or associated country

- **Description of the Trans-national Access activity**

Give an overview of the user-projects⁸⁵ and users supported in the reporting period indicating their number, their scientific fields and other relevant information you may want to highlight. You should maintain the list of the user-projects for which costs have been incurred in the reporting period. A user-project can run over more than one reporting period. In this case it should be inserted in the list of each concerned reporting period.

The list of user-projects must include, for each user-project, the acronym, objectives, as well as the amount of access granted to it on each installation used by the user-project in the reporting period. When the user-project is completed in the reporting period the list should also include a short description of the work carried out. The EDCTP Association reserves the right to request this list at any time.

In addition you must fill the following tables (see tables below):

- **List of users: Researchers who have access to research infrastructures/installations (one or more) through EDCTP2 support** under the grant either in person (through visit) or through remote access;

⁸³ See article 16.1 of the Grant Agreement.

⁸⁴ The selection panel must be composed of international experts in the field, at least half of them independent from the beneficiary, unless otherwise specified in Annex 1.

⁸⁵ A user-project is a proposal for access submitted by a user group to the consortium to be evaluated by the Selection Panel.

- **Research infrastructures made accessible to all researchers in Europe and beyond through EDCTP2 support and summary of trans-national access provision per installation per reporting period** indicate for each installation providing trans-national access under the project the quantity of access actually provided in the Reporting Period (expressed in the unit of access defined in Annex 1 for that specific installation).]

Scientific output of the users at the facilities

Give highlights of important research results from the user-projects supported under the grant agreement. Indicate the number and the type of publications derived by user-projects supported under the grant taking into account only publications that acknowledge the support of this EDCTP2 grant.

You should maintain a list of publications that have appeared in journals (or conference proceedings) during the reporting period and are resulting from work carried out under the Trans-national Access activity. List only publications that acknowledge the support of the EDCTP2 European Community. For each publication indicate: the acronyms of the user-projects that have led to the publication itself, the authors, the title, the year of publication, the type of publication (Article in journal, Publication in conference proceeding/workshop, Book/Monograph, Chapters in book, Thesis/dissertation, whether it has been peer-reviewed or not, the DOI (Digital Object Identifier), the publication references, and whether the publication is available under Open Access or not. The EDCTP Association reserves the right to request this list at any time.

User meetings

If any user meetings have been organised in the reporting period, indicate for each of them the date, the venue, the number of users attending the meeting and the overall number of attendees.

b. Virtual Access Activities (VA)

For the set of VA Work Packages, the integrated information described below should be provided.

Statistics on the virtual access should be provided in the period by each installation, including quantity, geographical distribution of users and, whenever possible, information/statistics on scientific outcomes (publications, patents, etc.) acknowledging the use of the infrastructure.

As indicated in Art. 16.2, the access providers must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the beneficiary. In the first periodic report, describe how the virtual access providers will comply with this obligation. In the following periodic reports indicate only changes to the existing procedure.

When an assessment is scheduled under the reporting period, the assessment report must be submitted as deliverable.

List of users

Researchers who have trans-national access to research infrastructures through EDCTP2 support

Researcher			Employing organisation/Home institution			Activity Domain (Discipline) ⁸⁶	Installations used by the researcher
Name (First and Last name)	Gender	Nationality ⁸⁷	Name	Legal status ⁸⁸	Country (35)		
	M/F						(list extracted by the GA) Multiple values possible in this field

⁸⁶ Indicate the discipline of the work carried out by the user on the installation. Drop down list: Physics, Chemistry, Life Sciences & Biotech, Earth Sciences & Environment, Engineering & Technology, Mathematics, Information & Communication Technologies, Material Sciences, Energy, Social Sciences, Humanities

⁸⁷ Drop down list : Countries

⁸⁸ Drop down list: UNI= University and other higher education organisations, RES= Public research organisation (including international research organisation as well as private research organisation controlled by a public authority), SME= Small or Medium Enterprise, PRV= Other Industrial and/or profit Private organisation, OTH= Other organisation not fitting in one of the above categories.

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Research infrastructures made accessible to all researchers in Europe and beyond through EDCTP2 support and summary of trans-national access provision per installation per reporting period (RP)

<i>Participant number</i>	<i>Organisation short name</i>	<i>Short name of infrastructure</i>	<i>Installation</i>		<i>Unit of access</i>	<i>Min. quantity of access to be provided in Annex I (A)</i>	<i>Access provided in RP1</i>	<i>Access provided in RP2</i>	<i>Access provided in RP3</i>	<i>Access provided in RP4</i>	<i>Total access provided (B)</i>	<i>Difference (B-A)</i>
			<i>number</i>	<i>Short name</i>								
1	AAA	InfrAA	1	a1	day	100	20	30			50	-50
1	AAA	InfrAA	2	a2	au	1000	250	200			450	-550
3	CCC	InfrCC	1	cc	un	500	100	200			300	-200
6	FFF	InfrFX	1	f1	au	1500	300	400			700	-800
6	FFF	InfrFX	2	f2	day	80	10	10			20	-60
6	FFF	InfrFY	1	gg	un	600	200	200			400	-200
<i>Integer</i>	<i>Text (50)</i>	<i>Text (50)</i>	<i>Integer</i>	<i>Text (50)</i>	<i>Text (50)</i>	<i>Double</i>	<i>Double</i>	<i>Double</i>	<i>Double</i>	<i>Double</i>	<i>Double</i>	<i>Double</i>

Grant Agreement number: [insert number] [insert acronym] [insert call/ identifier]

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Researchers who have access to research e-infrastructures through EDCTP2 support

Researchers who have access to research e-infrastructures through EDCTP2 support

e-infrastructure name	e-infrastructure service	Activity Domain (Discipline) ^[1]	Maximum possible number of users	Nr of actual users by max possible number in P1 (%)	Nr of actual users by max possible number in P2 (%)	Nr of actual users by max possible number in P3 (%)	Nr of actual users by max possible number in P4 (%)

^[1] Indicate the discipline of the work carried out by the user on the installation. Drop down list: Physics, Chemistry, Life Sciences & Biotech, Earth Sciences & Environment, Engineering & Technology, Mathematics, Information & Communication Technologies, Material Sciences, Energy, Social Sciences, Humanities

II. Financial statements

II.1. Implementation

Individual financial statements (Annex 4 to the GA) must be filled in by the beneficiary and by its linked third parties (if applicable). Financial statements must be sent to the EDCTP Association as part of the periodic reports.

II.2. Explanation of the use of the resources and financial statements –

The beneficiary must provide explanation of the use of resources in the financial statement (Annex 4 to the GA). (see scheme below).

A. Direct personnel costs

The only data requested is the Person-months per Work-Package (not per deliverable).

At this stage, the beneficiary does not have to provide names, level of experience etc...⁸⁹

Personnel costs of SME owners without a salary and of the beneficiary that are natural persons not receiving a salary reimbursed on the basis of unit costs have to be declared in column A.4.

B. Direct costs of subcontracting

The total direct costs for the period have to be broken down into the costs for individual subcontractants.

- Unforeseen subcontracting not indicated in the grant agreement - For the exceptional case of subcontracting not indicated in annex 1, in addition to the information provided in the technical report (par.1.2), the beneficiary shall specify in this section the cost for each subcontract.

A + D Direct costs of Third Parties (not linked third parties)

Direct cost related to in-kind contributions provided by third parties should be declared in the personnel and/or other direct costs columns, depending of the type of cost.

⁸⁹ Complementary information may be requested later in specific cases.

Unforeseen (not indicated in the grant agreement) use of in kind contribution from third party against payment or free of charge

For the exceptional case of use of in-kind contributions provided from a third party against payment or free of charge, not indicated in advance in Annex 1, in addition to the information provided in the technical report (par.1.2), the beneficiary shall specify in this section the cost of the resources.

C. Direct cost of financial support

Direct cost concerning the financial support to ("cascade funding" and prizes) (article 15 of the GA) third parties should be declared in the column C.

D. Other direct costs

Cost related to contracts to third parties for the provision of goods, works or services have been provided in column D (Article 10 of the GA).

1. If costs declared under "other direct costs" are equal to or less than 15% of claimed personnel costs for the beneficiary for that reporting period, then, no explanation needs to be provided (but the beneficiary must in any case keep all justifications in order to prove the costs they declare as eligible in case of check and audit).

2. If costs declared under "other direct costs" are higher than 15% of claimed personnel costs for the beneficiary for that reporting period, then other major direct cost items⁹⁰ need to be explained by the beneficiary. The explanations must be up to the level that the remaining costs are below 15% of personnel costs. Explanations should be given starting from the cost items of highest value in terms of cost amount.

If other direct cost items are reported, the beneficiary must provide:

- a. if foreseen in DoA: simple reference to DoA
- b. If not foreseen in DoA: cost/amount per item, description of the item, nature of item (travel, equipment, other goods & services), work package(s), action relevance/explanation

Example:

Personnel costs: 100000€

Other directs costs: 35000€

⁹⁰ An item is considered as a cost declared in the accountability book of each beneficiary according to their internal accountancy practices.

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Since the other direct costs represent 35% of the personnel costs, then for 20% of other direct costs, justification have to be given i.e. for 20000€.

So if the 35000€ is the sum of items recorded in the accounts e.g. 8500€ + 7500€ + 6500€ + 5500€ + 4000€ + 3x1000€, the beneficiary has to list and justify the items of 8500€, 7500€ and 6500€. The remaining amount (12500€) is below 15% of the personnel costs and remains undetailed.

F. Specific costs

Please report individual specific cost (as costs for energy efficiency measures in buildings', access costs for providing trans-national access to research infrastructures, costs for clinical studies) reimbursed on the basis of unit costs.

Additional information

Please declare again the different third party costs which need to be removed from the total eligible costs of the beneficiary for the calculation of the indirect costs (e.g. subcontracting, costs of in-kind contributions from third parties but only those which are not used on the premises of the beneficiary, costs of providing financial support to third parties, unit costs, lump sums - Article 6.2.E).

Scheme

MODEL ANNEX 4 FOR GENERAL MGA - MU - i-BENEFICIARY

FINAL STATEMENT FOR (BENEFICIARY [name]) / LINKED THIRD PARTY [name]

A. Personnel costs: Persons/month per WP WP1

C. Financial Support to Third parties: TP1

F. Specific costs: SP1, SP2 as per DoA

Costs of in kind contributions of 3rd party not used on premises: 1, 2 mentioned again here for information since the indirect cost should not be paid to the beneficiary

A. Direct personnel costs										B. Direct costs of subcontracting				C. Direct costs of financial support				D. Other direct costs				E. Indirect costs		F. Costs of ...		Receipts		EU contribution		Required contribution					
A.1 Personnel under contract		A.2 Personnel under contract		A.3 Salaried persons		A.4 Personnel for access to research infrastructure		A.5 Beneficiaries that are natural persons without salary		B.1 Subcontracting		B.2 Unforeseen - Subcontracting		C.1 Financial support		C.2 Financial support		D.1 Travel		D.2 Equipment		D.3 Other goods and services		E. Flat-rate		F.1 Costs of ...		F.2 Costs of ...			Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3		Reimbursement rate %		Maximum EU contribution ***
Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit	Actual	Unit
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)	(r)	(s)	(t)	(u)	(v)	(w)	(x)	(y)	(z)	(aa)	(ab)	(ac)	(ad)	(ae)	(af)	(ag)	(ah)	(ai)	

B Subcontracting SC1
SC2
Unforeseen - Subcontracting
USC1 €
USC2 €

In A & D
In kind contribution from third party against payment & free of charge as well as unforeseen use of in kind contribution from third party against payment & free of charge, should be included in the total amount of the beneficiary

D. Other direct costs: explanation of major cost items if the amount exceeds 15% of personnel costs:

Item Description	Cost €	Nature of item (drop down list: travel, equipment, other goods & services)	WP ...	Explanation if not foreseen in Annex 1
Item X				
Item Y				
	Remaining amount			