



Brussels, 25.11.2016
C(2016) 7553 final

COMMISSION DECISION

of 25.11.2016

modifying the Commission decision of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)¹, and in particular Article 10 thereof,

Having regard to Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020)², and in particular Articles 25 and 33 thereof,

Having regard to 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 Union³, and in particular Article 124 thereof,

Whereas:

- (1) On 7 March 2014 the Commission adopted a decision authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme,
- (2) This Commission decision gives the beneficiaries the opportunity to declare their costs following either an actual cost system or the unit cost system described therein,
- (3) Since the adoption of the Commission Decision, the applicants and beneficiaries concerned have raised concerns related to its practical implementation,
- (4) The main obstacle identified concerns the obligation to apply either the unit cost method or the actual costs method for all categories of costs without any flexibility,
- (5) A modification of the conditions set out in the Annex to the Commission decision is needed to introduce such flexibility,

¹ OJ L 347, 20.12.2013, p. 104

² OJ L 347, 20.12.2013, p. 81

³ OJ L 298, 26.10.2012, p.1

HAS DECIDED AS FOLLOWS:

Sole Article

The Annex of Commission decision C(2014) 1393 of 7.3.2014 authorising the reimbursement on the basis of unit costs for actions requiring the conduct of the clinical studies under 'Societal Challenge 1: health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme is replaced by the Annex to this decision.

Done at Brussels, 25.11.2016

For the Commission
Carlos MOEDAS
Member of the Commission

1. Form of costs and categories of costs covered

A ‘clinical study’ is defined for the purpose of this decision as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients or study participants. It includes but is not limited to clinical studies and clinical trials in the sense of the Clinical Trials Regulation EU No 536/2014 and, in so far as it remains applicable, the Clinical Trials Directive 2001/20/EC.

Beneficiaries of grants under ‘Societal Challenge 1: Health, Demographic Change and Wellbeing’ of the Horizon 2020 Framework Programme may determine the costs of clinical studies according to the following forms:

- (i) Unit costs per patient or study participant calculated on the basis of their historical data, or
- (ii) Cost actually incurred.

A grant may involve the conduct of several clinical studies, and each clinical study may be conducted by several entities. Hence, the grant agreement may foresee different forms for the costs of clinical studies per beneficiary or third party, under the following conditions:

- For the costs of personnel directly assigned to the conduct of clinical studies, each beneficiary or third party may only choose one of the forms (i) or (ii) .

NB This decision does not apply to personnel costs for horizontal tasks carried out by beneficiaries or third parties participating in the clinical study, such as study monitoring or study coordination tasks (these tasks are covered by provisions of the Grant Agreement).

- For categories (b) to (d) of direct eligible costs referred to in Part 2, beneficiaries and third parties may choose either of the forms (i) or (ii) for each cost item.

Unit costs per patient or participant will be specific to each beneficiary or third party and in each case only represent a proxy of their specific categories of costs (a) to (d) referred to in Part 2 below.

The unit costs shall be specified in the grant agreement to be used throughout the duration of the action. The proposal as well as the grant agreement should also specify the costs of the clinical study that will be determined as actual costs.

Costs of clinical studies declared by beneficiaries on the basis of unit costs shall be eligible if they correspond to the amount per unit set out in Annex 2 to the grant agreement multiplied by the number of actual units (patients or study participants) included in the clinical studies conducted under the action.

Third parties may contribute in kind to the action by making data obtained from patients or study participants enrolled in the clinical studies available to a beneficiary or linked third party. The related costs shall also take one of the forms referred to in points (i) and (ii) for the purpose of determining:

- the maximum amount of the eligible costs that the beneficiaries may declare, if the data are contributed against payment,
- the eligible costs that the beneficiaries may declare, if the data are contributed free of charge.

The categories of eligible costs covered by the unit costs referred to in point (i) are defined below:

- Direct costs of clinical studies:

(a) Personnel costs of doctors and other medical personnel and technical personnel (including data managers) directly assigned to the conduct of the clinical study;

(b) Costs of consumables specifically used for the conduct of the clinical study;

(c) Costs of the medical equipment specifically used for the conduct of the clinical study, corresponding to:

- the depreciation costs
- the other costs of service contracts necessary for their functioning (including specific cleaning, maintenance and repair);

(d) Costs of other specific service contracts necessary for the conduct of the clinical study (including data analysis, if subcontracted);

- Indirect costs of the clinical study

The categories of eligible costs covered by the unit costs exclude the travel and subsistence costs of patients or study participants. Those costs will be reimbursed on the basis of eligible costs actually incurred under the cost category “other direct costs”.

Other categories of eligible costs not covered by the present decision shall be reimbursed on the basis of:

- eligible costs actually incurred or,
- for other direct personnel costs, on the basis of other unit costs or,
- for other indirect costs, flat-rate financing.

2. Method to determine the unit costs

The amounts of the unit costs per patient or study participant are determined *as the sum of the amounts of the unit cost components defined in points (a) to (e) below*, corresponding to the categories of eligible costs defined in Part 1, for each beneficiary or third party identified in the grant agreement and each clinical study.

Each beneficiary or third party shall determine the direct costs by reference to their historical costs and the estimated resources consumed per task and per patient or participant.

The beneficiary and the third party shall use as historical costs the costs recorded in their certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant proposal).

The estimation of resources at the time of submission of the grant proposal shall be based on the applicable protocol for the clinical study and must be the same for all members of the consortium involved in one clinical study.

Those resources shall be indicated in the grant proposal and will be assessed by the experts evaluating the proposals.

The choice of form of costs (unit costs or actual costs per cost category or sub-category) has to be made at the time of the proposal submission. The resulting unit costs shall also be included in the grant proposal and in the Annex 2 to the grant agreement. However, the unit cost can be modified through an amendment to the grant agreement in the following cases:

- if there is a change in the protocol (e.g. due to requests from competent authorities, regulatory agencies or ethics committees) during the implementation of the action which results in a change of the estimation of resources needed to calculate the unit costs. In such a case, the Commission may ask the advice of independent experts for the assessment of the necessity of the resources.
- if an error occurred in the identification of costs recorded in the beneficiary's certified or auditable accounts for year N-1 (last closed financial year at the time of submission of the proposal) or wrong application of points (a) to (d) below.

Under no circumstances may such modifications result in a substantial change to the grant proposal or in an increase of the maximum amount of the grant specified in the grant agreement.

In case of any amendment the historical costs shall still be the costs recorded in the certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the proposal) of the concerned beneficiary or the third party

The Commission has the right to verify that these costs comply with the requirements defined in points (a) to (d) below and to correct the unit costs in case of non-compliance.

(a) Personnel costs of medical and technical personnel directly assigned to the conduct of the clinical study

The amount of the unit cost component ‘personnel costs’ is determined for each task described in the protocol as follows:

*{Average hourly cost for **Doctors** X Estimated number of hours worked by doctors for each task described in the protocol and for each patient or study participant*

+ Average hourly cost for **Other medical personnel** X Estimated number of hours worked by other medical personnel for each task described in the protocol and for each patient or study participant

+ Average hourly cost for **Technical personnel** X Estimated number of hours worked by technical personnel for each task described in the protocol and for each patient or study participant}

with

Average hourly cost for Doctors = Certified or auditable total personnel costs for Doctors for year N-1 / {1720 X number of full-time equivalent for the personnel category Doctors for year N-1}

Average hourly cost for Other medical personnel = Certified or auditable total personnel costs for other medical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Other medical personnel for year N-1}

Average hourly cost for Technical personnel = Certified or auditable total personnel costs for technical personnel for year N-1 / {1720 X number of full-time equivalent for the personnel category Technical personnel for year N-1}

and

Total personnel costs = Actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract or equivalent appointing act (see conditions set out in Article 6.2.A.1 of the model Horizon 2020 grant agreement).

The use of hourly costs determined according to another methodology, including according to the beneficiary's or third party's usual cost accounting practices, is not allowed.

(b) Costs of consumables specifically used for the conduct of the clinical study

The amount of the unit cost component 'costs of consumables' is determined for each task described in the protocol as follows:

{Average price per item for the first category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the second category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ Average price per item for the third category of consumables specifically used in the clinical study X Estimated number of items used for each task described in the protocol and for each patient or study participant

+ *idem for each category of consumables specifically used in the clinical study*}

with

Average price per item for a category of consumables used in the clinical study = *Certified or auditable total costs of purchase of the consumables in year N-1 for the category of consumables concerned / Total number of items purchased in year N-1 for the category of consumables concerned*

and

Total costs of purchase of the consumables = *Total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary or third party for consumables delivered in year N-1, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(c) Costs of the medical equipment specifically used for the conduct of the clinical study

The amount of the unit cost component ‘costs of medical equipment’ is determined for each task described in the protocol as follows:

{Average cost of depreciation and of directly related services for the first category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant

+ *Average cost of depreciation and of directly related services for the second category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant*

+ *Average cost of depreciation and of directly related services for the third category of equipment specifically used in the clinical study per unit of use X Estimated number of units of use of the equipment for each task described in the protocol and for each patient or study participant*

+ *idem for each category of equipment specifically used in the clinical study*}

with

Average cost of depreciation and directly related services per unit of use = *{Certified or auditable total depreciation costs in year N-1 for the category of equipment concerned + Certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned} / Total capacity in year N-1*

and

Total depreciation costs = Total depreciation allowances as recorded in the beneficiary's or third party's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + Total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees (see conditions set out in Article 6.2.D.2 of the model Horizon 2020 grant agreement).

Total costs of purchase of services = Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for services delivered in year N-1 for the functioning of the equipment, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).

Total capacity = Total time of use of the equipment expressed in hours, days or months and supported by evidence or the number of accesses to the equipment, for which supporting evidence may take the form of records or electronic log of units-of-access provision.

The total capacity must take due account of real constraints (e.g. opening hours), but must reflect the equipment full capacity and include any time during which the equipment is usable but not used or any unit of access available but not used.

(d) Costs of other specific contracts necessary for the conduct of the clinical study

The amount of the unit cost component 'costs of other specific contracts' is determined for each task described in the protocol as follows:

{Average cost of the first specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the second specific service necessary for the conduct of the clinical study per patient or study participant

+ Average cost of the third specific service necessary for the conduct of the clinical study per patient or study participant

+ idem for each specific service necessary for the conduct of the clinical study}

with

Average cost of a specific service per patient or study participant = Certified or auditable total costs of purchase of a service in year N-1 for the category of specific services necessary for the conduct of clinical studies / Total number of patients or participants included in the clinical studies for which the specific service was delivered in year N-1

and

***Total costs of purchase of a service** = Total value of the contracts concluded by the beneficiary or third party (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests (see conditions set out in Article 6.2.D.3 of the model Horizon 2020 grant agreement).*

(e) Indirect costs

The amount of the unit cost component ‘indirect costs’ is determined for each task described in the protocol by applying a flat rate of 25% of the sum of the unit cost components referred to in points (a), (b) and (c) above (excluding the unit cost component referred to in point (d) above and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties, as set out in Article 29(1) of Regulation (EU) No 1290/2013).

3. Justification

3.1. Nature of the supported actions

Clinical studies are the essential link in the translation of new knowledge generated by basic research into new health products, services and interventions. Without clinical studies, the validity of these products, services and interventions cannot be tested and proven, to the disadvantage of patients, citizens and the competitiveness of the European health sector.

Over the course of 7th Framework Programme for Research and Development (FP7) approximately one fifth of all projects in the ‘Health’ theme included clinical studies, with a significant rise in number in the last years of FP7 implementation. As Horizon 2020 gives greater emphasis to innovation than previous programmes, the percentage of funding allocated to clinical studies is likely to increase.

(a) Problems related to the determination of actual costs of clinical studies

The precise quantification of costs resulting from clinical studies is difficult. Clinical studies consist of a large number and variety of different elements, such as repeat hospitalisations or outpatient clinic visits (themselves including a number of elements ranging from receptionist's time to meals and laundry), a variety of individual doctors', nurses' and technicians' time, study drugs and auxiliary drugs as well as laboratory and imaging tests. These costs are incurred in the health and care settings (hospitals, clinics, etc.) which are at the present time relatively inexperienced beneficiaries of Framework Programmes and the accounting systems of which are frequently not equipped to track these costs.

The problem for beneficiaries required to follow the H2020 rules regarding actual costs is in proving the allocation of actual resources needed to perform clinical studies. Such proof would be both time consuming and in some cases not possible due to the unsuitability of beneficiaries’ accounting systems and management practices.

(b) Alternatives and consultation of stakeholders

In industry- or academically-funded clinical studies, hospitals are typically therefore reimbursed a lump sum per patient, calculated on the basis of a rough estimation of the actual costs. In large industrial trials this amount often includes a profit margin for the hospital or the participating doctors, whereas in academically-funded clinical studies, this amount usually does not cover the full costs and requires additional subsidy.

A number of stakeholders have called upon the Commission to adopt a similar approach for EU-funded clinical studies:

- A June 2012 note of the League of European Research Universities (LERU)¹ requests among other changes trial-specific “flat rates per patient”;
- A September 2013 workshop with representatives of three major German University Hospitals, the German National Contact Point and Clinical Research Organisations confirmed the urgent need to simplify the funding rules for clinical studies and welcomed the idea presented by the Commission (outlining the option in this Commission decision) as potential solution;
- The Commission also presented different options to the group of national experts at its meeting of 11 October 2013. Representatives of Member States also recognised the urgent need to simplify the accounting for clinical studies. The feedback received from most of the experts participating in this group is positive in respect to the option of declaring a 'unit cost per patient or participant involved in the study' as described in this decision;
- Numerous individual requests and meetings with project coordinators and hospital participants in FP7 projects have raised similar issues and potential solutions, which are the basis of the option proposed in this decision.

(c) Impact on grant management

Using unit costs considerably simplifies, streamlines and reduces the time needed for the financial management of projects, both at the Commission and beneficiary levels. A unit-cost system substantially decreases the number of recovery orders and de-commitments. It also significantly decreases the workload of the Commission or Agency when analysing cost statements and consequently speeds up the payment procedure. Furthermore, it implies additional simplifications at beneficiary level in terms of reporting requirements.

In summary, this approach provides simplification through:

- less complex funding rules contributing to easier understanding of actions;
- greater predictability for beneficiaries making their participation in the corresponding actions more attractive;
- less administrative burden for checking at the payment stage, reducing costs for the contracting authority and facilitating productivity gains;
- simplified reporting requirements (no certification of financial statement to be provided by beneficiaries for those costs);
- easier ex-post analysis and further reductions of the risk of error.

The use of unit costs is justified by the difficulty in determining the allocation of resources and is considered as an appropriate form of financing in order to simplify the administrative burden and financing conditions of supported actions. A unit-cost approach provides the opportunity to emphasise the quality of results. Moreover, the use of unit costs represents a further simplification for applicants ensuring certainty and transparency of funding levels.

3.2. Risks of irregularities and fraud and costs of control

The Financial Regulation (FR2) requires that the DGs and Agencies establish anti-fraud measures in their individual Internal Control Systems. In June 2011, the Commission adopted its first Anti-Fraud Strategy (CAFS) in which it requested the Commission Services to set up or update their sectorial Anti-Fraud Strategies. For the area of research the Anti-Fraud Strategy (RAFS) was adopted in December 2012. The RAFS builds strongly on and complements the CAFS by demonstrating how elements of the corporate strategy are addressed in the area of research. The sectorial strategy outlines some key principles of combating fraud, with a special focus on challenges which are common to the services of the research family and coordination mechanisms, which should ensure that strategic priorities are implemented in a most effective and coherent manner throughout the whole family.

The unit costs system is much simpler compared with the actual costs systems regarding the declaration of costs. As a consequence, the intrinsic risk on legality and regularity errors in cost claims leading to unjustified EU funding is very low and therefore the control and audit mechanism is lighter and less costly than in a system based on actual costs.

Reporting and control for clinical studies will focus on the realisation of the supported activity and the achieved results rather than on the resources allocated to the project, reducing the workload and scope for error of both participants and the Commission or Agency. The monitoring system will be set up in a manner ensuring efficiency and cost-effectiveness of the controls.

In fact, the unit costs will be subject to subsequent verification and audit to determine only the following:

- whether the number of patients or participants declared by the beneficiary corresponds to the number of patients or participants actually participating in the study, and
- whether the beneficiary has used the accounting data referred to in Part 2 for the determination of the unit costs set out in Annex 2 to the grant agreement.

However, the Commission will neither control the allocation of resources already agreed at the time of signature of the grant agreement nor the actual costs for the categories of eligible costs referred to in Part 1.

These controls will help the prevention of fraud while being simple and comprehensible both for the Commission or Agency and for the beneficiaries.

4. No-profit and co-financing principles and absence of double financing

The methodology for determining the unit cost per patient or participant included in the study described in Part 2 ensures respect for the no-profit and co-financing requirements and the absence of double financing of costs.

The clinical study is not expected to generate revenue or to be specifically funded by third donors. The unit cost per patient or participant set out in the grant agreement will not exceed the actual eligible costs as the calculation of the direct cost components will be based on

certified or auditable costs of a study which costs are recorded in the last closed accounts of the beneficiary. Furthermore, the funding for indirect costs is limited to 25% of the total direct eligible costs, excluding direct eligible costs for subcontracting. Therefore, the profit is a priori excluded and the remaining indirect costs are financed by the beneficiaries.

The reimbursement rate set out in the grant agreement will apply to the costs of clinical studies declared on the basis of unit costs.

The Commission avoids double funding by making checks at the time of evaluation and finalisation of the grant agreement that the costs falling under the categories covered by the unit costs, as referred to in Part 1, are not indicated in another budget category. A clear description of the activities covered by the unit cost will be included in the proposal and in the Technical Annex to the grant agreement, which will enable the Commission or Agency to reconcile the estimated eligible costs with the activities to be carried out. Similar checks will be performed during and after implementation of the grant agreement.

Funding based on unit costs encourages the recipient to use resources in an economical manner, given that the grant agreement is based on pre-established rates - without further adjustment of the amount of the grant based on the actual expenditure.