

Unit Cost Calculation for Clinical Studies in Horizon 2020

GUIDANCE DOCUMENT

This guidance document is intended to help with the calculation and application of Unit costs in clinical studies in H2020 projects. It has been prepared by a group of experts involved in the administration and implementation of multinational clinical studies in Horizon 2020.

The use of **unit costs** for the reimbursement of clinical studies funded under Horizon 2020 (Societal Challenge 1 “Health, demographic change and wellbeing”) was introduced by the European Commission (EC) into the Horizon 2020 as a part of the simplification process. The aim was to reduce the administrative burden for beneficiaries.

As a matter of fact, beneficiaries already using unit costs have confirmed that project implementation has become much easier. Importantly, there is **no need for time sheets, no need to demonstrate and justify** the resources spent for each patient during audit procedures, and the average salary calculation can be used for other studies/projects.

Nevertheless, experiences from the first Horizon 2020 calls showed that only very few beneficiaries opted for this simplified form of funding. Given the complexity of the calculation of unit costs, the expert panel on clinical trials felt it might be helpful to supply applicants with specific guidance.

The challenge of using unit costs lies in the unit costs’ calculation. At this regard, two different kinds of information need to be available at the time of submitting the project proposal.

First of all, a scientifically sound planning of the **overall resources needed for each patient**, including the estimation of the time of involved doctors and other medical or technical personnel, is needed. For this, the study protocol and the scientific expertise of the Principal investigators and/or partners involved in the design of the study are required.

In addition, the calculation has to be carried out on the basis of actual historical costs related to the last closed financial year (N-1) for personnel, consumables, medical equipment and service contracts. Therefore, certified or auditable accounting **data in the accounting system of each institution** willing to use unit costs per patient have to be available; no costs estimates are allowed. The EU grants office, administration and controlling departments of each institution are the key actors involved.

Requirements for the calculation of unit costs per patient

The following list guides through the preparation and application of unit cost calculation.

1. Splitting the clinical study into specific tasks

The work package(s) directly related to the recruitment and to the treatment of study participants or the intervention have/has to be split into tasks along the study protocol – this should be done by some responsible involved in the planning of the intervention, such as the sponsor of the trial, the PI, the coordinating researcher/doctor or task leader. Ideally this is done in collaboration with different partners involved in these tasks.

Clinical study sites that are Linked third parties or Third parties that provide in-kind contributions against payment can also use unit costs per patient

Subcontractors are not eligible to claim unit costs. Their costs have to be indicated in the project budget as “subcontracting” in the online budget table as well as in part B of the proposal (sections 3.4 and 4.2).

2. Assigning clinical study tasks to costs categories

The tasks have to be assigned to the different cost categories, i.e. (a) *personnel*, (b) *consumables*, (c) *equipment* and (d) *services*. Within the category (a) *personnel*, all the personnel involved has to be assigned to one of three categories: Doctors, other medical personnel or technical personnel. Assign tasks to the personnel category who is most likely to perform the task at most of the participants. Only the tasks directly related to individual patients are eligible.

- Doctors: medical doctors (of all income categories, including professors and junior physicians)
- Other medical personnel: e.g. study nurse, patient care, physiotherapist, mid-wife
- Technical personnel: lab technician, medical-technical-assistant, data manager, audiologist; academic researchers that carry out tasks related to individual patients in each study centre shall be also included in this category.

Here is a non-exhaustive list of activities that **cannot be claimed as unit costs** per patient (but as actual costs):

- monitoring of the trial,
- pharmacovigilance,
- general administration,
- regulatory submission/approval (this should be in a different WP than the recruitment),
- patient insurance,
- travel costs and catering of patients, patient compensation,
- drug preparation (if for several patients),
- sample transport.

3. Calculation of unit costs by Controlling Department/ Human Resources on the basis of historical costs

The calculation of the “personnel costs” component of the unit cost, including the allocation to the three categories, should be carried out by the Controlling Department, with the support of the Human Resources; these departments can provide the necessary information on personnel salaries. **To calculate the average hourly rate, the annual eligible personnel cost (as of art. 6.2.A Model Grant Agreement) related to the last closed financial year (N-1) per category have to be pooled and divided by 1720 annual workable hours.** Data of salaries need to comply with the definition of ‘basic remuneration’ according to MGA §6.2.A. This calculation can be used for other project proposals, too.

Historical costs need to be available in the accounting system at each institution, for each cost category. The accounting data used for the calculation can be subject to subsequent verification and audit at the GA stage.

See example in the tables (page 5-7): beneficiary #3 could not provide documentation for the depreciation costs of MRI for year N-1, therefore this beneficiary cannot claim unit costs for this cost item. The table lists 0 EUR for this cost item (in yellow). However, actual costs can be claimed.

The tasks/activities covered by the public health insurance as “standard care” differ between countries. These activities have to be listed and then set to zero for countries where the public health insurance covers them. *In the example on page 5-6: vital measurements are checked routinely*

for every in-patient in the institution of Beneficiary #1 and #2 as part of the “standard care”. These costs are covered by the public insurance and therefore will not be reimbursed by the EC (in green). If for some exams, e.g. MRI/CT/ECG, there is a cost/price defined by the national insurance system (e.g. in the DKGNT/GOÄ) which does not correspond with the real costs of the service, only the actual cost can be claimed, either as service (actual costs need to fulfill eligibility criteria of MGA §6.2.), or they can be split up into the categories (personnel, equipment, material, subject to their compliance with the requirements of the Clinical Study Template).

The estimation of the time needed per task is up to the PI. It should be reasonable to the contents of the task and be based on experiences from clinical routine. If the experts evaluating the proposal do not object in the evaluation phase, this won't be subject to an audit.

Cost for external services can be claimed as service, provided that historical costs for these services are recorded in the accounting system for the last closed financial year (year N-1).

The four administrative steps of calculating Unit Costs for Personnel

Step 1: Face-to-face meeting between the EU grants office and the central financial controlling department of the hospital/university hospital/clinical centre to discuss EU-requirements on the Unit Cost calculation method and definition of staff categories. Finally, a definition is made based on the legally binding staff categories of the institution.

Step 2: Calculation of average hourly rates by the controlling department based on historical costs (N-1) and full-time equivalents of doctors and other medical personnel at the hospital/university hospital/clinical centre. Subsequent submission of the calculation to EU grants office.

Step 3: Questions & feedback by EU grants office. Revised version submitted by Controlling Department.

Step 4: Information by EU grants office to project PI and calculation of project budget including Unit Costs

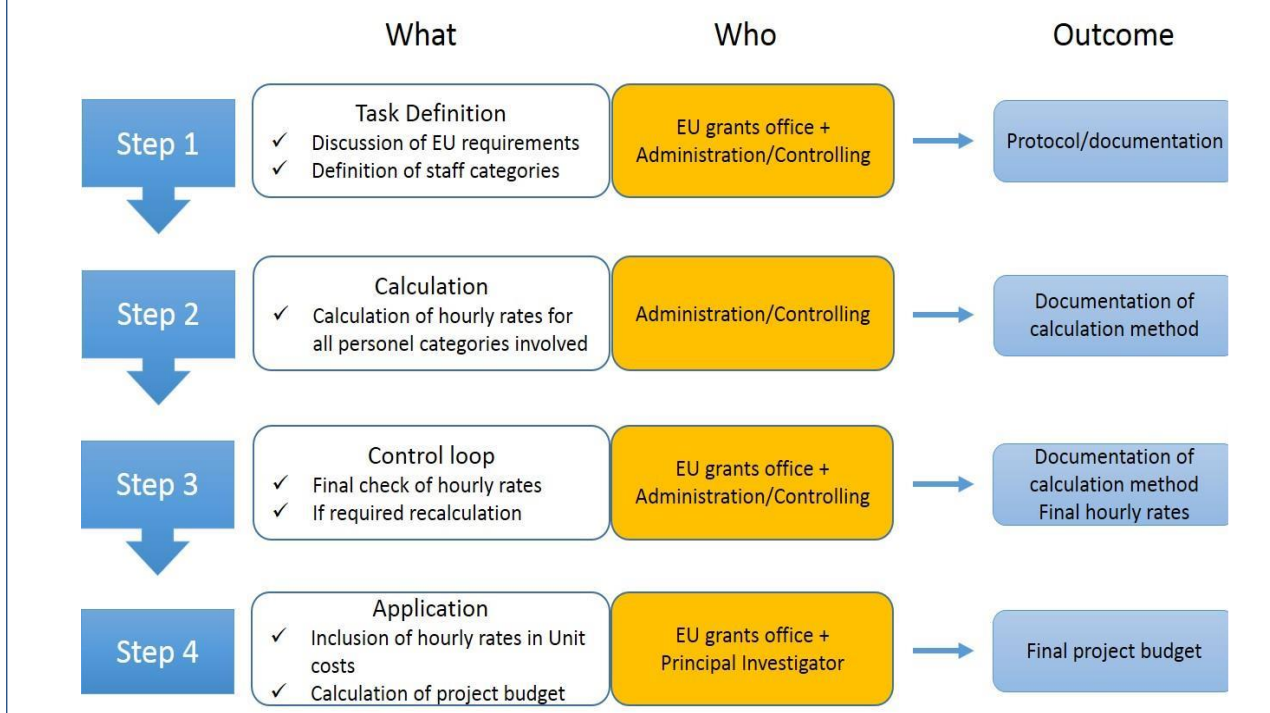


Figure 1: Institutional workflow for the calculation of Unit Costs taking personnel costs as an example

4. Sequential Unit Costs

If sequential visits are scheduled (e.g. several months apart), there is a **higher risk that patients drop out in the course of the study**. Given that, costs for patients that have not completed the whole study are not eligible for reimbursement, unit costs should be claimed for each visit or parts of the study (i.e. sequential unit costs) instead of the whole study. Thus, costs per patient will be reimbursed for each study visit (first visit corresponding to unit costs 1, second visit to unit costs 2 etc.). The recommended maximum number of sequences is three.

5. Table of Unit Costs Calculation in the Clinical study Template

Finally, these calculations have to be transferred into the table of the Clinical study template as part of the proposal application procedure. The working group has prepared an example of how to fill-in this table (see Example on following pages).

6. Helpful documents:

- Template for essential information to be provided for proposals including clinical trials/studies/investigations/cohorts
- Commission Decision of 25.11.2016 C (2016) 7553 (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 Horizon 2020)
- Annotated Model Grant Agreement (AMGA)

Example for unit cost calculation and filled table

An example is provided for the calculation of unit costs for a given clinical study with screening as Task 1 and the first visit as Task 2. For further visits sequential unit costs would be advisable.

Only the calculation of the average hourly salary for each personnel cost category (Table 1) and historical costs for equipment, consumables and services (Table 2) can be subject to an audit, not the allocation of the resources – the latter will be checked during the evaluation of the proposal.

Personnel costs per working hour in year N-1	Beneficiary 1	Beneficiary 2	Beneficiary 3	Third party
- Doctors	57,85 EUR	25,22 EUR	64,00 EUR	64,00 EUR
- Other Medical Personnel	32,22 EUR	8,36 EUR	28,00 EUR	36,00 EUR
- Technical Personnel	36,21 EUR	11,02 EUR	28,00 EUR	37,00 EUR

Table 1: average personnel cost per working hour – could be subject to audit!

Equipment Depreciation costs per hour MRI)	109,19 EUR	66 EUR	Not available for year N-1	112,23 EUR
Consumables Syringe and cannula blood container	0,32 EUR 0,02 EUR	0,22 EUR 0,015 EUR	0,33 EUR 0,018 EUR	0,32 EUR 0,02 EUR

Table 2: average cost for consumables and equipment listed in the task table – could be subject to audit!

Task, Direct cost categories	Resource per patient (in hours)	Costs in year N-1	Costs in year N-1	Costs in year N-1	Costs in year N-1
		Benef. 1	Benef. 2	Benef. 3	Third party
Task No. 1					
Screening					
(a) Personnel costs					
- Doctors					
Examination, informed consent	1,5	86,78	37,83	96	96
Blood analysis (e.g. glucose, gas, antibodies...)	0,75	43,39	18,92	48	48
CRF revision	0,5	28,93	12,61	32	32
imaging interpretation	0,5	28,93	12,61	32	32
Reporting medication and procedures	0,33	19,09	8,32	21,12	21,12
-Other Medical Personnel (Study nurse)					
Vital measurements (temperature, pulse, blood pressure)	0,25	█	█	7	9
Blood sampling and preparation (biomarkers)	1,5	48,33	12,54	42	54
CRF documentation of all parameters	1,33	42,85	11,12	37,24	47,88
Transfer of file to central server	0,33	10,63	2,76	9,24	11,88
- Technical Personnel					
Imaging	0,75	27,16	8,27	21	27,75
(b) Costs of consumables					
Syringe & Cannula	-----	0,32 EUR	0,22 EUR	0,33 EUR	0,32 EUR
Blood container		0,08 EUR	0,06 EUR	0,07 EUR	0,08 EUR
(c) Costs of the medical equipment					
Depreciation MRI	0,5	54,60	33,00	0	56,12
(d) Services					

(e) indirect costs					
Total direct		407,20	162,44	360,00	454,15
Total indirect		101,80	40,61	92,25	113,54
Total per patient (Task 1)		509,00	203,05	452,25	567,69

Table 3a: Unit cost table for Task 1 (Screening); see text for color code

Task, Direct cost categories	Resource per patient (in hours)	Costs in year N-1 Benef. 1	Costs in year N-1 Benef. 2	Costs in year N-1 Benef. 3	Costs in year N-1 Third party
Task No. 2					
First Visit					
(a) Personnel costs					
- Doctors					
Examination	0,5	28,93	12,61	32	32
Application and supervision of study medication	0,5	28,93	12,61	32	32
Interpretation of medical measurements	0,5	28,93	12,61	32	32
CRF revision and inspection of records	1	57,85	25,22	64	64
- Other Medical Personnel (study nurse)					
CRF documentation	0,5	16,11	4,18	14	18
Recording measurements (e.g. EEG, respiration) vital measurements	0,33	10,96	2,76	9,24	11,88
vital measurements	0,25			7	9
- Technical Personnel -----					
(b) Costs of consumables					
Syringe & Cannula	-----	0,32 EUR	0,22 EUR	0,33 EUR	0,32 EUR
Blood container		0,08 EUR	0,06 EUR	0,07 EUR	0,08 EUR
(c) Costs of the medical equipment					
Depreciation MRi	0,5	54,60	33,00	0	56,12
(d) Services					

(e) indirect costs					
Total direct		226,71	103,27	190,64	255,40
Total indirect		56,68	25,82	47,66	63,85
Total per patient		283,39	129,09	238,30	319,25

Table 3b: Unit cost table for Task 2 (First visit); see text for color code

Task, Direct cost categories	Resource per patient (in hours)	Costs in year N-1 Benef. 1	Costs in year N-1 Benef. 2	Costs in year N-1 Benef. 3	Costs in year N-1 Third party
Task 1 & 2 total costs					
<i>Total direct Total indirect Total per patient</i>		<i>633,91 158,48 792,39</i>	<i>265,71 66,43 332,14</i>	<i>550,64 137,66 688,30</i>	<i>709,55 177,39 886,94</i>

Table 4: Sum of Task 1 and Task 2, overview of total unit costs per patient per beneficiary or third party

Information about the authors

This document has been prepared by professionals actively involved in the design and/ or management of clinical trials working together in an informal Expert Panel on Clinical Trials in Horizon 2020. They agreed on a voluntary basis during the expert panel meeting in Brussels on March 15 2017 to set up a working group with the aim to develop further guidance for the use and calculation of unit costs. The working group met in Berlin on June 28 2017 to elaborate and prepare this document.

This guidance document has been prepared to the best of our knowledge, but is not legally binding.

Members of the working group:

Uta Baddack-Werncke, Health NCP DLR-PT, Bonn - Doris Bell, Health NCP DLR-PT, Bonn- Katrin Dinkla-Ritter, Hannover Medical School - Liesbeth Dorama, University Leiden - Eveline Fräßdorf, Charité University Hospital Berlin - Valeria Genovesi, University of Bologna - Frank Groen, AMC Medical Research B.V. Amsterdam - Valérie Handweiler, University Hospital Montpellier – Christiane Hennecke, University Medical Center Goettingen -Andreas Krell, KoWi Brussels - Danilo Petroni, Humanitas Mirasole SpA - Susanne Stoppel, Medical Faculty of the University of Tübingen

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DLR Projektträger
Nationale Kontaktstelle Lebenswissenschaften
(NKS-L)
Heinrich-Konen-Straße 1
D-53227 Bonn
Tel.: +49-228 3821 1697
E-Mail: nks-lebenswissenschaften@dlr.de

Kooperationsstelle EU der
Wissenschaftsorganisationen
(KoWi)
Rue du Trône 98
B- 1050 Bruxelles
Tel.: +32-2-548 02 10
Email: brussel@kowi.de

Dr. Uta Baddack-Werncke
Dr. Doris Bell

Dr. Andreas Krell

