



HORIZON EUROPE

THE EU RESEARCH & INNOVATION PROGRAMME

2021 – 2027

CLINICAL TRIALS IN HORIZON EUROPE: HOW TO DECLARE COSTS - EXAMPLES.



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Clinical trials costs under Horizon Europe (HE).

Contrary to H2020 rules, which provided for the category of the unit costs for clinical trials, **there are no special financial rules for clinical trials foreseen under HE.**

Clinical trials costs under HE can therefore be declared as:

- actual costs,
- subcontracting costs; or
- costs for internally invoiced goods and services;

provided that all the relevant eligibility conditions are met.

Clinical trials costs under Horizon Europe – actual costs.

In case of **actual costs**, the following eligibility conditions apply:

General eligibility conditions (Article 6.1 of the MGA):

- ✓ they must be actually incurred by the beneficiary;
- ✓ they must (in principle) be incurred during the action duration;
- ✓ they must be declared under one of the budget categories set out in the MGA, such as for example: personnel costs; purchase costs – including equipment and costs of other goods and services.

Additional specific eligibility conditions apply for each budget category and must be respected in addition to general eligibility conditions

Clinical trials costs under Horizon Europe – actual costs.

In case of actual costs, the following eligibility conditions apply:

General eligibility conditions (Article 6.1 of the MGA) - continued:

- ✓ they must be incurred in connection with the action and necessary for its implementation;
- ✓ they must be identifiable and verifiable (in particular recorded on beneficiary's accounts);
- ✓ they must comply with the applicable national law on taxes, labour and social security; and
- ✓ they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

Clinical trials costs under Horizon Europe – actual costs.

Examples of clinical trial costs declared as actual costs:

Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

	Cost (€)	Justification
Travel and subsistence	1,600	Attendance to 2 consortium meetings for 1 person
Equipment	15,000	DNA/RNA extractor only for this project
Other goods, works and services	22,557.60	Lab consumables RAPID ANTIGEN TEST FOR COVID BOX WITH 25 TESTS (3167.6 €); Maxwell RSC Total Viral TNA Kit (2473€); SCALP 23G (855€); VACUUM BLOOD COLLECTION TUBE WITH SEPARATOR GEL (682€); CRYOGENIC TUBE 2.0ml, POLYPROPYLENE INTERNAL THREAD W/50 (3545€); SEROLOGICAL PIPETTS 5ml (255€); SEROLOGICAL PIPETTS 10ml (255€); BOVINE FETAL SERUM 500ml (473€); FIBER CARDBOARD BOX 81 HOLES (310€); RACK W/ 96 TIPS OF 100-1000uL (1200€); FALCON TUBE 15ml PCT W/ 25UN (515€); MULTIPLE NEEDLE COLLECTION BLOOD AND STERIL VACUUM 22G 25X0 W/100 (100€); ANTIBODIES/MARKERS FOR CELL RESPONSE (8727€)
Total	39,157.60	

Clinical trials costs under Horizon Europe – actual costs.

Examples of clinical trial costs declared as actual costs:

Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

<p>Other goods, works and services</p>	<p>175 500€</p>	<p>WP2: Task 2.2 & 2.3 related. Laboratory (reagent and material costs) for immune-phenotyping and clotting studies: Immunophenotyping- 500€ x 60 antidotes = 30 000€, Clotting research= 46 000€: Coagulation biomarker analysis budget plan, (containing possible price reductions based on earlier contracts) 100 patients, 3 sampling points – 1) baseline, 2) 4-week, and 3) 12-week follow-up: Blood collection and sample processing - 1500€ Coagulation factor analysis- 7500€ APTT, PT, TT, fibrinogen, FVIII, antithrombin and D-dimer, VWF antigen and VWF activity assays 6000€ Protein C and protein S (1 and 2) 4000€ Thrombin generation with CAT assay 15 000€ ELISA assays for thrombin antithrombin complex 12 000€</p>
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Clinical trials costs under Horizon Europe - subcontracting

In case of subcontracting, the following eligibility conditions apply:

General eligibility conditions (Article 6.2. B of the MGA):

- ✓ Subcontracting costs for the action are eligible, if they are calculated on the basis of the costs actually incurred, they **fulfil the general eligibility conditions** and are awarded using the beneficiary's usual purchasing practices — provided these ensure subcontracts with **best value for money (or if appropriate the lowest price)** and that there is no conflict of interests
- ✓ The tasks to be subcontracted and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2

Clinical trials costs under Horizon Europe – subcontracting.

Example of clinical trial costs declared as subcontracts:

Participant Number/Short Name		
1. [REDACTED]	Cost (€)	Description of tasks and justification
Subcontracting	2,089,500	<p>[REDACTED] will involve up to 90 clinical sites listed below as subcontractors following [REDACTED] standard practices preventing conflict of interest. This list is provisional since we might not need to involve all those clinical sites. It will depend on the observed patient recruitment and clinical sites commitment. The clinical sites will be under contract with [REDACTED]. The clinical sites will screen, recruit, treat the patients and provide the data to [REDACTED]. Their costs for recruiting patients will be compensated 4500 euros per patient. It would cover partially the costs of the clinical sites for participating to the study (working time of the clinicians for screening patients and assessing eligibility, data entry and query management by study nurses, the costs of the clinical procedures, etc.). Clinical sites will be compensated based on their observed patient recruitment. The total budget for compensating patient recruitment is estimated 1,849,500 million euros.</p> <p>[REDACTED] will also compensate 40 clinical sites for the setup of the clinical trial. Each clinical site will receive once 2,500 euros compensating the costs from the administrative and regulatory staff, hospital management, insurances, site staff training and re training in case of protocol amendment, etc. The total budget for site setup is 100,000 euros.</p>

Clinical trials costs under Horizon Europe – internally invoiced goods and services

In case of internally invoiced goods and services, the following eligibility conditions apply:

- ✓ Internally invoiced goods and services means goods or services which are **provided within the beneficiary's organisation directly for the action** and which the beneficiary values on the basis of its usual cost accounting practices.
- ✓ Costs for internally invoiced goods and services directly used for the action may be declared as unit cost according to usual cost accounting practices if they fulfil the general eligibility conditions for such unit costs and the amount per unit is calculated:
 - using the actual costs for the good or service recorded in the beneficiary's accounts, attributed either by direct measurement or on the basis of cost drivers, and excluding any cost which are ineligible or already included in other budget categories; and
 - according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.
- ✓ These costs will not be taken into account for the indirect cost flat-rate.

Clinical trials costs under Horizon Europe – internally invoiced goods and services

- ✓ In case of clinical trials costs declared as internally invoiced goods and services the relevant beneficiaries should fill in **Table 3.1i** in their application form:

Table 3.1i: ‘Other costs categories’ items (e.g. internally invoiced goods and services)

Participant Number/Short Name		
	Cost (€)	Justification
Internally invoiced goods and services		
...		

Clinical trials costs under Horizon Europe – internally invoiced goods and services.

Example of clinical trial costs declared as internally invoiced goods and services:

Table 3.1.i 'Other costs categories' items (e.g., internally invoiced goods and services)

Participant number/Short Name		
1/	Cost (€)	Description of tasks and justification
Internally invoiced goods and services		WP1 , specific Biobank samples (PBMC) from LC cohort + control cohort patients, 1000 patients, 135€ per sample = 135 000€ Task 1.2. Cohort 2: clinical visit, 500 patients x 35€ per visit = 17 500€ Task 1.5. Control cohorts: clinical visit, 500 patients x 35€ per visit = 17 500€
Total	170 000€	

Clinical trials costs under Horizon Europe – internally invoiced goods and services.

Example of clinical trial costs declared as internally invoiced goods and services:

Table 3.1.i 'Other costs categories' items (e.g., internally invoiced goods and services)

Participant Number/Short Name	Internally invoiced goods and services	
	Cost (€)	Justification
01 [REDACTED]	€ 743.500	€ 433.500 Sampling (n=2.000), € 200.000 Imaging, € 30.000 Genotyping and € 80.000 Costs of mice
06 [REDACTED]	€ 67.760	The Norwegian Mother and Child Cohort Study
10 [REDACTED]	€ 2.000	Management of Clinical Trial Agreement

USEFUL LINKS

General Model Grant Agreement

see: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon- Euratom_en.pdf

Annotated Model Grant Agreement (draft)

see: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf

Helpdesk:

Externals:

Call EC Research Helpdesk at +32 229 92222 or e-mail them at EC-SEDIA-SUPPORT@ec.europa.eu





Thank you!

<http://ec.europa.eu/horizon-europe>

