

Revision of Commission Decision on Unit Costs for Clinical Trials



What are unit costs for clinical studies?

An alternative way of claiming costs for clinical trials:

- Proposal describes what is needed to do the study (**resources**, identical in each centre)
- Each beneficiary/third party that *wants* to use the unit costs, lists the **costs** of these resources in **year n-1** – based on its closed accounts

Why unit costs?

- No need for time sheets and detailed actual costs for each patients.
- Items audited: Number of patients enrolled and correctness of historical costs listed.

Unit Costs Calculation



Task, Direct cost categories	Resource patient/subject	per	Costs in year N-1 Benef.a 1 (short name)	Costs in year N-1 Benef.a 2 (short name)
Task No. 1				
Blood sample				
(a) Personnel costs: - Doctors				
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes		8,33 EUR ^b	11,59 EUR ^b
- Technical Personnel	Sample Processing (lab technician), 15 minutes		9,51 EUR ^b	15,68 EUR ^b
(b) Costs of consumables:	Syringe		XX EUR	XX EUR
	Cannula		XX EUR	XX EUR
	Blood container		XX EUR	XX EUR
(c) Costs of the medical equipment:	Use of -80° deep freezer, 60 days		XX EUR	XX EUR
....	Use of centrifuge, 15 minutes		XX EUR	XX EUR
(d) Services				
Total amount:			XX EUR	XX EUR



- ❖ **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**
- ❖ **Modified by Commission decision of 25.11.2016**



Additional flexibility

The beneficiaries the opportunity to declare their costs either as

- Cost **actually** incurred or
- **Unit costs** per patient or study participant calculated on the basis of their historical data

for different categories of eligible costs described in the Commission decision



Additional flexibility - exception

- **Exception:** 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 – either unit costs or actual costs for one clinical study
- NB: Does not apply to personnel costs for horizontal tasks carried out by entities participating in the clinical study, such as study monitoring or study coordination tasks



Unit cost modification

Through an amendment to the grant agreement if:

- there is a change in the protocol during the implementation of the action which results in a change of the estimation of resources needed to calculate the unit costs
- if an error occurred in the identification of costs recorded in the beneficiary's certified or auditable accounts for year N-1