



# Clinical Studies in H2020 Proposals

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# Financial and Contractual Aspects - Basics

- Clinical studies (CS) are subject to the same legal provisions and guidance notes as other activities in H2020 projects. No special 'derogations' (with the exception of special 'unit costs')
- BUT: Specific features of clinical studies require consistent application of existing rules



- I. Template  
'Essential information about clinical studies'
- II. Unit costs for clinical studies
- III. Status recruitment sites
- IV. Subcontracting
- V. Mandatory deliverables
- VI. Questions

## Purpose

- Providing structured information to experts for evaluation
- Giving applicants the chance to provide detailed information about clinical studies without page limitations.  
Reasons:
  - Detailed but important information, e.g. about Scientific Advice Meetings, in- / exclusion-criteria, etc.
  - potentially high number of studies
- Providing necessary information to request 'unit costs'

Available under 'call documents'<sup>1</sup> and in submission system

<sup>1</sup>e.g.: [http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2015-single-stage\\_rtd/1632634-essential\\_information\\_for\\_clinical\\_studies\\_2015callsv3\\_01122014\\_en.pdf](http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2015-single-stage_rtd/1632634-essential_information_for_clinical_studies_2015callsv3_01122014_en.pdf)

## Applicability / Definition

**1** A 'clinical study' is ... 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/**subjects**. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC).

- Broad, inclusive definition!

## Applicability

- Use of template mandatory for certain single-stage and second-stage topics
- These topics are listed in the template.
- **If**, a clinical study is included.

## Applicability

- ❑ For **each** clinical study<sup>1</sup> performed within the scope of the proposal ... compiled into one single document per proposal based on this template.
- ❑ In stage-1 proposals and in topics not listed, ‘Essential information on clinical trials/studies/investigations’ cannot be uploaded as a separate template. Instead, relevant aspects of this information must be integrated in part B of the proposal template. Nevertheless, the points listed below might serve as an orientation also in these cases.

### Scope

- ❑ Essential information – based on a generic CSP (Clinical Study Protocol)
- ❑ *When information is currently not available (e.g. a clinical study is planned for a later stage of the project and will be based on data of previous studies) the source of required data should be provided and / or the selection of the applied methodology should be described*
- ❑ *Each section must be shortly and concisely described. In case one or more issues do not apply to a particular study, please briefly explain/justify.*



## Scope

- ❑ *Ethical considerations have to be addressed in the respective separate section of the proposal.*
- ❑ *Risks and contingency plans have to be addressed in the respective section of the proposal (part B.3.2 and table 3.2.a) ... If contingency plans are not outlined in the proposal (and the grant agreement), **your grant agreement might be terminated and/or the EU contribution significantly reduced if a study cannot proceed as planned.***

Please note: Extension of project duration can generally not be granted in H2020. Significantly delayed key study milestones (e.g. 'first patient/first visit') might lead to the termination of the grant agreement.

### Scope

- Relevant information provided in this template does not need to be repeated elsewhere in the proposal, but can be referred to*
- Information provided that is not in the scope of this template will not be taken in account for the proposal evaluation.*



## Purpose / Scope

**Based on Commission Decision C(2014) 1393<sup>1</sup>**

**Unit costs** are:

- a fixed reimbursement amount
- for each study subject enrolled
- in a given centre
- calculated according to a **defined methodology**
- based on historical costs of the **beneficiary/third party**
- for the entire funding period of an action.

[NOT a flexible tool, adjustments during the time course of an action are not possible.]

<sup>1</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit\\_costs/unit%20costs\\_clinical\\_studies.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf)



## Legal Base/Purpose

### Based on Commission Decision C(2014) 1393<sup>1</sup>

- ❑ Ex-ante acceptance of unit costs = No need for time sheets and detailed tracking of resources used!
- ❑ Unit costs should encourage consortia to more realistically estimate their budget and time management for clinical studies.
- ❑ Unit costs are a **simple** and transparent method for calculating, reimbursing and auditing costs of clinical studies.

<sup>1</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit\\_costs/unit%20costs\\_clinical\\_studies.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf)



## Scope

- ❑ **Unit costs can be used in any action under SC 1**
- ❑ **Unit costs** can be used by:
  - beneficiaries
  - linked third parties [Art. 14]
  - third parties contributing in kind to the clinical study [Art. 11]
- ❑ **Unit costs** can be used for any type of clinical study.



## Conditions I

- ❑ *Alternative to the use of actual costs, on **voluntary basis**.*
- ❑ *Resources and costs will be **evaluated with the proposal**.*
- ❑ *Unit costs per patient/study subject fixed **for the entire duration** of the project.*
- ❑ *For costs **not included** in the unit cost, reimbursement **based on actual cost**.*

## Conditions II

- ❑ *Per clinical study subject: Estimation of the **resources***
  - per task on the basis of the protocol,
  - the same for all beneficiaries involved.
  
- ❑ *Per **beneficiary/third party**: Calculation of **costs** based on its historical costs:*
  - recorded in its certified or auditable profit and loss accounts,
  - for last closed financial year at the time of submission of the proposal.
  
- ❑ *Verification and **audit ex-post** only:*
  - number of patients/subjects declared = number of patients/subjects actually participating in the study
  - **Beneficiary/third party** has used the accounting data of year N-1.

## Conditions III

- ❑ **Direct costs** of clinical studies (defined categories, no other categories possible!)
  - Personnel (doctors, other medical, technical personnel)
  - Consumables
  - Medical equipment (depreciation and costs of service contracts necessary for their functioning)
  - Other specific service contracts necessary for the clinical study
  
- ❑ **Indirect costs** of the clinical study (25% of direct costs)
  
- ❑ Excluded from unit costs, e.g.: Travel and subsistence costs of patients/subjects are not included (reimbursed on the basis of eligible costs actually incurred under the cost category “other direct costs”)



# Unit costs



Task, Direct cost categories	Resource per patient/subject	Costs in year N-1 Benef. <sup>a</sup> 1 (short name)	Costs in year N-1 Benef. <sup>a</sup> 2 (short name)
<b>Task No. 1</b>			
<b>Blood sample</b>			
<b>(a) Personnel costs: - Doctors</b>			
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR <sup>b</sup>	11,59 EUR <sup>b</sup>
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR <sup>b</sup>	15,68 EUR <sup>b</sup>
<b>(b) Costs of consumables:</b>	Syringe	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR
<b>(c) Costs of the medical equipment:</b>	Use of -80° deep freezer, 60 days	XX EUR	XX EUR
....	Use of centrifuge, 15 minutes	XX EUR	XX EUR
<b>(d) Services</b>			
<b>Task No. X</b>			
...			
...			17
<b>Total amount:</b>		XX EUR	XX EUR

## Unit cost component 'personnel costs' (1)

### **3 unique and exclusive (!) personnel categories:**

- Doctors
- Other medical personal
- Technical personnel

No other personal category / calculation base for personal costs possible (e.g. categories for 'nurses' 'study nurses' or 'pharmacists' do not exist!)

## Unit cost component 'personnel costs' (2)



**TIP**

*Ask your institution's accounting department for the average hourly rates calculated following the method explained in the Commission decision in year **N-1** for each of these three personnel categories: 'Doctors', 'Other medical personnel' and 'Technical personnel'!*

- Requesting these three rates once every year will cover personnel costs for any clinical study in your H2020 proposals for that year!
- Consider a similar approach for frequently used consumables or service contracts!

## Unit cost component 'personnel costs' (3)

*Average hourly cost for Doctors/ Other medical and Technical personnel*

$$\text{Average hourly cost} = \frac{\text{Total personnel costs}}{1720 \times \text{FTE}}$$

**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) for the **specific personnel category** (e.g. **all** doctors of a hospital) based on **historic costs** of year N-1 (certified or auditable documentation) [see conditions set out in Article 6.1.A.1 of the model Horizon 2020 grant agreement]

**FTE** = number of full-time equivalent for the personnel category for year N-1

1720 = Working hours per year, **fixed rate**

## Unit cost component 'personnel costs' (4)

*Average hourly cost fictive example for Other medical personnel*

$$\text{Average hourly cost} = \frac{8\,596\,560}{1720 \times 100} = 49,98 \text{ €}$$

**Total personnel costs** for all 'other medical personnel' in the institution =  
(definition see above) = here 8 596 560 €

**FTE** = (number of full-time equivalent for the personnel  
category for year N-1) = here 100

1720 = Working hours per year, *fixed rate*



## Unit cost component 'consumables' (1)

### ***Category of consumable:***

- e.g. 10ml syringe type X of supplier Y
- e.g. all types of 10 ml syringes in use in hospital Z in the year N-1

***Total costs of purchase of the consumables*** (defined item or category) = ***Total value*** of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) ***concluded by the beneficiary*** for the consumables (defined item or category) delivered ***in year N-1*** provided (the supply contracts have to be compliant with H2020 rules, e.g. according to the principle of best value for money and without any conflict of interests).  
[see conditions set out in Article 6.1.D.3 of the model Horizon 2020 grant agreement]

## Unit cost component 'consumables' (2)

*Average cost of the consumables (defined item or category)*

***Total costs of purchase of the consumables***

**Average cost of the consumables =**

*—————  
Total number of items (defined item or category) purchased in year N-1 of consumables concerned*

## Unit cost component 'med. equipment' (1)

### ***Category of medical equipment:***

- A certain defined item (e.g. a deep freezer -20C type X of supplier Y)

**Total depreciation costs** = Total depreciation allowances as recorded in the beneficiary'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 or 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 6.1.A.1 of the model Horizon 2020 grant agreement)





## Unit cost component 'med. equipment' (2)

**Total costs of purchase of services** = Total value of the contracts concluded by the beneficiary (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 6.1.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.

## Unit cost component 'med. equipment' (3)

*Average cost of medical equipment  
(defined item)*

$$\begin{array}{l} \text{Average} \\ \text{cost} \\ \text{of} \\ \text{medical} \\ \text{equipment} \end{array} = \frac{\text{Total depreciation costs} + \text{Total costs of purchase of services}}{\text{Total capacity}}$$



## Unit cost component 'other specific service contracts' (1)

### ***Category of other specific service contract:***

- e.g. external analysis of LDL level by contract laboratory (data from a service contract in year N-1 must be available, see below)
- *Internally* invoiced costs have to be compliant with the requirements **lined out in the applicable version of the Annotated Model Grant Agreement (H2020 General MGA).**

## Unit cost component 'other specific service contracts' (3)

***Total costs of purchase of a service** = Total value of the contracts concluded by the beneficiary (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 6.1.D.3 of the model Horizon 2020 grant agreement)

***Total costs of purchase of the service***

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**Average cost of a specific service per patient or subject** =

*Total number of patients or subjects included in the clinical studies for which the specific service was delivered in year N-1*

## *Internal arrangements for agreed reimbursement*

- If consortium agrees internally to reimburse less than the unit costs or actual costs, this is perfectly fine.

**For example:** (Unit) cost per subject vary between 1000 and 5000 EUR/subject for different beneficiaries, but consortium agrees on an agreed reimbursement of 1000 EUR/subject for all beneficiaries.

-> Practically the beneficiaries should *claim* the full/unit costs but request for less (the agreed amount) as EU contribution

- The requested EU contribution cannot to be higher than the (unit) costs!



Clinical centres whose contribution is limited to subject recruitment or treatment may have status of:

- Full beneficiary -> **always preferred!**

But: if obstacles for centres to become beneficiary (or linked third party), two other options remain:

- Use of in-kind contributions provided by third parties against payment (Art. 11 MGA)
- Subcontractor (Art. 13 MGA)
- Please note: It is not possible to reimburse recruitment sites based on Article 10 MGA.



## Use of in-kind contributions provided by third parties against payment (Art. 11 MGA)

- *Third parties must be identified in DoA*
- *no profit, reimbursement of unit / actual costs (!)*
- *requires prior agreement with beneficiary – prior to start of work, not necessarily prior to signature of GA*
- *agreement might be 'ad-hoc'/specific to project*



## Subcontractor (Art. 13, MGA)

- *task (!) must be identified in DoA*
- *agreed 'price per patient/subject', profit possible*
- *best price/quality ratio, transparency equal treatment*
- *public bodies: internal rules and applicable legislation related to public procurement*
- *No indirect costs for beneficiary! **But in case of 100% reimbursement rate of direct costs, no more "shortfall" for linked beneficiary***





## Research Organisations (CROs)

- Only **limited part of the action** can be subcontracted (Art. 13 MGA)
- **Academic CROs** exist (e.g. ECRIN network) – might be willing to become beneficiary!
- Commercial CROs usually work 'for profit' → Commission will consider accepting subcontracting
- Please note: It is not possible to reimburse CROs based on Article 10 MGA.



## CROs

### **Rule of thumb** for amount of subcontracting:

- If clinical study is the main activity of the project:
  - Core study expertise cannot be subcontracted, but certain parts (GMP manufacturing, monitoring etc.) might be subcontracted as long as general regulatory expertise is available and the study design, high-level study management and oversight remain as tasks within the consortium (budget share: not essential criterion!)
- If clinical study is just a small part of the project, i.e. most of the project is preclinical activity:
  - Study might be subcontracted in its entirety



## Mandatory deliverables (1)

- 1) 'Submission package'**, for each included CS (prior to invitation / enrolment of first study subject):
  - a. Final version of study protocol as submitted to regulators / ethics committee(s)  
(no need to change deliverable if later amendments)
  - b. Registration number of clinical study in a WHO- or ICMJE- approved registry  
(Please note: Result posting for the study must be possible)
  - c. Approvals (ethics committees and national competent authority if applicable) required for invitation / enrolment of **first** subject in at least one clinical centre



## Mandatory deliverables (2)

- 2) 'All approvals package'**, for each included CS:  
*All* approvals from ethics committees and national competent authorities (if applicable) of all study sites once the last approval has been received.
  
- 3) Report on status of posting results in the study registry(s):**  
Report on the status of the result posting including timelines when final posting of results is scheduled after end of funding period.

## Ethics approvals for CT (1)

Note: Mandatory deliverables on approvals **are NOT sufficient for** compliance with Art. 34.2 of the MGA:

*Before the beginning of an activity raising an ethical issue, the coordinator must submit to the [Commission] 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*

## Ethics approvals for CT (2)

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



**Thank you**

[www.ec.europa.eu/research/health](http://www.ec.europa.eu/research/health)

[www.ec.europa.eu/research/horizon2020](http://www.ec.europa.eu/research/horizon2020)

### **Essential information** about clinical studies to be included in the **DoA**:

- All applicable sections of the template / each included study  
E.g. very important is scheduling for study conduct: Planning for first patient first visit, if applicable study medication etc.
- Do not include unnecessary explanations and justifications
- Do not include passages that are not in the scope of the template (e.g. additional annexes, new sections etc.)

The information has to be included in the section 2.3.1 of the DoA (e.g. as a task or (part of) work package)





## Experience, Common mistakes & misunderstandings

Only costs can be claimed under unit costs

- **No** lump sums
- **No** prices
- **Example:** HDL analysis of a blood sample (intern)
  - is a Task
  - Detailed definition of resources and correct estimation of cost categories is required  
(Personnel costs (doctors, other medical, technical personnel); consumables; medical equipment,...)



## Experience, Common mistakes & misunderstandings

Only costs can be claimed under unit costs

- **A special case** *'Other specific service contracts ...'* if
  - These are costs that occurred in every centre (and not by one centre for all beneficiaries)
  - The costs for the same kind of contract are recorded in the beneficiaries' accounts of year N-1
- **Examples:**
  - Framework contracts (or previous contracts) for blood sample analysis already established in the last closed financial year
  - Excluded: Study specific services of clinical CROs (it is extremely unlikely that the same study has been conducted within the same centres in year N-1)



## Experience, Common mistakes & misunderstandings

Costs for unit cost estimation have to be based on costs recorded in the beneficiaries' accounts of year N-1

Resources for unit cost have to be calculated based on the correct cost category

- **Example:** Cost category '*Personnel*', sub category 'Other medical personal'  
A sub category 'nurse' does not exist



## Experience, Common mistakes & misunderstandings

Tasks and resources have to be defined appropriately detailed / on an appropriate level of level of granularity

➤ **Examples:**

- Tasks: E.g. a medical visit (not whole study days)
- Resources: Defined activities, e.g. taking a blood sample, initial screening, etc.