Template for essential information to be provided for proposals including clinical trials / studies / investigations

Document history	
Version 2015callsV3	27 November 2014
Modifications (compared to previous version):	1.2 Reference to guidance documents added 1.4 Reference to special populations added 1.5 Sections on Sample size and Statistic Analysis combined 1.6 Section on cumulative safety information added 1.8 Reference to recruitment strategy added Editorial changes and re-ordering of paragraphs.

This template only concerns you if your proposal contains a clinical trial/study/investigation! In the following, clinical trials/studies/investigations are collectively referred to as 'clinical studies'[1]

Clinical studies have a number of methodological and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality of the proposal. The following guidance should help applicants to provide this essential information on clinical studies in a standardised format.

Single-stage- and stage-2 proposals: The use of this template is mandatory for all clinical studies[1] included in a single-stage- or stage-2 proposal submitted to topics PHC-2, PHC-3, PHC-11, PHC-14, PHC-15, PHC-16, PHC-18, PHC-22, PHC-24, PHC-33 and HCO-6[2]. For these topics, you will have the possibility to upload the completed template as a separate part of your application in the submission system.

Stage-1 proposals: In the limited frame of a stage-1 proposal not all methodological details of clinical studies can be fully elaborated. The individual characteristics of your study (and its importance for your overall proposal) will determine which aspects you will describe in what level of detail. Therefore in stage-1 proposals, '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 (within the limit of 7 pages). Nevertheless, the points listed below might serve as an orientation also for the information provided at stage 1.

[1] A 'clinical study' is defined for the purpose of this template 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. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC)

[2] For proposals containing clinical studies submitted to topics *not* listed here you may use the points listed below as an orientation and provide this information in section 1.3 ('Concept and approach') or in the relevant work package in section 3.1 ('Work plan – Work packages, deliverables and milestones') of part B of the proposal. If required, the table provided in section 1.9 of this template on unit costs can in this case be provided in section 3.4 ('Resources to be committed') of part B of the proposal.

For each clinical study performed within the scope of the proposal, information on the issues listed below should be provided, compiled into one single document per proposal based on this template[3]. 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.**

When the requested 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 from previous studies) the source of required data should be provided and / or the selection of the applied methodology should be described.

Information provided in this template does not need to be repeated elsewhere in the proposal, but can be referred to.

There are no page limitations applicable for this template, but explanations should be as concise as possible.

Information provided that is not in the scope of this template will not be taken in account for the proposal evaluation. No new chapters or additional annexes (containing e.g. complete study protocols) can be added to this template. Section headings should not be changed.

Ethical considerations have to be addressed in the respective separate section of the proposal. Similarly, risks and contingency plans have to be addressed in the respective section of the proposal (part B.3.2 and table 3.2.a) (not in this template!). 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.

1 Clinical study No. 1

1.1 Identifier

Title, short title or unique identifier.

1.2 Study design and endpoints

Description of selected study design and primary and secondary objectives (and how these objectives will be measured as endpoints/outcome measures).

Please include references to guidance documents considered to be relevant for the study: e.g. guidelines from scientific societies (e.g. addressing standard-of-care) or regulatory bodies (e.g. from the European Medicines Agency) and HTA agencies.

1.3 Scientific advice / protocol assistance / communication with regulatory / competent authorities / ethics committees

If scientific advice/protocol assistance from a competent/regulatory authority has been requested, please provide the full text answer of the authority or a comprehensive summary in this section of the document. If the answer is not available provide explanation of current status. Please also include in

[3] If the proposal contains more than one clinical study, each study should be described in its own main chapter (1.1, 1.2, 1.3…; 2.1, 2,2…; 3.1… etc.) as indicated in the example below.

this section any other relevant correspondence or minutes of meetings with regulatory authorities or ethics committees such as requested or granted approvals of clinical trial applications.

1.4 Subjects/population(s)

Definition of study population(s) by inclusion and exclusion criteria. Please discuss the potential inclusion of special populations, especially children and elderly (with defined relevant age groups). If there populations are excluded, please justify.

Definition of sub-populations if subgroup analysis is intended.

1.5 Statistic analysis

Definition and justification (power calculation) of sample size, definition of statistical methods and planning of statistical analysis.

1.6 Cumulative safety information

Concise presentation of relevant available information about safety and tolerability of study interventions: e.g. pre-clinical data from in-vitro or in-vivo studies; data from previous clinical studies; data from (pharmaco-)vigilance systems or other sources.

1.7 Conduct

Description of planned strategy for study management, recruitment strategy, monitoring, data management and (realistic!) planned schedule for study conduct (including provisions and timelines for ethics, further administrative approvals and date for 'First Patient, First Visit'). Please specify the trial sponsor (if applicable) and participating clinical centres. If a study medication is required, please provide information on whether manufacturing and/or labelling of the study medication is required and which plans are in place for this.

1.8 Orphan designation

If orphan designation has been granted provide the reference of the Commission Decision. If orphan designation has been requested but not granted, provide an update on the current status.

1.9 'Unit costs per patient' for clinical trials / studies / investigations

Commission Decision C(2014) 1393[4] *authorises the use of unit costs for clinical studies.* ***The use of unit costs is an alternative to the use of actual costs. Its use is voluntary, i.e. each beneficiary can decide whether to be reimbursed on the basis of unit costs or of actual costs for a given clinical study.*** *Beneficiaries can use different forms of reimbursement (unit costs or actual costs) for different clinical studies. Costs that are covered by unit costs cannot be declared as actual costs.* ***If no beneficiary intends to use unit costs, this section of the template does not need to be completed!***

When a beneficiary intends to use unit costs, the ***detailed and complete*** *calculation must be provided in Table(s) X.9 of this template (see below). The direct costs must be determined by estimating the*

[4] (http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf)

resources *used per task and per patient or subject and using its historical costs for these resources. The beneficiary must estimate the* resources *used specifically per patient for the conduct of the clinical study (i.e. personnel costs of doctors, other medical personnel and technical personnel; costs of medical equipment and costs of other service contracts) on the basis of the protocol for the clinical study. The resource estimate must be the same for all members of the consortium using unit costs in a particular study.*

The beneficiary must use as historical costs the costs recorded in its certified or auditable profit and loss accounts for year N-1 (last closed financial year at the time of submission of the grant application). The amount of unit costs per patient is fixed in the grant agreement for the entire duration of the project, without adjustment for inflation.

For detailed information please refer to Annex 1 of this document and/or to Commission Decision C(2014) 1393

The resources and costs identified will be evaluated by independent experts as part of the evaluation of the proposal.

If unit costs are to be used, the estimation of resources and historical costs must be provided in the following table as part of this document.

Text in blue fonts (examples) must be replaced by concrete estimations of resources and historical costs.

Table X.9: Unit cost declaration for (identifier, see 1.1)

Task, Direct cost categories	Resource per patient	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			
Task No. X *…*			
…			
Total amount:		*XX EUR*	*XX EUR*

[a]*Beneficiary, linked third parties or third parties contributing in kind to the clinical study: The estimated unit costs have to be presented per beneficiary, linked third party or third party contributing in kind to the clinical study. Please add columns for additional participants if needed.*

[b]*Costs incurred in another currency shall be converted into Euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), determined over the corresponding year N-1. If no daily Euro exchange rate is published in the Official Journal of the European Union for the currency in question, conversion shall be made at the average of the monthly accounting rates established by the Commission and published on its website (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), determined over the corresponding year N-1.*

Direct costs of activities carried out centrally by one (or a limited number of) beneficiary/ies for all patients/study subjects (or the patients/study subjects at several beneficiaries), such as a site monitoring or trial insurance should be reimbursed based on actual costs.

2 Clinical study No. 2 (if applicable)

2.1 Identifier

Title, short title or unique identifier.

etc.

3 Clinical study No. 3 (if applicable)

Etc.

Annex 1: Method to determine the unit costs

(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 subject*

*+ 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 subject*

*+ 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 subject}*

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 6.1.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 usual cost accounting practices, is not allowed.

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

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 subject

+ 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 subject

+ 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 subject

+ 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 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 6.1.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 subject

+ 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 subject

+ 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 subject

+ 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 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 6.1.A.1 of the model Horizon 2020 grant agreement)

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 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 subject

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

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

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

with

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

(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).