



The EU Framework Programme
for Research and Innovation

HORIZON 2020



H2020 Programme

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

Version 1.3
09 July 2018



History of changes

Version	Date	Change	Page
1.0 2018 callsV1 (based on 2017 callsV2)	18.10.2017	<ul style="list-style-type: none"> ▪ Introduction: Update on specific call topics and additional reference to section 3.4 or the proposal ('Resources to be committed') ▪ Sections 1.2.2: Additional references to patient priorities/preferences ▪ Section 1.3: Additional references regulatory requirements and procedures ▪ Various smaller edits 	
1.2	24.10.2017	<ul style="list-style-type: none"> ▪ Correction of footnote 	4
1.3	09.07.2018	<ul style="list-style-type: none"> ▪ Update of topics concerned 	1

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

Document history	
Version WP18-20 V1.3_20180709	09/07/2018
Modifications (compared to previous version WP18-20_V1.2_v20171024):	Update of topics concerned

This template only concerns you if your proposal contains a clinical trial/study/investigation/cohort! In the following, clinical trials/studies/investigations/cohorts 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.

Applicability:

For **Horizon 2020 collaborative research:**

Single-stage- and stage-2 proposals: The use of this template is mandatory for all clinical studies¹ included in a single-stage- or stage-2 proposal submitted to topics² SC1-BHC-02-2019, SC1-BHC-07-2019, SC1-BHC-14-2019, SC1-BHC-15-2018, SC1-BHC-22-2019, SC1-BHC-28-2019, SC1-BHC-30-2019, SC1-BHC-32-2019. 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. Depending on the characteristics of the study, however, key aspects of study design and conduct have to be convincingly addressed already at stage 1. This template cannot be uploaded as a separate document at stage 1, but relevant aspects of this information should be integrated in part B of the stage 1 proposal template.

For **IMI2:**

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 normally in section B.3.1. 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.

Single-stage and **stage-2** proposals: The use of this template is mandatory for all clinical studies. You can upload the completed template as a separate part of your application in the submission system.
Stage-1 proposals: see under Horizon 2020 collaborative research

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 template³. 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 prior studies) the source of this data and/or 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 for this template, but explanations should be as concise as possible.

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

Ethics considerations have to be addressed in the appropriate 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/IMI2 JU contribution significantly reduced should a study not proceed as planned.

Please include in section 3.4 of the proposal ('Resources to be committed') a concise cost estimation of the different tasks of the clinical study (unless you use the unit costs for clinical studies with the detailed table required in section 1.9 of this template).

Three **mandatory deliverables** have to be implemented in the proposal for each clinical study included in the proposal. Further information on the mandatory deliverables can be found in Annex 1.

1 Clinical study No. 1

1.1 Identifier

Title, short title or unique identifier.

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.

1.2 Study design and endpoints

1.2.1 Study design

Brief description of the objectives or hypotheses and concise description of the selected study design.

1.2.2 Primary and secondary endpoint(s)

Description of the primary and secondary endpoints/outcome measures (and how these relate to the objectives). For observational studies please refer also to other variables relevant to the study objectives, such as potential confounding variables and effect measure modifiers.

Explain how patient priorities / preferences have been or will be taken into account in the proposed study (e.g in relation to selection of design, endpoints, study populations etc.).

1.2.3 Relevant guidance documents

References to guidance documents relevant to the study, e.g. guidelines by/of

(a) Scientific societies and advisory bodies e.g. addressing:

- Best practice of treatments / standard-of-care*
- Good Clinical Practice ⁴*
- Good (Pharmaco)epidemiological Practice ⁵*

(b) Health Technology Assessment agencies / EUnetHTA

(c) Regulatory bodies (e.g. the European Medicines Agency, EMA⁶). For studies addressing development and/or optimisation of pharmacological therapies the following guidelines may have an impact on the later scientific/regulatory value and applicability of results:

- Clinical efficacy and safety guidelines for the evaluation of medicines in disease areas - e.g. diabetes (CPMP/EWP/1080/00 Rev. 1) or oncology (EMA/CHMP/EWP/205/95/Rev.4)*
- General guidelines e.g. addressing clinical pharmacology and pharmacokinetics (e.g. bioanalytical methods validation EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2 or pharmacokinetics in paediatric population EMEA/CHMP/EWP/147013/2004)*
- Methodological guidelines - e.g. statistical principles for clinical trials (CPMP/ICH/363/96) or clinical trials in small populations (CHMP/EWP/83561/2005)*

⁴ e.g. Good Clinical Practice Guidelines from ICH

⁵ e.g. *Guidelines for Good Pharmacoepidemiology Practices* from ISPE, *Good Practices for Outcomes Research* from ISPOR or *Good Epidemiological Practice* from IEA

⁶http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000043.jsp&mid=WC0b01ac05800240cb

1.3 Regulatory status and activities

1.3.1 Regulatory / ethics status

Clearly define the regulatory / ethics status and requirements for the study according to national and EU regulations.

Please specify if the clinical study falls under Directive 2001/20/EC (Clinical Trials Directive), Regulation EU No 536/2014 (Clinical Trials Regulation), Regulation EU No 2017/745 (Medical Device Regulation) or Regulation EU No 2017/746 (In-Vitro Diagnostic Medical Devices Regulation). Ensure that applicable requirements have been appropriately addressed.

Please include in this section any requested or granted approvals of clinical study applications or refer to the corresponding explanations in the Ethics Section of the proposal (Section 5).

Please include also any additional regulatory document (not addressed elsewhere in this template) relevant for the project, such as granted PIPs.

1.3.2 Scientific advice / protocol assistance

Summarise the activities planned in the context of regulatory scientific advice or protocol assistance⁷. If such advice/assistance from a competent/regulatory authority has already been requested, please provide a summary of the current status and – if available – the answer(s) of the authority (or a comprehensive summary).

1.3.3 Qualification advice

In the case of development of novel methodologies intended for use in the context of research and development of pharmaceuticals, please include a concise overview of the (planned) qualification advice⁸ (follow-up) activities (if any). If an answer(s) of the authority is already available, please include the answer(s) (or a comprehensive summary) in this section of the document.

1.4 Subjects/population(s)

Definition of study population(s) by inclusion and exclusion criteria. Please discuss appropriate inclusion of women and special populations, such as children and elderly (with defined age groups). If there are populations specifically excluded, please justify.

Definition of sub-populations if subgroup analysis is intended.

⁷http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_001883.jsp.

⁸ see 'Essential considerations for successful Qualification of Novel Methodologies' under:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_001883.jsp

1.5 Statistic analysis plan(ning) and power calculation

Definition and justification (power calculation) of sample size, definition of statistical methods and planning of statistical analysis (including stopping guidelines and/or procedures to control sources of bias and their influence on results, if relevant).

1.6 Cumulative safety and efficacy information

1.6.1 Cumulative safety information

Concise information on 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.

1.6.2 Cumulative efficacy information

Concise information on efficacy of study interventions based on (pre-)clinical data.

1.7 Conduct

1.7.1 Schedule for study conduct including timelines for key study milestones⁹

In this section, include a (realistic!) planning of the schedule for the study conduct, including provisions and timelines for ethics and other administrative approvals. As a minimum, include realistic planning and timing for the key study milestones below. Dates for key study milestones are defined relative to the starting date of the project (i.e. month 1, month 6 etc.):

- *First Patient (or study subject), First Visit (FPFV):*
- *Last Patient (or study subject), First Visit:*
- *Last Patient (or study subject), Last Visit:*
- *End of Study (including follow-up and data analysis):*

1.7.2 Description of recruitment strategy

Description of the recruitment strategy, including realistic estimates of the expected recruitment rate (subjects per month/per centre) based on available data.

Ensure that efficient contingency measures are included so that any potential delays during the recruitment phase can be compensated.

1.7.3 Description and assignment of intervention

Please describe the intervention(s) tested and methods for allocation and blinding.

1.7.4 Study management, study monitoring, data and sample management

Please include a description of

- *Planned strategy for study / trial management,*

⁹ Key study milestones will be scrutinised during the time course of the project. Significantly delayed key study milestones (e.g. FPFV) might lead to the termination of the grant agreement.

- *Study monitoring plan (monitoring visits, level of source data verification, etc.)*
- *Adverse event reporting*
- *Data collection and management (including mechanisms to ensure data quality, completeness and integrity)*
- *Sample management*

1.7.5 Sponsor, coordinating centre(s) and committees

Please specify the trial sponsor. Specify the role of the coordinating centre(s) and different committees (e.g. Data Safety Monitoring Board, Independent Data Monitoring Committee, etc.).

1.7.6 Study medication

If a study medication (investigational and non investigational medicinal products) is required, please provide information on whether manufacturing and / or labelling of the study medication is required and which plans and / or commitments are in place for this.

1.7.7 Clinical centres

Specification of criteria for site selection and indicative list of clinical centres / recruitment centres planned to be involved in the clinical study.

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\(2016\) 7553](http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit_costs_clinical_studies.pdf)¹⁰ 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 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.*

¹⁰ (http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit_costs_clinical_studies.pdf)

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(2016) 7553

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 font (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			
<i>Blood sample</i>			
<i>(a) Personnel costs: - Doctors</i>			
<i>- Other Medical Personnel</i>	<i>Phlebotomy (nurse), 10 minutes</i>	<i>8,33 EUR^b</i>	<i>11,59 EUR^b</i>
<i>- Technical Personnel</i>	<i>Sample Processing (lab technician), 15 minutes</i>	<i>9,51 EUR^b</i>	<i>15,68 EUR^b</i>
<i>(b) Costs of consumables:</i>	<i>Syringe</i>	<i>XX EUR</i>	<i>XX EUR</i>
	<i>Cannula</i>	<i>XX EUR</i>	<i>XX EUR</i>
	<i>Blood container</i>	<i>XX EUR</i>	<i>XX EUR</i>
<i>(c) Costs of the medical equipment:</i>	<i>Use of -80° deep freezer, 60 days</i>	<i>XX EUR</i>	<i>XX EUR</i>
<i>....</i>	<i>Use of centrifuge, 15 minutes</i>	<i>XX EUR</i>	<i>XX EUR</i>
<i>(d) Services</i>			
Task No. X			

...			
...			
<i>Total amount:</i>		<i>XX EUR</i>	<i>XX EUR</i>

^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: Mandatory deliverables for clinical studies

For each clinical study, the following mandatory deliverables (with the indicated title and scope as defined) have to be included in the proposal:

1. 'First study subject approvals package'

(prior to enrolment of first study subject):

- a. Final version of study protocol as approved by first regulator / ethics committee(s) (no need to change deliverable if later amendments)
- b. Registration number of clinical study in a WHO- or ICMJE- approved registry that also allows later posting of study results.

- c. Approvals required for invitation / enrolment of **first** subject in at least one clinical centre (if applicable): ethics committees, national competent authorities and copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority. If the position of a Data Protection Officer is established, its opinion/confirmation that all data collection and processing will be carried out according to EU and national legislation

2. 'Midterm recruitment report'

Deliverable to be scheduled for the time point when 50% of the study population is expected to have been recruited. The report shall include an overview of recruited subjects by study site, potential recruiting problems and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment.

3. 'Report on status of posting results'¹¹

Report on the status of posting results in the study registry/ies (including timelines when final posting of results is scheduled after end of funding period). To be scheduled for the time of expected results posting or for the last months of the project, whichever comes earlier.

¹¹ Please note the obligation to post results in the registry within 12 months of primary study completion in line with the WHO 'Joint Statement on public disclosure of results from clinical trials' (<http://www.who.int/ictrp/results/jointstatement/en/>)