

INFORMATION ON CLINICAL STUDIES

For calls that involve clinical studies¹, project participants must add this document to the application and upload it as separate annex to the proposal part B in the Submission System.

Clinical studies have a number of methodological, operational and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality and operational feasibility of the proposal. The following set of section headings guide applicants to provide essential information on clinical studies in a standardised format.

Applicability:

For **Horizon Europe collaborative research and innovation:**

Single-stage and stage-2 proposals: The use of this template is mandatory for single-stage or stage-2 proposals, if the application includes a clinical study¹ AND it concerns a topic including clinical studies².

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 clinical study 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 **IHI:**

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 Europe collaborative research and innovation

For each³ clinical study performed within the scope of the proposal, essential information according to the below structure should be provided and compiled into one single document per proposal. Each section must be addressed briefly and concisely. In case one or more sections do not apply to a particular study, please provide a short explanation.

When the requested information is currently not available (e.g. a clinical study is planned for a later stage of the project and it will be based on or influenced by future results of other studies), the source and the collection of the relevant input 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.

¹ Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

² For proposals containing clinical studies submitted to topics *not* foreseeing clinical studies, you may use the section headings of this template as an orientation and provide the related information in sections B.1 and B.3 of the proposal, if the submission system does not provide the possibility to upload the template.

³ If the proposal contains more than one clinical study, each study should be described separately, e.g. study A, study B, etc.

Information outside the scope of this template will not be taken into 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 mitigation measures have to be addressed in the respective section of the proposal (part B.3.1 and table 3.1e) and not in this template!

The below three **mandatory deliverables** apply to each clinical study included in the proposal:

1. Study initiation package (before enrolment of the first study participant) including:
 - Registration number of the clinical study in a registry meeting WHO Registry criteria⁴ (see also references given in subheading 1.1 of this template)
 - Final version of study protocol as approved by the regulator(s) / ethics committee(s)
 - Regulatory and ethics (if applicable, institutional) approvals required for the enrolment of the first study participant (In case of multicentre clinical studies, submission of approvals for the first clinical site is sufficient.)

2. Midterm recruitment report

This report is due when 50% of the study population is recruited. The report shall include an overview of the number of recruited participants by clinical sites, any problems in recruitment and, if applicable, a detailed description of implemented and planned measures to compensate for any incurred delays.

3. Report on the status of posting results

Irrespective of the successful completion of the clinical study, summary results must be posted in the applicable registry/ies (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

⁴ <https://www.who.int/clinical-trials-registry-platform/network/registry-criteria>

1 Description of the clinical study

- 1.1 Title, acronym, unique identifier (e.g. EudraCT Number⁵, or identifier from ISCRTN⁶, ClinicalTrials.gov⁷ if available) of the clinical study

[insert text]

- 1.2 Study rationale

Please provide the overall rationale for conducting the proposed study.

[insert text]

- 1.2.1 Extent and evaluation of current knowledge directly linked to the scientific question(s) to be answered by the clinical study

[insert text]

- 1.2.1.1 Outcomes (efficacy, safety) of completed and number of ongoing clinical studies utilising the same intervention in the same indication (including review of public registers)

[insert text]

- 1.2.1.2 Level of evidence related to the mechanism of action of the intervention in the planned clinical study population

[insert text]

- 1.3 Objective(s) of the clinical study

Please differentiate between primary and secondary objective(s)

[insert text]

- 1.4 Characteristics of the study population (size, age group, sex distribution, inclusion and exclusion criteria; all items with justification!)

[insert text]

- 1.4.1 Details on sample size and power calculation

[insert text]

- 1.5 Design of the clinical study (controlled / uncontrolled; randomised; open / blinded; parallel group / cross over / other; please justify the appropriateness of the selected design)

[insert text]

- 1.6 Type of intervention (medicinal product / advanced therapy medicinal product / medical device / in vitro diagnostic medical device / surgical or other invasive procedure / other medical intervention, including, e.g., counselling)

[insert text]

- 1.7 Description and timing of study procedures

Please provide an overview, preferably in a tabular format, about the schedule of study procedures. Please give a simple statement on how long individual patients or healthy volunteers participate in the clinical study.

⁵ <https://www.clinicaltrialsregister.eu/>

⁶ <https://www.isrctn.com/>

⁷ <https://clinicaltrials.gov/>

[insert text]

2 Preparedness status

2.1 Development of the clinical study protocol

Please describe how the below aspects have been or will be addressed in developing the clinical study protocol (if applicable):

2.1.1 Scientific advice from regulatory and health technology assessment bodies

[insert text]

2.1.2 Clinical efficacy, safety, and methodological guidelines (including guidelines on statistics)

[insert text]

2.1.3 Involvement of citizens / patients, carers in drawing up the clinical study protocol

[insert text]

2.2 Regulatory intelligence to ensure timely regulatory approval and ethics clearance of the clinical study in all jurisdictions where its implementation is planned

Please provide information on the following regulatory and ethics aspects:

2.2.1 How the consortium will ensure access to regulatory expertise necessary to get advice on, and management of, regulatory affairs activities in all concerned jurisdictions?

[insert text]

2.2.2 How the consortium will ensure access to ethics expertise necessary to get advice on current proceedings and documentation requirements of all concerned ethics committees?

[insert text]

2.3 How the scientific and operational governance of the clinical study will be ensured?

2.3.1 Please give details about the sponsor(s) (name, type of entity, seat or country of residence).

[insert text]

2.3.2 Please describe the composition, the role and the functioning of the planned board(s), governing bodies.

[insert text]

3 Operational feasibility

3.1 Please describe how the availability of the intervention(s) (including comparators) is secured throughout the entire implementation phase (give details on manufacturing, packaging / labelling operations, storage, logistical, import/export issues, etc.)

[insert text]

3.2 Please describe how the study population will be recruited

Please give details on the recruitment strategy, monitoring of progress and potential mitigation measures

[insert text]

- 3.2.1 How many clinical sites will contribute to the recruitment of the study population in which countries? Are these clinical sites part of an established clinical trial network? Please also describe the selection criteria of the clinical sites.

[insert text]

- 3.2.2 Will recruitment of the study population be of competitive nature between the clinical sites? (Please describe how underperformance of individual clinical sites in recruitment will be managed.)

[insert text]

- 3.2.3 What evidence supports the ability of the individual clinical sites to recruit the required number of study participants within the planned timeline (e.g. documented performance in previous clinical studies of similar complexity targeting very similar study population)?

[insert text]

- 3.3 Please describe what additional supply (e.g. an electronic device for remote data capture, a specific instrument for administering the investigational product, etc.) is necessary to carry out the required study procedures and how this supply will be made available to the clinical sites

[insert text]

- 3.4 Please provide plans on data management aspects (data standards, type of data capture, verification of data, central data collection, cleaning, analysis, reporting, security)

[insert text]

- 3.5 Please give details on how reporting obligations (regarding study initiation, safety of study participants, ethical concerns, quality issues, integrity of data, study results) to regulatory bodies and ethics committees will be met.

[insert text]

- 3.6 Please list all items of the sponsor's responsibilities (e.g. monitoring clinical sites, meeting regulatory obligations, data management, etc.) that will be supported by entities that are not part of the sponsor's organisation. Please describe how the sponsor will ensure oversight of these activities.

[insert text]

- 3.7 What are the plans for major study milestones and what evidence supports its feasibility?

Please describe a realistic plan (based on prior experience) detailing the time necessary for (i) compiling the required regulatory and ethics submission package, (ii) receipt of regulatory and ethics approval, (iii) initiation of clinical site(s), (iv) completion of recruitment of the study population, (v) final assessment of all study participants, (vi) analysis and reporting of the study results.

[insert text]

HISTORY OF CHANGES		
VERSION	PUBLICATION DATE	CHANGE
1.0	24.03.2021	Initial version (included in the standard HE proposal template)
1.1	08.04.2021	Reference to 'sex distribution' added in section 1.4.
2.0	13.10.2021	Standalone template document.
3.0	15.01.2022	Reformatting changes and change of document name.
4.0	24.03.2022	Removed reference to specific topics for a more generalised template