



EDCTP

European & Developing Countries
Clinical Trials Partnership

Essential information for EDCTP2 proposals involving clinical trials and diagnostics studies



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Document history		
Version	Date	Changes
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Template for essential information to be provided for proposals including clinical trials and diagnostic studies

Clinical trials and diagnostic studies have a number of methodological and regulatory specificities. Information on these issues is crucial for expert reviewers to assess the scientific quality of the proposal. The following guidance should help applicants to provide this essential information on clinical trials and diagnostic studies in a standardised format. If any of this information is already presented in the main body text of the online full application, please copy and paste it in the relevant section below.

Stage one of a two-stage submission process (Letters of intent)

For letters of intent, the annex 'Template for essential information to be provided for proposals including clinical trials and diagnostic studies' **cannot** be uploaded as a separate annex. Therefore, the relevant aspects of this information must be provided in the main proposal. Not all methodological details of clinical trials can be described fully in the letter of intent. The individual characteristics of your trial/study/investigation will determine which aspects you will describe and in what level of detail. Nevertheless, the points listed below might serve as an orientation also for the information you provide in the letter of intent.

Single-stage and stage two of a two-stage submission process (Full proposals)

The use of this template is **mandatory** for all clinical trials and diagnostic studies included in a full proposal submitted to EDCTP2. Please complete this template for each clinical trial or diagnostic study to be conducted. 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 or modified sections can be included.

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.

EDCTP proposal number

Please provide the EDCTP proposal number associated with this clinical trial.

[Add text here]

Full title of trial and acronym

Descriptive title that reflects the main objective of the clinical trial and an acronym for easy reference to the trial without using its full title. Please note that if you are proposing more than one clinical trial in your grant application, each clinical trial should have a unique acronym.



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[Add text here]

Purpose and objective(s)

Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.

[Add text here]

Trial design

Please address the following:

- *Study phase and classification*
- *Number of arms*
- *Method of allocation (e.g., randomised/non-randomised). Provide details on the randomisation method to be used, if applicable. If stratification or minimisation are to be used, give reasons and factors to be included.*
- *Describe the proposed methods for protecting against source bias (e.g. blinding or masking). If these methods are not possible, please explain why and give details of alternative methods proposed or implications for the interpretation of the trial's results.*
- *Specific details of the intervention(s) in the experimental arm(s) and control arms(s), including where the control is 'standard care'.*

[Add text here]

Primary outcome measures

Provide details of the primary outcome measures.

[Add text here]

Secondary outcome measures

Provide details of the secondary outcome measures.

[Add text here]

Study duration

Provide the total duration of the proposed clinical trial, and the estimated trial start and completion dates for each period in the trial (e.g. recruitment, intervention, follow-up).

[Add text here]



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Product(s) to be tested and supply

Please describe all the products to be used in the proposed clinical trial, including controls. Specify for each product whether it is still under development or whether it has been approved for use/registered in the countries where the trial will take place.

[Add text here]

Additionally, detail the arrangements for the supply of the products to be used in this trial, for both experimental and control arms, including:

- If applicable, whether manufacture and/or labelling of the product is required and who is responsible for manufacturing and/or labelling the product, and when this will be achieved?
- Guarantee of good manufacturing practice (GMP)-compliant investigational product(s)
- Details of any agreements made with companies or other organisations for supply of the products (experimental and control). Please indicate whether signed agreements/guarantees have already been obtained for supply of the products to be tested.

[Add text here]

Study population

Describe the proposed study population and rationale. List any planned inclusion and exclusion criteria for the study population. If applicable, define sub-populations if subgroup analysis is intended.

[Add text here]

Proposed sample size

Provide the proposed total sample size, including breakdowns for both control and treatment groups.

Additionally, provide a justification for this sample size, addressing the following:

- Brief description of the power calculations detailing the outcome measures on which these have been based (means, medians, event rates, etc., as appropriate), as well as any assumptions made underlying the power calculation and justification for these assumptions
- Size of difference that trial is designed to detect, and justification for this threshold
- How the sample size takes into account anticipated rates of non-compliance and loss to follow-up.

[Add text here]

Data management and analyses plan

Provide details on how the data of the trial will be managed and how results of this study will be analyzed, including the use of statistical or mathematical models.

[Add text here]



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Recruitment and retention

Give details of the planned recruitment rate, including the likely rate of loss to follow-up and potential problems with compliance by addressing the following:

- *How the recruitment will be organised*
- *Evidence that the planned recruitment rate is achievable*
- *Evidence on the likely rate of loss to follow-up*
- *Potential problems with compliance, including evidence for the compliance figures.*

References supporting these details should be included in the reference section at the end of this template.

[Add text here]

Trial site selection

Provide the rationale with supporting evidence for the selection of the trial sites, including factors such as prevalence of disease(s) being studied, the availability of appropriate study population, existing collaborations and/or established clinical trial infrastructure. References supporting these details should be included in the reference section at the end of this template.

[Add text here]

Patient and/or community involvement

Detail the involvement from patient and/or community groups in the development of the trial design and ongoing involvement in the trial.

[Add text here]

Clinical Trial Sponsor

Provide the name of the legal entity that will act as the clinical sponsor for this clinical trial. Provide details (trial registrations) of up to three recent clinical trials where the legal entity was the clinical sponsor.

[Add text here]

Ethical and regulatory approval

What is the ethical and/or regulatory approval process for this clinical trial? Please indicate which institution(s) or board(s) will undertake the review and give provisional timelines. 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 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.

[Add text here]



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Clinical Trial Registration

It is mandatory that all clinical trials supported by EDCTP are registered in a primary registry in the [WHO International Registry Network](#) or in [ClinicalTrials.gov](#) which is a data provider to the [WHO International Clinical Trials Registry Platform](#). Such registries meet internationally agreed criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. These primary registries also meet the requirements of the [ICMJE](#). Please indicate where you intend to register the trial.

[Add text here]

Trial safety

Give details of any risks to the safety of the subjects enrolled in the trial and staff conducting the trial and efforts taken to minimise these risks.

[Add text here]

Trial management

Give an overview of day-to-day management of the clinical trial. Justify why the structure and decision-making mechanisms are appropriate to the scale and complexity of the clinical trial. Please give details of the proposed composition of membership (number of members, expertise, names if known) of the trial steering committee and/or Data Safety Management Board.

[Add text here]

Trial monitoring and quality control

Provide the details of the monitoring plan during the clinical trial and justification for the proposed frequency of monitoring visits. Provide details on any additional quality control measures undertaken during the trial.

[Add text here]

References

Provide a list of all references cited.

[Add text here]