**Template for essential information to be provided for proposals that include clinical trials and public health intervention studies, as well as other types of clinical studies and investigations, including cohort studies**

|  |
| --- |
| **Document history** |
| **Version** | **Date** | **Changes** |
| 2 | 28-06-2017 | Template used for calls from the 2017 workplan |
| 3 | 25-05-2018 | * Updated for 2018 work plan in line with H2020 updates
* Updated description of types of studies this template should be used for
* Addition of notes on completing the template
* Addition of mandatory deliverables (Annex 1)
 |

This template **must be completed** and uploaded as annex for the following types of studies:

1. **Clinical trials and clinical intervention studies**: studies which meet the broad definition used by the World Health Organization (WHO) for a clinical trial1, which includes all studies evaluating the impact of interventions on human participants: “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”

Interventions may include drugs, vaccines, cells and other biological products, surgical procedures, radiological procedures, devices including diagnostic devices, behavioural treatments, process-of-care changes, preventive care, or other treatments. Clinical trials at all stages, from Phase 1 to Phase 4 and global health trials, are included in this policy.

2. **Public health intervention studies**: studies in which there is a public health intervention to promote or protect health, or prevent ill-health, in communities or populations rather than individuals.

3. **Observational studies**: studies in which the researcher assesses outcomes in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle or behaviours, or interventions that are part of routine care and not influenced by the researcher.

**The template does not apply to studies on previously collected human tissues and samples.**

**Please complete this template for each study to be conducted.**

**Notes on completing this template**

The template is mandatory for second stage and single stage proposals submitted to EDCTP2 that include clinical trials and clinical intervention studies; public health intervention studies and observational studies. These studies have a number of methodological and regulatory specificities. Information on these issues is crucial for reviewers to assess the scientific quality of the proposal. The following guidance should help applicants to provide this essential information on 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 into the relevant sections below. Note the following:

* Each section must be shortly and concisely described.
* Do not change the section headings and do not provide other information outside of the scope of this template.
* In case one or more issues do not apply to a particular study, please give a brief explanation/justification.
* 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 the data and/or the applied methodology should be described.
* Ethics considerations should be addressed in the main proposal (Ethics Issues table and Ethics self-assessment).
* Risks and contingency plans should be addressed in the main proposal
* Budget justification (costs of different tasks of the study) should be addressed in the main proposal.

Three mandatory deliverables must be included in the main proposal for each clinical study. These are listed in Annex 1 of this template.

## EDCTP grant application number

Please provide the EDCTP grant application number associated with this clinical study.

[Add text here]

## Full title of study and acronym

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

[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]

## Study design

Please address the following:

* Type of study (e.g. interventional, observational)
* 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 study’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 and secondary outcome measures

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

[Add text here]

## Schedule for study conduct including timelines for key study milestones

Provide details of the total duration of the proposed clinical study, and a realistic schedule of the study conduct (start date and completion dates for each period in the study such as timeline for ethics and regulatory approval, drug/device importation ( if applicable) , recruitment, intervention follow-up, as well as s. 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:

* Planned Interim analyses (if any)
* Planned 25%, 50%, 75% patient/subject enrollment
* Final database lock
* Study analysis
* Availability of final study report

• Study closure (ie. last patient off study and study documents are archive ready)

[Add text here]

## Product(s) to be tested and supply (where applicable)

Please complete the table below, describing all of the products to be used in the clinical study, including controls/comparators). Specify for each product whether it is still under development or whether it has been approved for use/registered for the indication under study in the countries where the study will take place. Give details and assurance of the arrangements for the supply and availability of the products to be used in this study, for both experimental and control arms, including:

* Who is responsible for manufacturing and/or labelling the product (if applicable) 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.

|  |  |  |
| --- | --- | --- |
| **Product name** | **Manufacturer** | **Details of product (approved for use/under development), GMP guarantee, supply and availability – see details above)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

[Add text here]

## Study population

Describe the proposed study population(s) by inclusion and exclusion criteria. 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. Define sub-populations if subgroup analysis is intended.

[Add text here]

## Statistical analysis plan(ning) and power calculation (sample size)

Definition and justification (power calculation) of sample size (including breakdowns for the control and intervention groups), 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).

Ensure that the following points are addressed:

* 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 study 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

How results of this study will be analysed, including the use of statistical or mathematical models

[Add text here]

## Recruitment strategy and retention

Give details of the planned recruitment rate (subjects per month/per centre), 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]

## Recruitment site selection

Specify the countries involved, the criteria for site selection and indicative list of the recruitment sites planned to be involved in the study. Provide the rationale with supporting evidence for the selection of the countries and study sites, including factors such as prevalence of disease(s) being studied, the availability of appropriate study population, existing collaborations and/or established clinical study 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 study design and ongoing involvement in the study, describing how your proposal fulfils good participatory practice guidelines.

[Add text here]

## Clinical Study Sponsor

Provide the name of the legal entity that will act as the clinical sponsor for this study. Provide details (trial registration numbers) of up to three recent clinical studies 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 study? Please indicate which institution(s) or board(s) will undertake the review and give provisional timelines. Where there have been formal discussions/communication with regulatory or ethics authorities about the study, please give full details of the discussions and a summary of any recommendations or advice from the regulators (such as the European Medicines Agency, US Food & Drug Administration) or ethics authorities. All clinical trials testing investigational new products must provide full details of their contact with regulators.

[Add text here]

## Clinical Study Registration

Registration of EDCTP-funded clinical studies is mandatory. Studies must be registered in a primary registry in the [WHO International Registry Network](http://www.who.int/ictrp/network/primary/en/) or [ICMJE approved registry](http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/) prior to recruitment of the first subject. EDCTP also expects that summary results of clinical studies will be posted to the results section of the clinical study registry within 12 months of primary study completion (last visit of last subject for data collection on the primary outcome). Please indicate where you intend to register the study.

[Add text here]

## Study safety

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

[Add text here]

## Study management

Give an overview of day-to-day management of the clinical study. Justify why the structure and decision-making mechanisms are appropriate to the scale and complexity of the study. Please give details of the proposed composition of membership (number of members, expertise, names and affiliations if known) of the Trial Steering Committee (which must include independent members and an independent Chair) and the Data Safety Management Board.

[Add text here]

## Study monitoring and quality control

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

[Add text here]

## References

List all references cited.

[Add text here]

## 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):

1. Final version of study protocol as approved by first regulator / ethics committee(s).
2. There is no need to change deliverables unless there are major amendments that change the study design, patient population, risk- benefit profile, sample size, study medications/ devices, original treatment plan or allocation; or study interruption due to unforeseen circumstances.

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

Applicants should also include an **All approvals package** as a deliverable where this is applicable (eg. multi-country studies).

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'

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.