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EDCTP

European & Developing Countries
Clinical Trials Partnership

Guidance for applicants on preparing full proposals (stage 2) and annex 1 of the grant agreement

History of changes

Version	Date	Changes
2	31 January 2019	First version

For more information, please go to the EDCTP website: www.edctp.org

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1. Introduction

EDCTP2 calls for proposals are run as single-stage (full proposals) or two-stage (letters of intent and full proposals) procedures. Following evaluation, proposals are ranked and selected for funding. Successful applicants are 'invited to grant preparation' and the submitted proposal becomes the Annex 1 (also known as the Description of the Action – DoA) to the EDCTP2 mono- or multi-beneficiary grant agreement, or the mono-beneficiary grant agreement with options for fellowships which is used for Training and Mobility Actions.
This document provides guidance to applicants preparing full proposals for submission and to successful applicants preparing Annex 1 of the grant agreement.

Disclaimer: This guidance document is for information only and does not constitute a legally binding document. The legal basis for information in this document can be found in the Horizon 2020 Rules for Participation and the EDCTP Annual Work Plans

2. Excellence

2.1 Eligibility considerations

When preparing your proposal, refer to the call text and the evaluation criteria in order to make sure that:

- The proposal fits the call and type of action
- The applicant(s) are eligible and the application complies with all of the eligibility criteria
- The total budget requested (total of direct + indirect costs) is within the maximum amount for proposals stated in the call
- All of the requested information is included in your proposal.

Your proposal will be considered ineligible and/or inadmissible if it fails on any one of the above four points. It will not normally go to external evaluation and it will be rejected. You will be notified of the decision on eligibility/admissibility only once the evaluation procedure has been completed.

The first evaluation criterion considered by the reviewers under Excellence is **Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description**. You must make sure that you are applying for the right grant and that your proposal fits the call topic. There are three different EDCTP2 grant types that support different types of studies:

Research and Innovation Actions (RIAs) support clinical research studies and clinical trials therefore proposals must include the clinical studies template(s) as a document upload

Coordination and Support Actions (CSAs) support non-research activities such as: i) activities to develop, strengthen and extend clinical research capacities in sub-Saharan Africa, ii) activities to promote networking and collaboration both between European and African researchers and among African researchers, clinical research institutions and sites, as well as iii) activities to foster coordination and cooperation between public and private funders.do not support SAs or clinical trials. Clinical studies and trials should not be conducted under CSA grants.

Training and Mobility Actions (TMAs) support the career development of individual fellows working in sub-Saharan Africa through training and mentorship of researchers, as well as promoting mobility of individual researchers and research staff. Small-scale clinical research studies may be conducted as part of the TMA. Fellows must make sure that they include the clinical studies template where they intend to conduct a clinical study. If this is not included, the proposal may be inadmissible.

The online application form in EDCTPgrants has a simple checking function to help applicants prepare their applications. The form has mandatory fields that must be filled in. However, you should not rely only on this system feature to ensure your eligibility/admissibility.

2.2 Clinical studies template

If you are conducting a clinical study (or studies) as part of the project, then you must upload the clinical studies template for each study to be conducted, as part of the Excellence section of the proposal.
Please check the broad definition of a clinical study below before you answer YES or NO to the question- Do you intend to conduct a clinical study within this project?

Clinical trials and clinical intervention studies: studies which meet the broad definition used by the World Health Organization (WHO) for a clinical trial (http://www.who.int/topics/clinical_trials/en/), 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.

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.

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.

If you answer NO to this question and do not upload the template but EDCTP considers that your proposal does include a clinical study that fits the above definition, then your application may be judged inadmissible and be rejected. This template must be uploaded for RIAs and for all TMAs which include clinical studies.

3. Impact

3.1 Dissemination and exploitation of results

Section 3 (Articles 23 to 31) of the EDCTP2 grant agreement describes the beneficiaries' rights and obligations related to background and results, with Article 28 referring to Exploitation of Results and Article 29 referring to Dissemination of Results – open access – visibility of EDCTP2 funding. All proposals must provide a draft plan (details) for the exploitation and dissemination of the results in the relevant section of the proposal. This is a requirement for admissibility. A Dissemination and Exploitation Plan must be included as a project deliverable in the deliverables and milestones section (see section 4.3 of this document for more information on deliverables and milestones). For applicants developing products and other interventions, access should also be considered and discussed under the Impact section.

3.1.1 Publications: open access and acknowledging EDCTP

The EDCTP2 programme is funded under H2020 and is committed to open access. Open access refers to the practice of providing access to scientific information that is free of charge to the end-user and reusable. This encompasses:

- Peer-reviewed scientific research articles (published in scholarly journals)
- Research data (data underlying publications, curated data and/or raw data) – see section 3.3

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results. Therefore, please ensure that the Impact section provides information on the expected publications, confirmation that publications will be **open access** and details of the mechanism of open access (green: self-archiving or gold: immediate open access publication). For more details see the H2020 guide on Open Access.

Beneficiaries have a contractual obligation to acknowledge funding by EDCTP and the European Union (EU) in all dissemination activities and publications that arise from activities funded wholly or partly by EDCTP and EU. More details can be found in Acknowledging EDCTP: A guide for grantees.

3.1.2 Registration and reporting of clinical trials and clinical studies

EDCTP is a signatory to the Joint statement on public disclosure of results from clinical trials, an initiative by the World Health Organisation to ensure prospective registration and timely public disclosure of results from clinical trials. Beneficiaries of EDCTP2 grants must comply with the joint statement and with the EDCTP2 policy on clinical trials registration, publication and data sharing. Proposals involving clinical studies must include specific deliverables and milestones (for more details see section 4.3.2.1 and 4.3.2.2 of this document).

3.2 Participation in the EDCTP Forum

EDCTP organises a biennial conference (EDCTP Forum) in Africa or Europe. EDCTP2 grant holders are expected to participate in the Forum and to present the results of their EDCTP project(s). Applicants should ensure that they allocate funding in their grant budget to cover the costs of their participation in the Forum. Applicants for EDCTP2 Fellowships should also allocate funds in their grant budget to cover the costs of participating in the EDCTP Alumni Network meetings which are held at the EDCTP Forum, normally the day before the Forum. Participation at the Forum should be added as a deliverable (see section 4.3.1.4)

3.3 Open research data: data management and sharing

EDCTP grant holders will engage in research data sharing, according to Article 29.3 of the EDCTP2 grant agreement. This means that beneficiaries must deposit and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate, free of charge for any user: (1) data needed to validate the results presented in scientific publications ('underlying data'); and (2) other data as specified by the beneficiaries in their Data Management Plan (DMP). Details about the repository, including its security, and access rights must be given in the DMP.

Details of the DMP must be provided in the relevant section of the proposal. A DMP is a mandatory deliverable (to be produced within 6 months). A template DMP is available in the H2020 online manual. Applicants that opt out of open access to research data must provide valid grounds and justification for the opt-out but should still include a DMP as a deliverable. Valid reasons for opting out of data sharing may include:

- Incompatibility with the EDCTP2 obligation to protect results that are expected to be commercially or industrially exploited
- Incompatibility with the need for confidentiality in connection with security issues
- Incompatibility with rules on protecting personal data
- Incompatibility with the project's main aim
- If the project will not generate / collect any research data
- If there are other legitimate reasons not to provide open access to research data

3.4 Communications activities

Applicants must take measures to promote the project and its findings during the period of the grant. A project website (or project-specific web pages) should be constructed. This must be included as a deliverable in the proposal. Funds for this activity should be allocated in the grant budget. The website must acknowledge the support of EDCTP and the EU, as per the guide Acknowledging EDCTP: A guide for grantees. In addition to a personal webpage on their institution's website with details of their fellowship, EDCTP2 Fellows must create and maintain a profile on the EDCTP Alumni Network Platform.

4. Implementation

4.1 Participants

EDCTP2 proposals should only include organisations (**legal entities**) that have:

- given their explicit consent concerning their participation
- confirmed their financial and operational capacity to carry out the proposed action
- confirmed their commitment to be jointly and severally liable for the technical implementation of the action (see Article 41.1 of the general EDCTP2 multi-beneficiary grant agreement) such that they will sign the Accession forms to the grant agreement.

The composition of the consortium cannot normally be changed during the grant preparation phase, and therefore participants (**the individuals and their organisations**) must be committed from the point of submission of the proposal. It is also important to make sure that the organisations are eligible to receive funding from EDCTP2 or are committed to participate as a beneficiary not receiving funds.

Please make sure of the following before you apply and at the grant preparation stage:

- The individuals (coordinator and co-applicants) have the explicit permission and agreement of their organisation (legal entity) to participate in the EDCTP2 proposal (and grant)
- The consortium meets the minimum eligibility criteria for the call
- The organisations requesting funding are all eligible to receive funding under EDCTP2 or if not eligible, are not seeking funding but are committed to sign the grant agreement and to be jointly and severally liable for the implementation of the action
- The correct H2020 type of organisation is selected for each organisation
- The individuals (coordinator and co-applicants) are employed by the respective organisations (legal entities) that will sign the grant agreement and accession forms
- The individuals are registered in the EDCTPgrants system using the same affiliation as the legal entity that will sign the grant agreement
- Include only one individual per organisation in the proposal. This individual will represent the organisation in the consortium. Other individuals within the same organisation may be mentioned in the body of the proposal under work packages, consortium and risk management, etc.
- All individuals and organisations (legal entities) included in the proposal have a **clear, well-described role** in the project.

Please avoid the following:

- Inclusion of a large number of individuals ('big names') and organisations in the proposal when these individuals and organisations have no clear or substantive role in the proposal
- Inclusion of individuals and organisations that are not fully committed to sign the grant agreement
- Requesting funding for organisations that are not eligible to receive EDCTP2 funding – check your eligibility to receive funds before applying.

If your proposal is selected for funding, alterations to the consortium are allowed only under exceptional circumstances, such as one of the organisations has gone bankrupt. If there are (substantial) changes to the organisations during grant preparation (i.e. organisations indicated in the proposal drop out prior to the grant agreement) then your proposal may be rejected on the basis that it is not the same as the proposal that was evaluated by EDCTP or it may be re-evaluated.

4.2 Work packages

Each work package should have a summary description with the main tasks indicated and the responsible partners. The main tasks may result in deliverables, which are specified later in the proposal, and may feature in the Gantt chart to be uploaded with the proposal. Applicants should estimate the cost of each work package.

4.2.1 Number of work packages

All projects differ and so it is impossible to provide set rules about the number and types of work packages that should be included in the proposal/Annex 1. The number of work packages should be proportionate to the scale and complexity of the project. One work package is probably not sufficient, even for small projects, and 10 work packages is probably too many, even for complex projects. Most EDCTP2 proposals have between 3 and 6 work packages in our experience, but applicants must judge for themselves how best to organise the proposal and its work packages. The guidance below provides suggestions and ideas to organise proposals into logical, relevant work packages. During the grant preparation phase EDCTP may request consolidation or addition of work packages in order to ensure that the project activities can be monitored appropriately.

4.2.2 Work packages relevant to EDCTP2 projects

The following examples of work packages should be considered by applicants as part of their proposal.

4.2.2.1 Clinical study

This work package is applicable to RIAs and to some TMAs. Normally, each clinical study included in the proposal should be a work package. Therefore, if a proposal has five clinical studies then there should be five separate work packages, one devoted to each study. Each clinical study should have a discrete set of deliverables and milestones, many of which are mandatory deliverables (see section 4.2) such as the study protocol, ethical approval, reporting of results etc. Please note that a clinical study conducted in more than one country (multi-country trial) should not be presented as one work package per country but rather as one work package overall.

4.2.2.2 Management or Project Management

Most projects include a work package that covers the management and monitoring of the project's progress. This work package may include activities such as the establishment of management and/or oversight committees and their terms of reference, consortium meetings (annual or otherwise), monitoring and evaluation reports, and other relevant activities. Decision-making structures should be described in detail, be practical and should have an appropriate North-South balance and this should be described in detail in the Consortium section.

4.2.2.3 Dissemination, exploitation and communication

Many projects have a work package that covers the activities relating to dissemination, exploitation and communication. Typical deliverables included here would be the project website/webpages, as well as the dissemination and exploitation plan. Other dissemination and public engagement activities should be included here, such as participation in the EDCTP Forum, presentations at conferences, meetings with policy makers, meetings with community advisory boards and community feedback sessions, newsletters, etc.

4.2.2.4 Data management and analysis

Many projects include a work package on data management and analysis, which would include the data management plan as a deliverable, and associated deliverables and milestones such as construction of the database, data lock, data analyses and etc.

4.2.2.5 Training and capacity building

Many projects have a work package on training and capacity building, which includes deliverables such as training workshops, training needs assessment, individual training plans, accreditation certificates and other relevant deliverables.

There are many other possible work packages, depending on the type and scope of project, such as health economics analysis, laboratory analysis, networking. Applicants should choose the appropriate and logical work packages for their project.

4.2.3 Work package leaders

For multi-beneficiary projects, the consortium should agree the distribution of responsibilities between the partners. Each work package should have a single work package leader (organisation and person). Multiple partners can be involved in each work packages and this should be detailed in the work package description but there should be one organisation and one person representing the organisation who is nominated to lead a work package. Please pay attention to the distribution of responsibilities between the partners. The coordinator or one organisation should not be designated as the lead of every work package. The consortium should be balanced and fair, with each partner having a clear role and responsibility in the execution of the project. Applicants should estimate the resources required to execute each work package.

For mono-beneficiary grants, by default the coordinator is the leader of all work packages. No other organisations can be listed as work package leaders or responsible for deliverables.

4.3 Deliverables and milestones

Deliverables and milestones provide an important means of tracking the outputs and progress of individual projects both for the consortium and for EDCTP. The EDCTP2 programme has specific objectives, targets (deliverables) and key performance indicators set out in the legal decision for the EDCTP2 programme. EDCTP collects data from individual projects to feed into the monitoring and evaluation framework for the EDCTP2 programme, and therefore, it may request applicants to include specific deliverables in the Annex 1 to the grant agreement.

4.3.1 Deliverables

A deliverable is a distinct output of the project, meaningful in terms of the project's overall objectives, and constituted by a report, a document, a technical diagram, a software, website etc.

Deliverables should be classified as public, confidential or classified as per the table below.

PU	Public, fully open, e.g. published on website
CO	Confidential under conditions set out in Grant Agreement.
CI	Classified information as referred to in Commission Decision 2001/844/EC.

In the spirit of transparent use of public funding and open access, the majority of deliverables should be classified as public. Only under specific, justified circumstances should a deliverable be classified as confidential. The grant agreement defines "confidential" as follows: Article 36: During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('confidential information'). This means that neither beneficiaries grantee, nor EDCTP, would be allowed to disclose any information from such deliverables. Therefore, the use of the status confidential must be justified. The status classified should be used only in exceptional circumstances where there are security considerations.

Designating a deliverable as public does not mean that private, personal or sensitive data will be made public. Beneficiaries and EDCTP must always comply with the EU General Data Protection (GDPR) Regulation.

Deliverables should be classified according to the H2020 types listed below
Deliverable type:

R	Document, report (excluding the EDCTP periodic and final reports) such as publications, trial protocol, clinical trial report, meeting minutes, SOPs
DEM	Demonstrator, pilot, prototype, plan designs
DEC	Websites, patents filing, press & media actions, public engagement & community feedback activities, videos, etc.
OTHER	Software, technical diagram, etc.

Applicants should not include the following as deliverables in the proposal: consortium agreement (must be agreed before the project starts); progress reports to EDCTP (contractual requirements).

For multi-beneficiary grants, each deliverable should have a single organisation responsible for ensuring that the deliverable is achieved. Multiple partners can be involved in each deliverable but there should be only one organisation nominated as responsible for the deliverable.

For mono-beneficiary grants, by default the coordinator (organisation) is responsible for all deliverables. No other organisations can be listed as responsible for deliverables.

4.3.1.1 Number, timing and examples of deliverables

The number of deliverables should be proportionate to the scale and scope of the project. Deliverables should be clear, distinct outputs of the project rather than simple descriptions of the project activities and tasks. The tasks in the project Gantt chart are not the same as the project deliverables. Applicants should use their judgement and common sense when determining the deliverables: 'just enough', and not too many nor too few. Applicants must include in their proposal several deliverables that are designated by EDCTP as mandatory. These deliverables are indicated below in the sections below, together with other suggestions of deliverables.

Each deliverable, or description of the deliverable, should be submitted to EDCTP when it is achieved or appended to the project's periodic report. It is not sufficient to include a few lines in the body of the periodic report as evidence that a deliverable was achieved. Each deliverable (or description of the deliverable) should be submitted as a separate document, clearly labelled with the project title and code, as well as the deliverable name and number (e.g. D2.3 Clinical trial protocol). See Annex 1 for a template for deliverables.

When inserting deliverables in the proposal, the deliverables must be organised according to work package and then according to chronological order within the work package. For example, deliverable 1.1 (D1.1) is the first deliverable of work package 1 to be achieved, followed by D1.2 which is achieved next, followed by D1.3. Deliverable 2.1 is the first deliverable of work package 2.

The timing of deliverables should be indicated in months from the start of the project. Be realistic about when the deliverables will be achieved otherwise there will be concerns raised if the deliverables are reported as delayed in your periodic reports. Approval of the report and the payment is linked to successful and timely achievement of the deliverables.

Make sure that you include deliverables that cover the progress and duration of the project. It is not acceptable to indicate that all/majority of the deliverables will be achieved in the last month of the project. It is not possible to include deliverables that will be achieved before or after the grant end date.

If a deliverable happens more than once during the course of the project, for instance annual meetings, in Annex 1 you can indicate multiple project months this deliverable will be reported on, for instance, month 12, 24, 38, 48.

4.3.1.2 Work package: Clinical study

Required for all RIAs and for TMAs, where applicable

Deliverable	**Details**
First study subject approvals package 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	**Mandatory** Report (R) Public See Article 34 of the grant agreement

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 This deliverable must be obtained for each clinical study prior to the enrolment of the first study subject.	The beneficiary must be able to show that the opinions, authorisations, notifications cover the tasks to be undertaken in the context of the action.
Final version of study protocol as approved by first regulator/ ethics committee(s). Later, updated versions of the protocol should be submitted with each periodic report. Major amendments to a protocol must be discussed with EDCTP prior to execution.	**Mandatory** Report (R) Public To ensure transparency, EDCTP expects the study protocol and analysis plan to be made publicly available. EDCTP recommends that details of where and how this information may be accessed be provided in the registry entry. The study protocol for clinical trials should comply with the SPIRIT Statement (Standard Protocol Items: Recommendations for Interventional Trials). The informed consent forms must be included with the protocol and submitted to EDCTP.
Registration number of clinical study in a WHO-primary registry or ICMJE- approved registry that also allows later posting of study results.	**Mandatory** DEC Public
Incidental findings policy *Policy and procedures that will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).* *Incidental findings are not restricted to medical observations but may include sociological and criminal findings including abuse, domestic violence, sex trafficking, etc.* *Must be in place prior to enrolment of subjects.*	**Mandatory** Report (R) Public The informed consent forms and information sheets for study subjects should have details of the procedures on handling incidental findings. Applicants should seek appropriate advice and guidance on this issue. For a discussion of potential issues, please see the following guide Framework on the feedback of health-related findings in research
Clinical trials insurance *Must be in place prior to enrolment*	*For all clinical trials* **Mandatory** Report (R) Confidential

Clinical trial progress plan with projected dates (month) First patient First visit (FPFV) 25%, 50%, 75% 100% enrolment (Last patient first visit-LPFV) Last patient last visit (LPLV) Database Lock (DBL) Clinical Study report (CSR) Must be in place prior to enrolment of subjects. The clinical trial progress should also be outlined in the clinical studies template.	*For all clinical trials* **Mandatory** Report (R) Confidential
All approvals package Approvals required for invitation/enrolment of the subjects in all clinical centres (where the study takes place in more than one centre/country): 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 Deliverable to be submitted once the approval in the last country/site has been obtained	*Where applicable* **Mandatory for multi-country trials** Report (R) Public
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.*	**Mandatory** Report (R) Confidential
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.	**Mandatory** Report (R) Public EDCTP expects timely reporting of clinical trial results. See the Joint statement on public disclosure of results from clinical trials
Investigator's brochure	*Where applicable* **Mandatory** Report (R) Public or Confidential
Clinical study report See ICH Guideline E3	*Where applicable* **Mandatory** Report (R) Public or Confidential
Patent or Patent Application	Report (R)

	Public or Confidential
Monitoring visit plan and quality assurance plan including any audit and site visit plans Applicants should have a risk-based monitoring approach and must justify the frequency of monitoring visits. *This deliverable may be part of the management work package rather than the clinical study work package*	**Mandatory** Report (R) Confidential
Monitoring visits (including site initiation and close-out visits) *This deliverable may be part of the management work package rather than the clinical study work package*	**Mandatory** Report (R) Confidential
Data Safety and Monitoring Board (DSMB) Charter Composition and terms of reference *This deliverable may be part of the management work package rather than the clinical study work package*	*Where applicable* **Mandatory** Report (R) Public
DSMB meeting (s) Only the open session of the DSMB may be reported on	*Where applicable* **Mandatory** Report (R) Confidential
Trial Steering Committee (TSC) Charter Composition and terms of reference *This deliverable may be part of the management work package rather than the clinical study work package*	*Where applicable* **Mandatory** Report (R) Public The role of the TSC is to provide oversight of the conduct of the trial The TSC should have independent members, including an independent Chair
TSC meeting(s)	*Where applicable* **Mandatory** Report (R) Confidential

4.3.1.3 Work package: Project Management

Required for RIAs and CSAs, and for TMAs where applicable

Deliverable	Description
Charter of decision-making and advisory bodies such as management committees and oversight committees Composition and terms of reference *Where applicable, this may be part of the clinical study work package*	**Mandatory** Report (R) Public or Confidential The EDCTP Project Officer should be included as an observer in the oversight committee
Consortium meeting (s) or project meeting (s)	Report (R) Public The EDCTP Project Officer should be informed in advance and invited to the meeting
Standard Operating Procedures (SOPs)	Report (R) Public

This deliverable may be part of other work packages, such as clinical study, lab analysis *For ethics committees (ECs) supported by a CSA grant, the SOPs should be publicly available and state the following:* *The authority under which the committee is established* *The functions and duties of the EC* *Membership requirements* *The terms and conditions of appointment* *The offices, the structure of the secretariat, internal procedures, and the quorum requirements.*	
Project plan and Gantt chart with critical path activities *Updated version to be submitted as deliverable within first three months of the project, and subsequently with each periodic report*	**Mandatory** Report (R) Confidential
Procedure for immediate reporting to EDCTP of the occurrence of events related to breaches of data integrity, data protection and privacy, scientific misconduct and ethics. *To be in place within first three months of the project* *Under such circumstances the beneficiaries shall submit to investigation and resolution procedures determined by EDCTP.*	**Mandatory** Report (R) Confidential
Results Framework	Report (R) Public
Materials Transfer Agreement	*Where applicable* **Mandatory** Report (R) Confidential
Data Transfer Agreement	*Where applicable* **Mandatory** Report (R) Confidential

4.3.1.4 Work package: Dissemination, exploitation and communication

Required for RIAs, CSAs, TMAs

Deliverable	Description
Dissemination and exploitation plan *Mandatory at project month 6. Later, updated versions should be submitted with each periodic report.*	**Mandatory** Report (R) Public

Project website *Smaller projects may have project-specific web pages on the institution's website* *Fellows must include details of the project on their staff web page of their institution*	**Mandatory** DEC Public
Dissemination toolkit *The toolkit normally includes specific tools (materials branded with the project logo and chosen colour theme, such as templates for project presentations, internal documents, meeting materials etc.) for dissemination and guidance on acknowledging funders for any dissemination of the project*	Report (R)Public
Publications in open access journals *The planned publications should be listed as individual deliverables with draft titles/topics*	**Mandatory** Report (R)Public
Other publications such as Book Popular press Press release Policy brief or policy document Newsletter *Each type of publication should be an individual deliverable*	Report (R)Public
Presentation(s) to different audiences such as National, international conferences Policy makers Community advisory boards Study subjects *Each type of presentation should be an individual deliverable*	DEC Public
Participation in the EDCTP Forum *The Forum is expected to take place in 2020, 2022, 2024*	**Mandatory** Report (R)Public
Social media, blog, twitter account	DEC Public
Communication campaign (radio, TV, press)	DEC Public
Set up of ORCID account *Relevant to junior researchers and some EDCTP fellows*	DEC Public
Profile on EDCTP Alumni Platform *EDCTP2 Fellows*	DEC Public
Profile on Research Ethics Web For EDCTP-funded ethics committees	DEC Public

4.3.1.5 Work package: Data management and analysis

Normally required for RIAs, CSAs, TMAs

Deliverable	Details
Data management plan *Mandatory at project month 6. Later, updated versions should be submitted with each periodic report.*	**Mandatory** Report (R) Public
Database	DEM CO
Statistical analysis plan	Report (R)Public

4.3.1.6 Work package: Training and capacity building

Normally required for RIAs, CSAs and TMAs

Deliverable	Description
Training plan *With chronological plan of key events*	Report (R) Public
Workshop *The agenda and report of the workshop, including the list of participants, and the participants' evaluation of the utility of the workshop, should be submitted as a deliverable*	Report (R) Public
Training manual	Report (R) Public
Training programme	Report (R) Public
PhD and Master's thesis	Report (R) Public *Where applicable*
Training plan/Career development plan/Individual learning plan For fellows and trainees	Report (R) Public
Mentorship plan For some fellowships	Report (R) CO
Mentor-mentee meetings	Report (R) CO
Re-integration plan *For some fellowships*	Report (R) Public

4.3.2 Milestones

4.3.2.1 Definition and number of milestones

A milestone is defined as a control point in the project that helps to chart progress. Milestones may correspond to the completion of a key deliverable, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems arise, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development, or a Go/No-go decision about the clinical development of a product. Critical path milestones should be detailed in the project plan.

Milestones should be included in the proposal according to work package and then according to chronological order within the work package. For example, M1.1 is the first milestone of work package 2 to be achieved, followed by M1.2 etc. For each milestone, applicants must add the 'means of verification' – the evidence that the milestone has been reached. This must be communicated and/or submitted to EDCTP.

How many milestones should be included? It depends on the nature of the project, but it is best to be practical and pragmatic about it. As a general rule a project should have fewer milestones than deliverables. Please consider the following points:

- Confirmation (evidence) that a milestone has been attained must be provided to EDCTP
- Milestones must be meaningful checkpoints/progress steps in the project
- All key decision points must be indicated as milestones
- Do not duplicate the milestones and deliverables – as a general rule, do not list the same thing as a deliverable and milestone
- Each deliverable does not need to have a corresponding milestone. For example, it is not necessary to put a draft agenda for a meeting (M1.1, month 10) as a milestone and the finalised agenda (D1.2, month 11) as the deliverable. Otherwise, you will have to submit the milestone (draft agenda) at month 10 to EDCTP and the deliverable (finalised agenda) at month 11 to EDCTP.

4.3.2.2 Mandatory milestones and other examples of milestones

Work package: Clinical study

Milestone
First subject in (start of recruitment) – mandatory
25% recruitment point – mandatory
75% recruitment point – mandatory
First subject, last visit – mandatory
Last subject out (last subject, last visit) - mandatory
Database set up – mandatory *(may be included in data management work package)*
Database lock – mandatory *(may be included in data management work package)*
Other examples: Product import license(s), Biosafety and lot release testing report, Materials Transfer Agreement

Work package: Training and capacity building

Examples of milestones
Advertising of postgraduate studentship(s), workshop, event etc
Selection of postgraduate student(s), trainees, participants etc
Registration of students
Submission of thesis

The consortium should agree upon the key, relevant milestones per work package.

4.4 Consortium and risk management

4.4.1 Management structure and procedures

The consortium should describe in detail the management and governance structure for the project, including the key decision-making and advisory bodies and how they interact. The relationship between the various bodies and the decision-making procedures should be explained. How are decisions taken – by consensus or majority? What if there is a disagreement? Decision-making structures should have an appropriate representation of project partners and North-South balance.

EDCTP recommends that RIA projects have an external, independent advisory body. This could be the Trial Steering Committee or other body, which comprises external experts not involved in the project, that provides advice to the project, usually at regular intervals throughout the year or connected to annual project meetings. EDCTP should be invited as an observer to the advisory body (ies).

4.4.2 Third parties involved in the project and sub-contracting

If sub-contracting is foreseen, this should be described in the proposal, the applicants/beneficiaries must ensure compliance with H2020 rules. Sub-contracting of essential activities is not allowed. Sub-contracting should not be seen as a means of getting around the rules on eligibility to receive funds.

If third party contributions are involved these should be described in the proposal. If it is anticipated that the third party contributions will be made against payment then YES should be answered in the relevant box and a description given. If the contribution(s) are given free of charge and will not be made against payment, then NO should be answered in the relevant BOX. Third party contributions given free of charge, such as cofunding in the EDCTP2 Strategic calls, should be described elsewhere in the proposal/annex 1.

4.4.3 Consortium as a whole

This section should be used to describe the consortium and how it matches with the project objectives. It should explain how the participants complement one another (and cover the value chain, where appropriate) and contribute to the project. You may describe here as well the involvement of other stakeholders (e.g. governmental, industrial, commercial) in the project and explain how their involvement will contribute to the successful implementation and to the impact of the project. All participants and their role must be included in this description.

4.4.4 Critical risks for implementation

This table describes any critical risks to the implementation of the project by work package(s) and outlines the proposed risk-mitigation measures. The consortium must have a procedure in place for immediate reporting to EDCTP of the occurrence of events related to breaches of data integrity, data protection and privacy, scientific misconduct and ethics. This should be included as a deliverable in the project management work package.

5. Ethics issues in research

5.1 Ethics issues table

All second-stage (full) proposals submitted to EDCTP must complete the Ethics Issues table in the proposal, answering YES or No to the questions. Make sure you read the questions and guidance thoroughly before you answer YES or NO. Almost all proposals submitted to EDCTP will involve ethics issues:
RIA proposals raise ethics issues – the proposals involve human subjects, the studies take place outside of the EU, personal data are collected, biological samples are collected, etc. Many of these ethics issues apply to TMA (fellowship) proposals too. For CSA proposals, although research is not conducted under these proposals, some of the studies or activities may involve ethics issues such as those relating to personal data collection and processing.

If you answer YES to any of the questions in the Ethics Issues table, then you must submit and upload an Ethics Self-Assessment document as part of your proposal. If you do not include the Ethics Self-Assessment, then your application may be rejected as inadmissible and will not go forward to scientific evaluation.

If you answer NO to all of the questions in the Ethics Issues table and EDCTP considers that these have been answered incorrectly, then this raises significant questions about the quality of your proposal and it will cause delays to the evaluation of your proposal.

5.2 Ethics Self-Assessment

The ethics self-assessment is a free-form document of unlimited length that must be uploaded with all proposals where an ethics issue has been identified (via a YES answer in the Ethics Issues table). Although the document is free-form, it must follow the the structure and guidance from H2020: How to complete your ethics self-assessment. This detailed guide explains step-by-step, the ethics aspects that should be considered and it includes links to other useful guidance. Additional guidance and reference documents can be found here on the H2020 website at this, including the Trust Project: Global Code of Conduct for Research

in Resource-Poor Settings. Applicants should complete the ethics self-assessment thoroughly, giving a full description and discussion of the potential ethics issues. Applicants are advised to consult qualified individuals at their institutions before submitting their proposal.

All proposals which are evaluated and ranked highly enough to receive funding will undergo first an Ethics Screening to identify if there are any ethics issues (carried out by EDCTP staff and/or independent experts) and if necessary, an Ethics Assessment. The majority of EDCTP proposals go through Ethics Assessment – a full and detailed evaluation of the ethics issues conducted by independent ethics experts.

The possible outcomes of the Ethics Screening and Ethics Assessment are:

- No ethics issues (clearance)
- Ethics clearance
- Conditional ethics clearance
- Request for additional information (intermediate outcome)
- No ethics clearance

5.3 Outcome of the ethics assessment and the grant preparation process

The majority of EDCTP proposals receive conditional ethics clearance because there are ethics requirements that must be fulfilled before grant agreement signature or during the course of the project. These ethics requirements will normally be included as deliverables in the Annex 1 of your grant. Examples of some of these deliverables are listed in section 4.2.2 of this document.

Sometimes proposals receive the status 'intermediate outcome' whereby a request is sent back for additional information because the ethics self-assessment was incomplete or not sufficiently detailed. This causes significant delays to the grant preparation process and a lot of extra work for you and for EDCTP. You can avoid this happening by making sure that you complete the self-assessment document in detail when you submit your proposal.

The ethics self-assessment document must be revised and updated in response to the comments in the ethics evaluation summary, as it will become part of Annex 1. The self-assessment should include text, where applicable, confirming/declaring compliance with fundamental ethical principles as follows:

The applicants confirm that:

- the proposal complies with ethical principles and with applicable international, EU and national laws
- the proposal complies with the Declaration of Helsinki and the principles laid down in the Oviedo Bioethics Convention
- the proposal complies with EU Regulation No 536/2014 on clinical trials on medicinal products for human use
- the research methodologies will not result in discriminatory practices or unfair treatment
- the collection, testing, processing, preservation, storage and distribution of human tissues and cells complies with applicable national and international law and with EU Directive 2004/23/EC
- for any additional materials collected for secondary use for future research, the donor's consent for such secondary use has/will be obtained and the possibility of opt-out of collection of additional materials for secondary use or biobanking is available
- transfer of materials (cells/tissues) from/to non-EU countries complies with the provisions on import/export as per EU Directive 2004/23/EC and with rules on data transfer and that all necessary licences and authorisations have been/will be obtained
- any data collected will be kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity
- informed consent has been obtained for collection and/or processing of personal data and that the necessary authorisations have been/will be obtained for any data transfer between countries
- the proposal complies with the EU General Data Protection Regulation

- for research activities conducted in non-EU countries, the research activities could have been legally carried out in an EU country
- the research complies with applicable health and safety procedures and with applicable international, EU and national law regarding the protection of humans, including research staff

There may be additional ethics requirements included for your project, such as inclusion of an Ethics Mentor or Ethics Advisor (see guidance: Roles and functions of Ethics Advisors/Advisory Boards in EU-funded projects). There may also be an Ethics Check (Audit) scheduled during the course of your project to check compliance and to check what ethics issues have arisen and how they are being addressed. The ethics evaluation and ethics check procedures carried out by EDCTP in no way replace or interfere with the national ethics review procedures. The purpose of EDCTP (H2020) ethics evaluation is to ensure not only that the legal framework for research is respected but also to enhance the quality of the research.