EDCTP2 Grants Manual

History of changes

Version	Date	Changes
2B	28 July 2015	• 2.3 Updated information on funding rates and levels • 6.3 Updated evaluation criteria • 9.3 Link to EDCTP2 model grant agreements added • 10.2 Update to complaints procedure for failed submissions via EDCTPgrants
3	7 July 2016	Updated in accordance with EDCTP Work plan 2016 and corresponding changes in H2020 procedures and editorial changes. • 2.2 Actions (Funding schemes) • 3 and 5.2 Eligibility: section on sole participants added, eligibility criteria for actions updated, Prizes added • 7 Evaluation procedure (revised in accordance with approved Work Plan 2016) • 8 Evaluation results (revised in accordance with approved Work Plan 2016
4A	9 June 2017	Updated in accordance with EDCTP2 Work plan and corresponding changes in H2020 procedures and editorial changes: 1 Scope 6 Evaluation criteria 7 Evaluation process

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

1 Introduction

The second programme of the European and Developing Countries Clinical Trials Partnership (EDCTP2) was launched in 2014 and will be implemented over a 10 year period. The overall objective of EDCTP2 is to contribute to the reduction of the social and economic burden of poverty-related diseases (PRDs) in developing countries by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa.

In EDCTP2, PRDs include: In the EDCTP2 programme, "poverty-related diseases (PRDs)" include HIV, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.

The EDCTP2 programme supports:

- Clinical trials and related research activities on PRDs. All phases of clinical trials (phases I to IV) for new or improved medical interventions, as well as advanced testing and field validation of new diagnostic tools can be supported under EDCTP2
- Capacity development for clinical trials and related research in sub-Saharan Africa. Capacity development activities supported by EDCTP aim to strengthen the enabling environment for clinical research in sub-Saharan Africa, in particular for conducting clinical trials in compliance with fundamental ethical principles and relevant national, Union and international legislation.

Moreover, EDCTP2 promotes networking, coordination, alignment, collaboration and integration of national research programmes and activities on PRDs at scientific, management and financial levels.

This manual aims to assist applicants to the EDCTP2 programme by providing an overview of the key steps in the EDCTP grant-giving process, and gives guidance and information to applicants on:

- How to apply to EDCTP2 calls for proposals (proposal or pre-submission phase: see the chapters 2, 3 and 4)
- How applications are processed and evaluated (assessment phase: see the chapters 5 and 6)
- The grant contract process for successful applicants (awarding phase: see the chapters 7 and 8)
- Other information relevant to EDCTP applicants (see chapter 9).

2 How to apply: Before proposal submission

2.1 EDCTP funding opportunities

Proposals to EDCTP for funding must be submitted in response to published calls for proposals. EDCTP does not consider unsolicited and spontaneous proposals for funding that are not directly related to a published call for proposals. An overview and indicative timetable for the publication of calls is provided in the EDCTP2 Annual Work Plan while notifications of individual calls for proposals are given under the Funding section of the EDCTP website and via the EDCTPgrants system. Each call contains the key information that is needed in order to prepare a proposal, including the eligibility and evaluation criteria. The call for proposals also includes contact details in case of enquiries about the call.

2.2   Funding schemes (Actions)

Three distinct types of actions are supported under EDCTP2:

- Research & Innovation Actions (RIAs)
- Coordination & Support Actions (CSAs)
- Training and Mobility Awards/Fellowships (TMAs)

2.2.1   Research and Innovation Actions (RIA)

Description: Action primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution.

In the EDCTP2 programme these are actions primarily consisting of clinical research activities and clinical trials in partnership with sub-Saharan Africa aiming at increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones, in particular in sub-Saharan Africa. Actions should normally include one or more clinical trial (phase I to IV) conducted in sub-Saharan Africa, in particular phase II and/or III trials. Actions involving the conduct of phase II and III trials of drugs and vaccines shall normally include a regulatory strategy. Whilst clinical trial(s) represent the main activity, the action may involve additional relevant research studies such as nested sub-studies or epidemiological studies. These actions may also involve supporting activities fostering networking (within Africa and within Europe, as well as between Africa and Europe) or capacity development of researchers, institutions and sites in sub-Saharan Africa to conduct clinical trials and related research, including observational studies.
Funding rate: 100%

2.2.2   Coordination and Support Actions (CSA)

Description: Actions consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of strategic planning, networking and coordination between programmes in different countries.

In the EDCTP2 programme CSAs address 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 and among African researchers, clinical research institutions and sites, as well as iii) activities to foster coordination and cooperation between public and private funders. Actions may involve activities of standardisation, dissemination, awareness-raising and communication, conduct of preparatory and accompanying studies, networking, coordination or support services, policy dialogues and mutual learning exercises and studies. Actions may also include complementary activities of strategic planning, networking and coordination between regional and national programmes. Actions may also involve targeted measures to maximise the public health impact of research results stemming from EDCTP-funded activities in sub-Saharan Africa by promoting their translation and supporting their uptake in policy-making, health systems and clinical practice at local, national and/or international level. In particular, CSAs will support sub-Saharan African countries in developing a robust ethical and regulatory framework for conducting clinical trials, targeting both national ethics committees (NECs) and national regulatory authorities (NRAs). Furthermore, CSAs will support regional clinical research networks in sub-Saharan Africa ("EDCTP regional networks") in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials according to ICH-GCP standards.
Funding rate: 100%

2.2.3 Training and Mobility Awards (TMA)

Description: In the EDCTP2 programme, these are actions primarily consisting of developing clinical research capacities and skills of researchers and clinical research staff from sub-Saharan Africa, and/or promoting mobility of researchers and research staff.
Funding rate: 100%

2.3 Funding rates and funding levels

The funding rate and level for calls is indicated in the text of the individual call. The funding rate will be 100% of direct costs as well as 25% overhead to cover indirect costs. It is important to note the maximum EDCTP contribution that can be requested per action.

3 Eligibility

Natural persons and legal entities that are public or private, for-profit or not-for-profit (e.g. universities, government departments, research organisations, non-governmental organisations, large companies and small to medium enterprises) regardless of their place of establishment or residence can participate in EDCTP2. They must demonstrate that they possess the operational and financial capacity to carry out the proposed tasks. While legal entities from anywhere in the world can participate in EDCTP2 projects, only legal entities established in the following countries and territories may become 'beneficiaries' and automatically eligible to receive funding:

Member countries of the EDCTP Association, including their overseas departments:

- Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom ("European Participating States" in the EDCTP2 programme)
- Burkina Faso, Cameroon, Congo, The Gambia, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda, Zambia ("African Participating States" in the EDCTP2 programme).

Other countries of sub-Saharan Africa:

- Angola, Benin, Botswana, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic Republic of), Djibouti,, Eritrea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mauritania, Mauritius, Namibia, Nigeria, Rwanda, São Tomé and Príncipe, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Togo, Zimbabwe.

Other Member States of the European Union, which are not member countries of the EDCTP Association, including their overseas departments:

- Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia.

Overseas Countries and Territories (OCT) linked to EU Member States:

- Anguilla, Aruba, Bermuda, Bonaire, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna.

Countries Associated in full to Horizon 2020[1] :

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[1] The latest information on which countries are associated, or in the process of association to Horizon 2020 can be found in the Participant Portal H2020 online manual

International European interest organisations are also eligible to receive funding from the EDCTP2 programme.

'Sole participants' formed by several legal entities (e.g. European Research Infrastructure Consortia, European Groupings of Territorial Cooperation, central purchasing bodies) are eligible if the above-mentioned minimum conditions are satisfied by the legal entities forming together the sole participant.

Legal entities established in countries not listed above and international organisations (e.g. WHO or UNICEF) will be eligible for funding:
- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the EU and an international organisation or a third country; [2]
- When the EDCTP Association deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme
- For Prizes, any legal entity, regardless of its place of establishment, or international organisation may receive funding [3].

4 How to apply

All proposals must be submitted online using EDCTP's electronic submission system EDCTPgrants which you can access via the EDCTP website. Only registered users of EDCTPgrants can apply for funding and submit proposals. EDCTP does not accept paper proposals or proposals sent via email attachment in response to calls for proposals. If you intend to participate in an EDCTP proposal, it is advisable to register with EDCTPgrants as soon as possible and well in advance of the call deadline.

4.1 Registering in EDCTPgrants

New users should click the Register button and follow the on-screen instructions to complete the registration process. As part of the registration process, you must agree to the EDCTPgrants Terms and Conditions. More information, including how to register, is available in the System Help guide on the registration page. A dedicated EDCTP helpdesk (edctpgrants@edctp.org) is available to deal with issues relating to the electronic submission of proposals.

Registration allows you to create your own home page where personal details are stored. It is important to keep your home page up to date as your personal details (name, affiliation, contact information) are imported directly from your home page into any EDCTP proposals that you make. Furthermore, EDCTP corresponds with grant applicants and award holders via EDCTPgrants making it important that your contact details are correct and up to date.

Upon registration with EDCTPgrants, you will be provided with a user name and password for your own use of EDCTPgrants. For reasons of confidentiality, you should not disclose your user name and password to any third party and you should also ensure that you log out of EDCTPgrants at the end of each session.

You may find the following notes useful:
- You will use the email address you register with to identify yourself to the system when logging in
- The system will use this email address for all correspondence, so please choose an address that you use regularly
- When you register, an email will be sent to you to allow you to confirm the registration and log in for the first time
- If you move to a new email address in the future, you can change your registered EDCTPgrants email

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[2] No agreements or arrangements of this kind are currently existing.
[3] Provided that natural or legal persons, groups or non-State entities are not covered by the Council sanctions in force.
Please see: the consolidated list of persons, groups and entities subject to EU financial sanctions, available at
http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

address if you need to

- If you are an EDCTP grant holder or if you have previously contributed to a proposal or review, your email address may already be pre-registered in EDCTPgrants. The system will detect this automatically and will invite you to log in via a short registration process
- The system allows you to store the answers to security questions to assist with the secure retrieval of your password if you ever forget it
- Please add edctpgrants@edctp.org to your email contacts to ensure receipt of emails from EDCTPgrants and to avoid the email ending up in your spam/junk folder.

If you forget your password, you can click the 'Forgotten Password?' link on the Registration and Login Page, and ask for a replacement password to be sent to you by email. This replacement password gives temporary access to the system, during which time you will be asked to provide a new, permanent password.

Persistent use of an incorrect password will lock your account; this is to protect you from attempts to access your data by a third party. If this happens you can request a new password via the 'Forgotten password' function.

4.2   Online proposal submission

Proposals in EDCTPgrants are created and submitted by a Coordinator (principal applicant) representing the organisation (legal entity acting as Coordinator) that will represent the project consortium towards EDCTP. Proposals may include other Participants (co-applicants). This is compulsory for RIA proposals (see 5.2). For CSA proposals, it is normally possible to include other participants, and in some cases, when specifically mentioned in the call, it is compulsory. TMA proposals are normally submitted by a single Participant. Other participants are added to the proposal by the Coordinator when the proposal is created in EDCTPgrants. Throughout the submission and the evaluation process the Coordinator is the sole point of contact for communication between EDCTP and the applicants.

EDCTPgrants is designed to guide the Coordinator step-by-step through the preparation of the proposal. The online form varies depending on the type of action and individual call for proposals, but typically includes the following sections:

Participants- Details of the individuals and organisations involved in the proposal

Project description- Detailed description of the project activities, including the key work packages (such as clinical research, clinical trials, capacity building, management, networking, communication and dissemination)

Budget– Details of the budget request (staff, reagents, equipment, travel, other) and the justification of the requested costs

Additional annexes– Supporting information in the form of mandatory or optional annexes (e.g. Gantt chart, clinical trial protocol, ethics information, references) may be requested or required, depending on the call for proposals. These annexes may be uploaded as pdf attachments in EDCTPgrants.

Before the proposal can be submitted, the Coordinator must confirm:
- The explicit consent of all participants on their participation and on the content of the proposal
- The correctness and completeness of the information contained in the proposal
- Compliance with ethical principles.

The information provided by the Coordinator will be verified prior to any award being made.

When the Coordinator is satisfied that the application is complete, the proposal should be validated before submission. During the validation step, EDCTPgrants carries out a series of checks for completeness of the proposal, internal data consistency, absence of virus infection, file types, size limitations, etc. Only upon

successful completion of these checks as well as completion of the declarations, will EDCTPgrants allow the Coordinator to submit the proposal. The validation checks carried out prior to submission do not replace the formal eligibility checks carried out by the EDCTP Secretariat and cannot assure that the contents of the proposal correspond to the requirements of the call. Submission is deemed to have occurred only when the Coordinator receives an email confirming successful submission of the proposal.

The e-receipt (acknowledgement email) contains the following information:
- Proposal title
- Proposal code
- The date and time of receipt.

4.3   Submission errors

EDCTPgrants will not allow submission of a proposal after the specified deadline. **Applicants are strongly advised, therefore, to submit their proposals as early as possible to avoid any last-minute technical problems.** EDCTP will assist applicants experiencing technical problems but please be aware that it cannot guarantee to answer questions submitted just before the call deadline. You should also bear in mind that the 'technical problems' may be on the user side rather than in EDCTPgrants.

If you consider that the submission of your proposal was not successful due to a technical error within EDCTPgrants, the Coordinator may lodge a complaint through EDCTPgrants. For the complaint to be admissible it must be filed within 4 calendar days following the call closure (see section 10). EDCTP will check the system logs with the system provider for errors in EDCTPgrants.

4.4   Withdrawal of proposals

Coordinators who wish to withdraw a submitted proposal must make a withdrawal request by emailing EDCTPgrants@edctp.org. The withdrawal request must include:
- The proposal reference number
- Title of the proposal
- Full name and organisation of the Coordinator.

Proposals withdrawn **before** the call deadline will not be considered subsequently for evaluation or for selection, nor count against possible re-submission restrictions. Proposals withdrawn **after** the call deadline will count against possible future resubmission restrictions if the withdrawal request is received on or after the day of the scientific review committee meeting and/or after the Coordinator has received the reviewers' comments for rebuttal.

If more than one version of the same proposal is submitted before the call deadline, only the most recent version will be kept for evaluation. In the case of similar proposals submitted by the same Coordinator, EDCTP may ask the Coordinator to withdraw one or more of the proposals concerned.

4.5   Confidentiality

EDCTP will process submitted proposals, including any related information, data and documents received from applicants in a confidential manner. EDCTP staff members, expert reviewers, scientific review committee members and EDCTP General Assembly members are bound by the terms of EDCTP's Code of Conduct and Declaration of Interests policy which assures confidentiality in the review process.

Proposals submitted to EDCTP are archived under secure conditions at all times. When no longer needed, all copies of proposals other than those required for archiving and/or auditing purposes shall be destroyed.

4.6   Personal data protection

EDCTP complies with the provisions of the "Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)", dated 6 July 2000, which Act is based on Directive nr. 95/46/EG (PbEG L 281) and adapted to the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD).

Registration with EDCTPgrants and grant proposal submission will involve the recording and processing of personal data. These data will be held securely, processed lawfully and retained for no longer than necessary by EDCTP. Data may be used to compile lists, including project details, of EDCTP grants, which will be made publicly available. By submitting the application, the participants in the project give EDCTP their consent to do so.

EDCTP will publish the summary details of awarded projects, including the names of all participants, the proposal abstract and the grant amount on its website and in other public media. Further, these data may be used to compile invitation lists for EDCTP conferences and alumni events. Applicants may enquire or make a complaint about the processing of their personal data to the EDCTP Data Protection Supervisor and subsequently the Dutch Personal Data Protection Commission or the European Data Protection Supervisor.

5   Admissibility and eligibility checks

Before proposals are sent for evaluation, they are checked by the EDCTP Secretariat for admissibility and eligibility. Proposals must meet the general and any specific admissibility and eligibility criteria laid down in the call text and EDCTP work plan in order to be evaluated. The general admissibility and eligibility criteria are listed below, while any specific eligibility criteria will be clearly indicated in the individual calls.

5.1   Admissibility criteria

To be considered admissible, a proposal must be:
- Submitted electronically in EDCTPgrants
- Submitted before the deadline given in the call for proposals
- Readable, accessible and printable
- Complete – accompanied by the relevant administrative forms, proposal description and any supporting documents specified in the call.

Incomplete proposals may be considered inadmissible.

The following supporting information will be required to determine the operational capacity, unless otherwise specified:
- A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed activities
- A list of up to five publications, and/or products, services (including widely-used datasets or software), or other achievements most significant or relevant to the call for proposals content
- A list of up to five relevant previous projects or activities connected to the subject of the proposal with a summary of their major outputs
- A description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work
- A description of any third parties that are not represented as project partners, but who will nonetheless be contributing towards the work (e.g. providing facilities, computing resources, providing study drugs).

As part of the admissibility and eligibility check, EDCTP may ask the Coordinator to provide missing information or to clarify supporting documents so long as such information or clarifications do not substantially change the proposal.

Word limits will apply to proposals. The limits will be set out clearly in EDCTPgrants; it is not possible to exceed the word limits in the online submission and the applicant will receive an automatic warning that the proposal must be revised before submission.

5.2   Eligibility criteria

All proposals must comply with the eligibility conditions set out in the Rules for Participation of Horizon 2020

(EU Regulation No.1290/2013) and any derogations to these as specified in the EDCTP2 Basic Act. A proposal is considered eligible if it meets the standard eligibility criteria and any other eligibility conditions set out in the call or topic page.

A proposal will only be considered eligible if:

- Its content corresponds, wholly or in part, to the topic description against which it is submitted
- It complies with the minimum criteria with respect to participants as set out in the table below.

Type of Action	Eligibility criteria
Research & Innovation Action (RIA)	At least three legal entities. Two of the legal entities shall be established in two different Participating States (European partner states) and one of the legal entities must be established in a sub-Saharan African country (listed in section 6.1). All three legal entities shall be independent of each other.
Coordination & Support Action (CSA)	At least one legal entity established in a Participating State or a sub-Saharan African country.
Training and Mobility Action (TMA)	At least one legal entity established in a Participating State or a sub-Saharan African country.
Prizes	See conditions for participation in the Rules of Contest.

The Participating States (European partner states) are: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom

If it becomes clear before, during or after the evaluation stage, that one or more of the eligibility criteria has not been met, the proposal will be declared ineligible and withdrawn from any further evaluation or grant agreement preparations. Where proposals are found to be ineligible, the grounds for such a decision and the mechanism for submitting enquiries and complaints will be given by EDCTP. Decisions on admissibility and eligibility are normally released after the evaluation of all proposals has taken place (within 3-5 months).

6   Evaluation of proposals

Principles of EDCTP peer review

EDCTP appoints independent experts (hereafter "experts") to carry out a technical evaluation of submitted proposals and to make funding recommendations to EDCTP. EDCTP abides by the following principles:

Excellence Projects selected for funding must demonstrate high scientific and technical quality in relation to the call topics and the evaluation criteria set out in the calls.

Transparency Funding decisions are based on clearly described rules and procedures. Applicants should receive adequate feedback on the outcome of the evaluation of their proposals.

Fairness and impartiality All proposals shall be treated equally. They must be evaluated impartially on their merits, irrespective of their origin, the identity of the submitting entity, the participants or any team member.

Confidentiality All proposals, associated annexes and related data, knowledge and documents submitted to EDCTP must be treated with the strictest confidence.

Efficiency and speed The evaluation process, preparation and award of grants should be dealt with as

priority matters, without compromising quality and/or due diligence by EDCTP.

Ethical considerations Proposals will undergo ethics evaluation prior to award. Proposals considered to contravene ethical principles will be excluded from any further evaluation in the process.

Research integrity considerations Any breach of research integrity rules may result in the exclusion of a proposal at any time.

6.1 Independent experts

EDCTP relies on experts to ensure that only proposals of the highest quality are selected for funding.

Experts are external and independent to EDCTP and, in performing their evaluation(s), are working in a personal capacity rather than as a representative of any organisation or scientific community. Experts are selected from the EDCTP database of experts to which potential experts may apply on EDCTP's website. Experts may be selected from any country in the world.

In assembling pools of experts, EDCTP seeks to ensure the highest level of scientific and technical expertise in areas appropriate to the call, taking into consideration other criteria such as:
- Gender balance
- Geographical diversity across Europe and sub-Saharan Africa, and reasonable inclusion of nationals of other countries
- Regular rotation of experts, consistent with the appropriate balance between continuity and renewal.

The identity of the experts assigned to individual proposals is not disclosed; however, the list of all experts used by EDCTP is compiled and published annually on the EDCTP website.

Any direct or indirect contact about the peer review evaluation of an EDCTP call between the applicants (individuals involved in a proposal; any team member and/or any person linked to the applicant legal entity submitting a proposal under the same call) and any independent expert involved (or believed to be involved) in that peer review evaluation is strictly forbidden. Any such contact may result in the decision by EDCTP to exclude the proposal concerned from any further processing and/or to exclude the expert reviewer from participating in EDCTP evaluations.

6.2 Nomination and exclusion of independent experts by a Coordinator

Coordinators of proposals to EDCTP may nominate via EDCTPgrants (at the time of submission of their proposal) up to three independent experts as potential peer reviewers of their proposal. Nominated reviewers must be recognised experts in the field of the research proposal. The nominated experts should not be collaborators or researchers with whom the participants have published in the past three years and should not be employed at the same organisation as the applicants. EDCTP reserves the right not to use the suggested experts.

Likewise, Coordinators of proposals to EDCTP may also request via EDCTPgrants at the time of submission of their proposal that up to three named individuals be excluded from evaluating their proposal. EDCTP may or may not exclude the named individuals from the review of the proposal as EDCTP must remain in the position to have the proposal evaluated comprehensively.

6.3 Evaluation criteria

Selection criteria

1. *Financial capacity:* In line with the EU's Financial Regulation No 966/2012 and the Horizon 2020 Rules for Participation Regulation No 1290/2013. For grants, coordinators will be invited – at the full proposal stage- to complete a self-assessment using an on-line tool.
2. *Operational capacity:* As a distinct operation, carried out during the evaluation of the award criterion 'Quality and efficiency of the implementation', experts will indicate whether the participants have operational capacity to carry out the proposed work, based on the competence and experience of the individual participant(s).
3. For prizes, neither financial capacity nor operational capacity is subject to evaluation.

Award criteria, scores and weighting

Grant proposals will be evaluated by experts, on the basis of the **award criteria** 'excellence', 'impact' and 'quality and efficiency of the implementation' (see Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013). The aspects to be considered in each case depend on the type of action as set out in the table below, unless stated otherwise in the call conditions. For all proposals involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Proposals will be evaluated on three criteria:
- Excellence
- Impact
- Quality and efficiency of implementation.

The aspects to be considered under each criterion depend on the type of action (see table below) and may also include additional aspects that will be specified in each call.

Evaluation criteria per action for EDCTP-funded activities

Type of Action	Award criteria		
	Excellence The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work plan.	**Impact** The following aspects will be taken into account:	**Quality and efficiency of the implementation** The following aspects will be taken into account:
All Types of Action	**Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.** **Importance, relevance/pertinence and clarity of the objectives.** **Soundness of the concept and credibility of the proposed approach/methodology.**	**The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.** **Likelihood to result in major advances in the field.**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables; Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met. Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise. Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role. Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).

Research & Innovation Action (RIA)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.** Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.** Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge	**Advancing the clinical development of new and improved products**. Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results. **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.** Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data where relevant.	Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).
Coordination & support action (CSA)	Clarity, pertinence and importance of the strategic vision. Soundness of the concept. Quality of the proposed coordination and/or support measures.	Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), and to manage research data where relevant. Sustainability of capacity beyond the end of the grant, where relevant. Contribution to networking, where relevant.	Quality of the leadership and a clear and effective governance structure.
Training & Mobility Action (TMA)	Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career. Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.	Contribution of the fellowship to the fellow's clinical research skills and career development. Contribution to strengthening clinical research capacity at the home or host organisation. Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data. Sustainability and retention of capacity post-award.	Suitability of the fellow's home organisation to support the fellowship project. Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.

6.3.1 Scoring and weighting

Unless otherwise specified in the call conditions:
- Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For full proposals, each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.
- For the evaluation of first-stage proposals under a two-stage submission procedure, only the criteria 'excellence' and 'impact' will be evaluated. Within these criteria, only the aspects in bold will be considered. The threshold for both individual criteria will be 4. The overall threshold, applying to the sum of the two individual scores, will be set at the level such that the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and in any case, not less than two and a half times the available budget. The actual level will therefore depend on the volume of proposals and funding request per proposal received. The threshold is expected to normally be set at 8 or 8.5.
- For the evaluation of first-stage proposals under a two-stage submission procedure, an arithmetic average (mean value) or median of the individual scores may be taken as the consensus score. The consensus report may consist of a collation of the individual evaluation reports or extracts from them. As part of the evaluation, a review committee may be convened to reach consensus on the applications proceeding to the second stage. For second-stage proposals as well as for single-stage evaluation procedures, unless otherwise indicated in the call text, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure).
- If special procedures apply, they will be set out in the call conditions.

Experts score each criterion on a scale from 0 to 5 (half marks are possible):

Score	
0	Proposal does not meet the criterion at all or cannot be assessed due to missing or incomplete information
1	Poor – the criterion is inadequately addressed or there are serious weaknesses
2	Fair – the proposal broadly addresses the criterion but there are significant weaknesses
3	Good – the proposal addresses the criterion well but there are a number of shortcomings
4	Very good – the proposal addresses the criterion very well but with a small number of shortcomings
5	Excellent – the proposal successfully addresses all relevant aspects of the criterion and any shortcomings are minor

The maximum overall score is thus 15 (3x5), unless the call text states that a weighting is applied. To be considered for funding a proposal must achieve a pre-defined qualifying score (threshold) on each criterion, as well as an overall qualifying score. Qualifying scores vary according to the type of action and between the first and second stage evaluations in the case of two-stage procedures. For each call, qualifying scores are stated in the call text.

6.3.2 Priority order for proposals with the same score

Unless the call conditions indicate otherwise, the following method will be applied (except for the first stage of two-stage calls, where proposals having the same score are kept together and no prioritisation is made).

If necessary, the EDCTP review committee will determine a priority order for proposals which have been awarded the same score within a ranked list. Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the topic description of the call. The following

approach will be applied successively for every group of ex aequo proposals requiring prioritisation, starting with the highest scored group, and continuing in descending order:

a) Proposals that address topics, or sub-topics, not otherwise covered by more highly-ranked proposals, will be considered to have the highest priority.

b) These proposals identified under (a), if any, will themselves be prioritised according to the scores they have been awarded for the criterion *excellence*. When these scores are equal, priority will be based on scores for the criterion *impact*.

If necessary, any further prioritisation will be based on the following factors, in order: gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the action; leverage of funding from third parties; relative number of sub-Saharan African countries involved; quality of the networking activities.

If a distinction still cannot be made, the EDCTP review committee may decide to further prioritise by considering the potential for synergies between proposals, or other factors related to the objectives of the call or the EDCTP2 programme in general. These factors will be documented in the report of the review committee.

c) The method described in point (b) will then be applied to the remaining *ex aequo* proposals in the group.

For prizes, the award criteria, scoring and weighting will be set out in the Rules of Contest.

7 Evaluation process

7.1 Single and two-stage evaluation procedures

EDCTP establishes the appropriate evaluation procedure for each call. The evaluation may comprise a single-stage procedure where full proposals are evaluated against the criteria of *Excellence*, *Impact* and *Implementation* or be a two-stage procedure where letters of intent (short outline proposals) are submitted to EDCTP. Whether proposals will undergo a single or two-stage evaluation procedure will be indicated in the call text of a given call for proposals.

For single and two stage evaluation procedures, the evaluation normally consists of two steps, namely:
- Individual assessment reports submitted remotely through EDCTPgrants by independent experts (step 1)
- A consensus meeting by the scientific review committee (step 2) to finalise the scores, rankings and recommendations.

Proposals are evaluated by independent experts (see Article 15(7) Horizon 2020 Rules for Participation Regulation No 1290/2013 for exceptional cases). As part of the evaluation by independent experts, the EDCTP review committee will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above. A ranked list will be drawn up for every indicative budget shown in the call conditions.

Proposal coordinators receive an Evaluation Summary Report (ESR), showing the results of the evaluation for a given proposal. For proposals that successfully pass the first stage of two-stage calls, standardised feedback is provided to all coordinators, but the first stage ESR is only sent after the second stage evaluation.

If special procedures apply, they will be set out in the call conditions.

Letters of intent are evaluated against the criteria of *Excellence* and *Impact* in the first stage of the evaluation, unless stated otherwise in the call for proposals and annual work plan. Those letters of intent which pass the quality threshold are invited to proceed to the second stage, which is the submission of a full proposal.

The full proposal is evaluated against the criteria of *Excellence*, *Impact* and *Implementation* as per a single stage procedure. To uphold the principle of equal treatment, proposals at the second stage of evaluation may be excluded if they deviate substantially from the corresponding first-stage proposal. Furthermore, second stage applicants will be asked to declare that their proposal is consistent with their first stage submission.

7.2 Expert assessments

Proposals will be assessed against the relevant criteria by independent experts who are qualified in the scientific and/or technological fields related to the proposal. Normally, a minimum of four independent experts evaluate each proposal. In the case of first stage proposals (letters of intent) in a two-stage evaluation procedure, for low-value grants, or in the case of oversubscription, it may be that only three experts are used. Before receiving any proposal for review, the expert must complete a declaration of interests, confirming that he/she has no conflict of interest with respect to the evaluation of that particular proposal and that he/she will adhere to EDCTP's Code of Conduct and Declaration of Interests Policy.

Each expert reviewer carries out an individual evaluation and submits a report via EDCTPgrants with comments and scores for each criterion. The written review and comments provided by the expert reviewers must be consistent with the scores awarded. The comments must give sufficient and clear reasons for the scores and, if appropriate, any recommendations for modifications to the proposal, should the proposal be retained. If a proposal is considered to be out of scope by all individual experts, it will be declared ineligible unless EDCTP considers that a further consideration by experts is necessary.

7.3 Rebuttal procedure

Unless otherwise indicated in the call text or work plan, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure) at the second stage of a two-stage evaluation procedure and for single-stage evaluation procedures. This rebuttal procedure is intended to allow the applicants to identify and comment on possible factual errors or misunderstandings that may have been made by the expert reviewers. The rebuttal procedure does not provide an opportunity for the applicants to modify the proposal.

The Coordinator will be sent the expert assessments (written comments only; scores are not provided) with a deadline of up to one week to provide a written response to the expert assessments. The deadline for the response may be shortened, depending on the timing of availability of the expert assessments.

7.4 Scientific Review Committee Meeting

EDCTP may organise a scientific review committee (SRC) meeting following the individual assessment stage in order to reach a consensus score and ranking for the proposals. The SRC may include some or all of the individual expert reviewers as committee members. The meeting may take place face-to-face or via video or teleconference. The evaluation procedure is described below.

EDCTP is responsible for briefing experts before each SRC meeting. The briefing covers:
- The terms of the experts' contract, including code of conduct (confidentiality, impartiality, declaration of interests) and completion of tasks including finalisation of the consensus evaluation summaries
- The evaluation process, including the criteria to be applied
- The content of the research topics under consideration
- The need to evaluate proposals as submitted and the limited scope for recommending improvements to highly scored proposals.

The SRC has a duty to examine proposals consistently and to operate in a coherent manner. Typically, the SRC is led by a Chairperson (moderator) who must ensure equal treatment and evaluation of the proposals. A group of rapporteurs may be appointed to draft the consensus evaluation summaries. Throughout the meeting, the EDCTP Secretariat will monitor the discussions of the SRC to ensure equal treatment and

evaluation of proposals, as well as consistency of treatment of proposals across the range of committees and the scientific/technological areas open in the call.

The SRC examines all of the proposals, evaluating them in line with the criteria as described in the call and work plan. The judgment of the SRC on a proposal and its position in the ranked list is based on the individual assessments, the rebuttal by applicants (where this is included in the evaluation procedure), discussion in the committee, and is arrived at by consensus. The outcome of the committee meeting is a consensus score and evaluation summary for each proposal that passes all thresholds. Proposals that have passed all thresholds are ordered on a list (ranking list) whereby the committee prioritises proposals for funding.

7.5 Interviews

If specified in the call text, an interview may form part of the evaluation procedure. Interviews may be conducted face to face or by electronic means (video link, teleconference or similar). Should a planned interview not be possible for reasons beyond the control of EDCTP, the committee will make its decision and recommendations based on the information made available to it. Travel and subsistence costs incurred in relation to interviews may be reimbursed by EDCTP.

7.6 Ethics review

In parallel to or immediately following the technical evaluation, EDCTP will contract, as necessary, independent ethics experts to check that proposals comply with ethical principles and relevant national, EU and international legislation. The main areas that are addressed during the ethics review process include:
- Human protection (in particular for study participants and researchers)
- Animal protection and welfare, where applicable
- Data protection and privacy
- Environment protection
- Participation of non-EU countries
- Potential for malevolent use of research results.

While the main focus of the review will be on the ethics dimension, EDCTP will also examine research integrity issues. Cases of scientific misconduct such as fabrication, falsification, plagiarism or misrepresentation of data that may arise during the evaluation or the granting process will be investigated and may result in exclusion of proposals from evaluation or from the grant preparation.

7.6.1 Ethics review procedure

The review procedure consists of:
- Self-assessment
- Ethics screening
- Formal ethics assessment
- Monitoring and checking ethical issues during the lifetime of the selected project.

7.6.2 Ethics self-assessment

All full proposals submitted under calls for RIAs and certain other types of actions must include an ethics self-assessment which involves:
- Completing an ethics issues table
- Providing a description of how the proposal meets the national legal and ethical requirements of the country (ies) where the tasks will be performed. In this context, the applicants should provide a copy of any obtained ethics committee opinion or notification or regulatory approval, as required by national legislation. If these documents are not available when submitting the proposal, the applicants must declare that, in case their project is selected for funding, they will communicate them to EDCTP, prior to the commencement of the relevant part of the research and indicate the timeframe for applying for opinion and/or for approval by any relevant authorities at institutional and national levels. When these documents are specifically obtained for the proposal, they will

contain an explicit reference to the title of the proposal.

- Discussing in detail how the ethics issues identified in the ethics issues table, will be addressed, in particular in relation to the research objectives (e.g. study of vulnerable populations, dual use, etc.); the research methodology (e.g. clinical trials, involvement of children and related consent procedures, human subjects protection, protection of data collected etc.) and the design of the research project from an ethics viewpoint; the potential impact of the research (e.g. questions related to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use etc.).

7.6.3 Ethics screening

The submitted proposals undergo an initial screen by the SRC for any ethical issues. This involves a critical reading of the proposals, including a discussion of the ethics self-assessment. Proposals with any identified or potential ethical issues will undergo a full ethics assessment (see below).

7.6.4 Ethics assessment

All proposals recommended for funding that have been identified as having (potential) ethical issues by the SRC will undergo an ethics assessment prior to the signature of the grant agreement. The assessment is an in-depth analysis of the ethical issues of the proposal by independent ethics experts. A report, which may include recommendations and/or contractual requirements, will be provided to the Coordinator for response and action prior to grant agreement signature.

8 Evaluation results

8.1 Selection and rejection of proposals

The SRC produces a ranked list of proposals that includes all proposals with scores above the qualifying score. If the call establishes indicative budgets for particular domains, e.g. fields of research, separate ranked lists may be prepared for each such field.

If the available budget is too small to fund all proposals that reached the qualifying score in the evaluation round, some proposals with scores above the qualifying score may be put on a reserve list of proposals that may be offered funding if a higher-scoring project does not go ahead or if additional funds become available. The Coordinator of a proposal on the reserve list will be notified at the time when the evaluation outcomes are given. EDCTP may specify a date after which grant agreement is unlikely to be offered. The remaining proposals are not retained for funding. This includes proposals that were ineligible, proposals below the quality threshold, as well as proposals which fall below a certain ranking but cannot be funded because the available budget is insufficient, including any proposals placed on a reserve list.

The assessment of quality, and the recommended rank order for funding of proposals on the retained list, is based on the peer review evaluation of the proposal against all relevant criteria. Where a proposal is judged not to achieve a quality threshold set for a particular evaluation criterion in the call, the proposal may be recommended for rejection during the course of the evaluation, without necessarily assessing it further against other applicable criteria.

Following formal approval of the evaluation outcome by the EDCTP Board and/or General Assembly, the grant agreement preparation phase is initiated with the successful applicants.

8.2 Financial viability and operational capacity

Coordinators will be invited at the full proposal stage to complete a self-assessment of financial viability using an online tool. Before granting funding, EDCTP may assess an organisation's financial capacity to implement the project. The financial assessment by EDCTP may include checking that the organisation is financially autonomous, solvent and has sufficient liquidity to cover its short-term commitments. EDCTP will

systematically verify the financial capacity of the Coordinator if the requested EDCTP project funding is equal or superior to €500,000 (five hundred thousand Euros). If an organisation's financial capacity has to be assessed, EDCTP will inform the applicant directly of the process and of the documents that need to be provided.

Operational capacity is assessed during the evaluation of the criterion *Implementation*. The expert reviewers will be asked to indicate whether the participants can demonstrate that they possess the operational capacity to carry out the proposed work, based on the competence and experience of the individual participant(s) and the consortium as a whole.

8.3   Feedback to applicants

Following the peer review evaluation and the formal grant decision taken by the Board and/or the GA, EDCTP provides feedback in the form of a proposal outcome letter to the Coordinator. For successful proposals, the letter serves to start the grant preparation phase. EDCTP's commitment to contribute financially to the project lapses automatically if the grant agreement is not concluded within three months of the date of the outcome letter.

All communication and feedback from EDCTP to the Coordinator is conducted electronically via EDCTPgrants. The call text for a given call for proposals indicates when the results of an evaluation are expected to be available.

Following the second stage of a two-stage evaluation procedure and following the single peer review evaluation in the case of a single stage evaluation, Coordinators of proposals receive feedback on the peer review evaluation in the form of an proposal outcome letter.

The feedback letter provides the outcome of the peer review evaluation with the final committee scores and the consensus evaluation report. In the case of the first stage of a two-stage evaluation procedure and where indicated in the work plan or call text, the mean or median value of the individual scores may be taken as the consensus score. The consensus report may comprise a collation of the individual assessments or extracts from them. For proposals recommended for funding, the outcome letter may indicate any recommendation made on the maximum amount of funding to be awarded, and any other appropriate recommendations on the conduct of the project, and/or suggestions for improvements to the methodology and planning of the work.

For proposals raising ethics issues, feedback on the ethics evaluation is communicated to the Coordinator. The feedback may include ethics requirements which become contractual obligations. Proposals rejected because of ethics and research integrity considerations are informed of the grounds for such a decision and the mechanism to address enquiries and complaints.

EDCTP will not modify the evaluation summary or individual reviewer's assessments except where necessary to improve readability or, exceptionally, to remove any factual errors or inappropriate comments, provided such errors or comments do not affect the evaluation results.

9   Preparation and signature of the grant agreement

9.1   Preparation of the grant agreement

In the case of successful proposals, and where there is sufficient budget available, details of the grant agreement preparation phase will be included in the proposal outcome letter sent to the Coordinator.

The grant agreement must be signed no later than three months after the receipt of the evaluation outcome letter. There is a strict deadline for each stage of the grant preparation phase to ensure that the agreement is signed in time.

During the preparation phase, the applicants will be asked to address any matters identified by the experts during the evaluation stage. The project will also be requested to provide additional legal, administrative and financial information that may be necessary for the preparation of the grant agreement. In the absence of a reply within the given deadlines, EDCTP may terminate the grant preparation phase for that proposal, and invite the next highest ranked proposal in the reserve list for grant preparations. In exceptional cases, when duly justified and requested by the Coordinator, EDCTP may extend the deadline to reply.

The legal and administrative aspects to be covered during the grant preparation include the verification of the existence and legal status of the applicants (legal entities), review of any optional provisions in the grant agreement or conditions required for the project, and other aspects relating to the development of the final grant agreement (including start date of project, timing of reports and other legal requirements).

The financial aspects will cover the amount of the pre-financing, the estimated breakdown of budget and financial contribution per participant, and the assessment of financial capacity.

During the grant preparation phase, if it is discovered that the declarations made by applicants are false, EDCTP may terminate grant preparations and invite the next highest ranked proposal in the reserve list for grant preparations.

The removal, addition or substitution of a legal entity before the signature of the grant agreement will only be permitted in duly justified cases.

If it proves impossible to reach agreement with the Coordinator and the other participants, or if any required supplementary conditions have not been met or agreements (such as the consortium agreement) have not been signed within a reasonable deadline, grant preparations may be terminated and the award withdrawn.

9.2   Consortium agreement

Consortium agreements are mandatory for all collaborative projects unless otherwise specified in the applicable work plan or call for proposals. The consortium agreement should set the framework for a successful project implementation (i.e. settle all issues that might hamper the smooth and seamless cooperation of the project partners). It should be negotiated and concluded before signing the grant agreement.

The consortium agreement is a private agreement between the project partners, which sets outs their rights and obligations. It does not involve EDCTP. The consortium agreement should complement the EDCTP grant agreement and must not contain any provisions contrary to it. Typically, the consortium agreement covers issues that will or may arise during the project (e.g. decision-making processes, resolving conflicts, protection, dissemination and exploitation of results). Please refer to the [Guidance on Drawing up a Consortium Agreement](#) available on the H2020 participant portal.

9.3   Signature of the grant agreement

Signing the grant agreement is the final stage of the grant preparation phase. It confirms formal approval by all parties of the agreement and its annexes. Please refer to the model [mono-beneficiary](#) and [multi-beneficiary](#) grant agreements for EDCTP2 for full details of the terms and conditions. The grant agreement enters into force on the day of the last signature. Typically, the Coordinator signs first, followed by EDCTP. It is the legal representative of the Coordinating institution that must sign the grant agreement. If the Coordinator does not sign the grant agreement within the specified timeline, EDCTP reserves the right to stop the grant preparations and to reject the proposal.

In a consortium, beneficiaries other than the Coordinator must accede to the grant agreement by signing an accession form. The accession form must be signed within 30 days after the grant agreement takes effect. In signing the accession form, beneficiaries accept the rights and obligations set out in the grant agreement as

of the date of entry into force.

If a beneficiary does not sign the accession form within 30 days of the grant agreement entering into force, EDCTP reserves the right to terminate the grant agreement. In this case, in order to continue with the project, the Coordinator must request an amendment, so that any changes needed to ensure that the project is carried out properly can be made. This request must be made within 30 days after the missed deadline for signing the accession form. The request for an amendment does not affect EDCTP's right to terminate the grant

EDCTP will publish the details of awarded grants on its website and in other media. EDCTP may also publish general information on the results of the peer review evaluation.

10 Enquiries, complaints and appeals

10.1 Enquiries

The call for proposals includes information on how applicants can seek assistance on any matter related to a call for proposals. Contact details are provided in the call for proposals for specific questions related to the call topic and for questions related to the electronic submission system. EDCTP will handle your enquiry as quickly as possible but cannot guarantee to provide an answer in time shortly before a call deadline. EDCTP has published a list of Frequently Asked Questions (FAQs) on its website. The FAQs provide additional guidance and aim to clarify and address questions from potential applicants. Please consult the FAQs before contacting EDCTP as the answer to your question may be contained within the FAQs.

10.2 Complaints

If you think that the submission of your proposal was not entirely successful due to a technical error within EDCTPgrants, the Coordinator may lodge a complaint through EDCTPgrants. For the complaint to be admissible it must be addressed to the EDCTP Executive Director, be submitted in writing on the official letterhead of the Coordinator and cc'd to the legal representative of the Coordinator. The Coordinator must submit the letter as an email attachment via EDCTPgrants. The complaint must be submitted within four calendar days following that of the call closure. You will receive an acknowledgement of receipt the same or next working day.

You should attempt to secure a PDF version of all the completed sections and annexes of your proposal holding a timestamp (file attributes listing the date and time of creation and last modification) that is prior to the call deadline, as well as any proof of the alleged failure (e.g. screen shots). Later in the procedure you may be requested to provide these items. Please, note that any information regarding the proposal will be treated in a strictly confidential manner.

In order that a complaint would be upheld, the IT audit trail (application log files and access log files of EDCTPgrants) must show that there was indeed a technical problem within EDCTPgrants that prevented you from submitting (or resubmitting) the proposal through EDCTPgrants.

You will be notified about the outcome of your complaint as soon as possible and no later than 15 working days following the receipt of your complaint. If a decision cannot be reached within this time period, you will receive a holding reply with an indication of when a response is expected.

If your complaint is upheld, the secured files (provided by you to the EDCTPgrants helpdesk) will be used as a reference for accepting the proposal for subsequent evaluation. In absence of such documents, the latest version present in EDCTPgrants at the time of the call deadline will be evaluated.

10.3 Appeals

10.3.1 General principles

Appeals are specific complaints by applicants that consider that the evaluation of their proposal has not been carried out by EDCTP in accordance with the procedures set out in the H2020 Rules for Participation, the relevant EDCTP2 work plan or call for proposals. The appeal must relate to the evaluation procedure (admissibility and eligibility check, peer review evaluation, ethics review, financial and operational capacity check) that the proposal has undergone following submission to an EDCTP call for proposals. The proposal outcome letter containing the results of the evaluation gives information on the appeals procedure, which is described below. The deadline for receipt of appeals is 30 days from date of dispatch of the proposal outcome letter by EDCTP.

10.3.2 Admissibility of appeals

For an appeal to be admissible the following conditions must be met:
- The appeal must be submitted by the Coordinator of the proposal to which the appeal relates
- The appeal must be submitted in writing on the official letterhead of the Coordinator and must be cc'd to the legal representative of the Coordinator
- The appeal must be addressed to the EDCTP Executive Director
- The appeal must be submitted via EDCTPgrants within the 30 day deadline.

The appeal must contain the following minimum information:
- The name of the call for proposals
- The proposal number
- The title of the proposal
- A description of the alleged shortcomings of the EDCTP evaluation procedure.

Upon receipt of an admissible appeal, EDCTP will send an acknowledgement of receipt within ten working days of receipt of the appeal. The acknowledgement shall state whether or not the appeal is admissible and outline the process for consideration of the admissible appeal and the anticipated date by which a decision on the appeal will be communicated to the applicant. As a guideline, all appeals received by the 30-day deadline will be processed together. EDCTP estimates that it will take six weeks from the 30-day deadline to process the appeal and to communicate the decision to the appellant.

10.3.3 Appeals procedure

The EDCTP Executive Director will establish an internal appeals committee, comprising three EDCTP Secretariat members. The role of the appeals committee role is to evaluate the admissible appeals according to the procedure, ensuring fair and equal treatment of applicants. Complaints that do not meet the above conditions, or do not deal with the evaluation of a specific proposal, will not be considered.

The appeals committee will provide its opinion on the implementation of the evaluation procedure on the basis of all of the available information related to the proposal and its evaluation. The committee does not evaluate the proposal itself, only the evaluation procedure of the proposal. Depending on the nature of the appeal, the committee may review the CVs of the independent experts, their individual comments, and the consensus evaluation report. The committee will not call into question the scientific judgment of appropriately qualified experts.

In the light of its review, the committee will make a recommendation to the EDCTP Executive Director. If the committee considers that there has been a failing in the evaluation procedure that may have influenced the evaluation outcome, it may suggest a further evaluation of all or part of the proposal by independent experts. The committee may uphold the initial outcome. The committee may make additional comments or recommendations. The outcome of the appeal will be communicated by letter to the Coordinator by EDCTP.