



EDCTP

The power of sharing science

EDCTP2 Grants Manual



History of changes

Version	Date	Changes
2B	28 July 2015	<ul style="list-style-type: none"> • 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	<p>Updated in accordance with EDCTP Work plan 2016 and corresponding changes in H2020 procedures and editorial changes.</p> <ul style="list-style-type: none"> • 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)
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6	27 May 2019	<p>Updated in accordance with EDCTP2 Work plan 2019 and H2020 procedures</p> <ul style="list-style-type: none"> • Update to evaluation procedure and evaluation criteria • Note on UK eligibility • Revision of text for clarity (section 4) • Update to scoring and weighting (6.3), rebuttals (8.3)
7	9 July 2019	<p>Update to section on appeals (requests for redress): extra details added on grounds for appeal.</p>

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

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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); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; 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 chapters 6-9)
- The grant contract process for successful applicants (awarding phase: see chapter 10)

2. How to apply: Before proposal submission

2.1 EDCTP funding opportunities: calls for proposals

Proposals to EDCTP for funding must be submitted in response to published calls for proposals. EDCTP does not normally 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 Grants awarded without a Call for Proposals

In case of a public health emergency (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082/2013/EU or under applicable national frameworks and regulations), research grants may be awarded in line with specific provisions of the Financial Regulation¹ that allow the awarding of grants without call for proposals in exceptional and duly substantiated emergencies. At that time, EDCTPgrants will open a dedicated section where research applications can be received. This will be communicated to the EDCTP General Assembly members. EDCTP will undertake an expedited evaluation procedure of proposals submitted in response to the emergency procedure.

2.3 Funding schemes (Actions)

Three types of actions are supported under EDCTP2:

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

2.3.1 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

¹Article 128.1 of Regulation (EU, Euratom) 966/2012 "Grants shall be subject to a work programme, to be published prior to its implementation. That work programme shall be implemented through the publication of calls for proposals, except in duly justified exceptional cases of urgency or where the characteristics of the beneficiary or of the action leave no other choice for a given action, or where the beneficiary is identified in a basic act."

Article 190.1 (b) of the Commission Delegated Regulation (EU) No 1268/2012 "Exceptions to calls for proposals: 1. Grants may be awarded without a call for proposals only in the following cases: [...] (b) in other exceptional and duly substantiated emergencies[...]"

<https://www.force11.org/group/fairgroup/fairprinciples>

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%

2.3.2 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. CSAs do **not** support clinical research studies – clinical research is supported under the RIA funding scheme, and in some cases under the TMA funding scheme.

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%

2.3.3 Training and Mobility Actions(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%

2.3.4 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. In addition, '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.

They must demonstrate that they possess the operational and financial capacity to carry out the proposed tasks. Please note that being eligible to participate is not the same as being eligible to receive funding. 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, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, 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, Equatorial Guinea, Eritrea, 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 Barthélemy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna.

Countries Associated in full to Horizon 2020² :

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.

Natural persons and/or 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;³
- When the EDCTP Association deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme
- For Prizes, any natural person or legal entity regardless of the place of establishment, or international organisation may receive funding⁴.

Please note that until the UK leaves the EU, EU law continues to apply to and within the UK, when it comes to rights and obligations; this includes the eligibility of UK legal entities to fully participate and receive funding in Horizon 2020 actions such as those called for in this work plan. Please be aware however that the eligibility criteria must be complied with for the entire duration of the grant. If the UK withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, they will no longer be eligible to receive EU/JU funding and their participation may be terminated on the basis of Article 50 of the grant agreement.

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

² 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](#)

³ No agreements or arrangements of this kind are currently existing.

⁴ 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.

attachment in response to calls for proposals. If you intend to participate in an EDCTP proposal, please 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 participate in. 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
- **Do not** create multiple accounts for yourself with different email addresses
- 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 address if you need to
- 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 lead organisation (legal entity acting as Coordinator) that will represent the project consortium towards EDCTP. Proposals for RIAs and CSAs may include other Participants (co-applicants). RIA proposals are submitted by consortia (see chapter 6). For CSA proposals, depending on the call these may be submitted by a single legal entity and/or with other other participants, and in some cases, when specifically mentioned in the call, it is compulsory. TMA proposals are submitted by a single organisation (Coordinator). Other people may be involved in the proposal but the grant is awarded to the Coordinator only.

Other participants (co-applicants and their organisations) 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. There must be one person per organisation in the proposal. The affiliations of the persons must match the organisations in the proposals. Only one person (lead person) is needed to represent the organisation therefore do not include multiple people/organisation. The roles of additional people may be mentioned in the proposal text. Before adding other participants, make sure that the organisation that they represent is willing to participate fully in the action by acceding to the EDCTP2 grant agreement.

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, data management, communication, dissemination and exploitation)

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 study template, 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 admissibility and 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 chapter 11). 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 may count against possible future resubmission restrictions if the withdrawal request is received after the evaluation has been conducted, in full or in part.

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 to the same call or to different calls, 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, review committee members and EDCTP General Assembly and Board 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. For more details, see chapter 5 on data privacy.

5. Data privacy statement

5.1 Privacy Statement on Grants Management

5.1.1. Introduction

This Privacy Statement states our reasons for collecting and processing your personal data, the way we protect your personal data, and the rights you may exercise in relation to your data.

The EDCTP-Association (EDCTP) is committed to protecting and respecting the privacy of applicants and its beneficiaries.

We currently manage one programme, EDCTP2, which is part of the European Framework Programme for Research and Innovation, Horizon 2020. The European Union (represented by the European Commission) and the EDCTP Association signed a Delegation Agreement in December 2014, under which the Commission entrusted budget implementation tasks to the EDCTP Association under Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014. The entrusted tasks include managing all stages (registration, grant proposal evaluation and awarding, grant management and follow-up) of Calls for Proposals. EDCTP (the Controller) collects personal data regarding these activities.

Applicants in the context used in this Statement refers to the legal entities that apply for funding through the submission of proposals. Beneficiaries are the successful applicants, i.e. participants in funded research action. Applications are submitted by principal investigators (or coordinator or lead applicant), the person who submits a proposal on behalf of the consortium via "EDCTPgrants", which is the online platform that EDCTP uses to process grant proposals submitted to EDCTP for funding. References made to grants in this document also apply to prizes.

5.2 Why do we process your data?

5.2.1 Purpose of the processing

The data you provide in "EDCTPgrants" are collected to allow EDCTP (the controller) to evaluate your proposal and/or organisation, to award funding if your proposal is successful, to manage grant agreements, and to fulfil its obligations towards its funders. The data may also be used for research purposes and/or for analysis at a programmatic level (which will, in principle, not involve the processing of personal data).

A limited subset of this information may be used by EDCTP for communication purposes, in accordance with the rules of each call for proposals or contest for prizes. EDCTP may also use the contact details of successful applicants to compile invitation lists for EDCTP conferences and other EDCTP organised events.

The contact details of administrative staff of beneficiaries may be shared with other interested parties (for example, funding agencies not involved in the action, researchers or journalists), but only after having received the unambiguous consent from the relevant data subjects.

5.2.2 Lawfulness of the processing

The personal data collected by EDCTP in relation to EDCTP Calls for Proposals are processed based on a legal obligation, which include:

- Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 ('EDCTP2 Decision');
- The Delegation Agreement between the EU, represented by the EC, and EDCTP (following from the EDCTP2 Decision);
- Regulation (EU, Euratom) No 1966/2012 of the European Parliament and of the Council of 25 October 2012 ('Financial Regulation,' as declared applicable in the EDCTP2 Decision);
- Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 ('Horizon 2020 Rules for Participation' as declared applicable in the EDCTP2 Decision); and
- The relevant EDCTP2 Work Plans (following from the EDCTP2 Decision).

5.3 Which data do we collect and process?

The data subjects include principal investigators, other investigators, fellows, staff of applicants/beneficiaries with assigned roles in the proposals/projects. The data are collected directly or indirectly from the data subjects, and are necessary for our reporting and entering into a contract with the successful applicants.

A detailed overview of which data are collected during which stage of the procedure and for which purpose are set out below:

5.3.1 Registration EDCTPgrants

Proposals in response to any Calls for Proposals must be submitted via EDCTPgrants. During the registration process (creating a login account in EDCTPgrants) personal data, including contact and identification details, are collected:

- Title
- First Name
- Last Name
- Date of Birth
- Nationality
- Position
- Email
- Address (usually organizational)
- Gender.

At the registration stage, there is the option to submit a curriculum vitae (CV). This is optional when registering for EDCTP grants, but a curriculum vitae is required when submitting a proposal (as it is required to determine operational capacity).

5.3.2 Submission of a Proposal

To submit a proposal, a CV or description of the profile of the person who will be primarily responsible for carrying out the proposed research is required (in addition to the identification data mentioned above). Educational data necessary to determine the eligibility and/or experience necessary for the evaluations of the proposed action(s) may be included in CV. However, personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, health or sexual orientation are not requested here (and will therefore only be present here if offered spontaneously). This kind of information will, in principle, not be processed, as it is not relevant for the application.

A proposal is submitted by a Coordinator (lead applicant). The proposal may include co-applicants (obligatory for RIA proposals.) The lead applicant must add details of other data subjects involved in the proposal. These data subjects must confirm their participation in the proposal to be submitted. This can either be done through EDCTP grants or the data subject must provide his/her unambiguous consent to the applicant/beneficiary in compliance with Article 5(d) of Regulation (EC) No 45/2001. The consent could be provided through the signature of a declaration of agreement (kept by each applicant/beneficiary and provided to the controller if there is a need for verification). A co-applicant (as invited by a lead applicant) can at any time inform EDCTP that he or she has been added to a proposal without their knowledge or permission and request for their data to be removed from the application.

In addition to the personal data of the lead applicant and other investigators, EDCTP will at the proposal submission stage also process personal data of all other individuals (data collected indirectly) included in the proposal. For fellowships this includes the name and contact details of the fellow's supervisor. These data are necessary for the evaluation of the proposal and for the grant agreement if the proposal is successful. By submitting the application, the lead applicants confirm that they have provided all staff with the Privacy Statement before submitting their data.

5.3.3 Grant preparation data

EDCTP will collect and process additional personal data for successful applicants in order to prepare and process the grant agreement. These include:

- The name of the legal representative of the lead applicant's organization and of all the co-applicants' organizations (collected in the legal entity form and declaration of honour);
- Bank account information and VAT number. This will, in principle, not be personal data, as EDCTP only signs grant agreements with legal entities;
- The name(s) of designated persons preparing financial reports within organizations receiving payments directly from EDCTP are collected as part of EDCTP's due diligence, which it must perform under the EDCTP 2 Decision (collected in the 'financial management questionnaire');
- Cost statements, including personnel costs which reflect the total remuneration, social security charges and other statutory costs (collected in the Budget form);
- Other categories of data: in compliance with Article 131(3) and 131(4) of Regulation (EU, Euratom) No 966/2012 (Financial Regulation). These include information contained in the declaration of honour, including the names person(s) representing them, members of their staff are not in one of the exclusion situations referred to in Article 106 (1), 107 and 108 of the amended Financial Regulation, i.e., for example, bankruptcy, professional misconduct, fraud, or corruption; and
- Additional documentation may be requested in the framework of the ethics screening/review/monitoring of actions, including, for example (but not limited to), training certificates, licenses, authorizations from local/regional/national competent authorities, permissions for secondary use of personal data.

5.3.4 Publication of the personal and contact details

For successful applicants the name of the project coordinator, and in case of fellowships and prizes, the name of the fellow or prize winner is published on the EDCTP website (in addition to details regarding the funded action, such as, for example, the name of the action and the grant amount). This information may also be included in reports.

5.3.5 Grant monitoring

In fulfilling the reporting requirements set out Article 20 of the Grant Agreement), beneficiaries periodically submit reports, including a periodic technical and financial reports to EDCTP. These reports may contain personal data (e.g. names of participants, staff members, trainees). Any information provided to EDCTP in relation to 'a summary for publication by the EDCTP Association,' in the periodic technical report (Article 20.3 of Grant Agreement) and final report (Article 20.4 of the Grant Agreement) may be published by EDCTP on its website and in (publicly available) reports.

The information provided during the reporting is necessary for the monitoring of the implementation of the Grant Agreement and for the processing of payments under the Grant Agreement.

5.4 How long do we keep your data?

For audit purposes EDCTP is required to keep all (personal) data processed in relation to its Calls for Proposals for a period of five years after the final payment of the balance of EDCTP, which is expected to take place in 2026.

5.5 How do we protect your data?

All data submitted via EDCTP grants are stored on servers managed by CC technology (the processor) in the United Kingdom. Only authorized staff of CC technology has access to this information. All data are transmitted over a secure internet connection (encrypted).

All data in electronic format are stored on either EDCTP servers or on computers, laptops of EDCTP staff – with appropriate security measures in place.

All stakeholders involved in the evaluation and granting process (EDCTP staff, expert reviewers, scientific review members, the EDCTP Board, and the EC) are reminded to handle personal data confidentially and to use the personal data only for the purpose for which they were transmitted and to disregard all irrelevant and excessive data received with the proposals. Furthermore, all stakeholders are bound by the terms of the [EDCTP Code of Conduct and Declaration of Interests policy](#), which assures confidentiality in the granting process.

5.6 Who has access to your data and to whom is it disclosed?

All recipients are reminded of their obligation to process the personal data provided to them only for the purposes for which they are collected or transmitted.

Access to personal data is given to EDCTP staff without requiring the consent of the data subject.

The EDCTP Secretariat has an office in Europe (The Hague, the Netherlands) and in Africa (Cape Town, South Africa), but functions as one office. For this reason, personal data may be transferred from Europe to our South African office, particularly in relation to its management of all stages of its Calls for Proposals. The EDCTP Africa Office will process personal data as much as possible in accordance with the data protection laws of the Netherlands and will in any case adhere to the data processing principles set forth in Annex A of the 'Standard contractual clauses for the transfer of personal data from the Community to third countries (controller to controller transfers).' (See Commission Decision of 27 December 2004 amending Decision 2001/497/EC as regards the introduction of an alternative set of standard contractual clauses for the transfer of personal data to third countries.) A data transfer agreement to this effect has been concluded between the two offices.

EDCTP staff, reviewers, advisory bodies and other external recipients are bound by the EDCTP Code of Conduct and Declaration of Interests policy, which assures confidentiality in the granting process.

Access to personal data is given to the following external recipients on need-to-know basis without requiring the consent of the data subject:

- CC Technology (the processor). Personal data submitted via EDCTP grants are accessible by their authorized staff. EDCTP has concluded a processor agreement with CC Technology;
- Independent experts, contractors, and beneficiaries of actions who are working for or on behalf of and under the responsibility of the Controllers (EDCTP) for the purposes of evaluation of proposals, monitoring of grants, networking among beneficiaries, as well as

design, monitoring and evaluation of the EDCTP2 Programme are provided with the necessary information for their purpose;

- External auditors;
- Authorized staff of partners in case of a joint Call – if a Call is organized together with another organization this will always clearly be stated in the Call text. Information is shared only for specific purposes (usually evaluation of proposals); and
- Authorized staff of the EC, as EDCTP is under the obligation to provide any information requested by the EC. All data transferred to the EC is processed pursuant to Regulation (EC) 45/2001.

5.7 What are your rights and how can you exercise them?

In accordance with Regulation (EU) 2016/679 (GDPR) and Regulation (EC) No 45/2001, you are entitled to access your personal data and to rectify/block or erase them in case the data are inaccurate or incomplete.

You can exercise your rights by contacting the EDCTP data controller (see contact information in chapter 5) or follow the procedure described below:

- At the registration stage, you can log into EDCTPgrants and modify your personal data.
- At proposal preparation or application stage, you can modify, correct or delete any personal data before the end of the call deadline. Once the call deadline has passed, proposals are still available, but no further additions or corrections of personal data are possible. During the evaluation review procedure, modifying the information that has been submitted is not allowed.
- At the end of the evaluations, the legal entities whose proposals have been approved for funding, will be invited to start the grant preparation phase. During this period, the data subjects can modify and/or delete their personal data (included in the proposal) by requesting the assigned EDCTP Project Officer to do so.
- After the Grant Agreement has been signed and during the implementation of the action, the coordinator can request the assigned EDCTP Project Officer (the EDCTP communication contact point specified in Article 52.3 of the Grant Agreement) to modify and/or delete any personal information. Such changes may require a formal request for an amendment of the Grant Agreement (Article 55 of the Grant Agreement).

You also have the right of recourse at any time to the European Data Protection Supervisor.

5.8 Contact information

Should you have any comments or questions, concerns, or a complaint regarding the way EDCTP collects, processes and manages your personal data in relation to EDCTPgrants, its Calls for Proposals, and any of its grant management processes, please send an email to: info@edctp.org.

6. 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 set out 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.

6.1 Admissibility criteria

To be considered admissible, a proposal must be:

- Submitted online in EDCTPgrants
- Submitted by 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 in EDCTPgrants. It is not possible to exceed the word limits in the online submission and the applicant will not be able to submit the application.

6.2 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 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.

Please note the above section on the status of the United Kingdom following Brexit.

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).

7. 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.

7.1 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.

7.2 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 and may also include additional aspects that will be specified in each call. See the work plan and call text for details of the evaluation criteria.

7.3 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. For each indicative budget-split in the call conditions, 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 RIA second-stage proposals as well as for single-stage evaluation procedures (RIAs) only, unless otherwise indicated in the call text, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure). There is no rebuttal procedure for CSA and TMA calls
- 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.

7.3.1 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:

- Proposals that address topics, or sub-topics, not otherwise covered by more highly-ranked proposals, will be considered to have the highest priority.
- 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 (for TMAs, female fellowship candidates shall have priority); relative number of sub-Saharan African countries involved, in particular involvement/representation of countries with more limited research capacities; leverage of funding from third parties; quality of the networking activities.

- d) If a distinction still cannot be made, the EDCTP Association 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.
- e) The method described in points (a), (b), (c) and (d) 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

8. Evaluation process

8.1 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 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.

8.2 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.

8.3 Rebuttal procedure

For RIAs only, 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 proposal is scored as it was submitted and not as modified by the rebuttal.

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.

8.4 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. The moderator may be a member of EDCTP Secretariat or an external expert. 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. An independent observer may be present to ensure compliance with procedures.

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.

8.5 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.

8.6 Ethics evaluation

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.

8.6.1 Ethics evaluation 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.

8.6.2 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 indicate the timeframe for applying for opinion and/or for approval by any relevant authorities at institutional and national levels, and obtain the relevant ethics and regulatory approvals prior to the commencement of the relevant part of the research. 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.).

8.6.3 Ethics screening

The submitted proposals undergo an initial screen by EDCTP Secretariat and/or independent experts 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).

8.6.4 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.

9. Evaluation results

9.1 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.

9.2 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.

9.3 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 a 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. The individual scores are not provided. 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.

10. Preparation and signature of the grant agreement

10.1 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.

10.2 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 out 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.

10.3 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.

11. Enquiries, complaints and appeals

11.1 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.

11.2 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 and must provide evidence of the alleged technical error within EDCTPgrants. 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.

11.3 Appeals

11.3.1 General principles

Appeals (Requests for redress) are specific complaints by applicants who 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 appeals procedure is not meant to call into question the opinions and judgement made by the expert evaluators; it will look at procedural shortcomings and – in rare cases – into factual errors. It is not intended for cases where the applicant simply disagrees with the opinion(s) of one or more of the expert reviewers.

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.

11.3.2 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 (email plus pdf attachment) 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.

11.3.3 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 judgement 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. EDCTP does not undertake to engage in any further discussion about the evaluation of your proposal beyond the definitive response.

EDCTP counts on your cooperation not to send in speculative appeals. Unless there is clear evidence of a procedural shortcoming there will be no follow-up or re-evaluation.