

Guidelines for Applicants



Call for the support of Member States Initiated projects within the scope of EDCTP activity areas

Version 2.0

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



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1 Introduction

The European and Developing Countries Clinical Trials Partnership (EDCTP) makes its funding decisions based on proposals submitted in response to calls published by EDCTP or, in exceptional cases, EDCTP decides to fund **projects** after successful brokering. These Guidelines for Applicants takes the applicant through the process of preparing and submitting a **proposal** in response to an EDCTP **Call for Proposals** and is essential reading. Chapter 2, 'Preparation of a proposal,' gives important information necessary for applicants to prepare a well-described and focussed proposal. Information about the new EDCTP funding scheme, requirements of the consortium, required language, cofunding and budget requirements and ethical and regulatory issues are given. For some subjects, we refer to the annexes of these guidelines, which are also essential reading.

Chapter 3, 'How to fill in the application form,' gives all the practical information required in order to correctly fill in the application form. Chapter 3 starts in section 3.0 with general information and proceeds with explanatory notes and requirements per work package: section 3.1 – work package 1 'Project Management;' section 3.2 – work package 2 'Clinical Trial;' section 3.3 – work package 3 'Capacity Building;' section 3.4 – Work package 4 'Networking'.

Chapter 4 is a checklist that provides a summary of all eligibility criteria and annexes that the applicant should attach to the full proposal.

In chapter 5, 'Submitting your proposal,' there is information about the requested format of the application.

Chapter 6 'What happens next' deals with the registration and evaluation procedure and aims to provide information on the selection criteria and what can be expected if the proposal is selected for funding.

Chapter 7 consists of a provisional timetable that indicates what is expected from the applicant as well as from EDCTP and how the different stages in the process from the launch of the call to the funding of a project relate to each other.

Finally, there are four annexes to these guidelines, namely: Annex I Guidelines for Good Partnership with Developing Countries, Annex II EDCTP General Contract Terms, Annex III Cofunding guidelines for EDCTP grants (including letter templates for cofunding) and Annex IV. EDCTP selection procedure and evaluation criteria.

Applicants are encouraged to read the EDCTP **Joint Programme** available on our website www.edctp.org. Other documents such as the **World Medical Association Declaration of Helsinki** or the **ICH** guidelines, which can be found at the links page of the EDCTP website are suggested reading.

*These Guidelines for Applicants includes a Glossary containing explanations and definitions used in this guideline. All words in **bold** are explained in the Glossary.*

2 Preparation of a proposal

2.1 About the funding scheme

*The funding scheme presented here is generally applicable to all EDCTP integrated calls. For the specific requirements per call, please read the specific **call text**!*

EDCTP, bringing together 15 EU countries, Norway, Switzerland (together the **EDCTP-EEIG Member States**) and 47 **sub-Saharan African countries**, aims to support the development of new or improved clinical interventions to fight HIV/AIDS, malaria and tuberculosis through European research integration and in partnership with African countries (please refer to Annex I). To ensure closer collaboration between National Programmes in the North and to create new and more effective North-South **joint activities**, EDCTP encourages multiple site activities. Coordination of European research collaborations with African scientists will benefit all partners and strengthen the visibility and impact of their work. In addition, EDCTP aims to improve the general environment for carrying out clinical trial activities in Africa. To integrate and raise the role and profile of African sites, centres and researchers is one of the major challenges at this stage. Success and sustainability of the EDCTP programme depends greatly on political commitments, co-ownership and leadership by the African partners. EDCTP differs from many other funding bodies in that it was established under Article 169 of the Treaty of the European Union. This allows the European Commission to contribute to research in conjunction with the national research programmes of the EDCTP-EEIG Member States. One effect of this is that research funded by EDCTP



normally incorporates cofunding from individual European member states alongside funding provided to EDCTP by the European Commission. In addition, one of the objectives of the EDCTP initiative is to integrate European national research programmes into Joint Programme activities involving at least two European member states.

2.2 Who can apply?

2.2.1 Overall consortium requirements

There is a mandatory requirement for the **project** to involve **collaborators** employed by at least two public institutions from different **EDCTP-EEIG Member States** as well as one from **sub-Saharan African countries**.

*If you need to find new partners to comply with the requirements for this proposal you may use **Project Partners**. Project Partners is a new web-database available at our website (www.edctp.org), developed to promote networking between European and African partners.*

2.2.2 The Project Coordinator

The **Project Coordinator** is the coordinator of the full project. The **Project Coordinator** is considered the only contact point with EDCTP for the proposed **project** during the review procedure and grant agreement preparations.

The **Project Coordinator** of the submitted project needs to adhere to the following requirements:

- The application can only have one Project Coordinator. All other researchers fulfil the role of collaborators.
- It is expected that the **Project Coordinator** has been awarded a postgraduate medical qualification, PhD, or equivalent with some years of experience. (Please note that EDCTP may require a copy of your certificate). Individuals with less experience and qualifications should apply as a **collaborator**.
- EDCTP strongly supports African leadership and encourages African nationals that reside in Africa or plans to return to Africa to take on the role of Project Coordinator.
- If the Project Coordinator is not an African national then the project must contain an element of training and mentoring to ensure that an African national involved with the project is able to act as Project Coordinator in the future.
- The Project Coordinator needs to be employed by a **public institution** from one the following EDCTP participating countries:

Sub-Saharan African countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Ivory Coast, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

EDCTP-EEIG Member States: Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

- If the Project Coordinator retires during the course of the study, he or she needs to identify a successor in the application. Retired researchers are requested to take the role of **collaborator** in the application.
- If the Project Coordinator knows that he or she will change employment during the course of the project, his or her new employer and, if applicable, his or her successor, need to be mentioned in the application.



2.2.3 Other collaborators

In principle, any person from a **legal entity** from any country may participate as **collaborator** in an EDCTP funded **project** as long as the minimal consortium requirements (section 2.2.1 of these guidelines) are met.

The **collaborators** of the submitted **project** need to adhere to the following requirements:

- All collaborators involved should hold at least a university degree in the relevant areas of their activity. (Please note that EDCTP may require a copy of your certificate). Collaborators with less experience should normally apply in collaboration with a more experienced and senior colleague.
- Retired researchers may have the role of collaborator in the application.
- Any collaborator who knows that he or she will change employment during the course of the trial needs to state his or her new employer and, if applicable, his or her successor, in the application.

2.3 How to apply

The work described in the **proposal** must correspond to a particular EDCTP **Call for Proposals** or in exceptional cases has to correspond to the indications given by invitation for a brokering approach. The **proposal** has to meet all **eligibility criteria** described in the **call text** and in these Guidelines (section 4.1). Proposals that fail to do so will be considered ineligible. The **selection criteria** (given in section 6.4), against which each proposal will be reviewed, must be taken into account.

Every project must include **cofunding** from the **EDCTP-EEIG Member States**.

In this chapter *2.3 How to apply?* We aim to give all information necessary for the preparation phase of the proposal. Please refer to the annexes of these guidelines for more background information on the following subjects:

- Annex I: Guidelines for Good Partnership with Developing Countries
- Annex II: EDCTP General Contract Terms
- Annex III: Cofunding and Financial Guidelines for EDCTP Grants
- Annex IV: EDCTP selection procedure and evaluation criteria

2.3.1 Language

The proposal must be written in the English language. All supporting document in languages other than English must be accompanied by an official translation.

2.3.2 Declaration of secured cofunding

Although proposals are submitted by the project coordinator, all proposals for Member States Initiated projects must be supported by an 'initiator' who must be a member of the EDCTP General Assembly (GA) and must have secured at least 75% of the total funding requirement from participating member state(s) or third parties. Persons submitting proposals to this call must therefore also provide official letters of 'declaration of secured cofunding' signed by the respective GA member(s) from each cofunding member state(s) and each third party donor or funder. Please see annex III of these guidelines for model or template letters which should be used.

2.3.3 Evidence of (scientific) review and approval

All proposals for Member States Initiated projects must have been fully peer reviewed and or approved by competent or designated bodies from the initiating member state. Persons submitting proposals must therefore submit the following supporting documents together with their application.

1. A report of scientific review with English translations (where applicable)
2. Either an official award letter or a letter of 'confirmation of scientific review and approval' signed by the GA member(s) from the initiating member state stating that the project has been approved. Where other participating member states have also required their own scientific review, confirmation of these approvals should also be provided together with any conditions that may apply. Please see annex III of these guidelines for model or template letters which should be used.



2.3.4 Cofunding from other sources

Cofunding from African partners

Cofunding from African partners is strongly encouraged but not compulsory. EDCTP would however like, where possible, to be able to demonstrate any direct or indirect African financial contribution to the partnership. Applicants are therefore asked to indicate any African cofunding contributions, whether in cash, in kind or from third parties.

Cofunding from third parties

EDCTP actively encourages third-party contributions to a **project**. These may be from any non-national public funding source including research funding international organisations, commercial companies, product development Partnerships (PDP), **private institutions** or foundations or countries other than the **EDCTP-EEIG Member States**. Similary contributions from consortia funded by the European Commission count as third party funding. There is no limit to the level of third-party contributions and whatever the amount involved it will not in any way affect the level of funding provided by EDCTP.

Please note that if cofunding has been applied for from an African source or third party the applicant must also provide a supporting letter from the relevant party mentioning that the party is aware of the proposal, indicating the amount of the requested cofunding and whether this has been secured or is still under review. The template letter in annex III can be used for this.

Please note that the amounts mentioned in these letters should correspond to the amount indicated in the budget form.

2.4 How to prepare your budget

Every application sent to EDCTP should be accompanied by a completed budget form (a budget template form is available on our website). Please ensure that the total value of your requested budget as EDCTP contribution is not above the ceiling per grant as stated in the call text. Not all costs are eligible. A detailed explanation of which costs are eligible and which are not eligible can be found in the EDCTP Financial Guidelines in Annex III. Please read these carefully.

2.5 Ethical considerations

Regulatory authorities require that all new investigational medicinal products intended for use in humans must be shown to be safe, effective and of the highest quality.

All studies that are funded by EDCTP must be implemented in accordance with the standards and codes of conduct accepted by the **International Conference on Harmonisation (ICH)** guidelines (follow the link on the links page of our website www.edctp.org) and in compliance with the local ethics requirements of the countries where these studies are to be conducted.

In accordance with these guidelines, all clinical studies have to be submitted to and approved by an **independent Ethics Committee** that complies with the World Health Organisation Operational Guidelines for Ethics Committees That Review Biomedical Research (TDR/PRD/ETHICS/2000.1). A link to this document can be found at our website (www.edctp.org) under the 'Calls and Grants' section in 'Guidelines and forms' together with the complementary guidelines to Operational Guidelines for Ethics Committees That Review Biomedical Research: Surveying and Evaluating Ethical Review Practices (TDR/PRD/ETHICS/2002.1).

"Compliance with these guidelines helps to ensure that rights, safety and well-being of research participants are promoted and that the results of the investigations are credible". The role of the Ethics Committee is to safeguard the interest of volunteers taking part in studies.

EDCTP will not support any studies that have not obtained approval from the local Ethics Committee.

Applicants are therefore encouraged to pay due attention to the various ethical aspects in the planning of studies including the process of obtaining verbal/ written **informed consent**, the obligations of investigators and **sponsors**, benefits and risks of study participation, recruitment, cultural values, and confidentiality measures in accordance to the **World Medical Association Declaration of Helsinki** ethical principles for medical research involving human subjects (follow the link on the links page of our website www.edctp.org). You will be asked to identify potential ethical issues in the application form (questions 2.12 and 2.13).



2.6 Regulatory requirements for conducting clinical trials

Regulatory requirements are part of the process of drug discovery and drug development and describe what is necessary for a new medicinal product to be approved for marketing in any country. Prior to testing on humans in clinical trials, medicinal products must be subjected to rigorous testing in the laboratory (preclinical trials) for which animals are used and must be approved by a competent authority for use in humans.

Although EDCTP's mandate focuses on phase II and III clinical trials, all investigational products used in EDCTP supported trials must have sufficient efficacy and safety data available from preclinical and phase I evaluation studies and must have been approved by a competent body. This is in order to ensure safety and enable future registration of these products in compliance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (**ICH**).

It is important that the rights, safety and well being of volunteers participating in clinical trials of new medicines are observed in sub-Saharan Africa. Although regulatory capacities in different countries may differ, all EDCTP supported studies must comply with the international ethical and scientific standards (**GCP - Good Clinical Practice**).

*In countries where approval of clinical trials from the **National Regulatory Authorities (NRAs)** is a prerequisite, EDCTP will require this clearance before funding these studies.*

The acting **sponsor** of the clinical trial components of the EDCTP application needs to be an identified legal entity with documented experience to act as a sponsor.

Clear guidance is also available from the **World Medical Association's Declaration of Helsinki**, the MRC Guidelines for **Good Clinical Practice** in Clinical Trials and the EU Directive 2001/20/EC on Good Clinical Practice (These documents can be downloaded from our website www.edctp.org).



3 How to fill in your application form

3.1 Check list

3.1.1 Is your proposal eligible?

The EDCTP eligibility criteria include:

- Application of **proposal** submission before the **deadline** in pdf-format
- Completeness
- Compliance with the rules stipulated in these Guidelines for applicants
- Correct length of the application form
- Application in the correct language (English)
- The legal status of the applicant
- **Proposals** must involve at least **one** institution from **sub-Saharan African countries** as well as **two public institutions** from different European **EDCTP-EEIG Member States**
- Participation from the private sector is encouraged but the **Project Coordinator** must be employed by a public institution and must be a resident from either an **EDCTP-EEIG Member State** or a **sub-Saharan African country**. Preference will be given to **proposals** where the **Project Coordinator** is based in Africa and of a sub-Saharan African nationality.
- Projects should preferably be completed before June 2013. All cofunding requirements as stated in the section on cofunding have been met.

3.1.2 Are all annexes included?

These are the same as indicated at the end of the application form. Please keep the numbering of the annexes the same as below:

- Annex 1 & 2: Curriculum vitae in the requested format of the **Project Coordinator, Collaborators** and **Component Coordinators**.
- Annex 3: Collaboration declarations
- Annex 4a, 4b etc: letters of declaration of secured cofunding'.
- Annex 5: Statement that the work presented in the **proposal** can be performed with the budget requested.
- Annex 6: A draft of the informed consent form prepared for the planned study. (for clinical trials)
- Annex 7: A letter from the clinical trial sponsor confirming that they are willing to take on this task.
- Annex 8: For all clinical research projects in work package 3 (other than the clinical trial): letters of proof that the project has been submitted to the relevant ethics committee(s) or clear and detailed plan for submission.
- Annex 9: If applicable, a recommendation letter from the head of institution employing the proposed MSc student
- Annex 10: If applicable, a recommendation letter from the head of institution employing the proposed PhD scholar.
- Annex 11: If applicable, a recommendation letter from the head of institution employing the proposed Postdoctoral fellow.

3.1.3 Submitting your proposal

Your **proposal** needs to be submitted in **PDF format** to the following email address:

proposals@edctp.org.



On our website www.edctp.org you can find a link to a PDF-converter. It is strongly recommended not to wait until the last moment to produce your PDF-file, as especially graphics may sometimes change. Only the PDF-version that has been received before the **deadline** will be reviewed! The **deadline** differs for each **Call for Proposals** and is stated in the specific **call text**.

The annexes to the application form can be sent in PDF format as separate files, if the file name clearly states the surname of the **Project Coordinator** as well as the correct number of the annex (as indicated)

Your application, including all required annexes must be received by EDCTP **before** the **deadline** as stated in the **call text**. Ineligible proposals will not be reviewed.

It is possible to withdraw a **proposal** at any time during the review process. Correcting or revising of **proposals** is only possible before the **deadline**. EDCTP will use the latest version of the proposal as received in the inbox for review.

4 What happens next

4.1 Registration & Acknowledgement of receipt

All received applications will be registered in a database by EDCTP. Every application receives a unique **Project code**, which will be stated in all correspondence with the **Project Coordinator**. All future correspondence will contain this unique code, which guarantees quick and correct handling by EDCTP.

Within one week after the closure date of a call (**deadline**) EDCTP will send the **Project Coordinator** an **Acknowledgement of receipt** of the **proposal per email**. The **Acknowledgement of receipt** (as all correspondence) will only be sent to the individual who is registered as **Project Coordinator** (the "person in charge" of the whole project).

If you have not received an **Acknowledgement of receipt** within one week after the **deadline**, you should contact EDCTP.

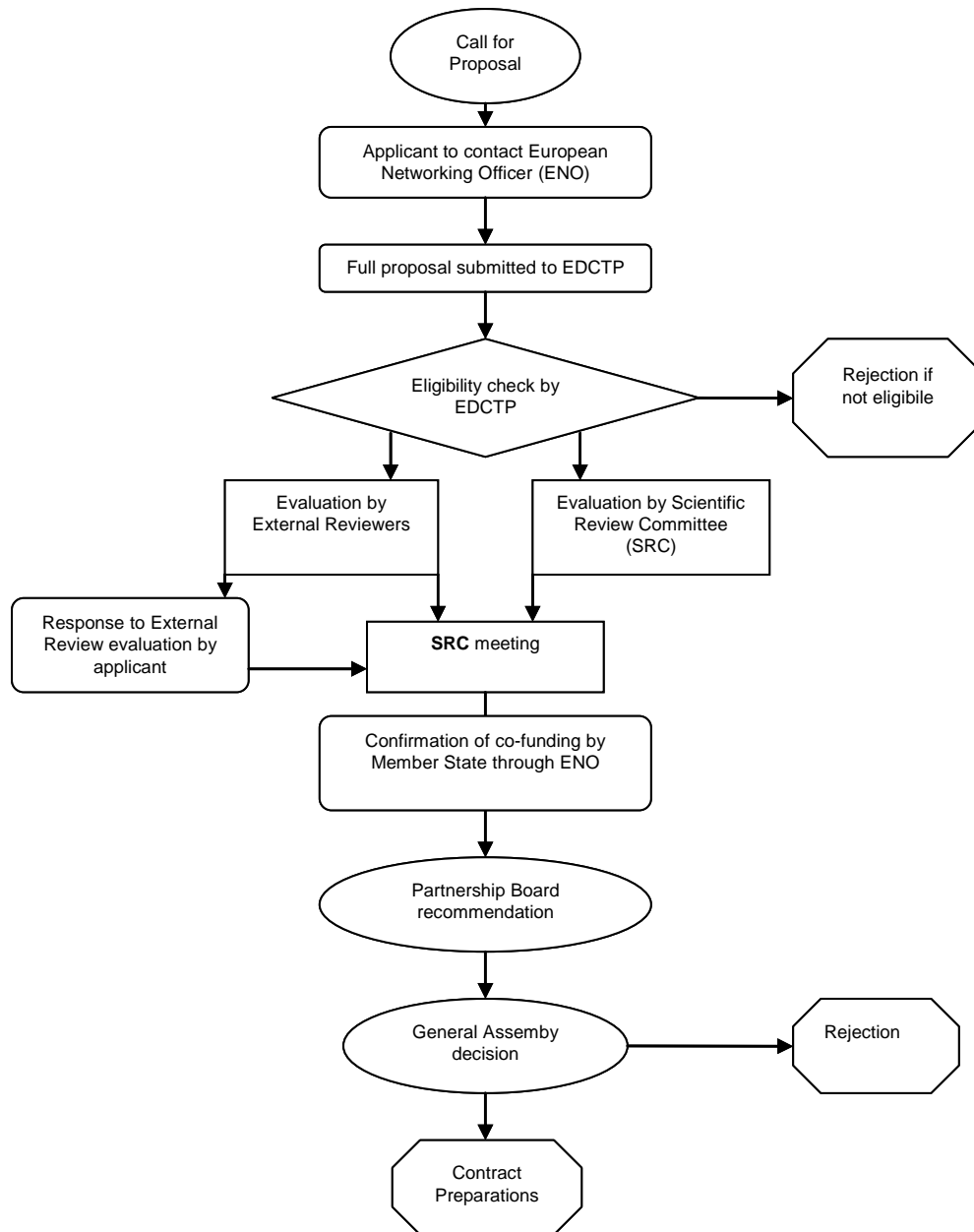
The sending of an **Acknowledgement of receipt** does not imply that a **proposal** is eligible for evaluation.

4.2 Eligibility check

EDCTP will check whether **proposals** meet the eligibility criteria as stipulated in the **call text** and these guidelines. Proposals may be excluded from further processing when they fail to meet any of the eligibility criteria. Applicants will receive a letter on the outcome of the **eligibility check** within four weeks after the **deadline** for submission.

4.3 Evaluation procedure

For the MSI call, the EDCTP General Assembly may, on the recommendation of the Partnership Board, approve a proposal which has already received a satisfactory scientific review without carrying out a further scientific review. EDCTP does however, reserve the right to carry out a further scientific review where deemed necessary. When EDCTP carries out its own evaluation, independent experts peer review proposals and identify those projects whose quality is sufficiently high to be considered for funding. They prepare a ranking of all submitted projects. This ranking is then discussed by the EDCTP Partnership Board (**PB**) which makes a recommendation on funding to the EDCTP General Assembly (**GA**). The General Assembly makes the final decision on funding. EDCTP will start **Grant Agreement preparations** with the **Project Coordinators** of those **proposals** that have successfully passed the evaluation phase. If the **Grant Agreement preparation** phase is successfully concluded, **Grant Agreements** are established with the applicants. The process that includes EDCTP scientific review is summarised in the diagram below. For more information refer to annex IV of these guidelines.





Selection criteria

Your application will be reviewed against the selection criteria listed below:

Selection criteria:

I. Project excellence: objectives, feasibility, impact, innovation, quality and record of investigators, quality of the proposed methodology.

II. EDCTP relevance: public health relevance for developing countries, adequacy of **proposal** in context of the call, alignment with the priorities of the EDCTP **Joint Programme**.

III. Potential impact: need for strengthening, restructuring existing research capacities, knowledge dissemination, sustainability.

IV. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.

V. Implementation Plan of Capacity Building: research activities, staff and facilities development, networking activities, training activities, mentorship programmes, consortium management activities, work planning and package of each participant including **deliverables** list, performance indicators.

VI. Consortium description: role of participants, achievement of objectives, involvement of private sector participation of at least two public institutions from European EEIG Member States as well as at least one African Institutions.

VII. Project management: organisational structure, decision-making mechanisms, knowledge management.

VIII. Clinical Trial Management: steering committee, sponsorship, daily management for the trial.

IX. Project resources: cofunding arrangements, mobilisation of resources - personnel, equipment and finances in accordance with EDCTP financial requirements.

X. Gender issues: promotion of gender equality, gender action plan concerning the staff involved in the project.

All selection criteria will be assessed on a scale of five categories from 'Poor' to 'Excellent'. EDCTP has defined an overall **threshold** for all selection criteria of 'Good' (third in the assessment scale) to ensure that all applications meet a minimum level of quality.

Exceptions are made for the following selection criteria:

X. Gender issues: this selection criterion does not include a threshold.

4.4 Preparation of clinical protocol

Applicants should note that if the application is successful, EDCTP will request a copy of the **clinical trial protocol** within four weeks from the start of **Grant Agreement preparations**. EDCTP will review the protocol to check adherence to the **ICH – GCP** Guidelines (see sections 2.5 and 2.6 of these guidelines). The Grant Agreement with EDCTP cannot be signed until EDCTP has received confirmation that the **clinical trial protocol** as approved by EDCTP has been submitted to all relevant ethical committees.

4.5 Confirmation of secured cofunding

Please refer to annex III of this guideline.

4.6 Start Grant Agreement preparations

If successful, the application will enter the stage of **Grant Agreement preparations**. As the main contact point for EDCTP, the Grant Agreement preparations will be done with the **Project Coordinator**. The following issues need to be addressed **before** the Grant Agreement can be signed:

- The **Project Coordinator** will be asked to respond to any comments that were made by the **SRC** and make amendments if required.
- The **Project Coordinator** will be asked to submit the **clinical trial protocol** that will be reviewed by EDCTP (see also section 5.5).



- EDCTP will request an official letter from the clinical trial **sponsor** that should include a statement of adherence to the **ICH – GCP** Guidelines.
- EDCTP will require proof that the **clinical trial protocol** has been submitted to the relevant local **ethics committee(s)**.
- EDCTP will require proof of ethical approval by the appropriate **ethics committee(s)** of any additional clinical research projects that are part of the application (as part of work package 3).
- The **Project Coordinator** will be requested to complete and return a Work Plan for the duration of the project.
- The **Project Coordinator** will be asked to fill in detailed budget forms which will be examined by the Financial Department of EDCTP. Any queries from EDCTP need to be addressed before the budget forms can be finalised.
- If applicable, EDCTP will request official confirmation letters from all African and third parties supplying cofunding to the project confirming the amount and type of cofunding.
- EDCTP will require a statement that the products used in the clinical trial will be readily available at an affordable price in developing countries in case of a successful trial and subsequent registration.
- The **Project Coordinator** will be asked to supply legal information about the partners in the project by filling in the 'EDCTP **legal entity** form' for each partner institution.

Please note that EDCTP requires that these Grant Agreement preparations are completed within 3 months of commencement, failure to do so may result in the grant being cancelled.



5 Glossary

The following specific explanations are provided for clarity and easy-reference of the terminology as used by EDCTP in these guidelines for applicants. They have no legal authority, and do not replace any official definitions as given in any other EDCTP document.

A

Acknowledgement of receipt:

Within one week after the **deadline** of a call the applicants are informed electronically that a proposal has been successfully submitted.

Actual employer:

The actual employer is the institution or company that determines the daily activities of its employee. In exceptional cases, the actual employer may not be the formal employer, which is the entity that has the employee "on its payroll". In case the host institution of the project is the actual employer, but not the formal employer of the Project Coordinator, additional action is required (see question 1.6 of the application form).

African sister institution:

This refers to less developed research institutions in terms of infrastructural and human capacity resources to conduct phase II and III clinical trials. These institutions should however have epidemiologically relevant populations, interested investigators and may have identified cohorts and ability to follow up study subjects. According to EDCTP criteria for classification of research institutions into various levels (table in section 2.2.1 Overall Consortium Requirements) these are either level 1 or 2 institutions.

Applicant:

The term applicant generally refers to the main applicant and his or her hosting institution with which EDCTP will conclude a grant agreement in case of awarding the application. The term **collaborator** or participant is used in a more limited sense for any entity that is co-applicant – in principle through the main applicant – will receive part of the EDCTP grant money for its role in the performance of the proposed **project**.

B

Baseline epidemiological study:

Epidemiological studies in which data on disease incidence and burden are collected to underpin clinical trial design. A high level of scientific rigour is expected to go into the design and conduct of these studies. The support of baseline studies should prepare cohorts for clinical trials.

C

Call for proposals:

The announcement to invite potential applicants to forward a proposal for research activities in a certain area of interest. The areas of interest to EDCTP are described in the **Joint Programme**, which can be downloaded from the EDCTP website.

Call identifier:

Code that identifies a certain **Call for Proposals**. The call identifier is used for correct registration of the application in our project database.



Call text:

Information that is, other than these guidelines, specifically applicable to the different EDCTP calls for proposals (on Malaria vaccines, Malaria drugs, HIV vaccines, HIV drugs, TB vaccines, TB drugs) such as e.g. purpose of the grant, specific selection criteria, available budget and **deadline**. The **call texts** are posted as separate documents on the EDCTP website.

Clinical trial protocol:

A document that describes the objective(s), design, methodology, statistical consideration(s), and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. The protocol has the objective to safeguard the health of the participants as well as to answer the specific research questions. A protocol describes what types of people may participate in the trial; the length of the study and the schedule of tests, procedures, medications and dosages.

Clinical trials registry:

An official record or data base of any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. This process involves assignment of a unique number, the International Standard Randomised Controlled Trial Number (ISRCTN), as recommended by the World Health Organisation.

All clinical trials supported by EDCTP have to be registered with an official and internationally recognised clinical trials registry before starting the trial. EDCTP supported clinical trials are encouraged to be registered with the EDCTP registry, the Pan African Clinical Trials Registry (PACTR; www.pactr.org). PACTR is run by the South African Cochrane Centre, has WHO primary status and is linked to the WHO International Clinical Trials Registry Platform (ICTRP) and search portal.

Cofunding:

The objective of EDCTP is to accelerate clinical trials in sub-Saharan Africa through integration of the national research programmes of its participating EDCTP-EEIG Member States. The EDCTP European Member States have agreed to match European Commission funding of the EDCTP's activities to a minimum of 200 Million Euro over the life of the EDCTP programme. Project partners from EDCTP-EEIG Member States are therefore required to seek national cofunding for their project.

Cofunding can be either in the form of "in kind " contributions i.e. the provision of goods or services including salaries costs by the partner towards the carrying out of the project or as cash directly to EDCTP. Where either is possible, cash cofunding is preferred. For more information on cofunding see annex III.

Collaborator:

Any entity, other than the **Project coordinator** and the **host institution** that plays a role in the project proposal and will receive part of the EDCTP grant money for that role. In principle any **legal entity** from any country may participate as collaborator after the minimal requirements on the consortium (section 2.2.1) are met. Collaborators need to adhere to the requirements as given in section 2.2.6.

Component coordinator:

The term Component Coordinator only applies to Work package 3. The component coordinator functions under the general responsibility of the work package leader and has the task to coordinate the activities proposed in the different components of the Capacity Building **Work package**. A component coordinator does not necessarily need to have the same employer as the work package leader.

Consensus discussion:

The stage in the proposal evaluation process when experts come together to establish a common view on a particular proposal.

D

DCCC-Developing Countries Coordinating Committee:



The Developing Countries Coordinating Committee (**DCCC**) is an independent advisory body of prominent African scientists, health professionals and policy makers. The DCCC is particularly involved in the identification of the institutional and human capacity building needed in Africa. It ensures the input and commitment of the African countries and researchers.

Deadline:

The date indicated on the call text is the last date that proposals will be accepted. The date and time of receipt on the server of proposals@edctp.org will be taken as the time of receipt. Proposals that are received after the **deadline** will not be taken into consideration.

Deadlines are strictly enforced.

Deliverable:

A **deliverable** represents a verifiable output of the project. Normally, each **Work package** will produce a certain amount of deliverables. Deliverables can be in the form of written reports, but also as successfully organised meetings, successful graduation of a PhD, etc.

E

EC-European Commission:

The European Commission (formally the Commission of the European Communities) is the executive body of the European Union. Alongside the European Parliament and the Council of the European Union, it is one of the three main institutions governing the Union (for further information see <http://ec.europa.eu/>).

EDCTP-EEIG Member States:

European states that participate in the EEIG-EDCTP initiative: Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

EEIG- European Economic Interest Grouping:

EEIG is a legal entity under the EC laws, with the objective to induce synergy between activities of organisations and individuals of the EU Member States. An EEIG is never allowed to gain profits. EDCTP is an EEIG initiative. The objectives are stipulated in the Joint Programme.

EEIG Assembly:

The EEIG Assembly or General Assembly (GA) is the ultimate and exclusive decision making body of the EEIG. It acts collectively and the full Members are jointly and severally liable for the actions of the EEIG. The principal responsibility of the Assembly is to ensure that all necessary activities are undertaken to achieve the statutory objectives of EDCTP, and that its resources are properly and efficiently managed.

Eligibility criteria:

The minimum conditions that a proposal must fulfil in order to be evaluated for funding. The eligibility criteria are generally the same for most of the EDCTP calls, and relate to e.g. submission before the deadline, application written in English, fulfilled requirements on minimum participation, proposal is complete, proposal is kept within the limits indicated. However, specific eligibility criteria may apply to certain calls, for which applicants have to check the appropriate call text.

ENNP-European Network of National Programmes:

The European Network of National Programmes is an advisory body to the EDCTP-EEIG-General Assembly as well as to EDCTP's other constituencies on the integration of the National Programmes of the EDCTP-EEIG Member States into a joint programme.

ENO-European Networking Officer:

The European Network of National Programmes consists of representatives of the European national programmes and develops proposals to coordinate and joint national activities and funding. These representatives are the so-called European Networking Officers.

ER-External Reviewer:



External reviewers are independent experts in the topic of the proposal who evaluate the proposal separately from the SRC. The outcome of the external reviewers will be corresponded to the applicant who then gets the opportunity to respond. The identity of the ER will not be revealed at any time, not to the applicants and not to the SRC members.

Established African institution:

This refers to more developed research institutions in terms of possessing the infrastructure and human capacity resources to conduct phase II and III clinical trials. These institutions should either have some clinical trial capacity to conduct phase III clinical trials or be fully capable of conducting phases I-III clinical trials. According to EDCTP criteria for classification of research institutions into various levels (table in section 2.2.1 Overall Consortium Requirements). These are either level 3 or 4 institutions.

Ethics Review Committee:

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Exchange visits:

Visits of participants that are conducted within the consortium to facilitate importing of skills that are not (yet) locally available. When people of two institutes plan to exchange a visit, detailed objective and expected outcomes have to be spelt.

G

GA – EDCTP General Assembly

See EEIG Assembly

GCP – Good Clinical Practice:

GCP is a quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

The GCP guidelines are internationally accepted guidelines provided by the **ICH-International Conference on Harmonisation**, are downloadable from EDCTP website www.edctp.org – Calls and Grants – Guidelines and Forms.

GCLP – Good Clinical Laboratory Practice:

Quality system for laboratories that analyse samples from Clinical Trials in accordance with Good Clinical Practice (GCP).

Grant Agreement:

The Grant Agreement that provides the arrangements between EDCTP and the **applicant** needed to guarantee the adequate monitoring and the successful performance of the awarded **proposal** in view of the EDCTP objectives, within the due period.

Grant Agreement preparations:

Final stage of preparations prior to the Grant Agreement, in which the successful **proposal** is brought in line with the SRC recommendations and the EDCTP conditions comprising the budget and legal issues.

H



Host Institution:

The legal entity and the employer of the Project Coordinator who, next to the Project Coordinator signs the grant agreement with EDCTP. In case the actual employer (who determines the daily activities) is not the formal employer (who has the Project Coordinator on its payroll) EDCTP requires a declaration of the formal employer approves the role of the Project Coordinator as described in the application.

I

ICH – International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use:

International Conference under the authority of the European Agency for Evaluation of Medical Products (EMA) defining the **GCP** guidelines & related aspects for developing and registering new medicinal products in Europe, Japan and the United States. The purpose of ICH-GCP is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines by recommending ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration. (The EMA ICH-GCP guidelines are downloadable from our website www.edctp.org - Calls and Grants – Guidelines and Forms)

Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

IRB – Institutional Review Board:

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Every institution that conducts or supports biomedical research involving human participants must have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants.

J

Joint Programme:

The Joint Programme describes the objectives and activities including specific strategies and action plans to be undertaken by EDCTP. The programme objective is to accelerate the development of new or improved drugs and vaccines against these diseases, with a focus on phase II and III clinical trials and on sub-Saharan Africa. A public version is available on our website www.edctp.org – About EDCTP – Strategy – Joint Programme.

L

Legal entity:

Any corporation, association or other organisation that has, in the eyes of the applicable national law, the capacity to make a contract or an agreement and the abilities to assume an obligation and to pay off its debts. A legal entity is responsible for its actions and can be sued for not performing in accordance with the Grant Agreement or damages.



Legal status:

In case of a public private partnership there are two possibilities: 1. the partnership has the form of a legal entity under private or public law, in which case the official name and status of this legal entity has to be entered in the form; 2. the partnership has no legal entity, in which case one of the partners fulfils the role of secretary filling in the official name of his or her entity in the application form. In the latter case the secretary is fully responsible and liable for the activities of the partnership.

M

MS-Member states:

See EDCTP-EEIG Member States.

Mentorship:

One-on-one learning relationship between a student and an expert in a specific topic or discipline. The mentor supports and supervises the student to develop in that area of interest.

Milestone:

Milestone is a project checkpoint signifying the completion of a major deliverable or set of deliverables. For example, a milestone may occur when a major result has been achieved if its successful attainment is a pre-requisite for the next phase of work.

N

NRA – National Regulatory Authority:

The public authority within any nation responsible for the health of its inhabitants and therefore having the power to regulate and to inspect public health within that nation. Permission and adherence to the conditions of the NRA are absolute requirements for any interference or actions in public health.

The NRA are responsible for registration of medicines, licensing and enforcement, authorisation and control of clinical trials, monitoring of adverse drug reactions, quality control of medicines and medical devices, training of evaluators of GMP inspectors and analysts etc.

P

PB-Partnership Board:

The Partnership Board is a scientifically independent expert panel of experts of which full members have voting rights. The Partnership Board designs the strategic framework of the EDCTP and advises the Assembly on technical and scientific matters relating to the EDCTP programme.

PPP - Public Private Partnership:

Cooperation between one or more public parties (government) and one or more private sector companies to realise governmental policies. For that reason the PPP (or P3) receives public funding.

Private institution:

Any institution operating under a private legal entity, which means an entity erected in conformity with civil law.

Project code:

Upon registration by EDCTP every application receives a unique project code, which will be communicated to the principle coordinator. All future correspondence will contain this unique code, which guarantees a quick and correct handling by EDCTP.



Project:

The term project is used for description of the complete proposal consisting of clinical trial(s), capacity building and networking components after approval by EDCTP.

Project Coordinator:

The overall manager of the project who signs – next to the **host institution** – the grant agreement with EDCTP and consequently acts as the point of contact to EDCTP. The **Project Coordinator** must adhere to the requirements as stipulated in section 2.2.1 of these guidelines.

Project Management:

The leadership role concerned with the overall planning and co-ordination of a **project** from inception to completion. The project management should be described in Work Package 1 and should include information on the overall objectives and plans, the consortium, co-ordination mechanisms, project resources and the budget.

Project manager:

The project coordinator should be assisted by a **project manager** for the day-to-day running of the project and for administrative support.

Project Partners:

An internet search program on the EDCTP website that allows scientists to create a profile of themselves which is searchable by other scientists all over the world.

Proposal:

The proposed application to EDCTP, describing planned research activities, information on who will carry them out, how much they will cost and how much is required for EDCTP funding.

Public institution:

Any institution supported primarily by public funds and operated by publicly elected or appointed officials who control the program and activities. For example, colleges or universities.

R

Regulatory requirements:

Regulatory requirements are part of the process of drug discovery and drug development and describe what is necessary for a new medicinal product to be approved for marketing in any country.

S

Selection criteria:

The criteria against which the independent experts assess eligible **proposals**. The selection criteria relate to quality, EDCTP relevance, impact, implementation, consortium, management and resources. Specific selection criteria are stipulated in section 6.4 of these guidelines.

SME- Small medium enterprise:

Please note that a new definition of SME entered into force on 1 January 2005. According to this, an SME (Micro, Small or Medium-sized Enterprise) is an enterprise that has fewer than 250 employees, has an annual turnover not exceeding 50 million euro and/or an annual balance-sheet total not exceeding 43 million euro.

For further information please consult the SME definition (Commission Recommendation 2003/361/EC of 6 May 2003), in particular Articles 1-6 of the Annex on:

http://europa.eu.int/comm/enterprise/enterprise_policy/sme_definition/index_en.htm

Sponsor:



An individual, company, institution, or organisation which takes responsibility for the initiation, management, and / or financing of a clinical trial

SRC-Scientific Review Committee:

The assessment committee consists of independent experts selected by EDCTP. The SRC evaluates the proposals by peer review and on the basis of the selection criteria as outlined in section 6.4, resulting in a ranking of the proposals. Based on this ranking the PB and GA decide on which projects will be funded by EDCTP.

Stakeholders Meeting:

A stakeholder meeting is a meeting where invited stakeholders start the process that leads to the decision of EDCTP funding of one or more projects through a call or brokering procedure. For more information see our website www.edctp.org.

Sub-contractor:

All individuals or entities that are engaged by the host institution or one of the collaborators to execute part of the activities under the project. EDCTP supposes that no core-activities will be outsourced (to a maximum of 15% of the budget of the involved institution).

Sub-Saharan African countries:

Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Ivory Coast, Equatorial Guinea, Eritrea, Ethiopia, Gabon, the Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

T

Threshold:

For a proposal to be considered for funding, certain selection criteria must be evaluated a minimum score or threshold ('good', third in the assessment scale of five categories from 'poor' to 'excellent'). Also refer to section 6.4 of these guidelines).

Training institution:

Institutions like universities that are traditionally involved in training, but may have limited clinical trial research activities.

V

Valorisation:

Valorisation is a strategy to disseminate results of projects. It can be defined as: "the process of disseminating and exploiting projects outcomes with a view to optimising their value, enhancing their impact and integrating them into training systems and practices at national as well as international level". A valorisation plan describes the possibilities and arrangements for dissemination and exploitation of innovative project results.

W



WP - Work package:

The work packages indicate a major subdivision between the Project Management, Clinical Trial, Capacity Building and Networking components of the **proposal**. All work packages are verifiable with deliverables and milestones in the overall project.

World Medical Association Declaration of Helsinki:

The declaration of Helsinki was developed by the World Medical Association and originally adopted in June 1964 in Helsinki, Finland. The most recent version is from 2000. It is a statement of ethical principles for the medical community regarding medical research involving human subjects. (follow the link on our website www.edctp.org – Calls and Grants –Guidelines and Forms or directly go to <http://www.wma.net/e/policy/b3.htm>).

Work package leader:

The work package leader is a research manager that has the responsibility that the activities proposed in the work package are executed and objectives are met. Work package leaders need to adhere to the same requirements as the **Project Coordinator** as stipulated in section 2.2.1 of these guidelines.



Annex I. Guidelines for Good Partnership with Developing Countries

To achieve the balance between scientific research in developing countries and the scientists, public and its stakeholders the implementation of EDCTP will require good practice in partnership with Developing Countries. Networking is a major EDCTP instrument to exploit and to mobilise the human and financial resources necessary to combat the three diseases in the developing countries. Through networking, the participating EEIG Member States commit to interact through EDCTP in their relations with other international initiatives, industry or other activities. This leads to (new) partnerships with international initiatives, and industry, with which EDCTP could develop joint projects.

A major principle is that EDCTP will not seek to compete with, or replace, successful initiatives already existing in this area. Rather the EDCTP will seek to form partnerships with such initiatives. Therefore, a partnership with international initiatives that provide a mutual surplus value will help EDCTP to succeed in achieving its objectives.

EDCTP has adapted the following 11 principles¹ for research in partnership between the participating Member States and developing countries:

1. Decide on the objectives together

It is essential to form collaboration among the partners to find appropriate answers to socially significant problems. Research priorities must be set which fit in with the interest of all those involved to avoid one-sided interests coming into play. These general priorities must be distinguished from the research question to be answered by a particular project. Wherever possible, local traditional knowledge should be taken into account. This can be of useful to avoid misunderstanding of the situation by outsiders and can prepare the ground at an early stage for achieving the expected results going into practice. The purpose of the partnership should be explicitly defined in terms of long-term vision, goals and activities, and should have a manageable focus.

2. Build up mutual trust

The creation of mutual trust can contribute largely to an honest and open collaboration. Besides a common framework new contacts and relationships are important to strengthen the networks of collaborating institutions. Therefore prejudice needs to be avoided to bridge the time and patience gaps in reaching a level of mutual trust.

3. Share information; develop networks

It is vital to set up a well-organised and effective communication system between the partners to reach a comparable level of information and knowledge about the joint research activities and its environment. If the communication infrastructure is inadequate, it is better to take action to acquire the necessary communication means for regular exchange of information. Apart from facilitating the North-North, North-South and South-South networks, partnerships need to facilitate strong link between institutions doing research and disease control programmes in countries where this is weak.

4. Share responsibility

All partners should be able to share the scientific and the technical leadership and management responsibility for the project implementation, taking into account the competence and the resources. It is advisable to discuss the division of tasks and responsibilities at an early stage. The roles and

¹ "Guidelines for Research in Partnership with Developing Countries, 11 Principles", developed by KFPE/Swiss Commission for Research Partnership with Developing Countries, KFPE, 1998. http://www.kfpe.ch/download/Guidelinelines_e.pdf



responsibilities of the partners ought to be consistent with their capabilities and competences, both current and envisaged. The involvement of all partners will provide those with less experience the opportunity to gain expertise in research management.

5. Create transparency

Partnership plans should be developed jointly from conception. It is necessary to disclose all contributions either in commitments or financial resources received from all partners to avoid conflict and possible misunderstandings. It is practical to prepare a binding agreement in writing which lays down the contribution to be made by all partners along with their rights and duties. There should be transparency on all aspects of the partnership planning especially managerial issues, authorship, ownership of results of research, access to resources, and other results of starting the partnership. Regular review of the accounts, audits, and periodic checking of inventories are essential to creating transparency.

6. Monitor and evaluate the collaboration

Monitoring the progress of research and development and the functioning of the partnership is critical. This requires continuous comparison of deliverables against the defined indicators to allow sufficient flexibility in responding to a dynamic and rapidly changing environment. Regular internal or external evaluations could assess the partnership in all of its aspects: management, communication, decision-making, implementation, and any improvement of partner's capacities, etc. The evaluation needs to be conducted in an impartial and independent manner.

7. Disseminate the results

It is a basic principle that there should be unlimited access to the results of research. Since research projects in partnerships between industrialised and developing countries are directed towards concrete problems, care must therefore be taken to ensure that the research results are communicated adequately and accessibly through appropriate media. This will smooth the path of bringing the results into fruition with the active participation of the local community. The dissemination of knowledge can occur in many ways, as long as the research results can be understood by a wider public than just the scientific community. Very often, the responses to these research efforts can be useful for other future work.

8. Apply the results

Partnerships projects raise expectations among the partners from the developing countries and within their own communities. Therefore the research teams are obligated to ensure and follow up on the results to benefit the target audience. The process of converting scientific results into practical projects and actual implementation is extremely complex. It is always wise to keep the local political decision-makers and/or government bodies well informed on the research progress and its results to ensure their active participation and to fulfil the expectations of the community.

9. Share contributions and profits equitably

Research results have intellectual value and may also have commercial value. All partners should share equally in the benefits of both values. The legal rights of all partners in the expected results should be discussed at an early stage and recorded in writing. International law (e.g. concerning patent rights) and the national regulations of the host country must be considered.

10. Increase research capacity

The main concern when research partnerships are established is to strengthen the capacity of all those involved for carrying out effective research, at the individual and institutional level. Moreover the South-South collaboration needs to be promoted in order to raise the level of achievements in research in those countries that have not reached the level of those in industrialised countries, and yet they bear the greatest burden of disease. The industrialised countries should provide support to achieve this goal. Gathering valuable experience can have other meaning when the participating research workers from the developing countries will be able to attend further education or training in an industrialised country to



learn new methods, exchange information and enlarge the network. Use of local resources, expertise and budgets (engagement of governments) should be optimised to ensure mutually respectful, effective and sustainable partnerships.

11. Build on achievements

In following a successful project there are three valuable outcomes: new knowledge, contribution to sustainable development, and new or more highly developed research capacity. New knowledge is recorded in publications. The contribution to sustainable development means the new knowledge is put into policy and practice in a sustainable way. However, to maintain the new research capacity means that existing institutions need to continue to thrive or new ones need to be established and the research workers involved in the project need to find suitable employment under acceptable conditions. Many developing countries participants face employment problems once the research project is completed. It happens all too often that good scientists leave their own country to find better job prospects in an industrialised country. The follow up after the finalisation of a research project is essential to overcome intellectual isolation. There should be measures to enable and ensure that partners can find future professional employment (e.g. by involving large international organisations). Partnerships should also develop institutional capacity and provide an enabling environment for training and research to better equip good scientists to apply and receive more competitive research grants.



Annex II EDCTP General Contract Terms

EDCTP GENERAL CONTRACT TERMS (August 2008)

WHEREAS, these General Terms shall, where applicable, as an **Annex A** be part of agreements providing grants to third parties;

NOW THEREFORE, the General Terms are:

ARTICLE 1: DEFINITIONS

1.1 The definitions given in ICH/GCP (CPMP/ICH/135/95. status: September 1997, version July 2002) are applicable.

1.2 The following expressions shall have the meanings specified.

Background Intellectual Property:	IP-rights relating to the subject matter of the Project and already existing at the Effective Date;
Collaborators:	all investigators of the research team other than the Project Coordinator (normally institutions) and, if any, their employees, and including any subcontractors who are hired by the Collaborators to carry out specific parts of the grant;
Confidential Information:	information regarding the Project that is designated 'confidential', or the nature of such information itself and/or the circumstances of such information's disclosure reasonably indicate that such information is considered confidential;
Contractor:	the party/parties – normally the Project Coordinator (PC) and his/her employer - with whom the EDCTP enters into a (grant) Agreement before contributing to the investigations and - if any - other proposed activities, and including any subcontractors who are hired by the Contractor or the PC to carry out specific parts of the grant;
EMA:	the European Medicines Agency, a decentralized body of the European Union with its headquarters in London, United Kingdom;
Financiers:	third parties providing/having provided a substantial financial contribution to the Action under this Agreement through EDCTP, being the sole counter-party of Contractor;
Force Major:	any unforeseeable occurrence beyond the reasonable control of Parties (inclusive strikes and lockouts) which prevents defaulting Party from fulfilling its obligations under the Agreement, not attributable to error or negligence of the defaulting Party, and/or not being defects in equipment or material needed for the performance of the project or delays in making them available,



and/or not being financial difficulties other than cessation of funding to EDCTP;

Foreground Intellectual Property:	IP-rights generated in or arising out of the Project;
IP-rights:	copyright and related rights as well as Industrial Property Rights, in particular patents;
Patent:	any and all patents and patent applications, including all related patents anywhere in the world or claiming priority there from;
Project:	the conduct and/or performance of research activities as described in the Project Document's Work Plan;
Results:	the results, conclusions and findings of the funded activities;
Subcontractors:	all consultants and subcontractors working for the Project directly or indirectly supervised by the PC other than Collaborators;
Trial Data:	all Information needed for the filing of the Investigational Product for a marketing authorization with the EMEA or similar regulatory agencies;
Knowledge management:	The procedure to protect, publish and/or translate any new findings from the study in order to make them available to the benefit of the general public.

ARTICLE 2: CURRENCY

- 2.1 All monetary amounts are in Euro. For reporting purposes foreign currency expenditure needs to be translated into Euro at the monthly rate which the expenditure is incurred as quoted by the European Commission (last known internet address being: <http://ec.europa.eu/budget/inforeuro/index.cfm?Language=en>).
- 2.2 Where there is a significant movement in the exchange rate (i.e. greater than 15%) between local currency and the Euro from the effective date of the contract, which would lead to any grantee or contractor not being able to carry out the action as originally intended without suffering losses, then, following a written application from the Project Coordinator to the Executive Director, EDCTP may, renegotiate all or part of the grant at its sole discretion. The renegotiation could cover either altering the size of the budget or the scope of the work to be carried out, or a combination of both. A new, revised budget will be required from the Project Coordinator which must be agreed as justified and reasonable by both the ED and FM in order for the amendment to be put before the General Assembly for formal approval.



ARTICLE 3: APPLICABLE STANDARDS

- 3.1 Contractor shall ensure a high level of scientific excellence and shall undertake the Project in conformity with fundamental and international accepted standards and ethical principles as well as in conformity with the current legislation and regulations in the countries where the research will be carried out and where the Project Coordinator is located.
- 3.2 As a specification of article 3.1 applies that documentation of research shall be consistent with the need to establish corroborated dates of invention and reduction to practice with respect to inventions where this is relevant.
- 3.3 Institutional policies regarding what care will be provided to personnel who are injured (for example but not exclusively by the so called needle stick injuries) as a result of their work to the Project shall be developed, approved and implemented with notice to employees similarly to the care and/or referrals available through participation in the Study.
- 3.4 Any reference to generally accepted accounting principles refers to International accounting standards.
- 3.5 Contractor warrants that it shall exercise reasonable care and take the precautions necessary to ensure that it shall not employ, contract with or retain any individual directly or indirectly to perform services under the Agreement if such a individual is debarred or disqualified by an internationally recognised drug authority or ethics committee, or is known as a person supporting or promoting violence, terrorist activity or related training, or money laundering. In the event that Contractor or its employees become aware of, or receive notification of, the debarment or disqualification of any individual and/or institution taking part in the performance of the Agreement, Contractor agrees hereby to notify EDCTP immediately and address the issue as mutually agreed by the Parties, such address including, but not limited to immediate removal of any such debarred or disqualified individual and/or institution from performance of the Project. The forgoing applies also when Contractor becomes aware of any fraud including attempts thereto, related to the Project.
- 3.6 There are potential negative environmental impacts associated with the development and production of drugs. These include handling and disposal of hazardous medical wastes and chemicals which have potential impact on the environment (pollution) and can also have impact on human health. Therefore Contractor agrees:
 - a. to conform to international guidelines minimizing environmental impact, and
 - b. to supply all relevant information requested by EDCTP on this area.

ARTICLE 4: CONFLICTS OF INTEREST

- 4.1 The Contractor shall take every necessary precaution to avoid any possible conflict of interest. In a situation constituting or likely to lead to a conflict of interest the Contractor shall take immediately all necessary measures to remedy the situation. A conflict of interest may arise in particular from economic interest, political or national affinities, family or emotional ties, or any other common interest that are liable to influence the impartial and objective performance of the Agreement.
- 4.2 Contractor declares that it has not granted and shall not grant, has not sought and shall not seek, has not attempted and shall not attempt to obtain, and has not accepted and shall not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or



involving corruption or supporting or promoting violence, terrorist activity or related training, either directly or indirectly, as an incentive or reward relating to the performance of the Agreement;

- 4.3 Contractor shall pass on the obligations laid down in the first three paragraphs of this Article in writing to his/her staff, and directors (if any) as well as to third parties involved in performance of the Agreement. A copy of the instructions given and the undertakings made in this respect shall be sent to EDCTP if requested.
- 4.4 In case EDCTP encounters a conflict of interest in the context of the Project, EDCTP reserves the right to impose additional measures after consultation with Contractor. In case the conflict of interest is sufficiently serious and its consequences cannot be corrected, the EDCTP may stop to financially contribute to the Project.

ARTICLE 5: DISSEMINATION OF KNOWLEDGE AND PROMOTIAL ACTIVITIES

- 5.1 Contractor shall take care that the investigator(s) shall disseminate as soon as practical the Results in scientific journals and/or the internet, irrespective of the success of the Project, and make oral and visual presentations at conferences where appropriate.
- 5.2 Any communication or publication by the Contractor about the Agreement, the performance thereof and the Results, including at a conferences or seminars, shall state in readable format:
"The author of this publication received funding from the EDCTP through a project entitled "(PROJECT TITLE)". However EDCTP can not accept any responsibility for information or views expressed herein."
- Contractor shall not make any statement or otherwise imply to the media, the general public or any other donor or investor that Contractors organisation, its operations, or its participation to this Project is supported by any organisation other than the EDCTP, unless Contractors organisation has directly received funds from the other organisation.
- 5.3 EDCTP retains the right to react without further notification to any dissemination having a direct or indirect relation with this Agreement or EDCTP and to disclose other views, and Trial Data or other Information regarding the Clinical Trial (where at stake) at its sole discretion.
- 5.4 The Contractor authorizes EDCTP and its Financiers to publish in any form and medium, including via the Internet, (i) the Contractors name and address, (ii) a summary of the Project including the subject and purpose of the Project, (iii) the amount granted, (iv) the proportion of the Studies total cost covered by the funding, and (v) the holder of the IP-rights of Information and Investigational Product (wherever applicable) used or generated in the Project.
However, upon a reasoned and duly substantiated request by the Contractor, EDCTP may agree to forgo such publicity if disclosure of the information indicated above would risk compromising the Contractors security or prejudicing his commercial interests.
- 5.5 In the event the Contractor and/or investigator(s) do not disseminate (part of) the Results within 2 years time, then EDCTP retains the right to publish such Information via its website, or otherwise in the public interest.



ARTICLE 6: OWNERSHIP/USE OF THE RESULTS AND IP-RIGHTS

- 6.1 In case the (specific granting) Agreement with Contractor does not contain any stipulations regarding intellectual property rights regulating the ownership of the results or Foreground Intellectual Property generated during the contingency of the Project, the terms as contained herein, shall apply to such Agreement.
- 6.2 All background intellectual property owned by the Contractor shall remain so vested.
- 6.3 Any background intellectual property owned by EDCTP shall remain so vested.
- 6.4 Any Foreground Intellectual Property Rights or results developed during the contingency of the Project shall be owned by the Contractor, however subject to the Contractor granting EDCTP the rights to make use of the results and/or such Foreground Intellectual Property of the Project as it deems fit, but at its own risk, and subject to the Contractor not being in breach of its obligations of confidentiality or - at the date of forwarding the application of the project - existing industrial and intellectual property rights, and provided that such use does not jeopardise the Project.
- 6.5 In spite of the previous paragraphs EDCTP shall, without any (further) action required or needed by the Contractor, in any case have and hold a transferable, non-exclusive and irrevocable (/sub)license at most favorable conditions to make use of the IP-rights anywhere and everywhere in the world to ensure that the Investigational Product or its successors shall in product form obtain and maintain the status of tiered priced product as pursuant in the Council regulation (EC) No 953/2003 of May 2003, regarding tiered priced products.
- 6.6 All know-how and other results of studies that were funded by EDCTP and for which it was decided not to apply for a patent or which results have appeared not to be patentable, shall become public knowledge and be easily accessible for the public.
- 6.7 EDCTP has the right to share according to a fair standard in any profits made with the Foreground Intellectual Property by Contractor and/or Collaborator(s) or their eventual successors in the Foreground Intellectual Property.

ARTICLE 7: CHECKS AND AUDITS

- 7.1 EDCTP and its Financiers may visit the Trial Site(s) and/or any other location where the Project is actually conducted and/or performed, at reasonable times and with reasonable frequency, to conduct financial and technical audits in order to verify the progress and conduct of the Project.
- 7.2 Contractor undertakes to allow EDCTP and its Financiers appropriate access to sites and premises of Contractor and to all the Information, including Information in electronic format, needed in order to conduct said audits. Duly authorised officers of Contractor who are dedicated to the Project shall assist EDCTP (officer) on its first request in scheduling such visits, and providing direct access to source data.
- 7.3 For Trials, the Contractor shall keep at the disposal of EDCTP and its Financiers all original documents, especially accounting, tax records and Results, or in exceptional and duly justified cases



certified copies of original documents, relating to the Agreement for a period of six years after the date of termination of the Agreement.

7.4 EDCTP and its Financiers shall enjoy the rights under this Article throughout the term of the Agreement and for a period of six years thereafter. At first written request of EDCTP to the Contractor, any third party designated by EDCTP as having a financial interest in this Agreement shall enjoy the same rights as EDCTP but only for the purpose of the audits as referred to in paragraph 7.1. Employees, agents, and authorized representatives from the organizations referred to in this paragraph shall enjoy the same rights as granted to their respective organizations.

ARTICLE 8: CONFIDENTIALITY

8.1 The Parties and its (/ex-)employees agree to keep the Confidential Information confidential for the duration of 6 (six) years after it received this confidential information for the first time and to take all reasonable precautions to prevent the disclosure of the Confidential Information to any third-party.

8.2 Notwithstanding the preceding, information shall not be considered Confidential Information if it:

- (i) is rightfully in the public domain other than by a breach of a duty to the disclosing party; or
- (ii) is proven by written records to be rightfully received from a third party without any obligations of confidentiality; or
- (iii) is proven to be rightfully known to Recipient Party or its employees without any limitation on use or disclosure prior to its receipt from the disclosing party; or
- (iv) is in the Agreement explicitly except from being Confidential Information or is disclosed after written permission of the Disclosing Party; or
- (v) has to be disclosed pursuant any judicial or governmental requirement or order, and only for that particular disclosure. In such a case the one Party shall inform the other Party prior to disclosure thereof, and the Party required to disclose shall limit the disclosure to the amount necessary, and shall place a confidentiality notice on all such Information.

ARTICLE 9: LEGAL AUTHORITY

9.1 Each of EDCTP and Contractor represents and warrants that it has the legal authority and is qualified to enter into the Agreement and that the terms of the Agreement are not inconsistent with its other contractual arrangements. Each of EDCTP and Contractor represents and warrants that it is not constrained by any existing agreement in performing its obligations under the Agreement.

9.2 For Trials, the Contractor represents and warrants nor currently being involved in any litigation, nor being aware of any pending litigation proceedings relating to its role in the conduct of a clinical trial, nor having received any warnings from the EMEA or other regulatory authority that deals with registration of pharmaceutical products.

ARTICLE 10: LIABILITY AND INDEMNIFICATIONS

10.1 The Contractor shall have sole responsibility for complying with any legal obligations incumbent on him/her/it under the Agreement and cannot recoup consequences/losses resulting from these obligations on EDCTP, its members or the Financiers and their members or financiers.



- 10.2 The EDCTP takes in good faith any signed statement by the legal representative(s) of Contractor, its Subcontractor(s), its financial manager(s), and/or the Project Coordinator of the Project that the figures in the financial reports, including the co funding figures, forwarded to EDCTP, are accurate and complete. If a financial or technical audit as meant in article 7 reveals that those figures are actually incorrect, the Hosting Institution(s) in deficit and the Contractor agree that they shall be held jointly and severally liable for the deficit(s) assessed by the audit.
- 10.3 Contractor shall indemnify, defend and hold harmless EDCTP and the Financiers, including the directors, officers, employees, representatives and agents of EDCTP and the Financiers, from and against any and all claims, suits, losses, damages, costs, fees and expenses (including reasonable attorneys' fees), and other liabilities asserted by any third party, resulting from or arising out of any breach, violation or non-performance of this Agreement by Contractor, safe to the extent that such claims, suits, losses, damages, costs, fees and expenses (including reasonable attorneys' fees), and other liabilities asserted by any third party are due to the breach, violation or non-performance of this Agreement by EDCTP.
- 10.4 The Contractor shall not, in any circumstances or on any grounds, hold EDCTP, its members or the Financiers and their members or financiers liable in the event of any claim of any third party relating to any damage caused during the execution of the Agreement and not falling under paragraph 10.2, safe to the extent that such claim is due to the breach, violation or non-performance of this Agreement by EDCTP.
- 10.5 The indemnity of the paragraphs 10.2 and 10.3 shall not apply to the EDCTP, being the sole counterparty of Contractor (a) if EDCTP fails to give Contractor prompt written notification of any claim it receives and such failure materially infringes Contractors rights, and (b) unless Contractor is given the opportunity to approve any settlement. Furthermore, Contractor shall not be liable for attorneys' fees or expenses of litigation of EDCTP unless EDCTP gives Contractor the opportunity to assume control of the defense or settlement. In addition, if Contractor assumes such control, it shall only be responsible for the legal fees and litigation expenses of the attorneys it designates to assume control of the litigation unless the competent judge decides differently. In no event shall Contractor assume control of the defense of EDCTP without the consent of EDCTP (which consent shall be given or not at its sole discretion).
- 10.6 The Contractor shall obtain adequate Clinical Trials insurance coverage and up until the Clinical Trial has been completed, be able at any time to produce a proof of the insurance coverage.
- 10.7 EDCTP and the Financiers assume no responsibility or liability in respect of any losses or injuries sustained by any party who's travel is funded by an EDCTP-grant. The Contractor is expected to obtain adequate insurance coverage for these purposes.

ARTICLE 11: FORCE MAJOR

- 11.1 Subject to Force Major, the Contractor shall use reasonable endeavours to fulfil the results intended for the project. The Contractor shall use reasonable endeavours to fulfil obligations of a defaulting Subcontractor. The Contractor shall not be liable to take actions beyond its reasonable control or to reimburse money due to a defaulting Subcontractor unless he/she/it has contributed to the default. Measures to be taken in the event of Force Major shall be agreed between EDCTP and Contractor.



11.2 Contractor shall notify the EDCTP in writing of the reason of the delay or failure within five (5) working days of the due date.

ARTICLE 12: TERMINATION OF THE AGREEMENT

12.1 Either Party may terminate the Agreement immediately by written notification to the other Party upon the occurrence of any of the following events:

- (i) If the defaulting Party commits a material breach of its obligations under the Agreement, and – if the breach is capable of remedy – fails to remedy the breach within thirty (30) days of being specifically required in writing to do so by the other Party; or
- (ii) If any execution, sequestration or other similar process is levied or enforced upon or against the property of the defaulting Party which is not discharged within thirty (30) days, or a liquidator is appointed over the whole or any substantial part of the defaulting Party's undertaking, property or assets, or an order is made or a resolution is passed for the winding-up or analogous proceedings in any jurisdiction of the defaulting Party; or
- (iii) That it becomes known to Parties that the Investigational Product is not safe to use or that the Project shall not achieve its objectives; or
- (iv) EDCTP shall cease to receive funding, in which case the already paid upfront payments shall be the final payments for the Project.

12.2 In the event of termination by EDCTP the disbursement of EDCTP contribution shall be suspended and EDCTP shall decide, in view of the concrete facts and circumstances, which percentage of the amounts already transferred to Contractors pursuant to Article 3 of this Agreement Contractor(s) shall have to pay back to EDCTP and within which term(s).

12.3 Should the Contractor fail to execute this Agreement as intended, EDCTP may decide to exclude Contractor from future grant calls.

Contractor agrees that EDCTP may deploy the means of reimbursement and financial penalties in cases of overstated expenses, for example following regular audits, without necessarily involving the termination/exclusion of the Contractor.



ARTICLE 13: REQUIRED INFORMATION

- 13.1 Any delay in receiving the signed clinical protocol and/or ethical clearance exceeding 3 months from the signing date of the Contract (the Effective Date), may prima facie result in EDCTP suspending or canceling the grant. If such delay is likely to occur, the Contractor must write to the Executive Director (ED) of EDCTP setting out the reasons for the delay and a time scale for the situation to be resolved.
- 13.2 Where the Project Coordinator signs (an) agreement(s) with the Subcontractor(s) which differ(s) in financial amount from the budget accepted by EDCTP in the signed contract, then a written explanation needs to be provided to the EDCTP Project Officer by the Project Coordinator. In case that explanation is not accepted, this may lead to a change in the approved Budget.

ARTICLE 14: MISCELLANEOUS

No waiver and sever ability

- 14.1 Either Party's failure to require the other party to comply with any provision of the Agreement shall not be deemed a waiver of such provision or any other provision of the Agreement. In case any one or more of the provisions contained in the Agreement shall be held invalid in any respect, such invalidity shall not affect the other provisions of the Agreement, and the applicable provision shall be deemed to be construed in the spirit of the Agreement.

Ban on making profits

- 14.2 Contractor declares not to make any profit, now or in the future, from the receipt of the Grant.

Notifications

- 14.3 Notifications shall be deemed received:
- (i) immediately, in case delivered personally, or
 - (ii) five (5) business days after sent if sent by recognized courier, as evidenced by such courier's written records, or
 - (iii) on the date transmitted if sent via facsimile with confirmation of receipt, or
 - (iv) within 7 (seven) days of posting if sent to the Parties at the addresses stated in the Agreement, or such other addresses as the Parties may designate in writing, or
 - (v) send via internet where acknowledged as received by EDCTP.

Assignment

- 14.4 The Agreement and/or any rights or obligations hereunder shall not be assignable or transferred by Contractor without the prior written consent of EDCTP; any such attempted assignment shall be deemed to be void.

Independent contractor

- 14.5 For the purpose of the Agreement each Party shall (deemed to) be an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party. EDCTP shall not be responsible for the employment of any individual



employed or otherwise engaged by Contractor. Neither Party shall be responsible for acts or omissions of individuals engaged by the other Party or for the health, safety and security of such individuals and their property. The foregoing takes exception in case Parties in writing explicitly agree differently.

Breach of General Terms/ Agreement

14.6 Any action or omission not in accordance with these terms and conditions set forth above is deemed to be null and void between Parties, unless the Agreement specifically provides for such act or omission. EDCTP is entitled to recover from Contractor any financial damage incurred by EDCTP pursuant of such non-compliant act or omission.

Modification of Agreement

14.7 Any modification to a signed Agreement concluded with EDCTP shall be made by an amendment signed by both of the Parties.



Annex III: Cofunding & Financial guidelines for EDCTP grants

Preamble:

A key requirement of a proposal submitted to an EDCTP call is funding from at least two EEIG-EDCTP Member States. If secured or applied for cofunding from African partners or third parties, applicants must also include in the application the relevant letters confirming this third-party contribution. EDCTP would like to stress that this will not in any way affect or reduce the EDCTP contribution to the project

The budget submitted for the project should include all the costs of carrying out the clinical trial including all work packages and take into account all Member State, third-party and other cofunding additional to the funds requested from EDCTP.

Types of donor cofunding to grantee

Cash paid through EDCTP

This is the simplest way to cofund through EDCTP and involves EDCTP applying a donor's funds to a project which they agree their funding to be used on. EDCTP finance department will allocate the money to sites in line with any donor preferences or requirements. The Project Coordinator (PC) needs to show in the detailed section of the yellow form how the money will be spent on a line item basis along with the rest of the EDCTP funding.

Cash paid directly to the grantee

Sometimes a donor will provide funding directly to one or more of the institutes involved in the project. The PC will need to ensure that the EDCTP has been provided with an authorised signed letter on headed paper from the donor organisation which verifies the amount of money they will be providing by that donor or funder to the project. No periodic update is required as EDCTP will accept the letter as prima facie evidence this sum will be provided without further questions. For cofunding by member states the annual certificate from the member state will also include these values as a second confirming verification.

In kind contributions to the grantee

The in kind donations for the budget should be filled in on a line item basis in the blue sheets but not on the yellow ones. These contributions will only be considered if they have arisen wholly, exclusively and specifically in relation to the cofunded project. They shall not be considered eligible if the cost or expenditure arising is a pre-existing cost not being used in connection with the project (i.e. a general contribution to the running costs of the organisation) or their use is at the management discretion of the donor i.e. can be used on purposes other than the cofunded project.

Third party in kind cofunding should be similarly confirmed by receipt of a signed letter from the donor. Where free clinical supplies, drugs, vaccines, medicines or equipment are made available then these should to be valued by the donor in the letter so that EDCTP can record their contribution to the grant.



Template support letters

Below you will find two template letters which should be used:

1. Letter of 'declaration of secured cofunding':

This letter must be submitted together with the application, by the deadline of the call. This letter must be signed by the EDCTP GA member(s) who is referred to as the "initiator". A copy of this letter should also be sent to the ENOs of the participating Member States. An official grant award letter (translated into English if necessary) from all cofunding Member States should also be provided.

To the responsible Project Officer EDCTP secretariat. Date
Subject: Declaration of secured cofunding for Applicant's name Proposal Call for Proposal: Applicant: Title of proposed project:
Dear Project Officer,
With reference to the above mentioned application in response to the above call for proposals, I hereby declare that the funding specified below has been secured.
Collaborator 1 Name and institution: name collaborator and name of institution of collaborator Name of funding organisation: Cofunding amount approved: € .. <in cash> Cofunding amount approved: € .. <in kind>
Collaborator 2 Name and institution: name collaborator and name of institution of collaborator Name of funding organisation: Cofunding amount approved: € .. <in cash> Cofunding amount approved: € .. <in kind>
Should you have any queries, please do not hesitate to contact me.
Kind regards, Name and signature of EDCTP GA member
Cc: to ENO



2. **Letter of 'confirmation of (scientific) review and approval':**

This letter must be submitted together with the application, by the deadline of the call. This letter must be signed by the EDCTP GA member(s) of the 'initiating' Member State. A copy of this letter should also be sent to the ENO of the respective Member States. Where other participating member states have also required their own scientific review, confirmation of these approvals should also be provided together with any conditions that may apply. Please enclose any official grant award letter (translated into English if necessary) from all cofunding Member States where available.

To the responsible Project Officer

EDCTP secretariat.

Date

Subject: confirmation of (scientific) review and approval' for Applicant's name Proposal

Call for Proposal:

Applicant:

Title of proposed project:

Dear Project Officer,

With reference to the above mentioned application in response to the above call for proposals, I would like to inform you that the project mentioned above has been officially reviewed and approved as stated below:

Review 1

Name of review body:

Date(s) of review(s):

Date of approval:

Review 2 (if applicable)

Name of review body:

Date(s) of review(s):

Date of approval:

Should you have any queries, please do not hesitate to contact me.

Kind regards,

Name and signature of EDCTP GA member

Cc: to ENO



Financial Guidelines (March 2009)

Financial records

All financial documents relating to the use of EDCTP funding should be held for a minimum period of 6 years from the date of the invoice or expenditure.

Budget format

For each grant with a value in excess of €250,000 a standard EDCTP budget form should be completed and forwarded with the final grant proposal for review by the finance department. Following this review, further information substantiating costs may be required or the amounts requested reduced. EDCTP budget forms can be downloaded from the [EDCTP website](#).

Where grants do not exceed €250,000 then the applicant may submit a budget in their own format.

Separate (yellow) budget forms should be completed for the project coordinator and each separate project collaborator, whilst the blue sheets need to be filled in for each donor to the project. A summary sheet totals all of the figures and indicates how much of the funding is provided by EDCTP versus member states and third party cofunding and also the particular type of cofunding.

Separate instructions on how to complete the budget and annual reporting forms are downloadable from the website. Please note that for the annual financial reports the 'actual costs' per year of the final budget form should be entered.

EDCTP shall pay for costs specified in the budget as agreed when the contract is signed. Cost items not identified in the budget may not be substituted or inserted into subsequent annual financial statement if not already specified in the agreed budget, unless this has been raised by the Project coordinator in writing with EDCTP finance department and agreed to beforehand.

Criteria for eligible costs

Only eligible costs may be entered on the budget and in the annual financial statement, these eligible costs must satisfy the following general criteria:

- They must be incurred by the Grantee.
- They must be directly concerned with the grant (see below).
- They must be necessary for performance of the grant covered by the contract.
- They must be reasonable and justified and accord with the principles of sound financial management, in particular in terms of value for money and cost effectiveness.
- They must be generated during the lifetime of the grant only. Any costs incurred before the last signature of the contract or after the expiry date will not be eligible.
- They must be actually incurred by the Grantee and recorded in their accounts and tax documents so as to be readily identifiable and verifiable.

Direct costs

Direct costs are the costs of a project that can be clearly identified and specifically related to a particular grant.

In particular the following direct costs are eligible:

- Costs of staff assigned to the grant comprising actual salaries plus social security charges and other statutory costs included in the remuneration provided that this does not exceed the average rates corresponding to the Grantee's usual policy on basic remuneration. **Please note that EDCTP can pay salary supplements to locally employed staff at African institutions where that person's total remuneration from their institution inclusive of all other salary supplements being paid by other donors does not exceed Euro 3,000 per month**; the budget form requires the amount requested to be clearly shown along with other supplements (if any) already being received by the staff member concerned and their basic gross salary. For staff earning over this



amount the institution can be reimbursed for a portion of their existing gross salary costs in relation to the time they are working on the grant in question but this payment must remain with the institution and not be used to increase the staff members monthly gross salary payment in any way.

- Under no circumstances are EDCTP funds to be used for loans or salary advances to staff.
- Travel and subsistence allowances for the staff taking part in the grant provided that they are in line with the Grantee's normal policy on such costs for staff traveling excluding any business class tickets,
- The purchase costs of equipment (new or second-hand) purchased by the Grantee, provided that the equipment remains on the premises of the Grantee for the duration and after the completion of the grant.
- Costs of consumables and supplies, provided that they are identifiable and assigned to the grant.
- Costs entailed by subcontracts awarded by the Grantee for the purposes of carrying out the grant, provided it has been awarded to the bid offering best-value for money following a transparent and equal treatment of potential subcontractors taking care in avoiding any conflict of interest.
- Costs of obtaining an audit certificate at the end of the grant for any grant site which exceeds 250,000 Euro, (an audit certificate being required for each separate site which receives over this amount).
- Clinical trial indemnity and clinical trials regulatory costs.

Period of first and last financial report

The first financial report is due on the anniversary of the date of the signing of the grant, in the case of a clinical trial which means that the first and all subsequent financial reports except the last one, will cover a period of 12 months each i.e. from the last signing date of the contract "the effective date" up to the following anniversaries. The last period will normally be less than 12 months as it runs from the last anniversary until the end date of the grant.

Release of funds from EDCTP after each financial report

EDCTP will make a first disbursement on signing the contract equal to the first one and a half years projected budget less the 10% that is with held at the end of the project; this is to ensure that the grant does not run into cashflow difficulties if there is a delay in getting the subsequent annual technical or financial reports approved. Thereafter, the subsequent annual payments will be based on the next year projected budget spend adjusted for the clawback of the extra half years payment included in the first payment. 10% of the value of the grant will be held back by EDCTP until the last annual technical and financial reports have been received.

Where a grantee has underspent on the annual financial report compared to the budget, on a cumulative basis as at the date of the annual financial report by more than 10%, then the amount of the payment due at that time may be reduced by the same level as the underspend compared to the cumulative budget; this is to stop excess funds building up at the grantee. At the time of the following disbursement after acceptance of the next annual financial report, the reduced payment(s) from earlier periods may be recouped up to the maximum level of the originally agreed cumulative budget at that time.

Tendering

All goods or services including (sub) contracts with a separate value exceeding €10,000 shall be required to be put out to tender in the case of a contract, and in the case of an item of equipment then 3 separate quotes are required. In the case where the cheapest bid is not the accepted bid then the reasons why this has not been accepted need to be clearly minuted and signed by the PC or collaborator and the Head of Finance at the site and made available at the time of any audit.

Overhead costs

All grantees are required to observe the EDCTP rates on overheads for grants (10% on all costs) and in no circumstances to apply the overhead rates of their own organisation. The overheads are intended to cover administrative and support costs plus bench fees, and all other internal recharges.



Where a grantee requests less overhead to accommodate more direct costs this can be accommodated in the contract budget at their request down to zero % if required. *(At the application stage requests to lower overheads to facilitate more direct costs should be addressed to the relevant project officer handling the call).*

Ineligible costs

The following costs shall be considered as ineligible:

- Debt and debt service charges
- Costs incurred by the Grantee before the effective date (signing date) i.e. any backdated costs
- Provisions for losses or potential future liabilities
- Other interest owed
- Doubtful debts
- Exchange losses
- Fiscal deductions from funding sent by EDCTP to the Grantee whether by the government of the country of the Grantee or any other body
- Costs declared by the Grantee within another grant or work programme receiving an EDCTP Grant
- Legal or financial compensation arising from accident or loss in respect of any travel paid for in an EDCTP grant
- Excessive or reckless expenditure
- Business or first-class travel expenses
- Loans
- Expenditures not included in the final approved budget
- Salary top-ups for staff at European institutions,
- Any costs which are proven to be fraudulent

Contributions in kind shall count as actual expenditure by the Grantee where verified by a supporting letter at the start of the project signed by the cofounder making the in kind costs

Determination of Final Grant

1. The total amount paid to the Grantee by EDCTP may not, in any circumstances, exceed the maximum amount of the grant as laid out in the budget to the contract.
2. The grant may not in any circumstances produce a profit for the Grantee. Profit shall mean any surplus in actual receipts over the eligible costs when the request for the final payment is made. Where eligible costs over the life of the grant are less than the amount awarded in the contract, then the excess will be deducted from the final payment or if necessary by requesting the Grantee to repay the amounts overpaid if the total amount already paid by EDCTP exceeds the final amount which is actually due.
3. Non-eligible costs shall always be covered by non- EDCTP resources; any ineligible costs discovered shall result in a corresponding reduction by EDCTP of the grant, and may therefore result in (part) recovery of already transferred amounts
4. Interest earned on the funds received from EDCTP, by the Project Coordinator only, must always be declared on the annual financial reports and used exclusively on the project; where this exceeds 1% cumulatively of the gross value of the grant then this will be deducted from the subsequent payments which EDCTP makes to the grantee. The purpose of this is to discourage slow disbursement by the Project coordinators and not to produce a profit on the grant which is strictly prohibited.



Authorised expenditure and cheque signatories

The grantee should ensure that all expenditures are authorised and approved in line with the normal institutions regulations. In particular cheque signatories to EDCTP funds should only be those people normally authorised to sign cheques under the coordinator or collaborator institutions' internal regulations.

Viring of funds

Grantees may vire amounts between expenditure lines for recurrent (consumables) and capital expenditure items and also between wages costs and either capital or consumables lines with the prior written permission of EDCTP finance department

Carrying forward of unused balances

Under-spent funds may be carried forward from one year to another over the course of the grant but not after the end date of the grant unless a no cost extension has been agreed.

Foreign exchange fluctuations

Where possible, grantees are strongly advised to open a Euro bank account – this is especially the case where the Project coordinator is involved and has to make onward disbursements to other collaborators in Euro. This is to guard against a foreign exchange risk of a devaluation of the local currency against the Euro. It is the responsibility of the Grantee to insure against any exchange rate movements between the Euro and the currency of the recipient bank account, however in cases where there is a severe appreciation of the local currency in which payments are made against the Euro then the EDCTP may renegotiate the size of the budget with the Grantee if the Grantee would not be able to carry out the work as originally envisaged in the project without suffering financial losses. In practice this means an appreciation of over 15% in the local currency against the Euro versus the rate at the signing date of the contract.

Investment of Grant Funds

All unspent or uncommitted grant funds must be deposited in an interest-bearing bank account with the primary objective of preservation of principal so that they remain available for the funding of the project. Any interest or other income generated by the grant funds, including currency conversion gains, must be applied to the research purposes of the project.

Investing EDCTP funding in any non callable deposit accounts or in any type of options, futures, swap, stocks or fund or other investment vehicle is strictly prohibited.

Exchange controls & Disbursement of funds from EDCTP

EDCTP will pay grants in Euro (which can be converted into local currency if necessary by the receiving bank) to the Project Coordinator (PC) who is then responsible for making all further disbursements to the collaborators, also in Euro and without any deductions from the original budget. However, EDCTP can be flexible in how the grant disbursements are made where exchange controls or government deductions would lead to difficulties in making disbursements to the collaborators on a project. In this case the Project coordinator will have the option of requesting that EDCTP pays directly to the collaborators. The responsibilities for reporting will always stay with the Project coordinator irrespective of which party to the grant is making the payments.

Separate or sub bank account

Grant recipients are requested, to open a separate or sub bank accounts for EDCTP grant funds so that auditors can easily trace the movement of funds through the accounts and back to the accounting statements, this also helps the grantee to reconcile the EDCTP funds at each month end and produce the annual financial report. The name of the account should always include the title of the institution and the name of EDCTP. The details of the account are to be clearly stated in the contract.

Financial report

- For each grant there is one Project coordinator (PC) who is responsible for filing the annual and final financial report which includes sheets for all collaborators on the project.



- The annual financial statements are incorporated into the budget sheets in the EDCTP standard report format except for grants below €250,000 where the report can follow the layout of the budget submitted.
- The annual financial statement submitted should be completed on cash accounting basis and not an accruals basis.
- All figures quoted on the financial statement should be in Euros. Any conversion of actual costs into Euro shall be made at the monthly accounting rate established by the European Commission and published on its website [ECB: Euro foreign exchange reference rates](#) for the months the expenditures occurred in, where funds are held in a Euro account and used to pay local expenses in a different currency. Where the funds received are converted immediately into a different currency and then held on deposit in that currency the rate at which the funds were converted from Euro into that currency will be the exchange rate which can be used up until the time when a new tranche of funds are received and converted at a new rate which then becomes the prevailing exchange rate.
- The financial report must be signed by the PC or collaborator and the Head of Finance of their respective institute. This should be mailed to the EDCTP office for the attention of the Director of Finance and Administration at EDCTP, Laan van Nieuw Oost Indie, 2593 CE Den Haag, The Netherlands.
- Alternatively a scanned signed copy may be sent by email to coloma@edctp.org.

VAT

All expenditure should include irrecoverable VAT (sales tax) only; where the institution can recover VAT on expenditure this should not be included in the annual financial report, otherwise the Institute will be being reimbursed for costs twice which is not allowable.

Financial audit certificates at the end of a grant

For grants over the value of €250,000, an audit certificate for each institution that is involved as Project coordinator or collaborator is required at the end of the grant only to support the final financial return (covering the whole period of the grant) and to receive the final payment. Grantees should expect interim audit visits from EDCTP and/or the European Commission.

In the event of unsatisfactory results of financial audit EDCTP retains the right to suspend any further payments under the grant.

Charging of staff hours

The EDCTP budget form includes a column for indicating what percentage of an individual staff member time is being spent on the project. As such, a reliable means of recording staff time per project should be kept available for inspection by auditors, which substantiate the amount of time each person is working on the project.

It is essential that no person included in the budget form is being charged out at more than 100% of their available time across all projects they are working on, personnel costs should only be charged from when the staff member is in post which is not necessarily the same date as the start of the project.

Other financial resources

EDCTP welcomes and encourages cofunding from other organisations on research projects which it funds and the PC must inform EDCTP when such cofunding has been secured.

It is very important that EDCTP expenditure items are correctly and separately identifiable (ringfenced) from the costs incurred and funded out of the other donor funding. This is to ensure that there is no risk that any of the budgeted expenditure items from the EDCTP application are being reported and paid for twice by the EDCTP and other donor(s). Where such multiple funding exists on a project it should be discussed with the EDCTP Director of Finance and Administration on how best to manage the situation



across the project so as to minimize this risk. Typically this can be by allocating EDCTP funding to separate sites involved in the project and then funding the other site(s) from other donor funds.

Ownership of assets

All capital equipment bought with EDCTP funding remains prima facie the property of EDCTP at the end of the grant, excepting where it has exhausted its useful economic life (see below). The EDCTP Executive Director (ED) in consultation with the Director of Finance and Administration may give permission at the end of the project to the grantee to use it on another project which is not funded by EDCTP or to transfer it to a separate EDCTP project at the same research site. Grantees are expected to maintain and take care of all EDCTP capital items in the same way that they do for items bought from their own core funding. In addition, all assets with an individual value of over €5,000 (plus all laptops and pc's) should be clearly labeled or stenciled as having been provided by the EDCTP, insured and listed separately in a register which can be audited.

EDCTP finance department has stickers which will be sent to the PC after signing the contract, to be disbursed amongst the sites carrying out the study and which should be attached to the equipment so that it is clearly identifiable.

Please note that after 6 years for vehicles, 4 years for motorcycles and computers, the equipment is deemed to have exhausted its useful economic life and therefore will automatically become the property of the grantee and not transferable to a new project if it this age before the new project begins

No-cost extensions

Where a PC wishes to apply for extra time to complete the study then with the approval of the EDCTP ED this can be granted on the conditions that no additional funding will be made available by EDCTP and that the request for the no-cost extension is made at least four months prior to the scheduled end date for the project.



Annex IV: EDCTP selection procedure and evaluation criteria

This annex aims to provide information on the selection procedure with regard to **proposals** submitted in response to the call for Member State Initiated proposals from EDCTP where a further EDCTP scientific review is deemed necessary. All such **proposals** that fulfil the eligibility criteria will be evaluated against the pre-set selection criteria as described in the Call for Proposals.

Principles of the selection procedure:

- i. Quality:** all grant applications will be objectively evaluated to reflect the highest scientific merit and relevance to EDCTP to fulfil the objectives of the Joint Programme.
- ii. Transparency:** the decision-making process is described in procedures, and these procedures are available to any interested party upon request.
- iii. Equality of treatment:** all applications will be evaluated following the same standard procedures, irrespective of their origins and/or the identity of the applicants.
- iv. Integrity and impartiality:** all applications will be reviewed thoroughly and objectively to avoid any possible circumstances which might interfere or compromise the result of the evaluation.
- v. Efficiency and speed:** EDCTP aims to ensure that an optimal assessment is achieved in a competent and efficient environment.
- vi. Ethical consideration:** any proposal that violates the fundamental ethical principles may be excluded from the selection process at any stage.

Identification of reviewers

EDCTP identifies reviewers by an open call for or nomination of scientific experts in the particular programme area on the basis of their expertise and appropriate range of competencies in pre-defined fields. Selected reviewers are then added to EDCTP's Reviewers Database. Reviewers are commonly individuals from industry and/or research institutions, internationally recognised in a relevant specialist area, and are expected to have the knowledge and expertise within the field in which they are consulted.

All independent experts must also have a high level of professional experience in the public or private sector in one or more of the following areas or activities:

- a. Research in the relevant scientific fields
- b. Evaluation of projects
- c. Use of the results of research and technological development projects
- d. Technology transfer and innovation
- e. International collaboration
- f. Knowledge on the conduct of clinical trials

Reviewers are expected to have an excellent command of English. They may be invited from countries other than EDCTP-EEIG Members States or sub-Saharan African countries. Under no circumstances may reviewers be applicants or collaborators within grant applications submitted in response to the Call for Proposals that they have been selected to review.

Following a **Call for Proposals** the EDCTP Secretariat will draw up a list of appropriate reviewers from the expert's pool based on their experience and appropriate range of competencies in the pre-defined fields relevant to EDCTP. Candidate reviewers are selected on the basis of their experience and appropriate range of competencies in pre-defined fields relevant to EDCTP. Candidate reviewers **cannot** be (co-) applicants.



Selected reviewers might be requested to serve either as External Reviewers or as SRC members. Since SRC members are normally appointed for a three-year period, their possible conflict of interest will be re-assessed each time the SRC members are invited for the peer-review of new grant proposals. EDCTP will take into consideration any arising conflicts while appointing reviewers in compliance with the EDCTP policy on conflict of interest. ERs are solely appointed for one specific Call for Proposals and their identities will remain anonymous.

The EDCTP Secretariat will appoint a Chair and a Deputy Chair for each call. The Chair will lead the discussion during the **SRC** meetings. In case the Chair is absent or has a conflict of interest, the Deputy Chair will perform this task. The EDCTP Secretariat will provide all necessary information on the procedure to the (deputy) Chair prior to the meeting. The (deputy) Chair of the **SRC** may be requested to act as rapporteur in follow up meetings of the Partnership Board or the General Assembly to clarify the consensus report or the meeting discussion.

EDCTP will ask experts to serve as member of a Scientific Review Committee (**SRC**) or as External Referees (**ER**) with the following terms of reference:

- i. To peer-review (comment, score, rank) the complete grant application for EDCTP and make a recommendation to the Partnership Board (PB);
- ii. To assist EDCTP in identifying priority projects and opportunities for the treatment/prevention and capacity building in the fields of HIV/AIDS, tuberculosis or malaria;
- iii. To review future progress reports (intermediate and final) of grants that are selected for EDCTP support;
- iv. The expert will work in a personal capacity and in performing this function will not represent any organisation/institution;
- v. Reviewers will be accountable to the Executive Director of EDCTP.

A declaration of confidentiality and conflict of interest is sent to all reviewers (**ER** and **SRC** members) before the selection of **proposals**. The reviewers are obliged to maintain the confidentiality of the information contained in the **proposals** they evaluate and of the selection process and its outcomes and to act with strict impartiality. The reviewers will also declare any potential conflicts of interests with respect to the **proposals** under review prior to the start of their tasks and upon receipt of the names of applicants in compliance with EDCTP Policy on Conflict of Interest.

When there are circumstances that may lead to a conflict of interest or circumstances that may be perceived by others to be a conflict of interest, the reviewer is required to divulge sufficient information to EDCTP in order to enable the EDCTP secretariat to determine the case and to agree on the appropriate action.

Evaluation of Proposals

In general, applications are submitted either following a Call for Proposals that involves a one-stage submission and selection procedure or as a result of a Brokering Initiative. Before an applicant submits the full proposal he/she should contact the European Networking Officer (ENO) in his/her respective country. Alternatively, the applicant can contact the ENO through the EDCTP website.

Eligibility check

After the closing date of a given Call for Proposals, EDCTP performs a preliminary screening to determine if each submitted application meets the eligibility criteria as described in the Call for Proposals. If a proposal does not meet the eligibility criteria, depending on the case, the applicant may be given the opportunity to prove eligibility within a specified time period.

If ineligibility becomes apparent in a later stage of the selection process, the application may be withdrawn at any stage of the evaluation process.

Review of proposals

As scientific consultants participating in the selection of specific grant applications, reviewers are expected to supply a complete report using the standard assessment forms.

EDCTP uses standardised assessment forms for the review of grant applications. In compliance with EDCTP standard procedures, each grant application must be reviewed by at least two ERs and two SRC members. All ER's and SRC members will be requested to carefully assess each application individually. ER reports will be sent to the applicants to give them the opportunity to respond in writing to the ERs'



comments. At this stage, SRC members will not have access to the ERs' assessments, to the applicant's response to the ERs' comments, and to the assessment forms completed by their fellow SRC members.

EDCTP will prepare and organise the SRC meetings. Within these meetings, all assessment forms (from SRC members, ERs and the applicant's response to the ERs' comments) and the preliminary ranking of all applications (based on the SRC and the ERs' assessments) will be discussed. SRC meetings aim to reach a final on each application, which may differ from the preliminary ranking. The assessment forms filled in by ER and SRC members will remain confidential.

Selection criteria

All proposals will be reviewed based on the following criteria:

I. Project excellence: objectives, feasibility, impact, innovation, quality and record of investigators, quality of the proposed methodology.

II. EDCTP relevance: public health relevance for developing countries, adequacy of **proposal** in context of the call, alignment with the priorities of the EDCTP **Joint Programme**.

III. Potential impact: need for strengthening, restructuring existing research capacities, knowledge dissemination, sustainability.

IV. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.

V. Implementation Plan of Capacity Building: research activities, staff and facilities development, networking activities, training activities, mentorship programmes, consortium management activities, work planning and package of each participant including **deliverable** list, performance indicators.

VI. Consortium description: role of participants, achievement of objectives, involvement of private sector participation of at least two public institutions from European EEIG Member States as well as two African Institutions)

VII. Project management: organisational structure, decision-making mechanisms, knowledge management

VIII. Clinical Trial Management: steering committee, sponsorship, daily management for the trial.

IX. Project resources: cofunding arrangements, mobilisation of resources - personnel, equipment and finances in accordance with EDCTP financial requirements

X. Gender issues: promotion of gender equality, gender action plan concerning the staff involved in the project.

Threshold

All selection criteria will be scored on a scale of five categories from 'Poor' to 'Excellent'. EDCTP has defined an overall threshold for all selection criteria of 'Good' (third in the assessment scale) to ensure that all applications meet a minimum level of quality. Any application receiving a score category less than a 'Good' for any selection criteria cannot be selected for funding.

Exceptions are made for the following selection criteria:

x. Gender issues (promotion of gender equality, gender action plan concerning the staff involved in the project).



Assessment

The **ER** and **SRC** assess the applications against the above-mentioned selection criteria and score each criterion according to the following category scale:

1. Poor
2. Weak
3. Good
4. Very Good
5. Excellent

On the assessment form the reviewer is required to provide reasons for the selected score category. This explanation should provide clear insight on how the reviewer has come to his/her conclusions.

Consensus approach

All **SRC** members will be sent all eligible proposals at least 2 weeks before the **SRC** meeting. During the meeting they will receive a summary of the **ER** assessment as well as the response of the applicant to the **ER** queries. Please note that the identity of **ER** will not be revealed to the **SRC** members at any time. The **SRC** members who were assigned to review a particular proposal will present their views during the meeting. All other **SRC** members will also be given the opportunity to voice their opinion. To help the **consensus discussion** during the meeting the EDCTP secretariat will provide a preliminary ranking of the applications based on the average scores given by **ER** and **SRC** members on the assessment forms. The **consensus discussion** will be based on the comments made by the reviewers, the applicants' response and on any other comments that may arise during the meeting. In the event consensus is not reached voting may be necessary. The consensus will result in a final ranking of all proposals.

The EDCTP Secretariat will prepare a consolidated including a summary of the SRC report on each proposal. A standard consolidated will contain a project summary, list of collaborators the requested budget, available cofunding, the final ranking as well as comments and recommendations of the **SRC**.

Partnership Board (PB) recommendation

The Partnership Board (**PB**) is responsible for preparing and maintaining the EDCTP scientific strategy. They assess whether the proposals recommended for funding by the SRC are in line with the EDCTP strategic priorities. The summary review reports and the minutes of SRC meeting will be discussed during a PB meeting. If needed, the SEC clarifies the procedure that was followed. In addition, the Chair of the SRC may be requested to act as rapporteur to clarify the consensus discussion. All participants at the PB meeting are asked to declare any conflicts of interest in compliance with EDCTP Policy on Conflict of Interest prior to the PB meeting. The outcome of the PB discussion on the SRC grant selection process is a list of applications recommended for funding that will be presented to the General Assembly for a final decision.

General Assembly (GA) decision

The EDCTP Secretariat compiles the summary review reports, the minutes of the SRC meeting and the recommendation of the PB and presents these to the General Assembly (GA) for their final decision. Again, all participants attending the GA meeting are asked to declare any conflicts of interest in compliance with EDCTP Policy on Conflict of Interest.

Upon final decision from the GA, EDCTP informs the applicants on the results of the selection procedure. If the proposal was selected for funding, the Grant Agreement preparations will commence.

Special notes for Member States Initiated projects

Please note that proposals that have already been reviewed, approved and funded by EDCTP-EEIG member states may or may not be subjected to review by an EDCTP scientific review committee depending on the circumstances. Each proposal will be evaluated on a case-by-case basis with advice from the EDCTP Scientific Advisory Committee, the Partnership Board.