EDCTP2-Guidance for expert reviewers

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The Power of Sharing Science

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Document history		
Version	**Date**	**Changes**
1	01-10-2016	First version
2	31-07-2017	• Additional guidance added on criteria regarding allocation of resources (including budget) • Minor text edits to improve on clarity & fixing of typos • Updated with workplan 2017 review criteria

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List of Acronyms

CSA	Coordination and Support Actions
DoI	Declaration of Interest
EDCTP	European & Developing Countries Clinical Trials Partnership
H2020	Horizon 2020
LoI	Letter of Intent
NID	Neglected infectious disease
RIA	Research and Innovation Actions
TMA	Treatment and Mobility Actions

1   Introduction

Thank you for agreeing to act as an expert reviewer for EDCTP. To assist you with your reviews, we have prepared this guidance about EDCTP, our funding schemes and evaluation procedures. If you have any questions or would like to discuss any aspects of the procedure, please contact the project officer managing the evaluation procedure.

2   About EDCTP

EDCTP aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases (NIDs) in sub-Saharan Africa. EDCTP supports all clinical trial phases (I-IV) including health services optimisation research, with a focus on phase II and III clinical trials. Supporting research and regulatory capacity development is integrated in the research funding strategy in order to strengthen the conditions for conducting clinical research in sub-Saharan Africa. The EDCTP2 programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020 and governed by the African and European countries participating in the EDCTP Association. EDCTP strategy is guided and/or implemented according to our Strategic Business Plan and Strategic Research Agenda, and EDCTP annual work plans.

3   EDCTP evaluation procedure

Calls for proposals may follow either a single-stage (i.e. full proposal only) or a two-stage procedure with a short letter of intent (LoI) as the first stage and the full proposal as second stage. Proposals submitted by the deadline in the online system EDCTPgrants for each call go through a series of steps (Figure 1):

1) Internal evaluation by EDCTP to determine if the proposal is admissible and eligible for a given call
2) External review of eligible proposals by a number of expert reviewers – this is done individually and remotely using EDCTPgrants
3) Rebuttal procedure – applicants are provided with the opportunity to submit a short rebuttal in response to the reviewers' comments after full proposal review
4) Consensus evaluation meeting (which may include a panel review), conducted remotely (virtual meeting) or on site at the EDCTP offices. An evaluation summary report is produced from the consensus evaluation
5) Final ranked list submitted for approval by the EDCTP Board
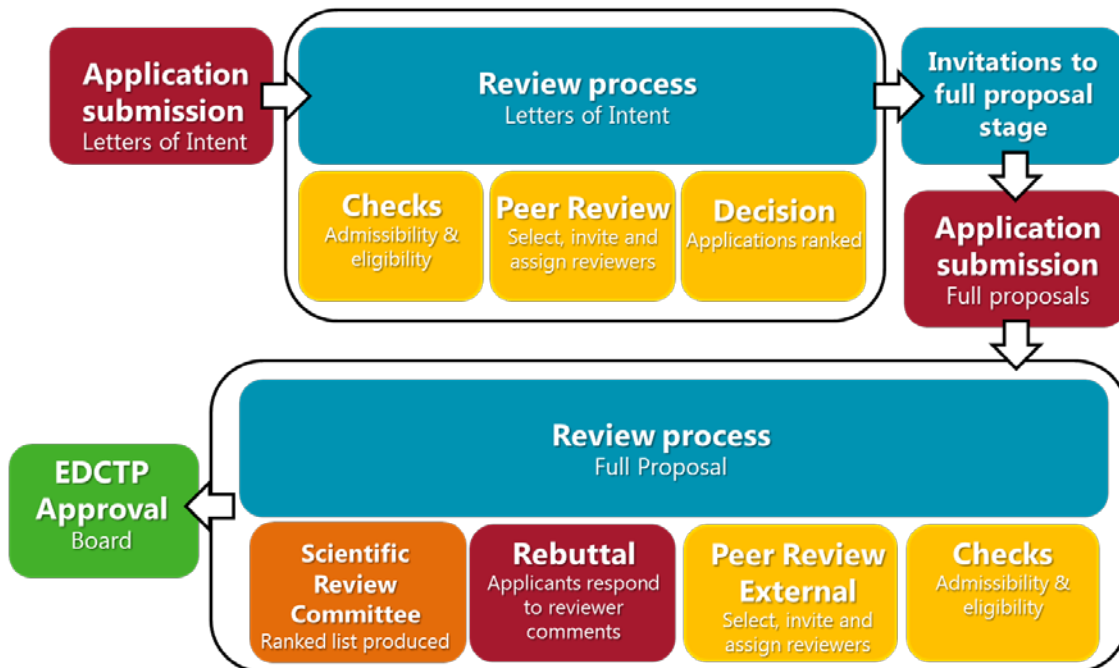6) Ethics review (screening and evaluation).

Figure 1: Steps of the review process

4 Types of action and evaluation criteria

The second EDCTP programme is supported under Horizon 2020 (H2020), the EU Framework Programme for Research and Innovation, and EDCTP follows the H2020 rules and procedures. EDCTP activities are supported via three funding schemes (known as Actions): Research & Innovation Actions (RIA), Coordination & Support Actions (CSA), and Training & Mobility Actions (TMA).

Expert reviewers in EDCTP2 evaluate proposals on the basis of three criteria:
- Excellence
- Impact
- Quality and efficiency of implementation

For a two-stage procedure, the first stage is the evaluation of the letter of intent (LoI). The LoI evaluation is based on the criteria Excellence and Impact only[1] and on a limited set of criteria (those criteria indicated in bold in the call text). For a full proposal all three criteria are evaluated. You are requested to evaluate each proposal by providing a score for each criterion plus review comments that justify the score given for each criterion. Your comments (or extracts of them) will be shared with the applicants. The evaluation procedure is confidential and the reviews are anonymous. The names of expert reviewers are never shared with applicants; however, EDCTP publishes annually on its website a list with the names and affiliations of all independent experts used during that year.

5 Responsibilities of expert reviewers

Expert reviewers act as independent experts and they evaluate proposals submitted in response to a given call. As an expert reviewer you are responsible in your personal capacity for carrying out the evaluation of the proposals assigned to you. You may not delegate the work to another person. During the evaluation, you must ensure that all documents are stored in strict confidentiality so that no one else has access to the proposals you are evaluating. Furthermore, you must adhere to the EDCTP Code of Conduct and Declaration

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[1] Unless specified otherwise in the call text and work plan

[of Interests Policy](#) and you must never release details about the applications, their evaluation and the funding recommendations or enter into any discussion with applicants.

Significant funding decisions will be made based on your advice and therefore we advise you to read the following information carefully.

6 Guiding principles

Expert reviewers act under the following guiding principles:

Independence	You are evaluating in a personal capacity. You represent neither your employer nor your country.
Impartiality	You must treat equally all proposals and evaluate them impartially on their merits, irrespective of their origin or the identity of the applicants.
Objectivity	You evaluate each proposal as submitted; meaning on its own merit and not its potential if certain changes were to be made.
Accuracy	You make your judgment against the official evaluation criteria and the topic the proposal addresses, and nothing else.
Consistency	You apply the same standard of judgment to all proposals.

7 Confidentiality

Confidentiality during the review process is maintained by adhering to the following principles. As an expert reviewer you are requested to:

- **Not discuss evaluation matters**, such as the content of proposals, the evaluation results or the opinions of fellow experts, with anyone, including other experts or any other person (e.g. applicants, colleagues, students) not directly involved in the evaluation of the proposal.
- **Not contact partners in the consortium, sub-contractors or any third parties.**
- **Not disclose the names of your fellow experts**, EDCTP publishes the names of the experts annually, but as a group, so that no link can be made between an expert and a proposal.
- **Maintain the confidentiality of documents**, paper or electronic, at all times and wherever you do your evaluation work (on-site or remotely). Return, destroy or delete all confidential documents, paper or electronic, upon completing your work, as instructed.

8 Conflicts of interest

Expert reviewers have to declare in advance of the evaluation any potential interests/conflicts of interest related to the applications allocated to them, based on the title of the application and the names and affiliations of the participants. EDCTP will decide whether the potential conflict is acceptable or not in terms of proceeding with the evaluation. Reviewers may notice a conflict of interest only after a full application has been provided to them. In this instance, the reviewer must immediately alert EDCTP to the potential conflict and await further instructions. Kindly refer to the [EDCTP Code of Conduct and Declaration of Interest (DoI)](#) policy for further details.

9 Scores

As a reviewer, you are required to score the proposal **as it was submitted**, rather than on its potential if certain changes were to be made. If you identify any significant shortcomings, please reflect this by awarding a lower score for the criterion concerned and by providing an explanation in the comments box.

The scores range from **0 to 5** and are interpreted as follows:

0 =   **Fails** to address the criterion (or cannot be assessed due to missing or incomplete information).

1 =   **Poor,** the criterion is inadequately addressed or there are serious inherent weaknesses.

2 =   **Fair,** the proposal broadly addresses the criterion but there are significant weaknesses.

3 =   **Good,** the proposal addresses the criterion well but a number of shortcomings are present.

4 =   **Very Good,** the proposal addresses the criterion very well but a small number of shortcomings are present.

5 =   **Excellent** the proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

Please note that half marks may be given. The full range of scores should be used in order to allow differentiation between the proposals.

10 Thresholds

Only proposals above the predefined score thresholds (as indicated in the call text and work plan) will be considered for further evaluation.

For the evaluation of Letters of Intent (LoI), only the criteria Excellence and Impact are evaluated. The threshold for individual criteria is **4** (out of a maximum score of 5). An arithmetic average (mean value) or median of the individual scores may be taken as the consensus score. The overall threshold, applying to the sum of the two individual scores, will be set at the level such that the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget. The actual level will therefore depend on the number of proposals and funding request per proposal received. The threshold is expected to normally be set at **8 or 8.5**.

For the evaluation of single-stage proposals or full proposals for two-stage evaluation procedures, the funding threshold for individual criteria is **3** (out of a maximum score of 5). The overall threshold, applying to the sum of the three individual scores is **10** (out of a maximum total of 15).

11 Scoring award criteria

Expert reviewers score proposals based on the following criteria:

a) The award criteria specified in EDCTP2 work plan and provided in the call text of a given Call for Proposals. Award criteria vary depending on the action type (grant scheme) and can be found in Table 1a for RIAs, Table 1b for CSAs and Table 1c for TMAs.
    Award criteria are specified for each of the sections of the application of Excellence, Impact and Quality and efficiency of implementation. You should use these award criteria to determine if the proposal addresses all of the points indicated under the criterion and allocate your score accordingly. **Important to note is that only award criteria in bold should be considered during the letter of intent stage;** award criteria in non-bold font type should only be considered during full proposal review, see Tables 1a-c).

b) Further, the call text specifies the scope of the call in question and expected impact for applications funded through the call and these should also be reviewed to determine if the proposal fits with the scope and the expected impact.

As a reviewer, you should take both the award criteria and the call text into consideration when giving your score.

For the evaluation of single-stage proposals and proposals at the second stage of a two-stage evaluation procedure, **reviewers should evaluate whether the requested resources are in line with the objectives and deliverables of the proposed work** as per the first review criteria under Quality and Efficiency of implementation (See Tables 1a-c). This criterion includes the assessment of budget requested and whether

the reviewer considers the proposal to be good value for money for EDCTP. Budgetary recommendations should be made by the reviewers if the activities are considered too costly and/or inflated.

12 Practical suggestions

Please bear in mind that your comments will be provided to the applicants, including the consensus scores (but not the individual scores). In the case of full proposals, the applicants have the right to respond (rebuttal) to the reviewers' comments before the review committee meeting.
After the funding decisions have been made, applicants have the right to redress and may appeal the decision if they consider that the evaluation procedure was not followed. This may include challenging the statements made by reviewers. In view of this, please ensure that:

- ✓ Your scores are consistent with the comments provided. You evaluate proposals as they are submitted, not on their potential if significant changes were to be made; so, if significant shortcomings are described these should be reflected in the scoring.
- ✓ Your comments refer and relate to the evaluation criteria. Do not mark down a proposal for the same critical aspect under two different criteria.
- ✓ Your review is clear and concise. Please avoid giving a lengthy summary of what the proposal is about. Make sure the language used is appropriate and professional.
- ✓ Avoid categorical statements if these have not been properly verified; *e.g. no safety data are provided; this drug has never been tested on children*.
- ✓ Do not provide funding recommendations, *e.g. this proposal should get funded; this proposal should not get funded.*
- ✓ Do not make comparisons to other proposals you reviewed in the call, *e.g. this is the best application I have reviewed; this application, unlike application X, does include a placebo-controlled group.*
- ✓ If you recommend a revision of the budget (i.e. too low or too high), please indicate an approximate amount in Euro (applicable only at the full proposal stage).
- ✓ Avoid referring to individuals in the proposal by name in your review, *e.g. Professor X does not have the sufficient experience to conduct this study*.
- ✓ You review the clinical trials annex for all full proposals that include a clinical trial.
- ✓ For Letters of Intent - do not evaluate proposals on award criteria not taken into consideration for letters of intent (i.e., award criteria not in bold that apply only to full proposals in the second stage).
- ✓ Finally, EDCTPgrants does not have an in-built spell-checker. Depending on the settings of your web browser, the spell check may be enabled or not. If spell-check is not enabled in your browser, we recommend that you first draft your comments in a word document, proof-read and copy-paste it into the online form.

Table 1a: Award criteria 2017 Work plan- Research and Innovation actions (RIA)

Award criteria (Only the criteria in bold are considered at the first stage (LoI) of a two-stage call)		
Excellence	**Impact**	**Quality and efficiency of the implementation**
• **Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.** • **Importance, relevance/pertinence and clarity of the objectives.** • **Soundness of the concept and credibility of the proposed approach/methodology.** • **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.** • Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. • **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.** • Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge	• **The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.** • **Likelihood to result in major advances in the field.** • **Advancing the clinical development of new and improved products.** • Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results. • **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.** • Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. • Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data	• Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables. • Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met. • Complementarity of the participants within the consortium, and the extent to which the consortium as a whole brings together the necessary expertise. • Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role. • Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. • Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. • Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s). • Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). • Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. • Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).

Table 1b: Award criteria 2017 Work plan- Coordination and Support Actions (CSA)

Award criteria (Only the criteria in bold are considered at the first stage (LoI) of a two-stage call)		
Excellence	**Impact**	**Quality and efficiency of the implementation**
Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description. **Importance, relevance/pertinence and clarity of the objectives.** **Soundness of the concept and credibility of the proposed approach/methodology.** - Clarity, pertinence and importance of the strategic vision. - Soundness of the concept. - Quality of the proposed coordination and/or support measures.	**The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.** **Likelihood to result in major advances in the field.** - Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), and to manage research data where relevant. - Sustainability of capacity beyond the end of the grant, where relevant. - Contribution to networking, where relevant.	- Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables. - Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met. - Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise. - Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role. - Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. - Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. - Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s). - Quality of the leadership and a clear and effective governance structure.

Table 1c: Award criteria 2017 Work plan- Training and Mobility Actions (TMA)

Award criteria (Only the criteria in bold are considered at the first stage (LoI) of a two-stage call)		
Excellence	**Impact**	**Quality and efficiency of the implementation**
• **Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.** • **Importance, relevance/pertinence and clarity of the objectives.** • **Soundness of the concept and credibility of the proposed approach/methodology.** • Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career. • Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.	• **The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.** • **Likelihood to result in major advances in the field.** • Contribution of the fellowship to the fellow's clinical research skills and career development. • Contribution to strengthening clinical research capacity at the home or host organisation. • Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data. • Sustainability and retention of capacity post-award.	• Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables. • Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met. • Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise. • Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role. • Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. • Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. • Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s). • Suitability of the fellow's home organisation to support the fellowship project. • Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.