EDCTP2 INDEPENDENT OBSERVER'S REPORT

Call ID: RIA2020I

observed: SRC meeting and Panel Review meeting

Dates of evaluation

25-27 November 2020 11 December 2020

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Present at the evaluation: 26-27 November (only 2 h on Nov 27),

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Signature and date

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Abbreviations

CES Consensus Evaluation Summary

EDCTP2 Second Programme of the European & Developing Countries Clinical Trials

Partnership Programme

H2020 Horizon 2020 Programme for Research and Innovation

IER Independent Evaluation ReportIOR Independent Observer's Report

SRC Scientific Review Committee

1. Overview

This report covers the evaluation procedure of one Call¹:

RIA2020I: "Innovative approaches to enhance poverty- related diseases research"
 Deadline: 13 August 2020, Call budget 23.4 M€

Prior to the Scientific Review Consensus (SRC) meetings, the appointed independent expert reviewers carried out an individual evaluation of the applications, and submitted an individual evaluation report (IER). Applicants were allowed to respond to the reviewers' comments with a Rebuttal aiming at clarifying some issues, whereas not allowing for providing additional information.

Guidance to the experts on the criteria to be applied in performing the remote evaluation and writing the IER was given in documents² prepared by the EDCTP Secretariat. For each application, a rapporteur and a variable number of confirmers (2-5) were assigned. Appointed Rapporteurs came to the SRC meeting with a draft of the Consensus Evaluation Summary (CES), prepared on the basis of the IER.

During the SRC meeting held in Zoom (25-27 November), the experts discussed the proposals and agreed on scores and comments. The Rapporteurs modified the CES drafts accordingly. During the ensuing Review Panel meeting (December 11), four experts were present, three who had participated to the SRC meeting and one who was not involved in the evaluation and could provide a fresh point of view. The experts produced a ranking list of the proposals, and revised the CES drafts in terms of adherence to the scores and equal treatment before their finalisation and communication to applicants.

It is since 2017 that EDCTP2 invites an independent observer to follow the SRC meetings, with the task of assessing the procedure pathway and its harmonisation with the H2020 criteria.

¹ See: https://www.edctp.org/funding-opportunities/calls-for-proposals-for-funding-of-clinical-research-on-poverty-related-infectious-diseases/

² EDCTP2-Guidance for expert reviewers, October 2019 - Version 5.0; and EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, November 2019 - Version 5.0; both available at http://www.edctp.org/funding-opportunities/expert-reviewers/

2. Key observations for these Calls

Call response

The Call RIA2020I received 57 applications, 47 of which were eligible and were evaluated. The EDCTP Secretariat checked eligibility, before assigning proposals to reviewers.

Remote evaluation

A total of 33 evaluators were engaged in remote evaluations, and 4-6 of them evaluated each proposal.

Several experts were at their first experience as EDCTP evaluators, in agreement with the H2020 recommendation of recruiting about 20% new evaluators across the programme. A good gender balance was reached (female/male ratio was 12/33), as well as a good representation of African countries (11 experts).

Recommendation 1

Maintain the excellent practice of involving the majority of the appointed experts in reading the submitted proposals. Having the large part of the panel involved in evaluating each proposal would make consensus and ranking very easy and highly harmonised.

As preparation for their work the independent expert reviewers received the relevant guidance documents and were granted access to the EDCTP online evaluation system.

The rebuttal procedure was applied. The individual IERs (without scores) were sent to the applicants, who were allowed for a rebuttal, exclusively for correcting misunderstandings or misinterpretations on the reviewers' side³. According to H2020 rules, proposals should be evaluated as they are written, and there are no opportunities for giving suggestions or asking additional information to the applicants. I should underline that the rebuttal practice at EDCTP is not in contrast with the H2020 guidance, as it exclusively aims at improving clarity and avoiding misinterpretation of specific issues, thereby improving the accuracy of the evaluation. Also, both the experts and the applicants welcome the opportunity of asking and providing clarifications. As in previous occasions, I should again underline the fact that the

³ "This rebuttal procedure is intended to allow the applicants to identify and comment on possible factual errors or misunderstandings that may have been made by the expert reviewers. The rebuttal procedure does not provide an opportunity for the applicants to modify the proposal."

applicants do not always understand the goal of rebuttals and tend to provide new information in the attempt of improving their proposals. The EDCTP Secretariat has given precise instructions to the reviewers to disregard any additional information provided in the rebuttal and to evaluate the proposals as submitted, and has repeated such instructions in many occasions during the SRC meeting.

Recommendation 2

The rebuttal procedure is not in contrast with the H2020 guidelines to evaluate proposals as they are written, as it is used only for clarifying some errors or unclear issues. The procedure is well received by both reviewers and applicants and it can be maintained. It is however necessary to make sure that both reviewers and applicants are completely aware of its meaning and do not use it for asking and providing additional information. If in the next framework programme the H2020 restrictions will be lifted, the rebuttal could be advantageously used for improving the proposals' value and impact.

A Rapporteur was appointed to each application. The Rapporteur had access to all the IERs and to the rebuttal and, based on these documents, prepared in advance a draft of the consensus report. The draft formed the basis for the consensus discussion and for the formal CES that was finalised after the meeting. All the other evaluators of the same proposal had the role of Confirmers.

Scientific Review Committee meeting

Of the eligible proposals that underwent remote evaluation, only 46 were examined during the SRC meeting, since one proposal was withdrawn. The independent experts involved in the remote evaluation were invited to attend the SRC meeting via a Zoom online meeting, because a face to face meeting was not possible. An extensive briefing opened the meeting and provided both the general scope of EDCTP2 and the specific aims and guidelines of the Call. A detailed agenda was prepared and a summary table with all the remote individual scores was shown on screen.

Recommendation 3

Maintain the good habit of exhaustively briefing the experts on the scopes and rules

of the Call. Keeping a summary table on-screen is excellent, as the experts can recheck details at any moment.

Recommendation 4

Maintain the good habit of preparing a precise agenda of the meetings. This greatly helps the experts in organising their work and in keeping the time.

Only three experts could not join the meeting, while others joined at given times, due to different time zones. Excellent expertise was recruited, fully covering the evaluation needs, and bringing about a fruitful discussion, without conflicts and in a very constructive fashion.

Recommendation 5

The online SRC meeting was a necessary choice. I still think that a face-to-face consensus discussion facilitates interaction and fosters a successful discussion. When circumstances will allow it, I would recommend to resume face-to-face meetings or to organise mixed meetings, in which some participants can join online. However, I must admit that this meeting went particularly well despite the circumstances, and that the discussion was excellent and constructive in all cases.

The SRC was led by a team of three internal Moderators (EDCTP Officers), who were very efficient in steering and leading the discussion of individual proposals. I think that this procedure is excellent. The previous procedure implied leaving the leadership of individual discussions to the Rapporteurs or to an external chair. Such procedure greatly depended on the personal skills of the Rapporteurs/Chairs and was therefore quite variable. In addition, it required the constant monitoring by the EDCTP moderators, to make sure that Rapporteurs/Chairs led the discussion in agreement with the evaluation guidelines and rules. Thus, having an internal Moderators as discussion leader ensured the full compliance with the guidelines. The three Moderators were excellent in steering the discussion, reaching a consensus and keeping as well the time. Having the SRC meeting fully online was not a problem in any way.

Recommendation 6

Maintain institutional Moderators as leaders of the SRC meetings. Such Moderators proved able to organise and steer the discussion very well, to ensure adherence to the rules and guidelines, and at the same time to allow free scientific and technical

discussion to develop until reaching a consensus.

As in the last call, all the evaluators of the same proposal had the role of Confirmers, *i.e.*, all of them contributed to the discussion and later countersigned the CES prepared by the Rapporteur and uploaded in the EDCTPgrants system.

Recommendation 7

Please maintain the current role of confirmers for all the evaluators involved in a proposal. This encourages them to actively participate to the discussion for reaching the consensus. Having all reviewers as confirmers enhances inclusion and involvement, fostering a better discussion and a fully shared consensus.

The Moderators endeavoured to structure the discussion by considering, in sequence, the three evaluation criteria identified in the guidelines. The Moderators asked the Rapporteurs to give a brief summary of the proposal, and then to start commenting along the Excellence criterion and propose a score. Then the Moderators called the confirmers to provide their comments and to discuss towards a consensus score. The Moderators also encouraged the non-involved experts to ask questions or provide comments, but to avoid taking part in the scoring. After having reached a consensus score for the first criterion, the same procedure was applied to the other criteria. In some cases, reaching a consensus took extended discussion to address discrepant opinions. Only in one case it was not possible to reach consensus. For this single proposal, preliminary scores and a draft consensus summary were produced, recording the different opinions. I should underline the fact that, while all rapporteurs did a good job, some of them were truly outstanding, leading the discussion with great capacity and reaching the consensus to everybody's satisfaction.

Recommendation 8

Please maintain and enhance this virtuous evaluation procedure. The well-structured procedure ensures an accurate identification and tackling of all the relevant issues and helps experts to satisfactorily reach consensus. However, I would ask to better clarify a possible contradiction between the procedure and the instructions provided in the initial briefing ("Some thoughts on reaching a consensus"), which seem to recommend to discuss the comments before deciding the score. The current procedure implies the Rapporteur proposing a score as a starting point, and then discuss on the comments to back up or change such score. I think this procedure

works very well and I would not change it.

Recommendation 9

Please give precise instructions to Rapporteurs and Confirmers on how to present the project and their comments. Several Rapporteurs feel compelled to engage in lengthy descriptions, and some Confirmers read aloud their written comments. This happened less frequently than in the past, but still it necessarily reduced the time for an interactive discussion. The Moderators may need to repeat their recommendations at the beginning of every discussion.

The Moderators encouraged Rapporteurs to prepare a concise CES, without including detailed explanations but including a mention to the rebuttal, to let the applicants know that their rebuttal was considered.

Panel Review meeting

The Panel Review meeting took place two weeks after the SRC meeting, again via Zoom. The scope of the meeting was that of ranking the 25 proposals that were scored above threshold. The EDCTP Secretariat had earmarked 5 of these proposals for additional discussion, due to some issues raised/occurring during the SRC meeting. These included the proposal on which consensus was not reached, during the SRC meeting, two proposals that were downgraded on Excellence because of insufficient novelty, one for which the scores of an absent expert were very different from the other scores, and one that required recruiting an additional expert because the Rapporteur did not feel as having sufficient expertise for a fair assessment. Four experts were present, three from the SRC meeting, and one external but with a long experience with EDCTP evaluations. All of them were outstanding. The 25 proposals were preliminarily listed based on the scores received during the SRC meeting and formed the basis for the discussion. The discussion was based on several issues: solving the problems of the five proposals flagged by EDCTP as needing further discussion, making sure that the evaluation criteria had been equally applied to all proposals (consistency), ranking the several proposals with the same total and even individual scores according to additional criteria, and eventually controlling that the comments corresponded well to the final scores. Each project was assigned to one of the experts, who, starting from the highest scoring one, briefly presented them, reviewed the scores and confirmed or re-discussed them. The five flagged cases were discussed within this process, and for all of them a consensus was easily reached. The panel, expertly led by one of the Moderators, then proceeded to ranking the proposals based on the confirmed scores, and applied the additional criteria for ranking proposals with the same score, *i.e.*, diversity of diseases addressed, Excellence score, Impact score, gender balance, presence of African countries and presence of resource-poor African countries. As in other occasions, some discussion arose on the first criterion, *i.e.*, disease coverage, because EDCTP considers NID as one disease category, while experts proposed to consider them as individual diseases, as the term NID defines a large number of diseases that are very different. Indeed, in some cases it was decided to consider individual NID as different diseases.

Recommendation 10

Please consider the possibility of considering NID as distinct diseases that need to be specifically addressed. Addressing them as distinct diseases may contribute to increase dedicated funding.

The summary of the evaluation outcome is provided in the table below. It was noted that many excellent proposals do not fall in the range of the currently available funding.

Call	N. submitted proposals	N. eligible proposals	N. proposals above threshold	N. proposals in the funding range
RIA2020I	57	47 (1 withdrawn)	25	6

As in past occasions, experts underlined the difficulties in discriminating between the Excellence and Impact criteria, and the EDCTP moderators reminded them that these criteria have been set as such in H2020, with Impact having a great value in the programme, and we should find a way for evaluating them as separate issues. Overall, the panel felt that the quality of the proposals has greatly improved with time, but that there is a clear need for additional mentorship, because many excellent ideas are not accompanied by sufficient grantsmanship and end up in unsatisfactory proposals. This was noted in particular for proposals led by African scientists.

Recommendation 11

Explore the possibility of offering measures for improving grantsmanship of African scientists.

2. Conclusions

After my observations during the SRC meeting of November 25-27, 2020, and the Panel Review meeting of December 11, 2020, all held via Zoom online meeting, I can say that the evaluation and ranking procedures were fully in line with those implemented in Horizon 2020, and were aiming at identifying the best proposals in a transparent and impartial fashion.

Despite the limitations imposed by the online meeting, the evaluation procedures were organised and managed by the EDCTP Secretariat in an excellent fashion. The guidance documents are very good, highly informative and easy to read, and the initial briefings were very useful as reminder of the guidelines for evaluation. The internal Moderators were excellent in conducting the sessions and in keeping the discussion focused, efficient and in time.

The selection of independent experts was excellent, and the SRC panel included all the expertise relevant to the specific calls and in parallel keeping a good gender balance and geographical distribution. The Panel Review meeting was outstanding in terms of experts, discussion, and conduction. The ranking list was finalised with a transparent and very well-balanced fashion.

My conclusion is that the scientific evaluations have been carried out in an honest, expert, transparent and unbiased fashion, in agreement with the H2020 guidelines and despite the limitations imposed by the Covid-19 pandemic.

3. Approach taken by the observer

As independent observer, I am expected to provide my opinion on the process implemented for project evaluation, and to assess its fairness, transparency and consistency with best practices, and adherence to the H2020 guidelines. In particular, I had the task to critically assess the way in which experts apply the evaluation criteria and perform the ranking, and to provide suggestions on how the evaluation procedures could be improved.

I received relevant background documents by email prior to the TC meetings and was given access to the EDCTPgrants website, where I could find further documents, the applications and the IERs. However, I decided to refrain from accessing the proposals, in order to keep my observation unbiased by scientific considerations. I attended the SRC meeting for the Calls RIA2020I on November 25-27, 2020, and the subsequent Panel Review meeting for the same call on December 11, 2020. The SRC meeting were opened by the EDCTP Executive Director Michael Makanga. Both meetings were introduced by presentations of the project officer in charge of the Calls, who then acted as the principal Moderator.

Since the meetings were online, I missed an important part of my observation tasks, *i.e.*, I could not exchange views and opinions with the Executive Director Michael Makanga, the Moderators, the EDCTP staff and the independent expert reviewers. Nevertheless, I think that I could observe the process quite in detail.

4. Other remarks

I do not have additional remarks, except praising once again the great effort made by everybody for making these meetings work at best.

5. Summary of recommendations

Recommendation 1

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