

**EDCTP2
INDEPENDENT OBSERVER'S REPORT**

Call IDs: RIA2019PD, RIA2019IR

observed: SRC meetings

Dates of evaluation

26-27 May 2020

28-29 May 2020

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Present at the evaluation: *26-27 May (in TC)*

28-29 May (in TC)

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 Report
IOR	Independent Observer's Report
SRC	Scientific Review Committee

1. Overview

This report covers the evaluation procedure of two Calls¹:

- RIA2019PD: **“Paediatric drug formulations for poverty-related diseases”**
Stage 2 deadline: 16 March 2020, Call budget 18 M€ - 10 applications invited
- RIA2019IR: **“Strategic actions on product-related implementation research”**
Stage 2 deadline: 23 March 2020, Call budget 20 M€ - 16 applications invited

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).

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 reviewers/confirmers 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 meetings held in TC (26-27 and 28-29 May), the experts acted both as consensus groups and as panel groups. During the consensus meetings, the experts discussed the proposals and agreed on scores and comments. The Rapporteurs modified the CES drafts accordingly. During the ensuing panel meetings, the experts produced a ranking list of the proposals, and Rapporteurs finalised the CES to be sent 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 RIA2019PD second stage received 10 applications, which were all eligible and evaluated.

The Call RIA2019IR second stage received 16 applications, which were all eligible and evaluated.

The EDCTP Secretariat checked eligibility, before assigning proposals to reviewers.

Remote evaluation

For the Call RIA2019PD, 11 evaluators were appointed. Four to 5 experts evaluated each proposal remotely.

For the Call RIA2019IR, 14 evaluators were engaged in remote evaluations, and 4-5 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 in the expert panel (female/male ratio was 4/7 for RIA2019PD and 8/6 for RIA2019IR), as well as a good representation of African countries (6 for both RIA2019PD and RIA2019IR).

Recommendation 1

Keep involving the majority of the appointed experts in reading the submitted proposals. Having the entire panel 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 for both topics. 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

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."

suggestions or asking additional information to the applicants. 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. However, I should underline the fact that the applicants do not have the concept clear, and in several instances take advantage of the rebuttal for modifying/re-writing parts of the proposal. Likewise, the reviewers in some case have the same problem, *i.e.*, they consider the rebuttal as an occasion given to the applicants for improving their proposal, and are disappointed if the applicants do not modify the text or add information according to the reviewers' suggestions. Thus, while I think the rebuttal is a useful tool that benefits both the applicants and the evaluators, I still see that its use is not clear, leading to several cases of misuse on both sides. During the SRC meetings, the reviewers were adequately instructed to disregard the changes and the additional information provided in some rebuttals. However, it was obvious that the instructions at the SRC meeting were new to some of the reviewers.

Recommendation 2

An additional effort is necessary for the optimal use of the rebuttal procedure. It looks like the procedure is sufficiently clear to the applicants, although some of them may try to take advantage of it for adding more information in their proposals. However, in particular for the new reviewers, the remote guidelines do not seem sufficiently clear, so that reviewers happen to ask for additional information or proposal implementation. I wonder whether a remote pre-meeting with the new reviewers might succeed in clarifying the issue.

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 consensus meetings. All the other evaluators of the same proposal had the role of Confirmers.

Scientific Review Committee meeting

The independent experts involved in the remote evaluation were invited to attend the SRC meeting in TC, because a face to face meeting was not possible. For each Call, a dedicated

SRC meeting was organised that started with an extensive briefing providing both the general scope of EDCTP2 and the specific aims and guidelines of the Call. A detailed agenda was prepared and, in some cases, a summary table with all the remote individual scores was shown on screen and provided by email.

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 re-check 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.

I witnessed the work of two SRCs, one for each Call.

For the Call RIA2019PD, nine of the 11 experts joined the TC meeting. Two technical advisors from EDCTP were also present, to give advice on some specific issues.

For the Call RIA2019IR, twelve experts attended the entire SRC meeting, while two (from USA) joined only in the afternoon. One technical advisor from EDCTP was also present.

Excellent expertise was recruited in all panels, fully covering the evaluation needs.

Recommendation 5

The SRC meeting in TC was a necessary choice. I think that a face-to-face consensus discussion facilitates interaction and fosters a fruitful discussion. The TC meeting necessarily limits both the interaction and the 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 in TC.

The SRCs were led by an internal Moderator (an EDCTP Officer), who in some instances also led the discussion of individual proposal. I think that this is a very good idea. Leaving the leadership of individual discussions to the Rapporteurs is the procedure adopted for the H2020 evaluation sessions. But such procedure greatly depends on the personal skills of the experts that act as Rapporteurs and is therefore quite uneven if left unchecked. This requires a great effort on the moderator's side for keeping the Rapporteurs on track. The

limited capacity of Rapporteurs to lead the discussion was more evident in the TC meetings, in which the personal contact was missing. Thus, the fact that the internal Moderators took the control of the individual discussions, discussing each criterion separately and calling each confirmer to participate to the discussion, was excellent and worked very well. The internal Moderators could ensure an evaluation procedure fully in line with the official requirements.

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. The institutional Moderators, in this particular circumstance that required a TC meeting, also helped significantly the Rapporteurs in leading the scientific discussion for each individual proposal.

At variance with previous calls, this time all the evaluators of the same proposal had the role of Confirmers, which means that all of them should contribute to the discussion and later countersign the CES prepared by the Rapporteur and uploaded in the EDCTPgrants system.

Recommendation 7

Please maintain the role of confirmers as it is now. For the first time in these calls all the evaluators were confirmers. They have equally contributed to the discussion of the applications they had reviewed, and have actively participated to reaching the consensus. Having all reviewers as confirmers enhanced 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. It should be noted that in several cases the non-involved experts asked important

questions that helped the reviewers to better address relevant issues. After having reached a consensus score for the first criterion, the same procedure was applied to the other criteria. Only in few cases reaching a consensus took extended discussion to address discrepant opinions, but in no case a consensus was not reached satisfactorily, and no minority opinions were recorded.

Recommendation 8

Please give precise instructions to Rapporteurs and Confirmers on how to present the project and their comments. The vast majority of Rapporteurs feel compelled to engage in lengthy descriptions, and many Confirmers read aloud their written comments. This necessarily reduces the time for an interactive discussion. The Moderators may need to repeat their recommendations at every discussion.

Recommendation 9

Please endeavour to 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.

The ranking of proposals took place after the individual consensus discussions were completed and scores given to all proposals. When scores were tentative, the first action was that of going through all the scores of all proposals to confirm them, after re-discussion the cases in which additional thinking was deemed necessary. Ranking implied solving several cases in which proposals had the same total score. The panels, expertly led by the Moderators, 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. Some discussion arose on the first criterion, *i.e.*, disease coverage, because the EDCTP position was to consider NID as one disease category. The panel discussed the fact that the term NID defines a large number of diseases that are very different, and some experts proposed to consider them as individual diseases. Eventually, the EDCTP suggestion was adopted, and proposals with equal scores were ranked by considering NID as one disease category.

Recommendation 10

Please consider the possibility of considering NID as distinct diseases that need to

be specifically addressed. Considering them as distinct diseases may contribute to increase dedicated funding thereby decreasing their neglect.

The ranking exercise was not always easy: in one of the calls too many good proposals were in the list. The panel succeeded in ranking them wisely and accurately, with general agreement and satisfaction, thanks to the expert guidance of the Moderator. One of the issues that raised discussion was that of co-funding, which was required in one of the calls and, in the guidelines for applicants, was indicated as “substantial”. Guidelines were not really precise in defining the required co-funding and in how to quantify the in-kind co-funding. Thus, the panel had to decide how to rank an excellent proposal with negligible co-funding. Experts asked if the lack of co-funding (or to reach a co-funding threshold) could be reason for ineligibility. The Moderator made clear that eligibility is based on a number of basic criteria that can be easily checked by the Secretariat, while the extent and relevance of co-funding should be evaluated by experts case by case and, if required, reflected in the scoring of the Excellence criterion, and also considered under Implementation in terms of the allocation of EDCTP funding and co-funding to the tasks.

The summary of the evaluation outcomes is provided in the table below. It was noted that many excellent proposals do not fall in the range of the currently available funding. The Moderators stressed that additional funding may become available, so that more proposals in the list could receive financial support.

<i>Call</i>	<i>N. submitted proposals</i>	<i>N. eligible proposals</i>	<i>N. experts</i>	<i>N. proposals above threshold</i>	<i>N. proposals invited to grant preparation</i>
RIA2019PD	10	10	11	9	5
RIA2019IR	16	16	14	15	4

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

As in past occasions, several experts underlined the need for a more penetrating advertising and for clearer and easier guidelines, so as to encourage and improve participation, in particular of West African scientists and African female scientists. A possible reason for low application rates might be the feeling of excessive difficulties in terms of procedures and

rate of success.

Recommendation 11

Implement a strong advertising strategy and increase the focus on African female scientists, in particular in Sub-Saharan and francophone countries, whose current participation is still very limited.

2. Conclusions

After my observations during the SRC meetings of May 26-29, 2020, held in TC, 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 TC, 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 Moderators also kept reminding the experts of the evaluation rules, and answered with endless patience to all their questions and doubts on the procedures.

The selection of independent experts was excellent, and the panels included all the expertise relevant to the specific calls and in parallel keeping a good gender balance and geographical distribution. The presence of technical advisors helped in tackling with the required depth some specific issues. The consensus discussions were successful, reaching consensus in all circumstances, and the ranking panels were conducted very expertly and completed without problems.

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. I attended two SRC meetings, for the Calls RIA2019PD and RIA2019IR, during four working days on May 26-29, 2020. These meetings were opened by the EDCTP Executive Director Michael Makanga, and introduced by presentations of the project officers in charge of the Calls. Both meetings were chaired by institutional Moderators.

Since the meetings were in TC, 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.

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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Recommendation 2

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