EDCTP2
INDEPENDENT OBSERVER'S REPORT

Call ID: RIA2019AMR

observed: single stage

Dates of evaluation
3-4 March 2020

Number of pages in this report (title page included): 15

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Present at the evaluation: *3-4 March 2020 (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 one single stage Call[1]:

- RIA2019AMR: **"New drugs and vaccines for priority pathogens in antimicrobial resistance"**

  Call deadline: 07 November 2019, Call budget 18 M€

Prior to the meetings of the Scientific Review Committee (SRC) in Den Haag, the appointed independent expert reviewers carried out an individual evaluation, and submitted an individual evaluation report (IER).

Guidance to the experts on how to do this was given in documents[2] prepared by the EDCTP Secretariat.

Applicants were allowed for a rebuttal, aiming at clarifying specific issues and doubts expressed by the reviewers in their IER.

During the meeting in Den Haag on February 3-4, the SRC acted both as consensus group and as panel group. During the consensus meeting, the SRC discussed the proposals, agreed on scores and comments, and modified and finalised the Consensus Evaluation Summaries (CES) that were drafted in advance by the Rapporteurs, based on both the IER and the applicants' rebuttals. During the following panel meeting, the SRC ranked the proposals above threshold and approved the final ranking list.

This is the sixth time that in EDCTP2 an independent observer has been invited to follow the evaluation activities in a SRC meeting, with the task of assessing the transparency and fairness of the evaluation procedure and its alignment with the H2020 criteria. Due to personal matters and the incumbent SARS-CoV-2 pandemic, the observer attended the meeting remotely by TC.

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[1] See: http://www.edctp.org/call/new-drugs-and-vaccines-for-priority-in-antimicrobial-resistance-2019/

[2] EDCTP2 guidance for expert reviewers, Oct 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 RIA2019AMR was a single stage call. The Call received 7 proposals, which were all eligible and were evaluated. Eligibility was checked by the EDCTP Secretariat according to well-defined eligibility criteria.

Remote evaluation

Fifteen evaluators were appointed for the remote evaluation of the proposals, of whom 12 participated in the SRC meeting: five of the 12 were female, four were African, and three were from industry

Each proposal was evaluated by six experts, among which a Rapporteur and three Confirmers were appointed.

Recommendation 1

In call receiving a low number of proposals, it is desirable that all or the majority of experts read all the submitted proposals. Having the entire panel evaluating each proposal would make consensus and ranking much easier, fully transparent 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.

IERs formulated by the experts were forwarded to the applicants, who were allowed for a rebuttal if information given in the application was misunderstood or misinterpreted by the reviewers. In principle, rebuttals were meant for correcting reviewers' mistakes while proposers are not supposed to add information that was not already present in the proposal's text, in agreement with the H2020 rule that instructs reviewers to evaluate the proposal as they are written[3]. The rebuttal procedure is somehow debatable, since the comments in IERs are personal points of view of the individual experts rather than the consensus opinion and because applicants tend to exploit the occasion for adding information and explanations to their proposal. On the other hand, applicants very much

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[3] EDCTP2 guidance document: *"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."*

appreciate being given the chance of correcting interpretation mistakes of the reviewers, and the reviewers like having their doubts clarified.

Recommendation 2

Please make sure that the rebuttal procedure is used well and in line with the H2020 guidelines implemented in H2020, stating that proposals must be evaluated as they are written. However, since the advantages of rebuttals are evident in enhancing the value of the projects, I would recommend to use this tool when deemed necessary or advantageous, keeping in mind that the goal is funding the best possible proposals.

A Rapporteur and three Confirmers were appointed for each proposal. Based on the relevant IERs and the rebuttal, the Rapporteur prepared a draft of the consensus report that formed the basis of the consensus discussion and of the formal Consensus Evaluation Summary (CES).

<u>Scientific Review Committee meeting</u>

The independent experts involved in the remote evaluation attended the SRC meeting in The Hague. Of the 13 evaluators, 12 attended the SRC meeting, with only one unable to attend for a last-minute urgent commitment. Two of the experts, as well as the Observer, attended the SRC meeting via TC. Two of the experts were at their first experience as evaluators for EDCTP.

Recommendation 3

The face-to-face SRC meetings are excellent, as they allow for a very productive personal interaction and facilitate the discussion and the final consensus. However, because of the many travelling issues or the restrictions imposed by the pandemic emergency, the use of TC and other tools for virtual meetings are welcome. The experience made by the observer in this occasion was very positive.

Recommendation 4

Make an effort to include, in each SRC meeting, a number of female experts and also some younger scientists at their first experience. Their role in the discussion

was always very constructive, and therefore their participation should be encouraged.

A detailed agenda prepared and circulated among participants a week in advance.

Recommendation 5
Maintain the good habit of preparing a precise agenda of the meetings. This greatly helps the reviewers in organising their work and in keeping the time.

The meeting was led by a Moderator (an EDCTP Officer), in place of a scientific Chair. A scientific Chair used to be appointed as leader of SRC meetings in the past, in order to steer expertly the scientific discussion and reach a scientifically sound consensus. However, after some discussion and some successful attempts, it was decided that appointing an institutional Moderator would be more advantageous. The advantage mainly resides in the perfect knowledge of the evaluation procedures, which makes much easier enforcing them during the meetings thereby ensuring the full correctness and transparency of the process. The institutional Moderator, in addition, will not have the possibility of intervening in the scientific discussions since these are out of her/his expertise, again ensuring full transparency. Conversely, the consensus is based on the scientific expertise of the Rapporteur, who will lead the specific discussion pertaining each proposal, and the expertise of the other evaluators, and does not need the presence of a scientific Chair (who could not in any case intervene in the discussion from the scientific point of view, not being one of the evaluators). The positive experience made with internal Moderators in the past was confirmed in this SRC meeting.

Recommendation 6
Maintain an institutional Moderator as leader of SRC meetings. The Moderator's role is that of keeping the discussion on track and ensure that all the rules and procedures are correctly followed, a role that is best covered by an internal officer. The scientific lead of each specific discussion will be taken by the appointed rapporteurs, and the consensus reached with the contribution of all the involved expert evaluators.

As already mentioned, a Rapporteur and three Confirmers were appointed for each

proposal. The Confirmers were called to contribute actively to the consensus discussion during the SRC meeting, and to formally confirm the CES in the EDCTPgrants system. The role of the other experts evaluating the proposal was not well-defined and was not clearly distinguished from that of other experts called to contribute to the discussion.

Recommendation 7
Besides the rapporteur, who will draft and finalise the CES, all other experts that have evaluated a proposal should have the same role as discussants and confirmers. Since confirming the CES is an online procedure that can be done remotely, there is no problem in obtaining it. This would be in line with the evaluation procedure implemented in H2020.

Some of the discussions were not well conducted by the Rapporteur, who acted as one of the experts, rather than as the leader of the evaluation process. The help of the Moderator was important, but overall the flow of the discussion very much depended on the personal attitude of the Rapporteur.

Recommendation 8
Decide who will lead the discussion, whether it will be the Moderator or the Rapporteur. Since Rapporteurs tend to behave just as one of the reviewers that has the additional task of assembling the CES, I would recommend that the Moderator should lead the discussion, structuring it along the sequential and separate examination of the three evaluation criteria (Excellence, Impact, Implementation), and calling one by one all the involved experts to give their comments. After having discussed the first criterion, a consensus score should be agreed before moving to the second criterion and to the third one. All the involved reviewers should participate to the discussion (however restraining from reading aloud their IERs) and agree on the score. The Moderator can call other experts, present at the meeting but not involved in the evaluation, to ask questions or provide information, making however clear that they should not express opinions or suggest scores, since they have not read the full proposals.

During the discussions, some issues came up. Some experts complained about the excessive length of the proposals, but the Moderators made clear that all proposals

complied with the guidelines and were within the allowed number of pages (the problem probably was in the length of the annexes).

Recommendation 9

It could be considered to revise the guidelines for applicants in order to receive proposals that are better structured (avoiding repetitions), clearer in their concept and workplan, and overall more succinct. Long annexes may be nevertheless necessary, in particular for clinical trials.

Another issue regarded the "portfolio", *i.e.*, whether proposals addressing different diseases should be preferred, rather than excellent proposals all on the same disease. In this case, it was made clear that the panel should aim at selecting the best proposals in terms of Excellence, irrespective of the disease they address. An issue that comes out almost every time was how to evaluate the criterion Impact, which experts tend to consider as dependent on Excellence, *i.e.*, a proposal that is not excellent cannot have an excellent impact. However, according to the H2020 rules, the criterion "Impact" should be scored based on the extent by which the proposal addresses the expected impacts listed under the topic. This implies that Impact should be considered in a more theoretical perspective, *i.e.*, the expected impact in the case the proposal reaches its declared objectives. This concept is usually not at all clear to the experts and calls for a special effort from the Moderators for guiding experts in the right direction.

Recommendation 10

Given the objective and persisting difficulties of experts in interpreting the "Impact" criterion correctly (*i.e.*, according to the H2020 indications), the Moderator should give precise indications and guide them in the interpretation every time that they are tempted to evaluate Impact depending on the scientific excellence of the proposal.

As in other occasions, the CES that were finalised after reaching consensus included a number of recommendations from the experts, aiming at improving some aspects of the proposal. While the recommendations to the failing proposals have a clear reason, according to the H2020 rules no recommendations can be given to successful proposals (which should be evaluated and accepted "as written") and winning proposals will enter the Grant Agreement without undergoing a negotiation phase. While not completely in line

with the current EU procedure, the inclusion of recommendations or suggestions in the CES for successful proposals is in my opinion a good thing. There won't be a real negotiation phase before signing the contract, but having a constructive feed-back from experts will certainly contribute to improving the already good proposals. This will help reaching the best value for money and increasing the overall impact of the funded studies. In my opinion, the current position in H2020 (no recommendations, no negotiation) needs a complete revision, as it does not allow for increasing the level and impact of the successful projects.

Recommendation 11
Keep including the experts' recommendations in the CES for successful proposals as well. If they can be seen as non-compulsory suggestions for improvement, this will not be in disagreement with the current H2020 guidelines that do not foresee a negotiation step. On the other hand, providing hints that could help enhancing the chances of success of a project is an important way of increasing the impact and importance of the EDCPT funded studies.

The summary of the evaluation outcomes is provided in the table below.

Call	N. submitted proposals	N. eligible proposals	N. experts	N. proposals above threshold	N. proposals in the funding range	N. proposals in the reserve list
RIA2019AMR	7	7	13	3	3	0

The EDCPTgrants IT tool (different from SEP, the one used in H2020) is user friendly and did not create problems to experts during the remote evaluation and is. A few problems for its use again were evident during the preparation of the consensus reports on site, but these were immediately solved with the help of the EDCTP personnel.

2. Conclusions

Following my observations during the SRC meeting of March 3-4 in Den Haag, I wish to say that the evaluation and ranking procedures were well in line with those implemented in Horizon 2020.

The evaluation procedure was well organised and smoothly managed by the EDCTP Secretariat. The guidance documents are very good, highly informative and easy to read.

The independent experts appointed to the evaluation had all the necessary expertise required for attaining a complete and fair assessment, and were able to deliver an excellent and comprehensive evaluation that included recommendations for further improvement.

From what I have observed, the procedures used for submission, as well as those for evaluation, selection, ranking and award, are consistent with H2020. I have seen only two procedural discrepancies, *i.e.*, the rebuttal and the recommendations in the CES, which are however instrumental to the specific EDCTP goals, and essentially not in contradiction with the H2020 rules.

In conclusion, I think that the scientific evaluations have been carried out in an honest, expert, transparent and unbiased fashion, and that they were in agreement with the H2020 guidelines.

3. Approach taken by the observer

As independent observer, my task was that of expressing my opinion on whether the process followed in the evaluation of Call are, in all material aspects, fair and consistent with best practices. In particular, I was called to critically assess the way in which evaluators apply the evaluation criteria, and how the evaluation procedures could be improved, and to verify that the procedures followed for the submission of proposals and the related evaluation, selection and award procedures are consistent with H2020 guidelines.

I received relevant background documents by email prior to the meetings in Den Haag and was given access to the EDCTPgrants website, where I could find further documents, the applications and the IERs. I attended by TC the SRC meeting for the Call RIA2019AMR during two working days on March 3-4, 2020. The meeting was opened by the EDCTP Strategic Partnerships & Capacity Development Manager Thomas Nyirenda (in TC from South Africa) and introduced with a briefing and then led as Moderators by the Project Officer Michelle Nderu and the Senior Project Officer Montserrat Blázquez Domingo. The EDCTP Executive Director Michael Makanga joined the meeting the second day, and stressed the point that EDCTP aims at funding excellent proposals, and that if more excellent proposals are identified than the available budget it is possible to secure additional funding. The Operations Manager Pauline Beattie was present and very active in the interaction with the experts during the final feed-back session. The EDCTP staff, in particular Andreia Cohelo and Lucien de Corte, were always present and available for helping solving whatever issue may have arisen.

4. Other remarks

There are no additional remarks worth mentioning.

I would just like to thank all the EDCTP staff for their continuous assistance and availability.

5. Summary of recommendations

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