

**EDCTP2
INDEPENDENT OBSERVER'S REPORT**

Call IDs: RIA2018SD, RIA2018SV, RIA2018V

observed: single stage

Dates of evaluation

12-14 February 2019

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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 three single stage Calls¹:

- RIA2018SD: **“Strategic action for overcoming drug resistance in malaria”**
Call deadline: 30 October 2018, Call budget 22 M€ - 3 applications (2 eligible)
- RIA2018SV: **“Strategic action for the comparison, selection and development of malaria vaccine candidates”**
Call deadline: 01 November 2018, Call budget 18 M€ - 2 applications
- RIA2018V: **“Vaccines for diarrhoeal diseases or lower respiratory tract infections”**
Call deadline: 30 October 2018, Call budget 23 M€ - 5 applications

Prior to the meetings of the Scientific Review Committees (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 documents² prepared by the EDCTP Secretariat.

During the meeting in Den Haag from 12 to 14 February, the SRCs acted both as consensus groups and as panel groups. During the consensus meetings, the SRCs 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. During the following panel meetings, the SRCs produced a ranking list of the proposals.

This is the third time that in EDCTP2 an independent observer has been invited to follow an evaluation of a series of SRC meetings, with the task of assessing the procedure pathway along the H2020 criteria.

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

² EDCTP2-Guidance for expert reviewers, Oct 2018 - Version 4.0; and EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, Jan 2019 - Version 4.0; both available at <http://www.edctp.org/funding-opportunities/expert-reviewers/>

2. Key observations for these Calls

Call response

All three calls were single stage calls.

Call RIA2018SD received 3 proposals, 2 of which were eligible and were evaluated.

Call RIA2018SV received 2 proposals, both eligible.

Call RIA2018V received 5 proposals, all eligible.

The EDCTP Secretariat checked eligibility, before proposals were assigned to reviewers.

Remote evaluation

For Call RIA2018SD, six evaluators were appointed, who remotely evaluated both proposals.

For Call RIA2018SV, seven evaluators were engaged in remote evaluations, and all seven examined both proposals. Due to the partially overlapping topic, three evaluators were in common with those of the previous Call.

For Call RIA2018V, nine evaluators were active in remote reviewing, two of which were also involved in evaluations of the previous Call. Given the different topics covered by the proposals received, not all reviewers read all the proposals. Two proposals were evaluated by six reviewers, while the other three proposals were evaluated by seven reviewers.

Recommendation 1

Keep as much as possible the practice of having all or the majority of experts reading 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.

Upon completion of the IERs, these were forwarded (minus the scores) 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. Indeed, the H2020 rule instruct reviewers to evaluate the proposal as they are written, and are not given the chance of asking for additional information or explanation, as indicated in the guidance document³. However, this was not always the case, and some applicants took advantage of the rebuttal for adding missing information. In addition, it should be noted that for the rebuttal procedure applicants receive the IERs written by the individual experts, and that these individual reports do not reflect an agreement reached by experts after discussion. As individual experts have specific expertise, only a consensus report is expected to reflect an overarching opinion that encompasses wide expertise. Thus, individual comments do not reflect the panel opinion and may be misleading for the applicants.

Recommendation 2

Consider seriously the need of sending the remote IERs to applicants to allow for a rebuttal. This is not fully in line with the guidelines implemented in H2020, which never disclose IERs and only send the ESRs at the very end of the evaluation (also in the case of two-stage calls). Proposals in H2020 must be evaluated as they are written, and no comments, modification, explanations are allowed. However, since the advantages of rebuttals are evident in enhancing the value of the projects, I would recommend avoiding to use this tool routinely, but to use it when deemed necessary or advantageous. We should not forget that the goal is that of funding the best possible proposals.

For each application, a rapporteur was appointed, who had access to all the relevant IERs and to the rebuttal. On the basis of these documents, the rapporteur prepared a draft of the consensus report, which would be the basis of the formal Consensus Evaluation Summary (CES) finalised after the consensus meetings. Two confirmers were also appointed to each proposal, who actively contributed to the discussion during the SRC meetings, and confirm the CES in the EDCTPgrants system.

Scientific Review Committee meeting

The independent experts involved in the remote evaluation were invited to attend the SRC meeting in The Hague. For each Call, a dedicated SRC meeting was organised, and a

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."*

detailed agenda prepared.

Recommendation 3

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.

I witnessed the work of three SRCs, one for each Call. For the Call RIA2018SD, six experts were present, all of them involved in the evaluation. One expert was female. For the Call RIA2018SV, seven experts were recruited, of which five attended the SRC meeting, one in TC, and one only performed the first remote evaluation. Of these seven, only one was female. For the Call RIA2018V, nine experts were appointed. Five of them attended the SRC meeting, one joined in TC and three were only remote. Five experts were female.

Recommendation 4

Make an effort for having experts to join in person the SRC meetings, as the face-to-face consensus discussion is key in reaching a comprehensive and well-thought consensus. The participation of female experts is important.

Each meeting was led by a Chair (an expert scientist not involved in the evaluation process) or a Moderator (an EDCTP Officer). From what I have observed, there are pros and cons in both cases. The scientific Chair can lead very expertly the discussion, and highlight important aspects that need attention, but may have difficulties in keeping completely detached from the discussion (thereby somehow limiting the freedom of the reviewers). In addition, the scientific Chair is usually less aware or less interested in enforcing the subtleties of the evaluation rules. Conversely, the institutional Moderator is much more effective in keeping the reviewers adhering to rules, while mostly leaving the scientific discussion in the hands of the experts. Therefore, this is my recommendation.

Recommendation 5

Take a decision on who will lead the SRC meetings. I am personally in favour of an institutional Moderator, because the broadness of vision needed in the discussion can be provided by the expert reviewers, while the capacity of adhering to the regulations can only be ensured by institutional officers. We should not forget that

discussing the merits of proposals is the role of the experts, who should just need some guidance on the sequence of topics and in keeping the time.

The discussion was usually not clearly structured, with the rapporteur giving a general picture of her/his evaluation of the proposal along all criteria, before asking the confirmers and then the other reviewers for their opinion. In the case of experts not attending the SRC, the Rapporteur or the Chair/Moderator read aloud or summarised their comments.

Recommendation 6

Give instructions to the Rapporteur to structure the discussion by examining the proposal for each of the three evaluation criteria (Excellence, Impact, Implementation) separately. After having discussed Excellence and reached a consensus score, the rapporteur could proceed with Impact, and then with Implementation. Discussing the proposal in general, and then trying to score it for the different criteria does not help the reviewers and risks to generate confusion.

During the discussions, it came out several times the issue of how to evaluate the criterion Impact. The Chair and all experts had a tendency to consider Impact as dependent on Excellence, *i.e.*, to consider that a proposal that is not excellent cannot have an excellent impact. While this makes complete sense from a logical point of view, the H2020 rules declare that the criterion "Impact" should be scored according to the extent by which the proposal addresses the expected impacts listed under the topic. This implies that experts should consider impact in a more theoretical perspective, *i.e.*, the expected impact in the case the proposal reaches its declared objectives. This is a bit against logical thinking for a scientist, and indeed the experts tended to disregard the many reminders given by the Moderators. This calls for a particular effort, on the Chair/Moderator's side, for guiding experts in the interpretation of the criterion.

Recommendation 7

Given the objective difficulties of experts in interpreting the "Impact" criterion correctly (*i.e.*, according to the H2020 indications), the Chair/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.

The CES that were finalised after reaching consensus included a number of recommendations from the experts, aiming at improving some aspects of the proposal. These recommendations would form the basis for the negotiation between EDCTP and applicants before signing the contract. This procedure is not really in line with the one applied in H2020, in which the Evaluation Summary Reports and the Consensus Reports do not include any kind of recommendation for improvement, and that does not imply a negotiation before signing the Grant Agreement. However, I do see the importance of giving a constructive feed-back to successful applicants, in view of improving the proposals thereby increasing their value for money, their chances of success and their expected impact.

Recommendation 8

Formulate the recommendations in the CES in a way that could help the applicants in improving their project, but that do not sound as compulsory requirements for signing the contract. Efforts for improving the chances of success and impact of the studies funded by EDCTP are welcome, but applicants must be free in accepting or rejecting recommendations provided in the CES.

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

<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 in the funding range</i>	<i>N. proposals in the reserve list</i>
RIA2018SD	3	2	6	1	1	0
RIA2018SV	2	2	7	1	1	0
RIA2018V	5	5	9	3	2	1

The EDCTP grants IT tool (different from SEP, the one used in H2020) did not create problems to experts during the remote evaluation, and was easily searchable for retrieving documents. A few problems for its use were evident during the preparation of the consensus reports on site, but these were immediately solved with the help of the EDCTP personnel. Despite still being surprised that EDCTP cannot use SEP, the current one does not seem to present particular problems and is more user friendly than SEP, and therefore I do not have particular recommendations in this regard.

Several experts had comments about the way proposals are structured, in particular about their length and the budget presentation/justification. Regarding budget, they often commented that the lack of details made very difficult evaluating its accuracy. Regarding

the proposal layout, they lamented exceedingly lengthy documents that took too much time to read, and a confused structure, without a logical flow, that included many repetitions. The latter is a problem likely due to the H2020 guidelines, since RIA proposals that include clinical studies should upload a clinical template annex (of unlimited length) in addition to the main proposal.

Recommendation 9

Without contradicting the H2020 guidelines, please define the guidelines for applicants in more detail, regarding the budget and the length of the proposal and its annexes. For the proposal structure, try to improve it so as to avoid repetitions.

2. Conclusions

Following my observations during the SRC meetings 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 differences, *i.e.*, the rebuttal and the recommendations in the CES, which are however instrumental to the specific EDCTP goals.

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 processes followed in the evaluation of Calls 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 found further documents, the applications and the IERs. I attended three SRC meetings for the three Calls RIA2018SD, RIA2018SV, and RIA2018V, during three working days on February 13-15, 2019. These meetings were opened by the EDCTP Executive Director Michael Makanga, and introduced by presentations of the project officers in charge of the Calls. The first two meetings were moderated by an appointed scientist, who acted as Chair of the SRCs, while an EDCTP manager moderated the third one.

During the three days of meetings, I had the opportunity to exchange views with the Executive Director Michael Makanga, the Operations Manager Pauline Beattie and the Senior Project Officer Montserrat Blázquez Domingo, in addition to several of the independent expert reviewers, and to ask their opinion on the evaluation process.

4. Other remarks

There are no additional remarks worth mentioning.

Just one logistic request was made by some experts regarding how to reach EDCTP from the hotel in the city centre. The request was that of lodging all experts in the same hotel, so that it would be possible to organise a common transfer to and from EDCTP. The indications given by the EDCTP Secretariat on the use of public transportation were indeed excellent, but did not take into account that trams can be exceedingly crowded in certain periods of the day and therefore not easily accessible by all.

5. Summary of recommendations

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