

**EDCTP2
INDEPENDENT OBSERVER'S REPORT**

Call IDs: RIA2018D, RIA2018CO

observed: second stage

Dates of evaluation

4-5 June 2019

11-12 June 2019

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Present at the evaluation: *4-5 June, 11-12 June*

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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 two-stage Calls¹:

- RIA2018D: **“Diagnostic tools for poverty-related diseases”**
Stage 2 deadline: 21 March 2019, Call budget 18 M€ - 19 applications
- RIA2018CO: **“Advances in product development for effective prevention treatment and management of co-infections and co-morbidities”**
Stage 2 deadline: 28 March 2019, Call budget 14 M€ - 5 applications

Prior to the Scientific Review Consensus (SRC) meetings in Den Haag, the appointed independent expert reviewers carried out an individual evaluation of the applications that were invited to second stage, 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. For each application, a rapporteur and two confirmers were appointed among the independent experts that reviewed the application.

During the SRC meetings in Den Haag (4-5 June and 11-12 June), the experts acted both as consensus groups and as panel groups. During the consensus meetings, the experts discussed the proposals, agreed on scores and comments, and modified the Consensus Evaluation Summaries (CES) that were drafted in advance by the Rapporteurs. During the ensuing panel meetings, the experts produced a ranking list of the proposals, and finalised the CES to be sent to applicants.

This is the fourth 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 and its harmonisation with 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

Both calls were two-stage calls. Stage 1 deadline was 11 October 2018 for RIA2018D and 18 October 2018 for RIA2018CO.

Call RIA2018D received 19 full applications, out of 21 invited to Stage 2.

Call RIA2018CO received 5 full proposals, out of 5 invited to Stage 2.

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

Remote evaluation

For Call RIA2018D, 15 evaluators were appointed. Four experts evaluated each proposal remotely.

For Call RIA2018CO, eight evaluators were engaged in remote evaluations, and 5-8 of them evaluated each proposal.

Recommendation 1

Maintain 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, 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' side. According to H2020 rules³, there is no room for giving suggestions or asking additional information to the applicants, and for allowing applicants to revise their proposals, which should be evaluated as they are written. The rebuttal practice at EDCTP is somehow open to questioning whether it is fully in line with the H2020 guidance, and this observer expressed in the past some doubts in this respect. However, after having heard the opinion of reviewers and EDCTP personnel, it seems that

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."*

the rebuttal can serve a good scope without breaking the H2020 rules. Receiving a request of clarifications and being allowed a rebuttal gives to applicants the feeling that their work is thoroughly considered, while at the same time giving to the reviewers the chance of clarifying some unclear issues thereby avoiding misunderstandings. This goes to the mutual benefit and to the overall transparency and straightforwardness of the evaluation procedure. Only in few cases the applicants took advantage of the rebuttal for adding missing information or modifying their proposal, but the reviewers were adequately instructed to disregard such implementations. 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 will reflect the consolidated and agreed opinion of a multidisciplinary panel. Thus, individual comments do not reflect the panel opinion, and may be misleading for the applicants.

Recommendation 2

Please try to avoid sending the remote IERs to applicants when asking for a rebuttal, as the individual comments may be contradictory, coming from experts with different background. Since the advantages of rebuttals are evident in enhancing the value of the projects (our goal is that of funding the best possible proposals), the procedure should be maintained, but I would recommend sending a summary of the questions and clarifications asked by the various experts, if feasible.

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 a draft of the consensus report. The draft forms the basis for the consensus discussion and for the formal Consensus Evaluation Summary (CES) that will be 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 that

started with an extensive briefing providing both the general scope of EDCTP2 and the specific aims and guidelines of the Call. Hard copies of the briefing were provided to experts, who could find the complete information at any time during the SRC. A detailed agenda was prepared.

Recommendation 3

Maintain the good habit of exhaustively briefing the experts on the scopes and rules of the Call. Providing hard copies is excellent, as the experts can go back and 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 RIA2018D, fifteen experts were involved, of which 12 were present in person and three joined by TC. Five experts were female, three of the 15 experts were from Africa, and an additional four were from outside Europe.

For the Call RIA2018CO, seven experts were present at the meeting, and one could not attend. Four experts were female, three from Africa, and one from outside Europe (excluding Africa). The SRC for RIA2018CO also had a Chairperson, female from Africa.

Excellent expertise was recruited in both panels, fully covering the evaluation needs. Several experts had also evaluated stage 1, while others were new.

Recommendation 5

It is important that all experts join in person the SRC meetings, as the face-to-face consensus discussion is key in reaching a comprehensive and well-balanced consensus. The use of TC for allowing absent experts to take part in the discussion is however an excellent solution for experts that had problems in joining in person. The participation of female experts and experts from Africa is important, therefore the current high standard of balanced panel composition should be maintained.

The SRC for RIA2018D was led by an internal Moderator (an EDCTP Officer), while the SRC for RIA2018CO was led by a Chair (an expert scientist not involved in the evaluation

process). As already commented in the past, 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 detached from the discussion and in refraining from providing her/his expert opinion (thereby somehow limiting the freedom of the reviewers). In addition, the scientific Chair is obviously less aware or less interested in enforcing the subtleties of the evaluation rules. On the other hand, the institutional Moderator is much more effective in keeping the reviewers adhering to guidelines, while mostly leaving the scientific discussion in the hands of the experts. On this basis, and based on the direct observation of the excellent outcome of the RIA2018D SRC (led by an institutional Moderator), this is my recommendation.

Recommendation 6

Consider the option of having an institutional Moderator leading the SRC meetings. The additional expertise of a scientific Chair may not be needed (at least not in all cases), since all the required expertise should be already present in the group. A good institutional Moderator can steer the discussion very well, making sure that the entire consensus meeting discussion adheres to the rules and guidelines, and is performed along the established criteria. The Rapporteurs, within the group, could be asked by the Moderator to lead the specific discussion of individual proposals.

The discussion was very well structured, taking in consideration the three evaluation criteria identified in the guidelines. Thus, the Moderator/Chair asked the Rapporteur to give a brief summary of the proposal, and then to start commenting along the Excellence criterion, involving in this discussion first the Confirmers, then the other experts that evaluated the proposal, and finally asking the experts that did not evaluate the proposal if they had questions or comments. After having reached a consensus score for the first criterion, the same procedure was applied to the Impact and Implementation criteria. The discussion and scoring were completed for all criteria also in cases in which the proposal had failed to reach threshold at the first criterion.

Recommendation 7

Please endeavour to maintain and enhance this virtuous evaluation procedure. The well-structured procedure has greatly helped experts in identifying the important issues on which they should base their scoring, thereby facilitating reaching

consensus.

Several issues came to my attention during the discussions. The previous issue of how to evaluate the criterion “Impact”, which is always problematic in H2020 evaluations, was not felt as a problem here, meaning that the information provided during the briefings and repeated by the Moderators during the discussion was complete and clear. Several experts felt that the proposals were weak and heterogeneous in describing the clinical trials, and that better and more precise guidelines should be provided by EDCTP2. Also, an expert noted that budget requests are often vague and incomplete. Another issue was the length of proposals, with a number of less important documents (e.g., CVs) diluting if not hiding the important parts of the proposal. A difficulty was that for evaluating Excellence, Impact and Implementation (and all their sub-criteria), the experts had to read back and forth through the proposal for finding where the relevant information could be found.

Recommendation 8

Consider revising the guidelines for proposers by giving very precise instructions regarding the design of clinical trials and the budget presentation (for instance with a table).

Recommendation 9

Consider reducing the maximum number of pages allowed for a full proposal, possibly by allocating less conceptual descriptions to annexes.

Recommendation 10

Also consider to provide guidelines asking to structure the proposal along the same criteria and sub-criteria the experts are called to evaluate.

As in the past, 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 EDCTP2 and applicants before signing the contract. This procedure may be considered not fully in line with the one applied in H2020, in which the Evaluation Summary Reports and the Consensus Reports should not include any kind of recommendation for improvement, and

that does not imply a negotiation before signing the Grant Agreement. However, it is really very important giving a constructive feed-back to successful applicants, in view of improving the proposals and increasing their value for money, their chances of success and their expected impact.

Recommendation 11

Formulate the recommendations in the CES as comments and suggestions for improvement, rather than as recommendations that applicant should comply with. This will be in line with the H2020 procedures while giving to EDCTP2 the possibility of discussing the comments with the applicants before contract signature.

The ranking of proposals took place after the individual consensus discussion were completed and tentative scores given to all proposals. Ranking implied solving some cases in which the tentative scores of some proposals were the same. While there are additional criteria that can allow for ranking proposals with the same score, the panels felt that it was possible to revise the scores to clearly highlight the difference between proposals. In this respect, many of the experts asked for the possibility of using decimals instead of half marks in the scoring. One expert was surprised by the fact that scores were adjusted during ranking, but the Moderator clearly explained that the final scores are given during the ranking, based on the tentative scores reached during the individual discussion and on the comparison between proposals.

Recommendation 12

Consider the possibility of using decimals in the scoring, or at least .25 steps. This is a need expressed by countless experts also in H2020. No convincing justification for the use of half marks was ever provided.

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>
RIA2018D	19	19	15	10	7	3
RIA2018CO	5	5	8	5	3	2

The experts found the EDCPTgrants IT tool (different from SEP, the one used in H2020) OK, although not all of them were able to retrieve all the documents they needed. The few problems for its use during the preparation of the consensus reports on site were solved

by the EDCTP personnel.

Recommendation 13

Continue working on the website so as to make it more user-friendly. The foreseen us of a common system with Horizon-Europe would be very much welcome.

A general observation was made by several experts, *i.e.*, that for some calls very few proposals are received, despite the important topic addressed and the significant funding available. This is the case of the call RIA2018CO that only received 5 applications, with an available budget that could cover 4-6 projects. This may be due to an inefficient advertising, together with hesitation in applying in a programme that is considered difficult in terms of procedures and rate of success.

Recommendation 14

Consider implementing a high-impact strategy for advertising and preferred target (African scientists). This may imply a professional communication strategy and information sessions/opportunities for young African scientists.

2. Conclusions

After my observations during the SRC meetings in Den Haag, I can say that the evaluation and ranking procedures were in line with those implemented in Horizon 2020, and were aiming at identifying the best proposals in a transparent and impartial fashion.

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

The selection of independent experts was excellent, and the panels included all the expertise relevant to the specific call while succeeding in keeping a good gender balance and a satisfactory geographical distribution. The consensus evaluations were excellent and comprehensive, and included comments and suggestions that would help the successful applicants to further improve their projects.

From what I have observed, the procedures used for submission, evaluation, selection, ranking and award are consistent with H2020. The two procedural differences that I had previously noted, *i.e.*, the rebuttal and the recommendations in the CES, are nevertheless not in contrast with the H2020 rules and are in any case 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

My task as independent observer is providing my opinion on the process implemented for project evaluation, with particular regard to fairness, transparency and consistency with best practices, and adherence to the H2020 guidelines. In particular, I was called 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 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 two SRC meetings for the Calls RIA2018D and RIA2018CO, during four working days on June 4-5 and 11-12, 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 meeting was chaired by an institutional Moderator (Pauline Beattie), while the second one was led by an appointed scientist, who acted as Chair of the SRC.

During the four meeting days, I had the opportunity to exchange views with the Executive Director Michael Makanga, the Operations Manager Pauline Beattie and the Project Officers Daniel Weibel and Johanna Roth, in addition to the many independent expert reviewers, and to ask their opinion on the evaluation process.

4. Other remarks

The small logistic issue noted in a previous occasion was still mentioned by several experts in this occasion, *i.e.*, the possibility of organising a common transfer from the hotel to EDCTP. Not all experts could easily use public transportation (as suggested by the EDCTP Secretariat) and, if lodging in the same hotel, it would be good having a common transfer to and from EDCTP. Apart from this, all the logistic information was provided to experts with plenty of useful details.

There is nothing else worth mentioning.

5. Summary of recommendations

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