EDCTP2
INDEPENDENT OBSERVER'S REPORT

Call IDs: RIA2019S, CSA2019ERC, TMA2019CDF

observed: SRC meetings

Dates of evaluation
10-11 February 2020
13-14 February 2020
17-19 February 2020

Number of pages in this report (title page included): 16

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Present at the evaluation: *10-11 February, 13-14 February, 17-19 February (in TC)*

Signature and date

20/02/2020

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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 Calls[1]:

- RIA2019S: **"Strategic actions supporting large-scale clinical trials"**
  Deadline: 7 November 2019, Call budget 20 M€ - 6 eligible applications (1 ineligible)
- CSA2019ERC: **"Ethics and regulatory capacity"**
  Deadline: 21 November 2019, Call budget 3 M€ - 18 eligible applications (5 ineligible)
- TMA2019CDF: **"Career development fellowships"**
- Deadline: 27 November 2019, Call budget 3.25 M€ - 68 eligible applications (25 ineligible)

Prior to the Scientific Review Consensus (SRC) meetings in Den Haag, 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 documents[2] prepared by the EDCTP Secretariat. For each application, a rapporteur and two confirmers were appointed among the independent experts that reviewed the application. 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 in Den Haag (10-11, 13-14 and 17-19 February), 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 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 fifth 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.

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[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 RIA2019S received 7 applications, 6 of which were eligible and evaluated.

The Call CSA2019ERC received 23 applications, 18 of which were eligible and evaluated.

The Call TMA2019CDF received 93 applications, 68 of which were eligible and evaluated.

The EDCTP Secretariat checked eligibility, before assigning proposals to reviewers. The eligibility of the proposals considered ineligible was re-checked together with the experts in the case of the calls RIA2019S and TMA2019CDF.

Remote evaluation

For the Call RIA2019S, 9 evaluators were appointed. Five to 8 experts evaluated each proposal remotely.

For the Call CSA2019ERC, 10 evaluators were engaged in remote evaluations, and 4-5 of them evaluated each proposal.

For the Call TMA2019CDF, 24 evaluators were appointed. Each proposal was assessed by 4 experts.

Several experts were at their first experience as EDCTP evaluators.

Recommendation 1
Maintain 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.

In the case of the call RIA2019S, 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. The rebuttal step was not applied to the calls CSA2019ERC and TMA2019CDF. According to H2020 rules[3], there is no room for giving suggestions or asking additional information to the applicants, and for allowing applicants to

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[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."*

revise their proposals, which should be evaluated as they are written. The rebuttal practice at EDCTP may not look as being fully in line with the H2020 guidance. However, when correctly used by applicants and reviewers, the rebuttal allows for improving the clarity of the proposal description, thereby avoiding possible misunderstandings and improving the accuracy of the evaluation. This would go to the mutual benefit and to the overall transparency and straightforwardness of the evaluation procedure. However, in some cases the applicants took advantage of the rebuttal for adding missing information or modifying their proposal. The reviewers were adequately instructed to disregard such implementations.

Recommendation 2
Although the rebuttals have advantages in enhancing the value of the projects (our goal is that of funding the best possible proposals), the procedure looks not fully in line with the H2020 guidelines that indicate that proposals should be evaluated as written. It may be maintained, when appropriate, making however clear that this is not a way for the applicants to modify their proposal. I would recommend, for the future Programmes, to re-establish a negotiation step, which would allow applicants to follow the reviewers' suggestions to improve their proposals. Eventually, this would lead to obtain the best value for money.

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. 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.

Recommendation 3
The role of confirmers is not clear. If five experts evaluate a given proposal, the appointed Rapporteur would be in charge of leading the discussion and seeking consensus, while all the other evaluators should equally contribute to the discussion and agree on scores, and later confirm the CES in the system. There is no point in excluding some evaluators from the active discussion and approval of consensus scores.

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 and, in several case, a summary table with all the remote individual scores was showed on screen.

Recommendation 4
Maintain the good habit of exhaustively briefing the experts on the scopes and rules of the Call. Providing hard copies and on-screen summaries is excellent, as the experts can re-check details at any moment.

Recommendation 5
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 three SRCs, one for each Call.
For the Call RIA2019S, nine experts were involved, of which 6 were present in person and three joined by TC. Three experts were female, two were from Africa, and an additional two were from outside Europe (plus one from UK).
For the Call CSA2019ERC, nine experts were present at the meeting, while one could not attend. Four experts were female, five from Africa, and one from USA.
For the Call TMA2019CDF, 24 experts were recruited (22 present at the meeting and one participating online). Fourteen experts were female, 8 from Africa, and 2 from outside Europe (excluding Africa, but including UK).
Excellent expertise was recruited in all panels, fully covering the evaluation needs.

Recommendation 6
I would stress again the importance of having all experts joining in person the SRC meetings. With a face-to-face consensus discussion is possible to reach a very

comprehensive and well-balanced consensus. The use of TC for allowing absent experts to take part in the discussion is a good solution when attendance in person is not possible. The participation of female experts and experts from Africa is important, therefore the current high standard of balanced panel composition should be maintained. I would recommend to maintain face-to-face SRC meetings also in the case of calls with many applications, such as the TMA call.

The SRCs were led by an internal Moderator (an EDCTP Officer), whereas no Chair persons (expert scientists not involved in the evaluation process) were appointed in this evaluation round. This follows one of my past recommendations, which underlined the advantages of having internal Moderators leading the SRCs. By exploiting their knowledge of the procedures and guidelines, internal Moderators could ensure an evaluation procedure fully in line with the official requirements. In addition, the fact that the internal Moderators are not expert scientists in the specific areas covered by the Calls ensures they will never be tempted to intervene or provide opinions in the scientific discussion, and leave the expert evaluators, led by the Rapporteur, entirely responsible for the evaluation, as expected. After a first experience in the past and after the present SRC meetings, I would make the following recommendation.

Recommendation 7
Keep institutional Moderators leading the SRC meetings. Such Moderators proved able to 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, called by the Moderator, expertly led the scientific discussion for each individual proposal, without the need for additional scientific inputs.

The discussion was very well structured, taking in consideration the three evaluation criteria identified in the guidelines. Thus, the Moderator 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 8

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

One issue that has been noted is that during such discussions some experts not directly involved in the evaluation were not only asking questions and clarifications, but also gave opinions and suggested scores. This should be discouraged, and only the experts that have evaluated a proposal should be allowed scoring. If the Rapporteur does not spot the problem (as it usually is the case), the Moderator should gently remind the misbehaving experts of the limits of their role.

Recommendation 9

Please make sure that the experts are made fully aware that their active participation in the scoring discussion is limited to the proposals they have evaluated. They are free and actually welcome to ask questions and provide relevant information, but should not intervene in the scoring of other proposals.

An additional issue may be worth mentioning. Several reviewers recommended to revise the guidelines to better define criteria and aims, as it was common for the applicants to misunderstand the call indications. One of the issues was the general area (in the case of the call TMA2019CDF), *i.e.*, the possible inclusion of basic scientific studies with only a far relation to clinical developments. Another issue was the interpretation of co-funding (for the RIA2019S call) that was variable among applicants and also among experts. A more focused description with clear rules may help both applicants and reviewers.

Recommendation 10

Consider revising the guidelines for proposers by giving more precise instructions to better guide applicants in preparing an eligible proposal.

The expert reviewers were surprised to know that they could not make recommendations

for improvement to successful applicants, according to the H2020 guidelines. All agree that recommendations may help improving the quality and impact of the projects, thereby obtaining higher chances of success and the best value for money.

Recommendation 11

Recommend to the EU Commission to revise the rules that do not foresee recommendation and negotiation for successful projects, so that these procedures could be activated in the next Framework Programme Horizon Europe.

The ranking of proposals took place after the individual consensus discussions were completed and tentative scores given to all proposals. Ranking implied solving some cases in which the scores of some proposals were the same. The panels did not feel like adjusting the initial scores, in order to reach a clear-cut ranking, but applied the additional criteria for ranking proposals with the same score, *i.e.*, diversity of diseases addressed, gender and country (privileging female applicants and countries with more limited resources). Ranking was always easily reached, with a complete agreement within the panel.

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
RIA2019S	7	6	9	3	1
CSA2019ERC	23	18	10	8	7
TMA2019CDF	93	68	24	38	22

The experts did not find particular problems in using the EDCTPgrants IT tool (different from SEP, the one used in H2020). The few problems for its use during the preparation of the consensus reports on site were solved by the EDCTP personnel.

Recommendation 12

Take action towards implementing the use of a common IT tool with Horizon-Europe.

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 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 13

Consider strengthening the 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 in Den Haag, I have ascertained 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.

The evaluation procedures were well organised and managed by the EDCTP Secretariat. The guidance documents are very good, highly informative and easy to read, and the initial briefing very useful. The internal Moderators were excellent in conducting the sessions and in keeping the discussion focused and efficient.

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 consensus evaluations were excellent and exhaustive, and the ranking panels smooth and precise.

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 three SRC meetings, two in person and one from remote, for the Calls RIA2019S, CSA2019ERC and TMA2019CDF, during seven working days on February 10-11, 13-14 and 17-19, 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. All three meetings were chaired by institutional Moderators.

During the meetings I have attended in person, I had the opportunity to exchange views with the Executive Director Michael Makanga, with all the moderators and many of the institutional staff, in addition to several independent expert reviewers.

4. Other remarks

It is worth mentioning that experts were offered lodging in a good hotel much closer to the EDCTP premises than the usual hotels downtown. This followed the complaints of some experts regarding the distance between hotel and meeting place and the problems in using public transportation (quite crowded in the morning). Despite the offer for a much more convenient hotel location, however, the totality of experts still opted for the downtown location, suggesting that the distance between hotel and meeting place was not a real issue.

5. Summary of recommendations

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