EDCTP2 INDEPENDENT OBSERVER'S REPORT

EDCTP

European & Developing Countries
Clinical Trials Partnership

CALL IDs

RIA2017NCT - 'Targeting control and elimination of NIDs through clinical trials'
Call deadline: 31 October 2017

RIA2017NIM - 'Targeting control and elimination of NIDs through product-focused implementation research'
Call deadline: 2 November 2017

CSA2017ERC - 'Ethics and regulatory capacities'
Call deadline: 21 November 2017

Single Stage Evaluation

Date of Evaluation 14 - 16 February and 20 - 21 February 2018

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Present at the evaluation: 14 - 15 February 2018

Number of pages in this report (title page included): 8

Date and Signature

27 February 2018

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Abbreviations

EDCTP2 - European & Developing Countries Clinical Trials Partnership

H2020 - Horizon 2020 Programme for Research and Innovation

IER - Independent Evaluation Report

IOR - Independent Observer Report

SRC - Scientific Review Committee

The practical evaluation steps are summarized on page 5 "Outline of the evaluation procedure", explaining amongst others the tasks of the chair respectively moderator, the rapporteur and the confirmers in some detail.

1.   Executive Summary

- **Overview**

This report covers the evaluation procedure of **three single stage** Calls[1]

- **RIA2017NCT -** 'Targeting control and elimination of NIDs through clinical trials'
  Call deadline: 31 October 2017 - 6 applications

- **RIA2017NIM -** 'Targeting control and elimination of NIDs through product-focused implementation research'
  Call deadline: 2 November 2017 - 6 applications

- **CSA2017ERC -** 'Ethics and regulatory capacities'
  Call deadline: 21 November 2017 - 19 applications

Prior to the meetings of Scientific Review Committees (SRCs) in Den Haag individual evaluations had been carried out remotely at the independent expert reviewers home or place of work involving the completion of an individual evaluation report (IER). Guidance for the experts on how to do this was given in documents, prepared by the EDCTP Secretariat[2].

During the meeting in Den Haag from 14 February until 16 February the SRCs acted **first as consensus groups**. The proposals were discussed, agreement on scores and comments was reached and the Consensus Evaluation Summaries, which had been drafted by the rapporteurs in advance, were updated and finalized.

In a second step the SRCs acted as panel groups: a ranking list was produced for each of the Calls. This means, that in case of identical scores a ranking according to the rules had to be established. These rules together with an outline of the whole range of activities of a SRC was provided by the EDCTP Secretariat in another document[3].

The updated consensus reports were signed by the rapporteur and two confirmers, the final ranked list of proposals, established in the panel groups, by the Chair (RIA2017NCT), respectively the two co-Chairs (RIA2017NIM). CSA2017ERC has been discussed and finalized at a later time.

This is the second time, that in EDCTP2 an independent observer had been invited to follow an evaluation and selection procedure; a comparison with the report of 2017 and its recommendations will follow below.

For further details concerning the foundation of EDCTP and its relation to the Commission, please have a look to the independent observer report, which has been published in 2017[4].

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[1] For details see: http://www.edctp.org/funding-opportunities/calls/

[2] EDCTP2 - Guidance for expert reviewers, July 2017 - Version 2.0 **and** for SRC members: EDCTPgrants - Guide for review rapporteurs and confirmers

[3] EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, Oct 2017 - Version 3.0, provided via EDCTPgrants

[4] See http://www.edctp.org/web/app/uploads/2017/08/Independent_Observer_Report_June_2017.pdf

- **Conclusion**

As in the first report, as a result of my observations I state that in the Calls mentioned, **the evaluation and selection procedures were fully in line with those of Horizon 2020** as requested.

The evaluation procedure was well structured and managed by the EDCTP Secretariat. The relevant expertise, diversity and quality of work produced by evaluators appointed by the secretariat were found to be very good.

The high standard of expertise of the evaluators and the professionalism and dedication of EDCT staff ensured an **impartial and fair review process**.

My conclusion is, that the scientific evaluations have been carried out in a just, transparent and unbiased manner. The ranked lists of applications selected for funding **have been produced according to the Regulation (EU) No 1290/2013**, as requested in DECISION No 556/2014/EU.

2. Introduction and approach taken by the observer

As independent observer, I received relevant background documents by email prior to the meetings in Den Haag and was given access to the web portal EDCTPgrants, where further documents and the applications together with the IERs were supplied.

I attended meetings of 2 of the 3 Calls (RIA2017NCT and RIA2017NIM) during 2 working days in the time 14 to 15 February. These meetings were opened by the Executive Director Michael Makanga and followed by presentations of project officers, responsible for the respective Calls. The meetings then were moderated by appointed scientists, who acted as Chairs of the SRCs.

In addition, I had the opportunity to exchange views with the executive director Michael Makanga, the Operations Manager Pauline Beattie and the Project Officer Michelle Helinski as well as with some of the independent expert reviewers.

The basics of my task have been laid down in my contract:

> "The expert in forming his/her opinion must critically assess the way in which evaluators apply the evaluation criteria, and how the evaluation procedures could be improved. The expert must verify that the procedures followed for the submission of proposals and the related evaluation, selection and award procedures are consistent with H2020 guidelines."

3. Observations of the process

Outline of the evaluation procedure

As preparation for their work the independent expert reviewers received the document
(1) EDCTP2 - Guidance for expert reviewers; July 2017 - Version 2.0
Those who were invited to act as rapporteur or confirmer received in addition
(2) EDCTPgrants - Guide for review rapporteurs and confirmers
and finally
(3) EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, Oct 2017 - Version 3.0

Since the basics of the evaluation didn't change, I can be short. But I want to emphasize again, that these documents are excellently written, concise, easy to read.

Each application was evaluated by 6, in one case by 7 independent experts (RIA2017NCT and RIA2017NIM). The reviews were finished prior to the meetings of the SRCs, the deadlines were met. These IERs were made available to the respective lead applicant, who had the opportunity to respond to them with a "rebuttal".

For each application, a rapporteur was appointed in advance, who had access to the IERs and a bit later the rebuttal as well. On the basis of these documents a draft consensus report was prepared and ready prior to the consensus meetings.

The appointed independent experts were invited to the SRC meetings. For each proposal three of them were asked to act as one rapporteur and two as so-called confirmers, respectively. They all discussed the draft Consensus Evaluation Summary, modified it, when considered necessary, finalized it and the rapporteur and the confirmers signed it after consensus had been found. The discussion was moderated by a scientist as appointed Chair of the SRC, who acted as moderator and was assisted by EDCTP2 project officers.

The final versions of the Consensus evaluation summaries then were submitted by the rapporteurs into the EDCTPgrants IT-tool and signed by the respective confirmers. The final ranked lists were signed by the chair (RIA2017NCT) respectively by the two co-chairs (RIA2017NIM).

Follow up of the first observation (June 2017)

Having been invited a second time to act as independent observer, I had the opportunity to compare my recommendations of last year with my observations of this year. **I will shortly comment the 4 recommendations of my last report and then add another one, which I will refer to as recommendation 5.**

–   *Recommendation 1: EDCTPgrants IT-tool*

As stated in my IOR of last year, I want to confirm, that the EDCTPgrants IT-tool is fully operational. It has the advantage, that all relevant information for an application is summarized in one document. It further on has the advantage, that it is easy to handle for the expert reviewers. But some preparatory work for the documents to be displayed in the system needs additional, manual work by EDCTP staff. In comparison to this in SEP, the "Submission and Evaluation of Proposals support system" of H2020 most of the processes are provided by the programme as automatic routines, whenever I have to admit, that SEP is quite a complex tool, which needs time to get accustomed to it.

My basic concerns, which I have articulated in the report of last year however have not changed.

Since I understand, that an immediate adjustment or alteration would need a greater effort and could only be done with the support of the Commission services I just list this recommendation under the summary of recommendations as a reminder.

–   *Recommendation 2: Rebuttals*

Rebuttals are an opportunity for applicants to respond to IERs (Independent eval-

uation Reports) prior to the final discussion in a SRC (Scientific Review Committee).

I needed some time to realize the importance of this simple fact. In my personal opinion, the expert reviewer - who is well informed about this and who knows that the IER will be provided to the applicant in an anonymized form - will take great care in writing comments and justifying his or her score, since there will be a critical reader - the applicant. Of course, I don't have a proof, but I am convinced of this.

There may be another aspect, which I consider a more psychological one: The opportunity to respond to an IER offers the applicant an active role in this process too.

This for the "pros". In case of H2020 however, there is a strong "con".

With the exception of correcting factual errors or misunderstandings in the IER[5], it is not allowed to use further information of the rebuttal, since according to the rules, the application has to be evaluated "as is". In the "Guidance for expert reviewer" it is stated accordingly:

> "As a reviewer, you are required to score the proposal **as it was submitted**, rather than on its potential if certain changes were to be made. If you identify any significant shortcomings, please reflect this by awarding a lower score for the criterion concerned and by providing an explanation in the comments box."

Now, and I understand this quite well, the lead applicant, having had the opportunity to read the IERs, gives, as a rule, additional, new or more information.

Occasionally in the discussions this had to sorted out: Factual errors or misunderstandings had to be taken into account, further elaborations, extensions or changes, which could enhance the potential of the proposal had to be ignored.

As the result of my observations and of a number of discussions I had in the meantime, I now have a much more positive appreciation of rebuttals. **Under the given circumstances however (present H2020 rules), in the end I will stay with my Recommendation 2 of the IOR of last year.**

– *Recommendation 3: Layout*

This recommendation already has been implemented in two of the three Calls. In the third Call this was partially the case and I recommend to continue until full implementation in near future.

In the third Call, there came up another small problem also related to the layout. In this Call three applications were ineligible. The EDCTPgrants IT-tool doesn't allow to list ineligible applications as part of the project list (comprising of 16 proposals as opposed to 19 applications). Expert reviewers nevertheless have to

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[5] In the "Guidance for expert reviewers" it is stated accordingly: "*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.*"

have access to them in order to verify the ineligibility. As a workaround, therefore the ineligible proposals have been listed under the general "Meeting documents". I think, this should be changed.

– *Recommendation 4 - unique Call identifier:*

This recommendation already has been implemented in the second half of 2017 (see 4. Summary of Recommendations).

New observation concerning the Moderation of the SRC Meetings

As in the Calls of last year the SRC meetings were chaired by scientists. In the Guidance for SRC members[6] it is stated: "The SRC meeting is led by the SRC Chair (one of the SRC members selected by the EDCTP Secretariat) and moderated by the PO" (Project Officer).

The Chair is in charge and the PO moderates. But what does this mean exactly?

What I have observed is, that the Chair acts as a moderator, when the SRC convenes as a consensus group and that he or she is supported by the PO, whenever necessary. This is in line with the Grants Manual[7]

 "The group has an impartial 'moderator' (normally a Commission/Agency staff member), who: seeks a consensus and that proposals are evaluated fairly, in line with the criteria."

My proposal therefore would be choosing the following formulation: "The SRC meeting is led by the SRC Chair who moderates the meeting, when convening as Consensus Group and is supported by EDCTP staff".

But I would even go a step further: At present the Chair is a scientist, who has been active as expert reviewer and/or rapporteur or confirmer. Now he/she is asked to act as moderator. **This double role, can be objectively difficult**. Of course, it can be done successfully, as I had the opportunity to observe, but it is particularly demanding and the chair might either prefer to act as a rapporteur or confirmer.

As a general rule, I therefore would propose either

(1) to select as moderator a scientist who has not been involved as an expert reviewer in the Call under discussion or

(2) to select as moderator an EDCTP staff member.

And I would apply this to the moderation of the SRC too, when it convenes as a panel meeting.

New recommendation: I **recommend** to redefine the role of the Chair of the SRC as a moderator, when the SRC acts as Consensus group. When the Chair

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[6] EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, Oct 2017 - Version 3.0

[7] Grants Manual - Section on: Proposal submission and evaluation (sections III.5, III.6, IV.1, IV.2) Version 1.4 28 May 2015

is a scientist, he or she should not have been involved in the Call under discussion as expert reviewer and/or rapporteur or confirmer. Preferably the moderator should be an EDCTP staff member.

4.   Summary of Recommendations

(Repetition) Recommendation/Consideration/Reminder 1 - EDCTgrants IT-tool:

Reopen the discussion between EDCTP2 and the Commission when there is an opportunity to assess existing IT-tools for evaluation and selection in order to find a way respectively consider to get access to SEP - the "Submission and Evaluation of Proposals support system", which is used in Horizon 2020 to evaluate and select proposals.

(Repetition) Recommendation 2 - rebuttals:

Since applications under Horizon 2020 rules have to be evaluated "as is" and shortcomings have to be reflected in the score, the value of the rebuttals, offered under EDCTP2, is of limited value, whenever I appreciate the opportunity to correct possible factual errors or misunderstandings that may have been made by the expert reviewers. Under Horizon 2020 rules in particular I recommend not to provide the opportunity of rebuttals.

(Repetition) Recommendation 3 - standardization:

I recommend to standardize the design of the general documents as part of EDCTPgrants ("Meeting Documents"), the designation and description of these documents as well as their layout, when opened. With the latter I only want to say, that the corresponding Call Identifier should immediately be visible, for example in the Call text.

This basically has been implemented. There is still a minor point, described in the main text.

(Repetition) Recommendation 4 - unique Call identifier:

Emphasis should be given to a unique Call Identifier to be used consequently throughout all publications, including those to be found on the EDCTP2 website http://www.edctp.org/funding-opportunities/calls/

This has been implemented.

(New) Recommendation 5 - moderation of the SRC meetings:

I recommend to redefine the role of the Chair of the SRC as a moderator, when the SRC acts as Consensus group. When the Chair is a scientist, he or she should not have been involved in the Call under discussion as expert reviewer and/or rapporteur or confirmer. Preferably the moderator should be an EDCTP staff member.