



EDCTP

European & Developing Countries
Clinical Trials Partnership

EDCTP2 INDEPENDENT OBSERVER'S REPORT

CALL IDs

RIA2016S - 'Strategic actions supporting large-scale clinical trials',
Call deadline: 16 March 2017

RIA2016MC - 'Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents'
Call deadline: 2 March 2017

RIA2016V - 'Vaccines for poverty-related diseases'
Call deadline: 16 March 2017

CSA2016S - 'Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives'
Call deadline: 2 March 2017

Stage 2 Evaluation

Date of Evaluation 29 May - 1 June and 6 - 9 June 2017

**Hans Lehmann, former Head of NCP Life Sciences,
Germany**

Present at the evaluation: 30 May - 1 June 2017

Number of pages in this report (title page included): 9

Date and Signature

11 June 2017

A handwritten signature in blue ink that reads "Hans Lehmann". The signature is written in a cursive style with a blue ink color.

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Abbreviations

EDCTP2 - European & Developing Countries Clinical Trials Partnership

H2020 - Horizon 2020 Programme for Research and Innovation

IER - Independent Evaluation Report

SRC - Scientific Review Committee

1. Executive Summary

- **Overview**

This report covers the evaluation procedure of the second stage of four two stage Calls¹

- **CSA2016S** - 'Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives'
Call deadline for stage 2: 2 March 2017 - 10 stage 2 applications
- **RIA2016MC** - 'Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents'
Call deadline for stage 2: 2 March 2017 - 10 stage 2 applications
- **RIA2016S** - 'Strategic actions supporting large-scale clinical trials',
Call deadline for stage 2: 16 March 2017 - 8 stage 2 applications
- **RIA2016V** - 'Vaccines for poverty-related diseases'
Call deadline for stage 2: 16 March 2017 - 15 stage 2 applications

Prior to four 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 EDCPT secretariat².

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 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 document³.

¹ For details see: <http://www.edctp.org/funding-opportunities/calls/>

² EDCTP2 - Guidance for expert reviewers, October 2016 - Version 1.0 and EDCTPgrants - Guide for review rapporteurs and confirmers

³ EDCTP2 - Guidance for Expert Reviewers attending Scientific Review Committee Meetings, April 2017 - Version 1.0, provided via EDCTPgrants

Since this is the first time, that in EDCTP2 an independent observer has been invited to follow an evaluation and selection procedure, the legal basis of this procedure is specified in short.

The second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) has been established by DECISION No 556/2014/EU. In this decision it is defined under article 6 - Rules for participation and dissemination - that "Regulation (EU) No 1290/2013 shall apply to indirect actions selected and funded by the EDCTP2-IS".

The regulation 1290/2013 had been adopted for the Horizon 2020 Programme for Research and Innovation.

The EDCTP Association is the dedicated implementation structure (IS) for the second EDCTP programme (EDCTP2; 2014-2024). It was established under Dutch law.

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. I can say this, since I know these procedures having been observed in Horizon 2020 in "health" related programmes before.

- **Key observation for the Calls**
EDCTPgrants IT-tool

EDCTPgrants is the central supporting instrument for the evaluation of applications, i.e. it gives remote access to the applications, allocated to the independent expert reviewers and it provides a template for the writing of individual evaluation reports (IERs). I had an opportunity to get a demonstration of the system and the operational performance was clearly confirmed too by the evaluators I spoke with.

The access to the "review documents" is organized per Call, for example: RIA2016MC Consensus Evaluation. Here a list of general "Meeting Documents" and the full list of "Applications" are supplied. All documents are available in pdf-format.

Each application is provided together with supporting documents. The individual evaluation reports, in short "Reviews", are attached to the applications as extensions together with a rebuttal of the "Lead Applicant" if provided, again in pdf-format.

Once the consensus evaluation summary has been finalized, a new set of "review documents" is created. In the already given example: RIA2016MC Consensus Confirmation.

This is fully operational and has the advantage, that all relevant information for an application is summarized in one document. However, the disadvantage is, that this is redundant, results have to be downloaded consecutively and overviews (for example scores of the different reviewers of one application) have to be generated in an extra process.

However, the most striking observation is, that there already exists a well established IT-tool, with a broader functionality that has been developed by the Commission for the management of H2020 applications. This is SEP - the "Submission and Evaluation of Proposals support system". It provides a monitoring of the evaluation process and lists - just to give one example - the allocation of evaluators to an

application together with their scores and IERs as a "task list", subject to the condition that reading access has been given, as in case of independent observers.

Upon request I have been told, that the use of SEP had been denied to EDCTP2. Without knowing the background of this decision, I simply want to state, that this is incomprehensible for me. Instead of making use of SEP, EDCTP2 had to develop its own tool at its own cost.

My recommendation therefore is:

Recommendation 1:

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.

• **Conclusion**

The evaluation procedure I have observed 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 3 of the 4 Calls (RIA2016S, RIA2016MC, CSA2016S) during 3 working days in the time 30 May to 1 June. 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 director of north-north cooperation Ole F. Olesen, the operations manager Pauline Beattie, several project officers and a number of 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; October 2016 - Version 1.0

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, April 2017 - Version 1.0

These are excellently written documents, concise, easy to read. The first document is fully in line with corresponding documents, which are used by Commission services for the preparation of independent expert reviewers. The second one gives guidance for the usage of the IT-tool EDCTPgrants and the third one corresponds to documents, used in Horizon 2020 for the preparation of consensus and panel meetings.

Each application was evaluated by 4 to 9 independent experts. The reviews had to be 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 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 conformers signed it after consensus had been found. The discussion was moderated by a scientist as appointed chair of the SRC, who was assisted by EDCTP2 project officers.

This is a well structured and managed process. Since the IERs of all independent experts could be taken into account by the rapporteur, when writing the draft Consensus Evaluation Summary, this compensates well, in case an evaluator could not participate in the SRC meeting in The Hague. The CR then was signed by the three expert reviewers, acting as rapporteur and confirmers.

I fully endorse this procedure. There is only one point, where I recommend a change. This concerns the rebuttal. My critical remark is related to the new Horizon 2020 rule, that applications have 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."

The expert reviewers were aware of this. This became clear during the discussions in the SRC meetings. Because of this, the value of the rebuttals is limited to the correction of obvious mistakes or misinterpretations in the IERs or one of the IERs.

Therefore I recommend:

Recommendation 2:

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.

Moderation of the meetings

The meetings were moderated by scientists, appointed as chair to the SRC and not project officers of the EDCTP secretariat. The moderation of consensus and later on panel groups is a demanding task. In all cases, I have to say, the moderations have been handled very professionally by the scientists. In cases of doubt or upcoming questions they were supported by the responsible project officer and the operations manager, who were present during the meetings. In a few cases it may have needed a bit extra time, to come to a consensus or conclusion, but overall the tight time schedules - half an hour for each application to reach consensus - were observed.

My impression is, that the excellent preparatory documents (see references 2 and 3), as well as the well structured management of the process contributed to this fact and - most important - the appointments of the chairs have been well considered.

The number of applications in the four Calls has been moderate. It was feasible therefore to discuss the applications in one group per Call, first acting as a consensus, than as a panel group.

As already stated under my conclusion, the relevant expertise, diversity and quality of work produced by the independent experts appointed by the secretariat were found to be very good.

Standardization

With access to the documents of all four Calls, I encountered minor difficulties in finding immediately the general documents, I needed. First of all these documents differ in number, in two cases the Call text was not enclosed - which is not a real problem, since it can be found elsewhere on the EDCTP web representation. Then there is no unique way of designation of the documents (the definition of the file names), again this is not a major problem, but life could be made easier for those, who attend more than one SRC meeting and finally, after having opened the documents, I would have preferred to find on all of them the respective Call Identifier;

in the two cases, where the Call texts had been part of the general documents, this was not the case for example. In other cases I found all the information I needed.

Recommendation 3:

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.

Recommendation 4:

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/>

4. Summary of Recommendations

Recommendation 1:

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.

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