



EDCTP

European & Developing Countries
Clinical Trials Partnership

EDCTP2 INDEPENDENT OBSERVER'S REPORT

CALL IDs

RIA2017MC - 'Clinical trials to reduce health inequities in pregnant women, newborns and children'

Stage 2 deadline: 14 March 2018

RIA2017S - 'Strategic actions supporting large-scale clinical trials'

Stage 2 deadline: 14 March 2018

Stage 2 Evaluation

Date of Evaluation 29 - 30 May and 31 May - 1 June 2018

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

Present at the evaluation: 29 - 31 May 2018

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Hans Lehmann

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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 **two two stage Calls**¹

- **RIA2017MC** - 'Clinical trials to reduce health inequities in pregnant women, newborns and children'
Stage 2 deadline 14 March 2018: 11 stage 2 applications
- **RIA2017S** - 'Strategic actions supporting large-scale clinical trials'
Stage 2 deadline 14 March 2018: 9 stage 2 applications

Since the basics of the evaluation procedure on the premises of EDCTP in Den Haag have not been changed since my last two observation periods I can be short.

For those, who are not familiar with the afore mentioned reports I nevertheless will summarize the essentials of the overview.

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 Secretariat².

During the meeting in Den Haag from 29 May until 1 June 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 document³.

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, respectively the Chair and in part by a moderator. The role of the moderator will be addressed further down.

- **Conclusion**

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

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

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 - as in the two preceding cases of observation - 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 two Calls (RIA2017MC and RIA2017S) during 3 working days in the time 29 to 31 May. 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 respectively by an EDCTP staff member.

3. Observations of the process

General remarks

The evaluation procedure has been outlined in my last two reports. Nothing new has to be added with the following exceptions:

- this time the number of independent experts for the evaluation of individual applications ranged from 5 to 7 and
- the RIA2017MC call was, as in former cases, moderated by the chair with the exception of one proposal. In order to avoid a conflict of interest, in this case the chair left the room and the discussion was moderated by an EDCTP staff member
- in case of RIA2017S at first four proposals were moderated by an EDCTP staff member and later on the moderation was continued by the Chair, who was present during the whole meeting.

Moderation of the SRC Meetings

In my former two engagements as Independent Observer I gave altogether 5 recommendations. I will not come back to my first 4 which have been discussed in detail in my second report. My 5th recommendation focused on the moderation of the SRCs as consensus as well as panel group.

I noted:

"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 op-

portunity to observe, but it is particularly demanding and the chair might either prefer to act as a rapporteur or confirmer."

I proposed (see also recommendation 5⁴):

" 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."

To make such a proposition is one thing, in contrast to this it's simply not possible to test it in a strict sense (I have to admit this as a trained physicist) and it's not possible to prove its evidence (we have a limited number of Calls), but there is a chance to check, whether it's reasonable. And the EDCTP secretariat was open-minded enough to do exactly this.

As regards (1), the Chairs of both Calls (RIA2017MC and RIA2017S) have not been involved as expert reviewers and consequently not as rapporteurs or confirmers.

As regards (2), in a quarter of the proposals the moderator was an EDCTP staff member.

This worked extremely well. The moderators were relaxed as well as the independent experts and as a rule, consensus was reached as planned within half an hour, which is not much time for complex proposals as in these Calls.

As already said, on the basis of just two Calls, at best a statement on reasonability can be made. In this sense my conclusion is, that moderators should be relieved from the burden of individual evaluations and as a rule, they should not act in addition as rapporteur or confirmer too. This enables them to fully concentrate on their challenging moderation task.

Moderating a group of experts is a skill, which - according to my limited experience - most scientists have acquired in their professional life. To my great pleasure I had the opportunity to follow some really excellent moderations during my obligation as Independent Observer.

Occasionally however, it may be difficult to find the proper person. In such a case I recommend to choose an EDCTP staff member, of course a person who knows the business of moderation and best of all one who knows the procedures by heart and has an extensive experience, as in the case of my observations this time.

⁴ **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.

4. Acknowledgements

I gratefully acknowledge that my role as Independent Observer was fully supported and seen as helpful by the evaluators and the staff. I would like to sincerely thank the expert evaluators and the EDCTP secretariat for their assistance and cooperation.

I particularly appreciated, that my observations and recommendations opened fruitful discussions. In the course of my three engagements I have seen adjustments and I have learned new things, for example the value of rebuttals.

My thank especially goes to the Director Michael Makanga, who took time to discuss differing views with me and to the Operations Manager Pauline Beattie and the Director of North-North Cooperation Ole F. Olesen.