



EDCTP

European & Developing Countries
Clinical Trials Partnership

Frequently asked questions (FAQs)

RIA2018V- Vaccines for diarrhoeal diseases or lower respiratory tract infections

Document history		
Version	Date	Changes
1	11-06-2018	First version

Disclaimer: The FAQs are for information only and do not constitute a legally binding document. The legal basis for information in the FAQs can be found in the Horizon 2020 Rules for Participation and the EDCTP Annual Work Plans.

For more information, please go to the EDCTP website: www.edctp.org



Purpose of the FAQs

These FAQs provide guidance for applicants to the EDCTP2 Call for Proposals “Vaccines for diarrhoeal diseases or lower respiratory tract infections” to supplement the information provided in the Call text and Call documents. The FAQs will be updated regularly in response to the questions received from applicants to the call. Please also refer to the [EDCTP2 FAQs](#).

Q: Which disease pathogens are included in this call?

A: Proposals should include one or more clinical trials (phase I to III) in sub-Saharan Africa for vaccine candidates towards one or more of the following pathogens:

- Diarrhoeal diseases: Shigella and/or enterotoxigenic E. coli (ETEC);
- Lower respiratory tract infections: Respiratory Syncytial Virus (RSV) or Group B streptococcus (GBS).

Proposals covering other disease pathogens are considered to be outside the scope of this call.

Q: The call text specifies that proposals should describe the target product profiles; particularly indication, target populations, safety and/or efficacy, and describe how the candidates contribute to the global product development pipeline for the disease- where should I address this?

A: The call text specifies the following: *‘Proposals should describe the target product profiles; particularly indication, target populations, safety and/or efficacy, and describe how the candidates contribute to the global product development pipeline for the disease.’* In addition, it states that *‘Full details of the clinical product development plan, including specific go/no-go criteria must be included in the proposal, as well as specific plans for the regulatory approval process and access strategy for patients in low-resource settings.’*

This information should be provided in the relevant sections of the application form where applicable (Excellence section including clinical study template, Impact and Implementation) and are elements considered during the review process.

Q: What is the funding limit for proposals in this call?

A: EDCTP considers that a project with a budget of between 5 and 10 million would allow for this challenge to be addressed appropriately. However, this does not preclude submission and selection of proposals requesting for more funding. Please be aware that the total call budget is €23 million and that the budget request will be evaluated under the criterion of implementation. You should ensure that the proposal represents value for money in terms of the expected outputs from your proposal and in terms of the justification of the requested costs.

Q: the call text states that ‘Proposals that leverage major relevant financial contributions from funders other than the EDCTP Association will be considered to have a higher impact’ – where should I address this in the application form?

A: Details of commitments, if any, should be described in the Excellence section and further information provided in the budget justification section under cofunding. Support letters may be uploaded as attachments to the main proposal in the budget justification section. Please note that the Budget page should reflect only the EDCTP requested contributions.

Q: The Call Text states that projects should incorporate activities to enhance and or develop the capacity of trial sites in sub-Saharan Africa - is infrastructure also included in this?

A: Funding requested to develop or enhance the capacity of trial sites must be justified in the context of the proposed trials to be conducted. Large infrastructure requests such as new buildings and/or extensive renovations of buildings are not normally supported.

Q: Are proposals that want to perform a phase I study in Europe followed by a clinical trial in SSA within scope of this call?

A: The call text states that the proposal should include one or more clinical trials (phase I to III) in sub-Saharan Africa (SSA), therefore studies that wish to perform a phase I in Europe followed by a clinical trial in SSA are within scope, however, applicants should take into account that such proposals may be considered to have higher risk if the trial in SSA is dependent on the outcome of the trial in Europe. The proposal may also be judged by the reviewers to fit less well with the scope compared to proposals performing all trials in SSA.