



**EDCTP**

European & Developing Countries  
Clinical Trials Partnership

## Frequently asked questions (FAQs)

### RIA2017NCT- Targeting control and elimination of NIDs through clinical trials

Document history		
Version	Date	Changes
1	28-06-2017	First version
2	20-07-2017	FAQs in blue were added

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](http://www.edctp.org)



## Purpose of the FAQs

These FAQs provide guidance for applicants to the EDCTP2 Call for Proposals “Targeting control and elimination of NIDs through clinical trials” 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: What diseases are included in this call?**

**A:** All the NIDs listed under note 1 in the Call text are included and these are Buruli ulcer, cysticercosis/taeniasis, dengue, dracunculiasis, echinococcosis, foodborne trematodiasis, leprosy (Hansen disease), human African trypanosomiasis, leishmaniasis, lymphatic filariasis, mycetoma, onchocerciasis, rabies, schistosomiasis, soil-transmitted helminthiasis, trachoma and yaws.

### **Q: I am looking for funding to support a vaccine or diagnostics project on NIDs, can I submit this here?**

**A:** This Call is targeted only at projects that test a new or improved drug or drug regimen and formulation, therefore vaccines and diagnostic projects are outside the scope of this Call. Product focussed post-registration implementation research on drugs and diagnostics may be submitted in the other NIDs Call launched in 2017; while the RIA Strategic Actions Call 2017 is open to all proposals in the scope of EDCTP that are large-scale projects for vaccines, diagnostics and drugs where 50% co-funding is secured.

### **Q: The call text specifies that proposals should describe the target product profile, product development milestones (including go/no-go criteria) and plans for further development, authorization and access- where should I address this?**

**A:** The call text specifies the following: *‘Proposals should clearly describe the desired target product profile for the drug candidate(s) and describe how it contributes to the global product development pipeline for the disease. Full details of the product development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorization, and an access strategy that will allow patients in low-resource settings to access the final product.’* This information should be provided in the relevant sections of the application form where applicable (Excellence section, 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 up to €5 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 €18.8 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: Does EDCTP have a priority list of diseases within the group of NIDs?**

**A:** There is no priority. All diseases are within the scope. Applicants must justify the importance of the question being addressed by the proposal and how the proposed activities will advance the field.

### **Q: Are studies investigating a new label indication for an approved drug (repurposing) within the scope of this call?**

**A:** Yes, studies seeking new label indications for approved drugs are within the scope of this call.

**Q: Are studies investigating a drug or drug combination in a clinical trial (phases I-III) that, if successful, may be used in mass drug administration programs within the scope of this call?**

A: Yes, although the call text states that proposals focused exclusively on implementation of mass drug administration programmes are outside the scope of this Call, studies investigating a drug or drug combination in a clinical trial (phases I-III) for possible later use in mass drug administration programs are within the scope of this call.