



EDCTP

European & Developing Countries
Clinical Trials Partnership

Frequently asked questions (FAQs)

RIA2017NIM- Targeting control and elimination of NIDs through product-focused implementation research

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

Purpose of the FAQs

These FAQs provide guidance for applicants to the EDCTP2 Call for Proposals "Targeting control and elimination of NIDs through product-focused implementation research" 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: The diagnostic tool I am working on is still under development, can I submit my proposal here?

A: This call for proposals is focussed on the translation of tools of proven efficacy into routine care; therefore studies to evaluation and develop new diagnostics are outside the scope of this Call.

Q: What is the difference between this Call and the other NID Call titled 'Targeting control and elimination of NIDs through clinical trials'?

A: This call is focussed on product-focused post-registration implementation studies. In specific it aims to support projects that translate medical interventions (diagnostics, drugs for treatment and prevention) of proven efficacy into routine care, or on improving population coverage and access to the intervention, retention in care and/or adherence to the intervention. The other call provides funding for clinical trials (phases I to III) conducted in sub-Saharan Africa to evaluate the safety and efficacy of new or improved drugs, drug regimens and formulations, including for prevention and post-exposure prophylaxis for NIDs.

Q: Where in the application form should I address the required plans for uptake of research results?

A: As mentioned in the Call text, proposals should include detailed plans for uptake of research results in international, regional or national guidelines and/or obtaining World Health Organisation (WHO) endorsement for improved disease management upon successful completion of the project. This information can be provided in the Impact sections of the application form as well as in the Implementation section as dissemination activities. If the proposal is successful, a data management and sharing plan must be prepared as a deliverable within the first six months of the project.

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

A: EDCTP considers that a project with a budget of up to €3 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 €11.2 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: What types of studies can be supported under this call? Are pragmatic trials eligible?

A: The call text states that *'Proposals including randomised controlled trials (RCTs) are encouraged, although other study designs and methodologies can be used, where the design is justified and appropriate to provide robust evidence to support policy changes.'* Effectiveness/pragmatic trials, including cluster randomised (community and health facility based) designs are in the scope of the call, as is product-focused implementation research relevant to EDCTP2 scope. Applicants should select the most appropriate study design to provide the evidence needed, within the scope and budget limitations of the call.

Q: What types of implementation research are supported under this call?

A: EDCTP2 supports operational and implementation research on delivery and uptake of medical products, including post-marketing (phase IV) trials and collection of safety data that may be part of active pharmacovigilance and controlled community-based interventions.

Q: Can I submit an application using a product that is about to undergo or currently undergoing regulatory review for registration?

A: The call focusses on post-registration implementation studies. Products that have not yet completed their registration during submission of the application may be submitted provided that their projected registration date aligns with the start date of projects funded under this call. Applicants are encouraged to provide realistic timelines for submission and registration, and should take into account that such proposals may be considered to have higher risk.