RIA2019LV - Lassa Fever Vaccines

Call Specific FAQs

Contents

Q1: Who can apply?

A: Applications must be submitted by consortia that meet the minimum eligibility criteria in terms of country composition (minimum of two legal entities from EDCTP2 European Participating States and a minimum of one legal entity from a sub-Saharan African country. The entities must be independent of each other). Consortia may comprise different types of applicants from the public and private sector. In this call, legal entities from anywhere in the world will be eligible for funding when the EDCTP Association and CEPI deem participation of the entity essential for carrying out the action.
Examples of applicants and consortia who may apply for this call include:

- Vaccine developers in conjunction with clinical trial site investigators
- Investigators, or a consortium of investigators, applying in conjunction with one or more vaccine developer

Q2: Where must the studies be conducted and the applicants based?

A: Applications must include a minimum of one clinical trial to be conducted in affected countries in sub-Saharan Africa to test the safety, immunogenicity and/or efficacy of a candidate vaccine. Therefore it is expected that the phase II/III trials will involve affected countries in West Africa https://www.who.int/emergencies/diseases/lassa-fever/geographic-distribution.png?ua=1

Q3: Can a single application propose to collaborate with more than one vaccine developer to test more than one vaccine?

A: Yes

- The applicant must have letters of agreement and collaboration from vaccine developers (if the developers are not applicants on the proposal). If applicants propose to work with just one developer or test just one vaccine, they should describe how their project plan would be affected if the given vaccine candidate is not successfully progressing towards advanced stage clinical development / field efficacy assessment for some reason. For applicants proposing to work with more than one developer or test more than one vaccine, trial designs creating efficiency in the use of infrastructure and resources are encouraged

Q4: Can applicants in West African countries not reporting Lassa cases ('non-hot spot') countries apply to conduct a vaccine trial?

A: Yes, in principle, applicants from anywhere in the world may apply (although all applicants may not be eligible to receive funding). For all applicants, their role must be described in the proposal. Applicants in non-hot spot countries / regions may apply and applicants must present justification for the location of the proposed trial(s), including how they will proceed to efficacy testing if the disease is not present in the country where their trial is to be conducted.

Q5: Can applicants in Lassa-endemic countries apply?

A: Yes

- Applications must include a minimum of one clinical trial to be conducted in affected countries in sub-Saharan Africa. However that does not preclude safety and immunogenicity trials not

targeting vaccine efficacy as an endpoint being conducted in populations whose risk of contracting the disease over the study period is very low.

Q6: How much information needs to be included about the Clinical Development Plan?

A: It is up to applicants to determine what information to include, however, it is expected that applicants will describe their Clinical Development Plan both for efficiently proceeding from Phase 1 dose finding studies through safety and immunogenicity trials to enable pivotal efficacy trials as quickly as possible. It is anticipated that efficacy trials may require more than one season to be completed.

Q7: Can applicants apply with a vaccine candidate that has not yet entered clinical development?

A: Yes

- Applicants need to provide full details of the development milestones, go-no go decisions, and timelines for testing of the vaccine candidates proposed in the application. The call focuses on phase II and III trials, and therefore applicants should explain clearly when the vaccine candidate(s) is expected to reach advanced clinical development including a phase 2b/3 field efficacy trial. Applicants should note the EDCTP2 programme end date and must anticipate that their EDCTP grant will close by end of 2025.
- If applicants propose to work with just one developer or test just one vaccine, they should describe how their project plan would be affected if the given vaccine candidate is not successfully progressing towards advanced stage clinical development / field efficacy assessment for some reason

Q8: Can applicants whose manufacturing processes for Clinical Trial Material used in the field efficacy trial have not yet been finally validated apply/using non-final scale CTM?

A: Yes

- Applicants should provide justification how a trial with non-final CTM supports a potential regulatory strategy towards vaccine licensure

Q9: Can EDCTP/CEPI funding be used partly for production of vaccine IMP for the conduct of the proposed clinical trial(s)?

A: Yes

- This Call is part of the EDCTP2 Programme, and follows Horizon 2020 Rules on costs eligibility for Research and Innovation Actions. Therefore, costs for GMP manufacturing of the investigational product (in this case vaccine candidate and/or adjuvant) will be supported.
- For investigational products already supported by CEPI for the production Clinical Trial Material stockpile, applicants will have to justify why the ongoing or planned production requires additional funding to secure doses for the EDCTP/CEPI-funded clinical development programme.

Q10: Can non-EU vaccine developers / entities apply?

A: Yes

- EDCTP and CEPI recognise that the participation of entities that are not normally eligible for funding under EDCTP2 rules (e.g. non EU, non sub-Saharan African countries) may be important

in this call. When the EDCTP Association and CEPI deem participation of the entity essential for carrying out the action, legal entities from anywhere in the world will be eligible for funding through this call for proposals. This means that the essential role of the partner must be described clearly in the proposal

- Applications must also comply with the standard EDCTP2 eligibility criteria (minimum of 2 EDCTP participating stages in Europe and a minimum of 1 sub-Saharan African country)
- Applications must include a minimum of one clinical trial to be conducted in affected countries in sub-Saharan Africa to test the safety, immunogenicity and/or efficacy of a candidate vaccine.

Q11: How much funding can I apply for under this call?

A: The maximum budget is 40M Euros and so a consortium may, in principle, apply for up to 40M Euros. EDCTP and CEPI expect to fund one or two proposals out of the 40M Euros.

Q12: Is it possible to apply for a small amount of funding to support one clinical study?

A: Applicants should consider whether this will fit with the call, which is intended to support one or two grants from the call budget of 40M Euros. This implies that a large- scale proposal(s) with a scope of activities costing between 20 and 40M Euros is anticipated.

Q13: Can pre-clinical research be supported under this call?

A: The scope of the call is to conduct one or more clinical trials in sub-Saharan Africa and pre-clinical research falls outside the scope.

Q14: How can I find the best location and African partners to test my vaccine?

A: Information about current trials supported by EDCTP can be found on the EDCTP portal LINK. CEPI also has details of trial sites operating in Lassa-affected areas.

Q15: How will projects be managed after the call between EDCTP and CEPI?

A: This is a joint call with funding from EDCTP and CEPI. The projects will be managed by EDCTP in collaboration with CEPI. Beneficiaries will sign a grant agreement with EDCTP and will provide reports to EDCTP and CEPI. Progress of the projects will be jointly monitored by EDCTP and CEPI through a joint oversight committee. Any project that receives CEPI funding must be willing to agree to CEPI's usual award policies and conditions via a separate Side Letter in line with CEPI's Equitable Access Policy. Please see the EDCTP model grant agreement and CEPI Policies for more details.

Q16: What is the CEPI Side Letter?

A: Successful EDCTP/CEPI Award recipients will be expected to enter the EDCTP Grant Agreement alongside a Side Letter with CEPI which will incorporate CEPI's usual award policies and will include the linked elements, by way of example. The exact conditions of the final Side Letter and the process by which an Equitable Access Plan is developed and agreed with CEPI through the development of the funded project and which will also form part of the Side Letter will be agreed with the relevant award recipients according to how each might be involved in that Plan.