EDCTP-CEPI Lassa Fever Vaccines Call

Online Information Meeting

27 January 2020

Jean Marie Vianney Habarugira | Project Officer, EDCTP
Part 1. EDCTP – Introduction

• The Partnership & funding programme
• Diseases and interventions in the scope
• Current Portfolio at a glance
• Strategic Research Agenda (SRA)
  • Emerging and Re-emerging infectious diseases
14 European Countries
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

2 Aspirant Members
Angola, Switzerland

16 African Countries
The EDCTP funding programme

**EDCTP Participating States**

- Select and administered by Participating States
- Funded by Participating States
- Application of Participating States' funding rules

**European Union**

- ≤ €683 M
  - Cash
  - Cash/In-Kind

**Third parties**

- ≥ €500 M
  - Cash/In-Kind

**Participating States' Initiated Activities**

- ≥ €683 M
  - Cash/In-Kind

**EDCTP Calls for Proposals**

- Selected and administered by EDCTP
- Funded by the European Union, Participating States and third parties
- Application of Horizon 2020 rules for participation
EDCTP programme implementation: integrated approach

- HIV/AIDS,
- malaria,
- tuberculosis
- dengue/severe dengue;
- rabies;
- human African trypanosomiasis (sleeping sickness);
- leishmaniasis;
- cysticercosis/taeniasis;
- dracunculiasis (guinea-worm disease);
- echinococcosis;
- foodborne trematodiases;
- lymphatic filariasis;
- mycetoma;
- Onchocerciasis (river blindness);
- schistosomiasis;
- soil-transmitted helminthiases;
- Buruli ulcer;
- leprosy (Hansen disease);
- trachoma; yaws;
- diarrhoeal infections;
- lower respiratory infections;
- Emerging infectious diseases of particular relevance for Africa, such as Ebola, yellow fever or Lassa Fever
Clinical studies supported by EDCTP

Discovery & Pre-clinical research

- Phase I: Human pharmacology
- Phase II: Therapeutic exploratory
- Phase III: Therapeutic confirmatory
- Phase IV: Therapeutic use

Implementation research

EDCTP remit

Clinical trials

- Safety and/or efficacy of investigational medicinal product
- Product formulation, dosing recommendations
- Biomarkers, Pharmacogenomics
- Clinical trial on specific populations
- Low intervention clinical trials
- Pragmatic trials
- Optimising the use of existing intervention
- Diagnostics test validation

Disease scope

- HIV, malaria, tuberculosis, neglected infectious diseases, epidemic infectious diseases, diarrhoeal infections and lower respiratory infections
EDCTP2 - Funded projects - up to Jul 2019

2014-July 2019

Total funding €551.66 M
In 247 projects awarded to date.

Clinical studies €489.38 M
to support 78 projects with large-scale clinical trials and other clinical research activities conducted by European-African consortia.

Clinical research capacity €33.69 M
to support 50 projects that strengthen the enabling environment for conducting clinical trials and clinical research.

Fellowship programme €28.59 M
to support 119 fellowships that focus on the career development of individual researchers.
Portfolio of projects: collaborative clinical trials and clinical studies

2014-July 2019

- Tuberculosis, 22 grants
  - €135.85 M
- Malaria, 11 grants
  - €106.28 M
- HIV & HIV-associated infections, 15 grants
  - €93.61 M
- Neglected infectious diseases, 13 grants
  - €49 M
- Emerging diseases, 9 grants
  - €41.61 M
- Diarrhoeal diseases, 4 grants
  - €34.94 M
- Lower respiratory tract infections, 4 grants
  - €28.09 M
The EDCTP Strategic Research Agenda (SRA) outlines the key research and capacity gaps for diseases within the EDCTP scope and ranks them in terms of priorities.

**Lassa Fever in the Section on “Emerging & Re-emerging infectious diseases with epidemic potential”**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
<th>Priority</th>
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<tbody>
<tr>
<td>Epidemiology</td>
<td>Epidemiological studies of Lassa fever to identify risk factors for infection and areas of high infection incidence/prevalence which might be suitable for Phase 2/3 vaccine trials</td>
<td>A</td>
</tr>
<tr>
<td>Prevention</td>
<td>Vaccines: Lassa Fever, Avian Influenza, Ebola Virus Disease, Yellow Fever</td>
<td>B</td>
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Emerging Diseases portfolio

EDCTP portfolio: Emerging diseases

**Drugs**

- **PEAU-EBOV-RDC** 0.5M
  - Dem. Rep. Congo, France, United Kingdom, Belgium

**Vaccines**

- **NIFTY** 3M
  - Senegal, Uganda, France, Kenya

- **PREVAC-UP** 15M
  - Guinea, Liberia, Mali, Sierra Leone, France, United Kingdom

**Diagnostics**

- **AdjustEBOVGP-Dx** 0.5M
  - Uganda, South Africa, France, Greece, Poland, Sweden

- **MobEBO-DRC** 0.5M
  - Dem. Rep. Congo, United Kingdom, Senegal, Canada, Germany

**Non-intervention specific**

- **PANDORA-ID-NET** 10M
  - Rep. Congo, Gabon, Tanzania, Zambia, Uganda, Sierra Leone, Sudan, Nigeria, France, Germany, Italy, UK

- **ALERRT** 10M

- **EPIRISK-Ebov** 0.5M
  - Rep. Congo, Gabon, France, Germany, UK

- **CAPA-CT II** 0.5M
  - Uganda, Italy, United Kingdom
ALERRT and PANDORA-ID-NET consortia

- Research and clinical management of patients in PRD epidemics in sub-Saharan Africa
- Aim: to establish a multidisciplinary consortium, able to provide **accelerated evidence for the optimal clinical management of patients, and for guiding the public health response to severe infectious outbreaks.**

- **17 African countries** (Cameroon, Central African Republic, Congo, Cote d’Ivoire, Democratic Republic of Congo, Gabon, The Gambia, Ghana, Madagascar, Nigeria, Sierra Leone, Senegal, South Africa, Sudan, Tanzania, Uganda and Zambia)

- **5 European countries** (Belgium, France, Germany, Italy, United Kingdom)

Strategic Research Agenda topic is addressed by the Consortia

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
<th>Priority</th>
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<tbody>
<tr>
<td>Critical infrastructure &amp; human development needs</td>
<td>Development of regional clinical trial capacity for the rapid conduct of GCP-compliant Phase 1, 2 and 3 trials of new vaccines and other interventions against emerging pathogens, including mobile laboratories.</td>
<td>A</td>
</tr>
</tbody>
</table>
Part 2.
The EDCTP-CEPI Joint Call on Lassa Fever Vaccines

• Scope and Expected Impact
• Application process -
  • Online environment
  • Co-applicants
  • Call specific questions
  • Mandatory fields

• Evaluation procedure - one stage
  • Eligibility
  • Rebuttals
  • Ethics assessment
  • Timelines and outcome
# 2019 Calls for proposals _ Lassa Fever Vaccines

## Vaccines against Lassa virus disease – Joint call with the Coalition for Epidemic Preparedness Innovations (CEPI)

**Status:** Active  
**Type of action:** Research and Innovation Action (RIA)  
**Call budget:** €40 million  
**Funding level:** 100% of eligible costs  
**Open date:** 2 November 2019, 00:00  
**Close date:** 7 April 2020, 17:00  

### €40 Million

**Expected number of grants:** 1-2  
**Call identifier:** RIA2019LV

## Description

**Background**  
Vaccines have contributed enormously to the successful control and elimination of many diseases, but few vaccines have so far been developed for the prevention and control of emerging infectious diseases. Lassa virus (LASV) has been added to the WHO R&D Blueprint list of diseases for which there is an urgent need for accelerated research and development, considering the disease’s potential to cause a public health emergency, and given the absence of efficacious drugs and/or vaccines. In the coming years, several candidate vaccines against LASV will enter clinical development and there is an urgent need to fast track their development. The aim is to facilitate the development of promising vaccines and the preparation of investigational sites in affected countries to be ready to perform proof of concept and/or pivotal efficacy trials.
Vaccines against Lassa virus disease – Joint call with the Coalition for Epidemic Preparedness Innovations (CEPI)

The aim is to facilitate the development of promising vaccines and the preparation of investigational sites in affected countries to be ready to perform proof of concept and/or pivotal efficacy trials.

Budget
Total Call Budget: 40 Million €
Budget per grant: not specified, cannot exceed call budget
Expected number of projects funded: 1-2
The purpose of this call for proposals is to support distinct strategic actions (clinical research activities) which are part of efforts to prepare and conduct a large-scale clinical trial that has the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of novel candidate vaccines against LASV.

Applications are invited for large-scale collaborative projects which include one or more clinical trials (phase II to III) aiming to accelerate the clinical development of Lassa candidate vaccines.

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.
In a nutshell: RIA2019LV- Expected impact

• Actions supported under this call for proposal should advance the development of promising LASV candidate vaccines moving towards regulatory licensure.

• The actions should also contribute towards a better understanding of the mechanisms of the reactogenicity (safety), immunogenicity and efficacy profile of the LASV candidate vaccine(s) and build capacity for the evaluation of vaccines against LASV and other EIDs in sub-Saharan Africa.
Application Process - www.edctpgrants.org

- All applications must be submitted via the EDCTPgrants system
- The lead applicant must have an EDCTPgrants portal account
- All co-applicants must have an EDCTPgrants portal account
- Co-applicants have to be invited by the Lead applicant

The goal of the European and Developing Countries Clinical Trials Partnership (EDCTP) is to reduce the social and economic burden of poverty-related diseases in developing countries, in particular sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for HIV/AIDS, tuberculosis, malaria and neglected infectious diseases.

Find out more about our grant opportunities by registering or signing in below.

If you are experiencing difficulties please contact EDCTP by emailing EDCTPgrants@edctp.org or calling +31 (0) 70 344 08 80.

Existing users
Please log in to access your account.

Email
Password

New users
Please register with us to create your account using your email address.

Register

Forgotten Password?

Remember me.

Login

System Help
The online application form

Only Registered users can enter the online application environment:

- To start a new application or
- To continue editing a draft application

To apply to one of our open Calls for Proposals or submit a PSIA / PS Other Contributions form, please click here.
Call-Specific Questions

If available,

• Details on cofunding must be provided
• Activities funded by other sources should be clearly outlined
Inviting co-applicants

Invited co-applicants must use the link in the invitation e-mail to accept participation.
Deliverables and Milestones

- Special attention to **Mandatory deliverables for clinical studies**
- Organisations added to the list in the Participants Section will appear here as a drop-down list
- Red dots mean the field MUST be completed
Organisations to budget for must be first added to the Participants Section.
The Budget – Total requested incl. indirect costs

- Total requested budget includes the 25% Indirect costs
- Online form will add the 25% automatically
- Make sure the total is not exceeding the available budget

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Total (€)</th>
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<tbody>
<tr>
<td>Medecins Sans Frontieres (MSF) - Amsterdam, Netherlands</td>
<td>5,000,000</td>
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<tr>
<td>Université Paris Descartes</td>
<td>250,000</td>
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<tr>
<td>Delta State University - Nigeria</td>
<td>250,000</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>€5,500,000</strong></td>
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<tr>
<th>Organisation</th>
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<tbody>
<tr>
<td>Medecins Sans Frontieres (MSF) - Amsterdam, Netherlands</td>
<td>25,000,000</td>
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<tr>
<td>Université Paris Descartes</td>
<td>3,250,000</td>
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<tr>
<td>Delta State University - Nigeria</td>
<td>1,250,000</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>€29,500,000</strong></td>
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<table>
<thead>
<tr>
<th>Category</th>
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<tr>
<td>EDCTP A Personnel Actual</td>
<td>€1,000,000</td>
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<tr>
<td>EDCTP A Personnel Unit</td>
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<tr>
<td>EDCTP B Sub contracting</td>
<td>€2,000,000</td>
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<tr>
<td>EDCTP C Financial support</td>
<td>€0</td>
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<tr>
<td>EDCTP D Other direct costs</td>
<td>€11,000,000</td>
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<tr>
<td>EDCTP E Indirect Costs</td>
<td>€5,500,000</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>€29,500,000</strong></td>
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</table>
To be able to submit:

- The validation summary page must be empty
- If it empty, the completion % must be 100
- If the summary is empty and completion is at 99.x% there must be a field left empty e.g. Country not listed in the records of a co-applicant
EDCTP Evaluation process – one stage

- Opened call: 2 Nov 2019
- Deadline 7 April 2020, **17:00 (Amsterdam time)**
- Admissibility and Eligibility check by the Secretariat
- Independent peer review
- Rebuttals (based on peer review comments)
- SRC meeting
- Board approval & Ethics review

**Application submission**
Full proposals

**Review process**
Full Proposal

- **Scientific Review Committee**
  Ranked list produced
- **Rebuttal**
  Applicants respond to reviewer comments
- **Peer Review External**
  Select, invite and assign reviewers
- **Checks**
  Admissibility & eligibility

**Ethics review**
Approved grants

**EDCTP Approval Board**
Eligibility

**Topic described in the Call**
Clinical trials (II-III) that have the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of **novel candidate vaccines against LASV**.

**Budget**
Not specified, but cannot exceed Call Budget (Call budget €40 Mill)
Expected number of grants: 1-2

**Participation**
*FOR ELIGIBILITY OF THE PROPOSAL:* AT LEAST 3 independent legal entities - 2 in two different European Participating States (PSs) and 1 in a Sub-Saharan African (SSA) Country

*ALSO ELIGIBLE FOR FUNDING:* Other EU Members States

**Call-specific note!**
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.

* Essential role – this should be described in the implementation section
## Eligibility – EU Participating States & SSA countries

### European Participating States:

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<tr>
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<th>Country</th>
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<tr>
<td>1</td>
<td>Austria</td>
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<td>2</td>
<td>Denmark</td>
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<td>The Netherlands</td>
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<td>Norway</td>
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<td>Portugal</td>
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<td>Sweden</td>
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<td>14</td>
<td>United Kingdom</td>
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### Sub-Saharan African (SSA) countries:

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<th>Country</th>
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<td>1</td>
<td>Angola</td>
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<td>Benin</td>
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<td>Botswana</td>
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<td>Burkina Faso</td>
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<td>Burundi</td>
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<td>Cameroon</td>
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<td>Cape Verde</td>
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<td>Congo (Republic)</td>
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<td>Côte d’Ivoire</td>
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<td>Djibouti</td>
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<td>Rwanda</td>
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<td>São Tomé and Príncipe</td>
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<td>Senegal</td>
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<td>Zambia</td>
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<td>49</td>
<td>Zimbabwe</td>
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Evaluation procedure

**Evaluation, scoring, thresholds and Rebuttal**

- This RIA 2019LV Call follows a single-stage application procedure.
- Following an admissibility and eligibility check, full proposals are evaluated by external, independent experts.
- Proposals are evaluated according to the criteria **Excellence, Impact and Implementation** (see Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013).
  - Each criterion will be scored out of 5.
  - The threshold for individual criteria will be 3.
  - The overall threshold, applying to the sum of the three individual scores, will be 10.
- **Rebuttal:** Applicants will have the opportunity to respond to peer review comments before final Consensus Evaluation and Ranking
Evaluation procedure

Ethics Review, Board approval & Outcome communication

• For all proposals involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.
• Ethics Issues Table (in the application form) and Ethics self-assessment must be properly completed
• Following and depending on Board approval, evaluation results are expected to be made available by 30 June 2020
• Outcome Letter Categories
  • Invitation to Grant Preparation
  • Reserve Letter
  • Reject Letter - Below available budget
  • Reject Letter - Below threshold
Further guidance

EDCTP Guidelines for application

• EDCTP2 Grants Manual for EDCTP2 Calls for proposals
• Preparation of full proposals and annex 1 of the grant agreement (PDF)
• Guidance for applicants for the online application procedure
• EDCTP2 policy on clinical trials registration, publication and data sharing (PDF)
• EDCTP2’s strategic research agenda

FAQs on Calls

• http://www.edctp.org/faqs-on-calls-2/

Lassa Fever Call specific FAQs

• http://www.edctp.org/web/app/uploads/2020/01/EDCTP_CEPI_Call_Lassa_specificFAQs.pdf

Reference documents

• International Council on Harmonisation – Good Clinical Practice (ICH-GCP)
• Global Code of Conduct for Research in Resource-Poor Settings (PDF)
Looking for potential partners/co-applicants?

- EDCTP Epidemic Preparedness consortia:
  - https://www.alerrt.global/
  - https://www.pandora-id.net/

- EDCTP Networks of Excellence
  - https://wanetam.org/
  - https://eaccr.org/
  - http://www.cantam.org/
  - http://www.tesanoe.org/

- EDCTPgrants public portal:
  - https://www.edctpgrants.org/publicportal#/search

- EDCTP1 projects portfolio:

- EDCTP Alumni Network – all former and current EDCTP Fellows:
  - https://edctpalumninetwork.org/

- H2020 participants portal
Thank You!

Questions?