

Guide for Applicants

Research & Innovation Action (RIA)

Strategic actions supporting large-scale clinical trials

Letters of Intent

July 2015

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Call Text: Strategic actions supporting large-scale clinical trials

Status: Active

Type of action: Research and Innovation Action (RIA)

Funding level: 100% of eligible costs

Open date: 28 January 2015, 17:00 CET

Close date: 15 October 2015, 17:00 CET

Changes to call text: The EDCTP call for 'Strategic projects with major cofunding' has been updated in order to conform to Horizon 2020 guidelines. In the call, the requirement for 50% cofunding has been removed as an eligibility criterion; instead, cofunding is one of the evaluation criteria. Please read carefully the changes that have been introduced to the call text in comparison with the previous call text. Since the EDCTP2 work plan for 2015 and its associated budget are awaiting approval, the call text may, in principle, be subject to further modification. If you have any questions regarding the revised Call for Proposals, please contact EDCTP on [edctpgrants\[at\]edctp.org](mailto:edctpgrants[at]edctp.org) or +31 70 344 0880.

Two-stage application procedure:

Stage 1 (Letter of Intent)

Opening date: 28 January 2015

Deadline for submission: Extended to 15 October 2015, 17:00 CET

Stage 2 (Full proposal)

Opening date: TBC

Deadline for submission: TBC

Expected number of grants: 2-5

Description

Background

There are multiple research opportunities arising continuously, some of which are of utmost strategic importance to advance clinical research in poverty-related diseases (PRDs). These research opportunities are often complex and resource-intensive, requiring financial investments that a single funder cannot bear alone. Extended international cooperation with other funders is vital to harness synergies and to ensure that the impact of research is maximised and resources and investments are leveraged.

Scope

The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are part of a large-scale clinical trial that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs. Such large-scale clinical trials are often expensive and may require clinical research in different countries or on different continents, including outside of Europe and Africa. Applications for a strategic action should focus on clinical trials on PRDs in sub-Saharan Africa, and may address any disease within the scope of the EDCTP2 programme¹. Proposals that include phase III trials are encouraged.

¹ All stages of clinical trials can be supported, from phase I to IV, including implementation research on optimisation of health services. For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa such as Ebola.

Proposals must present the large-scale clinical trial in its entirety, clearly indicate for which part of the trial EDCTP2 funding is requested and how the financing of the other parts of the trial is ensured, and present its relevance to reaching the objectives of the EDCTP2 programme. The ambition and design of the proposed large-scale clinical trial as well as the relevance of the proposed strategic action for the large-scale clinical trial must be presented clearly. Supporting information on the composition and scale, as well as on the management structures and procedures of the large-scale clinical trial, must be present to enable assessment of their appropriateness.

EDCTP considers that proposals for activities of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

The large-scale clinical trial must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders (i.e. from EDCTP2 Participating States and/or third parties). EDCTP considers that at least half of the costs of the large-scale clinical trial should be supported by other funders (i.e. from EDCTP2 Participating States and/or third parties) and that the foreseen total costs of the large-scale clinical trial should not be less than €3.0 million to provide this specific challenge with a strategic dimension.

Expected impact

Actions funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders; catalyse research synergies; leverage resources and investments; and maximise the impact of global research in PRDs. The large-scale clinical trial supported by the action should have the potential to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme. The requested EDCTP2 contribution should be leveraged by at least the same amount of funding from other funders (i.e. from EDCTP2 Participating States and/or third parties). Proposals that clearly demonstrate major support from other funders at the level of the large-scale clinical trial will be considered to have a higher impact.

Eligibility

Consortia comprising a minimum of three different legal entities are eligible to apply. Two of the legal entities must be established in two different European Participating States² of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country³. All three legal entities must be independent of each other.

In addition to these standard criteria, the following apply to this call for proposals:

1. The requested EDCTP contribution per action shall not exceed €10.0 million.

Procedure and application process

Submission and evaluation procedure

This is a two-stage application procedure comprising the following steps:

First stage: a letter of intent must be submitted via [EDCTPgrants](#) by 15 October 2015. Timelines for the evaluation results for the first stage are to be confirmed.

Second stage: successful applicants in the first stage will be invited to submit a full proposal via [EDCTPgrants](#) (timelines to be confirmed).

² Legal entities in the following European countries: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom

³ Legal entities in the following sub-Saharan African countries are eligible to apply: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé & Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

Evaluation criteria, scoring and thresholds

Following an admissibility and eligibility check, letters of intent and full proposals are evaluated by external, independent experts. Proposals are evaluated according to the criteria Excellence, Impact and Implementation. Each criterion is scored between 0 and 5.

Stage 1: Letters of Intent

For the evaluation of the first stage (Letters of Intent), only the criteria 'Excellence' and 'Impact' are evaluated. The threshold for each individual criterion is 4 and the overall threshold is 8.

Stage 2: Full proposals

For the evaluation of the second stage (Full Proposals), evaluation scores will be awarded for the criteria Excellence, Impact and Implementation. Each criterion is scored between 0 and 5. The threshold for individual criteria is 3 and the overall threshold for the sum of the three individual scores is 10. Applicants have the opportunity to submit a written response to the expert reviewers' comments prior to an expert review committee meeting convened by EDCTP to finalise the funding recommendations.

The following aspects are considered under the evaluation criteria:

1. Excellence

- **Fit with the scope and objectives of EDCTP2 and the call topic description:**
 - **Ambition and design of the proposed large-scale clinical trial**
 - **Relevance of the proposed strategic action for the large-scale clinical trial**
- **Importance, relevance and clarity of the objectives**
- **Credibility of the proposed approach**
- **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now**
- **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally**
- Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.

2. Impact

- **The expected impacts listed in the work plan under the relevant topic:**
 - **Contribution to increased international cooperation among researchers and funders**
 - **Catalyse research synergies**
 - **Leverage resources and investments**
 - **Maximise the impact of global research in PRDs**
 - **Demonstration of major support by other funders, with at least half of the costs of the large-scale clinical trial supported by other funders**
 - **Potential of the large-scale clinical trial to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme**
- **Likelihood to result in major advances for the field**
- **Advancing the clinical development of new and improved products**
- **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health**
- Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results
- Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.

3. Quality and efficiency of the implementation

- Coherence and effectiveness of the proposed work, including appropriateness of the allocation of tasks and resources
- Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant
- Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met
- Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues
- Complementarity of the participants within the consortium and gender balance among consortium members (when relevant)
- Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s)
- Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP)
- Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial
- Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).

Please note that:

- For the evaluation of letters of intent only the criteria '*Excellence*' and '*Impact*' will be evaluated. Within these criteria, only the aspects highlighted above **in bold** will be considered at the letters of intent stage.
- For all applications involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Financial provisions

The requested EDCTP contribution per action shall neither exceed 50% of the total cost of the large-scale clinical trial nor exceed €10.0 million. EDCTP considers that the foreseen total costs of the large-scale clinical shall not be less than €3.0 million. EDCTP considers that at least half of the costs of the large-scale clinical trial should be supported by other funders (i.e. from EDCTP2 Participating States and/or third parties).

EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals of a different duration.

Grant agreement

The Coordinator is required to sign a grant agreement with EDCTP (EDCTP2 multi-beneficiary agreement) within three months of receipt of the conditional award letter⁴. All participants in the project must sign a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

Application process

- The application must be submitted online via [EDCTPgrants](#)
- Only registered users of EDCTPgrants system can apply for grants and therefore you are advised to register on the system as soon as possible
- Please read the **Guide for Applicants** before submitting an application

Call documents

- [Call text](#) (PDF)
- [Guide for applicants](#) (PDF)

⁴ Grant awarding by EDCTP will depend on the final approval of the EDCTP2 work plan and associated budget for 2015 by the European Commission and the EDCTP Association

More information

For questions related to this call for proposals, please contact:

- Mr Jean Marie Vianney Habarugira, [habarugira\[at\]edctp.org](mailto:habarugira[at]edctp.org)

For questions and issues about EDCTPgrants and the online application submission please contact EDCTP via [edctpgrants\[at\]edctp.org](mailto:edctpgrants[at]edctp.org) or +31 (0) 70 344 08 80.

Applying to the Call for Letters of Intent

General

Please read the call text carefully prior to submission of your application and make sure that you have provided all of the requested information. Incomplete applications may not be accepted.

Applications should be submitted via EDCTPgrants (www.edctpgrants.org) by 16:00 GMT (17:00 CET) on the deadline indicated in the call text. EDCTPgrants will not allow submission of an application after the specified deadline and so you are advised to submit your application as early as possible to avoid any last minute technical problems.

Registering in EDCTPgrants

Before starting the online application, you need to register in EDCTPgrants. Please click 'Register' and follow the on-screen instructions to complete the registration process.

You may find the following notes useful:

- You will use the email address you register with to identify yourself to the system when logging in
- The system will use this email address for all correspondence, so it is a good idea to choose an address you use regularly
- When you register, an email will be sent to you to allow you to confirm the registration and log in for the first time
- Do not worry if you move to a new email address in the future – you can change your registered EDCTPgrants email address if you need to
- If you are an EDCTP grant holder or if you have previously contributed to an application or review, your email address may already be registered in EDCTPgrants. The system will detect this automatically and will invite you to log in without needing to re-register.
- The system allows you to store the answers to security questions to assist the secure retrieval of your password if you ever forget it
- Please add the edctpgrants@edctp.org email address to your contacts to ensure receipt of emails from EDCTPgrants in order to avoid the email ending up in your spam/junk folder.

If you forget your password, you can click the 'Forgotten Password?' link on the Registration and Login Page, and ask for a replacement password to be sent to you by email. This replacement password gives temporary access to the system, during which time you will be asked to provide a new, permanent password.

Persistent use of an incorrect password will lock your account; this is to protect you from attempts to access your data by a third party. If this happens you can request a new password via the 'Forgotten password' function.

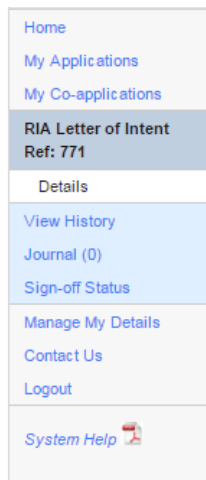
For more information on using the system, please see the System help guide on the registration page.

EDCTPgrants home page

On completion of your registration, you will be directed to your personal 'Home' page. The home page is your starting point to create applications, or to update your details, including your professional and academic CV. It is also where you, as a grant holder, can manage your grants, and as reviewer can participate in the review process.

Before starting your application, you should ensure that you have completed the CV details in your home page as this information is used to automatically populate sections of the application form.

Use the menu on the left of the page to navigate through different functions on the system. See below:

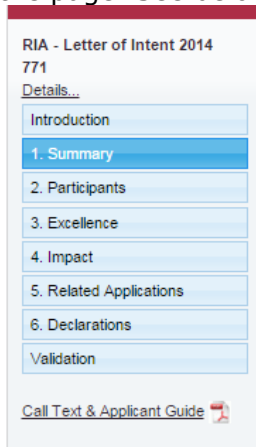


To apply for open calls, follow the instructions under 'New Grant Application'. You will be directed to the Current Grant Opportunities page that lists the EDCTP calls that are open for applications.

Click the 'More info' link to get further information on the call you are interested in. Click 'Apply' when ready to start the application process.

Starting your online application

When completing the online application you can click 'Next' to go to the next section of the application form (available at the top and bottom of the screen) or, go directly to another section by clicking on the link to the required section using the menu on the left hand side of the page. See below:



The online application can be completed over time. To save your application for completion at a later point in time, click 'Save and Close'. EDCTPgrants has an autosave function but you should always click 'Save and Close' prior to logging out.



This icon provides a notes field to assist you in tracking your progress in completing the form. Click on the icon to add your comments or reminders in each section of the form.

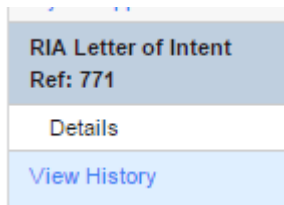


This icon contains instructions specific to each question in the application.



This icon indicates a mandatory field. The field has to be completed prior to submission of the application form.

To view a summary of your application details and to view or print a pdf copy of your application for your personal records, please use the 'Details...' link on the top left of the screen. See below:



Before allowing submission of your application, EDCTPgrants will carry out a validation check. This is to ensure completeness of each section and field in the application form. The validation check does not constitute the formal admissibility and eligibility check and cannot ensure that the contents of uploaded files correspond to the requirements of the call.

You cannot submit the application until the validation check has been completed successfully. Upon submission of your application to EDCTPgrants, a confirmation email will be sent to the email address specified in your profile. Please add the edctpgrants@edctp.org email address to your contacts to ensure receipt of emails from EDCTPgrants in order to avoid the email ending up in your spam/junk folder. Alternatively, please check your spam/junk folder in case you do not receive the confirmation email.

Once the application has been submitted, you will not be able to retrieve and edit the application. If you notice an error in your submitted application, it is possible to change this **before** the application deadline. Please note that it is not possible to make changes to a submitted application **after** the application deadline has passed.

For changes **before** the deadline, please email edctpgrants@edctp.org or submit a new application via EDCTPgrants. The new application must be submitted by the deadline. In the case where an applicant submits more than one application, only the latest version of the submitted application that is received before the deadline will be processed by EDCTP. The earlier, submitted versions of the application will be discarded.

Instructions on filling out the online form

1. Summary information about the proposal

1.1 Title

Please insert the title (maximum 150 words). The title should reflect the content of the proposal.

1.2 Acronym

Please add an acronym or abbreviation to identify your proposal.

1.3 Abstract

The abstract should be a short summary (400 words maximum) to explain clearly:

- The objectives of the proposal
- How they will be achieved
- Their relevance to the call topic

Do not include any confidential information.

Use plain typed text, avoiding formulae and other special characters.

1.4 Keywords

Select a maximum of five keywords relevant to the scope of your proposal from the drop-down menu under the different categories. Click on 'Add Keyword' if a keyword of choice is not listed in the drop-down menu.

By clicking on the + symbol, an expanded list of keywords applicable to the EDCTP remit will appear. Please choose keywords which describe the scope of your proposal. Other keywords relevant to your field can be added using the "Add Other Keyword" link. The total number of keywords should not exceed five.

1.5 Proposed start date

Please indicate your preferred start date for the project, if selected. The actual start date may be later than this date and will depend on when the grant agreement is signed.

1.6 Duration

EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately.

2. Participants

The Participants⁵ are the applicants and their respective organisations (legal entities) involved in the proposal. Please ensure that all participants are registered in EDCTPgrants before starting the online application.

Applications to this call for proposals must be submitted by consortia comprising a minimum of three different legal entities. Two of the legal entities must be established in two different European Participating States of the EDCTP Association and one of the legal

⁵ Participant means any legal entity carrying out an action or part of an action under Horizon 2020 (Regulation (EU) No 1291/2013) having rights and obligations with regard to EDCTP under the terms of the Horizon 2020 Rules for Participation. Upon signing the grant agreement with EDCTP, Participants become Beneficiaries. Beneficiary is the legal entity that has signed the Grant Agreement (GA) with EDCTP

entities must be established in a sub-Saharan African country. All three legal entities must be independent of each other.

2.1 Coordinator

The Coordinator is the lead applicant and his/her organisation (legal entity) involved in the proposal. The Coordinator is responsible for submission of the proposal on behalf of all participants and for all correspondence with EDCTP. The Coordinator is responsible for administration and management of the project, if selected for funding.

The Coordinator must be registered in EDCTPgrants in order to access the application form. Please make sure that the personal details, education and training and career summary are correct and up to date in the home page as these fields are used to populate automatically the application form.

2.1.1 Personal details

These details will be taken directly from your EDCTPgrants account into the application form. If they are incorrect, please amend them in the home page.

2.2 Other Participants

Please use the "Add participant" link to add another participant ("co-applicant") to the proposal. EDCTPgrants will search for the participant in the system.

If the participant is already registered with EDCTPgrants, an email will be sent to the participant informing of their addition to the application and asking for confirmation of their participation.

If the participant is not already registered with EDCTP grants, please enter the email address of the participant. An email will be sent to the participant with a temporary log-in and password to allow the proposal to proceed.

Please note the following important points:

- All participants must be registered with EDCTP grants in order to apply
- All participants must complete their registration details to ensure that correct and up to date information populates the application form
- All participants must confirm their participation in a proposal by clicking the hyperlink in the confirmation email.
- The online application cannot be submitted in EDCTPgrants unless all of the participants have confirmed.
- The edctpgrants@edctp.org email address should be added to your email contacts to ensure receipt of emails from EDCTPgrants and to avoid the email ending up in your spam/junk folder. Alternatively, please check your spam/junk folder in case you do not receive the confirmation email.

To avoid last-minute problems close to the deadline for submission, the Coordinator must ensure that the participants are registered and have confirmed their participation in the proposal. If you have any questions or problems regarding the registration and addition of participants, please contact EDCTPgrants@edctp.org.

3. Excellence

3.1 Research proposal

Provide a summary (maximum 2000 words) of the proposed large-scale clinical trial. Please ensure that the summary includes information on the following:

- **Fit with the scope and objectives of EDCTP2 and the call topic description:**
 - **Ambition and design of the proposed large-scale clinical trial**
 - **Relevance of the proposed strategic action for the large-scale clinical trial**
- **Importance, relevance and clarity of the objectives**
- **Credibility of the proposed approach**
- **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now**
- **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally**
- Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.

Please note: Citation of relevant literature should be included in your proposal but the list of references cited should be given in section 3.2.

3.2 References

Provide a list of any references (maximum 50) cited in the research proposal. References should be listed in Vancouver style:

Journal articles: Author Surname Initials. Title of article. Title of journal, abbreviated.

Date of Publication: Volume Number (Issue Number): Page Numbers and the DOI reference provided, where available.

The Digital Object Identifier (DOI) is the unique alphanumeric code assigned to a publication by the publisher.

Example:

Oscar W, Arrami N. Choosing wind energy. *Renew Sustain Energy Rev.* 2008;456 (22): 398-400. doi:11.1106/j.rser.2008.05.003

Books: Author Surname Initials. Title: subtitle. Edition (if not the first). Place of publication: Publisher; Year.

Example:

Cook GC and Zumla AI. *Manson's Tropical Diseases*. 22nd Edition. Oxford: Elsevier Ltd; 2009.

4. Impact

4.1 Impact of anticipated results

Give an overview (maximum 800 words) of the anticipated results and how they will be taken forward, indicating the likelihood that the research findings will result in major advances and describe the extent to which the outputs of the proposed work will contribute at the European, African and/or international level to:

- **The expected impacts listed in the work plan under the relevant topic:**
 - **Contribution to increased international cooperation among researchers and funders**
 - **Catalyse research synergies**
 - **Leverage resources and investments**
 - **Maximise the impact of global research in PRDs**
 - **Demonstration of major support by other funders, with at least half of the costs of the large-scale clinical trial supported by other funders**
 - **Potential of the large-scale clinical trial to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme**
- **Likelihood to result in major advances for the field**
- **Advancing the clinical development of new and improved products**
- **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health**
- Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results
- Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.

Please note that references can be added in section 4.2.

4.2 References

If applicable, any references for the impact section can be added here.

5. Supporting Information and Related Applications

5.1 Is this or a related application currently being submitted elsewhere?

If yes, you will be prompted to answer the following questions:

- If yes, to which organisation?
- By what date is a decision expected?

5.2 Has this, or a similar, application been submitted to EDCTP in the past two years?

If yes, you will be prompted to answer the following questions:

- In which year was the original application submitted?
- Please provide the EDCTP reference number
- What was the application outcome?
- Justification:
 - If the previous application was successful, please explain the relationship between the current application and the one that was funded. Please confirm that there is no overlap between the current application and the project that was funded.
 - If the previous application was unsuccessful, please provide a justification for the resubmission by stating how the current application differs from the original one.

Please note that the proposals that have been submitted to another EDCTP call for proposals in the preceding six months are ineligible and will not be processed.

6. Budget and cofunding

6.1 Cofunding overview

For each cofunding organisation, please add the necessary details as follows:

- Click on the "Add a cofunder" link.
- Click on the **Search** link, type any combination of three letters which are part of the organisation name, select the name of interest and continue; if the name of interest is not found, type in the name and click "Add".
- Please choose the applicable type of cofunding (cash or in-kind). If the same organisation is providing both cash or in-kind funding, please insert twice (once for cash and once for in-kind)
- Please insert the amount (in Euros) of cofunding provided or committed.

6.2 Details of the cofunding

In 6.2, please explain (maximum 400 words) how the cofunding will be used to support the proposal, including details of the activities to be supported by the cofunding, whether the funds are cash or in-kind contributions, any conditions on the use of funds, such as time limit, geographical, national restrictions, reporting requirements or any other conditions.

6.3 Total available cofunding

On completion of the cofunding details, the total available cofunding will automatically appear. Please copy and re-insert the total cofunding amount in 6.3

6.4 Amount requested from EDCTP

Please insert in 6.4, the amount (in Euros), you are requesting from EDCTP. The requested EDCTP contribution shall neither exceed 50% of the total cost of the large-scale clinical trial nor exceed €10.0 million.

6.5 Total Budget

Please check that the total budget (automatically calculated) is correct.

Cofunding letters

Please click on the link "Add an attachment" below to upload and attach cofunding letters and/or other evidence of financial commitments from the cofunders stated in your application.

7. Declarations

You must complete the declarations prior to submission of the application. Please note that it will not be possible to submit the application via EDCTPgrants unless all of the boxes have been checked.

8. Nomination and Exclusion of Reviewers

Please use this section to nominate reviewers for your application or requested exclusion of some specific individuals from your reviewing your application.

Coordinators of applications to EDCTP may nominate via EDCTPgrants at the time of submission of their application up to three independent experts as peer reviewers of their application. Nominated reviewers must be recognised experts in the EDCTP call topic and/or experts in the field of the research proposal. The nominated experts should not be collaborators or researchers with whom the participants have published in the past three years and should not be at the same organisation as the applicants. EDCTP reserves the right not to use the suggested experts.

This information will not be shared and is for internal use only.

Coordinators of applications to EDCTP may request via EDCTPgrants at the time of submission of their application that up to three named individuals be excluded from evaluating their proposal. EDCTP may exclude the named individuals from the review of the application as long as EDCTP remains in the position to have the proposal evaluated properly. EDCTP will not process requests to exclude independent experts by other individuals involved in an application.

This information will not be shared and is for internal use only.

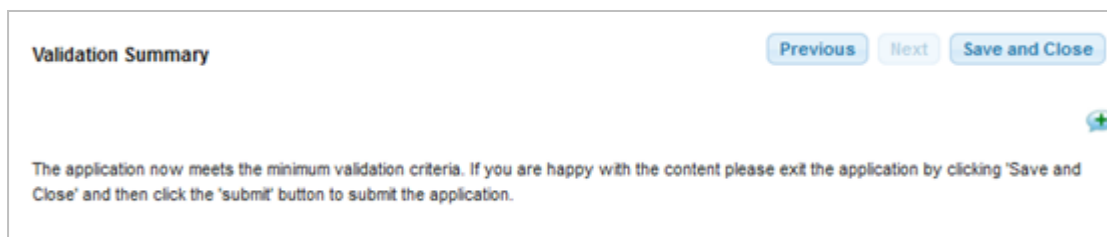
9. Validation and submission process

Before you submit your application, please check the content using EDCTPgrants validation checks:

- The Attachment Summary lists the files uploaded in support of your application, where applicable
- The Validate section checks whether all of the required fields have been completed and that the required files have been uploaded.

Click the 'Validate summary' section on the navigation menu on the left to generate a report showing any missing/incomplete information. Click on each highlighted link to return to the section that requires completion prior to submission.

When you have successfully completed the validation check, the message below will be displayed.



Click 'Save and Close' and prepare to submit the application.

You are now redirected to the Application Details page. This page gives you a summary of your application and provides different functions depending on how you would like to proceed with the application.

The screenshot displays the 'EDCTP Grants' interface. At the top, there is a red header with 'EDCTP Grants' and a green logo with 'CC Grant Tracker'. On the left, a navigation menu includes 'Ms Zee Anonymous', 'Home', 'My Applications', 'EDCTP-TDR Ref: 725', 'Details', 'View History', 'Journal (3)', 'Sign-off Status', 'Manage My Details', 'Contact Us', 'Logout', and 'System help'. The main content area shows application details:

- Title:** EDCTP-TDR Fellowship 2014 - ANONYMOUS
- Reference:** 725
- Status:** Pre-Submission
- Lead Applicant:** Ms Zee Anonymous
- Organisation:** EDCTP-EEIG European and Dev Countries CT
- Grant Type:** EDCTP-TDR
- Funding Round:** EDCTP-TDR Fellowship 2014
- Closing Date:** 30 January 2015 16:00 GMT
- Participants:** Director of Home Organization, Mister McDonald
- Created On:** 27 October 2014
- Last Updated:** 28 October 2014
- Validated:** 28 October 2014
- Applicant Submitted:**
- Submitted On:**

On the right side, there are several action panels:

- Role: Lead Applicant:** Actions shown below are for your involvement as a Lead Applicant.
- Edit the application:** Please click on the 'Edit' button if you wish to make any changes to your application. (Edit button)
- PDF the application (Print):** Please click on the 'ViewPrint' button to generate this application form as a PDF file. Please note: if your browser blocks the file download, please follow the instructions to allow the file to be downloaded. PDF Formatting Problems! (ViewPrint button)
- Validate the application:** To validate the application click 'Validate' and then 'Validate Form' within the application form. (Validate button)
- Submit the application:** To submit this grant application, please click on the 'Submit' button. Please note: you will not be able to make any alterations to the application form once it has been submitted. (Submit button)
- Delete the application:** If you are sure you wish to delete the application form, please click on the 'Delete' button. Please note: once an application has been deleted it cannot be recovered. (Delete button)

To submit the application, click 'Submit' and confirm that you are ready to submit by clicking 'Yes' on the dialog box that appears. When you have successfully submitted your application, a confirmation email acknowledging receipt of the application will be sent to you and the other participants.

The confirmation email states your application reference number, which you must quote in all correspondence with EDCTP. Please note that a temporary, pre-submission reference number is allocated to your application during the drafting stage. This number is replaced by the EDCTPgrants application reference number upon submission.

Contact information

For questions about EDCTPgrants please contact EDCTP

- via email: edctpgrants@edctp.org; or
- By telephone: +31 (0) 70 344 08 80.

For queries related to the funding scheme, please contact: Mr Jean Marie Vianney Habarugira, Habarugira@edctp.org

Personal data protection

EDCTP complies with the provisions of the “Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)”, dated 6 July 2000, which Act is based on Directive nr. 95/46/EG (PbEG L 281) and adapted to the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD). Registration with EDCTP grants and grant proposal submission will involve the recording and processing of personal data. These data will be held securely, processed lawfully and retained for no longer than necessary by EDCTP. Data may be used to compile lists, including project details, of EDCTP grants, which will be made publicly available. By submitting the application, the participants in the project give EDCTP their consent to do so.

EDCTP will publish the summary details of awarded projects, including the names of all participants, the proposal abstract and the grant amount on its website and in other public media. Further, these data may be used to compile invitation lists for EDCTP conferences and alumni events. Applicants may enquire or make a complaint about the processing of their personal data to the EDCTP Data Protection Supervisor and subsequently the Dutch Personal Data Protection Commission or the European Data Protection Supervisor.

Annex 1: Previous version of the Call Text

Call for Proposals: Strategic projects with major cofunding

Type of Action	Research & Innovation Action (RIA)
Funding level	50% of eligible costs
Expected number of grants	2-5
Stage 1: open for letters of intent	28 January 2015
Deadline for letters of intent	Extended to 3 September 2015, 17:00 (CET), 16:00 (GMT)
Status	Open

Background

There are multiple research opportunities arising continuously, some of which are of utmost strategic importance to advance clinical research in poverty-related diseases (PRDs). These research opportunities are often complex and resource-intensive, requiring financial investments that a single funder cannot bear alone. Extended international cooperation among research groups and public and private funders is vital in order to harness synergies and to leverage resources and investments in order to achieve maximum impact.

Scope

The purpose of this Call for Proposals is to provide cofunding to strategically important, large-scale research projects with the potential to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2. Applications for a strategic project should focus on clinical trials, related clinical research and/or capacity building efforts on PRDs in sub-Saharan Africa, and may address any area of research within the scope of EDCTP2⁶. Projects that include phase III trials and/or address research areas not covered by other open or forthcoming EDCTP2 Calls for Proposals in 2015 are encouraged. Applications must demonstrate financial commitment from other funders (i.e. EDCTP2 Participating States and/or third parties) and be of a sufficient scale and ambition to require EDCTP cofunding. Proposals should clearly indicate their relevance to reaching the objectives of EDCTP2.

EDCTP considers that proposals for activities of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact

Projects funded under this Call for Proposals will contribute to increased international cooperation among research groups and public and private funders; catalyse research synergies; leverage resources and investments; and maximise the impact of global research in PRDs.

Eligibility

Consortia comprising a minimum of three different legal entities are eligible to apply.

⁶ All stages of clinical trials can be supported, from phase I to IV, including implementation research on optimisation of health services. For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa such as Ebola.

Two of the legal entities must be established in two different European Participating States⁷ of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country⁸. All three legal entities must be independent of each other.

In addition to these standard criteria, the following apply to this call for proposals:

1. The requested EDCTP contribution shall neither exceed 50% of the total cost of the activity nor €10.0 million.
2. The total cost of the activity shall not be less than €3.0 million.
3. Letters of intent should provide evidence of financial commitments from other funders.

Submission and evaluation procedure

This is a two-stage application procedure comprising the following steps:

First stage: a letter of intent must be submitted via [EDCTPgrants](#) by 3 September 2015. The evaluation results for the first stage will be available by [TBC].

Second stage: successful applicants in the first stage will be invited to submit a full proposal via [EDCTPgrants](#) (timelines to be confirmed).

Evaluation criteria, scoring and thresholds

Following an admissibility and eligibility check, letters of intent and full proposals are evaluated by external, independent experts. Proposals are evaluated according to the criteria Excellence, Impact and Implementation. Each criterion is scored between 0 and 5.

Stage 1: Letters of Intent

For the evaluation of the first stage (Letters of Intent), only the criteria 'Excellence' and 'Impact' are evaluated. The threshold for each individual criterion is 4 and the overall threshold is 8.

Stage 2: Full proposals

For the evaluation of the second stage (Full Proposals), evaluation scores will be awarded for the criteria Excellence, Impact and Implementation. Each criterion is scored between 0 and 5. The threshold for individual criteria is 3 and the overall threshold for the sum of the three individual scores is 10. Applicants have the opportunity to submit a written response to the expert reviewers' comments prior to an expert review committee meeting convened by EDCTP to finalise the funding recommendations.

The following aspects are considered under the evaluation criteria:

1. Excellence

- **Fit with the scope and objectives of EDCTP2 and the call topic description**
- **Importance, relevance and clarity of the objectives**

⁷ So far, the following 14 European Participating States have joined the EDCTP Association as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom

⁸ Legal entities in the following sub-Saharan African countries are eligible to apply: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé & Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe

- **Credibility of the proposed approach**
- **Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now.**
- **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.**
- Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.

2. Impact

- **The expected impacts listed in the work plan under the relevant topic:**
 - **Contribution to an increased international cooperation among research groups, public and private funders**
 - **Catalysing research synergies;**
 - **Leveraging resources and investments; and**
 - **Maximising the impact of global research in PRDs.**
- **Likelihood to result in major advances for the field.**
- **Advancing the clinical development of new and improved products.**
- **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.**
- **Potential to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2**
- **Availability of guaranteed funds from other funders**
- Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results.
- Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials.
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.
- Contribution to improved North-North, North-South and South-South networking and collaboration.

3. Quality and efficiency of the implementation

- Coherence and effectiveness of the proposed work, including appropriateness of the allocation of tasks and resources.
- Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant.
- Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met.
- Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.
- Complementarity of the participants within the consortium and gender balance among consortium members (when relevant).
- Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).
- Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP).
- Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial.
- Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).
- Sufficient scale and composition to achieve rapid advances in the field of PRDs and to make a significant contribution to the objectives of EDCTP2.

Please note that:

- For the evaluation of letters of intent only the criteria 'Excellence' and 'Impact' will be evaluated. Within these criteria, only the aspects highlighted above **in bold** will be considered at the letters of intent stage.
- For all applications involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Financial provisions

The requested EDCTP contribution shall neither exceed 50% of the total cost of the activity nor €10.0 million, and the total cost of the activity shall not be less than €3.0 million.

EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals of a different duration.

Grant agreement

The Coordinator is required to sign a grant agreement with EDCTP (EDCTP2 multi-beneficiary agreement) within three months of receipt of the conditional award letter⁹. All participants in the project must sign a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

Application process

- The application must be submitted online via [EDCTPgrants](#)
- Only registered users of EDCTPgrants system can apply for grants and therefore you are advised to register on the system as soon as possible
- Please read the **Guide for Applicants** before submitting an application

Further information

For questions related to this call for proposals, please contact:

- Mr Jean Marie Vianney Habarugira, habarugira@edctp.org

For questions and issues about EDCTPgrants and the online application submission please contact EDCTP via edctpgrants@edctp.org or +31 (0) 70 344 08 80.

⁹ Grant awarding by EDCTP will depend on the final approval of the EDCTP2 work plan and associated budget for 2015 by the European Commission and the EDCTP Association.