## **Guide for Applicants**

## Research & Innovation Action (RIA) Letters of Intent



**November 2014** 



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## Call for Proposals: Diagnostic tools for povertyrelated diseases

**Type of Action** 

Call Budget
Expected number of grants
Stage 1: open for letters of intent
Deadline for letters of intent
Stage 2: open for full applications
Deadline for full applications

Status

Research and Innovation Action (RIA)

15M Euros

2 December 2014

2 March 2015, 16:00 (GMT); 17:00 (CET)

30 April 2015 7 July 2015

Open

4-8

#### Background

Disease diagnosis in sub-Saharan Africa is highly challenging, as the population is predominantly rural and the health care systems often have limited resources. Early and rapid diagnosis of poverty-related diseases (PRDs)<sup>1</sup> offers the best opportunity for patients to receive timely and appropriate treatment, but adequate diagnostic tools are not readily available because of a lack of drive to develop and deploy them in disease-endemic countries. Therefore, there is a clear need for the development and uptake of rapid, accurate, costeffective, scalable and field-friendly diagnostic tools.

#### Scope

The purpose of this Call for Proposals is to provide funding to projects focusing on validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for detection of any of the PRDs, including as co-infections. These tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, with a significant impact on clinical decision and health outcomes. Applications should focus on late stage development (e.g. evaluation and/or demonstration phase trials) or implementation studies in sub-Saharan Africa. Applications should further provide detailed plans for World Health Organisation (WHO) endorsement and/or implementation of the diagnostic tools and technologies upon successful completion of the project. Proposals focused entirely on early-stage, laboratory-based studies using biobanked samples are outside the scope of this call. Priority will be given to point-of-care diagnostics for use in resource-limited settings.

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 for activities of a different duration.

#### **Expected impact**

Projects funded under this Call for Proposals should lead to improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression and therapeutic response. Projects should thus contribute towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.

#### **Eligibility**

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

<sup>&</sup>lt;sup>1</sup> For this call, poverty-related diseases (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); echinococcosise; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

the legal entities must be established in two different European Participating States<sup>2</sup> of the EDCTP Association and one of the legal entities must be established in a sub-Saharan African country<sup>3</sup>. All three legal entities must be independent of each other.

#### 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 2 March 2015, 17:00 CET. The evaluation results for the first stage will be available by 30 April 2015.

Second stage: successful applicants in the first stage will be invited to submit a full proposal via EDCTPgrants by 7 July 2015, 17:00 CET. The evaluation results for the second stage will be available by 30 September 2015.

#### 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 individual criteria is 4 and the overall threshold is 8. Successful applicants will be invited to submit a full proposal in the second stage.

#### 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
- Credibility of the proposed approach
- Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now
- Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial
- 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.

#### 2. Impact

Likelihood to result in major advances for the field

<sup>&</sup>lt;sup>2</sup> So far, the following 13 European Participating States have joined the EDCTP Association as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, and the United Kingdom.

<sup>&</sup>lt;sup>3</sup> 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

- Advancing the clinical development of new and improved products
- Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results
- Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health
- 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
- Improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression
- Contribution towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resourcepoor settings.

#### 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).

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.

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 call budget is 15M Euros.

The requested EDCTP contribution per project should not exceed € 3.0 million, including indirect costs of 25%.

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 letter<sup>4</sup>. All participants in

<sup>&</sup>lt;sup>4</sup> Grant awarding by EDCTP will depend on the successful conclusion of a delegation agreement between the European Commission and

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 <u>EDCTPgrants</u>
- 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 carefully before submitting an application

#### **Further information**

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

• Dr Monique Rijks-Surette at surette@edctp.org

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

## Applying to the first-stage call for Letters of Intent

#### General

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

Applications should be submitted via EDCTPgrants (<a href="www.edctpgrants.org">www.edctpgrants.org</a>) 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:

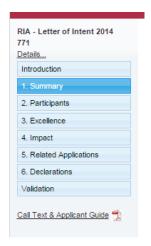


To apply for open calls, follow the instructions under 'New Grant Application'. You will be directed to the Current Grant Opportunities page that lists the EDCTP calls that are open for applications.

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 <a href="mailto:edctpgrants@edctp.org">edctp.org</a> 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 <u>grantshelpdesk@edctp.org</u> 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. 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 proposal 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. The start date cannot be earlier than 1 October 2015.

#### 1.6 Duration

What is the requested duration (in months) of this proposal? EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately.

## 1.7 Budget

Please complete the following budgetary information:

Total Amount requested (in Euros)

The funding level is 100% of direct costs (+25% for indirect costs).

Direct costs are the costs of a project that can be clearly identified and specifically related to a particular grant, as set out in the Grant Agreement.

Indirect costs (overhead) are costs that are not directly linked to the project implementation and therefore cannot be attributed directly to it.

## 2 Participants

The Participants<sup>5</sup> 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 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.

<sup>&</sup>lt;sup>5</sup> 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.

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 pooled from your registration 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 <u>must confirm their participation</u> 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.
- If all of the participants do not confirm, the application cannot be submitted in EDCTPgrants
- The <a href="mailto:edctp.org">edctp.org</a> 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 <a href="mailto:EDCTPgrants@edctp.org">EDCTPgrants@edctp.org</a>.

## 3 Excellence

## 3.1 Research proposal

Provide a description (maximum 2400 words) of the proposed research (clinical trial(s), other research studies/sub-studies), as well as details of proposed capacity development and networking activities. Please ensure that the summary includes information on the following:

- Fit with the scope and objectives of EDCTP2 and the call topic description
- Importance, relevance and clarity of the objectives
- Credibility of the proposed approach, including deliverables, milestones and timeline
- 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

**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 Sust Energ 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

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 call text. The topics in bold are part of the evaluation criteria:

- 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
- Improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression
- Contribution towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.

#### 4.1 References

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

## **5 Related Applications**

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

- 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, what was the application outcome?
- Please provide the EDCTP reference number.

Please note that the proposals that have been submitted to another EDCTP call for proposals in the preceding 6 months are ineligible and will not be processed.

## 5.3 Is this application a resubmission?

- If yes, when was it originally considered?
- Please provide the EDCTP reference number
- Provide a justification for the resubmission by stating how the current application differs from the original. Provide references if applicable.

#### 6 Declaration

You must complete the declaration 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.

Participants not exempt from the financial self-check should do so by consulting the <u>Horizon 2020 online Grants Manual (chapter on financial viability check)</u>. Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with H2020 Grants Manual.

You have now completed all sections of the online application.

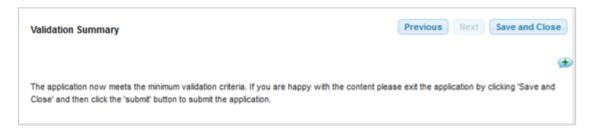
## Validation and submission process

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.

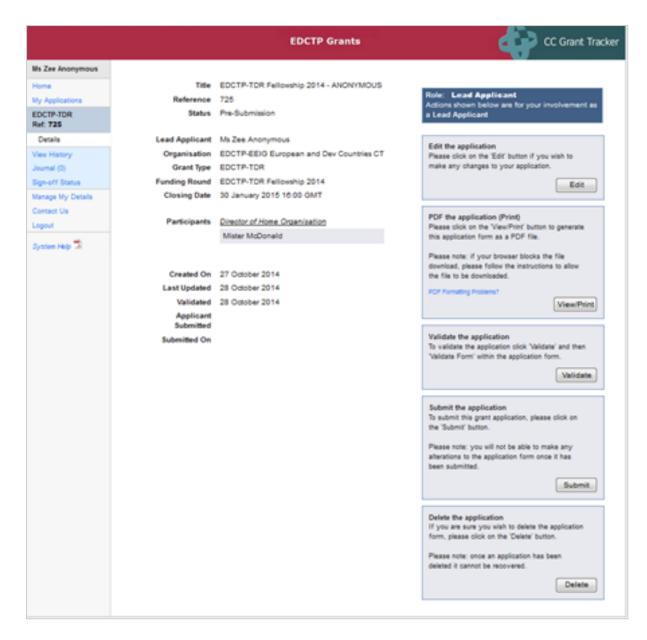
Click the 'Validate summary' section on the navigation menu on the left to generate a report showing any missing/incomplete information. Click on each highlighted link to return to the section that requires completion prior to submission.

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.



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 Director of your Home Organisation from EDCTPgrants.

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: <a href="mailto:grantshelpdesk@edctp.org">grantshelpdesk@edctp.org</a> or by telephone: +31 (0) 70 344 08 80.

For queries related to the funding scheme, please contact:

Dr Monique Rijks-Surette at surette@edctp.org

## Personal data protection

EDCTP is registered under the "Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)" and complies with the provisions of this Act (dated 6 July 2000), which is based on Directive nr. 95/46/EG (PbEG L 281) and the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD). Your grant application 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. These data may be used to compile lists of award holders, which will be made publicly available. Applicants may enquire or make a complaint about the processing of their personal data to the EDCTP Data Protection Supervisor or the European Data Protection Supervisor.