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Clinical Trials Partnership

## **EDCTP-GSK Senior Fellowships for co-morbidities between poverty-related diseases (PRDs) and non-communicable diseases (NCDs) - Joint Call with GlaxoSmithKline (GSK)**

Type of action	TMA
Indicative call budget	€3 M
Maximum funding	€500,000
Funding level	Up to 100% of eligible costs
Opening date	3 November 2017, 17:00 CET
Deadline	2 February 2018, 17:00 CET
Call identifier	TMA2017GSF

### **Description**

#### **Background**

There is a shortage of senior researchers and research mentors in sub-Saharan Africa with skills in the prevention, diagnosis and management of co-morbidities between poverty-related diseases (PRDs) and non-communicable diseases (NCDs). Support to develop senior researchers within an appropriate and supportive mentorship structure is required to build sustainable research capacity and provide a career pathway for researchers in sub-Saharan Africa.

Healthcare in Africa is facing a significant challenge from the double burden of NCDs on top of high rates of PRDs.

Often studied as two separate categories of disease, there is growing evidence for bi-directional relationships between PRD and NCD manifestation and progression, with a number of co-morbidities relevant to African healthcare identified to date. Examples include the inter-relationship between diabetes and tuberculosis; the link between Burkitt's lymphoma and malaria; the role of certain viral infections in tumorigenesis; and the potential increased risk of cardio-metabolic dysregulation reported for people living with HIV.

GSK and EDCTP are interested in implementing a Joint Call for Proposals to support clinical research and capacity development into the relationship between PRDs<sup>(1)</sup> and NCDs<sup>(2)</sup> in sub-Saharan Africa. Both partners have indicated willingness to contribute an equal amount of cash funding to the initiative. The budget will be used to support a number of Training and Mobility Actions (TMAs) that will be selected through an open call for proposals. The maximum budget allocated to each action will be up to € 500,000.

The Joint Call will include a joint evaluation and selection process in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. However, grant awarding and budget management will remain separate, at the discretion and under the management of each respective organisation. EDCTP will fund fellows employed by a research institution in any sub-Saharan African country, whereas GSK is focusing initially on a subset of sub-Saharan African countries and will fund fellows employed by a legal entity in Cameroon, Cote d'Ivoire, Ethiopia, Ghana, The Gambia, Kenya, Malawi, Nigeria, Uganda, Senegal, South Africa and Tanzania.

#### **Scope**

The purpose of this Call for Proposals is to provide funding to actions that aim to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior



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researchers with emphasis on hands-on research training linked to clinical trials activities in sub-Saharan Africa in the area of prevention, therapeutic management and prognosis of PRD and NCD co-morbidities.

The objectives of the scheme are two-fold:

1. To support senior researchers to advance themselves as recognised research leaders in clinical trial research and related activities.
2. To equip senior researchers with the necessary skills and experience to train and mentor junior researchers at host institutions in sub-Saharan Africa.

Applications should focus on hands-on research activities equipping the fellow with competences to train and mentor junior researchers in the area of prevention, therapeutic management and prognosis of PRD and NCD co-morbidities. Applications should include a clear and concise individual capacity development plan for the fellow with measurable indicators of how the project will advance the fellow's personal development towards scientific leadership. As a key component, the proposed work must include training and supervision of a minimum of two postgraduate students (PhD and/or Masters) with a clear training and mentorship plan for each student. Additionally, the fellow should indicate how their advancement in skills and competences for training and mentorship, as well as the capacity development of the junior researchers under their supervision fit into the overall institutional capacity development and sustainability strategies.

Fellows who plan to conduct training and mentorship on clinical trials must ensure that: 1) studies are appropriately designed and good clinical practice (GCP) compliant; 2) interventional studies only use regionally appropriate medicines; 3) All sponsor responsibilities can be fulfilled by the host institution (applicant legal entity where the fellow is employed).

In particular, fellows who plan to conduct training and mentorship on clinical trials should focus on clinical research that incorporates a significant PRD and NCD component in line with disease burden in resource-constrained regions of Africa and represents regionally appropriate standard of care. The studies should include one or more aspects of investigator-driven clinical research, clinical management and/or prevention and diagnosis of patients with PRD-NCD co-morbidities.

The following aspects in particular are out of scope for proposed work within this Call for Proposals: 1) Clinical studies involving GSK proprietary medicines and investigational products; 2) Clinical studies designed to test novel interventions using investigational, branded or proprietary drug products that do not represent regionally appropriate standard of care. Fellows should have a track record of publications in peer-reviewed journals in the area of prevention, therapeutic management, diagnostics and prognosis of PRD and NCD co-morbidities and show potential to become future research leaders working in sub-Saharan Africa.

Application for an EDCTP-GSK Senior Fellowship must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. The grants are awarded to the host organisation with the explicit commitment that this organisation offers appropriate conditions for the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.

Grants will be awarded for up to five years with a total funding of up to a maximum of €500,000. Fellows funded under this Call for Proposals will undergo a mid-term review that may result in discontinuation of the grant after three years in case of unsatisfactory performance.



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### Expected impact

Senior Fellows funded under this Call for Proposals will develop into recognised research leaders and contribute to an increased pool of scientific knowledge and mentors in sub-Saharan Africa. Fellows will have developed the ability to initiate, design, plan, execute and lead complex clinical research programmes and trials through interdisciplinary collaboration and, where relevant, across sectors. The fellows will produce high impact scientific and where applicable policy publications, and will be more competitive, assuming scientific leadership and capable of attracting funding from various sources. Ultimately this grant will contribute to the generation of a critical mass of researchers and the progression of institutional research capacity in sub-Saharan Africa. The senior fellowship grants will also contribute to reduce and reverse the brain drain of African scientists that moved out of or trained outside Africa by offering an opportunity to return to Africa and progress their career as independent research leaders.

### Eligibility

1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).**(3)**
2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant.**(3)**
3. The fellow must:**(3)**
  - be resident of or be willing to relocate to a sub-Saharan African country;
  - be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years' research experience after the post-graduate qualification;
  - have a minimum of 5 first-author publications in international peer-reviewed journals;
  - not have been funded under this fellowship scheme before.**(4)**
4. The requested total GSK and/or EDCTP contribution per action shall not exceed € 500,000.
5. The maximum fellowship duration shall be 60 months.

### Notes:

1. For the purpose of this call, PRDs include: HIV/AIDS, malaria, tuberculosis, and also the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as yellow fever.
2. For the purposes of this call, NCDs include: cancers (including those of viral origin), cardio-metabolic diseases, respiratory disorders and chronic kidney disease.
3. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support senior fellows in sub-Saharan Africa in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 basic act, Annex I, objectives 2b).



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4. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 basic act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.

## **Procedure and application process**

### **Submission and evaluation procedure**

This is a single-stage application procedure. Proposals must be submitted by **2 February 2018** via [EDCTPgrants](#). Evaluation results are expected to be made available by **11 June 2018**.

The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.

### **Evaluation, 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.

By submitting your application, you are consenting to having your proposal (including any personal information contained therein) transferred between and reviewed by EDCTP, GSK, and a selected panel of external, independent experts.

Proposal should fit the EDCTP's and GSK's strategic research agenda.

The following aspects are considered under the evaluation criteria:

#### **1. Excellence**

- Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.
- Importance, relevance/pertinence and clarity of the objectives.
- Soundness of the concept and credibility of the proposed approach/methodology.
- Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career.
- Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.

#### **2. Impact**

- The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.
- Likelihood to result in major advances in the field.
- Contribution of the fellowship to the fellow's clinical research skills and career development.
- Contribution to strengthening clinical research capacity at the home or host organisation.



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- Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data.
- Sustainability and retention of capacity post-award.

### 3. Quality and efficiency of the implementation

- Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;
- 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.
- Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise.
- Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role.
- Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant.
- Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.
- Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).
- Suitability of the fellow's home organisation to support the fellowship project.
- Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.

### Financial provisions

The indicative call budget is €3 million.

The requested financial contribution per project should not exceed €500,000. The funding level is up to 100% of eligible costs.

### Grant agreement

The legal entity employing the successful fellow ('host organisation') is required to sign a grant agreement with EDCTP ([EDCTP2 mono-beneficiary grant agreement with options for fellowships](#)) or with GSK (a Research Collaboration Agreement). For EDCTP agreements, we expect this to be within three months of receipt of the evaluation outcome letter. Research proposals shortlisted for funding under this TMA will be required to fulfil GSK and EDCTP's compliance requirements. For projects shortlisted for GSK funding, this includes a requirement for IRB ethical approval to be granted prior to contract signature and release of funds<sup>1</sup>.

### 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

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<sup>1</sup> There is no legal obligation on GSK to fund any project.



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## Documents and more information

### Documents

- [Application form - template](#) (Word)
- [Template for essential information to be provided for proposals including clinical trials](#) (Word)

### More information

- For questions related to this call for proposals, please contact: Shingai Machingaidze at [machingaidze@edctp.org](mailto:machingaidze@edctp.org)
- For questions and issues about [EDCTPgrants](#) and the online application submission please contact EDCTP via [edctpgrants@edctp.org](mailto:edctpgrants@edctp.org) or +31 (0) 70 344 08 80
- For guidance on online application procedure, please refer to the [Guidelines for applicants](#)
- For more information about EDCTP2 procedures, please refer to the [EDCTP2 Grants Manual](#) and [EDCTP2 FAQs](#)
- GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. We have 3 global businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products. Our goal is to be one of the world's most innovative, best performing and trusted healthcare companies. We aim to bring differentiated, high-quality and needed healthcare products to as many people as possible, with our 3 global businesses, scientific and technical know-how and talented people. More information about GSK can be found here.