

CALL FOR EXPRESSION OF INTEREST FOR THE SELECTION OF ORGANISATIONS TO BE REPRESENTED IN THE STAKEHOLDERS' GROUP OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING

1. Background

The Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3) is a partnership between the European Union and the European & Developing Countries Clinical Trials Partnership (EDCTP) Association whose members are several EU Member States and Associated countries and several African countries. Global Health EDCTP3 is established by Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe¹. It aims at supporting clinical research to deliver solutions to reduce the burden of infectious diseases in sub-Saharan Africa and strengthen research capacities to prepare and respond to emerging infectious diseases.

The first and second EDCTP programmes^{2,3} represent since 2003 a flagship for conducting sound multi-country clinical trials in sub-Saharan Africa, building a true partnership between Europe and Africa, and fostering African leadership in scientific research. These programmes have also contributed to improving linkages between African researchers and African research organisations, which resulted in the launch of four African Regional Networks of Excellence for clinical trials. Moreover, they have strengthened the ethics review capacity and national regulatory authorities in many African countries and contributed to establish relevant organisations in the region.

Building on the positive experience of the previous EDCTP programmes, Global Health EDCTP3 intends to:

- (a) Reduce the socio-economic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies;
- (b) Increase health security in sub-Saharan Africa and globally by strengthening the research and innovation-based capacities for preparedness and response to control infectious diseases.

Global Health EDCTP3 is established until 31 December 2031.

The governance of Global Health EDCTP3 is led by a Governing Board, in which both the EDCTP Association, representing the European and African countries, and the European Commission, representing the Union, have equal votes. The implementation of the programme is ensured by a Programme Office under the lead of an Executive Director. Global Health EDCTP3 is advised by a Scientific Committee and a Stakeholders Group.

The Stakeholders Group of Global Health EDCTP3 has the following tasks:

¹ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014 (OJ L 427 of 30/11/2021, p. 17–119)

² Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States EUR-Lex - 32014D0556 - EN - EUR-Lex (europa.eu)

³ Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States

- (a) provide input on the scientific, strategic and the technological priorities to be addressed by Global Health EDCTP3 as laid down in the Strategic Research and Innovation Agenda (SRIA) or any other equivalent document taking into account the progress and needs of the global health and adjacent sectors;
- (b) provide suggestions to enable concrete synergies to take place between Global Health EDCTP3 and the adjacent sectors or any sector with which synergies will be deemed of added value;
- (c) provide input to the EDCTP Forum.

2. Composition of the group

The Stakeholders Group is open to all public and private stakeholders, including organised groups, active in the field of Global Health EDCTP3, international interest groups from the Member States, associated countries, sub-Saharan African countries that are members of the EDCTP Association and other countries.

The Stakeholders Group shall have a balanced representation of stakeholders from a geographic, thematic and gender perspective, including in particular sub-Saharan African expertise.

Following prior calls for Expression of interest, the Governing Board has appointed 38 members whose term will expire shortly. This new call is launched to renew the membership of the group and stabilise it. Global Health EDCTP3 may also reach out to stakeholder organisations to invite them to submit candidatures through this call for Expression of Interest.

3. Appointment

The Governing Board of Global Health EDCTP3 will appoint up to thirty organisations to be represented in the Stakeholders Group for a two-year period. Upon recommendation by the Executive Director, the Governing Board may decide to renew the appointment for an additional period of up to two years.

The Governing Board will also approve a reserve list including up to twenty organisations that shall be valid for a two-year period. Upon recommendation by the Executive Director, the Governing Board may decide to renew the appointment of certain organisations for an additional period of up to two years.

In case of a vacancy, the Governing Board shall, subject to continuing positive assessment in terms of the criteria presented in section 5, select a new organisation to be represented from the reserve list for a period of two years or for the rest of the duration of the term of the organisation replaced within the Stakeholders Group, whichever is the shortest.

Following the appointment of organisations by the Governing Board, selected organisations must nominate a representative and an alternate that would have to meet the criteria set out in section 5. The representative and the alternate must be approved by the Executive Director, who will check that they meet the criteria. Selected organisations may request to change their representatives and alternates in case the approved persons have changed position or in other duly justified exceptional

cases. They must nominate new representatives and alternates if those originally appointed are no longer employed by them.

4. Rules of engagement and operation of the Stakeholders Group

The Stakeholders Group shall elect its chairperson and vice chairperson from among its members based on its rules of procedure.

The Stakeholders Group will meet at least once a year, in principle at the Global Health EDCTP3 premises or virtually depending on the circumstances. Meetings are convened by the Executive Director of Global Health EDCTP3. For hybrid meetings, in addition to the Members, the meetings will be attended, as required, by the Executive Director or his or her representative as well as a limited number of Global Health EDCTP3 Programme Office staff members providing the secretariat of the Stakeholders Group, invited observers and the chairperson of the SC.

Minutes of meetings of the Stakeholders Group will be drafted by the Global Health EDCTP3 programme office and will be reviewed by the Members. Following formal approval by the Stakeholders Group, the minutes will be published on the Global Health EDCTP3 website.

The Stakeholders Group will be regularly informed about Global Health EDCTP3 activities and will be invited to provide comments on its planned activities.

Meetings will be conducted in English and documents will be drafted in English. More detailed rules of procedures will be agreed during the first meeting involving new members.

The Global Health EDCTP3 Programme Office will provide secretarial services to the Stakeholders Group.

The members of the Stakeholders Group will be subject to the obligation of confidentiality, based on Article 33 of Council Regulation 2021/2085 and applicable decisions of the Governing Board.

Before appointment, all members of the Stakeholders Group will be required to complete a declaration of confidentiality as well as a commitment to disclose any actual or potential conflict of interest according to the procedure established by the Governing Board to give effect to Articles 33 and 42 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe.

The same rules on appointment, reimbursement of costs and allowances, applicable to external experts according to the rules of the European Commission and applicable decisions of the Governing Board shall apply to the members of the Stakeholders Group.

5. Application procedure, admissibility and selection criteria.

Interested organisations are invited to submit their application to Global Health EDCTP3 via the functional mailbox:

stakeholders-group@global-health-edctp3.europa.eu

Global Health EDCTP3 may also reach out to organisations to invite them to submit candidatures through this call for Expression of Interest.

Applications must be completed in one of the official languages of the European Union. However, applications in English would facilitate the evaluation procedure. If another language is used, it would be helpful to include a summary of the application in English.

An application will be deemed admissible only if it is sent by the deadline and includes a cover letter outlining how the organisation fulfils the selection criteria set out below.

Deadline for applications

The applications duly signed by an authorised representative must be sent by 5 September 2025 23:59:00 Brussels time (CEST) at the latest to the following e-mail address:
stakeholders-group@global-health-edctp3.europa.eu

The date of the e-mail will be the date of sending.

Selection criteria

1. The evaluation criteria for organisations represented are:

Expertise, activity or representation of interests in at least one of the following areas:

- Patient organisations;
- Civil society in global health, in particular as regards infectious diseases in sub-Saharan Africa;
- Professional international and regional organisations active in the areas of global health, especially infectious diseases in sub-Saharan Africa in alignment with the scope of the SRIA;
- Local or regional government representatives providing health services in sub-Saharan Africa and addressing infectious diseases;
- Social entrepreneurs and product development partnerships developing solutions for issues in global health, especially infectious diseases in sub-Saharan Africa;
- Businesses/industry/SMEs working in the area of global health, especially infectious diseases in sub-Saharan Africa;
- Research institutions addressing infectious diseases affecting sub-Saharan Africa;
- Other funders of global health research with a focus on low- and middle-income countries.

2. In its assessment, the Governing Board shall take into account:

- (a) The competences, expertise and representativeness that are necessary to provide input on the scientific, strategic and technological priorities to be addressed by Global Health EDCTP3, and identify synergies with other programmes and funders

- (b) The need to reflect balanced stakeholder representation from a geographic, thematic and gender perspective, including in particular sub-Saharan African expertise. As far as possible, the Global Health EDCTP3 Stakeholders Group should be balanced in terms of North-South representation with preference for European and sub-Saharan African stakeholders.

Selected organisations will be invited to appoint a representative and an alternate⁴.

The essential criteria for representatives and alternates are:

- (a) At least ten years of professional experience in the field as defined in the SRIA (as per Annex I).
- (b) Very good command of written and spoken English.
- (c) Proven experience of participation in advisory bodies.

Persons who are employed by a member of Global Health EDCTP3 or its constituent entities or staff (including external staff) of Global Health EDCTP3 shall not be eligible. This includes all EU institutions, agencies and bodies.

Persons who have been involved in the preparation of topic texts included in the Global Health EDCTP3 work programmes (for example as members of the Global Health EDCTP3 Scientific Committee) may not be involved in the preparation of proposals submitted under these topics, even if they eventually become representatives within the Stakeholders Group.

The composition of the Stakeholders Group must be gender balanced. The Executive Director shall therefore take this requirement into account before approving the representatives proposed by the organisations selected to be represented in the Stakeholders Group.

Selection procedure

The list of admissible candidate organisations will be proposed to an evaluation panel appointed by the Executive Director, composed of four members (two representatives from the European Commission and two representatives from the EDCTP Association), who will carry out an objective assessment of the candidates on the basis of all the selection criteria set out above. The panel will include people with adequate expertise and that are free of conflicts of interest, in addition to being gender balanced.

The outcome of the evaluation will be to establish a shortlist of up to 30 organisations. The shortlist will only include those organisations deemed best suited for appointment. In addition to this shortlist, the evaluation panel will also draw up a reserve list with up to 20 organisations.

The Executive Director will present the conclusions of the evaluation panel to the Governing Board. The Governing Board is also to be informed of:

- The organisations not included in the shortlist/reserve list; and
- The list of the organisations already excluded by the Executive Director in his/her initial selection based on the admissibility criteria.

⁴ Potential representatives and alternates should not be mentioned in the application under this call.

The Governing Board will appoint the stakeholders based on the shortlist. The Governing Board will also approve the reserve list based on the proposal of the evaluation panel. Any deviation from the proposals of the evaluation panel will be justified.

The candidate organisations are required to inform Global Health EDCTP3 immediately of any changes to their administrative and technical details, which would result in a change to their original application.

6. Further information

For any further information, please contact
stakeholders-group@global-health-edctp3.europa.eu

PROTECTION OF YOUR PERSONAL DATA

This privacy statement provides information about the processing and the protection of your personal data.

Processing operation: Processing of personal data in the framework of the selection of members of the Scientific Committee and of the Stakeholders' Group of the Global Health EDCTP3 Joint Undertaking (JU)

Records references: DPO-07-04

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1. Introduction

The protection of your privacy is of high importance to Global Health EDCTP3. Global Health EDCTP3 is committed to respecting and protecting your personal data and ensuring your privacy rights.

All data of a personal nature processed within the framework of the selection of members of the Global Health EDCTP3 Scientific Committee and Stakeholders Group, namely data that can identify you directly or indirectly, will be handled fairly, lawfully and with due care.

This processing operation is subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. The information in this communication is given pursuant to Articles 15 and 16 of Regulation (EU) 2018/1725.

The selection of members of the Scientific Committee and of members of the Stakeholders Group are carried out via a public call for expressions of interest. Global Health EDCTP3 demonstrates a high level of transparency of its activities and operations. This includes publishing on its website the names of individuals serving on the different governance bodies, including the members of the Scientific Committee and the Stakeholders' Group.

2. Controller/ Joint controllers/Processors

The relevant processing operation are under the responsibility of the Executive Director of Global Health EDCTP3, acting as the Data Controller. Your personal data are processed on the basis of applicable data protection legislation by Global Health EDCTP3, located Avenue de la Toison d'Or, 1060 Brussels, Belgium. Global Health EDCTP3 can be contacted by post (postal address TO-56, B-1049, Brussels, Belgium) or by email to Info@global-health-edctp3.europa.eu

Global Health EDCTP3 has appointed a Data Protection Officer (DPO). The task of the DPO is to ensure, in an independent manner, that the Union body complies with the data protection law and protects individuals' rights and freedoms by protecting effectively their personal data. The DPO of Global Health EDCTP3 can be contacted by post (postal address TO-56, B-1049, Brussels, Belgium) or by email to data-protection@global-health-edctp3.europa.eu.

3. Why and how do we process your personal data?

The Controller collects and uses your personal data to select the members of the Global Health EDCTP3 Scientific Committee and the members of the Stakeholders Group. In that context, in order to select among the applicants who best fulfil the selection criteria mentioned in the respective calls for expressions of interest, Global Health EDCTP3 collects and assesses personal information of candidate members of the Scientific Committee and Stakeholders Group, respectively.

For candidates, personal data is stored by the staff of Global Health EDCTP3 managing the Scientific Committee and Stakeholders Group.

After selection, by accepting the nomination or appointment, the Scientific Committee or Stakeholders' Group members agree with the publication of their names, country and affiliation on the Global Health EDCTP3 website.

Your personal data will not be used for an automated decision-making including profiling.

4. Categories of data subjects

Candidates 1) selected for the position of member and 2) placed on the reserve list of the Scientific Committee or the Stakeholders Group of Global Health EDCTP3.

5. Which personal data we collect and further process and on which legal grounds?

We process your personal data, because processing is necessary for the performance of a task carried out in the public interest (Article 5(1) (a) of Regulation (EU) 2018/1725), since it allows for the selection of members of the Scientific Committee and the Stakeholders Group.

The specific legal basis of the processing under Article 5(1)(a) and (b) of Regulation (EU) 2018/1725 is the Council Regulation (EU) 2021/2085 of 30 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014 and in particular Articles 21(4) and 22(3) thereof.

In order to carry out these processing operations, the Controller collects the following categories of personal data:

First Name and Last Name;

Date and place of birth;

Country of birth;

Function;

Nationality;

Gender;

Contact details (e-mail address, telephone number, mobile telephone number, postal address, company or university or research institution and department, country of residence).

Information for the evaluation of selection criteria or eligibility criteria (expertise, technical skills and languages, educational background, professional experience, including details on current and past employment);

Bank account details.

The provision to Global Health EDCTP3 of the personal data required is mandatory to meet a legal requirement of selecting members of the Scientific Committee and the Stakeholders Group as set in Council Regulation 2021/2085.

In principle, the name, country and affiliation of the selected members are made publicly available on the Global Health EDCTP3 website to ensure transparency on the composition and functioning of the Global Health EDCTP3 governance bodies.

If you do not provide the personal data required, possible consequences are that you will not be considered for selection as a member of the Global Health EDCTP3 Scientific Committee or the Stakeholders Group or, if already selected, your membership will be suspended.

6. Who has access to your personal data and to whom is it disclosed?

Access to your personal data collected in the course of the process of selection of members of the Global Health EDCTP3 Scientific Committee or the Stakeholders Group is provided to the Global Health EDCTP3 staff authorised for carrying out this processing operation and to other authorised Global Health EDCTP3 staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

The recipients of personal data can be - depending on the purpose of the meeting: Global Health EDCTP3 Executive Director; Global Health EDCTP3 staff: Assistant of the Executive Director, Legal

Officer and Data Protection Officer(s); other members and observers of the Global Health EDCTP3 governance bodies; External evaluators or experts assisting Global Health EDCTP3: Auditors, European Commission and its services; Police.

Access to personal data is also provided to the members of the Governing Board or their representatives who are involved in the selection of members of the Global Health EDCTP3 Scientific Committee or Stakeholders Group. Members of the Governing Board or their representatives are bound by the Rules of Procedure of the Governing Board to confidentiality of all its proceedings and sign a declaration of confidentiality and of conflict of interest to this effect.

The name, country and affiliation of the selected members, as explained in Heading 5, are made publicly available on the Global Health EDCTP3 website.

The information we collect will not be given to any third party, except to the extent and for the purpose we may be required to do so by law.

7. How long do we keep your personal data?

The Controller only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing. The following modalities apply:

Global Health EDCTP3 keeps personal data submitted to them as part of rejected applications for maximum three years after the end of the selection process and do not process them for other purposes; these personal data are not published.

The names of the members of the Scientific Committee, Stakeholders Group and the other Global Health EDCTP3 governance bodies and other types of personal data, as described in Heading 5, are published on the Global Health EDCTP3 website during the duration of existence of the respective bodies.

When an individual is no longer member of the Scientific Committee, the Stakeholders Group or one of the other governance bodies, all personal data related to this individual, is removed from the website and is therefore not public anymore.

Global Health EDCTP3 services keep personal data for the period during which the relevant individual is a member of the Scientific Committee, the Stakeholders Group or other Global Health EDCTP3 governance body and for 5 years after the date on which the individual is no longer member.

8. How do we protect and safeguard your personal data?

In order to protect your personal data, Global Health EDCTP3 has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational

measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

9. Transfer to a third country or international organisation

We process your personal data within the European Economic Area (EEA).

10. What are your rights and how to exercise them?

You have specific rights as a 'data subject' under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725. In particular:

- You have the right to request access to all personal data processed by us pertaining to you.
- You have the right to rectification, i.e. to ask that any personal data pertaining to you that are inaccurate, be corrected.
- You have the right to erasure, i.e. to request that personal data pertaining to you be deleted if these data are no longer required in the light of the purposes outlined above in Heading 3.
- You have the right to restriction instead of deletion, i.e. to request that we limit the processing of your personal data.
- You have the right to object to the processing of personal data if the processing by us is necessary for the performance of a task carried out in the public interest, unless if we demonstrate compelling legitimate grounds which override your interests, rights and freedoms or for the establishment, exercise or defense of legal claims.
- You have the right to data portability, i.e. to receive from us in a structured, commonly-used and machine-readable format all personal data you have provided to us if the processing is based on your consent or a contract with you and the processing is carried out by automated means.

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Global Health EDCTP3 Data Protection Officer by post (postal address TO-56, B-1049, Brussels, Belgium) or by email to data-protection@global-health-edctp3.europa.eu

The European Data Protection Supervisor (EDPS)

If you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by Global Health EDCTP3, as a data subject, you have a right to recourse to the European Data Protection Supervisor (EDPS) at any time by e-mail to edps@edps.europa.eu or a letter to the EDPS postal address marked for the attention of the EDPS DPO:

European Data Protection Supervisor
Rue Wiertz 60
B-1047 Brussels
BELGIUM

For more information on the EDPS, please consult their website: <https://www.edps.europa>.

11. Where to find more detailed information?

The Global Health EDCTP3 Data Protection Officer (DPO) publishes the Register of all processing operations on personal data by Global Health EDCTP3 on the Global Health EDCTP3 website. The Register can be found [here](#).

This specific processing operation has been included in the Global Health EDCTP3Public Register with the following Record reference: DPO-07-04.