

Memorandum of Understanding (MoU)

For: European and Developing Country Clinical Trials Partnership (EDCTP)
Association – contributions to EDCTP2 and Global Health EDCTP3

DHSC Reference: EDCTP 2: A7397_AA7397 / EDCTP 3: A7398_AA7398

Version: 2 - November 2023
Date: 08-Dec-2023 | 5:02 PM GMT

SECTION 1. PARTIES

1.1 THIS MEMORANDUM OF UNDERSTANDING (“**MoU**”) is between the following parties (“**Parties**”):

- (1) The Secretary of State for Health and Social Care of 39 Victoria Street, London SW1H 0EU (“**DHSC**”), and
- (2) The European and Development Countries Clinical Trials Partnership (EDCTP) Association, of Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands (“**Partner**”).

SECTION 2. BACKGROUND AND PURPOSE OF THIS MOU

2.1 The EDCTP is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union. EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat poverty related as well as emerging and re-emerging infectious diseases affecting sub-Saharan Africa.

- 2.1.1 DHSC have been providing ODA funding to the Partner since 2017 (through an MoU) to support phase II and III clinical trials and capacity strengthening in sub-Saharan Africa. This MoU sets out DHSC additional investment into and expected activities of EDCTP2 and a commitment to Global Health EDCTP3.
- 2.1.2 The EDCTP Association is the legal structure for the implementation of the EDCTP programme, and represents the governments of all countries (UK, European and sub-Saharan African) participating in the EDCTP partnership.
- 2.1.3 EDCTP investment aligns with DHSC’s primary research related outputs in our Theory of Change including High-quality policy/practice relevant research in line with global health research priorities, dissemination and knowledge exchange, Low and Middle-income Country (LMIC) and UK researcher capacity strengthening and strengthening equitable research partnerships linked to SDG17. These support DHSC’s long-term goals of health and health systems impact, and societal impact, particularly in LMICs (SDG3). By supporting clinical trials and capacity strengthening in sub-Saharan Africa EDCTP also contributes to a UK government focus on global health security and pandemic preparedness
- 2.1.4 The United Kingdom is one of the founding Participating States of EDCTP. The Medical Research Council (MRC) UKRI is the lead for UK government’s engagement with EDCTP and DHSC has a UK Deputy Delegate position at EDCTP General Assembly meetings. Contributions from the DHSC, under this MoU, will count as part of the overall UK contribution to the EDCTP programme.
- 2.1.5 Funds received from the UK must be used to fund high quality proposals selected following competitive, fair and transparent peer review processes centrally managed by the EDCTP.

- 2.2 The Partner should note that the Secretary of State for Health and Social Care proposes to pay the Contribution pursuant to his discretion under Section 1(1) of the International Development Act 2002.
- 2.3 The Partner will undertake the Activities in accordance with the provisions of this MoU.
- 2.4 This MoU establishes the responsibilities of the Parties and the general principles for their cooperation.
- 2.5 The Partner will not use any element of the Contribution for paid for lobbying, which means using the Contribution to fund lobbying (via an external firm or in-house staff) in order to undertake activities intended to influence or attempt to influence Parliament, Government or political activity or attempting to influence legislative or regulatory action.
- 2.6 This MoU is not intended to be legally binding and no legal obligations or legal rights will arise between the Parties from the provisions of the MoU. The Parties enter into the MoU intending to honour their commitments.

NOW THEREFORE the Parties have agreed to cooperate under the MoU as follows:

- 3.1 Unless the context otherwise requires, references to this MoU will be construed as a reference to this MoU as varied or amended in accordance with its provisions. Reference to a person includes a legal entity, words importing a gender include all genders and words importing the singular include the plural and vice versa.
- 3.2 In this MoU the words and phrases set out below will have the following meanings:

“**Activities**” means the list of activities conducted as part of the Programme as further detailed in Annex A (Activities).

“**Annex/es**” means the annexes attached to this MoU including those subsequently agreed between the Parties.

“**Commencement Date**” means the date of signature of this MoU: 08-Dec-2023 | 5:02 PM GMT

“**Confidential Information**” means any information which has been designated as confidential by either Party in writing or that ought to be considered as confidential (howsoever it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person or trade and all secrets, personal data and sensitive personal data within the meaning of applicable legislation. Confidential Information will not include information which:

- a) was public knowledge at the time of disclosure (otherwise than by breach of a duty of confidence by either Party);
- b) was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;

- c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or
- d) is independently developed without access to the Confidential Information.

“Contribution” means the sum or sums of money in GBP to be provided to the Partner in accordance with this MoU as set out in Annex C (Pricing)

“Data Protection Legislation” means (i) the UK GDPR; (ii) the Data Protection Act 2018 to the extent that it relates to the processing of Personal Data and privacy; (iii) all applicable Law relating to the processing of Personal Data and privacy; and (iv) (to the extent that it applies) the EU GDPR;

“Downstream Partners” means the Partner’s partners, consultants and sub-contractors involved in the delivery of the Activities;

“Financial Impropriety” means any credible suspicion of or actual fraud, corruption, money-laundering or any other financial irregularity or impropriety;

“FOIA” means the Freedom of Information Act 2000 as amended or updated from time to time;

“Funding Period” means the period for which the Contribution is awarded starting on the Commencement Date and ending at the conclusion the Global Health EDCTP3 programme.

“Government” means the government of the United Kingdom;

“IATI Standard” means the International Aid Transparency Initiative Standard;

“Intellectual Property Rights” means any patents, copyright, rights in and to inventions, trade marks, service marks, design rights, registered designs, know-how, database rights, moral rights, right in get-up, goodwill and the right to sue for passing off, rights to use, and protect the confidentiality of, confidential information, confidential formulae and applications for any of the foregoing, patents, trade marks, registered designs, copyright, database rights, know-how, trade or business names (including internet domain names) and other rights of a similar nature, whether registered or unregistered, existing now or in the future anywhere in the world.

“Memorandum of Understanding” or **“MOU”** means this Memorandum of Understanding including the Annexes;

“NIHR” means the National Institute for Health and Care Research

“ODA” means Official Development Assistance, including ODA administrative costs, as defined by the OECD from time to time;

“**OECD**” means the Organisation for Economic Co-operation and Development;

“**Programme**” means the EDCTP2 and Global Health EDCTP3, carried out by the Partner, as more particularly described in Annex A (activities);

“**Programme Funded Asset**” means any equipment and/or supplies purchased in part or fully from Grant funds if they have a useful life of more than one year; and either (1) the purchase price or development cost of the Asset is in excess of £500 or equivalent in local currency; or (2) is a group of lower value items (e.g. pharmaceutical products, food, relief packs, etc.) where the combined value is in excess of £500 or equivalent in local currency; or (3) can be considered an attractive item regardless of cost (e.g. mobile phones, cameras, laptops, tablets, satellite phones, vehicles, etc.);

“**Representatives**” means the lead representatives of each Party, as described in paragraph 26 (Liaison between the Parties). The authorised representatives and addresses for service of notices are listed in Annex D (authorised representatives and address for service of notices);

“**UKRI**” means UK Research and Innovation;

“**VAT**” means value added tax.

4.1 This MOU will commence on the Commencement Date and will continue for the Funding Period unless terminated earlier pursuant to Paragraph 29 ‘Term and Termination’ or extended by mutual agreement.

5.1 The Partner will perform the Activities described in Annex A (Activities). DHSC will perform those activities identified in Annex B (DHSC Commitments) and will make payments to the Partner for satisfactory completion of Activities in accordance with the provisions of Annex C (Pricing).

5.2 The Partner will comply with all applicable laws in carrying out the Activities.

SECTION 6. PRINCIPLES OF COLLABORATION AND THE PARTIES’ RESPONSIBILITIES The Parties agree to follow the principles set out at paragraph 6.1.1 below (“**Principles**”) at all times during the term of this MoU:

6.1.1 the Parties will:

6.1.1.1 be accountable to each other for performance of their respective roles and responsibilities as set out in this MoU;

6.1.1.2 share appropriate information, experience, materials and skills to learn from each other and develop effective working practices,

- 6.1.1.3 work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
- 6.1.1.4 adhere to statutory requirements and best practice (including any relevant Governmental protocols such as the Regulators Code, Ministerial and Civil Service Codes) as well as all applicable laws and standards including EU procurement rules, data protection and freedom of information legislation.
- 6.1.1.5 act in a timely manner;
- 6.1.1.6 ensure sufficient and appropriately qualified employees and other necessary resources are available and (in the case of employees) authorised to fulfil the responsibilities set out in this MoU.

SECTION 7. CONTRIBUTION The maximum amount that DHSC will pay under this MoU to the Partner is the Contribution, whether or not the Contribution is paid in a currency other than British Pounds Sterling. The Partner will manage the risk of currency fluctuations and the applicable exchange rate will be that in effect at the moment payment of the relevant proportion of the Contribution is made.

- 7.2 It is DHSC's intention that the Contribution will be categorised as ODA as defined by the OECD from time to time. The parties shall undertake reasonable endeavours to ensure that all monies paid to Downstream Partners can properly be categorised as ODA by the OECD
- 7.3 The Contribution is subject to revision and will depend on the fulfilment of the provisions of this MoU, any revisions to budgets, actual expenditure and need, the priorities of DHSC and the continuing availability of its resources.
- 7.4 Prior to effecting major changes between categories of expenditure as detailed in Annex C (Pricing) that may be found necessary in the course of implementing the activities, the Partner will obtain DHSC's prior written approval.
- 7.5 Should additional funding in excess of the Contribution be required for the Programme, the Partner will discuss the details with DHSC (including why such additional funding is required) and DHSC will have ultimate discretion to decide whether it will provide such additional funding.
- 8.1 The indicative DHSC spend profile to support the delivery of the Activities (the "**Spend Profile**") is as follows:

Period	Spend Profile
Year 1 of Programme (UK FY 2023/24)	Up to £8.7m
Year 2 of Programme (UK FY 2024/25)	Up to £10m
Year 3 of Programme (UK FY 2025/26)	Up to £10m
Year 4 of Programme (UK FY 2026/27)	Up to £10m
TOTAL	£38.7m

8.2 The Spend Profile reflects the schedule of work as presented in Annex A. It is indicative only and may be amended, dependent on actual expenditure, need and availability of funds. Payments will be scheduled by mutual agreement, dependent on the investments made in EDCTP 2 and Global Health EDCTP3 activities. Should not all funds allocated to a financial year in the Spend Profile be paid out by DHSC in that year, the unspent funds will roll over and be added to the Spend Profile of the following financial year.

8.3 In line with EDCTP accounting policy and procedures, financial contributions to EDCTP programmes are made in advance. Any interest earned on the cash balance of the Contribution are credited into DHSC’s deferred income account shall be used to offset bank charges and foreign currency loses of projects funded under this MOU.

8.4 The Partner will notify DHSC of variations to the Spend Profile as soon as possible as and when this occurs.

8.5 DHSC makes no commitment to renewing or continuing funding after the term of this MoU and will not be liable for any additional cost incurred by the Partner either during or after the Funding Period.

8.6 The Partner will provide evidence to the reasonable satisfaction of DHSC that the above provisions have been met in accordance with the requirements in Annex G (Spend Profile, payment profile and reporting).

8.7 The Partner agrees and accepts that it will not apply for duplicate funding in respect of any part of the Activities or any related administration costs that DHSC is funding in full under this MOU.

8.8 The Contribution will be deposited according to the payment schedule in paragraph 8.3 in the Partner’s bank account:

[REDACTED]

9.1 The Contribution will not, unless approved by DHSC in writing, be used to meet the cost of any import, customs duties or any other taxes or similar charges, applied directly or indirectly, by national governments or by any local public authority and payable by the Partner.

9.2 The Partner may use a maximum of 10% of the Contribution to cover the indirect costs of administrative support.

- 9.3 The Partner will administer and account for DHSC's Contribution in accordance with the Partner's financial regulations and other applicable rules, procedures and practices, and will keep separate records and accounts for the arrangement. The Partner will ensure that, to the best of its ability, all goods and services financed under this arrangement will be solely used for the purposes of the Funded Activities and any future arrangements made under this initiative.
- 9.4 DHSC is providing the Contribution without expectation of services to be supplied to DHSC and therefore considers payments made to the Partner to implement the Activities to be outside the scope of VAT.
- 9.5 Any unspent funds remaining at the scheduled end of the Funding Period, must be returned to DHSC within 90 days of the end of the Funding Period, unless specifically decided between the Parties, in advance and in writing.

SECTION 10. REPORTING REQUIREMENTS

- 10.1 The Partner will provide financial reports and technical reports to DHSC in accordance with the reporting schedule at Annex G (Spend Profile, payment profile and reporting).

SECTION 11. DUE DILIGENCE

- 11.1 EDCTP as an organisation is subjected to different independent audits annually ranging from statement of expenditure audits to statutory financial statements audits. These audits are reasonable assurance engagements, which DHSC can rely on for assurance on the Partner's capacity to effectively manage this funding. Where additional due diligence questions arise that are not covered in currently documented due diligence by the UK Government or partners, the Partner will co-operate fully with any additional due diligence assessments of its own internal controls and systems.
- 11.2 In utilising the Contribution, the Partner will exercise the same care in the discharge of its functions under this MoU as it exercises with respect to the administration and management of its own resources and affairs.
- 11.3 Additionally the Partner will take the necessary steps at the commencement of the Funded Activities and at regular intervals throughout the implementation to assess the internal controls and systems of any Downstream Partners. These assessments will be shared with DHSC, upon request and should determine, relative to programme risk:
- 11.3.1 Reliability and integrity of the Downstream Partner's financial controls, systems and processes;
 - 11.3.2 Effectiveness and efficiency of their project operations;
 - 11.3.3 Procedures for safeguarding project assets, and;
 - 11.3.4 Compliance with national legislation, regulation, rules, policies and procedures

SECTION 12. DELIVERY CHAIN MAPPING

- 12.1 The Partner will maintain an up to date and accurate record of Downstream Partners in receipt of DHSC funds and/or DHSC funded inventory or assets (the “**Delivery Chain Risk Map**”). This delivery chain risk map should identify the Downstream Partners, demonstrate how funds flow from the initial source to end beneficiaries, and where relevant, the risks and potential risks along the chain.
- 12.2 The delivery chain risk map should be updated regularly by the Partner and when there are material changes to the project risk assessment and/or to Downstream Partners in the chain. As a minimum the Partner will provide DHSC with an updated delivery chain map at the following intervals: within 6 months of the commencement of this MoU; annually, as part of the annual review Process; and at the end of the project, as part of the project completion review process.

SECTION 13. ODA TRANSPARENCY AND EVALUATION

- 13.1 The Partner and DHSC acknowledge and support the requirements of the IATI Standard. The Partner will work towards applying transparency standards in line with the UK aid Transparency Guarantee and the International Aid Transparency Initiative (IATI), to the funds received from DHSC. The Partner will make substantive efforts to publish information about DHSC funding in line with relevant categories of the IATI Standard, on their own website. The Partner gives consent for this arrangement (and any subsequent amendments) and associated funding to be published on DHSC's website.
- 13.2 The Partner will provide all reasonable co-operation and assistance necessary for DHSC to meet its obligations under the International Development (Official Development Assistance Target) Act 2015 and the International Development (Reporting and Transparency) Act 2006. Such reasonable cooperation and assistance will include but not be limited to the provision of all information and data necessary for the transparent, accurate, timely and comprehensive publishing of all data on all activities related to the delivery of the Funded Activities.
- 13.3 The Partner will publish to the IATI standard on all its DHSC ODA funding within six months of the start of this MOU. DHSC expects the Party to publish to the IATI standard on all its non-DHSC ODA funding and for its Downstream Partners to publish to the IATI standard on their ODA funding. The intention of this commitment is to allow traceability throughout the delivery chain. For more details on IATI standards see: <http://www.aidtransparency.net/>.
- 13.4 DHSC may decide to commission an independent evaluation of this programme, and the Partner will provide all reasonable co-operation and assistance necessary to allow the DHSC to do so.

SECTION 14. FRAUD, CORRUPTION AND ETHICAL PRACTICES

- 14.1 DHSC and the Partner will immediately and without undue delay inform the other Party of any event which interferes or threatens to materially interfere with the successful implementation of the Activities, including Financial Impropriety. Any allegations of Financial Irregularity should be reported in the first instance to the Authority's Anti-Fraud Unit at fraudenquiries@dhsc.gov.uk and according to EDCTP's Fraud Response plan (<http://www.edctp.org/web/app/uploads/2023/10/Fraud-response-plan.pdf>).
- 14.2 DHSC and the Partner have a zero tolerance approach towards Financial Impropriety that may lead to the misuse of the Contribution and agree in principle to recover such funds. The Partner will, at first, take timely and appropriate action to investigate credible allegations of Financial Impropriety, however both Parties will fully co-operate with investigations into such events, whether led by the Partner or DHSC.
- 14.3 In the event of any credible indications that the Contribution may have been subject to Financial Impropriety, DHSC, may, at any time during the period of this arrangement and up to five years after the end of the programme, arrange for additional investigations, on-the spot checks and / or inspections to be carried out. These may be carried out by DHSC, or any of its duly authorised representatives.
- 14.4 DHSC reserves the ability to recover the Contribution that has been subject to a proven fraud and will work with the Partner to do so. Where Financial Impropriety is alleged, DHSC reserves the ability to suspend or terminate funding with immediate effect, in preference to the standard notice period and irrespective of any contractual requirements.
- 14.5 The Partner must comply with the recommendations of the Public Accounts Committee and any other expenditure controls specified by the UK Government
- 14.6 Consistent with numerous United Nations Security Council resolutions including S/RES/1269 (1999), S/RES/1368 (2001) and S/RES/1373 (2001), both DHSC and the Partner are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of DHSC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, the Partner undertakes to use reasonable efforts to ensure that none of the DHSC Contribution provided under this MoU is used to provide support to individuals or entities associated with terrorism.

SECTION 15. SAFEGUARDING

- 15.1 The Parties have a zero tolerance for inaction approach to tackling sexual exploitation, abuse and harassment ("SEAH")¹. This means the Partner and its Downstream Partners will take all reasonable steps to prevent SEAH by of any person linked to the

¹ See UNGA Resolution A/RES/73/148 for the definition of sexual harassment and UNSG Bulletin ST/SGB/2003/13 for the definition of sexual exploitation and abuse. Both definitions are included in the DAC Recommendation on Ending Sexual Exploitation, Abuse, and Harassment in Development Co-operation and Humanitarian Assistance: Key Pillars of Prevention and Response.

delivery of this MOU by both its employees and any Downstream Partner and respond appropriately when reports of SEAH arise. The Partner will apply the IASC Six Core Principles Relating to Sexual Exploitation and Abuse and the following principles and practices when implementing the activities under this arrangement and provide evidence to demonstrate this where required:

- 15.1.1 Adherence to the IASC-Minimum Operation Standards on “Protection from sexual exploitation and abuse by own personnel” and/or the SEA elements of the Core Humanitarian Standard on Quality and Accountability;
 - 15.1.2 A victim/survivor-centred approach² to SEAH issues;
 - 15.1.3 Strong leadership and signalling on tackling SEAH;
 - 15.1.4 Make all reasonable efforts to address gender inequality and other power imbalances;
 - 15.1.5 Reporting to enhance accountability and transparency;
 - 15.1.6 Ensure that SEAH standards from this arrangement are reflected in funding templates with Downstream Partners.
- 15.2 The Partner will adhere to the following reporting requirements:
- 15.2.1 The Partner will promptly contact through written notice to ODAsafeguardingconcerns@dhsc.gov.uk to report any allegation credible enough to warrant an investigation of SEAH related to this MOU;
 - 15.2.2 The Partner should also promptly report to ODAsafeguardingconcerns@dhsc.gov.uk any allegation credible enough to warrant an investigation of SEAH that are not directly related to this MOU but would be of significant impact to the partnership with the Authority.
- 15.3 The report, as referred to in paragraph 15.2.1 and 15.2.2, will indicate: relevant DHSC Reference for the MoU, nature of the alleged misconduct, date of alleged misconduct, date of first report to Partner, location (as/if specified by Partner), involvement of Partner, state of affairs concerning the investigation and the action that will be taken by the Partner, and whether the case is referred to law enforcement. The organisation will provide updates on the status of the case. The notice will be given in writing and delivered to the point of contact mentioned in paragraph 15.2.1 and 15.2.2.
- 15.4 It is understood and accepted that the Partner’s arrangement to report on SEAH is subject to not compromising the safety, security, privacy and due process rights of any concerned persons.

² A victim/survivor centered-approach is one for which the victim/survivor’s dignity, experiences, considerations, needs, and resiliencies are placed at the center of the process, from the initial program design to investigating and responding to potential incidents. Consistent with the UN Protocol on Allegations of SEA Involving Implementing Partners, the victim/survivor should be informed, consulted during the decision-making process, and provide consent on the possible use and disclosure of their information. Those interacting with the victim/survivor and/or handling information regarding the allegation will maintain confidentiality, ensure safety of the victim/survivor, and apply victim/survivor-centered principles which are safety, confidentiality, respect, and non-discrimination. When the victim/survivor is a child, the approach will consider the best interests of the child and engage with the family/caregivers as appropriate. Staff and partners should comply with host country and local child welfare and protection legislation and international standards, whichever gives greater protection.

- 15.5 When the Partner becomes aware of reasonable suspicions, or complaints of SEAH, the Partner will, take reasonable, swift and appropriate action to stop harm occurring, investigate and report to relevant authorities (for criminal matters), as appropriate and when safe to do so, after considering the wishes of the survivor.
- 15.6 DHSC or any of its duly authorized representatives may, at all times, carry out reviews or evaluations or other assessment measures to verify the Partner's zero tolerance for SEAH. The Partner will fully cooperate with DHSC or any of its duly authorized representatives or agents to carry out such control measures.

SECTION 16. PROCUREMENT BY THE PARTNER

- 16.1 The Contribution may be used to purchase goods and services required for the Activities, in accordance with the Partner's regulations, rules, policies, procedures and directives.
- 16.2 Any Programme Funded Assets, specifically identified to be procured for the delivery of the Activities, will be operated and controlled by the Partner for the duration of the Funding Period. The Partner will be accountable to DHSC for the appropriate use and control of these assets, in line with the Programme's objectives. The Partner will establish and maintain an inventory of all Programme Funded Assets and provide it to DHSC in line with Annex G (Payment and Reporting Schedule), and within 5 Working Days of being requested to do so. Ultimate ownership of project assets, after Programme completion, will be decided in writing by all Parties.
- 16.3 For each entry in the inventory the following particulars must be shown where appropriate:
- a) date of acquisition;
 - b) description of the Asset;
 - c) cost, net of recoverable VAT
 - d) location of the Asset;
 - e) serial or identification numbers;
 - f) location of the title deeds;
 - g) date of any Disposal;
 - h) depreciation/amortisation policy applied;
 - i) proceeds of any Disposal net of VAT; and
 - j) the identity of any person to whom the Asset has been transferred or sold

SECTION 17. HEALTH, SAFETY AND SECURITY

- 17.1 The Partner is responsible for all security arrangements in relation to the Programme including the health, safety and security of any person employed or otherwise engaged as part of the Programme, including those employed or engaged by any Downstream Partners.
- 17.2 The Contribution cannot be used to fund any insurance premiums intended to cover medical expenses, injury or disablement, and death unless, by exception, explicitly agreed in writing in advance.

SECTION 18. VARIATION

- 18.1 This MoU, including the Annexes, may only be varied by written agreement between the Parties and approved by the authorised Representatives as given in Annex D (authorised representatives and address for service of notices).
- 18.2 Should DHSC request work to be completed over and above the services described in Annex A (activities) then both Parties will negotiate in good faith to ensure the Partner is fairly compensated for any agreed additional work undertaken.

SECTION 19. LIAISON BETWEEN THE PARTIES

Formal contact between DHSC and the Partner as Parties to this MoU will be through the Representatives.

- 19.2 The Representatives are duly authorised to send and receive notices under this MoU at the addresses specified in Annex D (Authorised Representatives and addresses for service of notices).
- 19.3 Either Party may change the Representative any time by notifying the other Party in writing.
- 19.4 The Representatives will:
- 19.4.1 meet at least twice a year at a time and place to be mutually agreed to review the Activities carried out under, and the operation of, this MoU and to address any issues arising from this MoU;
 - 19.4.2 provide assurance to the Parties that the Activities agreed between the Parties are being undertaken and that work is proceeding in accordance with the Principles; and
 - 19.4.3 document key decisions in writing.
- 20.1 Except as otherwise provided in this MoU, each Party will bear its own costs and expenses incurred in complying with its commitments under this MoU.
- 20.2 DHSC will not be responsible for the activities of any person, organisation or company engaged by the Partner with respect to the Programme or this MoU, nor will DHSC be responsible for any costs incurred by the Partner or its agencies in terminating the engagement of the aforementioned persons, organisations or companies.
- 20.3 The Partner will be solely responsible for the implementation of the Activities and the administration of the Contribution in accordance with the terms of this MoU. No liability will attach to DHSC in that regard.
- 21.1 The Partner will seek written consent from DHSC before using any third party to perform any of the Activities, which DHSC will have the right to grant or deny.

- 22.1 Any Intellectual Property Rights developed in all material (including, but not limited to, reports, data and designs, whether or not electronically stored) produced by the Partner or its personnel, members or representatives in the course of this Programme (the “**Material**”) will be the property of the Partner.
- 22.2 Subject to any third-party arrangements for the purposes of implementation of the Programme, the Partner will seek to grant to DHSC a non-exclusive, worldwide, royalty-free license to use and reproduce the Programme outputs for non-commercial purposes. The grant of any such license will be considered in good faith on a case-by-case basis and will be subject to a written agreement between the Parties.
- 22.3 In signing this MOU the Partner hereby grants to DHSC a worldwide, non-exclusive irrevocable and royalty-free licence to use all the Material, where “**use**” will mean, without limitation, the reproduction, publication and sub-licence of all the Material and the Intellectual Property Rights therein, including the reproduction and sale of the Material and products incorporating the same, for use by any person or for sale or other dealing anywhere in the world.

SECTION 23. FREEDOM OF INFORMATION AND VISIBILITY/ACKNOWLEDGMENT Each Party will provide to the other Party any information relevant to the Activities that may be reasonably requested by the other, subject to any confidentiality constraints, safeguards and statutory rules on disclosure. Each Party will consult the other Party before making to any third party any disclosures of information under the Freedom of Information Act 2000.

- 23.2 The requirements below are subject to any government requirements as to transparency which may apply to either Party from time to time.
- 23.3 The Parties will not make any announcement or other disclosure concerning the contents of this MoU or the Activities without the prior written consent of the other Party (such consent not being unreasonably withheld or delayed), except as required by law, any governmental or regulatory authority, any court, or any other authority or competent jurisdiction.
- 23.4 Where a formal public statement, press release or other publicity in relation to the initiative is required, the Parties will work together to ensure that the publicity statements are coordinated. DHSC will however be responsible for handling media inquiries relating to the Activities.
- 23.5 Neither Party will use the name, logo, trademarks or other brand collateral of the other Party without the owning Party’s prior written consent. DHSC’s contribution will be acknowledged as ODA funding and as such ODA communications guidance, as updated from time to time, will apply.

SECTION 24. CONFIDENTIAL INFORMATION Each of the Parties understands and acknowledges that it may receive or become aware of Confidential Information of the other Party (which may include information where the other Party owes a duty of

confidence to a third party) whether in the course of the performance of the Activities or otherwise.

- 24.2 Except to the extent set out in this paragraph 24 or where disclosure is expressly permitted elsewhere in this MoU, each Party will treat the other Party's Confidential Information as confidential and safeguard it accordingly (which will include complying with any protective markings on documents and instructions supplied by the other Party). In particular, neither Party will do anything that may place the other in breach of a duty of confidence owed to a third party. A Party in receipt of Confidential Information from the other Party will not disclose such Confidential Information to any non-Crown Body without the consent of the other Party.
- 24.3 The obligations of confidentiality in this paragraph 24 (Confidential Information) will continue in force until the information ceases to be confidential in nature.

SECTION 25. PROTECTION OF PERSONAL DATA The parties will duly observe all its obligations under Data Protection Legislation and comply with the applicable laws, regulations, orders and codes of practice from time to time in force relating to data protection.

- 25.2 Where the Partner controls or otherwise has access to third party sensitive information to which the DHSC reasonably requires access to enable it to pursue agreed activities, the Partner agrees to provide the DHSC with such information in accordance with the terms of the Partner's Information Management Policy (<http://www.edctp.org/web/app/uploads/2018/06/EDCTP-Privacy-Policy-May-2018.pdf>) and the terms of any agreement on information sharing concluded between the Parties.
- 25.3 The Partner accepts that DHSC, its employees, agents and contractors may use personal data from the Partner about the Partner's staff, officers, volunteers, partners and/or participants in the Activities, once consent from the individual has been sought and given, in order to administer, monitor and evaluate the Programme, and to exercise DHSC's rights under this MoU.
- 25.4 The Partner accepts that DHSC may share information about the Activities, the Partner and any personal data from the Partner within the UK Government, once consent from the individual has been sought and given so that such information may be uploaded to the Government grants or IATI databases where third parties may search the information.

SECTION 26. RESOLUTION OF DISPUTES Any dispute between the Parties arising out of or in connection with this MoU will in the first instance be resolved amicably between the Parties through the Representatives and, if no resolution is reached, escalated to the following senior personnel (at Director level):

- 26.1.1 For DHSC: Dr Val Snewin, Head of Global Health Research Partnerships

26.1.2 For the Partner: Mr Abdoulie Barry, Acting Executive Director and Director of Finance and Administration

26.2 If the matter cannot be resolved by the senior personnel specified in paragraph 26.1 within the lifetime of this MOU, the matter may be escalated to the Secretary of State for Health and Social Care for resolution.

SECTION 27. TERM AND TERMINATION This MoU will commence on 08-Dec-2023 | 5:02 PM GMT (subject to earlier termination on the provisions of this MoU) and will continue until the conclusion the Global Health EDCTP3 programme. This period may be extended by the mutual written agreement of the Parties.

27.2 This MoU may be terminated by either Party at any time by giving written notice to the other Party's Representatives as set out in Annex D (authorised Representatives and addresses for service of notices).

27.3 A Party terminating this MoU will give as much notice as reasonably possible and will offer all reasonable assistance to ensure:

27.3.1 an effective handover of Activities, if the Activities are not concluded at the time of termination, and

27.3.2 to mitigate the effect of termination on the other Party by fully co-operating with the other Party in order to achieve an effective transition without disruption to operational requirements.

27.4 Both Parties will at first negotiate in an attempt to resolve any issues that might arise during the Programme. All remaining funds in the Contribution other than those irrevocably committed in good faith before the date of termination, in line with the Activities and approved between the Parties as being required to finalise activities, will be returned to the DHSC.

27.5 If DHSC becomes concerned that the provisions of this MOU have not been fulfilled by the Partner, or if any activities occur which in DHSC's opinion will significantly impair the development value of the Programme, DHSC will discuss with the Partner and form an assessment. DHSC may then take any of the following actions:

- a) Signal a possible future response
- b) Delay or reduce the applicable funding comprised in the Contribution
- c) Stop aid under the termination provisions set out within this MoU

27.6 The Partner will, in a timely manner, inform DHSC of any delays, obstructions or events which, in the opinion of the Partner, interfere or threaten to interfere with the successful implementation of any part of the Programme. In the event that DHSC reasonably believes that timely and appropriate corrective action has not been taken to remove the delay or obstruction, it may request consultations at senior level between DHSC and the Partner and, where applicable and appropriate, the relevant authorities of the government in the country or region in which the Programme is implemented to determine the appropriate action to ensure that the Programme achieves the results as

defined in Annex A.

- 27.7 Notwithstanding any other provisions of this MoU, DHSC may immediately terminate this MOU by written notice to the Partner in the event that there is proven fraud in relation to the Activities and / or the Contribution.

SECTION 28. FINANCIAL CONSEQUENCES OF EXIT FROM THE MOU BY AN INDIVIDUAL PARTY

On termination of this MoU, a financial adjustment will be agreed according to the principle that DHSC will only be obliged to pay for Activities performed in accordance with the provisions of this MoU up to the date of termination (and upon request at any time, the Partner will provide a final report detailing the Activities it has performed).

- 28.2 Where DHSC has paid any Contribution in advance, the Partner will promptly repay amounts it has received which for Activities it has not performed (such amounts to be agreed with DHSC based on the final report provided further to the above paragraph 28.1).

SECTION 29. REVIEW AND AUDIT OF THE MOU

In addition to the regular review meetings to discuss performance in accordance with paragraph 19.4, whenever substantial changes occur to the policies, external relationships and structures of the Parties concerned. Any changes to this MoU will only be effective if set out in writing and signed by both Parties.

- 29.2 Each Party will keep and maintain until six (6) years after termination of this MoU full and accurate records of the Activities and all sums received in respect thereof. Each Party will on request afford the requesting Party or their Representatives such access to those records as may be requested in connection with the MoU or as otherwise required in connection with audit requirements (including, without limitation, audit by the National Audit Office).
- 29.3 In the event that an audit report of the Partner's external auditors contains observations directly relevant to the Contribution or its utilisation, the Partner will advise DHSC and provide it with a copy of the report.
- 30.1. The Partner will disseminate the results of the work funded by DHSC. Any articles which fall in scope of the NIHR Open Access publication policy must be published in accordance with that policy. Under the NIHR Open Access publication policy, in scope articles must be made immediately freely available in line with the requirements of the policy.
- 31.1 DHSC may occasionally conduct research exercises, including by way of surveys, or questionnaires, or requests for feedback, into the Partner's experience of the Contribution, and on the Partner's business needs, and other related matters. Participation in any such exercise would be confidential and voluntary, and the results will be handled in such a way that they do not identify individual respondents, unless consent is obtained or, for instance, the Partner agrees to be contacted as a case study.

31.2 For the purposes of analysing the outcome of any research, the Partner’s input may be combined with other information which DHSC has, but DHSC will do so in a way that does not affect the anonymity of the individual participants. DHSC will share any reports and findings of any such exercise on an anonymised basis with any or all of the UK Government from time to time.

31.3 Any information about the Partner and/or its business which is disclosed to DHSC in the course of any such exercise will be added to, and become part of, the Data, and the provisions of this MOU will apply to it.

SECTION 32. MISCELLANEOUS This MoU does not confer any rights on any third party. Nothing in this MoU will be interpreted as limiting, superseding, or otherwise affecting any Party’s normal operations in carrying out its statutory, regulatory or other duties. This MoU does not limit or restrict any Party from participating in similar activities or arrangements with other entities.

32.2 DHSC will have no obligation to incur any further fees under this MoU, nor will the Partner be required to perform additional Activities unless and until this has been agreed in writing.

32.3 This MoU will be governed by and construed in accordance with English law. Each Party agrees to submit to the exclusive jurisdiction of the courts of England and Wales.

SIGNATORIES

The duly authorised representatives of the Parties affix their signatures below.

Signed for and on behalf of DHSC

Signature:

Gail Marzetti

.....

Name:

Dr Gail Marzetti

Position:

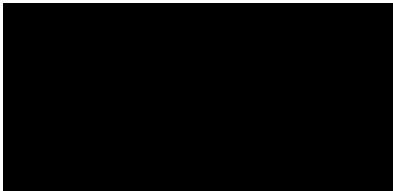
Deputy Director, Science Research and Evidence

Date:

08-Dec-2023 | 12:02 PM GMT

Signed for and on behalf of Partner

Signature:



Name:

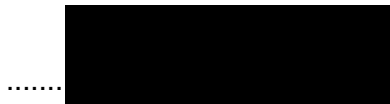
Acting Executive Director and Director of Finance and Administration

Position:

Date:

08-Dec-2023 | 4:37 PM GMT

Signature:



DHSC-EDCTP Association MOU – European and Developing Country Clinical Trials Partnership (Phase 2 and 3)

Name: [REDACTED]
Position: Operations Manager and Scientific
Adviser
Date: 08-Dec-2023 | 5:02 PM GMT