

Memorandum of Understanding (MoU)

For UKHSA and Guy's and St Thomas
NHS Trust

Date 12/01/2024

This Memorandum of Understanding (which expression shall include the Annexes) (“MoU”) is dated 12th of January 2024

Between

1. The UK Health Security Agency, an executive agency of the Department of Health and Social Care, located at 10 South Colonnade, London, E14 5EA, which expression shall include its successors in title (**“UKHSA”**) and
2. Guy’s and St Thomas’ NHS Foundation Trust, Accident & Emergency, Lambeth Palace Road, London, SE1 7EH, (**“GSTT”**).

Background and Purpose of this MOU

UKHSA wishes to carry out a study which will look at the Influenza Multiplex assay (Rapid Antigen Test) performance at detecting Influenza A/B and SARS-CoV-2 in UK population during the Influenza season 2023-24. The study will commence on the 15th of January and end on the 8th of April 2024.

To ensure operational delivery in line with the submission’s timeline, the study build upon prior cross-organisational expertise and knowledge shared between UKHSA and GSTT through the delivery of 1,000 Influenza Multiplex Assay (rapid Antigen Tests) and Influenza Multiplex Assay (RT-PCR tests).

For the essential preliminary gathering of recourses to take place immediately, the GSTT requires financial and contractual cover for an initial purchase of 1,000 Influenza Multiplex RT-PCR tests which they will be purchasing directly from the supplier and then be recharging UKHSA. In due course to ensure positive sample target for the study, upon written and agreed extension between GSTT and UKHSA, financial and contractual cover is to be extended to a further purchase of up to 1000 more Influenza Multiplex RT-PCR tests

This MoU is not intended to be legally binding and no legal obligations or legal rights shall arise between the Parties from the provisions of the MoU. However, the Parties enter into the MoU intending to honour their obligations.

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

1. Interpretation

- 1.1. Unless the context otherwise requires, references to this MoU shall be construed as a reference to this MoU as varied or amended in accordance with its terms. 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.

“Activities” means agreed activities set out in Annex A and **“Activity”** shall be

construed accordingly.

“Crown” means the government of the United Kingdom (including the Northern Ireland Executive Committee and Northern Ireland Departments, the Scottish Executive and the National Assembly for Wales), including, but not limited to, government ministers, government departments, government offices and government agencies.

“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 secrets and all personal data and sensitive personal data within the meaning of applicable legislation. Confidential Information shall 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.

“Data Protection Legislation” means (i) the UK GDPR as amended from time to time; (ii) the Data Protection Act 2018 as amended from time to time; (iii) regulations made under the Data Protection Act 2018; (iv) all applicable law about the processing of Personal Data.

“Intellectual Property Rights” means patents, utility models, inventions, trade marks, service marks, logos, design rights (whether registrable or otherwise), applications for any of the foregoing, copyright, database rights, domain names, plant variety rights, know-how, trade or business names, moral rights and other similar rights or obligations whether registrable or not in any country (including but not limited to the United Kingdom) and the right to sue for passing off.

“MoU Representatives” means the lead representatives of each Party (one to be provided by each Party), as described in paragraph 4.

“Personal Data” and **“Processing”** have the meaning given in the UK GDPR.

“Principles” has the meaning set out in paragraph 3.

“**UK GDPR**” means the General Data Protection Regulation (Regulation (EU) 2016/679) as transposed into United Kingdom national law by operation of section 3 of the European Union (Withdrawal) Act 2018, together with the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019.

2. Parties’ Responsibilities:

- 2.1. GSTT shall perform activities described in Annex A.
- 2.2. UKHSA shall reimburse GSTT [its costs and expense arising in the delivery of the activities in accordance with Annex [B] (Funding and Payment Arrangements).

3. Principles of collaboration and the Parties’ responsibilities

- 3.1. The Parties will adopt the following principles (“**Principles**”) at all times in respect of this MoU:
 - (a) the Parties will:
 - (i) be accountable to each other for performance of their respective roles and responsibilities as set out in this MoU;
 - (ii) share information, experience, materials and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
 - (iii) comply with the law and best practice, including any relevant Governmental protocols and guidance;
 - (iv) act in a timely manner;
 - (v) 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.

4. Liaison between the Parties

- 4.1. Formal contact between the Parties will be through the MoU Representatives. The MoU Representatives are:

The Authority: [REDACTED], Scientific Advisor
Diagnostic Evaluation Pipeline Review Manager at UKHSA.

The Partner/Authority: [REDACTED], Deputy Director, Centre for
Clinical Infection and Diagnostics Research, Guy’s & St Thomas’ NHS
Foundation Trust.

Either Party may change their MoU Representative at any time by notifying the

other in writing.

4.2. The MoU Representatives shall:

- (a) Review the Activities carried out under, and the operation of, this MoU and to address any issues arising from this MoU;
- (b) 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
- (c) document key decisions in writing.

5. Charges and liabilities

- 5.1. Except as otherwise provided in this MoU, each Party shall bear its own costs and expenses incurred in complying with its obligations under this MoU.
- 5.2. Both Parties shall remain liable for any losses or liabilities incurred due to their own or their employees' actions.

6. Use of Third Parties

- 6.1. GSTT may utilise third parties, to support the delivery of the Activities. GSTT will share the details of these with UKHSA for information.
- 6.2. Where the use of a third party by GSTT may incur additional costs for UKHSA (or reputational or data security risks), these should be communicated with UKHSA prior to signature.

7. Intellectual Property Rights

- 7.1. Any Intellectual Property Rights that arise from or are developed by either Party in carrying out the requirements of this MoU ("**Foreground IPR**") shall be vested in and owned by the Crown.
- 7.2. Both Parties will work together to ensure that in the performance of the Activities the use of any Foreground IPR does not infringe any Intellectual Property Rights belonging to a third party. Where use of Intellectual Property Rights belonging to a third party is required to perform the Activities or to use any Foreground IPR, the Partner/Authority 2 will use reasonable efforts to secure licences for both Parties to use any such Intellectual Property Rights on an irrevocable, royalty-free, non-exclusive basis. Where this is not possible, the Partner/Authority 2 will agree with the Authority such other means to procure the performance of the Activities and use of Foreground IPR without infringing such rights, which may include modification of the Activities to avoid infringement.

8. Freedom of Information and Communications to the Public

- 8.1. Each Party will provide to the other Party any information in its possession that may be reasonably requested by the other Party, 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 significant disclosures of information under the Freedom of Information Act 2000 and/or the Environmental Information Regulations 2004 in relation to this MoU.
- 8.2. The requirements below are subject to any Government requirements as to transparency which may apply to either or both Parties from time to time.
- 8.3. UKHSA and GSTT shall jointly be responsible for handling media inquiries relating to the Activities. Each Party shall seek the other Parties' consent before publishing any information resulting from the use of exchanged data received from the other Party. Consent shall not be unreasonably withheld and/or delayed.

9. Confidential Information

- 9.1. Each Party 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 performance of the Activities or otherwise.
- 9.2. Except to the extent set out in this paragraph 9 or where disclosure is expressly permitted elsewhere in this MoU, each Party shall treat the other Party's Confidential Information as confidential and safeguard it accordingly (which shall 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 Party in breach of a duty of confidence owed to a third party. A Party receiving Confidential information shall not disclose Confidential Information to any non-Crown bodies without the prior consent of the other Party.
- 9.3. The obligations of confidentiality in this paragraph 9 shall continue in force notwithstanding termination of this MoU.

10. Protection of Personal Data

- 10.1. The Parties shall comply with their responsibilities under the UK General Data Protection Regulations and Data Protection Act 2018 and shall not use any personal data exchanged under this MoU for any purposes which are incompatible with applicable data protection laws and regulations. No Personal data collated and/or exchanged under this MoU should be used for commercial purposes without the prior written agreement of the supplying Party (which use may be conditioned as the supplying Party sees fit).
- 10.2. Each Party must ensure that Personal Data collated or exchanged under this

MoU is not transferred outside the UK without the prior agreement of the other Party.

11. Resolution of disputes

11.1. Any dispute between the Parties arising out of or in connection with this MoU shall in the first instance be resolved amicably between the Parties through the MoU Representatives and, if no resolution is reached, referred to the following senior personnel:

- (a) **For UKHSA:** Lisa Stevens, lisa.stevens@ukhsa.gov.uk
- (b) **For GSTT:** Amy Day, Amy.Day@gstt.nhs.uk

12. Term and Termination

12.1. This MoU shall commence on the date that it is signed and (subject to earlier termination on the terms of this MoU) shall continue until the 4th of March 2024 but may be extended by the written agreement of the Parties.

12.2. This MoU may be terminated by either Party at any time by giving written notice to the other Party.

12.3. A Party terminating this MoU further to this paragraph 12 will give as much notice as reasonably possible and will offer all reasonable assistance to ensure an effective handover of Activities, if required, and to mitigate the effects of termination on the other. In particular, a Party terminating this MoU shall take reasonable steps to ensure the other Party is not put at risk of action for breach of any statutory or other legal obligations as a result of terminating this MoU. This will include compliance with the further specific handover requirements set out below.

12.4. If for any reason this MoU is terminated, the Authority may:

- (a) give such directions to the Partner/Authority 2 for the purpose of making arrangements for the handover of Activities (whether the Authority will continue the Activities itself or seek to agree replacement services with a third party); and/or
- (b) authorise another party to take over all or part of the Activities as the Authority may specify.

12.5. The Partner/Authority 2 shall co-operate fully with the Authority during any handover arising from the expiry or termination of this MoU. Such co-operation shall extend to allowing full access to, and providing copies of, all documents, reports, summaries and any other information necessary, within legal constraints, to the Authority or such other third party (or parties) authorised to take over all or part of the Activities in order to achieve an effective transition

without disruption to routine operational requirements.

13. Financial Consequences of exit from the MoU by an individual Party

- 13.1. On termination of this MoU, a financial adjustment will be agreed according to the principle that the Authority 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 termination the Partner/Authority 2 shall provide a final report detailing the Activities it has performed).
- 13.2. Where the Authority has paid any sums in advance, the Partner/Authority 2 will promptly arrange for repayment of amounts it has received for Activities it has not performed (such amounts to be agreed with the Authority based on the final report provided further to the above paragraph 13.1).

14. Review and audit of the MoU

- 14.1. Each Party shall 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 shall on request afford the other 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).

15. Miscellaneous

- 15.1. This MoU does not confer any rights on any third party. Nothing in this MoU shall 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 either Party from participating in similar activities or arrangements with other entities.
- 15.2. The Authority reserves the right to vary the requirements of the MoU should this become necessary at any time, following discussion with the Partner/Authority 2. The Parties will confirm all agreed variations in writing.
- 15.3. If any such variations require an adjustment to the Activities or the fees payable then the Parties will seek to reach an agreement on how these variations should be managed and documented. The Authority shall have no obligation to incur any further costs under this MoU, nor shall the Partner/Authority 2 be required to perform additional Activities unless and until this has been agreed in writing.

| | |
|--|---|
| Signed for and on behalf of the Supplier | Signed for and on behalf of the Buyer acting on behalf of the |
| <div></div> | |
| Date Signed: 12/01/2024 | Date Signed: 15/1/2024 |

Annex A. The Partner/Authority 2's Activities

GSTT SPECIFICATION

1. The UKHSA shall commission the study and GSTT shall manage and coordinate the study and share the produced data. The outline details of the study are as follows:

| | |
|---------------------------------------|----------|
| Estimated Start Date 20/01/2024 | |
| Length of study | 12 weeks |
| Estimated PCR tests 1000 | |
| Target unique participant sample size | 1000 |
| Weekly Uptake Rate Target (minimum) | 70 |
| Weekly Uptake Rate Target (preferred) | 85 |

2. As part of the project initiation phase UKHSA will work in partnership with GSTT on the following:

2.1. **Development of Business Case** – GSTT shall work with UKHSA to provide information including pricing, for the full study proposal to be submitted by 15th of January 2024.

2.2. **Memorandum of Understanding:** GSTT shall work with UKHSA to develop and agree a project-wide MOU to cover the full scope of the study and the final study design and detailed costings for approval by 15th of January 2024.

2.3. **Draft Data Sharing Agreement:** GSTT shall work to complete an appropriately scoped data protection impact assessment and agree a data sharing agreement for the study to allow for GSTT and UKHSA to become independent data controllers for the study outputs. As part of the data sharing agreement GSTT and UKHSA will also agree upon the roles they will perform as part of the study and data governance responsibilities.

2.4. **Reconsenting exercise:** GSTT shall provide an action/delivery plan to meet the required timeline for the proposed testing of 1000 study participants to meet the required study design sample size.

2.5. **Data Needs Analysis** – where applicable the GSTT shall work with UKHSA to ensure that both partners are able to produce the required outputs from the study. Below is an illustrative sample of organizational responsibilities in this area for ongoing development during the set-up phase:

| Need | Responsible org |
|---|-----------------|
| Acquisition of sufficient (1000 participants) Study Assay kits (both LFD and RT-PCR). | GSTT |
| Acquisition of sufficient (1000 participants) consumables and additional reagents | GSTT |
| Provision of suitable staff to perform study | GSTT |
| Multiplex LFD results: SARS-CoV-2 and Influenza A & B [Roche Diagnostics SARS-CoV-2 & Flu A/B Rapid Antigen Test and Orient Gene COVID-19/Flu A&B Ag Combo Rapid Test Cassette] Each LFD to have <ul style="list-style-type: none"> - Pos/Neg result for SARS-CoV-2 - Pos/Neg result for Flu A - Pos/Neg result for Flu B | GSTT to UKHSA |
| Multiplex RT-PCR results: CE marked, CTDA approved [RT-qPCR Roche Cobas® SARS-CoV-2 & Influenza A/B] Results to include: <ul style="list-style-type: none"> - CT value for SARS-CoV-2 - CT value for Flu A - CT value for Flu B - assay internal control data. | GSTT to UKHSA |
| Participant ID | GSTT to UKHSA |
| Date of primary tests | GSTT to UKHSA |
| Result of primary tests | GSTT to UKHSA |
| Ensure Participant Inclusion Criteria and Exclusion Criteria adhered to according to study protocol | GSTT |
| Collection of Participant demographics and symptom status/date of symptom onset | GSTT |
| Data Outputs: Collation of study data. Data submitted to UKHSA weekly | GSTT to UKHSA |
| Data analysis: statistical analysis, conclusions, reports | UKHSA and GSTT |

Annex B. Payment and Funding Arrangements

- a. The funding shall be calculated as set out in this Annex B (Payment and Funding Arrangement).
- b. Unless otherwise stated, the funding shall remain fixed and is the entire price payable by the UKHSA to Guys and St Thomas in respect of the MoU and includes, without limitation, any royalties, licence fees and supplies used by the NHS Trust, travel costs, accommodation expenses, the cost of Staff and all appropriate taxes (excluding VAT), duties and tariffs and any expenses arising from import and export administration.
- c. The charges are exclusive of VAT, which, if properly chargeable, the UKHSA shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.
- d. The UKHSA shall verify and pay each valid and undisputed invoice received in accordance with Annex B within thirty (30) days of receipt of such invoice at the latest. However, the UKHSA shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Paragraph 1.4 of this Annex B, the invoice shall be regarded as valid and undisputed for the purposes of this Paragraph 1.4 after a reasonable time has passed.
- e. Where the UKHSA raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to Dispute Resolution Procedure. For the avoidance of doubt, the UKHSA shall not be in breach of any of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Paragraph 1.5 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the UKHSA has then failed to pay such sum within a reasonable period following such determination.

- f. If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.
- g. Each Party's Study Representative shall act as the single point of contact for the other Party for any financial or strategic matters in relation to this MoU.

Funding

The following arrangement shall apply with regards to funding and payment for GSTT by UKHSA for its conduct of the specification set out in Annex A of this MoU. The following list of charges shall be claimable by GSTT as set out below.

The following funding has been agreed **(£41,528.90) (excluding VAT)**. The sum will be payable in full following the completion of the purchase by GSTT from the supplier.

Annex C – Invoicing schedule

Invoicing – General

GSTT may submit the invoice for the contract price to the UKHSA on a basis in accordance with the invoicing procedure set out in paragraph 3 below. The charges invoiced by the Supplier shall consist of those due from Annex B (Payment and Funding Arrangement).

The UKHSA's obligations in respect of payment of the Charges shall be as set out in this Annex B (Payment and Funding Arrangement).

Each invoice submitted by the Supplier must contain the relevant purchase order number (which will be provided to the Supplier by the UKHSA within 3 weeks following the Commencement Date) and be accompanied by sufficient details of the charges payable under the Invoice, as well as applicable details of the UKHSA Contract Manager, his/her telephone number and email address.

The Invoice Particulars must be clear and legible, and the items to which they relate clearly and easily identifiable.

The UKHSA may inform the Supplier of changes to the Invoice Particulars from time to time. Each invoice may be submitted electronically by the Supplier if it complies with the standard on electronic invoicing as set out in the European standard and any of the syntaxes published in Commission Implementing Decision (EU) 2017/2870.

All invoices must be submitted to Payables@ukhsa.gov.uk for payment.