

MEMORANDUM OF UNDERSTANDING ADDENDUM NOTICE

**THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (“DHSC”)
(the Authority)**

and

**FOUNDATION FOR INNOVATIVE NEW DIAGNOSTICS (“FIND”)
(the Party)**

MOU reference number 2018/031

MOU date 16 May 2018

Addendum Notice no 3

1. The Parties have agreed to vary the Memorandum of Understanding (MOU) to provide an extra £601,829 (six hundred and one thousand, eight hundred and twenty nine pounds sterling) to FIND for the delivery of the Funded Activities in the gonorrhoea project [3.1(b)], as per the terms set out in this Addendum Notice.
2. As a result, we wish to amend the MOU to extend the end date of the gonorrhoea project [3.1(b)] by 8 months (from 31 July 2021 to 31 March 2022) as set out in this Addendum Notice with effect from 1 August 2021 (“Variation Date”).
3. The Funded Activities of the substandard and falsified medicines project [3.1(c)] will be deemed closed as of 1 April 2021, as under original MOU. The Funded Activities of the connectivity project [3.1(a)] will be deemed closed as of 31 July 2021 as under the Addendum Notice No 2.
4. With effect from the Variation Date the Parties agree the following amendments to the MOU:

Revised Funding Period:	Clause 4.1 “Commencement and Period of Operation” is amended to read as follows: The Funding Period starts on 16 May 2018 and ends on 31 March 2022 unless terminated earlier in accordance with this MOU.
Revised Contributions:	Clause 5.1 of the MOU shall be amended to read as follows: DHSC will make available the following contributions to support the specified programmes and activities set out in Annex 4 (the Funded Activities): (a) a sum not exceeding £10,722,062 (ten million, seven hundred and twenty two thousand, and sixty two pounds sterling) from the DHSC Global AMR Innovation Fund to

	<p>support the aims of clauses 3.1(a) and (b). The amount will be paid in the following tranches (UK Financial Year):</p> <table border="1" data-bbox="523 300 1422 645"> <thead> <tr> <th></th> <th>Connectivity [3.1(a)]</th> <th>Gonorrhoea [3.1(b)]</th> </tr> </thead> <tbody> <tr> <td>Q1 2018/19</td> <td>£348,652</td> <td>£0</td> </tr> <tr> <td>Q3 2018/19</td> <td>£348,652</td> <td>£342,713</td> </tr> <tr> <td>Q1 2019/20</td> <td>£1,395,316</td> <td>£2,328,496</td> </tr> <tr> <td>Q3 2019/20</td> <td>£700,000</td> <td>£698,549</td> </tr> <tr> <td>Q1 2020/21</td> <td>£1,163,954</td> <td>£931,398</td> </tr> <tr> <td>Q3 2020/21</td> <td>£1,163,954</td> <td>£698,549</td> </tr> <tr> <td>Q2 2021/22</td> <td>£0</td> <td>£368,221</td> </tr> <tr> <td>Q3 2021/22</td> <td>£0</td> <td>£233,608</td> </tr> </tbody> </table>		Connectivity [3.1(a)]	Gonorrhoea [3.1(b)]	Q1 2018/19	£348,652	£0	Q3 2018/19	£348,652	£342,713	Q1 2019/20	£1,395,316	£2,328,496	Q3 2019/20	£700,000	£698,549	Q1 2020/21	£1,163,954	£931,398	Q3 2020/21	£1,163,954	£698,549	Q2 2021/22	£0	£368,221	Q3 2021/22	£0	£233,608
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Revised Funded Activities:	<p>The Funded Activities in Annex 4b of the MOU shall be amended to include the following activities:</p> <ol style="list-style-type: none"> 1. Field evaluation and feasibility studies for the <i>Neisseria gonorrhoea</i> lateral flow assay and reader. This will allow FIND to obtain more data on real-life performance of the test that can be used for the Request for Proposals for the tech transfer. 2. Screening of <i>Chlamydia trachomatis</i> antibodies. This will be the seed work for the next step towards a combination test for gonorrhoea/chlamydia. 3. New gonorrhoea antibodies test. These new antibodies were developed as a contingency plan in case the existing antibodies did not show good results. If one of the new antibodies is successful, it could be used in combination with those in the lateral flow assay to improve specificity. 4. Ongoing sample collection of vaginal swabs in South Africa. 																											
Revised Outputs/Long term Outcomes and Key Performance Indicators:	<p>The Agreed Outputs/Long term Outcomes and Key Performance Indicators in Annex 5b of the MOU shall be amended to include the following:</p> <p>Activity 1: Field evaluation and feasibility studies for the <i>Neisseria gonorrhoeae</i> (NG) lateral flow assay (LFA) and reader</p> <ol style="list-style-type: none"> a. One field evaluation performed in an low- and middle-income country (LMIC) b. One usability study for the use of the LFA reader performed <p>Activity 2: Screening of <i>Chlamydia trachomatis</i> (CT) antibodies</p> <ol style="list-style-type: none"> a. Number of relevant CT antibodies tested and identified for possible Phase 2 development of the CT/NG dual test 																											

	<p>Activity 3: New gonorrhoea antibodies tested</p> <p>a. New NG antibodies tested and identified for possible Phase 2 development of the NG LFA without reader needs</p> <p>Activity 4: Ongoing sample collection of vaginal swabs in South Africa</p> <p>b. 40 NG positive vaginal swabs samples obtained for final analytical evaluation of the NG LFA</p> <p>The overall purpose of these outputs is to deliver the following outcome:</p> <ul style="list-style-type: none"> • NG LFA developed and ready for technology transfer and manufacturing capacity • Feasibility analysis for further development of dual development of a CT/NG LFA 	
Revised Reporting Schedule:	The reporting schedule in Annex 3.1 of the MOU shall be amended to include the following:	
	Date	Requirement
	31 Aug 2021	<p>Progress report <i>Template: DHSC progress reporting</i></p> <p>Programme reporting to cover:</p> <ul style="list-style-type: none"> • Narrative of activities for 1 October 2020 to 30 June 2021 <p>Financial reporting to cover:</p> <ul style="list-style-type: none"> • expenditure reporting for 1 October 2020 to 30 June 2021 • year to date budget for 1 April 2020 to 31 March 2021 • forecast for 1 April 2021 to 31 March 2022 • include quarterly breakdown (UK financial year) <p>Payment request <i>Covering 1 August to 31 December 2021</i></p>
	31 Oct 2021	<p>End of project report for the connectivity project [3.1(a)] <i>Template: DHSC end of project reporting, as used for project [3.1(c)]</i></p> <p>Programme reporting to cover:</p>

		<ul style="list-style-type: none"> • Narrative of all activities undertaken for the whole project to 31 July 2021 <p>Financial reporting to cover:</p> <ul style="list-style-type: none"> • expenditure reporting for 1 October 2020 to 31 July 2021 • expenditure reporting and final reconciliation of budget for the whole project to 31 July 2021 <p>Annual financial audit report <i>KPMG report</i></p> <ul style="list-style-type: none"> • audited expenditure for 1 April 2020 to 31 July 2021 (16 months)
	31 Dec 2021	<p>Progress report <i>Template: DHSC progress reporting</i></p> <p>Programme reporting to cover:</p> <ul style="list-style-type: none"> • Narratives of activities for 1 July to 30 September 2021 <p>Financial reporting to cover:</p> <ul style="list-style-type: none"> • Expenditure reporting for 1 July to 30 September 2021 • Forecast for 1 October 2021 to 31 March 2022 • include quarterly breakdown (UK financial year) <p>Payment request <i>Covering 1 January to 31 March 2022</i></p>
	30 Jun 2022	<p>End of project report for the gonorrhoea project [3.1(b)] <i>Template: DHSC end of project reporting, as used for project [3.1(c)]</i></p> <p>Programme reporting to cover:</p> <ul style="list-style-type: none"> • Narrative of all activities undertaken for the whole project to 31 March 2022 <p>Financial reporting to cover:</p> <ul style="list-style-type: none"> • expenditure reporting for 1 October 2021 to 31 March 2022 • expenditure reporting and final reconciliation of budget for the whole project to 31 March 2022

	<p>31 July 2022</p>	<p>Final report for the connectivity project [3.1(a)] and gonorrhoea project [3.1(b)] <i>Template: FIND report</i></p> <p>Programme reporting:</p> <ul style="list-style-type: none"> once all data has been received from the partners, narrative of all activities undertaken, overall findings and conclusion and outlook <p>Financial reporting:</p> <ul style="list-style-type: none"> expenditure reporting for the full projects
<p>Revised Indicative Spending Profile:</p>	<p>The project budget breakdown table in Annex 7b of the MOU and Annex 7c in the Addendum Notice No 2 shall be amended to include the the project budget breakdown table in Annex A as set out in this Addendum Notice.</p>	

5. Apart from that set out in the table above, the rest of the MOU, including any previous Addendum Notices, shall remain in full force and effect.
6. Terms defined in the MOU shall have the same meaning when used in this Addendum Notice, unless defined otherwise.

Authorised to sign for and on behalf of the Secretary of State for the Authority

Authorised to sign for and on behalf of FIND

Signature

Signature

DocuSigned by:

F3EC30F0C1AC467

DocuSigned by:

B9CDC3C05BC342F

Name in Capitals:
 NICK ADKIN

Name in Capitals:
 BILL RODRIGUEZ

Position at DHSC:
 Deputy Director, Global Health Security

Position in FIND:
 Chief Executive Officer

Date 23-Sep-2021 | 4:37 PM BST

Date 23-Sep-2021 | 7:05 PM CEST

Annex A

Revised Indicative Spending Profile for the Gonorrhoea project [3.1(b)]:

USD to GBP 0.71

	Aug – Sep 21	Oct – Dec 22	Jan – Mar 22	TOTAL (Aug 21 – Mar 22)
TOTAL				£527,920.42
INDIRECT COST 14 %				£73,908.86
GRAND TOTAL				£601,829.28