Witness Name: Prof. Christopher Molloy

Statement No.: 1

Exhibits: CM/001 – CM/154

Dated: 10 April 2025

UK COVID-19 INQUIRY

DRAFT WITNESS STATEMENT OF

PROFESSOR CHRISTOPHER MOLLOY

Contents

I, Christopher Molloy, a Director and Chief Executive Officer of Medicines Discovery Catapult Limited at Block 35g, Mereside Alderley Park, Macclesfield, Cheshire SK10 4ZF will say as follows:

1 Introduction

1. I make this statement in response to a request addressed to me as Chief Executive Officer of Medicines Discovery Catapult Limited ("MDC") from the Inquiry dated 26 July 2024 made under Rule 9 of the Inquiry Rules 2006 (the "Request") asking for a witness statement in connection with Module 7 of the Inquiry.

2. I am authorised to make this statement on behalf of MDC and do so in response to the Request.

3. This statement deals with my and MDC's involvement in the UK Government Coronavirus (Covid-19) National Testing Programme (the "National Testing Programme"). Specifically, it deals with the setting up and operating of the Polymerase Chain Reaction ("PCR") testing programme that took place at laboratory sites that became known as the Lighthouse Laboratories (the "Lighthouse Labs"); an eventual network of commercial high throughput mass testing laboratories coordinated at a national level (the "Network"). This was part of the UK Government response to the Covid-19 pandemic caused by the SARS-Cov-2 virus and came under the umbrella of Pillar 2 of the National Testing Programme (namely, non-NHS PCR swab testing at mass scale). I exhibit two documents outlining the programme: Exhibit CM/001 [INQ000249515] and Exhibit CM/002 [INQ000106325].

4. I christened the Lighthouse Labs as such because of the totemic image of a lighthouse in dark and uncertain times and because light is generated and measured during the conduct of a PCR test.

5. Between March 2020 and July 2020, my role was to:

- Provide executive coordination services in relation to the setting up of the Network and to be responsible to the Department of Health and Social Care ("DHSC") for it.
- Define and maintain a purposeful, consistent and deliverable plan for the Network.
- Co-ordinate and drive Network decision-making and problem-solving.
- Co-ordinate the Network's activities across what was then 3 to 4 sites across England and Scotland, and in parallel to the laboratory provided separately in Northern Ireland by Randox.
- Be responsible to Pillar 2 for the output of the Lighthouse Labs and to the Lighthouse Labs for access to Pillar 2 resources, and
- Liaise with essential stakeholders (including, amongst others, the National Health Service ("NHS"), the Health and Safety Executive ("HSE"), various industry players, the DHSC and external supply chain providers.

I exhibit the following documents which illustrate some of the work I did in this role: Exhibit CM/003 [INQ000510875], Exhibit CM/004 [INQ000510963], Exhibit CM/005 [INQ000510964], Exhibit CM/006 [INQ000510966], Exhibit CM/007 [INQ000511022].

6. My co-ordination services were provided to the DHSC under an agreement made between it and MDC. MDC was also responsible for setting up and running the Lighthouse Laboratory at Alderley Park, Cheshire, as part of the Network, which remained in service until March 2022.

7. It follows that during my early tenure with the Network I was primarily concerned with the Lighthouse Labs at: (1) Alderley Park (MDC); (2) Milton Keynes (UK Biocentre Limited (the service arm of the UK Biobank) ("UBL")); (3) Glasgow (University of Glasgow), and (4) Cambridge (AstraZeneca ("AZ") (in association with the University of Cambridge). I exhibit an Organogram of the Lighthouse Labs as at 7 April 2020 (Exhibit CM/008 [INQ000511033]).

8. In June and July 2020, I was also seconded to the group managing Pillar 2 which I knew as the executive. The principal colleagues with whom I dealt were: Kristen McLeod CBE (my principal contact in the early months), Alex Cooper OBE (who came to lead Pillar 2), Mike Standing (a Lead Partner at Deloitte UK ("Deloitte") seconded

to the DHSC), and Dr Tom Fowler (who provided expert clinical leadership to Pillar 2).

9. In July 2020 (officially confirmed on 1 August 2020) Professor Dame Anna Dominiczak, Regius Professor of Medicine, Glasgow University, took over the co-ordination role and became Director of Lighthouse Laboratories. Under her stewardship the Network expanded with the onboarding of further Lighthouse Labs to a core of approximately 11 (including: Brants Bridge, Newcastle, IP5 (Newport), Plymouth, HSL and the Rosalind Franklin Laboratory at Royal Leamington Spa which was purpose built and commissioned by DHSC).

10. From August 2020, as CEO of MDC, my role was to maintain overall responsibility and accountability for the Alderley Park Lighthouse Lab in its delivery, contractual responsibilities and ultimately its disposal.

11. Between August 2020 and May 2021, I was also involved on a personal voluntary basis with work being done by PA Consulting (on instructions from the DHSC) in relation to the development of UK-based rapid Lateral Flow (antigen) testing and in relation to UK-developed rapid antibody testing. I chaired a series of consortia that brought together key industry and public sector stakeholders, focused on (1) the development of high-capacity UK manufacturing of lateral flow devices and (2) the domestic development of new rapid testing products. Where relevant I have included in this statement aspects of my wider and personal involvement in matters relating to testing in the UK during the pandemic. I have done so not only to provide a fuller picture, but also if it might assist the Inquiry.

12. Throughout this statement, I have endeavoured to make clear the capacity in which my evidence is given.

13. I have also been asked to carefully consider the outline scope for Module 7 in responding to the Request. It is ultimately for the Inquiry to assess the extent to which my and MDC's involvement in the National Testing Programme is relevant to its Terms of Reference. My and MDC's roles related to the delivery of one particular aspect of the emergent testing strategy rather than the formulation of the strategy itself. I do not consider that I or MDC was involved in determining the policies and strategies that were developed and deployed in relation to testing as part of the UK's

response to the Covid-19 pandemic beyond the strategic goals of the Lighthouse Labs and domestic lateral flow production. The decisions I and MDC were involved in are detailed in this statement.

14. Neither I nor MDC have any previous experience of providing evidence to a public inquiry, so I have had assistance in preparing this statement from solicitors instructed by MDC to ensure (1) that the necessary steps were taken to secure any evidence relevant to matters the subject of enquiry, and (2) to assist me in responding to the Request. However, the evidence I give in this statement is my own, and my statement has been prepared on that basis alone.

15. The facts and matters set out in this statement are within my own knowledge unless otherwise stated and I believe them to be true. Where I refer to information provided by others, I have identified the source of the information.

16. I and all my colleagues at MDC were and remain keenly conscious of the very heavy toll that the Covid-19 pandemic took on the lives of so many people in the UK, many of whom continue to suffer directly and indirectly. I wish to publicly express our condolences to those who lost and were separated from loved ones and express sympathy to those who continue to suffer because of this disease. We recognise the importance of the work being undertaken by the Inquiry and aim to assist as best we can. Everything in this statement is tendered with that intent.

17. In the time available to prepare this statement, it has only been possible for me to review and consider a limited amount of documentation. I only have access to the material held by MDC. If the Inquiry want me to consider and comment upon any specific document, I shall be happy to do so.

18. When considering my evidence, I should be grateful if it could be borne in mind that my work during the pandemic (and that of many others) took place under extreme pressure and pace that regularly involved working in excess of 16 hours a day, 7 days a week, initially for me in an unbroken period of over 100 days. This is not said to elicit sympathy, but solely to state the full and proper context in which I (and many others) made decisions and took steps with the sole intention of contributing to the national effort.

2 Qualifications and relevant experience

19. Provided with this statement is a *curriculum vitae* (Exhibit CM/009 [INQ000578186]) which summarises my relevant qualifications and experience.

20. I am a Director and Chief Executive Officer ("CEO") of MDC. Following a career in industry in international life sciences research and development disciplines, I was appointed MDC's first CEO in November 2016.

21. I am an Honorary Professor at the University of Manchester.

22. I also chair the Industry Advisory Board at the National Institute for Health and Care Research Manchester Biomedical Research Centre (NIHR MBRC).

23. I chaired the Intellectual Property Advisory Committee for the Association of Medical Research Charities (a membership organisation of the leading medical and health research charities in the UK).

24. In short (and amongst other things), I have a 30-year record in industry including at board and executive level across a range of life sciences research and development disciplines. This includes close involvement with the industrialisation of high throughput discovery based on large scale biological testing. Allied to that, I have substantial experience in how data and associated systems are used to progress high throughput testing, life science research and health records. My track-record and drive, exemplified by my current role at MDC, is to bring stakeholders together (public and private) in purposeful programmes to reshape drug discovery for patient benefit.

25. During the pandemic, I and my fellow directors had a single motivation: to offer and deploy the industrial and scientific skills we have at MDC to support the national effort in addressing the threat caused by the SARS-Cov-2 virus.

3 Some key concepts

26. I appreciate that the Inquiry will have experts in the field of testing to explain in detail the types of testing that were available and the testing methodologies. It is therefore probably sufficient for me to summarise, at the start, some key concepts that touch on our involvement.

(a) High Throughput Screening ("HTS")

27. I and MDC have significant experience in industry-class High Throughput Screening ("HTS"), that was directly relevant to the establishment and running of the Lighthouse Labs.

28. HTS is an established, industrially robust process undertaken by pharmaceutical companies worldwide. It involves the performance of single biological tests at high capacity and quality assurance that accurately tests hundreds of thousands of discreet chemicals per day as potential new drug candidates. For example, testing half a million different chemicals against one type of cancer cell. A global industry has developed over 30 years in the equipment, processes, data management and quality analysis of this activity, exemplified by the Society for Biomolecular Screening ("SBS"), European Laboratory Research and Innovation Group ("ELRIG") and others. HTS is a specialised industrial discipline performed by pharmaceutical companies, some agri-tech and contract research companies. I have been involved in, and published on, HTS since the late 1990s.

29. What the Lighthouse Labs did was test up to half a million patient samples a day for specific viral RNA. In principle therefore, it is similar to HTS in process, biological machinery, data analysis and quality assurance but, in the case of Covid-19, it was handling human samples and for the purpose of diagnostics rather than seeking a new drug for human disease.

(b) Polymerase Chain Reaction ("PCR")

30. MDC's staff have significant experience with relevant testing technologies including PCR. PCR is one of the most well-known techniques in molecular biology. It was

developed as a research tool in the 1980s and since then has become an integral part of molecular biology, with applications ranging from basic research to disease diagnostics, agricultural testing and forensic investigation. It has been routinely used by industry in HTS testing, including by members of the MDC in their former industry leadership roles.

31. PCR is not a test that is unique to detecting the SARS-Cov-2 virus. PCR is very well-established, generic technique in science that is used clinically to detect the presence of specific DNA or RNA from a variety of different viruses and cancers. PCR amplifies any DNA or RNA to a point where its sequences can be robustly and specifically detected. This is done in a laboratory using a range of sample preparation and temperature cycling machines. The PCR machine detects the virus by recognising the presence of specific combinations of viral genetic material. At the time, PCR was recognised as being the most sensitive technique to identify genetic material of SARS-Cov-2.

32. There are many types of PCR, and several methods, that can be used to deliver the technique in a test setting. When I became involved, a specific PCR test had already been identified and secured for use, namely the Thermo Fisher Quantitative Reverse Transcription PCR test ("qRT-PCR") which was FDA (U.S. Food and Drug Administration) approved. Although MDC was not involved in the decision-making as to the selection of this test, I had no reason to doubt that this was an appropriate product both in relation to the target virus (SARS-Cov-2) and in relation to its potential for use in an HTS setting.

4 Key people

33. Provided with this statement is a *Dramatis Personae* (Exhibit CM/010 [INQ000578187]), in table format, which identifies the people referred to in this statement.

34. It identifies some key people at MDC engaged in the provision of testing services to the UK Government during the pandemic.

35. It further identifies some key people with whom we dealt in relation to the set up and operation of the Network, including persons at key stakeholders such as the DHSC, the NHS, the HSE and other third-party providers including Deloitte.

36. In the following section 5, I explain what MDC is and introduce associated companies relevant to the provision of testing services to the DHSC during the pandemic.

37. In section 6, I provide a narrative overview as to what happened with a focus on the nascent stage of the Network, the co-ordination of which I was initially responsible for.

38. In section 7, I talk through each of the contractual arrangements through which services were provided by me, MDC and associated companies during the pandemic. I take each of these arrangements in chronological order.

5 MDC and relevant associated companies

(a) MDC company background and purpose

39. MDC was incorporated on 23 December 2015. Its registered office is at Block 35g, Mereside Alderley Park, Alderley Edge, Macclesfield, Cheshire SK10 4ZF.

40. MDC is an independent, not-for-profit research and technology organisation. The not-for-profit organisation ("NFPO") status means it is a company limited by guarantee (i.e. it has no shareholders) and, as such, it does not pay any dividends or distributions from any profits generated. Any surplus revenue generated by its activities must be reinvested by MDC to serve the national purpose for which it was created.

41. The Board of Directors of MDC are subject to the same fiduciary duties as any other private company and must comply with the statutory duties of the Companies Act 2006 along with good corporate governance practices.

42. MDC is one of 9 'Catapults', or national innovation centres, established, and part funded, by Innovate UK, which is part of UK Research and Innovation ("UKRI"), to undertake targeted innovation in key sectors. It is a national research technology facility whose facilities and services support the UK medicines sector. MDC's established vision (as set out in its Annual Reports) is to "*Reshape UK drug discovery for patient benefit*", delivering on its purpose to "*Transform great UK science into better treatments through partnership*". It delivers to the nation in three distinct ways: de-risking technology innovations in drug discovery, de-risking private investments in SME biotech companies and developing then running national Research and Development ("R&D") programmes. I exhibit the Annual Reports of MDC for the relevant years 2020 to 2024: Exhibit CM/011 [INQ000511394], Exhibit CM/012 [INQ000511368], Exhibit CM/013 [INQ000511369], Exhibit CM/014 [INQ000511370].

43. MDC has created a research and technology centre for the UK biotech sector at Alderley Park and a national network of contract research providers. It has improved access to ethically consented bio-samples and health data and deployed a "*syndicated*" model for multiparty international collaborations that puts patient need – and their research charities – at the heart of modern drug discovery. By way of example, MDC is running an international Psychiatry Medicines Consortium, the national R&D programme combatting antimicrobial resistance (PACE), a national R&D platform for Cystic Fibrosis, a national innovation center for intracellular drug delivery, the delivery of the Dame Barbara Windsor National Dementia Mission and the deployment to the NHS and industry of Total Body PET imaging (NPIP).

44. MDC, as with most Catapults, also delivers national and international collaborative R&D programmes relevant to their sector skills, sector knowledge and technology understanding.

45. MDC's workforce comprises clinical, industry, academic and technology experts.

(b) <u>Medicines Discovery Catapult Services Limited ("MDCS")</u>

46. MDC incorporated a wholly owned subsidiary, Medicines Discovery Catapult Services Limited ("MDCS") on 1 August 2016.

47. MDC receives some core grant funding. The grant income received from Innovate UK is subject to a multi-year Grant Funding Agreement which sets out a range of delivery and performance obligations. One such obligation is a requirement to generate independent income at commercial market rates to enhance the grant income and increase the impact which MDC can deliver in the sector in pursuit of its overriding purpose.

48. MDCS enabled MDC to meet that obligation and provided the company vehicle by which it could provide commercial services at market rates.

49. From December 2020 (by which time which the Alderley Park Lighthouse Laboratory and Network were established at cost) to its demobilisation in March 2022, it was MDCS that provided commercial testing services at the request of the DHSC.

50. MDCS was dissolved on 24 May 2024.

(c) Medicines Discovery Catapult Services Commercial Limited ("MDCSC")

51. Medicines Discovery Catapult Services Commercial Limited ("MDCSC") was incorporated in August 2021. This company is not relevant to the provision of testing services to the DHSC but was set up as part of MDC's ultimately failed attempts (in consultation with DHSC) to find a long-term private buyer for the Lighthouse Labs.

6 The provision of testing services by MDC - a narrative overview

(a) First involvement - 19 March 2020

52. My first involvement in the response to the pandemic was when I placed MDC at the service of key national stakeholders.

53. On 19 March 2020 at 09:12, I emailed (Exhibit CM/015 [INQ000510835]): (1) Fiona Watt, Head of Medical Research Council ("MRC"); (2) Louise Wood, Head of National Institute for Health and Care Research ("NIHR"); and (3) Professor Sir John Bell, then

Regius Professor of Medicine at University of Oxford (now President of the Ellison Institute of Technology, Oxford). I had confidence that each of these must have been engaged with the UK Government in relation to the pandemic response.

54. Shortly after my email on 19 March 2020, I received a call from Sir John. During this call, I was asked if I could assist the DHSC with the National Testing Programme by creating industry-scale qRT-PCR testing capability that could augment the capacity of Public Health England ("PHE") and the NHS.

55. I recall being told that PHE could not directly support the number of tests that would be needed to respond to this national emergency - perhaps only able to produce 8,000 tests per day where the aim was to be conducting tests in quantities ten times greater or more.

56. Sir John knew my background and experience in HTS. MDC knew all the right players in the industry to be able to support the testing programme. We had contacts in academia, universities, research institutes, our own core team at Alderley Park, and AZ who were still performing HTS at the Alderley Park site for their own projects. I knew we had access to the relevant team that could build and scale up the testing capacity.

57. Sir John informed me during this call that UBL, based in Milton Keynes, had already been tasked with adapting and reconfiguring their facility. The leader of UBL was Dr Tony Cox OBE, whose similar preparations had been ongoing for a few days.

58. UBL were being assisted in the set-up process by the DHSC and Deloitte. My understanding was that Deloitte was assisting the DHSC centrally in several different ways. Deloitte was assisting the UBL in 'standing up' the current laboratory by organising logistics, developing processes and securing staff. I was informed that Deloitte could be called upon for a range of support activities.

59. My instruction from Sir John was that he wanted me and MDC to help set up a laboratory in the Northwest. This was a decision that had already been taken on the basis that there was a need to spread the testing capacity nationally rather than one central place for the entire nation which carried huge logistical and operational risks. Sir John wanted to 'spread the load'.

60. To set up a high-capacity, safe site in the Northwest, we would have to find a site, adapt it and convert the space into something that had a very specific purpose. Hundreds of systems, processes, supply chains and data would need to be organised. Hundreds of pieces of capital equipment and thousands of personnel with a broad array of skills would need to be mobilised. This in itself was an unprecedented effort that may never be seen again. However, a similar concept was something I had worked on 15 years previously when I was at GSK: the industrialisation of testing activity using the concept of a "HTS factory". This term simply refers to an industrial approach to high throughput screening (which I explain above at paragraphs 27 to 29) using robust infrastructure, quality, process controls and equipment in a specific location.

61. Neither I nor MDC was involved in the decision to create such mass capacity, nor the selection of the qRT-PCR test. This was a decision that was already made prior to our involvement. We played no role in policy or testing strategy. My role was to co-ordinate the design – and MDC the delivery – of high-capacity, high-quality, nationally consistent and connected labs to deliver a single qRT-PCR test.

62. There was never any intention to replace what the NHS was doing, but rather augment it with discrete, high-quality capacity. The remit here was to do just one thing at an impressive, unprecedented scale. We had to put together a production line that was automated, controlled, process driven, highly accurate and scalable. It was industrial scale, with industrial process tools and industrial quality control. This was exactly what I was asked to do.

63. Professor Peter Simpson was our Chief Scientific Officer at MDC. Professor Simpson is a career veteran in industrial science and a former Director of HTS at AZ. He had used PCR testing in HTS testing and I was confident that we already had all the directly relatable skills and experience at MDC to make this work. It was the right application of the right people.

64. I asked Sir John what was already in existence in terms of assets i.e., what physical assets do we already have in the nation to give to this effort. Sir John said there were *circa* 6m individual Thermo Fisher qRT-PCR tests secured.

65. It was explained to me that the technicalities of the test enabled it to identify 3 distinct elements of the SARS-Cov-2 virus' genetic material. The existing Covid-19 PCR tests (manufactured by Roche) that were being used in many NHS labs were only identifying 2 elements of the virus. After explaining the nature of the Thermo Fisher qRT-PCR test, it appeared a valid choice. I was not asked for my opinion on the adequacy of the test, but I was comfortable that it was appropriate.

66. It was also important that the Thermo Fisher qRT-PCR test was not a test that was commonly used across the NHS. This is of paramount importance as, during the response to the pandemic, we had to ensure that individual NHS laboratories' supply of Covid-19 PCR tests and its associated consumable items would not be compromised or cannibalised by the high-capacity labs. In simple terms, if the industrial scale testing intended to be undertaken by our work used the same PCR tests as a large number of NHS facilities (such as the Roche test kit), we would be targeting the same equipment, materiel and consumables required by the NHS. The aim was to develop and deliver Covid 19 PCR test capacity alongside the NHS to augment capacity, not to undermine it. In the build phases of the Lighthouse programme we were occasionally approached by NHS colleagues for access to materiel we had in stock and they could use, and were pleased to be able to supply them.

67. After a short consultation with my senior team and Chairman at MDC, I responded by email at 12:21 (Exhibit CM/016 [INQ000510836]) to Sir John to confirm that MDC was willing to assist and that we would start finding space to create a lab in the Northwest, collate extendable groups of lab staff, and liaise with the regional stakeholders.

68. At 12:49 (Exhibit CM/016 [INQ000510836]), Sir John replied advising that he had a list of relevant PCR testing machines in the country and that Thermo Fisher would send this through. He copied in Kristen McLeod, Sir Jeremy Farrar and Claire Wallace.

69. Kristen McLeod CBE, then Director of the Office for Life Sciences ("OLS"), became the Senior Responsible Officer for Pillar 2 of the National Testing Programme. I knew

Kristen McLeod from my MDC dealings and I knew her responsibility was in part to develop and deliver Covid-19 PCR capacity alongside the NHS to augment capacity.

70. Sir Jeremy Farrar was the head of the Wellcome Trust. It was clear at that point that he had offered to use Wellcome's network to provide access to testing machines deployed in academic laboratories across the UK should they be needed. At 16:39, I emailed Sir Jeremy (Exhibit CM/017 [INQ000510837]). I was put in contact with individuals at Wellcome Trust who were preparing to source these capital assets from the academic community that would form the core of the materiel capacity.

71. Claire Wallace was a Thermo Fisher employee, based in Glasgow, and was the designated corporate contact point for the Thermo Fisher UK Covid PCR programme.

(b) Setting up the site at Alderley Park

72. The first challenge we had with setting up a laboratory was finding the space to do it. Alderley Park is a world leading science technology park where MDC has its premises. However, MDC had no existing laboratory space suitable for clinical diagnostic testing at its premises at Alderley Park.

73. I called Marcus Harrison (Chief Operating Officer ("COO")) and Professor Simpson at MDC and asked them to assist with investigating space at the University of Manchester. I called Professor Dame Nancy Rothwell, Vice Chancellor of the University of Manchester, and Professor Graham Lord, Head of Faculty of Medicine at the University of Manchester, to see if they could assist with resources and space. Marcus Harrison visited and reviewed the University-owned spaces that could have been practicable for conversion Exhibit CM/018 [INQ000510838]. Professor Simpson reviewed the non-MDC facilities at Alderley Park, under the management of Alderley Park Ltd, a subsidiary of the property developer Bruntwood Ltd.

74. At Alderley Park, there was an empty block, which was a mix of office and lab facilities. Given the urgency and based on the investigations conducted, I formed the view in consultation with colleagues (and within 24 hours) that adapting this space and its facilities would be the preferred option. The Alderley Park site was made

immediately available and presented a feasible and practicable option for rapid delivery.

75. At 22:46 on 19 March 2020 (Exhibit CM/019 [INQ000511374]), I emailed Kristen McLeod and Claire Wallace to advise that we had made fast progress on options for space and staff in Manchester. Within this email I asked for access to the contacts at Milton Keynes and Glasgow.

76. Kristen McLeod replied at 23:01 (Exhibit CM/019 [INQ000511374]) to put me in touch with Ed Whiting (then Director of Strategy at the Wellcome Trust), Ed Blandford (OLS) and Kevin Tsang (Deloitte) for an update on the latest plan.

77. I exhibit documents that illustrate the sort of planning work that was shortly undertaken to assess the site at Alderley Park (Exhibit CM/020 [INQ000510854], Exhibit CM/021 [INQ000510844], Exhibit CM/022 [INQ000510865], Exhibit CM/023 [INQ000510867], Exhibit CM/024 [INQ000510868], Exhibit CM/025 [INQ000510866]) and consider the testing that would be undertaken (Exhibit CM/026 [INQ000510882]).

(c) Co-ordination role appointment – 21 March 2020

78. On 21 March 2020, at 21:49 (Exhibit CM/027 [INQ000510846]), I received an email from Kristen McLeod expressing thanks that I had offered to Ed Blandford (OLS) to step up and take on a co-ordination role for the three planned centres. At 22:50 (Exhibit CM/027 [INQ000510846], I received an email from Kristen McLeod formally asking me to take on the national co-ordination role and that the OLS and Deloitte staff would report to me. This is what became known as the Network.

79. My role as coordinator of the Network required constant communication, liaison, planning and decision-making with a broad variety of stakeholders in the Lighthouse Labs Network, commercial third parties, national, regional and laboratory host organisation stakeholders and the National Testing Programme. I saw my role as being one of an enabler: maintaining a strong guiding purpose, bringing diverse skilled teams together and providing energetic direction.

(d) Setting up the site in Glasgow

80. Within the first 48 hours there were conversations by telephone around setting up a site in Scotland. Those conversations were with Kristen McLeod, Sir John and with representatives at the Prime Minister's Office, so far as I recall, principally Dr William Warr OBE, former senior health policy adviser to the Prime Minister.

81. On 22 March 2020, I began discussions by telephone with the Scottish Government via its Chief Scientist (Health) based in Edinburgh, Professor David Crossman, to establish a suitable facility in Scotland. We had extensive telephone discussions around what we were building in Alderley Park and Milton Keynes and what the Scottish site would need in terms of equipment, assets and industry-experienced people.

82. It was agreed that the Glasgow University Hospital would be the new site (Exhibit CM/028 [INQ000510900]. Sponsorship of this site was ably given by Professor Dame Anna Dominiczac, the Regius Professor of Medicine at Glasgow University. Executive leadership for this site was then drawn from similar industry-class experience volunteered and deployed under Dr Phil Jones from both BioAscent Ltd (a Scotland-based contract pharmaceutical research services company) and industry-experienced staff from the University of Dundee.

83. I coordinated discussion across the experienced teams at MDC and UBL. This led to the decisions as to how we were going to set up and run the HTS in relation to the qRT-PCR Thermo Fisher test.

(e) The following three weeks

84. At the point I became responsible for the co-ordination of the Network, I delegated the establishment of the specific Alderley Park Lab to Professor Peter Simpson. He picked up oversight of test requirements/facilities/what the testing regime would constitute and standard equipment requirements. Marcus Harrison was asked to assist him on its operational set up.

85. At this point, site heads were in place, Professor Peter Simpson for Alderley Park, Dr Tony Cox OBE for Milton Keynes and Dr Phil Jones for Glasgow. I was also given access to a small group of Deloitte staff who had been allocated to Pillar 2, and who were working primarily at that time for or at UBL.

86. The network was originally coordinated by me, through leaders at each of the three sites, and I reported through to Pillar 2, at a minimum daily. I reported principally by telephone. Initially and during the first months I reported to Kristen McLeod CBE. Alex Cooper OBE then came to lead Pillar 2. I also interacted with Mike Standing on some matters, such as the allocation of equipment across the labs and also in relation to matters being dealt with by his Deloitte team for Pillar 2. Cross-site decisions were collective, and responsibilities were clear as practicable under the circumstances.

87. The partnership between UBL, Glasgow and MDC was based upon collective decision-making and close peer-to-peer interaction. The parties contracted separately with DHSC but recognised my co-ordination role and accountability to Pillar 2 on their behalf. As I will describe in detail later in this statement, the NHS were involved in the development, quality assurance and clinical oversight of the Network from its inception and daily. Before any samples were tested, we received input and guidance from NHS laboratory operational leaders/advisors and a range of national and regional virology and pathology leaders who became clinical leads for each lab. The sites were examined by NHS teams before clinical samples were run and back-to-back sample confirmation testing was performed alongside NHS labs. Our analytics systems were kept under permanent review and optimisation by these clinical leads.

88. At that early stage, the process of establishing the Network involved pulling together a multi-disciplinary team of experts to assist with the rapid expansion of the National Programme across multiple UK sites. My growing team and I worked to identify further individuals with expertise in clinical screening, infectious disease, technology, facilities management and a range of other disciplines. We pulled these individuals together from the NHS, academia and commercial organisations which we felt could assist. We also intended to train and deploy experienced volunteers into the operation.

89. This scaling needed to be done at exceptionally high speed and was unprecedented in the UK diagnostics industry. Each of the Milton Keynes, Alderley Park and Glasgow

Lighthouse Labs were established from concept to first clinical test in only three weeks. I cannot emphasise enough the unique pace and scale of this undertaking. To accommodate such an increase in testing required, amongst other things, drastic increases in building lab infrastructure, recruitment of a substantial number of additional personnel, extensive supply chain management, sourcing, relocation and commissioning over 400 pieces of capital equipment loaned by the UK bioscience community, constant liaison between stakeholders in the testing process and the identification of individuals with the particular expertise to assist our initiative in continuing smoothly and successfully at pace. All of this was done with a focus on delivering high quality clinical testing to provide UK citizens and government with accurate data. Alongside this was the parallel development of a sample logistics and delivery system that would provide millions of human samples of unknown infectivity to the labs across the country.

90. Although PHE were not actively involved in the Lighthouse Labs testing, I was in regular communication principally by telephone and sometimes by email with PHE leadership regarding issues such as the efficiency and safety of swab transport medium, viral inactivation (See paragraph 183) and with the team at the Defence Science and Technology Laboratory, Porton Down ("Porton Down") who maintained a PCR capacity throughout the pandemic and were also responsible for the validation of rapid tests.

91. Despite the many challenges, unknowns and risks, I and others took on this project understanding its importance to the UK and the need to build high quality testing capacity as quickly as possible to save lives, provide national health systems with accurate information and to allow the public to make decisions on their own health and for those they cared for.

92. It must be accepted that the whole process I've described was absent of the typical, formal mechanisms that might ordinarily relate to an undertaking of this scale and nature if made outside a response to national crisis, but the challenge was presented at a time of national need and, for our part, it had to be met.

93. Without hesitation MDC and its local partners in the Northwest took significant risk in embarking on this mission. People, facilities, capital and cash were released to

provide rapid action in setting up a High Throughput PCR facility at Alderley Park, trusting that these unbudgeted and significant expenses would be reimbursed at some point. We were instinctively willing to do this as part of our national service and remain convinced that timeliness was of more importance than bureaucracy.

94. In the event, all costs incurred in relation to the set-up of Alderley Park (apart from the supply of Thermo Fisher PCR reagents) were incurred by MDC itself. These set-up costs amount to in excess of £1.5m and were not reimbursed by the DHSC until 27 April 2020. During this period MDC and other Lighthouses were effectively resourcing the national testing response. Inevitably with such a complex project funding issues arose from time to time: (Exhibit CM/028.1 [INQ000510983], Exhibit CM/029 [INQ000511103], Exhibit CM/030 [INQ000511209], Exhibit CM/031 [INQ000511228]).

(f) Professor Dame Anna Dominiczac appointed – 1 August 2020

95. In July 2020 (and I think officially confirmed on 1 August 2020), the Network was co-ordinated by Pillar 2 through my successor Professor Dame Anna Dominiczac, who was employed by the DHSC.

(g) Testing targets

96. MDC had no part in setting national testing targets - including the 100,000 per day target for April 2020 - for, or with, the UK Government. The target was a totemic objective set for the programme. The Lighthouse Labs were a tool of national delivery and sought to respond to demand as it was expressed and amended by the National Testing Programme and its modelling. My co-ordination role was to make the National Testing Programme aware of the constraints and to scale and manage the Network within those constraints to meet those demands safely. The key constraints were: (1) Extant testing capacity at a given point in time relative to a testing target; (2) Demand forecasting (essentially trying to predict and manage the number of tests that would be taken by the population at any one time or place and the variables affecting that); (3) Logistics (the volume of samples, their location and their transportation to the

respective Lighthouse Labs); (4) The availability and supply of materiel (including key equipment and consumables); (5) Variable sample inputs and the deleterious effect of these on increasing capacity at scale (See further, paragraphs 171 to 175).

97. To illustrate the above I exhibit the following documents: (1) Examples of DHSC capacity communications and submissions to the Secretary of State copied to me (Exhibit CM/032 [INQ000511069], Exhibit CM/033 [INQ000511070], Exhibit CM/034 [INQ000511183], Exhibit CM/035 [INQ000511185], Exhibit CM/036 [INQ000511291], Exhibit CM/037 [INQ000501913], Exhibit CM/038 [INQ000511296]; (2) An email from May 2020 in which I asked to see the DHSC longer term capacity modelling (I was not ordinarily party to it) Exhibit CM/039 [INQ000511196]; (3) An email to Pillar 2 where I provide some high level views on capacity in relation to the Lighthouse Labs (Exhibit CM/040 [INQ000511239]); (4) Example of DHSC Laboratory Capacity Programme Board Minutes (Exhibit CM/041 [INQ000511250], Exhibit CM/042 [INQ000511251]); (5) Example DHSC presentation looking at the performance of the Lighthouse Labs that was provided to me (Exhibit CM/043 [INQ000511299], Exhibit CM/044 [INQ000511300]).

7 The provision of testing services by MDC – the contractual arrangements

(a) Contract between MDC and DHSC dated 21 April 2020

98. An agreement for the provision of Covid-19 testing services was recorded in a contract between MDC and DHSC dated 21 April 2020 (the "April 2020 Agreement") (Exhibit CM/045 [INQ000511055]) (Exhibit CM/046 [INQ000511358]), the term of which was deemed to have begun on 1 March 2020.

99. The purpose of this contract was to formalise (1) my appointment to a national executive co-ordination role in the set up and operation of a national network of screening laboratories for Covid-19 (that would become the Lighthouse Lab Network), and (2) MDC's appointment to procure, build and operate one such screening facility at Alderley Park.

100. As stated above, at that time other proposed sites for Lighthouse Labs were discussed, including those at Milton Keynes, under the auspices of UBL, and Scotland (ultimately Glasgow, under the auspices of the University of Glasgow). The organisations behind each Lighthouse Lab were however responsible for negotiating their own contractual arrangements with the DHSC.

101. Any costs incurred by MDC in relation to the operation of this contract were incurred on a 'pass-through' basis. This meant that MDC did not benefit from a margin on any of the costs incurred or services provided by MDC, which it would have done under an ordinary commercial agreement. The direct costs were simply passed through to the DHSC for reimbursement.

102. MDC produced a budget of projected expenditure and there was full transparency with the DHSC of the costs that were actually incurred. All costs incurred were reasonable, appropriate and attributable to MDC's performance of its obligations under the April 2020 Agreement. There was no attempt made by MDC to establish or demand commercial terms for this service, which MDC believed was a national service in support of the DHSC, provided at cost and supported reciprocally by the DHCS through an indemnity (Exhibit CM/047 [INQ000511054]). The DHSC still maintained procurement responsibilities for several items including PCR testing capital equipment, some bulk reagents and PCR reagents.

103. I should underline that a key provision of the April 2020 Agreement was the liability position of me, MDC and the DHSC. Essentially, in the performance of the services under the April 2020 Agreement we were to be indemnified in full by the DHSC.

104. MDC was content to continue with the April 2020 Agreement, but the strong desire by the DHSC to limit the indemnity meant a new contract had to be entered into on a full commercial basis with services charged at market rate.

(b) <u>Novation agreement dated 23 December 2020</u>

105. In or around August 2020, MDC was approached by the DHSC to enter into revised terms for the provision of diagnostic testing services.

106. There are two important aspects here (i) the purpose of the revised contract and (ii) why MDCS had to be the contracting party and MDC could not.

(i) Purpose of the revised contract

107. The principal purpose of the revised contract was the desire on the part of the DHSC to limit the full indemnity provision that existed in the April 2020 Agreement.

108. In effect this required the arrangement to be made on a commercial footing because the limitation of the indemnity meant that the contracting party (ultimately MDCS) was at risk and would be liable for (amongst other things) any loss, damage, costs or expenses incurred by it through its performance of the revised agreement. The contracting party (MDCS) was therefore required to obtain insurances for any insurable loss and provide from its contract for potentially uninsurable losses.

(ii) Why MDCS was the contracting party

109. Following the request from the DHSC to put in place revised terms, a separate issue arose as to whether MDC could continue to be the company through which the services were delivered.

110. As a grant funded not-for-profit entity (subject to a Grant Funding Agreement) MDC is not itself a suitable contracting entity to enter into commercial services at market rate. Therefore, as with all other Catapults, any commercial services are provided by a subsidiary company of the Catapult. As explained above, in the case of MDC, that subsidiary was MDCS.

111. It was also important that MDC and MDCS did not fall foul of the Subsidy rules (previously known as State Aid). In plain terms, compliance with those rules meant that MDCS had to charge commercial market rates for its services in order to not distort the market or create an economic disadvantage.

112. In an agreement dated 23 December 2020 (the "December 2020 Agreement") (Exhibit CM/048 [INQ000511360]), MDC therefore transferred its rights under the April 2020 Agreement to MDCS. MDCS agreed to perform the April 2020 Agreement and be bound by the terms in every way as if it were the original party to it.

113. The December 2020 Agreement took effect from 1 December 2020. The duration of the December 2020 Agreement was to the earlier of (a) 31 December 2021 or (b) the date the DHSC declared the Covid-19 PCR testing was complete in respect of MDCS.

114. The December 2020 Agreement included restated terms and conditions which took precedence over the original terms and conditions in the April 2020 Agreement.

115. The services that MDCS was being contracted to provide under the re-stated terms and conditions remained the same, bar two exceptions: (1) As I had stepped down from my coordination role in July 2020, instead of me providing 'executive co-ordination for the set up and operation of the sites', MDCS were simply contracted to 'work as part of the sites', and (2) An updated test and capacity building plan with additional phases and altered targets was given for MDCS to perform Covid-19 PCR testing.

116. The December 2020 Agreement also contained a de-mobilisation plan that both parties were required to follow if the agreement was terminated for any reason. The DHSC retained all procurement and supply obligations as *per* the April 2020 Agreement.

(c) <u>National Microbiology Framework and the Framework Agreement (the "Framework Agreement")</u>

117. At the time the December 2020 Agreement was entered into, the DHSC indicated there would be a need for ongoing Covid-19 PCR testing in the UK. As such, there was already an intention, at that stage, to tender for such services.

118. PHE had received a mandate from the Cabinet Office to create a new National Microbiology Framework. PHE was to lead on this framework in collaboration with the DHSC and the Cabinet Office.

119. The creation of the National Microbiology Framework would enable all diagnostic suppliers, regardless of size, the opportunity to showcase their goods and services. In plain terms, the Framework was simply a new national public health procurement scheme intended to help grow capacity, push innovation and build resilience within relevant supply chains of goods and services. It provided a list of approved suppliers under four categories or 'lots'. We were concerned with Lot 4, Clinical Laboratory Diagnostic Testing Services, which created a pool of approved suppliers who could be called upon for testing capacity, as and when required. This framework was crucial to the work of Pillar 5 of the UK Government's strategy for scaling up of testing programmes and the UK diagnostics industry.

120. As MDC (and ultimately MDCS) was already providing these testing services, there was a requirement in the December 2020 Agreement for MDCS to seek, using all reasonable efforts, appointment to Lot 4 – Clinical Laboratory Diagnostic Testing Services – of the National Microbiology Framework when the invitation to tender was issued.

121. The tender for Lot 4 was issued with a commencement date of 22 March 2021. Fifty suppliers were awarded a place onto Lot 4 of the Framework, including MDCS, which enabled the public sector to enter into contracts to access clinical laboratory diagnostic testing services. Lot 4 was not exclusively for the provision of Covid-19 PCR testing, it was also intended to support any future requirements for clinical laboratory diagnostic testing services in a public health emergency.

122. There was a 'call off' procedure within the Framework Agreement which would govern the relationship between the relevant public sector entity and the supplier, by way of an Order Form, for an agreed fixed fee. There was an option for reduced pricing to be negotiated on the basis of value or volumes, but the price could not be increased above the agreed fixed rate.

123. On 31 March 2021, MDCS was appointed to be a potential supplier of Lot 4 services to the DHSC under the Framework Agreement. I was signatory to the Framework Agreement on the part of MDCS (Exhibit CM/049 [INQ000511361]) (Exhibit CM/050 [INQ000511393]).

124. On 31 December 2021, the December 2020 Agreement expired. By that date, the need for qRT PCR Covid-19 testing had significantly decreased.

125. On 1 January 2022, in accordance with the 'call off' procedure in Lot 4 of the Framework, 'call off' contracts were entered into between DHSC and MDCS (the "Winter Surge Contract" and the "Winter Capacity Contract") (Exhibit CM/051 [Q000511396] (Exhibit CM/052 [INQ000511395]). Notwithstanding these contracts, it was increasingly unclear the extent to which services would actually be required. Moreover, with the commissioning of the DHSC's Rosalind Franklin Laboratory at Royal Leamington Spa this signalled, to my mind, the start of a managed decline in capacity at Alderley Park.

(d) Value for money

126. I and MDC believe the cost and fees paid to MDC for the services provided were reasonable in all the circumstances.

127. The April 2020 Agreement was on an open book pass-through basis underpinned by an indemnity. All costs were reasonable and attributable to the performance of our obligations. As set out above, no margin was applied to these costs. We were content to work on this basis, but that option was not subsequently available to us.

128. The December 2020 Agreement was, at the request of DHSC, on reasonable commercial terms and accepting significant commercial liabilities. Our commercial model reflected the standing costs of maintaining high quality capacity and aimed not to place sample volume-based commercial barriers to the maximum use of its capacity.

129. The Framework Agreement was on reasonable commercial terms and tested through a public procurement exercise.

130. Neither I nor MDC were privy to any of the commercial negotiations between Pillar 2 (or the DHSC) and any other laboratory in the Network. Therefore, I cannot comment on the comparative value of the services provided by MDC.

131. However, given my global commercial experience and public domain knowledge of the prevailing costs of PCR testing, I and MDC believe that we intended to, and did, deliver value for public money in the establishment of the facility and the testing of over 20 million samples during two years of service.

132. In our work with the Network, neither I nor MDC were motivated by commercial profit or personal benefit. The work was gruelling, the pressure relentless and the challenges extreme. Our work was done for citizens, like ourselves, and the national good.

133. Any surplus that was made from the services provided on a commercial basis to the DHSC is being and will continue to be reinvested by MDC to serve the national purpose and community for which it was created, namely as a not-for-profit organisation with a vision to "Reshape UK drug discovery for patient benefit".

(e) Demobilising the Lighthouse Labs

134. Following the expiry of the December 2020 Agreement, it was already becoming apparent that the DHSC had no intention to maintain the existing quantum of diagnostic testing capacity within the UK.

135. After consultation with the DHSC, the MDC board resolved to try and secure a sustainable legacy for the Alderley Park facility and its staff by developing a spin-out that would commercialise a wider range of diagnostics testing services. The intention – that was communicated to interested third parties - was to seek a long-term private sector investor through a transparent public process so that the diagnostic expertise and infrastructure could be retained to support the evolution of the UK diagnostics sector and retain high-value regional employment in the region, whilst being available to serve the nation again should that be required.

136. MDC believed then and does today that the capacity and skills that had been developed at the Alderley Park Lighthouse Lab, and its counterparts elsewhere, offered the UK a fit-for-purpose, trained and battle-hardened diagnostics facility. It

had, by 2021 a range of PCR and other diagnostics capacity with strong links to both logistics and NHS data systems. Regarding data systems, the Lighthouse Labs did not have, nor needed to have, NHS data systems incorporated into its operations. The Lighthouse Labs produced simple standalone test result data (positive/negative/void) allied to a barcode and secured this within its Laboratory Information Management System ("LIMS"). Lighthouses then made use of the already existing National Pathology Exchange ("NPEx"): software used by the NHS to allow data from external diagnostics laboratories to port data into NHS systems (See paragraph 250). Thus the simple Lighthouse data was securely ported into the NHS data environment where the test data was, by reference to the barcode, matched to the patient and reported through NHS systems. I explain this process in more detail in this statement (See paragraph 153 (which explains how test kits were received and processed using a barcode), paragraphs 167 to 170 (which explain the Laboratory Information Management System ("LIMS") used by the Lighthouse Labs) and paragraphs 256 to 260 (which deal with data sharing and NPEx)). The Board and executive of MDC believed that the fully functional Lighthouse Lab offered: i) a potential testbed for the UK diagnostics industry, ii) the ability to augment the NHS through the provision of testing capacity for cancers and other diseases using PCR and associated techniques, and iii) established fast-response capacity for future pandemics. Given the likely reduction in Covid-19 PCR testing from the DHSC, MDC believed that these objectives were best served by divesting the Alderley Park Lighthouse Lab, to be supported by private investment but with strict conditions that it would be made available for national use should the need arise.

137. To make MDCS more saleable MDCS purchased the PCR testing equipment, bought as part of the Covid-19 PCR response, from the DHSC at full market rate (Exhibit CM53 [INQ000511367]). This exercise was completed by an independent consultant to ensure full transparency and independence.

138. After a process lasting several months and incurring significant costs for MDC (and in the context of the relative decline in the need for Covid-19 PCR testing compared to that which had been required during periods of the pandemic) no long-term private investor was secured for MDCS and the sales process had to be terminated.

139. MDCS was ultimately dissolved in May 2024, with asset disposals handled by Mazars, an established UK administrator.

140. A new start-up company Alderley Lighthouse Labs Ltd ("APLL") subsequently incorporated and acquired some of the capital assets via Mazars. MDC has no financial, commercial, equity or other interests or corporate relationship with APLL.

8 Specific themes

141. In the following sections I address specific themes relating to my role as executive co-ordinator between March and July 2020 and that of MDC (and associated companies) in the provision of testing services to the UK Government during the pandemic.

9 The adopted testing methodology

(a) Knowledge of testing infrastructure and capacity prior to the pandemic

142. Prior to the pandemic, I had no specific knowledge of the national PCR testing capacity or its specific infrastructure within the UK. I knew that individual NHS labs performed their own diagnostic testing for patients and that part of that service would have been outsourced to the private sector (for capacity reasons) as is standard practice for a wide range of standard and specialized diagnostic tests.

143. I had no knowledge and was not made aware of what may have been in place in relation to any form of mass testing by way of infrastructure or capacity. The request from the DHSC for the creation of this capacity indicated to me that no such infrastructure or plan existed.

144. In relation to available technologies for use in clinical diagnostic testing, my general scientific knowledge made me aware of what was available as I have had a career in infectious disease, drug discovery and development. As already stated, PCR testing is an established technique in HTS in pharmaceutical science, and with which I had familiarity. I did not have familiarity with any the national infrastructure in place for

sample acquisition or testing or how the NHS and healthcare system tested for viral infection or disease at scale in any specific region or at what capacity.

(b) Approach to mass testing in principle

145. During my initial call with Sir John Bell on 19 March 2020, he advised that the nation needed to do one test at an extremely high throughput and at scale. MDC had extensive experience of HTS in relation to drug discovery rather than virus identification, but we were able to perform mass testing – it was just a different use case. The parallels were so obvious, and our expertise was so relevant. The Thermo Fisher qRT-PCR test had already been secured in considerable volumes and that was the one test to be deployed by means of HTS.

146. As discussed with Sir John and other stakeholders at the time, to deliver on what was required it would be important to have scale, consistency and efficiency. HTS on the scale required was – on a risk-managed basis – best achieved with a small number of large labs rather than a large number of small labs where the capacity was not predictably scalable, sample logistics and supply chains would be extremely complex, quality control methods hard to align and data linkages to the NHS system numerous and fragile. The purpose of the Network therefore was to mitigate operational and quality risk by centralising, industrialising and nationalising as opposed to devolving, distributing and disseminating.

147. Others may (and at the time did) disagree with this approach. Some commentators considered that a national network of small local facilities serving local communities was a preferred approach. This was not the approach directed by the UK Government. I was not involved in the making of that strategic decision, but at the time (as now), I thought that the industrial approach to mass testing indicated by Government was reasonable and correct in principle, reducing the operational, logistical and quality control risks in providing unprecedented uniform PCR testing across the UK.

148. Scaling up to mass community testing was inevitably going to present challenges in practice, but overall, I think the approach taken was vindicated by the sheer number

of qRT-PCR tests that were performed by the Lighthouse Labs in short order. I have looked to elaborate on the key challenges in the body of this statement, but the headline challenges were: (1) Extant testing capacity at a given point in time relative to a testing target; (2) Demand forecasting (essentially trying to understand and predict the number of tests that would be taken by the population at any one time or place and the variables affecting that); (3) Logistics (the volume of samples, their location and their transportation to the respective Lighthouse Labs); (4) The availability and supply of materiel (including key equipment and consumables); (5) Variable sample inputs and the deleterious effect of these on increasing capacity at scale (See further, paragraphs 171 to 175). On a point of process detail, I would also add, (6) agreeing testing methodologies, standards and quality control.

149. To put some numbers to the scale of the undertaking, a DHSC Report in January 2023 [INQ000101642] said "On 23 March 2020, testing in the community and study-based testing (often referred to as pillar 2, under the COVID-19 Testing Delivery Programme) tested 23 samples per day. By late April, testing capacity exceeded 100,000 tests a day and continued to expand throughout the pandemic. In the month of December 2021 alone the UK laboratory network processed over 13 million samples." [INQ000101642_0190].

(c) Thermo Fisher qRT-PCR tests

150. As I have said, the decision to use the Thermo Fisher qRT-PCR tests was a decision that had already been made before my involvement. That being said, I had no reason to doubt that this was an appropriate product both in relation to the target virus and in relation to its potential for use in HTS.

151. To assist with understanding how PCR testing works in relation to detecting Covid-19, there are a series of steps to follow, which I set out below:

(i) Swabs

152. These were undertaken at test sites or in an individual's home and were sent inside a tube with liquid medium that maintained the viability of the virus to a laboratory for processing and reporting.

(ii) Sample handling

153. The samples arrived from regional testing centres, satellite sites, mobile testing units, care homes or home tests. All samples were securely packed in a unique box or bag with a unique barcode which anonymised the individual but allowed for them to be identified exclusively within and by NHS data systems at a later stage. The samples were transported to the Lighthouse Labs in either a box (if the test was completed at home) or in a bag (if from a mobile testing site). When in the lab, an operator removed the sample from its bag and handled the swab sample in a category 2 bio safety cabinet (also known as an MSC). The sample was logged into a Laboratory Information Management System ("LIMS") using a barcode reader. The sample tube was taken out of the bag to check it had not leaked. The sample was then racked for processing. The racking was always manual. An operator would manually process the sample. The processing involved the transfer of the sample liquid from the tube into a deep well plate that contains a lysis buffer. Lysis is a detergent that dissolves the viral envelope, killing the virus and both allowing access to – and stabilising – its genetic material. This 'plate' originally contained 96 individual sample wells (later increased to 384 to improve throughput and productivity).

(iii) RNA extraction

154. After 15 minutes in the buffer, the virus is deactivated, and the sample is prepared for RNA extraction. This separates the genetic material from the rest of the virus. At first, this extraction was undertaken manually but it was later automated. This involved the following steps:

a. Sample purification: The plate is placed into a sample preparation machine called a Kingfisher (Thermo Fisher) which extracts the genetic material using the beads that are in the buffer and a magnet to hold them. The machine

purifies (washes) the sample to purify any genetic material. This process takes 30 minutes of machine time.

b. Primer addition: A mixture of 3 specific genetic marker molecules called probes or primers is added to each well in the plate. This started as a manual pipetting process but was later automated using laboratory liquid dispensing machines. These primers only bind to areas of SARS-Cov-2 viral genetic sequence, providing accuracy and sensitivity across potentially variable viral strains.

c. Master mix addition: The master mix is the final set of chemicals that allow for the amplification of the genetic material needed for the PCR. It is the basic chemicals that enable a PCR to be run.

d. Thermocycling (Real time PCR): The sample with the primer addition and PCR master mix added goes into Thermocycling. A Thermo Fisher Quant Studio machine is used which raises and lowers the temperature of the reaction mixture in cycles over a period of 45 mins. If the primers have contacted their target, on each cycle they will create a chemical that then emits light, which is measured by the instrument. If the viral genetic sequence is present the instrument measures an increasing amount of light with time. The more of the primers that bind, the more light is measured, and if this happens earlier in the cycles, the more Covid-19 material is present. This is a sensitive, quantitative infection test, but we focused on three relatively simple diagnostic results, 'Positive', 'Negative' or 'Void'. These results are obtained through the next stage which is data analysis.

(iv) Data analysis

155. The Quant Studio machine sends a data file (which is a time lapse for each of the individual samples that have been tested) to the UgenTec software solution used within the testing process to analyse the data. The light measurement 'curve' for each sample within each well of the plate (which indicates the amount and speed of the development of the light signal) is analysed by an algorithm within the UgenTec software. Each well of the multi-well plate contains either a patient sample or; a known

control sample (a negative control (with no SARS-Cov-2 virus) or; a positive control (containing a known concentration of SARS-Cov-2 virus).

156. The data analysis algorithm first reviews the control samples. If they are not within normal range as predefined through extensive testing, all the samples need to be retested.

157. If they are, then the samples in the plate may then be analysed:

a. If there is no curve generated (a flatline) then the sample is reported negative.

b. If there is a curve of standard shape then the sample is reported as positive.

c. If the shape of the curve is abnormal (not smooth or interrupted) the data are reviewed manually, this may indicate:

(i) An experimental artifact that does not affect the final outcome.

(ii) A reading which – in itself or in a pattern – may indicate an experimental artifact (perhaps of reagent addition or failure) that will require repetition.

(iii) A reading which may indicate a specific viral strain. In this case a positive will be reported. Strain specific information was not reported through the NHS systems as this was not of practical use to citizens.

158. The UgenTec software returns results for each of the sample wells. Abnormal results would be subject to human checking before being processed further. The human would either be i) an expert in reading the data or ii) one of the Clinical Leads across each lab. The clinical leaders were also actively responsible for setting and evolving the quality control criteria that the UgenTec software used. They were regularly reviewing how the software was analysing the data in relation to variants and during changes of process that increased operational capacity. In this was the Lighthouse Labs 'learned' from the increasingly large set of data they were producing and were able to deploy improvements across the Network using centralized changes in quality control criteria

159. A key priority of the Network was to ensure the same equipment was being used across all Lighthouse Labs to ensure consistency and quality of results. It was always a priority to speed up the process of testing, but it was of utmost importance that quality and safety was not compromised in any way.

(d) Laboratory automation

160. Due to the industrial volumes of testing that were foreseen at each site in the Network (a minimum of 20,000 to 30,000 tests per day), it was necessary to build automation into each of the laboratories, both in elements of sample processing, specifically in sample handling, and in quality control. The need for automation was clear to me within days of my involvement in the National Testing Programme and from my experience in running high-capacity industrial testing for new drug candidates.

161. The MDC, UBL and Glasgow leadership teams included expertise in laboratory automation and data systems suitable for the daily testing of hundreds of thousands of samples. The teams collectively agreed, and I approved that (1) laboratory automation and (2) LIMS, which are routinely used in industrial High Throughput Screening, would both be required to establish longer term scaling of capacity.

(e) Liquid-handling automation

162. As noted above, sample handling was in the first instance an entirely manual process. It was important that this process was automated by using large liquid handling robotics rather than operators transferring every sample by hand. A liquid handling automation system would increase efficiencies by reducing the number of humans and bench space that was needed. In the early days, we did not have access to any automated large liquid handling robots. UBL had some instruments, but we had to buy everything new for Alderley Park and Glasgow. A shortlist of standard, prevalent liquid handling automation systems was agreed through discussions across the Lighthouse Labs by those with established laboratory automation experience in the Lighthouse Labs at that time and in consultation with wider expertise from HTS automation colleagues across pharma and biotech.

163. Efficiency improvements were made from June by the implementation of multiple liquid handling automation robotics, which had been procured by the Lighthouse Labs during their manufacture in early April 2020. The automated machines had to be built on production lines across the world and were going to take two months or more. They were ordered March/April 2020, often in competition with other international parties who were doing likewise. As they were completed and shipped (the end of April/early May) there was a gradual, managed commissioning and introduction of these systems, with notable increases in capacity, and the redeployment of staff to manual handing tasks, which were proving to be an unexpected bottleneck in the process.

164. Another method the Network used to scale up was by increasing the density of the plate that contained the individual samples from 96-wells per plate to 384 wells per plate. This is a standard method of improving throughput in HTS but was not able to be implemented from the beginning because the Kingfisher and Quant Studio machines available across the UK only used 96-well plates.

165. The entire Network eventually moved to 384 wells per plate, but this required the replacement of the original Kingfisher and Quant Studio machines at each site with new machines to allow for a capacity of 384 tests per plate.

166. These machines were manufactured by Thermo Fisher and, due to the number of new machines that were needed across all sites in the Network, significant CAPEX approval was needed. This was granted through the Pillar 2 system and all procurement was done through DHSC. The change from 96 to 384 happened around August/September 2020. All the smaller units that were originally used were given back to the universities, labs and various other sites from where they were originally borrowed or replaced as new if they were deemed unserviceable.

(f) Laboratory Information Management System ("LIMS")

167. In relation to a LIMS system, it was agreed by consensus of the Lighthouse Laboratory leaders, supported by their internal experts and approved by me, to

deploy the extant LIMS system that was already in place at UBL across the entire Network. That was the LIMS system designed by Brooks Life Sciences (renamed Azenta Life Sciences from 2021). LIMS was discussed with NHS colleagues from the outset (I exhibit two example emails (Exhibit CM/054 [INQ000510873] Exhibit CM/055 [INQ000510892]). I exhibit the Agreement relating to the Brooks Life Sciences LIMS for the Network (Exhibit CM/056 [INQ000511233]).

168. By way of explanation, the purpose of the LIMS system is to ensure custody and traceability for each sample received. The bag would arrive with the sample tube inside. The bag would have a barcode on it and this barcode is scanned by an electronic reader into the LIMS system. The sample would then go through the entire testing process. There are barcodes attached to each stage of the process which are then scanned into the system so that every sample could be traced. This was all made possible using an established LIMS system which tracked everything from sample arrival to the data file being sent out and received back from the separate cloud-based data analysis software (UgenTec).

169. No patient data were provided to the Lighthouse Labs, nor stored within its systems. The barcode alone was used as a sample identifier. Downstream NHS systems matched this barcode with patient identifiers and handled patient communication of the Lighthouse Lab result. At paragraphs 247 to 255 below I explain sample custody control and the barcode system. At paragraphs 256 to 260 below I explain how the data generated by the Lighthouse Labs was shared with the NHS and its data systems.

170. To achieve consistency across all sites, and on the basis that the Brooks LIMS system was an already established system at UBL, MDC arranged with Brooks to extend their licence and support across Alderley Park and Glasgow. Having one system across all sites from the start meant we could extract the same process data from every site. By May 2020, this combined picture was used to assimilate process data across the Lighthouse Labs to measure load and performance. To elaborate on how this worked in practice, the LIMS system at each site gave us the following key process data: (1) the number of samples received and processed; (2) test results (positive/negative/void) and for the avoidance of doubt, with no access to any personal data; (3) quality control data (results for the test plates and controlled samples used as part of the quality control system (explained at paragraphs 230 to

237 below); (4) processing time (the time taken from receipt of a sample to the completion of the test and the posting of the result). These process data were made available via an internal webpage at each site (a form of intranet) to form real time process dashboards that were a rapid tool to assess performance. For my part a key outcome was load balancing – being able to see in real time where capacity was stretched or under used and being able to adjust. It also enabled issues to be identified if they arose, for example if a particular Lighthouse Lab had a high incidence of void test results this could be examined with the respective site to understand the causes. This was a dynamic system used for practical purposes. For my part I would mainly address issues by speaking directly on the telephone with staff at respective Lighthouse Labs and Pillar 2 (for these matters, principally Kevin Tsang of Deloitte). As to the headline test result numbers, these were available to and monitored by Pillar 2 daily. This was done principally by Deloitte personnel working for the DHSC. They assimilated the results and used the data for their reporting purposes.

(g) Impact of variable inputs to the Lighthouse Labs

171. Any industrial process, and its ability to deliver outputs, can be hampered by the complexity of its inputs.

172. In the early stages our efforts to scale up testing capacity was significantly hampered on a daily basis by the wide variety of different input variables we received. By way of example, we would receive different sample tube sizes, different shape tubes, barcode stickers being used as sealants round the tube because the lid would not screw on securely. All of these variables have little impact on low-throughput labs but had a dramatic effect on the throughput of process-driven labs requiring extensive additional manual handling, preparation of duplicate (automatable) tubes with barcodes, leakages and automation failures.

173. The variety was caused, in the main, by a volatile supply chain (no available or consistent supply of simple kit like plastic tubes) and/or a lack of understanding of the downstream impact of these seemingly modest matters within the rapidly scaling test centre organisation. The mobile testing centres did not realise, in the early days, the impact on capacity of a bewildering variance in tubes, tube sizes, swab sizes and

different bags. We estimated that our net capacity was going down by 60% simply because of what was being sent in.

174. This also had a major impact on test voiding rates through leakages that were unsafe to handle and therefore unreliable in outcome.

175. It is recognised that if one wishes to run an effective and efficient production line one needs to limit the variation of its inputs – in this case the tubes, swab bags and boxes that the labs received 24 hours per day. I had numerous conversations with Deloitte to try to influence the supply chain upstream, but the variability of input caused considerable frustration and – often without warning - decreased effective capacity at labs that received non-standard or poorly prepared materials that would require significant increases in manual handling, increasing void rates for un-processable samples. By way of specific examples:

(1) Swab bags: there were issues with swabs not being bagged correctly. Some swabs were being sealed in Asda or other supermarket sandwich bags. I exhibit the following communications: Exhibit CM/057 [INQ000511040], Exhibit CM/058 [INQ000511065], Exhibit CM/059 [INQ000511067].

(2) Changes to the test kits: the plastic tubes used in test kits were changed because there was no available or consistent supply. Some tubes were simply not fit for purpose and unautomatable in a lab setting requiring manual workarounds to process the samples with consequent implications for capacity and turnaround. I exhibit the following communications: Exhibit CM/060 [INQ000511104], Exhibit CM/061 [INQ000511111], Exhibit CM/062 [INQ000511113], Exhibit CM/063 [INQ000511120].

(3) Poor quality consumables: at times poor quality consumables were used in test kits which meant patient samples were not securely sealed in the tube leading to leaked patient samples arriving for processing. Key consequences were resultant problems in relation to safe testing and void rates. There were challenges in attempting to address these matters including the administrative processes in raising concerns. For example, needing to file "NHS Supply Chain Customer Complaint" forms in relation to a particular type of tube the Lighthouse Labs considered unsuitable. I exhibit the following communications: Exhibit CM/064 [INQ000511242], Exhibit CM/065 [INQ000511245], Exhibit

CM/066 [INQ000511243], Exhibit CM/067 [INQ000511253], Exhibit CM/068 [INQ000511099], Exhibit CM/068.1 [INQ000511280], Exhibit CM/068.2 [INQ000511290].

(h) New technology and process evaluation

176. From early April 2020, I and the Lighthouse Labs site directors were contacted directly, or through government channels (including the Government Commercial Function) by a wide range of UK and international parties offering help and support. These were welcomed but often exceeded the daily capacity for rapid response which, although causing understandable frustration at the time, I trust will be forgiven given the circumstances.

177. Many of these offers led to accessing key reagents, material and expertise. There were also several approaches offering to test, prove and deploy new ways of running Covid-19 PCR tests which had the potential to drive efficiency.

178. Therefore, from in or around April/May 2020, the Network undertook a set of new technology evaluations (the key evaluations are explained below at paragraph 180). These started at UBL. It is important to note that the focus here was on machine and process technologies, not the analysis of the results. That is a separate issue.

179. Any machine or process changes that were to be accepted would have to have been implemented across the Network to retain consistency and failover capacity. They therefore required significant operational planning and capital investment.

180. Although the Network was focused on minimising new technology risk, several alternative new systems were evaluated, predominantly at the UBL site, beginning in early May 2020. Whatever solutions were selected they had to be able to be implemented across all the Lighthouse Labs to ensure consistency of process and result. The approaches that were tested included *inter alia*:

a. End-Point PCR Testing: These included specific machines which could perform PCR tests faster.

(i) Hydrocel: One example that was examined, around April/May 2020, was Hydrocel. This work was done at UBL on behalf of the Network. These machines optimised one part of the process, which was the number of samples that could go into the PCR reader machine. This was – unexpectedly – not the rate limiting factor for the whole process. That was the manual handling of bags, boxes and manual racking of samples.

The Network Lab leaders agreed to examine the Hydrocel solution and both Tony Cox and I believed it had merit in the element of the process it targeted. However, it was decided by Network lab leaders in consultation with DHSC and clinical leads that, after evaluation, it would not offer significant overall efficiencies across the whole Network and one of the main clinical concerns was its use of a single end-point measurement of light production, rather than an evaluation of the curve. This 27 minute, single-read 'end-point' approach was not one that was consistent with the NHS back-to-back testing that we had approved with NHS.

qRT-PCR was the gold standard for detecting the virus. End point PCR is useful where you are dealing with something that is predictable and the end point is certain in terms of output. At this point there were too many unknowns with Covid-19. To invest in this technology would have gone against the priority of using low risk technology to achieve consistency and quality of result.

(ii) LGC: This was another large-scale end-point PCR automation platform with provenance in North American water/soil testing where contaminants in water sampling were easy to detect with end-point testing. LGC is an *ultra*-high throughput solution with one large piece of capital equipment with samples going in at one end and results coming out at the other. This was initially brought to the attention of the Network by NHS colleagues as part of routine information-sharing on new technologies. UBL again assisted with this/their evaluation of the equipment. It was super-fast technology. However, it had the same trade off as the Hydrocel as it only gave an end point result rather than a curve. It had the benefit of simplicity with the deficit of underlying data fidelity.

Due to the process-change requirements and lead-time of these machines the LGC technologies were not a realistic choice for the extant Lighthouse Labs to consider, However, the NHS decided to buy some of these instruments for future purposes beyond Covid-19. They would not be ready for at least another year at this point and the intention was to build an entirely new lab at Royal Leamington Spa (this was to become the publicly owned mega lab at the Rosalind Franklin Laboratory).

I exhibit the following documents to illustrate how these matters were discussed: Exhibit CM/069 [INQ000511121], Exhibit CM/070 [INQ000511197], Exhibit CM/071 [INQ000511198], Exhibit CM/072 [INQ000511143].

b. Other recommended technologies tested included alternative PCR tests (Perkin Elmer, a manufacturer of equipment like Thermo Fisher), novel reagent systems, prototype unbagging tools and many others.

c. External QC standards (Qnostics, QCMD, NIBSC) were all tested across all Lighthouse Labs.

181. There was always a general sharing of information and a transparency of what was being tested between the NHS (Pillar 1) and Pillar 2. Largely (and from my perspective) this was both informal at a regional level and formalized at a relatively high level. The individuals at DHSC concerned with this work appeared to share process and performance information routinely. The Lighthouse teams in various regions also had relationships with local NHS (Pillar 1) labs. As for Pillar 3, I and site directors had discussions on new test methods. I had regular interaction with Professor Dame Sue Hill and her team at the NHS. So far as I recall, the sharing of Lighthouse to Pillar 3 information was not set up in any formal structured way, but Lighthouses were involved in testing a number of new approaches with NHS teams where the technologies could be safely and effectively tested within our facilities (for example the testing of end-point PCR at UBL explained at paragraph 180 above). Otherwise, Pillar 1, 2 & 3 datasharing is a matter for the DHSC and I cannot say what was or was not in place. In my assessment there was always full visibility and co-working which I considered extremely valuable.

182. In the event, the Network stuck with the Thermo Fisher machines and moved to 384 testing capacity plates. In my view, this was the most practicable and low-risk, consistent approach. As part of the evaluation exercise, some technologies worked, and some did not. Some just were not practical to roll out. At the end of the day, I and the Lighthouse Lab directors had to make informed judgements and make the call across all of the Lighthouse Labs.

183. To address the massive, hitherto unexpected manual handling constraint, we considered methods that would remove the requirement for use of safety cabinets. Significant work was therefore done to examine the utility of adding a reagent (guanidine hydrochloride) to the patient test pack that would inactivate the virus before transit. Some of these are used in other 'at home' sampled PCR tests. This approach would have delivered additional efficiencies by allowing automation from an earlier stage of the process, decreasing lab process steps and lowered lab safety risks. However, it was decided by PHE that this carried some risk to patients and was not implemented. In short, it was my understanding that PHE determined that the potential health hazards (possible harm if swallowed or possible skin or eye irritation) created by the initially proposed inactivation reagent (guanidine hydrochloride) were too great and outweighed the process and throughput benefits of improved safety across the supply chain, reduced void rate, and faster time between the sample arriving in the lab and the result being provided (I exhibit key documents relating to this topic: Exhibit CM/073 [INQ000511019], Exhibit CM/074 [INQ000511020], Exhibit CM/075 [INQ000511047], Exhibit CM/076 [INQ000511048], Exhibit CM/077 [INQ000511118]. It is my understanding that the inactivation of samples is now being considered as part of the UK's updated pandemic preparedness.

184. These potential innovations were shared via the Government Commercial Function across the NHS, Academic Health Science Networks, Test and Trace. Where these technologies could be readily introduced into the Lighthouse production line (for example liquid handling robots) they were implemented systematically and alongside extensive testing to ensure the compatibility that would drive consistency in sample testing.

185. It is natural that those who committed time and expertise to proffering and developing new solutions were unhappy if their proposals were not taken up. Recourse to the press to try and influence or criticise these decisions with their inferences of

management incompetence, ignorance or both was a regrettable but not unusual reaction. Despite this, their efforts and ideas should be recognised even if (in our assessment) their deployment would have led to significant discontinuity of service or systems that could not be made compatible with the process at that time.

10 Standards and Accreditation

(a) Overview

186. From the outset a key priority was to ensure that the Alderley Park site (and the laboratories within the Network) maintained appropriate standards in relation to the task they were undertaking. This meant that appropriate standards had to be settled that were capable of being recognised, accepted and approved. It was fundamentally important that the relevant principal bodies (including the NHS, the HSE, and the DHSC) and the public at large had confidence in the Alderley Park laboratory and the Network. Critical to the whole operation was confidence in the quality of the results delivered by the Lighthouse Labs.

187. In the main, my role was to ensure that the right people were in place at Alderley Park (and in the Network) to work with the relevant principal bodies to settle and deliver the required standards, so although I was engaged in some of the initial key discussions in relation to standards at Alderley Park, much of the detailed work on required standards (and compliance with those standards) was delegated to competent individuals.

188. In practice the approach taken was confirmed in the April 2020 Agreement, deemed to be effective from 1 March 2020.

189. The April 2020 Agreement made provision in relation to the settling of Standard Operating Procedures ("SOPs") at Alderley Park. It said:

4. Standard Operating Procedures (SOPs)

Although the overall strategy and direction of the COVID-19 Testing will remain under the control of the DHSC, in order to set up the Alderley Park Site and implement the COVID-19 Testing at the Alderley Park Site the MDC will review SOP's from other Sites (where appropriate) and develop and finalise SOPS for use at the Alderley Park Site. The process, safety, sample handling and operating SOPs will be reviewed and approved by representatives of HSE and NHS and shall also need the written agreement of both the MDC (the CEO or CSO) and the DHSC. The overall responsibility for ensuring these SOPs are appropriate and meet the requirements needed for COVID-19 Testing remains with DHSC (Exhibit CM/045 [INQ000511055]).

Work was undertaken in line with the above with close cooperation between MDC, the NHS, the HSE and the DHSC. Appropriate SOPs were produced for the Alderley Park lab that were recognised, accepted, and approved. Overall responsibility for ensuring that the operating procedures at Alderley Park were appropriate and Covid-19 testing requirements met remained with the DHSC.

190. The April 2020 Agreement required that any Covid-19 testing undertaken "*will be performed to the standards set out in the SOPs*" referred to, and that "*no other license or accreditation (including Medical Laboratory ISO 15189 accreditation) is required*" (Paragraph 5) (Exhibit CM/045 [INQ000511055]).

191. It follows that in the beginning it was a matter of working collaboratively with the principal bodies to produce a standards framework that was appropriate for the conduct of Covid-19 testing at Alderley Park (and in the Network). The validation process for the Lighthouse Labs remained under review and discussion beyond the time of my coordination role for the Network (See for example, Exhibit CM/078 [INQ000511348]).

192. It should also be appreciated that in addition to the SOPs there would be the necessary risk assessments applicable to the conduct of a clinical diagnostic laboratory generally, but also specifically in response to any regulation or guidance relating to the SARS-Cov-2 virus as from time to time was made available. This involved close cooperation with the HSE.

193. The work undertaken at Alderley Park to settle appropriate standards (which drew on existing measures already in place at Milton Keynes (UBL)) and at the other Lighthouse Labs provided a resource that could be reviewed, referenced and developed as necessary for the settling of site-specific SOPs at subsequent laboratories within the Network.

194. A key factor in the Network was process standardisation: to deliver mass testing at considerable scale and across sites running the same test in the same process. However, given the pace at which these centres were configured, from diverse starting-points, the laboratories within the Network were not identical facilities. Some were created from open plan warehousing space, some from existing lab spaces and some from a mixed laboratory and office space. Each site therefore inevitably needed elements of site-specific provision to be settled and implemented.

195. From 15 December 2020, new laws made it mandatory for providers of Covid-19 testing services to be working towards full accreditation with the United Kingdom Accreditation Service ("UKAS") under a new regulatory end-to-end scheme run by UKAS. Accreditation involved three stages, application, appraisal and full UKAS accreditation (the latter of which included full accreditation to ISO Standard 15189:2012). I recall that both the laboratories at Alderley Park (MDCS) (initial accreditation 23 August 2021 (Exhibit CM/079 [INQ000511373]) and Milton Keynes (UBL) were duly assessed and accredited by UKAS as required.

196. Given the recent changes in the law mentioned above, the December 2020 Agreement did not have any material bearing on applicable standards or accreditation requirements. However, the fact that liabilities were no longer underwritten by the UK Government was a salutary reminder, if one were needed, to ensure that appropriate standards were being maintained at Alderley Park and in the Network.

197. In or around November 2020, PHE set up the new National Microbiology Framework. This Framework was stated to be crucial to the government's strategy for scaling up of testing programmes. Lot 4 of the Framework was focused on Clinical Laboratory Diagnostic Testing Services.

198. On 31 March 2021, MDCS entered into an agreement with DHSC (acting through PHE) in relation to Lot 4 under the Framework.

199. The Framework Agreement set out a more prescribed system for the provision of clinical laboratory diagnostic testing services (Framework Agreement, Schedule 5 – Specification and Tender Response Document – Section 5 (Lot 4) (Exhibit CM/049 [INQ000511361]). This included provision relating to "Applicable Standards" and the process of obtaining any relevant accreditations and regulatory approvals (Framework Agreement, Schedule 5 – Appendix 4 – Lot 4 Specification: Clinical Laboratory Diagnostic Testing Services (Exhibit CM/049 [INQ000511361]).

200. Eleven items were listed under "Standards (among others)" which PHE may require a supplier to comply with (Section 4) (Exhibit CM/049 [INQ000511361]). The specific Standards applicable to any given "call-off" contract under the Framework Agreement were then to be defined within the requirements for that specific contract. The list included seven ISO Standards, including ISO 15189:2012.

201. The first 'call-off' contract under the Framework Agreement for Alderley Park was not presented until the end of 2021 (when the December 2020 Agreement was due to expire). From 1 January 2022 (with an initial term expiry of 31 March 2022 extendable on notice thereafter for terms of four weeks) "call-off" contracts for the provision of clinical diagnostic services by MDCS were in place in relation to Alderley Park.

202. The "call-off" contracts (Section 2. Goods and/or services requirements, at clause (2.5) Quality standards (Exhibit CM/051 [INQ000511396], Exhibit CM/052 [INQ000511395]) referred back to the Framework Agreement (Schedule 5 – Specification and Tender Response Document) but did not specify any Applicable Standards in relation to the overall services. However, the "call-off" contracts further required the services to be provided in accordance with approved SOPs (Order Form, Appendix 1, Section 5) and there were specific requirements in relation to certain aspects of the service, for example, the LIMS requirements (Order Form, Appendix 1, Section 7).

203. In any event, it will be recalled that by this time Alderley Park was already fully accredited by UKAS under ISO Standard 15189:2012 and had been since August 2021.

204. I now address the multiple and foundational interactions with the NHS and the HSE in ensuring that appropriate standards were set and maintained. They demonstrate the importance to me (and the other Lighthouse Lab teams) of working closely and cooperatively from its nascent stage and throughout the life of the programme.

(b) National Health Service

205. Aside from any initial contractual requirement arising in the April 2020 Agreement, it was essential to engage with the NHS in setting up the Alderley Park laboratory and in the establishment and operating of the Network. As Network co-ordinator I also wanted NHS experience at each site and where possible some degree of NHS operational oversight built into the system.

206. In March 2020 I was in contact with the NHS-England leadership team (Professor Dame Sue Hill, Chief Scientific Officer and her deputy Angela Douglas MBE). The nature of this initial contact was by telephone. There were some meetings by Zoom where that was practicable. There was also email communication. I have looked to exhibit key communications in this statement. MDC was aware that there was already Covid-19 testing going on in the NHS laboratories and I needed to understand more about what they were doing and how they were doing it. It was important that all Lighthouse Lab leaders understood their processes regarding tests, machinery and quality control. The Network also had to ensure that the test results that it would produce at any lab could be fed back into the NHS system for onward communication to the patient by the NHS.

207. Professor Dame Sue Hill and Angela Douglas MBE provided further expert access to NHS laboratory operational leaders, NHS pathology laboratory leaders and virology leaders. They provided two important introductions:

a. Dr Ian Fry (former Head of Operations at Frimley Park Hospital);

b. Dr Malur Sudhanva OBE (then Consultant Medical Virologist, South London Specialist Virology Centre and Clinical Director of Pathology for the Viapath laboratories at King's College Hospital NHS Foundation Trust and Chair of the Panel of Examiners in Virology, Royal College of Pathologists. Now also

Honorary Senior Clinical Advisor for Public Health and Clinical Oversight at the UK Health Security Agency).

208. Both above worked closely with us to ensure that the Network was set up correctly and operated with appropriate standards. I explain the detail of this in the following sections. In particular, Dr Malur Sudhanva OBE became the resident Clinical Lead for the UBL Lighthouse Lab at Milton Keynes and acted as coordinator for the Clinical Leads subsequently appointed at the other sites.

209. On 26 March 2020, Ian Fry visited UBL at Milton Keynes and was in regular early contact through the planning phase of the Network. Around the same time Professor Dame Sue Hill proposed a method of NHS validation for the Lighthouse Labs which each laboratory went on to adopt. The method of validation had four key elements which I explain below, namely: (1) Agreed Standard Operating Procedures ("SOPs"); (2) Expert Clinical Leads in post at each site; (3) NHS inspections of each site, and (4) Back-to-back testing between NHS testing facilities and the Lighthouse Labs. There were also numerous introductions made and discussions had with NHS colleagues on the use of lab data, LIMS and analytical systems, and how the data created by the Lighthouse Labs could be securely transferred to the data system operated by the NHS (See paragraph 256 *et al* in this statement).

210. It follows that there was from the beginning and throughout close and effective cooperation between the Network and the NHS which resulted in four key ways in which appropriate standards for the Network were set and validated. These were:

(i) Agreed SOPs and other compliance materials

211. First, as explained above, at the outset appropriate SOPs and all suitable and sufficient risk assessments were settled and agreed for each Lighthouse Lab. SOPs were initially circulated between Lighthouse Labs (from Milton Keynes (UBL) to Alderley Park and then on to Glasgow). However, each site was ultimately responsible for its own SOPs and liaised directly with the HSE in that regard. In the case of the Alderley Park Lighthouse Lab SOPs, risk assessments etc. were initially settled and agreed between the MDC and HSE and provided to the DHSC. These materials would be added to and updated as the testing process changed and

progressed. With regard to Alderley Park, I exhibit a schedule of the SOPs that were in place (Exhibit CM/080 [INQ000511371]). I further exhibit email exchanges with the HSE: Exhibit CM/081 [INQ000510984], Exhibit CM/082 [INQ000510992], Exhibit CM/083 [INQ000510987], Exhibit CM/084 [INQ000510989], Exhibit CM/085 [INQ000510991], Exhibit CM/086 [INQ000510995], Exhibit CM/087 [INQ000510994], Exhibit CM/088 [INQ000510990], Exhibit CM/089 [INQ000510986], Exhibit CM/090 [INQ000510993], Exhibit CM/091 [INQ000510988], Exhibit CM/092 [INQ000510985], and an email exchange relating to providing the SOPs to the DHSC (Exhibit CM/093 [INQ000511288]).

(ii) Clinical Leads at each Site

212. Second, each site had a Clinical Lead. I liaised directly with Professor Dame Sue Hill in relation to this (Exhibit CM/094 [INQ000510902]). At the time these persons brought considerable experience of the NHS with them. All were leaders in clinical virology. The Clinical Leads quickly became structured and soon held scheduled meetings with NHS (and DHSC) colleagues where specific issues and related papers were discussed. To illustrate, I exhibit an example agenda dated 13 April 2020: Exhibit CM/095 [INQ000511026], Exhibit CM/096 [INQ000511029], Exhibit CM/097 [INQ000511027], Exhibit CM/098 [INQ000511028]. As the system bedded in Clinical Leads were able to raise and consider substantive matters. To illustrate, I exhibit the agenda for 11 May 2020 which included the following matters: (1) Swab kit sourcing and validation governance process; (2) Reporting clinical incidents; (3) Under 5 testing; (4) Sample pooling (an overview): Exhibit CM/99 [INQ000511122], Exhibit CM/100 [INQ000511124], Exhibit CM/101 [INQ000511126], Exhibit CM/102 [INQ000511123], Exhibit CM/103 [INQ000511125], Exhibit CM/104 [INQ000511127].

213. At Milton Keynes the Clinical Lead was Dr Malur Sudhanva OBE.

214. At Alderley Park the Clinical Lead was Professor Paul Klapper OBE, now Professor of Clinical Virology at Manchester University. At the time Professor Klapper was also a Clinical Advisor for testing within the DHSC.

215. At Glasgow the Clinical Lead was Professor Rory Gunson, Consultant Clinical Scientist, NHS Glasgow and the Clyde.

216. At Cambridge the Clinical Lead was Dr Nick Brown, Consultant Medical Microbiologist, Cambridge University Hospitals NHS Trust.

217. Dr Sudhanva OBE acted as lead for this group of Clinical Leads (Exhibit CM/105 [INQ000511063]).

218. The Clinical Leads provided ongoing advice and assistance to the Network. They advised on a raft of relevant matters including:

a. Suitable standards and their implementation (including the standards that PHE and the NHS worked to and how they performed and reported on SARS-Cov-2 testing).

b. Approaches to and the ensuring of Quality Control.

c. Clinical issues and potential scenarios arising on site.

d. Training and advice in relation to operational matters such as analytical systems applied across the Network.

e. Interpretation of equivocal SARS-Cov-2 RNA test results and underlying data.

f. Staff and ensuring suitable people were matched to appropriate tasks (including in relation to the assessment of equivocal test results).

219. The Clinical Leads were independent of the laboratory site directors and were able to raise issues as and when required, either directly to the site directors, to me as co-ordinator or table matters at the Clinical Leads meetings with colleagues from the NHS (and DHSC). The Clinical Leads were able to report on key issues as they saw them, and where necessary produce formal written advice as they saw fit. It is important to understand that in addition to the formal meetings I have explained above, the Clinical Leads were very much involved in the day-to-day issues that arose at each site.

(iii) NHS inspections of each Site

220. Third, under Professor Dame Sue Hill, Alderley Park and the Network laboratories were inspected by the NHS. There was a full site visit in relation to each premises including a full laboratory pathway walk and a complete check of the operating procedures. Milton Keynes (UBL) was inspected on 28 March 2020 (Exhibit CM/106 [INQ000510907], Exhibit CM/107 [INQ000510974], Exhibit CM/108 [INQ000510975]). Glasgow was inspected on 7 April 2020 (Exhibit CM/109 [INQ000511009], Exhibit CM/110 [NQ000511010]). Alderley Park (MDC) was inspected on 9 April 2020 (Exhibit CM/111 [INQ000511057], Exhibit CM/112 [INQ000511058]).

(iv) Back-to-back sample testing

221. Fourth, and specifically in relation to the effectiveness of the SARS-Cov-2 testing being undertaken at Alderley Park (and at the other laboratories in the Network), following the guidelines laid down by Dame Sue Hill and Dr Sudhanva, a series of back-to-back testing of samples was performed. This essentially involved the same batch of samples being tested in an extant NHS laboratory and at Network sites. The purpose was to demonstrate that the testing being undertaken was at least as effective as that being undertaken by the NHS. It was, and this was demonstrated to the satisfaction of all those concerned. Key documents relating to the back-to-back testing and comparison testing between Lighthouse Lab sites are exhibited: (1) Between Milton Keynes (UBL) and NHS Kings College Hospital (Exhibit CM/113-INQ000510904], Exhibit CM/114 [INQ000510905], Exhibit CM/115 [INQ000510959], Exhibit CM/116 [INQ000510905]); (2) Between Milton Keynes (UBL) and Alderley Park (MDC) (Exhibit CM/117 [INQ000511014], (Exhibit CM/118 [INQ000511015]); (3) Between Glasgow and Alderley Park (MDC) (Exhibit CM/119 [INQ000511046]); (4) Between Milton Keynes (UBL) and Cambridge (Exhibit CM/120 [INQ000511133]).

222. Alderley Park (and the Network) was never set up to compete with or rival extant testing provision within PHE or the NHS (Pillar 1), which was supplying diagnostic results to clinicians on behalf of patients, and also some NHS staff. The Lighthouse Labs existed to augment the NHS in this one single test, to an equivalent standard or

better, and return the data to the NHS for simple and safe onward reporting directly to the patient.

(c) Health and Safety Executive

223. As you would expect in relation to laboratory premises handling the SARS-Cov-2 virus, safety was of paramount importance. I trust it will be understood that the many people who ultimately contributed to the running of the Network, were charged with working in environments where millions of samples potentially containing live virus were being opened and processed. Therefore, by definition, everybody was acutely aware of the need for appropriate standards and reasonable safety.

224. There was close liaison with the HSE from the outset for Alderley Park and replicated at other laboratories in the Network. HSE approval was required in relation to each laboratory before testing activity could be undertaken. I and the Site Director worked with the HSE to ensure that our standards and practices were, so far as reasonably practicable, appropriate, and that our risk assessments in relation to our work were suitable and sufficient.

225. It will be recalled that as the pandemic unfolded regulations and associated guidance were made that dealt exclusively with the SARS-Cov-2 virus. Some of it was directly relevant to the Network's operations and therefore the Lab leaders, I and the HSE were keen to ensure that any specific requirements were met.

226. For example, on 20 March 2020 PHE (in collaboration with the HSE) issued specific updated guidance in relation to "Covid 19: safe handling and processing for samples in laboratories". This was provided by PHE using an extant email link. I do not have access to the linked version of the guidance. A contact at the HSE was quickly established, Mr Hefin Davies. The Site Risk Manager for Alderley Park considered the guidance on Sunday 22 March 2020 (Exhibit CM/121 [INQ000510853]). Based on information provided and assurances given by me and UBL at Milton Keynes, Mr Davies indicated that the HSE was content for the work to go-ahead (Exhibit CM/122 [INQ000510874]). On Tuesday 24 March 2020, a key contact with the HSE was established, Mr Vin Poran, with whom we subsequently worked. Emails illustrating

the work between the Network and Mr Poran of the HSE are exhibited: Exhibit CM/123 [INQ000510883], Exhibit CM/124 [INQ000510899], Exhibit CM/125 [INQ000510925], Exhibit CM/126 [INQ000511008], Exhibit CM/127 [INQ000511012], Exhibit CM/128 [INQ000511328]. At that time, I and the Lighthouse Lab leads were active in ensuring that all necessary processes and operating procedures were assessed for compliance, that suitable and sufficient risk assessments had been done and that control measures etc. were in place to meet the guidance (as then extant) and also to ensure that the HSE was content. The HSE was satisfied at that time and subsequently.

227. As a sense check, to the best of my recollection, it is notable that throughout the pandemic and the Lighthouse Lab's 150m PCR tests over two years, no laboratory site within the Network was closed due to a failure of health and safety, and no person working at any laboratory was found to have been infected from the receipt or subsequent handling of patient samples.

11 Quality Control

228. In a clinical diagnostic laboratory, a robust Quality Control ("QC") system is necessary to ensure the effectiveness and reliability of the testing work being undertaken.

229. The QC system that was employed at Alderley Park and the other laboratories within the Network had three key elements: (1) process controls in relation to testing; (2) data analytics (how the results were read and interpreted), and (3) sample custody control (how to take custody of a sample and then ensure end-to-end process continuity). I will deal with each in turn.

(a) Process controls

230. The Network, through co-ordinated local leadership and sharing of best practice, put in place internal process controls and external process controls.

231. With regard to internal process controls, the key step was to have a system for introducing control samples to each test plate processed by each laboratory. I referred to this when explaining the stages of a qRT-PCR test above. This essentially means that in each test plate you introduce samples that you know to be negative (they do not contain any SARS-Cov-2 virus) and that you know to be positive (they contain SARS-Cov-2 virus). These control samples are placed on each test plate and would undergo the same testing process as all the other patient samples on the same test plate.

232. When the diagnostic results are produced the samples enable you to judge whether there has been any issue with the diagnostic process used in relation to that plate. Basically, if the control samples fall outside rigorous accuracy criteria the remainder of the patient samples that had been tested in that batch would also be rejected as unreliable and subject to retesting.

233. The details of this quality control process were considered carefully at the outset (in March and April 2020) between experts from the NHS, the Clinical Leads and site directors. Professor Klapper led on this aspect and dealt with much of the detail. After a series of tests and evaluations the precise control samples that needed to be introduced and the number that needed to be placed on each test plate to best corroborate the effectiveness of the test procedure being undertaken were determined.

234. The control samples were purchased from outside each laboratory with the virus concentration in relation to the positive control samples having been settled and agreed in advance.

235. As to external process controls, all the laboratories within the network were members of a quality control scheme operated by Quality Control for Molecular Diagnostics ("QCMD"). QCMD is a not for profit, independent international External Quality Assessment (EQA) and Proficiency Testing organisation within the clinical molecular infectious disease diagnostic area.

236. In short, QCMD would provide the laboratories with anonymous (but known to them) viral samples of varied concentration levels which would be processed by the laboratory in a test plate in the same way as any other patient sample. The results would be returned to QCMD for independent verification.

237. During the pandemic, scores of countries subjected their SARS-Cov-2 virus diagnostic laboratories to the relevant QCMD challenge scheme. QCMD reported the qualitative performance of the Lighthouse Labs and global laboratories. All four Lighthouse Labs scored 6 out of 6 in correctly testing the QCMD essential 'core proficiency' samples. In relation to the more challenging 'all proficiency' samples, three out of four labs scored 8 out of 8. In my view, the worldwide QCMD challenge testing, demonstrated that the Lighthouse Labs had world class quality scores, which is no less than I expected. I exhibit the emails where I discussed this with Professor Klapper and the QCMD Report: Exhibit CM/129 [INQ000511255], Exhibit CM/130 [NQ000511256], Exhibit CM/131 [INQ000511257], Exhibit CM/132 [INQ000511264], Exhibit CM/133 [INQ000511279].

(b) Data analytics

238. I referred to this when explaining the stages of a qRT-PCR test above. In plain terms this refers to the process and systems you have in place for looking at the results produced by the diagnostic testing process and the data generated.

239. In a qRT-PCR test, light is produced in relation to those patient samples that contain viral genetic material. How much light there is, and how quickly it is generated in relation to the number of test cycles being run indicates the degree to which the virus is present. The visual representation of the result takes the form of PCR curves. These PCR curves may be reviewed by eye – as many were in NHS facilities – and are capable of being analysed in the minutiae.

240. However, the purpose of the Network was not to produce clinical reports of that nature. Therefore, it was agreed between me and Pillar 2 clinical leadership that the results would be recorded in relation to each sample as either positive, negative or void. Furthermore, the threshold at which a positive result was to be recorded would

be set low i.e. if during the test any light was produced such that a PCR curve was present in the test results a positive diagnostic result would be recorded.

In order to standardise and scale the analysis of these PCR curves (which could not be done by eye at the scale of the National Testing Programme and with the consistency required) an automated data analytical system was needed that could be trained by the available number of experts to read and analyse the output from PCR testing machines on a large and increasing scale with tireless consistency within and between laboratories.

241. During March 2020, four potential automated software solution providers were identified:

a) UgenTec, a Belgian company, proposed by Thermo Fisher (the provider of the PCR testing equipment) and operating in a reference lab in Belgium using Thermo Fisher PCR machines;

b) Genedata, a traditional software provider to the drug discovery industry, performing non-diagnostic automated testing at scale and already in use at the Alderley Park site;

c) Thermo Fisher itself who, on 24 March 2020, proposed a solution that they were launching in the United States; and

d) Diagnostics.Ai, recommended by Dr Sudhanva, as providers of PCR analysis based on its service at King's College Hospital.

242. Between 24 March 2020 and 28 March 2020, Dr David Murray, an Associate Director at AstraZeneca who was assisting the Lighthouse Lab at Alderley Park (and was later seconded to MDC), was asked to consider Thermo Fisher and Genedata. After initial expert consideration these providers were removed from the review.

243. On 23 March 2020, I provisionally agreed with UgenTec for them to undertake a two-week trial of their software, which was to be run by UBL in the Lighthouse Lab in

Milton Keynes as this was then the only laboratory immediately available Exhibit CM/134 [INQ000510863]. A comparative exercise was designed to evaluate the Diagnostics.AI solution also to be conducted at UBL. I thought it was necessary to conduct a comparative analysis with the Diagnostics.AI solution, even though this would cause some delay, because it would help us to make as informed a decision as possible on which provider to select. I was however conscious that we were acting in emergency circumstances and so, in the event, it was simply not possible to perform the sort of process which might be undertaken under normal circumstances.

244. I relied on UBL's findings on the accuracy and suitability of the solutions and their decision that UgenTec was the preferred platform, based on analytical performance and taking into account other support considerations.

245. I should record that after the decision had been taken Diagnostics.Ai brought proceedings in the High Court against UBL, MDC and the DHSC over the selection of UgenTec as provider of the data analytical solution for the Network. Litigation of this kind at such a critically important time was a tremendous additional burden. In the event, that matter was settled by the DHSC.

246. Once installed centrally and applied across the Network, the UgenTec software enabled the Clinical Leads to precisely train the software to determine whether a test was positive, negative or void. Working with the software engineers the laboratories were ultimately able to do considerable detailed work on analysing the PCR curves, the anomalies and the changes in patterns that emerged across the pandemic. The software successfully analysed over 150m tests across multiple laboratories. The UgenTec team should be congratulated for their product and service, but moreso for their forbearance as they remained unpaid throughout the legal challenge and could have legitimately denied service to the Network. They did not, to the great benefit of the UK and its citizens.

(c) Sample custody control

247. Another important aspect relevant to QC is the system you have in place for taking custody of a sample and the control you then exercise over that sample through the testing process to the delivery of the results at the end.

248. The Lighthouse teams jointly agreed the process by which test samples would be manually handled and prepared for qRT-PCR analysis. This was the most complex and variant element of the process.

249. As described previously, test swabs arrived and were removed from their packaging. The unique barcode related to each sample was scanned entering that sample into the Brooks LIMS.

250. The LIMS also had to be able to connect to the National Pathology Exchange ("NPEx") which is the national laboratory data exchange service used by the NHS to receive data from their many private sector laboratory providers. It was via this interface that the test results were provided for the NHS to give to the patient and for wider analysis and assessment.

251. In short, at each step of the testing process we had to implement a secure system of custody control over each individual sample. I was confident that we managed to do that. There were challenges that arose along the way. The key is to have systems in place to address issues that arise. To illustrate some of the challenges: (1) April 2020 – 25 duplicate and conflicting results were issued by Alderley Park. This was identified, assessed, reported on and corrective actions put in place. I exhibit the following related documents: Exhibit CM/135 [INQ000511080], Exhibit CM/136-INQ000511086], Exhibit CM/137 [INQ000511087], Exhibit CM/138 [INQ000511088]; (2) May 2020 – June 2020 – a wider Network issue was identified in relation to duplicate barcodes being used in relation to samples and the impact on processing and reporting of results. This was considered at length and a system wide solution had to be found. I exhibit key emails and documents to illustrate the discussion, and the solution arrived at: Exhibit CM/139 [INQ000511136], Exhibit CM/140 [INQ000511161], Exhibit CM/141 [INQ000511206], Exhibit CM/142 [INQ000511295], Exhibit CM/143 [INQ000511324], Exhibit CM/144 [INQ000511325], Exhibit CM/145 [INQ000511326].

252. Data was the product of the Network laboratories. At its simplest the input data were barcodes and output data were positive, negative or void test results. However, this rapid-turnaround, daily flow of sample data allowed the DHSC, NHS and PHE to see a 'live' picture of the development of the disease. This was evidenced with the

Lighthouse Labs as the first to identify what became known as the 'Kent Variant', something that was subsequently published in the scientific literature.

253. Generally, we were aware that the data generated by the Network was looked at by the DHSC, PHE and Pillar 2 teams to help identify local hot spots of disease where additional testing sites might be focused. Also areas where testing numbers were considered comparatively low could be identified and efforts could be made to encourage testing on the ground and to make testing sites more welcoming or efficient. We were not involved in the substantive assessment of these analyses which were undertaken by the DHSC and Deloitte, so I cannot speak precisely to how this was done. We were however involved in practical matters. For example, if new testing facilities were to be targeted in a specific location that would impact the volume of tests arriving at a specific Lighthouse Lab, we would wish to be informed to most accurately balance the load across the Network. These communications came principally from Deloitte staff. My main contact for logistical matters of this kind was Kevin Tsang.

254. Network laboratory leaders and data analysis leaders were also actively engaged in looking for trends in the data that might indicate the presence of a variant which we would then report to PHE. The role of the Network was not to analyse these variants. This would be done by the Wellcome Sanger Institute, with whom I, UBL and MDC had developed a sampling transfer route in the first weeks of the programme.

255. All this subsequent data analysis is only possible if the underlying results themselves are produced in laboratories where a robust and consistent QC system is in place. Despite the incredibly trying circumstances in which the laboratories in the Network had to create and implement such a QC system, I remain confident that we did so.

12 Data sharing

256. The Lighthouse Labs deliberately stored very simple data. It was also an early decision of mine with the NHS not to receive or process any patient information. Deloitte colleagues on behalf of DHSC (and with NHS colleagues) developed software that pulled fresh results data from the Network and passed it to the NPEx platform which linked it with NHS patient information.

257. The NPEx software was already in existence and in use by the NHS. It allowed non-NHS labs to routinely feed data back to the NHS data system. To my mind it was logical to use NPEx to share our test result data with the NHS. Deloitte managed the interface and monitored the flow of data. I exhibit an email to illustrate communication with NHS and Deloitte colleagues relating to NPEx, Exhibit CM/146 [INQ000511068].

258. I remain confident that the Network provided the NHS with quality-assured data at scale.

259. The Lighthouse Labs also routinely shared process and load data with Pillar 2 colleagues. I have explained elsewhere that this included a large team of talented people from Deloitte working for the DHSC in Pillar 2. My principal contact in relation to these matters and logistical matters generally was Kevin Tsang. The openness of this process data sharing allowed issues to be identified and addressed as soon as possible. Pillar 2 also monitored the flow of data into and through NPEx, which allowed temporary data blockages to be rectified. So far as it relates to data sharing, the key issue was to try and ensure that the data generated by the Network was not only deposited in the respective LIMS system but flowed into NPEx for onward assimilation by the NHS data systems. There were times when these data connections would temporarily stall leaving data to sit in one location or another delaying transmission of the test result to the patient. These were identified by tallying the approximate number of results generated with the number of tests reported and restarting any stalled data transfer systems. However, there was good and open communication between the Lighthouse Lab sites and the Deloitte team so where this happened any temporary blockages could be rectified.

260. We have no view on the effectiveness of other data sharing arrangements across the wider test, trace and isolate regime.

13 Locating equipment

261. As noted previously, on 21 March 2020, I was introduced to Ed Whiting, then Director of Strategy at the Wellcome Trust.

262. Mr Whiting was assisting with contacting all the universities in the UK to understand what equipment they had and what equipment would be available to help with the national effort.

263. Requests to donate the specific equipment we had selected were broadcast across the UK university system and beyond by Sir Jeremy Farrar, Director of the Wellcome Trust. These included requests for specific KingFisher PCR preparation machines and PCR cyclers (Quant Studio machines) (both known to function with the Thermo Fisher qRT-PCR test) alongside standard large scale laboratory equipment including class 2 safety cabinets, fridges, freezers, liquid handling automation systems and even manual pipettes. Over 400 pieces of pre-decontaminated equipment were volunteered and subsequently moved to the three new Lighthouse Lab sites by members of the Armed Forces, coordinated by a team at the Office of the Prime Minister. It is notable that many of these items arrived with notes of support and encouragement from their donors to the Lighthouse Lab programme.

264. Thermo Fisher assisted with scoping the request exercise as they were able to provide Pillar 2 and me with information about the hardware they knew had been sold in the UK and where it was. Wellcome used this information to source the equipment. Universities, other educational and scientific institutes and companies (some in the agricultural sector) donated equipment. Thermo Fisher also supplied their engineers who attended the sites to commission their equipment which were donated.

265. When the time came to return donated equipment, DHSC ensured the donor received the same or better (in some cases, new) equipment back. I believe that this was one way in which the generosity of the national community could be reflected by the programme.

266. Locating, de-contaminating, moving and recommissioning over 400 pieces of capital equipment around the UK was a major exercise conducted at pace, with exceptional co-operation from hundreds of organisations, people and the Armed Forces and is a testament to a national sense of urgency and public service. It was common for equipment to arrive accompanied by messages of goodwill from their donors.

14 Supply chain management

(a) Getting kit to the Lighthouse Labs

267. Andrew Gilligan at the Office of the Prime Minister organised the logistics of how all the equipment that we were obtaining from across the nation would reach each Lighthouse Lab. Andrew deployed the Armed Forces (which is why the initial effort was led by the Office of the Prime Minister). At a later stage, Pillar 2 was given access to the Armed Forces and were able to deploy them for the delivery of consumables and the erection of warehouses at each site.

(b) Consumables

268. It was always important that the Network did not disturb the supply chain of the NHS for consumables. In the early days when Pillar 1 was carrying out all the testing in NHS labs, the Milton Keynes site released some of its plastics and reagents to the NHS until the Network was in a position to scale up its capacity. I can't recall any time when I, as co-ordinator, was approached by NHS colleagues for consumables and said no.

269. Each Lighthouse Lab needed to develop supply chains for hundreds of different consumables that each would use including reagents, plasticware, PPE, all sorts of other ancillaries. Many of these were the same or similar. I believed it was therefore cost-effective and reduced operational risk to create some of these supply chains at the Network level. In the early days of the programme there was nobody with a strong supply chain background through Pillar 2.

270. I therefore sought help from industry and seconded Cassandra Wardle from AstraZeneca who was one of their manufacturing and supply chain experts. She worked with me and operational lab leaders for several weeks to establish a list of items and available routes of supply for those items and there were then multiple negotiations, contracts and so on established with the providers for a few hundred different items to ensure consistency of supply. Cassandra Wardle put the structure

and its scalability in place. Some orders that were placed centrally in bulk where it was better value for money and availability was sparse. The only exception to this was the Thermo Fisher kit which was always purchased centrally and directly through the DHSC. The Network labs never directly purchased any qRT-PCR kits. After the end of her secondment, Cassandra Wardle was replaced at MDC by Mike Hegarty – another supply chain professional, who then transferred full time into Pillar 2 and successfully served in logistics for PCR and lateral flow until the end of the pandemic. MDC also had some volunteers from laboratory supply chain companies, including the CEO of Amici Ltd, who helped discipline and manage stocks of key consumables.

15 Logistics and delivery of samples

271. The logistics of getting the samples from testing centres to the Lighthouse Labs was the responsibility of Deloitte.

272. Deloitte had very distinct groups responsible for the set-up and running of regional test centres. Neither I nor MDC were involved in this. They were also responsible for transport logistics (getting the samples from the test centres to the Lighthouse Labs) where the Lighthouse Labs were the recipients.

273. There were numerous interactions daily by phone and email with Kevin Tsang (Deloitte/Pillar 2) in relation to which Lighthouse Lab had capacity and where the samples should be sent to. This was called load balancing. For example, you could have one day where you have ample capacity, to the point where you are able to send people home from the shift to other days where you would have an influx of samples with a bad set of swabs in the tubes which required the redirection of samples to other Lighthouse Labs.

274. Through the frequent interactions with Pillar 2 (Kevin Tsang) on lab capacity and anticipated sample volumes, I and Lighthouse Lab leaders would generally have some estimate where capacity would be available. However, the prediction of daily capacity and delivery varied massively and was largely unpredictable as it varied depending on where in the country people were visiting test centres and the quality of the samples received.

275. On the whole, the system worked well, and the communication was good. I and Lighthouse Lab Leaders had the ability to influence the logistics upstream by diverting samples to different Lighthouse Labs as needed. As the variety of plastic tubes and swabs became more consistent lab-to-lab sample load management ran robustly as envisaged.

276. Other than to update upstream on our current capacity status, MDC was not involved in the logistics of how samples reached the Lighthouse Labs.

16 Staffing

277. Each Lighthouse Lab developed teams to serve each stage of the PCR process. These included sample reception, unbagging, initial acceptance and plating, sample purification, sample cycling and reading and data analysis. Supporting these functions were operational teams of laboratory facilities, PPE, disposals, health and safety, laboratory automation specialists, IT systems, HR and staff welfare.

278. In the first 6-8 weeks, the Lighthouse Labs were staffed with core teams from the host organisations, including scientists and leaders from UBL's and MDC's core teams and those I brought into Glasgow through UBL. They built the labs, established the operating procedures and ensured approval and validation from key stakeholders including the DHSC, the NHS and the HSE.

279. However, during this same period, DHSC and the individual laboratories were approached by many hundreds of staff willing to volunteer. Laboratories were only able to effectively onboard (approve, train and put to work) those volunteers once the laboratory developed scale with enough samples to be tested and were set up with the machinery needed.

280. This volunteer phase started during the first 'lockdown' and developed into labs with many hundreds of volunteer staff from across the UK, a great number of whom had NHS Biomedical Sciences certification, were science graduates, had doctorates or were doing post doctorates. These volunteers wanted to put their skills to good use, and to help the testing effort. Some of the volunteers lived locally, many did not,

putting themselves into service many hundreds of miles from their homes and families. This required the provision of accommodation and sustenance in local hotels and transport, across multiple shifts. Staffing involved self-testing to track any outbreaks and to maximise staff safety.

281. Each Lighthouse Lab extended its staffing, using our networks and contacts, through the structured selection of volunteers and subsequently employees, training and on-boarding them to ensure that each was skilled at an often repetitive but vitally important task before having access to patient samples. This was vital for staff safety as well as for quality and was identically applied to early-stage career scientists and volunteer professors.

282. Many volunteers were from universities (the Alderley Park site had many staff from Manchester University and many volunteers at UBL were from Oxford and Birmingham Universities), and from organisations such as Cancer Research and from MDC itself. Professor Peter Simpson had strong relationships with University of Manchester, Cancer Research UK and regional biotechnology leaders.

283. Out of respect for the NHS, we wanted to avoid hollowing out an already stretched NHS, so the Lighthouse Labs did not deliberately target NHS laboratory scientists (although many offered their services and some chose to resign and join a Lighthouse team). We were strongly criticised for this by commentators, but our Clinical Leads were all NHS leads in virology and, over time, an increasing number of our staff were members of the Institute of Biomedical Science ("IBMS") (the leading professional body for NHS biomedical scientists and support staff).

284. The structured selection, training, testing and on-boarding system in place at each site ensured the volunteers were competent in basic lab work. Each lab had a training programme and a training lab where people were trained in groups. The Lighthouse Labs collaborated on the training of staff and any differences in the training, which included health and safety training, reflected the physical differences at the sites. At UBL, a huge open floor lab was built, almost like a warehouse. The Alderley Park site was a 3-floor building, so we used each floor for one distinctive purpose. Whereas Glasgow was a mixture of some office and some lab premises.

285. The training did not include the use of live samples with volunteers instead being trained and tested using non-hazardous materials. The volunteers' laboratory skills were tested post-training, for example, their pipetting skills despite their background and CV in science and lab work. If accepted, they would have a site walk around, would then shadow volunteers working on the programme, then work side by side with them and then work under supervision. Only after this would they be allowed to work individually. The process took a couple of weeks to complete. There were shift captains and lab captains at the Lighthouse Labs whenever samples were being processed who had responsibility for productivity and safety. Volunteers could progress from doing basic lab work to managing a floor in 6 months if they showed they were capable.

286. Science graduates sometimes have uncertain lab skills although they may have done lab work but have enough awareness and knowledge of lab work to enable them to be trained for the basic, highly repetitive lab tasks being performed which did not need diverse skills. These tasks required essential, but not advanced, skills such as working in a safety cabinet, using a pipette and moving around a lab safely. More specialised skills were required for the automated work and tasks like putting the samples onto the plates and for qRT-PCR machine work and related reading skills, but fewer people were needed. Other work, including sample receipt, racking, unbagging required more general skills which was the work done by most of the volunteers. The Army, who had a big presence at UBL, were doing the 'heavy lifting', taking crates and boxes of samples off lorries and passing them on for unpacking. They also organised all of the consumables and were used at Alderley Park for warehousing work.

287. The training of the lab volunteers and, later, of contracted staff, was given by people who had been involved in establishing the process and/or had been in charge of safety or a floor of a lab and included MDC and/or UBL staff. When they could, Clinical Leads were also involved in the training.

288. In July 2020 (around the end of the first lockdown) the Network set out to build a pipeline of non-volunteer (contracted) staff for each facility. This was in line with the expansion plans for the Network - to prepare for the expected rise in infections in the autumn - and because volunteers would leave to return to work. This mass-pipelining of hundreds of qualified people per week across the country was achieved through a

combination of centralised Deloitte resources, including agencies such as Reed, in concert with local outreach using our networks and contacts and scaling our HR, finance and training teams and processes.

289. This pipeline of thousands then required structured vetting, training, testing and onboarding, alongside the running and continued scaling of the facilities. Six-to-twelve-month contracts were put in place between individual Lighthouse Labs and members of staff.

290. At the time of the first lockdown MDC had 130 employees. 9 months later that had increased to 1,200 people. Similar scaling had to take place across the Network. All of this expansion was initially funded directly by MDC, UBL and the University of Glasgow as operators of the Lighthouse Labs.

291. In my view, the selection, training, testing and on boarding system ensured that only those with the relevant skills and expertise were taken on to work in the Network.

292. So far as I was able at the time, I rejected the criticism made of the Lighthouse programme regarding the staffing of the Lighthouse Labs and shall continue to do so now.

293. The volunteers, with an average age of 26, are to my mind the true unsung heroes of the Lighthouse programme. They worked 8-hour shifts night and day, doing highly repetitive tasks, in safety critical environments, as part of flexible teams and conscious of the importance of their work. It was a humbling and affirming respite to visit Lighthouse Labs in all parts of the country and talk with these committed and selfless people.

294. Despite almost constant broadcast critique from outside the Lighthouse programme, the many thousands of Lighthouse Lab staff (volunteer and contracted) welcomed and valued their chance to serve the nation. The programme, in turn, gave a generation of young career scientists the training, opportunity, networks and purpose that will be their foundation.

17 Lessons learnt

295. In this section I set out the lessons learnt during my and MDC's involvement with the National Testing Programme. We are only able to realistically comment in relation to our own experience carrying out our specific role and the limitations of that (both in time, duration and scope).

296. To put our lessons learnt in context, it is also important to remember the point at which we started in relation to testing and capacity in the UK before the pandemic. I am aware that the Inquiry has already considered the overarching topic of preparedness in its Module 1 Report (including, Testing and contract tracing, paragraphs 5.62 to 5.68). The Report reflected my experience. In particular, the entirety of the UK's testing system was designed to deal only with small numbers of cases and there was no capacity for mass testing. We were therefore starting from scratch. In particular, and in relation to testing infrastructure, I and my fellow Directors agree with this statement:

5.68. The UK government and devolved administrations could and should have invested in this infrastructure in advance of the Covid-19 pandemic but had not done so. While policy decisions on the allocation of resources are ultimately a matter for elected politicians, and such investment would have been significant, the Inquiry believes it would plainly have been worthwhile, given the devastation wrought by the initial absence of effective infection control and the massive cost to the nation of building test and trace systems from scratch. The building blocks and essential structure of the test and trace systems established by the UK government and devolved administrations during the pandemic should be maintained so that these systems can be rapidly restored and adapted for use in the event of a future outbreak.

297. MDC has not been invited to any lessons learned exercises in respect of the National Testing Programme (either independently or with the Government) during or after the pandemic or after the demobilisation of the facility at Alderley Park. Neither I nor MDC are aware of what lessons had been learned from previous pandemics, incidents, exercises and approaches in the UK or adopted by other countries.

298. I was called (in my capacity as CEO, MDC) as a witness by the House of Commons Science, Innovation and Technology Committee (the "Committee"). The Committee

investigated on the subject of "Emerging diseases and the learnings from covid-19". I gave evidence on Wednesday 24 January 2024 with Professor Dame Anna Dominiczak, then Chief Scientist, Health Scotland, but also formerly the sponsor of the Glasgow Lighthouse and my successor as Director of Lighthouse Laboratories, and Dr Robert Howes, then Head of Discovery Sciences UK, Charles River Laboratories, but also formerly Director of the Rosalind Franklin Laboratory.

299. The overriding and abiding lesson from the beginning of our engagement with the National Testing Programme was the remarkable collaboration that took place to enable the Lighthouse Labs to be established in the first place. A coming together of colleagues both public and private, paid and volunteer, united in a single purpose to deliver these Lighthouse Labs for the good of the nation.

300. However, the fact that its people can rise to an occasion and respond to such a national emergency should not be taken for granted by the State and relied upon in any way as a substitute for proper planning and preparedness for the next such emergency.

301. Nothing I go on to say should be read as detracting in any way from the tremendous effort that everybody who came to the Network invested (for which our gratitude will never be enough), but there are a number of things I wish we knew from the outset and there are a number of things, I feel, we could do differently should we have to respond to a pandemic in the future.

(a) <u>Type of test and rapid lateral flow</u>

302. The lesson learnt, in the context of diagnostic testing during a pandemic, is to prepare better for the type of testing you might reasonably need, and to order your affairs such that you will be able to deliver what you need when you need it.

303. If we had access to validated lateral flow tests from the start, we would perhaps not have needed to establish the Network at the scale and capacity that we did.

304. There were no validated and manufactured lateral flow tests for Covid-19 at the start of the pandemic. The decision that was made to use qRT-PCT was not a case of choosing the wrong test, and it is no criticism of the effectiveness of the qRT-PCR test that was used; we used the test that was available. Lab-based PCR was used as a 'gold-standard' test of infection, with a necessary assumption (at the time) that this determined to a strong degree one's infectiousness towards others. By the end of the pandemic antigen lateral flow tests were being used in the home to test for infectiousness, with infection then able to be confirmed by a small number of PCR tests.

305. Lateral flow tests took approximately six to nine months to generate, validate and manufacture at scale. This was the case for tests derived from the UK and abroad. However, test development began in regions closer to the outbreak of the infection and only later in the UK. This is no failing of the UK diagnostics sector.

306. As mentioned previously in this statement, after my time acting as co-ordinator of the Network, I was involved with consortia looking to develop, manufacture and supply rapid testing technologies in the UK. This was fraught with challenges, not least the dominant role played by NHS procurement in the UK, which in this case meant that by the time any UK entity had developed, tested, evaluated and manufactured a product the NHS had already secured the supply chain it felt it needed from abroad.

307. Only one English supplier was ultimately used at scale (SureScreen Diagnostics, SARS-Cov-2 Antigen Rapid Test Cassette) but they had to rely on the international supply of antibodies. We had capacity within the UK to manufacture our own antibodies, but the NHS chose to procure antibodies outside the UK. Anything procured outside the UK in relation to public health always creates a risk in terms of availability of supply, especially if borders shut down which was a real risk during the Covid-19 pandemic.

(b) <u>Premises (space and capacity)</u>

308. Locating and converting suitable space was one of the biggest challenges we had at the outset. There were no facilities that would not require significant reconfiguration. Although we identified a number of potential premises in a short time, each of the Lighthouses needed to undertake significant works to convert them to useable spaces for the industrial scale 'production lines' for PCR. Whilst the technology needed for a future pandemic response may be different, had we the safety cabinets, sample handling and machine room space we could deploy people to such spaces more rapidly, re-configure and deliver more quickly than we could in 2020 from a standing start.

309. The lesson learnt was that valuable time (potentially as much as 4 to 6 weeks) was lost at the beginning because suitably configured and pandemic-ready premises had not been previously considered for build or identified from existing laboratory stock as suitable for rapid mobilisation.

310. What we needed, at the start of the pandemic, was access to space or a facility that could easily have been used for something else during non-pandemic times but, in the event of a crisis, had the option and potential to be brought into service.

311. As matters now stand the Network has been fully demobilised. The premises at Milton Keynes have reverted back to UBL. The Glasgow site has been completely demobilised. There is a small amount of diagnostic testing (not Covid-19 related) being done in Alderley Park by a small company that is not part of MDC. The remaining space has been completely demobilised and reverted to the landlord. The future use of the DHSC's flagship Rosalind Franklin Laboratory remains in question.

(c) <u>Tests with agreed methodologies, standards and quality control</u>

312. The sole purpose of the Network was to deliver diagnostic testing at scale, without compromising quality. To achieve this, we needed consistency of approach.

313. When the call came to set up the Network, apart from the type of test to be used, there was no pre-prepared plan that set out the quality standards that should have

been implemented, the quality controls that should have been put in place and the evaluation and accreditation requirements of the respective laboratories.

314. If all of this was in place, then the consistency issue is vastly improved. There will still be issues of reporting the results back to the NHS and the supply chain issues inherent in any industrial mass process, but the set-up of the labs and the standards by which they operate becomes consistent. This ultimately means you are better able to identify and address any quality issues as and when they arise.

315. We did not have a pre-prepared plan in place and were having to create the plan as we went along.

316. I remain confident that, in the event, the solution that was eventually put together in collaboration with all the principal stakeholders was appropriate and that quality was not compromised, but this could have been done better.

317. Allied to that and to give examples:

318. If there had been a pre-prepared plan, some of the issues that hit us hard in the early stages may have been identified and worked through before they happened. For example, I mention in this statement the issue that plagued us in relation to the input variables and the impact that had on us being able to scale up testing capacity. In the event, the significance of this wasn't appreciated until it happened, and we were faced with trying to problem solve on the spot at a critical time. For example, at Alderley Park in April 2020 in addition to setting up the lab and doing a day of testing, scientists embarked on assessing the suitability of kit and consumables such as input vial types: Exhibit CM/147 [INQ000511042], Exhibit CM/148 [INQ000511043].

319. Criticism was levied at the Network by the IBMS asserting (based on reports in the media) that the Network failed to deliver robust data and the data flow to the NHS was stilted. I did not agree with this criticism (which, as I indicted to the Committee, seemed to come, in part, from the absence of accurate information about the Network in the public domain. Also, the data do not support the contention). However, in my

view Government (in the form of Pillar 1 and Pillar 2) could have engaged directly with the leaders of the IBMS and brought them under the umbrella of the programme to work through their concerns ensuring, where relevant and material, that those concerns were addressed in the processes and procedures deployed in the Network. To the best of my knowledge that was not done as part of the arrangements we ended up working to.

(d) Evaluating systems and new technologies during a pandemic

320. Identifying, testing, purchasing and implementing into your system the various technologies you need in a HTS setting is challenging at the best of times.

321. A lesson learnt is that amid an ongoing pandemic that challenge is on a whole other level.

322. I, all Lab Leaders, volunteers and staff strived to do things correctly and effectively with our compass set squarely on securing consistency of approach and quality in relation to the ultimate test result, but there may have been occasions when in different circumstances we might have approached things differently.

323. I am not saying that I think consistency and quality were ultimately compromised, but I cannot categorically say that we did not miss an unseen opportunity to improve or do things better by taking a different approach or adopting an alternative or new technology.

324. There were endless offers of new technology, many of which were evaluated during the pandemic, but that is not an easy task. Moreover, the lead in time for any implementation of new technology, even if suitable, may have been too late and at the cost of downtime, changes in result consistency and output.

(e) Communication

325. We, as a Network, got on with the job in hand. However, the communication to the public about the purpose of the Network, the standards that were implemented, the

quality controls that were in place, the evaluation and accreditation that was in place became very reactive.

326. Early engagement on communication would have avoided all the miscommunication between all the different parties about what was happening. It would have also allowed us to spend more time focussing on the real issues in hand rather than responding to allegations that were, in my view, often misleading and incorrect.

327. All communication was handled by the DHSC. Given the time again, I would be communicating publicly, much more frequently and routinely and purposively.

328. This lack of communication led to uncertainty amongst the public. The public needed to be informed about what was happening. The lack of co-ordination, pro-activity, and the absence of clear information led to us always having to be on the back foot and having to respond to requests from the media and TV documentaries about what was going on. I exhibit two examples which illustrate how I was invited to assist in responding to media criticism (Exhibit CM/149 [INQ000511327], Exhibit CM/150-INQ000511344], Exhibit CM/151 [INQ000511345]).

329. I and MDC had nothing to hide and wanted to publicly share some of that exceptional collaboration that was happening on the ground.

18 Lessons for the future

330. It is inevitably with some trepidation that I approach the topic of lessons for the future and what recommendations to suggest to the Inquiry.

331. Unfortunately, when it comes to the provision of healthcare (including clinical diagnostics) in this country parties hold strident views, and to my mind much of the needed discussion is hampered by a public-private divide. I personally, and MDC as a Catapult, should much rather see a lot more of the collaboration between the state and industry that we saw at the start of the pandemic.

332. The UK comes together as a nation at times of crisis and did so in this effort. The default answer was 'yes' to almost any question asked. At the ending of the pandemic this 'can-do' attitude has retrenched into 'the problem with that is…' responses.

333. To our mind, preparation and preparedness with a purpose is key, and most of our comments are directed to that end.

334. Conscious that some may consider our suggestions as self-serving (which is not the intention), I and my fellow Directors would respectfully suggest as follows:

(a) Infrastructure

335. As above, MDC agrees with the Inquiry when it said that "The building blocks and *essential structure of the test and trace systems established by the UK government and devolved administrations during the pandemic should be maintained so that these systems can be rapidly restored and adapted for use in the event of a future outbreak."*

336. Specifically, provision needs to be made so that suitable premises are already identified and can rapidly be brought back into the required use. The identification of suitable premises should be approached collaboratively between the public and the private so that a complete and informed picture of potentially suitable assets is considered.

337. A contractual framework could be put in place that allows companies to operate and trade from facilities but also allows the facilities to be taken back instantly in the event of an emergency.

338. We are concerned at the current state. Although the lights of the Network were turned off at the end of the pandemic, we need to leave the safety light on. We need that available space to move back into, should we need to fight the next war. The technologies that we will use to fight the next war may not look like the technologies we used to fight the last one; but the space that we would need to put them in and to

take people to, so that we could effect the industrial process that we would again need, is paramount.

(b) System planning and preparedness

(i) Type of test and rapid lateral flow

339. We would strongly encourage investment in our sovereign lateral flow industry.

340. Each year there is a new virus or a pandemic type virus, there needs to be an immediate move to develop a 'stand-by' rapid lateral flow test. Just as, in relation to vaccination, there is with the flu vaccine which is updated each year. This would enable PHE to assess infectiousness and would allow the public to amend their behaviour based on the outcome of a test that they can do in their own home. Rapid lateral flow testing is transformative in enabling the public to change their behaviours and contain viral spread, which ultimately means you have the chance to prevent so much of the terrible losses that accrued in the pandemic.

(ii) A pre-prepared and agreed framework for the scaling up of mass testing

341. There should be a pre-prepared and agreed framework for the scaling up of mass testing. The framework should be the work of a triumvirate combining the State (including the NHS), industry and academia. The framework should address reasonably foreseeable scenarios and contain information on the type of test to be used, the quality standards to be implemented, the quality controls to be put in place, and the evaluation and accreditation requirements of the laboratories needed.

(iii) Sovereign capacity

342. There should be sovereign capacity in relation to essential elements required to deliver mass testing during a pandemic. Measures to facilitate and encourage investment on these shores are strongly recommended.

343. During the pandemic we were heavily reliant on the international borders staying open. We had no sovereign capacity for some consumables, even the basics, plastics being one. In terms of preparedness, the patency of the supply chains does need to be tested, checked and planned for. Border closures to trade would have been existential threats to the programme.

(iv) Pandemic response exercises (or 'war rooms') should include scaling up for mass testing

344. Prior to the pandemic there was no apparently relevant plan for mass testing. First, there should be a plan specifically dealing with mass testing. Second, any such plan should be tested in regular war room exercises against a range of threats and test types.

345. The production of the plan and its subsequent testing is best conducted by a triumvirate combining the State (including the NHS), industry and academia. This presents an opportunity to bring principal stakeholders together to address how the nation could have responded to a national emergency. It would include the availability of tests, supply chain for consumables, availability of equipment etc. and a commitment to evaluate new types of technology as part of the process.

346. A plan tested in this manner ought to save time and allow a 'faster twitch' response to any crisis.

(v) A Diagnostic Catapult

347. During the demobilisation period MDC made representations to Government for the establishment of a Diagnostics Catapult in the same vein as the existing Catapults. It seemed to us that the unique position that a Catapult can take, between the public and the private, could offer significant benefits in the area of clinical diagnostics and the scaling up of mass testing during pandemic scenarios. Such a Catapult could likely make a significant contribution to work in this area including in relation to

maintaining human capital and the necessary skill set and in relation to logistics (the necessary consumables, equipment etc., where there could be sources and how they could be delivered). I raised this initially in the summer of 2020 under the heading of "Next steps – Diagnostics Catapult" (I exhibit an email exchange (Exhibit CM/152 [INQ000511350]), my discussion paper (Exhibit CM/153 [INQ000511351] and a subsequent note (Exhibit CM/154 [INQ000511354]).

348. The establishment of the Lighthouse Labs and our ability to undertake mass diagnostic testing moved the diagnostics industry forward by a decade. To have been forced to close these facilities, and abandon this world-class capacity, is, in our view, a poor and short-sighted decision.

349. It caused a critical lack of capacity for augmenting our health services to reduce waiting lists, ca. 30% of whom are awaiting a diagnosis.

350. It belied the political promise to support the diagnostics industry in the UK which diagnostics sector may remain in the eyes of many a poor relation to biotech. It is and must not be. The nation must not demobilise and forget in the knowledge of the progress it made. It must take the best elements of the 'wartime' progress and persist them into 'peacetime' but ready for action again should it be needed.

351. The progress that was made in engaging citizens with their own health and the UK with diagnostics is ebbing away, an opportunity that could be recaptured and mistrust rebuilt with a Diagnostic Catapult

19 Reflections

352. I would like to add some personal reflections to this statement as follows:

353. The Lighthouse had a simple purpose. To deliver a qRT-PCR test at scale with consistency and quality, with robustness across the country, augmenting existing NHS capacity to allow that to deliver direct healthcare and population health management.

354. Nobody had ever done a diagnostic project of this scale and pace in all the industry. Volunteers, NHS and Lighthouse staff should feel proud of how they pulled together to deliver this unparalleled programme.

355. In doing this successfully, it provided more testing capacity per capita than in almost any other country and at world-class quality.

356. We were able to provide, in rapid time, a scaled, high quality, informative data service on population health to national health providers and to members of the public. The nation mobilised a combination of national health, industry and academia to run the nation's largest ever diagnostics programme. The Network led to thousands of early career scientists being trained, with a common skillset and sharing a real sense of achievement. Although this should and could have been built upon, the legacy of the Lighthouse Labs lives with these young people, who will have the Lighthouse Lab experience as a foundation of their CVs for decades to come.

357. With the diagnostic capability we built in response to the pandemic, we could have caught up and got ahead of the inevitable backlog of cancer sufferers by being able to test them for circular terminating tumour DNA at scale using PCR. We could have tested for common diseases. We could have used the serum testing capacity the Lighthouse Labs had built by that time to test for prostate cancers in men and thyroid deficiencies in women – up to 10% of the female population.

358. To de-mobilise the capacity that we set up without, so far as I am aware, full and proper consideration of how it could be used and funded to support the diagnostics industry and for improved healthcare provision was short-sighted and unambitious. We built, trained and established a national scale population healthcare powerhouse. We enabled and trained tens of millions of people to do testing in the home by PCR and lateral flow. Citizens were empowered to take control of their own health and change their behaviour as a result. A new shared responsibility for national healthcare was created as a result of a global health crisis. The tools to continue this were then rapidly dismantled, and the sector that served so instinctively was abandoned. We are seeing a retreat to where the nation was before Covid-19; the rebuilding of institutional walls that were removed in this Lighthouse programme and the primacy of remit appropriation over national progress. A strategic national lead and focus is

needed to give diagnostics its due place and support both healthcare systems and citizens to deliver the necessity of mass precision healthcare which existed for this short while. As a nation we have lost the ambition to lead globally and left that pandemic leadership in lab diagnostics like Mulberry Harbours, quietly rusting on a foreign shore.

20 Due recognition for those who served through the Lighthouse

359. Without seeking to detract from the core purpose of providing this statement, I wish to use this opportunity to say as follows.

360. Vital to helping this Inquiry to help the nation through my evidence is my wish and duty to publicly recognise this community of thousands of diligent and brave people who selflessly served their fellow citizens and were then rapidly demobilised without commendation. I respectfully ask the Inquiry to recognise, record and publicly thank these volunteers and contact workers, equipment donors and secondees for their national service and their legion of achievements.

361. Specifically, I wish to thank all of my MDC colleagues, my Chair Dr Robin Brown and Board, Peter Simpson, Marcus Harrison, scientists and staff who all took on new roles without question. The site heads, clinical leads, Kristen McLeod CBE and Alex Cooper OBE (who led Pillar 2) and Dr Tom Fowler (who provided its expert clinical leadership).

362. I would also like to thank Dr Mike Snowden, former VP Discovery at AstraZeneca, for his personal assistance, as well as his enabling the secondment of key industry staff and resources to the Alderley Lighthouse Lab which proved invaluable.

363. In addition to all the many colleagues I have mentioned in this statement, during my time with the Network and during the pandemic, I am particularly grateful for the consistent interaction with senior colleagues from Boots, Amazon and Evotec as well as academic colleagues from Universities of Oxford (Professor Derrick Crook) and Manchester (Professors Dame Nancy Rothwell, Professor Caroline Dive CBE, and

Professor Graham Lord). Also, to the team at the Wellcome Sanger Institute for their collaboration in the use of Lighthouse samples for viral sequencing.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: PD

Dated: 10 April 2025