Witness Name: Alexandra Jones

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UK COVID-19 INQUIRY

WITNESS STATEMENT OF ALEXANDRA JONES

Contents

Vaccine Taskforce: Structure, Role, People and Processes

Introduction

1. This is a statement on behalf of the Department for Science, Innovation and Technology (DSIT) in response to the R9 request dated 11 August 2023 in relation to Module 4 of the UK COVID-19 Inquiry.

2. I, Alexandra Jones, am the Director General of Science, Innovation and Growth at DSIT. Prior to this appointment, I was the Director of Science, Research and Innovation at the Department for Business, Energy and Industrial Strategy (BEIS) from April 2019 until May 2023. I was in this position throughout the reference period for this Rule 9 request (January 2020 to June 2022). Before that, I was Director of Industrial Strategy in BEIS from 2017 to 2019 and had previously held a range of senior positions at different organisations working on areas including economic development, labour markets and public service reform.

3. As I will explain in this statement, I had a significant role in the creation of the Vaccine Taskforce (VTF) in my capacity as Director of Science, Research and Innovation at BEIS. It is on the basis of my involvement in the work to establish the Vaccine Taskforce (VTF) that I was asked and duly authorised to make this statement on behalf of DSIT.

4. However, my involvement in the work of the VTF was much more limited following its formal establishment around May 2020. Accordingly, the facts in this statement come from both my personal knowledge, the records of DSIT/BEIS and GO-Science, and corporate memory from others involved at the time. Further, a degree of reliance on corporate memory and the relevant records has been required by the fast-paced and agile nature of the VTF, particularly for the early formative work in its establishment.

Overview

5. In the UK, Research and Development (R&D) funding is primarily a reserved matter, whilst public health is a devolved matter. Generally, funding of UK research comprises a combination of public and private monies, from the UK Government, Devolved Administrations (DAs), universities, charities, industry, and other sources **[AJ/1 – INQ000330774]**.

6. The VTF was a temporary unit established within BEIS in response to the COVID-19 pandemic, in keeping with the UK's objective to vaccinate the right proportion of the population against the disease as soon as possible. The aim of the VTF was to

promote the development and production of a vaccine within the UK. The VTF supported work to develop, manufacture and distribute a vaccine on a UK-wide basis, including the Crown Dependencies and Overseas Territories.

7. The VTF was the idea of Sir Patrick Vallance, who had identified by the end of March 2020 an urgent need to dedicate resources to developing work on vaccines and therapeutics.

8. As the pandemic progressed, naturally the focus of the VTF changed too. Priorities at different times included promoting research and development, developing manufacturing capability, and securing lines of procurement, with varying emphasis as time went on. Accordingly, its work required input from experts across the spectrum of vaccine-related expertise, including vaccine discovery, research and development, clinical development, and manufacturing and procurement.

9. The UK contributed to the discovery and development of vaccines used around the world, most notably the Oxford-AstraZeneca vaccine ChAdOx1. COVID-19 vaccines saved many millions of lives globally, as well as preventing other negative health impacts. The success of the vaccination programme in the UK was a critical factor in reducing the health impacts and other impacts of COVID-19 and allowing the country to begin to live with fewer restrictions from Spring 2021, as well as providing important protection later in the pandemic as new variants emerged.

10. As a unit based within BEIS and which reported to ministers, the VTF was not independent of central Government. Its organisational structure changed over time, as circumstances demanded.

11. While its work necessarily took place within the broader structure of central Government, processes were adapted to increase its chances of success within an acutely time-sensitive context. The VTF did not operate in a silo, but worked closely with several other arms of Government, of which several examples are described more fully below.

12. Therapeutics also made a significant impact, and trials funded and run in the UK helped identify some of the most effective and widely used treatments in the pandemic. These also saved many lives and reduced the severity of health impacts for many people. To support their development, a Therapeutics Taskforce (TTF), was established within DHSC in May 2020 to ensure that the Government had available to it expert advice in those areas from a range of expert sources.

13. In view of the success of the 'Taskforce' model, an Antivirals Taskforce (ATF) was established in the Spring of 2021, to work with industry experts to identify, develop, and procure novel oral antivirals that could be taken by patients following infection.

14. Sir Patrick was instrumental in the establishment of these Taskforces. The ATF and TTF were amalgamated in April 2022 into the Antivirals and Therapeutics Taskforce.

15. This statement also describes the National Core Studies (NCS) Programme. This was initiated in July 2020 to identify areas within UK research infrastructure that required development to further the aim of maintaining resilience in the UK against COVID-19, with a focus on six disciplines (for example, Epidemiology and Surveillance, and Clinical Trials Infrastructure).

16. In June 2022, it was announced that the VTF as a temporary unit would cease to operate, and its functions would be transitioned into long-term bodies across Government. Its legacy responsibilities are now shared between the UK Health Security Agency (UKHSA), DSIT, and the Department of Health and Social Care (DHSC).

17. DSIT was formed in February 2023 and took over some of the functions and responsibilities of the Department for Business, Energy and Industrial Strategy (BEIS), along with some functions from other departments. Much of this statement therefore refers to BEIS's role in the pandemic.

18. DSIT inherited the science portfolio (including sponsorship of UK Research and Innovation) of BEIS. DSIT also hosts the Office for Life Sciences (OLS) which is a joint unit with DHSC.

19. BEIS replaced the Department for Business, Innovation and Skills (BIS) and the Department of Energy and Climate Change (DECC) in July 2016, and existed until February 2023. BEIS was responsible for:

    - Business
    - Industrial strategy
    - Science, research and innovation
    - Energy and clean growth
    - Climate change

20. Mindful of the Inquiry's request to avoid duplication, this statement covers those areas where DSIT has relevant knowledge, documents, or policy responsibilities.

This statement therefore includes an overview of the work done by the VTF in support of manufacturing and onshoring during the pandemic.

21. I do not cover in detail those areas that I expect UKHSA or DHSC to address in their evidence to the Inquiry, where those departments and bodies are better placed to assist because areas of work undertaken by the VTF now fall within their responsibilities. For example, elements of the VTF's work including supporting clinical trials, vaccine selection, procurement and deployment are expected to be covered in evidence provided by UKHSA. Similarly, DHSC has primary responsibility in relation to international engagement (including with the COVID-19 Vaccines Global Access, known as COVAX). Where I consider that another organisation is better placed to assist the Inquiry in relation to a certain area, I make that clear in the relevant section below.

22. I also refer to the role of Sir Patrick Vallance, the Government Chief Scientific Adviser (GCSA) at the time of the COVID-19 pandemic, in establishing the VTF and the other areas discussed in this statement. The GCSA is responsible for providing scientific advice to the Prime Minister and members of the Cabinet, advising the government on aspects of science for policy and improving the quality and use of scientific evidence and advice in government. The GCSA is a permanent secretary level post and reports to the Cabinet Secretary. The GCSA is the head of the GSE profession and co-chair of the Council for Science and Technology (CST), an independent expert committee which provides advice to the Prime Minister. However, responsibility for the discovery, manufacturing, and deployment of vaccines do not sit formally within the remit of the GCSA's role. The involvement of Sir Patrick Vallance (the former GCSA) in the Vaccine Taskforce was therefore undertaken not as part of his formal responsibilities as GCSA, but instead in his capacity as a scientific expert with relevant expertise and experience.

23. Finally, I refer below to the Government Office for Science (GO-Science). GO-Science is responsible for: giving scientific advice to the Prime Minister, and when required, Cabinet committees; improving the quality and use of scientific evidence and advice in government; providing scientific advice in the case of emergencies, through its secretariat role with the Scientific Advisory Group for Emergencies (SAGE); helping the independent CST to provide high level advice to the Prime Minister; supporting strategic long-term thinking in government through Futures and Foresight; and developing the GSE profession. Further details on the role of the GCSA and GO-Science can be found in GO-Science's corporate witness statements for Module 1 and Module 2 (for Module 1: **[AJ/2 – INQ000148406]** and **[AJ/3 –**

INQ000148407]; for Module 2: **[AJ/4 – INQ000252449]** and **[AJ/5 – INQ000252450]**).

Early recognition of the need for vaccines and therapeutics

24. Previous GCSAs have had a range of scientific backgrounds; in Sir Patrick's case, he brought experience as a clinician and experience of working in the pharmaceutical industry. Therefore, although establishing new operational teams would not ordinarily be part of the role of a GCSA, Sir Patrick Vallance played a central role in identifying the need for and establishing the VTF. Once the VTF was established with a Chair in post, his involvement reduced greatly and was limited to offering ad hoc advice and support.

25. The Inquiry has asked whether, if a different GCSA (with a different scientific and professional background) had been in post, the VTF would have been established. I am not sure that I can answer that. The responsibility for vaccines may have remained within the DHSC, although the demands on that department and the need for cross-government action may have seen the formation of some form of bespoke organisation. What I can say is that it cannot be assumed in a future emergency that the GCSA will have the directly relevant scientific background and professional experience that Sir Patrick had in this case. The GCSA may not come from a biomedical background at all. Future planning will need to take this into account, as well as learn lessons from the experience of the Vaccine Taskforce.

26. The first relevant email relating to COVID-19 vaccines from Sir Patrick Vallance was on 22 January 2020. This was in an email to Sir Jeremy Farrar (former Director of the Wellcome Trust), where the GCSA noted the potential use of a self-amplifying mRNA vaccine approach in response to discussions about the emerging COVID-19 situation in Wuhan **[AJ/6 – INQ000330516]**. This was also referred to in an email on 25 January 2020 to Sir Jeremy Farrar, Professor Neil Ferguson (Imperial College) and Professor Sir Chris Whitty (Chief Medical Officer (CMO)), in which Sir Patrick Vallance said that *"this is exactly the type of things* [sic] *that is amenable to mRNA vaccine approach"* **[AJ/7 – INQ000330517]**.

27. Through January 2020 several emails were exchanged relating to vaccines (amongst other matters) between Sir Patrick Vallance and key figures in the scientific community. The most relevant of these are included as exhibits.

Bringing in external expertise and funders

28. Sir Patrick Vallance convened the first of a series of meetings of research funders in January 2020. These included the Medical Research Council (MRC), the Economic and Social Research Council (ESRC), UK Research and Innovation (UKRI), the National Institute of Health Research (NIHR), and the Wellcome Trust. Initially focussed on vaccines, these calls broadened out to cover therapeutics, diagnostics and facilities. These meetings laid the foundations for rapid funding of research programmes, including in genomics and vaccines. For example, the meeting of 27 January 2020 noted, amongst other things, the need for research on therapeutics and the potential importance of mRNA vaccines **[AJ/8 – INQ000063572]**. The minutes state that the *"Quickest option would be mRNA-based, but technology unproven and not an area of UK strength. Worth considering investment in UK mRNA production facilities"*.

29. Further meetings were held on 4 February 2020 **[AJ/9 – INQ000228646]**, 17 February 2020 **[AJ/10 – INQ000228663]**, 28 February 2020 **[AJ/11 – INQ000228688]** and 13 March 2020 **[AJ/12 – INQ000228773]**. Actions relating to vaccines were given to DHSC on 4 February 2020, including one to *"keep avenues open for all possible vaccine platforms"*.

30. Through February 2020, email discussions continued between the GCSA, the CMO, Sir Jeremy Farrar, and others, with a focus on accelerating vaccine discovery. An international endeavour, the Coalition for Epidemic Preparedness Innovations (CEPI), already had six vaccine programmes underway by 3 February 2020 **[AJ/13 – INQ000330518]** and the GCSA requested a 'landscape map' from contacts in industry, which he received on 7 February 2020 **[AJ/14 – INQ000330519], [AJ/15 – INQ000330520], [AJ/16 – INQ000330521]**. Conversations started in earnest about the potential vaccine candidates available (from Oxford, Moderna and others). In the interest of avoiding duplication with the UKHSA's evidence which will address matters related to vaccine selection, I will not cover this in detail here.

31. On 10 February 2020, Steve Bates (CEO of the Bio Industry Association (BIA)) contacted the GCSA to offer support from the biotech industry and through the BIA's networks **[AJ/17 – INQ000330522]**. The BIA consequently conducted a survey on UK manufacturing capability and the results of this came through on 3 March 2020 **[AJ/17A – INQ000408355], [AJ/17B – INQ000408358]**. It was therefore clear that there was a lack of mRNA vaccine manufacturing capacity in the UK, and Sir Patrick

Vallance suggested a need to focus on this in his reply **[AJ/18 – INQ000330525], [AJ/19 – INQ000330523]**.

32. On 21 March 2020, Steve Bates emailed the GCSA to summarise progress in manufacturing, including that of mRNA vaccines, and asked whether a BIA assembled taskforce focussed on vaccine manufacturing, including industry expert Ian McCubbin, could be connected with central Government. He asked if this could *"be adopted as a government taskforce on UK vaccine manufacturing (this could be announced), report directly into Sir Patrick to report progress, seek assistance and support"* **[AJ/20 – INQ000330530]**. While this BIA Taskforce was not directly adopted into the VTF, some of its key personnel did go on to support the VTF. Ian McCubbin and Steve Bates joined the VTF Steering group in May 2020 (see Annex B for a list of key groups), and the BIA worked closely with the VTF throughout its lifespan.

33. In view of the identified need for a co-ordinated discovery, research and development, clinical development, manufacturing and procurement approach led by experts, I supported Sir Patrick to assemble a group that included manufacturing experts such as Ian McCubbin, vaccines scientists including Professor Dame Sarah Gilbert (University of Oxford), people with venture expertise including Dame Kate Bingham (SV Health Investors), Richard Hatchett (Coalition for Epidemic Preparedness Innovations (CEPI)), regulatory experts including Dame June Raine (MHRA) and others. This group became the Expert Advisory Board (EAB) to the Vaccine Taskforce, sometimes referred to as the External Advisory Board. While structures were still evolving, this group was also occasionally referred to as the Vaccine Taskforce, and other similar names were also informally used. This group met for the first time on 3 April 2020 **[AJ/21 – INQ000330734]**. The membership of the Expert Advisory Board also evolved through the coming months (full membership listed in Annex A), and there were extensive discussions through to May 2020 about what should be included **[AJ/22 – INQ000330542], [AJ/23 – INQ000330555], [AJ/24 – INQ000330537], [AJ/25 – INQ000330562], [AJ/26 – INQ000330540], [AJ/27 – INQ000330580], [AJ/28 – INQ000330578], [AJ/29 – INQ000330579], [AJ/30 – INQ000330543]**.

34. The EAB anticipated many of the challenges that would be faced in the process of developing and delivering the vaccine, as well as the opportunities provided by technologies such as mRNA. There were also potential challenges and risks identified which did not materialise, such as the possibility of disease enhancement. It is my understanding that this is a phenomenon where the presence of antibodies can worsen a disease and is an issue with dengue virus. This possibility was

referenced in April 2020 in an email from Sir Mark Walport (former GCSA) to Sir Patrick Vallance **[AJ/31 – INQ000330553]**, this was discussed at the Expert Advisory Board **[AJ/32 – INQ000330728]** on 21 April 2020. Expert input was obtained on the issue, drawing on the work of CEPI and others **[AJ/33 – INQ000330735]**. While ultimately this did not end up presenting as an issue for COVID-19, it serves to illustrate the degree of uncertainty around the disease, particularly at this point in the process.

35. The GCSA and the CMO had oversight of a £30m 'fighting fund', managed by NIHR, which was established to fund urgent COVID-19 related research. £9.9m of this fund was released to fund some of the early work at Oxford **[AJ/34 – INQ000330551]**, which allowed it to begin clinical trials as quickly as possible.

Setting up the Vaccines Taskforce (VTF) for delivery

36. There was a need for a team of Civil Servants to lead the work on supporting the development and delivery of a vaccine, with ministerial oversight. This team developed in parallel to the Expert Advisory Board.

37. Until March 2020, DHSC was the lead department for vaccine development, but the GCSA and others were concerned that the approach to development of vaccines was receiving insufficient attention amongst the many other pressures on DHSC at the time, given the scale of the challenge to move from discovery through trials and to successful manufacturing and deployment **[AJ/35 – INQ000228652].**

38. Sir Patrick Vallance reiterated that delivering effective vaccines for COVID-19 was not primarily a procurement and distribution challenge – as it might be for a disease where there are existing vaccines – and that there were also major R&D and manufacturing challenges, needing a broad range of expertise and dedicated resources. Through March 2020, the need for such a dedicated team became clearer, leading to the proposal for the VTF.

39. During early March 2020, the GCSA continued scoping the possible avenues for vaccines and therapeutics through discussions with key individuals such as Mene Pangalos (Executive Vice President, BioPharmaceuticals R&D, AstraZeneca) and Sir Jeremy Farrar **[AJ/36 – INQ000330614], [AJ/37 – INQ000330528], [AJ/38 – INQ000330527], [AJ/39 – INQ000330526], [AJ/40 – INQ000330524]**. On 21 March 2020, GO-Science was commissioned by the Cabinet Office (CO) to lead on a vaccine strategy **[AJ/41 – INQ000330532], [AJ/42 – INQ000330529], [AJ/37 – INQ000330528], [AJ/43 – INQ000137306]**. This set out some of the key requirements, including continued coordination of research funding, continued

assessment of vaccine options, facilitation of clinical trials, proactive support for large-scale manufacturing and deployment, rapid procurement, and longer-term support for a manufacturing base for novel technologies (e.g. mRNA). It also set out that this should be a single unit, drawing on multiple government departments and partners from outside government.

40. On 24 March 2020, Sir Patrick Vallance asked Dominic Cummings (Chief Adviser to the Prime Minister) via WhatsApp whether he would support the creation of a Vaccine Taskforce: *"I want to set up a vaccines task force to really get things moving. Are you supportive? It can't all just sit in DHSC"*, to which Mr Cummings responded by saying *"Defo. Will support whatever you want"*. Sir Patrick Vallance then said he was *"Speaking to Chris Wormald* [DHSC Permanent Secretary] *now to try to get this going as a cross government thing with a mission. HMT* [Her Majesty's Treasury] *supportive"* **[AJ/44 – INQ000061750].**

41. On 25 March 2020, following the agreement from the Cabinet Secretary that this should be a cross-government effort led from BEIS, I was asked to support the work on vaccines. BEIS had strong existing links to industry, including to life sciences companies, through the OLS. It was clear that strong partnerships with industry and academia would be critical to the success of the VTF, and that DHSC was under considerable pressure at this point. Sir Patrick Vallance gave me an initial briefing setting out his view of what was required **[AJ/45 – INQ000330531]**.

42. On 26 March 2020, Sir Patrick Vallance spoke with Sir Alok Sharma (Secretary of State, BEIS) (see Annex A for key individuals) and formally proposed the creation of the VTF **[AJ/46 – INQ000330533]**. The same day, Alok Sharma wrote back, approving the proposal **[AJ/47 – INQ000330534]** and tasking officials to provide support.

43. On 27 March 2020, I emailed Sir Patrick with an initial outline of the VTF **[AJ/48 – INQ000330535]**, and I also sent a separate email emphasising the potential Moderna vaccine as an urgent strand of the VTF work **[AJ/49 – INQ000330536]**. The model for the VTF was informed by the 2019 Science Capability Review undertaken by Sir Patrick Vallance, "Realising our Ambition Through Science". That review identified several 'Critical factors in leadership, governance and delivery of Missions as part of UK Grand Challenges' **[AJ/50 – INQ000061614]**. Those factors are set out at Annex D of that review.

44. From the outset, the VTF was not independent from Government. It was accountable, and reported, to ministers. Strategic decisions on vaccines were taken by the VTF

Steering Group at official level and the relevant departmental minister or Ministerial Panel at Ministerial level. The Ministerial Investment Panel, which sat outside the VTF's central governance structure, provided a scrutiny function and was required to provide commercial and financial approvals for manufacturing and procurement contracts over a certain value (see paragraph 81 below). All investment proposals required a full business case, with accounting officer assessments carried out in the usual way.

45. However, the VTF was also an atypical unit within government, in that it was a temporary group set up to achieve specific objectives, which made extensive use of external expertise in the form of secondees and contractors. The fast pace required in the work meant that greater flexibility was afforded to the VTF than would ordinarily be expected in central Government processes, as appropriate. For example, BEIS' delegated authority limits were increased to permit the spending of smaller sums more swiftly.

46. As the outset of its development, the VTF began life as two separate boards: the Programme Board and the External Advisory Board. Oversight in these initial stages was provided by the Programme Board, established on 1 April 2020 to organise the VTF structure and ensure engagement of senior leaders across Whitehall **[AJ/51 – INQ000330761]**. I led this Programme Board (further details of attendees and remit are outlined in Annex A) which reported to the BEIS and DHSC Secretaries of State as well as the CMO and the GCSA.

47. The External Advisory Board was a group of external advisors drawn from Government, the private sector, and academia, and was the primary source of advice to the Programme Board. It was chaired by Sir Patrick Vallance. Appointments to the board followed discussions I had with Sir Patrick, and a range of industry and government bodies, including the OLS, the International Research and Innovation Directorate, and the BioIndustry Association Manufacturing Advisory Committee.

48. This dual Board structure existed until July 2020 when the expanded leadership team meant that new structures were introduced, as set out below. Full details of the governance arrangements beyond the initial setup will be covered by the evidence provided by UKHSA, in light of its responsibilities as set out at paragraph 21 above. To avoid duplication it is not covered here, though some further detail on the governance relevant to manufacturing and onshoring is given in this statement.

49. Throughout April 2020, I worked with Sir Patrick Vallance and others to further develop the aims and focus of the VTF **[AJ/52 – INQ000330544]**, **[AJ/53 –**

INQ000330558], [AJ/54 – INQ000330554], [AJ/55 – INQ000330559], [AJ/56 – INQ000330561], [AJ/57 – INQ000330568]. The VTF objectives were shared with the Scientific Advisory Group for Emergencies (SAGE) on 16 April 2020 **[AJ/58 – INQ000151747], [AJ/59 – INQ000330765], [AJ/60 – INQ000151747].** There was also a Cabinet Secretary Deep Dive on the same day to set out the support needed from across government **[AJ/61 – INQ000128374].** BEIS SoS (Sir Alok Sharma) publicly announced the creation of the VTF on 17 April 2020 **[AJ/62 – INQ000330548], [AJ/63 – INQ00065356].**

50. My team expanded rapidly over this period and made good progress, supported by expert advice from the EAB. However, it became clear that further leadership capacity and more embedded expertise was required, given the level of ambition which we had and the importance and difficulty of the task ahead. Stephen Lovegrove, Permanent Secretary at the Ministry of Defence (MoD) also became involved in late April 2020 for a short period to provide some senior support to the VTF.

51. On 25 April 2020, Dame Kate Bingham (at that point, a member of the VTF Expert Advisory Board) emailed Sir Patrick Vallance to raise a concern that the individual universities were *"engaged in contracting individually rather than working with CMC* [Chemistry, Manufacturing, and Controls] *experts who live and breathe this stuff."* She then suggested the creation of a *"central entity eg Vaccines UK (much like Genomics England) – owned and funded by the government and led by someone like Ian* [McCubbin]- *who is responsible for all contracting and delivery whether adeno, mRNA or antibodies?"* **[AJ/64 – INQ000330557].**

52. Sir Patrick Vallance agreed with the principle of the VTF having greater ability to help academics to partner with industry in ways which would provide maximum overall benefit to the UK, and the ability to deploy a budget on behalf of the UK. This was a particular concern because some of the partnerships which universities were exploring were with companies which were based outside of the UK, and which planned to manufacture vaccines outside the UK. This would have presented a significant risk to UK supply, as several countries have legislation which could allow them to prevent export while they had a domestic need for vaccines. This catalysed the development of the VTF so that it would be led by a Chair, with staff brought in from across the civil service as well as external experts.

53. On 20 April 2020, the DHSC SoS Matt Hancock commissioned the VTF to produce a vaccines strategy for publication on 23 April 2020. I suggested that the VTF asked

for more time to produce a fuller, more comprehensive strategy **[AJ/54 – INQ000330554]**. The draft Vaccines Strategy, setting out the priorities and approach of the VTF **[AJ/65 – INQ000330565]** was shared around 7 May 2020 with the DHSC SoS **[AJ/66 – INQ000330570]**, Sir Mark Sedwill (Cabinet Secretary) and other ministers.

54. It is my understanding that the vaccines strategy was not published by DHSC in draft as described above. Those involved in the senior leadership positions within the VTF will be better placed to assist the Inquiry in relation to the development of the VTF strategy once established.

55. As such, this statement provides only an overview of the governance for the period beyond this initial setup, as this will be addressed more fully in evidence given by UKHSA. It includes brief details to provide context to the role of BEIS in relation to relevant matters throughout the period in question, particularly matters relating to manufacturing and the establishment of vaccine manufacturing in the UK (i.e. 'onshoring'). Similarly, the GCSA's role after Dame Kate Bingham's appointment in May 2020 was much reduced and limited to providing advice where requested.

56. It remained the case throughout that despite the speed of operation of the VTF, it continued to function in line with the high standards of governance and approvals required when managing public money, and had ministerial oversight throughout. Wherever possible, existing governance processes were fast-tracked to enable rapid approvals – for example rapid reviews of business cases – and where new structures were established, these were agreed with the Permanent Secretary and ministers. Further details of the ministerial oversight arrangements are left to UKHSA's evidence to address in more detail.

57. I am asked about the involvement of the Devolved Administrations ("DAs") in the VTF. Having reviewed the papers from this early period, it appears that DA involvement in the genesis of the VTF was limited, most likely because of the pace required to set up the VTF and to start its work, as well as the initially very limited resources available. Questions about the nature and extent of DA involvement beyond the VTF's initial set up are most appropriately directed to the UKHSA.

Establishing the VTF leadership and team

58. The decision to appoint Dame Kate Bingham as chair of the VTF was made by the Prime Minister on 5 May 2020. She had been recommended and appointed as a member of the Expert Advisory Board in March 2020, on the basis of her experience

and expertise in the biotech and life sciences sectors within the Venture Capital field **[AJ/22 – INQ000330542]**.

59. The initial approach to Dame Kate Bingham was made on 5 May 2020 by DHSC SoS Matt Hancock **[AJ/67 – INQ000330567]** and she agreed in principle on 6 May 2020 to take the role. The appointment was confirmed on 16 May 2020, once the relevant processes to formalise this position were complete **[AJ/68 – INQ000330566], [AJ/69 – INQ000330574], [AJ/70 – INQ000330575], [AJ/71 – INQ000330573], [AJ/72 – INQ000330571], [AJ/73 – INQ000330572], [AJ/74 – INQ000330736]**. While the decision to appoint Dame Kate Bingham as Chair of the VTF was the Prime Minister's, my understanding is that it was based on her deep experience in the biotech and life sciences sectors.

60. In parallel, on 6 May 2020, upon Stephen Lovegrove's recommendation, the Cabinet Secretary Sir Mark Sedwill recruited Nick Elliot from MoD as the Director General of the Vaccine Taskforce **[AJ/75 – INQ000330563], [AJ/76 – INQ000330564]**. Nick Elliot was formally made Senior Responsible Owner for the VTF on 2 June 2020 **[AJ/77 – INQ000330591]**. As these appointments were made, I transitioned back to my permanent role as Director, Science Research and Innovation in BEIS.

61. The respective responsibilities of the Chair and departments were agreed on 13 May 2020 **[AJ/78 – INQ000330577]**. The scope of the VTF was also agreed at this point. In particular, it was agreed that therapeutics would be covered by a separate taskforce based in DHSC (see paragraphs 158 to 162 below), but that the VTF would continue to take forward work on some antibody therapies that were intended to complement vaccine rollout. For example, the VTF retained a role in work on prophylactic antibody therapy (which was ultimately not purchased) that was intended for around 500,000 immunocompromised individuals who would not obtain as much benefit from vaccination. Until June 2021, the VTF was also involved in work on monoclonal antibodies, as it was recognised that these can act as a therapeutic to complement the vaccine approach by affording protection to a proportion of the population who may not respond to vaccines due to efficacy or are not suitable for vaccines. The respective activities of the VTF and the Therapeutics Taskforce (TTF) on antibody therapies and the measures put in place to ensure close liaison between them are set out in **[AJ/78A – INQ000408356]**, a summary created by the VTF in October 2020 following a meeting on responsibilities with the TTF. Questions on how this work was divided between the VTF and TTF after both groups had been established are best directed to UKHSA.

62. The VTF Steering Group first met on 18 May 2020 with the aim of providing oversight, challenge and scrutiny on policies and strategies. Details of the membership of this group can be found in Annex A. Its first Terms of Reference **[AJ/79 – INQ000330593]** stipulated that the steering group would:

    a. set the direction and strategy of the VTF;

    b. oversee the delivery of the VTF programme;

    c. provide challenge and recommendations to VTF Programme Board;

    d. engage with the Expert Advisory Board (EAB) to ensure there are clinical views on proposals and recommendations;

    e. provide Industry specialists to challenge and advise on the VTF direction.

63. Discussions had previously taken place in May 2020 regarding the usefulness of the EAB, and Sir Patrick Vallance had indicated that he was content to close the group if it were no longer required **[AJ/28 – INQ000330578]**. The final regular meeting of the EAB was on 3 July 2020 though many of its members subsequently supported the VTF as secondees and contractors, meaning that the VTF had access to the required expertise. Others, including those with roles leading development of some of those vaccines, did not join VTF in order to allow them to focus on that important work. This also reduced the risk of potential conflicts of interest. A separate Expert Advisory Group was convened in January 2021 in order to consider the issues associated with COVID-19 variants **[AJ/80 – INQ000330601]**.

64. To ensure that potential conflicts of interest were identified and managed, the VTF established a dedicated resourcing team which applied BEIS's HR and recruitment processes and standards when bringing external experts and civil servants into the VTF. This included the BEIS 'Conduct – Conflicts of Interest' policy which had been introduced in 2018 **[AJ/80A – INQ000408357]**, which required the relevant people, including those who joined either the Programme Board or Expert Advisory Board, to fill out a declaration of conflicts of interest form in use at BEIS **[AJ/81 – INQ000330514]**. Conflicts management was further bolstered in November 2020 following a review **[AJ/82 – INQ000330596]**. From March 2021 conflicts of interest were managed through compliance with a VTF-specific policy **[AJ/83 – INQ000330737]** that applied to all staff, including those on either permanent or fixed term contracts working within the VTF (within BEIS) and those on secondment from other organisations. This included non-civil servants who worked for VTF including temporary agency workers, contractors, consultants, and advisers who were also

required to declare any actual, potential, or perceived conflict of interest relating to the work they were engaged to carry out. Declared conflicts were reviewed so that appropriate mitigations could be put in place if required. Finally, assurance was provided through Governance Statements as is usual within Government departments **[AJ/84 – INQ000330694]**.

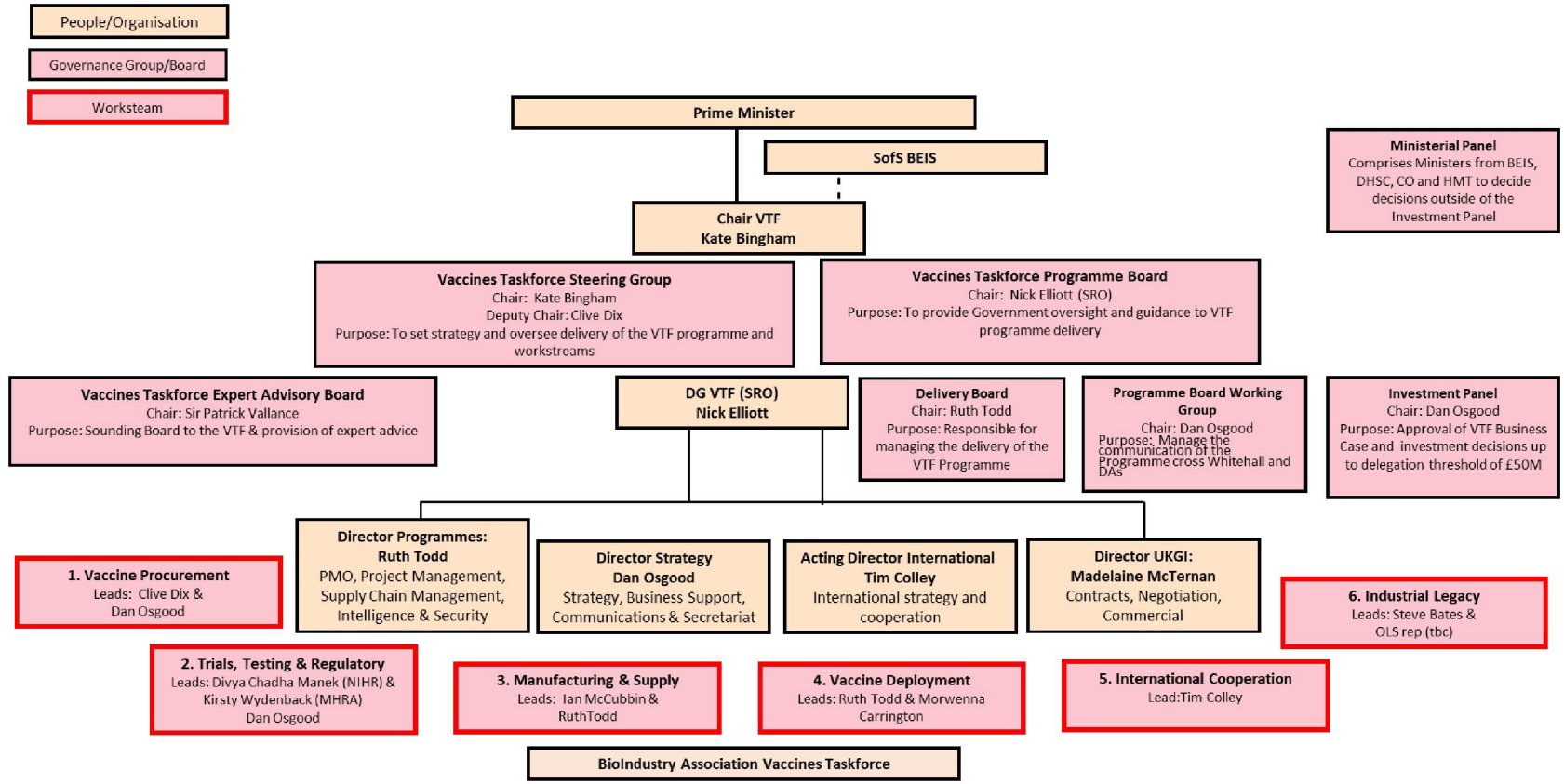
VTF business case, initial funding and structure

65. In June / July 2020, BEIS' Projects and Investment Committee (PIC) and HMT's Treasury Approval Process (TAP) Panel approved a Programme Business Case with initial funding of £5.23bn for the VTF Programme **[AJ/85 – INQ000330739]**. This was essential in enabling the VTF to invest in multiple vaccine options, and to enable rapid UK delivery through increasing domestic capacity for clinical trials and manufacturing. The Programme Business Case also set out ways of adapting existing governance structures to enable faster processes and decision-making while retaining robust scrutiny and oversight. This was crucial to ensuring that the UK could secure contracts with developers early on. My expectation is that the formulation of the business case, and evidence about procurement and vaccine selection, will be covered in greater detail in UKHSA's evidence to the Inquiry.

66. In line with this business case, VTF governance evolved in June 2020 to deliver against six workstreams: Vaccine Procurement; Trials, Testing and Regulation; Manufacturing and Supply; Vaccine Deployment; International Cooperation and Industrial Legacy. The organogram in **Figure 1** shows the structure of the VTF in July 2020, and provides brief descriptions of the various boards within the VTF. It shows the six workstreams, each led by members of the Steering Group and split between four directorates: Programmes; Strategy; International and UK Government Investments (UKGI)[1].

[1] UK Government Investments is an Arm's Length Body wholly owned by HM Treasury. Specialist resource with the capability to manage complex transactions were seconded into the VTF from UKGI, and Madelaine McTernan, Director of UKGI at the time, led on negotiations with pharmaceutical companies. In December 2020, Madelaine became Director General of the VTF.

Figure 1: July 2020 Governance Chart



SRO: Senior Responsible Owner

SofS: Secretary of State

67. For the purposes of this statement, the Manufacturing and Supply and Industrial Legacy workstreams are most relevant; others will be more relevant to the work of other departments and are expected to be covered in their evidence to the Inquiry.

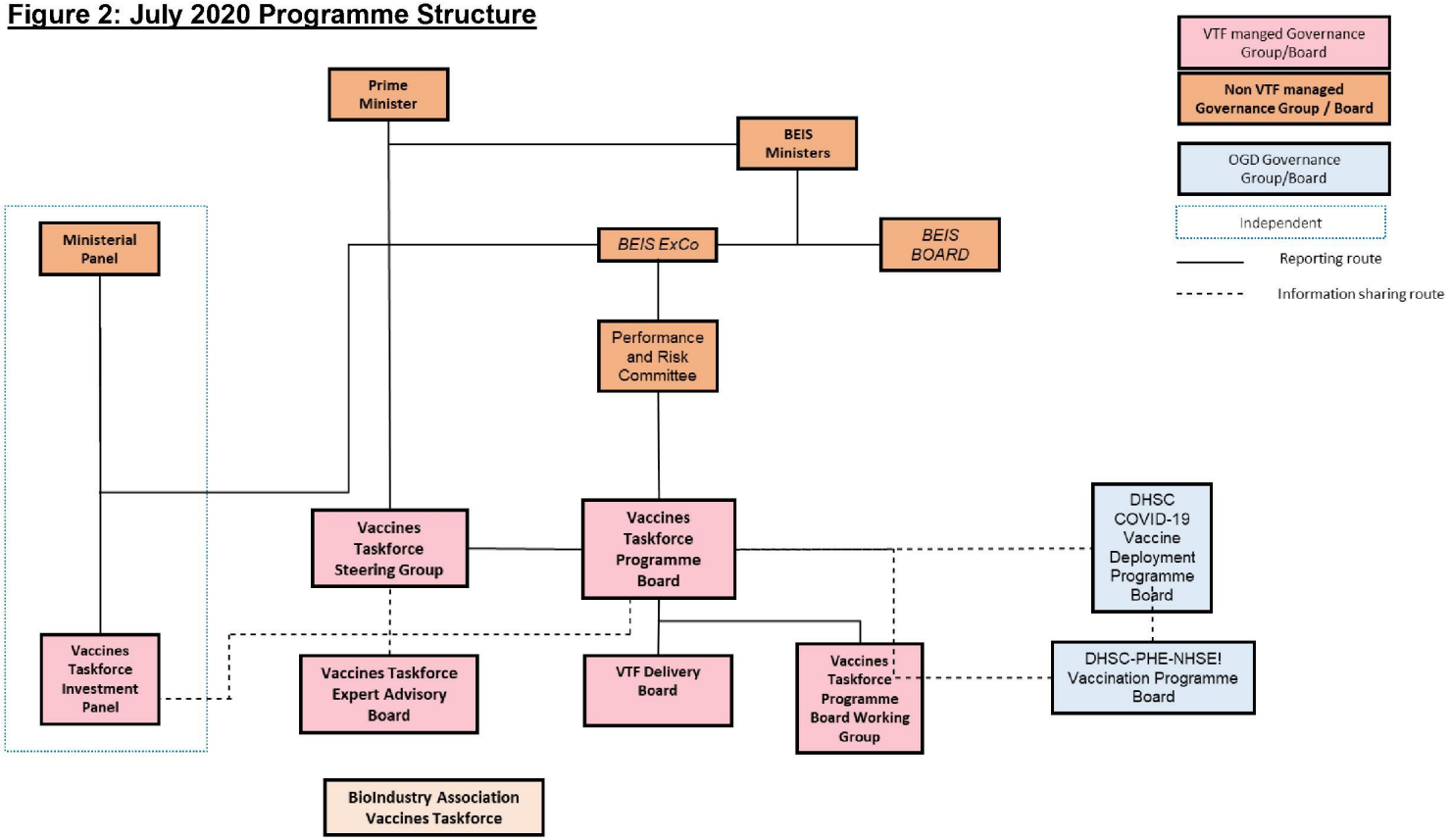
68. The objective of the manufacturing and supply workstream was to secure flexible vaccine manufacturing capacity, to ensure that a vaccine could be made available to the UK population as quickly as possible **[AJ/86 – INQ000330738]**, **[AJ/87 – INQ000330741]**. There were three key priorities under this objective:

- **Increasing HMG's ability to manufacture across different technologies**: ensure there is capacity to manufacture across several different technologies and modalities.
- **Improving the UK's manufacturing resilience in response to the pandemic**: secure enough capacity to ensure we are ready to manufacture different vaccine types at the pace and scale required to ensure fastest possible access for UK citizens and to maintain a vaccination programme.
- **Increasing the attractiveness of the UK's 'offer'**: offer manufacturing capacity and capability, to help secure deals with vaccine developers that ensure the UK has access to a vaccine sooner.

69. The industrial legacy workstream was focussed on maintaining a legacy of the investments and partnerships to ensure longer-term health resilience **[AJ/88 – INQ000330762]**. Investments such as the Vaccines Manufacturing Innovation Centre, the Benchmark site at Braintree in Essex and the Cell and Gene Therapy Catapult were included in this. The workstream sought to consider how to keep these 'warm' to ensure the UK retained an ability to respond effectively to different viral threats. Both this and the manufacturing and supply workstream were continued in the Onshoring directorate after its inception in in April 2021. Further details can be found in paragraphs 71 to 135 below.

70. **Figure 2** shows the programme structure of the VTF in July 2020.

Figure 2: July 2020 Programme Structure



ExCo: Executive Committee

OGD: Other Government Department

Governance of manufacturing and onshoring programmes from 2021

71. As is well-known, on 2 December 2020 the Medicines and Healthcare products Regulatory Agency (MHRA) approved the first COVID-19 vaccine, developed by Pfizer/BioNTech, for use in the UK.

72. Therefore the VTF refocused its priorities in January 2021 beyond discovery and development and towards delivery of vaccines. This reorganisation introduced a risk board, a finance board and two programme boards focussed on Vaccines and Antibodies, and Infrastructure and Enablers. The six initial workstreams were embedded into four refreshed directorates outlined in **Figures 3** and **4.** The VTF programme structures from 2021 and 2022 are shown in Annex C.

73. Alongside this, Clive Dix became interim Chair from December 2020, and remained in that post until June 2021. The steering board was replaced by new arrangements, including an operations board which responsible for setting the VTF strategy, overseeing the delivery of activity across each Directorate (Programmes, Strategy, Onshoring and International) and providing challenge and advice to the VTF programme, Therapeutics Taskforce (TTF) and Antivirals Taskforce (ATF).

74. An Onshoring directorate was created in the VTF in April 2021, with responsibility for delivery of these workstreams. It developed an onshoring strategy **[AJ/89 – INQ000412007]**, and an associated onshoring programme business case **[AJ/90 – INQ000330739]**, which was approved in February 2022 **[AJ/91 – INQ000330740]**.

75. Programme management of onshoring work was overseen by the Onshoring Delivery Group. This took over from the programme boards (alongside the Vaccines Delivery Group) and was responsible for the identification, monitoring and delivery of projects and related activities that will strengthen the UK's onshore capacity and capability in vaccine development, manufacturing, and the supply chain to provide resilience for this and future pandemics. This included the further mobilisation of existing UK capacity to participate in vaccine production, expansion of current UK vaccine development capability, production capacity, key materials and services, development of new capabilities and capacity across the supply chain to provide the UK with resilience, responsiveness and control in vaccine and related medicines supply. Onshoring Delivery Group leadership was provided by the VTF Onshoring Programme Director.

76. The Vaccines Delivery Group was responsible for the identification, monitoring and delivery of projects and related activities that would secure access to promising

vaccine/s for the UK population and achieve lasting immunity. Vaccines Delivery Group leadership was provided by the Vaccines Programme Director.

Figure 3: February 2021 Governance Chart

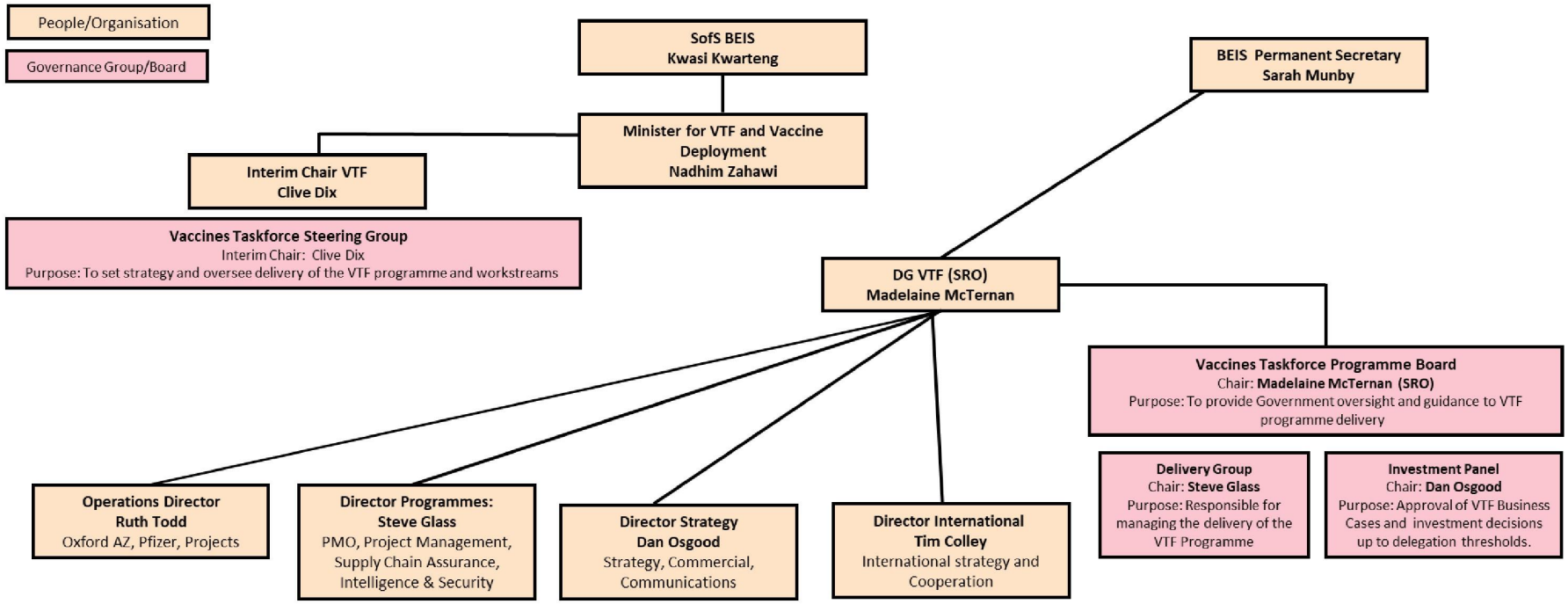
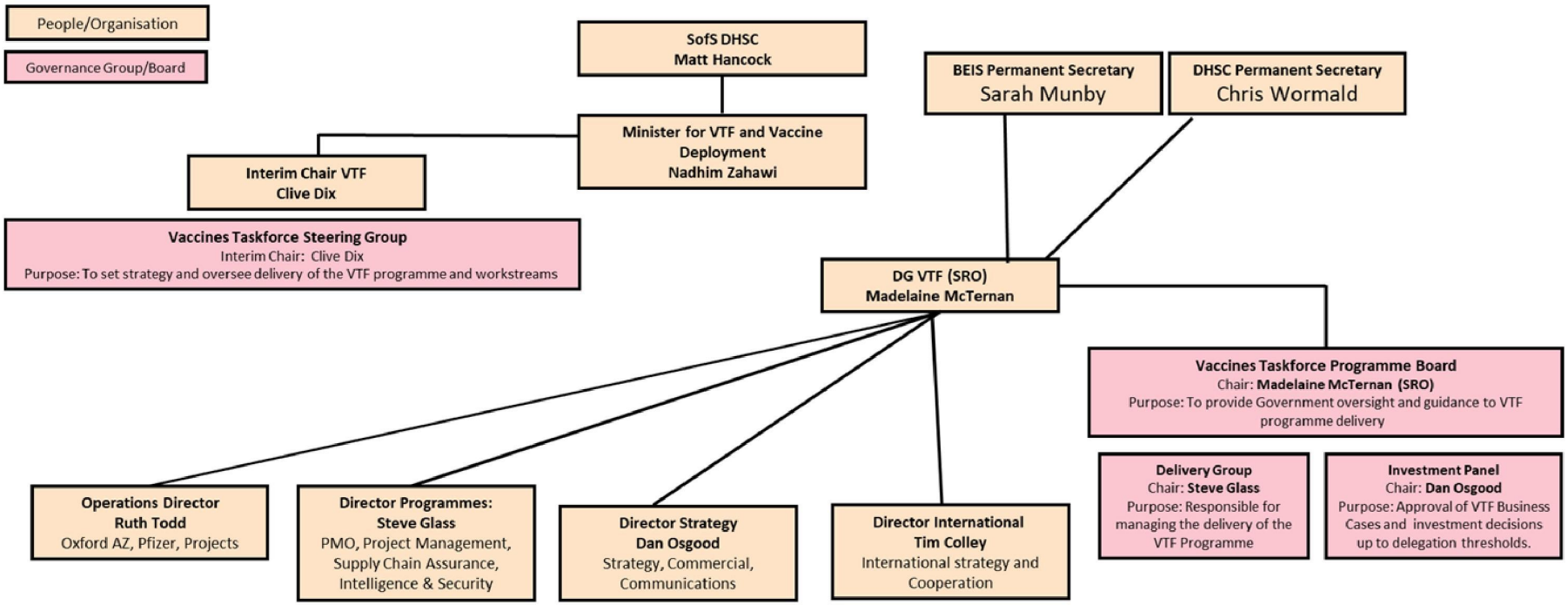


Figure 4: April 2021 Governance Chart



Working with other public bodies

77. The VTF, and BEIS, worked with a wide range of other organisations who were also involved in vaccine discovery, development and deployment efforts.

78. From the restructure around April 2021, there was a VTF External Stakeholder update on Mondays. In these meetings, a weekly update on key developments regarding vaccine supply and developing vaccine manufacturing capacity in the UK was shared with stakeholders across government, including CO and HMT. Senior Civil Servants from BEIS, the Foreign, Commonwealth and Development Office (FCDO), HMT, MoD and DHSC were also members of the Programme Board and Monday External Stakeholder Group.

79. The VTF had appropriate links (for instance, on provision of supply forecasts and information) to key decision-making bodies including the Joint Committee on Vaccination and Immunisation (JCVI). Vaccine allocation to the DAs, Crown Dependencies and the British Overseas Territories were organised through the VTF.

80. Annex D presents a landscape map of interactions between the VTF and OGDs as well as Public Bodies. BEIS, DHSC, FCDO and CO were the government departments most engaged with the VTF. Independent and non-departmental government bodies (e.g., JCVI and UKRI) were also key partners for the VTF. I have focussed here on those interactions that the VTF and BEIS had with other public bodies which are most relevant to the scope of this statement.

81. BEIS and DHSC worked closely together throughout the relevant period. DHSC ministers and officials received regular reporting from the VTF, and had some oversight through mechanisms such as the Ministerial Investment Panel and the Vaccines, Antivirals, and Therapeutics Strategy Board. The Ministerial Investment Panel consisted of ministers from BEIS, DHSC, HMT and CO. This representation from multiple departments made the approvals process more efficient. The panel provided commercial and financial approvals for vaccine manufacturing and procurement contracts over £150m, after they had been approved through BEIS's Project and Investments Committee. Alongside this, BEIS' delegated limits were increased by HMT and CO to enable smaller sums to also be spent more quickly when required. Investment proposals still required a full business case with BEIS accounting officer assessment **[AJ/92 – INQ000330585]**. As shown in Annex C, the Ministerial Investment Panel sat outside the central governance structure of the VTF and provided a decision-making and scrutiny function.

82. On 9 February 2021, the BEIS and DHSC Permanent Secretaries wrote to the Cabinet Secretary to advise that Ministerial accountability for the VTF should be held jointly by the SoS DHSC and SoS BEIS. Following a government announcement on 1 March 2021, this arrangement was formalised on 1 August 2021 with a Memorandum of Understanding between BEIS and DHSC. Ministers agreed to a split of Cabinet accountabilities where the "*DHSC SoS would be accountable to Parliament for the VTF's activity where the primary purpose is vaccine and antibody procurement and supply, clinical development, and research and development led by health bodies such as the National Institute for Health Research (NIHR). Whereas the BEIS SoS would be accountable to Parliament for the VTF's activity where the primary purpose is vaccine and antibody manufacturing and fill-finish, and research and development led by BEIS bodies such as UK Research and Innovation (UKRI)".*

83. These changes are reflected in the February 2021 and April 2021 organisation charts (**Figure 3** and **Figure 4** respectively). The Memorandum of Understanding (MoU) **[AJ/93 – INQ000330646]** between the two departments provided a framework for the effective transfer of responsibilities for part of the VTF's activities to DHSC, and for how DHSC and BEIS would oversee and support the work of the VTF in delivering Ministerial priorities. The VTF Senior Responsible Owner (Nick Elliot until December 2020, then Madelaine McTernan) worked under the delegated financial authority of the BEIS and DHSC Permanent Secretaries with controls in place to manage the VTF's administration and programme budgets. Other departments will be able to provide a fuller account of the VTF's interactions with DHSC over time.

84. The VTF also worked closely with the OLS, and as set out in paragraph 197 below, the Onshoring Directorate eventually transitioned into the OLS. OLS and VTF shared many stakeholders, and so found there were natural areas of collaboration.

85. The VTF worked with UKRI, particularly on the Vaccines Manufacturing and Innovation Centre (VMIC), outlined below at paragraphs 102 to 114 below. A Memorandum of Understanding **[AJ/94 – INQ000330592]** was produced by VTF leadership to govern the relationship between VTF, OLS and UKRI concerning VMIC. Annex E charts the interactions between the government, public and commercial entities involved in this arrangement.

86. Cabinet Office also had a significant interest in the work of the VTF, given its importance to the overall pandemic response. CO officials and ministers were regularly updated on the work of the VTF, and also had roles on the relevant panels for approving procurement. This reporting included a weekly update on key

developments on vaccine supply and developing vaccine manufacturing capacity in the UK.

87. Cabinet Office, FCDO and DHSC also had interests in the international work of the VTF, and held regular engagements, including a VTF-FCDO International Engagement working group. These departments coordinated COVID-19 Vaccines Global Access (COVAX), Global Vaccine Summit and G20. The VTF International Strategy centred upon three strands of activity: bilateral engagement with other companies and governments; multilateral leadership, establishing norms and principles for global cooperation; and working collaboratively with other like-minded countries, moving towards collaboration on procurement. It is expected that international engagement will be more fully addressed in evidence provided by other departments.

88. The JCVI is a statutory advisory committee which advises UK health departments on which vaccines to deploy in which populations. The work of the JCVI therefore had a strong bearing on the work of the VTF, including decisions on which vaccines should be prioritised in the portfolio. It is expected that the role of the JCVI and decisions on vaccine selection will be addressed in evidence provided by other departments.

89. The role of the Medicines and Healthcare Products Regulatory Agency (MHRA) as the independent safety regulator was key to ensuring that the VTF could meet its objectives as the speed of the regulatory processes would be a critical factor in the determining when vaccines could be deployed. It was identified in January 2020 that a rapid review and approval process was required to tackle the pandemic **[AJ/95 – INQ000063571]**. The VTF and MHRA worked closely together with VTF representatives attending VTF boards, including MHRA's CEO, Dame June Raine joining the EAB from the outset. This meant that a collaborative approach to adapting regulatory processes could be taken. MHRA staff stepped down from VTF boards in September 2020 in order to avoid any actual or perceived conflicts when data from manufacturers was submitted to the MHRA in order for it to make its regulatory decisions **[AJ/96 – INQ000330587]**. It is expected that the role of the MHRA will be more fully addressed in evidence provided by other departments.

90. The VTF also worked with the National Health Service (NHS), particularly on deployment. It is expected that this will be addressed in evidence provided by other departments.

91. Public health is a devolved matter. The VTF coordinated its work with the DAs, and reached agreement with each of them that it would procure vaccines on their behalf.

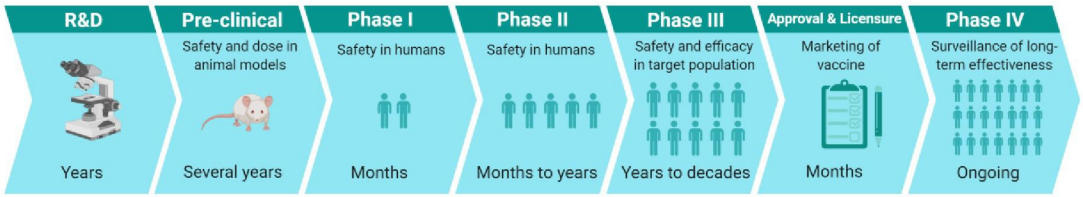
The DAs remained responsible for deployment activities. It is expected that procurement and deployment of vaccines will be addressed in evidence provided by other departments and the DAs.

Development and Manufacture of vaccines

Context

92. Developing, manufacturing, and deploying vaccines are all complex processes. The details of the processes vary depending on the type of vaccine and require specialist equipment and skills **[AJ/97 – INQ000330588], [AJ/98 – INQ000330589]**. The development of vaccines includes discovering substances which can provide the required immunity; Annex F provides an overview of the different vaccine types that currently exist. Typically, the whole end to end process (as shown in **Figure 5** below) of developing a vaccine can take many years.

Figure 5: Vaccine development timeline by Vax-Hub. Taken from: AJ/88 – INQ000330741



93. Candidate vaccines go through a three-phase clinical trial process to check whether they are safe and effective in different groups of people. A large proportion of vaccines do not make it through the clinical trial stages **[AJ/99 – INQ000330590]** and the likelihood of success of the vaccine candidates at the outset of the pandemic was not known. The VTF's programme business case quantified the likelihood of any individual vaccine being safe and effective as between 5% (pessimistic scenario) and 10% (optimistic scenario).

94. For those which are proven to be safe and effective, the complex manufacturing processes require the 'on-time' delivery of hundreds of inputs, and are dependent on biological, chemical, and physical processes. Alongside the active ingredient, vaccines also contain other ingredients such as adjuvants, which create a stronger immune response to the vaccine, stabilisers, and preservatives. These challenging

manufacturing processes, which have to be carried out in compliance with Good Manufacturing Practice (as regulated by the MHRA) means that the delivery schedule can also contain a significant degree of uncertainty. The VTF therefore built a broad portfolio of potential vaccines, to improve the chances of being able to vaccinate the UK population as soon as was practical and safe.

95. During the COVID-19 pandemic, many of the candidate vaccines were based on 'vaccine platforms' which involves inserting an appropriate antigen into a generic 'platform' which had already been tested, which speeds up the development process. In some cases, these platforms have been developed based on work done in other epidemics and outbreaks. For example, the Jenner Institute in Oxford ran a trial using a chimpanzee adenovirus-based vaccine for Ebola in West Africa in 2014; its ChAdOx1 platform (adenoviral vector for vaccines) was the basis for the COVID-19 vaccine that it produced. Using vaccine platforms may also mean that some elements of the manufacturing process have already been developed and tested.

96. Further details on the discovery process and the selection of vaccines for the VTF portfolio are expected to be covered in more detail in UKHSA's evidence and so I have kept my evidence focused on the onshoring and manufacture of vaccines, which fall within DSIT's responsibilities. I have also been asked to comment on processes and obstacles for procurement, contractual arrangements and approval of vaccines, however other departments including UKHSA will be better placed to address these questions and so to minimise duplication I have not commented in detail on those issues.

97. This section therefore focuses on manufacturing and onshoring, particularly the VTF's role in supporting this. As well as the biological and chemical processes to produce the bulk vaccine, there are 'fill and finish' processes to transfer it into vials ready for use, and extensive quality control and quality assurance processes.

98. Given the specialist nature of each element of the manufacturing process, vaccine supply chains are international and the UK has a significant dependence on other countries for vaccines. It also has dependence on international supply chains for raw materials or components of vaccines even for those where the final manufacturing stages are carried out here. At the time the Onshoring Programme Business Case was approved in February 2022, of the UK's COVID-19 vaccine supply, 62% had been imported from overseas manufacturers, 3.6% had both UK and overseas manufacture, and 34.4% was derived entirely from a UK manufacturer (Oxford/AstraZeneca).

Onshoring Vaccine Manufacturing

99. Prior to the pandemic, despite a strong R&D base in the UK, there was limited manufacturing capacity, and no mRNA vaccine manufacturing capacity **[AJ/18 – INQ000330525], [AJ/19 – INQ000330523], [AJ/96 – INQ000330587]**. Fill and finish capacity was also very limited **[AJ/10 – INQ000412008]**. Dependence on international supply chains presented a challenge in part because of the high levels of demand from other countries from these supply chains, and in part because of the possibility of other countries not allowing export of vaccines to the UK when they had unmet domestic needs for vaccines (e.g. by using their step-in rights).

100. Therefore, the VTF had an objective to strengthen the UK's onshore capacity and capability in vaccine development, manufacturing, and supply chain, for the COVID-19 pandemic and the longer-term. The VTF brought in manufacturing expertise, including Ian McCubbin, to support this work. At the outset of the pandemic, the VTF invested in manufacturing capability to provide greater vaccine onshore production (both manufacturing of drug substance and fill and finish). These investments were funded through the wider VTF programme funding, which was allocated £5.23bn on 11 September 2020 (excluding COVAX) **[AJ/85 – INQ000330739], [AJ/101 – INQ000330586]** to cover costs of the VTF programme (principally vaccine procurement) until December 2022. It was later increased to £6.1bn via a Programme Business Case refresh in 2021 **[AJ/90 – INQ000330739]**.

101. The key projects are outlined below. Some of the projects were based at centres known as 'Catapults'. Catapults are technology and innovation centres that connect businesses with the UK's research and academic communities. They were established and are overseen by Innovate UK.

Vaccines Manufacturing and Innovation Centre (VMIC)

102. In 2018, £181 million had been invested to speed up access to new medicines and healthcare through the 'Leading Edge Healthcare challenge' **[AJ/102 – INQ000330766], [AJ/103 – INQ000330767], [AJ/104 – INQ000330768]**, part of the Industrial Strategy Challenge Fund. The challenge was delivered by Innovate UK (part of UKRI), with assistance from OLS.

103. £65m of this was allocated by Innovate UK, to create the UK's first dedicated Vaccine Manufacturing Innovation Centre (VMIC), to develop new vaccine technologies. VMIC UK Ltd. was established in 2018 as a private company.

104. VMIC was established as an innovation centre, with an emergency response capability which would be able to produce something of the order of 1m-3m doses of vaccine within 3 months. It was still under construction at the time of the pandemic.

105. As the pandemic progressed, additional funding was provided to VMIC UK Ltd to accelerate completion of the facility and refocus the project on manufacturing vaccines at population scale. This was consistent with the VTF's "multiple shots on goal" approach of covering multiple modality (vaccine type) options.

106. As the focus of the VMIC changed from innovation centre to population scale manufacturing, multiple funding decisions were required.

107. Funding provided for the VMIC from BEIS was set out in a 'Memorandum of Understanding' between BEIS and UKRI. Agreements regarding the funding, governance and objectives of the VMIC project are set out within the document. This brought the total funding allocated to around £205m. This comprised the initial £65m grant in 2018 **[AJ/105 – INQ000330742]**, **[AJ/106 – INQ000371340]**, a £93m grant in April / May 2020 **[AJ/107 – INQ000330743]**, **[AJ/108 – INQ000330604]**, and a £47m grant in December 2020 **[AJ/109 – INQ000412009]**.

108. While VMIC was being built in May 2020, the VTF through UKRI set up a rapid deployment facility ('virtual VMIC') at Oxford Biomedica. £8.75m was provided to purchase equipment and fit out clean room space at Oxford Biomedica. This supported early manufacture of the Oxford/AstraZeneca vaccine at this facility and provided a site to which VMIC staff could be recruited and trained, ahead of the planned VMIC opening.

109. In October 2021, the Board of Directors of VMIC UK Ltd considered that following the approval of the Oxford/AstraZeneca and Pfizer vaccines, and with the VMIC facility not yet completed and facing cost overruns, further funding would not be sought for the facility from the Government **[AJ/110 – INQ000330658]**. An important factor in this was that VMIC had been lined up for production of the ChAdOx1 vaccine, which is a viral vector vaccine (see the description of various modalities in Annex F). It would not have been able to support mRNA manufacturing, which by that point had become the modality of choice for combatting COVID-19. VMIC UK Ltd's Board of Directors decided to consider options for the future of the site **[AJ/110 – INQ000330658]**.

110. In late 2021, the Board of Directors of VMIC UK Ltd made the decision to sell the facility, through a competitive process. In April 2022, this process reached a conclusion, and the facility was sold to Catalent.

111. VMIC UK Ltd subsequently entered a voluntary liquidation. The courts appointed liquidators to act on behalf of creditors, and this process has now concluded. Catalent announced plans to invest £120 million to complete the facility and equip it for the development and manufacturing of therapeutics and vaccines, anticipating that, once completed, the site would employ more than 400 people **[AJ/111 – INQ000330769]**.

112. Catalent is a well-regarded global company and its investment in the UK is positive for the biotherapeutics industry. Catalent's purchase is intended to enable VMIC to remain as a manufacturing facility, and once completed, this is expected to make a positive contribution to UK manufacturing capacity and therefore resilience, albeit in a different way than the original objective of providing a national centre to help businesses to develop, commercialise and manufacture new vaccines.

113. Based on discussions with stakeholders it is currently considered that there may not be a need to create a facility to replace VMIC as an innovation centre. Since the initial decision to fund VMIC was made, the vaccine manufacturing landscape in the UK has changed because of significant investment, including in other innovation centres. Thought is being given to how to support vaccine development and collaboration in other ways. OLS continues to work with Innovate UK and others to consider how the initial objectives which the lay behind VMIC can be met, and to identify gaps in the UK vaccine innovation landscape and consider how these can be addressed. These discussions are reflecting on recent innovation and manufacturing investments (see below), and on the roles of DHSC and UKHSA, with pandemic preparedness in mind. I am not able to comment on whether or not the UK will be better prepared for the next pandemic because of the sale of VMIC, not least because work is ongoing to build resilience and it is difficult to evaluate the effect of the sale in isolation.

114. The investments referred to in the previous paragraph include the following, some of which are also discussed later in this statement:

    a. In respect of innovation: (i) £45m invested by UKRI's Transforming Medicines Manufacturing Programme, which is targeted at innovation in nucleic acid medicines, intracellular drug delivery and digitalisation and automation of medicines development and manufacturing; (ii) £10m of funding for an oligonucleotide manufacturing centre of excellence; (iii) the launch of the Medicines Manufacturing Innovation Centre; (iv) £12m of funding from EPSRC for a Future Vaccines Manufacturing Hub. As is discussed in the sections that follow, the VTF also supported the creation of what are now innovation centres in Braintree and Darlington.

b. In respect of commercial manufacturing: (i) the announcement in December 2022 of a 10-year partnership with Moderna which will provide mRNA vaccine development and manufacturing capacity; (ii) up to £38m for a Biomanufacturing Fund which will contribute to strengthening UK health resilience; (iii) a commitment of £520m to incentivise investment in life sciences manufacturing.

Cell and Gene Therapy Catapult (CGTC) Braintree

115. On 27 April 2020 the Executive Chairman of Benchmark Holdings contacted Sir Patrick Vallance to offer a site in Braintree, Essex which Benchmark had built in order to manufacture animal vaccines but which was no longer required for that purpose. Sir Patrick Vallance forwarded this email to the VTF with advice to follow up the offer **[AJ/112 – INQ000330560]**.

116. The VTF then conducted its own due diligence, including technical assessments, to understand what might be needed to convert the facility to something which could manufacture vaccines for humans. This was carried out with the support of BIA manufacturing experts **[AJ/113 – INQ000411941]**.

117. BEIS PIC approved £127.3m for the VTF's 'Project Knight' in July 2020 for the Cell and Gene Therapy Catapult (CGTC) to purchase Benchmark's facility in Braintree and transform it into a human therapeutics and vaccine manufacturing innovation centre.

118. The original delivery plan for this project included a transformation phase (from animal vaccine facility into human vaccine facility), a pandemic manufacturing phase (manufacture of a COVID-19 vaccine) and a cell and gene therapy innovation phase.

119. The VTF invoked the pandemic manufacturing phase in February 2021, directing the site to manufacture CureVac Generation 1 COVID-19 vaccine. At this point the facility and Project Knight was rolled into Project COVER. Project COVER was a project to use mRNA technology to tackle the threats posed by emerging variants.

120. The Braintree site was ultimately not required to manufacture COVID-19 vaccines during the pandemic due to the efficacy results of this vaccine and the success of others. Accordingly, the focus was changed from manufacturing to innovation earlier than originally planned. CGTC now contributes to the UK's long-term health resilience through developing Advanced Therapies (AT) innovation. It also strengthens the UK's onshore capacity in Viral Vector and Protein Sub-unit vaccines. The grant funding agreement is now being monitored by UKRI, with oversight by

OLS, and provides step-in rights for HMG for the duration of the agreement in the event of a future health emergency.

Centre for Process Innovation (CPI) Darlington

121. CPI is part of the High-Value Manufacturing catapult. CPI was initially approached in Spring 2020 by Imperial and VTF to provide vaccine manufacturing capacity for Imperial's saRNA (self-amplifying RNA) COVID vaccine. Ultimately a contract was not sought for this vaccine so CPI was no longer required for this. Therefore in December 2020, CPI was brought into the project to house the RNA library and provide manufacturing capacity for the CureVac mRNA vaccine. However, following the trial results for the CureVac vaccine, CPI was released from this project.

122. Project Cherry within CPI was created to secure a commercially sustainable facility (the RNA Centre of Excellence) to help companies bring innovative RNA products to market and support development of RNA therapies and vaccines. A long-term monitoring plan is in place, implemented by UKRI, with oversight by OLS and includes step-in rights of priority access to the facility for a 10-year period in the event of a future health emergency.

Valneva Livingston

123. In September 2020 the VTF agreed a partnership with Valneva to supply 60m doses of its whole inactivated viral vaccine, VLA-2001. Ultimately, the Valneva vaccine was not one of those used in the UK, and the contract was terminated in September 2021.

124. The Inquiry has asked questions about this contract and why it was eventually terminated. As this contract concerned the supply of a vaccine from a manufacturer, rather than onshoring, the UKHSA is better placed to address these questions. However, it is not unusual to have mechanisms for terminating contracts, especially where a product is no longer required.

Other manufacturing sites

125. Some pharmaceutical companies either used their own facilities to manufacture the vaccines which they had developed or partnered with Contract Development and Manufacturing Organisations (CDMOs), which are organisations contracted by the company to manage outsourced development and manufacturing of drug substances.

126. For example, Fujifilm Diosynth Biotechnologies partnered with Novavax to produce its vaccine at Billingham, Teesside. In December 2020 it announced a £400m investment in this facility.

127. AstraZeneca and Oxford Biomedica built upon the work of the 'virtual VMIC' at the Oxfordshire site and partnered to expand production at this site. This provided most of the supply of this vaccine deployed in the UK. Cobra Biologics in Staffordshire also produced drug substance for the Oxford-AstraZeneca vaccine.

128. The VTF provided support to other manufacturing sites and suppliers through the supply chain as needed, for example working within government to help prioritise them for testing of their staff where appropriate, or to enable international travel for those staff where essential to further the objective of vaccine development, manufacturing, and deployment.

Securing fill & finish capacity

129. As previously outlined, 'fill and finish' refers to the final process of producing a vial of vaccine ready for use. Fill and finish vaccine production capacity in the UK was limited in 2020. The BIA led a review to identify potential options for fill and finish **[AJ/101 – INQ000412008]**, and considered:

    1. Existing domestic human health fill-finishing
    2. Re-purposing of veterinary facilities
    3. Blow fill seal (BFS) i.e. use of plastic nebules (small container holding liquid medicine)
    4. Potential new fill and finish facilities

130. At the beginning of the pandemic, the exact requirements for fill and finish were unclear as it was not known what vaccines, if any, would successfully make it through clinical trials and be approved for use. However, the review concluded that use of glass multidose vials (MDVs) from existing facilities was the preferred option.

131. Of the available existing facilities, the review concluded that Wockhardt in Wrexham appeared the most favourable based on capacity and availability.

132. In August 2020 VTF agreed to reserve a fill and finish production line at Wockhardt. Securing this capacity meant that the VTF could later identify the most effective way to use it for the benefit of the UK, depending on which vaccines ended up proving safe and effective. The Wockhardt line was used for the Oxford/AstraZeneca vaccine.

Thermofisher in Swindon was another important UK fill and finish site, and partnered with Pfizer in the production of its vaccine.

Cell and Gene Therapy Catapult – Advanced Therapies Skills Training Network (ATSTN)

133. To ensure the UK had sufficient domestic expertise to respond to the urgent need to manufacture COVID-19 vaccines, the VTF worked with the Cell and Gene Therapy Catapult (CGTC) to develop a skills programme. In Autumn of 2020, the VTF provided CGTC with £4.7m over 3 years to establish the Advanced Therapies Skills Training Network (ATSTN).

134. This project aimed to quickly train people in Advanced Therapies Medicinal Products (ATMP) in response to COVID-19 vaccine manufacturing requirements. This included developing a virtual training platform and establishing national training centres to deploy existing infrastructure to meet the specialist skills demand for vaccine manufacturing.

135. The online training platform (vCATTS - later rebranded to 'Online training platform') provides a one-stop portal for access to industry standard training and development programmes from across the advanced therapies and vaccines manufacturing sector. The University of Birmingham, RoslinCT and the National Horizon Centre were selected as national training centres to provide dedicated, focused ATMP training.

Vaccine safety issues

136. All vaccines undergo rigorous processes to review their safety before being approved for use. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's independent regulator. Its role is to ensure medicines, including vaccines, work effectively and are safe for use. Products will only be authorised once they have met robust standards of effectiveness, safety, and quality.

137. Teams of scientists and clinicians rigorously review all data on safety, efficacy, and quality as soon as they become available, and did so throughout all tests and trials. The data includes all the results from laboratory studies, clinical trials, manufacturing and quality controls and testing the product.

138. The VTF was not responsible for approving vaccines (which is the role of the MHRA), or for recommending which vaccines should be used (which is the role of the JCVI).

139. Nonetheless, the VTF remained in close contact with the MHRA and manufacturers on regulatory issues to understand how processes could be made quicker and resolve any potential issues. This was to ensure that vaccines could be made available as quickly and as safely as possible.

140. The MHRA introduced some flexibilities to speed up pathways to regulatory approval, for example by instituting rolling review, which enabled vaccine developers to share data with the MHRA on a fortnightly basis during clinical trials. This allowed for more rapid assessment of the clinical data. It is also usual outside the VTF context for the MHRA to work with, for instance, vaccine manufacturers in order to facilitate the process of assessment. While the VTF worked with the MHRA to facilitate the process of scrutiny, it was crucial that the role of the MHRA in providing independent scrutiny of vaccine approval was maintained.

141. The MHRA had representation on some VTF groups until September 2020 so that it could update stakeholders on the approach it was taking to regulation, and work with them to resolve any issues. As outlined above at paragraph 89, MHRA staff then stepped down from these groups to avoid actual or perceived conflicts in their regulatory processes, as manufacturers began to send into the VTF packages of data which may, in due course, have fallen to be scrutinised independently by the MHRA.

142. Staying abreast of relevant safety issues, for example progress and outcomes from clinical trials or the progress of regulatory approvals, helped to inform the VTF as it made decisions on vaccine selection and negotiated contracts, as well as helping planning for deployment purposes. UKHSA will be better placed to provide evidence to the Inquiry on vaccine selection and deployment.

143. The VTF also supported the clinical trial process, which is an important part of demonstrating safety, for some vaccines. It is expected that this will be addressed further in evidence from other departments.

144. The MHRA is responsible for determining the details of regulatory policy and regulatory decisions affecting medicines and medical devices, and will be best placed to provide details of the systems for making such decisions.

145. I will instead explain the overall position of the VTF within the MHRA approval pipeline from the point at which the vaccine was ready for authorisation approval. This process is outlined in Annex G **[AJ/114 – INQ000330785]**.

146. As the VTF worked closely with vaccine manufacturers, VTF also kept other parts of government updated on progress towards regulatory approvals. VTF project teams would also update manufacturers on timelines and developments during the regulatory approval process.

147. The VTF and MHRA interacted on an ad hoc basis concerning the regulation of pharmaceutical manufacturing. This included interaction with the National Institute for Biological Standards and Control (NIBSC), part of MHRA. This included meeting with VTF staff in the early 2020 phase of the VTF **[AJ/115 – INQ000330745]**.

148. In common with the rest of MHRA's regulatory function, regulatory activities carried out by NIBSC such as certification grants and clearances of batch testing were done independently from the VTF.

149. As the VTF worked closely with vaccine manufacturers, VTF also kept other parts of government updated on progress towards regulatory approvals. VTF project teams would also update manufacturers on timelines and developments during the regulatory approval process.

Therapeutics and repurposed medications

Research and Clinical trials for therapeutics

150. The involvement of BEIS in respect of research into therapeutics and repurposing existing medications for the treatment for COVID-19 was primarily through its relationship with UK Research and Innovation (UKRI) which provided funding to several relevant trials.

151. UKRI is a non-departmental public body which invests in and facilitates, research and innovation across the UK. DSIT (previously BEIS) funds UKRI through the science budget and is the primary government point of contact for UKRI. The SoS for DSIT is accountable to parliament for UKRI **[AJ/116 – INQ000330515]**.

152. UKRI provides funding to a range of organisations, including universities and specialist institutes. This includes funding for institutions, which can be used flexibly, and funding for specific research projects. Decisions on funding individual research projects are taken by experts in those fields, and not by DSIT/BEIS.

153. UKRI provided funding for multiple projects, including working in partnership with the National Institute for Health Research (NIHR), focusing on developing new

therapeutics and repurposing existing medications for the treatment of COVID-19 [AJ/117 – INQ000330770]. Other organisations are likely to be best placed to provide evidence on these projects.

154. The Rapid Research Response [AJ/118 – INQ000330775] was established in February 2020 with initial funding of £20m. This fund was administered by UKRI's Medical Research Council (MRC) and NIHR (sponsored by DHSC), with the GCSA and CMO jointly agreeing on projects to be funded. Initially, this consisted of two research calls [AJ/119 – INQ000330776], both with deadlines in February 2020. The first call focussed on 'Active intervention development' and the second was on 'Diagnosing and understanding COVID-19'. In total, these two calls were funded at a cost of £25.5 million, with UKRI providing £12.6 million of this funding. A further rolling research call was launched under this initiative which ended up with a cost of £46.3 million, with £23.4 million of that coming from UKRI [AJ/120 – INQ000326361].

155. One project which received early funding through this mechanism was the RECOVERY trial which began in March 2020 and focused on repurposing existing medications for COVID-19. It assessed a range of potential treatments, including identifying one of the world's first COVID-19 treatments – dexamethasone (a readily available steroid). Importantly, it also identified treatments which did not show a clinical benefit.

156. UKRI's Medical Research Council (MRC) received additional funding to carry out vaccine and therapies research to develop new therapeutics and advise government. Details of other funding provided by UKRI, or UKRI councils and institutes, to projects developing new therapeutics or repurposing existing medications can be found on the UKRI website [AJ/117 – INQ000330770].

157. The 'Accelerating COVID-19 Research and Development' (ACCORD) programme was jointly funded by UKRI and DHSC in April 2020, as part of a co-ordinated therapeutic development pathway that was overseen by BEIS and delivered by UKRI. The ACCORD programme featured rapidly scaled-up national clinical trials, which accelerated the development of new drugs for COVID-19 patients. Drugs identified as being promising by government, academia and industry working together could enter the accelerated early-stage trials of ACCORD, allowing for early indications of effectiveness in treating coronavirus. The rapid testing through the ACCORD programme allowed for drugs identified as potentially effective in early-stage trials to be fed into larger-scale studies [AJ/121 – INQ000330777].

Therapeutics Taskforce (later Antivirals and Therapeutics taskforce)

158. At the time of its establishment, the possibility of the VTF working on therapeutics was considered. Although it was noted that there could be some advantages in combining both vaccines and therapeutics in one taskforce, each involved different challenges. For example, for therapeutics a key issue was running effective clinical trials for products already in existence, as well as supporting development of new treatments. For vaccines, there needed to be a much greater focus on discovery, and the manufacturing and deployment challenges were also quite different.

159. Vaccines was already such a challenging undertaking that broadening the scope of the VTF to include therapeutics too would result in leaders being spread too thinly. It was therefore agreed by the Prime Minister in May 2020 that it would be best for them to be separate bodies **[AJ/69 – INQ000330574]**.

160. There is some evidence in the papers I have seen **[AJ/69 – INQ000330574]** of tension between DHSC and BEIS around who should have what responsibility for work on therapeutics and vaccines. I cannot speak to this directly and would suggest that questions on this matter are directed to those who were more closely involved in those discussions. However, it is entirely normal for departments to discuss accountabilities for a new project or taskforce and to seek to clarify boundaries where responsibilities are closely aligned, so this debate does not strike me as out of the ordinary.

161. In mid-April 2020, the COVID-19 Therapeutics Taskforce ("TTF") was established as part of DHSC, and the Secretary of State for Health retained ministerial responsibility for work on therapeutics. The decision to exclude therapeutics from the scope of the VTF was made promptly, when the VTF was established in May 2020. Any question regarding the speed of establishing the TTF is best directed to DHSC. From my perspective, I would say that time spent carefully defining the scope of the VTF was time well spent; I take the view that it would have caused significant delays to the VTF's work overall if therapeutics had been within its remit throughout.

162. Other departments will be best placed to provide more substantial evidence on the work of the TTF, though I can outline here the involvement that Sir Patrick Vallance had in its establishment, and on supporting therapeutics research more broadly.

Role of the GCSA

163. Sir Patrick played an early role in bringing funders together (as outlined in section 1 above) including making the case for the Rapid Research Response initiative outlined above.

164. Sir Patrick's role within the TTF was limited to assisting and advising with its set-up in early 2020. This was similar to the role undertaken for the VTF, and also the role he later undertook in relation to the Antivirals Taskforce in April 2021 (which was merged with the TTF in April 2022).

165. Sir Patrick proposed the initiation of the TTF and therapeutics trials, and suggested people who could be involved **[AJ/122 – INQ000330538]**, **[AJ/123 – INQ000330539]**, **[AJ/124 – INQ000330541]**. He also provided advice on the proposed scope and responsibilities of the TTF **[AJ/125 – INQ000330545]**, **[AJ/126 – INQ000330546]**, **[AJ/127 – INQ000330547]**. He agreed with Dame Kate Bingham that vaccines and therapeutics should be dealt with separately (with the exception of antibody manufacturing which would remain within the VTF) **[AJ/128 – INQ000330576]**.

166. Once it was established, Sir Patrick Vallance attended several meetings of the TTF. Though this would not typically be a role for a GCSA, his professional and academic background as outlined above and his involvement in the pandemic response and regular contact with decision-makers meant that he was well-placed to provide advice. As with the VTF, Sir Patrick Vallance did not take an active role in the TTF once it was established.

167. In January 2021, Sir Patrick Vallance contacted the Director of the Therapeutics Taskforce in DHSC. He advised that it was critical that the TTF had a good overview of any antivirals being developed, and wanted to ensure that the TTF had industry experts with opinions on which antivirals would be most promising **[AJ/129 – INQ000330602]**.

168. Sir Patrick Vallance continued to promote the support for development of COVID-19 antivirals. He suggested a model whereby a new antiviral taskforce could select promising antiviral candidates and collaborate with a pharmaceutical company on every step of the process, from formula advice to the manufacturing of the antiviral, to provide the UK with a supply of two or more oral antivirals in time for Winter 2021 **[AJ/130 – INQ000330613]**. He noted in early February 2021 that to make such a model effective, the taskforce would require similar support from senior decision makers in Government as was given to the VTF **[AJ/131 – INQ000063381]**.

169. The importance of antivirals was raised by Sir Patrick Vallance at a meeting with the Prime Minister on 11 February 2021. The PM agreed that the taskforce model would be useful, and Sir Patrick Vallance agreed to provide No10 with suggestions of experts who could be approached **[AJ/132 – INQ000330610]**. Sir Patrick Vallance and DHSC TTF Director held meetings with industry experts to map the current antiviral landscape and identify the most promising antiviral candidates.

170. On 11 March 2021, the Prime Minister asked the Cabinet Office COVID-19 Taskforce to advise him on the proposal for the Antivirals Taskforce (ATF). The Cabinet Office COVID-19 Taskforce contacted Sir Patrick Vallance, to understand his views on how the ATF would function. He agreed that it could sit in DHSC and take a similar structure to the VTF, i.e. led by an industry expert in partnership with a senior civil servant.

171. In mid-March 2021, Sir Patrick Vallance was still pushing for an Antivirals Taskforce to be set up **[AJ/133 – INQ000330617]**. A workshop regarding the ATF was held in late March 2021, to provide HMT with a strategic case for antivirals, in order to secure funding for the taskforce **[AJ/134 – INQ000330618]**.

172. On 1 April 2021, the ATF was agreed in principle **[AJ/135 – INQ000330620]** and was announced on 8 April 2021 **[AJ/136 – INQ000330621]**.

173. Sir Patrick Vallance attended a number of meetings in an advisory capacity for the ATF, including providing input into the composition of ATF and assisting with shortlisting potential ATF members. Sir Patrick Vallance also suggested Eddie Gray (Former CEO of Dynavax Technologies and President of European Pharmaceutical Business, GSK), who was later appointed as Chair of ATF, as a possible candidate for the role. He was asked by Matt Hancock (Secretary of State, DHSC) to provide advice on several occasions, including in regard to both the governance of the ATF, and the identification of priority Antiviral compound candidates **[AJ/137 – INQ000063609]**, **[AJ/138 – INQ000330622]**.

174. The ATF and TTF were amalgamated in April 2022 into the Antivirals and Therapeutics Taskforce, which closed in March 2023.

The National Core Studies Programme

175. The National Core Studies (NCS) Programme was initiated by Sir Patrick Vallance in July 2020, and started work in October 2020. Experts involved in the COVID-19

response, including the GCSA and the CMO, identified gaps in UK research infrastructure that should be addressed in order to respond to strategic, policy and operational needs, and maintain resilience in the UK against COVID-19. Six National Core Studies were established, each led by experts in the relevant disciplines. These were:

- Epidemiology and Surveillance (Led by Professor Ian Diamond, UK National Statistician, Office for National Statistics): Collecting and analysing data to understand how COVID-19 affects the UK, including the prevalence of COVID-19 and in the general population and how it changes over time, and the economic and societal impacts of COVID-19.
- Transmission and Environment (Led by Professor Andrew Curran, Chief Scientific Adviser, Health and Safety Executive): Understanding transmission of COVID-19 in the workplace, on transport and in public places.
- Clinical Trials Infrastructure (Led by Professor Patrick Chinnery, Clinical Director, Medical Research Council and Dr Divya Chadha Manek, Head of Business Development, Vaccines Taskforce): Building on existing NIHR research infrastructure to expand and accelerate delivery of large scale COVID-19 vaccines and therapeutics trials.
- Immunity (Led by Professor Paul Moss, Professor of Haematology, University of Birmingham): Understanding immunity against COVID-19 by predicting individual risk, working to protect against infection, and preparing for future pandemic challenges.
- Longitudinal Health and Wellbeing (Led by Professor Nishi Chaturvedi, Professor of Clinical Epidemiology, University College London, and Professor Jonathan Sterne, Professor of Medical Statistics and Epidemiology, Bristol Medical School). Understanding the long-term impacts of COVID-19 on mental, physical and economic health.
- Data and Connectivity (Led by Professor Andrew Morris, Director, Health Data Research UK): Making UK-wide health and administrative data available and accessible to all.

176. Leads for the study areas were agreed in July, coordinated by the GO-Science NCS Secretariat. The Steering Group (known as the Oversight committee until August 2021) was chaired by Sir Patrick Vallance. This aimed to provide expert advice on the scope and delivery of the National Core Studies **[AJ/139 – INQ000330692]**. The

committee consisted of science experts, as well as representatives from the DAs. Two members of the Steering committee were partnered with each study area, offering expert advice, quality assurance and reviewing of funding requests. An international advisory panel also contributed to the NCS Programme, providing a global perspective to each study. Membership of the Steering Group and International Advisory Panels can be found in Annex A. Several government departments and organisations were involved in decision making, governance and funding for the NCS programme, including BEIS, GO-Science, UKRI, NIHR, Health and Safety Executive (HSE) and HMT.

177. NCS impact reports were published regularly in 2021 and 2022, highlighting achievements **[AJ/140 – INQ000330778]**, **[AJ/141 – INQ000330703]**.

178. UKRI funded three National Core Studies: Immunity, Longitudinal Health and Wellbeing, and Data and Connectivity **[AJ/142 – INQ000330779]**. Across these three studies, funding was broadly secured until September 2022, with UKRI agreeing that any underspend could be used to continue studies until the end of 2022 with a no cost extension. Studies that would require longer to complete had to apply to UKRI for funding from September 2022 onwards.

179. Some of these studies supported efforts to find effective vaccines and therapeutics; particularly the studies on clinical infrastructure trials and immunity.

Clinical Infrastructure Trials

180. The 'Clinical Infrastructure Trials' studies were funded through the Vaccines and Therapeutics Taskforces but remained connected to the NCS. The study's funding department was the DHSC, with research grants provided through NIHR. Two workstreams were created within the studies; a therapeutics workstream led by Professor Patrick Chinnery and a vaccines workstream led by Divya Chadha Manek.

181. The Therapeutics Workstream was established in July 2021 **[AJ/143 – INQ000330690]** and aimed to harness and develop existing clinical trials efforts in the UK to streamline efforts in the selection of candidate drugs for trial. The workstream was divided into two (trials and triage) and was supported by a small secretariat funded by Medical Research Council (MRC). Work in the triage stream was conducted by the UK COVID Therapeutics Advisory Panel (UK-CTAP) and the MRC secretariat. UK-CTAP made recommendations into trial platforms that were funded by NIHR and UKRI, in phases 1 to 3.

182. Funding allocated by the NCS programme to the workstream was managed by the Therapeutics Taskforce. The workstream had a variety of successful outcomes, including contributing to the recommendation of Baricitinib (traditionally a drug for rheumatoid arthritis) by UKCTAP for the RECOVERY+ trials, which was found to improve hospital mortality rates for COVID-19. It was agreed by Sir Patrick Vallance and Professor Patrick Chinnery in February 2022 that the Therapeutics stream should be stood down, and that any future work would be commissioned under 'Business as Usual' protocols.

183. The Vaccines Workstream functioned in a slightly different manner to other NCS. It provided a more external input into the NCS; assisting with data to inform other studies and providing updates on vaccine progress, as well as acting as a bridge to ensure work was not being replicated from the VTF. Divya Chadha Manek left her role in the VTF in September 2021. By this point vaccines trials infrastructure had been significantly strengthened and its use embedded within industry and usual practice. As such the specific vaccines workstream was no longer required and ended shortly after in November 2021.

Immunity

184. The Immunity study was led by Paul Moss from the University of Birmingham and Doreen Cantrell from the University of Dundee. The Study was allocated £11.5million from UKRI to answer questions regarding, including: 1) How does the immune system respond to vaccines, and what are the effects on those who are immune suppressed; 2) How do variants of concern effect immune control; 3) What are the features and failures of immune response that lead to re-infection or vaccine breakthrough.

185. The immunity studies were designed to build on other NCS studies (such as Data and connectivity) in order to provide solutions to issues such as susceptibility of COVID-19 on a scale that could not usually be addressed through regular UKRI funding support mechanisms **[AJ/144 – INQ000062857]**. This study supported the creation of the 'UK Vaccine Research Hub' **[AJ/145 – INQ000330780]**; an online facility for publishing up-to-date, reliable and accessible information on COVID-19 vaccine studies in the UK. A list of academic research studies supported by the Immunity NCS can be found online **[AJ/146 – INQ000330781]**.

DSIT/BEIS: other roles and responsibilities

186. BEIS' main role of relevance to the scope of Module 4 is its support for and oversight of the VTF. As outlined above, BEIS had corporate responsibilities relating to the VTF, including accountability for its spending, with the VTF SRO reporting to the BEIS Permanent Secretary who was the accounting officer. Key groups and people are outlined in Annexes A and B.

187. BEIS also provided functions such as HR support, with BEIS People and Operations Committee retaining oversight of issues relating to the performance management, development and welfare of the VTF's staff. Internal Audit functions were provided by BEIS's Internal Audit Department. BEIS also supported VTF on other corporate matters such as IT, finance and security.

188. There was also some support from the BEIS communications team around the work of the VTF. The VTF contracted its own communication specialists with relevant sector expertise, in order to help it support recruitment for clinical trials, as well as building confidence in the programme more generally. UKHSA will be best placed to comment on communications, including on issues around the impact of messaging on vaccine uptake and other deployment matters.

189. Following the decision by the BEIS and DHSC Permanent Secretaries for the VTF to become a joint unit between DHSC and BEIS, the VTF continued to refine and develop its governance structure to support delivery, decision making and to support monitoring across the portfolio. Under the terms of the MoU between the two departments, the internal governance structure oversaw the performance and risk management of the VTF, which was aligned with both BEIS and DHSC's corporate assurance expectations and subject to periodic review. The Programme structure in Annex C from June 2022 demonstrates that while some structures remained the same as before, several structures were renamed and changed.

190. GO-Science provided the secretariat to SAGE (Scientific Advisory Group for Emergencies) and the National Core Studies programme. SAGE had a very limited role on vaccines and therapeutics, given the scientific input being provided through the VTF and elsewhere. It was, however, periodically updated on progress **[AJ/147 – INQ000089720]**, given the importance of understanding likely availability and efficacy of vaccines and therapeutics when providing advice, for example on the potential trajectory of the epidemic overall, and on the impact of non-pharmaceutical interventions.

191. SAGE also provided science advice on related issues such as the potential role of 'certification' (SAGE 69 and SAGE 72) **[AJ/147 – INQ000089720]**. Many of the policy considerations were not ones which could be addressed by scientific advice alone. SAGE advice was published during the pandemic.

192. SAGE provided advice on behavioural science including how vaccination might affect behaviours, and factors which could encourage uptake (SAGE 73) **[AJ/147 – INQ000089720]**, including highlighting potential disparities between different population groups (e.g. by age, gender or ethnicity). SAGE was not responsible for operational elements or public communications.

193. SAGE provided only occasional input to the VTF, as the taskforce had its own expertise and was often addressing operational matters. SAGE highlighted the need for very effective pharmacovigilance in November 2020 (SAGE 67) **[AJ/147 – INQ000089720]**. SAGE also established a Vaccines Science Coordination Group led by Wendy Barclay, in December 2020, a working group which aimed to ensure relevant scientific questions were addressed in the right places in the advisory structures and providing a link between the various people and groups working on vaccines including those from SAGE and its subgroups **[AJ/148 – INQ000330751]**.

194. As well as the work of GO-Science and SAGE, BEIS was jointly responsible (with DHSC) for OLS. As outlined in section 1, DSIT has inherited these responsibilities. Although most of the functions of the VTF became part of UKHSA, the Onshoring Directorate became part of OLS. Those responsibilities which transitioned to UKHSA and DHSC are not addressed in this statement.

Transitioning the functions of the VTF to UKHSA and BEIS

195. The VTF was always intended to be a time-limited organisation to address a specific challenge during the COVID-19 pandemic. After the successful development and deployment of several vaccines, DHSC and BEIS ministers decided that the functions of the VTF should be incorporated into permanent organisations. **[AJ/149 – INQ000330763]**, **[AJ/150 – INQ000330786]**.

196. The planning and preparation work on the transition took place from Spring 2022, with a team set up to lead this work. The plan to transition the VTF into long-term functions across Government was formally announced on 15 June 2022. The aim was to retain the strengths of the VTF, but in a permanent structure which would maintain preparedness for future health emergencies.

197. Most of the VTF's functions transferred to UKHSA, as outlined above, but the Onshoring Directorate's work was more closely linked to OLS responsibilities and so it transferred there. The transition was finalised on 1 October 2022.

198. A new organisational structure in OLS has been implemented, to integrate the Onshoring functions and team into the organisation while maintaining many of the successful VTF ways of working, to maximise the benefits of the transition.

Lessons learned

199. The VTF underwent several reviews, both internal and external, to provide assurance of its effectiveness and to identify opportunities for improvement. The VTF, as a new organisation in a rapidly changing context, continually adapted to deliver its objectives, learning as it went.

200. In June 2020 Dame Kate Bingham asked Sir Richard Sykes (chair of the Royal Institution, who became chair of the VTF from June 2021) to review its strategy and goals **[AJ/151 – INQ000330782]**, **[AJ/152 – INQ000283321]**. This review concluded that:

    a. VTF had built an attractive portfolio of the most promising vaccines for the UK population;

    b. VTF had shaped new collaborative arrangements to ensure that successful vaccines will be distributed internationally;

    c. VTF had supported the UK's industrial strategy by reinforcing long-term vaccine capability to prepare the UK for future pandemics, helping to place the UK at the forefront of vaccine R&D, manufacturing and distribution, but more was needed.

201. The review by Sir Richard Sykes also made recommendations which were supplemented by a range of internal recommendations for the VTF and government. These included recommendations aimed at permanently maintaining some of the capabilities built in the VTF, which influenced proposals for further work **[AJ/153 – INQ000330659]**.

202. Internal to government reviews by the Infrastructure and Projects Authority (IPA) took place in November 2020 and May 2021 **[AJ/154 – INQ000330638]**, **[AJ/155 – INQ000128467]**. Recommendations were actioned with named leads responsible for specific areas **[AJ/156 – INQ000330733]**.

203. The Government Internal Audit Agency reviewed procurement **[AJ/157 – INQ000330651]**, which other departments will be best placed to address in their evidence.

204. The National Audit Office (NAO) also conducted two reviews. The first took place in December 2020 and considered preparations for potential COVID-19 vaccines **[AJ/158 – INQ000283340]**. The second looked at the "Rollout of COVID-19 19 Vaccination Programme in England" **[AJ/159 – INQ000065228]** and was published in February 2022, which concluded that the vaccine programme provided value for money and provided four recommendations for the VTF's future work relating to managing surpluses, maintaining flexibility, learning from the programme and developing a future model for COVID-19 vaccination. The VTF accepted these and took steps to implement them.

205. Sir Patrick Vallance has previously reflected on lessons learned from the Vaccines Task Force and had produced a document on the key features that led to the success of the VTF **[AJ/160 – INQ000101626]**. This includes the fact that "content experts were brought in rapidly", the VTF had an "at-risk investment mindset" and that "private sector engagement was key".

206. DSIT, and government more broadly, have also learnt from the success of the VTF, as noted in the 2021 BEIS innovation strategy **[AJ/161 – INQ000330783]**, stating that "[The VTF] successfully brought together the collective effort of government, industry and academia behind a single innovation mission".

207. For example, a VTF-style approach is currently being adopted to tackle some of the biggest public health challenges facing the UK. The OLS oversees delivery of 'healthcare missions', stemming from the Life Sciences Vision published in July 2021. Five of these missions are being delivered, and as with the VTF, are being led by an independent expert chair to spearhead their delivery and drive collaboration across partners across the public, private and third sectors. This was echoed in the VTF's legacy strategy **[AJ/162 – INQ000330746]** in which the department's Coordination and Infrastructure strand aimed to learn from the VTF's mission-orientated approach in health policy.

208. There are also lessons that can be learned from the experience of working with other organisations. The approach adopted during the pandemic by MHRA, as the regulator responsible for (amongst other things) reviewing applications for clinical trials, approving vaccines for human use and inspecting premises to ensure that they are producing products in line with appropriate standards, was widely recognised as

being key to ensuring that vaccines could be made available so quickly. This was in large part due to effective collaboration across public sector bodies and with industry.

209. Monitoring and evaluation of the VTF programme was carried out by a VTF Evaluation Board established in March 2021. An overall review of the VTF was published based on data up until the end of September 2022 **[AJ/152 – INQ000283321]**. Building on this, a monitoring and evaluation plan was developed for the Onshoring Programme, which involves annual monitoring reports **[AJ/163 – INQ000330729]** (the first one was produced for 2022/23) and evaluation (which has yet to take place).

210. Lessons have also been identified from individual projects. For example, the VMIC project highlighted some of the challenges associated with changing the scope of a project which is already underway.

Preparedness for future pandemics

211. Resilience for future health emergencies is a priority for government and requires a cross-government approach. The learning from the successes of the VTF will enable the UK to be more prepared for the next pandemic. The steps taken towards onshoring and strengthening supply chains and the life sciences sector will also mean that the UK is better placed to tackle future health emergencies. Other departments lead on pandemic preparedness and are expected to address these areas more substantively in their evidence, but I can outline some of the steps that DSIT/BEIS and GO-Science have taken in support of this.

212. The Pandemic Preparedness Partnership, chaired by Sir Patrick Vallance, set out the '100 Days Mission' at the UK hosted G7 in June 2021. This outlined a path to making diagnostics, therapeutics and vaccines available within 100 days of a pandemic threat being detected. The partnership comprised representatives from industry, international organisations and sector experts. This has informed government's work on pandemic preparedness.

213. Many of the technologies and processes which were developed and proven during the COVID-19 pandemic are likely to be of benefit in future health emergencies. For example, this was the first time that mRNA vaccines had been successfully developed and deployed. There is now R&D work underway to apply mRNA technology to tackle many other diseases. OLS supports the life sciences sector in the UK to make it an attractive place to carry out R&D.

214. The early stages of the COVID-19 pandemic highlighted the UK's dependence on the overseas manufacture of vaccines as well as the complex international supply chains that support this, which leaves the UK's vaccine supply vulnerable to disruption and export controls. This was compounded by a global vaccine market that is highly consolidated, raising questions about the resilience and security of supply chains for the UK. Pre-COVID-19, four companies were responsible for ~90% of total global vaccine sales with >80% of vaccines manufactured in the EU, China, India and the US. Vaccine supply resilience depends on global supply chains, domestic facilities with sufficient manufacturing capacity and access to new and emerging vaccine technologies (e.g. RNA). Onshoring vaccine originators and strengthening supply chains (capacity to manufacture and supply chain inputs), are important steps to build resilience for future health emergencies, which OLS is supporting, building on the work of the VTF.

215. In June 2021, the management consultancy McKinsey & Company was commissioned by the VTF Onshoring directorate **[AJ/164 – INQ000330626]** to produce a report on the global and UK vaccine landscape. This report considered lessons from the COVID-19 pandemic up to that point, which informed development of the Onshoring Programme **[AJ/165 – INQ000371341]**. It noted that resilience requires multiple vaccines and biotherapeutics candidates in as many modalities as possible and the ability to develop, produce and distribute quickly and at scale.

216. Key headlines from the McKinsey report included:

- The UK's manufacturing footprint is small when compared with a global peer set, however, it holds leadership positions in R&D.
- The UK's bio-manufacturing footprint includes small presence from some of the world's major CDMOs, but limited capacity from originators.
- Onshore drug substance capacity is fragmented across multiple producers with capacity gaps in new modalities.

217. The 2021 Spending Review (SR21) reviewed the VTF budget, and allocated funding for the year 2021/2022 to cover VTF onshoring and manufacturing investments, known as the VTF Onshoring Programme. The Onshoring Programme was allocated £429.5m at the SR21; £269.5m of this fell under the banner of the 'Global Britain Investment Fund' (also announced at SR21) which included a wider commitment to life sciences manufacturing. The objective of this work was, by 2025, to create a step-change in the UK's vaccine ecosystem to secure improved capability across multiple facilities to increase UK resilience by:

- Onshoring mRNA capability (including in development) - to strengthen the UK's mRNA capability by securing investment to support the long-term development of this technology and the ability to manufacture mRNA at scale in the UK. It will also ensure that this capability exists across several facilities to mitigate supply chain risks associated with single sourcing.
- Expand multi-modal vaccine manufacturing capacity (via previous investments) - developing this capability across a number of facilities in the UK, to maximise the number of 'shots on goal' and maximise the probability of onshoring the production of an efficacious vaccine in a future health emergency.
- Selective investments in onshore vaccine supply chain - targeted supply chain investments to support a flexible UK manufacturing base capable of manufacturing across more than one modality and/or technology. Through these investments, the UK also stands to gain much greater relevance in the global vaccine market, giving the UK the necessary leverage to deter foreign export controls.

218. The Onshoring Programme business case noted that in the event of a health emergency and significant trade barriers, the UK would only have access to existing domestic vaccine manufacturing capacity (viral vector and protein sub-unit only). This capacity was insufficient to protect the UK population, especially given the success of mRNA vaccines. In a health emergency, HMG would have to rely on both the UK's diplomatic and purchasing power to secure vaccines. Locating manufacturing capacity for vaccines and components in the UK confers a high level of assurance that vaccines can be accessed in the case of a health emergency. There would be no risk of export controls limiting access and proximity would speed up delivery.

219. The Onshoring Programme had intended to take a portfolio approach across different vaccine platforms – viral vector, mRNA and protein sub-unit. However, due to the focus on mRNA for booster revaccination, the speed-to-edit advantage of mRNA, and the critical gap in mRNA capacity and capability in the UK, mRNA vaccines were a key focus of the programme. In addition, work was scoped to support supply chain projects targeting critical components to prevent bottlenecks that might inhibit future vaccine supply.

220. The Programme business case was approved by the BEIS Project Investment Committee in February 2022 **[AJ/90 – INQ000330739], [AJ/166 – INQ000330747], [AJ/167 – INQ000330669]; [AJ/168 – INQ000330671]; [AJ/169 – INQ000330672]; [AJ/170 – INQ000371342] [AJ/171 – INQ000330673]; [AJ/172 – INQ000330670];**

[AJ/173 – INQ000330674]; [AJ/174 – INQ000330675]; [AJ/175 – INQ000330676]; [AJ/176 – INQ000330677] [AJ/177 – INQ000330678]; [AJ/178 – INQ000330679]; [AJ/179 – INQ000330680]; [AJ/180 – INQ000330681]; [AJ/181 – INQ000330682]; [AJ/182 – INQ000330683]; [AJ/183 – INQ000330684]; [AJ/184 – INQ000411966] [AJ/185 – INQ000330685]; [AJ/186 – INQ000330686]; [AJ/187 – INQ000330687]; [AJ/188 – INQ000330688]; [AJ/189 – INQ000330689] [AJ/190 – INQ000411967] and HMT subsequently approved £94.5m to be spent on the following specific interventions, building on the work that the VTF started as outlined at paragraphs 99 to 135 above:

- Cell and Gene Therapy Catapult, Braintree - £63m to expand multi-modal capacity, focussing on Cell & Gene Therapy manufacturing innovation to provide large-scale Viral Vector manufacturing and Advanced Therapeutic (AT) capabilities.
- Croda - £16m to expand domestic lipid nanoparticles production (critical to Pfizer-BioNTech mRNA vaccine supply chain).
- CPI - £10.65m to develop the RNA Centre of Excellence in Darlington, to support the development, scale-up and manufacture of new RNA therapies and vaccines.
- Advanced Therapies Skills Training Network (ATSTN) - £4.7m to drive growth across the advanced therapies and vaccine manufacturing industry, through offering access to national training facilities (University of Birmingham, RoslinCT and National Horizon Centre) and an online training platform to address the UK's demand for skills.

221. OLS officials remained in dialogue with HMT officials about how to achieve the goals of the Onshoring Programme, making use of the uncommitted funding. The delivery model proposed was a capital grants programme which would build on the experience of OLS of running the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF) and Life Sciences Innovative Manufacturing Fund (LSIMF) programmes.

222. HMT officials postponed approval of further spending until the outcome of discussions with Moderna on a 10 year partnership to build pandemic resilience through mRNA manufacturing and R&D, in order to consider any potential overlaps in the outcomes that both were trying to deliver. During this time, OLS officials remained in dialogue with HMT officials about how to achieve the goals of the Onshoring Programme, making use of the uncommitted funding. The strategic

partnership was announced in December 2022. It is anticipated that the UKHSA will provide more detail on this in its evidence.

223. The SoS of BEIS at that time (Grant Shapps) then chose not to allocate the uncommitted element of the Onshoring Programme budget to further onshoring projects in BEIS departmental budgetary prioritisation discussions in January 2023. By way of context, BEIS faced significant pressures on capital allocations from energy/Net Zero commitments that were a high priority for BEIS, HMT and No.10. As a result, the SoS in conjunction with HMT, agreed to repurpose £88m of the vaccines onshoring allocation in 23/24 and £80m in 24/25. This funding had not been committed at the time that it was repurposed. The projects set out at paragraph 220 above fell outside the scope of the reprioritisation exercise, so those projects are continuing unaffected.

224. Following the reprioritisation of capital funding for vaccines onshoring, OLS continued to work to secure capital funding to support improved health resilience for biomanufacturing more broadly. In May 2023, government announced a Biomanufacturing Fund of up to £38m as part of the Life Science for Growth Package. The fund has two key objectives, the first to improve the UK's health resilience for future pandemics and the second to drive economic growth in the UK. The package also included an additional £10m of funding for UKRI's Transforming Medicines Manufacturing programme to drive innovation in cutting edge medicines manufacturing that can bolster UK health resilience and £6.5m to strengthen the UK's medicines manufacturing skills ecosystem. In addition, the Autumn Statement in November 2023 announced a commitment of £520m to support life sciences manufacturing which will help to incentivise increased manufacturing investment across the life sciences sector, building on the UK's existing strengths in R&D and contributing to further improvements in health resilience.

225. OLS has continued to contribute to cross-government work on pandemic preparedness, which is led by DHSC and UKHSA. Other departments are expected to cover this work in more detail in their evidence.

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: Thursday 12th September 2024

List of Annexes

Annex A – Key individuals [AJ/191 – INQ000408359]

Annex B – Key groups [AJ/192 – INQ000408360]

Annex C – 2021 and 2022 VTF programme structures [AJ/193 – INQ000408361]

Annex D – VTF Cross-Government interactions map [AJ/194 – INQ000408362]

Annex E – Draft diagram outlining VMIC interactions with BEIS and UKRI [AJ/195 – INQ000408363]

Annex F – Vaccine types [AJ/196 – INQ000408364]

Annex G – MHRA vaccine authorisation pathway [AJ/197 – INQ000408365]

Annex H – Glossary of terms and acronyms [AJ/198 – INQ000408366]