Witness Name: Dr Samantha Roberts
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF DR SAMANTHA ROBERTS

I, Dr Samantha Roberts, will say as follows: -

1. I am the Chief Executive of the National Institute for Health and Care Excellence ["NICE"]. I commenced this role on 1 February 2022 following the retirement of the previous Chief Executive Professor Gillian Leng. Professor Leng was the previous deputy Chief Executive and Director of the Health and Social Care Directorate. She joined NICE in 2001 and was appointed as Chief Executive on 1 April 2020, following the retirement of Sir Andrew Dillon on 31 March 2020. Andrew had been Chief Executive since NICE's formation in 1999.

2. On behalf of everybody at NICE, I would like to start by expressing my deepest sympathy to all those who lost loved ones during the COVID-19 pandemic and those affected in many other ways, including those that continue to be affected.

3. I make this witness statement further to receipt of the Rule 9 letter from the Public Inquiry dated 2 June 2023, to assist the UK COVID-19 Public Inquiry in its understanding of NICE and to provide an overview of NICE's role, functions and aims. As requested, this statement will focus on the period between 1 March 2020 and 28 June 2022 ["the relevant period"] and should be read in conjunction with witness statements provided by NICE colleagues Helen Knight (Director of

Medicines Evaluation in the Centre for Health Technology Evaluation "CHTE") and Dr Paul Chrisp (former Director of Centre for Guidelines "CfG").

4. My role as Chief Executive involves leading the organisation and developing the strategy for the Board's approval. As NICE's Accounting Officer I am personally responsible for safeguarding the public funds entrusted to NICE; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of NICE.

5. As Chief Executive, I report to NICE's Board. I am Chair of the Executive Team ["ET"], which until January 2021 was known as the Senior Management Team ["SMT"] and Chair of the Guidance Executive ["GE"]. The ET is responsible for providing leadership to the organisation within the authority delegated by the Board. The GE comprises members of the ET and other senior managers and considers and approves NICE's guidance and advice, on behalf of the Board.

6. NICE as an organisation very much welcomes the work of the UK COVID-19 Public Inquiry and as it has done from the outset, will continue to work with the Inquiry in a very open and transparent manner to learn lessons and support any improvement to the country's ability to respond to a pandemic.

Personal background and experience

7. Before joining NICE, I was Managing Director of health and care at the financial firm Legal and General.

8. Prior to this, I was the first Chief Executive of the Accelerated Access Collaborative ["AAC"], a national umbrella organisation for health innovation, hosted by NHS England ["NHSE"]. The AAC is a unique partnership between patient groups, government bodies, industry, and NHS bodies, all working together to streamline the adoption of new innovations of healthcare.

9. In terms of formal qualifications, I trained as a doctor and practiced medicine in South Africa, the United Kingdom and Australia, before undertaking an MBA.

10. I then joined McKinsey and Company, where I worked in a wide range of industries before specialising in healthcare. Following this I moved into the NHS as a senior manager at University College London Hospitals NHS Foundation Trust. I was also director of UCL Partners, an Academic Health Sciences Centre and Network. In 2018, I took on the role of Director of Innovation, Research and Life Sciences at NHSE.

11. Over the last 10 years, I have become involved in research, working with health economic models to inform evidence-based policy at the London School of Economics. From there I attended the University of Oxford, where I undertook a DPhil in Evidence Based Healthcare.

NICE – Role, Function and Responsibilities

12. NICE, originally known as the National Institute for Clinical Excellence, was set up by the Government in 1999, as a Special Health Authority. It was then re-established as a non-departmental public body under the Health and Social Care Act 2012 ["HSC Act 2012"] and is now known as the National Institute for Health and Care Excellence, to reflect a role that encompasses health care, social care and public health.

13. NICE is led by a unitary board comprising of a Non-Executive Chairman and Non-Executive Directors ["NED's"] appointed by the Secretary of State for Health and Social Care, and Executive Directors appointed by the NED's. A high-level overview of NICE's Governance Structure dated January 2020 – June 2022, can be found at **Exhibit SR/1-INQ000252451**. The Board, accountable to the Department of Health and Social Care ["DHSC"], ensures that the ET is held to account for the performance of the organisation and that NICE meets the highest possible standards in its conduct. The Board exercises its duties via its formal board

meetings (which are usually held in public), the two board committees, and informal non-decision-making Board seminars.

14. In addition, the DHSC Permanent Secretary has appointed a Senior Departmental Sponsor ["SDS"] who acts as NICE's designated, consistent point of contact within DHSC and a link between NICE and departmental senior officials and Ministers. The SDS is supported by a DHSC Sponsor Team, which carries out the principal day-to-day liaison between DHSC and NICE. The DHSC Sponsor Team is the primary contact for NICE and they support the SDS in advising the responsible minister on the discharge of his or her responsibilities in respect of NICE. During the relevant period, the SDS was Elizabeth Woodeson, DHSC's Director of Medicines & Pharmacy.

15. I also attach to this statement NICE's Senior Leadership Organogram at **Exhibit SR/2-INQ000252455**, detailing key personnel within NICE during the relevant period. **Table 1** below also provides an overview of the key personnel involved in NICE's response to the pandemic:

Name	Position	Roles & Responsibilities during the pandemic.
Andrew Dillon	Chief Executive (retired 31.03.20)	• Chaired SMT until retired; and • Chaired Guidance Executive until retired.
Dr Gillian Leng	Chief Executive (01.04.2020 – 31.01.22) Previously Deputy Chief Executive and Director of Health and Social Care Directorate.	• Chaired SMT from April 2020 (known as ET from January 2021); • Chaired COVID Gold Group (Jennifer Howells chaired from 01.02.21); and • Chaired Guidance Executive.
Dr Samantha Roberts	Chief Executive (01.02.2022 – present)	• Board member • Chairs ET (formerly SMT); and • Chairs Guidance Executive.

Meindert Boysen	Deputy Chief Executive (01.04.2020 – 31.01.22) and Director of Centre for Health Technology Evaluation 'CHTE'.	• Sat on the Board, Member of SMT/ET and Guidance Executive; • Chaired COVID Response Group; • Established the RAPID C-19 pathway with partners (a multi-agency initiative for rapid patient access to effective COVID treatments); and • Chaired early meetings Rapid C-19 Oversight Group. This consisted of weekly meetings with other stakeholders, including NHSE, MHRA, NIHR and NICE. NICE decision maker on RAPID C-19, until Helen Knight took over (see below).
Dr Paul Chrisp	Director - Centre for Guidelines 'CfG'.	• Sat on the Board; • Member of SMT/ET, Guidance Executive and COVID Gold Group; • Strategic responsibility for all COVID-19 rapid guideline work and rapid evidence summaries; and • Led on engagement with NHSE in relation to COVID-19 rapid guidelines.
Jenniffer Howells	Director-Finance, Strategy, and Transformation Directorate (01.09.20 - 26.10.22	• Sat on the Board and Member of SMT/ET; • Chaired COVID Gold Group from February 2021; and • Chaired OMC from November 2021.
Dr Judith Richardson	Programme Director, Clinical Directorate Previously Acting Director-Health and Social Care Directorate (01.04.20 - 01.04.23)	• Attended Board, Member of SMT/ET, Guidance Executive and COVID Gold Group (from 01.04.2020); • Deputy Chair of COVID Response Group (became Chair in Meindert's absence); and • Strategic responsibility for external engagement with the health and social care system and some key partnerships (during role as Acting Director).

Eric Power	Programme Director – Medicines and Technologies, CfG	• Oversaw the early response and production of the early COVID-19 rapid guidelines, along with Dr Paul Chrisp and Fiona Glen, until COVID-19 Guidelines Team established in September 2020.
Fiona Glen	Programme Director – Public Health & Social Care, CfG	• Member of COVID Response Group; and • Oversaw the COVID-19 Guidelines Team, once established in September 2020.
Helen Knight	Director for Medicines Evaluation, CHTE	• Member of RAPID C-19 oversight group; • Deputy decision maker until November 2021, when became acting interim director and NICE RAPID C-19 decision maker; • Responsible for 'Medicines' and external CHTE relationships during the pandemic; and • Together with Jeanette Kusel, jointly covered Meindert Boysen's role as Director, CHTE during his sickness absence and then became Acting Interim Director of Medicines Evaluation in March 2022 before being appointed substantively to this role in December 2022. In these roles, was a member of ET and GE and attended the Board.
Jeanette Kusel	Director for Scientific Advice, CHTE	• Responsible for overseeing the stewardship of scientific advice and NICE International; and • Together with Helen Knight, jointly covered Meindert Boysen's role as Director, CHTE during his sickness absence and then became Acting Interim Director of Medtech in March 2022 until May 2022. In these roles, was a member of ET and GE and attended the Board.

Carla Deakin	Programme Director- Commercial and Managed Access, CHTE	• Responsible for NICE's secretariat in the Rapid C-19 pathway; and • Facilitator of the Rapid C-19 Oversight Group from November 2020.

Table 1: NICE key decision- makers

16. NICE is an arm's length body of the DHSC. Arm's-length bodies are a specific category of central government public bodies that are administratively classified by the Cabinet Office. A framework agreement exists between NICE and DHSC which sets out the parameters in which NICE operates and discharges its responsibilities, including the relationship between NICE and DHSC. I attach a copy of the framework agreement to this statement at **Exhibit SR/3-INQ000252456.** As can be seen in the framework agreement, NICE's role is to provide guidance and support to providers and commissioners to help them improve outcomes for people using the NHS, public health and social care services. NICE supports the health and care system by describing what good quality care looks like in the NHS, public health and social care sectors and helps promote the integration of health and social care. NICE does this by producing robust evidence-based guidance and advice, developing quality standards and providing information services for commissioners, practitioners and managers across the spectrum of health and social care.

17. NICE's statutory role and responsibilities are set out within the HSC Act 2012 and its supporting regulations (The National Institute of Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013). In its present incarnation, NICE was established by section 232 of the HSC Act 2012 and its functions are set out in Part 8 and Schedule 16 of the HSC Act 2012. In exercising its functions, in accordance with section 233(1), NICE must have regard to:

    a) *The broad balance between the benefits and costs of the provision of health services or of social care in England,*

b) The degree of need of persons for health services or social care in England, and

c) The desirability of promoting innovation in the provision of health services or of social care in England.

(2) Nice must exercise its functions effectively, efficiently and economically.

18. The Secretary of State is accountable to Parliament for the health system, including NICE, with support from the DHSC. The DHSC Permanent Secretary is the Principal Accounting Officer and is accountable to Parliament for the issue of any Parliamentary funding to NICE and for matters such as monitoring NICE's activities.

19. Although NICE is established as an English public body, it has agreements in place with the devolved administrations in Wales, Northern Ireland and Scotland, to enable these nations to utilise aspects of NICE guidance.

20. NICE was established to help ensure that people had equal access to clinically and cost-effective treatments wherever they live. NICE helps practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer. NICE does this by:

- Producing useful and usable guidance for health and care practitioners;
- Providing rigorous, independent assessment of complex evidence for new health technologies;
- Developing recommendations that focus on what matters most and drive innovation into the hands of health and care practitioners; and
- Encouraging the uptake of best practice to improve outcomes for everyone.

21. An overview of NICE's centres and directorates as at June 2022 can be found at **Exhibit SR/4-INQ000252457**. The Directorates primarily involved in the COVID-19 response were the Centre for Guidelines ["CfG"] and the Centre for Health Technology Evaluation ["CHTE"]. Dr Paul Chrisp and Helen Knight, respectively, will provide further details about these directorates within their witness statements,

but by way of overview: CfG was responsible for overseeing the production of COVID-19 rapid guidelines. CHTE oversaw the Research to Access Pathway for Investigational Drugs in COVID-19 ["RAPID C-19"] and was responsible for any relevant medical technology evaluations and diagnostic assessments.

Core Principles

22. The work NICE does is underpinned by a set of Core Principles. There is a structured approach to guidance development based on clearly defined processes and methods, which are published on the website, regularly reviewed and consulted upon in line with the requirements in the HSC Act 2012.

23. These Core Principles, are as follows:
    1) Prepare guidance and standards on topics that reflect national priorities for health and care;
    2) Describe our approach in process and methods manuals, and review these regularly;
    3) Use independent advisory committees to develop recommendations;
    4) Take into account the advice and experience of people using services and their carers or advocates, health and social care professionals, commissioners, providers and the public;
    5) Offer people interested in a topic the opportunity to comment on and influence recommendations;
    6) Use evidence that is relevant, reliable and robust;
    7) Base our recommendations on an assessment of population benefits and value for money;
    8) Support innovation in the provision and organisation of health and social care services;
    9) Aim to reduce health inequalities;
    10) Consider whether it is appropriate to make different recommendations for different groups of people;

11) Propose new research questions and data collection to resolve uncertainties in the evidence;
12) Publish and disseminate our recommendations and provide support to encourage their adoption; and
13) Assess the need to update our recommendations in line with new evidence.

24. Guidance development is informed by the experience, expertise and views of the people who will be affected. This includes patients, carers and members of the public, as well as professionals, representatives of NHS organisations, the life sciences industry and local government.

25. Guidance is developed by independent advisory committees that include experts such as clinicians, health economists, patients and carers. Consultation processes enable individuals and organisations to comment on draft recommendations.

26. NICE guidance aims to support strategies that improve population health as a whole, while offering particular benefit to the most disadvantaged. In addition to the protected characteristics in the Equality Act 2010, NICE also takes into account inequalities away from socioeconomic factors and the circumstances of certain groups of people, such as looked-after children and people who are homeless. NICE guidance aims to reduce and not increase identified health inequalities.

Status of NICE guidance

27. Different types of NICE guidance have a different status within the NHS, public health and social care services. Integrated care boards, NHSE, and local authorities are required to fund and resource technologies (predominantly medicines and treatments) recommended through the technology appraisals ["TA"] and highly specialised technologies ["HST"] programmes within the NHS.

28. The legal status of this mandatory funding is set out in the NHS Constitution and the HSC Act 2012. The NHS Constitution states that patients have the right to

medicines and treatments that have been recommended by NICE for use in the NHS, if the doctor responsible for the patient's care says they are clinically appropriate. When NICE recommends a treatment 'as an option' through the TA or HST guidance, the NHS must make sure it is available within 3 months (unless otherwise specified) of the guidance publication.

29. The HSC Act 2012 also states that the Secretary of State and the NHS Commissioning Board (now NHSE) should have regard to the quality standards prepared by NICE as part of their duty to secure continuous improvement in the quality of services.

30. The introduction of other selected technologies (devices, diagnostics and digital), which NICE recommends through its Medical Technologies Evaluation Programme, can also be accompanied by an NHS funding mandate (the Medtech Funding Mandate), but this is agreed by NHSE and not mandated in legislation.

31. In relation to all other NICE guidance, including the guidelines, it is expected that health and social care professionals will have regard to the recommendations to help them deliver the highest quality care. The recommendations are intended to support the professional expertise and clinical judgement of health professionals, as they discuss treatment options with their patients.

NICE's corporate response to the COVID-19 pandemic

32. In this section, I provide an overview of NICE's role in response to the pandemic. A more detailed account of the work undertaken by the key directorates can be found in the witness statements of Dr Paul Chrisp and Helen Knight.

33. On 10 March 2020, the SMT established a Gold group. It also established a Silver group, also known as the COVID-19 Response Group ["CRG"].

34. The Gold group, chaired by the then Chief Executive took overall responsibility for the COVID-19 response, working closely with the Silver group chaired by the Director of the CHTE, who was also the Deputy Chief Executive. The Gold and Silver groups were there to deal with the fast-changing circumstances in which the organisation was continuing to work, both internally and externally. As a consequence of the pace of change, 'Action' or 'Decision' logs rather than minutes were created for the Gold and Silver meetings.

35. The role of the Gold group was to oversee NICE's response to the COVID-19 pandemic and report to ET. To fulfil this role, it met initially daily. The frequency of meetings changed to mirror the changing nature of the pandemic. The role of CRG was to review and monitor the developing situation regarding COVID-19 epidemic and report to the Gold group. It developed and maintained a Situation Report ["SITREP"], which provided an overview of NICE's work on COVID-19 and impact on day-to-day business. Task and finish and oversight groups convened to address specific operational issues such as working practices, human resources, and office attendance.

36. The Gold group was stood down in August 2021 and then reinstated for a further meeting in December 2021. The CRG was stood down in July 2021. The experience of the CRG led to ET deciding to introduce a group to deal with cross-organisational operational issues, to free up time for ET to deal with the strategic issues. The Operational Management Committee ["OMC"] was established in November 2021 to provide a forum to discuss operational issues that have a cross-organisation impact, but which sit outside of ET's strategic role.

37. The GE increased the frequency of its meetings during the pandemic to respond to the pace of the new arrangements and to ensure that all guidance was considered and approved as appropriate.

38. An overview of the relationships between these groups and wider NICE stakeholders can be found in **Exhibit SR/5-INQ000252458.**

39. On 17 March 2020, following the request from NHSE to reprioritise its guidance work, to focus on the pandemic, the SMT (now known as ET) took the decision to prioritise and only publish work on topics that were therapeutically critical, such as cancer, and/or address COVID-19 diagnostic or therapeutic interventions. This was to avoid distracting the NHS at a time when it was facing unprecedented pressure and to release frontline staff who might otherwise be engaged in the advisory committees.

NICE's role during the pandemic and related advice and guidance

40. On 11 March 2020, James Palmer (National Director Specialised Services) from NHSE approached NICE to produce guidelines on COVID-19 topics, at pace. These guidelines became known as 'COVID-19 Rapid Guidelines' and were co-badged with NHSE.

41. On 13 March 2020, NICE received the first commission for rapid guidelines topics from NHSE (critical care, dialysis service delivery and delivery of systemic anticancer treatments). The first wave guidelines were published on 20 March 2020. A rolling programme of commissioned COVID-19 rapid guidelines continued following the publication of the first COVID -19 rapid guidelines.

42. During the relevant period NICE published 26 COVID-19 rapid guidelines. NICE's suite of COVID-19 rapid guidelines were viewed in excess of 4 million times during 2020/21[1] The topics covered by the guidelines, along with the publication date is shown in **Table 2** below:

[1] NICE Annual Report and Accounts 2020/21

Guideline number	COVID-19 rapid guideline title	Publication date
NG159	Critical care in adults	20.03.2020
NG160	Dialysis service delivery	20.03.2020
NG161	Delivery of systemic anti-cancer treatments	20.03.2020
NG162	Delivery of radiotherapy	28.03.2020
NG163	Managing symptoms (including at the end of life) in the community	03.04.2020
NG164	Haemopoietic stem cell transplantation	01.04.2020
NG165	Managing suspected or confirmed pneumonia in adults in the community	03.04.2020
NG166	Severe Asthma	03.04.2020
NG167	Rheumatological autoimmune, inflammatory and metabolic bone disorders	03.04.2020
NG168	Community-based care of patients with chronic obstructive pulmonary disease (COPD)	09.04.2020
NG169	Dermatological conditions treated with drugs affecting the immune response	09.04.2020
NG170	Cystic fibrosis	09.04.2020
NG171	Acute Myocardial injury	23.04.2020
NG172	Gastrointestinal and liver conditions treated with drugs affecting the immune response.	23.04.2020
NG173	Antibiotics for pneumonia in adults in hospital	01.05.2020
NG174	Children and young people who are immunocompromised	01.05.2020
NG175	Acute kidney injury in hospital	06.05.2020
NG176	Chronic kidney disease	15.05.2020
NG177	Interstitial lung disease	15.05.2020
NG178	Renal transplantation	05.06.2020
NG179	Arranging planned care in hospitals and diagnostic services	27.07.2020
NG186	Reducing the risk of venous thromboembolism in over 16's with COVID-19	20.11.2020
NG187	Vitamin D	17.12.2020
NG188	Managing the long-term effects of COVID-19	18.12.2020
NG191	Managing COVID-19	23.03.2021
NG200	Vaccine-induced immune thrombocytopenia and thrombosis (VITT)	29.07.2021

Table 2: COVID-19 Rapid Guidelines

43. On 23 March 2021, NICE published the first 'living guideline', on the management of COVID-19 (NG191). The managing COVID-19 guideline included a section on therapeutics for COVID-19 and consolidated a number of early COVID-19 rapid

guidelines, including NG159, NG163, NG171 and NG173, which were all subsequently withdrawn. This living guideline delivered real time updates for guidelines supporting the management of COVID-19. Further details about the COVID-19 rapid guidelines can be found within the witness statement of Dr Paul Chrisp.

44. The rapid guidelines were produced in 7-14 days whereas previously, the process to develop a NICE guideline would take 12-24 months. In addition, the methods and processes had to adapt to a dearth of evidence at the start of the pandemic to a rapidly emerging evidence base. In order to produce guidelines at pace, resources and expertise were drawn from across the organisation and new interim methods and process for developing the rapid guidelines was established. This was consolidated in September 2020 by the establishment of the COVID-19 guideline team. It also meant changes to the stakeholder engagement and consultation processes. To ensure prompt valuable input, a targeted peer review process was adopted. Early guidelines were produced in collaboration with NHSE using a cross-specialty clinical group, supported by the specialist societies and Royal Colleges.

45. As the pandemic progressed, the rapid guideline methods and processes developed to match the increasing availability of evidence, complexity of the subject, the different waves of the pandemic and emergence of new variants. The process and methods for the development of guidelines in response to health and care emergencies is now an addendum to the guideline's manual. The details of the changes to guidelines, methods and process can be found within the witness statement of Dr Paul Chrisp.

46. In the early response, working at speed and in areas where the evidence was limited meant initial recommendations sometimes needed to be modified quickly as further information emerged. A process of continual surveillance and updating was introduced to ensure guidance was informed by the emerging evidence base.

47. During the relevant period, the impact on people with characteristics protected under the Equality Act 2010 was considered during the development of COVID-19 rapid guidelines, as per the standard methods and process. To ensure that individual recommendations would not exacerbate inequalities, the Independent Advisory Expert Panel was specifically asked to consider the impact of their draft recommendations on people with characteristics under the Equality Act. An equality impact assessment ["EIA"] was completed, and quality assured by NICE staff before submission of the draft guideline to NICE's GE. Further details about the use of EIA's, health inequalities and COVID-19 rapid guidelines can be found in the witness statement of Dr Paul Chrisp.

48. An internal data and analytics task force was established to address data gaps. In July 2020, the taskforce published an interim framework to assess the quality of wider sources of data and evidence used to inform COVID-19 work. By December 2020, the framework had received over 600 views by users from 50 different countries.

49. During the relevant period NICE also produced 8 rapid evidence summaries on medicines used to manage COVID-19 or its symptoms. The rapid evidence summaries are set out in **Table 3** below and the latest iterations are exhibited. By way of explanation, rapid evidence summaries provided an evidence summary, underpinned by a detailed evidence review for new medicines and significant license extensions, off-label use of licensed medicines and unlicensed medicines They were produced between March 2020 and January 2021 to advise national and local decision makers on the best evidence available for therapeutics for COVID-19 as it emerged during the early stage of the pandemic. The summaries were not formal NICE guidance. They were withdrawn when formal recommendations were made on these therapeutics as part of COVID-19 rapid guidelines.

NICE ID	Rapid Evidence Summary title	Exhibit Reference
ES23	Acute use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19	**Exhibit SR/13 - INQ000328683**
ES26	Anakinra for COVID-19 associated secondary haemophagocytic lymphohistiocytosis (sHLH)	**Exhibit SR/14 - INQ000328684**
ES24	Angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) in people with or at risk of COVID-19	**Exhibit SR/15 - INQ000328685**
ES25	Long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19	**Exhibit SR/16 - INQ000328686**
ES27	Remdesivir for treating hospitalised patients with suspected or confirmed COVID-19	**Exhibit SR/17 - INQ000328687**
ES28/ER5	Vitamin D for COVID-19	**Exhibit SR/18 - INQ000328688**
ES33 / ER7	Tocilizumab for COVID-19	**Exhibit SR/19 - INQ000328689**
ES34 / ER8	Sarilumab for COVID-19	**Exhibit SR/20 - INQ000328690**

Table 3: Rapid Evidence Summaries

50. The rapid evidence summaries were produced for NHSE to inform commissioning policy. They provided up to date evidence to address hypothetical suggestions; in particular, unsupported opinions that gained traction on social media. They supported the wider system to provide evidence and facts in response to a rapidly changing information base.

51. In addition, NICE also produced 6 Medtech Innovation Briefings ("MIBs") - this is advice designed to support NHS commissioners and practitioners who are considering using new medical devices and or medical or diagnostic technologies by reviewing the evidence and likely costs.

Single point of access

52. In November 2020, NICE launched a new, single point of access to advise on the clinical management of COVID-19. NHSE COVID-19 specialty guides were transferred onto the NICE website. Prior to uploading, NICE reviewed each guide to ensure alignment with COVID-19 rapid guideline advice. Consequently, creating a single, easy-to-access resource for clinicians seeking advice on the management of COVID-19. During the relevant period 28 specialty guides were published on the website.

53. The specialty guides were produced by NHSE. They were for guidance only and were not mandatory. The majority of specialty guides aimed to help departments continue essential care for patients during the COVID-19 pandemic (including stroke services and immunisation programmes). Some specialty guides were concerned with managing conditions in people with COVID-19 (such as acute kidney injury). A few of the specialty guides were concerned with aspects of managing COVID-19 including the management of critical care for adults with COVID-19 during the coronavirus pandemic and the role and use of non-invasive respiratory support in adult patients with coronavirus (confirmed or suspected).

Rapid access to investigational drugs

54. NICE, NHSE, the Medicines & Healthcare products Regulatory Agency ["MHRA"] and the National Institute for Health and Care Research ["NIHR"] worked together to design and implement RAPID C-19. Other partner agencies involved included DHSC, the Scottish Medicines Consortium ["SMC"], Healthcare Improvement Scotland, the All Wales Therapeutics and Toxicology Centre ["AWTTC"], the All Wales Medicines Strategy Group ["AWMSG"], the Northern Ireland Health and Social Care Board ["NIHSCB"], Therapeutics and Anti-viral Taskforce ["T&AVTF"] and the UK Health Security Agency (formerly Public Health England ["PHE"]).

55. RAPID C-19 was a multi-agency initiative. It was established as part of temporary emergency pandemic arrangements to facilitate rapid patient access to therapeutics for COVID-19 when they were proven to be clinically beneficial and before more formal mechanisms of clinical and cost-effectiveness assessments were undertaken. Its role was to identify and monitor the development of potential medicines/therapeutics and their associated clinical evidence and licensing status/timelines; and to rapidly assess the emerging evidence to help support a route to patient access if the evidence of benefit was strong. RAPID C-19 would communicate its opinion to the CMO and others in the DHSC, who would decide whether to expedite the availability of therapeutics, as appropriate. This included both new therapeutics in development and the repurposing of existing ones.

56. On 6 April 2020 work commenced on this initiative, following discussions between Meindert Boysen (then Director, CHTE) and James Palmer (National Medical Director, Specialised Services and Senior Responsible Officer COVID-19 Specialised Services Cell, (NHSE)). RAPID C-19 was established on 29 April 2020.

57. NICE's role was to provide the secretariat function, along with horizon scanning and evidence synthesis when identifying medicines showing promise in clinical trials, which could be prioritised for rapid regulatory consideration, interim clinical policy development and access.

58. During this initiative, 89 topics were reviewed and approximately 105 trial investigators contacted. CMO reports were compiled for 20 topics. Patient access to repurposed treatments was facilitated within 10 days of the key trial readout (for example, dexamethasone, hydrocortisone, and tocilizumab in 2020), and access to new treatments facilitated within 14 – 42 days of marketing authorisation (for example, sotrovimab and molnupiravir in 2021). RAPID C-19 helped deliver for the NHS across all 4 nations of the UK, with more than 200,000 people receiving treatments for COVID-19 (as at the end of October 2022). Further detail on RAPID C-19 can be found within the statement of Helen Knight.

Fast track advice service

59. NICE provided a free fast track advice service for researchers developing novel diagnostics or therapeutics for COVID-19, to help to expedite breakthroughs in care and support the life sciences industry. This helped researchers from around the world optimise their approach to generating the essential evidence required to inform decision-making. Outside of a pandemic situation, NICE normally charges for these services, but because of the unprecedented need to accelerate these technologies into the NHS during the COVID-19 outbreak, NICE waived its fee and provided a free service. 17 free fast-track advice projects were provided in total: 4 for pharmaceuticals, 8 for medical technologies (including diagnostics) and 5 for digital health technologies.

International collaboration

60. NICE supported several international collaborations to develop rapid evidence-based reviews and guidance to help inform decision making across clinicians, policy makers and the public. NICE engaged in initiatives that aimed to coordinate across key stakeholders, at national and international levels, (and reduce unnecessary duplication of effort) evidence reviews and development of rapid guidelines and health technology assessments. Through participation in these initiatives, NICE contributed to and benefited from, international efforts to identify, analyse and synthesise rapidly emerging evidence on the diagnosis and treatment of COVID-19. This included the World Health Organisation ["WHO"], the Australian Living Evidence Consortium, the International Network of Agencies for Health Technology Assessment and the European Network for Health Technology Assessment. NICE contributed to the COVID-19 evidence network led by McMasters University, FDA diagnostics and therapeutics evidence accelerator, and the IMI EHDEN and the IMI Value Dx project, with access to rapid data analysis from eleven European countries covering over 150 million patient records.

61. NICE also helped to select priority areas for research through the Cochrane collaboration's rapid reviews on COVID-19. NICE made COVID-19 Rapid Guidelines freely available to health and care practitioners around the world without the normal international licensing fees.

Work with key partners in response to the pandemic

62. Prior to the pandemic, NICE worked closely with a range of key health care system partners and in some instances, had formal agreements in place. A summary of key health care system partners is set out in **Table 4** below and a more detailed overview can be found at **Exhibit SR/6-INQ000252459**.

Organisation	Nature of Relationship
NHS England	NHSE are legally required to fund and resource medicines and treatments recommended through NICE's technology appraisal (TA) and highly specialised technologies (HST) programmes. NHSE is also required to have regard to quality standards produced by NICE. While the majority of NICE's funding comes from the Department of Health and Social Care, NHSE also commission work from NICE including: • Guidelines; • Support for Managed Access Agreements to enable patients to access promising new drugs via the Cancer Drugs Fund and Innovative Medicines Fund; • Medtech Innovation Briefings-to provide briefings to the NHS on promising new technologies and work with stakeholders to identify new topic areas; • Providing technical support to the Accelerated Access Collaborative; and • HealthTech Scan- to support innovative activities in identifying and tracking emerging medical technologies via a secure shared database. This is in the process of being decommissioned.
Medicines and Healthcare products Regulatory Agency	NICE is responsible for considering whether technologies approved by the MHRA should be recommended for use in health

	and care services on the basis of their clinical and cost effectiveness. NICE and MHRA therefore have related interests in the safe and appropriate use of medicines and medical devices. They work together to ensure information about safety and effectiveness is shared, as appropriate to facilitate decision making. They also work closely to support innovation including through initiatives such as the Innovative Licensing and Access Pathway and Innovative Devices Access Pathway.
Office for Health Improvement & Disparities (OHID) and UK Health Security Agency (UKHSA) (formerly Public Health England)	NICE provides public health guidance and advice to support health, public health and social care commissioners, providers and others to make sure that the care and preventative services provided are of the best possible quality and offers the best value for money. The public health guidance makes recommendations for populations and individuals on activities and strategies that can help prevent disease or improve health.
Care Quality Commission (CQC)	The CQC will use NICE's guidance and quality standards as a reference when inspecting health and care providers.
NHS Digital (formerly HSCIC) – now part of NHSE	NICE and NHS Digital work together to share data to improve quality of care across health and social care, including increasing availability of real-world data in development of guidance. This includes to develop, publish and maintain a database of quality assured indicators – the national library of quality indicators. In addition, as outlined in the Health and Social Care Act 2012, as a principal body, NICE may request NHS Digital to establish and operate a system for the collection or analysis of information of a description specified in the request.
Health Education England (HEE)	NICE and HEE work together to help assist the spread of innovation across the NHS so that the health care workforce has the right skills, behaviours and training to support the delivery of high-quality services. NICE is commissioned to procure content (journals and databases) on behalf of all NHS professionals.
Devolved nations strategic health care partners	
Organisation	**Nature of Partnership**
Welsh Ministers	NICE has an agreement under section 83 of the Government of Wales Act to provide advice, administrative, professional and technical services to the Welsh Ministers in connection with

	evidence-based guidance and other products including production of the British National Formulary. The agreement includes allocation of a dedicated field team implementation facilitator from the NICE field team.
NI Department of Health	NICE has an agreement under Article 8 of the Health and Personal Social Services (Northern Ireland) Order 1991, to provide advice, administrative, professional and technical services in connection with evidence-based guidance and other products, including production of the British National Formulary. The agreement includes allocation of a dedicated field team implementation facilitator from the NICE field team.
Health Improvement Scotland	NICE has an agreement in place to provide services in connection with the use of NICE products and services to help resolve uncertainty about which treatments and procedures represent the best quality care for NHS Scotland. This agreement offers access to: • Interventional procedures; and • Use and reuse of NICE website content. It also states that NICE will work in collaboration with the Scottish Intercollegiate Guidelines Network (SIGN), Scottish Medicines Consortium (SMC) and Scottish Health Technologies Group on areas of common interest. In relation to SIGN the partnership is focused on collaborating on: • Topic prioritisation criteria; • Methods and processes that enable more rapid guideline development; • Technologies that enable digital presentation and easier access to guideline development; • Opportunities to develop UK wide guidance; and • Sharing information and forward planning, methods sharing.
All Wales Medicines Strategy Group and the Welsh Medicines Partnership.	Sharing information and forward planning, methods sharing.
Health Technology Wales	To join up strategic planning, development and delivery of advice in England and Wales to enhance and deliver timely, independent and authoritative advice on non-medicine technologies.

Health Inspectorate Wales (HIW)	NICE and HIW have a memorandum of understanding to work together to support the improvement in the quality of care. It covers the guidance, advice and other products that NICE provides for the healthcare system, the support HIW provides to assure and monitor the implementation of NICE guidance, quality standards and indicators, and the support NICE provides to HIW in order for HIW to fulfil its role in the regulation of healthcare services.

Table 4 – Key health care system partners

63. During the relevant period, NICE continued to work closely and collaboratively with a number of key partners across the health care system, including:
    - DHSC;
    - Chief Medical Officer;
    - Office for health improvement & disparities and UK Health Security Agency (previously PHE);
    - MHRA;
    - NHSE; and
    - The Care Quality Commission.

64. An outline of the nature of these relationships during the relevant period, is detailed below. NICE did not do any specific work with the Academy of Royal Medical Colleges focused on the pandemic response.

<u>Department of Health and Social Care</u>

65. During the pandemic, NICE continued to meet with the DHSC Sponsor Team through the quarterly accountability meetings, which discussed NICE's role in supporting the health and care system and the operational impact of the pandemic on the organisation.

Chief Medical Officer

66. On 16 March 2020 NICE was invited to join, and subsequently attended, the UK Senior Clinicians Group chaired by Professor Sir Chris Whitty. The membership included the Chief Medical Officers of Scotland, Wales and Northern Ireland, as well as various representatives from organisations including NHSE, PHE and DHSC. The group usually met twice weekly and ran until 09 November 2021. The meetings were not minuted, but from 12 May 2020, agenda and papers were frequently circulated.

67. The focus of the meeting, which evolved as the pandemic progressed, was:
    - General updates on the pandemic i.e., epidemiology, situation on testing, impact of cases on services;
    - Changing symptoms and case definitions;
    - Policy on testing, tracing, isolation and treatment;
    - Challenges across the 4 countries and alignment of approach.

Public Health England

68. Prior to the pandemic NICE had six-weekly "points of engagement" meetings with Public Health England and the DHSC (sponsor team) to share organisational work plans, select work topics/themes and identify opportunities for joint working.

69. At the beginning of the pandemic, NICE and PHE engagement changed to collaborative work within COVID-19 multi-agency working groups and initiatives as outlined above. The early COVID-19 rapid guideline development process used central government guidance (including PHE guidance) on preventing transmission or in identifying at risk groups as fundamental to NICE's recommendations. The relevant guidance was linked to within NICE guidance wherever appropriate. The COVID-19 rapid guidelines programme included PHE as a core stakeholder in all targeted consultations and comments received were acted upon as part of the process in developing the final published rapid guidelines. Where greater public

health expertise was required throughout the development process (e.g., Arranging Planned Care in Hospitals and Diagnostic Services), a PHE representative was invited to be a member of the core development group. PHE continued to be included as a stakeholder for consultation to ensure the wider organisation had the opportunity to be engaged prior to publication. Where appropriate (e.g., Arranging Planned Care in Hospitals and Diagnostic Services), the published guideline was co-branded with PHE alongside NHSE.

70. Following the disestablishment of PHE on the 1 October 2021, and the dispersal of its functions, some work continued to be undertaken on work focused on specific theme/topic-based guidelines, for example Long COVID and Vitamin D.

The Medicines and Healthcare products Regulatory Agency

71. In addition to the RAPID C-19 Pathway, detailed above, on 20 March 2020, the MHRA set up a COVID-19 Expert Working Group ["EWG"] - officially titled the Commission on Human Medicines COVID-19 Expert Working Group. The group was chaired by Professor Jonathan Friedland (Deputy Principal, St George's, University of London) and met weekly for the first month, and then fortnightly.

72. NICE attended the group as an observer, alongside the NHSE, DHSC and PHE and provided feedback to key staff in NICE teams. The agenda for meetings varied but usually involved:
    - An update on the clinical trial applications for testing COVID-19 treatments that had been made to MHRA;
    - Any developments on new treatments that were tested or for which evidence had been published;
    - What trials were being planned in the UK;
    - What treatments were being tested.

73. The group would then provide views on these developments and where relevant to NICE's ongoing work, NICE would be asked to comment or take action. For example, during the first meetings, topics discussed included ACE inhibitors due to the concern that people who used ACE inhibitors may have greater susceptibility to COVID-19. Similar concerns existed for non-steroidal anti-inflammatory drugs ["NSAIDs"], including ibuprofen. Although there was media attention at the time, there was very little evidence to support these concerns. The EWG did not consider there was evidence to support recommending stopping treatment with these drugs and agreed that advice from NICE and NHSE would be welcomed. NICE was already working internally on evidence reviews for both ACE inhibitors and NSAIDs and following the discussions at the EWG these evidence reviews were published soon after.

74. In October 2021, NICE produced an evidence collection guide in collaboration with the MHRA and the NIHR. Its purpose was to advise people running technology trials on what the different stages of evidence collection should look like for both the COVID-19 therapeutics and diagnostics studies. It was a general best practice guide and was co-badged with NIHR.

Care Quality Commission

75. Prior to the pandemic NICE and the CQC had quarterly meetings focused on providing updates on each organisation's work plan and how the CQC would use NICE's guidance and quality standards as a reference when inspecting health and care providers. At the beginning of the pandemic, NICE and the CQC switched to smaller more informal quarterly engagement meetings. These meetings focused on how the respective work programmes were changing, how to tackle NHS recovery planning and opportunities for closer collaboration. By October 2020, the standard formal meetings resumed.

NHS England

76. While the majority of NICE's funding comes from the DHSC, NHSE commissioned and supported a range of work from NICE to respond to the pandemic. This included:
    - COVID-19 rapid guidelines and topics;
    - Support for Managed Access Agreements to enable patients to access promising new drugs via the Cancer Drugs Fund;
    - COVID-19 Medtech Innovation Briefings; and
    - Sharing all its specialty guides, which NICE reviewed and published on the NICE website.

Devolved Nations

77. NICE is established in the HSC Act 2012 as an English public body but has agreements in place with the devolved administrations in Wales, Northern Ireland and Scotland, which set out NICE's role within each respective health care system (See exhibit SR/6). During the pandemic the devolved nations had access to all COVID-19 related products, including the rapid COVID-19 guidelines and COVID-19 related Medtech innovation briefings, medicines and prescribing briefings. NICE worked collaboratively with the Wales and Northern Ireland (NI) and to a lesser extent, Scotland. That is because the arrangements in Scotland are different from Wales and NI. The Scottish Intercollegiate Guidelines Network ["SIGN"] produces guidelines and Scottish Health Technologies Group produce technology appraisals.

78. SIGN is a standing stakeholder for NICE clinical guidelines and therefore would submit comments during the scope and guideline consultation phases of guideline development.

79. Since 2012, there have been a number of meetings between NICE and SIGN to discuss the issues and challenges that arose from both organisations having published guidance on the management of asthma. In February 2020, NICE

entered into an agreement with SIGN and the British Thoracic Society for the joint development of UK-wide guidance for the diagnosis and management of chronic asthma in adults, young people and children to address these issues. In 2018, NICE and SIGN co-hosted the Guidelines International Network ["GIN"] conference in Manchester.

80. The devolved nations were represented on the RAPID C-19 pathway, through the SMC - Healthcare Improvement Scotland, AWTTC and NIHSCB. In addition, while NICE provided the secretariat and led the development of the RAPID C-19 initiative, the SMC provided analytical support for the secretariat function.

Wales

81. The field team collaborated closely with the Welsh Government throughout the pandemic. They attended monthly meetings with NICE leads at the Welsh Government, exchanged regular emails providing updates, and shared work plans and priorities.

82. The Implementation Facilitator Wales and Associate Director South attended the annual accountability meetings between NICE and Welsh Government, including the Chief Medical Officer for Wales and Minister for Health and Social Services for Welsh Government in October 2020 and April 2022, with NICE Chief Executive and Chair, to discuss strategies and priorities for the upcoming year.

83. In October 2020, the meeting agreed to further strengthen relationships with key partners and support organisations with the implementation of guidance, as health services started to resume following the first wave of the pandemic. This included agreement to:
    - Engage with all health boards heads of midwifery;
    - Develop the Welsh NICE Health Network;
    - Explore ways to improve the usability of NICE products in Wales.

84. In addition, NICE worked with the following Welsh expert networks and organisations:

Welsh NICE Health Network

85. This included representatives from all Health Boards, Public Trusts, Welsh Government, AWMSG, Health Technology Wales ["HTW"] and Welsh Health Specialised Services Committee ["WHSSC"]. NICE's work plan was shared at the start of the pandemic and updates were provided at triannual meetings. The field team designed and circulated an online survey to Welsh NICE Health Network members to gain feedback on the impact of COVID-19, NICE's rapid COVID-19 guidelines and determine priority areas for 2020/21. The survey received over 100 responses and was subsequently rolled out to other regions across the UK. The results were used by NICE to refocus the Field Team's work to best support health organisations implement guidance and to CfG to inform guideline development.

All Wales Medicines Strategy Group / All Wales Therapeutics and Toxicology Centre

86. NICE's work plan was shared at the start of the pandemic and updates were provided at quarterly meetings. As a result of these meetings the AWTTC nominated representatives to input into the Long COVID & VTE scope/guideline consultations and became members of:

- RAPID C-19 Group (meetings / workshops);
- COVID-19 Oversight and Governance Group;
- AUS-CAN-UK collaboration;
- Innovative Licensing and Access Pathway ["ILAP"] with input into Access Tool; and
- Office for Market Access ["OMA"] Safe Harbour Group meetings (with observer status).

Welsh Health Specialised Services Committee

87. NICE worked with the WHSSC to facilitate effective consultation of NICE's rapid COVID-19 guidance by disseminating rapid guideline consultation material to key stakeholders (including Health Board executives, healthcare professionals including Medical Directors and their clinical teams and topic specific groups/experts).

Health Technology Wales

88. NICE's work plan was shared at the start of pandemic and updates were provided at quarterly meetings. Effective links were established between CHTE and HTW to promote close working during the pandemic, sharing emerging evidence for COVID-19 diagnostics and therapeutics. In addition, HTW worked directly with NICE Scientific Advice to provide rapid advice to industry, regularly sharing intelligence on specific topics.

Northern Ireland

89. The NICE Implementation Facilitator Northern Ireland worked with the Northern Ireland (NI) Department of Health to produce a circular to detail the 'Department of Health endorsement process for NICE Guidance, including the NICE rapid COVID-19 guidelines'. This was an adapted process by which the Department endorsed NICE rapid COVID-19 guidelines to determine whether any refinement might be required to support their local implementation. The aim was to expedite implementation from the point of publication to address the rapidly changing environment.

90. In addition, NICE provided quarterly updates to the health care system including a summary of new and updated NICE rapid COVID-19 guidelines.

Scotland

91. NICE developed the managing the long-term effects of COVID-19 rapid guideline in collaboration with SIGN and Royal College of General Practitioners ["RCGP"]. The engagement with SIGN changed in response to the COVID-19 pandemic by the co-production of a living guideline in an accelerated timeframe, and maintaining the guideline with continuous surveillance throughout the pandemic. The short timeframe necessitated frequent strategic and technical meetings and overall closer working arrangements. The three organisations agreed to work together to produce:
    - A single living guideline for managing the long-term effects of COVID-19; and
    - A broader set of materials to help support and implement the guidelines.

92. Methods and processes used:
    - A combination of SIGN and NICE rapid guidance methodology and processes was used, in line with Developing NICE guidelines: the manual (2014, updated 2023) and the Interim process and methods for guidelines developed in response to health and social care emergencies (2020) and SIGN 50: a guideline developer's handbook (2019);
    - The NICE policy on declaring and managing interests for advisory committees; and
    - The final output was a single product, produced collaboratively and jointly badged.

93. Once published the guideline was subject to the NICE COVID-19 guidelines surveillance process. For simple refreshes that improved the usability of the recommendations without changing the intent, NICE and SIGN updated the relevant sections of the guideline. For the 2021 update to the guideline, the collaboration was reinstated. Any materials produced to support and implement

the guideline have been maintained and updated in line with guideline changes and have been carried out by the relevant owner of the materials.

94. NICE had a lead role in developing best-practice guidance for the health technology assessment of tests & treatments for COVID-19, conducted as part of the external grant-funded Horizon 2020 HTx project. This was led by NICE's Science Policy and Research Team and attended by members of the SMC alongside other global health technology assessment agencies. This focused on country progress updates, review of health technology assessment and regulatory methods, construction of disease pathways and review of economic methods.

95. NICE Scientific Advice Team and our Science Policy and Research Team also held meetings with Health Technology Assessment ["HTA"] counterparts in Scotland (SMC) and Wales (AWMSG) and other HTA agencies globally to exchange on scientific issues and challenges of mutual interest relating to COVID 19 identifying opportunities for collaboration.

External challenge to NICE recommendations

96. During the pandemic, NICE received five letters before action pursuant to the Pre Action Protocol for Judicial Review. These related to alleged breaches of the Equality Act 2010 (namely sections 19 and 29) and the European Convention of Human Rights ["ECHR"] (namely articles 2, 8 and 14). Within these claims, NICE was named as either a defendant or an interested person ["IP"]. Four of these did not proceed beyond the original letter before action. However, one claim in which NICE were named as an IP, resulted in the claimant making an application to the court for permission to apply for judicial review; the court refused this application. Further information on these claims can be found in **Exhibit SR/12-INQ000252454**. The categories of documents held by NICE in relation to these matters are primarily letters before action, NICE's response to the letters and other written correspondence between the parties, including internal privileged communications between NICE and their legal representatives. In relation to the claim (and

subsequent application), copies of these proceedings and final order are held by NICE.

Lessons Learnt Exercise

Introduction

97. On 29 March 2022, I, along with colleagues in the ET made a decision to undertake an organisational lessons learnt exercise. While the experience was still fresh in the memory, NICE wanted to take the opportunity to capture the lessons learnt from the pandemic response. The purpose of this was to inform the wider health care system, build on any positive changes, and ensure an as effective response as possible to any future public health emergencies and pandemics.

98. NICE's COVID-19 main lessons learnt exercise took place between June and September 2022. It involved the following internal activities:

    - An all-staff survey (225 responses);
    - Two targeted workshops with key staff who played an important role in our organisational response to COVID-19; and
    - An emergency planning workshop to help ensure NICE is well prepared for any future crises.

99. In addition, in relation to RAPID C-19, Impact Psychology for Business ("PfB) were commissioned to undertake the independent facilitation of the survey and workshop and produce a summary report. They undertook a diagnostic survey to highlight the experience and lessons learned by those involved in the pathway and received 30 responses. The survey responses included representation from all RAPID C-19 partner organisations, with the aim of capturing the experience of the individuals involved. The face-to-face workshop included a subset of RAPID C-19 participants and discussed the results of the survey and considered how the lessons learned could be applied in the system as a whole. It took place on 14 July 2022 in the NICE offices in Manchester and included representatives from NICE, NHSE, NIHR, MHRA, ATTF and the devolved administrations.

RAPID C-19 findings and recommendations.

100. The RAPID C-19 report was finalised in October 2022 and disseminated to the RAPID C-19 members. A copy of the RAPID C-19 Pathway Lessons Learned Review is attached at **Exhibit SR/7-INQ000252460.**

Survey

101. The survey results included representation from all the organisations involved in RAPID C-19 and were overwhelmingly positive, with particular aspects highlighted in the comments such as the quality of the co-ordination, secretariat and facilitation, the quality of the documentation, the commitment of those involved and the friendly and supportive environment in which the initiative operated.

Face-to-Face Workshop

102. During the workshop discussions the themes that emerged with regards to the key enablers of the initiative were the shared vision and perception of a common purpose, resulting in full commitment and engagement and a willingness to truly collaborate, which helped to ensure effective communication, a consistent approach and unified delivery of agreed actions. The environment in which the Oversight Group conducted its business was also considered important – the feeling that it was an open forum or safe space for open dialogue, with all members being highly supportive and respectful as well as professional and responsive, which helped with the adaptive and flexible approach needed as the pandemic evolved. Information sharing was felt to overall be positive in terms of starting to break down the barriers between organisations, there was a willingness to engage in an open exchange of information, and empowerment for contribution and decision-making. The senior membership and cross-agency expertise also meant that all were empowered to contribute to discussion and decision-making– essentially having the right people involved with the right expertise was key to enabling rapid decision-making. Non-NICE members also commented on the high-

quality co-ordination and briefing documents provided by the secretariat as a key enabler.

Key barriers and challenges

103. The lessons learned exercise identified key barriers and challenges to the optimal operation of the RAPID C-19 initiative. The main themes identified by members were as follows:

104. In terms of challenges, the main and obvious challenge was the continuous landscape changes meant that it felt like the initiative was constantly playing catch-up, with published information quickly becoming irrelevant, together with 'information overload' and work pressure that at times felt unsustainable. The regular emergence of new variants was a significant issue and led to occasional lack of clarity about the role of RAPID C-19 in that it was not constituted to provide expert opinion on the likely or actual activity of the neutralising antibody technologies against new variants, or to review non-clinical evidence. The relevant expertise was sought to support the Oversight Group to understand the issues and interpret the data.

105. Some people noted an occasional lack of clarity about governance and roles which became more acute as the Oversight Group was being asked its opinion on whether certain treatments would work against the currently dominant variant, and the group needed to guard against its remit expanding into other areas which the group was not set up to address;

106. External communication was also identified as a challenge. It was not possible to dedicate resource to providing publicly available information about the operation of RAPID C-19 and its conclusions about specific therapeutics. Many felt that RAPID C-19 could have been more proactive and transparent which may have helped improve trust in the system, particularly at a time when there was much misinformation leading to a perceived lack of transparency. Each member

organisation received a large volume of enquiries, including freedom of information requests. Ideally, the initiative could have been more proactively transparent. It was acknowledged however that it is unknown whether more information about the initiative in the public domain would have led to fewer enquiries and freedom of information requests;

107. While the information sharing that occurred between partners was felt to be a key enabler, there were issues identified which occasionally slowed things down, particularly around sensitive or confidential commercial information. For example, on occasions where the DHSC ATTF had engaged with companies and invited RAPID C-19 members to meetings, each member had to sign an individual non-disclosure agreement. It was felt it might have been helpful if it could have been clear that engagement with one RAPID C-19 partner constituted engagement with all. Members also suggested a more systematic in confidence feed of information on the progress of products through licensing would have been helpful; and

108. An agreed standard of acceptable evidence was also raised as a point for consideration given there were sometimes different interpretations amongst partners of the relative value of preprints and press releases, and some levels of discomfort about any actions to progress to patient access based on results from these sources. The source of evidence available to RAPID C-19 during the pandemic ranged from press releases, preprints, draft manuscripts, submitted manuscripts, and published peer-reviewed papers. There was an inherent tension between the need to act quickly on positive signals from trial results and the desire to increase confidence in those results through the peer-review process. It presented a challenge to the usual approach and some discomfort at times with differing interpretations of the value of such sources as:

- **Press releases** – supported rapid response to potentially important results, but often lacking key data and issued by companies with stakeholder/commercial motivations.

- **Preprints** – supported rapid response to potentially important results, but paper had not been peer-reviewed. While trusted sources (e.g., the RECOVERY trial) utilised this method, there were also some very poor papers and/or studies made available on preprint servers (some studies were later discredited entirely).
- **Draft manuscripts shared in confidence** – supported rapid response to potentially important results before they were publicly available – were shared by both companies and UK platform trial investigators – useful for early consideration but data often not yet validated or peer-reviewed.
- **Submitted manuscripts shared in confidence** – supported rapid response to potentially important results before they were publicly available – were shared by both companies and UK platform trial investigators – useful for early consideration but paper not yet peer-reviewed.
- **Published papers** – high confidence in quality of the trial and robustness of the results but could often not be waited for in the context of the pandemic and the need for rapid access to effective treatments.

109. However, given the emergency nature of the pandemic and urgent need for treatments, a more pragmatic approach to assessing evidence in the context of uncertainty was necessary. It is unlikely that this approach would be appropriate in non-pandemic circumstances, particularly as it was not possible to consider cost-effectiveness, which is key to ensuring value for the taxpayer and the sustainability of the NHS.

Outcome

110. The outcome of the lessons learned review did not result in tangible, specific recommendations for implementation either in RAPID C-19 (as the initiative was coming to an end), or in business-as-usual practices. This was due to the unique circumstances of the pandemic and the unique pressure that put upon all the activity related to RAPID C-19.

111. In relation to what learning can inform whether similar bodies to RAPID C-19 and the Antivirals and Therapeutic Taskforce should be set up in the future and what the threshold should be for instigation NICE offers the following observations.

112. NICE's experience of RAPID C-19 underlined the importance of closer relationships with partner organisations and the value of a flexible and adaptive approach to effectively respond to specific circumstances. The collaborative multi-agency approach exemplified by the RAPID C-19 initiative helped enable the health system to organise and respond quickly to the immediate and significant need represented by the pandemic. This system-wide approach to therapeutics access has the potential to be evolved further to benefit outside of a pandemic scenario.

113. The pandemic experience helped establish when deviation from standard processes was necessary, with an understanding of the risks involved and the need to mitigate these where possible, in recognition of the pandemic situation and driving imperative to enable access to therapeutics that could help patients, and the system. For NICE, the issues posed by the evolution of the virus in terms of its impact on existing evidence and the general challenge of linkage of non-clinical data to clinical outcomes, has resulted in much greater awareness and understanding that can be leveraged in business-as-usual activities, as well as a future viral pandemic.

114. RAPID C-19 was instigated by health system partners reaching out, utilising existing links and being cognisant of the need for a co-ordinated approach to therapeutics access in a pandemic that would need to be designed and supported by all the key organisations involved in the development to access pathway for therapeutics. It was set up within 4 weeks of the initial contact from the National Medical Director for Specialised Commissioning (the day of the announcement of a nationwide lockdown). While its processes and procedures iterated over time, due to the immediate need to focus on potential treatments, the routine operation and main order of business for the Oversight Group, in terms of using the time to consider potentially effective therapeutics, was established from that first meeting.

The success of the initiative, and the maintenance of cross-system links in business-as-usual activities, suggests that a similar body could be established just as quickly in a future pandemic situation.

115. While it may not be appropriate for elements of the RAPID C-19 process itself to remain in place outside of pandemic circumstances, some aspects, in their broadest sense, can support business-as-usual activities, for example, having an appropriate governance framework to facilitate information sharing, cross-system collaboration, breaking down barriers between organisations, continuous improvement and empowered decision-making.

116. From the NICE perspective, the general concepts described above have been borne in mind with the set up and operation of other multi-agency collaborative initiatives such as the Innovative Licensing and Access Pathway (an initiative between the MHRA and NICE). Furthermore, the horizon scanning approach used in RAPID C-19 (the 'one version of the truth' concept), has informed the view of how cross-system horizon scanning could potentially work in future.

Overall NICE lessons learnt exercise findings, recommendations and implementation

117. On 27 September 2022, the lessons learnt key findings from the internal exercise and RAPID C-19 feedback were shared with the Executive Team. The key findings included:

- NICE could have been better prepared for COVID-19, but nonetheless responded well;
- Staff felt supported, but some areas of work were less positive or understood;
- The strong operational response and rapid adoption of new ways of working were widely recognised;
- Elements of the success were fragile and should not be assumed for future crises;

- Codifying elements of NICE's response to COVID-19 would help ensure NICE is better prepared for future crises;
- Further strengthening external relationships would provide more predictability and effectiveness;
- Continuing to invest in staff wellbeing and organisational effectiveness would increase organisational resilience;
- Top areas of learning for business as usual was consistent with NICE's transformational change programme and embedded in the business priorities, including flexible, agile methods and processes, enhanced external collaboration and use of data, and user-focused prioritisation; underpinned by a cross-organisational focus on addressing health inequalities;
- The specific actions underpinning these themes should be embedded in 2022/23 business plan priorities or supporting programmes; and
- Specific actions to support pandemic or crisis preparedness should be implemented, with a nominated ET lead for each action reporting to the OMC.

118. Further details can be found within the 'COVID-19 Lessons Learnt Report – ET', which is exhibited as **Exhibit SR/8-INQ000252461**.

119. The ET agreed that in order to strengthen and inform the findings, additional engagement activity should be undertaken with external partners. The findings set out in the report were approved by ET, with a caveat that findings be updated if necessary, following these additional external conversations.

120. Upon completion of the additional engagement activity with key external partners, a summary of the lessons learnt key findings was shared at the whole staff meeting on 16th March 2023 (see 'COVID-19 Lessons Learnt Report – All Staff' at **Exhibit SR/9-INQ000252462.**) This provided an overview of the key findings outlined above and confirmed that ET would share their response to the exercise.

121. Following this, the ET shared their response to the exercise with staff (**Exhibit SR/10-INQ000252452**). The response outlined a generally positive response from NICE and external partners recognised NICE's collaborative and flexible approach in producing rapid guidance and managing multi-partner processes, despite the challenges faced by staff. As set out in paragraph 53 above, the multi-agency initiative accelerated safe patient access to treatments that showed evidence of benefit on preventing and treating COVID-19.

122. NICE also identified areas that did not work so well and recognised that organisational improvements were required to improve communication internally to enable consistent messaging throughout the organisation. In order to support future pandemics or crisis preparedness, a set of actions (as shown on slides 19 and 20 of **INQ000252461**) were agreed by ET, each of which was taken forward under the leadership of a named ET member, with delivery reported to OMC at 6 monthly intervals.

123. It is important to note that whilst the above exhibits are referred to as "reports", they are presented in the form of a slide deck providing an overview of the findings. Similarly, a number of these exhibits are titled as 'summary' report, with reference to a 'full report' being available. The 'summary report' is the report that was presented and any reference to a 'full report' simply refers to the findings from the exercises that led to the production of the report, such as the surveys, and feedback from each workshop.

Findings, recommendations and implementation

Pandemic preparedness

124. There was broad agreement that while NICE could have been better prepared for COVID-19, it nonetheless responded well. This effective response included the following areas:

- The strong operational response providing business continuity;
- Rapid adoption of new ways of working;
- The development and adoption of new methods and processes to develop guidance and work with our external partners; and
- The use of new sources of evidence.

125. The external stakeholder feedback found that NICE's expertise and trusted position as the provider of guidance to the health care system would have been valuable in the very early days of the pandemic, and NICE could have been more involved in very early national pandemic response discussions. NICE supports this feedback and believes it is essential to strengthen its relationship with pandemic response bodies so that it is clear what NICE's role is from the outset and so that NICE is involved in early discussions.

126. It is important to note that NICE is an evidence-based organisation and therefore its role very early in the COVID-19 pandemic, where there was a dearth of evidence, was unclear. In addition, NICE is neither a Category 1 nor a Category 2 responder under the Civil Contingencies Act 2004. It also does not have a specified role under the DHSC Emergency Planning Regulations and the NHS England Emergency Preparedness, Resilience and Response ["EPPR"] framework. This meant that NICE was not actively involved in national level discussions in the very early days of the pandemic. However, once NICE was approached, the response was quick and effective.

127. Work has been progressing to strengthen NICE's pandemic preparedness and address the recommendations from the lesson learnt exercise set out in slides 19 and 20 of **exhibit SR/8** INQ000252461

128. By June 2023, nine actions had been completed, one had been superseded and five were still in progress. These are as follows:

- In March 2023, NICE designated the CMO as the ET pandemic preparedness lead. Work is in progress to engage in discussions with key partners (DHSC, NHSE, UKHSA and OHID) to agree our role within the EPPR, at the strategic emergency preparedness board level. The aim is to ensure NICE is alerted and engaged at a very early stage of any future pandemic;
- In June 2023, NICE's OMC agreed an updated Business Continuity Plan ("BCP"), which includes an emergency communication plan. The Pandemic BCP was updated and approved by OMC in November 2023;
- NICE is now connected to international and national alert processes and surveillance infrastructure, for example the Global Outbreak Alert and Response Network hosted by the WHO. In addition, plans are in progress to ensure that appropriate agreements and protocols for information sharing with the UKHSA All Hazard Intelligence team are in place;
- Significant work to build digital workplace resilience to enable secure remote working, reduce travel requirements, enable emergency information to be cascaded quickly, and allow for quickly changing work patterns/arrangements, has progressed. This work continues as part of NICE's digital workplace work stream; and
- There are regular updates of the guidelines methods and processes manual, which includes the arrangements for developing guidelines in response to health and social care emergencies that were informed by the initial pandemic experience. The next update is scheduled for later in 2023. In addition, work continues to review and test where evidence is emerging and rapidly changing as part of work in moving to digital living guidelines.

Actions embedded in NICE's transformational change.

Flexible, agile methods and processes

129. One of the key findings was NICE's ability to be innovative, agile and flexible, and respond rapidly to the health system's needs by quickly adapting methods and processes and making use of rapidly emerging real-world evidence to produce useful COVID-19 guidelines at pace. This included the willingness to explore data sources beyond peer-reviewed literature, the production of COVID-19 rapid guidelines and playing a central role in the multi-agency RAPID C-19 Pathway. This has been taken forward as a central part of NICE's transformation.

130. Further work progresses to make sure guidance is timely, useful and usable. Changes have been made to how the portfolio of guidelines is managed and maintained, with priority guideline recommendations updated more frequently and quickly, particularly where patient safety is a factor. Building on the experience of the COVID-19 guidelines, the aim is to embed the living guidelines model and update recommendations on key topics within 6-12 months of new, practice-changing evidence emerging.

131. The ability to use virtual working arrangements not only ensured continued production of advice and guidance but also offered new flexible ways of engaging health care system partners and to focus on the health care system needs. This new way of working, such as virtual committee meetings, has proved popular with committee members and is a more efficient use of their time.

132. In 2022/23 NICE developed a new, proportionate approach to technology appraisals, building on the work in the pandemic to develop flexible, agile methods and processes. Parts of the appraisal process were simplified, removed, or reconfigured. This meant that light-touch, faster evaluations were applied to simpler, low-risk treatments to enable more efficient rapid guidance production. As a result, the average time it takes to produce final technology appraisals or highly specialised technologies evaluations guidance was reduced by 17%.

133. In 2022/23 a series of pilots were undertaken to develop new ways of developing guidance including:

- Light-touch, faster evaluations of simpler, low-risk treatments. This proportionate approach will enable faster access to additional treatment options by around 45%; and
- Trialling an innovative approach to the way digital products, devices and diagnostics are assessed through the early value assessment programme for Medtech. This aims to provide a rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money, so the NHS and patients can benefit from these promising technologies sooner.

134. In February 2023, NICE announced the development of a new review process to update recommendations on the cost-effectiveness of COVID-19 treatments. This is so they can be made available more quickly to patients, if they show promise against new variants and are found to be cost-effective.

Prioritisation based on user needs.

135. The lessons learnt review highlighted the importance of prioritising NICE's work and focusing on the system's needs. A key priority in NICE's transformation is to therefore improve the way NICE prioritises the topics for its work, informed by systematically gathering intelligence from stakeholders. In the context of significant operational pressures on the health and care system, this will help ensure NICE is able to prioritise guidance to focus on what matters most in impacting health gain, equity, and implementation.

Enhanced external collaboration and use of data.

136. Another key finding was NICE's ability to utilise not only national but international developments, and emerging data and evidence, as part of the global response to

COVID-19. This enabled NICE to create new partnerships and further strengthen existing ones.

137. NICE has continued this work to utilise new sources of data and work collaboratively with partners. In 2022, a real-world evidence framework was published that supports the use of real-world data to resolve gaps in knowledge and drive forward access to innovations for patients. The framework has been viewed over 25,000 times by users worldwide in countries including the UK, USA, Australia and Germany.

138. Building on the collaboration on COVID-19 related issues, NICE has partnered with 5 international health technology assessment bodies to collaborate on shared opportunities and challenges. As well as further increasing global collaboration, this partnership will improve ways of working and enables NICE to efficiently address important strategic issues.

Health Inequalities

139. NICE recognises that it is clear that the pandemic had a disproportionate impact on people who already experience disadvantage and discrimination and the lessons learnt exercise highlighted the importance of health inequalities underpinning NICE's work.

140. In October 2022, NICE published a new health inequalities web resource. The resource brought together in one place all of NICE's guidance and advice on health inequalities for the first time. The guidance is aligned to system needs and recognised health inequalities frameworks including the CORE20Plus5, the adapted Labonte model, and the Marmot principles. Nearly 10,000 visitors engaged with the resource within the first month of its launch.

141. Since the relevant period the EIA used in guidance production has been revised to incorporate health inequalities in addition to the Equality Act protected characteristics. The new Equality and Health Inequalities Assessment ["EHIA"] was structured around four factors and piloted through our Digital Living Guideline Programme:

- Socio-economic status and deprivation (for example, unemployment, poor housing, poor education. Low income or people living in deprived areas);
- Protected characteristics (for example, age, sex, race, sexual orientation and disability);
- Vulnerable groups of society, or 'inclusion health' groups (for example, vulnerable migrants, homeless people, sex workers and Gypsy, Roma and Travellers); and
- Geography (for example, urban or rural areas).

142. Health inequalities were then measured through examining differences in 5 areas:

- Health status, for example, life expectancy and prevalence of health conditions;
- Behavioural risks to health, for example, obesity, diet and physical activity;
- Wider detriments of health, for example, housing, income, education. Employment, transport, access to green spaces and local environments;
- Access to care, for example, availability of treatments; and
- Quality and experience of care, for example, levels of patient satisfaction

143. There was recognition that there may be significant and complex overlap: people experience different combinations of these factors and interactions between the factors which can compound the severity of health inequalities experienced.

144. In addition, topic specific health inequalities briefings, a EIAU guidance and training resources were all produced to aid completion of the form and proactive consideration of health inequalities.

145. Further support to embed the guidance on health inequalities to the NHS directly includes mapping NICE quality standard statements aligned with the 7 principles in NHS England's Health Inequalities Improvement Planning Matrix. The matrix is being used by national NHS programme and work streams leads, and service leads at a regional, system and provider level. It helps ensure that programmes do not widen healthcare inequalities and covers areas including equitable access and co-production.

146. A NICE Listens health inequalities steering group was established in September 2021, In October and November 2021, 28 members of the public from across England met through online workshops for the first NICE Listens project on the topic of health inequalities. The group was made up of people of different ages, ethnicities, income levels and locations in England, and weighted more towards people who are more likely to be affected by health inequalities. The group considered the following:

- How should NICE act in regard to health inequalities;
- What value does the public place on different types of health inequalities? Are some more important for NICE to consider than others; and
- What other factors should inform committee deliberation when they are considering health inequalities.

147. The findings of the report, which I produce as **Exhibit SR/11-INQ000252453** highlighted two main areas where NICE could go further, namely the strengthening its approach to addressing health inequalities and the secondly, in strengthening its role to supporting the health and care system to address health inequalities. From the report, a number of recommendations were developed including to develop training on health inequalities for those involved in guideline development and to emphasise the importance of prevention in addressing health inequalities.

Business plan priorities

148. The theme of flexible agile methods and processes enhanced external collaboration and use of data, and user-focused prioritisation are central to the priorities in NICE's 2023/24 business plan. NICE will seek to:

- Increase the relevance of the guidance by developing a NICE wide horizon scanning & topic selection function enabled by coordinated stakeholder engagement and informed by system priorities;
- Increase the real-world impact of NICE's pre-evaluation support for industry by simplifying and improving NICE's early engagement with industry;
- Make advice easier to access by improving the digital presence and website experience for users;
- Increase the usability of the guidance by incorporating technology appraisals into guidelines and evolve the supporting resource impact assessments;
- Improve NHS decision making in new ways by developing a programme to provide advice on the value of classes of HealthTech products already in use;
- Improve the timeliness of guidance by implementing improvements to the methods and processes identified in 2022/23. This includes continuing to increase the speed in developing and updating guidelines, and to complete medicine evaluations by implementing process simplifications and improvements, and to shorten the Health Tech guidance timelines by implementing proportionate approaches trialled in our Early Value Assessment;
- Support implementation of the guidance by improving our measurement approach and develop an automated uptake and monitoring system for a priority topic; and
- Continue the internal transformation to build a brilliant organisation.

149. By implementing these priorities and focusing on what matters most, providing useful and usable advice, and constantly learning from data and implementation, NICE will take forward the learning from the pandemic to ensure it can fulfil its purpose of helping practitioners and commissioners get the best care to patients fast while ensuring value for the taxpayer.

150. NICE has built a reputation as a world leader in providing robust, independent, and trusted guidance and advice to the health and care system. Since the pandemic, the world has changed substantially and organisations such as NICE have had to adapt processes and operate more flexibly amidst ever-changing pressures. To maintain its role as a leader in health and care, it is important that NICE applies the lessons learned from the pandemic to meet future challenges.

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.

Personal Data

Signed: Dr Samantha Roberts

Dated: 17 November 2023