Witness Name: Professor Sir Peter Horby
Statement No.: 3
Exhibits: 54
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR SIR PETER HORBY

I, Professor Sir Peter Horby, will say as follows: -

1. This statement is provided in response to a rule 9 request from the UK COVID-19 Inquiry in relation to Module 4 and is intended to cover the relevant time period identified in the Module 4 Rule 9 request from 30 January 2020 to 28 June 2022.

Career history and professional background

2. I am a qualified medical doctor with a background in infectious diseases and public health medicine. I have led clinical and epidemiological research on a wide range of emerging and epidemic infections over the last twenty years including SARS, avian influenza, Ebola, Lassa fever, mpox (formerly monkeypox), plague and COVID-19.

3. From 1996 to 2003 I worked for the Public Health Laboratory Service (replaced by the Health Protection Agency in 2004, Public Health England in 2013, and the UK Health Security Agency in 2021).

4. From 2003 to 2006 I was head of communicable disease surveillance and response at the World Health Organization country office in Vietnam.

5. In February 2006 I joined the University of Oxford. From 2006 to 2011 I set up and led a clinical research unit at the National Hospital for Tropical Diseases in Hanoi, Vietnam.

6. I was based in Singapore from July 2011 to July 2014, working on infectious diseases, with a special focus on epidemic prone infectious diseases.

7. I returned to the UK in 2014 and remain employed by the University of Oxford as a clinical academic within the Nuffield Department of Medicine. I am currently the Director of the Oxford University Pandemic Sciences Institute.

8. I am a member of a number of different committees and hold a number of different advisory positions (both national and international) relating to preparedness for infectious disease threats.

Relevant roles

9. I hold several positions that are relevant to Provisional Outline of Scope for Module 4. These positions include:

    a) Director of the Pandemic Sciences Institute (PSI) at the University of Oxford. The PSI was officially launched in July 2022 and currently comprises 143 staff and 31 students. The Institute's mission is to discover, create, and enable practical solutions to infectious disease threats worldwide. This includes the development and evaluation of therapeutics for epidemic and pandemic prone infectious diseases.

    b) Executive Director of the International Severe Acute Respiratory and emerging Infections Consortium (ISARIC), a consortium of 57 international, national, and local research networks whose research activities span 132 countries worldwide.

c) Coordinator of the African Coalition for Epidemic Research, Response and Training (ALERRT), a sub-Saharan Africa consortium on clinical research for epidemic-prone infections, with 19 partner institutions and activities across 25 sub-Saharan Africa countries.

d) Co-chief Investigator of a randomised controlled trial of treatments for COVID-19: *'Randomised Evaluation of COVID-19 Therapy'* (RECOVERY).

e) Chair of the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) and a member of SAGE COVID-19.

Involvement with scientific advisory committees of relevance to the Provisional Outline of Scope for Module 4.

10. I was a member of the Department of Health and Social Care's (DHSC) expert scientific advisory committee called the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) since 1 August 2014 and held the position of Chair of the Committee from 21 May 2018 to 25 June 2024.

11. I attended SAGE COVID-19 meetings in my capacity as Chair of NERVTAG. I attended 89 of 105 SAGE COVID-19 meetings.

12. I attended and gave oral evidence at a private briefing on the COVID-19 outbreak to the House of Commons Science, Innovation and Technology Committee on 10 March 2020 **[PH3/1 - INQ000513283].**

13. I attended and gave oral evidence to the House of Commons Science, Innovation and Technology Committee 04 November 2020; '*Coronavirus: lessons learnt'* **[PH3/2 - INQ000513281]**.

14. I provided written evidence to the joint Science and Technology committee (commons) / Health and Social Care Committee '*Coronavirus: lessons learnt'* inquiry **[PH3/3 - INQ000513284].**

15. I attended and gave oral evidence to House of Commons Science, Innovation and Technology Committee 23 December 2020: *UK Science, Research and Technology Capability and Influence in Global Disease Outbreaks* **[PH3/4 - INQ000513282]**

16. I participated in a WHO [COVID-19] clinical management meeting on 9 January 2020 to provide input to the first WHO clinical management guidance document and subsequently participated in numerous meetings to review and update the WHO COVID-19 clinical management guidance.

17. Based on my RECOVERY experience and the data generated by the trial I have provided expert advice on NHS clinical commissioning policy for six COVID-19 treatments through membership of NHS National Expert Working Groups. I have also advised the European Medicines Agency (EMA), for example I presented results of the tocilizumab comparison to EMA on 15th February 2021, and the U.S. Food and Drug Administration (FDA), for example I presented results of the dexamethasone comparison to FDA on 11th September 2020, on treatments for COVID-19.

NERVTAG work of relevance to the Provisional Outline of Scope for Module 4.

18. I became a member of NERVTAG on 1 August 2014 when the committee was formed. I held the role of member until 20 May 2018 whereupon, following competitive interview, I was appointed Chair of NERVTAG on 21 May 2018 and held this position until 25 June 2024.

19. The role of NERVTAG is to provide the Chief Medical Officer (CMO) and, through the CMO, ministers, the DHSC and other Government departments, with independent scientific risk assessment and mitigation advice on the threat posed by new and emerging respiratory viruses and advice on options for their management. Seasonal influenza is excluded from the scope of NERVTAG.

20. NERVTAG members are independent experts who volunteer their time to serve on the committee. NERVTAG was constituted of about 15 scientists and health care

professionals, including clinicians, microbiologists, mathematical modellers, and public health practitioners, and colleagues in related disciplines. The committee was supported by a scientific secretariat from PHE (now the UK Health Security Agency). The number of attendees in meetings fluctuated due to the presence of observers, people with particular expertise co-opted for specific topics, and people presenting papers from other organisations or groups.

21. As well as the full NERVTAG committee meetings, there were specific *'task and finish'* subgroups of the main committee that were established as necessary to ensure adequate consideration of detailed technical aspects of the work of the committee.

22. When required, the Chair would propose that a subgroup be formed and ask for volunteers from the main committee to become members of the subgroup and for a chair to be selected for the subgroup.

23. The subgroups would meet separately to the main NERVTAG committee and the length of the existence of the subgroup was determined by the Chair based on completion of the allocated task. Once the task was finished the subgroup would then be closed. Subgroups could co-opt in expertise that the members considered was needed to help them to fully consider the task that they were concerned with.

24. Following the subgroup meetings, a paper would be prepared by the subgroup members jointly on the relevant topic for consideration and approval by the main NERVTAG committee before submission to DHSC.

25. There were 40 full NERVTAG committee meetings in 2020 and 16 to the end of June 2021. There were meetings of the NERVTAG main committee that took place in early January 2020, on 13 and 21 January 2020, prior to the Scientific Advisory Group for Emergencies (SAGE) being convened. In addition, there were 11 "Bird table" meetings in 2020. Extraordinary meetings were held to consider specific topics; novel therapeutics in February and March 2020, non-invasive ventilation (NIV)/high flow nasal oxygen (HFNO) in March 2020, contact tracing in April 2020, and four meetings on new SARS-CoV-2 variants in December 2020 and January

2021. In the 18 months from January 2020 to June 2021, NERVTAG held a total of 75 meetings.

26. There were seven NERVTAG COVID-19 meetings (13th, 21st, 28th, 30th Jan; 03rd, 07th, 21st Feb 2020) prior to the first NERVTAG COVID-19 Therapeutics Subcommittee meeting. Therapeutics were first discussed at the second NERVTAG COVID-19 meeting on 21st Jan 2020, where the minutes **[PH3/5 - INQ000023119]** note:

> *"There was an ongoing trial in one hospital in Wuhan of an HIV drug which had showed efficacy in animal models of MERS-CoV. Also, remdesivir, a broad-spectrum antiviral, has shown potent viricidal activity to coronaviruses in vitro. It was noted that WHO are working to prioritise potential therapeutics for evaluation in 2019-nCoV."*

27. Therapeutics were to be discussed at the third NERVTAG meeting on 28th Jan 2020 but the meeting overran and the minutes **[PH3/6 - INQ000047820** note:

> *"The meeting has overrun and the items listed for this meeting namely the items in relation to clinical management of severe cases and novel therapeutics will continue at another full NERVTAG meeting to be convened this Thursday."*

28. The fourth NERVTAG COVID-19 meeting on 30th January 2020 has an agenda item entitled 'Clinical management of severe cases and novel therapeutics'. At this meeting several potential treatments were discussed. The meeting minutes **[PH3/7 INQ000047819** record:

    a) *"At this point, NERVTAG is not able to recommend routine use of any experimental therapeutics in patients with confirmed 2019-nCoV."*
    b) *"Adjuvant Steroids in Adults with Pandemic influenza (ASAP) Trial can be amended to respond to a novel coronavirus outbreak; and he [WSL[1]] was in the process of modifying the ASAP trial to include novel coronavirus."*

29. The seventh NERVTAG COVID-19 meeting on 21st February 2020 had an agenda item entitled *"Advice on principles for trialling COVID-19 treatments in the UK?"*

[1] Professor Wei Shen Lim

For this agenda item I drafted a paper entitled '*Therapeutics for COVID-19*' **[PH3/8 - INQ000513295]**. Relevant content from this paper are:

> ***"Suggested principles***
>
> - *Experimental therapeutics for the treatment of COVID-19 should be evaluated for efficacy and safety within the context of clinical trials.*
> - *The UK should be prepared to initiate clinical trials for unproven therapeutics for COVID-19.*
> - *UK activities should align with international efforts, either through alignment of methods or direct participation in multi-country trials.*
> - *Some level of central coordination of clinical trials in COVID-19 is desirable to make sure: they happen, avoid competition for patients, avoid implementation of low value or poor-quality trials, align with international efforts, inform DHSC considerations.*
> - *If an unproven therapeutic (experimental or repurposed) is used outside of a clinical trial framework, then data should be collected systematically on safety and efficacy to inform future use.*
>
> ***Suggested actions***
>
> - *DHSC advised to convene a COVID-19 therapeutics task force. This task force should:*
> - *Monitor emerging data on therapeutic options for COVID-19.*
> - *Propose to DHSC a process for prioritising or deprioritising therapeutics for evaluation in COVID-19 in the UK.*
> - *Propose to DHSC a process for the evaluation of therapeutics for COVID-19 in the UK both within and out with the context of clinical trials."*

30. The seventh NERVTAG COVID-19 meeting on 21st February 2020 (at which the above paper was presented) made several recommendations **[PH3/9 - INQ000119469]**:

    a. *"NERVTAG endorsed the underlying scientific principles of the paper I drafted by PH and strongly recommend the principle that any unproven therapeutics for the treatment of COVID-19 should be evaluated for efficacy and safety within the context of clinical trials."*

b. *"NERVTAG view was since treatments are speculative and unproven they strongly recommend that experimental therapeutics for the treatment of COVID-19 should be evaluated for efficacy and safety within the context of clinical trials."*

c. *"NERVTAG recommended central oversight of clinical trials to ensure therapeutic evaluation, including patient enrolment, is co-ordinated. NERVTAG recommended that a sub-group of NERVTAG, co-ordinated by DHSC is formed to do this."*

d. *"Action 1: NERVTAG to set up a subgroup co-ordinated by DHSC is formed to have central oversight of clinical trials to ensure therapeutic evaluation, including patient enrolment, is co-ordinated."*

31. The principles and recommendations outlined in paragraphs 29 and 30 were largely taken forward. In the UK, experimental and unproven potential therapeutics for COVID-19 were evaluated for safety and efficacy in clinical trials with central oversight and coordination. A mechanism for prioritising potential therapeutics was established (see COVID-19 Therapeutics Advisory Panel paragraphs 44-51) and a therapeutic task force was established (see paragraph 56). In my view these actions were taken with appropriate speed.

32. There were two principles/recommendations that were not, to my knowledge, fully actioned. First, alignment of UK clinical therapeutic trials with international efforts was limited because the international landscape was complex, fragmented, rapidly changing, and in some cases of poor quality. I believe the UK took the right decision in pursuing its own stand-alone programme of clinical trials which, in my opinion, were more impactful than other national or international programmes. Countries that did seek strong international alignment struggled enormously and largely failed to deliver timely and impactful research. There are times when putting your head down and going it alone is the best course of action. Second, it is unclear to me the extent that the safety and efficacy of experimental drugs used outside of clinical trials was monitored. However, this is an insignificant issue since the data from such observations is not very informative, extensive clinical trials were initiated, and there was, I believe, limited use in the UK of unproven drugs outside of clinical trials.

33. The seventh NERVTAG COVID-19 meeting on 21st February 2020 also had an agenda item entitled *'What do we know about effective clinical treatments and patient recovery?*'. The committee's response to this agenda item was:

    a. *"NERVTAG view is that there are currently no robust data on treatment effectiveness."*

       ""Members recommended rapid throughput screening of potential therapeutics, utilising universities to generate that data."

34. The NERVTAG COVID-19 Therapeutics Subcommittee was subsequently convened and the first meeting took place on 27 February 2020, with further meetings on 2nd, 3rd and 9th March 2020. The minutes are exhibited at **[PH3/10; 11; 12; 13 – INQ000221982; INQ000221962; INQ000221964; INQ000221978]** and I was in attendance and chaired those meetings.

35. The terms of reference of the NERVTAG COVID-19 Therapeutics Subcommittee was "*To advise the Chief Medical Officer (CMO) on the development and implementation of national clinical trials of therapeutics for Coronavirus 2019 (COVID-19).*" **[PH3/14 - INQ000513296]**

36. The paper I drafted entitled '*Therapeutics for COVID-19*' **[PH3/8 - INQ000513295]** was re-presented at the first NERVTAG COVID-19 Therapeutics Subcommittee meeting on therapeutic options.

37. At this first meeting it was decided to split the work into three areas: drugs, and endpoints and populations, and supportive care. These sub-groups subsequently met on 02 March 2020, 03 March 2020, and 03 March 2020 respectively. I chaired all these subgroup meetings. The minutes are exhibited at **[PH3/11; 12; 15 - INQ000221962; INQ000221964; INQ000416126]**.

38. The NERVTAG COVID-19 Therapeutics Subcommittee reconvened again on 09 March 2020 **[PH3/13 - INQ000221978]**. At this meeting the following recommendations were made:

1. *Trial of chloroquine in mildly ill out-patients at risk of complications.*
2. *Platform trial in moderately ill inpatients, ranking intervention Remdesivir>Kaletra>IFN>steroids, less enthusiasm for Chloroquine.*
3. *REMAP-CAP – useful study, review viral domain, consider burden on ICUs. Consider recommend scale-up.*
4. *Standard O2 vs NIV in patients with ceiling of care.*
5. *JVT and PH will meet with CMO tomorrow. Recruitment within 3 weeks.*

39. There were no further meetings of the NERVTAG therapeutics subcommittee as the recommended platform trial was agreed and was being established and a preliminary list of repurposed therapeutics had been recommended. A separate process, independent of NERVTAG and of the trial principal investigators, was to be established to conduct due diligence on potential treatments for evaluation and to make recommendations (see UK-CTAP section).

Success or otherwise of NERVTAG with respect to matters relevant to Provisional scope of outline for Module 4.

40. NERVTAG was, in my opinion, successful in acting as a provisional source of expert advice on the evaluation of potential treatments for COVID-19.

41. At a very early stage NERVTAG identified and promoted several key principles:

    a) The critical importance of evaluating the safety and efficacy of unproven therapeutics for the treatment of COVID-19 through clinical trials.
    b) The establishment of a central therapeutics task force to monitor and guide therapeutic research and development.
    c) The need for central coordination of clinical trials to maximise effectiveness.

42. NERVTAG provided useful early advice on candidate therapeutics to be evaluated in clinical trials. However, the committee was not resourced or constituted to provide this advice in an ongoing basis.

43. The establishment of an alternative mechanism for reviewing and conducting due diligence on candidate therapeutics to be evaluated in clinical trials, that was independent from the trials, was a much better approach.

Other committees: UK COVID-19 Therapeutics Advisory Panel (UK-CTAP)

44. In June 2020 Professor Chris Whitty invited the Clinical Director of the Medical Research Council (Patrick Chinnery) to assemble the UK COVID-19 Therapeutics Advisory Panel (UK-CTAP). See exhibit **[PH3/16 - INQ000513285].**

45. UK-CTAP reviewed available scientific evidence and made recommendations to the principal investigators of each trial and Professor Chris Whitty, the Chief Medical Officer for England (CMO England) and Chief Scientific Adviser for the Department of Health and Social Care (DHSC).

46. Therapeutics for consideration for evaluation in clinical trials could be proposed through an online open nominations portal. From September 2020 to July 2021, UK-CTAP received 336 nominations and made 30 recommendations.

47. A list of treatment recommended by CTAP for clinical trials can be found at **[PH3/16 - INQ000513285]**.

48. The final decision on which treatments were included in trials rightly lay with the Chief Investigators, who have legal responsibility for the delivery of the trials, and Professor Chris Whitty, the Chief Medical Officer for England and Chief Scientific Adviser for the Department of Health and Social Care.

Success or otherwise of UK-CTAP with respect to matters relevant to Provisional scope of outline for Module 4.

49. UK-CTAP was, in my opinion, of enormous benefit.

50. First, UK-CTAP provided very detailed and high quality independent scientific and operational due diligence of proposed drugs for evaluation in clinical trials. I was somewhat exposed to the advice of other national and international prioritisation

committees, and CTAP was in my experience the most rigorous. UK-CTAP was highly regarded internationally. From the very early days of the RECOVERY trial my inbox was bombarded with suggested interventions (oftentimes repeatedly and passionately). The rigorous due diligence work of UK-CTAP relieved myself and other trial principal investigators of a heavy workload.

51. Second, UK-CTAP resulted in a shared responsibility for drug selection, thereby partially relieving the trial principal investigators of a heavy responsibility.

Other related committees or initiatives

52. **Prioritising urgent public health (UPH) research**. As a growing portfolio of clinical research began emerging in spring 2020, in March 2020 the National Institute for Health Research (NIHR) established a single UK-wide process to prioritise COVID-19 research for funding or Clinical Research Network support as urgent public health (UPH) research. RECOVERY was given Level 1a (top level prioritisation) UPH status by NIHR **[PH3/17 - INQ000513294]**.

53. **COVID-19 National Core Studies (NCS) programme**. The COVID-19 NCS programme was established by the CSA in October 2020 **[PH3/18 - INQ000211973]**. Six National Core Studies programmes were identified, of which one was clinical trials, which was to build '*on established NIHR infrastructure (and equivalent in DAs) to accelerate delivery of large scale COVID-19 trials for drugs and vaccines'*. Within this, RECOVERY was badged as a 'national core study'.

54. **COVID-19 Therapeutics Accelerator.** This was a funding initiative supported by Wellcome, BMGF, Mastercard with (initially) USD125m. The Accelerator provided funding for the development and evaluation of treatments for COVID-19. RECOVERY received funding from the COVID-19 Therapeutics Accelerator via the Wellcome Trust for extending the trial internationally **[PH3/19 - INQ000513292]**

55. **UKHSA technical briefings on COVID-19 therapeutic agents.** The UKHSA released four technical briefings on '*COVID-19 therapeutic agents: a programme of public health activities to support deployment of novel therapeutics for COVID-*

19". **[PH3/20 - INQ000513286]**. These reports provided data on genomic, virological, and epidemiologic surveillance in support of the deployment of specific COVID-19 therapeutics. Mostly these provided genomic data of relevance to the likely antiviral activity of small molecule antiviral drugs and monoclonal antibodies against newly emerging SARS-COV-2 variants.

56. A **Therapeutics Task Force** and an **Antiviral Task Force** were also established but I had only tangential contact with these groups and I was not fully aware of their remits **[PH3/21; 22 - INQ000513288; INQ000513244]**. Having had little involvement with these committees it is difficult for me to judge whether there would have been value in me being more involved. However, I can say that I saw no evidence of these committees having any prejudicial impact on the work I was doing, other than the single issue raised in paragraph 117. On the contrary, I believe it is likely that, behind the scenes, these committees facilitated the work I was doing.

Scientific Advisory Group for Emergencies (SAGE)

57. In my capacity as Chair of NERVTAG I attended 89 of 105 SAGE-COVID-19 meetings.

58. The CSA and CMO were highly supportive of the clinical trials of COVID-19 therapeutics, including RECOVERY, but SAGE was not active in the therapeutics arena.

59. SAGE did receive a small number of papers related to treatments for COVID-19 but to my knowledge there were no significant SAGE recommendations in this area. The papers received by SAGE were:

    a) SAGE #21, 31st March 2020 – paper presented to SAGE by NERVTAG "'At what point might meaningful results from clinical trials be available?". **[PH3/23 - INQ000119709]**
    b) SAGE #26, 16th April 2020 – paper - UK Government Therapeutics Taskforce. '*The aim is for the UK to ensure that promising therapies are tested as fast as possible and that patients in the UK get access to effective medicines as soon as possible'.* **[PH3/21 - INQ000513288]**

c) SAGE #34, 07 May 2020. HDR UK: A National Health Data Research Capability to Support COVID-19 Research Questions, 5 May 2020.RECOVERY progress mentioned in this report and subsequent HDR UK updates to SAGE. **[PH3/24 - INQ000513289]**

d) SAGE #98, 07 December 2021. In relation the emergence of Omicron (B.1.1.529) variant a paper was prepared and presented '*Antiviral drug resistance and the use of directly acting antiviral drugs (DAAs) for COVID-19'* (06 December 2021). **[PH3/25 - INQ000120656]** This paper was related to minuted text: *Pharmaceutical interventions including antivirals will also continue to be important. Though antivirals should be used in combination where possible to reduce the risk of resistance developing, this will not be possible in the forthcoming wave of infections due to availability and lack of clinical trial data for combination approaches. Resistance monitoring, particularly in immunocompromised patients, will be needed and preparation should be made for combination therapies to be tested and rolled out as soon as practical.*

Success or otherwise of SAGE with respect to matters relevant to Provisional scope of outline for Module 4.

60. The SAGE committee was not active in the programme of identifying and evaluating therapeutics for COVID-19. This was, in my view, the right approach since this area was very well covered by other actors, such as NERVTAG (initially), DHSC, NHS, UKRI, CTAP and the NCS programme.

CLINICAL TRIALS

Origins of the RECOVERY trial

61. Through my professional contacts with clinical colleagues in China and as the Executive Director of ISARIC, I was involved in China with the development of clinical trials of lopinavir/ritonavir and remdesivir in patients with 2019-nCoV in Wuhan, China at the end of January 2020.

62. The very first randomised controlled clinical trial (RCT) in COVID-19 (of lopinavir-ritonavir) enrolled its first patient in Wuhan on 18 January 2020, just 20 days after the outbreak was first made public. This trial was led by an ISARIC member and supported by the membership, including using the ISARIC tools for data capture and elements of a MERS-CoV clinical trial protocol provided by another ISARIC member. The very first randomised placebo-controlled clinical trial in COVID-19 (of remdesivir) enrolled its first patient in Wuhan on 6 February 2020. Again, this trial was led by an ISARIC member and supported by the membership. The resulting publications (of which I am a co-author) are exhibited at **[PH3/26; 27 - INQ000221986; INQ000222012].**

63. On 04 February 2020 the UK Research and Innovation (UKRI) and the Department of Health and Social Care, through the National Institute for Health Research issued a call for applications for research funding titled '2019-nCoV Rapid Response Call'. See links:

    a) https://webarchive.nationalarchives.gov.uk/ukgwa/20200923123848/https://mrc.ukri.org/news/browse/20-million-rapid-response-for-novel-coronavirus-research/
    b) https://webarchive.nationalarchives.gov.uk/ukgwa/20200923122628/https://mrc.ukri.org/funding/browse/2019-ncov-rapid-response-call/2019-ncov-rapid-response-call/

64. I applied for funding under this 'call' as Principal Investigator with an application titled "COVID-19 multi-arm, multistage adaptive clinical trial" to co-lead an adaptive platform trial in China, the trial protocol synopsis being exhibited at **[PH3/28 - INQ000513279]**. The closing date for the call on therapeutics was 13th February, necessitating very fast preparation of the application.

65. I was notified on 17th February that the application was successfully received, exhibited at **[PH3/29 - INQ000513254]**.

66. On 1st March I contacted Professor Sir Richard Peto and Professor Sir Rory Collins (two eminent clinical trial experts at the University of Oxford) for their advice on

designing a large scale RCT for COVID-19, exhibited at **[PH3/30 - INQ000513255]**.

67. On 2nd March 2020 Professor Martin Landray (Professor of Medicine and Epidemiology at the University of Oxford) contacted me following an email exchange he had with Jeremy Farrar (Director of the Wellcome Trust) on Friday 28th February, and he and I spoke on the phone later that morning.

68. On 4th March myself, Martin Landray, and Richard Peto met to discuss the trial design and set ourselves an ambition to be open for recruitment within two weeks.

69. On 5th March I was informed by email that UKRI had agreed to fund the trial subject to considering relocating the trial to the UK or EU as by this time the epidemic had come under control in China but was escalating rapidly in Europe and the UK **[PH3/31 - INQ000513256]**.

70. By 6th March Martin Landray had prepared the first draft protocol of what became the RECOVERY trial **[PH3/32 - INQ000513258]**. The protocol included some elements of a trial synopsis developed by Richard Peto and of the protocol I had submitted for UKRI funding but was essentially a new protocol that drew heavily on historic large scale (and highly influential) pragmatic clinical trials run by the Clinical Trials Service Unit at the University of Oxford.

71. On 10th March I met with the CMO Christopher Whitty and DCMO Jonathan Van Tam in Whitehall to outline the plans for the RECOVERY trial and seek DHSC endorsement. At this meeting the CMO and DCMO endorsed the plan, effectively giving us the "green light". As requested by the Inquiry, my handwritten note and email to Professor Sir Martin Landray dated 10 March 2020 on the occurrence and outcome of this meeting are exhibited at **[PH3/33; 34 - INQ000221947; INQ000222019]** respectively.

72. That same evening we settled on the name of the trial: 'Randomised Evaluation of COVID-19 Therapy (RECOVERY), see exhibit **[PH3/35 - INQ000513269]**.

73. Official confirmation of the grant award of £2,106,034.00 was made on 14th March by email **[PH3/36 - INQ000513270]** with formal letter **[PH3/37 - INQ000513274]**

74. The trial team and other stakeholders worked intensively during the first weeks of March to finalise the trial design and operations, secure all necessary approvals and contracts.

Design features of the RECOVERY trial

75. Whilst RECOVERY is co-led by Professor Martin Landray and myself, its success lies in the world leading capabilities of the clinical trial units at the University of Oxford and the outstanding expertise and dedication of a large multi-disciplinary team.

76. The RECOVERY trial was established to identify effective treatments for patients hospitalised with COVID-19, and for children hospitalised with Paediatric Multisystem Inflammatory Syndrome Temporally associated with SARS-CoV-2 (PIMS-TS, a rare inflammatory syndrome triggered by COVID-19). Its focus has been on identifying treatments that reduce mortality.

77. To allow rapid recruitment throughout the NHS during the pandemic, RECOVERY had a streamlined design that placed minimal burden on frontline clinical and research staff. This included maximising the use of routinely collected health data.

78. For each treatment, RECOVERY compared standard care at the participant's hospital plus the additional treatment, versus standard care alone. In a factorial design, participants could join more than one treatment comparison if eligible.

79. The primary outcome for COVID-19 was 28-day all-cause mortality, with secondary outcomes being time to hospital discharge and progression to invasive ventilation or death. The primary outcome for PIMS-TS comparisons was duration of hospitalisation. Data were collected via electronic case report forms and, in the UK, via linkage to routine healthcare data.

80. The COVID-19 comparisons recruited adults and children hospitalised with COVID-19. The PIMS-TS comparisons recruited patients under 18 years hospitalised with PIMS-TS. Individual comparisons had additional inclusion and exclusion criteria related to the particular treatment, described in the relevant

publication.

81. We established paediatric and obstetric working groups to provide advice on the design and conduct of the trial in children and pregnant women, since these groups are often excluded from clinical trials.

82. An overview of RECOVERY's design and implementation was published by the investigators **[PH3/38 - INQ000283344]**. The article describes the trial rationale, the use of quality-by-design principles, key design features (Table 1 therein), the streamlined set-up, study procedures, collection of data, use of routine healthcare data, the statistical analysis framework, and the impact on patient care and public health (at that time).

Implementation and result of the RECOVERY trial

83. On 19th March 2020 the first patient was enrolled into the RECOVERY trial, which was announced by the Prime Minister at the No.10 press conference that evening.

84. 177 NHS trusts in the United Kingdom and 23 sites in Asia (India, Indonesia, Nepal, Vietnam) and Africa (Ghana, South Africa) have recruited patients. Expansion internationally was intended to support evaluation of treatments in different settings and population groups (including low- and middle-income countries) and to help address the emergence of further new variants of SARS-CoV-2.

85. With over 48,500 patients recruited, the RECOVERY trial is the world's largest and most influential clinical trial of treatments for moderate to severe COVID-19.

86. RECOVERY has evaluated 16 treatments for COVID-19 and four treatments for PIMS-TS.

87. The trial found four treatments that reduce the risk of death from COVID-19:

    a) ***Dexamethasone*** is a widely available corticosteroid used for decades to treat inflammation. In RECOVERY it reduced mortality by around one-third in the sickest patients (those on invasive ventilation), and by around one-fifth in other patients requiring oxygen but had no benefit in patients not requiring oxygen.

b) ***Tocilizumab*** is a monoclonal antibody that blocks a specific inflammatory pathway mediated by interleukin-6. In RECOVERY it was tested in patients requiring oxygen with evidence of inflammation (blood CRP >75mg/L). It reduced mortality by about one-sixth, in addition to the benefit of dexamethasone.

c) ***Baricitinib*** is another immunomodulator that targets a different inflammatory pathway, mediated by Janus Kinase. In RECOVERY it reduced mortality by around one-eighth, in addition to the benefit of other dexamethasone and/or tocilizumab.

d) ***Casirivimab-imdevimab*** is a combination of neutralising monoclonal antibodies, which block viral invasion of host cells. RECOVERY found it reduced the risk of death by one-fifth in patients who had not yet developed their own antibody response to the virus, in addition to the benefit of other treatments. However, it had no benefit in patients who had already developed their own antibodies.

88. Ten COVID-19 treatments were not found to have any beneficial effect on mortality, time to discharge, or progression to ventilation or death; ***hydroxychloroquine, lopinavir, azithromycin, convalescent plasma, aspirin, colchicine, dimethyl fumarate, empagliflozin, molnupiravir,*** *and* ***nirmatrelvir***.

89. ***High-dose dexamethasone*** (20mg) was associated with a higher risk of death than the standard dose (6mg) in patients who were hypoxic but didn't require ventilatory support. The comparison was stopped early for these participants. It continued until March 2024 for patients requiring ventilatory support, and the results for this group are being analysed.

90. ***Sotrovimab***, another neutralising monoclonal antibody, was tested in a comparison that closed in March 2024, and these results are being analysed.

91. Between May 2020 and January 2022, 237 children were included in PIMS-TS comparisons. There was good evidence ***tocilizumab*** reduced the duration of hospitalisation (Bayesian posterior probability of benefit [PPB] >99%), and moderate evidence that ***corticosteroids*** and ***anakinra*** did so (PPB 87% and

84%, respectively). There was no good evidence of a benefit of ***intravenous immunoglobulin*** (PPB 59%).

92. RECOVERY results were rapidly and widely disseminated to maximise impact. Important results were communicated to policy-makers, researchers, clinicians, and the public within days of unblinding, and full results were generally available as preprints within weeks. Detailed information about the trial, including all results, are publicly available on the trial website (www.recoverytrial.net).

93. The RECOVERY collaborators have published fifteen primary reports, most in *The Lancet* or *NEJM*, and five other papers detail lessons learned from the trial. RECOVERY has had extensive media coverage, being mentioned in over 23,000 news items in 2020-2022, and participants have been kept informed about the trial via newsletters.

94. Widespread immunity means that few patients are now hospitalised with COVID-19 pneumonia, and the last COVID-19 comparisons closed in March 2024. RECOVERY is now studying treatments for influenza and community-acquired pneumonia.

95. None of this would have been possible without the dedication of thousands of NHS and NIHR staff and, of course, the 48,500 patients (and their families) who agreed to take part in RECOVERY.

Achievements of the RECOVERY trial

96. Results from the RECOVERY trial have demonstrably changed worldwide clinical guidelines for the treatment of moderate to severe COVID-19 worldwide.

97. The finding that dexamethasone saves the lives of seriously ill patients provided the first breakthrough in the COVID-19 response. In March 2021, NHS England estimated that the use of dexamethasone had already saved 22,000 lives in the UK and 1 million worldwide. This announcement is exhibited at **[PH3/39 - INQ000222008]**.

98. The RECOVERY trial was deliberately inclusive: the youngest participant was less than six months old and the oldest over 100 years; one third are women; and one sixth are of Black, Asian or Minority Ethnic (BAME) background. Over 300 children participated, as well as 100 pregnant women. Pregnant women are often excluded from trials resulting in a lack of evidence about treatments for them, and so pregnant women were invited to participate (unless there were good reasons to exclude them, such as known adverse effects of a study treatment on mother or child).

99. We have compared the characteristics of those who enrolled in the trial (about 10% of those admitted to hospital with COVID-19) with those who were not **[PH3/40 - INQ000513134]**. This shows that the RECOVERY participants were less frequently female (RECOVERY 37% vs reference population 45%) and were on average slightly younger than the reference population (mean age 63 vs 66 years). RECOVERY participants were more frequently of White background (83% vs 79%) but had similar deprivation status overall.

100. RECOVERY has received multiple awards including the David Sackett trial of the year, BMJ research paper of the year, Times Higher Education Research project of the year, Project Management Institute's best COVID-19 response project of the year, Health Data Research UK's Impact of the Year Award 2021, MRC Outstanding Team Impact Award 2023, and the Prix Galien UK Award 2023 for Best Public Sector Innovation.

101. The trial is cited as a 'world-leading' case study in the UK Government White Paper: *Saving and improving lives: the future of UK clinical research delivery* (March 2021) and is cited as an exemplar of UK life sciences excellence in the UK *Life Sciences Vision* (March 2021). These two documents are exhibited at **[PH3/41; 42 - INQ000221974; INQ000221968]**

102. The RECOVERY trial was also 'lauded' in the G7 report '100 Days Mission to prepare for future pandemic threats' (June 2021), which is exhibited at **[PH3/43 - INQ000101061]**

103. The trial provides a model for future clinical trials, particularly in pandemic settings; it has been described as a 'beacon of excellence' and championed as a model that should be adopted in other countries. For example, in the opinion piece entitled '*Benefits of Streamlined Point-of-Care Trial Designs Lessons Learned From the UK RECOVERY Study*' (December 2022) **[PH3/44 - INQ000221972]**, three of the US Food & Drug Administration leadership team have stated that "*Patients in the US would be more likely to benefit from novel findings of effectiveness earlier if a similar streamlined approach to clinical trials were adopted.*"

Innovations of the RECOVERY trial

104. RECOVERY embedded a streamlined clinical trial into routine care, allowing wider access to research and making it possible to recruit the large numbers of participants needed to produce clear, practice changing results.

105. The trial took a proportionate approach to assessing risks to patient safety and wellbeing, mindful that the risks associated with participating in the trial must be considered in the context of usual care for this (then new) disease and the associated high mortality.

106. RECOVERY pioneered extensive data linkage to routinely collected health data. Data are brought together from over 25 source files from seven organisations through deployment of 50 bespoke algorithms; this is the first time such broad linkage has been used in a clinical trial. Over 75 full cycles of data linkage have been completed. This outstanding work was led by Professor Marion Mafham.

107. RECOVERY pioneered the derivation and deployment of algorithms to combine various sources of information into study variables that were suitable for statistical analysis. As an example, information on death (the primary outcome) could come from eight different sources (the case report form, the separate personal demographic services in Wales and England, the separate hospital admissions datasets in England, Wales and Scotland; and the mortality registers for England and Wales and for Scotland).

108. By utilising the extensive routine healthcare data available in the UK, RECOVERY increased the completeness, accuracy and range of data on participants.

Appropriateness of making drugs available prior to testing for efficacy

109. Many early national COVID-19 treatment guidelines were recommending the use of treatments for which there were no clinical efficacy data in COVID-19 **[PH3/45 - INQ000513299].**

110. Most of these early recommended treatments were later shown to be ineffective.

111. There were many voices calling for putative treatments to be prescribed outside of well-designed and conducted clinical trials – see exhibit INQ46 **[PH3/46 - INQ000513280]** Light at the End of the Tunnel, to quote: *"Rather than offering therapeutic drugs only to those in the RECOVERY Trial, any hospitalised patients at risk of serious illness should be offered drugs now that are safe and meet a minimum level of efficacy. There is no safety issue. We should give these patients the drugs and track the data from them. There will be resistance to this, because it means altering the RECOVERY Trial process, but this is a lesser risk than denying potentially life-saving drugs to those who need them. The AstraZeneca therapeutic drug – _one of the most promising – _is not part of the RECOVERY Trial in the UK, but we should urgently investigate whether we can speed up its introduction, even with limited doses being available."*

112. I have seen this view repeated many times in health emergencies, when people are desperate for a remedy. Whilst well meaning, this view is wholly misguided.

113. There is incontrovertible evidence that giving unproven drugs outside of clinical trials is harmful in multiple ways:

a) In the US, over 100,000 COVID-19 patients were treated with convalescent plasma outside of a randomised trial, a practice that RECOVERY showed (by randomising 11,558 patients) was ineffective in patients with moderate to severe COVID-19. Unreliable observational data are, nevertheless, still being used to justify the use of convalescent plasma in this patient group.

b) US health insurers are estimated to have spent about $130 million per year on ivermectin for COVID-19, a drug for which is almost certainly ineffective for COVID-19 **[PH3/47 - INQ000513300]**.

c) Hydroxychloroquine was extensively used for COVID-19 but data from clinical trials show it is ineffective as a treatment for COVID-19 **[PH3/48 - INQ000513301]**.

114. Emergency (or compassionate) use of unproven treatments for COVID-19 outside of clinical trials wasted human and financial resources, impeded the generation of reliable evidence, may have caused direct harms to health, may have undermined trust in health care and scientific professionals, and promoted a regressive, non-evidence-based approach to healthcare interventions.

115. The belief that data from observational (non-randomised) studies or '*real world data*' provide reliable estimates of treatment effectiveness is misguided and dangerous.

Challenges for the RECOVERY trial

116. Establishing and running RECOVERY was itself an enormous operational challenge that required sustained high intensity work by a very large number of people. In addition, there were numerous external challenges, such as disagreements with our choice of drugs or the trial design. However, there were no serious structural or systemic barriers.

117. A proliferation of working groups during the pandemic did lead to some lack of clarity over decision making. CTAP had recommended a drug for inclusion in RECOVERY, which we had accepted, but this was then challenged by a separate group, the antiviral taskforce.

118. We had been lobbying DHSC to evaluate molnupiravir in RECOVERY from 12th October 2021, with little success. CTAP had been disbanded but was reconvened as we were entering the Omicron BA.1 wave and molnupiravir was formally recommended for inclusion in RECOVERY by CTAP on 13th December 2021. A recommendation that was accepted by the CMO, myself and Martin Landray that same day. We subsequently followed up with further requests for confirmation of

supply, culminating in a request on the 20th December 2021 following receipt of approval by ethics and regulatory bodies on 20th December 2021 of amendment 23 of the protocol, which included molnupiravir. In response to that request, a call was organised with Lucy Chappel Chief Scientist for DHSC on 21st December 2021. On this call we were told molnupiravir would not be supplied for RECOVERY. At that time, the reasons were not clear to us, but I believe it may have been due to constraints upon the use of the DHSC molnupiravir procurement.

119. As a result, Martin Landray and I wrote a letter to the CMO to contest the decision **[PH3/22 - INQ000513244]**. Agreement to supply molnupiravir was received from DHSC on 18th January and enrolment started on the 24th January. 923 patients were finally recruited to the molnupiravir comparison (445 allocated molnupiravir and 478 allocated usual care) and no significant difference in mortality was observed between the two groups. However, the comparison lacked statistical power to exclude a modest difference in outcomes. Had we been able to include molnupiravir from October or November 2021 we would have recruited more patients and would have had a more robust conclusion. The lesson from this event is that perhaps some complacency and/or fatigue had entered the system by late 2021 which led to disbanding CTAP and reduced urgency to supply new products for clinical evaluation.

120. RECOVERY was subjected to an MHRA audit in March 2021. This was problematic on several levels. First, it was an enormous burden on the clinical trials unit at a time when the RECOVERY trial was still extremely busy. Second, the inspection team did not appear to have the direct experience of leading clinical trials nor an appreciation of the principles of good clinical trials, instead applying a rigid application and interpretation, and sometimes over interpretation, of clinical trials guidance.

Systems and processes for clinical trials during the COVID-19 pandemic

121. The RECOVERY trial (and other clinical trials) was enormously facilitated by several **national structural assets**:

a) The NHS.

b) NHS digital and other national data systems (Hospital Episode Statistics, Scottish Morbidity Record, Secure Anonymised Information Linkage [SAIL, Wales], Intensive care data from the Intensive Care National Audit and Research Centre [ICNARC] and the Scottish Intensive Care Society Audit Group [SICSAG], UKHSA Coronavirus testing data from the Second Generation Surveillance System [SGSS]).

c) Single ethical and regulatory approvals with national legitimacy (HRA and MHRA).

d) The National Institute of Health Research (NIHR) and the NIHR Clinical Research Network.

e) PHE/UKHSA (allowing linkage to national diagnostic data from SGSS).

122. The RECOVERY trial success was in large part a result of clear and robust **national leadership** from the UK Government and other central institutions, particularly:

a. The clear support of the CMOs, DHSC and the NHS leadership for rigorously evaluating COVID-19 treatments through clinical trials **[PH3/49-53 - INQ000048103 INQ000068589 INQ000069095 INQ000070395 INQ000072041]**

b. DHSC and PHE/UKHSA support in drug provision and supply;

c. The designation and support by the National Institute of Health Research (NIHR) and the NIHR Clinical Research Network of a limited number of national Urgent Public Health prioritised studies and of the Government Office for Science of National Core Studies **[PH3/17 - INQ000513294]**;

d. Establishing the COVID-19 Therapeutics Advisory Panel (CTAP) to review and recommend drugs for evaluation;

e. Willingness of NHS Digital and others to support extensive data linkage as a mechanism to streamline the trial, and

f. Timely and constructive review and feedback on the trial by the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Authority (MHRA).

123. This central strategic and structural support combined with academic independence and leadership in delivering the trial proved very successful.

124. RECOVERY is used as a case study in the 2021 white paper 'Saving and improving lives: The Future of UK Clinical Research Delivery'. RECOVERY demonstrated that:

a) There is considerable scope to accelerate and simplify ethical, regulatory and contractual approval of clinical trials.

b) National infrastructure such as the NIHR Clinical Research Network enormously facilitate the conduct of large scale, practice-changing trials.

c) The completeness, accuracy and range of data on trial participants can be enhanced by utilising the extensive routine healthcare data available in the UK.

d) Embedding streamlined clinical trials into routine care allows wider access to research and make it possible to recruit the large numbers of participants needed to produce clear, practice-changing results.

e) Large-scale platform trials can be highly cost-efficient, with a cost per participant of several hundred pounds, versus thousands in a typical stand-alone trial.

The clinical research platforms established in the UK during the pandemic have been effectively stood down by UKRI and NIHR and any under-spend recovered. RECOVERY was asked to return unspent funds despite us presenting a case to UKRI and NIHR for using these funds to maintain the platform and study influenza, the most likely next pandemic threat **[PH3/54 - INQ000513303]**. Whilst it is impractical to maintain a whole suite of clinical trial platforms simply in preparation for the next major epidemic or pandemic, I believe there was a good case for a period of continued strategic investment to consolidate the most innovative and cost-effective platforms and redirect them to everyday health problems.

Lessons and recommendations

General

125. The pandemic resulted in the UK spearheading an unprecedented acceleration of health research, that demonstrably saved lives and protected the health care system. Examples of better ways of working included: national prioritisation and leadership, a strategic and coordinated portfolio of trials, proportionate and fast ethical and regulatory oversight, streamlined point-of-care trials embedded in routine care, adaptive platforms trials for efficient and continuous learning, and extensive use of electronic health data. **Recommendation 1:** ***Apply the lessons from the UK's successful research response to the pandemic more broadly to other health challenges, such as dementia and cancer. An appropriate body to embed this learning would be the National Institutes for Health and Care Research (NIHR).***

Product development

126. As the pandemic began, the UK, but more broadly the world, did not have a portfolio of potential therapeutics to evaluate against an emerging coronavirus. Initially RECOVERY was testing repurposed drugs with a low probability of success.

127. Those small molecule antiviral drugs that were eventually shown to have some benefits – remdesivir (Veklury), molnupiravir (Lagevrio), and nirmatrelvir plus ritonavir (Paxlovid) - were all developed by US companies. Whilst the UK does have the scientific capabilities to conduct the foundational research to develop such products, there is insufficient investment in their development.

128. Whilst monoclonal antibodies were shown to be beneficial, they were highly susceptible to the development of resistance in new SARS-CoV-2 variants. This problem might be overcome with further research and development. UK academic centres have demonstrated their capability for high-quality early-stage development of monoclonal antibodies, and this is an area where the UK can make an important contribution to the development of a suite of medical countermeasures against pandemic threats.

129. Despite initiatives such as the WHO R&D blueprint and the 100 Days Mission, we are not where we should be in terms of research and development for major infectious (and other biological) threats. There is not yet a coordinated and credible UK national or international programme for identifying, funding, commissioning and tracking the required research and development. Whilst the US National Institute of Allergy and Infectious Diseases (NIAID) and the WHO R&D blueprint have been working on identifying prototype pathogens for R&D, this needs to be translated into concrete progress. The US National Institute of Allergy and infectious Diseases ReVAMMP programme (Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness) is a good example of strategic government investment in a programme of research and development aimed at producing products ready for clinical evaluation.

130. The UK does not to my knowledge have a national strategy for strengthened health security through medical countermeasure development (drugs, vaccines and diagnostics). There is a need to (i) choose national research and development priorities, (ii) identify and support 'mission critical' domestic assets such as high containment research and development laboratories, GMP biomanufacturing at different scales, and clinical research capabilities, (iii) engage industry in a product development programme, and (iv) outline how the UK will partner internationally for mutual benefit with countries at risk of high-consequence infectious disease outbreaks and agencies like the US Biomedical Advanced Research and Development Authority (BARDA) and Defence Advanced Research and Development Authority (DARPA), and the EU Health Emergency Preparedness and Response (HERA) directorate. **Recommendation 2: *Develop a 5–10-year national research and development strategy for medical countermeasures for major infectious and other biological threats.*** The UK Advanced Research and Invention Agency (ARIA) could play a key role in catalysing and developing this strategy.

131. A research and development strategy needs implementation. The Coalition for Epidemic Preparedness Innovations (CEPI) has in part acted as a catalyst for research and development for vaccines for pandemic threats. Except the US ReVAMMP programme mentioned in paragraph 130, no similar initiative exists for therapeutics. **Recommendation 3: *Consider establishing a CEPI-like***

organisation to accelerate the development of therapeutics for major infectious and other biological threats.

132. A research and development strategy needs funding. The UK has invested in a Health protection Research Unit (HPRU) in emerging and zoonotic infectious diseases but this has had limited impact in enhancing UK medical countermeasure preparedness since (i) the funding level is very modest, (ii) animal research is not permitted, (iii) de novo development of new vaccines and therapeutics are not permitted, (iv) clinical trials are not permitted, and (v) the focus is largely domestic. Whilst there are intermittent funding "calls" from research funders like UKRI and Wellcome for R&D on medical countermeasures for infectious diseases, these are intermittent, short term, and often responsive rather than strategic. **Recommendation 4:** ***Invest in a medium-term programme of research and development on medical countermeasures for infectious and other biological diseases threats.***

Policies and practice

133. The UK was right to insist on rigorous evaluation of all proposed new treatments in clinical trials and was clearly the world leader in this respect. "Emergency Use Authorisation" by some regulatory authorities was deeply unhelpful in the pandemic and has been similarly unhelpful in other epidemics. **Recommendation 5:** ***The UK Government should lobby against "Emergency Use Authorisation" of unproven therapeutics (and vaccines) in infectious disease epidemics or pandemics when a clinical trial is feasible.***

134. The experience of delivering timely, high-quality approvals achieved during the pandemic should act as a spur to consistently deliver rapid, coordinated, consistent, and proportionate review. **Recommendation 6:** ***Explore the reasons for slow initiation of clinical trials in the UK and embark on a programme of reform and streamlining. This would require the involvement of NIHR, NHS, MHRA and HRA.***

135. The UK was right to put in place central prioritisation, coordination and facilitation of critical research, avoiding the chaotic and wasteful research experienced in much of the rest of the world. The Urgent Public Health (UPH)

status was particularly impactful. **Recommendation 7: *Maintain the UPH system and consider if it might usefully be extended to other health research priorities.***

Clinical trial research infrastructure

136. Running national-scale clinical trials for both emergency and common conditions is hugely facilitated by several national assets. The UK benefits enormously from NHS standard research costing and contracting, electronic health data (e.g. Health Data Research UK, NHS DigiTrials), and research nurses and associated staffing provided through the NIHR Clinical Research Networks. **Recommendation 8: *Commit to supporting and strengthening harmonised national infrastructure and systems for clinical trials, such as NIHR CRN, HDR UK and NHS DigiTrials.***

137. The NHS should recognise randomised clinical trials as a component of routine clinical care (not an optional add-on). This should be recognised in job plans and remuneration of individuals. Contribution to clinical trials activities should be a Board-level responsibility for all NHS organisations (acute hospital trusts and equivalent organisations) and a marker of the quality of the clinical service provided. **Recommendation 9: *Embed clinical research as a core component of high-quality NHS care.***

138. The NHS collects large quantities of clinical data (e.g. primary and secondary care, death registries, clinical audits, laboratory testing). There are opportunities to further improve the efficiency of health data services and the proportionality of information governance controls so that these data can be best used to support clinical research. **Recommendation 10: *Continue to promote and advance efficient access to NHS and other health data for the purposes of improving patient care, health service efficiency, and public health.***

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: _____

Dated: 28 November 2024