Witness Name: Roger Spencer
Statement No.: 1
Exhibits: 9
Dated: January 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF ROGER SPENCER

I, Roger Spencer, will say as follows: -

1. I am the Chief Executive Officer at The Christie NHS Foundation Trust ("The Christie"), a position that I have held since December 2013. I am a qualified nurse with a master's qualification in Business Administration and over 35 years' experience working in the NHS both clinically and in senior management roles in a number of NHS Trusts.

2. The statement is intended as an organisational response by The Christie and has been prepared with input from a number of key individuals. This statement has also been through a verification exercise to check the accuracy of the information contained herein. In providing this statement, I have received assurances from the key contributors and via the verification exercise that where information is not in my direct knowledge, it is accurate to the best of the knowledge and belief of The Christie, and in signing the statement of truth at the end of this statement I reasonably rely on those assurances.

Introduction

3. The Christie is one of Europe's leading cancer centres, treating around 60,000 patients a year. We have a history of over 100 years of leading cancer care. The Christie employs approximately 3,700 staff and last year had an annual turnover of £429 million. In addition to our commissioned NHS work, The Christie has a private patients' suite which increases income for our NHS services. The Christie Charity is the second largest hospital charity in the country with 50,000 active supporters to help bring in around £16 million a year which helps fund our research and additional patient services.

4. The Christie is one of Europe's experimental cancer research centres and an international leader in research and development. Our early clinical trials unit delivers over 650 trials at any one time, and we are an international leader in research, with world first breakthroughs for over 100 years. The Christie is ranked as the most technologically advanced cancer centre in the world outside North America. We have been named by the National Institute for Health Research (NIHR) as one of the best hospitals providing opportunities for patients to take part in clinical research studies. Manchester has been ranked as the best in the UK for cancer research, most of which is undertaken on the Christie Hospital site. We are part of the Manchester Cancer Research Centre in partnership with The University of Manchester and Cancer Research UK.

5. The Christie is a regional service and as a Trust, we have ambitions nationally and internationally. We are based in Manchester and serve a population of 3.2 million across Greater Manchester and Cheshire. We deliver care and treatment in multiple hospitals and Christie centres across Greater Manchester and Cheshire. As a national specialist, around a quarter of our patients are referred to us from other parts of the country.

6. The Christie is a tertiary care centre and patients are diagnosed with cancer prior to referral to us. Patients who live in England and get a cancer diagnosis, and are being treated on the NHS, can be referred to The Christie by their specialist doctor at their local hospital. The Christie is also able to provide second opinions to patients looking for additional advice and support. This is done by a patient's GP making a referral to The Christie.

7. The Christie has the largest radiotherapy department in the world on our main site in south Manchester, plus radiotherapy centres in Oldham, Salford and Macclesfield. We deliver chemotherapy treatment through the largest chemotherapy unit in the UK, as well as via 14 other sites and in patients' homes. We provide highly specialist surgery for complex and rare cancers and provide a wide range of support and diagnostic services. The Christie was the first NHS organisation in the UK to deliver high energy proton beam therapy. We are a provider of cutting-edge immunotherapy such as CAR-T therapy.

8. During the relevant period our focus was on maintaining cancer services for our patients.

Collaborative working by The Christie in response to the Covid-19 pandemic, during the relevant period, with:

a) NHS England;

b) other NHS Trusts.

9. The Christie Medical Director established and chaired a weekly virtual meeting of national cancer centre clinical leads from organisations across the country including The Royal Marsden, Mount Vernon, University College London Hospitals (UCLH), Guys & St Thomas's, Southampton, Birmingham, Sheffield, Nottingham, Cambridge, Preston, Leeds, Newcastle, Belfast and Clatterbridge Centre for Oncology to focus on the safe delivery of services to cancer patients through the pandemic. They discussed and shared information and experience on issues such as infection control and ensuring the continuation of the delivery of chemotherapy, radiotherapy and surgery. This included input from the NHS National Clinical Director for Cancer, Peter Johnson, and the Royal College of Radiologists. The meeting continues on a monthly basis to the present day and is an established forum for discussion of issues relating to cancer care and is supported by the Royal College of Radiologists.

10. Christie clinicians were involved in the national cancer clinical reference groups that were looking at adaptations to cancer care to keep patients safe, looking at issues such as infection control and adapting treatments such as radiotherapy, surgery and chemotherapy.

11. Our Executive Team, namely the Chief Operating Officer, Executive Chief Nurse and Medical Director participated in the national covid-19 briefing sessions facilitated by the Department of Health and Social Care (DHSC) and NHS England (NHSE).

12. NHSE asked the NHS organisations within Greater Manchester to set up the Greater Manchester (GM) Gold Command at the beginning of the pandemic. This was a group of leaders from across acute hospitals, mental health trusts, primary care and specialist providers. The attendees took turns in chairing the group. The purpose of the group was to coordinate the health response to the pandemic in GM and was part of the command-and-control structures that were implemented nationally at the beginning of the relevant period to ensure that there was consistency with response, clear leadership, accountable decision making, and accurate and up to date, far-reaching communication.

13. Our executive leads (initially Deputy Chief Executive Officer and then Director of Strategy and Chief Operating Officer) were involved in the Greater Manchester Gold Command meetings from its formation. These virtual meeting took place daily, 7 days a week in the first months of the pandemic and twice weekly after. They discussed all aspects of the

operational response including the need to protect services for conditions other than COVID, including cancer.

14. The Christie was designated as a green site by the GM Gold Command which meant that we were protected in terms of the acute care response to the pandemic. The ethos of 'green site' status was to minimise the number of covid positive patients on site so that the Trust could continue providing cancer care and protecting our beds to enable this to happen. This meant that our inpatient beds were not included in the acute bed stock that was discussed by the GM Gold Command meetings for use for the pandemic response. Our beds were protected solely for our cancer patients. We still looked after patients who were on our cancer treatments and who tested Covid-19 positive.

15. As part of the green site status, we established the Greater Manchester Surgical Cancer Hub which meant that The Christie provided oncology surgery for other Trusts across Greater Manchester and Cheshire who could not undertake cancer surgery due to the restrictions in place in their organisations. There were two surgical leads, Professor Sarah O'Dwyer (The Christie) and Mr Dominic Slade (Northern Care Alliance) and it was coordinated by the Greater Manchester Cancer Alliance. Cancer Alliances bring together clinical and managerial leaders from different hospital trusts with other health and social care organisations, third sector and service users to coordinate cancer services across regions. Cancer Alliances look at the care and support patients should expect to receive from diagnosis to follow-up support across whole populations of patients, so they can address variations in care and implement best practice. A Clinical and Operational Delivery Group was established to manage the Hub. This was a group that consisted of one of the surgical leads, an operational lead from The Christie and a representative from the GM Cancer Alliance. The group prioritised patients requiring cancer surgery and directed them to the appropriate place of treatment.

Representations made or advice provided by The Christie to any government department or agency, parliamentary select committee or NHS body in respect of care and treatment for cancer patients during the relevant period

16. Christie clinicians were part of the national clinical reference group for chemotherapy. Christie oncologists developed and provided the initial draft for what became the National Institute for Health & Care Excellence (NICE) guideline around the national classification and prioritisation of treatment for chemotherapy patients. The guide was a response to the

NHS action plan issued on 3 March 2020 for people to receive the essential care and support services they need, noting however that sometimes this might mean that other services are reduced temporarily. This document provided support to the challenge of continuing the proper management of these cancer services while protecting resources for the response to the pandemic by identifying those patients most at risk to access the right treatment. The guide defined the intention of the treatment for patients; the categories used in the guide are (i) patients who are very likely to be cured; (ii) those where the intention is to prolong life; and (iii) those for whom treatment was about symptom control at end of life. The Christie were not responsible for the approval of the final version of this national guidance, this was the role of the national clinical reference group. The Christie were involved in the development of the first iteration of it for consideration by the national group. Christie clinicians were also involved in the follow up discussions that resulted in the final approved version. The categorisation of patients by priority level for SACT (systemic anti-cancer therapy) was adopted word for word from the Christie document and the view of the Christie was that the final guidance was appropriate. The Clinical guide for the management of non-coronavirus patients requiring acute treatment: Cancer, 23 March 2020 Version 2 RS1 / INQ000470416, sets out the principles to be applied. The key principles of this guide, which is intended to support decision making by individual treating teams are:

- Definitions of a vulnerable patient and those cancer patients who were most at risk of becoming seriously ill if they contracted Covid-19, including;
- Support in decision making around cancer treatment so that those most at risk continue to receive access to treatment
- Categorisation of services
- Leadership
- Surgical patients and the categorisation of priority levels. The guide uses the following priority levels:
    - Level 1a: Emergency – operation needed within 24 hours to save life
    - Level 1b: Urgent – operation needed with 72 hours
    - Level 2: Elective surgery with the expectation of cure
    - Level 3: Elective surgery can be delayed for 10-12 weeks will have no predicted negative outcome
- Systemic anti-cancer treatment (chemotherapy) and categorisation of priority of treatment. The guide is clear that this would vary patient to patient, and will differ according to tumour type, but it suggested that clinicians begin to categorise patients into priority groups 1-6. If services were disrupted, patients could be

prioritised for treatment accordingly. The guide also prompted consideration as to whether systemic therapies could be given in alternative regimens, different locations or via other modes of administration to minimise patient exposure and maximise resources. It also encouraged alternative methods to educate, monitor and review patients on systemic therapies. Identify alternative arrangements to minimise patient exposure. The priority levels adopted in the guide where:

- Priority level 1
  - Curative therapy with a high (>50%) chance of success.
  - Adjuvant (or neo) therapy which adds at least 50% chance of cure to surgery or radiotherapy alone or treatment given at relapse
- Priority level 2
  - Curative therapy with an intermediate (20- 50%) chance of success.
  - Adjuvant (or neo) therapy which adds 20 – 50% chance of cure to surgery or radiotherapy alone or treatment given at relapse
- Priority level 3
  - Curative therapy of a low chance (10 – 20%) of success
  - Adjuvant (or neo) therapy which adds 10 – 20% chance of cure to surgery or radiotherapy alone or treatment given at relapse
  - Non-curative therapy with a high (>50%) chance of >1 year of life extension.
- Priority level 4
  - Curative therapy with a very low (0-10%) chance of success.
  - Adjuvant (or neo) therapy which adds a less than 10 chance of cure to surgery or radiotherapy alone or treatment given at relapse
  - Non-curative therapy with an intermediate (15-50%) chance of > 1 year life extension.
- Priority level 5
  - Non-curative therapy with a high (>50%) chance of palliation / temporary tumour control but < 1 year life extension.
- Priority level 6
  - Non-curative therapy with an intermediate (15-50%) chance of palliation or temporary tumour control and < 1 year life extension

- Radiation therapy and categorisation of priority of treatment as follows:
  - Priority level 1
    - Patients with category 1 (rapidly proliferating) tumours currently being treated with radical (chemo)radiotherapy with curative intent where there is little or no scope for compensation of gaps.

        - Patients with category 1 tumours in whom combined External Beam Radiotherapy (EBRT) and subsequent brachytherapy is the management plan and the EBRT is already underway.
        - Patients with category 1 tumours who have not yet started and in whom clinical need determines that treatment should start in line with current cancer waiting times.
    - Priority level 2
        - Urgent palliative radiotherapy in patients with malignant spinal cord compression who have useful salvageable neurological function.
    - Priority level 3
        - Radical radiotherapy for Category 2 (less aggressive) tumours where radiotherapy is the first definitive treatment.
        - Post-operative radiotherapy where there is known residual disease following surgery in tumours with aggressive biology.
    - Priority level 4
        - Palliative radiotherapy where alleviation of symptoms would reduce the burden on other healthcare services, such as haemoptysis.
    - Priority level 5
        - Adjuvant radiotherapy where there has been compete resection of disease and there is a <20% risk of recurrence at 10 years, for example most ER positive breast cancer in patients receiving endocrine therapy.
        - Radical radiotherapy for prostate cancer in patients receiving neo-adjuvant hormone therapy
- General measures across all services to reduce patient contact and maximise workforce capacity, through consideration of:
    - Minimising face to face appointments
    - Reducing dwell time in services
    - Input and support from self-isolating staff members.

17. Christie clinicians worked closely with the Royal College of Radiologists in the development of Coronavirus (Covid-19) clinical oncology resources that were published throughout March and April 2020 on the Royal College of Radiologists website. Christie clinicians were named as contributing to a number of the guidelines but the Royal College will be better placed to talk to any of those resources. In this statement I will only comment on documents relevant to this response.

Impact of Covid-19 on the diagnosis and treatment of colorectal cancer

How patients with colorectal cancer were treated at The Christie during the relevant period.

18. Colorectal patients continued to be referred from other hospitals and treated throughout the relevant period with chemotherapy, radiotherapy and surgery. Between April and May 2020 there was a reduction in surgical activity from a monthly average of 38 colorectal operations between March 2018 and March 2020 to a monthly average of 17.5 colorectal operations in April and May 2020.

19. No surgery took place on 26 and 27 March 2020. This was because the surgical team were adapting their practices to ensure the safety of patients and staff. On these 2 days the theatre teams undertook simulation-based training in theatres to reassure staff around the changes in practice. The surgical teams were also fit tested for the appropriate masks (FFP3) and where necessary head gear (hoods). This PPE was procured by the Trust with no issue. The simulation training tested out the changes in the way the theatres ran with additional precautions in place. The changes were outlined in the Intercollegiate General Surgery Guidance on Covid-19, 27 March 2020 RS2 / INQ000381145 This guidance outlined that there should be:
    - A minimum number of staff in theatre
    - Appropriate PPE for all staff in theatre depending on role and risk
    - Smoke evacuation for diathermy / other energy sources
    - Team changes will be needed for prolonged procedures in full PPE
    - Higher risk patients are intubated and extubated in theatre – staff immediately present should be at a minimum.

20. The implementation of the additional precautions detailed above, and changes to the type of surgery undertaken (see paragraph 39) initially resulted in longer theatre time and there was therefore a reduction in the number of operations that could be safely undertaken. This accounts for the drop in activity in April and May 2020 from an average of 38 colorectal surgeries per month to 17.5.

21. Radiotherapy and chemotherapy activity continued in line with our normal pre pandemic activity levels.

22. The referral criteria for colorectal cancer patients did not change during the relevant period. The only change to our normal referral criteria was that we took a small number of referrals (less than 10) for patients with suspected colorectal cancer for diagnostic investigations and surgical treatment. Prior to the relevant period, these diagnostics would have been done at the referring hospital prior to a referral being made. This small number of referrals for diagnostic investigations were not done at referring hospitals because an assessment was done on a case-by-case basis to see where patients could most appropriately be seen. We had some additional capacity at the Christie, but this was not quantified.

Details of the annual number of patients treated for colorectal cancer at The Christie during the relevant period.

23. There has been no significant change identified in the overall numbers and types of treatments delivered during the relevant period for colorectal cancer. There were 5778 treatments delivered (radiotherapy, chemotherapy and surgery) in the relevant period for colorectal patients compared to 5674 in the previous equivalent number of months, which represents a 1.8% increase.

Details of the type of treatments for colorectal cancer, including outpatient appointments and procedures, undertaken at The Christie during the relevant period.

24. The Christie continued all treatments (chemotherapy, radiotherapy and surgery) for colorectal cancer across the relevant period. There was a 5-week period in April to May 2020 where our activity decreased slightly from a monthly average of 236 treatments to 218 This relates to surgical colorectal activity. There were 19 colorectal surgical cases undertaken in April 2020 and 16 in May 2020 compared to a monthly average of 42 across the rest of the period. I have already address the reasons for a reduction in surgical activity during this period.

25. At The Christie we continued to review patients during their treatments. The frequency of these reviews did not change but they were delivered via an increased number of telephone and virtual reviews as well as continued face to face appointments. The purpose of this was to reduce footfall in the trust to protect both patients and staff and to allow patients to remain at home if they were shielding. Virtual and telephone appointments were offered for most outpatient appointments including new and follow-up appointments. A significant number of face-to-face attendances were moved to telephone and video

consultations. Staff were able to use a system called 'Attend Anywhere' that enabled video appointments to be carried out or they simply spoke to patients over the phone. Between March 2018 and March 2020, we did an average of 44 telephone appointments a month. Between April 2020 and June 2022, we did an average of 214 per month. That represents an average increase of 387% per month. The pandemic allowed us to bring forward these changes to the way we offer patients their outpatient appointments. These planned changes were done in partnership with patients who have told us that they like the option of doing some appointments over the phone or virtually. It can avoid patients having long journeys to the hospital site. We continue to get patient feedback around this.

The referral pathway to The Christie during the relevant period.

26. The only change to our normal referral criteria was that we took a small number of referrals for patients with suspected colorectal cancer for diagnostic investigations and surgical treatment (less than 10).

27. Referrals continued to be received in the usual way during the relevant period for specialist cancer work for colorectal patients. As I explained earlier in this statement, The Christie were also part of the GM Surgical Cancer Hub that prioritised patients in GM who required cancer surgery that could not be provided at their local hospital site. The criteria for referring patients with colorectal cancer to the GM Surgical Cancer Hub were:

    a) The patient had a diagnosis of colorectal cancer
    b) The patient had been discussed at their local multi-disciplinary team (MDT) meeting (this would take place in the patients local hospital)
    c) The MDT had decided that surgery was the appropriate treatment
    d) The patient was classified as priority 2 (procedures to be performed in < 1 month), in line with the Federation of Surgical Specialty Associations clinical guidelines
    e) Capacity was not available in the local hospital.

These processes were set out in a formal and agreed referral pathway for the GM Surgical Hub, in an agreed Standard Operating Procedure - RS3 / INQ000381146. The Federation of Surgical Speciality Association Clinical Guidelines issued the guidelines in its Clinical Guide to Surgical Prioritisation During the Coronavirus Pandemic which were followed by The Christie – RS4 / INQ000381147.

28. For non-surgical patients the pathway was not changed and patients continued to be diagnosed at other hospitals and referred for chemotherapy and radiotherapy treatment at The Christie.

The main issues that The Christie identified in relation to the diagnosis of colorectal cancer during the relevant period.

29. As a specialist cancer centre with a tertiary practice, The Christie receives referrals for colorectal cancer surgery for patients with complex and/or advanced disease. The Christie does not routinely receive referrals for patients with primary colorectal cancer. These patients are usually operated on within secondary care (other hospitals). The exception to this during the relevant period is where there was no surgical capacity at the local hospital, as detailed above.

30. As a specialist cancer centre with a tertiary practice, screening is not within the scope of the work delivered by The Christie. We also do not undertake primary diagnostics. During the relevant period, the change to our normal referral criteria was that we took a very small number of patients (less than 10) with suspected colorectal cancer for a diagnostic examination under anaesthesia (EUA).

31. During the period there was a change in our referrals related to a very small number of patients who were referred through the GM Surgical Cancer Hub with suspected primary colorectal cancer (i.e. not complex or advanced) on a two week wait referral (the NHS cancer wait standard that a suspected cancer referred by a GP should be seen for an urgent hospital appointment in 2 weeks). I have already detailed this process. Prior to the relevant period The Christie did not accept direct referrals for patients to be seen within two-weeks for suspected colorectal cancer.

32. The Christie are not involved in bowel screening or diagnostic colonoscopy services. We undertake surveillance or 'check-up' endoscopies only. These are used to check the bowel following the removal of a bowel cancer. Surveillance endoscopies were paused in their entirety for a 6-week period in March – May 2020 and restarted once we had the personal protective equipment (PPE) and testing in place for patients. This pause in surveillance endoscopies was done based on the guidelines issued from the Intercollegiate General Surgery Guidance on Covid-19 (Intercollegiate General Surgery Guidance on COVID-19 UPDATE, 27 March 2020 from the Royal Colleges of Surgeons RS2 / INQ000381145). Pre-pandemic there were an average of 27 surveillance scopes undertaken per month. In

March 2020, 15 were carried out, none were done in April and 6 in May 2020. From June 2020 to June 2022 an average of 36 surveillance scopes were undertaken per month. There were no challenges in procuring the required PPE, this was done in a timely way as the requirements were introduced.

33. The Christie do not receive direct referrals from GPs due to The Christie is a tertiary centre.

34. Technology was adapted for both the review and reporting of diagnostic scans and images, and for radiotherapy planning to be undertaken and delivered by staff working from home. The Christie implemented 'Attend Anywhere' virtual video consultation technology to allow patients to have their outpatient appointments virtually, as detailed earlier in this statement. We also implemented telephone appointments as an alternative.

35. The Christie experienced no specific issues in terms of the reluctance of, or delay in, symptomatic people accessing healthcare at The Christie. As a tertiary centre, those patients we saw were either under the care of other hospitals, or already under our care. Those patients who were under our care were spoken with and reassured. Our experience was that patients attended for their appointments or chose to have their appointments virtually or over the telephone, where that was possible.

36. During the relevant period, the average day on the patient pathway (from referral by the GP to receipt of the referral at The Christie) that colorectal referrals were received by the Christie increased, with the mean day that referrals for colorectal patients were received at The Christie was later than before the relevant period. Between March 2018 and March 2020, the average (mean) day referrals were received at The Christie for treatment was day 53 (median was 46). This increased to an average (mean) of day 64 in the relevant period (median was 56). This means patients pathways were getting longer. The Christie can however only comment on care from the point when a patient comes under our care which, as a tertiary centre, is further along the pathway.

37. Adaptations were made in terms of the requirements around personal protective equipment (PPE) use and testing of both patients and staff in line with the national guidelines as they came through. Beyond this, changes around the use of technology to support home working and virtual appointments, have already been dealt with. There were no specific changes to or implementation of new diagnostic tools.

The main concerns in relation to the treatment of colorectal cancer at The Christie during the relevant period.

38. The number of confirmed colorectal cancer cases referred for treatment in the relevant period was within a normal range.

39. As I have explained earlier in this statement, surgery was suspended for 2 days (Friday 27 and Monday 30 March 2020) to ensure appropriate protocols were in place including the appropriate PPE for surgical procedures, in line with the Royal College of Surgeons Covid-19 Good Practice for Surgical Teams – RS5 / INQ000381148. From 13 to 22 December 2020 surgery was reduced due to an outbreak of Covid-19 on the surgical ward meaning there were fewer beds to safely accommodate patients. We did use bed capacity in The Christie Private Care in this period to minimise the impact on services. This reduction meant the number of colorectal patients operated on in the month was 35 against a monthly average in the period of 42 cases.

40. In terms of cancellations or delays in treatment:
    a) Surgery: because we were designated as a green site we were able to carry on with our planned activity and to undertake the surgery referred through the GM Cancer Hub, our overall surgical activity increased during the relevant period from an average of 39 operations a month to an average of 42 per month. Surgery was, as I have detailed, suspended for 2 days (Friday 27 and Monday 30 March 2020) and reduced during outbreaks in December 2020 (as detailed above).
    b) Laparoscopic procedures: these are a technique for surgical procedures that are undertaken through small cuts and a camera inserted to operate inside the abdomen. This technique is potentially an aerosol-generating procedure which can increase the risk of transmission of Covid-19 and so in the first 3 months of the relevant period we undertook open procedures rather than laparoscopic procedures. Open procedures are surgery performed in a traditional technique where a patient is opened up. The open procedures were conducted with adequate infection control precautions as per guidance from specialist surgical associations (Intercollegiate General Surgery Guidance on COVID-19 UPDATE, 27 March 2020 from the Royal Colleges of Surgeons (RS2 / INQ000381145) (updated 30th May 2020) and Royal College of Surgeons Covid-19 Good Practice for Surgical Teams - RS5 / INQ000381148, and NHS England relating to the number of people in theatre, the type of PPE used (such as FFP3 masks and hoods where necessary). The first

laparoscopic case that we performed following the restrictions was 2 June 2020. From this date we resumed activity in line with practice prior to the pandemic. The inability to undertake procedures did not impact surgical activity or patients access to treatment but would have resulted in a slightly longer recovery time.

c) Anastomoses procedures: Colorectal anastomoses refers to a surgical procedure that joins together the remaining parts of the colon following removal of a bowel tumour. The recommendations regarding stoma formation (a surgical procedure that creates an opening in the abdomen to allow waste to exit the body) rather than anastomosis and laparoscopic resection were based on the recommendations on the Intercollegiate General Surgery Guidance on COVID-19 UPDATE, 27 March 2020 from the Royal Colleges of Surgeons (RS2 / INQ000381145). This guidance was followed, because we did not have a problem with getting patients into a critical care bed when they needed one, Anastomosis were not stopped.

d) Radiotherapy: we did not have any delays or cancellations for colorectal patients in radiotherapy.

e) Chemotherapy: for a period of two and a half weeks between 13 April 2020 and 30 April 2020, no new treatments that were classified as 'Priority Level 6' (see paragraph 16: non-curative therapy with an intermediate (15-50%) chance of palliation or temporary tumour control and less than 1 year life extension) were commenced (further detail is provided in paragraph 72 below). This only impacted on the care of one colorectal patient.

41. In terms of an increased used of preoperative radiotherapy, we did not increase the number of patients that received preoperative radiotherapy, however, there was a change in practice to giving more short course radiotherapy (5 doses of treatment over 1 week) rather than long course (25 doses of treatment over 5 weeks) to reduce hospital attendances. This was as advised by the International Expert Consensus Statement regarding radiotherapy treatment options for rectal cancer during the COVID 19 pandemic (Radiotherapy & Oncology 148 (2020) 213-215)) – RS6 / INQ000381149.

42. There was no discernible difference in the numbers of stoma forming procedures in the relevant period.

43. There was no difference noted in the length of hospital stays following surgery for colorectal patients when compared with the six months prior to and following the relevant period.

44. There was no disruption to follow up care. The method of follow up appointments did change with some appointments being moved to virtual or telephone consultation, where clinically appropriate.

Details of any adaptations or changes that were made to the care and treatment of patients with colorectal cancer during the relevant period.

45. As I have detailed earlier in this statement, The Christie was a designated surgical cancer hub for Greater Manchester, and I have addressed those changes in detail earlier in this statement.

46. Proton beam is not indicated for the treatment of colorectal cancer.

47. Prior to the relevant period, The Christie was already delivering chemotherapy via community-based hubs. No changes were made to this arrangement. Community based hubs are sites across Greater Manchester and Cheshire including hospices, other hospital sites, and primary care centres. This enables chemotherapy to be delivered closer to where patients live. This continued throughout the relevant period.

48. The Christie continued with a home care service that was established before the relevant period to deliver some chemotherapy treatments at home. During the relevant period, in line with our plans, we increased the number of chemotherapy treatments that could be delivered in the patient's own home and expanded the service. The activity increased from 5943 total treatments in 2020/21 (Chemotherapy) to 7444 total treatments in 2021/22 (chemotherapy) delivered at home.

49. We set up a new service for patients to have their blood taken closer to home in April 2022 to avoid patients having to come to the main Christie hospital site prior to their systemic anti-cancer therapy (chemotherapy). Where we had an existing chemotherapy service at a location around Greater Manchester and Cheshire, patients could go to their nearest service to have bloods done. Others would come to the main site. The new service expanded on this and set up a blood service (not associated with a chemotherapy delivery site) in new places in our geographical area. This meant that patients were seen in smaller hubs where there were fewer people, therefore minimising contacts. The closer to home hubs are situated throughout Greater Manchester and Cheshire.

50. Radiotherapy is a service The Christie only delivers in the hospital setting. However, and as detailed earlier in this statement, The Christie used short course radiotherapy to decrease the number of hospital visits.

51. The introduction of video and telephone consultations became routine practise. This meant patients did not have to leave their homes to have their appointments. The clinical teams were able to work from home as we were able to facilitate the appropriate technology in people's homes to allow clinicians to plan Radiotherapy treatments and report on diagnostic imaging. This reduced the need for staff to come on site.

Cancellation, delay or de-escalation of surgery for colorectal cancer at The Christie.

52. There were no significant delays around the cancellation or de-escalation of surgery for colorectal cancer in the period. Patients who were rescheduled when surgery was paused for 2 days (March 2020, see para 39) were rebooked and operated on without delay.

53. We are unable to comment on the practice of other providers.

54. The Christie waiting lists were well managed by working collaboratively between clinicians, the Trusts' operational team and the GM Cancer Surgical Hub. Waiting lists at the Christie are not the same as what would ordinarily be understood, because we are a tertiary centre and accept referrals from other Trusts and those referrals result in patient's being listed for treatment.

55. The findings of a study in The Lancet on the 'Impact of the COVID-19 pandemic on the detection and management of colorectal cancer in England: a population-based study', March 2021 RS/06a INQ000236234 which analyses colorectal two week wait presentations, diagnostic investigations, and treatment do not correlate with the experience of The Christie as a tertiary specialist cancer centre in the relevant period. We did not experience the sustained reduction in people referred, diagnosed and treated compared to the year prior.

The ability of The Christie's operating theatres and / or Critical Care Units to provide care and treatment for patients with colorectal cancer due to constraints on capacity caused by a lack of available beds, staff or equipment during the relevant period.

56. At the beginning of the relevant period (March 2020) a Service Level Agreement for anaesthetic services provided by Manchester University Foundation Trust (MFT) anaesthetic staff to cover Christie theatres and some Critical Care sessions was suspended. This was part of MFTs response to the pandemic that required them to use these staff at their own site. This resulted in a reduction in the number of anaesthetic sessions available to cover elective operating lists. The sessions were covered using waiting list initiatives, meaning that anaesthetic staff were offered additional contractual work to create more capacity. As a result, this did not impact colorectal cancer activity.

57. To maintain social distancing required to keep patients safe, the number of patient beds on the surgical wards was reduced from 28 to 22. This was mitigated by access to additional beds through our Christie Private Care facilities, initially through the national NHS contract that was in place with private providers and from September 2020 through a Service Level Agreement. This meant that there was no overall bed reduction. There was no impact on the ability to treat surgical patients over the relevant period due to availability of in-patient beds.

58. As I have previously stated, surgery was suspended for 2 days (Friday 27 and Monday 30 March 2020) to ensure appropriate protocols were in place including the appropriate PPE for surgical procedures (based on Royal College of Surgeons advice – Royal College of Surgeons Covid-19 Good Practice for Surgical Teams - RS5 / INQ000381148.. PPE was procured in line with the guidance through the procurement team and there were no shortages for our staff. From 13 to 22 December 2020 surgery was reduced due to an outbreak of Covid-19 on the surgical ward meaning there were fewer beds to safely accommodate patients. We did use bed capacity in the Christie Private Care in this period to minimise the impact on services.

59. Critical care capacity was increased from 6 to 8 beds from March 2020 and has been maintained since. As a designated green site we were able to accommodate cancer surgery patients on Critical Care throughout the relevant period.

<u>Capacity in The Christie's operating theatres and / or Critical Care Units, including the opening of or adaptations to current inpatient and outpatient units at the hospital.</u>

60. The Acute Assessment Unit (AAU) is the receiving ward for all emergency and urgent care admissions to the trust. The AAU moved to a new location on the Christie site with

improved facilities which included an ambulatory care area for non-elective patients on 15 May 2020. An ambulatory care area is where patients who need urgent or emergency care can come to, be seen and assessed and sent home where possible. This avoids unnecessary admission to hospital. The new facility also has more single person rooms which supports good infection control practices. Prior to 15 May 2020 the AAU did not have an ambulatory care unit as part of its facilities and very few single person rooms. This development was planned prior to the pandemic and was accelerated on the outset of it. During the relevant period all non-elective patients with colorectal cancer (patients coming into the hospital as an emergency from the community who would not have had a pre-admission covid test) were admitted through this route to allow covid testing and clearance in one location. Elective patients coming in for treatment for their colorectal cancer would have received a pre-treatment test and therefore could be admitted to a non-covid ward. This allowed protection for the surgical service and the Greater Manchester Hub patients.

61. Critical care capacity was, as already stated, increased from 6 to 8 beds from March 2020 and the layout of the unit was adjusted to support social distancing with additional partitions and as a designated green site we were able to accommodate cancer surgery patients on Critical Care throughout the time period.

62. In order to maintain social distancing to keep patients safe, the number of patient beds on the inpatient wards was reduced from 28 to 22 in March 2020 for the remainder of the relevant period. This was mitigated by access to additional beds through our Christie Private Care facilities, as detailed earlier in this statement. There was no significant impact on the ability to treat colorectal patients over the stated period due to availability of in-patient beds.

63. To optimise the use of our surgical beds, we accelerated the utilisation of the Day Surgery Admissions Unit (DOSA) at the outset of the pandemic. This reduced pre-operative length of stay by bringing patients in on the same day as their surgery (as opposed to the day before), this reduced the need for patients to stay in a bed therefore improving our bed capacity and keeping patients safe away with less time in hospital.

64. Integrated Procedures Unit is where procedures such as colonoscopies, sigmoidoscopies and gastroscopies are undertaken. There was no impact on the endoscopic colorectal service delivery on the IPU in the relevant period. The unit followed Trust policy for Covid-19 lower and upper GI endoscopies. Patients were confirmed as testing negative for

Covid-19 prior to being booked for their endoscopy. Staff used appropriate PPE and the unit had Red and Green zones (Covid and non-Covid) in the Unit to maintain patient and staff safety.

Critical Care Capacity.

65. The Christie's critical care was not required to support the regional Critical Care capacity.

Advice given to the immunocompromised to shield during the relevant period and whether this impacted their ability to care and treat patients with colorectal cancer.

66. As a tertiary cancer centre a significant proportion of our patients met the criteria for being immunocompromised. We identified which patients were immunocompromised and sent them letters with advice and guidance around shielding on 15th April 2020 – RS7 / INQ000381150. The letter advised that 'The safest course of action is for you to stay at home at all times and avoid all face-to-face contact for at least twelve weeks from today, except from carers and healthcare workers who you must see as part of your medical care. This will protect you by stopping you from coming into contact with the virus.'

67. The requirement to ensure our immunocompromised patients remained safe whilst receiving care during the relevant period was a primary driver to The Christie being designated a green site and the adjustments detailed earlier in this statement. This ensured that we continued to provide care and treatment to these patients.

The utilisation of resources from the private healthcare sector to care and treat NHS cancer patients had an impact on the provision of care and treatment by The Christie during the relevant period.

68. The Christie Private Care provided additional bed capacity and access to their operating theatres for the care and treatment of NHS cancer patients throughout the relevant period. For the period to September 2020 the Trust had easy access to the Independent Sector beds on site through the national arrangements for independent sector capacity. From September 2020 to the end of the relevant period we set up a Service Level Agreement for the use of 10 beds This SLA was extended to cover the use of The Christie Private Care's two theatres from October 2020 for the rest of the relevant period.

Inequalities in the diagnosis, treatment or follow-up care for colorectal cancer patients during the relevant period.

69. Data from the Greater Manchester Cancer Alliance (RS8 / INQ000381151) is outlined the following;

'We have examined the colorectal pathway in Greater Manchester, using two Cancer Wait Times standards:

1. *Referral to Faster Diagnosis (FDS) to represent the first stage of the pathway*
2. *Referral to First Treatment to represent those who go on to require treatment*

Our data source is the pathway-level submissions trusts make to NHS Digital, which later is aggregated to form the Published Cancer Waiting Times (CWT). This data can thus be taken as reasonably well validated. Our demographic information source is the Greater Manchester Master Patient Index (MPI), the ICB's central store of patient information.

We have found that whilst the pathway was clearly impacted by COVID and is currently performing below standard, no one group was disadvantaged more than any other. Furthermore, once the pathway began to recover, the recovery was relatively even.'

70. There was discussion at our twice weekly meetings of the clinical advisory group (CAG) where it was noticed that specific populations were at high risk of developing severe covid and there was a provision of providing Vitamin D through pharmacy to reduce the risks. This came from DHSC guidance around the management of the clinically extremely vulnerable in February 2021 – RS9 / INQ000381152.

Staffing capacity

The availability of staff and any reductions during the relevant period.

71. Staff availability was affected during the relevant period. The main reason was due to increased sickness absence over the period. The Trust's average sickness absence prior to the relevant period was 3.8%. During the relevant period the average increased to 6%. Absence was as high as 10% due to staff being absent from work with COVID symptoms or fulfilling isolation requirements.

72. High levels of covid related sickness absence in our nursing staff resulted in a reduced service for the treatment of patients with chemotherapy for a 2-week period 13 and 30 April 2020. Chemotherapy is delivered by nursing staff and the remaining staff concentrated on making sure treatment courses that had already started were able to finish. A proactive decision was made to suspend commencement of new treatments that were classified as 'Priority Level 6' according to the national guidance, and as detailed earlier in this statement. There were no further suspensions of chemotherapy activity throughout the period. This only affected 1 colorectal patient. Patients who were already on chemotherapy treatment were not impacted. This action was taken to avoid needing to suspend chemotherapy treatment for patients who had already commenced treatment if sickness absence levels increased further. Fortunately, this did not happen. Radiotherapy and surgery for colorectal cancer were maintained throughout the period.

73. Services were maintained throughout the relevant period using a daily escalation framework. Clinical staff were redeployed where necessary to cover staff absences to maintain patient treatment and care. Redeployment was managed on a weekly basis through a dedicated staffing meeting, with escalations addressed daily through the morning huddle meeting. The huddle was attended by the Chief Operating Officer, Executive on-call, operational leads, senior nursing and infection prevention and control team staff.

74. There is no evidence that availability of staff during the period impacted on the quality of treatments provided.

75. The Christie received fewer patient complaints and PALS contacts in the first 6 months of the relevant period and fewer clinical incidents were reported.

76. The Covid-19 pandemic undoubtedly impacted staff both emotionally and physically. Staff faced additional health challenges brought on by the threat of Covid as well as pressure associated with major organisational change during the period. Many of our staff took on new and challenging roles, and our teams used their exceptional abilities to introduce new innovations and ways of working to help us meet the demand for services. The Trust implemented a comprehensive support package for all staff to support their health and well-being during the period. However, staff absence increased significantly during the period as staff adhered to the guidance around isolation and shielding. We praised the amazing efforts of our staff at the time through our daily communications and continue to do so.

Redeployment of staff from The Christie during the relevant period.

77. The Christie redeployed very small numbers of nursing staff to support the Nightingale Hospital project to carry out nursing shifts. This was voluntary. The nursing staff went there to provide nursing care. Numbers were so few that it did not impact on our ability to provide care or treatment to our patients, we did not record these numbers as it was voluntary and the staff did this in addition to their shifts at the trust.

Home-working for staff members advised to shield during the relevant period.

78. Staff not required to be on site to deliver care to patients were required to work from home for the duration of the relevant period. Staff were provided with equipment and the Trust developed homeworking resources and guidance to aid this transition. Clinically vulnerable staff agreed alternative arrangements with their line managers for the period of the restrictions including homeworking wherever possible. Staff who could not work from home were advised not to go to work and continued to receive full pay. The impact was localised. Overall, the numbers of staff shielding did not reach levels where it had a significant impact on the trusts ability to provide care or treatment to patients.

The unequal impact of the Covid-19 pandemic on its staff (whether related to a protected characteristic under the Equality Act 2010, literacy or language difficulties, socioeconomic background or otherwise).

79. At the Christie we were aware that Asian and minority ethnic (BAME) communities were disproportionately affected by Covid-19 and that the evidence suggested that the impact may also be higher among men and those in the higher age brackets. We also recognised that the exposure faced by our frontline health workers puts them at a greater risk of catching Covid-19. Support for staff disproportionately affected by Covid-19 was put in place. These staff were given priority to PPE and fit testing, and to covid testing. Risk assessments were introduced in June 2020 and updated and reviewed regularly. These were repeated when there was a change in circumstances such as change in role, change to health status, or a return to work following absence. Our risk assessment process was developed with our Clinical Directors and was based on guidance from NHS Employers (published 30 April 2020). Line managers offered individual risk assessments to all workers who identified as being at higher risk. The risk assessment was completed jointly

between the individual and their line manager and involved agreeing an action plan to minimise any risks identified.

Infection prevention and control

Issues relating to infection prevention and control ("IPC") measures in its hospital or clinics and any impact this had on care pathways for colorectal cancer during the relevant period.

80. It is important to note before setting out our response to questions relating to IPC, that The Christie took proactive action to put measures in place prior to the first national lockdown being announced on 23 March 2020. On 9 March 2020 a decision was made by the Executive Directors led by me to start to shut down the Christie hospital site. This decision was made based on the advice of clinicians working in the organisation who had been in contact with colleagues in other countries (namely Italy) who were at a more advanced stage of seeing the impact of Covid-19. The steps taken from 9 March 2020 included;
    - Restricted access to the site for visitors and the public generally
    - Stopped school of oncology events / teaching in person
    - Put security and screening of patients in place at the door (taking proof of appointment and taking patients temperature)
    - Increasing spacing in waiting areas
    - Asking all staff who were able, to work from home
    - Shutting down cafés and retail outlets
    - Transferring all meetings to virtual
    - Amending governance arrangements to reflect command and control arrangements in the NHS

81. There were extensive changes to the infection prevention and control measures in the relevant period. I have provided the detail in relation to these IPC measures earlier in my statement, but by way of summary, they included the need to reduce the number of people on site and in clinical areas, the need to create greater distance between patients in beds and chemotherapy chairs, hand hygiene, the wearing of additional PPE when undertaking clinical procedures and the wearing of masks by everyone on site. We reduced the number of beds on wards from 28 to 22, introduced restrictions on visitors to site and asked staff who were able to perform their role remotely, to work from home. We introduced testing for patients and staff. Patients requiring surgery were brought in on the day of surgery rather than the day before to reduce their time in hospital and therefore reduce risk. Where

possible patient's outpatient appointments were done virtually or over the phone so that they could remain at home. Patients who needed to come on site as an emergency were seen through a new ambulatory unit on the Acute Admissions Unit, assessed and where possible sent home to be managed to avoid unnecessary hospital stays.

Testing and PPE.

82. We complied with the national guidance for testing of patients and staff as it was issued throughout the relevant period. Our procedures for testing patients and staff were formulated with the advice of our Clinical Advisory Group. We commenced testing of symptomatic patients and staff in March 2020 through the laboratories at Manchester Foundation Trust. Asymptomatic testing began in April 2020 for staff and patients. Chemotherapy, radiotherapy and surgery pathways were adapted to accommodate patient testing prior to starting treatment and during the on-going treatment or inpatient stay. All in-patients were tested according to the NHSE national guidance at the different times during the relevant period. This occasionally resulted in unused treatment capacity if a patient tested positive for Covid-19 but this did not impact our overall ability to care for and treat patients during the period. We did not identify any problems with availability of tests for patients and staff to meet the national requirements.

83. In April 2020 we developed and started to implement a plan for asymptomatic testing of staff. This prioritised clinical areas, porters and the catering team. On 28 and 29 April 2020 we took part in the prevalence of Covid-19 analysis, with 848 member of staff taking part in the testing. We established a clear set of instructions to support staff if they tested positive, which changed throughout the relevant period in line with NHSE guidance.

84. Our PPE standards at The Christie exceeded the national guidance in areas where we were caring for immunocompromised patients. This included use of FFP3 masks in some non-aerosol generating areas. The national supply we received of FFP3 masks during this period varied in type which meant additional fit testing was required. We did not identify any issues with availability of PPE that impacted the care and treatment we provided.

85. We provided fit testing facilities and training on use of PPE throughout the relevant period with staff trained to carry out the testing. Fitting of and training in the use of PPE did not affect our ability to provide services for patients with colorectal cancer during this period.

86. The Christie provided a selection of PPE to meet the individual needs of our staff. Staff with facial hair were offered the use of electronic hoods instead of FFP3 masks where required. All clinical staff wore scrub suits during this period.

87. Staff had access to clear facial visors instead of facemasks when required to communicate with patients or staff with communication needs.

88. The Christie purchased portable HEPA filter machines for use in the in-patient areas. Levels of ventilation within clinical settings did not affect our ability to care for and treat patients with colorectal cancer during this period.

89. Our risk assessment processes for Christie staff is detailed is described in paragraph 79.

90. We made the extremely difficult decision to stop all non-essential visitors to the hospital and general inpatient visiting from 27 March 2020 with the exception of patients in the last hours of life. However there was some flexibility for some patients under certain circumstances of decreased cognitive or physical ability where they were attending an outpatient appointment and were allowed to be accompanied. This was adjusted during the relevant period to accommodate visitors for patients on the Teenage and Young Adult unit and where a clinician deemed it appropriate for a patient to be accompanied to their appointment. Tablet devices were made available on each ward to support communication with patients and families. The visitor policy was reviewed regularly by the Clinical Advisory Group and was gradually relaxed in line with the NHSE national guidance on infection control.

91. Staff found the restrictions on visitors difficult as it caused anxiety for patients. Staff were having to deal with stressful situations with patients, their families and loved ones over the telephone. To provide additional support, some staff were redeployed in the outpatient department to accompany patients who were not able to bring anyone with them to appointments.

Other concerns or issues

92. The Clinical Advisory Group (CAG) was formed to advise on the best treatment approach for patients across service and research, responding to the changing situation on site and nationally. They considered emerging clinical questions in relation to Covid 19 in the cancer population and preparing briefings for clinical staff and information for patients and

families. They also made recommendations to the operational (Management Board) and strategic executive groups managing the Covid 19 responses within the trust. The initial membership was the Medical Director, Associate Medical Directors, Clinical Directors, Director of Research, Chief Pharmacist, and the Chair of the Drugs & Therapeutics Committee. Later other senior clinicians joined the group. The Clinical Advisory Group considered issues around the preservation of the most essential parts of the cancer services provided by the organisation. This included infection control and prevention guidance and biosecurity measures on site (PPE, maintaining low footfall whilst meeting patients needs, reducing risk of positive patients coming on site), suspension of some chemotherapy treatments, prioritisation of treatment for chemotherapy and radiotherapy, visitor policies, internal communications, the approach to conflict resolution for clinicians making difficult decisions, planning for recovery of services and standard operating procedures for all areas of clinical care delivered in the Trust.

93. The Clinical Advisory Group met twice weekly and allowed rapid decision making in the first wave of the pandemic and provided essential clinical input into operational decision making.

94. There are no further concerns not already addressed in this statement.

Recommendations that The Christie would seek to make in order to improve cancer care and/or conditions for its patients and staff members in the event of a future pandemic

95. **Ensuring timely and evidence based national guidance is essential to ensure consistency and equity.**

During the pandemic evidence emerged rapidly about the impact of COVID infection on cancer patients and the risks associated with treatment. We used local clinical expertise to adapt treatment regimes in line with the assessed risk and would do so again in the same circumstances. We shared our approach through the national coordination mechanisms referred to in this statement and this worked well. In the future if cancer treatment regimens need to be adapted to reduce risk due to the infection causing a pandemic, national coordination, communication, and oversight by NHSE would ensure that any changes are introduced early, consistently, monitored and evaluated. This process should be clinically led using expertise from cancer centres and royal colleges as

well as NHSE. The need for such approaches should be built into national emergency response plans.

96. **National pandemic response plans should give sufficient emphasis to other conditions.**

In the early stages of the pandemic our experience was that great emphasis was put by the system on managing the impact of large numbers of infected patients (i.e., with COVID). This was understandable because of the anticipated requirements for equipment and impact on staff. The Greater Manchester system recognised early that specific arrangements for other conditions, including but not limited to cancer, needed to be made. This led to the designation of certain hospitals for specific purposes (e.g., The Christie for cancer care) with deliberate efforts made to avoid the use of such sites for COVID patients, reduce the incidence of COVID-19 amongst patients, maintain existing capacity for cancer treatment and create spare capacity which could be offered to other hospitals. Building this into future plans could help to reduce the long-term impact and backlog caused by maintaining service levels. A prior understanding of these arrangements in each locality would facilitate implementation.

97. **Protecting hospital sites needs to be proactive and based on the precautionary principle.**

As described in this statement at The Christie we took proactive steps and restricted access to our site early. This proactive approach provided protection to our patients and reduced, insofar as we were able, the risk of exposure of staff and patients to catching Covid-19. We took steps ahead of national guidance based on reasonable assessments of risk. We monitored this through our Clinical Advisory Group. Many of these actions were based on well-established infection control principles such as hand hygiene, reduced footfall, exclusion of symptomatic individuals. The learning was to emphasise that we should not wait for further evidence to implement enhanced measures based on well-established principles.

98. **Ensuring designated sites is an effective way of enabling surgery and other cancer care to continue safely.**

Our experience is that we were able to deliver safe cancer care with limited impact on our services because The Christie Hospital was a protected site. Future planning should avoid blanket approaches to deferral of non-pandemic related treatments and instead ensure that prospective plans describe designated locations for treatment of serious conditions, including cancer. This should extend also to diagnostic facilities.

99. **Ensuring local leadership and authority.**

The daily meetings of senior executives across Greater Manchester worked very well in the early stages of the pandemic response because the source of authority and decision making was clear. In an emergency this authority needs to be made explicit including to clinicians to ensure changes are made rapidly, for example, opening more capacity when needed and arranging for clinicians to move to other locations as part of mutual aid and system wide responses.

100. **Enhancing professional networks and connections with bodies supporting the delivery of cancer care e.g., royal colleges, NHSE, National Cancer Team.**
We were able to implement changes rapidly including consideration of treatment protocols because of good existing relationships with other cancer centres and national bodies. This was critical, and these connections must be prioritised and maintained in future prospective national plans.

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 in its truth.

Signed: **Personal Data**

Dated: 11/01/2024