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Date: 5 July 2021

Re: Freedom of Information Request

Ref: 169-2021

Thank you for your email dated the 11<sup>th</sup> June 2021, requesting information in relation to patient treatment figures and trials.

The information that you require is as follows:

Please note, in accordance with the Data Protection Act 2018 our Trust is unable to release all of the information requested. The Clatterbridge Cancer Centre NHS Foundation Trust (CCC) is a relatively small Trust and by providing this level of detail where the number of patients is less than or equal to five increases any 'potential' risk of this data becoming identifiable information and thereby contravening one or more of the Data Protection Principles by releasing it into the public domain. Confidentiality is expected in such matters. This information is therefore exempt under Section 40: Personal Information, of the Freedom of Information Act 2000. The areas where this exemption has been applied are shown below:

- 1. Within your health trust, how many patients have been treated in the past 3 months for head and neck cancer (squamous cell carcinoma) with the following agents?
  - Carboplatin (monotherapy or in combination with 5-FU) = 8 patients
  - Cisplatin (monotherapy or in combination with 5-FU) = 57 patients (includes patients who had Cisplatin + Radiotherapy)

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- Cetuximab with/without chemotherapy = Exempt under S.40
- Cetuximab with radiotherapy = Exempt under S.40
- Pembrolizumab monotherapy = 15 patients
- Pembrolizumab with chemotherapy = 0 patients
- Nivolumab = 13 patients
- Docetaxel (monotherapy or in combination with 5-FU) = Exempt under \$.40
- Fluorouracil (5FU) = 0 patients monotherapy and 9 patients with Cisplatin (included in the 57 patients above)
- Radiotherapy only = 70 patients
- Other = 0 patients had a different regime than those stated above
- 2. Does your trust participate in any ongoing clinical trials for the treatment of head and neck cancer (squamous cell carcinoma)? If so, can you please provide the name of each trial along with the number of patients taking part?

**Head and Neck – Open to Recruitment** 

| Project Short Title | Project Full title  | Project type                    | Recruited               |
|---------------------|---|---------------------------------|-------------------------|
| PATHOS              | A Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer         | Non-<br>commercial<br>portfolio | 62                      |
| COMPARE             | Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer  | Non-<br>commercial<br>portfolio | 10                      |
| REPLIMUNE           | An Open-Label, Multicenter, Phase 1/2 Study of RPI as a Single Agent and in Combination with Immune Checkpoint Blockade or Other Standard of Care Regimens in Patients with Solid Tumours   | Commercial portfolio            | 9                       |
| POPPY               | A phase II trial to assess the efficacy and safety profile of pembrolizumab in patients with performance status 2 with recurrent or metastatic squamous cell carcinoma of the head and neck | Non-<br>commercial<br>portfolio | Exempt<br>under<br>S.40 |

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| Transgene | A randomized phase I trial in patients with newly-diagnosed, locoregionally advanced, HPV-negative, squamous cell carcinoma of the head and neck (SCCHN) evaluating a mutanomedirected immunotherapy initiated at completion of primary treatment or at time of recurrence | Commercial<br>Portfolio | Exempt<br>under<br>S.40 |
|-----------|--|-------------------------|-------------------------|
|-----------|--|-------------------------|-------------------------|

## Head and Neck - Follow-up

| Project Short<br>Title | Project Full title   | Project type                    | Recruited               |
|------------------------|--|---------------------------------|-------------------------|
| NIMRAD                 | A randomised placebo-controlled trial of synchronous NIMorazole versus RADiotherapy alone in patients with locally advanced head and neck squamous cell carcinoma not suitable for synchronous chemotherapy or cetuximab                         | Non-<br>commercial<br>portfolio | 20                      |
| CHECKMATE<br>141       | CHECKMATE 141: An Open Label, Randomized Phase 3 Clinical Trial of Nivolumab vs Therapy of Investigator's Choice in Recurrent or Metastatic Platinum-refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN)                             | Commercial portfolio            | Exempt<br>under<br>S.40 |
| CHECKMATE<br>143       | A Randomised Phase IIB Open Label<br>Study of Nivolumab or Nivolumab in<br>Combination with Ipilimumab versus<br>Bevacizumab in Adult Subjects with<br>Recurrent Glioblastoma (GBM)  | Commercial portfolio            | Exempt<br>under<br>S.40 |
| WISTERIA               | A Phase I trial of WEE1 inhibition with Chemotherapy and Radiotherapy as adjuvant treatment, and a Window of Opportunity trial with Cisplatin in Patients with Head and Neck Cancer  | Non-<br>commercial<br>portfolio | Exempt<br>under<br>S.40 |
| KESTREL                | A Phase III Randomized, Open-label, Multi-center, Global Study of MEDI4736 in Combination with Tremelimumab versus Standard of Care in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients (KESTREL) | Commercial portfolio            | Exempt<br>under<br>S.40 |
| CHECKMATE<br>714       | A Double-Blind, Randomized, Two<br>Arm Phase 2 Study of Nivolumab in<br>Combination with Ipilimumab versus<br>Nivolumab in Combination with  | Commercial portfolio            | Exempt<br>under<br>S.40 |

|          | Ipilimumab Placebo In Recurrent or<br>Metastatic Squamous Cell Carcinoma<br>of the Head and Neck (SCCHN)<br>(CheckMate 714)   |            |        |
|----------|---|------------|--------|
| De-      | De-ESCALaTE HPV: Determination of Epidermal growth factor receptor-inhibitor (cetuximab) versus Standard Chemotherapy (cisplatin) early And Late Toxicity Events in Human Papillomavirus-positive oropharyngeal squamous cell carcinoma | Non-       | Exempt |
| ESCALATE |   | commercial | under  |
| HPV      |   | portfolio  | S.40   |

- 3. Within your health trust, how many patients have been treated in the past 3 months with the following agents for colorectal cancer [CRC]?
  - Aflibercept = 0 patients
  - Bevacizumab = 8 patients (all in combination)
  - Capecitabine = 67 patients (as monotherapy with or without RT)
  - CAPIRI (Capecitabine + Irinotecan) = 9 patients (excluding those with Panitumumab)
  - CAPOX (XELOX) (Capecitabine + Oxaliplain) = 132 patients (excluding those with Panitumumab)
  - Cetuximab in combination with FOLFIRI = 25 patients
  - Cetuximab in combination with FOLFOX = 9 patients
  - Cetuximab not in combination with FOLFIRI or FOLFOX = 18 patients
  - Irinotecan only = 15 patients
  - FOLFIRI (Irin Mod De Gramont) = 58 patients (excluding those with Panitumumab or Cetuximab)
  - FOLFOX (Oxaliplatin Mdg) = 94 patients (excluding those with Pantimumab and Cetuximab)
  - Fluorouracil (5FU) only = 0 patients, however 22 patients had 5FU
     + Folinic Acid
  - Oxaliplatin only = 0 patients
  - Panitumumab in combination with FOLFIRI = Exempt under \$.40
  - Panitumumab in combination with FOLFOX = Exempt under \$.40

- Panitumumab not in combination with FOLFIRI or FOLFOX = 20
   patients
- Nivolumab = Exempt under S.40
- Raltitrexed = 0 monotherapy however 7 patients did with

## **Oxaliplatin**

- Ramucirumab = 0 patients
- Regorafenib = 0 patients
- Sorafenib = 0 patients
- Other SACT = 29 patients including:
  - Trifluridine + Tipiracil = 21 patients
  - Imatinib = Exempt under S.40
  - Pembrolizumab = Exempt under S.40
  - Folfoxiri = Exempt under S.40
  - Carboplatin + Etoposide = Exempt under S.40

Should you require any further information please do not hesitate to contact me on the email address provided below.

Please remember to quote the reference number above in any future communications.

If you are dissatisfied with the handling of your request, you have the right to ask for this to be investigated internally.

If you are dissatisfied with the information you have received, you have the right to ask for an internal review.

Both processes will be handled in accordance with our Trust's Freedom of Information Policy and the Freedom of Information Act 2000.

Internal investigation and internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to: Freedom of Information Review, The Clatterbridge Cancer Centre NHS Foundation Trust, Clatterbridge Road, Bebington, Wirral, CH63 4JY

If you are not satisfied with the outcome of the internal investigation/review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

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