## Performance in Initiating Research (PII) Q3 2017-18

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16/NW/0379 | 200426 | HRA Approval | Protocol I3O-MC-JSBF Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Gemcitabine and Cisplatin as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer | No | | 16/02/2016 | 20/03/2017 | 16/08/2016 | 20/03/2017 | 22/03/2017 | 25/04/2017 | Sponsor | Financial negotiations with sponsor, mutually agreed and new pathway realised. |
| 15/LO/1487 | 172859 | HRA Approval | A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination with Ramucirumab or Placebo in Previously Untreated Patients with EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer | No | | 23/03/2016 | 24/04/2017 | 16/05/2016 | 24/04/2017 | 09/05/2017 | 18/05/2017 | Both | Awaiting competing study to close before this study could open, this was mutually agreed with the Sponsor, but the competing study recruitment was unexpectedly slow. |
| 17/WS/0030 | 191416 | HRA Approval | A Phase Ib and II Open-Label, Multi-Center Study of MEDI4736 Evaluated as Single Agent or in Different Combinations in Patients with Metastatic Pancreatic Ductal Adenocarcinoma | Yes | 24/05/2017 | 12/04/2016 | 01/02/2017 | 12/04/2017 | 26/04/2017 | 26/04/2017 | 16/05/2017 | Neither | Sub-contract with partner Trusts for services. |
| 15/EE/0448 | 189797 | HRA Approval | Clinical Trial of Nivolumab (BMS-936558) Combined with Ipilimumab Followed by Nivolumab Monotherapy as First-Line Therapy of Subjects with Histologically Confirmed Stage III (Unresectable) or Stage IV Melanoma | No | | 27/07/2016 | 09/01/2017 | 07/06/2016 | 04/05/2017 | 09/05/2017 | 31/05/2017 | Sponsor | Contracting & Costing delayed by negotiations with the CRO on behalf of the Sponsor and the wait for receipt of two substantial amendments. Further delays due a request for additional changes to costings at CRO request. |
| 17/ES/0032 | 212775 | HRA Approval | A STUDY TO DETERMINE THE CONCORDANCE OF KEY ACTIONABLE GENOMIC ALTERATIONS AS ASSESSED IN TUMOUR TISSUE AND PLASMA FROM PATIENTS WITH NON SMALL CELL LUNG CARCINOMA (NSCLC) | Yes | 25/07/2017 | 27/01/2017 | 27/01/2017 | 28/03/2017 | 20/06/2017 | 27/06/2017 | 19/07/2017 | Sponsor | Sponsor queries and agreement re financials and then a 3 week delay on signing the contract from Sponsor. |
| 16/LO/1701 | 198559 | HRA Approval | ANNOUNCE-2: A Phase 1b (Open Label) / Phase 2 (Randomized, Double-Blinded) Study Evaluating the Efficacy of Gemcitabine and Docetaxel With or Without a Human Anti-PDGFRa Monoclonal Antibody (Olaratumab) in the Treatment of Advanced Soft Tissue Sarcoma | Yes | 19/09/2017 | 13/03/2017 | 13/03/2017 | 17/11/2016 | 07/08/2017 | 14/08/2017 | 23/08/2017 | Both | Sponsor queries in financial negotiations. Sub-contracting for ultra sound guided biopsies with a partner Trust. |
| 15/LO/1904 | 173980 | HRA Approval | MROC: The Impact of Multiparametric MRI on the Staging and Management of Patients with Suspected or Confirmed Ovarian Cancer. | No | | 18/02/2017 | 18/02/2017 | 09/08/2016 | 14/08/2017 | 22/08/2017 | 22/09/2017 | Neither | Excess treatment costs needed to be agreed. CCC is a contract site only and providing support to a partner Trust. Set-up depended on Tripartite agreements. |
| 16/WM/0409 | 204629 | HRA Approval | GLANCE: Global Longitudinal Assessment of Treatment Outcomes in Squamous Cell Carcinoma of the Head and Neck | Yes | 22/11/2017 | 10/03/2017 | 10/03/2017 | 26/10/2016 | 08/09/2017 | 19/09/2017 | 06/10/2017 | Sponsor | Sponsor queries in financial negotiations and sponsor delays in sending correct CTA. |

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| 16/LO/1222 | 191705 | HRA Approval | ATLANTIS: Phase III Randomized Clinical Trial of Lurbinectedin (PM01183)/Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients with Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line. | Yes | 14/11/2017 | 01/04/2016 | 07/10/2016 | 05/05/2017 | 21/08/2017 | 25/08/2017 | 10/10/2017 | Both | Sponsor queries in financial negotiations: CTA delays due to change of PI: Internal capacity issues. |
| 16/NE/0316 | 207651 | HRA Approval | CYP-001: An Open-Label Phase 1 Study to Investigate the Safety and Efficacy of CYP-001 for the Treatment of Adults With Steroid-Resistant Acute Graft Versus Host Disease | Yes | 30/10/2017 | 15/06/2017 | 01/07/2017 | 12/12/2016 | 12/10/2017 | 23/10/2017 | 23/10/2017 | Neither | CCC took over the haematology oncology from the Royal Liverpool Hospital which caused some delay in transition. |
| 14/LO/0259 | 134883 | HRA Approval | RE-AKT: A randomised Phase II study of enzalutamide (MDV3100) in combination with AZD5363 in Patients with Metastatic Castration - Resistant Prostate Cancer | No | | 01/07/2016 | 01/07/2016 | 30/06/2016 | 20/09/2017 | 08/09/2017 | 24/10/2017 | NHS Provider | Delay due to the allocation of Research Nurse |
| 16/NW/0828 | 210067 | HRA Approval | OPERA Study V3.1 - Radiation dose escalation in rectal adenocarcinoma | Yes | 16/11/2017 | 19/01/2017 | 22/03/2017 | 09/03/2017 | 09/10/2017 | 19/09/2017 | 30/10/2017 | Both | Delay due to contract negotiations. CC needed to give support to the Sponsor and CRO to assure correct governance and contracts. |
| 16/WM/0369 | 211361 | HRA Approval | XALT3: Phase 3 Randomized Study Comparing X-396 to Crizotinib in Anaplastic Lymphoma Kinase (ALK) Positive Non-Small Cell Lung Cancer (NSCLC) Patients | Yes | 05/12/2017 | 12/08/2016 | 12/08/2016 | 12/12/2016 | 30/05/2017 | 07/06/2017 | 06/11/2017 | Both | Sub-contracting delays with partner Trusts and Sponsor delayed agreement of financials. |
| 17/LO/0017 | 213632 | HRA Approval | A Phase 2 Open-label Extension Study for Subjects with Prostate Cancer Who Previously Participated in an Enzalutamide Clinical Study | Yes | 08/11/2017 | 12/01/2017 | 12/01/2017 | 08/03/2017 | 18/09/2017 | 05/10/2017 | 06/11/2017 | NHS Provider | Internal pharmacy capacity issues. |
| 16/LO/0052 | 187500 | HRA Approval | CARBON: A randomized phase IB/IIA study of CApecitabine plus Radium-223 (Xofigo) in breast cancer patients with BONe metastases (CARBON): an open-label interventional study | Yes | 08/12/2017 | 21/04/2016 | 01/06/2016 | 27/05/2016 | 21/08/2017 | 20/07/2017 | 15/11/2017 | Neither | Capacity and sub-contracting issues with partner Trust |
| 17/EM/0292 | 218440 | HRA Approval | EFACCT: Evaluating Follow-Up and Complexity in Cancer Clinical Trials | Yes | 14/12/2017 | 11/07/2017 | 21/07/2017 | 09/10/2017 | 14/11/2017 | 14/11/2017 | 15/11/2017 | Neither | Awaiting HRA approval |
| 17/SC/0231 | 221097 | HRA Approval | Pembrolizumab versus standard therapy in mesothelioma (PROMISE-meso) | Yes | 04/12/2017 | 28/11/2016 | 28/11/2016 | 27/06/2016 | 12/10/2017 | 27/10/2017 | 17/11/2017 | Neither | The study was set up in line with internal timelines- no real delay |
| 17/EE/0074 | 217180 | HRA Approval | Pfizer B7461006 NSCLC A PHASE 3, RANDOMIZED, OPEN LABEL STUDY OF LORLATINIB (PF 06463922) MONOTHERAPY VERSUS CRIZOTINIB MONOTHERAPY IN THE FIRST LINE TREATMENT OF PATIENTS WITH ADVANCED ALK POSITIVE NON SMALL CELL LUNG CANCER | No | | 21/11/2016 | 20/02/2017 | 26/05/2017 | 10/10/2017 | 17/10/2017 | 22/11/2017 | NHS Provider | There were queries around the patient pathway. The PI changed during set-up and the Sponsor had been informed that this study could only proceed once a competing study closed to recruitment. |
| 17/NW/0180 | 220257 | HRA Approval | INCYTE, Efficacy and Safety of INCB054828 in Cholangiocarcinoma | Yes | 18/12/2017 | 26/04/2017 | 26/04/2017 | 04/04/2017 | 26/09/2017 | 09/10/2017 | 22/11/2017 | Both | Sponsor queries in financial negotiations and internal pharmacy capacity caused a delay to start up. |
| 17/LO/1652 | 233586 | HRA Approval | CA209-9TW BMS Melanoma 1L Chart Review Study | No | | 14/09/2017 | 11/09/2017 | 25/09/2017 | 04/12/2017 | 08/12/2017 | 08/12/2017 | Sponsor | Sponsor queries in financial negotiations. |

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| 16/LO/2150 | 201093 | HRA Approval | OCTOVA: Phase II Trial of Olaparib, chemotherapy or olaparib and cediranib in patients with BRCA mutated platinum-resistant ovarian cancer | No | | 24/11/2016 | 24/11/2016 | 26/01/2017 | 06/12/2017 | 24/11/2017 | 14/12/2017 | NHS Provider | Needed to assure internal pharmacy capacity. |
| 17/NW/0312 | 211974 | HRA Approval | CaboGIST (EORTC 1317): Phase II study of cabozantinib in patients with metastatic gastrointestinal stromal tumor (GIST) who progressed during neoadjuvant, adjuvant or palliative therapy with imatinib and sunitinib. | No | | 10/05/2017 | 01/06/2017 | 13/07/2017 | 17/11/2017 | 24/11/2017 | 14/12/2017 | Both | Queries over patient pathway and funding queries. |