Performance in Initiating Research (PII) Q1 2017-18

Research Ethics Committee Reference Number	IRAS	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited ?	Date of First Patient Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Comments
16/LO/0529	182152	HRA Approval	CORE - A randomised trial of conventional care versus radioablation (stereotactic body radiotherapy) for extracranial metastases			Yes	24/01/2017	05/08/2016	05/08/2016	13/07/2016	11/01/2017	02/12/2016	Delay due to Research Nurse allocation to the study.
15/LO/1835	111728	HRA Approval	SIOP PNET 5 Medulloblastoma: An International Prospective Study on Clinically Standard-Risk Medullblastoma in Children Older Than 3 to 5 Years With Low-Risk Biological Profile (PNET 5 MB - LR) or Average-Risk Biological Profile (PNET 5 MB-SR)			No		10/10/2016	11/10/2016	20/10/2016	14/02/2017	08/02/2017	CCC to act as a radiotherapy site only to support a partner Trust. No recruitment will take place at CCC. Sponsor delays with funding.
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	Financial negotiations with sponsor, mutually agreed and new pathway realised.
16/NE/0142	202233	Please Select...	A RANDOMIZED, OPEN-LABEL, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVELUMAB (MSB0010718C) IN COMBINATION WITH AND/OR FOLLOWING CHEMOTHERAPY IN PATIENTS WITH PREVIOUSLY UNTREATED EPITHELIAL OVARIAN CANCER			Yes	13/04/2017	11/05/2016	25/08/2016	01/11/2016	25/08/2016	19/09/2016	Contract & costings negotiations delayed by Sponsor. Sub-contracts with other trusts for services were delayed. Communication issues as the Sponsor issued greenlight but did not inform CCC RM&G team.were not advised until the 7/3/17.
15/LO/1487	172859	Please Select...	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	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.

16/LO/1514	200096	Please Select...	A Phase III Study of Pembrolizumab (MK-3475) vs. Best Supportive Care as Second-Line Therapy in Subjects with Previously Systemically Treated Advanced Hepatocellular Carcinoma (KEYNOTE-240)			No		17/08/2016	17/08/2016	03/11/2016	20/04/2017	27/04/2017	Contract & costings negotiations delayed by Sponsor. Sub-contracts with other trusts were delayed. Internal delays were due to Pharmacy & Imaging Departmental capacity.
17/WS/0030	191416	Please Select...	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	Sub-contract with partner Trusts for services.
16/NW/0130	196702	Please Select...	A non-interventional biomarker study in patients with Non-Small Cell Lung Cancers (NSCLCs) of adenocarcinoma tumour histology treated in second line with nintedanib in combination with docetaxel			No		29/01/1900	29/11/2016	17/06/2016	29/11/2016	03/01/2017	Financial discussion and contract negotiations delayed study opening.
15/EE/0448	189797	Please Select...	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	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.