

Performance in Initiating Research (PII) Q2 2017-18

Research Ethics Committee Reference Number	Integrated Research Application System Number	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 Study Initiated	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Comments
15/LO/1835	111728	HRA Approval	SIOP PNET 5 Medulloblastoma: An International Prospective Study on Clinically Standard-Risk Medulloblastoma 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 I30-MC-JSBF Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestininib 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.
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	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	Sub-contract with partner Trusts for services.
16/NW/0130	196702	HRA Approval	A non-interventional biomarker study in patients with Non-Small Cell Lung Cancers (NSCLCs) of adenocarcinoma tumour			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	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	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.
16/WM/0473	213847	Please Select...	CA209-817 - Nivolumab and Ipilimumab in advanced malignancies			Yes	18/08/2017		05/10/2016	05/10/2016	02/03/2017	05/04/2017	10/04/2017	Delay due to change-over of Pharmacy staff and a change in PI which needed REC and relevant approvals.

17/ES/0032	212775	Please Select...	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	Sponsor queries and agreement re financials and then a 3 week delay on signing the contract from Sponsor.
15/LO/1077	173350	Please Select...	ABC-07 Addition of stereotactic radiotherapy to systemic chemotherapy in locally advanced biliary tract cancers			No			19/06/2015	21/06/2016	15/06/2016	16/03/2017	03/04/2017	Cross-over from NHS Permissions and HRA. SSI form was not submitted by deadline which caused delays due to HRA
16/LO/1701	198559	Please Select...	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	Sponsor queries in financial negotiations. Sub-contracting for ultra sound guided biopsies with a partner Trust.
15/LO/1904	173980	Please Select...	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	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.
15/LO/1302	169660	Please Select...	OCTOPUS: A Randomised, Phase II Umbrella Trial of Weekly Paclitaxel +/- Novel Agents in Platinum-Resistant Ovarian Cancer			No			22/10/2015	22/10/2016	12/05/2016	02/08/2017	20/07/2017	Sub-contracted services with partner trust caused delays which were compounded by internal capacity issues.
16/EE/0305	190307	Please Select...	PRIMETIME: Post-operative avoidance of radiotherapy in minimal risk women: patient selection using biomarkers			No			29/11/2016	29/11/2016	03/11/2016	10/07/2017	10/07/2017	RTTQA issues caused delay in study set-up.