Performance in Initiating Research (PII) Q4 2016-17

Research Ethics Committee Reference Number	IRAS 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 Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Comments
15/LO/0539	166304	NHS Permission	RAIDER: A Randomised phase II trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder	22/03/2016	17/05/2016	Yes	16/09/2016						Sponsor delay finalising contract. One patient consented but withdrew due to progressive health issues.
16/WA/0014	192888	NHS Permission	CHECKMATE 459: A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma(CheckMate 459: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 459)	29/03/2016	10/05/2016	Yes	04/01/2017						Study not yet activated to recruit by Sponsor, Sponsor delay.
11/LO/1915	92260	NHS Permission	PACE - International Randomized Study of Laparoscopic Prostatectomy vs Robotic Radiosurgery and Conventionally Fractionated Radiotherapy vs Radiosurgery for Early Stage Organ-Confined Prostate Cancer	24/03/2016	20/04/2016	Yes	31/05/2016						Target achieved
15/SC/0521	185323	NHS Permission	ABI-007-NSCL-006: A PHASE 2, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY TO ASSESS SAFETY AND EFFICACY OF NAB?-PACLITAXEL (ABI-007) WITH EPIGENETIC MODIFYING THERAPY OF CC-486, AND NAB?-PACLITAXEL MONOTHERAPY AS SECOND-LINE TREATMENT IN SUBJECTS WITH ADVANCED NONSQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC): ABOUND.2L	31/03/2016	18/04/2016	Yes	24/05/2016						Target achieved
15/LO/1044	173496	NHS Permission	ACTICCA-1: Adjuvant Chemotherapy With Gemcitabine and Cisplatin Compared to Observation After Curative Intent Resection of Biliary Tract Cancer	23/03/2016	18/04/2016	Yes	24/08/2016						Sponsor delay with finalising contract and activating study at site. Several patients approached within the target timeframe but high patient refusal rate due to treatment/randomisation options.

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15/EE/0418	188945	NHS Permission	CHECKMATE 451: A Randomized, Multicenter, Double-Blind, Phase 3 Study of Nivolumab, Nivolumab in Combination with Ipilimumab, or Placebo as Maintenance Therapy in Subjects with Extensive-Stage Disease Small Cell Lung Cancer (ED-SCLC) after Completion of Platinum-based First Line Chemotherapy	22/03/2016	04/04/2016	Yes	22/11/2016						Activation delayed due to PI availability to complete training. No eligible patients seen.
12/NW/0827	96956	NHS Permission	Euro Ewing 2012: International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours	22/03/2016	14/06/2016	No							Delay in granting NHS permission was due to a Sponsor delay with the contracts. Waiting for Sponsor to give 'green light' to open for recruitment.
15/WM/0392	180166	NHS Permission	SARON - Stereotactic ablative radiotherapy for oligometastatic non-small cell lung cancer.	24/03/2016	05/07/2016	Yes	12/08/2016						SSI submitted earlier than planned due to closure of CSP. Sponsor delay finalising contract. Delay with study being activated at site; activated 11/08/2016, patient approached on 11/08/2016 and recruited on 12/08/2016.
15/NE/0013	159719	NHS Permission	ROAM: Radiation versus observation following surgical resection of atypical meningioma: A randomised controlled trial	29/03/2016	12/07/2016	No							SSI submitted earlier than planned due to closure of CSP. Rare patient group.
15/LO/1635	178097	NHS Permission	ABACUS (MPDL3280A) A phase II study investigating pre-operative MPDL3280A in operable transitional cell carcinoma of the bladder	24/03/2016	27/06/2016	No							SSI submitted earlier than planned due to closure of CSP. Delay with booking Site Initiation Visit due to Sponsor and Site staff availability. Study still awaiting activation. To be updated Q3 2016/17
15/NW/0160	171155	NHS Permission	ABC08: Ph Ib Acelarin + cisplatin in advanced bililiary tract cancer	23/03/2016	27/07/2016	No							SSI submitted earlier than planned due to closure of CSP. Sponsor delay in finalising contract and organising Site Initiation Visit. Study not yet activated by Sponsor due to issue with drug administration.
16/LO/0919	201803	HRA Approval	CANC 5659 Medimmune MII41910-419010: A Phase 1 Study of MEDI4736 (Anti-PD-L1 Antibody) in Combination with Tremelimumab (Anti-CTLA-4Antibody) in Subjects with Advanced Solid Tumors			Yes	02/11/2016	24/03/2016	25/05/2016	13/07/2016	25/08/2016	05/10/2016	Delayed due to issues with sub-contract for a fresh biospy at a Partner Trust. Patient Consented/recruited two days after NHS acceptance letter was granted.

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16/NW/0275	204531	HRA Approval	EMR100070-007 (JAVELIN): A Phase III open-label, multicenter trial of maintenance therapy with Avelumab (MSB0010718C) versus continuation of first-line chemotherapy in subjects with unresectable, locally advanced or metastatic, adenocarcinoma of the stomach, or of the gastro-esophageal junction	17/05/2016	23/01/2017	No		17/06/2016	17/05/2016	01/09/2016	27/10/2016	28/11/2016	Sponsor and Trust delays due to costings queries
16/LO/0529	182152	HRA Approval	CORE - A randomised trial of conventional care versus radioablation (stereotactic body radiotherapy) for extracranial metastases	05/08/2016	16/01/2017	Yes	24/01/2017	05/08/2016	05/08/2016	13/07/2016	11/01/2017	02/12/2016	
15/NE/0406	186547	HRA Approval	CANC 4818 (OUTREACH): A First-in-Human, multi-centre, open-label, Phase 1 clinical study with RNA oligonucleotide drug MTL-CEBPA to investigate its safety and tolerability in patients with advanced liver cancer	18/01/2016	08/03/2017	No		18/01/2016	18/01/2016	18/04/2015	28/09/2016	18/10/2016	Sponsor delays due to costings queries & sub-contract delays with partner Trusts
15/EM/0103	130101	HRA Approval	SIOP Ependymoma II :SIOP Ependymoma II - An International Clinical Program for the diagnosis and treatment of children, adolescents and young adults with Ependymoma	27/01/2016	21/03/2017	No		27/01/2016	28/01/2016	15/06/2016	02/06/2016	24/05/2016	CCC to act as a radiotherapy site only to support a partner Trust. No recruitment will take place at CCC. Sponsor delays with funding.
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)	10/10/2016	21/03/2017	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.