

Clatterbridge Cancer Centre (CCC) Performance in Initiating Research (PII) Q3 2016/17

Research Ethics Committee Reference Number	IRAS Number	Submission Type	Name of Trial	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
14/SC/0171	120104	NHS Permission	Add-Aspirin Trial: A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours	22/01/2016	Yes	12/10/2016	N/A	N/A	N/A	N/A	N/A	Study put on hold by Sponsor due to drug availability. Activated by the Sponsor on 22/08/2016.
15/SC/0431	179483	NHS Permission	CANC - 4032 Ramucirumab plus BSC vs placebo plus BSC as 2nd line treatment in HCC (JVDE)	11/02/2016	Yes	17/03/2016	N/A	N/A	N/A	N/A	N/A	Target achieved
15/EM/0305	172320	NHS Permission	CANC - 4278 - GTx-024 in Advanced, AR+ TNBC	16/02/2016	No	-	N/A	N/A	N/A	N/A	N/A	1 patient approached within the 70 day target but was not eligible on further screening. Sponsor closed study in the UK 05/09/2016.
14/EE/1200	162637	NHS Permission	CANC - 3417 - A Phase III Randomized Trial of MK-3475 (Pembrolizumab) versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer	17/02/2016	No	-	N/A	N/A	N/A	N/A	N/A	
15/EM/0546	194511	NHS Permission	KESTREL: MEDI4736 or in combo with Tremelimumab vs SOC in 1st line SCCHN cancer	24/02/2016	Yes	14/03/2016	N/A	N/A	N/A	N/A	N/A	Target achieved
15/NW/0690	177116	NHS Permission	MK-3475 054: Adjuvant immunotherapy with anti-PD-1 monoclonal antibody Pembrolizumab (MK-3475) versus placebo after complete resection of high-risk Stage III melanoma: A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group	25/02/2016	Yes	27/04/2016	N/A	N/A	N/A	N/A	N/A	Target achieved
15/SC/0676	186964	NHS Permission	ANNOUNCE - A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Doxorubicin plus Olaratumab versus Doxorubicin plus Placebo in Patients with Advanced or Metastatic Soft Tissue Sarcoma	07/03/2016	Yes	15/03/2016	N/A	N/A	N/A	N/A	N/A	Target achieved
15/LO/1612	186328	NHS Permission	DANUBE: A Phase III, Randomized, Open-label, Controlled, Multi-Center, Global Study of First-Line MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Chemotherapy in Patients with Unresectable Stage IV Urothelial Bladder Cancer	10/03/2016	Yes	05/04/2016	N/A	N/A	N/A	N/A	N/A	Target achieved
15/WS/0121	173661	NHS Permission	Javelin Lung 200: EMR100070004:Phase III study of avelumab vs docetaxel in NSCLC	23/03/2016	No	-	N/A	N/A	N/A	N/A	N/A	Study not yet activated. Sponsor has put study on hold within the UK.
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	17/05/2016	Yes	16/09/2016	N/A	N/A	N/A	N/A	N/A	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)	10/05/2016	No	-	N/A	N/A	N/A	N/A	N/A	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-Confin ed Prostate Cancer	20/04/2016	Yes	31/05/2016	N/A	N/A	N/A	N/A	N/A	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	18/04/2016	Yes	24/05/2016	N/A	N/A	N/A	N/A	N/A	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	18/04/2016	Yes	24/08/2016	N/A	N/A	N/A	N/A	N/A	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.
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	04/04/2016	Yes	22/11/2016	N/A	N/A	N/A	N/A	N/A	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	14/06/2016	No	-	N/A	N/A	N/A	N/A	N/A	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/NW/0671	184963	NHS Permission	9785-CL-3021: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Enzalutamide in Subjects with Advanced Hepatocellular Carcinoma	17/03/2016	Yes	07/09/2016	N/A	N/A	N/A	N/A	N/A	Difficult patient group to recruit. 1 patient has been approached and awaiting an outcome. Patient now recruited 07/09/2016
15/WM/0392	180166	NHS Permission	SARON - Stereotactic ablative radiotherapy for oligometastatic non-small cell lung cancer.	05/07/2016	Yes	12/08/2016	N/A	N/A	N/A	N/A	N/A	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	12/07/2016	No	-	N/A	N/A	N/A	N/A	N/A	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	27/06/2016	No	-	N/A	N/A	N/A	N/A	N/A	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 biliary tract cancer	27/07/2016	No	-	N/A	N/A	N/A	N/A	N/A	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	N/A	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.