Clatterbridge Cancer Centre Performance in Initiating Research (PII) Q2 2016/17

Research Ethics Committee Reference 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	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Comments
15/LO/0897	NHS Permission	W029637 - A phase III, open-label, randomized study of MPDL3280A (Anti-PD-L1 antibody) in combination with bevacizumab versus sunitinib in patients with untreated advanced renal cell carcinoma	02/10/2015	09/10/2015	Yes	21/10/2015	7	12	19	Yes	Target achieved
15/LO/0159	NHS Permission	SELPAC Uveal Melanoma Study	30/10/2015	30/10/2015	Yes	10/11/2015	0	11	11	Yes	Target achieved
13/LO/1481	NHS Permission	MARS2: A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma	20/11/2015	20/11/2015	Yes	21/12/2015	0	31	31	Yes	Target achieved
14/SC/1156	NHS Permission	JAVA P: A phase II study of Cabazitaxel chemotherapy in relapsed locally advanced and/or metastatic carcinoma of the penis.	27/11/2015	27/11/2015	No		0			No	Rare disease group. (study currently suspended by Sponsor globally - 01/09/2016)
15/EE/0385	NHS Permission	NEPTUNE Lung: A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First Line Treatment of Patients with Advanced or Metastatic Non Small-Cell Lung Cancer (NSCLC)	23/12/2015	23/12/2015	Yes	07/01/2016	0	15	15	Yes	Target achieved
15/SC/0291	NHS Permission	MPDL3280A in solid tumours: An open label, multicohort, phase II study of MPDL3280A in advanced solid tumours	30/11/2015	01/12/2015	Yes	20/04/2016	1	141	142	No	Difficult study to recruit to given the study design and global availability of slots within each cohort. Strict eligibility criteria.
15/NW/0431	NHS Permission	Janssen Bladder: A Phase II, 2-Arm MultiCenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects with Metastatic or Surgically Uresectable Urothelial Cacner with FGFR Genomic Alterations	21/10/2015	22/10/2015	Yes	24/11/2015	1	33	34	Yes	Target achieved
15/WM/0011	NHS Permission	Alligator - ADC-1013 First-in-Human study	27/10/2015	09/11/2015	Yes	15/06/2016	13	219	232	No	First in Human study, strict eligibility criteria and rare patient group. Low recruitment target.
15/NE/0149	NHS Permission	CANC - 3928 - CONDOR: A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	01/10/2015	09/10/2015	Yes	13/11/2015	8	35	43	Yes	Target achieved
15/SC/0289	NHS Permission	AMG-319: A Cancer Research UK randomised, double blind, placebo controlled, Phase IIa trial of AMG-319 given orally a a neoadjuvant therapy in patients with human papillomavirus (HPV) negative head and neck squamous cell carcinoma (HNSCC)	19/11/2015	20/11/2015	No		1			No	Sponsor delayed study activation. Site initiation cancelled by Sponsor on 22/12/2015
15/YH/0388	NHS Permission	CLDK378A2112 Food Effect: A multi-center, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC)	23/12/2015	23/12/2015	Yes	22/03/2016	0	90	90	No	Very rare mutation group. Low recruitment target of 2. 4 patients recruited as of Q2 2016/17.

14/SC/0171	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	18/01/2016	22/01/2016	No		4			No	Study put on hold by Sponsor due to drug availability. Study still awaiting 'green light' from Sponsor - Sponsor delay.
15/SC/0431	NHS Permission	CANC - 4032 Ramucirumab plus BSC vs placebo plus BSC as 2nd line treatment in HCC (JVDE)	03/02/2016	11/02/2016	Yes	17/03/2016	8	35	43	Yes	Target achieved
15/EM/0305	NHS Permission	CANC - 4278 - GTx-024 in Advanced, AR+ TNBC	16/02/2016	16/02/2016	No		0			No	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	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	17/02/2016	No		0			No	
15/EM/0546	NHS Permission	KESTREL: MEDI4736 or in combo with Tremelimumab vs SOC in 1st line SCCHN cancer	24/02/2016	24/02/2016	Yes	14/03/2016	0	19	19	Yes	Target achieved
15/NW/0690	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	25/02/2016	Yes	27/04/2016	0	62	62	Yes	Target achieved
15/SC/0676	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	07/03/2016	Yes	15/03/2016	0	8	8	Yes	Target achieved
15/LO/1612	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	10/03/2016	Yes	05/04/2016	0	26	26	Yes	Target achieved
15/WS/0121	NHS Permission	Javelin Lung 200: EMR100070004:Phase III study of avelumab vs docetaxel in NSCLC	23/03/2016	23/03/2016	No		0			No	Study not yet activated. Sponsor has put study on hold within the UK.
15/LO/0539	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	No		56			No	Sponsor delay finalising contract. One patient consented but withdrew due to progressive health issues.
16/WA/0014	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	No		42			No	Study not yet activated to recruit by Sponsor, Sponsor delay.
11/LO/1915	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	27	41	68	Yes	Target achieved
15/SC/0521	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	18	36	54	Yes	Target achieved
15/LO/1044	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	26	128	154	No	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	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	No		13			No	Activation delayed due to PI availability to complete training. No eligible patients seen.
12/NW/0827	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		84			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/NW/0671	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	17/03/2016	Yes	07/09/2016	0	174	174	No	Difficult patient group to recruit. 1 patient has been approached and awaiting an outcome. Patient now recruited 07/09/2016
15/WM/0392	NHS Permission	SARON - Stereotactic ablative radiotherapy for oligometastatic non-small cell lung cancer.	24/03/2016	05/07/2016	No		103			No	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 12/08/2016 and registered for study screening - awaiting outcome. To be updated Q3 16/17
15/NE/0013	NHS Permission	ROAM: Radiation versus observation following surgical resection of atypical meningioma: A randomised controlled trial	29/03/2016	12/07/2016	No		105			No	SSI submitted earlier than planned due to closure of CSP. Rare patient group.
15/LO/1635	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		95			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	NHS Permission	ABC08: Ph Ib Acelarin + cisplatin in advanced bililiary tract cancer	23/03/2016	27/07/2016	No		126			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.