Clatterbridge Cancer Centre (CCC) Performance in Initiating Research Q3 2015/16

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Benchmark Met	Comments
14/NW/1258	NCRN - 3041:ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER	08/01/2015	13/01/2015	Yes	17/03/2015	Yes	Target achieved
14/LO/1739	NCRN - 3036 PRESIDE Continuing enzalutamide in chemo-naive CRPC	08/01/2015	13/01/2015	Yes	16/02/2015	Yes	Target achieved
14/SC/1014	JANUS 1: A Randomized, Double-Blind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study)	14/01/2015	20/01/2015	No		No	Rare patient group. Also delay incurred due to issue with sub-contract with partner Trust.
14\NW\1027	SORAMIC Evaluation of Sorafenib in combination with local micro-therapy guided by Gd-EOB-DTPA enhanced MRI in patients with inoperable hepatocellular carcinoma	22/12/2014	27/01/2015	Yes	28/05/2015	No	A partner Trust also opened as a full site in order to deliver the study. The partner Trust had not given NHS permission therefore as both Trusts had to open at the same time, the Sponsor would not activate CCC until the partner Trust gave NHS permission for the study.
14/WM/1055	NCRN - 3246: Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer	06/02/2015	17/02/2015	No			Study has not yet been activated to recruit and is currently in suspend at site (updated Q3 2015-16).
14/EM/0089	BRAVO: A phase III, randomized, open label, multicenter, controlled trial of niraparib versus physician?s choice in previously-treated, HER2 negative, germline BRCA mutation-positive breast cancer patients.	03/02/2015	18/02/2015	Yes	01/04/2015	Yes	Target achieved
14/NW/1110	REECUR: International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	17/02/2015	24/02/2015	Yes	15/12/2015	No	Rare disease group
14/LO/1385	REASURE (Radium-223: Evaluation of Activity and SUrrogate REsponse)	24/02/2015	25/02/2015	Yes	12/06/2015	No	Sponsor delayed activating our site due to Sponsor staff availability issues. CCC was activated in April 2015 and the first patient was recruited within 4 weeks of activation.

14/LO/1788	GO29294 AntiPDL1 Bladder Cancer : A Phase III open-label multicenter randomised study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 antibody) compared to chemotherapy in patients with locally advanced or metastatic bladder cancer after the failure with platinum-containing chemotherapy	11/03/2015	17/03/2015	Yes	18/03/2015	Yes	Target achieved
15/EE/0013	CA209040 Phase 1 of Nivolumab in Advanced HCC: A Phase I Dose Escalation Study to Investigate the Safety, Immunoregulatory Activity, Pharmacokinetics, and Preliminary Antitumor Activity of Anti-Programmed-Death-1 (PD-1) Antibody (BMS-936558) in Advanced Hepatocellular Carcinoma in Subjects with or without Chronic Viral Hepatitis	12/03/2015	24/03/2015	Yes	25/03/2015	Yes	Target achieved
15/LO/0016	MONARCH-3 - A randomized, double-blind, placebo-controlled, phase 3 study of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting	11/05/2015	13/05/2015	No		No	1 patient consented on 15/05/2015 within the 70 day target but was ineligible on full screening. Study closed to recruitment 23/10/2015, short recruitment window.
14/SW/1164	HAWK: A Phase II, Multi-Centre, single-arm, global study of MEDI4736 Monotherapy in patients with recrurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)	15/06/2015	18/06/2015	No		No	Rare patient group. 3 Patients consented within 70 day target but were ineligible on screening tests and central pathology review.
14/LO/1426	NCRN - 2960 - Unresected Stage IIIB - IVM1a Melanoma Treated with Talimogene Laherparepvec	01/07/2015	02/07/2015	Yes	24/11/2015	No	Rare disease group. 1 Patient approached within the 70 day target but was ineligible on further screening.
15/LO/0165	Janssen Prostate: A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects with Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)	17/07/2015	20/07/2015	Yes	01/09/2015	Yes	Target achieved
15/LO/0236	A Phase II Clinical Trial of Pembrolizumab (MK-3475) in Subjects with Advanced/Unresectable or Metastatic Urothelial Cancer	17/07/2015	21/07/2015	No			Study not activated until 17/08/2015. Patient consented within the 70 day target 30/09/2015 but is still undergoing screening procedures; the patient's archival tissue was not suitable and therefore had to proceed to re-biopsy for central testing for eligibility. Complex screening procedures and strict eligibility criteria. (to be updated Q4 2015-16)

15/LO/0691	Checkmate 171: An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy inSubjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer(NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment ofStage IIIb/IV SqNSCLCCheckMate 171: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 171	21/07/2015	22/07/2015	Yes	28/07/2015	Yes	Target achieved
13/LO/0066	TAX-TORC: A phase 1 multi-centre trial of the combination of AZD2014 (dual mTORC1 and mTORC2 inhibitor) and weekly Paclitaxel in patients with solid tumours	10/08/2015	21/08/2015	Yes	12/10/2015	Yes	Target achieved
12/LO/0864	FIESTA: FGFR Inhibition for Epithelial Solid Tumours: a Phase Ib trial of AZD4547 in combination with gemcitabine and cisplatin	28/08/2015	02/09/2015	Yes	01/10/2015	Yes	Target achieved
14/LO/2182	TS103: A Phase III Clinical Trial of Intra-arterial TheraSphere? in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)	02/09/2015	03/09/2015	No			Study awaiting activation to recruit by sponsor.
14/WA/1118	PATHOS: Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	07/09/2015	24/09/2015	No		No	Rare group of patients.
15/LO/0448	RAINFALL: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Capecitabine and Cisplatin With or Without Ramucirumab as First-line Therapy in Patients With Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (RAINFALL)	24/09/2015	30/09/2015	No		No	Study not activated to recruit until 23/10/2015. Strict eligibility criteria. Although no eligible patients were seen within the 70 day target, in Q3 15-16 report 4 patients have been approached; 2 declined as they wanted standard of care treatment, 1 ineligible on screening investigations and 1 awaiting a decision.
15/LO/0897	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	Yes	Target achieved
15/LO/0159	SELPAC Uveal Melanoma Study	30/10/2015	30/10/2015	Yes	10/11/2015	Yes	Target achieved
13/LO/1481	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	Yes	Target achieved
14/SC/1156	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		Within 70 Days	Within 70 day target - to be updated Q4 15-16 submission

15/EE/0385	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	No		Within 70 Days	Within 70 day target - to be updated Q4 15-16 submission
15/SC/0291	MPDL3280A in solid tumours: An open label, multicohort, phase II study of MPDL3280A in advanced solid tumours	30/11/2015	01/12/2015	No		Within 70 Days	Within 70 day target - to be updated Q4 15-16 submission
15/NW/0431	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	No			Rare patient group given strict eligibility criteria for randomisation. 2 patients have consented and awaiting outcome of screening tests in Q3 15-16 report (to be updated Q4 2015-16)
15/WM/0011	Alligator - ADC-1013 First-in-Human study	27/10/2015	09/11/2015	No		No	First in Human study, strict eligibility criteria and rare patient group. Low recruitment target.
15/NE/0149	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	Yes	Target achieved
15/SC/0289	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			Sponsor delayed study activation. Site initiation cancelled by Sponsor on 22/12/2015
15/YH/0388	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	No		Within 70 Days	Within 70 day target - to be updated Q4 15-16 submission. Study awaiting activation, delay with SIV by Sponsor and PI availability.