

Clatterbridge Cancer Centre Performance in Delivering Research (PID) Q4 2015-16

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Maximum Number Of Patients Agreed	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Reason For Closure Of Trial	Comments
13/LO/1581	138131	NCRN - 2643 DNIB0600A in patients with Platinum-Resistant Ovarian Cancer:A randomized, open-label, multicentre, Phase II trial evaluating the safety and efficacy of DNIB0600A compared to pegylated liposomal doxorubicin administered intravenously to patients with platinum-resistant ovarian cancer	Number Agreed	4	Date Agreed	01/01/2016	2	03/02/2015	Recruitment Finished	Rare patient group. 5 patients were pre-screened/approached and 2 recruited, non entry as follows: 1 screen failed and 2 ineligible.
11/LO/1369	77657	NCRN301 - ADI-PEG 20 + BSC vs Placebo + BSC in 2nd line advanced HCC: A Randomized, Double-Blind, Multi-Center Phase 3 Study of ADI-PEG 20 Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Subjects With Advanced Hepatocellular Carcinoma (HCC) Who Have Failed Prior Systemic Therapy	Number Agreed	3	Date Agreed	03/02/2016	4	03/02/2015	Recruitment Finished	Target Achieved
14/LO/0022	137837	IMmotion150 (previously known as RAPID) - NCRN - 2511 - MPDL3280A +/- bevacizumab vs sunitinib in untreated advanced RCC:IMmotion150 - A Phase II, Randomized Study Of MPDL3280A Administered As Monotherapy Or In Combination With Bevacizumab Versus Sunitinib In Patients With Untreated Advanced Renal Cell Carcinoma	Number Agreed	4	Date Agreed	07/01/2017	0	10/02/2015	Recruitment Finished	Rare patient group. Competitive recruitment, study closed earlier than anticipated. 6 patients screened.
12/WA/0058	101872	NCRN398 IMAGE: Observational Study in Patients with Unresectable or Metastatic Melanoma	Number Agreed	10	Date Agreed	31/07/2017	29	28/03/2015	Recruitment Finished	Target Achieved
14/LO/1042	151262	NCRN - 3021 aPDL1 Bladder study	Number Agreed	5	Date Agreed	01/05/2018	5	30/03/2015	Recruitment Finished	Target Achieved
13/NE/0269	134646	TESARO NCRN - 2489: A PHASE III RANDOMISED DOUBLE BLIND TRIAL OF MAINTENANCE WITH NIRAPARIB VERSUS PLACEBO IN PATIENTS WITH PLATINUM SENSITIVE OVARIAN CANCER	Number Agreed	3	Date Agreed	01/03/2017	5	07/04/2015	Recruitment Finished	Target Achieved

13/LO/0720	124090	NCRN492 - The NEMO trial (NRAS melanoma and MEK inhibitor): A randomized Phase III, open label, multicenter, two-arm study comparing the efficacy of MEK162 versus Dacarbazine in patients with advanced unresectable or metastatic NRAS mutation positive melanoma	Number Agreed	2	Date Agreed	20/10/2015	1	30/04/2015	Recruitment Finished	Rare patient group. 11 patients were approached and 1 recruited. Non entry as follows: 7 patients consented but failed screening on central pathology review, 2 patients declined and 1 clinician decision.
13/SC/0121	122173	NCRN572 - OBLIQUE: A Phase IV Observational study to assess Quality of Life in Patients with Pancreatic Neuroendocrine Tumors receiving treatment with oral 10mg Everlimus (Afinitor®) o.d.: The OBLIQUE Study (CRAD001PGB12)	Number Agreed	5	Date Agreed	12/12/2017	6	30/04/2015	Recruitment Finished	Target Achieved
14/NW/0350	155196	CANC - 3483 Checkmate 143: A Randomized Phase IIB Open Label Study of Nivolumab or Nivolumab in Combination with Ipilimumab versus Bevacizumab in Adult Subjects with Recurrent Glioblastoma (GBM) (CheckMate 143: CHECKpoint pathway and nivolumAB clinical Trial Evaluation 143)	Number Agreed	3	Date Agreed	31/01/2018	1	15/05/2015	Recruitment Finished	5 patients pre-screened/approached and 1 recruited. Non entry as follows: 2 declined, 2 ineligible.
14/NE/1079	156749	CANC - 3546 RELIEVE2	Number Agreed	5	Date Agreed	31/07/2015	1	16/06/2015	Withdrawn By Sponsor	Unable to achieve target recruitment as study closed earlier than planned.
14/SC/0199	151181	CheckMate 141 - Nivolumab in Head and Neck (CA209-141): An open label, randomised phase 3 clinical trial of Nivolumab vs therapy of investigator's choice in recurrent or metastatic platinum-refractory squamous cell carcinoma of the head and neck (SCCHN)	Number Agreed	3	Date Agreed	01/01/2016	2	23/06/2015	Recruitment Finished	10 patients pre-screened/approached and 2 recruited. Non entry as follows: 5 ineligible; 2 declined; 1 Clinician decision.
13/WA/0328	134115	NCRN - 2597 AEZS108 and doxorubicin in patients with endometrial cancer	Number Agreed	4	Date Agreed	30/09/2016	1	29/06/2015	Recruitment Finished	Rare patient group. Strict eligibility criteria and difficult to meet criteria within this patient group.
14/NW/0020	146245	NCRN 2630 Bayer 16507 Standard dose versus higher and extended dose of Radium 223 in CRPC.: A three arm randomized, 1 open-label Phase II study of radium-223 dichloride 50 kBq/kg versus 80 kBq/kg, and versus 50 kBq/kg in an extended dosing schedule in subjects with castration-resistant prostate cancer metastatic to the bone	Number Agreed	6	Date Agreed	30/09/2023	4	02/07/2015	Recruitment Finished	Study closed before target recruitment achieved.

13/LO/1050	133364	NCRN - 2446 Lenvatinib (E7080) vs. Sorafenib in First-Line Treatment of Unresectable HCC :A Multicenter, Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib (E7080) Versus Sorafenib in First-Line Treatment of Subjects With Unresectable Hepatocellular Carcinoma	Number Agreed	6	Date Agreed	01/06/2016	1	15/07/2015	Recruitment Finished	7 patients screened/approached. Difficult patient group to recruit due to complex screening procedures.
14/LO/1739	161138	NCRN - 3036 PRESIDE Continuing enzalutamide in chemo-naive CRPC	Number Agreed	10	Date Agreed	01/01/2018	16	29/07/2015	Recruitment Finished	Target Achieved
14/NW/1036	152581	SHIONOGI BLADDER 1408P192 A multicenter, open-label, phase 2 study of S-588410 as maintenance monotherapy after first-line platinum-containing chemotherapy in patients with advanced and/or metastatic bladder cancer	Number Agreed	4	Date Agreed	30/09/2017	5	03/08/2015	Recruitment Finished	Target Achieved
13/YH/0126	126242	SATIVEX: A two part study to assess the tolerability, safety and pharmacodynamics of Sativex in combination with dose-intense Temozolomide in patients with recurrent glioblastoma	Number Agreed	4	Date Agreed	30/09/2015	1	04/08/2015	Recruitment Finished	Rare patient group. 8 patients were screened/approached and 1 recruited. Non entry was patient choice, patients were concerned about toxicity profile of study drug.
13/EM/0230	131237	NCRN636 - VS-6063 in mesothelioma: A phase II randomised, double blind, placebo-controlled, multicentre study of VS-6063 in subjects with malignant pleural mesothelioma	Number Agreed	8	Date Agreed	31/12/2016	8	28/09/2015	Recruitment Finished	Target Achieved
15/LO/0016	164539	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	Number Agreed	6	Date Agreed	30/11/2015	0	23/10/2015	Recruitment Finished	Short recruitment window, study only open to recruitment for 5 months. 1 patient consented but ineligible on screening investigations.
13/SC/0478	136687	COLUMBUS: NCRN 567 - A Phase III randomized, 3-arm, open label, multicenter study of LGX818 plus MEK162 and LGX818 monotherapy compared with vemurafenib in patients with unresectable or metastatic BRAF V600 mutant melanoma	Number Agreed	3	Date Agreed	21/08/2017	1	18/11/2015	Recruitment Finished	Study closed before target recruitment achieved.
14/NW/1258	161891	ARAMIS: NCRN - 3041:ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER	Number Agreed	6	Date Agreed	30/06/2020	6	21/12/2015	Recruitment Finished	Target Achieved

14/SC/1014	156913	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)	Number Agreed	5	Date Agreed	26/01/2016	0	08/01/2016	Recruitment Finished	Strict eligibility criteria, difficult to meet criteria with this patient group.
14/LO/1490	158617	CHECKMATE 172: A Single-Arm, Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) for Subjects with Histologically Confirmed Stage III (unresectable) or Stage IV Melanoma Progressing Post Prior Treatment Containing an Anti-CTLA-4 Monoclonal Antibody	Number Agreed	6	Date Agreed	30/04/2019	13	25/01/2016	Recruitment Finished	Target Achieved
14/LO/1798	161154	NCRN - 3312 - MPDL3280A vs Chemotherapy in Urothelial 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	Number Agreed	6	Date Agreed	18/12/2017	13	29/01/2016	Recruitment Finished	Target Achieved
14/SW/0091	150889	NCRN - 2974 VESTA: Veliparib, carboplatin & paclitaxel in NSCLC: NSCLC M11089 A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	Number Agreed	4	Date Agreed	31/03/2016	8	12/02/2016	Recruitment Finished	Target Achieved
14/SW/1164	165411	HAWK - CANC3672 - D4193C00001	Number Agreed	3	Date Agreed	01/02/2017	1	31/03/2016	Recruitment Finished	Rare patient group. 8 patients pre-screened/approached and 1 recruited. Non entry as follows: 6 consented but screen failed on central pathology review, 1 patient declined.
15/NE/0149	164909	CANC - 3928 - CONDOR	Number Agreed	2	Date Agreed	31/01/2017	3	31/03/2016	Recruitment Finished	Target Achieved