

## Clatterbridge Cancer Centre Performance in Initiating Research Q1 2015/16

REC 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
12/WA/0345	NeoSCOPE: Neoadjuvant - Study of Chemoradiotherapy in OesoPhagEal Cancer	25/11/2013	16/07/2014	Yes	11/12/2014	No	Delays due to completion of Radiotherapy QA. Study closed to recruitment Feb 2015.
13/LO/1463	InterAACT - An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease	15/07/2014	17/07/2014	Yes	06/02/2015	No	
14/SW/0091	NSCLC M11089 A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	21/07/2014	23/07/2014	No		No	12 patients have been approached/screened, but either ineligible or declined to take part.
13/SC/0111	FOCUS4 Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	26/06/2014	25/07/2014	Yes	27/01/2015	No	Due to the complexity of the study set-up involving pathology departments from different partner Trusts, this study had to be opened at 4 different partner Trusts, this inevitably caused delays in set-up and with sub-contracts.
14/SC/0199	An open label, randomised phase 3 clinical trial of Nivolumab vs therapy of investigators choice in recurrent or metastatic platinum-refractory squamous cell carcinoma of the head and neck (SCCHN)	31/07/2014	12/08/2014	Yes	27/02/2015	No	Rare disease group. Delayed due to issues with sub-contract with a partner Trust
14/NW/0336	Quality at CCC - What matters to patients at CCC?	11/08/2014	13/08/2014	Yes	22/09/2014	Yes	
13/NW/0153	CIPHER - Phase II multicentre study assessing the efficacy of Cabazitaxel in Patients with HER2-negative metastatic breast cancer and having unresectable brain metastases	13/06/2014	14/08/2014	Yes	24/12/2014	No	CCC was not activated as a site until 10/10/2014. Delays due to a sub-contract concerning the translational element of the study.
13/NW/0134	NEOBLADE: Phase II randomised placebo controlled Neoadjuvant chemotherapy study of Nintedanib with Gemcitabine and Cisplatin in locally advanced muscle invasive bladder cancer	12/08/2014	19/08/2014	Yes	23/09/2014	Yes	
14/NW/0036	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	24/07/2014	26/08/2014	Yes	30/09/2014	Yes	
14/LO/1042	GO29293 - MPDL3280A in metastatic bladder cancer	28/08/2014	28/08/2014	Yes	30/09/2014	Yes	
14/LO/1052	A Phase 2, Randomized, Open-Label, Parallel Group Study Evaluating the Safety and Efficacy of TAK-385, an Oral GnRH Antagonist, for Patients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant Androgen Deprivation Therapy With External Beam Radiation Therapy (EBRT)	09/09/2014	10/09/2014	Yes	20/11/2014	No	Delay in study being activated by Sponsor

14/NW/1036	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	18/08/2014	10/09/2014	Yes	07/10/2014	Yes	
14/NW/0350	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)	11/09/2014	30/09/2014	Yes	14/01/2015	No	Rare Disease Group
13/EE/0397	A randomised placebo-controlled trial of synchronous NIMorazole versus RADiotherapy alone in patients with locally advanced head and neck squamous cell carcinoma not suitable for synchronous chemotherapy or cetuximab	09/12/2014	18/12/2014	Yes	20/03/2015	No	Issues with completion of Radiotherapy QA - complex QA completion
14/LO/1151	A Phase Ib/II, Multicentre, Open Label, Randomised Study of BI 836845 in Combination with Enzalutamide, versus Enzalutamide alone, in Metastatic Castration-Resistant Prostate Cancer (CRPC) Following Disease Progression on Docetaxel-Based Chemotherapy and Abiraterone	20/10/2014	06/11/2014	Yes	23/12/2014	Yes	Target achieved
14/SC/1167	PHASE 3, RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND, MULTI-CENTER, TWO-PART STUDY OF PATRITUMAB (U3-1287) IN COMBINATION WITH ERLOTINIB IN EGFR WILD-TYPE SUBJECTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON AT LEAST ONE PRIOR SYSTEMIC THERAPY U31287-A-U301	10/11/2014	13/11/2014	Yes	31/12/2014	Yes	Target achieved
14/SS/0095	Randomised phase II trial of cabazitaxel or prolonged infusional ifosfamide in metastatic or inoperable locally advanced dedifferentiated liposarcoma	27/10/2014	11/12/2014	No		No	Rare Disease Group. 2 patients have been pre-screened, 1 consented and failed on screening tests. 1 patient ineligible on pre-screening.
14/NE/1079	A randomized, double-blind, placebo-controlled study to evaluate the Efficacy of two different dose levels of orvepitant (10 and 30mg) compared with placebo on EGFRi- induced intense pruritus in oncology subjects	20/10/2014	23/10/2014	Yes	17/11/2014	Yes	Target achieved
14/LO/1672	Polo Pancreatic 217674	20/11/2014	27/11/2014	No		No	3 patients pre-screened, 2 consented and failed on screening tests. 1 ineligible on pre-screening. Rare cancer group. Also delayed as study was temporarily in suspend. Informed by Northwest Coast CRN that we were unable to grant NHS permission until the lead site had completed the relevant checks in CSP.
13/LO/0822	A Phase II Trial of Vinflunine chemotherapy in locally advanced and metastatic carcinoma of the penis	10/10/2014	13/10/2014	Yes	28/01/2015	No	Rare Disease Group

13/EM/0266	Phase II, randomised, placebo controlled, multicentre, feasibility study of low dose (metronomic) cyclophosphamide with or without nintedanib (BIBF 1120) in advanced ovarian cancer (METRO-BIBF)	18/09/2014	09/10/2014	Yes	11/12/2014	No	Rare Disease Group
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	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	3 patients screened, 1 consented on screening tests, 1 ineligible on pre-screen and 1 declined. Rare disease group. Also delay incurred due to issue with sub-contract with partner Trust. One patient has been approached - awaiting a decision.
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 is also opening 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		No	Study has not yet been activated to recruit
14/EM/0089	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	International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	17/02/2015	24/02/2015	No		No	Rare disease group
14/LO/1385	REASURE (Radium-223: Evaluation of Activity and SURrogate REsponse)	24/02/2015	25/02/2015	No		No	
14/LO/1788	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	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		Within 70 Days	Within 70 day target. 1 patient has consented but requires a 'washout' period before the patient can be screened for full eligibility.
14/SW/1164	D4193C00001 (HAWK)	15/06/2015	18/06/2015	No		Within 70 Days	Within 70 day target