

Clatterbridge Cancer Centre Performance in Initiating Research Q3 2014-15 (Apr-Dec 14)

Id	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	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Comments	Reasons for delay correspond to:
46251	13/LO/1020	A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma Who have Received Prior Sorafenib	24/03/2014	02/04/2014	Yes	09/07/2014	9	98	107	No		Neither
46252	12/NW/0792	CANTATA - A multicentre, phase II randomised controlled trial evaluating cabazitaxel versus docetaxel rechallenge for the treatment of metastatic Castrate Refractory Prostate Cancer, previously treated with docetaxel at inception of primary hormone therapy	04/04/2014	08/04/2014	No		4			No		Neither
46253	14/NW/0020	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	14/05/2014	15/05/2014	Yes	17/07/2014	1	63	64	Yes		Please Select...
46254	13/SW/0295	A Qualitative Study to Identify the Rehabilitation Needs and Acceptability of Rehabilitation Services in Patients Newly Diagnosed with Inoperable Lung Cancer	29/04/2014	30/04/2014	Yes	24/06/2014	1	55	56	Yes		Please Select...
46255	13/NI/0143	SIEGE - Scheduling nabpaclitaxel with Gemcitabine (SIEGE): Randomised phase II trial to investigate two different schedules of nabpaclitaxel (Abraxane) combined with gemcitabine as first line treatment for metastatic pancreatic ductal adenocarcinoma	10/04/2014	13/05/2014	Yes	09/06/2014	33	27	60	Yes		Please Select...
46256	13/LO/1581	NCRN - 2643 DNIB0600A in patients with Platinum-Resistant Ovarian Cancer	17/04/2014	22/05/2014	Yes	14/08/2014	35	84	119	No		Neither
46257	14/LO/0135	A phase III randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with abiraterone acetate and prednisone/prednisolone in the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve subjects with bone predominant metastatic castration-resistant prostate cancer (CRPC)	30/05/2014	30/06/2014	Yes	02/09/2014	31	64	95	No	Delays due to sponsor - issue with supply of study drug	Sponsor
46258	13/SC/0478	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	30/05/2014	05/06/2014	No		6			No		Neither
46259	14/LO/0022	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	29/04/2014	05/06/2014	No		37			No	Rare Disease Group	Neither
46260	13/LO/1050	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	15/11/2011	23/06/2014	Yes	10/10/2014	951	109	1060	No	This study had difficulty opening as it was due to be opened at our main site, then at one of our satellites instead. There were delays from the sponsor in inspecting the satellite and in set-up and delays from CCC due to the sub-contractor for translational work.	Both
46261	12/WA/0345	NeoSCOPE: Neoadjuvant - Study of Chemoradiotherapy in Oesophageal Cancer	25/11/2013	16/07/2014	No		233			No	Delays due to the completed of RT QA.	NHS Provider
46262	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	No		2			No		Neither
46263	14/LO/0536	NSCLC M11089 A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	21/07/2014	23/07/2014	No		2			No		Neither

46264	13/SC/0111	FOCUS4 ? Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	26/06/2014	25/07/2014	No		29			No	Due to the complexity of the study set-up involving pathology departments from different acute Trusts, this study had to be opened at 4 different sites, this inevitably caused delays in set-up and with sub-contracts.	Both
46265	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	No		12			No	Delayed due to issues with sub-contract with a partner Trust	NHS Provider
46266	14/NW/0336	Quality at CCC - What matters to patients at CCC?	11/08/2014	13/08/2014	Yes	22/09/2014	2	40	42	Yes		Please Select...
46267	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	62	132	194	No	CCC was not activated as a site until 10/10/2014	Neither
46268	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	7	35	42	Yes		Please Select...
46269	14/NW/0036	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	24/07/2014	26/08/2014	Yes	30/09/2014	33	35	68	Yes		Please Select...
46270	14/LO/1042	G029293 - MPDL3280A in metastatic bladder cancer	28/08/2014	28/08/2014	Yes	30/09/2014	0	33	33	Yes		Please Select...
46271	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	1	71	72	No	Delay in study being activated by Sponsor	Sponsor
46272	14/NW/1036	SHIONOGI BLADDER 1408P192 A multicenter, open-label, phase 2 study of S-588410 as maintenance monotherapy after first-line platinumcontaining chemotherapy in patients with advanced and/or metastatic bladder cancer	18/08/2014	10/09/2014	Yes	07/10/2014	23	27	50	Yes		Neither
46273	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)	11/09/2013	30/09/2014	No		384			No	Rare Disease Group	Neither
46292	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	No		9			Within 70 Days	no patients recruited to date - within 70 days	Please Select...
46293	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	17	47	64	Yes	Achieved	Please Select...
46294	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	No		3			Within 70 Days	no patients recruited to date - within 70 days	Please Select...
46295	14/SS/0095	EORTC Soft Tissue and Bone Sarcoma Group	27/10/2014	11/12/2014	No		45			Within 70 Days	Rare Disease Group	Neither
46296	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	3	25	28	Yes	Achieved	Please Select...
46297	14/LO/1672	Polo Pancreatic 217674	20/11/2014	27/11/2014	No		7			Within 70 Days	no patients recruited to date - within 70 days	Please Select...
46298	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	No		3			No	Rare Disease Group	Neither

46299	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	21	63	84	No	Rare Disease Group	Neither
46300	14/SW/0091	NSCLC M11089 A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	21/07/2014	23/07/2014	No		2			No	Rare Disease Group	Unknown