

UHSM DOH Submission Q1 2015 2016 Performance in Initiating

ID	TrustID	SubmissionID	MetaSub missionID	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 and first Patient	Duration on VRA and first Patient	Benchmark Met	A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:			
55419	965	2106	31	10/H0706/65	ARISTOTLE – A phase III trial comparing standard versus novel CRT as pre-operative treatment for MRI defined locally advanced rectal cancer	25/06/2014	10/07/2014	Yes	19/02/2015	15	224	239	No						Y						Patients seen but no eligible patients identified.	Neither		
55420	965	2106	31	14/WS/0004	Open-label Extension Study of EFC12492, R727-CL-1112, EFC12732 & LTS11717 Studies to Assess the Long-Term Safety and Efficacy of Alirocicab in Patients with Heterozygous Familial Hypercholesterolemia	01/07/2014	22/07/2014	Yes	14/08/2014	21	23	44	Yes													Please Select...		
55421	965	2106	31	13/EM/0459	Positive Sentinel Node: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes	03/07/2014	22/07/2014	Yes	03/12/2014	19	134	153	No						Y							Patients seen but no eligible patients identified.	Neither	
55422	965	2106	31	13/LO/0451	The United Kingdom Aortic Valve Implantation (UK TAVI) Trial: A multi-centre randomised controlled trial to assess the clinical effectiveness and cost-utility of TAVI, compared with conventional surgical aortic valve replacement in patients with severe symptomatic aortic stenosis at intermediate or high operative risk	15/07/2014	18/07/2014	Yes	23/09/2014	3	67	70	Yes													Please Select...		
55423	965	2106	31	14/NW/0253	Randomised prospective pilot study comparing conventional brain cooling with additional early trans-nasal cooling prior to surgery on the ascending aorta/proximal aortic arch	25/07/2014	05/08/2014	Yes	13/08/2014	11	8	19	Yes													Please Select...		
55424	965	2106	31	12/WM/0187	A randomised controlled trial of reinforcement of closure of stoma site using a biological mesh	30/07/2014	04/08/2014	Yes	11/08/2014	5	7	12	Yes													Please Select...		
55425	965	2106	31	13/WM/0419	MAMMO50: Mammographic surveillance in breast cancer patients aged 50 years and over	31/07/2014	15/08/2014	Yes	28/10/2014	15	74	89	No						Y							Patients seen but no eligible patients identified.	Neither	
55426	965	2106	31	14/NW/0008	Golimubab: A Phase 4, UK Open Label, Single arm Study on its Utilization and Impact in Ulcerative Colitis	05/08/2014	13/08/2014	No		8							Y									Sponsor delayed confirmation of study open to recruitment at site. It took 40 days to confirm study was open and ready for recruitment.	Sponsor	
55427	965	2106	31	14/SW/0091	Randomized, DoubleBlind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous Non Small Cell Lung Cancer (NSCLC)	11/08/2014	26/08/2014	Yes	30/10/2014	15	65	80	No							Y						Eligible patients seen chose not to participate in study - still looking but only targeted 4 patients in 1 year.	Neither	
55428	965	2106	31	14/WM/1088	Prevention of Cancer at Screening: Lifestyle Prevention (PROCAS Lifestyle Prevention) Feasibility Study. Does personalised information about risk of cardiovascular disease and diabetes enhance uptake and adherence to a weight loss programme amongst women	11/08/2014	16/09/2014	Yes	18/11/2014	36	63	99	No	Y												SSI submitted before ethical approval.	Sponsor	
55429	965	2106	31	14/LO/0521	A prospective, randomized, open label, two arm Phase III study to evaluate treatment free remission (TFR) rate in patients with Philadelphia positive CML after two different durations of consolidation treatment with nilotinib 300mg BID.	28/08/2014	04/09/2014	No		7									Y							patients screened but no eligible patients identified, problems recruiting to this trial on a national scale.	Neither	
55430	965	2106	31	12/EE/0445	A randomised double-blind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with Anemia undergoing Major Open Abdominal Surgery	01/09/2014	05/09/2014	Yes	20/11/2014	4	76	80	No						Y							Patients seen but no eligible patients identified.	Neither	
55431	965	2106	31	14/NW/0157	A pilot study of the value of delayed dynamic breast MRI sequences in the assessment of the extent of ductal carcinoma in situ	27/06/2014	21/07/2014	No		24											Y					Although local UHSM R&D approval was given in July, recruitment was delayed due to the unexpected need for a SSA with WMIC which was only received approval on 31st October.	Both	
55432	965	2106	31	14/SC/1097	A randomised controlled trial of the effect of intermittent energy restriction (IER) versus daily energy restriction (DER) on body fat stores and cancer related biomarkers	02/12/2014	13/03/2015	Yes	13/03/2015	101	0	101	No	Y												Study wide review not completed in time by NHS provider.	NHS Provider	
55433	965	2106	31	14/NW/0334	An investigation of a novel circulating tumour cell detection device (CellCollector) in non-small cell lung cancer	24/09/2014	08/10/2014	Yes	02/02/2015	14	117	131	No						Y							A problem with the protocol was recognised and a substantial amendment has been submitted.	Neither	
55434	965	2106	31	14/NW/1015	Copper Chelation in Hypertrophic Cardiomyopathy: Open-label pilot study of Trientine in patients with Hypertrophic Cardiomyopathy	08/10/2014	31/10/2014	Yes	25/03/2015	23	145	168	No						Y							Patients screened but no eligible patients identified.	Neither	
55435	965	2106	31	14/WM/0057	Multicentre randomised controlled trial to compare the clinical and cost effectiveness of a 'vein bypass first' with a 'best endovascular first' revascularisation strategy for severe limb ischaemia due to infrapopliteal arterial disease: Bypass vs. Angiop	09/09/2014	29/09/2014	No		20									Y							Patients screened but no eligible patients identified. No further eligible patients seen	Neither	
55436	965	2106	31	14/YH/1124	A phase IIb/IV randomised, controlled, open label, parallel group study to compare the efficacy of Vancomycin Therapy to extended duration Fidaxomicin Therapy in the sustained clinical cure of Clostridium Difficile Infection in an older population	02/12/2014	04/12/2014	No		2									Y							Patients screened but no eligible patients identified. Strict patient eligibility criteria. Sponsor has opened new sites and have recently obtained ethics approval to include a legal representative consent form to open up eligibility	Neither	
55437	965	2106	31	14/LO/1513	A Randomized, Open-Label, Phase 4 Study Evaluating the Renal Effect of 'elvitagravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz/Emtricitabine/T	08/12/2014	11/12/2014	Yes	09/03/2015	3	88	91	No						Y							Strict patient eligibility criteria no patients seen.	Neither	
55438	965	2106	31	12/YH/0452	A multicentre randomised phase II clinical trial of inotuzumab ozogamicin plus rituximab and cvp (IO-R-CVP) versus gemtacin plus rituximab and cvp (Gem-R- CVP) for the first line treatment of patients with diffuse large B cell lymphoma who are not suit	24/11/2014	27/11/2014	No		3									Y							Patients screened but no eligible patients identified.	Neither	
55439	965	2106	31	14/WM/0083	A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in situ (DCIS)	03/10/2014	04/11/2014	Yes	30/06/2015	32	238	270	No						Y							Patients screened but no eligible patients identified.	Neither	
55440	965	2106	31	14/LO/0818	A Randomised Open-label Phase II Trial of MK-3475 versus Platinum based Chemotherapy in 1L Subjects with PD-1 Strong Metastatic Non-Small Cell Lung Cancer	01/11/2014	02/02/2015	Yes	26/05/2015	93	113	206	No	Y												Local review not completed in time.	NHS Provider	
55441	965	2106	31	14/NW/1396	A Randomised phase II trial of intermittent energy restriction and resistance exercise in women receiving chemotherapy for advanced breast cancer	14/01/2015	10/02/2015	Yes	27/05/2015	27	106	133	No										Y			UHSM are not recruiting to this study.	Neither	
55442	965	2106	31	12/LO/0078	A Multicentre non blinded randomised controlled trial to assess the impact of regular early specialist symptom control treatment on quality of life in malignant mesothelioma - "respect meso "	09/03/2015	18/03/2015	Yes	18/05/2015	9	61	70	Yes														Please Select...	
55443	965	2106	31	14/SC/1223	A phase II randomised feasibility study of chemoresection and surgical management in low risk non muscle invasive bladder cancer	19/01/2015	27/01/2015	Yes	17/04/2015	8	80	88	No						Y							Patients screened but no eligible patients identified.	Neither	
55444	965	2106	31	13/LO/1434	A phase II open label multicentre randomised controlled trial comparin hyperthermia plus mitomycin	19/01/2015	21/01/2015	Yes	13/03/2015	2	51	53	Yes													Please Select...		
55445	965	2106	31	05/Q1206/16	PATCH: Prostrate Adenocarcinoma TransCutaneous Hormones A randomised-controlled trial of transcutaneous oestrogen patches versus LHRH analogues in prostate cancer	11/02/2015	19/02/2015	No		8									Y							Patients screened but no eligible patients identified.	Neither	
55446	965	2106	31	13/EM/0343	A randomized, comparative effectiveness study of complete versus culprit-only revascularization strategies to treat multi-vessel disease after primary percutaneous coronary intervention for ST-segment elevation myocardial infarction.	10/03/2015	16/03/2015	Yes	02/04/2015	6	17	23	Yes														Please Select...	
55447	965	2106	31	14/SC/1320	An exploratory clinical testing of readyspeech	21/01/2015	18/02/2015	Yes	17/04/2015	28	58	86	No						Y								Patients screened but no eligible patients identified.	Neither

