

Performance in Initiating Research UHSM 2015/2015 Quarter 4

ID	TrustID	SubmissionID	MetaSubmissionID	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 NRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between NRA 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	K - Not Used	L - Not Used	M - Not Used	N - Not Used	O - Not Used	Comments	Reasons for delay correspond to:				
50411	965	1748	30	13/NW/0612	A multicentre, randomised, double-blind, parallel group, placebo-controlled, phase III efficacy and safety study of benralizumab (MEDI-563) added to high-dose inhaled corticosteroid plus long-acting B2-agonist in patients with Uncontrolled asthma (SIRCOCCO)	14/04/2014	06/05/2014	Yes	19/06/2014	22	44	66	Yes																		Please Select...			
50412	965	1748	30	14/YH/0094	Senosense Study: Menstrual cycle related fluctuations in breast density measured using electrical impedance	01/04/2014	07/05/2014	Yes	23/06/2014	36	47	83	No	Y																	NHS Provider			
50413	965	1748	30	13/LO/0365	An efficacy and mechanism evaluation of Levosimendan for the Prevention of Acute Organ Dysfunction in Sepsis (LeOPARDS)	29/04/2014	07/05/2014	Yes	07/04/2015	8	335	343	No						Y												Patients seen but no eligible patients identified, then recruitment was closed for months, Recruitment has reopened now	Neither		
50414	965	1748	30	13/NW/0485	3D contrast enhanced ultrasound (3D CEUS) for detecting endoleak following endovascular aneurysm	23/04/2014	09/05/2014	Yes	21/05/2014	16	12	28	Yes																			Please Select...		
50415	965	1748	30	13/WA/0084	A Randomised, Double-Blind, Placebo-Controlled, Multicentre Study to Assess Cardiovascular Outcomes Following Treatment with MK-3102 in Subjects with Type 2 Diabetes Mellitus	07/05/2014	14/05/2014	Yes	21/08/2014	7	99	106	No						Y													Patients seen but no eligible patients identified.	Neither	
50416	965	1748	30	14/ES/0001	Randomised, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess Cardiovascular Outcomes Following Treatment with Ertugliflozin (MK-8835/PF-04971729) in Participants with Type 2 Diabetes Mellitus and Established Vascular Disease	01/05/2014	29/05/2014	Yes	02/06/2014	28	4	32	Yes																			Please Select...		
50417	965	1748	30	13/LO/0867	Double-blind, randomised, multicentre, phase II study of nintedanib in combination with pemetrexed/cisplatin followed by continuing nintedanib monotherapy versus placebo in combination with pemetrexed/cisplatin followed by continuing placebo monotherapy f	23/05/2014	04/06/2014	Yes	08/07/2014	12	34	46	Yes																				Please Select...	
50418	965	1748	30	14/NW/0003	Randomised prospective study comparing Phrenic Nerve Infiltration vs Non-Phrenic Nerve Infiltration on Open Thoracotomy	28/04/2014	05/06/2014	No		38									Y													Patients seen but no eligible patients identified.	Neither	
50419	965	1748	30	14/EM/0024	A phase III, randomized, double-blind, placebo-controlled multicenter study of subcutaneous secukinumab in autoinjectors, to demonstrate efficacy at 24 weeks and to assess the long term safety, tolerability and efficacy up to 3 years in subjects with	04/06/2014	10/06/2014	Yes	22/08/2014	6	73	79	No					Y														Sponsor delay in provision of study documentation. - GRAPPA training was not sent to site on time.	Sponsor	
50420	965	1748	30	14/NE/0016	IRIS-3: A 12 week double-blind, randomised, placebo-controlled, parallel group phase III study, followed by a 4-week randomised withdrawal period to evaluate the efficacy and safety of oral Ibodutant 10mg once daily in female patients with Irritable Bowel	19/06/2014	24/06/2014	Yes	13/08/2014	5	50	55	Yes																			Please Select...		
50421	965	1748	30	14/NW/0211	A double-blind, randomised, placebo-controlled, crossover study to assess the efficacy of XEN-D0501, a TRPV1 antagonist, in reducing the frequency of cough in patients with chronic idiopathic cough.	24/06/2014	27/06/2014	Yes	24/07/2014	3	27	30	Yes																				Please Select...	
50422	965	1748	30	11/H1307/6	SWITCH: Randomised -controlled trial of switching to alternative tumour-necrosis factor (TNF)-blocking drugs or abatacept or rituximab in patients with rheumatoid arthritis who have failed an initial TNF-blocking drug.	03/06/2014	30/06/2014	No		27									Y													Patients seen but no eligible patients identified.	Neither	
50423	965	1748	30	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	
50424	965	1748	30	14/WS/0004	Open-label Extension Study of EFC12492, R727-CL-1112, EFC12732 & LTS11717 Studies to Assess the Long-Term Safety and Efficacy of Alirocumab in Patients with Heterozygous Familial Hypercholesterolemia	01/07/2014	22/07/2014	Yes	14/08/2014	21	23	44	Yes																				Please Select...	
50425	965	1748	30	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	
50426	965	1748	30	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 sy	15/07/2014	18/07/2014	Yes	23/09/2014	3	67	70	Yes																				Please Select...	
50427	965	1748	30	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...	
50428	965	1748	30	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...	
50429	965	1748	30	13/WM/0419	MAMMOSO: 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	
50430	965	1748	30	14/NW/0008	Golimumab: 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	
50431	965	1748	30	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	No		15										Y												Eligible patients seen chose not to participate in study. - still looking but only targeted 4 patients in 1 year.	Neither	
50432	965	1748	30	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	No		36				Y																		SSI submitted before ethical approval.	Sponsor	
50433	965	1748	30	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 seen but no eligible patients identified.	Neither	
50434	965	1748	30	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	No		4									Y													Patients seen but no eligible patients identified.	Neither	
50435	965	1748	30	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
50436	965	1748	30	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	
50437	965	1748	30	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	

