

UHSM Performance in Initiating Quarter 2 2015/2016

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	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:
61175	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
61176	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
61177	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
61178	14/YH/1124	A phase IIIb/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			No					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
61179	14/LO/1513	A randomized, Open-Label, Phase 4 Study Evaluating the Renal Effect of 'elvitegravir/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
61180	12/YH/0452	A multicentre randomised phase II clinical trial of inotuzumab ozogamicin plus rituximab and cyp (IO-R-CVP) versus gemcitabine plus rituximab and cyp (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			No					Y						Patients screened but no eligible patients identified.	Neither
61181	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
61182	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. The SSI for this study was submitted before the costings had been finalised and the contracts signed therefore it took 94 days in which to give R&D approval	NHS Provider
61183	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
61184	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...
61185	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
61186	13/LO/1434	A phase II open label multicentre randomised controlled trial comparing hyperthermia plus mitomycin	19/01/2015	21/01/2015	Yes	13/03/2015	2	51	53	Yes												Please Select...
61187	05/Q1206/168	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			No					Y						Patients screened but no eligible patients identified.	Neither
61188	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...
61189	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
61190	14/NW/1350	Evaluation of orvepitant in an exploratory open label clinical study in chronic treatment refractory cough	03/02/2015	09/02/2015	Yes	26/02/2015	6	17	23	Yes												Please Select...
61191	15/NW/0052	Investigating the interaction between bronchoconstriction and cough in asthma	12/02/2015	18/02/2015	Yes	23/02/2015	6	5	11	Yes												Please Select...
61192	13/NE/0006	A pilot Randomised controlled trial of the use of ReCell autologous cell harvesting device for venous Leg Ulcers	19/02/2015	24/02/2015	Yes	09/03/2015	5	13	18	Yes												Please Select...
61193	14/NW/1195	Lung Clearance Index (LCI) as a Sensitive Measure of Early Airway Change in Cystic Fibrosis	15/10/2014	27/10/2014	Yes	21/11/2014	12	25	37	Yes												Please Select...
61194	15/NW/0100	Detection of atrial fibrillation in community locations using novel technology's as a method of stroke prevention in the over 65's asymptomatic population should it become standard practice	02/04/2015	13/04/2015	Yes	14/04/2015	11	1	12	Yes												Please Select...
61195	15/LO/0018	A Randomized double blind placebo controlled multiple dose study of subcutaneous AC2885 for the treatment of abdominal aortic aneurysm	07/04/2015	10/04/2015	Yes	10/06/2015	3	61	64	Yes												Please Select...
61196	15/EE/0003	A randomized, double-blind, placebo-controlled Phase 3 study of ISIS 304801 administered subcutaneously to patients with hypertriglyceridemia	09/04/2015	13/04/2015	No		4			No					Y						Patients screened but no eligible patients identified.	Neither
61197	14/EM/1141	A randomized double blind placebo controlled phase 3 study of ISIS 304801 administered subcutaneously to patients with familial chylomicronemia syndrome	14/04/2015	14/04/2015	Yes	12/08/2015	0	120	120	No					Y						Patients screened but no eligible patients identified.	Neither
61198	15/NW/0255	A phase 3, multi-center, randomised, open-label study of Carabance (Meropenem/RPX7009) versus best available therapy in subjects with selected serious infections due to Carabapenem-resistant Enterobacteriaceae	20/05/2015	29/05/2015	Yes	08/07/2015	9	40	49	Yes												Please Select...
61199	14/NW/1337	A Multicentre, Randomised, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-Acting B2-Agonist (BORA)	16/06/2015	17/06/2015	Yes	01/07/2015	1	14	15	Yes												Please Select...
61200	14/LO/0324	A multi-centre, randomised, double-blind, placebo-controlled study to Evaluate the Safety and Efficacy of Pulmaquin® in the Management of Chronic Lung Infections with Pseudomonas Aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28 Day Open-Label Extension and Pharmacokinetic Substudy	25/06/2015	30/06/2015	Yes	14/07/2015	5	14	19	Yes												Please Select...
61201	12/WM/0335	A pilot study for developing and evaluating a care pathway for cognitive problems after stroke (OCS-care)	02/06/2015	18/06/2015	Yes	18/06/2015	16	0	16	Yes												Please Select...
61202	12/YH/0539	an open label multi centre preoperative window of opportunity study of afatinib in stage Ia to Ib non small cell lung cancer	11/05/2015	01/06/2015	No		21			No								Y			having problems with The Christie in the set-up and use of a PET-CT scanner for the trial (an SLA is in place)it is a very logistically complicated study, hence the need to get it set-up properly before we start	Sponsor
61203	15/NW/0163	PATHWAY: Improving the effectiveness of Psychological Interventions for Depression and Anxiety in the Cardiac Rehabilitation Pathway. A single-blind, pilot, randomised, controlled trial with four-month and twelve-month follow-up comparing Group MCT plus usual CR (intervention) with usual CR (control).	09/06/2015	11/06/2015	Yes	23/07/2015	2	42	44	Yes												Please Select...
61204	15/WA/0132	EPIC AAA Study: Exercise Capacity, Physical Inactivity and Cardiovascular Risk in AAA Patients	08/04/2015	29/04/2015	Yes	14/05/2015	21	15	36	Yes												Please Select...
62158	14/EM/1280	A randomised controlled trial to investigate the effectiveness of ThOraic epidural and Paravertebral blockade in thoracotomy pain - TOPIC Feasibility Study	04/08/2015	17/08/2015	Yes	14/09/2015	13	28	41	Yes												Please Select...
62159	15/NW/0485	The Goal Directed Perfusion Trial	27/08/2015	01/09/2015	No		5			No												Please Select...
62160	15/NW/0022	A multicentre randomised clinical trial to investigate whether Bone Anchored Maxillary Protraction (BAMP) reduces the need for orthognathic (facial) surgery	23/07/2015	23/09/2015	No		62			No												Please Select...
62161	14/NE/1176	Multi-centre randomised controlled trial with economic evaluation and nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia versus arthroscopic capsular release for patients referred to secondary care with a frozen shoulder (Adhesive Capsulitis)	17/08/2015	01/09/2015	Yes	22/09/2015	15	21	36	Yes												Please Select...
62162	15/NW/0371	ReadySpeech for people with dysarthria after stroke: a feasibility study	16/06/2015	20/07/2015	Yes	15/09/2015	34	57	91	No					Y						NHS Provider staff availability - annual leave. SSI was submitted early and recruitment could not begin within 70 days due to staff being on annual leave	NHS Provider
62163	14/LO/1800	The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary Fibrosis with the addition of Co-trimoxazole (EME-TIPAC)	07/09/2015	22/09/2015	No		15			No												Please Select...
62164	14/NW/1497	The Role of GABA(B) Receptor Mechanisms in Cough: Double-Blind Randomised Controlled Trial of Lesgaberen in Chronic Cough Patients with Positive and Negative Symptom Association Probabilities	10/07/2015	10/07/2015	Yes	23/07/2015	0	13	13	Yes												Please Select...