

University Hospitals of Leicester NHS Trust

Research & Development Directorate

Performance in Initiating Research

1st October 2013 to 30th September 2014

REC Reference Number	Name of Trial	Date of Valid Research Application	Date of First Patient In	Reasons for not achieving the 70 day benchmark										
				A	B	C	D	E	F	G	H	I	J	
				Permission delayed / denied	Suspended by Sponsor	Closed by Sponsor	Sponsor delays	Staff availability issues	No eligible patients	No patients consented	Contracting delays	Rare diseases	Other	
11/LO/0485	Evaluation of the IncoStress device for female urinary incontinence: a feasibility study and a pilot randomised controlled trial.	19/09/2013	08/10/2013					Y						
13/ES/0088	A Multicentre, double blind, randomized, parallel group, placebo-controlled study to evaluate the effects of intravenous serelaxin infusion on micro - and macro-vascular function in subjects with coronary artery disease.	17/03/2014	17/03/2014				Y							
14/EM/0135	Motivation after Exercise in Chronic Kidney Disease: MaX CKD	25/04/2014	23/05/2014											Y
13/LO/1766	A Phase I, open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity of MSB0010718C in subjects with metastatic or locally advanced solid tumors and expansion to selected indicati	20/05/2014	22/05/2014							Y				Y
14/WM/10616	Next Gen IR Thermometer Clinical Site Beta Testing	15/09/2014	15/09/2014											
13/EM/0476	ABSORB UK Registry A postmarket registry of patients with de novo lesions in previously untreated vessels treated with Absorb BVS	19/09/2014	25/09/2014											
14/EM/1061	Investigating the effects of ultrasound guided autologous blood injection for chronic plantar fasciitis versus ultrasound guided dry-needling alone, a randomised controlled trial	25/09/2014	25/09/2014											
14/WS/1069	Assessing the benefits of the use of a tension night splint in patients with plantar fasciitis, a single-blinded randomised controlled trial	04/09/2014	10/09/2014											
13/NI/0148	A phase II, randomised, doubleblind, placebocontrolled, multicentre trial to assess the oral corticosteroidsparing effect of lebrikizumab in patients with with severe corticosteroiddependant asthma	02/12/2013	19/12/2013				Y							

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12/EE/0164	A multi-centre (UK) double-blind randomised parallel group placebo controlled trial to evaluate the efficacy, safety, and tolerability of Intravenous Immunoglobulin (IVIg) 0.5g/kg plus standard treatment, versus matched placebo plus standard treatment in	07/02/2014	18/02/2014											
12/NW/0467	Evaluating the efficacy of thoracoscopy and talc poudrage versus pleurodesis using talc slurry: a randomised trial to determine the most effective method for the management of malignant pleural effusions in patients with a good performance status.	17/02/2014	01/04/2014							Y		Y		
12/NE/0220	A phase 2 study of the efficacy and safety of Deferasirox administered at early iron loading in patients with transfusion dependent Myelodysplastic Syndromes	30/06/2014	30/06/2014										Y	
13/EM/0112	The short term effects of an AKT inhibitor (AZD5363) on biomarkers of the AKT pathway and anti-tumour activity in a breast cancer paired biopsy study (STAKT Trial)	19/12/2013	30/01/2014				Y			Y				Y
13/LO/0451	The United Kingdom Transcatheter 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	08/08/2014	18/08/2014											
13/WM/0311	Impact of liraglutide on cardiac function and structure in young adults with type 2 diabetes: an open label, randomised active-comparator trial.	19/11/2013	16/12/2013				Y							
12/NW/0694	A 12-week randomized, open-label, active comparator period followed by a 12-week safety extension period to evaluate the safety and efficacy of Fesoterodine in subjects aged 6 to 16 years and >25 kg with symptoms of detrusor overactivity associated with a	20/02/2014	27/02/2014				Y			Y				
12/YH/0475	A PHASE Ib MULTICENTER DOSE-FINDING AND SAFETY STUDY OF GDC-0199 AND OBINUTUZUMAB IN PATIENTS WITH RELAPSED OR REFRACTORY OR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA	25/09/2013	26/11/2013				Y			Y				
13/WA/0117	A randomised phase II trial of Olaparib maintenance versus placebo monotherapy in patients with non-small cell lung cancer	28/11/2013	17/12/2013				Y							

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13/LO/1115	UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy In Incident Haemodialysis Patients	15/10/2013	08/11/2013										
13/LO/0418	A multi-centre, randomised, placebo controlled double blind, two armed, parallel group study to evaluate efficacy and safety of IV Sildenafil in the treatment of neonates persistent pulmonary hypertension of the newborn (PPHN) or hypoxic respiratory failure	25/09/2013	30/11/2013				Y		Y			Y	
12/NE/0343	Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy	01/11/2013	18/11/2013				Y						
12/SS/0138	REstart or STop Antithrombotics Randomised Trial - RESTART	11/09/2014	16/09/2014										
12/SC/0515	Protocolised trial of invasive and non-invasive weaning off ventilation (the BREATHE study)	28/10/2013	29/10/2013				Y		Y				
13/LO/0578	A randomized, double blind, placebo controlled, multi-centre study to assess the pharmacodynamics, pharmacokinetics, safety and tolerability of BYM338 in chronic obstructive pulmonary disease patients with cachexia	10/02/2014	12/03/2014										
13/EM/0340	A Phase 2 Open-Label Study of the Efficacy of ABT-199 (GDC-0199) in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia Harboring the 17p Deletion	08/11/2013	03/12/2013										
13/WM/0445	The effect of implementing a 12 week supervised exercise programme 12 to 24 months post bariatric surgery on physical function and physical activity maintenance.	23/12/2013	21/01/2014										
13/EM/0460	A RANDOMIZED, MULTICENTER, OPEN-LABEL TRIAL COMPARING CHEMOTHERAPY PLUS TRASTUZUMAB PLUS PERTUZUMAB VERSUS CHEMOTHERAPY PLUS TRASTUZUMAB EMTANSINE PLUS PERTUZUMAB AS ADJUVANT THERAPY IN PATIENTS WITH OPERABLE HER2 POSITIVE PRIMARY BREAST CANCER	11/04/2014	13/04/2014				Y		Y				
13/LO/0395	Pilot Randomised Controlled Trial of Cardiac Rehabilitation vs. Standard Care after Aortic Aneurysm Repair to reduce Adverse Cardiovascular Events	29/07/2014	11/08/2014										

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13/YH/0140	Effect of ivabradine versus placebo on cardiac function, exercise capacity, and neuroendocrine activation in patients with Chronic Heart Failure with Preserved left ventricular Ejection Fraction An 8-month, randomised double-blind, placebo controlled, int	24/10/2013	28/10/2013				Y			Y				
13/SS/0051	Targeted Rehabilitation to Improve Outcome after knee replacement- A Physiotherapy Study (TRIO-Physio)	13/06/2014	23/06/2014							Y				
13/YH/0152	A Randomised Trial of the FLAMSA-BU Conditioning Regimen in Patients with Acute Myeloid Leukaemia and Myelodysplasia Undergoing Allogeneic Stem Cell Transplantation	28/03/2014	02/04/2014	Y			Y							
13/WM/0114	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Bendamustine and Rituximab (BR) in Subjects With Newly Diagnosed Mantle Cell Lymphoma	31/07/2013	19/02/2014				Y					Y	Y	
14/LO/0121	A Phase II, randomised, placebo-controlled study of paclitaxel in combination with the AKT inhibitor AZD5363 in triple-negative advanced or metastatic breast cancer	12/08/2014	13/08/2014				Y							Y
13/EM/0323	A feasibility study to inform the development of a multicentre randomised controlled trial of an asthma-tailored pulmonary rehabilitation programme versus usual care for individuals with severe asthma.	09/10/2013	25/11/2013	Y			Y							
13/YH/0162	HABSelect: Selection of sperm for Assisted Reproductive Treatment by prior hyaluronic acid binding: increasing live birth outcomes and reducing miscarriage rates - multicentre, randomised controlled, blinded trial	01/07/2014	02/07/2014											
13/SW/0132	Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial	09/01/2014	09/01/2014											
13/NI/0143	Scheduling nab-paclitaxel with Gemcitabine (SIEGE): Randomised phase II trial to investigate two different schedules of nab-paclitaxel (Abraxane) combined with gemcitabine as first line treatment for metastatic pancreatic ductal adenocarcinoma	11/02/2014	03/03/2014							Y				

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13/LO/1517	Phase 3, Randomized, Open Label, Active-Controlled Study to Evaluate the Efficacy and Safety of FG4592 in the Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis	16/05/2014	16/05/2014				Y	Y						
13/EM/0251	A multicenter, randomized, double-blind, placebo- controlled phase III study to evaluate the efficacy, safety and tolerability of Serelaxin when added to standard therapy in acute heart failure patients	10/09/2013	17/10/2013											
13/SC/0384	A Phase 2, Randomized, Double-blind Study Comparing Tremelimumab to Placebo in Second- or Third-line Treatment of Subjects with Unresectable Pleural or Peritoneal Malignant Mesothelioma	29/01/2014	13/02/2014				Y							
13/LO/1481	A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma	09/04/2014	16/04/2014				Y							
13/EM/0284	A phase III, multicenter, randomized, open-label study of oral LDK378 versus standard chemotherapy in adult patients with ALK-rearranged (ALK-positive) advanced non-small cell lung cancer who have been treated previously with chemotherapy (platinum double	03/10/2013	04/12/2013	Y			Y		Y					
13/EE/0241	Secukinumab In patients with moderate to severe active, chronic plaque psoriasis who have failed on TNFa antaGoNists: A clinical Trial EvalUating Treatment REsults (SIGNATURE)	08/01/2014	15/01/2014							Y				
13/EE/0377	A Phase 2b Study to Evaluate the Safety and Efficacy of Elagolix in Premenopausal Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids	21/01/2014	12/03/2014	Y			Y		Y					
13/NW/0692	A multicenter, international, randomized, parallel group, double blind, placebo-controlled Cardiovascular Safety & Renal Microvascular outcomE with LINAgliptin, 5 mg once daily in patients with type	05/12/2013	06/12/2013				Y		Y					
13/EE/0390	Pregnancy And chronic hypertension: NifeDipine or labetalol as Antihypertensive treatment	05/09/2014	12/09/2014											

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13/SC/0490	A Phase III, randomised, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of lebrikizumab in adolescent patients with uncontrolled asthma who are on inhaled corticosteroids and second controller medication.	19/05/2014	19/05/2014				Y						
13/EE/0247	A Phase 2a, 4-Week Treatment Period, Randomized, Double-Blind, Parallel Group, PA Phase 2a, 4-Week Treatment Period, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Proof of Concept Study to Evaluate Efficacy, Safety and Tolerability of Inhal	30/09/2013	04/11/2013										
13/WM/0451	A Multicenter, Phase 2, Single Arm, Two Cohort Study Evaluating the Efficacy, Safety, and Pharmacokinetics of AMG337 in subjects with MET Amplified Gastric/Gastroesophageal Junction/Esophageal Adenocarcinoma or Other MET Amplified Solid Tumors	03/04/2014	04/04/2014										
13/WA/0269	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Elagolix in Subjects with Moderate to Severe Endometriosis-Associated Pain	18/11/2013	31/01/2014	Y			Y						
13/EM/0344	Exercise Training in Chronic Kidney Disease	28/10/2013	26/11/2013										
13/EE/0326	REVACEPT, AN INHIBITOR OF PLATELET ADHESION IN SYMPTOMATIC CAROTID STENOSIS: A PHASE II, MULTICENTRE; RANDOMISED, DOSE-FINDING, DOUBLE-BLIND AND PLACEBO-CONTROLLED SUPERIORITY STUDY WITH PARALLEL GROUPS	06/01/2014	13/02/2014	Y									
14/NW/0001	A Phase 3b Continuation study of the Safety and Efficacy of PEGylated Recombinant Factor VIII (PEG-rFVIII; BAX 855) in Prophylaxis of Bleeding in Previously Treated Patients with Severe Hemophilia A	10/02/2014	31/03/2014										
13/SC/0616	A Phase II, randomised, observer-blind, placebo-controlled, multi-centre study to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' investigational vaccine GSK2838504A, when administered intramuscularly according to a 0. 2 month s	07/07/2014	07/07/2014										

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13/EM/0414	A Double-blind, Randomised, Placebo-controlled Study to Investigate the Efficacy and Safety of Mepolizumab in the Treatment of Eosinophilic Granulomatosis with Polyangiitis in Subjects Receiving Standard of Care Therapy.	02/12/2013	04/02/2014				Y						
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	20/06/2014	23/06/2014				Y						
13/EM/0423	A randomised, double blind, placebo controlled, parallel group, dose ranging study of GWP42004 as add on to metformin in the treatment of participants with Type 2 diabetes	17/01/2014	24/01/2014										
14/EM/0101	An exploratory, 12 week, randomised, partially double-blinded, placebo-controlled, parallel group trial to explore the effects of once daily treatments of orally inhaled tiotropium + olodaterol fixed dose combination or tiotropium (both delivered by the R	28/05/2014	29/05/2014				Y						
14/YH/0141	nMARQ™ Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation	29/07/2014	11/08/2014										
14/SC/0065	A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus	13/05/2014	30/05/2014										
14/LO/0673	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Citrate (MLN9708) Maintenance Therapy in Patients With Multiple Myeloma Following Autologous Stem Cell Transplant	22/08/2014	26/08/2014						Y				
14/SC/0104	A Phase 2b, Randomized, Double blind, Placebo-controlled, Parallel group, Multicentre, Dose finding Study to evaluate the Efficiency, Safety and Tolerability of AZD1722 to Treat Hyperphosphataemia in End-Stage Renal Disease on Haemodialysis(ESRD-HD)	07/04/2014	25/04/2014										
14/YH/0086	RESPOND: Repositionable Lotus Valve System – Post Market Evaluation of Real World Clinical Outcomes	05/08/2014	05/08/2014										

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14/SC/0092	A multi-centre randomised, double blind, placebo-controlled, parallel group trial of the effectiveness of the nocturnal use of a Temperature Controlled Laminar Airflow (TLA) Device (Airsonett®) in adults with poorly controlled, severe allergic asthma.	02/07/2014	03/07/2014										
14/EE/0102	A prospective, randomized, open-label, blinded endpoint evaluation (PROBE) parallel group study comparing edoxaban (DU-176b) with enoxaparin/warfarin followed by warfarin alone in subjects undergoing planned electrical cardioversion of nonvalvular atrial	26/08/2014	26/08/2014				Y						
14/LO/1050	A Multicenter Phase 3 Randomized Open-Label Study of Bosutinib versus Imatinib in Adult Patients with Newly Diagnosed Chronic Phase Chronic Myelogenous Leukemia.	19/08/2014	21/08/2014										
14/SC/0185	A Randomized, Double-Blind Trial Comparing the Effect of Dulaglutide 1.5 mg with Placebo on Glycemic Control in Patients with Type 2 Diabetes on Basal Insulin Glargine (AWARD-9: Assessment of Weekly Administration of LY2189265 in Diabetes - 9)	05/06/2014	06/06/2014										
14/EM/0143	Study 201312: A Multi-Centre, Open-Label, Study of Mepolizumab in a Subset of Subjects with a History of Life Threatening/Seriously Debilitating Asthma Who Participated in the MEA115661 Trial	26/06/2014	03/07/2014										Y
10/MRE00/55	BIG 307 DCIS (Ductal carcinoma in situ) boost trial	02/12/2013	02/12/2013										
10/H0717/14	Prognostic value of Interferon Gamma Release Assays in predicting active tuberculosis among individuals with, or at risk of, latent tuberculosis infection - The UK PREDICT Study	30/04/2014	01/05/2014										
10/H0802/46	Revascularisation for Ischaemic Ventricular Dysfunction (REVIVED)	18/11/2013	09/01/2014						Y				
11/SC/0528	A phase III multicentre trial of weekly induction chemotherapy followed by standard chemoradiation versus standard chemoradiation alone in patients with locally advanced cervical cancer	13/02/2014	27/02/2014				Y		Y				
11/WS/0090	A Randomised Phase II study investigating pazopanib vs weekly paclitaxel in relapsed or progressive Transitional Cell Carcinoma (TCC) of the urothelium.	21/10/2013	28/10/2013				Y		Y				

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12/YH/0339	A Phase II Study of Pazopanib in Metastatic Merkel Cell Carcinoma	21/03/2014	02/04/2014							Y			Y	
12/LO/1901	A Phase II Trial of Vorinostat in Combination with Bortezomib and Dexamethasone in Patients with Relapsed and Relapsed Refractory Multiple Myeloma	07/08/2014	07/08/2014											
12/ES/0023	Does oral sodium bicarbonate therapy improve function and quality of life in older patients with chronic kidney disease and lowgrade acidosis? A multicentre randomized placebo controlled trial	21/10/2013	21/10/2013											
12/LO/1168	Subcutaneous Bortezomib, Cyclophosphamide and Rituximab (BCR) versus Fludarabine, Cyclophosphamide and Rituximab (FCR) for initial therapy of Waldenstrom macroglobulinaemia: a randomised phase II study.	27/01/2014	28/01/2014							Y			Y	
12/LO/1078	A phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse or primary refractory multiple myeloma.	28/03/2014	03/04/2014											
12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	23/06/2014	23/06/2014				Y							

For data queries please contact Khurram Memon on 0116 258 4573 or Khurram.Memon@uhl-tr.nhs.uk