

## University Hospitals of Leicester NHS Trust

## Research &amp; Development Directorate

Performance in Initiating Research

1st January 2014 to 31st December 2014

Trial Submission Number	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	
1	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	28/10/2014				Y							
2	14/EM/0135	Motivation after Exercise in Chronic Kidney Disease: MaX CKD	25/04/2014	18/08/2014											Y
3	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				Y			Y					Y
4	14/WM/10616	Next Gen IR Thermometer Clinical Site Beta Testing	15/09/2014	20/11/2014											
5	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	05/11/2014											
6	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	27/10/2014											
7	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	24/09/2014											
8	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	04/04/2014											

Performance in Initiating and Delivering Clinical Research

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9	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							Y		Y		
10	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										Y	
11	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)	30/01/2014				Y			Y				Y
12	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	22/09/2014										
13	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	06/05/2014				Y		Y				
14	12/SS/0138	REstart or STop Antithrombotics Randomised Trial - RESTART	11/09/2014					Y		Y				
15	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	01/04/2014										
16	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	24/02/2014										
17	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	02/09/2014				Y		Y				
18	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	24/09/2014										

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19	13/SS/0051	Targeted Rehabilitation to Improve Outcome after knee replacement- A Physiotherapy Study (TRIO-Physio)	13/06/2014				Y		Y					
20	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		Y			Y						
21	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				Y					Y	Y	
22	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				Y							Y
23	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	16/07/2014										
24	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	18/02/2014										
25	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	02/07/2014						Y				
26	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	11/08/2014				Y	Y					
27	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	09/07/2014				Y						
28	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					Y						

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29	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	23/10/2014							Y				
30	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	20/05/2014	Y			Y			Y				
31	13/EE/0390	Pregnancy And chronic hypertension: NifeDipine or labetalol as Antihypertensive treatment	05/09/2014	06/11/2014											
32	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					Y							
33	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	29/04/2014											
34	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	25/02/2014	Y			Y							
35	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		Y		Y								
36	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	16/04/2014											
37	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	20/08/2014											

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38	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	13/02/2014				Y							
39	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	30/09/2014				Y							
40	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	17/03/2014											
41	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	22/08/2014				Y							
42	14/YH/0141	nMARQ? Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation	29/07/2014	27/08/2014											
43	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	10/07/2014											
44	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	12/11/2014						Y					
45	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 AZD11722 to Treat Hyperphosphataemia in End-Stage Renal Disease on Haemodialysis(ESRD-HD)	07/04/2014	14/05/2014											
46	14/YH/0086	RESPOND: Repositionable Lotus Valve System ? Post Market Evaluation of Real World Clinical Outcomes	05/08/2014	01/09/2014											

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47	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	18/08/2014											
48	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	15/12/2014				Y		Y					
49	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	17/09/2014											
50	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	10/07/2014											
51	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	10/09/2014											Y
52	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	12/05/2014											
53	10/H0802/46	Revascularisation for Ischaemic Ventricular Dysfunction (REVIVED)	18/11/2013	01/03/2014							Y				
54	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	29/08/2014				Y		Y					
55	12/YH/0339	A Phase II Study of Pazopanib in Metastatic Merkel Cell Carcinoma	21/03/2014	21/08/2014							Y			Y	
56	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	10/08/2014											

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57	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	12/08/2014							Y			Y	
58	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	02/06/2014											
59	12/LO/1125	Occlutech percutaneous PFO closure: Safety and Efficacy OPPOSE Registry	23/06/2014				Y								
60	13/SC/0111	FOCUS4 - Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trial programme.	30/10/2014				Y								
61	13/EM/0434	Randomized multicentre pilot study of LCZ696 versus irbesartan in patients with chronic kidney disease: UK Heart and Renal Protection (HARP) - III	15/10/2014	12/12/2014											
62	13/EE/0202	Intergroup Trial for Children or Adolescents with B-Cell NHL or B-AL: Evaluation of Rituximab Efficacy and Safety in High Risk Patients	05/12/2014												
63	14/SC/0181	Extension study to evaluate the long-term safety and efficacy of Elagolix in subjects with moderate to severe endometriosis-associated pain	04/09/2014				Y					Y			
64	14/EE/0076	A Phase 4, Randomised, Double-Blind study with a safety extension period to evaluate the effect of aspirin on flushing events in subjects with relapsing-remitting multiple sclerosis (MS) treated with Tecfidera (dimethyl fumarate) delayed-release capsules	13/10/2014	31/10/2014											
65	11/AL/0042	A randomised placebo controlled clinical trial to evaluate cardiovascular outcomes after treatment with Exenatide once weekly in patients with type 2 Diabetes Mellitus.	04/11/2014												
66	14/EM/0209	An open label, intra-subject, controlled multi-centre study to assess the concordance (specificity and sensitivity) between Colourstart® Test 73 mcg Cutaneous Patch and Finn Chamber in the detection of para-Phenylenediamine (PPD) allergy in subjects with known or clinically suspected allergy and those with no known allergy.	06/11/2014												

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67	14/WM/1055	A prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) to placebo in combination with FOLFIRI in second line treatment of patients with metastatic colorectal cancer	10/11/2014												
68	14/NE/1072	A Phase II, Randomised, Double-Blind, Placebo-Controlled bronchoscopy study to evaluate the effects of Lebrikizumab on airway eosinophilic inflammation in patients with uncontrolled asthma on inhaled corticosteroids and a second controller medication	17/12/2014												
69	13/EM/0159	BREVITY: A phase II study of brentuximab vedotin using a response adapted design in patients with Hodgkin lymphoma unsuitable for chemotherapy due to age, frailty or co-morbidity	26/11/2014	13/01/2015											
70	14/LO/0818	A Randomized Open-Label Phase III Trial of MK-3475 versus Platinum based Chemotherapy in 1L Subjects with PD-L1 Strong Metastatic Non-Small Cell Lung Cancer	01/10/2014				Y								
71	14/LO/0865	A Phase 2, Multi-Center, Randomized, Double-Blind, Ascending-Dose, Placebo-Controlled Clinical Study to Assess the Safety and Efficacy of Fostamatinib in the Treatment of IgA Nephropathy	13/10/2014	03/12/2014											
72	14/NE/1018	A randomised, double-blind, chronic dosing (56-week), placebo-controlled, parallel group, multicentre, phase III study to evaluate the efficacy and safety of 2 doses of benralizumab (MEDI-563) in patients with severe to very severe Chronic Obstructive Pulmonary Disease (COPD) with a history of COPD exacerbations (GALATHEA)	06/11/2014	08/01/2015											
73	14/NW/0017	A Prospective, Single-Arm, Clinical-Setting Study to Describe Efficacy, Tolerability and Convenience of Teriflunomide Treatment Using Patient Reported Outcomes (PROs) in Relapsing Multiple Sclerosis (RMS) Patients	24/09/2014				Y								
74	13/LO/6758	The use of GnRH antagonist versus co-flare protocol for women with low ovarian reserve undergoing first cycle of in vitro fertilisation	05/06/2014				Y								
75	14/EM/0034	A MULTICENTER, PHASE III, OPEN-LABEL, RANDOMIZED STUDY IN RELAPSED/REFRACTORY PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO EVALUATE THE BENEFIT OF GDC-0199 (ABT-199) PLUS RITUXIMAB COMPARED WITH BENDAMUSTINE PLUS RITUXIMAB	02/10/2014				Y								

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76	14/WM/0159	Safety of Nasal Influenza Immunisation in Egg Allergic Children - The SNIFFLE 2 study	03/10/2014	16/10/2014											
77	14/EM/0159	A Phase 3, Multi-Centre, Randomised, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	22/10/2014	19/01/2015				Y						Y	
78	14/YH/1152	Response to one-legged cycling in patients with idiopathic pulmonary fibrosis	06/10/2014	14/11/2014											
79	14/EM/0186	A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Thrombocytopenia and Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis	02/12/2014												
80	14/EM/0168	MYL-GAI-3001. AN OPEN-LABEL, RANDOMIZED, MULTI-CENTER, PARALLEL-GROUP CLINICAL TRIAL COMPARING THE EFFICACY AND SAFETY OF MYLANS INSULIN GLARGINE WITH LANTUS® IN TYPE 1 DIABETES MELLITUS PATIENTS.	24/11/2014	13/01/2015											
81	14/NE/1143	The feasibility of undertaking Appendicectomy to impact upon the Clinical Course of Ulcerative Colitis - The ACCURE Trial Feasibility Study	05/12/2014	16/01/2015											
82	13/NW/0283	GLOBAL LEADERS: Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current-day intensive dual antiplatelet therapy in all-comers patients undergoing percutaneous coronary intervention with bivalirudin and BioMatrix family drug-eluting stent use.	01/12/2014	07/01/2015											

For data queries please contact UHL R&D Data Management team on 0116 258 4573 or RDDData@uhl-tr.nhs.uk