University Hospitals of Leicester NHS Trust

Research & Development Directorate

Performance in Delivering Research

1st January 2014 to 31st December 2014

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
1	06/MRE01/102	A Multi-center, Randomized, Double-blind, Placebo-controlled, Phase 3 Study of Single-agent Tarceva® (erlotinib) Following Complete Tumor Resection with or without Adjuvant Chemotherapy in Patients with Stage IB-IIIA Non small Cell Lung Carcinoma who have	10	31/03/2010	Closed - follow up complete	N
2	08/H0502/132	BH21260- A randomised, controlled, open-label, multi-centre, parallel-group study to assess all-cause mortality and cardiovascular morbidity in patients with chronic kidney disease on dialysis and those not on renal replacement therapy under treatment wit	9	14/10/2011	Closed - follow up complete	Y
3	09/H0706/22	Aliskiren vs enalapril in chronic heart failure	4	14/12/2013	Closed - follow up complete	Y
4	09/H0802/125	An OpenLabel, MultiCenter, Single Arm Study to Evaluate the Safety and Tolerability of Intravenous Zanamivir in the Treatment of Hospitalised Adult, Adolescent and Paediatric Subjects with Confirmed Influenza Infection	1	27/01/2017	Closed - follow up complete	N
5	12/SC/0527	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of BIIB033 in Subjects With First Episode of Acute Optic Neuritis	2	26/02/2014	Closed - follow up complete	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
6	07/MRE08/40	A double-blind randomized, placebo-controlled Phase III study to assess the efficacy of recMAGE-A3 + AS15 Antigen -Specific Cancer immunotherapeutic as adjuvant therapy in patients with resectable MAGE-A3 - postive Non -Small Cell Lung Cancer	12	31/05/2012	Closed - in follow up	N
7	09/H0605/87	TECOS - A Randomised, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycaemic Control on Mono or Dual Combination Oral Antihyperglycaemic The	35	31/05/2012	Closed - in follow up	Y
8	09/H0406/110	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction (CLCZ696B2	6	11/10/2012	Closed - in follow up	Y
9	09/H0402/101	A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ-28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus (The CANVAS Trial: CANagliflozin CardioVascular Assessment Study)	8	31/01/2011	Closed - in follow up	Y
10	09/H0206/40	A Phase I/II Multi-centre Study of AZD8931 in Combination with Weekly Paclitaxel to Assess the Safety, Tolerability, Pharmacokinetics and Efficacy in Patients with Advanced Solid Tumours and in a selected population with Low HER2-expressing Locally Recurr	10	30/03/2011	Closed - in follow up	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
11	10/H0405/23	A prospective, multi-center, randomized, double-blind trial to assess the effectiveness and safety of 12 versus 30 months of dual antiplatelet therapy (DAPT) in subjects undergoing percutaneous coronary intervention (PCI) with either drug-eluting stent	22	31/05/2011	Closed - in follow up	Y
12	09/H0405/44	A Randomized Double-blind Placebo-Controlled Trial of Neratinib (HKI-272) After Trastuzumab in Women With Early-Stage HER-2/neu Overexpressed/Amplified Breast Cancer.	10	10/10/2011	Closed - in follow up	N
13	10/H0808/109	Evaluation of XIENCE PRIME™ or XIENCE V® versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization.	25	30/04/2014	Closed - in follow up	Y
14	11/YH/0121	A phase II, randomized double-blind study of efficacy and safety of two dose levels of LDE225 in patients with locally advanced or metastatic basal cell carcinoma	2	11/01/2013	Closed - in follow up	Y
15	11/NW/0298	A multicenter, Phase III, open-label, randomized study in previously untreated patients with advanced indolent non-Hodgkin's Lymphoma comparing GA101 (Ro5072759) plus chemotherapy with rituximab plus chemotherapy followed by GA101 or rituximab maintenance	5	17/01/2014	Closed - in follow up	Y
16	11/NW/0472	Phase III, open-label, multicentre, randomised trial to establish safety and efficacy of an EGF cancer vaccine in inoperable, late stage (IIIb/IV) NSCLC patients eligible to receive standard treatment and supportive care.	6	27/11/2013	Closed - in follow up	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
17	11/AL/0327	A Phase 2, Multicentre, randomised, double-blind, placebo controlled study of the safety, clinical activity and pharmacokinetics of Bosutinib (PF-05208763) versus placebo in subjects with autosomal dominant polycycstic kidney disease (ADPKD)	5	25/05/2012	Closed - in follow up	N
18	11/EM/0270	A Phase 2b, Randomized, Double-blind Study to Evaluate the Efficacy of Tralokinumab in Adults with Uncontrolled, Severe Asthma	4	14/05/2012	Closed - in follow up	N
19	11/LO/0548	An open-label, randomized, multi-center, Phase III study to compare the safety and efficacy of TKI258 versus sorafenib in patients with metastatic renal cell carcinoma after failure of anti-angiogenic (VEGF-targeted and mTOR inhibitor Therapies)	3	10/08/2012	Closed - in follow up	N
20	11/LO/1728	Determination of the efficacious and safe dose of ivabradine in paediatric patients with dilated cardiomyopathy and symtomatic chronic heart failure aged from 6 months to less than 18 years. A randomised, double-blind, multicentre, placebo controlled, pha	5	15/02/2013	Closed - in follow up	N
21	11/EM/0180	A clinical outcomes study to evaluate the effects of IL-6 receptor blockade with tocilizumab (TCZ) in comparison with etanercept (ETA) on the rate of cardiovascular events in patients with moderate to severe rheumatoid arthritis (RA)	6	13/03/2013	Closed - in follow up	N
22	11/WA/0309	A Comparison of LY2605541 versus Insulin Glargine as Basal Insulin Treatment in Combination with Oral AntiHyperglycemia Medications in Insulin Naive Patients with Type 2 Diabetes Mellitus: A DoubleBlind, Randomized Study: The IMAGINE 2 Study.	6	27/11/2012	Closed - in follow up	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
23	11/LO/1408	ABSORB II RANDOMIZED CONTROLLED TRIAL: A clinical evaluation to compare the safety, efficacy and performance of ABSORB TM everolimus eluting bioresorbable vascular scaffold system against XIENCE PRIME TM everolimus eluting coronary stent system in the tre	10	04/06/2013	Closed - in follow up	Y
24	12/EE/0005	A multicentre, double blind, randomised controlled Clinical Investigation to validate the EPS1 device as a treatment for stroke induced dysphagia. A Study of Swallowing Treatment using Electrical Pharyngeal Stimulation (STEPS Study)	3	30/06/2014	Closed - in follow up	Y
25	11/EE/0291	A Phase 3, Randomised, Open Label Trial of Lenalidomide/ dexamethasone With or Without Elotuzumab in Relapsed or Refractory Multiple Myeloma	7	26/09/2012	Closed - in follow up	N
26	11/NE/0124	A Phase III, Randomized, Comparative, Openlabel Study of Intravenous Iron Isomaltoside 1000 (Monofer®) Administered as Maintenance Therapy by Single or Repeated Bolus Injections in Comparison with Intravenous Iron Sucrose in Subjects with Stage 5 Chronic	10	09/08/2013	Closed - in follow up	Y
27	12/SC/0035	A 6-month safety and benefit study of inhaled fluticasone propionate/ salmeterol combination versus inhaled fluticasone propionate in the treatment of 6,200 paediatric subjects 4-11 years old with persistent asthma.	6	31/08/2015	Closed - in follow up	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
28	12/EM/0018	A randomised, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infaction patients with elevated hsCRP.	10	28/01/2014	Closed - in follow up	N
29	11/LO/0608	A Randomized, Double Blind, Phase II Efficacy and Safety Study of MDV3100 (ASP9785) vs. Bicalutamide in Castrate Men with Metastatic Prostate Cancer	4	14/06/2013	Closed - in follow up	N
30	12/WS/0230	NEFIGAN Trial: A Multicentre, Interventional treatment, Randomized, Double-Blind, Single Group Assignment Placebo Controlled Study to Evaluate the Efficacy and Safety of Two Different Doses of Nefecon® in primary IgA nephropathy patients at risk of develo	4	20/12/2013	Closed - in follow up	Y
31	12/EM/0284	A multi-centre, open-label, long term safety study of mepolizumab in asthmatic subjects who participated in the MEA112997 trial	5	25/03/2013	Closed - in follow up	Y
32	12/LO/1285	A prospective, randomized, open label, parallel group, active controlled, multicenter study exploring the efficacy and safety of once daily oral rivaroxaban (BAY 597939) compared with that of dose adjusted oral vitamin K antagonists (VKA) for the preventi	13	30/09/2013	Closed - in follow up	Y
33	12/EM/0308	A multicenter, double-blind and open label, 2 year extension study of subcutaneous secukinumab in prefilled syringes, assessing long-term safety, tolerability and efficacy in subjects with moderate to severe chronic plaque-type psoriasis treated with eith	2	28/02/2013	Closed - in follow up	Y
34	12/NE/0314	Safety, Efficacy and Pharmacokinetics of NNC-0156-0000-0009 in Previously Treated Children with Haemophilia B	1	28/02/2013	Closed - in follow up	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
35	12/LO/1590	A phase III randomised, partially double-blind and placebo-controlled study of BI 207127 in combination with faldaprevir and ribavirin for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those i	1	23/03/2013	Closed - in follow up	N
36	11/EE/0311	A randomized study comparing maintenance therapy with subcutaneous rituximab continued until progression with observation only in patients with relapsed or refractory, indolent nonHodgkin's lymphoma who completed and responded to rituximabbased immunochem	5	31/03/2014	Closed - in follow up	Y
37	12/EM/0349	A multicenter, open-label, randomized phase II study to evaluate the efficacy of AUY922 vs pemetrexed or docetaxel in NSCLC patients with EGFR mutations who have progressed on prior EGFR TKI treatment	3	11/06/2014	Closed - in follow up	Y
38	12/EM/0395	A randomised, double-blind, parallel group, multicentre phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischaemic stroke in patients with established Peripheral Artery Diseas	30	27/02/2014	Closed - in follow up	Y
39	12/SC/0435	Efficacy and safety of 3 doses of S38093 (2, 5 and 20mg/day) versus placebo in coadministration with donepezil (10mg/day) in patients with moderate Alzheimer's Disease. A 24 week international, multicentre, randomised, doubleblind, placebocontrolled phase	10	31/07/2014	Closed - in follow up	N
40	13/NE/0001	NN7088-3885 (Pathfinder 5): A multinational, open-label, non-controlled trial on safety, efficacy and pharmacokinetics of NNC 0129-0000-1003 in previously treated paediatric patients with severe haemophilia A	1	07/02/2014	Closed - in follow up	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
41	13/YH/0003	An Open-label, Single arm, Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 (Ibrutinib) in Patients with Relapsed or Refractory Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma with 17p Deletion	1	31/08/2013	Closed - in follow up	Y
42	12HAEM15	Polycythemia Vera Symptom Study Evaluating Ruxolitinib Versus Hydroxyurea in a Randomized, Multicenter, Double-Blind, Double-Dummy, Phase 3 Efficacy and Safety Study of Patient Reported Outcomes	5	22/11/2013	Closed - in follow up	N
43	13/EM/0097	MEA115661: A multi-centre, open-label, long-term safety study of mepolizumab in asthmatic subjects who participated in the MEA115588 or MEA115575 trials	8	11/12/2013	Closed - in follow up	N
44	12/LO/1697	BEL114674: A 2 year study of efficacy and safety of intravenous belimumab versus placebo in subjects with idiopathic membranous nephropathy	1	25/10/2013	Closed - in follow up	N
45	13/EM/0084	A Phase 2/3, Multi-Center, Open Label Study of Efficacy, Safety, and Pharmacokinetics of PEGylated Recombinant Factor VIII (BAX 855) Administered for Prophylaxis and Treatment of Bleeding in Previously Treated Patients with Severe Hemophilia A	1	31/10/2013	Closed - in follow up	Y
46	13/SC/0010	A Phase IIa, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Assess the Safety and Efficacy of 28 Day Oral Administration of BAY 85-8501 in Patients with non-Cystic Fibrosis Bronchiectasis	3	10/04/2014	Closed - in follow up	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
47	11/SC/0438	REPLACE (Randomised evaluation of fibrinogen versus placebo in complex cardiovascular surgery): a prospective, multinational, multicenter, randomised, double-blind, placebo-controlled, phase III study for the use of Fibrinogen Concentrate (Human) (FCH) in	7	31/07/2014	Closed - in follow up	N
48	13/NI/0044	A STUDY TO MEASURE SERUM PERIOSTIN, ASTHMA RELATED BIOMARKERS AND RESPONSE TO PREDNISOLONE IN ADULT AND ADOLESCENT PATIENTS WITH SEVERE ORAL CORTICOSTEROID DEPENDENT ASTHMA	6	28/02/2014	Closed - in follow up	N
49	13/NE/0080	A randomized, open-label, active-controlled, 3-arm parallel-group, 26-week study comparing the efficacy and safety of lixisenatide to that of insulin glulisine once daily and insulin glulisine three times daily in patients with Type 2 diabetes insufficien	3	02/06/2014	Closed - in follow up	N
50	13/LO/0033	A Phase II, randomized study or paclitaxel with GDC-0941 versus paclitaxel with placebo in patients with locally recurrent or metastatic breast cancer	2	01/07/2014	Closed - in follow up	Y
51	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	6	13/06/2014	Closed - in follow up	Y
52	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.	3	31/07/2014	Closed - in follow up	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
53	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	3	18/06/2014	Closed - in follow up	N
54	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 AZDI1722 to Treat Hyperphosphataemia in End-Stage Renal Disease on Haemodialysis(ESRD-HD)	5	31/10/2014	Closed - in follow up	Y
55	14/EE/0076	A Phase 4, Randomized, 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	6	07/11/2014	Closed - in follow up	Y
56	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	7	07/11/2014	Closed - in follow up	N
57	10/MREC00/61	An Open Label, Multicenter, randomized, phase III study to investigate the efficacy and safety of Bendamustine compared with Bendamustine + RO5072759 (GA101) in patients with Rituximab-refractory, indolent Non-Hodgkin?s Lymphoma)	6	01/08/2014	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
58	11/LO/0954	LUXHead & Neck 2; A randomised, doubleblind, placebo controlled, phase III study to evaluate the efficacy and safety of afatinib (BIBW 2992) as adjuvant therapy after chemoradiotherapy in primary unresected patients with stage III, IVa, or IVb locoregiona	5	01/05/2017	Open	N/A
59	11/SS/0054	Clinical Trial of the SonRtip Lead and Automiatic AVV Optimization Algorithm in the Paradym RF SonR CRT-D (RESPOND CRT)	10	31/12/2014	Open	N/A
60	12/LO/0098	CAIN457 to assess safety tolerability efficacy & PK in asthma	5	28/02/2014	Open	N/A
61	12/WM/0039	INOVATEHF: INcrease Of VAgal TonE in chronic Heart Failure.	10	31/12/2014	Open	N/A
62	12/SC/0434	A randomised, multicentre, double blind, placebo controlled, crossover trial determining the efficacy of dry powder mannitol in improving lung function in subjects with Cystic Fibrosis aged six to seventeen years	4	31/12/2014	Open	N/A
63	13/NW/0003	A RANDOMIZED, DOUBLE–BLIND, PLACEBO–CONTROLLED, PHASE-3 STUDY TO ASSESS THE SAFETY AND EFFICACY OF ART-123 IN SUBJECTS WITH SEVERE SEPSIS AND COAGULOPATHY	6	01/03/2015	Open	N/A
64	12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	15	31/12/2014	Open	N/A
65	13/ES/0005	A Phase 3, Multicenter, Randomized, Double-blind Study to Compare the Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care versus Placebo Plus Best Supportive Care in Subjects with Red Blood Cell Transfusion-dependent Anemia and Thrombocytope	4	15/06/2015	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
66	13/SC/0092	A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of siponimod (BAF312) in patients with secondary progressive multiple sclerosis	6	29/05/2014	Open	N/A
67	13/SC/0102	A Phase II/III Randomized Trial of Two Doses of MK-3475 (SCH900475) versus Docetaxel in Previously Treated Subjects with Squamous Histology Non-Small Cell Lung Cancer	3	16/12/2014	Open	N/A
68	13/SC/0073	A Double-blind, Randomized, Placebo-controlled, Multicenter, Dose Escalation Study to Select and Evaluate an Oral Modified Release Formulation of Omecamtiv Mecarbil in Subjects with Heart Failure and Left Ventricular Systolic Dysfunction	6	31/08/2013	Open	N/A
69	12/LO/1825	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Rilotumumab (AMG 102) with Epirubicin, Cisplatin, and Capecitabine (ECX) as First-line Therapy in Advanced MET-Positive Gastric or Gastroesophageal Junction Adenocarcinoma	2	01/01/2015	Open	N/A
70	13/LO/0105	Open-label, single-arm, phase IV, multicentre trial to explore the immunogenicity of the liquid formulation of Saizen® in subjects with growth hormone deficiency (GHD) of adult onset	4	01/02/2015	Open	N/A
71	13/WA/0084	A Randomised, Double-Blind, Placebo-Controlled, Multicenter Study to Assess Cardiovascular Outcomes Following Treatment with MK-3102 in Subjects with Type 2 Diabetes Mellitus	7	06/10/2014	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
72	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 failu	3	31/03/2014	Open	N/A
73	13/LO/0326	A Randomized, Phase 3 Study of Ganetespib in Combination with Docetaxel versus Docetaxel Alone in Patients with Advanced Non-Small-Cell Lung Adenocarcinoma	8	02/03/2015	Open	N/A
74	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	5	30/10/2014	Open	N/A
75	13/LO/0021	Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment (PRESENT)	6	31/01/2015	Open	N/A
76	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	6	15/06/2015	Open	N/A
77	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	6	21/12/2015	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
78	13/EM/0230	A Phase II Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of VS 6063 in Subjects with Malignant Pleural Mesothelioma	10	01/08/2015	Open	N/A
79	13/EM/0149	Multicenter open-label study to evaluate efficacy of gadobutrol-enhanced cardiac magnetic resonance imaging (CMRI) for detection of significant coronary artery disease (CAD) in subjects with known or suspected CAD by a blinded image analysis	15	12/02/2015	Open	N/A
80	13/NW/0006	A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell lymphomas	3	31/03/2015	Open	N/A
81	12/LO/1950	A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma	8	28/11/2014	Open	N/A
82	13/LO/0219	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of GS-6624 in Subjects with Idiopathic Pulmonary Fibrosis (RAINIER)	5	01/12/2016	Open	N/A
83	13/LO/0491	A Phase IIa, Double-Blind, Placebo-Controlled, Randomised, Multi-centre Study of POL6326, a CXCR4 Antagonist, in Patients with Large Reperfused ST-Elevation Myocardial Infarction	5	30/11/2014	Open	N/A
84	13/LO/0704	A dose ranging study investigating the efficacy and safety of sublingual immunotherapy tablets of house dust mite allergen extracts in adults with house dust mite-associated allergic asthma	3	15/12/2014	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
85	12/WM/0341	A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination With Statin Therapy In Patients with Clinically Evident Cardi	10	30/11/2014	Open	N/A
86	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	2	31/12/2014	Open	N/A
87	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	10	29/12/2014	Open	N/A
88	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)	2	09/10/2014	Open	N/A
89	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	10	31/03/2016	Open	N/A
90	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	6	30/06/2015	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
91	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	3	31/08/2014	Open	N/A
92	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	5	01/09/2014	Open	N/A
93	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	2	30/03/2015	Open	N/A
94	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	12	27/05/2018	Open	N/A
95	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	4	04/05/2015	Open	N/A
96	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.	5	31/08/2018	Open	N/A
97	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	10	29/07/2016	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
98	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	7	05/05/2015	Open	N/A
99	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	7	14/02/2016	Open	N/A
100	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	3	20/10/2014	Open	N/A
101	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)	5	01/06/2015	Open	N/A
102	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	3	22/05/2015	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
103	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	9	31/12/2015	Open	N/A
104	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	30	29/12/2014	Open	N/A
105	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	8	15/06/2015	Open	N/A
106	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	8	28/02/2017	Open	N/A
107	14/YH/0086	RESPOND: Repositionable Lotus Valve System – Post Market Evaluation of Real World Clinical Outcomes	15	11/12/2020	Open	N/A
108	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.	7	01/06/2016	Open	N/A
109	14/YH/0141	nMARQ™ Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation	25	01/10/2018	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
110	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	10	24/12/2015	Open	N/A
111	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	4	01/12/2015	Open	N/A
112	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 Pul	6	31/07/2016	Open	N/A
113	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	3	30/07/2015	Open	N/A
114	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	5	14/02/2016	Open	N/A
115	14/EM/1059	A Phase 3, Multi-Centre, Randomised, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	2	15/12/2014	Open	N/A

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
116	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	2	01/04/2015	Open	N/A
117	14/EM/1068	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.	5	19/07/2015	Open	N/A
118	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 bivalirud	100	30/06/2015	Open	N/A
119	12/SC/0173	A Multicentre, Randomised, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) in Combination with Metformin IR or Metformin XR in Paediatric Patients with Type 2 Diabetes who have Inadequate Glycaemic Co	2	30/04/2014	Suspended	N/A
120	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	1	01/09/2014	Suspended	N/A
121	07/S0501/91	An open label, single arm, multi centre phase II trial with ofatumumab in patients with relapsed Diffuse Large B Cell Lymphoma (DLBCL) ineligible for transplant or relapsed after autologous transplant	5	31/12/2009	Closed - follow-up complete	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
122	08/H0206/34	A Multicentre, Double-Blind 3-Arm, Phase 1b/2 Study in Subjects with Unresectable Locally Advanced or Metastatic Gastric or Esophagogastric Junction Adenocarcinoma to Evaluate the Safety and Efficacy of First-line Treatement with Epirubicin Cisplatin and	7	31/07/2010	Closed - follow-up complete	N
123	08/MRE00/93	A single-arm, international, multi-centre trial investigating the efficacy and safety of atumumab re-treatment and maintenance treatment in patients with B-cell chronic lymphocytic leukemia who progressed following response or stable disease after of atum	10	30/11/2009	Closed - follow-up complete	N
124	08//H0703/132	An open-label, multi-centre, randomised, phase Ib study to investigate the safety and efficacy of RO5072759 given in combination with CHOP or FC chemotherapy in patients with CD20+ relapsed/refractory B-cell follicular non-Hodgkin's lymphoma.	2	30/09/2011	Closed - follow-up	Y
125	09/H0406/5	A phase IA/II multi-centre open label study of HCD 122 administered once weekly for four weeks in adult patients with advanced non Hodgkins or Hodgkins lymphoma who have progressed after at least two prior therapies	10	30/09/2010	Closed - follow-up complete	N
126	09/H0402/71	A phase I multicentre, open label, dose escalation study of oral LDE225 in patients with advanced solid tumours.	5	30/09/2011	Closed - follow-up	Y
127	09/H0402/92	A Randomized, Multicenter, Open-label, Phase 3 Study to Compare the Efficacy and Safety of Panitumumab and Cetuximab in Subjects with Previously Treated, Wild-type KRAS, Metastatic Colorectal Cancer.	10	31/08/2011	Closed - follow-up complete	Y

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
128	09-WSE04-55	An open-label, multi centre, three arm randomised, phase III study to investigate the efficacy and safety of R05072759 + chlorambucil (GClb), rituximab and chlorambucil (RClb) or chlorambucil (Clb) alone in previously untreated CLL patients with co-morbid	5	01/06/2012	Closed - follow-up	Y
129	10/H0402/33	CAVALIER: Perceval S valve clinical trial for extended CE mark	15	30/03/2012	Closed - follow-up	Y
130	09/H0903/51	An Extension Treatment Protocol for Subjects who have participated in a Phase 3 study of Tivozanib vs. Sorafenib in Renal Cell Carcinoma (Protocol AV-951-09-301)	5	31/12/2012	Closed - follow-up complete	N
131	10/MRA00/84	A phase I, multicenter, open-label dose escalation study of LDK378, administered orally in adult patients with tumors characterized by genetic abnormalities in anaplastic lymphoma kinase(ALK)	2	26/07/2013	Closed - follow-up	Y
132	10/H0406/90	A Randomized, Double-Blind, Placebo-controlled Phase 2 Study of Maintenance OSI-906 plus Erlotinib (Tarceva®), or Erlotinib plus Placebo in Patients with Nonprogression Following Four Cycles of 1st-line Platinum-based Chemotherapy for Advanced NSCLC	3	20/02/2013	Closed - follow-up complete	Y
133	10/H0806/106	An open Phase I Study of immunization with the recNY-ESO-1 + AS15 Antigen-Specific Cancer Immunotherapeutic in patients with NY-ESO-1-positive unresectable and progressive metastatic cutaneous melanoma	4	01/10/2012	Closed - follow-up complete	N
134	08/H0502/133	BH21260- A randomised, controlled, open-label, multi-centre, parallel-group study to assess all-cause mortality and cardiovascular morbidity in patients with chronic kidney disease on dialysis and those not on renal replacement therapy under treatment wit	10	31/03/2012	Closed - follow-up	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
135	11/EM/0225	A PHASE III, MULTICENTER, RANDOMISED TRIAL COMPARING THE EFFICACY OF GA101 IN COMBINATION WITH CHOP (G-CHOP) VERSUS RITUXIMAB AND CHOP (R-CHOP) IN PREVIOUSLY UNTREATED PATIENTS WITH CD20-POSITIVE DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)	5	30/06/2014	Closed - follow-up	N
136	11/NI/0147	Assessment of the 23mm St Jude Medical Portico transcatheter Aortic Valve Implant (TAVI) and the SJM TAVI Transfemoral Delivery System (Portico 23-TF EU)	12	30/04/2012	Open	Y
137	11/LO/1271	Anamorelin HCl in the Treatment of Non-Small Cell Lung Cancer - Cachexia (NSCLC-C): A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study to Evaluate the Safety and Efficacy of Anamorelin HCl in Patients with NSCLC-C	14	01/07/2012	Closed - follow-up	N
138	11/LO/1272	Anamorelin HCl in the Treatment of NonSmall Cell Lung Cancer Cachexia (NSCLCC): An Extension Study	14	01/07/2012	Closed - follow-up complete	N
139	11/LO/0054	NGR015: Randomized double-blind phase III study of NGR-hTNF plus best investigator's choice (BIC) versus placebo plus BIC in previously treated patients with advanced malignant pleural mesothelioma (MPM)	15	01/12/2012	Closed - follow-up	N
140	11/SC/0499	A UK openlabel, multicentre, phase II exploratory study of INC424 for patients with primary myelofibrosis (PMF) or post polycythaemia myelofibrosis (PPV MF) or postessential thrombocythaemia myelofibrosis (PETMF)	3	30/11/2012	Closed - follow-up	Y
141	11/AL/0393	A Randomized, Phase IIB/III Study of Ganetespib (STA-9090) in Combination with Docetaxel Versus Docetaxel Alone in Subjects with Stage IIIb or IV Non-Small-Cell Lung Cancer	20	01/06/2013	Closed - follow-up complete	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
142	12/LO/0806	A Multicenter, Single arm, Open Label Clinical Trial to Evaluate the Safety and Health-Related Quality of Life of Aflibercept in Patients with Metastatic Colorectal Cancer (mCRC) Previously Treated with an Oxaliplatin-Containing Regimen	5	30/04/2013	Closed - follow-up	Y
143	12-LO-0928	MASERATI 100 A prospective, Multicenter,postmarket,singleArmobSERvATIonal study to collect clinical outcome data on the use of Permacol™ Collagen Paste in the treatment of anorectal fistulas	10	28/02/2013	Closed - Follow up	Y
144	12/SC/0139	A Phase III Prospective, Two-cohort, Non-randomized, Multi-centre, Multi-national, Open Label Study to Assess the Safety of Assisted- and Self-administered Subcutaneous Trastuzumab as Adjuvant Therapy in Patients with Operable HER2-positive Early Breast C	10	30/11/2013	Closed - follow-up	N
145	12/EM/0204	An open-label, multi-centre, non-randomised phase I dose-escalation study to investigate the safety and tolerability of ONO-4059 given as monotherapy in patients with relapsed/refractory Non-Hodgkin's lymphoma (NHL) and relapsed/refractory chronic lymphoc	7	15/07/2015	Open	N/A
146	12/NW/0242	An open-label phase IIIb study of regorafenib in patients with metastatic colorectal cancer (CRC) who have progressed after standard therapy	15	01/03/2013	Closed - follow-up	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
147	12/NE/0009	A Phase II, Double-Blind, Placebo Controlled, Randomized Study Evaluating the Safety and Efficacy of Carboplatin/Paclitaxel and Carboplatin/Paclitaxel/Bevacizumab with and without GDC-0941 in patients with Previously Untreated Advanced or Recurrent Non-Sm	9	01/09/2015	Open	N/A
148	12/LO/1313	ROX CONTROL HTN Study: A Prospective, Randomized, Open-Label, Multicenter Study to Evaluate the ROX Coupler in Patients with Resistant Hypertension	20	31/12/2013	Closed - Follow up	N
149	12/EM/0206	An open label non-randomized phase 2 study evaluating SAR3419, an anti-CD19 antibody – maytansine conjugate, administered as single agent by intravenous infusion to patients with relapsed or refractory CD19+ diffuse large B cell lymphoma	2	30/09/2013	Closed - Follow-up	Y
150	12/NE/0333	A multicentre, open label, early stopping design, proof of concept study with tasquinimod in treating patients with advanced or metastatic hepatocellular, ovarian, renal cell and gastric carcinomas.	10	01/11/2013	Closed - follow-up	N
151	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.	30	30/06/2015	Open	N/A
152	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	3	31/10/2015	Suspended	N

Trial Submission Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
153	13/EM/0476	ABSORB UK Registry A postmarket registry of patients with de novo lesions in previously untreated vessels treated with Absorb BVS	30	17/11/2017	Open	N/A

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