University Hospitals of Leicester NHS Trust

Research & Development Directorate

Performance in Delivering Research

1st April 2014 to 31st March 2015

Reference 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 EGFR-positive Tumors.	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 with MIRCERA or reference Erythropoiesis-Stimulating Agents.	20	14/10/2011	Open	N/A
3	09/H0406/5	A phase lA/ll 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
4	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 - In Follow Up	Y
5	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	N
6	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-morbidities.	5	01/06/2012	Closed - In Follow Up	Y
7	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

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
8	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
9	10/H0808/109	Evaluation of XIENCE PRIME™ or XIENCE V® versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization.	25	06/02/2014	Closed - Follow Up Complete	Y
10	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 - In Follow Up	N
11	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
12	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 with MIRCERA® or reference Erythropoetin Stimulations Agents. (SUB STUDY)	10	31/03/2012	Abandoned	N
13	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 - In Follow Up	N
14	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	Closed - Follow Up Complete	Y
15	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
16	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 - In Follow Up	Y
17	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

Performance in Initiating and Delivering Clinical Research

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
18	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 - In Follow Up	Y
19	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 Complete	Y
20	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 Cancer	10	25/09/2013	Closed - In Follow Up	N
21	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 lymphocytic leukaemia (CLL).	7	20/02/2015	Closed - In Follow Up	Y
22	01/02/03	A Combined trial of an investigational medicinal product and an investigational mediacl device and other clinical trials to study a novel intervention or randmised clinical trial to compare interventions in clinical practice (CTIMP)	15	01/03/2013	Closed - In Follow Up	N
23	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-Small Cell Lung Cancer	9	06/01/2015	Closed - In Follow Up	N
24	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	14/04/2014	Closed - In Follow Up	N
25	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 - In Follow Up	Y

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
26	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 - In Follow Up	N
27	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
28	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 indications.	3	31/10/2015	Suspended	N
29	13/EM/0476	ABSORB UK Registry A postmarket registry of patients with de novo lesions in previously untreated vessels treated with Absorb BVS	30	31/10/2015	Open	N/A
30	14/SW/1062	An Open-label, Phase 1b Study of ACP-196 in Subjects with Relapsed or Refractory de Novo Activated B-cell (ABC) Subtype of Diffuse Large B-Cell Lymphoma	17	03/03/2016	Open	N/A
31	14/LO/1996	A Phase 1 Dose Escalation Study of VS-5584, a Dual PI3K/mTOR Inhibitor, Administered with a Fixed Dose of VS-6063, a Focal Adhesion Kinase Inhibitor, in Subjects with Relapsed Malignant Mesothelioma.	14	14/12/2016	Open	N/A
32	09/H0802/125	An open-label, multi-centre, single arm study to evalaute the safety, tolerability and pharmacokinetics of intravenous zanamivir in the treatment of hospitalised adult, adolescent and paediatric subjects with confirmed influenza infection	0	27/01/2017	Closed - Follow Up Complete	N
33	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	Closed - In Follow Up	N
34	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	5	15/05/2015	Open	Y

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
35	11NH/0140	Study to observe the effectiveness and safety of LUCENTIS® through individualised patient treatment and associated outcomes	20	07/12/2014	Closed - Follow Up Complete	Y
36	10/H1102/44	Registry for Patients with Niemann-Pick Type C Disease	1	31/12/2015	Open	N/A
37	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
38	11-EE-0333	A Post-Marketing Observational Study (PMOS) to Determine the Effectiveness and Patient Satisfaction with Adalimumab Treatment in Patients with Rheumatoid Arthritis (OPERA study)	10	30/09/2014	Closed - In Follow Up	Y
39	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	30/09/2014	Suspended	N
40	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
41	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	Y
42	12/LO/0098	A randomized, double-blind, placebo controlled, multiple dose study to evaluate the safety, tolerability, and efficacy of intravenous administration of secukinumab (AIN457) in patients with asthma not adequately controlled with inhaled corticosteroids and long acting beta-agonists	5	31/12/2014	Closed - In Follow Up	N
43	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

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
44	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
45	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	Closed - In Follow Up	Y
46	12/SC/0098	SAS115359, a Safety and Efficacy Study of Inhaled Fluticasone Propionate/Salmeterol Combination versus Inhaled Fluticasone Propionate in the Treatment of Adolescent and Adult Subjects with Asthma	10	22/07/2014	Closed - In Follow Up	N
47	12/WM/0039	INOVATEHF: INcrease Of VAgal TonE in chronic Heart Failure.	10	30/06/2015	Open	N/A
48	12/SW/0143	Pazopanib Observational Study (PRINCIPAL) - A prospective observational study to capture real world treatment patterns and determine treatment outcomes in patients with advanced or metastatic renal cell carcinoma (RCC) receiving pazopanib.	6	18/12/2014	Closed - In Follow Up	Y
49	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
50	12/WA/0220	A phase III randomized study, double blind placebo controlled of Fulvestrant in combination with oral BKM120 versus Fulvestrant plus Placebo, in the treatment of postmenopausal women with ER-positive HER2-negative, mTORi naive locally advanced or metastatic Breast Cancer (BC) refractory to Aromatase Inhibitor (AI)	4	19/11/2014	Closed - In Follow Up	N
51	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	22/05/2015	Open	Y
52	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	30/04/2015	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
53	12/EM/0395	A Prospective Multicenter Non-Interventional Study of Women Treated with ESMYA (Ulipristal Acetate) as Pre-operative Treatment of Moderate to Severe Symptoms of Uterine Fibroids	20	16/04/2014	Closed - In Follow Up	Y
54	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	30/11/2014	Closed - In Follow Up	Y
55	12/SC/0504	A Multicenter, Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of TAK-875 25mg and 50mg Compared to Glimepiride When Used in Combination with Metformin in Subjects with Type 2 Diabetes	1	01/06/2014	Withdrawn	N
56	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	30/10/2015	Open	N/A
57	13/LO/0021	Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment (PRESENT)	10	31/08/2014	Open	N/A
58	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	4	27/02/2015	Closed - In Follow Up	N
59	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
60	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	31/12/2014	Closed - In Follow Up	N
61	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	30/04/2015	Open	Y

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
62	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
63	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	10/04/2015	Open	Y
64	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
65	13/ES/0009	A Study Evaluating the Efficacy and Safety of BOTOX® and Solifenacin in Patients with Overactive Bladder and Urinary Incontinence	5	30/06/2014	Closed - In Follow Up	N
66	12/SC/0570	CFTY720D2406: Long-term, prospective, non-interventional, multinational, parallel cohort study monitoring safety in patients with MS recently initiated with fingolimod once daily or treated with another approved disease-modifying therapy	10	30/06/2015	Open	Y
67	12/LO/0491	Surgical Replacement And Transcatheter Aortic Valve Implantation (SURTAVI)	5	30/06/2015	Open	N/A
68	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
69	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	31/05/2016	Open	N/A
70	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
71	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 and at risk for PPHN, with a long term flow up investigation of developmental progress 12 and 24 months after completion of study treatment	1	01/10/2017	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
72	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	01/07/2015	Open	N/A
73	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	20/11/2014	Closed - In Follow Up	N
74	13/NW/0283	Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current-day intensive dual anitplatelet therapy in all-comers patients undergoing percutaneous coronary intervention with bivalirudin and biomatrix family drug-eluting stent use	100	30/06/2015	Open	N/A
75	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	01/05/2015	Open	N/A
76	13/WA/0080	Long term Experience With Abatacept SC in Routine Clinical Practice Study	5	30/11/2017	Open	N/A
77	13/NE/0125	A prospective double blind randomised controlled study to evaluate the immunological benefits and clinical effects of an elimination diet using an amino acid formula (AAF) with an added pre-probiotic blend in infants with Cow's Milk Allergy (CMA)	4	31/07/2015	Open	N/A
78	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)	2	01/12/2016	Open	N/A
79	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	4	15/06/2015	Open	N/A
80	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	30/06/2015	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
81	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	Y
82	13/NW/0464	A Placebo-Controlled, Multicenter, Double-Blind, Randomized, Pharmacokinetic and Pharmcodynamic Trial of IDN-6556 in Subjects with Acute-on-Chronic Liver Failure	2	31/07/2014	Closed - In Follow Up	N
83	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 2 diabetes mellitus at high vascular risk. CARMELINA	10	31/03/2016	Open	N/A
84	13/EM/0325	Multiple dose trial examining dose range, escalation and efficacy of oral semaglutide (NNC0113-0217) in subjects with type 2 diabetes	8	21/04/2014	Closed - In Follow Up	N
85	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	5	30/04/2015	Open	N/A
86	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	14	27/05/2018	Open	N/A
87	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	Y
88	13/SW/0236	Post-Authorisation Safety Study of Esbriet® (Pirfenidone): A Prospective Observational Registry to Evaluate Long-Term Safety in a Real-World Setting.	8	31/10/2014	Closed - In Follow Up	N
89	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
90	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.	4	14/05/2016	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
91	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
92	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
93	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	6	28/11/2014	Closed - In Follow Up	N
94	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	15/08/2015	Open	Y
95	12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	15	31/12/2015	Open	N/A
96	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	Y
97	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	Closed - In Follow Up	N
98	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 Treated with Tecfidera™ (dimethyl fumarate) delayed-release capsules	6	30/04/2015	Closed - In Follow Up	N
99	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	2	04/05/2015	Open	Y

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
100	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	31/05/2015	Open	N/A
101	14/EM/0101	A randomised, double-blind, placebo-controlled, parallel group trial to evaluate the effects of a 24 week exercise and activity training program in combination with once daily treatment with tiotropium and olodaterol in fixed dose combination on exercise capacity and physical activity in patients with Chronic Obstructive Pulmonary Disease (COPD) [PHYSACTOTM]	3	17/04/2015	Open	Y
102	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	31/05/2016	Open	N/A
103	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.	3	05/07/2015	Open	Y
104	14/LO/0091	An observational cross-sectional study to describe the patient profile and secondary care management pathways for patients with hidradenitis suppurativa (HS) in the UK	10	31/03/2015	Closed - In Follow Up	N
105	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	27/02/2014	Closed - In Follow Up	N
106	14/LO/0231	Patients with axial spondyloarthritis: multicountry registry of clinical characteristics, including radiographic progression, and burden of disease over 5 years in reallife setting	9	28/02/2015	Open	Y
107	07/H0607/101	Safer pre-natal diagnosis using free DNA in maternal blood test. IONA Study	10	30/10/2015	Open	Y
108	14/LO/1472	A Cross-Sectional Study of Patients with Chronic Immune Thrombocytopenic Purpura and Caregivers to Estimate the Proportion who Administer Romiplostim Correctly After Receipt of Home Administration Training Materials	2	29/12/2015	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
109	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	30/06/2015	Open	N/A
110	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	4	01/09/2015	Open	N/A
111	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)	4	31/10/2014	Closed - In Follow Up	Y
112	13/NE/0344	A Phase 3, Randomized, Double-Blind, Placebo Controlled, 26-Week Multicenter Study with a 26-Week Extension to Evaluate the Efficacy and Safety of Ertugliflozin Monotherapy in the Treatment of Subjects with Type 2 Diabetes Mellitus and Inadequate Glycemic	7	16/01/2015	Open	N/A
113	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	Y
114	14/EM/0143	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	6	09/09/2015	Open	N/A
115	14/EM/0034	Extension Study to Evaluate the Long-Term Safety and Efficacy of Elagolix in Subjects with Moderate to Severe Endometriosis-Associated Pain	0	29/04/2015	Open	N/A
116	14/LO/0818	A Randomized Open-Label Phase III Trial of MK-3475 versus Platinum based Chemotherapy in 1L Subjects with PD-L1 Positive Metastatic Non-Small Cell Lung Cancer	10	24/12/2015	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
117	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	01/04/2016	Open	N/A
118	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	5	23/10/2015	Open	N/A
119	14/EM/1003	A Randomized, Double-Blind, Placebo-Controlled Phase 2/3 Study to Evaluate the Efficacy and Safety of Blisibimod Administration in Subjects with IgA Nephropathy	4	31/07/2015	Open	N/A
120	14/YH/0086	RESPOND: Repositionable Lotus Valve System – Post Market Evaluation of Real World Clinical Outcomes	10	30/06/2015	Open	N/A
121	14/LO/1243	Patient Reported Outcomes with Fingolimod in Local Experience (PROFILE)	8	30/06/2015	Open	N/A
122	14/LO/1406	A PHASE II, OPEN-LABEL STUDY EVALUATING THE SAFETY AND EFFICACY OF GDC-0199 (ABT-199) PLUS BENDAMUSTINE PLUS RITUXIMAB (BR) IN COMPARISON WITH BR ALONE OR GDC-0199 PLUS RITUXIMAB (R) IN PATIENTS WITH RELAPSED AND REFRACTORY FOLLICULAR NON HODGKIN'S LYMPHOMA	5	30/09/2015	Open	N/A
123	14/YH/0141	nMARQ™ Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation	4	31/08/2015	Open	Y
124	14/EE/1001	A 6 month,prospective, randomized, multicentre, placebo controlled safety study of OTO104 given at 3 month intervals by intratympanic injection in subjects with unilateral Meniere's disease, followed by a 6 month open label extension.	5	31/03/2015	Open	Y
125	14/NE/1072	A PHASE II, RANDOMIZED, 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	4	30/09/2016	Open	N/A
126	14/NE/1190	Patients with Multiple Sclerosis treated with Fingolimod: Real World UK Experience (MSFine)	20	01/06/2015	Open	N/A

Reference Number	REC Reference Number	Name of Trial	Recruitment Target	Date recruitment closed	Trial Status	Target met?
127	14/SC/1321	ASSESS: A non-interventional study measuring the economic burden of acute heart failure to society in the United Kingdom via patient and caregiver surveys	40	29/05/2015	Open	N/A
128	13/LO/1328	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class IIIV) with preserved ejection fraction	10	15/08/2018	Open	N/A
129	14/EM/1071	Multicenter, open-label, randomised, pharmacokinetic (PK) and pharmacodynamic (PD) dose-ranging Phase II study of ticagrelor followed by a double-blind, randomised, parallel-group, placebo-controlled 4 weeks extension phase in paediatric patients with sic	1	30/05/2015	Open	N/A
130	14/LO/1443	A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in End Stage Renal Disease Subjects on Stable Dialysis	4	01/01/2016	Open	N/A
131	14/ss/1048	A Phase 3b, Multicenter, Randomized-withdrawal, Placebo-controlled, Double- blind, Parallel-group Trial to Compare the Efficacy and Safety of Tolvaptan (45 to 120 mg/day, Splitdose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease	5	06/08/2015	Open	N/A
132	14/EM/1102	A Double-Blind, Placebo Controlled, Multicenter Study to Assess the Effect of Evolocumab on Cognitive Function in Patients with Clinically Evident Cardiovascular Disease and Receiving Statin Background Lipid Lowering Therapy: A Study for Subjects Enrolled in the FOURIER Trial	3	31/12/2017	Open	N/A

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