NIHR Performance Metrics - Delivering Clinical Research

Quarter 1 2014-2015

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time
11/EM/0225	A PHASE III, MULTICENTER, OPEN-LABEL, RANDOMIZED TRIAL COMPARING THE EFFICACY OF GA101 (RO5072759) 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)	4	30/06/2012	Closed - In Follow Up	Y
12/NW/0014	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of Two Different Regimens of Mipomersen in Patients with Familial Hypercholesterolemia and Inadequately Controlled Low-Density-Lipoprotein Cholesterol (MIPO38)	Not Available	28/02/2013	Recruiting	Y
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.	14	31/05/2013	Recruiting	Y
13/NI/044	A RANDOMIZED, PHASE II, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING THE EFFICACY AND SAFETY OF MetMAb IN COMBINATION WITH EITHER BEVACIZUMAB + PLATINUM + PACLITAXEL OR PEMETREXED + PLATINUM AS FIRST-LINE TREATMENT IN PATIENTS WITH STAGE IIIB or IV NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)	15	30/07/2013	Closed - In Follow Up	N
12/SC/0633	A Multi-Center, Randomized, Double Blind, Placebo and Active-Controlled study with exploratory dose-ranging, to investigate the efficacy and safety of 16 weeks treatment with subcutaneous QGE031 in asthma patients not adequately controlled with high-dose inhaled corticosteroids and long acting ß2-agonists	3	30/09/2013	Recruiting	N
13/LO/0572	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Positive, Antiretroviral Treatment- Naïve Adults	10	30/09/2013	Closed - In Follow Up	N
12/NW/0798	A Prospective Observational Study to Evaluate the Relationship between Disease State and Change in Quality of Life in Ankylosing Spondylitis Patients treated with Remicade® (infliximab) or Simponi® (golimumab)	3	21/11/2013	Recruiting	Y

12/SC/0602	A long-term, randomised, double-blind, placebo-controlled, multinational, multi-centre trial to evaluate cardiovascular and other long-term outcomes with semaglutide in subjects with type 2 diabetes	13	21/11/2013	Follow-up	Y
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 immunochemotherapy induction and initial 2year rituximab maintenance therapy administered subcutaneously.	5	30/11/2013	Follow-up	Y
13/LO/0535	A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis	2	15/12/2013	Closed - In Follow Up	N
12/EM/0018	A randomized, double-blind, placebo-controlled, event driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP	10	31/12/2013	Closed - In Follow Up	Y
12/YH/0318	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GS1101 (CAL-101) in Combination with Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukaemia.	2	31/12/2013	Recruiting	Y
13/SC/0170	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Lumacaftor in Combination with Ivacaftor in Subjects Aged 12 Years and Older with Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation	3	31/12/2013	Closed - In Follow Up	Y
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.	7	03/01/2014	Recruiting	N
13/SC/0452	A Phase 3, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With Lumacaftor in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation	3	15/01/2014	Closed - In Follow Up	Y
13/YH/0011	A Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton’s Tyrosine Kinase Inhibitor PCI-32765 versus Chlorambucil in Patients 65 Years or Older with Treatment-naive Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma	2	28/02/2014	Closed - In Follow Up	N

11/NW/0338	HZC113782: A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.	4	31/03/2014	Completed	Y
13/LO/0002	PRINCIPAL: A Prospective Observational Study of Real World Treatment Patterns and Treatment Outcomes in Patients with Advanced or Metastatic Renal Cell Carcinoma Receiving Pazopanib	3	31/03/2014	Closed - In Follow Up	N
13/LO/0291	Insight Insulin Pump EU Study: A European Multicenter Study to Evaluate the Accu-Chek® Insight Insulin Pump in Routine Practice	10	30/04/2014	Recruiting	N
13/LO/0766	A Phase 4 Cross-sectional Study of Bone Mineral Density in HIV1 Infected Subjects	6	31/05/2014	Recruiting	N
13/LO/1245	A Phase 1b, Multicenter, Pilot, Randomized, Double-blind Trial to Determine the Pharmacokinetics and Pharmacodynamics of Orally Administered Tolvaptan 3.75, 7.5, and 15 mg Tablets in Subjects with Syndrome of Inappropriate Antidiuretic Hormone Secretion (Otsuka 156-12-203)	3	31/05/2014	Recruiting	Y
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 Disease (EUCLID – Examining Use of tiCagreLor In paD)	50	02/06/2014	Closed - In Follow Up	Y
13/LO/1258	SMT C1100 - A Phase 1, Open-label, Single and Multiple Oral Dose, Safety, Tolerability and Pharmacokinetic Study in Paediatric Patients with Duchenne Muscular Dystrophy	4	15/06/2014	Closed - In Follow Up	N
13/WA/0178	A Randomized, Double-blind, Phase III Study of the Efficacy and Safety of Gemcitabine in Combination With TH302 Compared With Gemcitabine in Combination With Placebo in Previously Untreated Subjects With Metastatic or Locally Advanced Unresectable Pancreatic Adenocarcinoma	5	07/07/2014	Recruiting	N
12/NE/0367	A Randomised, Double-blind, Active Treatment Study to Induce Clinical Response and/or Remission with GSK1605786A in Subjects with Moderately-to-Severely Active Crohn's Disease	2	10/07/2014	Completed	N

13/SC/0268	An open-label, crossover, interventional Phase IV study to compare the ease of use of tobramycin inhalation powder with tobramycin inhalation solution and nebulized colistimethate for the treatment of pulmonary Pseudomonas aeruginosa in patients with cystic fibrosis	5	14/07/2014	Recruiting	N
12/NW/0618	Open-label, uncontrolled Phase II trial of intravenous PI3K inhibitor BAY 80-6946 in patients with relapsed, indolent or aggressive Non-Hodgkin's lymphomas	2	31/07/2014	Recruiting	n/a
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	31/07/2014	Recruiting	N/A
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 EndStage Renal Disease on Haemodialysis(ESRDHD)	6	31/07/2014	Recruiting	N/A
13/NW/0583	A 24Week, International, Multicentre, Randomised, Parallel group, Double-blind Trial to Evaluate Metformin Extended Release Monotherapy Compared to Metformin Immediate Release Monotherapy in Adult Subjects with Type 2 Diabetes who have Inadequate Glycaemic Control with Diet and Exercise. (CV181206)	5	16/08/2014	Recruiting	N/A
13/NW/0215	A double blind, randomized, placebo controlled phase II study to assess the efficacy of recPRAME +AS15 Antigen-Specific Cancer Immunotherapeutic as adjuvant therapy in patients with resected PRAMEpositive, Non-Small Cell Lung Cancer	8	22/08/2014	Recruiting	Y
13/LO/1302	A Phase IIIb, randomized, open-label study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV-1 infected antiretroviral therapy naïve women	6	31/08/2014	Recruiting	n/a
12/WM/0160	A Randomised, Phase II, Multicenter, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of MetMAb in Combination with Paclitaxel and Cisplatin or Carboplatin as First-line Treatment for Patients with Stage IIIB (T4 Disease) or IV Squamous Non-Small Cell Lung Cancer (NSCLC)	10	30/09/2014	Completed	N
13/WA/0084	A Randomised, Double-blind, Placebo Controlled, Multicenter Study to Assess Cardiovascular Outcomes Following Treatment with MK3102 in Subjects with Type 2 Diabetes Mellitus	7	10/10/2014	Recruiting	N/A

13/LO/1795	A double-blind, randomized, placebo-controlled, cross-over study to evaluate the clinical efficacy and safety of subcutaneous administration of human plasma-derived C1-esterase inhibitor in the prophylactic treatment of hereditary angioedema (CSL830_3001)	5	31/10/2014	Recruiting	N/A
13/YH/0389	A 52 week, phase 3 double-blind, randomized, placebo controlled, parallel-group study to assess the efficacy, safety and tolerability of pf-04950615 in subjects with heterozygous familial hypercholesterolemia (B1481021)	6	30/11/2014	Recruiting	N/A
13/NW/0698	A phase III multicenter, randomized study of oral LDK378 versus standard chemotherapy in previously untreated adult patients with ALK rearranged (ALK positive), stage IIIB or IV, non squamous nonsmall cell lung cancer (CLDK378A2301)	2	14/12/2014	Recruiting	N/A
13/NW/0612	A multicentre, randomised, double-blind, parallel group, placebo controlled, phase III efficacy and safety study of benralizumab (MEDI563) added to high dose inhaled corticosteroid plus long acting B2agnoist in patients with uncontrolled asthma (SIROCCO)	1	19/12/2014	Recruiting	Y
13/NW/0829	A 52 week, double-blind, randomized, multinational, multi-centre, 2 arm parallel group, active controlled clinical trial of fixed combination of beclometasone dipropionate plus formoterol fumarate plus glycopyrrolate bromide administered via pMDI (CHF 5993) versus fixed combination of beclometasone dipropionate plus formoterol fumarate administered via pMDI in Patients with Chronic Obstructive	10	30/01/2015	Recruiting	N/A
11/LO/1711	An observational study of Avastin® (Bevacizumab) in combination with chemotherapy for treatment of first line metastatic colorectal adenocarcinoma.	30	28/02/2015	Recruiting	Y
09/H0903/46	A PHASE I, open label, multicentre study to assess the safety, tolerability, pharmacokinetics and preliminary anti tumour activity of ascending doses of azd4547 in patients with advanced solid mslignancies	4	31/03/2015	Recruiting	N/A
13/YH/0282	Open label, Phase IIIb study to evaluate the efficacy and safety of subcutaneous (SC) Tocilizumab monotherapy or combination therapy with methotrexate (MTX) or other nonbiologic disease modifying antirheumatic drugs (DMARDs) in patients with severe Rheumatoid Arthritis (RA) who are being treated with an	5	30/06/2015	Recruiting	N/A
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	30/06/2015	Recruiting	N/A

14/WM/0027	A Multinational, Randomised, DoubleBlind,Placebo Controlled Trial to Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus (THEMIS)	10	13/09/2015	Recruiting	N/A
13/WM/0301	A dose-finding phase Ib study followed by a randomized, double-blind phase II study of carboplatin and paclitaxel with or without buparlisib in patients with previously untreated metastatic non-small cell lung cancer (NSCLC) of squamous histology. (BASALT 2)	2	12/10/2015	Completed	n/a
13/SC/0490	A PHASE III, Randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of lebrikizumab in adolescent patients with severe uncontrolled asthma who are on inhaled corticosteroids and a second controller medication (WB28183)	9	31/12/2015	Recruiting	n/a
12/WS/0300	A Randomized, DoubleBlind, Placebo Controlled, Parallel Group Study to Evaluate the Effect of SAR236553/REGN727 on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome-ODYSSEY OUTCOMES	25	31/03/2016	Recruiting	N/A
13/NI/0148	A phase II, randomised, double-blind, placebo controlled, multicentre trial to assess the oral corticosteroidsparing effect of lebrikizumab in patients with with severe corticosteroid dependant asthma	12	31/05/2016	Recruiting	N/A
11/YH/0140	Luminous: Study to observe the effectiveness and safety of LUCENTIS(R) through individualised patient treatment and associated outcomes	50-100	Not Available	Recruiting	Y
12/EE/0357	A Prospective Multicenter Noninterventional Study of Women Treated with ESMYA (ulipristal acetate) as preoperative treatment of moderate to severe symptoms of uterine fibroids	Not Available	Not Available	Closed - In Follow Up	Y
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	5	Not Available	Recruiting	N/A
13/EE/0276	A Phase 3B Randomized, Open-Label, Multi-Center Trial Assessing Sofosbuvir + Ribavirin for 16 or 24 Weeks and Sofosbuvir + Pegylated Interferon + Ribavirin for 12 Weeks in Subjects with Genotype 2 or 3 Chronic HCV Infection. (GS-US-334-0153)	8	Not Available	Closed - In Follow Up	N

13/LO/0574	A Phase 3, Randomized, DoubleBlind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Treatment Naïve Adults	10	Not Available	Completed	N
13/NE/0080	A randomized, open-label, active-controlled, 3-armparallel-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 insufficiently controlled with insulin glargine with or without metformin.	Not Available	Not Available	Closed - In Follow Up	Y
13/NW/0208	Post-Authorisation Safety Study (PASS) MA25101: An Observational Cohort Study of the Safety of Brentuximab Vedotin in the Treatment of Relapsed or Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma	Not Available	Not Available	Recruiting	Y
13/LO/0501	A Phase 2, Randomized, Dose Ranging Study to Assess the Safety and Anticytomegalovirus (CMV) Activity of Maribavir versus Valganciclovir for Treatment of CMV Infections in Transplant Recipients Who Do Not Have CMV Organ Disease	10	Not Available	Completed	N