

NIHR Performance Metrics - Initiating Clinical Research Quarter 2 (2016 - 2017)

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	First Patient Recruited?	Date of First Patient Recruited	Benchmark Met	Reasons for delay
15/LO/0967	iINNOVATE Study: A randomized, double-blind, placebo-controlled, phase 3 study of ibrutinib or placebo in combination with Rituximab in Subjects with Waldenström's Macroglobulinemia	06/10/2015	No		No	Sponsor
14/WS/1021	A phase 3 efficacy and safety study of Ataluren (PTC124?) in patients with nonsense mutation Cystic Fibrosis	07/10/2015	No		No	Neither
13/WM/0017	Select-D: Anticoagulation Therapy in SELECTed Cancer Patients at Risk of Recurrence of Venous Thromboembolism (VTE).	16/10/2015	No		No	NHS Provider
14/YH/0128	Sacral nerve stimulation versus the FENIX magnetic sphincter augmentation for adult faecal incontinence: a Randomised Investigation (SaFaRI)	05/10/2015	Yes	21/10/2015	Yes	Please Select...
15/YH/0178	A Phase 3, Randomized, DoubleBlind, IvacaftorControlled, ParallelGroup Study to Evaluate the Efficacy and Safety of VX661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508delCFTR Mutation and a Second CFTR Allele With a Gating Defect That Is Clinically Demonstrated to be Ivacaftor Responsive.	03/11/2015	Yes	02/12/2015	Yes	Please Select...
14/YH/1199	GALACTIC:GA101(obinutuzumab) monoclonal Antibody as Consolidation Therapy In CLL	02/11/2015	No		No	Neither

14/SC/1059	A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy.	17/11/2015	Yes	20/01/2016	Yes	Please Select...
14/EE/1293	The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (CSTICH) Trial: A Randomised Controlled Trial of monofilament versus braided sutures for insufficient cervix	24/11/2015	Yes	14/12/2015	Yes	Please Select...
15/NW/0416	A randomised phase II trial of Cyclophosphamide and Dexamethasone in combination with Ixazomib, in relapsed or refractory multiple myeloma (RRMM) patients who have relapsed after treatment with thalidomide, lenalidomide and bortezomib.	30/11/2015	Yes	28/01/2016	Yes	Please Select...
15/WS/0153	A phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of a human monoclonal antibody, REGN2222, for the prevention of medically attended RSV infection in preterm infants.	03/12/2015	No		No	Both
15/NE/0317	MULTICENTER, OPEN-LABEL, SINGLE ARM STUDY TO EVALUATE LONG-TERM SAFETY, TOLERABILITY, AND EFFECTIVENESS OF 10 MG/KG OLESOXIME IN PATIENTS WITH SMA	14/12/2015	No		No	Neither
14/SC/1315	Exploring the Potential of Dual Kinase JAK1/2 Inhibitor Ruxolitinib (INC424) with Reduced Intensity Allogeneic Hematopoietic Cell Transplantation in Patients with Myelofibrosis	16/12/2015	No		No	Sponsor

15/LO/1163	A Phase3b,Randomized, Double Blind,Switch Study to Evaluate F/TAF in HIV 1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC	21/12/2015	Yes	25/01/2016	Yes	Please Select...
15/SW/0196	GO29431: A PHASE III, OPEN-LABEL, RANDOMIZED STUDY OF MPDL3280A (Anti-PDL1 ANTIBODY) COMPARED WITH CISPLATIN OR CARBOPLATIN+PEMETREXED FOR PD-L1-SELECTED CHEMOTHERAPY NAIVE PATIENTS WITH STAGE IV NON-SQUAMOUS NON-SMALL CELL LUNG CANCER	22/12/2015	No		No	Neither
15/SW/0197	GO29432: A PHASE III, OPEN-LABEL, RANDOMIZED STUDY OF MPDL3280A (ANTI-PDL1 ANTIBODY) COMPARED WITH GEMCITABINE+CISPLATIN OR CARBOPLATIN FOR PD-L1-SELECTED, CHEMOTHERAPY NAIVE PATIENTS WITH STAGE IV SQUAMOUS NON-SMALL CELL LUNG CANCER.	22/12/2015	No		No	Neither
15/LO/1678	An open-label study to evaluate the long-term safety of avoralstat in subjects with hereditary angioedema.	19/01/2016	No		No	Sponsor
15/NS/0070	Multicentre randomised controlled trial of clinical and costeffectiveness of drug coated balloons, drug eluting stents and plain balloon angioplasty with bailout bare metal stent revascularisation strategies for severe limb ischaemia due to atherosclerotic femoropopliteal, with or without infrapopliteal involvement, peripheral arterial disease	21/01/2016	Yes	29/01/2016	Yes	Please Select...

15/LO/1105	A Randomized, SingleBlind, Multicenter Phase 2 Study to Evaluate the Activity of 2 Dose Levels of Imetelstat in Subjects with Intermediate-2 or High-Risk Myelofibrosis (MF) Relapsed/Refractory to Janus Kinase (JAK) Inhibitor.	04/01/2016	Yes	11/05/2016	No	NHS Provider
13/SC/0317	A randomized, open label, multicentre, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy after rituximab containing chemotherapy regimens to patients with newly diagnosed Primary Mediastinal Large B-Cell Lymphoma (PMLBCL)	05/01/2016	Yes	15/06/2016	No	Neither
15/LO/1289	An international, multicenter, randomized, double-blind, placebocontrolled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures.	18/01/2016	No		No	NHS Provider
15/NE/0167	A Phase 3, Randomized, PlaceboControlled, DoubleBlind Study of Oral Ixazomib Maintenance Therapy After Initial Therapy in Patients With Newly Diagnosed Multiple Myeloma Not Treated With Stem Cell Transplantation.	26/01/2016	No		No	Neither
15/NW/0492	A Randomized, Multicenter, OpenLabel, Non-Inferiority, Phase 3 Study of ACP-196 Versus Ibrutinib in Previously Treated Subjects with High Risk Chronic Lymphocytic Leukemia.	08/02/2016	Yes	08/06/2016	No	Neither
13/SC/0645	Pre-eclampsia in Hospital: Early Induction or Expectant Management	23/02/2016	Yes	28/04/2016	Yes	Please Select...

15/SC/0521	A Phase 2, randomized, open-label, multicenter study to assess safety and efficacy of nabpaclitaxel (Abraxane) with epigenetic modifying therapy of CC-486, and nab-paclitaxel monotherapy as second-line treatment in subjects with advanced nonsquamous non-small cell lung cancer (NSCLC): ABOUND.2L	24/02/2016	Yes	17/05/2016	No	NHS Provider
15/EE/0421	Pomalidomide Specific Targeting in Relapsed and Refractory Myeloma.	14/03/2016	No		No	Neither
15/LO/1595	Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery	14/03/2016	Yes	04/04/2016	Yes	Please Select...
15/SW/0248	A Phase 3, Open-label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation.	21/03/2016	Yes	30/03/2016	Yes	Please Select...
15/WM/0261	Anticoagulants for Living FoEtuses in women with recurrent miscarriage and inherited thrombophilia : ALIFE 2	22/03/2016	No		No	Neither
16/LO/0029	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults.	21/03/2016	Yes	11/04/2016	Yes	Please Select...

15/LO/1592	A 26-week, randomized, double blind, parallel-group multicenter study to assess the efficacy and safety of QVA149 (110/50 mcg o.d.) vs tiotropium (18 mcg o.d.) + salmeterol/fluticasone propionate FDC (50/500 mcg b.i.d.) in patients with moderate to severe COPD.	21/03/2016	Yes	28/06/2016	No	NHS Provider
16/EM/0037	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 16 Week Study Followed by Long Term Evaluation of Efficacy and Safety of Ixekizumab (LY2439821) in TNFi-Experienced Patients with Radiographic Axial Spondyloarthritis	01/04/2016	Yes	21/06/2016	No	NHS Provider
15/YH/0388	A multi-center, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC)	01/04/2016	No		No	Neither
15/EM/0312	A phase II, multi-center, open-label, five-arm study to evaluate the efficacy and safety of oral ceritinib treatment for patients with ALK-Positive Non-Small Cell Lung Cancer metastatic to the brain and/or to leptomeninges.	01/04/2016	Yes	07/06/2016	Yes	Please Select...
15/EE/0464	A Phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	25/03/2016	No		No	Both

15/SC/0409	Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration	25/03/2016	No		No	NHS Provider
15/EE/0010	Phase III trial in IntrahepaTic CHolestasis of pregnancy (ICP) to Evaluate urSodeoxycholic acid (UDCA) in improving perinatal outcomes	30/03/2016	No		No	NHS Provider
15/EM0521	A?phase?III,?open label,?randomized?study?to?investigate?the?ef ficacy?and?safety?of?Atezolizumab?(anti-pd?l1?antibody)? compared?with?best?supportive?care?followin g?adjuvant?cisplatin ?based?chemotherapy?in?pd?l1- selected?patients?with? completely?resected?stage?Ib-IIIa?non- small?cell?lung?cancer.	01/04/2016	No		No	NHS Provider
15/LO/2045	A Phase 2 Clinical Study to Assess the Activity and Safety of Utrophin Modulation with SMT C1100 in Ambulatory Paediatric Male Subjects with Duchenne Muscular Dystrophy (C11005)	01/04/2016	No		No	Both
14/LO/1800	The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary Fibrosis with the Addition of Co-trimoxazole (EME-TIPAC)	01/04/2016	No		No	NHS Provider
15/LO/0141	The Efficacy and Safety of Brimatoprost SR in Patients With Open-angle Glaucoma or Ocular Hypertension	25/03/2016	No		No	NHS Provider
14/EM0121	RITUXILUP - An open label randomised multicentre controlled trial of RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis.	29/03/2016	No		No	NHS Provider

15/EE/0442	Phase III Study of AG-221 in Late Stage AML with IDH2 mutation	01/04/2016	No		No	NHS Provider
14/LO/1851	PrEscription of intraDialytic exercise to improve quALity of Life (PEDAL Trial) in patients with chronic kidney disease	24/03/2016	Yes	04/07/2016	No	NHS Provider
13/WM/0419	MAMMO50: Mammographic surveillance in breast cancer patients aged 50 years and over	01/02/2016	Yes	11/03/2016	Yes	Please Select...
15/WM/0164	GAPS- Graduated compression as an Adjunct to Pharmacoprophylaxis in Surgery	22/03/2016	No		No	NHS Provider
14/SC/1235	Effect of obstructive sleep apnoea on retinal vasculature reactivity following CPAP withdrawal.	29/03/2016	No		No	NHS Provider
15/LO/0023	Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplanteligible patients with symptomatic MM to evaluate the benefit of upfront ASCT	29/03/2016	No		No	NHS Provider
11/LO/1517	Cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) versus gemcitabine, cisplatin and methyl prednisolone (GEM-P) in the first line treatment of T-cell Lymphoma, a multicentre randomised phase II study.	30/03/2016	No		No	NHS Provider
14/SC/1416	A phase III multicentre randomised, double-blind, placebo-controlled trial to assess the role of intravenous immunoglobulin in the management of children with encephalitis (The IgNiTE study)	31/03/2016	No		No	Neither
14/SS/031	An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability.	29/03/2016	No		No	Neither

15/EM/0446	An observational study of non contrast computed tomography in assessment of regional ventilation of the lung.	26/01/2016	Yes	04/02/2016	Yes	Please Select...
15/NE/0350	Post Marketing study collecting long term safety and effectiveness data on the use of RePneu coils for the	29/03/2016	Yes	06/07/2016	No	Both
16/SC/0089	The REST Study: pRotective vEntilation with veno-venouS lung assist in respiratory	01/04/2016	Yes	27/06/2016	No	Neither
15/LO/1120	A randomised trial of dolutegravir (DTG)-based antiretroviral therapy vs. standard of care (SOC) in children with HIV infection starting first-line or switching to second-line ART.	29/03/2016	No		No	Sponsor
16/EM/0234	A Multicenter, Open-label, Safety Extension Study with Benralizumab (MEDI- 563) for Asthmatic Adults on Inhaled Corticosteroid Plus Long-acting ?2 Agonist (MELTEMI)		Yes	18/07/2016		Please Select...
16/LO/0261	A Phase IIa, two-part, randomised, multi-centre, multinational, double-blind, placebo-controlled, parallel group study to compare the efficacy and safety of BCT197 when added on to standard of care for the treatment of acute respiratory exacerbations of chronic obstructive pulmonary disease (COPD) requiring hospitalisation in adults		No			Sponsor
16/WM/0170	An Open-Label Extension Study of Volanesorsen Administered Subcutaneously to Patients with Familial Chylomicronemia Syndrome (FCS)		Yes	12/10/2016		NHS Provider
16/SC/0351	A Phase III, open-label, multicenter, three-arm, randomized study to investigate the efficacy and safety of cobimetinib plus atezolizumab and atezolizumab monotherapy vs. regorafenib in patients with previously treated unresectable locally advanced or metastatic colorectal adenocarcinoma		No			Neither

16/LO/0858	A randomized, double-blind, placebo-controlled, dose-ranging, parallel-group study to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of bcx7353 as a preventative treatment to reduce the frequency of attacks in subjects with hereditary angioedema		No			Neither
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