PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q2, 2014/15)

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met?	Reason for not meeting benchmark
13/LO/0365	An efficacy and mechanism evaluation study for Levosimendan for the prevention of accute organ dysfunction in sepsis (LeoPARDS)	10/01/2014	20/01/2014	Yes	
13/LO/0699	Evaluating the effects of the novel GLP-1 analogue, liraglutide, in patients with Alzheimers disease (ELAD Study).	05/12/2013	20/01/2014	Yes	
13/SC/0348	A randomized, OpenLabel, Phase 2 Study Evaluating LY2875358 Plus Erlotinib and LY2875358 Monotherapy in MET Diagnostic Positive NSCLC Patients with Acquired Resistance to Erlotinib	17/10/2013	27/11/2013	Yes	
13/LO/1375	A randomised controlled trial to evaluate the impact of psychological support intervention after chemotherapy for women with ovarian cancer	30/10/2013	28/11/2013	Yes	
13/YH/0275	Revitive for the treatment of venous insufficiency	28/01/2014	20/02/2014	Yes	
13/YH/0281	Evaluation of [18F]FETßAGTOCA for the imaging of NETs	10/03/2014	16/05/2014	Yes	
13/LO/1305	Systematic Assessment of Pulmonary Artery Haedodynamics using Wave Intensity Analysis	10/10/2013	12/12/2013	Yes	
13/LO/1352	A phase II, open-label, multi-centre, randomised study to investigate the efficacy and saety of MPDL3280A (ant-PD-L1 antibody) compared with docetaexl in patients with non-small cell lung cancer after platinum failure	23/10/2013	16/12/2013	Yes	
13/NW/0363	A Multicenter Openlabel Extension (OLE) Study to Assess the Long term Safety and Efficacy of AMG 145	14/10/2013	05/12/2013	Yes	
13/LO/1121	A Randomized, Controlled Phase 2 Study Evaluating LY2875358 plus Erlotinib versus Erlotinib as First Line Treatment in Metastatic Non Small Cell Lung Cancer Patients with Activating EGFR Mutations Who Have Disease Control after an 8 Week Lead In Treatment with Erlotinib	11/12/2013	29/01/2014	Yes	
13/LO/1332	A TwoPart Phase 1/2a, OpenLabel, Dose Escalation Study to Evaluate the Tolerability and Preliminary Antitumour Activity of OPB111001 in Patients with Advanced Cancers that are Poorly Responsive to Standard Anticancer Treatment	25/02/2014	14/04/2014	Yes	
12/SW/0264	Pulmonary Arterial Hypertension: Working on Anxiety and Stress	06/08/2014	02/10/2014	Yes	
13/LO/0849	Clinical Assessment of a Novel Microprobe Array Continuous Glucose Monitor for Type 1 Diabetes	23/10/2013	22/11/2013	Yes	
13/LO/1150	The role of left atrial ganglionated plexi sites that trigger pulmonary vein ectopy in the pathogenesis of paroxsymal atrial fibrillation	06/11/2013	02/12/2013	Yes	
13/EE/0257	A Phase II Clinical Trial to Study the Efficacy and Safety of a combination regimen of MK5172 and MK-8742 with Ribavirin (RBV) in Subjects with Chronic Hepatitis C Genotype 2 infection	22/10/2013	29/10/2013	Yes	
13/LO/1340	Defining a gold standard for ischaemia: Effects of interventional revascularisation versus optimum medical therapy on exercise capacity in patients with stable coronary artery disease	29/11/2013	11/12/2013	Yes	
13/EE/0276	A Phase 3B Randomized, OpenLabel MultiCenter 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	17/09/2013	31/10/2013	Yes	
13/WM/0231	Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE study	20/08/2013	17/10/2013	Yes	
13/SC/0383	A Two Part, Randomized Clinical Trial to Study Biomarkers of MK8237 (SCH 900237) Treatment in Subjects with House Dust Mite Induced Allergic Rhinitis or Rhinoconjunctivitis	22/10/2013	27/11/2013	Yes	
13/LO/0830	Phase 3 open label study evaluating the efficacy and safety of pegylated interferon lambda-1a, in combination with ribavirin and daclatasvir, for treatment of chronic HCV infection with treatment naive genotypes 1, 2, 3 or 4 in subjects co-infected with HIV	30/10/2013	19/11/2013	Yes	
13/LO/1677	Continence Across Continents to Upend Stigma and Dependency	10/02/2014	31/03/2014	Yes	

13/LO/1725	Prospective, multi-center, double blind, ranodmised study to test the safety of deferral of stenting in a physioogical non-significant lesions in a clinical population of intermediate senoses using iFR and FFR	09/01/2014	13/01/2014	Yes	
11/YH/0006	Magnetic Resonance Imaging to Enhance the Diagnosis of Foetal Developmental Brain Abnormalities in Utero	06/01/2014	14/01/2014	Yes	
14/LO/0057	iPre-Pare: Intelligent Pre-operative Planning for Adverse event Reduction during Endovascular and vascular surgery.	17/01/2014	27/02/2014	Yes	
14/LO/0302	A UK single centre study on the preoperative characterisation of ovarian tumours and conservative management of benign looking adnexal masses	21/03/2014	21/05/2014	Yes	
14/SC/0084	Electrical Stimulation in Diabetic Foot Ulceration	10/07/2014	11/09/2014	Yes	
1/LO/0671	A Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Safety and Efficacy of BIIB019, Daclizumab High Yield Process (DAC HYP), Monotherapy in Subjects With Multiple Sclerosis Who Have Completed Study 205MS301	07/01/2014	12/02/2014	Yes	
14/YH/0047	Intraoperative raman spectoscopy for immediate human brain tumour diagnosis and detection of tumour margin	11/08/2014	02/10/2014	Yes	
14/LO/0369	Determining the pathophysiological role of slow conduction channels identified by Ripple Mapping of the ventricular scar	30/07/2014	15/08/2014	Yes	
13/LO/1758	A Phase III, Randomized, PlaceboControlled, ParallelGroup, DoubleBlind Clinical Trial to Study the Efficacy and Safety of MK8931 (SCH 900931) in Subjects with Amnestic Mild Cognitive Impairment Due to Alzheimers Disease (Prodromal AD)	13/03/2014	25/04/2014	Yes	
14/LO/0445	A study of [11C]PBR28 TSPO PET as a disease marker in MS patients	17/07/2014	18/09/2014	Yes	
12/LO/1078	A phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse or primary refractory multiple myeloma patients.	16/05/2014	19/06/2014	Yes	
14/LO/0882	A phase III, open-label, multicenter,randomized study to investigate the efficacy and safety of MPDLI3280a anti-PD-L1 antibody) compared with docetaxel in patients with non-small cell lung cancer after failure with platinum-containing chemotherapy	05/08/2014	06/08/2014	Yes	
13/WM/0419	MAMMO-50: Mammographic surveillance in breast cancer patients aged 50 years and over	16/07/2014	19/09/2014	Yes	
14/YH/0123	An Expanded Access Protocol for Idelalisib (GS-1101) in Combination with Rituximab for Relapsed, Previously Treated Subjects with Chronic Lymphocytic Leukemia.	08/07/2014	12/08/2014	Yes	
14/LO/0704	The Effect of Short term Dietary Supplementation of Fermentable Carbohydrates on Propionate Production and Appetite Measures: A Pilot Study	17/06/2014	10/07/2014	Yes	
13/EE/0364	A Randomized, Doubleblind, Multicenter Phase 2 Trial of Denosumab in Combination with Chemotherapy as Firstline Treatment of Metastatic Nonsmall Cell Lung Cancer	24/06/2014	09/07/2014	Yes	
12/LO/1966	A Phase 3, Randomized, Placebocontrolled, Parallelgroup, Multicenter, Doubleblind Study to Evaluate the Efficacy and Safety of Telotristat Etiprate (LX1606) in Patients with Carcinoid Syndrome Refractory to Somatostatin Analog (SSA) Therapy	01/08/2014	14/08/2014	Yes	
14/YH/0034	IciCLLe: Assessment of the Mechanism of Action of Ibrutinib (PCI32765) in Bcell Receptor Pathway Inhibition in CLL	29/05/2014	15/07/2014	Yes	
14/SC/0132	A phase I, open label study to assess the pharmacokinetic profile, safety and tolerability of OBE001 after a single oral administration in pregnant women with medically indicated pregnancy termination	13/05/2014	30/06/2014	Yes	
13/LO/1115	UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy In Incident Haemodialysis Patients	10/06/2014	01/08/2014	Yes	
14/LO/0824	A Double-Blind, Randomised, Placebo-Controlled Dose Escalation Study to Assess the Safety, Tolerability and Efficacy of Single and Multiple Doses of PP 1420 in Healthy Subjects	15/08/2014	09/09/2014	Yes	
14/LO/0854	Electrical stimulation in peripheral arterial disease	15/08/2014	27/08/2014	Yes	
14/LO/1123	REBIRTH: Liver Regeneration: a singlecentre, prospective, randomised controlled trial comparing radiofrequency assisted liver partition with portal vein ligation (RALPP) with portal vein embolization (PVE) for preoperative induction f liver hypertrophy in patients with insufficient future liver remnant volume for major liver resection	11/08/2014	28/08/2014	Yes	
14/EE/0188	The Effects of Electronic Cigarettes on the Microcirculation of the Hand	28/07/2014	27/08/2014	Yes	

14/SC/0027	A Phase I/IIa Sporozoite Challenge Study to Assess the Safety and Protective Efficacy of Concomitant Administration of the Combination Malaria Vaccine Candidate Regimen of RTS,S/AS01B + ChAd63 and MVA encoding ME-TRAP and also RTS,S/AS01B alone	24/09/2014	06/10/2014	Yes	
13/EN/0348	Safety and Efficacy assessment of MonoprostÂ® (unpreserved latanoprost) in comparison with Lumigan 0.01 % and Lumigan 0.03% UD, in patients with primary open angle glaucoma or ocular hypertension, stabilized by Lumigan 0.01 % with ocular surface intolerance	10/03/2014	07/05/2014	Yes	
14/NW/0130	A randomised, double blind, multi-center, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss (RPL)	31/07/2014	04/09/2014	Yes	
14/LO/0665	A Phase III OpenLabel Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK5172MK8742 in Treatment Naive Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are on Opiate Substitution Therapy	28/08/2014	10/09/2014	Yes	
14/LO/0083	An Open Label Study Examining the Efficacy and Cardiovascular Risk of Immediate Versus Deferred Switch From a Boosted PI to Dolutegravir (DTG) in HIV Infected Patients With Stable Virological Suppression	22/09/2014	07/10/2014	Yes	
14/WM/1056	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks in Subjects with Chronic HCV	05/09/2014	01/10/2014	Yes	
14/YH/1057	A Phase 3, Multicenter, Randomized, OpenLabel Study to Compare the Efficacy and Safety of Sofosbuvir/GS5816 Fixed Dose Combination for 12 Weeks with Sofosbuvir and Ribavirin for 24 Weeks in Subjects with Chronic Genotype 3 HCV Infection	29/08/2014	25/09/2014	Yes	
14/YH/0049	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of the Combined Lysis of Thrombus with Ultrasound and Systemic Tissue Plasminogen Activator (tPA) for Emergent Revascularization (CLOTBUST-ER) in Acute Ischemic Stroke.	08/08/2014	07/10/2014	Yes	
14/LO/0121	A Phase II, Double Blind, Randomised, Placebo-Controlled Study of the AKT Inhibitor AZD5363 in Combination With Paclitaxel in Triple-Negative Advanced or Metastatic Breast Cancer	27/08/2014	07/10/2014	Yes	
10/H0405/29	Fistula-In-Ano Trial to compare Surgisis anal fistula plug versus surgeon's preference for transsphincteric fistula-in-ano	14/11/2013	04/02/2014	No	Patients seen/screened but none eligible or consented.
11/H0606/1	Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma: a randomised phase III trial	08/05/2013	13/03/2014	No	Rare disease study.
13/WM/0017	Anticoagulation Therapy in SELECTeD Cancer Patients at Risk of Recurrence of Venous Thromboembolism	14/05/2013	17/01/2014	No	Sponsor delays and contract negotiations.
13/LO/0855	A Phase 3, Randomized, Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Rituximab for Previously Treated Indolent Non-Hodgkin Lymphoma	02/08/2013		No	Challenging study entry criteria.
13/SC/0259	A Phase 3, Randomized, Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Bendamustine and Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas. Gilead GS-US-313-0125	02/10/2013	12/02/2014	No	Rare disease study.
12/NW/0802	A multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled study followed by an active treatment period, to evaluate the efficacy, safety and tolerability of two doses of oral administration of laquinimod (0.6 mg/day or 1.2 mg/day) in subjects with relapsing remitting multiple sclerosis (RRMS)	04/11/2013		No	Delay with external contractor supplying MRI services.
11/LO/1776	Urinary Proteomics for HIGH Risk pregancies (UP HIGH R) - PEACHES	20/06/2013	10/12/2013	No	Sponsor delays and contract negotiations.
13/SW/0199	A randomised clinical trial to compare early verus delayed endovenous treatment of superficial venous reflux in patients with chronic venous ulceration	01/10/2013	20/12/2013	No	Patients seen/screened but none eligible or consented.
13/YH/0174	A Multicenter, Randomized, Double-Blind, Study Comparing the Efficacy and Safety of Continuing versus Withdrawing Adalimumab Therapy in Maintaining Remission in Subjects with Non Radiographic Axial Spondyloarthritis	25/10/2013		No	Contracting delays and issues with staff availability.
13/LO/1296	Pilot study to evaluate diffusion weighted MRI (DWMRI) with Intravoxel Incoherent Motion (IVIM) and arterial spin labelling (ASL) at 3T in metastatic or locally advanced pancreatic neuroendocrine tumours (pNET): test-retest and response assessment	06/02/2014	24/09/2014	No	Patients seen/screened but none eligible or consented. Rare disease study.
13/LO/1279	To evaluate the role of LifeNote in rates of medicine adherence and also its acceptability in patients at high multifactorial risk of developing cardiovascular disease attending the MyACtion Westminster programmme	20/08/2013		No	Staff availability.

12/LO/1133	A randomised phase 2 trial investigating the additional benefit of hydroxychloroquine (HCQ) to short course radiotherapy (SCRT) in patients aged 70 years and older with high grade gliomas (HGG)	23/07/2013	11/02/2014	No	Rare disease study.
13/LO/0501	A phase 2, randomized, dose-ranging study to assess the safety and anti-cytomegalovirus (CMV) activity of maribavir versus valganciclovir for treatment of CMV infections in transplant recipients who do not have CMV organ disease	06/09/2013		No	Recruitment closed by Sponsor.
13/SC/0311	A randomized, controlled, doubleblind Phase III trial to compare the efficacy, safety and pharmacokinetics of GP2013plus cyclophosphamide, vincristine, prednisone vs. MabThea® plus cyclophosphamide, vincristine, prednisone, followed by GP2013 or MabThera® maintenance therapy in patients with previously untreated, advanced stage follicular lymphoma	07/08/2013	30/01/2014	No	IMP procedures required clarification.
13/LO/1081	A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients With Nonmetastatic Castration-Resistant Prostate Cancer	31/01/2014	11/09/2014	No	Patients seen/screened but none eligible or consented. Rare disease study.
13/NW0697	PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin Combination Chemotherapy With or Without APR-246	12/12/2013	06/05/2014	No	Imaging procedures required clarification.
13/SC/0291	An open label, phase I study to evaluate the impact of severe hepatic impairment on the pharmacokinetics and safety of vemurafenib in brafv600 mutation positive cancer patients	18/11/2013		No	Study abandoned by Sponsor before it started.
13/LO/1813	Effect of minocycline on chronic neuroinflammation following traumatic brain injury (TBI)	18/03/2014	11/07/2014	No	Study design amended.
13/SC/0368	Comparison of ultra low dose Oral versus Transdermal Hormone Therapy on coagulation activation and metabolic risk factors for Cardiovascular Disease	08/11/2013	18/03/2014	No	Study design amended.
12/LO/0923	A Phase 3, randomized, doubleblind, controlled trial of cabozantinib (XL184) vs. mitoxantrone plus prednisone in men with previously treated symptomatic castration-resistant prostate cancer	23/05/2014		No	Study abandoned by Sponsor at ICHT site.
13/LO/1639	Patient matched osteotomy to correct angular deformities in knee arthrosis	02/12/2013		No	Issue identified concerning particular x-ray software that was necessary for this study.
13/SC/0111	FOCUS 4B: Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	30/09/2013	04/08/2014	No	Lack of ophthalmology support for the study. Also a rare disease study.
13/EM/0374	A doubleblind, randomized, placebocontrolled, study to demonstrate the efficacy and safety of 250 mg or 1 g A3384 administered orally twice daily for two weeks to patients with Bile Acid Malabsorption (BAM)/Bile Acid Diarrhoea (BAD)	24/12/2013	13/03/2014	No	Patients seen/screened but none eligible or consented.
08/H1102/112	Safety and efficacy of intensive versus guideline antiplatelet therapy in high risk patients with recent ischaemic stroke or transient ischaemic attack: a randomised controlled trial	19/12/2013	11/07/2014	No	Sponsor delays. Patients now being identified but few consented.
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH2	30/07/2013	03/03/2014	No	Contracting delays. Patients being screened but none eligible.
13/LO/1050	A Multicenter, Randomized, OpenLabel, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib (E7080) Versus Sorafenib in FirstLine Treatment of Subjects With Unresectable Hepatocellular Carcinoma	02/12/2013	10/07/2014	No	Sponsor/CRO delays regarding study contract.
13/WA/0328	Randomized controlled study comparing AEZS-108 with doxorubicin as second line therapy for locally advanced, recurrent or metastatic endometrial cancer	31/10/2013	21/01/2014	No	Rare disease study.
12/SW/0378	Effect of BivaliRudin on Aortic Valve Intervention Outcomes 2/3 (BRAVO 2/3)	14/04/2014	18/09/2014	No	Staff availability.
13/NW/0702	A Phase III, randomised, multicentre,open label study of active symptom control (ASC) alone or ASC with oxaliplatin/5FU chemotherapy for patients with locally dvanced/metastatic biliary tract cancers previously treated with cisplatin / gemcitabine chemotherapy	28/03/2014	16/06/2014	No	Rare disease. incidence is approximately 1 in 100,000.
13/LO/0740	A randomized, multicenter, double blind phase 3 study ofPD 0332991 (oral CDK 4/6 inhibitor) plus letrozole versus placebo plus letrozole for the treatment of postmenopausal women with ER (+), HER2 () breast cancer who have not received any prior systemic anti cancer treatment for advanced disease	29/11/2013	12/02/2014	No	Contract delays.
14/LO/0067	The control of brain networks after traumatic brain injury: a neuroimaging and neuropsychological study of dopamine and cognition	28/04/2014	08/07/2014	No	Delay with ARSAC approval.
13/LO/1844	Electrical stimulation in diabetic peripheral neuropathy	15/10/2013	01/08/2014	No	Contracting delays. Patients being screened but none eligible.
13/LO/1916	Reproduceability of the 11C-PBR28 PET signal	11/12/2013	03/07/2014	No	Delay in NHS Trust divisional approval and in obtaining valid study documentation.

12/LO/0980	A randomized double-blind phase 3 trial comparing vintafolide (EC145) and pegylated liposomal doxorubicin (PLD/doxil®/caelyx®) in combination versus PLD in participants with platinum-resistant ovarian cancer	20/03/2014		No	Recruitment to study was suspended due to DSMB recommendation.
13/NW/0583	A 24-Week International, Multi-centre, 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	17/12/2013		No	Sponsor/CRO delays regarding study contract.
12/EE/0274	Tranexamic acid for the treatment of significant traumatic brain injury:an international randomised, double blind placebo controlled trial	22/02/2014	23/06/2014	No	Relevant staff resource not available.
13/NW/0464	A PlaceboControlled, Multicenter, DoubleBlind, Randomized, Pharmacokinetic and Pharmacodynamic Trial of IDN6556 in Subjects with Acute on ChronicLiver Failure	03/10/2013		No	Challenging study design. Substantial Amendment required.
12/YH/0236	A multi-centre randomised controlled trial comparing rubber band ligation with haemorrhoidal artery ligation in the management of symptomatic second and third degree haemorrhoids	08/08/2013	19/11/2013	No	Sponsor delays regarding study contract.
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	24/09/2013	28/10/2014	No	Challenging study design.
13/SW/0192	European multicenter registry using hybrid staged operationg room and interventional catheter ablation techniques to treat chronic atrial fibrillation	18/03/2014		No	Study abandoned due to staff availability.
13/LO/1290	A Followup Study to Assess Resistance and Durability of Response to AbbVie DirectActing Antiviral Agent (DAA) Therapy in Subjects Who Participated in Phase 2 or 3 Clinical Studies for the Treatment of Chronic Hepatitis C Virus (HCV) Infection	22/10/2013		No	Closed early by Sponsor.
13/LO/0683	Predicting Delirium After Neck of Femur Fracture	02/10/2013	01/07/2014	No	Staff availability issues and concerns around scheduling of patients and capacity, which delayed approval.
10/MRE09/29	A Phase I/II trial of isotoxic accelerated radiotherapy in the treatment of patients with non-small cell lung cancer (I-START)	20/06/2013	14/01/2014	No	Sponsor delays regarding study contract. Rare disease study.
13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer	08/10/2013		No	Rare disease study. Imaging needed to clarify the radiation exposure information.
13/NW/0634	A Phase 1b, multicenter, openlabel, dose escalation study of GSK2256098 (FAK inhibitor) in combination with Trametinib (MEK inhibitor) in subjects with advanced solid tumors	19/11/2013	15/05/2014	No	Originally no ophthalmology support for the study.
13/LO/1816	Intraocular Pressure And Tolerability Study of Preservative Free Bimatoprost 0.03% Unit Dose (BUDPF) or preservative free Latanoprost 0.005% Unit Dose (LUDPF) (Monoprost)in patients with Ocular hypertension or Glaucoma: A Randomised, single masked, 3 month cross-over, Investigator led, European multicentre Trial (SPORT)	11/12/2013	15/05/2014	No	Study initiation delayed due to IMP shipment and pharmacy protocol finalisation (Q4 reason). Difficult contract - did not use template agreement.
13/SC/0589	Optimisation of Onpulse technology for patients with post surgical or vascular oedema	08/01/2014	20/07/2014	No	Clinical pathway not clear.
14/SC/0038	PET imaging substudy associated with: a phase III, randomized, double-blind, placebo-controlled, parallel-group, multicenter, efficiacy, and safety study of gantenerumab in patients with mild Alzheimers disease	14/01/2014	22/07/2014	No	Imaging procedures required clarification.
13/EE/0365	Investigation of newly developed 1- and 2-piece convex ostomy products in subjects with ileostomy	11/12/2013		No	Sponsor delays regarding study.
12/EE/0231	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of the Safety and Tolerability of N-Acetylcysteine in Patients with Idiopathic Pulmonary Fibrosis with Background Treatment of Pirfenidone	07/04/2014		No	Study closed by Sponsor at end of May 2014 without recruitment. Rare disease.
14/NW/0300	A comparative study of two dressings for central venous catheters	18/02/2014	21/05/2014	No	Delays with internal approvals.
13/EE/0214	A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Risistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial	24/03/2014	10/06/2014	No	Challenging study entry criteria.
13/LO/0882	Slow wave sleep and daytime functioning in chronic fatigue syndrome: effects of sodium oxybate	27/02/2014	19/05/2014	No	Site initiation/staff training delayed. Patients are now being screened but none have consented to join the study.
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	18/06/2013	15/04/2014	No	Imaging procedures required clarification. Also delayed IMP shipment.
12/LO/1158	Bevacizumab And Combination Chemotherapy in rectal cancer Until Surgery: A Phase II, Multicentre, Openlabel, Randomised Study of Neoadjuvant Chemotherapy and Bevacizumab in Patients with MRI defined HighRisk Cancer of the Rectum (BACCHUS)	27/11/2013		No	Imaging procedures required clarification. Rare disease study.

13/EE/0429	A phase I/II open-label, dose escalation study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of GSK525762 in subjects with relapsed, refractory hematologic malignancies.	07/01/2014	16/06/2014	No	Complex contract negotiations.
13/NW/0265	A trial of de-escalation and stopping treatment in chronic myeloid leukaemia patients with excellent responses to tyrosine kinase inhibitor therapy(De- Escalation and Stopping Treatment of Imatinib, Nilotinib or sprYcel in chronic myeloid leukaemia	18/09/2013	17/03/2014	No	Contracting delays. Eligible patients were seen and approached but none consented.
14/LO/0026	The long-term safety and effect of renal denervation	17/02/2014	02/06/2014	No	Study team waiting for equipment to arrive from Sponsor.
13/NE/0125	PRESTO Neo.1.C/E	29/08/2013		No	Contract delays. Then unable to recruit due to study design / exclusion criteria (although 15 patients have been seen/screened for eligibility).
13/LO/1182	Pilot study to evaluate the feasibility of functional MRI in metastatic renal cell carcinoma (mRCC) with test-retest repeatability and early response assessment.	01/08/2013		No	Delayed study permissions. Rare disease study.
13/EE/0199	An Exploratory Study of the Safety and Efficacy of BOTOX for the Treatment of Premature Ejaculation	11/09/2013	15/01/2014	No	Complex and restrictive entry criteria for study. No eligible patients seen.
13/LO/1302	A Phase IIIb randomised, openlabel study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV1 infected antiretroviral therapy naive women	01/11/2013	12/02/2014	No	Delays with site initiation. Also a difficult study to recruit to.
13/LO/1380	I-Scan for the detection and characterisation of mucosal lesions a randomised controlled study	12/11/2013	11/03/2014	No	Sponsor delays during contract negotiations.
13/LO/0181	Optimisation and Individualisation of HeartSparing Breast Radiotherpay Techniques (The Heart Spare Study): stage II	06/01/2014	23/04/2014	No	Sponsor delays during contract negotiations. Template agreement not used.
13/LO/451	The United Kingdom Transcatheter Aortic Valve Implantation (UK TAVI) Trial. A multi-centre randomised controlled trial to assess the clinical effectiveness and cost-utility of TAVI, compared with conventional surgical aortic valve replacement, in patients with severe symptomatic aortic stenosis at intermediate or high operative risk	11/07/2014		No	Study team has been actively screening for suitable patients and had identified one, but they did not consent to participate.
14/LO/0864	A double blind, randomised controlled trial to assess the efficacy of paravertebral blocks for analgesia after cardiac surgery	13/08/2014	27/10/2014	No	Patients have been seen but have not consented to join the study.
13/NI/0188	A singlearm trial to evaluate the effectiveness of PCI of de novo 3vessel disease applying the SYNTAX score II with pressure wire functional assessment and IVUS guidance, using an everolimuseluting stent with biodegradable abluminal coating	03/04/2014	16/07/2014	No	NHS permission delays due to concerns over imaging procedures.
10/H0801/67	Focal MR-Guided Focused Ultrasound Treatment of Localized Low-Risk Prostate Cancer: Feasiblity Study	11/06/2014		No	Study team actively screening for patients. No patients recruited yet.
13/LO/1867	Role of bile salt hydrolases in C. difficile infection	09/01/2014	01/04/2014	No	Further clarification on study required from HTA, HRA and MHRA in relation to this innovative study, in line with GCP requirements.
13/WS/0282	Prospective, single-arm, global multi-center study to evaluate treatment of obstructive superficial femoral artery and/or popliteal lesions wiht a novel paclitaxel coated percutaneous angioplasty balloon	12/02/2014	02/10/2014	No	Regulatory approvals delay. No suitable patients have been found despite screening activity.
13/LO/1814	A phase III, randomized, controlled, single-blind, multicentre, parallel arm trial to assess the efficacy and safety of Pergoveris® (follitropin alfa and lutropin alfa) and GONAL-f® (follitropin alfa) for multifollicular development as part of an assisted reproductive technology treatment cycle in poor ovarian responders, as defined by the European Society of Human Reproduction and Embryology criteria	30/06/2014		No	No data returned by local PI.
13/EE/0444	Maximizing CRT Delivery by using Multipolar Coronary Sinus Lead Acuity x4	05/02/2014	24/07/2014	No	Difficult contract negotiations.
14/LO/0521	A prospective, randomized, open label, two arm Phase III study to evaluate treatment free remission (TFR) rate in patients with Philadelphia positive CML after two different durations of consolidation treatment with nilotinib 300mg BID	15/07/2014		No	Delayed site initiation. Rare disease study.
14/LO/0362	Prospective, randomized, placebo-controlled, double-blind, multicenter, parallel-group, 24-week study to assess the efficacy, safety and tolerability of macitentan in subjects with inoperable chronic thromboembolic pulmonary hypertension	07/07/2014		No	Rare disease study.
12/SS0/138	REstart or STop Antithrombotics Randomised Trial - RESTART	29/05/2014		No	Study had many amendments. No eligible patients have been consented (restrictive entry criteria).
14/NW/0156	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	25/06/2014		No	This is a rare patient group. We continue to screen every day.

12/LO/0858	An OpenLabel Study to Evaluate the Safety, Antiviral Activity and Pharmacokinetics of Direct Acting Antiviral Agent (DAA) Treatment in Combination with Peginterferon Î±2a and Ribavirin (pegIFN/RBV) in Chronic Hepatitis C Virus (HCV) Infected Subjects Who Have Experienced Virologic Failure in a Previous Abbott DAA Combination Study	01/05/2014	29/07/2014	No	Treatment roll-over study. Not possible to recruit earlier as clinical outcomes from original feeder studies were unknown.
13/LO/1323	The efficacy and safety of Ferriprox® for the treatment of transfusional iron overload in patients with sickle cell disease or other anaemias	05/06/2014		No	CRO/Sponsor postponed site initiation visit due to delay with delivery of the IMP.
14/LO/0130	Temperature Controlled Laminar Airflow (TLA) treatment in children with severe atopic eczema-Prospective Pilot Study	23/04/2014		No	Staff availability issues.
14/SC/0037	A phase III, randomized, double-blind, placebo-controlled, parallel-group, multicenter, efficacy and safety study of gantenerumab in subjects with mild Alzheimer's disease	12/05/2014	22/07/2014	No	Delays in recruiting to this study caused by difficult inclusion criteria, i.e. patients are actively being screened for the study but are not eligible.
14/SC/0178	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Bendamustine and Rituximab for Previously Untreated Chronic Lymphocytic Leukemia	06/06/2014	14/10/2014	No	This is a rare disease study (5.1 per 100,000 in Europe).
13/LO/1557	A Phase IV, Multicentre, Open label, Single Group Exploratory Study to Assess the Clinical Value of Enumeration of Circulating Tumour Cells (CTCs) to Predict Clinical Symptomatic Response and Progression Free Survival in Patients receiving Deep Subcutaneous Administrations of Somatuline®(lanreotide) Autogel® to treat the Symptoms of Functioning Midgut NeuroEndocrine Tumours (NET)	13/05/2014		No	Several patients have been screened but identified as non-eligible.