

## PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q3, 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
11/YH/0006	Magnetic Resonance Imaging to Enhance the Diagnosis of Foetal Developmental Brain Abnormalities in Utero	06/01/2014	14/01/2014	Yes	Benchmark met
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	03/07/2014	Yes	Benchmark met
12/LO/1177	Streamlining Staging of Lung Cancer with Whole Body MRI	27/10/2014	08/12/2014	Yes	Benchmark met
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	Benchmark met
12/SW/0264	Pulmonary Arterial Hypertension: Working on Anxiety and Stress	06/08/2014	02/10/2014	Yes	Benchmark met
12/WM/0199	A pragmatic randomised controlled trial assessing the impact of a low calorie Cambridge based diet programme (CDBP) on weight loss in obese patients with Type 2 diabetes mellitus treated with insulin	15/10/2014	04/11/2014	Yes	Benchmark met
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	Benchmark met
13/EM/0348	Safety and Efficacy assessment of Monoprost® (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	Benchmark met
13/EM/0395	Treatment of Advanced Glaucoma Study (TAGS): A multicentre randomised controlled trial comparing primary medical treatment with primary augmented trabeculectomy for people with newly diagnosed advanced glaucoma	11/09/2014	03/11/2014	Yes	Benchmark met
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	12/08/2014	20/10/2014	Yes	Benchmark met
13/LO/0365	An efficacy and mechanism evaluation study for Levosimendan for the prevention of acute organ dysfunction in sepsis (LeoPARDS)	10/01/2014	20/01/2014	Yes	Benchmark met
13/LO/0595	COgnitive behavioural therapy vs standardised medical care for adults with Dissociative nonEpileptic Seizures: A multicentre randomised controlled trial.	31/10/2014	03/12/2014	Yes	Benchmark met
13/LO/0671	A Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Safety and Efficacy of BIB019, Daclizumab High Yield Process (DAC HYP), Monotherapy in Subjects With Multiple Sclerosis Who Have Completed Study 205MS301	07/01/2014	12/02/2014	Yes	Benchmark met
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	Benchmark met
13/LO/1677	Continence Across Continents to Upend Stigma and Dependency	10/02/2014	31/03/2014	Yes	Benchmark met
13/LO/1725	Prospective, multi-center, double blind, ranodmised study to test the safety of deferral of stenting in a physiological non-significant lesions in a clinical population of intermediate senoses using iFR and FFR	09/01/2014	13/01/2014	Yes	Benchmark met
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 Amnesic Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD).	13/03/2014	25/04/2014	Yes	Benchmark met
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	27/08/2014	Yes	Benchmark met

13/NS/0002	A multicentre randomised controlled trial of extracorporeal shockwave lithotripsy, as first treatment option, compared with direct progression to ureteroscopic treatment, for ureteric stones	19/09/2014	27/10/2014	Yes	Benchmark met
13/NW/0778	A double-blind, randomised, placebo-controlled, Phase II study to evaluate ProCervix efficacy to clear HPV 16 and HPV 18 infection in women with normal cytology or ASCUS/LSIL	11/08/2014	03/10/2014	Yes	Benchmark met
13/SW/0132	Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial	01/10/2014	05/12/2014	Yes	Benchmark met
13/WM/0419	MAMMO-50: Mammographic surveillance in breast cancer patients aged 50 years and over	16/07/2014	19/09/2014	Yes	Benchmark met
13/YH/0162	HABSelect	17/09/2014	12/11/2014	Yes	Benchmark met
13/YH/0275	Revitive for the treatment of venous insufficiency	28/01/2014	20/02/2014	Yes	Benchmark met
13/YH/0281	Evaluation of [18F]FETβAGTOCA for the imaging of NETs	10/03/2014	16/05/2014	Yes	Benchmark met
13/YH/0317	Current Steering to Optimize Deep Brain Stimulation	02/10/2014	20/10/2014	Yes	Benchmark met
14/EE/0188	The Effects of Electronic Cigarettes on the Microcirculation of the Hand	28/07/2014	27/08/2014	Yes	Benchmark met
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	Benchmark met
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	Benchmark met
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	Benchmark met
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	Benchmark met
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	Benchmark met
14/LO/0445	A study of [11C]PBR28 TSPO PET as a disease marker in MS patients	17/07/2014	18/09/2014	Yes	Benchmark met
14/LO/0665	A Phase III OpenLabel Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK5172/ MK8742 in TreatmentNaïve Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are on Opiate Substitution Therapy.	28/08/2014	10/09/2014	Yes	Benchmark met
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	Benchmark met
14/LO/0717	A Multicenter Phase 3 Randomized Open-Label Study of Bosutinib versus Imatinib in Adult Patients with Newly Diagnosed Chronic Phase Philadelphia Chromosome Positive Chronic Myelogenous Leukaemia.	19/09/2014	10/11/2014	Yes	Benchmark met
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	Benchmark met
14/LO/0854	Electrical stimulation in peripheral arterial disease	15/08/2014	27/08/2014	Yes	Benchmark met
14/LO/0882	A PHASE III, OPEN-LABEL, MULTICENTER,RANDOMIZED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF MPDL3280A (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	Benchmark met
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 of liver hypertrophy in patients with insufficient future liver remnant volume for major liver resection.	11/08/2014	28/08/2014	Yes	Benchmark met
14/LO/1197	Phase IB open label study to assess the safety, pharmacokinetics and clinical activity of Acelarin (NUC-1031) given on days 1 & 8 with carboplatin on day 1, every three weeks for 6 cycles in participants diagnosed with recurrent ovarian cancer.	30/10/2014	27/11/2014	Yes	Benchmark met

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	Benchmark met
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	Benchmark met
14/SC/0084	Electrical Stimulation in Diabetic Foot Ulceration	10/07/2014	11/09/2014	Yes	Benchmark met
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	Benchmark met
14/WM/0159	Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE 2 study	02/10/2014	13/10/2014	Yes	Benchmark met
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	Benchmark met
14/YH/0034	IciCLL: Assessment of the Mechanism of Action of Ibrutinib (PCI32765) in Bcell Receptor Pathway Inhibition in CLL.	29/05/2014	15/07/2014	Yes	Benchmark met
14/YH/0047	Intraoperative raman spectroscopy for immediate human brain tumour diagnosis and detection of tumour margin	11/08/2014	02/10/2014	Yes	Benchmark met
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	Benchmark met
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	Benchmark met
14/YH/1057	A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks with Sofosbuvir and Ribavirin for 24 Weeks in Subjects with Chronic Genotype 3 HCV Infection	29/08/2014	19/09/2014	Yes	Benchmark met
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	Study approval delay; delayed SIV. Received Sponsor approval to recruit mid-May 2014. Patients now being identified but few consented. Difficulty lies in getting patients diagnosed and into within the 48-hour recruitment window. Considering alternative recruitment options with Sponsor.
10/H0801/67	Focal MR-Guided Focused Ultrasound Treatment of Localized Low-Risk Prostate Cancer: Feasibility Study	11/06/2014		No	Study team actively screening for patients. No patients recruited yet.
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	Closed by sponsor; Rare disease study
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	Staff availability issues
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH2	30/07/2013	03/03/2014	No	Sponsor delays; No patients consented; Contracting delays
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 a2a 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.
12/LO/0923	A Phase 3, randomized, doubleblind, controlled trial of cabozantinib (XL184) vs. mitoxantrone plus prednisone in men with previously treated symptomatic castrationresistant prostate cancer	23/05/2014		No	Closed by sponsor
12/LO/0980	PROTOCOL EC-FV-06: 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	Closed by sponsor
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	27/11/2013		No	Permissions delayed or denied; Rare disease study

12/LO/1889	Openlabel,single arm extension study to the doubleblind,randomized, multicenter, placebo controlled,parallel group study comparing the efficacy and safety of 0.5 mg FTY720 administered orally once daily versus placebo in patients with primary progressive multiple sclerosis	23/04/2014	11/07/2014	No	Study experienced long contract / budget negotiations.
12/NE/0343	Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy	01/10/2014		No	Rare disease study.
12/SS/0109	International Study of Comparative Health Effectiveness with Medical and Invasive Approaches	28/04/2014	30/09/2014	No	Despite ongoing patient screening activity at this site, no eligible patients have been seen during the reported period.
12/SS/0138	REstart or SToP Antithrombotics Randomised Trial - RESTART	29/05/2014		No	Yet to recruit despite daily screening. Restrictive study exclusion criteria.
12/SW/0378	Effect of Bivalirudin on Aortic Valve Intervention Outcomes 2/3 (BRAVO 2/3)	14/04/2014	18/09/2014	No	Bereavement within study team
13/EE/0214	A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance 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	US FDA regulations
13/EE/0365	Investigation of newly developed 1- and 2-piece convex ostomy products in subjects with ileostomy	11/12/2013		No	Closed by sponsor
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	Contracting delays
13/EE/0444	Maximizing CRT Delivery by using Multipolar Coronary Sinus Lead Acuity x4	05/02/2014	24/07/2014	No	Lengthy budget/contract negotiation.
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	No patients seen; No patients consented
13/LO/0150	A randomized, double blind, placebo-controlled, multicenter phase III study of regorafenib in patients with hepatocellular carcinoma (HCC) after sorafenib	21/08/2014		No	Rare disease study. 3 patients identified but all failed eligibility criteria.
13/LO/0181	Optimisation and Individualisation of HeartSparing Breast Radiotherapy Techniques ( The Heart Spare Study) : stage II	06/01/2014	23/04/2014	No	Contracting delays
13/LO/0740	A RANDOMIZED, MULTICENTER, DOUBLE BLIND PHASE 3 STUDY OF PD 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	Permissions delayed or denied; Sponsor delays; Contracting delays
13/LO/0882	Slow wave sleep and daytime functioning in chronic fatigue syndrome: effects of sodium oxybate	27/02/2014	19/05/2014	No	No patients seen; No patients consented
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 delays; Contracting delays
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	No patients consented; Rare disease study
13/LO/1115	UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy In Incident Haemodialysis Patients	10/06/2014	20/08/2014	No	First patient within before 70 days.
13/LO/1233	MAGnetic NANoparticle thermoBLATion Retention and Maintenance in prostate: A Phase 0 Study in Men (MAGNABLATE I Trial)	04/08/2014	10/12/2014	No	Sponsor suspended study due to patient safety issue. First patient has subsequently been recruited immediately after suspension lifted.
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	Rare disease study
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	30/10/2014	No	SIV has been postponed due to a delay with delivery of IMP.
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; Contracting delays
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 screened however eventually identified as non-eligible. Problem in recruiting patients all over UK due to study design. Inclusion criteria will probably be amended.

13/LO/1682	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients with Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer	08/09/2014		No	Eligible patients were identified and approached in under 70 days, but declined to take part.
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	Contracting delays
13/LO/1844	Electrical stimulation in diabetic peripheral neuropathy	15/10/2013	01/08/2014	No	No patients seen; Contracting delays
13/LO/1867	Role of bile salt hydrolases in C. difficile infection	09/01/2014	01/04/2014	No	Required additional clarification from regulatory bodies due to innovative nature of study.
13/LO/1916	Reproduceability of the 11C-PBR28 PET signal	11/12/2013	03/07/2014	No	Permissions delayed or denied; Staff availability issues
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 actively screening for suitable patients but none consented; continuing to screen against current protocol.
13/NE/0126	An exploratory, randomised, doubleblind, controlled study to assess the effect of an Amino Acid Based Formula with a synbiotic blend on gut microbiota and stool characteristics in infants with suspected gastrointestinal Non IgE mediated cow's milk allergy (CMA)	18/09/2014		No	Inclusion criteria difficult.
13/NI/0143	Scheduling nab-paclitaxel with Gemcitabine (SIEGE): Randomised phase II trial to investigate two different schedules of nab-paclitaxel (Abraxane) combined with gemcitabine as first line treatment for metastatic pancreatic adenocarcinoma	29/07/2014		No	Rare disease study. Study team actively looking for patients.
13/NI/0188	A singlearm trial to evaluate the effectiveness of PCI de novo vessel 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; safety concerns in relation to imaging component of study needed to be clarified with Sponsor.
13/NW/0583	A 24-Week International, Multi-center, Randomized, 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 Glycemic Control with Diet and Exercise	17/12/2013	31/03/2014	No	Sponsor delays; CRO delays
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	Staff availability issues
13/NW/0697	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	Query regarding imaging requirements; recommended that an amendment be submitted; contracting delays
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 advanced/metastatic biliary tract cancers previously treated with cisplatin / gemcitabine chemotherapy	28/03/2014	16/06/2014	No	Rare disease 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 (Protocol No: CBAF312A2304 )	18/06/2013	15/04/2014	No	Sponsor delays; IMP supply issues
13/SC/0111	FOCUS4 Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	30/09/2013	04/08/2014	No	Permissions delayed or denied; Staff availability issues; Rare disease study
13/SC/0559	A Phase 3, Randomized, Placebo-controlled, Multicenter, Double-blind Study to Evaluate the Safety and Efficacy of Telotristat Etiprate (LX1606) in Patients with Carcinoid Syndrome	17/09/2014		No	Delay with SIV; also a rare disease.
13/SC/0589	Optimisation of Onpulse technology for patients with post surgical or vascular oedema	08/01/2014	20/07/2014	No	Permissions delayed or denied; Staff availability issues; Contracting delays
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	Staff availability issues
13/WA/0117	A randomised phase II trial of Olaparib maintenance versus placebo monotherapy in patients with non-small cell lung cancer	06/10/2014	16/12/2014	No	Delays in site activation. ICHT still managed to quickly recruit first patient 4 days after Sponsor green light (missed benchmark by 1 day).

13/WS/0172	A Phase 2, Open-Label Study of Rucaparib in Patients with Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	06/08/2014		No	Recruitment suspended by Sponsor (Oct 2014); due to re-open March 2015. ICHT site opened end of August 2014 but no eligible patients seen in the 2 month period before suspension.
13/WS/0282	Prospective, single-arm, global multi-center study to evaluate treatment of obstructive superficial femoral artery and/or popliteal lesions with a novel paclitaxel coated percutaneous angioplasty balloon.	12/02/2014	02/10/2014	No	Regulatory approvals delay (MHRA). NHS Permission delayed due to change of CRO study management team which led to delays in contract approval. First patient not yet recruited - no suitable patients have been found despite screening.
13/YH/0152	A Randomised Trial of the FLAMSABU Conditioning Regimen in Patients with Acute Myeloid Leukaemia and Myelodysplasia Undergoing Allogeneic Stem Cell Transplantation	28/07/2014	13/11/2014	No	Delays in the procurement of Amsacrine (study drug). Drug only made available in the UK in October 2014. First patient then recruited in mid-November.
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	Sponsor delays; Staff availability issues; Contracting delays
13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer.	08/10/2013		No	Permissions delayed or denied; Rare disease study
13/YH/0424	Randomised trial of rapid outpatient rehydration versus hospital admission for management of hyperemesis gravidarum	29/05/2014	20/01/2015	No	Study suspended due to issues with clinical nursing resource support.
14/EE/0193	Adjuvant benefit of Neuromuscular Electrical Stimulation (NMES) in Supervised Exercise in Patients with Intermittent Claudication	20/10/2014		No	First patient consented but not yet entered study.
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	15/09/2014		No	Very rare disease study (less than 1 in 500,000).
14/LO/0026	The long-term safety and effect of renal denervation	17/02/2014	02/06/2014	No	No patients seen
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	Permissions delayed or denied; Radiopharmaceutical supply delays
14/LO/0102	A First Time in Human, Double Blind, Randomised, Placebo Controlled Phase I Study to Investigate the Safety, Tolerability and Pharmacokinetics of Single and Multiple Ascending Intravenous Doses of SNF472 in Healthy Male Volunteers, and a Single Intravenous Dose of SNF472 in Male Haemodialysis Patients	15/10/2014		No	Study opened to recruitment but no eligible patients yet consented.
14/LO/0130	Temperature Controlled Laminar Airflow (TLA) treatment in children with severe atopic eczema- Prospective Pilot Study	23/04/2014	15/01/2015	No	PI on leave - not possible to replace expertise for this study.
14/LO/0246	Does Right Rather than Left Lateral starting position lead to quicker completion of Colonoscopy?	23/03/2014		No	No patient seen / consented.
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.
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	24/11/2014	No	Site initiated by Sponsor on day 65. Also a rare disease study (affects 1 in 100,000).
14/LO/0600	Preventing Recurrent Gestational Diabetes Mellitus with Early Metformin Intervention	19/09/2014	27/01/2015	No	Participant identification more challenging than anticipated when study discussed at feasibility assessment due to changes in clinical pathways.
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.
14/LO/1053	A Phase 3 Randomised double blind Active study Evaluating Memelotinib vs Ruxolitinib in subjects with primary Myelofibrosis (PMF) or Post-poly cythemia Vera or Post-essential Thrombocythemia Myelofibrosis ( Post-PV/ET MF)	28/08/2014		No	Delays in supplying study drug. This study has not opened yet anywhere in the UK or Europe due to drug supply problems. ICHT is one of only two UK sites that have issued approval and are ready to start as soon as the drug is available. Expected activation for UK sites is end of Q1 2015.
14/NW/0008	Golimumab: A Phase 4, UK Open Label, Single arm Study on its Utilization and Impact in Ulcerative Colitis	17/09/2014	12/12/2014	No	Patients being seen and consented but none yet found eligible.
14/NW/0156	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	25/06/2014		No	Rare patient group (less than 1 in 2000). Site continues to screen every day.
14/NW/0300	A comparative study of two dressings for central venous catheters	18/02/2014	21/05/2014	No	Permissions delayed or denied
14/SC/0037	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER, EFFICIACY 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 pre-identified patients needing to be stabilised on cholinesterase inhibitors before meeting inclusion criteria, i.e. patients are actively being screened for the study but are not eligible.
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 ALZHEIMER'S DISEASE	14/01/2014	22/07/2014	No	Permissions delayed or denied; Sponsor delays

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	31/10/2014	No	This is a rare disease study (5.1 per 100,000 in Europe). All possible patients continue to be screened.
14/WM/0170	A Phase 3, Randomized Study To Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-essential Thrombocythemia Myelofibrosis who were Treated with Ruxolitinib. NCRN 3257	14/10/2014		No	Myelofibrosis is a rare disease.
14/YH/0085	Front-Line therapy in CLL: Assessment of Ibrutinib + Rituximab.	26/09/2014		No	Very rare disease study (0.6 in 10,000 in males & 0.4 in 10,000 in females).
09/H1005/28	Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies.	31/10/2014			70-day benchmark not yet expired
12/WM/0373	A randomised trial in new hearing aid users to measure the benefit of using 4 pre-set configurations of hearing aids with self learning characteristics	04/11/2014			70-day benchmark not yet expired
13/LO/1463	An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease	23/10/2014			70-day benchmark not yet expired
13/LO/1775	The PRAETORIAN Trial: A prospective, randomised comparison of subcutaneous and transvenous implantable cardioverter defibrillator therapy	26/11/2014			70-day benchmark not yet expired
13/NW/002	Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL® Hemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery (VICTORY Study)	10/12/2014			70-day benchmark not yet expired
14/EE/0086	Neuromuscular Electrical Stimulation (NMES) in Patients with Intermittent Claudication	29/10/2014			70-day benchmark not yet expired
14/EM/0130	A Phase 3, Open-Label, Randomized Study of Quizartinib (AC220) Monotherapy vs. Salvage Chemotherapy in Subjects with FLT3-ITD Positive Acute Myeloid Leukemia (AML) Refractory to, or Relapsed after, First-Line Treatment with or without Hematopoietic Stem Cell Transplantation (HSCT) Consolidation.	28/11/2014			70-day benchmark not yet expired
14/LO/0865	A Phase 2, Multi-Center, Randomised, Double-Blind, Ascending-Dose, Placebo-Controlled Clinical Study to Assess the Safety and Efficacy of Fostamatinib in the Treatment of IgA Nephropathy	07/11/2014			70-day benchmark not yet expired
14/LO/0871	A randomised controlled trial of a duodenal sleeve bypass device (EndoBarrier) compared with standard medical therapy for the management of obese subjects with type 2 diabetes	12/11/2014			70-day benchmark not yet expired
14/LO/1381	A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily versus Raltegravir 400 mg Twice Daily, Each in Combination with TRUVADA™, in Treatment-Naïve HIV-1 Infected Subjects	10/11/2014			70-day benchmark not yet expired
14/LO/1727	Diffusion tensor imaging (DTI tractography) in the prostate: Roadmapping the neurovascular bundle prior to radical prostatectomy.	24/11/2014			70-day benchmark not yet expired
14/NW/0290	Registry of Deep Brain Stimulation with the VERCISE™ System: Vercise DBS Registry	21/11/2014			70-day benchmark not yet expired
14/SC/0157	Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest	27/11/2014			70-day benchmark not yet expired
14/SW/0091	Randomized, DoubleBlind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous NonSmall Cell Lung Cancer (NSCLC)	30/10/2014			70-day benchmark not yet expired
14/WM/0057	Multicentre randomised controlled trial to compare the clinical and costeffectiveness of a 'vein bypass first' with a 'best endovascular first' revascularisation strategy for severe limb ischaemia due to infrapopliteal arterial disease: Bypass vs. Angioplasty in Severe Ischaemia of the Leg.	08/12/2014			70-day benchmark not yet expired