PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q2, 2015/16)

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
14/WM/1055	A prospective, multicenter, randomized, double blind, placebocontrolled, 2parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with FOLFIRI to placebo in combination with FOLFIRI	09/03/2015	11/05/2015	Yes	Study met 70-day benchmark
15/LO/0210	An exploratory, open-label, multicenter study to evaluate the safety and efficacy of ATIR, donor T-lymphocytes depleted ex vivo of host alloreactive T-cells, in patients with a hematologic malignancy, who received a CD34-selected (..) cell	13/04/2015	30/04/2015	Yes	Study met 70-day benchmark
14/EM/1314	Randomized, Blinded, Multicenter, Phase 2 Study Comparing Veliparib Plus FOLFIRI ± Bevacizumab Versus Placebo Plus FOLFIRI ± Bevacizumab in Previously Untreated Metastatic Colorectal Cancer	17/07/2015	28/08/2015	Yes	Study met 70-day benchmark
14/LO/1728	A Phase Ib Open Label Study of the Safety and Tolerability of ME-344 Given in Combination with Topotecan (Hycamtin?) in Patients with Solid Tumors	03/03/2015	17/04/2015	Yes	Study met 70-day benchmark
14/NW/1354	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	22/06/2015	07/07/2015	Yes	Study met 70-day benchmark
14/EM/1286	A Randomized, Double-Blind Study of Ruxolitinib or Placebo in Combination With Regorafenib in Subjects With Relapsed or Refractory Metastatic Colorectal Cancer	13/08/2015	30/09/2015	Yes	Study met 70-day benchmark
12/YH/0504	Assessment of the efficacy and safety of a new wound dressing in the local treatment of diabetic foot ulcers: A Prospective, randomised, controlled, doubleblind, European multicentre clinical trial.	12/02/2015	31/03/2015	Yes	Study met 70-day benchmark
14/SC/0262	A Phase IV, prospective, open-label, uncontrolled, European Study in patients with neovascular Age-related macular degeneration (nAMD), evaluating the efficacy and safety of switching From intravitreal Aflibercept to RanIbizumab 0.5mg: SAFARI study	07/01/2015	10/03/2015	Yes	Study met 70-day benchmark
13/LO/0326	A RANDOMIZED, PHASE 3 STUDY OF GANETESPIB IN COMBINATION WITH DOCETAXEL VERSUS DOCETAXEL ALONE IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG ADENOCARCINOMA	09/01/2015	10/03/2015	Yes	Study met 70-day benchmark
15/LO/0140	CLEANER Assessment of efficacy and safety for a new wound dressing URGO 310 3166 in the local treatment of venous or mixed leg ulcers: a European, randomised clinical trial.	04/06/2015	23/07/2015	Yes	Study met 70-day benchmark
15/EM/0021	A randomised, double blind, placebo controlled multicenter trial, examining the effect of Natrox™ on the rates of healing for chronic diabetic foot ulcers	23/07/2015	08/09/2015	Yes	Study met 70-day benchmark
15/WS/0037	A single-arm, post-market study of the Endo GI Reinforced Reload with Tri-Staple Technology	24/04/2015	05/05/2015	Yes	Study met 70-day benchmark
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	06/01/2015	Yes	Study met 70-day benchmark
14/SC/1014	A Randomized, DoubleBlind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas (The JANUS 1 study)	17/12/2014	20/01/2015	Yes	Study met 70-day benchmark
14/LO/2143	Measurement of low-energy stimulation in patients with atrial fibrillation	15/05/2015	11/06/2015	Yes	Study met 70-day benchmark
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	14/11/2014	Yes	Study met 70-day benchmark
13/NW/0002	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	20/01/2015	Yes	Study met 70-day benchmark
14/LO/1834	A Phase I randomised, placebo-controlled, double-blind, single and multiple ascending dose study of the tolerability and pharmacokinetics of GBT440 in healthy subjects and patients with Sickle Cell Disease	27/04/2015	28/05/2015	Yes	Study met 70-day benchmark

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	10/11/2014	08/01/2015	Yes	Study met 70-day benchmark
13/YH/0317	Current Steering to Optimize Deep Brain Stimulation	02/10/2014	16/10/2014	Yes	Study met 70-day benchmark
14/NW/0290	Registry of Deep Brain Stimulation with the VERCISE? System: Vercise DBS Registry	21/11/2014	21/01/2015	Yes	Study met 70-day benchmark
14/YH/1153	An Open-Label, Extension Study of the Effects of Leuco-methylthioninium bi (hydromethanesulfonate) in Subjects with Alzheimer?s Disease or Behavioral Variant Frontotemporal Dementia	18/11/2014	08/01/2015	Yes	Study met 70-day benchmark
14/NW/1506	BlueWind system safety and performance in treatment of patients diagnosed with overactive bladder (OAB)	14/07/2015	15/07/2015	Yes	Study met 70-day benchmark
14/WM/1262	An Open Label Study of Sofosbuvir/GS5816 FixedDose Combination in Subjects with Chronic HCV Infection	23/03/2015	27/04/2015	Yes	Study met 70-day benchmark
13/LO/1224	Assessing sensitivity to and tolerability of intravenous psilocybin in patients with treatment-resistant depression: A Pilot Study	12/03/2015	21/04/2015	Yes	Study met 70-day benchmark
14/LO/0117	Ablation versus anti-arrhythmic therapy for reducing all hospital episodes from recurrent atrial fibrillation.	27/03/2015	22/04/2015	Yes	Study met 70-day benchmark
14/EE/0086	Neuromuscular Electrical Stimulation (NMES) in Patients with Intermittent Claudication	29/10/2014	09/12/2014	Yes	Study met 70-day benchmark
14/EM/1302	Neuromuscular Electrical Stimulation for the treatment of Diabetic Peripheral Neuropathy.	13/02/2015	10/04/2015	Yes	Study met 70-day benchmark
14/EM/0121	An open label randomised multicentre controlled trial of RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis	08/04/2015	15/05/2015	Yes	Study met 70-day benchmark
14/LO/0805	Predictors of response to treatment with iron and erythropoietin in dialysis anaemia	14/05/2015	07/07/2015	Yes	Study met 70-day benchmark
14/EE/0193	Adjuvant benefit of Neuromuscular Electrical Stimulation (NMES) in Supervised Exercise in Patients with Intermittent Claudication	20/10/2014	08/12/2014	Yes	Study met 70-day benchmark
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	09/12/2014	Yes	Study met 70-day benchmark
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	Study met 70-day benchmark
13/LO/1775	The PRAETORIAN Trial: A prospective, randomised comparison of subcutaneous and transvenous implantable cardioverter defibrillator therapy	26/11/2014	08/12/2014	Yes	Study met 70-day benchmark
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	22/12/2014	Yes	Study met 70-day benchmark
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	Study met 70-day benchmark
14/LO/1833	Pilot study to evaluate diffusion weighted MRI (DWMRI) Whole Body MRI in relapsed Multiple Myeloma at 3T: test re test, early response assessment and exploratory imaging of renal function	16/02/2015	01/04/2015	Yes	Study met 70-day benchmark
14/LO/1727	Diffusion tensor imaging (DTI tractography) in the prostate: Roadmapping the neurovascular bundle prior to radical prostatectomy.	24/11/2014	26/01/2015	Yes	Study met 70-day benchmark
14/WS/1096	Uncovering obesity and diabetes related complex metabolic dysregulation associated to endometrial cancer	19/11/2014	15/01/2015	Yes	Study met 70-day benchmark
13/LO/1595	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	Study met 70-day benchmark
15/LO/0769	Left Atrial Appendage Occlusion Study III	09/09/2015	10/09/2015	Yes	Study met 70-day benchmark
14/LO/2060	A PROSPECTIVE MULTICENTRE STUDY OF EFFECTIVENESS OF RIPPLE MAPPING FOR ATRIAL TACHYCARDIA ABLATION	15/01/2015	02/02/2015	Yes	Study met 70-day benchmark
12/LO/1177	Streamlining Staging of Lung Cancer with Whole Body MRI	27/10/2014	08/12/2014	Yes	Study met 70-day benchmark
13/YH/0162	Hyaluronic Acid Binding Sperm Selection - HABSelect	17/09/2014	12/11/2014	Yes	Study met 70-day benchmark
14/SC/0157	Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest	27/11/2014	26/12/2014	Yes	Study met 70-day benchmark

13/WS/0056	Cancer and Venous Access (CAVA) A randomised controlled trial with associated qualitative research of venous access devices for the delivery of long-term chemotherapy	03/02/2015	24/03/2015	Yes	Study met 70-day benchmark
14/SC/1206	The Efficacy and Cost effectiveness of Real Time Ultrasound Elastography in The Investigation Of Thyroid Nodules and the diagnosis of thyroid cancer.	09/03/2015	21/04/2015	Yes	Study met 70-day benchmark
14/NW/1027	Evaluation of Sorafenib in combination with local microtherapy guided by GdEOBDTPA enhanced MRI in patients with inoperable hepatocellular carcinoma	16/02/2015	01/04/2015	Yes	Study met 70-day benchmark
13/YH/0394	Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease	30/04/2015	11/06/2015	Yes	Study met 70-day benchmark
15/LO/0227	The Sono-VE Study: Assessing the acceptability and feasibility of transperineal ultrasound and developing an ultrasound based predictive model for labour outcome; the sonopartogram.	14/04/2015	22/04/2015	Yes	Study met 70-day benchmark
15/LO/0300	Development and validation of a non-invasive, wearable sensor for fetal movement.	13/07/2015	23/07/2015	Yes	Study met 70-day benchmark
14/NE/1246	CUT*HIVTHER 001 - A randomized phase I/II study to assess the safety and immunogenicity of the DNAGTU vaccine administered by two novel routes compared to placebo in HIV-infected patients on antiretroviral therapy	14/04/2015	15/05/2015	Yes	Study met 70-day benchmark
14/WM/0185	Intranasal diagnostics in food allergy (INDY): a feasibility study	17/09/2014	27/10/2014	Yes	Study met 70-day benchmark
14/LO/1779	Incentive in Diabetic Eye Assessment by Screening (IDEAS) Trial	12/03/2015	19/03/2015	Yes	Study met 70-day benchmark
14/SC/1345	The effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding.	25/08/2015	15/09/2015	Yes	Study met 70-day benchmark
14/WM/0057	Bypass vs. Angioplasty in Severe Ischaemia of the Leg: Multicentre randomised controlled trial to compare the clinical and costeffectiveness of a ?vein bypass first? with a ?best endovascular first? revascularisation strategy	08/12/2014	31/01/2015	Yes	Study met 70-day benchmark
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	Study met 70-day benchmark
14/WM/0159	Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE 2 study	02/10/2014	13/10/2014	Yes	Study met 70-day benchmark
14/LO/1864	The CNS Integrase Inhibitor Study	12/06/2015	14/07/2015	Yes	Study met 70-day benchmark
14/LO/1493	A phase IV open-label, multi-centre, randomised, dual-arm, pilot study to assess the feasibility of switching individuals receiving Efavirenz with continuing Central Nervous System (CNS) toxicity, to Dolutegravir	22/01/2015	12/03/2015	Yes	Study met 70-day benchmark
09/H1005/28	Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies.	31/10/2014	02/12/2014	Yes	Study met 70-day benchmark
14/LO/0339	The ACORN study: Coping and Relaxation in Pregnancy	04/11/2014	41976	Yes	Study met 70-day benchmark
14/LO/2004	Methylnaltrexone for the Treatment of Opioid Induced Constipation & Gastro-Intestinal Stasis in Intensive Care Patients	21/07/2015	42261	Yes	Study met 70-day benchmark
14/LO/2078	A Phase 1, first in man, study to assess the safety, pharmacokinetic profile and antiretroviral efficacy of C34-PEG4-Chol, a novel peptide fusion inhibitor for the treatment of HIV-infection	26/02/2015	42108	Yes	Study met 70-day benchmark
14/LO/2044	The role of intrinsic cardiac autonomic nervous system in human arrhythmogensis	16/03/2015	42115	Yes	Study met 70-day benchmark
14/WM/0162	Barrier Enhancement for Eczema Prevention - BEEP	16/03/2015	01/04/2015	Yes	Study met 70-day benchmark
15/LO/0181	A multicentre randomised controlled trial of compression therapy following endovenous thermal ablation of varicose veins	30/04/2015	18/05/2015	Yes	Study met 70-day benchmark
14/EM/1284	Neo-AEGIS (NEOadjuvant trial in Adenocarcinoma of the oEsophagus and oesophagoGastric junction International Study): Randomised Clinical Trial of neoadjuvant and adjuvant chemotherapy (Modified MAGIC regimen) vs. (CROSS protocol) (?)	23/07/2015	29/07/2015	Yes	Study met 70-day benchmark
14/NE/1062	PHOTOdynamic versus white light-guided treatment of non-muscle invasive bladder cancer: randomised trial of clinical and cost-effectiveness	18/03/2015	14/05/2015	Yes	Study met 70-day benchmark
15/SC/0108	A Phase Ia clinical trial to assess the safety and immunogenicity of MVA-EBO Z alone and a heterologous prime-boost immunisation with ChAd3-EBO Z and MVA-EBO Z in healthy UK volunteers	21/05/2015	15/06/2015	Yes	Study met 70-day benchmark
11/NW/0246	A Randomised Multi-Stage Phase II/III Trial of Standard first-line therapy (sunitinib or pazopanib) Comparing Temporary Cessation with Allowing Continuation, in the treatment of locally advanced and/or metastatic Renal Cancer	01/04/2015	20/04/2015	Yes	Study met 70-day benchmark

15/LO/0813	Are gut hormone changes why the long-limb gastric bypass is more effective than the standard-limb gastric bypass in improving type 2 diabetes mellitus? The LONG LIMB trial	28/07/2015	31/07/2015	Yes	Study met 70-day benchmark
15/LO/1060	Assessment of digestion and metabolism following altered macronutrient intake	29/07/2015	17/08/2015	Yes	Study met 70-day benchmark
15/YH0333	Preoperative Pocket Echocardiography Trial	16/07/2015	31/07/2015	Yes	Study met 70-day benchmark
15/LO/0287	Boiled Oral Peanut Immunotherapy for the treatment of Peanut Allergy	05/05/2015	23/06/2015	Yes	Study met 70-day benchmark
14/LO/2103	Optimising effectiveness and minimising toxicity of intravenous salbutamol in children with acute asthma	26/05/2015	01/07/2015	Yes	Study met 70-day benchmark
15/LO/0087	A Phase I, Storer Design, openlabel, crosssectional, single site trial of ANX776 in healthy volunteers, progressive glaucoma/glaucomasuspect/ ocular hypertensive subjects and nonarteritic anterior ischaemic optic neuropathy subjects	16/04/2015	02/06/2015	Yes	Study met 70-day benchmark
15/WM/0009	A Phase 3, Randomised, Controlled, Openlabel Study of VELCADE (Bortezomib MelphalanPrednisone (VMP) Compared to Daratumumab in Combination with VMP (DVMP) in Subjects with Previously Untreated Multiple Myeloma who are Ineligible for Highdose Therapy	02/07/2015			Rare disease.
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,	14/10/2014	19/02/2015	No	Myelofibrosis is a rare disease.
13/LO/1227	A Multicenter, Randomized, DoubleBlind, PlaceboControlled, Phase III Study of ARN509 in Men with NonMetastatic (M0) CastrationResistant Prostate Cancer	16/04/2015			Eleven patients have been identified, but all were screning failures. Screening process is long as it requires 3 PSA rises before patients meet the eligibility criteria. Study target is only 5 patients over 3.5 years so study team was not envisaging consenting the first patient within 70 days.
14/LO/0673	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GS 1101 (CAL-101) in Combination with Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukemia.	13/02/2015	04/08/2015	No	Rare disease.
14/NW/1427	A Phase 3, Randomized Study Investigating the Safety of CVT-301 (Levodopa Inhalation Powder) in Parkinsons Disease Patients With Motor Response Fluctuations (OFF Phenomena) Compared to an Observational Cohort Control	29/04/2015	12/07/2015	No	Additional Information Governance requirement due to patient data being sent offsite.
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	28/11/2014			Rare disease.
14/YH/1234	A phase III, doubleblind, randomised study to assess the efficacy and safety of AZD9291 versus a standard of care Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor as firstline treatment in patients with (...) NonSmall Cell Lung Cancer	10/04/2015			Sponsor delay with green light and in providing imaging equipment / access to IWRS system needed to conduct the study.
14/WS/1105	REVEAL 101MS408 Multicenter study of Natalizumab v Fingolimod in MS	26/03/2015			Sponsor delays in negotiating service support from MRI unit caused site recruitment to be suspended. Site confirmed they are ready to start recruitment once equipment is in place.
14/EM/1059	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	05/02/2015			Rare disease.
14/EM/1060	A Phase 3 Open Label Extension Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	09/03/2015			Rare disease.
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	15/10/2014	03/02/2015	No	Study opened to recruitment but no eligible patients consented.
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			Initial NHS permission excluded use of tissue bank to store patient samples. Study team decided to wait until full approval was in place before starting to recruit. Several patients have been approached but declined to take part.
14/LO/1994	The AMARANTH study - A 24-month, Multicenter, Randomized, Double-blind, Placebo-controlled,Parallel-group, Efficacy, Safety, Tolerability, Biomarker, and Pharmacokinetic Study of AZD3293 in Early Alzheimer?s Disease	18/06/2015			Sponsor took 36 days from R&D approval to issue greenlight - SIV was on 24th July. Site started to recruit immediately but had difficulties in finding potential patients meeting all the criteria. The first patient has been consented and screened on the 14th of September. The second patient consented and was screened the 19th of October, we are now going through the eligibility criteria.

14/NE/1072	A PHASE II RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED BRONCHOSCOPY STUDY TO EVALUATE THE EFFECTS OF LEBRIKIZUMAB ON AIRWAY EOSINOPHILIC INFLAMMATION IN PATIENTS WITH UNCONTROLLED ASTHMA ON INHALED CORTICOSTEROIDS AND A SECOND CONTROLLER MEDICATION	16/01/2015			Sponsor delay in activating site. Delays in Sponsor sending equipment needed for the study. First volunteer identified within 8 days of receiving final PIS. Dozens of volunteers approached since but were either inegible or declined.
14/WM/1202	B0401016: A Phase 1b, Randomized, Double-Blind (Sponsor Open), Placebo-Controlled Study To Evaluate The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of Pf-04447943, (...) In Subjects With Stable Sickle Cell Disease	11/06/2015			Rare disease.
14/LO/2196	A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour	15/05/2015			Site has been very actively screening - 60 participants to date, but all ineligible for various reasons but mainly the requirement of gestational week between 34 and 36. Sponsor appreciates difficulties to find patients, and is now considering lowering requirement to 32 weeks of gestation. Other UK sites have declined to participate in the study due to difficulties by other sites in finding eligible patients. No sites have yet recruited in the UK; only 2 patients recruited study wide.
12/EE/0230	RITAZAREM: Rituximab vasculitis maintenance study - An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCAassociated vasculitis	14/04/2015	02/07/2015	No	Not possible to pre-screen these patients as study requires that they relapse, which can only be determined once they return later to clinic. Vasculitis is a rare condition. According to the Vasculitis UK, only 10-15 new cases per year (per million population) are being diagnosed with ANCA-associated vasculitis.
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	Sponsor delays in site activation. Site still managed to quickly recruit first patient 4 days after sponsor green light. Only missed the benchmark by 1 day.
14/EE/0192	Neuromuscular Electrical Stimulation (NMES) in patients with critical limb ischaemia	16/06/2015			Within the last 2 months the study team identified 3 suitable patients. The first patient did not respond to the invitation. The second and third patients delayed screening visits due to illness or being abroad; when the visit took place their health had deteriorated making them ineligible. Critical limb ischaemia (CLI) is a relatively rare presentation, plus very few patients have no tissue loss (no wounds or ulcers) on their feet - required for the use the foot plate device being studied.
14/LO/1295	One Stop Vein Clinic - Evaluating the Feasibility and Acceptance of a One Stop Vein Clinic	26/05/2015	29/09/2015	No	Several patients were identified but were screening failures. There was only one eligible patient found and approached, but patient declined to participate in the study.
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	22/09/2015	No	Rare disease study (less than 1 in 2000).
14/YH/0085	Front-Line therapy in CLL: Assessment of Ibrutinib + Rituximab.	26/09/2014	26/02/2015	No	Very rare disease study (0.6 in 10,000 in males & 0.4 in 10,000 in females).
13/NW/0714	ECASS-4: ExTEND - European Cooperative Acute Stroke Study-4 Extending the time for Thrombolysis in Emergency Neurological Deficits	03/02/2015	07/09/2015	No	Sponsor delays in sending drug shipment. Once site had drugs, they immediately started screening but were unable to recruit prior to the 70 day benchmark. No eligible patients have been identified yet.
14/WM/0083	A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in Situ (DCIS)	06/03/2015	06/08/2015	No	Rare disease.
13/NI/0160	Management of myocardial injury After NoncArdiac surgGEry (MANAGE)	25/03/2015			Study team have screened numeorus patients, but they did not meet the inclusion criteria and therefore were not suitable to be recruited to the study. One patient was eligible, but declined to take part.
14/SC/1056	A multicentre randomised controlled trial to compare the efficacy of ex-vivo oxygenated hypothermic machine perfusion with non-oxygenated hypothermic machine perfusion of kidneys older than 50 years of age and donated after circulatory death	04/03/2015			Site has no control over deceased organ allocations and there is no way to predict if and when we will be allocated organs for the study.
15/LO/0571	A phase II study of alternating eribulin and hormonal therapy in pre-treated ER+ve breast cancer (ALERT)	08/07/2015			Delays from the UKCRN in adopting the study onto the portfolio. All site documents in place from day 15 onwards.
14/NW/1076	Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma (RESCUE-ASDH) Study Short Title RESCUE-ASDH trial. Version 1.0	18/03/2015	16/07/2015	No	Sponsor recognised the difficulty in recruiting patients and new protocol has now been approved by REC.
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	13/02/2015	No	Team started looking for patients immediately after gaining approval and 9 days later the first patient was screened and consented (28/11/14). Seven screening failures over a 2 month period until first successful recruitment on 13/02/15.

12/EE/0029	A 12 week, single centre, open label study to evaluate the effect of fesoterodine flexible dosing regimen on the sexual function of women with overactive bladder.	22/01/2015	07/04/2015	No	Protocol design required complex and very lengthy interview times with patients, and due to the personal details required for the questionnaire, many patients either refused to consent or alternatively withdrew.
14/LO/1428	A phase 3 multi-centre double-masked randomised controlled trial of adjunctive intraocular and periocular steroid (triamcinolone acetonide) versus standard treatment in eyes undergoing vitreoretinal surgery for open globe trauma	06/01/2015	21/05/2015	No	Very specific eligibility criteria, making this essentially a rare disease. No-one in the UK has yet recruited either - study relies on a very specific eye trauma patient coming into A&E and that is both unpredictable and rare.
10/H0302/51	Improving the management and control of tuberculosis among hard to reach groups	09/02/2015	21/04/2015	No	The first suitable patient was identified 22 days after valid submission of study; eventually declined. Study team approached TB REACH Charity to discuss difficulties with screening. A patient was successfully recruited only 1 day after the benchmark of 70 days.
15/LO/0292	PILOT STUDY OF HOME ACTIGRAPHY MONITORING IN MS	01/04/2015	01/09/2015	No	Specialist supplier did not deliver essential equipment to site in time. Sponsor has now ordered alternative equipment.
13/SC/0157	ROMAZA: Phase I trial of combination therapy with romidepsin and azacitidine in patients with newly diagnosed, relapsed or refractory Acute Myeloid Leukaemia ineligible for conventional chemotherapy	16/06/2015			Rare disease.
14/NW/0036	ESPAC 5 - Four arm, prospective, multicentre, randomised feasibility trial of immediate surgery compared with neoadjuvant chemotherapies and neoadjuvant chemoradiotherapy	12/03/2015	19/06/2015	No	Borderline resectable pancreatic cancer is a rare disease (1 in 10,000).
13/SC/0583	MATCHPOINT - MAnagement of Transformed CHronic myeloid leukaemia: POnatinib and INTensive chemotherapy: a dose-finding study.	26/06/2015			Very rare disease.
14/SC/0237	A randomised controlled trial to determine the clinical and cost effectiveness of invasive urodynamic studies for diagnosis and management of bladder outlet obstruction in men in the National Health Service (NHS).	21/07/2015			Study team was actively screening patients immediately after site initiation visit. Inclusion criteria proved challenging.
15/LO/0863	AG348-C-003: A Phase 2, Open Label, Randomized, Dose Ranging, Safety, Efficacy, Pharmacokinetic and Pharmacodynamic Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency.	14/08/2015		not yet expired	70-day benchmark not yet expired
15/LO/1105	A Randomized, Single-Blind, 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	14/08/2015		not yet expired	70-day benchmark not yet expired
13/EM/0349	A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer.	04/09/2015		not yet expired	70-day benchmark not yet expired
14/NE/1214	A Randomized, Open-Label, Multicenter, Phase 2 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy (?) or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (...)	13/08/2015		not yet expired	70-day benchmark not yet expired
15/LO/0691	An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic (Sq) (NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment of Stage IIIb/IV SqNSCLC	21/08/2015		not yet expired	70-day benchmark not yet expired
14/WS/1146	Multicenter, randomized, double-blind, double-dummy, active-comparator, event-driven, superiority phase III study of secondary prevention of stroke and prevention of systemic embolism (...) (ESUS) aspirin 100 mg - NAVIGATE ESUS	30/07/2015		not yet expired	70-day benchmark not yet expired
15/LO/0273	A Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study Evaluating Safety and Efficacy of the Addition of Veliparib Plus Carboplatin Versus the Addition of Carboplatin to Standard Neoadjuvant Chemotherapy Versus (...) Early Stage TNBC	12/08/2015		not yet expired	70-day benchmark not yet expired
13/EE/0038	HALT-IT - Tranexamic acid for the treatment of gastrointestinal bleeding: an international randomised, double blind placebo controlled trial	09/08/2015		not yet expired	70-day benchmark not yet expired
14/SC/0032	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	30/07/2015		not yet expired	70-day benchmark not yet expired
14/SC/0033	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	30/07/2015		not yet expired	70-day benchmark not yet expired

13/LO/1618	A Multicenter, Long-term Extension Study to Further Evaluate the Safety and Tolerability of Telotristat Etiprate (LX1606)	04/08/2015		not yet expired	70-day benchmark not yet expired
15/SC/0165	A Single-Blinded, Randomized, Controlled Study to Evaluate the Safety and Effectiveness of EVICEL® Fibrin Sealant (Human) Compared to a Hydrogel Sealant as an Adjunct to Sutured Dural Repair	24/09/2015		not yet expired	70-day benchmark not yet expired
15/LO/0016	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative (?)	24/07/2015		not yet expired	70-day benchmark not yet expired
15SM2807	A Phase 2b Randomized, Active-Controlled, Double-Blind Trial to Investigate Safety, Efficacy and Dose-response of BMS-955176, Given on a Backbone of Tenofovir/Emtricitabine, in Treatment-Naive HIV-1 Infected Adults	14/08/2015		not yet expired	70-day benchmark not yet expired
14/SS/1031	An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability	27/07/2015		not yet expired	70-day benchmark not yet expired
15/LO/0153	NACAH - The Mechanism of Action of N-AcetylCysteine for Reducingthe Risk of Infection in Alcoholic Hepatitis	18/09/2015		not yet expired	70-day benchmark not yet expired
15/LO/0620	Dosing of Electrical Stimulation in Venous Insufficiency (DESiVI)	10/09/2015		not yet expired	70-day benchmark not yet expired
13/NE/0196	Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis	24/07/2015		not yet expired	70-day benchmark not yet expired
14/LO/1291	A phase II randomised study evaluating the biological and clinical effects of the combination of palbocicilib with Letrozole as neoadjuvant therapy in post-menopausal women with ER+ primary brest cancer	18/09/2015		not yet expired	70-day benchmark not yet expired
15/SC/0267	A Phase I, safety and immunogenicity trial of the heterologous prime-boost regimen combining the monovalent Zaire Ebola viral vector candidates ChAd3-EBO-Z and Ad26.ZEBOV in healthy UK adults	30/08/2015		not yet expired	70-day benchmark not yet expired
14/SC/0263	AWARE II (AWAreness during REsuscitation) - A Multi-Centre Observational Study of the Relationship between the Quality of Brain Resuscitation, and Consciousness, Neurological, Functional and Cognitive Outcomes following Cardiac Arrest	29/07/2015		not yet expired	70-day benchmark not yet expired
15/LO/1011	A Feasibility randomised controlled trial: Effects of oral sodium bicarbonate supplementation in patients on haemodialysis	11/09/2015		not yet expired	70-day benchmark not yet expired
13/SC/0309	A Phase Ib Study of Eltrombopag and Azacitidine in Patients with High Risk Myelodysplastic Syndromes and Related Disorders	11/08/2015		not yet expired	70-day benchmark not yet expired
14/LO/0612	Care of Late Stage Parkinsonism	12/08/2015		not yet expired	70-day benchmark not yet expired
15/LO/1087	An Open-label, Multi-centre Post-marketing Study to Assess the Efficacy and Safety of Voncento® in Subjects with Von Willebrand Disease	20/08/2015		not yet expired	70-day benchmark not yet expired
15/LO/0743	A phase I, randomised, double-blind, placebo-controlled, multicentre, ascending-dose trial to evaluate safety, tolerability and immunogenicity of Vaccine FP-02.2 in HBeAg-negative hepatitis B patients as an add-on treatment to entecavir or tenofovir	25/08/2015		not yet expired	70-day benchmark not yet expired