

PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q4, 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
11/LO/2036	A Phase I/II, Open-Label, Safety, Pharmacokinetic, and Preliminary Efficacy Study of Oral Rucaparib in Patients with gBRCA Mutation Ovarian Cancer or Other Solid Tumor	08/01/2016		No	Rare disease. Site currently has patients in screening but disease not yet measurable.
11/SW/0248	Gastric Bypass or adjustable gastric Banding surgery to treat morbid obesity: a multi-centre randomised controlled trial	16/09/2015	08/10/2015	Yes	Study met 70-day benchmark.
12/EE/0230	RITAZAREM: Rituximab vasculitis maintenance study - An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCA-associated 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.
12/EE/0445	A randomised doubleblind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with anaemia undergoing major open abdominal surgery	27/10/2015	15/12/2015	Yes	Study met 70-day benchmark.
12/WA/0230	Radiotherapy after Oesophageal Cancer Stenting Study	04/11/2015	13/01/2016	Yes	Study met 70-day benchmark.
12/WA/0374	Hughes Abdominal Repair Trial Abdominal wall closure techniques to reduce the incidence of incisional hernias: A multi-centre pragmatic randomised trial	26/02/2016	02/03/2016	Yes	Study met 70-day benchmark.
13/EE/0038	HALT-IT - Tranexamic acid for the treatment of gastrointestinal bleeding: an international randomised, double blind placebo controlled trial	09/08/2015	03/10/2015	Yes	Study met 70-day benchmark.
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	23/10/2015	Yes	Study met 70-day benchmark.
13/LO/1227	A Multicenter, Randomized, DoubleBlind, PlaceboControlled, Phase III Study of ARN509 in Men with NonMetastatic (M0) CastrationResistant Prostate Cancer	16/04/2015	04/03/2016	No	Valid reasons matched in previous quarter report. Eleven patients have been identified, but all were screening 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.
13/LO/1618	A Multicenter, Long-term Extension Study to Further Evaluate the Safety and Tolerability of Telotristat Etiprate (LX1606)	04/08/2015	10/09/2015	Yes	Study met 70-day benchmark.
13/LO/1691	An open label phase I/randomised, double blind phase II study in metastatic castration resistant Prostate Cancer of AZD5363 In combination with Docetaxel and prednisolone chemotherapy (ProCAID)	08/01/2016		No	Despite screening 3 patients, 1 was deemed ineligible after screening and 2 patients were eligible but declined to take part.
13/NE/0196	Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis	24/07/2015	20/10/2015	No	Valid reasons matched in previous report. Recurrent UTIs in patients who self-catheterise is essentially a rare disease patient group due to how experienced and well-trained our nurse specialists are and this is reflected in the low numbers we anticipated in recruiting. We did identify a suitable patient who agreed to consent in under 70 days, but they were ineligible.
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	12/11/2015	No	Valid reasons matched in previous report. Rare disease.
13/SC/0309	A Phase Ib Study of Eltrombopag and Azacitidine in Patients with High Risk Myelodysplastic Syndromes and Related Disorders	11/08/2015		No	Valid reasons matched in previous report. Rare disease study. Incidence of Myelodysplastic Syndromes is 4 cases per 100,000 - and this study is looking for high risk so the patient group is even rarer.
13/SC/0583	MATCHPOINT - Management of Transformed Chronic myeloid leukaemia: Ponatinib and Intensive chemotherapy: a dose-finding study.	26/06/2015		No	Valid reasons matched in previous quarter report. Very rare disease.
13/SW/0300	XENON AND COOLING THERAPY IN BABIES AT HIGH RISK OF BRAIN INJURY FOLLOWING POOR CONDITION AT BIRTH: RANDOMISED PILOT OUTCOMES STUDY	08/12/2015		No	This study will recruit up to 10 babies only due to the rare presentation of the condition - newborn infants with hypoxic-ischemic encephalopathy (HIE) - and a protocol requirement to recruit within a few hours of birth.
13/WM/0364	Targeted retreatment of incompletely recovered COPD exacerbations with ciprofloxacin: a double-blind, randomised, placebo-controlled, multicentre Phase III trial - WP4	25/10/2015		No	Long term sick leave of study team member.

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.
14/EE/0192	Neuromuscular Electrical Stimulation (NMES) in patients with critical limb ischaemia	16/06/2015	12/10/2015	No	Valid reasons matched in previous quarter report. Study team identified 3 suitable patients. First patient did not respond to the invitation. Second and third patients delayed screening visits due to illness or travel. Critical limb ischaemia (CLI) is a relatively rare presentation, plus very few patients have no tissue loss on their feet - required for the use the foot plate device being studied.
14/EE/1254	A Phase III, multi-centre, multi-national randomised controlled trial investigating 1cm v 2cm wide excision margins for primary cutaneous melanoma	13/01/2016	11/03/2016	Yes	Study met 70-day benchmark.
14/EE/1293	Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes Trial: a randomised controlled Trial of monofilament versus braided sutures for insufficient cervix	21/01/2016	25/02/2016	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/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/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.
14/EM/1309	The role of buspirone in LIDs in patients with Parkinson's disease	01/10/2015	26/10/2015	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/ES/1064	A randomized phase II/III study to assess the efficacy of trametinib (GSK 1120212) in patients with recurrent or progressive lowgrade serous ovarian cancer or peritoneal cancer (GOG0281)	10/10/2015	04/03/2016	No	Valid reasons matched in previous report. Sponsor delayed site activation as they wanted to activate all sites globally at the same time; there were global delays due to additional approvals required by the sponsor in the USA.
14/LO/0612	Care of Late Stage Parkinsonism	12/08/2015	08/12/2015	No	Additional Information Governance requirement.
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/LO/1043	A Multicentre Phase III Double-masked Randomised Controlled Non-Inferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for Macular Oedema due to Central Retinal Vein Occlusion (CRVO).	15/12/2015	01/03/2016	No	Sponsor delays with site activation.
14/LO/1291	A phase II randomised study evaluating the biological and clinical effects of the combination of palbociclib with Letrozole as neoadjuvant therapy in post-menopausal women with ER+ primary breast cancer	18/09/2015	10/11/2015	Yes	Study met 70-day benchmark.
14/LO/1295	One Stop Vein Clinic - Evaluating the Feasibility and Acceptance of a One Stop Vein Clinic	26/05/2015	17/08/2015	No	Valid reasons matched in previous report. Several patients were identified but were screening failures.
14/LO/1370	Macitentan in the Treatment of Inoperable chronic Thromboembolic pulmonary hypertension (Open-Label)	12/11/2015	24/11/2015	Yes	Study met 70-day benchmark.
14/LO/1800	The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary fibrosis with the Addition of Co-trimoxazole (EME-TIPAC)	27/10/2015	12/11/2015	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/1864	The CNS Integrase Inhibitor Study	12/06/2015	14/07/2015	Yes	Study met 70-day benchmark.
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	27/07/2015	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	14/09/2015	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.
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.
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		No	Valid reasons matched in previous quarter report. Site very actively screening - 60 participants to date, but all ineligible for various reasons. CRO aware of difficulties, and is now considering changing eligibility criteria. Other UK sites have declined to participate in the study due to difficulties by sites in finding eligible patients. No sites yet recruited in the UK; only 2 patients recruited study wide.
14/NE/1109	Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee)	30/10/2015	19/11/2015	Yes	Study met 70-day benchmark.
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	18/09/2015	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/NW/1344	Expediting the confirmation of acute myocardial infarction with point of care troponin testing to facilitate early intervention	16/03/2016			70-day benchmark not yet expired.
14/NW/1354	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	22/06/2015	07/07/2015	Yes	Study met 70-day benchmark.
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.
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/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	08/10/2015	Yes	Study met 70-day benchmark.
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	07/10/2015	Yes	Study met 70-day benchmark.
14/SC/0171	A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.	16/02/2016			70-day benchmark not yet expired.
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	09/10/2015	No	Valid reasons matched in previous report. Study team was actively screening patients immediately after site initiation visit. Inclusion criteria proved challenging and several tests had to be performed to rule out prostate cancer on each patient which eventually showed they were all ineligible.
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	09/12/2015	No	Valid reasons matched in previous report. Sponsor delays in organising setup of equipment.
14/SC/1030	A randomised controlled trial to compare the clinical effectiveness and safety of gentamicin and ceftriaxone in the treatment of gonorrhoea.	16/12/2015	25/02/2016	No	Sponsor delayed greenlight due to database not being ready to allow sites to recruit.
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/SC/1372	Research In Viral Eradication of HIV Reservoirs A two-arm (proof of concept) randomised phase II trial	24/11/2015	07/12/2015	Yes	Study met 70-day benchmark.
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	14/08/2015	Yes	Study met 70-day benchmark.
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	22/10/2015	No	Valid reasons matched in previous report. Very rare disease "less than 2.5 in 10,000 people in Europe".

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	28/08/2015	Yes	Study met 70-day benchmark.
14/YH/0038	Randomised trial comparing conventional versus contact force and electrical coupling index in atrial flutter ablation (VERISMART TRIAL)	12/02/2016	24/03/2016	Yes	Study met 70-day benchmark.
14/YH/1108	A RANDOMIZED PHASE III TRIAL COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION IN PATIENTS WITH LOW-RISK EARLY-STAGE CERVICAL CANCER	12/10/2015		No	Valid reasons matched in previous report. 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		No	Valid reasons matched in previous quarter report. Sponsor delay with green light and in providing imaging equipment / access to IWRS system needed to conduct the study.
15/EE/0385	A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment ... - NEPTUNE	03/03/2016			70-day benchmark not yet expired.
15/EE/0420	The Role of Ultrasound Shear Wave Elastography in the Management of Liver Disease	23/02/2016	15/03/2016	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/EM/0095	A Phase III, open label, multicentre randomised clinical study comparing Acelarin (NUC1031) with Gemcitabine in patient with metastatic pancreatic carcinoma	03/03/2016			70-day benchmark not yet expired.
15/EM/0487	A Randomized, Open-Label, Active-Controlled, Multicenter Study to Compare Efficacy and Safety of ABT-493/ABT-530 to Sofosbuvir Co-Administered with Daclatasvir in Adults with Chronic Hepatitis C Virus Genotype 3 Infection (ENDURANCE-3)	09/12/2015	01/02/2016	Yes	Study met 70-day benchmark.
15/ES/0184	A Phase 3, Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS9857 Fixed-Dose Combination for 12 Weeks in Direct-Acting Antiviral? - POLARIS-1	08/03/2016	14/03/2016	Yes	Study met 70-day benchmark.
15/ES/0185	A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS9857 Fixed-Dose Combination for 8 Weeks Compared to Sofosbuvir/Velpatasvir for 12 Weeks ... - POLARIS-2	08/03/2016	16/03/2016	Yes	Study met 70-day benchmark.
15/ES/0192	A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks ... - POLARIS-4	03/03/2016			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		No	Valid reasons matched in previous report. Sponsor delays in lab kit being shipped to site which postponed activation until. One patient was eligible but declined to take part. Furthermore, recruitment closed early nationally as achieved global target sooner than anticipated.
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/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/LO/0153	NACAH - The Mechanism of Action of N-AcetylCysteine for Reducingthe Risk of Infection in Alcoholic Hepatitis	18/09/2015	14/10/2015	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.
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.
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/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	04/12/2015	No	Valid reasons matched in previous report. Rare disease study. Incidence of Myelodysplastic Syndromes is 4 cases per 100,000 - and this study is looking for high risk so the patient group is even rarer.
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.
15/LO/0292	PILOT STUDY OF HOME ACTIGRAPHY MONITORING IN MS	01/04/2015	01/09/2015	No	Valid reasons matched in previous quarter report. Specialist supplier did not deliver essential equipment to site in time. Sponsor has now ordered alternative equipment.
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.
15/LO/0423	An open label study to investigate the safety and efficacy of abacavir/lamivudine/dolutegravir and the pharmacokinetic profile of dolutegravir in HIV-infected patients of 60 years of age and older	10/11/2015		No	Site team was actively recruiting but no eligible patients were identified.
15/LO/0460	SSAT058: A phase IV, openlabel, multi centre pilot study to assess changes in cerebral function parameters in patients without perceived Central Nervous System (CNS) symptoms when switched from tenofovir/emtricitabine/efavirenz (Atripla?) to a fixed dose combination of tenofovir/emtricitabine/rilpivirine (Eviplera?).	20/10/2015	15/12/2015	Yes	Study met 70-day benchmark.
15/LO/0571	A phase II study of alternating eribulin and hormonal therapy in pre-treated ER+ve breast cancer (ALERT)	08/07/2015	15/02/2016	No	Valid reasons matched in previous quarter report. Delays from the UKCRN in adopting the study onto the portfolio. All site documents in place from day 15 onwards.
15/LO/0620	Dosing of Electrical Stimulation in Venous Insufficiency (DESIVI)	10/09/2015	29/10/2015	Yes	Study met 70-day benchmark.
15/LO/0652	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		No	Valid reasons matched in previous report. Sponsor closed recruitment 2 weeks after site got R&D Approval. Recruitment was competitive and study reached full recruitment.
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	19/01/2016	No	Valid reasons matched in previous report. This is a rare disease group by virtue of the criteria as must be 3rd line treatment and hence very few patients
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	06/10/2015	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.
15/LO/0780	GLP-1 Receptor Agonist interVeniton for poor responders after barIAtric Surgery: The GRAVITAS trial.	10/12/2015	01/02/2016	Yes	Study met 70-day benchmark.
15/LO/0798	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) ... - MORAb-003	16/11/2015		No	Delays in R&D approval due to Christmas holiday and sick leave. Followed by Sponsor delay of 56 days to formally activate.
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/0833	IBIS 3: POLaR. An International Breast Intervention Study investigating Prevention Of Late Recurrence in ER+ breast cancer survivors following 5 years of adjuvant treatment	07/01/2016		No	Sponsor have put recruitment on hold for all sites until end of April 2016 at least; submission of substantial amendment likely prior to activating any sites. This was not known until after SIV. Site is ready to start but is yet to receive green light from sponsor.
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	25/11/2015	No	Valid reasons matched in previous report. This is a very rare disease, 1:20 000.
15/LO/0881	A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA? Once-Daily in Treatment-Na?ve HIV-1 Infected Subjects	27/11/2015		No	Sponsor closed study 2 weeks after site gained R&D approval. Recruitment was open during these two weeks but no eligible patients were seen.
15/LO/0940	A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Obinutuzumab Compared to Chlorambucil in Combination with Obinutuzumab for Previously Untreated Chronic Lymphocytic Leukemia	21/01/2016			70-day benchmark not yet expired.
15/LO/0989	Exploring Targeted Nutritional Interventions to Prevent Diabetes. The Effect of Weight Loss on Glucose Homeostasis in Subjects with isolated-Impaired Fasting Glucose Versus isolated-impaired Glucose Tolerance and Insulin-Only	12/01/2016	12/02/2016	Yes	Study met 70-day benchmark.

15/LO/1011	A Feasibility randomised controlled trial: Effects of oral sodium bicarbonate supplementation in patients on haemodialysis	11/09/2015	19/11/2015	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/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	25/01/2016	No	Valid reasons matched in previous report. Very rare disease.
15/LO/1091	Magnetic Resonance in Infection Primed Neonatal Encephalopathy and N-acetyl (MARINAC)	07/10/2015	05/11/2015	Yes	Study met 70-day benchmark.
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		No	Valid reasons matched in previous report. Myelofibrosis is a very rare disease. This is an uncommon disease, with an annual incidence of approximately 0.4 cases per 100,000
15/LO/1163	A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC	30/10/2015	17/01/2016	No	
15/LO/1185	Using Step Count to Enhance Daily Physical Activity in Pulmonary Hypertension	16/10/2015	23/11/2015	Yes	Study met 70-day benchmark.
15/LO/1228	An Open-Label Study to Evaluate the Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir with or without Dasabuvir in Adults with Genotype 1a or Genotype 4 Chronic Hepatitis C Virus (HCV) Infection, with Severe Renal Impairment (?) (RUBY-II)	23/09/2015	14/12/2015	No	Valid reasons matched in previous report. The first two patients consented within the 70-day benchmark. Unfortunately both were screening failures due to genotyping issues which made them ineligible.
15/LO/1302	A Randomised, Phase II Umbrella Trial of Weekly Paclitaxel +/- Novel Agents in Platinum-Resistant Ovarian Cancer	04/12/2015	12/02/2016	Yes	Study met 70-day benchmark.
15/LO/1341	Can ultrasound predict outcome of operative vaginal deliveries for prolonged second stage?	15/10/2015	29/10/2015	Yes	Study met 70-day benchmark.
15/LO/1351	The prognostic value of global longitudinal strain of the left ventricle in the risk assessment of patients with non-ST elevation myocardial infarction	23/10/2015	13/11/2015	Yes	Study met 70-day benchmark.
15/LO/1402	AV optimisation delivered with direct His bundle pacing, in patients with heart failure, long PR without left bundle branch block: randomised multicentre clinical outcome study The His Optimised Pacing Evaluated for Heart Failure Trial (HOPEHF)	05/01/2016	18/01/2016	Yes	Study met 70-day benchmark.
15/LO/1481	Neurokinin 3 Receptor Antagonism as a Novel Treatment for Menopausal Hot Flashes	14/01/2016	04/02/2016	Yes	Study met 70-day benchmark.
15/LO/1640	Global Clinical Study of Renal Denervation with the Symplicity Spyral™ multielectrode renal denervation system in patients with uncontrolled hypertension on standard medical therapy	09/02/2016			70-day benchmark not yet expired.
15/LO/1641	Global Clinical Study of Renal Denervation with the Symplicity Spyral™ multielectrode renal denervation system in Patients with Uncontrolled Hypertension in the Absence of Antihypertensive Medications (SPYRAL HTN-OFF MED Study)	02/01/2016		No	Study team has been screening actively and have identified two suitable participants; however, both declined to participate.
15/LO/1666	Effect of the CRTH2 Antagonist OC459 on the Response to Rhinovirus Challenge in Asthma	14/01/2016	21/01/2016	Yes	Study met 70-day benchmark.
15/LO/1679	Impact on Hypoglycaemia Awareness of Real Time CGM and Intermittent Continuous Glucose Data	24/11/2015	22/01/2016	Yes	Study met 70-day benchmark.
15/LO/1743	Pilot Study for Automated Detection of Atrial Fibrillation after Transient Ischemic Attack	20/01/2016	24/03/2016	Yes	Study met 70-day benchmark.
15/LO/1761	Self Assessment Method for Statin side-effects Or Nocebo (SAMSON)	03/03/2016	31/03/2016	Yes	Study met 70-day benchmark.
15/LO/1852	Tactile assessment and feedback in the neurohabilitation of the hand function.	16/03/2016			70-day benchmark not yet expired.
15/LO/1856	Enhancement of intraoperative ultrasound in brain tumour surgery with the use of microbubbles as a contrast agent, shear wave elastography, and advanced image processing.	11/02/2016	18/03/2016	Yes	Study met 70-day benchmark.
15/LO/1887	AVICCI Study- A feasibility study to assess the effects of Antiretroviral Intensification with Cenicriviroc for the management of HIV- associated Cognitive Impairment.	28/01/2016	22/03/2016	Yes	Study met 70-day benchmark.
15/LO/1904	The Impact of Multiparametric MRI on the Staging and Management of Patients with Suspected or Confirmed Ovarian Cancer.	28/01/2016			70-day benchmark not yet expired.
15/LO/1908	A Phase I/IIa Dose Escalation, And Subsequent Cohort Expansion Study Of The Safety, Tolerability, Pharmacokinetics, Pharmacodynamics And Preliminary Clinical Efficacy Of Intravenous DTP3 In Patients With Relapsed Or Refractory Multiple Myeloma	10/02/2016			70-day benchmark not yet expired.

15/LO/2131	The role of ambulatory oxygen in improving the effectiveness of pulmonary rehabilitation for COPD patients	04/02/2016			70-day benchmark not yet expired.
15/NE/0167	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Maintenance Therapy After Initial Therapy in Patients With Newly Diagnosed Multiple Myeloma Not Treated With Stem Cell Transplantation	03/02/2016			70-day benchmark not yet expired.
15/NE/0296	FIRST-line support for Assistance in Breathing in Children (FIRST-ABC) Feasibility Study: feasibility study for a randomised trial of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) (?) critically ill children	02/11/2015	14/12/2015	Yes	Study met 70-day benchmark.
15/NE/0314	RCT of compression therapy following foam sclerotherapy	16/12/2015	12/01/2016	Yes	Study met 70-day benchmark.
15/NW/0171	A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic chronic subdural haematoma	04/01/2016	07/03/2016	Yes	Study met 70-day benchmark.
15/NW/0416	A randomised phase II trial of Cyclophosphamide and Dexamethasone in combination with Ixazomib, in relapsed or refractory multiple myeloma (RRMM) patients who have relapsed after treatment with thalidomide, lenolidomide and bortezomib.	15/12/2015	21/01/2016	Yes	Study met 70-day benchmark.
15/NW/0700	M13-583 A Single-Arm, Open-Label Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 4, 5, or 6 Infection (ENDURANCE-4)	23/11/2015	15/12/2015	Yes	Study met 70-day benchmark.
15/NW/0871	A Single-Arm, Open-Label, Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Renally-Impaired Adults with Chronic Hepatitis C Virus Genotype 1 ? 6 Infection (EXPEDITION-4)	10/12/2015	21/01/2016	Yes	Study met 70-day benchmark.
15/SC/0003	An Open-Label, Multicenter, Phase 1/2 Study of E7438 (EZH2 Histone Methyl Transferase [HMT] inhibitor) as a Single Agent in Subjects With Advanced Solid Tumors or With B cell Lymphomas	26/10/2015	19/01/2016	No	Valid reasons matched in previous report. Rare disease.
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.
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	09/10/2015	Yes	Study met 70-day benchmark.
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	09/09/2015	Yes	Study met 70-day benchmark.
15/SC/0359	M13-694: A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade (?)	02/10/2015	03/11/2015	Yes	Study met 70-day benchmark.
15/SC/0386	Safety and immunogenicity of a protein particle malaria vaccine candidate, R21, administered with and without Matrix-M1 in healthy UK volunteers	29/10/2015	19/11/2015	Yes	Study met 70-day benchmark.
15/SC/0431	Randomized, Double-Blind, Placebo Controlled, Phase 3 Study of Ramucirumab and Best Supportive Care (BSC) Versus Placebo and BSC as Second-Line Treatment in Patients With Hepatocellular Carcinoma and Elevated Baseline AFP Following First-Line Therapy With Sorafenib	06/01/2016		No	Rare disease.
15/SC/0521	A phase 2, randomized, open-label, Multicenter study to assess safety and efficacy of nab*-paclitaxel (abi-007) with epigenetic modifying therapy of cc-486, and nab*-paclitaxel monotherapy as Second-line treatment ... - ABOUND	18/02/2016	08/03/2016	Yes	Study met 70-day benchmark.
15/SC/0543	Use of a High Density Mapping System to Complete Wide Area Circumferential Ablation of the Pulmonary Veins and Avoid Ostial Segmental Ablation	09/02/2016	07/03/2016	Yes	Study met 70-day benchmark.
15/SS/0186	A phase II randomized open-label clinical trial to study the efficacy and safety of the combination regimen of Grazoprevir/Elbasvir (GZR/EBR) and Sofosbuvir (SOF) with and without Ribavirin ® in cirrhotic subjects with chronic HCV GT3 infection	29/01/2016	08/02/2016	Yes	Study met 70-day benchmark.
15/WA/0106	Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in OBESE Patients – The PROBESE Randomized Controlled Trial	20/01/2016	24/02/2016	Yes	Study met 70-day benchmark.
15/WA/0358	An exploratory, open-label, multicenter study to evaluate the safety and efficacy of a two-dose regimen of ATR101, a T-lymphocyte enriched leukocyte preparation depleted ex vivo of host alloreactive T-cells ... - CR-AIR-008	22/03/2016			70-day benchmark not yet expired.
15/WA/0415	The role of propionate in energy homeostasis	04/01/2016	26/02/2016	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	13/10/2015	No	Valid reasons matched in previous report. Rare disease.
15/WM/0256	Efficacy & Safety of Nasal Influenza Immunisation in Children - The SNIFFLE-3 study	09/10/2015	19/10/2015	Yes	Study met 70-day benchmark.
15/WS/0011	BALLAD. A trial to evaluate the potential benefit of adjuvant chemotherapy for small bowel adenocarcinoma.	18/01/2016		No	Rare disease.
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.
15/WS/0147	A Multicenter, Open Label, Prospective, Post Approval Study of the INCRAFT? AAA Stent Graft System in Subjects with Abdominal Aortic Aneurysms	15/12/2015	27/01/2016	Yes	Study met 70-day benchmark.
15/YH/0333	Preoperative Pocket Echocardiography Trial	16/07/2015	31/07/2015	Yes	Study met 70-day benchmark.
15NS/0114	A randomised controlled trial evaluating the clinical and cost-effectiveness of a policy of freezing all embryos followed by thawed frozen embryo transfer, compared with a policy of fresh embryo transfer ... - E-FREEZE Trial	14/03/2016	30/03/2016	Yes	Study met 70-day benchmark.
16/LO/0102	A comparison of the "visualFields easy" app for iPad with the Humphrey Visual Field Analyser to diagnose and classify visual field defects in patients post-stroke	27/01/2016	28/01/2016	Yes	Study met 70-day benchmark.