PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q1, 2016/17)

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
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/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. There were delays from the UKCRN in adopting the study onto the portfolio. The study was granted R&D approval on day 72 after UKCRN provided their portfolio adoption outcome. All site documents were in place from day 15 onwards but we were awaiting the NIHR portfolio adoption team's decision before we could issue R&D approval.
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/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
15/YH/0333	Preoperative Pocket Echocardiography Trial	16/07/2015	31/07/2015	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/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/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/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
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
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. However we did identify a suitable patient who agreed to consent in under 70 days, but she turned out to be allergic to all of the antibiotics on the trial which made her ineligible.

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 the lab kit being shipped to site which postponed activation until the 11/08. One patient was eligible but declined to take part. Furthermore, the recruitment was stopped early nationally as they achieved their global target sooner than anticipated.
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
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
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/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/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/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
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/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/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
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
14/LO/0612	Care of Late Stage Parkinsonism	12/08/2015	08/12/2015	No	Valid reasons matched in previous report. The delays were due to the involvement of Information Governance who were unable to provide a timley informed decision with regard to (protected) patient data being sent offsite i.e. outside of the Trust (to sponsor / vendor).
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/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
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/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/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/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/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
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
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/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
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
15/LO/0769	Left Atrial Appendage Occlusion Study III	09/09/2015	10/09/2015	Yes	Study met 70-day benchmark
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/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
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
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
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	10/11/2015	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 at the Central Labs which made them ineligible.
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
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
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/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/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
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. Site was only activated on 15.01.2016 - 97 days after receving R&D approval.
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	20/06/2016	No	Valid reasons matched in previous report. Rare disease.

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/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/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?) ..	20/10/2015	15/12/2015	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
13/WM/0364	Targeted retreatment of incompletely recovered COPD exacerbations with ciprofloxacin: a double-blind, randomised, placebo-controlled, multicentre Phase III trial - WP4	23/10/2015		No	Valid reason matched in previous quarter. Site team member responsible for recruitment has been in long term sick leave.
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.
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
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
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
14/NE/1109	Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee)	30/10/2015	19/11/2015	Yes	Study met 70-day benchmark
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	17/12/2015	Yes	Study met 70-day benchmark
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
12/WA/0230	Radiotherapy after Oesophageal Cancer Stenting Study	04/11/2015	13/01/2016	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	Valid reason matched in previous quarter. Site team was actively recruiting but no eligible patients were identified.
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
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	10/05/2016	No	Valid reasons matched in previous quarter report. There wee delays in R&D approval du to Christmas holiday and staff member being off sick. This was followed by sponsor delay of 56 days to formally activate.
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
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
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/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	Valid reason matched in previous quarter. 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/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

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	18/05/2016	No	Valid reasons matched in previous quarter report. 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. This would exclude babies born during afterhours.
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/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/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/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/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
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 vs aflibercept vs bevacizumab for Macular Oedema due to (CRVO).	15/12/2015	01/03/2016	No	Valid reason matched in previous quarter. Sponsor delays with site activation.
15/NE/0314	RCT of compression therapy following foam sclerotherapy	16/12/2015	12/01/2016	Yes	Study met 70-day benchmark
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	Valid reason matched in previous quarter. Sponsor delayed greenlight due to sponsor's database not being ready to allow sites to recruit.
11/LO/1162	A prospective UK population-based study of incidence biology treatment and outcomes of non-Hodgkins Lymphoma in Young Adults	18/12/2015	12/02/2016	Yes	Study met 70-day benchmark
15/LO/1238	A Phase I clinical trial to assess the safety and immunogenicity of HIV DNA-C CN54ENV immunisations administered via the Intramuscular and Intradermal methods with and without electroporation followed by boosting with recombinant HIV CN54gp140?	22/12/2015		No	?coment on reason for delay
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	12/05/2016	No	Valid reasons matched in previous quarter report. The study team has been screening actively and they had two suitable participants, however, both of the participants declined to participate.
15/WA/0415	The role of propionate in energy homeostasis	04/01/2016	26/02/2016	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/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/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?	06/01/2016		No	Valid reason matched in previous quarter. Rare disease as defined by NIHR. Only aiming for 2 patients in total
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	Valid reason matched in previous quarter. Sponsor have put on hold recruitment for all sites for at least the end of April 2016 as they have issues with IMP, plus they want to submit a substantial amendment 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.
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	Valid reason matched in previous quarter. Rare disease. Site currently has a couple of patients in screening but their disease isn't yet measurable so not recruited yet.

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	Valid reason matched in previous quarter. Despite screening 3 patients, 1 was deemed ineligible after screening and 2 patients were eligible but declined to take part. Through patient choice we have therefore missed the benchmark. Please note, our target is also only 5 patients in total so we were only ever aiming fora small number.
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
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
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/1481	Neurokinin 3 Receptor Antagonism as a Novel Treatment for Menopausal Hot Flushes	14/01/2016	04/02/2016	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	06/04/2016	No	Valid reason matched in previous quarter. Rare disease.
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/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
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
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		No	Study was closed by Sponsor due to IMP safety concerns.
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
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	06/04/2016	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/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		No	Rare disease.
15/LO/2131	The role of ambulatory oxygen in improving the effectiveness of pulmonary rehabilitation for COPD patients	04/02/2016	18/04/2016	No	Delays with REC approval of study amendment. Recruiment could not start before REC final approval was received.
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/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		No	Study team has been screening actively and had found two suitable candidates for this study, however, both of them declined to participate.
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 RefractoryMultiple Myeloma	10/02/2016		No	Rare disease.
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

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/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		No	Sponsor delays with site activation.
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/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
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
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	23/03/2016	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/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	15/04/2016	Yes	Study met 70-day benchmark
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	10/05/2016	Yes	Study met 70-day benchmark
15/WM/0327	Clinical evaluation of the Therapeutic IntraVascular Ultrasound (TIVUS?) System for pulmonary artery denervation in patients with pulmonary hypertension	07/03/2016		No	rare disease
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
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
15/LO/1349	Validation of the Smart Socket Sensor System for amputee ambulation measurements	14/03/2016		No	Delays with R&D approval.
14/NW/1344	Expediting the confirmation of acute myocardial infarction with point of care troponin testing to facilitate early intervention	16/03/2016	01/04/2016	Yes	Study met 70-day benchmark
15/LO/1852	Tactile assessment and feedback in the neurohabiliation of the hand function.	16/03/2016	01/06/2016	No	
16/LO/0015	Examining the benefit of graduated compression stockings as an adjunct to low dose low molecular weight heparin in the prevention of venous thromboembolism in elective surgical inpatients identified as moderate or high risk ?	17/03/2016	12/05/2016	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 ATIR101, a T-lymphocyte enriched leukocyte preparation depleted ex vivo of host alloreactive T-cells ... - CR-AIR-008	22/03/2016		No	Very rare disease.
11/LO/1313	Phase I/II feasibility study of cetuximab with 5FU and mitomycin C or cisplatin with concurrent radiotherapy in muscle invasive bladder cancer	06/04/2016	02/06/2016	Yes	Study met 70-day benchmark
15/LO/1367	RetroMapping the distribution pattern of transient planar wavefronts during atrial fibrillation may indicate the underlying mechanism perpetuating activation.	11/04/2016	25/05/2016	Yes	Study met 70-day benchmark
14/LO/2163	Pomalidomide in relapsed and refractory multiple myeloma (RRMM)	11/04/2016		No	Rare disease.
14/LO/1559	Sorin Universal REgistry on Aortic Valve Replacement	15/04/2016	21/06/2016	Yes	Study met 70-day benchmark
13/NE/0005	Micra? Transcatheter Pacing System, Post-Approval Registry	18/04/2016	24/05/2016	Yes	Study met 70-day benchmark

15/NE/0406	MNA-3521-011 - A First-in-Human, multi-centre, open-label, Phase 1 clinical study with RNA oligonucleotide drug MTL-CEBPA to investigate its safety and tolerability in patients with advanced liver cancer (OUTREACH)	19/04/2016		no	This study did not meet the benchmark due to rarity of patient group; HCC is a rare disease, 4000-5000 new cases a year in the uk.HCC is a rare disease, 4000-5000 new cases a year in the uk. Despite this, 2 patients were considered but deteriorated straight after so were not able to participant. 2 further patients will be evaluated. Eligibility criteria were very stringent, so the sponsor had to amendment it.
15/SS/0148	A Phase 3 Multicentre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Aducanuma (BIIB037) in Subjects With Early Alzheimer's Disease	22/04/2016	26/04/2016	Yes	Study met 70-day benchmark
14/SC/1346	Multi-drug, genetic marker-directed, noncomparative, multi-centre, multi-arm phase II trial in non-small cell lung cancer	25/04/2016			70 day benchmark not yet due.
16/LO/0124	The ?RADIANCE HTN? Study. A study of the ReCor Paradise System in Clinical Hypertension	25/04/2016			70 day benchmark not yet due.
15/EM/0344	A Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Amatuximab in Combination with Pemetrexed and Cisplatin in Subjects with Unresectable Malignant Pleural Mesothelioma	26/04/2016			70 day benchmark not yet due.
15/EE/0350	A Phase III, randomised, double blind, placebo-controlled, parallel group, efficacy, safety and tolerability trial of once daily, oral doses of Empagliflozin as Adjunctive to insulin therapy over 26 weeks in patients with Type 1 Diabetes Mellitus	29/04/2016			70 day benchmark not yet due.
14/WA/1075	An investigator-initiated and conducted, international, multicentre, cluster, randomised cross-over controlled trial to establish the comparative effectiveness of different head positioning in patients with acute stroke	03/05/2016	11/05/2016	Yes	Study met 70-day benchmark
15/LO/2098	A Phase III Double-blind, Randomised, Parallel-Group Comparison of the Efficacy and Safety of FP-1201-lyo (Recombinant Human Interferon Beta-1a) and Placebo in the Treatment of Patients with Moderate or Severe Acute Respiratory Distress Syndrome	03/05/2016			70 day benchmark not yet due.
14/WM/1260	A phase Ib study to assess the safety and tolerability of oral Ruxolitinib in combination with 5-azacitidine in patients with advanced phase myeloproliferative neoplasms (MPN), including myelodysplastic syndromes (MDS) or acute myeloid leukaemia ?	04/05/2016	13/06/2016	Yes	Study met 70-day benchmark
16/EE/0013	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Safety and Efficacy of GS-9620 in combination with Tenofovir Disoproxil Fumarate (TDF) for the Treatment of Subjects with Chronic Hepatitis B?	11/05/2016	09/06/2016	Yes	Study met 70-day benchmark
15/LO/1538	A study to evaluate the effectiveness and safety of Exablate transcranial MRgFUS thalamotomy treatment of medication refractory essential tremor subjects	13/05/2016	16/06/2016	Yes	Study met 70-day benchmark
16/LO/0854	External pilot study to inform the design and conduct of the Fluids in Shock (FiSh) Trial	13/05/2016	12/07/2016	Yes	70 day benchmark not yet due.
15/LO/1192	A Randomized, Open-label, Phase 2 Trial of Ponatinib in Patients with Resistant Chronic Phase Chronic Myeloid Leukemia to Characterize the Efficacy and Safety of a Range of Doses	13/05/2016			70 day benchmark not yet due.
15/LO/0766	A novel robotic system for trans-anal endoscopic microsurgey	18/05/2016			70 day benchmark not yet due.
16/LO/0118	Valiant Evo International Clinical Trial	19/05/2016			70 day benchmark not yet due.
16/LO/0016	A Phase 3, Randomized, Open-Label Study to Evaluate the Safety and Efficacy of Switching from Regimens consisting of Boosted Atazanavir or Darunavir plus either Emtricitabine/Tenofovir or Abacavir/Lamivudine to GS-9883/Emtricitabine/Tenofovir ?	25/05/2016			70 day benchmark not yet due.
16/LO/0351	A double blind, randomized placebo controlled crossover multiple dose study of LJN452 to assess safety, tolerability and efficacy in patients with primary bile acid diarrhea (pBAD)	26/05/2016	16/06/2016	Yes	Study met 70-day benchmark
15/EE/0010	Phase III trial in Intrahepatic Cholestasis of Pregnancy (ICP) to Evaluate ursodeoxycholic acid (UDCA) in improving perinatal outcomes	26/05/2016			70 day benchmark not yet due.
14/LO/0722	RegenVOX Phase I/IIa clinical trial of stem cell based tissue engineered partial laryngeal implants in adult patients with end-stage laryngotracheal stenosis with 24 months follow up	01/06/2016			70 day benchmark not yet due.