PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q2, 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
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
11/LO/1595	Proof-of-concept study of AZD 4547 in patients with FGFR1 or FGFR2 amplified tumours	18/08/2016			70-day benchmark not yet due.
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.
12/EE/0023	Does oral sodium bicarbonate therapy improve function and quality of life in older patients with chronic kidney disease and low-grade acidosis? A multi-centre randomized placebo controlled trial	14/06/2016	26/07/2016	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
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/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	24/08/2016	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 for a small number.
13/LO/1837	A PHASE II MULTICENTRE TRIAL OF ENDOSCOPIC ULTRASOUND GUIDED RADIOFREQUENCY ABLATION OF CYSTIC TUMOURS OF THE PANCREAS	29/07/2016			70-day benchmark not yet due.
13/NE/0005	Micra™ Transcatheter Pacing System, Post-Approval Registry	20/05/2016	24/05/2016	Yes	Study met 70-day benchmark
13/NW/0501	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Compare Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Best Supportive Care as Maintenance Therapy in Subjects with Acute Myeloid Leukaemia in Complete Remission.	01/08/2016			70-day benchmark not yet due.
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.
13/WM/0364	WP4	23/10/2015		No	Valid reason matched in previous quarter. Site team member responsible for recruitment has been in long term sick leave.
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/1074	Post-Operative Pain after Pelvic Organ Prolapse Surgery. Double blind randomised multicentre study to assess the effect of local anaesthesia during vaginal hysterectomy.	31/05/2016		No	Sponsor did not include a crucial page in the site agreement - the PI declation page. Site promptly flagged this issue but sponsor has not yet rectified contract.

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/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/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	Valid reason matched in previous quarter. Sponsor delays with site activation.
14/LO/1370	Long Term, Multicenter, Single-arm, Open-label Extension Study of the MERIT-1 Study, to Assess the Safety, Tolerability and Efficacy of Macitentan in Subjects With Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH)	12/11/2015	24/11/2015	Yes	Study met 70-day benchmark
14/LO/1559	Sorin Universal REgistry on Aortic Valve Replacement	15/04/2016	21/06/2016	Yes	Study met 70-day benchmark
14/LO/1568	A Phase I/II Study of Thiotepa, Ifosphamide, Etoposide and Rituximab for the treatment of relapsed or refractory primary central nervous system lymphoma.	28/06/2016		No	Sponsor stopped the study due to change in first line treatment guidelines that would not allow patients to be recruit into study regimen.
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/2163	Pomalidomide in relapsed and refractory multiple myeloma (RRMM)	11/04/2016		No	Rare disease.
14/NE/1109	Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee)	30/10/2015	19/11/2015	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	01/04/2016	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	22/08/2016	No	Sponsor delays with site activation.
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.
14/SC/1059	A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy	12/02/2016		No	Sponsor failed to include in initial contract the setup of PIC sites which was essential for identifying patients. Sponsor had to submit amendment to add PIC sites; this took a long time as sponsor was slow to respond to our site requests. Amendment was finally submitted by sponsor on 02/07/2016 - 5 months after initial valid submission.
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/SW/0115	Safety and Efficacy of the Veniti Vici™ Venous Stent System (Veniti Inc.) when Used to Treat Clinically Significant Chronic Non-malignant Obstruction of the Iliofemoral Venous Segment Subtitle: A Study Looking at the Veniti Vici™ Venous Stent System (Veniti Inc.) to Treat Patients with Symptoms of Longstanding, Non-Cancerous Blockage(s) of a Major Vein in the Leg	05/09/2016	17/10/2016	Yes	Study met 70-day benchmark
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
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 (AML) arising from MPN.	04/05/2016	13/06/2016	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/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/1202	PREVenting infection using Antimicrobial Impregnated Long lines. An unblinded, 2-arm randomised controlled trial to determine the effectiveness of antimicrobial impregnated (with rifampicin and miconazole) long lines (termed peripherally inserted central catheters, or AM- PICC (AM-PICC)) compared with standard PICC (S-PICC) for reducing blood stream infection (BSI)	09/09/2016			70-day benchmark not yet due.
15/EE/0010	Phase III trial in Intrahepatic Cholestasis of Pregnancy (ICP) to Evaluate ursodeoxycholic acid (UDCA) in improving perinatal outcomes	26/05/2016	21/07/2016	Yes	Study met 70-day benchmark
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	12/07/2016	No	Principal Investigator had to take leave which caused delays in initiation.
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 of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC)	03/03/2016	10/05/2016	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
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/EM/0437	Columbus	08/08/2016			70-day benchmark not yet due.
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/GS-9857 Fixed-Dose Combination for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chronic HCV Infection	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 in Direct-Acting Antiviral-Naïve Subjects with Chronic HCV Infection	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 in Direct-Acting Antiviral-Experienced Subjects with Chronic HCV Infection who Have Not Received an NS5A Inhibitor	03/03/2016	15/03/2016	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.
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/0766	A novel robotic system for trans-anal endoscopic microsurgey	18/05/2016	08/07/2016	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/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) in Subjects with Low CA125 Platinum-Sensitive Ovarian Cancer	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/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.
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-Naïve 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/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.
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/1091	Magnetic Resonance in Infection Primed Neonatal Encephalopathy and N-acetyl	07/10/2015	05/11/2015	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/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/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		No	Rare disease.
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 or End-Stage Renal Disease (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/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/1349	Validation of the Smart Socket Sensor System for amputee ambulation measurements	14/03/2016		No	Delays with R&D approval.
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/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
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	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 Flushes	14/01/2016	04/02/2016	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
15/LO/1632	DEtection of Small for GestatioNal age fetus (SGA) a cluster randomised controlled trial to evaluate the effect of the Growth assessment protocol (GAP) programme	05/07/2016		No	Sponsor has run into serious delays due to funding and issue with study design; none of their sites has had initiation or randomisation as yet. Our site remains uncertain of the planned date after expediting urgent approval to meet the original time line.

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/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/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/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/1879	A Randomized, Open-label Study of Ponatinib Versus Nilotinib in Patients with Chronic Myeloid Leukemia in Chronic Phase Following Resistance to Imatinib	09/08/2016			70-day benchmark not yet due.
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	05/04/2016	Yes	Study met 70-day benchmark
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/2121	Phase IIb, Double-Blinded, Multicenter, Randomized Study to Assess the Effect on Central Nervous System (CNS) Toxicity of Switching from ATRIPLA™ (Efavirenz, Tenofovir, Emtricitabine) to MK-1439A (Doravirine, Tenofovir, Lamivudine) in Virologically-Suppressed Subjects	26/04/2016	07/07/2016	No	This has been very difficult to recruit to due to inclusion criteria that are conflicting with current clinic practice. This has made enrolment difficult for all sites. The sponsor has now amended the protocol and we awaiting for the approvals which will hopefully help increase enrolment.
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/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	29/07/2016	No	Rare disease.
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) for non-invasive respiratory support in critically ill children	02/11/2015	14/12/2015	Yes	Study met 70-day benchmark
15/NE/0314	A randomised controlled trial of compression therapy following foam sclerotherapy of varicose veins	16/12/2015	12/01/2016	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/NI/0258	A PERFORMANCE EVALUATION STUDY OF ARQUER'S MCM5 ELISA TEST TO AID IN THE DIAGNOSIS OF BLADDER CANCER	15/04/2016	18/04/2016	Yes	Study met 70-day benchmark

15/NS/0070	Multi-centre randomised controlled trial of clinical and cost-effectiveness of drug coated balloons, drug eluting stents and plain balloon angioplasty with bail-out bare metal stent revascularisation strategies for severe limb ischaemia due to atherosclerotic femoro-popliteal, with or without infra-popliteal involvement, peripheral arterial disease	21/06/2016	05/08/2016	Yes	Study met 70-day benchmark
15/NS/0114	Freezing of embryos in assisted conception: 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 in women undergoing in-vitro fertilization.	14/03/2016	30/03/2016	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/0671	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Enzalutamide in Subjects with Advanced Hepatocellular Carcinoma	25/08/2016			70-day benchmark not yet due.
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/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 Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	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	Valid reason matched in previous quarter. Rare disease as defined by NIHR. Only aiming for 2 patients in total
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 in subjects with advanced nonsquamous non-small cell lung cancer (NSCLC)	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/SC/0548	A Phase 1B study repurposing ATRA as stromal targeting agent along with gemcitabine and nab-Paclitaxel for pancreatic cancer (STAR_PAC)	02/06/2016	25/07/2016	Yes	Study met 70-day benchmark
15/SC/0616	An exploratory, randomised, double-blind, placebo-controlled study of the effects of dupilumab on airway inflammation of adults with persistent asthma	13/07/2016		No	Several patients have been screened but screen failed as none meet eligibility criteria for study to date.
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

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 ATIR101, a T-lymphocyte enriched leukocyte preparation depleted ex vivo of host alloreactive T-cells (using photodynamic treatment), in patients with a hematologic malignancy, who received a CD34-selected hematopoietic stem cell transplantation from a haploidentical donor	22/03/2016	01/07/2016	No	Very rare disease.
15/WA/0415	The role of propionate in energy homeostasis	04/01/2016	26/02/2016	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
15/WM/0327	Clinical evaluation of the Therapeutic IntraVascular Ultrasound (TIVUS™) System for pulmonary artery denervation in patients with pulmonary hypertension	07/03/2016	20/09/2016	No	Rare disease.
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/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/0478	A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis	29/06/2016	11/10/2016	No	Sponsor acknowledged that eligility criteraia was very restrictive and eventually submitted amendment to HRA to try to expand potential patient pool.
15/YH/0530	Assessment of VenetoCLAx (ABT-199) in combination with IbRutInib in relapsed/refracTory Chronic LymphocYtic Leukaemia	10/06/2016	11/07/2016	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 and who are currently not on Treatment	11/05/2016	09/06/2016	Yes	Study met 70-day benchmark
16/EM/0078	Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter, Exploratory Phase IIa Study to Assess Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Properties of GLPG1690 Administered for 12 Weeks in Subjects with Idiopathic Pulmonary Fibrosis (IPF)	14/09/2016			70-day benchmark not yet due.
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 for venous thromboembolism – a multicentre randomised controlled trial	17/03/2016	12/05/2016	Yes	Study met 70-day benchmark
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 Alafenamide in Virologically Suppressed HIV-1 infected Adults	25/05/2016		No	We received R&D approval 25/5 we then had to wait for the greenlight from the sponsor before we could begin screening but she was on leave so by the time it closed on 9/6 we had only been able to approach 2 people neither were interested in taking part so we are now closed as a site.
16/LO/0029	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults	09/05/2016		No	Sponsor closed study early.
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
16/LO/0118	Valiant Evo International Clinical Trial	25/05/2016	01/09/2016	No	Very stringent inclusion criteria made it extremelly challenging to find eligible patients.

16/LO/0124	A study of the ReCor Paradise System in Clinical Hypertension	25/04/2016	06/07/2016	No	Study team were actively screening and approaching patients, but suitable candidates were not consented in time.
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
16/LO/0717	A phase I first in human, double-blind, parallel, randomised and placebo controlled clinical trial of the safety of SSI's adjuvanted chlamydia vaccine CTH522 in healthy women aged 18 to 45 years	08/07/2016	15/08/2016	Yes	Study met 70-day benchmark
16/YH/0276	Does the wording of text message reminders improve uptake in breast screening? A RCT	29/06/2016	10/08/2016	Yes	Study met 70-day benchmark
13/NE/0299	EuroHYP-1: European multicentre, randomised, phase III clinical trial of therapeutic hypothermia plus best medical treatment versus best medical treatment alone for acute ischaemic stroke.	21/06/2016		No	Sponsor delays – site is still waiting for sponsor to provide equipment (catheters) for study to start.
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		No	Sponsor decided to delay site activation; eventually they decided to close our site without activating it.
14/LO/1842	Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis (ENDCaP-C) A Multicentre test accuracy study	09/06/2016	06/09/2016	No	Part of the screening of patients includes Standard of Care endoscopy appointments; there is a long waiting list for this test in the Trust so screening of patients was delayed.
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		No	Study team has been actively screening patients but has not yet identify anyone eligible.
15/EE/0464	A phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	28/06/2016		No	Sponsor delays in providing study drug to site.
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		No	Study team has been actively looking for patients since study was approved. There were 2 screening failures.
15/LO/0217	Effect of Remote Ischaemic Conditioning on clinical outcomes in ST-segment elevation myocardial infarction patients undergoing Primary Percutaneous Coronary Intervention (ERIC-PPCI): A multicentre randomised controlled clinical study	27/06/2016		No	There were delays within the Trust which delayed start of recruitment.
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 in healthy male and female volunteers	22/12/2015		No	Sponsor delay-no green light from sponsor yet as Sponsor has still not supplied IMP-They had problems with both the IMP stability, and with supply of a critical medical device – both requiring approval of amendments by the MHRA.
15/LO/1487	A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination with Ramucirumab or Placebo in Previously Untreated Patients with EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer	29/06/2016		No	Rare disease.
15/LO/1548	A randomised controlled trial of the sulfonylurea Gliclazide and the DPP4 inhibitor Linagliptin on the frequency of hypoglycaemia among patients with Type 2 Diabetes and chronic kidney disease (CKD) stage 3b and 4	09/06/2016	22/09/2016	No	Study team actively looking for patients once approval was granted; still no suitable patients found. First patient screened on 21/07/16 but failed screening.
15/LO/1852	Tactile assessment and feedback in the neurohabiliation of the hand function.	16/03/2016	01/06/2016	No	Study team actively looking for patietns but no eligible participants were identified.
15/NW/0431	A Phase 2, Two-arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety of Two Different Dose Regimens of a pan-FGFR Tyrosine Kinase Inhibitor JNJ-42756493 in Subjects with Metastatic or Surgically Unresectable Urothelial Cancer with FGFR Genomic Alterations	02/06/2016		No	Study team has been actively looking for patients; there were 8 screening failures..
16/NE/0027	A phase 3, multicenter, randomized, open-label study of avelumab (MSB0010718C) alone or in combination with Pegylated Liposomal Doxorubicin versus Pegylated Liposomal Doxorubicin alone in patients with platinum resistant/refractory ovarian cancer	11/07/2016		No	Rare disease.

16/SC/0089	A pragmatic randomised controlled trial to determine whether VV-ECCO2R in mechanically ventilated patients with hypoxaemic respiratory failure improves 90 day mortality.	08/06/2016		No	Sponsor delayed site initiation due to initial refusal by the sponsor to accept that a unique NHS Permission was to cover both hospitals (Hammersmith and Charing Cross) within our Imperial Trust. Eventually sponsor accepted the unique Trust approval.
14/SC/0221	A randomised phase II pilot study of 3 weekly Cabazitaxel versus weekly Paclitaxel chemotherapy in the first line treatment of HER2 negative metastatic breast cancer	13/05/2016		No	Sponsor took 2 months (20th May - 29th July) to amend contract. After that delayed was due to a combination of Trust contract delays and pharmacy approval delays due to shortage of staff.
15/NS/0113	Surgical Interventions for Renal Stones - The clinical and cost effectiveness of surgical interventions for stones in the lower kidney: The PUrE RCT- Percutaneous Nephrolithotomy (PNL), Flexible Ureterorenoscopy (FURS) and Extracorporeal Lithotripsy (ESWL) for lower pole Kidney stones	04/07/2016	23/08/2016	Yes	Study met 70-day benchmark
15/SC/0306	A phase 3,Randomized,Double-Blind,Placebo-Controlled Study of Ramacirumab plus Doxetacel vs Placebo plus Doxetacel in Patients with Locally Advanced or Unresectable or Metasthatic Urothelial Carcinoma Who Progressed or After Platinum-Based Therapy	09/09/2016	10/10/2016	Yes	Study met 70-day benchmark
15/WM/0276	Safety of Nasal Influenza Immunisation in Children with asthma – The SNIFFLE 4 study	20/05/2016	03/10/2016	Yes	Study met 70-day benchmark
16/EM/0032	A three-cohort study of oral cMET inhibitor INC280 in adult patients with EGFR wt, advanced NSCLC who have received one or two prior lines of systemic therapy for advanced/metastatic disease	01/07/2016			70-day benchmark not yet due.
16/LO/0512	Intraocular pressure and tolerability Study of Preserved Bimatoprost 0.1% (BIMMD) or Tafluprost Unit Dose Preservative Free 15microgram/ml (TUDPF) (Saflutan), in patients with Ocular hypertension or glaucoma suitable for prostaglandin therapy: A Randomized, single masked, 3 month cross-over, Investigator led, European multicentre Trial, II (SPORT II)	22/08/2016			70-day benchmark not yet due.
16/LO/0640	Glycaemic Index, extended bolusing and diabetes education in insulin pump therapy (GLIDE study)	19/05/2016	28/07/2016	Yes	Study met 70-day benchmark
16/LO/0796	Prospective, non-randomized, safety and efficacy study of a new occluder design for minimally invasive closure of the left atrial appendage in patients with atrial fibrillation	04/07/2016	18/07/2016	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	10/10/2016	No	There have been 11 screening failures; first patient screened within 70 days from Date Site Selected.
16/LO/0886	A Multicenter, Double-Blind, Placebo-Controlled, Randomized, Parallel-Group, Dose-Ranging Study to Evaluate the Safety and Efficacy of Intravenous Natalizumab (BG00002) in Acute Ischemic Stroke	12/08/2016			70-day benchmark not yet due.
16/LO/1270	Increasing home practice during a novel mindfulness and acceptance based intervention for long-term conditions.	12/08/2016	29/08/2016	Yes	Study met 70-day benchmark
16/NE/0078	A Phase I/II Open-Label Safety and Dose-Finding Study of Adeno-Associated Virus (AAV) rh10-Mediated Gene Transfer of Human Factor IX in Adults With Moderate/Severe to Severe Hemophilia B	19/09/2016			70-day benchmark not yet due.
16/NW/0169	An open-label, randomised, phase 2 study comparing S 95005 plus bevacizumab to capecitabine plus bevacizumab in patients with previously untreated metastatic colorectal cancer who are non-eligible for intensive therapy	12/07/2016			70-day benchmark not yet due.
16/WA/0215	A Pilot Study to Evaluate Using Point of Care Thrombelastograph (TEG) Analysis in Major Trauma Patients within the Emergency Department	14/09/2016	22/09/2016	Yes	Study met 70-day benchmark
16/YH/0022	A phase I, multicenter, open-label, single-sequence drugdrug interaction study to assess the effect of INC280 on the pharmacokinetics of midazolam and caffeine in patients with cMET-dysregulated advanced solid tumors	15/08/2016			70-day benchmark not yet due.
15/LO/1232	Additive Effect of Twice Daily Brinzolamide 1% /Brimonidine 0.2% Fixed Dose Combination as an Adjunctive Therapy to a Prostaglandin Analogue	20/05/2016		No	No information available on reason for delay
16/LO/0209	The Acute Effects of Food Structure on Appetite Regulation	20/05/2016	10/07/2016	Yes	Study met 70-day benchmark

16/LO/1250	A double blind, randomized, controlled study to assess the efficacy of continuous transversus abdominis plane (TAP) blocks for analgesia and enhanced recovery following major gynaecological surgery.	14/09/2016			70-day benchmark not yet due.
16/YH/0083	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination With nab Paclitaxel Plus Gemcitabine Compared With Placebo Plus nab Paclitaxel and Gemcitabine in Subjects with Hyaluronan-High Stage IV Previously Untreated Pancreatic Ductal Adenocarcinoma.	21/07/2016		No	No information available on reason for delay