PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q3, 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
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/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/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	22/09/2016	Yes	
13/SC/0638	Human papillomavirus infection: a randomised controlled trial of Imiquimod cream (5%) versus Podophyllotoxin cream (0.15%), in combination with quadrivalent human papillomavirus or control vaccination in the treatment and prevention of recurrence of anogenital warts (HIPvac Trial)	12/10/2016	29/11/2016	Yes	
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/LO/1559	Sorin Universal REgistry on Aortic Valve Replacement	15/04/2016	21/06/2016	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/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
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/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/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-Na?ve 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/0766	A novel robotic system for trans-anal endoscopic microsurgey	18/05/2016	08/07/2016	Yes	Study met 70-day benchmark
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/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/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/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/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/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/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/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/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/0385	A Four-Part Phase-1 Study Investigating the Tolerability, Safety and Pharmacokinetics (PK) of MBS2320 following Ascending Single and Multiple Oral Doses in Healthy Subjects and Multiple Oral Doses in Subjects with Rheumatoid Arthritis (RA) Also Treated with Methotrexate (MTX), the Effect of Food on the PK of MBS2320 in Healthy Subjects, the Relative Bioavailability in Healthy Subjects of Encapsulated Micronized MBS2320 versus MBS2320 in Suspension, and the PK Interaction of MBS2320 and MTX in Subjects with RA.	19/09/2016	03/11/2016	Yes	
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	02/11/2016	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	
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/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/0415	The role of propionate in energy homeostasis	04/01/2016	26/02/2016	Yes	Study met 70-day benchmark
15/WM/0276	Safety of Nasal Influenza Immunisation in Children with asthma ? The SNIFFLE 4 study	19/09/2016	03/10/2016	Yes	Study met 70-day benchmark
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/0009	A Phase 3,Randomized,Controlled, Multi-Center,Open-Label,Study To Compare Tivozanib Hydrochloride To Sorafenib In Subjects With Refractory Advanced Renal Cell Carcinoma	08/11/2016	16/12/2016	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/ES/0001	A Phase 3, randomized, double-blind, placebo-controlled, multicenter study to investigate the efficacy and safety of Mongersen (GED-0301) for the treatment of subjects with active Crohn's disease	21/10/2016	28/10/2016	Yes	Study met 70-day benchmark
16/LO/0007	Clinical Assessment of a Novel Microprobe Array Continuous Glucose Monitor for Type 1 Diabetes	03/02/2016	11/03/2016	Yes	Study met 70-day benchmark
16/LO/0014	A Prospective Multicenter Phase III Clinical Evaluation of the Safety and Efficacy of Lumason/SonoVue in Subjects Undergoing Pharmacologic Stress Echocardiography with Dobutamine for the Diagnosis of Coronary Artery Disease	14/10/2016	10/12/2016	Yes	Study met 70-day benchmark
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/0100	Distal Evaluation of Functional performance with Intravascular sensors to assess the Narrowing Effect – Combined pressure and Doppler FLOW velocity measurements.	04/08/2016	16/08/2016	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
16/LO/0209	The Acute Effects of Food Structure on Appetite Regulation	25/05/2016	10/07/2016	Yes	Study met 70-day benchmark
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/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/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/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/1205	Feasibility and Acceptability of a Psychoeducational Booklet to Support Women who have been Prescribed Tamoxifen	21/10/2016	23/11/2016	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	25/10/2016	Yes	
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/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	12/09/2016	Yes	Study met 70-day benchmark.
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	31/08/2016	31/10/2016	Yes	Study met 70-day benchmark
16/SC/0441	A Phase 1, First-in-Humans, randomized, double-blind (within dose level),placebo-controlled trial to evaluate the safety and immunogenicity of two intranasal doses of SynGEM®, an intranasal Respiratory Syncytial Virus (RSV) subunit candidate vaccine based on the F glycoprotein linked to an immunostimulatory Bacterium-like-Particle (BLP) carrier administered 28 days apart in adult healthy volunteers	30/09/2016	21/10/2016	Yes	
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/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
14/LO/1206	PLAnning Treatment For Oesophago-Gastric Cancer: a Randomised Maintenance Therapy Trial	06/12/2016		Within 70 Days	70-day benchmark not yet due.
15/LO/1044	Adjuvant chemotherapy with gemcitabine and cisplatin compared to observation after curative intent resection of cholangiocarcinoma and muscle invasive gallbladder carcinoma (ACTICCA1 trial)	07/11/2016		Within 70 Days	70-day benchmark not yet due.
15/NW/0160	Phase Ib, multicentre,openlabel study of a firstinclass nucleotide analogue Acelarin (NUC1031) in combination with cisplatin in patients with locally advanced/metastatic biliary tract cancers	30/11/2016		Within 70 Days	70-day benchmark not yet due.
16/LO/0542	An Open-Label, Phase 3 Study Examining the Long-Term Safety, Tolerability and Efficacy of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)	22/11/2016		Within 70 Days	70-day benchmark not yet due.
16/LO/0560	Can patient video testimonials augment the standard consent process? A Randomised Control Trial	29/11/2016		Within 70 Days	70-day benchmark not yet due.
16/LO/1263	Development of patient-specific tools to determine the need for adjunctive ablation following PVI for persistent AF using detailed characterisation of the substrate and the mode of recurrence	25/11/2016		Within 70 Days	70-day benchmark not yet due.
16/LO/1350	OPTIC - Optical Polyp Testing for In vivo Classification	29/11/2016		Within 70 Days	70-day benchmark not yet due.
16/SS/0134	A PHASE 1B MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE SAFETY AND TOLERABILITY AND DETERMINE THE MAXIMUM TOLERATED DOSE OF PF-05230907 IN SUBJECTS	03/11/2016		Within 70 Days	70-day benchmark not yet due.
16/SW/0232	A multi-centre, double-blind, randomised, controlled clinical trial of Rifaximin to reduce infection in patients admitted to hospital with decompensated cirrhosis	31/10/2016		Within 70 Days	70-day benchmark not yet due.
11/LO/1595	Proof-of-concept study of AZD 4547 in patients with FGFR1 or FGFR2 amplified tumours	18/08/2016		No	Several patients were screened within 70 days but none eligible for recruitment.
11/LO/1915	International Randomized Study of Laparoscopic Prostatectomy vs Robotic Radiosurgery and Conventionally Fractionated Radiotherapy vs Radiosurgery for Early Stage Organ-Confined Prostate Cancer	15/08/2016	23/11/2016	No	Study team screened many patients but most were ineligible.
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 study.
12/SS/0211	Efficacy and safety of MRI-based thrombolysis in wake-up stroke: a randomised, double-blind, placebo-controlled trial	06/07/2016		No	Study involves assessments that require overnight and weekend resourcing from study team. This has proved challenging within existing clinical commitments.

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	Screening taking place but patients did not consent.
13/LO/1837	A PHASE II MULTICENTRE TRIAL OF ENDOSCOPIC ULTRASOUND GUIDED RADIOFREQUENCY ABLATION OF CYSTIC TUMOURS OF THE PANCREAS	29/07/2016		No	Study team actively screening but no suitable patients identified yet.
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	Site awaiting equipment from Sponsor for study to start.
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	Corrections to contract needed by Sponsor. Potential patients identified but 3 months wait before surgery.
14/LO/0344	A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Center Study of Talazoparib (BMN 673) versus Physician's Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received Prior Chemotherapy Regimens for Metastatic Disease	13/05/2016		No	Rare disease study.
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 delayed site activation; eventually closed site without activating.
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 halted study due to change in first line treatment guidelines that would not allow patients to be recruit into study regimen.
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 so screening of patients was delayed.
14/LO/2163	Pomalidomide in relapsed and refractory multiple myeloma (RRMM)	11/04/2016	30/08/2016	No	Rare disease study.
14/LO/2182	A Phase III Clinical Trial of Intra-arterial TheraSphere in the Treatment of Patients with Unresectable Hepatocellular Carcinoma	02/08/2016		No	Late protocol amendment which necessitated revision of costs / contract. Patients now consented and being screened.
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/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	20/10/2016	No	Sponsor delay with contract amendment. Then further delays with contractual negotiation.
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/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	Omissions from initial contract relating to setup of PIC sites (essential for identifying patients). Sponsor had to submit amendment to add PIC sites.
14/SC/1072	In House' Preimplantation Oxygenated Hypothermic Machine Perfusion Reconditioning after Cold Storage versus Cold Storage alone in ECD Kidneys from Brain Dead Donors	24/06/2016		No	Sponsor delays with contract. Then very challenging to identify suitable patients.
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	21/12/2016	No	Study team has been actively screening patients - none yet eligible.
14/SC/1416	A phase III multi-centre randomised, double blind, placebo controlled trial to assess the role of intravenous immunoglobulin in the management of children with encephalitis	04/10/2016		No	20 screening failures within 70 days from clock start.
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	Study team absences.
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	Delay 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	06/12/2016	No	Study team actively looking for patients since study was approved. 2 screening failures.
15/EM/0437	Columbus	08/08/2016	22/11/2016	No	Study team searching for patients but very few are seen with disease during summer months.
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	15/11/2016	No	Site delays.
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	Site delays around Christmas holidays. Sponsor delay 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	28/10/2016	No	Sponsor put hold on recruitment for all sites (issues with IMP). Submitting substantial amendment prior to activating any sites.
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 closed by Sponsor due to IMP safety concerns.
15/LO/1077	Addition of stereotactic body radiotherapy to systemic chemotherapy in locally advanced biliary tract cancers - ABC-07	15/03/2016	02/08/2016	No	Lengthy budget negotiation between sponsor and site delayed contract being executed. Subsequently difficulties finding patients as this is a rare disease study.
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	26/09/2016	No	Rare disease study.
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	GCP course refresher required.
15/LO/1349	Validation of the Smart Socket Sensor System for amputee ambulation measurements	14/03/2016		No	Site delays with R&D approval.
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 study.
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; no suitable patients yet found.
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 delays due to funding and study design; no sites has had initiation or randomisation. Site expedited 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	29/10/2016	No	Study team screening actively within the 70-day period and had found two suitable candidates, however, both 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	Study team screening actively. Currently recruitment targetof 5 has been met and surpassed.
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 patients; no suitable patients yet found.
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		No	Rare disease study.

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	25/04/2016	No	Rare disease study.
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	21/09/2016	No	Study opened over the summer months when cases of ARDs are less frequent; recruitment has been challenging nationally.
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	Difficult to recruit to due to inclusion criteria that are conflicting with current clinic practice. Enrolment difficult for all sites. Sponsor has now amended the protocol.
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 study.
15/NE/0324	Simvastatin as a neuroprotective treatment for Parkinson's disease: a double-blind, randomised, placebo controlled futility study in patients of moderate severity	15/03/2016	22/06/2016	No	Study team actively recruiting but no eligible patients seen within 70 days.
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	Rare disease study.
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 identifying patients; several screening failures.
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 study.
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 study.
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 study.
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	Rare disease study.
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 criteria very restrictive. Then submitted amendment to HRA to try to expand potential patient pool.
16/EE/0195	A randomized, double-blind phase 3 study of vadastuximab talirine (SGN-CD33A) versus placebo in combination with azacitidine or decitabine in the treatment of older patients with newly diagnosed acute myeloid leukemia (AML)	09/05/2016		No	Site awaiting site activation by Sponsor.
16/EE/0386	A Multicentre, Randomised, Open-label, 3-Arm Phase 3 Study of Encorafenib + Cetuximab Plus or Minus Binimetinib vs. Irinotecan/Cetuximab or Infusional 5- Fluorouracil (5-FU)/Folinic Acid (FA) /Irinotecan (FOLFIRI)/Cetuximab with a Safety Lead-in of Encorafenib + Binimetinib + Cetuximab in Patients with BRAF V600E-mutant Metastatic Colorectal Cancer	26/09/2016		No	Rare disease study.

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	25/08/2016		No	Study team actively recruiting; several potential patients identified to date but all failed screening.
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		No	Rare disease study.
16/EM/0193	A phase III, double---blind, randomized placebo---controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal--GenE trial	01/06/2016	02/11/2016	No	Sponsor/CRO negotiation delays re: VAT costs.
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	Awaiting "green light" from Sponsor to begin screening.
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-Na?ve Adults	09/05/2016		No	Sponsor closed study early.
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 actively screening and approaching patients before the 70-day period ended, but suitable candidates were not consented in time. Currently study has reached and surpassed target recruitment ahead of time.
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		No	Study design challenging for patients, who were unwilling to consent for this reason.
16/LO/0581	Phase 2, Randomized Study of MLN0128 (a Dual TORC1/2 Inhibitor), MLN0128+MLN1117 (a PI3Ka Inhibitor), Weekly Paclitaxel, or the Combination of Weekly Paclitaxel and MLN0128 in women With Advanced, Recurrent, or Persistent Endometrial Cancer	23/05/2016	19/12/2016	No	Lengthy budget and indemnity negotiation between Sponsor and and site.
16/LO/0586	An Open Label Study to Evaluate the Efficacy and Safety of Ocrelizumab in Patients with Relasping Remitting Multiple Sclerosis who have had a Suboptimal Response to an Adequate Course of Disease- Modifying Treatment	19/07/2016	16/11/2016	No	Awaiting HRA to approve late amendment from Sponsor.
16/LO/0675	A PHASE 2, INTERNATIONAL, MULTICENTER, RANDOMIZED, OPENLABEL, PARALLEL GROUP STUDY TO EVALUATE THE EFFICACY AND SAFETY OF CC-486 (ORAL AZACITIDINE) ALONE AND IN COM+H768BINATION WITH DURVALUMAB (MEDI4736) IN SUBJECTS WITH MYELODYSPLASTIC SYNDROMES WHO FAIL TO ACHIEVE AN OBJECTIVE RESPONSE TO TREATMENT WITH AZACITIDINE FOR INJECTION OR DECITABINE	27/04/2016		No	Sponsor delays in negotiating contract / costs.
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	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	29/09/2016	15/12/2016	No	Delay in activating site and supplying equipment needed for recruitment.
16/LO/0952	An open-label, multicentre, international pilot study of paritaprevir/ritonavir, ombitasvir, dasabuvir with or without ribavirin for people with recently acquired hepatitis C virus infection with or without HIV co-infection.	01/08/2016		No	Delays negotiating contract.

16/LO/1040	The effect of L-phenylalanine on appetite	31/08/2016		No	Staff absences (maternity leave).
16/NE/0023	A Phase III, Multi-centre, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study with Open-Label Extension of Crenezumab in Patients with Prodromal-to-Mild Alzheimer's Disease	30/06/2016	06/10/2016	No	Sponsor delay giving green light to commence recruitment (late study amendment).
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.
16/SC/0161	A Phase III, Open-Label, Randomized Study Of Atezolizumab (Mpdl3280a, Anti-Pd-L1 Antibody) In Combination With Carboplatin Or Cisplatin + Pemetrexed Compared With Carboplatin Or Cisplatin + Pemetrexed In Patients Who Are Chemotherapy-Naive And Have Stage Iv Non-Squamous Non-Small Cell Lung Cancer	13/05/2016		No	Study team identified several patients but all were screen failures.
16/SC/0261	A Phase I/IIa Sporozoite Challenge Study to Assess the Safety and Protective Efficacy of adjuvanted R21 at two different doses and the Combination Malaria Vaccine Candidate Regimen of adjuvanted R21 + ChAd63 and MVA encoding ME-TRAP.	29/06/2016	27/10/2016	No	Awaiting HRA to approve late amendment from Sponsor.