PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q4, 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
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		20/10/2016	No	Sponsor delay in amending contract.
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		19/12/2016	No	Lengthy budget and indemnity negotiation with sponsor (non-standard terms).
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.		04/01/2017	No	Delays negotiating contract.
16/LO/1318	Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBsAg clearance		13/03/2017	No	Sponsor contract omitted key clauses covering samples to be collected; site contracts team raised issue with sponsor and propose/agree on terms to be added.
11/LO/1595	Proof-of-concept study of AZD 4547 in patients with FGFR1 or FGFR2 amplified tumours	18/08/2016		No	Several patients screened within 70 days but none was 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.
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/eligible patients found yet.
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 actively screening patients but has not yet identifed any 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		13/02/2017	No	20 screening failures within 70 days from clock start.
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 looking for patients but very few are seen with disease during summer months.
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	21/09/2016	No	Study team actively looking for patients but no suitable/eligible patients found. Many patients screened; all failed.
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/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		No	Extension study; no patients completed feeder study within 70 days in order to be rolled into the extension.
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	28/03/2017	No	Study team has been actively looking for patients; 8 screening failures.
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. Screen fail percentage globally was 70.6%.
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 were very restrictive and eventually submitted amendment to HRA to try to expand potential patient pool.
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		16/01/2017	No	Study team actively screening but no suitable/eligible patients found yet.
16/EM/0376	The LEADERSHIP 301 Trial: A 12-Week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Phase 3 Trial to Evaluate the Efficacy and Safety of 2 Doses of AQX-1125 Targeting the SHIP1 Pathway in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Followed by 14 or 40-Week Extension Periods			No	11 screening failures; first patient screened within 70 days from Date Site Selected.
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)			No	Study design challenging for patients, who were unwilling to consent for this reason.
16/LO/0854	External pilot study to inform the design and conduct of the Fluids in Shock (FiSh) Trial		10/10/2016	No	11 screening failures; first patient screened within 70 days from Date Site Selected.
16/LO/1891	A Phase 2, Double-Blind, Randomized Study Evaluating the Safety, Tolerability, and Efficacy of GS-4997 in Combination with Prednisolone versus Prednisolone Alone in Subjects with Severe Alcoholic Hepatitis (AH)			No	Study opened over the summer months when cases of ARDs are less frequent; recruitment has been challenging nationally.
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		03/01/2017	No	Study team identified several patients but all were screening 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.		27/10/2016	No	Awaiting HRA to approve late amendment from Sponsor.
16/SS/0115	MK-8931-019: Long Term Safety and Efficacy Trial of MK-8931		07/11/2016	No	Extension study - no patients completed feeder study within 70 days in order to be rolled into the extension.
16/WS/0005	A PHASE 3, LONG-TERM ACTIVE TREATMENT EXTENSION STUDY OF MONGERSEN (GED-0301) IN SUBJECTS WITH CROHN?S DISEASE			No	Very stringent inclusion criteria made it extremely challenging to find eligible patients. Site recruiting on time to meet target of 4 by July 2017.
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.

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.
15/EE/0317	Does early targeted trunk training improve mobility outcome at 6 months for patients who are unable to sit unsupported at admission? A mixed method feasibility study			No	Delays in internal reviews.
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/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 (contracts).
15/LO/1232	Additive Effect of Twice Daily Brinzolamide 1% /Brimonidine 0.2% Fixed Dose Combination as an Adjunctive Therapy to a Prostaglandin Analogue			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.
16/LO/1040	The effect of L-phenylalanine on appetite			No	Staff absences (maternity leave).
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		15/03/2017	No	Required study team member not in the UK immediately after site was confirmed.
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		No	Study team unexpected leave.
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.			No	Site pharmacy had drug administration issue in relation to the blinded/unblinded study drug.
17/LO/0052	Evaluation of Uterine Patency following Sonography-guided Transcervical Ablation of Fibroids			No	Staff availability issues.
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/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/2182	A Phase III Clinical Trial of Intra-arterial TheraSphere in the Treatment of Patients with Unresectable Hepatocellular Carcinoma		25/01/2017	No	Late protocol amendment which necessitated revision of costs / contract. Patients now consented and being screened.
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		26/01/2017	No	Sponsor delays with contract. Then very challenging to identify suitable patients.
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/LO/1071	Primary Radiotherapy And DIEP flAp reconstruction		08/02/2017	No	Sponsor delays (contract).

15/LO/1120	A randomised trial of dolutegravir (DTG)-based antiretroviral therapy vs. standard of care (SOC) in children with HIV infection starting first-line or switching to second-line ART		16/02/2017	No	Sponsor delays (contract).
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.
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)		27/03/2017	No	Site awaiting site activation by Sponsor.
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		02/11/2016	No	Sponsor/CRO negotiation delays re: VAT costs.
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/0560	Can patient video testimonials augment the standard consent process? A Randomised Control Trial			No	Technical issues with Sponsor's website which displays the video required for the intervention. Study team unable to recruit as consent occurs on the same day as the intervention.
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			No	Sponsor delays in negotiating contract / costs.
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		15/12/2016	No	Delay in activating site and supplying equipment needed for recruitment.
16/LO/1854	A Phase 3, Randomized, Double-blind Study to Evaluate the Safety and Efficacy of Emtricitabine and Tenofovir Alafenamide (F/TAF) Fixed-Dose Combination Once Daily for Pre-Exposure Prophylaxis in Men and Transgender Women Who Have Sex with Men and Are at Risk of HIV-1 Infection		21/03/2017	No	Sponsor delayed site activation; then closed site without activating.
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		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/0617	A Randomised Pilot Multiple Centre Trial of Conservative versus Liberal Oxygenation Targets in Critically Ill Children		09/03/2017	No	Sponsor delays with contract and providing randomisation tool. Randomisation tool unavailable and site not able to start recruiting until 06/03/2017.
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		12/01/2017	No	Sponsor delay - postponed start of recruitment to January 2017 (site confirmed in November 2016). Site waiting for study drug to be delivered.
14/LO/1206	PLAnning Treatment For Oesophago-Gastric Cancer: a Randomised Maintenance Therapy Trial			No	Sponsor submitted late amendment; then Sponsor unavailable to perform site activation for 5 weeks after site confirmed.
15/LO/1595	Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery		25/01/2017	No	Delay in internal site reviews and approvals.
15/SC/0409	Safety and Efficacy of Abicipar Pegol in Patients with Neovascular Age-related Macular Degeneration			No	Long contract/budget negotiations between Sponsor and site. Study was closed globally 1 month after recruitment had been opened.

16/EE/0357	Efficacy and safety of opicapone in clinical practice in Parkinson?s Disease patients with wearing-off motor fluctuations			No	Long contract/budget negotiations between Sponsor and site.
16/LO/0443	A multicentre, open-label, multiple-dose study to evaluate the safety, tolerability and efficacy of UCB7665 in subjects with primary immune thrombocytopenia			No	Due to wash out period of 3 months required by this trial, the first patient could not be recruited until April 2017.
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)			No	9 patients screened but none eligible to be recruited.
16/LO/1350	OPTIC - Optical Polyp Testing for In vivo Classification		07/03/2017	No	Challenging timing for study team as end of year made access to specific clinical equipment difficult. Also restrictions on patient access to the specific endoscopy required by study. Staff unavailability.
16/LO/1584	Spectroscopy for blood perfusion monitoring			No	Strict recruitment criteria has made recruitment very challenging. PI is looking at ways of amending the recruitment strategy.
16/NE/0142	A Randomized, Open-label, Multicenter, Phase 3 study to evaluate the efficacy and safety of Avelumab (MSB0010718C) in combination with and/or following chemotherapy in patients with previously untreated epithelial ovarian cancer?		24/01/2017	No	Delays in internal reviews and approvals.
16/NE/0279	Risk-stratified sequential Treatment with Ibrutinib and Rituximab (IR) and IR-CHOP for De-novo post-transplant Lymphoproliferative disorder (PTLD)			No	Delays in internal reviews and approvals.
16/SC/0277	Point of Care Testing for Sepsis in ICU Patients: A Diagnostic Accuracy Study			No	Sponsor delay in sending study supplies to site and training site staff.
16/SC/0390	A randomized, double-blind, double-dummy, parallel-group study comparing the efficacy and safety of ofatumumab versus teriflunomide in patients with relapsing forms of multiple sclerosis			No	Strict eligibility criteria made identifying patients extremely challenging.
16/SC/0422	A PHASE 2A STUDY OF TRC105 (WITH OPTION TO ADD STANDARD DOSE BEVACIZUMAB) IN PATIENTS WITH REFRACTORY GESTATIONAL TROPHOBLASTIC NEOPLASIA (GTN)			No	GCP course refresher required.