

Research Ethics Committee Reference Number	IRAS no	Full Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Reasons for not achieving the 70 day target from receipt of valid research application to 1st patient recruited										Comments	Reasons for delay correspond to:	
					A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other			
13/LO/1115	111572	UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy In Incident Haemodialysis Patients	08/04/2015	30/04/2015												70 day target met	Neither
11/SS/0100	84669	A multicentre randomised trial to establish the effect(s) of routine administration of Fluoxetine in patients with recent stroke	21/04/2015	03/06/2015												70 day target met	Neither
11/NE/0228	72777	IoN- Is ablative radioiodine Necessary for low risk thyroid cancer patients	15/04/2015	N/A					Y					Y		Site activation delayed by 65 days post-SIV because the Sponsor required further information. Site activation 22/6/15. Difficult recruitment criteria mean that only 1 eligible patient has been identified, and that patient declined. Still no patients as at 31.03.16	Both
13/LO/1463	130983	InterAACT- An International MultiCentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease.	23/04/2015	06/05/2015												70 day target met	Neither
14/SS/1048	154401	A Phase 3b, Multi-center, Randomized-withdrawal, Placebo-controlled, Double blind, Parallel-group Trial to Compare the Efficacy and Safety of Tolvaptan (45 to 120 mg/day, Split-dose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease	01/05/2015	26/05/2015												70 day target met	Neither
13/NI/0188	140146	A single-arm trial to evaluate the effectiveness of PCI of de novo 3-vessel disease applying the SYNTAX Score II with pressure wire functional assessment and IVUS guidance, using an everolimus-eluting stent with biodegradable abluminal coating	05/05/2015	28/05/2015												70 day target met	Neither
13/YH/0229	125373	GO2: A phase III, randomised, multi-centre, prospective, controlled open-label, non-inferiority trial of alternative chemotherapy for frail and elderly patients with advanced gastric or oesophageal cancer.	12/05/2015	27/07/2015	Y				Y							Delayed site activation - 7 weeks after SIV - due to issues relating to a study amendment. In spite of this, we only missed the FPR target by 4 days, with FPR taking 17 days from site activation. The study is not recruiting as well as expected nationally.	Sponsor
14/WM/1210	164208	A Phase 3, randomized, active-controlled, open-label study to evaluate the efficacy, safety and tolerability of switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in virologically-suppressed, human immunodeficiency virus type 1 (HIV-1) infected subjects.	03/06/2015	22/06/2015												70 day target met	Neither
11/SC/0528	73866	A phase III multicentre trial of weekly induction chemotherapy followed by standard chemoradiation versus standard chemoradiation alone in patients with locally advanced cervical cancer	09/06/2015	24/09/2015												No suitable patients found in 70 day window. We aim to recruit 2 patients per year, due to tight inclusion criteria and rarity. First patient recruited 24.9.15.	Neither

13/SS/0007	115286	A multi-arm, phase 2b randomised, double-blind, placebo-controlled clinical trial comparing the efficacy of three neuroprotective drugs in secondary progressive multiple sclerosis.	10/06/2015	05/08/2015											70 day target met	Neither
14/LO/2218	161762	Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer.	19/06/2015	N/A	Y			Y					Y		Delays with recruitment due to being unable to implement an amendment without the green light from the Sponsor about costings. Amendment implementation date was 20/7/15, but approval to proceed not received from Sponsor until 14/8/15. Changes to concomitant treatment need NHS England approval - causing pharmacy delays and limiting eligible patient population. 2 screen failed and 2 declined as at 31.3.2016	Sponsor
14/SS/1087	164169	Immediate-release Tolvaptan (OPC 41061, 30 mg to 120 mg/day, Split dose) in Subjects with Autosomal Dominant Polycystic Kidney Disease	24/06/2015	14/07/2015											70 day target met; 7 patients recruited as at 31/3/16.	Neither
14/NE/1185	152820	Short duration of dual antiplatelet therapy with Synergy® II everolimus eluting stent in patients Older than 75 years undergoing percutaneous coronary Revascularization. The SENIOR trial	01/07/2015	28/08/2015											70 day target met	Neither
15/YH/0045	168195	ABLATOR Ablation Observational Registry	08/07/2015	03/08/2015											70 day target met	Neither
13/NI/0138	120046	Portic 1 study International long-term follow-up study of patients	08/07/2015	24/08/2015											70 day target met	Neither
14/YH/1269	160993	Open-label evaluation of the population pharmacokinetic profile, safety, tolerability, and efficacy of intravenous tapentadol solution for injection for the treatment of post-surgical pain in children aged from birth to less than 2 years, including preterm neonates	08/07/2015	N/A									Y		Opened in April 2015. The study is struggling nationally. No patients have met criteria. Only cohort 3 (infants under one month old) open to recruitment, making recruitment extremely difficult. Protocol amendments mean we will now be able to proceed to TMBU for recruitment as from June 2016, this should improve recruitment nationally and locally	Neither
15/LO/0684	177109	Effects of ODM-109 on respiratory function in patients with ALS. A randomised, double blind, placebo-controlled, cross-over, 3-period,	13/07/2015	07/10/2015				Y	Y						Patient consented into trial 16.9.15, but failed screening. PI also unavailable for one month when study open due to having an operation.	NHS Provider
15/LO/0075	164748	A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects	27/07/2015	10/08/2015											70 day target met	Neither
13/LO/1207	86810	StereoTactic radiotherapy for wet Age-Related macular degeneration (STAR): A randomised, double-masked, sham-controlled, clinical trial comparing low-voltage X-ray irradiation with as needed bevacizumab, to as needed bevacizumab monotherapy.	27/07/2015	07/10/2015				Y							Sponsor delays mean site wasn't activated until 21 September 2015. First available clinic capacity was 07/10/15. 70-day target missed by 2 days.	Sponsor
14/NW/1531	165328	Comparative Testing of 3 mL TransFix/EDTA Vacuum Blood Collection Tubes (TVTs) and Cyto-Chex 5 mL Blood Collection Tubes (BCTs) Part 1: Equivalence Study	06/08/2015	24/08/2015											70 day target met	Neither

13/EE/0335	137965	COOL-AMI EU CASE SERIES CLINICAL STUDY: a single-centre case series clinical study to assess the feasibility of integrating therapeutic hypothermia (TH) using the ZOLL IVTM System as an adjuvant therapy in percutaneous coronary intervention (PCI) in patients with acute myocardial infarction (AMI)	26/08/2015	26/11/2015											No eligible patients found during target timeframe. This is a novel feasibility study in acute heart attack patients only being conducted in one other Trust. The exclusion criteria rule most patients out. We attended and screened ~40 patients to include the 4 we have recruited.	Neither
14/WM/0057	144764	Multi-centre randomised controlled trial to compare the clinical and cost-effectiveness of a 'vein bypass first' with a 'best endovascular first' revascularisation strategy for severe limb ischemia due to infra-popliteal arterial disease; Bypass vs. Angioplasty in Severe Ischemia of the Leg.	19/08/2015	N/A											This study is looking for a very specific condition and a very specific patient. PI and nurse attend weekly multi-disciplinary meeting to discuss potential patients. Nurse contacts BASIL study team with weekly updates	Neither
15/SC/0280	170452	Randomised Evaluation of dabigatran etexilate Compared to warfarin in pulmonary vein ablation: assessment of an uninterrupted periprocedural anticoagulation strategy (The RE-CIRCUIT Trial)	25/08/2015	29/10/2015											70 day target met	Neither
13/EM/0459	137785	POSNOC – Positive Sentinel Node: adjuvant therapy axillary versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatments in women with early stage breast cancer who have metastases in one or two sentinel nodes.	31/08/2015	N/A											Issues relate to patients having radioactive injection on the day before primary surgery. Issue now considered to be resolving, and we have identified a potential patient for this trial. Patient still considering trial. Further 4 potential patients identified, all patients having chemo first.	Both
14/SC/1030	155423	A randomised controlled trial to compare the clinical effectiveness and safety of gentamicin and ceftriaxone in the treatment of gonorrhoea.	14/09/2015	28/10/2015											70 day target met	Neither
15/LO/0881	177217	A Phase III Multicenter, Double Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-149A One Daily Versus ATRIPLA Once-Daily in Treatment Naive HIV - 1 Infected Subjects	28/09/2015	16/10/2015											70 day target met	Neither
15/NW/0505	177219	A Phase III Multicenter, Open-Label, Randomized Study to Evaluate a Switch to MK-1439A in HIV-1-Infected Subjects Virologically Suppressed on a Regimen of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	28/09/2015	07/01/2016										Y	Inclusion and exclusion criteria narrowed the number of eligible patients and there was a higher than expected number of patients not eligible due to adherence issues. Patients did not want to switch their meds.	Neither
14/SC/0171	120104	A Phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin in disease recurrence and survival after primary therapy in common non-metastatic solid tumours.	30/09/2015	13/10/2015											70 day target met	Neither
15/ES/0007	164449	Prescribing asthma controller medication according to gene status to improve quality of life in children and young people with asthma	01/10/2015	N/A										Y	Unable to find eligible patient within timeframe. One document (Parent PIS) was amended in early November, causing a recruitment delay	Sponsor
15/LO/0460	159277	SSAT058: A phase IV, open-label, 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)	03/11/2015	29/12/2015											70 day target met	Neither

15/LO/1324	181497	AMPLATZER Amulet Observational Post-Market Study	06/11/2015	11/11/2015															70 day target met	Neither
15/LO/1239	184169	A Phase 3, randomized, active-controlled, double-blind study to evaluate efficacy and safety of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once daily fixed dose combination regimen versus a regimen consisting of darunavir/cobicistat fixed dose combination coadministered with emtricitabine/tenofovir disoproxil fumarate fixed dose combination in antiretroviral treatment-naïve human immunodeficiency virus type 1 infected subjects.	16/11/2015	05/01/2016															70 day target met	Neither
15/SC/0085	171841	Acetic Acid guided biopsies in Barrett's surveillance for neoplasia detection versus non-targeted biopsies (Seattle protocol): A feasibility study for a randomised tandem endoscopy trial.	25/09/2015	02/12/2015															70 day target met	Neither
15/NW/0090	162325	Emergency Treatment with Levetiracetam or Phenytoin in Status Epilepticus in Children (ECLIPSE) – an open label randomised controlled trial	24/11/2015	28/01/2016															70 day target met	Neither
14/LO/1291	148513	A phase II randomised study evaluating the biological and clinical effects of the combination of palbocicb with letrozole as neoadjuvant therapy in post-menopausal women with ER+ primary breast cancer.	25/11/2015	15/01/2016															70 day target met	Neither
09/H0106/83	20419	ORAL INSULIN FOR PREVENTION OF DIABETES IN PATIENTS AT RISK FOR TYPE 1 DIABETES MELLITUS	01/12/2015	N/A															Patient was lined up on 8 December but declined to take part. Study closed to recruitment on 31 December 2015, 40 days in advance of the FPR target date.	Neither
14/LO/1206	154429	Planning treatment for oesophago-gastric cancer: a randomised maintenance therapy trial	01/12/2015	16/02/2016															6 patients screen failed, 2 on study as at 31/3/2016. FPR target missed by 7 days.	Neither
15/NW/0261	165083	Safety and Performance Registry for an all-comers patient population with the Limus Eluting Orsiro Stent System Within daily clinical practice - III (UK & Ireland Satellite)	09/12/2015	04/02/2016															70 day target met	Neither
15/NW/0543	181870	A Multicentre, Randomised, Double-blind, Placebo-controlled, Phase 3 Study Evaluating the Efficacy and Safety of Two Doses of Anifrolumab in Adult Subjects with Active Systemic Lupus Erythematosus	28/10/2015	N/A															2 patients initially screened but found to be ineligible. 2 patients in pipeline to screen in the next month. Training issues with PI/staff led to delay in opening.No patients found to be suitable - some patients not happy with the long placebo element of the study.	Both
14/EM/0121	143800	An open label randomised multicentre controlled trial of RTXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis	19/11/2015	N/A															Rare disease group	Neither
13/LO/1943	136525	UK Peritoneal Dialysis Outcomes and Practice Patterns Study	27/10/2015	23/11/2015															70 day target met	Neither
15/SC/0257	173423	Palliative long-term abdominal drains versus repeated drainage in individuals with untreatable ascites due to advanced cirrhosis : a feasibility randomised controlled trial	09/10/2015	11/01/2016															No eligible patients identified within target timeframe. Difficult to recruit to as this is a very sick patient group. 2 patients recruited as at 31/3/16.	Neither

