

Research Ethics Committee Reference Number	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/dented	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/0145	A multicentre phase III randomised controlled single masked clinical trial to test the clinical efficacy of LightMasks at preventing dark adaptation in the treatment of early diabetic macular oedema (CLEOPATRA)	09/01/2015	25/03/2015						Y						Research Nurse retired and there has been a delay in recruiting a replacement which has caused delays with recruitment. Missed 70 deadline by 5 days.	NHS Provider
14/LO/0203	Clinical Efficacy and Mechanistic Evaluation of Aflibercept for Proliferative Diabetic Retinopathy. A Multicentre Phase IIb	08/01/2015	10/06/2015						Y						Research Nurse retired and there has been a delay in recruiting a replacement which has caused delays with recruitment	NHS Provider
12/NW/0361	A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II)	19/01/2015	03/03/2015												70 day target met	Neither
14/LO/1443	A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in End Stage Renal Disease Subjects on Stable Dialysis	19/01/2015	N/A				Y								15 patients approached but all declined. One patient consented 4/3/15, but within days of randomisation the Sponsor said they were not included because they could not get hold of the required dose of the drug. Still no patients recruited as at 31.12.15	Sponsor
09/H0709/56	Plasma Exchange and Glucocorticoid Dosing in the Treatment of Anti-neutrophil Cyttoplasm Antibody Associated Vasculitis: an international Randomised Controlled Trial	13/01/2015	26/01/2015												70 day target met	Neither
13/NE/0336	A randomised, placebo controlled trial of extraoesophageal reflux treatment in the management of upper respiratory symptoms. [TOPPITS: Trial of Proton Pump Inhibitors in Throat Symptoms]	04/02/2015	08/04/2015												70 day target met	Neither
14/LO/1435	A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of CHS-0214 Versus Enbrel® in Subjects With Rheumatoid Arthritis and Inadequate Response to Treatment With Methotrexate	12/02/2015	N/A				Y			Y					Closed early by Sponsor when global recruitment target was met. Closure was 2.5 weeks in advance of the FPR target date.	Sponsor
14/LO/0117	Ablation Versus Anti-arrhythmic Therapy for Reducing All Hospital Episodes from Recurrent Atrial Fibrillation	17/02/2015	24/04/2015												70 day target met	Neither
14/LO/1493	A phase IV open-label, multi-centre, randomised, dual-arm, pilot study to assess the feasibility of switching individuals receiving Efavirenz with continuing Central Nervous System (CNS) toxicity, to Dolutegravir	06/01/2015	23/01/2015												70 day target met	Neither
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)	20/01/2015	06/03/2015												70 day target met	Neither

13/YH/0315	A randomized, parallel group, open-label, multicentre study to investigate the efficacy and safety of oral BAY 85-3934 and active comparator (darbeopetin alfa) in the maintenance treatment of anemia in pre-dialysis subjects with chronic kidney disease on darbeopetin treatment in Europe and Asia Pacific.	25/02/2015	N/A												Difficult recruitment criteria. Patients not eligible. Recruitment closed by sponsor 10/6/15.	Neither
13/WA/0004	Oral steroids for the resolution of otitis media in children study (OSTRICH)	04/02/2015	N/A												Difficult study to recruit to. No parent willing to put their child on steroids. All opted for surgery as preferential route. Following talks with main site, PI closed site to recruitment.	Neither
14/LO/1043	A Multicentre Phase III Doublemasked Randomised Controlled NonInferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for or Macular Oedema due to Central Retinal Vein Occlusion (CRVO).	30/03/2015	22/04/2015												70 day target met	Neither
13/LO/1115	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	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	IoN- Is ablative radioiodine Necessary for low risk thyroid cancer patients	15/04/2015	N/A												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 31.12.15	Both
13/LO/1463	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	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	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	G02: 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												Missed 23.7.15 FPR target by 4 days	Neither

14/WM/1210	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	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							Y					No suitable patients found in 70 day window. First patient recruited 24.9.15	Neither
13/SS/0007	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	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 commitment treatment need NHS England approval - causing pharmacy delays and limiting eligible patient population. 1 screen fail and 2 declined as at 31.12.15	Sponsor
14/SS/1087	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.	Neither
14/NE/1185	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	ABLATOR Ablation Observational Registry	08/07/2015	03/08/2015												70 day target met	Neither
13/NI/0138	Portic I study International long-term follow-up study of patients	08/07/2015	24/08/2015												70 day target met	Neither
14/YH/1269	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. Eligible patients screened in July and August have declined to participate. 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	Neither
15/LO/0684	Effects of ODM-109 on respiratory function in patients with ALS. A randomised, double blind, placebo-controlled, cross-over, 3-period,	13/07/2015	N/A				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	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	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	Comparative Testing of 3 mL TransFix/EDTA Vacumm 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	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						Y					Target missed because no eligible patients found during 70 day period	Neither
14/WM/0057	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						Y					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	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	POSNO – Positive Sentinel Node: adjuvant therapy alone 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						Y					On-going issues re patients having radioactive injection on the day before primary surgery. Issue now considered to be resolving. 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	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	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 Naïve HIV - 1 Infected Subjects	28/09/2015	16/10/2015											70 day target met	Neither
15/NW/0505	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	N/A							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	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	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	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	AMPLATZER Amulet Observational Post-Market Study	06/11/2015	11/11/2015											70 day target met	Neither
15/LO/1239	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	16/11/2015	N/A											Still within target timeframe as at 31/12/15	Neither
15/SC/0085	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	Emergency Treatment with Levetiracetam or Phenytoin in Status Epilepticus in Children (ECLIPSE) – an open label randomised controlled trial	24/11/2015	N/A											Still within target timeframe - 70 day target date is 2/2/16	Neither
14/LO/1291	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	N/A											Still within target timeframe as at 31/12/15	Neither
09/H0106/83	ORAL INSULIN FOR PREVENTION OF DIABETES IN PATIENTS AT RISK FOR TYPE 1 DIABETES MELLITUS	01/12/2015	N/A							Y				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	Planning treatment for oesophago-gastric cancer: a randomised maintenance therapy trial.	01/12/2015	N/A											No patients recruited yet - 70 day target date is 9/2/16	Neither
15/NW/0261	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	N/A											No patients recruited yet - 70 day target date is 17/2/16	Neither
15/NW/0543	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				Y	Y		Y				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	Both
14/EM/0121	An open label randomised multicentre controlled trial of RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis	19/11/2015	N/A									Y		No patients recruited yet - 70 day target date is 28/1/16	Neither
13/LO/1943	UK Peritoneal Dialysis Outcomes and Practice Patterns Study	27/10/2015	23/11/2015											70 day target met	Neither
15/SC/0257	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	N/A						Y					No eligible patients identified within target timeframe	Neither
14/LO/2137	Anti-Influenza Hyperimmune Intravenous Immunoglobulin Clinical Outcome Study	16/12/2015	N/A											No patients recruited yet - 70 day target date is 28/2/16	Neither
14/NW/1076	Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma (RESCUE-ASDH)	22/10/2015	01/12/2015											70 day target met	Neither
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	16/10/2015	30/11/2015											70 day target met	Neither