

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			
14/NE/1185	152820	Short duration of dual antiplatelet therapy with SynNergy® 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 I 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-Naive 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 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	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							Y					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							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	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 ale 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	11/04/2016						Y					Initially there were issues relating to patients having radioactive injection on the day before primary surgery. This issue was resolved, but patients identified needed to have chemo prior to joining trial.	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.	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 Levetiracetram or Pheytoin 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						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	154429	Planning treatment for oesophago-gastric cancer: a randomised maintenance therapy trial.	01/12/2015	16/02/2016						Y					Several patients screen failed prior to first patient being recruited. 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			Y	Y			Y				2 patients initially screened but found to be ineligible. 2 further patients screen failed but potentially 1 more patient for screening. Training issues with PI/staff led to delay in opening. 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 RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis	19/11/2015	N/A								Y			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						Y					No eligible patients identified within target timeframe. Difficult to recruit to as this is a very sick patient group.	Neither
14/LO/2137	164744	Anti-Influenza Hyperimmune Intravenous Immunoglobulin Clinical Outcome Study	16/12/2015	N/A					Y		Y				231 patients screened. 24 potentially eligible but not recruited due to planned discharges, unable to consent, declined, or having sufficient staff levels for IMP administration or sample processing .	NHS Provider
14/NW/1076	156623	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	170476	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
14/LO/1937	163652	A randomised comparison of femtosecond laser assisted vs manual phacoemulsification cataract surgery for adults with visually significant cataract	18/01/2016	14/03/2016											70 day target met	Neither
15/EE/0322	183313	A phase 2, double-blind, randomized, placebo-controlled study to investigate possible drug-drug interactions between clobazam and cannabidiol (GWP42003-P)	13/01/2016	26/04/2016							Y				Difficult inclusion criteria. Patients identified but they declined due to intense early protocol.	Neither
14/SC/1372	162784	RIVER research in viral eradication of HIV reservoirs	21/01/2016	28/01/2016											70 day target met	Neither

14/NW/1067	137736	Phase IIa, Randomised, Controlled, Open-Label Trial of Rosuvastatin for the Prevention of Aminoglycoside-Induced Kidney Toxicity in Children with Cystic Fibrosis	26/01/2016	03/05/2016														Patients were identified and approached within the target timeframe, but they declined to participate.	Neither
13/LO/1401	128104	An evaluation of a novel imaging based complex diagnostic and therapeutic pathway intervention for men who fail radiotherapy for prostate cancer	28/01/2016	16/02/2016														70 day target met	Neither
15/LO/0564	173148	ARMOR3-SV: A Phase 3, Randomized, Open-Label, Multi-Center, Controlled Study of Galeterone Compared to Enzalutamide in Men Expressing Androgen Receptor Splice Variant-7 mRNA (AR-V7) with Metastatic (M1) Castrate Resistant Prostate Cancer (CRPC)	04/02/2016	N/A														Rare subset of patients eligible for study - prescreening tissue sent on 6 patients, none eligible at 30/6/2016.	Neither
15/LO/1892	185335	EBC MAIN Trial THE EUROPEAN BIFURCATION CLUB LEFT MAIN STUDY; A RANDOMISED COMPARISON OF SINGLE VERSUS DUAL STENT IMPLANTATION FOR DISTAL LEFT MAIN TRUE CORONARY BIFURCATION LESIONS	09/02/2016	09/02/2016														70 day target met	Neither
15/LO/2106	178045	The Absorb Bifurcation Coronary study (ABC One); A randomised trial of provisional T-stenting using absorb bio-absorbable scaffolds in coronary bifurcations - Pilot study	16/02/2016	24/02/2016														70 day target met	Neither
11/LO/2019	76882	TOPARP: Phase II Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer	26/02/2016	14/04/2016														70 day target met	Neither
14/LO/0807	148365	A randomised multi-centre non-blinded prospective parallel group trial of total ankle replacement (TAR) versus ankle arthrodesis in the treatment of patients with end stage ankle osteoarthritis, comparing clinical trials and cost-effectiveness.	04/03/2016	N/A														As at 30.6.16, 3 eligible patients seen but nobody recruited. There is a national recruitment problem for this trial. PRH Research Office has sent posters to every local GP practice manager, and has been in touch with the CCG to add poster to their web site.	Neither
15/LO/1302	169660	Ovarian Cancer Trials of Weekly Paclitaxel - Umbrella Study A Randomised, Phase II Umbrella Trial of a Weekly Paclitaxel +/- Novel Agents in Platinum-Resistant Ovarian Cancer- Non Commercial Academic Study	07/03/2016	14/03/2016														70 day target met	Neither
11/LO/1261	74423	INOATYON: Phase III international, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 612 months of last platinum	14/03/2016	04/04/2016														70 day target met	Neither
15/LO/0217	163086	Randomised double blind placebo-controlled trial. Remote Ischaemic Conditioning (BP Inflation) in patients with STEMI and undergoing PPCI	16/03/2016	04/05/2016														70 day target met	Neither
15/LO/1923	187061	Evaluation of the Safety and Performance of the Twelve Transcatheter Mitral Valve Replacement System in High Risk Patients with Severe Symptomatic Mitral Regurgitation	17/03/2016	06/04/2016														70 day target met	Neither
15/LO/0638	176799	Paclitaxel assisted balloon Angioplasty of Venous stenosis in haemodialysis access. A multicentre double-blind randomised controlled trial in haemodialysis patients with a stenosis in a native arteriovenous	23/03/2016	N/A														One patient consented but ineligible on screening (19.5.16) Further patient booked in 21.7.16	Neither
15/EM/0095	166503	A Phase III, open label, multicentre randomised clinical study comparing Acelarin (NUC-1031) with Gemcitabine in patients with metastatic pancreatic carcinoma	22/03/2016	N/A														2 patients screen failed, 1 declined as at 30.6.16	Neither

15/EE/0010	138590	Phase III trial in intrahepatic cholestasis of pregnancy (ICP) to evaluate ursodeoxycholic acid (UDCA) in improving perinatal outcomes	23/03/2016	N/A													10 Screened as of 30/06/2016. 2 not eligible, 7 declined and 1 uncertain and for review on 15/7/2016.	Neither	
15/LO/1600	182262	A PHASE II, OPEN-LABEL, RANDOMIZED STUDY OF GDC-0810 VERSUS FULVESTRANT IN POSTMENOPAUSAL WOMEN WITH ADVANCED OR METASTATIC ER+/HER2-BREAST CANCER RESISTANT TO AROMATASE INHIBITOR THERAPY	29/03/2016	11/05/2016													70 day target met	Neither	
16/LO/0036	195359	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Abacavir/Dolutegravir/Lamivudine in HIV-1 Infected, Antiretroviral Treatment-Naive Adults	29/03/2016	22/04/2016													70 day target met	Neither	
16/LO/0026	195795	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	29/03/2016	12/04/2016													70 day target met	Neither	
16/LO/0019	180161	Bone Evaluation in women over 40 who Switch from Truvada/NNRTI to Trimeq	29/03/2016															Low number of potential patients. <10% women in clinic cohort. Patients seen every 6 months to once a year.	Neither
13/EM/0073	120873	The Role of Glasses Wearing in Amblyopia Treatment. A randomised controlled multi-centre trial	29/03/2016	N/A														PI has offered the study to several patients but they have not agreed to go on to the study. RN has made a recruitment plan which involves introducing the study at a different time point to ease burden for patients. No patients yet consented.	Neither
15/EE/0421	191851	Pomalidomide in Relapsed and Refractory Multiple Myeloma	29/03/2016	N/A														Site activation delayed by 21 days post-SIV due to Sponsor issues. 2 patients screen failed as at 30.6.16.	Sponsor
16/EM/0007	190428	Evaluate Rivaroxaban in Patients after Successful Transcatheter Aortic Valve Implantation	29/03/2016	24/06/2016	Y													SSI submitted early (29.3.16) due to changeover to HRA. Subsequently the sponsor did not issue the study drugs to pharmacy in time.	Sponsor
16/LO/0039	195230	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Switching from a Regimen containing Dolutegravir and ABC/3TC, or a Fixed Dose Combination (FDC) of ABC/DTG/3TC to a FDC of GS-9883/F/TAF in HIV 1 Infected Subjects who are Virologically Suppressed	29/03/2016	03/05/2016														70 day target met	
14/LO/1559	152866	Sorin Universal Registry on Aortic Valve Replacement	29/03/2016	07/06/2016														70 day target met	

16/LO/0240	199083	An open-label, prospective, non randomised, multicentre study to evaluate clear skin effect on health-related quality of life outcomes at 16 and 52 weeks in patients with moderate to severe plaque psoriasis treated with secukinumab 300 mg s.c. with or without previous exposure to systemic therapy	29/03/2016	03/05/2016											70 day target met	
15/NW/0171	168748	A randomised, double blind, placebocontrolled trial of a twoweek course of dexamethasone for adult patients with a symptomatic chronic subdural haematoma	29/03/2016	27/05/2016											70 day target met	
15/LO/0539	166304	A Randomised phase II trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder	29/03/2016	N/A	Y					Y					SSI submitted early (29.3.16) due to changeover to HRA. Study still not activated as at 30/6/16 as the QA requirement is that there should be 3 trained radiographers, but to date only one is part-trained.	NHS Provider
15/LO/0928	170943	Mitral Valve Repair Clinical Trial	29/03/2016	N/A	Y					Y					SSI submitted early (29.3.16) due to changeover to HRA. Subsequent to NHSP, the sponsor the stated they needed to obtain MHRA approval, having previously said they didn't need it. This was issued mid June and it still hasn't been possible to arrange an SIV	Sponsor
15/LO/2124	192795	A Randomized Multicenter Pivotal Study of CDX-011 (CR011-vcMMAE) in Patients with Metastatic, GPNMB Over-Expressing, Triple-Negative Breast Cancer	29/03/2016	N/A	Y										SSI submitted early (29.3.16) due to changeover to HRA. 3 patients have consented for pre screening tissue analysis, and we are awaiting results to see if they are eligible.	Neither
GTAC182	64830	A Randomised Parallel Group Double-Blind Phase II Trial to Assess the Activity of TroVax® (MVA-5T4) Versus Placebo in Patients with Relapsed Asymptomatic Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer	29/03/2016	N/A	Y						Y				SSI submitted early (29.3.16) due to changeover to HRA, SIV 31/5/16, study not activated until 21/6/16 due to missing delegation log information. No patient recruited as at 30.6.16 but planned for 18.7.16.	NHS Provider
16/NI/0034	194752	The Medtronic CoreValve™ Evolut R™ FORWARD Study	29/03/2016	N/A	Y										SSI submitted early on 29.3.16 due to changover to HRA Approval. We were not in a position to be able to issue R&D until 22/6/16.	Neither
15/EE/0435	191299	Stratified Treatment Optimisation for HCV-1 (STOPHCV-1)	29/03/2016	27/06/2016	Y										SSI submitted early on 29.3.16 due to changeover to HRA Approval. We were not in a position to be able to issue R&D permission until 21/6/16, and first patient was subsequently recruited within 1 week.	Neither
15/LO/2087	145273	Prospective, Randomised, Fellow Eye Study evaluating correlation between Ciliary Sulcus Anatomy with other Ocular Parameters using Ultrasound Biomicroscopy after horizontal or vertical placement of the intraocular lens in the capsular bag during standard cataract surgery.	29/03/2016		Y										SSI submitted early on 29.3.16 due to changeover to HRA Approval. We were not in a position to be able to issue R&D permission until 16/6/16	Neither