

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/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, OpenLabel Trial of Rosuvastatin for the Prevention of Aminoglycoside-Induced Kidney Toxicity in Children with Cystic Fibrosis	26/01/2016	03/05/2016											Y		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							Y						Rare subset of patients eligible for study - prescreening tissue sent on 6 patients, none eligible at 30/6/2016. Study closed by sponsor 25/7/16.	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	04/08/2016											Y		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 the poster to their web site. First patient recruited 4/8/16.	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	NOVATYON: 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 fistula.	23/03/2016	21/07/2016						Y					Two patients were randomised out of the 5 patients screened - patients consented but we only knew if they were eligible once they were in theatre.	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						Y					5 patients approached, 2 consented, all screen fails as at 31/12/2016	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							Y				22 patients screened as at 31/12/16. 6 not eligible. 16 patents declined to participate for various reasons. Senior research nurses attended WebEx on 30/9/16 with all participating sites, looking at approaches to recruitment and barriers and has enlisted help from the CI to tackle this problem	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/NRTI to Truemeq	29/03/2016	11/07/2016						Y					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							Y				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 (as at 31.12.16).	Neither
15/EE/0421	191851	Pomalidomide in Relapsed and Refractory Multiple Myeloma	29/03/2016	N/A					Y			Y			Site activation delayed by 21 days post-SIV due to Sponsor issues. 6 patients screen failed/declined as at 31.12.16; subsequent change in treatment pathway means no longer as interesting for patients. Drug became available through the cancer drugs fund and so study became less attractive	Sponsor

16/EM/0007	190428	Evaluate Rivaroxaban in Patients after Successful Transcatheter Aortic Valve Implantation	29/03/2016	24/06/2016	Y				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	Neither
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	12/01/2017	Y				Y							SSI submitted early (29.3.16) due to changeover to HRA. Study still not activated as at 31/12/16 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	26/07/2016	Y				Y							SSI submitted early (29.3.16) due to changeover to HRA. Subsequent to NHSP, the sponsor stated they needed to obtain MHRA approval, having previously said they didn't need it. This was issued mid-June but it wasn't possible to arrange an SIV until late July.	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	20/09/2016	Y							Y				SSI submitted early (29.3.16) due to changeover to HRA. 6 patients consented for pre screening tissue analysis, 3 screen failed, 1 on study, 2 awaiting pre screen 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	04/07/2016	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. H&S Executive approval also required for study set up. 1st patient recruited 4/7/2016.	NHS Provider
16/NI/0034	194752	The Medtronic CoreValve™ Evolut R™ FORWARD Study	29/03/2016	27/07/2016	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 approval until 22/8/16. First patient recruited 26/7/16, so within target timeframe from NHSP.	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	12/07/2016	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. First patient recruited 12/7/16, so within target timeframe from NHSP.	Neither
15/LO/0769	155035	Left Atrial Appendage Occlusion Study III	29/03/2016	N/A					Y	Y					Sponsor delay with setup, due to waiting for an amendment to go through. Delay initially at site as surgeon (PI) broke his hand. Practice has changed since we were approached, so we may not be able to recruit.	Both