

Research Ethics Committee Reference Number	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			
09/H0718/40	Study on Pharmacokinetics of newly developed Antiretroviral agents in HIV-infected pregNAnt women (PANNA).	07/02/2013	05/09/2013				Y						Y		Delayed due to Sponsor not being ready to set up satellite site. SSI submitted February; SIV not until June. Only 1-2 recruits expected nationwide. No pregnant women available locally within the target timeframe.	Sponsor
10/H1307/99	TRACTISS: A randomized double blind placebo controlled clinical TRIal of anti-B-Cell Therapy In patients with primary Sjögren's Syndrome	09/05/2013	31/10/2013								Y				4 patients screened before target date. All failed due to being unable to fulfil a baseline procedure.	Neither
11/AL/0163	PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples	22/04/2013	21/06/2013												70 day target met	
11/LO/0043	Weekly Chemotherapy in Ovarian Cancer v2.0	04/03/2013	19/09/2013				Y								Delayed confirmation from Sponsor due to query about lab accreditations.	Sponsor
11/LO/1570	Cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) versus gemcitabine, cisplatin and methyl prednisolone (GEM-P) in the first line treatment of T-cell Lymphoma, a multicentre randomise	26/04/2013	N/A	Y							Y				Delayed in obtaining SSA exemption for CISC. No eligible patients seen in target timeframe.	NHS Provider
11/SC/0398	The Contact PVI Study Does assessment of tissue contact during RF ablation using the St. Jude Medical™ Ensite™ Contact™ system increase rates of longterm pulmonary vein isolation? A prospective randomised study.	21/05/2013	-				Y				Y				Sponsor delay in training site staff. No patients recruited yet.	Sponsor
12/LO/0491	Surgical Replacement & Transcatheter Aortic Valve Impantation SURTAVI	11/12/2012	-				Y								Issues with the surgical risk score - sponsor had to complete an amendment so more patients could be recruited.	Sponsor
12/LO/1331	Preoperative treatment of a low haemoglobin in cardiac surgery: pragmatic open-label randomised controlled trial to compare treatment using intravenous iron plus darbepoetin versus standard care.	17/01/2013	18/04/2013	Y							Y				Pharmacy approval delay	NHS Provider
12/LO/1409	A prospective, observational study to examine the effects of ageing on the clinical outcomes of people living with HIV in England and Ireland.	03/05/2013	09/07/2013												70 day target met	
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	10/05/2013	25/10/2013				Y								Sponsor delay in supplying drug. Decided not to initiate site until August.	Sponsor
12/LO/1717	AN OPEN LABEL RANDOMISED PHASE II STUDY COMPARING AZD2014 VERSUS EVEROLIMUS IN PATIENTS WITH ADVANCED METASTATIC RENAL CANCER AND PROGRESSION ON VEGF TARGETED THERAPY	20/05/2013	04/07/2013												70 day target met	
12/LO/1753	Using expressive writing interventions to promote health in women after birth	03/04/2013	04/04/2014				Y	Y							Study material received late as delayed until Sponsor was able to print it; Research nurse recruited 11/11/13	Both
12/NI/0146	A Phase 3 Randomized, Double-Blind, Placebo-Controlled study of the safety and effectiveness of Immune Globulin Intravenous (Human), 10% solution (IVIG, 10%) for the treatment of mild to moderate Alzheimer's Disease (AD).	14/03/2013	01/05/2013												70 day target met	

12/NW/0105	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Adaptive Design Study of the Efficacy, Safety, and Tolerability of a Single Infusion of MK-3415 (Human Monoclonal Antibody to Clostridium difficile toxin A), MK-6072 (Human Monoclonal Antibody to	22/04/2013	02/07/2013												Following the SIV, there was month's delay in recruitment due to a delay with drug delivery. Despite this, we recruited our 1st patient on day 71, i.e. 1 day past the target date.	Sponsor	
12/NW/0214	TAILoR – (TelmisArtan and InsuLin Resistance in HIV): A Dose-Ranging Phase II Randomised Open-Labelled Trial of Telmisartan as a strategy for the Reduction of Insulin Resistance in HIV-Positive Individuals on Combination Antiretroviral Therapy (cART)	10/05/2013	24/10/2013										Y		Delay is providing contract and giving green light to recruit	Sponsor	
12/NW/0723	A multi-centre, open-label, long term safety extension of phase II studies ABE4869g and ABE4955g in patients with mild to moderate Alzheimer's Disease.	25/04/2013	04/07/2013												70 day target met		
12/WS/0305	A PROSPECTIVE RANDOMIZED COMPARISON OF THE BIOFREEDOM BIOLIMUS A DRUG COATED STENT VERSUS THE GAZELLE BARE METAL STENT IN PATIENTS AT HIGH RISK FOR BLEEDING	16/04/2013	28/06/2013										Y		1st patient seen was recruited, 3 days past 70 day target	NHS Provider	
13/EE/0038	Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial	24/05/2013	10/09/2013											Y	Time lag between NHS permission and SIV dates. No eligible patients were found before the 70 day target.	Neither	
13/LO/0033	Genentech GO28509-PEGGY: A PHASE II, randomized STUDY OF paclitaxel with GDC-0941 versus paclitaxel with placebo IN PATIENTS WITH LOCALLY RECURRENT OR METASTATIC BREAST CANCER	18/03/2013	08/10/2013											Y	Several patients failed screening so unable to find eligible patients within target time	Neither	
13/LO/0277	The 4 Mountains Test of spatial memory: evaluation of diagnostic sensitivity for mild cognitive impairment due to Alzheimer's disease.	07/05/2013	06/08/2013											Y	No eligible patients screened during the target timeframe	Neither	
13/LO/0613	Multimodal imaging of frontal lobe dementias.	20/06/2013	13/08/2013												70 day target met		
13/LO/0621	The 4 Mountains Test of spatial memory for diagnosis of early Alzheimer's disease: evaluation of diagnostic specificity.	07/06/2013	05/08/2013												70 day target met		
11/LO/1596	The percutaneous Coronary Intervention prior to transcatheter aortic Valve implantation (ACTIVATION) trial	25/06/2013	25/02/2014												Y	IRMER approval delay. SIV date delay (more than 6 weeks after NHS permission). Rare disease with only limited clinics at BSUH.	Both
11/NW/0338	A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardio	05/07/2013	N/A										Y	Y	PIC sites not identified / set up, then study withdrawn by Sponsor	Sponsor	
12/EE/0230	An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCA-associated vasculitis	30/07/2013	-												Y	More than 1 month between NHS permission and SIV dates (1/10/13). No eligible patients identified yet.	Both
12/EE/0274	Tranexamic Acid for the treatment of significant traumatic brain injury: an international, randomised, double blind, placebo controlled trial.	19/06/2013	17/12/2013											Y	First eligible patient seen was recruited	Neither	
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH-2	19/06/2013											Y	Y	Pharmacy approval delay and SIV date delay. No suitable patients screened within target timeframe.	Both	

12/LO/1534	A Multicentre Prospective Open-label Randomised Clinical Trial Comparing the Efficacy of Fixed versus PRN dosing of 700 µg Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) in patients with refractory diabetic macular oedema.	14/06/2013	09/10/2013				Y	Y					Sponsor delays with SIV and 'green light' dates. Delays also due to site personnel and BSUH staff on A/L.	Both
12/LO/1545	Medtronic CoreValve® ADVANCE DA Study	20/06/2013	02/08/2013										70 day target met	
12/SW/0206	Accuracy and cost-effectiveness of dynamic contrast enhanced computed tomography in the characterisation of solitary pulmonary nodules	29/07/2013	22/11/2013	Y			Y						Not opened by sponsor until 25/9/13 as they requested two SIVs (18.7.13 & 25.9.13)	Sponsor
12/SW/0378	Effect of Bivalirudin on Aortic Valve Intervention outcomes 2/3	18/09/2013	06/01/2014							Y	Y		More than 4 weeks between NHS permission and SIV dates. Rare disease with only limited clinics at BSUH	Neither
12/WM/0001	A randomised controlled trial of standard-of-care wound management versus negative pressure wound therapy in the treatment of adult patients with an open fracture of the lower limb	14/06/2013	12/08/2013										70 day target met	
13/EE/0102	PIVOT Neurocognitive function sub-study v1.0	08/05/2013	19/08/2013		Y		Y					Y	Suspension was due to Sponsor MHRA disagreement over study classification as CTIMP. London scanning unit was not ready.	Both
13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects	04/06/2013	No patients recruited									Y	PI sickness and short recruitment period so withdrew from study	Neither
13/LO/0314	Predictors of progression from mild cognitive impairment to dementia: brain functional network studies.	21/06/2013	05/08/2013										70 day target met	
13/LO/0572	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Tre	01/07/2013	25/07/2013										70 day target met	
13/LO/0574	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Tre	01/07/2013	13/08/2013										70 day target met	
13/LO/0821	A Phase 3 Open-label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single-Tablet Regimen in HIV-1 Positive Patients with Mild to Moderate Renal Impairment	16/07/2013	28/11/2013				Y			Y			Sponsor delayed the SIV. No eligible patients seen within target timeframe.	Sponsor
13/LO/0830	Phase 3 open label study evaluating the efficacy and safety of pegylated interferon lambda-1a, in combination with ribavirin and daclatasvir, for treatment of chronic HCV infection with treatment naive genotypes 1, 2, 3 or 4 in subjects co-infected with H	19/07/2013	30/09/2013	Y						Y			Delayed opening as REC approval of new protocol not received until 9/9/13. Despite this, the 1st patient was recruited 3 days after 70 day target. Several patients declined to participate before this.	Sponsor
13/NW/0002	Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL® Haemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery	24/06/2013	28/11/2013				Y				Y		Sponsor delays with contract and with staff training. Not open to recruitment until 10/10/13.	Sponsor

12/WA/0230	Radiotherapy after Oesophageal Cancer Stenting Study	02/12/2013	27/02/2014												SIV moved from 28.1.14 to 18.2.14 due to last-minute lack of availability of site staff.	NHS Provider
13/EE/0173	Assessment of the St. Jude Medical Portico™ Re-sheathable Aortic Valve System – Alternative Access (Portico ALT EU)	10/07/2013	-	Y			Y								Delayed IRMER approval. Sponsor did not have the equipment to give out to sites	Both
13/LO/0908	A Phase 2, Single-Arm, Open-Label, Multicenter Study of the Clinical Activity and Safety of Enzalutamide in Patients With Advanced, Androgen Receptor-Positive, Triple-Negative Breast Cancer	16/01/2014	19/03/2014												70 day target met	
12/EE/0445	A randomised double-blind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with anaemia undergoing major open abdominal surgery	20/01/2014	N/A							Y					No eligible patients have been screened	Neither
13/SC/0016	Randomized open label study of oral versus intravenous antibiotic treatment for bone and joint infections requiring prolonged antibiotic treatment: Multi-centre study	06/02/2014	08/04/2014												70 day target met	
11/WS/0118	Safety and Efficacy assessment of Monoprost® (unpreserved latanoprost) in comparison with Lumigan® 0.01 % and Lumigan® 0.03% UD, in patients with primary open angle glaucoma or ocular hypertension, stabilized by Lumigan® 0.01 % with ocular surface intoler	14/02/2014	N/A												No patients recruited yet. 70 day target 25/04/2014	
13/EM/0349	A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer.	10/02/2014	N/A												No patients recruited yet. 70 day target 21/04/2014	
13/YH/0389	52 WEEK, PHASE 3 DOUBLE-BLIND, RANDOMIZED, PLACEBOCONTROLLED, PARALLEL-GROUP STUDY TO ASSESS THE EFFICACY, SAFETY AND TOLERABILITY OF PF-04950615 IN SUBJECTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.	19/03/2014	N/A												No patients recruited yet. 70 day target 28/05/2014	
13/LO/1795	A double-blind, randomized, placebo-controlled, cross-over study to evaluate the clinical efficacy and safety of subcutaneous administration of human plasma-derived C1-esterase inhibitor in the prophylactic treatment of hereditary angioedema	20/03/2014	N/A												No patients recruited yet. 70 day target 29/05/2014	
12/LO/1078	A phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse and primary refractory multiple myeloma	25/03/2014	N/A												No patients recruited yet. 70 day target 03/06/2014. Opened to recruitment 14/4/14, but unable to approach patients until end of May due to IP not being available.	Sponsor