Brighton & Sussex University Hospitals NHS Trust

Performance in Initiating Research

1st October 2012 to 30th September 2013

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
				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	
12/YH/0236	A multi-centre randomised controlled trial comparing rubber band ligation with haemorrhoidal artery ligation in the management of symptomatic second and third degree haemorrhoids.	12/11/2012	21/02/2013					Y						
12/LO/1211	Phase 3, open-label, multi centre pilot study to assess the feasibility of switching individuals receiving Atripla or Kivexa plus Efavarinz with continuing CNS toxicity to a fixed dose combination of tenofovir/emtricitabine/rilpivirine (Eviplera)	04/09/2012	21/12/2012	Y										
12/LO/0777	Randomised open label study to evaluate efficacy & safety of maraviroc (MVC) as switch for either N(t)RTI or boosted PI/r in HIV-1 infected individuals with stable, well controlled plasma HIVRNA while taking first N(t)RTI + PI/r regimen of cART.	29/10/2012	10/01/2013						Y					
12/LO/1289	PRe-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV negative gay men	17/10/2012	08/01/2013				Y							
11/YH/0395	Liver Fibrosis Progression (LFP): A Substudy of Strategic Timing of AntiRetroviral Treatment(START)	29/11/2012	23/04/2013						Y					
09/H1102/107	A Randomised Stratified Multicentre Phase II Clinical Trial of Single-Agent ADI-PEG 20 (Pegylated Arginine Deiminase) in Patients with Malignant Pleural Mesothelioma.	11/09/2012	23/11/2012	Y										
11/LO/0328	A PHASE II SINGLE ARM, MULTI-CENTRE TRIAL OF TRIAMCINOLONE WITH A GNRH ANALOG FOR CASTRATION RESISTANT PROSTATE CANCER (TRICREST)	24/02/2012	13/12/2012	Y										
12/WS/0076	A Phase III randomized trial of metformin versus placebo on recurrence and survival in early stage breast cancer.	09/11/2012	24/04/2013							Y				

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09/H1005/29	Purine-Alkylator Combination In Follicular lymphoma Immuno-Chemotherapy for Older patients: a phase III comparison of first-line RCVP versus R-FC	12/09/2012		Y						Y				
11/LO/1857	NEOMERO2-PK and Safety of Meropenem in Infants with Meningitis (V1)	19/11/2012	05/06/2013						Y					
12/EM/0190	A randomised clinical trial of aesthetic durability and speed of alignment of tooth coloured archwires	07/11/2012	17/12/2012											benchmark met
10/NIR02/36	Hydroxymethylglutaryl-CoA reductase inhibition with simvastatin in Acute lung injury to Reduce Pulmonary dysfunction	06/11/2012	14/06/2013	Y										
11/NW/0489	A Randomized, Double-Blind, Double-Dummy, Parallel-Group study to evaluate the efficacy and safety of Ocrelizumab in comparison to Interferon Beta-1a (Rebif) in patients with Relapsing Multiple Sclerosis.	26/10/2012				Y								Site closed before recruiting a patient as study-wide recruitment completed
12/LO/1156	A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs. Prednisone in Metastatic Castration-resistant Prostate Cancer Patients who have Received Prior Docetaxel and Prior Abiraterone or MDV3100	21/12/2012	03/07/2013						Y					
12/SC/0035	A 6-month safety and benefit study of inhaled fluticasone propionate/ salmeterol combination versus inhaled fluticasone propionate in the treatment of 6,200 paediatric subjects 4-11 years old with persistent asthma	15/11/2012	23/06/2013						Y					
12/SC/0098	A safety and efficacy study of inhaled fluticasone propionate/ salmeterol combination versus inhaled fluticasone propionate in the treatment of adolescent & adult subjects with persistent asthma	16/11/2012	15/04/2013						Y					
12/EE/0176	Randomisd Ph 4 placebo-controlld comparative study to evaluate efficacy/safety of tapering MTX dosage vs maintaining dosage in severe active RA patients showing inadeq response to prior conventional DMARDs trtmt & initiatd RoActemra? in combo w/ MTX	20/08/2012	07/01/2013	Y					Y					
10/H1306/29	Iodine Lugols in Head and Neck Cancer Surgery	10/01/2013								Y		Y		Rare disease

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12/LO/0637	Adjunctive Rifampicin to Reduce Early mortality from Staphylococcus aureus bacteraemia: a randomised controlled trial	28/08/2012	23/01/2013	Y										
12/LO/1131	A randomised study comparing the difference in wound infection rates in patients undergoing cardiac surgery following skin preparation using Alcoholic Povidone-Iodine (Betadine) or Chlorhexadine-Alcohol (Chloraprep).	17/12/2012	25/04/2013				Y							
12/EE/0201	GORE Septal Occluder EU Clinical Evaluation: A Study to evaluate clinical success and performance in thetreatment of transcatheter closure of Patent Foramen Ovale (PFO)	22/11/2012	16/04/2013				Y							
09/H1005/28	Molecular Genetics of Adverse Drug Reactions: from candidate Genes to Genome wide association studies.	30/01/2013	22/04/2013						Y					
11/WM/0164	AntiEpileptic drug Monitoring in PREgnancy: An evaluation of effectiveness, costeffectiveness and acceptability of dose monitoring strategies	10/12/2012	28/03/2013						Y					
12/EM/0389	Study NOG112264, a Phase II Study of Ozanezumab(GSK1223249) versus Placebo in the Treatment of Amyotrophic Lateral Sclerosis	10/01/2013	20/02/2013											Met target
12/LO/1188	A Study of HSP90 Inhibitor AT13387 Alone or in Combination with Abiraterone Acetate in the Treatment of Castration-Resistant Prostate Cancer (CRPC) no Longer Responding to Abiraterone	21/01/2013	01/07/2013									Y		Rare disease
12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	15/02/2013	20/03/2013											Met target
12/SC/0469	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of SAR236553/REGN727 in Patients With Heterozygous Familial Hypercholesterolemia Not Adequately Controlled With Their Lipid-Modifying Therapy	23/01/2013	25/03/2013											Met target

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11/WM/0050	A PHASE 3, MULTICENTER, OPEN-LABEL, EXTENSION STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF EPRATUZUMAB TREATMENT IN SYSTEMIC LUPUS ERYTHEMATOSUS SUBJECTS	18/02/2013	03/05/2013				Y							Delayed SIV
12/SC/0429	A Phase II, multi-center, open-label, neoadjuvant, randomized study of weekly paclitaxel with or without LCL161 in patients with triple negative breast cancer	04/02/2013	16/05/2013						Y					
12/NI/0181	REPRISE II: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus? Valve System ? Evaluation of Safety and Performance.	22/02/2013	15/03/2013											Met target
09/H0605/114	A study of position during the late stages of labour in women with an epidural - the BUMPES study	13/03/2013	28/03/2013											Met target
12/NE/0198	Multicentre Single-Blind Randomised Parallel-Group Study to Assess Short & Long-Term Efficacy of Certolizumab Pegol + Methotrexate Compared with Adalimumab + Methotrexate in Subjects with Moderate to Severe RA Responding Inadequately to Methotrexate	10/12/2012	03/05/2013	Y										
13/LO/0006	A Phase 3, Open-label Study to Investigate the Efficacy and Safety of Sofosbuvir plus Ribavirin in Chronic Genotype 1, 2, 3 and 4 Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Co-infected Subjects	28/02/2013	22/04/2013											Met target
12/LO/0460	A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions.	01/03/2013	23/04/2013											Met target
09/H0718/40	Study on Pharmacokinetics of newly developed Antiretroviral agents in HIV-infected pregNAnt women (PANNA).	07/02/2013	05/09/2013	Y										Local review not completed in time
10/H1307/99	TRACTISS: A randomized double blind placebo controlled clinical TRial of anti-B-Cell Therapy In patients with primary Sj?gren?s Syndrome	09/05/2013								Y				

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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											Met target
11/LO/0043	Weekly Chemotherapy in Ovarian Cancer v2.0	04/03/2013	19/09/2013				Y		Y					Delayed confirmation from sponsor
11/LO/1570	Cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) versis gemcitabine, cisplatin and methyl prednisolone (GEM-P) in the first line treatment of T-cell Lymphoma, a multicentre randomise	26/04/2013								Y				
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					
12/LO/0491	Surgical Replacement & Transcatheter Aortic Valve Impantation SURTAVI	11/12/2012		Y						Y				IR(ME)R approval delay and 162 patients screened without finding an eligible one
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										Pharmacy approval delay
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											Met target
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	10/05/2013					Y							Sponsor delay in supplying drug
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											Met target

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12/LO/1753	Using expressive writing interventions to promote health in women after birth	03/04/2013					Y							Sponsor has delayed start of recruitment until after they have recruited an assistant and produce printed documents
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				Y								Sponsor closed study because of results of a similar study
12/NW/0105	Phase 3 Randomized Double-Blind Placebo-Controlled Adaptive Design Study of Efficacy/Safety/Tolerability of Single Infusion MK-3415, MK-6072 and MK-3415A in Patients Receiving Antibiotic Therapy for Clostridium difficile Infection	22/04/2013	03/07/2013							Y				
12/NW/0214	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					Y							Delay in providing contract and giving green light
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											Met target
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 consented
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					
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							Y					3 screen failures but no eligible patients seen

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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 seen
13/LO/0613	Multimodal imaging of frontal lobe dementias.	20/06/2013	13/08/2013											Met target
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											Met target
11/LO1596	The percutAneous Coronary inTervention prIor to transcatheter aortic VAlve implantaTION (ACTIVATION) trial	25/06/2013		Y			Y							IR(ME)R approval and SIV delay
11/NW/0338	Clinical Outcomes Study to compare the effect of Fluticasone Furorate/Vilanterol Inhalation Powder 100/25mcg + placebo on Survival in Subjects + moderate COPD and a history of or at increased risk for cardiovascular disease.	05/07/2013					Y							Questions regarding consent form (amendment required) and SIV delay through sponsor cancellation
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												Within 70 days
12/EE/0274	Tranexamic Acid for the treatment of significant traumatic brain injury: an international, randomised, double blind, placebo controlled trial.	19/06/2013							Y					No eligible patients seen
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH-2	19/06/2013		Y			Y							Delay in Pharmacy approval and SIV delayed
12/LO/1534	A Multicentre Prospective Open-label Randomised Clinical Trial Comparing the Efficacy of Fixed versus PRN dosing of 700 ?g 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 delayed SIV
12/LO/1545	Medtronic CoreValve? ADVANCE DA Study	20/06/2013	02/08/2013											Met target
12/SW/0206	Accuracy and cost-effectiveness of dynamic contrast enhanced computed tomography in the characterisation of solitary pulmonary nodules	29/07/2013												Within 70 days

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12/SW/0378	Effect of Bivalirudin on Aortic Valve Intervention outcomes 2/3	18/09/2013												Within 70 days
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											Met target
13/EE/0102	PIVOT Neurocognitive function sub-study v1.0	08/05/2013	19/08/2013	Y			Y							London scanning unit not ready
13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects	04/06/2013						Y						PI off sick so unable to initiate study
13/LO/0314	Predictors of progression from mild cognitive impairment to dementia: brain functional network studies.	21/06/2013	05/08/2013											Met target
13/LO/0572	Phase 3 Randomized Double-Blind Study to Evaluate Safety/Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide VS Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1+ Antiretroviral Treatment-Naive Adults	01/07/2013	25/07/2013											Met target
13/LO/0574	Phase 3 Randomized Double-Blind Study to Evaluate Safety/Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide vs Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1+ Antiretroviral Treatment-Naive Adults	01/07/2013	13/08/2013											Met target
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		Y			Y							Sponsor delayed SIV
13/LO/0830	Phase 3 open label study evaluating efficacy/safety of pegylated interferon lambda 1a, in combination + ribavirin and daclatasvir, for treatment of chronic HCV infection + treatment na?ve genotypes 1, 2, 3 or 4 in subjects co-infected + HIV	19/07/2013	30/09/2013							Y				Patients declined before 1st patient recruited

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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					Y							Contracting delays and delay in green light
13/NW/0316	Phase 4 trial comparing cumulative incidence of SCC after treatment + ingenol mebutate & imiquimod for multiple actinic keratoses on face &scalp. A multi-centre, randomised, two-arm, open label, active-controlled, parallel group, 36-month trial.	06/08/2013												Within 70 days
13/SC/0146	Phase 3 Randomised open label parallel group Active-controlled study of BI 207127 interferon-free regimen + Faldaprevir & Ribavirin compared to Telaprevir + pegylated interferon-a & ribavirin in Treatment-Na?ve Patients + Chronic Genotype 1b HCV	02/07/2013					Y							Sponsor delay - drug not available until 2014
13/SC/0279	A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically Suppressed, HIV1 Positive Subjects.	16/07/2013	14/10/2013	Y						Y				Patients declined before 1st patient recruited