Brighton & Sussex University Hospitals NHS Trust

Performance in Initiating Research

1st July 2012 to 30th June 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/SC/0018	Randomised studies to reduce groin lymphocyst	11/02/2012	20/09/2012	Y				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					
11/LO/1034	A randomised, prospective study, assessing changes in cerebral function in treatment naive HIV1 infected subjects commencing either boosted atazanavir with Truvada or boosted darunavir with maraviroc/lamivudine.	23/04/2012	08/03/2013				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										

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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										
10/H1313/2	Investigation of the effectiveness and cost effectiveness of the Enhanced Liver Fibrosis Test in detecting cirrhosis to facilitate early management of portal hypertension and detection of hepatocellular cancer	13/06/2012	12/12/2012						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				
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										
11/LO/1857	NEOMERO2-PK and Safety of Meropenem in Infants with Meningitis (V1)	19/11/2012	05/06/2013	Y										
09/H1102/110	Parent-determined oral montelukast therapy for preschool wheeze with stratification for arachidonate-5-lipoxygenase (ALOX5) promoter genotype. Wheeze and Intermittent Treatment WAIT	16/07/2012	28/11/2012							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											Met target
10/H0306/61	A randomised controlled trial to compare two different platelet count thresholds for prophylactic platelet transfusion to preterm neonates	10/07/2012				Y			Y					Study closed at site in October 2012
10/NIR02/36	Hydroxymethylglutaryl-CoA reductase inhibition with simvastatin in Acute lung injury to Reduce Pulmonary dysfunction	06/11/2012	14/06/2013	Y										
12/YH/0177	Ingenol Mebutate Gel, 0.015% Repeat Use for AKs on Face and Scalp	25/06/2012	11/09/2012							Y				
11/LO/1333	Randomised controlled trial of the tolerability and completion of maraviroc compared to Kaletra in combination with Truvada for HIV post exposure prophylaxis	22/05/2012	25/09/2012					Y						

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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							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		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					
11/LO/1810	A prospective, single arm feasibility study to evaluate the safety and performance of the SMT? Embolic Deflection Device in patients undergoing Transcatheter Aortic Valve Replacement (TAVR): DEFLECT I SMT Embolic DEFLECTion CE Marke Trial	24/07/2012	16/08/2012											Met target
12/NE/0114	Symptom Effectiveness Study of VizAblate?? Intrauterine Ultrasound-Guided RF Ablation (IUUSgRFA) in the Ablation of Large Uterine Fibroids	15/05/2012		Y										

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09/H0724/39	Evaluation of Safety and Effectiveness of the Formula? PTX? Balloon-Expandable Stent for Renal Artery Stenosis	13/09/2012	31/01/2013						Y					
09/S0802/56	Clinical and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse.	27/01/2012						Y						
10/H1306/29	Iodine Lugols in Head and Neck Cancer Surgery	10/01/2013										Y		Rare disease
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										Y		Rare disease
12/LO/1125	Occlutech percutaneous PFO closure:Safety and Efficacy OPPOSE Registry	15/02/2013	20/03/2013											Met target

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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
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

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09/H0718/40	Study on Pharmacokinetics of newly developed Antiretroviral agents in HIV-infected pregNAnt women (PANNA).	07/02/2013		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												Within 70 days
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					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												Within 70 days
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												Within 70 days
12/LO/0491	Surgical Replacement & Transcatheter Aortic Valve Impantation SURTAVI	11/12/2012		Y										IR(ME)R approval delay
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												Within 70 days
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	10/05/2013												Within 70 days

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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												Within 70 days
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 August 2013
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												Within 70 days
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												Within 70 days
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												Within 70 days

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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
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												Within 70 days
13/LO/0613	Multimodal imaging of frontal lobe dementias.	20/06/2013												Within 70 days
13/LO/0621	The 4 Mountains Test of spatial memory for diagnosis of early Alzheimer's disease: evaluation of diagnostic specificity.	07/06/2013												Within 70 days