

| 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 | | | |
| 10/H1306/29 | Iodine Lugols in Head and Neck Cancer Surgery | 10/01/2013 | | | | | | | | | Y | | Y | | Rare disease | Neither |
| 12/LO/0637 | Adjunctive Rifampicin to Reduce Early mortality from Staphylococcus aureus bacteraemia: a randomised controlled trial | 28/08/2012 | 23/01/2013 | Y | | | | | | | | | | | | NHS Provider |
| 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 | | | | | | | | | Sponsor |
| 12/EE/0201 | GORE Septal Occluder EU Clinical Evaluation: A Study to evaluate clinical success and performance in the treatment of transcatheter closure of Patent Foramen Ovale (PFO) | 22/11/2012 | 16/04/2013 | | | | Y | | | | | | | | | Sponsor |
| 09/H1005/28 | Molecular Genetics of Adverse Drug Reactions: from candidate Genes to Genome wide association studies. | 30/01/2013 | 22/04/2013 | | | | | | | Y | | | | | | NHS Provider |
| 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 | | | | | | NHS Provider |
| 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 | Neither |
| 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 | Neither |
| 12/LO/1125 | Occlutech percutaneous PFO closure: Safety and Efficacy OPPOSE Registry | 15/02/2013 | 20/03/2013 | | | | | | | | | | | | Met target | Neither |
| 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 | Neither |
| 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 | Sponsor |
| 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 | | | | | | NHS Provider |

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|--------------|---|------------|------------|---|--|---|--|--|---|---|--|--|--|--|--------------|
| 12/NI/0181 | REPRIS 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 | Neither |
| 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 | Neither |
| 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 | | | | | | | | | | | NHS Provider |
| 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 | Neither |
| 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 | Neither |
| 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 | NHS Provider |
| 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 | 31/10/2013 | | | | | | Y | | | | | | NHS Provider |
| 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 | Neither |
| 11/LO/0043 | Weekly Chemotherapy in Ovarian Cancer v2.0 | 04/03/2013 | 19/09/2013 | | | Y | | | Y | | | | | Delayed confirmation from sponsor | Both |
| 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 | | | | | | | | Y | | | | | NHS Provider |
| 11/SC/0398 | The Contact PVI Study Does assessment of tissue contact during RF ablation using the St. Jude Medical? Ensire? Contact? system increase rates of longterm pulmonary vein isolation? A prospective randomised study. | 21/05/2013 | | | | | | | Y | | | | | | NHS Provider |
| 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 | NHS Provider |

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| 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 | 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 | | | | | | | | | | | Met target | Neither |
| 12/LO/1698 | Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE) | 10/05/2013 | 25/10/2013 | | | | Y | | | | | | | Sponsor delay in supplying drug | 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 | | | | | | | | | | | Met target | Neither |
| 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 | Sponsor |
| 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 | Sponsor |
| 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 | | | | | NHS Provider |
| 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 | 01/11/2013 | | | | Y | | | | | | | Delay in providing contract and giving green light | 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 | | | | | | | | | | | Met target | Neither |
| 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 | NHS Provider |

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| 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 | | | | | | NHS Provider |
| 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 | | | | | 3 screen failures but no eligible patients seen | NHS Provider |
| 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 | NHS Provider |
| 13/LO/0613 | Multimodal imaging of frontal lobe dementias. | 20/06/2013 | 13/08/2013 | | | | | | | | | | | Met target | Neither |
| 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 | Neither |
| 11/LO/1596 | The percutaneous Coronary Intervention prior to transcatheter aortic Valve implantation (ACTIVATION) trial | 25/06/2013 | | Y | | | Y | | | | | | | IR(ME)R approval and SIV delay | Both |
| 11/NW/0338 | Clinical Outcomes Study to compare the effect of Fluticasone Furoate/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 | 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 | | | | | | | | | | | | Within 70 days | Neither |
| 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 | | | | | No eligible patients seen | NHS Provider |
| 12/EM/0369 | Tranexamic acid for hyperacute primary Intracerebral Haemorrhage TICH-2 | 19/06/2013 | | Y | | | Y | | | | | | | Delay in Pharmacy approval and SIV delayed | Both |
| 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 | Both |
| 12/LO/1545 | Medtronic CoreValve? ADVANCE DA Study | 20/06/2013 | 02/08/2013 | | | | | | | | | | | Met target | Neither |
| 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 | | | | | | | | | | | Within 70 days | Neither |
| 12/SW/0378 | Effect of Bivalirudin on Aortic Valve Intervention outcomes 2/3 | 18/09/2013 | 06/01/2014 | | | | | | | | | | | Within 70 days | Neither |

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| 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 | Neither |
| 13/EE/0102 | PIVOT Neurocognitive function sub-study v1.0 | 08/05/2013 | 19/08/2013 | Y | | | Y | | | | | | | | London scanning unit not ready | Both |
| 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 | NHS Provider |
| 13/LO/0314 | Predictors of progression from mild cognitive impairment to dementia: brain functional network studies. | 21/06/2013 | 05/08/2013 | | | | | | | | | | | | Met target | Neither |
| 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-Na?ve Adults | 01/07/2013 | 25/07/2013 | | | | | | | | | | | | Met target | Neither |
| 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-Na?ve Adults | 01/07/2013 | 13/08/2013 | | | | | | | | | | | | Met target | Neither |
| 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 SIV | Both |
| 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 | NHS Provider |
| 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 | 29/11/2013 | | | | Y | | | | | | | | Contracting delays and delay in green light | Sponsor |
| 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 | 08/11/2013 | | | | | | | | | | | | Within 70 days | Neither |
| 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 | Y | | | | | | | | Sponsor delay - drug not available until 2014 | Sponsor |

