PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q4, 2013/14)

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met?	Reason for not meeting benchmark
08/H1102/112	Safety and efficacy of intensive versus guideline antiplatelet therapy in high risk patients with recent ischaemic stroke or transient ischaemic attack: a randomised controlled trial	18/11/2013		No	Lengthy contract negotiation and no eligible patients seen.
09/H0801/96	A Phase I Study Of Everolimus Therapy Before Nephrectomy In Metastatic Renal Cell Cancer (E-PREDICT)	24/04/2013		No	No eligible patients were seen or consented.
1/LO/0671	A Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Safety and Efficacy of BIIB019, Daclizumab High Yield Process (DAC HYP), Monotherapy in Subjects With Multiple Sclerosis Who Have Completed Study 205MS301	07/01/2014	12/02/2014	Yes	
10/H0405/29	Fistula-In-Ano Trial to compare Surgisis anal fistula plug versus surgeon's preference for transsphincteric fistula-in-ano	11/09/2013	04/02/2014	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
10/H0715/48	A Randomised Multicentre Accelerated Radiotherapy Study of Dose Escalated Intensity Modulated Radiotherapy vs Conventional Dose Intensity Modulated Radiotherapy in Patients Receiving Treatment for Locally Advanced Laryngeal and Hypopharyngeal Cancer	15/02/2013	28/05/2013	No	Rare disease study.
10/H1107/46	Non cirrhotic portal hypertension: An emerging clinically significant liver disease in patients with human immunodeficiency virus	04/02/2013	04/07/2013	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
10/MRE09/29	A Phase I/II trial of isotoxic accelerated radiotherapy in the treatment of patients with non-small cell lung cancer (I-START)	20/06/2013	14/01/2014	No	Rare disease study.
11/EE/0256	Multi-centre, open label, prospective, consecutive series registry database of BioPoly RS Partial Resurfacing Knee implant	18/06/2013	12/11/2013	No	No eligible patients seen at clinic.
11/EM/0450	A study of pazopanib efficacy and safety in patients with advanced clear-cell renal cell carcinoma and ECOG Performance Status 2 (PaZ02)	02/04/2013		No	Lengthy contract negotiation; issues over version control. Rare disease/condition. Also delay obtaining ARSAC licence.
11/H0606/1	Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma ? a randomised phase III trial	08/05/2013	13/03/2014	No	Rare disease study.
11/LO/0185	PROMIS Prostate MRI Imaging Study (MRC PR11) Evaluation of Multi-Parametric Magnetic Resonance Imaging in the Diagnosis and Characterisation of Prostate Cancer	21/05/2013	13/11/2013	No	No eligible patients were seen or consented.
11/LO/1023	A 12Month, Multicentre, Randomised, Parallel Group Study to Compare the Efficacy and Safety of Ozurdex Versus Lucentis in Patients with Branch Retinal Vein Occlusion	03/06/2013	04/07/2013	Yes	
11/LO/1369	A Randomized, Double-Blind, Multi-Center Phase 3 Study of ADI-PEG 20 Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Subjects With Advanced Hepatocellular Carcinoma (HCC) Who Have Failed Prior Systemic Therapy	27/03/2013	02/10/2013	No	Rare disease study.
11/LO/1776	Urinary Proteomics for HIGH Risk pregancies (UP HIGH R) - PEACHES	20/06/2013	10/12/2013	No	Lengthy R&D approval and/or contract negotiation.
11/LO/1904	A randomized double-blind multiple-dose placebo-controlled trial to establish the efficacy of QBX258 (combination of VAK694 and QAX576) in asthma that is inadequately controlled with inhaled corticosteroids and long acting beta agonists	19/08/2013	06/01/2014	No	No eligible patients were seen or consented.
11/LO/2047	Outcome measures in sleeve gastrectomy after staple line reinforcement: Seamguard vs Duet TRS	22/05/2013		No	Issue with supply of materials (sutures) for the study.
11/NE/0214	Phase II study of aromatase inhibitors in women with potentially hormone responsive recurrent/metastatic gynaecological neoplasms	21/08/2013		No	Rare disease study.
11/NW/0075	Phase III study comparing post-operative conformal radiotherapy to no post-operative radiotherapy in patients with completely resected non-small cell lung cancer and mediastinal nodal N2 involvement	10/10/2012		No	Support service issue - radiotherapy QA. PI and radiotherapy physicists had to undertake a long and complex process of quality assurance before site initiation could be confirmed.
11/NW/0782	A phase III randomised trial of adjuvant chemotherapy versus observation in transitional cell carcinoma of the upper tract	21/05/2012	11/07/2013	No	No eligible patients were seen or consented, lengthy R&D approval and/or contract negotiation.
11/SS/0092	Trial of BIBW 2992 in suspected mutant EGFR lung cancer patients unfit for chemotherapy	11/09/2013	15/10/2013	Yes	
11/WS/0039	A Phase I/IIa trial of AZD4547 in combination with Cisplatin and Capecitabine (CX)	08/08/2013	23/10/2013	No	Rare disease study.
11/WS/0090	A Randomised Phase II study investigating pazopanib vs weekly paclitaxel in relapsed or progressive Transitional Cell Carcinoma (TCC) of the urothelium.	08/03/2013	29/08/2013	No	Rare disease study.

11/YH/0006	Magnetic Resonance Imaging to Enhance the Diagnosis of Foetal Developmental Brain Abnormalities in Utero	06/01/2014	14/01/2014	Yes	
11/YH/0260	Randomised Phase II of FC+ofatumumab vs FC+ofatumumab (high dose) for patients with relapsed CLL who are eligible for fludarabine-based therapy (i.e. late relapses after FC or FCR or prior therapy with alkylators)	25/04/2013		No	Rare disease study.
12/EE/0274	Tranexamic acid for the treatment of significant traumatic brain injury:an international randomised, double blind placebo controlled trial	31/10/2013		No	Lengthy R&D approval and/or contract negotiation.
12/EE/0400	GS-US-334-0109 ? An open label study of GS-7977 + Ribavirin for 12 weeks in subjects with chronic HCV infection who participated in prior studies evaluating GS-7977	10/01/2013	13/08/2013	No	Lengthy R&D approval and/or contract negotiation.
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH2	30/07/2013	03/03/2014	No	Patients screened but none eligible. As per recruitment target, we expect to see 1 patient per month eligible for this study. They will come through sporadically so we expect to see some months with no patients, and some with more than 1.
12/LO/0155	Randomised controlled trial of tailored home exercise versus advice and usual care for disability in people with immune mediated neuropathy	16/12/2013		No	Rare disease study.
12/LO/0261	Hellenic- Anglo Research into Morning or Night antihypertensive drug deliverY trial (HARMONY)	13/05/2013	22/07/2013	Yes	
12/LO/0720	A Phase 1 Randomised Study of MEDI-551 in Subjects with Relapsing-Remitting Multiple Sclerosis	25/06/2013		No	Issues with study design - amendments submitted by Sponsor.
12/LO/0894	The role of 123I SPECT-CT scintigraphy as a novel diagnostic test in patients with liver tumours	02/05/2013	10/06/2013	Yes	
12/LO/0984	A Randomized, Open-Label Phase 2 Study Of The Ido Inhibitor Incb024360 Versus Tamoxifen For Subjects With Biochemical-Recurrent-Only Epithelial Ovarian Cancer, Primary Peritoneal Carcinoma Or Fallopian Tube Cancer Following Complete Remission With F	20/05/2013	02/07/2013	Yes	
12/LO/1133	A randomised phase 2 trial investigating the additional benefit of hydroxychloroquine (HCQ) to short course radiotherapy (SCRT) in patients aged 70 years and older with high grade gliomas (HGG)	23/07/2013	11/02/2014	No	Support service issue - radiotherapy QA was delayed.
12/LO/1158	Bevacizumab And Combination Chemotherapy in rectal cancer Until Surgery: A Phase II, Multicentre, Open-label, Randomised Study of Neoadjuvant Chemotherapy and Bevacizumab in Patients with MRI defined High-Risk Cancer of the Rectum	27/11/2013		No	Rare disease study.
12/LO/1176	STREAMLINE-C: Streamlining Staging of Colorectal Cancer with Whole Body MRI	22/03/2013	17/06/2013	No	Lengthy R&D approval and/or contract negotiation.
12/LO/1188	A Study of HSP90 Inhibitor AT13387 Alone or in Combination with Abiraterone Acetate in the Treatment of CastrationResistant Prostate Cancer (CRPC) no Longer Responding to Abiraterone	01/08/2013		No	Study withdrawn by Sponsor.
12/LO/1343	A Phase 1, Randomized, Double-blind, Placebo-controlled Study Evaluating CNTO 3157 in Healthy Normal and Asthmatic Subjects Inoculated with Human Rhinovirus Type 16	21/05/2013	01/08/2013	No	Challenging study design. Due to phase and nature of the study, it is both a challenge to identify and attract eligible volunteers due to study complexity, number of visits, etc.
12/LO/1636	Validation of Sensium wireless device in a paediatric population	07/08/2013		No	Staff availability issues - study suspended at this site.
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE) Short	24/09/2013		No	No eligible patients were seen or consented.
12/LO/1762	Left ventricular MultiSpot Pacing for CRT (i-Spot)	22/05/2013	04/02/2014	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
12/LO/1823	A Randomized, Double-blind Phase 3B Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate Versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Infect	17/05/2013	10/09/2013	No	No eligible patients were seen or consented.
12/LO/1962	Self-Management education for adults with poorly controlled epILEpsy(SMILE): A project involving a randomised controlled trial	21/05/2013		No	No eligible patients were seen or consented.
12/LO/1981	A Randomized, Multicenter, Open-Label Phase III Study To Evaluate The Efficacy And Safety Of Trastuzumab Emtansine Versus Trastuzumab As Adjuvant Therapy For Patients With Her2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologi	02/05/2013	21/08/2013	No	Rare disease study.
12/NE/0315	Pragmatic Ischaemic Stroke Thrombectomy Evaluation: PISTE	25/03/2013	15/08/2013	No	Lengthy R&D approval and/or contract negotiation.
12/NE/0342	A multicentre, randomised, double blind, placebo-controlled pivotal study to evaluate the efficacy and safety of GFT505 80mg and GFT505 160mg on steatohepatitis in patients with non-alcoholic steatohepatitis (NASH)	11/03/2013		No	Suspended and eventually withdrawn by Sponsor.

12/NW/0682	A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate Safety, Tolerability and Efficacy of AMG 145 on LDL-C in Subjects with Heterozygous Familial Hypercholesterolemia	13/03/2013	20/05/2013	Yes	
12/NW/0711	Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 12-Month Trial of Leuco-methylthioninium bis(hydromethanesulfonate) in Subjects with Mild to Moderate Alzheimer's Disease (TRx-237-015)	06/06/2013	17/06/2013	Yes	
12/NW/0802	A multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled study followed by an active treatment period, to evaluate the efficacy, safety and tolerability of two doses of oral administration of laquinimod (0.6 mg/day	04/06/2013		No	Problem with external contractor supplying MRI services. Delays in negotiating contract. Study now abandoned.
12/SC/0538	A Double-Blind, Placebo-Controlled, Randomized, Parallel Group, 12-Month Safety and Efficacy Trial of Leuco-methylthioninium bis(hydromethanesulfonate) in Subjects with Behavioral Variant Frontotemporal Dementia (bvFTD)	28/11/2012	15/07/2013	No	Site Initiation Visit delay.
12/SC/0540	A phase III, Randomised, Partially Double-Blind and Placebo-Controlled Study of BI 207127 in combination with Faldaprevir and Ribavirin in Treatment-Naïve Patients with Chronic Genoptype 1 HCV Infection	12/10/2012	19/04/2013	No	Lengthy R&D approval and/or contract negotiation.
12/WA/0345	A randomised Phase II study of two preoperative chemoradiotherapy regimes (oxaliplatin and capecitabine followed by radiotherapy with either oxaliplatin and capecitabine or paclitaxel and carboplatin) for resectable oesophageal cancer.	26/03/2013	06/11/2013	No	Rare disease study.
12/WM/0087	Phase I/II Randomised Trial of 5-Azacitidine versus 5-Azacitidine in combination with Vorinostat in patients with Relapsed Acute Myeloid Leukaemic Ineligible for Intensive Chemotherapy (RAvVA).	26/02/2013	11/09/2013	No	Rare disease study.
12/WM/0341	To examine the effect of cholesterol-lowering on carotid plaque burden and stability, cerebrovascular disease and cognitive function in patients recruited to fourier.	01/08/2013		No	No eligible patients were seen or consented.
12/WM/0341b	A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular events When AMG 145 is Used in Combination With StatinTherapy in Patients with Clinically Evident	03/07/2013	04/09/2013	Yes	
12/WS/0184	Multi-Center, Open-Label, Randomized Study of Anti-CCR4 Monoclonal AntibodyKW-0761 or Investigators Choice in Subjects with Previously Treated Adult T-cell Leukemia-Lymphoma (ATL)	29/04/2013	02/07/2013	Yes	
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.	08/08/2013	19/11/2013	No	Lengthy R&D approval and/or contract negotiation.
13//YH/0174	A Multicenter, Randomized, Double-Blind, Study Comparing the Efficacy and Safety of Continuing versus Withdrawing Adalimumab Therapy in Maintaining Remission in Subjects with Non Radiographic Axial Spondyloarthritis	25/10/2013		No	Staffing issues.
13/EE/0010	CUTHIVAC 001 safety and immunogenicity of an HIV vaccine; version 1	08/03/2013	25/04/2014	No	Challenging study - HIV vaccine study with healthy volunteers. Strict screening criteria - many people who express interest are then pre-screened out.
13/EE/0102	PIVOT Neurocognitive function sub-study	03/07/2013	15/08/2013	Yes	
13/EE/0199	An Exploratory Study of the Safety and Efficacy of BOTOX for the Treatment of Premature Ejaculation	11/09/2013		No	Entry criteria for this study are very strict. Since initiation of 4 UK sites and 8 USA sites, only 8 patients have been consented.
13/EE/0257	A Phase II Clinical Trial to Study the Efficacy and Safety of a combination regimen of MK-5172 and MK-8742 with Ribavirin (RBV) in Subjects with Chronic Hepatitis C Genotype 2 Infection	22/10/2013	29/10/2013	Yes	
13/EE/0276	A Phase 3B Randomized, OpenLabel MultiCenter Trial Assessing Sofosbuvir + Ribavirin for 16 or 24 Weeks and Sofosbuvir + Pegylated Interferon + Ribavirin for 12 Weeks in Subjects with Genotype 2 or 3 Chronic HCV Infection	17/09/2013	31/10/2013	Yes	
13/EE/0365	Investigation of newly developed 1- and 2-piece convex ostomy products in subjects with ileostomy	11/12/2013		No	Study withdrawn by Sponsor.
13/EM/0374	A doubleblind, randomized, placebocontrolled, study to demonstrate the efficacy and safety of 250 mg or 1 g A3384 administered orally twice daily for two weeks to patients with Bile Acid Malabsorption (BAM)/Bile Acid Diarrhoea (BAD)	24/12/2013		No	No eligible patients were seen or consented.

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	09/04/2013	30/04/2013	Yes	
13/LO/0097	A phase 2b dose-ranging, randomized, double-blind, placebo controlled trial evaluating the safety and efficacy of GS-6624, a monoclonal antibody against Lysyl oxidase like molecular 2 (LOXL2) in subjects with advanced liver fibrosis but not cirrhosi	24/07/2013		No	Study burden on patients was excessive / heavy, and discouraged patients from consenting. Study since closed by Sponsor.
13/LO/0115	A phase I clinical trial investigating immunisation strategies using DNA, MVA and rgp140 adjuvanted with GLAAF to maximise antibody responses	22/03/2013	19/06/2013	No	Delay in setting a date for the site initiation visit. Delay issuing Green Light. Internal CRF design and release had not been finalised - paper CRF devised.
13/LO/0126	Proportion of excision volume and length after treatment for cervical intra-epithelial lesions: cervical healing, quality of regenerated tissue, immunology and pregnancy outcome.	23/04/2013	07/05/2013	Yes	
13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects	25/09/2013	27/01/2014	No	No eligible patients were seen or consented.
13/LO/0181	Optimisation and Individualisation of HeartSparing Breast Radiotherpay Techniques (The Heart Spare Study) : stage II	06/01/2014		No	Lengthy contract negotiation.
13/LO/0206	A phase 3 evaluation of Daclatasvir in combination with Peginterferon Lambda-1a and Ribavirin (RBV) or Telaprevir in Combination with Peginterferon Alfa-2a and RBV in Patients with Chroinic Hepatitis C Genotype 1b who are Treatment Naïve or Prior R	08/07/2013	12/08/2013	Yes	
13/LO/0223	Protexo Registry - A combined retrospective and prospective post marketing surveillance study in patients using Temperature controlled Laminar Airflow (TLA)	25/04/2013	23/05/2013	Yes	
13/LO/0365	An efficacy and mechanism evaluation study for Levosimendan for the prevention of accute organ dysfunction in sepsis (LeoPARDS)	10/01/2014	20/01/2014	Yes	
13/LO/0402	Optimisation of residual disease detection in chronic myeloid leukaemia patients responding to tyrosine kinase inhibitor therapy	03/05/2013	17/03/2014	No	No eligible patients were seen or consented.
13/LO/0410	Preventing enduring behavioural problems in young children through early psychological intervention: A pilot study (Healthy Start Happy Start: Helping with Childrenâ??s Behaviour)	07/06/2013	21/09/2013	No	Amendments have caused delays. Eligible patients identified but none agreed/consented to participate. It has taken time to build links with recruitment sites (health visitor clinics and children's centres).
13/LO/0420	The safety and immunogenicity of a potential HIV vaccine	04/09/2013	19/11/2013	No	Sponsor suspended study due to IMP issue.
13/LO/0425	A Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of the Combinationof ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267)and BT-333 With and Without Ribavirin (RBV) in Treatment-Naive Adults with Genotype 1a Chronic Hepati	18/04/2013	03/05/2013	Yes	
13/LO/0455	Retinal Embolisation in Transcatheter Aortic Valve Implantation: Pilot Study	17/05/2013	02/07/2013	Yes	
13/LO/0487	The effectivness and acceptability of a computerised self-help guide for women with vaginismus	09/05/2013	25/06/2013	Yes	
13/LO/0493	A randomised controlled trial of internet based cognitive behavioural therapy (CBT) versus treatment as usual (TAU) for pregnant women with symptoms of depression	10/06/2013		No	Staff availability issues - study was suspended at this site.
13/LO/0501	A PHASE 2, RANDOMIZED, DOSE-RANGING STUDY TO ASSESS THE SAFETY AND ANTI-CYTOMEGALOVIRUS (CMV) ACTIVITY OF MARIBAVIR VERSUS VALGANCICLOVIR FOR TREATMENT OF CMV INFECTIONS IN TRANSPLANT RECIPIENTS WHO DO NOT HAVE CMV ORGAN DISEASE	06/09/2013		No	Study-wide recruitment completed and then recruitment closed by Sponsor. Study required extensive protocol-specific training in various electronic systems.
13/LO/0535	A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis	23/05/2013	30/09/2013	No	Rare disease study.
13/LO/0541	Bedside screening for post-partum iron deficiency anaemia: An evaluation of the Hemacue 201 device for point of care testing to screen for post-partum anaemia	20/05/2013	14/08/2013	No	Staff availability issues at site.
13/LO/0552	SinuSys Patency of Maxillary Sinus Ostia Study	05/06/2013	12/06/2013	Yes	
13/LO/0615	A Randomized, Controlled, Open-Label, Phase 2, Trial of SGI-110 and Carboplatin in Subjects with Platinum-Resistant Recurrent Ovarian Cancer	29/08/2013	31/10/2013	Yes	
13/LO/0683	Predicting Delirium After Neck of Femur Fracture	02/10/2013		No	Lengthy contract negotiation and no eligible patients seen.
13/LO/0696	Glycaemic index testing of carbohydrate containing foods using a standardised method	23/05/2013	28/05/2013	Yes	
13/LO/0699	Evaluating the effects of the novel GLP-1 analogue, liraglutide, in patients with Alzheimerâ??s disease (ELAD Study).	01/10/2013	20/01/2014	No	Staff availability issues over Christmas holiday period.

13/LO/0740	A RANDOMIZED, MULTICENTER, DOUBLE BLIND PHASE 3 STUDY OF PD 0332991 (ORAL CDK 4/6 INHIBITOR) PLUS LETROZOLE VERSUS PLACEBO PLUS LETROZOLE FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH ER (+), HER2 () BREAST CANCER WHO HAVE NOT RECEIVED ANY PRIOR S	29/11/2013	12/02/2014	No	Rare disease study.
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 naïve genotypes 1, 2, 3 or 4 in subjects co-infected	30/10/2013	19/11/2013	Yes	
13/LO/0849	Clinical Assessment of a Novel Microprobe Array Continuous Glucose Monitor for Type 1 Diabetes	23/10/2013	22/11/2013	Yes	
13/LO/0855	A Phase 3, Randomized, Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Rituximab for Previously Treated Indolent Non-Hodgkin Lymphoma	02/08/2013		No	Highlighted to Sponsor that the proposed study regiment would be under-treating patients in relation to another study with the same IMP. However, decided to open this study as well to cover for the possibility of patients too frail to go into this other study. We expected minimal or even zero recruitment for this study and the Sponsor had been made aware of this. We also understand that the study has recruitment difficulties globally.
13/LO/0882	Slow wave sleep and daytime functioning in chronic fatigue syndrome: effects of sodium oxybate	08/01/2014		No	Lengthy R&D approval and/or contract negotiation.
13/LO/1081	A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients With Nonmetastatic Castration-Resistant Prostate Cancer	31/01/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
13/LO/1091	Non-invasive Pressure-Volume Analysis (NIPVA): extending comprehensive left ventricular pump function assessment to more patients and settings	13/08/2013		No	Study is on hold - investigator is on maternity leave.
13/LO/1121	A Randomized, Controlled Phase 2 Study Evaluating LY2875358 plus Erlotinib versus Erlotinib as First Line Treatment in Metastatic Non Small Cell Lung Cancer Patients with Activating EGFR Mutations Who Have Disease Control after an 8 Week Lead In Tr	11/12/2013	29/01/2014	Yes	
13/LO/1150	The role of left atrial ganglionated plexi sites that trigger pulmonary vein ectopy in the pathogenesis of paroxsymal atrial fibrillation	06/11/2013	02/12/2013	Yes	
13/LO/1182	Pilot study to evaluate the feasibility of functional MRI in metastatic renal cell carcinoma (mRCC) with test-retest repeatability and early response assessment.	01/08/2013		No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/LO/1279	To evaluate the role of LifeNote in rates of medicine adherence and also its acceptability in patients at high multifactorial risk of developing cardiovascular disease attending the MyACtion Westminster programmme	20/08/2013		No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/LO/1290	A Followup Study to Assess Resistance and Durability of Response to AbbVie DirectActing Antiviral Agent (DAA) Therapy in Subjects Who Participated in Phase 2 or 3 Clinical Studies for the Treatment of Chronic Hepatitis C Virus (HCV) Infection	22/10/2013		No	Closed by Sponsor due to recent results of a related study indicating that there would be need for fewer subjects to answer the study question.
13/LO/1296	Pilot study to evaluate diffusion weighted MRI (DWMRI) with Intravoxel Incoherent Motion (IVIM) and arterial spin labelling (ASL) at 3T in metastatic or locally advanced pancreatic neuroendocrine tumours (pNET): test-retest and response assessment	06/02/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
13/LO/1302	A Phase IIIb randomised, openlabel study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV1 infected antiretroviral therapy naive women.	01/11/2013	12/02/2014	No	No eligible patients were seen or consented.
13/LO/1305	Systematic Assessment of Pulmonary Artery Haedodynamics using Wave Intensity Analysis	10/10/2013	12/12/2013	Yes	
13/LO/1332	A TwoPart Phase 1/2a, OpenLabel, Dose Escalation Study to Evaluate the Tolerability and Preliminary Antitumour Activity of OPB111001 in Patients with Advanced Cancers that are Poorly Responsive to Standard Anticancer Treatment	25/02/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
13/LO/1340	Defining a gold standard for ischaemia: Effects of interventional revascularisation versus optimum medical therapy on exercise capacity in patients with stable coronary artery disease.	29/11/2013	11/12/2013	Yes	
13/LO/1351	Patient-specific virtual reality rehearsal prior to EVAR: Influence on technical and non-technical operative performance.	11/12/2013		No	Lengthy R&D approval and/or contract negotiation.
13/LO/1352	A PHASE II, OPEN-LABEL, MULTICENTER, RANDOMIZED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF MPDL3280A (ANTI-PD-L1 ANTIBODY) COMPARED WITH DOCETAXEL IN PATIENTS WITH NON-SMALL CELL LUNG CANCER AFTER PLATINUM FAILURE	23/10/2013	16/12/2013	Yes	

13/LO/1375	A randomised controlled trial to evaluate the impact of psychological support intervention after chemotherapy for women with ovarian cancer	30/10/2013	28/11/2013	Yes	
13/LO/1380	I-Scan for the detection and characterisation of mucosal lesions a randomised controlled study	12/11/2013	11/03/2014	No	Lengthy R&D approval and/or contract negotiation.
13/LO/1639	Patient matched osteotomy to correct angular deformities in knee arthrosis	02/12/2013		No	Delayed due to issue within required support service.
13/LO/1677	Continence Across Continents to Upend Stigma and Dependency	10/02/2014	31/03/2014	Yes	
13/LO/1725	Prospective, multi-center, double blind, ranodmised study to test the safety of deferral of stenting in a physioogical non-significant lesions in a clinical population of intermediate senoses using iFR and FFR	09/01/2014	13/01/2014	Yes	
13/LO/1813	Effect of minocycline on chronic neuroinflammation following traumatic brain injury (TBI)	18/03/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
13/lo/1816	Intraocular Pressure And Tolerability Study of Preservative Free Bimatoprost 0.03% Unit Dose (BUDPF) or preservative free Latanoprost 0.005% Unit Dose (LUDPF) (Monoprost)in patients with Ocular hypertension or Glaucoma: A Randomised, single masked,	11/12/2013		No	Study initiation delayed due to IMP shipment on way and pharmacy protocol finalisation.
13/LO/1844	Electrical stimulation in diabetic peripheral neuropathy	15/10/2013		No	Lengthy R&D approval and/or contract negotiation.
13/NE/0125	PRESTO Neo.1.C/E	29/08/2013		No	No eligible patients were seen or consented.
13/NE/0177	A phase II, randomised, double-blind, placebo-controlled study to evaluate LUM001, an apical sodium-dependent bile acid transporter inhibitor (ASBTi), in combination with ursodeoxycholic acid (UDCA) in patients with primary biliary cirrhosis	18/08/2013		No	Condition being studied meets the definition of rare disease - European prevalence of 13.5/100,000.
13/NW/0171	A Phase 2b, Randomized, Double-blind, Placebo-controlled Study Investigating the Efficacy and Safety of Inhaled CVT-301 (Levodopa Inhalation Powder) in Parkinson?s Disease Patients With Motor Response Fluctuations (OFF Phenomena)	13/05/2013	19/07/2013	Yes	
13/NW/0265	A trial of de-escalation and stopping treatment in chronic myeloid leukaemia patients with excellent responses to tyrosine kinase inhibitor therapy (De- Escalation and Stopping Treatment of Imatinib, Nilotinib or sprYcel in chronic myeloid leukaemi	18/09/2013	17/03/2014	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/NW/0363	A Multicenter Openlabel Extension (OLE) Study to Assess the Long term Safety and Efficacy of AMG 145	14/10/2013	05/12/2013	Yes	
13/NW/0464	A PlaceboControlled, Multicenter, DoubleBlind, Randomized, Pharmacokinetic and Pharmacodynamic Trial of IDN6556 in Subjects with Acute on Chronic Liver Failure	03/10/2013		No	Inclusion/exclusion criteria very restrictive. Other sites in UK also experienced problems consenting; Sponsor decided to broaden potential patient population. Substantial Amendments currently going through. These are very sick patients who are inpatients and normally on ITU, therefore issues with consenting.
13/nw/0583	A 24-Week International, Multi-center, Randomized, Parallel-group, Double-blind Trial to Evaluate Metformin Extended Release Monotherapy Compared to Metformin Immediate Release Monotherapy in Adult Subjects with Type 2 Diabetes who have Inadequate G	17/12/2013		No	Lengthy R&D approval and/or contract negotiation.
13/SC/0092	A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of Siponimod (BAF312)in patients with secondary progressive multiple sclerosis (Protocol No: CBAF312A23	18/06/2013		No	Lengthy R&D approval and/or contract negotiation.
13/SC/0111	FOCUS4 – Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	30/09/2013		No	Lengthy contract negotiation and in agreeing Radiology service support.
13/SC/0146	A phase III, randomised, open label, activecontrolled study of an interferonfree regimen of BI 207127 in combination with Faldaprevir and Ribavirin compared to Telaprevir in combination with pegylated interferonÎ± and ribavirin in treatmentnaÃ¯	03/05/2013		No	Study suspended by Sponsor due to IMP supply problems.
13/SC/0174	A phase 2b dose-ranging, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of GS-6624, a monoclonal antibody against lysyl oxidase like moleculae 2 (LOXL2) in subjects with Primary Sclerosing Cholangitis (PSC)	24/07/2013		No	Study burden on patients was excessive / heavy, and discouraged patients from consenting. Study since closed by Sponsor.
13/SC/0208	A Phase I/IIa Sporozoite Challenge Study to Assess the Safety and Protective Efficacy of the Combination Malaria Vaccine Candidate Regimen of RTS,S/AS01B + ChAd63 and MVA encoding ME TRAP and also RTS,S/A01B alone	25/08/2013		No	No eligible patients were seen or consented.

13/SC/0249	A phase 2b dose-ranging, randomized, double-blind, placebo controlled trial evaluating the safety and efficacy of GS-6624, a monoclonal antibody against Lysyl oxidase like molecular 2 (LOXL2) in subjects with compensated cirrhosis secondary to non a	29/07/2013		No	Study burden on patients was excessive / heavy, and discouraged patients from consenting. Study since closed by Sponsor.
13/SC/0259	A Phase 3, Randomized, Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Bendamustine and Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas. Gilead GS-US-313-0125	02/10/2013	12/02/2014	No	Rare disease study.
13/SC/0291	AN OPEN LABEL, PHASE I STUDY TO EVALUATE THE IMPACT OF SEVERE HEPATIC IMPAIRMENT ON THE PHARMACOKINETICS AND SAFETY OF VEMURAFENIB IN BRAFV600 MUTATION POSITIVE CANCER PATIENTS	18/11/2013		No	Study abandoned - unable to recruit due to being rare disease.
13/SC/0311	A randomized, controlled, doubleblind Phase III trial to compare the efficacy, safety and pharmacokinetics of GP2013 plus cyclophosphamide, vincristine, prednisone vs. MabThera® plus cyclophosphamide, vincristine, prednisone, followed by GP2013	07/08/2013	30/01/2014	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/SC/0348	A randomized, OpenLabel, Phase 2 Study Evaluating LY2875358 Plus Erlotinib and LY2875358 Monotherapy in MET Diagnostic Positive NSCLC Patients with Acquired Resistance to Erlotinib	22/08/2013	27/11/2013	No	Delayed Green Light.
13/SC/0360	A Phase 3 Blinded Randomized Study of Peginterferon Lambda-1a and Ribavirin Compared to Peginterferon Alfa 2a and Ribavirin, Each Administered with Telaprevir in Subjects with Genotype-1 Chronic Hepatitis C who are Treatment-Naive or Relapsed on Tre	29/08/2013	16/09/2013	Yes	
13/SC/0368	Comparison of ultra low dose Oral versus Transdermal Hormone Therapy on coagulation activation and metabolic risk factors for Cardiovascular Disease	08/11/2013	18/03/2014	No	Issues with study design. Most potential participants are already on some form of HRT prior to visiting the site (making them ineligible); amendment submitted by Sponsor.
13/SC/0383	A Two Part, Randomized Clinical Trial to Study Biomarkers of MK8237 (SCH 900237) Treatment in Subjects with House Dust Mite Induced Allergic Rhinitis or Rhinoconjunctivitis	22/10/2013	27/11/2013	Yes	
13/SW/0124	A PERFORMANCE EVALUATION STUDY OF UROSENS' MCM5-ELISA FOR THE DETECTION OF PROSTATE CANCER IN PATIENTS WITH KNOWN DISEASE AND IN THOSE PRESENTING WITH RAISED SERUM PROSTATE-SPECIFIC ANTIGEN AND/OR ABNORMAL PROSTATE GLAND MORPHOLOGY	16/07/2013	09/10/2013	No	Lengthy R&D approval and/or contract negotiation.
13/SW/0192	European multicenter registry using hybrid staged operationg room and interventional catheter ablation techniques to treat chronic atrial fibrillation.	18/03/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
13/SW/0199	A randomised clinical trial to compare early verus delayed endovenous treatment of superficial venous reflux in patients with chronic venous ulceration	01/10/2013	20/12/2013	No	No eligible patients were seen or consented.
13/WA/0064	A performance evaluation study of UROSENS Mcm5 ELISA test in the diagnosis of bladder cancer in patients presenting with haematuria and lower urinary tract symptoms with suspicion of malignancy	28/03/2013	02/07/2013	No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/WA/0178	A Randomized, Double-Blind, Phase III Study of the Efficacy and Safety of Gemcitabine in Combination With TH-302 Compared With Gemcitabine in Combination With Placebo in Previously Untreated Subjects With Metastatic or Locally Advanced Unresectable	14/08/2013	10/10/2013	Yes	
13/WA/0328	Randomized controlled study comparing AEZS-108 with doxorubicin as second line therapy for locally advanced, recurrent or metastatic endometrial cancer	31/10/2013	21/01/2014	No	Rare disease study.
13/WM/0017	Anticoagulation Therapy in SELECTeD Cancer Patients at Risk of Recurrence of Venous Thromboembolism	14/05/2013	17/01/2014	No	Lengthy R&D approval and/or contract negotiation.
13/WM/0027	Venous Insufficiency and Neuromuscular Stimulation	15/04/2013	04/07/2013	No	Staff availability issues.
13/WM/0231	Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE study	20/08/2013	17/10/2013	Yes	
13/YH/0117	Multi-Channel Near Infrared Spectroscopy to Detect Spreading Depolarisations in Brain Injured Patients	01/07/2013		No	No eligible patients were seen or consented; lengthy R&D approval and/or contract negotiation.
13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer.	08/10/2013		No	Rare disease study.
14/LO/0016	Intraoperative confocal endomicroscopy of parathyroid glands	06/02/2014	20/03/2014	Yes	
14/LO/0026	The long-term safety and effect of renal denervation	17/02/2014		Not yet applicable	70-days from Date of VRA not exceeded by end of reporting period.
14/LO/0057	iPre-Pare: Intelligent Pre-operative Planning for Adverse event Reduction during Endovascular and vascular surgery.	17/12/2013		No	Lengthy R&D approval and/or contract negotiation.