Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 1 (2015/16)

All clinical trials granted NHS Permission between 01 July 2014 - 30 June 2015

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Date of NHS Permission	Date of Receipt of Valid Research Application (VRA)	First Patient Recruited?	Date of First Patient Recruited	Calendar Days between VRA and First Patient	Benchmark Met?	Reason for Delay
C&W13/081	14/LO/0565	A Multicentre, Randomised, Placebo-controlled, Double-blind Study of the Efficacy, Safety, and Pharmacokinetics of Lubiprostone in Paediatric Subjects Aged = 6 Years to < 18 Years with Functional Constipation	03/02/2015	27/02/2015	No	Pending	Pending	Pending	**Source of delays: Sponsor** D - Delays caused by sponsor: sponsor delayed green light for recruitment following NHS Permission because of delayed Site Initiation Visit (SIV) and subseqeuent delays to response to queries raised at SIV. Green light for recruitment received on 23/05/2015, which was 85 days following VRA. G - No patients consented: daily screening resulting in 2 potential patients being screened. Both anticipated to be consented in August 2015 for patient private reasoning.
C&W13/085	13/EE/0270	A Global Registry to Evaluate Long-Term Effectiveness of Neurostimulation Therapy for Pain	04/07/2014	30/06/2014	Yes	15/07/2014	15	Yes	
C&W13/087	14/LO/1694	Mesh nebuliser versus standard jet nebuliser therapy in acute Chronic Obstructive Pulmonary Disease in the Emergency Department	02/02/2015	02/02/2015	Yes	09/02/2015	7	Yes	
C&W14/024	14/WM/1047	Trial of Improvisational Music Therapy's Effectiveness for Children with Autism (TIME-A): UK Arm of the TIME-A Study.	23/09/2014	22/09/2014	Yes	04/11/2014	43	Yes	
C&W14/025	14/EE/0188	The effects of electronic cigarettes on the microcirculation of the hand	31/07/2014	31/07/2014	Yes	25/08/2014	25	Yes	
C&W14/029	13/WM/0017	select-d: Anticoagulation Therapy in SELECTeD Cancer Patients at Risk of Recurrence of Venous Thromboembolism	07/07/2014	07/07/2014	Yes	08/08/2014	32	Yes	
C&W14/046	14/EE/1027	The Chelsea Critical Care Physical Assessment Tool (CPAx): Validation and Evaluation of a score to grade physical recovery from critical illness.	08/09/2014	21/08/2014	Yes	18/09/2014	28	Yes	
C&W14/066	14/LO/0803	Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Pharmacodynamics, Safety and Pharmacokinetics of BMS-955176 (Double-Blinded) and BMS-955176 with Atazanavir +/- Ritonavir (Open-Labeled) in HIV-1 Infected Subjects	14/07/2014	11/07/2014	Yes	29/07/2014	18	Yes	
C&W14/069	12/SC/0014	Vasopressin vs Noradrenaline as Initial therapy in Septic Shock (VANISH)	15/07/2014	07/07/2014	Yes	20/03/2015	256	No	**Source of delays: Sponsor** D - Delays caused by sponsor: sponsor refused to grant green light for recruitment following NHS Permission because of revised training requirements put in place by sponsor. Green light for recruitment received on 02/09/2014, which was 57 days following VRA. F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified, despite daily screening resulting in 6 potential patients being screened.
C&W14/079	14/EE/1063	A Phase III, Open Label, Randomized Study of AZD9291 versus Platinum-Based Doublet Chemotherapy for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer whose Disease has Progressed with Previous Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and whose Tumours harbour a T790M mutation within the Epidermal Growth Factor Receptor Gene	18/09/2014	18/09/2014	Yes	01/10/2014	13	Yes	
C&W14/083	14/LO/1288	A multiple dose, open label, pivotal, 4- period, 2-treatment, 2-sequence full replicative cross-over study to assess the bioequivalence (BE) of TEVA's generic once daily nevirapine 400 mg prolonged-release (PR) formulation compared with the approved reference product Viramune® 400mg prolonged-release tablets under fasted conditions in HIV-1 infected patients	14/01/2015	09/01/2015	Yes	26/01/2015	17	Yes	
C&W14/087	14/LO/1227	Pharmacokinetics of DOLUTEGRAVIR once daily and ELVITEGRAVIR/COBICISTAT once daily over 10 days following drug intake cessation in healthy volunteers	19/08/2014	19/08/2014	Yes	21/08/2014	2	Yes	
C&W14/092	14/LO/1513	A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/ Tenofovir DF or Efavirenz/ Emtricitabine/ Tenofovir DF) compared to Ritonavir boosted Atazanavir plus Abacavir/ Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR =70 mL/min	27/10/2014	14/10/2014	Yes	15/12/2014	62	Yes	
C&W14/098	14/LO/1381	A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Each in Combination With TRUVADA™, in Treatment-Naïve HIV-1 Infected Subjects	05/11/2014	04/11/2014	Yes	25/11/2014	21	Yes	
C&W14/107	14/LO/1493	A phase IV open-label, multi-centre, randomised, dual-arm, pilot study to assess the feasibility of switching individuals receiving Efavirenz with continuing Central Nervous System (CNS) toxicity to Dolutegravir	19/12/2014	19/12/2014	Yes	12/01/2015	24	Yes	
C&W14/111	10/H1107/70	Is a short course of azithromycin effective in the treatment of mild to moderate pelvic inflammatory disease (PID)?	26/11/2014	20/11/2014	Yes	20/02/2015	92	No	**Source of delays: Sponsor** D - Delays caused by sponsor: delay in provision of trial medication (initial batch received just 9 days prior to timeframe end, which was destroyed at site due to temperature excursions in transit, with the second batch received 29 January 2015) followed by protocol amendment (recruitment delayed pending confirmation from sponsor that patient reimbursement may take the form of vouchers rather than cash).

C&W14/120	14/LO/2196	A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour.	13/05/2015	13/05/2015	No	Pending	Pending	Pending	Benchmark could still be met.
C&W14/122	14/SC/1345	Effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding: A randomised placebo-controlled trial (PRISM Trial: PRogesterone In Spontaneous Miscarriage Trial)	03/03/2015	25/02/2015	Yes	02/06/2015	97	No	**Source of delays: Sponsor** D - Delays caused by sponsor: delay in provision of trial medication due to a delay in the execution of the contract between the trial sponsor and drug supplier. Greenlight for recruitment was received 19/05/2015, which was 83 days following VRA. Once green light was received, first recruit was achieved in just 14 days.
C&W14/126	14/YH/1269	Open label evaluation of the population PK profile, safety, tolerability and efficacy of tapentadol IV solution for the treatment of post-surgical pain in children aged from birth to less than 2 years, including pre term neonates (KF5503-73).	10/06/2015	10/06/2015	No	Pending	Pending	Pending	Benchmark could still be met.
C&W14/131	14/NE/1099	GA29103 - Phase III, randomised, multicentre, double blind, double dummy, study to evaluate the efficacy and safety of etrolizumab compared with infliximab in patients with moderate to severe active ulcerative colitis who are naive to TNF inhibitors	09/01/2015	09/01/2015	Yes	29/01/2015	20	Yes	
C&W14/132	15/WA/0026	Assessing the gut microbiome in children with Crohn's disease: Effects of a specific exclusion diet.	02/04/2015	02/04/2015	Yes	10/06/2015	69	Yes	
C&W15/002	15/WM/0050	Efficacy and safety of ingenol mebutate gel 0.015% compared to diclofenac sodium gel 3% in subjects with actinic keratoses on the face or scalp.	08/05/2015	01/05/2015	Yes	01/07/2015	61	Yes	
C&W15/008	13/YH/0066	Pressure Relieving Support Surfaces: A Randomised Evaluation 2	02/03/2015	25/02/2015	Yes	24/03/2015	27	Yes	
C&W15/011	15/LO/0031	A phase IV, open-label three-arm study investigating the impact of a combination of tenofovir disoproxil fumarate/emtricitabine with raltegravir or dolutegravir or elvitegravir/cobicistat on renal tubular function and renal transporters in HIV-1 antiretroviral naïve patients	04/03/2015	04/03/2015	Yes	23/04/2015	50	Yes	
C&W15/023	14/NE/1100	An open label, extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in etrolizumab phase III studies	18/03/2015	13/03/2015	No	Pending	Pending	Pending	**Source of delays: Neither Sponsor nor NHS** J - Other: trial is a rollover for patients succesfully completing REC 14/NE/1099 (C&W14/131) and sponsor requested issue of NHS Permission in line with the initial study. It is therefore not possible to recruit within the timeframe as no patients will have completed the initial study during that timeframe.
C&W15/052	14/WM/1210	A Phase 3, randomized, active-controlled, open-label study to evaluate the efficacy, safety and tolerability of switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in virologically-suppressed, human immunodeficiency virus type 1 (HIV-1) infected subjects.	06/05/2015	28/04/2015	Yes	10/07/2015	73	No	**Source of delays: Sponsor** D - Delays caused by sponsor: sponsor refused to grant green light for recruitment following NHS Permission due to drug delivery delay. Green light for recruitment received on 29/05/2014, which was 29 days following VRA.
C&W15/053	13/EE/0214	A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Risistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial.	12/05/2015	08/05/2015	Yes	29/06/2015	52	Yes	
C&W15/059	15/LO/0495	A phase 3b, randomised, double-blind, switch study to evaluate the safety and efficacy of emtricitabine / rilpivirine / tenofovir alafenamide (FTC/RPV/TAF) fixed dose combination (FDC) in HIV-1 positive subjects who are virilogically supressed on emtricitabine / rilpivirine / tenofovir disproxil fumarate (FTC/RPV/TDF).	05/06/2015	05/06/2015	No	Pending	Pending	Pending	Benchmark could still be met.
C&W15/060	15/LO/0496	GS-US-366-1160: A phase 3b, randomised, double-blind, study to evaluate switching from a regimen consisting of efavirenz / emtricitabine / tenofovir disoproxil fumarate (EFV/FTC/TDF) fixed dose combination (FDC) ito emtricibatine / rilprivirine / tenofovir alafenamide (FTC/RPV/TAF) FDC in virologically.	05/06/2015	05/06/2015	No	Pending	Pending	Pending	Benchmark could still be met.
C&W15/064	15/LO/0438	GS-US-337-1612: Open-label study to evaluate the safety and efficacy of ledipasvir / sofosbuvir (LDV/SOF) fixed-dose combination (FDC) for 6 weeks in subjects with acute genotype 1 or 4 hepatitis C virus (HCV) and chronic human immunodeficiency virus (HIV)-1 co-infection.	10/06/2015	08/06/2015	Yes	02/07/2015	24	Yes	