Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 2 (2015/16)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired West Middlesex University Hospital NHS Trust on 01 September 2015, and the submission for the former West Middlesex University Hospital NHS Trust has been subsumed into this submission

All clinical trials granted NHS Permission between 01 October 2014 - 30 September 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	Yes	07/09/2015	192	No	**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. Due to personal reasons, both potential patients (subsequently recruited) wished to proceed in September 2015 following school summer holidays.
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&W14/041	14/LO/0816	A Multicentre, Long-term Safety, Efficacy and Pharmacokinetics Study of Lubiprostone in Paediatric Subjects Aged =6 to <18 years with Functional Constipation	13/08/2015	06/08/2015	No	Pending	Pending	Pending	**Source of delays: Sponsor** B - Study suspended by sponsor: trial is a rollover for patients succesfully completing REC 14/LO/0565 (C&W13/081) 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&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&W14/092	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	**Source of delays: Sponsor** D - Delays caused by sponsor: delay in provision of pharmacy manual. Due to delays in confirmation of green light due to delayed shipment of IMP, site was unable to recruit until 21/08/2015, 100 days post valid research application. Screening is taking place daily since this date, but the study is very difficult to recruit to, having only recruited 2 patients across 18 sites in 5 countries to date.
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	**Source of delays: Neither Sponsor nor Trust** G - eligible patients seen during the relevant period but did not consent to participate in the trial: as of 30/09/2015, 112 days have passed since valid research application. Study required the parents/guardian of the patient to consent to administration of IMP to their child under 2 years of age and none have wished to do so.
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	FALSE	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: Sponsor** B - Study suspended by sponsor: 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&W15/032	15/LO/0423	An open label study to investigate the safety and efficacy of abacavir/lamivudine/dolutegravir and the pharmacokinetic profile of dolutegravir in HIV infected patients of 60 years of age and older	24/07/2015	15/07/2015	Yes	04/08/2015	20	Yes	
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	Yes	14/07/2015	39	Yes	
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	Not applicable	Not applicable	No	**Source of delays: Sponsor** C - Study closed by sponsor: study-wide recruitment completed at local day 52 (27/07/2015).
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 vrirus (HIV)-1 co-infection.	10/06/2015	08/06/2015	Yes	02/07/2015	24	Yes	
C&W15/054	15/ES/0076	A Phase 3, Multicenter, Open-label, Randomized Study of SGI-110 versus Treatment Choice (TC) in Adults with Previously Untreated Acute Myeloid Leukemia (AML) Who Are Not Considered Candidates for Intensive Remission Induction Chemotherapy.	28/08/2015	28/08/2015	No	14/09/2015	17	Yes	
C&W15/073	15/LO/0652	A Phase 2b Randomized, Active-Controlled, Double-Blind Trial to Investigate Safety, Efficacy, and Dose-response of BMS955176, Given on a Backbone of Tenofovir/Emtricitabine, in Treatment-Naive HIV-1 Infected Adults	14/07/2015	13/07/2015	Yes	23/07/2015	10	Yes	
C&W15/077	15/LO/0904	SSAT063: Pharamcokinetics of efavirenz 400mg once daily during pregnancy in HIV-1 infected women	31/07/2015	29/07/2015	Yes	24/09/2015	57	Yes	
C&W15/078	15/LO/0075	A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects	13/08/2015	13/08/2015	No	Pending	Pending	Pending	Study is within the 70 day window.
C&W15/081	15/LO/0519	Protocol AI438047: A Multi-arm Phase 3 Randomized Placebo Controlled Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1	08/09/2015	04/09/2015	No	Pending	Pending	Pending	Study is within the 70 day window.
C&W15/085	15/LO/1063	M14004 A Multipart, Openlabel Study to Evaluate the Safety and Efficacy of Ombitasvir (ABT450)/Paritaprevir (ABT267)/Ritonavir With and Without Dasabuvir (ABT 333) Coadministered With and Without Ribavirin in Adults With Genotype 1 or 4 Chronic Hepatitis C Virus Infection and Human Immunodeficiency Virus, Type 1 Coinfection (TURQUOISEI)	17/08/2015	13/08/2015	Yes	03/09/2015	21	Yes	
C&W15/100	15/LO/0881	MK1439A versus ATRIPLA in treatment naïve HIV1 infected subjects	11/09/2015	10/09/2015	No	Pending	Pending	Pending	Study is within the 70 day window.

C&W15/101	15/LO/1163	A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC	23/09/2015	18/09/2015	No	Pending	Pending	Pending	Study is within the 70 day window.
C&W15/102	15/NW/0505	A Phase III Multicenter, Open-Label, Randomized Study to Evaluate a Switch to MK-1439A in HIV-1-Infected Subjects Virologically Suppressed on a Regimen of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) – MK1439A-024.	11/09/2015	10/09/2015	No	Pending	Pending	Pending	Study is within the 70 day window.
14/essam/16	13/SC/0645	PHOENIX: Pre-eclampsia in Hospital: Early Induction or Expectant Management	17/10/2014	16/10/2014	Yes	19/01/2015	94	No	**Source of delays: Neither Sponsor nor Trust** G - No patients consented: study requires the patient to consent to potential early induction and none had wished to do so.
14/essam/17	13/SS/0081	TWICS: Theophylline with Inhaled Corticosteroid	24/10/2014	16/10/2014	No	Pending	Pending	Pending	**Source of delays: Neither Sponsor nor Trust** G - No patients consented: study requires the patient to consent to IMP over theophylline which is a popular standard care medication and none have wished to do so.
14/essam/19	13/LO/0393	INSIGHT: Investigation into biomarkers to predict preterm birth	30/10/2014	20/10/2014	Yes	13/11/2014	24	Yes	
14/essam/20	13/WM/0419	MAMMO-50: Mammographic surveillance in breast cancer patients aged 50 years and over	12/11/2014	10/11/2014	Yes	28/02/2015	110	No	**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 28/02/2015, which was 110 days following VRA. G - No patients consented: daily screening resulting in 5 potential patients being screened. All declined duye to additional mammograms required by protocol.
15/essam/03	11/SW/0036	TABLET: A Randomised Controlled Trial of the Efficacy and Mechanism of Levothyroxine Treatment on Pregnancy and Neonatal Outcomes in Women with Thyroid Antibodies	18/03/2015	18/03/2015	Yes	16/04/2015	29	Yes	
15/essam/05	14/LO/1842	ENDCaP-C Test Accuracy Study: Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis (ENDCaP-C): A Multicentre test accuracy study	22/04/2015	16/04/2015	No	09/07/2015	84	No	**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) . Green light for recruitment received on 09/07/2015, which was 84 days following VRA. G - No patients consented: daily screening resulting in 5 potential patients being screened but none have wished to participate.
15/essam/14	13/NE/0339	GOT-IT: Glycerine Trinitrate for retained placenta	27/07/2015	24/07/2015	Yes	18/08/2015	25	Yes	
15/essam/16	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)	03/09/2015	02/09/2015	Yes	30/09/2015	28	Yes	
15/essam/17	12/SC/0515	BREATH: A ventilation weaning	03/09/2015	03/09/2015	No	Pending	Pending	Pending	Study is within the 70 day window.