Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Delivering Clinical Research - Quarter 3 (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 hosted, commercial clinical trials active between 01 January 2015 - 31 December 2015

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
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	2	01/10/2015	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
C&W13/085	13/EE/0270	A Global Registry to Evaluate Long-Term Effectiveness of Neurostimulation Therapy for Pain	30	04/07/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	No target set by sponsor	No date agreed with sponsor	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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.	1	04/01/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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).	1	31/08/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	4	No date agreed with sponsor	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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.	12	30/11/2015	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	No target set by sponsor	No date agreed with sponsor	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
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.	5	01/12/2017	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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.	5	30/12/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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).	5	22/06/2017	Closed - in follow up	No	Trial remained in follow up during this reporting period. 4 patients were screened, of which 4s patient was enrolled. Recruitment was ended prematurely at an international level.
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	4	31/12/2017	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	5	01/03/2018	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	2	21/12/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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)	5	31/10/2015	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
C&W15/100	15/LO/0881	MK1439A versus ATRIPLA in treatment naïve HIV1 infected subjects	6	18/03/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	6	31/03/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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.	5	18/03/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
C&W11/075	11/SC/0329	A Phase 3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn's Disease	5	No date agreed with sponsor	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 5 patients were screened, of which 5 patients were enrolled.
C&W12/016	11/LO/1974	A Multicenter, controlled, Open-Label Extension (OLE) Study To Assess the Long-Term Safety and Efficacy of AMG 145	2	19/03/2013	Closed - in follow up	No	Trial remained in follow up during this reporting period. 1 patient was screened, of which 1 patient was enrolled.
C&W12/092	12/LO/1434	Lung Volume Reduction Coil Treatment in Patients with Emphysema (RENEW) Study	8	30/10/2014	Closed - in follow up	Yes	Trial remained in follow up during this reporting report.
C&W13/015	11/LO/1455	Gilead HCV Registry 0122 Responders	8	01/10/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. It was not possible to achieve the recruitment target, as only those patients enrolled to an earlier trial with a positive response to treatment were eligible. When the recruitment target was originally set for this trial, it was not possible to ascertain how many patients would be positive responders and therefore an arbitrary target was set, based upon the target for the earlier trial.
C&W13/016	11/LO/1456	A Long Term Follow-up Registry Study of Subjects Who Did Not Achieve a Sustained Virologic Response in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection	5	01/10/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. It was not possible to achieve the recruitment target, as only those patients enrolled to an earlier trial with a sustained virologic response to treatment were eligible. When the recruitment target was originally set for this trial, it was not possible to ascertain how many patients would be sustained virologic responders and therefore an arbitrary target was set, based upon the target for the earlier trial.
C&W13/039	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 (GS-US-292-0112)	5	01/02/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. 3 patients were screened, of which 1 patients was enrolled.
C&W13/044	13/SC/0279	A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically Suppressed, HIV1 Positive Subjects (GS-US-292-0109)	5	22/01/2016	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 9 patients were screened, of which 8 patients were recruited.
C&W13/050	13/LO/0572	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Treatment- Naïve Adults (GS-US-292-0104)	10	22/01/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. 8 patients were screened, of which 6 patients were enrolled.

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
C&W13/052	13/LO/0574	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Treatment- Naïve Adults (GS-US-292-0111)	10	22/01/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. 12 patients were screened, of which 9 patients were enrolled.
C&W13/068	13/EE/0241	Secukinumab In patients with moderate to severe active, chronic plaque psoriasis who have failed on TNFa antaGoNists: A clinical Trial EvalUating Treatment REsults (SIGNATURE)	2	16/01/2015	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 3 patients were screened, of which 2 patients were enrolled.
C&W14/062	14/SC/0225	A Phase 3, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV 1 Positive Subjects who are Virologically Suppressed on Regimens containing FTC/TDF (GS-US-311-1089)	8	15/06/2016	Closed - in follow up	No	Trial remained in follow up during this reporting period. 7 patients were screened, of which 6 patients were enrolled and due to sponsor closing recruitment sooner than anticipated, enrollment of a further 2 patients was not possible.
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	2	31/08/2015	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 7patients were screened, of which 5 patients were enrolled.
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	46	01/05/2015	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 46 patients were screened, of which 46 patients were enrolled.
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	3	04/06/2015	Closed - in follow up	Yes	Trial remained in follow up during this reporting period. 13 patients were screened, of which 13 patients were enrolled.
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.	8	15/10/2018	Closed - in follow up	No	Trial remained in follow up during this reporting period. It was not possible to achieve the recruitment target, as only those patients enrolled to an earlier trial with a positive response to treatment were eligible. When the recruitment target was originally set for this trial, it was not possible to ascertain how many patients would be positive responders and therefore an arbitrary target was set, based upon the target for the earlier trial.
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).	5	22/06/2017	Closed - in follow up	No	Trial remained in follow up during this reporting period. 4 patients were screened, of which 4s patient was enrolled. Recruitment was ended prematurely at an international level.

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
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.	7	31/10/2016	Closed - in follow up	Not applicable	Trial remained in follow up during this reporting period. 6 patients were screened, of which 3 patient was enrolled. Recruitment was ended prematurely at an international level.
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.	5	29/04/2016	Closed - in follow up	Not applicable	Trial remained in follow up during this reporting period. 4 patients were screened, of which 4 patients was enrolled. Recruitment was ended prematurely at an international level.
HHG09004NI	09/H1102/54	An International, Multicentre, Prospective Observational study of the safety of maraviroc used with optimized background therapy in treatment-experienced HIV-1 infected patients	5	No date agreed with sponsor	Closed - follow up complete	Yes	Last patient last visit took place 01/10/2014, with site having not met recruitment target. 44 patients were screened, of which 44 patients were enrolled.
C&W10/046	09/S501/68	A Randomised Multicenter, Open-Label, Phase 3 Study of Gemcitabine-Cisplatin Chemotheraphy Plus IMC-11F8 Versus Gemcitabine-Cisplatin Chemotherapy Alone in the First-Line Treatment of Patients with Squamous Stage IIIb or IV Non-Small Cell Lung Cancer (NSCLC)	4	31/01/2013	Closed - follow up complete	No	Last patient last visit took place 24/11/2014, with site having not met recruitment target. 2 patients were screened, of which 1 patient was enrolled.
C&W10/103	10/H0706/69	A Phase III, randomised, double blind study of the safety and efficacy of GSK1349572 50 mg once daily to raltegravir 400 mg twice daily both administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral therapy naive adult subjects.	10	31/01/2013	Closed - follow up complete	No	Last patient last visit took place 19/05/2015, with site having not met recruitment target. 13 patients were screened, of which 9 patients were enrolled.
C&W11/044	11/LO/0751	A Phase 3, Open-label Safety study of Cobicistat-containing Highly Active Antiretroviral Regimens in HIV-1 Infected Patients with Mid to Moderate Renal Impairment	5	31/07/2013	Closed - follow up complete	Yes	Last patient last visit took place 07/10/2014, with site having met recruitment target. 11 patients were screened, of which 7 were enrolled.
C&W11/052	11/LO/0785	A Multi-Centre, Randomised, Blinded, Placebo-Controlled Study to Evaluate the Safety of Maraviroc in Combination with Other Antiretroviral Agents in HIV-1 Infected Subjects Co-Infected With Hepatitis C and / or Hepatitis B Virus	2	30/09/2013	Closed - follow up complete	Yes	Last patient last visit took place 02/03/2015, with site having met recruitment target. 4 patients were screened, of which 3 patients were enrolled.
C&W12/017	11/SC/0523	A Phase 3b Randomized, Open Label Study to Evaluate Switching from Regimens Consisting of a Ritonavirboosted Protease Inhibitor (PI/r) plus Emtricitabine/Tenofovir FixedDose Combination (FTC/TDF) to the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate SingleTablet Regimen (EVG/COBI/FTC/TDF) in Virologically Suppressed, HIV 1 Infected Patients	8	01/03/2013	Closed - follow up complete	Yes	Last patient last visit took place 14/10/2014, with site having met recruitment target. 15 patients were screened, of which 8 patients were enrolled.
C&W12/018	11/SC/0524	A Phase 3b Randomized, Open-Label Study to Evaluate Switching from Regimens Consisting of a Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) plus Emtricitabine (FTC) and Tenofovir DF (TDF) to the Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate Single-Tablet Regimen (EVG/COBI/FTC/TDF) in Virologically-Suppressed, HIV-1 Infected Patients	8	01/03/2013	Closed - follow up complete	Yes	Last patient last visit took place 05/11/2014, with site having met recruitment target. 13 patients were screened, of which 9 patients were enrolled.

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Recruitment Target	Date Agreed to Recruit Target Number of Patients	Trial Status	Target Met Within Agreed Timeframe?	Comments
C&W13/075	13/EE/0276	A Phase 3B Randomized, Open-Label Multi-Center 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 (GS-US-334-0153)	5	21/05/2014	Closed - follow up complete	No	Last patient last visit took place 23/10/2014 with site hacing not met recruitment target. 3 patients were screened, of which 3 patients were enrolled.
C&W14/063	14/LO/0667	A Phase III Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Treatment-Naïve Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are Co-Infected with HIV	9	11/05/2015	Closed - follow up complete	No	Last patient last visit took place 10/04/2015, with site having not met recruitment target. 13 patients were screened, of which 8 were enrolled. Due to sponsor closing recruitment sooner than anticipated, enrollment of a further 1 patient was not possible.
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	22	23/12/2014	Closed - follow up complete	No	Last patient last visit took place 16/10/2014, with site having not met recruitment target. 6 patients were screened, of which 4 were enrolled.
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	5	30/03/2017	Closed - follow up complete	No	Last patient last visit took place 04/03/2015, with site not having met recruitment target. 2 patients were screened, of which 2 were enrolled.
13/essam/16	13/EE/0241	A UK multi-centre, open-label, non-comparator study to demonstrate the efficacy and safety of two doses of secukinumab in patients with moderate to severe active, chronic plaque psoriasis who have failed on TNFa antagonists.	3	25/09/2014	Closed - follow up complete	Yes	Last patient last visit took place 01/07/2015, with site having met the recruitment target.