Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 4 (2013/14)

All clinical trials granted NHS Permission between 01 April 2013 - 31 March 2014

Analysis
Number of clinical trials reported: 33 (100%)
Number of clinical trials meeting benchmark: 9 (27%)
Number of clinical trials still able to meet benchmark: 2 (6%)
Number of clinical trials unable to meet benchmark (due to no recruitment expected): 3 (9%)
Number of clinical trials failing to meet benchmark: 19 (58%)

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Date of NHS Permission	Detail 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&W12/080	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.	06/09/2013	01/09/2013	Yes	17/10/2013	46	Yes	
C&W13/026	13/LO/0425	the Efficacy and Safety of the Combination of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment-Naïve Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection	29/04/2013	17/04/2013	Yes	07/05/2013	20	Yes	
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)	26/07/2013	19/07/2013	Yes	27/09/2013	70	Yes	
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)	11/07/2013	10/07/2013	Yes	19/07/2013	9	Yes	
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)	11/07/2013	09/07/2013	Yes	12/08/2013	34	Yes	
C&W13/057	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 with HIV	16/08/2013	29/07/2013	Yes	23/09/2013	56	Yes	
C&W13/069	13/SC/0368	Comparison of ultra-low-dose Oral versus Transdermal Hormone Therapy on coagulation activation and metabolic risk factors for Cardiovascular Disease	21/10/2013	21/10/2013	Yes	07/11/2013	17	Yes	
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)	07/11/2013	30/10/2013	Yes	10/12/2013	41	Yes	
C&W13/083	13/YH/0424	Randomized Trial of Rapid Outpatient Rehydration versus Hospital Admission for Hyperemesis Gravidarum	17/12/2013	09/12/2013	Yes	14/02/2014	67	Yes	
C&W13/100	13/LO/1908	Evaluating the nutritional adequacy of a diet low in fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP's) in children with functional gastrointestinal disorders	17/02/2014	13/02/2014	No	Pending	Pending	Pending	Still able to meet benchmark.
C&W14/004	13/LO/0147	A phase IV study to determine the oral and genital tract concentration of Maraviroc required for ex vivo protection from HIV-1 using Maraviroc 300mg stat	10/03/2014	04/03/2014	No	Pending	Pending	Pending	Still able to meet benchmark.
C&W12/065	11/LO/1487	United Kingdom National Randomised Trial for Children and Young Adults with Acute Lymphoblastic Leukaemia and Lymphoma 2011	08/07/2013	11/07/2013	No	Not applicable	Not applicable	Not applicable	J - Other: no recruitment expected to take place at Trust, data collection only as shared care centre only.
C&W13/065	13/EM/0030	Speed of Increasing milk Feeds Trial	03/03/2014	16/02/2014	No	Not applicable	Not applicable	Not applicable	J - Other: no recruitment expected to take place at Trust, data collection only as continuing care centre only.
C&W13/070	13/SW/0199	A randomized clinical trial to compare early versus delayed endovenous treatment of superficial venous reflux in patients with chronic venous ulceration.	02/10/2013	25/09/2013	No	Not applicable	Not applicable	Not applicable	J - Other: no recruitment expected to take place at Trust, data collection only as shared care centre only.
C&W12/117	11/LO/0935	Genetic analysis for personalised medicine for morbid obesity	12/09/2013	11/04/2013	Yes	25/11/2013	228	No	A - Relevant permissions delayed and not granted in time: due to delay in obtaining a research passport for a key team member. F - No eligible patients seen during the reporting period: due to strict patient eligibility criteria, including requirement to wait six weeks between screening and consenting patients. J -Other: changes in funding for surgery resulted in a lack of eligible patients.
C&W12/121	12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	22/07/2013	09/11/2012	Yes	14/02/2014	462	No	H - Contracting delays: within sponsor organisation.
C&W13/012	13/EE/0038	Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial	08/05/2013	22/04/2013	Yes	22/08/2013	122	No	D - Delays caused by sponsor: site initiation delayed until 01/08/2013 as sponsor organisation unexpectedly delayed drug shipment to site. First patient recruited 21 days following initiation.
C&W13/015	11/LO/1455	Gilead HCV Registry 0122 Responders	27/08/2013	27/08/2013	Yes	14/02/2014	171	No	J - Other: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window.
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	27/08/2013	27/08/2013	Yes	06/02/2014	163	No	J - Other: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window.
C&W13/021	13/LO/0247	A two way cross over pharmacokinetic interaction study between raltegravir and amlodipine in healthy volunteers	24/04/2013	20/03/2013	Yes	03/06/2013	75	No	G - Eligible patients seen during the relevant period but did not consent to participate in the trial: trial is an intensive PK study, but is now closed follow up complete having recruited on time and above target.

C&W13/022	13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects (GS-US-104-0423)	12/07/2013	13/06/2013	Yes	31/10/2013	140	No	D - Delays caused by sponsor: delayed confirmation from sponsor organisation of study open to recruitment at site due to requirement for sponsor organisation to approve site DEXA machine.
C&W13/024	12/LO/1941	A randomised controlled trial investigating the effect of transcatheter renal sympathetic denervation on symptoms and cardiac function in patients with heart failure with preserved ejection fraction	08/04/2013	04/04/2013	No	Pending	Pending	No	G - Eligible patients seen during the relevant period but did not consent to participate in the trial.
C&W13/033	13/LO/0651	A randomised controlled trial of biomarker-based exclusion of VAP to improve antibiotic stewardship.	14/10/2013	14/10/2013	Yes	18/02/2014	127	No	D - Delays caused by sponsor: delayed confirmation from sponsor of study open to recruitment at site due to Case Report Forms not being received until 29/11/2014. F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified, despite daily screening.
C&W13/035	13/LO/0570	An open label, randomised, pilot trial of pegylated interferon, ribavirin and telaprevir versus pegylated interferon and ribavirin alone in the response guided treatment of acute hepatitis C genotype 1 virus infection in patients with HIV-1 co-infection	06/12/2013	28/05/2013	Yes	21/01/2014	238	No	D - Delays caused by sponsor: multiple protocol amendments were submitted by sponsor organisation, with sponsor organisation wishing to initiate our site following receipt of REC approval for these, which was received 06/12/2013.
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)	28/08/2013	16/07/2013	Yes	10/10/2013	86	No	D - Delays caused by sponsor: delayed site initiation visit as no representative from sponsor organisation was avaialable to conduct site initiation visit.
C&W13/047	08/H1008/25	Rheumatoid Arthritis Medication Study (RAMS)	02/10/2013	27/09/2013	Yes	21/02/2014	147	No	F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified despite regular patient screening.
C&W13/054	12/EM/0003	Induction of labour versus expectant management for nulliparous women over 35 years of age	24/09/2013	24/07/2013	Yes	20/11/2013	119	No	G - Eligible patients seen during the relevant period but did not consent to participate in the trial.
C&W13/059	12/NE/0343	Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy	05/09/2013	05/09/2013	No	Pending	Pending	No	F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified despite regular patient screening.
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)	10/10/2013	10/10/2013	No	Pending	Pending	No	G - Eligible patients seen during the relevant period but did not consent to participate in the trial.
C&W13/073	13/LO/1290	A Follow-up Study to Assess Resistance and Durability of Response to AbbVie Direct-Acting 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	31/10/2013	30/10/2013	No	Pending	Pending	No	J - Other: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window.
C&W13/084	13/ES/0145	The Beagle Böhler Walker - A Pressure Testing Validation Study	19/12/2013	08/11/2013	No	Pending	Pending	No	E - Staff availability issues at site: study assigned a BSc student to assist with data collection whom is yet to formally start.
C&W13/090	14/EE/0048	A comparison between thermal imaging (thermography) and laser doppler imaging for the assessment of adult burns injuries	23/01/2014	17/01/2014	No	Pending	Pending	No	J - Other: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window.
C&W13/094	13/EM/0154	A multi-centre randomised controlled trial evaluating cast treatment versus surgical fixation on wrist function for fractures of the scaphoid waist in adults	13/01/2014	13/01/2014	No	Pending	Pending	No	D - Delays caused by sponsor: protocol amendments implemented by sponsor organisation meant that recruitment packs were not received by site within reporting period.