Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 1 (2014/15)

All clinical trials granted NHS Permission between 01 July 2013 - 30 June 2014

Analysis
Number of clinical trials reported: 31
Number of clinical trials meeting benchmark: 13
Number of clinical trials failing to meet benchmark: 17
Number of clinical trials where benchmark is not applicable: 1

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&W12/074	12/NW/0214	TAILoR - (TelmisArtan and InsuLin Resistance in HIV): A Dose Ranging Phase II Randomised Open-Labelled Trial of Telmisartan as a strategy for the Reduction of Insulin Resistance in HIV-Positive Individuals on Combination Antiretroviral Therapy (cART)	12/05/2014	12/05/2014	Yes	20/06/2014	39	Yes	
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&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	D - Delays caused by sponsor: 255 calendar days passed between VRA and NHS Permission. This was due to delays in the review, approval and finalisation of the contract by the sponsor. Further 207 calendar days passed between NHS Permission and First Patient Recruited. This was due to a delay in scheduling of SIV by the sponsor as they had to arrange a contract with a UK based CRO for initiation and monitoring. In addition, sponsor withheld green light for recruitment pending REC acknowledgement of a non-substantial amendment to the protocol to allow for alternative testing for determination of HIV-1 infection (test originally specified rarely used in the UK). REC acknowledgement was not received until 14/10/2013. In addition, sponsor did not authorise drug shipment under release date of 08/11/2013, which prevented screening of patients to the study as drug supply was not confirmed as secure previous to this date. In spite of these delays, site recruited first UK patient and sponsor confirmed great satisfaction with service provided. H - Contracting delays: within sponsor organisation account for the 255 days between VRA and NHS Permission.
C&W13/015	11/LO/1455	Gilead HCV Registry 0122 Responders	27/08/2013	27/08/2013	Yes	14/02/2014	171	No	D - Delays caused by sponsor: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window. 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	D - Delays caused by sponsor: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window. 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&W13/022	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 due to requirement for sponsor organisation to approve site DEXA machine.
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 29/11/2013. F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified, despite daily screening, following the ability of the site to inititate recruitment on 29/11/2013. From receipt of the Case Report Forms, it took a further 81 days to recruit first patient.
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: valid application was received 28/05/2013, but sponsor organisation did not want to initiate site using the version of the protocol submitted with this valid application. Sponsor organisation requested that site only issue NHS Permission once regulatory approvals for the amended protocol were received, to ensure that the site would be initiated on the latest version of the protocol. All regulatory approvals were received 06/12/2013, which then allowed NHS Permission to be granted. First patient was recruited 46 days following NHS Permission.

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&W13/044	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&W13/047	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&W13/050	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&W13/054	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&W13/057	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&W13/059	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	Yes	12/06/2014	245	No	F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified despite regular patient screening.
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&W13/073	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	No recruitment	Not applicable	No	B - Study closed by sponsor: change in development pipeline within sponsor company - sponsor requested this roll over trial be approved, and prior to eligible patients rolling over, decided to close the trial on 02/04/2014 thus resulting in no recruitment at site. D - Delays caused by sponsor: trial is a roll over trial, and approved at sponsor organisation request despite eligible patients not rolling over within the 70 day window. 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&W13/075	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&W13/084	13/ES/0145	The Beagle Böhler Walker - A Pressure Testing Validation Study	19/12/2013	08/11/2013	Yes	29/03/2014	141	No	E - Staff availability issues at site: 41 calendar days between valid research application and NHS Permission due to delays incurred in the issue of a Research Passport for a key investigator. A further 100 calendar days between NHS Permission and first recruit because of further staff availability issues, due to delays in the researcher undergoing a change of emloyment circumstances from honorary employee to full contractual employee, substantively employed by C&W as opposed to another NHS Trust.
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	Yes	05/03/2014	47	Yes	
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 70 day period. E - Staff availability issues at site: Following 70 day period, staff changes in the clinical team affected ability to run study. Performance management plan now implemented between Trust and sponsor with a review date of 06/10/2014.
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	28/04/2014	74	No	G - Eligible patients seen during the relevant period but did not consent to participate in the trial - 2 were given info prior to deadline but due to Easter were unable to be scheduled in in time.
C&W14/002	14/LO/0083	An open label study examining the efficacy and cardiovascular risk of immediate versus deferred switch from a boosted PI to dolutegravir (DTG) in HIV infected patients with stable virological suppression	08/04/2014	08/04/2014	Yes	02/05/2014	24	Yes	

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	Yes	10/06/2014	98	No	D - Delays caused by sponsor: sponsor refused to grant green light for recruitment following NHS Permission because of a protcol amendment regarding exclusion criteria for heptatus A screening (despite original unamended protocol having regulatory approvals). Regulatory approvals for this amendment were received 09/05/2014 (REC) and 15/05/2014 (MHRA). Following receipt of these approvals, site was able to begin recruit. First patient was recruited 26 days following MHRA approval.
C&W14/022	13/SC/0436	ASAP - Early low dose steroids for adults admitted to hospital with influenza-like illness during a pandemic: a randomised placebo controlled trial	18/06/2014	18/06/2014	No	Not applicable	Not applicable	Not applicable	J - Other: study will sit in hibernation stage until C&W is activated as a research site in the event of a pandemic flu episode. Site will only be activated by sponsor, and therefore become open to recruitment, when a pandemic flu event is declared.
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	12/06/2014	06/06/2014	Yes	30/06/2014	24	Yes	
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	12/06/2014	09/06/2014	Yes	13/06/2014	4	Yes	