Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 2 (2014/15)

All clinical trials granted NHS Permission between 01 October 2013 - 30 September 2014

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&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	**Source of delays: Sponsor** 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. This was outside of the control of the NHS organisation as every effort was made to identify all potentially eligible patients.
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	**Source of delays: Sponsor** 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&W13/047	08/H1008/25	Rheumatoid Arthritis Medication Study (RAMS)	02/10/2013	27/09/2013	Yes	21/02/2014	147	No	**Source of delays: Neither Sponsor nor NHS** F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified despite regular patient screening. As such, the delay was outside of the control of the NHS organisation as every effort was made to identify all potentially eligible patients.
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	**Source of delays: Neither Sponsor nor NHS** G - Eligible patients seen during the relevant period but did not consent to participate in the trial: patients sought and eligible patients identified whom did not choose to consent. Eligible patients wishing to consent not identified despite regular patient screening. As such, the delay was outside of the control of the NHS organisation as every effort was made to identify all potentially eligible patients.
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	**Source of delays: Sponsor** C - 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	**Source of delays: Neither Sponsor nor NHS** 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&W13/085	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&W13/090	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	Not applicable	No	**Source of delays: Both Sppnsor and NHS** 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	Yes	28/04/2014	74	No	**Source of delays: Neither Sponsor nor NHS** 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. The fault therefore lies neither with the NHS Provider nor sponsor - patients would have consented if the public holiday fell on a different date.
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	**Source of delays: Sponsor** 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	Pending	Not applicable	Not applicable	**Source of delays: Neither Sponsor nor NHS** 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&W14/024	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	No	Pending	Not applicable	Pending	Deadline is 02 December 2014.
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&W14/062	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	
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	No	Pending	Not applicable	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 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&W14/087	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	