Performance in Delivering Clinical Research - Quarter 3 (2014/15)

All hosted, commercial clinical trials active between 01 January 2014 - 31 December 2014

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&W13/015	11/LO/1455	Gilead HCV Registry 0122 Responders	8	01/10/2016	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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)	62	31/12/2015	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target. Study recruitment window nationally extended from 30/09/2014 to 31/12/2015.
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	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target. Study recruitment window nationally extended from 09/10/2014 to 16/01/2015.
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&W14/079	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	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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	Open	Not applicable	Trial remains open and therefore is still able to meet recruitment target.
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 - in follow up	Yes	Trial remained in follow up during this reporting period. 44 patients were screened, of which 44 were 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 - in follow up	No	Trial remained in follow up during this reporting period. 13 patients were screened, of which 9 patients 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 - in follow up	Yes	Trial remained in follow up during this reporting period. 4 patients were screened, of which 3 patients were enrolled.
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. 1 patient was screened, of which 1 patient was 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&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.
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&W13/075	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 - in follow up	No	Trial remained in follow up during this reporting period. 3 patients were screened, of which 3 patients were enrolled.
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.
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&W13/039	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&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 - in follow up	No	Trial remained in follow up during this reporting period. 13 patients were screened, of which 8 patients were enrolled. Due to sponsor closing recruitment sooner than anticipated, enrollment of a further 1 patient was not possible.
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 - in follow up	No	Trial remained in follow up during this reporting period. 2 patients were screened, of which 2 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&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&W10/035	10/H0711/33	A Phase 3, Randomized, Double -Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Infected, Antiretroviral Treatment-Naive Adults QUAD	9	28/02/2013	Closed - follow up complete	Yes	Last patient last visit took place 21/06/2014, with site having met recruitment target.
C&W10/036	10/H0711/34	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS 9350-boosted Atazanavir versus Ritonavir-boosted Atazanavir Each Administered with Emtricitable/Tenofovir Disoproxil Fumarate in HIV 1 Infected, Antiretroviral Treatment-Naive Adults	11	28/02/2013	Closed - follow up complete	Yes	Last patient last visit took place 21/06/2014, with site having met recruitment target.
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&W11/100	11/LO/1034	A randomised, prospective study, assessing changes in cerebral function in treatment naive HIV-1 infected subjects commencing either boosted atazanavir with Truvada or boosted draunavir with maraviroc and Kivexa	7	No date agreed with sponsor	Closed - follow up complete	No	Last patient last visit took place 25/09/2014, with site having not met recruitment target. 6 patients were screened, of which 3 were enrolled.
C&W11/076	11/SC/0327	A Phase 3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Participants with Moderately to Severely Active Crohn's Disease	5	30/12/2014	Closed - follow up complete	Yes	Last patient last visit took place 14/03/2014, with site having met recruitment target.
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.
C&W13/010	12/EE/0400	An Open-Label Study of GS-7977+ Ribavirin for 12 Weeks in Subjects with Chronic HCV Infection who Participated in Prior Studies Evaluating GS-7977	1	04/09/2014	Closed - follow up complete	Yes	Last patient last visit took place 11/02/2014, with site having met recruitment target.
C&W12/047	12/LO/0497	Multicenter, Open-Label Study of Telaprevir in Combination With Peginterferon Alfa and Ribavirin in Human Immunodeficiency Virus/Genotype 1 Chronic Hepatitis C Coinfected Subjects With Severe Fibrosis or Compensated Cirrhosis	3	01/02/2014	Closed - follow up complete	No	Last patient last visit took place 22/04/2014, with site not having met recruitment target.
C&W12/075	12/NE/0266	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 Weeks in Treatment Naïve and Treatment Experienced Subjects with Chronic Genotype 2 or 3 HCV Infection	5	01/10/2014	Closed - follow up complete	Yes	Last patient last visit took place 08/01/2014, with site having met recruitment target.
C&W12/129	12/SC/0540	A Phase III, Randomised, Partially Double-Blind and Placebo-Controlled Study of BI 207127 in Combination with Faldaprevir and Ribavirin in Treatment-Naïve Patients with Chronic Genotype 1 HCV Infection.	5	01/01/2016	Closed - follow up complete	Yes	Last patient last visit took place 18/02/2014, with site having met recruitment target.
C&W13/013	13/LO/0006	A Phase 3, Open-label Study to Investigate the Efficacy and Safety of Sofosbuvir plus Ribavirin in Chronic Genotype 1, 2, 3 and 4 Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Co-infected Subjects	5	15/07/2014	Closed - follow up complete	Yes	Last patient last visit took place 01/07/2014, with site having met recruitment 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)	6	12/07/2014	Closed - follow up complete	No	Last patient last visit took place 10/03/2014, with site having not met recruitment target. This was a roll over study, to which 4 patients were recruited. Due to eligibility being based upon participation in the original study, recruitment of a further 2 patients was not possible.
C&W13/026	13/LO/0425	A Randomized, Double-Blind, Controlled Study to Evaluate 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 (PEARL-IV)	5	01/11/2014	Closed - follow up complete	No	Last patient last visit took place 29/07/2014, with site not having met recruitment target.
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	5	15/02/2015	Closed - follow up complete	No	Last patient last visit took place 29/09/2014, with site having not met recruitment target. 4 patients were recruited, and due to sponsor closing recruitment sooner than anticipated, recruitment 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&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	3	08/11/2016	Withdrawn	No	Trial closed by sponsor due to a change in development pipeline within sponsor company. Trial is a roll over trial, and sponsor decided to close the trial on 02/04/2014, prior to any patients rolling over on to the trial at site. As such, sponsor did not expect any recruitment at site.