

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

All hosted, commercial clinical trials active between 01 April 2013 - 31 March 2014

Analysis
 Number of clinical trials reported: 51(100%)
 Number of clinical trials that have met recruitment target: 19 (37%)
 Number of clinical trials that are open to recruitment and can still meet recruitment target: 11 (22%)
 Number of clinical trials that have not met recruitment target: 21 (41%)

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
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	01/02/2016	Open	Not applicable	
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	Open	Not applicable	Roll-over trial from 11/SC/0327.
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	Open	Not applicable	
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 draconavir with maraviroc and Kivexa	7	No date agreed with sponsor	Open	Not applicable	
C&W12/092	12/LO/1434	Lung Volume Reduction Coil Treatment in Patients with Emphysema (RENEW) Study	8	30/10/2014	Open	Not applicable	
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	Open	Not applicable	
C&W13/015	11/LO/1455	Gilead HCV Registry 0122 Responders	8	01/10/2016	Open	Not applicable	
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	Open	Not applicable	
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 naive genotypes 1, 2, 3 or 4 in subjects co-infected with HIV	5	15/02/2015	Open	Not applicable	
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	09/10/2014	Open	Not applicable	
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	Open	Not applicable	
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 - in follow up	Yes	
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 Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Infected, Antiretroviral Treatment-Naive Adults	11	28/02/2013	Closed - in follow up	Yes	
C&W10/046	09/S501/68	A Randomised Multicenter, Open-Label, Phase 3 Study of Gemcitabine-Cisplatin Chemotherapy 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 - in follow up	No	
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	
C&W11/018	11/SC/0007	A phase III, randomised, double-blind and placebo-controlled study of once daily BI 201335 120mg for 12 or 24 weeks or BI 201335 240mg for 12 weeks in combination with pegylated interferon- α and ribavirin in treatment-naive patients with genotype 1 chronic hepatitis C infection	8	28/02/2014	Closed - in follow up	No	
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 - in follow up	Yes	
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	
C&W11/055	11/SC/0176	A phase III, randomised, double-blind and placebo controlled study of once daily BI 201335, 240 mg for 12 or 24 weeks in combination with pegylated interferon- α and ribavirin in patients with genotype 1 chronic hepatitis C infection who failed a prior PegIFN/RBV treatment	6	28/02/2014	Closed - in follow up	No	
C&W11/073	11/SC/0326	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 Who Have Failed or Are Intolerant to TNF Antagonist Therapy	4	10/12/2012	Closed - in follow up	Yes	
C&W11/077	11/LO/1306	A Phase III open-label study to evaluate the safety, tolerability and efficacy of TMC435 plus PegIFN α -2a (Pegasys) and ribavirin (Copegus) triple therapy in chronic hepatitis C genotype-1 infected subjects who are co-infected with human immunodeficiency virus type 1 (HIV-1)	4	16/08/2013	Closed - in follow up	No	
C&W11/085	11/LO/1498	PROTEase inhibitor (DRV/tv) in mono- or triple therapy in suppressed HIV-1 infected subjects	10	02/01/2014	Closed - in follow up	No	
C&W12/007	12/LO/0036	Protocol A1444-03: A Phase 3, Open Label Study of Safety and Efficacy with BMS-790052 plus Peg-Interferon Alfa 2a and Ribavirin in Previously Untreated HCV Patients Coninfected with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)	4	28/05/2014	Closed - in follow up	Yes	
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	
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) 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 - in follow up	Yes	

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 - in follow up	Yes	
C&W12/041	12/LO/0268	Open-Label, Phase 3b Study to Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Virus Treatment-Naive and Treatment-Experienced Subjects with Genotype 1 Chronic Hepatitis C and Human Immunodeficiency Virus Type 1 (HCV-1/HIV-1) Coinfection	4	02/01/2014	Closed - in follow up	Yes	
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 - in follow up	No	
C&W12/089	12/NW/0241	A Randomised, Phase III, Multicentre, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of MetMab in Combination with Tarceva® (Erlotinib) in Patients with Met Diagnostic-Positive Non-Small Cell Lung Cancer (NSCLC) who have received standard chemotherapy for advanced or metastatic disease.	3	31/12/2014	Closed - in follow up	Yes	
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-Naive Patients with Chronic Genotype 1 HCV Infection.	5	01/01/2016	Closed - in follow up	Yes	
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 - in follow up	Yes	
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	
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/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment-Naive Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection (PEARL-IV)	5	01/11/2014	Closed - in follow up	No	
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	
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	
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- Naive Adults (GS-US-292-0104)	10	22/01/2016	Closed - in follow up	No	
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- Naive Adults (GS-US-292-0111)	10	22/01/2016	Closed - in follow up	No	
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	
08H&G017	08/H0717/2	First Into man Administration of Immunovex hsv 2 vaccine: An Open label Ascending dose Trial of Tolerability, Biodistribution and Induction of Immune Responses in Healthy Volunteers.	42	29/02/2012	Closed - follow up complete	No	
08H&G021	08/H0714/20	A phase 1, Multicentre, randomised, placebo-controlled, double-blind study to assess the safety, pharmacokinetics, pharmacodynamics and immunogenicity of intravenous and subcutaneous rhumab Beta 7 administered in a single-dose, dose-escalation stage followed by a multidose, parallel-treatment stage in patients with ulcerative colitis	9	13/03/2013	Closed - follow up complete	Yes	
09H&G002	08/H0703/118	Antiviral effect, safety and pharmacokinetics of once daily BI 201335 NA hepatitis C virus genotype infected treatment-naive patients for 24 weeks as combination therapy with pegylated interferon -a 2a and ribavirin (double-blinded, RCT, phase 2)	10	21/11/2011	Closed - follow up complete	No	
C&W10/070	10/H1107/42	A Multicentre, Single-Arm, Open-Label Study of the Repeated Administration of QUTENZA for the Treatment of Peripheral Neuropathic Pain	10	30/08/2013	Closed - follow up complete	Yes	
C&W10/082	10/H0720/60	Prospective, Multicentre, Randomised, Double-blind, Placebo-Controlled trial Comparing REMICADE (infliximab) and Placebo in the Prevention of Recurrence in Crohn's Disease Patients Undergoing Surgical Resection Who Are at an Increased Risk of Recurrence	3	01/09/2014	Closed - follow up complete	No	
C&W10/096	10/H0718/49	A Phase I/IIa Randomized, Observer-blind, Placebo-controlled, Multicenter Study to Evaluate the Safety and Immunogenicity of the GSK Biologicals' Herpes Zoster Vaccine, gE/AS01B in Comparison to Placebo when Administered as 3 Doses to Adult HIV-infected Subjects	10	14/05/2013	Closed - follow up complete	Yes	
C&W11/017	11/H0605/6	An open-label trial with TMC278 25mg q.d. in combination with a background regimen containing 2 nucleoside/nucleotide reverse transcriptase inhibitors in HIV-1 infected subjects, who participated in TMC278 clinical trials.	13	28/06/2013	Closed - follow up complete	No	
C&W11/029	11/LO/0275	A phase 3B, randomized, open-label study to evaluate the safety and efficacy of a single tablet regimen of Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate compared with a single tablet regimen of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 infected antiretroviral treatment-naive adults	5	02/11/2013	Closed - follow up complete	Yes	
C&W11/041	11/SC/0243	Safety and Efficacy of 240 mg BI 201335 once daily in combination with pegylated interferon alpha 2a and ribavirin for treatment of chronic Hepatitis C (HCV) genotype 1 infection in HIV/HCV-co-infected patients. A multinational, randomised, parallel group, open-label trial	10	18/08/2013	Closed - follow up complete	Yes	
C&W11/049	11/LO/1081	An open-label, randomised study evaluating a switch from a regimen of two nucleoside reverse transcriptase inhibitors plus any third agent to either a regimen of Atazanavir/Ritonavir once daily and Raltegravir twice daily or to a regimen of Atazanavir/Ritonavir once daily and Tenofovir/Emtricitabine once daily in virologically suppressed HIV-1 infected subjects with safety and/or tolerability issues on their present treatment regimen (the HARNESSE study).	4	30/12/2013	Closed - follow up complete	No	
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 Naive and Treatment Experienced Subjects with Chronic Genotype 2 or 3 HCV Infection	5	01/10/2014	Closed - follow up complete	Yes	
C&W12/102	12/WM/0193	A Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients With Diarrhea-Predominant Irritable Bowel Syndrome	3	21/07/2014	Closed - follow up complete	No	

C&W13/019	13/WM/0067	HIV1 Sample Collection for Validation and Evaluation of GS VType HIV1 Drug Resistance Test	150	22/07/2013	Closed - follow up complete	No	
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