Performance in Delivering Clinical Research - Quarter 1 (2016/17)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally aquired West Middlesex University Hospital NHS Trust on 01 September 2015, and the submission for the former West Middlesex University Hospital NHS Trust has been subsumed into this submission

All hosted, commercial clinical trials closed to recruitment in previous 12 months

Research Ethics Committee Reference Number	Name of Trial	Target Number of patients agreed?	Target date to recruit patients agreed?	Date agreed to recruit target number of patients	Total number of patients recruited at the agreed target date	Date that the trial closed to recruitment	Reason for closure to recruitment	Comments
15/LO/0652	AI468-038 A Phase 2b Randomized, Active-Controlled, Double-Blind Trial to Investigate Safety, Efficacy, and Dose-response of BMS-955176, Given on a Backbone of Tenofovir/Emtricitabine, in Treatment-Naive HIV-1 Infected Adults	Number Agreed	Date Agreed	31/12/2017	1	01/02/2016	Recruitment Finished	Study recruited globally before we could screen and recruit additional eligible patients
15/LO/0495	GS-US-366-1216 A Phase 3b, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed Dose Combination (FDC) in HIV-1 Positive Subjects who are Virologically Suppressed	Number Agreed	Date Agreed	22/06/2017	1	17/07/2015	Recruitment Finished	Study recruited globally before we could screen and recruit additional eligible patients
15/NW/0699	M13-590 (ENDURANCE-1) A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 1 Infection	Number Agreed	Date Agreed	31/01/2017	5	27/12/2015	Recruitment Finished	Study recruited to time and target locally
15/LO/1063	M14-004 (TURQUOISE-1) A Multipart, Open-label Study to Evaluate the Safety and Efficacy of Ombitasvir (ABT450)/Paritaprevir (ABT267)/Ritonavir With and Without Dasabuvir (ABT 333) Coadministered With and Without Ribavirin in Adults With Genotype 1 or 4 Ch	Number Agreed	Date Agreed	31/10/2015	8	26/11/2015	Recruitment Finished	Study recruited to time and target locally
15/LO/0881	MK-1439A-021 A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA? Once-Daily in Treatment-Na?ve HIV-1 Infected Subjects	Number Agreed	Date Agreed	18/03/2016	6	29/02/2016	Recruitment Finished	Study recruited to time and target locally
15/LO/1239	TMC114FD2HTX3001 (AMBER) A Phase 3, randomized, active-controlled, double-blind study to evaluate efficacy and safety of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once daily fixed dose combination regimen versus a regimen consis	Number Agreed	Date Agreed	30/11/2018	3	23/02/2016	Recruitment Finished	Study recruited globally before we could screen and recruit additional eligible patients
14/WM/1210	TMC114IFD3013 (EMERALD) A Phase 3, randomized, active-controlled, open-label study to evaluate switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consi	Number Agreed	Date Agreed	01/12/2017	11	22/12/2015	Recruitment Finished	Study recruited to time and target locally
14/LO/1513	GS-US-236-0140 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/	Number Agreed	Date Agreed	04/06/2015	13	17/07/2015	Recruitment Finished	Study recruited to time and target locally

15/LO/0438	GS-US-337-1612 (HARVONI) Open-Label Study to Evaluate the Safety and Efficacy of Ledipasvir/Sofosbuvir (LDV/SOF) Fixed-Dose Combination (FDC) for 6 Weeks in Subjects with Acute Genotype 1 or 4 Hepatitis C Virus (HCV) and Chronic Human Immunodeficiency Vir	Number Agreed	Date Agreed	29/04/2016	6	11/11/2015	Recruitment Finished	Study recruited to time and target locally
15/LO/0496	GS-US-366-1160 A Phase 3b, Randomized, Double-Blind Study to Evaluate Switching from a Regimen Consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/ Tenofovir Alafenami	Number Agreed	Date Agreed	31/10/2016	0	21/07/2015	Recruitment Finished	Study recruited globally before we could screen and recruit eligible patients
15/LO/0075	MK-1439-018 A Phase 3 Multicentre, Double-Blind, Randomised, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Eac	Number Agreed	Date Agreed	01/03/2018	0	11/09/2015	Recruitment Finished	Study recruited globally before any eligible patients could be screened and recruited
14/LO/1288	NEVIR5U14EU A multiple dose, open label, pivotal, 4- period, 2-treatment, 2-sequence full replicative cross-over study to assess the bioequivalence (BE) of TEVA?s generic once daily nevirapine 400 mg prolonged-release (PR) formulation compared with the ap	Number Agreed	Date Agreed	01/05/2015	46	23/06/2015	Recruitment Finished	Study recruited to time and target locally
14/LO/0565	MCRN2981 (SD637) Sucampo Orion Constipation Lubiprostone (1131)	Number Agreed	Date Agreed	31/03/2016	3	31/03/2016	Recruitment Finished	Study recruited to time and target locally
15/WM/0050	Efficacy and Safety of ingenol mebutate gel 0.015% compared to diclofenac gel 3% in subjects with Actinic Keratoses on the face	Number Agreed	Date Agreed	29/01/2016	4	29/01/2016	Recruitment Finished	Study closed to recruitment before local target was achieved. Complex Eligibility criteria.
15/LO/1163	GS-US-311-1717: A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC	Number Agreed	Date Agreed	31/03/2016	5	30/03/2016	Recruitment Finished	Study recruited to time and target locally