Performance in Delivering Clinical Research - Quarter 3 (2016/17)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired 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 active between 01 Janu: All hosted, commercial clinical trials active between 01 January 2016 - 31 December 2016

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	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	Total Number Of Study Participants Recruited	Reason For Closure Of Trial	Comments
15/LO/0652	173342	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	4	4	Date Agreed	31/12/2017	1	01/02/2016	1	Recruitment Finished	Study recruited globally (23 months early) before we could screen and recruit additional eligible patients
15/LO/0495	173450	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 Suppr	Range Agreed	5	5	Date Agreed	22/06/2017	1	16/07/2016	1	Recruitment Finished	Study recruited globally (two years ahead of schedule) and before we could screen and recruit additional eligible patients

15/LO/0881	177217	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	6	6	Date Agreed	18/03/2016	6	29/02/2016	6	Recruitment Finished	Recruited target number of patients.
15/LO/1239	184169	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	Number Agreed	5	5	Date Agreed	30/11/2018	3	23/02/2016	3	Recruitment Finished	Study recruited globally before we could screen and recruit additional eligible patients

14/LO/1513	158109	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 Efav	Number Agreed	2	2	Date Agreed	04/06/2015	13	26/01/2016	13	Recruitment Finished	Overrecruited at local level with agreement of Sponsor.
14/LO/0565	145189	MCRN2981 (SD637) Sucan	Number Agreed	3	3	Date Agreed	31/03/2016	7	31/03/2016	7	Recruitment Finished	Recruited target number of patients.
15/WM/0050	172460	ingenol mebutate gel 0.015% compared to diclofenac gel 3% in subjects with Actinic Keratoses on the face	Range Agreed	12	16	Date Agreed	29/01/2016	4	29/01/2016	4	Recruitment Finished	Study closed to recruitment before local target was achieved. Complex Eligibility criteria.
15/LO/1163	181430	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	Range Agreed	2	6	Date Agreed	31/03/2016	5	30/03/2016	5	Recruitment Finished	Recruited target number of patients.
15/EM/0238	165195	Efficacy and safety of intravenous neridronic acid in CRPS1	Number Agreed	5	5	Date Agreed	29/04/2016	0	29/04/2016	0	Recruitment Finished	Study closed to recruitment locally before any patients were recruited locally. Overall global target reached.

14/LO/2196	164991	A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour.	Number Agreed	1	1	Date Agreed	04/01/2016	0	25/07/2016	0	Withdrawn By Sponsor	Sponsor terminated the study early with only 10 patients recruited globally out of 100.
11/SC/0329	82940	A Phase 3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn's	Range Agreed	2	8	Date Agreed	31/08/2018	5	28/04/2016	5	Recruitment Finished	Recruited target number of patients.
15/SC/0580	184910	GAST 4466 (Ulcerative Colitis)	Number Agreed	4	4	Date Agreed	17/01/2020	0	23/09/2016	0	Recruitment Finished	A similar drug is now clinically available. We were hoping to recruit our patients in the open label phase of the study which unfortunately has been cancelled as the main study closed early due to poor interim results.
14/NE/1099	144103	PHASE III, RANDOMIZED, MULTICENTER DOUBLE-BLIND, DOUBLE-DUMMY STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ETROLIZUMAB COMPARED WITH INFLIXIMAB IN PATIENTS WITH MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS WHO ARE NAIVE TO TNF INHIBITORS	Number Agreed	3	3	Date Agreed	09/05/2019	0	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.
14/NE/1100	152481	AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES	Not Available / Not Agreed			Date Agreed	13/03/2024		25/11/2016	0	Withdrawn By Sponsor	Study was an extension study - no patients recruited into main study so no patients could be recruited to this study. PI left Trust and Sponsor terminated study locally.

15/NE/0144	179243	AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE PREVIOUSLY ENROLLEDIN THE ETROLIZUMAB PHASE III PROTOCOL GA29144	Number Agreed	3	3	Date Agreed	31/10/2024	0	25/11/2016	0	Withdrawn By Sponsor	Study was an extension study - no patients recruited into main study so no patients could be recruited to this study. PI left Trust and Sponsor terminated study locally.
15/NE/0143	174391	Bergamot	Number Agreed	3	3	Date Agreed	31/05/2019	0	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.