

Performance in Delivering Clinical Research - Quarter 4 (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 closed to recruitment between 01 April 2016 – 31 March 2017

Research Ethics Committee Reference Number	Name of Trial	Target	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial	Comments
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 Suppr	5	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/EM/0238	Efficacy and safety of intravenous neridronic acid in CRPS1	5	29/04/2016	0	Recruitment Finished	Study closed to recruitment locally before any patients were recruited locally. Overall global target reached.
14/LO/2196	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and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour.	1	25/07/2016	0	Withdrawn By Sponsor	Sponsor terminated the study early with only 10 patients recruited globally out of 100.

11/SC/0329	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 Disease	8	28/04/2016	5	Recruitment Finished	Recruited target number of patients.
15/SC/0580	GAST 4466 (Ulcerative Colitis)	4	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	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INFLIXIMAB IN PATIENTS WITH MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS WHO ARE NAIVE TO TNF INHIBITORS	3	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.
14/NE/1100	AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES		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	AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE PREVIOUSLY	3	25/11/2016	0	Withdrawn By Sponsor	Study was an extension study - no patients recruited into main study so no patients could be

	ENROLLED IN THE ETROLIZUMAB PHASE III PROTOCOL GA29144					recruited to this study. PI left Trust and Sponsor terminated study locally.
15/NE/0143	Bergamot	3	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.
15/LO/1261	A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	3	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.
14/LO/2196	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.	7	25/07/2016	0	Withdrawn By Sponsor	Sponsor terminated the study early with only 10 patients recruited globally out of 100.
15/LO/0652	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.	4	15/09/2016	1	Recruitment Finished	
15/NE/0144	AN OPEN-LABEL EXTENSION AND SAFETY MONITORING STUDY OF PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE PREVIOUSLY ENROLLED IN THE ETROLIZUMAB PHASE III PROTOCOL GA29144	3	25/11/2016	0	Withdrawn By Sponsor	PI left the Trust. Sponsor terminated study at site.
15/LO/1163	A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically	2	31/03/2016	8	Recruitment Finished	

	Suppressed on Regimens containing ABC/3TC					
16/LO/0439	A Phase II, Randomized, Multicenter, Dose-Ranging Study in Adult Subjects Evaluating the Efficacy, Safety, and Tolerability of Single Doses of GSK2140944 in the Treatment of Uncomplicated Urogenital Gonorrhoea Caused by Neisseria gonorrhoeae	5	14/06/2016	2	Recruitment Finished	