## Performance in Delivering Clinical Research - Quarter 2 (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? | Minimum 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 | 4 | Date Agreed | 31/12/2017 | 1 | 01/02/2016 | Recruitment Finished | Study recruited globally (23 months early) 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 Suppr | Number Agreed | 5 | Date Agreed | 22/06/2017 | 1 | 16/07/2016 | Recruitment Finished | Study recruited globally (two years ahead of schedule) and 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 | 5 | Date Agreed | 31/01/2017 | 5 | 27/12/2015 | Recruitment Finished | |
| 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 o | Number Agreed | 5 | Date Agreed | 31/10/2015 | 8 | 26/11/2015 | Recruitment Finished | |
| 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 | 5 | Date Agreed | 18/03/2016 | 6 | 29/02/2016 | Recruitment Finished | |
| 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 | Number Agreed | 5 | 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 | Number Agreed | 5 | Date Agreed | 01/12/2017 | 11 | 22/12/2015 | Recruitment Finished | |
| 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 Efav | Number Agreed | 3 | Date Agreed | 04/06/2015 | 13 | 26/01/2016 | Recruitment Finished | |
| 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 Immunodeficien | Number Agreed | 5 | Date Agreed | 29/04/2016 | 6 | 11/11/2015 | Recruitment Finished | |
| 14/LO/0565 | MCRN2981 (SD637) Sucampo Orion Constipation Lubiprostone (1131) | Number Agreed | 3 | Date Agreed | 31/03/2016 | 3 | 31/03/2016 | Recruitment Finished | |
| 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 | 12 | 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 | 2 | Date Agreed | 31/03/2016 | 5 | 30/03/2016 | Recruitment Finished | |
| 15/EM/0238 | Efficacy and safety of intravenous neridronic acid in CRPS1 | Number Agreed | 5 | Date Agreed | 29/04/2016 | 0 | 29/04/2016 | Recruitment Finished | Staffing Issues |

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| 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. | Number Agreed | 1 | Date Agreed | 04/01/2016 | 0 | 25/07/2016 | Recruitment Finished | Globally hard to recruit to , 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 | Number Agreed | 2 | Date Agreed | 31/08/2018 | 0 | 28/04/2016 | Recruitment Finished | No information from PI or site team |