Performance in Initiating Clinical Research - Quarter 4 (2015/16)
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 clinical trials granted NHS Permission between 01 January 2016 - 31 March 2016

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and First Patient	Benchmark Met	Reason for Delay
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.	13/05/2015	13/05/2015	No				Due to delays in confirmation of green light due to delayed shipment of IMP, site was unable to recruit until 21/08/2015, 100 days post valid research application. Screening is taking place daily since this date, but the study is very difficult to

								recruit to, having only recruited 2 patients across 18 sites in 5 countries to date.
14/YH/1269	Open label evaluation of the population PK profile, safety, tolerability and efficacy of tapentadol IV solution for the treatment of post-surgical pain in children aged from birth to less than 2 years, including pre term neonates (KF5503-73).	10/06/2015	10/06/2015	Yes	19/10/2015			First patient recruited 19th October. Difficult study to recruit to as study requires the parents/guardian of the patient to consent to administration of IMP to their child under 2 years of age. None have wished to do so before 19th October.

15/WA/0026	Assessing the gut microbiome in children with Crohn's disease: Effects of a specific exclusion diet.	02/04/2015	02/04/2015	Yes	10/06/2015			
15/WM/0050	Efficacy and safety of ingenol mebutate gel 0.015% compared to diclofenac sodium gel 3% in subjects with actinic keratoses on the face or scalp.	01/05/2015	08/05/2015	Yes	01/07/2015			
14/WM/1210	A Phase 3, randomized, active-controlled, open-label study to evaluate the efficacy, safety and tolerability of switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in virologically-suppressed, human immunodeficiency virus type 1 (HIV-1) infected subjects.	28/04/2015	06/05/2015	Yes	10/07/2015			Sponsor delayed green light for recruitment due to IMP delivery delays. Green light received 29/05/2015, thus reducing window by 29 days.

13/EE/0214	A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Risistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial.	08/05/2015	12/05/2015	Yes	29/06/2015			
15/LO/0495	A phase 3b, randomised, 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 virilogically supressed on emtricitabine / rilpivirine / tenofovir disproxil fumarate (FTC/RPV/TDF).	05/06/2015	05/06/2015	Yes	14/07/2015			
15/LO/0496	GS-US-366-1160: A phase 3b, randomised, double-blind, study to evaluate switching from a regimen consisting of efavirenz / emtricitabine / tenofovir disoproxil fumarate (EFV/FTC/TDF) fixed dose combination (FDC) ito emtricibatine / rilprivirine / tenofovir alafenamide (FTC/RPV/TAF) FDC in virologically.	05/06/2015	05/06/2015	No				Study closed by sponsor: study-wide recruitment completed at local day 52 (27/07/2015).

15/LO/0438	GS-US-337-1612: 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 vrirus (HIV)-1 co-infection.	08/06/2015	10/06/2015	Yes	02/07/2015			
14/LO/0816	A Multicentre, Long-term Safety, Efficacy and Pharmacokinetics Study of Lubiprostone in Paediatric Subjects Aged =6 to <18 years with Functional Constipation	06/08/2015	13/08/2015	No				Trial is a rollover for patients succesfully completing REC 14/LO/0565 (C&W13/081) and sponsor requested issue of NHS Permission in line with the initial study. It is therefore not possible to recruit within the timeframe as no patients will have completed the initial study

								during that timeframe.
15/LO/0423	An open label study to investigate the safety and efficacy of abacavir/lamivudine/dolutegravir and the pharmacokinetic profile of dolutegravir in HIV infected patients of 60 years of age and older	15/07/2015	24/07/2015	Yes	04/08/2015			
15/ES/0076	A Phase 3, Multicenter, Open-label, Randomized Study of SGI-110 versus Treatment Choice (TC) in Adults with Previously Untreated Acute Myeloid Leukemia (AML) Who Are Not Considered Candidates for Intensive Remission Induction Chemotherapy.	28/08/2015	28/08/2015	Yes	14/09/2015			
15/LO/0652	A Phase 2b Randomized, Active-Controlled, Double-Blind Trial to Investigate Safety, Efficacy, and Dose-response of BMS955176, Given on a Backbone of Tenofovir/Emtricitabine, in Treatment-Naive HIV-1 Infected Adults	13/07/2015	14/07/2015	Yes	23/07/2015			

15/LO/0904	SSAT063: Pharamcokinetics of efavirenz 400mg once daily during pregnancy in HIV-1 infected women	27/07/2015	31/07/2015	Yes	24/09/2015			
15/LO/0075	A Phase 3 Multicenter, Double-Blind, Randomized, 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, Each in Combination with TRUVADA? or EPZICOM?/KIVEXA?, in Treatment-Na?ve HIV-1 Infected Subjects	13/08/2015	13/08/2015	No				Study recruited globally before any patients were successfully screened at site.
15/LO/0519	Protocol AI438047: A Multi-arm Phase 3 Randomized Placebo Controlled Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1	04/09/2015	08/09/2015	Yes	15/12/2015			

15/LO/1063	M14004 A Multipart, Openlabel 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 Chronic Hepatitis C Virus Infection and Human Immunodeficiency Virus, Type 1 Coinfection (TURQUOISEI)	13/08/2015	17/08/2015	Yes	03/09/2015			
15/LO/0881	MK1439A versus ATRIPLA in treatment na?ve HIV1 infected subjects	10/09/2015	11/09/2015	Yes	26/10/2015			Information on 1st recruit not available
15/LO/1163	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	18/09/2015	23/09/2015	Yes	29/01/2016			Information on 1st recruit is not available

15/NW/0505	A Phase III Multicenter, Open-Label, Randomized Study to Evaluate a Switch to MK-1439A in HIV-1-Infected Subjects Virologically Suppressed on a Regimen of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) ? MK1439A-024.	10/09/2015	11/09/2015	Yes	07/12/2015			information on first recruit ios not available
14/LO/1842	ENDCaP-C Test Accuracy Study: Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis (ENDCaP-C): A Multicentre test accuracy study	16/04/2015	22/04/2015	Yes	09/07/2015			D - Delays caused by sponsor: sponsor delayed green light for recruitment following NHS Permission because of delayed Site Initiation Visit (SIV) . Green light for recruitment received on 09/07/2015, which was 84 days following VRA.

13/NE/0339	GOT-IT: Glycerine Trinitrate for retained placenta	24/07/2015	27/07/2015	Yes	18/08/2015			
14/SC/1345	Effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding: A randomised placebo-controlled trial (PRISM Trial: PRogesterone In Spontaneous Miscarriage Trial)	02/09/2015	03/09/2015	Yes	30/09/2015			
12/SC/0515	BREATH: A ventilation weaning	03/09/2015	03/09/2015	Yes	19/11/2015			
15/LO/0424	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers (SSAT 055)	13/11/2015	16/11/2015	Yes	15/12/2015			

13/LO/0691	Precise Study ? Patient-consented samples for STI diagnostic & biomarker evaluation	01/12/2015	11/12/2015	Yes	11/12/2015			
14/EE/1293	C-STITCH	29/12/2015	29/12/2015	Yes	29/12/2015			
15/SW/0263	A study to refine PROM?s that explore people?s experiences of living with a burn injury (A study to refine the CAR burns scales)???	27/10/2015	27/10/2015	Yes - Date Unavailable				Date of 1st recruit is not available
14/SC/1030	G-TOG	27/10/2015	27/10/2015	Yes	07/12/2015			

15/LO/12389	HIV Once Daily ARV Single Tablet bPI regimen na?ve patients AMBER	18/11/2015	18/11/2015	Yes - Date Unavailable				Date of 1st recruit is not available
13/LO/1705	C&W - Epilepsy in infancy: relating phenotype to genotype - Single SSI study	04/09/2015	17/11/2015	No				
15/WM/0344	eNewborn: European Neonatal Benchmarking and Evaluation Programme	19/10/2015	01/12/2015	No				
15/NW/0699	M13590: A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of ABT493/ABT530 in Adults with Chronic Hepatitis C Virus Genotype 1 Infection (Endurance 1)	12/11/2015	20/11/2015	Yes	15/12/2015			

14/LO/0816	Long term efficacy of Lubiprostone for paed. functional constipation	13/08/2015	13/08/2015	Yes	02/12/2015			Could not recruit any earlier as this is a follow up study requiring participants to complete visit 7 on the main study before they can be recruited to this study.