Performance in Initiating 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, clinical trials granted NHS permission between 1st July 2015 - 30 June 2016

Research Ethics Committee Reference Number	Name of Trial	Date of receipt of valid research application (VRA)	Date of NHS Permission	First patient recruited?	Date of first patient recruited	Duration between VRA and first patient	70 day benchmark met?	Reason for delay
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	Yes	02/12/2015	118	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 was therefore not possible to recruit within the 70 day timeframe as no patients had 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	20	Yes	
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	17	Yes	
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	10	Yes	
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	59	Yes	
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-Naive HIV-1 Infected Subjects	13/08/2015	13/08/2015	No			No	Study recruited globally before any patients were successfully screened at site (recruitment window was just 1 month)
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	102	No	Reason for delay unknown at time of submission
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	21	Yes	
15/LO/0881	MK1439A versus ATRIPLA in treatment na?ve HIV1 infected subjects	10/09/2015	11/09/2015	Yes	26/10/2015	46	Yes	
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	133	No	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	88	No	information on first recruit ios not available
13/NE/0339	GOT-IT: Glycerine Trinitrate for retained placenta	24/07/2015	27/07/2015	Yes	18/08/2015	25	Yes	
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	28	Yes	
12/SC/0515	BREATH: A ventilation weaning	03/09/2015	03/09/2015	Yes	19/11/2015	77	No	
15/LO/0424	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers (SSAT 055)	13/11/2015	16/11/2015	Yes	15/12/2015	32	Yes	
14/EE/1293	C-STITCH	29/12/2015	29/12/2015	Yes	29/12/2015	0	Yes	
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			No	Date of 1st recruit is not available
14/SC/1030	G-TOG	27/10/2015	27/10/2015	Yes	07/12/2015	41	Yes	
15/LO/12389	HIV Once Daily ARV Single Tablet bPI regimen na?ve patients AMBER	18/11/2015	18/11/2015	Yes - Date Unavailable			No	Date of 1st recruit is not available
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	33	Yes	
15/LO/1596	SSAT067 PK of atazanavir/cobicistat and darunavir/cobicistat	13/11/2015	17/11/2015	Yes	16/12/2015	33	Yes	
15/SC/0580	GAST 4466 (Ulcerative Colitis)	15/03/2016	28/04/2016	No			No	No eligibile patient seen during the reporting period
15/LO/2008	A Phase IIa Multicenter, Open-Label Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A in Treatment-Na?ve HIV-1 Infected Subjects with Selected Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) Transmitted Resistance Mutations (MK-1439A-030)????????	07/03/2016	16/03/2016	Yes	16/05/2016	70	Yes	
16/LO/0103	The effect of atazanavir/cobicistat on the pharmacokinetics of an oral contraceptive containing ethinylestradiol and levonorgestrel (Microgynon 30?) in healthy women	09/06/2016	29/06/2016	No				Within 70 Days at time of report
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 Gonorrhea Caused by Neisseria gonorrhoeae	24/03/2016	14/06/2016	Yes	13/07/2016	111	No	HRA in-flight study and delays with contracts with Sponsor.
10/H0604/51	Natural history and pathogenesis of systemic IgG4 disease	22/03/2016	04/04/2016	Yes	05/04/2016	14	Yes	
12/WM/0335	OCS-Care	17/05/2016	31/05/2016	Yes	07/07/2016	51	Yes	
14/EM/1173	Hi-Light Vitiligo Trial	18/01/2016	18/01/2016	Yes	02/03/2016	44	Yes	
14/ES/1004	Preventing Recurrence of Endometriosis by Means of Long Acting Progestogen Therapy (Pre-empt Trial): Move to Substantive Phase	01/03/2016	01/03/2016	No			No	Study amended (removal of arm) shortly after opening at site (April 2016).
14/NW/0176	Paediatric EVICEL? Soft Tissue Bleeding Study	08/03/2016	10/03/2016	No			No	Waiting for Sponsor's green light.
14/SC/0171	Add-Aspirin Trial	24/03/2016	17/05/2016	No			No	No eligible patients seen at site yet despite screening
14/SC/1372	RIVER - Research In Viral Eradication of HIV Reservoirs	18/01/2016	28/02/2016	Yes	02/05/2016	105	No	Sponsor requested additional completion of IT questionnaire following NHS permission.
15/EE00/10	PITCHES: Phase III trial of UDCA in ICP: V1	18/03/2016	27/04/2016	Yes	09/05/2016	52	Yes	
15/LO/0460	SSAT058:Atripla to Eviplera switch in patients without CNS symptoms	27/10/2015	10/11/2015	Yes	10/12/2015	44	Yes	

15/LO/1261	UNIFI: 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	11/01/2016	03/05/2016	No			No	Indemnity issues unresolved.
15/LO/1665	Safetxt: a randomised controlled trial of a safer sex intervention	17/03/2016	09/06/2016	Yes	14/06/2016	89	No	Sponsor delay with contracts
15/LO/2058	PlGF as a diagnostic test for pre-eclampsia (PARROT)	18/03/2016	29/04/2016	Yes	11/05/2016	54	Yes	
15/LO/2121	Phase IIb, Double-Blinded, Multicenter, Randomized Study to Assess the Effect on Central Nervous System (CNS) Toxicity of Switching from ATRIPLAT (Efavirenz, Tenofovir,Emtricitabine) to MK-1439A (Doravirine, Tenofovir, Lamivudine) in Virologically-Suppressed Subjects	22/02/2016	26/02/2016	Yes	02/05/2016	70	Yes	
15/NE/0143	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ETROLIZUMAB AS AN INDUCTION AND MAINTENANCE TREATMENT FOR PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN?S DISEASE	11/01/2016	01/02/2016	No			No	The study is placebo controlled and will be difficult to recruit to now that NICE approval for a similar drug has occurred
15/NW/0090	EcLiPSE:Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus	19/11/2015	20/01/2016	Yes	03/02/2016	76	No	HRA in-flight study.
16/LO/0026	A Phase 3, Randomized, Open-Label Study to Evaluate the Safety and Efficacy of Switching from Regimens Consisting of Boosted Atazanavir or Darunavir plus either Emtricitabine/Tenofovir or Abacavir/Lamivudine to GS 9883/Emtricitabine/Tenofovir Alafenamide in Virologically Suppressed HIV-1 Infected Adults	17/03/2016	10/05/2016	Yes	26/05/2016	70	Yes	
16/LO/0023	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Na?ve Adults	18/03/2016	10/05/2016	Yes	17/05/2016	60	Yes	
16/LO/0240	Prose - Cosentyx?/Secukinumab/AIN457	09/03/2016	21/03/2016	Yes	05/05/2016	57	Yes	
16/LO/0036	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Abacavir/Dolutegravir/Lamivudine in HIV-1 Infected, Antiretroviral Treatment-Na?ve Adults	08/03/2016	10/05/2016	Yes	17/05/2016	70	Yes	