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

Research Ethics Committee Reference Number	Name of Trial	Date of receipt of valid research application (VRA)	Date of NHS Permission or Date Site Confirmed	First patient recruited?	Date of first patient recruited	Duration between VRA and first patient	70 day benchmark met?	Reason for delay
15/LO/0424	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers (SSAT 055)	13/11/2015	16/11/2015	Yes	15/12/2015	29	Yes	
14/EE/1293	C-STITCH	29/12/2015	29/12/2015	Yes	29/12/2015	0	Yes	
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	29/03/2016	132	No	Study proved more difficult to recruit to than expected
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	25	Yes	
15/LO/1596	SSAT067 PK of atazanavir/cobicistat and darunavir/cobicistat	13/11/2015	17/11/2015	Yes	16/12/2015	29	Yes	
15/SC/0580	GAST 4466 (Ulcerative Colitis)	15/03/2016	28/04/2016	No			No	No eligibile patients 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	61	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	Yes	27/07/2016	28	Yes	
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	29	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	1	Yes	
12/WM/0335	OCS-Care	17/05/2016	31/05/2016	Yes	07/07/2016	37	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	Yes	15/08/2016	90	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	64	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	12	Yes	
15/LO/0460	SSAT058:Atripla to Eviplera switch in patients without CNS symptoms	27/10/2015	10/11/2015	Yes	10/12/2015	30	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 with Sponsor delayed opening of study.
15/LO/1665	Safetxt: a randomised controlled trial of a safer sex intervention	17/03/2016	09/06/2016	Yes	14/06/2016	5	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	12	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	66	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 is 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	14	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	16	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	7	Yes	
16/LO/0240	Prose - Cosentyx?/Secukinumab/AIN457	09/03/2016	21/03/2016	Yes	05/05/2016	45	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	7	Yes	
13/NW/0621	The early use of Antibiotics in at Risk Children with InfluEnza-ARCHIE		19/09/2016	No			No	70 days waiver - seasonal study (Flu)
15/LO/0485	SuPPoRT: Stitch,Progesterone or Pessary: a randomised controlled trial		19/09/2016	Yes	29/09/2016		No	
15/EE/0435	STOP-HCV-1 version 1.0	13/04/2016	21/09/2016	Yes	12/10/2016	21	No	Study Lab Manual not made available until 11th August. Sponsor green light issued 5th October 2016. Unable to begin screening prior to this date.
15/NW/0917	JAVELIN Lung 100 - CANC 5225	21/04/2016	12/07/2016	No			No	First Patient consented 19/09/2016, Failed screening
16/LO/0854	Fluids in Shock (FiSh) External Pilot Study Version 1.0		27/07/2016	Yes	12/10/2016		No	Only 1 patient recruited as he has been the only eligible patient we have seen in the timeframe. So far nationally only 15 patients have been recruited. The study itself is hard to recruit in to
13/SC/0645(a)	PEACOCK (PHOENIX-2) study	14/07/2016	03/08/2016	Yes	29/09/2016	57	No	Study brought under HRA, recruitment could not start until sponsor green light was given . Study was submitted as part of an amendment to the Phoenix 1 study.
13/SC/0645(b)	PHOEBE	14/07/2016	03/08/2016	Yes	29/09/2016	57	No	Study brought under HRA, recruitment could not start until sponsor green light was given . Study was submitted as part of an amendment to the Phoenix 1 study.
15/EM/0238	CRPS-1	26/11/2015	05/01/2016	No			No	Study closed early. No eligible patients screened.
15/NE/0144	GAST 4684	07/01/2016	15/02/2016	No			No	Study hard to recruit to , the IMPs have a very similar active drug already clinically available so for a patient to risk getting a placebo? especially when these patients are extremely ill, very difficult to recruit to.
15/LO/1632	The DESiGN Trial ? Detection of small for gestational age fetus (SGA)	17/03/2016	02/06/2016	No			No	Study suspended by the sponsor due to issues with the protocol
16/EE/0223	DIAB5124		21/09/2016	No			No	