Performance in Initiating Clinical Research - Quarter 3 (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 clinical trials Hosted between 01 January 2016 – 31 December 2016

NHS permission Studies

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date of Receipt of Valid Research Application	First Patient Recruited?	Date of First Patient Recruited	Date Study Initiated	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Comments
15/SC/0580	184910	GAST 4466 (Ulcerative Colitis)	15/03/2016	No									NHS permission delayed due to Radiology taking time to complete local IRMER review. 1st patient delay was due to no eligibile patients seen during the reporting period.
15/LO/2008	192214	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	Yes	16/05/2016								
16/LO/0103	194138	The effect of atazanavir/cobicistat on the pharmacokinetics of an oral contraceptive containing ethinylestradiol and levonorgestrel (Microgynon 30?) in healthy women	09/06/2016	Yes	27/07/2016								

16/LO/0439	198775	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	Yes	13/07/2016								HRA in-flight study and delays with contracts with Sponsor. Remove from report.
10/H0604/51	43801	Natural history and pathogenesis of systemic IgG4 disease	22/03/2016	Yes	05/04/2016								
12/WM/0335	97743	OCS-Care	17/05/2016	Yes	07/07/2016								
14/EM/1173	162392	Hi-Light Vitiligo Trial	18/01/2016	Yes	02/03/2016								
14/ES/1004	101577	Preventing Recurrence of Endometriosis by Means of Long Acting Progestogen Therapy (Pre-empt Trial): Move to Substantive Phase	01/03/2016	No									The Sponsor amended the study design (removal of arm) shortly after opening at site (April 2016) which impacted on recruitment at site.
14/NW/0176	148100	Paediatric EVICEL? Soft Tissue Bleeding Study	08/03/2016	No									Our PI sees under 1 year old children which the Sponsor has said cannot be recruited until the study as a whole has recruited sufficient over 1 year olds. This has not happened yet so the PI is unable to recruit any of the patients he sees for this study. The Sponsor has informed the site that the total of over 1 year olds is nearly there and that we should be able to recruit in early/mid 2017.
14/SC/0171	120104	Add-Aspirin Trial	24/03/2016	Yes	15/08/2016								NHS permission was delayed due to staffing issues at site (long term sickness). In terms of 1st patient no eligible patients seen at site yet despite screening.
14/SC/1372	162784	RIVER - Research In Viral Eradication of HIV Reservoirs	22/02/2016	Yes	02/05/2016								Sponsor requested the completion of an additional IT validation questionnaire following NHS permission which delayed the beginning of recruitment and Sponsor green light.
15/EE00/10	138590	PITCHES: Phase III trial of UDCA in ICP: V1	18/03/2016	Yes	09/05/2016								

15/LO/1261	163080	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	No									Sponsor refused to execute a form of indemnity with the Trust which delayed the opening of the study. This was eventually resolved and the Sponsor signed.
15/LO/1665	188241	Safetxt: a randomised controlled trial of a safer sex intervention	17/03/2016	Yes	14/06/2016								Sponsor delay with contracts
15/LO/2058	171900	PlGF as a diagnostic test for pre-eclampsia (PARROT)	18/03/2016	Yes	11/05/2016								
15/LO/2121	193977	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	Yes	02/05/2016								

15/NE/0143	174391	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	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	162325	EcLiPSE:Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus	19/11/2015	Yes	03/02/2016								HRA in-flight study.
16/LO/0026	195795	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	Yes	26/05/2016								

16/LO/0023	195696	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	Yes	17/05/2016								
16/LO/0240	199083	Prose - Cosentyx?/Secukinumab/AIN457	09/03/2016	Yes	05/05/2016								
16/LO/0036	195359	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	Yes	17/05/2016								
15/EE/0435	191299	STOP-HCV-1 version 1.0	13/04/2016	Yes	12/10/2016								Study Lab Manual not made available until 11th August therefore local labs unable to assess work/logisitcs before this time. Following reciept of lab manual labs completed assessment and NHS permission was issued. Sponsor green light was issued 5th October 2016. Unable to begin screening prior to this date.
15/NW/0917	190004	JAVELIN Lung 100 - CANC 5225	21/04/2016	Yes	22/11/2016								First patient was consent on the 19th September 2016 but failed a 28 day screening period. The first patient to pass the screening was consented on the 22nd November 2016. Note that our local target for this study is just 1 patient. Difficult to recruit to study this low target.
13/SC/0645(a)	143871 (a)	PEACOCK (PHOENIX-2) study	14/07/2016	Yes	29/09/2016								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)	143871 (b)	PHOEBE	14/07/2016	Yes	29/09/2016								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	165195	CRPS-1	26/11/2015	No									Sponsor closed study early. No eligible patients were recruited by time study was closed.

15/NE/0144	179243	GAST 4684	01/02/2016	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	180646	The DESiGN Trial ? Detection of small for gestational age fetus (SGA)	17/03/2016	No									Study suspended by the sponsor due to issues with the protocol

HRA Approved Studies

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15/LO/0485	138945	SuPPoRT: Stitch,Progesterone or Pessary: a randomised controlled trial		Yes	29/09/2016		19/08/2020	09/09/2016	15/06/2016	26/09/2016	19/09/2016	26/09/2016	
16/LO/0854	195544	Fluids in Shock (FiSh) External Pilot Study Version 1.0		Yes	12/10/2016		24/05/2016	24/05/2016	27/06/2020	14/07/2016	26/07/2020	01/08/2016	We have only recruited I patient 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
16/EE/0223	201450	DIAB5124		No			10/02/2016	06/09/2016	19/08/2016	08/09/2020	21/09/2016	21/09/2016	Study hard to recruit to. No eligible patients found yet.
14/SC/0221	145869	CONCEPT: A Phase II pilot study of 3 weekly Cabazitaxel versus weekly Paclitaxel chemotherapy in the first line treatment of Her2 negative metastatic breast cancer (mBC)		No			08/06/2016	21/09/2016	06/05/2016	04/10/2016	10/10/2016	10/10/2016	The research nurse supporting the study was off sick for a long period of time
15/LO/1003	173560	MINSTREL - Mri IN STaging REctal cancer pLanes		No			21/06/2016	17/11/2016	15/06/2016	17/11/2016	24/11/2016	19/12/2016	
16/LO/1205	193598	Psychoeducational intervention for women prescribed tamoxifen		No			24/06/2016	20/10/2016	13/10/2016	16/11/2016	15/11/2016	16/11/2016	The research nurse supporting the study was off sick for a long period of time
15/LO/2047	192515	Medivation D5170C00002		No			16/08/2016	16/08/2016	11/08/2016	08/12/2016	08/12/2016		Site Initiation Booked for February 2017. Sponsor Green light (date site ready to start) will follow SIV but is not known at time of submission.