Performance in Initiating Clinical Research - Quarter 4 (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 April 2016 – 31 March 2017
NHS Permission Studies

Research Ethics Committee Reference Number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	First Patient Recruited?	Date of First Patient Recruited	Comments
15/SC/0580	NHS Permission	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 eligible patients seen during the reporting period.
16/LO/0103	NHS Permission	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	NHS Permission	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	SSI form submitted into CSP shortly before end of March 2016. Delays in approvals and with contracts with Sponsor.

10/H0604/51	NHS Permission	Natural history and pathogenesis of systemic IgG4 disease	22/03/2016	Yes	05/04/2016	
12/WM/0335	NHS Permission	OCS-Care	17/05/2016	Yes	07/07/2016	
14/SC/0171	NHS Permission	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.
15/EE00/10	NHS Permission	PITCHES: Phase III trial of UDCA in ICP: V1	18/03/2016	Yes	09/05/2016	
15/LO/1261	NHS Permission	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	NHS Permission	Safetxt: a randomised controlled trial of a safer sex intervention	17/03/2016	Yes	14/06/2016	Sponsor delay with contracts
15/LO/2058	NHS Permission	PlGF as a diagnostic test for pre-eclampsia (PARROT)	18/03/2016	Yes	11/05/2016	
16/LO/0026	NHS Permission	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	NHS Permission	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/0036	NHS Permission	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	NHS Permission	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	NHS Permission	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)	NHS Permission	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)	NHS Permission	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/LO/1632	NHS Permission	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

Research Ethics Committee Reference Number	Submission Type	Name of Trial	First Patient Recruited?	Date of First Patient Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Comments

15/LO/0485	HRA Approval	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	HRA Approval	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	HRA Approval	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	HRA Approval	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	HRA Approval	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	HRA Approval	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	HRA Approval	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.

16/LO/1854	HRA Approval	Discover	Yes	02/02/2017	06/01/2017	06/01/2017	14/12/2016	06/01/2017	06/01/2017	25/01/2017	Sponsor Green light (date site ready to start- 25/1/2017) .
16/SC/0216	HRA Approval	The OPTIMIST-A Trial	Yes	25/03/2017	30/10/2016	30/10/2016	20/09/2016	15/02/2017	22/02/2017	23/02/2017	
16/LO/0673	HRA Approval	Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial (Sante project)	Yes	10/03/2017	07/12/2016	26/01/2017		01/02/2017	01/02/2017	02/02/2017	

16/LO/1871	HRA Approval	The pharmacokinetics of dolutegravir, darunavir/cobicistat when co-administered in healthy volunteers	Please Select...		06/02/2017	06/02/2017		06/02/2017	14/02/2017		
16/LO/1282	HRA Approval	QualVL	Yes	06/03/2017			23/08/2016			02/03/2017	