

Performance in Initiating Clinical Research

July 2018 – June 2019

Musgrove Park Hospital

HRA Process – Site Confirmation of Capacity and Capability

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Date of First Patient Recruited	Reasons for Delay	Comments	Reason for delay
16/WM/0472	211270	CONFIRM	01/05/2018	02/07/2018	14/03/2017	10/07/2018	11/07/2018	18/07/2018	09/10/2018	I - Rare diseases	Rare condition, site target of 2 in total	Neither
18/YH/0223	243476	METS2	15/02/2018	12/07/2018	09/07/2018	12/07/2018	07/12/2018	15/01/2019	13/03/2019	A - Permissions delayed/denied	Seasonal 'Flu study, C&C and opening not planned until early 2019.	Neither
18/LO/1187	240011	ATHENA	24/07/2018	24/07/2018	11/09/2018	26/02/2019	07/03/2019	07/03/2019		A - Permissions delayed/denied H - Contracting delays	Site selected date to HRA approval date exceeds 40 days. Costing negotiations exceeded 40 days.	Neither
18/YH/0014	224065	ACTIVE	26/09/2017	30/07/2018	13/02/2018	17/09/2018	10/10/2018	22/10/2018		H - Contracting delays	Contract returned to sponsor for final signatures, awaited return, exceeded 40 day metric.	Sponsor
18/SC/0242	238151	BLING III study	11/07/2018	24/08/2018	23/08/2018					H - Contracting delays	Study contract negotiations exceeded 40 days, non-model contract utilised by sponsor, contract detailed that it is the sites responsibility to fund research costs.	Sponsor
18/LO/1192	248843	SEAVUE - Safety and Efficacy of Adalimumab Vs Ustekinumab for one year	16/05/2018	28/08/2018	24/08/2018	21/09/2018	21/09/2018	24/09/2018	24/06/2019	I - Rare diseases	Rare condition, site target of 2.	Neither
17/SW/0080	215394	TILT	14/12/2017	31/07/2018	19/06/2017	16/11/2018	04/01/2019	07/01/2019	27/02/2019	H - Contracting delays	Honorary contract was required by researcher to assist with study delivery at site, time to arrange this exceeded 40 days.	Neither
18/LO/0219	235092	geko VLU efficacy study	14/05/2018	08/08/2018	08/04/2018	43355	13/09/2018	19/09/2018		F - No patients seen I - Rare diseases	40 day metric met. 30 day metric; no eligible patients seen, site target of 5.	Neither

18/ES/0042	241253	STARTUP	14/03/2018	06/09/2018	04/07/2018	19/11/2018	13/11/2018	23/11/2018	12/12/2018	H - Contracting delays	Study has ETCs, negotiation of support for ETCs exceeded 40 days	Neither
18/LO/0039	232257	NEMO (EORTC 08112-LCG): Nintedanib maintenance in mesothelioma	16/03/2017	12/10/2018	05/02/2018	15/11/2018	13/11/2018	23/11/2018	05/06/2019	I - Rare diseases	40 day metric achieved. 30 days metric; rare condition, site target of 4.	Neither
18/LO/0651	240503	Phase 2/3 study of rogaratinib vs chemo in FGFR+ urothelial carcinoma	28/02/2018	14/11/2018	13/06/2018	19/11/2018	21/11/2018	23/11/2018		I - Rare diseases	40 day metric achieved. 30 days metric; rare condition, site target of 1.	Neither
16/NW/0629	211995	CF START	20/06/2018	16/11/2018	22/09/2016	16/11/2018	31/01/2019	09/04/2019		H - Contracting delays I - Rare diseases	40 day metric; contracting delay . 30 days metric; rare condition, site target of 2.	Neither
17/LO/0731	219463	PIVOTALboost	26/07/2018	13/12/2018	27/07/2017	08/01/2019	14/01/2019	14/01/2019	14/02/2019	H - Contracting delays	Contract signature process exceeded 40 days, scanned contracts were not acceptable.	Neither
18/LO/1540	250125	Cemiplimab with/without ISA101b in?HPV16Positive Platin-Resistant OPC	27/07/2018	21/12/2018	23/11/2018	25/03/2019	12/04/2019	21/05/2019		H - Contracting delays	Sponsor communicated to site that national approvals were not expected until March 2019, were then issued in November 2018. Costing negotiations exceeded 40 days.	Neither
18/SW/0039	229163	The 'Big Baby Trial'	27/11/2018	10/01/2019	20/03/2018	10/01/2019	26/03/2019	28/03/2019	03/05/2019	H - Contracting delays	Wet signed contract required by sponsor and trial organisers, time taken to arrange signatures and transport between sites extended set up time lines.	Neither
18/NW/0514	249725	EX9536-4388 SELECT semaglutide cardiovascular outcome trial	20/06/2018	11/01/2019	03/01/2019	28/01/2019	14/02/2019	25/02/2019	25/02/2019		Benchmark met	Please Select...
18/SS/0085	243640	Alpha-2 agonists for sedation (A2B Trial)	14/11/2018	06/02/2019	14/12/2018	02/07/2019	24/05/2019			H - Contracting delays	Non model contract supplied by sponsor, contract was a locked version which did not allow for easy comparison and acceptance of wording.	Neither
18/EM/0003	234521	Ph3Study in Patients with Locally Advanced or Metastatic Breast Cancer	14/03/2018	08/02/2019	26/04/2018	18/01/2019	08/02/2019	14/03/2019	12/04/2019	I - Rare diseases	40 day metric; achieved. 30 day metric; Rare condition, site target of 3. 70 Day metric met.	Neither

17/WS/0267	234662	TOPSY trial ? Treatment Of Prolapse with Self- care pessary	18/09/2018	14/02/2019	09/03/2018	14/02/2019	27/03/2019	27/03/2019	24/06/2019	H - Contracting delays	Availability of Trust signatory	NHS Provider
17/LO/0621	191390	STARRT-AKI	17/10/2018	28/02/2019	22/05/2017					J - Other	Sponosr declind to open site, site target was reached.	Neither
18/SC/0243	240684	ORION-4	25/07/2018	02/11/2018	17/10/2018	04/02/2019	04/02/2019	04/02/2019	30/04/2019	D - Sponsor Delays	Sponsor delayed site opening, staff training required and reg approval needed.	Sponsor
17/EM/0077	206480	LACI-2	04/10/2018	04/10/2018	24/07/2017	16/01/2019	30/01/2019	06/02/2019		H - Contracting delays	Study contract signed by site but was advised by sponsor that it was not the current version, sponsor would not issue current version until they had received confirmation of how an incorrect version had been received.	Neither
18/NE/0125	238346	PROFHER2 Trial - Version 1.0	08/10/2018	08/10/2018	15/05/2018	43474	09/01/2019	18/01/2019		H - Contracting delays	Full contract review and execution exceeded 40 day metric, supplier forms were required in addition to a contract.	NHS Provider
18/LO/1558	248946	Phase 2 Trial of MK-3475 + Chemo and Radiotherapy in Stage III NSCLC	11/09/2018	04/12/2018	05/11/2018	04/12/2018	07/12/2018	15/01/2019	22/01/2019		70 Day metric achieved	
18/ES/0101	223790	The PRESTO study	28/08/2018	07/01/2019	14/09/2018	07/03/2019	15/03/2019	18/03/2019	02/04/2019	H - Contracting delays	Contract sponsor sign off took 3 weeks. Study recruitment was being completed in partnership with the Ambulance service, all parties needed to be ready for recruitment to commence.	Neither
18/LO/1186	236886	PRESTIGE-AF	05/11/2018	22/01/2019	07/12/2018	20/02/2019	21/03/2019	05/06/2019		A - Permissions delayed/denied H - Contracting delays	Site held C&C, SoE detailed ETC, SoECAT needed and confirmation that EWTC costs were detailed on the ODP app. Following Trust C&C sponsor took 76 days to issue green light.	Sponsor
17/EE/0347	201505	IASO	12/03/2019	29/03/2019	17/10/2017					H - Contracting delays	Contract wording required amdmmending, delayed sites confirmation of C&C	Neither
18/WM/0037	228917	M14-431 - Upadacitinib CD Ph 3 Biologics Inadequate Response	12/09/2018	26/04/2019	26/03/2018					A - Permissions delayed/denied	Amendment received following selection, site needed to recomplete feasibility to establish if the study was feasible at site	Neither

17/YH/0381	225986	GAP Study: Gabapentin in Post Surgery Pain	14/11/2018	30/04/2019	09/01/2018		27/06/2019				Within 70 day metric
18/NE/0365	239372	Decongestants in Obstructive Sleep Apnoea (DOSA)	04/03/2019	08/05/2019	30/01/2019	03/04/2019	30/05/2019	03/07/2019	16/07/2019		70 Day metric achieved
18/WM/0039	236159	M14-430 - Upadacitinib CD Ph 3 Maintenance & Extension	06/06/2019	06/06/2019	26/03/2018						Within 70 day metric
18/LO/0165	224726	POLEM	08/10/2018	17/06/2019	09/05/2018	11/07/2019	04/07/2019				Within 70 day metric
18/YH/0358	242342	The Sunflower Study	03/06/2019	24/06/2019	12/12/2018						Within 70 day metric
19/SC/0131	253657	B1761031 MYLOTARG- SINGLE-AGENT REGIMEN FOR RELAPSED CD 33- Positive AML	06/09/2018	28/06/2019	25/06/2019						Within 70 day metric

PLEASE NOTE: The data detailed above only includes clinical trials that have only ever received HRA approval and therefore the data does not detail all projects that have opened at this site since 01/07/2018.