Performance Of Initiation. Quarter 1, 2017-18.

Sandwell & West Birmingham Hospitals NHS Trust

REC REF	IRAS NO	Full TITLE	Date Site invited	Date site selected (DSS)	HRA Approval Date	Date Site Confirmed by Sponsor	Date Site Confirmed (DSC)	Date Site Ready to Start	Date First Participant Recruited (DFPR)	DSS to DSC (Days)	DSC to DFPR (Days)	DSS to DFPR (Days)	Bench mark Met?	Comment
16/WM/0339	193145	An observational study of non-vitamin K antagonist oral anticoagulants (NOACs) versus warfarin based on the SAMe-TT2R2 score strata in anticoagulant-naive patients with atrial fibrillation: TREAT-2 study	13/07/2016	25/09/2016	26/09/2016	13/10/2016	13/10/2016	13/10/2016	20/10/2016	18	7	25	Yes	
16/EM/0384	182787	BMS AGUSTUS. An Open-label, 2 x 2 Factorial, Randomized Controlled, Clinical Trial to Evaluate the Safety of Apixaban vs. Vitamin K Antagonist and Aspirin vs. Aspirin Placebo in Patients with Atrial Fibrillation and Acute Coronary Syndrome or Percutaneous Coronary Intervention.	24/03/2015	10/08/2016	21/11/2016	30/01/2017	30/01/2017	09/02/2017	01/03/2017	173	30	203	No	103 day period from receipt of full document set to HRA Approval. Delay in approval of final costings between Trust and Sponsor.
16/LO/1069	200813	PALLAS Study. PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	18/07/2016	19/07/2016	06/09/2016	23/02/2017	20/03/2017	24/04/2017	26/06/2017	244	98	342	No	PI left the Trust and new PI had to be arranged. 28 day return of Agreement to site for sign off. Further 32 day delay for SIV.
17/WM/0033	209469	A Skin-to-Skin Contact (SSC) Facilitating Device used within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.	29/09/2016	22/02/2017	21/02/2017	31/03/2017	31/03/2017	03/04/2017	09/05/2017	37	39	76	No	Delay due to training of Community Midwives prior to the start of recruitment.

16/SC/0508	199243	GRASP Trial - Getting it Right: Addressing Shoulder Pain. Clinical and cost effectiveness of progressive exercise compared to best practice advice, with or without corticosteroid injection, for the treatment of rotator cuff disorders: a 2x2 factorial randomised controlled trial	01/12/2016	31/01/2017	24/11/2016	15/03/2017	20/03/2017	07/04/2017	05/06/2017	48	77	125	No	Training for interventions delayed by three months after site selected.
17/WM/0059	205705	Gastric Emptying: in vivo studies in healthy volunteers (using scrambled egg and porridge) to determine reliable normal ranges.	05/09/2016	30/03/2017	30/03/2017	28/04/2017	28/04/2017	01/05/2017	02/05/2017	29	4	33	Yes	
16/LO/1024	195085	The BEAT Lupus Trial. A multicentre, UK phase II, randomised, double blind, placebo- controlled CTIMP investigating the safety and efficacy of Belimumab after B cell depletion therapy (which has been given as standard of care) in patients with active Systemic Lupus Erythematosus resistant to conventional therapy in accordance with NHS England guidelines.	19/01/2016	17/11/2016	11/10/2016	03/05/2017	15/05/2017	20/08/2017	18/09/2017	41				Trust unable to start recruiting to study due to IT issues between the co-ordinating site and participating site.

REC REF	IRAS NO	Full TITLE	Minimum No of Recruits Agreed	Maximum No. of Recruits Agreed	Date Agreed to Reach Target	Total No. Recruited at Target Date	Date Trial Closed to Recruitment	Total Recruitment to Trial
13/LO/1252	135692	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer): A Multinational, Randomized, Open-label Phase 3 Study of MEK162 vs. Physician?s Choice Chemotherapy in Patients with Recurrent or Persistent Low-grade Serous Carcinomas of the Ovary,	3	3	01/02/2016	3	01/07/2016	3
16/NW/0147	198056	Odyssey DM- A Randomised, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab versus Usual Care in Patients with Type 2 Diabetes and Mixed Dyslipidaemia at High Cardiovascular Risk with Non-HDL-C Not Adequately Controll	4	4	01/10/2016	0	01/10/2016	0
13/NE/0269	134646	TESARO: A Phase 3 Randomised Double blind Trial of Maintenance with Niraparib versus Placebo in Patients with Platinum Sensitive Ovarian Cancer	2	2	31/12/2015	2	30/09/2016	2
15/LO/1829	187483	ROSACEA: Phase 3, Randomized, Vehicle-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety & Efficacy of Once-Daily CLS001 Topical Gel vs Vehicle Administered for 12 Weeks to Subjects with Papulopustular Rosacea with a 4 Wk FU Period	2	5	05/04/2016	3	26/10/2016	3
14/SC/0032	142458	SPIRE 1 : B1481022 Phase 3 multi-center, double-blind, randomized, Placebo-controlled, parallel group evaluation of the Efficacy, safety, and tolerability of pf-04950615, in reducing the Occurrence of major cardiovascular events in high risk Subjects	5	15	20/12/2015	15	22/07/2016	15
14/LO/2011	159926	A prospective Randomised, open label, blinded endpoint (PROBE)study to Evaluate DUAL antithrombotic therapy with dabigatran etexilate (110mg and 150mg b.i.d.) plus clopidogrel or ticagrelor vs triple therapy strategy with warfarin (INR 2.0 – 3.0) plu	2	3	31/08/2016	4	31/10/2016	4