**Performance Of Initiation. Quarter 4, 2016-17.**

**Sandwell & West Birmingham Hospitals NHS Trust**

| REC Reference | IRAS No. | Name of Trial | Date of Receipt of Valid Research Application | Date of NHS Permission | First Patient Recruited? | Date of First Patient Recruited | Duration between VRA and NHS Permission | Duration between NHS Permission and First Patient | Duration between VRA and First Patient | Benchmark Met | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 14/YH/1108 | 141368 | SHAPE. Simple Hysterectomy And Pelvic node dissection in Early cervix cancer. | 24/03/2016 | 20/06/2016 | No | | 88 | | | No | |

| REC Reference | IRAS No. | Name of Trial | 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 of First Patient Recruited (DFPR) | DSS to DSC | DSC to DFPR | DSS to DFPR | Bench mark Met | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 16/EM/0193 | 190690 | A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The Dal-GenE trial | 11/08/2015 | 03/06/2016 | 03/06/2016 | 26/09/2016 | 03/10/2016 | 06/10/2016 | 01/11/2016 | 122 | 29 | 151 | No | Protracted costing negotiations and contract agreement |
| 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-naïve 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/0172 | 194491 | Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes (NOAH - AFNET 6) | 10/11/2015 | 01/06/2016 | 24/05/2016 | 25/11/2016 | 13/01/2017 | 16/01/2017 | 01/02/2017 | 226 | 19 | 245 | No | Staffing issues at site delayed the AAC of C&C. Sponsor requested a delay in opening until Jan 2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 DSS and HRA Approval. Delay in approval of final costings. |
| 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 | | 244 | | | No | PI left the Trust and new PI had to be arranged. 28 day delay in return of Agreement to site for sign off. 32 day delay for Sponsor to provide study 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 | | 37 | | | Within 70 Days | |

| 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 |