

Performance in Initiating Research, Oct 2019

| Research Ethics Committee Reference Number | IRAS No | Name of Trial | First Patient Recruited? | Date of First Patient Recruited | Duration between Date Site Selected and Date Site Confirmed | Duration between Date Site Confirmed and Date Frist Patient Recruited | Duration between Date Site Selected and Date First Patient Recruited | Date Site Invited | Date Site Selected | HRA Approval Date | Date Site Confirmed by Sponsor | Date Site Confirmed | Non-confirmation Status | Date Site Ready to Start | Reasons for Delay | Comments | Source of Delay |
|---|---------|---|--------------------------|---------------------------------|--|---|--|-------------------|--------------------|-------------------|--------------------------------|---------------------|-------------------------|--------------------------|-------------------|---|-----------------|
| 18/NE/0092 | 230286 | ELAN - Early versus Late initiation of direct oral Anticoagulants in postischaemic stroke patients with atrial fibrillation (ELAN): an international, multicentre, randomised-controlled, two-arm, assessor-blinded trial | Yes | 18/01/19 | 32 | 53 | 85 | 29/08/18 | 25/10/18 | 13/08/18 | 13/11/18 | 26/11/18 | | 14/01/19 | Sponsor Delays | Delayed Green Light date from Sponsor | Sponsor |
| 17/NW/0529 | 226070 | PPAC 2 - The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial | Yes | 11/03/19 | 23 | 117 | 140 | 27/03/18 | 22/10/18 | 05/12/17 | 31/10/18 | 14/11/18 | | 15/02/19 | Sponsor Delays. | Delayed Green Light date from Sponsor | Sponsor |
| 18/SS/0033 | 242190 | BICS - A randomised, double-blind placebo controlled trial of the effectiveness of the beta- blocker bisoprolol in preventing exacerbations of COPD | Yes | 06/08/19 | 45 | 183 | 228 | 28/10/18 | 21/12/18 | 09/08/18 | 24/01/19 | 04/02/19 | | 08/05/19 | Sponsor Delays | SIV held on 27 March 2019; Green Light from Sponsor not given until 8 May 2019. | Sponsor |

| 18/EM/0310 | 239782 | C-Stich 2: Emergency Cervical Cerclage to Prevent Miscarriage and Preterm Birth: a Randomised Controlled Trial | No | | 13 | | | 03/01/19 | 07/03/19 | 16/11/18 | 07/03/19 | 20/03/19 | | Sponsor Delays | Green Light from Sponsor outstanding | Sponsor |
|------------|--------|---|-----|----------|-----|----|-----|----------|----------|----------|----------|----------|----------|--------------------------|--|---------|
| 19/WA/0005 | 246081 | ATLANTA - Adjuvant treatment to the local tumour for metastatic prostate cancer: Assessment of novel treatment algorithms | No | | 21 | | | 18/12/18 | 26/03/19 | 14/03/19 | 26/03/19 | 16/04/19 | 28/05/19 | No patient consented. | Patients sought but no patients consented. (Patients have up-to 6 months from start of Standard of Care treatment before being able to consent to study; patient has been identified). | Neith |
| 16/EM/0322 | 202096 | TWIST - A randomised- controlled trial of thrombolytic treatment with tenecteplase for acute ischaemic stroke upon awakening | No | | 48 | | | 07/02/19 | 07/02/19 | 18/08/17 | 18/03/19 | 27/03/19 | 26/04/19 | No patient consented. | Patients sought but no patients consented. | Neither |
| 17/WS/0210 | 231280 | ALLEGRO - A placebo controlled randomised trial of intravenous lidocaine in accelerating gastrointestinal recovery after colorectal surgery | Yes | 02/07/19 | 40 | 71 | 111 | 07/01/19 | 13/03/19 | 27/04/19 | 17/04/19 | 22/04/19 | 31/05/19 | No patient consented. | Patients sought but no patients consented. | Neither |
| 15/LO/0485 | 138945 | SUPPORT - Stitch, Progesterone or Pessary: a Randomised Trial The prevention of pre-term birth in women who develop a short cervix. A multi-centre randomised controlled trial to compare three treatments; cervical cerclage, cervical pessary and vaginal progesterone; | No | | 104 | | | 13/12/18 | 01/02/19 | 15/06/16 | 18/03/19 | 16/05/19 | 25/09/19 | Sponsor | Delayed Green Light from Sponsor. | Sponsor |

| 19/WA/0019 | 248285 | ROSSINI 2 - Reductions of surgical site infection using several novel interventions | Yes | 25/06/19 | 12 | 34 | 46 | 21/03/19 | 10/05/19 | 01/02/19 | 14/05/19 | 22/05/19 | 19/06/19 | | | |
|------------|--------|---|-----|----------|----|----|----|----------|----------|----------|----------|----------|----------|-----------------------|---|---------|
| 19/NW/0158 | 259931 | SCIENCE - Surgery of cast for injuries of the epicondyle in children's elbows | No | | 22 | | | 18/04/19 | 13/05/19 | 25/03/19 | 16/05/19 | 04/06/19 | 06/06/19 | No patient consented. | Patients sought but no patients consented. | Neither |
| 17/LO/1819 | 210689 | BLADDERPATH - Image Directed Redesign of Bladder Cancer Treatment Pathways | No | | 24 | | | 10/04/19 | 13/05/19 | 04/12/17 | 04/06/19 | 06/06/19 | 13/06/19 | No patients seen. | Patients sought but no patients identified. | Neither |
| 19/LO/0452 | 250324 | CASTLE - Randomised factorial design controlled trial comparing carbamazepine, levetiracetam or active monitoring combined with or without sleep behaviour intervention in treatment naive children with rolandic epilepsy | No | | 53 | | | 10/04/19 | 13/05/19 | 02/05/19 | 14/06/19 | 05/07/19 | 20/09/19 | No patients seen. | Patients sought but no patients identified. | Neither |
| 17/SW/0039 | 229163 | BIG BABY - Induction of labour for predicted macrosomia | No | | 41 | | | 25/06/19 | 25/06/19 | 20/03/18 | 04/07/19 | 05/08/19 | 16/08/19 | No patients seen. | Patients sought but no patients identified. | Neither |
| 17/WM/0275 | | NOSTRA -Feasibility Study: A prospective non- randomised multi-centre feasibility study to assess if patients with residual cancer following dual- targeted neoadjuvant chemotherapy treatment for HER2-positive, ER- negative early breast cancer can be identified by multiple ultrasound-guided tumour bed core biopsies | No | | 6 | | | 08/04/19 | 11/09/19 | 15/08/19 | 19/08/19 | 17/09/19 | 24/09/19 | No patients seen. | Patients sought but no patients identified. | 7 |

| 19/EM/0142 | 260307 | BE-OPTIMAL - A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, ACTIVE REFERENCE (ADALIMUMAB) STUDY EVALUATING THE EFFICACY AND SAFETY OF BE OPTIAMAL - BIMEKIZUMAB IN THE TREATMENT OF SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS | No | | 53 | | | 30/04/19 | 05/08/19 | 01/08/19 | 19/09/19 | 27/09/19 | | No date given yet | Sponsor | Green Light from Sponsor outstanding | Neither |
|------------|--------|---|----|--|----|--|--|----------|----------|----------|----------|----------|--|----------------------|---------|---|---------|
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