

Submission

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| Submission Details | |
|--------------------|---|
| Status | Accepted |
| Open Date | 02/01/2017 |
| Deadline Date | 30/01/2017 |
| Date Submitted | 25/01/2017 |
| Type | Historic Performance in Initiating |
| NHS provider | Maldstone and Tunbridge Wells NHS Trust |

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| Research Ethics Committee Reference Number | Integrated Research Application System Number | Submission Type | 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 | Duration between Date Site Selected and Date Site Confirmed | Duration between Date Site Confirmed and First Patient Recruited | Duration between Date Site Selected and First Patient Recruited | Benchmark Met | Date Site Invited | Date Site Selected | HRA Approval Date |
|--|---|-----------------|---|---|------------------------|--------------------------|---------------------------------|---|---|--|---|--|---|---------------|-------------------|--------------------|-------------------|
| 95710 | 13/NW/0501 123836 | HRA Approval | QUAZAR CC-486-AML-001: A Phase 3, randomized, double-blind, placebo-controlled study to compare efficacy and safety of oral azacitidine plus best supportive care versus best supportive care as maintenance therapy in subjects with acute myeloid Leukemia in | | | Yes | 22/11/2016 | | | | 114 | 201 | 315 | No | 12/01/2016 | 12/01/2016 | 25/04/2016 |
| 95711 | 14/EM/0172 142310 | NHS Permission | BABY OSCAR- Outcome after Selective early Treatment for Closure of patent Ductus Arteriosus in Pre-term babies. | 13/10/2015 | 12/02/2016 | No | | 122 | | | | | | No | | | |
| | | | CARDAMON Carfilzomib/Cyclophosphamide/Dexamethasone | | | | | | | | | | | | | | |

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|-------|-------------|--------|-------------------|---|------------|------------|-----|--------------|-----|-----|--|--|--|--|--|--|--|----|----------------------------------|--|
| 95720 | 15/EE/0326 | 185205 | NHS Permission | Seattle Genetics: SGN35-023 A randomised, open label, phase 2 study of rituximab and bendamustine with or without brentuximab vedotin for relapsed or refractory CD30-positive diffuse large B-cell lymphoma | 23/03/2016 | 04/04/2016 | No | 12 | | | | | | | | | | No | | |
| 95721 | 14/SS/1043 | 142447 | NHS Permission | UNIRAD: Randomized, double-blind, multicentre phase 111 trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with poor prognosis, ER+ and HER2 - primary breast cancer who remain free of disease after receiving | 06/03/2016 | 09/03/2016 | Yes | 21/11/2016 3 | 257 | 260 | | | | | | | | No | | |
| 95722 | 15/SC/0409 | 183061 | NHS Permission | Safety and efficacy of Abicipar Pegol in Patients with neovascula age related macular degeneration MORAB-009-201 A randomised, double-blind, placebo-controlled study of the safety and efficacy of amaximab in combination with pemetrexed and cisplatin in subjects with unresectable malignant pleural mesothelioma | 22/01/2016 | 17/11/2016 | No | 300 | | | | | | | | | | No | | |
| 95723 | 15/EM/0344 | 183906 | NHS Permission | place-controlled study of the safety and efficacy of amaximab in combination with pemetrexed and cisplatin in subjects with unresectable malignant pleural mesothelioma | 14/03/2016 | 23/03/2016 | Yes | 19/07/2016 9 | 118 | 127 | | | | | | | | No | | |
| 95724 | 15/WWS/0011 | 122822 | HRA Approval | BALLAD: A trial to evaluate the potential benefit of adjuvant chemotherapy for small bowel adenocarcinoma | | | No | | | 12 | | | | | | | | No | 05/03/2015 27/05/2016 29/04/2016 | |
| 95725 | 13/NW/0153 | 104669 | NHS Permission | CIPHER: Phase 11 multicentre study assessing the efficacy of Cabazitaxel in patients with HER2-negative metastatic breast cancer and having unresectable brain metastases. | 16/02/2016 | 23/02/2016 | No | 7 | | | | | | | | | | No | | |
| 95726 | 15/LC/0539 | 166304 | HRA Approval | RAIDER - A Randomised phase 11 trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder | | | No | | | 196 | | | | | | | | No | 25/06/2015 24/03/2016 26/07/2016 | |
| 95727 | 15/EM/0400 | 178129 | NHS Permission | SOPHIA - A Phase 3, Randomised Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients with HER2+Metastatic | 16/02/2016 | 25/02/2016 | Yes | 22/11/2016 9 | 271 | 280 | | | | | | | | No | | |

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|-------|-------------|--------|----------------|--|-----|--|--|--|--|------------|--|--|--|----|------------|------------|------------|--|--|
| | | | | Breast Cancer Who Have Received Two Prior Anti-HER2 therapies and Require Systemic Treatment | | | | | | | | | | | | | | | |
| 95728 | 16/Y/H/0154 | 202759 | HRA Approval | DOMPERIDONE JUN-17296812: A multicenter, double-blind, randomised, Placebo-controlled, parallel-group, Prospective Study to Evaluate the Safety and Efficiency of Domperidone in 6 month old to 12 year old Pediatric Subjects with Nausea and Vomiting due to | No | | | | | 147 | | | | No | 26/11/2015 | 07/04/2016 | 26/08/2016 | | |
| 95729 | 16/LO/0092 | 194133 | NHS Permission | GO29834 - Harmony: A phase Ib/II study evaluating the safety and efficacy of Obinutuzumab in combination with Polatuzumab vedotin and lenalidomide in patients with relapsed or refractory follicular or diffuse large B-cell lymphoma. | No | | | | | 184 | | | | No | | | | | |
| 95730 | 15/LO/2110 | 136376 | NHS Permission | All Polyethylene Versus Metal Backed Tibial Components in Knee Replacement - A Comparison Study | No | | | | | 3 | | | | No | | | | | |
| 95731 | 16/LO/0075 | 191435 | HRA Approval | A prospective, multicentre, randomised trial: The effect of catheter valve Vs. standard catheter removal in outpatient settings on the patient discharge timings | Yes | | | | | 09/01/2017 | | | | No | 23/03/2016 | 31/05/2016 | 07/07/2016 | | |
| | | | | HART Hughes Abdominal Repair Trial - | | | | | | | | | | | | | | | |

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| 95732 | 12/WA/0374 | 95726 | NHS Permission | Abdominal wall closure techniques to reduce incidence of incisional hernias | 18/02/2016 | 23/02/2016 | Yes | 01/05/2016 | 68 | 73 | No | | | | | | | |
| 95733 | 14/NE/1176 | 16188 | NHS Permission | UK Frost- Multi-center randomised controlled trial with Economic evaluation nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia vs arthroscopic capsular release for patients referred to secondary care wit | 02/08/2016 | 06/09/2016 | No | 35 | 110 | 132 | No | | | | | | | |
| 95734 | 15/SC/0090 | 171171 | NHS Permission | EndoPredict: The use of a prognostic tool (EndoPredict) to inform adjuvant chemotherapy decisions in low to medium risk Oestrogen Receptor Positive, Her-2 Negative Early Breast cancer: Feasibility, Acceptability and Economic impact in Multicentre UK NHS P | 24/12/2015 | 15/01/2016 | Yes | 04/05/2016 | 110 | 132 | No | | | | | | | |

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