Version 1.0.3

## Submission

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| Submission Details | |
|---|---|
| Status | Accepted |
| Open Date | 01/04/2019 |
| Deadline Date | 30/04/2019 |
| Date Submitted | 30/04/2019 |
| Type | Performance in Initiating |
| NHS provider | Maidstone and Tunbridge Wells NHS Trust |

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| Id | Research Ethics Committee Reference Number | Integrated Research Application System Number | Name of Trial | First Participant Recruited? | Date of First Participant Recruited | Duration between Date Site Selected and Date Site Confirmed | Duration between Date Site Confirmed and First Participant Recruited | Duration between Date Site Selected and First Participant 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 | Reasons for delay correspor to: |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 136690 | 17/LO/1500 | 224823 | AGILE Study Agios AG120-C-009 A phase 3 multicentre double-blind randomised placebo-controlled study of AG-120 in combination with azacitidine in subjects over 18 years of age with previously untreated acute myeloid leukemia with an IDH1 mutation | Yes | 29/01/2019 | 47 | 230 | 277 | 06/11/2017 | 27/04/2018 | 06/03/2018 | 19/04/2018 | 13/06/2018 | Please Select... | 21/09/2018 | A - Permissions delayed/denied F - No patients seen | Discrepancies with costs that took an additional month to resolve and finalise. Delay in site reviewing costs and getting back to sponsor. DSC to FPR update 26/10 - study DSC-FPR now open to rec however no eligible pts seen as yet. Recruitment slow due to a rare condition. | NHS Provider |
| 136691 | 17/SC/0090 | 215068 | c-TRAK TN A randomised trial utilising ctDNA mutation tracking to detect minimal residual disease and trigger intervention in patients with moderate and high risk early stage triple negative breast cancer | Yes | 18/12/2018 | | | 222 | 24/04/2018 | 10/05/2018 | 22/06/2017 | | | Please Select... | 08/11/2018 | A - Permissions delayed/denied D - Sponsor Delays | In set up Delay in receiving SoE from sponsor to review attribution of activities, delay in receiving modified contract from sponsor, pharmacist signature was delayed due to annual leave. | Both |

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| | | | | | | | | | | | | | | | | | Pending ARSAC license to be issued. DSS to FPR target will not be met due to C&C not being issued. | |
| 136692 | 18/WA/0104 | 236930 | Pevonedistat 3001 A Phase 3 randomised controlled open-label clinical study of Pevonedistat Plus Azacitidine versus single-agent Azxacitidine as first-line treatment for patients with higher-risk myeloysplastic syndromes chronic myelomonocytic leukemia | No | | 79 | | | 05/03/2018 | 14/05/2018 | 29/04/2018 | 15/06/2018 | 01/08/2018 | Please Select... | 24/09/2018 | A - Permissions delayed/denied F - No patients seen H - Contracting delays | Delays with contract review and finalising final CTA. Sponsor errors needed correcting and delay in processing and returning for final execution.delay in obtaining SSD app &CD/GM sign off, C&C pending, therefore FPR target will not be met. 26/10 study DSC-FPR now open to rec but no eligible pts seen | Both |
| 136693 | 18/NE/0125 | 238346 | PROFHER-2 - PROximal Fracture of the Humerus: Evaluation by Randomisation Trial no. 2 (PROFHER-2 Trial): A three-arm randomised controlled trial to assess the effectiveness and cost-effectiveness of reverse shoulder arthroplasty versus hemiarthroplasty versus non-surgical care for acute three and four-part fractures of the proximal humerus in older adults | Yes | 19/11/2018 | 63 | 68 | 131 | 08/12/2017 | 11/07/2018 | 15/05/2018 | 17/07/2018 | 12/09/2018 | Please Select... | 27/09/2018 | A - Permissions delayed/denied G - No patients consented | Delay in obtaining local site feasibility sign off from trust signatories, due to staff annual leave. As of 30/08/18 still pending approved feasibility. C&C letter drafted, all governance reviews carried out, no issues, contract fully executed. C&C can be issued once TFF recv'd. Final TFF recv'd 12/09/18 - c&C issued 14/09/18. DSC-FPR delay 1 pt screened but declined, 1 pt currently booked in to consultant... pending | NHS Provider |
| 136694 | 17/YH/0289 | 231276 | ACE-CL-110 A Phase 1/2 Proof-of-Concept Study Investigating AZD6738 monotherapy and Acalabrutinib in Combination with AZD6738 (ATR inhibitor) in | No | | 64 | | | 15/03/2018 | 09/07/2018 | 18/10/2017 | 07/09/2018 | 11/09/2018 | Please Select... | 28/11/2018 | A - Permissions delayed/denied D - Sponsor Delays | Costings negotiations during annual leave period. Contract | Both |

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| | | | Subjects with Relapsed or Refractory High-risk Chronic Lymphocytic Leukemia (CLL). | | | | | | | | | | | | | | agreed by parties, delay in receiving partially executed agreement from sponsor for signing. TFF responses 43 working days. Although C&C issued, pharmacy green light still pending. | |
| 136695 | 17/EE/0340 | 213113 | "INTERIM: a randomised phase II feasibility study of INTERmittent versus continuous dosing of oral targeted combination therapy In patients with BRAFV600 mutant stage 3 unresectable or metastatic Melanoma" | Yes | 27/11/2018 | | | 132 | 26/06/2018 | 18/07/2018 | 05/10/2017 | 07/09/2018 | | Please Select... | 19/10/2018 | A - Permissions delayed/denied E - Staff availability issues | Internal C&C process delayed. Document circulated to SSDs until 03/09/18 due to capacity issues in team as this is a new disease area. C&C completed 15/10/18 and provided to governance team for completion and issuing of C&C letter | NHS Provider |
| 136696 | 18/SC/0242 | 238151 | BLING III - A phase III randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients | Yes | 11/02/2018 | | | -194 | 15/05/2018 | 24/08/2018 | 23/08/2018 | 25/09/2018 | | Please Select... | | A - Permissions delayed/denied D - Sponsor Delays | In set-up - DSS-DSC delays due to internal C&C review and obtaining SSD approvals. Pharmacy investigating stability of drug using the protocol admin method as conflicting evidence, obtaining advice from local network Sponsor delays with contract, provided different version to what was validated on HRA approval letter. HRA and sponsor contacted and updated contract and HRA letter provided. FE contracted recv'd 22/10/18. R&D | Both |

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| | | | | | | | | | | | | | | | | | C&C now in place | |
| 136697 | 18/LO/0165 | 224726 | POLEM Avelumab plus 5-FU based chemotherapy as adjuvant treatment for stage 3 MSI-High or POLE mutant colon cancer: A phase 3 randomised study | No | | | | | 17/05/2017 | 02/09/2018 | | | | Please Select... | | A - Permissions delayed/denied | Delay in obtaining SSDs approval. R&D C & C now in place. 2 patients screened, but failed the DMR Test which is required as part of the study requirement. | NHS Provider |
| 136698 | 17/EE/0382 | 220851 | Predicting outcomes for Crohn's disease using a molecular biomarker (PROFILE) trial | No | | | | | 02/07/2018 | 02/07/2018 | | | | Please Select... | | A - Permissions delayed/denied | DSS-DSC delays with C&C being drafted and circulated to SSDs and receiving responses. Still awaiting confirmation from IT regarding video recording guidance. Contract FE - pending Fully signed TFF prior to issuing C&C letter | NHS Provider |
| 136699 | 18/SW/0039 | 229163 | Induction of labour for predicted macrosomia 'The Big Baby Trial' | Yes | 24/01/2019 | | | 202 | 06/07/2018 | 06/07/2018 | 20/03/2018 | 06/07/2018 | | Please Select... | 08/01/2019 | A - Permissions delayed/denied | Delay in obtaining SDD sign off, R&D C&C now in place. | NHS Provider |
| 136700 | 17/LO/1875 | 219487 | RAMPART Renal adjuvant multiple arm randomised trial (RAMPART): An international investigator-led phase III multi-arm multi-stage randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at hi | No | | | | | | 04/12/2018 | | | | Please Select... | | | Currently in set up and local feasibility being undertaken. Currently on hold due to pharmacy concerned with safety. Project currently on hold. | Please Select... |
| 139043 | 19/EE/0130 | 252786 | BGB-A317-306 A randomised placebo-controlled double-blind phase 3 study to evaluate the efficacy and safety of tislelizumab (GB-A317) in combination with chemotherapy as first-line treatment in patients with unresectable locally advanced recurrent or metastatic esophageal squamous cell carcinoma | No | | | | | 16/08/2018 | 27/03/2019 | | 27/03/2019 | | Please Select... | | | Currently in set up, feasibility is being undertaken | Please Select... |
| 139071 | 19/NE/0011 | 255897 | A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant | No | | | | | 31/10/2018 | 09/01/2019 | | | | Please Select... | | | In Set Up, governance checks being finalised. | Please Select... |

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| | | | TriAl with Ribociclib [LEE011]: NATALEE). TRIO033 | | | | | | | | | | | | | | | |
| 139072 | 15/SS/0225 | 169859 | SYSTEMS-2 A randomised phase II trial of standard versus dose escalated radiotherapy in the treatment of pain in malignant pleural mesotherlioma | No | | | | | | 15/02/2019 | | 15/02/2019 | | Please Select... | | | In set up/ETC currently being identified and agreed. | Please Select... |
| 139073 | 18/NI/0204 | 247205 | A RANDOMIZED, OPEN-LABEL, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVELUMAB IN COMBINATION WITH CHEMOTHERAPY FOLLOWED BY MAINTENANCE THERAPY OF AVELUMAB IN COMBINATION WITH THE POLY (ADENOSINE DIPHOSPHATE [ADP]-RIBOSE) POLYMERASE (PARP) INHIBITOR TALAZOPARIB IN PATIENTS WITH PREVIOUSLY UNTREATED ADVANCED OVARIAN CANCER (JAVELIN OVARIAN PARP 100) | No | | | | | 02/08/2018 | 06/03/2019 | | | | Sponsor declined site confirmation | | | The sponsor have withdrawn this project from being undertaken at all sites. | Please Select... |
| 139472 | 16/WM/0472 | 32290 | CONFIRM trial nivolumab vs placebo in mesotherlioma | No | | | | | 06/04/2018 | 05/04/2018 | 06/12/2016 | 30/01/2019 | | Please Select... | | | In set up/Feasibility still be undertaken. | Please Select... |
| 139475 | 16/LO/1686 | 202638 | BARCODE2 Targeting cancer care with the use of genetic profiling | No | | | | | 29/06/2018 | 05/07/2018 | 21/04/2017 | 09/07/2018 | | Please Select... | | | Open, first patient not recruited, | Please Select... |
| 139480 | 17/YH/0369 | 232340 | Beigene BGB-3111-304 An international Phase 3 Open-label randomised study of BGB-3111 compared with bendamustine plus rituximab in patients with previously untreated chronic lymphocytic leukemia or small lymphocytic lymphoma | No | | | | | 13/11/2018 | 02/01/2019 | | | | Please Select... | | | In Set Up, governance checks being finalised. | Please Select... |
| 139591 | 17/WA/1056 | 154468 | AML19 Adults with acute myeloid leukaemia or high-risk myelodysplastic syndrome | No | | | | | 12/02/2018 | 05/06/2018 | 15/06/2016 | | | Please Select... | | | In set up, issues with the drug, ETC costs currently on hold | Please Select... |

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