

Version 1.0.3

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Submission Details	
Status	Accepted
Open Date	01/07/2019
Deadline Date	30/07/2019
Date Submitted	30/07/2019
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 correspond to:
145681	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	NHS Provider

145682	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 Subjects with Relapsed or Refractory High-risk Chronic Lymphocytic Leukemia (CLL).	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	consultant... pending Costings negotiations during annual leave period. Contract 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.	Both
145683	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
145684	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,	Both

																	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 C&C now in place	
145685	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
145686	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
145687	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

145688	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...
145689	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...
145690	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 Trial with Ribociclib [LEE011]: NATALEE). TRIO033	No					31/10/2018	09/01/2019					Please Select...			In Set Up, governance checks being finalised.	Please Select...
145691	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 mesothelioma	No						15/02/2019		15/02/2019			Please Select...			In set up/ETC currently being identified and agreed.	Please Select...
145692	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...
145693	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...
145694	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...
146357	17/NE/0061	215780	CONVINCE - COLchicine for prevention of Vascular Inflammation in Non-CardioEmboic	No		150			01/11/2017	07/01/2019	25/07/2017	07/01/2019	06/06/2019		Please Select...	17/06/2019	H - Contracting delays	Study approved, delays were	Sponsor

			stroke) - a randomised clinical trial of low-dose colchicine for secondary prevention after stroke.															caused due to the Sponsor wishing to update the GDPR in the previous contract.	
146433	18/LO/1946	249357	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of Baricitinib in Patients with Systemic Lupus Erythematosus	No		86		10/04/2017	29/01/2019	07/12/2018	24/04/2019	25/04/2019	Please Select...	01/05/2019				Study Approved	Please Select...
146512	15/NW/0926	178681	Randomised, phase II/III, 3 stage trial to evaluate the safety and efficacy of the addition of olaparib to platinum-based neoadjuvant chemotherapy in breast cancer patients with TNBC and/or gBRCA	No				15/05/2019	15/05/2019	02/04/2019			Site declined to participate					Delay in the study set up which related to pathology. This study also conflicts with KEYNOTE 522	Please Select...
146547	19/NW/0158	259931	SCIENCE Surgery or Cast for Injuries of the Epicondyle in Children's Elbows: A multi-centre prospective randomised superiority trial of operative fixation versus non-operative treatment for medial epicondyle fractures of the humerus in children.	Yes - Date Unavailable		75		30/10/2017	27/03/2019	25/03/2019	27/03/2019	10/06/2019	Please Select...	17/06/2019				Study Approved	Please Select...

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