Version 1.0.3

Submission

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Submission Details	
Status	Accepted
Open Date	02/01/2020
Deadline Date	31/01/2020
Date Submitted	30/01/2020
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 correspon to:
157943	17/YH/0369	232340	An International, Phase 3, Open-label, Randomized Study of BGB-3111 Compared with Bendamustine plus Rituximab in Patients with Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	No		113			17/09/2018	02/01/2019	03/01/2018	26/02/2019	25/04/2019	Please Select...	30/04/2019	A - Permissions delayed/denied C - Closed by sponsor	Review of the trial feasibility form of SSD and obtaining authorised signatures. Subsequent amendment received for review and costing during set-up. Sponsor disallowed agreed recruitment of 2 patients and closed site to screening/randomising patients. Sponsor withdrew site 5 days after approval due to global recruitment being reached	Both
157944	17/NE/0061	215780	CONVINCE - COLchicine for preventioN of Vascular Inflammation in Non-CardioEmbolic stroke) - a randomised clinical trial of low-dose colchicine for secondary prevention after stroke.	No		150			01/11/2017	07/01/2019	25/07/2017		06/06/2019	Please Select...	20/06/2019	D - Sponsor Delays G - No patients consented H - Contracting delays	Approval delays were caused due to the sponsor wishing to update the GDPR in the previous contract. 200 Patients have been screened but no suitable patients have been able to be recruited.	Sponsor
157945	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-	No		126			31/10/2018	09/01/2019	04/03/2019	18/04/2019	15/05/2019	Please Select...	22/05/2019	A - Permissions delayed/denied F - No patients seen J - Other	HRA approval received in March from Sponsor, Delays in approval from EME over ECG machine. No patients had been seen - patients need to be identified further	Both

			negative, early breast cancer (New Adjuvant TriAl with Ribociclib [LEE011]: NATALEE).													on in their treatment and actions have been taken to broaden the scope of area for identifying potential participants.	
157946	18/LO/1946	249357	A Randomized, Double-Blind, Placebo-Controlled,Parallel-Group, Phase 3 Study of Baricitinib in Patients with Systemic Lupus Erythematosus	Yes	31/07/2019	86	97	183	10/04/2017	29/01/2019	27/03/2019	24/04/2019	25/04/2019	Please Select...	01/05/2019	A - Permissions delayed/denied J - Other	HRA approval delayed due to contract problems. HRA approval received on 29/03/19, contract received and signed for return on 25/04/19. Target recruitment only 2 patients over a year, due to inclusion criteria patients cannot be screened far in advance as they have to be at a specific state of their disease at screening visit	Neither
157947	18/LO/0660	237150	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia	Yes	27/08/2019	128	74	202	06/02/2019	06/02/2019	23/07/2018	16/07/2019	14/06/2019	Please Select...	16/08/2019	D - Sponsor Delays	Trust approval issued on 19/06/2019. Contracts were sent to the Sponsors who are based overseas and fully signed contracts were not received until 07/07/2019	Sponsor
157948	15/SS/0225	169859	A randomised phase II trial of standard versus dose escalated radiotherapy in the treatment of pain in malignant pleural mesothelioma	No		213			28/01/2019	15/02/2019	05/10/2016	13/09/2019	16/09/2019	Please Select...	17/09/2019	A - Permissions delayed/denied D - Sponsor Delays F - No patients seen G - No patients consented	RTQQA delay, clarifications were sought for RECIST and ETC. SSD approvals had taken a few months awaiting all responses. Document version often did not match approvals. 3 wks pending final contract back from sponsor Patients eligibility depends on their pain scores and by the time they come to the radiotherapy team their pain scores have been managed. Not seen any patients that met the inclusion criteria	Both
157949	19/EE/0101	259240	INTERNATIONAL, MULTICENTER, RANDOMIZED, OPEN-LABEL, PHASE II CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF CONTINUATION OF PALBOCICLIB IN COMBINATION WITH SECOND-LINE ENDOCRINE THERAPY IN HORMONE RECEPTORPOSITIVE/ HER2-NEGATIVE ADVANCED BREAST CANCER PATIENTS	Yes	20/08/2019	145	27	172	28/02/2019	01/03/2019	11/06/2019	17/07/2019	24/07/2019	Please Select...	06/08/2019	A - Permissions delayed/denied D - Sponsor Delays	Received study application on 01/03/19 without HRA assessment/approval letter. The HRA approval was given on 11/06/19, and the final contract was sent to site on 03/07/19 to member of staff who was on annual leave, replied 11/07/19. The CCF was completed by the deadline on 31/05/19 the R&D department did not receive the CCF until 05/07/19 due to GM	Both

			WHO HAVE ACHIEVED CLINICAL BENEFIT DURING FIRST-LINE PALBOCICLIB-BASED TREATMENT														being on leave and further delay due to capacity. Site was opened by sponsor 2wks after issuing C&C.	
157950	18/LO/0555	237992	Preventing Ovarian Cancer through early Excision of Tubes and late Ovarian Removal	No		221			25/08/2018	04/03/2019	19/04/2018	25/08/2019	11/10/2019	Please Select...	17/10/2019	J - Other	Patients difficult to recruit due to the inclusion and exclusion criteria.	Neither
157951	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		C - Closed by sponsor	Received email from Pfizer informing sites of immediate discontinuation from 19Mar2019, Emailed our local contacts Brendan and Elizabeth and asked that they keep us informed of the next steps and to take to the sponsor our request for R&D and Pharmacy set-up fees	Both
157952	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	18/06/2019	75	8	83	30/10/2017	27/03/2019	25/03/2019		10/06/2019	Please Select...	17/06/2019			Please Select...
157953	19/EE/0130	252786	A Randomised, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Efficacy and Safety of Tislelizumab (BGB-A317) in Combination with Chemotherapy as First-Line Treatment in Patients with Unresectable, Locally Advanced Recurrent or Metastatic Oesophageal Squamous Cell Carcinoma	No		116			16/08/2018	28/03/2019	03/06/2019	10/07/2019	22/07/2019	Please Select...	03/09/2019	E - Staff availability issues G - No patients consented	Delays due to resources available during short-term sickness absence. Patients have been screened but not met the inclusion criteria.	NHS Provider
157954	19/YH/0027	249945	A Phase 3, randomized, blinded, placebo-controlled study of tislelizumab (BGB-A317) plus chemoradiotherapy followed by tislelizumab monotherapy in newly diagnosed, stage III subjects with locally	No					16/08/2018	10/04/2019				Sponsor declined site confirmation			Not all docs received. Sponsor terminated the trial 20/06/19 at all sites.	Please Select...

			advanced, unresectable non-small cell lung cancer															
157955	17/LO/0980	219505	Targeted therapy with or without dose intensified radiotherapy for oligo-progressive disease in oncogene-addicted lung tumours	No					20/05/2019	24/05/2019	10/07/2017			Please Select...		A - Permissions delayed/denied	16/12/19 Set up currently on hold. A lot of work has been undertaken with RQTTA, local feasibility, ARSAC and delivery of study. Study is being reviewed again by the radiotherapy clinicians and team to ensure site has capacity and capability to deliver the study safely. Radiotherapy services are delivered across two NHS Trust organisations.	NHS Provider
157956	19/LO/0989	259897	A multicentre randomised phase III trial comparing atezolizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment for advanced malignant pleural mesothelioma	Yes	04/11/2019	68	83	151	06/06/2019	06/06/2019	29/07/2019	17/06/2019	13/08/2019	Please Select...	07/10/2019	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	completed local feasibility however had 4 weeks pending for regulatory approvals. 2 weeks additional to obtain IRMER approval had been omitted at initial feasibility review. Two main reasons are PI on annual leave and coordinating times and dates with the sponsor arranging SIV. Once green light was issued and the site was open to recruitment the 1st patient was recruited in 8 days.	Both
157957	19/NW/0155	255226	A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement	No		37			14/08/2018	09/07/2019	30/05/2019	31/07/2019	15/08/2019	Please Select...	16/09/2019	A - Permissions delayed/denied E - Staff availability issues G - No patients consented	Study was submitted to REC but initial planned meeting 14/03/19 was not quorate and meeting was rescheduled for 11/04/19. There was a substantial number of queries that were sent to the sponsor to clarify. CCF delay additional days given for review due to service support departments being on annual leave. 2 patients were screened immediately after the study was opened but were ineligible. No further patients have been seen.	Both
157958	18/NS/0145	254786	A NON-INTERVENTIONAL, MULTICENTER, MULTIPLE COHORT STUDY INVESTIGATING THE OUTCOMES AND SAFETY OF	No		46			18/07/2019	18/07/2019	07/02/2019	23/08/2019	02/09/2019	Please Select...	09/10/2019	H - Contracting delays	Study was approved 46 days of receiving local pack. The patient pathway has changed since the opening of the study and re-negotiation of the	NHS Provider

			ATEZOLIZUMAB UNDER REAL-WORLD CONDITIONS IN PATIENTS TREATED IN ROUTINE CLINICAL PRACTICE														potential recruitment numbers is being considered.	
157959	19/LO/1270	261294	CRAFT: Cerclarge after full dilatation caesarean section; an investigation into the role of previous in labour caesarean section in future preterm birth risk and potential management strategies	Yes	24/12/2019	75	56	131	15/08/2019	15/08/2019	20/09/2019	18/11/2019	29/10/2019	Please Select...	18/11/2019	A - Permissions delayed/denied H - Contracting delays	Site set up delayed due to no funding for trial and procedure not being part of standard care. Only opening observational arm though this may change in the futureDocuments amended for final REC approval received 21/10/19	Both
157960	16/YH/0157	204585	PLATO - PersonaLising Anal cancer radioTherapy dOse - Incorporating Anal Cancer Trials (ACT) ACT3, ACT4 and ACT5	No		78			06/09/2018	21/08/2019	20/07/2016	12/11/2019	07/11/2019	Please Select...	05/12/2019	D - Sponsor Delays F - No patients seen	Delayed due to drug supply issues. Team is reliant on PI referring patients so will bring up again with him.	Sponsor
157961	17/NW/0634	209375	A randomized double blind placebo controlled Phase II clinical trial of Cediranib and Olaparib maintenance in advanced recurrent Cervical Cancer.	No					04/09/2019	05/09/2019	16/01/2018			Please Select...		E - Staff availability issues	21/01/2020 Feasibility completed, ready to be approved	NHS Provider
157962	19/LO/1408	253964	A Phase 2, Open-Label, Single-Arm Study to Evaluate the Efficacy and Safety of Camidanlumab Tesirine (ADCT-301) in Patients with Relapsed or Refractory Hodgkin Lymphoma	No					19/03/2019	18/09/2019	19/11/2019			Please Select...		E - Staff availability issues	Delay of site reviewing the costs and responding to the sponsor with comments/feedback due to staff annual leave and capacity.	NHS Provider
157963	19/ES/0100	261027	A Phase 3, Double-Blind, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE)	No						24/09/2019				Please Select...			Delaying approval as patients must complete 52 weeks of BRAVE-JAHZ before recruitment. The earliest date we can recruit is 29AUG20, assuming that patient completes trial treatment.	Please Select...
157964	19/LO/0452	250324	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						08/10/2019	02/05/2019			Please Select...				Please Select...
157965	18/SC/0242	238151	A phase III randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients.	Yes	11/02/2019	32	-274	-242	07/10/2019	11/10/2019	24/08/2018	11/11/2019	12/11/2019	Please Select...	15/11/2019			Please Select...
157966	19/LO/0236	230338	The Effect of Higher Protein Dosing in Critically Ill Patients: A	Yes	22/01/2020	39	41	80	24/09/2019	03/11/2019	01/07/2019	02/12/2019	12/12/2019	Please Select...	19/12/2019	E - Staff availability issues	Dietician team are covering long term sickness for clinical	NHS Provider

			Multicenter Registry-based Randomized Trial - The EFFORT Trial														work, research consenting is additional workload. Currently seeking agreement from CI as to whether the research nurse can consent patients with oversight/input from dietician.	
157967	19/LO/1357	269456	A PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED STUDY OF IPATASERTIB IN COMBINATION WITH ATEZOLIZUMAB AND PACLITAXEL AS A TREATMENT FOR PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC TRIPLE-NEGATIVE BREAST CANCER	No					11/07/2019	19/11/2019	21/12/2019			Please Select...		A - Permissions delayed/denied	HRA approval received 03Jan2020	Neither

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