

Q2 2019-20

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Submission

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Submission Details	
Status	Accepted
Open Date	01/10/2019
Deadline Date	30/10/2019
Date Submitted	30/10/2019
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:
151134	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...
151135	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	Yes	24/10/2019	117	94	211	16/08/2018	27/03/2019	03/06/2019	10/07/2019	22/07/2019	Please Select...	03/09/2019		Study Approved, feasibility now complete.	Please Select...
151136	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...
151137	15/SS/0225	169859	SYSTEMS-2 A randomised	No						15/02/2019		15/02/2019		Please			In set up/ETC	Please

			phase II trial of standard versus dose escalated radiotherapy in the treatment of pain in malignant pleural mesothelioma									Select...			currently being identified and agreed.	Select...		
151138	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													The sponsor have withdrawn this project from being undertaken at all sites.	Please Select...
151139	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	Yes	20/06/2019		169		13/11/2018	02/01/2019							In Set Up, governance checks being finalised.	Please Select...
151140	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	07/01/2019	06/06/2019	Please Select...	17/06/2019	H - Contracting delays	Study approved, delays were caused due to the Sponsor wishing to update the GDPR in the previous contract.	Sponsor
151141	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...
151142	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						Delay in the study set up which related to pathology. This study also conflicts with KEYNOTE 522	Please Select...
151143	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	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...

			medial epicondyle fractures of the humerus in children.															
151318	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	06/02/2019	14/06/2019	Please Select...	27/08/2019		Study Approved	Please Select...
151319	19/EE/0101	259240	PALbociclib rechallenge in hormone receptor-positive/HER2-negative Advanced breast cancer	Yes	20/08/2019	145	27	172	28/02/2019	01/03/2019	27/06/2019	17/07/2019	24/07/2019	Please Select...	06/08/2019		Study Approved	Please Select...
151568	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 advanced, unresectable non-small cell lung cancer	No					16/08/2018	10/04/2019	02/04/2019			Sponsor declined site confirmation			Sponsor discontinued pursuing study set up in the UK due to the study drug ownership being transferred to another pharmaceutical organisation.	Please Select...
151828	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 D - Sponsor Delays	Study approved. Regulatory approval was delayed, additional delays were related to the feasibility sign off on site.	NHS Provider
152058	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	02/07/2019		Please Select...			Study in set up, feasibility is currently being prepared.	Please Select...
152070	18/NS/0145	254786	A NON-INTERVENTIONAL, MULTICENTER, MULTIPLE COHORT STUDY INVESTIGATING THE OUTCOMES AND SAFETY OF ATEZOLIZUMAB UNDER REAL-WORLD CONDITIONS IN PATIENTS TREATED IN ROUTINE CLINICAL PRACTICE	No		46			18/07/2019	18/07/2019	07/02/2019	23/08/2019	02/09/2019	Please Select...				Please Select...
152071	16/YH/0157	204585	PLATO - Personalising Anal cancer radiotherapy dose - Incorporating Anal Cancer Trials (ACT) ACT3, ACT4 and ACT5	No					06/09/2018	21/08/2019	20/07/2016	06/09/2019		Please Select...			Study in the final set up stages, feasibility complete, contracts currently being in the process of being signed.	Please Select...

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