Version 1.0.3

Submission

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Submission Details	
Status	Accepted
Open Date	03/07/2017
Deadline Date	28/07/2017
Date Submitted	21/07/2017
Type	Performance in Initiating
NHS provider	Maidstone and Tunbridge Wells NHS Trust

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Format dd/mm/yyyy.

Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Patient Recruited?	Date of First Patient Recruited	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	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	Reasons for Delay	Comments	Reasons for delay correspo to:
104314	16/EM/0165	203281	AP26113-13-301 A phase 3 multicentre open-label study of Brigatinib (AP26113) versus Crizotinib in patients with ALK-positive advanced lung cancer	Yes	19/07/2017	108	258	366	No	18/04/2016	18/07/2016	10/06/2016	25/10/2016	03/11/2016	Please Select...	10/11/2016	A - Permissions delayed/denied D - Sponsor Delays	Delay by both parties in responding to finance queries. IRMER identified error in the PIS which had to be revised and submitted to the HRA as an amendment.	Both
104315	16/SC/0351	205155	GO30182 - A Phase III, open-label, multicentre, theree-arm, randomized study to investigate the efficacy and safety of cobimetinib plus atezolizumab and atezolizumab monotherapy vs regorafenib in patients with previously treated unresectable locally advan	No		67			No	15/06/2016	23/09/2016	31/08/2016	11/11/2016	29/11/2016	Please Select...	02/12/2016	A - Permissions delayed/denied C - Closed by sponsor D - Sponsor Delays E - Staff availability issues	Complex study with multi arm costing review, multi SSDs and funding of cellular patholgy work issues	Both
104316	16/LO/1069	200813	PALLAS PALbociclib CoLlaborative Adjuvant Study: A randomised phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human	Yes	08/06/2017	247	78	325	No	16/03/2016	18/07/2016	06/09/2016	07/12/2016	22/03/2017	Please Select...	24/03/2017	A - Permissions delayed/denied E - Staff availability issues	Delays with set-up due to staff shortages within oncology team. Also long delays obtaining SSD support confirmation. To date 90 patients have been screened who were ineligible	NHS Provider

			epidermal growth factor rec																
104317	16/LO/1083	202073	Quantum First:A phase 3, double-blind, placebo-controlled study of Quizartinib (AC220) administered in combination with induction and consolidation chemotherapy, and administered as maintenance therapy in subjects 18 to 75 years old with newly diagnosed F	Yes	14/07/2017	111	170	281	No	06/10/2016	06/10/2016	22/09/2016	11/01/2017	25/01/2017	Please Select...	17/03/2017	A - Permissions delayed/denied E - Staff availability issues	Delays in delivery team due to staff shortages. Also long delays obtaining SSD approvals. Pharmacy Green Light received 16.3.17	NHS Provider
104318	16/EM/0332	205699	MAXIMISE: Managing axial manifestations in psor;atic arthritis with secukinaumab, a randomised,double-blind, placebo-controlled, multicentre, 52 week study to assess the efficacy and safety of Secukinumab 150mg or 300mg s.c. in patients with active psoria	No		87			No	05/08/2016	21/10/2016	17/10/2016	06/12/2016	16/01/2017	Please Select...	05/04/2017	A - Permissions delayed/denied D - Sponsor Delays	3 weeks delay from receiving sponsor's agreement to proposed costs. Delay in obtaining CD signature. Delay in obtaining biochemistry support. Delay in receiving Drug from sponsor. Pharmacy greenlighted 05/04/17. 0 patients recruited - one too unwell	Both
104319	16/LO/1983	209521	EPOP2: Peri-operative isometric exercise programme: Basic Exercise Training to Enhance Recovery:- Evaluation of the feasibility of a perioperative isometric-resistance exercise intervention programme for patients undergoing elective abdominal surgery for	Yes	20/04/2017	3	38	41	Yes	07/06/2016	10/03/2017	09/03/2017	07/06/2017	13/03/2017	Please Select...	01/04/2017			Please Select...
104320	12/WA/0230	104136	The ROCs Trial: Radiotherapy After Oesophageal Cancer Stenting	No		247			No	11/02/2016	06/07/2016	15/06/2016	14/02/2017	10/03/2017	Please Select...	26/04/2017	A - Permissions delayed/denied E - Staff availability issues H - Contracting delays	Delays with radiotherapy department agreeing to funding and appointment of new staff member to carry out home visits. Also TFF delays with radiotherapy. CTA leaving post and lack of capacity within KOC research team also contiributed to set-up delays.	NHS Provider
104695	16/WM/0010	169512	PePS2 A phase II trial of pembrolizumab in patients with non-small cell lung cancer and a performance status of 2	Yes	17/05/2017	183	106	289	No	01/08/2016	01/08/2016	26/06/2016	02/12/2016	31/01/2017	Please Select...	16/03/2017	A - Permissions delayed/denied	TFF authorisations, approved study on 31/01/17 and the SIV was booked on 23/02/17. We then awaiting signatures on delegation log and pharmacy prescription which was received on	NHS Provider

																		15/03/17. 1st pt randomised in May, no other suitable patients presenting in clinic	
104696	16/NW/0517	188554	ACCoRD Myeloma XII A phase III study to determine the role of ixazomib as an augmented conditioning therapy in salvage autologous stem cell transplant (ASCT) and as a post-ASCT consolidation and maintenance strategy in patients with relapsed multiple myeloma	No		239			No	29/07/2016	27/10/2016	27/10/2016	17/11/2016	23/06/2017	Please Select...	11/07/2017	A - Permissions delayed/denied E - Staff availability issues	Signing of Contract did take 82 days as delay to get PI signature took 21 days. The feasibillity was delayed due to staff sickness/availability and a further delay in ensuring UCL/KCH sites able to provide bone marrow transplants for study patients. No suitable patients screened yet.	NHS Provider
104697	16/LO/1717	212505	ACE-CL-309 A randomised, multicentre, open-label, phase 3 study of Acalabrutinib (ACP-196) versus Investigator's choice of either Idelalisib plus Rituximab or Bendamustine plus Rituximab in subjects with relapsed or refactory chomic lymphocytic leukemia	No		176			No	02/08/2016	08/11/2016	07/11/2016	18/04/2017	03/05/2017	Please Select...	17/05/2017	A - Permissions delayed/denied D - Sponsor Delays	Contract was re-issued due to Amendment to study submitted whilst undertaking feasibility. Contract was pending sponsor signature (22 days). Costings negotiation and time to receive confirmations back. 2 patients screened 1 June 1 July, both ineligible	Both
104698	16/SC/0109	163094	UKSTAR: UK Study of tendo Achilles Rehabilitation – multicentre randomised clinical trial	Yes	05/04/2017	70	68	138	No	18/11/2016	18/11/2016	25/07/2016	14/01/2017	27/01/2017	Please Select...	30/01/2017	A - Permissions delayed/denied D - Sponsor Delays J - Other	Site not approved by HRA until 05/01/17. TFF not received by R&D until 13/01/17. number of patients have been screened but have not met the inclusion criteria	Both
104699	16/EE/0463	214371	CompLEEment-1 An open-label multicentre phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment ofmen and postmenopausal women with hormone receptorship (HR+) HER2-negative (HER2-) advanced breastcancer (aBC) with no prior hormonal therapy for advance disease	Yes	01/05/2017	131	28	159	No	24/10/2016	23/11/2016	30/01/2017	24/03/2017	03/04/2017	Please Select...	26/04/2017	A - Permissions delayed/denied	Delay in negotiating costs and obtaining ARSAC.	NHS Provider
104700	16/LO/1461	210300	STARflo Glaucoma Implant Clinical Experience Program in a Real-World Patient Population	Yes	26/03/2017	9	52	61	Yes	25/07/2016	24/01/2017	14/10/2016	25/07/2016	02/02/2017	Please Select...	25/02/2017			Please Select...
																		Delays obtaining feasibility and SSD. Capacity with KOC	

104701	14/LO/0801	137312	IMPRESS - Improving radical treatment through MRI evaluation of pelvic sigmoid cancers	No		62			No	08/02/2017	09/02/2017	15/06/2016	24/02/2017	12/04/2017	Please Select...	27/04/2017	A - Permissions delayed/denied E - Staff availability issues	research team also contributed to delays in set-up and providing R&D with TFF. 1 patient in screening July, first patient suitable since study opened.	NHS Provider
104702	16/LO/0880	205661	CREDO 2 - A randomised, double blind, parallel-group, placebo and active controlled, multicentre phase III study of the efficacy and safety of Olokizumab in subjects with moderately to severe active Rhumatoid Arthritis inadequatly controlled by Methotrexate therapy. Protocol CL04041023	No		55			No	04/07/2016	01/03/2017	21/02/2017	27/03/2017	25/04/2017	Please Select...	21/06/2017	D - Sponsor Delays	Contract was re-issued by Sponsor causing delay in confirming approval, also amendment was submitted late on in the process of reviewing feasibility. 1 patient screened in June but ineligible	Sponsor

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