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Submission Details	
Status	Accepted
Open Date	01/01/2018
Deadline Date	30/01/2018
Date Submitted	26/01/2018
Type	Performance in Initiating
NHS provider	Maldstone and Tunbridge Wells NHS Trust

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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 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 correspond to:
115240	16/L.O/1983	209521	EPOP2: Peri-operative isometric exercise programme: Basic Exercise Training to Enhance Recovery:- Evaluation of the feasibility of a peroperative isometric-resistance exercise intervention programme for patients undergoing elective abdominal surgery for	Yes	20/04/2017	38	41	41	Yes	07/06/2016	10/03/2017	09/03/2017	07/06/2017	13/03/2017	Please Select...	01/04/2017			Please Select...
115241	16/L.O/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			Neither
115242	16/L.O/0880	205661	CREDO 2 - A randomised, double blind, parallel-group, placebo and active controlled, multicentre phase III study of the efficacy and safety of Ciockzumab in subjects with moderately to severe active Rheumatoid Arthritis inadequately controlled by Methotrexate therapy. Protocol CL0404.1023	No	55				No	04/07/2016	01/03/2017	21/02/2017	27/03/2017	25/04/2017	Please Select...	21/06/2017	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	Contract was re-issued by Sponsor causing delay in confirming approval, also amendment was submitted late on in the process of reviewing feasibility. 1 June but ineligible patient screened in 11/10/17 further patient screened 3/8/17 but failed - no other pts so far who fit criteria 25/01/18 still no patients due to tight inclusion criteria	Both

115243	16/L/O/2010	212178	The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle	Yes	04/01/2018	218	124	342	No	22/09/2016	27/01/2017	25/01/2017	18/04/2017	02/09/2017	Please Select...	19/12/2017	A - Permissions delayed/denied D - Sponsor Delays	Delays due to complex study design and introduction of AMBER CARE into the service. Also delays with sponsor due to amendments to protocol and change to CI. Also staff capacity issues with research team due to a number of key staff leaving the department. 12/10/17 although C&C letter issued, site not activated to recruitment by sponsor - expedited Dec 17	Both
115244	16/W/S/0197	186191	ATLANTIS An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urothelial cancer	No		152			No	03/02/2017	03/02/2017	01/02/2017	08/06/2017	05/07/2017	Please Select...	25/07/2017	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues H - Contracting delays	TFE completion, contract delays. 11/10/17 - 3 patients screened 2 of which have signed a pre-screening consent and waiting biomarker results to confirm eligibility for randomisation. 25/01/18 3 patients have been in pre-screen but non eligible for recruiting to date	Both
115245	16/L/O/1106	207909	A randomised double blind phase III study of Pembrolizumab (MK3475) plus Chemotherapy vs Placebo plus Chemotherapy for previously untreated inoperable locally recurrent or metastatic triple negative breast cancer (keynote 355)	No		179			Site Not Confirmed	31/01/2017	17/02/2017	15/08/2016	24/07/2017	15/08/2017	Site declined to participate		A - Permissions delayed/denied E - Staff availability issues	Although C&C confirmed, study was not activated by oncology research team or sponsor due to capacity issues in the research team. R&D notified 25/1/18 that decision taken not to open study now as due to close to recruitment soon	Both
115246	16/SC/0271	187103	"PlasmaMATCH The UK plasma based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) Trial: A multiple parallel cohort, open-label, multi-centre phase IIa clinical trial aiming to provide proof of principle efficacy for designated targeted therapies in patients with advanced breast cancer where the targetable mutation is identified through cDNA screening"	No					No	09/02/2017	27/02/2017	21/09/2016			Please Select...		A - Permissions delayed/denied E - Staff availability issues	In set up - Breast team is not at fully capacity. Delays in setting up and undertaking feasibility. 13/12/17 Spoke with TS regarding set-up of study and she confirmed that TFE would not be looked at until into the new year Jan 18. She will be meeting with CH-W to discuss priority of trials and will let us know the outcome of meeting. 25/01/18 No further update from TS regarding set up of study.	NHS Provider
																		Delays due to ARSAC application, amendment to protocol	

115247	17/LO/0441	222471	KEYNOTE-604 MK-3475: A phase III randomised double-blind placebo-controlled trial of pembrolizumab (MK-3475) in combination with etoposide/platinum (Cisplatin or Carboplatin) for the first-line treatment of subjects with extensive stage small cell lung cancer	No	128																																																		
115248	16/LO/0592	179775	IDRIS Phase III randomised trial of immunomodulatory therapy in high risk solitary bone plasmacytoma	No																																																			
115249	17/LO/0427	199962	N3 A phase Ib/II trial of combination Nab-paclitaxel and Niraparib or Nab-paclitaxel and placebo in relapsed NSCLC adenocarcinoma	No																																																			
115250	16/LO/0998	192968	INGENZA - A diagnostic accuracy study to evaluate point of Care lipase/pH test strip to confirm correct nasogastric position	Yes	09/11/2017	174	43	217	No	06/04/2017	06/04/2017	27/10/2016	19/04/2017	27/09/2017		Please Select...	31/10/2017	A - Permissions delayed/denied D - Sponsor E - Staff availability issues	Delays due to staff capacity in office and TFF completion. Study not prioritised due to study centre advising (25/08/17) that test strips not currently available and therefore not commencing with new sites until resolved. Site visit planned for August did not go ahead. Continued with governance and approval issued. TFF received 18/08/17. No patients recruited as of 11/10/17 as study/centre only received strips 10/10/17 and are in process of organising an SIV which is expected to be soon	Both																																			
			KEYNOTE 522 - A Phase III randomized double blind study to evaluate Pembrolizumab plus															A - Permissions delayed/denied	Delays with study set-up due to both parties. Local SSD delays and agreeing costs. Contract delays as sponsor IT systems affected by cybersecurity incident which has hindered the progression of the contracts therefore																																				

115251	17/LO/0347	221524	Chemotherapy vs Placebo plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)	No	127					No	22/12/2016	10/04/2017	05/05/2017	20/07/2017	15/08/2017	Please Select...		D - Sponsor Delays E - Staff availability issues H - Contracting delays	study not progressed for at least a month. Also staff capacity issued in KOC contributed to delays in processing paperwork and obtaining local confirmation of support. Study approved by R&D, 25/01/18 Study not activated for recruitment as yet due to staff issues/capacity in K	Both
115252	16/SC/0462	208830	DRAFT 2 Distal radius acute fracture fixation trial. A randomised controlled trial of manipulation and surgical fixation with K-wires versus manipulation and casting in the treatment of adult patients with a dorsally displaced fracture of the distal radius	Yes	20/12/2017 90	146	236	No	26/04/2017	26/04/2017	11/11/2016	26/05/2017	27/07/2017	14/09/2017	Please Select...		A - Permissions delayed/denied	PI delay in attending GCP training. Seeking agreement from orthopaedic consultant colleagues. 11/10/17 no patients recruited referrals from doctors not coming through at present	NHS Provider	
115253	16/SC/0655	212212	KREBS - A Randomised Controlled Trial of the effect of a two-layer compression bandage system on knee function following Total Knee Arthroplasty	Yes	17/11/2017 111	64	175	No	26/05/2017	26/05/2017	08/02/2017	26/06/2017	14/09/2017	Please Select...		A - Permissions delayed/denied	Delay in receiving TFF (rev'd R&D 11/09/17) due to availability of staff. SSD support - sourcing and purchasing of bandages and holiday period. 11/10/17 no patients recruited to date, T&O waiting lists is so long it is causing problems with screening pts - currently being addressed with the pre assessment unit.	NHS Provider		
115254	16/LO/0585	188869	NeoART Phase II randomised double blind placebo controlled trial of neoadjuvant artesunate in stage III/IIII colorectal cancer	Yes	05/12/2017 124	60	184	No	20/03/2017	04/06/2017	15/09/2016	12/06/2017	06/10/2017	Please Select...		A - Permissions delayed/denied D - Sponsor Delays	Amendment submitted whilst undertaking C&C which needed to be considered as part of set-up. 11/10/17 No patients recruited, site not yet opened to recruitment	Both		
115255	16/LO/1502	178292	*CTC-STOP: Utilising Circulating Tumour Cell (CTC) Counts to Optimize Systemic Therapy of Metastatic Prostate Cancer*	No				No	23/05/2017	23/06/2017	07/10/2016			Please Select...		A - Permissions delayed/denied E - Staff availability issues	In set-up - Resources, staff capacity 25/01/18	NHS Provider		
115256	17/LO/0957	226146	CREDO 4 A Multicenter, Open-Label, Phase III Study of the Efficacy and Safety of Olaparib in Subjects with Moderately to	No				No	06/07/2017	06/07/2017	12/07/2017			Please Select...		A - Permissions delayed/denied	In set-up - Delays in obtaining TFF authorisation signatures. 25/01/18 not prioritised by research team as CREDO 2 has no patients recruited as	NHS Provider		

			subjects with active sigmoid's syndrome																		signatures25/01/18 no recruitment as yet due to tight exclusion criteria	
115263	16/W/0165	190574	ADSCAN: A Randomised Phase II study of Accelerated, Dose Escalated, Sequential Chemoradiotherapy in Non-Small Cell Lung Cancer	No							06/03/2017	15/06/2017	13/02/2017		Please Select...		A - Permissions delayed/denied D - Sponsor Delays	the completion of the schedule of events in particular attribution of CT scans, also fields completed incorrectly - as of 30/6 email received from SC to say that they are investigating with the sponsor, as of 11/10/17 no further update or responses received. .25/01/18 No further communication	Both			
115315	14/L/O/0801	137312	IMPRESS - Improving radical treatment through MRI evaluation of pelvic sigmoid cancers	Yes		21/09/2017	62	162	224	No	08/02/2017	09/02/2017	15/06/2016	24/02/2017	12/04/2017	Please Select...	A - Permissions delayed/denied E - Staff availability issues	Delays obtaining feasibility and SSD. Capacity with KOC 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. First patient recruited 21/9/17. 2 screened previous to this but due to logistics and tight time frames unable to recruit.	NHS Provider			

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