Version 1.0.3

Submission

Home > Submission

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Submission Details	
Status	Accepted
Open Date	02/10/2017
Deadline Date	30/10/2017
Date Submitted	12/10/2017
Type	Performance in Initiating
NHS provider	Maidstone and Tunbridge Wells NHS Trust

Showing records 1 to 25 of 28.
Pages: 1 2 Next >

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:
107725	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 16.3.172pts screened failed in June. 1st patient recruited in July	NHS Provider
107726	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	Yes	14/09/2017	87	241	328	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 11/10 First patient recruited 14/9/17, 2nd pt recruited 12/10 and 3 patients screened in total	Both
			EPOP2: Peri-operative isometric exercise programme: Basic																

107727	16/LO/1983	209521	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...
107728	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.11/10/17 no patients recruited, no eligible patients seen	NHS Provider
107729	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 chornic 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 11/10/17 no patients recruited, no eligible patients seen	Both
107732	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			Neither
108026	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	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 patient screened in June but ineligible 11/10/17 further patient screened 3/8/17 but failed - no other pts so far who fit criteria	Sponsor
																		Delays due to	

108027	16/LO/2010	212178	The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle	No		218			No	22/09/2016	27/01/2017	25/01/2017	18/04/2017	02/09/2017	Please Select...		A - Permissions delayed/denied D - Sponsor Delays	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 actiivated to recruitment by sponsor - expected Dec 17	Both
108028	16/WS/0197	186191	ATLANTIS An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urotherlial 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 E - Staff availability issues H - Contracting delays	TFF completion, contract delays. 11/101/7 - 3 patients screened 2 of which have signed a pre-screening consent and waiting biomarker results to confirm eligibility for randomisation.	Both
108029	16/LO/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			No	31/01/2017	17/02/2017	15/08/2016	24/07/2017	15/08/2017	Please Select...		A - Permissions delayed/denied E - Staff availability issues	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 study not progressed for at least a month. Also staff capacity issues in KOC contributed to delays in processing paperwork and obtaining local confirmation of support. Delays in pharmacy due to IMP and waiting decision as to which study would be prioritised (522 or 355)	Both
			"PlasmaMATCH The UK plasma based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) Trial: A multiple parallel														A -	In set up - Breast	

108030	16/SC/0271	187103	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 ctDNA screening"	No					No	09/02/2017	27/02/2017	21/09/2016			Please Select...		Permissions delayed/denied D - Sponsor Delays	team is not at fully capacity. Delays in setting up and undertaking feasibility.	NHS Provider
108031	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 Caboplatin) for the first-line treatment of subjects with extensive stage small cell lung cancer	No		128			No	26/01/2017	21/03/2017	08/05/2017	20/07/2017	27/07/2017	Please Select...	13/09/2017	A - Permissions delayed/denied E - Staff availability issues	Delays due to ARSAC application, amendment to protocol and 2nd costing template to review. Signed Contract back from Sponsor, Service support departments agreement from biochemistry. Sponsor delay in providing final Agreements for Trust signature. Pharmacy Green Light Received 13.09.17. As of 11/10/17 no patients recruited despite screening, PI has commnented that no pts have not been fit enough to go on study.	Both
108032	16/LO/0592	179775	IDRIS Phase III randomised trial of immunomodulatory therapy in high risk solitary bone plasmacytoma	No					No	31/03/2017	31/03/2017	09/08/2016			Please Select...		A - Permissions delayed/denied E - Staff availability issues	In set -up - Staff resources	NHS Provider
108033	17/LO/0427	199962	N3 A phase Ib/II trial of combination Nab-paclitaxel and Nintedanib or Nab-paclitaxel and placebo in relapsed NSCLC adencarcinoma	No					No	22/03/2017	03/04/2017	30/06/2017			Please Select...		A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	In set -up Staff resources - delay in reviewing costs with local study team availability	Both
108034	16/LO/0998	192968	INGENZA - A diagnostic accuracy study to evaluate point of Care lipase/pH test strip to confirm correct nasogastric position	No		174			No	06/04/2017	06/04/2017	27/10/2016	19/04/2017	27/09/2017	Please Select...		A - Permissions delayed/denied E - Staff availability issues H - Contracting delays	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.	Both

																		TFF received 18/08/17. No patients recruited as of 11/10/17 as studycentre only received strips 10/10/17 and are in process of organising an SIV which is expected to be in the up	
108035	17/LO/0347	221524	KEYNOTE 522 - A Phase III randomized double lind study to evaluate Pembrolizumab plus 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...		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 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, however due to capacity issued within KOC, study will be opened and then suspended to re	Both
108036	16/SC/0462	208830	DRAFFT 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	No		90			No	26/04/2017	28/04/2017	11/11/2016	26/05/2017	27/07/2017	Please Select...	14/09/2017	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
108037	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	No		111			No	26/05/2017	26/05/2017	08/02/2017	26/06/2017	14/09/2017	Please Select...	29/09/2017	A - Permissions delayed/denied D - Sponsor Delays	Delay in receiving TFF (recv'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 -	NHS Provider

																		currently being addressed with the pre assessment unit.	
108038	16/LO/0585	188869	NeoART Phase II randomised double blind placebo controlled trial of neoadjuvant artesunate in stage II/III colorectal cancer	No		124			No	20/03/2017	04/06/2017	15/09/2016	12/06/2017	06/10/2017	Please Select...		A - Permissions delayed/denied E - Staff availability issues	Amendment submitted whilst undertaking C&C which needed to considered as part of set-up. 11/10/17 No patients recruited, site not yet opened to recruitment	Both
108039	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	In set-up - Resources, staff capacity	NHS Provider
108040	17/LO/0957	226146	CREDO 4 A Multicenter, Open-Label, Phase III Study of the Efficacy and Safety of Olokizumab in Subjects with Moderately to Severely Active Rheumatoid Arthritis.	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	NHS Provider
108041	16/WM/0268	202984	PRODUCT: What after the first propess. A comparative prospective study	No					Site Not Confirmed	05/06/2017	06/07/2017	08/09/2016			Site declined to participate			Number of meetings held with local consultants to obtain decision to take part. Final decision was made not to participate in the study.	Neither
108042	17/SC/0231	221097	ETOP 9-15 PROMISE-meso A multicentre randomised phase III trial comparing pembrolizumab versus standard chemotherapy for advanced pre-treated malignant pleural mesothelioma	Yes	27/09/2017	35	42	77	No	31/03/2017	12/07/2017	27/06/2017	12/07/2017	16/08/2017	Please Select...	01/09/2017	A - Permissions delayed/denied	11/10/17 - First patient recruited 27/9/17 and another 3 pts possibly eleigible and under review	Neither
108043	17/NE/0149	224550	A randomised double-blind placebo-controlled phase 3 study of rovalpituzumab tesirine as maintenance therapy following first-line platinum-based chemotherapy in subjects with extensive stage small cell lung cancer - MERU M16-298	No					Within 70 Days	08/05/2017	31/07/2017	19/06/2017			Please Select...		A - Permissions delayed/denied E - Staff availability issues	In set-up/Delay in obtaining feasiblility approval, staff resources and capacity of team	NHS Provider
108044	17/NW/0351	224954	TITAN RCC A phase II single arm clinical trial of a Tailored ImmunoTherapy Approach with Nivolumab in subjects with metastatic or advanced Renal Cell Carcinoma	No					Within 70 Days	22/05/2017	03/08/2017	03/08/2017			Please Select...		A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	In set-up/Staffing and resources. Amendment submitted during C&C which impacts on local study documents and updated protocol version	NHS Provider

Showing records 1 to 25 of 28.
Pages: 1 2 Next >

< Back