Version 1.0.3

Submission
Home > Submission

You can use the options below to view your submission. Where appropriate you can also add to and update your submission and send the details for approval.

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

Showing records 1 to 25 of 32. Pages: 1 2 Next >

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115242	115241	115240	ld
115242 16/LO/0880	115241 16/LO/1461	115240 16/LO/1983	Research Ethics Committee Reference Number
205661	210300	209521	Integrated Research Application System Number
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	STARflo Glaucoma Implant Clinical Experience Program in a Real-World Patient Population	EPOP2: Penoperative isometric exercise programme: Basic Exercise Training to Enhance Recovery: Evaluation of the feasibility of a perioperative isometric-resistance exercise intervention programme for pogramme for patients undergoing elective abdominal surgery for	Integrated Research Application Name of Trial System Number
8	Yes	Yes	First Patient Recruited?
	26/03/2017 9	20/04/2017	Date of First Patient Recruited
<b>8</b>		ω	Duration between Date Site Selected and Date Site Confirmed
	52	38	Duration between Date Site Confirmed and First Patient Recruited
	61	41	Duration between Date Site Selected and First Patient Recruited
Z o	Yes	Yes	Benchmark Date Site Met Invited
04/07/2016	25/07/2016 24/01	07/06/2016	k Date Site Invited
04/07/2016 01/03/2017 21/02/2017 27/03/2017 25/04/2017 Select	24/01/2017	07/06/2016 10/03/2017 09/03/2017 07/06/2017 13/03/2017 Please	Date Site Selected
21/02/2017	/2017 14/10/2016 25/07/2016 02/02/2017	09/03/2017	HRA Approval Date
27/03/2017	25/07/2016	07/06/2017	Date Site Confirmed By Sponsor
25/04/2017	02/02/2017	13/03/2017	Date Site Confirmed
Select	Please Select	Please Select	Non- Date Site Confirmation Ready To Status Start
21/06/2017	25/02/2017	01/04/2017	
A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	-		Reasons for Delay
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 25/01/18 still no patients due to tight inclusion criteria			Comments
Both	Neither	Please Select	Reasons for delay correspon

	115246	115245	115244	115243	
	16/SC/0271	115245 16/LO/1106	115244 16/WS/0197 186191	115243 16/LO/2010	
	187103	207909	186191	212178	
	"PlasmaMATCH The UK plasma based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) Trial: A multiple parallel cohort, openlabel, multi-centre phase II a clinical trial aiming to provide proof of principle efficacy for designated trageted therapies in patients with advanced breast cancer where the targetable mutation is identified through ctDNA screening"	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)	ATLANTIS An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urotherial cancer	The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle	
	Zo	No	No	Yes	
			4	04/01/2018 2	
		179	152	218	
				124	
				342	
	Z <sub>o</sub>	Site Not Confirmed	N <sub>o</sub>	N <sub>o</sub>	
	09/02/2017 27/02/2017 21/09/2016	31/01/2017	03/02/2017	22/09/2016	
	27/02/2017	17/02/2017	03/02/2017	27/01/2017	
	21/09/2016	2017 15/08/2016 24/07/2017 15/08/2017	03/02/2017 03/02/2017 01/02/2017 08/06/2017 05/07/2017 Please	22/09/2016 27/01/2017 25/01/2017 18/04/2017 02/09/2017	
		24/07/2017	08/06/2017	18/04/2017	
		15/08/2017	05/07/2017	02/09/2017	
	Please Select	Site declined to participate	Please Select	Please Select	
			25/07/2017	19/12/2017	
	A - Permissions delayed/denied E - Staff availability issues	A - Permissions delayed/denied E - Staff availability issues	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues H - Contracting delays	A - Permissions 19/12/2017 delayed/denied D - Sponsor Delays	
Delays due to ARSAC application, amendment to protocol	in set up - Breast team is not at fully capacity. Delays in setting up and undertaking feasibility 13/12/17 Spoke with TS Spoke with TS study and she confirmed that TFF 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.	Although C&C confirmed, study was not activated by noncology research 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	TFF completion, contract delays. 11/101/7 - 3 patients screened 2 of which have signed a prescreening 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	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 expected Dec 17	
	NHS Provider	Both	Both	Both	

	115250	115249	115248	115247
	16/LO/0998	17/LO/0427	16/LO/0592	17/LO/0441
<u>'</u>	192968	199962	179775	222471
KEYNOTE 522 - A Phase III randomized double lind study to evaluate Pembrolizumab plus	INGENZA - A diagnostic accuracy study to evaluate point of test strip to confirm correct nasogastric position	N3 A phase Ib/II trial of combination Nab- paclitaxel and Nintedanib or Nab- paclitaxel and placebo in relapsed NSCLC adencarcinoma	randomised trial of immunomodulatory therapy in high risk solitary bone plasmacytoma	MK- 
· 	Yes	N <sub>O</sub>	No	N <sub>O</sub>
	09/11/2017			
	174			128
	43			
	217			
	N <sub>o</sub>	N <sub>o</sub>	N <sub>o</sub>	Z o
	06/04/2017	22/03/2017	31/03/2017	26/01/2017
	06/04/2017	22/03/2017 03/04/2017 30/06/2017	31/03/2017	21/03/2017 08/05/2017 20/07/2017 27/07/2017
	27/10/2016 1	30/06/2017	3/2017 09/08/2016	08/05/2017
	06/04/2017 06/04/2017 27/10/2016 19/04/2017 27/09/2017			20/07/2017
	7/09/2017 S	(0 T	(O.T.	27/07/2017
	Please Select	Please Select	Please Select	Please Select
	31/10/2017			13/09/2017
A - Permissions delayed/denied	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	A - Permissions delayed/denied E - Staff availability issues	A - Permissions delayed/denied E - Staff availability	A - Permissions delayed/denie D - Sponsor Delays 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	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 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 studycentre only received strips 10/10/17 and are in process of organising an SIV which is expected to be soon	In set -up Staff resources - delay in reviewing costs with local study team availability	In set -up - Staff resources 25/01/18	and 2nd costing emplate to review. Signed Contract back from Sponsor, Service support departments greement from Sponsor Service support departments greement from sichemistry. Sponsor chemistry. Sponsor Lelay in providing final Agreements for Trust signature. Pharmacy Green Light Received 13.09. 17. As of 11/10/17 no patients excruited despite screening. PI has commented that no other than on the service of the sponsor of the sponsor of the service of t
	Both	Both	NHS Provider	Both

http://ccfctp.nihr.ac.uk/Submission.aspx?MetaSubmissionId=51&SubmissionId=6853&TrustId=1119

-	115256	115255	115254	115253	115252	115251
	17/LO/0957	16/LO/1502	16/LO/0585	16/SC/0655	115252 16/SC/0462	115251 17/LO/0347
; <del>-</del>	226146	178292	188869	212212	208830	221524
2	CREDO 4 A Multicenter, Open- Label, Phase III Study of the Efficacy and Safety of Olokizumab in Subjects with	"CTC-STOP: Utilising Circulating Tumour Cell (CTC) Counts to Optimize Systemic Therapy of Metastatic Prostate Cancer."	NeoART Phase II randomised double blind placebo controlled trial of neoadjuvant artesunate in stage II/III colorectal cancer	S - A mised slied Trial of fect of a two- compression ge system on function fing Total Knee plasty	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	Chemotherapy vs Placebo plus Chemotherapy as Neoadjuvant Therapy and Penbrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)
	N <sub>o</sub>	Z <sub>o</sub>	Ύes	Yes	Yes	N <sub>O</sub>
			05/12/2017	17/11/2017	20/12/2017	
			124	111	90	127
ESOT- SAL			60	2	146	
1 1 1			184	175	236	:
,	N <sub>o</sub>	No	No	N <sub>o</sub>	N <sub>O</sub>	Z 0
ì	06/07/2017	23/05/2017	20/03/2017 04/06/	26/05/2017	26/04/2017	22/12/2016
	06/07/2017		, 04/06/2017	26/05/2017	28/04/2017	10/04/2017
	12/07/2017	23/06/2017 07/10/2016	15/09/2016	08/02/2017	11/11/2016	05/05/2017
			2017 15/09/2016 12/06/2017 06/10/2017	26/05/2017 26/05/2017 08/02/2017 26/06/2017 14/09/2017 Select.	26/04/2017 28/04/2017 11/11/2016 26/05/2017 27/07/2017 Select	22/12/2016 10/04/2017 05/05/2017 20/07/2017 15/08/2017 Please Select
			06/10/2017	14/09/2017	27/07/2017	15/08/2017
	Please Select	Please Select	Please Select	Please Select		Please Select
			07/11/2017	29/09/2017	14/09/2017	
	A - Permissions delayed/denied	A - Permissions delayed/denied E - Staff availability issues	A - Permissions Permissions D-Vi11/2017 delayed/denied D - Sponsor Delays	A - 29/09/2017 Permissions delayed/denied	A - on an	D - Sponsor Is Delays E - Staff E - Staff Is availability issues H - Contracting delays
	In set-up - Delays in obtaining TFF authorisation signatures. 25/01/18 not prioritised by research team as d CREDO 2 has no patients recruited as	18 s,	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	Delay in receiving 1FF (recvid 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 preassessment unit.	I delay in attending CP training. Seeking greement from rthopaedic consultant olleagues. 11/10/17 o patients recruited ferrals from doctors ot coming through at resent	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 activiated for recruitment as yet due to staff issues/capacity in K
4/6	NHS Provider	NHS Provider	Both	NHS Provider	NHS Provider	Both

115262	115261	115260	115259	115258	115257	
17/LO/0825	17/NS/0018	17/NW/0351 224954	115259 17/NE/0149	17/SC/0231	16/WM/0268 202984	
223457	223787	224954	224550	221097	202984	
GS-US-445-4189 A randomised phase 2 double-blind placebo-controlled study to assess the safety and efficacy of filgotinib GS-9976 and GS-4059 in adult	FUTURE Female urgency trial of urodynamics as routine evaluation	TITAN RCC A phase II single am clinical trial of a Tallored ImmunoTherapy Approach with Nivolumab in subjects with metastatic or advanced Renal Cell Carcinoma	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	ETOP 9-15 PROMISE-meso A multicentre randomised phase III trial comparing pembrolizumab versus standard chemotherapy for advanced pre-treated malignant pleural mesothelioma	PRODUCT: What after the first propess. A comparative prospective study	Severely Active Rheumatoid Arthritis.
Z o	Z <sub>0</sub>	N <sub>o</sub>	Z	Yes	Z o	
				27/09/2017 :		
146			137	35		
				42		
				77		
Z o	N <sub>O</sub>	N <sub>o</sub>	N <sub>o</sub>	Z o	Site Not Confirmed	
24/02/2017	04/07/2017	22/05/2017	08/05/2017	31/03/2017	05/06/2017	
25/05/2017	27/09/2017	03/08/2017	31/07/2017	12/07/2017	06/07/2017	
30/06/2017 03/10/2017 18/10/2017	27/09/2017 11/08/2017 19/12/2017	22/05/2017 03/08/2017 03/08/2017	31/07/2017 19/06/2017 10/11/2017 15/12/2017 Please	12/07/2017   27/06/2017   12/07/2017   16/08/2017	05/06/2017 06/07/2017 08/09/2016	
03/10/2017	19/12/2017		10/11/2017	12/07/2017		
18/10/2017			15/12/2017	16/08/2017		
Please Select	Please Select	Please Select	Please Select	Please Select	Site declined to participate	
02/11/2017			05/01/2018	01/09/2017		
A - Permissions O2/11/2017 delayed/denied D - Sponsor Delays	A - Permissions delayed/denied	A - Permissions Permissions E - Stadf E - Staff availability issues	A - Permissions Permissions delayed/denied E - Staff availability issues	A - 01/09/2017 Permissions delayed/denied		
In set-up/Delays negotiating costs and completing contract/review, 3 x substantial amendments received during set-up and delays in obtaining TFF authorisation	In set-up - TFF pending as of 21/12/17 - directorate sign off being cause of delay so far. As of 20/12/17 C.&C letter ready to be issued - still pending final signature for contracts - PI on leave until 28/12/17 PI signature - Still pending PI GCP/CV as at 26/01/18	n set-up/Staffing and resources. Amendment submitted during C&C which impacts on local study documents and updated protocol version	In set-up/Delay in obtaining feasibility approval, staff resources and capacity of team 25/01/18 No eligible patients seen as yet	11/10/17 - First patient recruited 27/9/17 and another 3 pts possibly eleigible and under review	ings btain part. as ticipate	yet, and this is a feeder study for CREDO 4.
Both	NHS Provider	NHS Provider	NHS Provider	Neither	Neither	

subjects with active sjogren's syndrome In set-up/Capacity issues for research radiographer - TFF prior to circulating to SSDs.22/06/17 email to tight exclusion signatures25/01/18 no recruitment as yet due review and completion drafted but with RR for

06/03/2017 15/06/2017 13/02/2017

Please Select..

Delays

CT scans, also fields schedule of events in

particular attribution of

Both

delayed/denied D - Sponsor

Permissions

queries in relation to the completion of the

sent to study centre with a number of

115263 16/WS/0165

190574

Accelerated, Dose escalated,

No

No

ADSCaN: A Randomised Phase II study of

Sequential Chemo-radiotherapy in Non-Small Cell Lung Cancer

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 resonses

urther communicati

received. .25/01/18 No

Delays obtaining feasibility and SSD. Capacity with KOC

Yes

21/09/2017 62

162

224

N<sub>o</sub>

08/02/2017 09/02/2017 15/06/2016 24/02/2017 12/04/2017

Please Select...

27/04/2017

delayed/denied E - Staff

patient in screening July, first patient

NHS

Permissions

set-up and providing R&D with TFF. 1

contributed to delays research team also

issues

suitable since study opened. First patient recruited 21/9/17, 2

this but due to logistics and tight time frames unable to recruit.

screened previous to

availability

Improving radical treatment through MRI evaluation of pelvic sigmoid MPRESS -

115315 14/LO/0801 137312

Showing records 1 to 25 of 32. Pages: 1 2 Next >

< Back

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