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	01/07/2018
Deadline Date	30/07/2018
Date Submitted	20/07/2018
Type	Performance in Initiating
NHS provider	Maidstone and Tunbridge Wells NHS Trust

Showing records 1 to 19 of 19.
Pages: 1

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 correspo to:
122857	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					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 yet, and this is a feeder study for CREDO 4. 70 day benchmark not due to R&D C&C not in place	NHS Provider
122858	16/WM/0268	202984	PRODUCT: What after the first propess. A comparative prospective study	No					05/06/2017	06/07/2017	08/09/2016			Site declined to participate		J - Other	Number of meetings held with local consultants to obtain decision to take part. Final decision was made not to participate in the study, due to conflicting with another study the consultants were interested in.	Neither
122859	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	31/03/2017	12/07/2017	27/06/2017	12/07/2017	16/08/2017	Please Select...	01/09/2017	F - No patients seen	DSC to FPR Patients screened but no eligible patients identified in reporting period. First patient recruited 27/9/17	Neither

																	and another 3 pts possibly eleigible and under review	
122860	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	Yes	20/04/2018	137	126	263	08/05/2017	31/07/2017	19/06/2017	10/11/2017	15/12/2017	Please Select...	05/01/2018	A - Permissions delayed/denied E - Staff availability issues	Delay with obtaining Service Support Depart approvals due to staff resources and capacity of team, this significantly delayed confirmation of C&C (DSC) meaning FPR target would not be met. DSC to FPR delay due to small patient population and strict inclusion criteria of having extensive disease - many patients not fit enough to take part, actively screening pts	NHS Provider
122861	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					22/05/2017	03/08/2017	03/08/2017			Please Select...		A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues	delay in negotiating costs between pharmacy and sponsor. Delay CTA/Nurse reviewing protocol and completing inhouse TFF due to work commitments and staffing capacity. Amendment SA1 submitted to site during feasibility - new version of protocol required inhouse TFF to be updated and re-circulated. DSS to FPR will not be met as C&C not issued.	Both
122862	17/NS/0018	223787	FUTURE Female urgency trial of urodynamics as routine evaluation	Yes	15/05/2018	127	103	230	04/07/2017	27/09/2017	11/08/2017	19/12/2017	01/02/2018	Please Select...	07/02/2018	A - Permissions delayed/denied J - Other	Delay obtaining SSDs confirmation and directorate sign off . Also delays with contract sign off due to PI being on annual leave. DSC to FPR delayed due to trust requiring a new urodinamic machine to be supplied and installed. Study centre then required 2 anonymous traces so had to	NHS Provider

																	wait for these to be confirmed before screening patients.	
122863	17/YH/0387	230570	"MK3475-715 A Randomized Phase 3 Study of the Combination of Pembrolizumab (MK-3475) Plus Epacadostat (INCB024360) Alone or with Platinum-based Chemotherapy Versus Pembrolizumab Plus Platinum-based Chemotherapy Plus Placebo as First-Line Treatment in Patients with Metastatic Non-Small Cell Lung Cancer"	No					16/10/2017	10/11/2017	03/01/2018			Sponsor declined site confirmation		A - Permissions delayed/denied C - Closed by sponsor E - Staff availability issues J - Other	25/01/18 In set up Resources, staff capacity.27/03/18 Merck have dropped our site - due to continued uncertainty over when the studies will realistically start at our site due to the ongoing resourcing delays. Site selected back in July-17).	Both
122864	17/LO/0731	219463	PIVOTALboost A Phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost	No		169			05/12/2017	05/12/2017	27/07/2017	10/05/2018	23/05/2018	Please Select...	30/05/2018	A - Permissions delayed/denied E - Staff availability issues F - No patients seen	25/01/18 Delay due to TFF, heamatology support not confirmed and IR(ME)R not yet received. Also Amendment 1 received 18/12/17 which meant TFF re-review. No patients screened during reporting period as R&D C&C not in place. DSC to FPR delayed due to research radiotherapist on annual leave and then left department. Replacement started wk comm 16/7/18 so screening of patients will commence once fully inducted and trained on study	NHS Provider
122865	17/WA/0347	234208	SCORED A randomised double-blind placebo-controlled parallel-group multicentre study to demonstrate the effects of sotagliflozin on cardiovascular and renal events in patients with type 2 diabetes,	No		104			28/09/2017	12/12/2017	12/01/2018	08/02/2018	26/03/2018	Please Select...	15/04/2018	A - Permissions delayed/denied	25/08/17 TFF still pending due to capacity issues in clinical team. Delay in reviewing costings with research nurse under pressure with other TFFs and supporting studies. No patients screened in reporting period due to R&D C&C not in place. DSC to FPR delayed due to lack of eligible	NHS Provider

			cardiovascular risk factors and moderately impaired renal function														F - No patients seen	patients, 2 patients screened but failed. PIC sites have been identified and approved however no patients referred to date. Research nurse in discussion with PI to establish a better way of identifying pts.	
122866	17/SW/0221	232448	SURPASS - A ransdomised partially-blinded active-controlled multicentre study of secukinumab to demonstrate reduction of radiographic progression versus adalimumab at 104 weeks and ato assess the long term safety toleratibility and effiacy up to 2 years in patients with active ankylosing spondylitis	No		97			10/03/2017	15/12/2017	28/11/2017	07/02/2018	22/03/2018	Please Select...	02/05/2018	A - Permissions delayed/denied D - Sponsor Delays F - No patients seen	TFF pending, costing and contract sent to sponsor for review - awaiting responses - contracts FE 12/02/18 retumed to sponsor. Amendment to update PICF recv 12/02/18 HRA/REC pending as of 13/02/17. TFF still o/s- recv'd 21/03/18. No patients rec in reporting period as C&C not issues. DSC to FPR delayed due to small numbers of pts eligible for study due to excl criteria requiring x-ray confirmation of disease - current standard now is MRI review , 1 patient failed pre sceen, actively screening	Both
122867	17/SC/0454	230182	CITADEL-204 A Phase 2, Open-Label, 2-Cohort Study of INCB050465, a PI3Kd Inhibitor, in Subjects With Relapsed or Refractory Marginal Zone Lymphoma With or Without Prior Exposure to a BTK Inhibitor	No		42			10/11/2017	20/03/2018	19/10/2017	12/03/2018	01/05/2018	Please Select...	30/05/2018	A - Permissions delayed/denied D - Sponsor Delays F - No patients seen	Local reviews not completed in time, C&C still pending from onc directorate. Sponsor did not provide HRA local info pack until 20/03/18 despite CTA and Costing being received and approved much earlier. DSC to FPR delay due to pharmacy green light being issued which delayed opening to recruitment.	Both

																	Since opening no eligible patients seen.	
122868	18/LO/0039	232257	EORTC 08112-LCG NEMO Study. Nintedanib as maintenance treatment of malignant pleural mesothelioma. A double-blind randomised phase II study of EORTC Lung Cancer Group	No					20/12/2017	16/01/2018				Please Select...		A - Permissions delayed/denied E - Staff availability issues	In set-up Delays with obtaining SSD approvals and capacity issues within team to progress set-up. No patients screening in reporting period as R&D C&C not in place	NHS Provider
122869	17/SW/0253	226354	Intradermal sterile water injections for relief of low back pain in labour: is a two injection technique as effecive as a four injection technique? A pilot study	Yes	05/05/2018	83	67	150	16/10/2017	06/12/2017	12/02/2018	16/10/2017	27/02/2018	Please Select...	27/02/2018	A - Permissions delayed/denied E - Staff availability issues	HRA issued approval on 12/02/2018, Half term week so Trust approval raised and issued on 20/02/2018. No patients screened in reporting period due to R&D C&C not being in place. DSC to FPR delayed due to lack of engagement on the ward due to staff capacity issues... subsequent meetings held with team which has improved delivery.	NHS Provider
122870	18/SC/0055	239091	Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage Be on the TEAM: Teenagers Against Meningitis	Yes	27/03/2018	47	7	54	10/12/2017	01/02/2018	05/03/2018	15/03/2018	20/03/2018	Please Select...	26/03/2018	A - Permissions delayed/denied H - Contracting delays	Awaiting details of STGs required for site to order from sponsor. Delays from sponsor who were awaiting the final contract and distribution of costs to sites to be agreed. Ongoing discussions with local labs around capacity to undertake local sample analysis or to send to central labs	Both
																A - Permissions	Delays with sponsor reviewing costing template and contract. Also sponsor not using the GoBalto portal for documents as originally stated. R&D not initially provided with	

122871	18/EM/0027	235145	OPT-302-1002 A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with neovascular age-related macular degeneration (wet AMD)	No		71			25/10/2017	06/02/2018	28/02/2018	03/04/2018	18/04/2018	Please Select...	21/05/2018	delayed/denied D - Sponsor Delays E - Staff availability issues H - Contracting delays	document pack therefore governance reviews delayed. DSC to FDR delays due to 1 RN leaving dept and 1 RN on sick leave, study requires one blinded and one unblinded nurse on study and therefore was unable to recruit due to short staff. 1 pt currently in screening	Both
123382	17/LO/1500	224823	AGILE Study Agios AG120-C-009 A phase 3 multicentre double-blind randomised placebo-controlled study of AG-120 in combination with azacitidine in subjects over 18 years of age with previously untreated acute myeloid leukemia with an IDH1 mutation	No		47			06/11/2017	27/04/2018	06/03/2018	19/04/2018	13/06/2018	Please Select...		A - Permissions delayed/denied J - Other	Discrepancies with costs that took an additional month to resolve and finalise. Delay in site reviewing costs and getting back to sponsor. DSC to FPR delay due to site not yet being activated by sponsor as require second step SIV with PI to ensure all staff have relevant access to vendor databases and are fully trained and ready to go. Call should have taken place on 10/07 however PI has not responded to any of the sponsor emails.	NHS Provider
123383	14/WM/0083	125950	"LORIS - A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in Situ (DCIS)."	No					05/04/2018	01/05/2018				Please Select...		A - Permissions delayed/denied	Contract reviewed and signed, returned to study centre 30/5. C&C still needs to be circulated and confirmed by SSDs. Amendment recv'd 25/06 which has impact on pathology and other departments so C&C needs to be re-reviewed. FPR target will not be met due to C&C letter not being issued in time.	NHS Provider
																	Delay in receiving SoE from sponsor to	

123384	17/SC/0090	215608	c-TRAK TN A randomised trial utilising ctDNA mutation tracking to detect minimal residual disease and trigger intervention in patients with moderate and high risk early stage triple negative breast cancer	No					24/04/2018	10/05/2018				Please Select...		A - Permissions delayed/denied D - Sponsor Delays	review attribution of activities, delay in receiving modified contract from sponsor, pharmacist signature was delayed due to annual leave. Pending ARSAC license to be issued. DSS to FPR target will not be met due to C&C not being issued.	Both
123385	18/WA/0104	236930	Pevonedistat 3001 A Phase 3 randomised controlled open-label clinical study of Pevonedistat Plus Azacitidine versus single-agent Azxacitidine as first-line treatment for patients with higher-risk myeloysplastic syndromes chronic myelomonocytic leukemia	No					05/03/2018	14/05/2018	29/04/2018			Please Select...		A - Permissions delayed/denied H - Contracting delays	Delays with contract review and finalising final CTA. Sponsor errors needed correcting and delay in processing and returning for final execution. Also delay in obtaining SSD approval and CD/GM sign off, C&C pending, therefore FPR target will not be met.	Both

Showing records 1 to 19 of 19.
Pages: 1

< Back