Version 1.0.3

Submission

Home > Submission

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Submission Details	
Status	Accepted
Open Date	02/01/2019
Deadline Date	31/01/2019
Date Submitted	24/01/2019
Type	Performance in Initiating
NHS provider	Maidstone and Tunbridge Wells NHS Trust

Showing records 1 to 15 of 15.
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 correspor to:
132868	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.. 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. Since opening no eligible patients seen. small pt population, still no eligible pts	Both
132869	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	05/02/2018			Please Select...		A - Permissions delayed/denied E - Staff availability issues	Delays with obtaining SSD approvals and capacity issues within team to progress set-up. No patients screened in	NHS Provider

																reporting period as R&D C&C not in place. Compllleted TFF recv'd 17/10. C&C letter pending final review	
132870	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
132871	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)	Yes	15/10/2018	71	180	251	25/10/2017	06/02/2018	28/02/2018	03/04/2018	18/04/2018	Please Select...	21/05/2018	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues H - Contracting delays	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 document pack therefore governance reviews delayed. DSC to FPR 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
132872	17/LO/1500	224823	AGILE Study Agios AG120-C-009 A phase 3 multicentre double-blind randomised	No		47			06/11/2017	27/04/2018	06/03/2018	19/04/2018	13/06/2018	Please Select...	21/09/2018	A - Permissions delayed/denied	Discrepancies with costs that took an	NHS Provider

			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													F - No patients seen	additional month to resolve and finalise. Delay in site reviewing costs and getting back to sponsor. DSC to FPR update 26/10 - study DSC-FPR now open to rec however no eligible pts seen as yet. Recruitment slow due to a rare condition.	
132873	17/SC/0090	215068	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	Yes	18/12/2018			222	24/04/2018	10/05/2018	22/06/2017			Please Select...	08/11/2018	A - Permissions delayed/denied D - Sponsor Delays	In set up Delay in receiving SoE from sponsor to 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
132874	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		79			05/03/2018	14/05/2018	29/04/2018	15/06/2018	01/08/2018	Please Select...	24/09/2018	A - Permissions delayed/denied F - No patients seen H - Contracting delays	Delays with contract review and finalising final CTA. Sponsor errors needed correcting and delay in processing and returning for final execution.delay in obtaining SSD app &CD/GM sign off, C&C pending, therefore FPR target will not be met. 26/10 study DSC-FPR now open to rec but no eligible pts seen	Both
132875	18/NE/0125	238346	PROFHER-2 - PROximal Fracture of the Humerus: Evaluation by Randomisation	No		63			08/12/2017	11/07/2018	15/05/2018	17/07/2018	12/09/2018	Please Select...	27/09/2018	A - Permissions delayed/denied	Delay in obtaining local site feasibility	NHS Provider

			Trial no. 2 (PROFHER-2 Trial): A three-arm randomised controlled trial to assess the effectiveness and cost-effectiveness of reverse shoulder arthroplasty versus hemiarthroplasty versus non-surgical care for acute three and four-part fractures of the proximal humerus in older adults													G - No patients consented	sign off from trust signatories, due to staff annual leave. As of 30/08/18 still pending approved feasibility. C&C letter drafted, all governance reviews carried out, no issues, contract fully executed. C&C can be issued once TFF recv'd. Final TFF recv'd 12/09/18 - c&C issued 14/09/18. DSC-FPR delay 1 pt screened but declined, 1 pt currently booked in to consultant... pending	
132876	17/YH/0289	231276	ACE-CL-110 A Phase 1/2 Proof-of-Concept Study Investigating AZD6738 monotherapy and Acalabrutinib in Combination with AZD6738 (ATR inhibitor) in Subjects with Relapsed or Refractory High-risk Chronic Lymphocytic Leukemia (CLL).	No		64			15/03/2018	09/07/2018	18/10/2017	07/09/2018	11/09/2018	Please Select...	28/11/2018	A - Permissions delayed/denied D - Sponsor Delays	Costings negotiations during annual leave period. Contract agreed by parties, delay in receiving partially executed agreement from sponsor for signing. TFF responses 43 working days. Although C&C issued, pharmacy green light still pending.	Both
132877	17/EE/0340	213113	"INTERIM: a randomised phase II feasibility study of INTERmittent versus continuous dosing of oral targeted combination therapy In patients with BRAFV600 mutant stage 3 unresectable or metastatic Melanoma"	Yes	27/11/2018			132	26/06/2018	18/07/2018	05/10/2017	07/09/2018		Please Select...	19/10/2018	A - Permissions delayed/denied E - Staff availability issues	Internal C&C process delayed. Document circulated to SSDs until 03/09/18 due to capacity issues in team as this is a new disease area. C&C completed 15/10/18 and provided to governance team for completion and issuing of C&C letter	NHS Provider
132878	18/SC/0242	238151	BLING III - A phase III	No					15/05/2018	24/08/2018	23/08/2018	25/09/2018		Please		A -	In set-up -	Both

			randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients												Select...		Permissions delayed/denied D - Sponsor Delays	DSS-DSC delays due to internal C&C review and obtaining SSD approvals. Pharmacy investigating stability of drug using the protocol admin method as conflicting evidence, obtaining advice from local network Sponsor delays with contract, provided different version to what was validated on HRA approval letter. HRA and sponsor contacted and updated contract and HRA letter provided. FE contracted recv'd 22/10/18. R&D C&C now in place	
132879	18/LO/0165	224726	POLEM Avelumab plus 5-FU based chemotherapy as adjuvant treatment for stage 3 MSI-High or POLE mutant colon cancer: A phase 3 randomised study	No					17/05/2017	02/09/2018					Please Select...		A - Permissions delayed/denied	Delay in obtaining SSDs approval. R&D C & C now in place	NHS Provider
132880	17/EE/0382	220851	Predicting outcomes for Crohn's disease using a molecular biomarker (PROFILE) trial	No					02/07/2018	02/07/2018					Please Select...		A - Permissions delayed/denied	DSS-DSC delays with C&C being drafted and circulated to SSDs and receiving responses. Still awaiting confirmation from IT regarding video recording guidance. Contract FE - pending Fully signed TFF prior to issuing C&C letter	NHS Provider
133050	18/SW/0039	229163	Induction of labour for predicted macrosomia 'The Big Baby Trial'	No					06/07/2018	06/07/2018	20/03/2018	06/07/2018			Please Select...		A - Permissions delayed/denied	Delay in obtaining SDD sign off, R&D C&C now in place.	NHS Provider
133059	17/LO/1875	219487	RAMPART Renal adjuvant multiple arm randomised trial (RAMPART): An international	No						04/12/2018					Please Select...			Currently in set up and local	Please Select...

			investigator-led phase III multi-arm multi-stage randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at hi													feasibility being undertaken.	

Showing records 1 to 15 of 15.
Pages: 1

< Back