Version 1.0.3

Submission

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Submission Details	
Status	Accepted
Open Date	02/04/2018
Deadline Date	30/04/2018
Date Submitted	25/04/2018
Type	Performance in Initiating
NHS provider	Maidstone 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 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:
118881	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					Site Not Confirmed	22/03/2017	03/04/2017	30/06/2017			Site declined to participate		A - Permissions delayed/denied E - Staff availability issues J - Other	In set -up Staff resources - delay in reviewing costs with local study team availability. 01/02/18 Issues with pharmacy, IMP contains human albumin. This adds significant additional steps in preparation and post preparation. Decision taken not to progress study on this basis.	NHS Provider
118882	16/LO/0998	192968	INGENZA - A diagnostic accuracy study to evaluate point of Care lipase/pH test strip to	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 Delays E - Staff availability	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	Both

			confirm correct nasogastric position															issues J - Other	ahead. Continued with governance and approval issued. No patients recruited as of 11/10/17. Site ready to start 31/1017 following SIV which was delayed by sponsor, FPR date outside 30 day target because of this.	
118883	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...	25/08/2017	A - Permissions delayed/denied D - Sponsor Delays E - Staff availability issues F - No patients seen H - Contracting delays	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 SSD support. 70 day benchmark not met due to R&D C&C not in place. DSC-FPR 30 day not met due to onc dept not opening to screeening	Both
118884	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	Yes	20/12/2017	90	146	236	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 D - Sponsor Delays F - No patients seen	PI delay in attending GCP training. Seeking agreement from orthopaedic consultant colleagues.70 day BM not met due to R&D C&C not in place. Exceed 30DAY DSC-FPR as site not activated and referrals from GPs not coming through at present	Both
																		Delay in receiving TFF (recv'd R&D 11/09/17) due to availability of staff, SSD	

118885	16/NE/0400	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...	29/09/2017	A - Permissions delayed/denied F - No patients seen	support - sourcing and purchasing of bandages and holiday period 70 day benchmark not met due to R&D C&C not in place. 11/10/17 no patients recruited to date, 30 day DSC-FPR not met due to T&O waiting lists is so long it is causing problems with screening pts - currently being addressed with the pre assessment unit.	NHS Provider
118886	16/LO/0585	188869	NeoART Phase II randomised double blind placebo controlled trial of neoadjuvant artesunate in stage II/III 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...	07/11/2017	A - Permissions delayed/denied D - Sponsor Delays F - No patients seen	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. FPR 30 day not met due to no eligible pts from those screened	Both
118887	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 J - Other	In set-up - Resources, staff capacity 25/01/18.14.03.18 - STUDY SET UP PUT ON HOLD UNTIL NOVEMBER WHEN THE CONFLICTING STUDY PROACT HAS FINISHED. STUDY CENTRE IN AGREEMENT AS OTHER SITES HAVE DONE THE SAME	NHS Provider
118888	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, 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

118889	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		J - Other	Number of meetings held with local consultants to obtain decision to take part. Final decision was made not to participate due to consultant having her own study in set-up which would conflict with this one.	NHS Provider
118890	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	F - No patients seen	Patients screened but no eligible patients identified in reporting period. 11/10/17 - First patient recruited 27/9/17 and another 3 pts possibly eleigible and under review	Neither
118891	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		137			No	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 F - No patients seen G - No patients consented	Delay in obtaining feasibility approval, staff resources and capacity of team 31/04/18 . 31/3/18 Exceeded 30 day DSC-FPR due to site not activiated, 1 pt screened not eligible, 2 pts declined, 1 pt currently considering participation	NHS Provider
118892	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					No	22/05/2017	03/08/2017	03/08/2017			Please Select...		A - Permissions delayed/denied 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. 70 day benchmark not met as R&D C&C not in place	NHS Provider
118893	17/NS/0018	223787	FUTURE Female urgency trial of urodynamics as routine evaluation	No		127			No	04/07/2017	27/09/2017	11/08/2017	19/12/2017	01/02/2018	Please Select...	07/02/2018	A - Permissions delayed/denied F - No patients seen	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	NHS Provider

																		GCP/CV as at 26/01/18 . Exceed 30 day DSC-FPR due to pts sought but none eligible. 1 pt currently considering participation	
118894	17/LO/0825	223457	GS-US-445-4189 A randomised phase 2 double-blind placebo-controlled study to assess the safety and efficacy of filgotinib GS-9876 and GS-4059 in adult subjects with active sjogren's syndrome	No		146			No	24/02/2017	25/05/2017	30/06/2017	03/10/2017	18/10/2017	Please Select...	02/11/2017	A - Permissions delayed/denied D - Sponsor Delays F - No patients seen G - No patients consented	Delays negotiating costs and completing contract/review, 3 x substantial amendments received during set-up and delays in obtaining TFF authorisation signatures. TFF received 18/10/17, C&C letter issued same day. 70 day Benchmark not met due to R&D C&C not in place. Exceed 30 day DSC-FPR due to small pt population with strict inc criteria. 1pt approached but declined	Both
118895	16/WS/0165	190574	ADSCaN: A Randomised Phase II study of Accelerated, Dose escalated, Sequential Chemo-radiotherapy in Non-Small Cell Lung Cancer	No					No	06/03/2017	15/06/2017	13/02/2017			Please Select...		A - Permissions delayed/denied D - Sponsor Delays	In set-up Capacity issues for radiographer - TFF drafted but with RR for review and completion prior to circulating to SSDs.22/06/17 email sent to study centre with a number of queries in relation to the completion of the S of E in particular attribution of CT scans,fields completed incorrectly - 30/6 email recv'd from SC to say that they are investigating with the sponsor, as of 11/10/17 no further update or responses received. Governance on hold as study not being progressed by onc depart	Both
			"MK3475-715 A Randomized Phase 3															25/01/18 In set up Resources, staff	

118897	17/YH/0387	230570	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					Site Not Confirmed	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	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
118898	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					No	05/12/2017	05/12/2017	27/07/2017			Please Select...		A - Permissions delayed/denied	In set-up 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. 70 day benchmark not met as R&D C&C not yet in place	NHS Provider
118899	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, cardiovascular risk factors and moderately impaired renal function	No		104			No	28/09/2017	12/12/2017	12/01/2018	08/02/2018	26/03/2018	Please Select...	23/04/2018	A - Permissions delayed/denied J - Other	Local reviews not completed in time 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. 70 day benchmark not met due to R&D C&C not in place. Exceed 30 day DSC-FPR as site not activated due to PI/Co-I not completing eCRF training requirements	NHS Provider
118900	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	No		97			No	10/03/2017	15/12/2017	28/11/2017	07/02/2018	22/03/2018	Please Select...		A - Permissions delayed/denied	TFF pending, costing and contract sent to sponsor for review - awaiting responses - contracts FE 12/02/18 retumed to sponsor. Amendment to update PICF received 12/02/18 HRA/REC pending as of 13/02/17. TFF still outstanding -	Both

			weeks and ato assess the long term safety toleratibility and effiacy up to 2 years in patients with active ankylosing spondylitis														D - Sponsor Delays	recv'd 21/03/18. 70 day bench mark not met due to R&D C&C not in place. 30 Day DSC-FPR not met due to delay in receiving sponsor green light due to an emergency telephone call out service being put in place	
119212	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					Within 70 Days	10/11/2017	20/03/2018	19/10/2017	12/03/2018		Please Select...		A - Permissions delayed/denied	In set-up 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.	NHS Provider
119213	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					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. 70 day benchmark not met as R&D C&C not in place	NHS Provider
119214	17/SW/0253	226354	Intradermal sterile water injections for relief of low back pain in labour: is a two injection technique as efffecive as a four injection technique? A pilot study	No		83			No	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 F - No patients seen G - No patients consented	HRA issued approval on 12/02/2018 day 68, Half term week so Trust approval raised and issued on 20/02/2018. 70 day benchmark not met due to R&D C&C not being in place. 30 day DSC-FPR not met due to pts declining participation, not fitting incl criteria, and capacity in dept to recruit due to other studies and lack of staff	NHS Provider
119215	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	Yes	10/12/2017	01/02/2018	05/03/2018	15/03/2018	20/03/2018	Please Select...	26/03/2018	A - Permissions delayed/denied	Local review not completed in time due to obtaining local SSD support and obtaining contract signature	NHS Provider

119216	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			Within 70 Days	25/10/2017	06/02/2018	28/02/2018	03/04/2018	18/04/2018	Please Select...		A - Permissions delayed/denied D - Sponsor Delays 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. 70 day Benchmark not met due to R&D C&C not in place and SIV not planned until 30/04/18	Both

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