

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Patient Recruited?	Date of First Patient 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 Correspond to	Comments
17/YH/0055	215194	MIDFUT: Multiple Interventions of Diabetic Foot Ulcer Treatment Trial	Yes	27/06/2019	16/11/2018	11/01/2019	24/05/2017	27/02/2019	08/03/2019	NA	18/04/2019	Sponsor	HRA approval confirming Stockport site addition was dated 27/03/19 with amendment only submitted by sponsor team to HRA on 13/03/19. To end of Q4 18/19 PID reporting period, site hadn't received these documents from sponsor, so local capacity and capability confirmation delayed until receipt - Main reason left as sponsor. Patients were sought ASAP. First patient consented and registered 09/05/19 but only the third recruit successfully randomised on 27/06/19 due to tight eligibility criteria.
19/NW/0045	255691	18B-MC-ITSB: A Prospective, Randomized, Double-Blind Comparison of LY900014 to Humalog with an Open-Label Postprandial LY900014 Treatment Group in Children and Adolescents with Type 1 Diabetes - PRONTO-PEDS	Yes	07/06/2019	09/11/2018	10/04/2019	10/04/2019	17/04/2019	18/04/2019	NA	03/05/2019	NA	Local capacity and capability confirmation completed promptly. 58 days between site selection and first patient in. No delays in process and in line with sponsor expectations.
18/NW/0838	255084	Financial Incentives for Preventing Post-Partum Return to Smoking - The FIPPS Feasibility Trials	No	NA	04/02/2019	09/04/2019	15/01/2019	24/06/2019	NA	Site declined to participate.	NA	NHS Provider	Head of Midwifery confirmed on 02/08/19 that due to other research activity and work already being undertaken with smoking cessation, we will not be proceeding with this study.
18/SW/0039	229163	The 'Big Baby Trial': Induction of labour for predicted macrosomia	Yes	10/10/2019	12/03/2019	18/07/2019	20/03/2018	09/08/2019	19/08/2019	NA	26/09/2019	Sponsor	No significant delays with local capacity/ capability assessment as site happy to sign contracts from 09/08/19 (22 days). Slight delay in sponsor sign off as this didn't happen until 19/08/19. Sponsor team also only provided Sep/ Oct site initiation visits dates, so this wasn't scheduled until 23/09/19. Green light issued on 26/09/19, with first participant recruited within 2 weeks.
19/SC/0347	263849	A 24-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre study evaluating the efficacy and safety of intranasal administration of 186 and 372 I 1/4g of OPN 375 twice a day (BID) in subjects with chronic sinusitis with or without the presence of nasal polyps.	No		13/03/2019	30/08/2019	15/11/2019	05/11/2019	13/11/2019	NA	09/01/2020	Both	Initial set-up delay (77 days from site selected) due to HRA approval not being issued until 15/11/19. Delay to 12/12/19 followed at site due to radiology capacity/ capability confirmation not being fully signed off due to staff unexpected unavailability. Sponsor green light didn't follow until 09/01/20 as delays with team gaining access/ completing training to numerous external systems and provision of study consumables/ equipment from sponsor. First patient booked for screening 20/01/20.
19/NE/0215	234453	FITNESS (UK-MRA Myeloma XIV): Frailty-adjusted therapy in Transplant Non-Eligible patients with newly diagnosed Multiple Myeloma - A phase III trial to compare standard and frailty-adjusted induction therapy with ixazomib, lenalidomide and dexamethasone and maintenance lenalidomide to lenalidomide plus ixazomib	No		25/09/2019	03/12/2019	07/11/2019			NA		Sponsor	Set-up currently underway. Sponsor confirmed in early Dec-19 that SIVs can't be scheduled until at least Feb-20 so local capacity and capability assessment is aligning with this.
19/SC/0021	249552	OPTimal TIMing of Anticoagulation after acute ischaemic Stroke: a randomised controlled trial (OPTIMAS)	No		10/04/2019	11/12/2019	04/04/2019			NA			Currently undergoing capacity/ capability review.
19/WA/0019	247285	ROSSINI 2: A Phase III, multi-arm, multi-stage (MAMS) pragmatic, blinded (patient and outcome assessor) multicentre, randomised controlled trial (RCT) with an internal pilot, to evaluate the use of three in-theatre interventions, alone or in combination, to reduce SSI rates in patients undergoing abdominal surgery.	No		05/04/2019	27/11/2019	01/02/2019	02/12/2019	10/12/2019	NA		Both	No delays in set-up phase as capacity and capability confirmed within 15 days of site selected date. However, site initiation date couldn't be scheduled until 06/01/20 after local capacity/ capability issued on 12/12/19 due to staff availability due to festive break.
17/LO/0731	219463	PIVOTAL BOOST: A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost.	No		13/08/2019	18/10/2019	27/07/2017	22/10/2019	05/11/2019	NA		Neither	No delay in local set-up. Site selected 18/10/19, contracts ready to sign in Oct-19. Couldn't confirm local capacity/ capability until shared care delegation schema was returned from The Christie Hospital (site conducting radiotherapy). The Christie was sent this from 30/10/19 but didn't sign off until 03/12/19. Local capacity/ capability issued 03/12/19. Sponsor green light 05/12/19. First patient identified 06/12/19 but clinics weren't until 15/01/20, when first consent/ recruit occurred.