

Performance in Initiating Q1 19-20

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Reasons for delay correspond to:
18/YH/0238	246466	Treatment of Wounds Using OasisA® Extracellular Matrix (ECM)in the Community Setting	Yes	26/09/2018	23/07/2018	23/08/2018	09/08/2018	23/08/2018	21/09/2018	21/09/2018	
17/NE/0174	224141	PERFORMANCE EVALUATION STUDY OF ARQUER'S MCM5 ELISA TEST TO AID IN THE MONITORING OF BLADDER CANCER RECURRENCE	Yes	28/12/2018	10/10/2018	11/12/2018	11/12/2018	27/11/2018	12/12/2018	12/12/2018	
18/SW/0162	248769	PICO 7 - A prospective follow up study to assess performance, safety and efficacy of the PICO 7 NPWT system for surgically closed incision sites and skin grafts	Yes	11/11/2018	02/08/2018	24/10/2018	07/09/2018	10/10/2018	29/10/2018	29/10/2018	
17/nw/0698	233163	ASCENT An International, Multi-Centre, Open-Label, Randomized, Phase III Trial of Sacituzumab Govitecan versus Treatment of Physician Choice in Patients with Metastatic Triple-Negative Breast Cancer Who Received at Least Two Prior Treatments	No		29/09/2017	01/10/2018	04/12/2017	16/10/2018	22/10/2018	22/10/2018	Study unexpectedly closed by Sponsor before recruitment began.
16/EM/0322	202096	Tenecteplase in Wake-up Ischaemic Stroke Trial (TWIST)	Yes	11/02/2019	13/03/2018	11/10/2018	18/08/2017	29/10/2018	02/11/2018	02/11/2018	Sponsor did not greenlight until early Jan, FPFV missed due to no suitable patients
18/SC/0243	240684	HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease	Yes	15/05/2019	14/02/2018	01/10/2018	01/10/2018	27/11/2018	14/02/2019	14/02/2019	Sponsor delayed in sending IMPs
18/LO/1674	244500	Randomised controlled trial of an app-based digital intervention to support breast cancer survivors prescribed hormone therapy (e-path study)	Yes	13/02/2019	21/09/2018	16/11/2018	16/11/2018	05/02/2019	07/02/2019	07/02/2019	Sponsor requested delays for confirmation due to submitting an amendment
18/ES/0072	241253	Stimulation of the Tibial Nerve – A randomised trial for urinary problems associated with Parkinson's - The STARTUP trial	Yes	11/04/2019	08/01/2019	15/02/2019	04/07/2018	19/03/2019	21/03/2019	21/03/2019	Awaiting part signed contract from sponsor

18/NE/0125	238346	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 patients over 65 years of age – Proximal Fracture Of the Humerus: Evaluation by Randomisation trial No.2 (PROFHER-2).	Yes	09/04/2019	08/01/2019	10/01/2019	15/05/2018	25/02/2019	08/03/2019	08/03/2019	awaiting contracts from the sponsor and internal authorisations from theatres
18/WM/0383	252607	A phase 3 study investigating the efficacy, safety, and tolerability of tralokinumab administered to adult subjects with severe atopic dermatitis who are not adequately controlled with or have contraindications to oral cyclosporine A.	No		31/10/2018	21/02/2019	06/02/2019	25/04/2019	22/05/2019	24/05/2019	Sponsor delayed opening of the study as they could not open new sites until June.
17/YH/0013	213247	A RandomizEd trial of ENtERal Glutamine to minimIZe thermal injury	No		15/11/2018	18/01/2019	27/04/2017	21/05/2019	13/06/2019	13/06/2019	Sponsor delayed sending the contracts for signing and held up opening new sites
18/WS/0235	253191	CODIFI2: Randomised controlled trial of swab versus tissue sampling for infected diabetic foot ulcers, and comparison of culture versus molecular processing techniques	Yes	07/05/2019	07/12/2018	07/02/2019	18/01/2019	10/04/2019	10/04/2019	10/04/2019	delays in finalising the contract with sponsor
18/NS/0145	254786	IM REAL A NON-INTERVENTIONAL, MULTICENTER, MULTIPLE COHORT STUDY INVESTIGATING THE OUTCOMES AND SAFETY OF ATEZOLIZUMAB UNDER REAL-WORLD CONDITIONS IN PATIENTS TREATED IN ROUTINE CLINICAL PRACTICE	No		07/11/2018	28/02/2019	07/02/2019	05/03/2019	08/03/2019	12/03/2019	
17/NW/0051	215796	CReST2 - Colorectal Endoscopic Stenting Trial 2	No		14/07/2017	10/09/2018	03/01/2017				Delay in providing contract by Sponsor to Site. Not received at date of completing this report.
18/SC/0454	249509	PeriOperative ISchemic Evaluation-3 Trial (POISE-3)	No		06/09/2018	30/11/2018					Study was declined prior to receipt of HRA letter so unable to complete date.
18/YH/0289	236504	Prospective Multi-Center Clinical Evaluation Following Total Hip Arthroplasty with the G7 Dual Mobility System	Yes	19/06/2019	09/07/2019	21/12/2018	14/12/2018	17/04/2019	02/05/2019	02/05/2019	Sponsor delays in agreeing contracts between Midyorks & Leeds, also delays in receiving IRMER certificates