## Performance of Initiation. Year 2018-19, Q4 January-March

## Sandwell & West Birmingham Hospitals NHS Trust

REC Number	IRAS 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- Confirm ation Status	Date Site Ready To Start	Reasons for Delay	Comments	Reason s for delay corresp ond to:
16/NS/0053		A randomised controlled trial comparing laparoscopic cholecystectomy with observation/cons ervative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gallstones	Yes	14/08/2018	55	35	90	16/03/2018	16/05/2018	01/09/2016	12/06/2018	10/07/2018	Please Select	10/07/2018	F - No patients seen	No patient eligible	Both
17/NW/0529		The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial	Yes	13/09/2018	35	58	93	09/05/2018	12/06/2018	05/12/2017	07/06/2018	17/07/2018	Please Select	24/08/2018	Sponsor	Awaiting greenlight from sponsor	Sponsor
16/NE/0238	204031	The British Heart Foundation older patients with non-ST SEgmeNt elevatIOn myocaRdial infarction Randomized Interventional TreAtment Trial	Yes	16/07/2018	24	7	31	01/05/2018	15/06/2018	08/08/2016	06/06/2018		Please Select	09/07/2018			Please Select
16/NE/0169	203949	A Phase II/III, Randomised, Multicentre	Yes	19/10/2018	24	81	105	18/01/2017	06/07/2018	27/06/2016	10/07/2018	30/07/2018	Please Select	30/07/2018	Sponsor	Awaiting greenlight from sponsor	Sponsor



		Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed or Refractory Diffuse Large B- Cell Lymphoma (R-R DLBCL) Who Are Not Eligible for High- Dose Chemotherapy (HDC) and Autologous Stem-Cell Transplantation (ASCT) – B- MIND															
17/LO/1060	187783	RANDOMISED DOUBLE-BLIND EFFICACY AND MECHANISM STUDY OF SUB-SENSORY SACRAL (OPTIMISED) NEUROMODUL ATION IN ADULTS WITH FAECAL INCONTINENC E	Yes	22/03/2019	0	255	255	13/06/2017	10/07/2018	29/09/2017	11/06/2018	10/07/2018	Please Select	10/07/2018	F - No patients seen	Strict inclusion criteria, no patient eligible	Neither
17/LO/0334	214459	FLO-ELA: FLuid Optimisation in Emergency LAparotomy. Open, multi- centre, randomised controlled trial of cardiac output - guided haemodynamic	Yes	15/10/2018	0	90	90	13/07/2017	17/07/2018	17/05/2018	17/04/2018	17/07/2018	Please Select	05/09/2018	D - Sponsor Delays	Awaiting greenlight from sponsor	Sponsor

		therenut															
		therapy compared to usual care in patients undergoing emergency bowel surgery.															
17/EM/0077	206480	LACunar Intervention (LACI-2) Trial-2: Assessment of safety and efficacy of cilostazol and isosorbide mononitrate to prevent recurrent lacunar stroke and progression of cerebral small vessel disease	Yes	30/10/2018	55	41	96	05/06/2018	26/07/2018	24/07/2017	06/09/2018	19/09/2018	Please Select	20/09/2018	Sponsor	Awaiting greenlight from sponsor	Sponsor
16/WM/0502	200319	Cognitive Behavioural Therapy to reduce anxiety and depression in patients with atrial fibrillation (CBT-AF)	Yes	22/10/2018	7	27	34	05/12/2016	18/09/2018	26/02/2017	18/07/2016	25/09/2018	Please Select	25/09/2018			Please Select
17/SC/0490	231037	FORECAST Trial - Fractional Flow Reserve Derived from Computed Tomography Coronary Angiography in the Assessment and Management of Stable Chest Pain.		13/11/2018	28	8	36	25/09/2018	08/10/2018	03/10/2017	17/10/2018	05/11/2018	Please Select	12/11/2018			Please Select
17/LO/0095	216048	TANDEM. COPD Tailored intervention for ANxiety and	Yes	08/03/2019	96	95	191	01/12/2017	29/08/2018	23/03/2017	03/12/2018	03/12/2018	Please Select	03/12/2018	availabilit		NHS Provider

		DEpression Management in COPD: A tailored, psychological intervention for mild to moderate anxiety or depression in people with chronic obstructive pulmonary disease (COPD)														time, resource issues	
18/LO/0900	154432	preterm neonates: a multi-centre, electronic patient record (EPR), randomised controlled point- of-care pilot trial		11/02/2019	35	61	96	27/07/2018	07/11/2018	06/07/2018	12/12/2018		Please Select	12/12/2018			Please Select
17/NE/0386	234030	BIOlogical Factors that Limit sustAined Remission in rhEumatoid arthritis (the BIO-FLARE study).	Yes	08/01/2019	0	19	19	09/03/2018	20/12/2018	23/02/2018	13/12/2018	20/12/2018	Please Select	21/12/2018			Please Select
17/LO/0438	047057	A RANDOMIZED, DOUBLE- BLIND, PLACEBO- CONTROLLED STUDY TO ASSESS THE	No		11			16/04/2018	05/10/2018	01/06/2018	05/06/2018	16/10/2018	Please Select	29/10/2018	E - Staff availabilit y issues	Confirmation of C&C issued but sponsor did not issue green light and study was abandoned at site due to	NHS Provider

		EFFECTS OF BEMPEDOIC ACID (ETC- 1002) ON THE OCCURRENCE OF MAJOR CARDIOVASCU LAR EVENTS IN PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCU LAR DISEASE WHO ARE STATIN INTOLERANT											unforeseen resources issue at site	
18/NW/0244	237571	services-The MSK-Tracker study	No	7	28/01/2019	07/03/2019	23/05/2018	14/03/2019	14/03/2019	Please Select	14/03/2019			Please Select
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	No	99	08/12/2017	29/10/2018	15/05/2018	05/02/2019	05/02/2019	Please Select		J - Other	Equipment not in place at site which contributed to delay in study being approved and being given green light	NHS Provider

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		Humerus: Evaluation by Randomisation trial No.2 (PROFHER-2).													
18/SC/0371	231957	A Two-Year, Three-Arm, Randomized, Double- Masked,Multicen ter, Phase III Study assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Adult Patients with Visual Impairment due to Diabetic Macular Oedema		35		18/04/2018	13/11/2018	22/08/2018	07/11/2018	18/12/2018	Please Select	13/02/2019	patients	Strict inclusion criteria, no patient eligible	Neither