

**Performance in Initiating Clinical Research - Quarter 4 (2021/22)**

All clinical trials hosted between 01 April 2021 to 31 March 2022

HRA Approval studies

Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Date of First Participant Recruited	Comments	Reasons for Delay correspond to
191043	20/LO/1051	285644	Evaluation Clinical Study Of The Ambulatory Monitoring Solution (AMS)	15/04/2020	04/01/2021	02/12/2020	16/12/2020	22/12/2020	26/02/2021	10/03/2021	None	
191044	21/WM/0017	287442	A Placebo-controlled RCT Volixibat Intrahepatic Cholestasis Pregnancy	12/10/2020	06/01/2021	08/03/2021	16/11/2021	17/11/2021	23/11/2021		Project site setup suspended - COVID-19	Neither
191045	20/LO/1020	286291	MARIPOSA	14/10/2020	24/01/2021	22/10/2020	01/03/2021	05/03/2021	08/03/2021		Rare condition (the target is 1)	Neither
191046	20/SS/0089	266798	TRIBE: TB PCR in BAL and EBUS-TBNA	16/03/2021	16/03/2021	08/10/2020	19/02/2021	10/06/2021	11/06/2021	07/07/2021	Sponsor delays	Sponsor
191047	20/EE/0102	280585	Acceptability and tolerance study of Resource Thicken up Junior	26/10/2020	04/03/2021	13/05/2020	02/06/2021	05/06/2021	09/06/2021	15/09/2021	The principal investigator was currently unwell. The study is not supported by the research delivery team.	NHS Provider
191048	21/LO/0252	281109	Strategies to optimise fertility treatment outcome in poor responders	10/03/2021	10/03/2021	27/04/2021	29/07/2021	29/07/2021	30/07/2021	05/08/2021	Delay at site due to change in PI's personal circumstances.	NHS Provider
191049	21/WA/0104	295710	EMPIRE - The Effect of Music on Patients in Critical Care	01/04/2021	01/04/2021	01/04/2021	13/04/2021	13/04/2021	13/04/2021	08/04/2021	None.	
191050	20/SC/0258	283660	COVID19 - Curosurf_ARDS_COV19	30/12/2020	14/04/2021	24/07/2020	18/06/2021	23/06/2021	12/08/2021	19/10/2021	The set-up was delayed due to COVID (need to prioritise vaccine and UPHI studies). Green light has now been issued and recruitment is going to plan.	Neither
191051	21/NW/0125	294164	COV-COMPARE Immunogenicity of vaccine VLA2001 compared to AZD1222	23/03/2021	22/04/2021	20/04/2021	28/04/2021	29/04/2021	05/05/2021	06/05/2021	None.	
191052	20/SC/0423	288506	UK-ROX	11/05/2021	20/05/2021	19/02/2021	25/05/2021	21/06/2021	05/07/2021	05/07/2021	None.	
191053	20/LO/1110	284958	Giant PANDA	23/11/2020	26/05/2021	17/12/2020	28/06/2021	16/07/2021	21/07/2021	11/08/2021	None.	
191054	20/LO/0891	286227	NASH	08/03/2021	17/06/2021	17/09/2020	22/07/2021	03/08/2021	24/09/2021		Consented first patient in October but screen failed to meet criteria.	
191055	21/FT/0048	289818	M19-977	24/03/2021	26/08/2021	14/06/2021	17/09/2021	27/09/2021	04/10/2021	29/10/2021	None.	
191056	21/SC/0191	299310	SYMPHLY	31/08/2021	31/08/2021	24/06/2021	30/09/2021	30/09/2021	05/10/2021	05/10/2021	None.	
191057	18/YH/0013	214831	The DUAL-ACS2 Trial	03/06/2021	05/07/2021	22/07/2020	05/08/2021	05/08/2021	13/08/2021	20/08/2021	None.	
191058	19/YH/0015	255446	Beta-blockers or placebo for primary prophylaxis (BOPPP) Trial	03/10/2019	03/09/2021	24/04/2019	27/09/2021	01/10/2021	19/10/2021		Patients screened failed to meet criteria	
191059	20/SC/0372	283157	CRASH-4	01/07/2021	19/07/2021	17/12/2020	03/09/2021	23/09/2021	28/09/2021	30/11/2021	We received the local information pack from the sponsor during the feasibility stage. The feasibility form was completed and sent back after receiving the LIP.	
191060	19/EM/0253	263682	Routine testing for Group B Streptococcus	19/12/2019	15/09/2021	23/10/2019	15/07/2021	22/10/2021	02/12/2021		None.	
191061	19/ES/0049	260196	The ADDAPT diet in reducing Crohn's disease inflammation - Version 1	04/03/2021	21/04/2021	15/07/2019	12/08/2021	27/08/2021	27/08/2021		The set-up was delayed due to IT and admin issues.	Both
191062	21/PR/0040	285475	STEEER-AF	12/05/2021	26/08/2021	24/03/2021	15/09/2021	15/09/2021			We have not received the green light yet to commence recruitment. All the sites in one country will be activated at the same time for this study.	Sponsor
195427	21/FT/0081	295684	PRIOH-1	06/07/2021	21/07/2021	09/08/2021	15/11/2021	20/12/2021	15/12/2021		Time lap of 5 days between DSC and OTR. No regulatory breach occurred during this period. The study have now consented it's first participant.	
195428	19/LO/1669	266322	The Rio Trial	14/01/2020	03/08/2021	12/12/2019	08/11/2021	09/11/2021	09/11/2021		Two patients already screened. Awaiting blood result to confirm eligibility	
195429	20/NW/0113	269405	Dequalinium versus usual care antibiotics for the treatment of bacterial vaginosis	03/03/2021	09/09/2021	12/05/2020	15/10/2021	18/10/2021			Awaiting green light from the sponsor	
195430	21/SW/0049	283345	(EL4BS)	09/08/2021	05/10/2021	21/05/2021	29/12/2021	04/01/2022			Awaiting for confirmation of SIV date	
195431	21/LO/0808	303028	OPTI BREECH	28/11/2021	07/12/2021	23/11/2021	13/12/2021	13/12/2021				
201676	19/EM/0258	266702	Fluids Exclusively Enteral from Day 1 (FEED1)	04/04/2021	04/05/2021	13/09/2019	27/08/2021	27/08/2021	27/08/2021	18/11/2021		
201677	20/LO/0848	272164	ALLTogether1	11/05/2021	11/05/2021	25/01/2021	17/11/2021	17/11/2021	23/03/2022		Delay in the receipt of green light- sponsor delay	Sponsor
201678	21/YH/0027	289572	RASECAL-Bronchosopic ambusampler RCT - safety and efficiency	01/11/2020	15/06/2021	15/06/2021	14/01/2021	14/01/2021	14/01/2022	14/01/2022		
201679	21/NI/0015	294144	Use of the HemoClear system for obstetric cell salvage: A pre-clinical proof of concept to cleanse blood salvaged in caesarean sections and vaginal delivery	10/02/2021	22/07/2021	10/02/2021	03/05/2021	23/07/2021	23/07/2021	27/07/2021		
201680	21/WM/0196	297458	CP340 SUN-Study Investigation of patient benefits with a new supporting ostomy product and support service in patients with a newly stoma formation.	30/09/2021	25/11/2021	03/11/2021	16/12/2021	20/12/2021	21/01/2022	26/01/2022		
201681	21/PR/0899	293493	Application of machine learning algorithm to identify patients at highest risk of atrial fibrillation for targeted screening	29/07/2021	02/12/2021	02/12/2021	06/08/2021	16/12/2021	16/12/2021		Awaiting algorithm to be tested from the maker- Sponsor delay	Sponsor
201682	18/NE/0296	248487	CArvedilol versus variceal Band ligation in primary pRevention of variceal bleeding in liver cirrhosis	12/09/2019	14/01/2022	19/10/2018	23/01/2020	25/02/2022	21/03/2022		Delivery team have had a few Patients screened . No eligible patient found. The screening continues.	
201683	19/NW/0462	251756	Chronic Endometritis and Recurrent Miscarriage - The CERM trial	17/05/2021	04/02/2022	20/08/2019	05/01/2022				Study has only just been activated. The delivery team have started screening patients	Sponsor
201684	21/PR/1738	300440	Efficacy of GLP-1 agonist Semaglutide in acute pulmonary embolisms: a biomarker-driven proof of concept open label phase II study	04/02/2022	09/03/2022	02/02/2022						
201685	22/LO/0062	1004685	A Randomized, Double-Blind, Phase 3 Study of MK-7654A Plus Chemotherapy Versus Pembrolizumab Plus Chemotherapy as First Line Treatment for Participants With Metastatic Non-Small Cell Lung Cancer	31/01/2022	16/03/2022	02/03/2022					Awaiting to finalise contract with the sponsor.	