

Research & Development Performance in Initiating & Delivering Research January, 2020

This document has been produced in line with guidance provided by the National Institute for Health Research (NIHR). It details the performance of clinical research trials at University Hospitals of North Midlands, covering the period 1st January 2019 – 31st December 2019.

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Introduction

Clinical trial performance at The University Hospital of North Midlands is now measured against two national benchmarks to improve the initiation and delivery of all clinical trials approved by the Trust. From April 2013 NIHR funding to the Trust will be conditional on meeting these benchmarks.

Initiation – The Department of Health and Social Care is committed to improving clinical trial performance and reducing site set up and participant recruitment time. As of Quarter 1 2018-19, this will no longer be assessed with a 70 day benchmark for the duration between Date Site Selected and date of First Patient Recruitment. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations.

Delivery – For all commercial clinical trials hosted by the Trust, the agreed number of patients must be recruited within the agreed recruitment period.

Performance in Initiating Clinical Research

MREC Number	IRAS Number	Trial Name	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	First Patient Recruited?	Date of First Patient Recruited	Reasons for delay correspond to:
18/NE/0092	230286	ELAN	07/02/2018	23/01/2019	13/08/2018	18/12/2018	11/02/2019	29/05/2019	Yes	04/06/2019	Please Select...
18/EM/0229	250101	PROTECT 021IGAN17001	10/10/2018	14/02/2019	04/10/2018	25/01/2019	21/02/2019	21/02/2019	No		Please Select...
17/NW/0662	220156	APPRAISE ATP	11/10/2018	02/01/2019	22/03/2018	19/02/2019	19/03/2019	25/03/2019	No		Sponsor
18/LO/0813	247105	IDDSI Level 2 ONS study - IDDSIL2	11/02/2019	07/03/2019	04/09/2018	08/03/2019	20/03/2019	22/03/2019	Yes	02/04/2019	Please Select...
18/EM/0365	252018	Nintedanib in PF-ILD (extension)	14/01/2019	22/05/2019	15/01/2019	13/05/2019	29/05/2019	11/07/2019	Yes	15/07/2019	Please Select...
19/NE/0011	255897	CLEE011O12301C (TRIO033) - NATALEE	31/10/2018	30/01/2019	04/03/2019	03/06/2019	04/06/2019	14/06/2019	No		Both
18/YH/0472	250095	ROSA	18/07/2018	16/01/2019	03/01/2019	04/04/2019	22/05/2019	07/06/2019	Yes	17/06/2019	Sponsor
19/NW/0158	259931	Surgery or Cast for Injuries of the EpicoNdyle in Children?s Elbows	13/03/2019	09/05/2019	25/03/2019	29/05/2019	10/06/2019	11/06/2019	No		Please Select...
16/EM/0322	202096	Tenecteplase in Wake-up Ischaemic Stroke Trial	12/10/2018	30/07/2019	18/08/2017	28/11/2018	22/08/2019	29/08/2019	Yes	18/09/2019	Please Select...
19/NE/0152	260824	Evolocumab Athero-Risk study	13/05/2019	12/09/2019	18/06/2019	25/09/2019	26/09/2019		No		Sponsor
18/NS/0145	254786	IMreal	12/07/2019	18/07/2019	07/02/2019	05/09/2019	11/09/2019	05/11/2019	No		Sponsor
19/LO/0236	230338	EFFORT Trial	02/04/2019	30/07/2019	01/07/2019	22/08/2019	27/08/2019	29/08/2019	Yes	17/09/2019	Please Select...
18/SC/0427	220853	The Bronchiolitis Endotracheal Surfactant Study (BESS)	08/12/2017	23/07/2019	15/10/2018	04/09/2019	26/09/2019	03/10/2019	No		Sponsor
18/YH/0466	254204	LEADER 75	29/06/2018	02/12/2019	05/06/2019	05/12/2019	11/12/2019		No		Please Select...
19/EM/0097	257082	TUDCA-ALS	27/09/2019	21/10/2019	22/05/2019	25/11/2019	28/11/2019	29/05/2019	No		Please

Performance in Delivering Clinical Research

MREC Number	IRAS Number	Trial Name	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed	Maximum Number Of Patients Agreed	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial
16/NE/0398	219462	BioVentrix Revivent TC	Number Agreed	6	6	Date Agreed	20/04/2018	0	24/01/2019	0	Recruitment Finished
17/LO/0041	219676	CardioMEMS HF System OUS Post Approval Study	Number Agreed	10	10	Date Agreed	30/09/2019	4	21/06/2019	4	Recruitment Finished
16/SC/0197	203554	NOSTRA-Traumatic Brain Injury-3559/0001	Number Agreed	6	6	Date Agreed	30/11/2018	0	28/02/2019	0	Recruitment Finished
17/LO/0339	219974	Pembrolizumab/placebo in combination with CRT- locally advanced HNSCC	Number Agreed	6	6	Date Agreed	30/04/2018	0	27/08/2019	0	Recruitment Finished
17/WA/0420	235469	IRL790C003 Phase IIA Parkinson's Dykinesia Study	Number Agreed	4	4	Date Agreed	30/04/2019	0	27/08/2019	0	Recruitment Finished
15/NW/0142	164099	4072 CARD AR	Number Agreed	20	20	Date Agreed	31/01/2019	17	27/08/2019	17	Recruitment Finished
18/EM/0063	239564	ARISE: pAdsevonil in drug-ResiStant Epilepsy	Number Agreed	4	4	Date Agreed	26/02/2020	0	23/10/2019	0	Recruitment Finished