

# **Research & Development Performance in Initiating & Delivering Research October, 2019**

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 1<sup>st</sup> October 2018 – 30<sup>th</sup> September 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:
<b>18/NE/0023</b>	230930	Enterogel in the treatment of Irritable Bowel Syndrome with Diarrhoea	23/08/2018	17/10/2018	27/02/2018	21/11/2018	22/11/2018	23/11/2018	Yes	14/01/2019	NHS Provider
<b>18/NE/0092</b>	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...
<b>18/EM/0229</b>	250101	PROTECT 021IGAN17001	10/10/2018	14/02/2019	04/10/2018	25/01/2019	21/02/2019	21/02/2019	No		Please Select...
<b>18/WA/0242</b>	232678	The RaCeR study: Rehabilitation following Rotator Cuff Repair	27/07/2018	26/11/2018	06/09/2018	04/01/2019	04/01/2019	08/02/2019	Yes	18/03/2019	Please Select...
<b>17/NW/0662</b>	220156	APPRAISE ATP	11/10/2018	02/01/2019	22/03/2018	19/02/2019	19/03/2019	25/03/2019	No		Sponsor
<b>17/NE/0325</b>	227986	EMPOWER Trial	14/07/2017	19/12/2018	30/11/2017	01/02/2019	21/02/2019	08/07/2019	No		Sponsor
<b>18/LO/0813</b>	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...
<b>18/EM/0365</b>	0	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...
<b>19/NE/0011</b>	255897	CLEE011O12301C (TRIO033) - NATALEE	31/10/2018	30/01/2019	04/03/2019	03/06/2019	04/06/2019	14/06/2019	No		Both
<b>18/YH/0472</b>	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
<b>18/LO/1397</b>	247266	Diabetic Gastroparesis Study 2	25/07/2018	29/11/2018	06/11/2018	05/02/2019	08/03/2019	16/03/2019	No		Both
<b>19/NW/0158</b>	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...
<b>16/EM/0322</b>	202096	Tenecteplase in Wake-up Ischaemic Stroke	12/10/2018	30/07/2019	18/08/2017	28/11/2018	22/08/2019	29/08/2019	Yes	18/09/2019	Please Select...

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:
		Trial									
<b>19/NE/0152</b>	260824	Evolocumab Athero-Risk study	13/05/2019	12/09/2019	18/06/2019	25/09/2019	26/09/2019		No		Sponsor
<b>18/NS/0145</b>	254786	IMreal	12/07/2019	18/07/2019		05/09/2019	11/09/2019		No		Sponsor
<b>19/LO/0236</b>	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...
<b>18/SC/0427</b>	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

## 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
<b>17/SC/0237</b>	220963	Investigation of BI 1467335	Number Agreed	2	2	Date Agreed	17/12/2018	0	02/12/2018	0	Withdrawn By Sponsor
<b>17/LO/1656</b>	229212	CO39722 - Cobimetinib and atezolizumab v's pembrolizumab in melanoma	Number Agreed	3	3	Date Agreed	07/11/2018	2	07/11/2018	2	Recruitment Finished
<b>18/LO/1002</b>	242654	Study of GSK285 in patients with RRMM who have failed on Daratumumab	Number Agreed	2	2	Date Agreed	01/12/2018	1	19/10/2018	1	Recruitment Finished
<b>16/WM/0317</b>	206807	Restore (STRO 4889)	Number Agreed	10	10	Date Agreed	31/12/2018	1	31/12/2018	1	Recruitment Finished
<b>16/NE/0398</b>	219462	BioVentrix Revivent TC	Number Agreed	6	6	Date Agreed	20/04/2018	0	24/01/2019	0	Recruitment Finished
<b>17/LO/0041</b>	219676	CardioMEMS HF System OUS Post Approval Study	Number Agreed	10	10	Date Agreed	30/09/2019	4	21/06/2019	4	Recruitment Finished
<b>16/SC/0197</b>	203554	NOSTRA-Traumatic Brain Injury-3559/0001	Number Agreed	6	6	Date Agreed	30/11/2018	0	28/02/2019	0	Recruitment Finished
<b>17/LO/0339</b>	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
<b>17/WA/0420</b>	235469	IRL790C003 Phase IIA Parkinson's Dykinesia Study	Number Agreed	4	4	Date Agreed	30/04/2019	0	27/08/2019	0	Recruitment Finished
<b>15/NW/0142</b>	164099	4072 CARD AR	Number Agreed	20	20	Date Agreed	31/01/2019	17	27/08/2019	17	Recruitment Finished