

Performance in Initiating and Delivering Clinical Research

Why are we doing this?

- Through the NIHR (National Institute for Health Research) the Government wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research.
- The aim is to increase the number of patients who have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research.
- From 2013 for clinical trials, the NIHR will publish outcomes against contract NIHR benchmarks. Alder Hey holds one of these contracts.
- These outcomes include an a time a provider of NHS services receives site selection (for HRA approval) to the time when that provider recruits the first patient for that study (***Performance in Initiating Clinical Research***).
- It also includes the NHS providers performance in recruiting to time and target for commercial contract clinical trials (***Performance in Delivery of Clinical Research***).



Performance in Initiating and Delivering Clinical Research

Review of Previous Quarter Data (Q4 01/04/2017 to 31/03/2018) Adjusted Report for PI

Comparison of Alder Hey Children's NHS FT against national average

Performance in Initiating

Mean number of days between receipt of Date Site Selected and date of First Patient Recruited

All Providers = 66.1 [SD 53.2].

Alder Hey Children's NHS Foundation Trust = 64.9 days

Alder Hey was ranked 12th in league & 85th of 222 Providers.

Percentage total trials meeting the 70 day benchmark

All Providers = [60.7% of adjusted trials 32.1% of absolute trials]

Alder Hey Children's NHS Foundation Trust = 66.7%.

Alder Hey was ranked 5th in league & 70th of 222 Providers.

Performance in Delivery

Total closed trials meeting time and target (All Providers) = 52.1%

Alder Hey Children's NHS Foundation Trust = 66.7% (of closed trials =3).



Analysis of Performance in Initiating Clinical Research

(Time to first patient recruitment)

- **Total Trials Reported – 14** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/07/2017 to 30/06/2018))*
- **Total trials with no delays– 7** *(50% of reported trials)*
- **Total trials with delays– 7** *(50% of reported trials) Clinical trials that had some sort of delay.*
- **Of trials having delays (7), trials where fault lies with NHS provider – 1** *(7% of reported trials)*

Mean number of Days between Site Selected and First Patient Recruited (# trials recruited to = 11) –62 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 11) –57 days



Reporting Period Q1 18/19

- 01/07/2017 to 30/06/2018

NIHR Central Commissioning Facility

Time to first patient recruitment

Alder Hey Children's



NHS Foundation Trust

Performance in Initiating Clinical Research Q1

Research Ethics Number	IRAS 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	Reasons for Delay
17/LO/0693	226490	EXIST3 Rollover study	06/01/2017	01/09/2017	06/09/2017	15/09/2017	18/09/2017	19/09/2017	26/09/2017	N/A
17/SC/0039	220282	MAGPIE	17/02/2017	06/07/2017	18/04/2017	06/07/2017	13/07/2017	03/08/2017	14/09/2017	N/A
17/LO/0779	224562	Check Mate	10/05/2017	07/07/2017	01/07/2017	01/08/2017	08/08/2017	15/08/2017	21/09/2017	Sponsor
17/LO/1139	209931	Fever Pilot Trial	24/07/2017	17/08/2017	11/08/2017	25/09/2017	25/09/2017	02/10/2017	13/10/2017	N/A
16/NE/0413	210215	Givinostat DMD Study	17/10/2017	25/10/2017	13/03/2017	08/11/2017	14/11/2017	16/11/2017	15/12/2017	Sponsor
17/YH/0393	234355	(Paediatric Use of the Abbott Sensor Based Glucose Monitoring System)	02/01/2018	02/02/2018	07/02/2018	14/03/2018	20/03/2018	21/03/2018		Both
17/LO/1240	225539	Roche (BMS) CN001016 DMD Study	11/10/2017	15/12/2017	12/10/2017	15/12/2017	25/01/2018	25/01/2018		Sponsor

Table 1 of 2



Reporting Period Q1 18/19

- 01/07/2017 to 30/06/2018

NIHR Central Commissioning Facility

Time to first patient recruitment

Alder Hey Children's



NHS Foundation Trust

Performance in Initiating Clinical Research

Research Ethics Number	IRAS 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	Reasons for Delay
15/104/01	209448	The SANDWICH Trial	27/07/2017	08/11/2017	29/09/2017	08/12/2017	12/12/2017	08/01/2018	06/02/2018	Sponsor
17/NW/0649	227917	ASPECT Study	12/07/2017	19/03/2018	23/11/2017	19/03/2018	09/04/2018	09/04/2018		Neither
18/NW/0100	235042	BATCH Trial	18/10/2017	20/04/2018	13/04/2018	23/04/2018	24/05/2018	05/06/2018	11/06/2018	N/A
16/NS/0106	212541	RAACENO	24/11/2017	27/02/2018	04/04/2017	27/03/2018	08/04/2018	11/04/2018	31/05/2018	Sponsor
17/NW/0511	226627	RelTlrate	20/11/2017	14/03/2018	06/11/2017	17/04/2018	19/04/2018	19/04/2018	11/07/2018	Neither
18/SW/0138	247465	CPEX In Children with CF	10/05/2018	13/06/2018	13/06/2018	13/06/2018	22/06/2018	22/06/2018	06/07/2018	N/A
18/NW/0018	236551	Renastep	12/02/2018	11/04/2018	06/04/2018	16/04/2018	17/04/2018	17/04/2018	11/05/2018	N/A

Table 2 of 2



Inspired by Children

Analysis of Performance in Delivery of Clinical Research

(Recruitment to Time and Target)

- **Total Trials Reported – 7** *(Clinical trials hosted by Alder Hey Children's NHS FT and closed within a 12 month period (01/06/2017 to 30/06/2018).*
- **Total Trials Closed NOT Meeting Time and Target – 2** *Reasons: No patients seen meeting inclusion criteria*
- **Total Trials Closed Meeting Time and Target – 5** *(71.4%)*



Performance in Delivery of Clinical Research

Ethics Reference Number	IRAS Number	Name of Trial	Target Number Agreed?	Minimum Number Of Patients Agreed	Maximum Number Of Patients Agreed	Date To Recruit Agreed?	Date Agreed to recruit target number of patients	Number Of Patients Recruited At The Agreed Date	Number Of Study Participants Recruited	Date Trial Closed To Recruitment	Reason For Closure Of Trial
17/SS/0021	213673	Dravet Syndrome-Zogenix-1504	Number Agreed	3	3	Date Agreed	01/11/2017	3	3	19/12/2017	Recruitment Finished
17/LO/0693	226490	EXIST3 Rollover study	Number Agreed	1	1	Date Agreed	31/12/2022	1	1	23/10/2017	Recruitment Finished
16/SC/0416	210405	Medimmune RSV Healthy Preterm Infants	Number Agreed	2	2	Date Agreed	30/11/2017	0	0	30/11/2017	Withdrawn By Sponsor
14/WM/0013	143136	RSV Study ALS-8176-503 (MCRN2947)	Number Agreed	8	8	Date Agreed	30/03/2018	0	0	31/03/2018	Withdrawn By Sponsor
16/LO/0814	199311	Sanofi - DRI Sarilumab1	Range Agreed	0	1	Date Agreed	30/03/2018	0	0	31/03/2018	Recruitment Finished
16/WM/0512	218042	Shield-Phase 1 ID Study	Range Agreed	6	9	Date Agreed	31/01/2018	8	8	31/01/2018	Recruitment Finished
15/LO/2045	193136	SUMMIT 05-SMT C1100 in Ambulatory Boys with DMD	Number Agreed	2	2	Date Agreed	15/03/2018	3	3	28/06/2018	Recruitment Finished

Table 1 of 1

