Reporting Period Q2 18/19
- 01/10/2017 to 30/09/2018

Alder Hey Children's NHS
NHS Foundation Trust

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 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)***.

Alder Hey Children's NHS
NHS Foundation Trust

Performance in Initiating and Delivering Clinical Research

Review of Previous Quarter Data (Q1 01/07/2017 to 30/06/2018) 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 = 88.9 [SD 64.6].

Alder Hey Children's NHS Foundation Trust = 60.4 days

Alder Hey was ranked 4th in league & 49th of 222 Providers.

Performance in Delivery

Total closed trials meeting time and target (All Providers) = **54.6**%

Alder Hey Children's NHS Foundation Trust = **57.1**% (of closed trials =7).

Alder Hey Children's NHS
NHS Foundation Trust

NIHR Central Commissioning Facility

Time to first patient recruitment

Analysis of Performance in Initiating Clinical Research

(Time to first patient recruitment)

- **Total Trials Reported – 15** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/10/2017 to 30/09/2018)*
- **Total trials with no delays– 11** *(73.3% of reported trials)*
- **Total trials with delays– 4** *(26.7% of reported trials) Clinical trials that had some sort of delay.*
- **Of trials having delays (4), trials where fault lies with NHS provider – 1** *(6.7% of reported trials)*

Mean number of Days between Site Selected and First Patient Recruited (# trials recruited to = 7) –65 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 7) –52 days

Reporting Period Q2 18/19 - 01/10/2017 to 30/09/2018

Alder Hey Children's NHS
NHS Foundation Trust

NIHR Central Commissioning Facility

Time to first patient recruitment

Performance in Initiating Clinical Research Q2

REC Ref Number	IRAS Ref Number	Name of Clinical Trial	Date site invited	Date site selected	HRA Approval Date	Date site confirmed by sponsor	Date site confirmed	Date ready to start	Date 1st Patient Recruited	Source of Delay
16/NE/04	210215	Efficacy and Safety of Givinostat i	17/10/2017	25/10/2017	13/03/2017	08/11/2017	14/11/2017	16/11/2017	08/03/2018	N/A
17/LO/12	225539	CN001016: Phase 2/3 Study of BI	11/10/2017	15/12/2017	26/09/2017	15/12/2017	25/01/2018	25/01/2018		Sponsor
17/NW/05	226627	ITI rFVIIIFc study in HaemophiliaA	20/11/2017	14/03/2018	06/11/2017	17/04/2018	19/04/2018	19/04/2018	09/08/2018	Niether
18/NW/0(	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
18/EE008	238897	Tezidolid (Merck Gram Positive)	22/09/2017	25/06/2018	30/05/2018	27/06/2018	03/08/2018	06/08/2018		Niether
18/LO/07	245151	SHP633-301	21/05/2018	25/06/2018	19/06/2018	23/07/2018	03/08/2018	13/08/2018		Niether
18/LO/01	239586	Phase 1 study of WVE-210201 in	16/04/2018	01/08/2018	12/04/2018	13/08/2018	07/09/2018	05/10/2018		Sponsor

Table 1 of 2

Alder Hey Children's NHS
NHS Foundation Trust

NIHR Central Commissioning Facility

Time to first patient recruitment

Performance in Initiating Clinical Research

REC Ref Number	IRAS Ref Number	Name of Clinical Trial	Date site invited	Date site selected	HRA Approval Date	Date site confirmed by sponsor	Date site confirmed	Date ready to start	Date 1st Patient Recruited	Source of Delay
17/WS/01	230186	T-2017-01-Ph 1 paediatric PK stu	15/05/2018	28/08/2018	04/07/2018	27/09/2018	02/10/2018	10/10/2018		Sponsor
17/EM/03	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
16/NS/01	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/0(	227917	ASPECT Study	12/07/2017	19/03/2018	22/11/2017	19/03/2018	09/04/2018	09/04/2018		Niether
18/NW/01	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
17/YH/01	203556	SeluDex	11/04/2018	12/06/2018	12/12/2017	12/06/2018	06/08/2018	10/08/2018		Niether
17/YH/03	234355	PUGS (Paediatric Use of the Abb	02/01/2018	02/02/2018	07/02/2018	14/03/2018	20/03/2018	21/03/2018		NHS Provider
18/SW/01	247465	CPEX In Children with CF	10/05/2018	13/06/2018	13/06/2018	13/06/2018	20/06/2018	22/06/2018	06/07/2018	N/A

Table 2 of 2

NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

Alder Hey Children's NHS
NHS Foundation Trust

Analysis of Performance in Delivery of Clinical Research

(Recruitment to Time and Target)

- **Total Trials Reported – 8** *(Clinical trials hosted by Alder Hey Children's NHS FT and closed within a 12 month period (01/10/2017 to 30/09/2018).*
- **Total Trials Closed NOT Meeting Time and Target – 4** *Reasons: No patients seen, Short recruitment & shortage of staff, Sponsor withdrawn, Recruitment ended.*
- **Total Trials Closed Meeting Time and Target – 4** *(50%)*

Alder Hey Children's NHS
NHS Foundation Trust

NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

Performance in Delivery of Clinical Research

MREC Ref Number	IRAS Ref Number	Name of Clinical Trial	Target Agreed Yes /No	Minimum Target Agreed	Maximum Target Agreed	Target Date Agreed	Date agreed to recruit to target	Recruited at agreed date	Recruitment Total	Date trial closed to recruitment	Reason for Closure of trial
17/LO/069	226490	Long-term safety of Everolimus in patients with TSC related seizures	Yes	1	1	Yes	31/12/2022	1	1	23/10/2017	Recruitment Finished
16/SC/041	210405	Safety and Efficacy of MEDI8897 Against RSV in Healthy Preterm Infants	Yes	2	2	Yes	30/11/2017	0	0	30/11/2017	Withdrawn By Sponsor
17/SS/002	213673	Efficacy & Safety of ZX008 as Adjunctive therapy in Dravet Syndrome	Yes	3	3	Yes	01/11/2017	3	3	19/12/2017	Recruitment Finished
17/YH/039	234355	PUGS (Paediatric Use of the AbbottSensorBasedGlucoseMonitoringSystem)	Yes	6	6	Yes	13/04/2018	0	0	31/03/2018	Recruitment Finished
16/WM/05	218042	ST10103	Yes	6	9	Yes	20/02/2018	8	8	31/03/2018	Recruitment Finished
16/LO/081	199311	Sanofi - DRI Sarilumab1	Yes	0	1	Yes	18/12/2017	0	0	16/05/2018	Recruitment Finished
17/EE/007	220827	ADVOCATE Study CL010_168	Yes	1	1	Yes	30/03/2020	0	0	04/07/2018	Withdrawn By Sponsor
17/SC/005	219468	Secukinumab JIA AIN457 Paed	Yes	1	2	Yes	04/11/2020	1	1	28/09/2018	Withdrawn By Sponsor

Table 1 of 1