Reporting Period Q2 16/17
- 1/10/2015 to 30/09/2016

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 an initial benchmark of 70 days or less from the time a provider of NHS services receives a valid research application 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 (Q1 01/07/2015 to 30/06/2016) 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 Valid Research Application and date of First Patient Recruited

All Providers = 46.0 [SD 36.2]

Alder Hey Children's NHS Foundation Trust = 24.1 days

Alder Hey was not ranked. All Providers 220

Percentage total trials meeting the 70 day benchmark

All Providers = [**77.6**% of adjusted trials **49.3**% of absolute trials]

Alder Hey Children's NHS Foundation Trust = **69.2**% of adjusted trials **53.8**% of absolute trials

Alder Hey was not ranked. All Providers 220

Performance in Delivery

Total closed trials meeting time and target (All Providers) = **45.6**%

Alder Hey Children's NHS Foundation Trust = 66.7% (of closed trials =8).

Alder Hey was not ranked. All Providers 220

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NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Analysis of Performance in Initiating Clinical Research

(70 day benchmark – Time to first patient recruitment)

- **Total Trials Reported – 8** *(Every clinical trial given NHS permission at Alder Hey within the previous 12 months (01/07/2015 to 30/06/2016)*
- **Total trials meeting the 70 day benchmark – 3** *(37.5% of reported trials) Clinical trials that have recruited the first participant within 70 days of a Valid Research Application*
- **Total trials still eligible to comply with 70 day benchmark – 0** *(0% of reported trials) Clinical trials where 70 day benchmark could still be met at end of reporting quarter*
- **Total trials NOT meeting the 70 day benchmark – 5** *(62.5% of reported trials) Clinical trials that either recruited the first patient after the 70 day target elapsed or have not yet recruited and 70 days have already elapsed*
- **Of trials not meeting 70 day benchmark (5), total trials where fault lies with NHS provider – 0** *(0% of reported trials) Clinical trials where reason for failure lies with NHS provider*

- **Mean number of Days between Valid Research Application and First Patient Recruited (# trials recruited to = 5) – 73 days**
- **Median number of Days between Valid Research Application and First Patient Recruited (# trials recruited to = 5) – 38 days**

NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Alder Hey Children's NHS
NHS Foundation Trust

Analysis of Performance in Initiating Clinical Research

(70 day benchmark – Time to first patient recruitment)

- **Total Trials Reported – 4** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/07/2015 to 30/06/2016)*
- **Total trials meeting the 70 day benchmark – 0** *(0% of reported trials) Clinical trials that have recruited the first participant within 70 days of a Valid Research Application*
- **Total trials still eligible to comply with 70 day benchmark – 1** *(25% of reported trials) Clinical trials where 70 day benchmark could still be met at end of reporting quarter*
- **Total trials NOT meeting the 70 day benchmark – 3** *(75% of reported trials) Clinical trials that either recruited the first patient after the 70 day target elapsed or have not yet recruited and 70 days have already elapsed*
- **Of trials not meeting 70 day benchmark (3), total trials where fault lies with NHS provider – 0** *(0% of reported trials) Clinical trials where reason for failure lies with NHS provider*

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NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Alder Hey Children's NHS
NHS Foundation Trust

Performance in Initiating Clinical Research Q1

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met	Comments
15/NW/0500	180608	POPPET Study (PK of continuous infusion of Pip/Taz in children)	07/12/2015	22/12/2015	Yes	
15/LO/0920	181642	A Phase I, 2-Part, Open-label, Multiple Oral Dose Study of the Safety, Tolerability and Pharmacokinetics of up to 2 Formulations of SMT C1100 in Healthy Adult Male Subjects and a Selected Formulation of SMT C1100 in Paediatric Subjects with Duchenne Muscular Dystrophy (DMD)	05/01/2016	26/01/2016	Yes	
15/LO/0718	174025	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	26/01/2016	04/03/2016	Yes	
14/NI/1075	161871	Study in infants and toddlers with Respiratory Syncytial Virus	26/10/2015		No	This was opened for the RSV season but so far the season hasn't happened.
15/EM/0103	130101	SIOP Ependymoma II	18/01/2016		No	Issues with radiology procedures that delayed all sites & still effects the study.
15/SC/0429	142341	Prospective study of understudied drugs in children	01/03/2016	30/05/2016	No	Sponsor changed the inclusion criteria within the approval process, so it took longer to see any eligible patients.
14/SC/1416	156215	IgNiTE: Immunoglobulin in the treatment of encephalitis	01/03/2016		No	No patients seen
15/NE/0357	160919	SBoCK	18/03/2016	05/10/2016	No	Low target, difficult to find patients, only us & 1 other site have recruited.

Table 1 of 2

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NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Alder Hey Children's NHS
NHS Foundation Trust

Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date of First Patient Recruited	Benchmark Met	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Comments
16/LO/0537	191351	ZX008 Adjunctive Therapy in Children with Dravet Syndrome	31/08/2016	No	21/06/2016	21/06/2016	21/06/2016	24/06/2016	24/06/2016	24/06/2016	Patient consented in time (19/7/16) but length of screening took it over the threshold by 1 day..
14/YH/1282	161739	A Phase 2 Randomised, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study To Evaluate The Safety, Efficacy, Pharmacokinetics And Pharmacodynamics Of PF-06252616 In Ambulatory Boys With Duchenne Muscular Dystrophy	31/10/2016	No	16/08/2016	16/08/2016	15/06/2016	16/08/2016	06/09/2016	08/09/2016	Patient consented in time (27/9/16) but length of screening (42 days) took it over the threshold.
16/LO/0814	199311	An Open-label, Sequential, Ascending, Repeated Dose-finding Study of Sarilumab, Administered with Subcutaneous (SC) Injection, in Children and Adolescents, Aged 2 to 17 Years, with Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA) Followed by an Extension Phase		No	06/07/2016	06/07/2016	06/07/2016	06/07/2016	09/09/2016	09/09/2016	Patient agreed to be in study on time, but the sponsor would not randomise as patients were put on a waiting list across Europe.
16/LO/0017	174562	A PHASE I/II, MULTICENTER, OPEN-LABEL, DOSE ESCALATION STUDY OF THE SAFETY AND PHARMACOKINETICS OF COBIMETINIB IN PEDIATRIC AND YOUNG ADULT PATIENTS WITH PREVIOUSLY TREATED SOLID TUMORS		N/A	23/08/2016	23/08/2016	08/08/2016	23/08/2016	23/08/2016	28/09/2016	Still time to recruit

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 – 12** *(Clinical trials hosted by Alder Hey Children's NHS FT and closed within a 12 month period (01/10/2015 to 30/09/2016).*
- **Total Trials Closed NOT Meeting Time and Target – 4** *Reasons:*
  Studies have rare condition /no patients seen.
- **Total Trials Closed Meeting Time and Target – 8** *(66.7%)*

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NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

Alder Hey Children's NHS
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Performance in Delivery of Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Reason For Closure Of Trial
14/LO/1387	157630	A DOUBLE-BLIND, PLACEBO-CONTROLLED, TWO-PART STUDY TO INVESTIGATE THE DOSE-RANGING SAFETY AND PHARMACOKINETICS, FOLLOWED BY THE EFFICACY AND SAFETY OF CANNABIDIOL (GWP42003-P) IN CHILDREN AND YOUNG ADULTS WITH DRAVET SYNDROME.	Number Agreed	7	7	Date Agreed	01/11/2015	7	01/11/2015	Recruitment Finished
11/NW/0659	81802	PMREC1207	Number Agreed	2	2	Date Agreed	30/06/2015	2	27/10/2015	Recruitment Finished
13/NW/0320	123739	A Phase Ib open label, multi-centre study to investigate the pharmacokinetics, pharmacodynamics, and safety of Tocilizumab following subcutaneous administration in patients with Polyarticular-Course Juvenile Idiopathic Arthritis - WA28117	Number Agreed	1	1	Date Agreed	01/12/2015	2	01/12/2015	Recruitment Finished
12/NW/0717	113172	Fosaprepitant PK/PD CINV in Pediatric Cancer Patients	Number Agreed	4	4	Date Agreed	22/03/2017	4	29/04/2016	Recruitment Finished
13/NW/0811	138665	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	Number Agreed	1	1	Date Agreed	01/04/2018	1	09/02/2016	Recruitment Finished
15/NE/0052	170560	PEDAL: Longterm Outcome of Children Enrolled in Study ROPP200801	Number Agreed	1	1	Date Agreed	01/08/2016	1	04/12/2015	Recruitment Finished
13/YH/0201	129722	Study of Sativex in Children (aged 818) with Severe Spasticity	Number Agreed	8	8	Date Agreed	29/02/2016	12	08/07/2016	Recruitment Finished
15/LO/0920	181642	SMTC11004 - Phase 1 study in healthy volunteers and DMD patients	Number Agreed	2	2	Date Agreed	30/06/2016	2	05/07/2016	Recruitment Finished
14/NI/1075	161871	Study in infants and toddlers with Respiratory Syncytial Virus	Number Agreed	1	1	Date Agreed	30/04/2016	0	04/02/2016	Withdrawn By Sponsor
12/EM/0393	110701	WA28029 Decreasing TCZ dosing frequency in patients with sJIA	Number Agreed	2	2	Date Agreed	01/10/2017	1	17/05/2016	Withdrawn By Sponsor
15/NW/0573	174966	NP25737 PK/Safety study of TCZ in patients <2yrs with active sJIA	Number Agreed	1	1	Date Agreed	01/01/2017	0	28/06/2016	Withdrawn By Sponsor
13/NW/0321	130144	WA28029 Decreasing TCZ dosing frequency in patients with sJIA	Number Agreed	1	1	Date Agreed	01/10/2016	0	24/08/2016	Withdrawn By Sponsor