Reporting Period Q3 16/17
- 1/1/2016 to 31/12/2016

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 (or 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)***.

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Alder Hey Children's NHS Foundation Trust

Performance in Initiating and Delivering Clinical Research

Review of Previous Quarter Data (Q2 01/10/2015 to 30/09/2016) 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 = 48.9 [SD 40.2]

Alder Hey Children's NHS Foundation Trust = 41 days

Alder Hey was ranked 10th in league & 74th all Providers.

Percentage total trials meeting the 70 day benchmark

All Providers = [**76.8**% of adjusted trials **45.2**% of absolute trials]

Alder Hey Children's NHS Foundation Trust = **50**% of adjusted trials **37.5**% of absolute trials

Alder Hey was ranked 19th in league & 150th all Providers.

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 =12).

Alder Hey was ranked 7th in league. All Providers 220

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Alder Hey Children's NHS
NHS Foundation Trust

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 – 6** *(Every clinical trial given NHS permission at Alder Hey within the previous 12 months (01/1/2016 to 31/12/2016)*
- **Total trials meeting the 70 day benchmark – 2** *(33.3% 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 – 4** *(66.6% 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 (4), 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 = 4) – 87.5 days**
- **Median number of Days between Valid Research Application and First Patient Recruited (# trials recruited to = 4) – 64 days**

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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 – 4** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/1/2016 to 31/12/2016)*
- **Total trials meeting the 70 day benchmark – 2** *(50% 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 – 2** *(50% 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 (2), 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 Site Selected and First Patient Recruited (# trials recruited to = 2) – 30.5 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 2) – 30.5 days

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NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

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Performance in Initiating Clinical Research Q3

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met	Comments
15/LO/0920	181642	NHS Permission	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/EM/0103	130101	NHS Permission	SIOP Ependymoma II	18/01/2016		No	Issues with radiology procedures that delayed all sites & still effects the study.
15/LO/0718	174025	NHS Permission	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	26/01/2016	04/03/2016	Yes	
15/SC/0429	142341	NHS Permission	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	NHS Permission	IgNiTE: Immunoglobulin in the treatment of encephalitis	01/03/2016		No	No patients seen
15/NE/0357	160919	NHS Permission	SBoCK	18/03/2016	05/10/2016	No	Low target, difficult to find patients, only us & 1 other site have recruited.

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NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	First Patient Recruited?	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/0814	199311	HRA Approval	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		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/NW/0629	211995	HRA Approval	The cystic fibrosis (CF) anti-staphylococcal antibiotic prophylaxis trial (CF START); a randomised registry trial to assess the safety and efficacy of flucloxacillin as a longterm prophylaxis agent for infants with CF	No		No		20/10/2016	16/09/2016		29/11/2016	29/11/2016	No patients seen
16/WM/0276	207822	HRA Approval	Safety of Nasal Influenza Immunisation in Children with Asthma: The SNIFFLE 4 study	Yes	13/10/2016	Yes	09/09/2016	09/09/2016	22/08/2016	09/09/2016	10/10/2016	10/10/2016	
16/YH/0269	187177	HRA Approval	A Study of the Palatability and Acceptability of Liquid Methotrexate (The PALM Study)	Yes	14/11/2016	Yes		18/10/2016	18/10/2016		18/10/2016	18/10/2016	

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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 – 11** *(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 – 5** *Reasons: Studies have rare condition /no patients seen.*
- **Total Trials Closed Meeting Time and Target – 6** *(54.5%)*

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NHS Foundation Trust

NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

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	Comments
14/NI/1075	161871	Study in infants and toddlers with Respiratory Syncytial Virus	Yes	1	1	Yes	30/04/2016	0	04/02/2016	Withdrawn By Sponsor	Rare condition
13/NW/0811	138665	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	Yes	1	1	Yes	01/04/2018	1	09/02/2016	Recruitment Finished	
12/NW/0717	113172	Fosaprepitant PK/PD CINV in Pediatric Cancer Patients	Yes	4	4	Yes	22/03/2017	4	29/04/2016	Recruitment Finished	
12/EM/0393	110701	WA28029 Decreasing TCZ dosing frequency in patients with sJIA	Yes	2	2	Yes	01/10/2017	1	17/05/2016	Withdrawn By Sponsor	Not enough patients seen
14/NE/0122	152119	Long term extension study of tocilizumab in children	Yes	1	1	Yes	30/11/2017	2	27/05/2016	Recruitment Finished	Only 1 patient seen.

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NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

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	Comments
15/NW/0573	174966	NP25737 PK/Safety study of TCZ in patients <2yrs with active sJIA	Yes	1	1	Yes	01/01/2017	0	28/06/2016	Withdrawn By Sponsor	No patients seen
15/LO/0920	181642	SMTC11004 - Phase 1 study in healthy volunteers and DMD patients	Yes	2	2	Yes	30/06/2016	2	05/07/2016	Recruitment Finished	
13/YH/0201	129722	Study of Sativex in Children (aged 818) with Severe Spasticity	Yes	8	8	Yes	29/02/2016	12	08/07/2016	Recruitment Finished	
15/LO/0718	174025	An open-label study to characterize the pharmacokinetics and pharmacodynamics of mepolizumab administered subcutaneously in children from 6 to 11 years of age with severe eosinophilic asthma	Yes	2	2	Yes	09/07/2016	1	09/07/2016	Recruitment Finished	
13/NW/0321	130144	WA28029 Decreasing TCZ dosing frequency in patients with sJIA	Yes	1	1	Yes	01/10/2016	0	24/08/2016	Withdrawn By Sponsor	No patients seen
13/LO/0010	112721	WA25615 - A phase IIa, international, multicenter, open-label, uncontrolled study to evaluate the safety and pharmacokinetics of 4 x 375 mg/m2 intravenous rituximab in paediatric patients with severe granulomatosis with polyangiitis (Wegener?s) or mi	Yes	1	1	Yes	30/09/2016	3	23/11/2016	Recruitment Finished	

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