

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 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 (Q1 01/7/2016 to 30/6/2017) 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 = 70.6 [SD 56.0].

Alder Hey Children's NHS Foundation Trust = 61.3 days

Alder Hey was ranked 18th in league & 64th of 196 Providers.

Percentage total trials meeting the 70 day benchmark

All Providers = [53.9% of adjusted trials 30.5% of absolute trials]

Alder Hey Children's NHS Foundation Trust = 54.5%.

Alder Hey was ranked 8th in league & 70th of 196 Providers.

Performance in Delivery

Total closed trials meeting time and target (All Providers) = 54.5%

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



Analysis of Performance in Initiating Clinical Research

(70 day benchmark – Time to first patient recruitment)

- **Total Trials Reported – 19** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/10/2016 to 30/9/2017))*
- **Total trials meeting the 70 day benchmark – 8** *(42.1% 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 – 11** *(57.9% 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 (11), total trials where fault lies with NHS provider – 2** *(10.5% 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 = 19) –59.6 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 19) –60 days



Reporting Period Q2 17/18

- 1/10/2016 to 30/9/2017

NIHR Central Commissioning Facility

70 day benchmark – Time to first patient recruitment

Alder Hey Children's



NHS Foundation Trust

Performance in Initiating Clinical Research Q2

Research Ethics Committee Reference Number	Integrated Research Application System 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 Patient Recruited	Comments	Reasons for delay correspond to:
17/SS/0021	213673	Dravet Syndrome-Zogenix-1504	31/10/2016	15/06/2017	14/06/2017	08/08/2017	10/08/2017	10/08/2017	15/09/2017	Contract negotiations took longer than expected	Both
16/YH/0452	130824	VINILO	07/12/2016	04/01/2017	09/12/2016	28/02/2017	14/04/2017	03/05/2017	No Patient Recruited yet	Complex costings & IRMER review (outside of trust) delays confirmation.	Neither
16/LO/1987	207718	CLIMB-CF	09/01/2017	30/03/2017	19/12/2016	30/03/2017	15/05/2017	01/06/2017	No Patient Recruited yet	We would have met the target but patient DNA'd & then PI was on leave.	Neither
16/NW/0629	211995	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	20/10/2016	20/10/2016	16/09/2016		29/11/2016	29/11/2016	06/02/2017	Staff were not available within the benchmark period to recruit in time.	NHS Provider
17/SC/0093	217353	AWARD-PEDS: Assessment of Weekly Administration of LY2189265 in Diabetes-PEDIatric Study	23/03/2017	23/03/2017	19/12/2016	26/06/2017	29/06/2017	29/06/2017	No Patient Recruited yet	Temporary staffing problems due to sickness & getting staff in post delayed the approval of study.	NHS Provider

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Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System 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 Patient Recruited	Comments	Reasons for delay correspond to:
16/SC/0596	214948	CONTRACT	26/10/2016	16/12/2016	11/01/2017	02/02/2017	23/01/2017	24/01/2017	10/03/2017	Sponsor delayed green light because a couple of things (unspecified) were not in place & they wanted all 3 sites to open simultaneously.	Sponsor
16/LO/2002	214578	ESSENCE	16/11/2016	26/04/2017	25/01/2017	19/04/2017	05/06/2017	20/06/2017	No Patient Recruited yet	Sponsor insisted on 2nd contract for surgical procedure but did not execute until everything else was in place.	Sponsor
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	Patient signed informed consent in time for benchmark (1/9/17) but could not be randomised as cohort was temporarily suspended & meant that it fell just outside of target.	Sponsor
17/SC/0055	219468	Secukinumab JIA	28/02/2017	28/02/2017	06/04/2017	16/08/2017	28/02/2017	02/10/2017	No Patient Recruited yet	Sponsor had its own timetable & it did not allow us to meet the benchmark.	Sponsor
16/SC/0416	210405	Medimmune RSV Healthy Preterm Infants	24/04/2017	26/06/2017	30/09/2016	28/09/2017	02/10/2017	02/10/2017	No Patient Recruited yet	Sponsor had its own timetable to open 1st week October for the RSV season & it did not allow us to meet the benchmark.	Sponsor
17/EE/0079	220827	ADVOCATE Study	21/12/2016	31/05/2017	06/04/2017	23/08/2017	29/08/2017	03/10/2017	No Patient Recruited yet	Sponsor controlled the timing & speed of setup & we could not meet benchmark.	Sponsor

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Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System 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 Patient Recruited	Comments	Reasons for delay correspond to:
16/YH/0269	187177	A Study of the Palatability and Acceptability of Liquid Methotrexate (The PALM Study)	18/10/2016	18/10/2016	18/10/2016	18/10/2016	18/10/2016	18/10/2016	14/11/2016		Achieved Benchmark
16/LO/0831	196728	"Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with Community-acquired Pneumonia (CAP): a randomised controlled trial."	17/11/2016	28/03/2017	11/11/2016	13/01/2017	23/01/2017	29/03/2017	17/04/2017		Achieved Benchmark
16/WM/0512	218042	A Phase 1, Open-Label, Randomised, Repeat Dose, Parallel Group Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Ferric Maltol at Three Dosage Levels in Paediatric Subjects aged 10-17 years of age with iron deficiency (with or without anaemia)	23/02/2017	23/02/2017	23/02/2017	10/03/2017	16/03/2017	28/03/2017	27/04/2017		Achieved Benchmark
16/EE/0286	205761	Closed Loop from Onset in Type 1 Diabetes (CLOuD)	03/04/2017	03/04/2017	10/11/2016	28/02/2017	24/04/2017	24/04/2017	10/05/2017		Achieved Benchmark
16/LO/2141	200571	Biomed	07/02/2017	02/05/2017	06/04/2017	18/04/2017	09/05/2017	24/05/2017	26/06/2017		Achieved Benchmark
17/LO/0693	226490	EXIST3 Rollover study	06/01/2017	01/09/2017	06/09/2017	15/09/2007	18/09/2017	19/09/2017	26/09/2017		Achieved Benchmark
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		Achieved Benchmark
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		Achieved Benchmark

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Analysis of Performance in Delivery of Clinical Research

(Recruitment to Time and Target)

- **Total Trials Reported – 3**

(Clinical trials hosted by Alder Hey Children's NHS FT and closed within a 12 month period (01/10/2016 to 30/09/2017).

- **Total Trials Closed NOT Meeting Time and Target – 0**

Reasons:

- **Total Trials Closed Meeting Time and Target – 3**

(100%)



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	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 the Agreed Target Date	Total Number of Study Participants Recruited	Date the Trial Closed to Recruitment	Reason for Closure of Trial
12/NW/0367	104793	MCRN177-PLUTO	Number Agreed	2	2	Date Agreed	31/1/17	2	2	20/2/17	Global target reached
13/LO/0010	112721	MCRN204-Rituximab PePRS	Number Agreed	1	1	Date Agreed	30/9/16	3	3	23/11/16	Global target reached
14/YH/1282	161739	Pfizer DMD study-PF-06252616	Number Agreed	2	2	Date Agreed	7/4/17	2	2	7/4/17	End of recruitment

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