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)***.

Alder Hey Children's NHS Foundation Trust

Performance in Initiating and Delivering Clinical Research

Review of Previous Quarter Data (Q1 01/07/2014 to 30/06/2015) 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 = 48.1 [SD 41.5]

Alder Hey Children's NHS Foundation Trust = 28.8 days

Rank of Alder Hey for Mean against All Providers 20th out of 211

Percentage total trials meeting the 70 day benchmark

All Providers = 75.4% of analysed trials

Alder Hey Children's NHS Foundation Trust = 92.9%

Rank for Alder Hey of % of Trials Meeting Benchmark out of All Providers 57th out of 209

Performance in Delivery

Total closed trials meeting time and target (All Providers) = 50.3%

Alder Hey Children's NHS Foundation Trust = 0.0% (of all the trials, only 2 closed)

Rank for Alder Hey of Proportion of Closed Trials Recruiting Time and Target 86th out of 209

Reporting Period Q2 15/16 – 01/10/2014 to 30/09/2015

Alder Hey Children's NHS
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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	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient	Benchmark Met	Comments
13/NW/0839	Midazolam Paediatric Accelerator Mass Spectrometry Evaluation Research Study(PAMS): a multi-centre clinical study to evaluate the use of a microtrace dose of 14C-labelled midazolam and Accelerator Mass Spectrometry (AMS) bioanalysis as new tools in drug development to determine pharmacokinetics in neonates, infants and toddlers.	14/07/2014	22/07/2014	8	Yes	
14/NE/0122	LONG-TERM EXTENSION STUDY TO EVALUATE THE SAFETY AND EFFICACY OF SUBCUTANEOUS TOCILIZUMAB IN PATIENTS WITH POLYARTICULAR-COURSE AND SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS	14/07/2014	29/07/2014	15	Yes	
14/NW/0302	BOTOX? in the Treatment of Urinary Incontinence Due to Overactive Bladder in Patients 12 to 17 Years of Age	28/08/2014	27/10/2014	60	Yes	
14/NI/1038	A Prospective Randomized Controlled Study Evaluating the Safety and Efficacy of EVICEL? used for SutureLine Sealing in DuraMater Closure during Paediatric Neurosurgical Cranial Procedures	09/09/2014	09/10/2014	30	Yes	
14/WM/0159	Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE 2 study	11/09/2014	08/10/2014	27	Yes	
14/NS/0089	Timing of Surgical Intervention for Developmental Dysplasia of the Hip	21/11/2014	02/01/2015	42	Yes	

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70 day benchmark – Time to first patient recruitment

Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient	Benchmark Met	Comments
14/NW/0069	A Phase I, OpenLabel, Multicentre Study to Assess the Pharmacokinetics and Safety of Naloxegol in Paediatric Patients Ages = 6 Months to < 18 Years Receiving Treatment with Opioids	02/12/2014	29/12/2014	27	Yes	
11/NW/0659	PMREC1207	19/02/2015	04/03/2015	13	Yes	
14/LO/1565	MYPAN	02/03/2015	09/03/2015	7	Yes	
14/LO/1773	A study to test the safety of the SMT C1100 in boys with DMD	07/01/2015	04/02/2015	28	Yes	
14/NW/1110	rEECur	04/02/2015	23/03/2015	47	Yes	
14/NW/1403	Non-invasive measurement of intracranial pressure and cerebral oxygenation in paediatric brain injury	05/04/2015	21/05/2015	46	Yes	
15/NE/0052	Long-term Outcome of Children Enrolled in Study ROPP-2008-01 Previously Treated with rhIGF-1/rhIGFBP-3 for the Prevention of Retinopathy of Prematurity (ROP) or Who Received Standard Neonatal Care	18/05/2015	12/06/2015	25	Yes	
14/LO/1794	An open label extension study to investigate the safety of cannabidiol (GWP42003-P; CBD) in children and adults with inadequately controlled Dravet or Lennox-Gastaut Syndromes	21/05/2015	07/07/2015	47	Yes	

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70 day benchmark – Time to first patient recruitment

Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient	Benchmark Met	Comments
09/H0405/9	A double blind randomised multicentre, placebo-controlled trial of combined ACE-inhibitor and beta-blocker therapy in preventing the development of cardiomyopathy in genetically characterised males with DMD without echo-detectable left ventricular dysfunction	25/07/2014	17/10/2014	84	No	1st patient identified recruited at first available opportunity. No eligible patients seen prior to this first patient within 70 day window. Site has a target of 10 with 10 now recruited. Study end date is 01/11/2017.
13/EE/0202	Intergroup Trial for Children or Adolescents with Bcell NHL or BAL: Evaluation of Rituximab Efficacy and Safety in High Risk Patients.	18/07/2014	28/11/2014	133	No	Sponsor (University of Birmingham) insist on only arranging a site initiation visit after R&D approval has been issued. This can mean dealys of weeks before green light is issued and centre can begin recruitment
14/LO/1387	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.	06/10/2014	30/12/2014	85	No	Patient approached and consented on 02/12/2014. However, the protocol requires a 28 day screening period and therefore at the point of randomisation into the study we have surpassed the 70 day benchmark by 15 days.
14/NW/1067	Phase IIa, Randomised, Controlled, Open Label Trial of Rosuvastatin for the Prevention of Aminoglycoside Induced Kidney Toxicity in Children with Cystic Fibrosis	05/02/2015			No	After approval was given sponsor delayed to to not having central lab accreditation
14/WS/1149	An Exploratory RCT of a Psychosocial Group Intervention for Epilepsy	30/03/2015			No	Study team thought it could be done with existing staff but now has assistance to deliver the study.
15/NW/0093	Study to evaluate the optimal dose of remifentanil infusion(effective dose in 80% of patients) required to ensure apnoea (of 30 seconds duration) during magnetic resonance imaging of the heart under general anaesthesia in children aged 1 to 6 years.	15/06/2015		N/A	N/A	

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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 – 20 (not adjusted 4 N/A)** *(Every clinical trial given NHS permission at Alder Hey within the previous 12 months (01/07/2014 to 30/06/2015)*
- **Total trials meeting the 70 day benchmark – 13** *(92.9% 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 – 2** *(14.2% 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 – 1** *(7.1% 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 (1), total trials where fault lies with NHS provider – 1** *(6.2% 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 = 14) – 29 days**
- **Median number of Days between Valid Research Application and First Patient Recruited (# trials recruited to = 14) – 27 days**

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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	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
12/NW/0367	MCRN177-PLUTO	2	13/04/2026	Open	N/A	
12/NW/0717	Fosaprepitant in Nausea & Vomiting	4	08/03/2017	Open	N/A	Currently suspended by Sponsor
13/NW/0321	A Phase Ib open label, multi-centre study to investigate the pharmacokinetics, pharmacodynamics, and safety of Tocilizumab following subcutaneous administration in patients with systemic juvenile idiopathic arthritis - WA28118	1	01/12/2015	Open	N/A	
13/YH/0201	THE EFFICACY, SAFETY AND TOLERABILITY OF SATIVEX AS AN ADJUNCTIVE TREATMENT TO EXISTING ANTISPASTICITY MEDICATIONS IN CHILDREN AGED 8 TO 18 YEARS WITH SPASTICITY DUE TO CEREBRAL PALSY OR TRAUMATIC CENTRAL NERVOUS SYSTEM INJURY WHO HAVE NOT RESPONDED ADEQUATELY TO THEIR EXISTING ANTI-SPASTICITY MEDICATIONS: A PARALLEL GROUP RANDOMISED, DOUBLE-BLIND, PLACEBOCONTROLLED STUDY FOLLOWED BY A 24-WEEK OPEN LABEL EXTENSION PHASE.	8	30/12/2015	Open	N/A	
14/WM/0013	A Randomized, Doubleblind, Placebocontrolled, 2Part Study of Orally Administered ALS008176 to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Dosing and Multiple Ascending Dosing in Infants Hospitalized with Respiratory Syncytial Virus (RSV) Infection	20	30/04/2015	Open	N/A	
13/NW/0811	A Single-Dose Study to Assess the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Odanacatib in Adolescents and Young Adults Treated with Glucocorticoids	6	11/01/2016	Open	N/A	

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Performance in Delivery of Clinical Research

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
14/EM/0084	A Prospective, Randomized, Controlled, Study Evaluating the Safety and Effectiveness of EVARREST? Sealant Matrix in Controlling Mild or Moderate Hepatic Parenchyma or Soft Tissue Bleeding During Open Abdominal, Retroperitoneal, Pelvic and Thoracic (non-cardiac) Surgery in Paediatric Patients	8	31/07/2015	Open	N/A	
14/NW/0176	A Prospective, Randomised, Controlled Study Evaluating EVICEL? Fibrin Sealant as an Adjunct to Haemostasis During Abdominal, Retroperitoneal, Pelvic or Thoracic (Non-Cardiac) Surgery in Paediatric Patients	7	30/06/2015	Open	N/A	
14/NW/0302	BOTOX? in the Treatment of Urinary Incontinence Due to Overactive Bladder in Patients 12 to 17 Years of Age	10	01/09/2016	Open	N/A	
14/NI/1038	A Prospective Randomized Controlled Study Evaluating the Safety and Efficacy of EVICEL? used for SutureLine Sealing in DuraMater Closure during Paediatric Neurosurgical Cranial Procedures	6	30/09/2016	Open	N/A	
14/NW/0069	A Phase I, OpenLabel, Multicentre Study to Assess the Pharmacokinetics and Safety of Naloxegol in Paediatric Patients Ages = 6 Months to < 18 Years Receiving Treatment with Opioids	4	31/05/2016	Open	N/A	
11/NW/0659	PMREC1207	2	30/06/2015	Open	N/A	
14/NW/1110	rEECur	3	30/09/2018	Open	N/A	
14/NW/1403	Non-invasive measurement of intracranial pressure and cerebral oxygenation in paediatric brain injury	45	07/04/2016	Open	N/A	
14/LO/1794	An open label extension study to investigate the safety of cannabidiol (GWP42003-P; CBD) in children and adults with inadequately controlled Dravet or Lennox-Gastaut Syndromes	1	01/01/2018	Open	N/A	

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Recruitment to time and target for commercial contract clinical trials

Performance in Delivery of Clinical Research

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
12/NW/0694	A 12 week randomized, openlabel, active comparator period followed by a 12 week safety extension period to evaluate the safety and efficacy of Fesoterodine in subjects aged 6 to 16 years and >25 kg with symptoms of detrusor overactivity associated with a neurological condition (Neurogenic Detrusor Overactivity).	2	31/12/2014	Closed - Follow Up Complete	No	No patients seen for this study, closed by sponsor.
13/SC/0183	A three-arm, randomized, double-blind, placebo-controlled study of the efficacy and safety of two trough-ranges of everolimus as adjunctive therapy in patients with tuberous sclerosis complex (TSC) who have refractory partial-onset seizures	2	08/02/2016	Closed - In Follow Up	No	Rare condition, 2 patients screended but 1 failed.
11/EM/0014	MCRN126 (F506-CL-0404) - A Long-term, Open-label, Non-comparative Study to Evaluate theSafety and Efficacy of a Modigraf? Based Immunosuppression Regimen in Paediatric Solid Allograft Recipients.	2	01/03/2018	Open	Yes	Still open & recruiting but reached target.
13/LO/0010	MCRN204-Rituximab	1	01/12/2014	Open	Yes	Still open & recruiting but reached target.
12/EM/0393	MCRN214 (WA28029) - A STUDY TO EVALUATE DECREASED DOSE FREQUENCY IN PATIENTS WITH ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) WHO EXPERIENCE LABORATORY ABNORMALITIES DURING TREATMENT WITH TOCILIZUMAB.	2	17/12/2015	Open	Yes	Still open & recruiting but reached target.
07/H0904/84	The national programme for enhanced pneumococcal surveillance - The national programme for enhanced pneumococcal surveillance of complicated pneumococcal pneumonia and empyema in UK children	60	01/08/2016	Open	Yes	Still open & recruiting but reached target.

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Performance in Delivery of Clinical Research

Research Ethics Committee Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
13/NW/0320	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	1	01/12/2015	Open	Yes	Still open & recruiting but reached target.
13/SC/0452	A Phase 3, 2Arm, Roll-OverStudy to Evaluate the Longterm Safety and Pharmacodynamics of Ivacaftor Treatment in Pediatric Subjects With Cystic Fibrosis and a CFTR Gating Mutation	1	31/12/2016	Open	Yes	Still open & recruiting but reached target.
14/NE/0122	LONG-TERM EXTENSION STUDY TO EVALUATE THE SAFETY AND EFFICACY OF SUBCUTANEOUS TOCILIZUMAB IN PATIENTS WITH POLYARTICULAR-COURSE AND SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS	1	01/07/2016	Open	Yes	Still open & recruiting but reached target.
14/LO/1387	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.	7	01/11/2015	Open	Yes	Still open & recruiting but reached target.
14/LO/1773	A study to test the safety of the SMT C1100 in boys with DMD	4	30/06/2015	Open	Yes	Still open & recruiting but reached target.
15/NE/0052	Long-term Outcome of Children Enrolled in Study ROPP-2008-01 Previously Treated with rhIGF-1/rhIGFBP-3 for the Prevention of Retinopathy of Prematurity (ROP) or Who Received Standard Neonatal Care	1	01/03/2020	Open	Yes	

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NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

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Analysis of Performance in Delivery of Clinical Research

(Recruitment to Time and Target)

- **Total Trials Reported – 27** — *(Clinical trials hosted by Alder Hey Children's NHS FT within a 12 month period (01/04/2014 to 31/03/2015).*
- **Total Trials Open – 25** — *(93% of reported trials) Clinical trials open to recruitment and have therefore not yet reached their end date but **10** have already **met the target.***
- **Total Trials Closed – 2** — *(7% of reported trials) Clinical trials now closed to recruitment and in Follow Up or Follow Up Complete status*
- **Total Trials Closed NOT Meeting Time and Target – 2** — *Reasons:*
  1st study: No patients seen, closed by sponsor. 2nd study: Rare condition, 2 patients screened but 1 failed.
- **Total Trials Closed Meeting Time and Target – 0** — *(0% of closed trials)*

Inspired by Children