

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.
- In May 2018, the Department of Health and Social Care announced its decision to remove the 70 day benchmark for clinical trials in England.
- These outcomes included 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***).



Performance in Initiating and Delivering Clinical Research

Review of Previous Quarter Data (Q2 01/10/2017 to 30/09/2018).

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 = 84.1 [SD 59.3].

Alder Hey Children's NHS Foundation Trust = 65.4 days

Alder Hey was ranked 11th in league & 65th of 204 Providers.

Performance in Delivery

Total closed trials meeting time and target (All Providers) = **53.5%**

Alder Hey Children's NHS Foundation Trust = **50%** (of closed trials =8).



NIHR Central Commissioning Facility

Time to first patient recruitment

Analysis of Performance in Initiating Clinical Research

(Time to first patient recruitment)

- **Total Trials Reported – 16** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/11/2018 to 31/12/2018))*
- **Total trials with no delays– 12** *(75% of reported trials)*
- **Total trials with delays– 4** *(25% of reported trials) Clinical trials that had some sort of delay.*
- **Of trials having delays (4), trials where fault lies solely with NHS provider – 1** *(6.25% of reported trials)*

Mean number of Days between Site Selected and First Patient Recruited (# trials recruited to = 9) –83 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 9) –78 days



NIHR Central Commissioning Facility

Time to first patient recruitment

Performance in Initiating Clinical Research Q3

REC Ref Number	IRASRef 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	Benchmark met or Source of Delay
17/YH/0393	234355	PUGS (Paediatric Use of the AbbottSensorBasedGlucoseMonitoringSystem)	02/01/2018	02/02/2018	07/02/2018	14/03/2018	20/03/2018	21/03/2018		NHS Trust
17/NW/0511	226627	ITI rFVIII Fc study in Haemophilia A Pts who failed previous ITI therapy	20/11/2017	14/03/2018	06/11/2017	17/04/2018	19/04/2018	19/04/2018	09/08/2018	Neither
18/NW/0018	236551	Renastep	12/02/2018	11/04/2018	06/04/2018	16/04/2018	17/04/2018	17/04/2018	11/05/2018	Benchmark met
18/EE/0080	238897	Tezidolid	22/09/2017	25/06/2018	30/05/2018	27/06/2018	03/08/2018	12/10/2018		Neither
18/LO/0755	245151	SHP633-301	21/05/2018	25/06/2018	19/06/2018	23/07/2018	03/08/2018	13/08/2018		Neither
18/LO/0126	239586	Phase 1 study of WVE-210201 in patients with DMD	16/04/2018	01/08/2018	12/04/2018	13/08/2018	07/09/2018	05/10/2018	12/11/2018	Sponsor
17/NE/0358	220871	My-CRA, Liquid 13 Cis Retinoic Acid	04/07/2018	27/08/2018	04/01/2018	27/09/2018	03/10/2018	15/11/2018		Neither
17/WS/0148	230186	T-2017-01-Ph 1 paediatric PK study of NATESTO™ (testosterone gel)	15/05/2018	28/08/2018	04/07/2018	27/09/2018	02/10/2018	10/10/2018		Neither

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NIHR Central Commissioning Facility

Time to first patient recruitment

Performance in Initiating Clinical Research

REC Ref Number	IRASRef 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	Benchmark met or Source of Delay
16/NS/0106	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/0649	227917	ASPECT Study	12/07/2017	19/03/2018	22/11/2017	19/03/2018	09/04/2018	09/04/2018	25/10/2018	Neither
16/NE/0325	199217	ECUSTEC	02/02/2017	12/04/2018	30/05/2017	12/04/2018	30/11/2018	03/12/2018		Both
18/NW/0100	235042	BATCH Trial	18/10/2017	20/04/2018	13/04/2018	23/04/2018	24/05/2018	05/06/2018	11/06/2018	Benchmark met
17/YH/0123	203556	SeluDex	11/04/2018	12/06/2018	12/12/2017	12/06/2018	06/08/2018	10/08/2018		Neither
18/SW/0138	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	Benchmark met
18/NW/0461	240082	Cerebral Perfusion in Neonates	04/10/2018	08/10/2018	08/10/2018	30/10/2018	30/10/2018	30/10/2018	20/11/2018	Benchmark met
18/SC/0427	220853	The Bronchiolitis Endotracheal Surfactant Study (BESS)	20/02/2017	16/10/2018	15/10/2018	30/11/2018	03/12/2018	14/12/2018	02/01/2019	Neither

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Analysis of Performance in Delivery of Clinical Research

(Recruitment to Time and Target)

- **Total Trials Reported – 5**
- **Total Trials Closed NOT Meeting Time and Target – 2**
- **Total Trials Closed Meeting Time and Target – 3**

(Clinical trials hosted by Alder Hey Children's NHS FT and closed within a 12 month period (01/1/2018 to 31/12/2018).

Reasons: No patients seen, Short recruitment & shortage of staff.

(60%)



NIHR Central Commissioning Facility

Recruitment to time and target for commercial contract clinical trials

Performance in Delivery of Clinical Research

REC Ref Number	IRAS Ref Number	Name of Clinical Trial	Was a Target Agreed	Minimum Number Agreed	Maximum Number Agreed	Was a Target Date Agreed	Date agreed to Recruit Target	Total Recruited at agreed Date	Total Recruited	Date Trial Closed to Recruitment	Reason for Closure of Trial
16/LO/0537	191351	CHIL4639	Yes	3	3	Yes	16/12/2017	3	3	16/03/2018	Recruitment finished
16/WM/0512	218042	ST10103	Yes	6	9	Yes	20/02/2018	8	8	31/03/2018	Recruitment finished
17/YH/0393	234355	PUGS (Paediatric Use of the AbbottSensorBasedGlucoseMonitoringSystem)	Yes	6	10	Yes	13/04/2018	0	0	31/03/2018	Withdrawn by Host
17/EE/0079	220827	CL010_168	Yes	1	1	Yes	30/03/2020	0	0	04/07/2018	Recruitment finished
17/SC/0055	219468	AIN457 Paed	Yes	1	2	Yes	04/11/2020	1	1	28/09/2018	Recruitment finished

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