

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 (Q3 01/01/2018 to 31/12/2018).

Performance in Initiating

Mean number of days between receipt of Date Site Selected and date of First Patient Recruited

Alder Hey Children's NHS Foundation Trust = 60 days

Performance in Delivery

Alder Hey Children's NHS Foundation Trust = **60%** (of closed trials =5).



NIHR Central Commissioning Facility

Time to first patient recruitment

Analysis of Performance in Initiating Clinical Research

(Time to first patient recruitment)

- **Total Trials Reported – 19** *(Every clinical trial opened with HRA approval at Alder Hey within the previous 12 months (01/04/2018 to 31/03/2019))*
- **Total trials with no delays– 14** *(73.6% of reported trials)*
- **Total trials with delays– 5** *(26.3% of reported trials) Clinical trials that had some sort of delay.*
- **Of trials having delays (5), trials where fault lies solely with NHS provider – 0** *(0% of reported trials)*

Mean number of Days between Site Selected and First Patient Recruited (# trials recruited to = 11) –69 days

Median number of Days between Site Selected and First Patient Recruited (# trials recruited to = 11) –52 days



NIHR Central Commissioning Facility

Time to first patient recruitment

Performance in Initiating Clinical Research Q4

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
18/NW/0644	248582	HUPK	25/5/18	4/2/19	30/11/18	7/3/19	11/3/19	23/4/19		Neither
18/NW/0018	236551	Renastep	12/2/18	11/4/18	6/4/18	16/4/18	17/4/18	17/4/18	11/5/18	Benchmark met
18/EE/0080	238897	Tezolidid	22/9/17	25/6/18	30/5/18	27/6/18	3/8/18	12/10/18		Neither
18/LO/0755	245151	SHP633-301	21/5/18	25/6/18	19/6/18	23/7/18	3/8/18	13/8/18		Neither
18/LO/0126	239586	Phase 1 study of WVE-210201 in patients with DMD	16/4/18	1/8/18	12/4/18	13/8/18	7/9/18	5/10/18	12/11/18	Sponsor
17/NE/0358	220871	My-CRA, Liquid 13 Cis Retinoic Acid	4/7/18	27/8/18	4/1/18	27/9/18	3/10/18	15/11/18		Neither
17/WS/0148	230186	T-2017-01-Ph 1 paediatric PK study of NATESTO™ (testosterone gel)	15/5/18	28/8/18	4/7/18	27/9/18	2/10/18	10/10/18	12/3/19	Sponsor
18/EE/0347	232051	A Single-dose Study of Tedizolid Phosphate in Pediatric Subjects < 2 Y	23/10/18	2/1/19	21/12/18	30/1/19	1/2/19			Neither
18/NE/0235	244048	VISION DMD	16/10/18	10/1/19	21/9/18	15/1/19	28/1/19	20/2/19	15/4/19	Neither
17/LO/1088	228921	VX15-770-126 Cystic Fibrosis	18/7/18	14/1/19	3/8/17	13/2/19	20/2/19			Sponsor

Table 1 of 2



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
18/LO/1238	245332	Open Label Extension study of WVE-210201 in patients with DMD	4/7/18	14/1/19	25/10/18	4/2/19	15/2/19		17/4/19	Sponsor
16/NE/0325	199217	ECUSTEC	2/2/17	12/4/18	30/5/17	12/4/18	30/11/18	11/1/19		Both
18/NW/0100	235042	BATCH Trial	18/10/17	20/4/18	13/4/18	23/4/18	24/5/18	5/6/18	11/6/18	Benchmark met
17/YH/0123	203556	SeluDex	11/4/18	12/6/18	12/12/17	12/6/18	6/8/18	10/8/18		Neither
18/SW/0138	247465	CPEX In Children with CF	10/5/18	13/6/18	13/6/18	13/6/18	20/6/18	22/6/18	6/7/18	Benchmark met
18/NW/0461	240082	Cerebral Perfusion in Neonates	4/10/18	8/10/18	8/10/18	30/10/18	30/10/18	30/10/18	20/11/18	Benchmark met
18/SC/0427	220853	The Bronchiolitis Endotracheal Surfactant Study (BESS)	20/2/17	16/10/18	15/10/18	30/11/18	3/12/18	14/12/18	2/1/19	Neither
18/WM/0324	246654	FORCE - Forearm fracture Recovery in Children Evaluation	11/7/18	24/12/18	16/11/18	25/1/19	31/1/19	8/2/19	14/2/19	Benchmark met
19/SC/0020	255890	MUSIC ED 255890	22/1/19	22/1/19	24/1/19	29/1/19	29/1/19	29/1/19	31/1/19	Benchmark met

Table 2 of 2



Analysis of Performance in Delivery of Clinical Research Q4

(Recruitment to Time and Target)

- **Total Trials Reported – 4**
- **Total Trials Closed NOT Meeting Time and Target – 1**
- **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, study closed early.

(75%)



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
17/EE/0079	220827	CL010_168	Yes	1	1	Yes	30/03/2020	0	0	04/07/2018	Recruitment closed early
17/SC/0055	219468	AIN457 Paed	Yes	1	2	Yes	04/11/2020	1	1	28/09/2018	Recruitment completed.
18/LO/0126	239586	Phase 1 study of WVE-210201 in patients with DMD	Yes	1	2	Yes	10/01/2019	2	2	10/01/2019	Recruitment completed.
17/NW/0511	226627	ITI rFVIII Fc study in Haemophilia A Pts who failed previous ITI therapy	Yes	1	1	Yes	14/01/2019	1	1	14/01/2019	Recruitment completed.

Table 1 of 1

