

Q1 19-20 Performance in Initiating and Delivering Research - Alder Hey Children's NHS FT

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	Comments	Date of First Participant Recruited	Reasons for delay correspond to:
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	No delays to study C&C but sponsor didn't give green light till 5th of October, 1st patient screened 19th of October.	12/11/2018	Sponsor
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	Sponsor green light checks took longer than expected.	12/03/2019	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	No delays to study opening. No patients seen that qualify for the study.		Neither
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	No delay in opening study.	20/11/2018	N/A
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	No delays in opening study. Sponsor green light slight delay but probably would have recruited earlier apart from holiday period/ staff holidays.	02/01/2019	Neither
18/NW/0644	248582	HUPK	25/05/2018	04/02/2019	30/11/2018	07/03/2019	11/03/2019	23/04/2019	No delays.		Neither
18/EE/0347	232051	A Single-dose Study of Tedizolid Phosphate in Pediatric Subjects < 2 Y	23/10/2018	02/01/2019	21/12/2018	30/01/2019	01/02/2019	04/03/2019	No delays. No patients consented, very difficult study to recruit to. Sponsor target was 0-1.		Neither

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18/NE/0235	244048	VISION DMD	16/10/2018	10/01/2019	21/09/2018	15/01/2019	28/01/2019	20/02/2019	No Delays, but green light process began before study opened.	15/04/2019	Neither
17/LO/1088	228921	VX15-770-126 Cystic Fibrosis	18/07/2018	14/01/2019	03/08/2017	13/02/2019	20/02/2019	10/04/2019	Delay to green light process.		Sponsor
18/LO/1238	245332	Open Label Extension study of WVE-210201 in patients with DMD	04/07/2018	14/01/2019	25/10/2018	04/02/2019	15/02/2019	22/03/2019	Delay to green light process.	17/04/2019	Sponsor
18/WM/0324	246654	FORCE - Forearm fracture Recovery in Children Evaluation	11/07/2018	24/12/2018	16/11/2018	25/01/2019	31/01/2019	08/02/2019	No Delays	14/02/2019	N/A
19/SC/0020	255890	MUSIC ED 255890	22/01/2019	22/01/2019	24/01/2019	29/01/2019	29/01/2019	29/01/2019	No Delays	31/01/2019	N/A
17/NW/0533	215339	DETECT study	08/01/2019	05/04/2019	05/04/2019	30/05/2019	31/05/2019	31/05/2019	No Delays	03/06/2019	N/A
18/LO/1808	253366	Phase II paediatric study of ostilodrostat in Cushing's patients	25/04/2019	03/05/2019	19/03/2019	04/06/2019	04/06/2019	17/06/2019	Patient screened in time but declined		Neither
19/NW/0158	259931	Surgery or Cast for Injuries of the Epicondyle in Children's Elbows	09/11/2018	10/05/2019	25/03/2019	11/06/2019	17/06/2019	17/06/2019	2 possible but 1 declined & 1 didn't speak English.		Neither
19/LO/0160	247457	Rett syndrome (RTT) GWND18064	28/02/2019	03/06/2019	30/04/2019	24/06/2019	01/07/2019		Still time.		Neither

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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	Total Number Of Study Participants Recruited	Date That The Trial Closed To Recruitment	Reason For Closure Of Trial	Comments
17/EE/0079	220827	ADVOCATE Study CL010_168	Number Agreed	1	1	Date Agreed	30/03/2020	0	0	04/07/2018	Withdrawn By Sponsor	No patients seen
17/SC/0055	219468	Secukinumab JIA AIN457 Paed	Range Agreed	1	2	Date Agreed	04/11/2020	1	1	28/09/2018	Withdrawn By Sponsor	Target Achieved
18/LO/0126	239586	Phase 1 study of WVE-210201 in patients with DMD	Range Agreed	1	2	Date Agreed	10/01/2019	2	2	10/01/2019	Recruitment Finished	Target Achieved
17/NW/0511	226627	ITI rFVIIIIfc study in HaemophiliaA Pts who failed previous ITI therapy	Number Agreed	1	1	Date Agreed	14/01/2019	1	1	14/01/2019	Recruitment Finished	Target Achieved
18/EE/0080	238897	Tezolidid	Range Agreed	0	1	Date Agreed	06/12/2019	0	0	14/12/2018	Withdrawn By Sponsor	No Patients consented
17/LO/0779	224562	CheckMate908	Number Agreed	1	1	Date Agreed	05/05/2021	6	6	22/02/2019	Recruitment Finished	Target Achieved
16/LO/0814	199311	CHIL4593 - Sarilumab, administered with subcutaneous (SC) injection, in patients aged 2 to 17, with polyarticular-course juvenile idiopathic arthritis (pcJIA) followed by an extension phase	Number Agreed	1	1	Date Agreed	31/03/2019	1	1	31/03/2019	Recruitment Finished	Target Achieved
16/NW/0233	197334	MENT 5175 (12710A)	Number Agreed	4	4	Date Agreed	31/03/2019	4	4	31/03/2019	Recruitment Finished	Target Achieved
17/NE/0358	220871	My-CRA, Liquid 13 Cis Retinoic Acid	Range Agreed	0	2	Date Agreed	31/12/2019	0	0	04/06/2019	Recruitment Finished	Recruitment Closed Global Target Met