

Deadline Date	30/10/2020
Date Submitted	24/09/2020
Type	Performance in Initiating
NHS provider	Norfolk and Norwich University Hospitals NHS Foundation Trust

Id	REC Reference Number	IRAS Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	A - Permissions delayed/denied	B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays	I - Rare diseases	J - Other	Reasons for Delay	Comments	Reasons for delay correspond to:
162437	18/WA/0092	230113	Phase II multi-centre, double-blind, randomised trial of Ustekinumab in adolescents with new-onset type 1 diabetes	No		38			15/01/2019	02/04/2019	21/09/2018	10/05/2019	10/05/2019	14/05/2019							Y		Y			First participants pre-screened 17/06/2019. 11 participants have been pre-screened, 4 were approached but declined to consent. It is expected that we will recruit 3 participants over a 3 year period.	Neither
162438	16/LO/0585	188869	Phase II Randomised, Double Blind, Placebo Controlled Trial of Neoadjuvant Artesunate in Stage II/III Colorectal Cancer (NeoART trial)	No		6			20/09/2018	23/04/2019	01/09/2016	07/03/2019	29/04/2019				Y	Y								Recruitment on hold due to COVID 19	Both
162439	19/NW/0158	259931	SCIENCE Surgery or Cast for Injuries of the Epicondyle in Childrens Elbows.A multi-centre prospective randomised superiority trial of operative fixation versus non-operative treatment for medial epicondyle fractures of the humerus in children.	Yes	03/07/2019	33	39	62	19/03/2019	02/05/2019	25/03/2019	04/06/2019	04/06/2019	11/06/2019													Please Select...
162440	19/EE/0185	259100	A phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of bimekizumab in subjects with active ankylosing spondylitis	Yes	09/01/2020	146			18/03/2019	03/05/2019	11/07/2019	26/09/2019	26/09/2019	01/10/2019	Y			Y				Y				We were selected 03/05/19, HRA Approval was 11/07/19 (69 days) confirmed by the Sponsor on 26/09/2019 (146 days) due to contracting delays by the Sponsor. Open to recruitment 01/10/2019. First participant consented on 16/12/2019 but was a post consent screening failure.	Sponsor
162441	19/EE/0167	260306	A phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of bimekizumab in subjects with active nonradiographic axial spondyloarthritis	Yes	02/07/2020	142			03/04/2019	07/05/2019	10/07/2019	26/09/2019	26/09/2019	01/10/2019	Y			Y				Y				We were selected 07/05/19, HRA approval was 10/07/19 (54 days), confirmed by Sponsor 26/09/19 (132 days) due to contracting delays by the Sponsor and opened to recruitment 01/10/2019 (137 days). First participant consented 16/12/2019 but was a post consent screen failure.	Sponsor
162442	18/LO/2013	252294	When to Induce Labour to Limit risk in pregnancy hypertension ? a multicentre, randomised controlled trial	No		29			10/04/2019	29/05/2019	10/01/2019	27/06/2019	27/06/2019	28/08/2019					Y		Y					Sponsor Green Light given 28/08/2019. Delayed due to the PI being on annual leave for most of August. To date 15 participants have been prescreened 2 have been approached but have not yet consented.	NHS Provider
162443	19/LO/0486	261099	Production of a device to obtain continuous ambulatory vestibular assessment (CAVA) - dizziness trial	Yes	10/07/2019	28	12	40	11/02/2019	31/05/2019	31/05/2019	28/06/2019	28/06/2019	01/07/2019													Please Select...
162444	17/WS/0267	234662	A multicentre randomised controlled trial, with nested process evaluation, to test the clinical and cost-effectiveness of self-management of vaginal pessaries to treat pelvic organ prolapse, compared to standard care to improve women's quality of life.	Yes	10/10/2019	28	98	126	20/03/2019	06/06/2019	09/03/2018	18/06/2019	04/07/2019	09/08/2019							Y					56 participants pre-screened and 33 approached. First recruitment 10/10/2019	Neither
162445	19/LO/0452	250324	Randomised factorial design controlled trial comparing carbamazepine, levetiracetam or active monitoring combined with or without sleep behaviour intervention in treatment naive children with rolandic epilepsy	No		113			02/05/2019	10/06/2019	02/05/2019	10/09/2019	01/10/2019	28/10/2019	Y			Y		Y						Recruitment on hold due to COVID 19	Sponsor
162446	16/LO/1355	168344	InPACT trial- International Penile Advanced Cancer Trial (International Rare Cancers Initiative study)	Yes	03/01/2020	43			16/12/2016	17/06/2019	11/10/2016	30/07/2019	30/07/2019	05/09/2019	Y					Y			Y			We were 3 days over the 40 day C&C target, the sponsor green light was given on 05/09/19 (80 days).No participants have been identified to date. This is a rare disease with a target of 1 participant	Sponsor
162447	19/YH/0054	258802	A pragmatic, multicentre, randomised controlled trial to assess the clinical and cost effectiveness of negative pressure wound therapy versus usual care for surgical wounds healing by secondary intention (SWHSI 2)	Yes	30/11/2019	22	115	137	13/05/2019	16/07/2019	05/04/2019	07/08/2019	07/08/2019	20/09/2019				Y			Y					We got the green light on 20/09/2019 and approached our first patient on 04/10/2019 who declined the study. We had 2 further refusals before we recruited our first patient on 26/11/2019.	Sponsor
162448	19/LO/0515	261604	Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes (SOUL)	Yes	19/09/2019	19	36	55	22/02/2019	26/07/2019	25/07/2019	12/08/2019	14/08/2019	20/08/2019													Please Select...
162449	19/WA/0222	266983	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis	No		118			13/02/2019	02/08/2019	02/09/2019	12/11/2019	28/11/2019		Y			Y				Y				We were selected 02/08/2019 but the contract was not sent till 12/11/2019 (102 days). Still waiting for the Sponsor Green Light.	Sponsor
162450	19/LO/1301	265936	A Phase 2, Randomized, Double Blind, Placebo Controlled, Multiple Center Study to Evaluate the Safety, Tolerability, and Efficacy of Seladelpar Administered for 24 Weeks in Adult Patients with Primary Sclerosing Cholangitis (PSC)	No					04/07/2019	05/08/2019	28/10/2019	11/11/2019					Y									The study was withdrawn by the sponsor on 09/12/2019	Sponsor
162451	19/LO/1270	261294	CRAFT: Cerclage after full dilatation caesarean section; an investigation into the role of previous in labour caesarean section in future preterm birth risk and potential management strategies	Yes	31/12/2019	55	41	96	19/08/2019	26/09/2019	11/09/2019	20/11/2019	20/11/2019	27/12/2019	Y							Y				There were issues around contracts/funding that delayed local approvals (55 days). The first participant was recruited on 31/12/2019.	Both
162452	19/NS/0147	266138	Long-Term Real-World Outcomes Study on Patients Implanted with a Neurostimulator	No		51			01/10/2019	01/10/2019	24/09/2019	13/11/2019	21/11/2019	12/12/2019	Y			Y				Y				Local review not completed in time. Contract received from Sponsor 13/11/2019 (43 days.) C&C given 21/11/2019 (51 days). Sponsor Green Light given 12/12/2019 (72 days)	Sponsor

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