

Performance in Initiating QTR 1 April- June 2019

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	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	Non-Confirmation Status	Date Site Ready To Start	A - Permissions delayed/denied	B - Suspende d 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	Comments	Reasons for delay correspond to:	
16/NS/0106	212541	HRA Approval	RAACEND - Reducing Asthma Attacks in Children using Exhaled Nitric Oxide as a biomarker to inform treatment strategy - a randomised trial	Yes	20/06/2019	35	296	331	24/11/2016	24/07/2018	04/04/2017	03/08/2018	28/08/2018	Please Select...	31/08/2018	Y					Y						Delays with Trust IT approval of App to be installed for use of smart inhalers. Difficult to recruit patients to this study at this site.	NHS Provider
17/YH/0120	208838	HRA Approval	DISC - Dupuytren's Interventions Surgery vs Collagenase	Yes	14/06/2019	131	186	317	13/11/2017	01/08/2018	25/05/2017	03/12/2018	10/12/2018	Please Select...	21/12/2018					Y		Y					Delays due to pharmacy capacity. Difficulty in finding patients willing to consent to the study.	NHS Provider
15/NI/0161	184748	HRA Approval	EASI-SWITCH v1.0 - Early switch to oral antibiotic therapy in patients with low risk neutropenic sepsis	Yes	12/03/2019	75	154	229	22/05/2018	26/07/2018	03/08/2016	01/11/2018	09/10/2018	Please Select...	01/11/2018						Y						date missing for Sponsor to confirm site, expected early Nov. CTA has been sent to sponsor for signature. Site selected in July 2018 however sponsor did not want to arrange SIV until Sept/Oct 2018. Delays in patients recruited due to no patients suitable for study	Sponsor
18/SC/0210	239572	HRA Approval	EFFICACY AND SAFETY OF PF-04965842 200 MG AND 100 MG QD MONOTHERAPY IN SUBJECTS WITH AD	No		10			13/10/2017	14/09/2018	02/08/2018	14/09/2018	24/09/2018	Please Select...	23/10/2018				Y	Y	Y						delays in set-up due to pharmacy staff shortage and sponsor not completing IT & PPQ forms for equipment. Also sponsor delays as awaiting EC confirmation to approve extension study - B7451015. 18/10/2018 IP approval received by sponsor. No patients presenting for study.	Both
18/EM/0281	251974	HRA Approval	EC2TEND - Tralokinumab in moderate-severe AD extension trial 1337	Yes	13/12/2018	14	15	29	24/05/2018	14/11/2018	14/11/2018	14/11/2018	28/11/2018	Please Select...	28/11/2018													Please Select...
18/WM/0347	250624	HRA Approval	A Phase 3 study of BMS-986165 in participants with plaque psoriasis	No		38			15/03/2018	10/01/2019	10/01/2019	02/04/2019	08/04/2019	Please Select...	17/05/2019					Y	Y						delays in set-up due to pharmacy staffing, delay with greenlight from sponsor due to site staff not completing training. No patients consenting for this study currently.	NHS Provider
18/NW/0813	256738	HRA Approval	CAIN457M2302 (SUNRISE): Secukinumab in hidradenitis suppurativa	No		149			09/05/2018	21/01/2019	16/01/2019	11/06/2019	19/06/2019	Please Select...	01/07/2019				Y	Y							delays in set-up due to pharmacy capacity. SIV bought forward from 04/07 to 13/06. Delay with greenlight from sponsor as awaiting drug delivery.	Both
18/YH/0027	223937	HRA Approval	UK CLL Long-term Follow-up Study	No		182			04/07/2018	04/07/2018	16/02/2018	02/01/2019	02/01/2019	Please Select...										Y		only starts when patients complete the previous trial they were randomised to	Neither	
17/LO/0962	220190	HRA Approval	Helping Pregnant smokers to quit: A multicentre RCT of electronic cigarettes vs. nicotine patches (usual care)	No		30			21/05/2018	14/11/2018	24/07/2017	14/12/2018	14/12/2018	Please Select...	14/12/2018					Y		Y					Delay in set up due to not having a PI. Very few pregnant smokers at this Trust	NHS Provider
18/SC/0454	249509	HRA Approval	POISE-3 - Perioperative Ischemic Evaluation-3 Trial	No					03/09/2018	30/11/2018	16/01/2019			Site declined to participate						Y							Pharmacy delays at site. Unable to meet required patient pathway for the study	NHS Provider
19/YH/0054	258802	HRA Approval	(SWHSI 2) 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	No					07/02/2019	11/04/2019	05/04/2019			Please Select...					Y	Y							Sponsor delay with sending full document pack. Some delay at site due to training and number of surgeons involved in trial.	Both
18/WM/0109	245185	HRA Approval	(ZEST trial) A randomized, double blind, placebo controlled multicenter dose ranging study to assess the safety and efficacy of multiple oral ZPL389 doses in patients with moderate to severe Atopic Dermatitis	No		5			27/02/2018	03/04/2019	04/12/2018	03/04/2019	08/04/2019	Please Select...	23/05/2019				Y	Y							some set up delays due to pharmacy and confirmation of costs. Site opening delayed as awaiting greenlight from sponsor.	Both
18/NE/0296	248487	HRA Approval	CALIBRE Study - Carvedilol versus variceal Band ligation in primary prevention of variceal bleeding in liver cirrhosis	No					13/05/2019	21/05/2019	19/10/2018			Please Select...					Y								Full document pack not received	Sponsor
16/EM/0172	194491	HRA Approval	NOAH - AFNET 6 - Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes	No					27/02/2018	27/05/2019	24/05/2016	12/06/2019		Please Select...					Y	Y							Initial delay due to pharmacy staff shortage. 05/07/2019 delay due to pharmacy issues with sponsor. a/w sponsor response. 17/07/2019 pharmacy greenlight received. 18/07/2019 a/w PI to complete sCRF training - completed today. Sponsor issued greenlight to commence recruitment.	Both
19/LO/0400	250289	HRA Approval	Inhale Work Package 3 - The Impact of using FilmArray Pneumonia Panel Molecular Diagnostics for Hospital-Acquired and Ventilator-Associated Pneumonia on Antimicrobial Stewardship and Patient Outcomes in UK Critical Care: A Multicentre Randomised Controlled Trial.	No					18/07/2018	28/05/2019	09/04/2019			Please Select...					Y								Delays with supply of equipment from suppliers in US	Sponsor