

Performance in Initiating Quarter 3 October- December 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 - Suspend 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:	
18/W/0347	250624	HRA Approval	A Phase 3 study of BMS-986165 in participants with plaque psoriasis	Yes	22/08/2019	88	136	224	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. Some patients failed screening.	NHS Provider	
18/NW/0813	256738	HRA Approval	CAIN457M2302 (SUNRISE): Secukinumab in hidradenitis suppurativa	Yes	15/08/2019	149	57	206	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. Some delays in patient recruitment due to screen failures.	Both	
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	Yes	02/09/2019	10	31	41	07/02/2019	23/07/2019	05/04/2019	24/07/2019	02/08/2019	Please Select...	22/08/2019				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/W/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	Y					some set up delays due to pharmacy and confirmation of costings. Site opening delayed as awaiting greenlight from sponsor. A number of patients seen, however have screen failed for trial.	Both	
18/NE/0296	248487	HRA Approval	CALIBRE Study - Carvedilol versus variceal Band ligation in primary pRevention of variceal bleeding in liver cirrhosis	Yes	10/12/2019	71	27	98	21/05/2019	03/09/2019	19/10/2018	14/11/2019	13/11/2019	Please Select...	14/11/2019				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	Yes	04/09/2019	49	51	100	27/02/2018	27/05/2019	24/05/2016	12/06/2019	15/07/2019	Please Select...	18/07/2019				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 eCRF training - completed today. Sponsor issued	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.	Yes	28/08/2019	63	29	92	18/07/2018	28/05/2019	09/04/2019	10/07/2019	30/07/2019	Please Select...	01/08/2019				Y							Delays with supply of equipment from suppliers in US	Sponsor	
19/LO/0040	253233	HRA Approval	EMBRACE - Apremilast Phase 4 Study on Quality of life in psoriasis manifestations	Yes	14/11/2019	13	63	76	01/06/2018	30/08/2019	19/02/2019	30/08/2019	12/09/2019	Please Select...	04/10/2019				Y	Y						delays in set-up due to pharmacy capacity and also sponsor not completing forms for equipment. Also S42 docs received 21/08/2019. 27/09/2019 further delays due to sponsor not completing forms for equipment - sent in Feb 2019	Both	
07/HO718/57	92703	HRA Approval	ITP Registry: United Kingdom Adult Idiopathic Thrombocytopenic Purpura (ITP) Registry: An Investigation of Disease Progression, Treatment Effectiveness, and Co-morbid Conditions	Yes	04/11/2019	14	45	59	23/11/2018	06/09/2019	29/01/2019	20/09/2019	20/09/2019	Please Select...	23/09/2019					Y						Delays in set up due to R&D Office staff availability (and one full time member of staff retiring)	NHS Provider	
19/SC/0344	263202	HRA Approval	Global SYMPLICITY Registry	No					23/05/2019	04/12/2019	26/11/2019	01/10/2019		Please Select...		Y			Y							Delay in set up due to HRA approvals. SIV postponed from Nov 2019 due to HRA delay in approval. Re-booked for Jan'20 due to sponsor availability. 17/01/2020 still awaiting sponsor green light to open to recruitment.Site selection letter from sponsor was received in May 2019, however the full document pack was not received by R&D Office, therefore site selection date has been entered at 04/12/19. Sponsor had signed CTA in October 2019, with NHS site signing once regulatory approvals received.	Sponsor	
19/NE/0115	255707	HRA Approval	SMR-3612 - An Open Label, Multi-Centre, 24 Week, Exploratory Study to Assess the Efficacy and Safety of Skilarence® (Dimethyl Fumarate) in Patients with Moderate Plaque Psoriasis	Yes	12/12/2019	92	48	80	18/10/2018	23/09/2019	03/07/2019	10/10/2019	25/10/2019	Please Select...	28/10/2019												Please Select...	
19/EM/0016	253279	HRA Approval	Evaluation of Efficacy and Safety of Sarilumab in Patients With GCA	No		17			10/09/2018	01/11/2019	25/10/2018	12/11/2019	18/11/2019	Please Select...	19/12/2019												Please Select...	
19/NW/0363	250571	HRA Approval	"14V-MC-JAIA Baricitinib in RA (RA-BRIDGE)I	No		31			29/03/2019	12/11/2019	08/08/2019	18/11/2019	13/12/2019	Please Select...	13/12/2019					Y							Satff availability issues to commence trial	NHS Provider
18/SS/0085	243640	HRA Approval	Alpha-2 agonists for sedation (A2B Trial)	Yes	05/12/2019	29	27	56	24/10/2018	10/10/2019	14/12/2018	25/11/2019	08/11/2019	Please Select...	25/11/2019												Please Select...	
18/ES/0119	245233	HRA Approval	Stopping Aminosalicylate Therapy in inactive Crohn's Disease (STATIC)	No					16/11/2018	16/12/2019	09/11/2018			Please Select...													Please Select...	
19/SC/0021	249552	HRA Approval	(OPTIMAS Trial) Optimal TIMing of Anticoagulation after acute Ischaemic Stroke: a randomised controlled trial	No					19/12/2018	20/11/2019	04/04/2019			Please Select...													Please Select...	