PII Q4 2019-20

Id	Research Ethics Committee Reference Number	Integrated Research Application System 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	Non-Confirmation Status	Date Site Ready To Start	Reasons for Delay	Comments	Reasons for delay correspond to:
159739	19/YH/0054	258802	(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	D - Sponsor Delays E - Staff availability issues	Sponsor delay with sending full document pack. Some delay at site due to training and number of surgeons involved in trial.	Both
159740	18/WM/0109	245185	(ZEST trial) A	Yes	01/03/2020	5	328	333	27/02/2018	03/04/2019	04/12/2018	03/04/2019	08/04/2019	Please Select...	23/05/2019	D - Sponso	some set up	Both

			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 Dermatis													r Delays E - Staff availability issues F - No patients seen	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.	
159741	18/NE/0296	248487	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	D - Sponsor Delays	Full document pack not received	Sponsor
159742	16/EM/0172	194491	NOAH - AFNET 6 - Non-vitamin K antagon	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	D - Sponsor Delays E - Staff availabil	Initial delay due to pharmacy staff shortag	Both

			ist Oral anticoagulants in patients with Atrial High rate episodes													ity issues	e. 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 greenlight to commence recruitment.	
159743	19/LO/0400	250289	Inhale Work Package 3 - The Impact of using FilmArray Pneumonia Panel Molecular Diagnostics for	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	D - Sponsor Delays	Delays with supply of equipment from suppliers in US	Sponsor

			Hospital - Acquired and Ventilator-Associated Pneumonia on Antimicrobial Stewardship and Patient Outcomes in UK Critical Care: A Multicentre Randomised Controlled Trial.															
159744	19/LO/0040	253233	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	D - Sponsor Delays E - Staff availability issues	delays in set-up due to pharmacy capacity and also sponsor not completing forms for equipment. Also SA2 docs received 21/08/2019. 27/09/2019 further delays due to	Both

																	sponsor not completing forms for equipment - sent in Feb 2019	
159745	07/HO718/57	92703	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	E - Staff availability issues	Delays in set up due to R&D Office staff availability (and one full time member of staff retiring)	NHS Provider
159746	19/SC/0344	263202	Global SYMPLICITY Registry	No		36			23/05/2019	04/12/2019	26/11/2019	01/10/2019	09/01/2020	Please Select...		A - Permissions delayed /deniedD - Sponsor Delays	Delay in set up due to HRA approvals.SIV postponed from Nov 2019 due to HRA delay in approval. Re-booked for Jan'20	Sponsor

																	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	

																	recieved.	
159747	19/NE/0115	255707	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	32	48	80	18/10/2018	23/09/2019	03/07/2019	10/10/2019	25/10/2019	Please Select...	28/10/2019	E - Staff availability issues	delay with pharmacy issuing greenlight due to staff availability	NHS Provider
159748	19/EM/0016	253279	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	B - Suspended by sponsor	suspended recruitment due to COVID pandemic	Sponsor
159749	19/NW/0363	250571	"I4V-MC-JAJA Baricitinib in RA (RA-BRIDGE) "	Yes	18/08/2020	31	249	280	29/03/2019	12/11/2019	08/08/2019	18/11/2019	13/12/2019	Please Select...	13/12/2019	E - Staff availability issues	Satff availability issues to commence trial	NHS Provider
159750	18/SS/0085	243640	Alpha-2 agonists for sedatio	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	B - Suspended by sponsor	study suspended due to	Sponsor

			n (A2B Trial)														COVID. Re-opened to recruitment on 20/07/2020	
159751	18/ES/0119	245233	Stopping Aminosalicylate Therapy in Inactive Crohn's Disease (STATIC)	No					16/11/2018	16/12/2019	09/11/2018			Please Select...		B - Suspended by sponsor	set-up suspended due to COVID.	Sponsor
159752	19/SC/0021	249552	(OPTIMAS Trial) OPtimal TIMing of Anticoagulation after acute ischaemic Stroke: a randomised controlled trial	Yes	04/02/2020	56	20	76	19/12/2018	20/11/2019	04/04/2019	15/01/2020	15/01/2020	Please Select...	15/01/2020	E - Staff availability issues	PI could not attend planned SIV, date rescheduled to accomodate	NHS Provider
164063	18/YH/0483	237481	BIOSTREAM HF: Observation of clinical routine care for heart failure patients implanted with BIOTRONIK CRT devices	Yes	05/03/2020	15	7	22	19/09/2019	12/02/2020	14/10/2019	17/02/2020	27/02/2020	Please Select...	03/03/2020	D - Sponsor Delays	delay with receiving sponsor greenlight to start recruitment.	Sponsor
164064	19/YH/0158	262107	TRANSITION -	No		42			14/01/2019	16/01/2020	26/07/2019	18/02/2020	27/02/2020	Please Select...	03/03/2020	H - Contrac	Following SIV,	Both

			An open-label, randomised, Phase IV study, to assess the efficacy and safety of tildrakizumab in patients with moderate-to-severe chronic plaque psoriasis who are non-responders to dimethyl fumarate therapy													ting delays	CTA had to be amended to reduce recruitment target.	
164065	19/LO/1035	264950	G PLUS - A Phase 3b, Multicenter, Interventional, Randomized, Placebo-controlled Study Investigating the Efficacy and Safety	No		4			11/01/2019	06/01/2020	29/07/2019	12/12/2019	10/01/2020	Please Select...	20/01/2020	D - Sponsor Delays E - Staff availability issues	December 2019 both CT pharmacists off sick. CRA off sick until 09/01/2020. 17/01/2020 Drs not completed IWRS training so sponsor	Both

			of Guselkumab for the Treatment of Palmoplantar non-Pustular Psoriasis														could not issue green light to commence recruitment. 10/02/2020 green light received.	
164066	19/NE/0328	270912	M19-164: A Phase 3b, multicenter, interventional, open-label study of adult subjects with moderate to severe plaque psoriasis who have a suboptimal response to secukinumab or ixekizumab and are switched to risankizumab.	No		0			24/06/2019	05/02/2020	19/11/2019	20/12/2019	05/02/2020	Please Select...	10/02/2020	D - Sponsor Delays E - Staff availability issues	SIV had to be rescheduled from Nov to Jan as approvals not received. Sponsor would not issue green light until Sub-PI in post. 10/02/2020 green light received.	Both