## PII Q1 2020-21

ld	Resear ch Ethics Commi ttee Refere nce Numbe r	Integrat ed Resear ch Applica tion System Numbe r	Name of Trial	First Particip ant Recruit ed?	Date of First Particip ant Recruit ed	Duratio n betwee n Date Site Selecte d and Date Site Confir med	Duratio n betwee n Date Site Confir med and First Particip ant Recruit ed	Duratio n betwee n Date Site Selecte d and First Particip ant Recruit ed	Date Site Invited	Date Site Selecte d	HRA Approv al Date	Date Site Confir med By Sponso r	Date Site Confir med	Non- Confir mation Status	Date Site Ready To Start	Reason s for Delay	Comme nts	Reason s for delay corresp ond to:
164293	19/YH/0 054	258802	(SWHSI 2) A pragmat ic, multice ntre, randomi sed controll ed trial to assess the clinical and cost effectiv eness of negativ e pressur e wound therapy versus usual care for surgical wounds healing by second ary intentio n	Yes	02/09/2 019	10	31	41	07/02/2 019	23/07/2 019	05/04/2 019	24/07/2 019	02/08/2 019	Please Select	22/08/2 019	D - Sponso r Delays E - Staff availabil ity issues	Sponso r delay with sending full docume nt pack. Some delay at site due to training and number of surgeon s involved in trial.	Both
164294	18/NE/0 296	248487	CALIBR E Study - CArvedi IoL	Yes	10/12/2 019	71	27	98	21/05/2 019	03/09/2 019	19/10/2 018	14/11/2 019	13/11/2 019	Please Select	14/11/2 019	D - Sponso r Delays	Full docume nt pack not	Sponso r

			versus variceal Band ligation in primary pREven tion of variceal bleedin g in liver cirrhosi s														receive d	
164295	19/LO/0 040	253233	EMBRA CE - Apremil ast Phase 4 Study on Quality of life in psoriasi s manifes tations	Yes	14/11/2 019	13	63	76	01/06/2 018	30/08/2 019	19/02/2 019	30/08/2 019	12/09/2 019	Please Select	04/10/2 019	D - Sponso r Delays E - Staff availabil ity issues	delays in set- up due to pharma cy capacity and also sponsor not complet ing forms for equipm ent. Also SA2 docs receive d 21/08/2 019. 27/09/2 019 further delays due to sponsor not complet ing forms for equipm ent - sent in Feb 2019	Both

164296	07/HO7 18/57	92703	ITP Registry:United Kingdo m Adult Idiopath ic Thromb ocytope nic Purpura (ITP) Registry: An Investig ation of Disease Progres sion, Treatm ent Effectiv eness, and Co- morbid Conditio ns	Yes	04/11/2 019	14	45	59	23/11/2 018	06/09/2 019	29/01/2 019	20/09/2 019	20/09/2 019	Please Select	23/09/2 019	E - Staff availabil ity issues	Delays in set up due to R&D Office staff availabil ity (and one full time member of staff retiring)	NHS Provide r
164297	19/SC/0 344	263202	Global SYMPLI CITY Registry	No		36			23/05/2 019	04/12/2 019	26/11/2 019	01/10/2 019	09/01/2 020	Please Select		A - Permiss ions delayed /denied D - Sponso r Delays	Delay in set up due to HRA approva Is.SIV postpon ed from Nov 2019 due to HRA delay in approva I. Rebooked for Jan'20 due to sponsor availabil ity. 17/01/2 020 still awaiting sponsor green light to open to	Sponso r

																	recruitm ent.Site selectio n letter from sponsor was receive d in May 2019, howeve r the full docume nt pack was not receive d by R&D Office, therefor e site selectio n date has been entered at 04/12/1 9. Sponso r had signed CTA in October 2019, with NHS site signing once regulato ry	
																	regulato ry approva ls recieve d.	
164298	19/NE/0 115	255707	SMR- 3612 - An Open Label, Multi- Centre, 24 Week,	Yes	12/12/2 019	32	48	80	18/10/2 018	23/09/2 019	03/07/2 019	10/10/2 019	25/10/2 019	Please Select	28/10/2 019	E - Staff availabil ity issues	delay with pharma cy issuing greenlig ht due to staff	NHS Provide r

			Explorat ory Study to Assess the Efficacy and Safety of Skilaren ce? (Dimeth yl Fumara te) in Patients with Moderat e Plaque Psoriasi s														availabil ity	
164299	19/EM/ 0016	253279	Evaluati on of Efficacy and Safety of Sarilum ab in Patients With GCA	No		17			10/09/2 018	01/11/2 019	25/10/2 018	12/11/2 019	18/11/2 019	Please Select	19/12/2 019	B - Suspen ded by sponsor	suspen ded recruitm ent due to COVID pandem ic	Sponso r
164300	19/NW/ 0363	250571	"I4V- MC- JAJA Baricitin ib in RA (RA- BRIDG E) "	Yes	18/08/2 020	31	249	280	29/03/2 019	12/11/2 019	08/08/2 019	18/11/2 019	13/12/2 019	Please Select	13/12/2 019	E - Staff availabil ity issues	Satff availabil ity issues to comme nce trial	NHS Provide r
164301	18/SS/0 085	243640	Alpha-2 agonist s for sedatio n (A2B Trial)	Yes	05/12/2 019	29	27	56	24/10/2 018	10/10/2 019	14/12/2 018	25/11/2 019	08/11/2 019	Please Select	25/11/2 019	B - Suspen ded by sponsor	study suspen ded due to COVID. Re- opened to recruitm ent on 20/07/2 020	Sponso r
164302	18/ES/0 119	245233	Stoppin g Aminos	No					16/11/2 018	16/12/2 019	09/11/2 018			Please Select		B - Suspen	set-up suspen ded due	Sponso r

			alicylate Therapy in Inactive Crohn's Disease (STATI C)													ded by sponsor	to COVID.	
164303	19/SC/0 021	249552	(OPTIM AS Trial) OPtimal TIMing of Anticoa gulation after acute ischae mic Stroke: a randomi sed controll ed trial	Yes	04/02/2 020	56	20	76	19/12/2 018	20/11/2 019	04/04/2 019	15/01/2 020	15/01/2 020	Please Select	15/01/2 020	E - Staff availabil ity issues	PI could not attend planned SIV, date resched uled to accomo date	NHS Provide r
164304	18/YH/0 483	237481	BIOST REAM HF: Observ ation of clinical routine care for heart failure patients implant ed with BIOTR ONIK CRT devices	Yes	05/03/2 020	15	7	22	19/09/2 019	12/02/2 020	14/10/2 019	17/02/2 020	27/02/2 020	Please Select	03/03/2 020	D - Sponso r Delays	delay with receivin g sponsor greenlig ht to start recruitm ent.	Sponso r
164305	19/YH/0 158	262107	TRANSI TION - An open- label, randomi sed, Phase IV study, to assess the	No		42			14/01/2 019	16/01/2 020	26/07/2 019	18/02/2 020	27/02/2 020	Please Select	03/03/2 020	H - Contrac ting delays	Followin g SIV, CTA had to be amende d to reduce recruitm ent target.	Both

			efficacy and safety of tildrakiz umab in patients with moderat e-to- severe chronic plaque psoriasi s who are non- respond ers to dimethy I fumarat e therapy													
164306	19/LO/1 035	264950	G PLUS - A Phase 3b, Multice nter, Interven tional, Rando mized, Placebo - controll ed Study Investig ating the Efficacy and Safety of Guselku mab for the Treatm ent of Palmopl antar non- Pustular	No	4		11/01/2 019	06/01/2 020	29/07/2 019	12/12/2 019	10/01/2 020	Please Select	20/01/2	D - Sponso r Delays E - Staff availabil ity issues	December 2019 both CT pharma cists off sick. CRA off sick until 09/01/2 020. 17/01/2 020 Drs not complet ed IWRS training so sponsor could not issue green light to comme nce recruitment. 10/02/2 020	Both

			Psoriasi s												green light receive d.	
164307	19/NE/0 328	270912	M19- 164: A Phase 3b, multice nter, interven tional, open- label study of adult subjects with moderat e to severe plaque psoriasi s who have a subopti mal respons e to secukin umab or ixekizu mab and are switche d to risankiz umab.	No	0		24/06/2 019	05/02/2 020	19/11/2 019	20/12/2 019	05/02/2 020	Please Select	10/02/2 020	D - Sponso r Delays E - Staff availabil ity issues	SIV had to be resched uled from Nov to Jan as approva Is not receive d. Sponso r would not issue green light until Sub-PI in post. 10/02/2 020 green light receive d.	Both