PII Q4 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:
178363	20/YH/0 004	272789	Long- Term Safety and Efficacy of BMS- 986165 in Subject s with Psoriasi s	Yes	20/08/2	15	21	36	02/10/2 019	15/07/2 020	09/06/2 020	23/07/2 020	30/07/2 020	Please Select	06/08/2 020	D - Sponso r Delays	confirm ation of C&C issued 30/07/2 020, sponsor replied that they should have us greenlig hted by the end of next week due to internal process es. 06/08/2 020 approva I receive d to recruit.	Sponso r
178364	19/WA/ 0365	261306	CAIN45 7M2301 E1 (SUN Extensi on) Secukin umab in hidrade nitis suppura tiva	Yes	03/09/2 020	3	14	17	16/10/2 019	17/08/2 020	23/01/2 020	19/08/2 020	20/08/2 020	Please Select	01/09/2 020	D - Sponso r Delays	Had to wait for sponsor greenlig ht, they would not issue until IMP receive d at site.	Sponso r

178365	20/SS/0 004	262376	LPS154 97	No	4		18/03/2 019	07/09/2 020	09/07/2 020	07/09/2 020	11/09/2 020	Please Select	22/10/2 020	J - Other	SIV planned for April 2020 but had to be postpon ed due to COVID 19 pandem ic.	Neither
178366	19/YH/0 400	271539	A Multice nter, Double-blind, Placebo - controll ed, Rando mized Withdra wal, Parallel Group Study of Patirom er for the Manage ment of Hyperk alemia in Subject s Receiving Renin-Angiote nsin-Aldoster one System Inhibitor (RAASi) Medicat ions for the Treatm ent of Heart Failure	No			17/07/2 019	19/09/2	09/01/2			Please Select		D - Sponso r Delays E - Staff availabil ity issues J - Other	SIV not available until after 15/04/2 020 as spec by sponsor . SIV delayed due to COVID 11/08/2 020 SIV postpon ed due to PI unavail ability due to personn el reasons . to be rebooked. SIV held 10/09/2 020 - pharma cy queries to resolve. 24/09/2 020 so can now issue C&C 28/10/2 020	Both

			(DIAMO ND)														STILL WAITIN G FOR GREEN LIGHT FROM SPONS OR. Waiting	
178367	20/EM/ 0198	283686	ARCAD IA Trial_S GS1656 .201_V 1.0	Yes	03/11/2 020	5	21	26	09/06/2 020	08/10/2 020	31/07/2 020	06/10/2 020	13/10/2 020	Please Select	29/10/2 020	J - Other	for pharma cy green light - due to e- prescrib ing and dispensi ng of the drug at weeken ds	NHS Provide r
178368	19/WM/ 0336	270551	Zanubr utinib + Rituxim ab vs Benda mustine + Rituxim ab for untreate d MCL	No					14/06/2 019	04/11/2 020	27/01/2 020	04/11/2 020		Please Select		J - Other	March 2020 - study set-up suspen ded due to COVID 19 pandem ic. August 2020 - set-up restarted. Delays due to pandem ic restricti ons and added pressur es on pharma cy and delivery teams. Nov 2020 sponsor	Both

															sent signed CTA as wanted it before SIV. As per HRA guidelin es, this is not feasible , hence delay with DGH final signatur e. 26/01/2 021 still awaiting pharma cy greenlig ht.	
178369	20/SC/0 031	275229	A Phase 3 study to assess Nemoliz umab in Atopic Dermati tis	No	52		25/10/2 019	24/11/2 020	27/08/2 020	24/11/2 020	15/01/2 021	Please Select	25/01/2 021	H - Contrac ting delays	Contract can't be issued until after greeligh t from pharma cy - pharma cy SIV is 30.11.2 020 and have informe d me that greenlight may not be given that week as request ed by sponsor . I have emailed	Both

															sponsor on numero us occasio ns saying thet we can't issue FE CTA until after pharma cy greenlig ht and SIV and it will be goven as part of confirm ation of C&C. 07.12.2 020 Pharma cy SIV complet ed 04.12.2 020 and main SIV to be rearran ged - pharma cy have informe d the	
															pharma cy have	
178370	19/NE/0 215	234453	Myelom a XIV (FiTNEs s)	No	0		18/05/2 018	13/10/2 020	07/11/2 019	26/01/2 021	13/10/2 020	Please Select	01/03/2 021	J - Other	opening suspen ded due to COVID. a/w further	Both

																	update from sponsor . Set-up comme nced, further delays due to pharma cy capacity	
178371	20/LO/0 790	280190	ARAMI S roll- over study	Yes	15/04/2 021	0	36	36	01/11/2 019	10/03/2 021	30/06/2 020	07/04/2 021	10/03/2 021	Please Select	07/04/2 021	E - Staff availabil ity issues	delays due to extra pressur es due to COVID. Further delay due to PI shieldin g hence needing to find a sub PI to prescrib e. Pharma cy delays due to capacity .	NHS Provide r