

PII Q3 2020-21

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:
176886	20/YH/004	272789	Long-Term Safety and Efficacy of BMS-986165 in Subjects with Psoriasis	Yes	20/08/2020	15	21	36	02/10/2019	15/07/2020	09/06/2020	23/07/2020	30/07/2020	Please Select...	06/08/2020	D - Sponsor Delays	confirmation of C&C issued 30/07/2020, sponsor replied that they should have us greenlighted by the end of next week due to internal processes. 06/08/2020 approval received to recruit.	Sponsor
176887	19/WA/0365	261306	CAIN457M2301 E1 (SUN Extension) Secukinumab in hidradenitis suppurativa	Yes	03/09/2020	3	14	17	16/10/2019	17/08/2020	23/01/2020	19/08/2020	20/08/2020	Please Select...	01/09/2020	D - Sponsor Delays	Had to wait for sponsor greenlight, they would not issue until IMP received at site.	Sponsor

176888	20/SS/004	262376	LPS15497	No		4			18/03/2019	07/09/2020	09/07/2020	07/09/2020	11/09/2020	Please Select...	22/10/2020	J - Other	SIV planned for April 2020 but had to be postponed due to COVID 19 pandemic.	Neither
176889	19/YH/0400	271539	A Multicenter, Double-blind, Placebo-controlled, Randomized Withdrawal, Parallel Group Study of Patiromer for the Management of Hyperkalemia in Subjects Receiving Renin-Angiotensin-Aldosterone System Inhibitor (RAASi) Medications for the Treatment of Heart Failure	No					17/07/2019	19/09/2020	09/01/2020			Please Select...		D - Sponsor Delays E - Staff availability issues J - Other	SIV not available until after 15/04/2020 as spec by sponsor. SIV delayed due to COVID 11/08/2020 SIV postponed due to PI unavailability due to personnel reasons. to be re-booked. SIV held 10/09/2020 - pharmacy queries to resolve. 24/09/2020 so can now issue C&C 28/10/2020	Both

			(DIAMOND)															STILL WAITING FOR GREEN LIGHT FROM SPONSOR.	
177681	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	
177682	19/LO/1035	264950	G PLUS - A Phase 3b, Multicenter, Interventional, Randomized, Placebo-controlled Study Investigating the Efficacy and Safety of Guselkumab for the Treatment of Palmoplantar non-Pustular	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 could not issue greenlight to commence recruitment	Both	

			Psoriasis G PLUS - A Phase 3b, Multicenter, Interventional, Randomized, Placebo-controlled Study Investigating the Efficacy and Safety of Guselkumab for the Treatment of Palmoplantar non-Pustular Psoriasis															
177807	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 - Contracting delays	following SIV on 13/02/2020 CTA had to be amended to reduce the recruitment target.	Both
177808	19/NE/0328	270912	M19-164 Plaque Psoriasis	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	SIV booked for Nov but had to be delayed	Sponsor

																	until end of Jan as approvals not received. SIV booked for 30/01/2020. Sponsor won't issue green light until sub-Inv in post. 10/02/2020 green light received.	
178348	20/EM/0198	283686	ARCADIA Trial_SGS1656.201_V1.0	Yes	03/11/2020	5	21	26	09/06/2020	08/10/2020	31/07/2020	06/10/2020	13/10/2020	Please Select...	29/10/2020	J - Other	Waiting for pharmacy green light - due to e-prescribing and dispensing of the drug at weekends	NHS Provider
178349	19/WM/0336	270551	Zanubrutinib + Rituximab vs Bendamustine + Rituximab for untreated MCL	No					14/06/2019	04/11/2020	27/01/2020	04/11/2020		Please Select...		J - Other	March 2020 - study set-up suspended due to COVID 19 pandemic. August 2020 - set-up re-	Both

																	started. Delays due to pandemic restrictions and added pressures on pharmacy and delivery teams. Nov 2020 sponsor sent signed CTA as wanted it before SIV. As per HRA guidelines, this is not feasible, hence delay with DGH final signature. 26/01/2021 still awaiting pharmacy greenlight.	
178350	20/SC/0031	275229	A Phase 3 study to assess Nemolizumab in Atopic Dermatitis	No		52			25/10/2019	24/11/2020	27/08/2020	24/11/2020	15/01/2021	Please Select...	25/01/2021	H - Contracting delays	Contract can't be issued until after greenlight from pharmacy - pharmacy SIV is	Both

																	cy have informed the sponsor that greenlight may not be given until	
178351	19/NE/0215	234453	Myeloma XIV (FITNESs)	No		0			18/05/2018	13/10/2020	07/11/2019	26/01/2021	13/10/2020	Please Select...	01/03/2021	J - Other	opening suspended due to COVID. a/w further update from sponsor. Set-up commenced, further delays due to pharmacy capacity.	Both