

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	031-21	Kajian BE	Pantoprazole Tablet 40mg	Clinical and Bioanalytical site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
2.	BX-BE21-AMP-003	Kajian BE	Zitracin Film Coated Tablet 500mg	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor Bioanalytical Site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang	LULUS
3.	BE.669/EQL/2021	Kajian BE	YSP Hydroxychloroquine Film Coated Tablet 200mg	Clinical site and Bioanalytical site: PT Equilab International Jl. RS. Fatmawati Persil 33 Jakarta 12430, Indonesia.	LULUS
4.	BX-BE21-AMP-004	Kajian BE	Ezycor Tablet 10mg	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor Bioanalytical Site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang	
5.	NN9500-4656	Fasa II	<ul style="list-style-type: none"> a) NNC0194-0499 B 50 mg/ml, 3 mL underfilled cartridge (1 mL solution) b) Semaglutide B 3 mg/ml, 3 ml PDS290 pen-injector c) NNC0174-0833 A 10 mg/ml, 3 mL underfilled cartridge (1 mL solution) d) Placebo C, 3 mL underfilled cartridge (1 mL solution) e) Semaglutide Placebo, 3 mL PDS290 pen-injector f) Placebo NNC0174-0833 A, 3 mL underfilled cartridge (1 mL solution) 	<ul style="list-style-type: none"> a) Hospital Selayang b) Hospital Universiti Sains Malaysia c) University Malaya Medical Centre 	LULUS
6.	BCX9930-203	Fasa II	<ul style="list-style-type: none"> a) BCX9930 250 mg Tablet b) Placebo for BCX9930 250 mg Tablet c) Meningococcal Group B Vaccine Trumenba® 0.5mL Prefilled Syringe 	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Ampang c) Sarawak General Hospital/ Hospital Umum Sarawak 	LULUS
7.	GRN163LMYF3001	Fasa III	Imetelstat sodium lyophilized powder for solution 210 mg	<ul style="list-style-type: none"> a) Hospital Umum Sarawak b) Hospital Pulau Pinang c) Hospital Raja Perempuan Zainab II 	LULUS

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				d) Hospital Ampang	
8.	TG2102V01	Fasa III	a) Recombinant SARS-CoV-2 fusion protein vaccine, injection, 10µg (0.5 mL)/vial b) Placebo for Recombinant SARS-CoV-2 fusion protein vaccine, injection, 10µg (0.5 mL)/vial	a) Hospital Taiping b) Hospital Sultan Abdul Halim c) Hospital Pakar Sultanah Fatimah d) Sarawak General Hospital e) Hospital Seri Manjung f) Hospital Pulau Pinang g) Sunway Medical Centre Velocity (SMCV) h) Sunway Medical Centre (SunMed) i) Klinik Kesihatan Seremban 2 j) Hospital Sibu	LULUS