

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	236-22	Kajian BE	Mycophenolate Mofetil tablets 500 mg	Clinical site & Bioanalytical site: Axis Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500049, India	LULUS
2.	BE22-003	Kajian BE	Azimac Tablet 500mg	Clinical site & Bioanalytical site: Questra Bio-Clinical Research Centre, Questra Clinical Research Sdn. Bhd. No. 6, Jalan Desa Pauh, Taman Desa Pauh, 13700 Permatang Pauh, Pulau Pinang.	LULUS
			Zithromax Tablet 500mg		
3.	DNDi-OXA-07-HAT	Fasa I	Acoziborole 320mg, Tablet	Clinical Trial Unit, Hospital Ampang	LULUS
			BECHILAR 3 mg/mL Syrup		
			Midazolam-ratiopharm® 2 mg/mL Oral Solution		
4.	MBI-003-LIVE	Fasa II	AlloStim® cryopreserved 1.0x10 ⁷ cells/ml, 0.5ml in 2.0ml cryovial	a) Aurelius Hospital Nilai b) Hospital Sultan Ismail c) Hospital Sultanah Bahiyah d) Hospital Pulau Pinang	LULUS

5.	UPAMOSTAT-LHG/002	Fasa II	Upamostat 200mg capsule	Hospital Ampang	LULUS
			Placebo to Upamostat 200mg capsule		
6.	C1B02537	Kajian BE	Pitolisant Tablets 17.8 mg	<p>Clinical site: Cliantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India</p> <p>Bioanalytical site: Cliantha Research Limited Cliantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India</p>	LULUS
7.	C1B02538	Kajian BE	Pitolisant Tablets 17.8 mg	<p>Clinical site: Cliantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India</p> <p>Bioanalytical site: Cliantha Research Limited Cliantha Corporate,</p>	LULUS

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