

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	SLN124-002	Fasa I (First-In Human)	SLN 124, Solution for Injection, 100mg/mL	Hospital Umum Sarawak	LULUS
2.	0077-20	Kajian BE	Tadalafil Tablet 20 mg	Clinical and Bioanalytical Site: Lambda Therapeutic Research Ltd., Lambda house, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
3.	IK2140-(02) Entecavir	Kajian BE	Entecavir Tablets 0.5mg	Clinical Site: Borneo Kinetics Sdn Bhd, CRC Research Ward Level 6, Sarawak General Hospital Heart Centre, 94300 Kota Samarahan, Sarawak Bioanalytical Site: Info Kinetics Sdn Bhd 5th Floor Gleneagles Penang, 1, Jalan Pangkor, 10050 George Town, Penang, Malaysia.	LULUS
4.	0091-20	Kajian BE	Pregabalin Capsule 150 mg	Clinical and Bioanalytical site: Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
5.	NN8022-4392	Fasa III	a) Liraglutide 6.0 mg/mL, Solution for Injection b) Liraglutide Placebo, Solution for Injection	a) University Malaya Medical Centre b) Hospital Putrajaya	LULUS
6.	ARC-10	Fasa III	a) AB 122 for Injection, 120mg/4mL, Concentrated solution for intravenous (IV) infusion b) AB154 for Injection, 80mg/4mL, Concentrated solution for intravenous (IV) infusion	a) Hospital Umum Sarawak b) Hospital Kuala Lumpur c) Hospital Sultan Ismail d) University Malaya Medical Centre e) Mount Miriam Cancer Hospital f) Hospital Pulau Pinang g) Hospital Tengku Ampuan Afzan	LULUS
7.	0403-20	Kajian BE	Entecavir Tablet 0.5 mg	Clinical and Bioanalytical site: Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS
8.	D910FC00001	Fasa III	Durvalumab (MEDI4736) solution for infusion (50mg/mL)/500mg/vial	Hospital Umum Sarawak	LULUS
9.	INS1007-301	Fasa III	a) INS1007 (Brensocatib) Film-Coated Tablets, 10mg b) INS1007 (Brensocatib) Film-Coated Tablets, 25mg c) INS1007 (Brensocatib) Film-Coated Tablets, Placebo	a) Hospital Universiti Teknologi Mara, Selayang Campus b) Institut Perubatan Respiratori c) Hospital Raja Perempuan Zainab II d) Hospital Tengku Ampuan Afzan e) Sarawak General Hospital f) University Malaya Medical Centre	LULUS