

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	BX-BE-AMP-005	Kajian BE	Levozin Film Coated Tablet 5mg	<p>Clinical Site: Clinical Research Ward Clinical Trial Unit, Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical Site: Bioxis Sdn. Bhd., PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	LULUS
2.	ARL/21/118	Kajian BE	Apixaban Film-Coated Tablets 5mg	<p>Clinical Site: Accutest Research Laboratories (I) Pvt. Ltd. 101 to 113 & 201 to 204, 1st and 2nd floor, Synergy Square Complex, Krishna Industrial Estate, BIDC, Gorwa, Vadodara – 390016, India</p> <p>Bioanalytical Site: Accutest Research Laboratories (I) Pvt. Ltd., A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, India</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
3.	0191-21	Kajian BE	Etoricoxib Tablet 120 mg	Clinical & 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
4.	CABL001A2302	Fasa IIIb	ABL001 (Asciminib) 40 mg film-coated tablet ABL001 (Asciminib) 20 mg film-coated tablet	Hospital Pulau Pinang Hospital Queen Elizabeth Hospital Ampang Hospital Sultanah Aminah	LULUS
5.	CABL001J12301	Fasa IIIb	ABL001 (Asciminib) 40 mg film-coated tablet	Hospital Pulau Pinang Subang Jaya Medical Centre Hospital Ampang Hospital Tengku Ampuan Afzan	LULUS
6.	OPT-302-1004	Fasa III	OPT-302 40mg/mL Solution for injection Lucentis 10mg/mL Solution for Injection Sham solution for Injection	Hospital Selayang Hospital Shah Alam Tun Hussein Onn National Eye Hospital	LULUS
7.	MK-4280A-007	Fasa III	MK4280A 20/5 mg/mL (MK-4280 20mg/ml and MK-3475 5mg/ml), Solution for Infusion, 40mL vial	University Malaya Medical Centre National Cancer Institute/ Institut Kanser Negara Beacon Hospital Pantai Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	GO42784	Fasa III	Giredestrant, 30mg Hard Capsules Letrozole 2.5 mg Film-coated Tablets Anastrozole 1 mg Film-coated Tablets Exemestane 25 mg Film-coated Tablets Tamoxifen 20 mg Tablets	Beacon Hospital Hospital Kuala Lumpur Hospital Pulau Pinang Hospital Umum Sarawak Institut Kanser Negara Pantai Hospital Sungai Petani University Malaya Medical Centre	LULUS
9.	IIT-CRM2020001	Fasa II	Talazoparib 0.25 mg capsules Talazoparib 1 mg capsules	University Malaya Medical Centre	LULUS
10.	ESDY-121-0084	Fasa I	Femoston 1/5 mg Tablet Femoston 0.5/2.5 mg Tablet	Info Kinetics Sdn. Bhd.	LULUS
11.	60569	Fasa II	Ivervid Tablet 6mg Placebo to match Ivervid 6mg	Pejabat Kesihatan Daerah Batang Padang Pejabat Kesihatan Daerah Kerian Pejabat Kesihatan Daerah Kinta Pejabat Kesihatan Daerah Kuala Kangsar Pejabat Kesihatan Daerah Larut Matang and Selama Pejabat Kesihatan Daerah Manjung Pejabat Kesihatan Daerah Muallim Pejabat Kesihatan Daerah Seberang Perai Tengah Pejabat Kesihatan Daerah Kuala Muda Pejabat Kesihatan Daerah Kangar	KELULUSAN BERSYARAT
12.	JH-COR-003	Fasa III	10 µg/ml Novaferon (Nebulizer solution for inhalation use)	Hospital Pulau Pinang Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			Placebo for 10 µg/mL Novaferon	University Malaya Medical Centre Hospital Miri Hospital Pengajar Universiti Putra Malaysia	
13.	DW_DWJ1248201	Fasa II/III	DWJ1248 200mg film-coated tablet Matching placebo for DWJ1248 200mg film-coated tablet	Hospital Miri Hospital Duchess of Kent University Malaya Medical Centre	LULUS BERSYARAT
14.	0135-0347	Fasa IIb/III	Alteplase (TPA-05) 50 mg Powder in Vial and 50 mL solvent for Alteplase (TPA-05) Powder for solution for injection/infusion	Hospital Queen Elizabeth Hospital Miri University Malaya Medical Centre	LULUS