

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2021**

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	003-20	Kajian BE	Solifenacin Succinate Tablet 10mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio), India	LULUS
2.	056-20	Kajian BE	Amlodipine and Valsartan Tablets 10 mg /160 mg	AXIS Clinicals Limited, India	LULUS
3.	027-20	Kajian BE	Rosuvastatin Tablets 20 mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio), India	LULUS
4.	285-20	Kajian BE	Tamsulosin CR Tablet 0.4mg	AXIS Clinicals Limited, India	LULUS
5.	286-20	Kajian BE	Tamsulosin CR Tablet 0.4mg	AXIS Clinicals Limited, India	LULUS
6.	ARL/20/120	Kajian BE	Gliclazide MR tablets 60mg	Accutest Research Laboratories (I) Pvt. Ltd., India	LULUS
7.	ARL/20/121	Kajian BE	Gliclazide MR tablets 60mg	Accutest Research Laboratories (I) Pvt. Ltd., India	LULUS
8.	42847922MDD3002	Fasa III	1) Seltorexant 20mg Film-Coated Tablet 2) Matching Placebo for Seltorexant 20mg Film-Coated Oral Tablet	a) Hospital Kuala Lumpur b) University Malaya Medical Centre c) Sunway Medical Centre d) Hospital Sibul	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
9.	ALN-TTRSC02-003	Fasa III	1) ALN-TTRSC02 (Vutrisiran) 50 mg/mL (Free Acid), 0.5 mL Dose in a 1 mL Pre-filled Syringe 2) TTRSC02 Placebo, 0.9% w/v Saline 0.5 ml Dose in a 1 mL Pre-filled Syringe 3) ELEVIT PRONATAL Film coated tablets	a) Universiti Teknologi Mara Private Specialist Centre b) Institut Jantung Negara c) Hospital Tengku Ampuan Afzan	LULUS
10.	73841937NSC3003	Fasa III	1) JNJ-61186372 350 mg (50 mg/ml), 7 ml Solution 2) Lazertinib 80mg Tablet 3) Placebo to Lazertinib 80mg Tablet 4) Osimertinib 40mg Capsule 5) Osimertinib 80mg Capsule 6) Placebo to Osimertinib 40mg Capsule 7) Placebo to Osimertinib 80mg Capsule	a) University Malaya Medical Centre b) Hospital Sultan Ismail c) Beacon Hospital Sdn Bhd d) Hospital Tengku Ampuan e) Hospital Pulau Pinang f) Hospital Kuala Lumpur	LULUS
11.	Exec B	Fasa I	1) High Dose B-Vitamin Multivitamin: Product A 2) High Dose B-Vitamin Multivitamin: Product B 3) High Dose B-Vitamin Multivitamin: Product C	a) Taylor's University b) Universiti Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
12.	0493-19	Kajian BE	Ezetimibe/ Simvastatin Tablet 10/40mg	Lambda Therapeutic Research Ltd., India.	LULUS
13.	61186372NSC3001	Fasa III	JNJ-61186372 350mg (50mg/ml), 7ml vial	a) University Malaya Medical Centre (UMMC) b) Hospital Sultan Ismail c) Hospital Pulau Pinang d) Hospital Kuala Lumpur	LULUS BERSYARAT

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