

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2023**

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	D8531C00002	Fasa III	AZD9833 Film-coated Tablet 75 mg	(a) Hospital Wanita dan Kanak-Kanak Sabah	LULUS
			Anastrozole Film-coated Tablet 1 mg	(b) Hospital Sultan Ismail	
			Letrozole Film-coated Tablet 2.5 mg	(c) Penang Adventist Hospital	
			Exemestane Film-coated Tablet 25 mg	(d) Hospital Universiti Sains Malaysia	
			Tamoxifen Film-coated Tablet 20 mg	(e) University Malaya Medical Centre (f) Hospital Kuala Lumpur (g) Mahkota Medical Centre	
2.	D5982C00005	Fasa III	Metered Dose Inhaler (MDI) Pressurized Inhalation Suspension budesonide/ formoterol fumarate 80/4.8 µg per actuation, 120 actuations	(a) Hospital Miri	LULUS
			Metered Dose Inhaler (MDI) Pressurized Inhalation Suspension budesonide (BD), 80 µg per actuation, 120 actuations	(b) University Malaya Medical Centre (c) Hospital Raja Permaisuri Bainun (d) Hospital Pulau Pinang (e) Hospital Serdang	
			BFF/BD MDI Placebo (for training)		
3.	Version 1.00 / 27.07.22	Fasa IV	Mupirocin Cream USP 2% (15g)	Hospital Canselor Tuanku Muhriz UKM (HCTM)	LULUS
4.	F7TG2202	Fasa III	LR769 - eptacog-beta (activated) 5mg/vial, 1mg/mL after reconstitution, powder for solution for injection	(a) Hospital Queen Elizabeth (b) Hospital Ampang	LULUS
			Sterile Water for Injection – 5.2 ml pre-filled syringe, intravenous		
5.	D9604C00001	Fasa III	Andexanet Alfa Powder for Solution for Infusion 200 mg/vial	(a) Hospital Queen Elizabeth (b) International Islamic University Malaysia	LULUS
6.	NN1436-4910	Fasa III	Insulin Icodec 700U/mL Solution for Injection, 3mL pre-filled pen-injector	(a) Hospital Miri	LULUS
			Semaglutide 1.34mg/mL in 1.5mL pre-filled PDS290 pen-injector	(b) Hospital Putrajaya (c) Universiti Teknologi MARA (UiTM) (d) Hospital Universiti Kebangsaan Malaysia	
7.	BRII-835-002	Fasa II	Vial containing 0.5 mL BRII-835 (VIR-2218) at 200 mg/ mL, Solution for Subcutaneous Injection	(a) Hospital Queen Elizabeth (b) Hospital Sultanah Bahiyah (c) Sarawak General Hospital	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Pre-filled Syringe of Peginterferon alfa-2a 180mcg/0.5mL, Solution for Injection	(d) University Malaya Medical Centre (e) Hospital Sultanah Aminah	
			Pre-filled Syringe of Peginterferon alfa-2a 135mcg/0.5mL, Solution for Injection		
8.	DMX-200-301	Fasa III	DMX-200 (repagermanium) 120 mg Capsule	(a) Hospital Tengku Ampuan Afzan	LULUS
			Matching Placebo for DMX-200 (repagermanium) 120 mg Capsule		