

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

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	010-23	Kajian BE	Pharmaniaga Metformin UC Tablet 500 mg	Cohance Lifesciences Ltd	LULUS
2.	22-VIN-0218	Kajian BE	Vildagliptin and Metformin Hydrochloride Tablets 50 mg/500 mg	Veeda Clinical Research Ltd.	LULUS
3.	22-VIN-0029	Kajian BE	Vildagliptin and Metformin Hydrochloride Tablets 50 mg/1000 mg	Veeda Clinical Research Ltd.	LULUS
4.	D7020C00001	Fasa I/II	AZD2936 50mg/mL concentrate for solution for infusion, 15mL/vial	(a) University Malaya Medical Centre (b) Hospital Umum Sarawak	LULUS
5.	FURMO-004	Fasa III	Furmonertinib 40mg Tablets	(a) Hospital Raja Perempuan Zainab II (b) Hospital Umum Sarawak (c) Hospital Pulau Pinang (d) Hospital Kuala Lumpur (e) Hospital Canselor Tuanku Muhriz UKM	LULUS
			Pemetrexed for injection for intravenous infusion 500mg, 20mL in a vial		
			Carboplatin injection for intravenous infusion 600mg, 60mL in a vial		
			Cisplatin injection for intravenous infusion 100mg, 100mL in a vial		
6.	BGB-A317-A445-101	Fasa I	BGB-A445 200 mg/10mL Concentrate for solution for infusion	(a) Hospital Umum Sarawak (b) University Kebangsaan Malaysia Medical Centre (c) University Malaya Medical Centre	LULUS
			BGB-A317 100 mg/10 mL Concentrate for solution for infusion		
7.	70033093AFL3002	Fasa III	JNJ-70033093 (Milvexian) 100mg Tablet (70 Tablets per Bottle)	(a) Hospital Tengku Ampuan Afzan (b) Hospital Seri Manjung (c) Hospital Taiping (d) Hospital Queen Elizabeth II (e) Hospital Sultanah Bahiyah (f) Hospital Universiti Sains Malaysia (g) Hospital UiTM Puncak Alam (h) Institut Jantung Negara	LULUS
			Matching Placebo for JNJ-70033093 (Milvexian) 100 mg Tablet		
			Apixaban 5mg Capsules (70 Capsules per Bottle)		
			Apixaban 2.5mg Capsules (70 Capsules per Bottle)		
			Matching Placebo for Apixaban 5mg Capsules (70 Capsules per Bottle)		
			Matching Placebo for Apixaban 2.5mg Capsules (70 Capsules per Bottle)		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Apixaban 5mg Tablets (60 Tablets per Bottle)		
			Apixaban 2.5mg Tablets (60 Tablets per Bottle)		