

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2020

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	0628-19	Kajian BE	1) Atorvastatin Tablet 40mg 2) Lipitor Tablet 40mg	Lambda Therapeutics Research Ltd. Lambda House, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad- 382481 Gujarat, India	Lulus
2.	DLS19001	Fasa II	1) DavosLife E3 Complete Softgel 2) Matching Placebo to DavosLife E3 Complete Softgel	Pusat Perubatan Universiti Kebangsaan Malaysia	Lulus
3.	CRSU-P-1-1019	Fasa II	1) SKF7™ 187.5mg Capsule 2) Matching Placebo of SKF7™ 187.5mg Capsule	1) Hospital Melaka 2) Hospital Tunku Ja'afar 3) Klinik Kesihatan Seremban 2 4) Klinik Kesihatan Masjid Tanah 5) Klinik Kesihatan Kuang 6) Klinik Kesihatan Greentown	Lulus
4.	19-11-1319	Fasa II	1) SKF7™ 187.5mg Capsule 2) Matching Placebo of SKF7™ 187.5mg Capsule	1) Indonesian Medical Education and Research Institute (IMERI), Clinical Research Supporting Unit, FKUI 2) Rumah Sakit Universitas Indonesia (RSUI), Universitas Indonesia 3) Klinik Satelit Makara, Universitas Indonesia 4) Fakultas Kedokteran dan Ilme Kesehatan Universitas Kristen Krida Wacana	Lulus

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
5.	AC-055-315	Fasa III	1) Macitentan 10 mg Film-Coated (FC) Tablets 2) Macitentan 75 mg Film-Coated (FC) Tablets 3) Macitentan 37.5 mg Film-Coated (FC) Tablets 4) Macitentan 10 mg Film-Coated (FC) Tablets Matching Placebo 5) Macitentan 75 mg Film-Coated (FC) Tablets Matching Placebo 6) Macitentan 37.5 mg Film-Coated (FC) Tablets Matching Placebo	1) Hospital Serdang 2) Hospital Pulau Pinang	Lulus
6.	CBYL719G12301	Fasa III	1) BYL719 (Alpelisib) 50 mg Film-coated tablet 2) BYL719 (Alpelisib) 200 mg Film-coated tablet 3) Placebo to BYL719 (Alpelisib) 50 mg Film-coated tablet 4) Placebo to BYL719 (Alpelisib) 200 mg Film-coated tablet	Pantai Hospital Kuala Lumpur	Lulus