

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Nama Pemohon	Pusat Kajian Klinikal	Jangkaan Tempoh Masa Kajian Klinikal*	Status Permohonan
1	0200-22	Kajian BE	Linagliptin 5mg Film-coated Tablets	Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.	Tapak Klinikal & Bionalitikal: Lambda Therapeutic Research Ltd. Lambda house, Plot No.38, Survey no. 388, Near Silver Oak Club, S.G. Highway, Gata, Ahmedabad-382481, Gujarat, India.	Tidak berkenaan	LULUS
2	PT3_AFLD	Fasa II	1) Tocovid TM Suprabio TM 200mg Capsule 2) Placebo to Match Tocovid Suprabio Capsule	Hovid Berhad	Hospital Canselor Tuanku Muhriz UKM	01-Dis-2023 hingga 10-Nov-2024	LULUS
3	D361DC00001	Fasa Ib/III	1) Capiwasertib (AZD5363) 200mg Tablet 2) Capiwasertib (AZD5363) 160mg Tablet 3) 5 mL Fulvestrant Solution for injection 50 mg/mL 4) Tablet Palbociclib 75mg 5) Tablet Palbociclib 100mg 6) Tablet Palbociclib 125mg 7) Capsule Palbociclib 75mg 8) Capsule Palbociclib 100mg 9) Capsule Palbociclib 125mg 10) Ribociclib Tablet 200mg	AstraZeneca Sdn Bhd	a) Pantai Hospital Kuala Lumpur b) Hospital Pulau Pinang c) University Malaya Medical Centre d) Sarawak General Hospital e) Penang Adventist Hospital f) Beacon Hospital g) Institut Kanser Negara h) Hospital Kuala Lumpur	01-Jan-2024 hingga 02-Apr-2029	LULUS
4	EFC16035	Fasa III	1) Tolebrutinib/SAR442168 60 mg film coated tablet 2) Placebo matching with tolebrutinib (SAR442168)/ Film Coated Tablet	Sanofi-Aventis (Malaysia) Sdn Bhd	Hospital Kuala Lumpur	11-Feb-2023 hingga 02-Apr-2029	LULUS
5	D926QC00001	Fasa III	1) DS-1062a Lyophilised powder for concentrate for solution for infusion, 100 mg/vial 2) 10 mL Durvalumab (MEDI4736) Concentrate for solution for infusion, 50 mg/mL (500 mg/vial)	AstraZeneca Sdn Bhd	a) Hospital Pulau Pinang b) University Malaya Medical Centre c) Pantai Hospital Kuala Lumpur d) Hospital Umum Sarawak e) Institut Kanser Negara	01-Feb-2024 hingga 01-Feb-2031	LULUS
6	WA43966	Fasa III	1) RO7434656 70 mg/0.7 ml, solution for injection in a vial 2) Matching placebo for RO7434656 70 mg/0.7 ml, solution for injection in a vial	PPD Development (S) Pte. Ltd	a) Hospital Tengku Ampuan Afzan b) Hospital Sibu c) Hospital Ampang d) Hospital Miri e) Hospital Seri Manjung f) Hospital Taiping g) Universiti Malaya Medical Centre h) Hospital Kuala Lumpur	15-Nov-2023 hingga 31-Dis-2026	LULUS
7	FPSMA-01	Fasa III	F-18 PSMA-1007 90-110 mCi/ml Injectable Solution	Jabatan Perubatan Nuklear, Institut Kanser Negara	Fasiliti PET-CT, Jabatan Perubatan Nuklear, Institut Kanser Negara	01-Jun-2022 hingga 01-Dis-2023	LULUS

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8	ITOP-322-016	Fasa III	1) Itopride Hydrochloride 150mg Extended Release Tablets 2) GANATON® 50mg Tablets (Itopride Hydrochloride)	Antah Pharma Sdn Bhd	a) University Malaya Medical Centre (UMMC) b) Hospital Queen Elizabeth c) Hospital Sultanah Bahiyah d) Pantai Hospital Kuala Lumpur	01-Jan-2024 hingga 30-May-2025	LULUS
9	FF-2021-519	Fasa IV	1) Bio-D3 800IU Capsule 2) Matching Placebo for Bio-D3 800 IU Capsule	Pharma Nord Sdn Bhd	Hospital Pakar Kanak-kanak UKM	01-April-2022 hingga 31-Okt-2023	LULUS
10	LG-GDCL010	Fasa III	1) Tigulixostat 100mg Tablet 2) Tigulixostat 200mg Tablet 3) Allopurinol 100mg Over-encapsulated Tablet (Capsule) 4) Allopurinol 200mg Over-encapsulated Tablet (Capsule) 5) Allopurinol 300mg Over-encapsulated Tablet (Capsule) 6) Matching Placebo to Tigulixostat 100mg Tablet 7) Matching Placebo to Tigulixostat 200mg Tablet 8) Matching Placebo to Allopurinol 100mg/200mg/300mg Over-encapsulated Tablet (Capsule)	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Selayang b) Sarawak General Hospital c) Hospital Seri Manjung d) Klinik Kesihatan Masjid Tanah e) Klinik Kesihatan Kuala Lumpur f) Klinik Kesihatan Kuang g) University Malaya Medical Centre	02-Jan-2024 hingga 31-Dis-2025	LULUS
11	R3767-ONC-2235	Fasa II/III	1) 16mL of 50mg/mL of Fianlimab (REGN3767) Liquid Solution in Vial 2) 7mL of 50mg/mL of Cemiplimab (REGN2810) Liquid Solution in Vial	Antah Pharma Sdn. Bhd.	a) Hospital Sultan Ismail b) Hospital Pulau Pinang c) Mahkota Medical Centre d) Hospital Tengku Ampuan Afzan e) Institut Kanser Negara f) Hospital Kuala Lumpur	01-Jan-2024 hingga 11-Mac-2029	LULUS
12	R3767-ONC-2236	Fasa II/III	1) 16mL of 50mg/mL of Fianlimab (REGN3767) Liquid Solution in Vial 2) 7mL of 50mg/mL of Cemiplimab (REGN2810) Liquid Solution in Vial 3) 50mL of Paclitaxel AqVida 6 mg/mL Concentrate for Solution for Infusion 4) Carboplatin Hikma 10 mg/mL Solution for Infusion, 150mg 5) 20mL of Pemetrexed EVER Pharma 25 mg/mL Concentrate for Solution for Infusion 6) Cisplatin Concentrate for Solution for Infusion 1mg/mL 100mL	Antah Pharma Sdn. Bhd.	a) Hospital Sultan Ismail b) Hospital Pulau Pinang c) Mahkota Medical Centre d) Mount Miriam Cancer Hospital e) Hospital Tengku Ampuan Afzan f) Institut Kanser Negara g) Hospital Umum Sarawak	01-Jan-2024 hingga 31-Dis-2029	LULUS

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13	SB27-3004	Fasa III	1) Pembrolizumab (SB27) 100 mg/4 ml (25 mg/ml) concentrate for solution for infusion 2) Pembrolizumab (Keytruda®) 100 mg/4 ml (25 mg/ml) concentrate for solution for infusion 3) Carboplatin (10 mg/ml) concentrate for solution for infusion 4) Pemetrexed (25 mg/ml) concentrate for solution for infusion	Antah Pharma Sdn. Bhd.	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) University Malaya Medical Center (UMMC) d) National Cancer Centre	26-Jan-2024 hingga 01-Jul-2027	LULUS
14	P-SP420-THAL-01	Fasa II	SP-420 Capsules 400mg	Questra Clinical Research Sdn. Bhd.	a) Hospital Sultanah Aminah b) Tuanku Ja'afar Hospital Seremban c) Hospital Raja Perempuan Zainab II d) Hospital Sultanah Bahiyah e) Hospital Tengku Ampuan Afzan f) Hospital Ampang	27-Mei-2024 hingga 13-Okt-2025	LULUS
15	VT3996-202	Fasa II	1) VRx-3996 (nanatinostat) tablets, 10 mg 2) Valganciclovir 450 mg Tablets	Questra Clinical Research Sdn. Bhd.	a) Hospital Umum Sarawak b) University Malaya Medical Centre	22-Apr-2024 hingga 01-Feb-2027	LULUS
16	747-308	Fasa II/III	1) OCA, 0.1 mg tablet 2) OCA, 1.5 mg tablet 3) Matching Placebo for OCA, 0.1 mg tablet 4) Matching Placebo for OCA, 1.5 mg tablet	Syneos Health Malaysia Sdn. Bhd.	a) Universiti Malaya Medical Centre b) Hospital Raja Perempuan Zainab II	31 -May-2024 hingga 31-May-2028	LULUS
17	D9723C00001	Fasa III	1) Tablet AZD5305 20mg 2) Placebo for Tablet AZD5305 20mg	AstraZeneca Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Hospital Sultan Ismail d) Hospital Umum Sarawak e) Hospital Likas f) Hospital Kuala Lumpur	01-Mar-2024 hingga 31-Oct-2031	LULUS
18	PR/BE/23/324	Kajian BE	Noriquine 200mg Tablet	Noripharma Sdn. Bhd.	Tapak Klinikal: Raptim Research Pvt. Ltd. A-226 (Clinical Unit), T.T.C Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India (Dr Raviraj Jagdhani) Tapak Bionalitikal: Raptim Research Pvt. Ltd. A-242, T.T.C Industrial Area, Mahape M. I.D.C., Navi Mumbai – 400710, India	Tidak berkenaan	LULUS
19	MK-2870-005	Fasa III	MK-2870 200mg/vial, Lyophilized powder for IV Infusion (MK-2870-005)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	a) University Malaya Medical Centre b) Pantai Hospital Kuala Lumpur	01-Feb-2024 hingga 29-Nov-2028	LULUS

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20	ARL-23-017	Kajian BE	1) Sitagliptin 100 mg Film-Coated Tablets 2) Januvia 100 mg Film-Coated Tablet	Hovid Berhad	Tapak Klinikal dan Tapak Bioanalytical: Accutest Research Laboratories (I) Pvt. Ltd. A-31, M.I.D.C., T.T.C. Industrial Area, Khairne, Navi Mumbai, 400709 Maharashtra, INDIA.	Tidak berkenaan	LULUS
21	1807361301 (Previously known as 2015H0112)	Fasa II	1) Mixed Tocotrienols 200mg capsule 2) Mixed Tocotrienols 200mg Matching placebo capsule	Hovid Berhad	Indiana University Health University Hospital	Tidak berkenaan	LULUS
22	D9350C00001	First-In Human	1) AZD9592 100 mg/vial Powder for solution for infusion 2) IV Bag Protectant 1 mL/vial Concentrate for solution for infusion 3) Tablet Osimertinib 40mg 4) Tablet Osimertinib 80mg	AstraZeneca Sdn. Bhd.	Hospital Umum Sarawak	1 Mei 2024 hingga 22 Ogos 2025	LULUS
23	D9800C00001	Fasa II	AZD0901 50mg / vial, Lyophilisate for concentrate for solution for infusion	AstraZeneca Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Sarawak General Hospital d) Institut Kanser Negara e) Hospital Sultan Ismail	1 Feb 2024 hingga 31 Dis 2026	LULUS
24	AP063-003	Fasa III	1) AP063, 150 mg powder for concentrate for solution for infusion 2) Herceptin®, 150 mg powder for concentrate for solution for infusion 3) Docetaxel, 160mg/8mL concentrate for solution for infusion 4) Epirubicin Hydrochloride 200mg/100mL concentrate for solution for infusion 5) Cyclophosphamide, 500mg powder for solution for injection 6) Cyclophosphamide, 1000mg powder for solution for injection	Syneos Health Malaysia Sdn. Bhd.	a)University Malaya Medical Centre b)Columbia Asia Hospital – Bukit Rimau c)Institut Kanser Negara d)Hospital Pulau Pinang e)Sarawak General Hospital f)Hospital Sultan Ismail g)Hospital Al-Sultan Abdullah h)Hospital Kuala Lumpur	29 Mar 2024 hingga 30 Jul 2026	LULUS
25	MK-2870-004	Fasa III	1) MK-2870 200mg/vial, Lyophilized powder for IV Infusion 2) Docetaxel 20mg/mL, Solution for IV Infusion, 80mg vial 3) Pemetrexed, Lyophilized Powder for Solution for Infusion, 500mg/vial	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Umum Sarawak b) Hospital Raja Perempuan Zainab II c) Institut Kanser Negara	1 Nov 2023 hingga 30 Jun 2031	LULUS

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26	MK-6194-006	Fasa II	1) MK-6194 3mg/mL, 1mL Sterile Solution for Injection / Pre-filled syringe 2) MK-6194 Placebo, 1mL Sterile Solution for Injection / Pre-filled syringe	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Taiping b) University Malaya Medical Centre c) Hospital Tengku Ampuan Afzan d) Hospital Canselor Tuanku Muhriz UKM	1 Feb 2024 hingga 19 Nov 2027	LULUS
27	D5985C00002	Fasa III	1) MDI – Metered-dose Inhaler Pressurized Inhalation Suspension Budesonide/Glycopyrronium/Formoterol Fumarate (BGF HFO) 160/7.2/4.8 µg Per Actuation 2) MDI - Metered-dose Inhaler Pressurized Inhalation Suspension BGF Placebo 120 Actuations 3) MDI - Metered-dose Inhaler Pressurized Inhalation Suspension Budesonide/Glycopyrronium/Formoterol Fumarate (BGF) 160/7.2/4.8 µg Per Actuation	AstraZeneca Sdn. Bhd.	a) Hospital Pulau Pinang b) Institute of Respiratory Medicine c) Hospital Raja Permaisuri Bainun d) Hospital Sultanah Nur Zahirah	NA	LULUS
28	D4325C00010	Fasa III	1) Zibotentan/Dapagliflozin 0.25mg/10mg 2) Zibotentan/Dapagliflozin 0.75mg/10mg 3) Tablet Dapagliflozin 10mg	AstraZeneca Sdn Bhd	a) University Malaya Medical Centre b) Hospital Raja Permaisuri Bainun c) Hospital Seri Manjung	1 Apr 2024 hingga 31 Okt 2027	LULUS
29	22-002	Fasa IV	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion	University Malaya Medical Centre	University Malaya Medical Centre	1 Oct 2023 hingga 31 Dis 2025	LULUS
30	D3466C00001	Fasa III	1) 2 mL Anifrolumab Concentrate for solution for infusion 150mg/mL 2) 2 mL Placebo Concentrate for solution for infusion 150mg/mL	AstraZeneca Sdn Bhd	(a) University Malaya Medical Centre (b) Hospital Selayang (c) Hospital Serdang (d) Hospital Tengku Ampuan Afzan (e) Hospital Raja Permaisuri Bainun (e) Hospital Taiping	03 Jun 2024 hingga 31 Jan 2029	LULUS
31	CGME751A12101	Fasa I	1) GME751 (Pembrolizumab) 25 mg/mL Concentrate for Solution for Infusion 2) Keytruda (Pembrolizumab) EU 25 mg/mL Concentrate for Solution for Infusion 3) Keytruda (Pembrolizumab) US 25 mg/ml Concentrate for Solution for Infusion	Parexel International (Malaysia) Sdn Bhd	(a) Institut Kanser Negara (b) Hospital Sultan Ismail (c) Hospital Umum Sarawak (d) Mahkota Medical Centre (e) Hospital Kuala Lumpur (f) University Malaya Medical Centre	31 Jan 2024 hingga 18 Julai 2025	LULUS

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32	CGME751A12301	Fasa III	1) GME751 (Pembrolizumab) 25 mg/mL Concentrate for Solution for Infusion 2) Keytruda (Pembrolizumab) EU 25 mg/mL Concentrate for Solution for Infusion 3) Carboplatin 10mg/mL concentrate for solution for infusion 4) Cisplatin 1mg/ml concentrate for solution for infusion 5) Pemetrexed 25mg/ml concentrate for solution for infusion	Parexel International (Malaysia) Sdn Bhd	(a) Beacon International Specialist Centre (b) Pusat Perubatan Universiti Sains Malaysia Bertam (PPUSMB) (c) Universiti Kebangsaan Malaysia Medical Centre (d)) Onco Life Centre (e) Sarawak General Hospital (f) Institut Kanser Negara (g) Pantai Hospital Kuala Lumpur (h) Hospital Tengku Ampuan Afzan (i) Hospital Sultan Ismail (j) Mahkota Medical Centre	31 Jan 2024 hingga 25 Jun 2027	LULUS
33	045-23	Kajian BE	Empagliflozin Tablets 25 mg	Duopharma Innovation Sdn Bhd	Cohance Lifesciences Limited	Tidak berkenaan	LULUS
34	NN7415-4616	Fasa III	1) Concizumab C 10 mg/mL solution for injection, 1.5 ml pen-injector 2) Concizumab C 40 mg/mL solution for injection, 1.5 ml pen-injector 3) Concizumab C 100 mg/mL solution for injection, 1.5 ml pen-injector	Novo Nordisk Pharma (Malaysia) Sdn. Bhd.	(a) Hospital Tunku Azizah (b) Sarawak General Hospital (c) Hospital Pulau Pinang (d) Hospital Sultanah Nur Zahirah	1 Julai 2024 hingga 14 Mar 2030	LULUS
35	BP44135	First-In Human	1) RO7507062 Sterile Solution 125 mg/5 mL 2) Tocilizumab 20mg/mL Concentrate for Solution for Infusion, 10mL Vial	Roche (Malaysia) Sdn. Bhd.	Hospital Umum Sarawak	18 Julai 2024 hingga 31 Dis 2034	LULUS
36	D6402C00012	Fasa III	1) Capsule Balcinrenone 15mg + Dapagliflozin 10mg 2) Capsule Balcinrenone 40mg + Dapagliflozin 10mg 3) Dapagliflozin 10mg tablet 4) Placebo for Balcinrenone/ Dapagliflozin capsule 5) Placebo for Dapagliflozin tablet	AstraZeneca Sdn Bhd	1. Hospital Sultan Idris Shah Serdang 2. Hospital Queen Elizabeth II 3. Pusat Jantung Sarawak 4. Hospital Sultanah Nur Zahirah 5. Hospital UiTM Sungai Buloh 6. Institut Jantung Negara 7. Hospital Tengku Ampuan Afzan	01 Mei 2024 hingga 31 Julai 2027	LULUS

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37	D6405C00002	Fasa II	1) Capsule Balcinrenone 15mg + Dapagliflozin 10mg 2) Capsule Balcinrenone 40mg + Dapagliflozin 10mg 3) Dapagliflozin 10mg tablet 4) Placebo for Balcinrenone/ Dapagliflozin capsule 5) Placebo for Dapagliflozin tablet	AstraZeneca Sdn Bhd	1. Hospital Raja Permaisuri Bainun 2. University Malaya Medical Centre 3. Hospital Raja Perempuan Zainab	01 Julai 2024 hingga 29 May 2026	LULUS
38	AC-203-EBS-007	Fasa II/III	1) AC-203 Diacerein 1% Ointment 2) Placebo of Diacerein Ointment	Questra Clinical Research Sdn Bhd	Hospital Tunku Azizah (Hospital Wanita dan Kanak-Kanak Kuala Lumpur)	10 Jun 2024 hingga 30 Jun 2025	LULUS
39	XL092-305	Fasa II/III	1) Zanzalintinib (XL092) 40 mg tablet 2) Zanzalintinib (XL092) 60 mg tablet 3) Zanzalintinib (XL092) 100 mg tablet 4) Matching Placebo for Zanzalintinib (XL092) 40 mg tablet 5) Matching Placebo for Zanzalintinib (XL092) 60 mg tablet 6) Matching Placebo for Zanzalintinib (XL092) 100 mg tablet 7) Pembrolizumab Concentrate Solution for Injection 100 mg/4 mL (25 mg/mL) vial	IQVIA RDS Malaysia Sdn. Bhd.	1) Institut Kanser Negara 2) Hospital Kuala Lumpur 3) University Malaya Medical Centre	05 Julai 2024 hingga 08 Julai 2026	LULUS
40	BE23-002	Kajian BE	NicePower F.C Tablet 20 mg	Nano Medic Care Sdn. Bhd	Questra Clinical Research Sdn. Bhd.	10 Jun 2024 hingga 13 September 2024	LULUS
41	D6972C00003	Fasa III	1) Baxdrostat 1mg Tablet 2) Baxdrostat 2mg Tablet 3) Placebo for Baxdrostat Tablet 4) Tablet Dapagliflozin 10mg	AstraZeneca Sdn Bhd	1. Hospital Tuanku Ja'afar 2. Hospital Taiping 3. Hospital Kuala Lumpur 4. University Malaya Medical Centre 5. Hospital Tengku Ampuan Afzan 6. Hospital Queen Elizabeth 7. Hospital Tengku Ampuan Rahimah	01 Julai 2024 hingga 19 Julai 2028	LULUS

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42	MK-5684-003	Fasa III	1) MK-5684 2.5mg tablet 2) Abiraterone acetate 250mg tablet 3) Prednisone 5mg tablet 4) Enzalutamide 40mg soft capsule 5) Fludrocortisone acetate 0.1mg tablet 6) Dexamethasone 0.5mg tablet 7) Hydrocortisone 100mg powder and 2mL solvent for solution for injection vial 8) Hydrocortisone 10mg tablet	Merck Sharp & Dohme (Malaysia) Sdn Bhd	1. Sarawak General Hospital 2. University Malaya Medical Centre 3. Hospital Kuala Lumpur 4. Institut Kanser Negara / National Cancer Institute 5. Hospital Sultan Ismail	15 Mac 2024 hingga 31 Mac 2030	LULUS
43	MK-5684-004	Fasa III	1) MK-5684 2.5mg tablet 2) Abiraterone acetate 250mg tablet 3) Prednisone 5mg tablet 4) Enzalutamide 40mg soft capsule 5) Fludrocortisone acetate 0.1mg tablet 6) Dexamethasone 0.5mg tablet 7) Hydrocortisone 100mg powder and 2mL solvent for solution for injection vial 8) Hydrocortisone 10mg tablet	Merck Sharp & Dohme (Malaysia) Sdn Bhd	1. Sarawak General Hospital 2. University Malaya Medical Centre 3. Hospital Kuala Lumpur 4. Institut Kanser Negara / National Cancer Institute 5. Hospital Sultan Ismail	15 Mar 2024 hingga 30 Jun 2032	LULUS

*Data adalah diperolehi daripada laman sesawang National Medical Research Register (NMRR). Sila layari <https://nmrr.gov.my/research-directory> untuk maklumat terkini dan lanjut.