

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
1	D6973C00001	Fasa III	Baxdrostat 1mg Tablet Baxdrostat 2mg Tablet Placebo for Baxdrostat Tablet Dapagliflozin 10mg Tablet	AstraZeneca Sdn Bhd	a) Hospital Miri b) Hospital Tengku Ampuan Afzan c) Pusat Jantung Sarawak d) Hospital Sultanah Bahiyah e) Hospital UiTM Sungai Buloh	28-Mar-2025 hingga 07-Jan-2030	LULUS
2	1368-0140	Fasa III	BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial Matching Placebo BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial	IQVIA RDS Malaysia Sdn Bhd	a) Hospital Raja Permaisuri Bainun b) Hospital Pulau Pinang c) Hospital Umum Sarawak	01-Jan-2025 hingga 31-Oct-2027	LULUS
3	UM/ICU/FOiL/2024	Fasa II	OMEGA VEN (fish oil triglycerides) injectable emulsion, for intravenous use. 10g/100 ml (0.1 g/mL) in a single-dose bottle	University Malaya Medical Centre	University Malaya Medical Centre	01-Dec-2023 hingga 01-Dec-2025	LULUS
4	PR/BE/24/284	Kajian BE	Diabetmin ER 500 mg Tablet	Hovid Bhd	Raptim Research Pvt. Ltd.	Tidak Berkenaan	LULUS
5	OZ101A	Fasa I	Ozanimod TDS 0.92 mg/day Formulation 1 Ozanimod TDS 0.92 mg/day Formulation 2 Zeposia Capsule 0.92 mg	Info Kinetics Sdn Bhd	Clinical Site: Clinical Research Ward, Hospital Ampang Bioanalytical Site: Info Kinetics Sdn Bhd	01-Dec-2024 hingga 31-Jul-2025	LULUS
6	D6972C00002	Fasa III	Baxdrostat 1mg Tablet Baxdrostat 2mg Tablet Placebo for Baxdrostat Tablet Tablet Dapagliflozin 10mg	AstraZeneca Sdn Bhd	a) University Malaya Medical Centre (UMMC) b) Hospital Kajang	01-Apr-2025 hingga 24-Jul-2030	LULUS
7	ENV-IPF-103	Fasa II	ENV-101 (Taladegib) 25mg Tablet ENV-101 (Taladegib) 100mg Tablet Matching Placebo to ENV-101 (Taladegib) 25mg / 100mg Tablet	Parexel International (Malaysia) Sdn. Bhd.	a) Institut Perubatan Respiratori b) Hospital Al-Sultan Abdullah UiTM c) Hospital Canselor Tuanku Muhriz	05-Aug-2024 hingga 03-Mar-2027	LULUS
8	ID-064A302	Fasa III	Cenerimod 4 mg Film-Coated Tablets Matching Placebo for Cenerimod 4 mg Film-Coated Tablets	Novotech Clinical Research (M) Sdn. Bhd.	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Canselor Tuanku Muhriz UKM d) Hospital Sibu e) Hospital Selayang f) Hospital Tuanku Fauziah	10-Mar-2025 hingga 17-Nov-2026	LULUS
9	CT01-ATOM-MY-2022	Fasa III	Atropine Sulphate 0.025% w/v Eye Drops Placebo Eye Drops	Antah Pharma Sdn. Bhd.	a) Hospital Pakar Kanak-Kanak Universiti Kebangsaan Malaysia (HPKK UKM) b) University of Malaya Medical Centre (UMMC)	Tidak Berkenaan	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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10	ORIC-114-01	Fasa III	ORIC-114 tablet, 10 mg	Syneos Health Malaysia Sdn. Bhd.	a) Universiti Malaya Medical Centre b) Hospital Umum Sarawak c) Sultan Ahmad Shah Medical Centre d) Hospital Pulau Pinang e) Hospital Kuala Lumpur	14-Jan-2025 hingga 30-Apr-2026	LULUS
11	CDX0159-12	Fasa I	Barzolvolimab (CDX-0159) 150 mg/ml solution for injection in 1ml pre-filled syringe Placebo matching Barzolvolimab (CDX-0159) 150 mg/ml solution for injection in 1ml pre-filled syringe Epinephrine injection, USP auto-injector, 0.3mg pre-filled autoinjectors	Victory Pharma Consultancy	a) Hospital Raja Permaisuri Bainun b) Hospital Kuala Lumpur c) Hospital Pulau Pinang d) Hospital Sultan Ismail e) Hospital Umum Sarawak	01-Mar-2025 hingga 31-Aug-2027	LULUS
12	Protocol version number: 1.4	Fasa III	Doxyline capsule 100mg Matching placebo for Doxyline capsule 100mg	Jabatan Pediatrik, Klinik Kesihatan Luyang	a) Hospital Queen Elizabeth b) Klinik Kesihatan Menggatal	01-Oct-2024 hingga 31-Di-2027	LULUS
13	BB-031-CLIN-201	Fasa II	BB-031 Liquid for Injection 50mg/mL (2mL per vial) Placebo Injection for BB-031 Liquid for Injection 50mg/mL (2mL per vial)	George Clinical Asia Pacific Limited	a) Hospital Seberang Jaya b) Hospital Umum Sarawak c) Hospital Universiti Sains Malaysia	21-Oct-2024 hingga 31-Di-2028	LULUS
14	GS-US-699-7184 (Substudy-01)	Fasa II	Domvanalimab Concentrate for Solution for Infusion, 60 mg/mL Zimberelimab Concentrate for Solution for Infusion, 30 mg/mL Paclitaxel Concentrate for Solution for Infusion, 6 mg/mL Carboplatin Concentrate for Solution for Infusion, 10 mg/mL	IQVIA RDS Malaysia Sdn Bhd	a) Institut Kanser Negara b) Hospital Pulau Pinang c) Hospital Pantai Kuala Lumpur d) Hospital Umum Sarawak e) Hospital Kuala Lumpur	01-Di-2024 hingga 31-Di-2027	LULUS
15	STML-ELA-0422	Fasa III	Elacestrant 86mg Film Coated Tablets Elacestrant 345mg Film Coated Tablet Anastrozole 1 mg film-coated tablets (EU authorized products) Anastrozole 1 mg film-coated tablets (US authorized products) Exemestane 25 mg film-coated tablets (EU authorized products) Exemestane 25 mg film-coated tablets (US authorized products) Letrozole 2.5 mg film-coated tablets (EU authorized products) Letrozole 2.5 mg film-coated tablets (US authorized products) Tamoxifen 20 mg tablets (EU authorized products) Tamoxifen 20mg tablets (US authorized products)	Parexel International (Malaysia) Sdn. Bhd.	a) University Malaya Medical Centre b) Beacon Hospital c) Hospital Universiti Sains Malaysia d) Pantai Hospital Kuala Lumpur e) Hospital Canselor Tuanku Muhriz UKM f) Institut Perubatan & Pergigian Termaju (IPPT) – USM g) Hospital Raja Permaisuri Bainun h) Hospital Kuala Lumpur i) Hospital Sultan Ismail j) Institut Kanser Negara k) Mahkota Medical Centre l) Hospital Pulau Pinang	15-Mar-2025 hingga 15-Mar-2033	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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16	D5989C00001	Fasa III	MDI - metered-dose inhaler inhalation aerosol Budesonide/glycopyrronium/formoterol fumarate (BGF) 160/7.2/4.8 µg per actuation MDI - metered-dose inhaler inhalation aerosol Glycopyrronium/formoterol fumarate (GFF) 7.2/4.8 µg per actuation MDI - metered-dose inhaler inhalation aerosol Placebo	AstraZeneca Sdn. Bhd.	a) Hospital Duchess of Kent b) Hospital Miri c) Hospital Sultan Idris Shah Serdang d) Hospital Sibu e) Hospital Tuanku Jaafar f) Institut Perubatan Respiratori g) Hospital Tuanku Ampuan Najihah h) Hospital Sultanah Bahiyah	01-Jul-2024 hingga 30-Mar-2028	LULUS
17	PR/BE/24/297	Kajian BE	Diabetmin ER 1000mg Tablet	Hovid Berhad	Raptim Research Pvt. Ltd.	Tidak Berkenaan	LULUS
18	SE101	Kajian BE	Selegiline TDS 6mg/24 hours EMSAM® TDS 6mg/24 hours	Info Kinetics Sdn Bhd	CRC Research Ward Level 6, Sarawak General Hospital Heart Centre	02-Sept-2024 hingga 31-Mar-2025	LULUS
19	D798KC00001	Fasa II	Volrustomig (MEDI5752) Lyophilised Powder for Solution for Infusion (250 mg/vial)	Parexel International (Malaysia) Sdn. Bhd.	a) Sunway Medical Centre Penang b) Hospital Umum Sarawak c) University Malaya Medical Centre	15-Mar-2025 hingga 01-Jun-2028	LULUS
20	BP44474	First-In Human	Film-coated tablets RO7589831 25mg Film-coated tablets RO7589831 200mg Pembrolizumab, Concentrate for solution for infusion, 100mg/4mL	Roche (Malaysia) Sdn. Bhd.	a) Hospital Umum Sarawak	05-Dis-2024 hingga 31-Dis-2034	LULUS
21	AG10-501	Fasa III	Acoramidis 356 mg film-coated tablets Placebo for Acoramidis 356mg film-coated tablets	Antah Pharma Sdn Bhd	a) University Malaya Medical Centre	28-Mar-2025 hingga 28-Mar-2032	LULUS
22	MK-2140-010	Fasa III	MK-2140 60mg Lyophilized powder for IV infusion, 60mg vial Rituximab 10mg/mL, Concentrate for solution for Infusion, 50 mL vial Cyclophosphamide 1g/vial, Powder for solution for injection (or Cyclophosphamide 1000mg (as Cyclophosphamide monohydrate) vial) Doxorubicin Hydrochloride 2mg/mL, Concentrate for Solution for Infusion, 25mL Vial Prednisone 50mg tablet Vincristine Sulfate 1mg/mL, Solution for Injection, 2mL Vial	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Umum Sarawak b) Hospital Miri c) Hospital Ampang d) Hospital Queen Elizabeth e) Sunway Medical Centre	01-Feb-2025 hingga 30-Jun-2033	LULUS
23	INBRX106-01-201	Fasa II/III	INBRX-106 20 mg/mL Solution for Injection (5 mL per vial) Pembrolizumab 100 mg/4 mL (25 mg/mL) Solution for Injection	George Clinical Asia Pacific Limited	a) Sarawak General Hospital b) Hospital Canselor Tuanku Muhriz UKM c) Hospital Universiti Sains Malaysia d) Institut Kanser Negara	30-Nov-2024 hingga 31-Mei-2029	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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24	INSIGHT 012	Fasa III	Anti-COVID-19 Hyperimmune Globulin (Human); for intravenous use; 5 g/50 mL	University Malaya Medical Centre	a) University Malaya Medical Centre	01-Okt-2024 hingga 31-Dis-2025	LULUS
25	PR/BE/24/366	Kajian BE	Diabetmin ER 750 mg Tablet	Hovid Bhd	Raptim Research Pvt. Ltd.	Tidak Berkenaan	LULUS
26	WAL0921-02	Fasa II	WAL0921, 50 mg/mL Solution for IV Infusion	George Clinical Asia Pacific Limited	a) Hospital Canselor Tuanku Muhriz UKM b) Hospital Tengku Ampuan Afzan c) Hospital Kuala Lumpur d) Hospital Sultan Idris Shah Serdang e) Sunway Medical Centre f) Universiti Malaya Medical Centre	03-Mar-2025 hingga 31-Mar-2027	LULUS
27	BP45381	First-In Human	Eciskafusp alfa 20 mg/2 ml BCG Medac , Powder for intravesical suspension	Roche (Malaysia) Sdn. Bhd.	a) Hospital Umum Sarawak	01-Feb-2025 hingga 31-Dis-2035	LULUS
28	122-24	Kajian BE	Rivaroxaban Tablet 20mg	Duopharma Innovation Sdn Bhd	VerGo Pharma Research Pvt. Ltd (Division - VerGo Clinicals), India	Tidak Berkenaan	LULUS
29	C1B05321	Kajian BE	Nilotinib Capsules 200 mg	Novugen Oncology Sdn. Bhd	Cliantha Research Limited, India	Tidak Berkenaan	LULUS
30	BE24-008	Kajian BE	Metadoxil Tablet (Metadoxine 500mg) (Interthai) Metadoxil Tablet (Metadoxine 500mg) (Baldacci)	Questra Clinical Research Sdn Bhd	Questra Clinical Research Sdn Bhd	04-Okt-2024 hingga 13-Dis-2024	LULUS
31	V181-005	Fasa III	V181 Quadrivalent Vaccine rDENVΔ30 >= 1.1E+03 IU/dose DENV1 / >= 3.8E+03 IU/dose DENV2 / >=4.7E+03 IU/dose DENV3 / >=1.1E+03 IU/dose DENV4, lyophilized powder for reconstitution for injection, 2ml vial Sterile Diluent for Reconstitution (Sterile Water) 0.7ml V181 Placebo, lyophilized powder for reconstitution for injection, 2ml vial	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Sibul b) Hospital Tunku Azizah c) Hospital Tunku Ampuan Besar Tuanku Aishah Rohani, Hospital Pakar Kanak-Kanak Universiti Kebangsaan Malaysia d) Universiti Malaya Medical Centre e) Sunway Medical Centre f) Hospital Ampang g) Hospital Al-Sultan Abdullah, Universiti Teknologi MARA h) Klinik Kesihatan Pandamaran	15-Mei-2024 hingga 01-Sep-2031	LULUS
32	CVAY736S12201	Fasa II	Ianalumab (VAY736) 150mg/1ml solution for injection in pre-filled syringe (PFS) Placebo to Ianalumab (VAY736) 150 mg/1 mL solution for injection in pre-filled syringe	Parexel International (Malaysia) Sdn Bhd	a) Hospital Canselor Tuanku Muhriz UKM b) University Malaya Medical Centre	07-Jul-2025 hingga 07-Jan-2030	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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33	D781PC00001	Fasa III	DS-8201a Powder for concentrate for solution for infusion. 100mg/vial 15 mL AZD2936 Concentrate for solution for infusion. 50 mg/mL (750 mg/vial) 10 mL Durvalumab (MEDI4736) Concentrate for solution for infusion. 50 mg/mL (500 mg/vial)	AstraZeneca Sdn Bhd	a) Hospital Pulau Pinang b) Hospital Umum Sarawak c) Hospital Kuala Lumpur d) Hospital Sultan Ismail e) University Malaya Medical Centre	14-Feb-2025 hingga 23-Aug-2029	LULUS
34	CLOU064J12301	Fasa III	LOU064 (Remibrutinib) 10mg film-coated tablet LOU064 (Remibrutinib) 25mg film-coated tablet Matching placebo to LO0064 (Remibrutinib) 10mg film-coated tablet Matching placebo to LOU064 (Remibrutinib) 25mg film-coated tablet	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Pulau Pinang b) Hospital Pakar Sultanah Fatimah c) Hospital Raja Perempuan Zainab II d) Sarawak General Hospital e) University Malaya Medical Centre f) Hospital Sultanah Nur Zahirah	01-Nov-2024 hingga 31-Oct-2028	LULUS
35	CLOU064J12302	Fasa III	LOU064 (Remibrutinib) 10mg film-coated tablet LOU064 (Remibrutinib) 25mg film-coated tablet Matching placebo to LO0064 (Remibrutinib) 10mg film-coated tablet Matching placebo to LOU064 (Remibrutinib) 25mg film-coated tablet	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Kuala Lumpur b) Hospital Putrajaya c) Hospital Raja Permaisuri Bainun d) Hospital Selayang e) Hospital Sultanah Aminah f) Hospital Queen Elizabeth	01-Nov-2024 hingga 30-Nov-2031	LULUS
36	VT-001-0051	Fasa II	1 mL of 150 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection	Antah Pharma Sdn Bhd	a) Hospital Kuala Lumpur b) Hospital Taiping c) University Malaya Medical Centre	11-Apr-2025 hingga 11-Jun-2028	LULUS
37	C1B05320	Kajian BE	Eltrombopag Tablets 75 mg	Novugen Pharma Sdn. Bhd.	Cliantha Research Limited, India	Tidak Berkenaan	LULUS
38	USM-SACHA INCHI OIL	Fasa II	Huamega Breinzema Softgel 520mg Matching Placebo to Huamega Breinzema Softgel 520mg	Universiti Sains Malaysia	Advanced Medical and Dental Institute	01-Mei-2024 hingga 12-Di-2025	TOLAK
39	CSL300_2301	Fasa II/III	CSL300 1.25mg/mL Solution for injection (2.5mg per vial) Placebo for CSL300 1.25mg/mL Solution for injection (2.5mg per vial)	Antah Pharma Sdn Bhd	a) Hospital Seri Manjung b) Hospital Seberang Jaya c) Hospital Raja Permaisuri Bainun d) Queen Elizabeth Hospital II e) University Malaya Medical Centre f) Hospital Sultan Idris Shah Serdang	24-Mac-2025 hingga 16-Jun 2029	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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40	19920	Fasa III	Finerenone 10mg Coated Tablet Finerenone 20mg Coated Tablet BAY 94-8862 Granules 3.4% 3 g For Oral Suspension Placebo to BAY 94-8862 Coated Tablet Placebo to BAY 94-8862 Granules 3.4 % 3g For Oral Suspension	Bayer Co. (Malaysia) Sdn. Bhd.	a) Hospital Tunku Azizah b) Hospital Selayang c) Hospital Tuanku Ja'afar d) Hospital Pakar Universiti Sains Malaysia e) Sunway Medical Centre	19-Mei-2025 hingga 30-Sep-2027	LULUS
41	CLNP023A2201	Fasa II	LNP023 200 mg hard gelatin capsule	Parexel International (Malaysia) Sdn Bhd	a) Hospital Serdang	30-Mei-2025 hingga 30-Nov-2028	LULUS
42	MB12-C-02-24	Fasa III	Pembrolizumab MB12 100mg/4mL (25mg/mL) vial, Concentrate for Solution for Infusion Pembrolizumab KEYTRUDA® EU 100mg/4mL (25mg/mL) vial, Concentrate for Solution for Infusion Pembrolizumab KEYTRUDA® US 100mg/4mL (25mg/mL) vial, Concentrate for Solution for Infusion Pemetrexed, 500mg/20ml (25mg/mL) vial, Concentrate for Solution for Infusion Carboplatin, 150mg/15mL (10mg/mL) vial, Concentrate for Solution for Infusion Carboplatin, 450mg/45mL (10mg/mL) vial, Concentrate for Solution for Infusion Cisplatin, 50mg/50mL (1mg/mL) vial, Concentrate for Solution for Infusion Cisplatin, 100mg/100mL (1mg/mL) vial, Concentrate for Solution for Infusion	Questra Clinical Research Sdn Bhd	a) Hospital Raja Perempuan Zainab II b) Hospital Canselor Tuanku Muhriz c) Cengild G.I Medical Centre	23-Jun-2025 hingga 13-Mei-2027	LULUS
43	ARL-24-113	Kajian BE	Dapagliflozin Hovid 10 mg Film-Coated Tablet	Hovid Bhd	Accutest Research Laboratories (I) Pvt. Ltd., India	Tidak berkenaan	LULUS
44	CRD-750-201	Fasa II	Toviontrine tablets 2.5 mg Toviontrine tablets 25 mg Toviontrine tablets 50 mg Placebo for Toviontrine tablets	Antah Pharma Sdn Bhd	a) University Teknologi MARA (UITM) b) Hospital Sultan Idris Shah Serdang c) Hospital Tengku Ampuan Afzan d) Hospital Sultanah Nur Zahirah e) Sultan Ahmad Shah Medical Centre f) Hospital Universiti Sains Malaysia g) University Malaya Medical Centre	06-Dis-2024 hingga 06-Dis-2027	LULUS
45	BG-60366-101	First-In Human	BG-60366 Tablet, 10mg BG-60366 Tablet, 50mg BG-60366 Tablet, 100mg	Beigene Malaysia Sdn. Bhd.	Hospital Umum Sarawak	01-Jun-2025 hingga 31-Julai-2027	LULUS
46	CA056-015	Fasa II	Luspatercept lyophilized cake/powder 25mg / glass vial Luspatercept lyophilized cake/powder 75mg / glass vial	Antah Pharma Sdn Bhd	Hospital Tunku Azizah Hospital Sultanah Aminah	29-Ogos-2024	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

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47	SEMA HQV	Fasa IV	Semaglutide 1.34 mg/ml, 1.5 ml Semaglutide Placebo 1.34mg/ml, 1.5ml	Hospital Canselor Tuanku Muhriz	Hospital Canselor Tuanku Muhriz UKM	01-Dis-2021 hingga 31-Ogos-2022	LULUS
48	VX01-DR-201	Fasa II	VX-01 150 MG Film-Coated Tablets Matching Placebo For VX-01 150 MG Film-Coated Tablets	Novotech Clinical Research (M) Sdn. Bhd.	a) Hospital Al-Sultan Abdullah UiTM Puncak Alam b) Hospital Selayang c) Hospital Shah Alam d) Hospital Pulau Pinang e) University Malaya Medical Centre	17-Mac-2025 hingga 15-Ogos-2027	LULUS
49	TACTI-004	Fasa III	Eftilagimod Alfa, Solution for Injection, 25 mg/mL, 30 mg/1.2 ml Placebo matching Eftilagimod Alfa, Solution for Injection, 1.2 ml/Vial Pembrolizumab (25 mg/mL) solution for infusion, 100 mg/4 ml Cisplatin 1 mg/ml concentrate for solution for infusion, 100 mg/100 ml Carboplatin 10 mg/ml concentrate for solution for infusion, 450 mg/45 ml Paclitaxel 6 mg/ml concentrate for solution for infusion, 300 mg/50 ml Pemetrexed 25 mg/ml concentrate for solution for infusion (500 mg/20 ml)	Antah Pharma Sdn Bhd	a) Hospital Tengku Ampuan Afzan b) Gleneagles Hospital Penang c) Hospital Pulau Pinang d) Hospital Umum Sarawak	16-Mei-2025 hingga 04-Dis-2029	LULUS
50	0021-25	Kajian BE	Hydroxychloroquine Sulphate Film-Coated Tablet 200mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd	Lambda Therapeutic Research Ltd	Tidak Berkenaan	LULUS
51	GS-US-600-6165	Fasa III	Sacituzumab Govitecan Lyophilized Powder for Solution for Infusion, 200mg Topotecan 1 mg/mL Concentrate for Solution for Infusion	IQVIA RDS Malaysia Sdn Bhd	a) Sarawak General Hospital b) University Malaya Medical Centre c) Pantai Hospital Kuala Lumpur d) Sunway Medical Centre e) Beacon Hospital	01-Ogos-2025 hingga 01-Dis-2029	LULUS
52	CAAA817A12201	Fasa II/III	[225AC]AC-PSMA-617 1 MBQ/ML SOLUTION FOR INJECTION/ SOLUTION FOR INFUSION PSMA-11 25mcg Kit for the radiopharmaceutical preparation of [68GA]Ga-PSMA-11 Galliapharm 68Ge/68Ga-Generator 1.85 GBq (50 mCi) (68Ga)Ga-PSMA-11 Solution for Injection (AAA517)	Parexel International (Malaysia) Sdn Bhd	a) University Malaya Medical Centre b) Beacon Hospital c) Institut Kanser Negara	01-Jun-2025 hingga 31-Dis-2029	LULUS
53	MK-1084-001	First-In Human	MK-1084 25 mg tablets MK-1084 50 mg tablets MK-1084 100 mg (Form 2) Tablets MK-3475 (Pembrolizumab) 25mg/mL, Sterile Solution for IV Infusion, 4mL Vial Cetuximab 5 mg/mL, 20 mL sterile solution for IV infusion / vial	Merck Sharp & Dohme (Malaysia) Sdn Bhd	Hospital Umum Sarawak	01-Okt-2024 hingga 15-Sept-2026	LULUS

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54	CELC-G-302	Fasa III	Gedatolisib 180 mg powder for solution for infusion in vial Ibrance® (Palbociclib) 75 mg film-coated tablet Ibrance® (Palbociclib) 100 mg film-coated tablet Ibrance® (Palbociclib) 100 mg film-coated tablet Kisqali® (Ribociclib) 200 mg film-coated tablets Fulvestrant 250 mg/ 5mL solution for injection in pre-filled syringe Dexamethasone oral solution 0.5 mg/5 mL (500 mL/bottle) Dexamethasone 2 mg soluble tablets	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Umum Sarawak b) Institut Kanser Negara c) Pantai Hospital Kuala Lumpur d) Hospital Kuala Lumpur e) Hospital Pakar Universiti Sains Malaysia	2-Mei-2025 hingga 11-Okt-2029	LULUS
55	ITL-2001-CL-311	Fasa III	NTLA-2001 1.5mg/mL suspension (dispersion) for infusion (10.2 mg in 10mL vial) 0.9% Sodium Chloride Injection, USP (250mL)	Antah Pharma Sdn Bhd	University of Malaya Medical Centre	8-Jun-2025 hingga 3-Ogos-2028	LULUS
56	D5241C00006	Fasa III	1.91 mL Tezepelumab (MEDI9929) Solution for injection 110 mg/mL (210 mg/syringe) Placebo for Tezepelumab Solution for injection 110 mg/mL (210 mg/syringe)	AstraZeneca Sdn Bhd	a) University Malaya Medical Centre b) Hospital Tengku Ampuan Afzan c) Hospital Sultan Idris Shah Serdang	1-Jul-2025 hingga 1-Jul-2029	LULUS
57	D702AC00001	Fasa III	Rilvegostomig (AZD2936) Concentrate for solution for infusion. 50 mg/mL (750 mg/vial) T-DXd (DS-8201a) Powder for concentrate for solution for infusion. 100 mg/vial	AstraZeneca Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Hospital Wanita dan Kankar-Kanak Sabah d) Hospital Raja Permaisuri Bainun	1-Ogos-2025 hingga 28-Feb-2031	LULUS
58	NCT06317051	Fasa III/IV	Dapagliflozin 10mg Film-Coated Tablet Pitavastatin 4mg Film-Coated Tablet Rosuvastatin 10mg/Ezetimibe 10mg Film-Coated Tablet Placebo Dapagliflozin Film-coated Tablet	AstraZeneca Sdn. Bhd.	University Malaya Medical Centre	25-Mac-2025 hingga 31-Dis-2027	LULUS
59	BH-30643-01	First-In Human	BH-30643 Capsules 10 mg BH-30643 Capsules 40 mg	Questa Clinical Research Sdn Bhd	Hospital Umum Sarawak	05-Sept-2025 hingga 31-Julai-2029	LULUS
60	1378-0023	Fasa II	10mg Vicadrost (BI 690517) film-coated tablets 10mg Empagliflozin (BI 10773) film-coated tablets Matching Placebo to 10mg Vicadrost (BI 690517) film-coated tablets	IQVIA RDS Malaysia Sdn Bhd	a) Hospital Tuanku Fauziah b) Hospital Canselor Tuanku Muhriz UKM c) Hospital Sultan Idris Shah Serdang d) Hospital Kuala Lumpur	16-Julai-2025 hingga 01-Jun-2027	LULUS
61	MK-7240-001	Fasa III	MK-7240 100mg/mL Concentrate Solution For Infusion, 5mL/Vial MK-7240 Placebo Concentrate Solution For Infusion, 5mL/Vial MK-7240 200mg/mL Solution For Injection, 1.2mL/Autoinjector MK-7240 Placebo Solution For Injection, 1.2mL/Autoinjector	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Tuanku Jaafar c) Hospital Universiti Sains Malaysia d) Hospital Sultanah Aminah d) Hospital Ampang	01-Mei-2025 hingga 31-Jan-2030	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
62	NVL-655-04	Fasa III	NVL-655 50 mg Film-coated tablet NVL-655 150 mg Film-coated tablet Alecensa (alectinib) 150 mg Capsule	Victory Pharma Consultancy	a) Hospital Umum Sarawak b) Hospital Beacon c) Institut Kanser Negara d) Hospital Kuala Lumpur e) Hospital Pulau Pinang	19-Feb-2025 hingga 30-Mar-2030	LULUS
63	CVAY736L12301	Fasa III	Ianalumab (VAY736) 150mg/1mL solution for injection in pre-filled syringe Placebo to Ianalumab (VAY736) 150mg/1mL solution for injection in pre-filled syringe	Parexel International (Malaysia) Sdn Bhd	a) Hospital Sultan Idris Shah Serdang b) Hospital Sultanah Aminah	01-Sept-2025 hingga 29-Mar-2030	LULUS
64	849-007	Fasa II/III	Adagrasib (BMS-986503), Film Coated Tablets, 200 mg Pembrolizumab, Concentrate for Solution for Infusion, 25mg/mL (100mg/4mL)	Questa Clinical Research Sdn Bhd	a) Hospital Kuala Lumpur b) Sunway Medical Centre c) Hospital Pulau Pinang d) Gleneagles Penang (Pulau Pinang Clinic Sdn Bhd)	04-Mei-2026 hingga 30-Jun-2029	LULUS
65	031-24	Kajian BE	Pharmaniaga Metformin UC Tablet 500mg	Pharmaniaga Manufacturing Berhad	Cohance Lifesciences Limited, India	Tidak berkenaan	LULUS
66	BX-BE25-AMP-001	Kajian BE	Valplex Film Coated Tablet 500mg	Y.S.P. Industries (M) Sdn. Bhd.	Clinical Research Ward Hospital Ampang	21-Julai-2025 hingga 31-Ogos-2025	LULUS
67	ANT-010	Fasa III	Abelacimab, Solution for injection, 150 mg/mL Placebo to Abelacimab, Solution for injection, 150mg/mL	Antah Pharma Sdn Bhd	a) Hospital Sultan Idris Shah Serdang b) Hospital Seberang Jaya c) Sarawak Heart Centre d) Hospital UiTM Sungai Buloh e) University Malaya Medical Centre f) Hospital Miri g) Columbia Asia Hospital h) Hospital Tengku Ampuan Afzan i) Hospital Putrajaya j) Hospital Umum Sarawak k) Sultan Ahmad Shah Medical Centre l) Hospital Sibu m) Hospital Sultanah Bahiyah	30-Julai-2025 hingga 31-Mei-2027	LULUS
68	BE25-009	Kajian BE	Mirtazapine Orodispersible Tablet 30 mg	Duopharma Innovation Sdn Bhd	Questa Clinical Research Sdn. Bhd.	01-Ogos-2025 hingga 21-Nov-2025	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
69	DNTH103-CIDP-301	Fasa III	DNTH103 Drug Product 150 mg/mL Solution DNTH103 Placebo	Info Kinetics Sdn Bhd	a) Hospital Kuala Lumpur b) Hospital Universiti Sains Malaysia c) Universiti Kenanga Malaysia Medical Centre d) Universiti Malaya Medical Centre e) Hospital Sultanah Aminah	06-Ogos-2025 hingga 31-Okt-2031	LULUS
70	DS8201-772	Fasa III	DS-8201a Powder for Concentrate for Solution for Infusion 100 mg, 20mg/mL Bevacizumab 25 mg/mL	IQVIA RDS Malaysia Sdn Bhd	1. Hospital Umum Sarawak 2. Institut Kanser Negara 3. Hospital Kuala Lumpur 4. Hospital Sultan Ismail	18-Jun-2025 hingga 18-Feb-2032	LULUS
71	D7960C00012	Fasa III	AZD0780 30mg Tablet Placebo for AZD0780 Tablet	AstraZeneca Sdn Bhd	1. Hospital UiTM Sungai Buloh 2. Hospital Seri Manjung 3. Hospital Miri 4. Hospital Raja Permaisuri bainun 5. Hospital Sibu 6. Sarawak General Hospital 7. Hospital Sultan Abdul Halim	01-Sept-2025 hingga 31-Julai-2027	LULUS
72	77242113PSA3002	Fasa III	JNJ-77242113 200 mg Film-Coated Tablet JNJ-77242113 Placebo 200 mg Film-Coated Tablet	Johnson & Johnson Sdn. Bhd	1. Hospital Raja Permaisuri Bainun 2. Hospital Selayang 3. Hospital Sultan Ismail 4. Hospital Tuanku Ja'afar 5. Hospital Sultanah Bahiyah 6. Hospital Kuala Lumpur	08-Ogos-2025 hingga 18-Okt-2028	LULUS
73	MK-2870-011	Fasa III	MK-2870 200mg/vial, Lyophilized Powder for IV Infusion MK-3475 (Pembrolizumab) 25mg/ml, Concentrate For Solution For Infusion, 4ml vial Paclitaxel 6mg/ml, Concentrate for Solution For Infusion, 16.7ml vial Paclitaxel 5mg/ml, Powder for Dispersion For Infusion, 20ml vial Gemcitabine 1000mg Vial Powder for Solution for Infusion Carboplatin 10mg/ml, Concentrate for Solution for Infusion, 60mL Vial Dexamethasone Oral Solution 0.5mg/5ml, 500ml bottle	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	1. Hospital Umum Sarawak 2. Institut Kanser Negara 3. Pantai Hospital Kuala Lumpur 4. University Malaya Medical Centre	28-Jun-2025 hingga 28-Jun-2031	LULUS
74	SKP-0141_HemA_ I /III_2024	Fasa Ib/III	SKP-0141, 500 IU of plasma-derived FVIII Lyophilized powder and solvent for solution for injection	IQVIA RDS Malaysia Sdn Bhd	1. Hospital Pulau Pinang 2. Hospital Tunku Azizah 3. Hospital Ampang 4. Hospital Sibu 5. Hospital Raja Perempuan Zainab II	24-Mei-2025 hingga 08-Mei-2027	LULUS
75	0180-25	Kajian BE	Sunitinib Malate Capsules, 50 mg	Novugen Oncology Sdn. Bhd.	Lambda Therapeutic Research Ltd., India	Tidak berkenaan	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2025

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
76	CA2450001	Fasa III	BMS-986489 (BMS-986012/Nivolumab) Concentrate for solution for infusion, 140 mg/120 mg/vial (70 mg/60 mg/mL) Atezolizumab Concentrate for solution for infusion (1200 mg/20 mL), 60 mg/mL Carboplatin concentrate for solution for infusion, 10 mg/ mL, 45 mL per vial Etoposide concentrate for solution for infusion, 20 mg/ mL, 5 mL per vial	Syneos Health Malaysia Sdn. Bhd.	1. Hospital Kuala Lumpur 2. Sarawak General Hospital 3. University Malaya Medical Centre	31-Jan-2025 hingga 30-Julai-2032	LULUS
77	MCLA-158-CL03	Fasa III	Petosemtamab for solution for infusion at 20mg/mL (100mg/5mL in 10mL vial) Pembrolizumab for solution for infusion at 25mg/mL (100mg/4mL in 10mL vial)	Antah Pharma Sdn Bhd	1. Institut Kanser Negara 2. Hospital Umum Sarawak 3. Hospital Sultan Ismail	10-Okt-2025 hingga 11-Ogos-2028	LULUS
78	D702GC00001	Fasa III	1 vial 15ml Rilvegostomig (AZD2936) Concentrate for solution for infusion 50mg/ml (750mg/vial) 4 ml Pembrolizumab Concentrate for solution for infusion 25mg/ml (100mg/vial)	Antah Pharma Sdn Bhd	1. Hospital Kuala Lumpur 2..Institut Kanser Negara 3. Hospital Raja Perempuan Zainab II 4. Sunway Medical Centre Penang 5. Penang Adventist Hospital	01-Mac-2025 hingga 31-Ogos-2030	LULUS
79	CX-4945-16	Fasa I	CX-4945 E.C. Capsules 100 mg CX-4945 Formulated Capsules 200 mg	Info Kinetics Sdn Bhd	Info Kinetics Sdn Bhd	02-Ogos-2025 hingga 01-Nov-2025	LULUS
80	C25133	Kajian BE	Empagliflozin Tablets 25 mg	Novugen Pharma Sdn. Bhd	Aizant Drug Research Solutions Pvt. Ltd., India	Tidak berkenaan	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.