

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	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) TocovidTM SuprabioTM 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) Capivasertib (AZD5363) 200mg Tablet 2) Capivasertib (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 (MED14736) 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 Sibul 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
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

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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
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

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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
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 Bioanalytikal: Accutest Research Laboratories (I) Pvt. Ltd. A-31, M.I.D.C., T.T.C. Industrial Area, Khairme, 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

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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
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 Actuators 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

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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
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
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

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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
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
44	BGB-LC-201 Substudy: BGB-LC-2	Fasa II	1) LBL-007 85 mg/ 5.0 mL Concentrate for Solution 2) BGB-15025 50 mg Tablets 3) BGB-A445 200 mg/ 10mL Concentrate for Solution 4) BGB-A317 100 mg/10 mL Concentrate for Solution	Questra Clinical Research	1. Beacon Hospital 2. Hospital Umum Sarawak 3. Hospital Tengku Ampuan Afzan 4. Hospital Sultan Ismail 5. Hospital Pulau Pinang	29-Sep-2023 hingga 31-Dis-2027	LULUS

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45	FYB206-C3-02	Fasa III	1) FYB206 25 mg/mL Concentrate for Solution for Injection 2) Keytruda 25 mg/mL Concentrate for Solution for Injection	Syneos Health Sdn. Bhd.	1. Hospital Pulau Pinang 2. Hospital Umum Sarawak 3. University Malaya Medical Centre 4. Columbia Asia Hospital Bukit Rimau	10-Jun-2024 hingga 31-Dis-2027	LULUS
46	1490-0004	Fasa II/III	1) BI 1839100 Film-coated tablets 50mg 2) Matching Placebo to BI 1839100 Film-coated tablets	IQVIA RDS Malaysia Sdn Bhd	1. Hospital Sultan Idris Shah Serdang 2. Institut Perubatan Respiratori 3. Hospital Umum Sarawak	14-Jun-2024 hingga 14-Jun-2026	LULUS
47	CJPB898A12301	Fasa III	1) JPB898 Concentrate for Solution for Infusion (100 mg/mL) 2) YERVOY (Ipilimumab) (50mg) 5 mg/mL Concentrate for Solution for Injection 3) Opdivo (EU) (Nivolumab) (100 mg) 10 mg/mL Concentrate for Solution for Injection 4) Opdivo (EU) (Nivolumab) (120 mg) 10 mg/mL Concentrate for Solution for Injection 5) Opdivo (EU) (Nivolumab) (240 mg) 10 mg/mL Concentrate for Solution for Injection 6) Opdivo (US) (Nivolumab) (100 mg) 10 mg/mL Concentrate for Solution for Injection 7) Opdivo (US) (Nivolumab) (120 mg) 10 mg/mL Concentrate for Solution for Injection 8) Opdivo (US) (Nivolumab) (240 mg) 10 mg/mL Concentrate for Solution for Injection	Antah Pharma Sdn. Bhd.	1. University Malaya Medical Centre 2. Institut Kanser Negara 3. Hospital Pulau Pinang 4. Hospital Sultan Ismail	02-Ogos-2024 hingga 09-Dis-2027	LULUS
48	V940-002	Fasa III	1) MK 3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Injection 2) V940 (mRNA 4157) 1.0 mg/mL, 1.3mL Sterile Solution	Merck Sharp & Dohme (MSD) Malaysia Sdn Bhd	1. Hospital Umum Sarawak 2. University Malaya Medical Centre 3. Hospital Tengku Ampuan Afzan 4. Hospital Pulau Pinang 5. Institut Kanser Negara	01-Apr-2024 hingga 31-Dis-2035	LULUS
49	ALXN1210-IgAN-320	Fasa III	1) Ravulizumab 100mg/mL (1100mg), 11mL Concentrate for Solution for Injection 2) Placebo for Ravulizumab 100mg/mL (1100mg) 3) Amoxicillin 500mg Dispersible Tablet 4) Bexxero Suspension [Meningococcal Group B] 5) Ciprofloxacin 500mg Film-coated Tablet 6) Menveo Powder and Solution (Meningococcal)	AstraZeneca Sdn. Bhd.	1. University Malaya Medical Center 2. Hospital Taiping 3. Hospital Raja Permaisuri Bainun 4. Hospital Tuanku Ja'afar 5. Hospital Sultanah Aminah	01-Ogos-2024 hingga 30-Nov-2031	LULUS
50	XmAb717-06	Fasa I/II	1) XmAb 20717® 100 mg vial, 10 mg/mL solution for injection 2) KEYTRUDA, 25 mg/mL concentrate solution for injection 3) Carboplatin Hikma 450 mg/45 mL concentrate for injection 4) Pemetrexed 500 mg/20 mL concentrate solution for injection	Victory Pharma Consultancy Sdn Bhd	1. Hospital Umum Sarawak 2. Hospital Sultan Ismail 3. Institut Kanser Negara 4. Columbia Asia Hospital -Bukit Rimau 5. Pantai Hospital Ipoh 6. Hospital Canselor Tuanku Mukhriz, UKM Medical Centre	01-Jun-2024 hingga 31-Ogos-2027	LULUS
51	20230127	Fasa I	1) ABP 234 (4mL contains 100mg of ABP 234 liquid) 2) Pembrolizumab EU (4mL contains 100mg of Pembrolizumab)	Antah Pharma Sdn Bhd	1. Hospital Raja Perempuan Zainab II 2. Hospital Canselor Tuanku Mukhriz UKM 3. Hospital Sultan Ismail 4. Hospital Umum Sarawak	19-Jun-2024 hingga 22-Okt-2026	LULUS
52	1462-0004	Fasa II	1) BI 1819479 Film-coated tablets 0.05 mg 2) BI 1819479 Film-coated tablets 0.3 mg 3) Matching Placebo to BI 1819479 Film-coated tablets	IQVIA RDS Malaysia Sdn Bhd	1. Hospital Sultan Idris Shah Serdang 2. Institut Perubatan Respiratori 3. Hospital Umum Sarawak	08-Jul-2024 hingga 02-Feb-2027	LULUS
53	BIO-PERTUZ-301	Fasa III	1) Pertuzumab (PERT-IJS) 420 mg/14 mL Vial, Solution for Injection 2) Pertuzumab (EU-Perjeta) 420 mg/14 mL Vial, Solution for Injection 3) 1 Vial of Trastuzumab 420 mg/vial. Powder for Injection	IQVIA RDS Malaysia Sdn Bhd	1. Hospital Kuala Lumpur	01-Ogos-2024 hingga 01-Ogos 2025	LULUS

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Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Nama Pemohon	Pusat Kajian Klinikal	Jangkaan Tempoh Masa Kajian Klinikal*	Status Permohonan
54	BE24-007	Kajian BE	Metformin DC Tablet 500mg	GoodScience Sdn Bhd	Tapak Klinikal & Bionalitikal: Questra Clinical Research Sdn. Bhd. Questra Bio-clinical Research Centre, No.6, Jalan Desa Pauh, Taman Desa Pauh137	Tidak berkenaan	LULUS
55	BV100-006	Fasa II	1) BV100 concentrate for solution for infusion con 2) Acetic acid 4%, solvent for concentrate for sol	University Malaya Medical	a) University Malaya Medical Centre b) Hospital Seberang Jaya c) Hospital Raja Permaisuri Bainun d) Hospital Pulau Pinang	01-Jul-2024 hingga 31-Dec-2025	LULUS
56	GS-US-409-5704	Fasa II	1) GS-1427 Film-coated Tablets, 25 mg 2) GS-1427 Film-coated Tablets, 75 mg 3) GS-1427 Film-coated Tablets, 100 mg 4) GS-1427 Placebo Tablets, 25 mg 5) GS-1427 Placebo Tablets, 75 mg 6) GS-1427 Placebo Tablets, 100 mg	PPD Development (S) Pte	a) Hospital Queen Elizabeth b) Hospital Tengku Ampuan Afzan c) Hospital Sultan Idris Shah Serdang d) Universiti Malaya Medical Centre e) Sultan Ahmad Shah Medical Centre @IIUM f) Hospital Universiti Sains Malaysia	01-Oct-2024 hingga 30-Sep-2028	LULUS
57	MK-2870-015	Fasa IV	1) MK-2870 200mg/vial, Lyophilized powder for IV 2) Docetaxel 20mg/mL, Solution for IV Infusion, f 3) Paclitaxel 6mg/mL, Concentrate for Solution F 4) Irinotecan Hydrochloride 20mg/mL, Solution fo 5) Trifluridine/Tipiracil 15mg/6.14 mg film-coated 6) Trifluridine/Tipiracil 20mg/8.19 mg film-coated	Merck Sharp & Dohme (M	a) Hospital Umum Sarawak b) University Malaya Medical Centre c) Hospital Pulau Pinang d) Institut Kanser Negara e) Pantai Hospital Kuala Lumpur	01-Jun-2024 hingga 31-May-2028	LULUS
58	1378-0006	Fasa III	1) BI 690517 Film-Coated Tablet 10 mg 2) Placebo of BI 690517 Film-Coated Tablet 10 r 3) Empagliflozin Film-Coated Tablet 10mg	Klinsel Sdn. Bhd.	a) Hospital Sultanah Aminah b) Hospital Raja Permaisuri Bainun c) University Malaya Medical Centre d) Hospital Pulau Pinang e) Hospital Kulim f) Hospital Selayang g) Hospital Tengku Ampuan Afzan h) Hospital Melaka i) Hospital Kajang j) Hospital Tuanku Ja'afar k) Hospital Kuala Lumpur l) Hospital Ampang m) Faculty of Medicine, Universiti Kebangsaan Malaysia n) Hospital Taiping o) Hospital Pakar Sultanah Fatimah p) Hospital Umum Sarawak q) Hospital Sultan Haji Ahmad Shah r) Hospital Tengku Ampuan Rahimah s) Hospital Tuanku Ampuan Najihah t) Hospital Sibul u) Hospital Tuanku Fauziah v) Hospital Seberang Jaya w) Hospital Queen Elizabeth x) Hospital Raja Perempuan Zainab II y) Hospital Sultanah Nora Ismail z) Hospital Sultan Abdul Aziz Shah-HSAAS (Hospital Pengajar UPM) aa) Hospital Teluk Intan	03-Jun-2024 hingga 30-Jun-2029	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
59	AR-DEX-22-02	Fasa III	1) Dexpramipexole 75mg Tablet 2) Dexpramipexole 150mg Tablet 3) Matching Placebo to Dexpramipexole 75mg / 150mg Tablet	Parexel International (Malaysia) Sdn Bhd	a) Hospital Tunku Azizah b) Hospital Miri c) Hospital Pulau Pinang d) Hospital Raja Perempuan Zainab II e) Hospital Seri Manjung	01-Okt-2024 hingga 31-Dis-2026	LULUS
60	22615	Fasa III	1) BAY 2927088 Coated Tablet 10mg	Bayer Co. (Malaysia) Sdn. Bhd.	a) Beacon Hospital b) Sunway Medical Centre c) Sunway Medical Penang d) University Malaya Medical Centre (UMMC)	19-Ogos-2024 hingga 15-Mei-2028	LULUS
61	20210033	Fasa III	1) ABP 234 (4mL contains 100mg of ABP 234 liquid solution in vial) 2) Keytruda (Pembrolizumab) US [4mL of concentrate for solution for infusion contains 100mg (25mg/mL)] 3) Pembrolizumab EU (4 mL contains 100 mg of Pembrolizumab EU liquid solution in vial) 4) Carboplatin 10 mg/ml solution for infusion (60 ml vial contains 600 mg carboplatin) 5) Carboplatin 10 mg/ml solution for infusion (15 ml vial contains 150 mg carboplatin) 6) Pemetrexed, 500 mg of pemetrexed (as pemetrexed disodium) powder for concentrate for solution for infusion 7) Cisplatin 1 mg/mL concentrate for solution for infusion (100 ml vial contains 100 mg cisplatin)	Antah Pharma Sdn Bhd	a) Mahkota Medical Centre Sdn Bhd b) Hospital Raja Perempuan Zainab II c) Hospital Canselor Tuanku Muhriz UKM d) Universiti Malaya Medical Centre e) Hospital Sultanah Bahiyah f) Hospital Umum Sarawak	21-Feb-2024 hingga 06-Jun-2028	LULUS
62	R3767-ONC-2266	Fasa II	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) Carboplatin Solution for infusion 10 mg/mL, 150MG vial 4) Paclitaxel Concentrate for Solution for infusion, 6mg/mL, 50ml vial 5) Cisplatin Concentrate for Solution For Infusion 1mg/mL, 100mL vial 6) Pemetrexed Concentrate for Solution for infusion, 25mg/ml, 500mg/20ml vial	Antah Pharma Sdn Bhd	a) Hospital Umum Sarawak b) Hospital Kuala Lumpur c) University Malaya Medical Centre d) Hospital Pulau Pinang	01-Ogos-2024 hingga 31-Mei-2029	LULUS
63	X4P-001-110	Fasa III	1) Mavorixafor (X4P-001) 100 mg Capsules 2) Matching Placebo for Mavorixafor (X4P-001) 100 mg Capsules	Novotech Clinical Research (M) Sdn. Bhd.	a) Hospital Pakar Kanak-Kanak Universiti Kebangsaan Malaysia (HPKK-UKM)	26-Sep-2024 hingga 30-Nov-2026	LULUS

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
64	SRF201	Fasa II	1) 2mL Amlitelimab 125mg/mL Solution for Subcutaneous Injection in Prefilled Syringes 2) 2mL Placebo Solution for Subcutaneous Injection in Prefilled Syringes 3) 18mg BI 1015550 in Film Coated Tablets for Oral Use Only 4) Matching Placebo for 18mg BI 1015550 in film coated tablets for oral use only	Antah Pharma Sdn. Bhd.	a) Hospital Tengku Ampuan Afzan b) Sarawak General Hospital c) University Malaya Medical Centre	19 Nov 2024 hingga 28 Oct 2026	LULUS
65	D3460C00002	Fasa III	1) Anifrolumab (MEDI-546) Solution for injection 150 mg/mL (0.8mL pre-filled syringe) 2) Placebo for Anifrolumab (MEDI-546) Solution for injection 150 mg/mL (0.8mL pre-filled syringe)	AstraZeneca Sdn Bhd	a)Hospital Umum Sarawak b)Hospital Kuala Lumpur c)University Malaya Medical Centre d)Hospital Pulau Pinang	01 Sep 2024 hingga 29 Feb 2028	LULUS
66	C1B03677	Kajian BE	Empagliflozin 25mg Film-Coated Tablets	Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.	Clinical and Bioanalytical Site: Clantha Research Limited Clantha Corporate, TP 86, FP 28/1, Off S.P.Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India	Tidak berkenaan	LULUS
67	BX-BE24-AMP-001	Kajian BE	Ridosyl Film Coated Tablet 10mg	Y.S.P. Industries (M) Sdn. Bhd.	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah 68000 Ampang, Selangor. Bioanalytical Site: Bioxis Sdn. Bhd. PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak 14100 Simpang Ampat Pulau Pinang.	Tidak berkenaan	LULUS
68	BX-PL24-AMP-001	Kajian BE	Valplex Film Coated Tablet 500mg	Y.S.P. Industries (M) Sdn. Bhd.	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah 68000 Ampang, Selangor. Bioanalytical Site: Bioxis Sdn. Bhd. PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak 14100 Simpang Ampat Pulau Pinang.	Tidak berkenaan	LULUS
69	CAAA617D12302	Fasa II	1) REGN7999 (C1P1), Drug Product, Lyophilized Powder for Solution for Injection, 265mg in 20mL vial 2) Lyophilized Placebo, in 20mL vial	Antah Pharma Sdn Bhd	a) Hospital Tunku Ampuan Besar Tuanku Aishah Rohani, UKM Specialist Children's Hospital b) Hospital Umum Sarawak c) Hospital Ampang d) Hospital Queen Elizabeth	25 Sept 2024 hingga 24 Jan 2029	LULUS
70	CT2ASYN01	Fasa II	1) Synacinn 300 mg Capsule 2) Placebo for Synacinn 300 mg Capsule 3) Placebo for Metformin 500 mg Tablet	George Clinical Asia Pacific Limited	a) Hospital Universiti Sains Malaysia	01 Dec 2023 - 31 Dec 2024	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
71	D516KC00001	Fasa III	1) DS-1062a (Dato-DXd; Datopotamab Deruxtecan) 100 mg/vial lyophilized powder for concentrate for solution for infusion 2) Osimertinib (AZD9291) 80mg tablet 3) Osimertinib (AZD9291) 40mg tablet	Parexel International (Malaysia) Sdn Bhd	a) Hospital Canselor Tuanku Muhriz UKM b) Sunway Medical Centre c) Hospital Umum Sarawak d) Beacon Hospital Sdn. Bhd. e) University Malaya Medical Centre f) Hospital Sultanah Bahiyah g) Sunway Medical Centre Penang h) Hospital Sultan Ismail	12 Nov 2024 - 31 May 2028	LULUS
72	MK-7240-008	Fasa III	1) MK-7240 100mg/mL Concentrate Solution For Infusion, 5mL/Vial 2) MK-7240 Placebo Concentrate Solution For Infusion, 5mL/Vial 3) MK-7240 200mg/mL Solution For Injection, 1.2mL/Autoinjector 4) MK-7240 Placebo Solution For Injection, 1.2 mL/Autoinjector	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	b) Sarawak General Hospital (SGH) c) Hospital Universiti Sains Malaysia d) Hospital Sultanah Aminah e) Hospital Ampang	14 Oct 2024 - 30 Dec 2033	LULUS
73	MK-2870-020	Fasa III	1) MK-2870 200mg/vial, Lyophilized powder for IV Infusion	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Pantai Hospital Kuala Lumpur b) Penang Adventist Hospital c) Universiti Malaya Medical Centre d) Sunway Medical Centre	22 Aug 2024 - 21 Jul 2029	LULUS
74	CAAA617D12302	Fasa III	1) PSMA-11 25mcg kit for the radiopharmaceutical preparation of [68Ga]Ga-PSMA-11 2) Gallipharm 68Ge/68Ga-Generator 1.85 GBq (50mCi) 3) (68Ga)Ga-PSMA-11 Sterile Injection 4) [177Lu]Lu-PSMA-617 1000MBq/mL solution for injection/solution for infusion	Parexel International (Malaysia) Sdn Bhd	a) Beacon Hospital b) University Malaya Medical Centre	1 December 2024 - 1 January 2031	LULUS
75	D9690C00005	Fasa II	1) AZD7798 200mg/vial powder for solution for in	AstraZeneca Sdn Bhd	a) Hospital Sultanah Aminah b) Hospital Umum Sarawak c) Universiti Malaya Medical Centre d) Hospital Queen Elizabeth e) Hospital Raja Perempuan Zainab II	16 October 2024 - 1 September 2027	LULUS
76	D926TC00001	Fasa III	1) AZD2936 50mg/mL Concentrate for Solution for Infusion (15mL vial, 750mg per vial) 2) DS-1062a Lyophilised Powder for Concentrate for Solution for Infusion, 100mg/vial	AstraZeneca Sdn Bhd	a) University Malaya Medical Centre b) Pantai Hospital Kuala Lumpur c) Hospital Pulau Pinang d) Hospital Kuala Lumpur e) Institut Kanser Negara f) Hospital Umum Sarawak	3 November 2024 - 8 November 2035	LULUS
77	61186372NSC2011	Fasa II	1) JNJ-61186372 co-formulated with rHuPH20, 1600 mg (160 mg/mL), 10 mL Solution 2) JNJ-61186372 co-formulated with rHuPH20, 2240 mg (160 mg/mL), 14 mL Solution 3) Lazertinib 80 mg Tablet	Johnson & Johnson Sdn. Bhd.	a) Beacon Hospital Sdn.Bhd. b) Hospital Kuala Lumpur c) Hospital Pulau Pinang d) Sunway Medical Centre e) University Malaya Medical Centre	6 February 2025 - 15 June 2028	LULUS

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
78	61186372COR3001	Fasa III	1) JNJ-61186372 co-formulated with rHuPH20, 1600mg (160mg/mL), 10mL Solution 2) JNJ-61186372 co-formulated with rHuPH20, 2240mg (160mg/mL), 14mL Solution 3) Cetuximab, 500 mg (5 mg/ml), 100 ml Solution	Johnson & Johnson Sdn Bhd	a) University Malaya Medical Centre b) Hospital Umum Sarawak c) Hospital Pulau Pinang d) Hospital Kuala Lumpur e) Hospital Sultan Ismail f) Hospital Raja Permaisuri Bainun g) National Cancer Institute h) Hospital Canselor Tuanku Muhriz Universiti Kebangsaan Malaysia (UKM)	10 December 2024 - 15 Jun 2028	LULUS
79	1404-0064	Fasa III	1) BI 456906 (Survodutide) 0.6 mg/mL Solution for Injection in 0.5 mL PFS 2) BI 456906 (Survodutide) 1.2 mg/mL Solution for Injection in 0.5 mL PFS 3) BI 456906 (Survodutide) 2.4 mg/mL Solution for Injection in 0.5 mL PFS 4) BI 456906 (Survodutide) 4.8 mg/mL Solution for Injection in 0.5 mL PFS 5) BI 456906 (Survodutide) 7.2 mg/mL Solution for Injection in 0.5 mL PFS 6) BI 456906 (Survodutide) 9.6 mg/mL Solution for Injection in 0.5 mL PFS 7) BI 456906 (Survodutide) 12.0 mg/mL Solution for Injection in 0.5 mL PFS 8) Placebo to BI 456906 (Survodutide) Solution for Injection in 0.5 mL PFS	Parexel International (Malaysia) Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Universiti Sains Malaysia c) Hospital Queen Elizabeth d) Hospital Ampang	1 December 2024 - 30 June 2029	LULUS
80	BGB-A317-290-LTE1	Fasa III	1) BGB-A317 100mg/10ml Concentrate for Solution for Infusion 2) BGB-A445 200mg/10ml Concentrate for Solution for Infusion	Beigene Malaysia Sdn. Bhd.	a) Hospital Umum Sarawak b) University Malaya Medical Centre	1 November 2024 - 31 December 2027	LULUS
81	D6933C00002	Fasa III	1) Budesonide/albuterol sulfate (BDA HFO) 80/90 µg per actuation 2) Budesonide/albuterol sulfate (BDA HFA) 80/90 µg per actuation 3) Placebo HFA to match Budesonide/albuterol sulfate (BDA HFA) 4) Placebo HFA 120 actuations for oral inhalation practice	AstraZeneca Sdn. Bhd	a) Klinik Kesihatan Kuang b) Hospital Duchess of Kent c) Hospital Canselor Tuanku Muhriz d) Klinik Kesihatan Ampang	Tiada maklumat	LULUS
82	ISIS 678354-CS15	Fasa III	1) 0.8mL ISIS 678354 (Olezarsen) solution for subcutaneous injection (100mg/mL) in autoinjectors 2) 0.8mL ISIS 678354 (Olezarsen) solution for subcutaneous injection (62.5mg/mL) in autoinjectors	Antah Pharma Sdn Bhd	a) University Malaya Medical Centre b) Hospital Taiping c) Hospital Sultanah Bahiyah d) Hospital Pulau Pinang	30 June 2025 - 2 November 2026	LULUS
83	EFC17919	Fasa III	1) Frexalimab 1200mg/8mL Solution Vial (150mg/mL) 2) Teriflunomide 14mg Film-coated Tablet 3) Matching Placebo for Frexalimab 1200 mg/8 mL Solution Vial 4) Matching Placebo for Teriflunomide 14 mg Film-coated Tablet	Sanofi-Aventis (Malaysia) Sdn Bhd	a) Hospital Kuala Lumpur	Tiada maklumat	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Nama Pemohon	Pusat Kajian Klinik	Jangkaan Tempoh Masa Kajian Klinik*	Status Permohonan
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*Data adalah diperolehi daripada laman sesawang National Medical Research Register (NMRR). Sila layari <https://nmrr.gov.my/research-directory> untuk maklumat terkini dan lanjut.