

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2026 (Jan-April)

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Nama Pemohon	Pusat Kajian Klinikal	Jangkaan Tempoh Masa Kajian Klinikal*	Status Permohonan
1	C1B06557	Kajian BE	Nilotinib 200 mg Capsules	Novugen Oncology Sdn. Bhd.	Cliantha Research Limited	Tidak Berkenaan	LULUS
2	C1B06161	Kajian BE	Tranexamic Acid 500 mg Tablet	Hovid Bhd	Cliantha Research Limited	Tidak Berkenaan	LULUS
3	347-25	Kajian BE	Empagliflozin and Metformin Hydrochloride Tablets, 12.5 mg/1000 mg	Novugen Pharma Sdn. Bhd.	AXIS Clinicals Limited	Tidak Berkenaan	LULUS
4	0273-25	Kajian BE	Pantoprazole Enteric-Coated Tablets 40mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd	Lambda Therapeutic Research Ltd.	Tidak Berkenaan	LULUS
5	0274-25	Kajian BE	Pantoprazole Enteric-Coated Tablets 40mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd	Lambda Therapeutic Research Ltd.	Tidak Berkenaan	LULUS
6	TAS6417-302	Fasa III	Zipalertinib 50 mg Tablet Matching Placebo for Zipalertinib 50 mg Tablet Carboplatin, 450mg/45mL (10mg/mL) vial, Concentrate for Solution for Infusion Cisplatin, 50mg/50mL (1mg/mL) vial, Concentrate for Solution for Infusion Pemetrexed, 500mg/20mL (25mg/mL) vial, Concentrate for Solution for Infusion	Questa Clinical Research Sdn Bhd	a) Hospital Kuala Lumpur b) Hospital Pulau Pinang c) Sunway Medical Centre d) Hospital Raja Perempuan Zainab II e) Hospital Picaso	12-Feb-2026 hingga 08-Dis-2032	LULUS
7	ARL-25-136	Kajian BE	Empagliflozin and Linagliptin Tablets, 25 mg/5 mg	Novugen Pharma Sdn. Bhd.	Accutest Research Laboratories (I) Pvt. Ltd.	Tidak Berkenaan	LULUS
8	C1B06136	Kajian BE	Aripiprazole 10 mg Tablet	Hovid Bhd	Cliantha Research Limited	Tidak Berkenaan	LULUS
9	001/ST/SML-0052/2025	Fasa II	Ursodiol Solution for Injection 625 mg/25 mL (25 mg/mL) Ursochol Tablets 450 mg	Info Kinetics Sdn Bhd	a) Hospital Queen Elizabeth b) Hospital Sultanah Nur Zahirah c) Hospital Umum Sarawak d) Hospital Sultanah Aminah	30-Dis-2025 hingga 30-Dis-2026	LULUS
10	MK-1084-007	Fasa III	MK-1084 25 mg Tablets – Spray-dried Intermediate-Based Oral Compressed Tablets (SDI-OCT) MK-1084 50 mg Tablets - Spray-dried Intermediate-Based Oral Compressed Tablets (SDI-OCT) MK-1084 25 mg Tablets - Spray-dried Intermediate-Based Film Coated Tablets (SDI-FCT) MK-1084 50 mg Tablets - Spray-dried Intermediate-Based Film Coated Tablets (SDI-FCT) MK-3475A 165 mg/mL, 2.4mL Sterile Solution for Injection, Pre-Filled Vial MK-3475A 165 mg/mL, 4.8mL Sterile Solution for Injection, Pre-Filled Vial Pemetrexed Disodium (Equivalent to Pemetrexed 500 mg), Lyophilized Powder for IV Infusion, 500mg Cisplatin 1mg/mL, 50mL Concentrate for Solution for Infusion Carboplatin 10 mg/mL, 60 mL Concentrate for Solution for Infusion	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	a) Hospital Pulau Pinang b) Sarawak General Hospital c) Hospital Sultan Ismail d) University Malaya Medical Centre e) Sunway Medical Centre	01-Dis-2025 hingga 02-Mei-2033	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2026 (Jan-April)

11	OP-1250-302	Fasa III	Palazestrant (OP-1250) Film-coated Tablets, 30 mg Palazestrant (OP-1250) Film-coated Tablets, 60 mg Palazestrant (OP-1250) Film-coated Tablets, 90 mg Matching Placebo for Palazestrant (OP-1250) Film-coated Tablets, 30 mg Matching Placebo for Palazestrant (OP-1250) Film-coated Tablets, 60 mg Matching Placebo for Palazestrant (OP-1250) Film-coated Tablets, 90 mg Ribociclib 200 mg Film Coated Tablets Letrozole capsules, 2.5 mg Matching Placebo for Letrozole capsules, 2.5 mg Goserelin 3.6 mg implant in pre-filled syringe	Novotech Clinical Research (M) Sdn. Bhd.	a) Hospital Umum Sarawak (Sarawak General Hospital) b) Institut Kanser Negara c) Beacon Hospital d) Universiti Malaya Medical Centre e) Hospital Pulau Pinang f) Hospital Raja Permaisuri Bainu g) Hospital Kuala Lumpur h) Hospital Wanita dan Kanak-kanak Sabah	12-Jan-2026 hingga 30-Jul-2032	LULUS
12	C1B06552	Kajian BE	Enzalutamide Tablets, 80 mg (T1) Enzalutamide Tablets, 80 mg (T2) Enzalutamide Tablets, 80 mg (T3)	Novugen Oncology Sdn. Bhd.	Cliantha Research Limited	Tidak Berkenaan	LULUS
13	C1B06553	Kajian BE	Enzalutamide Tablets, 80 mg (T1) Enzalutamide Tablets, 80 mg (T2) Enzalutamide Tablets, 80 mg (T3)	Novugen Oncology Sdn. Bhd.	Cliantha Research Limited	Tidak Berkenaan	LULUS
14	0346-25	Kajian BE	Rivaroxaban 10 mg film-coated tablet	Hovid Berhad	Lambda Therapeutic Research Ltd.	Tidak Berkenaan	LULUS
15	CA2400029	Fasa II/III	BMS-986504 200 mg film-coated tablet Matching Placebo for BMS-986504 200 mg film-coated tablet	Syneos Health Malaysia Sdn. Bhd.	a) Universiti Malaya Medical Centre b) Hospital Umum Sarawak	8-Sep-2025 hingga 12-Aug-2031	LULUS
16	1434-0017	Fasa III	BI 764198 film-coated tablets, 20 mg Placebo to BI 764198 film-coated tablets, 20mg	IQVIA RDS Malaysia Sdn. Bhd.	a) Sunway Medical Centre b) University Malaya Medical Centre c) Hospital Tuanku Ja'afar d) Hospital Kuala Lumpur e) Hospital Sultan Idris Shah, Serdang f) Hospital Queen Elizabeth	Jan-2026 hingga Jan-2031	LULUS
17	EFC18244	Fasa II/III	Lunsekimig 300 mg/2 mL (150 mg/mL) solution for injection in pre-filled syringe Matching placebo to Lunsekimig 300 mg/2 mL (150 mg/mL) solution for injection in pre-filled syringe	Sanofi-Aventis (Malaysia) Sdn. Bhd.	a) Universiti Malaya Medical Centre b) Hospital Al Sultan Abdullah Universiti Teknologi MARA c) Hospital Raja Perempuan Zainab II d) Hospital Pulau Pinang e) Hospital Miri f) Hospital Sultan Idris Shah Serdang g) Hospital Sibul	15-Dec-2025 hingga 22-Jan-2030	LULUS
18	0421-24	Kajian BE	Vaxcel Enoxaparin Injection (Ovine) 6000IU (60mg)/0.6mL Prefilled Syringe	Kotra Pharma (M) Sdn. Bhd.	Lambda Therapeutic Research Ltd.	Tidak Berkenaan	LULUS
19	440-24	Kajian BE	Rivaroxaban 20mg Film-Coated Tablets	Xepa-Soul Pattinson (Malaysia) S	AXIS Clinicals Limited	Tidak Berkenaan	LULUS
20	25-VIN-0701	Kajian BE	Sitagliptin and Metformin HCl Extended-Release Tablets, 100 mg/1000 mg	Novugen Pharma Sdn. Bhd.	Veeda Clinical Research Ltd.	Tidak Berkenaan	LULUS
21	25-VIN-0702	Kajian BE	Sitagliptin and Metformin HCl Extended-Release Tablets, 100 mg/1000 mg	Novugen Pharma Sdn. Bhd.	Veeda Clinical Research Ltd.	Tidak Berkenaan	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2026 (Jan-April)

22	0136-25	Kajian BE	Telmisartan Tablets 80 mg	Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.	Lambda Therapeutic Research Ltd.	Tidak Berkenaan	LULUS
23	CFUB523A12302B	Fasa III	FUB523 300 mg/2 mL solution for injection in pre-filled syringe with needle safety device (PFS+NSD)	Parexel International (Malaysia) Sdn Bhd	(a) Hospital Kuala Lumpur (b) Hospital Sultan Idris Shah Serdang (c) University Malaya Medical Centre (d) Hospital Sibul (e) Hospital Tengku Ampuan Afzan	01-Apr-2026 hingga 31-Dec-2028	LULUS
24	ITZ101	Kajian BA	Inhibitor Therapeutics Itraconazole Capsule 65 mg Inhibitor Therapeutics Itraconazole Capsule 75 mg Tolsura Capsule 65 mg	Info Kinetics Sdn Bhd	Clinical Site: Borneo Kinetics Sdn Bhd Bioanalytical Site: Info Kinetics Sdn Bhd	01-Apr-2026 hingga 01-Oct-2026	LULUS
25	1438-0012	Fasa III	BI 764532 (Obixtamig) Powder for Solution for Infusion, 30mg/vial Atezolizumab Concentrate for Solution for Infusion, 1200 mg/vial (60mg/mL) Carboplatin 10mg/ml Concentrate for Solution for Infusion (60ml Vial) Etoposide 20mg/ml Concentrate for Solution for Infusion (5ml vial)	IQVIA RDS Malaysia Sdn Bhd	(a) Hospital Umum Sarawak (b) Institut Kanser Negara (c) Hospital Pulau Pinang (d) Sunway Medical Centre (e) Hospital Wanita dan Kanak-Kanak Sabah	17-Mac-2026 hingga 28-Mei-2029	LULUS
26	80202135SLE3001	Fasa III	Nipocalimab 460 mg (230 mg/mL), 2 mL Prefilled Syringe-Autoinjector Nipocalimab Corresponding Placebo 460 mg (230 mg/mL), 2 mL Prefilled Syringe- Autoinjector	Johnson & Johnson Sdn. Bhd	a) Hospital Umum Sarawak b) University Malaya Medical Centre c) Hospital Sultan Ismail d) Hospital Taiping e) Hospital Putrajaya f) Hospital Sultanah Nur Zahirah g) Hospital Pulau Pinang h) Sunway Medical Centre	27-Mac-2026 hingga 16 May 2031	LULUS
27	0272-25	Kajian BE	Celecoxib Capsules 400mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd,	Clinical and Bioanalytical site: Lambda Therapeutic Research Ltd., India.	Tidak Berkenaan	LULUS
28	BGB-58067-101	Fasa I	BGB-58067 Tablets, 50mg (24 Tablets/ Bottles) BGB-58067 Tablets, 50mg (31 Tablets/ Bottle) BGB-58067 Tablets, 200mg (24 Tablets/ Bottle) BGB-58067 Tablets, 200mg (31 Tablets/ Bottle) BGB-A317 100mg/10ml Concentrate for Solution for Infusion	BeOne Medicines Sdn. Bhd.	a) Hospital Pulau Pinang b) Hospital Umum Sarawak c) Hospital Kuala Lumpur d) Hospital Raja Perempuan Zainab II e) Universiti of Malaya Medical Centre	01-Apr-2026 hingga 29 Dec-2027	LULUS
29	ID-064A303	Fasa III	Cenerimod 4 mg Film-Coated Tablets	Novotech Clinical Research (M) Sdn. Bhd.	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Sibul	01-Apr-2026 hingga 28-Feb-2029	LULUS
30	1434-0027	Fasa II	BI 764198 film-coated tablets, 20mg Placebo to BI 764198 film-coated tablets, 20mg	IQVIA RDS Malaysia Sdn. Bhd.	a) Sunway Medical Centre b) Hospital Sultan Idris Shah, Serdang c) Hospital Selayang	08-Jul-2026 hingga 30-Sep-2028	LULUS
31	BCA101X301	Fasa II/III	Ficerafusp Alfa Lyophilized Powder for Concentrate for Solution for Infusion, 375 mg/vial Pembrolizumab, 25 mg/mL Concentrate for Solution for Infusion, Vial	IQVIA RDS Malaysia Sdn Bhd	a) Mount Miriam Cancer Hospital b) Hospital Umum Sarawak c) Hospital Kuala Lumpur d) Hospital Pulau Pinang e) Universiti of Malaya Medical Centre	01-Jun-2026 hingga 06-Aug-2031	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2026 (Jan-April)

32	SNDX-5613-0710	Fasa III	Revumenib (SNDX-5613) 25 mg Tablets Revumenib (SNDX-5613) 110 mg Tablets Revumenib (SNDX-5613) 160 mg Tablets Matching Placebo for Revumenib (SNDX-5613) 25 mg Tablets Matching Placebo for Revumenib (SNDX-5613) 110 mg Tablets Matching Placebo for Revumenib (SNDX-5613) 160 mg Tablets Cytarabine 500 mg/5 ml (100 mg/ml) solution for injection Cytarabine 2 g/20 ml (100 mg/ml) solution for injection Daunorubicin 20 mg powder for solution for infusion or injection Idarubicin 20 mg/20 ml (1 mg/ml) solution for infusion or injection	Parexel International (Malaysia) Sdn Bhd	a) Hospital Sultanah Aminah b) Sunway Medical Centre c) Beacon Hospital d) Pantai Hospital Kuala Lumpur	1-Apr-2026 hingga 11-Feb-2031	LULUS
33	TAK-226-3001	Fasa III	Elritercept 100 mg/mL Solution for Injection, 200 mg/vial Retacrit 2 000 IU/0.6 mL Solution for Injection in Pre-filled Syringe	IQVIA RDS Malaysia Sdn Bhd	a) Hospital Pulau Pinang b) Hospital Sultanah Aminah c) University Malaya Medical Centre	30-Apr-2026 hingga 30-Apr-2034	LULUS
34	CJDQ443B12105B	Fasa I/II	JDQ443 100 mg Tablet	Parexel International (Malaysia) Sdn Bhd	Sarawak General Hospital	01-Jun-2026 hingga 12-Mar-2029	LULUS
35	NW-3509/022/III/2024	Fasa III	Evenamide 15 mg Capsule Matching Placebo to Evenamide Capsule	Victory Pharma Healthcare Sdn. Bhd.	a) Hospital Tuanku Fauziah b) Hospital Sultan Abdul Halim c) Hospital Sentosa Kuching d) Hospital Kuala Lumpur	29-Dec-2025 hingga 31-May-2027	LULUS
36	IPPT-CTH-001	Fasa II	Gewelry Ganolux Vegetable Capsule 400mg	Institut Perubatan dan Pergigian Termaju Universiti Sains Malaysia Bertam	Institut Perubatan dan Pergigian Termaju Pusat Perubatan Universiti Sains Malaysia Bertam	01-Oct-2024 hingga 30-Sept-2026	LULUS
37	ARL-26-023	Kajian BE	Eltrombopag Tablets, 75 mg	Novugen Pharma Sdn. Bhd.	Clinical and Bioanalytical site: Accutest Research Laboratories (I) Pvt. Ltd., India	Tidak Berkenaan	LULUS
38	C1B06139	Kajian BE	Empagliflozin Tablet 25mg	Pharmaniaga Manufacturing Berhad	Clinical and Bioanalytical site: Cliantha Research Limited, India	Tidak Berkenaan	LULUS
39	CDAK539A12303	Fasa III	Pelabresib (DAK539) 25 mg film-coated tablets Pelabresib (DAK539) 100 mg film-coated tablets Placebo to Pelabresib (DAK539) 25 mg film-coated tablets Placebo to Pelabresib (DAK539) 100 mg film-coated tablets Ruxolitinib (INC424) 5 mg tablets Ruxolitinib (INC424) 10 mg tablets Ruxolitinib (INC424) 15 mg tablets Ruxolitinib (INC424) 20 mg tablets	Parexel International (Malaysia) Sdn Bhd	a) Hospital Umum Sarawak b) Hospital Queen Elizabeth c) Hospital Pulau Pinang d) Hospital Sultanah Aminah e) Hospital Ampang	30-Jun-2026 hingga 30-Jun-2031	LULUS
40	INS1009-312	Fasa III	Treprostiniil Palmitil Inhalation Powder 80 µg capsules Treprostiniil Palmitil Inhalation Powder 160 µg capsules Treprostiniil Palmitil Inhalation Powder 320 µg capsules Treprostiniil Palmitil Inhalation Powder 640 µg capsules Treprostiniil Palmitil Inhalation Powder placebo capsules	PPD Development (S) Pte. Ltd.	a) Hospital Raja Perempuan Zainab II b) Hospital Umum Sarawak c) Sultan Ahmad Shah Medical Centre at IIUM d) Hospital Sultanah Bahiyah e) Hospital Sultan Idris Shah Serdang	01-Jun-2026 hingga 31-Oct-2031	LULUS
41	R7508-DVT-24120	Fasa III	REGN7508, Powder for solution for infusion, 265mg/vial Aspirin 81mg capsule Placebo to REGN7508, Powder for solution for infusion, 0 mg/vial Placebo to Aspirin capsule	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Sultan Abdul Halim b) Hospital Tengku Ampuan Afzan c) Hospital Queen Elizabeth II d) Hospital Universiti Sains Malaysia (HUSM) e) University Malaya Medical Centre	05-Dec-2025 hingga 16-Jul-2027	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2026 (Jan-April)

42	BG-C477-101	Fasa I	BG-C477 100mg Powder for concentrate for solution for infusion Tislelizumab (BGB-A317) 100mg/10ml Concentrate for Solution for Infusion	BeOne Medicines Malaysia Sdn. Bhd.	a) Hospital Umum Sarawak b) Universiti of Malaya Medical Centre (UMMC) c) Institut Kanser Negara d) Hospital Kuala Lumpur e) Sunway Medical Center f) Hospital Wanita dan Kanak-kanak Sabah	01-Jun-2026 hingga 31-Dec-2029	LULUS
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