

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	003-20	Kajian BE	Solifenacin Succinate Tablet 10mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio), India	LULUS
2.	056-20	Kajian BE	Amlodipine and Valsartan Tablets 10 mg /160 mg	AXIS Clinicals Limited, India	LULUS
3.	027-20	Kajian BE	Rosuvastatin Tablets 20 mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio), India	LULUS
4.	285-20	Kajian BE	Tamsulosin CR Tablet 0.4mg	AXIS Clinicals Limited, India	LULUS
5.	286-20	Kajian BE	Tamsulosin CR Tablet 0.4mg	AXIS Clinicals Limited, India	LULUS
6.	ARL/20/120	Kajian BE	Gliclazide MR tablets 60mg	Accutest Research Laboratories (I) Pvt. Ltd., India	LULUS
7.	ARL/20/121	Kajian BE	Gliclazide MR tablets 60mg	Accutest Research Laboratories (I) Pvt. Ltd., India	LULUS
8.	42847922MDD3002	Fasa III	1) Seltorexant 20mg Film-Coated Tablet 2) Matching Placebo for Seltorexant 20mg Film-Coated Oral Tablet	a) Hospital Kuala Lumpur b) University Malaya Medical Centre c) Sunway Medical Centre d) Hospital Sibul	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
9.	ALN-TTRSC02-003	Fasa III	1) ALN-TTRSC02 (Vutrisiran) 50 mg/mL (Free Acid), 0.5 mL Dose in a 1 mL Pre-filled Syringe 2) TTRSC02 Placebo, 0.9% w/v Saline 0.5 ml Dose in a 1 mL Pre-filled Syringe 3) ELEVIT PRONATAL Film coated tablets	a) Universiti Teknologi Mara Private Specialist Centre b) Institut Jantung Negara c) Hospital Tengku Ampuan Afzan	LULUS
10.	73841937NSC3003	Fasa III	1) JNJ-61186372 350 mg (50 mg/ml), 7 ml Solution 2) Lazertinib 80mg Tablet 3) Placebo to Lazertinib 80mg Tablet 4) Osimertinib 40mg Capsule 5) Osimertinib 80mg Capsule 6) Placebo to Osimertinib 40mg Capsule 7) Placebo to Osimertinib 80mg Capsule	a) University Malaya Medical Centre b) Hospital Sultan Ismail c) Beacon Hospital Sdn Bhd d) Hospital Tengku Ampuan e) Hospital Pulau Pinang f) Hospital Kuala Lumpur	LULUS
11.	Exec B	Fasa I	1) High Dose B-Vitamin Multivitamin: Product A 2) High Dose B-Vitamin Multivitamin: Product B 3) High Dose B-Vitamin Multivitamin: Product C	a) Taylor's University b) Universiti Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
12.	0493-19	Kajian BE	Ezetimibe/ Simvastatin Tablet 10/40mg	Lambda Therapeutic Research Ltd., India.	LULUS
13.	61186372NSC3001	Fasa III	JNJ-61186372 350mg (50mg/ml), 7ml vial	a) University Malaya Medical Centre (UMMC) b) Hospital Sultan Ismail c) Hospital Pulau Pinang d) Hospital Kuala Lumpur	LULUS BERSYARAT

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STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN FEBRUARI 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BX-BE20-AMP-004	Kajian BE	Lexib Capsule 200mg	<p>Clinical Site: Clinical Research Ward Clinical Trial Unit, Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical Site: Bioxis Sdn Bhd Plot 301(b), Jalan Perindustrian Bukit Minyak 8 Taman Perindustrian Bukit Minyak 14100 Simpang Ampat Pulau Pinang</p>	LULUS
2.	BE18-001	Kajian BE	<p>a) Purinetone Tablet 50mg b) Mercaptopurine Tablet 50mg</p>	<p>Clinical site: Institut Perubatan & Pergigian Termaju (IPPT) Universiti Sains Malaysia, Bertam, 13200 Kepala Batas, Pulau Pinang</p> <p>Bioanalytical site: Questra Bio-Clinical Research Centre Questra Clinical Research Sdn. Bhd. No. 6, Jalan Desa Pauh, Taman Desa Pauh 13700 Permatang Pauh, Pulau Pinang.</p>	LULUS
3.	21597	Kajian BE	a) UI 1614605 – Naproxen Sodium 220 mg Soft Gelatin Capsule	<p>Clinical site and bioanalytical site: Info Kinetics Sdn Bhd</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			b) UI 1600169 – Naproxen Sodium 220 mg Tablet	5th floor, Gleneagles Penang, No.1 Jalan Pangkor, 10050 Pulau Pinang.	
4.	21598	Kajian BE	a) UI 1614605 – Naproxen Sodium 220 mg Soft Gelatin Capsule b) UI 1600169 – Naproxen Sodium 220 mg Tablet	Clinical site and bioanalytical site: Info Kinetics Sdn Bhd 5th floor, Gleneagles Penang, No.1 Jalan Pangkor, 10050 Pulau Pinang.	LULUS
5.	42847922MDD3005	Fasa III	a) JNJ-42847922 20mg Capsule b) Quetiapine 50mg Capsule c) Quetiapine 150mg Capsule d) Matching Placebo for Seltorexant 20mg, quetiapine 50mg and quetiapine 150mg Capsule	a) Hospital Tuanku Jaafar b) Hospital Permai c) Hospital Raja Permaisuri Bainun	LULUS
6.	CRTH258A2303E1	Fasa IIIb/IV	a) Brolucizumab (RTH258) 6mg/0.05mL solution for injection in prefilled syringe b) Brolucizumab (RTH258) 6mg/0.05mL solution for injection	a) Hospital Shah Alam b) Hospital Selayang c) Southern Specialist Eye Centre	LULUS
7.	APD334-202	Fasa II/III	a) Etrasimod 1mg Tablet b) Etrasimod 2mg Tablet c) Etrasimod Placebo Tablet	a) University Malaya Medical Centre b) Hospital Tengku Ampuan Rahimah c) Hospital Universiti Sains Malaysia	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	CLNP023A2301	Fasa III	a) LNP023 200 mg hard gelatin capsule b) Matching Placebo for LNP023 200 mg hard gelatin capsule	a) Hospital Kuala Lumpur b) University Malaya Medical Centre	LULUS
9.	53718678RSV3001	Fasa III	a) JNJ-53718678-ZCL eq. 217.4 mg/g Powder for Suspension/Bottle b) Placebo to JNJ-53718678-ZCL c) JNJ-53718678-ZCL Solvent 19.4mL	a) Hospital Miri b) Hospital Selayang c) Hospital Sibul d) Hospital Taiping e) Hospital Wanita dan Kanak-kanak Sabah f) Hospital Bintulu	LULUS
10.	CKJX839C12301	Fasa III	a) Inclisiran (KJX839) sodium 300 mg (equivalent to 284 mg Inclisiran) in 1.5 mL solution for injection in pre-filled syringe b) Placebo to Inclisiran (KJX839) sodium 300 mg (equivalent to 284 mg Inclisiran) in 1.5 mL solution for injection in pre-filled syringe	a) University Malaya Medical Centre b) Faculty of Medicine, UiTM Sungai Buloh	LULUS
11.	NN9931-4553	Fasa III	a) Semaglutide D 0.5 mg/mL, solution for injection, 0.5mL pen-injector b) Semaglutide D 1.0 mg/mL, solution for injection, 0.5mL pen-injector c) Semaglutide D 2.0 mg/mL, solution for injection, 0.5mL pen-injector	a) University Malaya Medical Centre b) Hospital Selayang c) Hospital Universiti Sains Malaysia	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			<ul style="list-style-type: none"> d) Semaglutide placebo Ia, solution for injection, 0.5mL pen-injector e) Semaglutide D 2.27 mg/mL, solution for injection, 0.75mL pen-injector f) Semaglutide D 3.2 mg/mL, solution for injection, 0.75mL pen-injector g) Semaglutide placebo Ib, solution for injection, 0.75mL pen-injector 		
12.	D3614C00001	Fasa III	<ul style="list-style-type: none"> a) Tablet Capivasertib (AZD5363) 200 mg b) Tablet Capivasertib (AZD5363) 160 mg c) Placebo for Capivasertib (AZD5363) 200 mg d) Placebo for Capivasertib (AZD5363) 160 mg e) Paclitaxel concentrate for solution for infusion 6 mg/mL (100mg/vial) 	<ul style="list-style-type: none"> a) Hospital Kuala Lumpur b) National Cancer Institute c) Pantai Hospital Kuala Lumpur d) Hospital Umum Sarawak e) University Malaya Medical Centre 	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	SLN124-002	Fasa I (First-In Human)	SLN 124, Solution for Injection, 100mg/mL	Hospital Umum Sarawak	LULUS
2.	0077-20	Kajian BE	Tadalafil Tablet 20 mg	Clinical and Bioanalytical Site: Lambda Therapeutic Research Ltd., Lambda house, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
3.	IK2140-(02) Entecavir	Kajian BE	Entecavir Tablets 0.5mg	Clinical Site: Borneo Kinetics Sdn Bhd, CRC Research Ward Level 6, Sarawak General Hospital Heart Centre, 94300 Kota Samarahan, Sarawak Bioanalytical Site: Info Kinetics Sdn Bhd 5th Floor Gleneagles Penang, 1, Jalan Pangkor, 10050 George Town, Penang, Malaysia.	LULUS
4.	0091-20	Kajian BE	Pregabalin Capsule 150 mg	Clinical and Bioanalytical site: Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
5.	NN8022-4392	Fasa III	a) Liraglutide 6.0 mg/mL, Solution for Injection b) Liraglutide Placebo, Solution for Injection	a) University Malaya Medical Centre b) Hospital Putrajaya	LULUS
6.	ARC-10	Fasa III	a) AB 122 for Injection, 120mg/4mL, Concentrated solution for intravenous (IV) infusion b) AB154 for Injection, 80mg/4mL, Concentrated solution for intravenous (IV) infusion	a) Hospital Umum Sarawak b) Hospital Kuala Lumpur c) Hospital Sultan Ismail d) University Malaya Medical Centre e) Mount Miriam Cancer Hospital f) Hospital Pulau Pinang g) Hospital Tengku Ampuan Afzan	LULUS
7.	0403-20	Kajian BE	Entecavir Tablet 0.5 mg	Clinical and Bioanalytical site: Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS
8.	D910FC00001	Fasa III	Durvalumab (MEDI4736) solution for infusion (50mg/mL)/500mg/vial	Hospital Umum Sarawak	LULUS
9.	INS1007-301	Fasa III	a) INS1007 (Brensocatib) Film-Coated Tablets, 10mg b) INS1007 (Brensocatib) Film-Coated Tablets, 25mg c) INS1007 (Brensocatib) Film-Coated Tablets, Placebo	a) Hospital Universiti Teknologi Mara, Selayang Campus b) Institut Perubatan Respiratori c) Hospital Raja Perempuan Zainab II d) Hospital Tengku Ampuan Afzan e) Sarawak General Hospital f) University Malaya Medical Centre	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN APRIL 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	21-VIN-0037	Kajian BE	Sitagliptin Tablets 100mg	Clinical Site: Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi, Ahmedabad, 380015 India (Dr. Hirenkumar Shah) Bioanalytical Site: Veeda Clinical Research Pvt. Ltd. Rev. Sur. No. 12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S.G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India	LULUS
2.	1404-0043	Fasa II	BI 456906 0.6 mg/mL Solution for Injection in 0.5ml PFS BI 456906 1.8 mg/mL Solution for Injection in 0.5ml PFS BI 456906 3.6 mg/mL Solution for Injection in 0.5ml PFS BI 456906 4.8 mg/mL Solution for Injection in 0.5ml PFS BI 456906 6.0 mg/mL Solution for Injection in 0.5ml PFS	University Malaya Medical Centre Hospital Selayang	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Matching Placebo to BI 456906 Solution for Injection in 0.5ml PFS		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0284-19	Kajian BE	Olanzapine Orodispersible Tablet 5mg	Clinical and Bioanalytical Site: Lambda Therapeutic Research Ltd., Lambda house, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
2.	MES/2020/1791 MES/2020/1792	Kajian BE	Mesalamine Extended-Release Capsules USP, 500mg	Clinical site: Synchron Research Services Pvt Ltd Clinical Department, 201 & 301, 2nd & 3rd Floor, Satva, Opp Bhavin School, Thaltej, Ahmedabad 380059 Gujarat, India. Bioanalytical site: "Synchron House", Behind Mondeal Park, Near Gurudwara, S.G. Highway, Ahmedabad – 380059, Gujarat, India	LULUS
3.	1366-0022 1366-0005	Fasa II	a) BI 685509 film-coated tablets 1 mg b) BI 685509 film-coated tablets 2 mg c) BI 685509 film-coated tablets 3 mg d) Matching placebo to BI 685509 film-coated tablets 1 mg e) Matching placebo to BI 685509 film-coated tablets 2 mg f) Matching placebo to BI 685509 film-coated tablets 3 mg	a. Hospital Raja Permaisuri Bainun b. University Malaya Medical Centre c. University Kebangsaan Malaysia Medical Centre d. Hospital Selayang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
4.	POD0030/CP/R	Fasa I/II	Cyto-MSC (Allogeneic Mesenchymal Stem Cells), 25 million cells in 1.8ml of cryoprotectants (90% human serum and 10% dimethyl sulfoxide (DMSO)) in a 2.0ml polyethylene (PE) cryovial	<ul style="list-style-type: none"> a. Hospital Ampang b. Sunway Medical Centre c. Hospital Canselor Tuanku Muhriz UKM 	LULUS
5.	2021L001	Fasa III	<ul style="list-style-type: none"> a) SARS-CoV-2 Vaccine (Vero Cells), Inactivated, 5µg/0.5ml b) Placebo of SARS-CoV-2 Vaccine (Vero Cells), Inactivated 	<ul style="list-style-type: none"> a) Alps Medical Centre b) Clinique Healthy Malaysia c) Columbia Asia Hospital, Klang d) Columbia Asia Hospital, Bukit Rimau e) Life Care Diagnostic Medical Centre f) Sri Kota Specialist Medical Centre g) Nilai Medical Centre 	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUN 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	039-19	Kajian BE	Pregabalin Capsule 150mg	Clinical site & Bioanalytical site:: RA Chem Pharma Limited Clinical Research & Biosciences Division Plot-No. 26 & 27, Technocrat Industrial Estate (TIE) Balanagar, Hyderabad-500037, India.	LULUS
2.	21-VIN-0135	Kajian BE	Sitagliptin and Metformin Hydrochloride Tablets 50 mg/1000 mg	Clinical site: Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi Ahmedabad, 380015, India. Bioanalytical site: Veeda Clinical Research Pvt. Ltd. Rev. Sur. No. 12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S. G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India.	LULUS
3.	21-VIN-0136	Kajian BE	Sitagliptin and Metformin Hydrochloride Tablets 50 mg/500 mg	Clinical site: Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi Ahmedabad, 380015, India. Bioanalytical site: Veeda Clinical Research Pvt. Ltd.	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Rev. Sur. No. 12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S. G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India.	
4.	IK2284-(01) Buprenorphine&Naloxone	Kajian BE	a) Buprenorphine/Naloxone SL Film System A 8mg/2mg (T1) b) Buprenorphine/Naloxone SL Film System B 8mg/2mg (T2)	Sarawak General Hospital	LULUS
5.	MK 6482-012	Fasa II	a) MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial b) Lenvatinib 4 mg Capsule c) Lenvatinib 10 mg Capsule d) MK-1308A, Solution for Infusion, 25mg/400mg (MK-1308 25 mg/MK-3475 400mg), 17.5mL Vial e) Belzutifan (MK-6482) 40mg Tablet	a) Universiti Malaya Medical Centre b) National Cancer Institute/Institut Kanser Negara c) Hospital Kuala Lumpur d) Hospital Sultan Ismail	LULUS
6.	D4325C00001	Fasa II	a) Dapagliflozin film-coated tablet 10 mg b) Zibotentan hard gelatin capsule 5 mg c) Zibotentan hard gelatin capsule 1.5 mg d) Zibotentan hard gelatin capsule 0.25 mg e) Matching placebo for Dapagliflozin film-coated tablet 10 mg f) Matching placebo for Zibotentan hard gelatin capsule 5 mg	a) Hospital Tengku Ampuan Afzan b) Hospital Kuala Lumpur c) Hospital Raja Permaisuri Bainun d) Hospital Sultan Abdul Halim e) Hospital Pakar Sultanah Fatimah f) University Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			g) Matching placebo for Zibotentan hard gelatin capsule 1.5 mg h) Matching placebo for Zibotentan hard gelatin capsule 0.25 mg		
7.	2017-001-COPAF	Fasa III	a) Colchicine 0.5mg capsules b) Matching placebo Colchicine 0.5mg capsules	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Serdang Hospital	LULUS
8.	NW-3509-014-II-2019	Fasa II	a) Evenamide 7.5 mg Capsule b) Evenamide 15 mg Capsule c) Evenamide 30 mg Capsule	a) Hospital Bahagia Ulu Kinta b) Hospital Permai c) University Malaya Medical Centre	LULUS
9.	NW-3509-015-II-2019	Fasa II	a) Evenamide 7.5 mg Capsule b) Evenamide 15 mg Capsule c) Evenamide 30 mg Capsule	d) Hospital Bahagia Ulu Kinta e) Hospital Permai f) University Malaya Medical Centre	LULUS
10.	CMIJ821A12201	Fasa II	MIJ821 20mg Lyophilisate in vial, powder for solution for infusion	a) University Malaya Medical Centre b) Hospital Tuanku Ja'afar c) Hospital Kuala Lumpur	LULUS
11.	D8532C00001	Fasa III	a) AZD9833 film-coated tablet 25mg b) AZD9833-Placebo film-coated tablet 25mg c) AZD9833 film-coated tablet 75mg d) AZD9833-Placebo film-coated tablet 75mg e) Anastrozole film-coated tablet 1mg (Arimidex) f) Anastrozole-Placebo film-coated tablet 1mg	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Pantai Hospital Kuala Lumpur d) Hospital Sultan Ismail e) Institut Kanser Negara f) Hospital Umum Sarawak g) Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			g) IBRANCE hard capsules 75mg (Palbociclib) h) IBRANCE hard capsules 100mg (Palbociclib) i) IBRANCE hard capsules 125mg (Palbociclib)		
12.	ALXN2040-PNH-301	Fasa III	a) Danicopan (ALXN2040) Film Coated Tablets 50mg b) Danicopan (ALXN2040) Film Coated Tablets 100mg c) Matching Placebo for Danicopan 50 mg Tablet d) Matching Placebo for Danicopan 100 mg Tablet e) Ultomiris (ravulizumab) 300mg/30mL (10mg/mL)	a) Hospital Umum Sarawak b) Hospital Miri c) Hospital Ampang d) Hospital Queen Elizabeth	LULUS
13.	MK-7684A-002	Fasa II	a) MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial b) Docetaxel 20 mg/ml, Solution for IV infusion, 80mg vial	a) Hospital Tengku Ampuan Afzan b) Hospital Sultan Ismail c) Beacon Hospital Sdn Bhd d) University Malaya Medical Centre	LULUS
14.	MK-7684A-003	Fasa III	a) MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial b) MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) Gleneagles Penang Medical Center d) National Cancer Institute e) University Malaya Medical Centre	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JULAI 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	20-VIN-0498	Kajian BE	Fexofenadine 180mg Tablet	<p>Clinical site: Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi, Ahmedabad, 380015 India</p> <p>Bioanalytical site: Veeda Clinical Research Pvt.Ltd. Rev. Sur. No.12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S.G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India</p>	LULUS
2.	BX-PL21-AMP-001	Kajian BE	Tadalafil Film Coated Tablet 20mg	<p>Clinical site: Clinical Research Ward Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	LULUS
3.	105-21	Kajian BE	Midodrine Hydrochloride Tablets USP, 5mg	<p>Clinical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Bioanalytical site: AXIS Clinicals Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.	
4.	106-21	Kajian BE	Midodrine Hydrochloride Tablets USP, 5mg	Clinical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India. Bioanalytical site: AXIS Clinicals Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.	LULUS
5.	AV104-102	Kajian BA	a) AV104 8 mg film, pH 4.25 b) AV104 8 mg film, pH 5.50 c) AV104 8 mg film, pH 7.0	Borneo Kinetics Sdn. Bhd., Sarawak General Hospital Heart Centre	LULUS
6.	MK-3475-905	Fasa III	a) Enfortumab Vedotin 30mg/Vial Lyophilized Powder for IV Infusion b) MK-3475 (Pembrolizumab) 25mg/ml, Concentrate for Solution for Infusion, 4ml Vial	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Pulau Pinang	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
7.	MK-3475-B15	Fasa III	<ul style="list-style-type: none"> a) Enfortumab Vedotin 30mg/Vial Lyophilized Powder for IV Infusion b) MK-3475 (Pembrolizumab) 25mg/ml, Concentrate for Solution for Infusion, 4ml Vial c) Gemcitabine 1000mg vial powder for solution d) Cisplatin 1mg/mL, 50mL Concentrate for Solution for Infusion 	<ul style="list-style-type: none"> a) Sarawak General Hospital b) University Malaya Medical Centre c) Sunway Medical Centre 	LULUS
8.	MAA-304	Fasa III	4.6mg of Marzeptacog alfa (activated) [MarzAA] powder in 5mL vial	<ul style="list-style-type: none"> a) Hospital Sultanah Bahiyah b) Hospital Queen Elizabeth c) Hospital Tunku Azizah d) Hospital Ampang e) Hospital Raja Perempuan Zainab II f) Hospital Tuanku Ja'afar 	LULUS
9.	MOR202C206	Fasa II	Felzartamab powder for concentrate for solution for infusion, 325 mg/vial in ISO 20R vial	University Malaya Medical Centre	LULUS
10.	GT0918-MR-3001	Fasa III	GT0918 (Proxalutamide) 100mg Tablet	Hospital Miri	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	072-21	Kajian BE	Sitagliptin Tablet 100 mg	Clinical and Bioanalytical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500049, India	LULUS
2.	ARL/21/118	Kajian BE	Rivaroxaban Film-Coated Tablets 10 mg	Clinical Site: Accutest Research Laboratories (I) Pvt. Ltd. 101 to 113 & 201 to 204, 1st and 2nd floor, Synergy Square Complex, Krishna Industrial Estate, BIDC, Gorwa, Vadodara – 390016, India Bioanalytical Site: Accutest Research Laboratories (I) Pvt. Ltd. A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, India	LULUS
3.	MK-1654-004	Fasa II/III	a) MK-1654 150mg/ml, Sterile Solution for IM Injection, 0.9ml/vial b) MK-1654 Sterile Saline Placebo (0.9% w/v Sodium Chloride), Solution for IM Injection, 1ml/vial	a) Hospital Sibul b) Hospital Wanita Dan Kanak-Kanak Sabah c) Hospital Seri Manjung d) Hospital Pulau Pinang e) Hospital Raja Perempuan Zainab II f) Hospital Seberang Jaya g) Hospital Taiping	LULUS
4.	CLNP023C12301	Fasa III	a) LNP023 10mg Hard Gelatin Capsule	a) Sarawak General Hospital	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			b) LNP023 200 mg hard gelatin capsule	b) Hospital Queen Elizabeth	
5.	CLNP023C12001B	Fasa III	a) LNP023 10mg Hard Gelatin Capsule b) LNP023 200 mg hard gelatin capsule	a) Hospital Queen Elizabeth	LULUS
6.	MOR208C310	Fasa III	a) Tafasitamab 200mg vial, powder for concentrate for solution for infusion b) 10 mg Lenalidomide hard capsules c) Placebo for 10 mg Lenalidomide hard capsules d) 15 mg Lenalidomide hard capsules e) Placebo for 15 mg Lenalidomide hard capsules f) 25 mg Lenalidomide hard capsules g) Placebo for 25 mg Lenalidomide hard capsules	a) Hospital Ampang b) Hospital Umum Sarawak c) Hospital Tengku Ampuan Afzan d) Hospital Pulau Pinang e) Subang Jaya Medical Centre f) Sunway Medical Centre g) University Malaya Medical Centre h) Hospital Raja Permaisuri Bainun i) Hospital Sultanah Bahiyah j) Hospital Sultanah Aminah k) Hospital Taiping l) Hospital Universiti Sains Malaysia	LULUS
7.	CK-301-301	Fasa III	a) CK-301 Injection 300 mg/5 mL (60 mg/mL) vial b) Pemetrexed Alvogen 500 mg vial c) Ribocarbo®-L (carboplatin) 450 mg vial, 10 mg/ml d) CISPLATIN ACCORD, 50mL vial, 1 mg/mL	a) Pusat Perubatan Universiti Kebangsaan Malaysia b) University Malaya Medical Centre c) Hospital Pulau Pinang d) Hospital Raja Perempuan Zainab II e) Beacon Hospital f) Hospital Sultan Ismail	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	EDP 938-102	Fasa II	a) EDP-938 200mg Tablets b) EDP-938 200mg Placebo Tablets	a) Universiti Teknologi Mara, UITM Sungai Buloh Campus b) Sunway Medical Centre Berhad c) Hospital Miri d) Hospital Sultanah Nur Zahirah e) Hospital Tuanku Fauziah	LULUS
9.	ENV-IPF-101	Fasa II	a) ENV-101 (Taladegib) 100mg Tablet b) Placebo for ENV-101 (Taladegib) 100mg Tablet	a) Institut Perubatan Respiratori b) Hospital Raja Perempuan Zainab II c) University Malaya Medical Centre d) Universiti Kebangsaan Malaysia Medical Centre e) UiTM Selayang Campus	LULUS
10.	VIR-2218-1006	Fasa II	a) 1 Single Use Vial of VIR-3434, 300mg/vial b) Vial Containing 0.5mL VIR-2218 at 200mg/mL	a) University Malaya Medical Centre b) Hospital Serdang c) Hospital Selayang	LULUS
11.	C4671002	Fasa II/III	a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg	a) Klinik Kesihatan Kuang b) Hospital Raja Perempuan Zainab II c) Hospital Miri d) Hospital Taiping e) Hospital Seberang Jaya	LULUS BERSYARAT
12.	C4671005	Fasa II/III	a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg	a) Hospital Miri b) Hospital Taiping	LULUS BERSYARAT

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			<ul style="list-style-type: none"> b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg 	<ul style="list-style-type: none"> c) Hospital Seberang Jaya d) Hospital Umum Sarawak 	
13.	C4671006	Fasa II/III	<ul style="list-style-type: none"> a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg 	<ul style="list-style-type: none"> a) Klinik Kesihatan Kuang b) Hospital Raja Perempuan Zainab II c) Hospital Miri d) Klinik Kesihatan Greentown e) Hospital Seberang Jaya 	LULUS BERSYARAT

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	PRO-nCOV-3002	Fasa III	a) Inactivated SARS-CoV-2 virus 600SU/0.5ml pre-filled syringe b) Matching placebo for inactivated SARS-CoV-2 virus 600SU/0.5ml pre-filled syringe	a) Hospital Sibul b) Klinik Kesihatan Cheras Baru c) Hospital Miri d) Hospital Seberang Jaya e) Hospital Raja Permaisuri Bainun f) Hospital Wanita dan Kanak-Kanak Sabah g) Hospital Sungai Buloh h) University Malaya Medical Centre i) Hospital Pengajar UiTM Puncak Alam	LULUS
2.	JSVCT109	Fasa III	a) Recombinant COVID-19 vaccine (Sf9 Cells), 40µg/1.0 mL/vial Suspension for Injection b) Placebo for Recombinant COVID-19 vaccine (Sf9 Cells), 1.0 mL/vial Suspension for Injection	a) Klinik Kesihatan Pandamaran	LULUS
3.	ARCoV-005	Fasa III	a) SARS-CoV-2 mRNA Vaccine, Injection, 0.5mL/syringe, containing 15µg of mRNA b) Placebo for SARS-CoV-2 mRNA Vaccine, Injection, 0.5mL/syringe, containing 15µg of mRNA	a) Hospital Seberang Jaya b) Hospital Ampang c) Klinik Kesihatan Greentown	LULUS
4.	BX-BE21-AMP-001 BX-BE21-AMP-002	Kajian BE	Dulotine Enteric Microencapsulated Capsule 60mg	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				<p>Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical Site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	
5.	026-20	Kajian BE	Etoricoxib Tablets 120 mg	<p>Clinical Site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	LULUS
6.	MI-21-rivaroxaban-06	Kajian BE	Rivaroxaban Film-coated Tablets 20mg	<p>Clinical Site: Siriraj Institute of Clinical Research (SICRES) 10th floor, Siriraj Medical Research Center (SiMR) Faculty of Medicine Siriraj Hospital, Mahidol University</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
				<p>2 Wanglang Road, Siriraj, Bangkoknoi, Bangkok 10700, Thailand</p> <p>Bioanalytical Site: Medica Innova Co. Ltd. 5-7th Floor, 147 Soi Sabaijai, Suthisarnwinichai Road, Bangkok 10310, Thailand</p>	
7.	PR/BE/21/305	Kajian BE	Dapagliflozin Tablets 10 mg	<p>Clinical Site: Raptim Research Pvt. Ltd. A-226, PAP-213 (Clinical Unit), T.T.C. Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India</p> <p>Bioanalytical Site: Raptim Research Pvt. Ltd., A-242 (Bioanalytical and Biostatistical Unit), T.T.C. Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India.</p>	LULUS
8.	040-21	Kajian BE	Ezetimibe and Simvastatin Tablets 10 mg/10 mg	<p>Clinical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27,</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				<p>Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	
9.	041-21	Kajian BE	Ezetimibe and Simvastatin Tablets 10 mg/40 mg	<p>Clinical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	LULUS
10.	SIR365-AU-102	Fasa Ib	<p>a) SIR1-365 tablets 100 mg</p> <p>b) Matching Placebo for SIR1-365 tablets 100 mg</p>	<p>a) Subang Jaya medical Centre</p> <p>b) Hospital Kuala Lumpur</p> <p>c) Hospital Selayang</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				d) University Malaya Medical Centre e) Oriental Melaka straits Medical Centre f) Sunway Medical Centre	
11.	A4250-012	Fasa III	a) Odevixibat (A4250) 200mcg Capsules b) Odevixibat (A4250) 600mcg Capsules c) Odevixibat (A4250) 400mcg Capsules d) Odevixibat (A4250) 1200mcg Capsules e) Placebo to match Odevixibat (A4250) 200mcg or 600mcg f) Placebo to match Odevixibat (A4250) 400mcg or 1200mcg	a) University of Malaya Medical Centre	LULUS
12.	CBYL719K12301	Fasa III	a) Olaparib 100mg Film-Coated Tablet b) Olaparib 150mg Film-Coated Tablet c) BYL719 (Alpelisib) 50 mg Film-Coated Tablet d) BYL719 (Alpelisib) 200 mg Film-Coated Tablet	a) Hospital Wanita Dan Kanak-Kanak Sabah b) Hospital Kuala Lumpur a) Universiti Malaya Medical Centre	LULUS
13.	EX6018-4758	Fasa III	a) Ziltivekimab B 15mg/mL 1X1mL Prefilled Syringe b) Placebo 1 X 1mL Prefilled Syringe	a) Hospital Universiti Sains Malaysia b) Sarawak Heart Centre c) Hospital Raja Perempuan Zainab II d) University Malaya Medical Centre e) Institute Jantung Negara f) Hospital Queen Elizabeth II g) University Technology MARA h) Hospital Tuanku Ja'afar i) Hospital Sultanah Bahiyah	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
14.	67896049PAH4005	Fasa IV	a) Tablet Selexipag 200µg (140tabs/bottle) b) Tablet Selexipag 200µg (60tabs/bottle) c) Tablet Selexipag 400µg (60tabs/bottle) d) Tablet Selexipag 400µg (60tabs/bottle) e) Tablet Selexipag 600µg (60tabs/bottle) f) Tablet Selexipag 800µg (60tabs/bottle) g) Tablet Selexipag 1000µg (60tabs/bottle) h) Tablet Selexipag 1200µg (60tabs/bottle) i) Tablet Selexipag 1400µg (60tabs/bottle) j) Tablet Selexipag 1600µg (60tabs/bottle)	a) Institut Jantung Negara	LULUS
15.	MO42541	Fasa III	a) Atezolizumab 1200mg/20ml, concentrate for solution for IV infusion b) Lenvatinib 4mg hard capsules	a) Institut Kanser Negara b) Beacon Hospital Sdn. Bhd. c) University Malaya Medical Centre	LULUS
16.	R3918-PNH-2092	Fasa II	a) Pozelimab, Solution for Injection, 200 mg/mL, supplied in 6R glass vial b) Cemdisiran, Solution for Injection, 200 mg/mL, supplied in 2 mL glass vial	a) Hospital Miri b) Hospital Sultanah Nur Zahirah c) Hospital Sibu	LULUS
17.	Kod NN21-40	Fasa III	a) AB-LIFETM Probiotic for Intestinal Health Lactobacillus Plantarum CECT7527, CECT7528 and CECT7529 at total 1.2 billion CFU/cap b) AB-LIFETM Probiotic for Intestinal Health (Placebo) Lactobacillus Plantarum CECT7527, CECT7528 and CECT7529 at total 1.2 billion CFU/cap	a) Endocrine Clinic of Pusat Perubatan Universiti Kebangsaan Malaysia	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
18.	VT-001-005	Fasa IIb	a) 1mL of 25 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection b) 1mL of 75 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection c) 1 mL of 150 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection d) 1 mL of Placebo Solution in Prefilled Syringe for Subcutaneous Injection	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Hospital Tengku Ampuan Afzan d) Hospital Taiping	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	031-21	Kajian BE	Pantoprazole Tablet 40mg	Clinical and Bioanalytical site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
2.	BX-BE21-AMP-003	Kajian BE	Zitracin Film Coated Tablet 500mg	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, Penang	LULUS
3.	BE.669/EQL/2021	Kajian BE	YSP Hydroxychloroquine Film Coated Tablet 200mg	Clinical site and Bioanalytical site: PT Equilab International Jl. RS. Fatmawati Persil 33 Jakarta 12430, Indonesia.	LULUS
4.	BX-BE21-AMP-004	Kajian BE	Ezycor Tablet 10mg	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				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, Penang	
5.	NN9500-4656	Fasa II	<ul style="list-style-type: none"> a) NNC0194-0499 B 50 mg/ml, 3 mL underfilled cartridge (1 mL solution) b) Semaglutide B 3 mg/ml, 3 ml PDS290 pen-injector c) NNC0174-0833 A 10 mg/ml, 3 mL underfilled cartridge (1 mL solution) d) Placebo C, 3 mL underfilled cartridge (1 mL solution) e) Semaglutide Placebo, 3 mL PDS290 pen-injector f) Placebo NNC0174-0833 A, 3 mL underfilled cartridge (1 mL solution) 	<ul style="list-style-type: none"> a) Hospital Selayang b) Hospital Universiti Sains Malaysia c) University Malaya Medical Centre 	LULUS
6.	BCX9930-203	Fasa II	<ul style="list-style-type: none"> a) BCX9930 250 mg Tablet b) Placebo for BCX9930 250 mg Tablet c) Meningococcal Group B Vaccine Trumenba® 0.5mL Prefilled Syringe 	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Ampang c) Sarawak General Hospital/ Hospital Umum Sarawak 	LULUS
7.	GRN163LMYF3001	Fasa III	Imetelstat sodium lyophilized powder for solution 210 mg	<ul style="list-style-type: none"> a) Hospital Umum Sarawak b) Hospital Pulau Pinang c) Hospital Raja Perempuan Zainab II 	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
				d) Hospital Ampang	
8.	TG2102V01	Fasa III	a) Recombinant SARS-CoV-2 fusion protein vaccine, injection, 10µg (0.5 mL)/vial b) Placebo for Recombinant SARS-CoV-2 fusion protein vaccine, injection, 10µg (0.5 mL)/vial	a) Hospital Taiping b) Hospital Sultan Abdul Halim c) Hospital Pakar Sultanah Fatimah d) Sarawak General Hospital e) Hospital Seri Manjung f) Hospital Pulau Pinang g) Sunway Medical Centre Velocity (SMCV) h) Sunway Medical Centre (SunMed) i) Klinik Kesihatan Seremban 2 j) Hospital Sibu	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN NOVEMBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0327-21	Kajian BE	Eltrombopag Tablets 75 mg	<p>Clinical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India (Dr. Poojan Patel)</p> <p>Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India</p>	LULUS
2.	0328-21	Kajian BE	Eltrombopag Tablets 75 mg	<p>Clinical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India (Dr. Poojan Patel)</p> <p>Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota,</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Ahmedabad - 382481, India	
3.	0333-21	Kajian BE	Telmisartan and Amlodipine tablets 80mg/10mg	<p>Clinical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Solver Oak Club, S.G. Highway, Gota, Ahmedabad - 382481, India (Dr. Poojan Patel)</p> <p>Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Solver Oak Club, S.G. Highway, Gota, Ahmedabad - 382481, India</p>	LULUS
4.	2020-BE-005	Kajian BE	hovid-Clofenac 50 mg Enteric Coated Tablet	<p>Clinical Site: Clinical Research Ward Clinical Trial Unit, Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor (Dr. Damenthi Nair A/P Narayanan)</p> <p>Bioanalytical Site: BA/BE Laboratory Attest Research Sdn. Bhd. Lot 16030, Plot 88G, Lintang Bayan Lepas 10, Kawasan Perindustrian Bayan Lepas, 11900 Bayan Lepas,</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
				Pulau Pinang	
5.	NN1535-4593	Fasa III	<ul style="list-style-type: none"> a) IcoSema 700U/mL + 2mg/mL, solution for injection, 1.5 ml prefilled pen-injector b) Insulin Glargine 100U/mL, solution for injection, 3mL prefilled pen-injector c) Insulin Aspart 100U/mL, solution for injection, 3ml prefilled pen-injector 	<ul style="list-style-type: none"> a) University Malaya Medical Centre (UMMC) b) Hospital Miri c) Klinik Kesihatan Simpang Kuala d) Hospital Universiti Sains Malaysia (HUSM) e) University Technology MARA (UiTM) f) Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur (UKMMC) 	LULUS
6.	CLOU064A2302	Fasa III	<ul style="list-style-type: none"> a) LOU064 (Remibrutinib) 25mg Film-Coated Tablet b) Matching Placebo to LOU064 (Remibrutinib) 25mg Film-Coated Tablet 	<ul style="list-style-type: none"> a) Hospital Putrajaya b) Hospital Pakar Sultanah Fatimah c) Hospital Pulau Pinang d) Hospital Kuala Lumpur e) Hospital Raja Permaisuri Bainun 	LULUS
7.	CDRB436J12301	Fasa III	<ul style="list-style-type: none"> a) DRB436 (DABRAFENIB) 50mg Hard Non-Gelatin Capsule b) DRB436 (DABRAFENIB)75 mg Hard Non-Gelatin Capsule c) TMT212 (TRAMETINIB) 0.5 mg Film Coated Tablet d) TMT212 (TRAMETINIB) 2 mg Film Coated Tablet e) Placebo to DRB436 (DABRAFENIB) 50mg Hard non-gelatin capsule f) Placebo to DRB436 (DABRAFENIB) 75mg Hard non-gelatin capsule g) Placebo to TMT212 (TRAMETINIB) 0.5mg Film Coated Tablets 	<ul style="list-style-type: none"> i) Hospital Kuala Lumpur j) Hospital Pulau Pinang k) Pantai Hospital Kuala Lumpur l) University Malaya Medical Centre 	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			h) Placebo to TMT212 (TRAMETINIB) 2mg Film Coated Tablets		
8.	8.0	Fasa II	S-649266 powder for solution for infusion 1g/vial	a) University Malaya Medical Centre b) Universiti Sains Malaysia Health Campus	LULUS
9.	MK-4482-013	Fasa III	a) MK-4482 200mg capsules b) MK-4482 Placebo capsules	a) Hospital Raja Perempuan Zainab II b) Klinik Kesihatan Masjid Tanah	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	BX-BE-AMP-005	Kajian BE	Levozin Film Coated Tablet 5mg	<p>Clinical Site: Clinical Research Ward Clinical Trial Unit, Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical Site: Bioxis Sdn. Bhd., PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	LULUS
2.	ARL/21/118	Kajian BE	Apixaban Film-Coated Tablets 5mg	<p>Clinical Site: Accutest Research Laboratories (I) Pvt. Ltd. 101 to 113 & 201 to 204, 1st and 2nd floor, Synergy Square Complex, Krishna Industrial Estate, BIDC, Gorwa, Vadodara – 390016, India</p> <p>Bioanalytical Site: Accutest Research Laboratories (I) Pvt. Ltd., A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, India</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
3.	0191-21	Kajian BE	Etoricoxib Tablet 120 mg	Clinical & Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
4.	CABL001A2302	Fasa IIIb	ABL001 (Asciminib) 40 mg film-coated tablet ABL001 (Asciminib) 20 mg film-coated tablet	Hospital Pulau Pinang Hospital Queen Elizabeth Hospital Ampang Hospital Sultanah Aminah	LULUS
5.	CABL001J12301	Fasa IIIb	ABL001 (Asciminib) 40 mg film-coated tablet	Hospital Pulau Pinang Subang Jaya Medical Centre Hospital Ampang Hospital Tengku Ampuan Afzan	LULUS
6.	OPT-302-1004	Fasa III	OPT-302 40mg/mL Solution for injection Lucentis 10mg/mL Solution for Injection Sham solution for Injection	Hospital Selayang Hospital Shah Alam Tun Hussein Onn National Eye Hospital	LULUS
7.	MK-4280A-007	Fasa III	MK4280A 20/5 mg/mL (MK-4280 20mg/ml and MK-3475 5mg/ml), Solution for Infusion, 40mL vial	University Malaya Medical Centre National Cancer Institute/ Institut Kanser Negara Beacon Hospital Pantai Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	GO42784	Fasa III	Giredestrant, 30mg Hard Capsules Letrozole 2.5 mg Film-coated Tablets Anastrozole 1 mg Film-coated Tablets Exemestane 25 mg Film-coated Tablets Tamoxifen 20 mg Tablets	Beacon Hospital Hospital Kuala Lumpur Hospital Pulau Pinang Hospital Umum Sarawak Institut Kanser Negara Pantai Hospital Sungai Petani University Malaya Medical Centre	LULUS
9.	IIT-CRM2020001	Fasa II	Talazoparib 0.25 mg capsules Talazoparib 1 mg capsules	University Malaya Medical Centre	LULUS
10.	ESDY-121-0084	Fasa I	Femoston 1/5 mg Tablet Femoston 0.5/2.5 mg Tablet	Info Kinetics Sdn. Bhd.	LULUS
11.	60569	Fasa II	Ivervid Tablet 6mg Placebo to match Ivervid 6mg	Pejabat Kesihatan Daerah Batang Padang Pejabat Kesihatan Daerah Kerian Pejabat Kesihatan Daerah Kinta Pejabat Kesihatan Daerah Kuala Kangsar Pejabat Kesihatan Daerah Larut Matang and Selama Pejabat Kesihatan Daerah Manjung Pejabat Kesihatan Daerah Muallim Pejabat Kesihatan Daerah Seberang Perai Tengah Pejabat Kesihatan Daerah Kuala Muda Pejabat Kesihatan Daerah Kangar	KELULUSAN BERSYARAT
12.	JH-COR-003	Fasa III	10 µg/ml Novaferon (Nebulizer solution for inhalation use)	Hospital Pulau Pinang Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Placebo for 10 µg/mL Novaferon	University Malaya Medical Centre Hospital Miri Hospital Pengajar Universiti Putra Malaysia	
13.	DW_DWJ1248201	Fasa II/III	DWJ1248 200mg film-coated tablet Matching placebo for DWJ1248 200mg film-coated tablet	Hospital Miri Hospital Duchess of Kent University Malaya Medical Centre	LULUS BERSYARAT
14.	0135-0347	Fasa IIb/III	Alteplase (TPA-05) 50 mg Powder in Vial and 50 mL solvent for Alteplase (TPA-05) Powder for solution for injection/infusion	Hospital Queen Elizabeth Hospital Miri University Malaya Medical Centre	LULUS