

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
LABCORP HONG KONG SERVICES LIMITED	A global, phase 2 study of ARX788 in HER2-positive metastatic breast cancer patients whose disease is resistant or refractory to T-DM1, and/or T-DXd, and/or Tucatinib-containing regimens	Hong Kong United Oncology Centre
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A long-term extension study to evaluate the safety of Filgotinib in subjects with Crohn's disease	Queen Mary Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A long-term extension study to evaluate the safety of Filgotinib in subjects with Crohn's disease	Tuen Mun Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A long-term extension study to evaluate the safety of Filgotinib in subjects with ulcerative colitis	Queen Mary Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A long-term extension study to evaluate the safety of Filgotinib in subjects with ulcerative colitis	Prince of Wales Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A long-term extension study to evaluate the safety of Filgotinib in subjects with ulcerative colitis	Princess Margaret Hospital
IQVIA RDS HONG KONG LIMITED	A multicenter, double-blind, randomized, placebo-controlled, phase II/III study to evaluate the efficacy, safety and pharmacokinetics of JT001 (VV116) for the early treatment of coronavirus disease 2019 (COVID-19) in participants with mild to moderate COVID-19	Phase I Clinical Trial Centre, The Chinese University of Hong Kong
IQVIA RDS HONG KONG LIMITED	A multicenter, double-blind, randomized, placebo-controlled, phase II/III study to evaluate the efficacy, safety and pharmacokinetics of JT001 (VV116) for the early treatment of coronavirus disease 2019 (COVID-19) in participants with mild to moderate COVID-19	CUHK Medical Centre
MERCK SHARP & DOHME (ASIA) LTD.	A multicenter, open-label, phase 3 study to evaluate the long-term safety and efficacy in participants who are currently on treatment or in follow-up in studies that include Pembrolizumab	Queen Mary Hospital
HONGKONG TIGERMED CO., LIMITED	A multi-center, randomized, double-blinded, parallel and placebo-controlled phase III clinical study to evaluate the efficacy and safety of PB-201 in Type 2 diabetic mellitus patients with poor glycemic control via Metformin hydrochloride monotherapy	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
HONGKONG TIGERMED CO., LIMITED	A multi-center, randomized, double-blinded, parallel and placebo-controlled phase III clinical study to evaluate the efficacy and safety of PB-201 in Type 2 diabetic mellitus patients with poor glycemic control via Metformin hydrochloride monotherapy	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
IQVIA RDS HONG KONG LIMITED	A multi-center, randomized, double-blinded, parallel, Vildagliptin and placebo-controlled phase III clinical study to evaluate the efficacy and safety of PB-201 in treatment-naïve patients with type 2 diabetes mellitus	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
IQVIA RDS HONG KONG LIMITED	A multi-center, randomized, double-blinded, parallel, Vildagliptin and placebo-controlled phase III clinical study to evaluate the efficacy and safety of PB-201 in treatment-naïve patients with type 2 diabetes mellitus	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 1, double-blind, randomized, placebo-controlled, first-in-human study of subcutaneously administered ALG-020572 to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics after single ascending doses in healthy volunteers (Part 1) and multiple doses in subjects with chronic hepatitis B (Part 2)	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
FORTREA HONG KONG LIMITED	A phase 1, first-in human study of ARB202, bispecific antibody to CDH17 and CD3 in advanced gastrointestinal malignancies	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
RESEARCH PHARMACEUTICAL SERVICES, CLINICAL TRIALS CENTRE, THE UNIVERSITY OF HONG KONG	A phase 1, open-label, pharmacokinetic study of intravenous NTM-001 (A novel formulation of Ketorolac Tromethamine applied by continuous intravenous infusion from a pre-mixed bag) in healthy Chinese subjects	Phase 1 Clinical Trials Centre, The University of Hong Kong
IQVIA RDS HONG KONG LIMITED	A phase 1/1b/2 study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of AMG 193 alone and in combination with Docetaxel in subjects with advanced MTAP-null solid tumors	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 1/2 study of PBI-200 in subjects with NTRK-Fusion-Positive advanced or metastatic solid tumors	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 1/2 study of PBI-200 in subjects with NTRK-Fusion-Positive advanced or metastatic solid tumors	Queen Mary Hospital
IQVIA RDS HONG KONG LIMITED	A phase 1b/3 study of Bemarituzumab plus chemotherapy and Nivolumab versus chemotherapy and Nivolumab alone in subjects with previously untreated advanced gastric and gastroesophageal junction cancer with FGFR2b overexpression (FORTITUDE-102)	Prince of Wales Hospital
ICON CLINICAL RESEARCH HONG KONG LTD.	A phase 2 open-label extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study	Prince of Wales Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	Queen Elizabeth Hospital

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	HKSH Cancer Centre (Island East)
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	Queen Mary Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	Hong Kong United Oncology Centre
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A phase 2 open-label study of Sacituzumab Govitecan (IMMU-132) in subjects with metastatic solid tumors	Hong Kong Integrated Oncology Centre
FORTREA HONG KONG LIMITED	A phase 2 study of BA3011 alone and in combination with Nivolumab in adult patients with metastatic non-small cell lung cancer (NSCLC) who had prior disease progression on a PD-1/L-1, EGFR, or ALK inhibitor	ICON Cancer Centre
GILEAD SCIENCES HONG KONG LIMITED	A phase 2 study of Magrolimab combination therapy in patients with head and neck squamous cell carcinoma	Princess Margaret Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 2 study of Magrolimab combination therapy in patients with head and neck squamous cell carcinoma	Hong Kong Sanatorium & Hospital, Ltd.
GILEAD SCIENCES HONG KONG LIMITED	A Phase 2 Study of Magrolimab Combination Therapy in Patients with Unresectable, Locally Advanced or Metastatic Triple-Negative Breast Cancer	Princess Margaret Hospital
GILEAD SCIENCES HONG KONG LIMITED	A Phase 2 Study of Magrolimab Combination Therapy in Patients with Unresectable, Locally Advanced or Metastatic Triple-Negative Breast Cancer	Prince of Wales Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 2, randomized, open-label study evaluating the safety and efficacy of Magrolimab in combination with Bevacizumab and FOLFIRI versus Bevacizumab and FOLFIRI in previously treated advanced inoperable metastatic colorectal cancer (mCRC)	Hong Kong United Oncology Centre
GILEAD SCIENCES HONG KONG LIMITED	A phase 2, randomized, open-label study evaluating the safety and efficacy of Magrolimab in combination with Bevacizumab and FOLFIRI versus Bevacizumab and FOLFIRI in previously treated advanced inoperable metastatic colorectal cancer (mCRC)	Hong Kong Integrated Oncology Centre
GILEAD SCIENCES HONG KONG LIMITED	A phase 2, randomized, open-label study evaluating the safety and efficacy of Magrolimab in combination with Bevacizumab and FOLFIRI versus Bevacizumab and FOLFIRI in previously treated advanced inoperable metastatic colorectal cancer (mCRC)	Queen Mary Hospital
GLAXOSMITHKLINE LTD.	A phase 2, single-blinded, randomised, controlled multi-country study to evaluate the safety, reactogenicity, efficacy and immune response following sequential treatment with an anti-sense oligonucleotide (ASO) against chronic hepatitis B (CHB) followed by chronic hepatitis B targeted immunotherapy (CHB-TI) in CHB patients receiving nucleos(t)ide analogue (NA) therapy	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase 2/3 randomized, controlled, open-label study of KRT-232 in subjects with primary myelofibrosis (PMF), post-polycythemia vera MF (Post-PV-MF), or post-essential thrombocythemia MF (Post-ET-MF) who are relapsed or refractory to janus kinase (JAK) inhibitor treatment	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase 2/3 randomized, controlled, open-label study of KRT-232 in subjects with primary myelofibrosis (PMF), post-polycythemia vera MF (post-PV-MF), or post-essential Thrombocythemia MF (Post-ET-MF) who are relapsed or refractory to janus kinase (JAK) inhibitor treatment	Prince of Wales Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 2/3, multicenter, open-label trial to evaluate the long-term safety, tolerability, and efficacy of Sibeprenlimab administered subcutaneously in subjects with immunoglobulin A nephropathy	Queen Mary Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 2/3, multicenter, open-label trial to evaluate the long-term safety, tolerability, and efficacy of Sibeprenlimab administered subcutaneously in subjects with immunoglobulin A nephropathy	Princess Margaret Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 2/3, multicenter, open-label trial to evaluate the long-term safety, tolerability, and efficacy of Sibeprenlimab administered subcutaneously in subjects with immunoglobulin A nephropathy	Yan Chai Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 2/3, multicenter, open-label trial to evaluate the long-term safety, tolerability, and efficacy of Sibeprenlimab administered subcutaneously in subjects with immunoglobulin A nephropathy	Tung Wah Hospital
PPD DEVELOPMENT (HK) LIMITED	A phase 2/3, randomized, open-label study to compare Bempegaldesleukin combined with Pembrolizumab versus Pembrolizumab alone in first-line treatment of patients with metastatic or recurrent head and neck squamous-cell carcinoma with PD-L1 expressing tumors (PROPEL-36)	Queen Mary Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 2a, open-label study to evaluate the safety and efficacy of Selgantolimod (SLGN)-containing combination therapies for the treatment of chronic hepatitis B (CHB)	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 2a, randomized, blinded, multicenter study investigating a combination of AB-729 and VTP-300 in virologically-suppressed chronic hepatitis B participants	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
Dr. LAU M.C. Edith	A phase 2a, randomized, double-blind, placebo-controlled trial of the efficacy and safety of LEVI-04 in patients with osteoarthritis of the knee	Hong Kong Center for Clinical Research

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 2b, open-label study to evaluate the efficacy, safety, tolerability, immunogenicity and treatment regimens of VTP-300 combined with low-dose Nivolumab in chronic hepatitis B infection	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
MERCK SHARP & DOHME (ASIA) LTD.	A phase 3 multicenter, randomized, double-blinded, active-controlled, clinical study to evaluate the safety and efficacy of Lenvatinib (E7080/MK-7902) with Pembrolizumab (MK-3475) in combination with transarterial chemoembolization (TACE) versus TACE in participants with incurable/non-metastatic hepatocellular carcinoma (LEAP-012)	Queen Mary Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A phase 3 multicenter, randomized, double-blinded, active-controlled, clinical study to evaluate the safety and efficacy of Lenvatinib (E7080/MK-7902) with Pembrolizumab (MK-3475) in combination with transarterial chemoembolization (TACE) versus TACE in participants with incurable/non-metastatic hepatocellular carcinoma (LEAP-012)	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase 3 multinational, randomized, double-blind, placebo-controlled systemic gene delivery study to evaluate the safety and efficacy of SRP-9001 in subjects with Duchenne muscular dystrophy (EMBARK)	Hong Kong Children's Hospital
MEDPACE HONG KONG LTD	A phase 3 study of the hepcidin mimetic rusfertide (PTG-300) in patients with polycythemia vera	Queen Mary Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL)	Prince of Wales Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL)	Hong Kong United Oncology Centre
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL)	Princess Margaret Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Sibeprenlimab administered subcutaneously in subjects with Immunoglobulin A nephropathy	Princess Margaret Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Sibeprenlimab administered subcutaneously in subjects with Immunoglobulin A nephropathy	Prince of Wales Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Sibeprenlimab administered subcutaneously in subjects with Immunoglobulin A nephropathy	Yan Chai Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Sibeprenlimab administered subcutaneously in subjects with Immunoglobulin A nephropathy	Queen Mary Hospital
GEORGE CLINICAL ASIA PACIFIC LIMITED	A phase 3, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of Sibeprenlimab administered subcutaneously in subjects with Immunoglobulin A nephropathy	Tung Wah Hospital
JOHNSON & JOHNSON (HONG KONG) LTD.	A phase 3, open-label, randomized study of Amivantamab and Lazertinib in combination with Platinum-based chemotherapy compared with Platinum-based chemotherapy in patients with EGFR-mutated locally advanced or metastatic non-small cell lung cancer after Osimertinib failure (MARIPOSA-2)	Queen Mary Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, randomized, double-blind, active-control study of Pelabresib (CPI-0610) and Ruxolitinib vs. placebo and Ruxolitinib in JAKi treatment naive MF patients	Queen Mary Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, randomized, double-blind, active-control study of Pelabresib (CPI-0610) and Ruxolitinib vs. placebo and Ruxolitinib in JAKi treatment naive MF patients	Princess Margaret Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A phase 3, randomized, double-blind, active-control study of Pelabresib (CPI-0610) and Ruxolitinib vs. placebo and Ruxolitinib in JAKi treatment native MF patients	Prince of Wales Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Magrolimab versus placebo in combination with Venetoclax and Azacitidine in newly diagnosed, previously untreated patients with acute myeloid leukemia who are ineligible for intensive chemotherapy	Queen Mary Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Magrolimab versus placebo in combination with Venetoclax and Azacitidine in newly diagnosed, previously untreated patients with acute myeloid leukemia who are ineligible for intensive chemotherapy	Tuen Mun Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Magrolimab versus placebo in combination with Venetoclax and Azacitidine in newly diagnosed, previously untreated patients with acute myeloid leukemia who are ineligible for intensive chemotherapy	Princess Margaret Hospital
GILEAD SCIENCES HONG KONG LIMITED	A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Magrolimab versus placebo in combination with Venetoclax and Azacitidine in newly diagnosed, previously untreated patients with acute myeloid leukemia who are ineligible for intensive chemotherapy	Prince of Wales Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase 3, randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of KBP-5074, a mineralocorticoid receptor antagonist, in subjects with uncontrolled hypertension who have moderate or severe (Stage 3b/4) chronic kidney disease	Tung Wah Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase 3, randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of KBP-5074, a mineralocorticoid receptor antagonist, in subjects with uncontrolled hypertension who have moderate or severe (Stage 3b/4) chronic kidney disease	Queen Mary Hospital
SYNEOS HEALTH HONG KONG LIMITED	A phase 3, randomized, open-label study of Lorlatinib (PF-06463922) monotherapy versus Crizotinib monotherapy in the first-line treatment of patients with advanced ALK-positive non-small cell lung cancer	Queen Mary Hospital
SYNEOS HEALTH HONG KONG LIMITED	A phase 3, randomized, open-label study of Lorlatinib (PF-06463922) monotherapy versus Crizotinib monotherapy in the first-line treatment of patients with advanced ALK-positive non-small cell lung cancer	Tuen Mun Hospital
CMIC ASIA-PACIFIC (HONG KONG) LIMITED	A phase 3, randomized, placebo-controlled, double-blind study of Vimseltinib to assess the efficacy and safety in patients with tenosynovial giant cell tumor (MOTION)	Prince of Wales Hospital
JOHNSON & JOHNSON (HONG KONG) LTD.	A phase 4, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Guselkumab administered subcutaneously in bio-naïve participants with active psoriatic arthritis axial disease	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase I, open-label, multi-center study of KFA115 as a single agent and in combination with Pembrolizumab in patients with select advanced cancers	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase Ib/II open label dose confirmation, proof of concept study of Siremadlin in combination with Venetoclax plus Azacitidine in unfit adult AML participants who responded sub-optimally to first-line Venetoclax plus Azacitidine treatment and in participants with newly diagnosed unfit AML presenting with high-risk clinical features	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase Ib/II, multicenter, open-label study of EGF816 in combination with INC280 in adult patients with EGFR mutated non-small cell lung cancer	Queen Mary Hospital
Dr. LEUNG Y.H. Anskar	A phase II single-arm open-labeled study evaluating combination of Quizartinib and Omacetaxine mepesuccinate (QUIZOM) in newly diagnosed or relapsed/refractory AML carrying FLT3-ITD	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase II, open-label, non-controlled, intra-patient dose-escalation study to characterize the pharmacokinetics after oral administration of Eltrombopag in pediatric patients with refractory, relapsed or treatment naïve severe aplastic anemia or recurrent aplastic anemia	Prince of Wales Hospital
FORTREA HONG KONG LIMITED	A phase II, randomized, adaptive, open-label platform trial to evaluate efficacy and safety of multiple combination therapies in participants with chronic hepatitis B	Queen Mary Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
ROCHE HONG KONG LIMITED	A phase II/III, randomized, double blind, placebo controlled study of Tiragolumab in combination with Atezolizumab plus Pemetrexed and Carboplatin/Cisplatin versus Pembrolizumab plus Pemetrexed and Carboplatin/Cisplatin in patients with previously untreated advanced non-squamous non-small-cell lung cancer	Hong Kong United Oncology Centre
PPD DEVELOPMENT (HK) LIMITED	A phase IIb, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Astegolimab in patients with chronic obstructive pulmonary disease	Tuen Mun Hospital
SINOVAC BIOTECH (HONG KONG) LTD	A phase IIb, randomized, double-blinded trial to evaluate the immunogenicity and safety study of the booster dose using the high or medium dose of COVID-19 vaccine (vero cell), inactivated in healthy adults who have completed two doses of mRNA vaccine in Hong Kong	Gleneagles Hospital Hong Kong
SINOVAC BIOTECH (HONG KONG) LTD	A phase IIb, randomized, open-labeled trial to evaluate the immunogenicity and safety of one or two doses of booster vaccine with the COVID-19 vaccine (Vero Cell), inactivated, Omicron strain in adults above 18 years old who have completed two or three doses of mRNA vaccine or CoronaVac® in Hong Kong	Gleneagles Hospital Hong Kong
MERCK SHARP & DOHME (ASIA) LTD.	A phase III randomized double-blind study of Pembrolizumab plus best supportive care vs. placebo plus best supportive care as second-line therapy in Asian subjects with previously systemically treated advanced hepatocellular carcinoma (KEYNOTE-394)	Pamela Youde Nethersole Eastern Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A phase III randomized double-blind study of Pembrolizumab plus best supportive care vs. placebo plus best supportive care as second-line therapy in Asian subjects with previously systemically treated advanced hepatocellular carcinoma (KEYNOTE-394)	Princess Margaret Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase III randomized, controlled, open-label, multicenter, global study of Capmatinib in combination with Osimertinib versus platinum-Pemetrexed based doublet chemotherapy in patients with locally advanced or metastatic NSCLC harboring EGFR activating mutations who have progressed on prior 1st/2nd generation EGFR-TKI or Osimertinib therapy and whose tumors are T790M mutation negative and harbor MET amplification (GEOMETRY-E)	Hong Kong Integrated Oncology Centre
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase III randomized, controlled, open-label, multicenter, global study of Capmatinib in combination with Osimertinib versus Platinum-Pemetrexed based doublet chemotherapy in patients with locally advanced or metastatic NSCLC harboring EGFR activating mutations who have progressed on prior 1st/2nd generation EGFR-TKI or Osimertinib therapy and whose tumors are T790M mutation negative and harbor MET amplification (GEOMETRY-E)	Queen Mary Hospital



\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A phase III randomized, controlled, open-label, multicenter, global study of Capmatinib in combination with Osimertinib versus Platinum-Pemetrexed based doublet chemotherapy in patients with locally advanced or metastatic NSCLC harboring EGFR activating mutations who have progressed on prior 1st/2nd generation EGFR-TKI or Osimertinib therapy and whose tumors are T790M mutation negative and harbor MET amplification (GEOMETRY-E)	Queen Elizabeth Hospital
FORTREA HONG KONG LIMITED	A phase III, open label, randomised, 3-arm, multi-centre study of Savolitinib plus Durvalumab versus Sunitinib and Durvalumab monotherapy in participants with MET-driven, unresectable and locally advanced or metastatic papillary renal cell carcinoma(PRCC) (SAMETA)	Prince of Wales Hospital
BAYER HEALTHCARE LIMITED	A phase III, randomized, double-blind, controlled, multicenter study of intravenous PI3K inhibitor Copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma(iNHL) - CHRONOS-4	Prince of Wales Hospital
PPD DEVELOPMENT (HK) LIMITED	A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant Giredestrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer	Pamela Youde Nethersole Eastern Hospital
PPD DEVELOPMENT (HK) LIMITED	A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant Giredestrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer	UNIMED Medical Institute
ROCHE HONG KONG LIMITED	A phase IIIB, multicenter, randomized, visual assessor-masked study of the effectiveness and safety of a 36-week refill regimen for the port delivery system with Ranibizumab vs Aflibercept treat & extend in subjects with neovascular age-related macular degeneration (Diagrid)	Hong Kong Eye Hospital & CUHK Medical Centre
ROCHE HONG KONG LIMITED	A phase IIIB, multicenter, randomized, visual assessor-masked study of the effectiveness and safety of a 36-week refill regimen for the port delivery system with Ranibizumab VS. Aflibercept treat and extend in subjects with neovascular age-related macular degeneration (Diagrid)	Grantham Hospital
ROCHE HONG KONG LIMITED	A phase I-III, multicenter study evaluating the efficacy and safety of multiple therapies in cohorts of patients selected according to biomarker status, with locally advanced, unresectable, stage III non-small cell lung cancer	Queen Mary Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A pivotal phase 3 randomized, placebo-controlled clinical study to evaluate the efficacy and safety of the sGC stimulator Vericiguat/MK-1242 in adults with chronic heart failure with reduced ejection fraction	Grantham Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A pivotal phase 3 randomized, placebo-controlled clinical study to evaluate the efficacy and safety of the sGC stimulator Vericiguat/MK-1242 in adults with chronic heart failure with reduced ejection fraction	Queen Mary Hospital

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
MERCK SHARP & DOHME (ASIA) LTD.	A pivotal phase 3 randomized, placebo-controlled clinical study to evaluate the efficacy and safety of the sGC stimulator Vericiguat/MK-1242 in adults with chronic heart failure with reduced ejection fraction	Prince of Wales Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A pivotal phase 3 randomized, placebo-controlled clinical study to evaluate the efficacy and safety of the sGC stimulator Vericiguat/MK-1242 in adults with chronic heart failure with reduced ejection fraction	Princess Margaret Hospital
IQVIA RDS HONG KONG LIMITED	A pivotal phase 3, multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) who are receiving an angiotensin II receptor blocker (ARB)	Pok Oi Hospital
IQVIA RDS HONG KONG LIMITED	A pivotal phase 3, multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) who are receiving an angiotensin II receptor blocker (ARB)	Princess Margaret Hospital
IQVIA RDS HONG KONG LIMITED	A pivotal phase 3, multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) who are receiving an angiotensin II receptor blocker (ARB)	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A post-trial access roll-over study to allow access to Ribociclib (LEE011) for patients who are on Ribociclib treatment in Novartis-sponsored study	Queen Mary Hospital
Dr. KO K.Y. Jennifer	A prospective cohort on use of Letrozole in ectopic pregnancies treated with intralesional Methotrexate	Queen Mary Hospital
Dr. KARMAKAR Manoj Kumar	A prospective randomized comparison of the effects of Lidocaine and Levobupivacaine on block dynamics after a subparaneural popliteal sciatic nerve block	Prince of Wales Hospital
SYNEOS HEALTH HONG KONG LIMITED	A prospective, multi-centre study (B-Sure) to evaluate long-term durability of sustained virologic response in chronic hepatitis B participants with and without nucleos(t)ide therapy who have received and responded to GSK3228836 in a previous treatment study	Queen Mary Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A randomized open-label phase III study of Sacituzumab Govitecan versus treatment of physician's choice in subjects with Metastatic or locally advanced unresectable urothelial cancer	Hong Kong United Oncology Centre
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A randomized open-label phase III study of Sacituzumab Govitecan versus treatment of physician's choice in subjects with metastatic or locally advanced unresectable urothelial cancer	Prince of Wales Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A randomized open-label phase III study of Sacituzumab Govitecan versus treatment of physician's choice in subjects with Metastatic or locally advanced unresectable urothelial cancer	Tuen Mun Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A randomized phase 3 study of MRTX849 in combination with Cetuximab versus chemotherapy in patients with advanced colorectal cancer with KRAS G12C mutation with disease progression on or after standard first-line therapy	Hong Kong Integrated Oncology Centre
PRA HEALTH SCIENCES (HONG KONG) LIMITED	A randomized phase 3 study of MRTX849 versus Docetaxel in patients with previously treated non-small cell lung cancer with KRAS G12C Mutation	Prince of Wales Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED	A randomized phase 3 study of Nivolumab plus Ipilimumab or Nivolumab combined with Fluorouracil plus Cisplatin versus Fluorouracil plus Cisplatin in subjects with unresectable advanced, recurrent or metastatic previously untreated esophageal squamouscell carcinoma	Princess Margaret Hospital
PPD DEVELOPMENT (HK) LIMITED	A randomized, blinded, placebo-controlled, dose-ranging phase 1b study of the safety, pharmacokinetics, and antiviral activity of ABI-H3733 in subjects with chronic hepatitis B virus infection	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
GILEAD SCIENCES HONG KONG LIMITED	A randomized, double-blind evaluation of the pharmacokinetics, safety, and antiviral efficacy of Tenofovir Alafenamide (TAF) in children and adolescent subjects with chronic hepatitis B virus infection	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of Remibrutinib versus Teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label Remibrutinib	Prince of Wales Hospital
Dr. LAU M.C. Edith	A randomized, double-blind, international multicenter, parallel-controlled phase III clinical study to evaluate recombinant anti-RANKL human monoclonal antibody injection (HLX14) versus Denosumab injection (Prolia) in postmenopausal women with osteoporosis at high risk of fracture	Hong Kong Center for Clinical Research
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A randomized, double-blind, multicenter, placebo-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of oral BCX9930 monotherapy for the treatment of paroxysmal nocturnal hemoglobinuria	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A randomized, double-blind, parallel group, placebo-controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of lanalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRU-IUS-LN)	United Christian Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A randomized, double-blind, parallel group, placebo-controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of lanalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRU-IUS-LN)	Tuen Mun Hospital
MERCK SHARP & DOHME (ASIA) LTD.	A randomized, double-blind, placebo-controlled phase III clinical trial of Pembrolizumab (MK-3475) in combination with Cisplatin and 5-fluorouracil versus placebo in Fluorouracil as first-line treatment in subjects with advanced/metastatic esophagealcarcinoma (KEYNOTE-590)	Queen Mary Hospital
BAYER HEALTHCARE LIMITED	A randomized, double-blind, placebo-controlled, parallel-group, multicenter phase 3 study to investigate the efficacy and safety of Finerenone, in addition to standard of care, on the progression of kidney disease in patients with non-diabetic chronic kidney disease	Princess Margaret Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
RESEARCH PHARMACEUTICAL SERVICES, CLINICAL TRIALS CENTRE, THE UNIVERSITY OF HONG KONG	A randomized, double-blinded, cohort clinical study on evaluating the safety and immunogenicity of sequential immunization of two doses of BIBP inactivated COVID-19 vaccine (Omicron), WIBP inactivated COVID-19 vaccine (Omicron) or inactivated COVID-19 vaccine (prototype) in population aged 18 years and above who have completed two or three doses of inactivated or mRNA vaccine	Community Vaccination Centre (Sun Yat Sen Memorial Park Sports Centre)
RESEARCH PHARMACEUTICAL SERVICES, CLINICAL TRIALS CENTRE, THE UNIVERSITY OF HONG KONG	A randomized, double-blinded, placebo-controlled study to evaluate the safety and immunogenicity of DeINS1-2019-nCoV-RBD-OPT1 as booster vaccine for COVID-19 in healthy adults who have received 2 or 3 doses of BNT162b2	Phase 1 Clinical Trials Centre, The University of Hong Kong
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A randomized, open-label, multicenter, parallel-group study to evaluate the efficacy, safety, and tolerability of oral BCX9930 monotherapy for the treatment of paroxysmal nocturnal hemoglobinuria in subjects with inadequate response to C5 inhibitor therapy	Prince of Wales Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	A randomized, open-label, multicenter, parallel-group study to evaluate the efficacy, safety, and tolerability of oral BCX9930 monotherapy for the treatment of paroxysmal nocturnal hemoglobinuria in subjects with inadequate response to C5 inhibitor therapy	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
IQVIA RDS HONG KONG LIMITED	A randomized, open-label, phase 3 study of Abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone in patients with high risk, node positive, early stage, hormone receptor positive, human epidermal receptor 2 negative, breast cancer	Queen Mary Hospital
IQVIA RDS HONG KONG LIMITED	A randomized, open-label, phase 3 study of Abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone in patients with high risk, node positive, early stage, hormone receptor positive, human epidermal receptor 2 negative, breast cancer	Tuen Mun Hospital
GILEAD SCIENCES HONG KONG LIMITED	A randomized, open-label, phase 3 study of Sacituzumab Govitecan and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced, inoperable, or metastatic triple-negative breast cancer, whose tumors express PD-L1	Hong Kong Sanatorium & Hospital, Ltd.
GILEAD SCIENCES HONG KONG LIMITED	A randomized, open-label, phase 3 study of Sacituzumab Govitecan and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced, inoperable, or metastatic triple-negative breast cancer, whose tumors express PD-L1	Queen Mary Hospital
GILEAD SCIENCES HONG KONG LIMITED	A randomized, open-label, phase 3 study of Sacituzumab govitecan and Pembrolizumab versus treatment of physician's choice and Pembrolizumab in patients with previously untreated, locally advanced, inoperable, or metastatic triple-negative breast cancer, whose tumors express PD-L1	Prince of Wales Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
SYNEOS HEALTH HONG KONG LIMITED	A randomized, open-label, phase 3 trial of Dato-DXd plus Pembrolizumab vs Pembrolizumab alone in treatment-naïve subjects with advanced or metastatic PD-L1 high (TPS ≥ 50%) non-small cell lung cancer without actionable genomic alterations (Tropion-Lung08)	Queen Elizabeth Hospital
SYNEOS HEALTH HONG KONG LIMITED	A randomized, open-label, phase 3 trial of Dato-DXd plus Pembrolizumab vs Pembrolizumab alone in treatment-naïve subjects with advanced or metastatic PD-L1 high (TPS ≥ 50%) non-small cell lung cancer without actionable genomic alterations (Tropion-Lung08)	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	A single-arm, open-label, phase II study of Sabatolimab in combination with Azacitidine and Venetoclax in adult participants with high or very high risk myelodysplastic syndrome (MDS) as per IPSS-R criteria	Queen Mary Hospital
Dr. SINGH G.H. Harry	A study to explore allelic burden of genes under P1101 treatment in the patients who have previously participated in the P1101 ET study (SURPASS ET)	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	An adaptive, randomized, double-blind, dose exploration, parallel group, placebo-controlled, multicenter phase 2 trial to evaluate the efficacy, safety and tolerability of LNP023 in combination with standard-of-care with and without oral corticosteroids in adult patients with active lupus nephritis class III-IV, +/- V	Queen Mary Hospital
BAYER HEALTHCARE LIMITED	An open label, first-in-human study of BAY 2927088 in participants with advanced non-small cell lung cancer (NSCLC) harboring an EGFR and/or HER2 mutation	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
CMIC ASIA-PACIFIC (HONG KONG) LIMITED	An open label, randomised phase 2 study to evaluate the safety and efficacy of MTL-CEBPA administered in combination with Sorafenib or Sorafenib alone in TKI naïve participants with previously treated advanced hepatocellular carcinoma (HCC) and hepatitis B or hepatitis C virus (OUTREACH2)	Queen Mary Hospital
CMIC ASIA-PACIFIC (HONG KONG) LIMITED	An open label, randomised phase 2 study to evaluate the safety and efficacy of MTL-CEBPA administered in combination with Sorafenib or Sorafenib alone in TKI naïve participants with previously treated advanced hepatocellular carcinoma (HCC) and hepatitis B or hepatitis C virus (OUTREACH2)	Prince of Wales Hospital
Dr. HUNG F.N. Ivan	An open-label randomized controlled trial on Bismuth Subsalicylate/ N-acetyl-cysteine compared with Molnupiravir for hospitalized COVID-19 infection	Queen Mary Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	An open-label, multicenter phase 1b/2 study of Nanatinostat and Valganciclovir in patients with advanced Epstein-Barr virus-positive (EBV+) solid tumors and in combination with Pembrolizumab in patients with recurrent/metastatic nasopharyngeal carcinoma	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	An open-label, multicenter phase 1b/2 study of Nanatinostat and Valganciclovir in patients with advanced Epstein-Barr virus-positive (EBV+) solid tumors and in combination with Pembrolizumab in patients with recurrent/metastatic nasopharyngeal carcinoma	Queen Mary Hospital (including Phase 1 Clinical Trials Centre, The University of Hong Kong)
GILEAD SCIENCES HONG KONG LIMITED	An open-label, multicenter, phase 2 study of Sacituzumab Govitecan combinations in first-line treatment of patients with advanced or metastatic non-small-cell lung cancer (NSCLC) without actionable genomic alterations	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
GILEAD SCIENCES HONG KONG LIMITED	An open-label, multicenter, phase 2 study of Sacituzumab Govitecan combinations in first-line treatment of patients with advanced or metastatic non-small-cell lung cancer (NSCLC) without actionable genomic alterations	Queen Mary Hospital
GILEAD SCIENCES HONG KONG LIMITED	An open-label, multicenter, phase 2 study of Sacituzumab Govitecan combinations in first-line treatment of patients with advanced or metastatic non-small-cell lung cancer (NSCLC) without actionable genomic alterations	Queen Elizabeth Hospital
GILEAD SCIENCES HONG KONG LIMITED	An open-label, multicenter, phase 2 study of Sacituzumab Govitecan combinations in first-line treatment of patients with advanced or metastatic non-small-cell lung cancer (NSCLC) without actionable genomic alterations	Hong Kong United Oncology Centre
ASTRAZENECA HONG KONG LIMITED	An open-label, randomized, multicenter, phase 3 study to assess the efficacy and safety of Trastuzumab deruxtecan as first-line treatment of unresectable, locally advanced, or metastatic NSCLC harboring HER2 exon 19 or 20 mutations (DESTINY-Lung04)	Tuen Mun Hospital
ASTRAZENECA HONG KONG LIMITED	An open-label, randomized, multicenter, phase 3 study to assess the efficacy and safety of Trastuzumab deruxtecan as first-line treatment of unresectable, locally advanced, or metastatic NSCLC harboring HER2 exon 19 or 20 mutations (DESTINY-Lung04)	Queen Mary Hospital
ASTRAZENECA HONG KONG LIMITED	An open-label, randomized, multicenter, phase 3 study to assess the efficacy and safety of Trastuzumab deruxtecan as first-line treatment of unresectable, locally advanced, or metastatic NSCLC harboring HER2 exon 19 or 20 mutations (DESTINY-Lung04)	Hong Kong Integrated Oncology Centre
Dr. SO Ho	Anti-CD20 monoclonal antibodies versus cyclophosphamide for the treatment of anti-MDA5 positive dermatomyositis with interstitial lung disease: a randomized controlled trial	Prince of Wales Hospital
Dr. CHOW Kai-ming	Blood pressure control with thiazide diuretics in peritoneal dialysis patients with residual renal function	Prince of Wales Hospital
IQVIA RDS HONG KONG LIMITED	Brightline-1: A phase II/III, randomized, open-label, multi-center study of BI 907828 compared to Doxorubicin as first line treatment of patients with advanced dedifferentiated liposarcoma	Prince of Wales Hospital
FORTUNE PHARMACAL COMPANY LIMITED	Clinical bioequivalence study on two Sitagliptin tablet 100mg formulations	Phase I Clinical Trial Centre, The Chinese University of Hong Kong

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
Dr. CHAN Ping-kwan	Clinical trial on antibiotic-lock in Tenckhoff catheter for relapsing and repeat peritonitis	Alice Ho Miu Ling Nethersole Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	Combined phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of Filgotinib in the induction and maintenance of remission in subjects with moderately to severely active Crohn's disease	Queen Mary Hospital
PRA HEALTH SCIENCES (HONG KONG) LIMITED	Combined phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of Filgotinib in the induction and maintenance of remission in subjects with moderately to severely active Crohn's disease	Tuen Mun Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	daNIS-3: An open label, multi-centre, phase II platform study evaluating the efficacy and safety of NIS793 and other new investigational drug combinations with standard of care (SOC) anti-cancer therapy for the second line treatment of metastatic colorectal cancer (mCRC)	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	daNIS-3: An open label, multi-centre, phase II platform study evaluating the efficacy and safety of NIS793 and other new investigational drug combinations with standard of care (SOC) anti-cancer therapy for the second line treatment of metastatic colorectal cancer (mCRC)	Queen Mary Hospital
Dr. HUI S.C. David	Effect of long term Clarithromycin for prevention of exacerbations in non-cystic fibrosis bronchiectasis in Asian populations	Prince of Wales Hospital
Dr. SIM, PUI YIN JOYCELYN	Efficacy and safety of adding asciminib to the standard-of-care for post allogeneic hematopoietic stem-cell transplant (HSCT) maintenance in Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL) or blastic transformed CML (myeloid or lymphoid) (CML-BP)	Queen Mary Hospital
Dr. LEE Shui-shan	Efficacy of a meningococcal B vaccine against Neisseria gonorrhoeae infections among men who have sex with men: a randomised-controlled clinical trial	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	EPIK-B3: A phase III, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Alpelisib (BYL719) in combination with Nab-Paclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinases catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation	Queen Mary Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	EPIK-B3: A phase III, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Alpelisib (BYL719) in combination with Nab-Paclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation	Princess Margaret Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	EPIK-B3: A phase III, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Alpelisib (BYL719) in combination with Nab-Paclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	EPIK-B4: A phase II, multicenter, randomized, open-label, active-controlled study to assess the safety and efficacy of Dapagliflozin + Metformin XR versus Metformin during treatment with Alpelisib (BYL719) in combination with Fulvestrant in participants with HR+, HER2-, advanced breast cancer with a PIK3CA mutation following progression or/after endocrine-based therapy	Queen Elizabeth Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	Evaluation of safety and efficacy of the IBE-814 intravitreal implant in patients with diabetic macular oedema and macular oedema due to retinal vein occlusion	Prince of Wales Hospital
NOVOTECH CLINICAL RESEARCH (HONG KONG) LIMITED	Evaluation of safety and efficacy of the IBE-814 intravitreal implant in patients with diabetic macular oedema and macular oedema due to retinal vein occlusion	Grantham Hospital
Prof. MONTERO Barril David	Exercise-induced erythropoiesis: the mechanistic of angiotensin II	School of Public Health, The University of Hong Kong
Dr. KWOK Mei-kwun	Experimental triheptanoin treatment for a patient with pyruvate dehydrogenase complex deficiency	Hong Kong Children's Hospital
Dr. HUNG F.N. Ivan	FREEDOM COVID-19 anticoagulation strategy randomized trial	Queen Mary Hospital
SYNEOS HEALTH HONG KONG LIMITED	HERTHENA-Lung02: A phase 3, randomized, open-label study of Patritumab deruxtecan versus Platinum-based chemotherapy in metastatic or locally advanced epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after failure of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TK1) therapy	Queen Mary Hospital
Dr. YAN P.Y. Bryan	In-hospital initiation of Empagliflozin for the treatment of new-onset acute heart failure regardless of ejection fraction: A pilot study	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	KontrASt-02: A randomized, controlled, open label, phase III study evaluating the efficacy and safety of JDQ443 versus Docetaxel in previously treated subjects with locally advanced or metastatic KRAS G12C mutant non-small cell lung cancer	Hong Kong United Oncology Centre
Dr. WAN S.F. Rebecca	Letrozole in preventing recurrence of endometrioma following laparoscopic ovarian cystectomy	Princess Margaret Hospital
Dr. LAM Mei-ting	Letrozole in preventing recurrence of endometrioma following laparoscopic ovarian cystectomy	Queen Elizabeth Hospital / Kwong Wah Hospital
Dr. WONG Ka-yan	Letrozole in preventing recurrence of endometrioma following laparoscopic ovarian cystectomy	Pamela Youde Nethersole Eastern Hospital
Dr. YAM C.S. Jason	Low-level RED light-low concentration Atropine for myopia progression study (RED-LAMP)	CUHK Eye Centre, Hong Kong Eye Hospital



\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
Dr. LEUNG Kai-shun	Metformin as a neuroprotective therapy for glaucoma - a randomized controlled trial	The HKU Eye Centre / Grantham Hospital
Dr. KARMAKAR Manoj Kumar	Minimum effective local anaesthetic volume of 0.5% Levobupivacaine required for ultrasound guided superior trunk block	Prince of Wales Hospital
Dr. KARMAKAR Manoj Kumar	Minimum effective local anaesthetic volume of 1:1 mixture of 2% lidocaine with 5ug/ml of epinephrine and 0.5% levobupivacaine required for ultrasound guided selective trunk block: a dose finding study	Prince of Wales Hospital
Dr. CHAN C.W. Shirley	Open-label, non-inferiority randomized controlled trial of dose reduction of biologic therapy in axial spondyloarthritis (SpA)	Queen Mary Hospital
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED	Open-label, randomized trial of Nivolumab (BMS-936558) plus Pemetrexed/Platinum or Nivolumab plus Ipilimumab (BMS-734016) vs Pemetrexed plus Platinum in stage IV or recurrent non-small cell lung cancer (NSCLC) subjects with epidermal growth factor receptor (EGFR) mutation who failed 1L or 2L EGFR tyrosine kinase inhibitor therapy	Queen Elizabeth Hospital
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED	Open-label, randomized trial of Nivolumab (BMS-936558) plus Pemetrexed/Platinum or Nivolumab plus Ipilimumab (BMS-734016) vs Pemetrexed plus Platinum in stage IV or recurrent non-small cell lung cancer (NSCLC) subjects with epidermal growth factor receptor (EGFR) mutation who failed 1L or 2L EGFR tyrosine kinase inhibitor therapy	Queen Mary Hospital
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED	Open-label, randomized trial of Nivolumab (BMS-936558) plus Pemetrexed/Platinum or Nivolumab plus Ipilimumab (BMS-734016) vs Pemetrexed plus Platinum in stage IV or recurrent non-small cell lung cancer (NSCLC) subjects with epidermal growth factor receptor (EGFR) mutation who failed 1L or 2L EGFR tyrosine kinase inhibitor therapy	Prince of Wales Hospital
Dr. SINGH G.H. Harry	Phase 2 study to assess the safety and efficacy of Bomedemstat (IMG-7289) in combination with Ruxolitinib in patients with myelofibrosis	Queen Mary Hospital
PPD DEVELOPMENT (HK) LIMITED	Phase 2a, randomized, double-blind, placebo-controlled trial of PRV-3279 evaluation in lupus (PREVAIL-2)	Tuen Mun Hospital
PPD DEVELOPMENT (HK) LIMITED	Phase 2a, randomized, double-blind, placebo-controlled trial of PRV-3279 evaluation in lupus (PREVAIL-2)	Queen Mary Hospital
PPD DEVELOPMENT (HK) LIMITED	Phase 3, multicenter, randomized, double-masked, placebo-controlled study to evaluate the safety and efficacy of Tinlarebant in the treatment of Stargardt disease in adolescent subjects	Hong Kong Eye Hospital
Dr. IP Patrick	Prevalence, genetic risk factor and the use of intradermally-administered inactivated influenza vaccine with topical Imiquimod in influenza vaccine non-responsive children	Queen Mary Hospital
Dr. CHEUK K.L. Daniel	Quadruple immunotherapy for paediatric patients with relapsed or refractory neuroblastoma	Hong Kong Children's Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	Randomised, double-blind, placebo-controlled and parallel dose group trial to investigate efficacy and safety of multiple doses of oral BI 690517 over 14 weeks, alone and in combination with Empagliflozin, in patients with diabetic and non-diabetic chronic kidney disease	Queen Mary Hospital

\*This list includes those certificates issued via manual application since January 2022. For application for Certificate for Clinical Trial/Medicinal Test via mandatory Electronic Clinical Trial System (e-CTS) since 30 June 2022, please refer to the website at: <https://www.drugoffice.gov.hk/CTEnquiry>

<b>Certificate holder</b>	<b>Protocol title</b>	<b>Site(s)</b>
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	Randomised, double-blind, placebo-controlled and parallel dose group trial to investigate efficacy and safety of multiple doses of oral BI 690517 over 14 weeks, alone and in combination with Empagliflozin, in patients with diabetic and non-diabetic chronic kidney disease	Prince of Wales Hospital (including Phase I Clinical Trial Centre, The Chinese University of Hong Kong)
Dr. LU Evelyn Ruoyun	Randomized controlled trial comparing the efficacy and safety of lower dose mydriatics over standard dose mydriatics for pupil dilation in the retinopathy of prematurity examination	Queen Mary Hospital
SYNEOS HEALTH HONG KONG LIMITED	Randomized, double-blind, placebo-controlled phase 2 study to evaluate the efficacy and safety of Maralixibat in the treatment of subjects with biliary atresia after hepatoportoenterostomy	Queen Mary Hospital
IQVIA RDS HONG KONG LIMITED	Randomized, open-label, phase 3 study of Acapatamab vs standard of care in metastatic castration-resistant prostate cancer (CAPTIVATE)	Prince of Wales Hospital
PAREXEL INTERNATIONAL (HONG KONG) COMPANY LIMITED	SOAR, Interventional phase II single-arm study to assess efficacy and safety of Eltrombopag combined with Cyclosporine as first line therapy in adult patients with severe acquired aplastic anemia	Queen Mary Hospital
HONGKONG TIGERMED CO., LIMITED	The BURAN study of Buparlisib (AN2025) in combination with Paclitaxel compared to Paclitaxel alone, in patients with recurrent or metastatic head and neck squamous cell carcinoma	Queen Mary Hospital
Dr. LUI T.W. David	The effect of Simvastatin on bone density in postmenopausal women with type 2 diabetes: a double-blind, randomized, active-comparator (Ezetimibe) controlled clinical trial	Queen Mary Hospital
Dr. TAN C.B. Kathryn	The effect of Zoledronate on the prevention of pneumonia in hip fracture patients (Zoo-P): an open-label, pragmatic, randomised controlled trial	Caritas Medical Centre
Dr. TAN C.B. Kathryn	The effect of Zoledronate on the prevention of pneumonia in hip fracture patients (Zoo-P): an open-label, pragmatic, randomised controlled trial	United Christian Hospital
Dr. TAN C.B. Kathryn	The effect of Zoledronate on the prevention of pneumonia in hip fracture patients (Zoo-P): an open-label, pragmatic, randomised controlled trial	Prince of Wales Hospital
Dr. CHAN W.S. Agnes	The use of JAK-1/3 inhibitor (Tofacitinib) in Stevens-Johnson Syndrome and toxic epidermal necrolysis - a pilot study	Prince of Wales Hospital
ROCHE HONG KONG LIMITED	Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (TAPISTRY) phase II platform trial	Hong Kong Children's Hospital
Dr. Ong T.Y. Michael	Vitamin D as an intervention for improving quadriceps muscle strength in patients after anterior cruciate ligament reconstruction: a randomized, double-blinded, placebo-controlled clinical trial	Prince of Wales Hospital