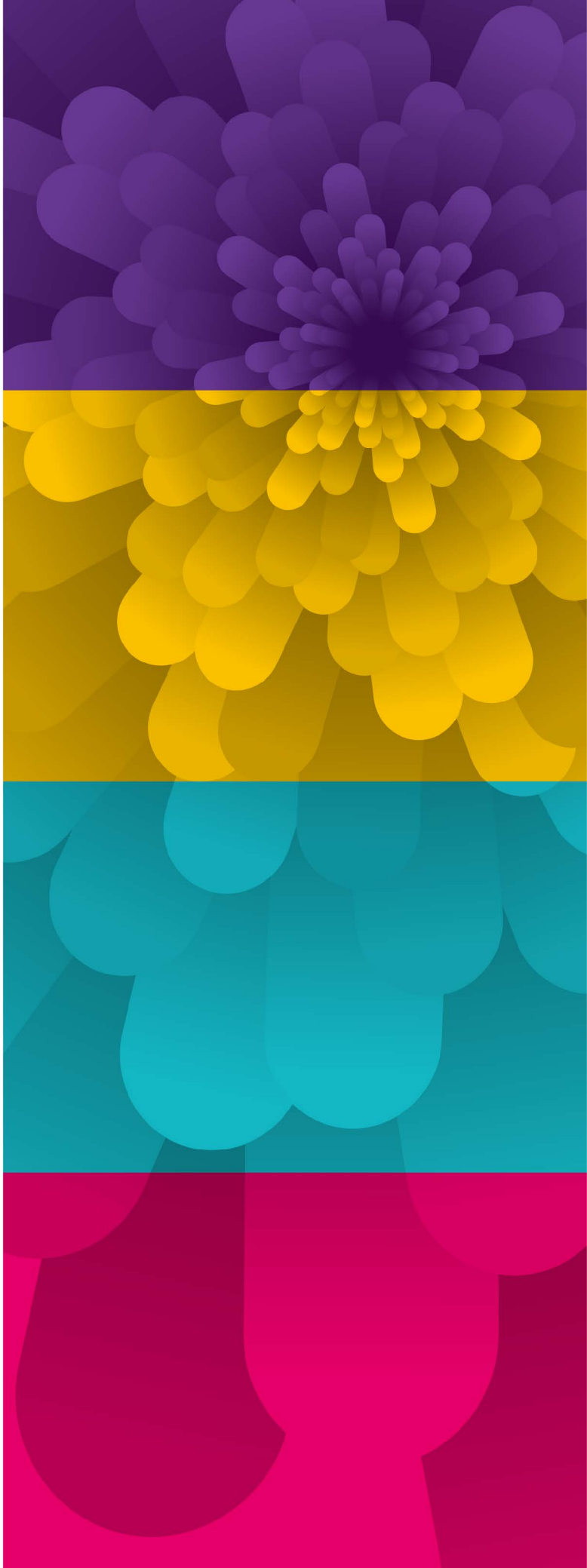
2013
2014

BIENNIAL REPORT

Clinical Trials Centre
The University of Hong Kong

Contents



Chief Director's Letter

The Years of Blossom

Clinical research is always evolving – in terms of science, operations, regulations and ethics. In October 2013, a new version of the Declaration of Helsinki was released, with special emphasis on advancing the knowledge of research personnel and research ethics committee members in clinical research ethics. The International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has also started the process of reviewing and revising its Guideline for Good Clinical Practice (GCP), in which the modern concepts on risk-based quality management are anticipated to be introduced. Without doubt, the international clinical research community, consisting of investigators/research personnel, academic/research institutions, regulatory authorities and the industry, is making good effort in advancing clinical research around the three pillars – subject protection, scientific validity and data integrity – which perfectly aligns with the mission of The University of Hong Kong Clinical Trials Centre (HKU-CTC). In line with the aforesaid international initiatives, we have been making substantial investment – in forms of human resources, finance and time – in upgrading our clinical research governance and quality management systems.

During 2013 and early-2014, we assisted the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) to establish a Governance Committee (GC) with representation from both HKU and HA HKW Cluster. A Phase 1 Clinical Trials Review Panel under HKU/HA HKW IRB and an independent Joint Scientific Committee (JSC) were established to strengthen the ethics and scientific oversight for phase 1 trials. A new, comprehensive standard operating procedure was also developed for HKU/HA HKW IRB and subsequently adopted by other research ethics committees in Hong Kong, contributing to harmonisation of the standards for clinical research ethics and scientific oversight in Hong Kong.

To ensure effective quality management during our rapid expansion, a new quality management system based on the concepts of total quality management (TQM) was designed during 2013 and launched in 2014. Under the leadership of HKU-CTC's senior management, the operational processes were reevaluated with the involvement of all staff members and by taking into consideration the relevant compliance requirements and stakeholders' expectations. Over 100 new or revised policies and standard operating procedures were issued under this new system, and an online learning management system (LMS) was developed to facilitate staff learning of the upgraded quality standards anytime, anywhere.

The investment in quality has been rewarding. This was demonstrated by the successful completion of the reevaluation by the China Food and Drug Administration (CFDA) in September 2013 and continuation of our accreditation in clinical trial. Leveraging on HKU-CTC's outstanding quality and management capabilities, HKU/QMH continued to be active in conducting clinical studies and the number of active studies reached a record high. By the end of 2014, a total of 409 clinical studies, including 311 industry-sponsored studies and 98 investigator-initiated studies, were ongoing or yet to be initiated under our coordination.

With the strong support by the Food and Health Bureau (FHB), the Hospital Authority (HA) and Queen Mary Hospital (QMH), the HKU Phase 1 Centre has come into operation in February 2014. The centre is a 24-bed, dedicated clinical research facility specifically designed for conducting phase 1, early phase and clinical pharmacology trials. Clinical studies in both patients and healthy volunteers have already started in the centre, and more studies in a wide range of therapeutic areas are under planning in the pipeline. Establishment of the HKU Phase 1 Centre greatly advanced our clinical research capability, strengthening HKU's leading position in international clinical research.

After 16 years of development, HKU-CTC has evolved into a full-service academic clinical research management organization, and we are willing to share our experience with the international clinical research community through knowledge exchange activities on a global scale. For instance, our proprietary training programme, PRACTISE®, was specifically designed for clinical investigators and study site personnel worldwide. Since its launch in 2012, it has become popular in Asia, Middle East and North Africa and with workshops delivered to hospitals, universities, research institutions and governmental organizations in Egypt, UAE, Vietnam, the Chinese mainland, Taiwan and Hong Kong. PRACTISE® *Core* – comprising the core modules of PRACTISE® – has also been recognised as a training program meeting the minimum criteria for ICH GCP investigator site personnel training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. To facilitate continuous education in human research ethics and GCP, we also entered into strategic collaboration in the Training and Resources in Research Ethics Evaluation Programme (TRREE), under which investigators and clinical research personnel can get access to the web-based learning platform free-of-charge.

Promoting human healthcare through clinical research must involve international effort. In this regard, we have been exploring strategic collaboration with clinical trial centres/ institutions worldwide, in anticipation of forming networks supporting multinational clinical studies and exchange of expertise and experience. In particular, expanding collaboration with centres in the Chinese mainland will be a focus, and unleashing the clinical research potential of HKU-Shenzhen Hospital will offer a golden opportunity in the years to come.

2013-14 were the years of blossom – with strengthened governance, enhanced quality management, improved capabilities, increased research activities, extended knowledge exchange activities and expanded opportunities of international collaboration. The whole HKU-CTC team is prepared to take any new challenge ahead, and will strive for a new height where success flourishes!

Professor Yu-lung Lau
Chief Director
Clinical Trials Centre
The University of Hong Kong

Committee of Management

HKU-CTC's Committee of Management (COM) now consists of 12 members including a Chairman; the Dean and Associate Dean (Research) of the HKU Medical Faculty; the Cluster Chief Executive of the HA HKW Cluster; the Chief Director and Managing Director of HKU-CTC; the Service Director (Pathology) of the HA HKW Cluster; the Director of the HKU School of Chinese Medicine; an expert in pharmacy, pharmacology or clinical pharmacology; two clinical investigator representatives; and a co-opted member. The COM holds regular meetings to formulate policies and discuss key issues related to the governance of clinical studies and to oversee the development and performance of HKU-CTC.

Professor Suet-yi Leung
Associate Dean (Research)
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Dr. Che-chung Luk
Cluster Chief Executive
Hong Kong West Cluster
Hospital Authority

Mr. Henry Yau
Managing Director
Clinical Trials Centre
The University of Hong Kong

Prof. Ching-wan Lam
Clinical Professor
Department of Pathology
The University of Hong Kong

Professor Karen Siu-ling Lam
Head
Department of Medicine
The University of Hong Kong
Chairman

Professor Gabriel Leung
Dean
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Professor Yu-lung Lau
Chief Director
Clinical Trials Centre
The University of Hong Kong

Prof. Sydney Tang
Clinical Professor
Department of Medicine
The University of Hong Kong

Prof. Bernard Cheung
Clinical Professor
Department of Medicine
The University of Hong Kong

Prof. Sidney Tam
Service Director (Pathology)
Hong Kong West Cluster
Hospital Authority

Prof. Li-xing Lao
Director
School of Chinese Medicine
The University of Hong Kong

Prof. Hung-fat Tse
Chair Professor
Department of Medicine
The University of Hong Kong

Management Framework

Expansion of HKU-CTC

Over the last 16 years, HKU-CTC has organically grown from a small academic research organisation staffed by three members to its current status as a comprehensive one-stop organisation with 40 members. In 2014, three new functional teams including the Phase 1 Centre Operations Team, Pharmacokinetics Laboratory Operations Team and Quality Assurance Team were established. This new structure, which comprises six functional teams, has further strengthened the clinical trial management capability of HKU-CTC, enabling us to attract more high quality clinical trials and particularly phase 1 clinical trials to HKU/Queen Mary Hospital (QMH).

Phase 1 Centre Operations Team (PIOT)

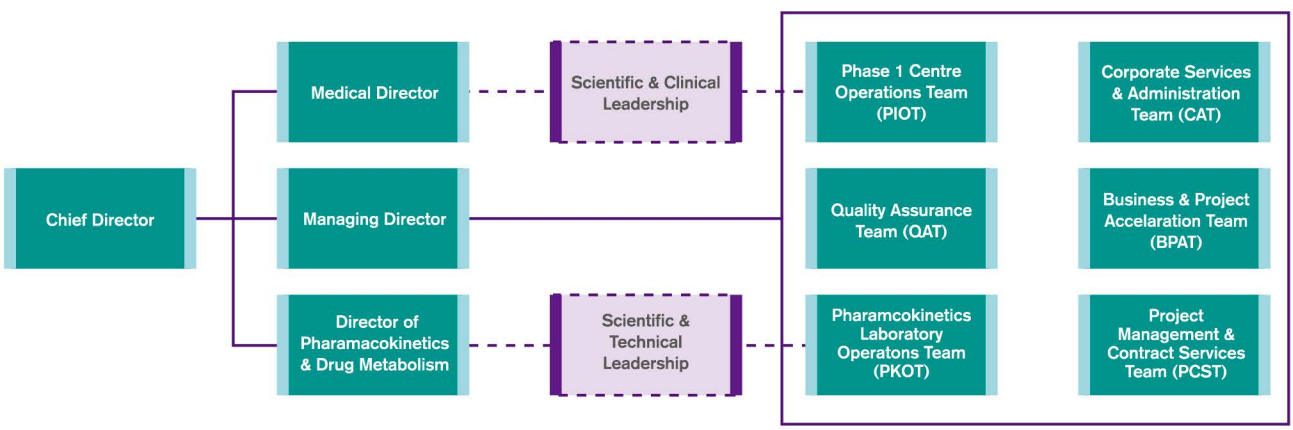
The HKU Phase 1 Clinical Trials Centre (Phase 1 Centre) was established in February 2014 to support the development of high quality drugs for various kinds of diseases. The Phase 1 Centre is a dedicated, state-of-the-art clinical research facility under the management of HKU-CTC and operated by its Phase 1 Centre Operations Team (PIOT). With this advanced establishment and robust management, more high impact phase 1, early phase and clinical pharmacology clinical trials will be conducted and more novel or affordable treatments will emerge to combat different diseases and to advance the well-being of Hong Kong citizens and the mankind.

Pharmacokinetics Laboratory Operations Team (PKOT)

In line with the development of the Phase 1 Centre, the HKU Pharmacokinetics Laboratory was also established. Equipped with advanced analytical instruments for separation and quantification of drugs and their metabolites, the HKU Pharmacokinetics Laboratory is capable of offering pharmaco-kinetic analysis services for small molecule drugs and peptide/protein drugs for local and overseas pharmaceutical companies and academic research institutions.

Quality Assurance Team (QAT)

Being an ethical and responsible clinical study management organisation that aims to attain sustainability and long-term success, HKU-CTC established a dedicated Quality Assurance Team (QAT) empowered by top management. The QAT adopts the concepts of total quality management (TQM) by involving all staff members, focusing on stakeholders' requirements and enforcing continuous improvement in quality.



From start to finish, CTC is here to help!

Have difficulties in conducting feasibility assessments?
Our strong investigator network in Hong Kong can help sponsors/CROs identify suitable investigators.

Encounter hurdles in study start-up?
Each clinical study conducted at HKU/QMH is closely followed by a designated project coordination executive who is expert in study start-up.

Need to make regulatory application but without a local representive?
CTC offers tailored, comprehensive contract research services, including regulatory applicaton, which suit your needs.

Lose your clinical reasearch coordinator?
CTC provides full CRC support, including subject recruitment, study drug management, specimen management, CRF completion and more.....

Seek solution for study drug disposal?
Our MedDrop™ service provides an easy solution for local drug disposal in full compliance with local regulations and with complete accountability records.

Require storage space for study document archiving?
Our ArchiveEasy™ service provides long-term document storage solution and assistance for document retrieval if necessary.

Mission

HKU-CTC aspires to enhance human healthcare by attracting and facilitating clinical research and safeguarding the core principles of subject protection, scientific validity and data integrity.

As a unique and innovative academic research organisation (ARO) at the forefront of clinical research enhancement, HKU-CTC offers one-stop clinical research solutions to investigators, clinical trial sponsors, contract research organisations (CROs) and other clinical research organisations. Our professional, high caliber and efficient team attract and facilitate clinical studies through comprehensive ethical considerations, leading scientific expertise, effective quality management and continuous education. HKU-CTC is a people-orientated organisation, in which everybody continues to strive for better performance and you can only expect nothing but excellence here!

Highlights of 2013-2014

2013

1st International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP 2013) & Open Day of the HKU Phase 1 Clinical Trials Centre

[Apr 2013]

Commencement of operation of HKU Phase I Clinical Trials Centre

[Feb 2014]

Site alliance partnership with PAREXEL

[May 2014]

Launch of CREDIT Solutions™, a clinical research electronic data management service

[Apr 2013]

Collaboration in clinical research and training with Hong Kong Urological Association

[Feb 2014]

Collaboration on TRREE, an online platform for training and resources in research ethics evaluation

[Mar 2014]

Registration of PRACTISE® *Core* with TransCelerate

[Mar 2014]

Issuance of the new HKU/HA HKW IRB SOP

[Apr 2014]

Visit by the Food and Health Bureau of Hong Kong on 24 September 2014

Mr. Richard Yuen, the Permanent Secretary for Food and Health (Health), visited the HKU Phase 1 Clinical Trials Centre on 24 September 2014, and met with the Senior Management and Operations Team. Mr. Yuen was briefed on the management and operation of the HKU Phase 1 Centre and expressed his support for the Phase 1 Centre and its success in the years to come. [Sep 2014]

Launch of the new HKU-CTC website

[Nov 2014]

2014

Public Education

As a leading academic clinical research organisation, HKU-CTC is enthusiastic in its efforts to raise public awareness of clinical research. Since September 2014, HKU-CTC has invited individual investigators of different specialties to write articles about the latest development of therapies and clinical research in a monthly health magazine. Four articles had been issued by the end of 2014.

Leaflets introducing clinical research and phase 1 clinical trials were also produced for distribution to the public. [Sep 2014]

Launch of the electronic learning management system (LMS)

[Oct 2014]

Performance Overview

Industry-sponsored Clinical Studies

The numbers of newly contracted industry-sponsored studies in 2013 and 2014 steadily increased to 69 and 74, respectively. By the end of 2014, the cumulative number of contracted industry-sponsored studies amounted to 824, 227 of which were on-going.

	2014	2013	2012
Contracted Industry-sponsored Clinical Studies			
New Studies	74	69	57
Cumulative Studies	824	750	681
Active Studies	227	204	213
Distribution by Research Areas of New Studies (Top 5)			
1	Oncology (34%)	Oncology (30%)	Oncology (37%)
2	Cardiovasculology (19%)	Cardiovasculology (16%)	Haematology (18%)
3	GI & Hepatology (9%)	Haematology (12%)	Neurology (9%)
4	Neurology (7%)	Immunology & Allergy (9%)	GI & Hepatology (7%)
5	Haematology (4%)	Endocrinology (7%)	Cardiovasculology (6%)
Distribution by Study Phases of New Studies			
I	4%	6%	5%
II	20%	17%	25%
III	54%	52%	59%
IV	6%	10%	0%
Others	16%	15%	11%

Investigator-initiated Clinical Studies

HKU-CTC has been delegated to oversee investigator-initiated clinical studies (IISs) since November 2009. By the end of 2014, HKU-CTC had supported 83 IISs, 66 of which were active.

	2014	2013	2012
Confirmed Investigator-initiated Clinical Studies			
New Studies	33	15	10
Cumulative Studies	83	50	35
Active Studies	66	39	30

Collaborative Trial Sponsors

AB Science	Boehringer Ingelheim	Ipsen	Otsuka
Abbott	Bolton Medical	Isis	Penumbra
AbbVie	Boston Scientific	Janssen	Pfizer
ABIVAX	BrainsGate	Johnson & Johnson	Pharmacia
Access Business Group	Bristol-Myers Squibb	Keryx	Pharmascience
Achillion	Bukwang	Kinex	Pharmasset
Actelion	Celgene	Kowa	PowderMed
Advanced Herbal Therapeutics	Cell Tech	Kyowa Hakko Kirin	Progen
Alcon	CELLTRION	La Jolla	Puma Biotechnology
Alexion	Celsion	Laboratoire HRA Pharma	QuantaNova
Algeta	CK Life Sciences	Lee's Pharmaceutical	Retina Implant
Allergan	Clovis	LEO	Rigel
Altana	Codman	LG Life Sciences	Roche
A Menarini	Cook	Light Sciences	Sanofi
Amgen	Critical Biologics	Luitpold	Schering Plough
Anaborex	Daiichi Sankyo	Lundbeck	SciClone
Anthera	DePuy	Medigen	Scios
AO Foundation	Diagram BV	MedImmune	Servier
AO Spine	EBR System	Medivation	SFJ
ApoPharma	Eisai	Medtronic	St. Francis
ARIAD	Eli Lilly	Medwaves	St. Jude Medical
Arrow	Ellipse	Merck Serono	Synthes
Arrowhead	EndoStim	Merck Sharp & Dohme	Taiho
Artisan	EnteroMedics	Millennium	Takeda
Astellas	EVER Neuro Pharma	Miramar Labs	Task Force for Global Health
AstraZeneca	Everpride	Morphotek	Tekmira
Aurinia	FeRx	Mundipharma	Theranostics (Xanthus)
Aventis	FibroGen	Nanogen	Theravance
BARRX	Fujirebio	NanoPass	Thrombosis Research Institute
Baxter	Galderma	NephroGenex	Triangle
Bayer	Genentech	NIDEK	Trius
BCIRG	Genzyme	Novartis	TTY
Bio-Cancer	Gilead	Novira	Tularik
Biocompatibles	GlaxoSmithKline	Novo Nordisk	Tyco
BioCryst	Grunenthal	Nycomed	UCB
Biogen Idec	Guidant	OrbusNeich	Vigconic
Biomeasure	Human Genome Sciences	Organon	VitaGreen
Biosensors	Idenix	Orient EuroPharma	Wealthy Creative
Bioteque	ImClone	Orygen	Wyeth
Biotronik	Inovio	OSI	Zila

Industry-sponsored Clinical Studies Contracted in 2013 and 2014

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Cardiovasculology	Acute Coronary Syndrome	III	Dr. David CW Siu	Medicine, QMH
Cardiovasculology	Acute Coronary Syndrome	IV	Professor Stephen WL Lee	Medicine, QMH
Cardiovasculology	Arrhythmias	O	Dr. Carmen WS Chan	Medicine, QMH
Cardiovasculology	Atrial Fibrillation	O	Professor HF Tse	Medicine, QMH
Cardiovasculology	Atrial Fibrillation	III	Professor Stephen WL Lee	Medicine, QMH
Cardiovasculology	Bleeding	III	Dr. David CW Siu	Medicine, QMH
Cardiovasculology	Bleeding	O	Professor Stephen WL Lee	Medicine, QMH
Cardiovasculology	Cardiac Arrhythmia	IV	Professor HF Tse	Medicine, QMH
Cardiovasculology	Cardiovascular Disease	III	Dr. Michael PH Chan	Medicine, QMH
Cardiovasculology	Cardiovascular Events	III	Professor HF Tse	Medicine, QMH
Cardiovasculology	Cardiovascular Events	O	Professor HF Tse	Medicine, QMH
Cardiovasculology	Cardiovascular Events	III	Professor Stephen WL Lee	Medicine, QMH
Cardiovasculology	Diabetes Mellitus	III	Professor Kathryn CB Tan Dr. KH Yiu	Medicine, QMH Medicine, QMH
Cardiovasculology	Dyslipidemia	O	Dr. David CW Siu	Medicine, QMH
Cardiovasculology	Dyslipidemia	III	Dr. David CW Siu	Medicine, QMH
Cardiovasculology	Heart Failure	O	Professor HF Tse	Medicine, QMH
Cardiovasculology	Heart Failure	III	Professor HF Tse	Medicine, QMH
Cardiovasculology	Hypertension	III	Dr. David CW Siu	Medicine, QMH
Cardiovasculology	Pacing	III	Dr. Carmen WS Chan	Medicine, QMH
Cardiovasculology	Pacing	III	Professor HF Tse	Medicine, QMH
Cardiovasculology	Stroke	III	Dr. Richard SK Chang	Medicine, QMH
Cardiovasculology	Tachycardia	O	Dr. Carmen WS Chan	Medicine, QMH
Cardiovasculology	Tachycardia	O	Professor HF Tse	Medicine, QMH
Cardiovasculology	Vascular Intervention	O	Professor Stephen WL Lee	Medicine, QMH
Cardiovasculology	Ventricular Arrhythmias	O	Professor HF Tse	Medicine, QMH
Dermatology	Androgenetic Alopecia	O	Dr. Johnny CY Chan	Medicine, QMH
Dermatology	Facial Skin Rejuvenation	O	Dr. Johnny CY Chan	Medicine, QMH
Endocrinology	Diabetes Mellitus	III	Professor Kathryn CB Tan	Medicine, QMH
Endocrinology	Hyperlipidemia	III	Dr. David CW Siu Dr. Gabriel WK Yip	Medicine, QMH Medicine, GRH*
Endocrinology	Diabetes Mellitus	III	Professor HF Tse Dr. WS Chow	Medicine, QMH Medicine, QMH
Endocrinology	Diabetes Mellitus	III	Professor Sydney CW Tang	Medicine, QMH
Endocrinology	Diabetes Mellitus	III	Professor Kathryn CB Tan Professor Sydney CW Tang	Medicine, QMH Medicine, QMH
Endocrinology	Diabetes Mellitus	II	Dr. WS Chow	Medicine, QMH
Endocrinology	Diabetes Mellitus	II	Dr. WS Chow	Medicine, QMH
Esophageal and Gastrointestinology	Gastroesophageal Reflux Disease	O	Professor Simon YK Law	Surgery, QMH
Gastroenterology & Hepatology	Hepatitis B	I	Professor CL Lai	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine, QMH

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Gastroenterology & Hepatology	Hepatitis B	II	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	I	Dr. Tommy T Cheung	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor CL Lai	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor CL Lai	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor MF Yuen	Medicine, QMH
Haematology	Advanced Classical Hodgkin Lymphoma	III	Professor YL Kwong	Medicine, QMH
Haematology	Aplastic Anemia	O	Professor Anskar YH Leung	Medicine, QMH
Haematology	Chronic Myeloid Leukemia	III	Professor YL Kwong	Medicine, QMH
Haematology	Diffuse large B-cell lymphoma	III	Professor YL Kwong	Medicine, QMH
Haematology	Follicular Non-Hodgkin's Lymphoma	III	Professor YL Kwong	Medicine, QMH
Haematology	Hemophilia A	II	Professor YL Kwong	Medicine, QMH
Haematology	Lymphoma	I	Professor YL Kwong	Medicine, QMH
Haematology	Multiple Myeloma	III	Professor CS Chim	Medicine, QMH
Haematology	Myelodysplastic Syndromes	III	Professor YL Kwong	Medicine, QMH
Haematology	Myeloproliferative Neoplasms	O	Professor YL Kwong	Medicine, QMH
Haematology	Non-Hodgkin's Lymphoma Multiple Myeloma	O	Professor Anskar YH Leung	Medicine, QMH
Immunology & Allergy	Ankylosing Spondylitis	II	Professor CS Lau	Medicine, QMH
Immunology & Allergy	Systemic Lupus Erythematosus	IV	Professor CS Lau	Medicine, QMH
Immunology & Allergy	Rheumatoid Arthritis	IV	Professor CS Lau	Medicine, QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine, QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine, QMH
Immunology & Allergy	Lupus Nephritis	III	Professor TM Chan Dr. Temy MY Mok	Medicine, QMH Medicine, QMH
Immunology & Allergy	Lupus Nephritis	II	Professor TM Chan Dr. Temy MY Mok	Medicine, QMH Medicine, QMH
Immunology & Allergy	Systemic Lupus Erythematosus	III	Dr. Temy MY Mok	Medicine, QMH
Infectious Disease	Clostridium Diffcile Infection	O	Dr. Ivan FN Hung	Medicine, QMH
Infectious Disease	Herpes Zoster	III	Professor Albert KW Lie	Medicine, QMH
Nephrology	IgA Nephropathy	II	Professor TM Chan	Medicine, QMH
Nephrology	Lupus Nephritis	II	Professor TM Chan	Medicine, QMH
Nephrology	Nephropathy	II	Professor Sydney CW Tang	Medicine, QMH
Neurology	Alzheimer's Disease	III	Professor LW Chu	Medicine, QMH
Neurology	Alzheimer's Disease	O	Professor LW Chu	Medicine, QMH
Neurology	Multiple Sclerosis	O	Dr. KH Chan	Medicine, QMH

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Neurology	Relapsing Neuromyelitis Optica	III	Dr. KH Chan	Medicine, QMH
Neurology	Relapsing Neuromyelitis Optica	III	Dr. KH Chan	Medicine, QMH
Neurology	Stroke	III	Professor Raymond TF Cheung	Medicine, QMH
Neurosurgery	Traumatic Brain Injury	IV	Dr. Gilberto KK Leung	Surgery, QMH
Obstetrics & Gynaecology	Human Papillomavirus Infection	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology, QMH
Obstetrics & Gynaecology	Preeclampsia	IV	Dr. Thomas KT Li	Obstetrics & Gynaecology, QMH
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery, QMH
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery, QMH
Oncology	Breast Cancer	II	Dr. Ava Kwong	Surgery, QMH
Oncology	Breast Cancer	II	Dr. Janice WH Tsang	Clinical Oncology, QMH
Oncology	Breast Cancer	III	Dr. Janice WH Tsang	Clinical Oncology, QMH
Oncology	Breast Cancer	III	Dr. Ava Kwong Dr. Janice WH Tsang Dr. Thomas CC Yau	Surgery, QMH Clinical Oncology, QMH Medicine, QMH
Oncology	Breast Cancer	II	Dr. Janice WH Tsang Dr. Thomas CC Yau	Clinical Oncology, QMH Medicine, QMH
Oncology	Colorectal Cancer	III	Dr. KO Lam	Clinical Oncology, QMH
Oncology	Colorectal Cancer	III	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Gastric Cancer	IV	Professor KM Chu	Surgery, QMH
Oncology	Gastric Cancer	IV	Professor KM Chu	Surgery, QMH
Oncology	Gastroesophageal Cancer	II	Professor Dora LW Kwong	Clinical Oncology, QMH
Oncology	Head & Neck Cancer	III	Professor Dora LW Kwong	Clinical Oncology, QMH
Oncology	Liver Cancer	II	Dr. Thomas CC Yau	Medicine, QMH
Oncology	Liver Cancer	II	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery, QMH
Oncology	Lung Cancer	III	Dr. David CL Lam	Medicine, QMH
Oncology	Lung Cancer	II	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	II	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine, QMH
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	III	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr. James CM Ho Dr. Victor HF Lee	Medicine, QMH Clinical Oncology, QMH

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Oncology	Lung Cancer	III	Dr. James CM Ho Dr. Victor HF Lee	Medicine, QMH Clinical Oncology, QMH
Oncology	Lung Cancer	III	Dr. David CL Lam Dr. Victor HF Lee	Medicine, QMH Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr. James CM Ho Dr. Victor HF Lee	Medicine, QMH Clinical Oncology, QMH
Oncology	Lung Cancer	III	Dr. James CM Ho Dr. Victor HF Lee	Medicine, QMH Clinical Oncology, QMH
Oncology	Pancreatic Cancer	III	Dr. Thomas CC Yau	Medicine, QMH
Oncology	Pancreatic Cancer	III	Dr. Thomas CC Yau	Medicine, QMH
Oncology	Pancreatic Cancer	III	Dr. Victor HF Lee	Clinical Oncology, QMH
Oncology	Prostate Cancer	III	Dr. James HL Tsu	Surgery, QMH
Oncology	Prostate Cancer	III	Dr. Philip WK Kwong	Clinical Oncology, QMH
Oncology	Prostate Cancer	III	Dr. WK Ma	Surgery, QMH
Oncology	Solid Tumours	I	Professor Ronnie TP Poon	Surgery, QMH
Ophthalmology	Diabetic Macular Edema	III	Dr. Ian YH Wong	Ophthalmology, QMH
Ophthalmology	Polypoidal Choroidal Vasculopathy	IV	Dr. Ian YH Wong	Ophthalmology, QMH
Ophthalmology	Polypoidal Choroidal Vasculopathy	III	Dr. Ian YH Wong	Ophthalmology, QMH
Ophthalmology	Age-related Macular Degeneration	O	Dr. Ian YH Wong	Ophthalmology, QMH
Orthopaedics & Traumatology	Non-Inflammatory Degenerative Joint Disease	IV	Professor Peter KY Chiu	Orthopaedics & Traumatology, QMH
Orthopaedics & Traumatology	Spinal Deformity	O	Professor Kenneth MC Cheung	Orthopaedics & Traumatology, QMH
Paediatrics	Spinal Muscular Atrophy	III	Dr. Sophelia HS Chan	Paediatrics & Adolescent Medicine, QMH
Paediatrics	Systemic Juvenile Idiopathic Arthritis	III	Professor YL Lau	Paediatrics & Adolescent Medicine, QMH
Pain Management	Chronic Pain	IV	Dr. CW Cheung Dr. Temy MY Mok	Anaesthesiology, QMH Medicine, QMH
Psychiatry	Generalized Anxiety Disorder	III	Dr. KF Chung	Psychiatry, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	II	Dr. David CL Lam	Medicine, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	II	Dr. David CL Lam	Medicine, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr. David CL Lam	Medicine, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr. David CL Lam	Medicine, QMH
Respiratory Medicine	Non-cystic Fibrosis Bronchiectasis	III	Dr. David CL Lam	Medicine, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr. David CL Lam	Medicine, QMH
Urology	Benign Prostatic Hyperplasia	III	Professor MK Yiu	Surgery, QMH
Vascular Surgery	Abdominal Aorta	O	Professor Stephen WK Cheng	Surgery, QMH

 # O: Studies not classified as Phase I, II, III or IV studies, such as medical device and observational studies.

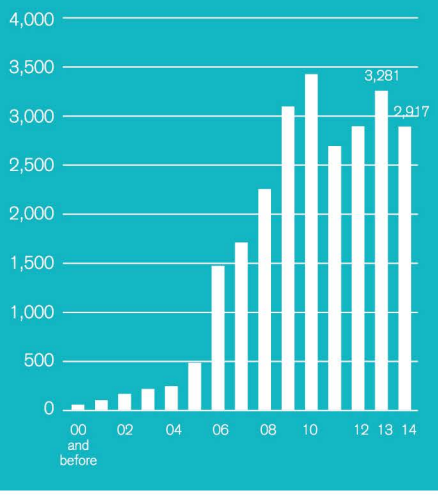
*** Study Site: QMH: Queen Mary Hospital; GRH: Grantham Hospital**

Study Site Project Management

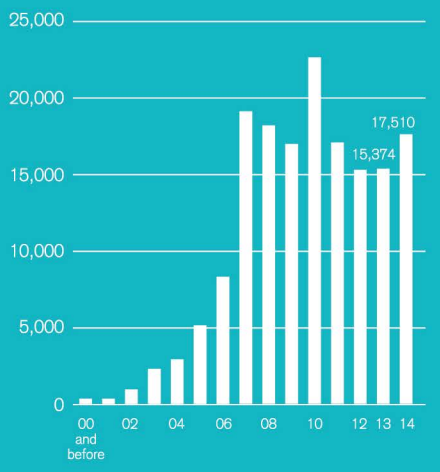
In 2013 and 2014, HKU-CTC's Study Site Project Management Unit (SPMU) continued to facilitate study site logistical arrangements and coordinate communication between investigators, sponsors, ethics committees and various internal/external parties. At the end of 2014, the SPMU was coordinating 227 industry-sponsored clinical studies. During this 2-year period, 157 initial applications and 39,082 subsequent submissions were compiled and submitted to ethics committes.

Initial Submissions

Subsequent Submissions (Excluding SAE reports)



SAE Reports

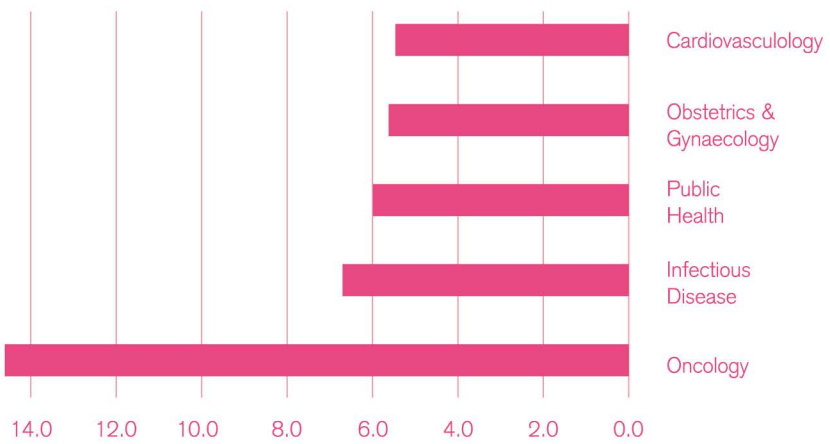


HKU Clinical Trials Registry (HKUCTR)

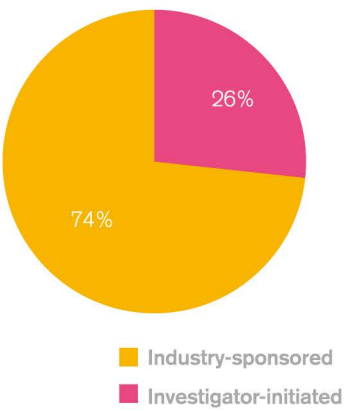
Since 2005, the HKU Clinical Trials Registry has attracted investigators and the industry to register their clinical studies, with 1,846 studies registered by the end of 2014. Of the studies registered, oncology and infectious diseases represented the top research areas, accounting for 15.4% and 7.1% of the total number, respectively.

HKUCTR
HKU CLINICAL TRIALS REGISTRY

%Distribution of Clinical Studies by Disease Areas by the End of 2014 (Top 5)



Number of Registered Clinical Studies by the End of 2014



Being professional, reliable and helpful is CTC's code of conduct!

Our 900+ clinical trial projects have been benefited from CTC's tailored clinical trial solutions over the last 16 years!

Clinical Research Coordinator (CRC) Supports

HKU-CTC's clinical research coordinators (CRCs) have continued to offer professional study coordination support to investigators and study sites. At the end of 2014, our CRCs were coordinating 16 clinical studies across three public hospitals in Hong Kong, including Queen Mary Hospital, Grantham Hospital and Yan Chai Hospital.

CRISP Clinical Research Investigative Site Professionals
• Study Coordinator Service
Clinical Trials Centre, The University of Hong Kong

Study Drug Management Services

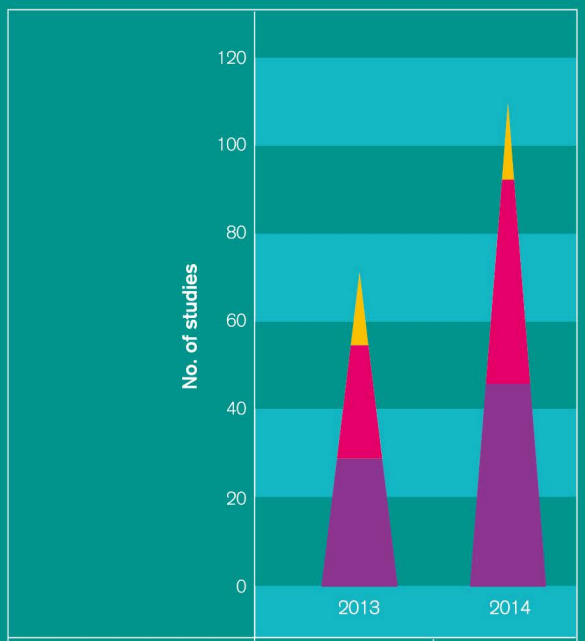
HKU-CTC's Site Services Unit (SSU) has continued to collaborate closely with the Department of Pharmacy at QMH in offering drug management services – including receipt, storage, processing, dispensing and accountability – to support the clinical drug trials conducted at HKU/QMH.

During 2013 and 2014, SSU and QMH Pharmacy together managed 112 new studies, a sharp increase over previous years.

MedDrop

HKU-CTC's drug disposal service MedDrop™ has been well recognised by the industry since its launch in 2012. MedDrop™ offers a secure, one-stop solution to sponsors for drug disposal, with complete disposal records in compliance with local regulatory requirements and Good Clinical Practice (GCP).

MedDrop™ services support study sites anywhere in Hong Kong. Over the past 2 years, SSU has already managed 24 disposal applications for local and international pharmaceutical companies.



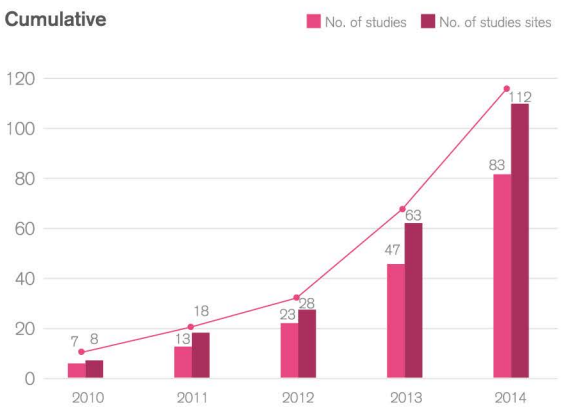
	2013	2014
Study-specific request laboratory forms & labels	14	20
Specimen storage	27	44
Specimen handling, packaging & coordination	28	46

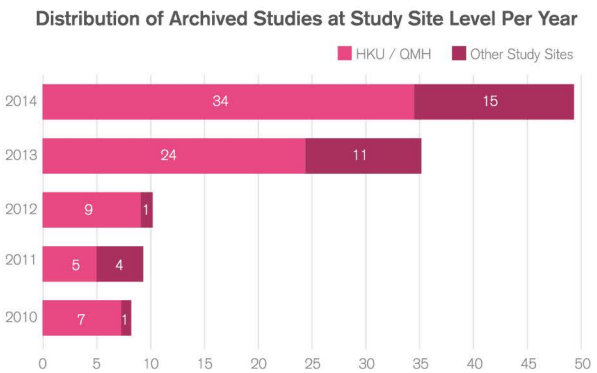
Specimen Management

HKU-CTC's SSU helps coordinate specimen logistics and facilitate communication between sponsors, study sites and clinical laboratories, assuring proper management and processing of all specimens in accordance with study protocol requirements. In 2014, the number of studies requiring the SSU's specimen management service surged upward by 59% to 110.

ArchiveEasy™

Long-term study document archiving has never been easy for study sites in Hong Kong due to the limited storage capacity of hospitals. After five years of development, our study site document archiving service – ArchiveEasy™ – has proved to be a popular service welcomed by the industry and study sites, as evidenced by the cumulative 83 archived studies conducted at 112 study sites in Hong Kong by the end of 2014.





Contract Research Services

HKU-CTC's Project Management & Contract Services Team (PCST) offers a variety of comprehensive contract research services to sponsors and investigators, ranging from protocol development to regulatory affairs, study project management, study site monitoring, study data management, medical statistics and final clinical study report development. In the past two years, our clinical research services covered a total of 26 local and international clinical studies.

Since 2013, HKU-CTC's PCST has been heavily engaged in supporting international, multicentre investigator-initiated studies (IISs) by providing contract research services to investigators or local and overseas collaborative partners. Nine of the 26 clinical studies covered were IISs.

Data Management

In recent years, HKU-CTC has been striving to offer full electronic data management solutions to investigators and research organisations. HKU-CTC's Data Management Team, which includes data managers, data management specialists and IT specialists, is able to provide professional IT support and ensure data quality using its in-house data validation programme, document tracking system and automated error correction system. Developed and launched in April 2013, CREDIT Solutions™ (Clinical Research Electronic Data and Information Technology Solutions) offers full data management support for both local and multinational, multicentre clinical studies. During 2013-2014, our electronic data management services supported eight studies conducted in Hong Kong, the Chinese mainland and Europe.

Contract research services performed

Regulatory Affairs

HKU-CTC is a holder of a Wholesale Poison Licence and is eligible to apply for Clinical Trial Certificates required for importing study drugs and conducting clinical drug trials in Hong Kong. Our experience and professional regulatory specialists are able to recommend the best regulatory strategies and provide a full range of regulatory affair services, including initial and continuing applications; progress and final reporting; and the submission of safety reports to the local regulatory authority.

During 2013 and 2014, we provided regulatory affairs services for 18 studies. In 2014, we began to extend our regulatory affairs services to pharmaceutical companies and contract research organisations without full representation in Hong Kong, allowing clinical studies to materialise in full compliance with local regulations.

or planned during 2013-2014

HKU Phase 1 Clinical Trials Centre

The HKU Phase 1 Clinical Trials Centre (Phase 1 Centre) is a purpose-built, 24-bed clinical research facility specifically designed for conducting phase 1, early phase and clinical pharmacology trials. Backed by its dedicated medical and clinical operations teams and with the full support of HKU-CTC and QMH, the Phase 1 Centre is capable of conducting a wide range of clinical trials such as first-in-human (FIH) trials, proof-of-concept (POC) trials, cardiac safety (QT/TQT) trials and bioavailability/bioequivalence (BA/BE) trials.

Medical and Clinical Operations Team

The medical and clinical operations team comprise dedicated investigators, research nurses, pharmacists, dispensers and phlebotomists.

The Phase 1 Centre is under the management of HKU-CTC. Clinical research coordinators (CRCs) in HKU-CTC's Site Services Unit (SSU) are able to support the activities of the Phase 1 Centre, including blood-taking, specimen handling and data entry.

HKU-CTC is also maintaining a pool of part-time nurses and healthcare personnel to offer back-up support to the Phase 1 Centre.

Emergency Support from Queen Mary Hospital Intensive Care Unit

Subject protection is the core principle of ICH GCP. Our Phase 1 Centre considers subject safety a priority for every clinical study. In addition to our purpose-built resuscitation facility and emergency handling plan, the Phase 1 Centre is supported by the Central Resuscitation Team of QMH.

In July 2014, the first emergency drill was performed at the Phase 1 Centre. During the drill, the Central Resuscitation Team managed to arrive at the Phase 1 Centre in about five minutes upon receipt of the emergency call. The emergency management flow was verified and proved effective.

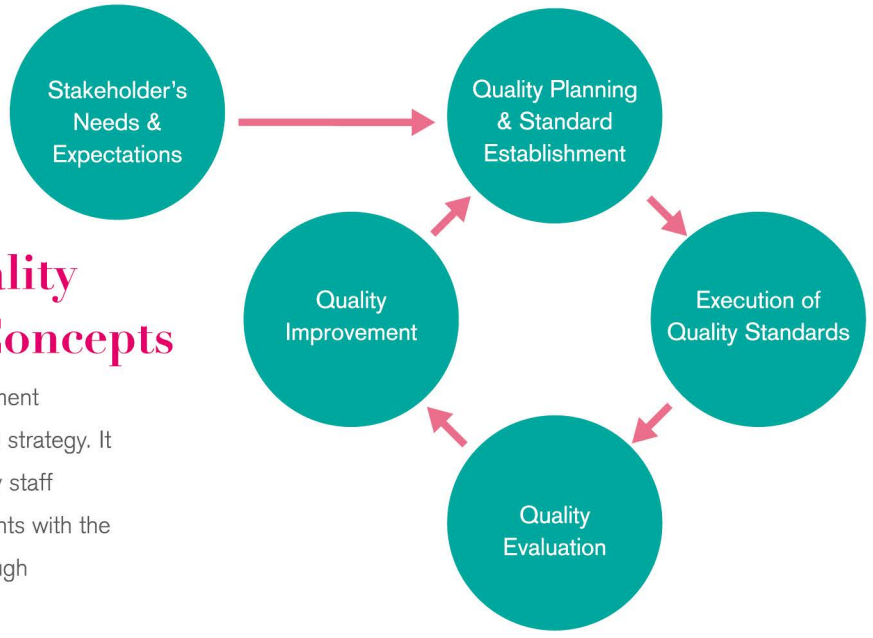
Quality Assurance

Quality is the cornerstone of good clinical research. In 2014, HKU-CTC implemented the following quality management measures:

- Establishment of a robust quality assurance scheme based on concepts of Total Quality Management (TQM).
- Issuance of internal standard documents.
- Launching of an in-house Learning Management System (LMS).
- Execution of the Quality Issue Management (QIM) scheme.

Adoption of Total Quality Management (TQM) Concepts

TQM is a continuous, organisation-wide management approach incorporated into HKU-CTC's corporate strategy. It is empowered by top management, involves every staff member and focuses on stakeholders' requirements with the ultimate aim of achieving long-term success through stakeholder satisfaction.



Issuance of Internal Standard Documents

To document the quality plan and standards clearly and systematically, three levels of internal standards documents were issued during the period, including:

- policies (POLs);
- standard operating procedures (SOPs); and
- working manuals (WOMs).

Personnel involved in performing the relevant activities, processes or functions participated in drafting these documents to ensure their practicality. The standards will be reviewed and updated regularly. Any change made to the documents must be re-approved.

All HKU-CTC staff members are well trained in the applicable standards before assuming their duties.

Quality Issue Management (QIM)

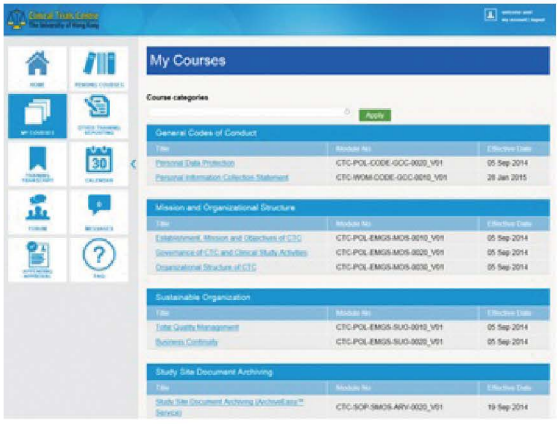
A QIM scheme was implemented in 2014 to achieve long-term sustainability and continuous quality improvement. It involves:

- the identification and reporting of quality issues;
- the classification and escalation of quality issues; and
- the performance and monitoring of corrective and/or preventive actions (CAPA).

Launch of the Learning Management System (LMS)

HKU-CTC launched its LMS in October 2014 to provide investigators, clinical research personnel and HKU-CTC staff members with convenience access to current internal standards documents. This tailor-made, web-based platform offers the following key features:

- Training on applicable internal standards documents can be completed on-line anywhere and at any time.
- Each individual's training progress can be closely monitored.
- Training reports can be documented on the paperless secure central platform.
- An individual's training transcript can be generated with just one click.



Preparation for China Food and Drug Administration (CFDA) Accreditation

With its advanced healthcare infrastructure, research capability and data quality, Hong Kong is expected to play a more active role when collaborating on clinical trials with medical institutions in the Chinese mainland. QMH/HKU has been accredited in seven clinical specialties by the CFDA since 2006 and successfully passed re-inspection in 2012.

It is anticipated that an application for the accreditation of additional clinical specialties will be submitted to the CFDA in 2015.

Clinical Specialties Accredited by the CFDA since 2006:
Anaesthesiology
Cardiology
Endocrinology & Metabolism
Haematology & Bone Marrow Transplantation
Hepatobiliary / Pancreatic Surgery & Liver Transplantation
Obstetrics & Gynaecology
Respiratory Medicine

Education and Knowledge Exchange

Being a leading academic research organisation dedicated to safeguarding the three pillars of clinical research – subject protection, scientific validity and data integrity – HKU-CTC was actively involved in educational and knowledge exchange activities on a global basis in 2013 and 2014.

HKU-CTC's Educational and Knowledge Exchange Activities during 2013-2014

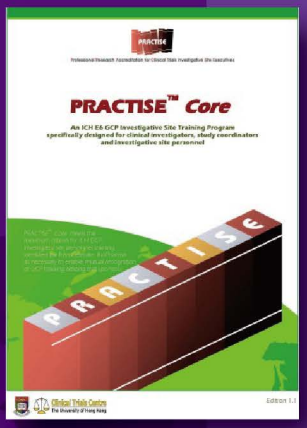
Date	Event	Venue	Role
17-18/12/14	PRACTISE® Workshop	Guiyang, China	Co-organiser & Speaker
13-14/12/14	PRACTISE® Workshop	Shanghai, China	Co-organiser & Speaker
04/12/14	Symposium on Clinical Research and Research Ethics Evaluation	Shenzhen, China	Speaker
29-30/11/14	PRACTISE® Workshop	Shanghai, China	Co-organiser & Speaker
22-23/11/14	PRACTISE® Workshop	Shanghai, China	Co-organiser & Speaker
10/11/14	Seminar on Best Practice Sharing for Applying Clinical Trial Certificate	Hong Kong, China	Panel Facilitator
07/11/14	Regional East Asian Clinical Trial Annual Forum	Busan, Korea	Supporting Organization & Speaker
03/11/14	HA Practical Workshop on Clinical Research Ethics Oversight & Research Ethics Committee Operations for Research Ethics Committee Secretaries & Staff	Hong Kong, China	Co-organiser & Speaker
13-14/09/14	PRACTISE® Workshop	Dubai, UAE	Co-organiser & Speaker
05/09/14	Seminar on Research and Development on Chinese Medicines 2014	Hong Kong, China	Speaker
13/08/14	Seminar of the 307th Hospital of Chinese People's Liberation Army	Beijing, China	Speaker
01/08/14	PRACTISE® Workshop	Hong Kong, China	Co-organiser & Speaker
27/06/14	Hospital Authority New Territories West Cluster Research Ethics Committee Meeting	Hong Kong, China	Speaker
21/05/14	NPC Area of Excellence Thematic Meeting	Hong Kong, China	Speaker
13/05/14	Seminar on Phase 1 Clinical Trial Ethics	Hong Kong, China	Co-organiser & Speaker
16/03/14	Hong Kong Pharmacy Conference	Hong Kong, China	Speaker
20&27/02/14	HA Practical Workshop on Investigator-initiated Clinical Studies	Hong Kong, China	Co-organiser & Speaker
18&25/02/14	HA Practical Workshop on Investigator-initiated Clinical Studies	Hong Kong, China	Co-organiser & Speaker
13/02/14	2014 HA Practical Workshop on Clinical Research Compliance	Hong Kong, China	Co-organiser & Speaker
16/01/14	2014 HA Practical Workshop on Clinical Research Compliance	Hong Kong, China	Co-organiser & Speaker
14/12/13	Practical Workshop on Basic Statistical Analysis Using SPSS	Hong Kong, China	Co-organiser & Speaker
23-24/11/13	PRACTISE® Workshop	Taipei, Taiwan	Co-organiser & Speaker
13-14/09/13	Regional East Asian Clinical Trial Annual Forum	Busan, Korea	Supporting Organisation & Speaker
03-05/09/13	National Conference for Clinical Research 2013	Kuala Lumpur, Malaysia	Plenary Speaker & Panelist
26-30/08/13	Sino-Swiss Clinical Research Symposium	Zurich, Switzerland	Speaker
28/06/13	Seminar on Effective Management of Clinical Trial Agreements and Personal Data (Privacy) (Amendment) Ordinance	Hong Kong, China	Speaker
15-16/06/13	PRACTISE® Workshop	Taichung, Taiwan	Co-organiser & Speaker
08-09/06/13	PRACTISE® Workshop	Taichung, Taiwan	Co-organiser & Speaker
18-19/05/13	PRACTISE® Workshop	Dubai, UAE	Co-organiser & Speaker
26/04/13	International Conference on Phase 1 and Early Phase Clinical Trials	Hong Kong, China	Organiser & Speaker
25/04/13	Open day of HKU Phase 1 Centre	Hong Kong, China	Organiser
19/03/13	2013 HA Practical Workshop on Clinical Research Compliance	Hong Kong, China	Co-organiser & Speaker
04/03/13	Seminar on Clinical Research Ethics	Shenzhen, China	Speaker
22/02/13	2013 HA Practical Workshop on Clinical Research Compliance	Hong Kong, China	Co-organiser & Speaker
10/01/13	2013 HA Practical Workshop on Clinical Research Compliance	Hong Kong, China	Co-organiser & Speaker
17-18/01/13	PRACTISE® Workshop	Hanoi, Vietnam	Co-organiser & Speaker

On-site Training

PRACTISE®

Since the launch of the unique, comprehensive PRACTISE® programme for investigators, study coordinators and study site personnel in 2012 by HKU-CTC, the programme or its individual modules have been delivered to various study sites, research institutions, hospitals and governmental organisations in Hong Kong and overseas. In 2013 and 2014, a total of 16 practical workshops were conducted in Asian, Middle Eastern and North African regions, individually supported by governmental bodies, medical associations, medical institutions and pharmaceutical companies. Positive feedback and acknowledgement were received from workshop participants.

The programme is available in English, Mandarin and Cantonese.



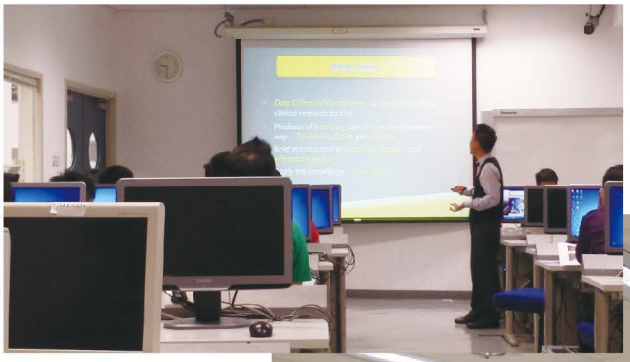
PRACTISE® *Core*

PRACTISE® *Core* is the essence of the PRACTISE® programme. It comprises eight of the 25 modules of the full programme, adding up to five lecture hours.

Since March 2014, PRACTISE® *Core* has met the minimum criteria for ICH GCP investigator site personnel training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. Each participant successfully completes a PRACTISE® *Core* workshop is issued a certificate considered acceptable by TransCelerate's member companies.

Practical Workshop on Basic Statistical Analysis Using SPSS

In December 2013, a Practical Workshop on Basic Statistical Analysis Using SPSS was organised in collaboration with the Hong Kong Urological Association at the Computer Aided Learning Centre, Yu Chun Keung Library of The University of Hong Kong. HKU-CTC's medical statistics and data management professionals conducted a one-day workshop comprising lectures devoted to data entry, manipulation and basic statistical analysis in addition to comprehensive practical case studies of statistical analysis using SPSS. The workshop was highly appreciated by the 30 urology specialists in attendance.



Practical Workshops on Investigator-initiated Clinical Studies

In January and February 2014, the HA commissioned HKU-CTC to organise two-day workshops for investigators and study site personnel interested in learning more about the management of IISs, including study design, financial planning, ethics and regulatory compliance, public registration, legal affairs and risk management. These workshops comprised lectures and practical, interactive case studies and attracted some 40 research personnel from the two medical colleges and seven hospital clusters in Hong Kong.

Practical Workshop on Clinical Research Ethics Oversight & Research Ethics Committee Operations for Research Ethics Committee Secretaries and Staff

In November 2014, the HA commissioned HKU-CTC to organise a practical training workshop devoted to clinical research ethics oversight and research ethics committee operations for the secretaries and administrators of the six cluster research ethics committees (RECs) in Hong Kong. HKU-CTC's research ethics and quality assurance professionals gave an overview of the fundamental concepts of research ethics and shared the views and tools they used to streamline the operations of RECs. Some 20 administrators and secretaries from the six RECs attended and acknowledged the usefulness of the measures and ideas given in the workshop.

On-line Training

Collaboration in the Training and Resources in Research Ethics Evaluation (TRREE) Programme

On 1 April 2014, HKU-CTC and TRREE of the University of Neuchâtel, Switzerland entered into an international strategic collaboration. This collaboration unites the research ethics expertise of the West and the East and integrates TRREE's on-line e-learning approach (www.TRREE.org) with HKU-CTC's on-site training. It is anticipated to contribute significantly to the protection of research participants and quality of human research globally. Under this collaboration, HKU-CTC helped TRREE to obtain recognition from TransCelerate in July 2014. The collaboration has also contributed to the development of the TRREE-Taiwan version to be released in partnership with the Bioethics and Law Center of the National Tsing Hua University.

Good Clinical Practice (GCP) Examination

HKU-CTC offers a GCP examination once per month. A candidate who successfully passes the examination is issued a GCP Certificate. By the end of 2014, a cumulative total of 515 certificates had been issued to investigators, clinical research coordinators and clinical research professionals in Hong Kong.

The University of Hong Kong
Li Ka Shing Faculty of Medicine
Clinical Trials Centre
This is to certify that

CHAN Tai-Man

having successfully passed
the required test on 10th Day of October 2014
and has been awarded the

Certificate in Good Clinical Practice

Professor Yu-lung Lau
Chief Director,
Clinical Trials Centre

Professor Karen Lam
Chairman,
Clinical Trials Centre


SUBJECT PROTECTION
DATA INTEGRITY
SCIENTIFIC VALIDITY

Conferences, Symposia and Seminars

International Conference on Phase 1 and Early Phase Clinical Trials in 2013 (ICPOEP 2013)

The 1st International Conference on Phase 1 and Early Phase Clinical Trials was successfully held on 26 April 2013 at Cheung Kun Hai Conference Centre in the HKU Faculty of Medicine Building. Renowned international speakers from the Chinese mainland, Hong Kong, Japan, Korea, New Zealand, Singapore and the UK, representing the pharmaceutical industry, research organisations and medical institutions, exchanged their knowledge of and experience with international trends; phase 1 strategies and early phase clinical development; regulatory and ethical perspectives in phase 1 and early phase clinical trials; and operations and quality assurance for phase 1 clinical trial centres. The event attracted more than 250 participants worldwide.

The 2nd International Conference on Phase 1 and Early Phase Clinical Trials will be held in November 2015. Experts from North America, Europe and Asia will share their insights on phase 1 and early phase clinical trial operations and the latest trends of new drug development to treat various diseases.

Zurich-Shanghai-Hong Kong-Kunming Sino-Swiss Clinical Research Symposium

The Zurich-Shanghai-Hong Kong-Kunming Sino-Swiss Clinical Research Symposium was organised by the Clinical Trials Center of the University and University Hospital Zurich on 26-30 August 2013 with funding support from the Sino Swiss Science and Technology Cooperation. Delegations from HKU-CTC, Shanghai Clinical Research Centre, Shanghai Longhua Hospital of TCM, Huashan Hospital of Fu Dan University and Kunming Yan'an Hospital exchanged ideas on scientific and management aspects of clinical research. The conference served as a prelude to partnerships and collaborations for future multinational, multicentre IISs. Representatives of HKU-CTC shared their experience on collaborating strategies with other clinical trial centres and managing IISs.

The 7th National Conference for Clinical Research (NCCR 2013)

The 7th National Conference for Clinical Research was organised by the Ministry of Health in Malaysia and successfully held in Kuala Lumpur on 3-5 September 2013. Representatives of HKU-CTC shared their views on the importance of collaboration between clinical trial centres in Asia and the essence of ethics oversight for subject protection and introduced the novel initiative of HKU-CTC's Platform for Electronic Adverse Reports Submission (PEARS).

Regional Asian Clinical Trial Annual Forum (REACTA) 2013 and 2014

The first Regional Asian Clinical Trial Annual Forum (REACTA) was jointly organised by the Dong-A University Hospital CTC and Pusan National University Hospital CTC on 13-14 September 2013 in Busan, with strong support from the Korean government through the Korea National Enterprise for Clinical Trials (KoNECT) and the Korea Drug Development Fund (KDDF). More than 200 local and overseas investigators, clinical research personnel and industry collaborators attended the forum. Hospital/University CTCs from Hong Kong, Korea, Japan, Taiwan and the US were the key members at the REACTA Forum and were dedicated to establishing a robust network to attract clinical studies from the industry and leverage on the strength of different CTCs to collaborate on multinational IISs. Representatives of HKU-CTC gave a lecture on the importance of establishing partnerships between CTCs.

The feedback from the first forum was encouraging and contributed to the second REACTA Forum held in Busan on 7 November 2014.

Seminar of the 307th Hospital of the Chinese People's Liberation Army

The 307th Hospital of the Chinese People's Liberation Army GCP office organised a seminar on 3 August 2014 that was attended by more than 200 investigators, clinical research personnel, ethics committee members and hospital support staff. HKU-CTC presented its clinical research management model and received positive feedback from the audience. The seminar paved the way for future collaboration between the 307th Hospital and HKU-CTC.

Seminar on Clinical Research and Research Ethics Evaluation at HKU-Shenzhen Hospital

Research ethics is the cornerstone of subject protection in clinical research. After setting up its research ethics committee in March 2013, HKU-SZH jointly organised a seminar on clinical research and research ethics evaluation with the Shenzhen Experimental Medicine Professional Committee at HKU-SZH on 4 December 2014, attracting more than 250 clinical research professionals from different hospitals in Shenzhen. The Continuing Medical Education Committee awarded the programme CME credits. Representatives of HKU-CTC presented on topics related to the governance and ethical principles of clinical research.

Academic Exchange

ASAN Medical Center and Ajou University Medical Center, Korea

A delegation of nine representatives from ASAN Medical Center and Ajou University Medical Center visited HKU-CTC on 10 February 2013 to exchange ideas on clinical research management and to explore future collaborative opportunities on multicentre IISs. [10 Feb 2013]

Kyoto University Hospital, Japan

On 19 August 2014, the Director (Dr. Takatani) and Deputy-Director (Dr. Shimizu) of the Institute for Advancement of Clinical and Translational Science (iACT) of the Kyoto University Hospital visited HKU-CTC to share information about the development of the iACT and explore collaborative opportunities on clinical research.

[19 Aug 2014]

2013

2014

Peking University Shenzhen Hospital, China

A delegation of six representatives led by Peking University Shenzhen Hospital Vice President Dr. Xiao Ping visited HKU-CTC, the Phase 1 Centre and the Clinical Research Pharmacy at Queen Mary Hospital on 10 October 2014. HKU-CTC introduced its clinical research management model and arranged a facility tour of the Phase 1 Centre. The delegates were impressed by the centre's state-of-the-art facilities and expressed their interest in collaborating with HKU-CTC on clinical research and various knowledge exchange activities.

[10 Oct 2014]

Clinical Trials Centre
The University of Hong Kong

Main Office:
8/F, Clinical Pathology Building,
Queen Mary Hospital,
102 Pokfulam Road, Hong Kong

Sassoon Office:
1/F HKJC Bldg. for Interdisciplinary Research,
5 Sassoon Road, Hong Kong

HKU Phase 1 Clinical Trials Centre:
2/F, Block K,
Queen Mary Hospital,
102 Pokfulam Road, Hong Kong

HKU Pharmacokinetics Laboratory:
2/F, Laboratory Block,
Li Ka Shing Faculty of Medicine,
21 Sassoon Road, Hong Kong