GROW STRONG & FLOURISH

2015
ANNUAL REPORT

Clinical Trials Centre
The University of Hong Kong

CONTENTS

MESSAGE FROM THE CHIEF DIRECTOR AND MANAGING DIRECTOR

FROM QUALITY TO EXCELLENCE

Clinical research is essential to the advancement of human healthcare, as an unlimited number of clinical questions are yet to be answered. However, clinical studies cannot bring real benefits to people unless they are designed, planned, managed, conducted and reported with high ethical, scientific and data quality. This is why HKU-CTC and all its members have always striven for excellence around the three pillars of clinical research – subject protection (ethical quality), scientific validity (scientific quality) and data integrity (data quality) – over the past 17 years.

Everybody talks about quality, but not everybody delivers quality, because doing so is easier said than done. The journey toward good quality is long, tough and costly. An organisation may fail to achieve or maintain its quality standards if it does not make quality a priority (for the entire organisation), does not invest enough (in people and infrastructure) and/or does not show persistence. On 22 July 2015, the China Food and Drug Administration (CFDA) issued a public notice warning of stringent enforcement actions against sub-standard clinical trial activities in the country. This wave of regulatory actions led to the disqualification or sanction of many sponsors, contract research organisations (CROs), clinical trial institutions and investigators and triggered the "voluntary withdrawal" of 1,193 marketing authorisation applications for new drugs and generic drugs. Unfortunately, these sub-standard cases are not unique. Various quality issues in clinical research can also be found in developed countries in North America and Western Europe. Apparently, organisations and people who do not invest in quality end up paying a higher price.

To HKU-CTC, quality is the primary consideration. With a passion for continuous quality improvement, in 2014, we reconstructed our quality system based on the concepts of total quality management (TQM). Everybody on the HKU-CTC team was engaged; quality documents such as written policies (POLs), standard operating procedures (SOPs) and working manuals (WOMs) were enhanced; and an electronic learning management system (LMS) was launched. In 2015, this initiative was extended further to the study sites in HKU/QMH. A new set of 33 study site POLs/SOPs templates were developed for various clinical specialties, and training workshops were conducted to brief investigators and study site personnel on the concepts of TQM and the key content of the new POLs/SOPs.

Among all types of clinical trials, phase 1 trials are most strictly regulated. The 24-bed HKU Phase 1 Centre in QMH opened in 2014. Since then, the TQM scheme has been implemented in every part of its operations and has proven effective. This was demonstrated by the successful completion of a number of audits by sponsors and CROs and the increasing number of clinical trials allocated. By the end of 2015, the HKU Phase 1 Centre had already completed three trials. Eight trials were ongoing, and another 10 trials were under planning. HKU-CTC's practical experience in phase 1 centre operation is being leveraged in plans for a 48-bed phase 1 centre at HKU-Shenzhen Hospital

(HKU-SZH). This strategic move is anticipated to put HKU-CTC and HKU-SZH in a more competitive position and to encourage clinical research collaboration between Hong Kong and the Chinese mainland.

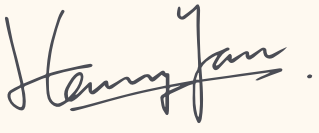
With a robust TQM scheme in place, applications for accreditation by the CFDA for the HKU Phase 1 Centre and seven additional clinical specialties (on top of the seven clinical specialties already accredited since 2006) were submitted in late 2015 and an on-site inspection was completed in March 2016. Combining our mature quality management system and HKU/QMH's rich experience in conducting clinical trials, we are delighted to announce that an accreditation has just been granted in July 2016!

Training and learning for research personnel is an essential element contributing to good quality. As a leading clinical trial institution, HKU-CTC is always willing to share its knowledge and experience with the international clinical research community. Its proprietary training programme on GCP and study site operations – PRACTISE® – has gained even stronger popularity, particularly in the Chinese mainland, Taiwan and Hong Kong because of its availability in English, Mandarin and Cantonese. The launch of the Chinese version of TRREE (Training and Resources in Research Ethics Evaluation) was further good news to investigators and clinical research personnel in the Chinese-speaking community, as it offers free-of-charge online learning in human research ethics and GCP in the Chinese language.

To promote clinical research capabilities worldwide, the International Clinical Trial Center Network (ICN) was established in September 2015. HKU-CTC is one of the 10 founding members, which include globally renowned, top-quality centres such as Harvard Clinical Research Institute (HCRI), Cambridge Clinical Trials Unit (CCTU), University of Zurich Clinical Trials Center and the Institute for Advancement of Clinical and Translational Science of Kyoto University (iACT). Under ICN, the members will share and exchange their expertise, experience and capacity, and encourage international collaboration in clinical research addressing global medical needs.

Quality is the only way to achieve excellence. HKU-CTC will continue to invest in quality, and we are sure the return will be sweet – for our patients and for every one of us!

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



Henry Yau
Managing Director & Honorary Assistant Professor
Clinical Trials Centre
The University of Hong Kong

HKU-CTC HAS GONE FROM STRENGTH TO STRENGTH OVER THE PAST 17 YEARS

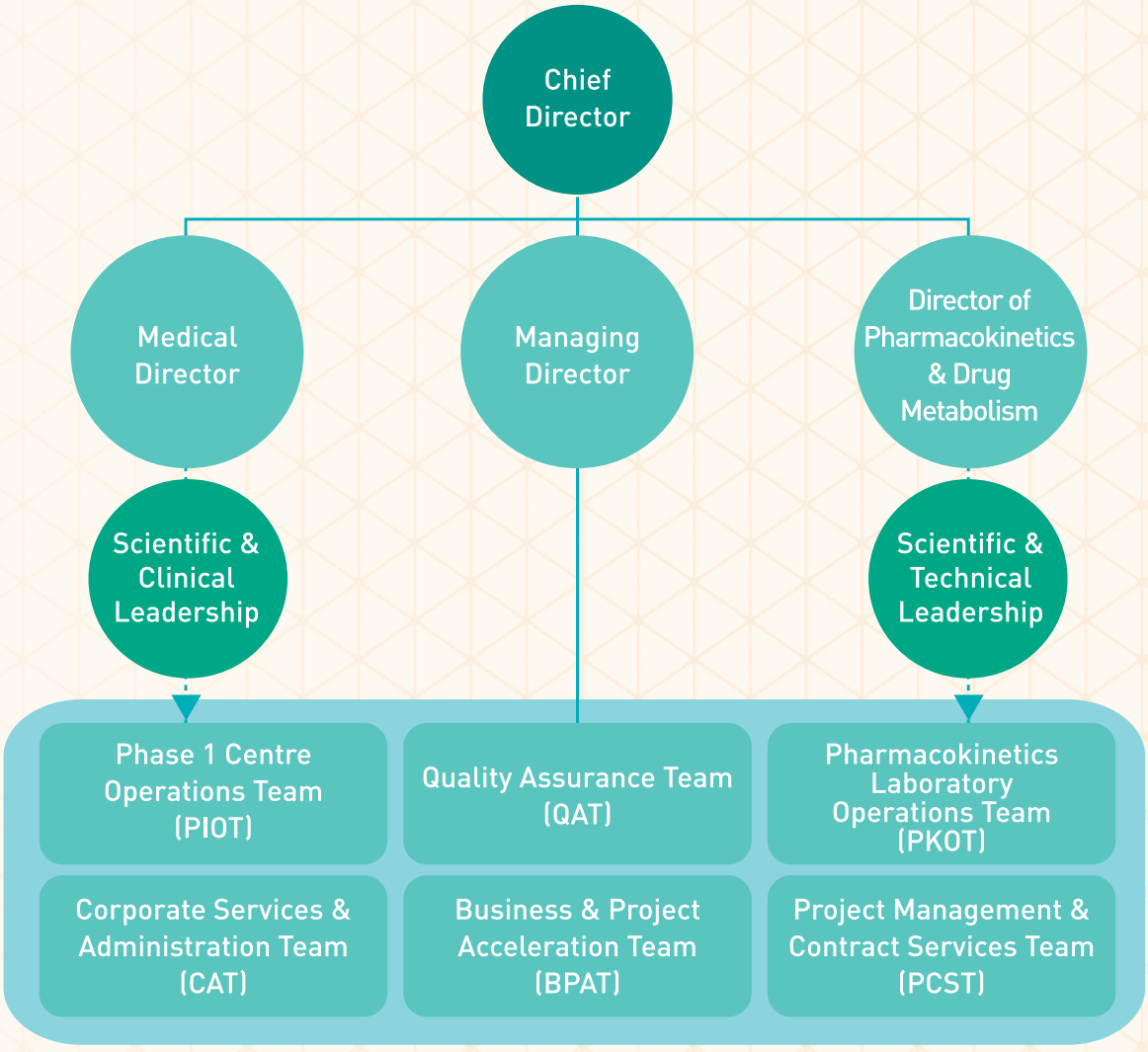
WE STRIVE TO BE AN EXEMPLAR MODEL OF SMO (SITE MANAGEMENT ORGANISATION) IN THE REGION

VISION

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-calibre and efficient team attracts and facilitates 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 – you can expect nothing but excellence here!

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.



COMMITTEE OF MANAGEMENT

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

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

Chairman

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

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

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

The Committee of Management (COM) is the governing body of HKU-CTC. It now consists of 12 members, including the 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 Sidney Tam
Service Director (Pathology)
Hong Kong West Cluster
Hospital Authority

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

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

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

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

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

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

PASSION IS THE CUTTING EDGE OF HKU-CTC


CPOEP 2015
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HIGHLIGHTS OF 2015

COMPLETION OF THE FIRST PHASE 1 HEALTHY VOLUNTEER STUDY AT THE HKU PHASE 1 CENTRE

The HKU Phase 1 Clinical Trials Centre successfully completed its first phase 1 healthy volunteer clinical study in April and received positive feedback from the participants.
[Apr 2015]

PUBLIC COMMUNICATION: TV PROGRAMME ON CLINICAL TRIALS

HKU-CTC was invited by a local television station to produce a 22-minute TV programme in English (Pearl Report) to introduce the recent clinical trial development in Hong Kong to the general public. The programme was aired on 27th July 2015.
[Jul 2015]

VISIT BY THE AFFILIATED HOSPITAL OF GUIZHOU MEDICAL UNIVERSITY

[Apr 2015]

PRESS CONFERENCE ON "HKU PHASE 1 CLINICAL TRIALS CENTRE MOVES FORWARD TO ITS 1ST ANNIVERSARY: FOCUS ON PHASE 1 AND EARLY PHASE CLINICAL TRIALS TO BRING NOVEL TREATMENTS"

[Jun 2015]

VISIT BY THE FOOD AND HEALTH BUREAU OF HONG KONG

Dr Wing-man Ko, BBS, JP, the Secretary for Food and Health, visited our HKU Phase 1 Clinical Trials Centre on 25 July 2015 and met with the

LAUNCH OF THE NEW HKU CLINICAL TRIALS REGISTRY WEBSITE

[Aug 2015]

ESTABLISH THE VOLUNTEER RESOURCE CENTRE (VRC) FOR HEALTHY VOLUNTEER RECRUITMENT FOR CLINICAL TRIALS

[Sep 2015]

INTERNATIONAL CLINICAL TRIAL CENTER NETWORK (ICN) INAUGURATION MEETING ON 11 SEPTEMBER 2015

ICN, a network of leading academic and government-based clinical research institutions that collaborate to promote excellence in clinical research, was inaugurated in Zurich on 11 September 2015. HKU-CTC was one of the 10 founding members.

[Sep 2015]

Senior Management and Operations Team of HKU-CTC. Dr Ko was briefed on the operation logistics and business strategies of our HKU Phase 1 Clinical Trials Centre, and he expressed his enthusiastic support for the Phase 1 Centre and the healthcare industry in Hong Kong.

[Jul 2015]

2ND INTERNATIONAL CONFERENCE ON PHASE 1 AND EARLY PHASE CLINICAL TRIALS (ICPOEP 2015)

[Nov 2015]

PERFORMANCE REVIEW

OVERVIEW

INDUSTRY-SPONSORED CLINICAL STUDIES

The number of newly contracted industry-sponsored studies remained high in 2015, at 74. By the end of 2015, the cumulative number of contracted industry-sponsored studies had reached 898, 225 of which were ongoing.

	2015	2014	2013
Contracted Industry-sponsored Clinical Studies			
New Studies	74	74	69
Cumulative Studies	898	824	750
Active Studies	225	227	204
Distribution of New Studies by Research Area (Top 5)			
1	Oncology (36%)	Oncology (34%)	Oncology (30%)
2	GI & Hepatology (14%)	Cardiovasculology (19%)	Cardiovasculology (16%)
3	Haematology (11%)	GI & Hepatology (9%)	Haematology (12%)
4	Cardiovasculology (8%)	Neurology (7%)	Immunology & Allergy (9%)
5	Endocrinology (7%)	Haematology (4%)	Endocrinology (7%)
Distribution of New Studies by Study Phase			
I	7%	4%	6%
II	27%	20%	17%
III	53%	54%	52%
IV	3%	6%	10%
Others	10%	16%	15%

INVESTIGATOR-INITIATED CLINICAL STUDIES

Since November 2009, HKU-CTC has been delegated to oversee investigator-initiated clinical studies (IISs). By the end of 2015, HKU-CTC had supported 120 IISs, 94 of which were active.

	2015	2014	2013
Confirmed Investigator-initiated Clinical Studies			
New Studies	37	33	15
Cumulative Studies	120	83	50
Active Studies	94	66	39

COLLABORATIVE TRIAL SPONSORS

AB Science	Boehringer Ingelheim	Ipsen	Penumbra
Abbott	Bolton Medical	Isis Pharmaceuticals	Pfizer
AbbVie	Boston Scientific	Janssen	Pharmacia
ABIVAX	BrainsGate	Johnson & Johnson	Pharmascience
Access Business Group International LLC	Bristol-Myers Squibb	Keryx	Pharmasset
Achillion	Bukwang	Kinex	PowderMed
Actelion	Celgene	Kowa	Progen
Advanced Herbal Therapeutics	Cell Tech	Kyowa Hakko Kirin	Puma Biotechnology
Alcon	CELLTRION	La Jolla	QuantaNova
Alexion	Celsion	Laboratoire HRA Pharma	Regeneron
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
ASLAN	EVER Neuro Pharma	Miramar Labs	Tekmira
Astellas	Everpride	Morphotek	Theranostics (Xanthus)
AstraZeneca	FeRx	Mundipharma	Theravance
Aurinia Pharmaceuticals	FibroGen	Nanogen	Thrombosis Research Institute
Aventis	Fujirebio	NanoPass	Triangle
BARRX	Galderma	NephroGenex	Trius
Baxter	Genentech	NIDEK	TTY
Bayer	Genzyme	Novartis	Tularik
BCIRG	Gilead	Novira	Tyco
Bio-Cancer	GlaxoSmithKline	Novo Nordisk	UCB
Biocompatibles	Grunenthal	Nycomed	Vigconic
BioCryst	Guidant	OrbusNeich	VitaGreen
Biogen Idec	Human Genome Sciences	Organon	Wealthy Creative
Biomeasure	Idenix	Orient EuroPharma	Wyeth
Biosensors Europe	ImClone	Orygen	Zila
Bioteque	Incyte	OSI	
Biotronik	Inovio	Otsuka Pharmaceutical	

INDUSTRY-SPONSORED CLINICAL STUDIES CONTRACTED IN 2015

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Cardiovasculology	Atrial Fibrillation	I	Professor HF Tse	Medicine, QMH
Cardiovasculology	Bradycardia	O	Professor HF Tse	Medicine, QMH
Cardiovasculology	Chronic Heart Failure	III	Dr David CW Siu	Medicine, QMH
Cardiovasculology	Heart Failure	O	Professor HF Tse Dr Katherine YY Fan	Medicine, QMH Medicine, GRH
Cardiovasculology	Stroke	O	Dr Simon CC Lam	Medicine, QMH
Cardiovasculology	Venous Thromboembolic Events	O	Dr Eric WC Tse Dr KH Yiu	Medicine, QMH Medicine, QMH
Dermatology	Atopic Dermatitis	III	Dr Johnny CY Chan	Medicine, QMH
Dermatology	Atopic Dermatitis	III	Dr Johnny CY Chan	Medicine, QMH
Dermatology	Atopic Dermatitis	III	Dr Johnny CY Chan	Medicine, QMH
Endocrinology	Diabetic Kidney Disease	II	Dr WS Chow	Medicine, QMH
Endocrinology	Diabetes Mellitus	III	Dr Paul CH Lee	Medicine, QMH
Endocrinology	Diabetes Mellitus	III	Dr Paul CH Lee	Medicine, QMH
Endocrinology	Diabetes Mellitus	IV	Professor Kathryn CB Tan	Medicine, QMH
Endocrinology	Diabetes Mellitus	IV	Dr YC Woo	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	I	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor MF Yuen	Medicine, QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor MF Yuen	Medicine, QMH
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	Liver Transplantation	III	Dr James YY Fung	Medicine, QMH
Gastroenterology & Hepatology	Ulcerative Colitis	III	Professor WK Leung	Medicine, QMH
Gastroenterology & Hepatology	Ulcerative Colitis	III	Professor WK Leung	Medicine, QMH
Haematology	Acute Myeloid Leukaemia	III	Professor Anskar YH Leung	Medicine, QMH
Haematology	Chronic Myeloid Leukaemia	II	Professor YL Kwong	Medicine, QMH
Haematology	Chronic Myeloid Leukaemia	III	Professor YL Kwong	Medicine, QMH
Haematology	Haemophilia A	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine, QMH
Haematology	Non-Hodgkin's B-cell Lymphoma	II	Professor YL Kwong	Medicine, QMH
Haematology	Non-Hodgkin's B-cell Lymphoma	III	Professor YL Kwong	Medicine, QMH
Haematology	Non-Hodgkin's B-cell Lymphoma	III	Professor YL Kwong	Medicine, QMH
Haematology	T-Cell Lymphoma	II	Professor YL Kwong	Medicine, QMH
Immunology & Allergy	Lupus Nephritis	III	Professor TM Chan Dr Temy MY Mok	Medicine, QMH Medicine, QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Dr Tommy T Cheung	Medicine, QMH
Infectious Disease	Influenza	II	Dr Ivan FN Hung	Medicine, QMH

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Study Site*
Infectious Disease	Respiratory Syncytial Virus Infection	II	Dr Ivan FN Hung	Medicine, QMH
Nephrology	Chronic Kidney Disease	III	Professor TM Chan	Medicine, QMH
Nephrology	Diabetic Nephropathy	III	Professor TM Chan	Medicine, QMH
Nephrology	Kidney Transplantation	O	Professor TM Chan	Medicine, QMH
Neurology	Limb Spasticity	O	Dr Leonard SW Li	Medicine, TWH
Neurology	Neuromyelitis Optica	II	Dr KH Chan	Medicine, QMH
Obstetrics & Gynaecology	In vitro Fertilisation	III	Professor Ernest HY Ng	Obstetrics & Gynaecology, QMH
Oncology	Breast Cancer	I	Dr Joanne WY Chiu	Medicine, QMH
Oncology	Breast Cancer	II	Dr Joanne WY Chiu Dr Ava Kwong	Medicine, QMH Clinical Oncology, QMH
Oncology	Breast Cancer	II	Dr Janice WH Tsang Dr Thomas CC Yau	Clinical Oncology, QMH Medicine, QMH
Oncology	Breast Cancer	II	Dr Ava Kwong	Surgery, QMH
Oncology	Breast Cancer	III	Dr Joanne WY Chiu	Medicine, QMH
Oncology	Breast Cancer	III	Dr Joanne WY Chiu	Medicine, QMH
Oncology	Breast Cancer	III	Dr Joanne WY Chiu Dr MY Luk	Medicine, QMH Clinical Oncology, QMH
Oncology	Colorectal Cancer	III	Dr Victor HF Lee	Clinical Oncology, QMH
Oncology	Gastric Cancer	III	Dr KO Lam	Clinical Oncology, QMH
Oncology	Gastric Cancer	III	Dr KO Lam	Clinical Oncology, QMH
Oncology	Head & Neck Cancer	III	Professor Dora LW Kwong	Clinical Oncology, QMH
Oncology	Liver Cancer	I	Dr Thomas CC Yau	Medicine, QMH
Oncology	Liver Cancer	III	Dr Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	II	Dr James CM Ho	Medicine, QMH
Oncology	Lung Cancer	II	Dr James CM Ho	Medicine, QMH
Oncology	Lung Cancer	II	Dr James CM Ho	Medicine, QMH
Oncology	Lung Cancer	II	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	III	Dr James CM Ho	Medicine, QMH
Oncology	Lung Cancer	III	Dr James CM Ho Dr Victor HF Lee	Medicine, QMH Clinical Oncology, QMH
Oncology	Lung Cancer	III	Dr James CM Ho Dr Thomas CC Yau	Medicine, QMH Medicine, QMH
Oncology	Lung Cancer	III	Dr Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	III	Dr Victor HF Lee	Clinical Oncology, QMH
Oncology	Lung Cancer	O	Dr James CM Ho	Medicine, QMH
Oncology	Prostate Cancer	II	Dr Steven WK Siu Dr Thomas CC Yau	Clinical Oncology, QMH Medicine, QMH
Ophthalmology	Glaucoma	III	Professor Jimmy SM Lai	Ophthalmology, QMH
Paediatrics	Spinal Muscular Atrophy	III	Dr Sophelia HS Chan	Paediatrics & Adolescent Medicine, QMH
Paediatrics	Venous Thromboembolism	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine, QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr David CL Lam	Medicine, QMH
Urology	Benign Prostatic Hypertrophy	O	Dr James HL Tsu	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 TWH: Tung Wah Hospital**

SITE MANAGEMENT ORGANISATION (SMO) SERVICES

With a passionate staff of 15 clinical research professionals, HKU-CTC's Business and Project Acceleration Team (BPAT) is dedicated to supporting clinical research by offering one-stop, comprehensive SMO services to study site personnel at HKU/QMH. These services include but are not limited to strategic research consultation, study feasibility assessment, study site project management, research ethics affairs, safety reporting, study site budget and payment management, study site contract management and legal affairs, clinical research coordinator support, biological specimen management, study drug management and study site document archiving.

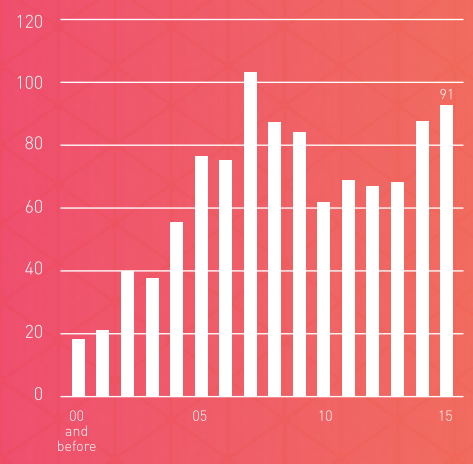
STUDY SITE PROJECT MANAGEMENT

The Study Site Project Management Unit (SPMU) of BPAT continued to demonstrate its effectiveness in facilitating study site logistical arrangements and coordinating communication between investigators, sponsors, ethics committees and various internal/external stakeholders in 2015. At the end of 2015, the number of ongoing industry-sponsored clinical studies being coordinated by SPMU had remained steady at 225.

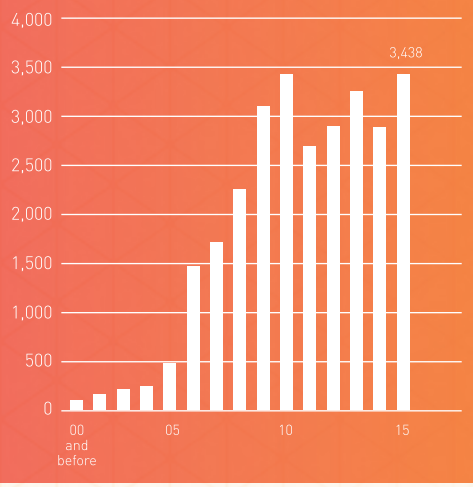
ETHICS AFFAIRS

During this year, 91 initial ethics applications were compiled, while subsequent submissions compiled and submitted to ethics committees increased by 18% to 23,940.

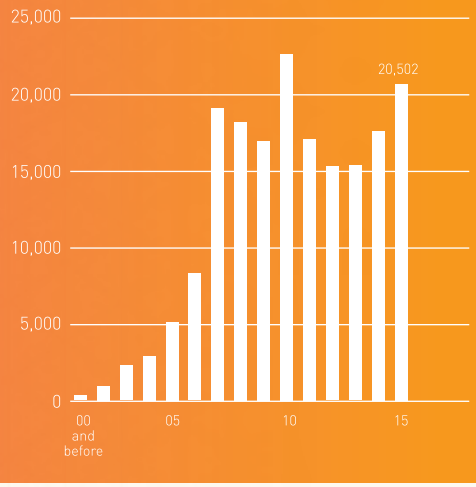
Initial Submissions



Subsequent Submissions (Excluding SAE reports)



SAE Reports



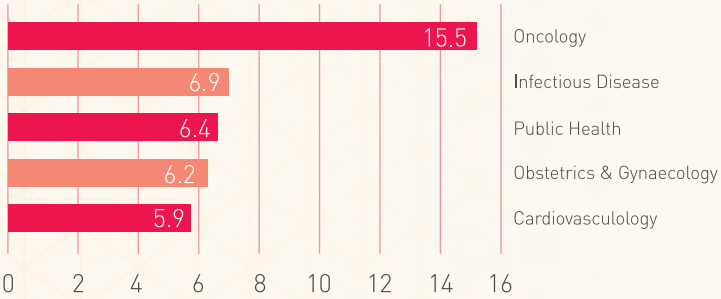
HKU CLINICAL TRIALS REGISTRY (HKUCTR)

HKU Clinical Trials Registry (www.hkuctr.com) has continued to gain in popularity since its launch in 2005. By the end of 2015, 1,989 studies were registered; of these, 76% were investigator-initiated studies. Oncology and infectious diseases represented the top research areas, accounting for 15.5% and 6.9% of the total number, respectively.

Being dedicated to promoting transparency of disclosure of clinical research activities and public awareness in clinical research in Hong Kong, HKUCTR was upgraded in August 2015 to offer a more user friendly, informative and professional interface on 27 August 2015.

HKUCTR
HKU CLINICAL TRIALS REGISTRY

%Distribution of Clinical Studies by Disease Areas by the End of 2015 (Top 5)



BEING PROFESSIONAL, RELIABLE AND HELPFUL IS CTC'S CODE OF CONDUCT!

OVER THE LAST 17 YEARS, OUR 1,000+ CLINICAL TRIAL PROJECTS HAVE BENEFITED FROM CTC'S TAILORED CLINICAL TRIAL SOLUTIONS!

CLINICAL RESEARCH COORDINATOR (CRC) SERVICES

HKU-CTC's dedicated, well trained and experienced Clinical Research Coordinators have continued to offer major support to investigators and study sites. This support includes but is not limited to subject recruitment, study visit management, clinical procedures management and data collection for nine multinational industry-sponsored clinical studies at Queen Mary Hospital (QMH) and Grantham Hospital by end of 2015.

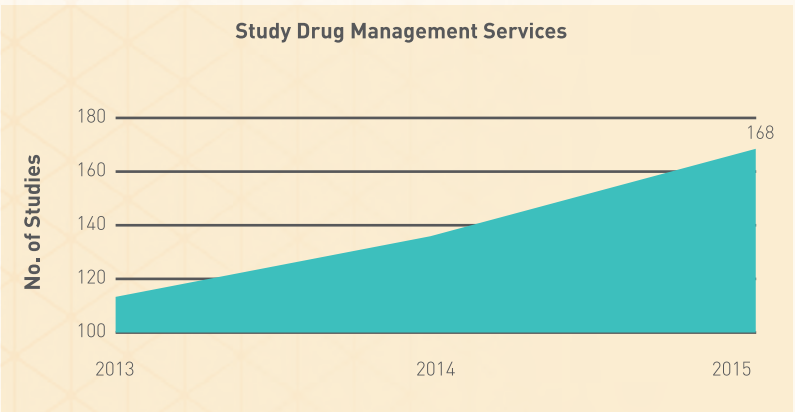
CRISP
Clinical Research Investigative Site Professionals
•Study Coordinator Service
Clinical Trials Centre, The University of Hong Kong

STUDY DRUG MANAGEMENT SERVICES

Over the years, HKU-CTC's Site Services Unit (SSU) and Department of Pharmacy at QMH have closely collaborated to provide one-stop study drug management services, including receipt, storage, processing, dispensing and accountability for clinical studies conducted at HKU/QMH. In 2015, some 168 studies were managed under this platform, a 25% increase from 2014.

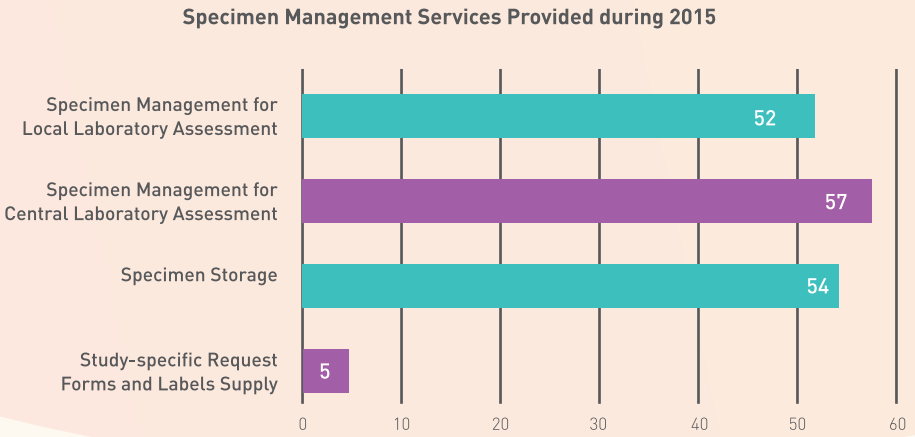
Local drug disposal service has been increasingly demanded by the pharmaceutical industry for multi-centre clinical studies. MedDrop™ – the professional drug disposal service offered by HKU-CTC – had managed 85 drug disposal applications by the end of 2015.

MedDrop



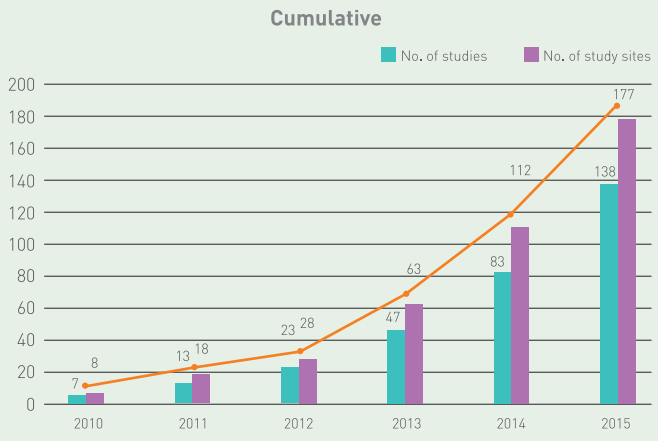
SPECIMEN MANAGEMENT

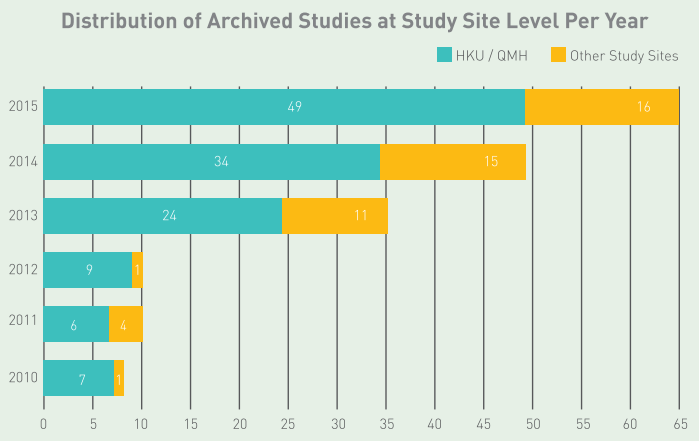
HKU-CTC's SSU has continued to provide one-stop biological specimen management services for clinical studies, including processing, storage, packaging and shipment arrangement for local and central laboratory assessments. In 2015, more than 50 new clinical studies benefited from SSU's specimen management services.



STUDY SITE DOCUMENT ARCHIVING SERVICE

Long-term study document archiving is challenging for study sites in Hong Kong because of the limited storage capacity in hospitals. Launched in 2010, ArchiveEasy™ – HKU-CTC's study site document archiving service – has become increasingly popular, supporting post-study document archiving for 138 studies in 177 study sites.





CONTRACT RESEARCH ORGANISATION (CRO) SERVICES

Over the years, HKU-CTC's Project Management & Contract Services Team (PCST) has played an active role in providing comprehensive one-stop contract research services, including protocol development to regulatory affairs, study project management, study site monitoring, study data management, medical statistics and final clinical study report development, to sponsors and investigators.

PROFESSIONAL SUPPORT FOR SPONSORED AND INVESTIGATOR-INITIATED STUDIES

In 2015, PCST supported 33 local and international clinical studies. In particular, PCST expanded its support for multicentre investigator-initiated studies (IISs). By the end of 2015, 13 of the 33 clinical studies covered were IISs, including 7 multicentre IISs.

DISTRIBUTION OF STUDIES SUPPORTED BY HKU-CTC'S CRO SERVICES

REGULATORY AFFAIRS

As a Wholesale Poison Licence holder, HKU-CTC is eligible to apply for Clinical Trial Certificates, which are required to import study drugs for clinical drug trials in Hong Kong. With its team of experienced and professional regulatory specialists, HKU-CTC is able to formulate the best regulatory strategies for pharmaceutical companies and contract research organisations and to 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.

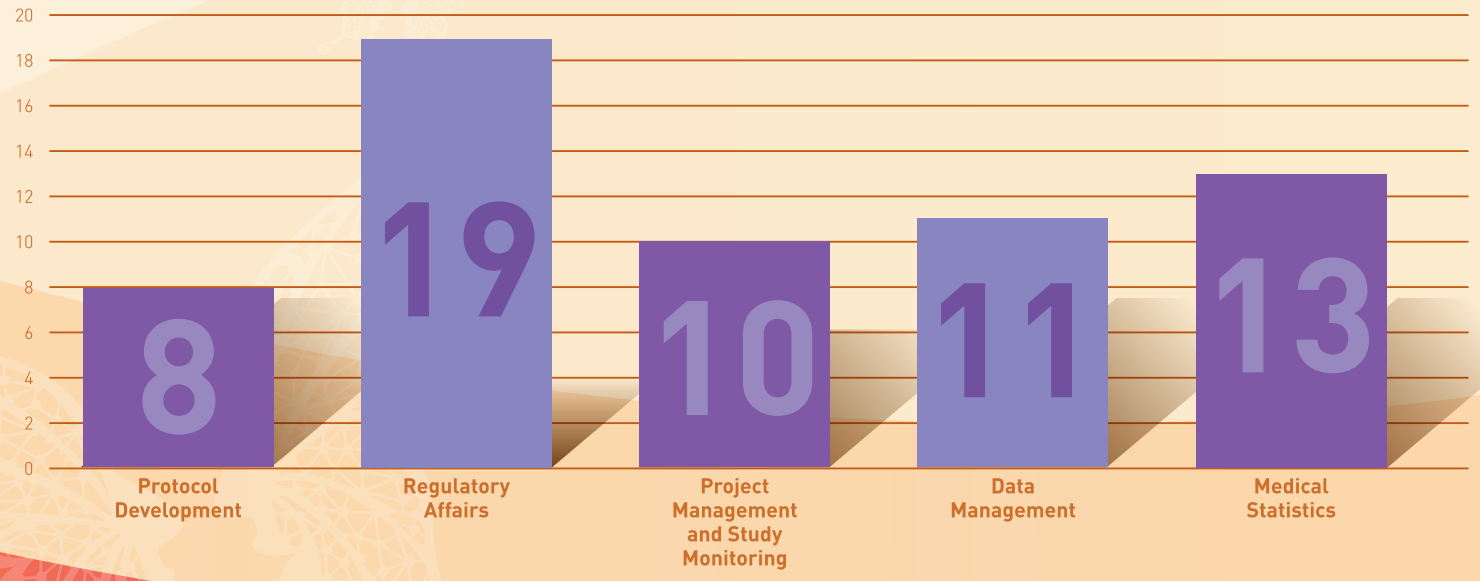
In 2015, regulatory affairs services were provided in support of 19 clinical studies.

DATA MANAGEMENT

Electronic Case Report Forms (eCRFs) are gradually replacing traditional paper CRFs for data collection in clinical studies. CREDIT Solutions™ (Clinical Research Electronic Data and Information Technology Solutions), HKU-CTC's electronic data management services, offers practical solutions to investigators, research institutions and sponsors worldwide.

Comprising data managers, data management specialists and IT specialists, HKU-CTC's Data Management Unit provides professional data management and IT support and safeguards data quality using its in-house data validation programme, document tracking system and automated error correction system. In 2015, CREDIT Solutions™ supported 10 clinical studies conducted in Hong Kong, the Chinese mainland and Europe.

CONTRACT RESEARCH SERVICES PERFORMED OR PLANNED IN 2015



HKU PHASE 1 CLINICAL TRIALS CENTRE

Phase 1 and early phase clinical studies are an essential milestone in translating pre-clinical study results into clinical data in modern drug development. Amid increasing demand for high quality phase 1 centres in the Asia-Pacific region, the HKU Phase 1 Clinical Trials Centre (HKU Phase 1 Centre) was established in mid-2014 to deliver high quality clinical trial data by leveraging our medical expertise and quality standards. The HKU Phase 1 Centre is dedicated to conducting phase 1, early phase and clinical pharmacology studies in various therapeutic areas, whether in healthy volunteers or in patients.

PERFORMANCE OVERVIEW

In 2015, 18 studies were on going or under preparation at the Phase 1 Centre. In total, 142 subjects/patients were successfully dosed/randomised and 1,992 subject visits were performed.

Study Type		Healthy Volunteers	Patients	Total
No. of Subjects Dosed/Randomised		60	82	142
No. of Subject Visits	In-patient	124	0	124
	Out-patient	1069	799	1,868

VOLUNTEER RESOURCE CENTRE (VRC)

The Volunteer Resource Centre (VRC) was established in September 2015. Its dedicated team is responsible for subject recruitment activities for healthy volunteer studies. The VRC plays an active role in formulating volunteer recruitment strategies and collaborates closely with the medical and clinical operations team of the HKU Phase 1 Centre in performing pre-screening activities.

PHARMACOKINETICS LABORATORY (PK LAB)

Pharmacokinetic sampling and pharmacokinetic analysis are fundamental procedures in phase 1, early phase and clinical pharmacology trials. The HKU Pharmacokinetics Laboratory (PK Lab) is a professional laboratory dedicated to providing pharmacokinetic analysis services for small molecule drugs and peptide/protein drugs. The PK Lab is equipped with state-of-the-art analytical instruments for separating and quantifying drugs and their metabolites in pharmacokinetic samples, supporting further development of new drugs and registration or procurement requirements for generic drugs.

PUBLIC COMMUNICATIONS

HKU-CTC has been dedicated to promoting clinical trials to the general public in Hong Kong. In the past few years, it has put forth major efforts to raise public awareness and encourage participation in clinical studies.

To celebrate the first anniversary of the Phase 1 Centre, a press conference entitled "HKU Phase 1 Clinical Trials Centre moves forward to its 1st anniversary: Focus on phase 1 and early phase clinical trials to bring novel treatments" was held on 3 June 2015 to highlight the activities at the HKU Phase 1 Centre and to promote the value of early phase clinical studies to modern healthcare.

HKU-CTC was invited by a local TV station to produce an English TV programme – *Pearl Report: "MEDS TEST"* – to review the recent development of clinical trials in Hong Kong. The programme aired on 27 July 2015. The current status of clinical trials in Hong Kong, including local drug development, research ethics and regulations, clinical trial participation and social value were discussed from the perspectives of research personnel, research ethics committees, government officials, the pharmaceutical industry and trial participants.

SUCCESSFUL CASE SHARING OF A HEALTHY VOLUNTEER STUDY

DAY 0	**DAY 133**	**DAY 150**
Receipt of draft protocol from sponsor	Receipt of DOH approval	Study initiation
DAY 9	**DAY 95**	**DAY 259**
Issuance of study proposal by CTC to sponsor	Receipt of IRB approval	Completion of study visits
DAY 38	**DAY 53**	**DAY 297**
Confirmation of site selection by sponsor	Submission to IRB and DOH	Study database lock

QUALITY ASSURANCE

Quality is key to the success of any clinical research institutions and organisations because of the need for high quality clinical research data assurance through efficient management of clinical trial projects. Since 2014, HKU-CTC's Quality Assurance Team (QAT) has established and adopted a robust quality assurance scheme based on the concepts of Total Quality Management and the three pillars of clinical trials (subject protection, scientific validity and data integrity), which comprises

- quality planning and standard establishment;
- execution of quality standards;
- quality evaluation; and
- quality improvement.

QUALITY PLANNING AND STANDARD ESTABLISHMENT

To ensure the quality of clinical studies, QAT established 404 quality documents, including policies (POLs), standard operation procedures (SOPs), working manuals (WOMs) and standard forms (FOMs) in 2015 for HKU-CTC and study sites at QMH.

Quality Documents Issued/Updated in 2015		
Quality Documents	**HKU-CTC**	**Study Sites**
POL	5	32
SOP	44	232
WOM	11	N/A
FOM	80	N/A

EXECUTION OF QUALITY STANDARDS

HKU-CTC's tailor-made and web-based Learning Management System (LMS) is a platform for investigators, clinical research personnel and HKU-CTC staff members to access current internal quality documents and generate training transcripts with just one click. To assist users in familiarising themselves with the quality documents issued and the functionality of the LMS, QAT also provides training and technical support for the LMS to all users.

QUALITY EVALUATION: VENDOR MANAGEMENT SCHEME

To ensure the standards of vendors align with HKU-CTC's quality requirements, QAT implemented a vendor management scheme in 2015. QAT assessed over 30 vendors in 2015 using evaluation forms, vendor questionnaires and on-site assessments.

QUALITY EVALUATION: AUDIT AND INSPECTION

As an internal quality control measure, QAT performed regular internal reviews of HKU-CTC's functional teams and units and facilitated audits and inspections by regulatory authorities and sponsors/CROs.

Five sponsor audits were coordinated in 2015, and the results were satisfactory. Regulatory inspections from the U.S. FDA, and CFDA and Hong Kong Department of Health (HKDOH) are planned for 2016.

Year	U.S. FDA	Japan PMDA	HKDOH	CFDA
1998	√			
2002	√	√		
2004	√			
2006			√	√
2008	√			
2009	√		√	√
2012			√	√
2016	Planned		Planned	Planned

SCIENTIFIC
VALIDITY

DATA
INTEGRITY

SUBJECT PROTECTION

EDUCATION & KNOWLEDGE EXCHANGE

Following the waves of educational and knowledge exchange activities conducted in previous years, HKU-CTC continued to actively participate in educational and knowledge exchange events in 2015.

HKU-CTC'S EDUCATIONAL AND KNOWLEDGE EXCHANGE ACTIVITIES IN 2015

DATE	EVENT	VENUE	ROLE
05-06/12/15	PRACTISE® Workshop	Shanghai, China	Co-organiser & Speaker
26-27/11/15	Regional East Asian Clinical Trial Annual Forum	Chiba, Japan	Supporting Organisation & Speaker
20-21/11/15	2nd International Conference on Phase 1 and Early Phase Clinical Trials New Drug Research for Tomorrow – in Asia and Worldwide (ICPOEP 2015)	Hong Kong, China	Organiser
11/11/15	Study Site Standard Operating Procedures Workshops	Hong Kong, China	Organiser
10/11/15	Study Site Standard Operating Procedures Workshops	Hong Kong, China	Organiser
10/11/15	China GCP and Regulations Workshops	Hong Kong, China	Organiser
06/11/15	PRACTISE® Workshop	Hong Kong, China	Organiser
04/11/15	PRACTISE® Workshop	Hong Kong, China	Organiser
02/11/15	China GCP and Regulations Workshops	Hong Kong, China	Organiser
30/09/15	Symposium on Clinical Research Ethics	Hong Kong, China	Organiser
10-11/09/15	International Clinical Trial Center Network (ICN) Symposium & Inauguration Meeting	Zurich, Switzerland	Steering Board Member & Speaker
27-30/08/15	Seminar of the China Medical University Hospital	Taichung, Taiwan	Speaker
18/05/15	Hong Kong Paediatric Haematology & Oncology Study Group Monthly Scientific Meeting	Hong Kong, China	Speaker
09/05/15	PRACTISE® Workshop	Shenzhen, China	Co-organiser & Speaker
25/03/15	Hong Kong Sanatorium & Hospital Comprehensive Oncology Centre: Phase 1 Oncology Drug Trials in Hong Kong	Hong Kong, China	Session Chair & Speaker
10/03/15	HKU Research Integrity Symposium	Hong Kong, China	Speaker
11/02/15	2015 HA Training Symposium on Clinical Research Compliance: Clinical Research Ethics & Good Clinical Practice	Hong Kong, China	Co-organiser & Speaker
11/02/15	2015 HA Training Symposium on Clinical Research Compliance: Clinical Research Planning	Hong Kong, China	Co-organiser & Speaker
01/02/15	Hong Kong Doctors Union Symposium	Hong Kong, China	Speaker
29/01/15	2015 HA Training Symposium on Clinical Research Compliance: Clinical Research Ethics & Good Clinical Practice	Hong Kong, China	Co-organiser & Speaker
29/01/15	2015 HA Training Symposium on Clinical Research Compliance: Clinical Research Legal & Regulatory Affairs	Hong Kong, China	Co-organiser & Speaker
10/01/15	Kiang Wu Hospital Symposium on Hospital Governance for Clinical Research	Macau, China	Speaker

ON-SITE TRAINING

PRACTISE® WORKSHOPS

HKU-CTC's PRACTISE® programme continued to be popular in 2015. Four PRACTISE® workshops were held in 2015, including two in Hong Kong and two in the Chinese mainland.

The two PRACTISE® workshops conducted in November in QMH specifically targeted the investigators and clinical research personnel of HKU and QMH. More than 200 participants from eight clinical specialties attended the workshops and received practical tips on running clinical trials at their study sites.

To prepare HKU-Shenzhen Hospital (HKU-SZH) to initiate its clinical research activities, a PRACTISE® workshop was held in May 2015 at the hospital. In addition to the staff of HKU-SZH, the workshop attracted clinical research personnel from other hospitals in Hong Kong, Shenzhen and Quanzhou. The concise but comprehensive coverage of the key concepts of good clinical practice and clinical trial operations was greatly appreciated by over 300 participants.

A two-day PRACTISE® workshop was held in Shanghai in December 2015. Sixty-six attendees from 13 cities in China experienced an intensive but interesting learning journey through their active participation in interactive lectures, case studies, group discussions, quizzes and games.

TRAINING WORKSHOPS ON CLINICAL RESEARCH COMPLIANCE

In January and February 2015, the HA commissioned HKU-CTC to organise four clinical research compliance workshops for investigators, study site personnel and staff interested in conducting clinical research. HKU-CTC's experts in legal affairs, regulatory affairs, research ethics and quality assurance presented topics related to clinical research ethics, good clinical practice, clinical research legal and regulatory affairs and clinical research planning. The four workshops together attracted more than 700 participants and received very positive feedback.

TRAINING WORKSHOPS ON CHINA GCP & REGULATIONS

Since 2006, HKU/QMH has been recognised by the CFDA as an accredited drug clinical trial organisation in seven clinical specialties. To update clinical research personnel on the latest China GCP and regulatory requirements and to prepare for applications for accreditation by the CFDA in other clinical specialties, two workshops were held in November 2015. Over 150 investigators, study coordinators, pharmacists and ethics committee members attended the workshops.

TRAINING WORKSHOPS ON STUDY SITE POLICIES AND SOPS

To cope with the dynamic clinical research environment, HKU-CTC developed a new set of study site policies and SOPs for reference by the clinical specialties in HKU/QMH. Two workshops were held in November 2015 to introduce the structure and key content of the new set of documents. The workshops were particularly useful for clinical specialties applying for accreditation by the CFDA.

ON-LINE TRAINING

TRAINING AND RESOURCES IN RESEARCH ETHICS EVALUATION (TRREE)

Since the start of the collaboration with the University of Neuchatel, Switzerland on TRREE in 2014, HKU-CTC has actively promoted this comprehensive online training platform in Asia, particularly in Hong Kong and the Chinese mainland. By the end of 2015, more than 330 users from Hong Kong and the Chinese mainland had registered with TRREE, ranked the second in Asia in terms of the number of users.

The Chinese version of TRREE was launched in 2015 in coordination with National Tsing Hua University in Taiwan with HKU-CTC as an independent reviewer of the translated language. The Chinese version quickly attracted over 270 users from Chinese speaking communities, including Hong Kong, Taiwan and the Chinese mainland.

TRREE


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

GCP EXAMINATION

HKU-CTC continued to run monthly GCP examinations in 2015. By the end of the year, a total of 546 certificates had been issued to investigators, clinical research coordinators and clinical research professionals in Hong Kong.

CONFERENCES, SYMPOSIA AND SEMINARS

INTERNATIONAL CONFERENCE ON PHASE 1 AND EARLY PHASE CLINICAL TRIALS IN 2015 (ICPOEP 2015)

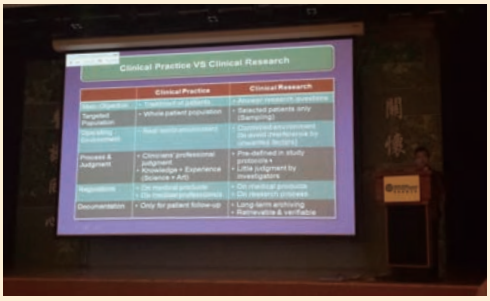
The 2nd International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP 2015) was successfully held on 20–21 November 2015. The conference attracted about 340 participants from five continents who shared ideas about phase 1 and early phase clinical trials and drug development on an international horizon.

In line with the theme of "New Drug Research for Tomorrow – In Asia and Worldwide", 18 distinguished speakers presented a wide range of perspectives. The panel discussion and Q&A sessions also fostered active discussions among speakers, session chairs, panellists and the enthusiastic audience.

The 3rd International Conference on Phase 1 and Early Phase Clinical Trials (ICPOEP 2016) will be held in November 2016. World-renowned experts will again share their insights and wisdom on the future of innovative drug development.

HONG KONG DOCTORS UNION (HKDU) SYMPOSIUM

HKU-CTC was invited to share its views on the clinical research environment and potential development in the private healthcare sector in the Hong Kong Doctors Union Symposium held on 1 February 2015. This symposium was part of the Continuing Medical Education (CME) program of HKDU. Over 100 participants attended the event.



RESEARCH INTEGRITY SYMPOSIUM

The University of Hong Kong Li Ka Shing Faculty of Medicine held a symposium on Clinical Research Ethics: The Rights of the Human Research Subjects on 10 March 2015. Featuring an inspiring keynote lecture on research ethics from historical and legal points of view by Professor Dominique Sprumont of the University of Neuchatel, the founder/coordinator of TRREE, and a presentation on informed consent principles and practice by HKU-CTC's Managing Director, this event concluded successfully with more than 80 participants.

SEMINAR OF THE CHINA MEDICAL UNIVERSITY HOSPITAL (CMUH)

The China Medical University Hospital Ministry of Clinical Trial Center of Excellence held a seminar on 28 August 2015, attracting more than 100 participants, including investigators, clinical research personnel and hospital support staff. Representatives from HKU-CTC shared their experiences on HKU Phase 1 Centre's management and operations and received positive feedback from the audience. The seminar paved the way for a Memorandum of Understanding between CMUH and HKU-CTC in November 2015.

REGIONAL ASIAN CLINICAL TRIAL ANNUAL FORUM (REACTA) 2015

The 3rd Regional Asian Clinical Trial Annual Forum (REACTA) was held by the Chiba University Hospital on 26–27 November 2015 in Chiba, Japan. The two-day forum attracted over 150 attendees from Hong Kong, Taiwan, Korea, Japan, the Philippines and Thailand. Representatives from HKU-CTC talked about the importance of collaboration among clinical trials centres in the region and discussed HKU-CTC's successful expansion regarding the development of an academic research organisation in the past 17 years.

ACADEMIC EXCHANGE AND COLLABORATION

ESTABLISHMENT OF THE INTERNATIONAL CLINICAL TRIAL CENTER NETWORK (ICN)

The ICN was officially established at the inauguration meeting in Zurich, Switzerland on 11 September 2015.

The ICN is an international network of leading academic and government-based clinical trial centres worldwide. Established jointly by 10 reputable founding members from Europe, North America and Asia, the ICN aims to improve the capabilities and quality of clinical research institutions by sharing and exchanging research expertise, experience and capacity and performing collaborative multinational academic clinical research addressing global healthcare needs and challenges. It is anticipated that ICN will continue to grow and attract high-calibre clinical trial centres sharing the same mission and goals.

A Symposium on "Connecting International Excellence in Clinical Research" was held on 10 September 2015 before the inauguration meeting. Senior representatives of the University of Zurich and representatives of the ICN founding members highlighted the latest developments of their centres and the clinical research environments of their places of origin. Over 150 participants attended the meeting and enjoyed the opportunity to interact with global clinical trial management experts.

Founding Members of ICN	
Boston, USA	Harvard Clinical Research Institute (HCRI)
Cambridge, United Kingdom	Cambridge Clinical Trials Unit (CCTU), Cambridge University Hospitals NHS Foundation Trust
Freiburg, Germany	Clinical Trials Unit Freiburg, Albert-Ludwigs-University of Freiburg, University Hospital Freiburg
Hong Kong, China	Clinical Trials Centre, The University of Hong Kong (HKU-CTC)
Istanbul, Turkey	Center of Excellence for Clinical Research, University of Istanbul
Kyoto, Japan	Institute for Advancement of Clinical and Translational Science, Kyoto University and Kyoto University Hospital
Munich, Germany	Munich Study Center, Technical University of Munich
Shanghai, China	Shanghai Clinical Research Center (SCRC)
Singapore	Singapore Clinical Research Institute (SCRI)
Zurich, Switzerland	Clinical Trials Center (CTC), University of Zurich and University Hospital Zurich

THE AFFILIATED HOSPITAL OF GUIZHOU MEDICAL UNIVERSITY (GMUAH)

[28–29 APRIL 2015]

A delegation of five representatives led by the Director of the GCP office of the Affiliated Hospital of Guizhou Medical University, Dr He Yan, visited HKU-CTC during 28–29 April 2015.

Representatives from different functional units of HKU-CTC introduced their daily operations. The delegates were impressed by the centre's team, site management model and clinical research management capabilities. The visit served as a prelude to the collaboration between GMUAH and HKU-CTC.

GUANGDONG PROVINCIAL HOSPITAL OF TRADITIONAL CHINESE MEDICINE (GDHTCM)

[11 DECEMBER 2015]

A delegation of five representatives from Guangdong Provincial Hospital of Traditional Chinese Medicine visited HKU-CTC on 11 December 2015. Delegates from GDHTCM and representatives of HKU-CTC exchanged ideas on clinical research management and explored collaborative opportunities on clinical trial management and investigator-initiated studies.

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 Building 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