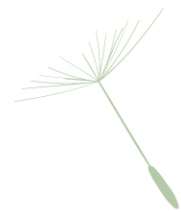
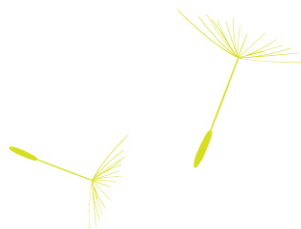
2011-2012
Biennial Report

Clinical Trials Centre
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Mission

Clinical Trials Centre (CTC) of The University of Hong Kong (HKU) aspires to enhancing human healthcare by attracting and facilitating clinical research and safeguarding the core principles of subject protection, scientific validity and data integrity.





Vision

As a unique and innovative academic research organization (ARO) always progressing at the forefront of the international effort to enhance clinical research, CTC offers one-stop clinical research solutions to investigators, clinical trial sponsors, contract research organizations and clinical research organizations. Our professional, high caliber and efficient team attracts and facilitates clinical studies through serious ethical considerations, leading scientific expertise, effective quality assurance and continuous education. CTC is a people-oriented organization. We continue to thrive for better performance and you can only expect nothing but excellence here!

Contents

Chief Director's Letter

Chance favors the prepared mind. Clinical trials are blooming in Asia, and The University of Hong Kong Clinical Trials Centre (CTC) is well prepared to catch the wind!

Clinical trials, being a crucial step bringing new therapies, diagnostics and prophylaxes from bench to bedside, have always been an essential element in medical research and education. Over more than 14 years' development, CTC has become a solid core platform for enhancing and supporting clinical trials in The University of Hong Kong (HKU) and enhancing clinical trial collaboration in Hong Kong, Asia and worldwide.

Years 2011 and 2012 were years of forward change and advancement for CTC. Following the successful governance by the former Board of Director, CTC's governance structure was further enhanced through reorganization into the new Committee of Management comprising 13 members representing all the key stakeholders of clinical trials in HKU and Queen Mary Hospital (QMH), and I am honored to be appointed the Chief Director of CTC.

The clinical trial capability and capacity have been growing in HKU. In early-2011, the Hong Kong Government announced its support to build a Phase 1 Clinical Trials Centre in QMH. Strategically located

in a leading acute care hospital, the HKU Phase 1 Clinical Trials Centre will have 24 beds and be equipped with state-of-the-art facilities and equipment dedicated to supporting phase 1 and clinical pharmacology trials – both in patients and in healthy volunteers. At the same period of time, the HKU Medical Faculty materialized the collaborative project with the Shenzhen Municipal Government in establishing the HKU-Shenzhen Hospital, and also entered into strategic collaboration with GHK Hospital Limited to develop a new private hospital – Gleneagles Hong Kong Hospital – in Wong Chuk Hang, Hong Kong as HKU's affiliate teaching hospital. All these paramount developments will create great value to HKU's clinical trials in terms of scope, impact, quantity, quality and collaboration, and are anticipated to bring CTC to a higher level of success.

Compliance management and continuous education remained a main responsibility of CTC. During the period, CTC successfully facilitated the regulatory inspections by the China State Food and Drug Administration and the Hong Kong Department of Health. PRACTISE™ – a unique and comprehensive training program specifically designed for clinical investigators and clinical study site personnel – was launched and delivered to various institutions, hospitals and governmental organizations in many countries and places in the Asian, Middle East and North African regions.

14-year is not a short period of time, but we take it only as the start. The CTC team will continue to strive for excellence in the challenging global clinical trial environment and contribute to advancement of human healthcare.

I want to specifically thank Professor Sum-ping Lee, the Dean of the Medical Faculty, and Professor Karen Lam, Chairman of CTC, for their full support to CTC and in particular steering the establishment of the HKU Phase 1 Clinical Trials Centre. Last but not the least, I also thank Mr. Henry Yau, Managing Director of CTC, for contributing to the management of CTC over the past 12 years.

Professor Yu-lung Lau

Chief Director

Clinical Trials Centre
The University of Hong Kong

Committee of Management

Chairman

Prof. Karen Lam

- Head, Department of Medicine, HKU
- Chair Professor and Chief of Endocrinology & Metabolism, HKU

Prof. Yu-lung Lau

- Chief Director, Clinical Trials Centre, HKU
- Associate Dean (Research), Li Ka Shing Faculty of Medicine, HKU
- Chair Professor in Paediatrics & Adolescent Medicine, HKU

Prof. Sum-ping Lee

- Dean, Li Ka Shing Faculty of Medicine, HKU

Dr. Che-chung Luk

- Cluster Chief Executive, Hospital Authority Hong Kong West Cluster

Prof. Yiu-fai Cheung

- Assistant Dean (Research), Li Ka Shing Faculty of Medicine, HKU
- Professor in Paediatrics & Adolescent Medicine, HKU

Prof. Daniel Chan

- Chief of Service, Department of Medicine, QMH
- Professor and Chief of Nephrology, HKU

Prof. Bernard Cheung

- Medical Director, HKU Phase 1 Clinical Trials Centre
- Professor in Clinical Pharmacology, HKU

The Committee of Management is the governing body of CTC. Established in January 2012 and evolved from the former CTC Board of Directors, the Committee now comprises 13 members with full representation from all the clinical trial stakeholders in HKU and QMH. The Committee is responsible for formulating the organizational policies for clinical research and overseeing the development, management, quality and financial performance of CTC.

Prof. Pak-chung Ho

- Acting Director, School of Chinese Medicine, HKU
- Chair Professor in Obstetrics & Gynaecology, HKU

Prof. Ching-wan Lam

- Director of Pharmacokinetics & Drug Metabolism, HKU Phase 1 Clinical Trials Centre
- Professor in Chemical Pathology, HKU

Dr. David Siu

- Associate Professor in Cardiology, HKU

Prof. Sidney Tam

- Service Director (Pathology), Hospital Authority Hong Kong West Cluster
- Deputy Hospital Chief Executive, QMH

Prof. Ian Wong

- Head, Department of Pharmacology & Pharmacy, HKU

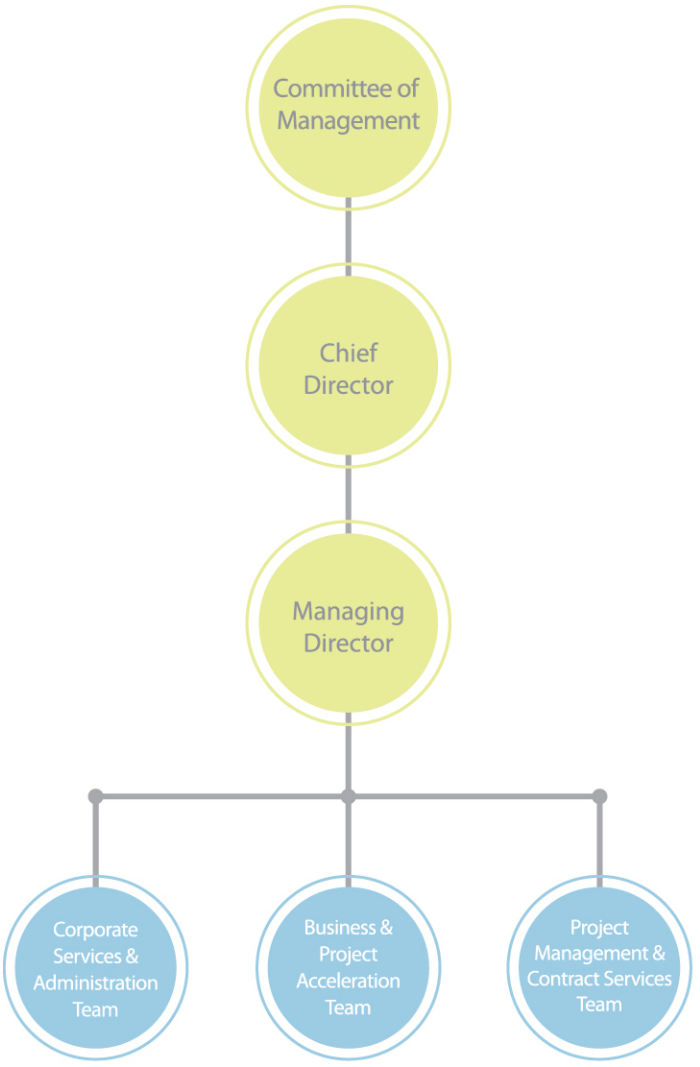
Mr. Henry Yau

- Managing Director, Clinical Trials Centre, HKU

Governance Framework

Re-organization of CTC

In response to the rapid development of the clinical research activities in HKU, CTC was reorganized into three functional teams comprising eight operating units. This new structure strengthens the communication and cooperation among CTC's personnel and enhances efficient management of clinical research in HKU.



Chairman

Professor Karen Lam, the Head of HKU Department of Medicine and Chair Professor and Chief of Endocrinology and Metabolism, was appointed the Chairman of the newly established CTC Committee of Management in January 2012. Professor Lam was also the Chairman of the former CTC Board of Director during the periods of 2002-2006 and 2010-2011. Her significant contribution to a multinational clinical trial in a new drug for type 2 diabetes mellitus drew appreciation by the U.S. FDA following a successful inspection in year 2002 (i.e. No Action Indicated).

Chief Director

In January 2012, Professor Yu-lung Lau was appointed the Chief Director of CTC. Professor Lau is the Chair Professor in Paediatrics and Adolescent Medicine and the Associate Dean (Research) of the HKU Faculty of Medicine, and also the former Head of HKU Department of Paediatrics and Adolescent Medicine during 1999 to 2012. His research team for a multinational clinical trial in a novel rotavirus vaccine for children successfully recruited over 1,800 paediatric subjects in Hong Kong. His great contribution in terms of quantity and quality of study data resulted in publications in high impact scientific journals (e.g. Vaccine 2013 (in press); Vaccine 2012;30(30):4552-7; Vaccine 2009;27(43):5936-41). The large recruitment number is still a Hong Kong record in terms of subject recruitment from a single site for industry-sponsored clinical drug trials.

Managing Director

Mr. Henry Yau, formerly CTC's Assistant Director and Chief Business Officer, was appointed the Managing Director from April 2012. Mr. Yau began his service in the pharmaceutical industry in 1993 and joined CTC in year 2000. Over the past 12 years, he designed and developed the effective and efficient site management model – BPAT (Business and Project Acceleration Team) – and established research collaboration with over 130 pharmaceutical, biopharmaceutical and medical device companies worldwide through some 650 sponsored clinical studies.

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

Business Consultation	Clinical Trial Insurance Arrangement	Project Coordination	Study Monitoring	Data Management
Scientific & Clinical Consultation	Contract Management & Legal Affairs	Clinical Research Personnel Training	Study Payment Management	Medical Statisticals
Feasibility Assessment	Study Budgeting	Subject Recruitment	Information Technology Support	Study Report Write-up
Protocol Development	Regulatory Affairs	Central Laboratory Management	Study Site Operational Support	Study Drug Disposal
Project Management	Ethics Affairs	Specimen Management	Study Drug Management	Study Site Document Archiving

Our 650 clinical trial projects have been benefited from CTC's tailored clinical trial solutions over the past 14 years!

Performance Overview

Industry-sponsored Clinical Studies

Years 2011 and 2012 continued the success of previous years. By the end of 2012, the cumulative number of contracted industry-sponsored studies reached 681, of which 213 were active.

	2012	2011	2010
Contracted Industry-sponsored Clinical Studies			
New Studies	57	55	50
Cumulative Studies	681	624	569
Active Studies	213	207	206
Distribution of New Studies by Research Areas (Top 5)			
1	Oncology (37%)	Oncology (38%)	Oncology (46%)
2	Haematology (6%)	Cardiovasculology (18%)	Cardiovasculology (16%)
3	Neurology (9%)	GI & Hepatology (7%)	GI & Hepatology (6%)
4	GI & Hepatology (7%)	Nephrology (5%)	Endocrinology (6%)
5	Cardiovasculology (6%)	Ophthalmology (5%)	Orthopaedics & Traumatology (6%)
Distribution of New Studies by Study Phases			
I	5%	4%	6%
II	25%	25%	22%
III	59%	42%	54%
IV	0%	9%	6%
Others	11%	20%	12%

Investigator-initiated Clinical Studies

Following the success in establishing a management system for industry-sponsored clinical studies since 1998, CTC has been delegated to oversee contractual and risk management issues and provide other professional supports for investigator-initiated clinical studies since November 2009. The number of active investigator-initiated studies coordinated by CTC has then been increasing steadily to 35 by the end of 2012.

	2012	2011	2010
Confirmed Investigator-initiated Clinical Studies			
New Studies	10	16	4
Cumulative Studies	35	25	9
Active Studies	30	20	5
Distribution of New Studies by Research Areas (Top 3)			
1	Cardiology (20%)	GI & Hepatology (38%)	Nephrology (67%)
2	Obstetrics & Gynaecology (20%)	Nephrology (13%)	Neurology (33%)
3	GI & Hepatology (10%)	Obstetrics & Gynaecology (13%)	

Collaborative Trial Sponsors

Abbott
Achillion
Actelion
Advanced Herbal Therapeutics
Aegera
Alcon
Algeta
Allergan
Allos
Altana Pharma
Amgen
Anaborex
Anthera
AO Foundation
AOSpine
ARIAD
Arrow
Artisan
Astellas
AstraZeneca
BARRX
Baxter
Bayer
BCIRG
Bio-cancer
Biocompatibles
BioCryst
Biogen idec
Biomeasure
Biosensors
Boehringer Ingelheim
Boston Scientific
BrainsGate
Bristol-Myers Squibb
Bukwang
Celltech
Celsion
CK Life Sciences
Codman
Cook
Critical Biologics
Daiichi Sankyo
DePuy
EBR System
Eisai
Eli Lilly
Ellipse
Enteromedics
EVER Neuro Phama
Everpride
FibroGen
Galderma
Genentech
Gilead
GlaxoSmithKline
Guidant
Idenix
ImClone
Ipsen
Johnson & Johnson
Keryx
Kinex
Kowa
La Jolla
Lee's
LEO
LG Life Sciences
Light Sciences
Luitpold
Lundbeck
Medigen
MedImmune
Medtronic
Medwaves
Merck KGaA
Merck Sharp & Dohme
Morphotek
NIDEK
Novartis
Novo Nordisk
Nycomed
OrbusNeich
Organon
Orygen
OSI
Penumbra
Pfizer
Pharmasset
Pi Medical
PowderMed
Progen
Retina Implant
Roche
sanofi-aventis
Schering Plough
Scios
Servier
SFJ
St. Francis
St. Jude Medical
Synthes
Taiho
Takeda
Theravance
TTY Biopharm
Tularik
Tyco
UCB
Vigconic
VitaGreen
Wealthy Creative
Wyeth
Xanthus Life Sciences
Zila

Industry-sponsored Clinical Studies Contracted in 2011 and 2012

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Department	Study Site*
Cardiovasculology	Acute Coronary Syndrome	O	Professor Stephen WL Lee	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Cardiovascular Events	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Coronary Artery Lesions	O	Professor Stephen WL Lee	Medicine	QMH
Cardiovasculology	Familial Hypercholesterolemia	III	Dr. KH Yiu	Medicine	QMH
Cardiovasculology	Heart Failure	O	Dr. HW Chan	Medicine	QMH
Cardiovasculology	Heart Failure	O	Professor HF Tse	Medicine	QMH
Cardiovasculology	Hypercholesterolemia	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Hypertension	III	Dr. KH Yiu	Medicine	QMH
Cardiovasculology	Hypertension	O	Dr. Carmen WS Chan	Medicine	QMH
Cardiovasculology	Pacing	O	Dr. Katherine Fan	Medicine	GRH
Cardiovasculology	Percutaneous Coronary Intervention	O	Professor Stephen WL Lee	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Dr. David CW Siu Professor Bernard MY Cheung	Medicine Medicine	QMH QMH
Endocrinology	Diabetes Mellitus	III	Professor Kathryn TB Tan	Medicine	QMH
Endocrinology	Diabetes Mellitus	IV	Dr. WS Chow	Medicine	QMH
Endocrinology	Hyperlipidemia	III	Dr. CY Yeung	Medicine	QMH
Endocrinology	Osteoporosis	III	Dr. YC Woo	Medicine	QMH
Gastroenterology & Hepatology	Crohn's Disease	II	Professor WK Leung	Medicine	QMH
Gastroenterology & Hepatology	Crohn's Disease	III	Professor WK Leung	Medicine	QMH
Gastroenterology & Hepatology	Crohn's Disease	III	Professor WK Leung	Medicine	QMH
Gastroenterology & Hepatology	Crohn's Disease	III	Professor WK Leung	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	IV	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis C	II	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor MF Yuen	Medicine	QMH
Haematology	Chronic Immune Thrombocytopenic Purpura	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH
Haematology	Diffuse Large B-cell Lymphoma	I	Professor YL Kwong	Medicine	QMH
Haematology	Diffuse Large B-cell Lymphoma	II	Professor YL Kwong	Medicine	QMH
Haematology	Leukemia	I	Professor YL Kwong	Medicine	QMH
Haematology	Lymphoma	I	Professor YL Kwong	Medicine	QMH
Haematology	Multiple Myeloma	I	Professor CS Chim	Medicine	QMH
Haematology	Multiple Myeloma	III	Professor YL Kwong	Medicine	QMH
Haematology	Hemophilia A	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH
Haematology	Hemophilia A	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH
Haematology	Hemophilia A	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH
Haematology	Hemophilia B	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH

Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Department	Study Site*
Haematology	Hemophilia B	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	II	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	II	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Systemic Lupus Erythematosus	II	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Systemic Lupus Erythematosus	II	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Systemic Lupus Erythematosus	II	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Systemic Lupus Erythematosus	II	Professor CS Lau	Medicine	QMH
Infectious Diseases	Complicated Bacterial Skin and Soft Tissue Infections	III	Dr. George KH Li	Surgery	QMH
Infectious Diseases	Complicated Bacterial Skin and Soft Tissue Infections	III	Dr. Ivan FN Hung	Medicine	QMH
Infectious Diseases	Herpes Zoster	III	Professor Albert KW Lie	Medicine	QMH
Infectious Diseases	HPV Infection	III	Professor YL Lau	Paediatrics & Adolescent Medicine	QMH
Infectious Diseases	Postherpetic Neuralgia	III	Dr. CW Cheung	Anaesthesiology	QMH
Nephrology	Chronic Kidney Disease	II	Professor TM Chan	Medicine	QMH
Nephrology	Diabetic Nephropathy	II	Professor Sydney CW Tang	Medicine	QMH
Nephrology	Lupus Nephritis	II	Professor TM Chan	Medicine	QMH
Nephrology	Renal Transplant	IV	Professor TM Chan	Medicine	QMH
Nephrology	Systemic Lupus Erythematosus	I	Professor TM Chan	Medicine	QMH
Neurology	Alzheimer's Disease	III	Professor LW Chu	Medicine	QMH
Neurology	Idiopathic Cervical Dystonia	O	Professor SL Ho	Medicine	QMH
Neurology	Seizures	III	Professor Raymond TF Cheung	Medicine	QMH
Neurology	Seizures	III	Professor Raymond TF Cheung	Medicine	QMH
Neurology	Seizures	III	Professor Raymond TF Cheung	Medicine	QMH
Neurology	Seizures	III	Professor Raymond TF Cheung	Medicine	QMH
Obstetrics & Gynaecology	Contraception	III	Dr. Ernest HY Ng	Obstetrics & Gynaecology	QMH
Oncology	Acute Venous Thromboembolism	III	Dr. Steven WK Siu	Clinical Oncology	QMH
Oncology	Breast Cancer	II	Dr. Janice WH Tsang	Clinical Oncology	QMH
Oncology	Breast Cancer	II	Dr. Thomas CC Yau	Medicine	QMH
Oncology	Breast Cancer	II	Dr. Ava Kwong Dr. Janice WH Tsang	Surgery Clinical Oncology	QMH QMH
Oncology	Breast Cancer	II	Dr. Janice WH Tsang	Clinical Oncology	QMH
Oncology	Breast Cancer	III	Dr. Janice WH Tsang Dr. Thomas CC Yau	Clinical Oncology Medicine	QMH QMH
Oncology	Breast Cancer	III	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	Surgery Clinical Oncology	QMH QMH
Oncology	Breast Cancer	IV	Dr. Janice WH Tsang	Clinical Oncology	QMH
Oncology	Breast Cancer	O	Dr. Thomas CC Yau	Medicine	QMH
Oncology	Colorectal Cancer	III	Dr. Thomas CC Yau	Medicine	QMH
Oncology	Colorectal Cancer	III	Dr. Thomas CC Yau	Medicine	QMH

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

* Study Site: GRH :Grantham Hospital
QMH:Queen Mary Hospital
UCH :United Christian Hospital

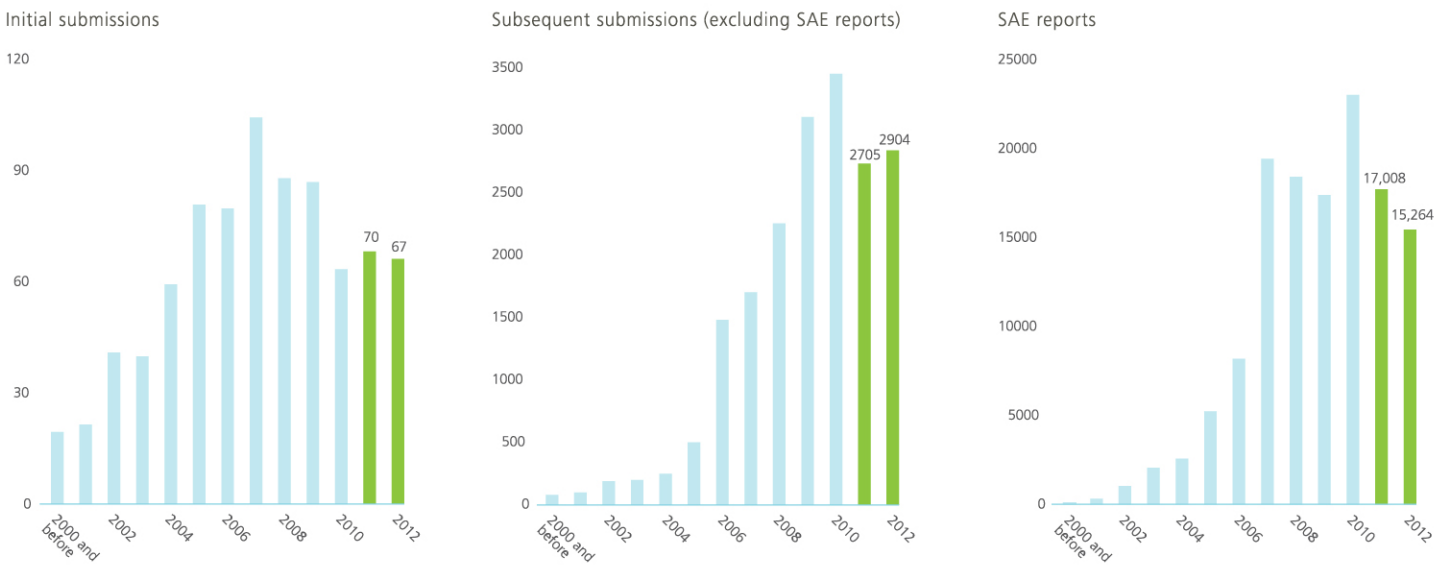
Therapeutic Area	Disease Area	Study Phase#	Principal Investigator	Department	Study Site*
Oncology	Fallopian Tube Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Gastric Cancer	II	Dr. Thomas CC Yau	Medicine	QMH
Oncology	Gastroesophageal Cancer	III	Dr. Victor HF Lee	Clinical Oncology	QMH
Oncology	Gastroesophageal Cancer	O	Professor KM Chu	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Lung Cancer	II	Dr. James CM Ho	Medicine	QMH
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology	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. Victor HF Lee	Clinical Oncology	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. Victor HF Lee	Clinical Oncology	QMH
Oncology	Lung Cancer	III	Dr. Victor HF Lee	Clinical Oncology	QMH
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Ovarian Cancer	0	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Prostate Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH
Oncology	Renal Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH
Ophthalmology	Glaucoma	III	Professor Jimmy SM Lai	Eye Institute	QMH
Ophthalmology	Retinal Degeneration Blindness	0	Professor David Wong	Eye Institute	QMH
Ophthalmology	Retinal Thickness Diagnosis	0	Dr. Kenneth Li	Ophthalmology	UCH
Orthopaedics & Traumatology	Fracture Healing	III	Dr. Frankie KL Leung	Orthopaedics & Traumatology	QMH
Orthopaedics & Traumatology	Fracture Healing	0	Dr. Frankie KL Leung	Orthopaedics & Traumatology	QMH
Orthopaedics & Traumatology	Osteonecrosis of Hip	III	Professor Peter KY Chiu	Orthopaedics & Traumatology	QMH
Orthopaedics & Traumatology	Scoliosis	0	Professor Kenneth MY Cheung	Orthopaedics & Traumatology	QMH
Orthopaedics & Traumatology	Spinal Deformity	0	Professor Kenneth MY Cheung	Orthopaedics & Traumatology	QMH
Pain Management	Cancer Pain	II	Dr. CW Cheung	Anaesthesiology	QMH
Pain Management	Cancer Pain	II	Dr. CW Cheung	Anaesthesiology	QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr. David CL Lam	Medicine	QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	IV	Dr. David CL Lam	Medicine	QMH
Respiratory Medicine	Community Acquired Pneumonia	0	Dr. Ivan FN Hung	Medicine	QMH

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

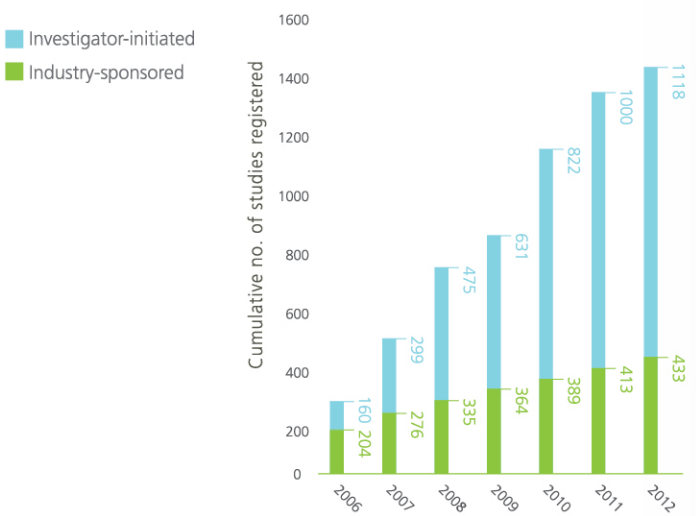
* Study Site: GRH :Grantham Hospital
QMH:Queen Mary Hospital
UCH :United Christian Hospital

Project Coordination and Ethics Submissions

During the 2-year period, CTC's Project Coordination Unit (PCU) continued to strive for excellence in facilitating study site logistical arrangements and communications between sponsors, investigators and ethics committees. At the end of 2012, 273 sponsored clinical studies were being coordinated by the PCU. 137 initial applications and 37,881 subsequent submissions were compiled and made to the ethics committees.



Submissions to ethics committees



Clinical studies registered at the HKU Clinical Trials Registry

Clinical Trials Registries

The HKU Clinical Trial Registry – www.HKClinicalTrials.com – continued to serve as an important open platform for providing updated information about clinical research in Hong Kong to clinical research personnel, medical professionals and the general public. Since its establishment in 2006, the number of clinical studies registered with the HKU Clinical Trials Registry has been increasing steadily to 1,551 by end-2012.

CTC has also been the account administrator for HKU's organizational account with the U.S. Clinical Trial Registry – www.ClinicalTrials.gov. Over the years, 91 user accounts have been opened under the HKU organizational account and 138 clinical studies have been registered.

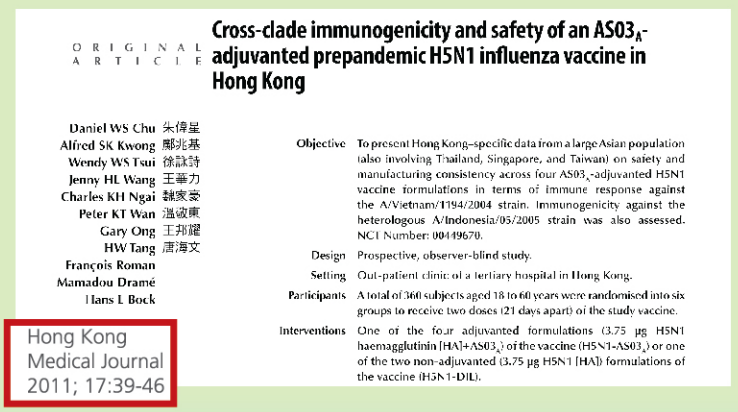
Clinical Research Coordinator (CRC) Supports

CRCs are important members of successful clinical study teams, taking major roles in the efficient and effective operations of clinical studies – from pre-study preparation to subject recruitment, study visit scheduling, logistics coordination, study procedure arrangement and implementation, case report form completion, study document management, and facilitation of monitoring, auditing and inspections. CTC has a team of qualified and well-trained CRCs who are prepared to offer professional study coordination supports to investigators and study sites. During 2011 and 2012, CTC's CRCs have offered major supports for multinational sponsored clinical studies at four public and private hospitals in Hong Kong involving a total of 383 subjects.

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

Successful completion of a vaccine study in healthy volunteers

During 2007 to 2011, CTC collaborated with Dr. Daniel WS Chu, the then Cluster Service Coordinator of the Hospital Authority Hong Kong East and West Clusters in Family Medicine and Primary Healthcare, in conducting a phase III, multicentre H5N1 influenza vaccine study in healthy volunteers. The success in subject recruitment and smooth completion of the study was attributable to the experience and efforts of Dr. Chu's research team and CTC's CRCs. The important results and high quality data of the study led to publications in two scientific journals.



ORIGINAL ARTICLE

Cross-clade immunogenicity and safety of an AS03$_A$-adjuvanted prepandemic H5N1 influenza vaccine in Hong Kong

Daniel WS Chu 朱偉呈
Alfred SK Kwong 鄺兆基
Wendy WS Tsui 徐詠詩
Jenny HL Wang 王華力
Charles KH Ngai 魏家豪
Peter KT Wan 溫啟東
Gary Ong 王邦耀
HW Tang 唐海文
François Roman
Mamadou Dramé
Hans L Bock

Objective To present Hong Kong–specific data from a large Asian population (also involving Thailand, Singapore, and Taiwan) on safety and manufacturing consistency across four AS03$_A$-adjuvanted H5N1 vaccine formulations in terms of immune response against the A/Vietnam/1194/2004 strain. Immunogenicity against the heterologous A/Indonesia/05/2005 strain was also assessed. NCT Number: 00449670.

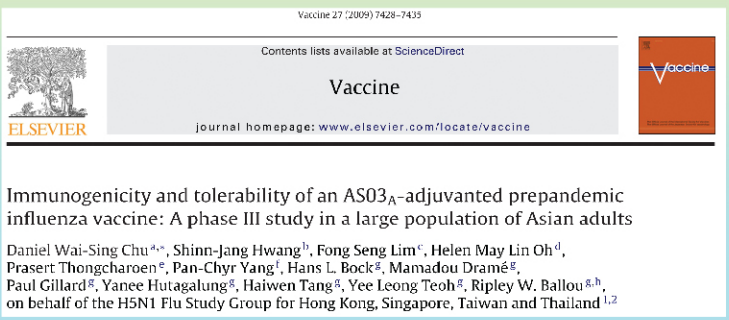
Design Prospective, observer-blind study.

Setting Out-patient clinic of a tertiary hospital in Hong Kong.

Participants A total of 360 subjects aged 18 to 60 years were randomised into six groups to receive two doses (21 days apart) of the study vaccine.

Interventions One of the four adjuvanted formulations (3.75 μg H5N1 haemagglutinin [HA]+AS03$_A$) of the vaccine (H5N1-AS03$_A$) or one of the two non-adjuvanted (3.75 μg H5N1 [HA]) formulations of the vaccine (H5N1-DIL).

Hong Kong Medical Journal 2011; 17:39-46



Vaccine 27 (2009) 7428–7435

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/vaccine

Immunogenicity and tolerability of an AS03$_A$-adjuvanted prepandemic influenza vaccine: A phase III study in a large population of Asian adults

Daniel Wai-Sing Chu[a,*], Shinn-Jang Hwang[b], Fong Seng Lim[c], Helen May Lin Oh[d], Prasert Thongcharoen[e], Pan-Chyr Yang[f], Hans L. Bock[g], Mamadou Dramé[g], Paul Gillard[g], Yanee Hutagalung[g], Haiwen Tang[g], Yee Leong Teoh[g], Ripley W. Ballou[g,h], on behalf of the H5N1 Flu Study Group for Hong Kong, Singapore, Taiwan and Thailand[1,2]

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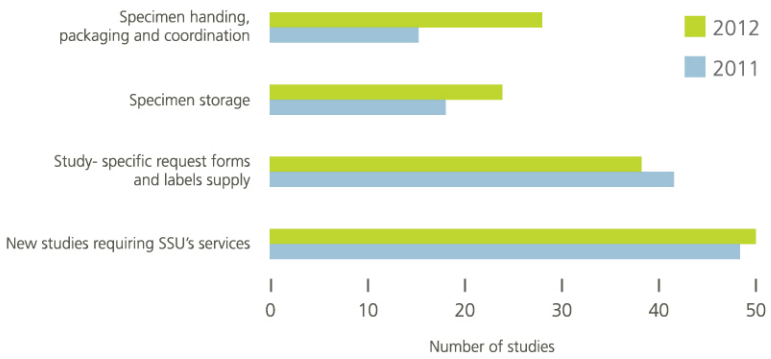

Specimen management services provided during 2011 and 2012

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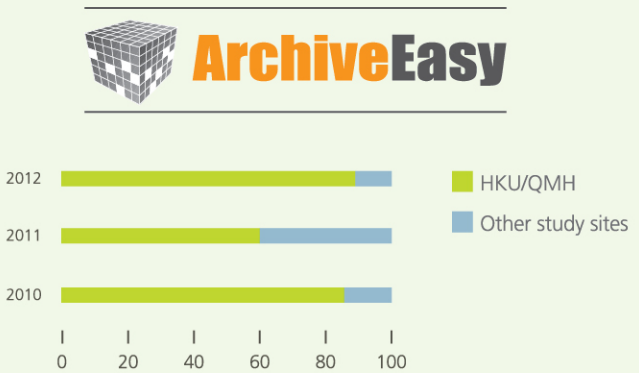

Percentage distribution of study sites using ArchiveEasy™ service

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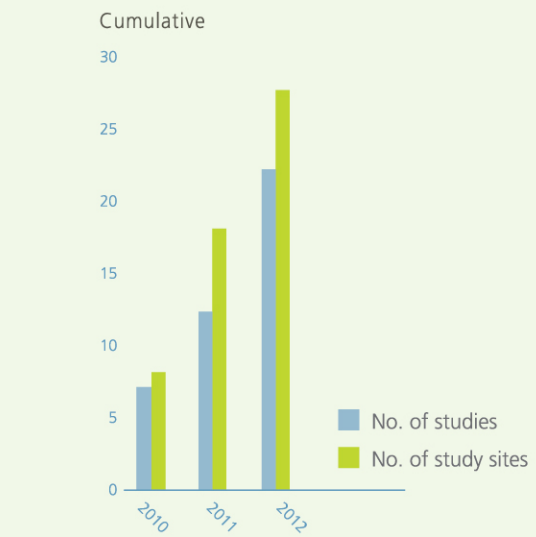
CTC's SSU collaborates with the QMH Department of Pharmacy in offering drug management services – including receipt, storage, processing, dispensing and accountability – in support of clinical drug trials conducted in HKU/QMH. Its newly launched drug disposal service – MedDrop™ – provides a one-stop platform for proper disposal of study drugs locally in Hong Kong, evidenced by a complete set of disposal records in full compliance with local regulatory requirements. MedDrop™ service is available for supporting study sites anywhere in Hong Kong.

MedDrop



Number of studies / study sites using ArchiveEasy™ service

Contract Research Services

CTC's Project Management & Contract Services Team offers comprehensive contract research services to sponsors and investigators, both locally and internationally. The comprehensive services include but not limited to protocol development, regulatory affairs, study set-up and management, study site monitoring, study data management and medical statistical analysis.

During the 2-year period, our contract research services have covered 23 local and international clinical studies involving 27 study sites in Hong Kong.

Study Monitoring

10 studies
19 sites

Data Management/ Medical Statistics Analysis

7 studies

Comprehensive Contract Research Services

6 studies
8 sites

From start to finish,

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 a regulatory application but without a local representitve?	CTC offers tailored, comprehensive contract research services, including regulatory application, which suit your needs.
Lose your clinical research 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.

CTC is here to help!


Subject Protection
Scientific Validity
Data Integrity

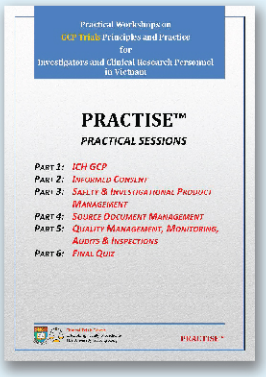
Education Portfolio

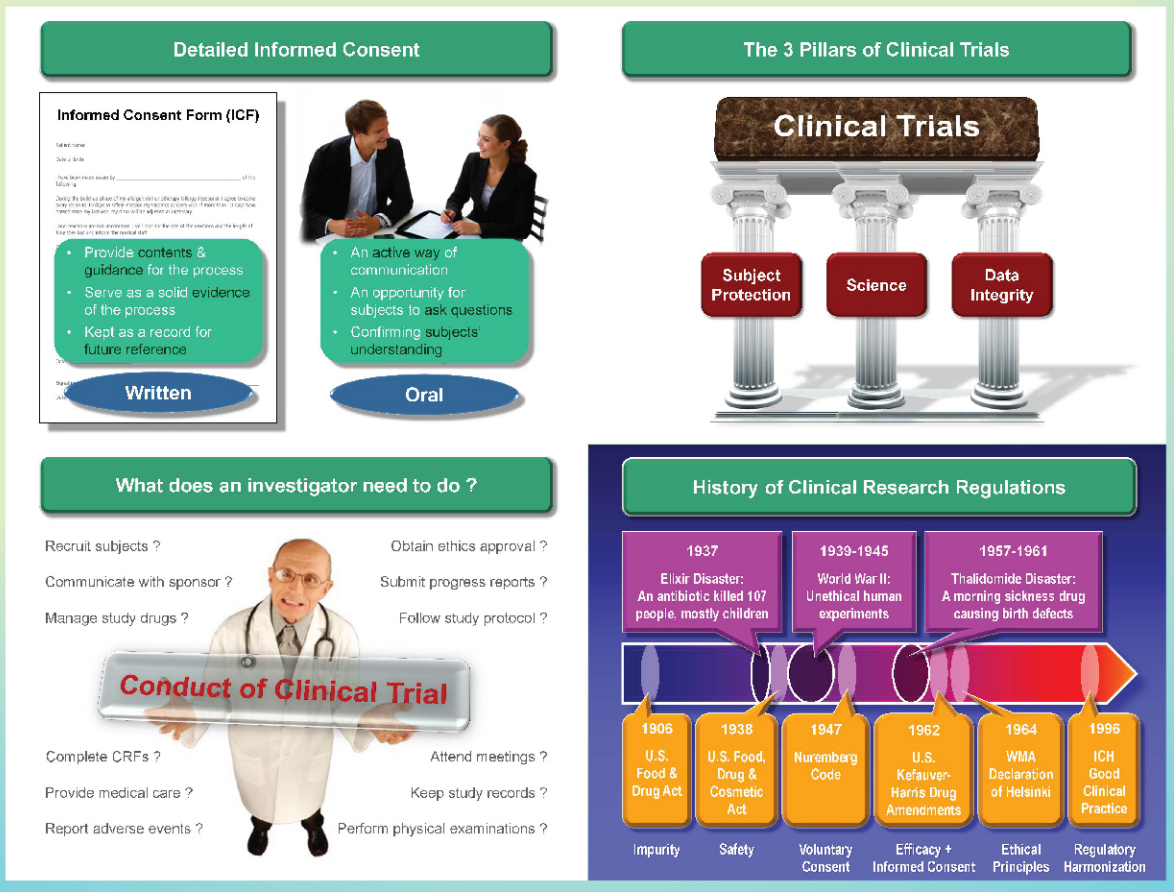
PRACTISE™

In April 2012, CTC launched its unique, comprehensive training program called PRACTSE™ (Professional Research Accreditation for Clinical Trials Investigative Site Executives). PRACTISE™ is specifically designed for meeting the practical needs of investigators, study coordinators and other study site personnel. The program comprises 25 teaching modules, each lasting for 15 to 60 minutes, and could be supplemented by practical sessions including case studies and quizzes. PRACTISE™ is highly welcomed by study site personnel within and outside Hong Kong and has quickly gained popularity in just a few months.

PRACTISE

Professional Research Accreditation for Clinical Trials Investigative Site Executives





Practical Workshop on GCP Trials Principles & Practice for Investigators & Clinical Research Personnel in MENA

Since mid-2012, CTC has entered into a strategic training collaboration with an international pharmaceutical company in conducting commissioned training workshops for investigators and study site personnel in the Asian and MENA regions based on CTC's PRACTISE™ program. The first workshop was conducted in Cairo, Egypt in September 2012. The 2-day workshop comprised lectures and practical sessions, and was highly appreciated by the participants.

Practical Workshop on Study Design and Statistical Analysis in Clinical Research

In December 2012, a Practical Workshop on Study Design and Statistical Analysis was organized in collaboration with the Hong Kong Urological Association. CTC's clinical research and medical statistics professionals gave an overview on clinical study designs and medical statistics to 25 urology specialists.

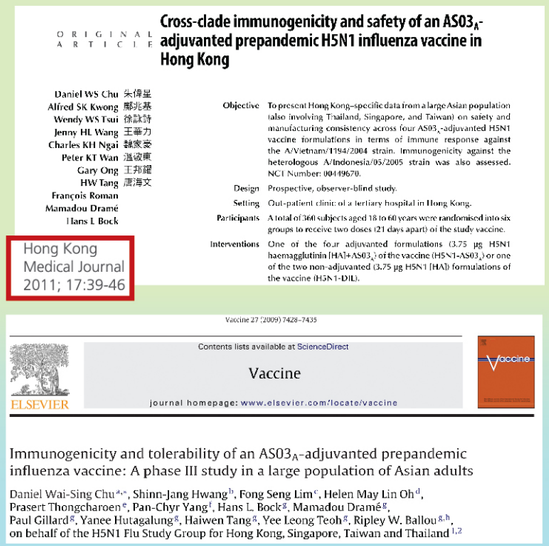
Clinical Research Coordinator (CRC) Supports

CRCs are important members of successful clinical study teams, taking major roles in the efficient and effective operations of clinical studies – from pre-study preparation to subject recruitment, study visit scheduling, logistics coordination, study procedure arrangement and implementation, case report form completion, study document management, and facilitation of monitoring, auditing and inspections. CTC has a team of qualified and well-trained CRCs who are prepared to offer professional study coordination supports to investigators and study sites. During 2011 and 2012, CTC's CRCs have offered major supports for multinational sponsored clinical studies at four public and private hospitals in Hong Kong involving a total of 383 subjects.

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

Successful completion of a vaccine study in healthy volunteers

During 2007 to 2011, CTC collaborated with Dr. Daniel WS Chu, the then Cluster Service Coordinator of the Hospital Authority Hong Kong East and West Clusters in Family Medicine and Primary Healthcare, in conducting a phase III, multicentre H5N1 influenza vaccine study in healthy volunteers. The success in subject recruitment and smooth completion of the study was attributable to the experience and efforts of Dr. Chu's research team and CTC's CRCs. The important results and high quality data of the study led to publications in two scientific journals.


ORIGINAL ARTICLE

Cross-clade immunogenicity and safety of an AS03$_A$-adjuvanted prepandemic H5N1 influenza vaccine in Hong Kong

Daniel WS Chu 朱偉呈
Alfred SK Kwong 鄺兆基
Wendy WS Tsui 徐詠詩
Jenny HL Wang 王華力
Charles KH Ngai 魏焌基
Peter KT Wan 溫卓庭
Gary Ong 王邦躍
HW Tang 唐海文
François Roman
Mamadou Dramé
Hans L Bock

Objective: To present Hong Kong–specific data from a large Asian population (also involving Thailand, Singapore, and Taiwan) on safety and manufacturing consistency across four AS03$_A$-adjuvanted H5N1 vaccine formulations in terms of immune response against the A/Vietnam/1194/2004 strain. Immunogenicity against the heterologous A/Indonesia/05/2005 strain was also assessed. NCT Number: 00449670.

Design: Prospective, observer-blind study.

Setting: Out-patient clinic of a tertiary hospital in Hong Kong.

Participants: A total of 360 subjects aged 18 to 60 years were randomised into six groups to receive two doses (21 days apart) of the study vaccine.

Interventions: One of the four adjuvanted formulations (3.75 μg H5N1 haemagglutinin [HA]-AS03$_A$) of the vaccine (H5N1-AS03$_A$) or one of the two non-adjuvanted (3.75 μg H5N1 [HA]) formulations of the vaccine (H5N1-DIL).

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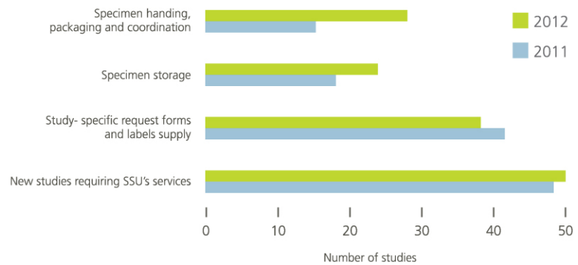

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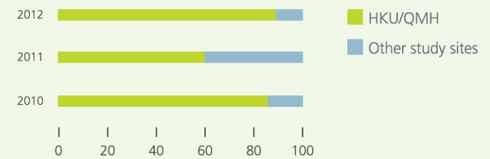
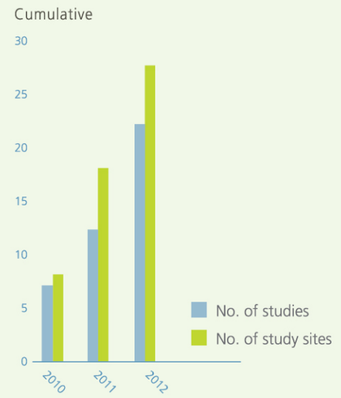


Percentage distribution of study sites using ArchiveEasy™ service



Number of studies / study sites using ArchiveEasy™ service

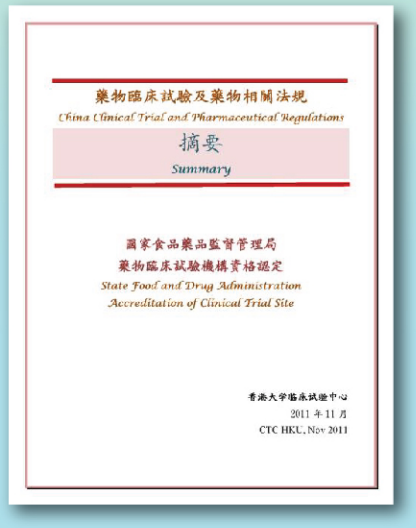
Medical Ethics Forum and Workshop for Preparing Macau for International Clinical Research

Macau is getting more active in clinical research! To support the development of clinical research in Macau, CTC facilitated the Medical Ethics Forum in September 2011 and the Workshop for Preparing Macau for International Clinical Research in February 2012 on the invitation of the Centro Hospitalar Conde de Sao Januario. CTC's clinical research experts shared their views and experience to the hospital's investigators and medical professionals interested in clinical research.

Training on China Regulations and GCP

Compliance with China regulations for clinical trials is one of the key requirements under the accreditation for clinical drug trials by the China State Food and Drug Administration (SFDA). In order to refresh and strengthen the knowledge of investigators and study site personnel in China regulations for clinical trials, CTC developed a "China Clinical Trial and Pharmaceutical Regulations Summary Booklet" which includes major elements of China regulations on new drug registration and clinical trials. A comparison table between ICH-GCP and China GCP is also listed for reference.

In addition to the Summary Booklet, four training workshops on China GCP and relevant regulations were conducted for investigators and study sites personnel of the accredited specialties in 2012.



Highlights of Years 2011 and 2012

International Collaboration with the Industry

Supporting Novel Drug Development by a Hong Kong Biopharmaceutical Company

CTC and investigators of HKU have been collaborating with Bio-Cancer Treatment International Limited (BCT) in conducting clinical trials of a novel biological drug, PEG-BCT-100, since year 2005. BCT is a biopharmaceutical company based in Hong Kong and has been developing PEG-BCT-100, pegylated recombinant human arginase 1 (Peg-rhArg1), for oncology therapies. Peg-rhArg1 has been granted the status of "Investigational New Drug (IND)" from the U.S. Food and Drug Administration (FDA), which means that it can go into clinical trials in the U.S.

The phase 1 dose-escalating study of Peg-rhArg1 in patients with advanced hepatocellular carcinoma has led to a publication in a scientific journal in 2012. The fruitful collaboration between BCT and CTC demonstrates the great value of industry-academic research collaboration in novel drug development.

Invest New Drugs
DOI 10.1007/s10637-012-9807-9

PHASE I STUDIES

A phase 1 dose-escalating study of pegylated recombinant human arginase 1 (Peg-rhArg1) in patients with advanced hepatocellular carcinoma

Thomas Yau · P. N. Cheng · Pierre Chan · William Chan · Li Chen · Jimmy Yuen · Roberta Pang · S. T. Fan · Ronnie T. Poon

Received: 5 January 2012 / Accepted: 22 February 2012

Summary *Background* Hepatocellular carcinoma (HCC) cells are auxotrophic for arginine, depletion of which leads

haematological adverse events (AEs) were diarrhea (13.3%), abdominal discomfort (6.7%) and nausea (6.7%). No drug-

Partner Site Alliance with Quintiles

Following over a decade's collaboration in industry-sponsored clinical trials, Quintiles and CTC entered into a partner site alliance in June 2012. The tightened collaboration is anticipated to increase clinical research opportunities for Hong Kong and bring further success to industry-sponsored clinical trials at HKU.

International Collaboration with Academic Institutions

Visit to Regional Clinical Trial Center of Dong-A University Hospital (DAUH) in Busan, Korea

In October 2012, CTC's Managing Director, Mr. Henry Yau, was invited by DAUH to officiate the opening of its new Regional Clinical Trial Center and as a speaker in its first Clinical Trial Symposium.

Representatives of DAUH visited CTC in 2010. Impressed by CTC's unique BPAT model (Business & Project Acceleration Team) for clinical trials centre management, DAUH subsequently adopted the idea and established its own BPAT team.

The shared vision and open exchange among research centres in Asia are anticipated to create tighter collaboration and enhance Asia's competitiveness in clinical research.

Forum for Clinical Trial Center Excellence in Beijing, China

The Forum for Clinical Trial Excellence was jointly organized by the First Affiliated Hospital of Peking University, the Chinese Pharmacological Society and Bayer Healthcare in November 2011 in Beijing, China. Mr. Henry Yau, the then Assistant Director of CTC, participated as a speaker and shared CTC's experience in managing a clinical study site management organization (SMO).

Collaboration in Clinical Research and Training with University of Zurich and University Hospital Zurich

In December 2012, CTC entered into a Memorandum of Understanding with the Clinical Trials Center of the University of Zurich and the University Hospital Zurich to promote knowledge exchange, training and education in clinical research. The collaboration is anticipated to encourage open exchange of experience in clinical research management between Europe and Asia. The first knowledge exchange event – the Zurich-Shanghai-Hong Kong Tripartite Clinical Research Workshop – is being planned and will be conducted in Zurich in August 2013.

Quality Assurance

Inspection by China SFDA

Seven clinical specialties of QMH have obtained the SFDA's accreditation for clinical drug trials since August 2006. In September 2012, the SFDA performed a regulatory re-inspection on selected specialties, hospital pharmacy, ethics committee and CTC. CTC's established central management model is deemed an essential infrastructure securing compliance and quality management for clinical trials.

Inspection by Hong Kong Department of Health

In line with the increasing importance of clinical trials in Hong Kong, the Hong Kong Department of Health performed its first formal regulatory inspection in March 2012 for a clinical trial conducted under the HKU Department of Obstetrics & Gynaecology at QMH. The inspection outcome was satisfactory and formed a solid basis for reference for future clinical trials.

Internal Audit by HKU

In November 2011, an internal audit to CTC was performed by the HKU Internal Audit Office. The purpose of the internal audit was to assess the effectiveness of CTC's governance and management, the level of compliance with HKU's policies, and the efficiency of CTC's operation. The audit was completed satisfactorily and CTC was well regarded as a unique and successful centre in HKU.

Clinical Specialties Accredited by the SFDA

- Anaesthesiology
- Cardiology
- Endocrinology & Metabolism
- Haematology & Bone Marrow Transplantation
- Hepatobiliary & Pancreatic Surgery
- Obstetrics & Gynaecology
- Respiratory Medicine

HKU Phase 1 Clinical Trials Centre

Asia has been gaining importance in global clinical trials over the last decade. Hong Kong is among the earliest Asian cities involved in global clinical trials and has been known for its strong clinical expertise and high clinical research quality. In order to build capability and capacity for phase 1 clinical trials and strengthen Hong Kong's status as a hub for international clinical trials, the HKU Phase 1 Clinical Trials Centre is being established with the strong support from the Hong Kong Government.

The HKU Phase 1 Clinical Trials Centre is a modern and world standard clinical research infrastructure located in QMH, and specifically designed for conducting phase 1 clinical drug trials. Equipped with state-of-the-art research facilities and staffed with a professional management team and leading clinical and scientific experts, the 24-bed Phase 1 Clinical Trials Centre will be capable of conducting various types of phase 1 clinical trials in novel chemical and biological drugs, as well as bioavailability and bioequivalence trials in generic drugs – whether in patients or healthy volunteers.

The HKU Phase 1 Clinical Trials Centre will come into operation in the second quarter of 2013. An International Conference on Phase 1 and Early Phase Clinical Trials will be held on April 26, 2013 in line with this new and important development.

Insights on Phase 1 Clinical Trials Centre

Professor Karen Lam

Head, Department of Medicine, HKU

"I am pleased that the government has decided to support the establishment of phase 1 clinical trials centres units in Hong Kong, one each in the two university hospitals. This will provide the platform for training and participation in early stage clinical research involving novel therapeutic products. Through this phase 1 clinical trial centre, our investigators will be able to play a more active role in the research and development of novel therapeutic agents in the international arena. In the long term, major benefits to the biomedical industry-locally, nationally and internationally-are to be expected."

Professor Tak-Mao Chan

Professor, Department of Medicine, HKU

"Enhancement to our clinical trial facilities is responding to the evolving needs and challenges and is a key to continued success."

Professor Bernard Cheung

Professor, Department of Medicine, HKU

"Together with the opening of a similar unit at the Prince of Wales Hospital, the establishment of the HKU Phase 1 Clinical Trials Centre is a new milestone in the development of clinical research in Hong Kong. I am honoured to contribute to this centre and anticipate that it will be a great success."

Eliza Tan

Associate Director
Quintiles Hong Kong Limited

"With the quality healthcare system in Hong Kong and the world class set up of the HKU Phase 1 Clinical Trials Centre, it certainly will attract pharmaceutical companies to run early phase studies here and make Hong Kong a hub for conducting phase 1 studies in the near future."

Dr. Qiny-yong Dai

Medical Director
Roche Hong Kong Limited

"I believe this will be a good platform to pool the resources together between local, highly qualified investigators and the pharma industry with cutting-edge drug development plans. I very much look forward to seeing the new height to be reached in the field of the early drug development in Hong Kong. Roche is willing to be actively involved."

Maria M DeAssis

Associate Director
Boehringer-Ingelheim Hong Kong Limited

"A phase 1 clinical trials centre will enhance the capability of Hong Kong in terms of collecting early data with speed and quality and this can only position Hong Kong in a better light given that other phase 1 clinical trials centres in Asian region have a much stricter and require a longer regulatory approval process. Furthermore it will assist with the integration of drug development process managed by China SFDA."

Dr. Heng-wee Choo

Senior Research Physician
Pfizer Clinical Research Unit

"The establishment of a Phase 1 Clinical Trials Centre at The University of Hong Kong is demonstrative of Asia's commitment to enhancing quality and expertise in early clinical drug development."

Dr. Victor Lee

Clinical Assistant Professor
Department of Clinical Oncology, HKU

"Setting up the HKU Phase 1 Clinical Trials Centre can undoubtedly gather researchers from different streams and departments to perform large-scale phase 1 clinical trials and magnify the research opportunities in Queen Mary Hospital and The University of Hong Kong."

Professor Hextan Ngan

Head, Department & Chief of Service
Obstetrics & Gynecology, HKU/QMH

"Gynaecological cancers though not forming the major cancers burden in Hong Kong, it did contribute to 3 of the 10 most common cancers in women. A phase 1 centre is important in selecting the most promising drug for further study in Phase 2 and 3 studies."

Dr. Janice Tsang

Clinical Assistant Professor
Department of Clinical Oncology, HKU

"The upcoming Phase 1 Clinical Trials Centre serves as an important platform for multidisciplinary collaboration, from pre-clinical drug discovery, proof-of-principles, to evaluation of novel agents on specific cancer types, thus enhancing our ability to translate basic scientific research into new personalized medicine, with particular reference to our ever-growing cancer population in the community."

The Road Ahead

PEARS™

To accommodate the rapidly increasingly volume of safety reports for clinical studies, PEARS™ – the Platform for Electronic Adverse Reports Submission – has been being developed by CTC and is scheduled for launch in the second quarter of 2013. Through PEARS™, sponsors and CROs will be able to submit safety reports online and receive instantaneous acknowledgement of receipt. Investigators on the other hand can easily review and endorse safety reports anytime, anywhere through the internet. All the safety reports and time points for submission and endorsement are centrally tracked on the platform. PEARS™ has been validated for U.S. 21 CFR Part 11 compliance.

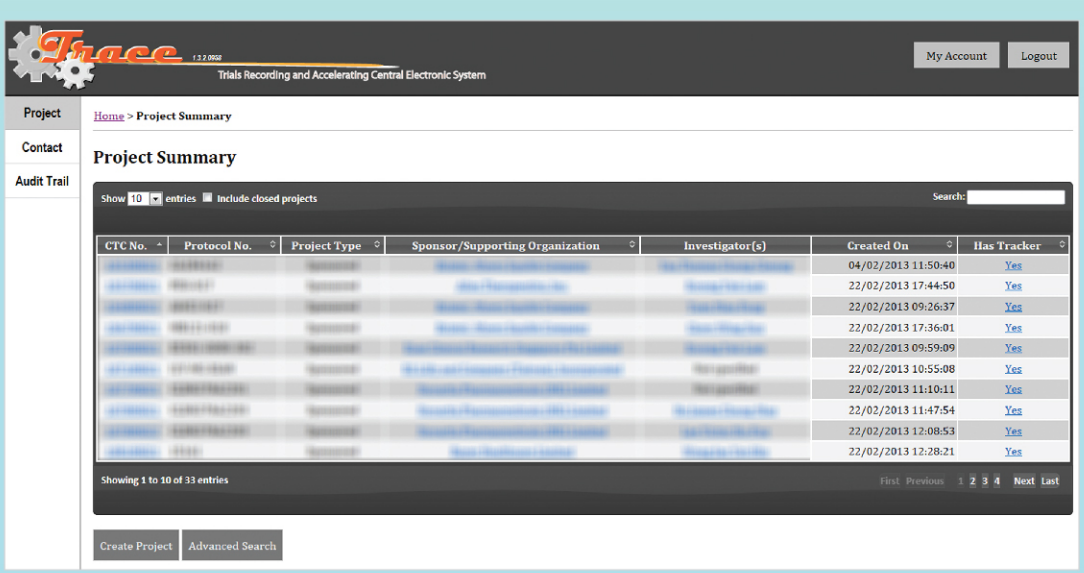
P E A R S

www.pearshk.com

Platform for Electronic Adverse Reports Submission

TRACE™

TRACE™ – the Trials Recording and Accelerating Central Electronic System – is a novel central clinical trials management system designed and developed by CTC. After over two years' development, the system is anticipated to be launched in the first quarter of 2013. TRACE™ will replace CTC's existing electronic management modules and form a central information hub for clinical study management in CTC.



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