science
ethics
human healthcare
education
academic research
quality

2005 ANNUAL REPORT

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

Clinical Trials Centre (CTC) of Li Ka Shing Faculty of Medicine of The University of Hong Kong (HKU) is a leading academic research organization dedicated to offering one-stop clinical research solutions. Established in 1998, CTC is committed to enhancing global healthcare by promoting the quality and efficiency of clinical research through ethical consideration, scientific expertise, quality assurance and education. Our core competences range from protocol development, project management, site management, data management, medical statistics and central laboratory support for industry-sponsored clinical studies to academic research consultation, training and education.

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Message from the Director

Background

Clinical and biomedical research is becoming increasingly competitive globally. Long-term collaborations are being established between academic institutions and the industry. The winning academic institutions are those responding to the industry and fulfilling its needs – providing highly competent and well-trained clinical investigators and researchers pursuing efficient research administration and logistics by developing and maintaining effective quality assurance systems in line with international standards. The concept of centralized management of clinical trial activities is becoming more and more popular in medical institutions. In 1997, only 23% of medical institutions in the US had central offices for clinical trials. By 2001, the proportion had increased to 67%. A recent survey found that the industry prefers to collaborate with medical institutions with a central trials administration facility for better quality control, convenience of administration and easier management of trial sites. Central clinical trials offices are now generally regarded as the ideal interface for long-term collaboration between the industry and medical institutions.

Chapel Hill stay in 1989 – the eye opener

On a fellowship in clinical epidemiology from the Swedish Medical Research Council, I spent 1989 at the University of North Carolina at Chapel Hill. At the time, the SAS Institute in the North Carolina 'Research Triangle' emerged as the world's leading statistical software company – a significant milestone for medical statisticians. It was also a time of rapid expansion of the drug development industry. As a consequence, a new industry evolved – the contract research organization (CRO) industry. One example was Quintiles, or Quintiles Transnational as it is known today. Established in 1982 by two statisticians from the University of North Carolina, it rapidly grew into a mature company and by 1989 had a large office in the Research Triangle. In the 1980s and 90s, few academic centres appreciated the drug development process was fast-changing, with growing demand from the pharmaceutical industry for fast, high quality studies of new medicines. Universities failed to match the level of services provided by the developing CRO industry. Many clinical trial contracts were lost to non-academic health care facilities, including private practitioners. But there were exceptions. Duke University located in Durham, close to Chapel Hill, grasped the opportunity early and created a service-minded clinical research centre for international cardiovascular clinical trials. Duke is now the largest academic clinical trial organization in the world.

"I will try to establish a high quality academic clinical trial organization"

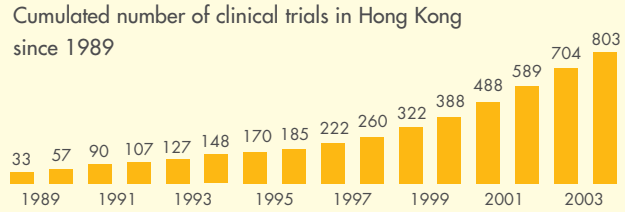
Returning to the University of Göteborg in 1990, I made up my mind to try to establish a high quality academic clinical trial organization. It happened, though requiring much more effort than I expected, taking several years to establish. In 1993 I joined the Department of Paediatrics at The University of Hong Kong (HKU). On arrival I visited the local offices of several international pharmaceutical companies to enquire about their regional clinical trial activities. Surprisingly, there were virtually no research and development teams in place among the companies visited – and most clinical trials they sponsored were merely of marketing phase IV types, using small sample sizes, no control groups and without monitoring.

When did it start?

It was not until 1996 – with the establishment of the ICH GCP Guideline – that clinical trial activity began in the region, with Merck organizing a GCP symposium in Hong Kong, and Quintiles establishing an office in Singapore.

The figure below shows the impact of the ICH GCP process on the number of international clinical trials conducted in Hong Kong over the past two decades; with a rapid increase seen in 1997. The figure gives the cumulated number of clinical trials conducted by international pharmaceutical companies in Hong Kong – with the striking acceleration of trials notable from 1997 onwards.

From 2001 to 2003, 100-115 new clinical trials were initiated annually in Hong Kong, compared to some 20-25 annual trials prior to the introduction of the ICH GCP guideline. Also noteworthy is that more and more sites outside the two academic hospitals in Hong Kong became involved in clinical trials. In 2002 alone, 115 new clinical trials were initiated at 175 Hong Kong sites: 100 in the two academic hospitals and 75 in non-academic public hospitals *(source: Department of Health, Hong Kong SAR)*. These numbers relate mainly to new drug application submissions in the US, EU and/or Japan.



Source: Department of Health, Hong Kong SAR. There may be one or more sites for each trial.

Constitution of CTC

Founding of faculty-based committee

I raised the idea of establishing a clinical trials centre in line with leading US institutions in 1995. The Dean of the HKU Medical Faculty, Professor SP Chow, responded positively to the proposal and formed an investigatory committee consisting of leading clinical researchers, including the Head of the Department of Medicine, Professor SK Lam (the current Dean).

Seeking advice

To start, we contacted some 500 medical faculties around the world to establish how many were conducting trials with a central clinical trial organization taking care of contracts, budgets and administration – and to seek advice from them. We obtained positive replies from some 20 North American universities – most from the US, with a few from Canada. There were no positive replies from Europe or anywhere else. The trend was clear: the US was at the frontline. The same exercise today would identify hundreds of clinical trials offices in the US and Canada, since about 75% of all their medical schools have since set up central trial organizations.One of the most impressive "Office of Clinical Trials" identified in 1995 was at the Presbyterian Medical College in New York. It was established in 1992 by a former Wall Street financial manager, Michael Leahey (who became a good friend, but sadly died in 2003).

The "Columbia Office" he founded has up to now negotiated over 1,600 contracts representing over 500 sponsors and is the leading trial office in the US. Mr. Leahey offered the following key advice on how to establish and maintain our centre, which was critical to our success:

- A clinical research centre must be authorized by an institution as a single central organization in handling all legal contracts and budgets for clinical trials for the purposes of safeguarding the rights of the institution and research personnel and assuring availability of sufficient financial resources for such research activities. A mandatory mechanism is the number one critical success factor.

- A clinical research centre should not intervene in study site activities. The responsibilities for organizing and conducting clinical trials should always stay with individual clinical investigators.

- The first person to be employed under a clinical research centre should not be a clinician, a researcher, a nurse, a pharmacist, a statistician, a data manager or a laboratory technician, but an MBA with sound experience in finance and contract management.

We followed this advice from the very early days and I would not recommend anyone else to do differently.

Foundation

The Faculty committee agreed to establish CTC, although it took about a year to reach a consensus that it would process all the Faculty's clinical trial contracts. Finally, it was agreed to go ahead for a test period of two years. CTC was formally established in 1996 with approval from the HKU Senate and I was appointed the first Director (honorary). However, at the time it was just a "virtual centre" with no financial support, no office and no staff.

Establishing mission and funding

In 1996, CTC gained an Advisory Committee with representatives from all clinical departments. The committee subsequently became CTC's Board of Directors in 2001. In 1996-1997 we discussed the mission of CTC and how its operation should be financed. We came up with a proposal for consideration at a Faculty Dean and Heads Meeting. The most important points of this proposal were:

- CTC should be an academic research organization rather than a for-profit organization. The mission was to build an interface for long-term collaboration between the Faculty and the industry, attracting and facilitating international clinical trials with high academic value and good potential of leading to high impact scientific publications.

- Sustainability of CTC should be maintained by direct funding from the Faculty – like other departments – without relying on sharing of revenue from each clinical trial. All direct revenue from each clinical trial should be distributed to the relevant clinical investigators and participating units. Any indirect revenue should be shared among the HKU central, the Faculty and relevant departments.

The proposal was accepted by the Faculty and the HKU Finance Office in mid-1998. CTC was funded by the Faculty with US$800,000 for the first three years of operation.

How CTC become a leading educator

With the rapid increase in clinical trial activities in Hong Kong, there has been a growing need for GCP educational and quality assurance activities. CTC has been involved in many educational activities, including organizing two international trial conferences and GCP symposia/courses with 3,000 participants, and training 150 ethics committee members.

Since 1998, CTC has also offered a Master degree programme in Clinical Trials Research Methodology. This programme continues to attract candidates from a wide range of scientific and medical backgrounds including clinicians, nurses, pharmacists and paramedical professionals, as well as clinical research personnel from the healthcare and pharmaceutical industry. With the increasing popularity of the programme a second Master degree programme, in Medical Statistics, was subsequently introduced in 2002, providing students with organized knowledge in medical statistics from both theoretical and practical perspectives. So far, over 50 candidates have graduated from our Master degree programmes. Postgraduate Diploma and Postgraduate Certificate in Clinical Trials Research Methodology or Medical Statistics were also introduced in 2002. These two programmes, requiring no dissertation, involve 200 and 80 contact hours respectively and are tailored for busy professionals who wish to grasp key, updated knowledge relating to clinical trials or medical statistics.

CTC today

CTC is today the only full-service academic research centre in Asia. By the end of 2005, CTC had 229 clinical studies contracted with the international pharmaceutical and healthcare industry. Of these, 120 were ongoing. CTC had also developed master study site agreements with over 50 trial sponsors worldwide.

Johan Karlberg BSc (Stat & Edu), MD, PhD (Anat & Cell Bio)
Director & Professor

Organization

Professor Karen Lam
Chairman
Chief, Division of Endocrinology
Department of Medicine
The University of Hong Kong

Dr. Bernard Cheung
Associate Professor
Department of Medicine
The University of Hong Kong

Dr. Lawrence Lai
Hospital Chief Executive
Queen Mary Hospital

Professor CS Lau
Co-chief, Division of Rheumatology
Department of Medicine
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Dr. Robert Collins
Chief of Service
Department of Pathology
and Clinical Biochemistry
Queen Mary Hospital

Professor Ricky Man
Head
Department of Pharmacology
The University of Hong Kong

Professor Johan Karlberg
Director
Clinical Trials Centre
The University of Hong Kong

Professor Ronnie Poon
Assistant Dean (Research)
Faculty of Medicine
The University of Hong Kong

Board of Directors

Professor CL Lai
Chief, Division of Gastroenterology
and Hepatology
Department of Medicine
The University of Hong Kong

Professor Y Tong
Director
School of Chinese Medicine
The University of Hong Kong

Clinical Trials Centre

- Research consultation
- Protocol development
- Project management
- Regulatory affairs
- Budget management
- Contract management
- Study monitoring
- Site management
- Central laboratory
- Research pharmacy
- Data management
- Medical statistics
- Medical writing
- Education and training

Achievements

Industry Collaboration

Expanding collaboration

With a mission to enhance clinical research in the region, CTC continues to devote great effort and resources expanding its collaboration with the industry. By the end of 2005, the number of trial sponsors with master study site agreements developed through CTC increased to 53, with 11 trial sponsors adding to the list. Existence of master study site agreements vastly enhances the contract negotiation and study preparation process, and is an important asset contributing to the efficient setup and success of clinical studies.

List of trial sponsors with a master study site agreement developed through CTC	
Abbott Laboratories	Light Sciences
Achillion Pharmaceuticals	Lundbeck
Actelion Pharmaceuticals	MedImmune
Advanced Herbal Therapeutics	Medtronic
Altana Pharma	Merck KGaA
Arrow Therapeutics	Merck Sharp & Dohme
AstraZeneca	Novartis
BCIRG	Novo Nordisk
Bio-cancer Treatment	Organon
Biocompatibles	OSI Pharmaceuticals
Biomeasure	Pfizer
Boehringer Ingelheim	Pi Medical
Boston Scientific	Roche
Bristol-Myers Squibb	Sanofi-Aventis
Celltech	Schering-Plough
Celsion	Scios
CK Life Sciences	Serono
EBR System	Servier
Eli Lilly	St. Jude Medical
Enteromedics	Theravance
Everpride Biopharmaceutical	Triangle Pharmaceuticals
GlaxoSmithKline	Tularik
Guidant	Vigconic
Idenix Pharmaceuticals	Wyeth
Johnson & Johnson	Xanthus Life Sciences
Kowa	Zila
LG Life Sciences	

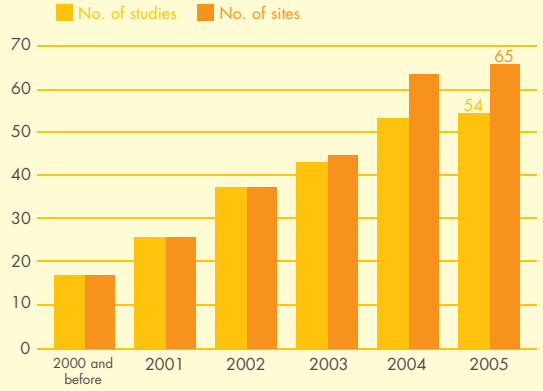
Closer industry-academic partnership arrangements

In addition to extending collaboration with trial sponsors worldwide, CTC also entered into serious discussions on closer partnership arrangements with a number of major trial sponsors in 2005. Closer industry-academic partnership is considered a new trend in the modern healthcare industry, and is anticipated to create extra momentum for CTC's future growth and development.

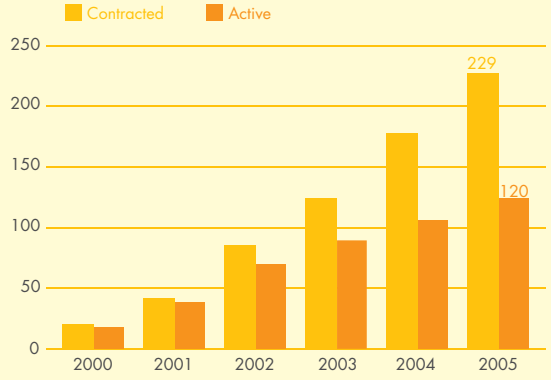
Sustained growth

Keeping pace with the previous year, CTC continued to set up new clinical studies in 2005 at an average rate of more than one study per week, achieving a record high of 54 studies over the year. The cumulative number of clinical studies contracted through CTC since its establishment reached 229 – with 120 still active by the year-end.

Number of clinical studies contracted through CTC (per annum)



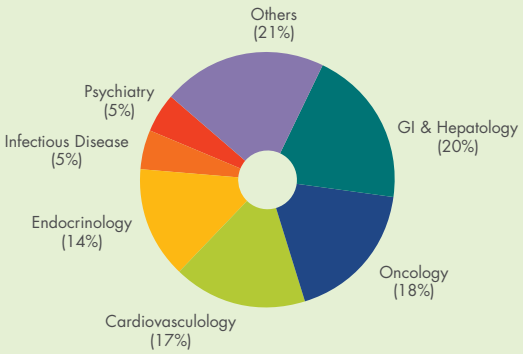
Number of contracted and active clinical studies coordinated through CTC (cumulative)



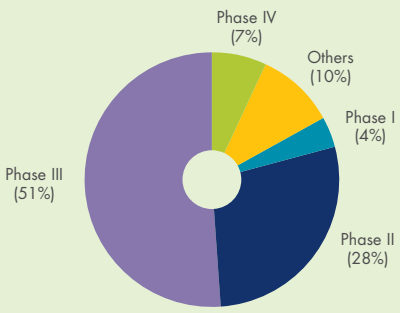
Variety of research types

Gastroenterology & hepatology continued to be the most popular research area – accounting for 20% of all industry-sponsored clinical studies coordinated through CTC. Oncology and cardiovasculology research picked up very fast, respectively contributing 18% and 17%. In terms of study phases, the proportion of Phase II and III studies remained at 79%.

Types of clinical studies coordinated through CTC by research area (1999-2005)



Types of clinical studies coordinated through CTC by study phase (1999-2005)



Achievements

Industry Collaboration

Industry-sponsored clinical studies contracted in 2005					
Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Anaesthesiology	Opioid-Induced Bowel Dysfunction	II	Dr. Michael Irwin Dr. Anne SK Kwan	Anaesthesiology Anaesthetics	QMH UCH
Anaesthesiology	Opioid-Induced Bowel Dysfunction	III	Dr. Michael Irwin Dr. Anne SK Kwan Dr. Steven HS Wong	Anaesthesiology Anaesthetics Anaesthesia	QMH UCH QEH
Cardiovasculology	Acute Coronary Syndrome	III	Dr. WH Chen	Medicine	QMH
Cardiovasculology	Angina Pectoris	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Artherosclerosis	III	Dr. WH Chen	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	N/A	Professor HF Tse Dr. Katherine YY Fan	Medicine Medicine	QMH GRH
Cardiovasculology	Atrial Fibrillation / Atrial Flutter	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Bradyarrhythmias	N/A	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Heart Failure	II	Professor HF Tse	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Heart Failure	III	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Dr. Stephen WL Lee	Medicine	QMH
Cardiovasculology	Hypertension	III	Dr. Bernard MY Cheung	Medicine	QMH
Cardiovasculology	Hypertension	III	Dr. Bernard MY Cheung	Medicine	QMH
Cardiovasculology	Hypertension	III	Dr. Stephen WL Lee	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Professor Karen SL Lam	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Dr. Kathryn CB Tan	Medicine	QMH

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Endocrinology	Obesity	II	Professor Karen SL Lam	Medicine	QMH
Endocrinology	Obesity	N/A	Professor KM Chu	Surgery	QMH
Endocrinology	Osteoporosis	N/A	Professor Annie WC Kung	Medicine	QMH
Endocrinology	Syndrome of Inappropriate Antidiuretic Hormone Secretion	III	Professor KN Lai	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor CL Lai	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor CL Lai	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Dr. MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Liver Transplantation Rejection	III	Professor CM Lo	Surgery	QMH
Gastroenterology & Hepatology	Hepatitis B	IV	Dr. MF Yuen	Medicine	QMH
Haematology	Leukemia	III	Professor Raymond HS Liang	Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine	QMH
Immunology & Allergy	Rheumatoid Arthritis	III	Professor CS Lau	Medicine	QMH
Infectious Disease	Methicillin-Resistant Staphylococcus Aureus	IV	Dr. WM Chan	Medicine	QMH
Neurology	Acute Intracerebral Hemorrhage	III	Dr. Raymond TF Cheung	Medicine	QMH
Oncology	Chemotherapy-Induced Nausea & Vomiting	II	Professor Richard Epstein	Medicine	QMH
Oncology	Gastrointestinal Stromal Tumor	II	Dr. Raymond TT Chan	Clinical Oncology	QMH
Oncology	Head & Neck Cancer	III	Dr. Raymond WM Ng Dr. Anne WM Lee Dr. Roger KC Ngan	Surgery Clinical Oncology Clinical Oncology	QMH PYH QEH
Oncology	Liver Cancer	II	Professor Richard Epstein	Medicine	QMH

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Lung Cancer	III	Professor Kenneth WT Tsang Dr. Daniel TT Chua	Medicine Clinical Oncology	QMH QMH
Oncology	Lung Cancer	II	Dr. James CM Ho Dr. Daniel TT Chua	Medicine Clinical Oncology	QMH QMH
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan Dr. WT Ng	Obstetrics & Gynaecology Clinical Oncology	QMH PYH
Oncology	Renal Cancer	II	Professor Richard Epstein Dr. Ashley CK Cheng Dr. Y Tung	Medicine Oncology Clinical Oncology	QMH PMH TMH
Paediatrics	Transfusion-dependent Iron Overload	III	Dr. SY Ha	Paediatrics	QMH
Paediatrics	Refractory Partial-Onset Seizures	III	Professor Virginia CN Wong	Paediatrics	QMH
Psychiatry	Major Depressive Disorder	III	Professor SW Tang	Psychiatry	QMH
Psychiatry	Major Depressive Disorder	IV	Professor SW Tang	Psychiatry	QMH
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Professor Kenneth WT Tsang	Medicine	QMH
Urology	Premature Ejaculation	III	Dr. Andrew WC Yip	Surgery	KWH

*Study Phase
N/A : 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
KWH : Kwong Wah Hospital
PMH : Princess Margaret Hospital
PYH : Pamela Youde Nethersole Eastern Hospital
QEH : Queen Elizabeth Hospital
QMH : Queen Mary Hospital
TMH : Tuen Mun Hospital
UCH : United Christian Hospital

Achievements

Integrated Clinical Study Management

Project management

Benefited from the rising interest of trial sponsors worldwide in conducting clinical studies in Hong Kong and the eager demand for highly professional study management, project management became the fastest growing branch for CTC in 2005.

During the year, CTC actively provided or planned for various project management services for 14 industry-sponsored clinical studies – including Phase I, II and III studies of chemical drugs, biologics, Chinese medicines and medical devices in a diverse range of therapeutic areas. Demand for study monitoring services was especially strong.

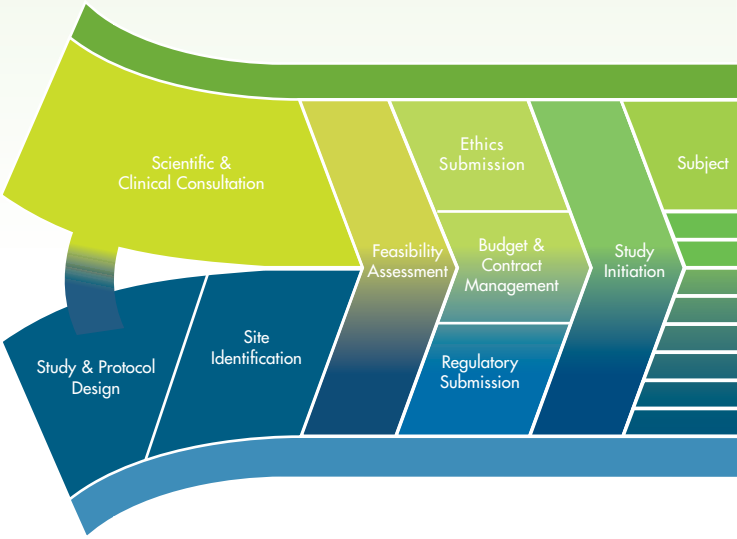
Leveraging on the integrated project management – site management platform, project management will continue to serve as a powerhouse for CTC's future growth.

Project Management Services Performed or Planned for Industry-Sponsored Clinical Studies during 2005

Therapeutic Area	Study Phase	Services					
		Overall Project Management	Protocol Development	Regulatory Submission	Study Monitoring	Drug Management	Data Management & Medical Statistics
Endocrinology	III					■	
Endocrinology	Device	■			■		
Gastroenterology & Hepatology	II	■	■	■	■	■	■
Gastroenterology & Hepatology	II	■	■		■	■	■
Gastroenterology & Hepatology	III				■		
Gastroenterology & Hepatology	III			■		■	
Infectious Disease	II	■	■	■	■	■	■
Neurology	II	■	■		■	■	■
Oncology	I				■		
Oncology	I			■	■	■	
Oncology	III	■		■	■		■
Oncology	III					■	
Oncology	III					■	
Paediatrics	III				■		

Integrated project management – site management platform

Clinical research involves a series of interlocking activities requiring superior integration, prioritization, synchronization and optimization. For decades, clinical research players have strived to improve the efficiency and effectiveness of individual activities in the process, leading to the emergence of commercial service providers such as contract research organizations (CROs) and site management organizations (SMOs). Some academic institutions and study sites have responded by establishing their own clinical research offices to facilitate research administration. However, harmonization of sponsor activities and study site activities remains the biggest challenge for industry-sponsored clinical studies.



HKU Clinical Trial Register

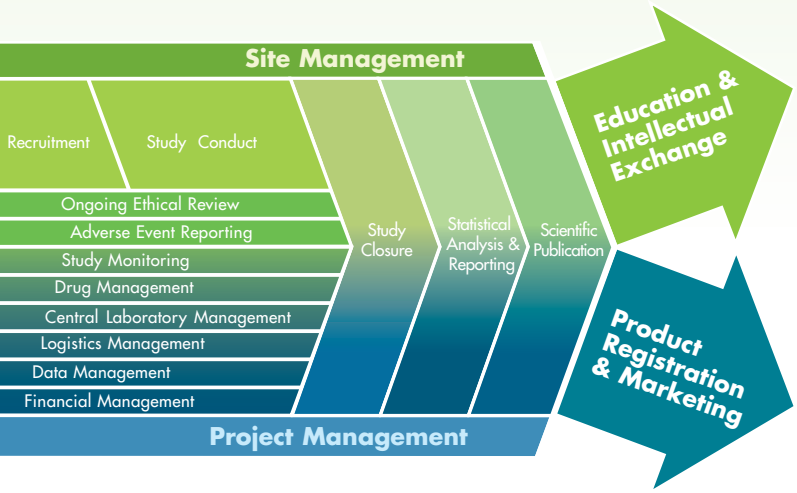
The rapidly extending scope and intensity of clinical research in Asia has stimulated growing public awareness. To enhance public disclosure of clinical research activities, the first public clinical trial register in Hong Kong – HKU Clinical Trial Register – was launched on June 30, 2005.

The register is an open platform freely accessible by the public through the Internet at www.hkclinicaltrials.com. It was designed to meet the criteria for public registration of clinical trials by the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO).

The register serves as a comprehensive source of information about clinical research in Hong Kong, and is anticipated to help improve public understanding of the field. Details of over 100 clinical studies have already been posted on the register – and the list is expanding fast.

HKU Clinical Trial Register at www.hkclinicaltrials.com

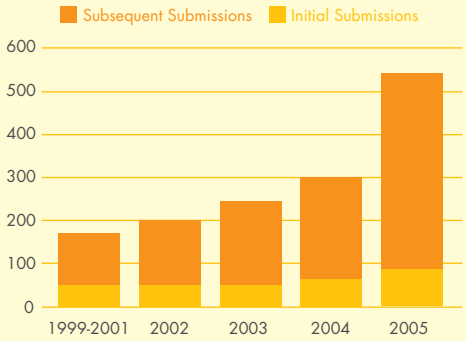
CTC is fully aware of the importance of harmonization. Over the years CTC has developed a fully integrated clinical study management platform combining its project management and site management capabilities. Under this platform, sponsor activities and study site activities are planned for and coordinated in a holistic rather than segregated manner, creating the most beneficial conditions for prioritization and synchronization of activities – and optimization of the entire research process. The unique platform now forms the base of CTC's core operations and is a key success factor for industry-sponsored clinical studies.



Ethical review

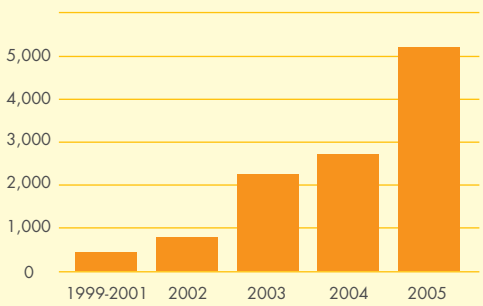
The upsurge in active clinical studies greatly increases the volume of ethical submissions. During the year, CTC facilitated 77 initial applications and 474 subsequent submissions to ethics committees. The number of serious adverse event reports jumped 87% from the preceding year to 5,146.

Annual number and type of submissions* made to ethics committees through CTC



*Remark: Excluding serious adverse event reports

Annual number of serious adverse event reports submitted to ethics committees through CTC

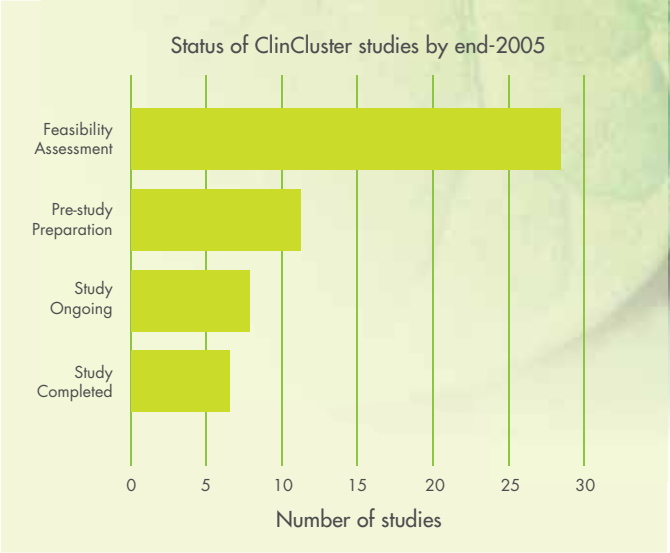


ClinCluster

ClinCluster – CTC's unique multicentre clinical study site management platform launched in 2004 – proved a great success in 2005.

In addition to the most welcomed "one budget, one contract" concept, which substantially streamlines the budget and contract negotiation process for multicentre studies, the highly effective feasibility assessment service is considered another cutting edge of ClinCluster. Since its establishment, over 50 feasibility assessments have been performed. 15 studies were successfully initiated in 14 hospitals/clinics – seven of which were completed by the end of the year. Another 11 studies were under active preparation for initiation in the first quarter of 2006.

Over 20 trial sponsors have so far benefited from ClinCluster's premium services. ClinCluster is destined to be increasingly popular in the coming years, and become a major attraction encouraging trial sponsors to undertake multicentre clinical studies in Hong Kong.



Clinical studies coordinated through ClinCluster in 2005

Therapeutic Area	Disease Area	Study Phase*	Study Site#
Cardiovasculology	Atrial Fibrillation	N/A	GRH / QMH
Gastroenterology & Hepatology	Opioid-Induced Bowel Dysfunction	II	QMH / UCH
Gastroenterology & Hepatology	Opioid-Induced Bowel Dysfunction	III	QEH / QMH / UCH
Oncology	Head & Neck Cancer	III	PYH / QEH / QMH
Oncology	Ovarian Cancer	III	PYH / QMH
Oncology	Renal Cancer	II	PMH / QMH / TMH
Urology	Premature Ejaculation	III	KWH

*Study Phase
N/A : Studies not classified as Phase I, II, III or IV studies, such as medical device, observational, epidemiology and compassionate studies

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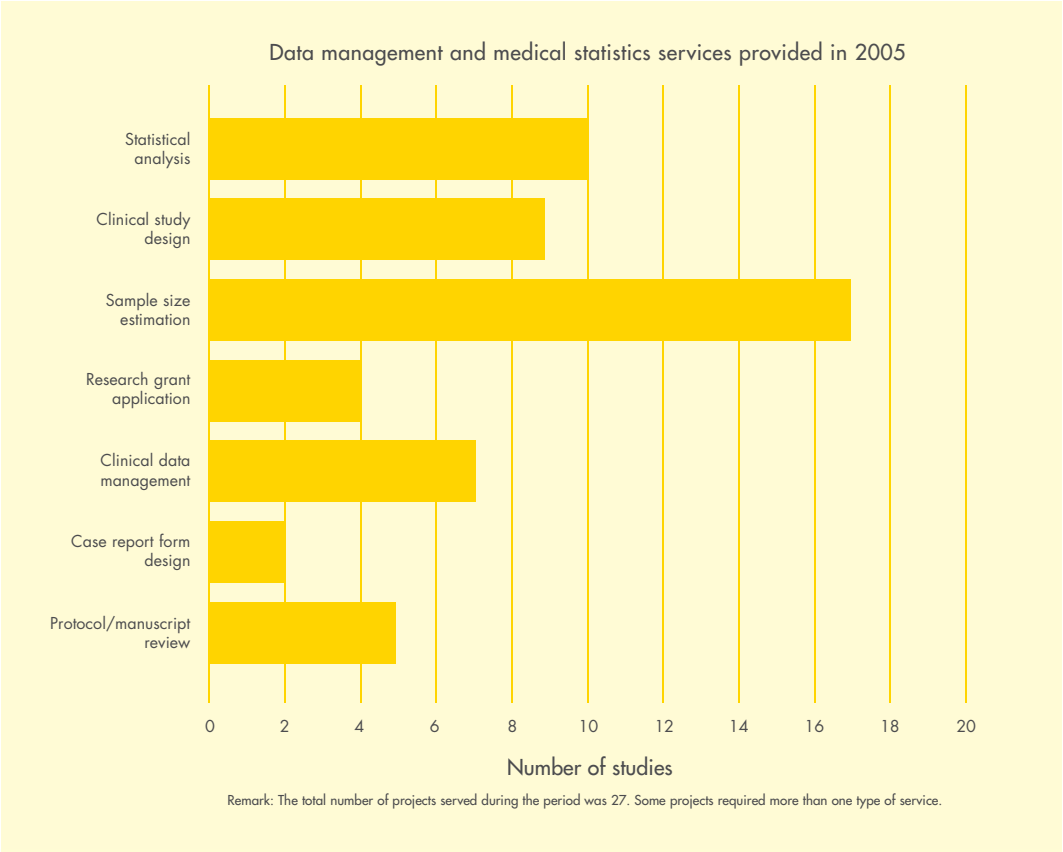
Achievements

Data Management and Medical Statistics

Consolidation of strategic transformation

Integration of the data management and medical statistics team with the project management team since 2004 proved an effective strategic approach – resulting in direct, deeper involvement of the team in the planning and management process of each clinical study rather than just providing individual segregated services. This strategic transformation adds great value to CTC's integrated study management platform and is expected to contribute to greater success with clinical studies coordinated by CTC.



Remark: The total number of projects served during the period was 27. Some projects required more than one type of service.

Support for investigator-initiated academic clinical research

Medical statistics is a central pillar of contemporary evidence-based medicine. With the growing academic clinical research at HKU, there has been a call for stronger medical statistics support for HKU clinical investigators.

Following the initiation of ethics submission and regulatory support for investigator-initiated academic clinical research in late-2004, CTC laid a solid plan to extend its support for academic research to the area of medical statistics consultation. With the backing and financial assistance of HKU and the Medical Faculty, CTC will strengthen its data management and medical statistics team in 2006 to offer more comprehensive medical statistics services to HKU clinical investigators, from statistical method consultation and sample size calculation to research grant application. This development underlines CTC's commitment to academic clinical research in line with the missions of HKU and the Medical Faculty.

Achievements

Central Laboratory

ALab – beyond a lab

ALab – CTC's clinical study central laboratory service platform launched in mid-2004 – became fully operational in 2005.

ALab is not simply a laboratory. It is a central laboratory platform with comprehensive project management, outstanding analytical and specimen management capabilities, full logistics support, advance data management, and multi-level quality assurance.

Strategically located in Hong Kong, a prime logistical hub less than five hours by airplane from most of Asia, ALab is advantageously positioned to serve regional clinical studies.

ALab thinks locally on a global scale. With partner laboratories in North America, Europe and mainland China, ALab is competent in delivering customized global solutions and local support for large-scale multinational clinical studies. ALab is an A-class central laboratory platform, from Asia and beyond Asia.

ALab – a central laboratory that thinks locally on a global scale

- **ALab**
- Partner Laboratory

Project Management

- One-stop laboratory solutions
- Flexible project management
- Protocol-specific manuals
- Professional training and support for study teams

Logistics Support

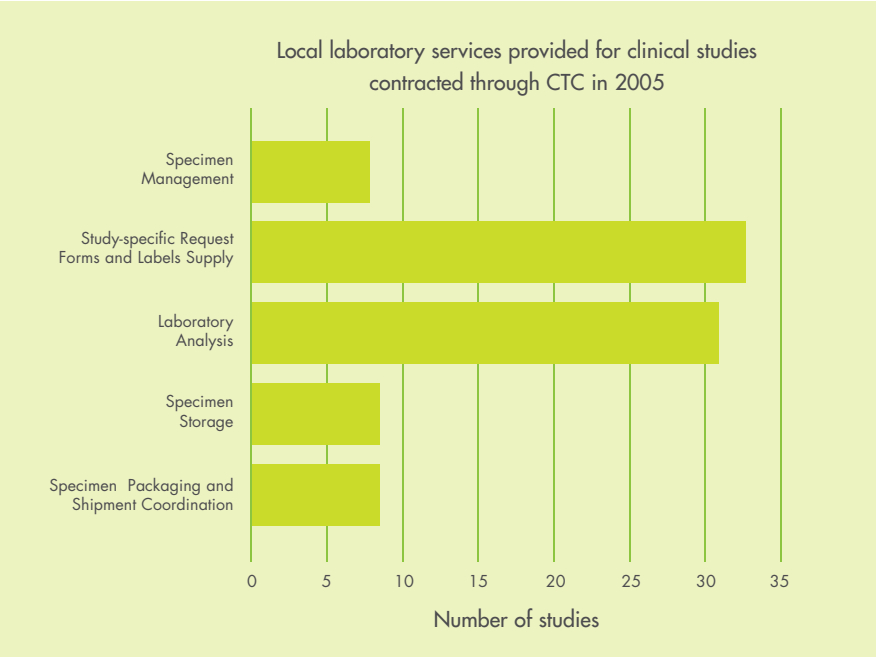
- Custom-assembled kits and supplies
- Global logistics support
- Customized shipment schedules
- Close tracking of specimens

Quality Assurance

- Fully accredited by CAP
- Ongoing internal quality assurance programme
- Inspection by regulatory bodies and third parties
- Comprehensive standard operating procedures

Strong local laboratory support

In addition to central laboratory services for multicentre clinical studies, CTC also provides local laboratory support for clinical studies conducted at HKU. Among the 54 industry-sponsored clinical studies contracted in 2005, 32 require various combinations of local laboratory support – from specimen management, study-specific request forms / labels supply and laboratory analysis to specimen storage, packaging and shipment coordination. With the industry's increasing emphasis on quality, demand for local laboratory support will continue to be strong.



Analytical and Specimen Management Capabilities

- Advanced analytical technology and facilities
- High analytical throughput and capacity
- Standardized testing methodologies
- Long-term specimens archiving capability

Data Management and Reporting

- Protocol-specific databases
- Customized report formats
- 24-hour turnaround for routine safety analyses
- Electronic results reporting capability

Achievements

Education

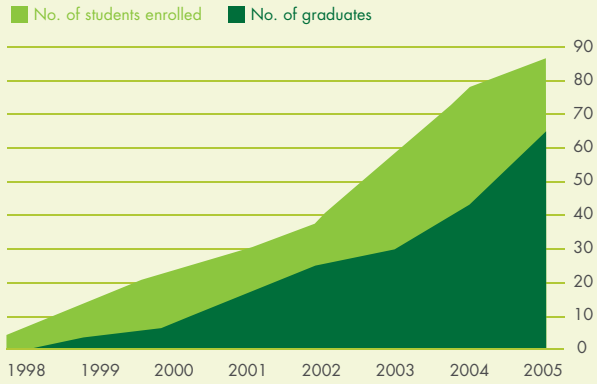
Postgraduate programmes

Providing high quality education in clinical research is a key element of CTC's mission as an academic research organization.

Over the past seven years, CTC's postgraduate programmes – including the Postgraduate Certificate, Postgraduate Diploma, and Master of Public Health programmes – have acquired an enviable reputation in the healthcare industry.

Since the launch of CTC's first postgraduate programme in 1998, 86 students have enrolled and 63 have graduated. In 2005, nine new candidates were admitted.

Cumulative number of students enrolled in and graduated from CTC's postgraduate programmes between 1998 and 2005



AccreditGCP – the online GCP training and accreditation programme

Responding to demand from clinical investigators and study site personnel for continuous education, the first online GCP training and accreditation programme in Hong Kong – AccreditGCP – was launched in mid-2005.

AccreditGCP is a web-based self-learning programme specifically designed for busy clinical investigators, study coordinators, ethics committee members and other study site personnel. Participants can plan their own learning schedules and study through the Internet anytime, anywhere. Participants successfully completing the programme and passing a final examination will be awarded a Certificate of Accreditation.

AccreditGCP is an excellent platform for both new research personnel to get started in clinical research and for experienced research professionals to keep up-to-date with the international trends, requirements and developments. More than 40 participants have already been accredited by the end of the year.

■ AccreditGCP website at www.accreditgcp.com

■ Certificate of Accreditation for successful participants

Examiners for CTC's postgraduate programmes

Internal Examiners

Professor M.S.M. Ip, Department of Medicine, HKU

Professor R.Y.K. Man, Department of Pharmacology, HKU

Professor L.C.K. Low, Department of Paediatrics and Adolescent Medicine, HKU

Dr. C.L.K. Lam, Department of Medicine, HKU

Professor C.L. Lai, Department of Medicine, HKU

Dr. R.Fielding, Department of Community Medicine, HKU

Dr. C.M. Wong, Department of Community Medicine, HKU

Professor T.H. Lam, Department of Community Medicine, HKU

Dr. T.T.H. Lao, Department of Obstetrics and Gynaecology, HKU

Dr. L.W.C. Chow, Department of Surgery, HKU

Professor R.H.S. Liang, Department of Medicine, HKU

Dr. Susan Chiu, Department of Paediatrics and Adolescent Medicine,HKU

Professor L.C. Chan, Department of Pathology, HKU

Professor A.A. Nanji, Department of Pathology, HKU

Dr. H.P. Sheng, Department of Physiology, HKU

Dr. Paul Yip, Department of Statistics and Actuarial Sciences, HKU

Dr. Jean Paul Yih, Eye Clinic, Queen Mary Hospital

Professor Y.L. Lau, Department of Paediatrics and Adolescent Medicine, HKU

Dr. W.M. Tang, Department of Orthopaedics and Traumatology, HKU

Dr. B.M.Y. Cheung, Department of Medicine, HKU

Dr. G.M. Leung, Department of Community Medicine, HKU

Dr. W.K. Ho, Department of Surgery, HKU

Professor R. Epstein, Department of Medicine, HKU

Dr. M.G. Irwin, Department of Anaesthesiology, HKU

Professor C.Y. Lo, Department of Surgery, HKU

Dr. Athena Liu, Faculty of Law, HKU

Dr. W.N. Chan, Department of Ophthalmology, Queen Mary Hospital

Professor J.F. Chiu, Institute of Molecular Biology, HKU

Professor R.T.P. Poon, Department of Surgery, HKU

Dr. John Nichols, Department of Pathology, HKU

External Examiners

Professor B. Tomlinson, Department of Medicine and Therapeutics, The Chinese University of Hong Kong

Professor Benny Zee, Department of Clinical Oncology, The Chinese University of Hong Kong

Dr. N.P. Maurice, Consultant in Pharmaceutical Medicine, United Kingdom

Dr. J. Seldrup, Biostatistics, Quintiles France

Professor L.A. Hanson, Department of Clinical Immunology, University of Göteborg, Sweden

Professor M. Ritzen, Department of Woman and Child Health, Karolinska Instutet, Stockholm, Sweden

Professor Lai Shi Long, National Training Center for Design, Measurement and Evaluation in Clinical Research, Guangzhou University of Traditional Chinese Medicine, PRC

Professor K.G. Albertsson-Wikland, Department of Paediatrics, Göteborg University, Sweden

Professor D. Machin, Institute of Primary Care and General Practice, University of Sheffield, United Kingdom

Professor Z. Laron, Endocrinology and Diabetes Research Unit, WHO Collaborating Centre For the Study of Diabetes in Youth, Schneider Children's Medical Centre of Israel

Dr. Joseph T.S. Wee, Department of Therapeutic Radiology, National Cancer Centre Singapore

Dr. B. Kristiansson, Tawam University Hospital, Tawam University Hospital, United Arab Emirates

Dr. N.W. Leung, Department of Medicine and Therapeutics, Prince of Wales Hospital, The Chinese University of Hong Kong

Professor Jean Woo, Department of Medicine and Therapeutics, The Chinese University of Hong Kong

Professor G.R. Norman, Department of Clinical and Epidemiology and Biostatistics, McMaster University, Canada

Professor C. Howden, Department of Medicine, Feinberg School of Medicine, North Western University Chicago Il, United States of America

Dr. T. Chiu, Hong Kong Polytechnic University

Professor T.F. Fok, Department of Paediatrics, The Chinese University of Hong Kong

Professor Juliana Chan, Department of Medicine and Therapeutics, The Chinese University of Hong Kong

Professor Gavin Joynt, Department of Anaesthesia, and Intensive Care, The Chinese University of Hong Kong

Professor K.C. Lee, School of Pharmacy, The Chinese University of Hong Kong

Dr. Arthur C.K. Cheng, Department of Ophthalmology, The Chinese University of Hong Kong

Professor Gary Wong, Department of Paediatrics, The Chinese University of Hong Kong

Dissertations of the first 50 students of CTC's master programmes

- Meta-analysis of the Efficacy and Safety of Meropenum vs. Imienum/Cilasin in the Treatment of Bacterial Infections
- Clinical Ginseng Research - a Critical Review
- Health Status in Bangladesh - a Critical Review
- A Critical Review of Clinical Trials and Meta-analysis in Dental Research
- Quality of Life Questionnaires in Respiratory Disease
- Clinical Trials Laboratory Services- Industry Demands and Cost Variations
- An Overview of Clinical Trials in Occupational Therapy
- Psychometric Evaluation of Hong Kong Chinese Version on SF-36 Health Survey Among Cancer Patients in Hong Kong
- Compliance with Ethics Committee Operational Guidelines in Hong Kong
- Validation of the Chinese (Hong Kong) Version of Beck Anxiety Inventory (BAI) and Beck Depression Inventory (BDI)
- Statistical Analysis of a Phase IV Clinical Trial in Patients with Allergic Rhinitis
- Key Issues of Evidence-based Vaccinology as demonstrated by Pneumococcal Vaccine Development
- A Case Control Study on Infant Outcomes in Subjects with Diabetes Mellitus in Pregnancy
- Patients Perceptions of Traditional Chinese Medicines
- Systematic Review on Meta-analysis in the BMJ, New England Journal of Medicine, the Lancet and JAMA
- Patient Recruitment Strategies in Clinical Trials
- Possible Fibrino(geno)lytic Activity in an Earthworm Extract: Development of a Protocol to Identify Initial Efficacy, Safety and Further Clinical Development
- Review of Hepatitis B Treatment in Practice and in Development
- Insulin-like Growth Factor I and Linear Growth at Birth to Five Days in Rats
- Meta-analysis of Different Anti-fungal Prophylactic Treatments in Neutropenic Patients
- Systematic Review of Postoperative Treatment for Lasik Eye Surgery
- Fertility Rate Trends in Hong Kong between 1981-1997
- Cardiac Risk Factors in Hong Kong Adults
- A Single Centre, Randomised Trial on Harvest Cell Yield and Marrow Engraftment Using Haematopoietic Growth Factor Primed Bone Marrow
- Quality of Life Changes after Knee - Joint Replacement
- Variation in Clinical Trial Registration, Regulation and Practices among Ten Asian Countries

Dissertations of The First 50 Master Degree Students of CTC

- Treatment of Knee Osteoarthritis with Lyprinol in Chinese Patients: A Double-blind Randomised Placebo Controlled Trial
- Clinical Implications of Cytochrome P Polymorphisms in Patients receiving Proton Pump Inhibitors: A Qualitative Overview
- Association of Physical Activity During Leisure Time and Pain at the Lower Back and Neck
- On the Prediction of Adult Shortness and Tallness
- On the Use of Multiple Imputation in Handling Missing Values in Longitudinal Studies
- On the Construction of Growth Reference Values during the Paediatric Years
- A Randomised Controlled Trial to Compare the Efficacy and Safety between Two Different Mydriatic Regimens
- A Single blind, Randomised 7-day Study of the Efficacy of Patanol versus Loratadine on Allergic Conjunctivitis in Hong Kong
- Current Good Clinical Practice (GCP) Knowledge among Investigators and Pharmaceutical Employee
- The Effect of Guolin Qigong on Patients receiving Transcatheter Arterial Chemoembolisation for Inoperable Carcinoma of the Liver
- Sample Size Planning for Clinical Trials with Repeated Measurements
- Angiotensin Converting Enzyme Inhibitor Alone or in Combination with Angiotensin II Type I Receptor Blocker, in Patients with Chronic Proteinuric Nephropathies: A Systematic Review of Clinical Trials
- Survey of Albumin Use by Doctors in Hong Kong Public Hospitals
- Filing of Complaints by the US Food and Drug Administration
- Biochemical Screening Algorithms for Pheochromocytoma in Hong Kong
- A Survey of the Perceptions of Impact Factor Among Gastrointestinal Researchers
- Comparative Analysis of Refractive Outcome using Partial Coherence Interferometry and ultrasound Biometries in Pharmacoemulsification Cataract Surgery
- Current and Future Trends in Proteomics (SELDI-TOF Technology) in Clinical Diagnosis and Clinical Research
- Clinical Research and Drug Prescription Patterns among Private Practitioners in Hong Kong
- Review of Clinical Trial Publications in Hong Kong from 1994 – 2004
- A Longitudinal Study of White Matter Fractional Anisotropy in Childhood Medulloblastoma Survivors by Diffusion Tensor MR Imaging
- Secular Change in BMI from 1974 to 2000 in Swedish Children
- The Impact of Regional Treatment to Residual Neck Node of Nasopharyngeal Carcinoma (NPC) Patients
- Psychological Factors of Disordered Eating in Pregnant Women

Achievements

Academic Research

China Spinal Cord Injury Network

The China Spinal Cord Injury Network (ChinaSCINet) – an international research network dedicated to developing promising therapies for spinal cord injured patients – is now fully operational following its establishment in 2004.

CTC has been appointed the coordinating centre for the network. During the year, ChinaSCINet organized one international symposium, three large meetings and three training courses. The first multicentre clinical study was also initiated in both mainland China and Hong Kong, with a target of enrolling 600 acute and chronic spinal cord injured patients.

ChinaSCINet has gained enthusiastic support from local and international societies. Over HK$3.5 million was raised through fundraising events in 2005, and so far HK$12.7 million has been raised worldwide.

Major events of the China Spinal Cord Injury Network in 2005	
March 14	The second China SCI Network meeting in Hong Kong
March 14-15	Training course on neurological assessment of spinal cord dysfunction in Hong Kong
March 16	Training programme on Good Clinical Practice in Hong Kong
May 5	The second fundraising event – "Perfume" drama premiere in Hong Kong
July 10-13	Training course on spinal cord injury model, therapy methods and outcome measures in Hong Kong
October 15-16	The first China SCI Network investigator meeting in Beijing
October 20	Initiation of the first multicentre clinical study in mainland China and Hong Kong
December 17-20	The first International Spinal Cord Injury Treatments and Trials Symposium in Hong Kong
December 18	The second China SCI Network investigator meeting in Hong Kong

Selected publications in international scientific journals by CTC staff members in 2005

- Ansari M.T., Cheung B.M.Y., Huang J., Eklof B. and Karlberg J.P.E., Traveler's thrombosis: A systematic review, *Journal of Travel Medicine*. 2005, 12(3): 142-154.
- Cheung B.M.Y., Lo L.F., Fong D.Y.T., Chan M.Y., Wong S.H.T., Wong V.C.W., Lam K.S.L., Lau C.P. and Karlberg J.P.E., Randomised controlled trial of qigong in the treatment of mild essential hypertension, *J Hum Hypertens*. 2005, 19(9): 697-704.
- Cheung S.T., Leung K.L., Ip Y.C., Chen X., Fong D.Y.T., Ng I.O.L., Fan S.T. and So S., Claudin-10 expression level is associated with recurrence of primary hepatocellular carcinoma, *Clinical Cancer Research*. 2005, 11(2 Pt 1): 551-556.
- Cheung S.T., Ho J.C.Y., Leung K.L., Chen X., Fong D.Y.T., So S. and Fan S.T., Transcript AA454543 is a novel prognostic marker for hepatocellular carcinoma after curative partial hepatectomy, *Neoplasia*. 2005, 7(2): 91-98.
- Huang J., Zheng G., Hunt R.H., Wong R.W.M., Lam S.K., Karlberg J.P.E. and Wong B.C.Y., Do patients with non-ulcer dyspepsia respond differently to Helicobacter pylorieradication treatments from those with peptic ulcer disease? A systemic review, *World Journal of Gastroenterology*. 2005, 11 (18): 2726-2732.
- Lam K.F., Fong D.Y.T. and Tang O.Y., Estimating the proportion of cured patients in a censored sample, *Statistics in Medicine*. 2005, 24: 1865-1879.
- Mok T.M.Y., Chan E.Y.T., Fong D.Y.T., Leung K.F.S., Wong W.S. and Lau W.C.S., Antiphospholipid Antibody Profiles and Their Clinical Associations in Chinese Patients with Systemic Lupus Erythematosus, *The Journal of Rheumatology*. 2005, 32 (4): 622-8.
- Ni G., Lu W.W., Chiu P.K.Y. and Fong D.Y.T., Review article: Cemented or uncemented femoral component in primary total hip replacement? A review from a clinical and radiological perspective, *Journal of Orthopaedic Surgery*. 2005, 13(1): 96-105.
- Wang W.H., Huang J., Zheng G., Wong R.W.M., Lam S.K., Karlberg J.P.E., Xia H.H.X., Fass R. and Wong B.C.Y., Is Proton Pump Inhibitor Testing an Effective Approach to Diagnose Gastroesophageal Reflux Disease in Patients With Noncardiac Chest Pain?, *Archives of Internal Medicine. 2005,* 165: 1222-1228.
- Wong R.W.M., Huang J., Xia H.H.X., Fung F.M.Y., Tong S.M., Cheung K.L., Ho Y.K., Lai K.C., Chan C.K., Chan O.O., Hui C.K., Lam S.K. and Wong B.C.Y., Low-dose rabeprazole, amoxicillin and metronidazole triple therapy for the treatment of Helicobacter pylori infection in Chinese patients , *Journal of Gastroenterology and Hepatology*. 2005, 20(6): 935-940.
- Chan Y.M., Lee P.W.H., Fong D.Y.T., Fung A.S.M., Wu L.Y.F., Choi A.Y., Ng T.Y., Ngan H.Y.S. and Wong L.C., Effect of individual psychological intervention in Chinese women with gynecologic malignancy: A randomized controlled trial, *Journal of Clinical Oncology*. 2005, 23(22): 4913-4924.
- Cheung B.M.Y., Lo J.L., Fong H.Y., Chan M.Y., Wong S.H., Wong C.M., Lam K.S.L., Lau C.P. and Karlberg J.P.E., Randomised controlled trial of qigong in the treatment of mild essential hypertension, *J Hum Hypertens*. 2005, 19: 697-704.
- Mok T.M.Y., Chan E.Y.T., Fong D.Y.T., Leung K.F., Wong R.W.S. and Lau W.C.S., Antiphospholipid Antibody Profiles and their Clinical Associations in Chinese Patients with Systemic Lupus Erythematosus, *J Rheumatol*. 2005, 32: 622-8.
- Karlberg J.P.E., Establishing a full-service Academic Clinical Trials Centre in Asia - pt 1, *SPIN*. 2005, Summer: 12-13.
- Karlberg J.P.E., Establishing a full-service Academic Clinical Trials Centre in Asia - pt 2, *SPIN*. 2005, Autumn: 8-10.

Remarkable Events

April Publication of the 2004 CTC annual report

May Completion of the second fundraising event of the HKU Spinal Cord Injury Fund, through which over HK$1 million was raised

June Launch of HKU Clinical Trial Register – the first public clinical trial register in Hong Kong

July Launch of AccreditGCP – the online GCP training and accreditation programme

August Contracting the 200th industry-sponsored clinical study coordinated through CTC

October Initiation of the first multicentre clinical study in spinal cord injured patients in mainland China and Hong Kong through the China Spinal Cord Injury Network

November First submission of applications for the "Clinical Research Base" designation by the China State Food and Drug Administration

December Organization of the first International Spinal Cord Injury Treatments and Trials Symposium in Hong Kong

CTC Homepage
www.hku.hk/ctc

HKU Clinical Trial Register
www.hkclinicaltrials.com

ClinCluster
www.clincluster.com

ALab
www.alaboratory.com

AccreditGCP
www.accreditgcp.com

HKU SCI Fund
www.hku.hk/hkuscif

Clinical Trials Centre

Li Ka Shing Faculty of Medicine
The University of Hong Kong