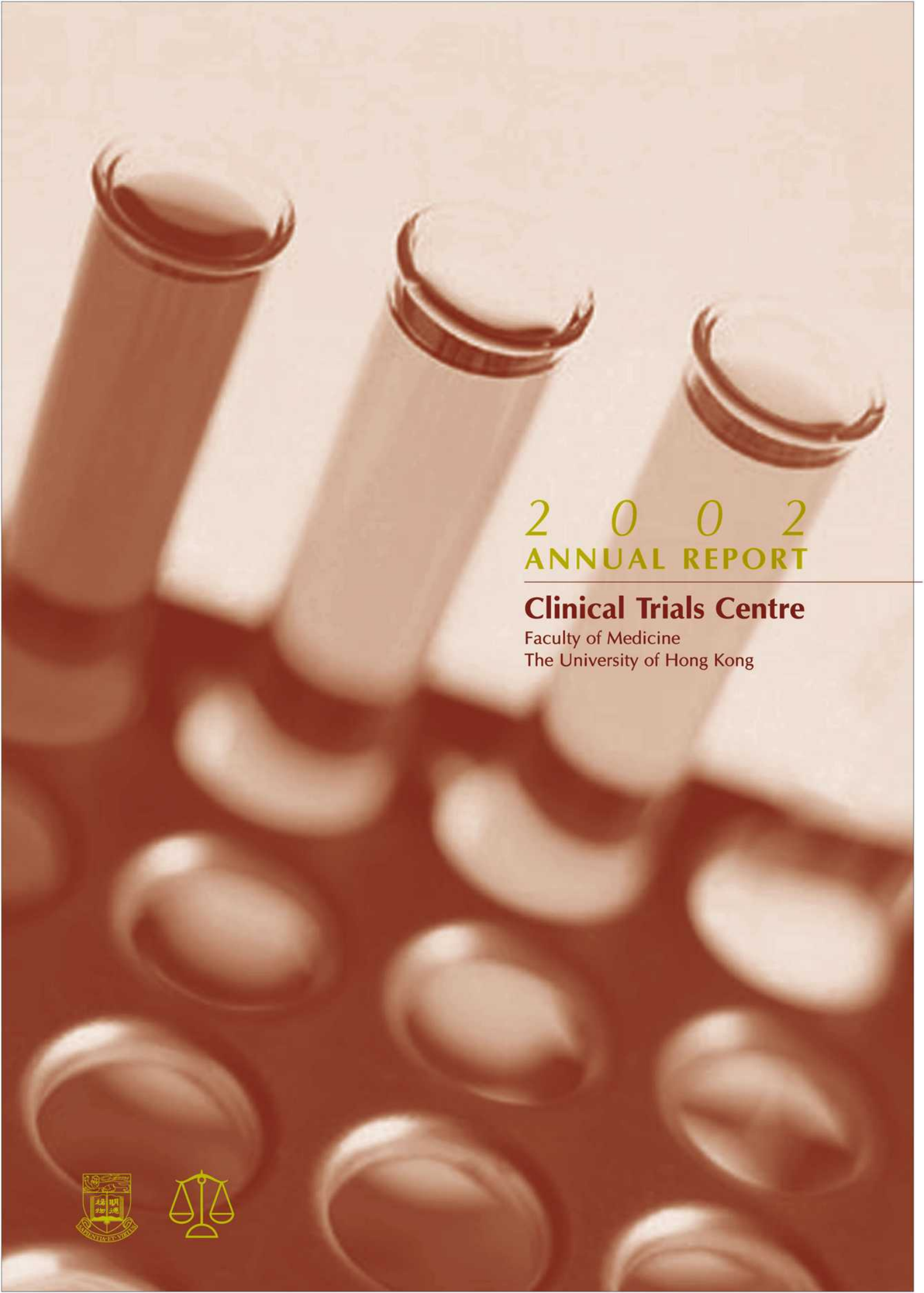

2002 ANNUAL REPORT

Clinical Trials Centre

Faculty of Medicine
The University of Hong Kong

Clinical Trials Centre
Faculty of Medicine
The University of Hong Kong

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Foreword

2002 was an important year for the Clinical Trials Centre as it marked the completion of its infrastructure-building phase and commencement of the second phase of development – expansion and diversification.

Hong Kong: An Asian hub for clinical trials

Clinical trials are crucial as they are required at the final stage of development of every new therapy – be it a drug, device, diagnostic test, traditional therapy or medical/surgical procedure claiming efficacy and safety. Clinical trials account for about 40% of all publications in leading medical journals such as The Lancet, BMJ, New England Journal of Medicine and JAMA.

Clinical trials have been conducted in Asia for decades, but a rapid increase in such activities did not emerge until the mid-1990s. In Hong Kong, for example, the number of clinical trial certificates issued by the Department of Health (DOH) only averaged about 20 per year in the early-1990s – yet the number shot up to over 100 for the first time in year 2000. As Asia gathers momentum in modernisation and globalisation, multinational and regional pharmaceutical companies are attaching more and more emphasis and importance to the Asian region, not only in marketing but also in research and development. At the same time, China-based pharmaceuticals have started breaking out of the region into the international arena.

In response to the rapidly changing international environment over the past few years, Hong Kong has converted itself into an important Asian centre for international clinical trials and biomedical research. Indeed, as the Hong Kong SAR Government expresses a vision of developing Hong Kong into a knowledge-based society, biotechnology is anticipated to be a focus of future development. Mr. Michael Dixon, IBM's Regional Vice-President for Life Sciences, also acknowledges that Hong Kong is positioned to become an important player in biotechnology, supported by such advantages as efficient infrastructure, global marketing abilities, admired research institutes and sophisticated logistics. With the joint effort and collaboration of the industry, academic institutions and the Government, Hong Kong can become an important hub for international biotechnology development.

The trend of centralised management

Clinical and biomedical research is becoming increasingly competitive on a global basis. Long-term collaborations are being established between academic institutions and the industry, and the winners among academic institutions are those that can respond to and fulfill the needs of the industry – by providing highly competent and well-trained clinical investigators and research personnel, by pursuing efficient research administration and logistic, and by developing and maintaining effective quality assurance systems in line with international standards.

The concept of centralised management of clinical trial activities is becoming more and more popular in medical institutions. In 1997, only 23% of medical institutions in the United States 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 office for better quality control, convenience of administration and easier management of clinical trial sites. Clinical trials central offices are now generally regarded as a good interface enhancing long-term collaboration between the industry and medical institutions.

From infrastructure development to expansion and diversification

The Clinical Trials Centre (CTC) was founded under the Faculty of Medicine of The University of Hong Kong (HKU) in 1998 and is the first and currently the only full-service academic research organisation in the Asian region offering one-stop solutions to clinical trial sponsors and investigators. Our mission is to enhance human healthcare by promoting the quality and efficiency of clinical trials through ethical considerations, scientific expertise, quality assurance and education.

2002 was an important year for the CTC as it marked the completion of its infrastructure-building phase and commencement of the second phase of development – expansion and diversification. A Board of Directors was also established to accomplish the changing development strategy. I am proud to announce that after our four years of effort the CTC has developed into a mature, sustainable organisation with well-trained professional staff in all its functional units and with important achievements in different dimensions. Some of our major achievements during the year include:

- Contracted the 79th clinical trial project and achieved a cumulative contract value of HK$55 million;
- Completed the inspection of the clinical laboratories at the Queen Mary Hospital (QMH) for accreditation under the Laboratory Accreditation Programme (LAP) of the College of American Pathologists (CAP) (Remarks: Accreditation was granted in January 2003);
- Entered into a Memorandum of Understanding with CentraLabS Clinical Research Limited, a UK-based international laboratory testing company, to establish a strategic alliance for pursuing the international clinical trials central laboratory business;
- Entered into a Memorandum of Understanding with Fudan University of Shanghai for long-term collaboration on international clinical trials;
- Graduation of the 25th student from the Master of Medical Sciences degree programme in Clinical Trials Research Methodology.

The road ahead

"Holistic medicine" is a new concept in biomedical research and development. The underlying principle is: a medicine that works is a medicine, no matter whether it is a conventional chemical drug, biologic, traditional Chinese medicine or alternative medicine. Amidst the East and the West, Hong Kong is in a strategically advantageous position for research and development of holistic medicine. The CTC will continue to improve its team, its infrastructure and its services with the objective of enhancing holistic medicine research in Hong Kong on a global basis.

" The CTC will continue to improve its team, its infrastructure and its services with the objective of enhancing holistic medicine research in Hong Kong on a global basis. "

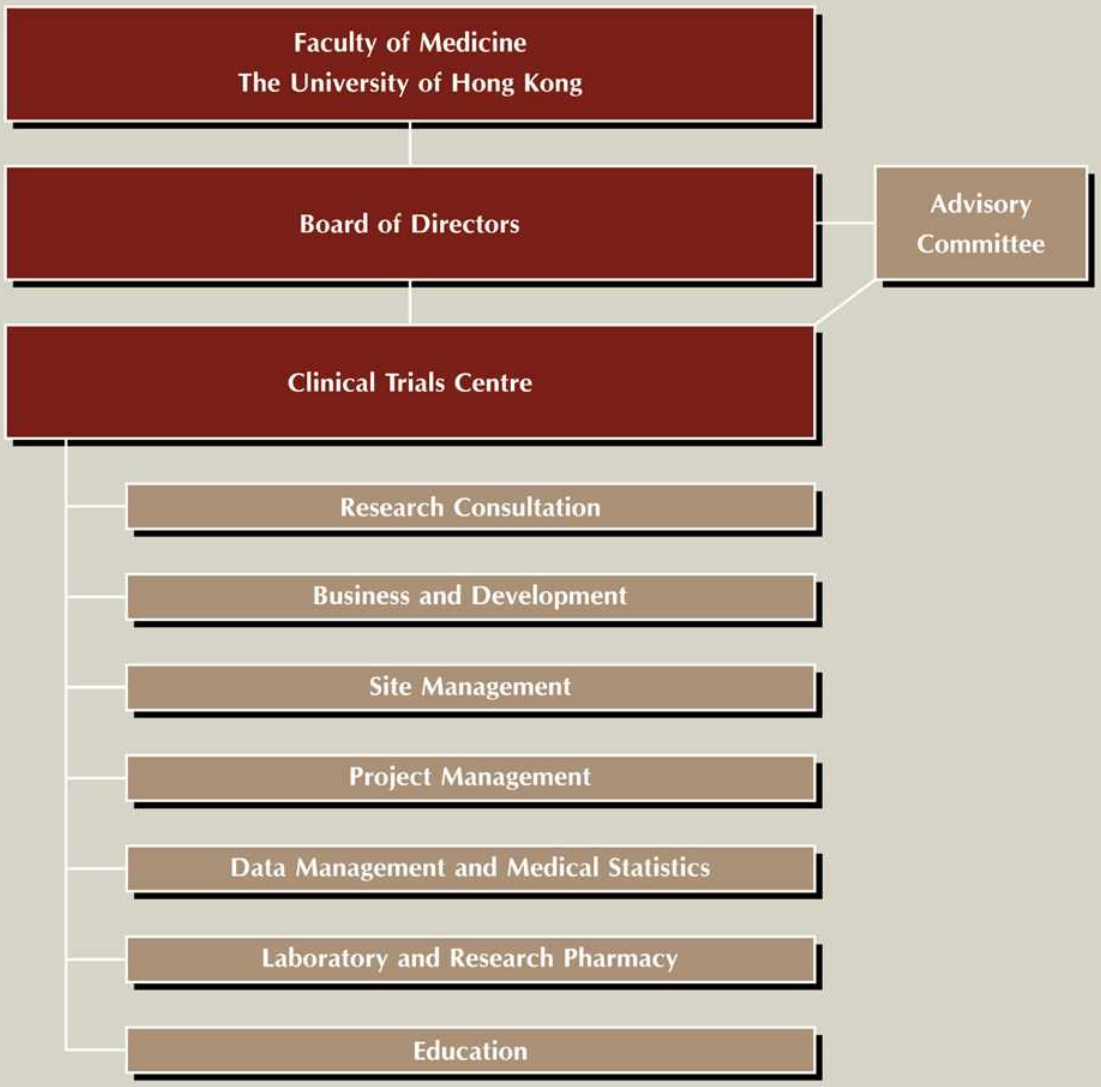
Johan Karlberg

Johan Karlberg MD, PhD
Director
Clinical Trials Centre
Faculty of Medicine
The University of Hong Kong

February 12, 2003

Organisation Structure

The year 2002 was an important milestone for the CTC, marking its successful evolvution into a full-service academic research organisation comprising seven functional units after four years' continuous development. In line with the rapid growth of the CTC, a Board of Directors was first established in June. The Board is directly responsible to the Faculty of Medicine of the HKU and is composed of representatives from all related bodies under the HKU and the QMH involved in clinical trial activities, including the Dean of the Faculty of Medicine of the HKU, the Hospital Chief Executive of the QMH, the Director of the CTC, the Executive Director of the School of Chinese Medicine of the HKU, an expert in pharmacology, two representatives of clinical investigators and a representative of the clinical laboratories.



Board of Directors

Chairman

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

Members

Professor SK Lam
Dean, Faculty of Medicine
The University of Hong Kong

Dr. York Chow
Hospital Chief Executive
Queen Mary Hospital

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

Professor Cyres R Kumana
Chief, Division of Clinical Pharmacology
Department of Medicine
The University of Hong Kong

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

Professor CS Lau
Co-chief, Division of Rheumatology
Department of Medicine
The University of Hong Kong

Professor Samuel TH Chan
Executive Director, School of Chinese Medicine
The University of Hong Kong

Dr. Robert J Collins
Chief of Service
Department of Pathology and Clinical Biochemistry
Queen Mary Hospital

Secretary

Mr. Henry KC Yau
Business Development Manager, Clinical Trials Centre
The University of Hong Kong

The CTC's Team

Director
Professor Johan PE Karlberg MD, PhD

Research Consultation

Professor Johan PE Karlberg MD, PhD	Professor
Dr. Jiaqing Huang MSc, MSc (Epid), MD	Assistant Professor (Research)
Dr. CW Kwan BSc, PhD	Medical Statistician
Mr. William PY Wong BSc, MPhil	System Analyst

Business and Development

Mr. Henry KC Yau BSc, MBA	Business Development Manager
Ms. Gretel YM Yiu BBA	Business Development Officer
Ms. Haley HL Wong	Secretary

Project Management and Site Management

Dr. Selene YM Tam BHSc, MMedSc, PhD, RN	Project Manager
Ms. Yolanda SM Yan BScN, MMedSc, RN	Site Manager

Data Management and Medical Statistics

Dr. Daniel YT Fong BSc, MPhil, PhD	Senior Medical Statistician
Mr. Jeremy CM Li BSc, MMedSc	Clinical Data Manager

Specimens Handling Unit and Research Pharmacy

Ms. Stella WS Wong BSc, MMath, RegMLT	Research Unit Coordinator
Dr. Rex LS Hung BSc, PharmD	Research Pharmacist (Part-time)

CAP Accreditation

Ms. Betty SY Leung MBA, CFIAC, MAIMS, RegMLT	CAP-LAP Coordinator

Education

Mr. James Thorburn BSc	Education Coordinator

Office and General Affairs

Ms. Josephine SY Yuen	Secretary
Mr. MW Cheng	Clerical Assistant
Ms. Mabel MC Cheng	Caretaker

New Team Members

Dr. Jiaqing Huang, Assistant Professor (Research)
Dr. Huang is a Medical Doctor and was a Consultant Gastroenterologist and Associate Professor of Medicine at the Peking Union Medical College Hospital for five years. Since 1995, Dr. Huang worked under the Division of Gastroenterology at McMaster University Medical Center of Canada until joining The University of Hong Kong in November 2002. Dr. Huang has expertise in conducting systematic reviews, clinical trials and teaching of clinical research methodology, and serves as a reviewer for 12 international gastroenterology journals. Dr. Huang is now serving both the CTC and the Department of Medicine with his major responsibilities include teaching of systematic reviews, evidence-based medicine and conducting EBM research.

Mr. William PY Wong, System Analyst
Mr. Wong obtained his BSc and MPhil degrees in computational physics at The University of Hong Kong in 1995 and 1999 respectively and has been a Delphi Developer in developing applications for telecommunication and document management using Borland Delphi for six years. Mr. Wong joined the CTC as a System Analyst in October 2002 and provides technical supports in information technology for externally sponsored clinical research projects.

Ms. Haley HL Wong, Secretary
Ms. Wong was a professional secretary trained from the Sacred Heart Canossian Commercial School and the Hong Kong Baptist University School of Continuing Education, and has over eight years' secretarial experience in different companies before she joined the CTC as a Secretary in September 2002.

Clinical Investigators

More clinical investigators at the HKU became involved with clinical trials of different kinds in 2002. By the end of the year, the cumulative number of clinical investigators at the HKU acting as principal investigators for industry-sponsored clinical trials coordinated through the CTC was up to 31. With the rapidly increasing clinical trial activities in Hong Kong, the list of clinical investigators is anticipated to expand continuously in the coming years.

Department	Principal Investigator
Anaesthesiology	Dr. Karl Young
Clinical Oncology	Dr. Raymond TT Chan Professor Jonathan ST Sham
Medicine	Dr. Bernard MY Cheung Dr. LW Chu Professor Annie WC Kung Professor CL Lai Professor CP Lau Professor CS Lau Dr. George KK Lau Professor Karen SL Lam Professor SK Lam Dr. Kathy LF Lee Professor Raymond HS Liang Dr. Kathyrn CB Tan Dr. Kenneth WT Tsang Dr. Benjamin CY Wong Dr. Adrian YY Wu
Microbiology	Dr. PL Ho
Obstetrics and Gynaecology	Professor Hextan YS Ngan Professor Grace WK Tang
Paediatrics	Dr. Henry Hui Professor YL Lau Dr. NS Tsoi
Psychiatry	Dr. Eric YH Chen Dr. SE Chua
Surgery	Dr. Louis WC Chow Dr. KW Chu Dr. WK Ho Dr. PC Tam Professor William Wei

* In addition to the above principal investigators, some 100 co-investigators were also involved with industry-sponsored clinical trials coordinated through the CTC by end-2002.

Achievements

Industry-Sponsored Clinical Trials

Strong growth in sponsored trials

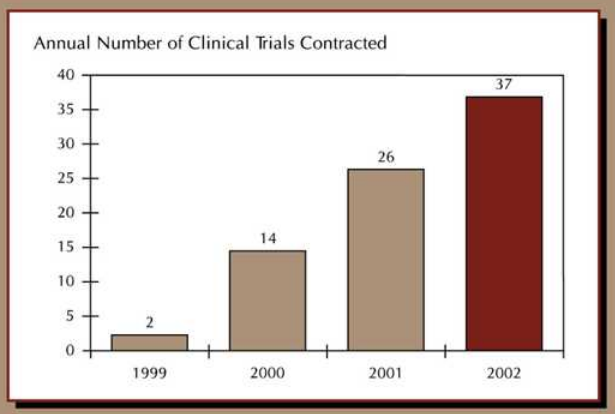
2002 was an encouraging year. The number of industry-sponsored clinical trials coordinated through the CTC increased by 42% to 37 and the corresponding contract value increased by 87% to HK$23.6 million. Both figures reached record highs since the establishment of the CTC. The diversity of therapeutic areas of clinical trials kept expanding over the year, although Gastroenterology and Hepatology is still the most actively involved area. Other active areas include Endocrinology and Metabolism, Cardiology and Clinical Oncology. Among all the completed and ongoing trials, Phase II and III trials together account for 83%.

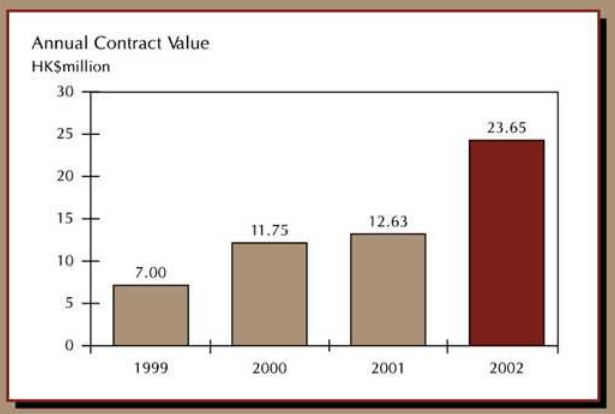
Master contracts

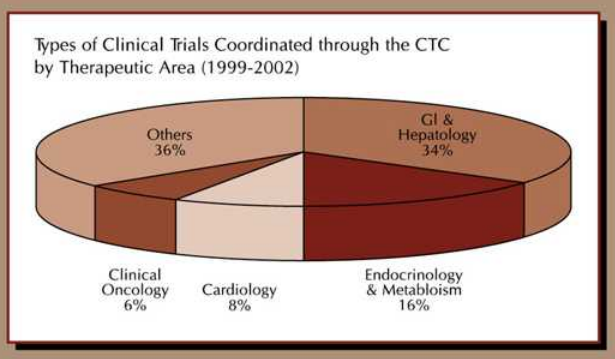
In order to enhance the efficiency of contract administration, the CTC has been striving to develop a master clinical trial contract applicable to all future clinical trial projects with each trial sponsor. By the end of 2002, the CTC had developed master contracts with 29 sponsors worldwide, and many others are under discussion.

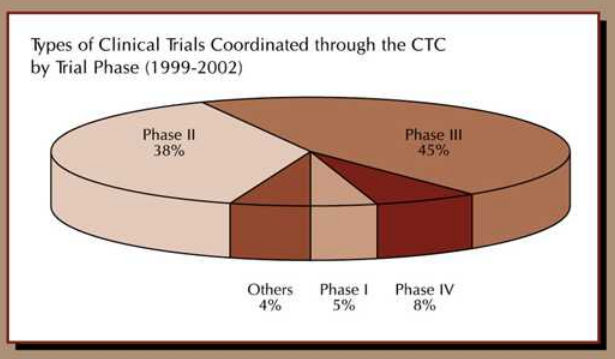
Clinical Trial Sponsors Developed a Master Clinical Trial Contract with the CTC

Abbott Laboratories	Merck Sharp & Dohme
Achillion Pharmaceuticals	Novartis
Advanced Herbal Therapeutics	Novo Nordisk
AstraZeneca	OSI Pharmaceuticals
Aventis Pharma	Pfizer
BCIRG	Pharmacia
Biomeasure	Pi Medical
Bristol-Myers Squibb	Roche
Eli Lilly	Schering-Plough
Everpride Biopharmaceutical	Serono
FeRx	Triangle Pharmaceuticals
GlaxoSmithKline	Tularik
Idenix Pharmaceuticals	Wyeth Pharmaceuticals
Janssen	Zila
Kowa	









Industry-Sponsored Clinical Trials Contracted in 2002

Department	Principal Investigator	Disease Area	Phase	Status
Clinical Oncology	Dr. Raymond TT Chan	Breast Cancer	II	Active
Clinical Oncology	Dr. Raymond TT Chan	Liver Cancer	II	Active
Medicine	Professor Annie WC Kung	Oesteoporosis	III	Active
Medicine	Professor CL Lai	Hepatitis	II	Active
Medicine	Professor CL Lai	Hepatitis	II	Active
Medicine	Professor CL Lai	Hepatitis	III	Closed
Medicine	Dr. KC Lai	Oesteoarthritis	III	Active
Medicine	Professor Karen SL Lam	Diabetes Mellitus	III	Closed
Medicine	Professor Karen SL Lam	Diabetes Mellitus	IV	Active
Medicine	Professor Karen SL Lam	Diabetes Mellitus	IV	Active
Medicine	Professor CP Lau	Atrial Fibrillation	III	Active
Medicine	Professor CS Lau	Psoriasis	II	Active
Medicine	Professor CS Lau	Systemic Lupus Erythematosus	II	Active
Medicine	Dr. George KK Lau	Cirrhosis	III	Active
Medicine	Dr. George KK Lau	Hepatitis	III	Active
Medicine	Dr. George KK Lau	Hepatitis	III	Active
Medicine	Dr. George KK Lau	Hepatitis	I	Closed
Medicine	Dr. George KK Lau	Hepatitis	II	Active
Medicine	Dr. George KK Lau	Hepatitis	II	Active
Medicine	Dr. Kathy LF Lee	Dyslipidemia	II	Active
Medicine	Dr. Kathy LF Lee	Dyslipidemia	II	Active
Medicine	Dr. Kenneth WT Tsang	Lung Cancer	III	Active
Medicine	Dr. Benjamin CY Wong	Pancreatic Cancer	III	Active
Medicine	Dr. Benjamin CY Wong	Gastric Ulcer	III	Closed
Medicine	Dr. Adrian YY Wu	Asthma	III	Active
Microbiology	Dr. PL Ho	Pneumonia	III	Closed
Obstetrics & Gynaecology	Professor Grace WK Tang	Human Pappillomavirus	III	Active
Paediatrics	Professor YL Lau	Influenza	III	Active
Paediatrics	Dr. Henry Hui	Asthma	III	Active
Psychiatry	Dr. Eric YH Chen	Schizophrenia	O *	Active
Psychiatry	Dr. SE Chua	Schizophrenia	III	Active
Surgery	Dr. Louis WC Chow	Breast Cancer	III	Active
Surgery	Dr. Louis WC Chow	Breast Cancer	III	Active
Surgery	Dr. Louis WC Chow	Breast Cancer	III	Active
Surgery	Dr. KW Chu	Colorectal Infection	IV	Active
Surgery	Dr. WK Ho	Allergic Rhinitis	IV	Closed
Surgery	Dr. PC Tam	Erectile Dysfunction	II	Active
Surgery	Dr. PC Tam	Erectile Dysfunction	II	Active

* O - Observational study

Achievements

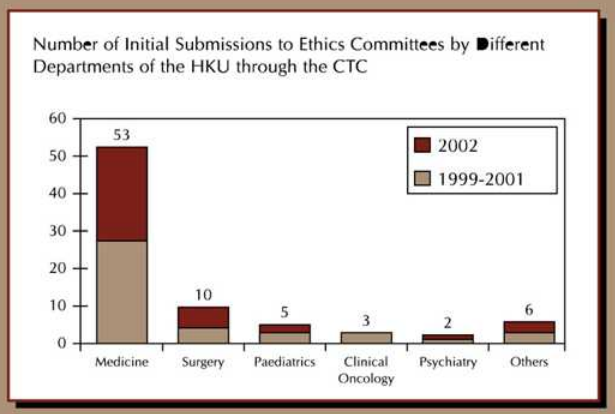
Site Management

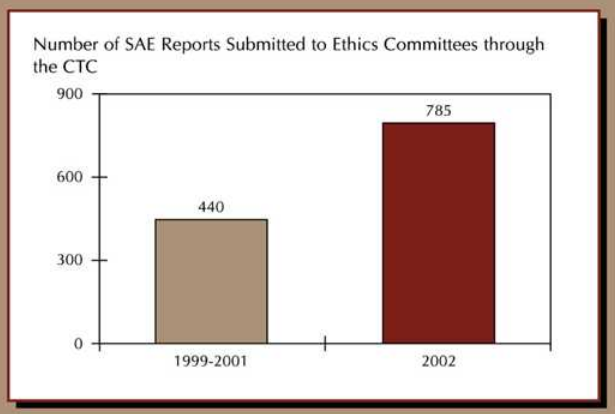
Ethics committee

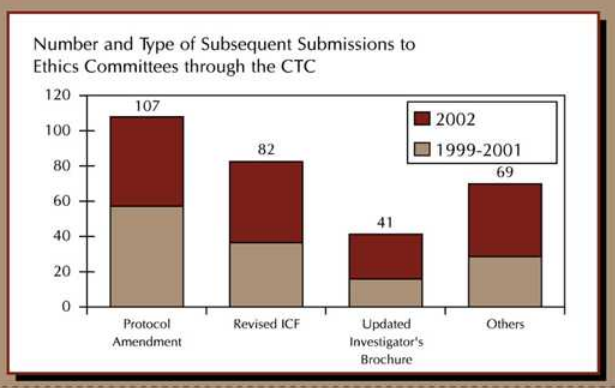
Ethics committees are the fundamental infrastructure responsible for trial subject protection. Globalisation of clinical trial activities in recent years has aroused concerns about the operations of ethics committees worldwide. Since its establishment in 1998, the CTC has been authorised by the Faculty of Medicine of the HKU to assist clinical investigators in trial subject protection by complying with ethics committees' requirements. During the year 2002, 40 initial submissions and 163 subsequent submissions were made to ethics committees through the CTC – both figures being higher than the respective totals between 1999 and 2001. A total of 785 reports for serious adverse events (SAEs) were also submitted, which represented a 78% increase over the tally of the preceding three-year period. A total of 42 standard operating procedures for site management had been developed by the end of the year.

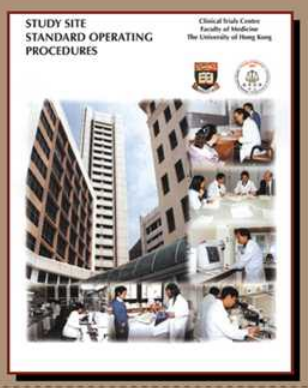
Trial subject recruitment

In addition to facilitating communication with ethics committees, the CTC continued to provide trial sites with various supports such as trial subject recruitment. During the year, the CTC assisted a number of trial sites in recruiting suitable trial subjects, including successful recruitment of 48 healthy volunteers for a multinational vaccine trial within a short period of two weeks.









Study sites are managed professionally and ethically at the HKU in accordance with international standards.

Achievements

Specimens Handling and Laboratory Services

Specimens Handling Unit

The Specimens Handling Unit is an infrastructure set up in 2001 for handling clinical trials specimens. The Unit is staffed by a team of professionally qualified laboratory technicians and equipped with advanced facilitates such as refrigerated centrifuges, freezers with a total capacity of 50,000 specimens under various storage conditions (4˚C, -25˚C and -70˚C) and a 24-hour monitoring system. The set of 41 standard operating procedures was fully developed in the year 2002 and is now being implemented for all the works and processes in the Unit. To further enhance the Unit's performance, the CTC has also started developing a "specimens tracking system" which is anticipated to be in full operation in mid-2003.

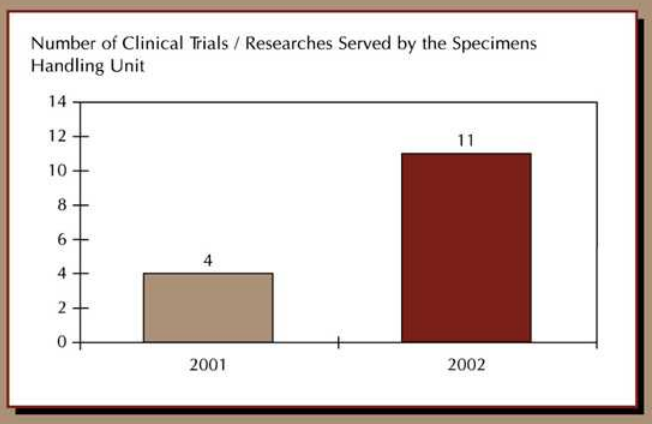
The level of activities increased substantially compared with the previous year. During 2002, the Unit provided services for 11 clinical trials / researches conducted in the HKU. With the rapid increase in the number of clinical trials at the HKU, the usage level of the Unit will continue to increase in the coming years.

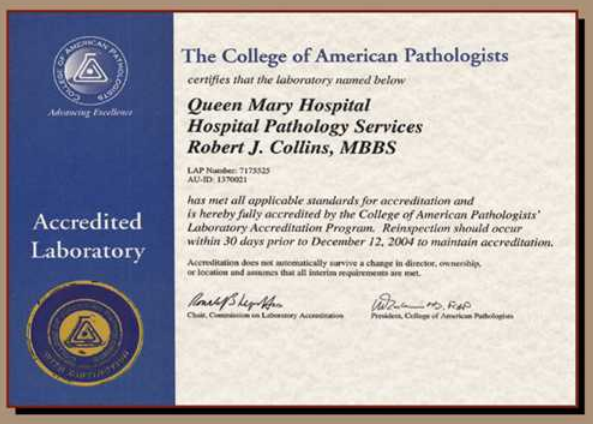
Central laboratory services

In response to the increasing clinical trial activities in the Asian region and the elevating demand for clinical trials central laboratory services, the CTC is planning to launch its central laboratory services together with the clinical laboratories at the QMH. The target is to serve not only trial sites at the HKU but also other trial sites in Hong Kong, mainland China and other Asian countries. To facilitate this development, a Memorandum of Understanding was executed with CentraLabS Clinical Research Limited (CentraLabS) in October 2002 and the plan is to have the CTC and the QMH's clinical laboratories as the Asian operation arm of the global central laboratory business network of CentraLabS.

Accreditation by the CAP

Quality assurance is the key to laboratory services for clinical trials. January 27, 2003 was a memorable day for the CTC and the clinical laboratories at the QMH as a full accreditation with distinction, which is a real first for large multidiscipline laboratories in a hospital in Hong Kong, was officially granted by the College of American Pathologists (CAP) after two years' continuous preparation by the whole team and the formal inspection in December 2002. The CAP accreditation signifies international recognition of the quality of the team, the facilities and the operations, and is an important milestone for achievement of excellence by the clinical laboratories at the QMH.





Accreditation by the CAP signifies the excellent performance of the clinical laboratories at the QMH.

Achievements

Project Management and Trial Monitoring

Project management

The CTC continued to expand its project management services in the year, keeping pace with accelerating international clinical trial activities and a boom of the local biotechnology industry in Hong Kong. During the year 2002, the CTC's project management team secured five Certificates for Clinical Trial from the DOH of Hong Kong on behalf of clinical trial sponsors from the United States, Europe and Japan. A clinical trial of a modernised traditional Chinese medicine (TCM) product sponsored by a local pharmaceutical company was also completed in the year with great satisfaction and in accordance with the highest international standards under the sole management of the CTC. The success of the trial demonstrated the strong capability of the CTC in clinical trial project management in terms of both quality and efficiency.

Trial monitoring

Trial monitoring is an important quality assurance measure and is an integral part of clinical trial project management. The CTC has a team of professionally qualified and experienced monitors and is able to help sponsors to monitor trial sites for any single or multi-centre trial. A full set of eight standard operating procedures for trial monitoring activities was completely developed and fully implemented during 2002. By the end of the year, the CTC had provided trial monitoring services for 10 clinical trials / researches.

List of Standard Operating Procedures for Trial Monitoring

- CRA01 Study preparation
- CRA02 Investigator meetings
- CRA03 Study initiation visits
- CRA04 Study monitoring visits
- CRA05 Management of serious adverse events
- CRA06 Data clarification
- CRA07 Study site closeout visits
- CRA08 Archiving

Monitoring Services for Clinical Trials / Researches

Project	Phase	Centre	Research Type	Therapeutic Area	No. of Subjects	Status
1	n/a	Single-centre	Alternative Medicine	Endocrinology	100	Closed
2	n/a	Single-centre	Alternative Medicine	Cardiology	100	Closed
3	n/a	Single-centre	Alternative Medicine	Oncology	80	Closed
4	n/a	Single-centre	Alternative Medicine	Oncology	300	Closed
5	II	Multi-centre	Drug	Hepatology	30	Closed
6	II	Multi-centre	Drug	Respiratory	30	Closed
7	I	Single-centre	TCM	Cardiology	30	Closed
8	II	Multi-centre	Drug	Hepatology	30	Active
9	I	Multi-centre	Device	Otorhinolaryngology	15	Active
10	II	Multi-centre	Drug	Hepatology	30	Active

Achievements

Clinical Data Management and Medical Statistics

Expanding clientele

In 2002, the CTC provided a total of 112 services in clinical data management and medical statistics, which represented a 56% increase over the previous year. Most services were provided to medical departments of the HKU, whilst some others were for other research institutes, hospitals, government agencies, private practitioners, healthcare companies and contract research organisations. 21 (19%) of the services led or are leading to publications in peer reviewed journals.

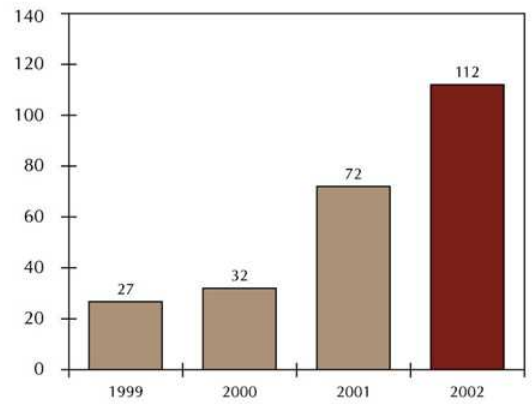
Service scope

The types of services provided include statistical analysis, sample size estimation, design of clinical trial, clinical data management, review of trial protocol and manuscript, reply to comments from journal reviewers and assistance in research grant application. Particularly, our clinical data management services range from case report form design, database design, data acquisition and data cleaning to data listing. So far 22 standard operating procedures for clinical data management and medical statistics have been developed.

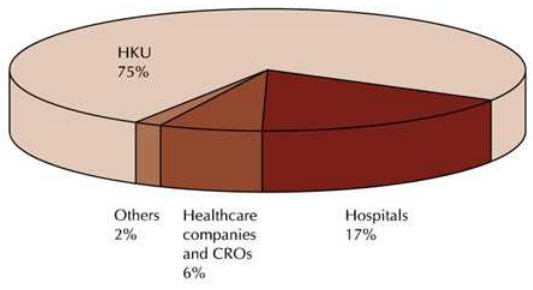
Types of Clinical Data Management and Medical Statistics Services Provided in 2002

Type of Service	%
Statistical analysis	68
Sample size estimation	17
Design of clinical trial	14
Clinical data management	6
Protocol/manuscript review	6
Reply to reviewer's comment	7
Research grant application	5

Number of Clinical Data Management and Medical Statistics Services Provided



Clientele for the CTC's Clinical Data Management and Medical Statistics Services



Achievements

Education

Clinical Trials Research Methodology

The CTC has been offering the Master of Medical Sciences degree programme (MMedSc) in Clinical Trials Research Methodology since 1998. The 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. A total of nine students graduated from the programme in the year 2002.

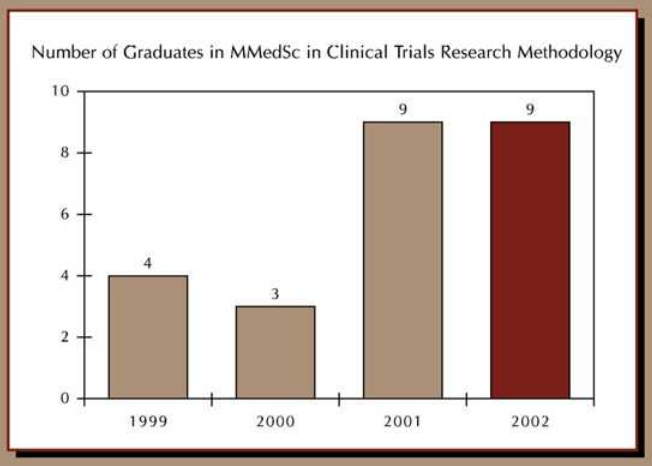
New programmes

With the increasing popularity of the Master of Medical Sciences in Clinical Trials Research Methodology, another master programme – Master of Medical Sciences in Medical Statistics – was subsequently introduced in September 2002. The objective is to provide students with organised knowledge in medical statistics from both theoretical and practical perspectives.

Two other new programmes – Postgraduate Diploma and Postgraduate Certificate in Clinical Trials Research Methodology or Medical Statistics – were also introduced in September 2002. The two programmes involve 200 and 80 contact hours respectively, require no dissertation, and are tailored for busy professionals who wish to grasp key, updated knowledge relating to clinical trials or medical statistics.

Symposium and GCP training

A symposium on "Transportation of Infectious Materials" was organised in March 2002, which attracted approximately 100 participants. A training course on Good Clinical Practice (GCP) was also arranged for the Faculty of Dentistry of the HKU in May 2002.



The Master of Medical Sciences in Clinical Trials Research Methodology is getting more and more popular to candidates with various scientific, medical or paramedical backgrounds.

Achievements

Research and Peer-reviewed Publications

Being an academic research organisation, the CTC conducts research in areas such as medical statistics, epidemiology and meta-analysis. In 2002, the CTC's staff contributed a total of 23 publications to different medical and scientific journals.

1. Cheung Y.B., Yip P.S.F. and Karlberg J.P.E. Size at birth and neonatal and postneonatal mortality. *Acta Paediatric* 2002, 91: 447-452.
2. Karlberg J.P.E., Yip P.S.F. and Chong S.Y. Apgar Score and Postnatal Outcomes, *Journal of Paediatrics, Obstetrics and Gynaecology* 2002, Jul/Aug: 15-22.
3. Lam Y.H., Lee C.P., Sin S.Y., Tang R., Wong H.S., Wong S.F., Fong D.Y.T., Tang M.H.Y. and Woo H.H.N. Comparison and integration of first trimester fetal nuchal translucency and second trimester maternal serum screening for fetal Down syndrome. *Prenatal Diagnosis* 2002, 22: 730-735.
4. Karlberg J.P.E. Asia on trials - how will we know? *Clinical Trials Reporter* 2002, 1(1):2.
5. Lau A.K.L., Chang C.H., Tai J.W.M., Eremenco S., Liang R.H.S., Lie A.K.W., Fong D.Y.T. and Lau C.M. Quality of life – Translation and validation of the Functional Assessment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT) Version 4 Quality of Life Instrument into Traditional Chinese. *Bone Marrow Transplantation*. London, U.K., Macmillan Publishers Ltd, 2002, 29: 41-49.
6. Karlberg J.P.E. Fodelsetidpunkt och tidig barnadodlighet i Sverige 1973-1995. *Lakartidningen* 2002, 99(19): 2155.
7. Karlberg J.P.E. Operational efficiencies and deficiencies of Ecs. *Clinical Trials Reporter* 2002, 1(2): 2.
8. Lau G., Nanji A.A., Hou J., Fong D.Y.T., Au W.S., Yuen S.T. and Lin M.C. Thymosin-_1 and famciclovir combination therapy activates T-cell response in patients with chronic hepatitis B virus infection in immune-tolerant phase. *Journal of Viral Hepatitis* 2002, 9: 280-287.
9. Karlberg J.P.E. Secular Trends in Pubertal Development. *Hormone Research* 2002, 57(suppl 2): 19-30.
10. Albertsson Wikland K., Luo Z.C. and Karlberg J.P.E. Swedish population-based longitudinal reference values from birth to 18 years of age for height, weight and head circumference. *Acta Paediatrica* 2002, 91: 739-754.
11. Lau G.K.K., Leung A.Y.H., Fong D.Y.T., Au W.Y., Kwong Y.L., Lie A.K.W., Hou J.L., Wen Y.M., Nanji A.A. and Liang R.H.S. High hepatitis B virus (HBV) DNA viral load as the most important risk factor for HBV reactivation in patients positive for HBV surface antigen undergoing autologous hematopoietic cell transplantation. *Blood* 2002, 99: 2324-2330.
12. Xu X., Wang W.P., Guo Z.P. and Karlberg J.P.E. Longitudinal Growth During Infancy and Childhood in Children from Shanghai: Predictors and Consequences of the Age at Onset of the Childhood Phase of Growth, *Pediatric Research* 2002, 51(3): 377-385.
13. Cheng Y.H., Chi I., Chou K.L., Lou W. and Kwan C.W. Functional status of the elderly and support required among community dwelling aged persons in Hong Kong. *Australasian Journal of Ageing* 2002, 21.4 (Suppl 1): 19.
14. Poon R.T.P., Lo S.H., Fong D.Y.T., Fan S.T. and Wong J. Prevention of pancreatic anastomotic leakage after pancreaticoduodenectomy. *The American Journal of Surgery* 2002, 183: 42-52.
15. Cheung Y.B., Albertsson-Wikland K., Luo Z.C., He Q. and Karlberg J.P.E. Benn Index at Birth is Associated with Postnatal Linear Growth. *Journal of Pediatric Endocrinology & Metabolism* 2002, 15 (8): 1161-1166.
16. Karlberg J.P.E., Albertsson-Wikland K., Kwan C.W. and Chan F.Y.S. Early Spontaneous Catch-Up Growth. *Journal of Pediatric Endocrinology & Metabolism* 2002, 15, Suppl 5: 1243-55.
17. Huang J.Q., Sridhar S., Hunt R.H. Role of H. pylori infection and non-steroidal anti-inflammatory drugs in peptic ulcer disease: a meta-analysis. *The Lancet* 2002, 359: 14-22.
18. Karlberg J.P.E. and Luo Z.C. Shared responsibilities have decreased adverse neonatal outcomes in the 1990's. *British Medical Journal* [Electronic Response] 2002.
19. Lau G., He M.L., Fong D.Y.T., Bartholomeusz A., Au W.Y., Lie A.K.W., Locarnini S. and Liang R.H.S. Preemptive Use of Lamivudine Reduces Hepatitis B Exacerbation After Allogeneic Hematopoietic Cell Transplantation. *Hepatology* 2002, 36 (3): 702-9.
20. He Q., Karlberg J.P.E. Probability of adult overweight and risk change during the BMI rebound period. *Obesity Research* 2002, 10: 135-40.
21. Huang J.Q., Goldwater D.R., Thomson A.B., Appelman S.A., Sridhar S., James C.F., Chiu Y.L. Acid suppression in healthy subjects following lansoprazole or pantoprazole. *Aliment Pharmacological Therapies* 2002, 16: 425-33.
22. Lam C.L.K., Fong D.Y.T., Lauder I.J. and Lam T.P. The effect of health-related quality of life (HRQOL) on health service utilisation of a Chinese population. *Social Science & Medicine* 2002, 55: 1635-1646.
23. Cheung YB, Khoo KS, Karlberg J, Machin D. Association between psychological symptoms in adults and growth in early life: longitudinal follow up study. *British Medical Journal* 2002:325:749-51.

New Developments

Global Alliance

Collaboration with CentraLabS

In October 2002, the CTC and CentraLabS Clinical Research Limited (CentraLabS) entered into a Memorandum of Understanding and initiated planning for formation of a strategic alliance pursuing central laboratory business in support of multinational clinical trials conducted in the Pan-Asian region. CentraLabS is the wholly owned subsidiary of Huntingdon Life Sciences Limited, which is a reputable laboratory testing company based in the United Kingdom. The potential collaboration will bring together the specialised local expertise of the CTC, the excellent quality of the clinical laboratories at the QMH and the global capabilities of CentraLabS, which will give birth to an outstanding central laboratory services provider able to "think local" on a global scale. The plan is to start offering services to the industry from mid-2003.

China Alliances

Collaboration with Fudan University

On October 30, 2002, the Faculty of Medicine of the HKU and Fudan University of Shanghai entered into a Memorandum of Understanding for long-term collaboration on international multi-centre clinical trials. The Shanghai Medical College of Fudan University is one of the top medical colleges in mainland China and designated a "clinical research base" by the State Drug Administration of China. The CTC will help Fudan University to set up its central office for industry-sponsored international clinical trials in accordance with the ICH GCP guidelines and other international standards. The objective is to create a platform for attracting large-scale international clinical trials to the China/Hong Kong region, capitalising on the CTC's international experience and the Shanghai Medical College's strong hospital network and large patient pool.

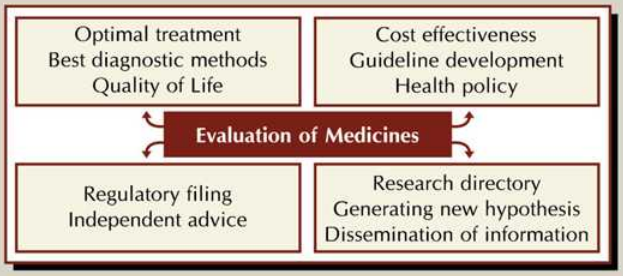
Education programmes in China

The quality of research personnel is the key to development of clinical trial activities. The CTC has entered into a Memorandum of Understanding with a business consultancy based in China to introduce the CTC's clinical trials education programmes to clinical research personnel in the pharmaceutical industry and medical institutions in mainland China. It is anticipated that the programmes will contribute to medical research and development in mainland China.

New Service

Evaluation of medicines

In the age of information explosion, critical appraisal of medical literature in a systematic, comprehensive and well-balanced manner across different specialties of medicine is the optimal method of evaluating existing and new medicines. Evaluation of medicines is a part of the evidence-based medicine process which contributes to improvement of healthcare quality in four different aspects. Recent developments in identification, retrieval, appraisal, distillation, synthesis, integration, dissemination and application of scientifically evaluated medical information have shown much promise in overcoming some of the existing problems. Our mission is to provide innovative evidence-based information products to healthcare professionals, pharmaceutical companies and policy makers, as well as to the general public.



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