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ANNUAL REPORT

CLINICAL TRIALS CENTRE
Faculty of Medicine
The University of Hong Kong

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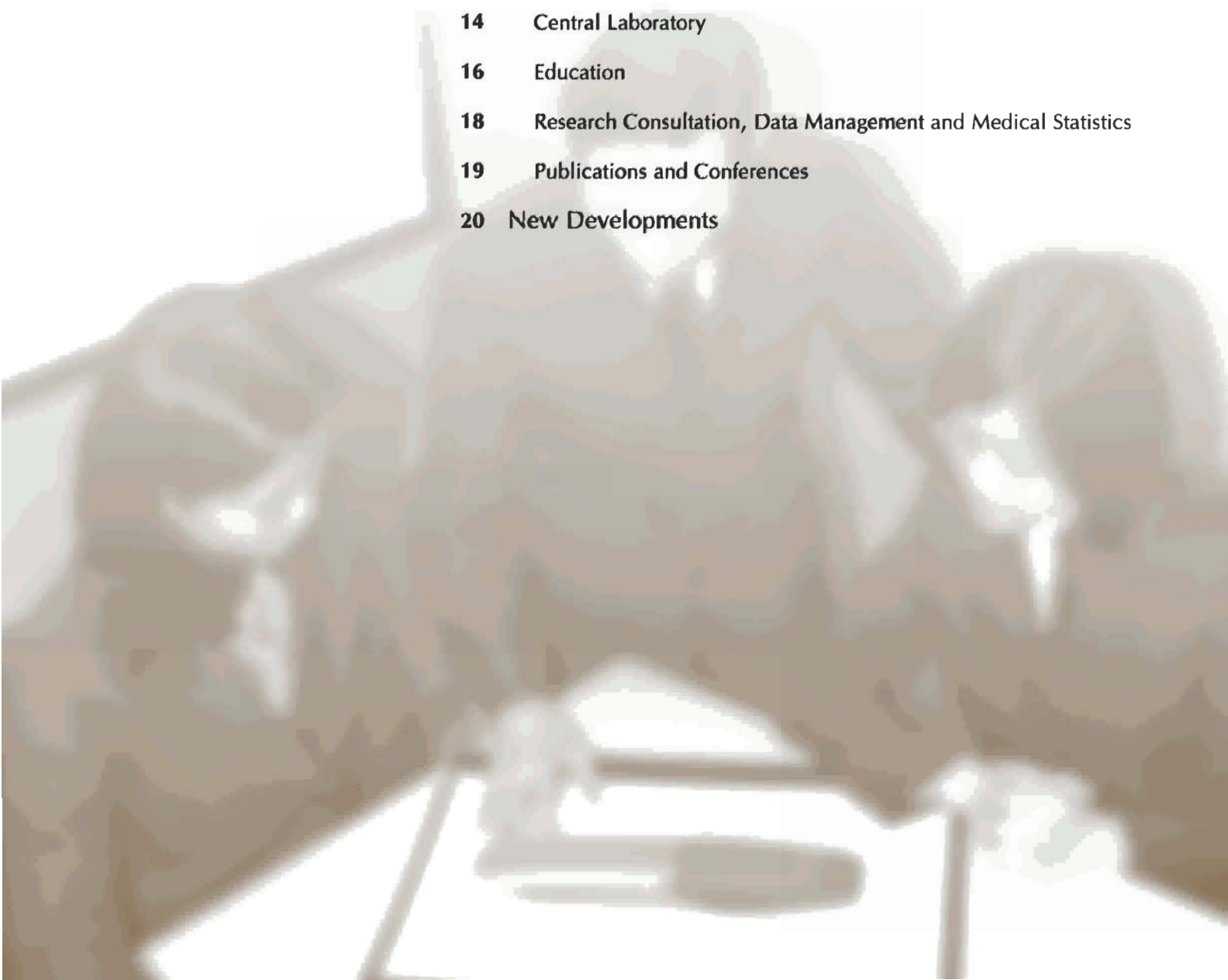
Faculty of Medicine
The University of Hong Kong

The Clinical Trials Centre (CTC) is a leading academic research organization established under the Faculty of Medicine of The University of Hong Kong (HKU). We are committed to enhancing human healthcare by promoting the quality and efficiency of clinical trials through ethical considerations, scientific expertise, quality assurance and education, and are dedicated to offering one-stop solutions in support of clinical trials. Our main activities include research consultation, regulatory affairs, budgeting and contract administration, trial network management, project management, site management, laboratory services, research pharmacy, data management, medical statistics and education. In 2003, CTC joined the global network of a multinational laboratory testing company to launch its clinical trial central laboratory services on a global scale.

Contents



Foreword

The Three Phases to Success

When CTC was first established in 1998 we set our target as developing the best full-service academic research organization worldwide with the ultimate aim of bringing new effective therapies to the bedside. We understood that this was a very challenging task requiring a big leap through three phases of development – infrastructure development, track record building and expansion. I am glad to announce that CTC has successfully gone through the first two phases of development and started the expansion phase, whereby the current team of 18 full-time staff members is anticipated to expand substantially during the coming years.

Completion of phase two development has been clearly illustrated by the increasing number of long-term collaborations with local and overseas sponsors originating from the US, Europe and Asia. This is due to CTC's superior quality, strong commitment and high efficiency, as well as competitive pricing.

The key milestones achieved during 2003 are four-fold:

- **Sponsored Clinical Studies:** 43 new industry-sponsored clinical studies were contracted through CTC in 2003, taking the cumulative number of sponsored studies up to 122 by the end of the year.

- **Central Laboratory Services:** Following accreditation of CTC's affiliated clinical laboratories at Queen Mary Hospital by the College of American Pathologists (CAP) in early-2003, CTC entered into a strategic alliance with a UK-based international central laboratory services provider, named CentraLabS Clinical Research Limited, in October 2003. The alliance brings CTC and its affiliated laboratories into a global network which allows us to provide central laboratory services in support of multinational, multicentre clinical studies.

- **Cluster Ethics Committees:** CTC took an active role in the reorganization of the ethics committees of the Hospital Authority of Hong Kong. They were reorganized into six cluster ethics committees and CTC advised on the development of standard operating procedures and organized training for the committee members. Altogether, the six cluster ethics committees oversee clinical research in the Hospital Authority's 43 hospitals / institutions.

Rewarding Challenges

Smooth seas do not make skillful sailors. 2003 was a tough year surrounded by an atmosphere of pessimism and uncertainty in the society. The SARS outbreak, war in Iraq and global economic stagnation led to consolidation and adjustment of capital investment in many industries, including research and development in the healthcare industry.

In spite of such unfavourable conditions, CTC continued to invest in building infrastructures and developing services that match the needs of the healthcare industry. With the common vision and effort of every team member, we attained a healthy growth of 16% in terms of the number of newly contracted clinical trials coordinated through our centre, and for the first time secured a revenue of over HK$10 million from clinical research-related activities during the year. The number of clinical trial sponsors who developed a master clinical trial contract with HKU through our centre also increased substantially to 38. Such encouraging figures prove that CTC has acquired through experience the competence and momentum for achieving its long-term goals.

Our success in the past years gives us strong confidence for our future. In the coming years, CTC will continue to strengthen its operations and expand the scope of services in the direction of establishing the best academic research organization worldwide.

Henry Yau BSc (Biochem), MBA (Finance)
Business Development Manager

- **Hospital Network Initiative:** In late-2003 CTC initiated discussions with certain major hospitals in Hong Kong to explore the feasibility of setting up a network of hospitals / institutions in support of multicentre clinical studies. Through the network, trial sponsors will have access to clinical investigators in various research areas and to a patient population on the scale of millions. The network is anticipated to start its operation in the first quarter of 2004.

After five years of continuous development, CTC has emerged into a full-service academic research organization that operates in full compliance with all applicable standards, varying from the Declaration of Helsinki, the ICH GCP guidelines, local government regulations, ethics committees' guidelines and CTC's 250-plus standard operating procedures. In 2004, CTC will further expand its scope of services with a special focus on supporting multicentre clinical studies in the region.

" I am glad to announce that CTC has successfully gone through the first two phases of development and started the expansion phase. "

Johan Karlberg

Johan Karlberg MD, PhD
Director and Professor

Ethics Committees Reengineering

In 2003, the Hospital Authority of Hong Kong upgraded all its ethics committees with the aim of enhancing their quality and operational efficiency.

Being an academic research organization, it was CTC's honour to be invited by the Authority to take an active role in the reengineering process, including the development of standard operating procedures, design of application forms and organization of a structured training programme for all ethics committee members.

In Hong Kong, local government regulations for clinical research are relatively simple. Ethics committees are expected to play a major role in safeguarding research ethics and the well-being of human subjects. The ethics committee reengineering initiative was an important milestone that marked achievement of international standards and harmonized operations throughout Hong Kong.

With the rapidly improving infrastructure and operations, we are confident that Hong Kong will continue to be the powerhouse for clinical research in the region.

Selene Tam BHSc, MMedSc, PhD, RN
Project Manager

Organization Structure

Faculty of
The University

Board of

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

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

Dr. York Chow
Hospital Chief Executive
Queen Mary Hospital

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

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

Clinical Tr

- Research Consultation
- Business and Development
- Trial Network Management
- Project Management

Medicine of Hong Kong

Directors

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 Chan
Executive Director
School of Chinese Medicine
The University of Hong Kong

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

Mr. Henry Yau (Secretary)
Business Development Manager
Clinical Trials Centre
The University of Hong Kong

ials Centre

- Site Management
- Data Management and Medical Statistics
- Laboratory and Research Pharmacy
- Education

CTC's Team

Director

Johan Karlberg MD, PhD

Research Consultation

Johan Karlberg MD, PhD	Director and Professor
Jiaqing Huang MSc, MSc (Epid), MD, PhD	Assistant Professor
Daniel Fong BSc, MPhil, PhD	Senior Medical Statistician
Gillis Heller BA, JD	Financial and Development Consultant
Chi-wai Kwan BSc, PhD	Senior Medical Statistician
William Wong BSc, MPhil	Systems Analyst
William Lai BSc, MPhil, MA	Editor (Part-time)

Business and Development

Henry Yau BSc, MBA	Business Development Manager
Gretel Yiu BBA	Business Development Officer
Janet Ho BBA	Executive Assistant

Trial Network Management

Henry Li BPharm, MSc, MRPharmS	Clinical Research Manager

Project Management

Selene Tam BHSc, MMedSc, PhD, RN	Project Manager

Site Management

Yolanda Yan BScN, MMedSc, RN	Site Manager

Data Management and Medical Statistics

Daniel Fong BSc, MPhil, PhD	Senior Medical Statistician
Jeremy Li BSc, MMedSc	Clinical Data Manager

Clinical Laboratory and Research Pharmacy

Stella Wong BSc, MMath, RegMLT	Clinical Laboratory Services Manager
Henry Li BPharm, MSc, MRPharmS	Clinical Research Manager
Rex Hung BSc, PharmD	Research Pharmacist (Part-time)

Education

James Thorburn BSc, PGCert	GCP-QA Manager

Office and General Affairs

Josephine Yuen	Secretary to Director
Janet Ho BBA	Executive Assistant
Man-wai Cheng	Clerical Assistant
Mabel Cheng	Caretaker

Clinical Investigators

With the rapidly increasing clinical trial activities at HKU and Queen Mary Hospital (QMH), 14 more clinical investigators under various HKU/QMH clinical departments assumed the role of principal investigator in industry-sponsored clinical studies. These clinical studies coordinated through CTC bring the cumulative number of principal investigators up to 45 by the end of the year. In addition, over 100 co-investigators were also involved in industry-sponsored clinical studies of various therapeutic areas.

List of Principal Investigators

Anaesthesiology
Dr. Karl Young

Clinical Oncology
Dr. Raymond TT Chan
Dr. Daniel TT Chua
Professor Jonathan ST Sham

Medicine
Professor TM Chan
Dr. Henry Chan
Dr. WH Chen
Dr. Bernard MY Cheung
Dr. Raymond TF Cheung
Dr. LW Chu
Professor Annie WC Kung
Professor CL Lai
Professor SK Lam
Professor Karen SL Lam
Professor CP Lau
Professor CS Lau
Dr. George KK Lau
Dr. Kathy LF Lee
Professor Raymond HS Liang
Dr. Albert Lie
Dr. Kathyrn CB Tan
Dr. Kenneth WT Tsang
Dr. HF Tse
Dr. Benjamin CY Wong
Dr. Adrian YY Wu
Dr. MF Yuen

Microbiology
Dr. PL Ho

Obstetrics and Gynaecology
Professor Hextan YS Ngan
Professor Grace WK Tang

Orthopaedics and Traumatology
Dr. Jimmy Wong

Paediatrics
Dr. Henry Hui
Professor YL Lau
Dr. NS Tsoi

Pharmacy
Mr. William CM Chui

Psychiatry
Dr. Eric YH Chen
Dr. SE Chua
Professor SW Tang

Surgery
Dr. Louis WC Chow
Dr. KM Chu
Dr. KW Chu
Dr. WK Ho
Dr. WM Lui
Dr. Ronnie Poon
Dr. PC Tam
Professor William Wei

Industry Collaboration

Being a platform between investigators and the industry, CTC is devoted to encouraging industry-sponsored clinical trial activities. In addition to carrying on with its long-term collaborators, in 2003 CTC facilitated clinical research collaborations with 10 more international trial sponsors based in Canada, Denmark, France, Hong Kong, Korea, the Netherlands, the UK and the US.

To establish closer, long-term collaboration with the industry, CTC continued its effort in developing master clinical trial contracts with trial sponsors worldwide. By the end of 2003, the total number of trial sponsors with a master clinical trial contract with HKU developed through CTC increased sharply to 38. The availability of master clinical trial contracts eliminated the hassle of contract negotiation and added great efficiency to setting up clinical trials.

Trial Sponsors with a Master Clinical Trial Contract with HKU

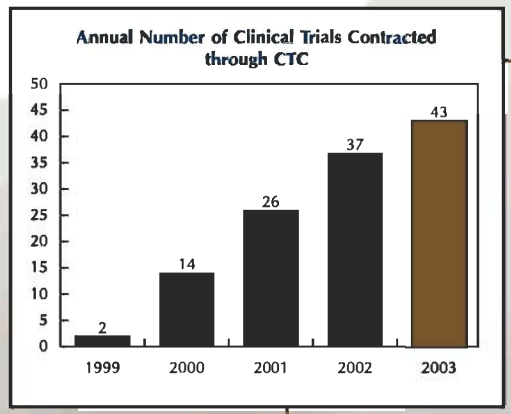
Abbott Laboratories
Achillion Pharmaceuticals
Advanced Herbal Therapeutics
AstraZeneca
Aventis Pharma
BCIRG
Biomeasure
Biocompatible
Boston Scientific
Bristol-Myers Squibb
Eli Lilly
Everpride Biopharmaceutical
FeRx
GlaxoSmithKline
Idenix Pharmaceuticals
Johnson & Johnson
Kowa
LG Life Sciences
Lundbeck
Medtronic
Merck Sharp & Dohme
Novartis
Novo Nordisk
OSI Pharmaceuticals
Organon
Pfizer
Pi Medical
Roche
Sanofi-Synthelabo
Schering-Plough
Serono
St. Jude Medical
Triangle Pharmaceuticals
Tularik
Vigconic
Wyeth Pharmaceuticals
Xanthus Life Sciences
Zila

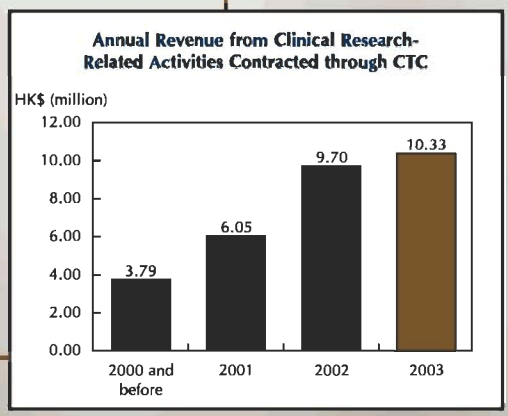
Achievements

Industry-Sponsored Clinical Studies

Continuous Growth

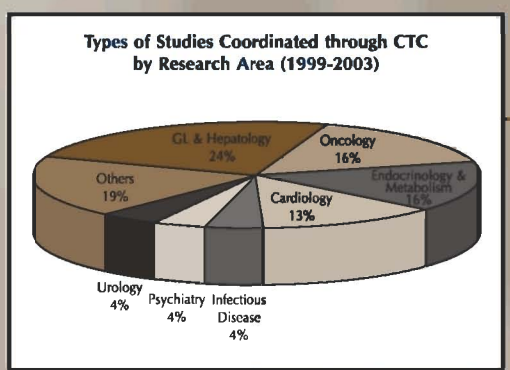
2003 was a highly challenging year. In spite of the adverse impacts of the SARS outbreak, war in Iraq and global economic stagnation, CTC continued with its growth as in the preceding years and managed to contract 43 new industry-sponsored clinical studies, which represents a 16% increase over 2002. The annual revenue from clinical research-related activities also reached the record high of HK$10.33 million.

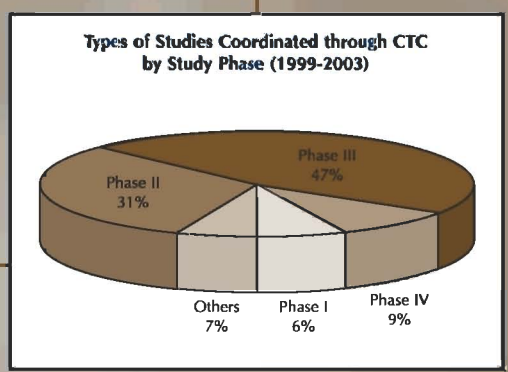




Diversity in Research Types

Phase II and III remained the major study phases, jointly representing 78% of all clinical studies coordinated through CTC. In terms of research areas, Gastroenterology and Hepatology accounted for 24% of all studies and was still the most active area. Oncology, Endocrinology and Metabolism, and Cardiology, were also popular research areas, accounting for 45% of all studies.





Industry-Sponsored Clinical Studies Contracted in 2003

Department	Principal Investigator	Disease Area	Phase	Status
Clinical Oncology	Dr. Raymond TT Chan	Gastric Cancer	III	Active
Clinical Oncology	Dr. Daniel TT Chua	Brain Metastases from Lung Cancer	III	Active
Clinical Oncology	Professor Jonathan ST Sham	Cancer	II	Active
Orthopaedics & Traumatology	Dr. Jimmy Wong	Post-operative Analgesia	IV	Active
Medicine	Dr. Henry Chan	Atopic Dermatitis	III	Active
Medicine	Professor TM Chan	Renal Transplant Rejection	III	Active
Medicine	Dr. WH Chen	Acute Coronary Syndrome	III	Active
Medicine	Dr. WH Chen	Acute Myocardial Infarction	III	Active
Medicine	Dr. WH Chen	Acute Myocardial Infarction	III	Active
Medicine	Dr. WH Chen	Ischemia	III	Active
Medicine	Dr. Raymond TF Cheung	Acute Ischemic Stroke	II	Active
Medicine	Dr. Raymond TF Cheung	Ischemia	III	Active
Medicine	Dr. LW Chu	Alzheimer's Disease	III	Active
Medicine	Professor Annie WC Kung	Osteoporosis	II	Active
Medicine	Professor Annie WC Kung	Osteoporosis	O*	Active
Medicine	Professor CL Lai	Hepatitis	I	Active
Medicine	Professor CL Lai	Hepatitis	II	Active
Medicine	Professor CL Lai	Hepatitis	II	Active
Medicine	Professor CL Lai	Hepatitis	III	Active
Medicine	Professor CL Lai	Hepatitis	III	Active
Medicine	Professor Karen SL Lam	Diabetes Mellitus	III	Active
Medicine	Professor Karen SL Lam	Diabetes Mellitus	III	Closed
Medicine	Professor Karen SL Lam	Diabetes Mellitus	III	Closed
Medicine	Professor Karen SL Lam	Diabetes Mellitus	IV	Active
Medicine	Dr. George KK Lau	Hepatitis	III	Active
Medicine	Dr. Kathy LF Lee / Professor CS Lau	Cardiovascular and Gastrointestinal Toxicity in Osteoarthritis or Rheumatoid Arthritis Patients	III	Active
Medicine	Dr. Kathy LF Lee	Dyslipidemia	II	Closed
Medicine	Dr. Albert Lie	Fungal Infection	IV	Closed
Medicine	Dr. Kathyrn Tan	Ischemia	III	Active
Medicine	Dr. HF Tse	Atrial Fibrillation	O*	Active
Medicine	Dr. HF Tse	Transvenous Phrenic Nerve Stimulation	O*	Active
Medicine	Dr. MF Yuen	Hepatitis	I	Active
Pharmacy	Mr. William CM Chui	Sepsis	O*	Closed
Psychiatry	Dr. Eric YH Chen	Bipolar Disorder	IV	Active
Psychiatry	Dr. Eric YH Chen	Schizophrenia	IV	Active
Psychiatry	Professor SW Tang	Schizophrenia	III	Active
Surgery	Dr. Louis WC Chow	Breast Cancer	II	Active
Surgery	Dr. Louis WC Chow	Breast Cancer	III	Active
Surgery	Dr. KW Chu	Colon Cancer	III	Active
Surgery	Dr. WM Lui	Intracranial Atherosclerosis	O*	Active
Surgery	Dr. Ronnie Poon	Liver Cancer	I	Active
Surgery	Dr. Ronnie Poon	Liver Cancer	II	Active
Surgery	Dr. PC Tam	Erectile Dysfunction	III	Active

* O – Others, including medical device and observational studies

Achievements

Site Management

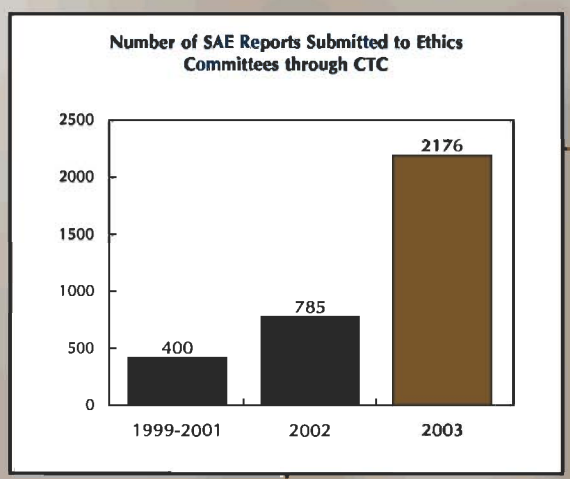
Ethics Committee

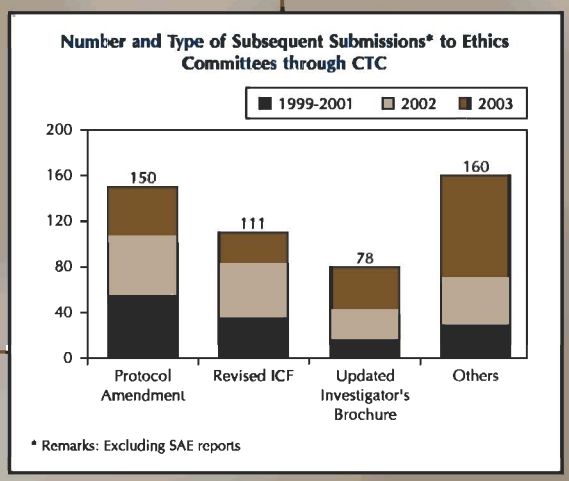
The ethics committees of HKU and QMH were integrated in March 2003 to form the Institutional Review Board of The University of Hong Kong / Hospital Authority Hong Kong West Cluster (HKU / HA HKW IRB) which oversees ethics review applications from HKU and seven hospitals within the HA HKW Cluster. The new ethics committee consists of 50 scientific members and 15 lay members, operates in full compliance with the ICH GCP guidelines and holds regular biweekly meetings. The integration not only streamlined the operations of the original ethics committees but also marked a significant advance in protection of the rights, safety and well-being of human subjects in clinical research. CTC took an active role in advising on the integration process and the operation of the new ethics committee, including development of the committee's standard operating procedures and application form.

In 2003, CTC continued to assist clinical investigators in complying with the requirements of the ethics committee. There were 38 initial submissions, 200 subsequent submissions and 2176 reports for serious adverse events (SAEs) submitted respectively to the ethics committee during the year.

Multicentre Studies

In response to the increasing interest of the industry for setting up multicentre trials in Hong Kong, CTC accelerated expansion of its site management services to study sites outside HKU. During the year 2003, CTC provided site management supports to eight hospitals / institutions. Services offered ranged from ethics review submissions to study budgeting, contract administration, trial specimens handling and study site logistics coordination.

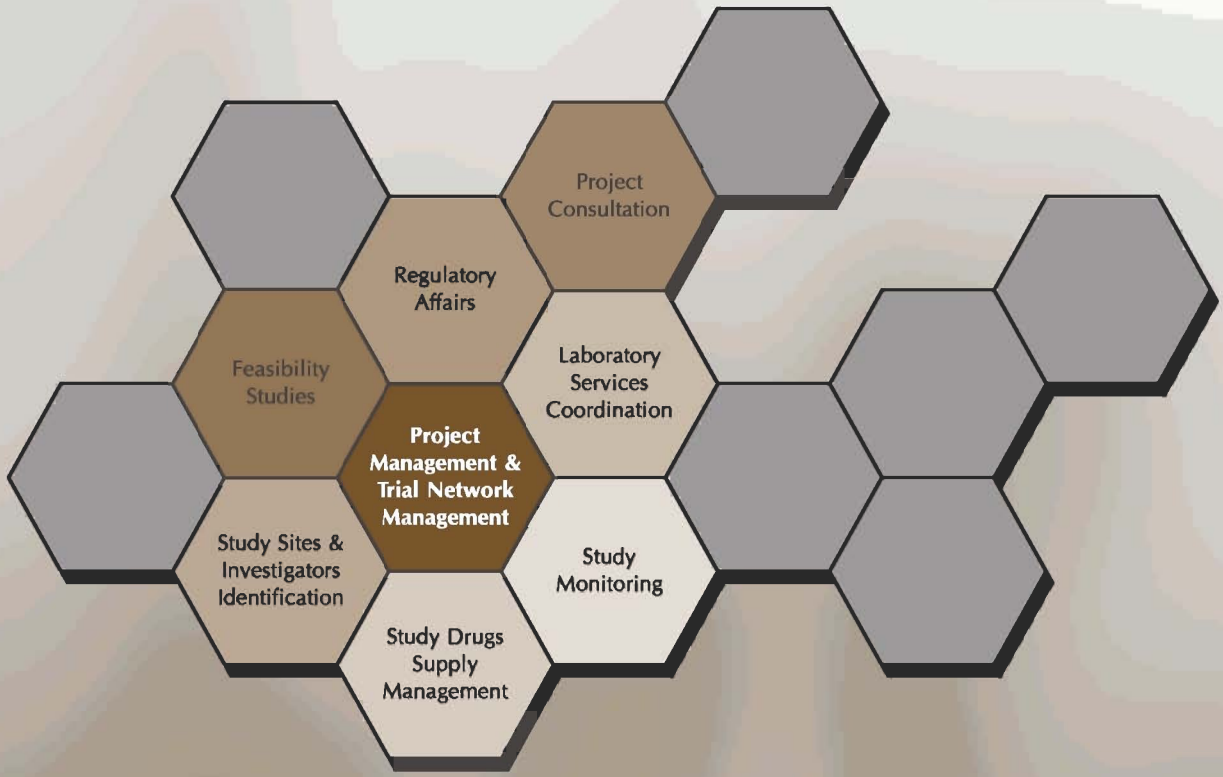




Project Management and Trial Network Management

Expanding Scope

The increasing complexity of clinical trials induces a growing demand for capable one-stop service providers. During the year CTC continued to diversify and strengthen its project management services to meet the needs of the industry. In addition to project consultation, regulatory supports and study monitoring, substantial resources have been allocated to the development of project management services including feasibility studies, study sites and investigators identification, study drugs supply coordination and central laboratory services coordination. So far CTC has provided project management services to 21 trial sponsors in support of their clinical trials at eight hospitals / institutions.



Feasibility Studies and Study Sites Identification

Every successful clinical trial starts from a good feasibility study and identification of appropriate study sites. As more trial sponsors become interested in doing clinical trials in Hong Kong, there is an increasing demand for comprehensive feasibility studies and advice on study sites identification. Being an interface between trial sponsors and study sites, CTC assisted 12 sponsors and research organizations in conducting feasibility studies and identifying suitable study sites during the year.

Achievements

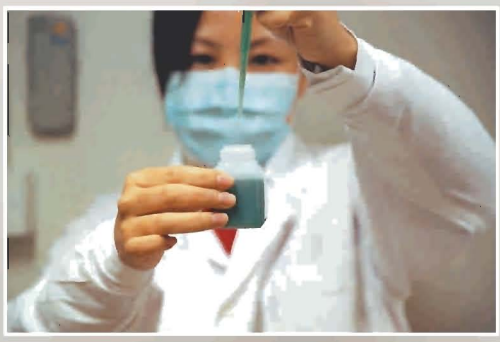
Central Laboratory

Going Global

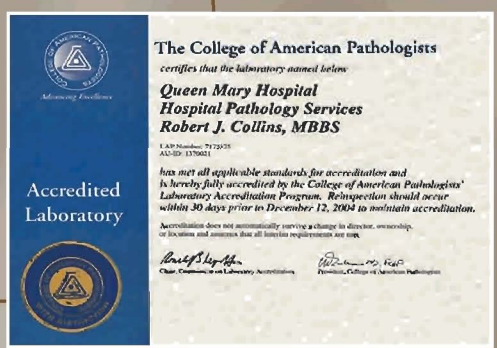
In late-2003, CTC entered into negotiation with CentraLabS Clinical Research Limited (CentraLabS) for forming a strategic alliance to pursue central laboratory business in support of multinational clinical trials. This is anticipated to bring together the specialized local expertise of CTC and the global capabilities of CentraLabS with the ultimate goal of building up a strong central laboratory network which "thinks local" on a global scale.

After months of constructive discussion and preparation, an exclusive alliance was finalized and a collaboration agreement was executed in October 2003. This collaboration with CentraLabS is the second important milestone of the development of clinical trial central laboratory services following accreditation of CTC's affiliated large multidiscipline laboratories at QMH by the College of American Pathologists (CAP) in January 2003.

CentraLabS is an affiliate of the Huntingdon Life Sciences group based in the UK and has been a leading laboratory services provider in the pharmaceutical and healthcare industry for over 30 years. In addition to its own facilities in the UK and the US, CentraLabS has alliance laboratories in South America and South Africa. CTC's affiliated clinical laboratories at QMH form the largest multidiscipline laboratory in Asia with more than 250 laboratory professionals. Through the strategic alliance between CTC and CentraLabS, comprehensive central laboratory services can be made available to trial sponsors and research organizations over five continents.



The seven-floor clinical laboratories at QMH are equipped with state-of-the-art laboratory facilities and staffed with over 250 laboratory professionals. The SARS coronvirus was first identified there.



CTC's affiliated clinical laboratories at QMH have been fully accredited by CAP since early-2003.

Full Support

Global Capabilities

- Extensive network of laboratories in Hong Kong, the UK, the US, Brazil and South Africa
- Harmonized specimen testing and management methodologies
- Ongoing quality assurance and cross validation programmes
- Flexible project management
- Global logistics support
- Centralized database

Analytical and Specimen Management Capabilities

- Full analytical support for Phase I to IV clinical trials
- Advanced analytical technology and facilities
- High analytical throughput and capacity
- Standardized and consistent testing methodologies
- Large storage capacity for long-term archiving of specimens at required conditions

Quality Assurance

- Fully accredited by CAP and other international quality assurance bodies
- Cross-validated laboratories within the network
- Ongoing internal quality assurance programme
- Inspection by regulatory bodies and third parties

Project Management

- One-stop solutions to the laboratory components of all clinical trials
- Consultation and support early in the protocol development stage
- Flexible project management matching each sponsor's unique requirements
- Comprehensive, protocol-specific manuals and instructions for sponsors and study sites
- Custom-assembled specimen handling kits and clinical supplies
- Professional training at investigator meetings and study sites
- Efficient and timely interaction with investigator sites
- Internet platform for online review of study status

Logistics Support

- Dedicated logistics team providing global support
- Capability and experience in handling ambient, refrigerated and frozen shipments, as well as infectious and non-infectious specimens
- Specially-designed specimen collection kits for facilitating easy packaging and shipment of specimens
- Customized shipment schedules that allow for maximum flexibility
- Close tracking of shipments to ensure safe and prompt delivery
- Automated re-supply of specimen collection kits and clinical supplies

Data Management and Reporting

- Protocol-specific database
- 24-hour turnaround for routine safety testing
- Report format in line with case report forms and sponsors' specific requirements
- Results available through courier, facsimile and electronic transmission
- Internet platform for online review of laboratory results
- Audited complete database available upon closure of study

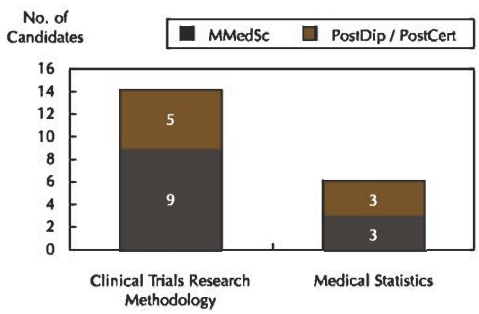
Achievements

Education

Postgraduate Programmes

Being an academic research organization, CTC has been offering cutting-edge education programmes in clinical research, including the Master of Medical Sciences / Postgraduate Diploma / Postgraduate Certificate programmes in Clinical Trials Research Methodology and in Medical Statistics. In 2003, a total of 20 candidates enrolled in these postgraduate programmes. Since the introduction of the first programme in 1998, they have attracted 57 candidates and about 30 have graduated so far. The programmes are appealing to people of different scientific and medical backgrounds who wish to deepen their knowledge in clinical research.

Number of Candidates Enrolled in the Postgraduate Programmes Offered by CTC in 2003



Number of Candidates Enrolled in the Postgraduate Programmes Offered by CTC (1998-2003)

Year	Number of Candidates Enrolled
2003	20
2002	8
2001	6
2000	9
1999	10
1998	4

Presentation by CTC at Clinical Trial-Related Conferences (2003)

- Life Science Academic Output in Predominantly Chinese Communities in 1990-2001: China, Hong Kong, Singapore and Taiwan, *Biotechnology Forum – From Scientific Innovations to New Medicines, Hong Kong*
- Good Clinical Practice (GCP) Education and Compliance in Hong Kong, *Good Clinical Practices, Singapore*
- Clinical Trials for Medical Devices in Hong Kong, *Symposium on Hong Kong Medical & Healthcare Device Industry 2003 - Future Trend of Medical Device Industry and Technologies, Hong Kong*
- The Institutional Review Board, *Legal & Regulatory Issues in Clinical Trials, Singapore*

Training Programmes Conducted by CTC (2003)

- Biostatistics, Statistical Methods for Validation of Quality of Life Instruments, and Experience in Validation of QoL Instruments in Hong Kong, Chinese Medicine Unit, Department of Health, Hong Kong
- Commissioned Training Course for Hospital Authority Cluster Research Ethics Committee Members, Hospital Authority, Hong Kong
- Research Paper Writing Workshop for Higher Surgical Trainees, Hospital Authority, Hong Kong

Training Programme for Ethics Committee Members

In 2003, CTC was invited by the Hospital Authority of Hong Kong to organize a comprehensive training programme for 154 members from six cluster ethics committees overseeing clinical research projects in 43 hospitals / institutions under the Authority. The programme consisted of three rounds of 12-hour interactive training sessions covering all necessary dimensions such as responsibilities, functions and operations of ethics committees, good clinical practice, ethical standards, scientific aspects and legal aspects of clinical research. It was the first and the only one so far since the reorganization and integration of the Authority's numerous ethics committees into six cluster ethics committees.

Biotechnology Forum

CTC and the Genome Research Centre of HKU jointly organized the Biotechnology Forum on March 2, 2003. The aim of the forum was to exchange views and experiences in biomedical innovations. Professors from HKU and four Swedish universities – Karolinska Institutet, University of Lund, University of Uppsala and University of Göteborg – gave expert highlights of the latest biomedical development, including trends in pharmaceutical technology development, perspectives of scientific innovations in Hong Kong and new scientific innovations for future medicines. The event attracted some 200 professionals from the biomedical industry, academic institutions and governmental bodies.

Achievements

Research Consultation, Data Management and Medical Statistics

Protocol Development and Review

Protocol development is a highly professional task involving a team of experts including medical scientists, clinical investigators, medical statisticians and regulatory professionals. During the year CTC was engaged in developing or reviewing clinical trial protocols by many local and overseas trial sponsors, research organizations and investigators, including development of a protocol for a SARS treatment trial coordinated by the Hospital Authority of Hong Kong.

Evaluation of Medicines

The service for evaluation of medicines has been welcomed by the industry. Since the launch of the service last year, a lot of inquiries have been received and CTC has started to provide the service to a few companies. Further development of the service is expected in 2004.

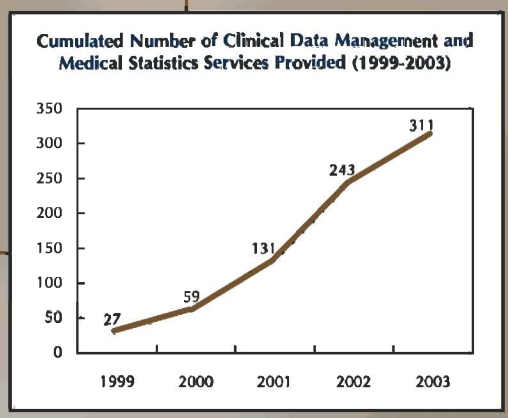
Data Management and Medical Statistics

CTC continued to provide data management and medical statistics services in support of clinical research. During the year, CTC assisted various trial sponsors and investigators in 68 research projects, bringing the cumulative number of projects supported by CTC to 311 since 1999. Types of services provided include statistical analysis, sample size estimation, clinical trial design, clinical data management, protocol and manuscript review, reply to reviewer's comments and research grant application.

Types of Clinical Data Management and Medical Statistics Services Provided in 2003

Type of Service	%*
Statistical analysis	68
Sample size estimation	23
Design of clinical trial	6
Clinical data management	2
Protocol / manuscript review	8
Reply to reviewer's comments	6
Research grant application	3

*Remark: Some projects require more than one type of service. The sum of all items does not add up to 100%



Publications and Conferences

Selected International Publications in 2003

- Karlberg J.P.E., Yau K.C., Fong D.Y.T., Huang J., Tam S.Y.M., Yan Y.S.M., Thorburn J. and Wong S.W.S. The Clinical Trials Centre at The University of Hong Kong: A modern academic organization in Asia. *Drug Information Journal* 2003, 37(Suppl): 27(S)-39(S).
- Dodgson J.E., Tarrant A.M., Fong D.Y.T., Peng X.H. and Hui Choi W.H. Breastfeeding patterns of primiparous mothers in Hong Kong. *Birth* 2003, 30: 195-202.
- Huang J., Zheng G., Sumanac K., Irvine E.J. and Hunt R.H. Meta-analysis of the relationship between cagA seropositivity and gastric cancer. *Gastroenterology* 2003, 125: 1636-1644.
- Khong P.L., Chan G.C.F., Lee S.L., Au W.Y., Fong D.Y.T., Tsang K.W.T. and Ooi C.G.C. β-Thalassemia major: Thin-section CT features and correlation with pulmonary function and iron overload. *Radiology* 2003, 229: 507-512.
- Jacobs E.G.J., Leung M.P. and Karlberg J.P.E. Birthweight distribution in southern Chinese infants with symptomatic congenital heart disease. *Journal of Paediatrics and Child Health* 2003, 39: 191-196.
- Huang J. and Hunt R.H. The evolving epidemiology of Helicobacter pylori infection and gastric cancer. *Canadian Journal of Gastroenterology* 2003, 17 (Suppl B): 18B-20B.
- Fong D.Y.T., Kwan C.W., Lam K.F. and Lam K.S.L. Use of the Sign Test for the Median in the Presence of Ties. *The American Statistician* 2003, 57(4): 237-240.
- Karlberg J.P.E., Kwan C.W. and Albertsson-Wikland K. Reference values for change in body mass index from birth to 18 years of age. *Acta Paediatrica* 2003, 92: 648-652.
- Wong W.M., Lai K.C., Lam K.F., Hui W.M., Hu W.H.C., Lam C.L.K., Xia H.H.X., Huang J., Chan C.K., Lam S.K., Wong B.C.Y. Prevalence, clinical spectrum and health care utilisation of gastro-oesophageal reflux disease in Chinese population: a population-based study. *Aliment Pharmacol Ther* 2003, 18(6): 595-604.
- Luo Z.C., Cheung Y.B., He Q., Albertsson-Wikland K. and Karlberg J.P.E. Growth in Early Life and Its Relation to Pubertal Growth. *Epidemiology* 2003, 14(1): 65-73.
- Ng E.H.Y., Yeung W.S.B., Fong D.Y.T. and Ho P.C. Effects of age on hormonal and ultrasound markers of ovarian reserve in Chinese women with proven fertility. *Human Reproduction* 2003, 18(10): 2169-2174.
- Wong W.M., Lam K.F., Lai K.C., Hui W.M., Hu W.H., Lam C.L., Wong N.Y., Xia H.H., Huang J., Chan A.O., Lam S.K. and Wong B.C. A validated symptoms questionnaire (Chinese GERDQ) for the diagnosis of gastro-oesophageal reflux disease in the Chinese population. *Aliment Pharmacol Ther.* 2003, Jun 1;17(11): 1407-13.
- Karlberg J.P.E. and He Q. Prediction of Adult Overweight from Childhood Body Mass Index and Not Childhood Height. *Pediatrics* 2003, 111: 224-225.
- Lau G., Yiu H.H.Y., Fong D.Y.T., Cheng H.C., Au W.Y., Lai L.S.F., Cheung M., Zhang H.Y., Lie A.K.W., Ngan K.C. and Liang R.H.S. Early is superior to deferred preemptive lamivudine therapy for hepatitis B patients undergoing chemotherapy. *Gastroenterology* 2003, 125: 1742-1749.
- Wang W., Huang J., Zheng G., Lam S.K., Karlberg J.P.E. and Wong B.C.Y. Non-Steroidal Anti-Inflammatory Drug Use and the Risk of Gastric Cancer: A Systematic Review and Meta-Analysis. *Journal of the National Cancer Institute* 2003, 95(23): 1784-1791.
- Ng I.O.L., Chan K.L., Shek W.H., Lee J.M.F., Fong D.Y.T., Lo C.M. and Fan S.T. High frequency of chimerism in transplanted livers. *Hepatology* 2003, 38: 989-998.
- Huang J., Lam S.K., Malfertheiner P. and Hunt R.H. Has Education about H. pylori Infection Been Effective? – Worldwide Survey of Primary Care Physicians. *Journal of Gastroenterology and Hepatology* 2003, May;18(5): 512-520.

Book Published in 2003

- Karlberg J.P.E. *Life Science Academic Output In Predominantly Chinese Communities 1990 to 2001: China, Hong Kong, Singapore and Taiwan.* 2003, 159pp.

New Developments

ClinCluster – The Hong Kong Hospital Network for Clinical Trials

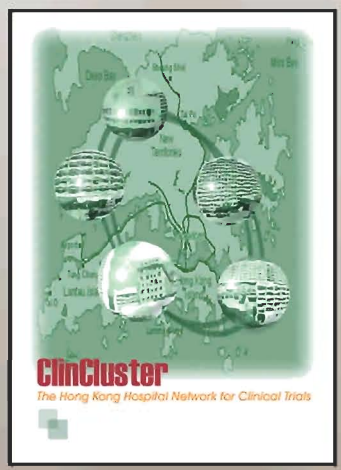
ClinCluster is the first and only network of hospitals / institutions in Hong Kong that share a common vision in clinical trials. The objective is to integrate the member institutions' medical and scientific expertise, clinical research facilities and patient populations through a common coordination platform, creating a unique, strong alliance which facilitates efficient conduct of high standard multicentre clinical trials across a wide range of research areas.

ClinCluster is an initiative taken by CTC in response to international trends and demands of the industry. It is anticipated that ClinCluster will help to fully unleash the clinical research potential of Hong Kong, and further position Hong Kong as a leading place for clinical trials worldwide.

Web-based Investigator Certification Programme

Formal training for clinical investigators is in great demand owing to the increasing complexity of clinical trials, ever more stringent regulatory requirements and rising research ethics standards. However, there are very limited training opportunities that meet the schedules of busy clinical investigators.

CTC is developing a novel web-based training programme that combines comprehensiveness, interactiveness and flexibility. Any clinical investigator who has access to the Internet can participate in the programme anytime, anywhere. The programme will be a good channel for new investigators to get started in the area of clinical research and for experienced investigators to keep up with the latest developments. A certificate will be issued to every investigator who successfully completes the programme.



Master of Public Health (MPH)

The outbreaks of SARS and avian influenza have re-ignited public awareness of the importance of public health. CTC, in collaboration with the Department of Community Medicine at HKU, will launch the Master of Public Health programmes in Clinical Trials Research Methodology and in Medical Statistics for the 2004/05 academic year. The programmes will replace the Master of Medical Sciences programmes in Clinical Trials Research Methodology and in Medical Statistics.

ANNUAL REPORT **2003**

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