annual report

09

Clinical Trials Centre (CTC) of The University of Hong Kong (HKU) Li Ka Shing Faculty of Medicine is a leading academic research organization dedicated to one-stop clinical research solutions. Established in 1998, CTC is committed to enhancing global healthcare by promoting the quality and efficiency of clinical research and testing of new chemical drugs, biologics, vaccines, traditional Chinese medicines, medical devices and diagnostic tools through ethical consideration, scientific expertise, quality assurance and education. Our core competences range from research consultation, training and education to protocol development, feasibility assessment, regulatory and ethics affairs, finance and contract management, project management, monitoring, data management, medical statistics, site management, drug management and central laboratory support for industry-sponsored clinical studies and investigator-initiated clinical studies.

Contents

Concerns about the Globalization of Clinical Research

The ongoing globalization of clinical research - especially industry-sponsored clinical trials - was triggered by the launch of the International Conference on Harmonisation - Good Clinical Practice (ICH-GCP) Guideline.The ICH-GCP Guideline, regulating clinical trials of new medicines, was adopted by drug regulatory authorities in the United States, the European Commission, and Japan in 1996. The impact of these international quality standards has been substantial, since pharmaceutical companies can collect trial data worldwide, rather than only in established regions, for filing new drug applications in established regions.

As a consequence of the introduction of the ICH-GCP Guideline, more and more industry-sponsored trials are conducted in emerging regions, especially East Europe, Asia, and Latin America. Study site selection criteria differ between pharmaceutical companies, but they are commonly an amalgamation of factors, such as patient population size, trial experience, data quality, start-up time, regulatory framework, language skills, cost, and market size. Although emerging regions with low gross domestic product (GDP) offer competitive trial budgets, selection of study sites by sponsors is primarily based on non-financial issues. Most important, however, is whether "an investigator will be able to deliver a sufficient number of subjects on time and in full compliance with the protocol."

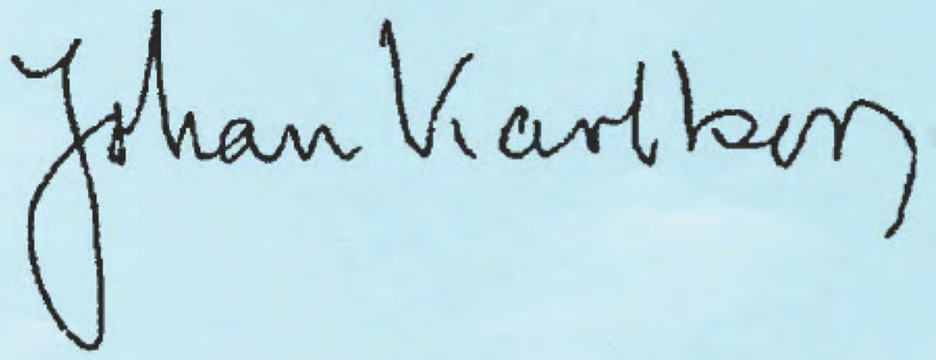
The 2010 Inspector General Report by the Office of Inspector General, U.S. Department of Health and Human Services, indicates that in 2008, 80% of U.S. FDA-approved marketing applications for drugs and biologics contained data from foreign clinical trials; over half of the clinical trial subjects and sites were located outside the United States. The globalization of clinical research is in many ways a positive phenomenon and follows the general globalization trend. Globalization is a process by which regional economies, societies, and cultures have become integrated through a global network of communication, transportation, and trade. However, recently, drug regulatory authorities in both the United States and the European Union have expressed concerns about the ethics, quality, and validity of the clinical trial data collected in emerging clinical trial regions.

The Inspector General Report shows that the number of subjects per study site is significantly higher in emerging clinical trial regions than in established regions. The industry is facing a merciless battle to obtain regulatory approval for its new medicinal products in order to secure sound financial revenue over the relatively short remaining patent period. On average, each drug passes through 30-35 clinical trials, totaling thousands of participants, and the industry is making every effort to complete each trial in a timely manner. Today, emerging clinical trial regions contribute about one in four study subjects, thus providing considerable support to the industry. Subsequently, clinical trials are completed much earlier than if only established trial regions were involved. The globalization of clinical research is thus driven by the industry. This process will certainly continue as long as emerging regions conduct clinical trials ethically, thereby meeting international standards. The Inspector General Report concludes, "Based on the increase in foreign clinical investigators conducting clinical trials under INDs over the last 10 years and the observations of FDA reviewers, sponsors' reliance on foreign clinical trials for FDA-regulated drugs and biologics appears likely to grow."

The Inspector General Report shows that the U.S. FDA inspected clinical investigators at only 1.2% of clinical trial sites for applications approved in fiscal year 2008. The U.S. FDA inspected 1.9% of the total number of U.S. trial sites, as compared with 0.7% of all foreign trial sites. Therefore, one can easily understand why the Department of Health and Human Services made recommendations in the report for the U.S. FDA to strengthen inspections of foreign clinical trial sites.

It has been reported by others that a statistically significant higher number of investigative site deficiencies occurred following U.S. FDA inspections in Western Europe than in other regions. The analysis was based on U.S. FDA inspections performed between 1997 and 2008, where 2,614 inspections took place in the United States, 287 in Europe (formerly Western Europe), and 310 in the rest of the world (ROW), excluding Canada. Relatively speaking, the ROW had the best overall results, where 5.5% of its site inspections were observed to have three or more deficiencies, as compared with 13.4% for the United States and 20.2% for Europe (statistically significant). A significant relatively higher number of deficiencies were also reported for European sites, notably 43.6% for "failure to follow investigational plan," as compared with 33.9% for North America and 27.5% for the ROW.

As mentioned above, the globalization of industry-sponsored clinical trials was driven by the launch of the ICH-GCP Guideline in 1996. Full compliance with the ICH-GCP Guidelines provides assurance that the clinical studies are scientifically sound and ethical and deliver acceptable data quality so that the data can be used for filing new drug applications in other jurisdictions. As a result, over 50% of the subjects included in U.S. FDA overseen industry-sponsored clinical trials are today recruited in countries outside the United States. Understandably, this has raised concerns in the United States. More importantly, close to 50% of all industry-sponsored trials are not overseen by the U.S. FDA at all, and only a small fraction of those participating sites were located to the United States. Both the United States and Europe have recently raised various concerns about the ethics, science, quality, and standard medical practice of trials conducted in emerging regions. In spite of the concerns raised, the industry has decided to go global due to the lack of investigators and study participants in North America and Europe. This trend will most certainly continue. Perhaps both the United States and Europe should consider implementing regulations for the mandatory registration of trials as required by other countries (e.g., China, Japan, and South Korea). The pharmaceutical market in general and manufacturers in particular will likely experience significant geographic shifts in the near future.



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Division of Clinical Biochemistry
Department of Pathology &
Clinical Biochemistry
Queen Mary Hospital

Organizational Structure

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The University of Hong Kong

Board of Directors

Director

Clinical Trials Centre

Business & Project Acceleration Team

- Feasibility Assessment
- Project Coordination
- Ethics Affairs
- Budget & Payment Management
- Service Proposal Development
- Contract Management
- Business Development & Marketing

Site Operation Team

- Medical Research Clinic Operation
- Subject Recruitment
- Study Coordinator

Project Operation Team

- Protocol Development
- Regulatory Affairs
- Project Management
- Study Monitoring

Special Projects Team

- Clinical Trial Magnifier Publication
- Conference Organization
- Education & Training Programs Organization
- Quality Assurance

Study Site Services Team

- Specimen Management
- Central Laboratory Management
- Study Drug Management

General Affairs

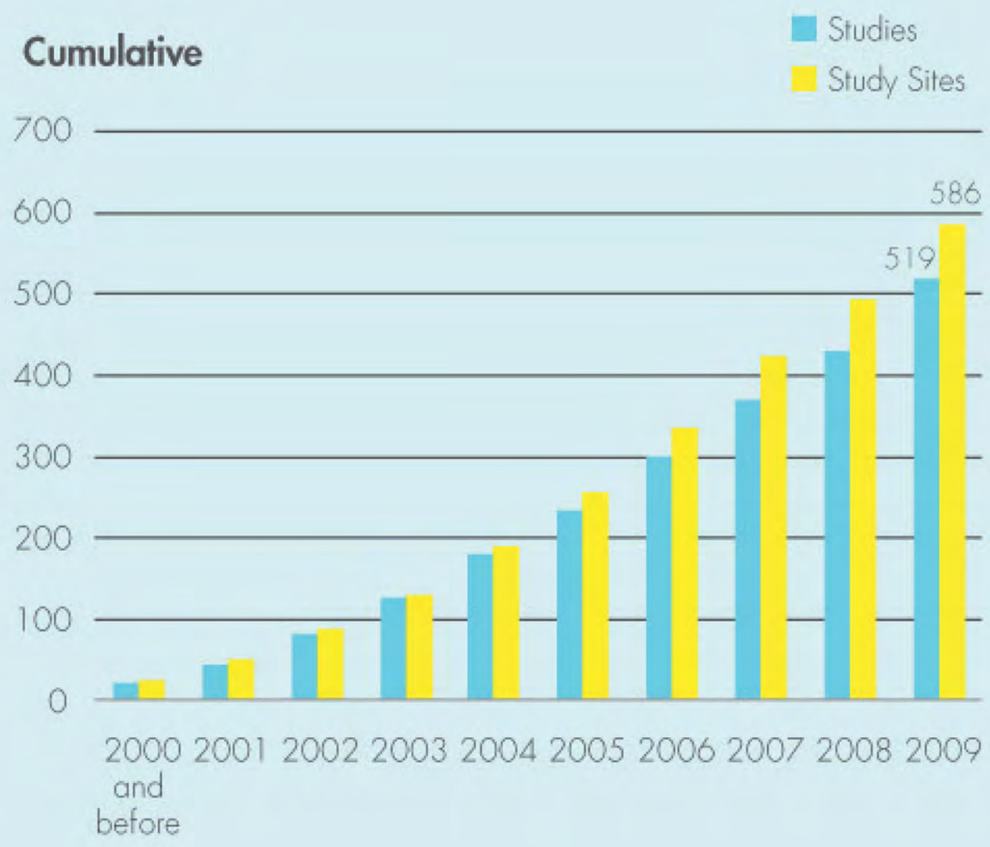
Information Technology

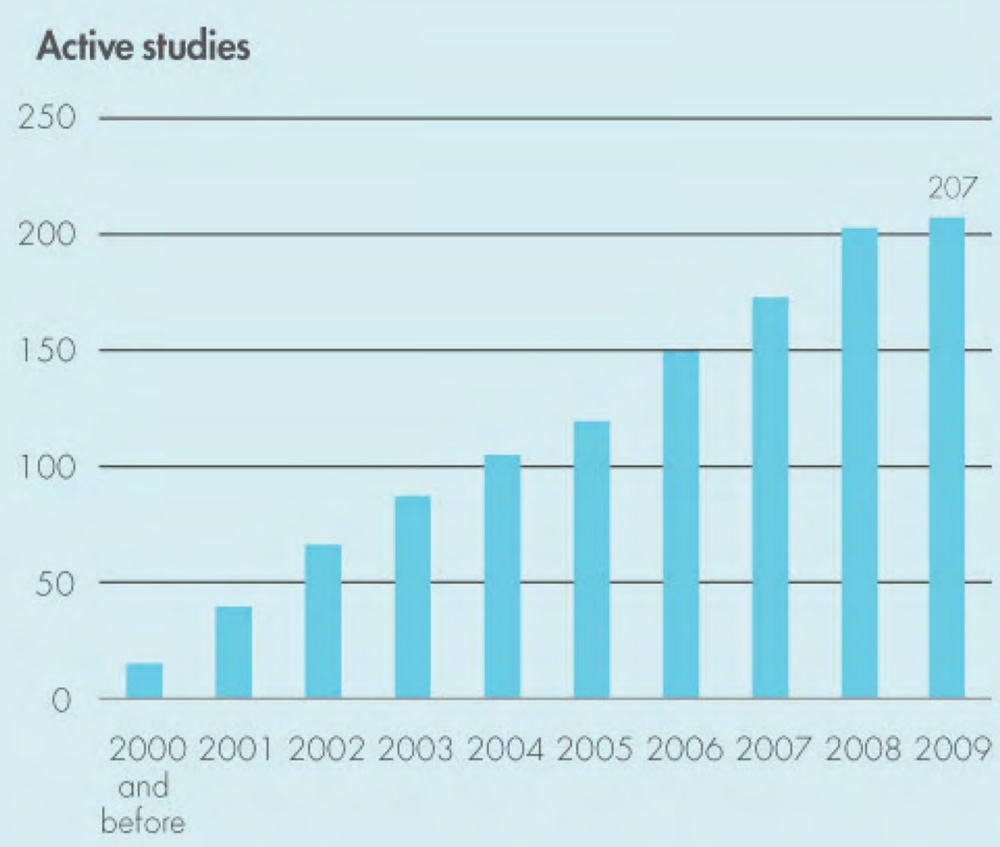
Data Management & Medical Statistics Team

- Medical Statistics
- Data Management
- Research Consultation

Operation Highlights for 2009

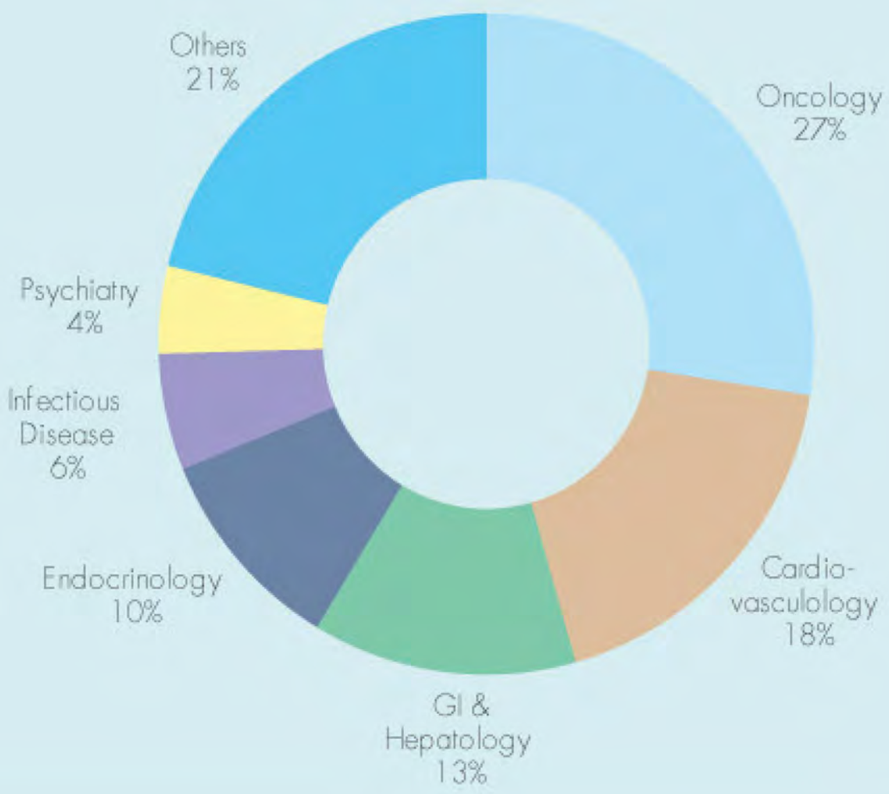
Contracted industry-sponsored clinical studies



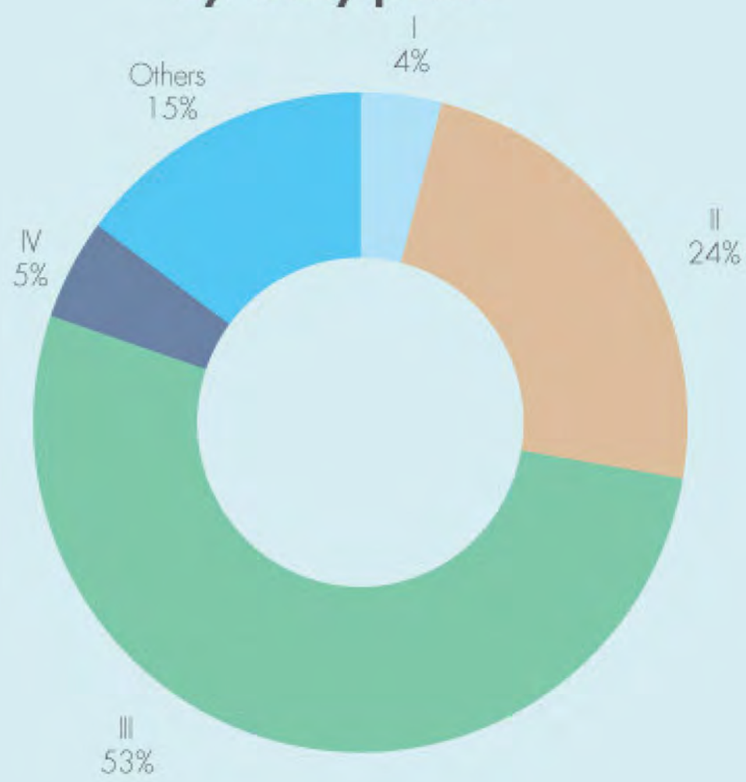


Types of clinical studies (All years)

By research area



By study phase



No. of **initial ethics submissions**: **85**
No. of **subsequent submissions (excluding serious adverse event reports)**: **3,129**
No. of **serious adverse event reports**: **16,794**
No. of **trial subjects** monitored: **463**
No. of **study visits** monitored: **1,634**

Collaborative trial sponsors

Abbott	Critical Biologics	Novo Nordisk
Achillion	Daiichi Sankyo	OrbusNeich
Actelion	EBR System	Organon
Advanced Herbal Therapeutics	Eisai	OSI Pharmaceuticals
Algeta	Eli Lilly	Pfizer
Allergan	Ellipse	Pharmasset
Altana Pharma	Enteromedics	Pi Medical
Amgen	Everpride Biopharmaceutical	PowderMed
Anaborex	Galderma	Progen
Arrow	Genentech	Roche
Artisan	Gilead	sanofi-aventis
Astellas	GlaxoSmithKline	Schering Plough
AstraZeneca	Guidant	SCI Network
Baxter	Idenix	Scios
Bayer	Johnson & Johnson	Servier
BCIRG	Keryx	St. Francis
Bio-cancer	Kowa	St. Jude Medical
Biocompatibles	La Jolla	Takeda
BioCryst	LG Life Sciences	Theravance
Biomeasure	Light Sciences	TTY Biopharm
Boehringer Ingelheim	Luitpold	Tularik
Boston Scientific	Lundbeck	Tyco
BrainsGate	MedImmune	UCB
Bristol-Myers Squibb	Medtronic	Vigconic
Bukwang	Medwaves	VitaGreen
Celltech	Merck KGaA	Wealthy Creative
Celsion	Merck Sharp & Dohme	Wyeth
CK Life Sciences	Morphotek	Xanthus Life Sciences
Codman	Nanogen	Zila
Cook	Novartis	

Highlighted Events in 2009

CTM conference

The Clinical Trial Magnifier (CTM) Conference was a success in Hong Kong on November 13-15, 2009. There were 47 speakers and chairpersons and 247 participants who came from 19 different countries across four continents, making the conference a truly global event. The CTM Conference is truly unique in Asia because it is the first of its kind to address the essentials related to agreements, budgets, regulations, and operations for clinical trials.

The following are highlights of some of the topics covered at the conference.

Dr. Edmund S. Tsuei, the Asia-Pacific-Africa Regional Head of Pharma Development Operations of Roche Products Pty Limited, gave a plenary lecture about Asia's roles in the globalization of clinical trials. Dr. Tsuei pointed out that the clinical trials market in Asia has grown significantly and rapidly. U.S. FDA audit data proved that the quality of clinical trials in Asia is at least as good as in Western countries. Despite the concerns about increasing costs, there is still a significant financial attraction in conducting clinical trials in Asia.

Professor Michael G. Irwin, the head of the Department of Anesthesiology, The University of Hong Kong, spoke on "The Perfect Investigator." Professor Irwin pointed out that "Lots of Patients" and "Lots of Patience" are two key elements for clinical investigators. To make a clinical trial a success, investigators must be appropriately motivated – in terms of early involvement with new or innovative treatment, education, publication, and research support.

Professor Louis Chow, the Medical Director of the Comprehensive Centre for Breast Diseases at the UNIMED Medical Institute in Hong Kong, shared his experiences and challenges in establishing an Asian clinical trial network for breast cancer trials. Professor Chow explained that Asia is a good place for conducting clinical trials on breast cancer mainly because of its great variety of patients. However, Asia as a whole needs to face a number of major challenges, including financial resources, information and technology transfer, and standardization of clinical practices.

The second CTM conference will be held in Malaysia in November 2010. The conference will address the key issues related to the incentives for investigators to participate (and continue to participate) in industry-sponsored clinical trials.

China SFDA inspection

Following its accreditation by the China State Food and Drug Administration (SFDA) in August 2006, Queen Mary Hospital / The University of Hong Kong was re-visited by the SFDA in March 2009. During that visit, representatives of QMH/HKU introduced to the SFDA officials the latest developments regarding clinical trials management. Extension of the accreditation system to Hong Kong is anticipated to help strengthen clinical research collaboration between mainland China and Hong Kong.

U.S. FDA inspection

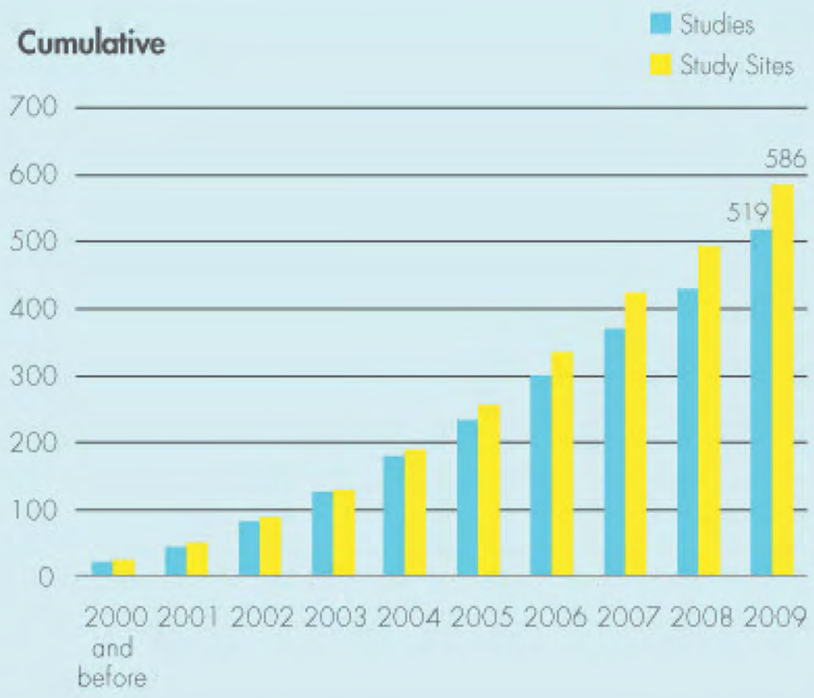
Following inspections in 1998, 2002, 2004 and 2008, Queen Mary Hospital / The University of Hong Kong was inspected in April 2009 by the U.S. Food and Drug Administration (FDA) for its participation in a global ovarian cancer study. The satisfactory results not only demonstrate QMH/HKU's exceptional competence in clinical research and its outstanding data quality, but also confirmed the importance of Hong Kong's participation in multinational clinical research activities.

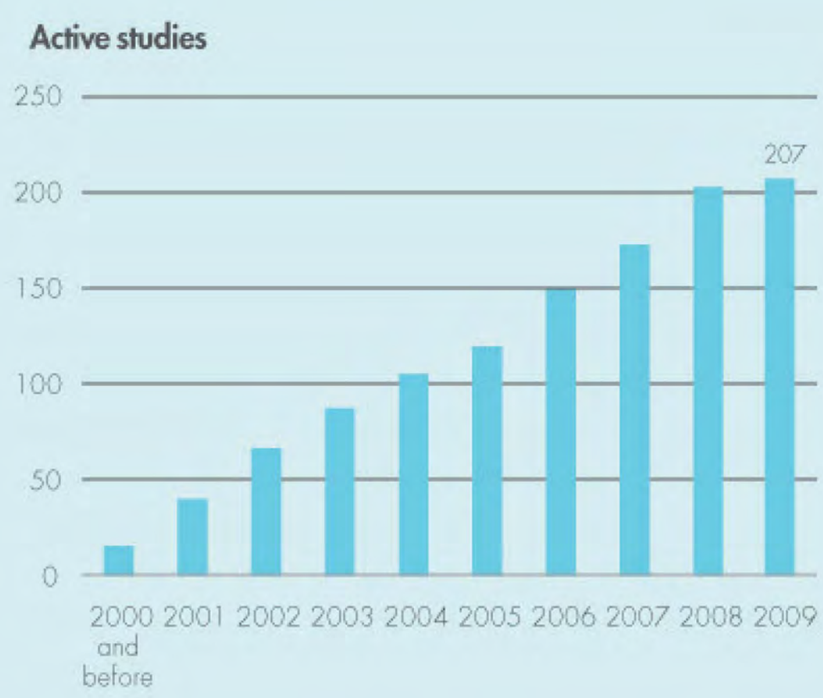
Business & Project Acceleration

Industry-sponsored clinical studies

The year 2009 was successful as the total number of contracted new clinical studies skyrocketed to 88, representing an increase of 46.7% over 2008. By the end of 2009, the cumulative number of contracted clinical studies reached 519, and 207 studies were still ongoing.

Contracted clinical studies and study sites



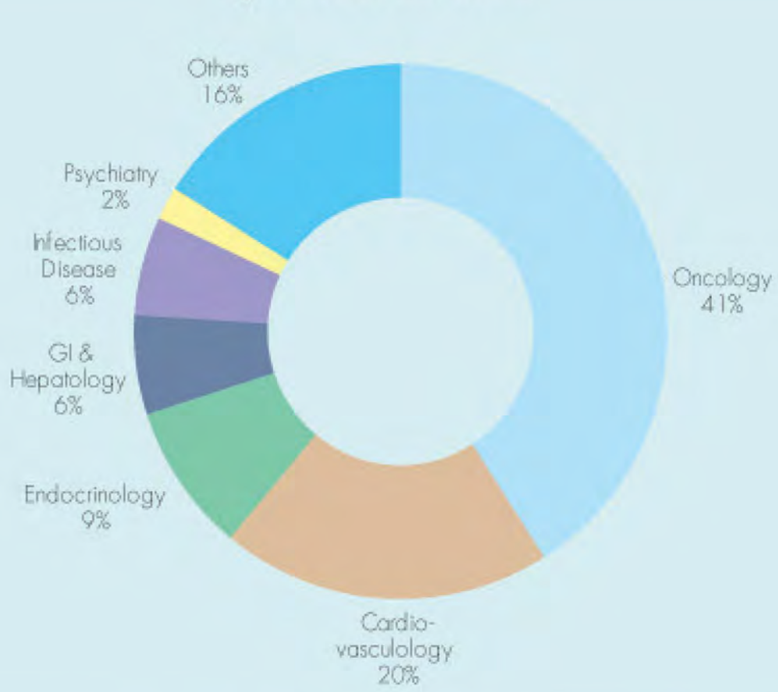


Study area and study phase

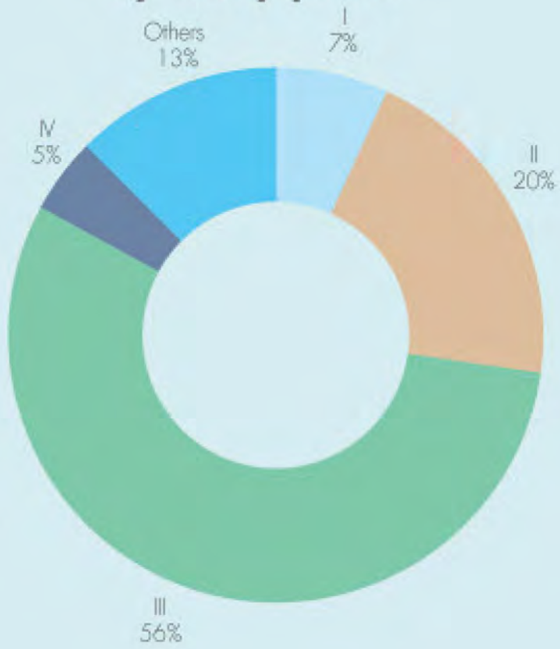
Similar to the previous years, oncology and cardiovasculology continue to be areas of great interest in the industry. Among the 88 clinical studies newly contracted, these two areas accounted for 41% and 20%, respectively. In terms of study phases, the distribution remained steady compared to last year, with phase II and III studies together represented 76% of all new studies contracted during the year.

Types of clinical studies in 2009

By research area



By study phase



Collaborative trial sponsors

As a leading organization dedicated to providing one-stop clinical research solutions for the industry, CTC continued to offer its professional expertise and services to the sponsors worldwide. In 2009, six new sponsors initiated clinical studies through CTC, raising the accumulated number of collaborative trial sponsors to 89.

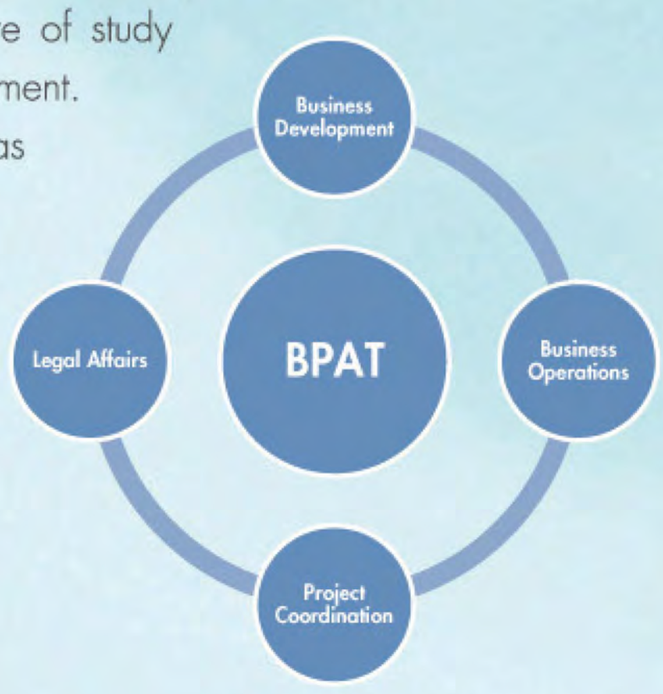
Investigator-initiated clinical studies

Since November 2009, CTC has been designated to provide contract management and insurance management supports to clinical investigators for their investigator-initiated clinical studies. With clear written guidelines developed and master clinical trial insurance coverage arranged, management of investigator-initiated clinical studies is enhanced and more high academic value clinical studies become feasible.

BPAT restructuring

Being in operation for two years after the formation of CTC's Business & Project Acceleration Team (BPAT) in 2007, BPAT has proven to be a successful model for efficient management and coordination of clinical studies, and is greatly welcomed and acknowledged by clinical investigators and the industry.

In line with the expanding scope of activities, during the year BPAT underwent another phase of restructuring by reshuffling its duties into four units – Business Development, Business Operations, Project Coordination and Legal Affairs. The Business Development Unit focuses on marketing, client relationship development, feasibility assessment and service proposal development. The Business Operations Unit takes care of study budgeting and payment management. The Project Coordination Unit acts as the primary contact point between investigators and the industry, providing supports on ethics affairs and study site logistics. The Legal Affairs Unit is responsible for contract management and providing advice on legal matters.



Operating Review & Achievements

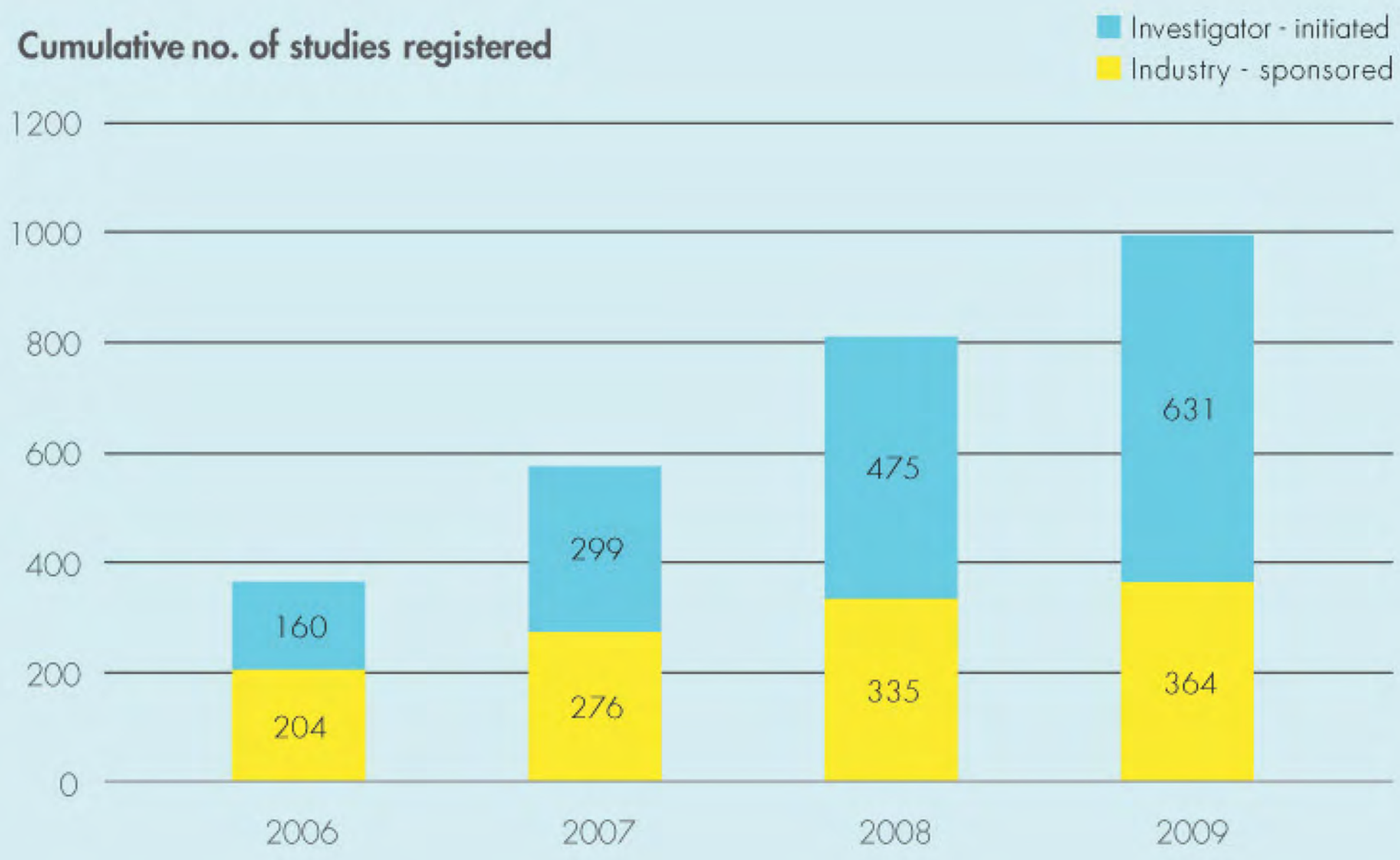
Feasibility assessments and business solutions

CTC's Business Development Unit has developed an extensive network of study sites and investigators in Hong Kong over the years. Being an active player in the clinical trial industry, the CTC understands needs and expectations of investigators, sponsors, and contract research organizations and responds swiftly by offering creative, unique, cost-effective, and practicable solutions leading to the materialization of clinical studies at different study sites. By the end of 2009, 53 feasibility assessments were completed for sponsors and contract research organizations by leveraging CTC's expertise and network

HKU Clinical Trial Register (www.HKClinicalTrials.com)

Since the call for more transparent disclosure of clinical trial activities by the International Committee of Medical Journal Editors (ICMJE) in 2004, registration of clinical studies with public clinical trial registries has become a standard practice worldwide. Since the launch of the HKU Clinical Trial Register in 2005, it has continued to thrive and has become an important local registry that provides a comprehensive picture of clinical research activities in Hong Kong and also serves as an extra channel for trial subject recruitment. By the end of 2009, the total number of clinical studies posted on the register reached 995, of which 364 were industry-sponsored studies and 631 were investigator-initiated studies.

Clinical studies registered at the HKU Clinical Trial Register



Project coordination

Since the establishment of the Project Coordination Unit in 2007, its Project Coordinators have demonstrated their importance by connecting sponsors and study sites and facilitating smooth and effective communications on all kinds of pre-study, in-study and post-study site activities. In particular, the Project Coordinators have taken a central role in assisting investigators to compile initial study applications and subsequent submissions to relevant ethics committees and facilitating resolution of ethics committees' comments and queries.

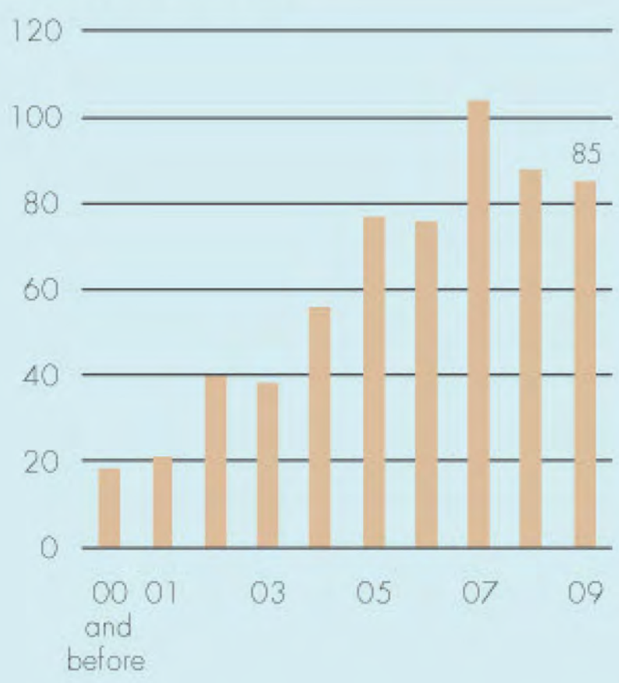
In view of the increasingly stringent requirements for the protection of human subjects, reporting of serious adverse events (SAEs) to ethics committees is becoming a bigger burden to investigators and sponsors. To streamline the reporting process and hence enhance the protection of human subjects, CTC has developed a novel SAE reporting e-platform, namely Platform for Electronic Adverse Reports Submission (PEARS), during the year. The platform is expected to greatly reduce the time and cost associated with SAE submissions and facilitates tracking the submissions. PEARS is undergoing a validation process and will be launched in the year to come.

Ethics affairs

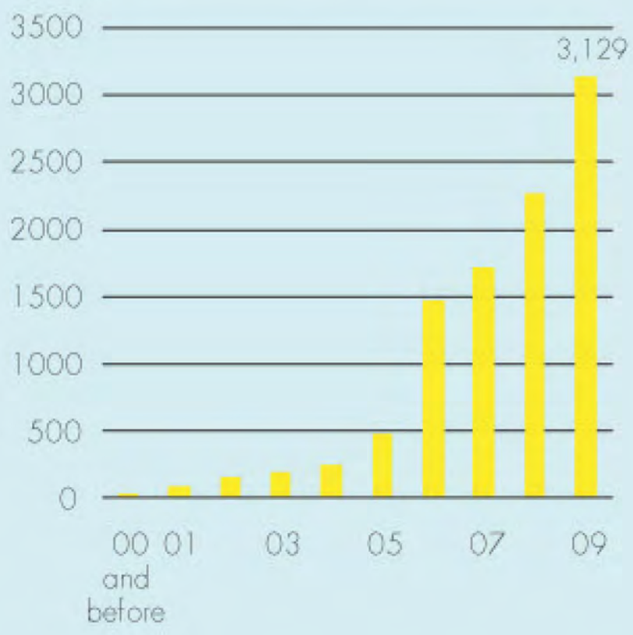
During the year, CTC facilitated some 85 initial ethics submissions. Attributing to the increasing number of active clinical studies, the number of subsequent submissions (excluding SAE reports) increased by more than 38% to a total of 3,129 and the number of SAE reports remained at a high level of 16,794. It is foreseeable that the ever increasing ethics submissions will continuously pose a challenge to the Project Coordination Unit.

Submissions to ethics committees per annum

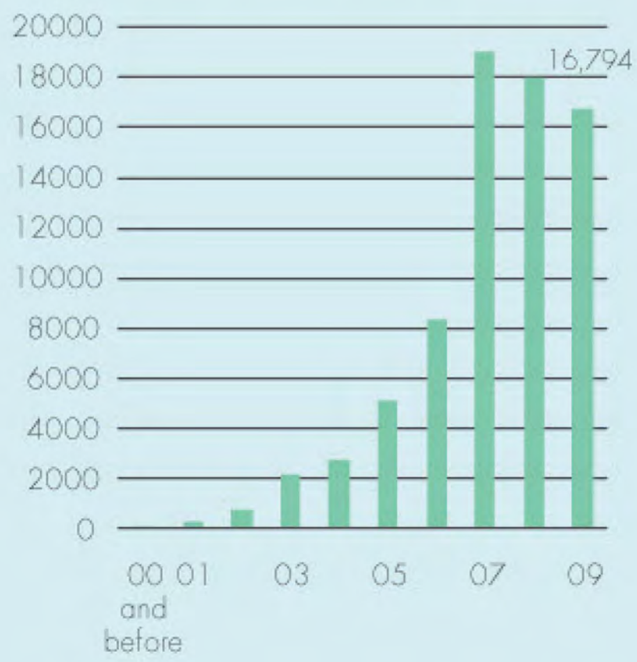
Initial submissions



Subsequent submissions (excluding serious adverse event reports)



Serious adverse event reports



Project Operations

Professional clinical study management

Over the years, CTC's Project Operation Team played an active role in providing comprehensive one-stop study management services to local and overseas sponsors, including protocol development, regulatory affairs, project management, monitoring, and coordination of data management and medical statistics.

In 2009, the Project Operation Team coordinated / participated in 20 clinical studies at 31 study sites. Oncology is a major therapeutic area, accounting for 25% of the total.

Professional clinical study management services performed or planned during 2009

Therapeutic Area	Study Phase	Services					
		Overall Project Management	Protocol Development / Review & Revision	Regulatory Affairs	Study Monitoring	Data Management	Medical Statistics
Cardiovasculology	D						
Critical Care	I						
Urology	O						
Dermatology	I						
Gastroenterology & Hepatology	III						
General Health	II						
Gastroenterology & Hepatology	II						
Infectious Disease	III						
Infectious Disease	D						
Infectious Disease	D						
Obstetrics & Gynaecology	II						
Oncology	I						
Oncology	I						
Oncology	II						
Oncology	III						
Oncology	III						
Orthopaedics & Traumatology	D						
Orthopaedics & Traumatology	D						
Orthopaedics & Traumatology	D						
Urology	O						

D: Device Study
O: Observational Study

No. of **trial subjects** monitored in 2009: **463**
No. of **study visits** monitored in 2009: **1,634**

Comprehensive services

During 2009, the Project Operation team has been providing full services for six clinical studies. Despite the stringent study initiation timeline, the team was able to set up the studies in an ethical, professional and timely manner.

Pre-study

- Protocol development
- Other essential documents development, e.g. ICF, subject diary
- Recruitment strategies planning
- Case report form design and development
- Regulatory submission
- Study procedures manual development
- Study site initiation visit
- Data Safety Monitoring Committee (DSMC) set up
- GCP training to study site staff

In-study

- On-site study monitoring with source data verification and safety reporting to sponsor
- Keeping track of study progress and reporting to sponsor
- Data transfer to data management team

Post-study

- Study closure

Site Operations

Medical Research Clinic (MRC)

Increasingly sophisticated clinical study designs call for professional management of clinical studies in dedicated facilities. Since its establishment in 2007, CTC's Medical Research Clinic (MRC) has been actively involved in a number of multi-national clinical studies. Located in a prime location in Queen Mary Hospital and staffed with a team of dedicated, experienced Clinical Research Coordinators, the MRC will continue to play a crucial role in the conduct of clinical studies in Hong Kong.

Subject Recruitment

Stringent protocols, competitive study timelines, and competition among clinical studies have made subject recruitment a major challenge. Through years of experience, CTC's Site Operations Team has developed effective recruitment strategies to facilitate subject recruitment. The total number of subjects recruited in 2009 was 470.

Provision of Clinical Research Coordinators

Availability of experienced Clinical Research Coordinators is a key to the success of clinical studies. In early 2009, CTC started to supply well-trained, experienced Clinical Research Coordinators to support investigators, whether within or outside Queen Mary Hospital, in conducting their clinical studies. This service is greatly welcomed by investigators and sponsors, and the demand is anticipated to grow continuously.

Successful conduct of a vaccine study in healthy volunteers

MRC demonstrated its value by successfully conducting a phase III, multicentre H5N1 influenza vaccine study supervised by Dr. Daniel W. S. Chu and initiated in 2007. With the close collaboration of Dr. Chu, his study team, and MRC's staff, 360 healthy subjects were recruited to participate in the study within a stringent timeline of three weeks, making the study site the best recruiting site for the study worldwide. The speedy recruitment and outstanding quality of the site led to the award of the first authorship in the first publication of the study.

Vaccine 27 (2009) 7428–7435

Contents lists available at ScienceDirect

Vaccine

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

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

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

[a] Dept. of Medicine, Queen Mary Hospital, The University of Hong Kong, 102 Pokfulam Road, Hong Kong

Study Site Services

Study drug management

CTC's Study Site Services Team collaborated closely with the Department of Pharmacy of Queen Mary Hospital on study drug management, offering one-stop solutions that included drug storage, drug repackaging/labeling, drug handling/preparation, drug accountability, drug dispensing, and drug disposal/return utilizing a systematic tracking system.

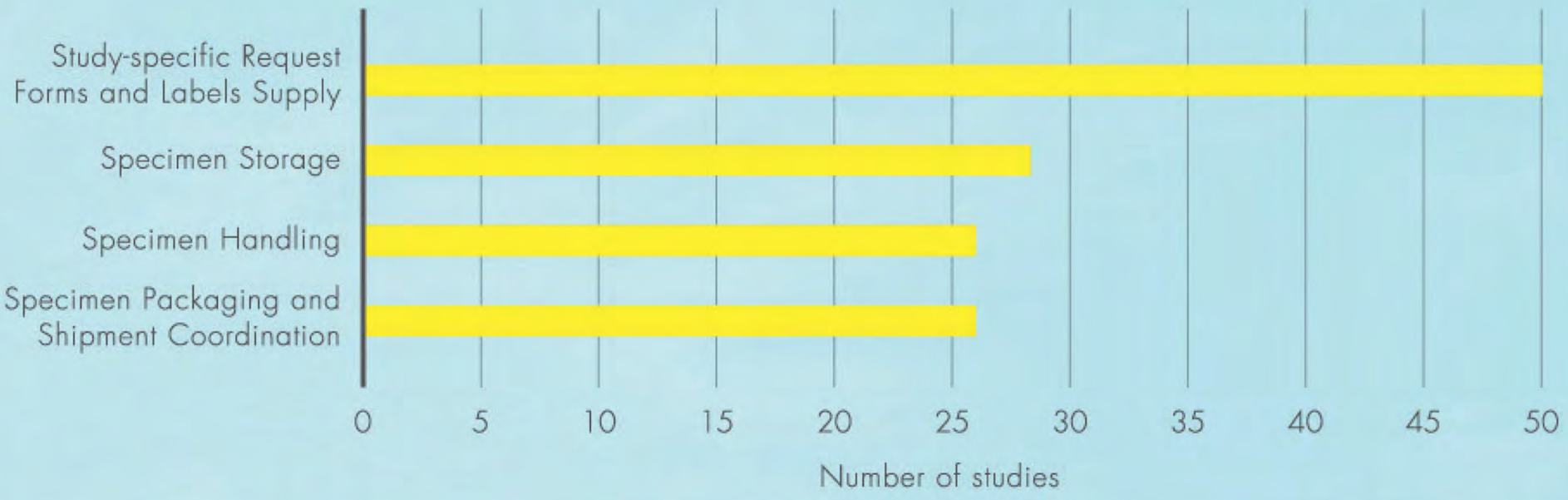
Specimen management

Staffed with professional personnel and well-equipped with specimen management facilities and instruments, including centrifuges, refrigerated centrifuges, and freezers (4°C, -20°C, -70°C) with backup power-supply, CTC's specimen handling unit is dedicated to providing a full range of clinical trial specimen services that includes general specimen processing, short-term and long-term specimen storage, pharmacokinetics specimen processing, and logistics coordination for local and overseas shipment of specimens. Efficient and accurate tracking of the specimens is ensured by its barcode tracking system.

Central laboratory

Standing at the hub of Asia, ALab is ideally located to provide efficient and high quality central laboratory services across the region. Staffed by 250 laboratory professionals, ALab collaborates closely with the affiliated laboratories at Queen Mary Hospital to offer comprehensive project management, outstanding analytical and specimen management capabilities, full logistics support, advanced data management and multi-level quality assurance. The laboratories are fully accredited by the College of American Pathologists (CAP).

Laboratory supporting services provided during 2009



ALab as a reliable central laboratory partner supporting multicentre clinical studies

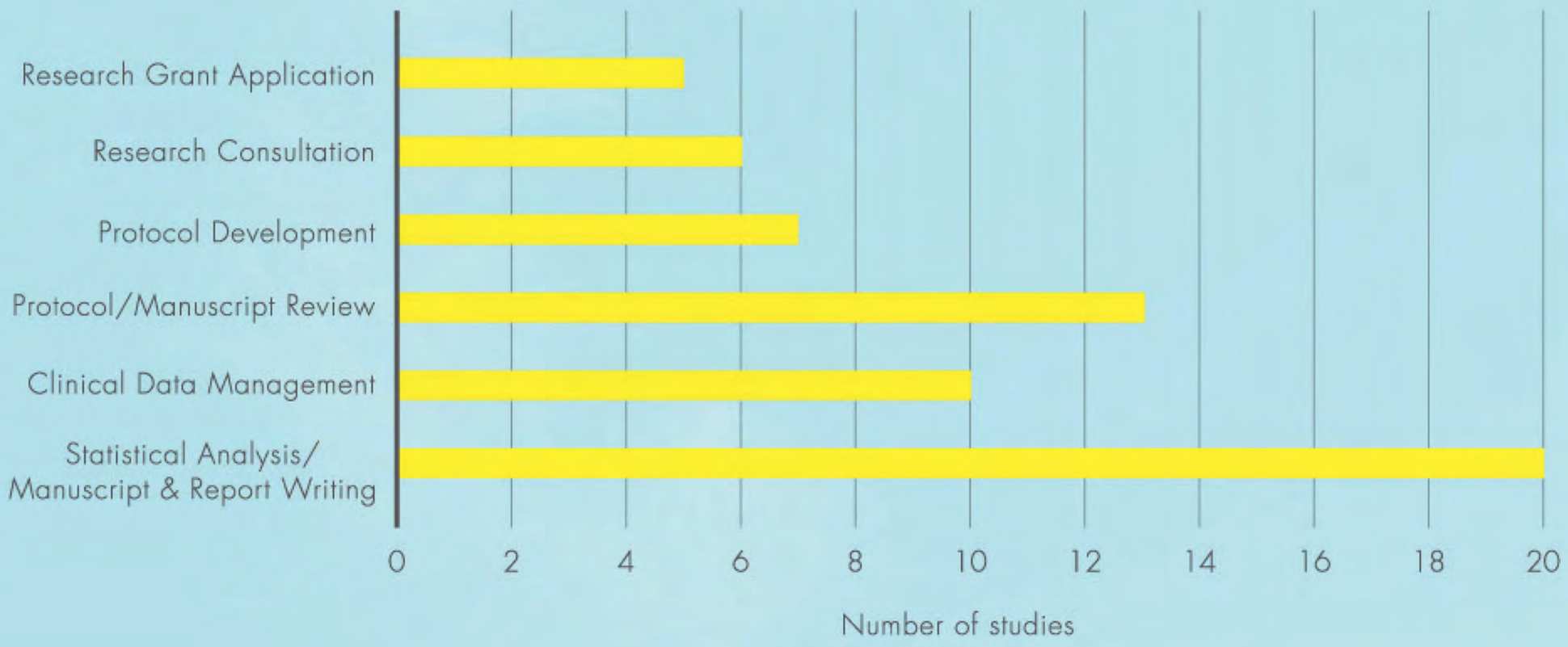
In late-2009, a large pharmaceutical company contracted with ALab to support a multicentre clinical study that was to be started in early 2010. Within a month (in spite of the holiday season at the beginning of the year), CTC's professional central laboratory management team, leveraging its solid experience and using the effective allocation of manpower and resources, managed to set up a study-specific electronic platform; coordinate with laboratory personnel regarding all required laboratory tests; sort out all specimen transportation, storage, and logistics issues; fabricate all test kits; compile a comprehensive laboratory manual; and synchronize with the sponsor regarding data transfer. The sponsor greatly appreciated the efficient and high-quality services, which are anticipated to contribute to the success of the study in 2010.

Data Management & Medical Statistics

After years of operation, CTC has developed an experienced Data Management and Medical Statistics Team, which is actively involved in medical research data and statistics management. The team offers consultation and support to the sponsors and clinical investigators to ensure the quality and reliability of medical data obtained throughout the conduct of clinical study.

In 2009, the team continued to provide a wide range of professional services concerning database development, sample size estimation, statistical analysis, protocol review and development, clinical data management, research consultation and grant application. It is expected that the demand for these services will continue to be strong.

Data management and medical statistics supports and services provided in 2009



Education & Publications

Education

In line with the fast-changing clinical research industry, CTC has redesigned the curriculum for the specialized module – Introduction to Clinical Trials Research Methodology – under the Master of Public Health Program. The revised module will be launched in the 2010/11 academic year and is anticipated to continue gaining popularity among those who are involved in or preparing to take part in the clinical research industry.

Introduction to Clinical Trials Research Methodology

- Ethics and Bioethics
- Clinical Trials in the Context of Biomedical Research
- Clinical Trial Players and their Responsibilities
- Declaration of Helsinki
- Features of Clinical Trials (I)
- Features of Clinical Trials (II)
- ICH Good Clinical Practice (GCP)
- Science of Clinical Trials
- Protocol Development
- Ethics of Clinical Trials
- Quality of Clinical Trials
- Legal and Contractual Issues

Publications

1. Clinical Trial Magnifier

The Magnifier is a free newsletter available online since 2008 and has attracted more than 20,000 subscribers from nearly 160 countries. It is the first newsletter reporting on clinical trials related issues from the perspective of investigators.

2. Reviewing Clinical Trials: A Guide for the Ethics Committee

The Ethics Guide was written by the Director of CTC, Professor Johan Karlberg and reviewed by a group of international experts. It aimed to address the tremendous global demand for educating ethics committee members on clinical trial documents review, especially in health care organizations in emerging clinical trial locations. The guide can be downloaded free of charge on www.ClinicalTrialMagnifier.com or one can order the printed version.

3. Clinical Trial Terminology Handbook

The handbook includes the most commonly used terms related to clinical trials and is specifically developed as a reference for all players involved in the fast-changing industry related to clinical trials. The ICH-GCP guideline is also incorporated therein.

Feature Interviews:

1. *Dr. Tsang, when did you start conducting clinical research? What are the main incentives for your active involvement in clinical research?*

I started conducting clinical research about eight years ago during a time when cancer research was entering the era of targeted therapies. Clinical trials provide opportunities for patients to get access to new potential therapies and help investigators better understand and share experiences related to those new therapies, thus leading to further advancement of cancer care. I remember that during a breast cancer trial, our research team first discovered deranged liver functions in three trial subjects, leading to a subsequent revision of the global protocol and enhanced safety of the subjects participating in the trial. Clinical research indeed provides a platform for sharing experiences and knowledge with experts around the world and for the betterment of patient care.

Dr. Janice Tsang
Department of Clinical Oncology

2. *From your point of view, is clinical research of any significance to the general public? What advice in relation to clinical research would you give to patients or volunteers?*

Clinical research is of huge significance to the general public. Through participating in clinical trials, patients may be provided with access to standard treatments or test articles free of charge in the context of research. Furthermore, trial patients are monitored much more closely per trial protocols, and they can contact our research personnel for enquiries throughout the trial period. Patients and their family members are always welcome to discuss openly the pros and cons of clinical trials. However, they should understand that participation in clinical trials may not directly benefit the patients themselves and are instead geared toward benefitting patients in the future.

3. *What are the challenges in conducting clinical trials, especially industry-sponsored ones?*

Clinical research is indeed demanding in terms of time and energy, from protocol preparation to patient accrual, conducting the clinical trials until data collection and analysis. These require the concerted effort of everyone on a research team, including investigators, research nurses, and research assistants. Without them, no clinical trial could be conducted properly. Major challenges in conducting industry-sponsored clinical trials include the pressure to recruit the target number of patients within a finite period of time and much more close and intensive monitoring of trial patients than patients in the usual clinical setting. Additional efforts are also needed for compliance with the Good Clinical Practice (GCP).

4. *What advice can you give new clinical investigators wanting to get involved in clinical research?*

I think the zeal to learn with an open mind and the passion for clinical trials and translational research is of paramount importance. A new investigator wanting to get involved in clinical research could start by initially becoming a co-investigator on a team, through which he/she will get hands-on experience with GCP and be better able to plan for a research career. Speaking with experienced investigators, consolidating scientific knowledge through updated medical literature, and even considering further study in molecular biology, bioinformatics, or translational research will all be helpful.

1. *Dr. Yau, when did you get started in conducting clinical trials? Could you mention any impressive experience?*

I started my first clinical trial when I was in London seven years ago. At that time I was working as a registrar. Since I returned to Hong Kong, I have conducted more than 40 clinical trials. The most impressive experience to me was a 25-year-old patient who suffered from advanced hepatocellarcarcinoma (HCC). Everyone at that time was telling him he could not live for more than two months. Afterward he enrolled in an early-phase clinical trial. Now he is surviving - four years after the trial - and he was married and promoted in his job. This is the best incentive for me to do clinical trials. The results and knowledge arising from clinical trials could finally contribute to the public and improve the medical standards.

Dr. Thomas Yau
Department of Medicine

2. *What are the differences between conducting clinical research in Hong Kong now and at the time you got started? Compare to other Asian places, what are the advantages of conducting clinical trials in Hong Kong?*

The quality of clinical research in Hong Kong has improved a lot in the seven years since I first participated. The location of clinical trials shifted from Europe and the U.S. to Asia in recent years so researchers could explore a larger population. We are happy to see that Hong Kong, being a part of the Asian region, has increased its clinical trial activities in the past few years. Although the population in Hong Kong is small compared to that of mainland China or other Asian countries, we have a more solid track record of high-quality clinical research.

3. *What future developments do you want to see with respect to clinical research in Hong Kong?*

I hope to see more phase I studies in Hong Kong. We could definitely participate in more high scientific value phase I trials rather that doing mainly phase III trials for confirmation and studies for obtaining pharmacokinetic and/or pharmacodynamic data. We could also contribute more to clinical research in mainland China through collaboration with oncology research groups there.

4. *How do you balance your clinical research activities with routine clinical and academic duties? What are your research plans for the near future?*

Time management is a key issue considering my heavy workload of clinical, research, and teaching duties. I have to rely heavily on our team in doing clinical trials. The success in conducting clinical trials is not only dependent on the principal investigator but also on the tight collaboration among other team members including dedicated medical oncologists, research nurses and clinical trial coordinators. Recently, our team has conducted several multicentre trials with Singapore. In the coming months, we are going to establish a link with the U.K. and U.S. by conducting more global and multicentre clinical trials.

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2009

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Cardiovasculology	Acute Coronary Syndrome	III	Professor Stephen WL Lee	Medicine
Cardiovasculology	Acute Ischemic Stroke	III	Professor Raymond TF Cheung	Medicine
Cardiovasculology	Acute Ischemic Stroke	III	Professor Raymond TF Cheung	Medicine
Cardiovasculology	Atrial Fibrillation	N/A	Professor HF Tse	Medicine
Cardiovasculology	Cardiovascular Events	III	Professor Stephen WL Lee	Medicine
Cardiovasculology	Coronary Artery Disease	I	Professor Stephen WL Lee	Medicine
Cardiovasculology	Coronary occlusive disease	N/A	Professor Stephen WL Lee	Medicine
Cardiovasculology	Endovascular Aneurysm Repair	I	Professor Stephen Cheng	Surgery
Cardiovasculology	Endovascular Aneurysm Repair	N/A	Professor Stephen Cheng	Surgery
Cardiovasculology	Heart Failure	N/A	Dr. Kathy LF Lee	Medicine
Cardiovasculology	Hypertension	III	Professor Stephen WL Lee	Medicine
Cardiovasculology	Hypertension	III	Professor Stephen WL Lee	Medicine
Cardiovasculology	Hypertension	N/A	Professor HF Tse	Medicine
			Dr. Katherine YY Fan	Medicine
Cardiovasculology	Hypertension & Diabetes	II	Dr. WS Chow	Medicine
Cardiovasculology	Major Adverse Cardiovascular Events	III	Dr. David Siu	Medicine
Cardiovasculology	Thrombosis	III	Dr. Eric WC Tse	Medicine
Cardiovasculology	Thrombosis	III	Dr. Eric WC Tse	Medicine
Cardiovasculology	Thrombosis	III	Dr. David Siu	Medicine
Dermatology	Psoriasis	I	Dr. CK Yeung	Medicine
Endocrinology	Diabetes	III	Dr. Annette Tso	Medicine
Endocrinology	Diabetes	III	Professor TM Chan	Medicine
Endocrinology	Diabetes Mellitus	II	Dr. Sydney CW Tang	Medicine
Endocrinology	Diabetes Mellitus	II	Dr. WS Chow	Medicine
Endocrinology	Diabetes Mellitus	II	Dr. Annette Tso	Medicine
Endocrinology	Diabetes Mellitus	III	Dr. Annette Tso	Medicine
Endocrinology	Diabetes Mellitus	III	Dr. Annette Tso	Medicine
Endocrinology	Osteoporosis	N/A	Professor Annie WC Kung	Medicine
Gastroenterology & Hepatology	Hepatitis B	IV	Dr. CK Chan	Medicine
Gastroenterology & Hepatology	Hepatitis B	N/A	Professor MF Yuen	Medicine
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine
Gastroenterology & Hepatology	Hepatitis B	II	Professor CL Lai	Medicine
Gastroenterology & Hepatology	Hepatitis C	II	Professor MF Yuen	Medicine
Geriatrics	Alzheimer's disease	II	Dr. LW Chu	Medicine

Industry-sponsored clinical studies contracted in 2009

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Haematology	Hemophilia	I	Professor YL Kwong	Medicine
Infectious Disease	Community Acquired Pneumonia	II	Dr. Matthew KY Wong	Medicine
Infectious Disease	Infection	IV	Dr. WM Chan	Medicine
Infectious Disease	Influenza	N/A	Dr. Susan Chiu	Paediatrics & Adolescent Medicine
Infectious Disease	Influenza	IV	Dr. Dennis KM Ip	Community Medicine
Infectious Disease	Sepsis	II	Dr. CW Kam	Accident & Emergency
Neurology	Seizures	III	Professor Raymond Cheung	Medicine
Neurosurgery	Vasospasm-related Morbidity	III	Dr. WM Lui	Surgery
Obstetrics & Gynaecology	Contraception	III	Dr. Ernest Ng	Obstetrics & Gynaecology
Obstetrics & Gynaecology	Human Pappillomavirus Infection	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Obstetrics & Gynaecology	Menorrhagia	IV	Dr. TC Pun	Obstetrics & Gynaecology
Oncology	Breast Cancer	II	Dr. MY Luk	Clinical Oncology
			Professor Raymond HS Liang	Medicine
Oncology	Breast Cancer	III	Dr. MY Luk	Clinical Oncology
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	II	Dr. Janice Tsang	Clinical Oncology
Oncology	Breast Cancer	III	Professor Raymond HS Liang	Medicine
			Dr. Janice Tsang	Clinical Oncology
Oncology	Breast Cancer	III	Professor Raymond HS Liang	Medicine
Oncology	Colorectal Cancer	II	Dr. Thomas Yau	Medicine
Oncology	Gastric Cancer	III	Professor KM Chu	Surgery
Oncology	Gastric Cancer	II	Dr. Victor Lee	Clinical Oncology
			Dr. Thomas Yau	Medicine
Oncology	Gastric Cancer	III	Professor KM Chu	Surgery
Oncology	Gastric Cancer	II	Professor KM Chu	Surgery
Oncology	Gastrointestinal Cancer	N/A	Dr. Rico KY Liu	Clinical Oncology
Oncology	Gastrointestinal Stromal Tumors	III	Professor KM Chu	Surgery
Oncology	Glioblastoma	III	Dr. Janice Tsang	Clinical Oncology
Oncology	Glioblastoma Multiforme	III	Dr. Janice Tsang	Clinical Oncology
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2009

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Lung Cancer	III	Dr. Victor Lee	Clinical Oncology
Oncology	Multiple Myeloma	III	Dr. CS Chim	Medicine
Oncology	Ovarian Cancer	II	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Ophthalmology	Diabetic Macular Edema	III	Dr. Wico WK Lai	Ophthalmology
Orthopaedics & Traumatology	Osteoarthritis	N/A	Professor Peter Chiu	Orthopaedics & Traumatology
Orthopaedics & Traumatology	Scoliosis	N/A	Professor Kenneth Cheung	Orthopaedics & Traumatology
Orthopaedics & Traumatology	Spinal Cord Injury	III	Dr. HY Kwok	Orthopaedics & Traumatology
Psychiatry	Schizophrenia	II	Dr. KF Chung	Psychiatry
Psychiatry	Schizophrenia	III	Professor Eric Chen	Psychiatry
Respiratory Medicine	Chronic Obstructive Pulmonary Disease	III	Dr. Matthew KY Wong	Medicine
Rheumatology	Rheumatoid Arthritis	III	Dr. Temy MY Mok	Medicine

*** 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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