The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

To Enhance the Clinical Trial Capacity in Hong Kong

Introduction

Formed in 1968, the Hong Kong Association of the Pharmaceutical Industry (HKAPI), represents 37 international companies engaged in the research and development of pharmaceuticals including the world's top 20, welcomes the opportunity to submit its views on how to promote Hong Kong's innovation and technology capacity.

International pharmaceutical companies constantly engage in research and development of new drugs and more and more clinical trials have been conducted in Asia in the last decade.

In our opinions, it is vital for Hong Kong to enhance its capacity as a regional research and clinical trial centre to attract more scientific and clinical research, which can speed up the process of new drug development, benefit medical industry in Hong Kong, and also patients in terms of expedient drug access.

Recommendations

We conducted a research in 2010 on the capacity and critical success factors for Hong Kong to develop into a regional hub for clinical trials (please refer to Appendix 1 for details of the research), and put forward some suggestions to relevant parties based on the findings and analyses of our research. We are glad to see a lot of initiatives from the government in the past 2 years such as two clinical trial centers were developed in the two Universities, and the Department of Health did a lot to expedite the approval of clinical trial application. However, we would like to further strengthen Hong Kong's position as a clinical trials centre in Asia with the following suggestions.

1. Enhance of the infrastructure

There are four areas for Hong Kong to strengthen its capacity of clinical trial and the Hospital Authority (HA) plays a key role in it.

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A. Establish a Dedicated team at the Hospital Authority

At present, lack of coordination within Hospital Authority regarding clinical trials causes delay in starting the trial; the timeline provided by the Ethics Committees in different hospitals varies greatly from 1 to 6 months and is unpredictable. To speed up the start-up time of clinical studies, HA should have a dedicated team that handle all the issues related to clinical trials with sufficient resources including research nurses, legal personnel, testing laboratories and equipment tailored for clinical trials. Most HA doctors have heavy workload and are preoccupied with attending patients. HA should motivate and give more recognition to doctors who are willing to undertake clinical trials.

B. Developing human resources in clinical studies

Apart from doctors in the public hospitals, Hong Kong can leverage the expertise from private practitioners in carrying out clinical trials, observational studies and registry studies.

All the research staff involved in clinical trials should be GCP certified to ensure the quality of the study is high and the results are credible. A platform should be established for all the clinical researchers in Hong Kong to share their expertise and best practices through information exchange, seminars, training etc to enhance the capacity of clinical studies in Hong Kong.

C. Patient recruitment and public awareness on clinical studies

To facilitate the recruitment of patients for clinical research, HA should establish a management system that can quickly identify the number of patients available for a particular trial, possibly through linking up with the e-health record.

The government should also increase public's awareness regarding the benefits of clinical trials, so the general public and patients will have more confidence in these studies and will be more willing to participate.

D. Focus on comparative advantages

In terms of disease areas, Hong Kong should focus on its strengths such as oncology, hepatology, respiratory diseases, and infectious diseases. Clinical trials centre shall focus on Phase I or early phase studies to encourage medical research.

Those well-established study sites in Hong Kong can be showcased to pharmaceutical companies so that research associates from the head office can come for a visit and have a better understanding on Hong Kong's capacity in conducting clinical trials.

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2. Facilitating clinical research in China

More importantly, Hong Kong, with its advanced medical infrastructure, research capability and efficient clinical trial approval, should play the role of facilitating clinical trials in China. The two university-based hospitals have obtained approved from the State Food and Drug Administration (SFDA) of China to carry out clinical trials for China registration purpose in a number of disciplines and the clinical data generated from these studies are recognized by their health authorities. To position Hong Kong as a principal site for conducting clinical research and to further facilitate industry collaboration with research institutions in China, the Government should facilitate the accreditation of additional clinical trial sites and ensure clinical data transferability for trials conducted in Hong Kong.

To summarize, it is important for Hong Kong to strengthen its competitiveness in medical and clinical research in Asia.

1. The setting up of a dedicated team that handle all the related procedures to speed up the start up time.
2. The team should be equipped with sufficient resources including research investigators, nurses, legal personnel, laboratory and equipment tailored for clinical research.
3. HK should have a phase I unit that focuses on early phase studies and niche disease areas such as oncology, hepatology, respiratory diseases and infectious diseases.
4. Hong Kong should leverage its proximity to China, its advanced medical infrastructure, high-quality and experienced research investigators to position itself as the principal clinical trials site for clinical studies from China.

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Appendix 1:

Study on how to develop and strengthen the clinical trial capacity of Hong Kong

Objectives of the study

The objective of the study is two-fold, firstly to understand the extent of clinical trials undertaken by international pharmaceutical companies in Hong Kong over the past ten years (Appendix 2). Second and more importantly is to understand the major problems faced by the industry when conducting clinical trials in Hong Kong and how clinical studies can be facilitated and enhanced which resulted in a more conducive research environment.

Research Methodology

To study Hong Kong's existing capacity in conducting clinical trials and how to further enhance it, both quantitative and qualitative research methods were employed. First of all, a survey was conducted among the members of HKAPI. Following the survey, a number of interviews were carried out with regional clinical trials directors as well as research associates of pharmaceutical companies to solicit their views on the advantages and disadvantages of conducting clinical trials in Hong Kong.

A taskforce among HKAPI members is also set up with representatives specialized in conducting clinical trials in Hong Kong to leverage their knowledge on the main considerations from the pharmaceutical companies' point of views when choosing the site for clinical trials and the problems encountered by the industry when conducting these trials in HK.

Desk research on the development of clinical trials in other countries including China, Singapore, South Korea, Taiwan was also conducted to understand and analyze the critical success factors of developing Hong Kong into a regional clinical trials centre.

Scope of Research

Through survey questionnaire, quantitative information on the number of clinical trials, phases of studies, the therapeutic areas of study, the number of patients and sites involved in each trial, amount

of sponsorship were gathered from our members whereas the critical success factors that contribute to the development of clinical trials capacity and where HK stands in terms of infrastructure, human resources, regulatory framework were the main focus of the secondary research. Also, studies that assessed the clinical trials capacity in other Asian countries such as Singapore, South Korea, Taiwan, China were reviewed.

Critical factors for clinical trials

The critical success factors for clinical trials are identified and where Hong Kong stands in terms of these important areas are summarized in the following table.

Crucial factors for clinical trials	**HK situation**
Top class/advanced medical infrastructure and clinical trial sites that are self-contained with modern medical equipment and laboratories	• Hong Kong has two medical schools with high quality clinical research output and participated in over 1000 global clinical trials, all requiring ICH GCP compliance.
Well trained and experienced investigators who are motivated to participate in clinical trials	• Investigators observe good clinical trial (GCP) practice and standards • Quality of investigators is good but sometimes company has difficulties to identify suitable investigators. • A lot of doctors may be preoccupied with healthcare services and do not have time and research team to support them, it will be good to promote the importance of clinical trials to them.
Friendly Regulatory system/framework	• The cluster ethics committees operate according to the international standards eg. the Declaration of Helsinki and ICH GCP and also according to a unified operational guideline. Meetings are scheduled every two weeks. • Framework for testing news drugs in HK is quite simple which requires an ethics committee approval which is followed by an automatic approval for trial conduct and an

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	import license for the test drugs, the whole approval process takes about 2 months. • Approval time for clinical trial certificate from the Department of Health is around 9-10 weeks. • HK is one of the few countries that require the submission of drug sample when applying for the clinical trials certificate. Pharmaceutical companies may have difficulties in providing a sample before getting approval from the Department of Health and this can cause delay to the approval process. •
Cost effectiveness	• Geographical proximity and the size of the trial sites can make HK clinical trial cost-effective. • The remuneration for investigators/ related staff is very high. Eg. 1500 per hour.
Ease of patient recruitment, population size	• HK has a population of 7 million and 90% of the medical care services in HK are provided by the 42 public hospitals.
High literacy rate, education level, language proficiency	• People in HK has a fairly high literacy rate and education level which contributes to higher compliance.
Gateway to China	• The role of HK may be to facilitate clinical trials in China and collaborate with them, but some departments in our hospitals are not accredited by SFDA and therefore cannot become one of the trial sites and help with recruiting patients. • For studies that involve sites in both China and HK, the pharmaceutical company needs to obtain approval from China SFDA first before it can start applying for clinical trials in HK, this can lead to the loss of competitive edge in terms of time.

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Start up time	• The Clinical Trial Centre at HKU has established a trial network – ClinCluster under which among the 42 public hospitals, contract, budget, ethics committee applications are uniform. • The review of HA contract/agreement takes 1-1.5 months after EC approval, if HA can shorten the review process, the start up time can be shortened.
Role of clinical trials centres	• The clinical trial centres in HK mostly facilitate the submission of documents and the preparation of budget. In other countries such as Korea, the support from government may involve the setting up of clinical trials centre that helps to review the protocol and progress of the trials from time to time.

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Appendix 2

Key Findings of the Survey on Clinical Trials conducted by HKAPI

Survey on clinical trials

- **Received 26 replies from 44 full members and affiliated members with a response rate of 59%**
- **A total of 436 clinical trials studies have been conducted by 19 of our members in HK between 1999 and 2008.**

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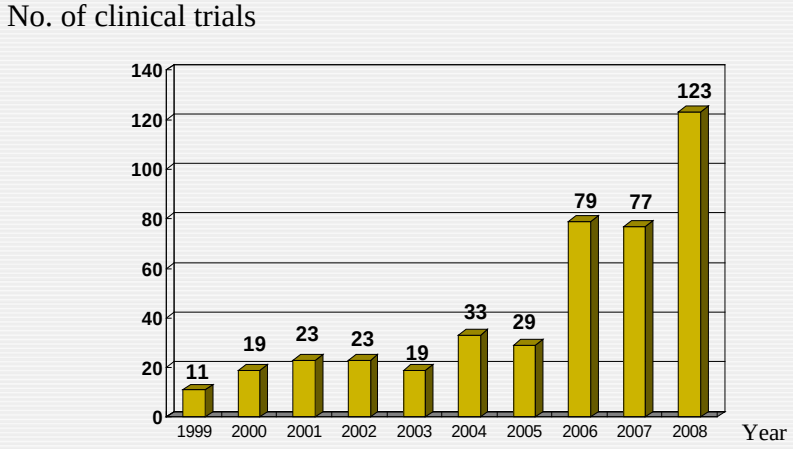
Clinical trials conducted by HKAPI members



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Top 5 therapeutic areas

Top 5 therapeutic areas of clinical study

- Oncology (26%)
- Endocrinology (8.4%)
- Gastroenterology & Hepatology (8.4%)
- Cardiology (7%)
- Respiratory (5.3%)

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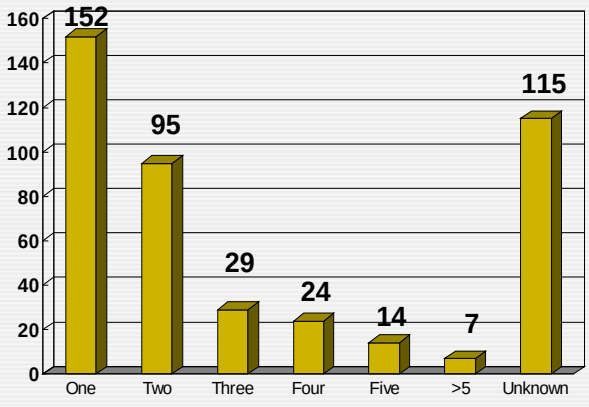
No. of Hospitals involved

No. of clinical trials



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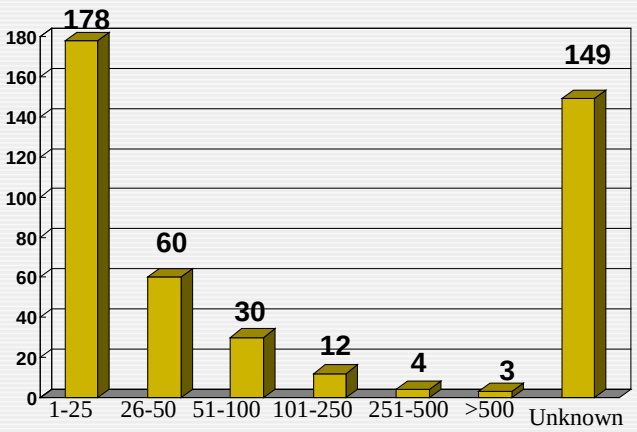
No. of Patients involved

No. of clinical trials



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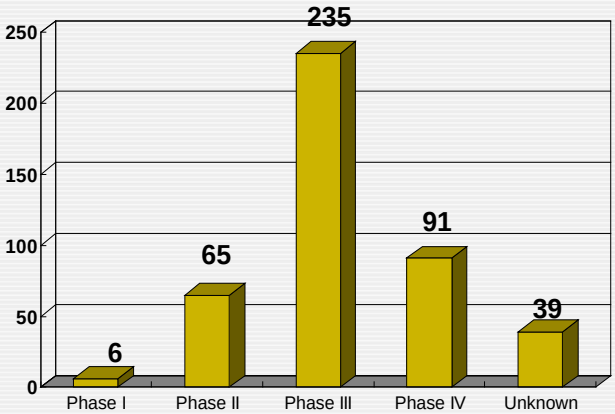
Study Phase of the Clinical trials

No. of clinical trials



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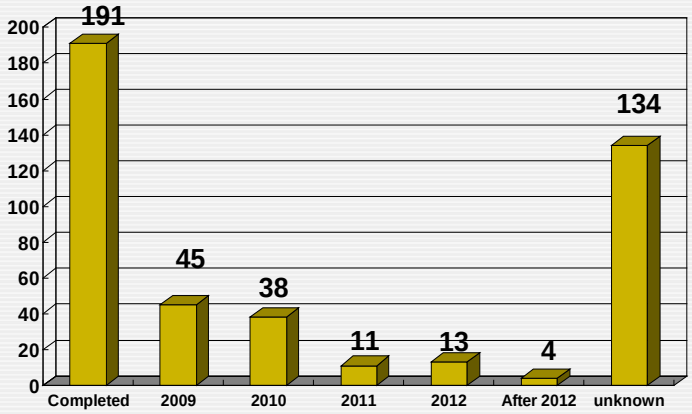
Date of completion

No. of clinical trials



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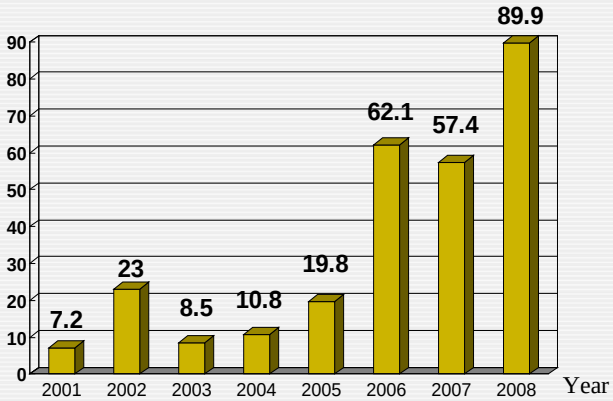
Amount of sponsorship per year

HK$ (Million)



Data provided by 14 members

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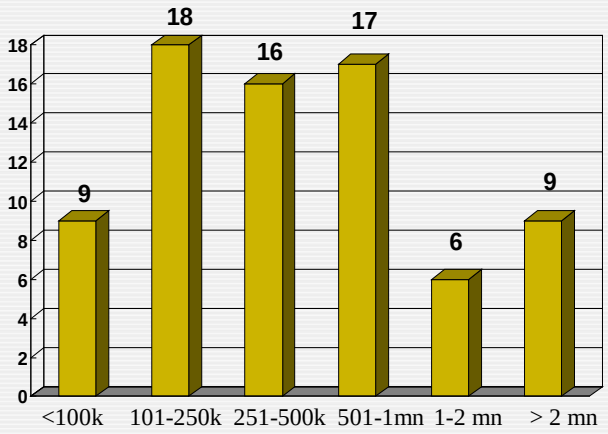
Amount of sponsorship (HK$) per trial

No. of clinical trials (N=75)



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Major Findings

- **47.4% of the studies involved 1 hospital**
- **62% of the studies involved 25 patients or less**
- **More than half of the studies are in Phase III (58.2%)**
- **63% of the studies are completed and 31% will be completed by 2011**
- **Average amount of sponsorship is 48 million for the last 5 years**

Note: percentage calculated base on the number of valid responses

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