

CONTRACT RESEARCH ORGANIZATIONS (CROs) in ASIA 2014

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Conducting Clinical Trials in Asia

Drug development has always been a long and expensive process, generally costing over \$100 million per drug and taking about 10 years from creation of the drug to sale in the market. In recent years, this trend has been complicated by rising costs of research and development, while at the same time fewer drugs are being approved and going to market. More than ever before, pharmaceutical, medical device, and biotechnology firms are being compelled to seek ways of cutting costs. An increasing number of firms have begun outsourcing clinical research programs and clinical trials overseas to countries such as India, Singapore, Taiwan, or China. What is the appeal of outsourcing clinical trials and what are the risks of doing so? How does one go about selecting a contract research organization (CRO) in Asia to conduct clinical trials? What are the names of CROs in the different Asian countries? This report will examine these issues.

WHY GO TO ASIAN CROs?

A major motivating factor for moving clinical trials overseas is cost. In general, sometimes it is simply cheaper to run a business in a less developed country where the costs of labor, overhead, and maintenance are much lower than in the US. Some drug companies have stated that going abroad to India or China to conduct clinical trials can reduce their costs significantly. Hospital fees, clinical research associates, etc. are all cheaper. In general, the cost of doing clinical trials is about 25% of the US cost in China and India, about 60% in Taiwan and Hong Kong, and about 80% in Singapore.

One of the reasons why outsourcing clinical trials reduces costs is that patient recruitment in these countries is generally easier and faster. Recruitment is a time-consuming task, and usually accounts for about half of the time required for the clinical trial. In fact, almost 90% of clinical trials experience an unexpected delay of some sort, and problems with recruiting patients are generally the number one reason for these delays. In some of the Asian countries, much of the population is drug-naïve, meaning that they do not have much history of exposure to different types of medication. This makes it significantly easier to determine the success of the drug. In addition, many of these Asian people may be willing to undergo testing due to the increased access to medication and care that they otherwise would not be able to afford. Also, a country like India, for example, offers tremendous genetic diversity, allowing companies to obtain results and reactions for a wider range of ethnicities. In some cases, people in Asia may also be less wary than Westerners are of participating in clinical trials.

Another factor affecting cost is the regulatory environment, which is generally more lax in some of the Asian countries, excluding Japan. For example, governments in some Asian countries may have a less conservative stance on what population segments or parts of the body are permitted for testing. Some countries may also have less complicated regulatory regimes, allowing for faster approval times. A less conservative regulatory environment can have some negative effects, however, particularly if the looser regulatory environment allows companies or CROs to sidestep ethical requirements and obligations normally followed in the US or Europe.

WHAT TO WATCH OUT FOR

Despite the many advantages of outsourcing clinical trials, however, there are also concerns and potential pitfalls that should be addressed. One concern is the lax enforcement of intellectual property laws in some of the Asian countries, or lax intellectual property laws in general. It may be difficult for a pharmaceutical company doing trials in China, for example, to ensure that a Chinese CRO will keep the formula for its new drug strictly confidential. Confidentiality agreements, which in theory are binding in the West, may not be so in reality in other countries, especially Asia. Enforcement of intellectual property is not uniform throughout the Asian region.

It is important to get as clear an estimate as possible of the *total* cost of the clinical trial. In addition to the hidden transaction costs of doing business overseas, like document translation or overseas freight charges, CROs also charge “pass-through” costs, i.e., reimbursements for charges they incur during the clinical trial. These pass-through costs supplement the original quoted fee, and can become quite substantial. Examples of pass-through costs include the grant paid to the investigator, transportation costs, regulatory fees, or any other unanticipated costs not accounted for in the original proposal. Ultimately, the amount saved should more than cover the increased costs of going overseas. Otherwise, conducting a clinical trial overseas is obviously not worthwhile.

Another concern of pharmaceutical companies working with foreign CROs is that the research and clinical trial data will be of low quality. This is certainly a legitimate concern. In some developing countries, the quality of facilities, infrastructure, and equipment may not be as high as one might expect in a typically modern, high-tech hospital in the US, Europe, or Japan. However, the situation is constantly improving. In places like Singapore and Hong Kong, the facilities are comparable to Western standards. This is also increasingly the case for facilities in Chinese cities like Beijing and Shanghai, where healthcare sophistication is approaching Western levels.

There is also a concern about unethical treatment of patients in countries that do not have specific laws protecting patients who participate in clinical trials. Some countries may not get the “informed consent” of the subjects in the trial beforehand. Also, many CROs purport to run facilities that are compliant with the International Committee on Harmonization (ICH) standards of Good Clinical Practice (GCP), but it is possible that they do not actually do so. In addition, ICH-compliant GCP is not required in all of the Asian countries, so GCP may vary from country to country.

Another issue is the language barrier. Dealing with technical jargon can be tricky in itself, let alone in a foreign language. It may be difficult to communicate exactly what one needs or wants to be done, and then it may also be difficult to ensure that the study has been done according to the correct specifications and that the data are representative of what the company really wants.

HOW TO CHOOSE A CRO

Typically, outsourcing entails delegating some or all of the clinical trial process to the overseas CRO. When choosing a CRO, it is important to be clear about what services are needed in order to determine which CRO will best meet that need. Some companies may choose to have the CRO take full control of the clinical trial, i.e. from recruitment to completion, while others may only need help with certain segments of the trial, such as data management.

Understandably, it can be daunting to find an appropriate, qualified CRO in an Asian (or any foreign) country. The conventional choice is to pick one of the large global CROs that has offices around the world and an excellent reputation. However, this may not always be the best choice for every company. A CRO may have done excellent work in the US or Europe, for example, but its offices in farther-off locales like Asia may not be staffed with the same quality of personnel as the headquarters office is. A smaller local CRO may be better suited for a small clinical study because it will be able to devote more attention to smaller projects, and because it may value each client more than a large global CRO would. A smaller regional or local CRO will generally have employees with expertise in local regulations, as well as close ties to local regulatory authorities. A global CRO may be more concerned about keeping its large pharmaceutical clients, with their large, multi-site studies with hundreds of patients, happy.

In addition to choosing a CRO, companies must also choose an investigator. Choosing a good investigator is crucial in planning a clinical trial. It is important to have someone who is experienced in clinical trials, and better yet, has experience in the particular field of the study; for example, cardiology, oncology, neurology, etc. Sometimes CROs may have existing relationships with investigators, and it is useful to find out whether they know investigators that have expertise in these fields, or whether they can establish a rapport with new investigators. However, just because the CRO has a relationship with Dr. XYZ, that doctor may not be the best person to take charge of your study in that Asian country. It is always good to do your own research for the key doctors in the country you will do your trials in.

Once a CRO is chosen, it may also be a good idea to hire a local regulatory person, independent from the CRO, to oversee the trials. CROs that are monitored locally normally provide their services in a timelier manner and at a higher level of quality. Having a local monitor is also helpful if you choose a CRO in a country where English is not spoken widely. In such countries (China, Japan, Korea, Taiwan, Thailand, Vietnam, etc.), use of translators or interpreters may be necessary to communicate fluently and in detail. However, a local monitor will speak the local language and therefore can communicate frequently with the CRO management and staff to make sure your requirements are being met on a day-to-day basis.

WHICH COUNTRIES?

When outsourcing to Asian CROs, it is important to examine the factors that differentiate one country from another, in order to determine which country is best suited for a particular clinical trial. Aside from differences in cost, one should also look at other attributes of each country's regulatory and health care environment. Ease of regulatory approval can vary significantly depending on each government's regulations and laws on drugs, medical devices, and clinical research. Some countries may be able to provide large numbers of patients that suffer from a particular disease or illness, while other countries may not have such patient populations. Sometimes you may be willing to do the trials in a foreign language, while in other cases, English is required.

This report identifies the major CROs in the Asian countries and will be presented in three tiers. The first tier is Japan, which has a very high quality, but also a very conservative medical community. Clinical trials in Japan are normally *more* expensive than comparable trials in the West, and the quality of the clinical research is generally just as high. As more medical companies enter Japan, it is often necessary to have at least some local clinical research done in order to achieve Japanese marketing approval.

The second tier includes Taiwan, Korea, Singapore, and Hong Kong. These countries provide clinical trial services at a relatively high level of quality and at slightly lower cost than in Japan or the West.

The third tier includes India, China, Malaysia, Philippines, Indonesia, Thailand, and Vietnam. Clinical trials in these countries can be of decent quality and normally offer significantly lower cost.

DEMOGRAPHIC DATA

Country	Population (millions) (2013)	Population Growth (2013)	GDP (PPP) (2012)	GDP Real Growth Rate (2013)	Per capita GDP (PPP) (2012)	Life Expectancy (Years) (2013)
China	1,351	0.46%	\$12.2 trillion	7.7%	\$9,100	75
Hong Kong	7	0.39%	\$366 billion	3%	\$50,900	82
India	1,221	1.28%	\$4.7 trillion	3.8%	\$3,800	67
Indonesia	251	0.99%	\$1.2 trillion	5.3%	\$4,900	72
Japan	127	-0.1%	\$4.6 trillion	2%	\$35,900	84
Korea	49	0.18%	\$1.6 trillion	2.8%	\$31,900	80
Malaysia	30	1.51%	\$495 billion	4.7%	\$16,800	74
Philippines	106	1.84%	\$420 billion	6.8%	\$4,400	72
Singapore	5	1.96%	\$323 billion	3.5%	\$60,800	84
Taiwan	23	0.27%	\$894 billion	2.2%	\$38,400	80
Thailand	67	0.52%	\$645 billion	3.1%	\$9,500	74
Vietnam	92	1.03%	\$336 billion	5.3%	\$3,800	73

Source: CIA World Factbook, PBM estimates.

HEALTH CARE STATISTICS (2013)

Country	Hospital Beds per 1,000 People	Physicians per 1,000 People	Total Per Capita Spending on Healthcare (USD)
China	4.0	1.9	\$394
Hong Kong	5.1	1.9	\$1,899
India	0.9	0.6	\$82
Indonesia	0.6	0.2	\$136
Japan	13.8	2.1	\$4,833
Korea	10.4	2.0	\$2,239
Malaysia	1.8	1.2	\$486
Philippines	1.0	1.2	\$122
Singapore	2.7	1.9	\$2,645
Taiwan	4.3	1.8	\$1,358
Thailand	2.1	0.3	\$242
Vietnam	2.3	1.2	\$114

Sources: Various, PBM estimates

ASIAN PHARMACEUTICAL MARKET SIZE (2013)

Country	Pharmaceutical Market Size (US\$)
China	\$65 billion
Hong Kong	\$7 billion
India	\$20 billion
Indonesia	\$5.9 billion
Japan	\$104 billion
Korea	\$15 billion
Malaysia	\$3.1 billion
Philippines	\$3.4 billion
Singapore	\$840 million
Taiwan	\$5.4 billion
Thailand	\$4.8 billion
Vietnam	\$3.2 billion

All data collected by Pacific Bridge Medical

ASIAN DEVICE MARKET SIZE (2013)

Country	Device Market Size (US\$)
China	\$13 billion
Hong Kong	\$860 million
India	\$4.2 billion
Indonesia	\$790 million
Japan	\$29 billion
Korea	\$5 billion
Malaysia	\$1.2 billion
Philippines	\$315 million
Singapore	\$540 million
Taiwan	\$2.6 billion
Thailand	\$1.1 million
Vietnam	\$640 million

All data collected by Pacific Bridge Medical

I. JAPAN

Japan's medical business is generally very sophisticated, and can be compared to Western standards. Western companies looking to outsource clinical trials to save money and time should not go to Japan. However, in almost all cases, Western companies will need to do at least some clinical trials in Japan to get product approval to sell drugs or medical devices in the Japanese market. Most of the time, foreign clinical data by itself will not suffice for Japanese product approval.

The Ministry of Health, Labor, and Welfare (MHLW) oversees the regulation and safety of pharmaceuticals, medical devices, cosmetics, and food. Since the passage of the revised Pharmaceutical Affairs Law (PAL) in 2002, the MHLW has undergone substantial restructuring. One of the most significant changes is the establishment of the independent Pharmaceutical and Medical Devices Agency (PMDA) in April 2004. The PMDA was formed by merging three separate organizations that previously oversaw regulatory affairs for drugs and medical devices. The goal of this new independent administrative agency is to reduce submission time and to improve the quality of approval applications in order to bring safer and more effective medical products to the market more quickly.

Through a new formal consultation program, the PMDA provides guidance, offers consultations, and performs reviews on new drugs and medical devices. However, despite the PMDA's stated mission, it is possible that new medical products may still have some difficulty getting approval, or just as important, appropriate reimbursement. Since starting with a staff of 250, the PMDA was significantly understaffed for several years. However, it has been addressing this issue by increasing its review and safety staff. The PMDA currently has approximately 700 staff members.

The revised PAL requires the sponsor to submit a clinical trial notification (CTN) to the MHLW at least 30 days prior to starting the clinical trial. The CTN includes protocol and other supporting documentation such as SOP, analysis plan, etc. The MHLW will then review it and make a decision on the notification. In addition, the clinical trial protocol must be reviewed by an institutional review board (IRB) or ethics committee before the trial may proceed.

The revised PAL of 2002 was formally implemented in April 2005. Its provisions also revised Japanese Good Clinical Practice (GCP). The 2005 GCP outlined specific requirements for the composition of IRBs, relating to number of members, their professional fields, and inclusion of independent members. It also required written informed consent based on the Declaration of Helsinki from patients participating in the clinical trial. During the clinical trial, the principal investigator (PI) must inform the sponsor and the director of the hospital where the study is being conducted of any adverse events. He or she must also report all serious adverse events to the PMDA.

From 1997, investigators and sponsors shouldered the burden of the increased paperwork and activities required to comply with the new GCP guidelines. The result is that Japan's clinical

trials have been said to be time consuming, occasionally of poor quality, and always expensive.

Currently, the government is promoting a clinical trial network called the Network for Multi-Center Clinical Trials (NMCCT) to facilitate large-scale clinical trials. The revised PAL also allows sponsor-investigator studies, in which investigators sponsor their own studies on non-approved orphan products or high-risk products. The clinical data generated from these studies can be used in subsequent approval applications. Under certain specific conditions, especially if foreign trials conform to Japanese GCP, foreign clinical data can be accepted as strong (but not complete) support in approval applications.

As a result of these various measures, the climate for clinical research in Japan has improved somewhat. In 2006, the government for the first time approved a drug that had conducted Japan testing at the same time as foreign testing, as opposed to after. Even in this case, approval took significantly longer than it had elsewhere. The percentage of domestic Japanese pharmaceutical firms testing their own new drugs outside of Japan has also been increasing significantly.

Consultation sessions with PMDA staff are available to discuss regulatory requirements and other relevant issues in setting up and conducting clinical trials. Although these sessions can be somewhat expensive, they are the primary way to get substantive responses when the regulators' preferences are in question. According to PMDA statistics, there were 355 consultation sessions held for pharmaceutical clinical trials in the 2010 fiscal year (ending March 31, 2011), as well approximately 83 sessions for medical device and in vitro diagnostic clinical trials. Consultation sessions usually last 1.5-2 hours.

In the past, consultation sessions were divided into four types, but the number of types has increased significantly over the years. The types of sessions relating to clinical trials are as follows, with their fees:

Pharmaceuticals

<i>Session topic / phase</i>	<i>Fee (USD approx.)</i>
General procedures	\$1,396
Bioequivalence	\$5,552
Safety	\$17,802
Quality	\$14,762
Prior to start of Phase I trial	\$42,527
Prior to start of Phase IIa trial	\$16,499
Prior to start of Phase IIb trial	\$30,242
After completion of Phase II trial	\$60,032
Product application	\$60,031
Planning for clinical trial for reevaluation / reexamination	\$33,160
After completion of clinical trial for reevaluation / reexamination	\$33,148
Follow-up	\$26,719
GLP/GCP compliance	\$28,716

Medical Devices

<i>Session topic / phase</i>	<i>Fee (USD approx.)</i>
Pre-development	\$1,350
Safety confirmation (not including biologic devices)	\$8,210
Safety confirmation, biologic devices	\$9,089
Quality (not including biologic devices)	\$7,743
Quality, biologic devices	\$9,201
Performance testing	\$8,448
Clinical evaluation	\$10,251
Exploratory trials	\$11,038
Product application	\$24,099
Clinical trials	\$24,097
Application procedures	\$1,350
Follow-up	\$11,285
Cellular or tissue-based products (gene therapy)	\$2,232

IVDs

<i>Session topic / phase</i>	<i>Fee (USD approx.)</i>
Pre-development	\$1,397
Quality	\$3,450
Standards compatibility	\$4,421
Performance testing	\$15,925
Clinical evaluation	\$6,745
Product application	\$15,925
Application procedures	\$1,350
Follow-up	\$9,263

1 USD = 103 JPY

Ministry of Health, Labor and Welfare (MHLW)

1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916, Japan

Tel: +81 3 5253 1111

Email: www-admin@mhlw.go.jp

Website: <http://www.mhlw.go.jp/english/>

Pharmaceutical and Medical Devices Agency (PMDA)

Shin-Kasumigaseki Bldg.

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013, Japan

Tel: +81 3 3506 9456

Fax: +81 3 3506 9572

Email: info.pmda.f10@pmda.go.jp

Website: <http://www.pmda.go.jp/english/>

Japanese CRO Association

Tel: +81 120 353 125
Fax: +81 120 353 126
Email: info@jcroa.gr.jp
Website: www.jcroa.gr.jp

Local CROs

1.1 ACRONET Corp.

www.acronet.jp

Established: 2003
Employees: 495
Services: Clinical trial support services including clinical IT solutions

Address: 9th Floor (Reception)/10th Floor/17th Floor
Sumitomo Fudosan Korakwen Building
1-4-1 Koishikawa, Bunkyo-ku
Tokyo 112-0002, Japan

Phone: +81 3 3830 1122
Fax: +81 3 3830 1155
Email: info@acronet.jp

Comments:

- ACRONET was originally the clinical services division of CRC Solutions Corporation, specializing in clinical data management and analysis from 1997. In 2003, it was spun off into a separate company.
- ACRONET provides a range of clinical development services including clinical IT solutions, clinical monitoring, data management and statistical analysis, case registration, GCP auditing, quality control and assurance, report writing, and training. ACRONET is known for providing IT-based solutions for data analysis and management, including the development of an electronic CRF system.
- From 2005 to 2008, ACRONET conducted 78 clinical trials. Of these, 20 were Phase I; 42 were Phase II or III; 15 were Phase IV (post-marketing studies); and 1 was a bioequivalence study.
- ACRONET is the first CRO in Japan to utilize SAS Clinical Data Integration. This program ensures the standardization and unification of clinical data. It is compliant with CDISC standards.
- In July 2009, ACRONET and Bellsystem24, a Japan CRO, formed an alliance to establish reciprocal cooperation. Sharing information and resources will expand both companies' capability to undertake more extensive contracts.

1.2 ASKLEP Inc.
www.asklep.co.jp

Established: 1992
Employees: 540
Services: Clinical trial support services for Phases I – IV

Address: World Import building, 8F
3-1-3 Higashi Ikebukuro Toshima-Ku,
Tokyo 170-8630, Japan

Phone: +81 3 5979 1001
Fax: +81 3 3590 7111
Email: info-e@asklep.co.jp

Comments:

- Originally established as IBRD Corporation, ASKLEP provides the full range of clinical trial support services for Phases I – IV. It also provides services for enrollment and follow-up, data management, biostatistics, medical writing, post-marketing surveillance, training and development, and IT and system solutions.
- ASKLEP’s clinical trial experience includes therapeutic areas such as cardiovascular, endocrine disorders, digestive, central nervous system, and infections.
- ASKLEP is part of the INTAGE Group, one of Japan’s top market research companies.
- In 2006, ASKLEP signed a nonexclusive agreement with Harrison Clinical Research, a European CRO based in Munich. Under this agreement, Harrison will provide its European facilities for ASKLEP’s Japanese clients, and ASKLEP will provide its Japanese facilities for Harrison’s clients.
- In October 2008, ASKLEP began a strategic partnership with ASKA Research, a Canadian CRO, to conduct multinational trials.
- In January 2009, ASKLEP signed a strategic partnership agreement with DreamCIS, a Korean CRO. ASKLEP now offers clinical research expertise in three key Asian countries. In addition to Japan and Korea, ASKLEP also has a presence in Taiwan, where they are partners with Qualitix Clinical Research.
- In June 2010, ASKLEP established a representative office in Shanghai, china.
- In November 2010, ASKLEP established its local subsidiary, ASKLEP CHINA Inc., in Shanghai, China.

1.3 EPS Co., Ltd.
www.eps.co.jp

Established: 1991
Employees: 1,717
Services: Clinical trial support services for Phases I – IV

Address: Tsuruya Building 8F
2-23 Shimomiyabi-cho, Shinjuku-ku
Tokyo 162-0822, Japan

Phone: +81 3 5684 7801
Fax: +81 3 5804 0361
Email: info@eps.co.jp

Comments:

- EPS stands for “Ever Progressing System.” EPS provides a complete range of clinical trial support services, including protocol development, patient registration, software development, data management, statistical analysis, clinical monitoring, pharmacovigilance, regulatory, auditing, and medical writing. It also covers medical devices and equipment.
- As of March 31, 2009, EPS had provided services for over 1,083 studies with 496 still ongoing. Its experience ranges across many therapeutic areas, but the top areas are oncology, cardiovascular, brain/nerve, endocrine/metabolic, and muscle/bone.
- EPS has subsidiaries and joint ventures in Korea, China, Taiwan, Hong Kong, and Singapore.

1.4 Medical Industries Corp.
www.micjp.co.jp

Established: 1986
Employees: 319
Services: Clinical trial support services for drugs and medical devices

Address: Akasaka I Intercity,
1-11-44 Akasaka, Minato-ku,
Tokyo 107-0052, Japan

Phone: +81 3 6685 6900/6920 (Business Development)
Fax: +81 3 6685 6897/6899
Email: mic@micjp.co.jp

Comments:

- MIC provides support services for the clinical development of pharmaceuticals and medical devices, as well as support for the development of new medical technologies.
- MIC provides the following services for pharmaceutical development: clinical development planning, monitoring, data management and statistical analysis, quality control/assurance, and medical writing.
- MIC also provides clinical development planning for medical devices, as well as strategic regulatory planning and assistance with approval and license applications. It has done clinical monitoring for device types including operating equipment,

implantable devices, measuring and monitoring equipment, dental equipment, and surgical devices.

- MIC has 46 pharmaceutical clients and 57 medical device clients.

1.5 CMIC Co., Ltd.

www.cmic.co.jp

Established: 1985
Employees: 1,870
Services: Clinical trial support services

Address: Kongo Bldg.
7-10-4, Nishi-Gotanda, Shinagawa-ku
Tokyo 141-0031, Japan

Phone: +81 3 5745 7050
Fax: +81 3 5745 7075
Email: information@cmic.co.jp

Comments:

- CMIC provides the whole range of clinical trial support services including product development, patient recruitment, monitoring, data management, pharmacovigilance, site management, medical writing, auditing, training, and post-market surveillance. CMIC provides consulting services in a number of areas, such as strategy development, regulatory pharmaceutical affairs, sales and marketing, and intellectual property development. It can also act as an MAH.
- CMIC has conducted more than 100 clinical trials in a variety of therapeutic areas, including central nervous system, sensory organs, cardiovascular, respiratory, gastrointestinal, and hormones. CMIC also provides support for the development of medical devices.
- CMIC's subsidiary, CMIC Asia-Pacific, conducts trials in Singapore, Malaysia, Taiwan, and Hong Kong. CMIC has a separate subsidiary in Korea as well.
- CMIC is Japan's largest domestic CRO. It also operates in the areas of contract manufacturing and contract sales.

1.6 Shin Nippon Biomedical Laboratories, Ltd.

www.snbl.co.jp

Established: 1957
Employees: 2,121 (across group); 1,188 (parent firm)
Services: Clinical trial support services for Phases I – IV

Address: St. Luke's Tower 12F
8-1 Akashi-cho, Chuo-ku

Tokyo 104-0044, Japan

Phone: +81 3 5565 5001
Fax: +81 3 5565 6160
Email: info@snbl.co.jp

Comments:

- SNBL was the first CRO to operate in Japan. It offers services ranging across the entire drug life cycle, including basic research, preclinical studies, clinical studies, drug approval, and post-marketing studies.
- SNBL has a subsidiary in Everett, WA, SNBL USA, which conducts preclinical drug safety research, mostly in the area of animal testing.
- Clinical trials are undertaken by two different parts of SNBL. Site management is done by the SNBL Clinical Pharmacology Center, Ltd. SNBL has conducted 134 protocols, covering therapeutic areas such as cardiovascular, respiratory, endocrine, gastrointestinal, and nephrology, among others. Another section, the Clinical Research Division, provides protocol preparation, site selection and recruiting, reporting, data management, statistical analysis, and quality control and assurance.
- SNBL uses a number of partners in China and Indonesia for some preclinical testing operations. It also has two subsidiaries in China.

1.7 Ultmarc Inc.
www.ultmarc.co.jp

Established: 1962
Employees: 131
Services: Clinical trial support services for Phases I – IV

Address: 2-45-1 Nihonbashi-hamacho, Chuo-ku
Tokyo 103-0007, Japan

Phone: +81 3 3249 8233
Fax: +81 3 3249 8238
Email: f_hata@ult-tokyo.co.jp

Comments:

- Ultmarc was established as a marketing research company specializing in statistical analysis. It created a computer database for doctors and hospitals (DCF) in Japan in 1972.
- Ultmarc provides clinical trial support services for Phase I to IV trials, including recruitment, monitoring, data entry and analysis, and report generation. The CRO business has been an important part of Ultmarc's overall business; it has worked with 50 pharmaceutical companies and 200 products.
- Ultmarc also provides management of medical IT systems and maintains a medical article and conference report database system.

1.8 Bellsystem24, Inc.

www.bell24.co.jp

Established: 1986 (clinical division)
Employees: 2,068
Services: Clinical trial support services for Phases I – IV

Address: Harumi Island Tritan Square Office Tower Y
8-11 Harumi 1-chome, Chuo-ku
Tokyo 104-6113, Japan

Phone: +81 3 6843 0024
Fax: +81 3 5992 1824
Email: uenotets@bell24.co.jp

Comments:

- The Pharmaceutical and Medical Support Services division of Bellsystem24, Inc. provides regulatory consultation and strategic planning for Phase I to III trials, post-marketing trials, and pharmacodynamic and pharmacokinetic studies. Other services include: protocol development, feasibility studies, site selection, patient enrollment, data management and biostatistics, and medical writing. Bellsystem24 will also assist with NDA submissions at MHLW and post-market surveillance.
- Bellsystem24's clinical division was certified for ISO 9001 compliance in May 2001.
- Bellsystem24 also has divisions offering services in marketing, call centers, and business process outsourcing.
- In July 2009, Bellsystem24 and ACRONET, a Japan CRO, formed an alliance to establish reciprocal cooperation. Sharing information and resources will expand both companies' capability to undertake more extensive contracts.

1.9 Mitsubishi Chemical Medience

www.medience.co.jp

Established: 1988, reorganized 2007
Employees: 3,052
Services: Clinical testing, data services, and site management

Address: 4-2-8 Shibaura, Minato-ku
Tokyo 108-8859, Japan

Phone: +81 3 6722 4000
Fax: +81 3 6722 4001
Email: Shidachi.Kiyoshi@mh.medience.co.jp, info@nm.medience.co.jp

Comments:

- Mitsubishi Chemical Medience was formed in 2007 by the combination of Mitsubishi Kagaku Bio-Clinical Laboratories, Mitsubishi Kagaku Iatron, and Mitsubishi Chemical Safety Institute. The first of these, which provided CRO services, is now called the Med-Chem division of Medience.
- Medience is one of the largest comprehensive clinical testing centers in Japan, and is accredited by the College of American Pathologists (CAP). It is in compliance with ISO/IEC17025 standards.
- Medience provides services in site management, pre-clinical studies, drug discovery, central laboratory work, bioanalysis, and quality management. It has agreements with over 100 hospitals in Japan for conducting studies. Clinical research coordinators ensure that all sites conduct clinical trials in accordance with Japanese GCP standards.
- Medience's C-Lab is a central laboratory dedicated to clinical trials, able to test over 2,000 items. Its laboratory's information system is compliant with the FDA Part 11 Rule on electronic record-keeping.
- Medience is experienced in therapeutic areas including diabetes, respiratory, rheumatism, and osteoporosis.

1.10 Mediscience Planning Inc.

www.mpi-cro.co.jp

Established: 1982
Employees: 702
Services: Clinical trial support services for Phases I – IV

Address: Nomura Fudosan Higashi-Nihonbashi Bldg.
1-1-7 Higashi-Nihonbashi, Chuo-ku
Tokyo 103-0004, Japan

Phone: +81 3 5820 7071
Fax: +81 3 5820 7607
Email: kazumi.koyayashi@mpi-cro.jp, info@mpi-cro.jp

Comments:

- Mediscience offers a full range of support services for Phase I to IV clinical trials, including protocol design, site and investigator selection, monitoring, quality control/assurance, data management, biostatistics, and medical writing. It also provides strategic consulting for pharmaceutical development.
- Mediscience's therapeutic experience includes anti-infectives, central nervous system, respiratory, and cardiovascular.

1.11 InCROM CRO, Inc. (formerly RABITON Institute, Inc.)

www.incrom.com/cro

Established: 1993
Services: Clinical trial support services for Phases I – III

Address: Across Shin-Osaka 6F
4-1-6 Miyahara, Yodogawa-ku
Osaka 532-0003, Japan

Phone: +81 6 6395-7221
Fax: +81 6 6395-7225
Email: cro_info@incrom.com

Comments:

- Rabiton is the parent company of the InCROM group, which provides CRO services for pre-clinical and Phase I to III trials. The CRO services provided by the original group, with the full name of International Clinical Research Organization for Medicaments, came under the control of Rabiton Institute Inc. in 2003.
- Rabiton's services include data management, medical writing, statistical analysis, and translation. Rabiton is currently developing a global clinical development system along with its London and Shanghai offices.
- As of April 2008, Rabiton had conducted a total of 624 projects. Of those, 162 were data management, 154 were statistical analyses, and 208 were medical writing. 90% of the total was in support of Phase I trials.
- In December 2010, the Rabiton Operations Department was spun off to form InCROM CRO, Inc.

1.12 Sogo Clinical Sciences Corporation
www.sogo-rinsho.jp

Established: 1989, reorganized 2007
Employees: 460
Services: Site management services and clinical trials for Phases I – IV

Address: 2-4-1 Shinjuku NS Building, 13th Floor
Nishi Shinjuku, Shinjuku-ku
Tokyo 163-0813, Japan

Phone: +81 3 6901 6085
Fax: +81 3 5381 0076
Email: publicity@po.sogo-rinsho.jp

Comments:

- Sogo Clinical Sciences Corporation is a site management organization providing support for clinical trials conducted at medical institutions. Sogo conducts Phase I and bioequivalence clinical trials and provides a range of support services for all

phases, including monitoring, data management, statistical analysis, medical writing, etc. It also provides pharmacovigilance, case registration, and medical education services.

- Sogo's clinical research coordination services specializes in types of support services that do not involve medical diagnosis, such as subject screening, data collection, informed consent support, and schedule management. These activities relieve some of the workload of the physicians overseeing the trial. Sogo also provides support for hospitals that need to arrange and operate institutional review boards, including secretariat services. The secretariat serves as a general contact for matters or inquiries related to the clinical trial.
- Sogo has clinical trial experience in a number of therapeutic areas including central nervous system, antibacterials, urology, cardiovascular, insomnia, and ophthalmology. It is affiliated with over 1,000 medical institutions in Japan

1.13 System Inn Nakagomi Ltd.

www.sin.co.jp

Established: 1982
Employees: 72
Services: Clinical trial support services

Address: 1-8-2 Yamanokami Ryutsu Danchi, Tatomi-cho
Nakakoma-gun, Yamanashi 409-3845, Japan

Phone: +81 55 230 7611
Fax: +81 55 230 7612
Email: izuru@sin.co.jp

Comments:

- System Inn Nakagomi started its CRO IT business in 1995. It provides clinical trial support, post-marketing surveillance, report writing, clinical data management, and consulting for information security management.

1.14 Translational Medicinal Research Center Co., Ltd.

www.tmrc.co.jp

Established: 2002
Employees: 12
Services: Clinical trial support services for Phases I – III

Address: Contact Address:
Hamamatucho OS Building
1-10-11, Hamamatasucho, Minato-ku
Tokyo 105-0013, Japan

Head Office:
MI Building
1-12-12, KitaShinjyuku, Shinjyuku-ku,
Tokyo 169-0074, Japan

Phone: +81 3 6435 6472
Fax: +81 3 6435 6475
Email: higashi.yumiko@tmrc.co.jp, info.ddl@tmrc.co.jp

Comments:

- TMRC was established as a specialized cancer CRO in 2002. It provides clinical trial support services for Phase I to III and post-market trials. These include protocol and CRF design, site and investigator selection, monitoring, informed consent form design, distribution and collection of medicines, quality control, and GCP compliance.
- TMRC also does drug development research into new oncological compounds.
- In March 2009, TMRC became a 100% owned subsidiary of Sugi Medical Co., Ltd., a unit of Sugi Holdings Co., Ltd., a Japan-based retail company.

1.15 JGC Corporation

www.jgc.co.jp

Established: 1928
Employees: 2,237
Services: Clinical trial support services

Address: New Ohtemachi Building
2-2-1, Ohtemachi, Chiyoda-ku
Tokyo 100-0004, Japan

Phone: +81 3 3279 5441
Fax: +81 3 3273 8047
Email: pharma-service@jgc.co.jp

Comments:

- In September 2010, JGP purchased Tokyo CRO, Inc.
- JGP incorporated the assets of Tokyo CRO into a new JGP subsidiary under the name JGC Pharma Services Co., Ltd.

1.16 The Institute of Japanese Union of Scientists & Engineers

www.i-juse.co.jp

Established: 1958
Employees: 166

Services: Clinical IT solutions

Address: 5-10-11 Sendagaya, Shibuya-ku
Tokyo 151-0051, Japan

Phone: +81 3 5379 1319
Fax: +81 3 5379 1530
Email: miyagi@i-juse.co.jp

Comments:

- The Institute of Japanese Union of Scientists & Engineers has many business relationships with government entities, pharmaceutical companies, and computer companies. It provides clinical data management, statistical analysis of clinical data, support for data management systems, and training. The Institute's data management system is adaptable for foreign regulatory entities, such as the FDA.

1.17 Mebix, Inc.
www.mebix.co.jp

Established: 2001
Employees: 89
Services: Clinical trial support services

Address: 1-11-44 Akasaka, Minato-ku
Tokyo 107-0052, Japan

Phone: +81 3 6229 8932
Fax: +81 3 6229 8947
Email: info@mebix.co.jp

Comments:

- Mebix provides total support for large-scale clinical trials, including protocol and CRF design, monitoring, data management and statistical analysis, and report writing.
- Mebix's software program, "CapTool," is one of the most commonly used software programs in Japan for clinical trial evidence-support systems.
- Mebix conducted 66 clinical trials over the 12 months ending in April 2008. Out of its 192 total completed trials, 30% were in the cardiovascular area, 18% gastrointestinal, and 13% metabolic.
- Mebix ranked 332 in Deloitte's 2008 Technology Fast 500 Asia Pacific list.

1.18 Yukms Co., Ltd.
www.yukms.com

Established: 1985

Employees: 18
Services: Clinical trial support services and IT solutions

Address: 2-37-15, 208 Yoyogi, Shibuya-ku
Tokyo 151-0053, Japan

Phone: +81 3 3378 5099

Fax: +81 3 3378 5344

Email: info@yukms.com

Comments:

- Yukms Co.'s specialty is supporting clinical and non-clinical trials and data analysis for epidemiological research. It offers protocol design, monitoring, data and document management, quality control, report writing, and post-market surveillance. Yukms also provides medical software and computer system development for clinical and non-clinical trials.

1.19 Iberica Holdings Co. Ltd.

www.iberica.co.jp

Established: 1996

Employees: 78

Services: Clinical trial support services for Phases I – IV

Address: 2-18-30-8F, Hakataeki-higashi, Hakata-ku
Fukuoka 812-0011, Japan

Phone: +81 92 437 1100

Fax: +81 92 437 1102

Email: eigy@iberica.co.jp

Comments:

- Iberica conducts clinical research as well as translational research (bridging basic research and its clinical applications). In-house, it operates the Kurume Translational Research Center, offering academic research organization (ARO) services.
- Iberica's clinical arm is a clinical establishment within the Kurume University Medical School. Although it conducts trials in Phases I-IV, it focuses on Phase I, Phase IIa, proof of concept, pharmacokinetic and pharmacodynamic studies. It also does post-marketing research, clinical data management, and health food trials.
- A US subsidiary, Iberica USA, also exists in Fort Lee, NJ. It specializes in bridging studies to bring products to the Japanese market, and maintains a database of ethnic Japanese volunteers in the US for this purpose.
- In October 2008, Iberica transferred its monitoring business to ACRONET, another Japanese CRO, to focus on conducting trials directly.

1.20 SRL Medisearch
www.srlmedi.com

Established: 1997
Employees: 146
Services: Clinical trial support services

Address: 10F, Shinjuku I-Land-Tower
6-5-1 Nishishinjuku, Shinjuku-ku
Tokyo 163-1310, Japan

Phone: +81-3-5324-2601
Fax: +81-3-5324-3507
Email: infosrlg@srl.srl-inc.co.jp

Comments:

- Medisearch’s parent company, SRL, primarily provides central laboratory services. Medisearch makes use of its parent’s hospital network to provide clinical monitoring and site management services for pharmaceutical trials.

1.21 SRD
www.cro-srd.co.jp

Established: 1989
Employees: 193
Services: Clinical trial support services for Phases I – IV

Address: 2F, RBM Kyobashi Building
3-4-8 Hatchobori, Chuo-ku
Tokyo 104-0032, Japan

Phone: +81 3 5543 0296 (+81 3 3553 8401 for English)
Fax: +81 3 5543 0184
Email: group1@cro-srd.co.jp

Comments:

- SRD provides services in clinical trial support, quality system management, statistical analysis, and consulting.
- To date, SRD has done 12 trials in orthopedics, 8 in internal medicine, 8 in dermatology, 4 in anesthesiology, 3 in obstetrics and gynecology, and many others. Overall, about two-thirds of its trials have been either Phase II or Phase III.
- SRD has also done 8 trials for medical devices, 4 for “quasi-drugs” (usually OTC products), and 15 for health foods.

1.22 Increase Co. Ltd.

www.inc-cro.co.jp

Established: 2001
Employees: 30
Services: Clinical trial support services for Phase I-IV

Address: Forecae Ichigaya 4F
3-29 Ichigaya Honmura-cho
Sinjuku Tokyo 162-0845, Japan

Phone: +81 3 5227 3690
Fax: +81 3 5227 3691
Email: somu-jinji@inc-cro.co.jp

Comments:

- Increase provides services in clinical trial support, data management, statistical analysis, consulting, medical writing, and clinical trial staffing.
- Increase has provided services for 30 trials to date. The products tested have been in the therapeutic areas of orthopedics, internal medicine, cardiovascular, diabetes, dialysis, and others.
- Increase is 30% foreign-invested.

Local Offices of Large Foreign CROs

1.23 Covance Japan Co., Ltd.

www.covance.com

Established: 1997
Employees: 1,000 +
Services: Clinical trial support services and commercialization

Address: Kyobashi Yamamoto Bldg. 7F
3-12-7 Kyobashi, Chuo-ku
Tokyo 104-0031, Japan

Phone: +81 3 5159 3363
Fax: +81 3 5250 1234
Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations

in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.

- Covance has Asian offices in Japan, Singapore, and China.

1.24 Quintiles Transnational Japan K.K. / Innovex

www.quintiles.co.jp

Established: 1998
Employees: 2,300
Services: Clinical trial support services for Phases I – IV and commercialization

Address: Head Office:
Keikyu First Building
4-10-18 Takanawa, Minato-ku
Tokyo 108-0074, Japan

Phone: +81 3 6859 9500

Laboratory:
2-18-17 Nishiochiai, Shinjuku-ku
Tokyo 161-0031, Japan

Phone: +81 3 6895 9620

Email: kenji.takeda@quintiles.com, qjpn.corpmktg@quintiles.com

Comments:

- Headquartered near Durham, NC, Quintiles Transnational is the “world’s first global healthcare outsourcing company” with 23,000 employees in 50 countries. Quintiles Transnational is the parent company of Innovex, a contract sales organization that provides outsourcing for overall pharmaceutical sales and marketing operations. Quintiles’ investment group, PharmaBio Development, offers strategic alliances and partnerships to pharmaceutical or biotech companies to share development costs in exchange for a portion of the financial returns.
- Quintiles began working in Japan in 1993 with the establishment of the Quintiles Asia Inc. (Japan Office). Quintiles Transnational Japan K.K. was Japan’s first contract pharmaceutical organization. In 2001, the two offices were integrated into a single operation based in Tokyo, which serves as the head office to several other Japanese Quintiles locations.
- Quintiles Transnational Japan K.K. provides the whole range of clinical trial support services for Phase I to IV trials, including clinical monitoring, data management and statistical analysis, GCP inspection, quality assurance, medical writing, training, and approval application support. It also offers pharmaceutical regulatory consultation and can act as an MAH.
- Since 1993, Quintiles has completed over 400 clinical trials in Japan. Quintiles can also provide accelerated regulatory approval through an alliance with Hawaii Pacific Health, a non-profit healthcare organization. The Japanese drug regulatory authority

has announced that it would accept clinical data from trials done on ethnic Japanese living outside Japan, and Quintiles formed an alliance with Hawaii Pacific Health to conduct clinical trials on the large population of ethnic Japanese in Hawaii.

- Quintiles Transnational's eClinical services use advanced information technology to make the clinical trial process more efficient. The Quintiles Academy also provides up-to-date training for clinical research associates.
- Quintiles Transnational has offices in Japan, Taiwan, Korea, Singapore, Hong Kong, India, Indonesia, China, Malaysia, the Philippines, Thailand, and Vietnam.

1.25 Theorem Clinical Research (formerly Omnicare Clinical Research)

www.theoremclinical.com

Established: 2002
Services: Clinical trial support services

Address: Dogenzaka Square Suite 503
5-18 Shibuya-ku
Tokyo, Japan

Phone: +81 3 5403 3439
Email: information@theoremclinical.com

Comments:

- Headquartered in King of Prussia, PA, Omnicare Clinical Research is a global CRO with more than 1,000 employees in 31 countries. It offers the full range of clinical trial support services, including patient recruitment, investigator services, data management, quality assurance, clinical writing, and regulatory affairs. It has extensive therapeutic experience in more than 100 conditions.
- Omnicare Clinical Research Japan was opened in 2002 to develop Omnicare's presence in Japan and to better serve its Japanese pharmaceutical clients.
- Omnicare has locations throughout Asia in Japan, Taiwan, Singapore, India, Korea, and China.
- In 2011, Omnicare Clinical Research became Theorem Clinical Research.

1.26 PAREXEL International Inc.

www.parexel.co.jp

www.parexel.com

Established: 1995
Employees: 250
Services: Clinical trial support services for Phases I – IV

Address: Urban Ace Sannomiya Bldg. 9F (local office)
4-1-22 Hyogo Prefecture, Chuo-ku

Kobe 651-0088, Japan

Phone: +81 78 262 5174
Fax: +81 78 271 8408
Email: yoshitaka.hayashi@parexel.com

Address: Tokyo Office:
6F, Kayaba-cho First Bldg.
1-17-21, Shinkawa, Chuo-ku
Tokyo 104-0033, Japan

Phone: +81 3 3537 5900
Fax: +81 3 3552 0451

Comments:

- Headquartered in Waltham, MA, PAREXEL is a global biopharmaceutical services company with over 9,000 employees and offices in 52 countries. It provides a broad range of services including clinical research, medical writing, data management and analysis, regulatory consulting, medical marketing, information technology solutions, and publications. Perceptive Informatics, Inc., a PAREXEL company, has developed a number of web-based service offerings including clinical trial management systems and interactive voice response systems.
- PAREXEL's Japan office opened in 1995. It has been focused on clinical trial development and pharmaceutical affairs consulting, but is looking to expand into other areas.
- In September 2007, PAREXEL acquired APEX International Clinical Research Co. Ltd., a leading Taiwanese CRO operating in multiple countries across Asia. APEX was renamed PAREXEL APEX International.

1.27 ICON Japan K.K.
www.iconclinical.com

Established: 1996
Employees: 50
Services: Clinical trial support services for Phases I – IV

Address: MD Kanda Building 6F & 7F (local office)
9-1 Mitoshiro-cho, Chiyoda-ku
Tokyo 101-0053, Japan

Phone: +81 3 4530 4200
Fax: +81 3 4530 4201
Email: info@iconaus.com.au

Comments:

- ICON Clinical Research is a large global CRO headquartered in Dublin, Ireland. ICON provides full clinical trial services for Phases I to IV and employs over 7,100 people in 71 offices across 38 countries. In June 2005, ICON Clinical Research was named a Top CRO by CenterWatch. ICON provides clinical research, biometrics, interactive technologies, laboratory, clinical pharmacology, and consulting services. It was the first CRO to achieve ISO registration in 1994 and its Quality Management System is ISO 9001:2000 registered. ICON laboratories are both CAP and ISO 17025 accredited.
- ICON Japan K.K. opened in 1995. It provides clinical trial support services for all clinical phases, as well as data management and analysis, quality control, and quality assurance. Many of its clinical trials have been conducted overseas as well as in Japan.

1.28 PPC (Japan)

www.ppccro.com

Services: Clinical trial support services for Phases I – IV

Address: Matsuzaki Building 3F
6, Kandatomiyama-cho, Chiyoda-ku
Tokyo 101-0043, Japan

Phone: +81 3 4530 3926

Email: contact@ppckk.co.jp

Comments:

- This is the Japan branch office of PPC, an international CRO headquartered in Taipei, Taiwan.

1.29 AAI Japan Inc.

www.aipharma.com

Established: 1997

Employees: 450+ (globally)

Services: Clinical trial support services and business development

Address: Wakamatsu Building, Level 7 (local office)
3-3-6 Nihonbashi Honcho, Chuo-ku
Tokyo 103-0023, Japan

Phone: +81 3 6202 7509

Fax: +81 3 6202 7504

Email: kobayashi@aaijapan.co.jp

Comments:

- AAI Japan is a branch of AAI Pharma USA, headquartered in Wilmington, NC. It has done business with 50 major Japanese companies and 15 overseas companies.
- AAI Japan's services include full support for clinical trials in Phases I-IV, data management, new drug and preclinical development, and contract manufacturing.

1.30 PPD (Japan)

www.ppd.com

Established: 2009

Address: Shinjuku Nomura Building 28F (local office)
1-26-2 Nishi-Shinjuku, Shinjuku-ku
Tokyo 163-0528, Japan

Phone: +81 3 6738 8400

Fax: +81 3 6738 8401

Comments:

- This is the Japan branch office of PPD, a large global CRO headquartered in Wilmington, NC.

1.31 inVentiv Health Clinical Japan (formerly PharmaNet Ltd.)

www.inventivhealthclinical.com

Address: 7F, Glass City Koraku
1-1-7 Koraku, Bunkyo-ku
Tokyo 112-0004, Japan

Phone: +81 3 5804 3945

Fax: +81 3 5804 3959

Email: pni@inventivhealth.com

Comments:

- This is the Japan subsidiary of inVentive Health Clinical, a large global CRO based in Princeton, NJ.

1.32 PRA Japan

www.prainternational.com

Established: 2004

Address: Regus Shinjuku Park Tower Ctr

N30F Shinjuku Park Tower, Nishishinjuku 3-7-1
Shinjuku-ku
163-1030 Tokyo Japan

Phone: +81 (3) 5326-3010
Fax: +81 (3) 5326-3016

Comments:

- Headquartered in Raleigh, NC, PRA International is a global CRO with over 3,500 employees throughout North America, Europe, South America, the Middle East, Africa, Australia, and Asia.

II. Taiwan, Singapore, Hong Kong, and Korea

The following Asian countries (Taiwan, Korea, Singapore, and Hong Kong) comprise the “second tier” of clinical research. They are very good locations for conducting clinical trials because they offer high quality at a lower cost than the West. The health care systems in Singapore, Taiwan, Korea, and Hong Kong are highly advanced and many doctors in these countries have been trained in the US or Europe. Of the four, Taiwan and Singapore are the more popular sites for Western companies to do clinical research.

TAIWAN

Taiwan is a country where CROs are becoming very active. Several new CROs have started up their businesses in Taiwan in the last several years. Quality standards for clinical trials in Taiwan adhere to the accepted international standards of ICH Good Clinical Practice (GCP). GCP guidelines were implemented by Taiwan’s Department of Health in 1997 and further revised several times to be consistent with ICH standards. The Department of Health became the Ministry of Health and Welfare (MOHW) in July 2013. The MOHW conducts GCP inspections on nearly all clinical trials to ensure their quality and credibility. There are generally few restrictions or limitations that make conducting clinical trials in Taiwan different than in other countries. Furthermore, a majority of medical research is conducted in English.

In 2013, there were 258 clinical trial applications submitted to the Taiwanese FDA by international pharmaceutical companies. Of these, almost 75% were applications for multicenter, multi-country clinical studies. An increasing number of domestic and foreign biopharmaceutical firms are conducting clinical trials in Taiwan -- either as local studies or as part of multi-center studies spread across the region or globe. Many of these are outsourced to CROs.

Before a clinical trial in Taiwan can begin, approval of the clinical trial protocol must be obtained from both an Institutional Review Board (IRB) and the MOHW. The IRB or ethics committee of the individual hospitals will review the protocol for any ethics concerns. Approval takes about two to four months.

In addition to IRB approval, the clinical trial protocol must also be reviewed and approved by the Taiwanese FDA (part of the MOHW). Submissions to both the IRB and the MOHW can be made simultaneously. The Center for Drug Evaluation (CDE), a non-governmental, non-profit organization, assists in reviewing all clinical trial protocols submitted to the MOHW. In addition, it also provides regulatory consultation, reviews informed consent documents, and facilitates the drug development process in Taiwan. Its objective is to provide a transparent and efficient system for the regulation and approval of drugs. Since its establishment in 1998, the CDE has helped to reduce overall protocol review time in Taiwan. The CDE also cooperates with the National Adverse Drug Reaction Reporting Center in evaluating adverse event reports during clinical trials. The average protocol review time at the MOHW is 30-60 days. The total clinical trial application review time is about 2.5 to 5 months.

The MOHW also allows certain clinical trials to be fast-tracked. For instance, a drug that has IND approval from the Taiwanese FDA and is already being studied in a clinical trial in the US qualifies for expedited regulatory approval. The sponsor should submit documentation of its IND and the Taiwanese FDA's approval letter stating that the clinical trial can proceed.

In 1997, a joint Institutional Review Board (JIRB) was established to review clinical trial protocols for multi-center trials in an efficient and high-quality review process. The JIRB is an independent and non-profit organization that is not affiliated with any individual hospital. Rather than obtain individual approvals from each local hospital's IRB when conducting a multi-center trial, it is much more efficient to obtain approval from an impartial JIRB whose members are nominated by Taiwan's top five medical centers. In order to function successfully, each local IRB must recognize JIRB approval. However, even when the JIRB has approved a clinical trial protocol, any of the local IRBs has the right to review it. Review by the JIRB is more costly than review by local IRBs, but for multi-center clinical trials, it may be worth the expense to get an expedited review process. The average protocol review time at the JIRB is about 25 working days and JIRB approval letters have been accepted by more than 40 local hospitals in Taiwan. The JIRB has helped to attract more multi-center trials in Taiwan.

Ministry of Health and Welfare (MOHW)

No.36, Tacheng St., Datong District, Taipei City 10341, Taiwan

Tel: +886 2 8590 6666

Fax: +886 2 2341 8994

Website: <http://www.mohw.gov.tw/EN/Ministry/>

Center for Drug Evaluation (CDE)

3F, No. 465, Sec. 6, Zhongxiao E. Rd., Taipei, Taiwan 11557

Tel: +886 2 8170 6000

Fax: +886 2 8170 6001

Website: www.cde.org.tw/

Joint Institutional Review Board (JIRB)

No.5-1, Lane 331, Sec.2, Shipai Road, Peitou District, Taipei City, Taiwan

Tel: +886 2 2873 7133

Fax: +886 2 2873 7136

Email: jirb@jirb.org.tw

Website: www.jirb.org.tw

Local CROs

2.1 StatPlus Inc.

www.statplus.com

Established: 1997

Services: Clinical trial support services

Address: 3F-3, No. 415, Sec. 4, Shinyi Rd., Shinyi Chiu
Taipei 110, Taiwan

Phone: +886 2 8788 3182
Fax: +886 2 8788 3219
Email: service@statplusinc.com

Comments:

- StatPlus is headquartered in Taiwan, with offices in Hong Kong and the US. It provides services including non-clinical, pre-clinical, and clinical drug research and development.
- StatPlus also provides bioavailability, bioequivalence, pharmacokinetic and pharmacodynamic studies, market research, pharmacoeconomic studies, and botanical product and health food trials and submissions.
- StatPlus was founded by Dr. Shein-Chung Chow, Ph.D., and Dr. Huey Lin Ju, Ph.D. Dr. Chow has over 15 years of experience working for leading pharmaceutical and CRO companies, including Covance, Inc., Bristol-Myers Squibb Company, and consults with the Taiwanese Department of Health.
- Dr. Ju has over 10 years of experience in drug research and development, particularly in clinical research. She was previously associated with Bristol-Myers Squibb and with National Chengchi University as the founding Director of the Statistical Consulting Laboratory.

2.2 Virginia Contract Research Organization Co., Ltd.
www.vcro.com.tw/

Established: 1997

Services: Clinical trial support services

Address: 3F, No. 2, Ln. 258, Ruiguang Rd., Neihu District
Taipei 114, Taiwan (Times Plaza)

Phone: +886 2 2657 5399
Fax: +886 2 2657 9678
Email: Kent.Ko@vcro.com.tw, customer@vcro.com.tw

Comments:

- VCRO has done clinical trials for Phases I-III in various therapeutic specialties since 2001. It was founded by Dr. Chun-Chun Li to address the pharmaceutical industry's growing need for ICH-quality clinical trials.
- VCRO claims to be the most experienced contract research organization in Taiwan with the longest history.

- In 2005, VCRO received funding from Taiwan’s Department of Health to co-run a Clinical Research Center for Stroke & Traumatic Head Injuries.
- In 2006, VCRO launched its Interactive Voice Response System, an automated telephone system meant to make its clinical trials more efficient by automating some processes of data collection, randomization, etc.

2.3 Genovate Biotechnology Co., Ltd.

www.genovate-bio.com

Established: 1995 (clinical division 1996)
Employees: 120 (clinical division 80)
Services: Clinical trial support services

Address: Taipei Office:
 9F, No.12, Sec.2, Ren-Ai Road
 Taipei 10060, Taiwan

Phone: +886 2 2321 1978 – 2621 (Cindy Chu, Director International Affairs)
Email: ccchu@genovate-bio.com

Hsinchu Office:
 21 R/D Rd. II, 2F
 Hsinchu Science Park
 Hsinchu, Taiwan

Phone: +886 2 3598 2221
Fax: +886 2 3598 2804
Email: service@genovate-bio.com

Comments:

- Genovate Biotechnology is an innovative drug development firm that also provides CRO services. To date, it has conducted 50 trials in 13 therapeutic areas, and has established relationships with 33 hospitals in Taiwan. Its customers include Eli Lilly, GlaxoSmithKline, and Wyeth. Its top three therapeutic areas are antineoplastic, circulatory, and respiratory. Most of its studies have been Phase II or III.
- In 2008, Genovate Biotechnology spun off its CRO business into a subsidiary, Qualitix Clinical Research, which concluded a partnership agreement with ASKLEP, a major Japanese CRO.

Local Offices of Large Foreign CROs

2.4 Protech Pharmservices Corporation (PPC)

www.ppcro.com

Established: 1997
Employees: 150
Services: Clinical trial support services for Phases I – IV

Address: 11F, No. 3, Park St.
Nangang District
Taipei City 11503, Taiwan

Phone: +886 2 5558 0000
Fax: +886 2 5558 0055
Email: contact@ppccro.com

Comments:

- Protech Pharmservices is headquartered in Taipei, Taiwan, with other offices in Japan, Singapore, Hong Kong, Malaysia, and China, as well as Bethesda, MD and Sunnyvale, CA.
- PPC established the first Central Laboratory in Taiwan for new drug development in Taiwan and is accredited by both the College of American Pathologists (CAP) and the Commission on Office Laboratory Accreditation (COLA).
- Its experience in Phase I and II trials includes 18 completed projects in the following therapeutic areas: oncology, neuroscience, gastroenterology, endocrinology, gynecology, urology, and orthopedics.
- PPC provides ICH-GCP compliant clinical trial management for Phase I to IV trials, as well as bioequivalence and bioavailability studies. It also provides data analysis, training, quality assurance, central laboratory services, pharmacoeconomic studies, and botanical drug R&D.
- Since 2002, PPC has had a partnership with ECRON, a multinational contract research organization composed of a network of independent CROs across the world.
- In 2003, PPC entered into a strategic alliance with Taiwan's Industrial Technology Research Institute to promote global submissions of Chinese herbal medicines.
- In 2008, PPC partnered with ACRONET, a Japanese CRO, to conduct clinical trials in multiple Asian countries cooperatively.

2.5 PAREXEL International
www.parexel.com

Established: 1999
Employees: > 380 (globally)
Services: Clinical trial support services for Phases I – IV

Address: 22F, Far Glory International Center
No. 200, Sec.1, Keelung Road
Taipei 11071, Taiwan

Phone: +886 2 2727 1100

Fax: +886 2 2346 5211
Email: asiabiz@parexel.com

Comments:

- PAREXEL's Taiwan office was originally APEX, a leading CRO based in Taiwan and operating in over 8 other Asian countries. It was purchased by the US-based CRO PAREXEL in September 2007, becoming PAREXEL APEX. In 2008, its Asian operations were renamed simply PAREXEL.
- PAREXEL in Asia offers a complete range of clinical research services, including international project management, site management, product development consultation, medical writing, and data management. It has successfully provided Phase I to Phase IV global clinical studies to 110 global pharmaceutical, biotech, and medical device companies based in the US and Europe.
- PAREXEL has been successfully audited by several global pharmaceutical/biotech companies for FDA requirements and ICH-GCP guidelines.

2.6 Quintiles Taiwan
www.quintiles.com

Established: 1998
Address: 8F, No. 134, Sec. 3 (local office)
Cathy Life Cosmos Building
Min-Sheng East Road
Taipei 105, Taiwan

Phone: +886 2 2175 6500
Fax: +886 2 2175 6511
Email: asia@quintiles.com

Comments:

- In 1998, Quintiles Transnational agreed to acquire More Biomedical Contract Research Organization Ltd., one of Taiwan's top CROs, which then began operating as Quintiles Taiwan. At the time, this acquisition made Quintiles the leading provider of CRO services in Taiwan.

2.7 Theorem Clinical Research (formerly Omnicare Clinical Research)
www.theoremclinical.com

Address: 7F-5, No.205, Sec.1, Dunhua S. Road
Da'an District
Taipei City, Taiwan

Phone: +886 2 2778 2875
Fax: +886 2 2778 3249

Email: information@theoremclinical.com

Comments:

- This is the Taiwan branch office of Theorem Clinical Research, a large global CRO headquartered in King of Prussia, PA.
- In 2011, Omnicare Clinical Research became Theorem Clinical Research.

2.8 ICON Clinical Research Pte Ltd

www.iconcplc.com

Address: 2F, No.96, Sec.1, Chien Kou North Road
Taipei 10495, Taiwan

Phone: +886 2 7706 6300

Fax: +886 2 7706 6345

Email: info@iconaus.com.au

Comments:

- This is the Taiwan branch office of ICON Clinical Research, a large CRO based in Dublin, Ireland.

2.9 PPD (Taiwan)

www.ppdi.com

Established: 2001

Address: Suite 1810, 18th floor (local office)
Taipei World Trade Center
333 Keelung Road, Section 1
Taipei City 110, Taiwan

Phone: +886 2 2757 9650

Fax: +886 2 2757 9498

Comments:

- This is the Taiwan branch office of PPD, a large global CRO headquartered in Wilmington, NC.

2.10 PRA Taiwan

www.prainternational.com

Established: 2004

Address: Office 1:
9F-1 # 100, Section 2, Roosevelt Road (local office)
Taipei, Taiwan 10084

Phone: +886 2 7725 6600
Fax: +866 2 7724 6600

Address: Office 2:
14F, Shin Kong Manhattan Building
No.8, Sec.5, Xin Yi Road
Taipei 110, Taiwan

Phone: +886 2 8758 2222
Fax: +866 2 8758 2333

Comments:

- Headquartered in Raleigh, NC, PRA International is a global CRO with over 3,500 employees throughout North America, Europe, South America, Africa, Australia, and Asia. PRA expanded its operations to Asia in 2004 with the opening of offices in Taiwan. It now has locations in China, Hong Kong, Korea, and India as well.

2.11 CMIC Asia-Pacific Pte. Ltd. (Taiwan)

www.cmic-ap.com

Address: 5F-1, No.149, Sec.3 Hsin Yi Road, Da'an District
Taipei 10658, Taiwan

Phone: +886 2 2706 9947
Fax: +886 2 2706 9908

Comments:

- This is the Taiwan office of CMIC Co. Ltd., a large global CRO based in Tokyo, Japan. It is a branch of CMIC's Singapore subsidiary.

2.12 EPS Taiwan

www.epsgr.com

Established: 2007

Address: 10F, No.111, Sec.1, Xincheng S. Road, Da'an District
Taipei City 10625, Taiwan

Phone: +886 2 2779 2069
Fax: +886 2 2721 6429

Email: info@epsgr.com

Comments:

- This is the Taiwan branch office of EPS Co. Ltd., a large Japan-based CRO.

2.13 inVentiv Health Clinical (formerly PharmaNet Taiwan Ltd.)
www.inventivhealthclinical.com

Address: 14F, Shin Kong Manhattan Building
No.8, Sec.5, Xinyi Road
Taipei 11049, Taiwan

Phone: +886 2 8758 2350
Email : pni@inventivhealth.com

Comments:

- This is the Taiwan subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

2.14 Covance Taiwan Services Limited
www.covance.com

Services: Clinical trial support services and commercialization

Address: 18F, No. 1 Song Kao Rd
Taipei, Taiwan

Phone: +886 2 8758 0888
Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance has Asian offices in Japan, Singapore, India, the Philippines, South Korea, and China.

SINGAPORE

Singapore is a good location for conducting clinical trials because it boasts the second-best health care system in Asia (after Japan). Singapore has 5 million people, high quality facilities, and highly educated doctors -- many of whom went to school in the US or Europe (especially England). However, one of the drawbacks of doing clinical trials there is its small population; sometimes trials in Singapore can encounter difficulty recruiting enough patients. In addition, it may be more difficult to persuade people to participate in clinical studies due to the fact that Singaporeans are generally conservative and some may be wary of what they are getting involved in.

The Health Sciences Authority (HSA), established in 2001, is generally responsible for the quality, safety, and efficacy of drugs and devices. The Health Products Regulation Group (HPRG), a division of the HSA, regulates and evaluates drugs and medical devices and contains a Clinical Trials Unit with responsibility for clinical trials. All clinical drug trials in Singapore require HPRG approval in the form of a Clinical Trial Certificate (CTC) before the trial can proceed. The CTC is specific to the drug/device, protocol, and institution where the trial will be conducted and is issued in the name of the PI. If the sponsor is conducting a multi-site study, each individual site must have a CTC. The HSA issued 297 CTCs in 2013, up from 165 in 2001.

The CTC application submitted to the HSA must include the following information:

- Clinical trial information (title, protocol number, date, summary, objective and significance)
- Investigational drug details
- Comparator drug details
- Concomitant products to be used
- Local center(s) to be used for trial, principal investigator(s), IRB(s)
- Local CRO to be used
- Sponsor details
- Clinical trial protocol
- Patient information sheet and informed consent form
- Subject recruitment procedures, including any advertisements
- Listing of overseas trial center(s), if any
- PI's curriculum vitae
- GMP certificate or certificate of accreditation for drug manufacturer
- Certificates of analysis for drugs to be used
- IRB approval
- Other relevant supporting documents

It is possible to simultaneously apply for government approval and institutional review board (IRB) approval (that is, not submitting IRB approval as part of the government application), as long as both approvals are obtained before the study starts.

The HSA's Medical Clinical Research Committee reviews applications for CTCs, in addition to conducting continuing reviews of the clinical trial and monitoring adverse events. The

entire approval process takes about 1-2 months. Once granted, the CTC is valid for 2 years unless otherwise stated. If the trial is not completed when the CTC expires, the sponsor must apply for an extension and submit a clinical trial report on the ongoing study.

The CTC application should be submitted online. This system also allows tracking of submissions, amendments to existing CTCs, requests for extensions, and submission of clinical trial reports.

The import of clinical trial materials (CTM), i.e., investigational products, also requires approval by the HSA. A CTM application must include the following:

- CTC application number
- Contact information for importer
- Business registration number of importer (if different from local sponsor)
- Details of test materials, comparator drugs, and concomitant products (including generic name / active ingredient, brand name, strength)
- Quantity of test materials, comparator drugs, and concomitant product to be used in trial

CTM approval is valid for the duration of the CTC it accompanies. If the CTC is withdrawn or cancelled, the CTM will also be invalid.

All clinical trials conducted in Singapore must comply with the Singapore Guidelines for Good Clinical Practice (SGGCP), which are adapted from ICH-GCP standards and originally were implemented in 1998. Singapore has heavily promoted GCP standards and GCP training for clinical research workers through the national “Singapore Good Clinical Practice Program.”

Ministry of Health (MOH)

College of Medicine Building, 16 College Road, Singapore 169854

Tel: +65 6325 9220

Fax: +65 6224 1677

Email: moh_info@moh.gov.sg

Website: www.moh.gov.sg

Clinical Trials Branch, Centre for Drug Administration, Health Products Regulation Group, Health Sciences Authority (HSA)

11 Biopolis Way #11-01 Helios, Singapore 138667

Tel: +65 6866 3446

Fax: +65 6478 9034

Website: www.hsa.gov.sg

Email: HSA_info@hsa.gov.sg

Contact: Foo Yang Tong, Deputy Director, Foo_Yang_Tong@hsa.gov.sg

Local CROs

3.1 Singapore Clinical Research Institute (SCRI)
(formerly Clinical Trials & Epidemiology Research Unit “CTERU”)
www.scri.edu.sg

Established: 1996
Employees: 25
Services: Clinical trial support services for Phases I – III

Address: 31 Biopolis Way, Nanos #02-01
Singapore 138669

Phone: +65 6508 8300
Fax: +65 6508 8317
Email: contact@scri.edu.sg

Comments:

- CTERU is a full-service academic CRO established with funding from the National Medical Research Council (NMRC) to provide essential infrastructure to support not-for-profit public sector research.
- Since 2003, CTERU has been jointly managed by SingHealth and the National Healthcare Group, while still receiving funding from the NMRC.
- It has been involved in collaborative studies with hospitals and national institutions in Singapore, as well as a number of other hospitals in the region. CTERU has several regional centers throughout Asia and Australia.
- CTERU’s therapeutic specialties include oncology, cardiology, nephrology, dentistry, gastroenterology, and ophthalmology.

3.2 Phoenix Pharma Central Services (S) Pte Ltd
www.phoenixpcs.com

Established: 2001
Services: Clinical trial laboratory services

Address: 11 Changi North Street 1, #04-05/08
Changi North Industrial Estate
Singapore 498823

Phone: +65 6542 4784
Fax: +65 6542 7238
Email: info@phoenixpcs.com

Comments:

- Phoenix Pharma Central Services is a dedicated central laboratory offering a variety of lab services for clinical trials.

3.3 Maccine

www.maccine.com

Established: 2003
Services: Preclinical research and development support services
Address: 10 Science Park Road #01-05
The Alpha, Singapore Science Park II
Singapore 117684
Phone: +65 6622 9540
Fax: +65 6778 7305
Email: business.development@maccine.com

Comments:

- Maccine provides preclinical services including pharmacokinetic/pharmacodynamic testing, toxicology, discovery support, safety assessment, and laboratory services.
- Maccine's facilities are compliant with GLP. They have also been accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- Maccine was originally founded in the 1990's by a research group from Monash University in Australia, and moved to Singapore in 2003.

Local Offices of Large Foreign CROs

3.4 Covance (Asia) Pte. Ltd.

www.covance.com

Established: 2000
Services: Clinical trial support services
Address: 1 International Business Park (local office)
#01-01 The Synergy
Singapore 609917
Phone: +65 6568 6588
Fax: +65 6569 6006

Comments:

- Covance (Asia) Pte. Ltd. is the Singapore office of Covance Inc., one of the world's largest international drug development service companies. Covance Inc. opened a new central laboratory in Singapore in 2000 and recently expanded its testing services for clinical trials.

3.5 Quintiles East Asia Pte Ltd

www.quintiles.com

Established: 1995 (lab in 1998)
Employees: 80+
Services: Clinical trial support services and commercialization

Address: 79 Science Park Drive, #06-08 (local office)
CINTECH IV, Science Park One
Singapore 118264

Phone: +65 6602 1000
Fax: +65 6872 0430
Email: asia@quintiles.com

Address: Central Laboratory
Quintiles Laboratories Singapore
No. 1 Jalan Kilang
#03-02 Dynasty Industrial Building
Singapore 159402

Phone: +65 6274 4222
Fax: +65 6274 4292

Comments:

- Quintiles Transnational was the first international CRO to open an office in Asia, and Singapore was the first Asian office. The Singapore office became the head office for the Asia Pacific region in 2000. It has over 80 employees in three locations. Clinical trials are generally managed out of the head office in Science Park.
- Quintiles East Asia offers the full range of clinical development services including clinical operations, project management, safety surveillance reporting, quality assurance, and regulatory consulting.
- The Quintiles Laboratory, which opened in 1998, is the largest central lab in Asia and has allowed many customers to be able to conduct large-scale Phase II and III studies in the Asia Pacific. It has provided lab services for over 200 clinical studies and is accredited with distinction by the College of American Pathologists (CAP). There is also a clinical supplies facility in Singapore.
- Quintiles East Asia is also the parent of Innovex Singapore, which serves as the regional office for the Asia Pacific. Innovex offers commercialization solutions and other outsourced marketing and sales services.

3.6 Theorem Clinical Research (formerly Omnicare Clinical Research)

www.theoremclinical.com

Address: 18 Cross Street #07-06/07
China Square Central
Singapore 048423

Phone: +65 6372 1153
Fax: +65 6372 1154
Email: information@theoremclinical.com

Comments:

- This is the Singapore branch office of Theorem Clinical Research, a large global CRO headquartered in King of Prussia, PA.
- In 2011, Omnicare Clinical Research became Theorem Clinical Research.

3.7 EPS Global Research Pte Ltd (formerly Gleneagles CRC Pte Ltd)
www.epmgr.com

Address: 150 Beach Road
#06-02 The Gateway West
Singapore 189720

Phone: +65 6294 1678
Fax: +65 6294 0678
Email: info@epmgr.com

Comments:

- This is the Singapore branch office of EPS, a large Japan-based CRO.

3.8 ICON Clinical Research Pte Ltd
www.iconplc.com

Address: 3A International Business Park (local office)
#06-01/02/03/04/05 ICON@IBP
Singapore 609935

Phone: +65 6895 8200
Fax: +65 6896 2438
Email: info@iconaus.com.au

Comments:

- This is the Singapore branch office of ICON Clinical Research, a large global CRO headquartered in Dublin, Ireland.

3.9 PPD Development (S) Pte Ltd

www.ppdi.com

Established: 1998

Address: Development:
1 Fusionopolis Walk
#08-11 North Tower, Solaris
Singapore 138628

Phone: +65 6872 3588

Fax: +65 6872 3522

Address: Laboratory:
61 Science Park Road
#02-12-14 Galen
Singapore 117525

Phone: +65 6594 6200

Fax: +65 6872 3522

Comments:

- This is the Singapore branch office of PPD, a large CRO headquartered in Wilmington, NC.
- In 2002, PPD acquired ProPharma Pte. Ltd., a CRO in Singapore that runs pan-Asian clinical trials to GCP standards.

3.10 PAREXEL International

www.parexel.com

Address: 51 Bras Basah Road (local office)
#08-01/02/03&08 Manulife Centre
Singapore 189554

Phone: +65 6220 9326

Fax: +65 6220 9554

Email: info@parexel.com

Comments:

- This is the Singapore branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

3.11 ECRON ACUNOVA Pte Ltd (formerly aCRONordic Pte Ltd)

www.ecronacunova.com

Established: 2003
Employees: 52
Services: Clinical trial support services

Address: 420 North Bridge Road,
#03-38, North Bridge Centre
Singapore 188727

Phone: +65 6549 7750
Fax: +65 6549 7011
Email: bd.asia@ecronacunova.com; Singapore@ecronacunova.com

Comments:

- aCROnordic is a CRO based in Denmark with hubs in Sweden and Singapore. It provides a range of clinical trial support services, including clinical development, data management, biostatistics, monitoring, clinical data capture, quality assurance, and GCP hosting. It has experience with Phase I to IV trials, and provides Phase I trials through a strategic partnership.
- aCROnordic has strategic partnerships with the following companies: PhaseOne Trials A/S, GXP International, J.D. Young Consulting Inc., IWA Consulting ApS, Oracle Corporation, SAS Institute, and Capio Diagnostik.
- In May 2011, Encron Acunova became the majority shareholder of aCROnordic A/S.

3.12 CMIC Asia-Pacific Pte. Ltd.
www.cmic-ap.com

Established: 2006
Address: 6 Shenton Way
#24-08 A OUE Downtown2
Singapore 068809
Phone: +65 6222 2655
Fax: +65 6222 2606

Comments:

- This is the Singapore subsidiary of CMIC Co. Ltd., a large global CRO based in Tokyo, Japan.

3.13 inVentiv Health Clinical (formerly PharmaNet Pte Ltd.)
www.inventivhealthclinical.com

Address: 89 Science Park Drive

#03-03 The Rutherford
Singapore 118261

Phone: +65 6594 3570
Fax: +65 67792274
Email: pni@inventivhealth.com

Comments:

- This is the Singapore subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ. PharmaNet has approximately 2,300 employees and 40 facilities. It has many office locations in Asia, including Hong Kong, Taiwan, Singapore, Korea, India, and the Philippines, as well as field-based staff in Malaysia and Thailand.
- In March 2009, the company was acquired by JLL Partners, a leading private equity investment firm.

3.14 PRA Singapore
www.prainternational.com

Established: 2004

Address: 73 Science Park Drive, #02-12, Cintech I
Singapore 118254

Phone: +65 6505-3700
Fax: +65 6505-3799

Comments:

- Headquartered in Raleigh, NC, PRA International is a global CRO with over 3,500 employees throughout North America, Europe, South America, Africa, Australia, and Asia. PRA expanded its operations to Asia in 2004 with the opening of offices in Taiwan. It now has locations in China, Hong Kong, Korea, and India as well.

HONG KONG

Hong Kong is an emerging market for clinical trials. The city is one of the most active cities in Asia for industry-sponsored clinical trials, along with Seoul and Taipei. The country has advanced medical care, a highly developed infrastructure, strong presence of academic institutions, and high-quality investigators. Doctors are highly educated and have often studied in the West, particularly in England. There is ample infrastructure for conducting clinical trials. Hong Kong also has less stringent regulations on pharmaceuticals than in other Asian countries. The majority of clinical trials conducted in Hong Kong are in Phases II to IV. The regulatory process is fairly predictable and fast. Clinical trials are regulated by the Department of Health's Drug Service.

Under the Pharmacy and Poisons Regulations, a certificate for a Clinical Trial or Medicinal Test (CTC) is required before conducting a clinical trial. The PI should first submit the final protocol with other supporting documents, including the informed consent form and investigator's brochure, to the hospital's Ethics Committee (EC). Obtaining EC approval generally takes 4-8 weeks. The operation of the EC must comply fully with the ICH GCP guidelines and the Declaration of Helsinki (1996). However, Hong Kong has *not* formally adopted GCP guidelines for conducting clinical research. It has, though, developed courses and educational programs on clinical trial methodology and GCP principles. Since the introduction of GCP ICH guidelines, Hong Kong has taken part in more than 1,000 clinical trials.

The trial's sponsor must apply for the CTC. The CTC submission will include the protocol, investigator's brochure, information on the drug (pharmaceutical data, pharmacological action, toxicology, any previous clinical studies, package inserts, etc.), pre-clinical study results, a sample of the drug to be used, GMP certificate for the drug's manufacturer, certificate of analysis for the drug, the EC approval letter, an informed consent form, and a confirmation letter from the PI as well as his or her curriculum vitae. There is also an application fee of HKD 1,420 (about US\$183). The CTC is usually granted to the PI after 1-2 months. Once it is granted, the CTC is valid for 2 years.

Because of the managerial expertise available in Hong Kong, it is sometimes used as a site to coordinate trials across sites in China. In cases where a clinical trial submitted for a CTC is also being submitted for mainland Chinese regulatory approval, the Hong Kong government will also ask for proof of regulatory approval from the Chinese FDA (as soon as it is available), as well as the exact protocol submitted to the CFDA.

The sponsor must also apply for an import license at the DOH's Pharmaceuticals Registration and Import/Export Control Division for permission to import samples of the drug for the purpose of obtaining the CTC. This will generally be available within a week. A copy of the CTC will be required when the drugs are actually imported for clinical testing. The total approval time will be about 2-4 months.

This process does not apply to clinical trials of medical devices, since medical devices do not currently require registration to be sold or used in Hong Kong. However, a voluntary

regulatory system is being tested, and after it is made mandatory over the next several years, its scope may expand to include device trials.

While the clinical trial is taking place, yearly progress reports must be submitted to the DOH's Drug Service on provided forms. Once the clinical trial is complete, a final report must be submitted. All adverse drug reactions that are both *serious* and *unexpected* must be reported to the Drug Service as soon as possible, within 7 days if the reaction is fatal or life-threatening, or within 15 days otherwise. All other adverse reactions can simply be listed in the final report.

Department of Health (DOH)

21/F, Wu Chung House, 213 Queen's Road East, Hong Kong

Phone: +852 2961 8989

Fax: +852 2836 0071

Email: enquiries@dh.gov.hk

Website: www.dh.gov.hk

Drug Office (Department of Health)

3/F Public Health Laboratory Centre, 382 Nam Cheong Street, Shek Kip Mei, Kowloon, Hong Kong

Phone: +852 2319 8458 (for clinical trial approval)

+852 2319 8460 (for import approval)

Fax: +852 2803 4962

Email: pharmgeneral@dh.gov.hk

Website: www.drugoffice.gov.hk

Local CROs

4.1 Clinical Trials Centre

www.hkuctc.com

Established: 1998

Employees: 18

Services: Clinical trial support services for Phases I – IV

Address: 8/F, Clinical Pathology Building, Queen Mary Hospital
102 Pokfulam Road, Hong Kong

Phone: +852 2855 4664

Fax: +852 2974 1248

Email: ctcentre@hku.hk

Comments:

- The Clinical Trials Centre is part of the University of Hong Kong and was established as part of the School of Medicine in 1998. It claims to be the first, and currently the

only, full-service academic CRO in the Asian region dedicated to offering one-stop solutions to clinical trial sponsors and investigators.

- CTC's affiliated clinical laboratory at Queen Mary Hospital is accredited by the College of American Pathologists (CAP).
- CTC recently established an "investigator network" named ClinCluster that is able to perform feasibility studies.
- CTC's therapeutic specialties include hepatology and gastroenterology, oncology, endocrinology and metabolism, and cardiology.

4.2 Centre for Clinical Research & Biostatistics (CCRB)

www.cct.cuhk.edu.hk

Established: 2003

Services: Clinical trial support services for Phases I – IV

Address: Room 501 School of Public Health and Primary Care
Prince of Wales Hospital
Chinese University of Hong Kong
Shatin, NT, Hong Kong

Phone: +852 2252 8865

Fax: +852 2646 7297

Email: ccrb@cuhk.edu.hk

Comments:

- The Centre for Clinical Trials has wide experience with conducting clinical trials for multinational drug companies, including GlaxoSmithKline, AstraZeneca, Novartis, and Pfizer. It is also certified as a clinical site by the Chinese State Food and Drug Administration, in order to conduct and coordinate trials to put drugs on the Chinese market.
- The Chinese University of Hong Kong's Centre for Clinical Trials should not be confused with the University of Hong Kong's Clinical Trials Centre above.

Local Offices of Large Foreign CROs

4.3 Quintiles Hong Kong Limited

www.quintiles.com

Established: 1996

Address: Unit 2212-19, Level 22 (local office)
Metroplaza Tower One
223 Hing Fong Road
Kwai Fong, NT, Hong Kong

Phone: +852 2830 9200
Fax: +852 2830 9288
Email: asia@quintiles.com

Comments:

- Quintiles opened its Hong Kong office in 1997 to expand its presence in the East Asian region. It provides a range of clinical trial support services and assists in monitoring clinical studies in China, Taiwan, and Hong Kong.

4.5 ICON Clinical Research Pte Ltd
www.iconplc.com

Address: Suite 3606, 36th Floor, Office Tower, Skyline Tower
No.39 Wang Kwong Road
Kowloon Bay, Hong Kong

Phone: +852 3511 6911
Fax: +852 30090770
Email: info@iconaus.com.au

Comments:

- This is the Hong Kong branch office of ICON Clinical Research, a large global CRO headquartered in Dublin, Ireland.

4.6 PPD (Hong Kong)
www.ppd.com

Address: Suites 802-04, 8F (local office)
625 King's Road, North Point
Hong Kong

Phone: +852 29110 110
Fax: +852 29110 123

Comments:

- This is the Hong Kong branch office of PPD, a large global CRO headquartered in Wilmington, NC.

4.7 PAREXEL International
www.parexel.com

Address: 1st Floor, Harbour View 2

No. 16 Science Park East Avenue, HK Science Park
Shatin, Hong Kong

Phone: +852 2402 3263
Fax: +852 2402 3103
Email: info@parexel.com

Comments:

- This is the Hong Kong branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

4.8 CCBR Hong Kong

www.ccb.com/patient/en

Established: 2008

Address: 6 Floor, Tower II, New World Tower (local office)
18 Queen's Road Central, Hong Kong

Phone: +852 3110 6699
Fax: +852 3110 1012
Contact: Edith Lau, Managing Director
Email: edith.lau@ccb.com
ccb.hongkong@ccb.com

Comments:

- This is the Hong Kong clinical trial center for CCB, a global CRO based in Denmark. CCB is a subsidiary of Synarc, a pharmaceutical services company based in San Francisco, CA.
- CCB's therapeutic specialties include cardiology, neurology, oncology, orthopedics, osteoporosis, and arthritis.
- Although CCB Hong Kong was only established recently, it is registered as taking part in a global phase III osteoporosis study sponsored by Novartis and Nordic Bioscience.
- CCB also has a branch in Beijing, China, which has existed for some time.

4.9 Medpace Hong Kong Ltd.

www.medpace.com

Address: Unit 320, 3F, Core Building 2
No.1 Science Park West Avenue, HK Science Park
Shatin, New Territories, Hong Kong

Phone: +852 3173 0700
Fax: +852 2607 4333

Email: info.hk@medpace.com

Comments:

- This is the Hong Kong office of Medpace, a large global CRO based in Cincinnati, OH.

4.10 EPS Hong Kong

www.epsgr.com

Established: 2009

Address: Room2202, 22F, 101 King's Road
Hong Kong
c/o Singapore Office

Comments :

- This is the Hong Kong branch office of EPS Co. Ltd., a large Japan-based CRO.

4.11 PRA Hong Kong

www.prainternational.com

Address: Hong Kong Millennium City 1, 32F, Tower 1
388 Kwun Tong Road
Kowloon, Hong Kong

Phone: +852 3972 2580
Fax: +852 3972 2537
Email: trials@praintl.com

Comments:

- This is the Hong Kong branch office of PRA, an international CRO headquartered in Raleigh, NC, with over 3,500 employees worldwide.

4.12 inVentiv Health Clinical (formerly PharmaNet (Hong Kong) Ltd.)

www.inventivhealthclinical.com

Address: 51/F Hopewell Centre (local office)
183 Queen's Road East
Wanchai

Fax: +85 2 3602 3050

Comments:

- This is the Hong Kong subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

4.13 Covance Hong Kong Services Limited

www.covance.com

Services: Clinical trial support services and commercialization

Address: Rm4703a, 47/F Central Plaza
18 Harbour Road,
Wanchai, Hong Kong

Phone: +85 2 2588 6816

Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance also has Asian offices in Japan, Taiwan, India, the Philippines, South Korea, and China.

KOREA

The Korean Ministry of Food and Drug Safety (MFDS), originally the Korean FDA, is the main regulatory body for drugs, medical devices, food, and cosmetic products. It also implements rules and guidelines that govern the use and safety of these products. To conduct a clinical trial in Korea, the sponsor must obtain both regulatory approval and IRB approval. The MFDS provides optional pre-IND consultation services, and it is generally recommended that the sponsor engage in these consultations. The sponsor will then submit the clinical trial application dossier with the appropriate supporting documents to the MFDS (Clinical Trials Management Division, under the Pharmaceutical Safety Bureau). The full clinical trial application must be translated into Korean.

The MFDS will consult with the Central Pharmaceutical Affairs Committee in making its decision. Regulatory approval will take about 1-2.5 months, especially if the MFDS asks for supplementary information. However, the Korean government has made efforts in recent years to decrease approval times. The IRB approval process can be done in parallel to the regulatory approval process; IRB approval takes 1-2 months.

Clinical trials must be conducted in accordance with Korean Good Clinical Practice (GCP), which was implemented in 1995 and later revised in 2001 to be in accordance with ICH guidelines. According to Korean GCP, clinical trials must be continuously monitored by an IRB.

The Korean government has made efforts to improve the clinical development environment by providing grants for clinical trial centers to provide infrastructure for and to facilitate multi-site trials. It has also increased training for investigators and clinical research associates. In addition, it has also begun implementing investigator-initiated clinical trials. The government established the Korea National Enterprise for Clinical Trials (KoNECT) in 2007 to advance standards, forge industry partnerships, and build a clinical trial infrastructure. By 2010, \$60 million had been invested by the Korean government to build 15 regional clinical trial centers. In 2011, the Korea Drug Development Fund was launched to develop a minimum of 10 new drugs by 2019.

Streamlined regulations have led to a growing number of clinical trials in Korea, in particular after the implementation of ICH guidelines and the separation of NDAs and INDs. Korea is ranked in the top 15 countries globally for the number of clinical trials. In 2012, the MFDS approved 367 local clinical trials and 303 multinational studies, for a total of 670 trials. Ten years previously, the government had only approved 27 local trials and 18 multinational clinical trials. In addition, the number of Phase I global trials has increased rapidly, as have local Phase I and Phase II studies. Phase III trials have also been growing. Oncology trials account for approximately one-third of the global clinical trials conducted in Korea.

Ministry for Health, Welfare and Family Affairs

13, Duom 4-Ro, Sejong 339-012, Korea

Website: english.mohw.go.kr

Ministry of Food and Drug Safety (MFDS)

Osong Health Technology Administration Complex

187 Osongsalngmyeong 2(i)-ro

Osong-eup, Cheongwon-gun, Chungcheongbuk-do, Korea 363-700

Tel: +82 43 719 1564

Website: www.mfds.go.kr

Local CROs

5.1 DreamCIS Inc.

www.dreamcis.com

Established: 2000

Services: Clinical trial support services for Phases I – IV

Address: Room No. 10, 10F, Jeoksun Hyundai Building
80 Jeoksun-dong, Jongno-gu
Seoul 110-756, Korea

Phone: +82 2 2010 4500

Fax: +82 2 720 5385

Email: dreamcis@dreamcis.com

Comments:

- DreamCIS is a leading CRO in South Korea. Since 2000, DreamCIS has been providing clinical research services to top Korean and multinational pharmaceutical companies, as well as biotechnology, medical device, and health food companies.
- DreamCIS's clinical trial support services include phase I-IV clinical trials, post-marketing research, QA auditing, data management, statistical analysis, pre-clinical trial management, and training and dispatch of clinical nursing personnel.
- DreamCIS offers a range of clinical development services including pre-clinical studies, toxicology testing, efficacy testing, PMS and bridging studies, and regulatory affairs.
- DreamCIS has conducted almost 100 clinical trials. Of these, about 40% were post-marketing studies. Of its clinical trials, about half were Phase III. It has experience in many therapeutic areas, but some of the top ones are vaccines, neurology, cardiovascular, oncology, urology/nephrology, and muscular/skeletal.
- DreamCIS is the Korea partner of four global CROs: Aptuit, InCrom, Gleneagles CRC, and PPC.
- In January 2009, DreamCIS signed a strategic partnership agreement with ASKLEP, a Japan CRO.

5.3 LSK Global Pharma Services Co. Ltd.

www.lskglobal.com

Established: 2001
Employees: 60
Services: Clinical trial support services for Phases I – IV

Address: 16F, Coryo Daeyungak Tower
97 Toegye-Ro, Jung-Gu
Seoul 100-706, Korea

Phone: +82 2 546 1008
Fax: +82 2 546 0081
Email: information@lskglobal.com, jacklee@lskglobal.com

Comments:

- LSK, formerly Lifecord Stat-Korea, is a full-service CRO. It conducts site and investigator selection, protocol and SOP preparation, site monitoring, data management and analysis, and regulatory submission services.
- LSK has completed or commenced more than 250 clinical trials, over 150 of them for multinational pharmaceutical companies. Although it usually deals with their Korean branches, it also has the capability to deal with overseas sponsors directly.
- LSK has conducted global trials in cardiovascular, oncology, dermatology, neurology, and orthopedics. It also has wide experience in other therapeutic areas.
- LSK has expertise in planning and conducting bridging studies for KFDA marketing approval.
- The President of LSK, Dr. Young Jack Lee, has a PhD from Ohio State University and was formerly Biometric Branch Chief at the US National Institutes of Health.

5.4 ADM Korea Inc.

<http://www.admkorea.co.kr/>

Address: #711 (Royal Bldg, Danju-dong)
19, Saemunanro5-gil, Jongro-Gu
Seoul 110-721, Korea

Phone: +82 2 730 1457
Fax: +82 2 722 0152
Email: admcorea@admcorea.co.kr, smyoon@admcorea.co.kr

Comments:

- ADM Korea focuses on clinical trial services for new drug development. It has been involved in a number of studies that led to the submission of NDAs by Western pharmaceutical companies to the KFDA.

- ADM Korea also provides other services including data management, statistical analysis, quality assurance and auditing, medical translation, postmarketing studies, and pharmacovigilance.
- ADM has done trials in a range of therapeutic areas, particularly oncology, endocrinology, hematology, and vaccines.

5.5 C&R Research

www.cnrres.co.kr

Established: 1997
Services: Clinical trial support services
Address: 3rd Floor, Bunam Bldg
 447, Samil-daero, Jongno-Gu
 Seoul 110-310, Korea
Phone: +82 2 6251 1500
Fax: +82 2 6250 1504
Email: biyoon@cnrres.co.kr

Comments:

- C&R Research has conducted 300 projects since its founding in 1997. Its services include clinical trial management, pharmacovigilance, data management, statistical analysis, and regulatory affairs.
- C&R Research is a local partner of Omnicare Clinical Research, a large global CRO headquartered in King of Prussia, PA.
- C&R Research won the 2008 Frost & Sullivan Excellence in Healthcare Award in the category of South Korea clinical research organizations.

Local Offices of Large Foreign CROs

5.6 Quintiles Transnational Korea

www.quintiles.com

Established: 2000
Services: Clinical trial support services
Address: 13F, World Tower Bldg. (local office)
 7-25 Sincheon-dong Songpa-gu
 Seoul 138-731, South Korea
Phone: + 82 2 2046 8888
Email: asia@quintiles.com

Comments:

- Quintiles Transnational Korea is a subsidiary of Quintiles Transnational Corporation, one of the world's largest healthcare outsourcing companies. The Korea office is the company's third largest Asia office. It provides clinical development (clinical operations and regulatory) and commercialization services (sales and specialists teams, vacancy management, health management, consultancy, and training).

5.7 PPD (Korea)

www.ppdi.com

Established: 2005

Address: 402, 4th Floor Keungil Tower (local office)
677-25 Yeoksam-dong
Gangnam-gu, Seoul 135-080, Korea

Phone: +82 2 3490 1709

Fax: +82 2 3490 1710

Comments:

- This is the Korea branch office of PPD, a large CRO headquartered in Wilmington, NC.

5.8 PAREXEL International

www.parexel.com

Address: 18F, Haesung BD, 942 (local office)
Daechi-Dong, Gangnam-gu
Seoul, 135-725 Korea

Phone: +82 2 3453 8838

Fax: +82 2 3453 8839

Email: info@parexel.com

Comments:

- This is the Korea branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

5.9 CMIC Korea Co., Ltd.

www.cmic.co.kr

Established: 1998

Services: Clinical trial support services

Address: Teheran-ro 78-12, Gangnam-gu, Seoul, Korea
(6F, MSA Building, Daechi-dong 891-43
Gangnam-gu, Seoul, Korea)

Phone: +82 2 3708 3600
Fax: +82 2 3789 6900
Email: cmickor@cmic.co.kr

Comments:

- CMIC Korea offers clinical research services for Phase I-IV. It is a branch office of CMIC Co. Ltd., a large Japanese CRO.
- CMIC Korea offers related services such as protocol design, CRF development, QA and QC, data management, pre-clinical study coordination, new drug consulting, and medical writing.
- CMIC Korea's General Manager, Lee Byung-kwon, has been Korea regulatory affairs manager for both Schering Plough and Merck.

5.10 ICON Clinical Research

www.iconplc.com

Address: 18th Floor, Captial Building (local office)
736-1, Yeoksam I-dong, Gangnam-gu
Seoul, Korea

Phone: +82 5 520 5200
Fax: +82 2 520 5330
Email: info@iconaus.com.au

Comments:

- This is the Korea branch office of ICON Clinical Research, an international CRO based in Dublin, Ireland.

5.11 EPS International Korea

www.epsgr.com

Address: 5th Fl. Songchon building
503 Nonhyun-ro Gangnam-gu
Seoul 135-910, South Korea

Phone: +82 70 4640 2317
Fax: +82 2-552-5402
Email: info@epsgr.com

Comments:

- This is the Korea branch office of EPS Co. Ltd., a large Japan-based CRO.

5.12 Seoul CRO Co., Ltd.

www.seoulcro.co.kr

Established: 2009

Address: 2FL, Noveltech Bd.
201-6 Nohyun-Dong, Gangnam-gu
Seoul, Korea

Phone: +82 2 3447 0181

Fax: +82 2 3447 0182

Email: nryang@seoulcro.co.kr

Comments:

- Seoul CRO is a subsidiary of Tokyo CRO, Inc., a Japan-based CRO.

5.13 PRA Korea

www.prainternational.com

Address: Office 1:
L11 Samsung-dong 3 Bldg
157-1 Samsung-dong, Gangnam-gu
Seoul 135-090, Korea

Phone: +82 2 2192 0818

Address: Office 2:
14F, Gangnam Finance Center
Teheran-ro 152, Gangnam-gu
Seoul 135-984, Korea

Phone: +82 2 2222 6400

Fax: +82 2 2222 6499

Email: trials@praintl.com

Comments:

- This is the Korea branch office of PRA, an international CRO headquartered in Raleigh, NC, with over 3,500 employees worldwide.

5.14 Theorem Clinical Research (formerly Omnicare Clinical Research)
www.theoremclinical.com

Established: 2009

Address: Stargallery Bridge 6F
1553-3 Seocho-dong 554, Seocho-gu
Seoul, 136-070, Korea

Email: information@theoremclinical.com

Comments:

- This is the Korea branch office of Omnicare Clinical Research, a large global CRO headquartered in King of Prussia, PA.
- In 2011, Omnicare Clinical Research became Theorem Clinical Research.

5.15 inVentiv Health Clinical Korea (formerly PharmaNet)
www.inventivhealthclinical.com

Address: 13th Floor, Gangnam Finance Center
152 Teheran-ro, Gangnam-gu
Seoul 135-984, South Korea

Phone: +82 2 6206 1600

Fax: +82 2 6206 1699

Email: pni@inventivhealth.com

Comments:

- This is the Korea subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

5.16 Covance Korea Services Ltd
www.covance.com

Services: Clinical trial support services and commercialization

Address: 13th Floor, POBA Gangnam Tower
343, Hakdong-ro, Gangnam-gu
Seoul 135-820, Korea

Phone: +82 2 6004 3500 (Clinical Phase II-IV)

+82 2 503 0780 (Pre/Early-Clinical)

Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance also has Asian offices in Japan, Taiwan, Singapore, India, the Philippines, and China.

III. INDIA, CHINA, MALAYSIA, PHILIPPINES, INDONESIA, THAILAND, AND VIETNAM

The third tier of clinical research includes countries whose health care infrastructure may not be as highly developed as in wealthier Asian countries. However, clinical trial services offered here are generally significantly less expensive than in the second tier countries, and can be of decent quality. Even amongst these countries there is some variation. For example, India has a highly educated human resource pool and existing infrastructure for drug production, which has made it easier for Indian companies to transition into clinical research. There are many local CROs that are headquartered in India, along with many satellite offices of global CROs. Similar to India, China has become a likely locale for foreign companies to do clinical trials. Western companies do clinical trials in China for many of the same reasons as in India. In the Southeast Asian countries, however, there are not many local “homegrown” CROs and only a few branch offices of large global or regional CROs -- though these are growing in number. Not many foreign medical companies focus on Southeast Asia (Malaysia, Philippines, Indonesia, Thailand, and Vietnam) when looking to do clinical trials in the region.

INDIA

For a number of reasons, India’s clinical trial business grew rapidly over the past decade. Perhaps the major factor for such growth is the fact that clinical trials in India are significantly cheaper than in the West. Another factor spurring growth in the Indian market is the large, already-existing presence of pharmaceutical know-how and capacity. India has a history in generic drug production. Add to that the tremendous diversity of its population, huge geographic expanse, the number of foreign-educated doctors, and the fact that English is the country’s common language, it is no surprise that India became a prime spot for clinical research activity.

India’s technological and regulatory standards are beginning to catch up with those in the West. The country has the benefit of a large population with less past exposure to Western drugs. India has a good level of investigator experience and many sites are run efficiently. It also has numerous accredited central laboratories and the infrastructure to sustain clinical trials. Site investigators are knowledgeable about the ICH-GCP guidelines, and all study monitors and clinical research associates (CRAs) are trained in standard operating procedures that follow GCP, GLP, and ICH. Ethics Committees are also governed by GCP. There are more than 500 registered ethics committees in India; recent regulatory changes mean that these committees now undergo formal government-sponsored training. Indian guidelines for clinical research are based on the Declaration of Helsinki, WHO, and ICH requirements for GCP.

Clinical trials are regulated under the Drug and Cosmetics Act of 1940. The Indian government has been fairly strict about what types of foreign drug trials it will allow in-country. Phase I trials in India are limited to domestically discovered drugs, except in cases where the potential drug could be applied to medical crises in India, or in cases where Phase I trials have already been completed in another country. In 2005, clinical trial legislation was revised to allow concurrent new chemical entity (NCE) Phase II and III clinical trials --

previously, these trials were only allowed with a phase lag to better ensure the safety of the trials. Phase II, III, and IV trials have most commonly been conducted in the therapeutic areas of infectious disease, psychiatry, endocrinology, oncology, and cardiovascular disease.

Historically, the Drug Controller General of India (DCGI) has been responsible for approving clinical trial applications. From July 3 to August 31, 2013, the DCGI reviewed 259 NCE clinical trial applications. Of these, 162 were approved. All drugs that have been approved in other well-regulated countries require Phase III trials in India. Local clinical trial waivers are only available in certain conditions -- such as orphan drugs, national emergency, and drugs that are the first treatment available in their therapeutic fields.

Intellectual property has been historically difficult to enforce in India, since the government only patented drug manufacturing processes as opposed to the end product. In March 2005, though, the government passed a new patent law conforming to TRIPS (Trade-Related Aspects of Intellectual Property Rights), the WTO's standards on intellectual property. Under the new law, companies can apply to receive 20-year formula patents. Companies that were previously selling generic drugs already approved by the government must now pay royalties to the patent holders. Despite this new legal framework, actual enforcement of intellectual property rights can still be troublesome.

CROs in India received a new stimulus in 2008. That year, 125% of payments for R&D services became deductible from a company's taxes. This is an incentive for companies to outsource their R&D activities. In 2010, 500 global clinical trials were approved in India, while around 2,000 trials in total were being conducted. In 2011, this number rose to over 3,000. The clinical trial industry was forecasted to grow at more than 10% annually and be worth \$1.1 billion by 2017.

It is important to note that clinical trials in India have a political context that is mostly absent in other countries. As noted above, Phase I trials in India are currently restricted for foreign products, mostly due to a worry that they could lead to the abuse of Indian citizens as "guinea pigs" for the benefit of other countries. Western companies operating in India should be especially careful to follow laws and requirements strictly, since adverse events connected to non-compliant practices could lead to public outcry.

For example, in November 2008, Wyeth found itself surrounded by controversy when an infant in a vaccine trial died. This infant had been selected for the study despite a cardiac abnormality that the protocol did not allow. (A waiver from the protocol would have been possible, but the DCGI said such a waiver would have needed its approval, although Wyeth claims that GCP was followed in full.) The DCGI has halted the trial. The government and public are particularly alert to problems in trials on infants because of the discovery in August 2008 that 49 infants had died over 2 years in trials by a public medical school, the All India Institute of Medical Sciences.

In fact, there has been increasing controversy over the number of deaths during clinical trials -- from 2005-2013, almost 3,500 clinical trial participants died. Although the government maintains that only 89 were related to the trials, public outcry has forced the government to

act. New, stricter regulations over the past two years have significantly reduced the number of pharmaceutical clinical trials in India, dropping to just 19 in 2013. There were 500 clinical trials in 2011.

In late 2012, the Drugs and Cosmetics Act was amended with new regulations on ethical supervision and regulation of clinical trials. Securing permission for a clinical trial is now a *much more rigorous* process. Strict rules on liability for death or injury to drug trial volunteers have also been instituted. Compliance with good clinical practices (GCP) and adverse events reporting regulations were also included. Organizations conducting pharmaceutical trials must set up audio and video recording of the entire trial process. All stakeholders involved in a trial must also be registered and accredited.

The Ministry of Health's ability to approve Indian clinical trials was revoked by the Indian Supreme Court early last year. Instead, three *new* committees have been set up to clear clinical trials: an apex committee, a technical committee, and a New Drug Advisory Committee (NDAC). However, these three committees only approved clinical trials for 5 drugs over the September-December 2013 period. In late October, the Supreme Court suspended over 150 trials that had been previously approved until the three new committees could review the cases.

This has had a corresponding effect on new drug discoveries and registrations in India. More than 260 new drugs were approved in 2008, compared with less than 25 in 2013. The approval process for global drugs sold in India used to be about 6 months; the timeline has now increased to over 3 years. In early February 2014, the Indian Minister of Health and Family Welfare acknowledged that clinical trial regulations were hurting innovation and that the new norms might be relaxed.

Other countries have benefitted from this decrease in Indian clinical trials. China is now the number one non-Western destination for trials, pushing India to second place. Many multinational pharmaceutical companies have taken India off their list of potential clinical trial sites. The US National Institutes of Health (NIH), one of the largest research funders in the world, shut down more than 35 clinical trials underway in India.

Domestic companies have also moved clinical trials abroad, making their drug development costs up to 20 times more expensive. For example, Piramal Enterprises moved trials to Taiwan, Germany, the US, Canada, the Netherlands, and Australia. Biocon and Lupin have also moved some of their trials to the U.S. and Europe. Several Indian CROs have set up trial centers in Southeast Asian nations like Malaysia and Thailand. Phase I and II trials are especially rare in India now.

Due to the rapid expansion of the contract research industry in India in the 2000s, CROs struggled to locate and retain skilled professionals, such as CRAs, project managers, etc. As a result, salary levels increased rapidly, and some CROs chose to train less-skilled employees from the ground up. Particularly in short supply is experience with foreign sponsors and international GCP. Employment of key talent is an increasingly critical benchmark when choosing an Indian CRO.

While there are over 150 CROs in India, we have chosen some that have good reputations in the marketplace.

Ministry of Health and Family Welfare, Department of Health

Nirman Bhavan, Maulana Azad Road

New Delhi 110011, India

Tel: +91 11 2306 1863

Email: secyhlth@nb.nic.in

Website: www.mohfw.nic.in

Central Drugs Standard Control Organization (CDSCO)

Directorate General of Health Services, Ministry of Health and Family Welfare

FDA Bhavan, ITO, Kotla Road, New Delhi 110002, India

Tel: +91 11 2323 6965/75

Fax: +91 11 2323 6973

Email: dcf@nic.in

Website: www.cdscoc.nic.in

Local CROs

6.1 AXIS Clinicals

www.axisclinicals.com

Employees: 400+

Services: Clinical trial support services for Phases II – IV

Address: 1-121/1, Miyapur
Hyderabad 500049
India

Phone: +91 40 4040 8080/8090

Fax: +91 40 4040 8060

Email: bd@axisclinicals.com

Comments:

- AXIS Clinicals has conducted more than 800 clinical studies, with over 250 Abbreviated New Drug Applications (ANDA) submissions with 14 recent FDA approvals. The company also works on EU, Canadian, Brazilian and Australian regulatory submissions.
- The company's clinical researchers have worked with more than 200 clinical investigators across 110 research sites. Their fields of expertise include oncology, central nervous system, cardiology, respiratory, orthopedic, endocrinology and metabolism, as well as vaccine studies.

6.2 Actimus Bioscience
www.actimusbio.com

Established: 2005
Employees: 100+
Services: Clinical trial support services

Address: Varun Towers, 4th Floor
Kasturiba Marg, Siripuram
Visakhapatnam 530003
Andhra Pradesh, India

Phone: +91-89 1667 2000 extn 103
Fax: +91-89 1667 2111
Email: info@actimusbio.com

Comments:

- Actimus Bio is a full service BA/BE CRO catering to pharmaceutical and biotechnology companies.
- The company offers an extensive range of clinical services in bioavailability, and bioequivalence. These include study design, project management, medical safety monitoring, biostatistics, quality assurance auditing, regulatory submissions and scientific communications.

6.4 Areli Life Sciences
www.areli.org

Services: Clinical trial support services for Phases I - IV

Address: India Office:
403 A Maheswari Towers
Opposite ICICI Bank Towers
Road No. 1 Banjara Hills
Hyderabad 500034
India

Phone: +91 40 6555 4577
Fax: +91 40 2337 0017
Email: info@areli.org / bd@areli.org

Address: UK Office:
4 Ashdown
Eaton Road
Hove, East Sussex

BN3 3AQ, United Kingdom

Phone: + 44 75 4513 8648

Email: venkat@areli.org

Comments:

- Areli conducts clinical trials across all therapeutic disease areas in phases IB, II, III and IV. The company caters to biopharmaceutical companies and hospitals.
- The company also provides training and regulatory consulting for clinical trials, independent audits, clinical surveys and contract research staffing.

6.5 Arête Clinical Research

www.aretecr.com

Services: Clinical trial support services for Phases I - IV

Address: India Office:
DBS House, 1-7-43-46
Sardar Patel Road
Secunderabad 500003, India

Phone: +91 40 4050 9200

Fax: +91 40 4050 9300

Email: sheriff@areteclinicalresearch.com

Address: US Office:
4610 Granby Circle
Cumming, CA 30041

Phone: (703) 459-7875

Email: info@areteclinicalresearch.com

Comments:

- Arête is a full service contract research organization that provides services to conduct, coordinate and manage Phase I through Phase IV clinical trials in India. Our large network of research sites, hospitals and GCP trained Investigators from different therapeutic areas facilitates cost effective and high quality drug development research services.
- Arête has experience to maintain the required quality standards and regulatory compliance as per ICH-GCP and FDA/EU standards.
- Arete entered a strategic partnership with US-based Apex Medical Research to jointly provide quality clinical research services in India. Apex Medical Research is a multi-specialty clinical research center.

6.6 Asiatic Clinical Research

www.asiaticclinical.com

Services: Clinical trial support services for Phases II - IV

Address: India Office:
277/A, 10th Main, 6th Cross, 1st Block, Jayanagar
Bangalore 560 011, India

Phone: +91 80 5533 7902/5532 2260
Fax: +91 80 2657 3329
Email: mithra@asiaticclinical.com / info@asiaticclinical.com

Address: US Office:
300 Aurelia Trace
Alpharetta, GA30004, USA

Phone: 770-410-5047
Fax: 503-907-8835

Comments:

- Asiatic focuses on Phases II - IV trials, servicing pharmaceutical and biotechnology companies.

6.7 Clinigene International

www.clinigeneintl.com

Established: 2000
Employees: 150+
Services: Clinical trial support services for Phases I – IV

Address: India Office:
“Clinigene House,” Tower 1, Semicon Park
Electronic City, Phase II, Hosur Road
Bangalore 560 100, India

Phone: +91 80 2808 2780
Fax: +91 80 2808 2737/2801
Email: bd@clinigeneintl.com, denzil.benjamin@clinigeneintl.com

Address: US Office:
876 Highlands Circle
Los Altos, CA94024

Contact: Dr. Brain Treco, Head – Business Development

Phone: 609-638-8203

Address: UK Office:
50, Elm Quay Court
30, Nine Elms Lane
SW8 5DF, London, UK

Contact: Nehal Vora, Sr. Manager of Marketing
Phone: +44 207 819 9788

Comments:

- Clinigene is a subsidiary of the global Indian pharmaceutical company Biocon. Biocon has another subsidiary that performs research for the development of biopharmaceuticals.
- Clinigene is a major CRO with strong clinical trial, regulatory, and laboratory capabilities for drug development. Its Human Pharmacology Unit has experience conducting Phase I to IV clinical trials and BA/BE studies. It also provides a full range of clinical trial support services, including protocol and CRF design, post-marketing surveillance, investigator selection, site monitoring, bioanalysis, data management, biostatistical services, and central laboratory services.
- Clinigene's clinical laboratory was the first in India to be accredited by the CAP (College of American Pathologists). It was recently accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL).
- Clinigene's therapeutic specialties include diabetes, oncology, cardiology, neuropsychiatry, nephrology, immunology, rheumatology, infectious diseases, and gastroenterology.

6.8 ClinInvent Research Pvt. Ltd.

www.clininvent.com

Established: 2003
Services: Clinical trial support services for Phases I – IV

Address: A-103, Everest Chambers
Marol Naka, Andheri-Kurla Road
Andheri (E), Mumbai 400 059, India

Phone: +91 22 6781 8600
Fax: +91 22 6781 8701
Email: arunbhatt@clininvent.com

Comments:

- ClinInvent Research provides comprehensive services for complete clinical trial and data management and conducts international quality clinical research in quality hospitals in India at a competitive cost. ClinInvent is managed by a team of clinical

research professionals who have experience organizing clinical trials for international pharmaceutical companies in India.

- ClinInvent provides the complete range of clinical trial support services including project management, quality assurance, site monitoring, data management, pharmacovigilance, medical writing, GCP training, clinical trial supplies management, and regulatory affairs.
- The president of ClinInvent previously worked as Medical Director at Novartis India and has over 2 decades of experience managing clinical trials in diverse therapeutic fields.
- ClinInvent's staff has expertise in areas including infectious diseases, oncology, dermatology, respiratory, diabetes, immunology, and cardiology.
- 45% of the trials conducted by ClinInvent have been Phase III, 24% Phase II, 20% Phase IV, and 11% Phase I.
- ClinInvent is a division of TCG Lifesciences, which also has divisions for pharmaceutical R&D and laboratory services.

6.10 CliniReach Clinical Services

www.clinireach.in

Established: 2007
Services: Clinical trial support services

Address: No.143-42, 3rd Floor, MM Chamber
6th "C" Main, 4th Block, Jayanagar
Bangalore, India

Phone: +91 80 3256 8809
Email: info@clinireach.in

Comments:

- CliniReach started operations in 2007. It provides services in clinical research, biotechnology, bioinformatics, pharmaceutical, biopharmaceutical, agrochemical and chemical industries.
- Other services offered by the company include CRO site recommendations and selection, protocol design and implementation, study monitoring, report review and evaluation, as well as regulatory document preparation for clinical tests.

6.11 GVK Biosciences

www.gvkbio.com

Services: Clinical trial support services for Phases I - IV

India Office:

Address: Plot No. 28 A, IDA Nacharam
Hyderabad 500076
India

Phone: +91 40 6692 9999
Fax: +91 40 6692 9900
Email: bdcrd@gvkbio.com

Address: US Office:
5457 Twin Knolls Rd. Suite 101
Columbia, MD21045

Phone: 403-542-5805
Fax: 703-940-4088

Address: Singapore Office:
333, North Bridge Rd.
#08-00, KH KEA Building
Singapore 188721

Phone: +65 6837 2133

Comments:

- GVK Biosciences is a part of the \$1 billion GVK group, a large conglomerate in India. GVK Biosciences caters to pharmaceutical and biotechnology companies. It has more than 100 customers, encompassing large pharmaceutical companies, agricultural and life-sciences companies.
- The company is headquartered in Hyderabad with five branch offices in other parts of India.

6.12 Integrity Healthcare Services (IHS)
www.ihsindia.com

Established: 1990

Services: Clinical trial support services for Phases I - IV

Address: Opulence
301-302, 6th Road, Santacruz East
Mumbai 400055, India

Phone: +91 22 6195 5955, +91 22 6195 5921
Fax : +91 22 6195 5901
Email: info@ihsindia.com

Comments:

- IHS is a CRO aimed at providing customized solutions for complete healthcare and pharmaceutical industry requirements. The company is managed by professionals specializing in healthcare, R&D, marketing and financial management.
- Since 1990, the company has conducted more than 50 trials.
- IHS' clinical trials dose escalation, proof of concept, bioavailability, bioequivalence, PK/PD, fed-fasted, as well as drug-alcohol interactions.
- IHS also has a well-established track record of performing special population studies in targeted patient populations, such as cardiovascular, metabolic, osteoarthritis, urologic and dermatologic disorders.

6.13 Lambda Therapeutic Research Pvt. Ltd.

www.lambda-cro.com

Established: 1999
Employees: 500
Services: Clinical trial support services for Phases I – IV

Address: Near Gujarat High Court
S.G.Highway, Gota
Ahmedabad 380 061, Gujarat, India

Phone: +91 79 4020 2020
Fax: +91 79 4020 2021
Email: business@lambda-cro.com, mkracht@lambda-cro.com

Comments:

- Lambda's clinical lab received CAP (College of American Pathologists) accreditation on May 4, 2005. It has a track record of more than 1,000 projects, 35 of which were Phase II or III trials.
- Lambda has three facilities in India. They are located in Ahmedabad (the headquarters), Mumbai, and Chennai, with 410 beds and over 250,000 square feet of space combined.
- Lambda also does bioavailability and bioequivalence tests, laboratory services, clinical data management, and quality assurance.
- In mid-2007, Lambda acquired a Polish CRO, CBK-MPR Pharma.

6.14 Lotus Labs Pvt. Ltd.

www.lotuslabs.com

Established: 2001
Services: Clinical trial support services for Phases I – IV

Address: Lotus House

No 7, Jasma Bhavan Road, Millers Tank Bed Area
Opp. Guru Nanak Bhavan, Vasanth Nagar
Bangalore 560 052, India

Phone: +91 80 2237 0912/3/4/5
Fax: +91 80 4270 8466
Email: info@lotuslabs.com, prasad_rao@lotuslabs.com

Comments:

- Lotus Labs is a wholly owned subsidiary of Actavis PTC ehf, a \$1.4 billion generic pharmaceutical company headquartered in Iceland.
- Lotus Labs completed over 1500 studies (including bioequivalence and bioavailability studies) in its first 7 years of operation. It has expertise in the entire clinical, analytical, and data management spectrum.
- Lotus Labs' 12,000 square foot facility in Bangalore has 4 clinics and a 120 bed capacity. Lotus Labs has also signed a memorandum of understanding with St. John's Academy of Health Sciences in Bangalore, a 1,200 bed hospital, for conducting Phase I, II, and III trials.
- Lotus Labs' facility has been successfully audited by the US FDA by regulatory agencies in France, Brazil, and India, and by the WHO.

6.15 Synchron Research Pvt. Ltd.

www.synchronresearch.com

Established: 1998
Services: Clinical trial support services for Phases I – IV

Address: The Chambers, 3rd Floor
Sarkhej-Gandhinagar Highway
Bodakdev, Ahmedabad 380 054, India

Phone: +91 79 2685 3419
Fax: +91 79 2685 3415
Email: info@synchronresearch.com, gaurav@synchronresearch.com

Comments:

- Synchron provides a wide range of clinical services for Phase I to Phase IV studies, including bioequivalence, bioavailability, pharmacokinetics/pharmacodynamics, statistical analysis, data management, and quality assurance. Its areas of therapeutic experience include antibiotics, diuretics, analgesics, CNS drugs, and cardiovascular drugs.
- Synchron offers highly skilled professionals who are well trained in GCP/GLP.
- In 2004, Synchron was chosen as the preferred partner for all of PAREXEL International's Phase II to IV activities in India. In 2006, Synchron's Bangalore operations were transferred into a new joint venture, PAREXEL International

Synchron Pvt. Ltd. PAREXEL also purchased a 19.5% stake in Synchron's remaining operations in Ahmedabad.

- In March 2007, Synchron opened a 30-bed clinical facility in Bangkok, Thailand.
- In April 2007, Synchron purchased Innovance, another growing CRO in Ahmedabad, India, with an 80-bed clinical facility.
- In March 2008, Synchron purchased a bio-analytical and bio-marker laboratory in France from PAREXEL. At the same time, PAREXEL increased its stake in Synchron to 31%.

6.16 Vimta Labs Limited

www.vimta.com

Established: 1984
Employees: 707
Services: Clinical trial support services for Phases I – III

Address: 142, IDA, Phase II, Cherlapally
Hyderabad 500051, Andhra Pradesh, India

Phone: +91 40 2726 4141
Fax: +91 40 2726 3657
Email: mndo@vimta.com

Comments:

- Vimta claims to be the largest CRO in India. It has conducted clinical trials on approximately 120 drugs. Its professional staff includes 442 scientists. Vimta's services include testing and validation, Phase I to IV clinical trials, central lab services, BA/BE studies, pharmacokinetic studies, and pharmacodynamic studies.
- Vimta's clients have included six Fortune 500 companies and three of the world's "Top Ten" generic drug development companies.

6.17 Asian Clinical Trials Limited

www.act-india.com

Established: 2001
Services: Clinical trial support services for Phases II – IV

Address: Serene Chambers, Rd #5 Avenue 7 Banjara Hills
Hyderabad 500 034, India

Phone: +91 40 2354 3314
Fax: +91 40 2355 0501
Contact: Satish Marukurthi, Sr. Manager, Business Development
Email: msatish@act-india.com; bd@act-india.com

Comments:

- ACT designs and conducts preclinical and clinical Phase II to IV trials for pharmaceutical, biotechnology, and medical device companies, compliant with ICH-GCP standards. It provides a variety of clinical trial support services, including protocol design, project management, data management and statistical analysis, medical writing, study site support, safety surveillance, clinical compliance (including ICH-GCP review and IRB audits), and regulatory affairs.
- The Phase III studies ACT has conducted include myocardial infarction, typhoid, hepatitis B, and chronic lower back pain.
- ACT is a subsidiary of Suven Life Sciences, an Indian drug development and manufacturing services company.
- In April 2008, ACT formed a partnership with VPSCRO, a noted Beijing-based CRO, to conduct trials in both China and India.

6.18 Catalyst Clinical Services

www.catalystclinicalservices.com

Services: Clinical trial support services for Phases II – IV

Address: 119 State Bank Colony, GT Karnal Road
Delhi 110009, India

Phone: +91 11 2746 6248

Fax: +91 11 4238 4005

Email: info@catalystclinicalservices.com

Comments:

- Catalyst Clinical Services is an independent full-service CRO offering the full range of clinical trial support services, including protocol/CRF design, investigator and site selection, quality control/assurance, site monitoring, data management, and regulatory affairs.
- In 2002, Catalyst created Clinical Quest, India's first monthly publication for clinical research professionals.
- Catalyst offers training services for clinical investigators, clinical site personnel, and ethics committee members. It also offers classes specifically focused on oncology trials, GCP, and US regulations on clinical trial data management (21 CFR Part 11).

6.19 SIRO Clinpharm India Pvt. Ltd.

www.siroclinpharm.com

Established: 1997

Employees: > 140

Services: Clinical trial support services for Phases II – IV

Address: 2nd Floor, DIL Complex
Near Vidyapeeth, Swami Vivekanada Rd.
Thane West 400 610, India

Phone: +91 22 2584 8000
Fax: +91 22 2584 8281
Email: bd@siroclinpharm.com

Comments:

- SIRO is one of India's largest local CROs, as well as one of India's first CROs. SIRO provides a wide variety of clinical trial support services including clinical data management, medical monitoring, regulatory consulting, quality assurance, clinical trial supplies management, and project risk assessment and management.
- SIRO has recruited 5,000 subjects in 45 studies across a wide spectrum of therapeutic areas. It also offers cutting-edge data management solutions using the latest database management tools. SIRO has signed an agreement with Pfizer to provide data management and biometrics services for all of its global clinical trials.
- SIRO has conducted clinical trials in multiple global locations simultaneously in head and neck cancer (Phase III, 750 patients), uveitis (Phase III, 260 patients), and glioma (51 patients).
- In 2007, SIRO was awarded the Frost and Sullivan "Partner of Choice" for conducting clinical trials in India.
- In April 2008, SIRO acquired the Omega Mediation Group, a European CRO with operations in Germany, Greece, Estonia, and Israel.
- In April 2009, SIRO and Advanced Clinical Trial Solutions LLC, a US-based company, signed a strategic alliance, enabling SIRO to expand its clinical development in oncology. In August, SIRO formed a partnership with CambReg Regulatory Services, a UK-based company, to help register its products in Europe.

6.20 Accutest India Pvt. Ltd.
www.accutestindia.com

Established: 1998
Services: Clinical trial support services for Phases I-IV

Address: A-31, TTC Industrial Area, Khairane MIDC
Thane Belapur Road
Navi Mumbai 400 709, India

Phone: +91 22 2778 0718/19/21
Fax: +91 22 2778 0720
Email: business@accutestindia.com

Comments:

- Accutest offers a wide range of drug development services, focusing on bioavailability/bioequivalence studies and formulation development. It also provides clinical data management services.
- Accutest has been successfully audited as a clinical site by the US FDA, EMEA, and WHO.
- To date, Accutest has submitted over 140 applications to the US FDA (mostly Abbreviated New Drug Applications), as well as 29 bioprojects, and submitted over 42 applications to the UK MHRA.
- Accutest has full clinical operations sites in Mumbai, Pune, and Ahmedabad.

6.21 Transgene Biotek Ltd.

www.transgenebiotek.com

Established: 1991
Services: Biopharmaceutical clinical trial support services for Phases I-II

Address: Plot 68, 69 & 70, IDA Bollaram
 ANRICH Industrial Area, IDA Bollaram
 Medak District, Andhra Pradesh 502 325, India

Contact : Ms. K.S. Shastry, VP of Marketing
Mobile : +91 98485 61226
Phone: +91 8458 279103/40 6558 9499
Fax: +91 8458 279755
Email: marketing@transgenebiotek.com; info@transgenebiotek.com

Comments:

- Transgene Biotek Ltd. is primarily a biopharmaceutical development company. It was one of the first Indian companies to enter this field in 1991. More recently, it has branched out into pre-clinical and clinical services for biopharmaceuticals.
- Transgene Biotek has particular expertise in bio-generics, vaccines, oncological drugs, and new drug delivery systems.

6.22 Reliance Clinical Research Services

www.relclin.com

Established: 2002
Services: Clinical trial support services for Phase I-IV

Address: Mumbai Office (India headquarters):
 Dhirubhai Ambani Life Sciences Centre
 R - 282, TTC Area of MIDC
 Thane Belapur Road, Rabale
 Navi Mumbai 400 701, India

Phone: +91 22 6767 8000
Fax: +91 22 6767 8299

Address: Bangalore Office:
No: 65-373-2, 1st Phase, 2nd Stage
CPR Towers, BTM Layout
Bangalore 560 076, India

Phone: +91 80 6626 1111
Fax: +91 80 6626 1275
Email: ClinicalResearch.Enquiry@relclin.com

Comments:

- Reliance Clinical Research Services (RCRS) was set up by the Reliance Group, a well-known Indian conglomerate that does business in petrochemicals, textiles, financial services, and telecommunications.
- RCRS offers clinical services in pharmaceutical, vaccine, biotechnology, and medical device areas. It also offers related services including preclinical studies, diagnostic laboratory services, clinical training, and medical writing and translation.
- RCRS has experience in areas including oncology, cardiovascular health, endocrinology, gastroenterology, and infectious diseases.

6.23 Piramal Clinical Research (formerly Wellquest Clinical Research)

Established: 2000
Services: Clinical trial support services for Phase I-III

Address: 4th Floor, Mirra Kamshetty Mall
Opp. Doordarshan Bhavan Ramanthapur
Hyderabad 500013
Andhra Pradesh, India

Phone: +91 40 27032 945/628/630
Fax: +91 40 27033 454
Email: bd.pcr@piramal.com

Comments:

- Wellquest is the clinical arm of Piramal Healthcare Ltd., a prominent Indian pharmaceutical manufacturer and healthcare provider. It makes use of the NPIL's private hospital network, and is housed entirely in its Wellspring Hospital in Mumbai.
- Wellquest conducts bioavailability and bioequivalence tests as well as clinical studies. For Phase II and III studies, it offers other services such as feasibility assessment, protocol generation, laboratory services, and data management.

- Wellquest has a 52-bed ward with a 6-bed ICU, and a database of 2000 healthy patients. Its investigators' specialties include oncology, diabetes, and dermatology.
- To date, Wellquest has conducted 15 pilot studies and 85 pivotal studies for drugs. Its pivotal studies so far have been for Western countries other than the US, such as EU countries, Canada, and Australia. It has received GCP accreditation from the UK's MHRA.

6.24 Sipra Labs Pvt. Ltd.

www.sipralabs.com

Established: 1994
Services: Clinical trial support services for Phases II-IV
Address: 7-2-1813/5/A, Adj, to Post Office
 Industrial Estate, Sanathnagar
 Hyderabad 500 018, Andhra Pradesh, India
Phone: +91 40 2380 2000
Fax: +91 40 2380 2005
Email: sipra@sipralabs.com

Comments:

- Sipra Labs was founded in 1994 focusing on bioequivalence studies, and moved into the clinical trial area in 2001. It has conducted over 200 bioequivalence studies.
- Sipra Labs also conducts stability studies, formulation development, method validation, and pharmacopeial studies.
- Sipra Labs conducts its own laboratory services, which are accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL).
- Sipra Labs has done work for multinational companies including Johnson & Johnson, Procter & Gamble, Novartis Nutrition, and Wyeth.

6.25 Max Neeman International

www.neeman-medical.com

Established: 2001
Employees: 172
Services: Clinical trial support services for Phase I-IV
Address: Max House, GF-1
 Dr. Jha Marg, Okhla
 New Delhi 110 020, India
Phone: +91 11 2632 2816/4077 2100
Fax: +91 11 2632 2846

Email: Dr. Renu Razdan, rrazdan@neemanasia.com
bd@neemanasia.com

Comments:

- From 2001 through 2009, Max Neeman had conducted or commenced 150 clinical trials, with more than 16,000 enrolled patients and 800 available investigators. Many of these were for prominent global pharmaceutical companies, including GlaxoSmithKline, Novartis, Merck, and Pfizer.
- Max Neeman has done three pivotal phase III studies for NDAs in the US. It has also been successfully audited for GCP compliance four times by the US FDA.
- Max Neeman has agreements with several large hospitals across India for clinical trial operations. It also has subsidiary operations in Latin America and the US.
- Max Neeman has a good deal of experience in oncology, endocrinology, ophthalmology, dermatology, cardiology, medical devices, and pulmonology.
- Max Neeman has regional offices in New Delhi, Mumbai, Chennai, Bangalore, Hyderabad, and Pune, and actively uses 102 clinical sites in 22 cities in India.
- Originally named Neeman Medical International, this company is now a subsidiary of Max International, a major Indian healthcare network.

6.26 Veeda Clinical Research

www.veedacr.com

Established: 2005
Employees: 100
Services: Clinical trial support services for Phases I - IIa

Address: Shivalik Plaza-A, Near IIM
Ambawadi
Ahmedabad 380 015, India

Phone: +91 79 3001 3000
Fax: +91 79 3001 3010
Email: info@veedacr.com

Comments:

- Veeda Clinical Research is an Anglo-Indian company, formed through Veeda CR's acquisition of an experienced UK CRO called Phase 1 Clinical Trials Unit Ltd. Veeda also has offices in Germany, Belgium, and Mumbai.
- Veeda CR has a 116-bed Ahmedabad site, specializing in Phase I through IV trials as well as bioequivalence and bioavailability studies. It also offers laboratory services, clinical data management, medical writing, and pharmacovigilance services. It has 61 beds in the UK. Its Mumbai and Belgium locations are biometric facilities.
- Veeda CR's areas of expertise include studies with elderly or female populations, cardiovascular, oncology, diabetes, and renal disease.

6.27 Apothecaries Ltd.
www.apothecaries.net

Established: 1993
Services: Clinical trial support services for Phases I-IV
Address: 876 Udyog Vihar, Phase V
Gurgaon 122016, HR, India
Phone: +91 8588 57484/85
Fax: +91 124 245 1451
Email: ReachUs@Apothecaries.net

Comments:

- Apothecaries offers services in site management, project management, biostatistics, data management, medical writing, regulatory affairs, and clinical pharmacology.
- In the past, Apothecaries has conducted studies for major pharmaceutical companies including GlaxoSmithKline, Eisai, Sanofi Aventis, and Merck.
- In January 2007, Apothecaries signed a non-exclusive agreement with Averion International Corp., a CRO based in Southborough, Massachusetts, to provide clinical services in oncology.
- Apothecaries has provided laboratory services for a World Health Organization-backed survey of counterfeit drugs in India.

6.28 ClinWorld
www.clinworld.org

Services: Clinical trial support services
Address: 102, Arvind Chambers
Western Express Highway
Andheri East
Mumbai 400 069, India
Phone: +91 22 6698 1992, +91 93247 97963 (Sameer Nair)
Fax: +91 22 6698 1994
Email: mumbai@clinworld.org, sameernair@samilabs.com

Address: Bangalore Office:
19/1 & 19/2, 1st Main
IInd Phase
Peenya Industrial Area
Bangalore 560 058, India

Phone: +91 80 2839 7973-75/78
Fax: +91 80 2837 3035

Comments:

- ClinWorld provides clinical trial services, pharmaceutical and biopharmaceutical analysis, pre-clinical services, and regulatory services.

6.29 B.V. Patel Pharmaceutical Education and Research Development Centre (PERD Centre)

www.perdcentre.com

Established: 1990
Services: Clinical trial support services

Address: Sarkhej-Gandhinagar Highway, Thaltej
Ahmedabad 380 054, Gujarat, India

Phone: +91 79 2743 9375, 2741 6409
Fax: +91 79 2745 0449
Email: perd@perdcentre.com

Comments:

- The PERD Centre is a nonprofit organization dedicated to advancing pharmaceutical R&D and the pharmaceutical industry in India. It was founded by the B.V. Patel Education Trust and the Indian Pharmaceutical Association. Besides contract research services, it also conducts original research and offers a Ph.D. program and continuing education for pharmaceutical researchers.
- The PERD Centre conducts clinical trial management, data management, statistical analysis, toxicity and stability studies, bioavailability and bioequivalence studies, QA testing, and product development.
- The PERD Centre has an in-house clinical facility with 36 beds.

6.30 QPS Bioserve India (formerly Bioserve Clinical Research Pvt. Ltd.)

www.qpsbioserve.com

Established: 2005
Services: Clinical trial support services (Phases II-III)

Address: QPS Bioserve India
6-56/6/1A, Opp: IDPL NH9
Hyderabad 500037, AP, India

Phone: +91 40 2377 0873/74
Fax: +91 40 2377 0877

Email: bd@qpsbioserve.com

Comments:

- Bioserve conducts clinical trials in phases II and III for pharmaceutical and biotech products. It also offers services in bioavailability, bioequivalence, and pharmacokinetic studies, site monitoring, investigator training, source data audits, quality assurance, and bioanalysis.
- Bioserve has a GCP-compliant clinical facility with 92 beds.
- Bioserve's therapeutic specialties include cardiovascular, pulmonology, dermatology, psychiatry, oncology, infectious disease, and inflammatory and metabolic disorders.

6.31 Clinsys Clinical Research, Ltd.

www.clinsys.com

Established: 1992
Employees: 300 (global)
Services: Full-service clinical research support

Address: Uttar Pradesh Office:
C-46, Sector 62
Noida 201307, UP, India

Phone: +91 120 4364000
Fax: +91 120 2404336
Email: Surinder Kher, CEO, India, skher@clinsyscro.com

Address: Bangalore Office:
#96, Industrial Suburb, 2nd Stage Industrial Area
Yeshwanthpur, Bangalore 560022, India

Phone: +91 80 6662 8400
Fax: +91 80 6662 8333

Comments:

- The parent of Clinsys is Jubilant Organosys, a major Indian drug research and development services company. In 2005, Jubilant acquired a US-based CRO, CRO Target Research Associates. Clinsys now has its global headquarters in Bedminster, New Jersey.
- Clinsys offers services in project management, site management, biometrics, medical writing, QA, clinical staffing, etc.
- Clinsys's therapeutic specialties include oncology, cardiovascular, central nervous system, dermatology, and respiratory.

6.32 Fermish Clinical Technologies Pvt. Ltd.

www.fermish.com

Established: 2005
Services: Clinical trial support services for Phases I – IV

Address: A-21, Sector 65
Noida 201 301 India
New Delhi 110 020, India

Phone: +91 12 0421 8091/92/93
Email: contact@fermish.com

Comments:

- Fermish provides clinical trial contract management, clinical trial material logistics management, regulatory affairs, call-center and IT services for clinical research, and e-learning.

6.33 Cliantha Research Ltd. (formerly BA Research India Ltd.)
www.cliantha.in

Established: 2004
Services: Clinical trial support services for Phases I and BA/BE

Address: Office 1:
Opposite Pushparaj Towers
Near Judges Bungalows
Bodakdev, Ahmedabad 380 054, India

Phone: +91 79 2685 3088
Fax: +91 79 2685 3093

Address: Office 2:
1st Floor, Silver Arcade, Mujmahuda Rd.
Akota, Vadodara 390 020, India

Phone: +91 265 232 4373
Fax: +91 265 232 4378

Contact: Naveen Sharma-COO; Rahul Nijhawan-Director of Global Project
Email: nsharma@cliantha.in; rnijhawan@cliantha.in

Comments:

- BA Research is a leading Indian CRO, focusing on Phase I trials and bioavailability/bioequivalence studies. It has also conducted transdermal, cardiac

monitoring, and pulmonary studies, as well as studies in post-menopausal women. Overall it has conducted over 380 studies, 14 of those approved by the US FDA.

- BA Research has seven clinical units with a total of 322 beds.
- BA Research's other services include drug analysis, statistical analysis, pharmacokinetics, and QC/QA.

Local Offices of Large Foreign CROs

6.34 ECRON AcuNova Ltd.

www.acunovalife.com

Employees: 300
Services: Clinical trial support services for Phase I-IV

Address: Mobius Towers, SJR i-Park
EPIP, Whitefield
Bangalore 560 066, India

Phone: +91 80 6691 5700
Fax: +91 80 6691 5719
Email: bd.asia@ecronacunova.com

Comments:

- ECRON AcuNova is a joint venture between the Manipal Healthcare Group, a private healthcare and medical education company, and AcuNova Ltd. Its CRO business has access to the 19 hospitals in the Manipal Group, which treat 1.5 million patients annually, for clinical trials and recruitment. It also has agreements with other university hospitals, including the prestigious All India Institute of Medical Sciences in New Delhi.
- ECRON AcuNova has conducted over 50 clinical studies to date. It is particularly known for clinical services for biopharmaceuticals and medical devices.
- ECRON AcuNova offers subsidiary services including clinical data management, bioavailability and bioequivalence tests, laboratory services, site management, and clinical supply management.
- ECRON AcuNova has served clients including Novartis, GE Healthcare, and BioCon.
- Originally called Manipal AcuNova, this company purchased ECRON, a German CRO, in November 2007. ECRON AcuNova is the result of the merging of these two companies' operations, which include a number of Eastern European sites.
- In August 2009, ECRON AcuNova and Essential CRO, a US-based company, formed a global strategic alliance, giving ECRON access to 18 countries for clinical research.

6.35 Quintiles Research (India) Pvt. Ltd.

www.quintiles.com

Established: 1997
Services: Clinical trial support services and commercialization

Address: 2nd Floor, Etamin Block, Prestige Technology Park II
Sarjapur – Marathahalli Outer Ring Road
Bangalore 560 103, India

Phone: +91 80 7131 7778/79
Fax: +91 79 6630 3366
Email: india@quintiles.com

Comments:

- Quintiles India was the first global CRO in India, and is the only CRO in India to be recognized by the Department of Scientific and Industrial Research as a commercial R&D company. Quintiles India has conducted more than 175 clinical studies involving almost 35,000 patients, at over 1,300 sites. All studies are conducted in compliance with ICH-GCP requirements.
- Quintiles India provides clinical trial services for Phase I to IV studies, including protocol development, monitoring, data management, quality assurance, regulatory affairs, and training. It has experience in a variety of therapeutic areas including oncology, psychiatry, endocrinology, anti-infectives, cardiology, and neurology.

6.36 Theorem Clinical Research (formerly Omnicare Clinical Research)
www.theoremclinicalresearch.com

Established: 2002
Employees: 75

Address: HM Towers, 1st and 2nd Floor (local office)
No. 58 Brigade Road
Bangalore 560 001, India

Phone: +91 80 4064 0400/4065 0400
Fax: +91 80 4065 0465

Comments:

- This is the India branch office of Omnicare Clinical Research, a large global CRO headquartered in King of Prussia, PA.
- Omnicare's India office has therapeutic specialties in cardiovascular, neurology, psychiatry, oncology, gastroenterology, ophthalmology, respiratory, osteoporosis, and infectious diseases.

6.37 ICON Clinical Research India Private Limited
www.iconplc.com

Established: 2005
Services: Data management and biometrics

Address: RMZ Millennia Business Park, Building 3A, 2nd Floor (local office)
143 Dr. M G R Road, Kandhanchavady
Chennai 600096, India

Phone: +91 44 4390 2800
Fax: +91 44 4390 2801

Address: Bangalore Office:
No. 56/4, Sharadha Towers (Unit II), 2nd floor
Nandidurg Road
Bangalore 560046, India

Phone: +91 80 4039 4000
Fax: +91 80 4153 5356

Address: New Delhi Office:
#447, Regus Business Centre
Level-4, Sector 53, Augusta Point, Gurgaon-122 002
Haryana 122 002, New Delhi, India

Phone: +91 11 4060 1170
Fax: +91 11 4060 1235
Email: info-India@iconcr.com

Comments:

- ICON Clinical Research opened its Chennai, India office in January 2005. The India office will develop ICON's data management capabilities and biometrics services. ICON also recently acquired Biomines Research Solutions, an Indian data management company, whose co-founders stayed on at ICON.
- ICON India has also added several clinical research associates to its staff to support its expanding clinical development services.
- This is the India branch office of ICON Clinical Research, a large global CRO based in Dublin, Ireland.

6.38 PPD (India)
www.ppd.com

Established: 2004

Address: Pine Valley, Stylus Office
Embassy Golf-Links Business Park
Bangalore 560 071, India

Phone: +91 80 4176 4567
Fax: +91 80 4176 4553

Address: 01-Dynasty B Wing (Kanakia Spaces)
Andheri – Kurla Road, Andheri (E)
Mumbai 400 059, India

Phone: +91 22 4247 2900
Fax: +91 22 4247 2999

Address: Vatika City Point
11th Floor, Sector 25, Mehrauli Gurgaon Road
Gurgaon 122002, India

Phone: +91 80 4176 4567
Fax: +91 80 4176 4553

Comments:

- This is the India branch office of PPD, a large global CRO based in Wilmington, NC.

6.39 PRA International India
www.prainternational.com

Address: 40, IInd Main Road (local office)
R.A. Puram
Chennai 600 028, India

Phone: +91 44 4553 5341
Fax: +91 44 4553 5343
Email: trials@praintl.com

Address: The Qube, A-602 & A-603
C.T.S. No.1498 A/2, M.V. Road, Marol Andheri (East)
Mumbai 400 059, India

Phone: +91 22 7123 4100
Fax: +91 22 7123 4198

Comments:

- This is the India branch office of PRA, an international CRO headquartered in Raleigh, NC with over 3,500 employees worldwide.

6.40 PAREXEL International (India) Private Limited

www.parexel.com

Address: Parexel International Clinical Research
MFAR Silver Line Tech Park
Plot #180, 3rd Floor, EPIP II Phase, Whitefield
Bangalore 560 066, India

Phone: +91 80 4053 8100

Fax: +91 80 4095 6536

Comments:

- This is the India branch office of PAREXEL, a large international CRO based in Waltham, MA. It was purchased from the Indian CRO Synchron in 2006.

6.41 inVentiv Health Clinical (formerly Pharmanet Clinical Services Private Ltd.)

www.inventivhealthclinical.com

Established: 1996

Employees: > 800

Services: Clinical trial support services

Address: 7th Floor, Corporate Center
Andheri-kurla Road, Andheri (East)
Mumbai 400 059, India

Phone: +91 22 3056 9156

Fax: +91 13 3056 9159

Address: Marwah Center, 7th Floor
A&B Wing, Krishanlal Marwah Marg
Andheri (East)
Mumbai 400 072, India

Phone: +91 22 4095 7300

Fax: +91 22 4095 7399

Address: 701-703, Tower B, Apex One, Millennium Plaza
Suchant Lok-1
Gurgaon 122 002, India

Phone: +91 124 309 4000

Fax: +91 124 306 3050

Email: pni@inventivhealth.com

Comments:

- Pharmanet is an international drug development company offering its expertise to the pharmaceutical, biotechnology, medical device, and combined-product industries. It has offices in North America, Europe, and India and was rated as a top 3 CRO in the US and Europe in a 2005 CenterWatch survey.
- Pharmanet provides the full range of clinical trial support services, including protocol/CRF design, project management, quality control/assurance, data management, pharmacovigilance, site management, biostatistics, medical writing, and regulatory affairs.
- Client projects are assigned to dedicated teams that have full access to PharmaNet, an integrated global network linked by data management/biostatistics centers in the US, U.K., and India.

6.42 Medpace Clinical Research India Pvt. Ltd.

www.medpace.com

Address: Reliable Plaza, Ground Floor (local office)
K-10, Kalwa Industrial Area
Thane-Belapur Road, MIDC
Navi Mumbai 400 708, India

Phone: +91 22 6786 3000

Fax: +91 22 6786 8009

Email: info.in@medpace.com

Comments:

- This is the India branch office of Medpace, a large global CRO based in Cincinnati, Ohio.

6.43 Covance India Pharmaceutical Services Limited

www.covance.com

Services: Clinical trial support services and commercialization

Address: Unit Num. 1531-41, 15th Floor, Dev Corpora,
Pokhran Road No.1, Eastern Express Highway
Opp. Cadburys, Thane (W)
Mumbai 400601, India

Phone: +91 22 6700 4810

Fax: +91 22 6700 495

Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It

also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.

- Covance also has Asian offices in Japan, Taiwan, Singapore, the Philippines, South Korea, and China.

CHINA

The China Food and Drug Administration (CFDA) is the national authority that approves and reviews clinical research. The regulation of drugs and clinical trials is outlined by the Drug Administration Law of the People's Republic of China, which went into effect in December 2001, and the Drug Registration Regulation of 2002. Clinical trials are required for all new drug and most imported drug registrations. Trials are also necessary for all generic biological products, as well as certain generic drug applications.

Before a clinical trial may be carried out in China, it must first be approved by the CFDA. The sponsor should prepare and submit the dossier and drug samples to the CFDA, which will consult with the Center for Drug Evaluation (CDE) before issuing a clinical trial approval letter. This process can take 7 to 8 months, but can easily take as much as a year. Historically, this has been due to understaffing at the CDE. In 2012, it was reported that the average approval time for clinical trial application review was 10 months. A clinical trial approval expires after 3 years. The CFDA also has a new, mandatory online registration system for all clinical studies in China. Preliminary registration must be submitted within 1 month of receiving trial application approval from the CFDA, while the registration process must be completed before the start of trial subject enrollment.

Fast track review is available for clinical trials of drugs that treat serious or life-threatening illness, innovative products, and drugs that are the same kind of drug as one that has already been approved. Several months' reduction in the clinical trial application timeframe is also possible in certain cases in which China is part of an international multicenter study. Furthermore, in late 2013 China announced a draft amendment that would make the clinical trial approval process for generic drugs faster and simpler.

A new clinical trial must also be granted approval from the Ethics Committee (EC), submitted in written form to the CFDA before the review of the clinical trial application is completed. This means that the submissions for regulatory approval and EC approval are *sequential*, not parallel as in most countries. EC approval can take a further 2 to 3 months. Clinical trials are only permitted with doctors and hospitals that have been approved by the government and must be conducted according to Chinese GCP, which went into effect in 1999 and was updated in 2010.

In the Administrative Provisions for Drug Registration effective from September 2003, GCP compliance is mandatory for all clinical research supporting drug registration. Informed consent and contracts with investigators must all be translated into Chinese. Principal investigators are responsible for reporting all adverse events to the sponsor, EC, and CFDA, and must provide treatment to the patient immediately. Since 2005, clinical trials must also be conducted in certified clinical hospitals. As of March 2013, 378 such centers had been certified by the CFDA, with different therapeutic specialties.

There are some key elements of Chinese GCP which alter the landscape for clinical trials. Only medical institutions, not independent sites, may be certified to conduct clinical trials. A

principal investigator must be a medical practitioner. Finally, all clinical trials must receive government approval, not merely those used to support product marketing approval.

Phase I clinical trials are generally not recommended in China because lead times are long and cost savings are not very significant. However, there are certain exceptions for proof of concept trials or if China is expected to play a significant sales role after the drug's development. Multi-country trials can generally only start in China after the drug has completed Phase II trials outside of China. Also, although China has agreed to follow the WTO standards on intellectual property rights, enforcement is still a problem.

There are about 100 local CROs in China, as well as numerous affiliate offices of global CROs.

China Food and Drug Administration (CFDA)

26 Xuanwumen Xidajie, Beijing 100053, China

Phone: +86 10 6831 3344

Fax: +86 10 6831 0909

Email: inquires@sfda.gov.cn

Website: eng.sfda.gov.cn

Center for Drug Evaluation (CDE), China Food and Drug Administration

Jia-1, Fuxing Road, Haidian District, Beijing 100038, China

Phone: +86 10 6858 5566

Fax: +86 10 6858 4181

Website: www.cde.org.cn

Local CROs

7.1 Accelovance, Inc.

www.accelovance.com

Established: 1999

Services: Clinical trial support services for Phases II – IV

Address: Hanwei Plaza West Tower 7B20
No.7 Guang Hua Road
Chao Yang District
Beijing 100004, China

Phone: +86 010 5165 4686 x 22

Fax: +86 10 5165 4686 x21

Email: information@accelovance.com

Comments:

- Accelovance is based in Rockville, MD and has 7 clinical sites in the US

- Accelovance’s China division was originally more focused on market research and business development. Accelovance opened its first China office in Beijing in May 2005, and it began conducting clinical trials in 2006.
- Accelovance provides a range of clinical trial support services including patient recruitment, investigator selection, and trial management. It focuses on assisting clinical plans with recruitment troubles, needing testing on certain demographics, or recruiting for very specific indications. It also facilitates market entry into China.
- Accelovance is a vaccine-focused CRO that has successfully completed Phase I-IV studies in general health and nutritional/OTC medications.
- Accelovance was awarded “Best CRO,” a Vaccine Industry Excellence award, at the 2009 World Vaccine Congress.

7.2 PHDS Healthcare Research

www.cnphds.com

Services: Clinical trial support services

Address: A 1201, Ocean Express Reception
No. 66, Xiaguan, North of East Third Ring Road, Chaoyang District
Beijing 100027, China

Phone: +86 10 8446 6229/28/27

Fax: +86 10 8446 6225

Email: customer@cnphds.com

Comments:

- PHDS Healthcare Research is a leading Chinese CRO offering services in international site selection and management, protocol design, subject recruitment, monitoring, data collection and analysis, and NDA submission. It is equipped to do trials from Phases I – IV, and also works in new drug development, pre-clinical research, bioequivalence and bioavailability studies, regulatory affairs, and market research.
- PHDS has conducted 97 clinical trials, many on behalf of foreign pharmaceutical companies, including Chiron (a Novartis subsidiary). 50 of these were global clinical trials, conducted in other countries simultaneously. Top therapeutic areas were oncology, anti-inflammatory, diagnostics, cardiovascular, gastroenterology, and respiratory.

7.3 Vivo Development Ltd.

www.vivodevelopment.com/

Services: Clinical trial support services

Address: Suite 109, 518 Bibo Road

Zhang Jiang High Tech Park, Pudong District
Shanghai 201203, China

Phone: +86 21 5027 5346/7/8
Fax: +86 21 5027 5349
Email: contact@vivodevelopment.com

Comments:

- Vivo Development was founded by Chinese returnees with significant experience in global pharmaceutical companies in the US and Europe.
- Vivo offers clinical trial support services in Phases I-III, including study design and planning, project management, and medical writing. It also has businesses in technology transfer and pharmaceutical consulting.
- Vivo's particular therapeutic specialty is in psychiatric medicine: it is partnered with the Shanghai Mental Health Center and has conducted 33 clinical trials for various psychiatric disorders, including four multi-national trials with large Western pharmaceutical companies. It also has experience in cardiology, clinical pharmacology, oncology, and biostatistics.
- Vivo is in partnership with Arianne Consulting, a California-based CRO with offices in Serbia, India, and Singapore.

7.4 Venturepharm Services CRO Group

www.venturepharm.com

Established: 2000
Services: Clinical trial support services for Phases I-IV

Address: Venturepharm Towers
No. 3 Jinzhuang, Si Ji Qing, Haidian District
Beijing 100097, China

Phone: +86 10 8850 0088 x397
Fax: +86 10 8850 0080
Email: info@venturepharm.net

Comments:

- Venturepharm Services CRO Group, or VPSCRO, is a Sino-Canadian-American joint venture of Venturepharm Laboratories Limited, which also has operations in drug discovery and development, contract API manufacturing, and contract drug sales and marketing.
- VPSCRO has completed over 100 clinical trials and has about 70 trials ongoing. Its therapeutic specialties include oncology, central nervous system, cardiovascular, gastrointestinal, respiratory, allergy and immunology.
- VPSCRO has had GlaxoSmithKline, Novartis, and other major drug companies as clients.

- VPSCRO has alliances with over 200 hospitals in 20 Chinese provinces.
- In April 2008, VPSCRO formed a partnership with ACT, a noted Indian CRO, to conduct trials in both China and India.

7.5 Newsummit Biopharma

www.newsummitbio.com

Established: 2001
Services: Clinical trial support services for Phases I-IV

Address: 2F, No. 780, Cailun Rd.
 Zhangjiang High Technology Park, Pudong District
 Shanghai 201203, China

Phone: +86 21 5079 8788
Fax: +86 21 5079 8788*8088
Email: ibd_information@newsummitbio.com

Comments:

- Newsummit Biopharma supports conducting international multi-center trials, as well as trials for traditional Chinese medicine and biological drugs. Its therapeutic specialties include cardiovascular, pulmonary, anti-infection, rheumatism, and gastroenterology. It also offers pre-clinical studies, laboratory services, contract manufacturing consulting, and NDA filing.
- Newsummit is also developing its own new biopharmaceutical products, with several dozen candidates at various pipeline stages.
- Newsummit has a partnership with the Harvard Medical School Department of Cell Biology.

7.6 Giant Med-Pharma Services, Inc.

www.med-pharmachina.com

Established: 2001
Services: Clinical trial support services for Phases I-IV

Address: Room 2002, Jianguo Wuhao Plaza
 No.5 JianGuoMen North Street
 Dongcheng District
 Beijing, 100005, China

Phone: +86 10 5128 1119
Fax: +86 10 6611 2200
Email: giant@giantcro.com

Comments:

- Giant offers services in clinical trial management, clinical monitoring, biostatistics, study report writing, quality control, healthcare market research, and translation services.
- Giant has successfully completed 20 clinical trials and currently has 10 more under way. It has worked for clients including GlaxoSmithKline, AstraZeneca, Novartis, and Wyeth.
- Giant is led by Dr. Winston Wu, a medical doctor who has investigated psychiatric drugs at Peking University and also has management experience with Watson Pharmaceuticals.

7.7 Shanghai SLG CRO Co., Ltd.

www.china-cro.com

Established: 2005
Services: Clinical trial support services for Phases I – IV

Address: Room 1204, Orientgolden Building
No. 729 Pujian Road
Shanghai 200127, China

Phone: +86 21 6146 4128
Fax: +86 21 6146 9793
Email: bd@china-cro.com.cn, bd@china.cro.com

Comments:

- SLG offers a variety of clinical trial support services, including clinical trial management for Phases I-IV, biostatistics, clinical data management, pharmacovigilance, and development and marketing consulting.
- SLG has provided services for Novo Nordisk, Pfizer, Wyeth, Roche, Eli Lilly, AstraZeneca, and GlaxoSmithKline.
- SLG is partnered with three Western CROs (Monitoring Force, based in Washington, DC; ReSearch Pharmaceutical Services, based in Fort Washington, PA; and ResearchPoint, based in Austin, TX) and one SMO (Global Rank Team, based in Lombard, IL). It is also a business partner of the major Chinese pharmaceutical firm Fosun.
- SLG has branch offices in Beijing and Shijiazhuang (in Hebei province).

7.8 Tigermed Consulting

www.tigermed.net

Established: 2002
Services: Clinical trial support services for Phases I – IV

Address: Hangzhou (registered headquarters)
Floor 17, Baoyichuangyi Plaza
No. 3760 Nanhuan Rd.
Binjian District, Hangzhou, Zhejiang Province 310053, China

Phone: +86 571 28887227

Fax: +86 571 88211196

Email: bd@tigermed.net

Address: Shanghai (operational headquarters)
Suite 813, No. 999 West Zhongshan Road
Shanghai 200051, China

Phone: +86 21 3250 3700/6278 0991/92

Fax: +86 21 3250 3707

Address: Beijing
Suite 805 Union Plaza
No. 20 Chaoyangmenwai Street
Chaoyang District, Beijing 100022, China

Phone: +86 10 65889599/65885988

Fax: +86 21 65889119

Comments:

- Tigermed's services include management of clinical trials in all phases, as well as biostatistics, manufacturing and quality consulting, regulatory affairs, and medical translation.
- Tigermed has grown quickly since its founding in 2002, now having over 300 staff in total, 21 branch offices across China, and one subsidiary in the US with two offices.
- Since 2002, Tigermed has completed 110 clinical trials. It has worked with drugs, medical devices, diagnostic reagents, and functional food products. Its therapeutic areas include oncology, HBV, vaccines, and cardiovascular.
- In November 2008, Tigermed formed partnerships with two foreign CROs, OCT in Russia and LSK in Korea. The aim was to create a global clinical trial network together with these two companies.
- In April 2010, Tigermed signed a collaboration agreement with Ireland-based ICON to offer pharmaceutical and biotechnology companies better access to Chinese patients. ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries.

7.9 Guangzhou Boji Clinical Research Center

www.gzboji.com

Established: 1998

Services: Clinical trial support services for Phases I – IV

Address: 15th Floor, Yin Hui Building
Wu Shan Long Yi Road, Tianhe District, Guangzhou
Guangzhou, China

Phone: + 86 20 3847 3208/09
Fax: + 86 20 3847 3053
Email: boji588@163.com
Contact: Dr. Wang
+86 20 3847 3067; +86 186 888 58278

Comments:

- Guangzhou Boji was one of the earliest CROs in China. It is a subsidiary of the Boji Medicinal Service Group.
- The company has conducted more than 500 trials over the last 10 years. Currently, more than 100 trials are being conducted.
- Guangzhou Boji has 25 other offices in China, including Beijing, Xi'an, Shanghai, Wuzhou and Chongqing.

7.10 Huaxipharm Group
www.huaxipharm.com/en/

Services: Clinical trial management for Phases I-IV

Address: Advanced Materials Building
No.7 Fenghuizhong Road
Haidian District
Beijing, 100094, China

Phone: +86 10 8072 0737/8034/8016
Fax : +86 10 8072 0803
Email: manage@huaxipharm.com, market-2@huaxipharm.com
investment@huaxipharm.com

Comments:

- Huaxipharm is a research-based pharmaceutical company in Beijing. The company is focused on the discovery, development and marketing of medicines, active pharmaceutical ingredients and CRO services in China.

7.11 WuXi PharmaTech (WuXi AppTec)
www.wuxiapptec.com/index.html

Established: 2008

Services: Clinical trial support services for Phases I-III

Address: WuXi AppTec (Shanghai) Co Ltd
288 Fute Zhong Road
Waigaoqiao Free Trade Zone
Shanghai 200131, China

Phone: +86 21 5046 1111

Fax : +86 21 5046 1000

Email: info@wuxiapptec.com

Comments:

- WuXi PharmaTech is a leading global contract research outsourcing provider. The company was a result of the merger between China's WuXi PharmaTech Inc. and US-based AppTec Laboratory Services Inc.
- The company is headquartered in Shanghai. It has operations in both China and the US.
- WuXi Pharma Tech has a trained workforce of about 4,500 employees, of which, about 3,500 are scientists.

7.12 MedKey Med-Tech Development

Address: Floor 14Ath, East Ocean Centre
No. 618 Yan'an Rd. Huangpu District
Shanghai 200001, China

Phone: +86 137 0115 0792; +86 21 5306 1011

Fax: +86 21 5306 1029

Email: info@wuxiapptec.com, lin_zhong@wuxiapptec.com

Comments:

- MedKey conducts clinical trials in Phases I through IV, including project planning, protocol design, CRFs, informed consent forms, and site selection. It also offers data management, statistical analysis, regulatory affairs, and market research services.
- MedKey's past clients include large multinationals such as GlaxoSmithKline, Merck, AstraZeneca, Sanofi-Aventis and Medtronic.
- MedKey was purchased by WuXi AppTec as a wholly-owned subsidiary.

7.13 Shanghai Pharma Engine Co., Ltd

www.pharma-engine.com/EN/index.asp

Services: Clinical trial support services

Address: 2F, Sec. A, 781 Cailun Road
Zhangjiang Hi-Tech Park, Pudong New Area

Shanghai 201203, China

Phone: +86 21 5855 5018
Fax : +86 21 5855 8075
Email: mail@pharma-engine.com

Comments:

- Shanghai Pharma Engine Co Ltd provides whole solutions and consulting services to bio-pharmaceutical companies in the area of new drug development and clinical research.

7.14 Shanghai ChemPartner Co. Ltd

www.shangpharma.com

Established: 2003
Services: Clinical trial support services

Address: No. 5 Building, 998 Halei Road
Zhangjiang Hi-Tech Park
Pudong New Area
Shanghai 201203, China

Phone: +86 21 5132 0088

Email: sales@chempartner.cn

Comments:

- Shanghai ChemPartner is one the leading CROs in China, serving more than 120 customers. The company provides chemistry, biology, pharmacology, DMPK, process R&D, pre-formulation, and analytical development services to global pharmaceutical and biotech companies.
- The company has more than 1,200 scientists in total, with branch offices in the US, Canada, Japan and Europe.

Local Offices of Large Foreign CROs

7.15 Covance

www.covance.com

Established: 1998
Services: Clinical trial support services

Address: Beijing
Units 1501-1508, Tower A, Gemdale Plaza (local office)

No. 91, Jianguo Rd., Chaoyang District
Beijing 100022, China

Phone: +86 10 6569 4118
Fax: +86 10 6569 4119

Shanghai
1st Floor, No. 6 Building
No. 151 Li Bing Road, Zhangjiang Hi-Tech Park
Shanghai 201203, China

Phone: +86 21 6171 1200
Fax: +86 21 6434 03027
Email: info@covance.com

Comments:

- Covance Inc. opened its Beijing office in 1998 and was the first company of its kind to test traditional Chinese medicines for the approval of the US FDA. This was done through a strategic agreement with the China Innovation Center for Life Sciences (CICLS), a department of the Chinese Ministry of Science and Technology, in conjunction with a number of Chinese pharmaceutical companies.
- In 2004, Covance Inc. partnered with Excel PharmaStudies Inc., the largest local Chinese CRO, to expand its clinical trial services in China. Covance also provides ongoing training to Excel PharmaStudies.
- To date, Covance has managed more than 2,200 patients and 100 investigator sites in China.
- Covance has China offices in Beijing, Shanghai, and Hong Kong.

7.16 EPS International China Co., Ltd.

www.epscn.com / www.eps-inter.com/en/index.html

Established: 2001
Services: Clinical trial support services for Phases I – IV

Address: Shanghai Office:
5th Floor, Building B, Gateway Plaza
No.329 Tianyaoqiao Road,
Xuhui District
Shanghai, 200030, China

Phone: +86 21 3363 2793
Fax: +86 21 3363 2784

Address: Beijing Office:
Room 1012, North Junefield Plaza

No.10, Xuanwumenwai Street
Xuanwu District
Beijing 100052, China

Phone: +86 10 6310 2821
Fax: +86 10 6310 4961

Address: Guangzhou Office:
Room 15A, Chung Kiu Building
No. 76 Xianlie Middle Road
Guangzhou 510095, China

Phone: +86 20 8732 4885
Fax: +86 20 8732 4887
Email: info@epsgr.com

Comments:

- EPS China Co. Ltd. is a branch of EPS Co., Ltd. of Japan.
- EPS China Co. Ltd. provides a range of clinical support services including patient enrollment, trial monitoring, test drug management, data management and statistical analysis, auditing, document preparation, site and investigator selection, and training.

7.17 CMIC (Beijing) Co., Ltd.

www.cmic.co.jp/corporate/group/beijing.shtml

Established: 1998
Services: Clinical trial support services for Phases I – IV

Address: Beijing
B610-612, COFCO Plaza
No. 8 Jianguomennei Avenue
Beijing 100005, China

Phone: +86 10 6513 9211
Fax: +86 10 6513 9213

Shanghai
Suite 20E, Tower 1
Lane 99 Caoxi (N) Road
Shanghai 200030, China

Phone: +86 21 5406 0501

Comments:

- CMIC Beijing provides a range of clinical trial support services for Phase I to IV trials, including data management, strategic consulting, and post-market surveillance.
- CMIC Beijing is a subsidiary of CMIC Japan, a large Tokyo-based CRO.

7.18 Quintiles

www.quintiles.com

Established: 1997

Address: Beijing Office:
Office Tower 3, Unit 901-919
Sun Dong An Plaza
138 Wang Fu Jing Da Jie, Dong Cheng District
Beijing 100006, China

Phone: +86 10 5911 7888

Fax: +86 10 5911 7999

Email: clinical.info@quintiles.com, asia@quintiles.com

Address: Shanghai Office :
3F, 5F, Building A
388 Feng Lin Road
Shanghai 200032, China

Phone: +86 21 2422 8888

Address: Dalian Office :
10-02/04, 10F Bldg#1, Hui Xian Yuan
Dalian High-tech Industrial Zone
Dalian 116025, China

Phone: +86 411 8498 8188

Comments:

- Quintiles Transnational opened its Beijing office in 1997 to expand its presence in the East Asian region. The Beijing office was the 9th Quintiles office in the Asia Pacific. It provides a range of clinical trial services, as well as health care consulting.
- Innovex China, a Quintiles subsidiary, was established in 1998 and provides a range of services to both local and international pharmaceutical companies, including commercial solutions, marketing, sales, and health management.
- In January 2008, Quintiles Transnational began consolidating its Global Clinical Laboratories and Clinical Development Services units into one new 17,000 square-foot facility in Beijing.

7.19 INC Research (previously MDS Pharma Services (China))

www.incresearch.com

Established: 1997
Services: Clinical trial support services and central laboratory

Address: Beijing Office
Suite 608, CBD International Mansion
No. 16 Yong An Dong Li, Chaoyang District
Beijing 100022, China

Phone: +86 10 5809 2300

Fax: +86 10 6588 9010

Address: Shanghai Office:
11th Floor, Unit 2
Shanghai Times Square
93 Huaihai Zhong Road
Shanghai 200021, China

Phone: +86 21 6171 6800

Contact: Louise Hogan, VP of Business Development, Asia
+61 3 9567 7625

Comments:

- US-based INC Research acquired MDS Pharma Services from MDC Inc. in July 2009. Prior to the acquisition, MDC Pharma was the first global CRO to set up offices in China. Its China office continues to offer the full range of clinical development services. It also provides regulatory consulting, product registration, recruiting, and consumer product services.
- The company conducted the largest global Phase II and III hepatocellular carcinoma trial ever in China. One hundred patients were recruited at 13 sites in China, and regulatory approval was obtained in 8 months.
- In 2002, the company's (then known as MDC Pharma) central clinical laboratory in Beijing became the first laboratory in China to receive accreditation from the College of American Pathologists.
- In addition to global central lab services, it also provides support and testing services including standardized assays and methodologies, remote data access, blood collection and hematology services, ECG services, and drug screening. All clinical sites are in compliance with GCP and GLP.
- The Beijing lab has also received Level II certification from the National Glycohemoglobin Standardization Program.

7.20 inVentiv Health Clinical China (formerly PharmaNet Ltd.)

www.inventivhealthclinical.com

Address: Beijing Office:
7F, Room 701, Tower A, Gemdale Plaza
No. 91 Jianguo Road, Chaoyang District
Beijing 100022, China

Phone: +86 10 5962 8300

Fax: +86 10 5962 8310

Address: Shanghai Office:
15F, Room 1507-1508, Grant Gateway
No.1 Hongqiao Road, Xuhui District
Shanghai 200030, China

Fax (only): +86 21 6037 1959

Email: pni@inventivhealth.com

Comments:

- This is the China subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

7.21 PPD (China)

www.ppdi.com

Established: 1998

Services: Clinical development

Address: Beijing Office (Development):
8/F, Tower B, Central Point Plaza
No. 11, Dongzhimen South Avenue
Dongcheng District
Beijing 100007, China

Phone: +86 10 5763 6250

Fax: +86 10 5763 6251

Address: Beijing (PPD Global Central Lab):
Beijing Lawke Health Labs Ltd.
D101 Zhongguancun Life Science Park
No. 29 Changping Shengmingyuan Road
Beijing 102206, China

Phone: +86 10 8072 0625

Fax: +86 10 8072 0632

Address: Shanghai Office (Development):
Suite 2009, Liu Lin Tower
No.1 Huai Hai Zhong Road
Shanghai 200021, China

Phone: +86 21 5383 4000

Fax: +86 21 6386 3808

Comments:

- This is the China branch office of PPD, a large global CRO based in Wilmington, NC.

7.22 PAREXEL International

www.parexel.com

Services: Clinical development for Phases I - IV

Address: Shanghai Office:
20F, Taiping Finance Tower
No. 488, Middle Yincheng Rd.
Pudong, Shanghai 200120, China

Phone: +86 21 5111 8000

Fax: +86 21 6160 9193

Email: info@parexel.com

Address: Beijing Office:
Room 1115, 11F, Kuntai International Mansion Building
Yi, No.12 Chao Yang Men Wai Street
Chao Yang District
Beijing 100020, China

Phone: +86 10 5763 1500

Fax: +86 10 5879 7671/72

Comments:

- This is the China branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

7.23 Astrom Research International

www.astromresearch.com

Services: Clinical trial support services for Phases I – IV

Address: Room 2103, Dongbo Building
168 Shangwen Road
Shanghai, China

Address: Karl XII gatan 4
Se 22220 Lund, Sweden

Contact: Dr. Stefan Åström, Chief Executive Officer
Mobile: +46 708 634909
Phone: +46 46 14 40 39
Email: stefan@astromresearch.com

Comments:

- Astrom Research is a CRO and specialized consultancy focusing on clinical trials and medical research in China for pharmaceutical, biotech, and medical device companies. Astrom provides complete service for clinical trials through a well-established local network of high quality university hospitals located in all major Chinese cities. It assists with the start-up, performance, and reporting of clinical trials in China, and also provides data management, ICH-GCP monitoring, and GCP training. In addition, it also assists with clinical trial applications and medical device product registration in China.
- Astrom's therapeutic expertise covers a variety of areas including cardiovascular, infectious diseases, neurology, respiratory, gynecology, rheumatology, nephrology, endocrinology, and hematology.
- The company's CEO, Dr. Stefan Astrom, previously served as CEO for Sweden-based Hylae Clinical Research and as Clinical Research Director for Astra in Toronto.

7.24 Protech Pharmservices Corporation (PPC) (China)
www.ppcro.com

Established: 2003
Services: Clinical development for Phases 1- IV

Address: Beijing Office:
Room 704, Tower 3, Beijing International Center
No. 38 Dong San Huan Bei Road, Chaoyang District
Beijing 100026, China

Address: Shanghai Office:
Room 801, SunYoung Center
No. 398 Jiangsu Road, Changning District
Shanghai 200050, China

Email: contact@cro.asia, sha@ppcro.com, protech@protechlab.com.tw

Comments:

- This is the China office of PPC, an international CRO based in Taipei, Taiwan.

7.25 Theorem Clinical Research (formerly Omnicare Clinical Research)

www.theoremclinical.com

Established: 2008
Services: Clinical trial support services for Phases I – IV

Address: Beijing Office:
Unit 1510, Beijing East Ocean Centre (local office)
JianGuoMenWai Street
ChaoYang District
Beijing 100004, China

Phone: +86 10 65156177
Fax: +86 10 65671916

Address: Shanghai Office:
Room 2001-2004
No. 83 Lou San Guan Road
New Town Center
Shanghai 200336, China

Phone: +86 21 6236 8678
Fax: +86 21 6236 8679

Comments:

- This is the China branch office of Theorem Clinical Research, a large global CRO headquartered in the US.
- In 2011, Omnicare Clinical Research became Theorem Clinical Research.

7.26 ICON Clinical Research

www.iconplc.com

Established: 1990 (Dublin headquarters)
Services: Clinical trial support services for Phases I – IV

Address: Beijing Office:
Room 1101-05, Tower B, Global Trade Center
No. 36 East Third Ring North Road, Dongcheng District
Beijing 100013, China

Phone: +86 10 5781 5100

Fax: +86 10 5781 5199

Address: Shanghai Office:
Room 703 A-B, Chong Hing Finance Center
No. 288 Nanjing West Road
Shanghai 200003, China

Phone: +86 21 6361 9001

Fax: +86 21 6361 9006

Email: info@iconaus.com.au

Comments:

- This is the China branch office of ICON Clinical Research, an international CRO based in Dublin, Ireland. ICON has two other branch offices in Shanghai and Tianjin.

7.27 CCBR Beijing Center

www.synarc.com

Established: 1992

Services: Clinical trial support services for Phase II - III

Address: 1st Floor Tower C, No. 29
Life Science Park Road
Changping District
Beijing, China 102206

Phone: +86 10 8072 9990

Fax: +86 10 8070 5506

Contact: Pengchang Ha, GM

Mobile phone: +86 1342 601 9977

Email: pengchang.ha@ccbr.com; ccbr.beijing@ccbr.com

Comments:

- CCBR is a Danish CRO, founded in 1992 with multiple clinical centers mostly in Eastern Europe. In 2006, CCBR was acquired by Synarc, a pharmaceutical services company based in San Francisco, but kept its name.
- CCBR Beijing offers services in clinical trial management (phases II and III only), biostatistics, clinical data management, trial design, and trial registration with the CFDA. It works in partnership with the Beijing Friendship Hospital, which is one of Beijing's well-reputed hospitals and is often used by foreigners.
- CCBR Beijing's therapeutic specialties include osteoporosis, arthritis, women's health, cardiovascular, and obesity.

7.28 PRA International China
www.prainternational.com

Established: 1981 (US headquarters)
Services: Clinical trial management for Phases I - IV

Address: Shanghai Office:
Unit 1830, 18F Bund Centre
222 Yan'an Road East
Huangpu District, Shanghai 200002, China

Phone: +86 21 6340 4425
Fax: +86 21 6340 4763

Address: Beijing Office:
Room 2308-2318, 23F, Tower B, Gemdale Plaza
No. 91 Jianguo Road, Chaoyang District
Beijing 100022, China

Phone: +86 10 6561 0216
Fax: +86 10 6561 0217
Email: trials@praintl.com

Comments:

- This is the China branch office of PRA, an international CRO headquartered in Raleigh, NC with over 3,500 employees worldwide.

7.29 Beijing Medpace Medical Science & Technology Ltd.
www.medpace.com

Established: 2002 (US headquarters)
Services: Clinical trial management for Phases 1 - IV

Address: No 23, East Business Tower
Sheng Shi Long Yuan
No 1005, Gao Bei Dian Xiang Xi Dian
Chaoyang District
Beijing 100022, China

Phone: +86 10 8770 6500
Fax: +86 10 8770 6422
Email: info.cn@medpace.com

Comments:

- This is the China office of Medpace, a large global CRO based in Cincinnati, Ohio.

7.30 Beijing CRO Bio-Pharmaceutical Development Co., Ltd.

www.b-cro.com

Established: 2004
Services: Clinical trial support services for Phases I – IV
Address: Room 2201, Tower 1, Handerson Center
No. 18 Jianguomen Nei Street, Dongcheng District
Beijing, China
Phone: +86 10 6561 8582/ 6561 9100
Email: info@cro.co.jp

Comments:

- Beijing CRO is a subsidiary of Tokyo CRO, Inc., a Japan-based CRO.

7.31 Shanghai InCROM Pharma Development Co.

www.incrom.com/English/china/

Established: 2005
Services: Clinical trial support services
Address: Shanghai Head Office:
Room 603, Building C, Hi-Tech Building
900 Yishan Road,
Shanghai, China 200233
Phone: +86 21 5423 4291
Fax: +86 21 5423 4292
Address: Beijing Office:
D-2713 SOHO New Town
No.88 Jianguo Road, Chaoyang District
Beijing 100022, China
Phone: +86 10 8580 3606
Fax: +86 10 8580 4058
Email: china-info@incrom.com

Comments:

- Shanghai InCROM is a unit of Japan InCROM (International Clinical Research Organisation for Medicine). Japan InCROM was one of the first clinical research providers in Japan. It also has offices in Beijing, Chengdu and Guangzhou.

MALAYSIA

Malaysia is a popular location for clinical trials because of its relatively developed hospital infrastructure, advanced regulatory environment, and easy access to both doctors and patients. The entire approval process can take as little as three months, significantly less than other countries in the Asia Pacific region.

The National Pharmaceutical Control Bureau (BPFK, abbreviated from its Malaysian name) oversees pharmaceutical regulations in Malaysia and undertakes the daily activities of drug and cosmetic registration, as well as other monitoring and surveillance activities. Under the Control of Drugs and Cosmetics Regulations (1984), the Drug Control Authority of the BPFK is the licensing and regulatory authority. The Clinical Research Centre, set up in 2000, promotes and supports clinical research at Ministry of Health hospitals and teaching hospitals.

The Malaysian government has also launched a plan to support the clinical trial industry in Malaysia, hoping to have 1,000 trials taking place in the country by 2020. Training clinical researchers is one of the essential aspects of this plan -- with a goal to have 1,000 new clinical investigators by 2020.

The sponsor of a clinical trial in Malaysia must complete two primary approval processes before the trial may begin. First, the clinical trial must be reviewed for scientific merit and ethical concerns. Approval is granted by the Research Review Committee (RRC) and the Medical Research Ethics Committee (MREC). Second, the clinical trial must be approved by the BPFK to receive a clinical trial import license/permit. These two applications may be made in parallel. If the clinical trial will be conducted at a Ministry of Health hospital, the clinical trial applications should be submitted to the RRC and MREC. If the clinical trial will be conducted at a university or other private facility, the applications should be submitted to the RRC/MREC-equivalent body at the institution.

For RRC and MREC approval, the sponsor should submit the appropriate documents to the Secretariat to the Standing Committee for Medical Research (SSCMR). The Standing Committee for Medical Research is located in the Institute for Medical Research (IMR), and is the executive body for research in the Ministry of Health. The SSCMR will then pass along the relevant documents to the RRC and MREC.

The Research Review Committee evaluates the scientific merit and expected benefits of the research proposal. It meets six times a year (typically in February, May, July, August, September, and November), at which time the principal investigator must defend the research proposal. The Medical Research Ethics Committee evaluates the ethical aspects of the study to ensure that it complies with internationally accepted standards. The MREC generally meets 3 to 4 weeks after the RRC meeting, and will review the research proposal and recommend approval, rejection, or revision of the proposal.

The comments of the RRC and the MREC will be sent to the Director-General of Health, who makes the final decision. The time from submission to the RRC/MREC until final approval is about 3 to 4 months.

The sponsor or principal investigator must also apply to the BPFK for an import license/permit for importation of the drug. There are four types: 1) a clinical trial import license (CTIL); 2) a permit for a clinical trial of an unregistered drug manufactured in Malaysia (CTX); 3) a permit for a clinical trial of a registered drug with special labeling; and 4) a permit for a clinical trial of a new indication on a registered product.

The application should include an approval letter from the RRC and MREC, GMP certificate from the country of manufacture, and other supporting documents. Starting in January 2012, all new generic drugs applying for clinical trials must also provide a bioequivalence study. Furthermore, all clinical trials requiring a license must be registered with the National Medical Research Register (NMRR) *before* applying for an import license -- or else the import license application will fail.

The Clinical Trial Regulatory Unit (CTRU), established in July 2004, evaluates the import license application documents. The approval process generally takes 4 to 8 weeks after submission of the application. CTILs are valid for 3 years. In 2011, the Malaysian government approved 224 CTILs and 10 CTXs.

Malaysian GCP guidelines were implemented in 1999, with the most recent (third) edition in 2011, and are adapted from the ICH-GCP guidelines and the Declaration of Helsinki. All investigators are required to receive approved GCP training and certification before overseeing a clinical study. The Malaysia government has established centers for training investigators and is developing a nationwide training program. All fatal and life-threatening adverse reactions occurring in the course of a clinical study must be reported to the Malaysia Adverse Drug Reactions Advisory Committee within 7 days after the principal investigator first learns of the adverse event.

In 2011, there were 67 clinical trials conducted in Malaysia (excluding bioequivalence studies). Of these, approximately 8 were Phase I trials, 14 were Phase II trials, 37 were Phase III trials, and 1 was a Phase IV trial.

Institute for Medical Research

Jalan Pahang, 50588 Kuala Lumpur, Malaysia

Tel: +60 3 2616 2666

Fax: +60 3 2693 9335

Email: infoimr@imr.gov.my, portal@imr.gov.my

Website: www.imr.gov.my

National Pharmaceutical Control Bureau

Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia

Tel: +60 3 7883 5400

Fax: +60 3 7956 2924

Email: eishah@bpfk.gov.my

Website: www.bpfk.gov.my

National Committee for Clinical Research

National Pharmaceutical Control Bureau, Lo 36, Jalan Universti
42600 Petaling Jaya, Malaysia; Attn: Dr. Kamaruzaman Saleh

Tel: +60 3 7883 5400

Fax: +60 3 7955 1030

Email: kazan@bpfk.gov.my

Website: www.nccr.gov.my

Local CROs

8.1 Clinical Research Centre

www.crc.gov.my

Established: 1997 (operational in 2000)

Services: Clinical trial support services

Address: Level 3 Dermatology Block, Kuala Lumpur Hospital
Jalan Pahang 50586, Kuala Lumpur, Malaysia

Phone: +60 3 2692 4249, +60 3 2691 1486

Fax: +60 3 2691 1682

Email: contact@crc.gov.my

Comments:

- The Clinical Research Centre (CRC) functions as the clinical research arm of the Ministry of Health (MOH) of Malaysia. It has been operational since 2000 and aims to be one of Malaysia's leading clinical research organizations. It now contains 27 clinical centers in MOH hospitals across Malaysia, with access to more than 25,000 doctors in public hospitals and clinics.
- The CRC is one of several research organizations under the umbrella of the National Institute of Health of the MOH. Its role is to promote, support, and conduct clinical research. It also aims to encourage more clinicians, especially those working in MOH hospitals, to participate in industry-sponsored trials.
- The CRC provides a wide range of clinical trial services, with the core services being: study design, investigator recruitment, site management, study monitoring, safety surveillance, data management, biostatistics, electronic publishing, and regulatory submissions. It has particular strength in Phase II and III trials, but also supports Phase IV trials to investigate new indications and can provide post-marketing pharmacovigilance.
- The CRC serves both public and private clients such as pharmaceutical and biotech companies, medical device companies, medical research organizations, and health care providers. Its private clients include AstraZeneca, Sanofi-Aventis, Merck, Baxter, and Pfizer.

- The CRC has strong information technology capabilities and has the ability to manage complex medical databases. Its therapeutic strengths are in hypertension, dialysis and transplantation, oncology, cardiovascular disease, and nephrology.

8.2 Info Kinetics SDN BHD (IKSB)

www.info-kinetics.com

Services: Clinical trial support services

Address: 5th Floor, Jalan Pangkor
10050 Penang, Malaysia

Phone: +60 4 228 5760

Fax: +60 4 228 5715

Email: admin@info-kinetics.com

Comments:

- Info Kinetics is a one-stop CRO that provides study management services for Phase I to IV clinical trials and bioavailability and bioequivalence studies.
- Info Kinetics has formed a strategic alliance with Gleneagles Clinical Research Centre (Gleneagles CRC), a pan-Asian CRO based in Singapore. This strategic alliance gives Info Kinetics access to a network of 150 hospital sites for conducting clinical trials in Singapore, Malaysia, Indonesia, Thailand, Vietnam, Philippines, China, Hong Kong, Taiwan, India, and Australia.
- Info Kinetics' services include: protocol design and review, pharmacokinetics consultation, subject recruitment, Ethics Committee submissions, state-of-the-art bioanalytical testing, analytical method development and validation, data management, pharmacostatistical analysis, study report writing, and screening of adulterants in pharmaceutical and nutraceutical products.
- Its clinical trial specialties for Phase I studies include: bioequivalence, food effects, bioavailability, race effects, ADME (pharmacokinetics studies), gender effects, and drug-drug interaction. For Phase II to IV Studies, its specialties include cardiology, obstetrics and gynecology, endocrinology, oncology, fertility, and ophthalmology.
- Info Kinetics has its own pharmacokinetics laboratory that provides enhanced drug analytical services at the Universiti Sains Malaysia. It has a clinical site in Gleneagles Medical Centre in Penang with 24 beds.
- Info Kinetics has conducted trials sponsored by Pfizer, Eli Lilly, Bristol-Myers Squibb, and GlaxoSmithKline.
- In May 2008, Info Kinetics joined with Australia's Murdoch University to develop a joint venture providing drug analysis services.

Local Offices of Large Foreign CROs

8.3 Quintiles Malaysia

www.quintiles.com

Established: 2001

Address: Suite D-08-02 Plaza Mont' Kiara (local office)
No.2 Jalan Kiara, Mont' Kiara
50480 Kuala Lumpur, Malaysia

Phone: +60 3 6207 1213
Fax: +60 3 6207 1200
Email: asia@quintiles.com

Comments:

- Quintiles Kuala Lumpur provides a range of clinical trial support services, and reportedly has high patient recruitment levels compared to other sites around the world.

8.4 PAREXEL International

www.parexel.com

Address: Unit 1104, Level II, Uptown 2
No. 2 Jalan SS21/37 Damansara Uptown
Petaling Jaya, Selangor Darul Ehsan 47400 Malaysia

Phone: +60 3 7724 6200
Fax: +60 3 7665 0010
Email: info@parexel.com

Comments:

- This is the Malaysia branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

8.5 Covance Services Malaysia Sdn Bhd

www.covance.com

Services: Clinical trial support services and commercialization

Address: 1005 BLK B Level 10/1, Phileo Damansara 1
9 Jalan 16/11, Off Damansara
46350 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Phone: 1800 801 842
Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance also has Asian offices in Japan, Taiwan, Singapore, India, the Philippines, South Korea, and China.

8.6 CMIC Asia Pacific (Malaysia) Sdn Bhd

www.cmic-ap.com

Address: Level 10 Plaza IGB, 1 Jalan Wan Kadir
Taman Tun Dr Ismail
60000 Kuala Lumpur, Malaysia

Comments:

- This is the Malaysia office of CMIC Co. Ltd., a large global CRO based in Tokyo, Japan.

8.7 PPD (Malaysia)

www.ppdi.com

Established: 1998
Services: Clinical development

Address: Level 8, Pavilion KL
168, Jalan Bukit Bintang
55100 Kuala Lumpur, Malaysia

Phone: +60 3 9205 8400
Fax: +60 3 9205 7788

Comments:

- This is the Malaysia branch office of PPD, a large global CRO based in Wilmington, NC.

8.8 EPS International (Malaysia)

www.epmgr.com

Address: 85-3 Jalan Amansiara, 1 Taman Amansiara
68100 Selayang
Selangor, Malaysia

Phone: 60 123 033 121
Email: info@epsgr.com

Comments:

- This is the Malaysia branch office of EPS Co. Ltd., a large Japan-based CRO.

8.9 inVentiv Health Clinical (formerly PharmaNet Development)
www.inventivhealthclinical.com

Address: Level 30, The Gardens North Tower
Mid Valley City
Lingkaran Syed Putra
59200 Kuala Lumpur, Malaysia

Phone: +60 3 2035 9219
Fax: +60 3 2035 9775
Email: pni@inventivhealth.com

Comments:

- This is the Malaysia subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

THE PHILIPPINES

The Philippine FDA oversees clinical trials and drug evaluation and registration. The clinical trial sponsor must comply with principles of Good Clinical Practice (GCP), first introduced in 1993. The growth rate of clinical trials was more than 20% in 2010. The Philippines was ranked 3rd in Southeast Asia for number of clinical trials in 2012 -- with 528 ongoing trials registered. The Philippine FDA received 335 clinical trial applications in 2011.

Updated guidelines for clinical trial regulation were released in June 2012. Clinical trial approval by the Philippine FDA is required for all Phase I, II, III and IV clinical trials. Applications for clinical trials must include information on the trial protocol, pharmaceutical data, and safety and efficacy data. Once the Clinical Trial Management Unit (part of the Philippine FDA's Policy Planning and Advocacy Division) has received a clinical trial application, the information is sent to an accredited institution-based Ethical Review Board/Committee (ERB/ERC). After an ethical and technical review that should not exceed 60 days, the ERB/ERC will submit their recommendations regarding the acceptance of the application to the Philippine FDA. Taking these recommendations into account, the Philippine FDA will approve or deny the trial application.

The ERBs/ERCs have been audited and accredited by the Philippine Health Research Ethics Board (PHREB), part of the Philippine National Health Research System (PNHRS) -- itself part of the Department of Science and Technology (DOST). This ensures that ERBs/ERCs comply with national and international standards. As of June 2012, there were 6 accredited ERB/ERC institutions.

After a clinical trial application has been approved by the Philippine FDA, an Import Permit application can be submitted to the Product Services Division of the Philippine FDA. The application can be submitted by the principal investigator, an authorized representative of the study sponsor, or an authorized CRO. The Import Permit should be issued within 7 days of receiving the application.

Within 30 days of an application for clinical trials has been granted, the study sponsor must upload the trial information to the electronic Philippine Clinical Trial Registry.

Food and Drug Administration (FDA)

Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781 Philippines

Tel: +63 2 165 332

Fax: +63 2 807 0751/8511

Email: info@fda.gov.ph

Website: www.fda.gov.ph

Department of Health (DOH)

San Lazaro Compound, Tayuman, Sta. Cruz, Manila, Philippines 1003

Tel: +63 2 743 8301

Fax: +63 2 711 6744

Email: info@doh.gov.ph

Website: www.doh.gov.ph

Philippine Council for Health Research and Development

3/F DOST Main Building, Gen. Santos Ave., Bicutan, Taguig City 1631 Philippines

Tel: +63 2 837 7534

Fax: +63 2 837 2924

Website: www.pchrd.dost.gov.ph

Local Offices of Large Foreign CROs

9.1 Quintiles Philippines Inc.

www.quintiles.com

Established: 1998

Employees: 10+

Services: Clinical trial support services

Address: 43F Unionbank Plaze (local office)
Meralco Avenue Corner, Onyx Road, Ortigas Center
Pasig City 1605, Philippines

Phone: +63 2 858 5600

Email: asia@quintiles.com

Comments:

- The Quintiles Philippines office has grown rapidly, and had undertaken more than 18 clinical trials by 2001. It provides both clinical development regulatory services.
- Quintiles Philippines is one of the first companies in the Asia Pacific to provide integrated Clinical Development and Commercialization (Innovex) Services.

9.2 EPS International Philippines (formerly Gleneagles CRC)

www.epmgr.com

Address: Unit 1410, 14th Floor, Raffles Corporate Center
Emerald Avenue, Ortigas Center
Pasig City 1605, Philippines

Phone: +63 2 900 3378

Fax: +63 2 900 3380

Email: info@epmgr.com

Comments:

- Gleneagles CRC was purchased by EPS International, a Japan-based CRO, as a wholly-owned subsidiary.

9.3 PAREXEL International

www.parexel.com

Address: 4F CYA Land
110 Rada Street, Legaspi Village
Makati City 1229, Philippines

Phone: +63 2 889 2456
Fax: +63 2 889 3137
Email: bd@apex-cro.com

Comments:

- This is the Philippine branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

9.4 inVentiv Health Clinical (formerly PharmaNet Clinical Service Philippines)

www.inventivhealthclinical.com

Established : 2009

Address: 27th Floor, BPI Buendia Center
372 Sen-Gil Puyat Avenue
Makati City 1226, Philippines

Phone: +63 2 464 9015
Fax: +63 2 464 9061
Email: pni@inventivhealth.com

Comments:

- This is the Philippines subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

9.5 Covance Asia-Pacific Inc. - Philippines

www.covance.com

Services: Clinical trial support services and commercialization

Address: Unit 4017 Level 40 PBCom Tower
6795 Ayala Avenue corner V.A. Rufino Street
Makati City 1226, Philippines

Phone: +65 6568 6588
Fax: +632 830 8659

Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance also has Asian offices in Japan, Taiwan, Singapore, India, South Korea, and China.

9.6 PPD (Philippines)

www.ppd.com

Established: 1998
Services: Clinical development

Address: 9th Floor, Sun Life Centre
5th Avenue corner Rizal Drive
Bonifacio Global City
1634 Taguig City, Philippines

Phone: +632 689 6501
Fax: +632 689 6502

Comments:

- This is the Philippines branch office of PPD, a large global CRO based in Wilmington, NC.

INDONESIA

At 250 million, Indonesia has the third-highest population of any Asian country, behind only China and India. Although there are fewer available CROs, clinical research is growing in Indonesia. There are approximately 50 clinical trial centers around the country. There were about 30 applications for clinical trials in Indonesia per year in 2005 and 2006, but the number leapt to 72 in 2007. In the first four months of 2008 alone, there were 49 applications.

The National Agency of Drug and Food Control (NADFC) oversees clinical trials and regulatory approval of drugs in Indonesia. The sponsor must first obtain ethical clearance from the Institutional Ethics Committee (IEC) and scientific justification from the Scientific Committee. The clinical trial protocol, investigational brochure, informed consent form, and other supporting documents should then be submitted to the NADFC. If a drug is being imported for the purpose of the study, a temporary import license must also be obtained. The NADFC may consult the National Advisory Board on Clinical Trials in making its decision. The entire approval process can take 2 to 3 months. Once the approval decision is made, the NADFC will issue a license on clinical trial implementation and a drug import license within 10 working days.

Indonesian GCP was introduced in 2001 and is based on ICH-GCP and Procedures for Clinical Trial Applications. The NADFC ensures that all clinical trials in Indonesia are conducted in accordance with GCP guidelines with periodic GCP inspection. The National Commission of Ethics in Health Research, established by a Ministry of Health decree, promotes ethics in health research and monitors the operation of IECs. GCP training for investigators provided by the Indonesian government has increased the quality of clinical trials.

National Agency of Drug and Food Control (NADFC)

Jl. Percetakan Negara No. 23, Jakarta 10560, Indonesia

Tel: +62 21 4288 3309/3462/4244691

Fax: +62 21 4263 333

Email: ulpk@pom.go.id

Website: www.pom.go.id

Local CROs

10.1 Prodia Clinical Laboratory

www.prodia.co.id

Established: 1973

Employees: 1,000+

Services: Clinical trial support services

Address: Jl. Kramat Raya, No. 150

Jakarta, Pusat Jawa, 10330, Indonesia

Phone: +62 21 314 4182
Fax: +62 21 314 4181
Email: prodia@prodia.co.id

Comments:

- Prodia has Indonesia's largest network of clinical laboratory services. It has over 2,700 employees including 500 analysts, 200 university graduates, and other specialists.
- Prodia has worked with several well-known pharmaceutical companies, including Bayer, Pfizer, Glaxo-Wellcome, Hoechst, Schering-Plough, Novartis, Eli Lilly, Roche, Sandoz, Squibb, Smith Kline Beecham, and Warner Lambert-Parke Davis. It has conducted worldwide Phase II to IV trials. Prodia has 99 branch laboratories in Indonesia that can conduct 2,000 different types of examinations.
- Prodia also has a cooperative arrangement with the Bio-Analytical Research Corporation (BARC), a central laboratory in Ghent, Belgium.
- Prodia has been awarded the ISO-9002 certificate and is currently preparing to participate in an accreditation program conducted by the College of American Pathologists (CAP).

10.2 PT Equilab International

www.equilab-int.com

Established: 2002
Employees: 30
Services: Clinical trial support services

Address: Jl. RS. Ratmawati Persil 33
Jakarta 12430, Indonesia

Phone: +62 21 7695513/7515932
Fax: +62 21 7509668
Email: info@equilab-int.com

Comments:

- Equilab is the first ISO/IEC 17025-accredited testing laboratory in Indonesia. It serves domestic and international pharmaceutical companies.
- For most of the time since its founding, Equilab only provided bioavailability, bioequivalence, and pharmacokinetics study services. In November 2006, it expanded to add Phase I-IV clinical trial support.
- In June 2007, Equilab signed an agreement with Prodia to work together on clinical trials, combining their different expertise.

Local Offices of Large Foreign CROs

10.3 PAREXEL International

www.parexel.com

Address: Suite 18, 18F Cyber tower, Jl.
HR Resuna Said Block X-5
Jakarta 12950, Philippines

Phone: +62 2902 1796/97/98

Fax: +62 5799 8741

Email: bd@apex-cro.com

Comments:

- This is the Indonesia branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

10.4 EPS International (formerly Gleneagles CRC Pte. Ltd.)

www.epsg.com

Address: Wisma Tamara, 9th floor, Suite 999 (local office)
Jl. Jend. Sudirman Kav. 24
Jakarta 12920, Indonesia

Phone: +62 21 520 7739

Fax: +62 21 520 7751

Email: info@gleneaglescrc.com

Comments:

- Gleneagles CRC was purchased by EPS International, a Japan-based CRO, as a wholly-owned subsidiary.

10.5 Quintiles Indonesia

www.quintiles.com

Established: 2006

Address: DM Plaza, 24th Floor, Suite 2401 (local office)
Jl. Jend. Sudirman Kav. 25
Jakarta 12920, Indonesia

Phone: +62 21 2557 9700

Fax: +62 21 2557 9799

Email: asia@quintiles.com

Comments:

- This is the Indonesia branch office of Quintiles Transnational, an international CRO based in Durham, North Carolina.

THAILAND

There are no specific laws regulating the conduct of clinical trials in Thailand. A variety of Ministry of Public Health (MOPH) departments have control over different aspects of clinical trials -- the Food and Drug Administration (FDA), Department of Medical Services, Department of Communicable Diseases Control, National Sub-Committee of HIV Vaccine, and the Ethical Review Committee for Research in Human Subjects.

Sponsors do need to obtain certain approvals before beginning a trial. After selecting a research facility and researchers to conduct the study, the trial sponsor must receive ethical approval for the clinical trial protocol. This can either be from the independent ethics committee (IEC) of the research facility (usually a hospital or university) at which the trial will take place or from the MOPH's Ethical Review Committee for Research in Human Subjects (ERC). The process of receiving approval from an IEC or the ERC usually takes 2-3 months. For single-site trials, if approval is given by the research facility's IEC, it is usually not necessary to also receive approval from the ERC. However for multi-institutional trials, both IEC and ERC approval are required. These approvals are sequential.

Once the protocol has been approved, the sponsor must then apply to the Thai FDA of Thailand to obtain permission to import the drug for use in the clinical trial. The sponsor needs to submit the IEC and/or ERC approval along with documentation on the trial and the drug substance that will be imported. Approval of an import license usually takes 30 days. The license expires after a year -- so if the clinical trial is ongoing, a new import license would be required. The time from submission of the protocol to patient enrollment usually totals about 4 months.

For clinical trials that involve AIDS vaccines, the clinical protocol must first be submitted to the Department of Communicable Diseases Control of the MOPH and be reviewed and approved by the National Sub-Committee of HIV Vaccine of the MOPH before it can be submitted to the ERC. ICH GCP was introduced in 2000, and these guidelines should be followed by sponsors and clinical investigators in the conduct of clinical trials.

The Thailand Centre of Excellence for Life Sciences (TCELS) was established by the Thai government in 2003 to promote life-science research and business. Currently, the TCELS is trying to promote clinical trials in Thailand and develop domestic CROs. The government is also considering creating a regulatory framework for all clinical trials.

The majority of clinical trials in Thailand are Phase III studies. From 2010 to 2012, there were 215 Phase III trials conducted, compared with 5 Phase I trials, 40 Phase II trials, and 26 Phase IV trials. The most common therapeutic areas of clinical trials in Thailand are infectious diseases and oncology.

Food and Drug Administration (FDA), Ministry of Public Health (MOPH)

88/24 Avenue Rd. Muang, Nonthaburi 11000 Thailand

Tel: +66 2 590 7000

Email: drug@fda.moph.go.th

Website: www.fda.moph.go.th

Thailand Centre of Excellence for Life Sciences (TCELS)

22th Floor CMMU Building 69 Vibhavadi-Rangsit Road Samsen Nai,
Phayathai Bangkok 10400 Thailand

Tel: +66 2 644 5499

Fax: +66 2 644 9538

Contact: Ms. Jiraphan Namsa, Business Development & Investment Manager

Email: hotline@tcels.or.th

Website: www.tcels.or.th

Local CROs

11.1 Bio-Innova and Synchron Co., Ltd.

www.bio-innova.com

Established: 2007

Services: Clinical trial support services for Phases I-IV

Address: 19/11-14 Soi Wattana
Sukhumvit 19 Road
Klongtoeynua, Wattana
Bangkok, Thailand 10110

Phone: +66 2 254 9008/9

Fax: +66 2 254 9007

Contact: Ms. Sukrita Karalai, Business Development Manager

Email: info@bio-innova.com

Comments:

- Bio-Innova and Synchron (B&S) was established in April 2007 by Synchron, a major Indian CRO based in Ahmedabad. It claims to be the first CRO in Thailand not part of a major multinational CRO. It has a 30-bed facility in Bangkok.
- B&S offers services for all phases of clinical trials, as well as bioequivalence and bioavailability, pilot tests, interactions, drug delivery systems, and trials for cosmetic and herbal products, as well as data management and statistical support.
- B&S also has a bioanalytical laboratory compliant with GLP.

11.2 Asia Global Research.

www.asiaglobalresearch.com / www.agr-cro.com

Established: 2006

Services: Clinical trial support services for Phases I-IV

Address: 5th Floor, Ploenchit Center
2 Sukhumvit Rd.
Bangkok 10110, Thailand

Phone: +66 0 2667 1700
Fax: +66 0 2667 1800
Email: info@agr-cro.com

Comments:

- Asia Global Research (AGR) is a subsidiary of Bangkok-based Bumrungrad International Hospital PLC. AGR's trial management capabilities include establishing and monitoring trials in Thailand, Vietnam, Malaysia, the Philippines, Myanmar, China, Russia, India and the Middle East.
- About 46% of the company's clinical experiences comprise clinical trial support services for Phases II to IV.

Local Offices of Large Foreign CROs

11.3 Quintiles (Thailand) Co., Ltd.

www.quintiles.com

Established: 1998
Services: Clinical trial support services

Address: 23rd Floor, Room No. 1-5, Silom Complex Building
191 Silom Road, Kwaeng Silom
Bangkok 10500, Thailand

Phone: +66 2 686 2300
Email: asia@quintiles.com

Comments:

- Quintiles Thailand, established in 1998, offers both clinical development and regulatory services. There are currently 8 Thai CRAs and a Thai Clinical Manager in the office, who oversee monitoring for sites in Thailand, as well as in Vietnam and Indonesia.
- In Thailand, Quintiles's Innovex subsidiary, Clinical Development and Commercialization Services, is the largest Quintiles Asia CPO (Contract Pharmaceutical Organization) office outside of Singapore.

11.4 EPS International Thailand (formerly Gleneagles CRC (Thailand) Co., Ltd)

www.epmgr.com

Established: 1998

Address: #06-66 Thai CC Tower (local office)
889 South Sathorn Road
Sathorn, Bangkok 10120, Thailand

Phone: +66 2 673 9183

Fax: +62 2 673 9184

Email: info@epsgr.com

Comments:

- Gleneagles CRC was purchased by EPS International, a Japan-based CRO, as a wholly-owned subsidiary.

11.5 PPD (Thailand)

www.ppdi.com

Established: 2000

Address: The Offices at Central World, 25th Floor (local office)
999/9 Rama I Road, Patumwan
Bangkok 10330, Thailand

Phone: +66 2 646 2100

Fax: +66 2 646 1089

Comments:

- This is the Thailand branch office of PPD, a large global CRO based in Wilmington, NC.

11.6 PAREXEL International

www.parexel.com

Address: Mercury Tower, 10F, Unit 1001
540 Ploenchit Road, Lumpini, Pathumwan
Bangkok 10330, Thailand

Phone: +66 2 639 3200

Fax: +66 2 658 5570

Email: info@parexel.com

Comments:

- This is the Thailand branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

11.6 ICON Clinical Research Pte Ltd

www.iconplc.com

Address: Empine Tower, Unit 2408, Tower 3
195 South Sathorn Road, Yannawa, Sathorn
Bangkok 10120, Thailand

Phone: +66 2 697 2600

Fax: +66 2 670 0040

Comments:

- This is the Thailand branch office of ICON Clinical Research, a large global CRO headquartered in Dublin, Ireland.

11.7 Ecron Acunova Company Limited, Thailand

www.ecronacunova.com

Established: 2007

Services: Clinical trial support services for Phases I-IV

Address: 153/3 Goldenland Building, Level 3
Room G3, Soi Mahadlekluang 1
Ratchadamri Road, Lumpini, Pathumwan,
Bangkok 10330
Thailand

Phone: +66 2 652 1027

Fax: +66 2 652 1029

Email: bd.thailand@ecronacunova.com

Comments:

- Ecron Acunova (Thailand) is a 74% subsidiary of the global Ecron Acunova group. It is an expert CRO for clinical development.
- In January 2011, the company announced a collaboration with Jamjuree Innovations Co. Ltd, which is owned by Bangkok's Chulalongkorn University.
- Ecron Acunova (Thailand) employs regional pioneers and experts in ICH-GCP guided clinical research. Apart from Thailand, the company in Bangkok provides clinical services to clients in Malaysia, Vietnam and Cambodia.

11.8 Covance Services Thailand Ltd

www.covance.com

Services: Clinical trial support services and commercialization

Address: 1 Q House Lumpini, Level 27th,
South Sathorn Road, Tungmahamek,
Sathorn, Bangkok 10120, Thailand

Phone: +66 2 610 3669

Email: info@covance.com

Comments:

- Headquartered in Princeton, NJ, Covance Inc. is one of the world's largest drug development service companies with a full range of clinical trial support services. It also has the world's largest central laboratory network. Covance Inc. has operations in more than 25 countries with 9,800 employees around the globe. It also offers pre-clinical, central diagnostic, and market access services.
- Covance also has Asian offices in Japan, Taiwan, Singapore, India, the Philippines, South Korea, and China.

11.9 inVentiv Health Clinical
www.inventivhealthclinical.com

Established : 2013

Address: 23/F, M Thai Tower, All Seasons Place
87 Wireless Road
Lumpini, Pathumwan
Bangkok 10330, Thailand

Phone: +66 2 6279125

Fax: +66 2 6270162

Email: pni@inventivhealth.com

Comments:

- This is the Thailand subsidiary of PharmaNet Development Group, Inc., a large global CRO based in Princeton, NJ.

VIETNAM

Clinical research regulation laws did not exist in Vietnam until January 11, 2007. These followed guidelines released in late 2005. Because the laws are relatively new, they are somewhat fragmented and non-comprehensive. However, the Vietnam Ministry of Health (MOH) has been working to develop the regulatory framework for clinical trials as well as the quality of researchers in Vietnam. The MOH released guidelines for GCP in 2008 (following ICH GCP), new clinical trial regulations in February 2012, and guidelines for CROs in August 2012. Clinical trials have increased quickly, with more than 140 taking place between May 2012 and February 2013. Of these, about 40 are Phase III trials.

The MOH's greatest priority is to increase the number of trained clinical research personnel in Vietnam GCP and ethics standards. Other goals include establishing a monitoring and evaluation system (M&E) in accordance with GCP and developing a data management system. Over the past several years, the MOH has held a variety of workshops and training programs for CROs, site management organizations (SMOs), and investigators. More than 1,000 Vietnamese researchers took part in in MOH GCP training workshops in 2012.

There are several different government agencies involved in clinical trial regulations. The MOH's Science Technology and Training Administration (STTA, formerly the Department of Science and Training) is responsible for trial regulation, guidance, applications, approvals, and trial site inspections. The Drug Administration of Vietnam (DAV) is in charge of issuing import licenses. Export of biological samples takes place through the Administration of Preventative Medicine.

To receive clinical trial authorization, the trial sponsor must first submit an application to the STTA to register the clinical trial. The MOH will provide an initial approval letter within 15 working days. Then, clinical research protocols and product information must be submitted to the STTA for approval by the Ethics Committee and the Science Committee. The protocols must follow MOH format and be written in English or Vietnamese. The two committees have 60 working days to evaluate the scientific and ethical aspects of the proposed trial. Following their evaluation, the STTA provides a response within 15 working days -- either sending the application to the Minister of Health for approval or asking the trial sponsor for additional information. Many research facilities also have a local institutional review board (IRB) that must give approval before an application can be submitted to the STTA.

If approved, protocols may not be revised without prior approval by the STTA. The STTA is responsible for technical and ethical review, while financing aspects and funding procedures are reviewed by other departments within the MOH. After STTA approval, it takes about 4 weeks to obtain an import license from the DAV.

The investigating organization must be equipped to comply with Vietnam's GCP and must be a central level health institute directly managed by the MOH. Sponsors wishing to conduct clinical trials in provincial level hospitals can only do so in Ho Chi Minh City with

prior approval from the Provincial Health Services. The sponsor can either select an MOH-suggested institute or contact an institute directly and propose it to the MOH.

Vietnam Ministry of Health (MOH)

138A Giang Vo, Ba Dinh, Hanoi, Vietnam

Tel: +84 4 6273 2273

Fax: +84 4 3846 4051

Email: banbientap@moh.gov.vn

Website: www.moh.gov.vn

Local CROs

12.1 SMART Research Co. Ltd.

<http://www.smartresearch.com.vn/>

Established: 2011

Services: Clinical trial support services

Address: SISC Building, Floor 1, No. 27-29-31, Street 9A
Trung Son Residential Area, Binh Chanh District
Ho Chi Minh city, Vietnam

Phone: +84 9 3868 4449

Fax: +84 8 5431 9544

Email: info@smartresearch.com.vn

Comments:

- SMART Scientific Research Support Service is the first local CRO to receive approval from the Vietnamese MOH.
- SMART assists with EC/IRB approval, MOH (STTA) application, trial management for local and regional trials, etc.
- The CRO has particular experience in Phase III and IV clinical trials and has worked with multinational CROs like Covance as well as pharmaceutical companies like AstraZeneca, Novartis, Sanofi, and GlaxoSmithKline.

Local Offices of Large Foreign CROs

12.2 Quintiles Vietnam

www.quintiles.com

Established: 2005

Services: Clinical trial support services

Address: Unit 2118, 21st Floor, Him Lam Business Center, Capital Tower

109 Tran Hung Dao Street, Hoan Kiem District
Hanoi, Vietnam

Phone: +84 4 577 1727
Email: asia@quintiles.com

Comments:

- This is the Vietnam branch office of Quintiles Transnational, an international CRO based in Durham, North Carolina.

12.3 Parexel International

www.parexel.com

Address: Regus Melinh Point Tower, Level 7, Unit 719
02 Ngo Duc Ke Street, Ben Nghe Ward, Dist.1
Ho Chi Minh City, Vietnam

Phone: +84 8 3823 7850
Fax: +84 8 3823 7840
Email: info@parexel.com

Comments:

- This is the Vietnam branch office of PAREXEL, a large international CRO headquartered in Waltham, MA.

12.4 EPS International Vietnam

www.epsgr.com

Established: 1998

Address: Unit Room 201C, Hoa Lam Building
No.2 Thi Sach Street, Ben Nghe Quarter, District 1
Ho Chi Minh City, Vietnam

Phone: +84 8 6299 0973
Fax: +84 8 6299 0974
Email: info@epsgr.com

Comments:

- This is the Vietnam branch office of EPS Co. Ltd., a large Japan-based CRO.

Pacific Bridge Medical

7315 Wisconsin Avenue, Suite 609E

Bethesda, MD 20814

(301) 469-3400

(301) 469-3409

Email: contact@pacificbridgemedical.com

www.pacificbridgemedical.com

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