Directory of Clinical Research Companies
In India

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Cygnus
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Preface

India is fast emerging as a favoured destination for clinical trials by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations. Two major reasons for its popularity are: easy access and availability of a large, diverse and therapy-naïve population with vast gene pool and lower cost of technical services resulting into lower per patient trial cost. India also has the advantage of having a large pool of highly trained physicians, nurses, and technical personnel; numerous world-class medical facilities; broadly developed information technology infrastructure; a favourable IPR environment (post signing the WTO agreement) and use of English as the primary business and medical language. The total value of clinical research performed in India in 2004-05 was about US$100 million. The major companies involved in Clinical research in India have a wide range of services to offer. Thus, the industry needs to know the companies operating in this field.

The directory of ‘Clinical Research Companies in India’ is the answer to it and has been prepared as a ready-reckoner for use by the industry globally – pharma and biotech companies, contract research companies, funding organisations and others. It has been compiled, considering the companies involved in clinical research and support services. As it is an emerging market and also as most of the companies may not be listed on stock exchangers, the list may not be comprehensive. The directory covers 61 companies and each profile includes details like description of the company, name of Director/CEO, areas of operation, clinical trial expertise, contact details and other information. The details have been obtained from published sources like the respective websites of the companies as of November 2005. All the companies are listed in alphabetical order.
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Clinigene is a Clinical Research Organisation that offers global biotechnology and pharmaceutical majors strong clinical trial, regulatory and laboratory capabilities for drug development. Established in the year 2000 as a Biocon subsidiary, the company set up India's first CAP (College of American Pathologists) accredited Central Reference Laboratory with clinical specialisations in biochemistry, haematology, histopathology and microbiology. The value-added services include patient registries and clinical databases in diabetes, lipidemia, oncology and cardiovascular diseases.

**Directors**

A. S. Arvind, Chief Operating Officer

**Contact details**

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URL: www.biocon.com/clinigene.asp

**Products**

-

**Services**

-

**Clinical Trials expertise**

Clinigene conducts well-defined clinical studies in select disease segments. The company works closely with specialised clinics to create large analytical databases that dovetail with the data mining capabilities of the collaborative partners. Conforming to the highest standards of bioethics, patients under investigation in the various research programmes are assured of systems and protocols that emphasise accuracy and transparency. In employing a proteomics platform, the company identifies new biomarkers that will eventually result in proprietary diagnostics and therapies. Disease segments profiled at Clinigene in the initial phase include non-insulin dependant diabetes, asthma and lipidemia.

The Bangalore-based Clinigene says India’s huge population allows new-drug studies to be completed much faster. Last year, when a biotechnology company from the US needed 400 diabetics for a study, Clinigene began by heading to a nearby hospital specialising in diabetes, where a dozen new patients arrive every day and more than 40,000 are in its records.

**Pre Clinical**

-

**Phase I**

Yes

**Phase II**

Yes

**Phase III**

Yes

**Phase IV**

Yes

**R&D**

-

**Corporate location**

Bangalore

**Infrastructure**

The state-of-the-art Central Reference Laboratory uses pre-defined databases and visit-specific collection kits to facilitate the accumulation of complete and accurate data. As a result, the company is able to complete trials faster and arrive at more robust conclusions. Clinigene has developed its own system of Lab Logistics that offers full-service specimen transportation and storage capabilities. The unique ID and bar coding system allows us to track/retrieve/send specimens and related material anywhere in the country.
We offer the storage facilitates even if the material is not protocol-specific or Clinigene is not directly involved with the testing.

<table>
<thead>
<tr>
<th>Experience areas</th>
<th>Clinigene's HPU has expertise in conducting world class, cost-effective clinical trials (Phase I - IV) Clinical Trial Management includes protocol and CRF design, site monitoring, auditing, clinical supplies management, data management, bio statistical analysis, pharmacokinetic analysis, electronic data transfer and clinical trial reporting.</th>
</tr>
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<td>Regulatory approvals &amp; Recognitions</td>
<td>Clinigene's Clinical Lab conducts trials and studies that conform to ICH-GCP guidelines and meets international regulatory requirements. It is the first lab in India to be accredited by CAP (College of American Pathologists). More recently, the company has also been accredited by NABL (National Accreditation Board for Testing and Calibration Laboratories).</td>
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<tr>
<td>Other information (if any)</td>
<td>It also conducts longitudinal studies to determine biomarkers. In keeping with the commitment to provide quality laboratory results to the global clientele, the company participate in internationally recognised certification programmes.</td>
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