

Directory of Clinical Research Companies In India

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Cygnus

Business Consulting & Research

Knowledge Partner For Profitable Growth

4th & 5th Floors, Astral Heights, Road No. 1, Banjara Hills, Hyderabad-500034, India

Tel: +91-40-23430203-07, Fax: +91-40-23430208, E-mail: info@cygnusindia.com

Website: www.cygnusindia.com

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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.

List of Companies

1. Accutest Research Laboratories (I) Pvt. Ltd.....	5
2. Ace Biomed Pvt. Ltd.	7
3. Actimus Biosciences Pvt. Ltd.....	9
4. Apothecaries Ltd.	11
5. Asian Clinical Trials Limited.....	12
6. Aurigene Discovery Technologies	14
7. Avra Laboratories.....	15
8. Bharat Biotech International Ltd.	16
9. BioArc Research Solutions	19
10. Bioserve Clinical Research Pvt. Ltd.....	21
11. Cadila Pharmaceuticals Limited	23
12. Chembiotek Research International	25
13. Clinigene	27
14. Clininvent Research Pvt. Ltd.....	29
15. ClinTec International.....	31
16. Clintrac International.....	33
17. D & O CRO.....	35
18. Dr Reddy's Laboratories Limited.....	36
19. Eli Lilly and Company (India) Pvt. Ltd.....	38
20. GlaxoSmithKline.....	40
21. GVK Biosciences Pvt Ltd.....	42
22. iGATE Clinical Research International	44
23. Intas Pharmaceuticals	46
24. INTOX Private.....	48
25. Jubilant Clinsys	50
26. Johnson & Johnson, India	51
27. Kendle India.....	53
28. Lambda Therapeutic Research Ltd.....	55
29. Lotus Labs Pvt. Ltd.	57
30. Lupin Limited	59
31. Magene Life Sciences.....	61
32. Manipal Acunova	63
33. Matrix Laboratories Ltd.	65
34. Metropolis Clinical Laboratories.....	66
35. Merck Limited.....	68
36. Novartis	70
37. Novo Nordisk India Private Ltd.....	71
38. Ocimum Biosolutions.....	73
39. Omnicare Clinical Research.....	75
40. Panacea Biotech.....	76
41. Pfizer Limited	78
42. Pharma-Olam International.....	80
43. Pharmanet	81
44. PPD Pharmaceutical Development India.....	83
45. Quintiles Research (India) Private Limited	85

46. Ranbaxy Laboratories Limited	87
47. Reliance Clinical Research Services	89
48. Reamatrix India	90
49. Roche India Ltd.....	92
50. Sanofi-Aventis (Aventis Pharma Limited).....	94
51. Sipra Labs Pvt Ltd.....	96
52. Siro Clinpharm Pvt Ltd.	98
53. Sristek.....	100
54. SRL Ranbaxy.....	102
55. Sterling Synergy Systems	104
56. Synchron Research Pvt. Ltd.	106
57. Triesta Sciences.....	108
58. Torrent Pharmaceuticals Limited.....	110
59. Veeda Clinical Research	112
60. Vimta Labs Limited	114
61. Zydus Cadila	116

Company Profile		Clinigene					Clinigene						
Therapeutic Class		Captive		Global CRO		Indian CRO					√		
Generic	New Drug	Facilities		InPatient Registration		Value Chain							
√	√			No of Beds							26		
Overseas Offices				√	Tie up with hospitals?		√	Pre	I	II	III	IV	DM
GCP Certification				√	Specialised Equipments		√	√	√	√	√	√	
			Software packages		√	No of Certified Investigators							
Company Description		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		20th KM Hosur Road Electronics City Bangalore 560 100 India Ph: 91 80 2852 2972, 2808 2808 Fax: 91 80 2783 3356, 2852 3423 E-mail: contact.us@biocon.com, arvind.atignal@biocon.com URL: www.biocon.com/clinigene.asp											
Products		-											
Services		-											
Clinical Trials expertise		Clinigene conducts well-defined clinical studies in select disease segments.the company work 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 identify 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 facilities even if the material is not protocol-specific or Clinigene is not directly involved with the testing.
Experience areas	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.
Regulatory approvals & Recognitions	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).
Other information (if any)	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.
Employees	-