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Pharmaceutical Outsourcing Landscape in India – An Overview

Presentation


Zinnov LLC

April, 2006

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report, please send your
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AGENDA

 Focus of Discussion

- Outsourcing in Pharmaceutical Industry

- Drug Discovery and Development (R&D)*

- Contract Research and Manufacturing Services (CRAMS)

- IT Services

- Business Process Outsourcing (BPO)

- Offshoring and Outsourcing Initiatives by Leading Pharmaceutical MNCs to India**

*And related activities such as Clinical Data Management and Site Management; ** Top 10 Pharma MNCs excluding Johnson & Johnson

Pharmaceutical Outsourcing Landscape in India

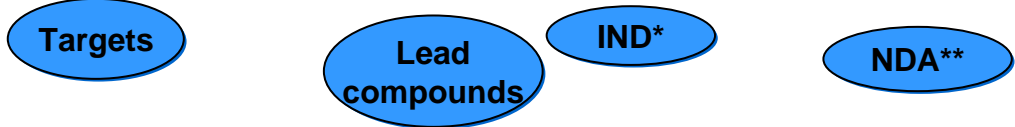
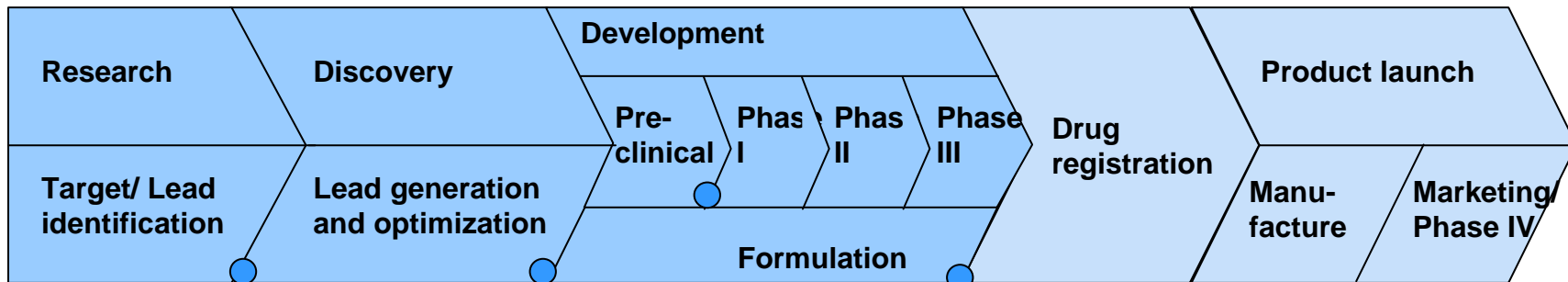
- Drug Discovery and Development (R&D)
 - The Drug Innovation Process
 - The Key Drivers for Outsourcing/ Offshoring of R&D
 - Outsourcing across the R&D value chain
 - City-Wise Vendor Analysis
 - Other Emerging Trends

- Offshoring and Outsourcing Initiatives by Leading Pharmaceutical MNCs to India

- Appendix
 - Offshoring and Outsourcing Initiatives by Top Ten Pharmaceutical MNCs to India – Manufacturing, IT, R&D, BPO
 - Profiles of Leading Contract Research Organizations in India
 - List of Service Providers for various Outsourcing activities

The Drug Innovation Process

Focus of Discussion



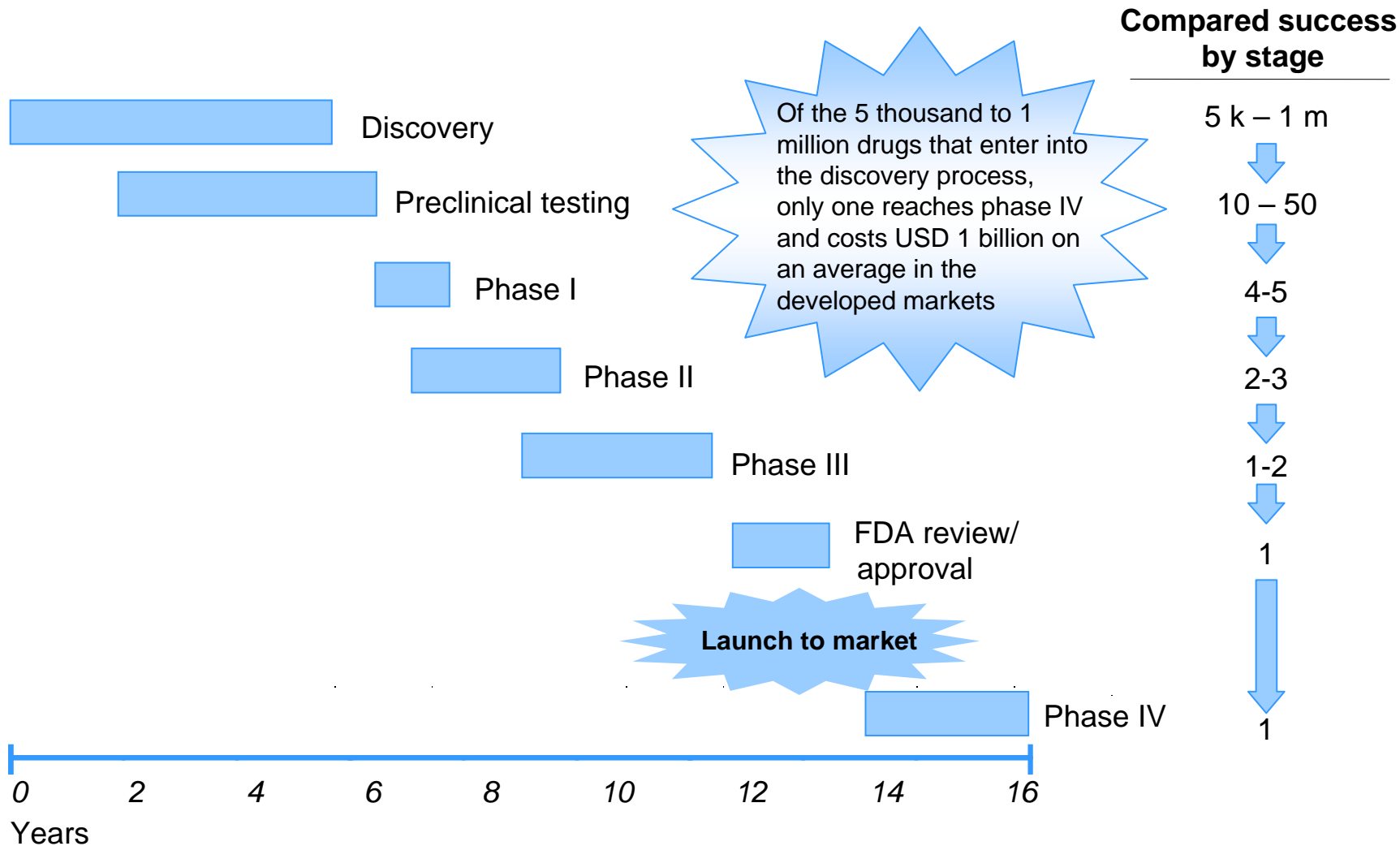
Output

Main objective

- Develop workable hypothesis linking drug target with disease
- Identify product with high likelihood of improving disease outcome
- In early stages, generate safety and efficacy information on a smaller number of patients to improve decision-making before full development
- In later stages (full development) develop product by testing a larger (statistically significant) number of patients to obtain drug registration
- Obtain permission to market the product
- Raise awareness of new drug among prescribers and gather additional information regarding efficacy and possible adverse drug reactions

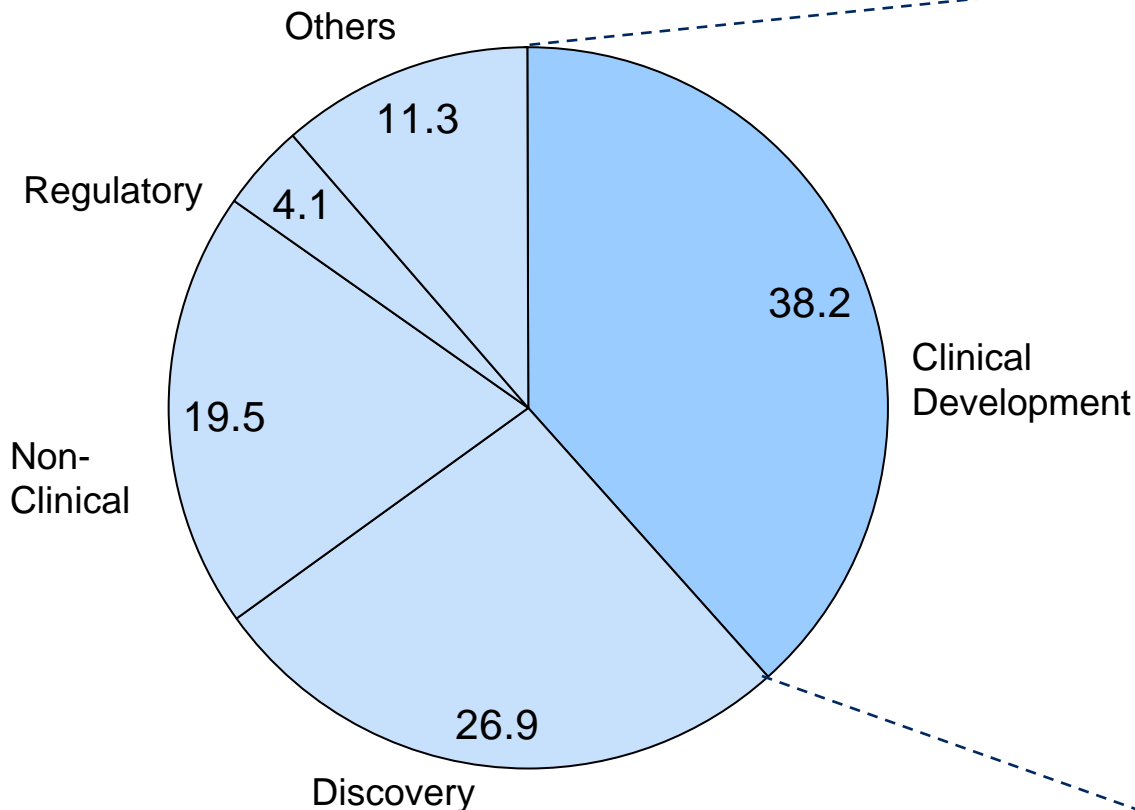
*Investigational New Drug; **New Drug Application

The road to market is quite long and expensive and can take anywhere from 12-16 years...

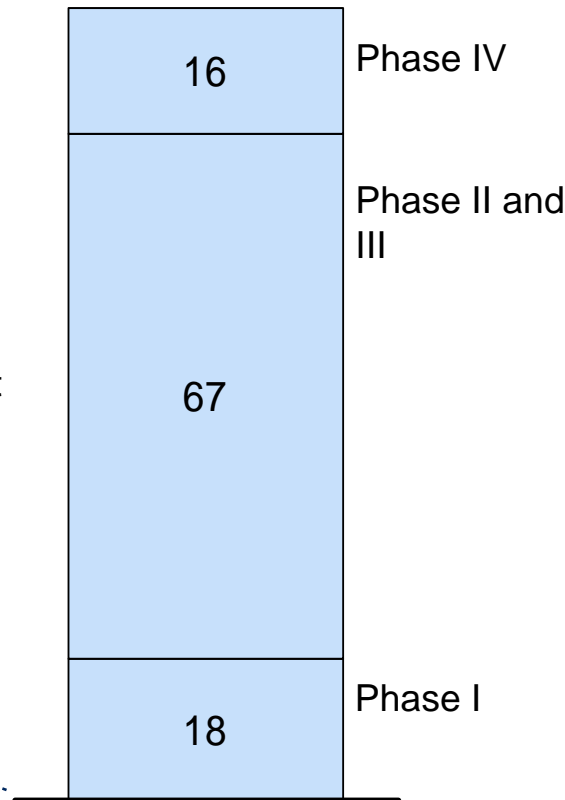


...Clinical Development, Discovery and Non-Clinical services account for almost 85% of the R&D budget...

R&D Budget Break-Up
Percentage



Clinical Budget Break-Up
Percentage
100%



...The long road to market can be shortened and costs can be reduced by using specialized organizations for R&D...

Study by the Tufts Center for the Study of Drug Development

- **Sponsor of the study**
 - Association of Clinical Research Organizations (ACRO) - Its members represent 65 to 70 percent of all CRO revenues worldwide
- **Objectives**
 - Examine the contribution CROs make to the pharmaceutical industry's overall development capacity
 - Assess the impact clinical outsourcing has on development-project performance
- **Methodology**
 - Held a series of wide-ranging interviews with representatives of 31 pharmaceutical and biotechnology companies of varying size
 - Gathered data on 79 New Drug Application (NDA) and four Biologics License Application (BLA) submissions made between 2000 and 2004
 - Collected data from ACRO member companies

Drug companies with a high reliance on CROs stay closer to schedule than those making less use of CROs

CROs expand the speed and capacity of product development pipeline while maintaining quality and high levels of regulatory compliance

CROs help companies reduce R&D costs.

...Using CROs in India can offer even better advantages such as diverse and large patient pool, strong talent pool, low cost and high quality

Illustrative

Speed of Patient Enrollment

- Fast speed of patient enrollment
- Shorter time for clinical trials – up to 75% faster

Gene pool advantage

- Heterogeneous mix of people
- Vast and diverse disease and patient population

Talent Pool

- A very large pool of highly trained nurses, physicians and technical personnel. Eg. India has the second largest pool of qualified doctors
- India has great IT skills

Infrastructure

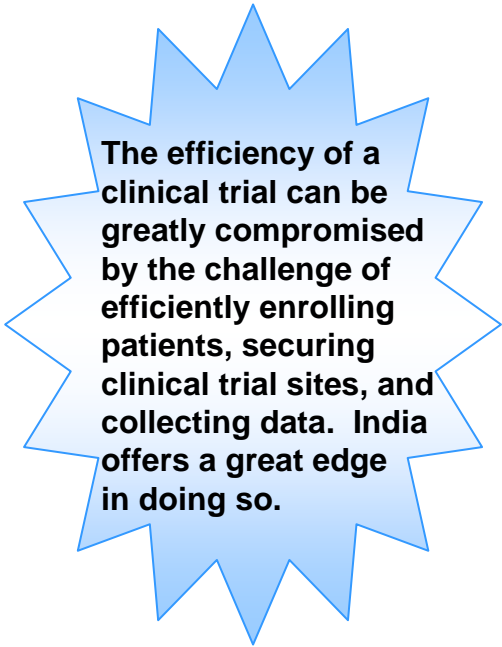
- Numerous world-class medical facilities that meet global requirements for clinical testing

Cost

- 30-50% cheaper than in the U.S.

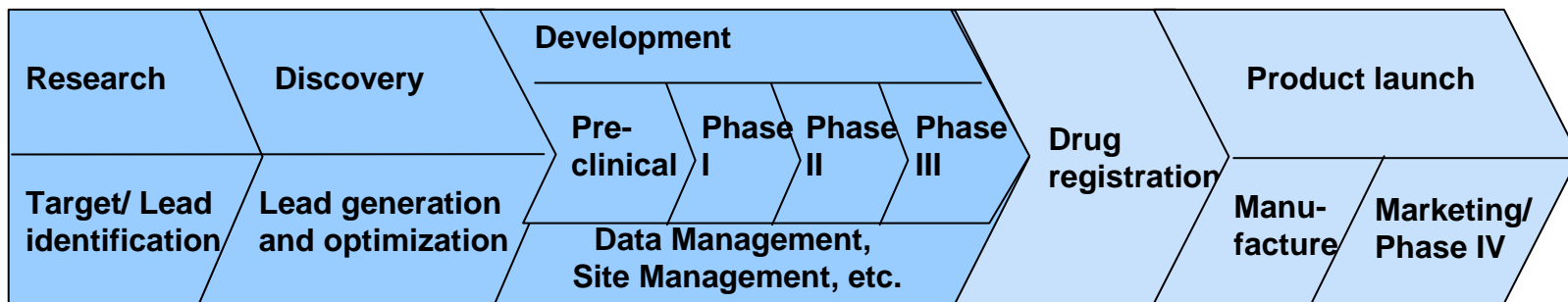
Quality

- Compliance with global ethical and regulatory standards such as ISO, ICH (International Conference on Harmonization), GCP (Good Clinical Practice), GLP (Good Laboratory Practices), etc.



The efficiency of a clinical trial can be greatly compromised by the challenge of efficiently enrolling patients, securing clinical trial sites, and collecting data. India offers a great edge in doing so.

Outsourcing in India across the R&D value chain varies according to complexity level of the service and the vendor landscape



	Research	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Drug registration	Manufacture	Marketing/Phase IV
Commonly outsourced?	Low	Good	Good	High	Very High	Very High			
Complexity Level	High	High	Average	Average	Good	High			
Vendor Landscape in India	Low	Good	Good	High	Very High	Very High			

Research (Lead Identification) is generally not outsourced and Discovery (Lead Generation and Optimization) outsourcing is evolving in India

Illustrative

	Research	Discovery
Commonly outsourced?	<ul style="list-style-type: none"> No instance of any of the top 10 Pharmaceutical company outsourcing lead identification Companies do offshore to captive R&D centers <ul style="list-style-type: none"> AstraZeneca – Bangalore Aventis Pharma - Mumbai 	<ul style="list-style-type: none"> Instances of companies outsourcing discovery services as well as entering into alliances for the same <ul style="list-style-type: none"> GSK – Ranbaxy: Ranbaxy responsible for lead generation and optimization for leads for a wide range of therapeutic areas
Complexity Level	<ul style="list-style-type: none"> Requires high level of pharmaceutical expertise, understanding and an innovative approach 	<ul style="list-style-type: none"> Can take up to five years Out of thousands of molecules, a few ones are selected
Vendor Landscape in India	<ul style="list-style-type: none"> None of the 22 leading vendors selected for the purpose of the study provide this service 	<p>22 Vendors</p> <ul style="list-style-type: none"> GVK Biosciences Aurigene Syngene International Chembiotek Research, etc.

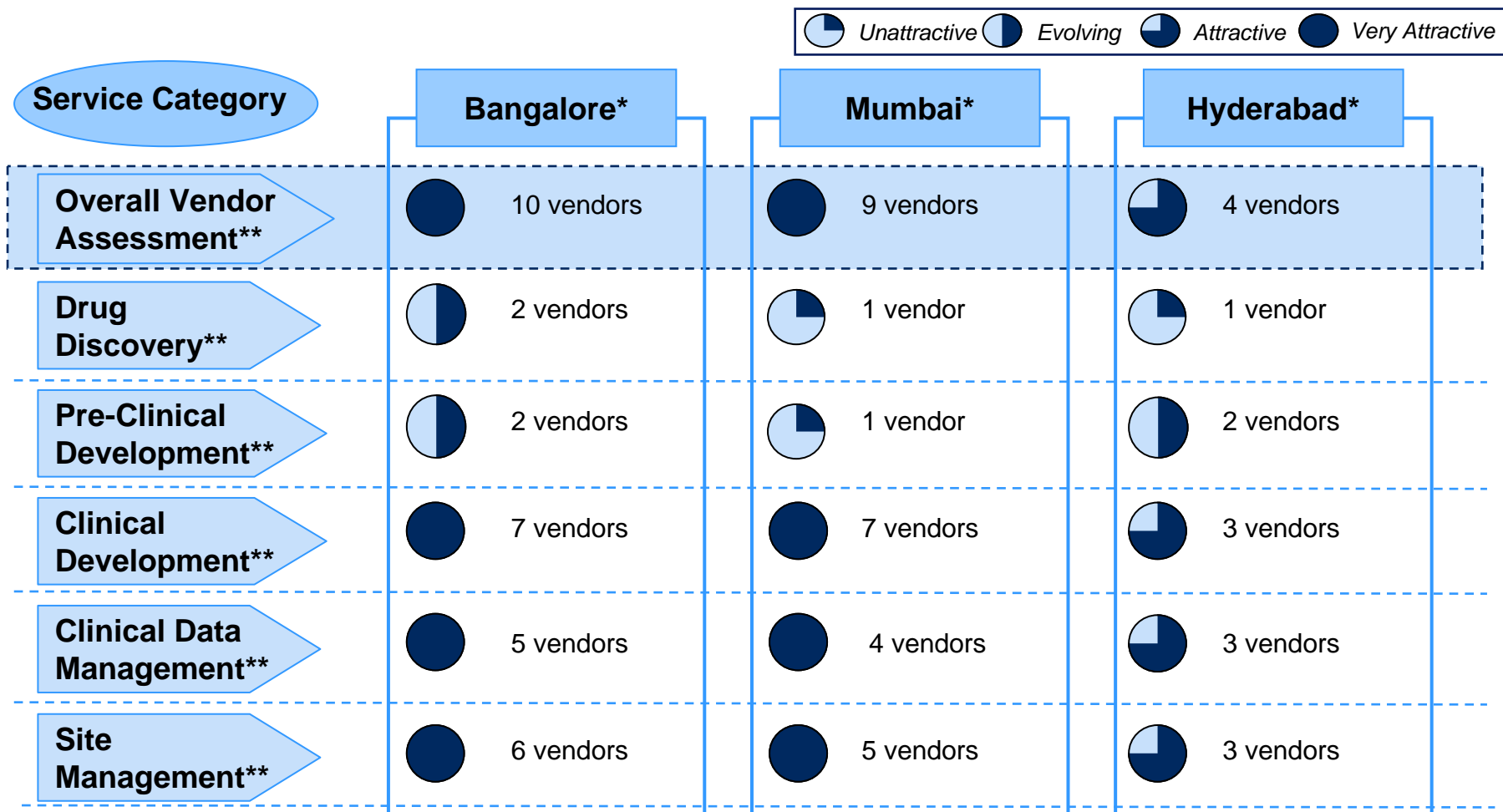
India is very well suited for clinical development whereas Pre-clinical development is still in the evolving stage

	Pre-Clinical Development	Clinical Development
Commonly outsourced?	<ul style="list-style-type: none"> It is outsourced on a large scale in countries such as China In India, the regulatory environment is not very conducive to pre-clinical development The space is evolving in India 	<ul style="list-style-type: none"> Most commonly outsourced in India <ul style="list-style-type: none"> GSK Aventis Pfizer Novartis AstraZeneca Eli Lilly Merck & Co., etc.
Complexity Level	<ul style="list-style-type: none"> Not a complex step Trials are conducted on animals such as rodents, dogs, monkeys and pigs This step only checks whether human trials are feasible or not 	<ul style="list-style-type: none"> Phase I is not very complex Phase II and III are increasingly complex and costly
Vendor Landscape in India	<ul style="list-style-type: none"> Five out of the 22 vendors provide pre-clinical development services <ul style="list-style-type: none"> GVK Biosciences Aurigene Reliance Clinical Research Rallis Research Centre Vimta Labs 	<p>22 Vendors</p> <ul style="list-style-type: none"> Clingene International Quintiles Spectral Vimta Labs SIRO Clinpharm Lotus Labs, etc.

India scores very high on Clinical Data Management and Site Management Outsourcing

	Clinical Data Management	Site Management			
Commonly outsourced?	<ul style="list-style-type: none"> • Many MNCs are outsourcing data management to CROs or IT service Cos <ul style="list-style-type: none"> – Pfizer - Cognizant Technologies – Wyeth - Accenture • Many companies have built strong in-house offshore capability <ul style="list-style-type: none"> – Novartis – Pfizer – GSK, etc. 	<ul style="list-style-type: none"> • Quite commonly outsourced in India <ul style="list-style-type: none"> – GSK – Aventis – Pfizer – Novartis – AstraZeneca – Eli Lilly – Merck & Co., etc. 			
Complexity Level	<ul style="list-style-type: none"> • Average complexity 	<ul style="list-style-type: none"> • Average complexity 			
Vendor Landscape in India	<ul style="list-style-type: none"> • 11 out of the 22 vendors provide clinical data managements services <ul style="list-style-type: none"> – Clingene International – Lotus Labs – SIRO Clinpharm – Synchron Research Services – GVK Biosciences, etc. 	<p>22 Vendors</p> <table border="1"> <tr> <td>10</td> <td rowspan="2"> <ul style="list-style-type: none"> • Clingene • Quintiles Spectral • GVK Biosciences • iGATE Clinical Research • Metropolis, etc. </td> </tr> <tr> <td>12</td> </tr> </table>	10	<ul style="list-style-type: none"> • Clingene • Quintiles Spectral • GVK Biosciences • iGATE Clinical Research • Metropolis, etc. 	12
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12					

India is overall an attractive destination for Pharma R&D and Bangalore, Mumbai and Hyderabad have emerged as hubs for such activities



* Other upcoming cities in India are Ahmadabad, Pune, Chennai, Delhi and Kolkata; **Based on the service offerings of 22 leading CROs in India

India has a strong CRO landscape and most CROs boast of a prominent clientele

Vendor	Set up year in INDIA	FTEs - INDIA	Number of facilities in India	Clients in Top 10 Pharma MNCs
Metropolis	1981	-	5	4
Vimta Labs	1984	506	2	6
Syngene	1994	290	2	6
SIRO Clinpharm	1996	200	1	1
Quintiles	1997	900	3	Yes
iGATE Clinical Research	1997	-	1	2
Clingene	2000	50	2	6
Chembiotek	2000	100	2	3
Wellquest	2000	-	1	1
Lotus Labs	2001	-	1	6
Asian Clinical Trial	2001	-	1	-
GVK Biosciences	2002	800	1	1
ClinInvent	2003	50	1	1
Manipal AcuNova	2005	-	3	3
Apothecaries Ltd	-	-	1	1

Number of FTEs is no indication of the prominence of a CRO. Clingene has only 50 FTEs but a great clientele

CROs have started to adopt a multi-location strategy to avail of larger resources and the trend will only increase

The CRO activity gained momentum in the late 1990s and has grown steadily since 2000

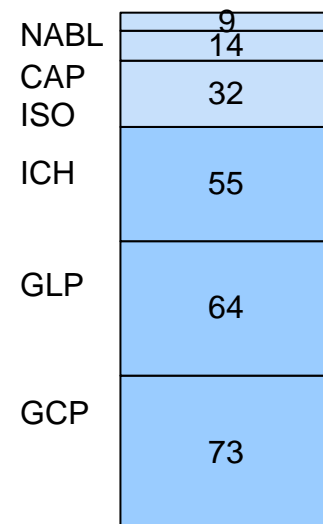
The fact that most CROs have been able to bag deals with leading pharma MNCs, indicates confidence of clients in the capabilities of CROs

Most CROs in India comply to International Quality Standards

Vendor	ISO	ICH ¹	GCP ²	GLP ³	CAP ⁴	NABL ⁵
Quintiles Spectral (India)		✓	✓			
Syngene International	✓					
Clingene International		✓	✓		✓	✓
Wellquest			✓	✓		
SIRO Clinpharm		✓	✓	✓		
Vimta Labs	✓		✓	✓		
Lotus Labs		✓	✓	✓		
Reliance Clinical Research		✓	✓	✓		
GVK Biosciences	✓	✓	✓	✓		
Metropolis Health Services	✓				✓	✓
Rallis Research Centre	✓	✓		✓		
Synchron Research		✓	✓	✓		
Chembiotek			✓	✓		
ClinInvent		✓	✓	✓	✓	
Manipal AcuNova	✓	✓	✓	✓		
Asian Clinical Trial		✓	✓			
Apothecaries Limited			✓	✓		
iGATE Clinical Research	✓	✓	✓	✓		
Omnicare Clinical Research			✓	✓		

Quality assessment of CROs in India

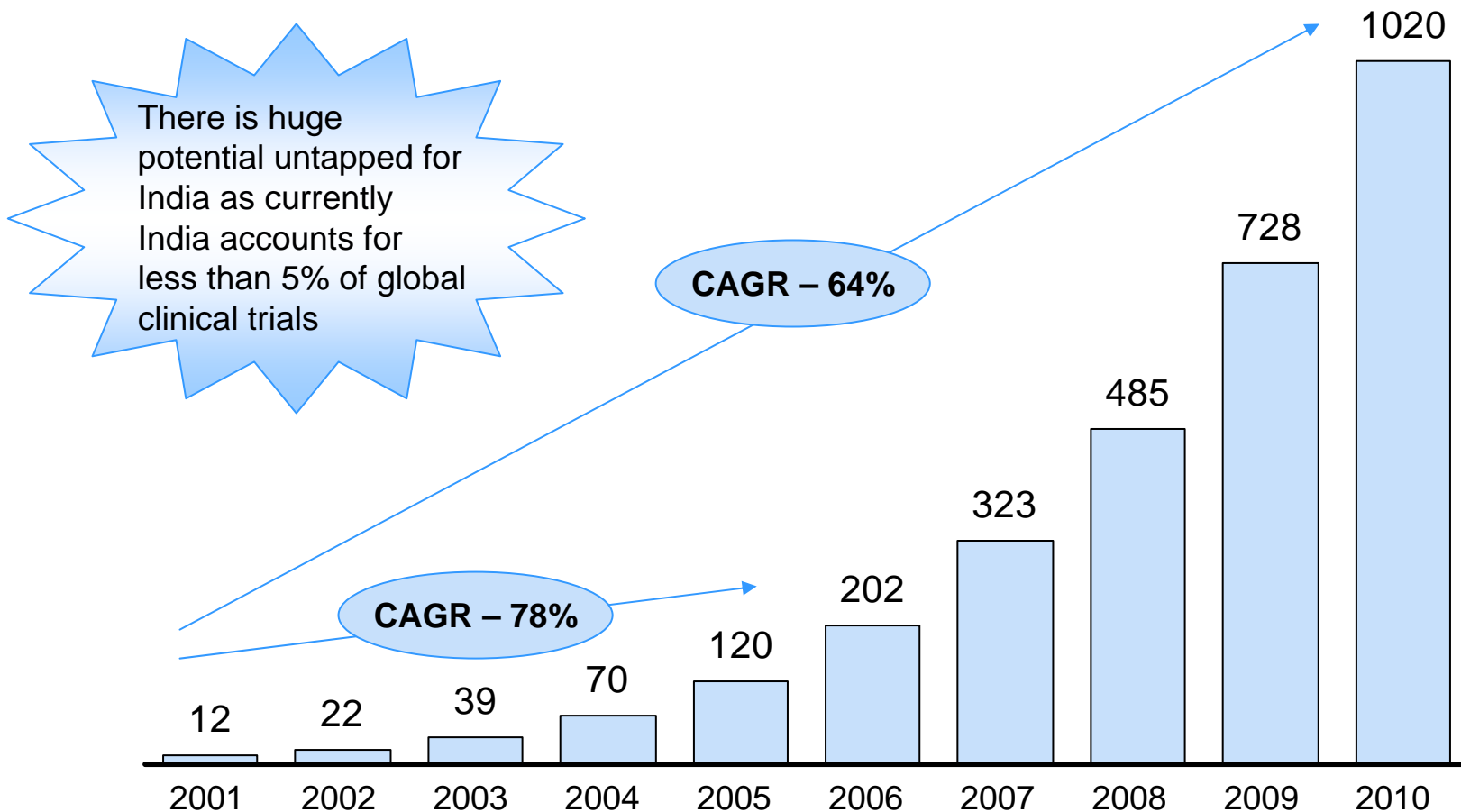
Percentage (Out of a sample of 22 CROs)



Most CROs in India comply to GCP, GLP and ICH standards and are ISO certified – this assures high quality services

CRO market in India has been growing at a fast pace since 2001 and is expected to cross a billion mark by 2010

Outsourced R&D Market - Revenue Forecasts (India), 2001-2011 (USD million)

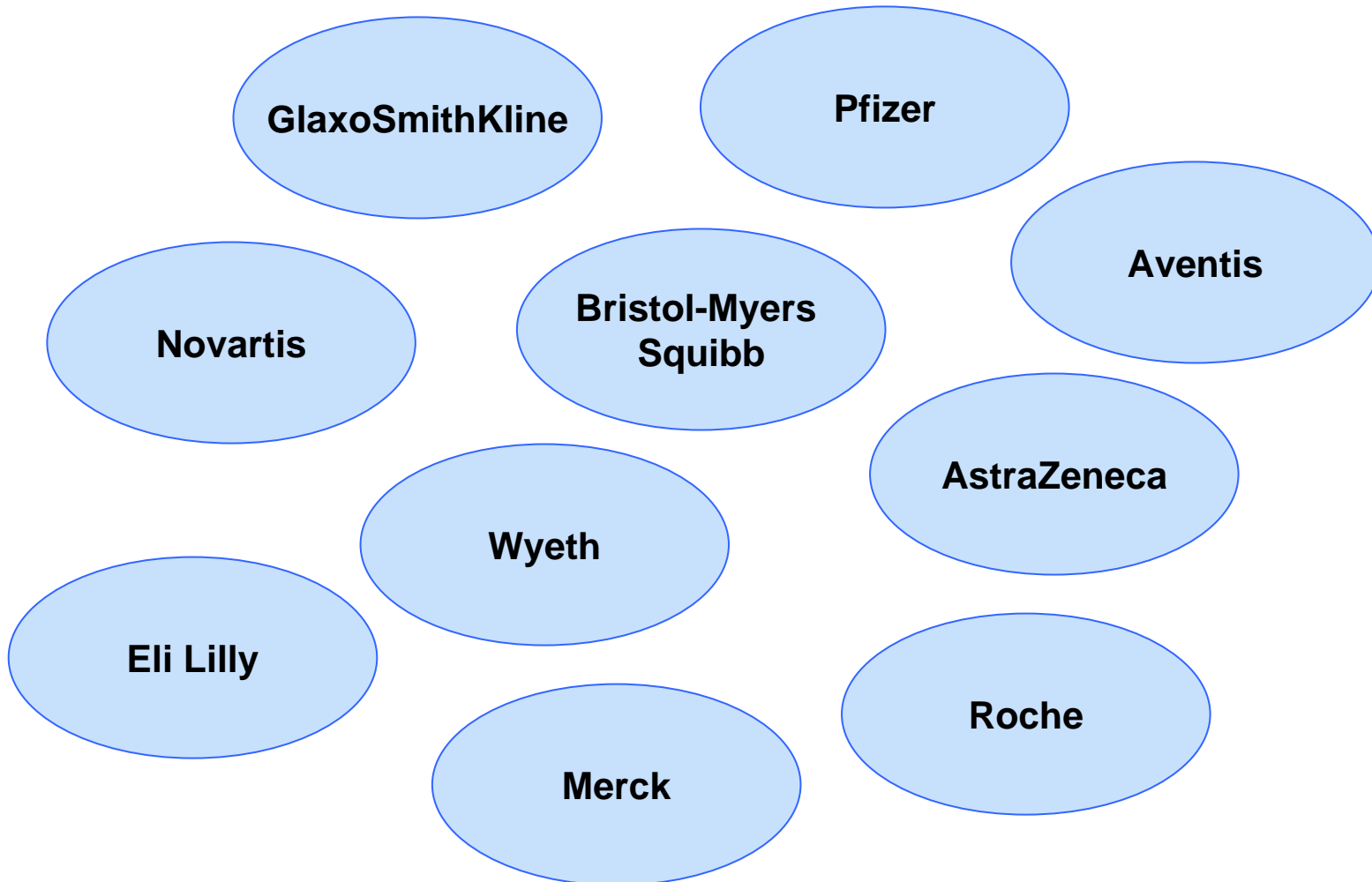


Pharmaceutical Outsourcing Landscape in India

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India is high on the radar of leading MNC Pharmaceutical Companies for Outsourcing and/or Offshoring Various activities to India...

Illustrative



... And many companies have already made huge strides in making India an R&D hub

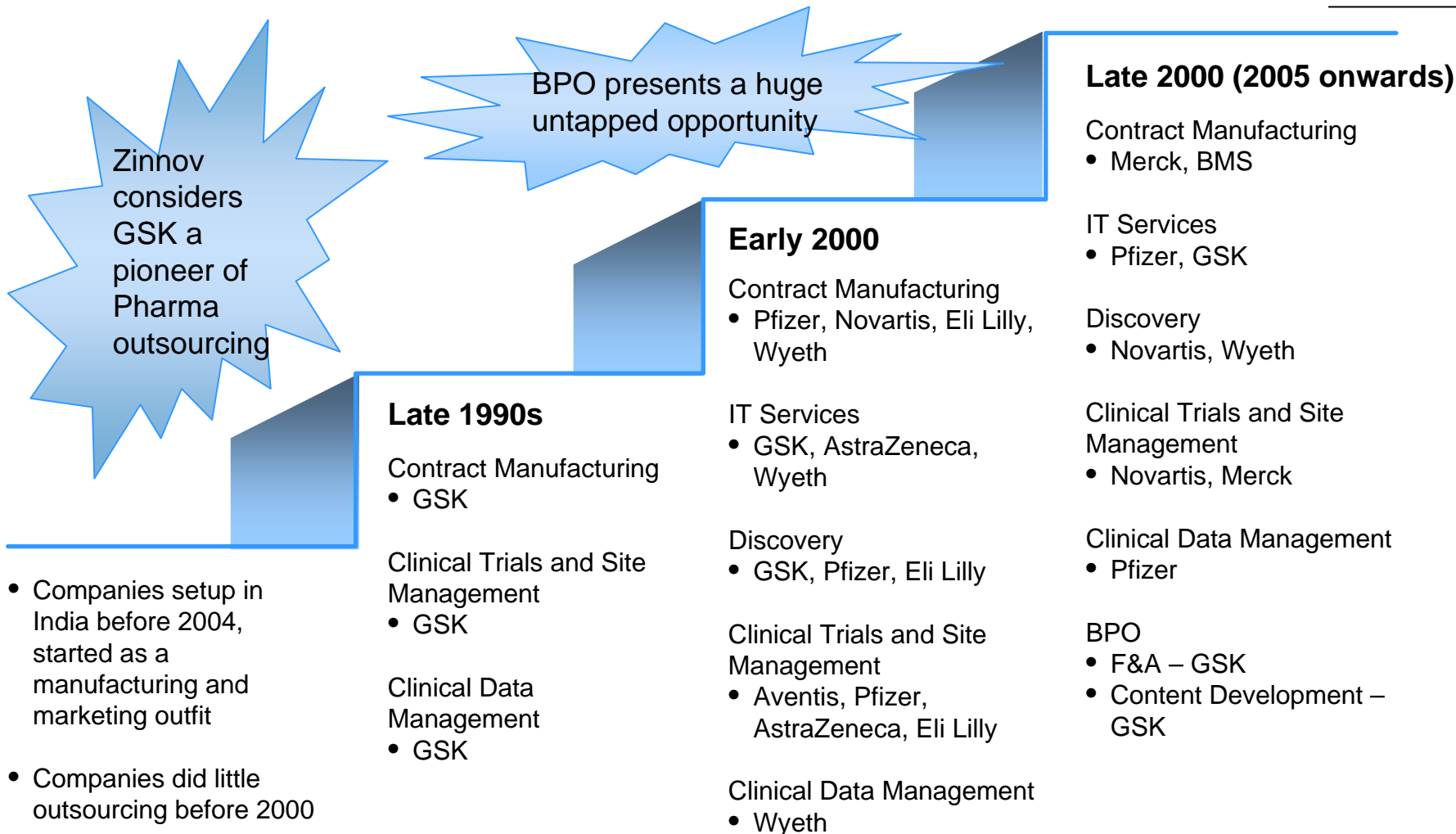
GSK is making huge strides in the outsourcing of pharmaceutical research. So much so that it says the number of drugs discovered by outsourcing partners could eventually outnumber the number of drugs discovered in-house.

Pfizer has invested more than USD 13 million in R&D in India

AstraZeneca has already invested more than USD 10 million and plans to spend USD 40 million by 2010

Outsourcing of R&D, IT and Manufacturing by leading MNCs started in late 1990s and early 2000 and has been growing while BPO started in 2005...

Illustrative



... And various multi-million dollar deals have taken place so far with multiple vendor deals in R&D

Illustrative

Year	Company	Vendor	Service Category	Deal Value	Tenure
2000	Aventis	IBM	IT services	USD 1500 million	10 years
2001	Astra Zeneca	IBM	IT services	USD 1700 million	7 years
2005	GSK	PDI Inc.	Sales and Marketing	USD 70 million	3 years
2006	Wyeth	GVK Biosciences	R&D	USD 40 million	5 years

Company	R&D Vendors					
Pfizer	Clingene	iGATE Clinical Research	Manipal AcuNova	Metropolis	SIRO Clinpharm	Syngene
Novartis	Manipal AcuNova	Syngene	Wellquest			
Merck	Apothecaries Ltd.	Clingene	Syngene			
BMS	Clingene	Syngene				
GSK	Metropolis	Syngene				
Aventis Pharma	Manipal AcuNova	Metropolis				
Astra Zeneca	Clingene	Syngene				
Eli Lilly	iGATE Clinical Research					

Most companies are relying on a multiple vendor relationship in order to take advantage of expertise of various vendors for different services and reduce risks.

There is growing optimism around R&D in India amongst leading Pharmaceutical companies

Illustrative

We believe that India offers a truly exciting opportunity to expand our drug discovery capabilities by accessing the ever-growing chemistry skills base in India

- Frank Walsh, EVP and head of discovery research at Wyeth

Quick patient enrollment is a direct function of India's huge population and the prevalence of a wide spectrum of disease conditions (and even endemic zones).

- Novartis Spokesperson

GSK's initiatives indicate its confidence in the recent product-patent regime.

- Managing Director, GSK India

Commercial operations, R&D and sourcing opportunity would be the three key areas of focus in India

- Jan-Willem Eleveld, managing director (India) Bristol-Myers Squibb

The cost of clinical trials in India could be half or even lower when compared with that prevailing in the west, depending on the nature of the product/disease.

- GlaxoSmithKline Spokesperson

The need to contain costs and improve time to market is a key driver for moving R&D to India

Illustrative

The growing concern in the global pharmaceutical industry is to contain or reduce research and development costs and improve patient recruitment rates. Both these are very difficult to attain unless the clinical development shifts to low cost sites like India.

- Bristol-Myers Squibb Spokesperson

The cost of drug development has considerably increased during the past twelve years compelling pharmaceutical companies to look for smarter ways of conducting clinical research to help faster drug development at a lower cost. India offers immense opportunities in this aspect.

- Pharmaceutical Industry Expert

While for companies like ours it is important to speed up our Phase two and three studies to cut down drug development time, for several patients faced with life threatening diseases like cancer, it could be an opportunity to save their lives.

- Dr Shoibal Mukherjee, Head of Pfizer's clinical development

The company's outsourcing goal is to improve service levels and lower costs.

- GSK Spokesperson

Offshore moves by leading pharmaceutical companies speak volumes about the R&D opportunity in India (1/3)

Illustrative

R&D – In-house Offshore Initiatives to India

GSK

- GSK plans to make India as R&D Base
 - Emphasis will be on collaborative research work with GSK-R&D, UK.
 - Already has an R&D Center in India, which carries out R&D in the following key areas:
 - Development of indigenous technologies for major drugs, process improvements, technology absorption
 - Process improvements, technology absorption and optimization for basic drugs, process simplification
 - Started building its in-house capability for clinical research in 2004 and plans to enhance it considerably by 2007
 - Has identified India as a hub for clinical research and it is in the process of identifying institutes for long-term collaborations

Pfizer

- Pfizer plans to Plans to make India a prime R&D hub
 - Has already invested more than U\$13 million on R&D in India for clinical trials in India in the segments of psychiatry, cancer, ophthalmology, infectious diseases, etc.
 - Has conducted more than 20 clinical studies so far

Offshore moves by leading pharmaceutical companies speak volumes about the R&D opportunity in India (2/3)

Illustrative

R&D – In-house Offshore Initiatives to India

Aventis

- Plans to make India an Research hub and shift a major part of its global R&D operations into India
- Plans to make India a base for clinical development
 - Has set up clinical trial infrastructure in India
 - Plans to conduct clinical trials in the cardiovascular, diabetes and oncology segments

AstraZeneca

- AstraZeneca is upbeat about R&D activities in India
 - Has a captive center in Bangalore, India, set up in 2001 to discover new drugs for the treatment of infectious diseases for the developing world
 - Concentrates on the development of new drugs for the treatment of tuberculosis
 - Initial investment in the facility was U\$10 million
 - Plans to invest U\$40 million in the next 4 years in the facility
 - The R&D centre works in collaboration with parent's laboratories
 - Plans to scale up its operations in India with expansion of its Process R&D group in Bangalore
 - Plans to make India a base for clinical development
 - Initiated extensive clinical trials in India with asthma-related drugs in 2003
 - Plans to focus on the oncology, cardiovascular and respiratory segments

Offshore moves by leading pharmaceutical companies speak volumes about the R&D opportunity in India (3/3)

Illustrative

R&D – In-house Offshore Initiatives to India

Eli Lilly

- Plans to make India a prime R&D hub
- Has already made India a global hub for clinical trials
 - Actively involved in clinical trials in India since 1995
 - Has been conducting clinical research activities in the field of infectious diseases, oncology and endocrinology
 - Conducts Phase II, III and IV trials in India

Novartis

- Plans to make India a prime R&D hub
- Exploring collaborations with Indian pharmaceutical firms in R&D in areas like oncology, dermatology, cardiovascular disease, transplantation, nervous system, etc.

Roche

- Roche wants to make India a base for clinical development
 - Considering India for Roche's future clinical trials involving new drugs and therapies for treatment of different variants of cancer and colorectal diseases
 - Has already conducted various clinical trials such as on breast cancer, lung cancer, etc.

Besides doing in-house Offshore R&D in India, many leading companies are also outsourcing R&D, Manufacturing and IT services

Illustrative

Company	Contract Manufacturing	IT Services		Discovery	Development		
		IT application and development	IT Infrastructure support		Clinical Trials	Clinical Data Management	Site Management
GSK	✓	✓	✓	✓	✓	✓	✓
Aventis			✓	✓	✓		✓
Pfizer	✓		✓	✓	✓	✓	✓
Novartis	✓				✓		✓
Astra Zeneca		✓	✓		✓		✓
Eli Lilly	✓			✓	✓		✓
Merck	✓						
BMS	✓						
Roche							
Wyeth	✓	✓		✓		✓	

Apart from GSK, there is no significant instance of BPO and hence there is immense potential to be tapped

Pharmaceutical Outsourcing Landscape in India

Additional information on the following topics are available in our full report.

To obtain a copy of the full report, please send a mail to info@zinnov.com

- **Appendix (Detailed profiles)**
 - Offshoring and Outsourcing Initiatives by Top Ten Pharmaceutical MNCs to India – Manufacturing, IT, R&D, BPO
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Zinnov Research Overview

Zinnov – About us

Company Overview

- We are a knowledge services and consulting company with offices both in US and in India.
- We help our clients reduce the time, money and risks involved in organizational initiatives using combination of consulting and knowledge solutions delivered by global teams.

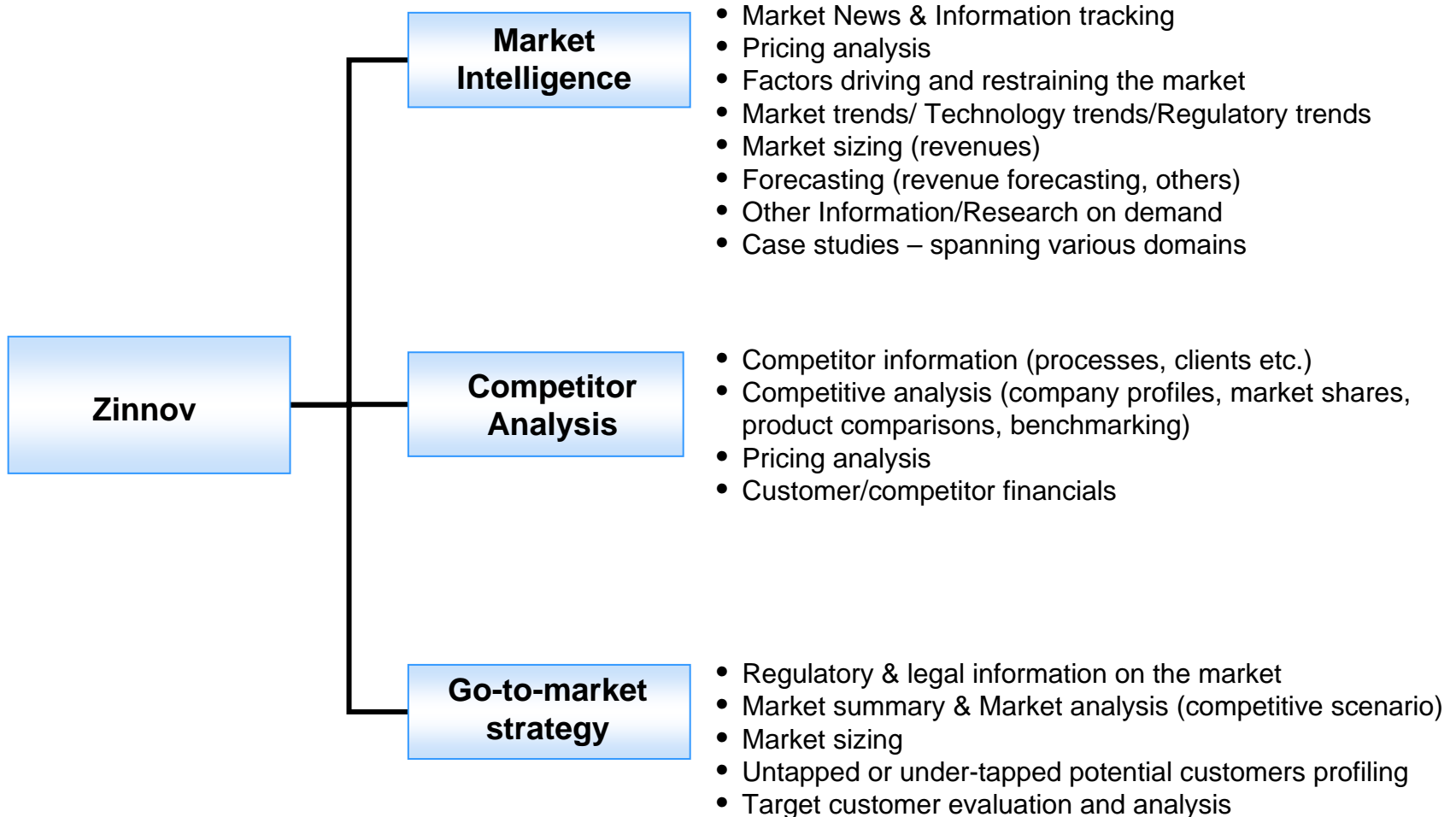
Market Research

- **Research services**
 - Customized market studies
 - Competitive Benchmarking
 - Data Analytics
 - Market Intelligence
- **Go-To-Market Services:**
 - Help companies enter the India market by helping them scope and segment the market, provide on-ground sales and marketing support to tap into the local market.

Knowledge Services

- **Dedicated Knowledge Centers (DKCs):**
 - We provide dedicated teams that help our customers in the areas of market research, competitor analysis, business research, data analytics and pre-sales support. DKCs act as an augmentation to our customer teams and provide cost effective and high value services.
 - We have provided our research and consulting solutions to more than two dozen customers. Today, our client roster included reputed NASDAQ listed companies, small to medium sized independent software vendors, strategy consulting firms and other large enterprises in domains such as BFSI, IT services and Infrastructure management.

Zinnov research team can help clients with market intelligence, competitor analysis and go-to-market strategy



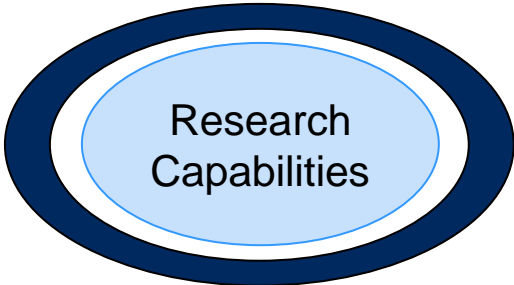
Zinnov has expertise in all areas of market intelligence & competitor analysis

Primary Research

Zinnov's extensive telecom industry contacts and established network in the Indian telecom market enables us to quickly identify key people for interviews

Secondary Research

Experience in gathering quality information through various sources helps timely delivery



Research Capabilities

Report creation

Consultants are seasoned in powerpoint, Word reports which helps in creating desired impact

Competitor Analysis

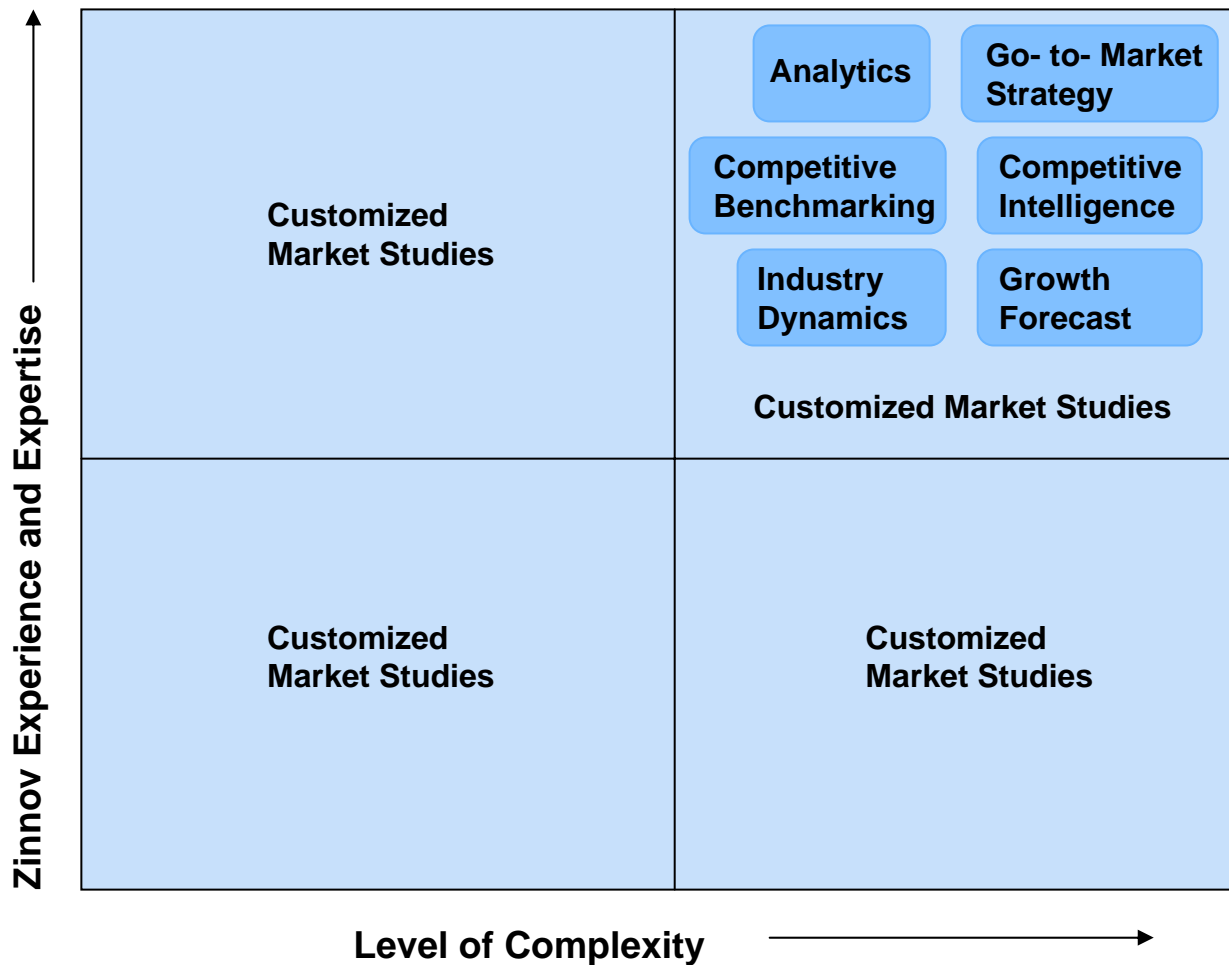
Research team is skilled in tracking & benchmarking competitors of client

Analysis & Forecasting

Research team has experience in doing various type of analysis that helps to provide valuable recommendations

A. Market Research: Zinnov has a very strong Market Research Capability with expertise across the value chain, specifically in the high end space

Illustrative



Zinnov's Differentiators

- Rich experience with High end market research enabling strategic decisions such as go-to-market strategy
- Excellent primary and secondary research capability
- Excellent pool of resources with strong capability to create customized reports for clients in any sector

B. Financial Analysis: Zinnov has a strong Financial Analysis Capability which complements both market and business research

Financial Statements

- Balance Sheet
- Income Statement
- Cash Flow Statement

Ratio Analysis

Profitability ratios

- Returns - Return on equity; Return on Assets, etc.
- Margins - Gross Margin; Net Margin

Turnover ratios

- Total Asset turnover
- Fixed asset turnover
- Working capital turnover
- Inventory turnover

Liquidity ratios

- Current ratio
- Quick ratio
- Cash ratio

Solvency ratios

- Debt to equity
- Debt to total capital
- Interest Coverage
- Total Coverage

Market Valuation

- Share Price
- Market Value of Equity
- Enterprise Value

Multiple Analysis

Trading Multiples

Transaction Multiples

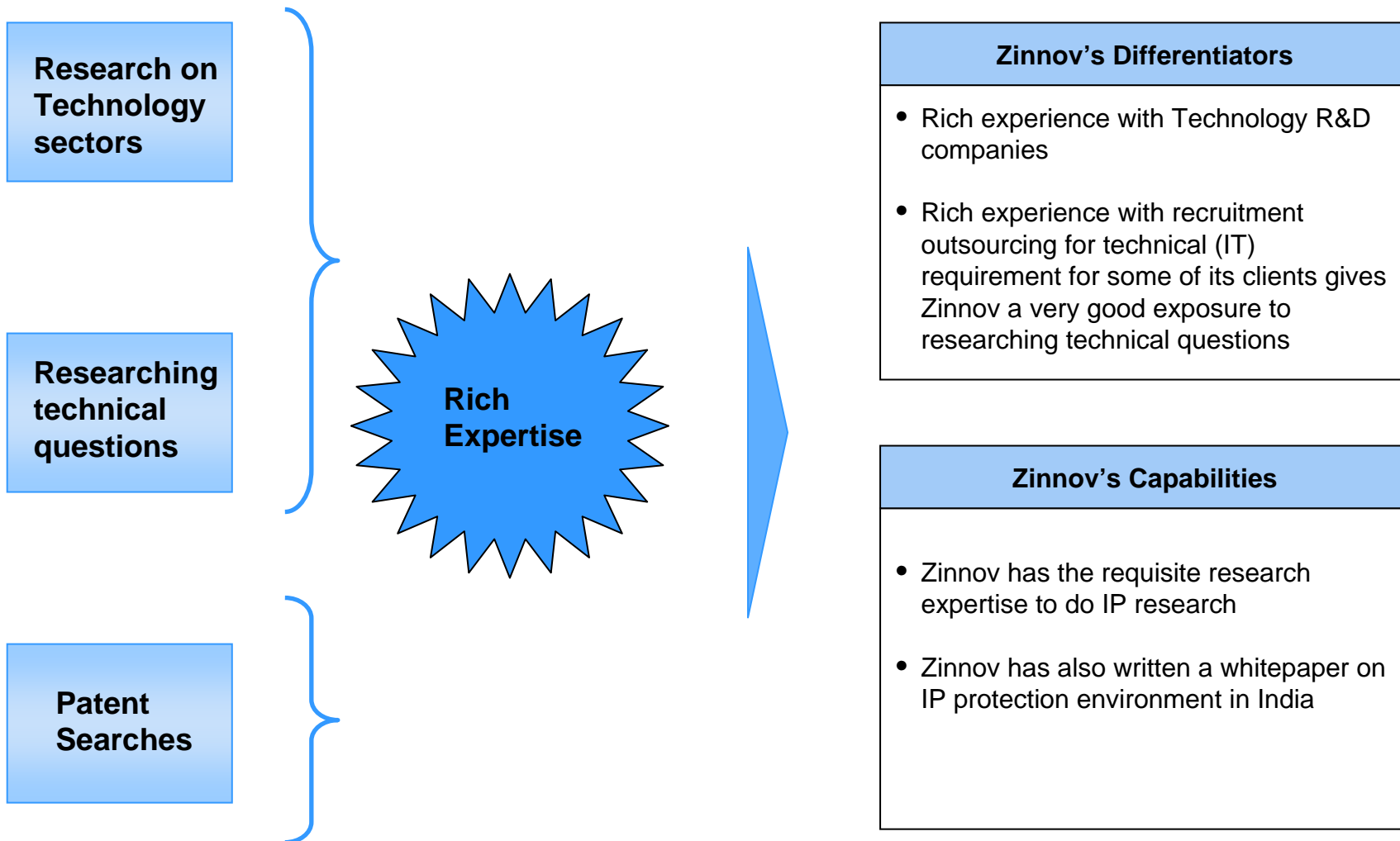
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Business Research – Company Performance Evaluation

Market Research – Competitive Benchmarking and Intelligence

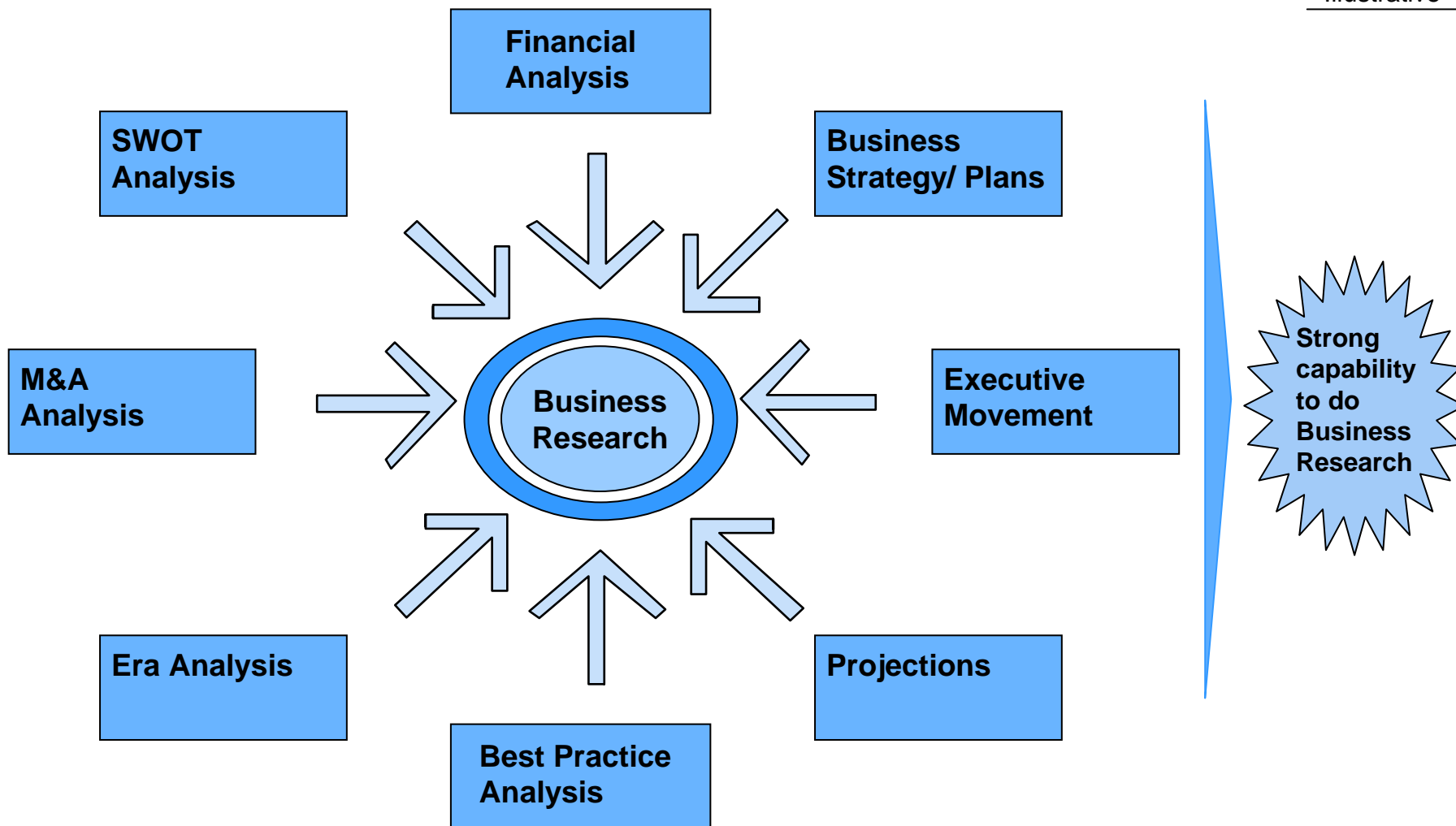
C. Technical Research: Owing to its rich and diverse experience with multiple IT R&D companies, Zinnov also has a strong Technical Research capability

Illustrative



D. Business Research: Zinnov has a strong Business Research Capability as well, covering various facets of business

Illustrative



E. Market Mapping – Competitive Mapping and Benchmarking

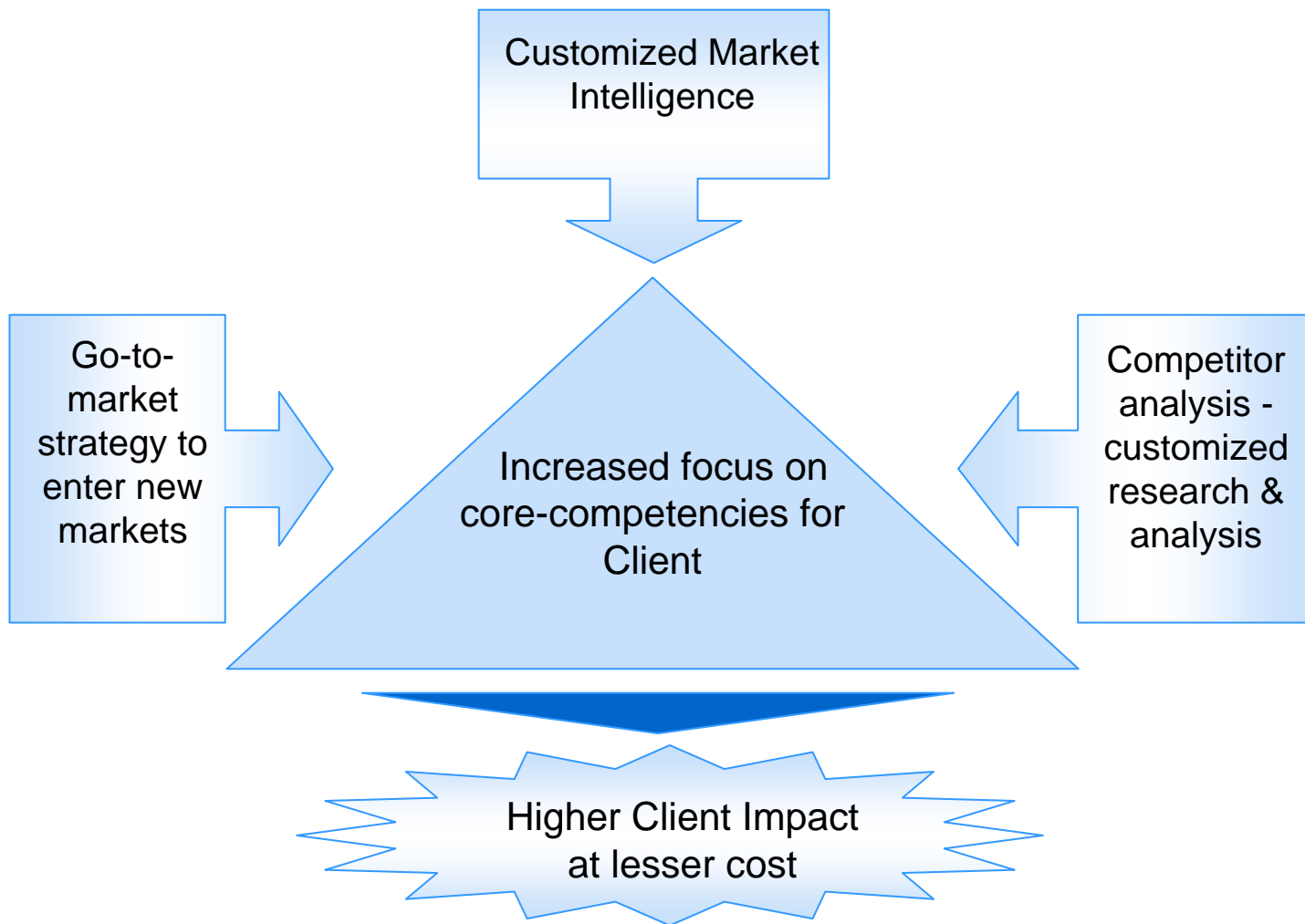
Illustrative

Financial Strength and Soundness
Margins - Gross
Margins - Operating
Margins - Net
Returns on Equity
Returns on Assets
Returns on Capital Employed
Solvency ratios - Debt to equity
Solvency ratios - Debt to total capital
Solvency ratios- Interest Coverage
Liquidity ratios - Current Ratio
Liquidity ratios – Quick Ratio
Liquidity ratios - Cash Ratio
Top line - Compounded annual growth rate (CAGR)
Trading Multiples

Capability Analysis
Management Team Expertise
Technological Capability
Products/ Services
Quality Processes
Market Share
R&D Investment/ Initiatives
Marketing Strategies
Geographical Presence
Years of existence
Personnel
Past successes and failures
Future strategies/ plans
Clientele
Alliances/ Partnerships/ M&A
Enterprise Business Solutions



Our clients are benefited by cost and time effective research that Zinnov offers



Zinnov is proud to maintain 100% client references. Our clients include reputed consulting firms and industry organizations

Your comprehensive report on our competitors enabled us to make informed and objective decisions on penetrating global markets

**-SVP, Marketing
Incentive Management Software**

Thanks for the quick turnaround of the survey analysis. We look forward to your help in producing similar reports for all our industry surveys

**- Executive Director
Industry Organization**

You help us compete with McKinsey in India

- Principal, Management Consulting Firm

The level of details you capture and analyze is great.

**- VP, Operations
Employment Screening Company**

The quantitative analyzer is one of the most flexible model I have ever seen. We used it for analyzing 'what if' scenarios in our meeting with the client and they loved it!

**- Principal
Management Consulting Firm**

Thank You !

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