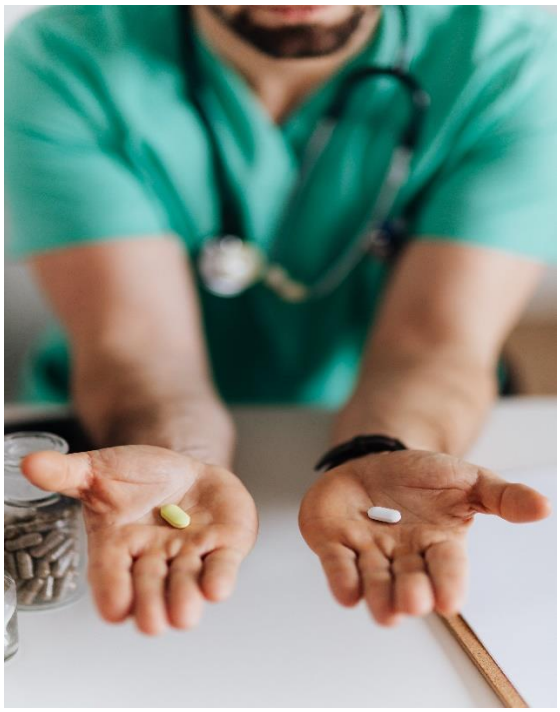
STUDY ON CRO SECTOR IN INDIA
CONDUCTED BY DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA
AUGUST, 2023



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1. INTRODUCTION

1.1. Background

Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers is nodal agency for the scheme “Strengthening of Pharmaceutical Industry (SPI)", with a total financial outlay of Rs.500 Cr for the period from FY 21-22 to FY 25-26. The scheme aims to address the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.

The objectives of the Scheme “Strengthening of Pharmaceutical Industry (SPI)” are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharmaceutical Sector. Under the Scheme, there is a provision for the financial assistance to pharma clusters for creation of Common Facilities.

Further, in order to upgrade the production facilities of SMEs and MSMEs so as to meet the national and international regulatory standards (WHO-GMP or Schedule-M), the incentives like interest subvention or capital subsidy on their capital loans is being provided to facilitate the growth in volumes as well as in quality of drugs in India.

The SPI Scheme of Department of Pharmaceutical has broadly 3 components / sub-schemes:

Assistance to Pharmaceutical Industry for Common Facilities (APICF): To strengthen the existing pharmaceutical clusters’ capacity for their sustained growth by creating common facilities. Under the API-CF sub-scheme, support for clusters for creation of common facilities with the focus on R&D Labs, Testing Laboratories, Effluent Treatment Plants, Logistic Centres and Training Centres in this order of priority with an outlay of 178 Cr for the scheme period of five years is proposed.

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS): To facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards. Under the PTUAS sub-scheme, support for about SME Industries is proposed, either through up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention or through Credit linked Capital subsidy of 10%. In both the cases, the loan supported under this is to a limit of 10 Crores and the eligible components of the loan has been listed out in the scheme guidelines. An outlay of 300 Cr has been earmarked for sub scheme for the scheme period of five years.

Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS): To facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry. Under the PMPDS sub-scheme, knowledge and awareness about the Pharmaceutical and MedTech Industry will be promoted. This will be done by undertaking studies, building databases and bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the Pharma and Medical Devices sector. An outlay of 21.5 Cr has been earmarked for the sub scheme for the scheme period of five years. It is expected that the units supported under this scheme will act as Demonstration Firms for the pharma clusters and MSE Pharma Industries, to develop on quality and technology upgradation fronts.

The Pharmaceutical global contract outsourcing market has been picking up after the covid pandemic. During the years between 2022-30, the global contract research outsourcing market is expected to grow @ CAGR of 7 % and reach USD 90.4 Billion by 2030. Out of this about USD 61.2 Billion will be contributed only by the outsourcing done in the domain of clinical development. The CRO sector in India has been growing @ CAGR of 10.75 % and will reach USD 2.5 Billion by the year

2030. Hence, it is imperative to identify the emerging opportunities for the Indian CRO sector beforehand, draft and implement strategies which will help in promoting the Indian CRO business. Under the PMPDS Scheme, the Department of Pharmaceutical, Government of India took an initiative to conduct an independent study on the CRO sector/ market in India to identify and understand the real issues faced by CROs operating in India and work out a proposed roadmap to resolve those issues and make the necessary policy revisions.

1.2. Study Assumptions and Study Definition

Study Assumptions:

- The study assumed that the information available on various secondary sources of data regarding CROs, their locations, their services/offerings, their revenues, their clients and regulatory approvals are accurate and reliable.
- This study assumed that the contract research services market has been increasing steadily over the past few years and are these services are widely sought after by multiple industries, such as pharmaceuticals, biotechnology, healthcare, medical devices and research organisations.

The study also assumed that key factors influencing the decision of sponsor companies to outsource research projects to contract research organizations (CROs) include cost-effectiveness, robust regulatory compliance, geographical coverage, specialized expertise and time efficiency. This assumption suggests that organizations choose to outsource their research projects to CROs primarily to leverage cost savings, access specialized knowledge and skills, and expedite the bench to market pathway.

Study Definition: The assessment study, "**Study of CRO Market/ Sector**," aimed to help the government to identify the existing gaps and major issues commonly faced by CROs/Users, thereby enabling to design a roadmap for quick addressal and upgradation of the existing policies.

The study encompassed the following key components:

- Market survey for listing of all CROs using different search engines like Google
- Setting up the specific questions based on preliminary discussion from CROs and users including pharmaceutical biotechnology medical device and academic research institutes.
- Identifying the major services offerings of the CROs like Discovery Services, Preclinical Services, Clinical trials, End to end product development services, post-marketing surveillance etc.
- Identifying the major therapeutic segments in which the CROs are primarily working, the available facilities with the CROs, nature of regulatory approvals and accreditations required by CROs.
- Identifying the drivers on the basis of no. of employees, segment wise expertise, annual turnover, major clients and thrust areas of the CROs.
- Categorizing the CROs in a region-specific manner with the help of pi-charts.
- Identify the challenges for pharmaceutical promotion and design the CRO's to strengthen the objective of users.
- Working out a proposed roadmap to resolve those issues and policy revision for proposing to the government

1.3 Base Estimates and Working

Base Estimate:

- **Duration:** The study was estimated to be conducted over a period of 6 months.
- **Resources:** The study required a team of researchers, analysts, and subject matter experts with expertise in the pharmaceutical industry, Contract Research Market, Pharmaceutical product development, Discovery Services Preclinical Research, Laboratory Research, Clinical research and Market Analysis. The team allocated by BHPL included experienced individuals in the above-mentioned areas along with skills in data analysis, research methodology and report writing in Pharmaceutical CRO Sector.
- **Data Sources**: The study primarily relied on publicly available data sources such as websites of CROs, the annual reports of CRO, industry reports, CTRI Platform, and scholarly articles. Additionally, the primary data was collected using the questionnaires and semi structured interviews with CRO representatives, users, industry experts and key stakeholders to gather insights and opinions.
- **Target Respondents:** In the context of a market survey, the target respondents included the representatives of CROs offering Discovery services, Pre-clinical Services, Bioequivalence & Bioavailability Services and Clinical Trial Services. On the user/ customer side the sponsors like Pharmaceutical, Biotechnology and Medical Device companies and government research organisations were included in the study.

- **Sample Size:** Purposive sampling was employed to ensure representation of key stakeholders during the primary data collection**.** In the context of the market survey, the secondary data of 50 Indian CROs was collated. The primary survey data was collected from representatives of 24 CROs and 20 users using the questionnaires, telephonic interviews, face to face interviews and focussed group discussions using ICTs. In addition, the inputs of the Directors of seven NIPERs were also taken for coming up with the suggestions and way forward. No financial incentives were provided to the respondents during the study.

Working Approach:

The study employed a combination of quantitative and qualitative research methods, including, literature review, online questionnaires, stakeholder's interviews and expert opinions. Before distributing the online questionaries to the target respondents, a pilot test was conducted within the BHPL team and a small group of respondents to identify the potential issues with the survey design, question clarity and other technical problems.

After the data collection was complete, the data was cleaned and analysed to summarize the responses and examine key patterns and trends. Further the survey findings were interpreted in the context of the given research objectives and existing literature and industry reports to provide a comprehensive understanding of the market.

2. RESEARCH FRAMEWORK

2.1. Primary Research

Five robust and comprehensive questionnaires were used for the primary data collection of different type of CROs and users during the study. The Semi-Structured and In-Depth Interviews with Pharmaceutical & CRO industry experts, policymakers, and key stakeholders were conducted to gather qualitative insights and opinions.

2.2. Secondary Research

Reputable and reliable sources of information relevant to the research objectives were identified and utilized in secondary data collection. Systematic literature review was conducted to gather relevant academic articles, research studies, case studies related to the patent cliff and drug pricing methodologies and scholarly publications. These sources included were not limited to:

- **Academic databases:** Databases like CTRI, PubMed, Scopus, or Google Scholar to access scholarly articles and research studies related to the CRO industry dynamics.
- **Industry reports and Articles:** Reports and Articles published by market research firms, industry associations, or consulting agencies that provide insights on the pharmaceutical industry, latest market trends in CRO industry etc.
- **Recent Conferences:** In addition, some of recent Focus Group Discussions of the experts from CRO and pharmaceutical industry on CRO market in recent conferences were observed to gather overall perception of the industry.
- **Regulatory databases**: Clinical Trial databases like Clinical Trials Registry Indian (CTRI) managed by Indian Council of Medical Research (ICMR).
- **Government publications:** Reports and Gazette Notifications from governmental bodies such as ICMR and regulatory agencies like CDSCO.

2.3. Data Triangulation

The data was validated by cross-referencing the information obtained from different sources. The quantitative and qualitative data gathered from various sources, including primary and secondary sources was combined to enhance the robustness of the analysis. Data was checked for consistency and coherence in the findings across the sources and converging evidence for consistent overarching trends, themes and patterns in the data. As a result of this holistic understanding of the data, the key insights were derived from the triangulation process.

2.4. Insight Generation

The key findings were interpreted within the broader context of the pharmaceutical industry, market dynamics, regulatory environment, and relevant economic factors to synthesize insights. The generated insights were validated by checking their alignment with the data, analysis, and research objectives. It was ensured that the generated insights were logical, supported by evidence, and consistent across different sources and methods used in the study.

EXECUTIVE SUMMARY

3. EXECUTIVE SUMMARY

India is the largest provider of generic drugs globally and is known for its affordable vaccines and generic medications. The Indian Pharmaceutical industry is currently ranked third in pharmaceutical production by volume after evolving over time into a thriving industry growing at a CAGR of 9.43% since the past nine years. According to a recent EY FICCI report, Indian pharmaceutical market is estimated to touch US$ 130 billion in value by the end of 2030.

India has the highest number of pharmaceutical manufacturing facilities that are in compliance with the US Food and Drug Administration (USFDA) and has 500 API producers that make for around 8% of the worldwide API market. Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. The domestic pharmaceutical industry itself includes a network of 3000 plus drug companies and more that 10000 manufacturing units. The Pharmaceutical industry in India is the third largest in the world in terms of volume and 14th largest in terms of value. India enjoys an important position in the global pharmaceuticals sector and rightfully called the Pharmacy of World.

One of the key factors contributing to India's success in the pharmaceutical sector is its strong contract research foundation. The CROs or contract research originations are entities hired by a Pharmaceutical, Biotechnology or medical device company to conduct research and development activities on its behalf in a defined geography with full or partial scope of work. The evolution of Contract Research Organizations (CROs) stems from the mid-20th century. Companies like Huntingdon Life Sciences and Charles River Laboratories came into being during the 1940s and 1950s, addressing the growing demand in the pharmaceutical sector. However, the modern shape of the CRO industry began to crystallize in the late 1970s and early 1980s. This period witnessed the establishment of leading organizations such as Quintiles (now IQVIA) and Parexel, which diversified the traditionally confined role of preclinical testing to embrace broader areas like clinical trials, data management, pharmacovigilance and logistics.

Unlike the CROs which are service driven, the core area of interest for a pharma company is increasing its product portfolio and registering its pharmaceutical products across new geographies. Registration of a new pharmaceutical product in new geography requires the extensive research and regulatory compliant data which needs to be generated through extensive and reproducible research. Most pharma companies do not want to invest their time and resources in this domain and look for professional expertise, which is offered by the CROs.

The CRO sector in India has been growing @ CAGR 10.75 % is expected to reach USD 2.5 Billion by the year 2030. The CRO sector is driven by specialized research and development service providers which can assist the pharmaceutical and biotechnology companies in overall drug discovery and development programs. These include Discovery CROs, Pre- Clinical CROs, Clinical CROs and the CROs offering bioequivalence and bioavailability services. CROs range from large, international full-service organizations to small, niche specialty groups and can offer their clients the experience of moving a new drug or device from its conception to marketing approval without the drug sponsor having to maintain a staff or research centre for these services.

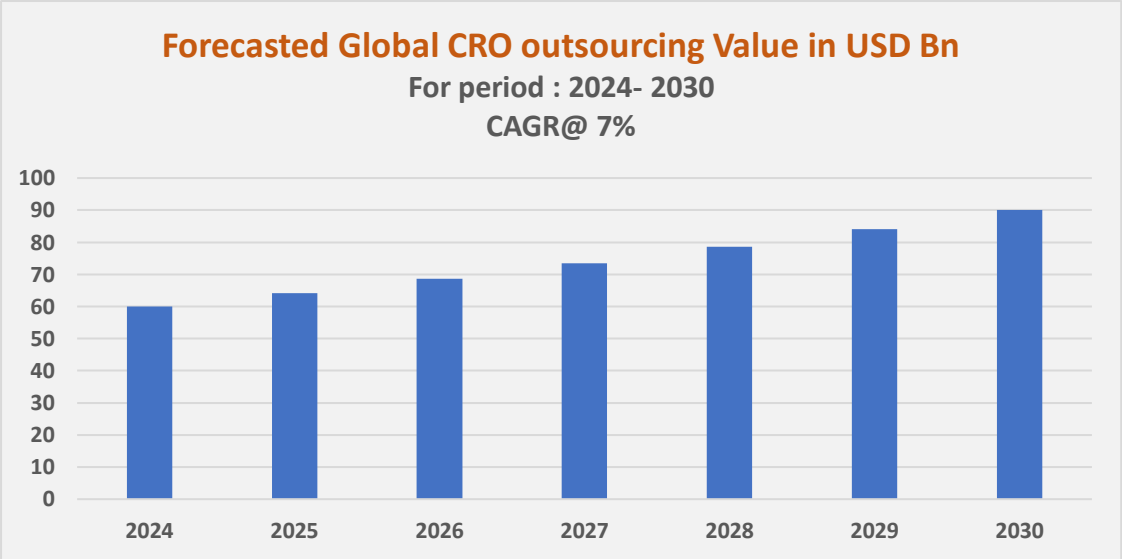
Depending on the requirements, Pharmaceutical and biotechnology companies can partially or full outsource their research and development activities to these CROs. By outsourcing research activities, pharmaceutical and biotechnology companies save time and cost as they do not need to invest into research infrastructure and manpower and therefore, these companies can focus on their core competencies and areas of expertise. In newer models, initial innovation often comes from the CROs, who establish early chemistry and biology entry points into disease and then approach potentially interested pharma companies to collaborate as strategic drug discovery partners. Such projects can be structured in different ways, including milestone and royalty payments, FTE payments, and event potentially jointly owned intellectual property rights commercialized as joint ventures or spin-off companies.

Mostly, the clinical CROs work on "Fee for Service model" however there have been cases where CROs have worked on the Full-Time Equivalent (FTE) model, where the pharmaceutical company hires a clinical trial project team at CRO premises and pays for all the materials and other project expenses. The FTE model is suitable for the complex projects, where flexible continuous work is anticipated.

3.1. Business Trends in CRO industry

1. **Global Growth Pattern:** During the years between 2022-30, the global contract research outsourcing market is expected to grow @ CAGR of 7 % and reach USD 90.4 Billion by 2030 (Refer Exhibit 1) The contract research outsourcing market in US which was estimated to be USD 20.1 Billion in 2022 is expected to grow @ CAGR of around 8% and reach USD 37.20 Billion by 2030. US will be the biggest contributor to the contract research outsourcing market with share of around 41% of global pharmaceutical contract research outsourcing market. China is expected to steadily moving at a CAGR@ 10.1% during the forecast period of 2022-2030 and reach a market of USD 5.6 Billion by 2030.

Exhibit 1: Forecasted Global CRO Market for the period 2022-2030



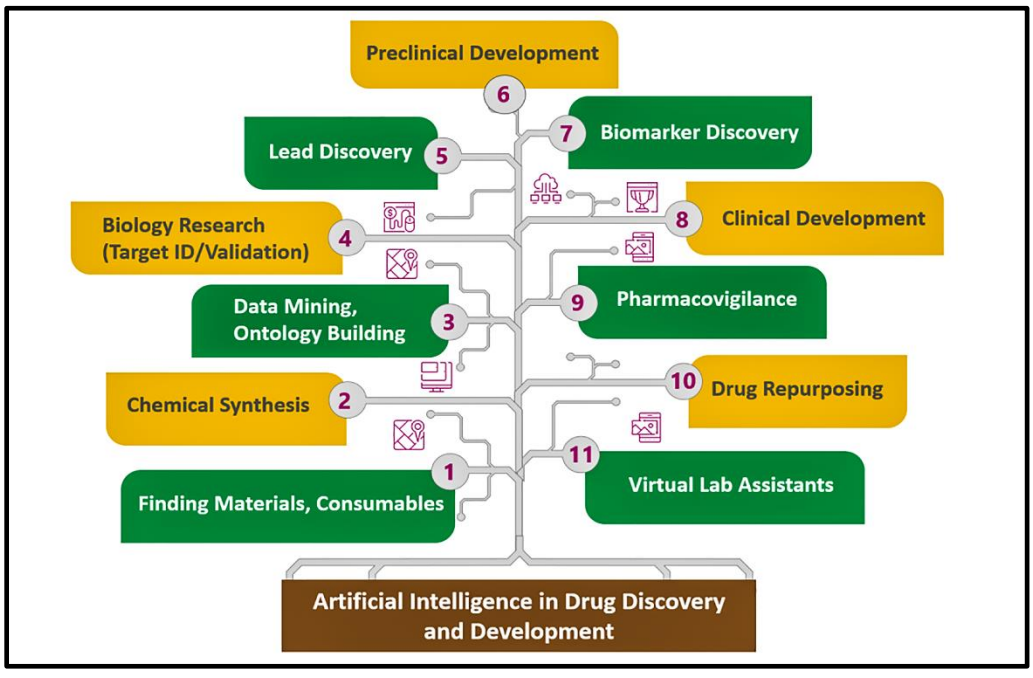
2. **Collaborations, Partnerships and Consolidation in CRO industry:** Discovery CROs are increasingly forming long term strategic collaborations and partnerships with pharmaceutical and biotechnology companies, academic institutions, and other CROs. These collaborations can involve co-development of drugs, joint ventures, or preferred provider agreements, enabling both parties to leverage each other's strengths and expand their capabilities. These collaborations allow for sharing of expertise, resources, and technologies, fostering innovation and accelerating the drug discovery process. Such partnerships also help in de-risking the drug development process and sharing the costs associated with research. For example, Syngene has a dedicated research facilities name BBRC for Amgen, Baxter, and Bristol-Myers Squibb for specialist discovery, development, and manufacturing facilities in Bangalore. The CRO industry has also witnessed numerous mergers and acquisitions in recent years. Large CROs have acquired smaller, specialized CROs to expand their service offerings, geographic reach, or therapeutic expertise. This consolidation aims to create comprehensive CROs that can provide end-to-end solutions to pharmaceutical, biotech, and medical device companies. Consolidation has allowed CROs

to broaden their service portfolios. Some of the noteworthy consolidations in recent times include the mergers of InVentiv Health with INC Research (2017), and Quintiles with IMS (2017); the acquisition of Covance by LabCorp (2014), of WIL Research (2016), MPI Research (2018), KWS Biotest (2018) and Citoxlab (2019) by Charles River Laboratories, and of Selcia (2018), Villapharma (2016) and DiscoverX (2017) by Eurofins. Other notable mergers and acquisitions in 2021, for example, included ICON's procurement of PRA and Thermofisher's purchase of the PPD. Further, Genesis Drug Discovery & Development (GD3), a Member of Genesis Global Group, acquired JSS Medical Research to expand its clinical services Portfolio in May,2023. Despite the significant consolidation in the CRO industry, smaller sponsors still have opportunities to find boutique CROs that can cater to their specific needs.

3. **Increasing Focus on Targeted Therapies to drive the Discovery CRO service area**: Precision and personalized medicine's demand specially in the therapeutic areas like immuno-oncology a is going to drive the Discovery CRO market. In addition, the expansion in the earlier less explored therapeutic areas such as rare diseases, gene therapy, cell therapy, and neurodegenerative diseases is also going to present significant opportunities for drug discovery CROs with capabilities and expertise to offer services like genomics, proteomics, high-throughput screening (HTS) and bioinformatics analysis are going to be benefited from it.

4. **Artificial Intelligence and Machine learning technologies in Drug Discovery:** The 2022 thematic research report titled 'Artificial Intelligence (AI) in Drug Discovery' from GlobalData predicts that the total expenditure on AI by the pharmaceutical sector is projected to escalate to more than $3 billion by the year 2025. Some of the applications of Artificial Intelligence on overall CRO sector are mentioned in Exhibit 2

Exhibit 2: Artificial Intelligence in Drug Discovery and Development



Artificial and Machine learning have been integrated into the drug discovery process by many organisations, and the CROs which have the capabilities to leverage these tools to assist in virtual screening, lead optimization, prediction of drug-target interactions, and identification of novel drug candidates are going to spearhead the drug discovery area in terms of efficiency and productivity. In addition, the use of robotics, automation, miniaturization, and innovative assay formats by such CROs to screen large compound libraries more quickly and cost-effectively is going to provide a competitive edge to such CROs. Discovery CROs are also adopting big data analytics approaches to handle and interpret complex datasets generated from various sources, including genomics, proteomics, and electronic health records. Integrating and mining these datasets can provide valuable insights for target identification, lead optimization, and decision-making. Some of the examples include IQVIA's AI-based NextGen smart trial platform, used by dozens of pharma clients, Evotec's $15 million investment in AI-driven biotech Exscientia, and Eurofins' collaboration with UgenTec to apply AI for high-throughput molecular testing. In September 2022, Pfizer announced the expansion of its multi-year partnership with Israel-based AI in pharma company CytoReason. Under this agreement, Pfizer will invest $20M in equity, with the option to license CytoReason's platform and disease models and fund further project support in a deal that could reach up to $110M over the next five years. Since the initiation of the collaboration in 2019, Pfizer has utilized CytoReason's biological models in its research to boost the understanding of the immune system for the development of drugs for immune-mediated and immuno-oncology diseases. This additional investment will aid the development of more disease models and the creation of high-resolution models across various therapeutic areas. Sanofi also announced a multi-year, multi-target research collaboration with Hong Kong-based Insilico Medicine, leveraging the latter's Pharma. AI platform to expedite drug discovery. Insilico, a pioneer in applying deep learning for drug discovery, will assist Sanofi in developing treatments in areas such as cancer, fibrosis, and immunity. The collaboration signifies a $21.5m investment by Sanofi for upfront and target nomination fees, granting access to Insilico's AI platform and their interdisciplinary team of scientists. The partnership holds potential for further payments up to $1bn if key R&D and sales milestones are reached.

5. **Increased use of Data Analytics in Pre-clinical research:** The preclinical CRO market is witnessing technological advancements that enhance efficiency and data quality. Automation and robotics are being employed to streamline processes, reduce turnaround times, and improve accuracy. Furthermore, there is a growing adoption of advanced analytical techniques, such as genomics, proteomics, and metabolomics, to provide comprehensive insights during preclinical studies. Data analytics and informatics are increasingly being integrated into preclinical research to extract meaningful insights from large datasets. In March 2023, AstraZeneca presented preclinical data on an AI-generated target, the Serum Response Factor (SRF), for idiopathic pulmonary fibrosis (IPF) -- from its collaboration with UK-based AI company BenevolentAI. The target, discovered via BenevolentAI's AI-enabled drug discovery engine, underwent thorough experimental validation by AstraZeneca, involving CRISPR screening in primary human lung fibroblasts and validation via SRF gene silencing or pharmacological SRF pathway inhibition. The presented data indicates that inhibiting SRF-driven transcription of pro-fibrotic genes in lung fibroblasts could potentially lead to antifibrotic efficacy in IPF. To date, the

collaboration between BenevolentAI and AstraZeneca has resulted in five AI-generated targets selected for portfolio entry, three of which are for IPF. This successful partnership was expanded in January 2022 for another three years, including two new disease areas - systemic lupus erythematosus and heart failure.

6. **Increased Outsourcing:** Conventional global pharmaceutical companies have been dependent on their inhouse research and development centres to provide the services related to discovery, preclinical and clinical development for developing the innovative molecules. But over the last two decades. the companies have been increasing outsourcing at various stages of their drug development processes to contract research organizations (CROs). This trend allows pharmaceutical companies to leverage the expertise and resources of specialized CROs, leading to cost savings, faster development timelines, and access to advanced technologies.

7. **Focus on Specialized Service CROS for Niche areas:** With the complexity of drug development increasing, pharmaceutical companies have been seeking CROs with specific expertise and capabilities. There is a rising demand for specialized preclinical services, such as toxicology studies, safety assessment studies, multi-drug and metabolite-based bioanalysis and complex pharmacokinetic studies. Similarly in the clinical development domain, growing demand for tailored clinical trial solutions that cater to specific therapeutic areas or patient populations, the CROs offering specialized services in niche areas like medical devices, rare diseases and personalized medicine are well-positioned to capitalize on this trend.

8. **Emergence of Medical Device CROs:** As per a recent report of Grandview research, the global medical device contract research organization market size was valued at USD 7.21 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 8.8% from 2023 to 2030. The market growth can be attributed to an increase in the number of medical device-specific clinical trials, the growing demand for advanced medical devices, and a rise in the focus among medical device companies to reduce the cost associated with research. During the COVID-19 recovery period, the pipeline of medical devices witnessed a steady rise. The growing demand for novel technologies and the increasing need to make devices patient-friendly are expected to improve the pipeline of medical devices.

9. **Increase in Global Footprint of CROs:** The pharmaceutical contract research market has been expanding into emerging markets, such as Asia-Pacific, Latin America, and Eastern Europe. CROs are establishing or expanding their presence in global markets to cater to the rising demand for contract research services. These regions offer cost advantages, large treatment naïve patient populations, and a growing number of clinical trial sites with adequate infrastructure.

10. **Acceptance of Remote Clinical Trial Services:** The adoption and acceptance of virtual and decentralized clinical trials by pharmaceutical companies and regulatory agencies has gained momentum in recent years and this trend has been accelerated by the COVID-19 pandemic in the year 2020. Virtual trials leverage technologies like telemedicine, wearable devices, and remote clinical trial monitoring to reduce the burden on patients, reduce the cost, enhance recruitment rates, and increase geographical diversity in clinical trial populations, which highlighted the need for flexible and remote trial designs.

11. **Bioprinting:** Clinical testing on human beings is a lengthy and tedious process which is affecting the pharmaceutical business. A new substitute called bioprinting is emerging to replace it where procedures comparable to 3D printing, may manufacture human organs and tissue replicas. In clinical studies, these organs can be used to substitute living participants.

12. **Increasing Operational efficiencies of the Clinical CROs:** The CROs offering the clinical services are increasingly utilizing data analytics to improve clinical trial design, patient recruitment, site selection, and overall regulatory compliance. The CROs are using complex algorithms to analyse large volumes of patient data, including electronic health records (EHRs), to identify eligible candidates for clinical trials. Additionally, real-world data and evidence are being integrated into the drug development process of global to provide more robust insights into drug safety and efficacy.

13. **Ever increasing Regulatory Complexity:** The pharmaceutical industry is facing evolving regulatory landscapes, with stricter requirements for drug development and clinical trial conduct. CROs are adapting to these complexities by strengthening their regulatory expertise and ensuring compliance with regulations across multiple jurisdictions. This trend highlights the importance of regulatory knowledge and capabilities for successful contract research partnerships.

3.2. Service Type Trends in CRO industry

1. **Clinical Development to lead among CRO Service areas:** Clinical trial management services continue to be a core offering in the contract research industry. For the forecasted global pharmaceutical contract research outsourcing market of USD 90.4 Billion by 2030, it is estimated that USD 61.2 Billion (approximately 67 %) will be contributed only by the outsourcing done in the domain of clinical development services. With the drugs worth USD 251 Billion going off-patent by the year 2030, the Indian clinical CROs operating in Bioequivalence and Bioavailability services have numerous opportunities to capitalize on.

2. **Surge in Demand for Discovery Chemical Services:** The global drug discovery outsourcing market which was valued at USD 3.8 Billion in the year 2022 is increasing @ CAGR of 7.3% and is expected to reach USD 6.2 Billion by the year 2031. On the basis of service type, the market is segmented into biology services and chemical services. Gene editing, stem cells, immunotherapies and new types of biologics are now mega-trends in the pharmaceutical industry, however, there are several hot areas in small molecule drug discovery, suggesting a lot of untapped potential and investment prospects in this more “traditional” pharmaceutical research space. The Discovery Chemical Segment, focussed on small molecules has accounted for largest market share in year 2022. This trend is expected to continue till the year 2030. Biology services is expected to witness the fastest growth of 7.5% from 2023 to 2030. The growing demand for technical experts to conduct drug discovery services while abiding by regulatory requirements is one of the key factors promoting segment growth. Furthermore, the presence of a significant number of biology drug discovery service providers, such as Eurofins, Aurigene Pharmaceutical Services Ltd., and Syngene International Limited, is further supporting segment growth in India.

3. **Pre-Clinical CROs to face tough times ahead:** Preclinical CROs typically use the animals like rats, mice, guinea-pigs, rabbits, canines, bovines or non-human primates in testing the

drugs for checking the safety profiles. In the year 2022, 42 countries worldwide have banned or restricted cosmetic animal testing, including all 27 countries in the EU, Australia, Colombia, Guatemala, Iceland, India, Israel, Mexico, New Zealand, Norway, South Korea, Switzerland, Taiwan, Turkey, and the United Kingdom. In India, a recent amendment to the New Drugs and Clinical Trial Rules (2023), passed by the Government of India, aims to replace the use of animals in research, especially in drug testing. The amendment authorises researchers to instead use non-animal and human-relevant methods, including technologies like 3D organoids, organs-on-chip, and advanced computational methods, to test the safety and efficacy of new drugs.

4. **Building the scientific writing and regulatory capabilities**: The regulatory landscape in the pharmaceutical industry is constantly evolving, with stricter and unharmonized regulations and guidelines. CROs are expanding their high-quality medical writing, documentation and regulatory capabilities to assist pharmaceutical companies in navigating region specific complex regulatory requirements, ensuring compliance, and expediting the regulatory approval process.

5. **Emergence Biomarker and Companion Diagnostics Services:** The use of biomarkers and companion diagnostics has gained prominence in personalized medicine and targeted therapies. CROs are expanding their capabilities in biomarker identification, validation, and application, as well as offering services related to companion diagnostic development and testing. These services enable pharmaceutical companies to better stratify patient populations, improve clinical trial outcomes, and develop precision therapies. AstraZeneca announced a strategic research collaboration with Illumina, a global pioneer in DNA sequencing and array-based technologies. This collaboration aimed to expedite drug target discovery by melding their respective competencies in AI-based genome interpretation and genomic analysis. The initiative will examine if a unified approach utilizing these technologies can bolster the efficiency and certainty of target discovery in pursuit of promising drugs built upon human omics insights. AstraZeneca's Centre for Genomics Research will adopt a framework merging the AI-based tools of both companies, leveraging next-generation AI interpretation tools like Illumina's PrimateAI and SpliceAI, along with AstraZeneca's own tools such as JARVIS and in silico predictors.

3.3 Therapeutic Area Trends in CRO industry

While the top 20 pharma activity for the major therapeutic areas in India has remained largely constant in the last decade, growth opportunities exist across key diseases (e.g., pain, epilepsy, cervical cancer) and orphan diseases (β-thalassemia, Duchenne Muscular Dystrophy).

1. **Oncology:** Oncology continues to be a dominant therapeutic area in pharmaceutical contract research. As per a study conducted in 2023, oncology segment held more than 53.9% Asia Pacific market share in 2021, due to growing incidences of cancer. Moreover, rise in the number of oncology CRO services in the region is another contributing factor in the segment growth. The high demand for novel cancer therapies and the increasing complexity of oncology clinical trials have led to a significant focus on oncology research. With new regulatory guidance emerging and different alternatives from the standard maximum tolerated dosing in proving a treatment's efficacy and toxicity, there are excellent opportunities for CROs specialized in Biostatistics to carve a niche as sponsors will require

specialized CROs who understand complex trial types and adaptive trial designs. CROs capable of providing specialized services in oncology, including patient recruitment, biomarker analysis, imaging services will have a competitive edge. More than 900 next-generation biotherapeutics are now in the R&D pipeline, with increased activity in CAR T and NK cell therapies as well as gene editing and nucleic acid vaccines. More than 40% of next-generation biotherapeutics in development in 2022 were for oncology, bringing great promise for cancer treatment. Oncology trials have increased in demand due to the increased prevalence of cancer which has required sponsors to develop different for improved management of cancer.

2. **Respiratory:** The respiratory systems segment accounted for the one of the largest shares of over 14% of the global pharmaceutical revenue in 2022. Lung diseases are responsible for over 700,000 hospital admissions and over 6 million inpatient bed-days in the U.K. per year. An estimated 1.2 million people are living with diagnosed COPD in the U.K. As per the 2019 report of the National Health Portal of India, 41,996,260 cases and 3,740 deaths from respiratory infections were recorded across India in 2018. India contributes to 18% of the global population, with severe acute respiratory infections (SARI) as one of the prominent causes of mortality in children >5 years of age. The high incidence of respiratory disorders, such as bronchitis, tuberculosis, Chronic Obstructive Pulmonary Diseases (COPD), and asthma, coupled with increasing cases of drug resistance are of significant interest in pharmaceutical research and it has influenced the growth of this therapeutic area. Additionally, the introduction of novel drug delivery technologies, such as nasal sprays, has been identified to be the key contributor to the segment revenue. Respiratory diseases, including asthma, chronic obstructive pulmonary disease (COPD), and cystic fibrosis. Clinical CROs that are involved in clinical trials focused on respiratory diseases, offering services such as respiratory function testing, bronchoscopies, and specialized assessments related to clinical endpoints for evaluating treatment efficacy will have competitive edge over the conventional CROs.

3. **Rare Diseases:** Rare diseases, also known as orphan diseases, affect a small percentage of the population but pose significant challenges in terms of diagnosis and treatment. With an estimated 300 million people worldwide affected by rare diseases, the demand for treatments is growing. The global rare disease treatment market was valued at $195 billion in 2023 which has resulted in a rising demand for CROs to support sponsors of clinical trials. There are several reasons for this trend including regulatory incentives, advancements in genomics, precision medicines, patient advocacy groups, and the increased emergence of biotech, particularly in the U.S. market. Many CROs are expanding their capabilities and expertise in conducting rare disease trials to meet this demand. CROs are increasingly supporting clinical research in rare diseases, providing expertise in patient recruitment, trial design, regulatory strategies, and patient registries. In India, top pharma sponsored trials for orphan disease has increased by 4% in India in the last decade (2010-21), primarily led by global companies like Novartis, Sanofi, and AstraZeneca.

4. **Infectious Diseases:** The recent COVID-19 pandemic has increased the focus on infectious diseases. The infectious disease treatment market was valued at $72.5 billion In 2021 and is predicted to grow to $106.4 billion by 2026, at a CAGR of 8.2%.4 The biggest driver for this growth in demand is the vaccines or treatments for SARS-CoV-2 virus and other infectious diseases.

5. **Central Nervous System (CNS) Disorders:** The prevalence of CNS disorders such as Alzheimer's disease, Parkinson's disease, and mental health disorders has led to a growing emphasis on research in this therapeutic area. CROs are offering services in CNS-focused clinical trials, including patient recruitment, cognitive assessments, neuroimaging, and biomarker analysis. The development of novel therapies for CNS disorders remains a priority for many pharmaceutical companies.

6. **Immunology and Autoimmune Diseases:** The field of immunology and autoimmune diseases has seen significant advancements in recent years. CROs are supporting research in areas such as rheumatoid arthritis, multiple sclerosis, and inflammatory bowel disease. Services in this therapeutic area include patient recruitment, immunogenicity assessments, cytokine profiling, and specialized assays for measuring immune response.

7. **Cardiovascular Diseases**: Cardiovascular diseases, including heart disease and stroke, remain leading causes of mortality worldwide. CROs are involved in cardiovascular research, providing services such as patient recruitment, cardiovascular imaging, electrocardiography, and monitoring of cardiovascular endpoints in clinical trials. The development of innovative therapies for cardiovascular diseases continues to be an area of interest for pharmaceutical companies.

3.4 End user Trends in CRO industry

Pharmaceutical and biotechnology companies continue to be the primary end users of contract research services. There has been emergence of some other sectors like the Academic research institutions, medical device companies and nutraceutical companies which have started outsourcing the contract research to specialized CRO service providers. Some of the recent trends in CRO sector on user/ client end are mentioned below:

1. There has been an increasing focus on strategic partnerships with contract research organizations (CROs) to foster long-term collaborations and drive innovation. This involves preferred provider agreements, risk-sharing models, and joint development of drugs or therapies. A recent research from the University of Cambridge suggests that there has been a significant change in how pharmaceutical firms interact with contract research organizations, with a clear shift towards strategic alliances over one-time transactions. The data shows that while a quarter of outsourced projects still use a transactional approach, the remaining 75% are split between preferred providers and strategic partnerships, highlighting a preference for long-term collaborations.

2. There is a growing demand for specialized expertise in niche therapeutic areas, such as oncology, rare diseases, immunology, or personalized medicine. Pharmaceutical and biotechnology companies seek CROs with deep knowledge and experience in specific areas to support their research and development efforts. Pharmaceutical and Biopharmaceutical companies have started opting for small to medium size CROs for their clinical development requirements.

3. Pharmaceutical and biopharmaceutical companies are beginning to adopt a nimbler business model of innovations. One of the characteristics of this more agile model is a shift in emphasis toward mining many early innovations externally (instead of prioritizing several high-cost programs) -- via open science, venture funds, industry-academia partnerships, accelerator programs, etc. to come up with the potential pipelines of products and "Killing projects early" so as to choose only the most promising and validated programs for development.

4. From the pharmaceutical company's perspective, the potential partner Clinical Trial CROs or Bioequivalence CRO should be affordable, financially stable, have a brand image, strong Quality Management System (QMS) and Experienced teams with the subject disease and/or indication and study phase.

5. Pharmaceutical companies prefer to work with CROs which have experienced Project Management team which can communicate effectively and provide a consultative, value-added, and transformational approach towards the clinical trials.

6. The BA/BE CROs with strong Regulatory experience with the clinical trial audits and inspections from International regulatory bodies like USFDA, EMEA, TGA, ANVISA are preferred as compared to the CROs with only the national regulators.

7. Compliance to ICH-GCP, HIPAA, HITECH, the Privacy Rule, GDPR, and any other applicable law and regulation of the country concerning data privacy and patient confidentiality is one of the most important factor for the sponsors while selecting the CROs for the clinical studies.

MARKET DYNAMICS

4. MARKET DYNAMICS

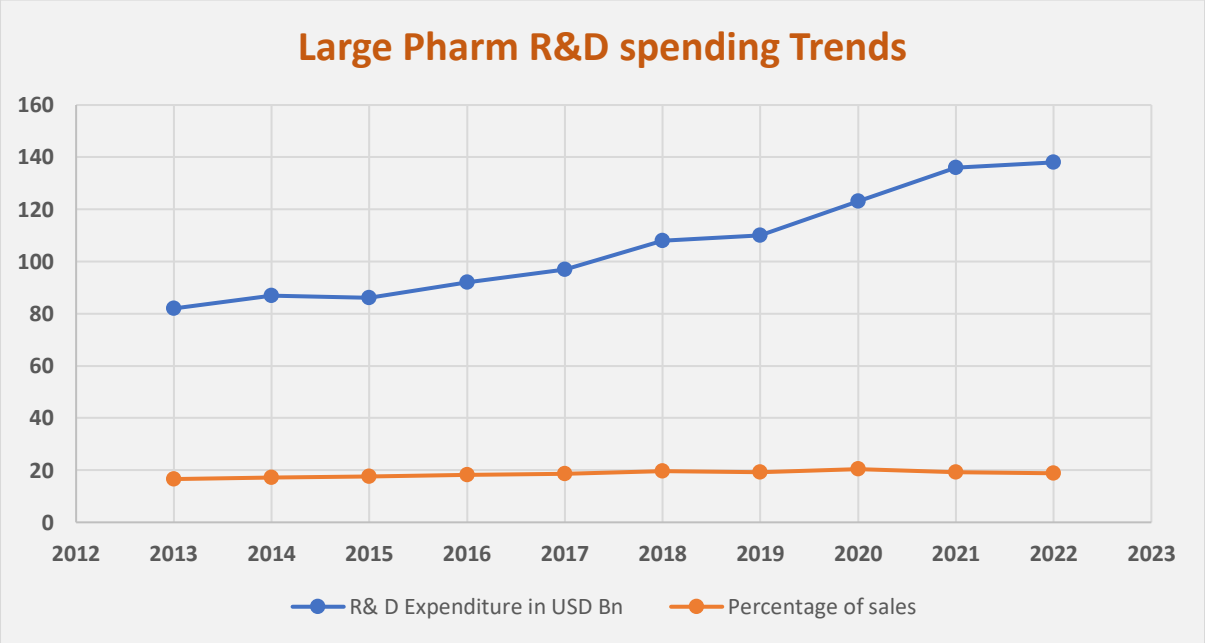
4.1. Market Drivers:

CROs play a crucial role in providing cost-effective and efficient services, allowing pharmaceutical companies to outsource certain aspects of their R&D activities while focusing on core competencies. By outsourcing specific research activities to CROs, pharmaceutical companies not only have access to expertise and dedicated resources but can also optimize their R&D costs by allocating resources strategically, mitigate financial risks, and improve overall operational efficiency. In the highly competitive pharmaceutical industry, the operational efficiencies bring new drugs and therapies to the market quickly, helping pharmaceutical companies gain a competitive advantage and generate revenue faster. Additionally, partnering with CROs has provided pharmaceutical companies with flexibility to adapt to changing market needs and scalability in managing their R&D activities which is otherwise difficult for pharmaceutical companies if these companies maintain inhouse research and development centres which require significant investments in infrastructure, personnel and fixed costs. Some of the factors which have been contributing towards growth of CRO sector globally are mentioned below.

4.1.1. Increasing R&D expenditure worldwide

The worldwide increase in research and development (R&D) expenditure is a significant market driver for the pharmaceutical contract research organization (CRO) market. The largest pharmaceutical companies together spent more than USD 138 Billion on research and development in 2022, up 1.7% from 2021. Since 2017, R&D spending for large companies has increased by 43% with a five-year CAGR of 7.4%. (Refer to Exhibit 3)

Exhibit 3: Large pharma R&D spending and spending as a percentage of sales 2013–2022*, USD Billion



Source: Financial statements of companies; IQVIA Institute, Jan 2023.

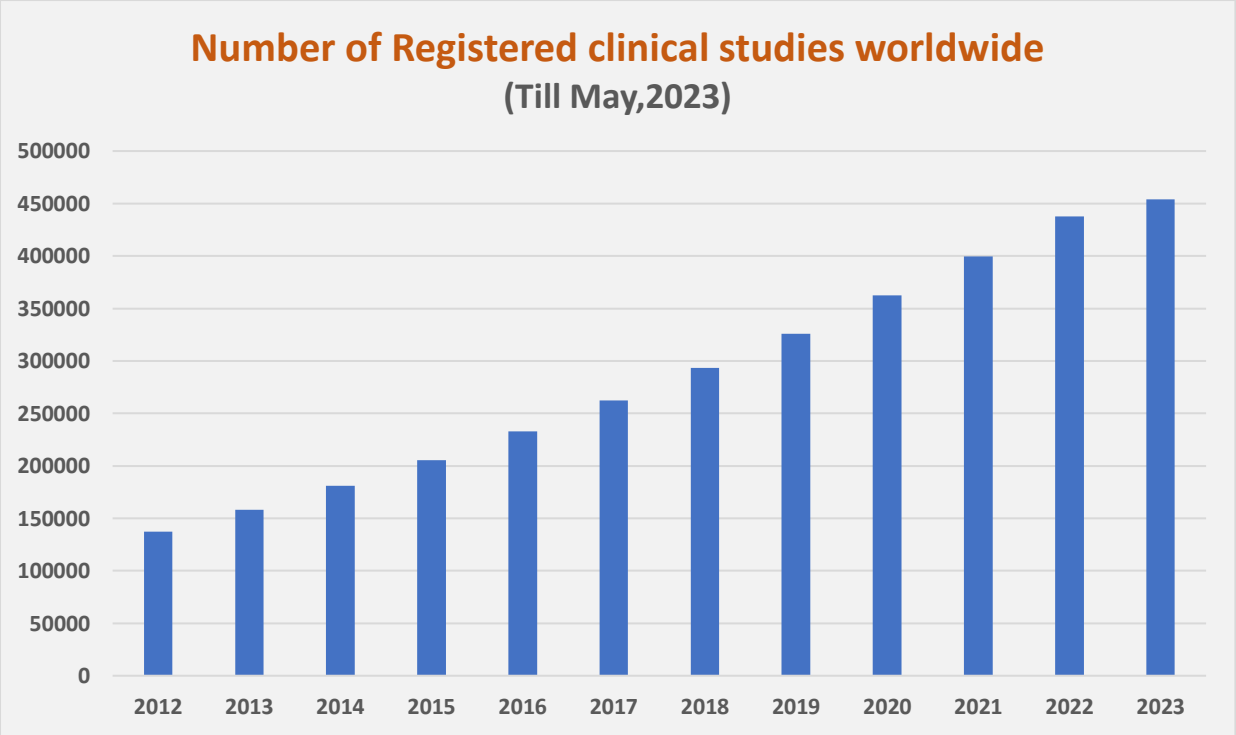
The increase in R&D expenditure by pharmaceutical companies globally signifies a higher investment in the development of new drugs, therapies, and healthcare solutions. As pharmaceutical companies

allocate more resources to R&D, there is a greater need for specialized support and expertise in various stages of the drug development process. The research and development pipeline of major pharmaceutical companies remained with 6,147 products in active development from Phase I to regulatory submission was higher by 49% since 2017. Overall, the worldwide increase in R&D expenditure drives the demand for pharmaceutical CRO services. As pharmaceutical companies invest more in research and development, partnering with CROs enables them to access specialized expertise, optimize costs, accelerate timelines, and. The Indian CRO market can also benefit from this trend by providing essential services and support in various aspects of the drug development process, making it a crucial component of the pharmaceutical industry ecosystem.

4.1.2. Growing number of clinical trials worldwide

The growing number of clinical trials is a major market driver for the global contract research organization (CRO) market. Clinical CROs offer specialized expertise in clinical trials, data management, regulatory support, and post-marketing surveillance. Pharmaceutical companies leverage the knowledge and experience of CROs to enhance their research capabilities and overcome challenges in specific therapeutic areas or research domains. As per the latest Statista report there were 4,53,803 clinical studies registered worldwide as on May,2023. The exhibit 4 demonstrates the increase in the number of registered clinical studies since 2012

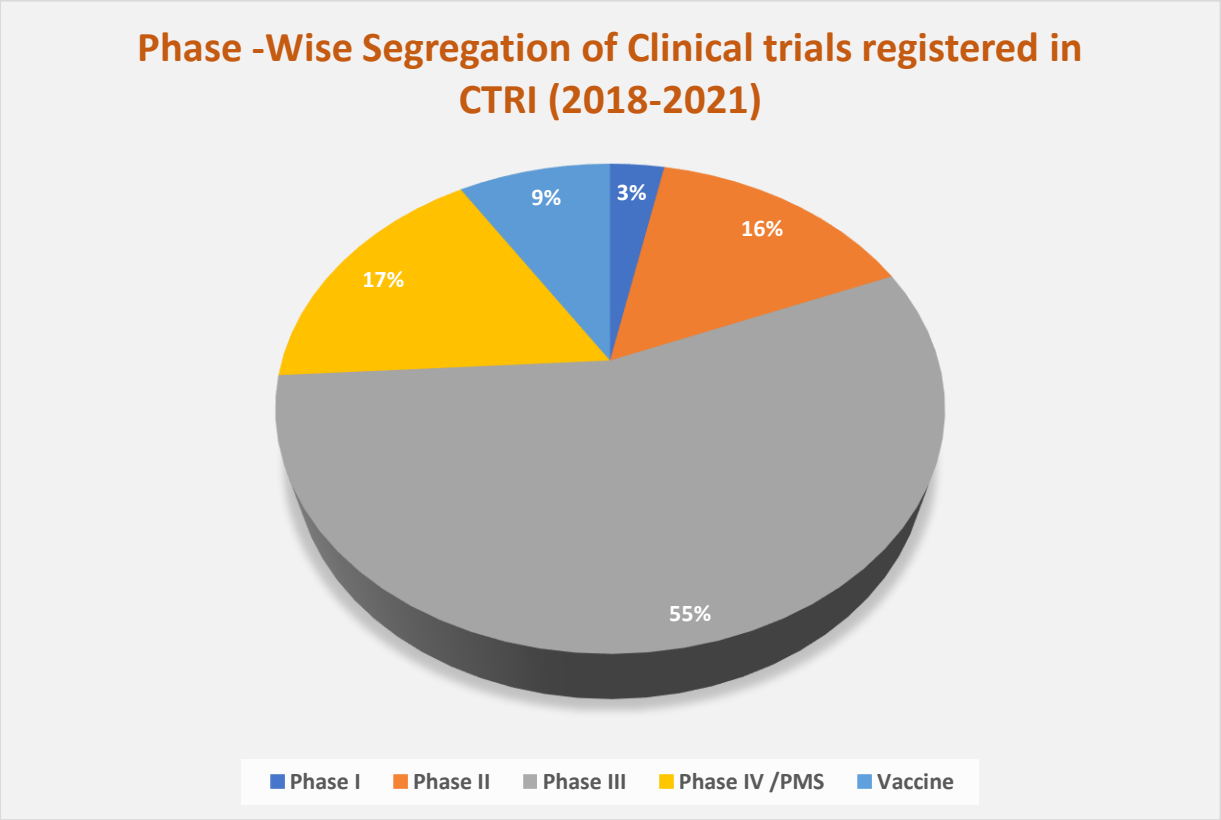
Exhibit 4: Registered Clinical Studies worldwide till May,2023



As per the data available on Clinical Trial Registry India CTRI the average number of advance phase clinical trial (Phase I- Phase IV) have been in the range of 225 to 235 per during the period 2018-2021. This number does not include the pilot and pivotal bioequivalence clinical studies conducted in healthy subjects by the CROs and Pharma companies.

The break-up of the studies across the different phases in shown in Exhibit 5

Exhibit 5: Phase-wise segregation of Clinical Trials in India (2018-2021)



It is to be noted that despite India being the second most populous country and having one of the highest global disease burdens, India's global clinical trial participation has been significantly low (2-3%) as compared to countries like US where is participation is as much as 30%. In India the states Maharashtra, Tamil Nadu, Gujarat, Delhi, Karnataka account for 65% sites in India and the presence of these sites is more concentrated in metro and Tier 1 cities.

4.1.3. Growing outsourcing of R&D activities.

Outsourcing has become an integral part of how research and early development (R&D) is executed in biotech companies and large pharmaceutical organizations. During the years between 2022-30, the global contract research outsourcing market is expected to grow @ CAGR of 7 % and reach USD 90.4 Billion by 2030.CROs offer specialized expertise across various stages of the drug development process, including preclinical research, clinical trials, data management, regulatory support, and post-marketing surveillance. Pharmaceutical companies can leverage the knowledge and experience of CROs to enhance their research capabilities and overcome challenges in specific therapeutic areas or research domains. The availability of specialized expertise, accelerated timelines and cost efficiencies are the compelling reason for global pharmaceutical companies to outsource their R&D activities to CROs, driving the overall demand for CRO services. The Pharmaceutical companies can choose from several operational models when partnering with a contract research service provider, ranging from short-term, fee-for-service (FFS)-based arrangements to more strategic full-time-equivalent (FTE)-based collaborations and even risk-sharing relationships thereby making outsourcing a value-based proposition.

4.1.4. Rising technological advancements.

A Global Data survey last year revealed that over 70% of pharma industry respondents anticipate drug development will be the area most impacted by the implementation of smart technologies. CROs equipped with advanced research tools can provide valuable insights and generate high-quality data, attracting pharmaceutical companies to outsource their research activities New pharmaceutical technological advancements like high-throughput screening, molecular profiling, next-generation sequencing, bioinformatics analysis, and advanced imaging technologies are a significant driver of the early discovery CRO market./ Advances in genomics, proteomics, and other molecular profiling techniques have paved the way for personalized medicine approaches in drug development.

CROs with expertise in biomarker identification, validation, and companion diagnostic development are playing a crucial role in supporting personalized medicine initiatives. CROs focussed on harnessing the futuristic AI along with supercomputing will be able to offer specialized services that support various stages of the drug development process. Technological advancements have also impacted clinical development, regulatory compliance and safety monitoring in pharmaceutical R&D. CROs are utilizing these technologies to enhance preclinical and clinical trial simulations, training programs for investigators and study participants, and patient education initiatives.

By providing immersive and interactive experiences, virtual and augmented reality technologies improve understanding, engagement, and retention, contributing to more efficient and effective drug development processes. Electronic data capture (EDC) systems, electronic health records (EHRs), and pharmacovigilance tools have facilitated efficient data collection, tracking, and reporting of adverse events in the clinical trials.

4.2. Growth Restraints and Challenges for CRO Industry in India

4.2.1. Industry -Academia collaboration gap

The industry-academia gap poses a significant challenge for the growth of the contract research organization (CRO) industry specially in India. There is often a lack of effective collaboration and knowledge transfer between the academic research community and the industry, including CROs. Academic research institutions like NIPERs often generate innovative discoveries and potential drug candidates. However, many of these findings may not progress beyond the academic setting due to the challenges associated with commercialization. CROs, with their expertise in clinical development and regulatory compliance, can play a crucial role in bridging the gap between academic research and commercialization. The gap between academia and industry limits the exchange of knowledge, expertise, and innovative ideas, hindering the growth and innovation potential of the CRO industry. Bridging the industry-academia gap would facilitate better access to shared resources, enabling CROs to enhance their research capabilities and deliver higher value to their clients. Collaborative efforts between academia and CROs can facilitate the translation of academic discoveries into viable products, driving innovation and contributing to the growth of the CRO industry.

4.2.2 Regulatory Complexity and Approval delays

The regulatory landscape in the pharmaceutical industry is complex and constantly continuously evolving. CROs need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally must navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines

The clinical development is a most regulated segment of drug development process because it deals with humans. ICH-GCP norms are globally followed while conducting the clinical trials to ensure t the safety, rights and wellbeing of the clinical trial participants. In addition, country specifical applicable rules and regulations are also applicable of the pharmaceutical companies conducting the clinical trials.. Regulatory agencies often require extensive documentation, data analysis, and review processes before granting approval for clinical trials or new drug applications. These approval delays can have substantial financial implications for CROs and sponsors, as they lead to extended timelines, increased costs, and potential loss of market opportunities. This has paved a way for the pharmaceutical companies to move to other attractive destinations in Asia Pacific regions like China and Australia.

Regulatory timelines for clinical trials in India are non-starter for foreign companies exploring India as destination for clinical trial in recent past. Delays in the approval process for clinical trials and drug development have significantly impacted the CRO industry. Central Drugs Standards Control Organisation (CDSCO), the top most regulator of clinical trials in India, has been at loggerheads with Indian pharma and CROs over the unprecedented delays in approval of clinical trials in past. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent. The below mentioned table represents some of the regulatory approvals, registration, accretions and the certifications the different kind of CROs need to maintain in order to be complaint to the applicable quality and regulatory requirements.

Service Area	Applicable Regulatory Approvals, Accreditations & Certifications
Discovery CROs	GLP certification by National GLP Compliance Monitoring Authority, DST, GoI
	Department of scientific and industrial research (DSIR) Certification
	GMP certification by state FDA
	ISO 9001:2015 (Quality Management System)
	ISO 17025:2017 (Laboratory Management System) Testing and Calibration Labs
Pre-Clinical CROs	GLP certification by National GLP Compliance Monitoring Authority, DST, GoI, India
	Committee for the Purpose of Control & Supervision of Experiments on Animals (CPCSEA)
	AAALAC accreditation.
	ISO 9001:2015 (Quality Management System)
Bioequivalence Bioavailability CROs	BE center approval from Central Drug Standards Control Organization (CDSCO), India
	Independent Ethics committee (IEC) registration with Central Drug Standards Control Organization (CDSCO), India
	Foreign Regulatory Approvals like USFDA, EMEA, UKMHRA, ANVISA, TGA etc.
	NABL certification as per ISO 15189:2016 or College of American Pathologists (CAP) certification for Safety Testing Laboratory
	GLP compliance of Bioanalytical Section of Bioequivalence centre
	ICH-GCP compliance
	ISO 9001:2015 (Quality Management System)
Clinical Trials (Phase I-IV) CROs	CRO registration with CDSCO is not mandatory yet. CDSCO is going to make it mandatory very soon.
	Institutional Ethics committee (IEC) or Institution Review Board registration with Central Drug Standards Control Organization (CDSCO), India
	ICH-GCP compliance
	ISO 9001:2015 (Quality Management System)

4.2.3. Data Integrity Issues

There have been few cases in past where Indian and global pharmaceutical sponsor companies have been caught in the crosshairs of serious issues related to misconduct and data integrity violations by their hired CROs particularly working in the domain clinical bioequivalence and bioavailability studies. Since this had resulted in the submission of invalid study data to regulatory agencies, many of the previous Marketing authorizations licenses which were approved on basis of the studies conducted at the facilities of these CROs, were also cancelled.

4.2.4. Historical Perception of Clinical Trials in India:

India has the perceived disadvantage of a country with vulnerable population to clinical trials. The country has gained its fair share of media attention of late owing to the ICH- GCP violations and unethical drug trials being conducted on ineligible patient populations. There have been instances in the past where unethical practices, inadequate participant protection, or adverse events in clinical trials have garnered negative media attention. Such incidents contributed to public mistrust and raise concerns about the safety of clinical trial participants. Addressing these safety concerns and ensuring stringent ethical standards and participant protection measures are crucial to improving India's image as a clinical trial destination.

4.2.5 Patient Recruitment and Retention

Patient recruitment and retention pose significant challenges for the clinical research organization market in India. Limited awareness among the general population about clinical trials and their importance can hinder patient recruitment efforts. Many individuals may have misconceptions or reservations about participating in clinical trials, including concerns about safety, efficacy, and potential side effects. Educating the public about the benefits of clinical research, addressing misconceptions, and providing accurate information can help improve patient recruitment in India. Socioeconomic factors, such as income levels, education, and healthcare accessibility, can influence patient participation in clinical trials. India is a geographically vast country with diverse population distribution. Most of the clinical trial sites, investigators and laboratories have been concentrated in metro cities. There is significant competition among CROs and research sites to enrol eligible patients across these sites. Managing the clinical trial sites in Tier 1 and Tier 2 cities can be challenging because of the limited healthcare infrastructure and other logistic issues and therefore the CROs normally compete for the patient recruitment at limited clinical trials sites.

4.2.6. Guinea Pig Syndrome

Negative Public perception of clinical trials (Guinea Pig Syndrome) indeed poses a challenge for the growth of the contract research organization (CRO) market in India. Most of the potential clinical trial participants have limited awareness and understanding of clinical trials and their significance in advancing medical research and developing new treatments. This lack of awareness can lead to scepticism, fear, and misconceptions among the public including the media, making it challenging to recruit participants for clinical trials. Effective communication strategies are essential for improving public perception of clinical trials. Clear and accurate information about the purpose, procedures, potential risks, and benefits of clinical trials should be provided to the public. Engaging with the community, healthcare providers, patient advocacy groups, and local influencers can help disseminate accurate information, address concerns, and build trust.

4.2.7. Patient Data Confidentiality

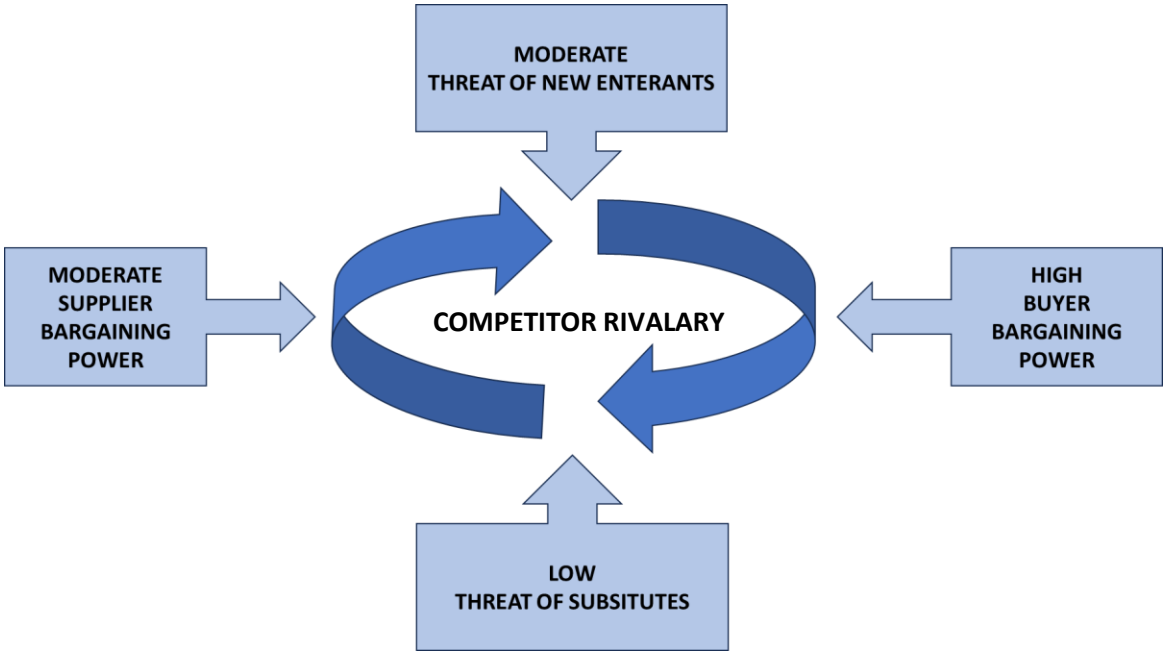
CROs operate in a highly regulated environment, and compliance with data protection regulations is of utmost importance. Regulations such as the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the United States impose strict requirements for the collection, storage, processing, and transfer of personal and

health-related data. CROs handle sensitive and confidential data throughout the clinical research process, including patient health records, medical histories, and research findings. Maintaining the privacy and confidentiality of this data is crucial to protect the rights and privacy of participants, maintain regulatory compliance, and uphold ethical standards. Any breach of data confidentiality can have severe consequences, including legal and reputational damage. Ensuring compliance with these regulations can be complex, especially when working with multinational studies and handling data from different regions.

To meet the international regulatory obligations, Indian CROs need to invest in regular training programs to educate employees on data protection practices, cybersecurity protocols, and compliance requirements. CROs must prioritize data security and confidentiality as core principles and implement best practices to protect sensitive information. Building trust with clients, sponsors, and participants through transparent communication and a strong commitment to data confidentiality is vital for the sustainable growth and success of the CRO sector.

4.3. Porter 5 force Analysis of Indian CRO Industry

Exhibit 6: Porter 5 Force Analysis for Indian CRO sector



4.3.1. Industry rivalry

The Pharmaceutical CRO market in India is characterized by intense competition among existing players. Numerous CROs, both domestic and international, operate in the market, offering a range of services. On one hand there are Global CROs with rich therapeutic experience while on the hand Indian CROs with similar capabilities. In addition, many pharmaceutical companies have in house research and clinical development resources and centres and therefore these companies only partially outsource to the CROs. The competition is driven by factors such as pricing, brand image, comparative timelines, access to the investigator sites, service quality, therapeutic expertise, geographical footprint and client relationships. CROs need to continually innovate, enhance their service offerings, differentiate themselves, and maintain strong client relationships to stay competitive in the industry. This can be understood by the Porter 5 force analysis for CRO sector in India (Refer Exhibit 6) Overall, the Pharmaceutical CRO market in India faces moderate barriers to entry, high buyer power, moderate supplier power, low threat of substitutes, and intense rivalry among existing players. CROs need to differentiate themselves through specialized services, strong client relationships, and a focus on quality and efficiency to thrive in this competitive landscape.

4.3.2. Buyer Bargaining power

Buyers in the CRO market, such as Pharmaceutical, Biopharmaceutical and Medical Devices companies typically have a high bargaining power. They can choose among various CROs of different sizes for their research and development needs, demanding competitive pricing, high-quality services, and time bound delivery. These companies can often negotiate contracts, seek alternative suppliers, or develop in-house capabilities, reducing their dependency on individual suppliers. This creates pressure on the CROs to differentiate themselves from their competitors, be price competitive and provide value-added services to their clients.

4.3.3. Supplier Bargaining power

Suppliers in the Pharmaceutical CRO market, including different types of CROs like Discovery, Preclinical and Clinical CROs, typically have a moderate bargaining power. CROs rely on these services provider to access necessary resources, technology, and expertise for their operations.

4.3.4. Threat of substitute

The threat of substitutes in the Pharmaceutical CRO market is relatively low. CROs play a crucial role in supporting pharmaceutical companies in various stages of drug development, including clinical trials, data management, regulatory compliance, and post-marketing surveillance. The specialized expertise, infrastructure, and regulatory knowledge offered by CROs make it challenging for substitutes to replicate their comprehensive services effectively.

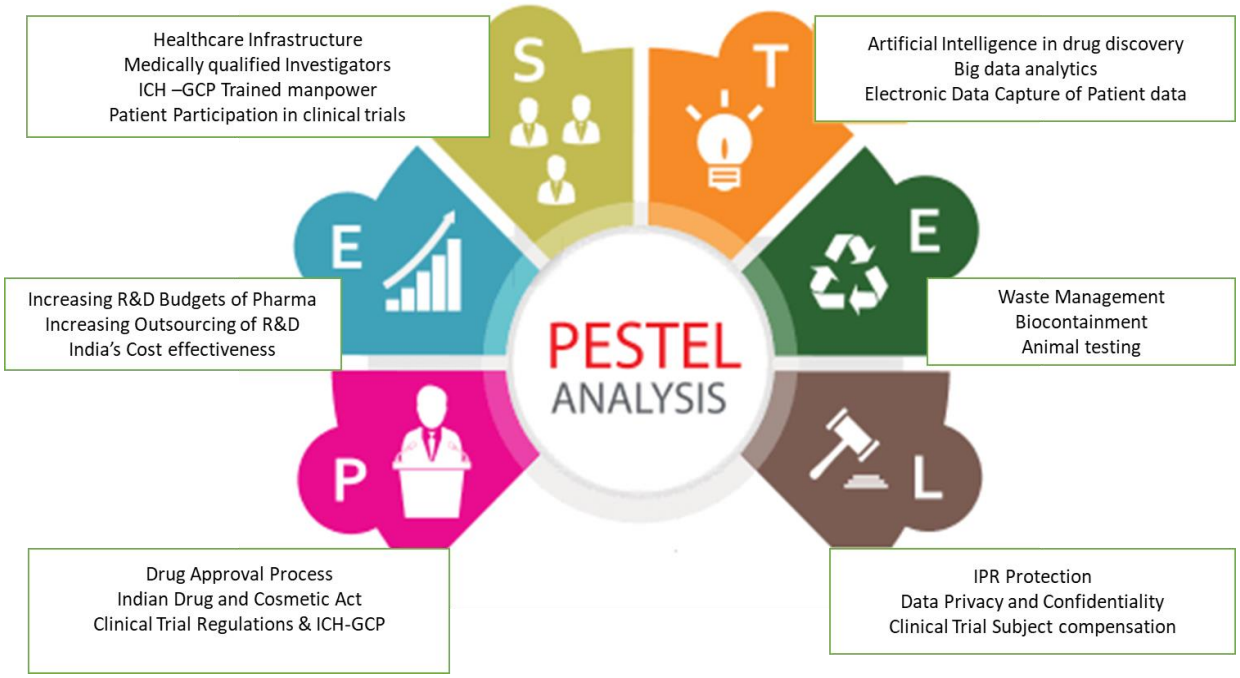
4.3.5. Threat of new entrants

The threat of new entrants to the Pharmaceutical CRO market in India is relatively moderate. While the industry requires significant investments in infrastructure, expertise, and regulatory compliance, the potential for new entrants exists. However, established CROs often benefit from economies of scale, established client relationships, and expertise in navigating complex regulatory frameworks, creating barriers to entry for new players.

4.4. PESTEL Analysis of CRO sector

Understanding the political, economic, sociocultural, technological, environmental, and legal factors is vital for assessing the opportunities and challenges in the CRO market in India. CROs must adapt to changes in these external factors, navigate regulatory requirements, leverage technology advancements, and align their strategies with the evolving needs of the pharmaceutical industry to succeed in the Indian market. Exhibit 7 below summarizes the PESTEL Analysis for the Indian CRO sector.

Exhibit 7: PESTEL Analysis of India CRO Market



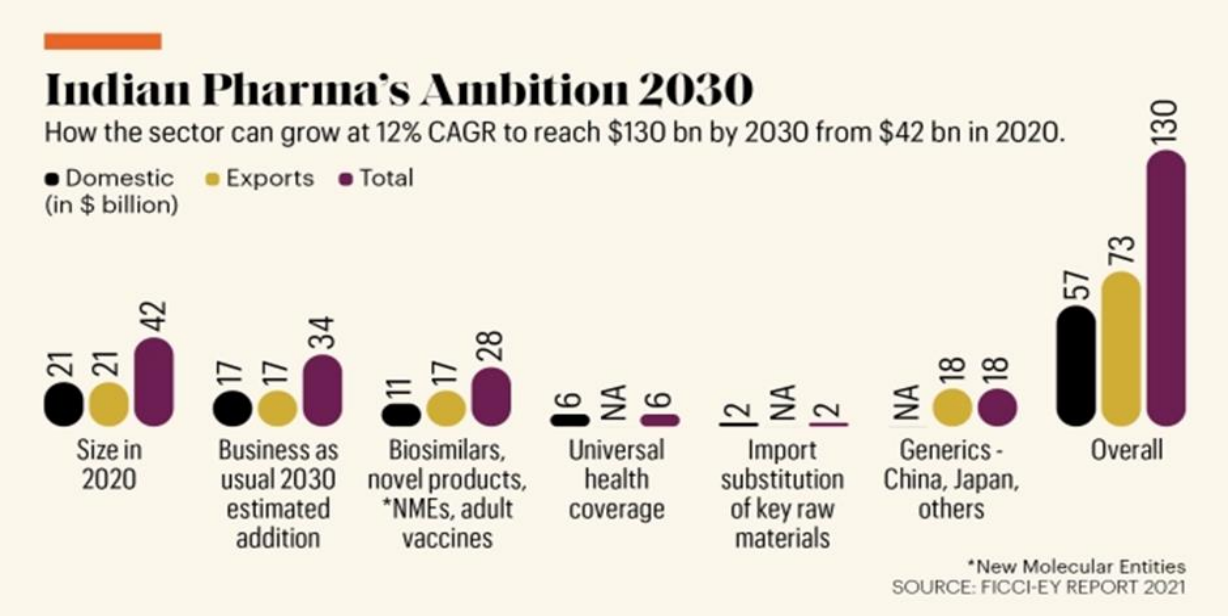
4.4.1. Political

The political landscape in is quite stable with a government which believes in promoting the Indian Pharmaceutical industry at a global level. The government has consistently raised the budget spending on healthcare which has gone up by 13 per cent to Rs 89,155 crore in FY24. Of this, Rs 2,980 crore has been earmarked for healthcare research. Department of Pharmaceuticals under the aegis of Ministry of Chemicals and Fertilizers, Government of India has been running various schemes under the initiative “Strengthening of Pharmaceutical Industry (SPI)", with a total financial outlay of Rs.500 Cr (USD 60.9 million) for the period from FY 21-22 to FY 25-26. The regulatory scenario in India, including drug approval processes, clinical trial regulations, and intellectual property protection has significantly improved significantly post 2014. Further progressive and industry friendly changes in government policies, regulations, and the enforcement of ethical guidelines are going to positively influence the operational and legal frameworks within which CROs operate. The government will table New Drugs, Medical Devices and Cosmetics Bill, 2023, in the Parliament in the monsoon session which seeks to regulate “the import, manufacture, distribution and sale of drugs, medical devices and cosmetics; and ensure their quality, safety, efficacy, performance and clinical trial of new drugs and clinical investigation of investigational medical devices and clinical performance evaluation of new in vitro diagnostic medical device including AYUSH drugs, medical devices and cosmetics with the objective of highest possible regulatory standards and a transparent regulatory regime and to repeal the Drugs and Cosmetics Act, 1940.

4.4.2. Economical

India's economic growth and overall investment in healthcare and pharmaceutical sectors play a significant role in the growth of the CRO market. The Indian economy is expected to grow at an average rate of 6.7 percent till 2026 fiscal. Per capita income of India is steadily increasing implying more spending on healthcare specifically by middle class and rich Indians. This also means that pharmaceutical companies will have to invest more in R&D to understand the health profile of their consumer segment. As per a latest report by FICCI (refer Exhibit 8) the total Market size of Indian Pharmaceutical industry is expected to reach US$130 bn by 2030. A growing economy and increased healthcare spending can lead to higher research and development activities and demand for CRO services. In addition, India's comparatively lower labour costs and operational expenses can make it an attractive destination for outsourcing discovery services, preclinical research, clinical research and development activities, driving the growth of the CRO market. The Government has allowed up to 100 percent FDI through automatic route to Greenfield pharmaceutical projects. For Brownfield projects also Indian government has permitted the FDI allowed is up to 74% through automatic route and beyond that through government approval.

Exhibit 8: Indian Pharma's ambition 2030 (Source FICCI report 2021)



4.4.3. Social

India has a huge population of 1.4 billion with one of highest disease burden. There is an urgent need for new drugs, therapies medical devices and healthcare facilities to cater to increasing healthcare need of this populations. The prevailing lifestyle of Indians specially in urban areas has resulted in life long chronic lifestyle disease. There is also a big chuck of old and elderly people above 60 years of age (numbering about 138 million) in this population who require specialized healthcare services. Thus R &D in India can specifically revolve around this segment also as isa huge market in itself. The availability and quality of healthcare infrastructure in India impact the capabilities and attractiveness of the CRO market. State of Art research and development centre, adequate healthcare facilities, specialized CROs, ICH-GCP trained investigators and well qualified and English-speaking workforce contribute to a conducive environment for conducting clinical trials and other research activities in India.

4.4.4. Technological

Rapid advancements in technology, such as Artificial intelligence. High throughput drug screening, electronic data capture, cloud computing, big data analytics, and wearable devices, have transformed the CRO landscape. Precision medicine and Gene Editing which are crucial to pharmaceutical development has been revolutionised by gene editing tools which can brings a razor-sharp molecular scalpel to the research lab. In future, this technology could become the turning point in the quest to discover new drugs. CROs need to stay updated with emerging technologies to enhance their capabilities, improve efficiency, and offer innovative solutions to pharmaceutical clients.

4.4.5. Environmental

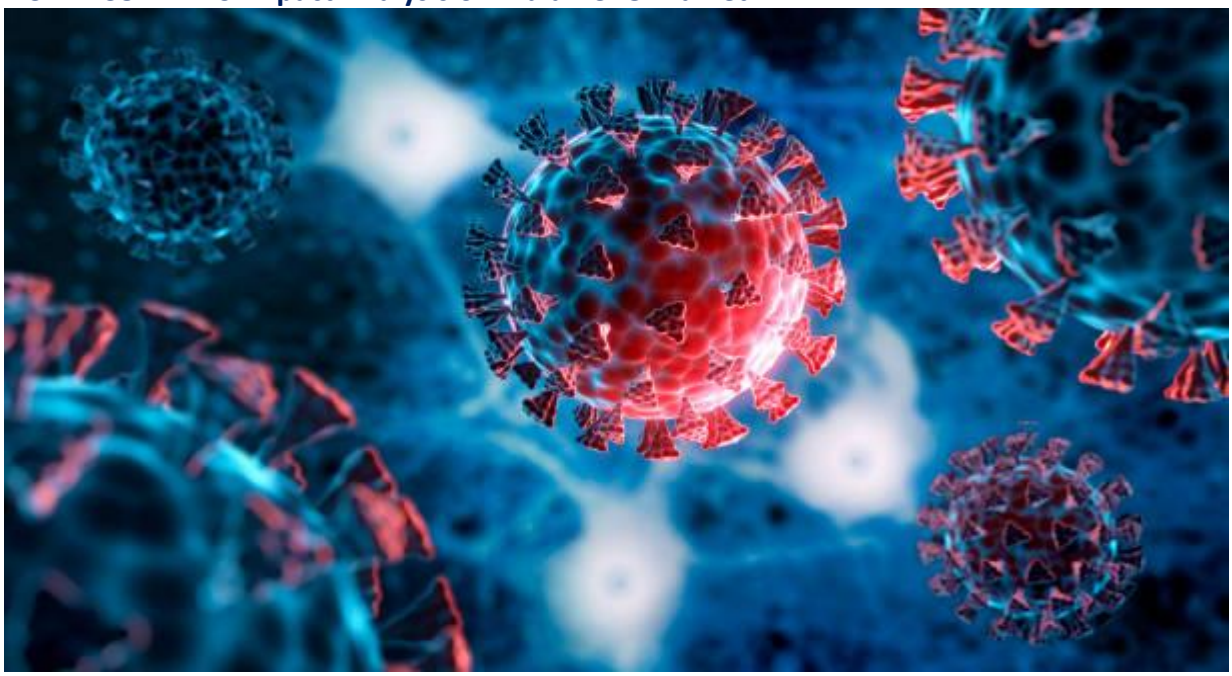
Environmental Regulations: Increasing environmental awareness and regulations regarding waste management, animal testing, and environmental impact assessment can influence the conduct of clinical trials and research activities. CROs need to ensure compliance with environmental regulations and adopt sustainable practices.

4.4.6. Legal

The strength of intellectual property protection laws in India affects the attractiveness of the CRO market. Strong IP protection is essential to incentivize pharmaceutical companies to invest in research and development activities in India, which in turn drives the demand for CRO services. The legal framework and regulations related to data privacy and confidentiality, including personal health information, genetic data, and clinical trial data also impact the operations of CROs. The Acts like Drugs

and Cosmetics Act 1940 and Rules 1945, schedule Y for clinical research by Central Drugs Standard Control Organisation or CDSCO and the ICMR and GCP guidelines covers a set of regulations to assure safety, protection and welfare of subjects in conducting clinical trials in India. In addition, Clinical Trial Rules, 2019 issued by Government of India has comprehensive set of rules which regulates the process for approval of medicines in India. This rule covers new drugs, investigational new drugs for human use, clinical trials, bio equivalence studies, bio availability studies and provide for the constitution, registration and role of the ethics committees in a clinical trial.

4.5. COVID -19 Impact Analysis on Indian CRO market



The COVID-19 pandemic has had both positive and negative impacts on the overall Pharmaceutical CRO (Contract Research Organization) market. The global pharmaceutical supply chain experienced disruptions due to Covid led lockdowns, transportation restrictions, and increased demand for essential medical supplies. These disruptions affected the availability of necessary materials, equipment, and resources required for discovery research. CROs had to adapt and find alternative suppliers or adjust their timelines accordingly. On the front of clinical CRO services, the pandemic led to a surge in the demand for clinical trials related to COVID-19 treatments, vaccines, and diagnostics. Pharmaceutical companies, government agencies, and research organizations collaborated with CROs and among themselves to accelerate the development and testing of new therapies and vaccines. This increased demand has provided growth opportunities for CROs specializing in infectious diseases and clinical trials. At the same time, many ongoing non-COVID clinical trials faced significant disruptions. Lockdowns, travel restrictions, and prioritization of healthcare resources toward the pandemic response led to delays, suspensions, or cancellations of clinical trials in various therapeutic areas. This disruption impacted the revenue and operations of CROs involved in these trials.

On the positive side, the CRO industry saw some of the most expedited clinical trial approvals and the adoption of virtual and decentralized clinical trial methodologies to mitigate the challenges posed by travel restrictions and social distancing measures. The pandemic also highlighted the importance of real-world data and evidence generation to understand the impact of treatments and interventions in a real-world setting. CROs that have adapted to the changing landscape, embraced technology, and diversified their service offerings are now better positioned to navigate the challenges and capitalize on the opportunities arising from and after the pandemic.

5. INDIAN CRO MARKET, BY END USER

5.1. Overview

The Indian pharmaceutical contract research market has experienced significant growth and has emerged as a prominent destination for outsourced research and development (R&D) activities. Here's an overview of the market: In the contract research services market, several end user trends have emerged in recent times indicating the changing dynamics and preferences of organizations that utilize contract research services. Below are some of the prominent end users of CRO services:

5.2. Pharmaceutical and Biotechnology Companies: Pharmaceutical and biopharmaceutical

companies are among the primary sponsors of contract research services. All top ten Global Pharmaceutical and Biopharmaceutical companies are conducting some of their research and development in India. Pharmaceutical and biopharmaceutical companies often outsource specific services to CROs to leverage their specialized expertise and infrastructure. This includes outsourcing of activities such as preclinical studies, bioanalytical testing, clinical trial management, pharmacovigilance, regulatory affairs, medical writing, statistical analysis, and data management. By outsourcing these services, sponsors tap into the CRO's capabilities, streamline their own operations, reduce costs, and benefit from the CRO's experience in delivering those services. In addition to it, even Indian Pharma companies outsource plenty of discovery and clinical development services to Indian and Global CROs.

5.3. Academic and Research Institutions

Academic and research institutions play a significant role in contract research services, particularly in preclinical research and early-stage drug development. These institutions often collaborate with CROs to conduct preclinical studies, pharmacology testing, toxicology evaluations, and other research activities. The trend in this segment is towards increased collaboration between academic institutions and CROs, fostering knowledge exchange and leveraging the expertise of both parties to advance scientific discoveries. Academics with an interest in drug discovery can work with CROs to raise the value of their projects to potential future pharma partners. Alliances are being formed between Universities and CROs, for example, Evotec and Oxford University's "Academic Bridge" initiative. In India, many research institutions like Indian Institute of Technology Mumbai, CSIR-Indian Institute of Integrative Medicine, Jammu, CSIR- Indian Institute of Chemical Technology, and Central Drug Research Institute, Lucknow and Central council of Research in Ayurvedic Sciences, Delhi outsource clinical trials and some preclinical studies to CROs in India.

5.4 Medical Device and Diagnostic Companies

Contract research services are also sought after by medical device and diagnostic companies. Medical device companies rely on contract research services to facilitate various stages of product development, including feasibility studies, design verification, prototyping, and preclinical testing.

CROs provide specialized expertise, equipment, and facilities to conduct these activities, ensuring that devices meet safety, efficacy, and quality standards. During the clinical development phase, Thes medical device companies often require clinical trials, regulatory support, and post-market surveillance studies for their products. CROs catering to the medical device and diagnostic market offer specialized services such as clinical investigation studies (pilot and pivotal studies), performance evaluation studies, validation studies, and expertise in navigating regulatory pathways specific to medical devices and diagnostics.

5.5 Government and Non-Profit Organizations

Government agencies and non-profit organizations are important end users of contract research services, particularly in the context of public health research, epidemiological studies, and clinical trials for public health interventions. These organizations collaborate with CROs to conduct research on disease prevention, public health initiatives, vaccine development, and evaluation of healthcare programs. In India many government organisations like Indian Council of Medical Research, Central Council of Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Défense Research Development Organisation (DRDO), Government of India have outsourced pre-clinical studies (toxicity and genotoxicity studies) and clinical trials to Indian CROs. The CROs need to get themselves registered on the public procurement platforms like etender.com, eprocure.com and GEM in order to participate in bidding for such projects.

5.6 Contract Research Organizations (CROs)

CROs can also be end users of contract research services. In some cases, larger CROs may outsource certain specialized activities or specific phases of a project to other CROs, creating a network of collaborations within the contract research industry. CROs further utilize the services of Site Management Organisations to manage the conduct of clinical trials at sites. This trend allows CROs to leverage the expertise and resources of other SMOs to enhance their service offerings and meet the diverse needs of their clients.

5.7 In-house & Hybrid CROs Model of Indian Pharmaceutical Companies

The whole pharma R&D outsourcing concept revolves around the idea that it is more efficient to contract out standard and routine R&D activities such as chemical synthesis, toxicology, drug metabolism, clinical trials, Bioequivalence studies etc, while maintaining more creative and judgmental processes in-house. Not only standard and routine tasks, but also well-understood science, robust and repetitive, is believed to be suitable for outsourcing models of cooperation. The in-house CRO (Contract Research Organization) model refers to the establishment of an internal department within a pharmaceutical company to handle various research and development (R&D) activities traditionally outsourced to external CROs. It is important to know that many Indian pharmaceutical companies like Aurobindo, Intas, Sun Pharma, Torrent, Alkem, Cadila have their inhouse clinical development centres or sister concern entities, which not only caters to their own requirements but also carry out the research work on contractual basis for other sponsor companies. These centres are established to gain greater control and oversight over the drug development process and intellectual property, reduce reliance on external vendors, and enhance efficiency in R&D operations. By bringing certain functions in-house, pharmaceutical companies aim to streamline processes, optimize costs, and improve collaboration between different R&D teams. Depending on the requirements and availability of in-house resources, many global pharmaceutical companies operating in India adopt the hybrid models, combining in-house capabilities with external collaborations. These companies may still outsource certain specialized services or partner with external CROs for specific therapeutic areas, geographic regions, or expertise that may not be available in-house. This approach allows companies to leverage the benefits of both in-house and external expertise.

6. INDIA CRO MARKET, BY SERVICE TYPE

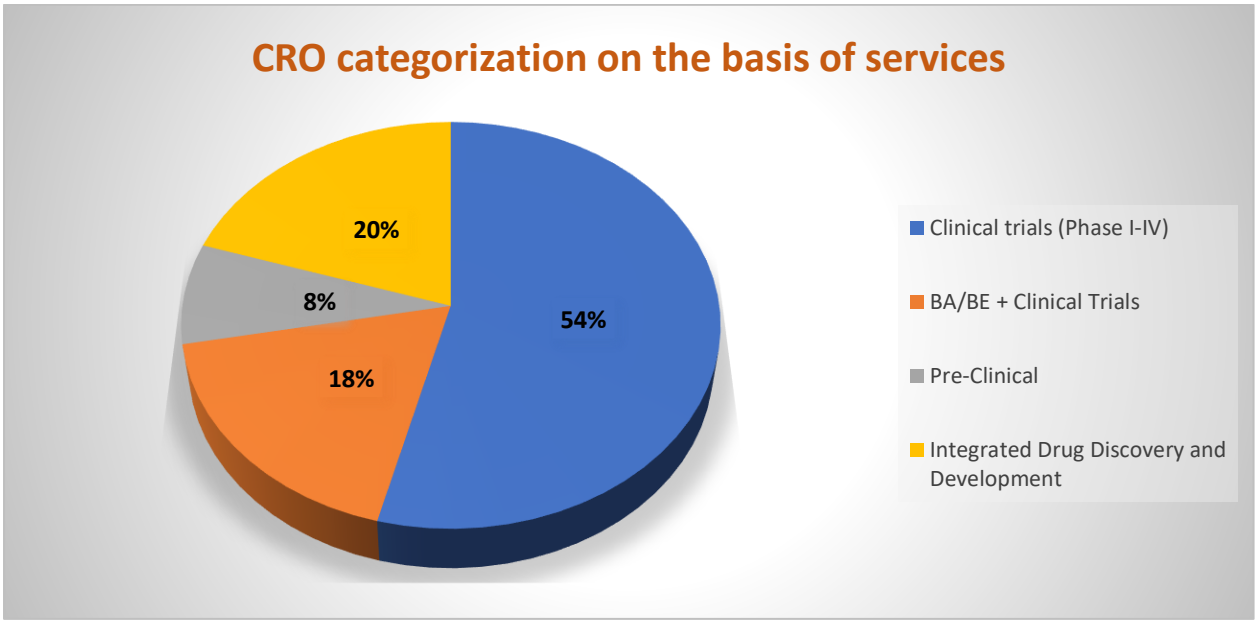
6.1. Overview

The Indian Pharmaceutical CRO market can be classified into four categories by broad service types:

- Discovery CROs offering the Medicinal and Biology Services.
- Preclinical CROs offering the animal testing services.
- Clinical Trial CROs offering the Phase I-IV clinical trial services.
- Bioequivalence Clinical CROs offering the Pharmacokinetic studies in healthy subjects.

While the Discovery, Preclinical and advance stage clinical development CROs primarily work on the New Chemical Entities and New Biological entities, the Bioequivalence/Bioavailability Clinical CROs are primarily on developing the generic drugs through Abbreviated New Drug applications (ANDAs). It is interesting to note that many CROs operating in India like Syngene, Jubilant, Parexel etc have the capabilities to offer the various combinations of above-mentioned services as well as end to end product development services. As per the data analysed for 50 CROs in the study (refer to the Exhibit 9),54% of the CROs operating in India are operating in the service areas related to patient-based Phase I-IV clinical trials conducted at the hospitals. This major chunk of CROs not only include Indian CROs like JSS Medical Research, SiroClinpharm, Navitas, Reliance, Ardent, Ethicare, Novobliss, Target Research but also include the multinational CROs like IQVIA, Parexel, Syneos, PPD etc. It is followed by the segment (18% of the total number) which primarily offers the clinical Bioequivalence/ Bioavailability service from their inhouse BE centres and normally conduct the Pharmacokinetic studies in healthy subjects for ANDA submissions sand generic product marketing authorisations but also have the capabilities to conduct the patient-based studies in hospitals. India also has good percentage (20%) of integrated drug discovery and development companies like Syngene, Jubilant, Jai research Foundation which offer end to end services including chemistry/biology discovery, preclinical and clinical development services. A small percentage (8%) of preclinical CRO like Dabur research foundation and Eurofins Advinus also work in which offer the animal testing services for the pharmaceutical, biotech and medical device companies.

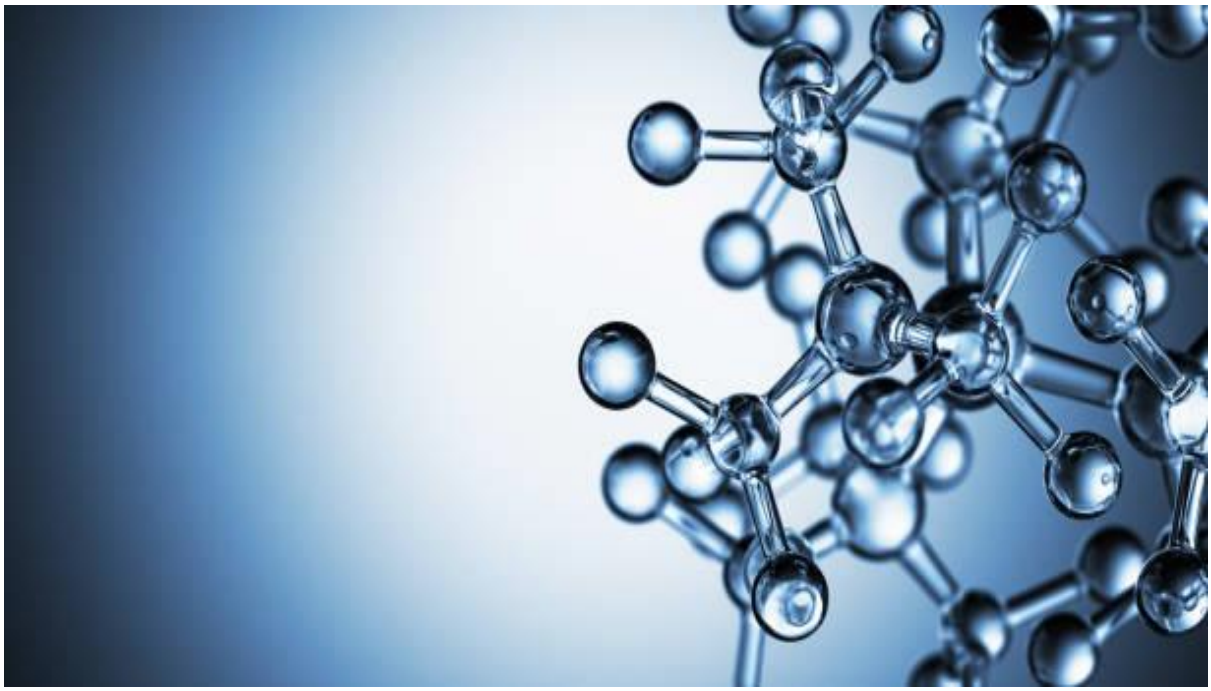
Exhibit 9: CRO categorization on the basis of services



DISCOVERY CRO SERVICES

6.2. Discovery Services

In the field of drug development, drug discovery plays a pivotal role in the identification and optimization of small molecule drug candidates. However, the complexities and resource-intensive nature of medicinal chemistry require specialized expertise and infrastructure. This is where Contract Chemistry and Medicinal Discovery Services come into play, offering pharmaceutical and biotechnology companies access to a range of expertise and resources to expedite the drug discovery process. Outsourcing medicinal chemistry activities to CROs can provide significant cost and time savings for pharmaceutical and biotechnology companies. CROs have the necessary infrastructure, compound libraries, and expertise readily available, eliminating the need for companies to invest in establishing and maintaining their own medicinal chemistry capabilities. In India companies like Jubilant and Aurigene provide contractual discovery services for small molecule drug candidates. By leveraging the specialized services of CROs, companies can focus on their core competencies while accelerating their drug discovery programs.

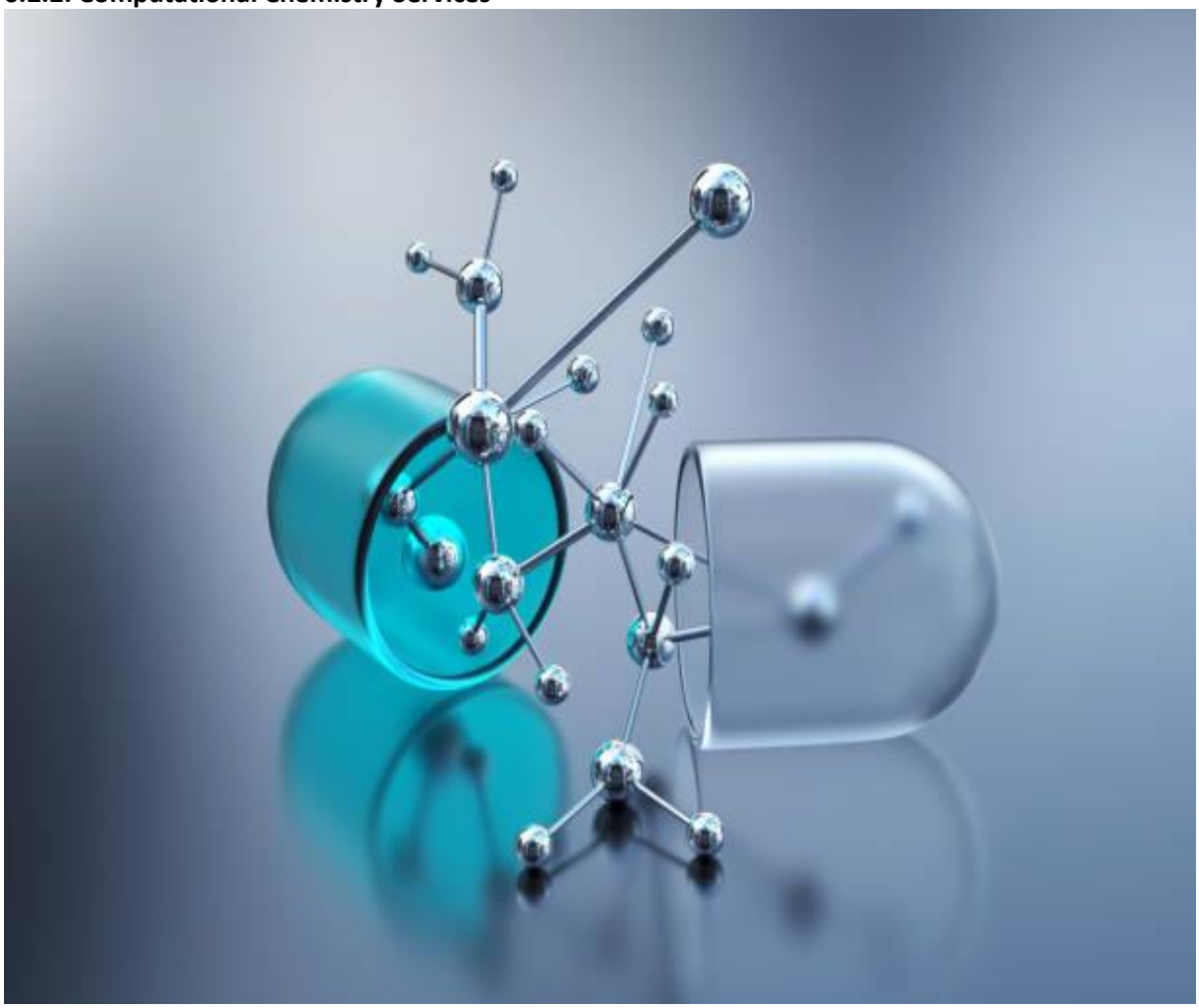


6.2.1. Medicinal Chemistry Services

These Services involve outsourcing medicinal chemistry activities to specialized Contract Research Organizations (CROs) that have a dedicated team of medicinal chemists, state-of-the-art facilities, and a proven track record in drug discovery. These services enable companies to leverage the expertise and infrastructure of CROs, accelerating the identification and optimization of potential drug candidates. Some of the services offered by such CROs include:

1. **Hit Identification and Lead Optimization services**
2. **Structure-Activity Relationship (SAR) Study services**
3. **Fragment-Based Drug Design (FBDD) services**

6.2.2. Computational Chemistry Services



In the field of drug discovery, computational chemistry has emerged as a powerful tool to expedite the identification and optimization of potential drug candidates. Contract Discovery Computational Chemistry Services involve outsourcing computational chemistry activities to CROs that have a dedicated team of computational chemists, access to cutting-edge software and hardware, and a deep understanding of drug discovery processes. These services enable companies to leverage computational power, accelerating the drug discovery process and improving the efficiency of lead identification, optimization, and decision-making. Some of the services offered by such CROs include:

1. **Virtual Screening and Ligand Design Services**
2. **Structure-Based Drug Design (SBDD) Services**
3. **ADME-Tox Prediction Services**
4. **QSAR and Machine Learning Models.**

6.2.3. Synthesis Services

The synthesis of novel drug candidates / compounds is one of the most crucial steps in the identification and development of potential drug candidates. However, the complexity and resource-intensive nature of organic synthesis pose significant challenges for pharmaceutical and biotechnology companies. Contract Discovery Chemistry Synthesis Services involve outsourcing organic synthesis activities to CROs that have a dedicated team of synthetic chemists, state-of-the-art laboratories, and a track record in drug discovery. By outsourcing synthesis activities to CROs, companies can expedite the identification and optimization of potential drug candidates while minimizing the challenges associated with organic synthesis. These services enable companies to leverage the expertise and resources of CROs, accelerating the synthesis of novel compounds and facilitating the drug discovery process. Some of the services offered by such CROs include:

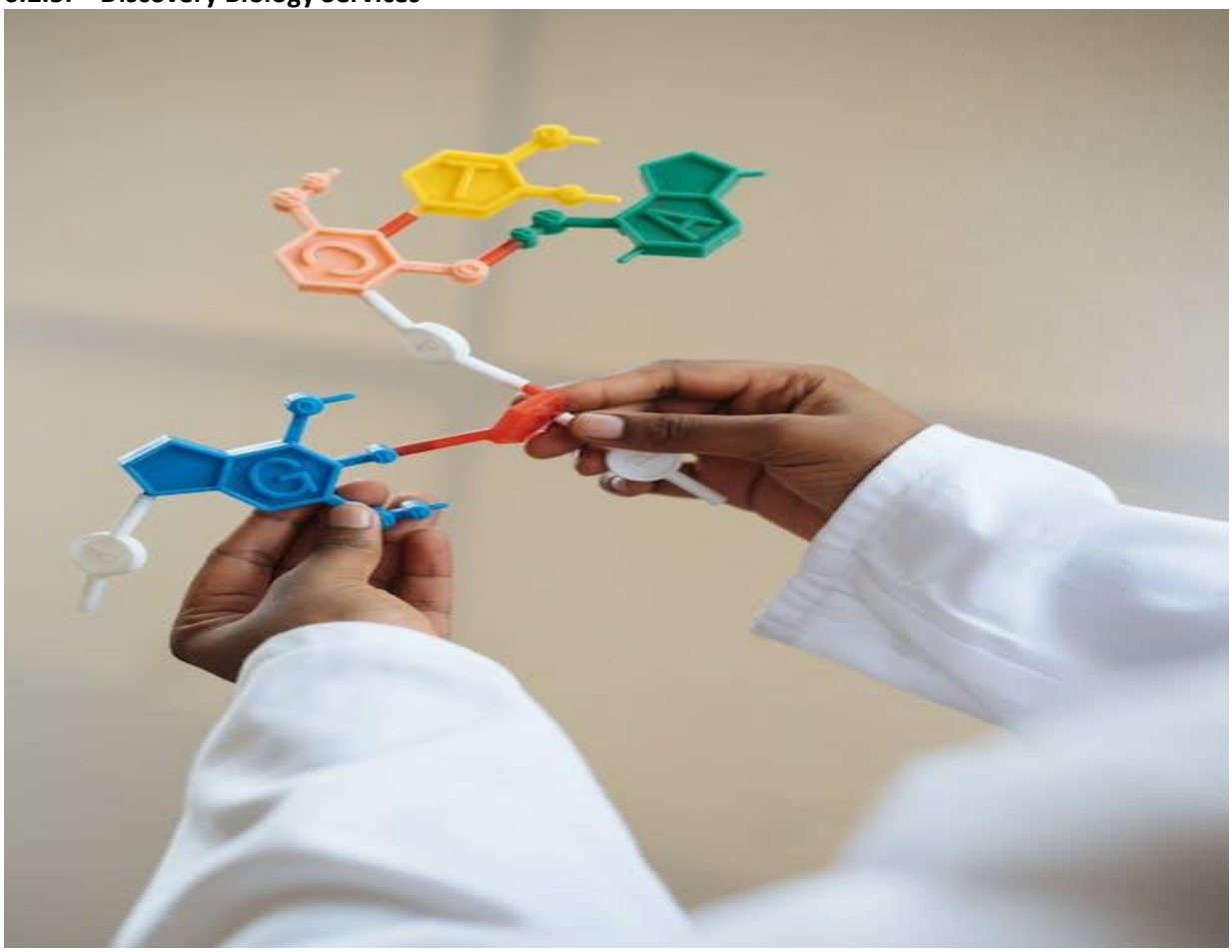
1. **Custom Synthesis Services**
2. **Scale-up Synthesis Services**
3. **Synthetic Route Design and Optimization Services**

6.2.4. Analytical Chemistry Services

Analytical chemistry involves the application of various techniques and methods to assess the quality, purity, and safety of drug substances and products. Analytical Chemistry Services, offered by specialized laboratories and Contract Research Organizations (CROs), provide pharmaceutical and biotechnology companies with access to a wide range of analytical equipment's like HPLC, LCMS-MS and expertise and capabilities to offer these services. These services ensure that drugs meet regulatory requirements, maintain consistent quality, and are safe for patient use. Some of the services offered by such CROs include:

1. **Method Development and Validation Services**
2. **Identification and Structural Elucidation Services**
3. **Stability Studies Services**
4. **Impurity Profiling and Quantification Services**
5. **Quality Control Testing**
6. **Regulatory Compliance and Support**
7. **GMP and GLP Compliance**

6.2.5. Discovery Biology Services



6.2.5.1 Reagent Generation

In biological research and drug development, the availability of high-quality reagents is essential for conducting experiments, understanding disease mechanisms, and discovering new therapeutic targets. Reagent Generation Discovery Biological Services offer pharmaceutical and biotechnology companies access to specialized expertise and resources for the generation and validation of biological reagents. These services play a crucial role in accelerating research and development efforts, facilitating target identification, and supporting the discovery of novel therapeutics. Some of the services offered by such CROs include:

1. **Recombinant Protein Production Services**
2. **Antibody Generation Services**
3. **Stable Cell Line Development Services**
4. **Functional Assay Development**
5. **High-Throughput Screening (HTS)**

6.2.5.2. Assay Development and Validation

Assay development and validation involve the design, optimization, and validation of assays that measure specific biological activities, biomarkers, or target interactions. Assay Development and Validation Discovery Biological Services provide pharmaceutical and biotechnology companies with access to specialized expertise and resources for the efficient development and validation of robust assays. These services play a crucial role in accelerating research, enabling high-throughput screening, and supporting the discovery of novel therapeutics. Some of the services offered by such CROs include:

1. **Custom Assay Development Services**
2. **High-Throughput Screening (HTS) Assay Services**
3. **Biomarker Assay Development Services**
4. **Assay Performance Validation Services**
5. **Pharmacokinetic and Pharmacodynamic (PK/PD) Assays Services**

6.2.5.3. Screening and Mechanism of Action

Screening and mechanism of action (MoA) discovery are crucial steps in biological research and drug development. They involve the identification and characterization of compounds or drugs that exhibit specific biological activities and understanding the molecular targets and pathways through which they exert their effects. Screening and Mechanism of Action Discovery Biological Services provide pharmaceutical and biotechnology companies with access to specialized expertise and resources to accelerate the discovery of active compounds and elucidate their mode of action. Some of the services offered by such CROs include:

1. **High-Throughput Screening (HTS) Services**
2. **Hit Confirmation and Validation Services**
3. **Mechanism of Action Studies Services**
4. **Target Identification and Validation Services**
5. **SAR and Lead Optimization Services**
6. **Phenotypic Screening Services**
7. **Data Analysis and Interpretation Services**

6.2.5.4. Ex-Vivo Assays

Ex Vivo Assays Discovery Biology Services offer a valuable approach to studying complex biological processes, assessing drug efficacy, and facilitating target validation in a more physiologically relevant context. These services play a crucial role in bridging the gap between in vitro and in vivo research, ultimately contributing to the development of safer and more effective therapeutics.

This enables the investigation of complex biological interactions and the evaluation of drug candidates in a more physiologically relevant setting. These services bridge the gap between in vitro and in vivo research, offering a valuable platform for understanding disease mechanisms, assessing drug efficacy, and predicting clinical outcomes. Some of the services offered by such CROs include:

1. **Tissue-Based Assays development and validation Services**
2. **Disease Modelling and Mechanism Studies**
3. **Drug Efficacy and Safety Assessment Services**
4. **Mechanistic Studies and Target Validation Services**
5. **Customization and Protocol Optimization Services**

6.2.6 ADMET Services

ADMET services are essential in evaluating the pharmacokinetic and pharmacodynamic properties of drug candidates, identifying potential toxicities, and optimizing compounds for further development. By assessing ADMET parameters early in the drug discovery process, these services contribute to the selection of safe and effective drug candidates, ultimately reducing the time and cost associated with late-stage failures in drug development. The CROs offering ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) services provide pharmaceutical and biotechnology companies with comprehensive evaluation and characterization of compounds or drug candidates in terms of their pharmacokinetic and pharmacodynamic properties, as well as their potential toxicity. By assessing the ADMET profile of compounds early in the drug development process, ADMET services help inform decision-making, optimize drug candidates, and reduce the risk of late-stage failures. Some of the services offered by such CROs include:

1. **Absorption Assessment Services**
2. **Distribution Analysis Services**
3. **Metabolism Studies Services**
4. **Excretion Evaluation Services**
5. **Toxicity Screening Services**
6. **Drug-Drug Interaction Studies**
7. **In Silico Predictions Services**

6.2.6.1. Physicochemical Testing

Physicochemical Testing Discovery Biology Services provide comprehensive evaluation of the physical and chemical properties of drug candidates. By assessing key physiochemical parameters, these services help guide compound optimization, predict drug behaviour in biological systems, and support formulation development. The data generated through physiochemical testing play a crucial role in selecting drug candidates with optimal drug-like properties and increasing the likelihood of successful drug development. Below are some of the Physiochemical Testing offers services offered to the clients:

1. **Solubility and Dissolution Testing.**
2. **Lipophilicity and Hydrophilicity Studies**
3. **Solid-State Characterization**
4. **Stability Assessment**
5. **Permeability and Transporter Studies**

6.3. Contract Laboratory Services

Contract laboratory services primarily consist of the biomarker discovery, genomic analysis and immunogenicity services offered on contractual basis to pharmaceutical companies working on areas related to personalized medicine. Some of the services offered by the CROs working in contract laboratory service.

1. **Biomarker Discovery Services**
2. **NGS based Genomic Analysis Services**
3. **Development and validation services for molecular diagnostic**
4. **Pharmacogenomics services**
5. **Companion Diagnostics development services**
6. **Bioanalytical Method Development, Validation and Analysis Services**
7. **Immunogenicity Testing Services**

PRE-CLINICAL DEVELOPMENT CRO SERVICES

6.4. Pre-Clinical Development Services

Preclinical development is a stage of drug development that begins after before clinical trials (testing in humans) and during which important feasibility, iterative testing and drug safety data are collected, typically in laboratory animals. The main goals of preclinical studies are to determine a starting, safe dose for first-in-human study and assess potential toxicity of the products . The preclinical CRO is an independent entity specializing in managing the complexities inherent to the preclinical phase of drug development and is employed by pharmaceutical organizations

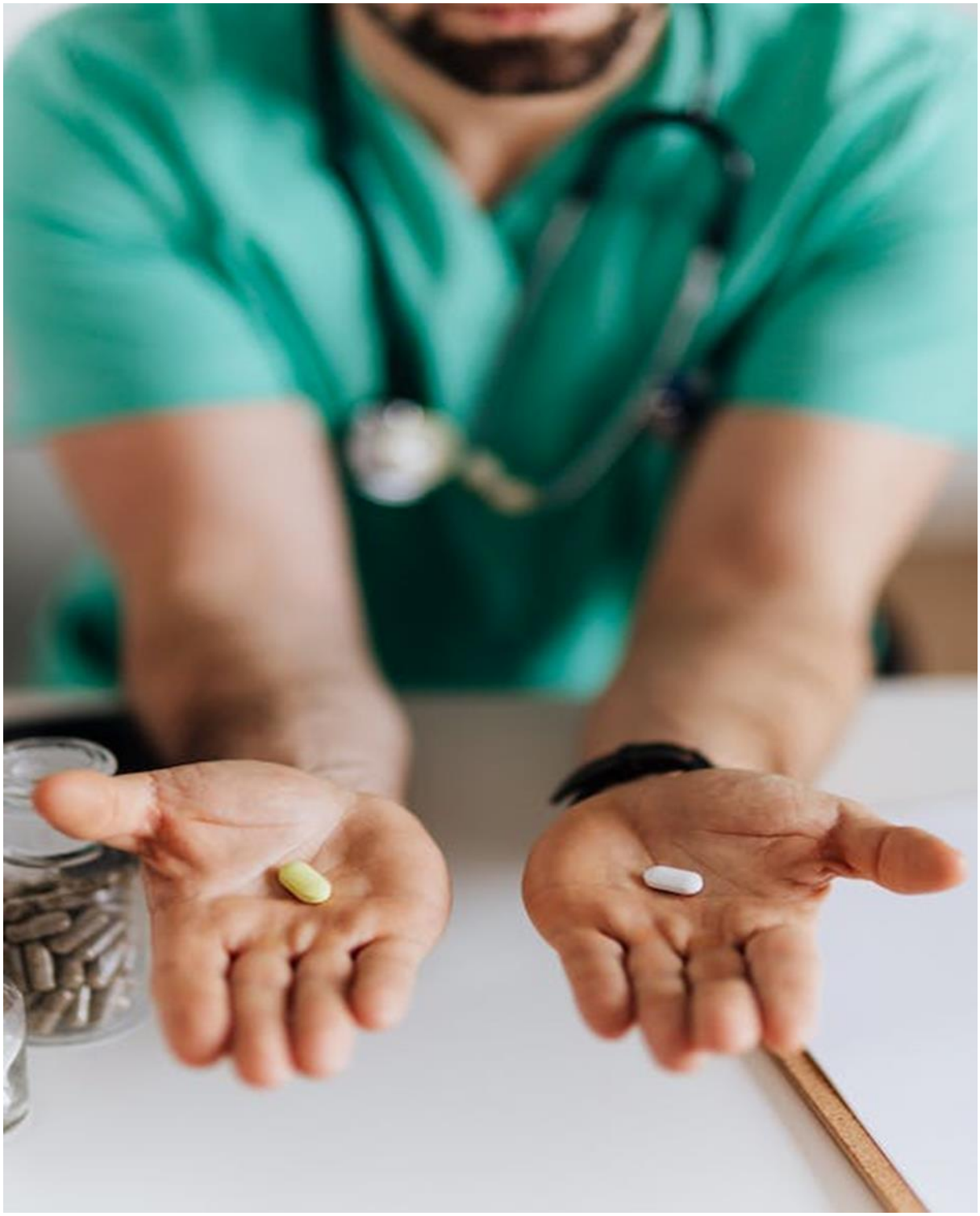
Once a pharmaceutical company find a promising target (and has a patent in hand!), it has to characterize the preclinical safety profile using animal models The preclinical phase utilizes a range of animal models to simulate human physiology and provide valuable insights into the biological activity, pharmacological effects, and potential risks associated with drug candidates. Preclinical CROs offer their expertise in the multifaceted management of this initial stage of the process, which may include selection of suitable animal models or alternatives, and the execution of toxicity assays. The goal for a pharmaceutical organization in engaging a preclinical CRO is the efficient progression of a potential drug to the market, especially given the expensive nature of the preclinical phase and the specific skill sets it requires, which may not be readily available within the company. Within the competitive field of medical research, where the process of bringing a new drug to market may span approximately a decade, preclinical CROs can facilitate and accelerate this process. Services offered by these organizations span project management, data collection, medical testing, toxicology, regulation compliance, safety reporting, and quality analysis, with some CROs offering specialized expertise in certain fields. The CROs offering the preclinical development services help the pharmaceutical companies to make informed decisions regarding further development and clinical testing of potential therapies. have a deep understanding of regulatory guidelines and requirements, such as those provided by regulatory agencies like the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). They ensure that genotoxicity studies are conducted in accordance with relevant regulatory standards, including Good Laboratory Practice (GLP) or other applicable guidelines.

The CROs in India like Eurofins Advinus, Dabur Research foundation, Jai research foundation, Jubilant, Syngene etc offer the contract preclinical services to the Indian and multinational pharmaceutical companies.

Below are some of the prominent services offered by such preclinical service providers:

1. **In Vivo Pharmacology Services**
2. **Toxicology Study Services.**
3. **Genotoxicity Services like Ames Test (Bacterial Reverse Mutation Assay), In Vitro Mammalian Cell Chromosomal Aberration Tests, In Vitro Mammalian Cell Micronucleus Test etc.**
4. **DMPK Study Services to elucidate ADME (Absorption, Distribution, Metabolism, and Elimination) pattern of Drugs**
5. **Drug-Drug Interactions (DDI) Study services**
6. **Pharmacokinetic Modelling and Simulation services**
7. **Scientific Consultation services**

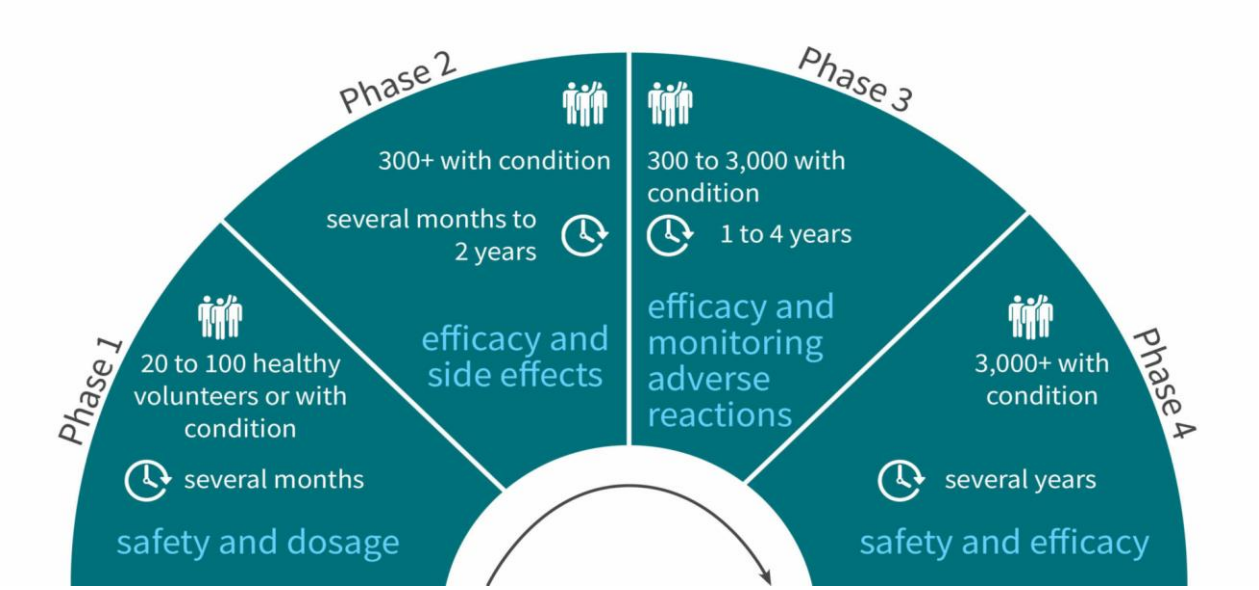
CLINICAL DEVELOPMENT CRO SERVICES



6.5 Clinical Development Services (Phase I-IV)

Clinical development is a stage of drug development that begins after the successful testing of investigational new drugs in laboratory animals. In case of New Chemical entities, after the completion of successful preclinical toxicology studies, an Investigational New Drug (IND) or Clinical Trial Application (CTA) is filed by a company and it prepares itself for the testing of drugs in humans.

Exhibit 10: Phase I-IV with each part serving a different purpose



This Clinical testing is further split into Phases I-IV with each part serving a different purpose (Refer to Exhibit 10. In Phase I the companies are concerned with the safety, tolerability, and the pharmacokinetic/pharmacodynamic (PK/PD) profile of new investigational drug. If the results support it, the pharmaceutical companies move on to a larger Phase II trial where further characterization of the safety profile of candidate drug and its efficacy is determined. Once proven, these drugs are moved into Phase three where large patient population is tested to confirm previous findings, compare the new drug to the current standard of care or placebo, as well as observe the adverse effect profile. If the Investigational new drug is found to be safe, effective and efficacious in Phase II Trial, the marketing approval is given to the pharmaceutical company to market the product for the labelled indication. After the drugs reach the market. The pharmaceutical companies have to conduct Phase IV or Post Marketing Surveillance studies to assess the long-term safety and effectiveness of the FDA approved drug. For medical devices, the clinical development comprises of pilot and pivotal clinical studies in which the medical devices are tested for their safety and performance in human subjects.

Most of the top 20 global pharmaceutical and biopharmaceutical companies are conducting their studies in India, South Korea, Taiwan and China. The countries like Hong Kong, Philippines, Thailand, Singapore, Japan, and Malaysia are slow but steady gainers. Other countries such as Indonesia, Pakistan, Srilanka and Vietnam, remain less attractive to clinical trials because of their economic and political instabilities.

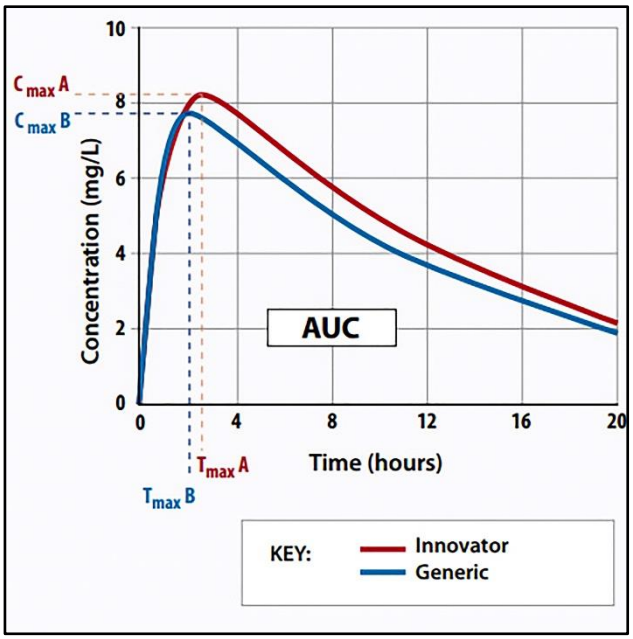
Amongst the top 20 pharma, AstraZeneca, Novartis, Eli Lilly, Pfizer, and J&J are the top sponsors of clinical trials in India, however the number of the clinical trials being done cannot be directly translated into the revenues generated and available for the CROs because most of these clinical trials are done by the in-house clinical development teams of these companies (Indian offices of these MNCs) which manage the clinical trials on their own. These companies normally conduct global clinical trials and India happens to be one of the destinations among various other countries a part of the global clinical trials in India. However, India by virtue of its cost-effectiveness and educated, trained and English-speaking workforce happens to be major delivery centre for outsourcing of some activities of clinical trials like clinical data management, medical writing and Pharmacovigilance. On the other hand, Indian companies readily outsource the clinical trial projects to Indian CROs. For every project the companies in India float the RFP to at least 3-5 Indian CROs. The global CROs do not fit in the price bracket of most of the Indian sponsors and therefore the Indian CROs have always a good chunk of business available in Indian market. The business from Indian Pharmaceutical companies is not that lucrative for Indian CROs in terms of profit margins but it has been steady even in the last few years. The Indian CROs have learnt the art of managing the costs and have come up with cost efficient operational models which make them suitable for catering to india specific requirements of Indian clients. The clinical CROs have access to multiple clinical trial sites across the geographies where they engage the investigators to recruit the subjects as per specification the trial protocol. The clinical CROs offer comprehensive clinical trials to the pharmaceutical companies which include but are not limited to:

- **Medical & Scientific writing services**
- **Regulatory Approvals and Ethics Committee submission services**
- **Clinical Trial Feasibility assessment services**
- **Investigator identification and site management services**
- **Randomization, study drug labelling, and packaging services**
- **Clinical Trial Supplies Management services**
- **Clinical Trial Project Management services**
- **Clinical Trial Monitoring services**
- **Clinical Data Management & Biostatistics Services**
- **Pharmacovigilance and Safety reporting services**
- **Publication support services**

6.6 Bioequivalence & Bioavailability CRO services:

For the generic pharmaceutical products, the pharmaceutical companies do not need to go through entire clinical development cycle of Phase I to Phase IV. It is because the innovator drugs are in the market for a long period and have been already been proven to be safe and efficacious in a particular disease indication. In such case, the generic companies need to perform the Bioequivalence clinical studies to prove that their products have similar pharmacokinetic profile and safety profile to the innovator drug and therefore can substitute the innovator product (Refer to exhibit 11)

Exhibit 1 1: Pharmacokinetic profile and safety profile of innovator drugs v/s generic drugs



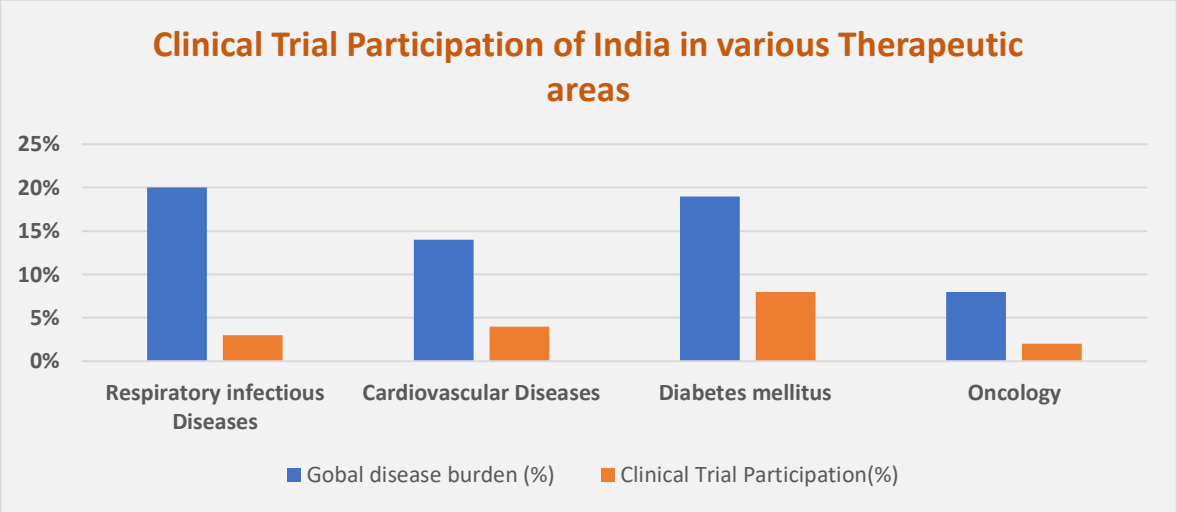
There are numerous CROs in India which maintain state-of-the-art multi-bedded clinical facilities and well-equip ped bioanalytical laboratories to conduct the bioequivalence studies. Some of the examples include Lambda Therapeutics, Veeda, Raptim, Axis, Syngene, Jubilant, Accutest, Synapse, Vimta, Mediclin etc. These CROs maintain a database of healthy subjects of nearby areas. The generic drugs of the clients of CRO are tested on these healthy subjects and the biological samples of these subjects are then tested for pharmacokinetic parameters in the associated bioanalytical laboratories equipped with high end machines like HPLC and LCMS. The bioequivalence data provided by the these CROs is an integral part of Abbreviated New Drug Application filed in USFDA by the pharmaceutical companies to get the approval for generic products. It is important to note that many of the CROs mentioned above also provide the clinical trial services at the hospitals for some of advance phase (Phase II-IV) clinical trials. Bioequivalence CROs also follow the ICH-GCP norms and come under the regulatory framework of CDSCO. Some of the services offered by the Bioequivalence CROs include:

- Protocol development & Study documentation
- Regulatory approval of BA/BE studies from CDSCO office
- Clinical conduct of the BA/BE study
- Method Development and Validation services
- Bioanalysis of plasma samples
- Data management and PK analysis
- Report writing and eCTD preparation
- Dossier preparation with complete data compilation

7. CRO CATEGORIZARION BY THERAPEUTIC AREAS:

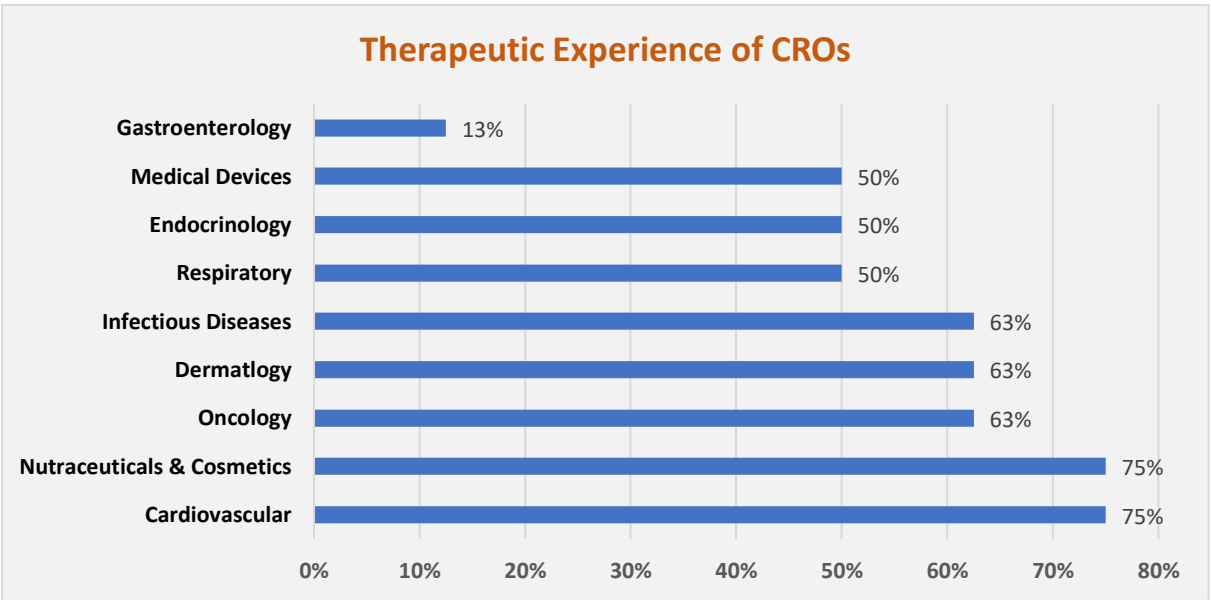
As per a latest Report on the clinical trials in India, India has an overall clinical trial participation of less than 2% but contributes upwards of 15% (Refer to Exhibit 12) to the global burden of most high prevalent diseases (e.g., respiratory infections, cardiovascular, diabetes, cancer), representing an untapped potential for top pharmaceutical and clinical research company.

Exhibit 12: Clinical trial participation of India in various Therapeutic areas



During the study, the therapeutic experience of Bioequivalence CRO was not considered in the analysis because the bioequivalence studies typical analyses the pharmacokinetic profiles of the drugs and there is no therapeutic benefit to the otherwise healthy subjects. As per the data analysis, 75% of the companies had expertise in therapeutic areas like cardiology, nutraceuticals and cosmetics. Furthermore, more than 60% of the CROs has experience in therapeutic areas like oncology, dermatology and infectious diseases. It was also found that 50% of companies had experience of working in medical devices and in therapeutic areas of respiratory and metabolic diseases. The CROs with experience of working into gastroenterology was only 13%.

Exhibit 13: Therapeutic Experience of CROs



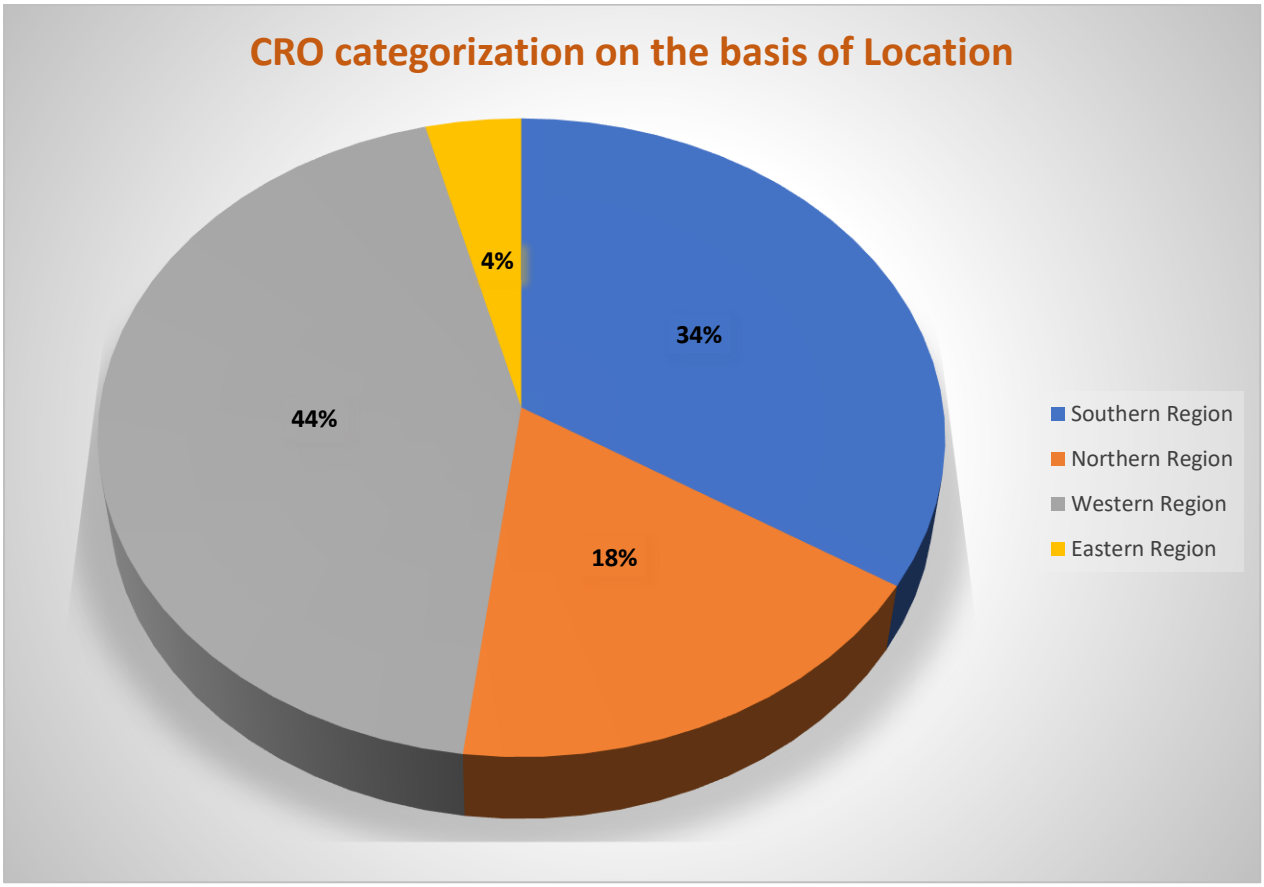
8. CROs CATEGORIZATION BY LOCATION

8.1. Overview

Except for the central part of India, the contract research organisation are present across all major regions in the country. Many CROs have multiple research centres/ offices and may have presence across various regions. It may also be noted that many Clinical Trial CROs operate at the hospital across the country. These companies may not have full-fledged brick and mortar offices in and around these hospitals but may have regional employees working from home.

For the ease and uniformity of the data analysis during the study, the main research centre/ office of CRO was considered for location-based categorization of CRO.

Exhibit 14: CRO categorization on the basis of Location



As per the data analysis, most of the CROs (40%) are based in the western region comprising of Mumbai, Pune, Ahmedabad, Vadodara. It is followed by Southern region where 34 % of the CROs have presence mainly in cities like Bangalore, Chennai and Hyderabad. The northern part of India has around 18% of the contract research organsiations which are mainly located in and around Delhi/NCR area. The eastern region of the country stands at 4% with CROs located in. The data analysis further elucidates that CRO generally prefer to set up their centres and offices in Metro or Tier 1 cities across the country Exhibit 14 represents the location of different CROs across various regions of India.

Western	Southern	Northern	Eastern
Accutest Global	Aragen	Accelsiors	Infoclin
ACM Global Laboratories	Abiogenesis Clinpharm	APCER Life sciences	TCG lifesciences Pvt. Ltd.
Ardent clinical research	Actimus Bio	CliniRx	
Charles River Lab	Aurigene	Dabur Research foundation	
Cliantha Research	AXIS Clinicals	JSS Medical Research	
Ethicare Clinical Trials	Clinexa Life sciences	Jubilant	
Global Clinical Trials	Clinsync Clinical Research	Labnetworx	
Intox Lab (Aragen)	Eurofins Advinus	Parexel International	
IQVIA	Fortrea	Syneos Health	
Jai Research Foundation	Laxai		
Lambda Therapeutics Research Limited	Lotus Labs		
Mediclin clinical Services	Navitas Life Sciences		
Medpace	PRA health Sciences (Icon)		
Novobliss Research	Sai Life Sciences		
PPD	Suven Life Sciences		
Prorelix Research	Syngene		
Reliance Life Sciences	Vimta Labs		
Synchron Research Services			
Synergen			
Target Institute of medical education and research			
The SIRO Clinpharm			
Veeda Clinical Research			

9. CRO CATEGORIZATION BY SIZE (REVENUES & EMPLOYEES)

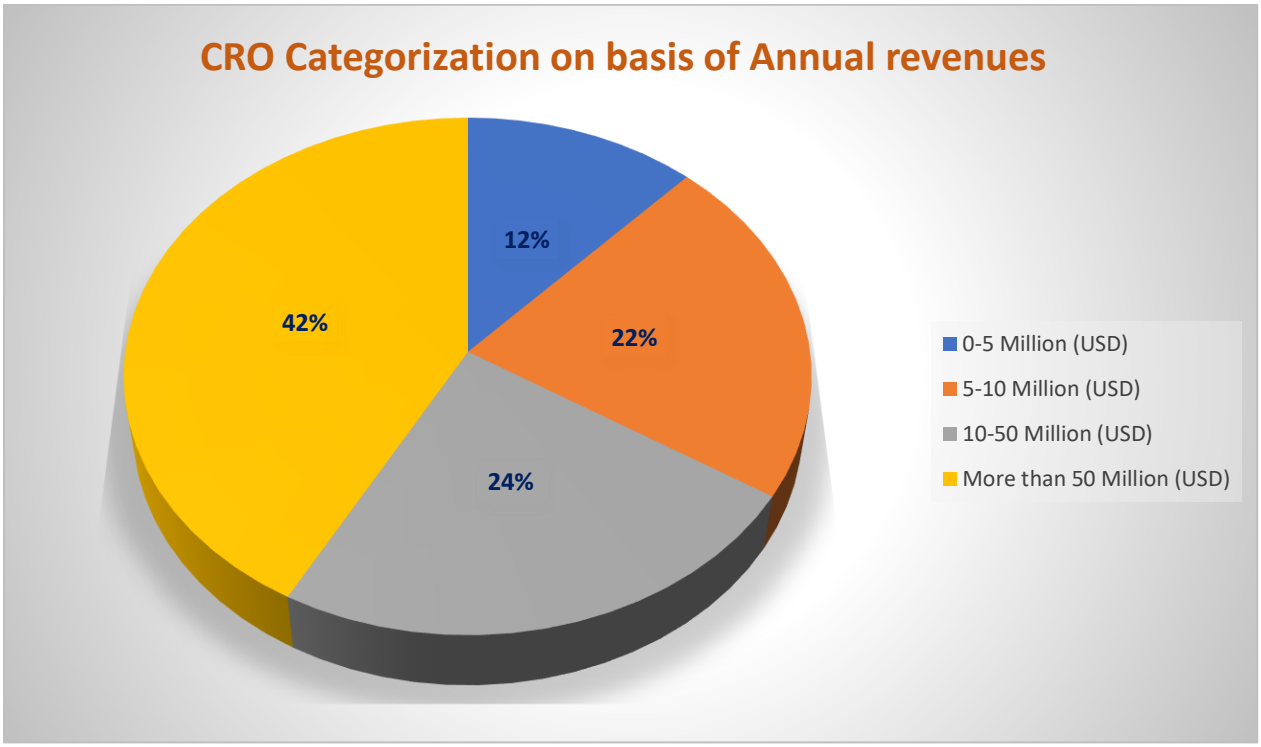
9.1. Overview

CROs of all sizes operate in India. On one hand, there are global CROs who have set up their regional office/s, delivery centres and R&D centres in India, while on the other hand there are small niche Indian CROs with expertise in a particular therapeutic area. Size can be a relative term and therefore for the ease and uniformity of the data analysis, the revenues and employee numbers of CROs were considered as the key parameters for the size categorization of CROs. Further it may be noted that the contract value per project (Ticket size) across different types of CRO services vary considerably and therefore it is imprudent to compare a Preclinical CRO with Clinical CRO in term of revenues. However, for the uniformity and ease of data analysis the revenues of the 50 CROs in the database has been considered irrespective of the specific CRO service area.

9.2. Size by Revenue

As per the data analysis, (Refer to Exhibit 15) the annual revenue of 12% of CROs was in the range of USD 0-5 Million while those of 22% of the CROs were in the range of USD 5- 10 million. This total segment of around 34 % CRO comprised the micro and small segment by revenues. There were 24% medium sized CROs whose revenues were in the range of USD 10-50 Million. The large sized CRO segment comprised of around 42% CROs (mainly the multinational CROs) whose revenues were more than USD 50 Million. The data infers that on the basis of revenues, majority of CROs (58%) operating in India are of small to medium size and there is large chunk of CRO market (42%) is dominated by big size global CROs.

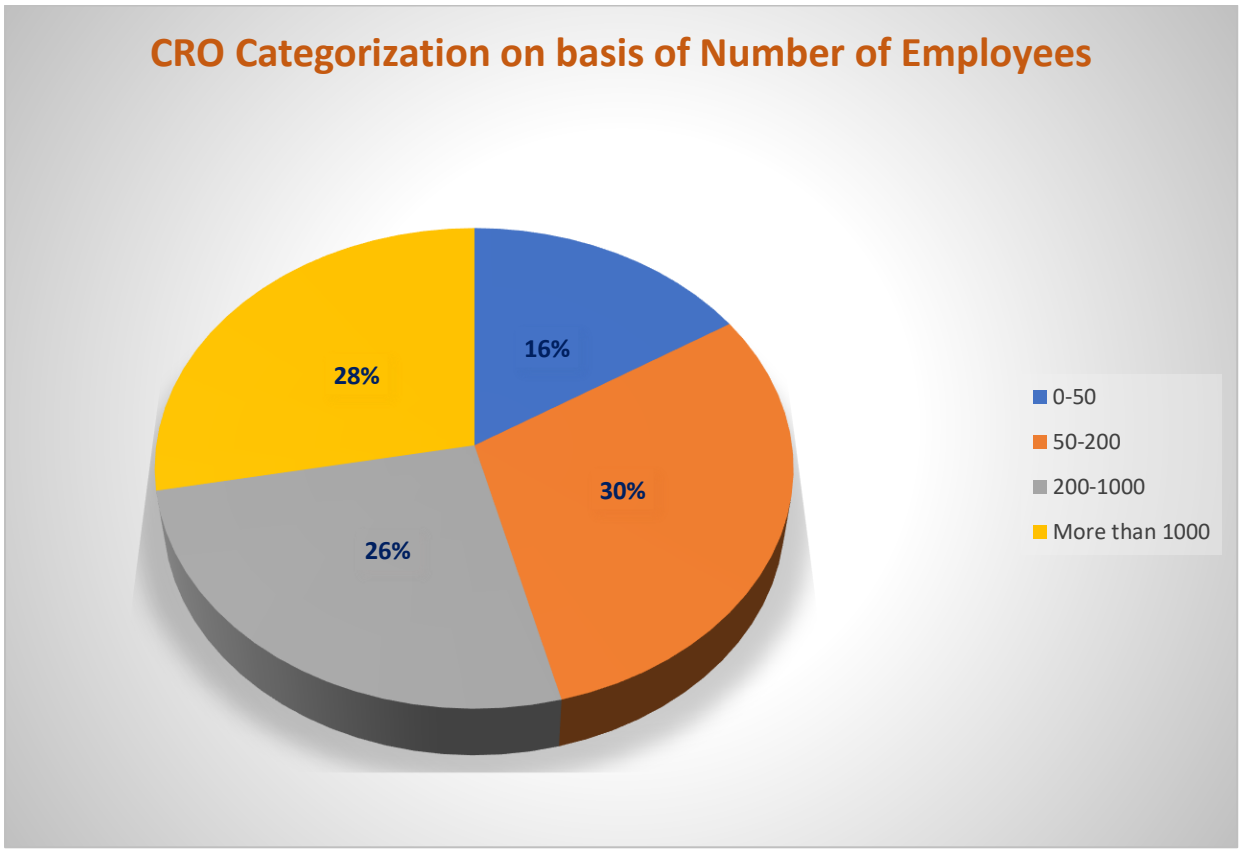
Exhibit 15: CRO categorization on the basis of Annual revenues



9.3. Size by Employee Strength

As per the data analysis (Refer to Exhibit 16) the employee number of 16% of CROs were in the range of 0-50 while those of 30 % of the CROs were in the range of 50- 200. This total segment of around 46 % CRO comprised the micro and small CRO segment by employee number. There were 24% medium sized CROs whose employee number were in the range of 200-1000. The large sized CRO segment comprised of around 28% CROs (mainly the multinational CROs) whose employee strength more than 1000. The data infers that on basis of employee numbers majority of CROs (72 %) operating in India are of small to medium size and another chunk of CRO market (28 %) is dominated by big size global CROs.

Exhibit 16: CRO categorization on the basis of number of employees



PROFILES OF SOME PROMISING CROs OPERATING IN INDIA

10. PROFILES OF SOME PROMISING CROs OPERATING IN INDIA

Eurofins Advinus

Year Of Establishment: 2005
Location: Head Office: Eurofins Advinus Pvt Ltd. Bangalore.

Corporate Offices:
Eurofins Advinus - Discovery Chemistry Centre - Bangalore, Karnataka
Eurofins Advinus Biopharma Services India - CDMO Site - Bidadi, Karnataka
Eurofins Biopharma Product Testing India Pvt Ltd - Chennai, Tamilnadu
Eurofins Advinus Hyderabad - Shameerpet, Telangana

Service Portfolio:
- Discovery Services: Chemical and Biological Discovery, ADMET
- CDMO Services: Process Research and Development, Analytical Development, Process Safety, Manufacturing
- GMP Analytical Testing: Extractable & Leachable Testing
- Medical Device Testing: Chemical Characterization
- AgroSciences Services: Five Batch Analysis, Physical Chemical Property Testing, Environmental Fate, Metabolism in Plants and other Biological Matrices, Residue and Persistence, Ecotoxicology, Toxicology of Crop Protection Agents, Process Development & optimization, Elemental Analysis, Field Trials/Testing Services, Skin Absorption: In-vitro Method, Efficacy Testing-Household Pesticides.
- Other Services: DMPK, Bio-analytical Services, Safety Assessment (Toxicology Services), Biologics/Biosimilars Testing Services, Registration, Evaluation and Authorization of Chemicals Support, Insourcing Services

Management Team:
- Rajiv Malik - CEO & Managing Director

Prominent Collaborations:
Eurofins Advinus is a pioneer in drug discovery services in India and has collaborated with companies like Takeda, Merck, J&J, Novartis, Celgene and DNDi.

Last Year's Turnover: Eurofin's Advinus' annual revenue for 2022 was USD 28.6 Million.

Key Development:

- Eurofins Advinus has expanded Peenya Campus and new facilities are located in Genome Valley, Hyderabad in December 2022.
- Eurofins Advinus acquired all the assets of Gomti Life Sciences Pvt Ltd through a business transfer agreement on February 05, 2020.

Unique Selling Points:
Eurofins Advinus is a preclinical CRO offering drug discovery, preclinical and development stage contract research services including discovery services, CMC services, regulatory Toxicology (Safety Assessment), DMPK and Analytical R&D Services. Eurofins Advinus manufactures drug substances to support Toxicology and clinical studies. Eurofins Advinus is the only contract research organization (CRO) in India to have developed data in support of 90+ end-to-end IND enabling packages to be submitted to global regulators such as USFDA, EMA, MHRA, Health Canada and others.

JSS Medical Research

Year of Establishment: 1985

Location:

Corporate Head Office: St-Laurent (Montreal)

Regional Office:

- Faridabad, Haryana
- Bogotá, Colombia
- Warsaw, Poland

Services Portfolio:

Advanced Clinical Trial Management, Market Access & HEOR, Consulting, Biostatistics and Medical Writing, Insourcing, Clinical Development Plan, Strategic Assessments, Risk Management, Patient Reported Outcomes, Literature Review and Advanced Biostatistics and Rescue Analysis

Management Team:

- Mr John S. Sampalis (Chief Executive and Scientific Officer)
- Louise Bussieres, CPA (President and Chief Financial Officer)
- Stella Boukas BA, CCRP (Chief Operations Officer)
- Emmanouil Rampakakis (Executive vice President)
- Peter Heessels (Vice President, Business Development)
- Marianna Boukas (Senior Director of Quality Assurance)
- Jimmy Fragos (Global Director of Bioinformatics)
- Yohana Paola Granados (Director of Clinical Operations - Latin America)
- Dr Ajoy Kumar (Country Head - India, JSS Asia Pacific Private Limited)
- Dr Renu Razdan (Vice President of Operations - India, JSS Asia Pacific Private Limited)

Prominent Clients:

OPKO Biologics, Mylan Laboratories, Octapharma AG, Cumberland Pharma Inc, Human Vaccine LLP, Dr Reddy's, and Incozen Therapeutics are some of the prominent clients of JSS medical research.

Last Year Turnover:

JSS Medical Research's annual revenue was USD 22 million in 2021.

Key Development:

Genesis Drug Discovery and Development (GD3), a member of Genesis Global Group (GGG), has acquired JSS Medical Research with corporate headquarters in Montreal, Canada, and regional offices in Bogotá, Columbia, Faridabad, India, and Warsaw, Poland.

Unique Selling Points:

- Full-service provider with strong academic affiliations offers a wide range of services internationally. One of their distinguishing attributes is methodological knowledge and expertise in the design and execution of clinical studies including Phase I, II and III, and post-approval studies.
- Clinical Trials range from small to large complex multinational projects. Benefit from the planning, execution and proactive management of clinical programs designed to succeed which includes PHASE I, PHASE II, PHASE III-IIIB, MEDICAL DEVICES.

Jubilant

Year of Establishment: 1978

Location: Corporate Office:

Jubilant Pharmova/Ingrevia- Sector 16A, Noida, Uttar Pradesh, India

Subsidiaries:

- Jubilant Biosys Limited - Industrial area, Yeshwantpur, Bengaluru, India
- Jubilant Biosys Limited - Sector 59, Noida, Uttar Pradesh, India
- Jubilant Generics Limited - Sector 16A, Noida, Uttar Pradesh, India

Service Portfolio:

Drug Discovery Services, CRAMS, Active Pharmaceutical Ingredients, Proprietary Novel Drugs/Biomolecule.

Management Team:

- Shyam S Bhartia (Chairman)
- Hari S Bhartia (Co-Chairman)
- Priyavrat Bhartia (Managing Director)

Prominent Clients: Supernus Pharmaceuticals, Novartis, Eli Lilly, Pfizer, Merck, and Bristol Myers Squibb are some prominent clients of Jubilant.

Last Year Turnover: Jubilant Pharmova's annual revenue in 2022 was USD 76 Million

Key developments:

- Jubilant Therapeutics appointed Nadir Patel as an independent member of its Board of Directors
- Jubilant Therapeutics Inc.'s Selective Orally administered PAD4 inhibitor demonstrates activity in Rheumatoid Arthritis Preclinical models
- Jubilant Therapeutics receives Orphan Drug Designation for the PRMT5 inhibitors - JBI-778 for the treatment of Glioblastoma, JBI-802 for AML and SCLC
- Jubilant's radio pharma business receives NDA approval for Technetium Mertiatide Injection

Unique Selling Points:

- It is an integrated global pharmaceuticals company having three business segments Pharmaceuticals, Contract Research and Development Services and Proprietary Novel Drugs.
- Pharmaceuticals business through Jubilant Pharma Limited is engaged in the manufacturing and supply of Radiopharmaceuticals with a network of over 45 radiopharmacies in the US, Allergy Therapy Products, Contract Manufacturing of Sterile Injectables and Non-sterile products, Active Pharmaceutical Ingredients and Solid Dosage Formulations through six USFDA approved manufacturing facilities in the US, Canada and India.
- Contract Research and Development Services business represented by Jubilant Biosys Limited provides innovation and collaborative research to global pharmaceutical innovators through two world-class research centres in Bengaluru and Noida in India.
- Proprietary Novel Drugs business through Jubilant Therapeutics Inc. is an innovative patient-centric biopharmaceutical company developing breakthrough therapies in the area of oncology and auto-immune disorders.

Syngene

Year Of Establishment: 1993

Location: **Corporate Office:**

Syngene International Ltd - Biocon Park, Jigani Link Road, Bangalore.

Clinical Development: Syngene International Ltd, Semicon Park, Hosur Road, Bangalore

Service Portfolio:

- Small Molecules:
    - Discovery (Chemistry, Biology, Safety Assessment, Computational and Data Sciences)
    - Development (Chemical, Formulation, Analytical, Clinical)
    - Commercial Manufacturing
- Biologics:
    - Discovery (Molecular Biology, Protein Sciences, Cell Line Development, Antibody Generation)
    - Development and Manufacturing (Development & manufacturing services, Analytical characterization & Quality Control, Viral Testing & Clearance, Bioanalytical Laboratory Services)
    - Other Drug Modalities: Peptides, Oligonucleotides, Antibody Drug Conjugates, PROTACs, CAR-T, Rare and Orphan Diseases
    - SynVent Integrated Drug Discovery
    - End-to-End Drug Discovery Services: Pharmaceutical & Biotech, Animal Health, Agrochemical, Nutrition, Performance & Specialty Material/others

Management Team:

- Jonathan Hunt (Managing Director and Chief Executive Office)
- Mahesh Bhalgat (Chief Operating Officer)
- Sibaji Biswas (Chief Financial Officer)

Prominent Clients:

International Centre for Genetic Engineering and Biotechnology, Manipal Institute of Virology, Bristol Myers Squibb, Amgen, Herbalife, Zoetis, GlaxoSmithKline, and Baxter International are some of the clients of Syngene.

Last Year Turnover: Syngene's annual Revenue for 2022 was USD 327.82 Million.

Key Developments:

Syngene International Limited signed a 10-year agreement with leading animal health company, Zoetis, to manufacture the drug substance for Librela® (bedinvetmab), a first-in-class monoclonal antibody used for treating osteoarthritis in dogs. Launched in Europe, UK and Switzerland, the product won 'Best new companion animal product' by IHS Market Connect in 2021 for its transformational impact on pain relief for canines suffering from this debilitating condition.

Unique Selling Points:

Syngene is contract research, development and manufacturing organisation offering integrated scientific services from early discovery to commercial supply. It offers clients focussed customised, end-to-end solutions to fulfil their R&D and manufacturing requirements. well-established safety framework, a track record of quality and compliance, and a robust supply chain.

Ethicare Clinical Trial Services

Year Of Establishment: 2009

Location:

Head Office: Ethicare Clinical Trial Services - Ahmedabad, Gujarat

Branch Offices: White House Station, New Jersey USA

Service Portfolio:

Clinical Trial Management, Medical Writing, Quality Assurance, Biostatistics, Feasibility, Project Management, Medical Services, Pharmacovigilance, Clinical Monitoring, Regulatory Consulting & Guidance, Clinical Data Management are some of the services provided by Ethicare.

Management Team:

- Dr Milan Satia - President and CEO
- Mr Raxesh Satia - CFO

Prominent Collaborations:
Bonyf AG, HLL Lifecare Limited, Renew Bioscience LLC, HLL Lifecare Limited, Pharma Base SA, Mankind Pharma Limited, Zim Laboratories Limited, Lincoln Pharmaceuticals Ltd, Inventia Healthcare Private Limited, Lyka Labs Limited,

Last Year's Turnover: Ethicare's annual revenue for 2022 was USD 8 Million.

Key Development:

- Ethicare clinical trial services exhibited at Meridian Clinical Trials 2023 - Continuum Globe Ltd
- Ethicare clinical trial services has arranged a workshop for US FDA Inspection Expectation
- Ethicare exhibited at ACE clinical trials Summit 2023 - ACE EXPO Ltd on 02-03 March 2023.

Unique Selling Points:

Ethicare supports local and global projects of all types and phases for the pharmaceutical, biotechnology, Nutraceutical and medical device industries. Services include end to end Study Planning and its Management, Clinical Monitoring, Medical Writing, Pharmacovigilance (including post marketing safety), Data Management, Biostatistics, and Electronic publishing.

Ethicare's skilled professionals operate nationally within India and internationally through collaborative approaches and will benefit your projects by applying high-level of expertise, state-of-the-art industry best practices and thorough knowledge of regulatory requirements.

Ethicare support investigators and sponsors both in every aspect of protocol development, contract execution, and trial maintenance.

Raptim Research

Year Of Establishment: 2005

Location:

Corporate Office: Navi Mumbai, Maharashtra

Registered Office: Gandhinagar, Gujarat

International Office: Skillman, New Jersey

Service Portfolio:

- **BA/BE studies**: Healthy Subject (Bioequivalence & Bioavailability) Studies, Patient Based Studies
- **In-vitro Studies:** In-Vitro Release Rate Test (IVRT) & In-Vitro Permeability Test (IVPT), In-vitro Binding Studies, Bcs Biowaiver Studies, In-Vitro Feeding Tube Studies.
- **Special Studies:** In-vivo Tape Stripping, In-Vivo Dermal Microdialysis, Skin Blanching Studies, Skin Irritation and Sensitization Test, Glucose Clamp Studies
- **Clinical Trials Management**: Early Phase Clinical Trials, Phase II-IV Clinical Trial & Post Marketing Studies

Management Team:

- Dr Rajen Shah (Founder and Director)
- Mr Viraj Shah (Founder and Director)
- Dr Chirag Shah (Head - Clinical Operations)
- Dr Milind Bagul (Head - Analytical Services)
- Mrs Usha Ramakrishnan (Head - Quality Assurance)

Prominent Clients:
Cipla Ltd, Annora Pharma Pvt Ltd, Sun Pharma Laboratories and Intas Pharmaceuticals are some of the prominent clients.

Last Year Turnover: Raptim's annual revenue in 2022 was USD 18 Million.

Key Development:

- Raptim has successfully secured approval for BCS Biowaiver studies (USFDA-approved Studies: Cevimeline, Amitriptyline, Doxepin; EU Approved studies: Varenicline, Health Canada: Buspirone)
- Also cleared a US Food and Drug Administration inspection scope that includes both in-vitro (IVRT/IVPT) & BE studies for the best quality for their customers.

Unique Selling Points:
Raptim applies innovative tools and processes to our clinical development and supports end-to-end services under the Clinical Research domain for all Global Pharmaceutical companies. With experience and enhanced capabilities, we are in a unique position to assist our Sponsors with unparalleled support and provide them a single, global research network.

Dabur Research Foundation

(Althea DRF Life Sciences)

Year of establishment :1979

Location:
Sahibabad, Ghaziabad, Uttar Pradesh, India

Service Portfolio:
Drug discovery & development, Regulatory Packages, Animal Free cosmetic Testing, Formulation & Development, Process development & Scale up, Crop Care/ Agrochemical, Biocides, Consulting & Collaboration

Management Team:

- Dr. Manu Jaggi (Chief Operating officer)
- Atul Kapil (Deputy Manager-Finance and Accounts)
- Shruti Bhatia (Human Resources Executive)
- Preeti Shukla (Head of Regulatory Affairs)
- Kishan Rawat (Assistant officer IT)
- Arvind Tiwari (Head of Department)

Prominent Clients: CIDP biotech, Indian Government's research Institutes are clients of the organisation.

Last Year Turnover: Dabur Research Foundation's annual revenue for 2022 was USD 40 million.

Key Development:

- Bengaluru-based Khoday Group of Industries in collaboration with Althea DRF Life Sciences has rolled out a first-of-its-kind Ayurvedic Immuno-modulator 'ViraNorm,' which helps in the speedy recovery of Covid patients, approved by the Union Ministry of AYUSH (Ayurveda, Yoga, Naturopathy, Unani, Sidda, Sowa-Rigpa and Homeopathy) as per its Clinical Trials Registry-India (CTRI) guidelines.
- Dabur Research Foundation™ and Flowerkist Incorporated™ Co-Developed and Launched a Wide Range of CBD Infused Topical Therapeutic and Age Management Products.
- Dr. Deepak Chopra Aligns with Plant-Based Therapeutics Company ProVEDA to Highlight Topical Pain Relief Solutions. Dabur utilises artificial intelligence to select key Ayurvedic plant-based ingredients to blend with THC-free hemp-derived CBD.

Unique Selling Points:

Drug Discovery and Development, ranging from identification of potential lead molecules, drug development to IND enabling studies. DRF offers preclinical services to global Biotech, Pharma, Phytopharmaceuticals Cosmeceuticals and academia sectors. Their services broadly fall into the functional areas of In Vitro, Ex-Vivo & In Vivo Pharmacology, Exploratory & GLP Toxicology & DMPK.

Axis Clinical Research

Year Of Establishment: 2004

Location:
Corporate Office:
Axis Clinicals Limited, Hyderabad, Telangana
International Office: Axis Clinicals LLC, Dilworth, Minnesota

Service Portfolio: BA/BE studies, PK/PD and Patient Studies, Bio-analytical Services, Clinical trial Phase II-IV, Project Management, PK/Biostatistics & Programming, Medical Writing, Regulatory Services, Quality Assurance and Compliance, Clinical Data Management and Clinical Central Lab.

Management Team:

- B. Phani Bhushana Reddy (Executive Director)
- Dr A. Jayachandra Reddy (Executive Director)
- Dr Subhra Lahiri (VP- Clinical Research)
- Abhijit Chaudhari (VP - Business Development)
- Dr Nirav R. Shah (AVP & Head Operations - Ahmedabad)
- Dr Rajani Kumar (AVP, Bioanalytical)
- Dr Ravinder Sreedasyam (General Manager - Quality Assurances)
- Dr Nagaraj Kumar N (General Manager - Pharmacokinetics and Biostatistics)
- Dr Someswara Rao (Sr General Manager - Pharmacokinetics and Biostatistics)

Prominent Clients and Collaborations: Novartis, Pfizer, GlaxoSmithKline, Eli Lilly, QuintilesIMS, Covance, Parexel, ICON, Harvard University, Stanford University, University of Oxford, Food and Drug Administration, National Institute of Health and European Medicine Agency.

Last Year Turnover: Axis Clinicals' annual revenue for 2022 was USD 105 Million.

Key Development:

- Axis is supporting clinical research for NDA, 505(b)(2) Pharmacology Enabling Clinical Projects Ophthalmology, Oncology, Dermatology & Others Encompassing full-service CRO support Phase 1 Early-Stage Capabilities.
- Axis Clinicals have received ERT certification, a certificate program that ensures sites are proficient in collecting the highest quality ECG data.
- Axis Clinicals Dilworth, MN has expanded its US clinical site with the addition of 45 hospital beds, offering the flexibility of 225 total beds in four clinical units and one outpatient unit.

Unique Selling Points:

Axis Clinicals Provides comprehensive end-to-end clinical research services to the global innovator, biotech, and generic pharmaceutical industries. With a commitment to excellence, our experienced team of 1500+ professionals utilises cutting-edge technology and innovative solutions to provide a full spectrum of clinical trial solutions spanning from preclinical research to post-marketing studies.

Lambda Therapeutics Research Limited

Year Of Establishment: 1999

Location:
Corporate Office: Lambda House, Ahmedabad, Gujarat
Novum Corporate office: Pittsburgh, USA

Service Portfolio:
Bioanalytical, BA/BE, Clinical trial Phase I-II & IV, Scientific Affairs, Pharmacovigilance, Medical & Scientific Writing, Central Clinical Lab, Medical Imaging, LAB (Lambda Advisory Board) and Late Phase clinical trial.

Management Team:

- Bindi Chudgar (Founder and Management director)
- Dr Tousif Monif (President - Global Operations)
- Dr Mrinal Kammili (Executive Director & Global Head - Business Development)
- Dr Prashant Kale (Senior Vice President - India BA/BE Operations)
- Dr Nirav Gandhi (Senior Vice President - India Operations [CTM, CDM, PV, MA & Imaging)
- Manmeet Singh (Vice President - Information Technology)
- Naresh Khemani (Head of Finance & purchase)

Prominent Clients: Inox Air Product, and Medidata are the prominent collaborators of Lambda therapeutics.

Key Development:

- Lambda Therapeutic Research Ltd acquired US-based Novum Pharmaceutical Research Services in 2019. Lambda Therapeutics Research partners with Medidata to automate and streamline data management processes for greater clinical trial efficiency
- Lambda Therapeutic Research successfully clears another European Medicines Agency (EMA) Inspection for two PK studies in Oncology on Metastatic Breast Cancer and Ovarian Cancer patients

Unique Selling Points:

Lambda Therapeutics Provides comprehensive end-to-end clinical research services to the global innovator, biotech, and generic pharmaceutical industries. With a commitment to excellence, our experienced team of 1500+ professionals utilises cutting-edge technology and innovative solutions to provide a full spectrum of clinical trial solutions spanning from preclinical research to post-marketing studies.

Siro Clinpharm

Year Of Establishment: 1996

Location:
Corporate Office: SIRO Clinpharm Pvt Ltd, Thane, Maharashtra
Registered Office: SIRO Hyderabad, Gachibowli, Hyderabad
International Office:

- SIRO Clinpharm, Overlook Center, Princeton, New Jersey
- SIRO Clinpharm, Alexander Road, Princeton, New Jersey

Service Portfolio:

- Clinical Operations
- Medical Writing: Regulatory Medical Writing, Real World Outcomes, Transparency, Narratives, Publications, Drug Safety and Risk Management
- Biostatistics
- Data management
- Clinical Trial Supplies

Management Team:

- Mr Akshay Daftary (Director - Global Business development, Client Management)
- Mr Karan Daftary (Director - Finance, Human resource, Quality Assurance, IT, Legal and Corporate Marketing)
- Dr Vatsal Shah (Global Chief Operating Officer and Country Head-USA)
- Mr Rahul Srivastava (President - Strategy and Process Improvement)
- Dr Ganesh Divekar (Vice President - Clinical Operations and Biometrics)

Prominent Clients: Large Pharmaceutical companies from USA, Europe and Japan.

Last Year's Turnover: SIRO clinpharm's annual revenue for 2022 was USD 31 million.

Key Development:

- The application of Oracle Health Sciences InForm enables SIRO to automate and streamline solutions for the global biopharma and medical devices companies in their clinical development process across therapeutic areas and phases.
- SIRO Clinpharm launches SIRO Clinical Research Institute (SCRI) to create CRO-industry ready professionals.
- 5th April 2021: SIRO Clinpharm, became a partner of ACROSS Global Alliance (ACROSS) and will help represent India in working towards the common goals and objectives of ACROSS in bridging a gap in the pharmaceutical service provider market.

Unique Selling Points:

Clinical Research Organisation supporting trials from Phase II to Phase IV and beyond post-launch of products. SIRO offers a range of services, from clinical operations to data services, data analytics and medical writing in compliance with international standards.

Syneos Health

Year Of Establishment: 1998

Locations: Corporate Office:

Morrisville, North Carolina, USA

North America: North Carolina, Florida, Quebec, New York, Pennsylvania, New Jersey, Quebec, California, South San Francisco, Ontario, Ohio. **Latin America**: Colombia, Argentina, Mexico

Europe: Netherlands, Spain, Serbia, Romania, Hungary, United Kingdom, Turkey, Ukraine, United Kingdom, Italy, Russia, Germany, France, Czech Republic, Sweden, Greece, Poland, Zurich, Switzerland

Middle East: Israel, Lebanon **Africa**: Egypt, South Africa **Asia Pacific:** Thailand, Beijing, Dalian, Gurugram-India, Hongkong, Indonesia, Malaysia, Japan, Philippines, Salem-India; Seoul-South Korea; Shanghai, Singapore, Tokyo, Japan

Service Portfolio:

- Clinical development: Bioanalytical Solutions, Early Phase, Phase II-IV (Phase II-III, Phase IIIb-IV, Site Startup, Biostatistics and statistical Programming, Clinical Data Management, Clinical Monitoring, Medical Writing, TMF Operations, Investigator management solutions), Real world and late phase, Decentralised Solution, Site and Patient Access, FSP 360
- Full-service Development, full-service commercialization, Global risk Management and Full-service REMS, Non-Core Asset Development

Management Team:

- Michelle Keefe (Chief Executive Officer)
- Michael Brooks (Chief Operating Officer)

Prominent Collaborations: Microsoft, FivepHusion, ConcertAI, MIMS, Janssen, Equicare, Medable, are some prominent collaborators of Syneos Health.

Last Year Turnover: Syneos Health's annual revenue for 2022 was USD 5393.1 Million.

Key Developments:

- Syneos Health® and uMotif will partner on an eClinical platform, with uMotif providing integrated eCOA and ePRO capabilities, which will build upon Syneos Health's StudyKIK recruitment technology platform.
- FivepHusion, an advanced clinical-stage biotechnology company, announced its collaboration with Treehill Partners and Syneos Health.

Unique Selling Points:

A leading fully integrated biopharmaceutical solutions organisation, to develop and bring a novel, enhanced chemotherapeutic product to market. They translate unique clinical, medical affairs and commercial insights into outcomes to address modern market realities. Together they share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. They support a diverse, equitable and inclusive culture.

IQVIA

Year Of Establishment: 1982

Location: North America: Canada, United States
Asia and Oceania: Asia Pacific, Australia and New Zealand, China, India, Indonesia, Japan, Korea, Malaysia, Pakistan, Philippines, Republic of Kazakhstan, Singapore, Sri Lanka, Thailand, Vietnam

Europe: Adriatic, Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland and Italy

Latin America: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Paraguay, Peru, Uruguay and Venezuela

Middle East and Africa: Algeria, Egypt, Ghana, Israel, Jordan, Kenya, Kuwait, Lebanon, Nigeria, Palestine Territory, South Africa, Tunisia and UAE

Service Portfolio:

Research and Development: Clinical Trials, Functional Services, Decentralised Trials, Consulting, Therapeutic expertise, site and Investigators
Real World Evidence: Real World Data Sets, Medical Affairs, Health Data Transformation, Study Design, Platforms, Evidence Networks, Health Economics and Value, Regulatory and Safety, Genomics.
Technologies: Orchestrated Clinical Trials, Enterprise Information Management, Performance Management & Insights, Provider Reference Data Network, Customer Engagement, Safety, Regulatory, Quality Compliance, Developer, Partner Programs, Technology Insights

Management Team:

- Ari Bousbib (Chairman and Chief Executive Officer)
- Ron Bruehlman (Executive vice President and Chief financial officer)

Prominent Collaborations: Pfizer, Novartis, Johnson and Johnson, Roche, Gilead Sciences, Biogen, Moderna, Mayo Clinic, Cleverland, Kaiser Permanente, UnitedHealth Group, CVS Health, Anthem, UNIH, Harvard Medical School, Stanford University and the University of Cambridge.

Last Year's Turnover: IQVIA's annual revenue for 2022 was USD 14,410 Million.

Key Developments:

- IQVIA Wins Prestigious "Best AI-based Solution for Healthcare" Award in 2023 Artificial Intelligence Breakthrough Awards
- IQVIA Launches RIM Smart Labelling to Deliver Intelligence-Driven Approach for Global Label Management

Unique Selling Points:

IQVIA delivers on its mission by helping to speed drug development, ensuring product quality and safety, improving commercial effectiveness, getting the right treatments to patients, improving access and delivery of healthcare, and ultimately driving better health outcomes. And always strive to be extraordinary – every step of the way. With IQVIA Connected Intelligence™ they achieve powerful results by connecting unparalleled data, advanced analytics, innovative technologies, and deep healthcare and scientific expertise. This enables a highly customised approach to address unique challenges.

INSIGHTS & RECOMMENDATIONS

11. INSIGHTS & RECOMMENDATIONS:

Promoting and building up the CRO sector in India requires a strategic approach involving collaboration between the government, industry, academia and general public. The CRO sector plays a crucial role in drug development, and strengthening it can contribute to India's position as a global hub for pharmaceutical research rather than just a manufacturer of affordable generic drugs. A growing CRO market will help India move up the value chain. On the basis of this short-term study below are the BHPL'S recommendations to help the CRO market thrive in India:

1. **Create dedicated CRO clusters in Government funded Drug and Medical Device Parks**
   Department of Pharmaceuticals, Government of India has already got a mandate to establish four medical devices parks in the country. In addition, various new bulk drug parks are also going to be set up in a period of few years from now. All these government funded research parks should have dedicated space for the CROs operating within their boundaries and theses CROs should be given incentives like concessional tax rates, export subsidy and other subsidised service rates for availing the common services. The Government further needs to bring together CROs, academic institutions, and Sponsors of contract research. These CROs clusters can foster collaboration, knowledge exchange, and collaborative resource sharing.

2. **Global positioning of India as destination for Drug Discovery and Development**:
   The government should take marketing initiatives to position and market India as a preferred destination for pharmaceutical discovery, preclinical and clinical research. India has a growing CRO sector, benefiting from its medical and scientific skilled workforce, best in class research and development centres, hospitals, cost efficiency and a large patient population across various therapeutic areas. Like the US, India also has one of the largest pharmaceutical markets globally, with a high demand for innovative drugs and therapies. The country's rising middle class, increasing healthcare expenditure, and aging population have created a significant demand for such innovative drugs and therapies. Therefore, instead of being only a market for the global pharmaceutical companies, the focus should be to create sizable opportunities for CROs to partner with global pharmaceutical companies in the field of early discovery, preclinical and clinical research.

3. **Tax Incentives on Drug Discovery and Development for Pharmaceutical companies:**
   Pharmaceutical innovation is risky and capital intensive. Indian pharmaceutical companies which primarily comprise of generic companies have limited risk appetite and therefore have very limited research and development budgets. Top ten global pharmaceutical companies on the other hand spend about 18.56 % of their annual revenues on new research and development. As per existing taxation regime of India, global companies working with Indian CROs do not have to pay the goods and service tax (GST) on the CRO services as the services offered by CROs are considered to be for export purpose. However, if Indian pharmaceutical companies have to outsource any services to Indian CROs, they have to pay the GST@18%. This creates an uneven playfield for the pharmaceutical companies of Indian origin. In order to promote the domestic CRO sector, the government can think on exempting the CROs services from GST. This will reduce the R& D associated financial burden on the pharmaceutical companies making more funds available for CROs.

4. **Investment in Research Infrastructure**: In order to attract Foreign Direct Investment (FDI) into the CRO sector, the policy makers need to create a business-friendly environment for the pharmaceutical companies. The US and European countries have a robust investment ecosystem, with venture capital firms and government agencies providing substantial funding for biotech and pharmaceutical research. This availability of ample capital for pharmaceutical sector supports the growth of contract research organisations in these regions. The Indian government needs to invest in state-of-the-art common research infrastructure, including shared specialised laboratories, advanced equipment and research centres focused on early drug discovery and clinical trial facilities. The government needs to allocate significant resources to support pharmaceutical research and development. This research infrastructure should be available for the private CROs on "pay as use" basis. Further there is need of large-scale funding of academic institutions like NIPERs and promotion of public-private partnerships focused on drug discovery and development. This will attract both domestic and international pharmaceutical companies to conduct research in India, ultimately giving a push to the CRO industry.

5. **Commercialisation of the Government Funded Research infrastructure:** The pharmaceutical sector is capital intensive and technology changes outpace most of the government research investments. The government agencies should be very careful in investing into new technologies and do a proper pay-back period analysis before investing into any new technology, equipment or infrastructure because of its limited usage in academic and research settings. Inspite of this, the Indian government needs to invest in state-of-the-art common research infrastructure, including specialised laboratories, advanced equipment, and research centres focused on early drug discovery and clinical trial facilities. To ensure adequate return on the investments this research infrastructure should be made available for the private pharmaceutical companies and the CROs on "pay as use" basis. It is important to note that to make government funded research infrastructure profit making, productive and efficient, it should be professionally managed by independent agencies. This will ensure that the potential CROs and Pharmaceutical companies are not struck in the maze of rules and regulations set out by the government research institutions.

6. **Regulatory Support and streamlining:** Most of the regulated markets like US, Europe, Australia and Japan have a well-defined and stable regulatory environment for clinical trials and drug development. The Food and Drug Administration (FDA) sets clear guidelines for drug testing and approval, providing a streamlined process for conducting clinical trials and bringing new drugs to market. This predictability is appealing to pharmaceutical companies seeking CRO services. The Indian government also needs to further streamline the regulatory approval process for early-stage research projects to reduce timelines and bureaucratic hurdles which will attract more pharmaceutical and biopharmaceutical companies to conduct research in India. Post 2014, there have been important regulatory reforms in Indian Pharmaceutical and CRO sector which have simplified and expedited the regulatory approval process for clinical trials and bioequivalence studies while ensuring that ethical considerations are not compromised at any level. An efficient ethics approval registration and approval system has also been implemented in India. More regulatory clarity on the regulatory processes and creating a conducive regulatory environment for clinical research is the need of hour.

7. **Research Grants and Funding Support to Private Sector companies:** Currently the most of the research grants from the government bodies like Department of Science and Technology (DST), Indian Council of Medical Research (ICMR), Department of Pharmaceuticals etc are only available for the government research institutions and academic centres. However, Department of Biotechnology has few schemes under which it provides the research funding in the form of

grants and soft loans to multiple innovative private companies and startups working in the field of medical devices and healthcare products. Department of Pharma should have similar provisions for research grants, financial incentives, and funding support to encourage the domestic CROs working in the field of early discovery and clinical research in India.

8. **Skill Development and Training of manpower:** A thriving CRO sector can drive economic growth, create job opportunities, and enhance India's global reputation in the field of contract research. Government agencies including the Department of Pharmaceuticals, Department of Science and Technology, Department of Biotechnology, Indian council of Medical Research need to collaborate and establish specialized interdisciplinary training programs in institutes like NIPERs to develop a skilled workforce in early drug discovery and research conducting high-quality clinical trials. Training should not only cover fundamental courses related to pharmaceutical industry but should also include courses related to Good Laboratory Practices, Good Manufacturing Practices, Good Clinical Practices, Good Documentation Practices, Bioinformatics, High-throughput screening, Next Generation Sequencing, Artificial intelligence, Machine learning and Biomedical research.

9. **Academic and Industry Collaborations:** The government should facilitate collaborations between academic institutions and pharmaceutical/biotech companies to work on early-stage drug discovery projects. Such partnerships can leverage academic expertise and industry resources to accelerate research. A conducive and supportive research eco-system needs to developed and nurtured by government to encourage technology transfer and licensing agreements between research institutions and CROs. This enables CROs to access and commercialize innovative discoveries from academia.

10. **Intellectual Property Protection:** Intellectual property protection is crucial for pharmaceutical research, as it ensures that companies' innovations are safeguarded. The US has strong intellectual property laws, providing more confidence to companies investing in research and development. Historically, India has faced concerns over intellectual property protection, in recent past but the country has taken steps to improve this aspect. Strengthen intellectual property protection laws to safeguard innovative discoveries made during early discovery research. Robust IP protection encourages companies to invest in research without fear of intellectual property theft. Strengthen intellectual property protection laws to safeguard pharmaceutical innovations.

11. **Patient Data Privacy and Protection:** Strengthening the patient data privacy and protection laws to assure confidentiality and security for patient data involved in clinical trials will enhance trust and confidence among companies conducting research in India. The Indian data privacy laws need to be synced and harmonised with the internationally accepted norms so as to build the confidence among the sponsors conducting clinical trials in India.

12. **International Collaborations for Regulatory Harmonization**: In recent times India has emerged as a torchbearer of international diplomacy. The CRO sector operates across multiple countries and regions, each with each region/country having its regulatory requirements and processes. Improved regulatory harmonization and mutual acceptance of accreditations/certifications would create a more standardized and efficient environment for conducting global clinical trials. This would reduce duplication of efforts and streamline the approval process, facilitating faster drug development and commercialization. Data standardization and sharing are crucial for enhancing collaboration and data exchange among CROs, pharmaceutical companies, and regulatory authorities. The adoption of common data standards would enable seamless integration of data from multiple sources and promote more extensive analysis and insights. The

Government needs to use it diplomatic relationships to foster collaborations between Indian CROs and international pharmaceutical companies or research organizations. Such partnerships can bring in advanced research projects and increase global exposure for Indian CROs. The similar diplomatic relationships should be utilised for collaboration among the various regulatory agencies and mutual acceptance of the data across the cooperating countries. This would reduce duplication of efforts and streamline the approval process, facilitating faster drug development and commercialisation.

13. **Explore the Tier 2 and Tier 3 cities for clinical development**: CROs need to realign the patient recruitment and retention strategies and focus more on the tier-2 cities where large untapped patient population across the various therapy areas is available. CROs may have to invest into training of the investigators and the paramedical staff of such sites on ICH-GCP.

14. **Quality and Compliance Standards:** There have been few cases related to data integrity and patient's rights violations in recent past in India. However, most of the CROs are quality conscious and have international certifications, recognitions and approvals for conduct the contract research. The CROs need to re-calibrate their quality management systems and further emphasize on adherence to international quality and compliance standards in contract research. Meeting global quality benchmarks will enhance the credibility and reliability of research conducted in India and will help the brand India image.

15. **Patient Participation and Engagement:** The Clinical CRO industry needs to involve patient advocacy groups, regulators and healthcare professionals in order to build a trust. The CROs should take initiatives to encourage patient participation and engagement in clinical trials through awareness campaigns and community outreach programs and educate patients about the importance of clinical research and its impact on public health. Such initiatives can help promote accurate information and dispel myths surrounding clinical trials among the clinical trial participants.

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