AVENTIQ BIO

Mitigate Risk. Accelerate Success.

INDIA CRO/CDMO MARKET INTELLIGENCE

SUMMARY

The document explains the CRO and CDMO outsourcing markets, their role in drug development, and why India is an important hub. It also provides market size estimates for the global and Indian CRO/CDMO segments, along with the main growth drivers, including rising R&D, complex therapies, cost pressure, and regulatory needs.

It highlights that both the global and Indian markets are growing, with India showing strong potential due to its skilled workforce, patient pool, and cost advantage. Oncology is the leading therapeutic area, while other important areas include infectious diseases and metabolic disorders.

Yet, despite India's strengths, global companies repeatedly face execution barriers in the region not due to scientific gaps, but due to governance blind spots, inconsistent oversight, regulatory misalignment, and variable vendor maturity.

1. Definition and Scope

Contract Research Organisations (CROs) offer preclinical, clinical, and regulatory management services, while Contract Development and Manufacturing Organisations (CDMOs) offer formulation, scale-up, and manufacturing services. The two services, integrated, are provided by Contract Research, Development and Manufacturing Organisations (CRDMOs) [1]. They are crucial for the pharmaceutical industry, as they help accelerate development, ensure regulatory compliance, and manage manufacturing capacity without increasing costs by purchasing new facilities and equipment or hiring additional personnel [2]. These organisations provide facilities ranging from generics and small molecules to complex modalities such as biosimilars, monoclonal antibodies, antibody-drug conjugates, vaccines, cell and gene therapy, and precision medicine [3].

Fig 1: CRO Value Chain

Fig 2: CDMO Value Chain

2. Market Overview

3.1 CRO Market

The global CRO market was valued at 69.56 billion USD in 2025, while the Indian market was valued at 6.74 billion USD. The markets are expected to grow to 133.75 and 12.00 billion USD by 2035, at rates of 6.76% and 6%, respectively [4,5].

Fig 3: The Indian and Global CRO Market Size

3.1.1 Factors Influencing the CRO Market

Increasing Research and Development Activities – As research and development by pharmaceutical and biotech firms increases, the demand for pre-clinical, regulatory and clinical services also rises, thus expanding the CRO market.

Growing Patient Population – Globally, the incidence of chronic diseases is rising, creating a need for clinical trials across multiple healthcare areas. The CROs utilise these growing numbers to deliver wider services, including complex healthcare needs.

Increasing Drug Development Complexity – The market demands specialised CROs to handle complex trials for advanced therapies and personalised treatments, which require new regulatory standards to advance the industry [4].

As companies' demand for outsourcing services grows, India remains a strong market thanks to its skilled workforce for specialised services, a large patient population, and standards that meet global regulatory requirements.

3.1.2 Therapeutic Area

In the Indian CRO market, oncology leads by therapeutic area, followed by infectious diseases. Oncology encompasses a wide variety of cancer types, and its growth is driven by the increasing use of targeted therapies. The Metabolic Disorders sector, which includes conditions like diabetes and obesity, is also expected to grow, particularly due to the expanding

market for GLP-1 analogues. Other notable areas include ophthalmology, respiratory health, and dermatology.

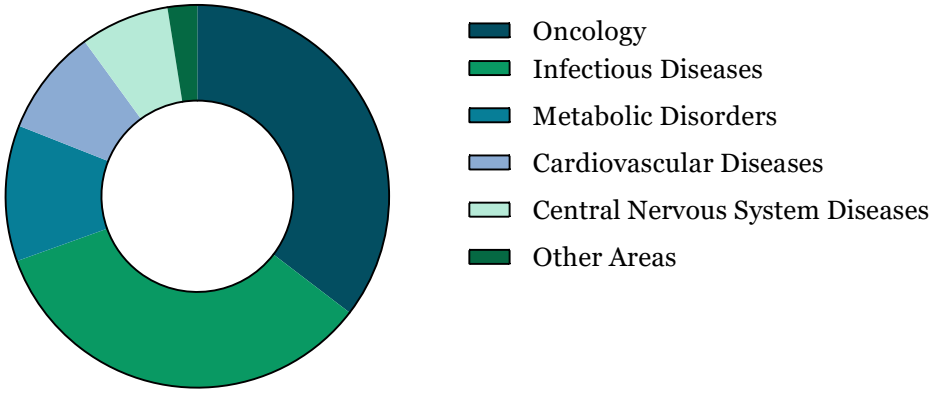

Fig 4: Indian CRO Market by Therapeutic Area

3.2 CDMO Market

The global pharmaceutical CDMO market size was valued at USD 197.40 billion in 2025 and is projected to reach approximately USD 392.67 billion by 2035, expanding at a CAGR of 7.12% [6]. The Indian CDMO market was valued at USD 25.51 billion in 2025 and is expected to grow at a CAGR of 10.80% to reach USD 71.14 billion by 2035 [7].

Fig 4: The Indian and Global CDMO Market Size

3.2.1 Growth of CDMO Market

• High costs associated with drug development encourage pharmaceutical companies to seek cost-effective solutions. However, services offered by CDMOs help reduce costs incurred in the drug development process.

• CDMOs are adept at navigating regulatory environments, encouraging pharmaceutical and biotechnology companies to collaborate with them to ensure compliance.

India's robust capabilities in developing and manufacturing complex generics, biosimilars, antibody-drug conjugates and other complex modalities attract global pharmaceutical companies seeking cost-effective drug development through the CDMO structure. Similar to the CRO structure, oncology dominates the Indian market even in the CDMO structure.

3. Why India – Now More than Ever?

India has evolved from a generics' powerhouse into a globally competitive ecosystem spanning:

- Complex Biologics
- Monoclonal Antibodies
- Antibody-Drug Conjugates
- Cell & Gene Therapy
- HPAPI Manufacturing
- Biosimilars
- Precision Medicine
- Vaccines

The combination of cost advantage, scientific skill, and regulatory-aligned facilities has positioned India as a preferred destination for outsourcing across preclinical, clinical, CMC, and manufacturing workflows.

Yet increased opportunity brings increased operational complexity.

As global companies scale their presence in India, the need for independent, vendor-neutral governance has become a critical success factor.

4. India's Opportunity: Why Global Companies Choose Indian CRO/CDMOs

- **Cost Advantage-**
  It is the top reason for outsourcing to India:
  - 30–60% lower cost than Western markets
  - Substantial savings in labor-intensive workflows
  - Reduced capital investment need
- **Modality Breadth-**
  India is one of the only regions offering such broad modality coverage — from small molecules to CAR-T support.
- **Talent Depth-**
  Large pool of scientists, chemists, analytical experts, quality professionals, and regulatory specialists.
- **Regulatory Alignment-**
  Many Indian sites now hold approvals from: USFDA, EMA, MHRA, PMDA, WHO, TGA
- **Scalability-**
  India can rapidly add capacity often faster than Western markets.

5. The Hidden Challenges: Why Outsourcing to India Fails

Despite India's ecosystem maturity, global companies consistently face execution challenges that derail timelines, increase costs, and compromise regulatory submissions.

- **Vendor-Reported Data vs. Ground Reality-**
  Vendors often curate data for upward reporting. Independent verification is rarely built into contracts. While vendors (CDMOs/CROs) often market end-to-end capabilities and high-tech efficiencies, the reality on the ground often involves fragmented systems, communication hurdles, and critical capacity constraints.

- **Execution Drift During Critical Phases-**
  CMC, analytical validation, tech-transfer, and GMP batches are high-risk phases where oversight gaps produce:
  - Deviations that go unreported
  - Changes to methods without sponsor visibility
  - Underpowered qc review
  - Poor batch documentation quality
- **Misalignment with FDA/EMA Expectations-**
  Vendors follow operational SOPs — not global agency expectations for:
  - Data integrity
  - Batch records
  - Change control
  - Analytical rigor
  - Chain of custody
- **High Vendor Variability-**
  India has over 600+ CRO/CDMO providers with maturity levels that vary widely. Different vendors exhibit significant inconsistencies in service quality, technical expertise, speed, and regulatory compliance. This variability makes vendor selection a critical, high-risk strategic decision for pharmaceutical and biotech companies, often leading to fragmented accountability and project delays.
- **Lack of Technical Stewardship-**
  Global sponsors lack an on-ground, technically competent representative acting as their fiduciary. They have to trust sales-aligned pitches from companies without on-the-ground knowledge.

This creates a governance gap, often leading to:

- Batch failures
- Regulatory findings
- Revalidations
- IND delays
- Contract renegotiation costs
- Program resets

6. Aventiq Bio Governance Insight: The Outsourcing Risk Model

Aventiq Bio's on-ground experience inside Indian CRO/CDMOs reveals a predictable pattern of failure points:

- It identifies the **early-stage** risks**,** be it overpromising timelines or execution capability.
- **Mid-stage** operational risks include undocumented changes, slow CAPA responses, and a lack of statistical rigour, which cannot be tracked without on-ground reality, which Aventiq Bio provides.
- OOS/OOT management problems, non-compliance issues, and regulatory unpreparedness occur during **late-stage** project completion, but the continuous monitoring by Aventiq Bio helps mitigate them.

7. Aventiq Bio's Independent Governance Framework

- **Vendor-Neutral Positioning-**
  Aventiq Bio doesn't take commissions from vendors or operate any labs of its own, ensuring there is no conflict of interest and your decisions remain defensible.
- **Governance Audit-**
  Before the project starts, Aventiq Bio hands you a comprehensive review of the CRO/CDMO that provides:
  - Vendor readiness
  - Data integrity assessment
  - Regulatory alignment
  - Risk map
  - Mitigation plan

- **Continuous Intelligence™ Retainer-**
  Aventiq Bio acts as your permanent eyes and ears on the ground, replacing one-shot audits. It provides you with:
  - Weekly dashboards
  - Deviation early-warning system

- On-ground checks
- Documentation oversight
- QC/QA alignment
- Escalation pathways

- **Program Governance-**
  Aventiq Bio provides end-to-end oversight across your project, be it CMC, Method Development, Tech Transfer, Scale-Up, GMP batches, Pre-Approval Readiness

  Outcome: Zero-Surprise India Execution.

8. Strategic Recommendations for Global Biotech & Pharma

- **Treat India as a High-Potential, High-Governance Market**
  The opportunity to expand the base is strong, but governance must keep pace with the technical complexity.
- **Perform Independent Technical Due Diligence Before Contracting**
  Ensure proper audits and on-ground reality checks eliminate early alignment failures.
- **Implement Continuous Oversight, Not Episodic Audits**
  The cost of a deviation detected early is <5% of the cost of a late surprise. Continuous oversight will help you tackle mid-stage risks.
- **Establish Regulatory-Grade Documentation Expectations Upfront**
  Most delays originate from documentation, not science. Unorganised or non-compliant data hinders the approval process, causing delays; thus, it is important to ensure regulatory compliance throughout the project.
- **Use Vendor-Neutral Governance for Objectivity**
  Governance must be independent from execution. A vendor-neutral framework provides objectivity by separating the decision-making process from the vendor ecosystem, allowing organisations to select the best-of-breed solutions rather than being confined by vendor lock-in, proprietary restrictions, or supplier favouritism. Vendor-neutral systems make it possible for you to make decisions based entirely on the needs of your business.

9. Conclusion

India is becoming one of the most strategically important outsourcing hubs in the global life sciences economy. The next decade will see explosive growth across the CRO and CDMO segments as biopharma pipelines expand into more complex modalities.

However, alongside opportunity comes operational exposure. Without independent oversight, outsourcing becomes unpredictable and costly.

Aventiq Bio's governance framework provides the missing link — transforming India outsourcing from a risk to a strategic advantage.

To know more about our Governance Framework:

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