CLINICAL RESEARCH ORGANIZATION (CRO) MARKET REPORT

January 2022

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SCOPE OF THE REPORT

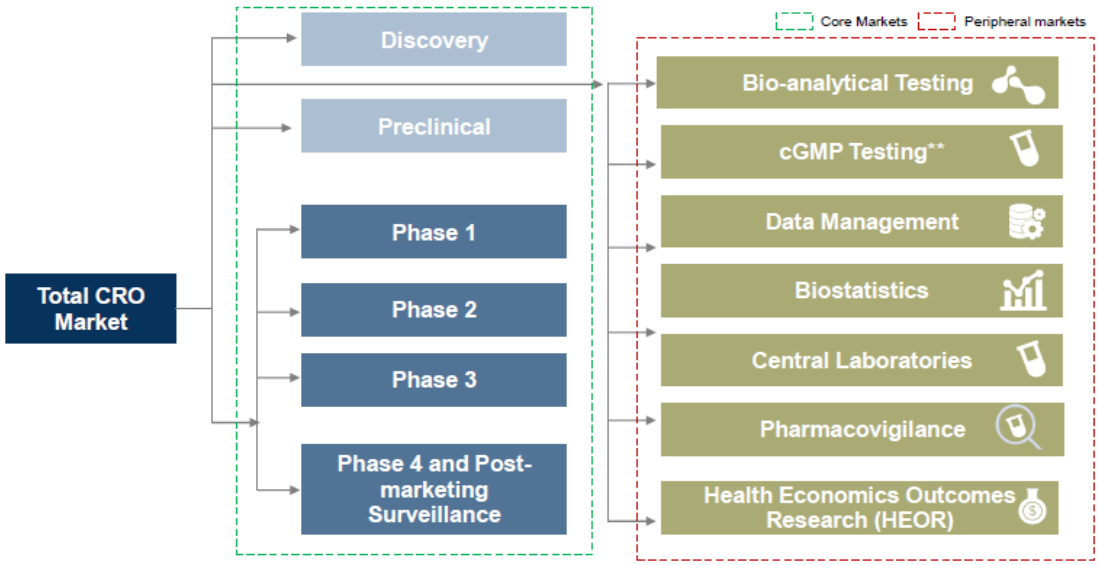
Regions and Countries

Following is the list of various geographic regions and countries included in the report:

US	EU	INDIA	ROW
USA	FRANCE	INDIA	BRAZIL
	ITALY		MEXICO
	GERMANY		KINGDOM OF SAUDI ARABIA (KSA)
	UNITED KINGDOM (UK)		
	SPAIN		

STUDY PERIOD: 2020 TO 2026
BASE YEAR: 2020
FORECAST PERIOD: 2021 TO 2026
MONETARY UNIT: US DOLLARS

This research service analyses the global CRO market which covers in-depth analysis of clinical phases (discovery, preclinical, phase I, II, III, IV) and BA/BE studies. A high-level overview of peripheral segments, covering HEOR, bio-analytical testing (ADME and PK/PD), cGMP, biostatistics, pharmacovigilance, data management and central labs, has been included.



Note: BA/BE, ADME and PK/PD studies are included under bio-analytical testing segment

ABBREVIATIONS AND DEFINITIONS

Abbreviation	Expansion
GDP	Gross Domestic Product
NBFC	Non-Banking Financial Companies
OPEC	Organization of the Petroleum Exporting Countries
BA	Bioavailability
PK	Pharmacokinetics
PD	Pharmacodynamics
BE	Bioequivalence
CMO	Contract Manufacturing Organization
CRO	Clinical Research Organization
cGMP	Current Good Manufacturing Practice
MCO	Managed Care Organization

Key Terms	Definitions
ADME Profiling	In vitro ADME profiling: Determination of chemical stability of compounds, passive absorption, GIT permeability, stability of drug candidates and determination of drug plasma protein binding In vivo ADME profiling: Quantitative determination of the distribution of compounds in organs and tissues of small rodents (mouse, rat) by LC-MS and qualitative determination of the distribution of compounds in organs and tissues of small rodents (mouse, rat) by Matrix Assisted Laser Desorption Ionization- Time of Flight Imaging (MALDI-TOF).
Anti-drug Antibodies	Anti-drug antibodies are commonly used for detection and quantification of therapeutic antibodies during the drug development process.
Bio-analytical Services	Bio-analysis is a sub-discipline of analytical chemistry covering the quantitative measurement of xenobiotics (drugs and their metabolites, and biological molecules in unnatural locations or concentrations) and biotics (macromolecules, proteins, DNA, large molecule drugs, metabolites) in biological systems.
Bio-analytical Testing	Bio-analytical testing helps determine the design implications, limitations, favorable conditions, and suitability of a drug for the intended treatment.
Bio-pharmaceutics	Biopharmaceutics is a major branch in pharmaceutical sciences which relates between the physicochemical properties of a drug in dosage form and the pharmacology, toxicology, or clinical response observed after its administration.
Bioassays	A bioassay is an analytical method to determine concentration or potency of a substance by its effect on living cells or tissues. Bioassays are quantitative biological assays used to estimate the potency of agents by observing their effects on living animals (in vivo) or tissue/cell culture systems (in vitro).
Bioavailability	Bioavailability refers to the extent a substance or drug becomes completely available to its intended biological destination. More accurately, bioavailability is a measure of the rate and fraction of the initial dose of a drug that successfully reaches either; the site of action or the bodily fluid domain from which the drug's intended targets have unimpeded access.
Bioequivalence	The property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity.
Biomarker Assays	Biomarkers assays are becoming increasingly important in clinical development. These assays can be used to aid the selection of a lead candidate and to understand the mechanism of action of a drug, as a surrogate / pharmacodynamics (PD) marker for monitoring clinical efficacy.
Biomarker Testing	Biomarker testing is a way to look for genes, proteins, and other substances (called biomarkers or tumor markers) that can provide information about cancer. Each person's cancer has a unique pattern of biomarkers. Some biomarkers affect how certain cancer

	treatments work. Biomarker testing may help the patient and the doctor choose a specific cancer treatment.
Biosimilars	A biosimilar is a biologic medical product (also known as biologic) highly similar to another already approved biological medicine (the 'reference medicine').
Clinical Research Organization	Clinical Research Organization is an organization contracted by a pharma, bio-pharma or a medical device company to take the lead in managing that company's trials and medical testing responsibilities. These organizations reduce the cost of research and development to help businesses and institutions meet the needs of the evolving pharma, bio-pharma and medical device industry. These studies also reduce time of drug development.
Early Phase Trials (Phase I, II)	Early phase, or phase I and phase II, trials are the first step in testing new medicines that have been developed in the lab. The people who take part in phase I and phase II trials may be amongst the first patients to be given a new treatment. The number of subjects involved in early phase trials range from 10 to 500.
Generic and Large Molecules	A generic drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. Chemical drugs are called small molecules while biologic drugs are termed as large molecules primarily because of the size of the molecule. Small molecule drugs are typically composed of only 20 to 100 atoms; while, biologics, such as hormones, are typically composed of 200 to 3000 atoms, and other biologics, such as antibodies, are typically composed of 5000 to 50,000 atoms.
Glucose clamp	Glucose clamp technique is a method for quantifying insulin secretion and resistance. It is used to measure either how well an individual metabolizes glucose or how sensitive an individual is to insulin.
Late Phase Trials (Phase III and IV)	Late-stage clinical development primarily aims at demonstrating efficacy, safety, and cost-effectiveness. It corresponds to phase III confirmatory studies and sometimes inclusive of phase IV studies. The product is tested in larger clinical studies, often as compared with the therapeutic 'gold standard' or standard-of-care (SoC), if any. The collection of safety data on a larger scale enables the confirmation of the product's safety profile. The number of subjects involved in late phase trials range from 500 to 5,000.
Medical Writing	Medical writing involves creating well-structured scientific documents that include clinical research documents, content for healthcare websites, health magazines, journals and news. Medical writing can be classified into two types: Regulatory medical writing and educational medical writing.
Metabolic Profiling	Metabolic profiling (metabolomics/metabonomics) is the measurement in biological systems of the complement of low-molecular-weight metabolites and their intermediates that reflects the dynamic response to genetic modification and physiological, pathophysiological, and/or developmental stimuli.
Neutralizing antibody	A neutralizing antibody (NAb) is an antibody that is responsible for defending cells from pathogens, which are organisms that cause disease. They are produced naturally by the body as part of its immune response, and their production is triggered by both infections and vaccinations against infections.
New Chemical Entities	A New Chemical Entity (NCE) is a drug that does not contain any active moiety that has been approved by the regulatory body(ies) with any other application.
Patch Studies	Patch studies involve drug delivery through skin or transdermal drug delivery. This route of drug delivery has certain advantages over other systems of drug administration which in turn leads to increased patient compliance. Its non-invasive nature, ease of application and removal, pre-determined rate of drug permeation, increased bioavailability of drug and decreased hepatic metabolism; all these factors make this system most suitable for systemic delivery of drug over long time periods of 24hrs. Patch Studies involves testing above mentioned dynamics of the patch.
Pharmacodynamics	Pharmacodynamics is broadly defined as the biologic effects resulting from the interaction between drugs and biologic systems.
Pharmacokinetics	The activity of drugs in the body over a period of time, including the processes by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted.
Pharmacovigilance	Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.
Potency Assays	Potency assays are used to measure the ability of a drug to elicit a particular response at a certain dose in a relevant biological system. Potency assays are usually required by regulatory

	agencies for release of drug product under GMP. They are also useful in drug discovery to rank potential therapeutic candidates.
Preclinical Studies	A study to test a drug, a procedure, or another medical treatment in animals. The aim of a preclinical study is to collect data in support of the safety of the new treatment.
Suppositories	A form of medicine contained in a small piece of solid material, such as cocoa butter or glycerin that melts at body temperature. A suppository is inserted into the rectum, vagina, or urethra and the medicine is absorbed into the blood stream.
Bio-betters	Bio-betters are new drugs designed from existing peptide or protein-based therapeutics by improving their properties such as affinity and selectivity for the target epitope, and stability against degradation.
505(b)(2) NDA	The 505(b)(2) New Drug Application (NDA) is a streamlined NDA process in which the applicant relies upon one or more investigations conducted by someone other than the applicant and for which the applicant has not obtained right of reference.

SECTION I: MACROECONOMIC OVERVIEW

1. An Overview of the Indian Economy

The Indian economy has grown by leaps and bounds over the past few decades. From just 4.4% average GDP growth in the 1970s and 1980s, challenged by factors such as a restrictive foreign direct investment (FDI) policy and a regulated industrial sector, the economy accelerated to 7.1% average growth between 2009-10 and 2019-20[1]. India in fact often emerged as the fastest-growing major economy in the past decade.

The Indian economy was seen to be slowing down in 2019-20, restrained by factors such as tepid private demand and a liquidity crunch amongst non-banking financial companies (NBFCs). This slowdown was further aggravated by the COVID-19 pandemic, with India seeing a sharp contraction in 2020/21, similar to the global trend. India is expected to register 11.3% growth in the 2021/22 fiscal, much higher when compared to other major economies such as China and the US. The medium-term growth prospects of India also appear to be strong.

In terms of the structure of the economy, services makes up the major share of the economy, with 2019-20 data revealing that services value-add accounted for 55.0% of real GDP contribution. The shares for manufacturing and agriculture respectively stood at 16.9% and 14.7%, with the remaining accounted for by mining and quarrying, construction etc.[2]. The manufacturing sector share is smaller when compared to China, although accelerating manufacturing is a key government priority, as evidenced by policies such as Make in India and the production-linked incentive scheme (PLI).

In terms of the regional growth, pre-pandemic analysis revealed that the states of Maharashtra, Tamil Nadu and Gujarat were set to become trillion dollar economies by around 2030, with Maharashtra to take the lead in achieving the same. With regards to city-level dynamics, tier- 2 and tier-3 cities are expected to increasingly contribute to India's growth over the next decade, especially with Indian metros constrained by factors such as market saturation, high real estate costs, and resource pressures.

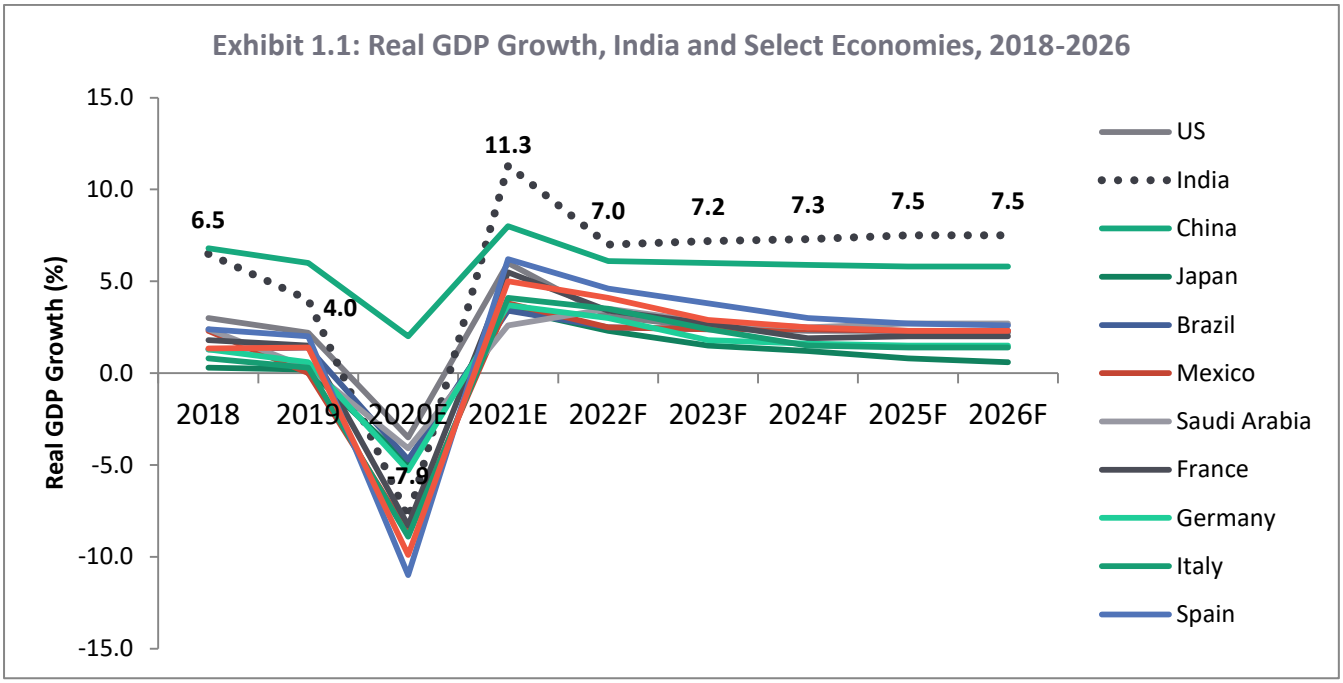
2. India's GDP Growth and GDP Size in the Context of the Global Economy

The world economy entered into a deep recession in 2020 amidst the COVID-19 pandemic. Global lockdowns negatively affected trade and supply-chains, caused sharp spikes in unemployment, and weakened confidence levels. Global rebound expectations for 2021, however, are strong, in the light of factors such the easing of restrictions, improving confidence levels, continuing fiscal and monetary policy support, and vaccination progress.

The below chart examines GDP growth rates for India and select other countries. The strong 2021 rebound is also partially reflective of the low 2020 base effect.

[1] Sources: World Economic Forum; World Bank; International Monetary Fund (IMF)

[2] Ministry of Statistics and Program Implementation



Source: International Monetary Fund (IMF); World Bank; National Statistic Offices; Frost & Sullivan

Note: Data stands updated as on or prior to 31st March 2021. India's data is presented for the fiscal years- for example, 2020 data refers to data for the fiscal year April 2020–March 2021.

The Indian economy was seen to be slowing down before the onset of the pandemic, with GDP growth weakening from 6.5% in 2018-19 to 4.0% in 2019-20. This slowdown was brought about by factors such as demand weakness and a liquidity crunch. With the onset of COVID-19 and the associated lockdowns and restrictive measures, the Indian economy is estimated to have contracted by 7.9% in 2020-21. Other economies which saw an above 7% contraction for 2020 included Mexico, France, Italy, Spain, and the UK.

India should see growth accelerating to 11.3% for the 2021-22 fiscal according to Frost & Sullivan forecasts, supported by drivers such as demand revival, strong vaccine manufacturing capabilities, large-scale vaccine deployment, new manufacturing investment expectations, and the low base effect. In regards to India's longer-term growth prospects, growth should converge to around 7.5% for the forecast period until 2026. Strong growth expectations are fuelled by factors such as India's expanding middle class, expected structural reform measures, and anticipated production shifts from China to India. China, on the other hand, will see its growth slowing down over the forecast period, with 5.8% growth expected by 2026.

A lot of economies will see their growth rates slowing down after the strong rebound in 2021, in part because of the normalization of growth levels.

The European region has been under pressure from the re-imposition of restrictive measures from late Q4 2020 to curb the virus. Consequently, most of Europe is expected to remain in recession through Q1 2021 as well. The avoidance of a no-deal Brexit between the UK and the EU is a major economic relief for the region, although some disruptions have been witnessed from the start of 2021 as businesses get accustomed to the new trading conditions. The UK's growth should near 2.3% towards 2026, compared to less than 1.5% growth in 2018 and 2019. Pre-pandemic growth in the UK was however affected by Brexit uncertainty, and with the finalization and implementation of the Brexit deal, growth prospects should improve over the forecast period. Germany's export-dependent economy came under pressure in recent years from global trade wars, with exports again coming under pressure from the pandemic. Global trade recovery in 2021 will support Germany,

as will the German economy's sizeable manufacturing sector, which is more resilient to the pandemic when compared to services.

The US's 2021 growth prospects are strong, with 6.0% growth expected for 2021, following 3.5% contraction in 2020. The March 2021 passage of a USD 1.9 trillion US stimulus package has especially helped boost the economy's growth prospects. Other key 2021 growth drivers include USD 900 billion in stimulus approved earlier in December 2020, a near-zero interest rate, and the vaccine administration process.

The below section compares the respective size of the economies in terms of current price GDP, also known as nominal GDP.

Exhibit 1.2: Current Price GDP, India and Select Economies, 2018

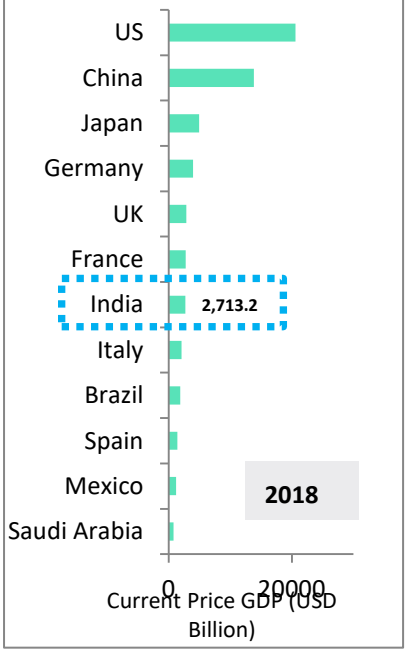


Exhibit 1.3: Current Price GDP, India and Select Economies, 2022

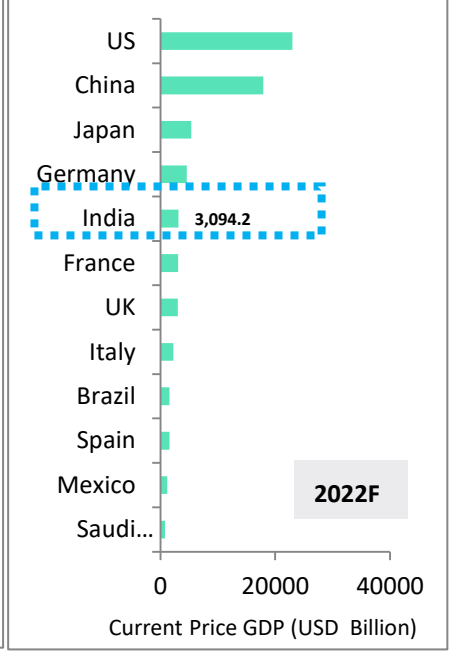
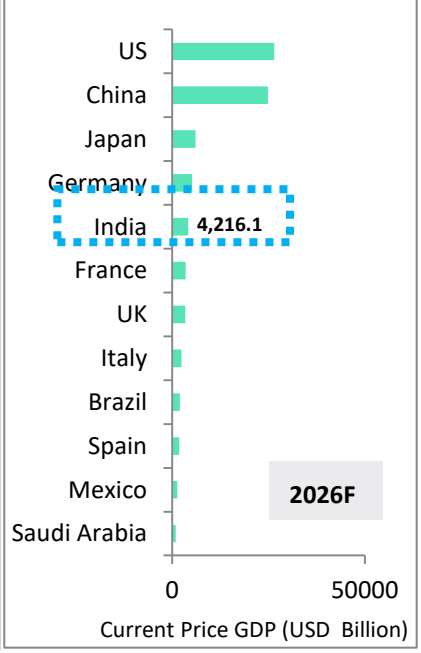


Exhibit 1.4: Current Price GDP, India and Select Economies, 2026



Source: IMF; Frost & Sullivan

Note: Data stands updated as of October 2020. India's data is presented for the fiscal years- for example, 2020 data refers to data for the fiscal year April 2020–March 2021.

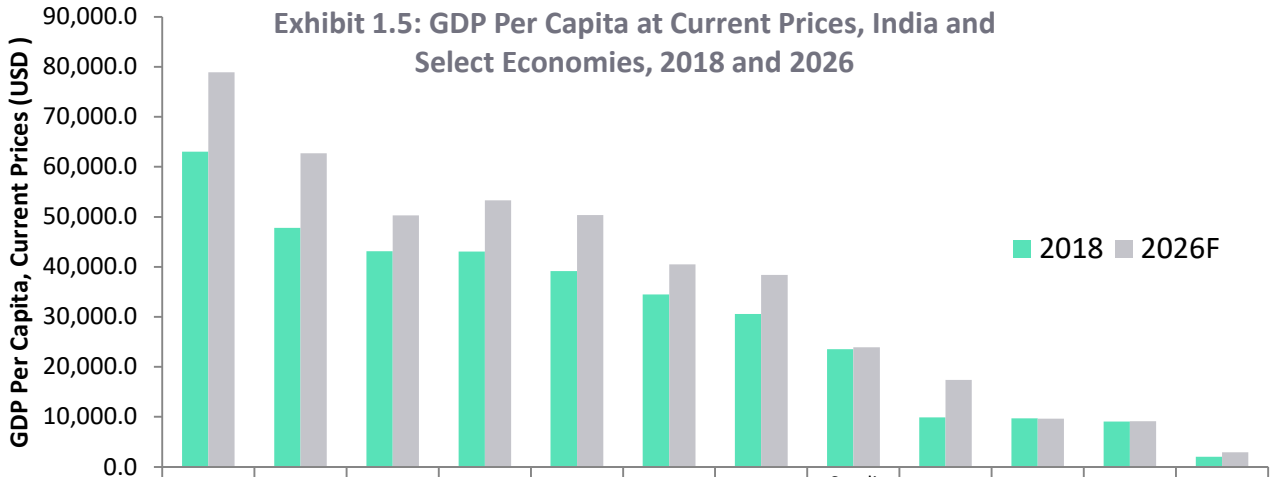
The US, China, and Japan were the top 3 largest economies in 2018, and will remain the three largest in 2026 as well. The US is forecast to reach a GDP size of USD 26.5 trillion by 2026, while the GDP size for China and Japan will respectively touch USD 24.8 trillion and USD 6.1 trillion.

India was the 7th largest economy, within the selected countries, in 2018. Between 2018 and 2022, India should overtake France and the UK to become the 5th largest economy, and retain this position in 2026 as well. India's expansion will be supported by its higher growth rate trajectory, with India to see 7% and above growth in 2022 and beyond, in comparison to just nearly 4% and under growth for France and the UK. India looks set to fortify its position as an emerging market heavyweight in the coming years.

3. India's GDP Per Capita in the Context of the Global Economy

The chart below compares GDP per capita levels across India and select economies for the years 2018 and 2026.

Exhibit 1.5: GDP Per Capita at Current Prices, India and Select Economies, 2018 and 2026



	US	Germany	UK	France	Japan	Italy	Spain	Saudi Arabia	China	Mexico	Brazil	India
2018	63,056.0	47,832.1	43,114.2	43,083.5	39,150.3	34,500.2	30,579.2	23,538.9	9,919.8	9,687.0	9,043.2	2,005.9
2026F	78,922.2	62,717.2	50,293.5	53,321.7	50,349.3	40,533.2	38,414.7	23,906.0	17,379.1	9,651.7	9,124.5	2,920.3

Source: IMF; Frost & Sullivan

Note: Data stands updated as of October 2020. India's data is presented for the fiscal years- for example, 2020 data refers to data for the fiscal year April 2020–March 2021.

GDP per capita across economies shrank in 2020 amidst the pandemic, with recovery expected from 2021 onwards. Clearly, India trails behind other major economics in regards to GDP per capita levels, with India categorized as a lower-middle income economy according to the World Bank (with the lower-middle income category ranging from USD 1,036-USD ,4,045, as per updated July 2020 classifications). In contrast, all the above countries are classified as high-income and upper middle-income economies. India's 2019 Gross National Income per Capita stood at USD 2,120 according to World Bank data.

The expansion of manufacturing through new policies, attraction of increased investments from abroad and so on would be vital in pushing India to a higher growth trajectory, in turn helping to expand the size of the economy, and accelerate per capita levels.

4. Current Economic Trends

a. Global Economic Trends

The global economy is expected to make a substantial rebound in 2021. The continuation of some pre-pandemic trends along with the emergence of new trends is seen to be presently shaping the global economy. Examined below are some of these pertinent trends.

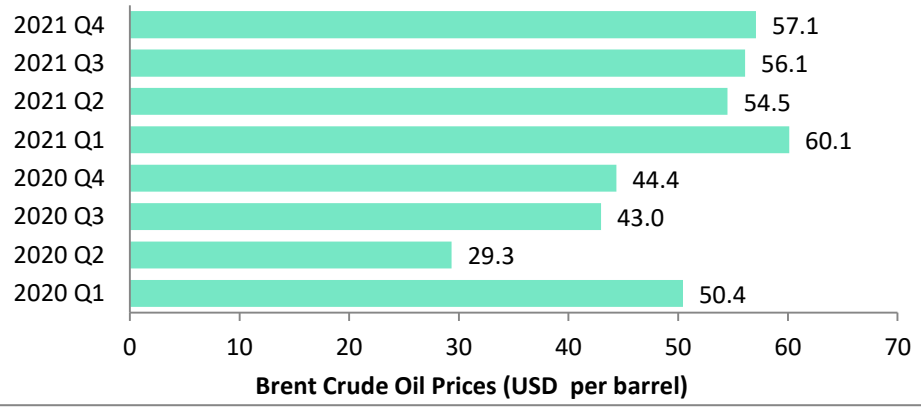
Government Fiscal Support Continuing Through 2021: In 2021, governments are seen to be prolonging stimulus support through extensions of previous measures or newer packages. However, stimulus support will be scaled down from the approximately USD 12 trillion rolled out in 2020, due to escalating debt levels. The US released a USD 1.9 trillion stimulus package in early March 2021 that is expected to significantly boost US consumer spending and also drive global growth recovery.

Trade and Supply-Chain Shifts to Persist in 2021: Re-shoring of global supply-chains, to better insulate from disruption, is expected to continue in 2021 as advanced economies look to improve manufacturing activities and automate for efficiency. The immediate stability of global supply-chains remains uncertain due to potential fresh outbreaks and lockdown extensions in importing countries. Diversification away from China due to trade wars and COVID-19 will also see a continuation in 2021. Over-reliance on Chinese production will prompt companies to increasingly diversify to locations across Southeast Asia, India, and Mexico, for example.

Brexit Deal Causes Near-Term Trade Disruptions: The new Brexit deal struck between the UK and the EU retains zero tariffs. While the deal is beneficial for traders on both sides, further border checks are already increasing delivery delays and pushing up costs. In January 2021, the UK experienced a drop of 41% in exports to the EU. Overall trade uncertainty and higher costs for EU and UK businesses will persist through 2021.

Oil Prices Rally Following Pandemic-Induced Crash: A swift wipe-out of global oil demand cause a plunge in Brent crude oil Prices to USD 18.4/barrel in April 2020. Oil prices saw gradual recovery in H2 2020, with further increase seen in Q1 2021, with oil prices crossing the USD 60/barrel mark in February. Recovery of oil demand, Organization of the Petroleum Exporting Countries (OPEC+) production cuts, and diminishing oil inventories are seen to be driving up oil prices in 2021.

Exhibit 1.6: Brent Crude Oil Prices, Global, Q1 2020- Q4 2021



Source: U.S. Energy Information Administration (EIA); Frost & Sullivan

Note: Data stands updated as on 31st March 2021. Estimates start from Q1 2021.

Reduction in Job Losses as Economic Restrictions Ease: 2020 saw an estimated 114 million employment losses, relative to 2019, with significant variation across regions. In addition, working-hour reductions within employment significantly reduced labor income. In 2021, with workplaces resuming from closures, both unemployment and working-hour reductions will be normalizing. However, the potential reimposition of restrictions due to fresh outbreaks threatens sustained recovery.

b. India Economic Trends

The following are trends that are seen to be emerging in India 2021 in response to the pandemic and required structural changes.

Key Interest Rate Continues to be Held at 4.0%: In line with the global trend of reduced interest rates in response to the subdued spending and investment activities, the Reserve Bank of India slashed the key interest rate twice in 2020 to 4%. The rate is expected to be held steady in 2021 to boost lending and consumption activities essential for economic recovery.

2021-22 Government Budget Outlay Higher than 2020-21: The overall budgeted capital expenditure at USD 75.46 billion (Rs. 554, 236 Crore) in FY 2021-22 is 26.2% higher than the budgeted expenditure in FY2020-21 of USD 59.79 billion (Rs.439,163 Crore). Major schemes such as Pradhan Mantri Kisan Samman Nidhi (minimum income support for farmers), National Education Mission, Metro Projects, Jal Jeevan Mission, and so on are budgeted to receive increased funding in FY 2021-22. The healthcare sector has also received a boost with an increment of 137.0% in budget allocation in FY2021-22 compared to the total outlay in the previous year.

Divestment Process Back on Track in 2021: Privatization of state-owned enterprises is set to begin from April 2021 after being delayed by the pandemic. The government aims to privatize the national carrier Air India, oil and gas provider Bharat Petroleum Corporation, one general insurance company, and two public sector banks. Divestment of these public corporations opens up opportunities to private sector investments.

Manufacturing Gains from China Production Shifts: The Maharashtra state government had announced mega permits in 2020, in the wake of production shifts from China, allowing companies to initiate factory operations and thereafter procure required permits. Similar measures to improve the ease of doing business can be expected for 2021. The Japan government had also in fact extended incentives to Japanese companies relocating from China to India.

5 Economic Outlook and Growth Drivers

a. Global Economic Outlook and Growth Drivers

Expansionary Monetary Policy to Create Favorable Medium-Term Financing Conditions: Global central banks are expected to keep interest rates at record low-levels until 2022, in order to boost investment and spending. The US interest rate has remained anchored at 0-0.25% since March 2020, with a change unlikely until 2023. Similarly, the European Central Bank continues to maintain a 0% benchmark refinancing rate and a negative 0.5% deposit rate, with no expectations of a hike until 2022. Interest rates and consequent subdued borrowing costs will support cheaper business financing, consumer borrowing, and medium-term price stability.

Rise in Reshoring to Drive Domestic and Regional Manufacturing Activities: China-centric global supply chains suffered massive disruptions in 2020. Since then, businesses have been increasingly looking to re-shore manufacturing closer to end-consumers. This is especially true for mission-critical sectors such as healthcare. As more businesses opt to regionalize and re-shore supply chains and manufacturing units, domestic and regional industrial and manufacturing activities are expected to pick-up. The shift in supply chains and rise in regional manufacturing stands to be further supported by newer regional trade agreements which have gone into effect recently.

Pandemic-Induced Oil Crash to Accelerate Non-Oil Diversification in Oil-Exporting Nations: Oil exporting countries experienced a significant reduction in revenues in 2020 due to oil demand weakening seen from early March 2020. The severe restriction to oil revenues stands to push oil-exporting countries to accelerate economic diversification measures. Low-cost producers such as the UAE and Qatar, have a higher capacity to diversify. The increasing shift away from fossil fuel dependence to renewable energy sources is expected to be expedited in the next decade, with demand for fossil fuels to decline in the forecast period gradually.

b. India Economic Outlook and Growth Drivers

Significant Push for Manufacturing through the Production-Linked Incentive (PLI) Scheme: The PLI scheme rolled out in 2020 targets 13 sectors such as mobile and electronic components production, pharmaceuticals, telecom, automobiles and components, food products, steel, and so on. The scheme entails a 4-6% incentive depending on incremental sales for goods manufactured in domestic units. PLI is expected to help attract foreign investments and expand existing manufacturing units from 2021 onwards, with USD 520 billion expected in new production over the next five years.

Expansion of National Infrastructure: In 2021, the Indian government revealed plans to expand the energy sector through 100% electrification of Broad Gauge Routes by 2023 and an additional increase of 139 gigawatts of installed capacity. The increased focus on infrastructure expansion should create contract opportunities for private enterprises. Likewise, the National Rail Plan 2030 targets to increase rail share in freight from 27% to 45%. As a result, domestic supply chains and logistics services should benefit from improved connectivity.

FDI-Friendly Policies to Boost Investments: The most recent FDI supportive policy introduced by the government in 2021 entails a rise in the FDI cap in the insurance sector from 49% to 74%, in a move to further increase insurance penetration in India through foreign direct investments. As the Indian insurance sector attracts more international players, product portfolios available in the country stand to increase in the coming years vastly. Similar support for FDI was seen in 2020, with a revision in guidelines to allow for 100% FDI in Direct-to-Home (DTH) broadcasting services. The relaxation in FDI limits will help accelerate post-pandemic recovery and boost investment attraction.

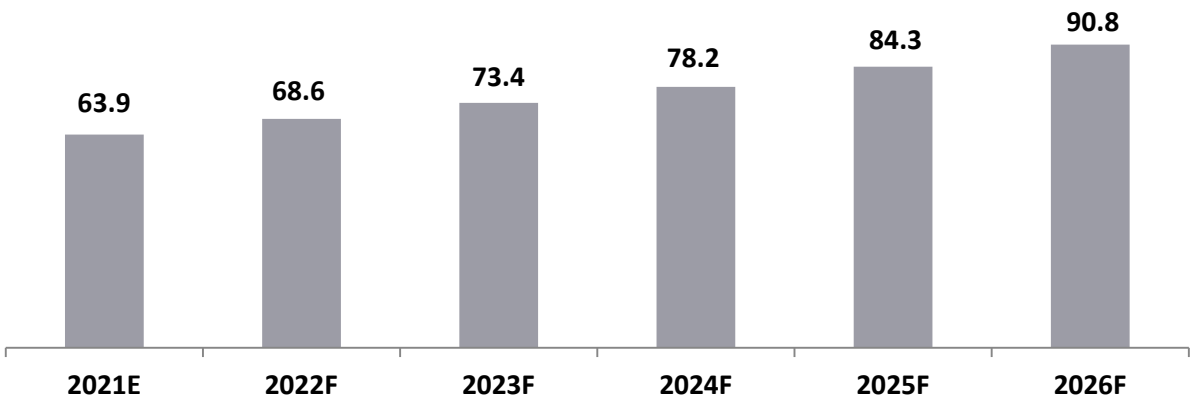
SECTION II: GLOBAL CRO MARKET OVERVIEW

Global Clinical Research Organization (CRO) Market Overview

CROs are a key constituent of the drug development process, providing a range of services to pharmaceutical, biotechnology, and medical device companies, as well as governments, academic institutions, and other research entities. These services can encompass all phases of the drug development lifecycle, from compound selection, discovery, preclinical (pre-human in-vitro and in-vivo) research, clinical (in-human) testing, as well as post-approval functions such as commercialization, safety assessment, monitoring, and consulting, among other services. Overall, CROs help pharmaceutical companies manage the drug development process, and given CROs' Global scale and therapeutic expertise, they are often able to do so more cost effectively and with a shorter time-to-market than in-house research and development departments at pharmaceutical companies.

The global CRO market is projected to reach USD 90.8 Bn by 2026 from USD 63.9 Bn in 2021. With more than 1,000 competitors and an ever changing market landscape, **the global CRO industry is expected to witness a CAGR of about 7.3% between 2021 and 2026.** Market growth can be attributed to the growing R&D expenditure, increased outsourcing of R&D activities, and an increasing number of clinical trials, to name a few. Pharmaceutical companies are currently focusing on outsourcing research activities to various academic institutes and private CROs to gain a competitive edge and remain flexible.

Exhibit 2.1: Global CRO Market: Revenue Forecast, 2021–2026, USD Billion
CAGR (2021–2026): 7.3%



Source: Frost & Sullivan Analysis

Market Segmentation by Select Geographies

Region	Market Size by Revenue (USD Bn)	Global Market Share by Revenue (%) (2021)	Global Market Share by Revenue (%) (2026)	CAGR (2021-2026)
North America	23.6	37%	38%	7.6%
Europe	22.1	35%	34%	6.9%
APAC	14.4	22%	24%	8.4%
ROW	3.8	6%	5%	3.4%
India	1.9	3%	4%	12.0%

Note: The India CAGR (2021-2026) of 12% represents growth in the Indian consumption of CRO services over the next five years.

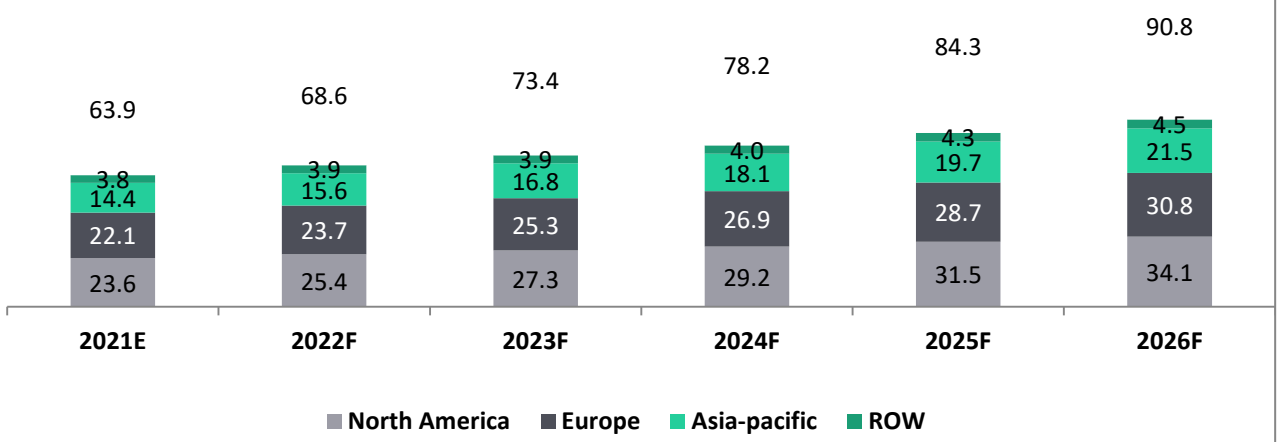
North America and Europe emerge as the leading markets in the Global CRO industry: Geographically, the global CRO services market has been segmented into four major regional segments - North America, Europe, APAC and Rest of the World (ROW). North America and Europe continue to be the strongest markets in the global clinical CRO industry. Despite a higher clinical research activity in Europe, North America emerges as the leading market, with a majority of industry leaders being based out of the region. In 2021, North America is estimated to account for the largest share of the CRO market (37%), followed by Europe (35%) and Asia Pacific (22%).

North America is expected to witness a CAGR of 7.6% to reach USD 34.1 Bn by 2026. North America's leading position in this market is primarily attributed to the high-quality standards in the pharmaceutical industry, rapid growth in its biosimilar and biologics market, and an increase in clinical trial activity. Europe is the second-largest market for clinical CRO and is estimated at USD 22.1 Bn in 2021. The market expects to show a 6.9% growth in the next five years to reach to about USD 30.8 Bn by 2026. High clinical trial activity in the region is the primary contributor to the higher global market share.

Owing to the better infrastructure and improved trial monitoring facilities, North America and Western Europe dominate the CRO market. However, considerable cost differences, especially with Eastern and Southern Europe, alongside APAC, will support higher research activity being outsourced to these regions. APAC is slowly expected to capture higher market share (24% by 2026) and is emerging as the go-to market for CRO industry lead by China, Japan, India, and other Southeast Asian countries. The cost of conducting trials is one of the key contributing factors propelling CRO industry in the region. According to the industry sources, **APAC allows a cost reduction of around 40% to 50% compared to the US** which in itself is a major driving factor. Additionally, owing to a higher population base, local CROs enjoy widespread patient and hospital networks that aid CROs in hassle-free R&D activities.

Indian CRO market captures about 3% of the global market share by value, estimated at USD 2 Bn in 2021 and is expected to grow with a CAGR of about 12% from 2021 to 2026: The recent favorable changes in the Indian regulatory landscape for the CRO industry, higher acceptability of India as an outsourcing destination by the Global pharmaceutical companies and favorable demographics of India in terms of cost, technical skills (English speaking population) and diversity of volunteers required for trials are expected to drive the Indian CRO market. More details are included in the sections of the report.

Exhibit 2.2: Global CRO Market Revenue Forecast by Region, 2021–2026, USD Billion, CAGR (2021–2026): 7.3%

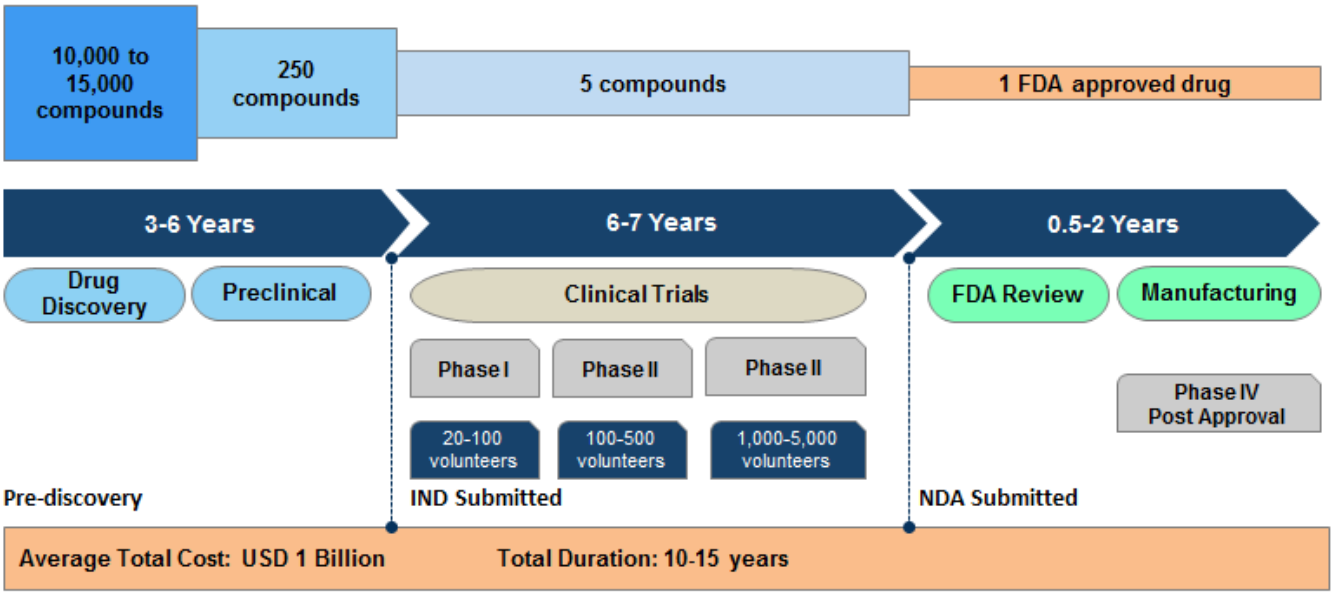


Source: Frost & Sullivan Analysis

The CRO Value Chain

The drug pipeline moves through various phases during the research and development process and CRO players function as contributors at the various stages incentivized for their efforts through monetization at every milestone.

Exhibit 2.3: Drug Development Life Cycle: Timeline for New Drug Approvals as per US FDA



Source: US FDA

Exhibit 2.4: Broad Scope of Services across the CRO Value Chain

Global CRO Market	Preclinical development				Early Clinical Phase		Late Clinical Phase (Phase III)				Generics / Contract Manufacturing	
	Discovery Services	Chemistry	Bio analysis	Toxicology	Phase I	Phase II	Functional Services	Central Lab	Imaging	Phase IV	BA / BE	Patient Based
Market Size USD Bn	13.4	5.2			0.6	3.5	31.4			4.3	1.7	
CAGR (2021-2026)	5.60%	10.30%			6.10%	7.90%	7.50%			7.20%	12.60%	

Source: Frost & Sullivan Analysis

Drug Discovery: The ultimate goal of the drug discovery phase is to find a promising molecule, or lead compound, that has the potential to become a new medicine. Researchers assess the underlying disease pathway and identify potential target compounds, narrowing the field of compounds to one lead compound that shows potential to influence the target.

Preclinical Research: Relevant compounds are tested in-vitro (test tubes) and in-vivo (animals) over a wide range of doses to establish relative toxicity of the compound and detect any potential adverse reactions to the therapeutic. If results of preclinical research indicate that the compound is safe and

potentially effective, the sponsor submits initial study results to the regulatory body/ (ies) along with a complete Investigational New Drug Application (IND). An IND includes, among other things, preclinical study data, Chemistry, Manufacturing and Controls (CMC) information, and an investigational plan for clinical trials, and it must become effective before proceeding to clinical trials. An IND automatically becomes effective 30 days after receipt by the regulatory body, unless the regulatory body raises concerns relating to proposed clinical trials within the 30-day time period, in which case the regulatory body's concerns must be addressed before clinical trials can commence. Before clinical trials can begin at a study site, the site's Institutional Review Board (IRB), an independent expert body charged with protecting patient safety and privacy, must give their approval, separately from the IND submission.

Clinical Studies: Of the 250 compounds that advance to preclinical testing for a particular project, only five, on average, progress to clinical (human) testing. Clinical trials are completed to determine the safety and efficacy of a drug. Clinical trials can last six to seven years and comprise Phases I-III, with Phase IV or post-commercial marketing studies often required by the regulatory bodies as well.

Phase I trials are the first tests of a drug with a small number of healthy human subjects. Patients are generally only used if the mechanism of action of a drug indicates that it will not be tolerated in healthy people. They are primarily designed to assess the safety and tolerability of a drug, but the pharmacokinetics and, if possible, the pharmacodynamics is also measured.

Phase II trials are performed on larger groups of patients (100 to 500 volunteers) and are designed to assess the efficacy of the drug and to continue the phase I safety assessments. Most importantly, phase II clinical studies help to establish therapeutic doses for the large-scale phase III studies.

Phase III trials are randomized controlled multi-center trials and provide most of the long-term safety data. Phase III trials investigate the efficacy and safety of a new drug over 6 to 12 months or longer in a large patient population (1,000 to 5,000 subjects) under conditions that reflect daily clinical life much more closely than the phase I or II trials and allow evaluation of the overall benefit-risk relationship of the drug. Only about 25-30% of drugs in phase II proceed to phase III. Phase IIIA studies are used for the approval of the drug from the appropriate regulatory agencies (known as Pivotal study). The results of these studies are included in the submission package to regulatory authorities. Drug-drug intervention (DDI) studies may be part of another large phase II or phase III study. However, the DDI program depends on DDI potential of the drug.

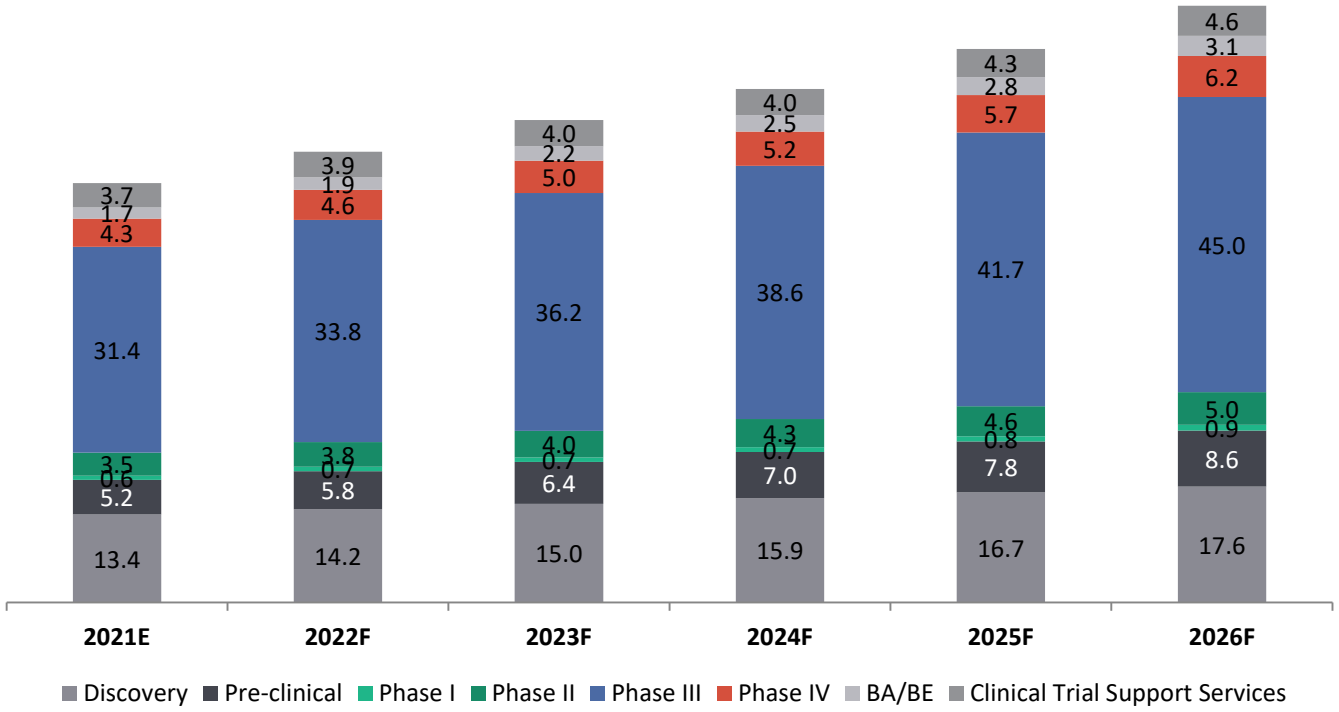
Phase IV trials are also known as post-marketing surveillance trials involving safety surveillance (pharmacovigilance) and ongoing technical support after approval. However, not all phase IV studies are post-marketing surveillance studies. There are multiple observational designs and evaluation schemes that can be used in phase IV studies to assess the effectiveness, cost-effectiveness, and safety of an intervention in real-world settings.

BA/BE Studies: Bioavailability (BA) and Bioequivalence (BE) studies are carried out for developing a new formulation or for marketing a generic drug. In order to market a generic drug, BA/BE studies

are required for approval from health authorities like US FDA. The drug that is being tested is studied against a well-known and commercially available drug, at same concentrations and under conditions that are similar. Companies file their Abbreviated New Drug Application (ANDA) according to 505 (j) or 505b (2) to the US FDA or other regulatory body/(ies) seeking marketing authorization in respective countries. Selection of the right clinical research organization is vital for a successful market launch.

CRO Market Segmentation by Sub-Segments

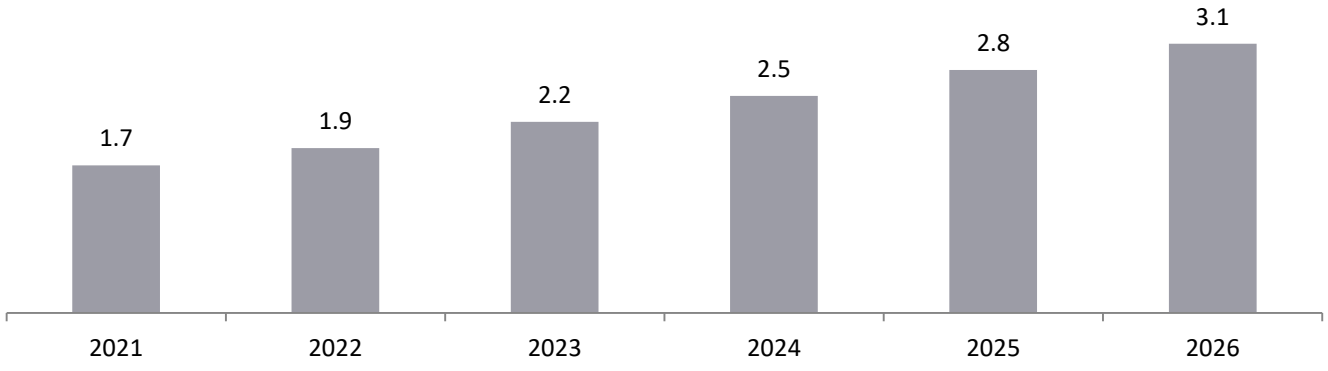
Exhibit 2.5: Global CRO Market: Revenue Forecast by Sub-segments, 2021–2026, USD Billion, CAGR (2021–2026): 7.3%



Source: Frost & Sullivan Analysis

Note: *Clinical trial support services: ADME, PK/PD, biomarker assays, bio pharmaceutics etc.*

Exhibit 2.6: Global Market for BA / BE Studies, 2021- 2026, USD Billion CAGR (2021-2026): 12.8%



Source: Frost & Sullivan Analysis

Drug discovery and preclinical research segment is expected to witness 7% growth over the next five years (2021-2026). This is driven by increased outsourcing of early-stage activities by small-to-mid segment pharmaceutical companies. Drug discovery and preclinical research being lab-oriented testing, account for about 21% and 8%, respectively in 2021. These two segments capture the second largest market share after the phase III trials segment (49%) of the total market share in 2021. North America and Europe are the key dominating segments for discovery and preclinical research, with more than 50% of the market for early-stage drug development, as most of big CRO participants function in these regions, followed by APAC.

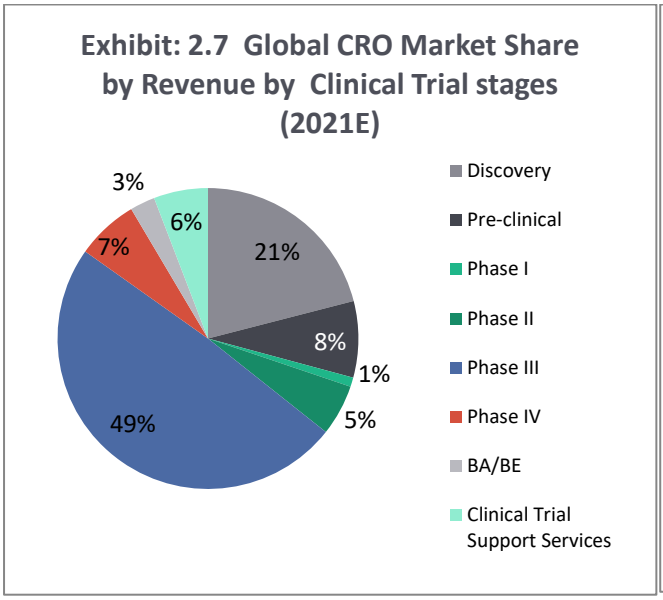
All processes from chemistry to IND submissions involve the non-clinical activities of drug development. Bio-analytical testing activities, such as PK/PD, Absorption, Distribution, Metabolism, and Excretion (ADME), BA/BE studies for early-stage drugs and generic drugs support the assessment of drug stability and efficiency to move to the next stage of clinical research or ANDA filing, respectively.

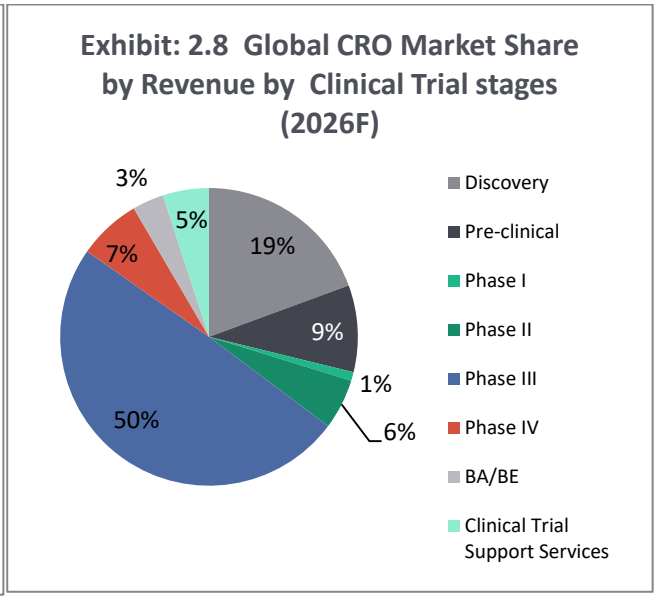
The sub-segment, with highest revenue generating potential in the CRO industry is the clinical trials segment which accounts for the largest share (62%) in 2021. This could be attributed to the rapid growth in the geriatric population (> 60 years), subsequent increase in the prevalence of chronic diseases, increasing development of new drugs, and growing acceptance of evidence-based medicine for various therapeutic areas.

Phase III segment is set to dominate the clinical trial landscape for CROs: Owing to a higher outsourcing rate for clinical research, higher investments and a corresponding higher number of trials, phase III trials segment accounts for the maximum share of the global CRO market (49% market share in 2021) and is expected to grow by about 7.5% over the next five years to reach to about USD 45 Bn by 2026.

BA/BE segment expected to witness a growth rate of about 13%: The clinical trial support services segment is estimated to capture about 9% of the total market share in 2021 with BA/BE studies contributing to 30% of USD 5.4 Bn of the clinical trial support services market in 2021. Though BA/BE segment captures only about 3% of the total market share, this segment is expected to witness a growth rate of about 12.6% between 2021 and 2026, primarily driven by greater adoption of generic drug manufacturing and emergence of biosimilars.

Global CRO Market (2021) = USD 63.9 Bn	Global CRO Market (2026) = USD 90.8 Bn

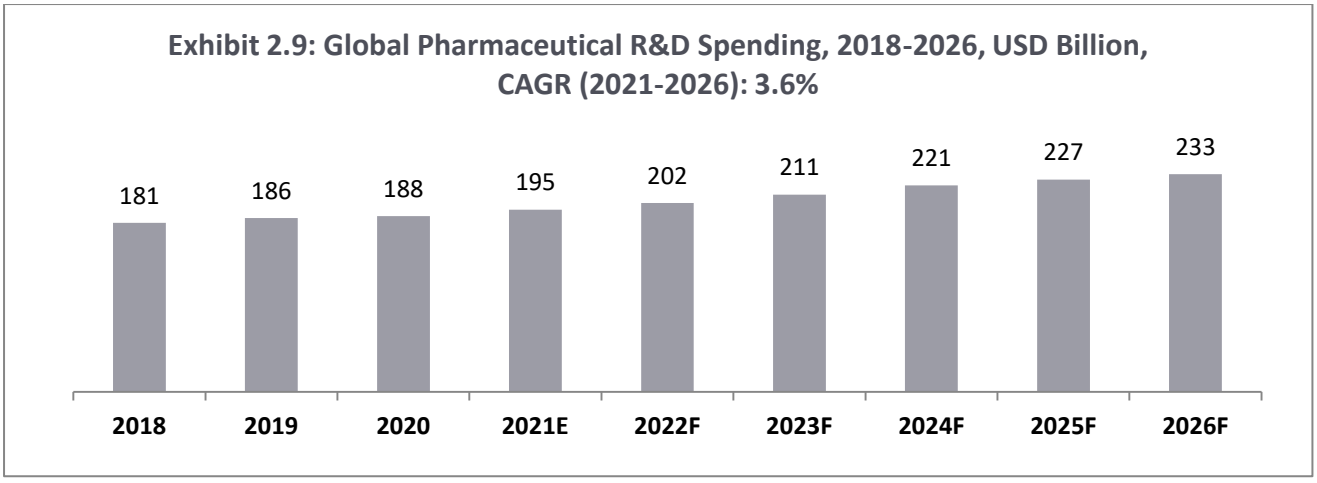




Source: Frost & Sullivan Analysis

Trends Expected in Pharmaceutical R&D Spends

Global pharmaceutical R&D spending is expected to increase at a CAGR of 3.6% between 2021 and 2026: Global pharmaceutical R&D spending is continuously increasing since 1970s. The average cost to develop one drug and commercialize in the market has increased by 10.2% from USD 1.18 Bn in 2010 to USD 1.3 Bn in 2020. The R&D spending was estimated to be around USD 195 Bn in 2021 and it is estimated to grow to about USD 233 Bn by 2026 at a CAGR of about 3.6%.

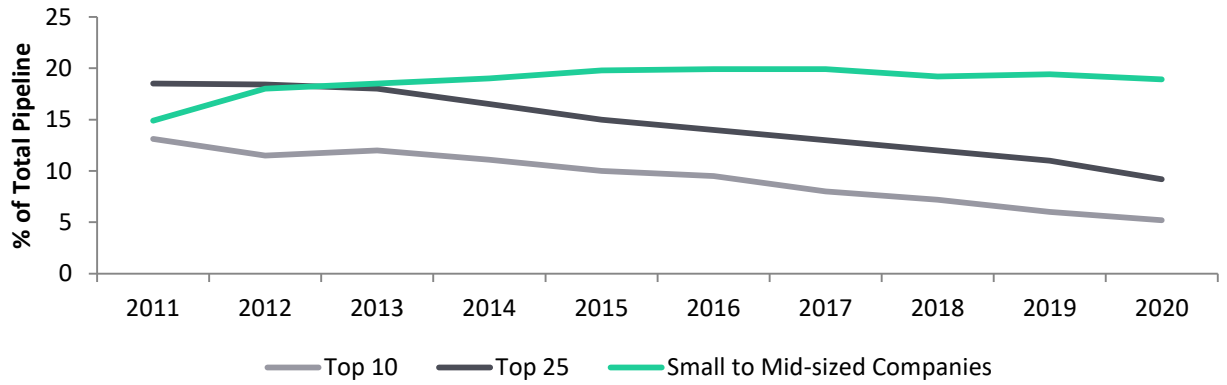


Source: Frost & Sullivan Analysis

R&D spend by small and mid-sized pharmaceutical companies in terms of proportion of number of drugs in development is positively increasing than the large pharmaceutical companies: The share of the total pipeline, which large sized pharmaceutical companies (top 10 and top 25 companies) contribute has been declining over the past few years, and this trend is expected to continue for the

next five years (2021-2026). In the below graph, it is evident that the contribution from small and mid-sized firms with less than 10 products is on a growth trajectory (3% growth from 2011 to 2020).

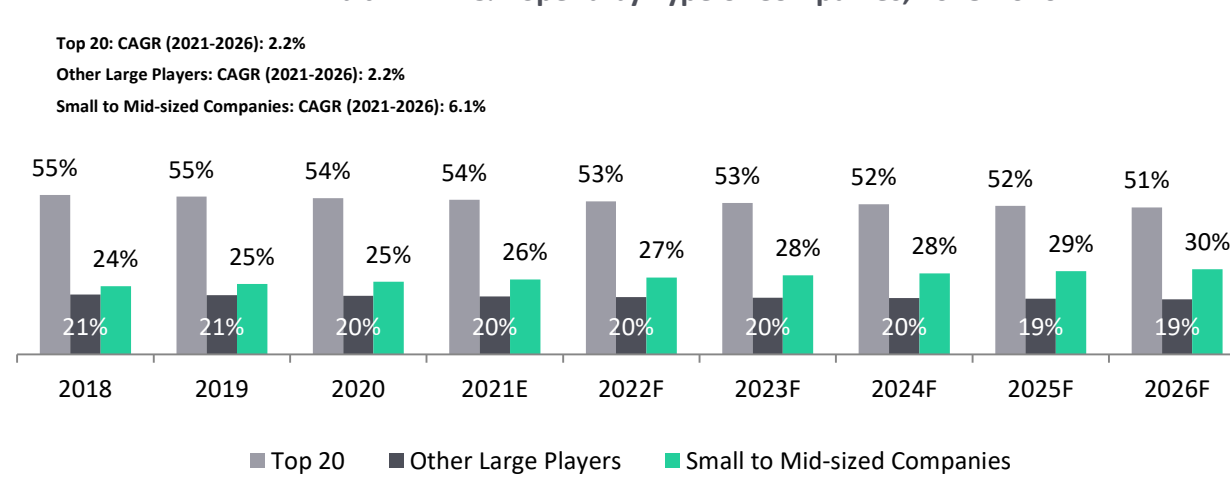
Exhibit 2.10: Percentage Share of Number of Drugs in Development, 2011-2020



Source: Pharmaprojects 2020, Frost & Sullivan Analysis

R&D spend by top 20 and other large players form the largest segment of the pie (7%) by 2026,; however, small and mid-sized pharmaceutical companies will drive the spending at a CAGR of 6.1%: The proportion of the R&D spend by the top 10 and top 25 companies saw a decline by 8 and 5% respectively, between 2018 and 2020; while, the R&D spend by the small and mid-sized companies grew by 7% during the same time period. It is expected that the overall R&D spend in the next five years (2021-2026) will largely be driven by small and mid-sized companies.

Exhibit 2.11: R&D Spend by Type of Companies, 2018-2026F



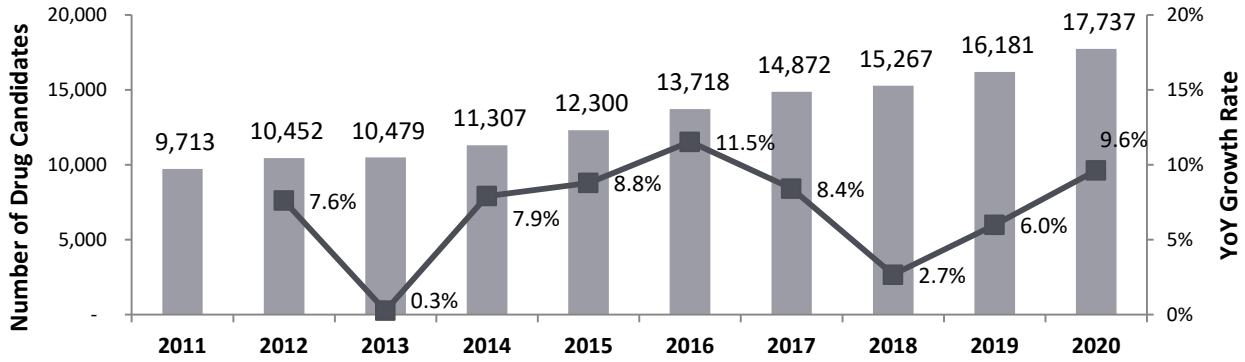
Source: Pharmaprojects 2020, Frost & Sullivan Analysis

The overall R&D spend of the top twenty players is expected to increase at 2.2% CAGR from USD 98 Bn in 2017 to USD 119.2 Bn in 2026; **while, the overall spend of the small and mid-sized players is expected to grow at about 6.4% during the same period.** The total R&D spend is forecasted to increase at 3.6% CAGR from USD 195 Bn in 2021 to USD 233 Bn in 2026 emphasizing the aggressive

catch up by smaller players. The Indian CRO players have an opportunity to contest for a part of this R&D spend by established and emerging players.

Number of molecules in R&D stage is on the rise: There are more than 17,000 molecules currently in preclinical development, which is attributed to the constant effort of discovering new drug candidates. Pharmaceutical companies continue to invest in developing new drugs, therefore, supporting large-scale drug discovery activities. In the year 2020, 17,737 molecules were in R&D stage of development. Not only has the overall size of the pipeline increased to 17,737 drugs, but the growth rate has also shot up, to 9.62% in 2020 as compared to the growth rates of 5.99% in 2019 and 2.66% in 2018. As compared to the trend over the last three years (2017-2019), the growth rate in the number of drugs in R&D were 8.41% (2017), 2.66% (2018) and 5.99% (2019), which averages out at 5.69%, making 2019 growth rate slightly above the three-year mean.

Exhibit 2.12: Total R&D Pipeline Size, Number of Drug Candidates, 2011-2020



Source: Pharmaprojects 2020, Frost & Sullivan Analysis

Consistent effort and spend towards development of NCEs being launched is increasing which is driving more products through the funnel. R&D productivity is increasing due to firms focusing on core R&D and outsourcing CRO functions and higher number of small and medium size dossier companies.

NCE Approvals and Spend per NCE, 2010-2019	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of NCEs	27	30	39	27	41	45	22	34	59	48
Spend per NCE (USD Bn)	5.6	5.3	4.5	6.7	4.5	4.2	8.9	5.9	3.6	4.6

Source: Evaluate Pharma, Frost & Sullivan Analysis

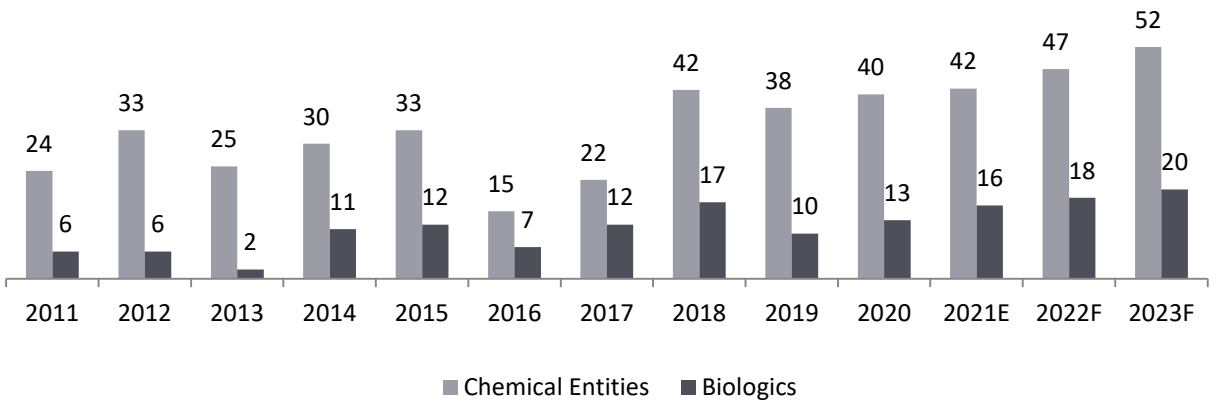
Increased productivity driving more products through the funnel: Given the improvements in R&D productivity, continued increase in R&D investments, the number of R&D projects at every stage is exhibiting a steady increase from 2010-2020. This, in turn, is expected to drive a steady number of new approvals over the medium term.

Research pipeline for NCEs remain robust (2015-2020)	2015	2016	2017	2018	2019	2020	2021E	2022F	2023F	2024F	CAGR (2021-2024)
Pre-clinical	12,300	13,718	14,872	15,267	16,181	17,737	19,084	20,534	22,094	23,772	7.6%
Phase I	750	774	799	825	851	879	907	936	966	997	3.2%
Phase II	825	830	835	840	845	850	855	861	866	871	0.6%
Phase III	227	229	232	235	237	240	242	245	248	250	1.1%
Pre-registration	40	42	44	46	48	51	53	56	59	61	4.9%
Registered	15	16	18	20	22	24	26	28	31	34	9.5%
Launched	1523	1539	1579	1608	1637	1667	1697	1728	1760	1792	1.8%

Source: Evaluate Pharma, Frost & Sullivan Analysis

Biologic drugs to lead the next wave of US FDA approvals: Increase in R&D spending is visible in terms of an increasing number of new FDA approvals, rebounding from 22 new molecular entities in 2016 to 55 and 59 in 2017 and 2018, respectively and even though a slight decrease was observed in 2019 with 48 approvals, the numbers raised to 53 drugs in 2020. Of the 48 new drug approvals in 2019, 10 were biologics and 38 were small molecules. The industry is moving towards incorporating more and more biologics in their portfolios with the share of biologic approvals increasing from ~14% in 2013 to ~27% in 2018. However, the number of biologics expected to be approved in the next 3 years is expected to grow by about 10% over the next three years. Monoclonal antibodies (mAbs) continue to be an important class of biologics and year 2020 saw an approval of nearly 12 mAbs.

Exhibit 2.13: Number of NCEs and Biologics Approved, US FDA, 2011-2023



Source: USFDA, MPDI, Frost & Sullivan Analysis

The Outsourced CRO Industry and the Driving Tailwinds

Higher rate of outsourcing to CROs observed in clinical trials and toxicology phases of the drug value chain: CROs are professional companies providing R&D outsourcing services to pharmaceutical companies through contract. In general, CRO services can be divided into preclinical and clinical trials. Due to the different technical difficulties at each stage, the outsourcing rate of CRO varies at all stages with a low rate of outsourcing observed during early stages of research and development and a higher rate during the clinical trial phase due to more work on process standardization. Because of the need for GLP laboratory, pharmacological toxicology testing has a high barrier, and thus a higher outsourcing rate.

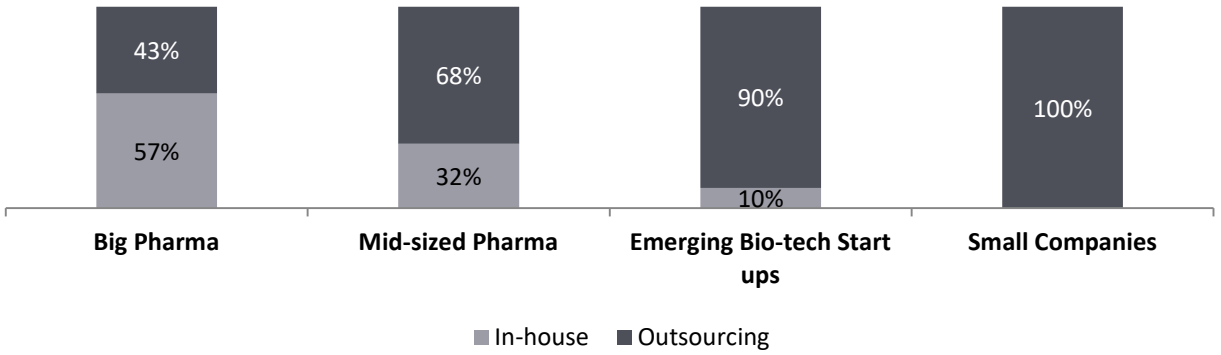
Exhibit 2.14: Life Cycle of Drug Development

Research Phase	Drug Discovery	Drug Development	Phase I	Phase II	Phase III	Phase IV	BA/BE Studies (Generics)
Purpose	Screening of drug candidates	In-vitro safety study	Human safety, dose	Efficacy, side effects	Long-term effects, side effects	Adverse reactions, efficacy monitoring	Dose, absorption, generic drugs equals innovator drugs
Subjects	Cells, Animals		20-100 people	100-500 people	1000-5000 people	5000+ people	12 to 15 people
Research Cycle	3-6 Years		6-12 months	1-2 years	2-4 years	0.5-2 years	N/A
R&D Spending	17%		9%	11%	28%	11%	N/A
Candidate Compounds	10,000-15,000	250	5	4	2	1	N/A
Scope	Lead compound discovery	Drug metabolism, toxicology research	Protocol design, principal investigator and patient recruitment, institution selection, clinical trial monitoring, site management organization, central laboratory, data management statistics, application of approval documents				Drug metabolism, absorption
Core Competence	Efficient compound screening platform	Animal model, GLP qualification	Clinical trial institution resources, principal investigator resources, global multicenter clinical capacity				GLP Qualification

Source: Frost & Sullivan Analysis

Mid-sized, emerging bio-tech and small pharmaceutical companies (together constitutes 26% of pharmaceutical R&D spend in 2020) drive outsourcing: Currently, big pharmaceutical companies outsource around 40-45% of their activities to CROs, and this number is expected to grow to about 60% by 2028. On the contrary, medium-sized companies outsource up to 65-70% and the emerging biotech startups typically outsource up to 90% of their activities, and few of the smaller companies are aiming for 100% outsourcing as they have fewer internal resources. The increased R&D budget and willingness to spend in the next 5 years is a significant opportunity for CRO companies, as pharmaceutical companies are increasingly outsourcing research activities to academic and private CROs as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, increasingly sophisticated technologies and an unstable economic environment. This increased outsourcing trend is also driven by other factors like growing regulatory scrutiny, rising commercialization costs and rising patent expirations of blockbuster drugs. This will lead to significant increase in outsourcing percentage of BA/BE studies and this could benefit companies like Veeda, Vimta, and Lambda etc. who have focus in BA /BE segment.

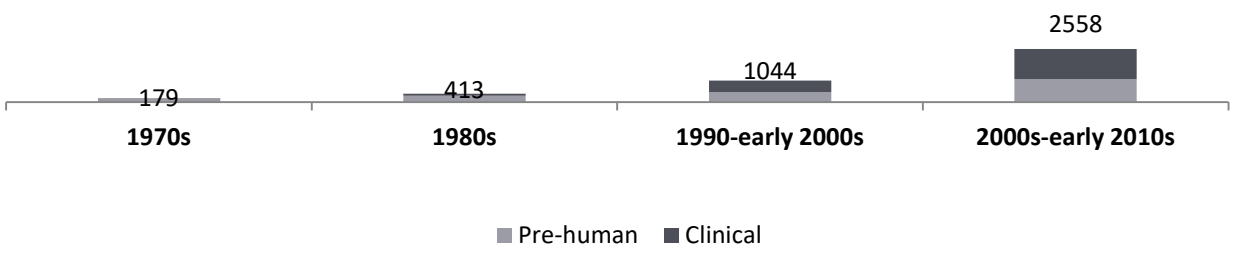
Exhibit 2.15: Percentage of Pharma R&D Outsourcing, By Type of Company, 2021



Source: Frost & Sullivan Analysis

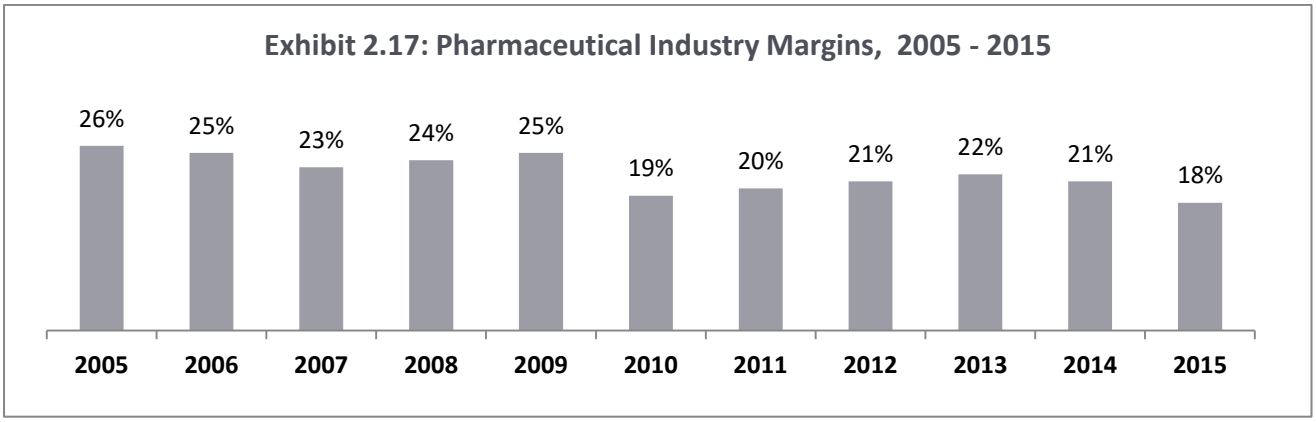
Rising costs of therapeutic development and pressure on pharmaceutical margins leading to increasing outsourcing: Only five out of every 10,000-15,000 experimental compounds that enter preclinical trials advance to human testing, and only one ultimately gains regulatory approval and is commercialized. With rising costs of development and commercialization of new therapeutics, it is financially impractical for sponsors to maintain redundant development teams and facilities, and pharmaceutical companies are increasingly reliant on CROs to optimize fixed overhead costs, shorten the development timeline, and expand clinical trial management capabilities globally. Based on the increase in investment per project / NCE since 1970s, it indicates a significant opportunity for BA/BE focused players.

Exhibit 2.16: R&D Costs (USD Mn) per Approved New Drug Increased by 14X Since 1970



Source: Frost & Sullivan Analysis

Additionally, pricing pressure from government and private third party payors, as well as patent expirations and rising generic utilization, are **pressuring profit margins of pharmaceutical companies, driving demand for outsourcers, such as CROs,** to increase development capacity and reduce overall fixed costs.



Source: Frost & Sullivan Analysis

Complexity of the drug discovery and preclinical research increases outsourcing opportunities for CROs: Discovering and developing a new therapeutic can take 10-15 years, on average, with costs often exceeding USD 1 Bn. The increasingly complex drug development process requires therapeutic expertise, advanced technological capabilities, and familiarity with the increasingly complex regulatory process. With the enormous costs at hand and risks involved throughout the process, pharmaceutical companies, seek outsourcing partners that possess the necessary expertise and scale to maximize the chances of ultimate approval, navigate the regulatory hurdles, compress the development timeline where possible, and produce a quality end-product with a successful clinical trial. This generally positions larger CROs more favorably than smaller providers, given their broader therapeutic expertise and global footprints, regulatory expertise in numerous geographies, and advanced technological capabilities.

Increasing complexity of therapeutics and associated clinical trials: Complex small molecules and biologics require highly specific drug technologies and expertise to handle highly potent and targeted therapies, namely, cell and gene therapies, cytotoxic/highly potent active pharmaceutical ingredients (HPAPIs), and antibody drug conjugates (ADCs). Advances in research and technology, increasingly dire needs to address broader global disease threats (i.e. oncology) and orphan indications, rising demand for complex generics, specialty 505(b)(2) molecules and biosimilars along with heightened regulatory protocols and burdensome penalties for non-compliance, have increased the duration, cost, and complexity of clinical trials. Thus, **with increasing cost and complexity of drug development, pharmaceutical companies are outsourcing an increasing portion of development projects to maximize efficiencies and capitalize on fixed cost flexibility that CROs can provide.**

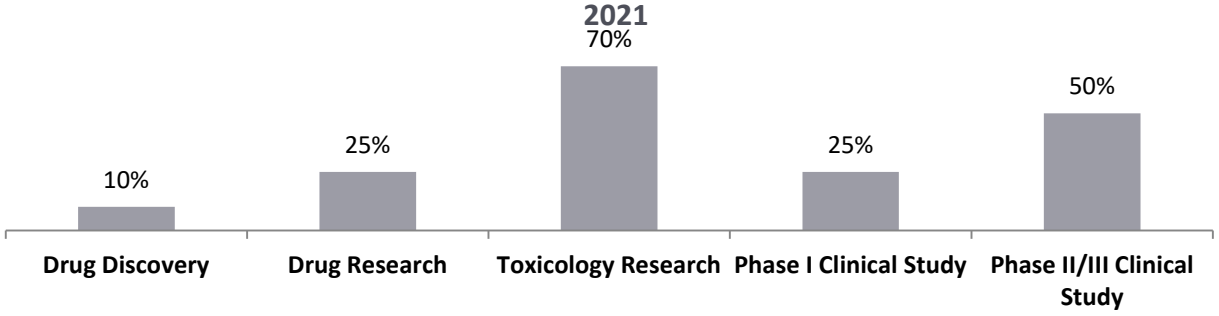
Increasing scope of CRO services with demonstrated significant efficiencies on time, cost and good track record of compliance: Pharmaceutical companies choose R&D outsourcing mainly based on the following two reasons:

- **CRO enterprises have specific expertise:** As CRO companies adopt a focus on specific research and development links; they have cost and resource advantages, especially in the global multicenter clinical, core principal investigator recruitment and other aspects.

- **Improving the efficiency of new drug research:** The CRO business model can save an average of 20 to 30 weeks of the drug development time, thereby indirectly increasing the revenue of pharmaceutical companies.

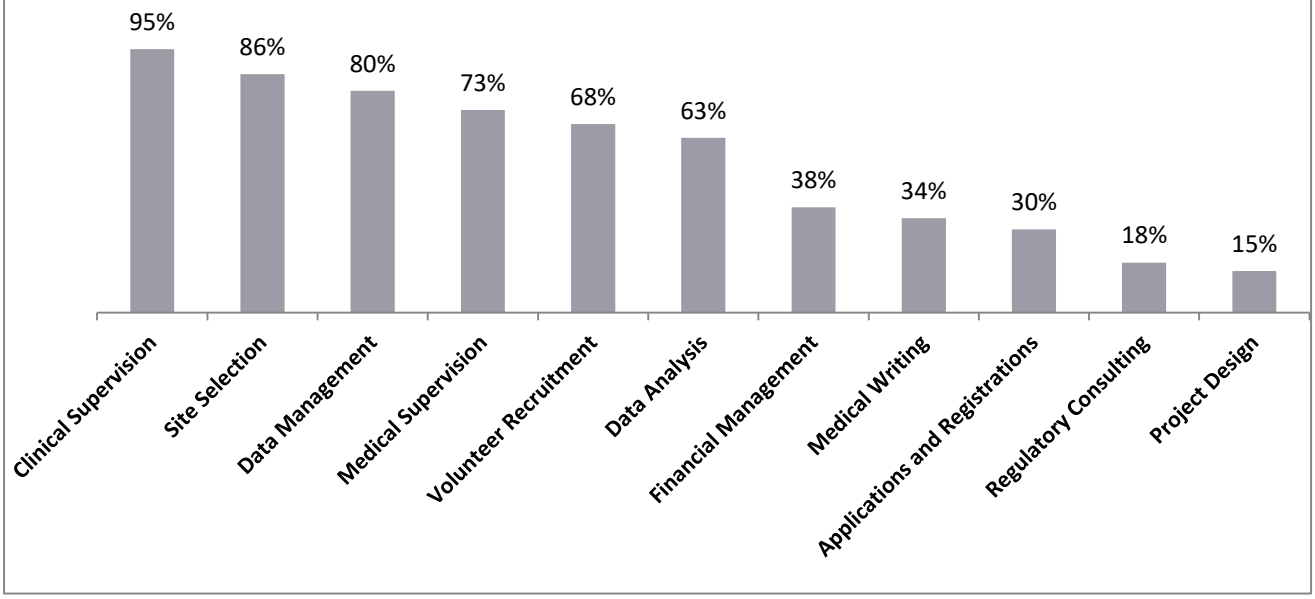
Higher outsourcing in the preclinical and generic drug space (due to higher complexity and pricing pressure): The outsourcing rate in the drug discovery stage is lower (around 18%); while, the outsourcing rate in the clinical trials phase is higher, between 25 and 50%, and the highest outsourcing is observed in the toxicology research stage (about 70%) due to increasing complexity and pricing pressures. Within the clinical trials, highest outsourcing (~78%) is observed in data analysis, volunteer recruitment, medical supervision, data management, site selection and clinical supervision segments.

Exhibit 2.18: Outsourcing Ratio of Each Stage of New Drug Development, 2021



Source: Frost & Sullivan Analysis

Exhibit 2.19: Proportion of Outsourcing in Clinical Trials, By Segments, 2021



Source: Frost & Sullivan Analysis

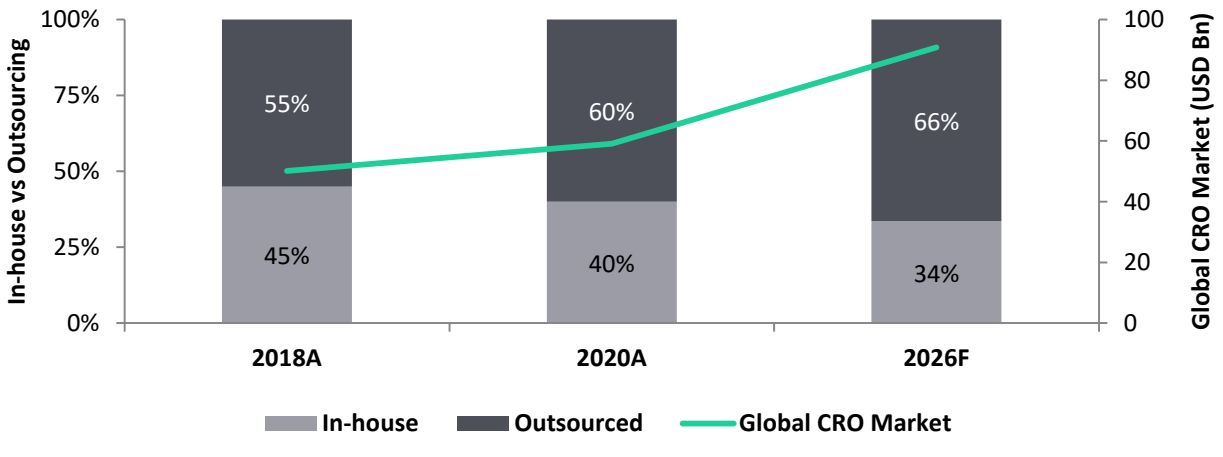
Outsourced portion of the discovery and preclinical activities captured by the CROs is expected to grow at 7% CAGR from 2021 to 2026: Discovery studies market is estimated to be USD 13.4 Bn, with 25% penetration rate, while preclinical development market is estimated to be USD 5 Bn in 2021, and 30% penetration rate. The discovery market is expected to grow in line with overall research spend, and the preclinical development market is expected to grow in line with overall development spend. Currently, about 95% of discovery and preclinical activities are outsourced by most small-to-mid segment pharma companies to boost profit margins, avoid high capital expenditure, and reduce the time duration to validate the process and product.

Rising number of patent loss drive the generic drug industry thereby creating an opportunity for the CRO industry: The global CRO market growth is contributed by the significant growth of the generic drug industry, which is driven by the rising number of loss of patents and exclusivities of innovator drugs. Around 56 drugs lost their patents between 2020 and 2022 and around 107 drugs are losing their patents from 2023 to 2025. As drug makers respond to the COVID-19 pandemic by developing vaccines and therapeutics, many of them are losing patent protection on older and once lucrative medicines. In 2021, expected losses of US exclusivity include Roche's macular degeneration blockbuster drug, Lucentis. Other top drugs to lose patent include Bystolic, Vascepa, Northera, Narcan, Brovana, Sutent, Saphris, Amitiza and Feraheme.

Summary of Outsourcing Trends in the CRO Industry

Overall, in a tougher drug development backdrop, as it relates to costs, timelines, probability of success, regulatory hurdles, and other variables, CROs have emerged as efficient providers of value-added services for pharmaceutical companies. As pharmaceutical companies focus on internal efficiencies and optimizing cost structures, CROs should benefit from increased outsourcing of research and development functions, as well as expanding service offerings, beyond traditional clinical work, that pharmaceutical companies may choose to outsource.

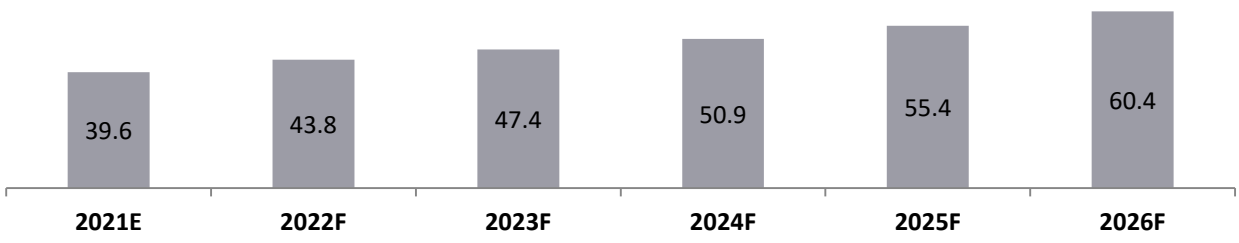
Exhibit 2.20: Global CRO Market, Penetration Rate, 2018–2026



Source: Frost & Sullivan Analysis

Thus, the growth of the global CRO market has been largely driven by the increased outsourced development spend by the pharma companies. It has also been influenced by the shift in the industry, with more companies focusing on rare diseases with unmet medical needs, areas where research is lacking historically and therefore a large R&D investment is required. Whilst the CRO market is expected to reach USD 90.8 Bn by 2026, outsourcing penetration is expected to increase to 66% by 2026, driving the overall growth of the Indian CRO market.

Exhibit 2.21: Global CRO Outsourced Market by Revenue, 2021-2026
USD Billion, CAGR (2021-2026): 8.8%

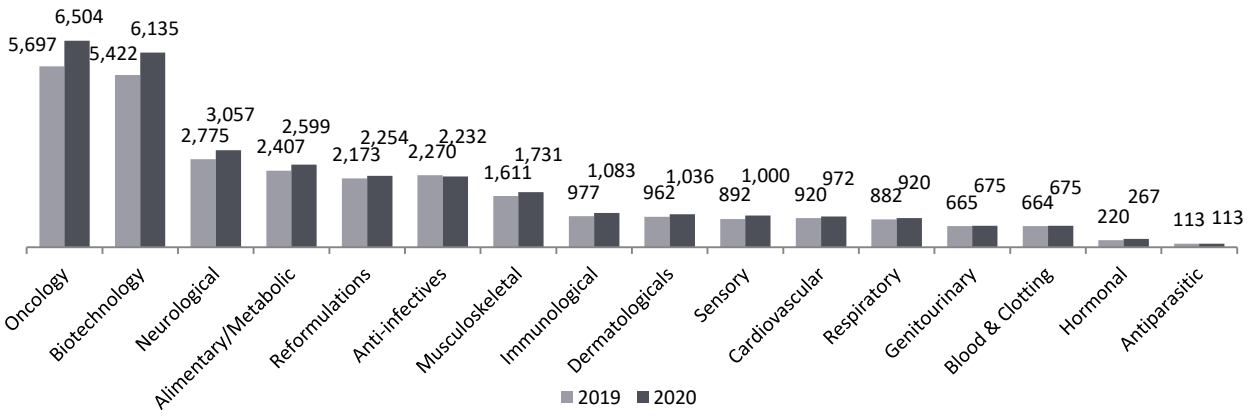


Source: Frost & Sullivan Analysis

Market Segmentation by Therapy Areas

Oncology emerges as the leader both in terms of R&D pipeline and number of clinical trials: With 6,504 drugs in R&D, cancer drugs capture 36.7% of the total share, and the total oncology therapy area has grown by 14.2%, outpacing the overall level of pipeline expansion. Drugs indicated for neurological diseases post fewer than half as many candidates, and show a modest increase, with a 10.2% growth rate. These two indications are followed by drugs for alimentary tract / metabolic diseases capturing a smaller portion of about 8% market share.

Exhibit: 2.22 Global R&D Pipeline by Therapy Areas, Drug Count, (2020)



Source: Frost & Sullivan Analysis

The table below shows the top indications by number of drugs in development in each region. Cancer and diabetes are the most commonly researched indication in the US, Asia, Canada and the EU.

Exhibit 2.23 Top indications by number of drugs in active development by region, 2020

Position/ Region	Africa	Asia	Canada	EU	Europe. Non-EU	Oceania	South America	US
1	Diabetes, type 2	Cancer, breast	Cancer, breast	Cancer, breast	Cancer, breast	Cancer, breast	Cancer, breast	Cancer, breast
2	Cancer, breast	Cancer, lung, non-small cell	Cancer, lung, non-small cell	Cancer, lung, non-small cell	Cancer, lung, non-small cell	Cancer, lung, non-small cell	Arthritis, rheumatoid	Cancer, lung, non-small cell
3	Infection, HIV/AIDS	Cancer, colorectal	Cancer, colorectal	Arthritis, rheumatoid	Arthritis, rheumatoid	Cancer, melanoma	Cancer, lung, non-small cell	Cancer, pancreatic
4	Arthritis, rheumatoid	Cancer, gastrointestinal, stomach	Cancer, leukemia, acute, myelogenous	Cancer, ovarian	Diabetes, type 2	Diabetes, type 2	Diabetes, type 2	Cancer, ovarian
5	Chronic constructive pulmonary disease	Diabetes, type 2	Cancer, ovarian	Diabetes, type 2	Crohn's disease	Cancer, leukemia, acute, myelogenous	Cancer, prostate	Cancer, leukemia, acute, myelogenous
6	Asthma	Cancer, liver	Cancer, myeloma	Cancer, leukemia, acute, myelogenous	Cancer, ovarian	Cancer, myeloma	Cancer, gastrointestinal, stomach	Cancer, myeloma
7	Haemopholia	Cancer, pancreatic	Cancer, renal	Cancer, Myeloma	Cancer, gastrointestinal, stomach	Cancer, pancreatic	Asthma	Cancer, liver
8	Infection, tuberculosis	Cancer, renal	Cancer, gastrointestinal, stomach	Cancer, gastrointestinal, stomach	Cancer, renal	Cancer, renal	Chronic constructive pulmonary disease	Cancer, gastrointestinal, stomach

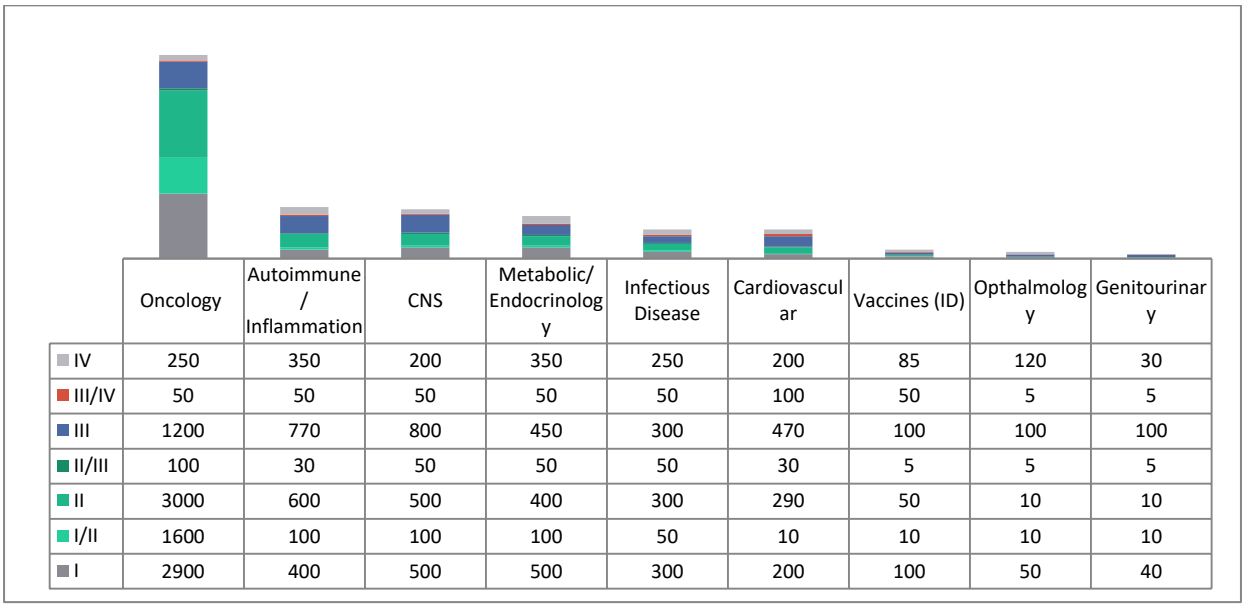
Key: Cancer | Alimentary/ Metabolic | Musculoskeletal | Respiratory | Infectious Disease | Blood & clotting

Source: Pharmaprojects, Jan 2020

Clinical trial landscape, by therapeutic area, 2020

The below chart clearly depicts that number of active trials for oncology and the concentration of trials in phase I and II.

Exhibit 2.24 Number of active trials by phase of development, 2020

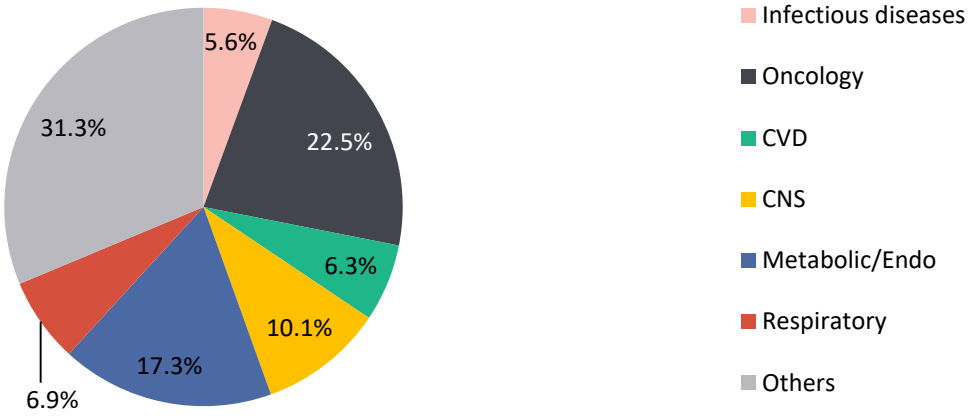


	Oncology	Autoimmune / Inflammation	CNS	Metabolic/ Endocrinology	Infectious Disease	Cardiovascular	Vaccines (ID)	Opthalmology	Genitourinary
IV	250	350	200	350	250	200	85	120	30
III/IV	50	50	50	50	50	100	50	5	5
III	1200	770	800	450	300	470	100	100	100
II/III	100	30	50	50	50	30	5	5	5
II	3000	600	500	400	300	290	50	10	10
I/II	1600	100	100	100	50	10	10	10	10
I	2900	400	500	500	300	200	100	50	40

Source: Pharmaprojects, Jan 2020

Global CRO Market (2021) = USD 63.9 Bn

Exhibit: 2.25 Global CRO Market Share by Revenue, by Therapy Areas (2021E)



Others include dermatology, ophthalmology, gastroenterology, immunology, musculoskeletal, orphan diseases

Source: Frost & Sullivan Analysis

Oncology leads the charts in terms of revenue, owing to a higher research focus on the segment in the form of CAR-T cell therapies and many other targeted immunotherapies. Icon is the leader in oncology trials with more than 40% of its trials focused on this area. Additionally, Covance, PSI CRO, and Medpace are other participants contributing to the clinical research in this area.

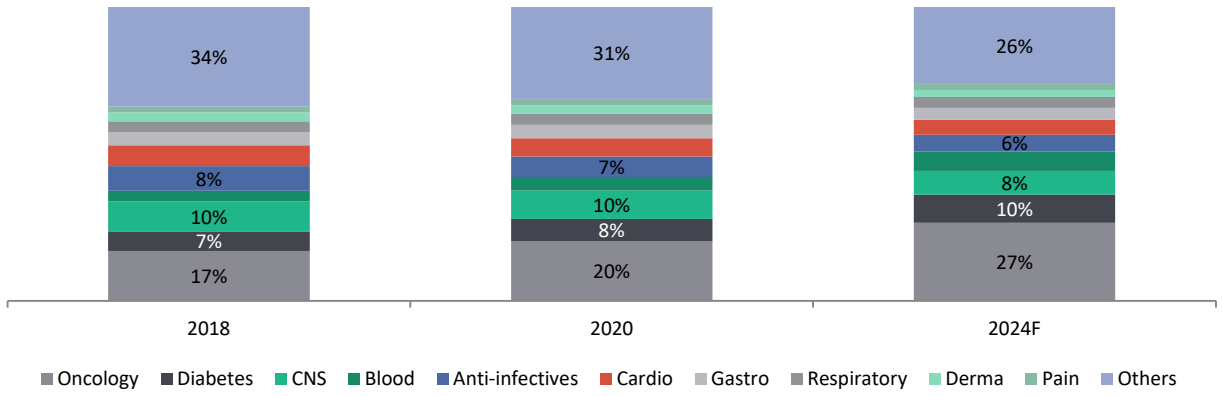
A high prevalence of metabolic conditions, especially in the APAC region, results in consistent efforts from industry participants, thus, contributing to a 17.3% CRO revenue share for the segment. On the other hand, a growing prevalence of neurodegenerative conditions, such as Parkinson‘s and Alzheimer‘s, and rising geriatric populations are contributing to the increased efforts toward drug development in the CNS segment. Syneos Health is a strong competitor in this segment, alongside small-to-mid segment participants, such as CROS NT and Veristat.

Additionally, with a consistent growth in CVD and infectious diseases globally, considerable focus on developing anti-infectives and cardiovascular therapies is observed, with several small-to-mid segment participants collaborating with CROs to develop newer treatment options.

Oncology is the largest and fastest growing therapeutic area (20% of Rx and OTC sales in 2020): The proliferation of immuno-oncology therapies is helping to drive greater R&D funding and alliances between CROs and pharmaceutical companies. However, there are critical hurdles in the development of immuno-oncology therapies that must be addressed including, identifying appropriate biomarkers to increase probability of success, clinical trial recruitment difficulties, reimbursement and commercialization that CROs could better address than pharmaceutical companies to increase returns on associated R&D investments. Spending on all oncology therapeutics totaled USD 230 Bn worldwide in 2020 (+12% from 2018), according to IMS Health, and

it is projected to exceed USD 300 Bn by 2026. This is partially reflective of growing adoption of newer, pricier therapies that are often more complex than older therapies, as well as an increasing numbers of patients receiving treatment for longer durations, which in turn benefits the CRO industry.

Exhibit 2.26: Global Prescription and OTC Sales by Therapy Areas, Market Share (2018 vs 2020 and 2024F)



Others: Genito-urinary, vitamins, sensory, hormones, anti-parasitic, electrolytes.

Source: Frost & Sullivan Analysis

COVID-19 has given an additional boost to the CRO Industry: With lockdowns and restrictions put in place by the Government and regulatory bodies due to COVID-19 pandemic, it became extremely difficult in running clinical trials and getting healthy volunteers for BA/BE studies. However, rising demand for drugs, vaccines, medical devices and test kits for COVID-19 infection and its complications, created a huge demand for CRO services amidst pandemic situation.

Global and Indian CROs have now been working on trials wherein drugs, vaccines and medical devices are being tested in COVID-19 patients. Easy access to patient population has created a huge opportunity for the Indian CROs in completing the trials early. The pandemic has also significantly fast tracked the regulatory approval timelines paving way for a higher growth of the CRO industry.

The vaccine development by domestic companies like Bharat Biotech has further propelled the Indian CRO industry. COVID-19 has also created the need to handle many aspects of the trials remotely, which has thus given rise to **increased adoption of remote monitoring of trials.** CROs like SIRO have adopted remote monitoring of trials which has enabled them to continue with their trials even in the middle of the pandemic. **Other services like eClinical solutions have also seen an upsurge.**

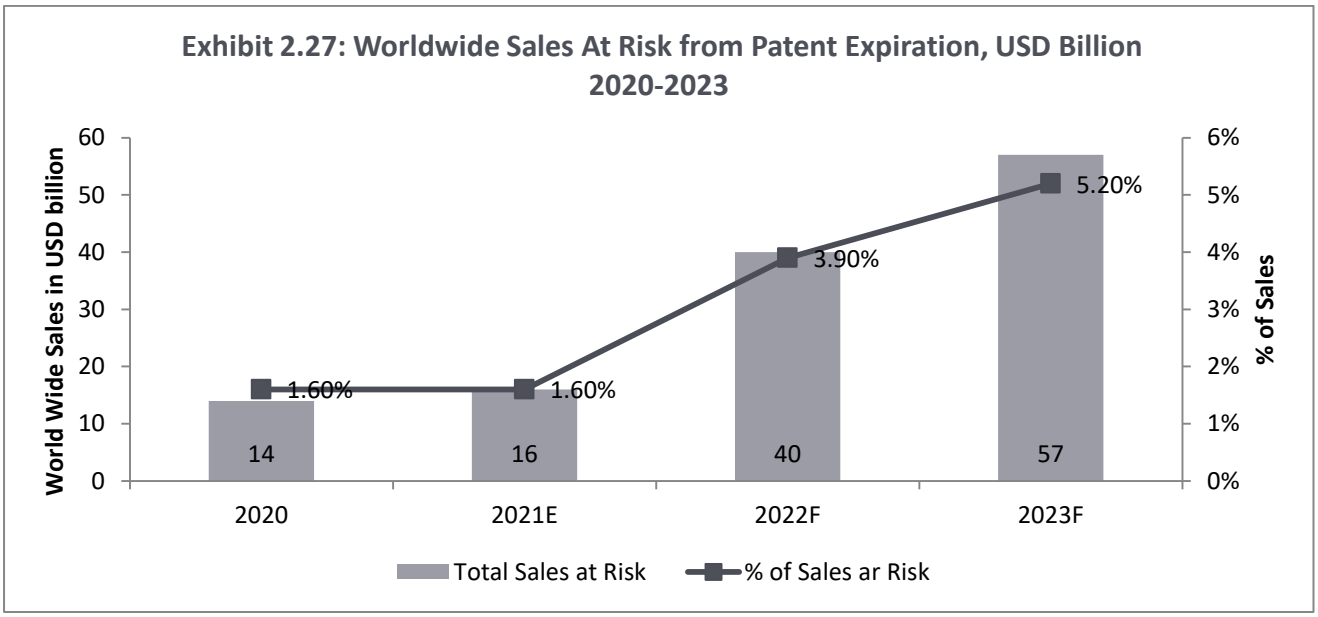
Overview of Generic Drug Industry Boosting the CRO Market

Rising number of patent loss drive the generic drug industry thereby creating an opportunity for the CRO industry: The global CRO market growth is contributed by the significant growth of the generic drug industry, which is driven by the rising number of loss of patents and exclusivities of innovator drugs. Around 56 drugs lost their patents between 2020 and 2022 and around 107 drugs are losing their patents from 2023 to 2025[1]. As drug makers respond to the COVID-19 pandemic by developing vaccines and therapeutics, many of them are losing patent protection on older and once lucrative medicines. In 2021, expected losses of US exclusivity include Roche's macular degeneration blockbuster Lucentis. Other top drugs to lose patent include Bystolic, Vascepa, Northera, Narcan, Brovana, Sutent, Saphris, Amitiza and Feraheme[2].

Bristol Myers Squibb's blood cancer medicine Revlimid will face limited generics after March 2022, under a patent settlement between the drug giant and Dr. Reddy's Laboratories. AbbVie's, Humira, the world's bestselling medicine, will face staggered biosimilar launches throughout 2023. Other examples include Novartis' Gilenya for multiple sclerosis, Sandostatin LAR for metastatic carcinoid tumors, Regeneron's macular degeneration drug Eylea and AstraZeneca's Symbicort.

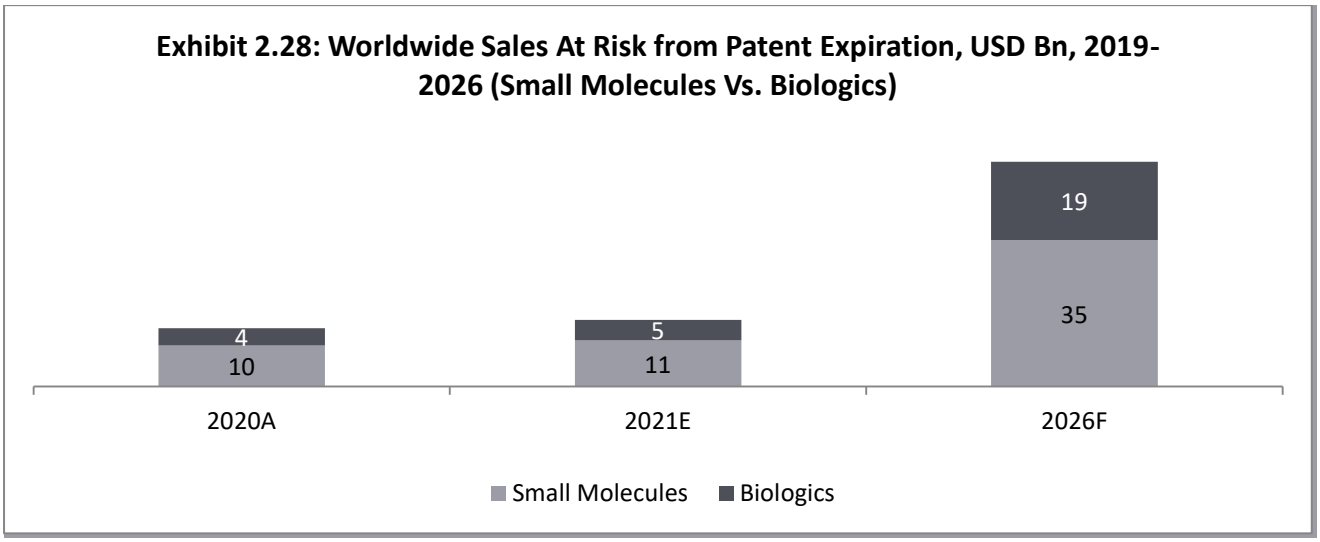
1. *Drug Patent Watch*
2. *https://www.fiercepharma.com/special-report/top-10-drugs-losing-u-s-exclusivity-2021*

Worldwide Sales at Risk from Patent Expiration (2019-2024): Patent loss of key biologics paves way for biosimilar industry and hence higher opportunity for BA/ BE Studies: Market estimates indicate that USD 198 Bn is at risk between 2019 and 2024, with 2023 set to see the expiry of key patents for a number of biologic drugs including Humira and Stelara. Additionally in 2025, USD 50 Bn prescription drugs would be at risk of losing patent and thereby sales.



Source: Evaluatepharma, Frost & Sullivan Analysis

USD 57 Bn of innovative drug sales under risk in 2023 paving the way for generics and hence more opportunity for BA / BE studies: High market erosion is expected in 2023, as nearly USD 57 Bn of innovative product sales are at risk due to patent expiration, followed by USD 40 Bn and USD 32 Bn in 2022 and 2024, respectively. This could be a promising opportunity for CROs globally as the pharmaceutical companies would opt for reducing their costs on R&D and clinical trials in order to survive the sales erosion phase. Thus, a high rate of outsourcing to CROs could be witnessed from 2022 to 2024.



Source: Drug Patent Watch, Frost & Sullivan Analysis

Patent expiration is expected to affect both small molecules and biologics; however, the proportion of small molecules losing patent would start decreasing from 71% in 2019 to 65% in 2026. On the contrary, the proportion of biologics losing patent is expected to increase from 29% in 2019 to 35% in 2026. Though, small molecules have higher market shares, the major impact of patent expiration are expected to be on the biologic molecules, leading to a rising demand for biosimilar development.

Market Restraints for the CRO players

- **Lack of sufficient talent pool** for R&D activities, especially in APAC and ROW regions and s**hortage of skilled personnel,** especially to conduct rare disease, specialty drug trials, as well as lack of understanding of local regulatory standards impacting the growth of the CRO market.
- **The regulatory mandates** of certain countries and specifically for some of the drugs, mandates the **clinical trials to be conducted in countries where the drug is intended to be registered**. Example: China, Japan etc. These mandates increase the cost and timelines thereby impacting the market growth.
- Despite emerging markets showing high potential, challenges such as a **decentralized regulatory landscape** and improper investigator experience impacts the market growth.
- **COIVD-19 and its impact on patient recruitment**: The impact of COIVD-19 has put the CROs into a hard situation as there is poor participation of healthy human volunteers for clinical trials to conduct bio-availability (BA) and bio-equivalence (BE) studies on approved drugs. COVID-19 has also created a huge pressure on CROs to complete the trials more rapidly and accomplish greater precision. An estimated 50% of companies have paused recruitment for the majority of clinical trials with approximately 75% pausing site activation as the focus of trials has now shifted to COVID-19 vaccines and drugs. However, clinical trials for other drug candidates have begun to display signs of resumption since end of 2020.
- **Patient recruitments and retention:** Challenges in patient recruitment and retention, with about 30% drop out rate, impacts the overall trial outcomes and timelines.
- **Higher complexity of protocol design**, owing to a growing focus on developing complex therapies, impacts the overall study execution in a timely manner.
- **High cost of conducting clinical trials** (around USD~1 billion) imposes a burden on small-to-mid tier participants, causing payment delays for trial sites.
- **Direct competition from specialized patient recruitment and clinical trial service providers** can cause a potential reduction in CRO penetration in the pharma industry.
- Relying on multiple CRO partners by sponsor companies leads to a **disintegrated sponsor-CRO relationship.**

Summary of Key CRO Industry Trends

- **APAC to lead the future global clinical research landscape, currently dominated by North America and Europe:** Across regions, North America and Europe will continue to dominate the global CRO industry, as majority of the participants are present in these regions. However, Europe has surpassed North America in the number of clinical trials offering cost-effective and advanced drug development solutions with a rise in small-to-mid tier participants in the region. Additionally, Eastern Europe and APAC regions are expected to lead the future clinical research landscape, owing to cheaper costs and availability of larger patient pools, thus, ensuring higher probability of timely completion of trials.
- **Growth in outsourcing penetration to up to 66% by 2026:** While greater reliance on predictive analytics is leading to a gradual decline in clinical research activity Year on Year (YoY), there will be a simultaneous growth in outsourcing penetration to up to 65% to 66% by 2026, resulting in an 8.8% growth in the global CRO industry.
- **Rising trend of outsourcing of preclinical activities to CROs:** A large number of novel NDAs are mainly filed by small innovator companies and there is a rising trend of outsourcing of preclinical studies to CROs by these companies as a cost saving strategy. The shorter and less costly regulatory pathway provides incentives, especially for smaller specialty pharma.
- **Generic CRO industry expected to grow faster due to patent cliffs:** The global CRO market growth is contributed by the significant growth of the generic drug industry, which is driven by the rising number of loss of patents and exclusivities of innovator drugs. Around 56 drugs lost their patents between 2020 and 2022 and around 107 drugs are losing their patents from 2023 to 2025. Market estimates indicate that USD 198 Bn is at risk between 2019 and 2024, creating opportunities for CRO industry.
- **Biosimilars on the rise; creating opportunities for CROs:** In the next five years, pharmaceutical industry will be seeing a new wave of patent expirations which will give rise to development of biosimilars, bio betters and bio-generics. This trend creates opportunities for CROs in both preclinical and clinical services segments. CROs and CMOs are becoming more involved in the development of biosimilars due to their expertise in and streamlining of the research, development, manufacturing, and up-scaling of biologic products.
- **Rise in consolidation of the industry:** Emergence of novel biologics in the form of regen-med and mAbs, calls for improved early-stage drug testing activities (e.g., bio-analytical testing). As a result, the market is expected to continue on its consolidation spree, with several large and mid-tier participants mutually collaborating to gain early-stage drug development expertise.
- **Quicker time-to-market model:** CROs are now positioning themselves as end-to-end solution providers making their services more cost effective, time saving and offering services across the value chain. Thus, participants are resorting to M&A activities to gain access to specific service portfolios, such as preclinical development and bio-analytical testing.
- **Expansion of therapeutic focus:** Alongside oncology, CROs are broadening their focus to grab emerging opportunities in neurology, metabolic therapies, and cardiovascular therapies catering to small-to-mid segment pharma participants.

- **Growing focus on data analytics and IT-enabled services:** With predictive analytics solutions capable of predicting the success rates of trials, a higher demand for technology implementation is imperative for the CROs to implement in their portfolio of services.
- **Disruptive business models; virtual and adaptive trials on the rise:** Emergence of embedded/integrated business models alongside the development of newer trial designs, such as virtual and adaptive trials, is altering the clinical research paradigm across the CRO industry.
- **Increased adoption of virtual trials and eClinical solutions:** While COVID-19 has certainly challenged CROs in administration of on-site activities and clinical trials; it has also fostered heightened innovation and implementation of effective remote technology. Virtual trials and eClinical solutions have gained increased adoption as CROs seek creative options for decentralized management of clinical trials. In 2021, 57% of CROs expect to adopt or increase technology in order to expand patient reach and engagement.
- **Strong funding support for biotech companies:** Considerable rise in small pharma/ biotech funding is a tailwind for quality CROs, as these companies typically outsource 100% of their R&D. With a record USD 7.1 Bn raised in the first quarter of Q1 2021, the cash available to private drug developers shows no signs of drying up. Multiple sources of biotech funding provide easy availability of capital for funding R&D needs. Biotech continues to benefit from a robust funding environment from capital markets/ IPOs and VCs. Some examples are stated below:

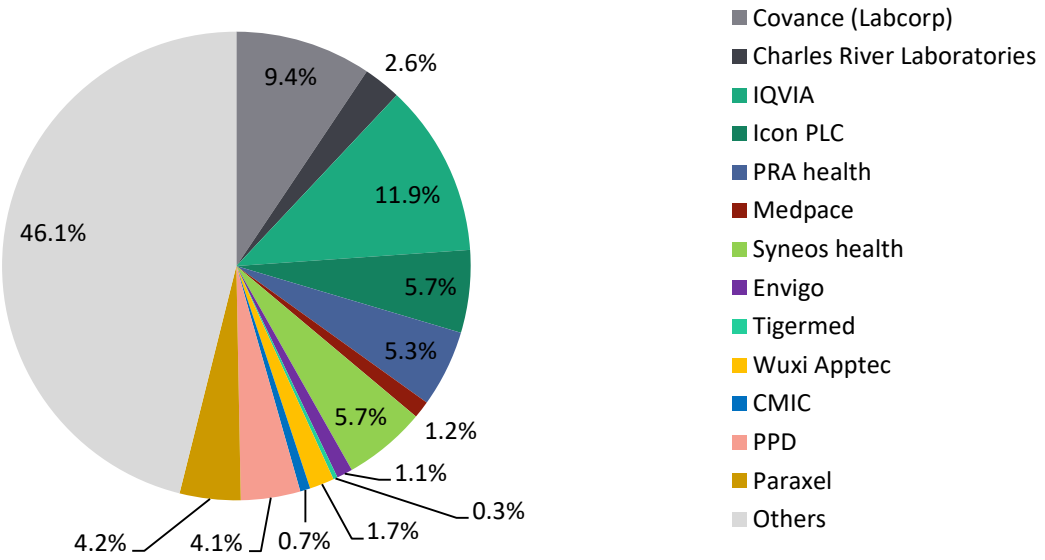
Top five rounds of Q1 2021			
Company	**Investment (USD Mn)**	**Financing round**	**Description**
Elevatebio	525	Series C	Cell and gene therapy researchers and company incubator
EQRx	500	Series B	Development of affordable medicines, oncology initial focus
Centessa Pharmaceuticals	250	Series A	Asset-centric developer created from merger of 10 private biotechs
Clover Biopharmaceuticals	230	Series C	Chinese developer of vaccines
Affinivax	226	Series C	Infectious disease researcher with phase 2 pneumococcal project

Source: Evaluatepharma

- **Positive impact of COVID-19 on drug approval timings:** CRO industry has expertise of quicker recruitments and conducting trials at shorter timelines; with COVID-19 experience, regulators such as US FDA are approving drugs at record a rate, which is a tailwind and may continue for the next few years.

Global CRO Competitive Landscape

Exhibit 2.29: Global CRO Market Share of Key Competitors, 2020



Source: Frost & Sullivan Analysis

*Others include Pharmaron, PPD, Piramal Health, KCR CRO, Novotech CRO, MD Biosciences, Shanghai Chempartner, Orphan Reach, Synteract, and Clinipace

Summary of Key Players in the Preclinical and Clinical Development:

Preclinical (USD 5.2 Bn)	
Charles River 17% Share	CRL focuses on preclinical research and development, and has the broadest library of research models (over 150 strains), with higher utilization than other early-stage CROs (at about 85% compared with the broader industry at approximately 75%), due to its focus on operating efficiency.
LabCorp (LH) *14% share*	Through its acquisition of Covance in February 2015, LabCorp expanded into the preclinical (specializes in toxicology and chemistry) and clinical development markets, both areas of the R&D process that Covance historically operated in, along with a central laboratory.
Envigo *5% share*	Following its acquisition of Huntingdon Life Sciences and Harlan Laboratories in June 2015, Envigo now offers a comprehensive range of drug development and environmental sciences services, as well as an animal model library second only to CRL.
Pharmaceutical Product Development (PPD) *1% share*	PPD offers specialized consulting globally for nonclinical pharmacology/toxicology, chemistry, manufacturing and controls (CMC), as well as Phase I clinical research services that includes conducting complex, procedurally intensive research, along with a range of other services.
Clinical (USD 39.8 Bn)	
Quintiles/IQVIA (Q) *13% share*	Quintiles/IQVIA is the world's largest contract research organization, focused on Phases II-IV clinical trials, as well as associated laboratory and analytical services. Its diverse customer base includes the 20 leading pharmaceutical companies.
Pharmaceutical Product Development (PPD) *8% share*	PPD is one of the largest global CROs, providing discovery, product development, including clinical testing, laboratory services, biostatistical analysis, regulatory services, clinical trial and data management, and post-approval services.
PAREXEL (PRXL) *7% share*	PRXL is the world's second largest public CRO, providing solutions across the entire drug development and commercialization spectrum. Its informatics business offers integrated platforms/applications and clinical data services, while it's consulting business offer more flexible solutions.

PRAHS *6% share*	PRAHS conducts clinical trials across all phases of clinical development globally, with services across all stages of the clinical development process, offering both project-based services for Phases I through IV as well as functional outsourcing services through its Strategic Solutions Group.
ICON (ICLR) *5% share*	ICON provides services across all stages of the clinical development process, from compound selection to Phase I-IV clinical studies, with the bulk (approximately 70%) of its business focused on late stage (mostly Phase III) development.
inVentiv *4% share*	inVentiv provides clinical services across Phases I-IV, as well as commercial services, including selling solutions, communications, medical adherence, and consulting. It is one of the few, large, global CROs that cover the entire clinical and commercialization cycle.
INC Research (INCR) *4% share*	INCR operates primarily in the clinical development market, with nearly all (98%) of revenues stemming from services for Phases II-IV. The company has expanded its capabilities and services organically and through acquisitions, closing 11 transactions since 2001.
LabCorp (LH) *4% share*	LabCorp operates the world's largest reference laboratory, and with the addition of Covance in 2015, LabCorp now provides clinical trial services across preclinical and clinical development, as well as some commercialization services, such as consulting and selling solutions.
Medpace *1% share*	Medpace provides services across Phases I-IV clinical trials, as well operating a central laboratory. It operates a full service, integrated model, and focuses on small and mid-sized pharmaceutical companies globally.
Chiltern *1% share*	Chiltern is a global mid-sized CRO, focused almost exclusively on clinical trial services, with a strategic service provision as well. Its services include clinical development, clinical supplies, data and analysis, medical, regulatory and pharmacovigilance services.
PSI *1% share*	PSI is a full-service CRO specializing in on-time delivery of clinical studies. PSI offers a range of services that supports all clinical trials from Phase II to Phase IV, including feasibility, medical writing, trial support services, and statistics, among others.

- In the CRO market, the first-mover advantage of CRO industry is very important.
- The CRO industry is characterized by the low threshold for enterprises but difficult to become an integrated service provider for large pharmaceutical enterprises.
- Overseas and domestic CRO market pattern shows that about 10 large CROs account for 50% of the market share, while the remaining 50% of the market is occupied by hundreds of small and medium sized CROs.

Revenue and Business Layout of Global CRO Enterprise

Company	Year of foundation	CRO Revenue in 2018 (billion $)	Preclinical				Clinical		
			Pharma Discovery	Pharma Trial	I Period	II Period	III Period	Central Laboratory	IV Period
Quintiles	1982	5.5		√	√			√	
Covance	1989	2.7	√	√	√	√	√		√
Syneos	1982	1.5		√	√	√	√		
PRA	1976	2.1		√	√	√	√		
Paraxel	1985	2		√	√	√	√		
Charles River	1947	1.8	√						
PPD	1885	1.	√	√	√	√	√		
ICON	1990	1.8		√	√	√	√		
WuXi Apptec	2000	1		√	√	√	√	√	√

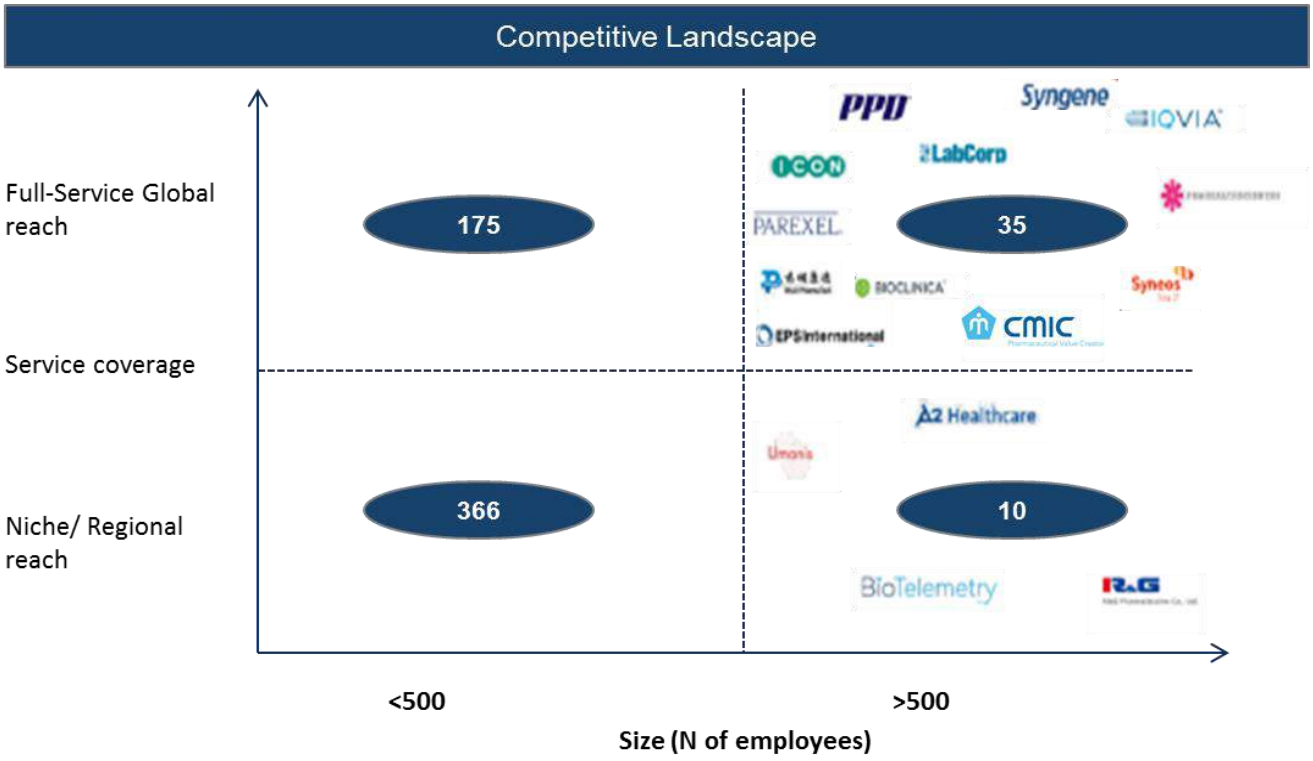
Source: Frost & Sullivan Analysis

Competition Pattern of Global CRO:

North America (48% market share) and Europe (33%) still occupy the main share of the CRO market: Due to the offshore outsourcing feature of the CRO industry (mainly preclinical), the CRO market in developed countries continues to shift to the low cost Asia Pacific region (15%), where the CRO market is growing rapidly.

Significant scope for consolidation globally: While, top 13 CROs have 54% market share by value, there are over 1,000 CROs with less than 500 employees, which represent 92% of the total number of CROs globally. Most of the large CROs like LabCorp, IQVIA offer full services for global coverage, while small CREs offers niche services and regional coverage.

Competitive Landscape:



Source: Frost & Sullivan Analysis

Clinical CRO Market: Key Players, By Regions, 2021

Key Players	USA	Europe	APAC	RoW	Global
IQVIA	17%	12%	10%	9%	11.9%
Syneos	12%	8%	10%		7.5%
Covance	11%	9%	9%	9%	9.4%
Charles River	5%	3%	2%	1%	2.6%

Parexel	9%	6%	6%		5.3%
Icon	2%	12%	8%	1%	5.7%
Wuxi			7%		1.7%
Others	45%	50%	48%	81%	55.9%

- **IQVIA is the market leader**, with 11.9% market share, followed closely by Covance (9.4%). Envigo, which is now a part of Covance (Labcorp), supported the market growth with its early-stage and preclinical expertise.
- The **recent merger of Inventiv Health and INC research** resulted in the formation of Syneos Health (5.7%), **making it one of the top 3 participants** in the CRO industry.
- **Icon plc dominates the oncology trial landscape** with a strong presence in certain specialty trials (e.g., CAR-T cell therapies), thereby positioning itself as a strong participant in the industry.
- Furthermore, **Parexel,** despite capturing a smaller share is among the very few CROs, including IQVIA, with **in-house digital solutions for clinical trials**, thereby establishing itself as a leading provider of digital clinical trial solutions.
- **PPD stands out in the competition owing to the launch of their Accelerated Enrollment Solutions (AES) business unit**, which focuses mainly on the patient centricity when recruiting patients for trials.

SECTION III: CHINESE CRO SUCCESS STORY AND GLOBAL M&A TRENDS

Chinese CRO Success: A Case Study

Along with WuxiApptec there are many players in China who have been benefited from regulatory reforms made by the Chinese Government.

The Chinese government has made certain regulatory reforms to increase trial site availability and address the growing demand for BA/BE studies.

Earlier Regulation

- CFDA would certify sites to conduct trials based on disease, condition, or drug type. Only such CFDA accredited hospitals could perform trials in China.

Revised Regulation

- CFDA will no longer issue accreditation to clinical trial sites and will instead allow any sites that meets the protocol criteria to conduct a clinical trial after submitting a notification to CFDA
- To maintain site quality, the site must pass inspection and auditing before resulting trial data will be accepted by CFDA

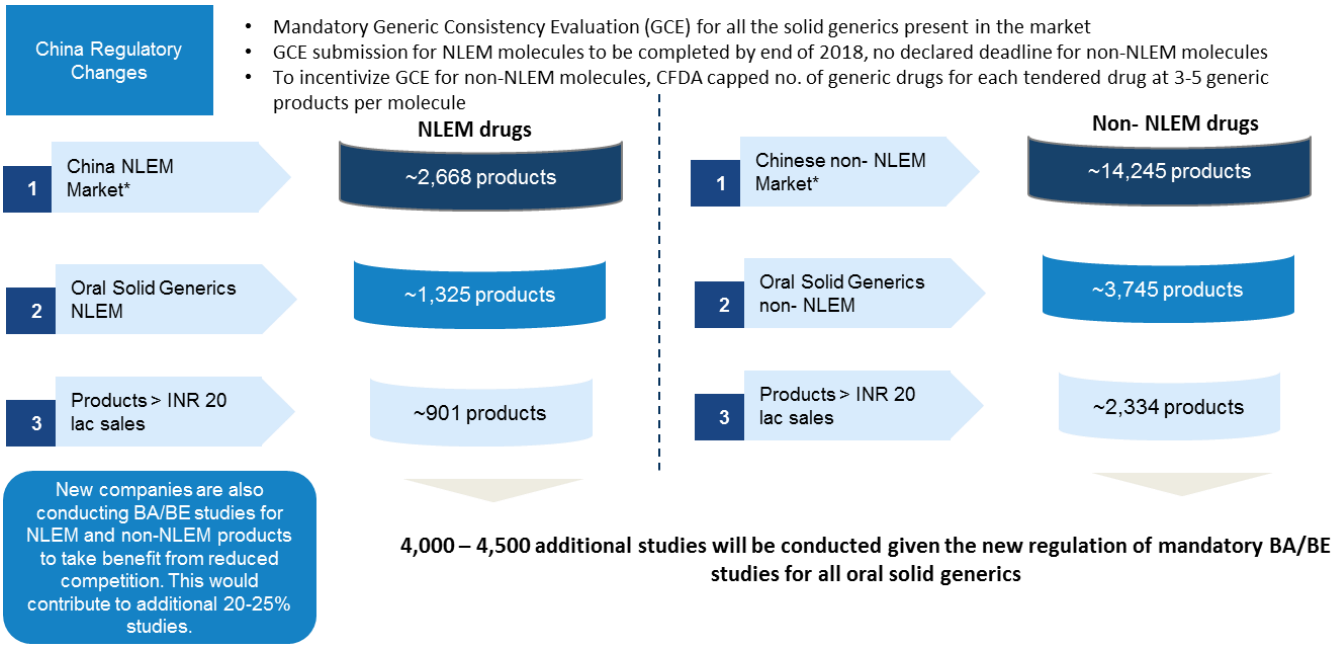
With new regulations, China will be able to expand its network of clinical trial sites and remove current time delays experiences by sites awaiting CFDA accreditation

Across provinces, the number of hospitals performing BA/ BE trials are higher than the number of CFDA certified sites

Province	# of sites	# of CFDA certified sites
Beijing	22	19
Jiangsu	15	10
Shanghai	12	10
Guangdong	6	5
Hunan	10	7
Liaoning	6	5
Tianjin	8	7
Zhejiang	5	4
Shanxi	4	4
Sichuan	5	4
Shandong	5	4
Others	31	26
Total	129	105

Source: Frost & Sullivan Analysis

Mandatory BA/BE for all generic drugs in China have created a market of ~ 4,000 BA/BE studies over the next five years (2021 to 2026)

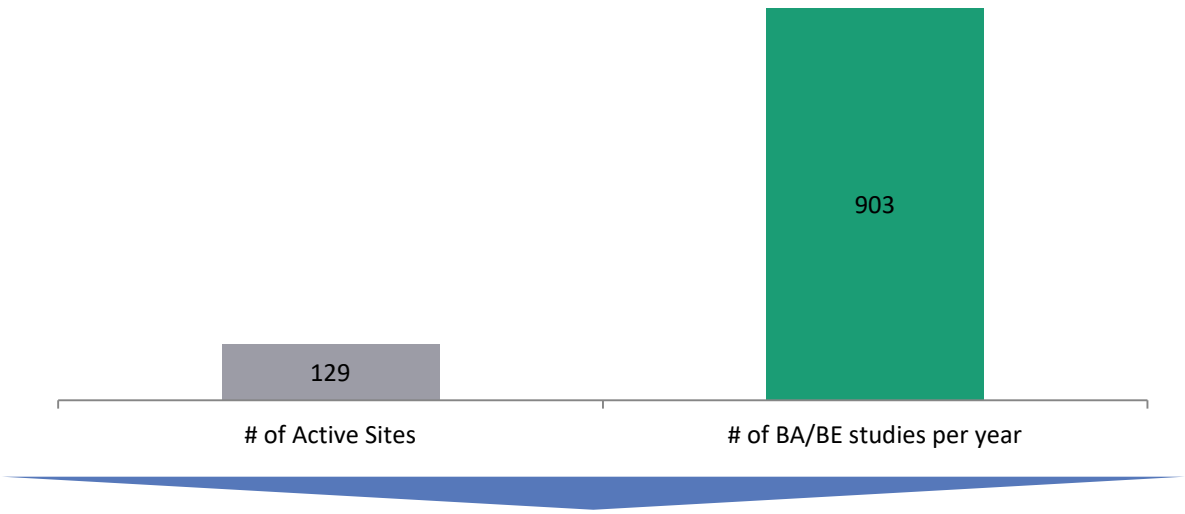


4,000 – 4,500 additional studies will be conducted given the new regulation of mandatory BA/BE studies for all oral solid generics

Source: Frost & Sullivan Analysis

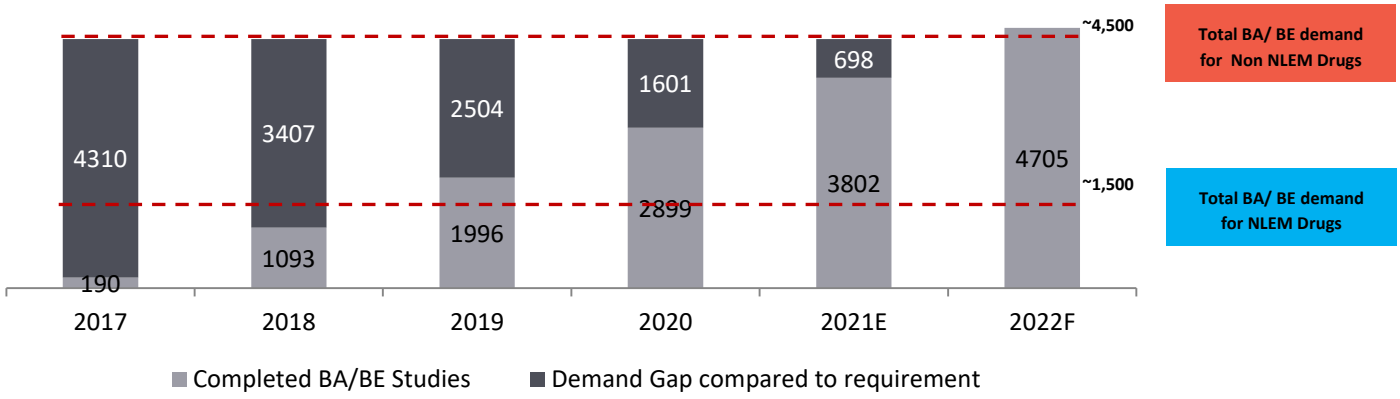
The current capacity is not sufficient to meet the immediate demand and China would be able to address the total demand over the next 4-5 years: Currently there are ~130 active BA/BE sites in China which could conduct ~900 BE studies per year. At current capacity the total demand for additional BA / BE studies in China would be addressed by 2022.

Exhibit 2.33 Number of BA/BE Studies Conducted in China, 2020



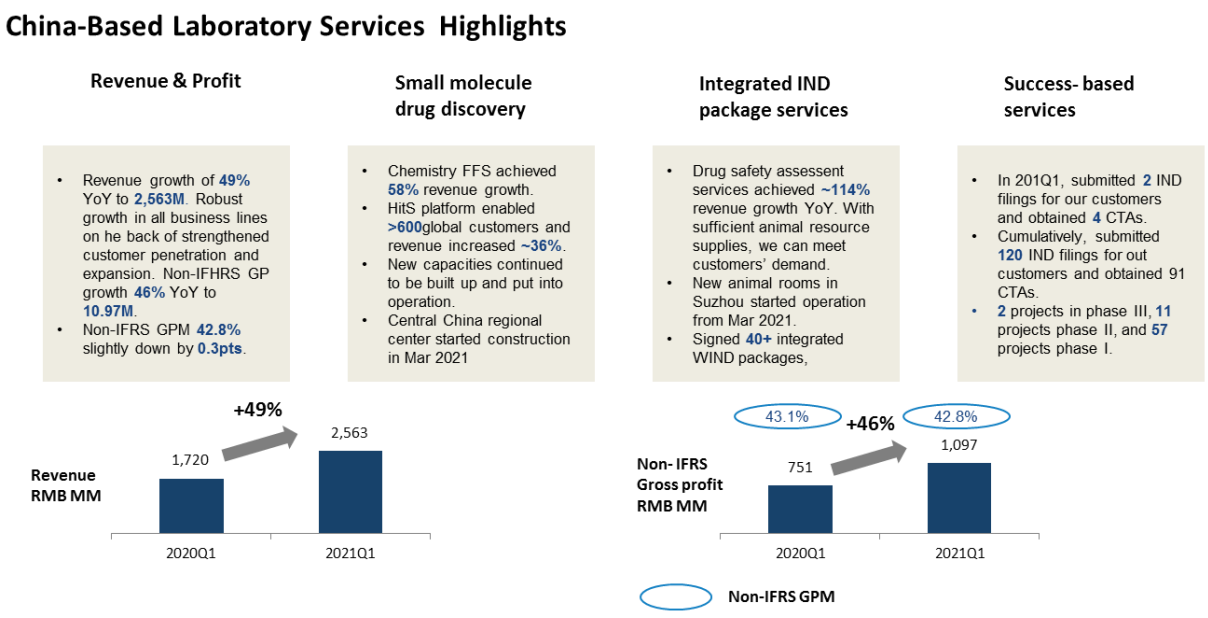
Source: Frost & Sullivan Analysis

Exhibit 2.34 Current Gap in BA/BE studies versus existing demand, 2020



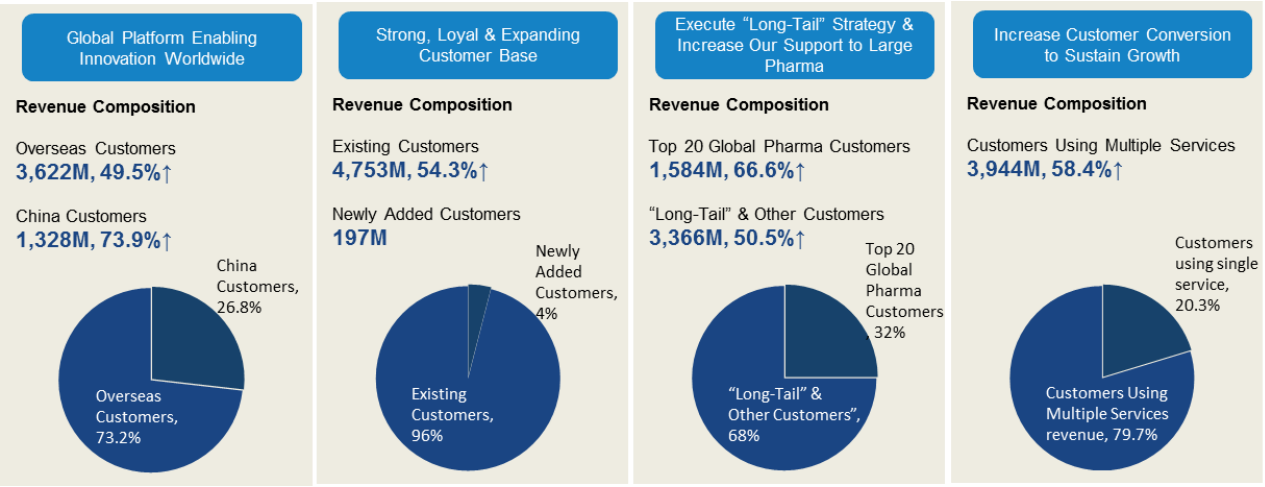
Source: Frost & Sullivan Analysis

- The regulatory reforms in China has encouraged its CROs perform better and this has led to increase in revenues.
- Owing to the eased regulations, the infrastructure of many CROs is expected to upgrade.



Source: Frost & Sullivan Analysis

- WuxiApptec, an end-to-end solution provider, has a smaller share of the global market. Owing to its stronger presence in the APAC region, the company focuses specifically on bio-analytical testing and lab-testing solutions.
- WuxiApptec's Platform and Business Model Continues to perform well



Source: Frost & Sullivan Analysis

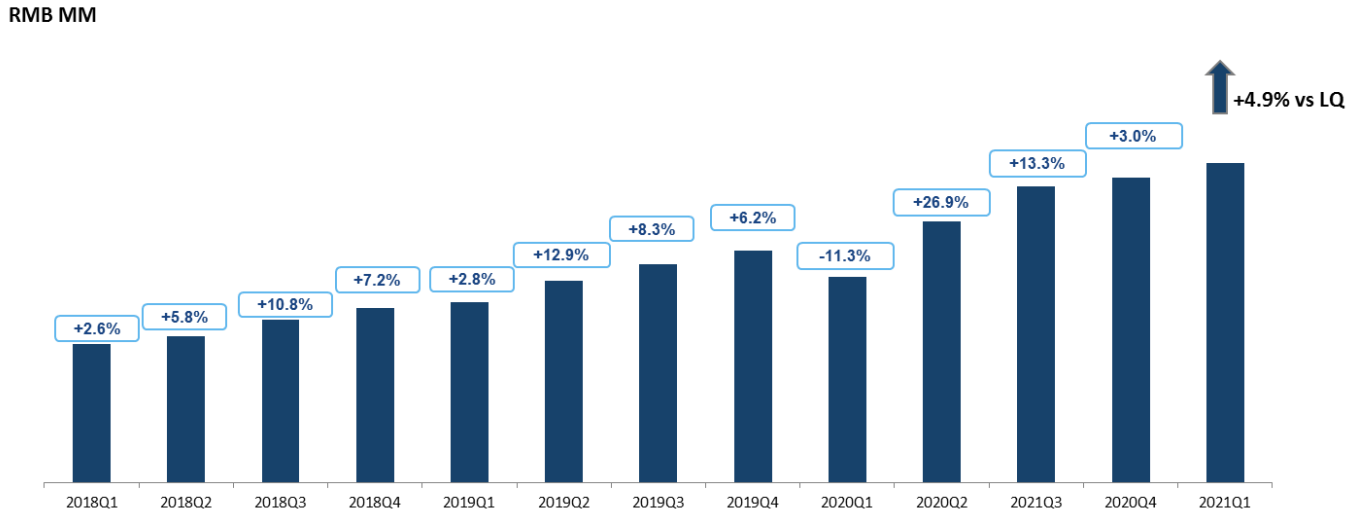
The Company has excellent PE ratio of 85.63, and investors are expecting higher earnings in the future compared to other companies

Market Capitalization of the company	
Parameters	Values
Market Cap	CNY 363.708 Billion

PE Ratio	85.63
EPS	1.74

The company has exhibited a consistent growth Q-o-Q, even during the time of pandemic execept Q1 2020.

Consistent Track Record of Setting New Records Quarter After Quarter



Source: Frost & Sullivan Analysis

Case studies of value creation in CRO space in Asia:

- **Partnership with pharmaceutical companies drives growth of integrated CROs:** Integrated CROs provide the partners with creative structures, such as risk sharing, with a one-stop services platform; for example, the joint venture between Wuxi AppTec and AZ/MedImmune for the development, manufacturing, and commercialization of novel biologics, or the ShangPharma partnership with Jiangsu Hengrui Medicine for the development of mAbs.
- **Drug discovery partnerships drive growth of niche CROs:** Niche CROs prefer a traditional fee-for-service model for their specialty offering, although they are also attempting to establish strategic drug discovery partnerships to support novel product development. Examples include the 3D BioOptima partnership with BeiGene to provide a dedicated **preclinical DMPK service to support new anticancer drug candidates**, including the second-generation BRAF inhibitor BGB-283, which BeiGene out licensed to Merck-Serono.
- **Collaborations for providing broader range of services:** There are increasing collaborations among niche CROs to help provide broader offerings for customers. One such example is the **strategic partnership between Viva Biotech,** with strengths in structure-based drug discovery, and HitGen, a hit identification and lead generation CRO, **to provide customers with full range of drug discovery services.** By following the similar trend in Asian countries like China, Indian players like ACG, a provider of integrated pharmaceutical manufacturing solutions, has purchased a significant stake in India-based CRO IQGEN-X. **ACG's strategic**

investment augments its technical expertise, portfolio strategy and corporate vision to create a robust portfolio of limited competition complex products for regulated markets.

Collaboration with Pharmaceutical Companies:

- Whether international or domestic, **leading CROs and large pharmaceutical companies are usually closely related.** At present, overseas leading CRO enterprises and large pharmaceutical enterprises have been working together for more than 20 years.
- **In China**, the co-operation between CRO and large pharmaceutical companies is lesser than that of overseas, but the **number of cooperation cases has increased rapidly in recent years**, and there is also cooperation with international pharmaceutical companies, like Lilly, AstraZeneca.
- **Cooperating with pharmaceutical companies can ensure the quality of research and development services** reduce the risk of intellectual property rights and further enhance barriers of the industry.
- **Examples of CRO/pharma collaborations in India include: Collaboration of Icon and Parexel with Pfizer, INC research with Astellas, Covance with Sanofi, Covance and IQVIA with Takeda, Parexel with Lilly and Veeda with Novartis for bio-analytical testing.**

Strategic Cooperation Between Large Pharmaceutical and CRO Enterprises

	CRO Company	Pharmaceutical Companies	Cooperation Start Time
China	WuXi AppTec	Zhongsheng	2015.7
		Eli Lily	2015.11
		CCTQ	2016.1
		GLORIA Pharma	2015.5
		Ganlee	2016.8
	Joinn Lab	AstraZeneca	2015.1
		Hansoh Pharma	2017.6
		Asymchem	2018.6
	Tigermed	AstraZeneca	2019.7
Overseas	IQVIA	MSD	2013.5
		Ascendancy Health	2013.7
		Biogen Idenc	2014.4
	Syneos	Astellas	2012.4
		Elligo	2018.6
	PPD	Elan	2011.2
		Sellas	2015.2
	PRA Health	Amgen	2012.4
		Takeda	2016.9

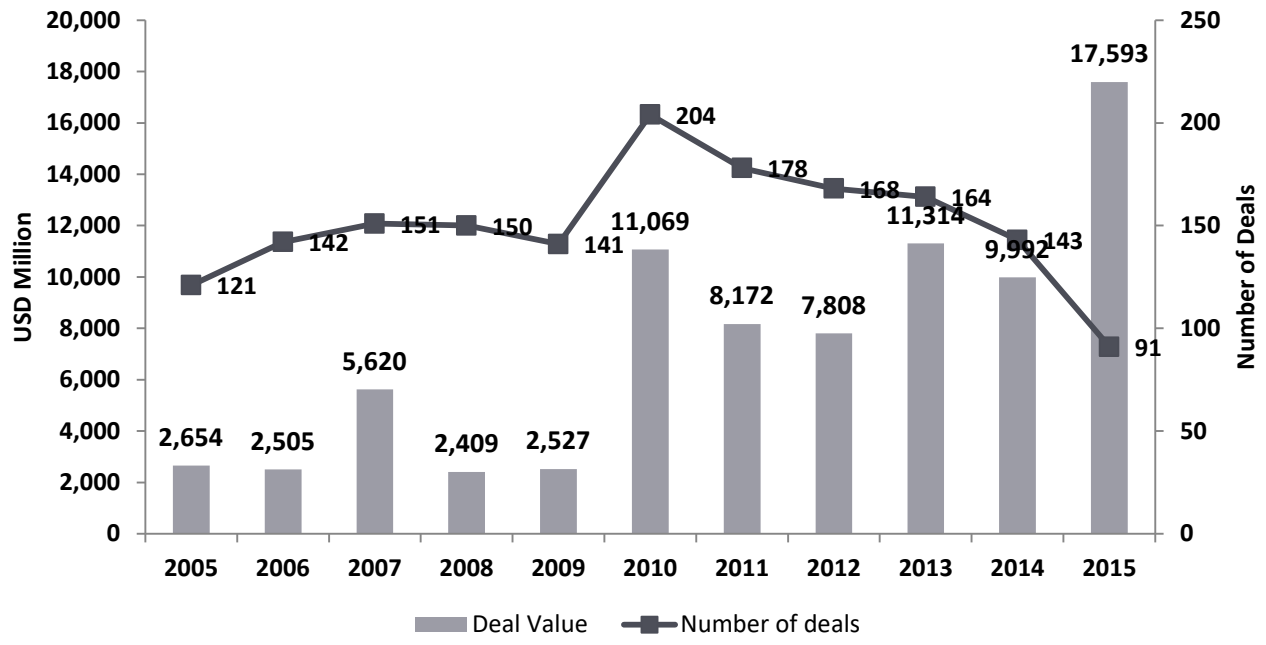
Source: Secondary Research, Frost & Sullivan Analysis

Global M&A Trends in the CRO Industry and Success Stories (Case Studies)

Globally, CROs have created value through consolidation: As of October 2015, the number of pharmaceutical outsourcing deals decreased by 36.4% from 143 in 2014 to 91 in 2015. However, deal values skyrocketed by more than 76% from USD 9.9 Bn in 2014 to nearly USD 17.6 Bn in 2015. This value was driven from both clinical trial and contract drug manufactures.

The chart below shows the total number of deals and deal values in the pharmaceutical outsourcing services sector from 2005-2015:

Exhibit 2.35: Pharmaceutical Outsourcing Deals, 2005-2015



Source: Secondary Research, Frost & Sullivan Analysis

While, the above graph highlights the deals till 2015, the largest 2 deals around USD 30 Bn were signed in 2020-2021. Examples: Thermofischer's acquisition of PPD for USD 47.5 Bn and ICON's acquisition of PRA for USD 12 Bn.

Some of the examples of high-valued transactions include LabCorp's USD 6.1 Bn purchase of Covance, and WuXi being sold for USD 3.3 Bn to a Chinese private equity group. Other examples like Siegfried Holding AG, an API company based in Switzerland, bought BASF's pharmaceutical supply business, and Lannett acquired Kremers Urban Pharma (a subsidiary of UCB), a specialty generic drug maker for USD 1.2 Bn, increased the deal size by more than 100% between 2014 and 2015.

Key Trends:

- **The emergence of strategic partnerships; a shift in the CRO business model:** There is no one size fits all solution for outsourcing. Developing long-term strategic partnerships that are increasingly more individualized and customized in nature have become an essential aspect of CRO offerings, particularly as **strategic partners are increasingly focused on breadth of services** as part of a larger effort to reduce the number of service providers and drive incremental development efficiencies, while leveraging the broader, full-service capabilities, and therapeutic and regulatory expertise, as well as the increasing flexibility that CROs are able to provide.
- **85% of pharmaceutical executives viewed strategic partnerships to be positively impacting the CRO-sponsor relationships.** However, sponsors still prefer multiple primary vendors to maintain a rational, competitive environment. The emergence of these strategic partnerships is expected to continue, disproportionately benefitting larger CROs with the necessary size, scale, and geographic footprint, making it more difficult for smaller, more specialized CROs to successfully compete against their larger competitors. This will further support a continuation in industry consolidation, as larger players continue to add to their global footprint, enhance their capabilities, and expand their service offerings.
- **Hybrid outsourcing models that combine technology with functional outsourcing** are also increasingly common, further supporting the view that technology investments are critical to remaining competitive. As a result of this dynamic, clients become more embedded in and reliant on a provider's cohesive full-service solutions, which contributes to the strategic partnerships being long term.
- **Consolidation of CROs:** Consolidation across the CRO industry has increased, leaving only a handful of larger CROs with the global scale and infrastructure, therapeutic and development expertise, capital, and technical resources to manage the demanding drug development programs of pharmaceutical and medical device companies. **The pace and scale of acquisitions has accelerated,** as CROs expand their addressable opportunity through more comprehensive solutions, and while continued consolidation of the CRO industry is expected to continue, focus will likely shift more towards targeted ancillary services, technologies, and geographies where the synergies are potentially greater.
- **Greater investments in technology and big data:** A major industry theme following the merger of IMS Health and Quintiles, technology and big data investments are an important focus across the industry, which serve to enhance the overall CRO offering and improve their value proposition to pharmaceutical companies of outsourcing a greater portion and variety of their R&D and commercialization-related activities. CROs are also increasingly leveraging data from wearables to help improve the quality and efficiency of trials, and investments in these areas (technology and data) can be differentiators for CROs as the industry evolves.
- **Bolstering late phase and commercialization capabilities:** Larger clinical CROs are expanding their capabilities in post-approval and commercialization solutions, as their pharmaceutical partners continue to place increasing value on a broader service offering. With an increasingly retail/consumer-centric focus across the pharmaceutical supply chain, commercialization efforts often begin in the development process, and there are significant synergies that can

be captured by successfully integrated clinical and commercial functions, better aligning the marketing and sales practices. An increasingly complex payor landscape will also serve to support CROs' increased focus on post-approval services. Recent transactions in this area include ICLR's acquisition of Aptiv (May 2014) and MediMedia (February 2015), PRXL's acquisition of HERON (April 2013) and QSI (April 2015). Quintiles, through its IHS business, and inVentiv also have meaningful exposure to the post-approval services market.

- **Central laboratory capabilities:** While there are diverging trains of thought among industry constituents, several large CROs have recently combined or partnered with clinical and reference laboratories as part of a broader effort to improve the quality and quantity of their data and analytics capabilities. Acquisition of Covance by LabCorp, and Quantiles' JV with Quest Diagnostics, formed in February 2015, are the two primary examples that highlight what seems to be a focus of some larger industry participants.
- **Other areas of potential M&A targets include specialty capabilities**, where CROs could better monetize clinical data and support for specialty pharmacies, as well as **preclinical services,** which is less of a focus, but certain CROs aiming for greater exposure to a full-service offering may see the need to bolster earlier stage services.

Impact of the M&As on the buyer company includes:

- **Scalability and geographic expansion:** As a consequence of CROs global expansion through acquisition, their customers gain access to on-demand scalability for their trials and benefit from access to a wider patient population pool.
- **Access to new therapeutic expertise and capabilities:** Many CRO mergers are driven by the desire to add additional therapeutic expertise and service capabilities to their offerings. As CROs expand their offerings, sponsors gain the ability to access more services from a single partner.
- **Cost savings:** Operating under a "one-stop shop" model, there will be cost and operational savings for CROs which are able to benefit from a greater workload from sponsors through a strategic partnership model and thereby generate savings from economies of scale.
- **Technology improvements:** Technologies can have a big impact in shortening clinical timelines and improving clinical trial success through, for example, enabling between site identification, selection, and startup activities. Often, it's only when CROs are operating at a critical mass are they able to justify the high investment in technologies which are able to accrue such benefits and returns.

Some of the examples of Global M&As and their business success factors:

- **In April 2021, Thermofischer announced to acquire PPD for USD 17.4 Bn and in Feb 2021, ICON announced to acquire PRA Health Sciences for USD 12 Bn USD.**
- In 2019, Results Healthcare advised on the **sale of Xendo to ProPharma Group**. This deal gave ProPharma a substantially **bigger European presence and added key regulatory consulting capabilities to the group.**

- **Syneos Health acquired Kinapse in August 2018, from the private equity firm HG Capital**. The total value of the deal was around USD 160 Mn. Syneos Health benefited from Kinapse's **advisory and operational solutions,** capitalized on its pharmacovigilance and regulatory operations. Syneos Health being one of the top 3 CROs in the market **increased its geographic presence across Asia-Pacific as well as doubled its footprint in Europe**.
- **LabCorp acquired Chiltern, a UK-based CRO**, in a deal valued at USD 1.2 Bn, in July 2017. By acquiring Chiltern, **LabCorp strengthened its position in becoming the global leader in clinical outsourced services**, further expanding its workforce to over 20,000 employees and providing LabCorp access to Chiltern's extensive expertise in oncology.
- **In May 2016, Quintiles and IMS Health announced an all-stock transaction to merge the two entities** (combined equity value of USD 17.6 Bn) which later became IQVIA. This deal created the second largest CRO in the world with over 50,000 employees operating in more than 100 countries. The driving force behind this mega-merger was a desire to create a global Real World Evidence (RWE) solutions platform.
- **Charles River's recent acquisitions include** MPI Research (**drug discovery and safety CRO**), KWS BioTest (**in-vitro and in-vivo discovery testing services**) and Brains On-Line (**preclinical specialist CRO focusing on CNS targeted drugs**).
- ICON's USD 1.8 Bn deal acquiring Mapi Group enabled **strengthening of research, regulatory and commercialization services.**
- Wuxi AppTec acquired a CRO, ResearchPoint Global, and a preclinical and drug discovery CRO, HD Biosciences, for USD 1 Bn, and **expanded its services across the clinical research value chain.**
- In April 2020, Frontage Laboratories, a CRO, acquired BioTranex, a leading provider of drug metabolism and pharmacokinetic (DMPK) studies for pharmaceutical and biotechnology clients. Fontage provides research, analytical, and development solutions to drug sponsors from the discovery through development stages. Frontage Holdings generated USD 100.4 Mn in revenue in 2019, according to its annual report. It will **leverage BioTranex to expand its geographic presence, bolster its transporter assay capabilities, and enhance is DMPK offerings.** The transaction marks Frontage's fourth acquisition since 2019 and precedes its purchase of CRO Acme BioScience in July 2020 for an enterprise value of USD 26 Mn.
- Some of the M&As in the Indian CRO industry include purchase of stakes of IQGEN-X by ACG, merger of PPC and Novotech, acquisition of Advinus Therapeutics by Eurofins Scientific, acquisition of Novum Pharmaceutical Research Center (CRO in the USA) by Lambda Therapeutics and acquisition of Bioneeds, a preclinical CRO, by Veeda Clinical Research, to name a few.

Examples of Select M&As in the CRO Industry Since 2017

Date	Buyer Company	Target Company	Country	Implied Value Chain	Details about Target Company
Oct-20	Novotech	PPC	India (APAC)	Clinical	Novotech and PPC Group ("PPC"), two leading Asian contract research organizations (CROs) has merged to form Novotech Health Holdings ("Novotech Holdings"), creating a seamless and scalable CRO platform to serve the rapidly growing demand for quality clinical trial services in Asia. The new entity will become the largest biotech specialist CRO that can deliver full clinical services, from first-in-human to phase IV clinical studies, in Asia.
Feb-20	Eurofins Advinus	Gomti Life Sciences Private Limited	India	Clinical	With this acquisition, Eurofins Advinus will be able to manufacture RSMs, intermediates, APIs and NCEs. The company can now support drug substance requirements from multi kilogram to MT scale for Toxicology studies, clinical trials and launch quantities
Nov-20	ACG	IQGEN-X	India	Clinical	IQGEN-X has a modern research and development (R&D) facility for niche and complex generic products. It offers technology transfer, regulatory, IP and compliance services to meet the requirements of the US, European and other regulated markets
Apr-21	Thermofischer	PPD	USA	Clinical	The deal enables Thermofischer to expand from its traditional medical equipment business into clinical research services
Feb-21	ICON	PRA Health Sciences	USA	Clinical	The deal consolidates two significant players in the contract research organization arena, in a deal reportedly worth approximately USD 12 Bn
Aug-20	Genesis Drug Discovery & Development (GD3)	Comparative Biosciences Inc	USA	Preclinical	The acquisition allowed GD3 to expand its preclinical services to GLP, or good laboratory practice, based studies
Apr-20	Frontage Laboratories	Biotranex	USA	Preclinical	Biotranex offers drug metabolism, transport, pharmacokinetic, and analytic services
Feb-20	ICON	MedPass	France	Medical device	MedPass is a medical device CRO
Feb-20	Altasciences	Alliance Contract Pharma	USA	Lab services	Alliance provides laboratory services, clinical trial services, and manufacturing of liquid and powder filled capsules
Nov-19	Nuvisan	Inamed	Germany	Clinical	Inamed is a global CRO that engages in the research of respiratory and inhalation medicines
Oct-19	ICON	Symphony Clinical Research	USA	Clinical	Symphony Clinical Research provides in-home and alternative-site clinical trial services
Oct-19	NSF International	Amarex	USA	Clinical	Amarex provides clinical regulatory strategy and product development Services
Oct-19	Apex Innovation Sciences	Clinical Trial Centers Alliance (The Alliance)	USA	Clinical	CNS Network and the Hassman Research Institute merged to form Apex Innovation Sciences, which then acquired The Alliance
Sep-19	Accelerated Enrollment Solutions (AES)	Site Business of BioClinica	USA	Clinical	AES acquired the clinical sites business from Bioclinica
Feb-19	Charles River	Citoxlab	France	Clinical	Non-clinical CRO
Jan-19	Elligo Health Research	Protenium Clinical Research	USA	Clinical	Conducts clinical stage pharmaceutical studies in a broad range of therapeutic areas
Dec-18	Atlantic Research Group	CCA Clinical Research	UK	Clinical	Clinical trials of rare diseases, immunology, and neurodegenerative disorders
Nov-18	JLL Partners/ Water Street Healthcare Partners	Cato Research	USA	Preclinical +Clinical	Full service CRO
Nov-18	Cobepa	BioAgilytix Labs	USA	Preclinical	Bio analytical testing lab
Oct-18	Precision	ApoCell	USA	Preclinical	Next-generation lab specializing in the identification and

	Medicine Group				analysis of biomarkers
Jun-18	Genstar	CRF Health	USA	IT+Data Management	eCOA solutions including patient reported outcomes, observer reported outcomes, and clinician or rater reported outcomes
Mar-18	Linical	Accelovance	USA	IT+Data Management	CRO focused on oncology, vaccine and general medicines Phase I-V programs
Feb-18	Charles River Laboratories	MPI Research	USA	Preclinical +Clinical	Full-service CRO
Jan-18	Spectris	Concept Life Sciences	UK	Preclinical	Drug discovery, development and analytical testing consultancy
Dec-17	JSR Corporation	Crown Bioscience	Taiwan	Preclinical	Worldwide drug discovery and development solutions company
Aug-17	INC Research	inVentiv	USA	Clinical	Clinical and commercial CRO, merged to rebrand as Syneos Health
Jul-17	LabCorp	Chiltern	UK	Preclinical +Clinical	Full-service CRO
Jun-17	Pamplona Capital	Parexel	USA	Preclinical +Clinical	A pharmaceutical outsourcing services company
Jan-17	LDC	Fishawack	UK	Preclinical +Clinical	A full-service medical communications agency, offering clinical and regulatory writing services

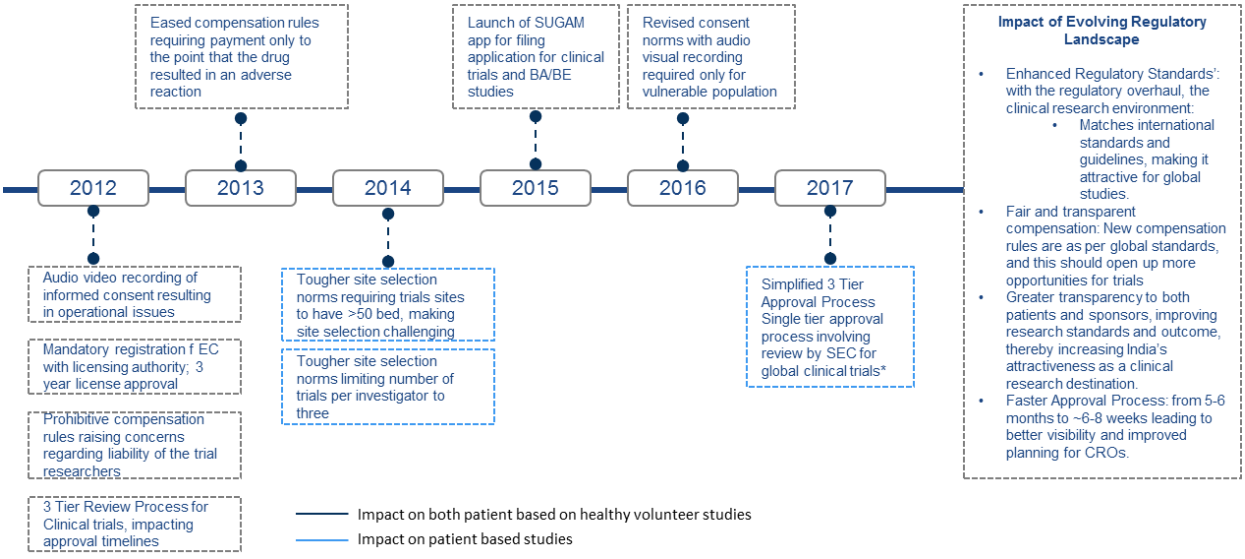
SECTION IV: INDIAN CRO MARKET OVERVIEW

India's Clinical Research Organization (CRO) Market

CRO is a large part of the pharmaceutical value chain, but has historically been relatively under-represented in India, due to various reasons like growing concern for data security and patient security, lack of collaboration between Universities and industry and others. Adverse changes in the Indian regulatory environment for novel drug clinical trials and animal studies between 2012 and 2016 shook the confidence of global pharma innovators (non-compliance to regulatory standards). Further, some Indian CROs faced regulatory scrutiny linked to data integrity.

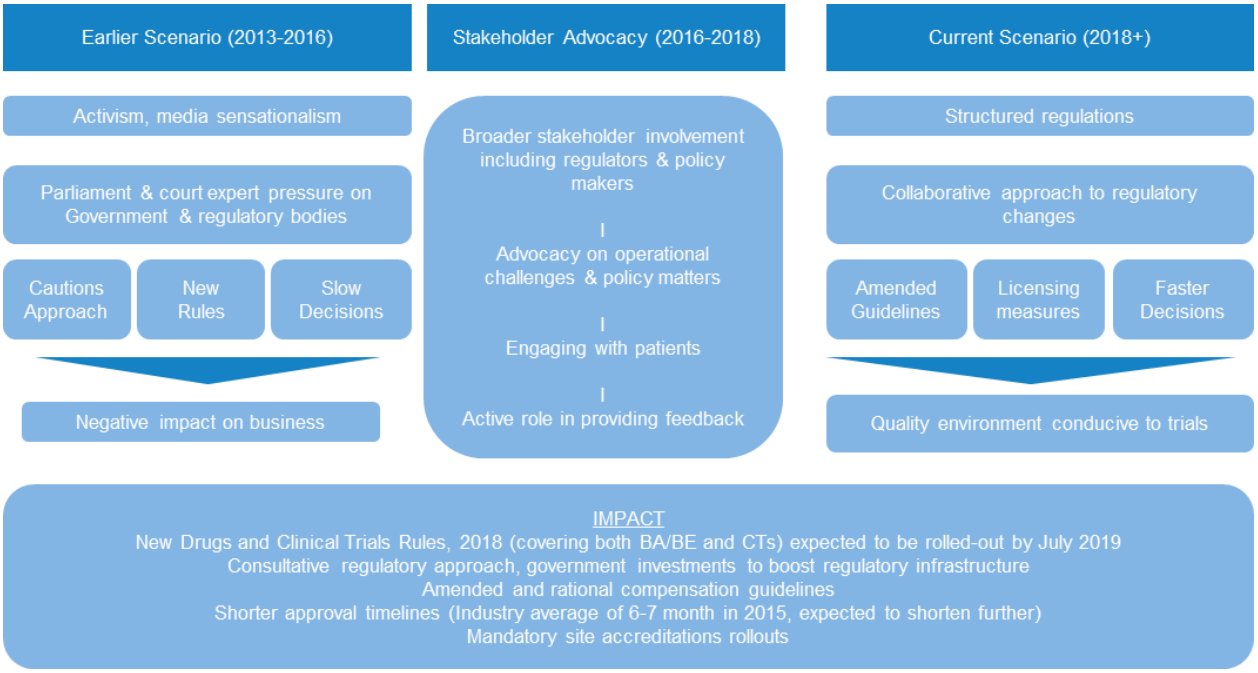
Regulatory environment is now stable for CROs in India. The journey of India as a potential drug developmental destination started in late 20th century but the recent restructuring of the regulatory process and increased capacity building has certainly helped the country to establish as one of the leading innovation and manufacturing hubs. Even during the pandemic, the regulators and Institutional Review Board (IRB) showed immense flexibility and logical thinking to review the clinical trial proposals and often provided useful guidance on planning and conduct of the trials. This certainly can be leveraged to crunch start-up timelines whenever possible.

Exhibit 4.1 Indian Regulatory Landscape



Source: Frost & Sullivan Analysis

Exhibit 4.2 Indian CRO Regulatory Environment, 2020



Source: Frost & Sullivan Analysis

With the transforming regulatory scenario of the Indian market, Indian CROs adopted strategic routes to gain profits:

1) Some **CROs successfully shifted to BA/BE testing** for generic companies, benefitting from increasing share of Indian generic players.

2) **Global generic players began outsourcing BA/BE trials to India** to benefit from lower costs and quicker test cycles.

3) With **flight towards quality**, leading CROs increased their market share.

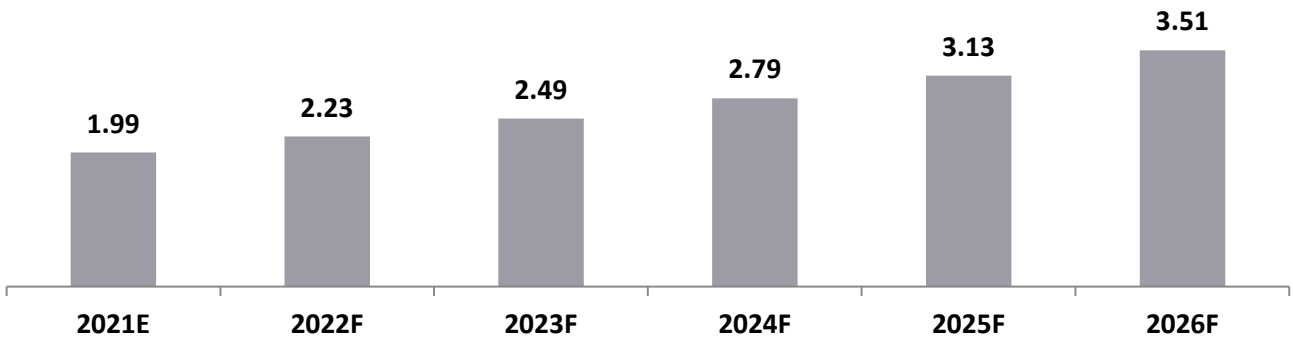
4) Growing criticality of **BA/BE services for large molecule** drugs e.g. biosimilars; therapies like inhalation drugs with difficult test protocols and time sensitive first-to-file generics.

5) Finally, with a stable and more transparent regulatory regime, novel drug clinical trials have been coming back to India.

Indian CRO Market Dynamics:

The Indian CRO market is projected to reach USD 3.51 Bn by 2026: With the major reforms over the past couple of years, the Indian CRO industry is expected to witness a CAGR of about 12% between 2021 and 2026. Market growth in India's CRO industry can be attributed to significant growth in the generic drug manufacturing in India, availability of a cost-competitive, professional labor force, regulatory reforms and steadily improving economic conditions. Pharmaceutical companies are currently focusing on outsourcing research activities to various academic institutes and private CROs to gain a competitive edge and remain flexible.

Exhibit 4.3: Total Indian CRO Market by Revenue, USD Billion
2021–2026, CAGR (2021–2026): 12%



Source: Frost & Sullivan Analysis

Note: CAGR of 12% has been estimated considering the historic growth of the Indian CRO market, historic growth rate of the Indian pharmaceutical market, rising drug demand due to COVID-19, rising vaccine demand due to COVID-19, relatively-lower demand for trials and drugs catering to orphan diseases, dermatology and other therapy areas, increased rate of outsourcing of R&D activities to Indian CROs, and increased revenues of CRO companies. The CAGR has been validated based on the insights obtained from industry experts as well as from publicly available industry reports.

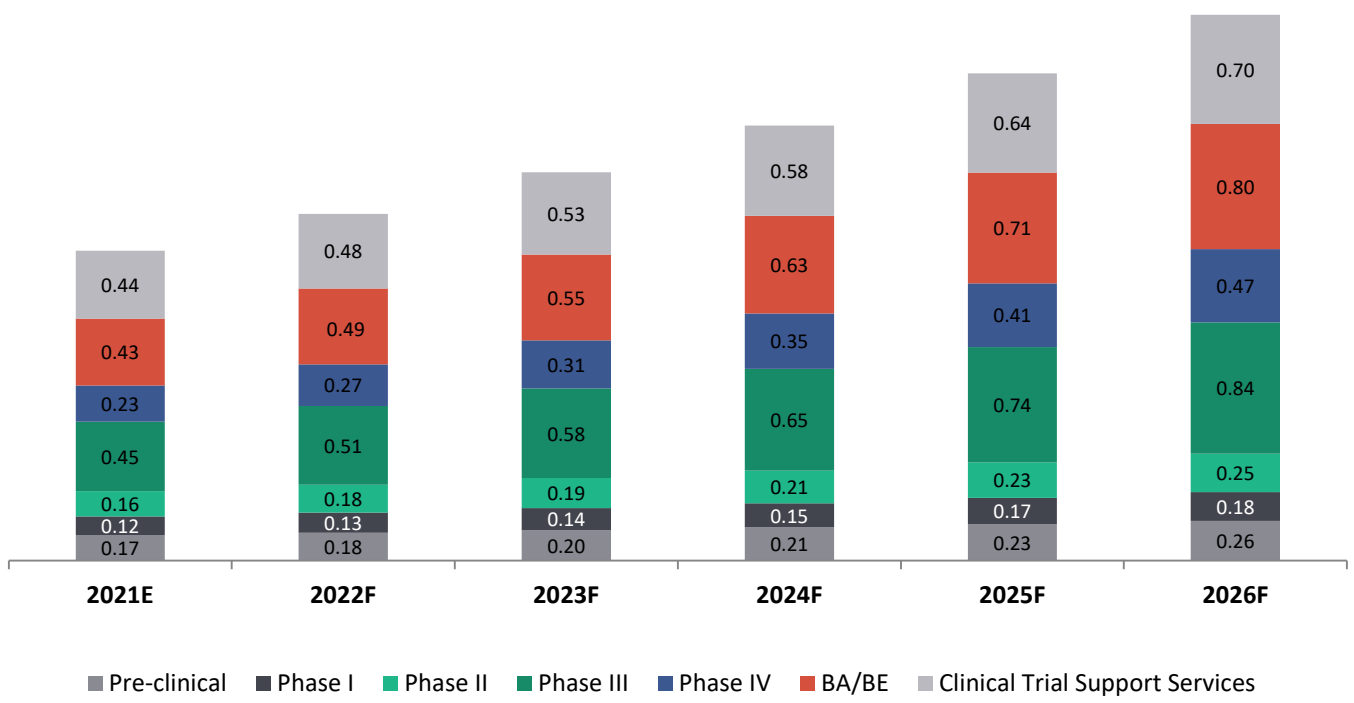
Cost-efficiency and availability of large population makes India an attractive market: India holds the advantages of a large population suffering from chronic diseases. This factor coupled with cost efficiency has made an attractive destination to conduct clinical trials.

Supportive regulatory framework: With the implementation of the new rules, CDSCO has made sweeping changes in the regulatory framework governing the clinical trials in India. The new rules provide for a predictable, clear and transparent system for regulation of clinical trials. The changes such as **reduced approval period and online registry are expected to revive and drive the growth of the clinical trials industry in India in the next decade**. The condition of **waiving local clinical trials under the new rules** will help early access to drugs for patients in India. The **faster approval process will also speed up the trial procedure and encourage local drug development**.

GLOCAL Collaborations (alliances between Global and local companies) driving the market: Most of the trials are industry-sponsored. Local and global CROs are actively involved in this activity while the number of MNC-sponsored trials continues to rise. **Many global CROs** are expanding their presence in Asia by opening up offices in the continent and **forming alliances with local CROs**. Even global CROs such as IQVIA, ICON Plc, PPD have set up shops in India to do mostly centralized services such as PV, medical writing, data management, biometrics which are not governed by regulations. Local CROs also continue to expand their presence by offering more services and an in-depth knowledge of the regulations in the country.

Market Segmentation by Sub-segments

Exhibit 4.4: Indian CRO Market: Revenue Forecast by Sub-segments, 2021–2026, USD Billion, CAGR (2021–2026): 12%



Source: Frost & Sullivan Analysis

Preclinical research; an attractive segment in the Indian CRO market: India is able to provide a cost saving of about 50–60% compared to markets like US, UK and other developed nations making it an attractive destination for preclinical research outsourcing. To save cost and time, global pharmaceutical companies are increasing the share of outsourced preclinical research as a percentage of overall preclinical research spending to India.

Number of phase I and phase II studies and complex trials are expected to see a rise: India's capacity to participate in increasingly complex multi-national studies is increasing rapidly, leading to a rise in the number of clinical trials being conducted in the country. With the increasing number of drugs being launched, the number of phase III studies in India is expected to rise. The number of phase I and phase II studies is also expected to increase gradually driven by the rising interest of pharmaceutical companies and CROs.

BA/BE studies and phase III trials capture the largest market share (44%) in 2021: As shown in the graph above, majority of the revenue is generated from phase III trials, BA/BE studies and clinical trial

support services (22% each). This is driven by the availability of large population (availability of patients and healthy volunteers).

Demand for BA/BE studies, a strong driver for the Indian CRO market: Drug manufacturers' require replenishing their respective pipelines as the majority of the big sellers are going off-patent, thereby investing a significant amount in development. This, in turn, is driving the market for BA/BE services. The key drivers for the growth of this segment include:

- Increase in complexity and number of standards, which a single molecule may have to comply with, is driving substantial growth in the pharmaceutical analytical testing services outsourcing market.
- Development of biosimilars, combination molecules, and other innovative medicines has resulted in an increased demand for BA/BE studies.

Clinical trial support services has been an attractive segment since the last 5 years: Within the clinical trial support services, clinical data management is the fastest growing segment and, the most profitable segment of the CRO market owing to the increase in the outsourcing of clinical trial services to India. Growth is mainly driven by the growth of the IT industry and the profitability of clinical trial services. This trend has encouraged many IT companies, such as Cognizant, Tata Consultancy Services Limited (TCS), iGATE, and Genpact, to expand their businesses to clinical trial data management while maintaining their cost-competiveness. Biostatistics, which is a segment that is forecasted to generate USD 90 Mn revenue by end of 2021, is an important component of clinical trials and is largely outsourced to India because of the low cost advantage the country offers. Another driving force behind this trend is the **ready availability of skilled biostatisticians who are proficient in English**. Most pharmaceutical companies partner with an ITES/BPO company in India for biostatistics. In recent years, partnerships between IT-based companies, such as Accenture and the Institute of Clinical Research India (ICRI), the launching of the Wipro Clinical Collaboration Portal, and the venturing of TCS and iGATE into the provision of clinical trial management services, shows that there is a trend toward IT companies expanding their businesses into the clinical trials space.

Partnerships and alliances on the rise: Over the years, R&D investments by domestic companies have gradually increased and collaborations between domestic companies and MNCs are expected to rise as Indian companies make more investments in R&D. However, lesser number of GLP-certified labs that meet international standards will continue to be a disadvantage for India.

Strong capabilities for central laboratory testing: With a large number of excellent laboratories with internationally accepted quality certifications, especially in urban areas, India has no shortage of central laboratory testing for clinical research activities. Both local companies and MNCs, including IQVIA, ICON, Clinigene, and DiagnoSearch Life Sciences Pvt Ltd., have established central laboratories in India.

India is an emerging market in pharmacovigilance outsourcing: Pharmacovigilance is also growing importance with the growing number of adverse drug reactions (ADRs) involving various categories

of drugs which has created awareness about the necessity of ensuring the safety of a drug before and after it reaches the market.

Health Economics and Outcomes Research (HEOR) is gradually gaining importance in India: As for HEOR services, the high prevalence of generic drugs in India gives little room for the development of new drugs and biomolecules, resulting in the limited development of HEOR services. Despite its significance, the segment is not prioritized in India. However, HEOR is gradually gaining importance as sponsors are realizing the importance of this research to make strategic decisions about their products and their commercial success.

Indian CRO Market (2021E) = USD 1.99 Bn	Indian CRO Market (2026F) = USD 3.51 Bn

Exhibit: 4.5 Indian CRO Market Share by Revenue by Clinical Trial stages (2021E)

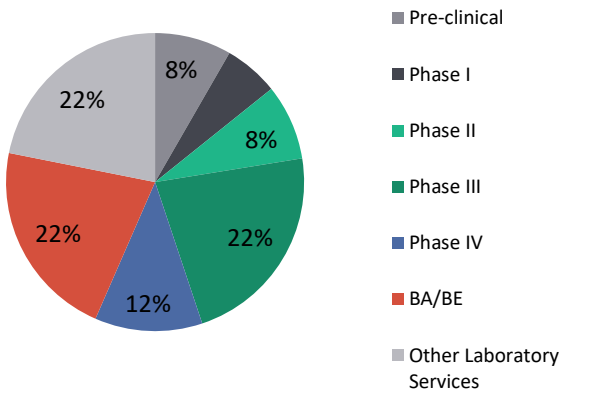
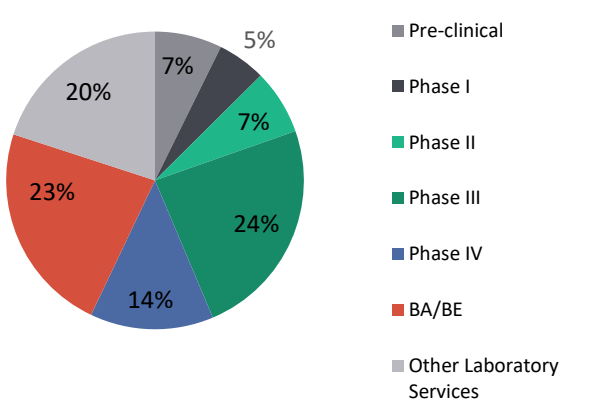


Exhibit: 4.6 Indian CRO Market Share by Revenue by Clinical Trial stages (2026F)

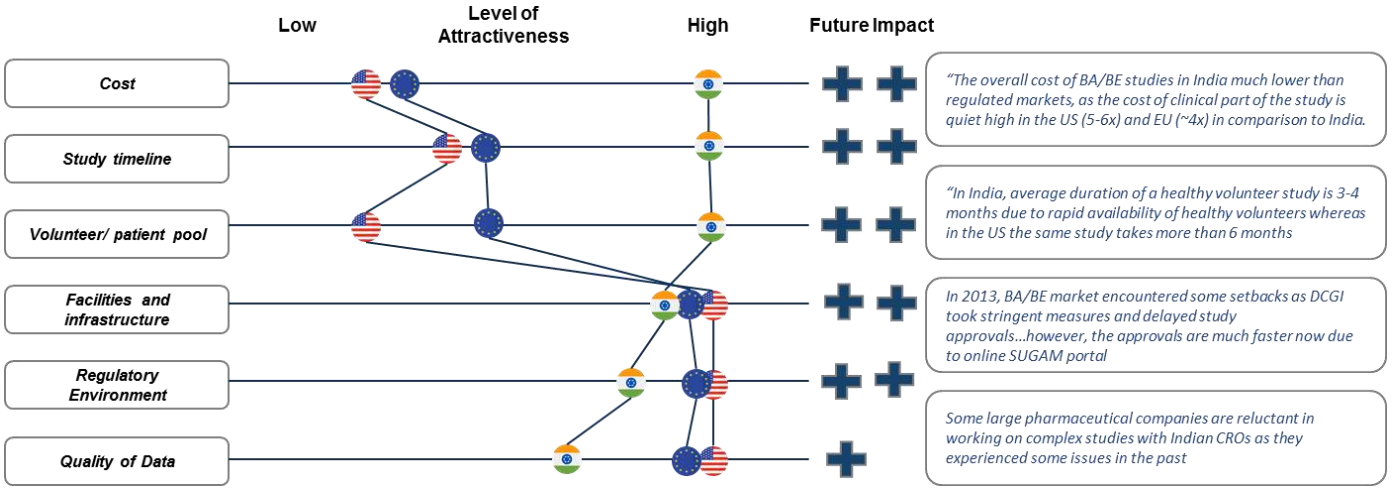


Source: Frost & Sullivan Analysis

Phase III clinical trials and BA/BE studies segments will continue to dominate the CRO market in India: Phase III trials account for about 22% share in the Indian CRO market in 2021 and is expected to grow by about 13.5% over the next five years to reach to about USD 0.84 Bn, capturing 24% market share in 2026; while, BA/BE studies market, the second largest segment, accounts for about 22% market share in 2021 and is expected to grow by about 13.4% over the next five years to reach to about USD 0.8 Bn by 2026 (23% Indian CRO market share in 2026).

Cost competitiveness and availability of volunteers makes India an attractive destination for clinical research on the International grounds: India is developing as a clinical research hub in the international arena which earlier was employed as a fertile ground for a comparative cost advantage for good quality with a cost-effective and affordable expertise. The Indian story has moved from niche to large corporate CROs, a destination for end-to-end market services in the industry propelled by a diverse and thriving population and supportive regulations.

Low cost and vast volunteer database enabling speedy recruitment and study completion continue to be an advantage for India



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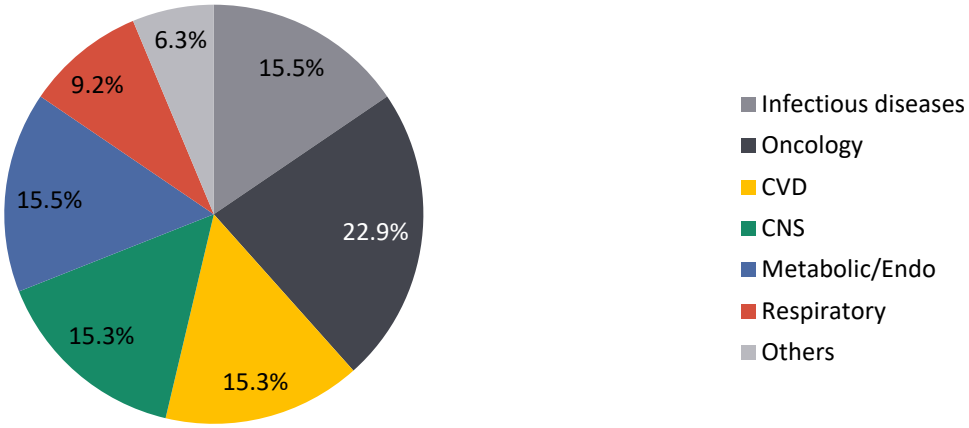
Source: Frost & Sullivan Analysis

Market Segmentation by Therapy Areas

Indian CRO Market (2021E) = USD 1.99 Bn

Exhibit 4.7: Indian CRO Market Share by Revenue (%), by Therapy Areas (2021E)



Others include dermatology, ophthalmology, gastroenterology, immunology, musculoskeletal, orphan diseases

Source: Frost & Sullivan Analysis

With a ~23% market share, oncology holds the highest interest for multi-national pharmaceutical companies in terms of revenue due to the rising cancer burden in developing countries and patient willingness to leverage the latest treatment options. Infectious diseases, cardiovascular diseases, diseases pertaining to central nervous system, and metabolic disorders capture about 15.3-15.5% market share each.

Key Industry Trends

- **Countries like China and India are moving into more lucrative stages of the drug development chain which includes preclinical studies,** such as toxicology and other animal research. With an abundant supply of rodents, and little animal rights advocacy, China and India have become favorable destinations for preclinical and toxicology studies.
- **Demand for phase III trials and BA/BE studies:** The demand for late-stage services like phase III and BA/BE studies is growing exponentially with rising outsourcing to Indian companies.
- **Growing biosimilars and biotechnology markets:** Pharmaceutical companies are making significant investments in the R&D of novel drugs and biosimilars. Indian CROs are becoming more involved in the development of biosimilars due to their expertise in and streamlining of the research, development, manufacturing, and up-scaling of biologic products.
- **Local companies to offer diversified services:** Besides clinical studies, the demand for other services, such as data management, biostatistics and pharmacovigilance, is expected to grow.
- **New legislations** have been introduced which aim in aligning Indian clinical trials to global standards and also protect the safety of participants.

- **Benefits of integrated research model** includes enabling research to be performed through a network and platform that connects multiple stakeholders including providers, patients, and payers, and Research data silos are broken down, enabling interventional and observational data to be included in the same research protocol.
- **Rising number of independent CROs:** An independent CRO promotes objectivity that benefits the safety of the subjects, integrity of the trial and minimizes conflict of interest. An independent CRO can establish a protection between sponsor and the safety management boards, freeing sponsors and their study of any additional scrutiny for potential for bias. Through standardization procedures and by managing the safety boards, an independent CRO bring consistency to sponsor's clinical trials. Finally, a standalone service provider offers the flexibility to work with individuals from not only across the country, but around the globe, providing sponsors with a greater network of therapeutic expertise to use for the study.

Market Drivers

- **English-speaking health care specialists and expert clinicians** is an added advantage, along with India's strong reputation as a growing hub for clinical trials.
- **Access to massive, treatment-naive, ethnically diverse patient pool** suffering from conditions of global health relevance. This is a significant advantage as it has become a challenge to recruit sufficient number of patients for clinical trials, in Western countries.
- **Cost-effectiveness through competitive operational costs and internationally harmonized regulations that attract investment.** Conducting clinical trials in the country offers a major cost-saving advantage of up to 50–60% when compared to trials conducted in other regions, such as the United States or Europe.

Opportunities for Indian CROs

CROs are the integral part of the pharmaceutical value chain. In the last few decades, India has created a significant value for generic drug manufacturing and API industry. There is a significant brown space in the Indian CRO industry, driven by the below stated market drivers, that is available for monetization.

- **Indian regulatory framework revamped with a fast-track strategy; thereby boosting the Indian CROs:** Implementation of the new rules in the regulatory framework governing the clinical trials in India, digitization of the application process, reduction in the approval timelines to 30 days for drugs manufactured in India and 90 days for drugs developed outside India, improved compensations rolled out for trial participants in case of death or permanent disability, waiver for requirement of local trials in some select cases, are expected to make India an attractive destination for clinical trials industry.
- **Most Indian CROs have well-established central laboratories (for clinical research testing) that aid in conducting discovery and preclinical drug development activities.** The initial processes, such as BA/BE studies, biomarker testing, drug stability testing, toxicity analysis, formulation,

and pre-formulation are primarily conducted in a laboratory, thereby, establishing the importance of central laboratories in drug development.

- **Preclinical segment is the fastest growing outsourced segment in the industry:** Indian CROs are at par with global CROs because of the Indian GLP certification and stringent rules which was internationally recognized. At present, a total of 50 organizations are Indian GLP certified which includes CROs, and R&D Labs. Indian CROs are now gearing up for the challenge to establish them to provide preclinical development services at par with global CROs. Indian CROs have a successful history of providing toxicology support by delivering high quality data to its customers.
- **Clinical CRO market on the rise primarily driven by its cost-efficiency and regulatory framework**: Nearly fifth of all trials globally are hosted by India which has a huge potential for financial and scientific gains (clinical trials in India are 50% cheaper as compared to developed countries). CROs are taking an edge of gaining large patient pool, qualified medical investigators, lower drug development costs and winding up the clinical trials in India on time.
- **Rising generic drug utilization driven by the patent cliff of blockbuster drugs; thus, driving the need for BA/BE services:** India is emerging as a force to reckon with in the global pharmaceutical space. India is one of the top five manufacturers of bulk drugs in the world and ranks amongst the top 20 pharmaceutical exporters in the world. Every fifth application for marketing a generic drug in the US, the world's largest pharmaceutical market, is filed by an Indian company. Indian pharmaceutical companies used the reverse engineering route to make and sell generic drugs. This trend is further driven by the rising number of patent loss thereby creating an opportunity for the CRO industry. Around 56 drugs lost their patents between 2020 and 2022 and around 107 drugs are losing their patents from 2023 to 2025.
- **The growth of biosimilars (driven by patent loss of biologics) is leading to very high rates of outsourcing** which, in turn, propels the CRO participants to provide high-quality bio-analytical techniques, thus, accelerating the growth of this segment. The biosimilar market in Europe is the largest in the world, representing approximately 60% of global biosimilar market. However, demand is higher in India considering the increase in prevalence of diseases like cancer, rheumatoid arthritis, cardiovascular diseases etc. and rising spending power. Around 95 biosimilars are approved in India and some of the major Indian players actively growing in the biosimilars space include Biocon, Glenmark, Torrent, Zydus, Reliance, USV, and Dr. Reddy’s Laboratories Ltd. etc. Biocon, for instance, earned INR 1,517 Crore or nearly 28% revenue from biosimilars in FY19 proving that biosimilar launches are commercially rewarding. Similarly, Roche entered into an agreement with Emcure to produce an affordable version, bicletis, of its drug Herceptin so as to address the issue of access of medicines in India. The active participation of the Indian companies in the biosimilars space is seen by the fact that 201 active biosimilars are in the pipeline of 52 Indian companies. The Global market for biosimilars is estimated to be at USD 35.7 Bn in 2021 and is expected to grow at 17.3% CAGR to reach to about USD 79.2 Bn by 2026. India captures about 1.7% market share and is valued at USD 0.6 Bn in 2021 and expected to grow at a CAGR of 34% reaching to about USD 2.54 Bn by 2026.
- **The BA/BE segment dominates the bio-analytical testing services market:** Bio-analytical testing is one of the most crucial aspects of drug discovery and development. Some of the

key activities involved in bio-analysis include BA/BE testing, biomarker testing, immunogenicity testing, toxicology, and pharmacokinetic testing which essentially span across the entire drug development value chain. BA/BE studies is an integral and major part in testing generic drugs, and the market is primarily driven by factors like rising demand for generic medicines in rural markets; thereby creating a big opportunity for CROs globally for BA/BE studies.

- **Revised versions of the EMA's overarching biosimilars guideline and non-clinical and clinical issues.** The updated guidance allows clinical trials conducted using reference medicines authorized outside the European Economic Area to be used for the EU filing. In the past, these trials would have had to be repeated in European patients, using an EU-approved reference medicine, at extra cost to the sponsor.
- **Cost-efficiency and quicker turnaround time are the major industry tailwinds for the Indian CRO industry:** All the pharmaceutical companies are experiencing vital challenge to trim down the cost efficiency and also the time consumption in R&D for New Chemical Entities (NCE's) approval, which helps in launching their new formulation into the market. However, cost cutting is not the only imperative for outsourcing. It is a strategic option, which is being exercised by many companies to augment their efficiency and expertise. It also provides an opportunity to partner companies, establish and foster long-term, strategic relationships; thereby making them more proficient and better prepared to match their capabilities and offerings in tune with market and demand dynamics.
- **Artificial Intelligence (AI) and Machine Learning (ML) have been used by CROs to increase the efficiency of the process:** AI and ML have been an area of focus for many big pharma companies. Pfizer, for instance, focused on leveraging AI for drug discovery. Now, many companies are seeking improvements in drug discovery as well as clinical operations; hence, large CROs are stepping in by offering AI/ML solutions to both emerging biopharmaceutical companies, as well as Big Pharma. AI/ML is a series of techniques that leverage machine learning, natural language processing-NLP-or other techniques that help create new insights, drive operational efficiencies and accelerate decision-making in new ways. Companies like IQVIA, had remarkable results applying AI techniques to clinical design and execution. The company has conducted a number of trials using AI, and the benefits are mostly around accelerating the clinical process (about a 40% faster site identification process and 30% faster recruitment rate) and cost-saving for pharmaceutical companies.
- **New categories of emerging biologics and advances in cell and gene therapies are further driving the CRO industry:** The rapid growth and uptake of technologies, such as CRISPR, CAR-T cells, bi-specifics and more, are significantly influencing the landscape of biotech and pharma drug development. To keep pace and provide the required support, CROs are investing in cutting-edge technology and growing their service offerings. Large CROs like Charles River laboratories, Wuxiapptec, Paraxel and IQVIA are upgrading their infrastructure and building their capability to handle requests on cell and gene therapies. India is picking up with the rest of the world in contributing to research in the gene therapy space. Adding impetus to further research in India is the release of revised guidelines like the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017'' and the "National Guidelines for Stem Cell Research, 2017"; thereby, encouraging

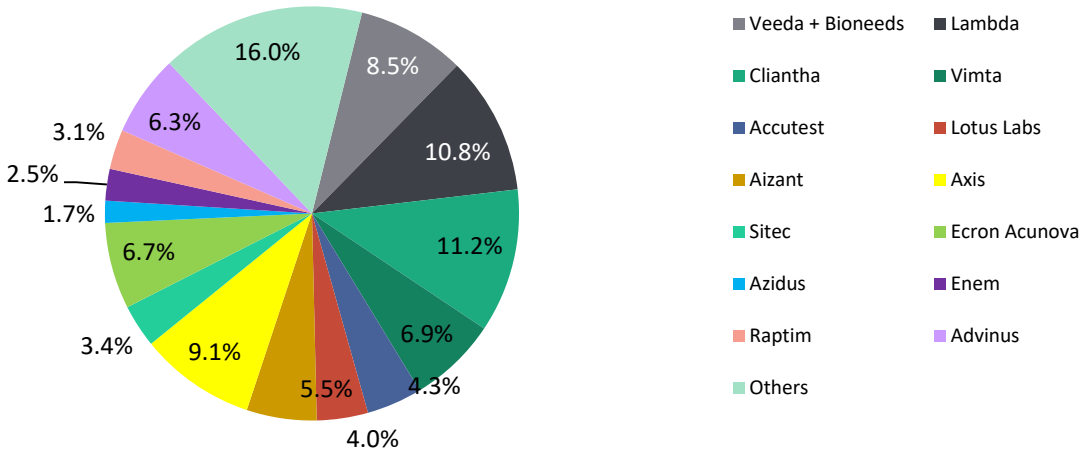
research in the field of somatic cell gene therapy for conditions where no treatment is available.

- **Virtual clinical trials (VCTs), also called remote or decentralized trials would drive the future growth of the CRO industry**: It represents a relatively new method of conducting clinical research taking full advantage of technologies such as apps, electronic monitoring devices, telemedicine and online social engagement platforms. In a country like India, virtual clinical trials would have a tremendous advantage in expanding the reach of clinical trials and providing access to diverse patient populations, but it would also help address one of the toughest challenges in a clinical study which is that of patient recruitment.

Competitive Scenario

Competitor Market Share (2020)

Exhibit: 4.8 Market Share of Key Indian CROs, 2020



Total India CRO Market (2020) = USD 1.74 Bn; ~22% of this market involves preclinical, clinical and BA/BE studies. The remaining 78% of the Indian CRO market is contributed by the backend offices and data management services.

Others include Micro Therapeutics, Sipra Labs, Synchron, Panexcell, Auriga, Vergo, Actimus, Quest Life Sciences

Source: Frost & Sullivan Analysis

Independent Players	FY 2020 Revenue (INR Million)	Non-Independent Players	FY 2020 Revenue (INR Million)
Veeda+Bioneeds	2,245	**Cliantha**	2,982
Vimta	1,837	**Lambda**	2,865
Ecron Acunova	1,790	**Axis**	2,407
Advinus	1,683	**Lotus Labs**	1,060
Aizant	1,450		
Accutest	1,153		
Sitec	891		
Raptim	824		
Enem	656		
Azidus	458		

Source: Frost & Sullivan Analysis

Note: Syngene has not been included in the analysis as the company offers CRAMS (contract research, development and manufacturing) services.

Around 49% of the market share is captured by independent CROs and 51% of the market share is captured by other CROs. Veeda + Bioneeds, Vimta, Ecron Acunova, Advinus and Aizant are the top five independent CROs capturing about 38.3% market share; while, Cliantha and Lambda together capture about 22% market share in the other CROs category. Lambda, Cliantha, Axis and Lotus Labs have collaborations with pharmacaeutical companies (Intas, Zydus and Aurobindo, respectively). Veeda Clinical has existing capabilities of conducting BA/BE studies and extensive ability to develop biosimilars. With the

recent acquisition of Bioneeds, Veeda strengthens its preclinical capabilities and clinical trial services, thereby emerging as the top independent full service provider.

The top players offer a range of services within the CRO value chain:

- Lambda offers bio-analytical studies, phase I to IV trials for drug development, pharmacovigilance, clinical data management, clinical laboratory services and medical imaging services.
- Ecron Acunova is a full-service CRO offering clinical research in the areas like oncology, diagnostic imaging, HIV, cardiovascular diseases, metabolic disorders, nutrition, stem cell research, pulmonology, rheumatology, neurology, ophthalmology, dermatology, ENT. The company also offers services like medical monitoring, medical writing, pharmacovigilance, biostatistics, data management and project management & monitoring.
- Cliantha specializes in early phase (Phase I/IIa), late phase (Phase II-IV), BA/BE studies, clinical endpoint trials, bioanalytical testing, biosimilars and pharmacovigilance services.
- AXIS performs DCGI and NABL studies for testing and calibration laboratories, clinical pharmacology, clinical assay and clinical data management. It also conducts complex studies of first-in-human, drug-drug interactions, food effects, alcohol interactions, pharmacokinetics/pharmacodynamics, bioavailability/bioequivalence studies.
- Veeda + Bioneeds offer preclinical, clinical from phase I to III, BA/BE services for generics and biosimilars, bioanalytical studies and data management.
- Vimta offers contract research and testing activities in various areas, such as advanced molecular biology, analytical testing of food and drugs, clinical reference laboratory services, clinical research.
- Aizant offers solutions for pre formulation, formulation development of conventional and novel drug delivery products, analytical development, cgmp scale-up, niche commercial manufacturing, stability, bioavailability, bioequivalence, bioanalysis, pharmacokinetics, biostatistics and clinical diagnostics.

SECTION V: GLOBAL CLINICAL TRIALS MARKET OVERVIEW

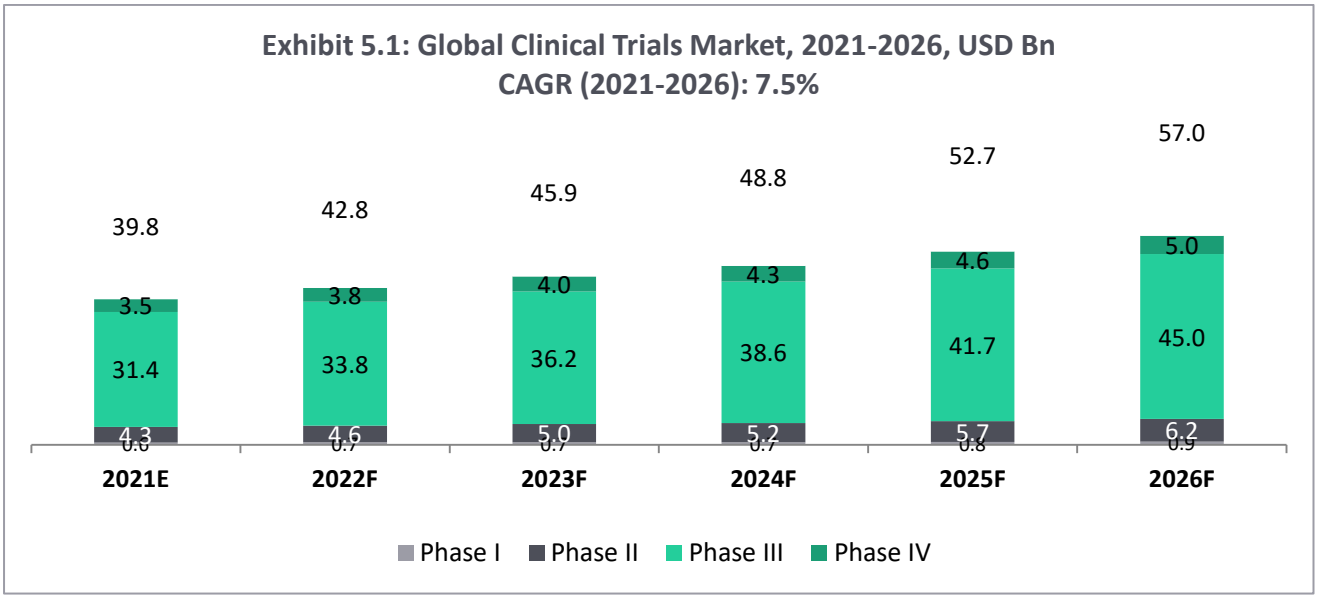
Global Clinical Trials Market Overview

Indian clinical trials market to surpass Global clinical trials growth rate (13% versus 8%): The global clinical trials market is estimated to grow from USD 39.8 billion in 2021 to USD 57 billion in 2026 with a CAGR of 7.5%. While, the Indian clinical trials market is estimated at USD 0.96 Bn in 2021 and is expected to grow by about 12.7% to reach USD 1.75 Bn by 2026. The Indian clinical trials captures 2.4% of the global clinical trials market in 2021 and is expected to grow faster than the global market to capture about 3.1% of the market share by 2026.

Phase III trials hold 79% market share in the Global clinical trials industry. This growth is attributed to the fact that phase III trials are the most expensive ones and involves a large number of patients and a longer period of enrollment. The median cost for a single phase III trial is around USD 18 Mn. In the Indian clinical trials market, phase III trials captures about 46% market share, phase IV trials with 24% share and phase II trials with 17% share.

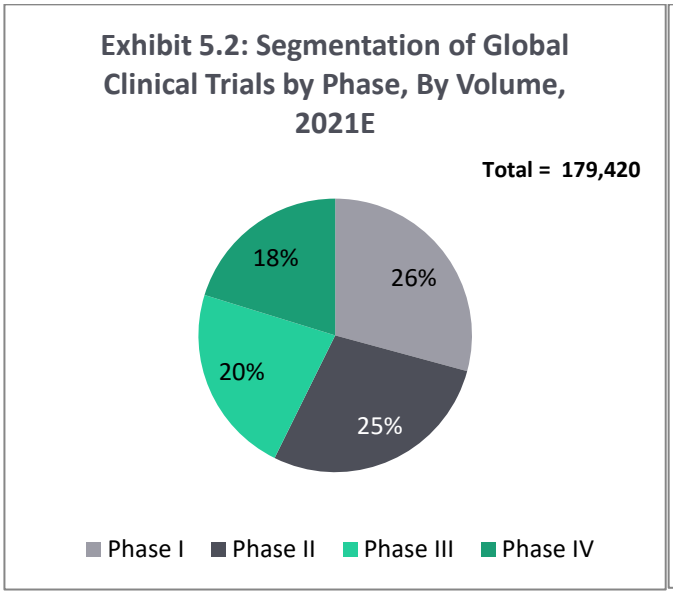
Globally, the clinical trial industry is witnessing a shift of trials from North America to Europe and Asia-Pacific. Europe dominates the clinical trial landscape with more than a third of research activity centered in the region. Currently there are a total of 376,229 clinical trials globally as of April 04, 2021 in progress at various stages like active, on-going, under-recruitments, completed and some of them are in terminated or suspended phases due to failure in reaching the primary/ secondary endpoints.

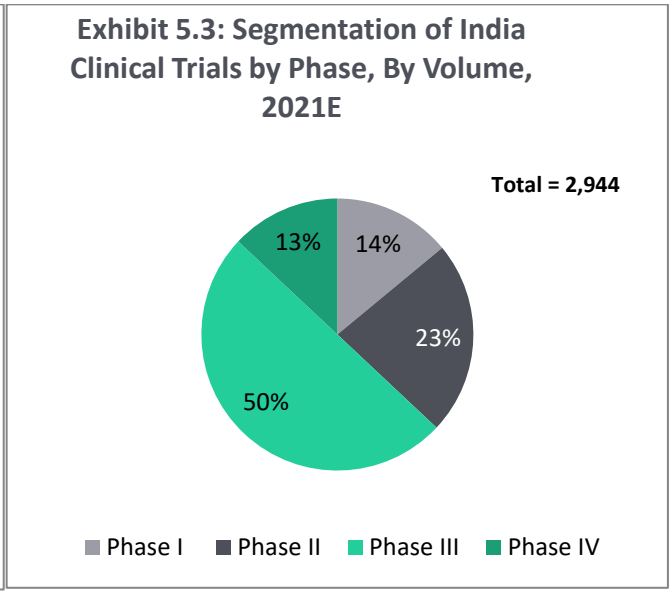
Growing demand for new drugs and vaccines, increasing investments in R&D and digitization in biomedical research are driving the clinical trials market: Multiple products under development for various therapeutic categories, growing demand of effective therapies, and an increase in the investments on research & development by many pharmaceutical and biotechnological companies are likely to cause a surge in demand of clinical trials. The growing demand of CROs for conducting clinical trials in the pharmaceutical sector due to the diversified expertise of CROs and the adoption of advanced technologies in clinical trials is supporting the market growth. Digitization in biomedical research is also paving the way for market growth. The market is also driven by the emergence of the global pandemic caused by coronavirus. The rapidly evolving threat due to the outbreak of COVID-19 is impacting lives, communities, businesses, and industries around the world. The pandemic has also negatively impacted the current ecosystem of clinical trials. It has affected many ongoing trials for various therapeutic areas. However, to overcome this, researchers are rapidly trying to develop innovative therapeutics and vaccines against COVID-19, which is supporting market growth.



Source: Frost & Sullivan Analysis

Clinical Trials Market Share by Number of Trials by Phases (Phase I, II, III, and IV): Global Vs. Indian





Source: Clinicaltrials.gov, RGCB, Frost & Sullivan Analysis

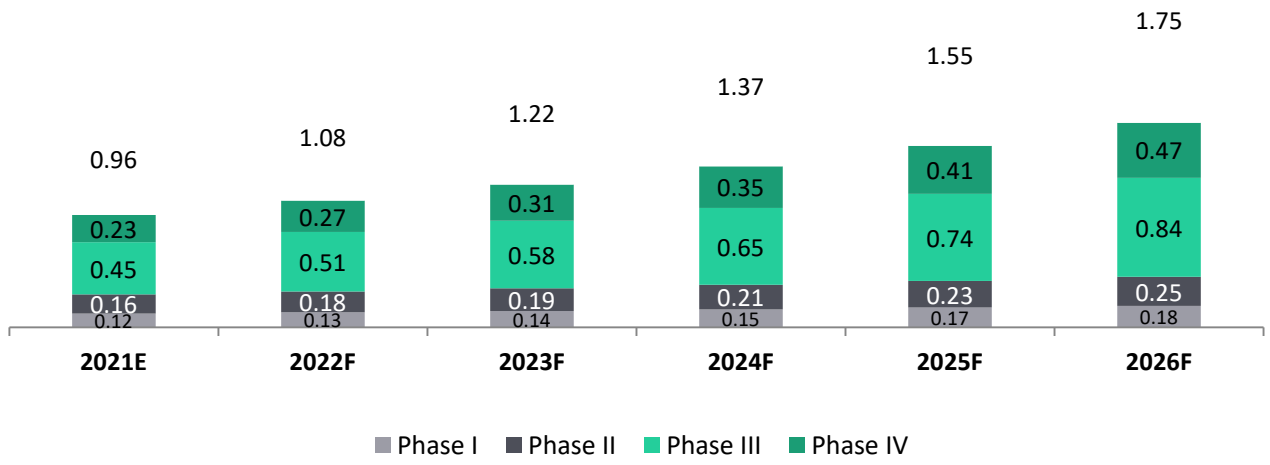
Globally the number of trials by various phases is equally distributed. On the contrary, phase III trials in India dominate the market size by volume capturing about 50% share. India contributes to around 1.3% of the global clinical trials conducted.

Note:

1. ***The above mentioned analysis is only for trials from Phase I to Phase IV, we have excluded the trials of early phase I (A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body.), Phase Not Applicable (Describes trials without FDA-defined phases, including trials of devices or behavioral interventions) etc.***
2. ***However the overall number of clinical trials globally inclusive of phase 0, Phase NA and Other trials as of April 04,2021 are 376,229 and for India will be 4,698***

The increasing prevalence of chronic disease and the growing demand for clinical trials in developing countries is fueling this market's growth. The market is also driven by a rising number of biologics, the need for personalized medicines and orphan drugs, and the demand for advanced technologies. Factors such as globalization of clinical trials, technological evolution, and demand for CROs to conduct clinical trials are further projected to drive the market. Additionally, clinical trial services are likely to dominate the global CRO market share and collaborations amongst key players to outsource clinical trials are expected to grow.

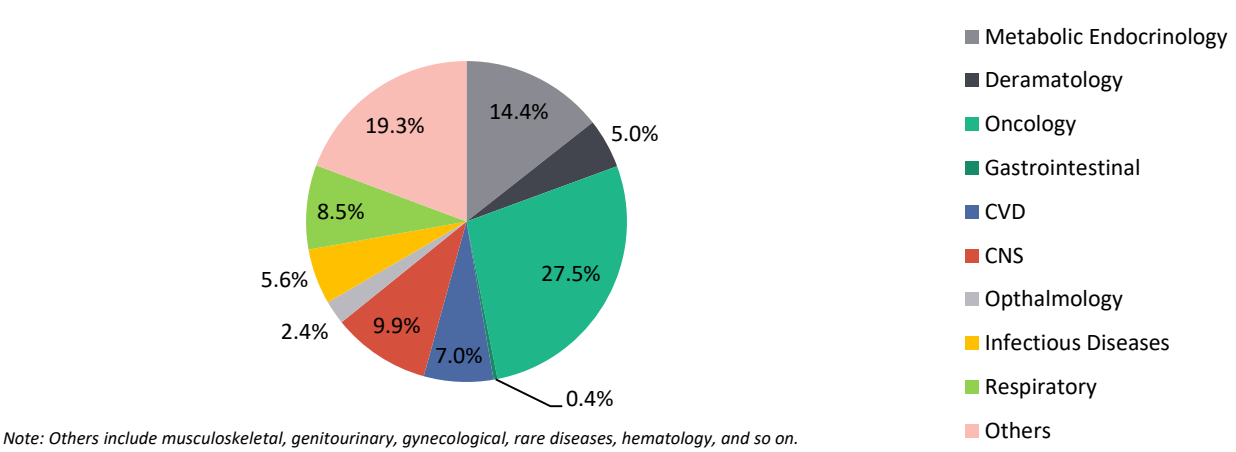
Exhibit 5.4: India Clinical Trials Market, 2021-2026, USD Bn
CAGR (2021-2026): 12.7%



Source: Frost & Sullivan Analysis

Global Clinical Trials Market Share by Therapy Area

Exhibit 5.5: Segmentation of Clinical Trials by Therapy Area, By Volume, 2021E

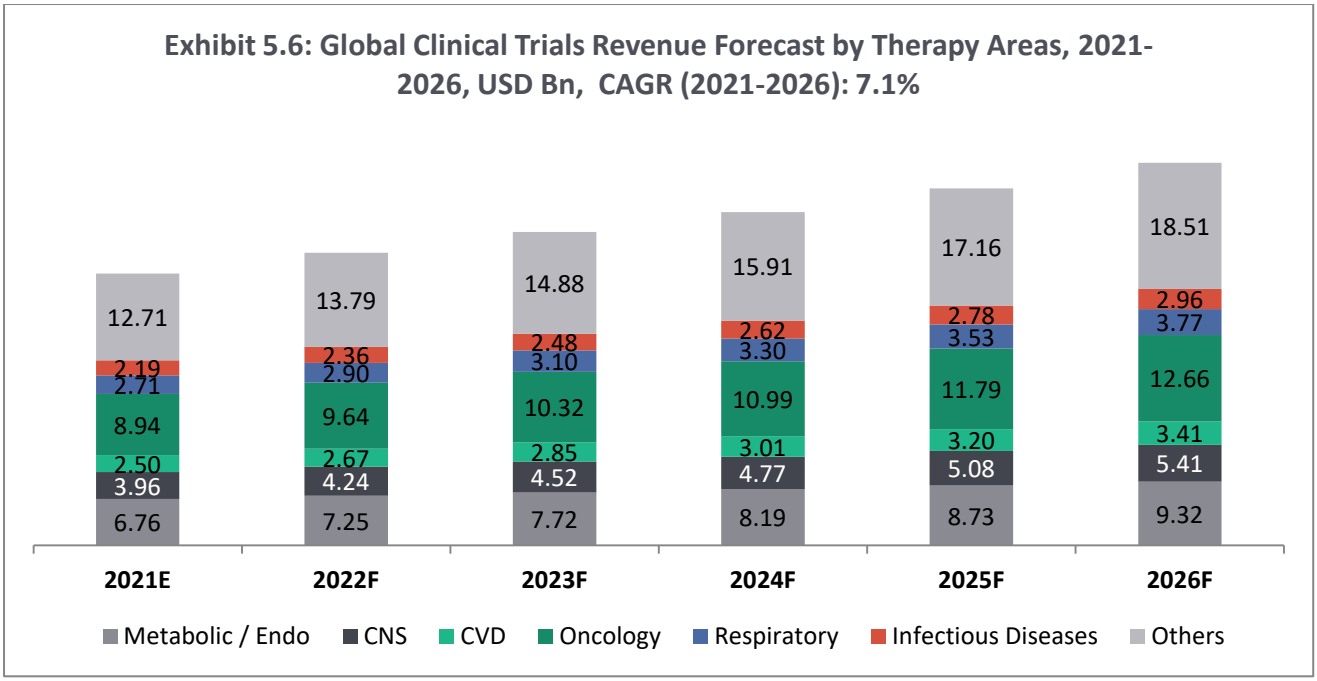


Note: Others include musculoskeletal, genitourinary, gynecological, rare diseases, hematology, and so on.

Source: Frost & Sullivan Analysis

***Only 80% to 85% of the total clinical trials are considered for market estimations. 15% studies showed insufficient data on trial phase/region.*

Although oncology and metabolic therapies continue to dominate the clinical research space, neurology and other therapy areas are slowly gaining traction, owing to the discovery of innovative large molecule therapies.



Source: Frost & Sullivan Analysis

Note: Others include dermatology, ophthalmology, gastroenterology, immunology, musculoskeletal, orphan diseases, and so on.

A growing prevalence of neurodegenerative conditions, such as Parkinson's and Alzheimer's, and rising geriatric populations are contributing to the increased efforts toward drug development in this segment. Syneos Health is a strong competitor in this segment, alongside small-to-mid segment players, such as CROS NT and Veristat.

Additionally, with a consistent growth in CVDs and infectious diseases globally, considerable focus on developing anti-infectives and cardiovascular therapies is observed, with several small-to-mid segment players collaborating with CROs to develop newer treatment options.

Opportunities in the Clinical CRO Market:

North America:

- **North America (NA), the home for some of the leaders of the CRO Industry**, is the most dominant market with a high adoption potential for technologies, such as AI and machine learning, therefore, creating greater opportunities for digitization in the CRO industry.
- **Well Established Clinical Trial Network:** Several organizations (e.g., the North American Clinical Trials Network (NACTN)), are working with industry players to bring in novel curative therapies into clinical research, making North America a leading market for outsourcing services. Additionally, a well-organized regulatory environment ensures an ethical environment for clinical research, further enhancing the credibility of the region**.**
- **Greater Adoption of Digital Solutions:** Companies such as IQVIA and Parexel are among the two big CROs with in-house digital solutions for clinical research. Both these participants are headquartered in the NA region, and hence, allow higher collaborations. Additionally, higher outsourcing activity is a result of their strong service portfolio around bio analytical testing, cGMP testing, and central laboratory services.
- **Niche Therapeutic Focus**: The region is witnessing the rise of niche CRO participants with focus on specific therapeutic areas, pertaining not just to oncology but also rare diseases, ophthalmology, etc. This is, in turn, supporting the rise of small-to-mid tier CRO participants, thus, increasing the competition in the region. Additionally, a growing number of industry participants are expected to further drive consolidation, with bigger companies merging with niche companies to gain specific expertise.

Europe:

- Owing to the presence of highly advanced medical infrastructure and the rise of local Eastern and Southern European CRO participants providing significant cost effectiveness and time reduction, **Europe is set to surpass the North American CRO industry with the highest clinical trial volume in the next five years.**
- **Eastern and Western Europe**: With more than 15,000 trials in Europe alone, the region is already breaking tradition by emerging as the leading location for clinical research. Countries such as Lithuania, Romania, and Poland provide a huge cost advantage of 45% to 50% or more compared to the US, thereby, making the region highly profitable for outsourcing.
- **Advanced Clinical and Non-clinical Infrastructure:** The presence of bigger industry participants, such as Covance, IQVIA, and Icon plc, allow for a well-established infrastructure of central laboratories, therefore, contributing to a higher share in the clinical CRO market. A higher prevalence of oncology is leveraged on by participants such as Icon and Covance by positioning themselves as the leaders for these trials using their specialized laboratories.
- **Niche Therapeutic Focus:** The region is also witnessing the rise of niche CRO participants with focus on specific therapeutic areas, pertaining to non-oncology conditions, such as rare diseases and ophthalmology, the trials for which are specifically conducted in the European region. Players such as Argint International, Orphan Reach, Iris Pharma, and Crom Source are local CROs with specialized therapeutic focus supporting market growth.

APAC:

- **Asia-Pacific CRO market at a strong 10.9% growth:** Availability of a highly diverse population base, supported by higher prevalence of chronic illnesses and the emergence of numerous regional and local participants alongside global CRO participants, is expected to boost the Asia-Pacific CRO market at a strong 10.9% growth.
- **Specific Therapeutic Focus:** Asia-Pacific has very high cases of cancer such as breast and lung cancer, alongside diabetes and other metabolic conditions. Therefore, oncology and metabolic diseases trials have the highest volume compared to other therapy areas, thus, capturing the highest CRO market share in the region.
- **Availability of Diverse Populations:** Not only ethnic diversity, but Asia-Pacific is home to a large genetically diverse population base, making it an ideal location for recruiting sample populations for novel drug trials (e.g., cell and gene therapies). Additionally, with South Korea and other countries supporting large-scale genome projects, the region will potentially emerge as a hub for specialty clinical trials, especially in post-marketing surveillance activities, with the availability of genomic data profiles.
- **Supportive Regulatory Environment:** Individual country governments are amending their regulatory policies, allowing for higher outsourcing and also providing opportunities for CROs and CMOs to position themselves in the region. For example, the PMD and SRM acts in Japan allow outsourcing. Moreover, China now accepts clinical trial data outside China for drug approval in the country, paving the way for higher outsourcing in the region.

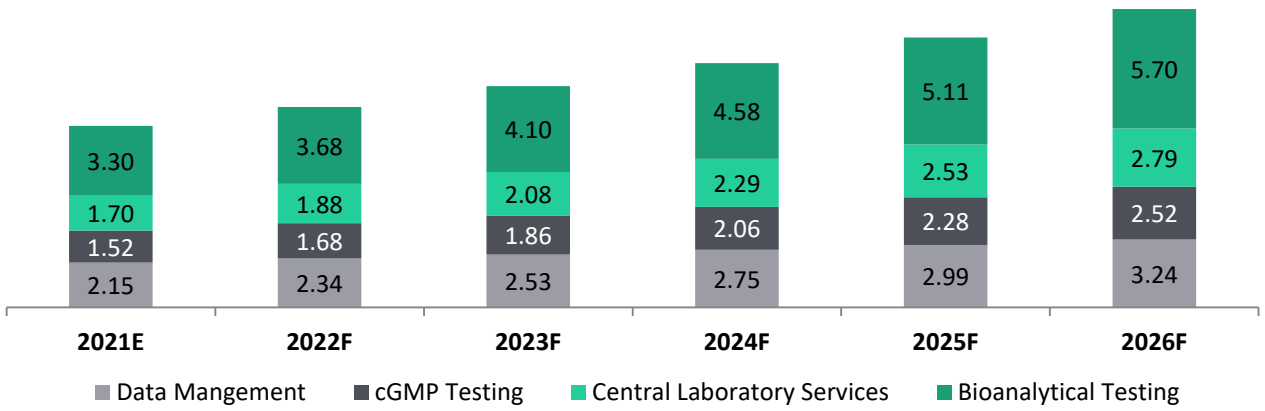
Rest of the world:

- **Higher Disease Prevalence**: Countries in the ROW region, especially in the Middle East, show a high prevalence of metabolic conditions (e.g., the prevalence rate of diabetes is higher than 9%) alongside CVDs and infectious diseases, making them easy locations for these clinical trials. Additionally, a simultaneous rise in cancer cases is propelling research in the segment, with several CROs supporting R&D activities.
- **Greater Scope for Technology Adoption:** Despite being among the smaller markets in the global CRO industry, the region has been highly receptive to new technology adoption, and is, therefore, paving the way for innovative bio statistical and data management techniques. The region also allows cross-border monitoring, with significantly lower translational costs, owing to lesser language barriers and a harmonized regulatory environment.
- **Availability of Skilled Manpower**: The region has an abundance of highly trained medical professionals, with excellent medical training and English proficiency which makes it easier for them to participate in global trials. Moreover, the availability of world-class medical facilities in the present scenario is likely to change the trend of conducting trials for existing molecules, allowing for novel biologic trials in the region.

Global Preclinical and Discovery Services Overview

CROs have been rapidly investing in developing specialized central laboratories to support sponsor companies in discovery and preclinical studies: All processes from chemistry to IND submissions involve the non-clinical activities of drug development. Bio analytical testing activities, such as PK/PD, Absorption, Distribution, Metabolism, and Excretion (ADME) and metabolism, and bioequivalence studies for early-stage drugs, support the assessment of drug stability and efficiency to move to the next stage of clinical research. Several sponsor companies are now open to outsource drug discovery and development activities to CROs.

Exhibit 5.7: Discovery and Preclinical CRO Services Market: Global Revenue Forecast, 2021-2026, USD Bn, CAGR (2021-2026): 10.4%



Source: Frost & Sullivan Analysis

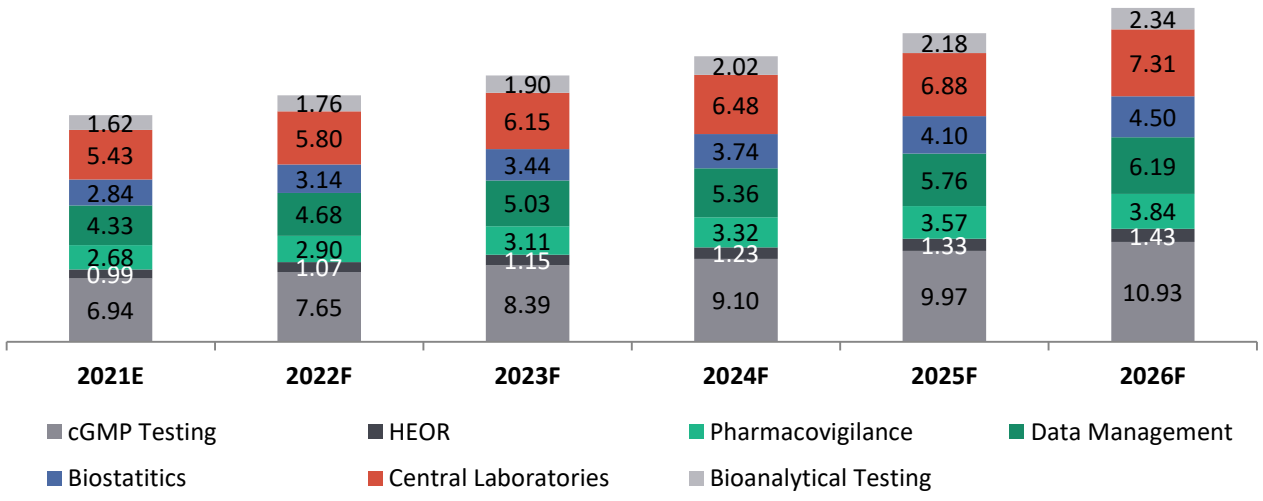
CROs have been rapidly investing in developing specialized central laboratories to support sponsor companies in discovery and preclinical studies of novel molecules, thereby gaining a strong market position in the non-clinical drug development space.

Across critical non-clinical activities, Chemistry Manufacturing and Controls (CMC) account for a cost share of 45% to 50%, followed by toxicology studies capturing more than 20% of the non-clinical study budgets. Additionally, data management, which is crucial to these studies, further accounts for 10% to 12% of the study costs.

Global Clinical CRO Services Overview

An expected rise in cGMP outsourcing is driven by high quality services at competitive prices. Acquisition of mid-tier companies by independent service providers to expand the geographical services portfolio and the **rise in integrated services** are likely to further accelerate market growth. There is an opportunity for consolidation due to a highly fragmented market, thereby strengthening the position of larger firms.

Exhibit 5.8: Global Clinical CRO Services Market Estimates, 2021-2026, USD Bn, CAGR (2021-2026): 8.0%



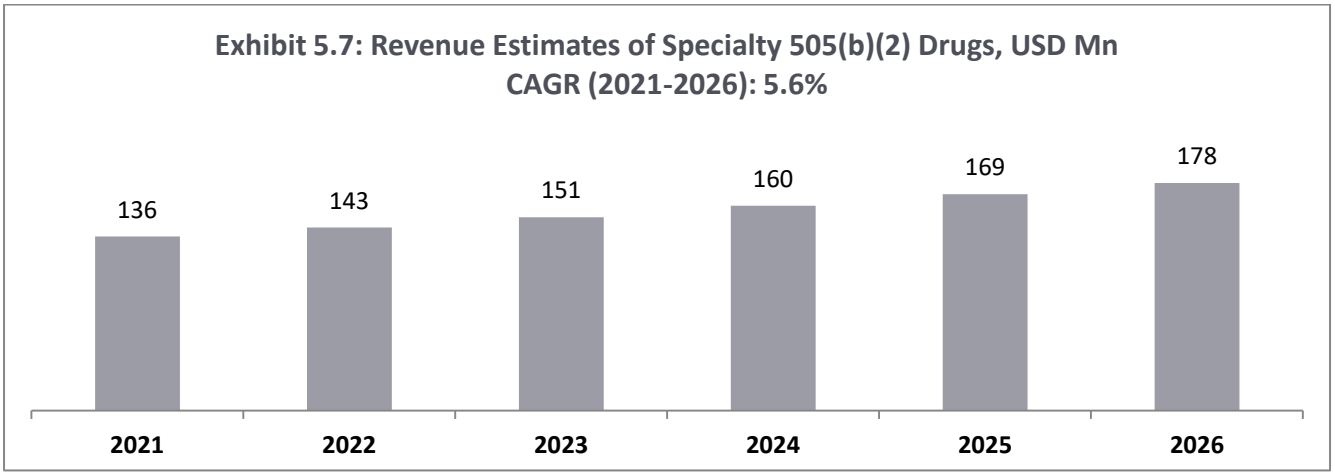
Source: Frost & Sullivan Analysis

Innovation in biosimilars as well as therapeutic development is expected to boost the bio-analytical segment: Increased outsourcing of large molecules along with technological advances is expected to provide a tremendous growth to the segment. Across the globe, emerging markets are expected to show the fastest revenue growth in this segment.

Central laboratory services expected to witness a higher demand in the next five years: With an aim of mitigating cost and drug development risks, central labs are considered crucial outsourcing services by the pharma industry. Big pharma companies rely on CROs' central lab services that span multiple countries and regulatory agencies. Nearly 60% of the data submitted to the FDA is generated through central laboratories. Some key players in this segment are Cirion, LabCorp, Eurofins, and SRL Medisearch. Hence, based on the above, the increase in outsourcing of these clinical activities provides a significant opportunity for CROs globally and locally.

Specialty (505)(b)(2) Products Segment: Market Estimates (2021-2026)

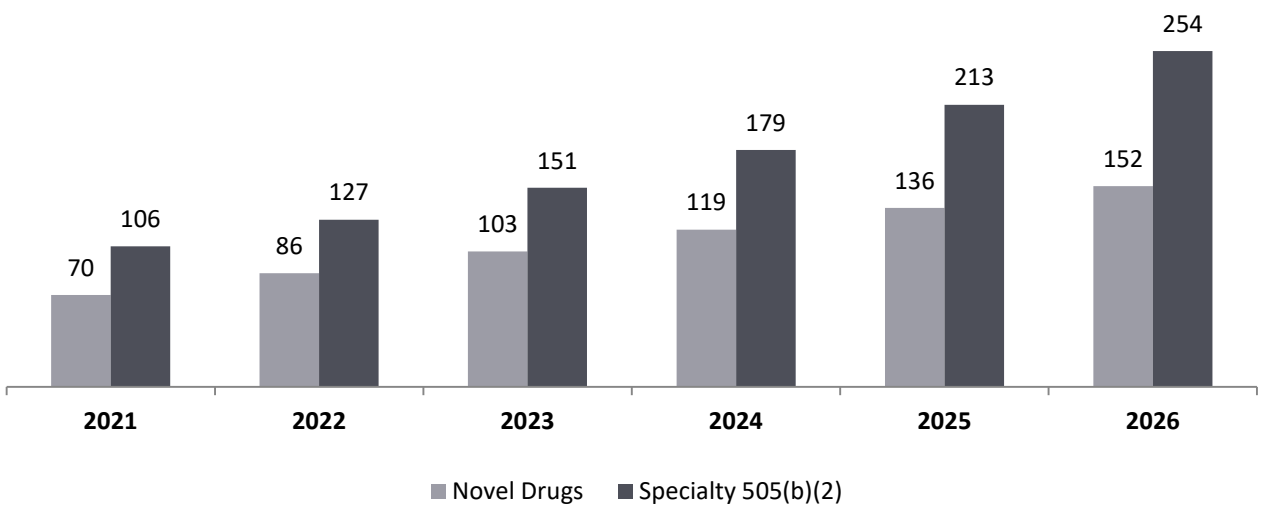
The specialty 505(b)(2) drug market is estimated at USD 136 Mn in 2021 from the sales of 188 products (cumulative sales from 73 products approved in 2017, 60 products approved in 2018, 55 products approved in 2019) and the sales is expected to grow at a 1.5% CAGR (2021-2026) to reach to about USD 178 Mn by 2026. This growth is attributed to the increased number of filings/ approvals for drugs with extended release formulations, new dosage forms and new combinations.



Source: Frost & Sullivan Analysis

There has been a steady growth in the number of 505(b)(2) filings from 2014 to 2019. Around 75 505(b)(2) applications were accepted by the FDA in 2018 and these 75 approvals marked a 19% improvement over the previous year and were more than 27% higher than the number of novel drug approvals during that year (2018). 505(b)(2) approved drugs grew at a CAGR of 8.3% from 2014 to 2019, in comparison to novel drugs which grew at 3.2% during the same period. In 2018, the majority of drugs approved through the 505(b)(2) pathways were in the areas of anti-infectives, pulmonary, cardiovascular, metabolism, and endocrinology.

Exhibit 5.8: Estimated Global Novel and Specialty 505(b)(2) Drug Approvals, Number of Drugs, 2021-2026



Source: Frost & Sullivan Analysis

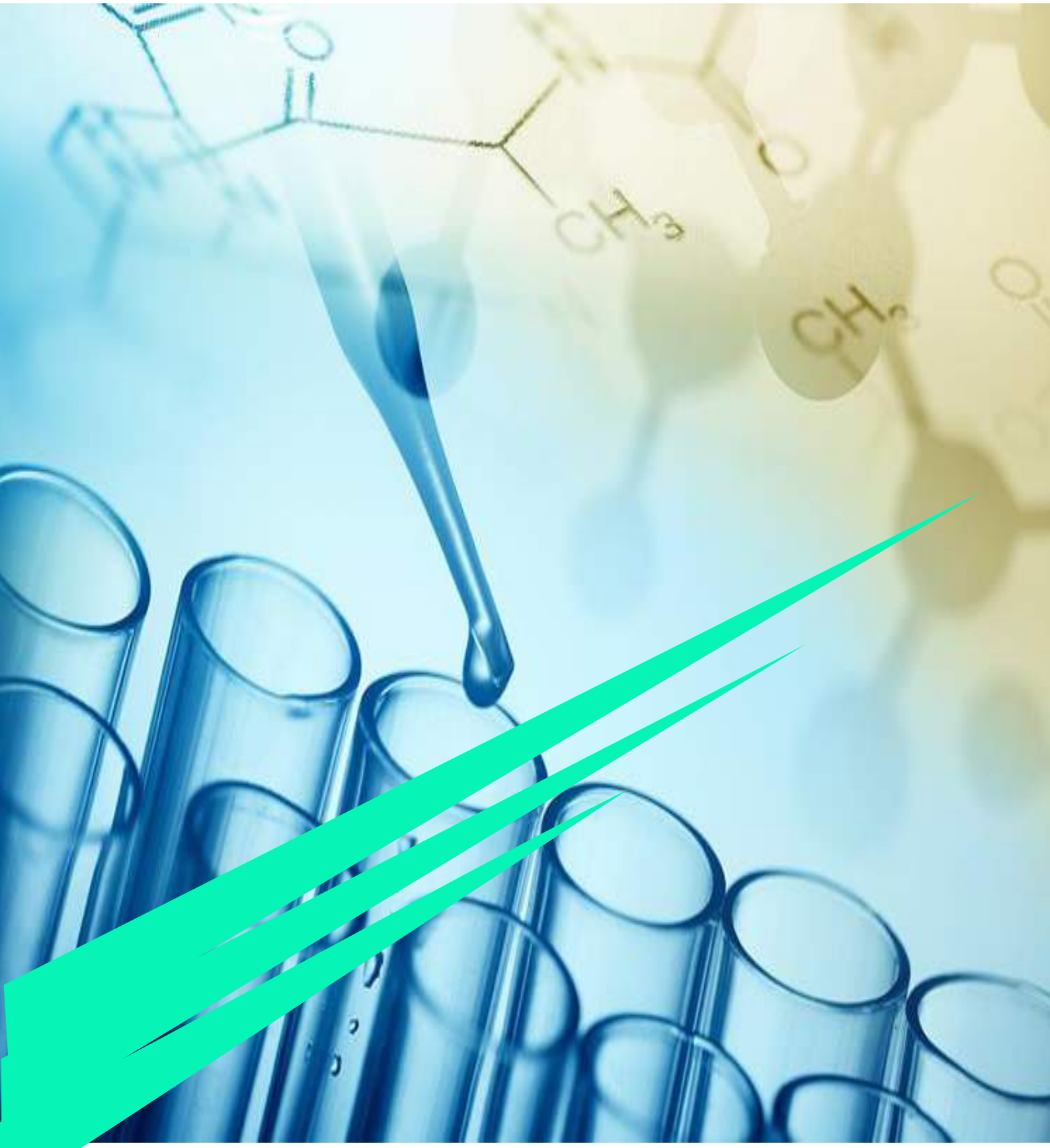
The number of drugs getting approved under the category of 505(b)(2) is expected to be much higher in the next 5 years compared to novel drug approvals. Factors driving this trend include companies cutting costs and 505(b)(2) specialty drugs carrying lower risks and higher returns. Even the duration of developing this category of drugs is shorter compared to the tedious and lengthy process of developing a novel drug in which the approval rate is less than that of 505(b)(2) specialty drugs. As novel drugs face the risk of lack of efficacy, issues with safety, or a lack of funding to complete a trial, as well as other factors such as failing to maintain good manufacturing protocols, failing to follow FDA guidance, or problems with patient recruitment, enrollment, and retention result in huge developmental costs, 505(b)(2) products are relatively less risky with definite returns, making this segment most lucrative.

Key Trends and Drivers of Specialty 505(b)(2) Drugs Segment

- **Strong sales and low development costs lead to significant ROI:** Costs for development can range from as little as USD 3.0 Mn for those with no clinical trials to as high as USD 50.0 Mn when additional trials are required. Hence risk of developing products and filing under 505(b)(2) is lower and returns are higher.
- **Convenience and lower product costs:** Products offer a greater dosing convenience, lower costs, and new formulations as compared to their existing referenced products. As an example, RAVICTI (glycerol phenyl butyrate) was approved in 2013 for the chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary restriction and/ or supplements alone. Offering greater dosing convenience over the reference drug BUPHENYL (sodium phenyl butyrate); RAVICTI garnered USD 824 Mn in sales from launch through 2018.
- **Indian companies shift towards specialty drugs:** Indian Drug makers are shifting focus from their once lucrative generics medicines to specialty drugs amid continued price erosion in its biggest market, the US. The focus on specialty medicines has been accelerated by measures

taken by the US FDA to increase competition in generic medicines to bring down prices. **Specialty drugs are high value prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis.** The price erosion, caused by increased competition and channel consolidation in the US, has put pressure on Indian generic drug companies over the past few years to look at newer avenues. India's largest drug maker Sun Pharmaceuticals has around ten 505(b)(2) filings between 2018 and 2019. As the focus is now shifting towards specialty drugs, this could be a highly beneficial proposition for CRO companies as nearly 50% to 90% of the R&D and clinical trial activities will be outsourced while developing a specialty drugs.

SECTION VI: GLOBAL BA/BE STUDIES, BIOSIMILARS AND PRECLINICAL MARKET OVERVIEW



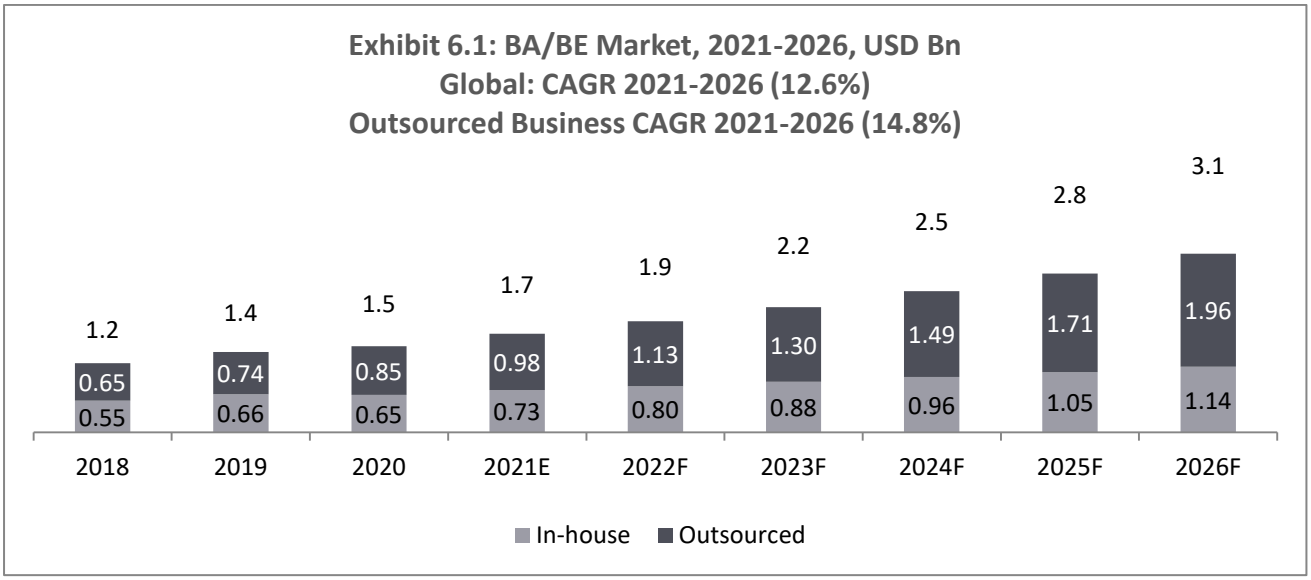
Global Bioavailability (BA) / Bio-equivalence (BE) Market Overview

BA/BE testing plays a vital role in generic drug development. BA/BE studies are important elements in support of INDs, NDAs, ANDAs, and their supplements. To introduce a generic drug in to a regulated market, the generic drug industry needs to meet the stringent criteria in the same way as innovative drugs. India is emerging as a force to reckon with in the global pharmaceutical space. India is one of the top five manufacturers of bulk drugs in the world and ranks amongst the top 20 pharmaceutical exporters in the world. Every fifth application for marketing a generic drug in the US, the world's largest pharmaceutical market, is filed by an Indian company; thereby creating a great opportunity for Indian CROs in the BA/BE segment.

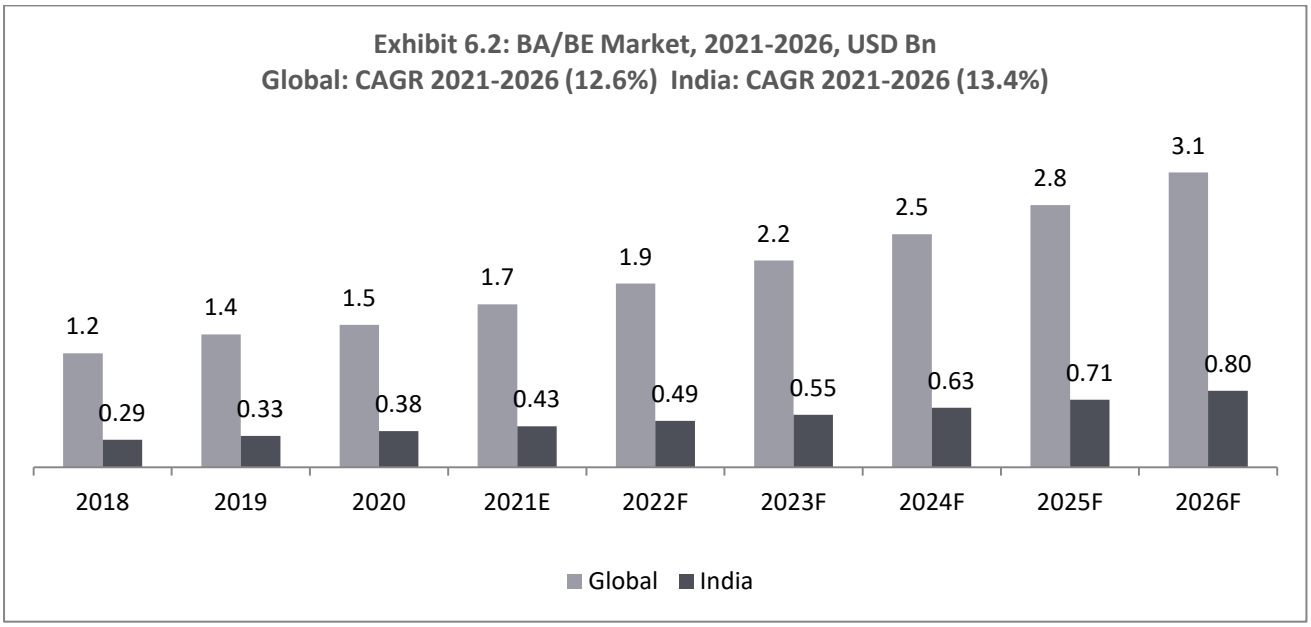
The BA/BE market in India is expected on a higher growth trajectory as compared to the global trends (13.4% vs. 12.6%): The global BA/BE market is estimated to grow from USD 1.7 Bn in 2021 to USD 3.1 Bn by 2026 at a CAGR of about 12.6%. The BA/BE market in India is estimated to grow from USD 0.4 Bn in 2021 to USD 0.8 Bn by 2026 with a CAGR of 13.4%.

India is considered as one of the major destinations for BA/BE studies due to its current CRO infrastructure, increased outsourcing rate of these studies to Indian CROs, emergence and growth of the biosimilars industry, increased demand for complex generics, availability of a large population base to participate in the BA/BE studies, cost-efficiency, changing regulatory landscape and evolving clinical trials evaluation standards in the country. Additionally, India accounts for 20% of global generic drug exports and captures 70% of the global generic drug market share by revenue. These attributes also drive the BA/BE studies market in India.

BA/BE studies expected to be made mandatory for all the approved drugs in India further driving the market growth: The impact of COVID-19 has put the CROs in the country into a tough situation as there is a poor participation of healthy volunteers for clinical trials to conduct BA/BE studies. **Though the pandemic has temporarily hampered the growth of the BA/BE studies market, this segment is expected to see a double digit growth amidst the growth factors stated above** as well as BA/BE studies expected to be made mandatory for all the approved drugs in India as the Indian government is evaluating steps to promote generic versions of all medicines as a cost-containment strategy.



Source: Frost & Sullivan Analysis



Source: Frost & Sullivan Analysis

The BA/BE segment dominate the bio-analytical testing services market and has been estimated to hold the largest revenue share of about 52% in 2021. This can be attributed to the high demand for these services in generic drug manufacturing. The rising patent expiration of branded drugs is encouraging key manufacturers to introduce effective generic drugs, which, in turn, is significantly contributing to the market growth. Going forward, the generic drug market value is projected to reach USD 517 Bn by 2026, expanding at a CAGR of 4.9% during the forecast period (2021-2026).

Government initiatives and rising demand for generic drugs in the domestic markets are set to propel the Indian BA/BE market: BA/BE studies being an integral and major part in testing generic drugs, the market is primarily driven by factors like **rising demand for generic medicines in rural** markets; thereby creating a big opportunity for CROs globally for BA/BE studies. From an Indian market perspective, **the Government plans to provide free generic medicines to half the population**

at an estimated cost of USD 5.4 billion. Affordable medicines under Pradhan Mantri Bhartiya Janaushdhi Kendra's (PMBJKs) achieved an impressive sale of INR 100.40 Crores (USD 14.24 Mn) in first two months of FY21. Thus, rise in the generic drug penetration is an encouraging sign for increased demand for BA/BE studies for Indian CROs.

Some key players operating in the bio analytical testing services market include PPD, ICON, Covance, LabCorp, Charles River Laboratories, inVentiv Health, SGS SA, Toxikon Inc. and Intertek group.

Growth Drivers and Trends

- **The global CRO market outsourcing is contributed by the growth of the generic drug industry,** which is driven by the rising number of loss of patents and exclusivities of innovator drugs. Around 56 drugs lost their patents between 2020 and 2022 and around 107 drugs will be losing their patents from 2023 to 2025.
- **Due to patent cliff that is expected in the next 5 years and expected erosion of prescription sales of USD 198 Bn, emerging markets like India and China would be preferred for outsourcing BA/BE studies.** This trend is driven by large patient population, availability of multispecialty hospitals, increased outsourcing by small and medium pharmaceutical companies, presence of an ethnically and genetically diverse patient pool, availability of educated patient pool, low operational expenditure due to relatively lower human resource costs, and the presence of various types of climatic conditions, thereby, allowing favorable conditions for BA/BE studies to be executed with ease in one destination.
- **The filings are shifting towards complex drugs.** COVID-19 pandemic has further propelled the outsourcing for complex molecules, biologics and biosimilars to CROs; thereby creating a demand for BA/BE studies market.
- **Increasing penetration of biologics and biosimilars propels demand for high quality bio-analytical testing services:** CRO market penetration for biologic drug product outsourcing is currently at less than 15%. However, fuelled by over 13% growth expected from 2021 to 2023, pharma companies are more comfortable in outsourcing the less technologically challenging and IP dependent drug product part of the manufacturing process. The challenge is that biologic development processes are more complex than those for small molecule drugs, and expert bio-analytical testing experience is required to ensure bio-therapeutics can uphold both clinical efficacy and safety.
- **Share of companies that are standalone and not fully integrated (chemo, Pharmathen, Calyx, Icon etc.) is increasing:** Many of the top Global CROs like Paraxel, Covance, IQVIA, ICON etc. are standalone companies offering dossier services.

Global Competitive Landscape

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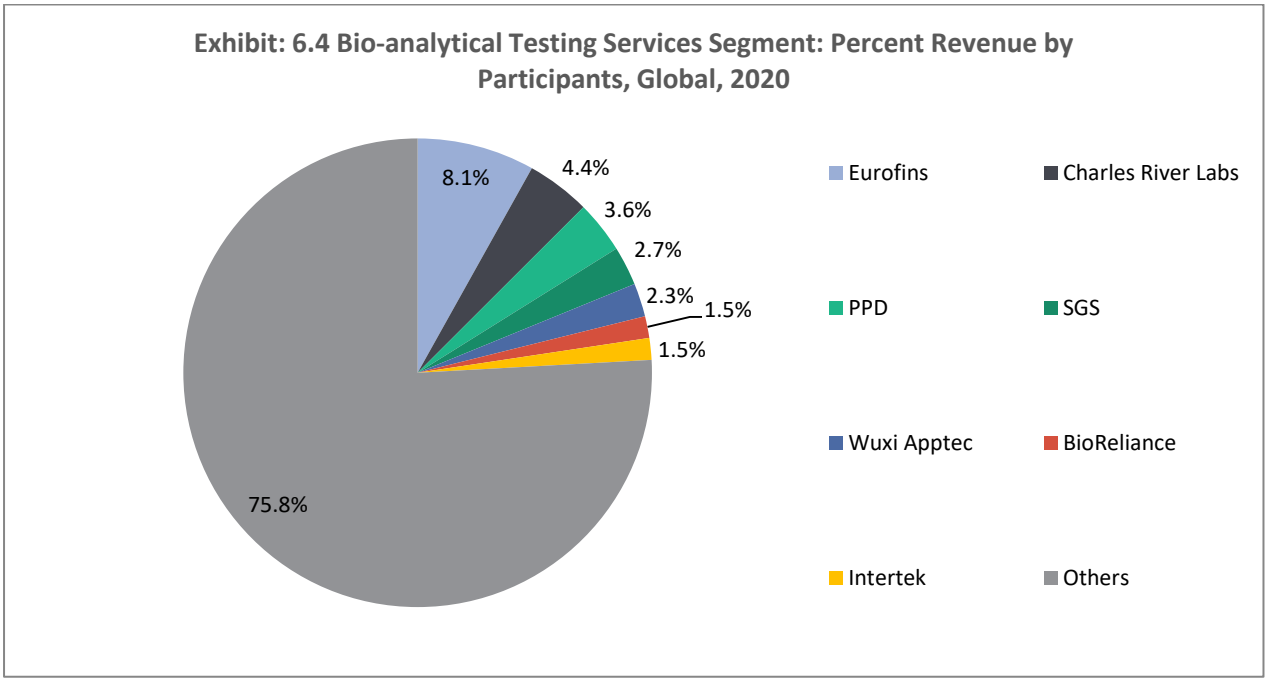


Source: Frost & Sullivan Analysis

Others include Amatsi Group, ABC labs, Irvine, Toxikon, Quotient Bioresearch, Texcell, BioOutsource, BASi, Frontage Labs, AAIPharma, Pacific BioLabs and so on

The bio-analytical testing services segment is highly fragmented and ripe for consolidation. Approximately 28.3% of the market is shared by top companies, with Eurofins Scientific taking the lead with 9.5% market share. With new expansion in biologics testing facility, Charles River labs occupy about 5.2% and securing the second position in the market. The rest includes PPD, SGS Life Sciences, WuXi AppTec, Intertek and BioReliance (Sigma Aldrich).

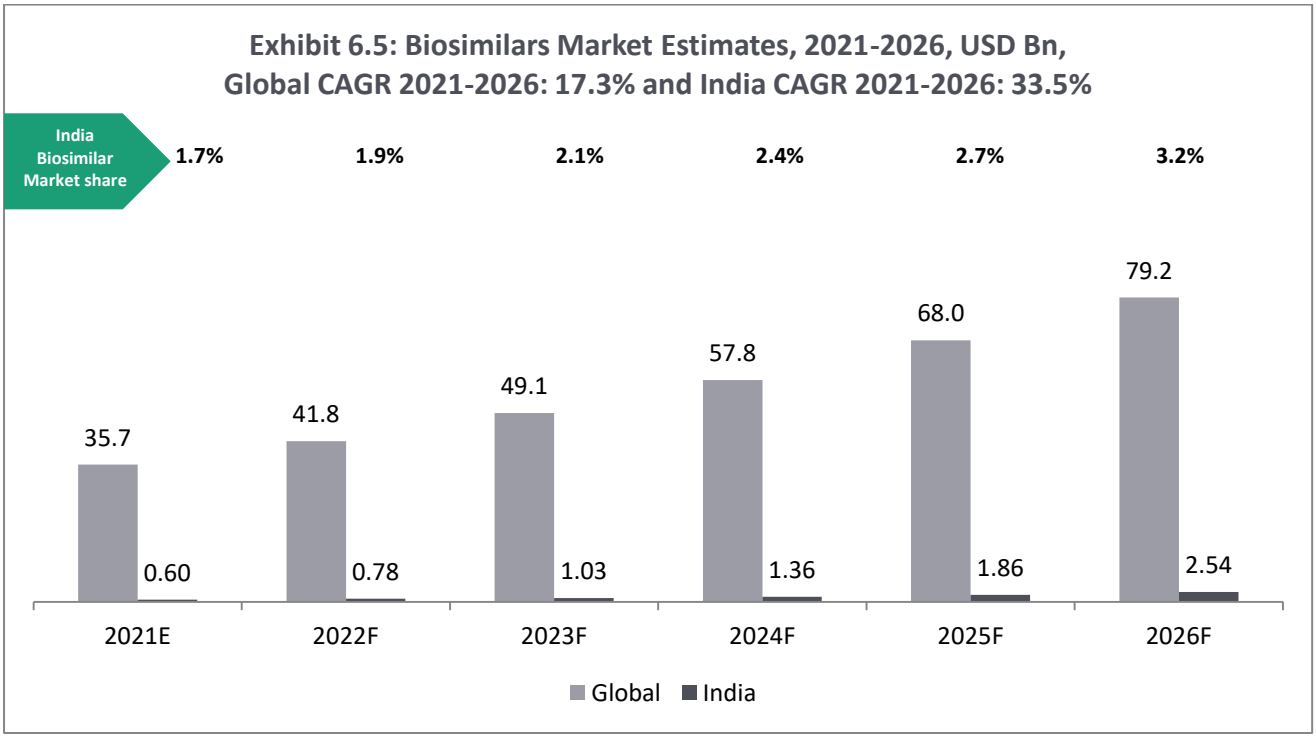
At the bottom level, more than 100 mid-tier and niche players hold 71.7% of the market share. Other players include Amatsi Group, ABC labs, Irvine, Toxikon, Quotient Bioresearch, Texcell, BioOutsource, BASi, Frontage Labs, AAIPharma, Pacific BioLabs.

The business environment is intensely competitive with top-level companies adopting acquisition strategies to strengthen their footprint in new geographies.

Global Overview of Biosimilars Market:

Biosimilars Segment: Market Estimates (2021E-2026F)

The global biosimilars market is expected to witness its highest year-on-year growth rate during the forecast period of about 17.3% between 2021 and 2026 which can be attributed to the steep uptake of third-wave biosimilars such as biosimilars of Ranibizumab, Omalizumab, Aflibercept, and Adalimumab (HUMIRA).

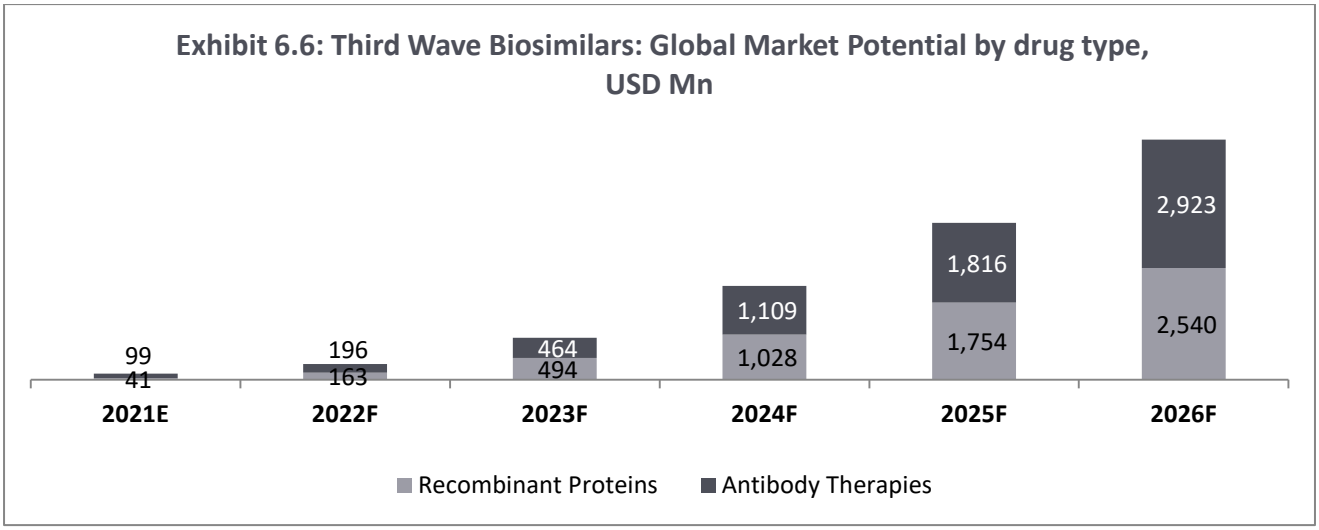


Source: Frost & Sullivan Analysis

The penetration of biosimilars ranges from 5% to 10% to up to 90% across different geographies. Factors like the tender systems (which favors price discounts), acute treatments (where rotation of patients is higher), number of competitors, and the type of competitors, determine the rate of penetration. A rise in affordability, as in most cases, will drive overall biosimilars market growth in India increasing its share from 12.7% in 2021 to around 15.4% in 2026 in the global market. This is certainly an encouraging sign for CROs majorly involved in biosimilars like Cliantha and Veeda + Bioneeds in India.

Key Trends and Drivers of the Biosimilars Market

The third-wave of biosimilars will lead to strategic manufacturing outsourcing collaborations due to the complexity of these drugs as well as the access to newer therapy areas.



Source: Frost & Sullivan Analysis

- **Manufacturing outsourcing collaboration for complex third-wave biosimilars:** Outsourcing collaborations aimed at optimizing operational efficiency and side stepping infrastructure costs will provide both short-term opportunities in emerging markets as well as long-term benefits in global markets.
- **Innovation orientation towards bio betters for biosimilar companies:** Bio-better innovations are evolving from being a go-to-strategy for innovative biologic companies to strengthen their market share and decreasing commercial risk, to potentially offering a faster route to market and increase access to biosimilar companies.
- **Developing and manufacturing of biosimilars in India for the global market:** India is a great biosimilar manufacturing destination for the global market with low infrastructure investment, a huge pool of skilled and cheap labor, and government incentives such as reduced compliances and accelerated approval mechanisms.
- **Interchangeability approvals for increased biosimilar uptake in the US market:** Avoiding pitfalls in the interchangeability designation process and securing interchangeability approvals will play a key role in the biosimilar uptake in the US biosimilar market as the approval will help sway physician opinions.
- **Ophthalmology biosimilars for First-to-Market advantage:** Companies targeting third wave biosimilars such as ranibizumab and aflicercept in the ophthalmology therapy area can thrive in the market which currently sees limited competition in terms of the clinical pipeline and can provide first-to-market advantages in various geographies.

Biosimilar industry in India is expected to cross USD 2.5 Bn by 2026 driven by the lower cost and less stringent regulatory process. This is due to large patent cliff that is expected in the next 5 years. The cost to develop a biosimilar in the EU or US is estimated between USD 100 and USD 200 Mn; while, in India it costs about USD 10 to USD 20 Mn. This lower cost of development is attributed to several factors, including the lower cost of recruiting patients, fewer labor and service fees, as well as less stringent regulatory approval criteria. This trend could be a driving factor for CROs. The Government plans to allocate USD 70 Mn for local players to develop biosimilars in India.

Government initiatives opens doors for biosimilar for the domestic market: India currently has over 95 biosimilar molecules approved. The Ayushman Bharat yojana, a universal health care coverage program, plans to allow underserved population to access costly drugs such as biosimilars. This initiative has opened a large industry for biosimilars within India. Pharma Vision 2020 is aimed at making India a global leader in end-to-end drug manufacturing. The "Make in India" scheme has made it easier to develop biosimilar manufacturing units with incentives, tax subsidies, and up to 100% FDI in green-field projects.

Multiple pharma companies are manufacturing biosimilars on their own and some of them are developing JVs or alliances to outsource to R&D intensive firms like CRO/ CRMs. Few of the partnership with Indian CROs include Biocon-Sandoz, Biocon-Mylan, and DRL-MerckGA for global industry. Indian companies like Glenmark, Intas, Biocon, Lupin and Zydus are activity focusing on biosimilars. Biocon Biologics earned about INR 769 Crore in Q3 FY21 up by 11% from INR 693 Crore in Q3FY 20.

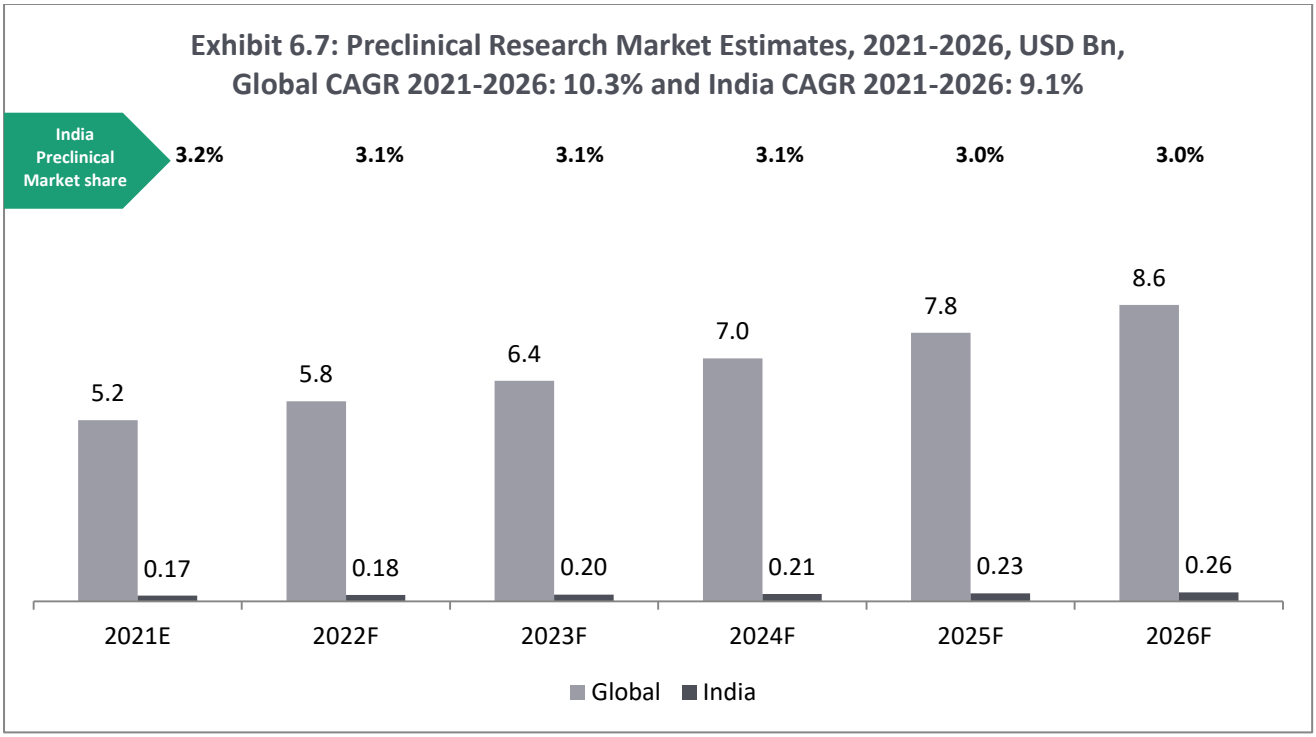
Global Overview of Preclinical Research Market

Preclinical research segment captures about 8% of the total global CRO market and is expected to witness 10.3% growth over the next five years (2021-2026). This is driven by increased outsourcing of early-stage activities by small-to-mid segment pharmaceutical companies. North America and Europe are the key dominating segments for discovery and preclinical research, with more than 50% of the market for early-stage drug development, as most of big CRO participants function in these regions, followed by APAC.

Rising patent cliffs leads to increased outsourcing in this segment: The preclinical market is expected to show an robust double-digit growth of 10.3% between 2021 and 2026 mainly attributed to the advent of advanced screening processes for molecules as well as rising patent cliffs of existing drugs, thus ensuring greater R&D. Growth in the end of the forecast period could be largely attributed to the continued need for new treatment by the overall healthcare industry. Drug development, especially across niche disease areas, is the major requirement across this industry.

Owing to a strong and continued demand for improved therapies, the preclinical trials segment is considered the most promising segment in the CRO Market. Drug candidates for oncology, central nervous system, and cardiovascular diseases predominantly occupy this market segment. These growing demands are also considered to be the reason for growing investments in the segment. Despite the pricing pattern showing promise, concerns regarding the rising competitive forces and pricing pressures from developing countries offering outsourcing at a much lower cost than developed countries, pose a threat to the global CRO market. Expansion in developing drugs across disease types helps the preclinical trials segment further strengthen its position in the market.

Exhibit 6.7: Preclinical Research Market Estimates, 2021-2026, USD Bn, Global CAGR 2021-2026: 10.3% and India CAGR 2021-2026: 9.1%



Source: Frost & Sullivan Analysis

The market is expected to show an robust double-digit growth of 10.3% between 2021 and 2026 mainly attributed to the advent of advanced screening processes for molecules as well as rising patent cliffs of existing drugs, thus ensuring greater R&D.

Key trends:

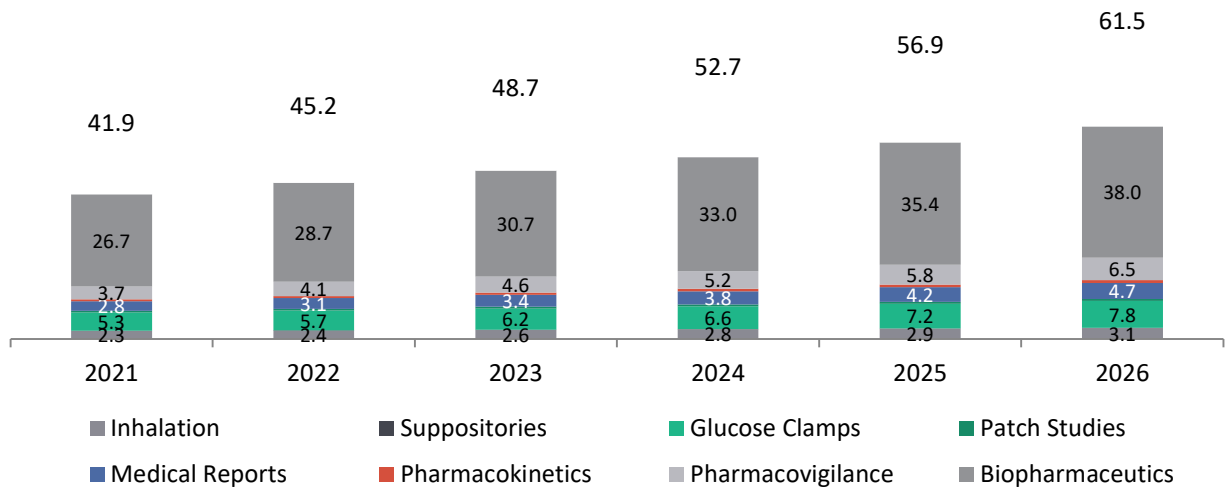
- Increased penetration in preclinical outsourcing market arising from the growing need for innovative therapies.
- Increased investment in preclinical toxicity testing because of a higher demand from pharma companies.
- The uptick in preclinical outsourcing will continue, as pharmaceutical companies are trying to reduce the cost.
- Preclinical toxicity testing reduces R&D spending; thereby, increasing demand for toxicology testing.
- Lower costs due to strong demand for outsourcing of preclinical research activities to Asian companies than other developed nations.

SECTION VII: GLOBAL CRO INDUSTRY OVERVIEW: SPECIFIC SEGMENTS

Global Market Overview of Specialized Services in the CRO Industry (Inhalation, Suppositories, Glucose Clamps, Patch Studies, Medical Reports, Pharmacokinetics, Pharmacovigilance, Pharmaceuticals only)

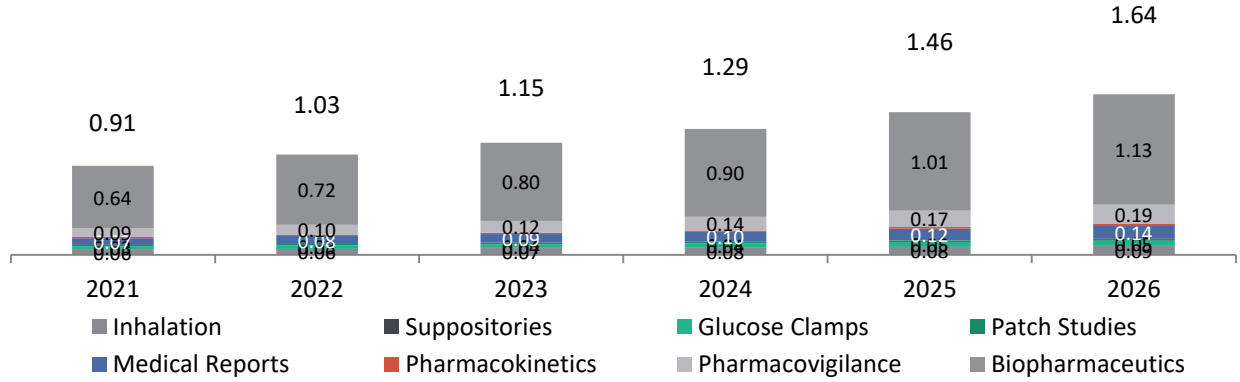
Developing differentiated drug delivery format is additional opportunity for CRO players. The global CRO market for specialized services (in scope of this report) is estimated at USD 41.9 Bn in 2021 and is expected to grow at a CAGR of 8% to reach to about USD 61.5 Bn by 2026. The Indian CRO market for specialized services is estimated at USD 0.91 Bn in 2021 and is expected to grow at about 12.5% in the next five years to reach to about USD 1.65 Bn. Indian CRO players like Veeda are also developing capabilities and focusing on these specialized categories.

Exhibit 7.1: Specialized Services Global Market for CROs, USD Bn, 2021-2026, Global CAGR 2021-2026: 8%



Source: F&S research and analysis

Exhibit 7.2: Indian Specialized Services Market for CROs, USD Bn, 2021-2026, India CAGR 2021-2026: 12.5%



Source: F&S research and analysis

Specialized Services	Global Opportunity (USD Bn)			India Opportunity (USD Bn)		
	2021	2026	CAGR (2021-2026)	2021	2026	CAGR (2021-2026)
Inhalation	2.300	3.120	6.3%	0.055	0.092	10.8%
Suppositories	0.046	0.066	7.7%	0.001	0.002	12.2%
Glucose Clamps	5.300	7.780	8.0%	0.032	0.050	9.1%
Patch Studies	0.500	0.610	4.1%	0.012	0.018	8.4%
Medical Reports	2.800	4.660	10.7%	0.070	0.140	14.9%
Pharmacokinetics	0.530	0.790	8.3%	0.011	0.019	11.6%
Pharmacovigilance	3.700	6.480	11.9%	0.089	0.192	16.6%
Bio pharmaceutics	26.700	38.010	7.3%	0.640	1.130	12.0%
Total	41.88	61.52	8.0%	0.910	1.642	12.5%

Source: F&S research and analysis

Specialized Services: Inhalation

The global inhalation market for CROs is expected to register a CAGR of about 6.3% bringing the market size to about USD 3.1 Bn by 2026 from USD 2.3 Bn in 2021. The same segment in India is expected to generate revenue of about USD 55 Mn in 2021 and grow by about 11% CAGR to reach to about USD 92 Mn by 2026.

The growth in the market of the inhalation segment is driven by the rising cases of asthma, COPD, cystic fibrosis, lower respiratory tract infections, pneumonia, tuberculosis and current rise in cases of COVID-19 infections. This will provide a significant opportunity for the global CROs to conduct studies on inhalation drugs due to rising demand for effective pulmonary drug delivery systems. Currently Covance is one of top players in this segment.

About 2.5-5% of Indians suffer from respiratory ailments such as asthma and there is prevalence of other respiratory diseases such as chronic bronchitis, emphysema and COPD in the country. Additionally, **pollution caused by rapid urbanization and rising geriatric population (>60 years) is also driving the demand for inhalation drugs for managing respiratory ailments.**

Specialized Services: Suppositories

The global suppositories market for CROs is expected to grow from USD 46 Mn in 2021 to USD 66 Mn by 2026 with a CAGR of about 7.7%. The Indian CRO market for suppositories is expected to grow from USD 1.10 Mn in 2021 to USD 1.96 Mn expected to grow at a CAGR of about 12.3%.

The fat-based suppositories play a crucial role in drug delivery, majorly in geriatric and pediatric patients. The rectal route serves as an excellent alternative for drug delivery amongst these populations. In addition, the increasing demand for fat-based excipients is mainly due to their benefits such as the potential for absorption into the lymphatic system, and quick absorption of multiple low molecular weight drugs. Moreover, the increasing number of product launches is anticipated to generate a lucrative opportunity for the growth of the global market. For instance, in July 2017, Cipla launched fat-based rectal suppositories for the treatment of malaria. These factors may lead to driving the growth of global fatty bases for suppositories market, over the forecast period. **On the other hand, the complexities in the developing of oil-based suppositories are expected to restrain the growth of the market, during the analysis period.**

Specialized Services: Glucose Clamps

Glucose clamping has become a standard, widely used technique in researching diabetes treatment as well as obesity and fatty liver studies. Globally, the clamp studies market for CROs is expected to grow with a CAGR of 8.0% from USD 5.3 Bn in 2021 to reach to about USD 7.78 Bn by 2026. While, in India, the glucose clamp studies market is expected to reach to about USD 0.050 Bn in 2026 from USD 0.032 Bn in 2021 at a CAGR of about 9.1%.

This market is driven by increase in the prevalence of diabetes, obesity and fatty liver cases. The risk factors for the increase in these chronic disorders are sedentary lifestyle, excessive consumption of junk food and increased alcohol consumption. This has been witnessed especially in the age group of 20-45 Years. The rise in geriatric population also contributes to the growth of the above mentioned disorders. Thus, glucose clamp studies have a great market opportunity for CROs as pharma companies are increasingly outsourcing these activities and the rate of outsourcing is currently at about 45% and expected to reach to about 60% in the next five years.

Specialized Services: Patch Studies

The global CRO market for patch studies is expected to grow from USD 0.5 Bn in 2021 to reach USD 0.61 Bn by 2026 at a CAGR of about 4.0%. The Indian CRO market for patch studies is expected to grow from USD 12.0 Mn in 2021 to USD 18.1 Mn by 2026 at a CAGR of about 8.5%.

The growth is mainly due to the companies resuming their operations and adapting to the new normal while recovering from the COVID-19 impact, which had earlier led to restrictive containment measures involving social distancing, remote working, and the closure of commercial activities that resulted in operational challenges.

Advances in modern technologies increase the number of drugs being delivered transdermally including small molecule hydrophobic drugs, hydrophilic drugs, and macromolecules. The new technological advances add to the increased efficiency and increased use of transdermal drug delivery systems (TDDS) thus, increasing the popularity and demand for TDDS. For instance, in 2019, few technological advances in the TDDS included transdermal patch formulation improvements, introduction of pressure-sensitive adhesives and permeation enhancers, which lead to increased product diffusion and increased drug retention ability in larger quantities. The advances in technologies are expected to increase the demand for transdermal patches owing to its benefits thereby driving the growth of the market.

As a result, there are increased M&As seen in this space in 2019, Canoa Inc., a Delaware based healthcare and pharmaceuticals company, acquired ProSolus® Inc. to enhance its position and development of new products in transdermal space. Similarly, in 2019, Mylan, a pharmaceutical company providing transdermal skin patches, with Upjohn, a subsidiary of Pfizer announced the formation of a new company named Viatris.

This provides a great opportunity for global CROs to conduct patch studies as there is a considerable growth in this segment driven by advances in technology.

Specialized Services: Medical Reports Writing

The global market medical writing / reports is expected to grow at a CAGR of about 10.7% to reach USD 4.66 Bn by 2026 from USD 2.80 Bn in 2021. The Indian medical reports market is estimated to grow from USD 67.3 Mn in 2021 to reach to about USD 138.1 Mn by 2026 at a CAGR of 15.5%.

This segment of the market is driven by increased outsourcing of some of the medical writing activities like clinical data management (82% outsourced), followed by clinical IT (80% outsourced) and biostatistics (72% outsourced). These outsourcing percentages are expected to even reach 90-100% from the small and medium pharmaceutical companies.

India is the preferred country for outsourcing due to its cost effectiveness and international standard infrastructure. India is also leading due to availability of skilled manpower in the clinical research and related fields. Increasing number of patents expiring is a key factor driving the growth in the medical writing industry. It has been observed that with various patents expiring, the need for the medical writers has increased for the preparation of drafts of new patents as well as writing product specifications. With inclusion of more diverse products in the industry, the need for medical writing increases, which is another force driving for the market.

Specialized Services: Pharmacokinetics

The global CRO market for pharmacokinetics is expected to grow from USD 0.53 Bn in 2021 to USD 0.79 Bn by 2026 at a CAGR of about 8.3%. Rising adoption of pharmacokinetic and toxicology studies for determination of several parameters such as no-observed-effect levels (NOEL), human equivalent doses (HED) levels, and pharmacokinetic/pharmacodynamics (PK/PD) drivers are expected to fuel the market growth.

The pharmacokinetics market for CROs in India is expected to grow from USD 10.7 Mn in 2021 to USD 19.1 Mn by 2026 at a CAGR of about 12.4%. Emerging nations such as India and China are expected to open new growth opportunities for pharmacokinetics service providers over the forecast period. Service providers adopt integrated systems and technologies, such as robotic automation and Laboratory Information Management System (LIMS), advanced mass spectrometry, and bioassays, to facilitate sensitivity and accuracy in the analysis of samples. The growth of biologics and the outsourcing of biologics development are key trends accelerating the growth of this segment.

Companies like Charles River Laboratories, Parexel and Eurofins Scientific are some of the key service providers. These CROs are undertaking various initiatives in order to capitalize on new market avenues and enhance their future market shares.

Specialized Services: Pharmacovigilance

The global CRO market for pharmacovigilance is expected to grow from USD 3.7 Bn in 2021 to USD 6.48 By 2026 with a CAGR of about 11.9%. Alongside early-stage drug development activities, the advent of biologics is generating the need for improved post-marketing activities which include pharmacovigilance and HEOR.

The Pharmacovigilance market for CRO in India is estimated to grow from USD 89 Mn in 2021 to USD 192 million by 2026 with CAGR of 16.7%. Accelerating demand for personalized medicines will drive the market expansion along with strict regulations for reporting adverse drug reactions coupled with large number of companies offering pharmacovigilance outsourcing services across the region will foster the market growth.

Pharmacovigilance holds importance, especially in late-stage phase III and post-marketing surveillance. With regulatory requirements continuing to be the biggest challenge for most pharmaceutical companies, pharmacovigilance becomes a key aspect of ensuring drug quality assessment. Global pharmaceutical firms have found India to be a favored marketplace for clinical trials due to large clinical research space and attractive opportunities. Improved compliance with the international guidelines such as the ICH-GCP and the rules set down by the US FDA offers enormous opportunities for clinical trials in the country.

Specialized Services: Bio pharmaceutics

The Global CRO market for bio pharmaceutics is expected to reach USD 38 Bn by 2026 from USD 26.7 Bn in 2021 at a CAGR of 7.3%. The Indian CRO market for bio pharmaceutics is expected to grow from USD 0.64 Bn by 2026 from USD 1.13 Bn in 2021 at a CAGR of 11.9%.

The ongoing COVID-19 pandemic globally is expected to have a significant impact on the pharmaceutical industry. Most of the pharmaceutical companies are striving extensively for the development of vaccines against the SARS-CoV2 virus. Some of the candidates are traditional-type vaccines such as inactivated and attenuated products; however, most of the vaccine candidates being developed are advanced DNA, RNA, and protein subunit vaccines. This factor is expected to boost the growth of the pharmaceuticals market. The market is also largely driven by the growing geriatric population, rising chronic diseases, and increasing acceptance of pharmaceuticals. Thus, the demand for CRO bio pharmaceutics will be increased driven by the rising demand for pharmaceuticals.

The Indian biotechnology industry amounted to USD 63 Bn in 2019 and is estimated to reach to about USD 102 Bn by 2025, with a CAGR of 10.9%. By 2025, the contribution of the Indian biotechnology industry in the global biotechnology market is expected to grow to 19% from 3% in 2017. Pharmaceutical is the largest segment that contributed ~58% to the Indian biotechnology market in 2019, followed by bio-agriculture, which accounted for 19% and bio-services, which accounted for 15% in 2019. Bio-services, which accounted for 15% of the biotechnology industry in India, is becoming a leading destination for clinical trials, contract research and manufacturing activities in the country. Thus these are encouraging factors for bio pharmaceutics CRO services in India.

SECTION VIII: CONCLUSIONS

Veeda Clinical Research (hereafter referred as "Veeda") is one of the largest independent full service clinical research organizations ("CRO") in India. Veeda has a long-standing relationship with its clients mostly in India, USA, UK and Belgium among others. Further, its clientele is diversified with top 10 customers contributing around 32% and 24% to TOI of the company during FY20 and 10MFY21, respectively.

Veeda has demonstrated a superior track record of regulatory compliance with its facilities have been inspected by regulatory authorities like USFDA, UK-MHRA, WHO, ANVISA, MCC, DCGI, AGES, AFSSAPS and NPCB. Veeda has also set up a new facility at Mehsana, Gujarat with 162 beds which increased the total capacity of Veeda to 514 beds as on 31 December 2020.

Somru BioScience Inc., a leading Canadian-based biotechnology company based in Charlottetown, Prince Edward Island, and Veeda started an establishment of an innovation-centric bio-analytical laboratory in Ahmedabad, India. Somru Bioscience has a vision to become a preferred CRO clinical partner in product development's success journey from early inception to product launch.

As discussed earlier, CROs are becoming more and more involved with the development of biosimilars due to their expertise in and streamlining of the research, development, manufacturing, and up-scaling of biologic products. Companies like Veeda Clinical Research and Lambda Therapeutics Research (both Indian companies), for instance, have positioned themselves well in this space by providing specific services tailored to biosimilar development and manufacturing. **Veeda is providing a basket of services for the development of biosimilars including consulting, regulatory, laboratory and clinical developmental services. It has a team of experts with experience on working over 20 biosimilar molecules for India and Global registration.**

Veeda is known for its scientific capabilities to execute complete solutions for its customers, whether it is in the sphere of generics or more complex molecules. Over 90% of its submissions are to leading global regulatory authorities. **It offers regular bioequivalence studies for generic drugs in healthy volunteers, pharmacokinetic and clinical endpoint studies for generic drugs in patient volunteers and bio-analytical work for NCE for innovators**, and they are fast developing their capabilities in the large molecules and biosimilar space. **Veeda has performed 750 clamp studies and has a total of 500 beds with advanced equipments and trained staff.**

Biosimilars, complex generics and patient-based clinical trials are the three core areas of growth where the company has focused on strengthening its clinical and bio-analytical capabilities. It is also focusing to increase its presence in the European and US markets where it has strong relationships with leading pharmaceutical companies. Additionally, it is working actively to set up a base in China. **Finally, it has completed end-to-end service offering to its clients by acquiring preclinical services company, Bioneeds, into its portfolio to support its clients' development programs in biosimilars and complex generics, besides NCEs.**

Veeda CRO expertise mapping with the growing segments of various therapeutic areas

Therapeutics Area	Global CAGR (2021-2026)	Veeda Therapeutic Area CRO Experience	Veeda Indication Specific CRO Capability
Oncology	7.20%	Yes	CML, Metastatic Breast cancer, NSCLC, RCC, Colorectal, Ovarian Cancer, SCLC
Respiratory	6.81%	Yes	N/A
Metabolic / Endo	6.63%	Yes	N/A
CNS	6.42%	Yes	Schizophrenia
CVD	6.42%	Yes	N/A
Infectious Diseases	6.19%	Yes	HIV-1
Others	NA	Yes	Rheumatoid Arthritis, Avascular Necrosis, Articular Cartilage Defects, Dermatology

Source: Veeda, Frost& Sullivan Analysis

Oncology is the leading segment in terms of revenue and expected growth and Veeda has an extensive experience in CRO related activities for this therapeutic area. The other potential therapy areas include CNS and infectious diseases where Veeda has its presence in line with the market demands.

Veeda Clinical Research has completed more than 29 patient based clinical studies so far, out of these 23 studies are PK endpoint studies and 6 clinical endpoint studies. It has enrolled more than 1,250 patients in various therapeutic areas and worked with more than 125 sites across India in different therapeutic areas such as oncology, psychiatry, ophthalmology, HIV, rheumatology, dermatology and bone diseases.

Veeda expertise mapping with the growing segments of clinical research value chain

Segments	Global CAGR (2021-2026)	India CAGR (2021-2026)	Veeda CRO Capability
Preclinical	10.3%	9.1%	Yes
Phase I	6.1%	9.4%	Yes
Phase II	7.9%	8.7%	Yes
Phase III	7.5%	13.5%	Yes
Phase IV	7.2%	15.2%	Yes
BA/BE Studies	12.6%	13.4%	Yes

Source: Veeda, Frost& Sullivan Analysis

Exhibit: 8.1 Mapping clinical research services of select companies

Company	Drug Discovery and Preclinical Development				Early Clinical Phase		Late Clinical Phase III			Generics / Contract Manufacturing		Biosimilars and Biologicals
	Discovery Services	Chemistry	Bioanalysis	Toxicology	Phase I	Phase II	Functional Services	Central Lab	Phase IV	BA / BE	Patient Based	
Veeda+Bioneeds	■	■	■	■	■	■	■	■	■	■		■
Vimta	■	■	■	■	■	■		■		■		
Accutest		■	■		■		■			■		■
Aizant	■	■	■	■						■	■	
Sitec	■	■	■							■		
Ecron Acunova	■	■	■		■	■	■	■	■	■		
Azidus					■	■		■		■		
Enem			■				■			■	■	
Raptim		■	■			■			■	■		

The chart shows clearly that Veeda + Bioneeds emerges as one of the leading independent CROs in the Indian CRO market offering 11 out of 12 clinical services in the CRO value chain. Veeda + Bioneeds is followed by Ecron Acunova with 9 out of 12 clinical services and Vimta with 8 out of 12 clinical services.

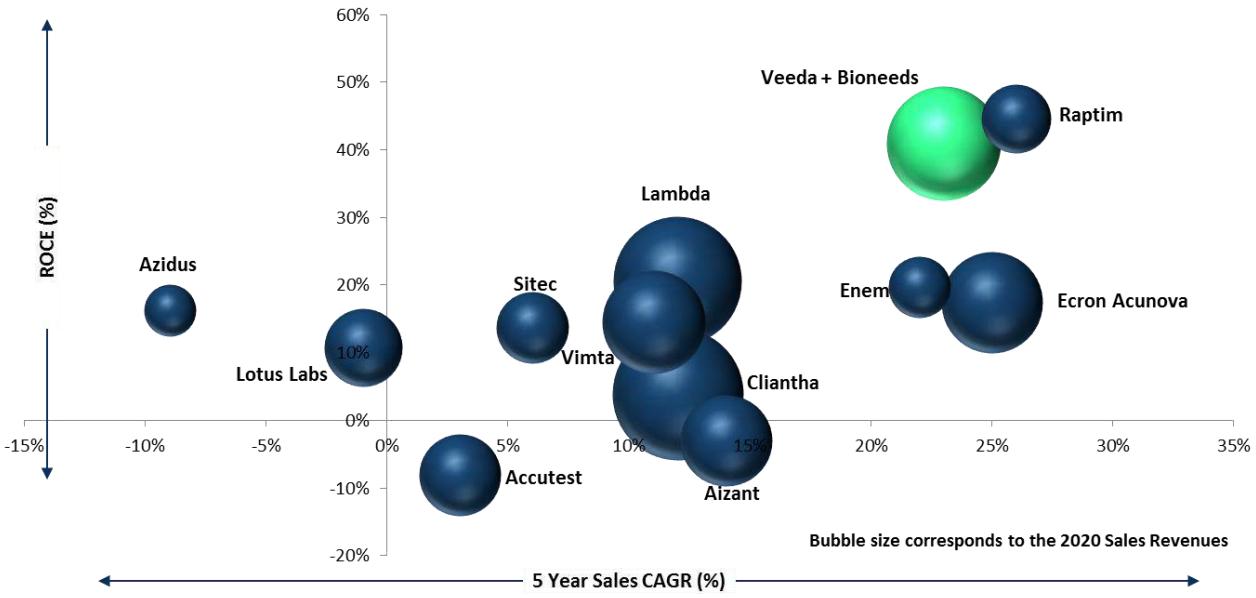
Note: Clinical services included in the analysis are discovery, preclinical, bio-analysis, PK/PD, clinical trials, BA/BE studies, generics, and biologics/biosimilars.
The table above compares the clinical research services of companies that are purely in to clinical research activities. Syngene has not been included in the analysis as the company offers CRAMS (contract research, development and manufacturing) services.

Benchmarking Veeda + Bioneeds and its Competitors

- *Companies playing in the Indian CRO market who are exclusively offering preclinical, clinical, BA/BE, PK/PD and other bio-analytical services in the value chain have been considered for the benchmarking exercise.*

- *CROs having other business segments like contract manufacturing (Ex. Syngene) and Global CROs which have their back-end office for data management (IQVIA, Parexel etc.) have not been included in the benchmarking exercise.*

Exhibit 8.2: Benchmarking Veeda vis-à-vis Select Competitors, 2021



The above bubble chart determines the future potential and attractiveness of the companies in terms of 5-year sales growth, ROCE and 2020 sales revenue. Veeda + Bioneeds emerge as a leader on the basis of 2020 sales revenue and sales growth and return ratio (ROCE) in the Indian CRO industry.

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