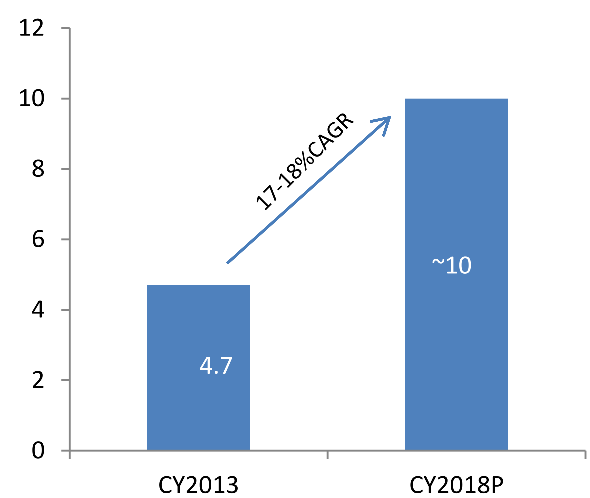
Indian CRAMS players to cram in growth: CARE Ratings

CARE Ratings expects Indian Contract Research and Manufacturing Services (CRAMS) players to register strong growth rates – a CAGR of 18-20% by 2018. In the past with global innovators rationalizing inventories and reducing Research & Development spend; Indian players faced a gloomy phase. Going forward factors like patent cliff, favorable currency and focus on new product development shall drive the growth. In CARE Ratings' opinion this augurs well for the credit profiles of the Indian CRAMS players.

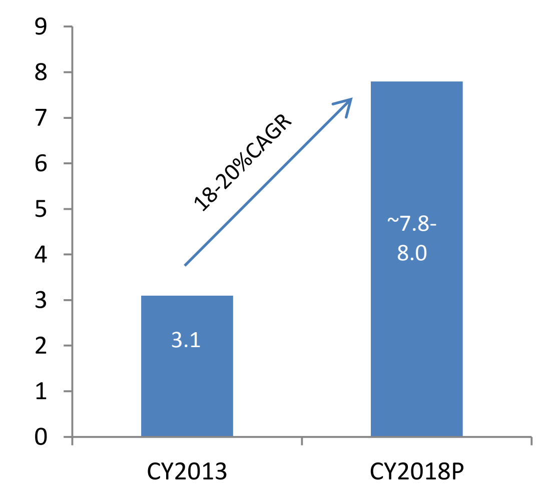
Indian CRAMS industry - regaining health

The growth rate for Indian CRAMS players slowed down to 5-8% CAGR during 2009-2011. The industry underwent tough times on account of inventory rationalization and reduction in Research and Development (R&D) budget by multinational pharma companies in the face of global slowdown. Amid slowdown, CRAMS players also faced rising cost pressures, especially with new products not being launched in the market. However, the growth rate gradually picked up to low double digits in subsequent years. Going forward, CARE Ratings expects gradual improvement (expected CAGR 18-20%) on the back of recovery signs witnessed in US markets. Further, global pharma companies are slated to enhance their allocations towards R&D in order to increase their drug pipeline. Increase in fresh orders and new assignments will aid in revival of CRAMS business.

CMS (US$ bn.) and growth (%)



CRS (US$ bn.) and growth (%)



Source:- CARE Ratings

Several models of arrangements of pharma companies with CRAMS players have emerged in recent years:

- CRAMS companies have become steady suppliers of active pharmaceutical ingredients (APIs), used in the manufacture of formulations. For e.g. Dishman Pharmaceuticals and Chemicals Ltd., Divi's Laboratories Ltd. and Jubilant Life Sciences Ltd.
- The manufacture of formulation drugs are carried out by CRAMS companies at lower costs due to economies of scale.
- CRAMS companies specialising in research have taken up assignments in formulation development, drug development or conducting trials.

Contract Manufacturing Segment (CMS) to grow at ~18% CAGR till 2018

Patented drugs worth approximately US$85 billion in potential annual sales in US are expected to come off patent during 2014-2020. Some of the major drugs going off patent are Nexium, Cymbalta, Celebrex, Abilify, Gleevec and Crestor to name a few. Once drugs lose patent protection, the focus would shift to price competitiveness and ensuring manufacture of such generic drugs in the most cost-effective manner. India is one of the world's best known low-cost manufacturing centers, with highest number of U.S. Food and Drug Administration (USFDA) approved manufacturing plants outside the US. This is likely to boost the prospects of Indian CMS companies. With the Indian CRAMS industry gradually moving up the value chain and players investing in better technology and higher capacities, manufacture of value-added products for biotech and specialty therapy areas may be outsourced to Indian players in future. CARE Ratings expects Indian CMS to grow at approximately 17-18% CAGR till 2018.

Contract Research Segment (CRS) to grow at ~20% CAGR, outgrowing CMS

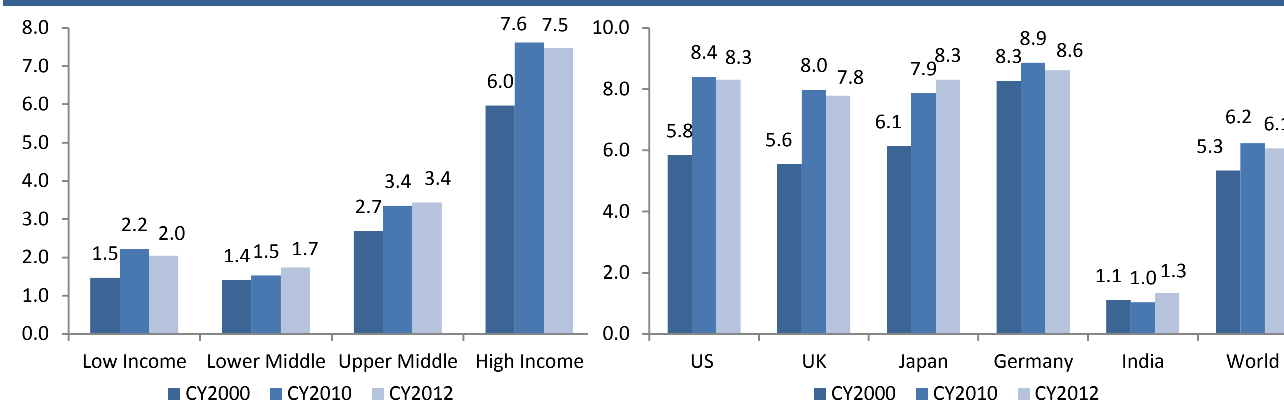
The Indian pharma research industry benefits from structural factors such as the presence of English speaking population, highly skilled labour force and low cost of employees. As most of the outsourcing to Indian CRAMS industry is from the western countries where English is widely spoken/understood, this is a natural advantage to the Indian CRS industry as compared to other geographies (China, Vietnam, etc). With R&D costs increasing and productivity declining in regulated markets, global pharma companies are looking for measures, including outsourcing, to enhance their drug pipeline (for instance, in finished drugs portfolio). CARE Ratings expects Indian CRS to grow at approximately 18-20% CAGR till 2018.

Growing generics opportunity offers long term growth prospects

Global health care spending has risen from 9.3% of GDP in 2000 to 10.2% in 2012. As governments spread their welfare nets wider, and enhance social spending; their share of total health expenditure increased from 57.5% in 2000 to 59.5% in 2012. As a result, government health care spending as a proportion of GDP increased from 5.3% in 2000 to 6.1% in 2012. Traditionally, ‘High Income’ group of countries have witnessed higher government spending on health care as a proportion of the GDP. This may be due to structural reasons such as well-targeted schemes for universal health care, extensive distribution chains, advanced health infrastructure and better awareness of medical conditions.

Government spending on health care as a percentage of GDP (%)

Group-wise **Country-wise**



Source:- World Health Statistics (2014), World Health Organization, CARE Ratings

However, with fiscal constraints mounting in the aftermath of the global financial crisis, many governments have taken steps to stem the rising cost of health care. It is also expected that global spending on medicines will shift towards generics. The share of generics is expected to rise from 27% in 2012 to 36% by 2017. While, in the developed economies, the generics share is expected to rise from 16% to 21% during the same period.

State of the Industry: Global CRAMS

Global CRAMS market grew by 15-16% CAGR over 2005-2010, while Indian CRAMS market during the same period increased by 25-30% CAGR. Furthermore, with consolidation in the pharma industry globally & cost cutting measures implemented coupled with adverse currency movement, the growth rate for domestic CRAMS industry tapered down to 5-8% CAGR during 2009-2011 period. The growth rate gradually picked up to 15-16% during 2011-2014. Going forward, the Indian CRAMS industry is expected to increase approximately to US$18 billion in

2018 from about US$7.6-7.8 billion in 2013, registering 18-20% CAGR. The growth would be mostly led by increase in strategic alliances and expanding footprints to major geographies through strategic partnership.

The cost of developing new drugs is estimated to have reached approximately US$5 billion (Source: Forbes). Major pharma companies are witnessing a decline in their R&D productivity on account of (a) diminishing discoveries of path breaking molecules, (b) fewer new molecules being approved by the USFDA and (c) increasing research costs. With a depleting drug pipeline, the pharmaceutical industry is under pressure to enhance the productivity of its R&D functions. Also, many developed economies are trying to curtail their health care spend and have introduced various measures too. These factors may enhance outsourcing of manufacturing and research activities by global pharmaceutical companies, thereby benefitting the global CRAMS industry.

Drivers for Indian CRAMS players

New drug development – a time consuming affair	• From initiation to launching new drug to market it takes ~10-15 years • Thus to work on more complex molecules, outsourcing research would be preferred to reduce drug development time
Innovators shift focus to core competencies	• Decreasing R&D productivity &rising costs has led innovators companies to outsource non core activities thereby minimizing the capital invested in plant and production process
Patent cliff imminent	• With patent expiry, innovators are expected to outsource production to low cost destinations.

The opening up of global pharma and setting up of supply chains globally has resulted in increased contribution of exports to earnings of Indian CRAMS companies. Exports accounted for more than 75% of revenues in 2014 of CRAMS industry, up from 62% in 2010. Efficiency in manufacturing and maturity of business models led to containment of cost of manufacturing approximately to 55% of sales. To capture greater global market share, Indian CRAMS companies have added capacity at a rate exceeding growth in sales.

However, the growth of the Indian CRAMS industry may be negatively impacted by regulatory directives. Indian pharma companies have been issued various letters/notices by USFDA regarding non-compliance with the testing, hygiene and cGMP standards. At least 16 such instances have been reported during the period June 2013 to July 2014. Such notices/import alerts/recalls of drugs may impair the goodwill of the Indian pharmaceutical industry globally, adversely impacting the outsourcing of work to the Indian CRAMS industry. This might impact India's position compared with competing countries like China, Russia, Brazil, Taiwan, etc. Also, recent regulations on patient compensation and delay in approvals would impact clinical trial business of domestic CROs. But in the long term, the Supreme Court of India directives would ensure safer and more transparent clinical trial regime in India.

Emerging trends in the Indian CRAMS industry

Growth in biopharma	•~5,000 new bio-medicines in development stage • R&D cost per employee is highest in bio-research •~25% new drugs under approval are biologics
Other areas of research	•Oncology and high-potency APIs •Antibody drug conjugates (ADCs). •Clinical trials at stage II-IV •Data management
Use of cloud computing	•Expedite data sharing at low cost •Real-time access to high memory capacity •Faster processing •Manage big data generated in research process
Qualified research professionals	•Research into new diseases •Cheaper drugs and bio-medicals •XIIth Five Year Plan allocation of INR 20bn •Six new National Institutes of Pharmaceutical Education and Research (NIPERs)

Source: Planning Commission Working Group & CARE Ratings

CARE Ratings expects Indian CRAMS industry's share to increase to approximately 8-9% of global CRAMS market by 2018 from approximately 6% in 2013. As the trend of outsourcing picks up among the pharma emerging markets (non-regulated, non-developed markets), Indian CRAMS industry is expected to capitalise on its expertise in the pharma outsourcing space and establish its presence in such new markets. However, the players are likely to encounter strong competition at global level, pricing pressures and higher input prices.

CARE-rated CRAMS companies (as on January 30, 2015)

Companies	Rating	
	Long term	Short Term
Advinus Therapeutics Limited	BBB-	A3
Arch Pharmalabs Limited	D	
Dishman Pharmaceuticals And Chemicals Ltd	BBB+	A3+
Divi's Laboratories Ltd	AA+	A1+
Emcure Pharmaceuticals Limited	AA-	A1+
Flamingo Pharmaceuticals Ltd	BBB-	A3
Gennova Biopharmaceuticals Limited	AA-(SO)	A1+(SO)
Glochem Industries Limited	BB+	A4
Lambda Therapeutic Research Ltd	A+	A1
Parabolic Drugs Limited	D	
Renown Pharmaceuticals Pvt. Ltd	B	A4
Sharon Bio-Medicine Ltd	BBB-	A3
SMS Pharmaceuticals Limited	BBB+	A3+
Sovereign Pharma Private Limited	A-	A2
Veeda Clinical Research Private Limited	BBB	A3+

Of the total 15 CRAMS companies rated by CARE, 73% are in investment grade category ('BBB' and above category) due to several factors such as relatively stable performance metrics, comfortable solvency position and moderate liquidity profile. The companies that have superior ratings enjoy access to wider geographical markets and are involved in the manufacture of well-diversified products. During FY2016 the credit profiles of CARE rated CRAMS players are expected to remain stable.

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