

IPA CONVENTION 2007

Credible India: Sustaining Competitive Advantage



CRAMS v/s CRAMS

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CRAMS Vs CRAMS

Transition from Contract Research to
Collaborative Research Partnership

A Pragmatic Approach to Value Creation

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CRAMS

- The imperative to cut costs driving big pharma for increased outsourcing be it may be R&D or manufacturing
- Changing mindset of big pharma to partner with competent players
- Partnerships with cost-effective players such as India and China mainly enhances competitiveness.



CRAMS

- Increasing price pressures for innovators to minimize manufacturing costs
(Merck scrapping of \$2bn capex and Pfizer to save \$4bn cost savings)
- Increasing reliance on CMOs to accelerate product development process
- Increased development of new drugs by small biotechs who lacks manufacturing capacity
- Increased demand for niche manufacturing capabilities viz Steroids, sterile prods etc.



CRAMS

- All these leading to accelerated clinical development process, reliable supply source post commercialization and post patent expiry
- Frost & Sullivan Estimates CRAMS based custom manufacturing to be at \$25 Billion by 2011



**R&D Break up of Pharmaceutical Research and Manufacturers
of America (PhRMA) companies in 2004**

Category	\$ millions and R&D Personnel	% of total
Prehuman/preclinical	9,585	<u>25.9</u>
Phase 1	2,473	6.7
Phase 2	3,770	10.2
Phase 3	9,682	<u>26.2</u>
Approval	3,415	9.2
Phase 4	4,903	13.2
Uncategorized	3,188	<u>8.6</u>
Total	37,016	100



**CONTRACT RESEARCH AND
MANUFACTURING SERVICES
(CRAMS)**

Vs

**COLLABORATIVE RESEARCH AND
MANUFACTURING SERVICES
(CRAMS)**



CRAMS Vs CRAMS

- To alleviate bottlenecks in the R&D pipeline
- To reduce the R&D costs
- To accelerate clinical trials



CRAMS Vs CRAMS

- Speed and efficiency are key for the drug development and to combat rising R&D costs.
- Tufts Centre for the study of Drug Development
 - Medicines developed by the companies faster between 2000 and 2005
 - Gained an average of \$1.1 billion in incremental prescription revenues
 - Saved an average of \$30million in out of pocket costs.



CRAMS Vs CRAMS

Booz Allen Hamilton study on R&D spending

“There is no discernable statistical relationship between R&D spending levels and nearly all measures of business success, including sales growth, gross profit, operating profit, enterprise profit, market capitalization or total shareholder return”



CRAMS Vs CRAMS

Booz Allen Hamilton study on R&D spending

R&D spending appears to yield better gross margins.

“Superior results seem to be a function of the quality of an organization’s innovation process – the bets it makes and how it pursues them – rather than either the absolute or relative magnitude of its innovating spending”



CRAMS Vs CRAMS

Global Pharma is reshaping the business practices and strategy by outsourcing more of the R&D functions and partnering in preclinical activities through drug developments with CRO's.

For smaller companies this is more relevant and implementing these strategies, the sooner the better.



CRAMS Vs CRAMS

Smaller companies will have either expertise in biology with limited chemistry or extensive chemistry with limited biology.

The activities outsourced are process development and scale up, integrated pharmacology PK(ADME) and toxicology studies, Clinical trial planning and management plus regulatory support.



CRAMS Vs CRAMS

Outsourcing to CRO's leads to

- speed in drug discovery and development
- some cost savings.

Savings minimal - Tufts CSDD

Partnership with CRO's leads to

- speed, cost savings and innovation.



CRAMS Vs CRAMS

CRO's are moving upstream

Offering Drug discovery and development support services (DDDSS)

Establishing long term partnerships

Sharing in the royalty stream

Enhancing the activity into their own drug discovery program.



CRAMS Vs CRAMS

Evaluation of prospective CRO or a partner.

Size is not critical but technology, commitment , project management and financial strengths are more important.

Micro management or spoon feeding may not yield the great results but often delays the process while loosing the innovative edge.



CRAMS Vs CRAMS

Evaluation of prospective CRO or a partner

Selecting a provider or a partner solely on price or timelines rather than the overall picture is a mistake.

Working on a piecemeal basis rather than broad outsourcing or partnering policy is another mistake



CRAMS Vs CRAMS

Evaluation of prospective CRO or a partner

- Track record
- New and evolving companies from Asia may not have the track record but everything else.
- If the outsourcer can help them by molding them to meet their requirements by training will yield great results
- Finding a good partner or provider and giving them enough freedom will also yield greater results.



CRAMS Vs CRAMS

- Pharmaceutical Industry has no boundaries -- Going global.
- During 90's big pharma is content with the growth, profit and productivity in R&D and engaged in plain outsourcing activity only.
- Emerging markets don't have IP protection.



CRAMS Vs CRAMS

In the 21st century global Pharma has R&D productivity crisis.

Lost many blockbusters to generics.

Global pharma bottom lines hurt

Industry ranked very low compared with the other fortune group.



CRAMS Vs CRAMS

- India enacted IP protection in 2005.
- India has embarked on Pharma R&D service sector
- Indian Pharma spending money on Drug Discovery.



CRAMS Vs CRAMS

- Emerging markets like India and China will have booming domestic growth by 2010.
- Global pharma collaborative partnerships in this region will prop up R&D pipelines by reversing the R&D productivity decline.



CRAMS Vs CRAMS

- Governments in Developing countries are changing their mind sets to align globally by altering their policies
- Reverse Brain Drain
- Growth in R&D skills in India and China



CRAMS Vs CRAMS

- Booming growth in domestic markets of developing countries
- Developing markets commercial valuations are rising
- Change in the mind set of management of big pharma to outsource or to collaborate outside of big three regions.

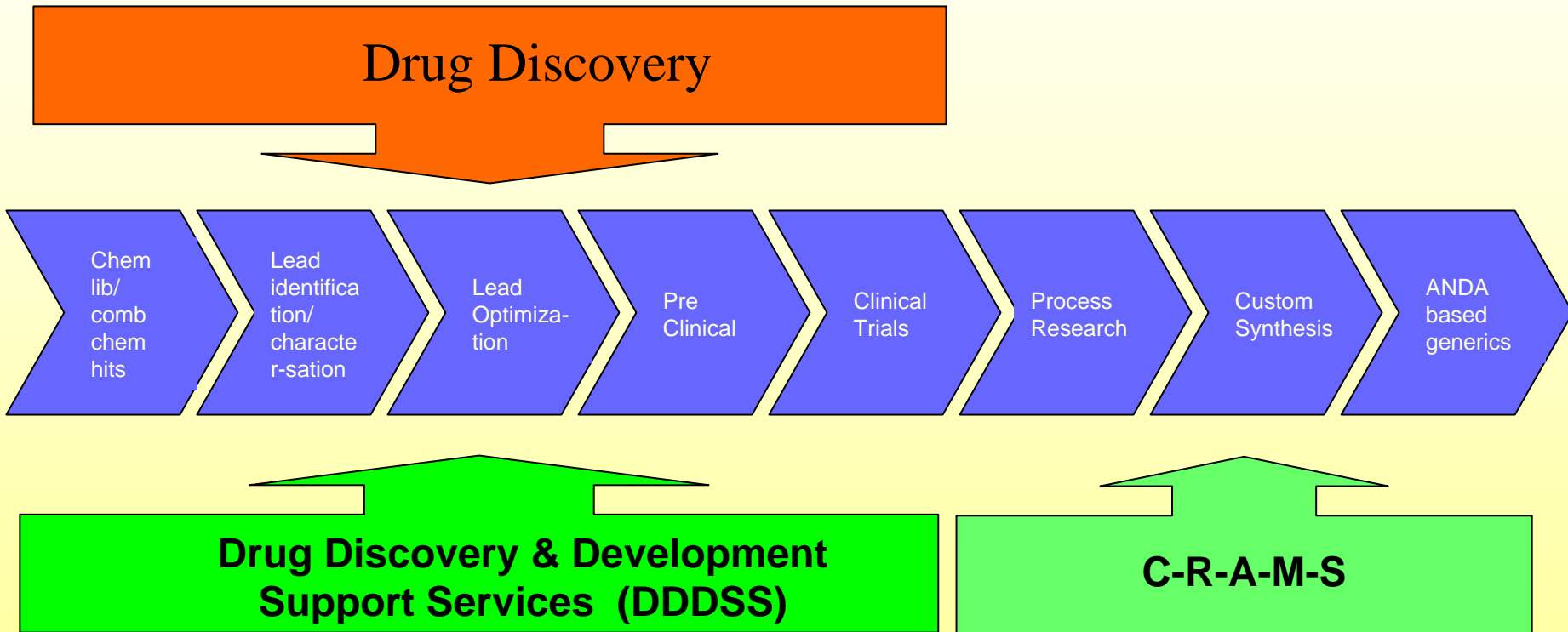


CRAMS Vs CRAMS

- Drug Discovery and Development capabilities in developing countries is leading to collaborations
- Collaborations or risk reward partnerships leading to higher economic benefits



Suven's Business Model



Collaborative Research Partnership Seamless transition



THANK YOU