

India as a Global Innovation Hub for the Pharmaceutical Industry



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Challenges Facing the Pharma Industry

- ⊙ Low productivity and rising R&D costs
- ⊙ Too few “un-drugged” targets
- ⊙ Biotech industry constrained to provide early stage innovation
- ⊙ Failures in the clinic and product recalls
- ⊙ The generics cliff-hanger
- ⊙ Majority of Top-10 Pharma expected to have negative growth rates for the next 5 years
- ⊙ Stock valuations and shareholder returns do not compensate the risk

"Over the next few years, the pharmaceutical business will hit a wall. The wall sits at the year 2012. The industry is “doomed, if we don’t change,” [Sidney Taurel, Chairman, Eli Lilly & Co.]

The India Opportunity

- ⊙ In-licensing opportunities from Indian Pharma currently somewhat limited but evolving
- ⊙ The CRO model works better to deliver innovation
 - ⊙ Flexible structure
 - ⊙ Large talent pool trained on-the job and via secondments
 - ⊙ Returning experienced expats
 - ⊙ Global protocols established
 - ⊙ Showcase Indian academic strengths
 - ⊙ Multiple shots at goal due to lower cost
 - ⊙ No IP conflicts
- ⊙ Clinical CROs provide fast patient recruitment and drug naïve patients
- ⊙ As markets mature, India provides fast growing commercial opportunities

“There is a great willingness to collaborate in India. There is also a great ability of Indian companies to adapt to western needs, while there exists a huge medical need in India especially for infections diseases. This is the golden age for drug discovery.” [Martin MacKay, GHR&D, AZ]

Innovation Offerings from Leading CROs

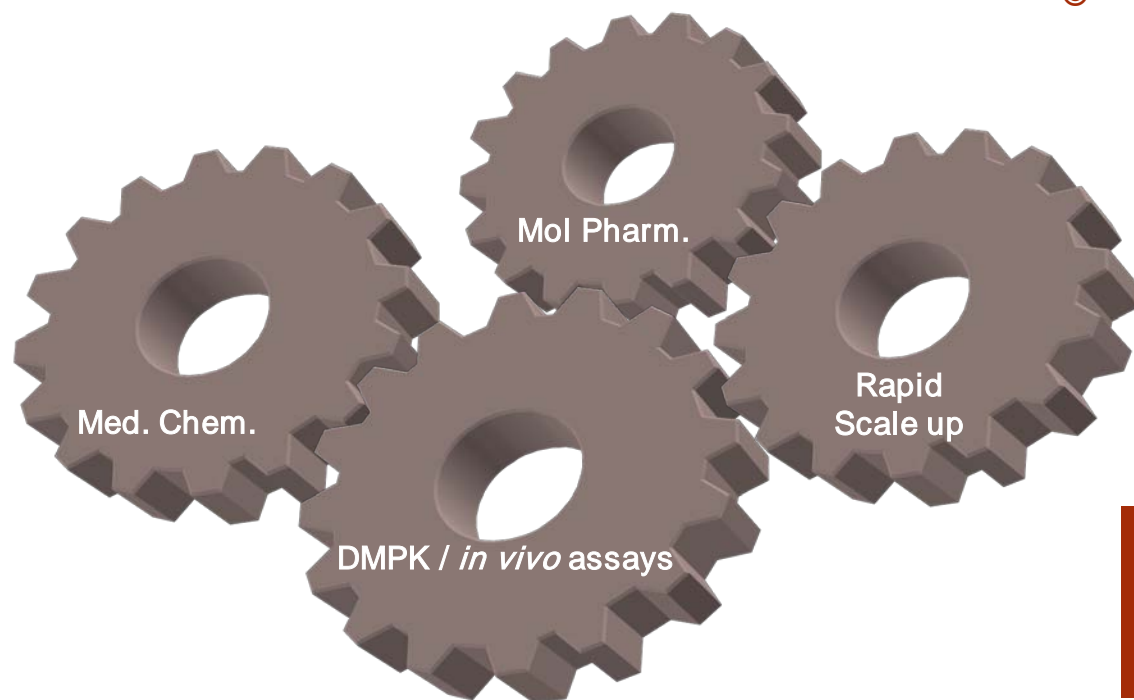
- ⊙ Entrepreneurial culture
- ⊙ A highly efficient “SAR Engine”
- ⊙ Rapid scale up to cGMP “First in Man” compound supply
- ⊙ Integrated capabilities with ability to deliver pre-clinical candidates
- ⊙ Attractive academic collaborations
- ⊙ In the process of building up regulatory tox and Phase I/IIB clinical studies
- ⊙ Established capabilities in large Phase II/III trials

“TCG will develop a portfolio of undisclosed molecules in several discovery target programs up to the nomination of preclinical candidates. The TCG relationship has developed over several years, with the Indian company initially providing discovery chemistry work under a master services agreement, which Pfizer expanded in February 2009 to include integrated research services.”

[Rod McKenzie, Head of Asia Strategy, Pfizer]

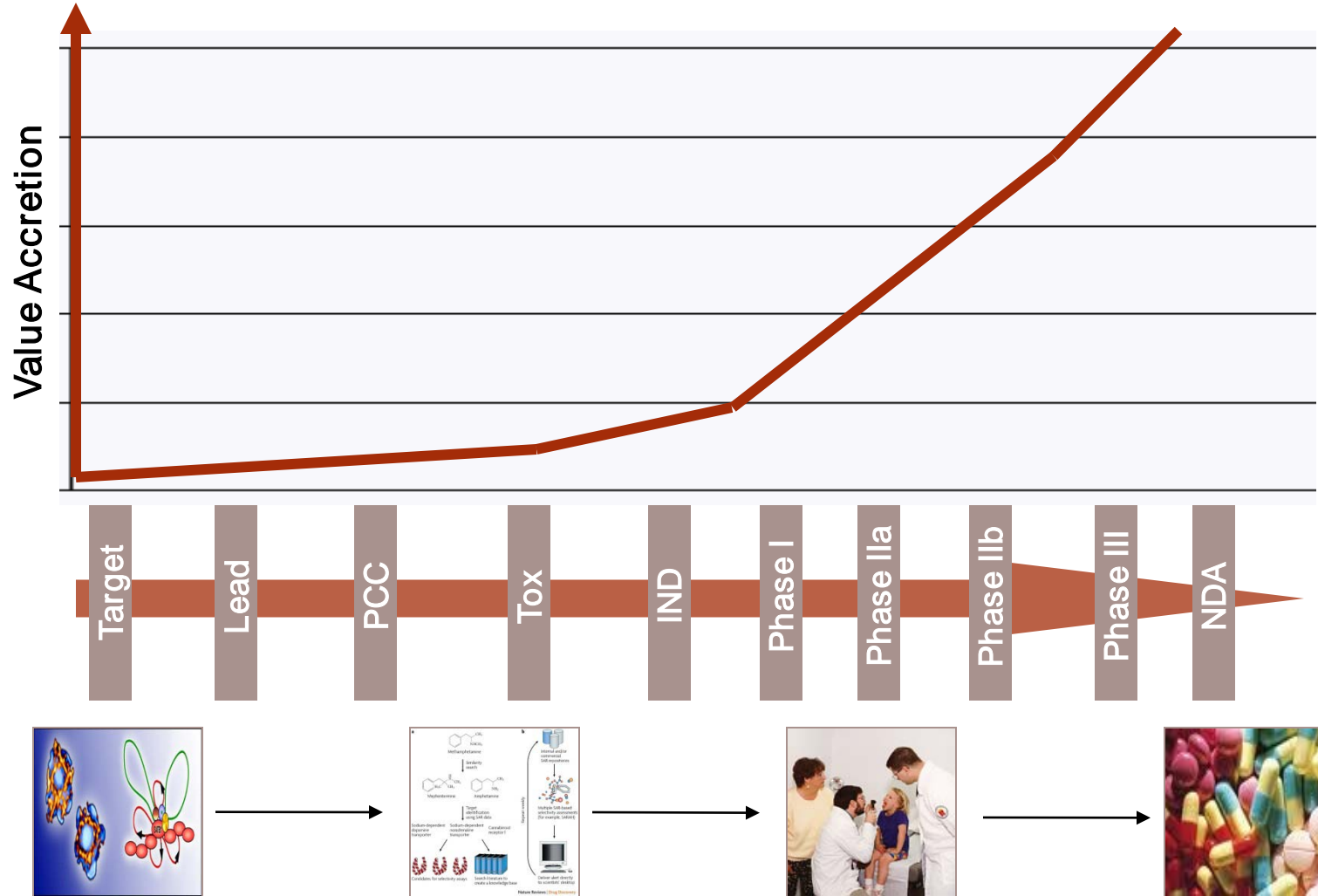
“Frugal” Innovation Engine

- ⊙ Robust and efficient SAR engine
- ⊙ Less than 2 weeks cycle time
- ⊙ Rapid hit follow up
- ⊙ Seamless transfer of data and initiation of new SAR
- ⊙ Rapid scale up through PRD



- ⊙ Hit to PCC nomination
 - ⊙ 18 to 24 months
 - ⊙ \$1mn to \$2.5mn

Value Accretion Strategy

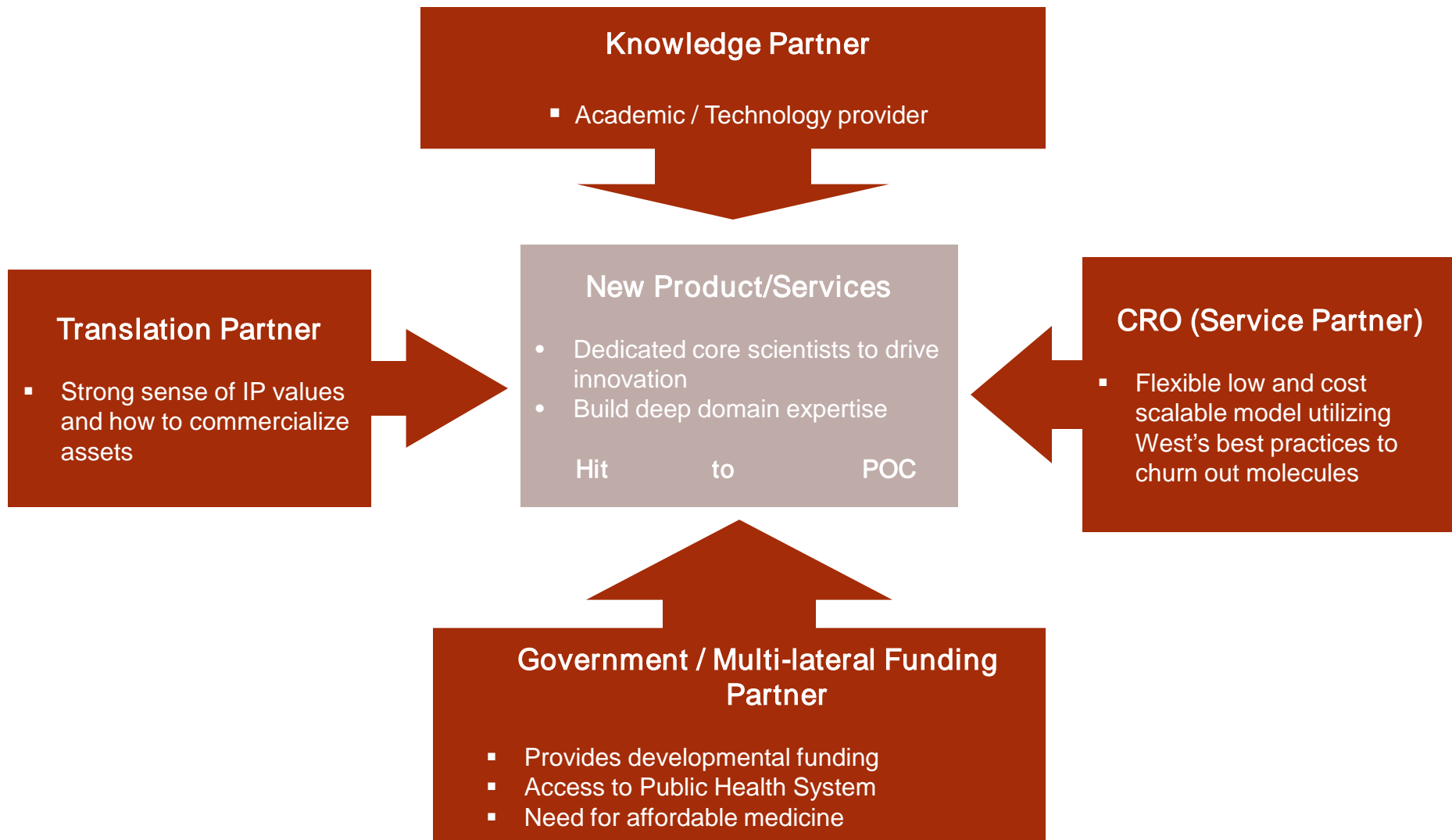


Attributes for Successful Innovation Engine

- ⊙ **Challenging conventional techniques**
 - ⊙ Clinic-to-bench and back
 - ⊙ Open source discovery
- ⊙ **Networked approach**
 - ⊙ Academia, domain experts, technology provider etc
 - ⊙ Translation partner
- ⊙ **Innovating the business model**
 - ⊙ Risk shared, portfolio approach, repositioning, open platforms
- ⊙ **Organization structure to fit the bill**
 - ⊙ Entrepreneurial, “drug hunting”, deep domain knowledge
- ⊙ **Funding**
 - ⊙ Govt, multilateral, foundations, angels, service as equity for early stage
 - ⊙ VC/Development partners

Being a part and sharing the ‘whole’ rather than standing apart and monopolizing the whole -- the Fully Integrated Pharma Network model

Case Study – Networked Innovation Engine



- ⊙ Synergizing the capabilities of Indian & Australia, there exists a host of collaboration opportunities, like
 - ⊙ **Identify and validate novel targets:**
Most discovery programs are based on same few targets. Opportunities exist in leveraging genomics/proteomics platforms in India + disease biology capabilities of Australian academics
 - ⊙ **Early stage innovation:**
Australian capability in in vivo pharmacology and regulatory tox + Indian capabilities in SAR
 - ⊙ **Human safety and POC clinical studies:**
Indian regulatory limitations and lack of research driven clinicians are a hurdle for handling such studies. Australian capability in Phase I/IIa trials and Regulatory Management + Indian capability in patient recruitment & management
 - ⊙ **Data management and research informatics:**
India has built strong capabilities in the IT arena and can support a host of informatics applications like CTDM, EDC, ELN, LIMS etc.

Thank You