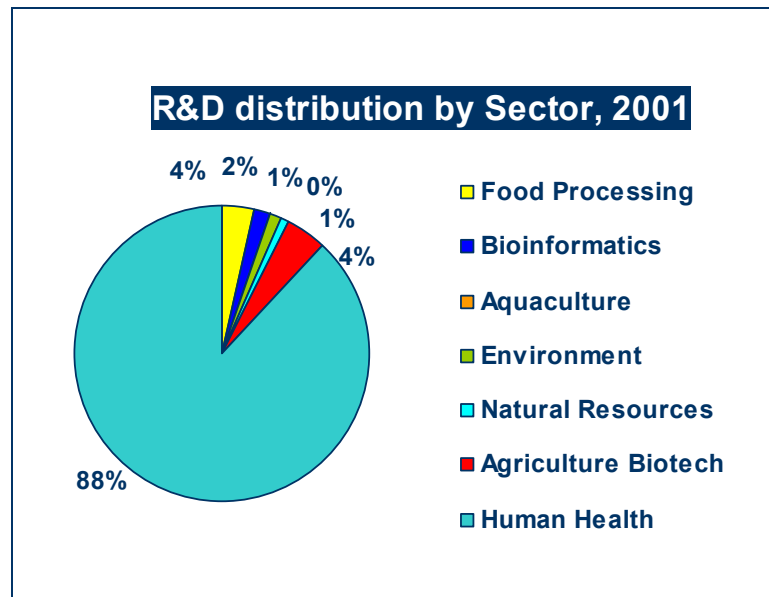
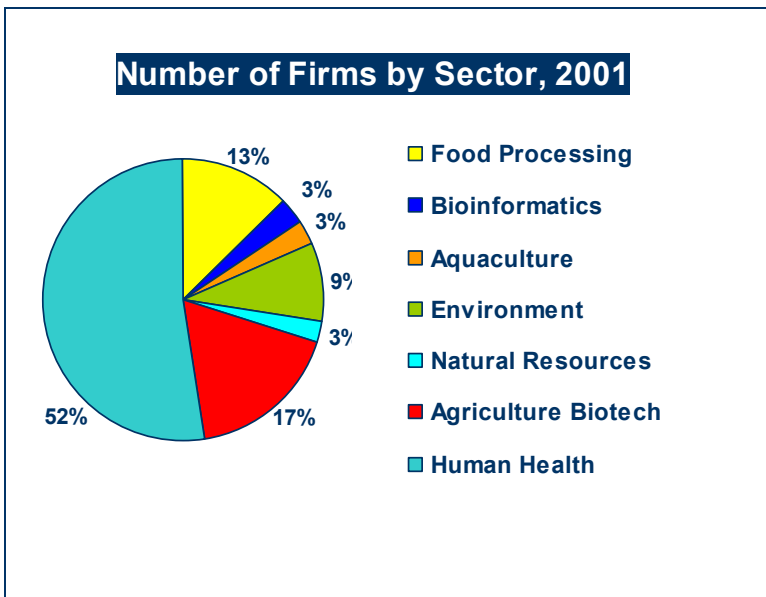




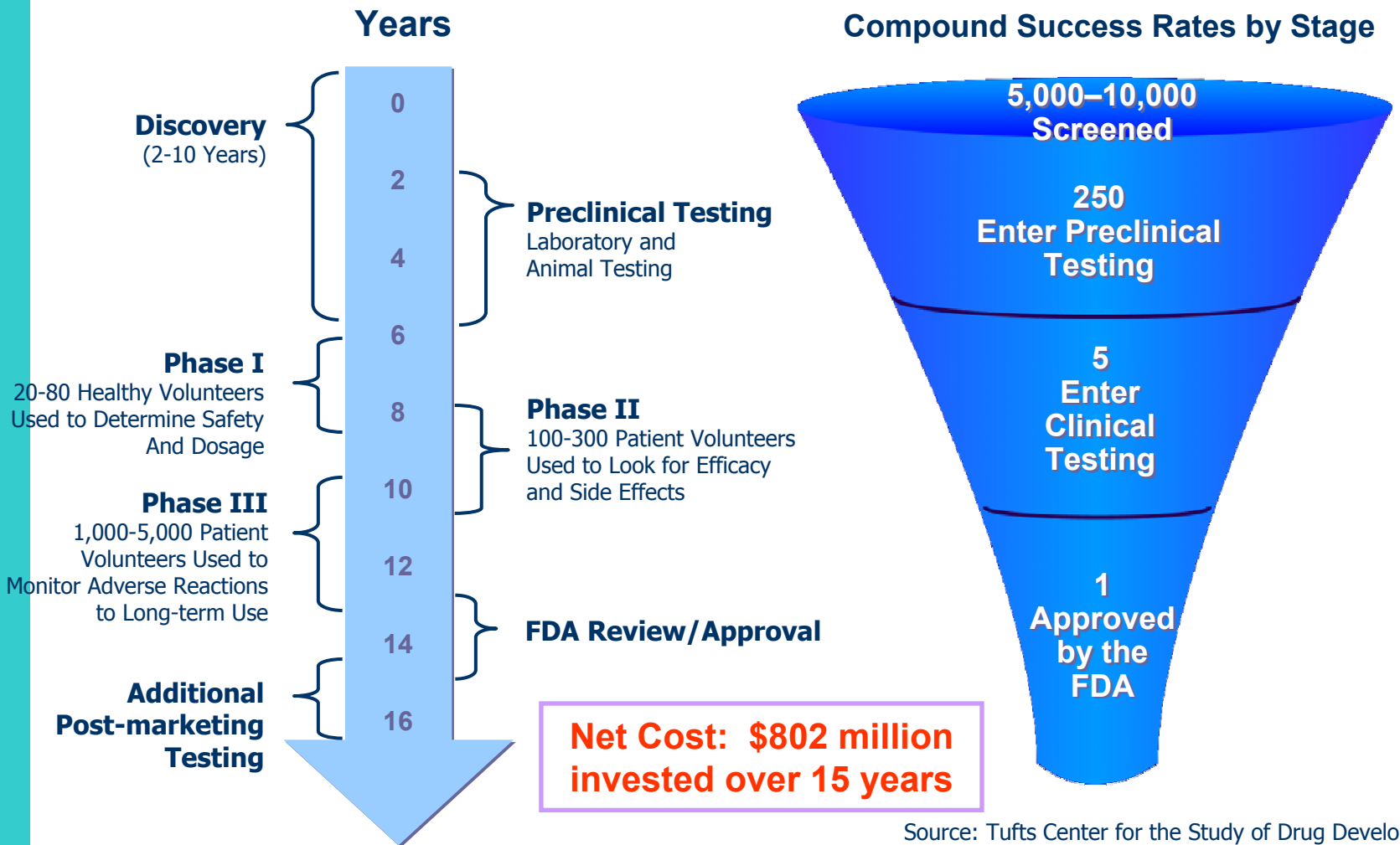
BioServices: Clinical Trials & India's potential

Dr Krathish Bopanna
Chief Technology Officer
Manipal Acunova
Bangalore

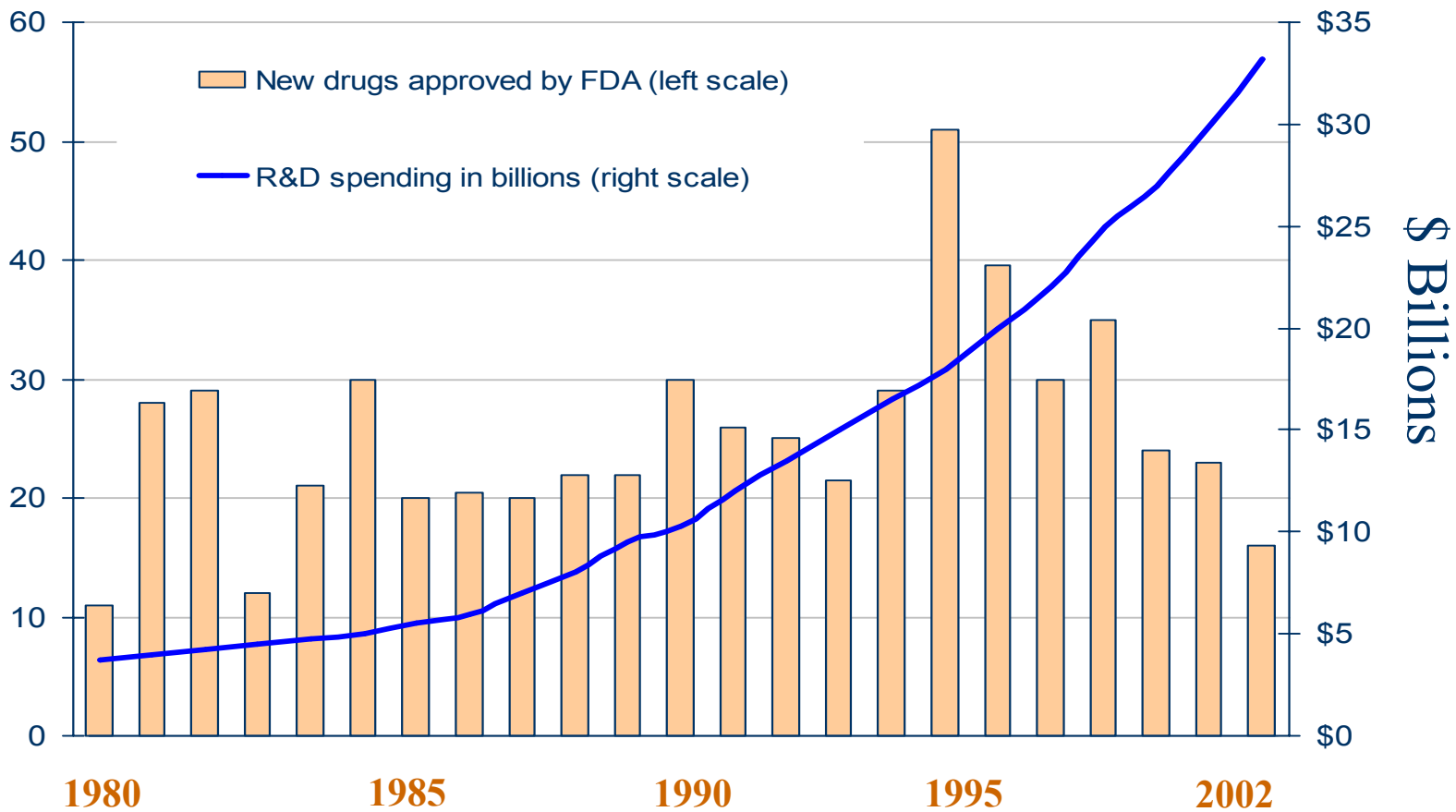
The human health sector accounts for 52% of the total biotech firms and for 88% of the total \$1,337M in R&D spending



Source: Statistics Canada, *Biotechnology Use and Development Survey, 2001*



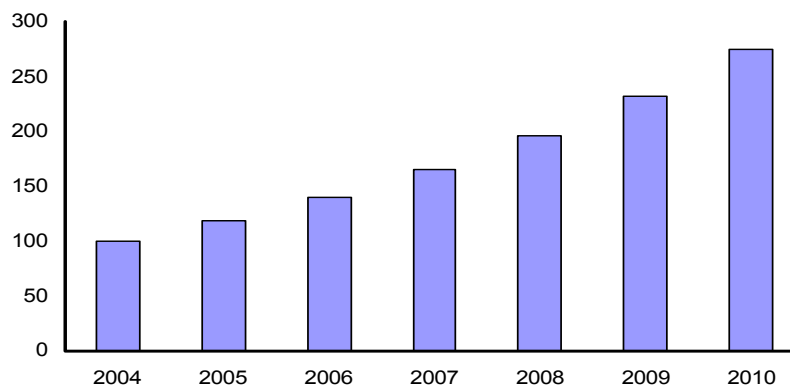
Drug development is a risky and expensive proposition



Source: Food & Drug Administration; PhPharma; Kaiser Family Foundation

Key reasons of outsourcing R&D activities

- Clinical trials in India is growing at a 60% AAGR
- Crossed USD 100 million in 2004.
- By 2010, the industry will spend USD 300M+ on clinical trials in India.

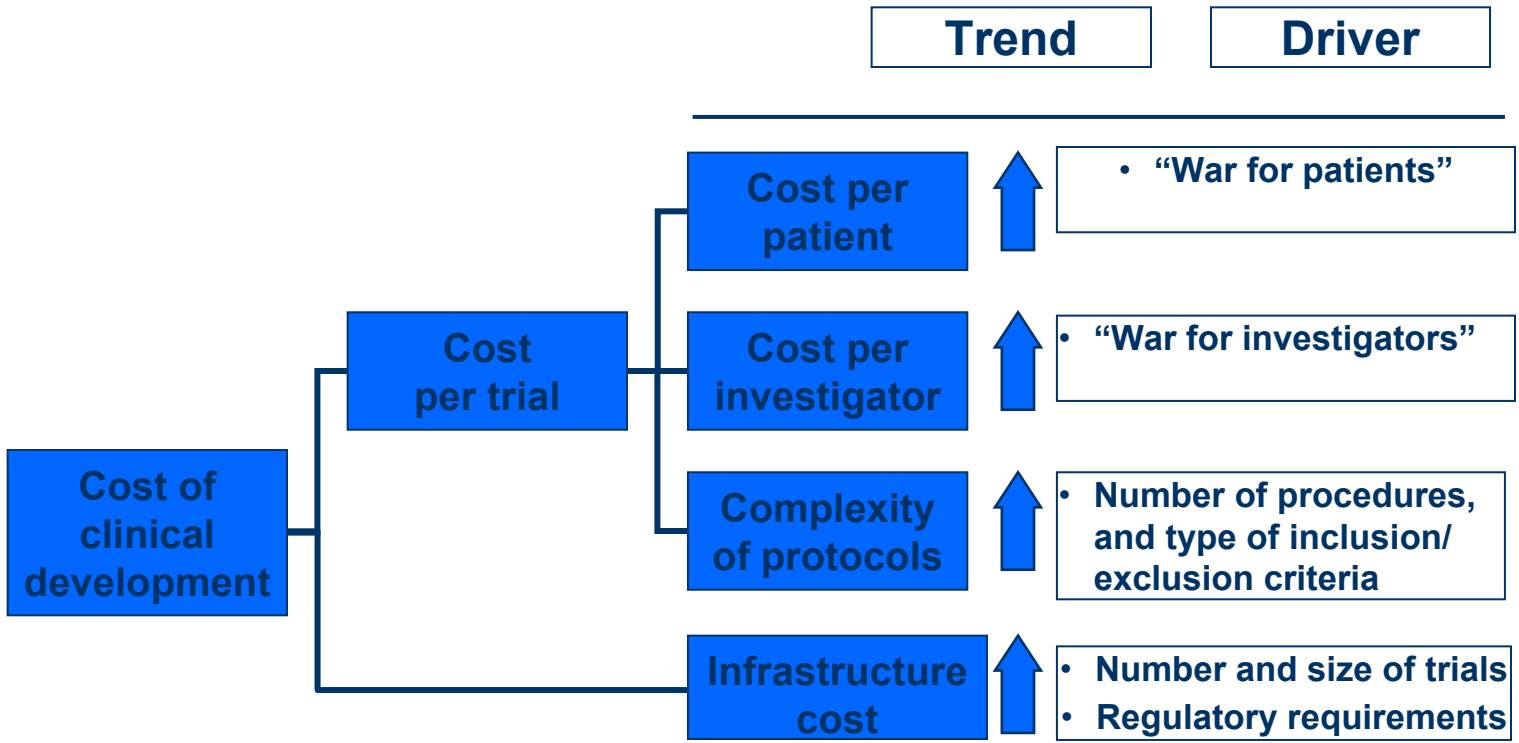


Estimated Market Size of Clinical Trials in India (USD mn)
Source CenterWatch

- 20 CRO's including Quintiles, Manipal Acunova offer Phase I to IV trials complying with ICH-GCP guidelines.
- With 80 hospitals serving as sites for clinical trials, India is emerging as one of the fastest recruiter of subjects across the world.

	Estimate (2003)	Conservative Potential (2008)	Speculative Potential (2008)
Value (US \$)	\$ 50 M	\$ 200 M	\$ 1,000 M
Value (INRs)	Rs 225 Cr	Rs 1,100 Cr	Rs 5,500 Cr
Full-time staff	800	4,000	20,000
Site staff	1,500	6,000	30,000
Patients	10,000	50,000	3,00,000

Estimates of over 1 Bio USD by 2008



Source: McKinsey 2004

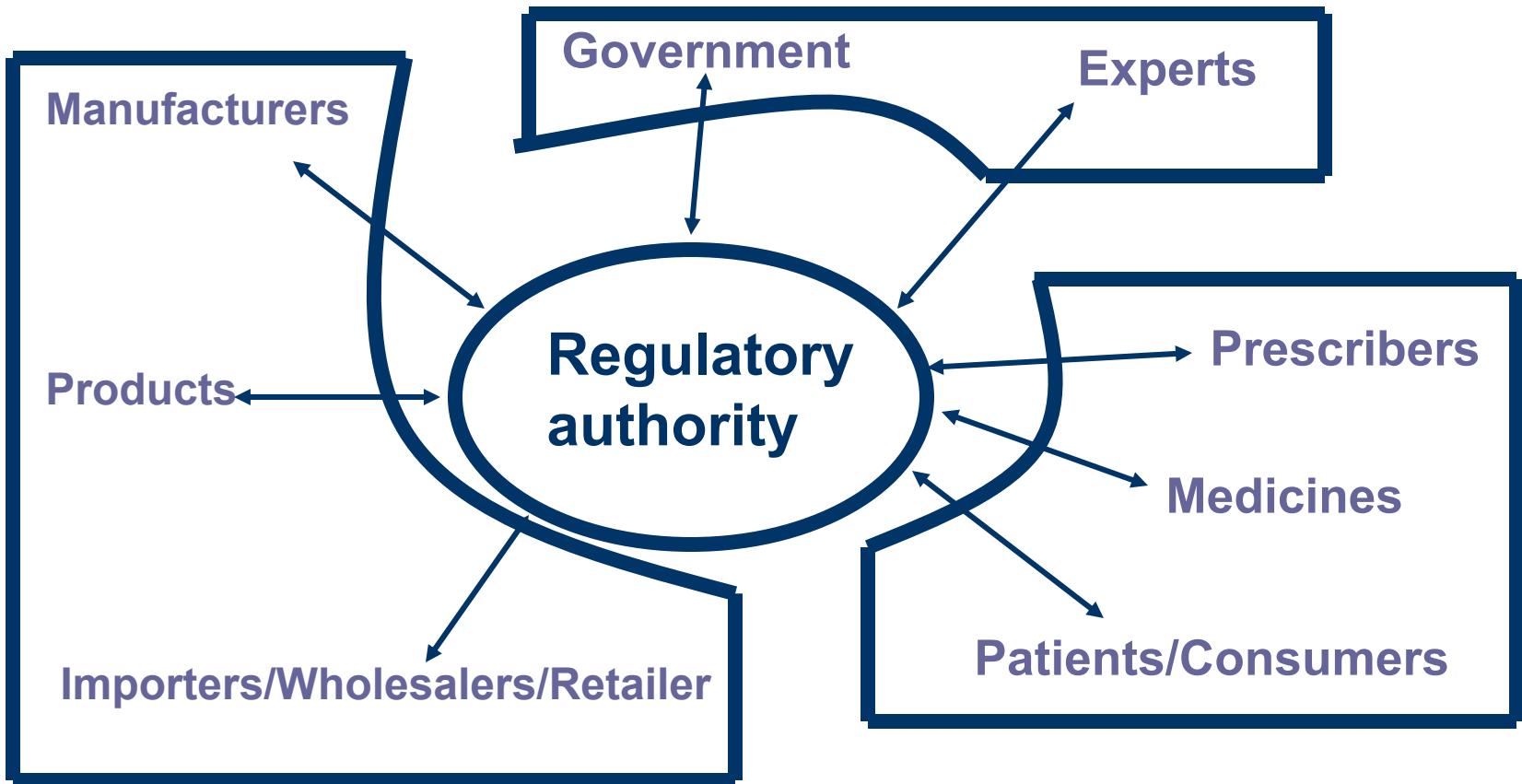
**Global trend is unavailability of Patients and PI's!
 & High cost**



	India	Israel	P-pines	Ireland	Canada	China	Russia
Government Support	High	Medium	Medium	High	High	High	Low
Labour Pool	High	Medium	Medium	Medium	High	Low	High
Infrastructure	Medium	High	Medium	High	High	Medium	Low
Educational System	High	High	Medium	High	High	Medium	High
Cost	High	Medium	High	Low	Medium	High	High
Process Quality	High	Medium	Medium	High	Medium	Low	Low
Cultural Compatibility (US)	Medium	High	High	High	High	Low	Medium
Legal System	Low	Medium	Low	High	High	Low	Low
Globalisation Skills	Medium	Low	Low	Low	Low	High	Medium
Overall Climate	High	Low	Medium	High	High	Low	Low

Source: Gartner Report, Jan 2003

India has distinct advantages over all other countries



Source: Bio 2004

Patent granted for 20 years from application

**12 years
to develop the drug**

**8 years
to sell it exclusively**

Invest 800 Million US\$

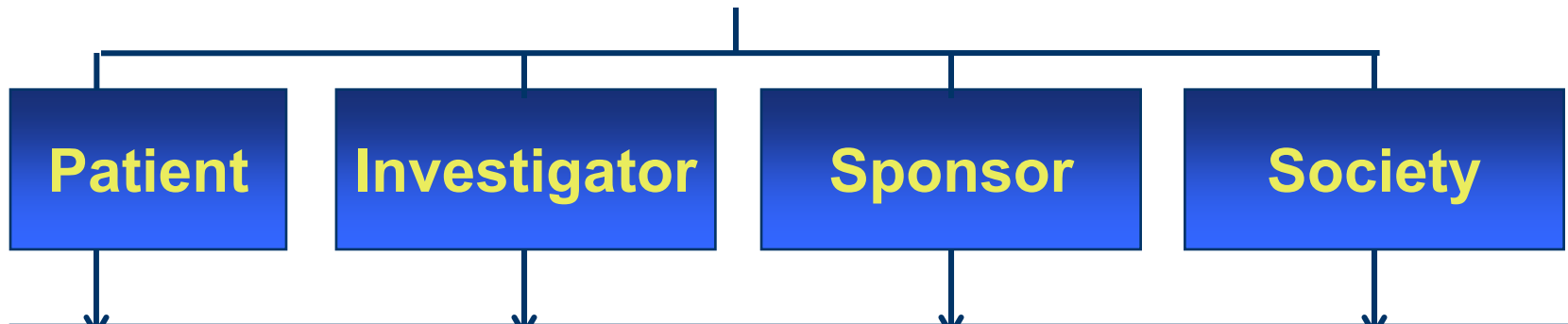
Recoup the investment

*Only 1 out of every 12 marketed drugs
recoups the investment mega brand status*



***Prolong patents by developing
new formulations and/or new indications***

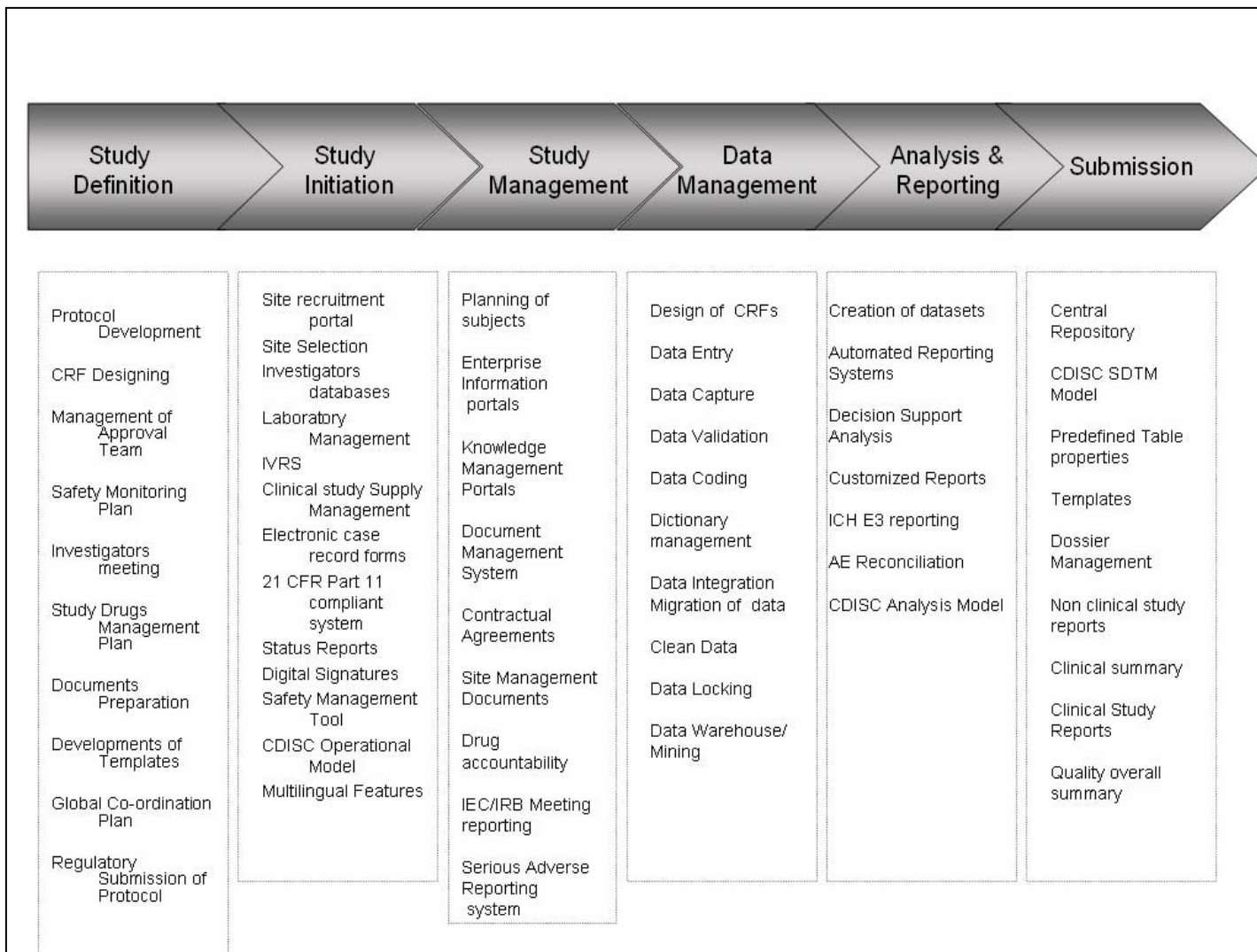
Safeguards the interest of

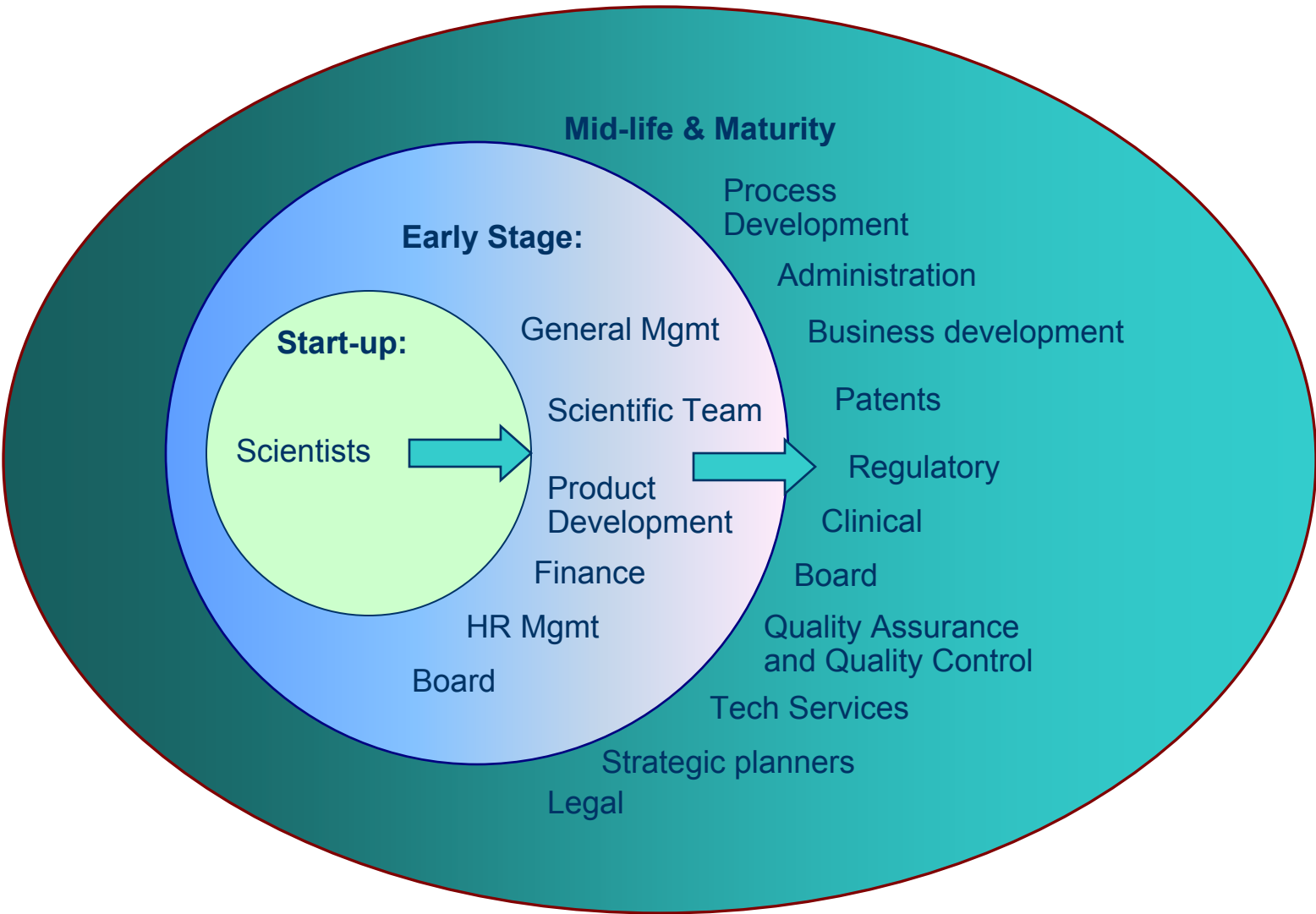


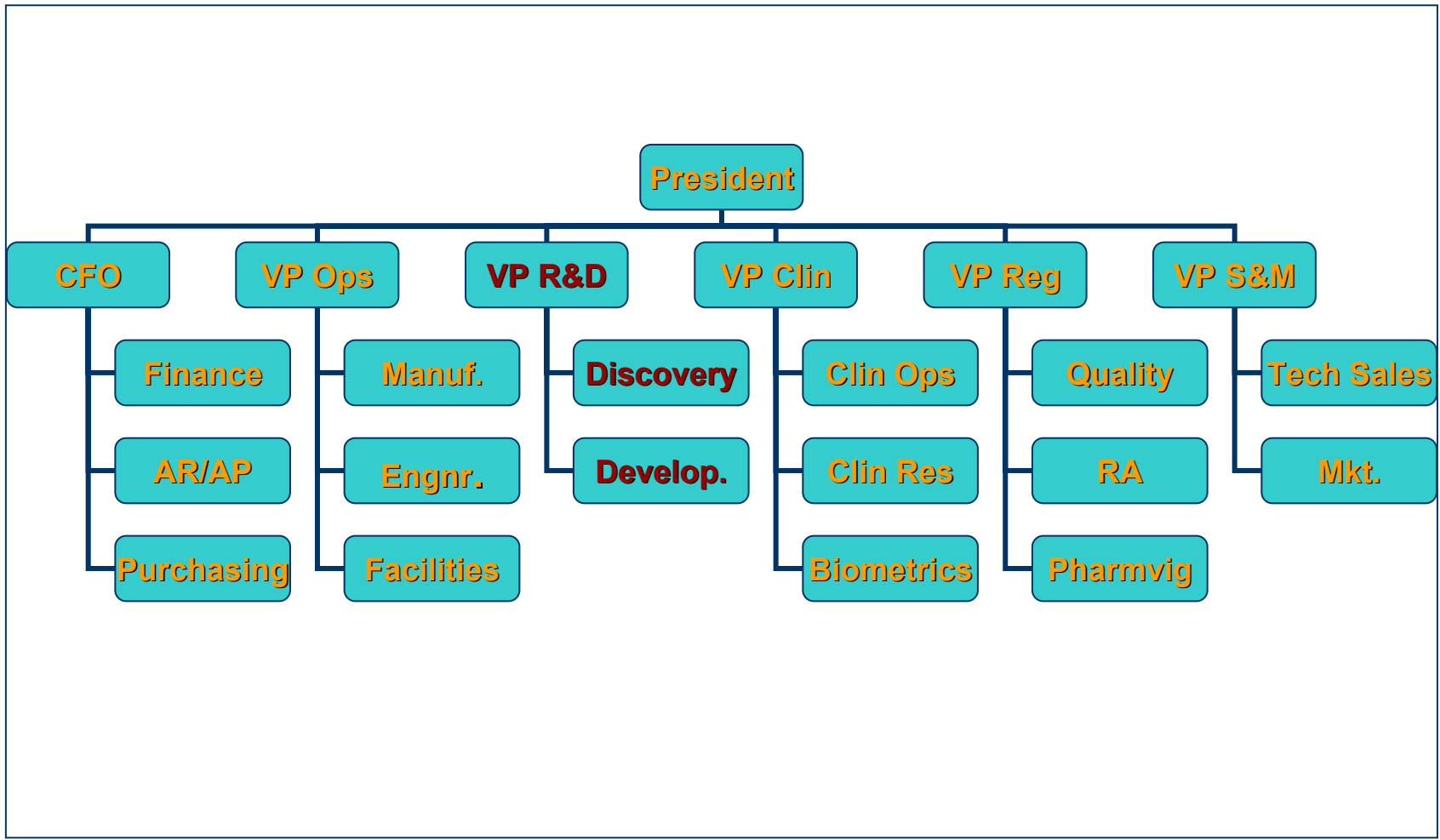
- Definition of Responsibilities of Investigators, Sponsors, Ethics Committees
- Protection of trial subjects (Informed consent, Safety reporting)
- Data Quality / Study documents / record keeping
- Quality Assurance / Audit

Source: www.ich.org

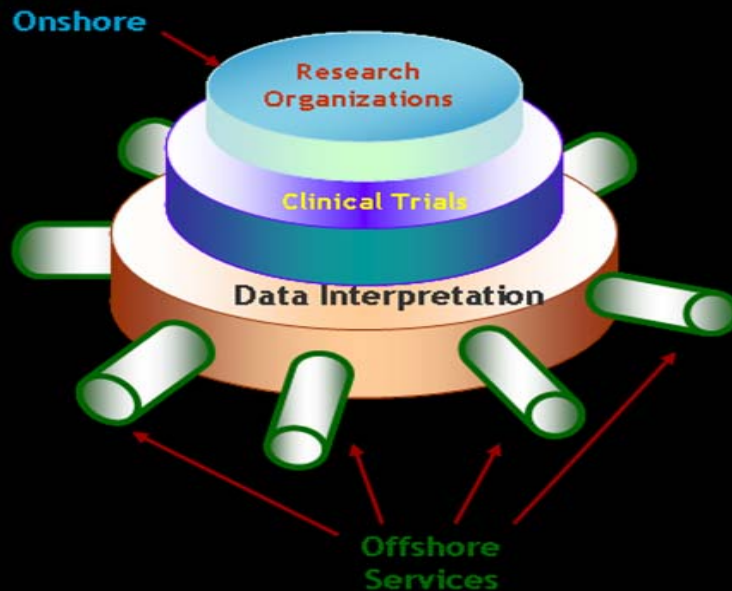
***Ensuring that only quality clinical trials are performed
Provide reliable support for regulatory approval of new drugs***







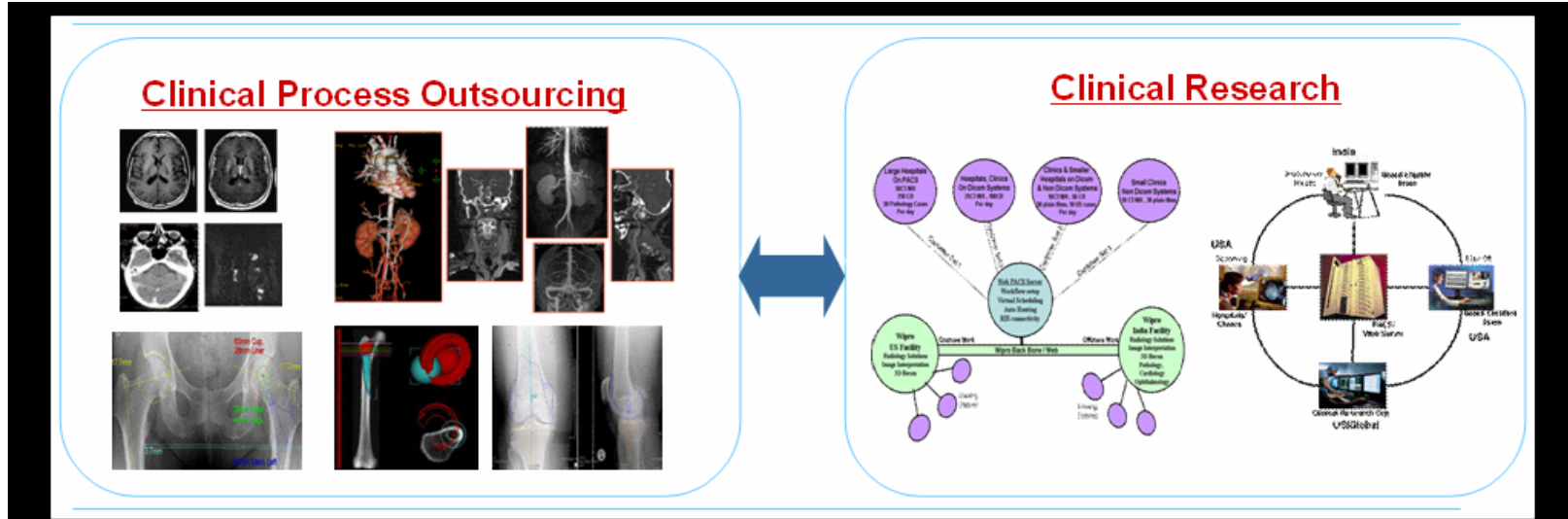
Bridging the gap in manpower resource shortage for Clinical Research, by offering collaborative services under the guidance of the Research Organizations



Various Research Needs

- Molecular Imaging
- Imaging for clinical trials
- IMRT Trials
- Reading Fusion / PET-CT studies
- Pathology Readings
- Cardiology Reading
- Ophthalmology Reading

Source: GCRC



Benefits

- **Imaging for Clinical trials, Drug discovery, Molecular Imaging**
- **Building new protocols and clinical research**
- **Processing & Monitoring by Medical Staff**



Source: GCRC

Using our intellectual capital to support Global Studies!

R&D		18%
QA/QC	7%	
Clinical Research		38%
Process Development/Mfg		10%
Sales and Marketing		9%
Admin/Operations		7%
Information systems		5%
Regulatory Affairs		5%
Finance	4%	
Business Development		4%
HR		0.5%



Source: Data on File

- Very rapid growth in number and size of companies
- Spectrum of skills required in scarcity
- Lack of specialization
- Limited pool of experienced people
- IT enabled services: Cross functional approach
- Lack of differentiation
- **New emerging platform technologies and convergence of disciplines**

Adaptability and Flexibility are key factors that drives this business opportunity !