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# Outsourcing and Offshoring of R&D in the Pharmaceutical Industry: Evidence and Policy Implications from a Global Value Chain Analysis

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# Argument of paper

- Significant changes  in the way Pharma MNCs are organising their R&D activities with important implications for the knowledge base of firms, the geographical location of R&D, the science and research capabilities of countries, global knowledge flows.

- Requires a reconceptualise of the MNC. Focus should not only be on ownership of international assets but on the ***power of the MNC to coordinate and control international operations even when it does not own them*** (Dicken, 2007).

- Means that MNC (lead firm) influences the strategies and capabilities of firms it does not own…and that these firms, in tunr, influence the strategy, capabilities and performance of the lead firm (MNC)

- It is not only the internal capabilities that are important but relationships with complex global network of independently owned R&D service providers.

- GVC framework (Ernst and Kim, Gereffi, Sturgeon)

# Advantages of GVC Approach

- Vertical disaggregation and geographical dispersal of value adding activities.
- Allows more detailed analysis of organisation and location of very specific activities of value chain
- Brings into analysis the international network of independently-owned suppliers, service providers, and customers whose activities, strategies and in-house capabilities strongly contribute to the competitive advantage and long-term performance of the MNC
- Explores different forms of coordination and governance including, but not limited to, ownership and arms-length market relationships.

# Methodology

- Semi- structured interviews with senior R&D managers in sample of top European and US pharmaceutical firms.

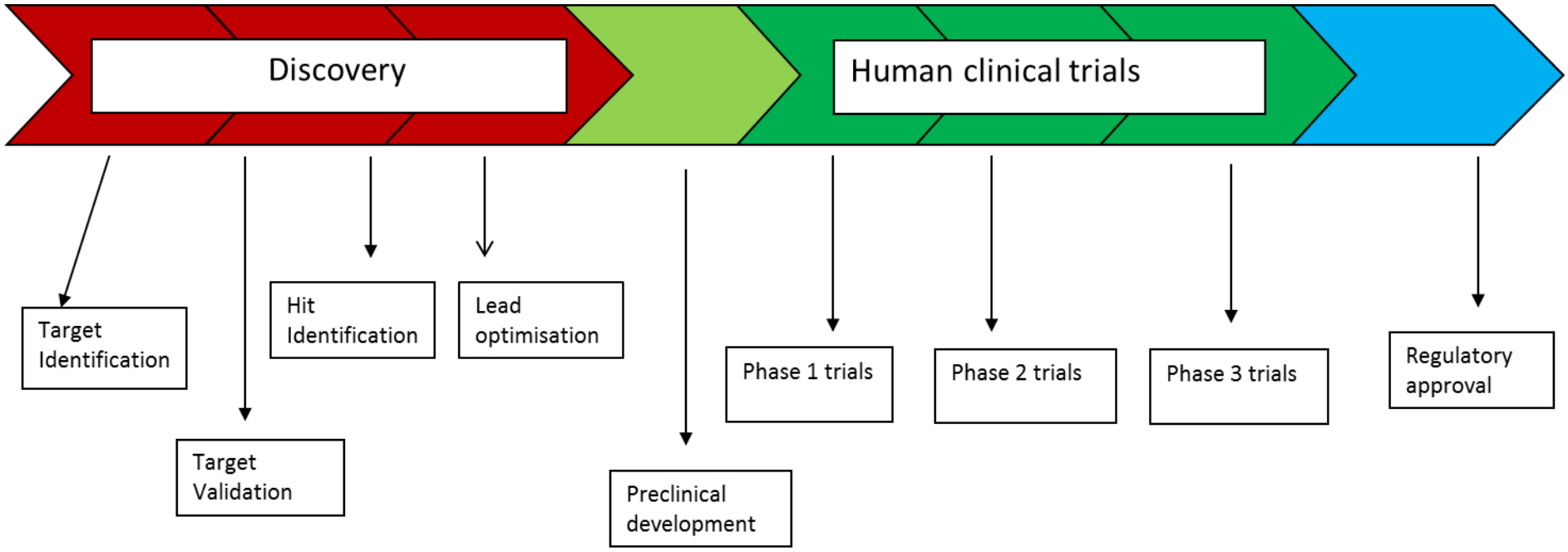
- Semi-structured interviews with European, US and Indian R&D service providers (Contract Research Organisations- CROs)

- GlaxoSmithKline
- AstraZeneca
- Hoffman-La Roche
- Novartis
- Pfizer
- Merck

- Boehringer Ingelheim
- Bayer

- CROs: 9 European CROs and 5 Indian CROs

# Pharmaceutical R&D value chain



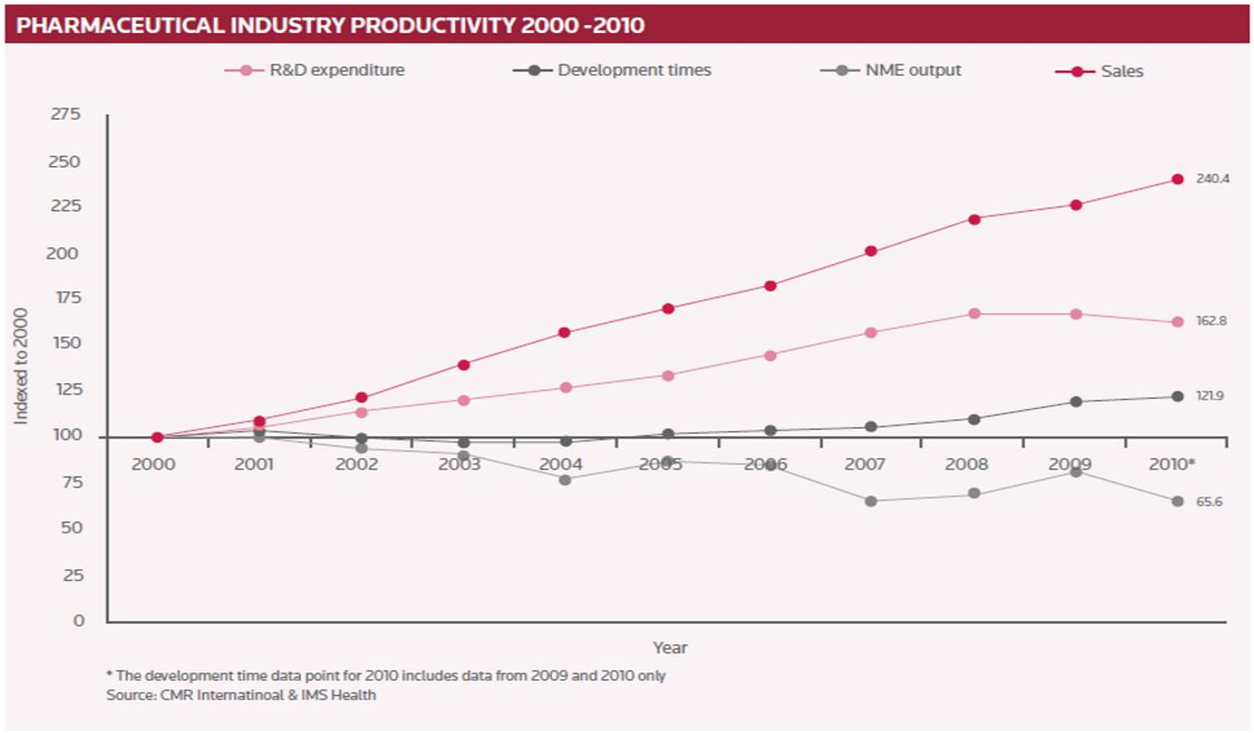
# Pharmaceutical Industry

- Very R&D intensive, historically area of European strength
- 1990s- European flows of R&D investment towards USA:
  (i) to access new science and technology
  (ii) Access to dynamic market
- 1990s significant cross-border mergers and acquisitions. Resulted in international dispersal of R&D activities… 'globalisation of R&D'.
- Crisis of productivity: Despite significant increases in R&D expenditure number of NCE stagnated.
- *First in class* – Pharma not getting the breakthroughs
- *Best in class*- Increasingly difficult to get Governments and insurance companies to buy

# R&D productivity crisis

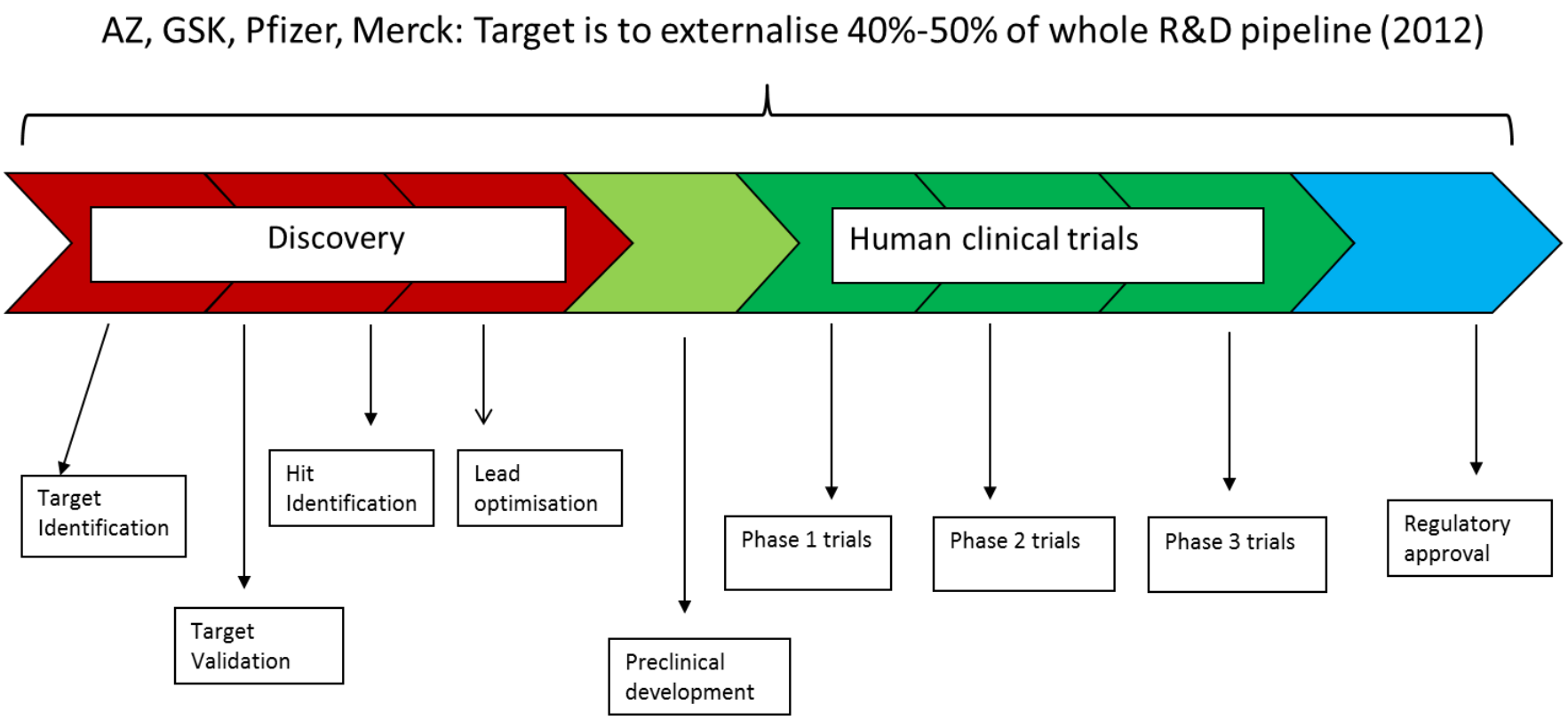
THOMSON REUTERS™

2011

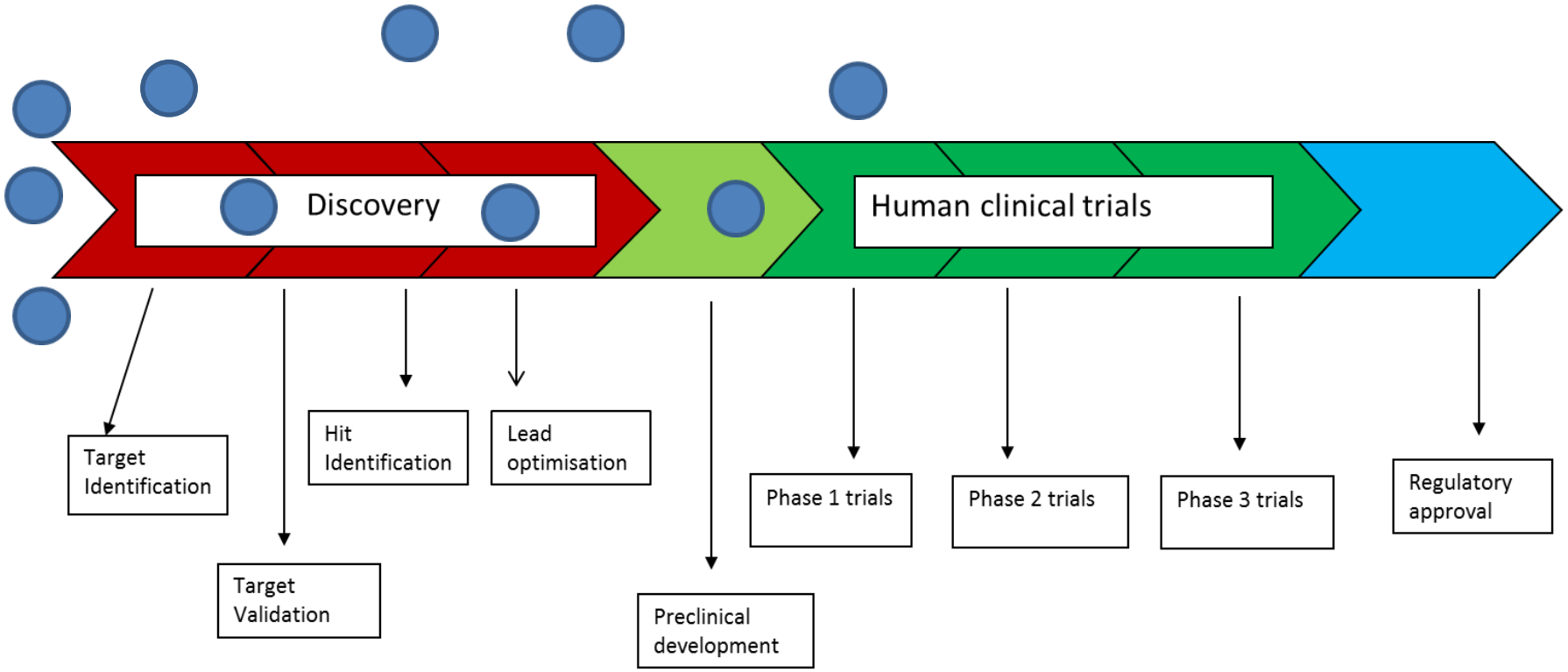



- 'Easy' diseases… 'low hanging fruits' already discovered
- Regulation stricter
- **Main blockage** is lack of scientific knowledge about causes of more complex diseases.

# Response: Externalisation of R&D



# Risk reduction: Buy-in molecules at later stages of development



# Industry-academic collaborations: what is new?

- Since 1980s: Strategic alliances with academia/biotechs to access new scientific knowledge and technologies (biotechnologies and ICT)
- Now: Collaborations with academia/biotechs becoming central to on-going **product development work** of Big Pharma
- "* is doing basic scientific research. It is establishing labs inside academic facilities….Academic researchers are also involved in the validation of targets so there is a lot of cooperation along the value chain. ***So academics are part of the drug identification and development stage***" (German Pharma)
- The scale of the collaborative effort with academia and biotechs
- Variety of complex types of deals and governance forms
- Indicates more systematic integration of the public science-base into industry R&D value chain. Public science-base increasingly becoming part of competitive strategy of firms

# Locational implications

- Need to locate in-house R&D effort close to centres of scientific knowledge (Boston, Cambridge)…..Though location where academic alliances are taking place more numerous e.g. Roche.

- Closure of large R&D labs located close to manufacturing facilities (industrialised R&D model) …Including important historic facilities in home country (e.g. Pfizer- Connecticut; AZ- Alderley Edge; Roche in Nutley). Overall, rationalisation of R&D.

- Results: Geographic re-centralisation of in-house R&D in few world clusters of scientific excellence…This is reversal of process of geographical expansion seen in 90s

| Firm | Closure | Year Annoucement |
|---|---|---|
| Bayer | • Closed research operations in West Haven, CT and Richmond CA (US). | 2006 |
| Pfizer | • Sandwich (UK)<br>• Cambridge, Massachusetts (US)<br>• Significant reductions in Grotton, Connecticut (US) | February 2011 |
| AstraZeneca | • Montreal (Canada)<br>• Södertälje (Sweden) | February 2012 |
| Roche (Swiss) | • USA (Nutley site) | June 2012 |
| Boehringer-Ingelheim | • Close site in Laval (Canada) | September 2012 |
| Novartis | • Closed neuroscience division in Basel(Switzerland) | 2011 |
| Sanofi | • Sold Porcheville (France) and Alnwick (UK)<br>• Closed research labs in Malvern, Pa., and Bridgewater, N.J.(US)<br>• Cut 900 jobs by 2015 (France) | 2009 and 2012 |

# Academic alliances: more dispersed

## Expanding the Innovation Network – Academia

*Source of new innovation for Roche*

Forging novel relationships with the world's leading academic institutions and world class innovators, to gain early access to innovation with cost effective and flexible approaches

Access to 49 universities worldwide

Areas with:

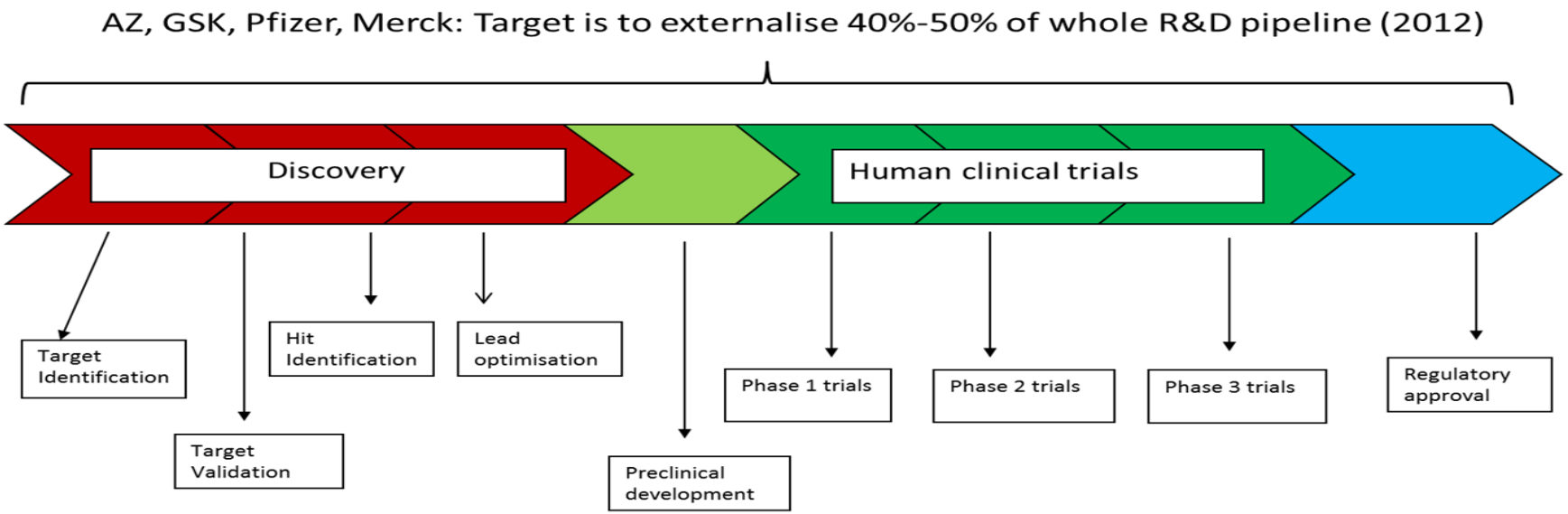
- World-class innovation
- Good infrastructure
- Interest in medical progress

Partners with:

- Start-up track record
- Scientific network
- Aligned goals with Roche

| Market Factors: Opening of R&D facilities in China | | |
|---|---|---|
| Roche | The R&D Centre in Zhangjiang Hi-Tech Park, Shanghai | 2004 |
| Sanofi-Aventis | Chinese R&D Centre | 2005 |
| Pfizer | Pfizer China Research and Development Center, Shanghai | 2005 |
| AstraZeneca | AstraZeneca Innovation Center China, in Shanghai. | 2006 |
| GSK | Established global R&D Centre on neurodegeneration in Shanghai.<br>Established Clinical Research Centers. | 2007 |
| Novartis | Novartis Institute for BioMedical Research , Shanghai. | 2007 |
| Bayer | Announcement that R&D centre to be established in Beijing | 2009 |
| Merck & Co | Asian R&D headquarters, Beijing | 2011 |

# R&D Outsourcing




- Outsourcing to CROs all along the discovery and development value chain but do not outsource the whole R&D value chain or chunks of it…yet no modular
- All parts of the discovery process that require judgement, creativity and cannot be articulated in a Standard Operating Procedure (SOP) are kept in-house.
- Molecule design & key studies kept in-house
- Routine R&D activities such as toxicology, drug metabolism, formulation can be outsourced (internally organised to compete with outside suppliers)
- The science that is well understood, robust and repetitive can be outsourced

# Reasons for outsourcing

- Flexibility: Research becomes a variable cost rather than fixed cost (e.g. close down buildings; reduce scientific headcount; increase speed to kill projects…But significant increase in search and monitoring costs)
- Cost reductions: CROs cheaper. Rent back same scientists at cheaper rate
- Reduction of risk: 'Buy-in' projects further down the pipeline
- But pharma loss of cumulative knowledge base with dissolution of R&D teams and weakening of significant R&D capability as doing less R&D… Now building capability as '***buyer of R&D***'
- Closure of R&D sites and break-up of specialist teams weakens national industrial knowledge base and national industrial research base
- CROs under intense productivity pressure- less time to reflect, think, learn and train. Yet much of the 'doing' is being done here…so weakening of 'learning by doing'
- European/US CROs under significant pressure from Chinese and Indian CROs

# Who are the European and US CROs

- University spin-out firms  (e.g. Evotec)
- Spin-out from major pharma on the basis of specialised technologies or molecules  (E.g. Astex)
- Firms formed as a result of redundancies from major pharma firms (e.g. Biofocus)

- **Different types of funding models**
- Private funding  (owners and family provide funding) (Confometrix)
- Venture capital funding
- Acquired by mid-size European pharmaceutical firms (e.g. Galapagos, Evotec)
- Acquired by mid-size US pharmaceutical firms (e.g. Astex)

- **Different types of strategies and services…very dynamic**
- Most European and US firms have develop increasingly more sophisticated strategies to compete with Indian and Chinese CROs

# How do CROs contribute to Pharma's R&D productivity?

- They have highly qualified scientists (individuals and teams that have lost their jobs in pharma as a result of re-structuring).

- CROs perform tasks following client's instructions
- CROs sell scientists' time to pharma (rent out scientists by hour- FTE)
- CROs help find R&D solutions (contribute own knowledge to pharma)
- CROs sell their potential product to pharma (CROs sells its IPR) and do further work on product- i.e. sell their product plus service to develop product (Joint IPR between CRO and pharma)

- CROs can work in joint teams with big Pharma (pharma owns IPR)
- CROs work independently and give results to pharma (pharma owns IPR)

- Mainly 'network' rather than 'market' relationships. Involve exchange of data, knowledge, insights, collaboration in problem-solving.

- European and US CROs 'outsource' some of their routine work to Indian and Chinese CROs

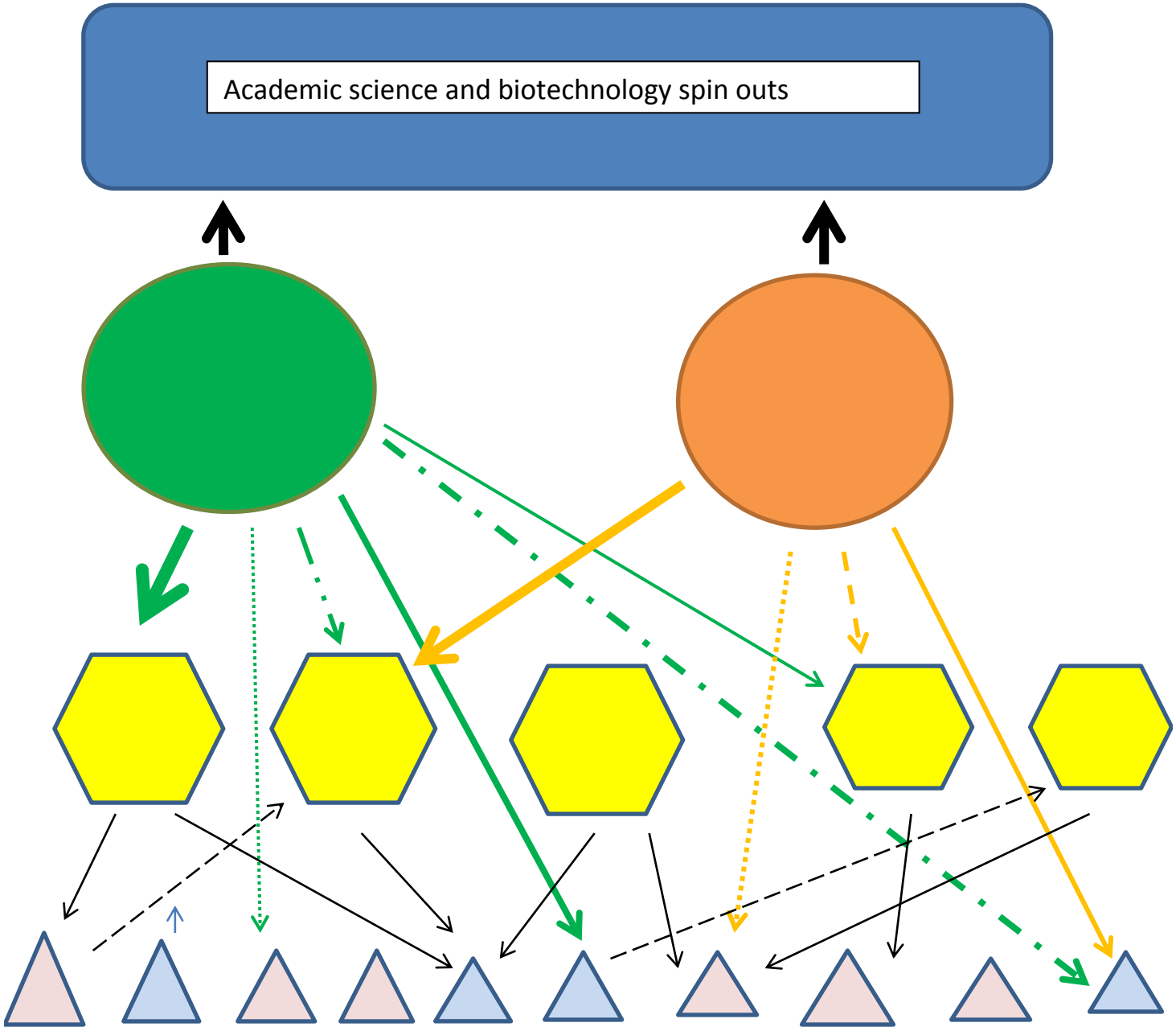
# Indian CROs

- Also different strategies and services

- CROs perform simple R&D tasks  following client's instructions
- CROs perform more complex tasks following clients instructions
- CROs sell scientists' time to pharma (rent out scientists by hour-FTEs)
- CROs help find R&D solutions (contribute own knowledge to pharma)
- CROs sell their potential product to pharma (Joint IPR between CRO and pharma)

- Some Indian pharma firms have own product (do not sell R&D services) but want to buy European and US CROs services in order to sell their products in European and US markets or sell their IPR to European/US pharma. Need to collaborate with European and US CROs to gain legitimacy

- Indian industry does not have legitimacy, regulatory experience, access to patient data-bases of European and US firms


Academic science and biotechnology spin outs

# R&D in pharma is now complex Global System

- R&D in pharma organised as global R&D network based with big pharma increasingly playing role of ‘Buyer’ of R&D.
- Offshoring: location close to centres of scientific excellence, dynamic markets, but also via the outsourcing of R&D to wider range of international R&D service providers
- Important power relations within network. Big pharma very powerful as ‘buyer of R&D services’ as well as in-house R&D.
- Mutual dependency between and R&D partners but significant tensions within network as pharma tries to get ‘better value’ from R&D partners.
- CROs increasingly important organisation for R&D in pharma as accumulating industrial knowledge. But CROs under intense pressure for productivity by pharma; intense competitive pressure from emerging country CROs. Could be detrimental for knowledge of industry as ‘tight resources’.
- Some CROs being acquired by mid-size pharma could lead to closing the gap between big and mid-size pharma?…more competition

# Policy implications

- Importance of public investment in basic science as this is the main obstacle in R&D productivity in this industry. Firms want basic, blue-sky research.
- Importance of 'scientific commons' in areas where lack of scientific knowledge is block to technological progress. Variety of firms benefit from access to science.
- Workforce skills development needs to emphasis: problem-solving, independent, creative thinking and ideas generation. Need to differentiate from 'routine' science and technology that can now be done in many places.
- Institutional system that supports new firm formation and experimentation with new business models (e.g. finance, science incubators facilities… Closure of big-pharma facilities could have been used by CROS )..need a new pharma industry?
- Beware of policies that focus on IPR to stimulate innovation- e.g. 'patent-box'. CROs do not own IPR- their clients do- yet they are doing the R&D and contributing in significant ways to innovation. Need to see industry as dynamic eco-system with different types of firms with different needs…One type of policy tool is not relevant for all players
- Dangers of prolonged 'austerity'. Slow shift of R&D to Asia (China) linked to future 'dynamic market'.

# Thank You