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## **Conducting Clinical Trials in India – a Case Study**

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## India R&D SWOT – MNC Perspective

### **Strength**

- Lower Operating Costs, IT
- Talent, solid education levels
- Large Patient populations, more enthusiasm to volunteer for clinical trials
- Work ethics, willingness to excel

### **Opportunities**

- Entry into rapidly growing market
- Cultural, ethnic diversity
- Almost endless scalability
- Cost, time advantage

### **Weaknesses**

- Longer supply chains
- Compliance and service level varies widely
- Investment in technology transfer is essential.

### **Risks**

- IP situation still under debate
- Uncertainty on foreign authorities' level of data acceptance
- Cost spiral, competition, heated market



“Lets do it in India, its going to be a lot cheaper” !

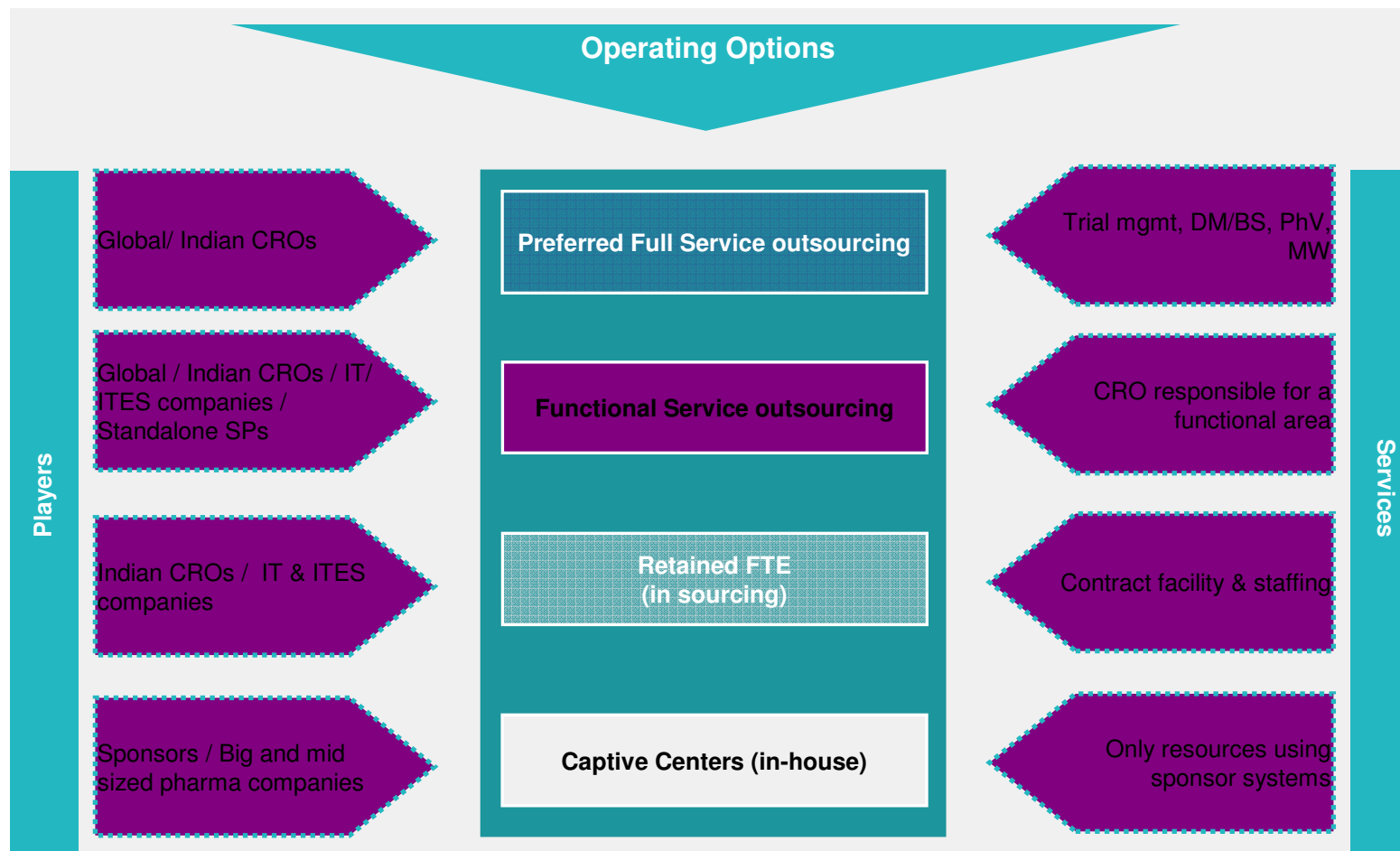
- **In the end it is not about costs or speed (alone)**
- **It is about getting quality data in a reasonable time frame, or at all,**
- **...that allow for a founded decision making of initiating the next, usually even more costly step.**



# India Offshoring – Overview Operating Options

Outsourcing and Offshoring Models:

Suited strategy and long term commitment are needed for value creation

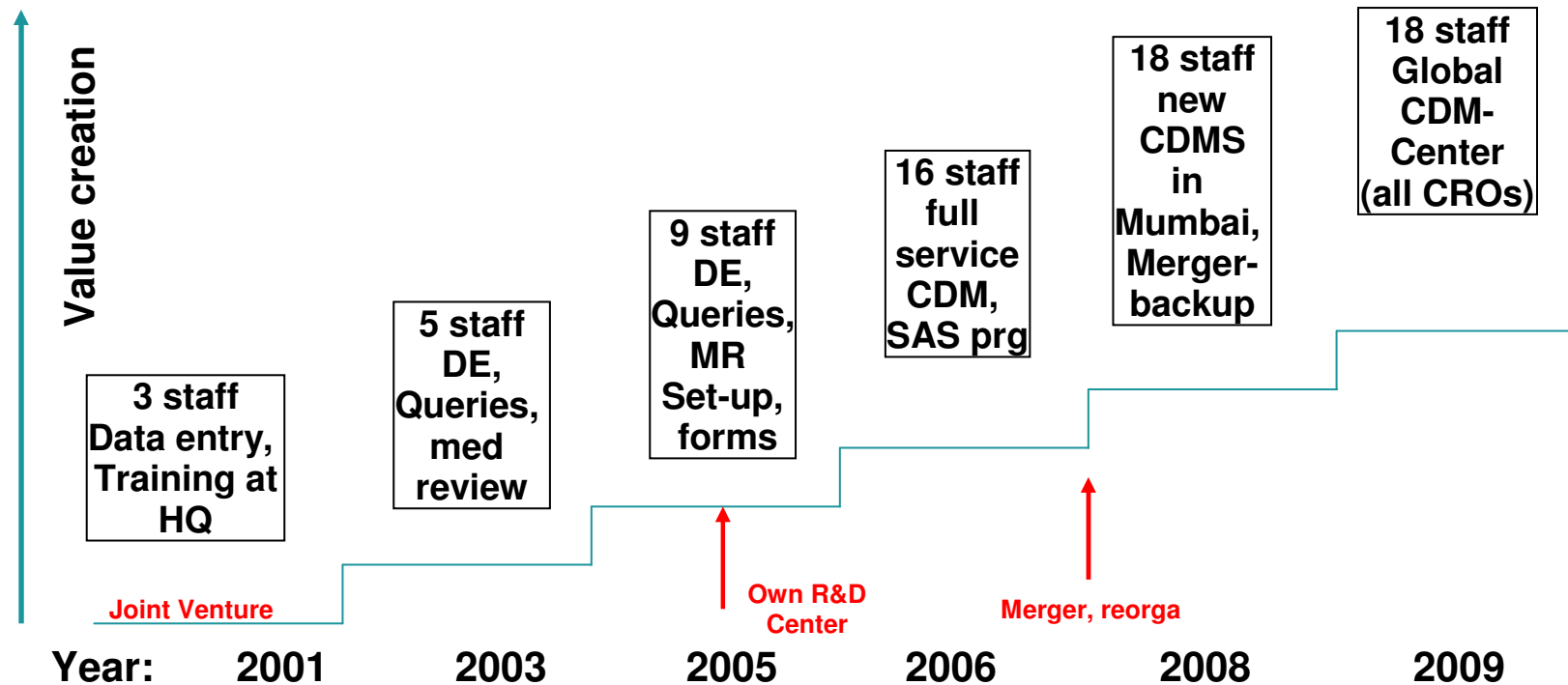


Source: Ernst & Young FICCI report 2009



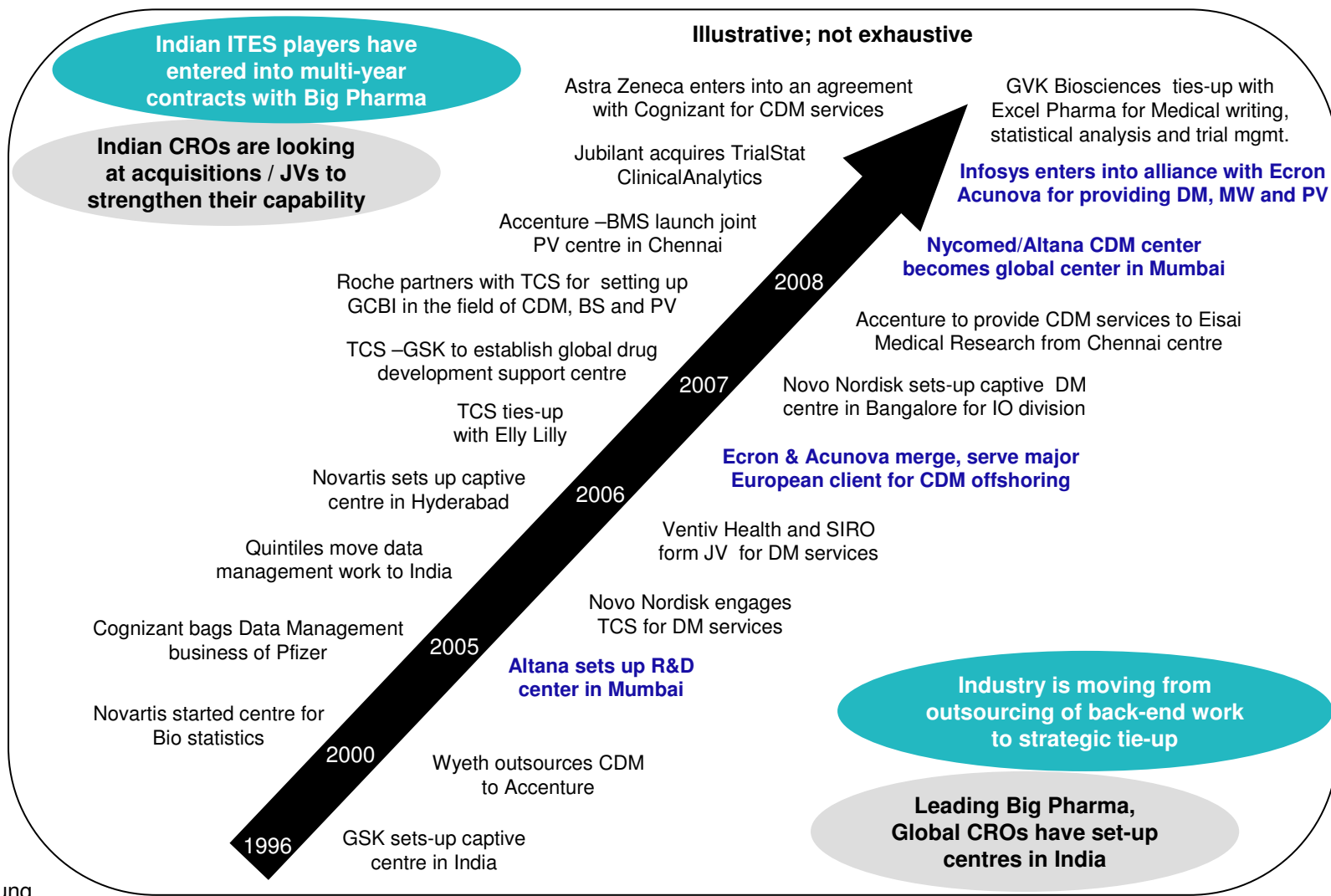
## Genesis of a German Pharma's Captive CDM Center in India

- **Nine (9) years of development, since 2005 captive R&D center**
- **Relevant contingency and backup role during merger**
- **Significant cost savings (>1 mio € p.a.)**





# India CDM Offshoring – The Pharma and CRO Landscape



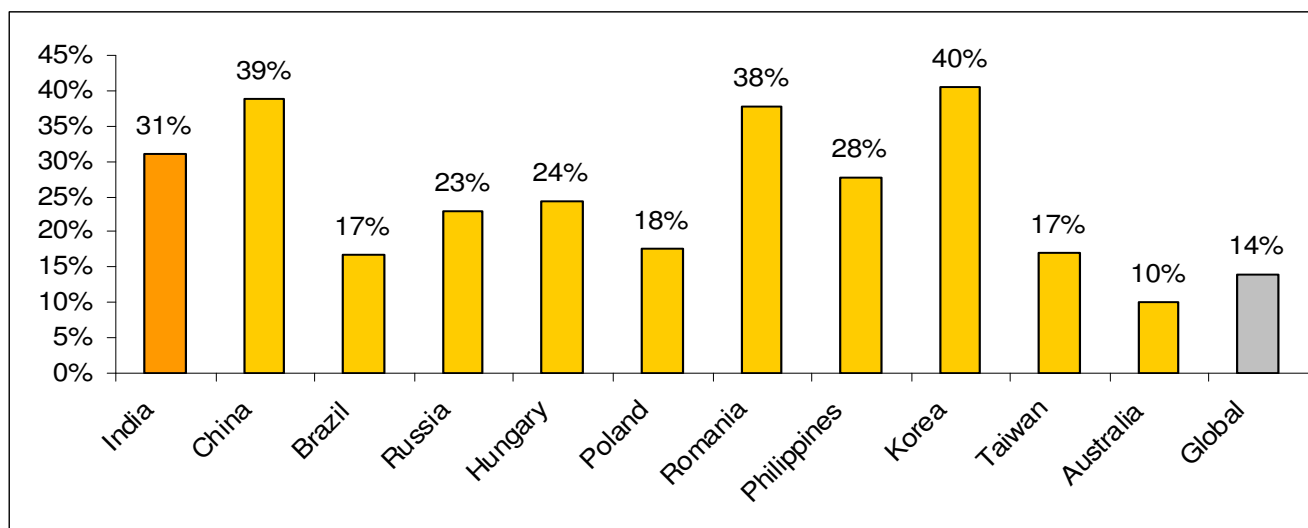
Source:  
Ernst & Young  
FICCI report 2009, own



## Clinical Trials Market India vs. Global: Growth Rates

- **Newest data: 7% of all Phase III and 3% of studies globally are conducted in India**
- **India in top 15 countries, and may be considered an established force in CTs**

**Growth rates clinical trials in selected high-growth markets (CAGR: 2004-08)**

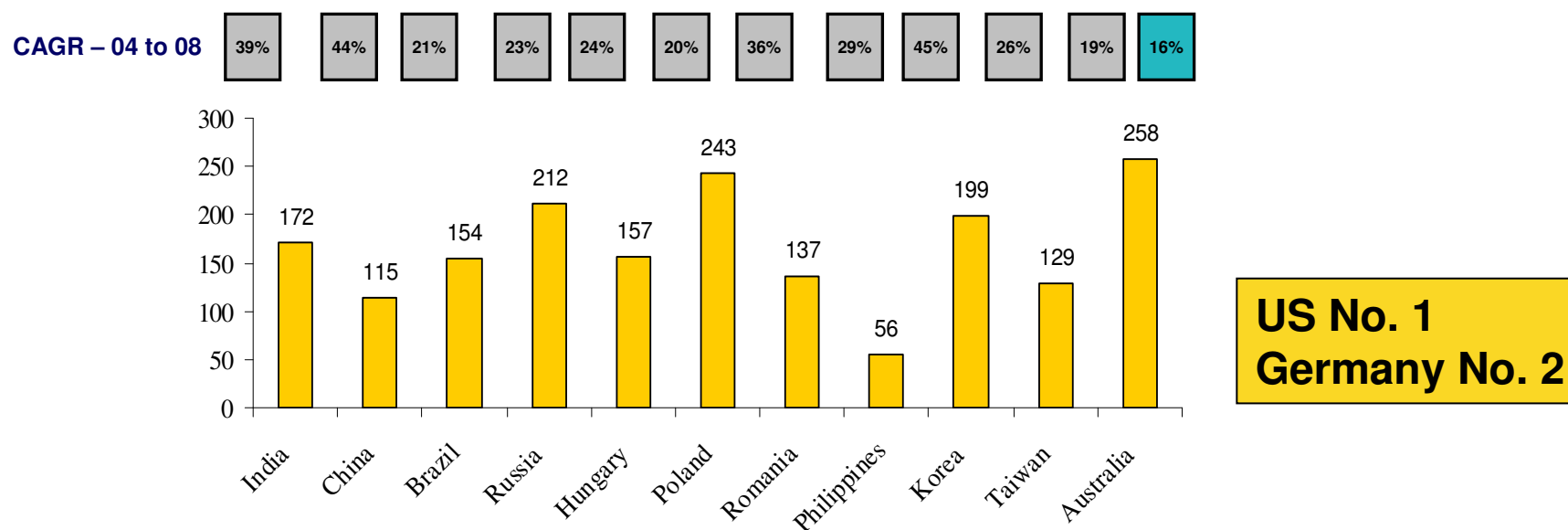




## Clinical Trials Market India vs. Global – Number of Trials

- Currently estimated ca. 600 centers in India with noteworthy CT experience
- Patient pool for almost any indication including lifestyle diseases (CV, diabetes, respiratory, oncology etc.)
- India suitable for most but not all indications and trials
- Start to see “Eastern Europe Effect” (price inflation, competition)

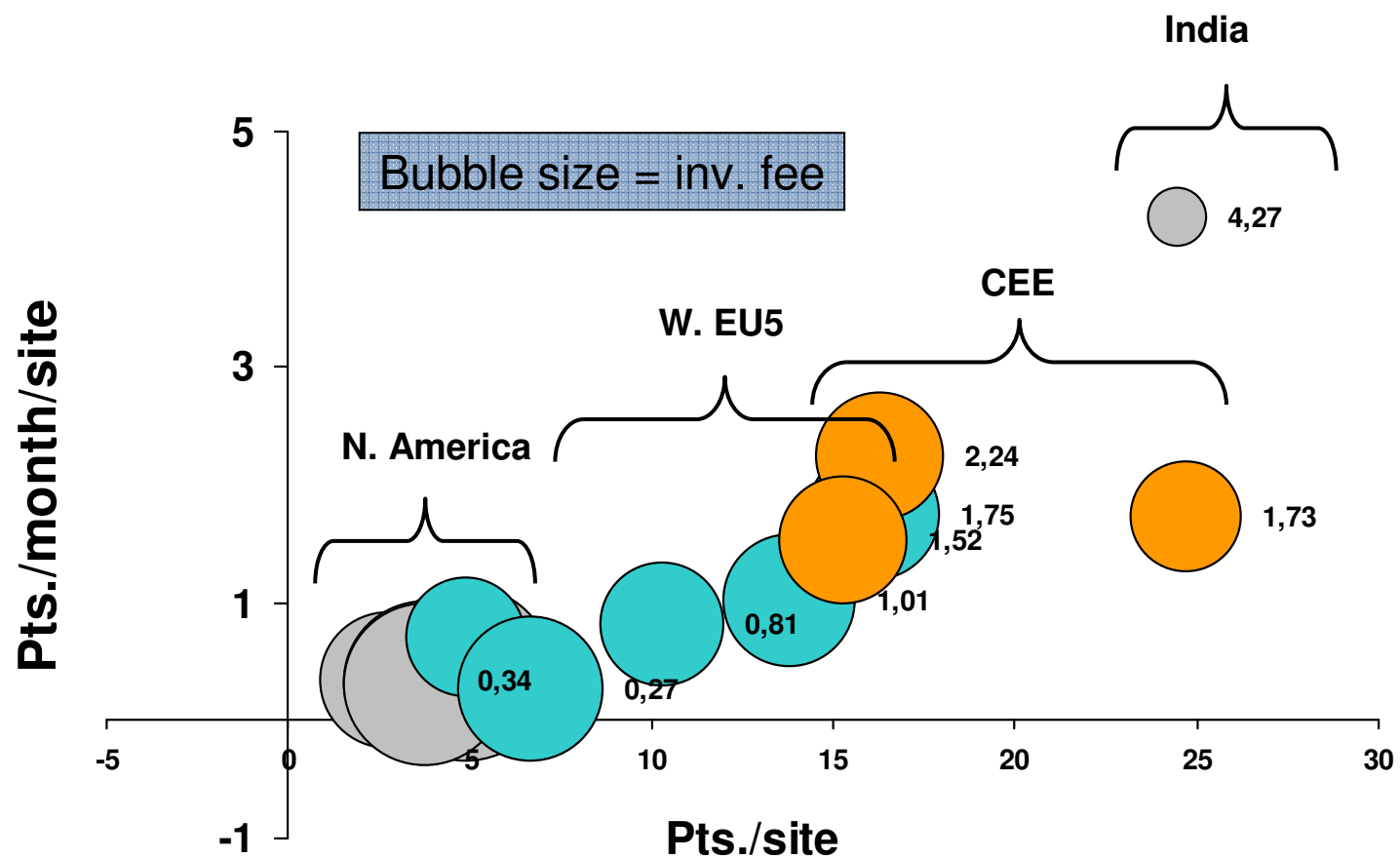
**No. of industry sponsored trials started in 2008**





# Clinical Trials in India: Speed, Efficiency & Cost

Speed (pts./month/site) vs. Efficiency (pts./site)





## Regulatory Authorities, IEC, compliance

### Status quo regulatory & compliance:

- DCGI: Class A & class B procedure, 3-5 months and reliable, but longer times for special products (recombinant, gene therapy, radio-labelled, controlled substances)
- Reorganization of DCGI and staff increase
- Indian GCP (schedule Y) judged adequate, FIM regulation critical
- FDA offices now in Delhi and Mumbai
- Ethics committees usually positive experiences, slow improvement in procedures and compliance
- Translations patient docs needs to be considered
- Success, especially data quality is a function of careful CRO/vendor/site selection and training efforts
- **Overall, situation is comparable, and in most cases better than in other emerging markets.**





## Summary & Conclusion

- India is a highly attractive and by now established location in the global pharmaceutical value chain, especially also in the R&D area
- The role of India, its regulators, its market force is only going to increase
- Oversight, vendor management and a true commitment to an India strategy are a must for success
- Cultural and communications issues are expected. Commitment to and love for the country and its people are the most promising success factors.
- The diligent combination of Western expertise & technology, ie. from Switzerland, Germany, with the delivery and scalability capabilities of India are the most promising combination to truly enhance value in global drug development



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