An exploration of the Contract Research Organisation sector in India

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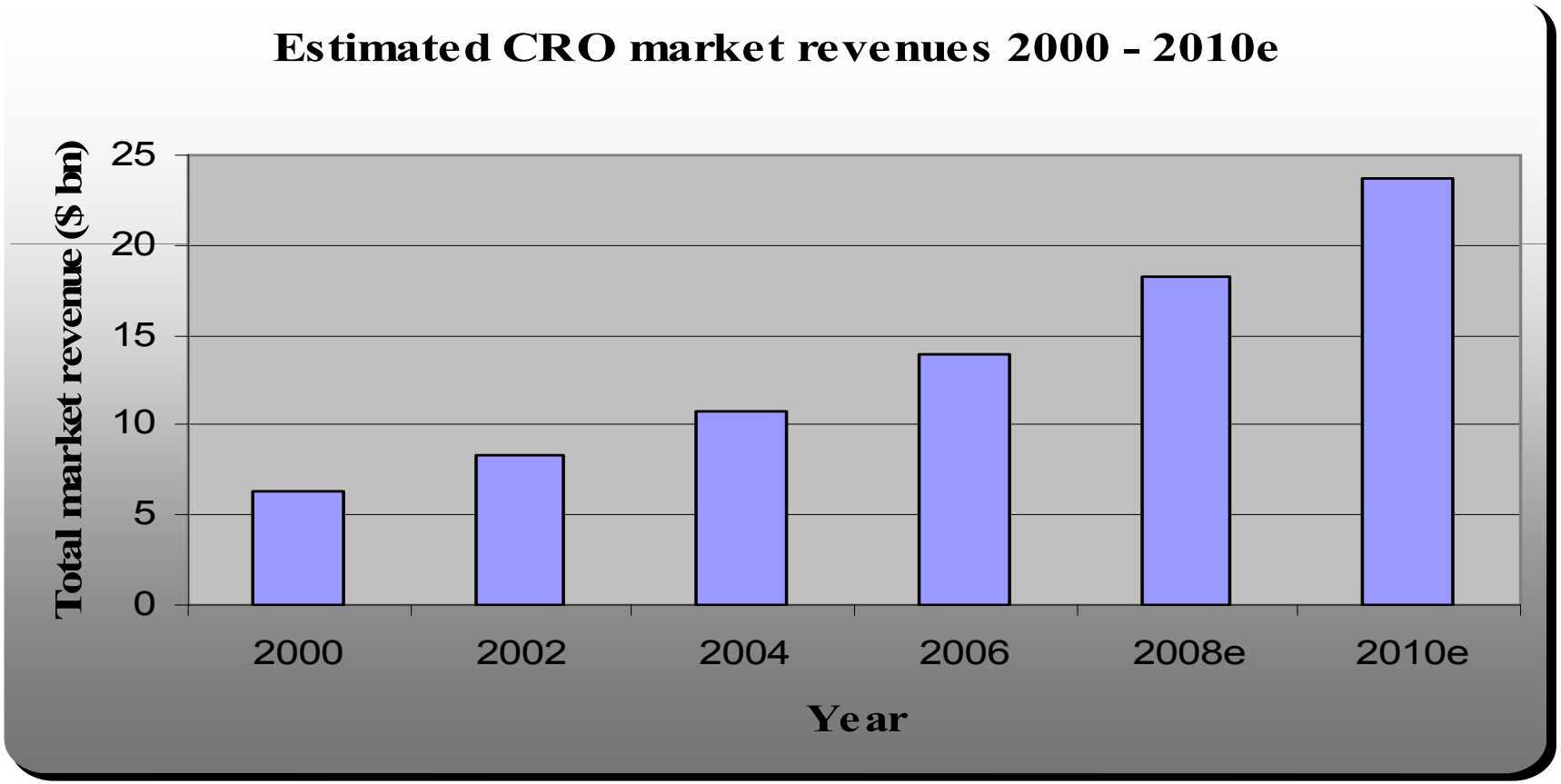
Global scenario

- Outsourcing clinical trials- the new trend



Source: Jakovcic K, Business Insights, "The CRO Market Outlook: Emerging markets, leading players and future trends", 2007, http://www.globalbusinessinsights.com/content/rbcr0001t.pdf (2010 June 11).

- 1993 to 2003: 28% to 64% (involvement in phase 1,2, 3 trials)
- Preferred clinical trials destinations globally- China, India and Latin America
- 1100 CROs
- 45 % of market share- top 5 companies
- Quintiles- 14% of global market share

Source:

Jakovcic K, Business Insights, “The CRO Market Outlook: Emerging markets, leading players and future trends”, 2007, http://www.globalbusinessinsights.com/content/rbcr0001t.pdf

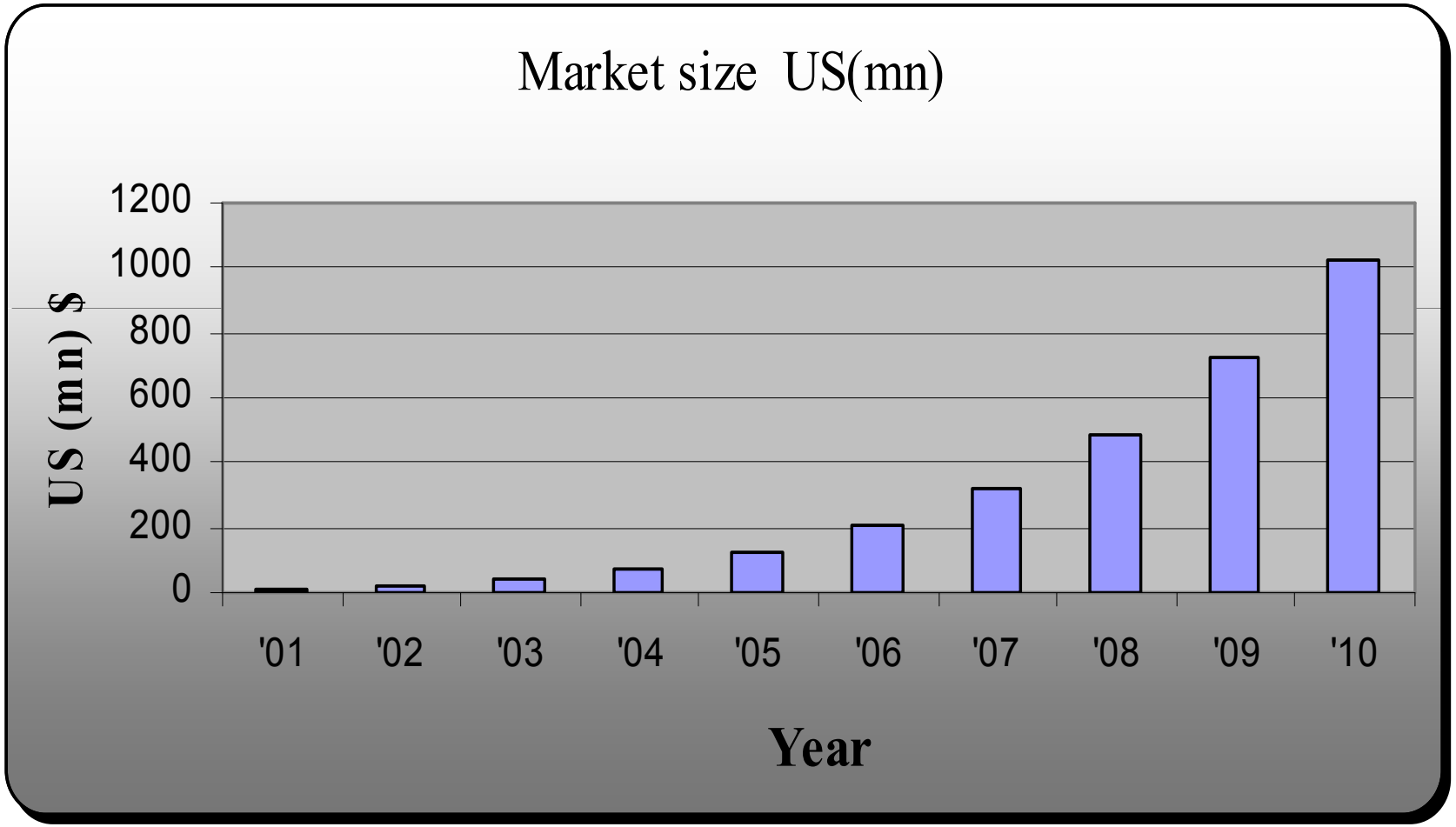
India- the clinical research and CRO hub

- 20% of Asian study sites
- Second largest number of study sites after Japan in Asia
- 30 major CROs, 100 medium CROs

	2003	**2008**	**2010 (e)**
Human resources requirement- full time	800	4000	20,000
Site requirement of human resources	1500	6,000	30,000
Patient load	10,000	50,000	300,000

Source: Mc Kinsey report on CROs

CRO market size in India across years
(projected figures)



Source: Report of the task force of Ministry of Commerce and Industry for increasing exports of pharmaceutical products

Emergence of the sector

Facilitating factors

- Cost- reduction by 30-50%
- Infrastructure
- Human resources
- Perceived patient advantage- large no. of treatment naïve patients & prevalence of diseases.
- Shorter time requirements owing to ease of patient recruitment

Policy changes

- Revision of the schedule Y of the DCA- 2005: eliminated the phase lag
- Change in patent laws in 2005, shift from process patent to product patent.
- Draft National Pharmaceutical Policy- 2006: direct and indirect incentives to CROs and clinical trials sector.

Improved credibility

- Presence of internationally accredited IRBs: IRBs registered with US Office for Human Research Protection in India
- Ethical Guidelines for Biomedical Research-ICMR, 2000 (revised in 2006).
- CTRI- Clinical Trials Registry, India-2007; improving transparency

Strategic partnerships

- Fee for service provider to service partner to risk sharing investor
- CROs partially fund the molecule being tested.
- Objective role of CROs?
- Potential conflict of interest

Services

- Early stages of development- IEC approval, DCGI approval etc
- Site identification and initiation
- Conducting & monitoring the clinical trials
- Marketing of the drugs
- Post marketing surveillance

No involvement/ role in

- Designing the study
- Ownership over data

Perceived advantages

- Revenue generation
- International standards of research, training, infrastructure and technology.
- Advanced treatment options for patients
- Greater job opportunities with the growth of clinical trials and CRO industry

Challenges

Logistical and manpower challenges

- 150/14,000 general hospitals: equipped for conducting clinical trials
- Around 200 GCP trained practitioners
- Lack of laboratories with GLP.

Lack of transparency in the sector

- Non declaration of COI
- Reluctance to share information

Regulatory Challenges

- DCGI- understaffed and lacks expertise

- *"……I will sum up DCGI like this. It is understaffed, it is highly incompetent and most importantly it is a highly corrupt organisation"……* IEC member

- ICMR- Lack of regulatory role & policing powers

Role of IECs

- IECs- expertise, regularity in meeting, composition, enforcing and monitoring role, lack of SOP
- IECs being headed by insiders
- Guidelines not followed by many IECs
- Conflicting review by IECs- CROs shopping for IECs/ institutions.
- *"……. in some private hospitals at times in an IEC of 11 people, I have come across situations in which only 3 people were present at the time of approving the study. So its obvious what will be the quality of that review"…….* Clinical Investigator
- *"…… IEC workload is so high that people hardly read anything."……* IEC member

Accountability issues

- CRO as the middle man
- Direct accountability for the trials or through the clients?
- CROs – flying under the radar- Michelle Mello of Harvard.
- *"…… how the CROs and sponsors delegate the responsibilities amongst themselves will depend on their contract and it is here that the question of accountability comes into play. We do not know who is supposed to do what"……* Expert on clinical trial sector.

Way ahead

- Capacity building of investigators, CRO staff, IECs, DCGI
- Accreditation of CROs and IECs
- Enforcement of ICMR guidelines
- Enhanced monitoring & availability of monitoring reports in public domain.
- *"…… say that CROs are not a bad thing. They are playing and they will continue to play a significant role in developing research. There is a need for CROs. The thing that has to be kept in mind is that we should not compromise on the quality of the research"……* Clinical investigator