

India – a Strategic Imperative for Clinical Trials



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Agenda

- Indian clinical research market – overview
- Case study
 - Clinical project management
 - Data management
- India's advantages



INDIAN CLINICAL RESEARCH MARKET – OVERVIEW

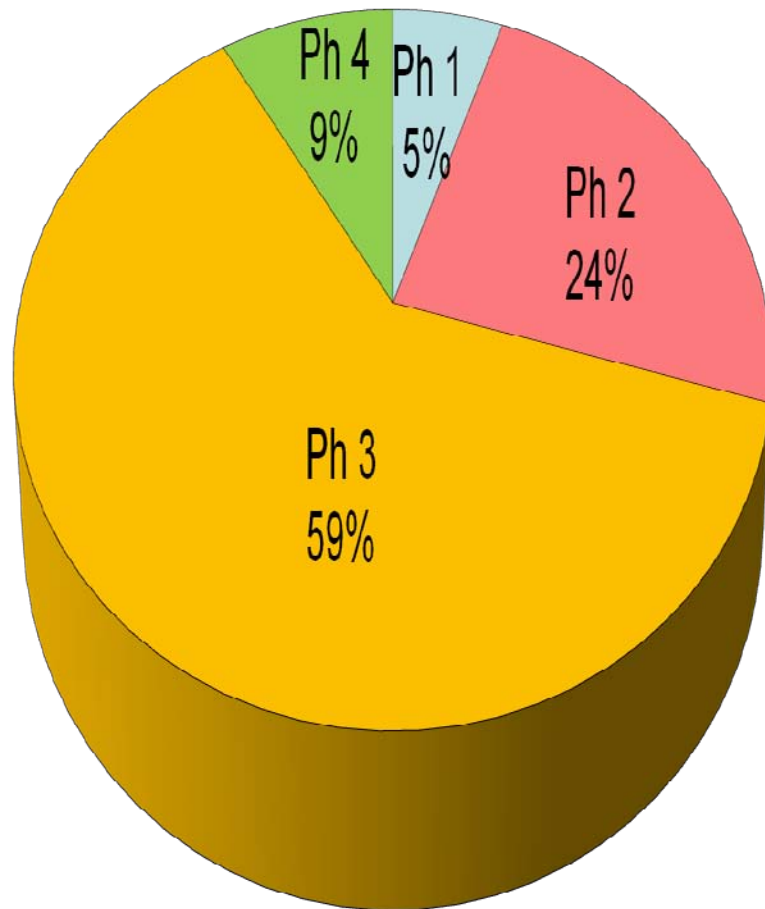
India's Potential for Clinical Research

- India's participation in global clinical trials nearly quadrupled between 2001 and 2005 (Centerwatch 2006)
 - Broad regulatory reforms – IPR and Schedule Y
 - Potential for multi patient recruitment at major cities across the country
 - Pool of Highly skilled and well trained doctors, investigators, and medical personnel
 - IT expertise and infrastructure
 - Compliance with International regulatory and GCP standards

Growing Clinical Research Industry

- Since 2004, number of trials growing at CAGR 28%
- 2008 number of trials 299
- Big pharma share over 60%
- 2009 Clinical trials market US\$ 275 million
- 2008 Data management market US\$ 106 million

Clinical Trials - Phases and Indications



- Oncology
- Neuro-psychiatry
- Cardiology
- Diabetes
- Infections



CASE STUDY

CLINICAL PROJECT MANAGEMENT

Clinical Project Management : Case Study

- US biotech's project of ulcerative colitis in 492 patients
- US recruitment 150 patients from 81 sites over 1 year
- Indian sites expected to recruit up to 300 patients in 6 months

Challenges for CRO

Time

- Time from award to database lock 12 months
- Tasks to be completed
 - Site selection visits to large number of sites
 - Regulatory approval
 - Ethics committee approval
 - EDC / IVRS set-up
 - Enrollment time
 - Treatment & Follow-up

Quality

- FDA 1572 study
- Study complexity
- Stringent patient selection criteria
- Monitoring
- Resolution of data queries

Enrollment Strategy

- Regulatory, ethics and legal process completed within 12 weeks
- 30 selection visits completed by senior team within 3 weeks
- Sites advised to identify potential patients and complete pre-screening log before SIV
- 1 wk prior to the SIV sites reminded to call identified potential patients for screening
- Sites asked to slow down if recruiting very fast to maintain quality of completed CRFs/ essential documents

Quality Process

- Approx 40000 pages were monitored by 10 monitors within 8 months by conducting 210 visits
- On average 200 pages were monitored at each monitoring visit
- Quality control visits by PM
- Audits by sponsor and Clininvent QA of 14 sites

Comparison of Key Indicators

	US	India
Number of sites	81	18
Number of patients screened	544	229
Screen failures	42%	24%
Number enrolled	318	174
Enrolment time months	18.9	4.5
Recruitment rate / month	17	38
Recruitment rate / site / month	0.2	2.1
Data query rate / CRF page	1.8	1.6

Enrollment Experience

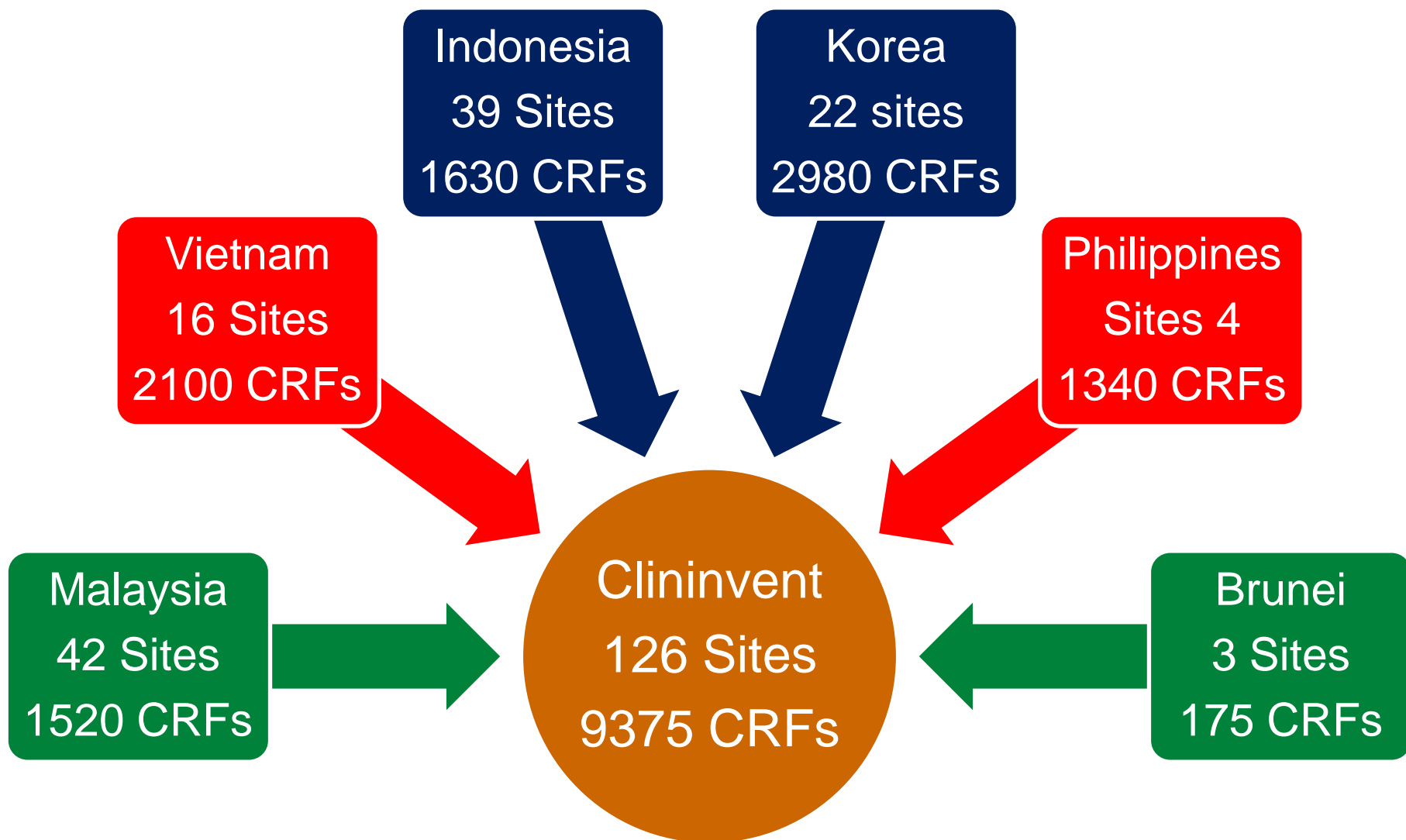
Indication	Patients enrolled	Enrollment rate /site/ month
Breast Ca	146	2
Colorectal Ca	17	2
Lymphoma	14	1
Non Small Cell Lung Ca	25	3
Coronary Heart Disease	300	10
Asthma	280	6
Chronic Renal Failure	140	5



CASE STUDY

DATA MANAGEMENT

European Sponsor's Asia Pacific Trial in 1800 subjects



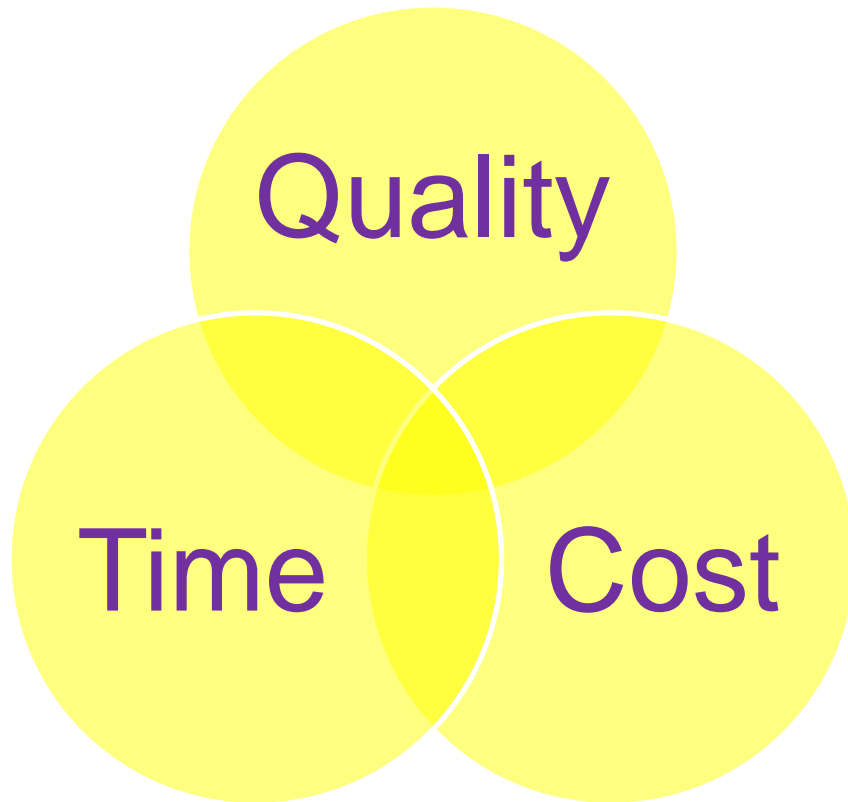
Data Management : Case Study (2)

- Multi-country project of Indian big pharma
 - Sites in Canada and India
 - Database with a Canadian CRO
 - Canadian CRO closed down before project completion
 - Clininvent DM team built database within 48 hrs and transfer complete database to India for handling data management activities.
 - Server and environment was successfully validated along with documentation.
 - 100% data cleaning was done and the queries were resolved within the timeline and successfully closed the database in India



INDIA'S ADVANTAGES

QTC Expectations



FDA Inspections in India

- Inspections 14 - NAI 8 VAI 6

High quality clinical studies have been and can be successfully conducted in India

Dr David Lepay
Senior Advisor U.S. FDA
DIA 2007

India's Strategic Advantage

- Direct cost saving
 - Indian cost 50% of US cost
 - Less Indian sites
 - High enrollment per Indian sites
- Indirect cost saving
 - Faster completion of enrollment
 - Saving of time
- Data management
 - Cost effective
 - High tech IT support

India as a Strategic Option

- Phase II – III up to 50% of subjects
- Phase IV up to 20% of subjects
- Data management full support for all countries/ sites
- Other potential areas
 - Statistical analysis
 - Medical writing
 - Pharmacovigilance

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