Clinical Research Opportunities in India

Presented at

Confederation of Indian Industries

New Delhi 07 Feb. 2003

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Clinical Research Opportunities in India

- Clinical Trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective.
- A clinical trial is a research study to answer specific questions about drugs, new therapies or new ways of using known treatments.
- Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

Various types of clinical trials include:

>Treatment trials - test new treatment, new combinations of drugs, or new approaches to surgery or radiation therapy.

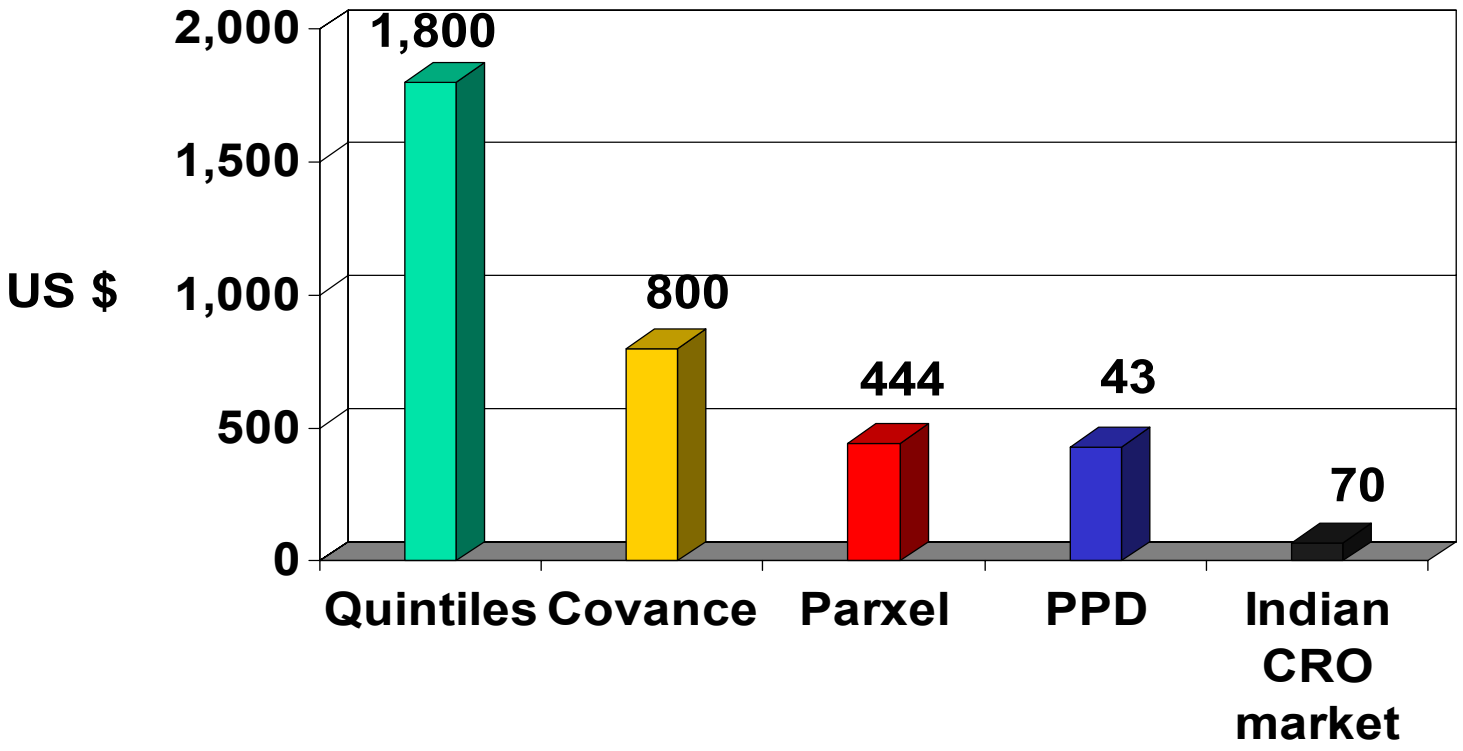
> Prevention trials - look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals or lifestyle changes.

> Screening trials – test the best way to detect certain diseases or health conditions.

> Quality of life trials (or supportive care trials) – explore ways to improve comfort and the quality of life for individuals with a chronic illness

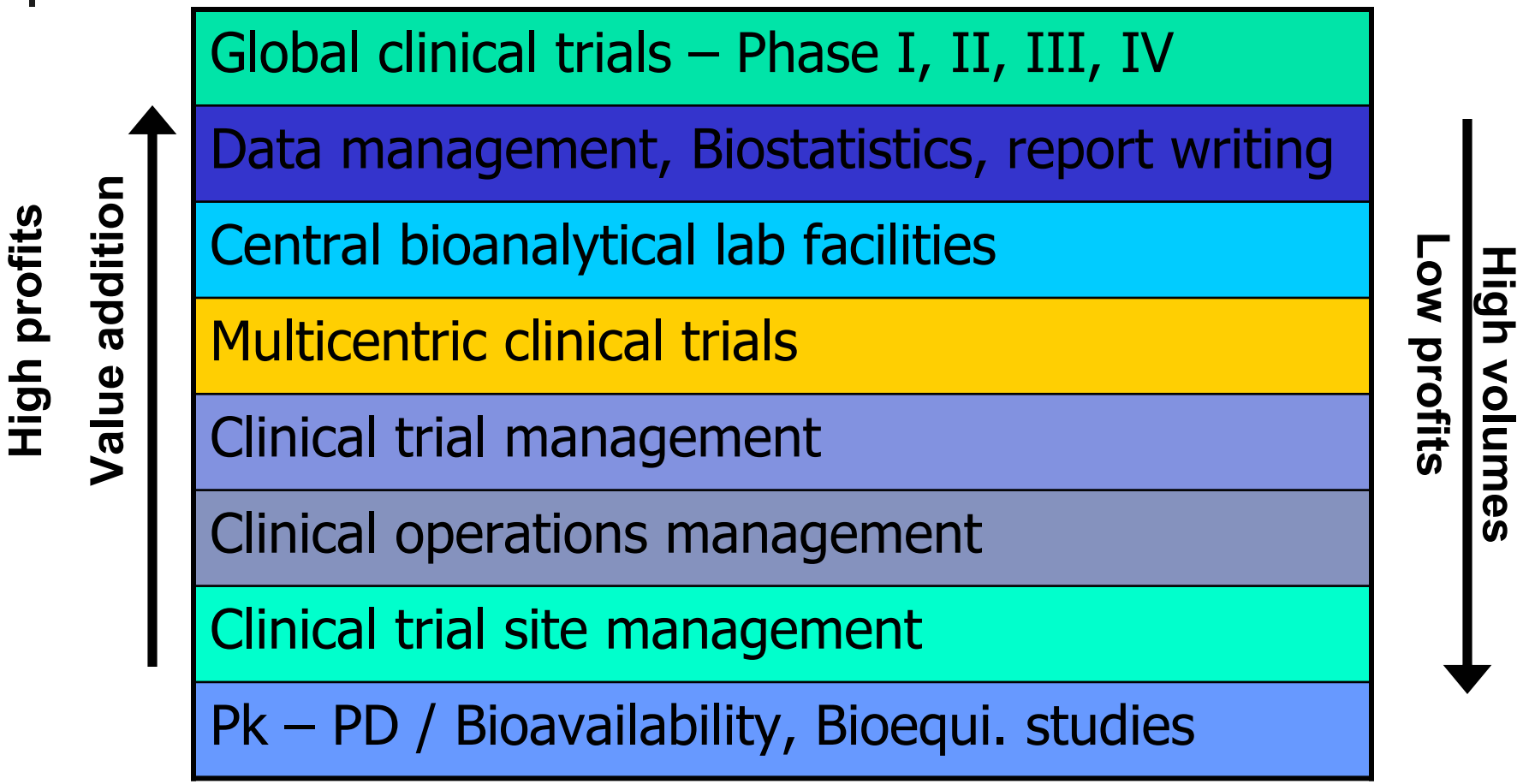
- Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:
- In **Phase I** trials, researchers test a new drug or treatment in a small group of healthy people (20 -80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In **Phase II** trials, the study drug or treatment is given to a selected group of patients (100 – 300) to see if it is effective and to further evaluate its safety.
- In **Phase III** trials, the study drug or treatment is given to a large group of patients (1000 – 3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- In **Phase IV** trials, post marketing studies delineate additional information including the drug's risks, benefits and optimal use.

Global clinical trial CRO revenues (2002)



Advantage India

- Patient diversity
- Patient heterogeneity
- World class medical infrastructure
- Familiarity with western medical facilities
- English competency
- Cost competency (patient recruitment, shorter timelines, manpower etc.,)
- ICH / GCP guidelines implementation
- Project management competencies
- Central lab facilities (Internationally, nationally accredited)
- Regulatory guidelines and government policies – helping clinical research in India (MOH, DCGI, ICMR, DBT etc.,)


Global clinical trials – Phase I, II, III, IV
Data management, Biostatistics, report writing
Central bioanalytical lab facilities
Multicentric clinical trials
Clinical trial management
Clinical operations management
Clinical trial site management
Pk – PD / Bioavailability, Bioequi. studies
High profits
Value addition
High volumes
Low profits

PK – PD / Bioavailability, Bioequivalency studies involve:

-Design of study protocol

-Non – compartmental analysis

-PK fitting and modeling

-Determination of PD parameters

-Writing PKD reports

-Complete bioavailability studies

-Complete bioequivalence studies

-PK simulation

-Evaluation of PK / PD relationship

-Statistical analysis on PK and PD data

Clinical trial site management involves:

- Presenting qualified, pre – screened, principal investigators for participation in clinical trials in any specialty area/s, as required by the sponsor

-Ensure timely and accurate regulatory board submission and data collection

- Provide access to a specified large patient study population

-Provide ongoing and effective communication between sites, investigators and customers

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Clinical operations management involves coordinating :

-Feasibility check

-Selection of investigators, patient population

-Timelines, site selection, monitoring

-Managing recruitment goals

-Site instruction

-Monitoring & logistics

-Clinical data review

-Local quality audits

Clinical trial management / Multicentric clinical trials involve

-Feasibility check

-Regulatory approvals for the study

-Protocol development

-Selection of investigators & patient population

-Site selection

-Clinical monitoring

-Data management

-Biostatistics

-Medical writing

-Report writing

-Clinical data review

-Managing recruitment goals

-Quality audits (incl. GCP)

-GCP training

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Central bioanalytical laboratory facilities need to have:

-Broad range of bioanalytical competency

- Sample collection management competency

-Real time investigator support

-Samples, specimen transport storage competency

-Real time high quality, clinical, analytical data

-International and National accreditations and certifications

Data mgmt. Biostatistics, report writing involves:

-Review of clinical information prior to data entry

-Entry screen development and database design

-Data entry and verification, visual audits

-Creation, programming and execution of computerized validations

-Quality assurance audit, database lock & release

-Statistical analysis of data

-Report writing – medical, pharmaceutical, regulatory etc.,

Regulatory issues

-Specific guidelines available to conduct clinical trials of new drugs

(Chemicals. biologicals, vaccines, genetically modified drugs etc.,)

-Specific guidelines available to import and export new drug molecules ands or samples, biological specimen etc.,

-Rapid scrutiny of clinical applications

-Facilitating new rules to conduct Phase I to Phase IV clinical studies, trials in India

-Ministry of Health, Indian council of Medical Research, Department of Biotechnology etc.,working in tandem to promote growth of clinical research in India

What We need to do …

-Rapid build up required infrastructure and implementation competencies

-Meet ICH, GCP, GLP (GXP) guidelines

-Attain recognition as quality clinical trial destination – data to be trustworthy and reliable

- generated data to be accepted to global regulatory authorities, medical fraternity, patients etc.,

-Train ourselves to attain global recognition through accreditations & certifications

India has clinical research resources on par or better vis – a – vis the world

	India vs Western countries	India vs. China
+	• Patient enrollment •Diversity •Genetic uniqueness •Costs	• Diversity •Genetic uniqueness •English competency •Medical infrastructure •Familiarity with western medicine
=	• English competency •Medical infrastructure •Western medicine familiarity •Companies with international standards	• Costs •Patient enrollment
-	• IPR reputation •Industry standards •Less established infrastructure	• Foreign partnerships •Resources •Patent regime

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QUESTIONS ???