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DRUG REGULATORY AFFAIRS IN CLINICAL RESEARCH AND IT'S SCOPE

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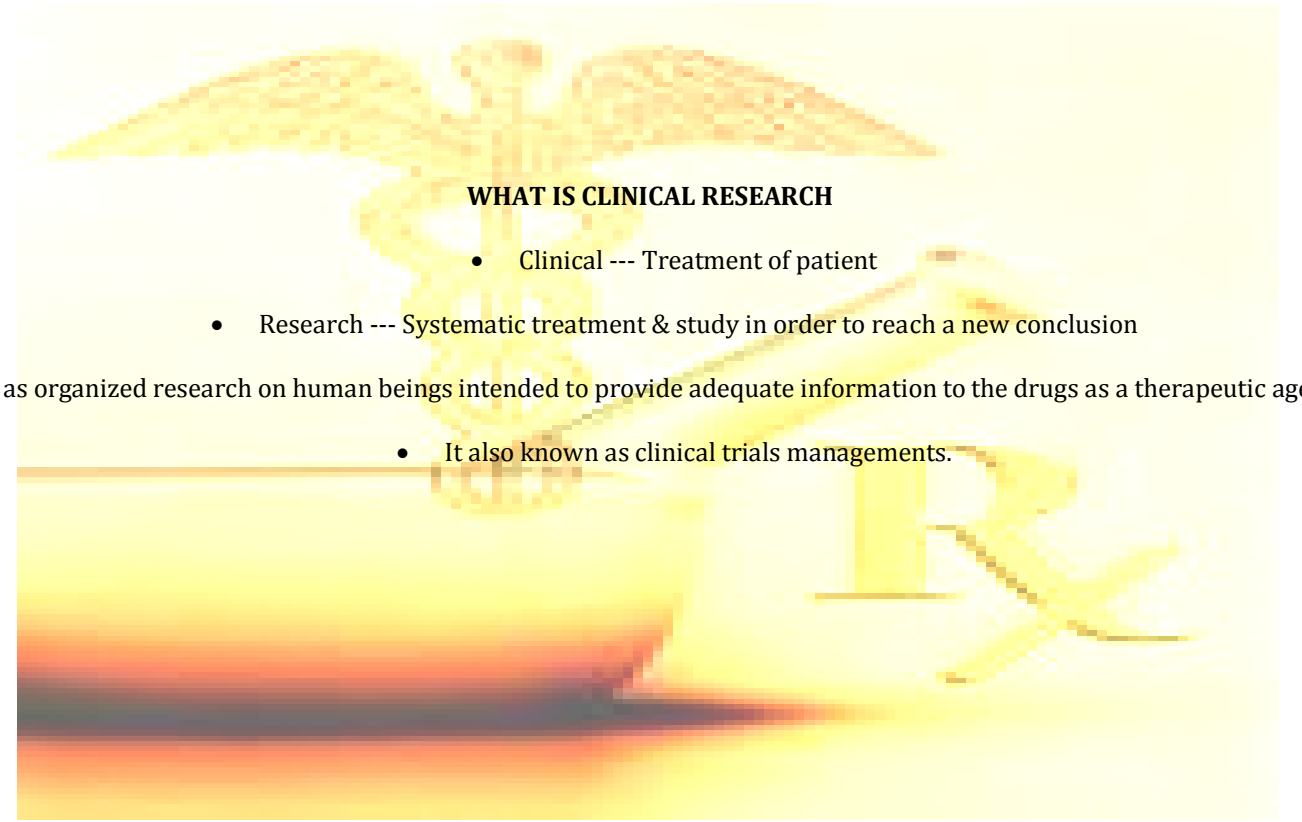


WHAT IS CLINICAL RESEARCH

- Clinical --- Treatment of patient
- Research --- Systematic treatment & study in order to reach a new conclusion
- Thus it is defined as organized research on human beings intended to provide adequate information to the drugs as a therapeutic agent for is safety & efficacy.
- It also known as clinical trials managements.

OBJECTIVE OF CLINICAL RESEARCH

Clinical research consists of fallowing aims--

- To determines the safety and efficiency of medications, diagnostic products and other treatment regimens for humans
  - Drug discovery
- Formulation & development
  - Clinical trials
- Commercialization

CLINICAL TRIALS

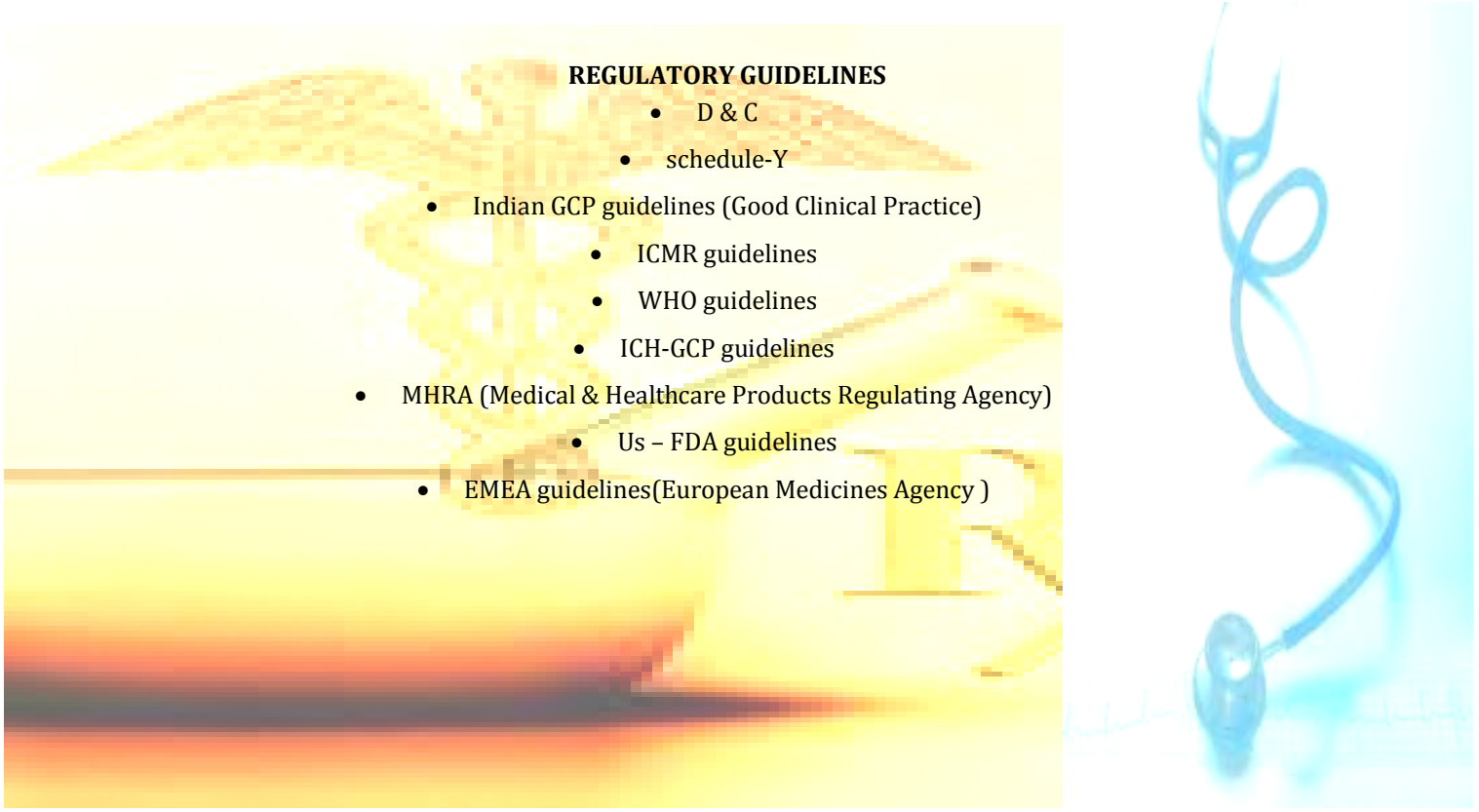
- Clinical trials are studies performed with human subjects to evaluate drug, treatment, surgical procedure and medical devices.
- The aim is to ensure the safety, reduced side effect and better treatment to improved health care.

CLINICAL TRIAL PHASES

- Phase-I- Clinical pharmacology, safety of new drugs
- Phase-II -safety and efficacy of new drug in patients, exploratory trial.
- Phase-III -multicentric confirmatory trial.
- Phase-IV -post- marketing surveillance

CLINICAL TRIALS

	Preclinical Testing		Phase I	Phase II	Phase III		FDA		Phase IV
Years	3.5		1	2	3		2.5	12 Total	
Test Population	Laboratory and animal studies		20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers				
Purpose	Assess safety and biological activity	File IND at FDA	Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness, monitor adverse reactions from long-term use	File NDA at FDA	Review process / Approval		Additional Post marketing testing required by FDA
Success Rate	5,000 compounds evaluated		5 enter trials				1 approved		


REGULATORY GUIDELINES
D & C
schedule-Y
Indian GCP guidelines (Good Clinical Practice)
ICMR guidelines
WHO guidelines
ICH-GCP guidelines
MHRA (Medical & Healthcare Products Regulating Agency)
Us – FDA guidelines
EMEA guidelines(European Medicines Agency)

ROLES OF REGULATORY AFFAIRS

- Ensuring that a company's products comply with the regulations of the Global drug regulatory agencies
- keeping up to date with a company's product range
- Developing and writing clear arguments and explanations for new product licenses and license renewals
- Preparing submissions of license variations and renewals
- Monitoring license variations and renewal approvals
- Writing clear, accessible product labels and patient information leaflets
- Planning and developing product trials and interpreting trial data
- Undertaking and managing regulatory inspections
- Reviewing company practices and providing advice on changes to systems
- Specifying storage, labeling and packaging requirements.

THE SCOPE OF CLINICAL RESEARCH

- The demand for clinical research professional is seems to be increasing in the recent past years in India.
- With a conspicuous figure of $1 billion, this business field has touched the new height in 2010 in the global market.
- This indeed has raised the requirement of professionals in this field and has brought in a whole new positive change in the nation's economy and medical sector.
- As per a recent survey conducted there are more than 50,000 job openings available in India in this year and figures seem countless worldwide. All these facts are making this field, one of the most promising careers for sure.
- Undoubtedly, clinical research in India promises to be a convincing career choice for many.

CARRIER IN CLINICAL RESEARCH

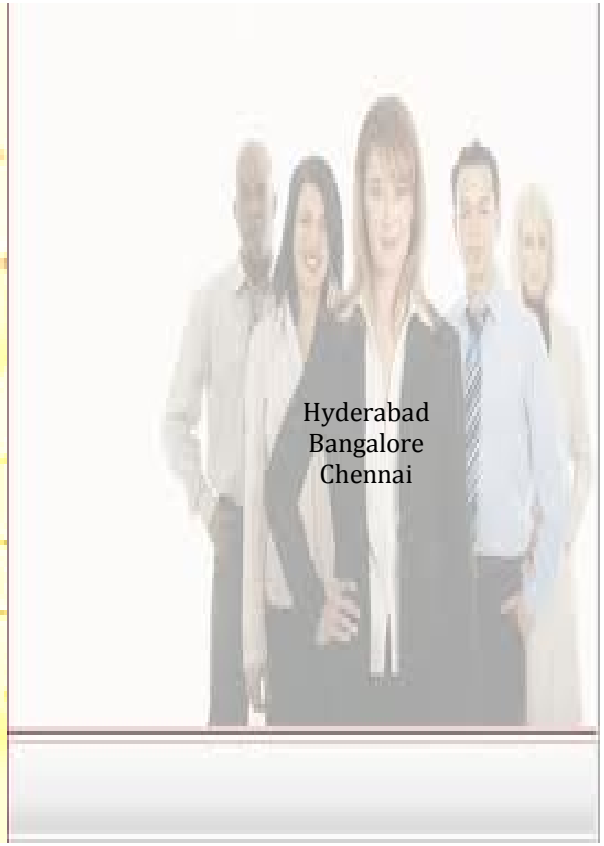
Pharma company	Data managements	Site management organization	Clinical research training institute
•Clinical trial assistant (CTA) •Clinical research associates (CRA) •Senior CRA •Clinical team leader •Project manager •Senior PM •Medical & regulatory manager •Q A manager •Medical director •Associate director	•Data entry operator •Data manager •Data validation executive •Q A manager •Q A executive •Data reviewer •Data base designer •Head data manager	•Clinical research co-ordinate •Principle investigator •Co- investigator •Medical monitor •Project manager •Senior manager •Medical &	• Trainer clinical trial management • Trainer Data manager • Trainer Project manager • Trainer director • Trainer co-ordinate • Trainer biostatics • Trainer

TYPES OF EMPLOYERS

Pharmaceutical Companies
Contract Research Organization
Hospitals
Non Government Organization
WHO

KEYS CITIES IN INDIA FOR CLINICAL RESEARCH

Delhi &NCR Region
Mumbai
Pune
Ahmadabad



Hyderabad
Bangalore
Chennai

SOME PHARMA COMPANIES IN CLINICAL RESEARCH

Astra Zeneca Pharma India Ltd, Bangalore

Astra Zeneca Foundation, Bangalore

Aventis Pasteur, Delhi

Pfizer Ltd, Mumbai

Pfizer Biometrics, Mumbai

Altana(Zydus), Mumbai

Novartis Pharma, Mumbai

Eli Lilly, Delhi

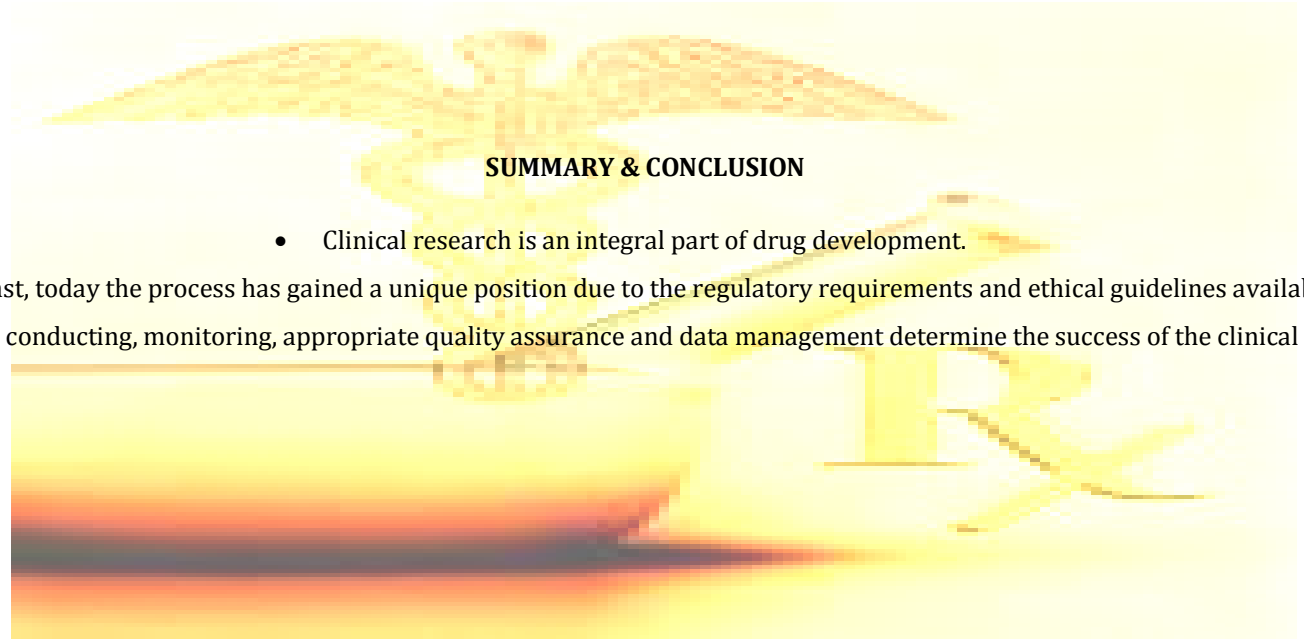
Boston Scientific, Delhi

Merck ,Delhi

Sanofi Aventis Syntho Lab, Mumbai

GSK, Glaxo SmithKline Pharmaceuticals Ltd , Mumbai

Novartis International Clinical Development Center,



SUMMARY & CONCLUSION

- Clinical research is an integral part of drug development.
- Unlike the past, today the process has gained a unique position due to the regulatory requirements and ethical guidelines available globally.
- Designing, conducting, monitoring, appropriate quality assurance and data management determine the success of the clinical research.