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REVIEW ON RECENT TRENDS IN CLINICAL RESEARCH

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ABSTRACT

In this paper, we mainly focus on the term of new trends in clinical research based area & also Indian scenario regards clinical research. Clinical research is the bridge between the lab and the market for new drugs, and that market is expanding rapidly. India is fast emerging as a favoured destination for clinical trials by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations. Two major reasons for its popularity are: easy access and availability of a large, diverse and therapy-naïve population with vast gene pool and lower cost of technical services resulting into lower per patient trial cost.

INTRODUCTION

Many thousands of chemical substances are investigated each year for their possible benefits in human and animal Diseases. Every compound investigated for pharmaceutical potential must undergo rigorous testing as prescribed by government regulation. It is estimate that up to 5,000 compound may be investigated for every one that ultimately makes it to the market as a pharmaceutical. In the united state drug evaluation and testing is overseen by the food & drug administration [FDA] The drug discovery and drug development process is designed to ensure that only those pharmaceutical products that are both safe And effective are brought to market.

A. Phase 0: Phase 0 is a recent designation for exploratory, first-in-human trials conducted in accordance with the United States Food and Drug Administration's(FDA) 2006

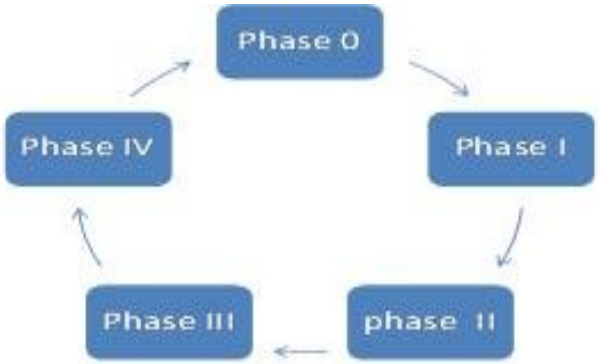

Figure 1. Phases of clinical research

Phase 0 trials are also known as human micro dosing studies and are designed to speed up the development of promising drugs.Distinctive features of Phase 0 trials include the administration of single sub therapeutic doses of the study drug to a small number of subjects (10 to 15) A Phase 0 study gives no data on safety or efficacy, being by definition a dose too low to cause any therapeutic effect. Drug development companies carry out Phase 0 studies to rank drug candidates in order to decide which has the best pharmacokinetic parameters in humans to take forward into further development. They enable go/no-go decisions to be based on relevant human models instead of relying on sometimes inconsistent animal data[1].

B .Clinical Trial:

It is also known as clinical research as per GCP .A systematic study of pharmaceutical product on human subject Study in human beings that follow a pre-defined protocol.Clinical trails can vary in size from a single center in one country to multicenter trials in multiple countries.

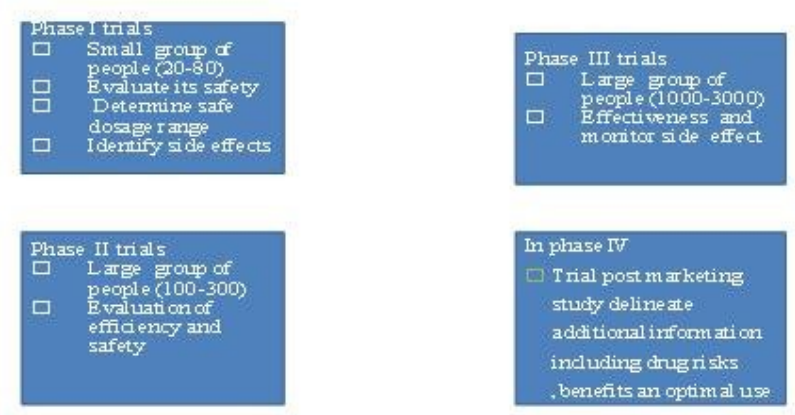

Figure 2. Phases of clinical Trial

Clinical trials in Indian Scenario

India became member of WTO/GATT in 1995 and implemented the product patent regime in 2005. As part of WTO/GATT, pharmaceutical industries has the right to patent products as well as processes throughout the world including India. This has lead to a significant growth in pharmaceutical industries in increased stakes of multinational companies in Indian operation. Clinical research has emerged as lading knowledge based industries of new millennium. Clinical research is carried out on healthy volunteers and patient with disease to ensure that drug, which is to be marketed, is safe and effective. It take approximately 12 years and U.S $900 million to introduces a new drug to a market.

A. Clinical Research – India Advantage

• Lower drug development cost

• Abundance of patient with genetic diversity.

• Wide spectrum of disease.

• Trained medical professionals.

• Skilled man power and it enabled infrastructure at low cost[2].

NOVEL MOLECULE IN PIPELINE

Glenmark Initiates Phase IIb Human Trials Globally for its Novel Molecule 'Revamilast'Revamilast is a PDE4 inhibitor, under development for Asthma, Rheumatoid Arthritis and other inflammatory disorders.The molecule successfully completed pre-clinical trials and Phase I studies .Phase I studies on healthy volunteers were carried out mainly in the UK .Nektar Initiates Phase I Clinical Study Evaluating NKTR-181, A Novel Opioid Molecule for Treatment of Pain. Phase I clinical study to evaluate NKTR-181, the company's next-generation opioid analgesic candidate.

NKTR-181 is being developed to effectively treat pain

Taiho Pharmaceutical Announces Results Of Randomized Phase II Clinical Trial With Novel Antitumor Agent TAS-102 .Taiho Pharmaceutical Co., Ltd. (HQ: Tokyo, President: Toru Usami) announced on July 22 2011 the results of a randomized, Phase II clinical trial for the novel oral ucleoside antitumor agent TAS-102 under development by the company for metastatic colorectal cancer.The trial was a randomized, double-blind, placebo-controlled study with a primary outcome measure of overall survival involving 172 patients with refractory metastatic colorectal cancer .

Sr. No.	Company	Novel molecule	In phase	Disease Category	Year
1	Glenmark	Revumilast	II	Asthma, Rheumatoid	2011
2	Nektar	NKTR-181	I	Pain	2011
3	Taiho	TAS-102	II	Cancer	2011
4	Plexxikon U.S.	PLX4032	III	Melanoma	2011
5	Dr.Reddy's	DRL-17822	II	CHD	2011

Table 1:Novel Molecule in pipeline of different companies

Dr Reddy's starts Phase-II trials of DRL-17822 molecule Dr Reddy's have started a Phase-II study in Europe to test the safety and efficacy of 'DRL-17822' molecule. Phase-II clinical trials [3,4,5] are conducted on a larger sample of human subjects (20-300) to assess how well a drug work for treating coronary heart diseases.

BOOMING CLINICAL MARKET IN INDIA

India is fast emerging as a favored destination for clinical trials[6,7] by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations.Two major reasons for its popularity are: easy access and availability of a large, diverse and therapy population with vast gene pool and lower cost of technical services resulting into lower per patient trial cost. It is well documented that the average cost of doing Phase I/II/III drug trials in US are $20/50/100 million respectively Whereas in India they are 50-60% of the same and could be up to75% faster. India also has the advantage of having a large pool of highly trained physicians, nurses, technical personnel and numerous world-class medical facilities. Broadly developed information technology, infrastructure, Favorable IPR environment (post signing the

WTO agreement). The size of the global clinical trials market is nearly US$10 billion today.Clinical trial spending in 2010 is an estimated $25 billion and is expected to reach $28.5 billion by 2014.In 2010, the number of clinical trials in the U.S. is 25,992. This number is expected to increase at a 5.7% Approximately 90,000 clinical trials were performed globally and nearly nine million patients.

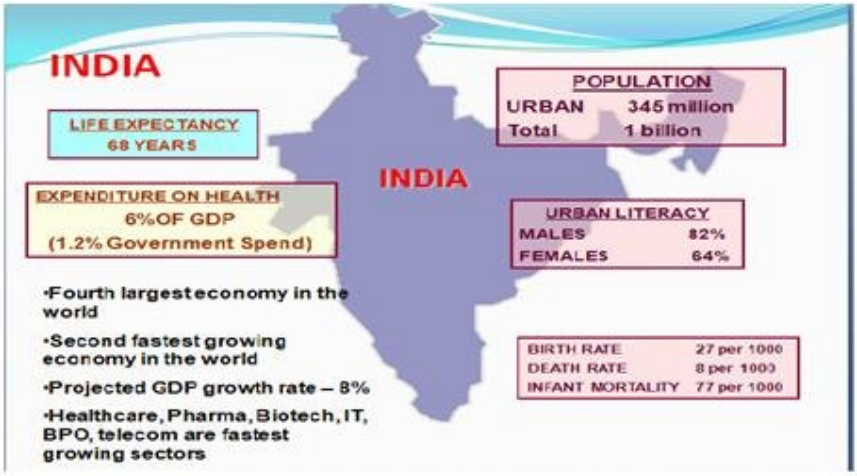

Figure 3.Indian scenario relating with population

DEVELOPMENT OF NEW RESEARCH SITE

Clinical research site is the place where trial activities are actually conducted. It is generally a medical or dental hospital ,clinic or conducting and managing all trial related duties at site assign by sponsored as per CGP (Good clinical practice) guidelines[8].

• Apply for the ethics committee approval of trial and compli as per the direction of the ethics committee.

• Constitution of studiting at trial side comprising co-investigator research coordinator, technician, nurse & other support staff.

• Ensure require resources & clinical trial specific infrastructure .

• Attend investigator meeting.

• Requirement / enrollment of the subject in study.

• Inform concern procedure administration.

• Medical care of the trial subject & ensure safety.

• Compliance with the protocol .

• Compliance with ICH /GCP & applicable regulatory requirement.

• Investigation product storage,dispense & accountability .

• Communication with the sponsor.

• Documentation & completion of case record form.

• Facilate data collection & monitoring by sponsor /CRO.

• Ensuring confidentiality.

• Facilate & co-operate insite audit.

• Submit final report to ethics committee.

• Facilate during site closure.

• Return of equipment, unused investigational product at the end of study.

• Archival of trial; data for the duration according to initial contact.

• Publication (as per sponser policy & agreement)

CRO MARKET TO TRIPLE IN NEXT DECADE

The global CRO[9] industry revenues are said to triple in next 10 years ,to $ 65 billion ,with the top ten CRO likely to benefit from more than half of this figure. A new report from visiongain has calculated the based on annual growth rate of 11 % of the market of clinical trial services, worth $ 22 billion in 2010 ,is said to see slightly staggered growth to 2015.as the pharma industry continue to recover from the global recession ,then accelerate growth from 2015 to 2021,result in tripling of market worth. The market is expected to grow at a compound annual growth rate (CAGR) of around 9 % for 2010 to 2015,then speed to a CAGR of 13% for 2016 to 2021.The following recession ,pharmaceutical companies have slow their spending on drug development, which has impacted CRO revenue in recent years, explain the report author Rechard lang. He cited several factors that will come into play in the rapid growth in next 10 years, specifically pharma sponsor looking to developing new drug more cheaply and efficiently, pharma companies focusing more on core competencies, the rising complexity of drug molecules and the increasing clinical data demands from healthcare payers and regulators.

CONCLUSION AND FUTURE WORK

Clinical research industry looks promising in india but motivating more and more doctors ,hospital ,administrators and other life science professional towards a clinical research is require to achieve a sustain growth . Global standard quality sites with ample pool are one of the most attractive features global pharmacetical and biotechnology,giants.Developing new clinical research site will certain open many more door for clinical research outsourcing in india.

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