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A Comperative Study on Health Sector in South Asia and Middle East Countries (Clinical Trial Studies)

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ABSTRACT

Pharmaceutical industries found suitable option in conducting clinical trial in south Asia and Middle East countries due less cost compare to western countries, pool of patient, and supported by highly infrastructural hospital, well trained staffs, liberalized policy of the concerned government. (E.g. in India), however once the products were succeeded, it denied access to the common man in affordable rate. the studies conducted on 463 participant from the region of middle east and from south Asian countries This studies revealed that there is a positive and highly correlation on fraudulent activities in clinical trial due to lack of ethical obligation and professional standards and on by scarcity of state and local law, shortage of tracking facility which encouraged this nefarious situation, even for the lawsuits, victim worried to comes forward.

Keywords: Clinical Trial, Quality of Life, Middle East *and south Asian countries*

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INTRODUCTION

The fruitfulness of clinical trial considered as morally acceptable and beneficial to large in achieving long-sought medical gains. But some researchers conduct experiments without their knowledge and found to fail to disclose the facts which were known and obvious. The person on financial crisis from the region of south Asian and African counterparts, forced in to participate on clinical trial triage, most of them illiterate, this gullible person's grievance often neglected in later follow-up procedures. Apart from this researchers can make quick prediction, biased decisions, finally prejudiced judgment about the overwhelming information which were encountered on his studies, recently lot of pharmaceutical products withdrawn from the market clearly supports above statement. The following description clearly supported the above facts, Elizabeth Loder (2017) reviewed research article around four year's data in BMJ shows success of trial registration sponsored by private industries compare to public one. Here the pharmaceutical industries and medical equipment innovators aimed to retain status of the company. In 2017 USA alone data shows such national institute of health along with 20 countries registered for the sake of prospective terms instead of evaluating, proceeding on relevant topics. The author explained failure on registration on clinical trial due to lack of familiarity on the right of patient, muddled responsible authorities for this, misconception regarding what composed in clinical trials and so on. Here author arrived conclusion on ICMJE (Recommendations for the conduct, Reporting, Editing, and Publication of Scholarly work in medical journal) primarily any criteria for registration whether it upgraded or executed in trial system and secondly characteristics of health care providers' accustomed such as medical error, omission involved on proceedings and so on. There is no universal standard for publishing clinical trial article; here some of the journal put forward on prospective terms, accountable, and adhered on standardized protocol. Others does not needed such yardstick (e.g. Ethic committee approval) to publish data, here publishers disclosed facts any way, authenticity of data seems to be fallacious.

For under reporting various factors involved such as the project result not probably positive one, lack of data to support on this matter and concerned on such outcome not yet published Chan et al (2013), faulty assumption with no output, grievance on part of participants who underwent on trial, generated data less useful, marginal difference for input and output, disputes raised later concerned on intellectual property right or and other commercial attack, and needs to be faced legitimate concerns. Once the product were found success rate in commercialization, spread out messages within short span of time, apprehension on commercial attack, the author widely condemned because of the international law abiding bodies guarded on trade related problem.(intellectual property right). And other contention on this regards, researcher's idea hided or

repelled from the competitors' attention; however the idea were rebuffed to get pinnacle services to the community. Hilal (2014) peer reviewed articles described the importance of clinical trials conducted regarding orphan drugs, approach should be changed because of these diseases rarely existing, difficult to get comprehensive view on part of researcher, it needs to be concern, health care providers diligent to meet unprecedented facts, initiatives and subsidies from the public sector and established legislative policies by the regulatory authorities. Social media those whom genuine information passed to the public, not only support awareness programs but also can access efficient therapeutic information recently evolved. Here the national and transnational cooperation facilitated for collection of précised data, prevalence rate should be concluded especially on these rarely encountered diseases prone in certain area (Middle East).

Benater SR (2000) provides description on number of factors which determine the attractiveness of clinical trial in developing countries as in developing countries like India, less cost comparative to western countries, highly infrastructure hospital, back grounded by professional team, and loopholes on existing legislative system. Here deplorable condition that one forced in to clinical trial triage impoverished one, apostle that stringent regulation and enforcement absolutely necessary to hospital morphing both in sick as well as healthy volunteers. Annas, George J (2009) propounded that economic advantages in India cant denied on clinical trial depending on the number of patients and investigators. Here the most sponsors enjoys 30 to 50 percentage operating cost over similar trial in the US and Europe. Liquid chromatography and mass spectrometry as the same in worldwide, central laboratory services and other analytical services even do not provide any deep discounts, here labor cost meagerly low, which saves 10-20 percentage on analytical services.

Aslam A, Ayman El-Menyar (2013) given brief description on clinical trial conducted in human subjects revealed that investigational agencies exposed fraudulent activities in realm of clinical trial practices conducted both by sponsors and on by trial investigators. Fabrication of data and even the providers hided negative finding for claiming in front of regulating authorities. While publishing clinical practices, and author illustrated view on declaration of Helsinki, the trial must be registered, public accessible data before recruitment on this subject, to fulfill twenty mandatory (pre requisite information) should be passed. Nida khan (2014) reviewed articles exposed downtrodden situation in developing countries , concerned on negligence on part of post research responsibilities by the research institutes, once the trial completed medicines supplied as free of cost in industrialized countries, here advocated for an investigation on existing judiciary system to implement it in a proper channel, here poor patient pushed in to clinical trial adventure, to those whom found sacrificed his/hers lives on uncertain things, but once the clinical trial succeeded, , it is shameful he/she can't access these medicines at affordable rate. Author opined at least sponsors can delivers generic version of this products for poor countries, present scenario quite different sponsors initially alliance with international as well as public private partnership. Once the product succeeded in the market, the concerned countries, ministry of health by international bodies (such as global alliance for vaccination and immunization, global fund for HIV, malaria and tuberculosis so on) or should be compensated cost of this product proportionately. Here author weighed impact on valuable services provided by the researcher by disseminating valuable information whether it is success or failure. The similar theorem proposed by Sisira siribaddana (2013) from in Sri Lanka, there is lack ethical obligation facility (statutory bodies) which hastened physician industry relationship, recent presses release clearly supported the above fact, and they have been paid off 1.5 lack rupees for recruiting patient. He described that noncommercial clinical trial can carried out in academic or health care institution and with other collaborative individuals or groups in public health care system , the above statement considered as a suggestive method to avoid clandestine arrangement made in initial stage between researcher and pharmaceutical industries.

However the innocent man willing to participate in clinical trial studies, Darzen (2007) et al based on his studies explained participant were enthusiastic to publish data on them trial conducted and expressed felicitous manner. Similar studies conducted by Tamer Hifnawy (2018) shows similar statement that on Egypt, Saudi Arabia, Sudan, and Lebanon clearly indicated that patient were willing to participate on clinical trial studies on humanitarian concern. However the patient opined exploited privileges on patient's condition, jobless, illiterate man willing to participation whatever situation circumscribed, similar studies conducted in south India exposed similar facts,

METHODOLOGY

As the studies focus on health care providers, professional commitment, attitudes towards practicing, people concerned expectations as well as contributing factors on ethical dilemma, and also dialectical peculiarities were noticed. The research based on direct personal contact and also online reply by the respondents. For the justification, it used specific research tools, "questionnaire and interview guide" to study survey, point out that in qualitative and quantitative in nature, in fact questionnaire at large and interview guide at lesser extent to gather exhaustively bigger information in all 463 samples (physician – 179, Dentist 43, pharmacist 66, nurses 45, Researcher 52, professors-66) considered on this part of studies.

In the survey design, the most important facts to design standardized questionnaire, it free from personal bias, initially data collection done by observing on consumer's attitude, concerned general perception whole community in health care system, the researcher spend time in Dubai (UAE), Sohar, Muscat (Oman), in which large amount of international migrant met from the region of south Asia and middle east, and in south India, it takes four years and takes maximum efforts to reach in a conclusion. Here author not only closely inspected on attitude, and perception of people related on health promoting activities but also behavior of shoppers, and health care providers and other intermediate agencies (representatives, consultant agencies), systematic approach done throughout this studies to carry out functioning on this research studies which attributed in quantitative and in qualitative terms.

Sample unit

Health care providers were professional experts being actively involved in clinical trial and as a policy maker, professors with high medical back ground, the physician as well as allied health workers minimum three years of experience included.

Sample techniques

For this study, simple stratified random sampling techniques as well as direct personal approach concerned through questionnaire, In this study researcher bottom out both primary and secondary data, the research survey limited

only a few of the members distributed in wild geographic area. There are 463 respondents are chosen using random sample techniques, in which lottery method used for the selection of respondents.

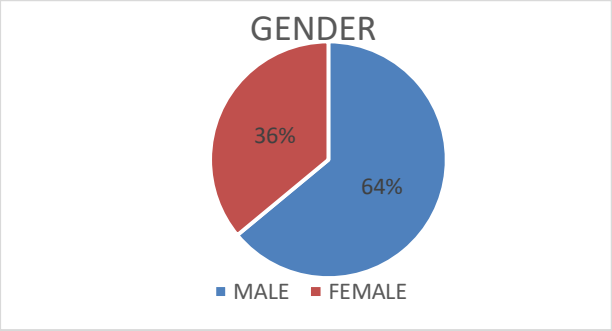
In the first part of questionnaire were closed one, here participants can mark any one of the option based on his/hers presumption. In the second question 6 point likert sale considered, one in agreed and disagreed terms, and in last part closed one, question hinted favored circumstance, for immoral way of conducting clinical trial .

Time Dimension

The present studies were cross sectional one, as the nature of studies it have limitation on to conduct longitudinal research, repeated research articles relevant to topic published in different areas partially implicated failure on to implementation of health policy, without suggesting any remedial solution, data collection for this research studies carried over eleven months from expert members under this subject consideration in south Asia (India, Pakistan, Bangladesh and, Nepal) middle east countries (Egypt, turkey, Saudi, Oman, UAE, Iran, Iraq, Jordan).

DATA ANALYSIS

Analysis classification of Data (Demographic Profiles)



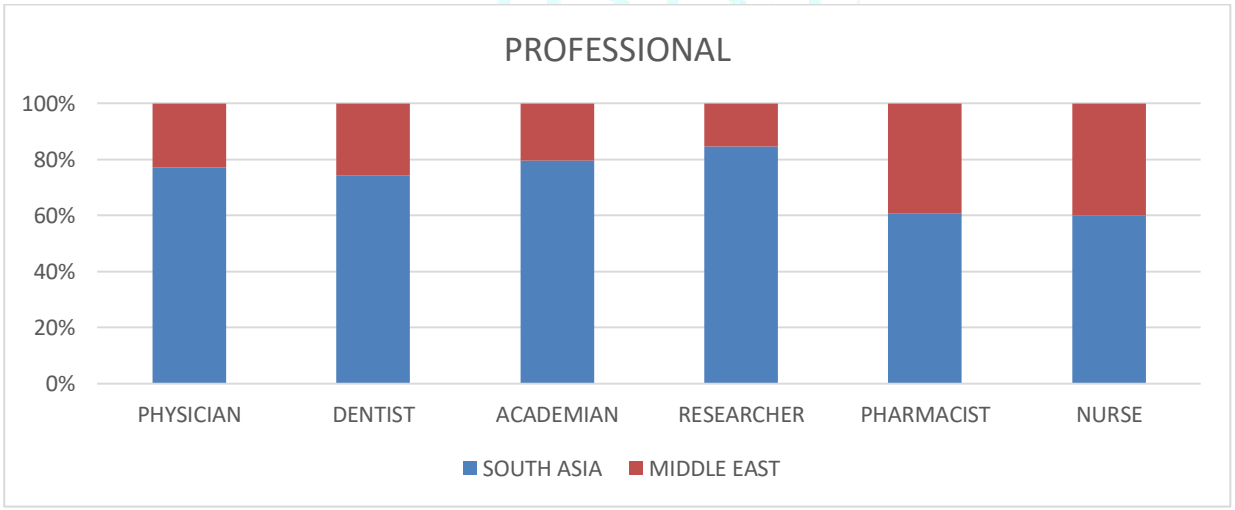
Demographic data profile almost research data interpreted, in certain extent it have crucial role to play based on subject studies, the analysis of diagram represented a total of 463 participant in which 296 participants were found male, and remaining 167 respondents were found female, the weightage given almost same for both sex (male/female)

Analysis classification of Data (Profession)

the subjects related on health care, almost all section of the societies who served in clinical field considered on this subjects, here priority given to the physician because of all role on this relevant field subjugated (accustomed in their clinical practice), by them. Even this studies under consideration education of participants, which reflected on this studies many factors like quality of participants, behavior of respondents, research competencies, and innovative capabilities.

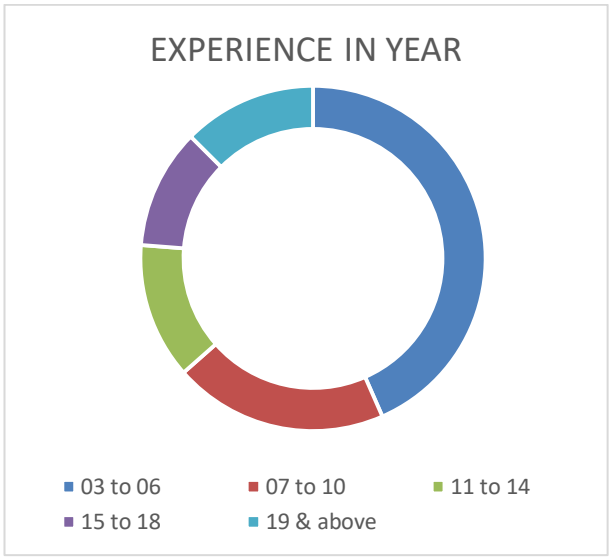
The analysis of above data represented different stake holders in health care field like physician, dentist, professors, researcher, pharmacist, nurses. In which overall 179 physician in the region of South Asia (138) and counterpart Middle East countries (41).Dentist being participated on this research studies a total of 43 from south Asian region (32), and one from Middle East found eleven participants.

And a total 78 highly experienced medical professors worked in familiar institutes around the globe, from the south Asian region (62), and one counterpart from Middle East countries (16), and a total of 62 well expert researches practicing in clinical field, from South Asian countries (44), from Middle East countries (8), and pharmacist who were well known things based on his clinical exposure, A total of 66 pharmacist participated on this studies from south Asian region (40) and one from Middle East (26), one of the major mediator in clinical field like 45 nurses participated on this studies from the region of south Asia (27), counterpart from Middle East countries (18).



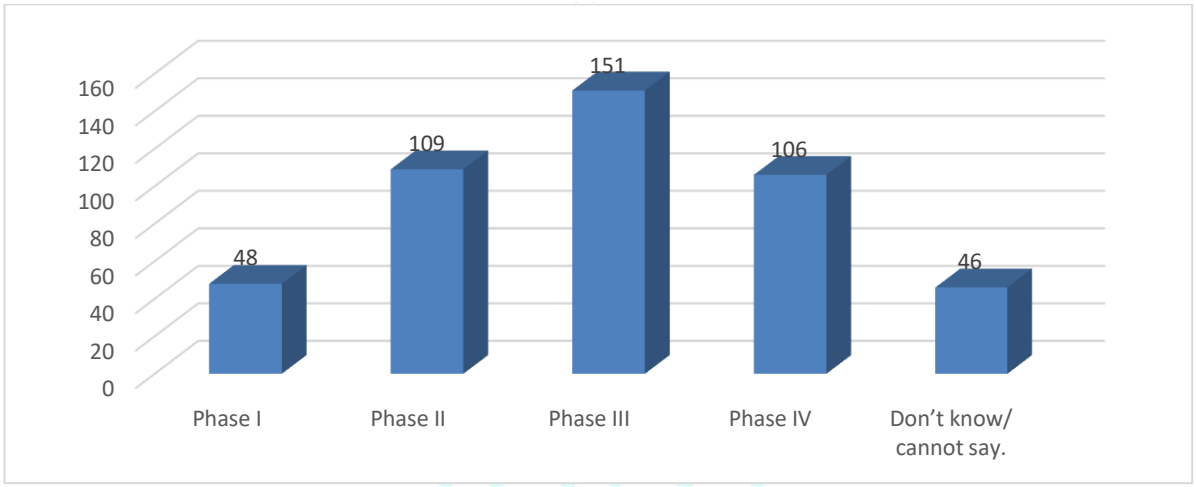
The above table illustrated on experience of health care providers in their clinical practices. Initially a total of 520 participants responded on this research studies, through online survey conducted by using Google forms (admaero2017@gmail.com, admaero2000@gmail.com, admaero2018@gmail.com,) and on by offline service through by personal approach. However 57 participants rejected due to incomplete data, and on by below three years experiences found. Based on subjects considered importance of experience in clinical fields' minimum of three years

Finally selected a total of 463 participants to those whom experience between 3 to 6 years found (201+43.19%), between 7 to 10 years (93+20.08%), between to 11 to 14 (59+12.74%), between 15 to 19(52+11.23%), between 20 and above (58+12.52%)



Analysis of classification of Data (knowledge on clinical trial)

Efficacy and monitoring of adverse drug reaction conducted in which clinical trial phase?



On the above picture illustrated on knowledge of clinical trial relevant to ADR studies conducted, here the corrected one found one third of participants 151(32.8%) participants, 46(valid 10 percentages) participants revealed ignorance on the above statements, wrong answer made phase 1(48+10.4%), phase 2(109+23.7%), phase 4(106+23%), three of them withdrawn to comment on this statement, the above statement partially suggested that general belief on pharmaceutical products well established ADR system before coming on to the market.

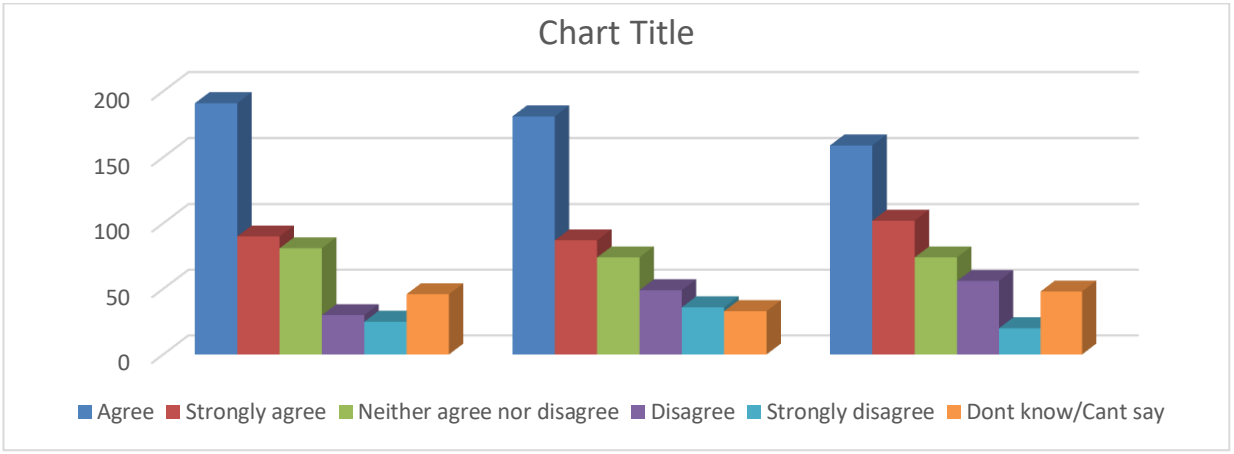


Chart A: While reporting the finding of clinical trials, a few adverse drug reactions reported.

Chart B: Clinical trial conducting team not providing reliable information to those administered patients (Understanding entire procedures & risks involved)

Chart C: Medical professional are given substantial incentives to recruit their own patient to clinical trial

The above charts illustrated on clinical trial studies conducted in immoral ways, circumstance provides favorable situation, more over opportunity leaded to commit fraudulent activities such as clinical trial conducting team not providing reliable information to those administered patients (Understanding entire procedures & risks involved, out of 463 participants arrived values aggregated 234 (strongly agreed 87*2, agreed 181*1, neither agreed nor disagreed 74*0, disagreed 49*1, strongly disagreed 36*2 equal to 234,here36 person withdrawn to comment on this statement. choices were made on while reporting the finding of clinical trials, a few adverse drug reactions reported, on this statement shows similar manner (90*2+191*1+80*0+30*-1+25*-2=290) 46 person withdrawn to comment on this statement. and one third statement "Medical professional are given substantial incentives to recruit their own patient to clinical trial", participants made declaration, aggregated values were found (102*2+159+1+74*0+56*-1+20*-2 equal to 267), here 40 participants withdrawn to comment on this statement.

Analysis of classification of data (attributes relevant to unethical practice of in clinical trial.

Would you recommend the favorable condition to conduct clinical trials in immoral way?

The above picture illustrated on finding of favorable situation to conduct clinical trial studies such as hospital privileges (54+ 11.8%), by scarcity of state and local law (48+10.5%), lack of ethical obligation and professional standards (100+21.8%), out of 463 participants on the above all question marked by179 participants (valid percentages 39), more than one sixth participants withdrawn to comment on this statement (78+17%), here four participants not at all commented.

RESULTS

The data shows significant difference on different aspects muddled on immoral way of conducting clinical trial triage, "Efficacy and monitoring of adverse drug reaction conducted in which clinical trial phase?" on this statement nearly one third of participants made right choice, more than two third of the participants wrong choices made, clearly indicates less knowledge on relevant matters amongst the health care professionals, trials were conducted hush-hush way, on later statement confirmed the above facts, "Would you recommend the favorable condition to conduct clinical trials in immoral way?" like hospital privileges, scarcity of state and local law, lack of ethical obligation and professional standards, here one above all parameters agreed by the 40 percentage of participants. one fourth of the participants opined lack of ethical obligation and professional standards versed on scarcity of state and local law, hinted failure on implementation legislative procedures, here one sixth of the participants emphasized on hospital privileges.

Proceeding statement gives more clarification on the above statement "while reporting the finding of clinical trials, a few adverse drug reactions reported, Clinical trial conducting team not providing reliable information to those administered patients (Understanding entire procedures & risks involved, Medical professional are given substantial incentives to recruit their own patient to clinical trial". Here more than two third of participants agreed on the above three statements. The statement, nearly one tenth of participants withdrawn to comment on this statement.

DISCUSSION

Studies shows significant difference on immoral way of conducting clinical trial triage, "Efficacy and monitoring of adverse drug reaction conducted in which clinical trial phase?" on this statement nearly one third of participants made right choice, more than two third of the participants wrong choices made, clearly indicates less knowledge on relevant matters amongst the health care professionals, the above finding assured by the studies conducted Waheed S, Siddiqui E et al (2013) on clinical trial issues, here research assistant usually appointed medical students or graduated found lack of knowledge relevant to international conference on Harmonization and Good clinical practice Guidelines (ICH GCP guidelines). As the case in India found, pharmaceutical industries focused on to developing countries due to favorable situation like low literacy, poverty, loopholes in existing legitimacy in clinical trial system. Halidou Tinto, Ramadhani A.Noor et al (2013), recommended theoretical clinical practices alone not sufficient to ensure proper clinical outcomes and for facilitation of medical research, the situation often worsened due to high workloads on health care providers in peripheral settings, want to monitor routine checkup to validate this situation, and the risk of double standard keeping amongst the patients (free of cost services versed on cost paid services), here need to take practical consideration and up gradation of knowledge on relevant subjects especially in low middle income countries,

The later statement confirmed the above facts, "Would you recommend the favorable condition to conduct clinical trials in immoral way?" like hospital privileges, scarcity of state and local law, lack of ethical obligation and professional standards, the above all parameters agreed by the 40 percentage of participants. One fourth of the participant's opined lack of ethical obligation and professional standards versed on scarcity of state and local law, hinted failure in implementation legislative procedures, here one sixth of the participants emphasized hospital privileges favored to conduct clinical trials in immoral ways. succeeding statement gives more clarification on the above statement such as "While reporting the finding of clinical trials, a few adverse drug reactions reported, Clinical trial conducting team not providing reliable information to those administered patients (Understanding entire procedures & risks involved, Medical professional are given substantial incentives to recruit their own patient to clinical trial". Here more than two third of participants agreed on the above three statements, hesitated to comment on this statement one tenth of participants.

The core principles while conducting clinical trial in human subjects, should be conducted ethically and on propounded by international guidelines (declaration of Helsinki), the

subjects matter should be scientifically justified one, and it needs foreseeable and forecasted on difficulty raised in trial participants, outweighed possible risks and benefit for entire society, it needs approval from ethical committee or from institutional review boards prior to initiation to conduct studies in individual subjects, and complied with approval committees protocol, informed consent needs to be furnished, data communicated through by understandable language, and preferred one in vernacular language to get more assurance on individual subjects, the subjects followed and validated risk benefit ratio on individual patient, and prudent on later complication.

Peter C Gotsche (2009) pear reviewed data onto counterfeit scientific misconduct especially noted as ghost writing finkelstein and Temin (in reasonable Rx solving the drug price crisis) opined public sector should be take independent, nonprofit organization for drug development. Schafer's counter parted studies supported the above facts, research wing adjudicated and should be separated from commercial activities, another theorem discussed by national bodies to manage clinical trial in health organization (USA) compensation should be pay off under purview of authorized body, curbed access of pharmaceutical industries to direct influence on researchers.

It needs to address this problem as one suggested by Ms Irene Schipper (SOMO Publication, 2009), on topic of Clinical trials in developing countries: How to protect people against unethical practices, described on clinical trial practices that one not approved in western EU, clinical trials were sanctioned dominant countries like china, Russia, Argentina. Not at all barriers for marketing as one found in EU. In developing countries Helsinki declaration relevant to ethical practices on clinical trial utterly neglected. Further implementation procedures through legislative and regulatory follow up procedures aggravated this situation. Memorandum passed in World health assembly 2010 by the organized bodies working in research and development, expert opined to build up a trusteeship with all countries contribution of 0.01 percentage of their GDP, it was rejected on proceeded meeting by some of the countries, the author hinted that financial motives and political dominance put certain barrier on transparency and accountability of existing system, lack of addressing such bodies leads to encourage voluntary concept system, noted in ethical violation by pharmaceutical industries and repercussion on relevant term, here denied not only quality of health service to reach the common man but also indirectly leaded to deterioration of health status, that leads to wastage of money too.

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