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Conducting Global Clinical Trial in Nigeria: Issues, Challenges and Prospects

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Abstract
Background*: There has been great innovation over the past decade with the emergence of new drugs with increasing adoption of targeted therapies in the pharmaceutical industry where they invest significant capital and resources into preserving the patient's life and the subsequent profits of products which take several years to develop. This research looks at the challenges, issues, and prospects involved in conducting global clinical trials with emphasis on the Nigerian context in particular. The main objective is to highlight potential challenges in the conduct of global clinical trials in Nigeria and outline ways in which these can be overcome.*
Methodology: *Opinion Survey research design was used in which Questionnaire & personal talk were used as instruments to collect the necessary information from stakeholders about the challenges, issues and prospects of Conducting Global Clinical Trials in Nigeria.*
Conclusion: *It can be concluded that ethical norms, funding, regulatory standards, research and development capacity, availability of skilled personnel, and the infrastructure required to host and manage clinical trials are the major issues and challenges that comes with the conduct of global clinical trials in Nigeria, furthermore; Patient retention, cultural, religious &language barriers also pose a great challenge. With high patient pool and being the most populated county in Africa Nigeria is likely to emerge as best destination in the continent for many pharmaceutical companies to carry out clinical trials and research in the next coming years. To encourage and increase enrollment of participants in the conduct of clinical trials in Nigeria it is recommended that: Government should enforce trial sponsors to justify the medical and social relevance of the trial to the host community*

Keywords: *Clinical, Trials, Global, Issues, Challenges, Prospects.*

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I. Introduction

The conduct of clinical trials for the development and licensing of drugs is a very important aspect of healthcare. Drug research, development and promotion have grown to a multi-billion dollar global business. Like all areas of human Endeavour involving generation and control of huge financial resources. Clinical trials are now a global phenomenon with giant Pharmaceutical and Biotechnology companies creating a paradigm shift by outsourcing clinical trials to third world Developing countries. China, India, Latin America are few top contenders, other countries in the African region have today managed to attract the attention of western sponsors. Nigeria is now amongst one such destination. Clinical trials in Nigeria are picking up pace even with the few CROs that operate in the region. (3)

The global clinical trials market size was valued at USD 46.8 billion in 2019 and is expected to grow at a compound annual growth rate (CAGR) of 5.1% from 2020 to 2027. Increasing prevalence of chronic disease and growing demand for clinical trials in developing countries is fueling the market growth. Rising number of biologics, need for personalized medicines and orphan drugs, and demand for advanced technologies are other factors projected to fuel the growth. Factors such as globalization of clinical trials, innovations in treatments such as personalized medicine, technological evolution, and demand for Contract Research Organizations (CROs) to conduct clinical trials are projected to drive the growth. Diversified expertise of CROs as compared to pharmaceutical companies when it comes to performing clinical trials in wide array of geographies and development of drugs in specific therapeutic areas, are few factors responsible for the growing demand for the CROs in pharmaceutical segment. (2)

The need to develop more effective and safer drugs to tackle existing disease and also tackle new and emerging diseases cannot be over-emphasised.

Problem Statement

The major challenges in conducting global clinical trials have been lack of awareness about clinical trials, Patient recruitment and Retention, Funding, Outsourcing, the quality of Informed consent, Justification of medical and social relevance of a clinical trial to host community, lack of qualified study personnel (investigator, Clinical Research Associate (CRA)/monitor, and Clinical Research Coordinator), Regulatory Affairs, e.t.c. it is in the light of this problem that this research work is based in order to ascertain this challenges in Nigerian context.

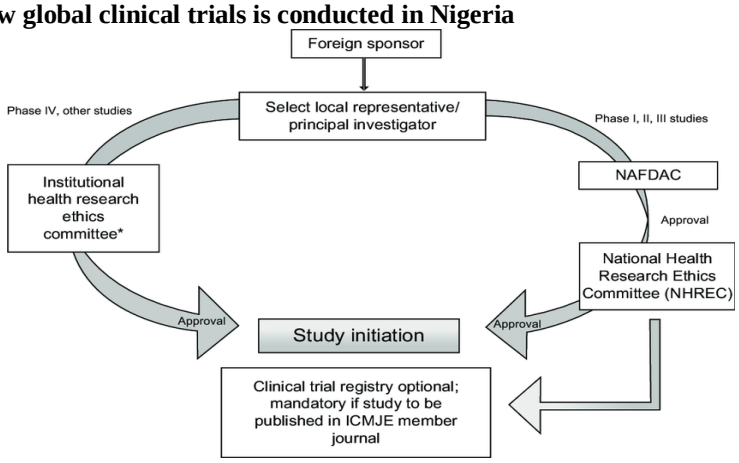
Clinical trials are experiments or observations done in clinical research. Such prospective biomedical or behavioural research studies on human participants are designed to answer specific questions about biomedical interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on safety and efficacy. (4)

Clinical Trials in Nigeria

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is the regulatory body that oversees research and clinical trials. (1)

Clinical trial Registration can be done at the Nigeria Clinical Trials Registry; the registration is a prerequisite if the study is to be published in an International Committee of Medical Journal Editors, member journal. (5) Ethical research practices, in adherence to ethical guidelines and the protection of human research participants, are governed by the National Health Research Ethics Committee (NHREC). In addition, the institutes conducting the research can have their own internal health research ethics committee (HREC) that has to be registered with the NHREC. The registration is valid for 2 years, after which a re-registration with NHREC has to be done. A foreign sponsor has to present the protocol to HREC, which has a maximum of 3 months from the date of receipt of a valid application to give its decision to the applicant. For a multi-centric trial, the HREC of each site has to be approached if sites are less than three. In the event that the trial sites are more than three, the sponsor can directly approach the NHREC. In the event that some animal samples have to be sent out of Nigeria, a material transfer agreement has to be signed by all the stakeholders and then reviewed by the HREC. For ethical clearance, the trial has to fulfill all the requirements, as specified by the guidelines. (6)

Flow chat of how global clinical trials is conducted in Nigeria



Source: clinicaltrial.gov

The guidelines for conducting a clinical trial in Nigeria are broadly similar to those in sub-Saharan Africa. A clinical trial is mandatory for new or relatively new chemical entities, drugs for new indications, drugs for new population groups, new combinations, new dosages, and new drug delivery systems. (5) For drugs already registered in other countries, the approval has to be sought from an institutional HREC, which will have to revert its decision within 3 months. The application to carry out the clinical trial has to be submitted to NAFDAC with a submission fee of Nigerian Naira (NGN) 5,000 +5% value added tax. In addition, an approval/authorization fee of NGN 750,000 for imported drugs and NGN250, 000 for locally developed drugs is charged for the industry-sponsored trial. The clinical trial application form should be accompanied with the protocol, informed consent form, Investigators Brochure, evidence of agreement between the sponsor and the investigator, evidence of registration of the institutional review board (IRB) with the NHREC, a list of IRB members, the minutes of meeting held to approve the protocol and informed consent form, evidence to show that the investigator(s) have undergone basic GCP trainings in the last 2years, the curriculum vitae of the investigators, a sample of all case report forms or electronic case report forms for the study, evidence of

insurance coverage for the trial participants, the name and qualification of the trial monitor, and a list and charter of the DSMB. The study including the planning, approval, conducting, recording, and reporting thereof shall be carried out in due compliance with the principles outlined in the code of HREC, the relevant laws, the provisions of the federal ministry of health's guidelines, the provisions of the current Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP E6) and the provisions of the current ISO 14155-1, 14155,2 (2003): Clinical Investigation of medical Devices for Human Subjects, as well as regulations and guidelines published periodically by the federal ministry of health. (7).
Any Serious Adverse Events have to be submitted to NAFDAC within 7 working days of notification. The final study report and any related information also needs to be submitted to NAFDAC. (5)

Overview of some clinical trials conducted in Nigeria from 1994-2019

Over the years Nigeria has been a global clinical trial attracting country with large patient pool and variety of emerging diseases, but past unethical clinical trials hinders the conduct of the trials as participants/patients fear for their life. According to Record of Global Clinical Trial Data posted on its website (Retrieved, 28-Dec-2019) over 248 clinical trials were carried out in Nigeria, the chart and table below shows the trials based on their sponsorship and status:

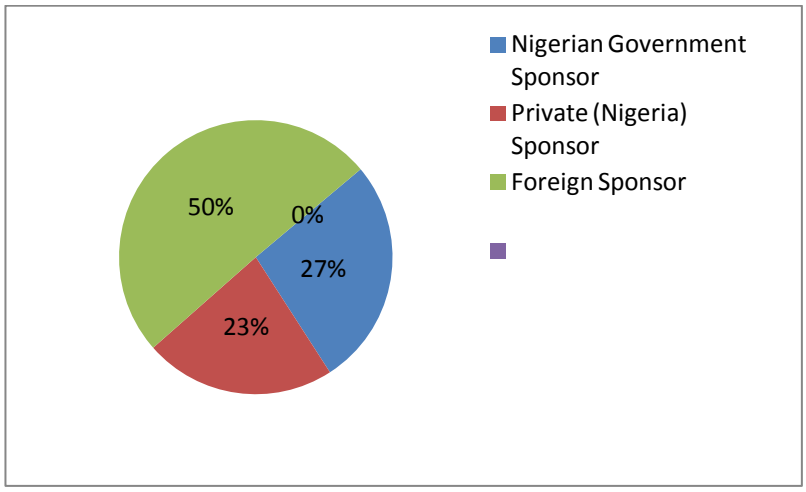


Table 1. The status of global clinical trials conducted in Nigeria from 1994-2019

S/N	Status	No of trials
1.	Completed	121
2.	Recruiting	61
3.	Not yet recruiting	24
4.	Unknown status	28
5.	Enrolment by invitation	7
6.	Withdrawn	3
7.	Terminated	3
8	Suspended	1

The table above shows the status of some trials as per global clinical trial data retrieved 28 Dec 2019, the reason for the withdrawal and termination of some of the trials were based on safety issues regarding the intervention administered, while the one which was suspended was based on ethical issues. Previous literatures indicate that Nigeria is making a paradigm shift towards becoming a hub for clinical trials in the next 10 years to come.

Nigerian Clinical Trial Registry (NCTR)

The NCTR is a collaborative initiative of the National Agency for Food & Drug Administration and Control, with support from the National Health Research Ethics Committee and the Federal Ministry of Health

Why do we register for Clinical Trial in Nigeria?

There are both ethical and scientific reasons for registering trials. People who participate in clinical trials expect their contributions to be made use of in improving health care for everyone. Open access to information about ongoing and completed trials will satisfy the ethical duty to trial participants and will promote greater trust and public confidence in clinical research. Clinical trial registration in open access registries will

also reduce selective publication of trial results, because by registering a trial the researchers commit to report the findings in accordance with basic ethical principles.

Selective reporting, regardless of the reason for it, leads to an incomplete view of the trial and its results. In addition to the above, clinical trial registration will decrease wasteful duplication of research, promote international research collaboration and ensure more efficient and effective allocation of research funds

Clinical trial registration has greatly improved transparency in clinical trial research. However, these improvements have not taken place equally in all parts of the world. Achieving compliance with registration requires a coalescence of global and local measures, and remains a key challenge in many countries. Poor quality of registered trial data and the inaccessibility of trial protocols, results and participant data further undermine the potential benefits of clinical trial registration. National and regional registries and the ICTRP have played a leading role in achieving the successes of trial registration to date and should be supported in addressing these challenges in the future. (6)

Phases of Clinical Trials

Before pharmaceutical companies proceed to clinical trials, preclinical trials (*in vitro* and *in vivo* animal studies) would have been conducted to obtain data that would justify progression to clinical trials. Clinical trials are in four phases.

Phase I

Phase I clinical trials are conducted on healthy volunteers. The objective is to establish the safety and toxicity profile of the test drug. It is also to study the pharmacokinetics and pharmacodynamics of the drug in humans.

Phase II

Phase II clinical trials involve drug trials with a few numbers of patients that suffer the disease of interest. The objective is to establish efficacy of the test drug.

Phase III

Phase III clinical trials involve conduct of drug trials with a large number of patients. It is usually an expanded and more focused studies of clinical effectiveness and safety.

Phase IV

Also called Post-marketing surveillance. At this phase of clinical trial, drug has been licensed for treatment and its usage is continually monitored for adverse effects.

Advantages of Conducting Clinical Trials in Nigeria

1. Availability of Patient Population: Nigeria has the largest patient pool in terms of African race. This helps to collect data which is relevant and collected from all regions and races while conducting a clinical trial.

2. Regulatory process: The entire clinical trial process in Nigeria is regulated by the Federal Ministry of Health (FMOH). It has 2 functional parts:

a. National Agency for Food, Drugs Administration, and Control (NAFDAC): The Agency is responsible for protocol review and authorization of clinical trial before it is conducted in Nigeria. It is also responsible for carrying out inspection of trial sites to monitor the conduct of authorized studies to ensure that well-being and safety of the participants is protected and credible data is obtained from the study. (3)

b. National Health Research Ethics Committee (NHREC):

The Committee is responsible for accreditation of Independent Ethics Committee (IEC) and or Institutional Review Board (IRB) that give ethical opinion on study protocols depending on the number of trial sites involved. In order to reduce processing timeline for Clinical Trial applications, the study protocol can be submitted simultaneously to NAFDAC and Ethics Committee. However, ethical opinion must be obtained before NAFDAC issues final authorization for the conduct of the trial subject to satisfactory review.

These regulatory authorities have created a scenic which is in amateur stage yet; however it has defined a healthy environment for good conduct of clinical trials in accordance with Good Clinical Practices (GCP).

3. Developing countries undoubtedly have always been an economical option for US and European pharma giants. Outsourcing to such economical destinations has given them an advantage of investing further into new drug development.

4. Role of NGO and GCP association: There has been a mega share of NGO in creating awareness amongst the patients about clinical trials. The Association for Good Clinical Practice in Nigeria (AGCPN) is continuously putting efforts in creating a GCP complaint atmosphere. With the above mentioned advantages the saying that Nigeria is also becoming a destination for clinical trials, would be fair enough.

Few challenges such as having expert clinical research professionals are need of hour in countries such as Nigeria who are on the pathway of becoming busy clinical trial destinations in near future. (3)

Unethical Clinical Trials

The literature on ethics of clinical trials of drug candidate is replete with notable instances of poor ethical conduct. The following are two examples of some ethical pitfalls in Nigeria which makes volunteers fear for uncertainty:

The AZT Trials in African and other developing countries

The AIDS Clinical Trial Group (ACTG) in 1994 reported the findings of their study 076 in which the use of Zidovudine also known as Azidothymidine (AZT) during pregnancy, in labour and to the new born reduced the Mother to Child Transmission (MTCT) of HIV by two-thirds. With this finding, use of oral AZT during pregnancy and intravenous AZT during labour and oral AZT to the neonate became the standard of care for HIV-positive mothers in the United States and Europe. However in Africa, where the burden of HIV was high, this regimen was considered unaffordable. The World Health Organisation summoned a meeting to discuss the conduct of research into finding less expensive and affordable interventions to prevent MTCT of HIV in developing countries. Subsequently a series of placebo-controlled trials were conducted in Africa and Asia. Many bioethicists have questioned the morality of using a placebo-controlled design in these studies. They argued, that with the results of the ACTG 076 study, the appropriate research question should be - 'Can we have a cheaper intervention compared to the standard ACTG 076 without compromising on the demonstrated efficacy of ACTG 076'.

Thus the study design would be an equivalence study with ACTG 076 being given as the control arm. But by using placebo-controlled design, the research question became, 'are these cheaper interventions better than nothing' or 'Is the short course of AZT better than nothing'. Ethicists argued that since a placebo-controlled trial would not be acceptable in developed countries (as AZT had become the standard of care), it smacked of moral imperialism and double standard to offer such to developing countries. (8,9,10,11,12) By conducting placebo-controlled trials of AZT in developing countries many neonates who would have been saved from contracting HIV infection if their mothers had been given the AZT rather than placebo were not saved. (13)

The Pfizer Trovan study in Nigeria

In 1996, a group of Researchers from Pfizer in the United States conducted a clinical trial of the antibiotic Trovan during an outbreak of cerebrospinal meningitis in Kano, in Northern Nigeria. Various allegations of impropriety have since been made.

About fifty families claim that Pfizer violated the ethical principles of autonomy and non-maleficence (do no harm). Among the 200 stricken children enrolled in the experiment, eleven died and others suffered from severe meningitis-related complications such as deafness, blindness, seizure, and in one case, an inability to walk or talk.

Many believe that the trial drug was unsafe, inadequately pre-tested and caused many serious side effects among the children. Based on reviews of the Trovan study by Ahmad and Stevens, a variety of ethical flaws can be seen. First, parents of the children who participated in the trial allege that they were not informed of the procedure or risks of the study. Although Pfizer officials insist that they received verbal informed consent from the largely illiterate population. Second, the study design also suggests substandard practice. Despite the availability of chloramphenicol, the first-line treatment for bacterial meningitis, only one-third of the recommended dose was given to the children in the controlled arm of the study. In the treatment arm, Pfizer tested oral instead of intravenous Trovan, which is the standard therapy in the US. The study has been trailed by a myriad of allegations, which are sub-judice in the US. If the local ethical review board had done a sufficiently thorough review, the study would not have been approved.

The study was, however, criticised severely for falling short of ethical standards. (14) The allegations were that:

1. Pfizer never obtained ethical clearance before conducting the study;
2. Pfizer did not obtain informed consent before recruiting participant and did not inform the study participants that the drug was an experimental drug;
3. Pfizer capitalised on the poor, illiterate and desperate situation of the people; and,
4. Pfizer left the town after conducting the study despite the fact that the epidemic was still on-going. (14,15)

The Government panel set up to investigate the study reached these conclusions:

- Pfizer never obtained authorisation from the necessary authorising agencies including ethical clearance
- That Pfizer's experiment was "an illegal trial of an unregistered drug" and "a clear case of exploitation of the ignorant." (15) Pfizer later agreed to a $75 million out of court settlement.

These two case studies illustrate some ethical challenges that may arise in the conduct of clinical trials. There are several ethical considerations that all key stakeholders in the conduct of clinical trials must make to ensure that clinical trials meet ethical standards.

The National Health Research Ethics Committee (NHREC)

The National Health Research Ethics Committee is the apex body responsible for the provision of and ensuring adherence to guidelines that governs ethical research practice in order to ensure the protection of human research participants in Nigeria.

The committee came into being in October 2005 as a mechanism that will ensure the protection of Nigerians as they participate in researches. The committee was an offshoot of the dormant health research ethics committee which had been in existence since early 1980's.

The National Code of Health Research Ethics in section E, subsection d (i) states that:

HREC shall review prescribed application materials and have authority to approve, require modifications in (to secure approval) or disapprove all health research activities covered by this code.(16)

All research involving human subjects (including clinical trials) must be approved by a HREC. In the Trovan study, it was established that the clinical trial protocol did not pass through ethical review process in Nigeria. In fact, there was no HREC in the health facility where the children were treated and the Kano State Ministry of Health had no HREC. It must be emphasised that clinical trial protocols must pass through ethical review and be approved in both the country of sponsorship and where the research would be conducted. Ethical approval from the country of sponsorship does not substitute for ethical approval from the country where the research will be conducted.

It is pertinent to acknowledge the efforts of the Nigerian government through the National Health Research Ethics Committee to promote ethical conduct of research in Nigeria. In the same vein, it is important to appreciate the assistance of the Government of the United States of America through the Fogarty Centre of the National Institute for Health that has provided grants for training in research ethics to Nigeria and many developing countries. It is expected that HREC would review a clinical protocol using several benchmarks. (16)

Guidelines for Conducting Global Clinical Trials

Several documents have prescribed guidelines for conducting global clinical trials and research in general. These documents include

1. Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects. World Medical Association, WMA.
2. International Ethical Guidelines for Biomedical Research involving Human subjects. Council for International Organization of Medical Sciences, CIOMS.
3. Standards and Operational Guidelines for Ethical Review of Health-Related Research with Human Participants. World Health Organization, WHO.
4. Most countries having adopted the ethical principles in these international documents have gone further to produce their own guidelines. The United States of America has the Code of Federal Regulations. The United Kingdom has the Health Research Authority (HRA) of the National Health Service (NHS) which regulates the various aspects of human research including clinical trials. In Nigeria, the National Health Research Ethics Committee (NHREC) has published the National Code of Health Research which contains benchmarks for conducting clinical trials and other research involving human participants.

II. Methodology of the study

This section discusses how the research was carried out by collecting the relevant information from various stakeholders within Nigeria. Literatures from Nigerian Ministry of Health (National Health Research Ethics), global clinicaltrial.gov and clinical trial registry were retrieved and used.

Opinion Survey research design was used in which Questionnaire & personal talk were used as instruments to collect the necessary information from stakeholders about the challenges, issues and prospects of Conducting Global Clinical Trials in Nigeria.

The population of the study comprises of all stakeholders in clinical research in Nigeria. The stakeholders selected are sponsors/pharmaceutical companies, Regulators, Researcher/investigators and Contract Research Organisations (CROs).

Electronic mail Questionnaire and personal talk (phone interview) was used as instrument of data collection for the study. A total of 200 questionnaires were distributed and 30 persons interviewed.

Descriptive statistics was used to generate frequencies and percentages from the collected data. The data was then presented in a Table for easy interpretation

III. Results

Out of the 230 questionnaires distributed 170 were retrieved representing 73.9% of the total population of respondents. 21 of the respondents are from Contract Research Organizations (CRO's) representing 12% of the total respondents, 93 are from Pharmaceutical Companies representing 54.7%, 16 of the respondents are

Clinical Trial Site Personnel representing 9.4% and 40 of the respondents are from Regulatory Agencies representing 23.5% of the total respondents.

Table 2: Below is the table of responses base on four figure scale represented in percentages:

RESPONSES	Strongly agree (%)	Agree (%)	Strongly disagree (%)	Disagree (%)
Are social and cultural issues related to trial participation a challenge in conduct of clinical trials?	65.8	23.5	6	4.7
Do you believe Lack of awareness about clinical trials causes set-back on global clinical trial conduct?	71	24.3	4.7	-
Is Complexity of study protocol an issue/problem of concern on the conduct of clinical trial?	82.9	15.3	1.8	-
Will un-availability of Facilities such as lab, ICU, radiology lab etc at the site hinders conduct of clinical trial?	66.5	22.9	6.4	4
Investigator commitment & Experience towards clinical trial conduct is a big challenge?	64.7	23.5	6.4	5
Lack of Qualified and experienced personnel (CRA/ Monitor) is also a challenge that can affect global clinical trial conduct?	67	28.2	0.5	4.1
Do you consider Project Management as an issue which will hinder trial conduct :	80	8.2	10	1.7
Is funding a challenge in conducting global clinical trial in Nigeria?	70	25.2	4.1	0.6
Is Patient recruitment and retention another big challenge in conducting global clinical trial in Nigeria?	94.7	1.1	-	4.1
Justifying the medical and social relevance of the clinical trials to the host community is also a challenging issue of trial conduct in Nigeria?	77	20.5	-	2.4
A challenge which causes lack of clinical trial participation is the quality of informed consent?	46.4	41.1	8.2	4.1
The standard of care given to participant during and after clinical trial conduct is a big challenge in Nigeria?	88.8	8.8	2.9	-
Do you believe Post-trial availability of interventions can improve patient enrolment in global clinical trial?	82.9	6.4	-	10.5
Outsourcing and Externalization is a major challenge in conducting clinical trial in Nigeria?	64.7	16.4	2.9	15.8
Are you of the opinion that Compensating for injury or death related to a clinical trial will improve trial participation?	88.8	10.5	0.5	-

Table 3

RESPONSES	YES (%)	NO (%)
Do you consider insecurity as a challenge in conducting clinical trial in Nigeria?	82.3	17.6
Do you Consider Poor Technological Advancement as a challenge?	77.1	22.9
Is Nigeria's Political uncertainty a problem?	86	14

IV. Discussion

89.3% of the respondents are of the view that Social and cultural issues related to clinical trial participation is a big challenge in the conduct of clinical trials in Nigeria this corresponds with the findings of (17), who says Many of the words used in research and Western societies do not have perfect translations in local Nigerian languages. Similarly, many Western terms are not freely used in local conversations because of cultural taboos.

Lack of awareness about clinical trials also causes set-back in the conduct of global clinical trial in Nigeria as 95.3% of the respondents unanimously agree to it. 98.2% of the responses are of the view that Complexity of study protocol is an issue/problem that raises concern on the conduct of clinical trial this in somewhat also corresponds to the finding by (17), who also said One of the greatest challenge for researchers in Nigeria is developing an effective mechanism to inform participants about the purpose, method, risks and benefits of the research.

Un-availability of Facilities such as lab, ICU, radiology lab etc at the site hinders conduct of clinical trial (89.4%), 88.2% of the respondents view Investigators commitment & Experience towards clinical trial conduct as a big challenge as the success of any clinical trial lies on the expertise of the investigator and his commitment.

Lack of Qualified and experienced personnel (CRA/ Monitor) in Nigeria is also a challenge that affects the conduct of global clinical trial; this hypothetical statement is supported by 95.2% of the respondents.

88.2% of the respondents consider Project Management as an issue which will hinder global clinical trial conduct in Nigeria as the success of any given project lies on how well the project is managed, funding is globally considered as a big challenge in conducting global clinical trial, Nigeria is not an exception as 95.2% of the major stakeholders interviewed during this research strongly believe that conducting clinical trial with fund is not feasible.

95.8% of the responses shows that Patient recruitment and retention is also a challenge in conducting global clinical trial in Nigeria, this also corresponds with the findings of (18), who states challenge of recruitment and retaining a numbers of patients is not new to the global clinical trial industry when he discovered that Forty-eight per cent of sites miss their enrolment targets and 80% of trials are delayed due to recruitment

Another problem which is faced in Nigeria is justifying the medical and social relevance of the clinical trials to the host community 97.5%. 87.5% of the responses I got believe quality of informed consent brings about lack of clinical trial participation as participants are not well informed about the investigational product to their comprehension there by voluntarily consenting to participate.

Other participants who participate in a trial in Nigeria view lack of availability of standard of care given to them during and after clinical trial conduct not appreciable (97.6%)

89.3% of the stakeholders who responded believe Post-trial availability of interventions can improve patient enrolment in global clinical trial in Nigeria

81.1% believe Outsourcing and Externalization is one of the major challenge faced in the conduct of clinical trial in Nigeria as Nigeria has very few CROs that a project can be outsourced to in other to speed up the trial process, this was supported by a finding by (18) One of the trends driving both opportunities and challenges is the increased use of outsourcing. By 2020 it is estimated almost 75% of all clinical trials will be run by CROs

Compensating participant in case of injury or death as result of clinical trial will improve trial participation, (98.8%)

82.3% of the respondents are of the view that Insecurity poses a great challenge in conducting clinical trial in Nigeria, as Nigeria has been battling with insurgency for almost a decade, this has cause Nigeria to lag behind in terms of technological advancement which prompted 77.1% of the respondents to viewing Poor Technological Advancement as a challenge in conducting clinical trial in Nigeria, while 86% of the respondents believe Nigeria's Political uncertainty as a challenge which will affect the conduct of global clinical trial in Nigeria.

V. Conclusion

Conducting clinical trial is a key to the development of new therapies and medications for diseases, although it is a complex process; it is the integral part of approval for new drugs and biologics.

Conducting clinical research in accordance with the standards of regulatory authorities and within the guidelines of the good clinical practice (GCP) is a matter of concern. Conducting global clinical trials in Nigeria raises the concern of regulatory authorities regarding the quality, transparency and how the trials are carried out due to ethical norms.

It can be concluded that ethical norms, funding, regulatory standards, research and development capacity, availability of skilled personnel, and the infrastructure required to host and manage clinical trials are the major issues and challenges that comes with the conduct of global clinical trials in Nigeria, furthermore; Patient retention, cultural, religious &language barriers also pose a great challenge. With high patient pool and being the most populated county in Africa Nigeria is likely to emerge as best destination in the continent for many pharmaceutical companies to carry out clinical trials and research in the next coming of years to come due to the.

VI. Recommendations

To encourage and increase enrollment of participants in the conduct of clinical trials in Nigeria it is recommended that:

1. Government should enforce trial sponsors to justify the medical and social relevanvce of the trial to the host community
2. Trial sponsors should make trial intervention available after the conduct of trials as significant respondents are of the view that post-trial availability of the intervention will improve patient enrolment
3. Government should make compensation and insurance a binding rule and a requisite to conduct of global clinical trials in nigeria.

Conflict of interest:

There is no conflict of interest

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