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## A Cross-Sectional Survey of Availability and Technical Feasibility of Basic Medical Equipment to Run Community-Based Clinical Trial Sites, in Cross River State, Nigeria

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### Abstract

**Background:** The ravaging penetration of communities and rural populations by epidemics of new diseases needs be matched with suitable drugs to treat variety of diseases. To develop drugs in developing countries there is need for suitable infrastructure to run efficient clinical studies in a community-based setting. The selection of trial sites by sponsors must meet with certain criteria which may include, among others, the availability of appropriate medical equipment. This study surveyed the availability and technical feasibility of basic medical equipment in community-based clinical trial sites in Cross River State, Nigeria.

**Materials and Method:** Eighty-five 85 community-based clinical trials sites met inclusion criteria for the study. Seventy eight were randomly selected after adjusting for 97% response rate set by the researcher. A close ended questionnaire of 14 questions was the data collection tool. A direct observation of the equipment was also made by the researcher in the participants trial sites. Basic medical equipment and facilities such as small onsite laboratory, pharmacy with storage space, refrigerator, electrocardiography machine, urinalysis device, handheld glucometer

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centrifuge, computer with internet access, pregnancy test device and electric power generating set were assessed, for availability and functionality in 75 community-based clinical trial sites.

**Results:** Out of the 78 participants randomly selected, seventy-five completed the study. Seventy nine percent of the participating community-based clinical trial sites had onsite laboratory facility, 92% had a pharmacy with space for study drug storage. A functional centrifuge was available in 73% of the sites and computer with internet access was available in 76% of the participating community-based clinical trial sites. Urinalysis device and a refrigerator were each available in 100% of the study sites. A power generating set for electricity backup was available in 99% while electrocardiography (ECG) machine was available in 52% of these private-sector community-based clinical trial sites.

**Conclusion:** These resources finding very unique study revealed that the community-based clinical trial sites in Cross River State, Nigeria, had all necessary basic medical equipment which can be sufficient to run Pharmaceutical company sponsored clinical studies. The availability and technical feasibility of the equipment in these trial sites were adequate to influence perception of affordability of care for patients; ensure quality and safety to trial subjects, generate, and document reliable clinical trial data.

### Keywords

Clinical trial; Pregnancy test device; Pharmacy; Nigeria

## Introduction

No time has there been more need for community-based clinical trial sites in Nigeria than now that emerging new diseases are fast penetrating and ravaging the rural areas. Community-based clinical trials allow the private clinicians to impact their patients and their communities with cutting-edge therapies in their contributions to society's greater good [1]. The African region and indeed, Nigeria, is beginning to experience a growing impatience for recognition and engagement of their private-sector physicians in the fast expanding global contract research by pharmaceutical industries. In the past, clinical trials in developing countries had been perceived as an exclusive domain for academic medical centres. Trial activity was and sometimes still is counted as grade awarding point in academic promotion of physicians in University medical centres. The private-sector medical practitioners were confined to providing the needed day-to-day medical care to their patient populations, therefore limiting their involvement in the provision of innovative drugs to the rural communities through clinical trials.

The upsurge in the occurrence of epidemics of new diseases such as HIV, Lassa fever, Ebola and currently COVID 19 pandemic, has necessitated a simultaneous exponential growth in clinical trials initiated by both investigators and pharmaceutical industries. The emergence of these new diseases requiring urgent medications has led to further need for speeding up drugs development process, especially clinical trial component. The bureaucracy experienced in public academic medical centres is a cog in the wheel of rapid clinical trial activities. There is delay in signing contract agreements, delay in participants recruitments, and quite often, not being able to meet up with datelines in trial activities. In developed economies, pharmaceutical companies have fast trans located clinical trials to community-based trial sites because the community physicians waste no time in reviewing proposals and signing contract [2]. Most importantly, academic medical institutions in Nigeria are all located in urban centres, far out of reach to the rural community dwellers. This necessitates the incorporation of private-sector

medical practices as clinical trial sites in rural communities with high disease burden.

However, the choice of a clinical trial site by the trial sponsors is highly influenced and impacted by the ability of the site to perform the required clinical evaluation. Among other factors, experience and qualifications of the investigator, availability of adequate and suitable patient population and the availability of necessary diagnostic or therapeutic equipment, are given primary consideration in site selection. Apart from non-achievement of recruitment targets, many other factors contribute to compromising achievement of the aims and quality of a study in a trial site. Among such factors are lack of enthusiasm and interest of the site in clinical research; lack of technical feasibility and non-availability of required equipment in a clinical trial site. A score as high as 20 had been attributed to availability of facilities and equipment for clinical trial site selection [3].

This research evaluated the availability and technical feasibility of basic medical equipment in potential community-based clinical trial sites in Cross River State, Nigeria. These sites were operated by private-sector medical practices.

## Materials and Methods

Analytics measured in clinical trials constitute important materials used in evaluation of the study drug. The analytics that can be measured at the point of care are varied and increasing in range. Analysers used vary from simple devices to large and complex hospital equipment. Procurement of right equipment for clinical trials ensures success of the trial, but as essential as this may be, scanty information exists on how to source them [4]. This study surveyed simple and basic medical equipment which included:

Small but functional local Laboratories: Hospitals including private-sector practices may be divided into departments such as laboratory, pharmacy or radiology [5]. Laboratory handles specimen testing. Clinical laboratory test results are useful parameters for monitoring effect of investigational new drug on the subjects. These results may be generated from central laboratory or at the point of care. Local laboratory could be used to perform tests in the occurrence of adverse event during trials. Onsite laboratories in hospitals are purely clinical laboratories which investigate diagnostics, safety, or potential treatment as opposed to research laboratories which perform scientific investigations [6]. Testing that is performed near or at the site of the patients is made with simple equipment or devices that are often affordable by private-sector general medical practices, rural and remote hospitals or health clinics in Nigeria. The devices are equally increasing in variety, but the validated type of analyser is defined by the study protocol. This ensures that laboratory results remain of highest quality to protect the trial subjects and provide reliable trial data [7]. The validation and verification of unapproved test methods could be scheduled well in advance of the commencement of clinical trial activities to avoid delays in the target dateline for the clinical Trials. Some of the key equipment which need to be available in clinical trial execution set up are listed : a) Fridge) hand held glucometers c) computer [8] d) centrifuge e) ECG machine [9] f)Pharmacy [10,11] g) pregnancy test device [12] h) electric power generating set [13] i) urine analysis device etc:

## Method

A qualitative research design with semi structured closed ended questions. This was a cross-sectional survey with observational visits to the 75 randomly selected private-sector medical practices.

## Setting

The federal republic of Nigeria, in West Africa, is made up of 36 federating states. Cross River State is one of these. Cross River State, Nigeria, has a population of 3.8million people in a land area of 20,156km<sup>2</sup>. It occupies the south southern part of the country and shares borders with the republic of Cameroun. There are public, private and faith-based hospitals and health clinics in the state. The public healthcare institutions include one academic medical institution, sixteen general hospitals, one hundred and ten private-for-profit hospitals, two faith-based hospitals and one hundred and ninety six public primary health centres. The primary health centres are public health care facilities run by paramedical staff of the state government.

The private-for-profit healthcare institutions are hospitals and medical centres established by individuals to provide medical care to members of the public in Nigeria at acceptable service fees. At the time of this research, Cross River State government had accredited and registered 110 existing private-for-profit health care establishments, 25 of these were owned and run by paramedical personnel such as midwives, nurses and community health workers. Eighty-five (85) were owned by medical doctors certified to practice medicine by the medical and dental council of Nigeria. These were run as hospitals with in-patients and out-patients services. The 85 private-for-profit hospitals were distributed covering 18 local government areas that made up Cross River State. They provided services to members of many large communities' resident in the state. They were close to many hard-to-reach communities in the local government areas of Cross River State.

The medically qualified and professionally certified doctors who operated these hospitals doubled as medical directors of the hospitals and principal investigators of their clinical trial sites.

**Participants:** The subjects of this research were principal investigators of these private-sector community based clinical trial sites, who were also the principal medical officers' in-charge of the private-for-profit medical practices they operated.

**Eligibility criteria:** The inclusion criteria were participants who managed: (i) Private-sector owned medical establishment providing day-to-day healthcare services and led by a medically qualified person accredited and licensed by the Cross River State government to provide medical care to the public on private-for-profit basis (ii). the medical establishment generated and spent its income to run the services, paid its staff salaries, without annual or monthly subvention by government. (iii). Not managed by civil servants from the state civil service.(iv). Headed by a medically qualified person certified by the Medical and Dental council of Nigeria (v). Lead doctor was directly responsible for the day-to-day medical treatment of the patients who attended the hospital. The lead doctor was free to delegate this duty.

**Exclusion criteria:** (i) Medical establishments carrying out similar functions but run by paramedical staff were excluded. (ii) Similarly, medical establishments owned by governments of Nigeria but run by the civil service medical doctors were excluded.

**Recruitment:** Taking advantage of a list of all accredited and registered private-sector health facilities with the Cross River State Ministry of Health, phone calls were made to reach all medically certified doctors licensed by the state to run private sector medical practices. Selected participants were followed up with phone calls. This was to recruit them in to the research. Further information on the research was provided them at a visit to administer questionnaire consisting ten short structured questions and observation of the functionalities of the equipment of the community-based clinical trial sites that had agreed to participate.

**Variables:** The community-based clinical trial sites of private-sector medical practices were independent variables, while the equipment types were dependent variables. The principal investigators identified by ticking out of the 10 types of equipment listed in the questionnaire which they owned. The equipment was verified by the researcher. The equipment was accepted as available, if it was feasibly demonstrated as functional. Equipment that used reagents was accepted as functional if the reagents were also available in the hospital at the time of this research. Equipment, new or old, and functional but had no trained personnel to operate, therefore not often in use, was regarded as not functional. This was noted as not available in the hospital.

**Data sources/measurement:** Questionnaires, containing all equipment under consideration in this research, were provided to the principal investigators of the participating private-sector community-based clinical trial sites for identification of availability and functionality of the equipment by ticking. The researcher visited each of the participating private-sector community-based clinical trial sites to verify the availability and its technical feasibility of the equipment. Each equipment in the questionnaire was ticked as available or not available; in use whenever need arose or not; had trained staff operating it or not.

**Sampling:** Simple random sampling was applied to select 78 private-sector medical practices from the 85 that met inclusion criteria. Out of the 78 selected, 75 responded and returned the questionnaire on time, one returned the questionnaire after analysis of results had been concluded by the researcher and so it was rejected, one opted out of the research and one did not return the questionnaire because the principal investigator and medical director of the hospital was on annual vacation. The private-sector community-based trial sites were led by their principal medical officers who doubled as principal investigators and medical directors of their practices. These responded to the questionnaires and led the researcher to observe their equipment in this survey.

## Sample Size

Sample size for the finite population of 85 private-sector community based clinical trial sites was derived from the formula:

$$n = \frac{Z^2 \cdot N \cdot P \cdot q}{N \cdot E^2 + Z^2 \cdot P \cdot q}$$

Where n = is sample size

Z= confidence level N= Population size P=q= population variability= .05 E= sampling Error

The researcher had confidence that there was a 99% chance that the sample was distributed in the way as the private sector community-based clinical trial sites in Cross River State, Nigeria. Hence confidence level (probability level) was established at 99%. In a related concern, the researcher was willing to accept 2% error as confidence interval. The summary of estimates of this study variable was intended to be statistically expressed in percentages. Therefore standard error of percentage for this simple random sample was derived from the formula.

$$SEp = \frac{\sqrt{p \times 100 - p^2}}{n}$$

Where p = 5%

n = sample size

A sample size of 76 was arrived at by calculation and confirmed with commercial sample size calculator from the internet. This figure was adjusted for response rate set at 97% by the researcher.  $n = 76/.97 = 78$

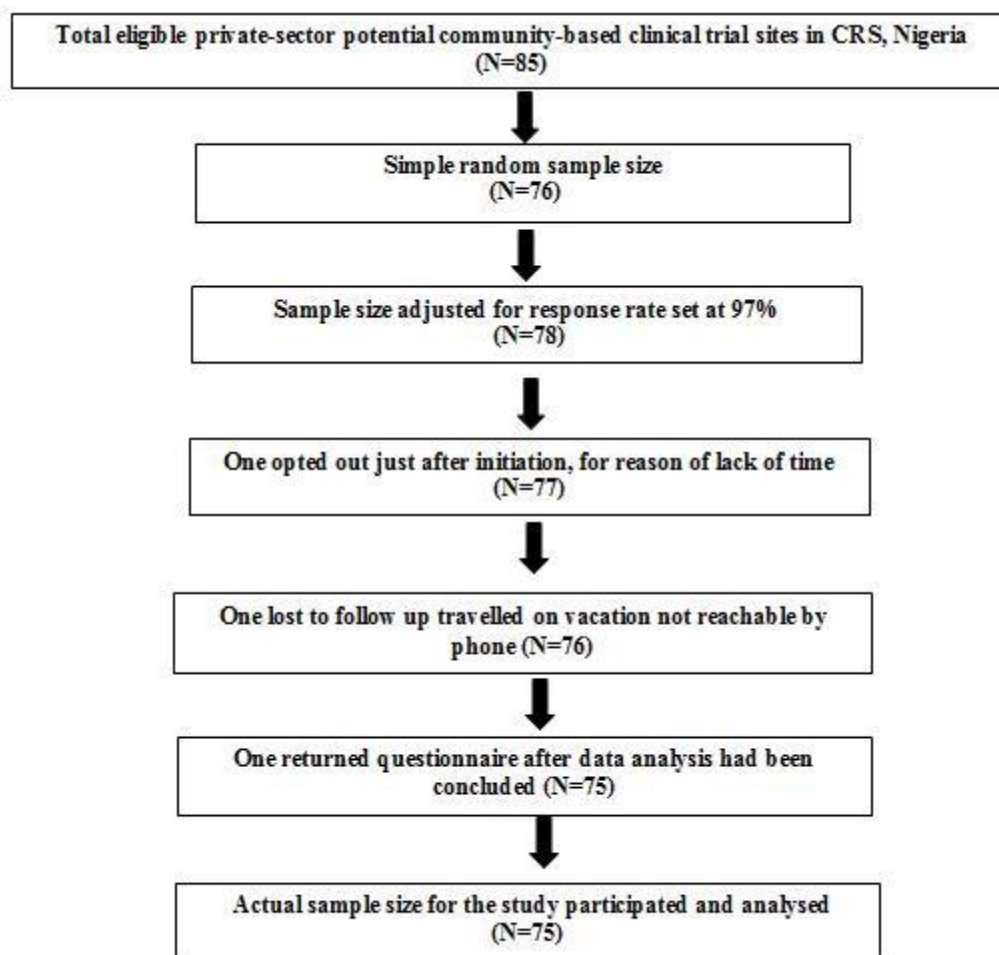
Adjusted for expected proportion of eligible community-based clinical trial site was 100%. This is so because only eligible private sector medical practices with certified medical doctors were screened from the register of the Cross River State Ministry of health for accredited private-sector health Institutions. Therefore adjusting for eligibility brings the sample size to  $n = 78/1 = 78$

This sample set 78 private-sector community-based clinical trial sites, selected from the entire eighty-five eligible community-based clinical trial sites in Cross River State, Nigeria. Selection was aided by the use of table of random numbers. This provided independent and equal chance of all the private-sector community-based clinical trials in the state of being selected into the sample group.

**Data collection:** Research data were collected with a questionnaire consisting of 13 closed ended short questions and observational visits by the researcher.

## Results

Adjusted sample size of this study was 78. Seventy-eight (78) questionnaires were prepared to serve 78 principal investigators of their potential clinical trial sites. Out of this number, seventy-seven (77) were actually served as one of these potential principal investigator of these potential sites opted out of the research for lack of time. One of the principal investigators who travelled for a two-week vacation did not return the questionnaire, and another questionnaire form was returned well after all collation and analysis of data had been done and concluded. Flow chart of this study participants practices is provided in (Figure 1).



**Figure 1:** Flow chart of the study.

Demographic characteristics of these private-sector medical practices and their principal medical officers, doubling as principal investigators of their potential clinical trial sites comprised of two female doctors and seventy three males. The principal officers' ages ranged from 48 to 79 years, and years of existence of the practices ranged from 4-51 years. Ownership of the facilities showed that one was owned by inheritance from parents, 6 were re-purchased from families of deceased doctor-owners and 68 were established by current principal medical officers. They were the medical directors (as they were referred to in CRS, Nigeria) of their hospitals and they functioned as principal investigators of their practices. They were held accountable for quality of care by the applicable regulators of health in Nigeria.

This study showed that sixty nine, 69 (92%) of the 75 private medical practices for community-based clinical trial sites had pharmacy stores with safe cabinets for drug storage. A dedicated computer with internet services for trial documentation was available in fifty seven, 57 (76%) of the private-sector practices that participated in this research. Laboratory services were provided in fifty nine, 59 (79%) of the participating private-sector medical practices. Fridges were available in all 75 practices. The details



on the availability of equipment's their functional status and presence of suitable staff is provided in (Table 1).

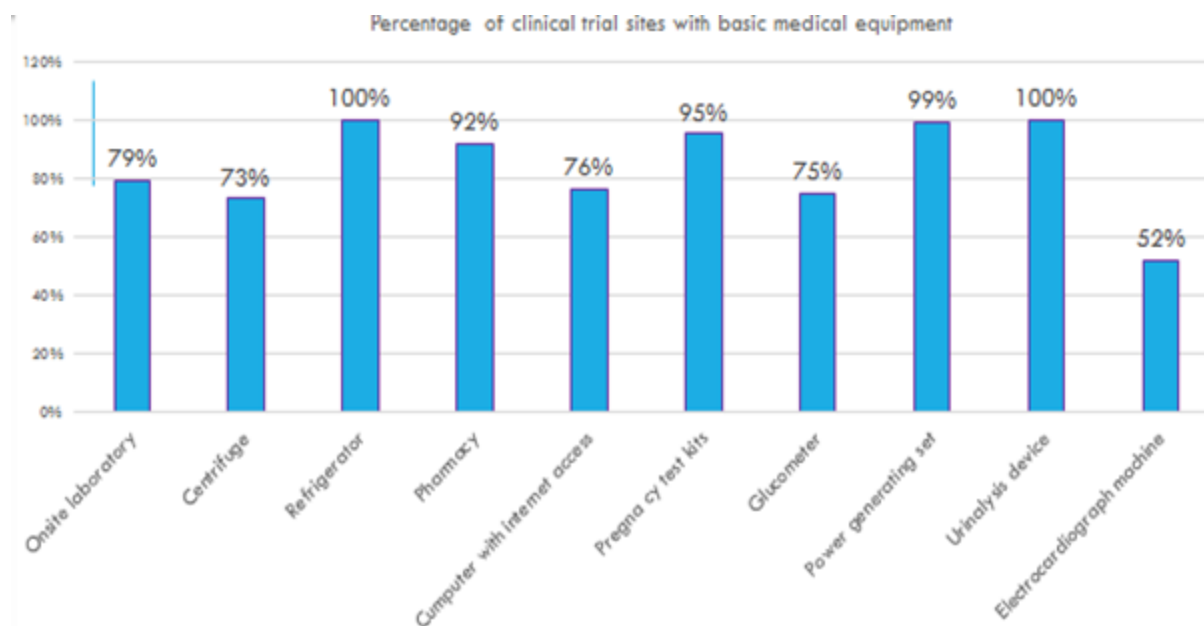
Equipment	Available		Functional		Trained personnel		Available (%)	
	Yes	No	Yes	No	Yes	No	Nos	%
Do you have the following								
Onsite medical laboratory?	59	16	59	0	59	16	59	79%
A Centrifuge?	60	15	55	5	55	5	55	73%
A refrigerator?	75	0	75	0	75	-	75	100%
A pharmacy with space for study drug storage?	73	2	71	2	69	4	69	92%
A computer with internet access	57	18	57	0	57	0	57	76%
A pregnancy testing device?	71	4	71	0	71	0	71	95%
A hand-held glucometer?	56	19	56	0	56	0	56	75%
A power generating set?	75	0	74	1	74	0	74	99%
A urinalysis device?	75	0	75	0	75	0	75	100%
An electrocardiography (ECG) machine	50	25	39	11	44		39	52%

**Table 1:** Summary of the equipment availability, functionality and staffing at the potential community-based clinical trial sites.

Technically feasible electrocardiographic equipment of not less than 3 leads was confirmed available in, 39 (52%) of these private-sector clinical trial sites, while a functional centrifuge machine was found in 55 (73%) of the 75-participating private-sector community-based clinical trial sites. For determination of approximate concentration of glucose in the blood, a hand-held glucometer device was confirmed available in 56 (75%) of the 75 participating practices. Twenty-two (29%) of the trial sites had available all the basic medical equipment considered in this research available in their research sites. See (Figure 2) below for details of the available equipment at the various trial sites that participated.

The result showed that 71 (95%) trial sites had devices for testing pregnancy in their subjects, while 75 (100%) sites had urinalysis devices in use. Functional power generating set were available in 74 (99%) of the sites that participated in this research. Five (7%) community-based trial sites had non-functional centrifuges, 2 (3%) had no pharmacy space and 4 (5%) had pharmacy without any trained personnel to custody/dispense the drugs. Electrocardiography machines in 11 (15%) of the trial sites were faulty and non-functional, while 1 (1%) of the community clinical trial site had a faulty and non-functional generating set.





**Figure 2:** Details of the available equipment at the various sites participated.

## Discussion

This unique study was a cross-sectional survey carried out from 5<sup>th</sup> May to 4<sup>th</sup> July, 2020. This study was conducted to identify the availability and technical feasibility of basic medical equipment in potential community-based clinical trials sites of private-sector medical practices in Cross River State, Nigeria.

The availability of pharmacy storage facilities in 92% of the participating private-sector medical practices indicated ability of the community-based clinical trial sites to custody the investigational new drugs (IND) in safety. This ensures quality, integrity and confidentiality of the testing drugs in the community-based trial site. It's even more possible for the sites to store the study drugs as the inventory of medical supplies to study centres is usually fixed in small and limited study drugs [14].

Measures taken during trials to ensure the safe handling and storage of investigational pharmaceutical product may require storage cabinets in a safe environment such as the pharmacy store in the practice. From this study an excellent percentage of private-sector community-based clinical trial sites showed good capacity to maintain the potency of the investigational new drug. A high percentage of these private-sector community clinical trial sites could meet up with the sponsor's determination of acceptable storage condition for the investigational therapy. The trial sites exhibited evidence that they could establish a system within their health institution for proper management of the products as per the protocol procedures.

Basic laboratory services were available in 59 (79%) of the 75 private-sector medical practices that participated in the research.. Trials involving therapeutics of some tropical diseases such as malaria,

helminthiasis, typhoid, enteric fever may have need for hospital laboratories in these community based private-sector clinical trial sites since study site selection is also based on prevalence and incidence of the diseases to be studied<sup>10</sup>. The importance of these laboratories in the private medical trial sites may be to provide prompt and adequate resources and services to trial subjects. Medical care could be given to trial subjects with adverse events, including clinically significant laboratory values, related to the trial. The presence of basic medical laboratory equipment in potential community-based clinical trial sites of private-sector medical institutions established the fact that community-based clinical trials could be conducted and monitored adequately in private-sector medical institutions. These private medical institutions in Cross River State, Nigeria, had capacity to monitor clinical trial subjects for their wellbeing, and for the direct effect of the study drug on the subject. Both physical findings and variety of analytics could adequately be acquired with the available basic medical devices/equipment in the onsite medical laboratories.

Fridges served as good storage facility for the community based clinical trial sites in private medical practices. Maintenance of potency of vaccines and parenteral administered drugs such as insulin were stored in some of the fridges found in these community-based trial sites. This assured that investigational pharmaceutical products requiring storage under certain temperatures could be accommodated in this tropical private-sector community based clinical trial sites. Electrocardiography equipment was found in 52% of the participating research subject. This meant that simple cardiovascular monitoring could be taken in some of the community-based practices which intend to run cardiovascular therapy trials in their sites.

A centrifuge device enables particles to separate from solutions such as plasma, serum, whole blood, or precipitated solids from other liquids during laboratory investigations. Clinical trial sites of private-sector medical practices in this research showed possession of this device in 73% of the practices. This assured adequate preparation of trial samples that may need centrifugation. Rapid screening of patients for blood glucose level could be conducted easily in 75% of the 75 participating private practice community-based clinical trial sites which had functional glucometers.

Simple devices to exclude pregnancy in most clinical trial subject were available in nearly all the participating community trial sites 95% of the 75 private-sector medical practices. Lack of evidence-based guidelines for a testing method to exclude pregnancy in clinical trials allowed this researcher to accept available pregnancy testing strips with minimal acceptable risk as appropriate to provide exclusive criteria for participation in a clinical trial and to prevent unintended exposure of the foetus to study drug.

The computer continues to remain a relatively inexpensive and easily accessible tool for clinical trial activities. With computer and internet services available to 76% of the community-based clinical trial sites that participated in this research, it was a clear demonstration of the private-sector medical centres to utilize the rapid technology and best-practice medical care afforded by computers in clinical trials in their rural communities. This shows that these private-sector community-based clinical trial sites could comfortably participate in multicentre or international clinical trials. Documents could be stored and retrieved easily; communication with sponsors, clinical research organizations (CRO) and report of

adverse events and serious adverse events could be made effortlessly.

One of the most common tests in out-patient and emergency departments is urinalysis. This research showed that 100% of the 75 community-based clinical trial sites could carry out urinalysis with urinalysis devices in their private-sector medical practices. This implied that the need for urinalysis arising from effects of investigational new drugs or screening for inclusion/exclusion criteria could be adequately performed within these local trial sites.

A very common constrain of effective healthcare delivery in resource-constraint societies is poor and inadequate electric power supply. This was confirmed in this research by the 99% availability of electric power generating set in the 75 community-based clinical trial sites that participated in this research. All of the facilities, had backup generating sets, but at the time of this research the power generating set in one of the hospitals was found not functional and was therefore not counted as available, according to the study protocol. The high level of availability of power generating set backup, 99%, gave an inference of how highly the principal investigators and the clinical trial sites placed value on the well-being of their patients and trial subjects. It also demonstrated the capacity of the sites to sustain electricity supply for the storage of therapeutic agents in this hot tropical environment.

The implementation of International Conference on Harmonization (ICH) E4 guidance in 2005 had limited the rate of drugs withdrawal from the markets due to cardiac toxicity. Careful assessment of ECG parameters eliminated compounds that were suspected to have cardiac effect. Although modern ECG machines are advancing toward virtual and siteless ECG use, trial sites in remote and resource-limited societies would still be dependent on site ECG test for quick screening of cardiac toxicity during suspected adverse events in their trial subjects. We noted that 52% of the community trial sites with ECG machines. Fifty of the sites, (67%), had ECG machines, but eleven of these machines were found faulty by the researcher and were therefore counted as not available. The ECG technicians of five of the sites were re-assigned to task shift duties in other departments of the private-sector medical practice. The private-sector community-based clinical trial sites in this research showed commitment towards proper monitoring of their patients or trial subjects with functional ECG machines.

These community-based clinical trial sites could treat patients from their communities with innovator drugs for evolving community acquired infections such as HIV, Ebola, Lassa fever or Covid-19 diseases [15]. These institutions are equipped adequately to serve as vehicles on which clinical trials benefits could be transmitted to the rural communities. The trial sites with basic medical equipment spent less on procurement and maintenance of expensive hospital gadgets. Correspondingly, their overhead cost is less and their fees for clinical trial services could show significant lower charges compared to the urban, large academic medical institutions.

## Conclusion

This unique study established that there was adequate availability and technical feasibility of basic medical equipment to design, plan and conduct community-based clinical trials and these sites were prepared to run such scientific regulated clinical studies in Cross River State, Nigeria. These private-

sector community-based clinical trial sites were equipped suitably to provide a robust platform to run post marketing clinical studies, clinical studies for community based observational, cross sectional studies as well as studies with innovative new drug chemical entities for various infectious and lifestyle diseases.. This study provides a good evidence where the private medical practices can be generously involved in the plan, design and conduct of clinical studies in the Cross River state. This study also gives a scientific hope to the medical fraternity to contribute their decades of clinical experience to run some finest clinical studies for the betterment of the population of Nigeria. A structured pilot studies on feasibility assessments, resources, ethical committees and the appropriate good clinical practice training of the physicians and the staff is warranted to boost the field of clinical research in Cross River State, Nigeria. There is also need to build a robust public, private partnership eco-system to foster the clinical trials and drug development culture in Nigeria.

### Limitation

The scientific validity, internal and external, of this research were apt for Cross River State, Nigeria, but a study with larger sample size and wider sample distribution is recommended to offer external validity and generalizability of these findings for the entire country, Nigeria.

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